



cobas[®] 6000 analyzer series

*Operator's Manual
Software Version 05-01*

Document information

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- Edition notice* Operator's Manual of the cobas® 6000 analyzer series
 This document is for users of the cobas® 6000 analyzer series.
 Every effort has been made to ensure that all the information contained in this document is correct at the time of printing. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.
 Any customer modification to the instrument will render the warranty or service agreement null and void.
 Software updates are done by the technical support.
- Intended use* The cobas® 6000 analyzer series is a fully automated system for immunological and clinical chemistry analysis intended for the in vitro quantitative/qualitative determination of analytes in body fluids. It is important that the operator read this document thoroughly before using the system.
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Instrument approvals The **cobas®** 6000 analyzer series meets the protection requirements laid down in IVD Directive 98/79/EC. Furthermore, our instruments are manufactured and tested according to the following international standards:

- IEC 61010-1
- IEC 61010-2-010
- IEC 61010-2-081
- IEC 61010-2-101
- UL 61010-1
- CAN/CSA C22.2 No. 61010-1-04

The **cobas®** 6000 analyzer series complies with the emission and immunity requirements described in the following standard:

- IEC 61326-2-6

The Operator's manual meets the European Standard EN 591.

Compliance is demonstrated by the following marks:



Complies with the IVD directive 98/79/EC.



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Preface

The **cobas®** 6000 analyzer series is a fully automated, random-access, software-controlled system for immunoassay and photometric analysis intended for qualitative and quantitative in vitro determinations using a wide variety of tests. The **cobas®** 6000 analyzer series is a powerful tool for complete diagnostic laboratory automation. It is optimized for high throughput workloads using a combination of an ion selective electrode (ISE) and photometric analysis (c 501 module), and an immunoassay analysis module (e 601 module).

This manual has detailed descriptions of features of the **cobas®** 6000 analyzer series and general operational concepts, specification functions and use of controls, operating techniques, emergency procedures, product labeling and maintenance procedures.



Observe the instructions of the Operator's Manual for safe operation of the system

- If the system is used in a manner not specified in this Operator's Manual, the protection provided by the system may be impaired.
 - Keep this manual in a safe place to ensure that it is not damaged and remains available for use.
 - This Operator's Manual should be easily accessible at all times.
-

Where to find information

The following documents are provided to assist in finding desired information quickly:

Operator's Manual Contains information about safety, hardware modules and operating the system as well as maintenance and troubleshooting. A table of contents at the beginning of the book and each chapter, and an index at the end of this book help you to find information quickly.

Online Help Contains a detailed description of the software of the **cobas®** 6000 analyzer series. In addition to the software description, the whole Operator's Manual is embedded into the Online Help. This makes it possible to retrieve information from both Online Help and Operator's Manual using the search functions available for electronically stored documents.

COBI CD The COBI CD (Compendium of Background Information) provides you with background information about the technologies, test principles, their theory and calibration methods used by the **cobas®** 6000 analyzer series. It also provides a complete glossary. The information can be read and printed using Adobe Acrobat Reader.



You cannot use the COBI CD on the control unit of the analyzer because the COBI CD requires Adobe Acrobat Reader to be viewed correctly. Adobe Acrobat Reader is not installed on the control unit and must not be installed.

Online Help system

The **cobas®** 6000 analyzer series has a context sensitive online Help feature to aid in operating the instrument. “Context sensitive” means that wherever you are located within the **cobas** 6000 software, choosing the **Help** feature displays Help text or a screenshot relating to that area of the software. The online Help offers a quick and convenient way to find information, such as explanations of screens and dialog boxes and how to perform particular processes.

- F1 Help* There are two main entry points for the online Help: A context sensitive entry via the **Help** buttons in the software or F1 on the keyboard, or the main entry via the **Help** icon in the bottom left of the screen. The context sensitive entry displays text or a screenshot relating to your current location in the software.

Customer information

- Customer training* Contact your local technical support for any questions or information regarding **cobas®** 6000 analyzer series training.
- Contact customer service* Contact your local technical support for further information regarding service agreement for the **cobas®** 6000 analyzer series.
- Ordering information* Replacement parts, consumable materials, reagents, calibrators and controls should be ordered from your local technical support. When ordering, please use the Roche Diagnostics catalog number and reference name for each item. Contact your local technical support for the detailed ordering list.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in this manual.

Symbols The following symbols are used:

Symbol	Used for
►	Start of procedure
•	List item
👁	Cross-reference
☞	Call-up (software reference)
💡	Tip
	Safety alert
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE.
	The symbol denotes that the equipment must not be disposed of in the municipal waste system.

Abbreviations The following abbreviations are used:

Abbreviation	Definition
A	
ANSI	American National Standards Institute
C	
c 501 (ISE)	ISE unit of the c 501 module
c 501 (P)	photometric unit of the c 501 module
CLAS 2	Clinical Laboratory Automation System 2
CLIA	Clinical Laboratory Improvement Amendments
COBI CD	Compendium Of Background Information
CSA	Canadian Standards Association
D	
dBA	decibel weighted against the A-frequency response curve. This curve approximates the audible range of the human ear.
DIL	diluent
E	
EC	European Community
ECL	electrochemiluminescence
EMC	electromagnetic compatibility
EN	european standard
H	
HCFA	Health Care Financing Administration

Abbreviation	Definition
I	
IEC	International Electrical Commission
IS	internal standard (ISE module)
ISE	ion selective electrode
IVD	in vitro diagnostic
IVDD	in vitro diagnostic directive
K	
KVA	kilovolt-Ampere. Unit for expressing rating of AC electrical machinery.
L	
DDL	lower detection limit <i>see</i> analytical sensitivity
LIS	laboratory information system
LLD	liquid level detection
M	
MBC	matrix barcode
MSDS	material safety data sheet
N	
n/a	not applicable
NCCLS	National Committee for Clinical Laboratory Standards
P	
PC/CC	ProCell M (ProCell) /CleanCell M (CleanCell)
PSM	process system manager (software)
Q	
QC	quality control
R	
REF	reference solution for ISE module
S	
SD	standard deviation
SIP	ISE sipper syringe
SVGA	Super Video Graphics Adapter
T	
TPA	tripropylamine
U	
UL	Underwriters Laboratories Inc.

System description

A

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General safety information

Before operating with the cobas® 6000 analyzer series it is essential that the warnings, cautions, and safety requirements contained in this manual, as well as the explanation of safety labels on the system are read and understood by the user.

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Safety classifications

This section explains how precautionary information is formatted in the manual.

☞ For more information, see *Safety labels of the system* on page A-13.

The safety precautions and important user notes are classified according to ANSI Z535 standards. Familiarize yourself with the following meanings and icons:



Warning

Indicates a possibly hazardous situation which, if not avoided, may result in death or serious injury.

Caution

Indicates a possibly hazardous situation which, if not avoided, may result in slight or minor injuries, and/or damage to equipment.

Important information which is not security relevant is indicated with the following symbol:



Tip

Indicates additional information on correct usage of the system or useful tips.

Safety precautions

Particular attention must be taken of the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury. Each precaution is important.

Operator qualification



Incorrect results or damage to the analyzer due to wrong operation

Operators are required to be licensed persons according to the country specific laws. They should have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
 - Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
 - Leave maintenance that is not described in the Operator's Manual to trained technical support.
 - Follow standard laboratory practices, especially when working with biohazard material.
-

Intended use



Intended use

This instrument is designed for immunological and clinical chemistry analysis intended for the in vitro quantitative/qualitative determination of analytes in body fluids.

Please note that other analyses may not be applicable to this instrument.

Installation and disposal of the analyzer

Environmental conditions



Incorrect results or damage to the analyzer due to heat and humidity

Use the instrument indoor only.

Installation



Incorrect results or damage to the analyzer due to wrong installation

Follow the specified installation instructions carefully.

Correct grounding of the power supply cord is essential for correct function of the analyzer. Contact your technical support for any changes of the power supply cord.

Leave installation, transportation, and relocation that are not described in the Operator's Manual to trained technical support.

Disposal recommendations



Disposal of instrument

The instrument must be treated as potentially biohazardous waste. Decontamination (i.e., a combination of processes, including cleaning, disinfection and/or sterilization) is required before reuse, recycling or disposal of the instrument.

Dispose of the instrument according to the appropriate local regulations. Before disposing of the instrument, contact your technical support.



Disposal of control unit components

Components of your control unit (such as the computer, monitor, keyboard) which are marked with this symbol are covered by the European Directive on *Waste Electrical and Electronic Equipment* (WEEE, 2002/96/EC).

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your technical support.

Constraint:

It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat in the same way as the instrument.

Working with the analyzer

Electrical safety



Electrical shock by electronic equipment

Do not attempt to work in any electronic compartment. Do not remove any cover of the instrument, other than specified in this Operator's Manual. Installation, service, and repair must only be performed by authorized and qualified personnel.

Mechanical safety



Injury or damage to the analyzer due to contact with instrument mechanism

Do not put your hands into the pathway of any moving parts during instrument operation.

Instrument covers



Injury or damage to the analyzer due to contact with instrument mechanism

Keep all covers closed and in place while the instrument is operating.

- Material inside could be airborne and potentially hazardous.
- Leave the keys to the protective covers of the instrument only to trained personnel.
- Do not use the key for the other purpose than locking and unlocking the cover.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-1, F-10, R-2.

Operation and maintenance



Injury or damage to the analyzer due to contact with instrument mechanism

Do not touch any parts of the instrument other than those specified. During operation and maintenance of the instrument, proceed according to the instructions.

Damage to the analyzer due to the use of organic solvents for cleaning

Do not use organic solvents except for Isopropyl alcohol or ethanol, which is used in operation and maintenance.

Handling samples, reagents, and waste

Reagents and other working solutions



Skin inflammation caused by reagents

Direct contact with reagents may cause skin irritation, inflammation, or burns. When handling reagents, be sure to wear protective equipment (like goggles, gloves) and observe the cautions given in the instructions for use.

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury. When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the instructions for use, and observe the information given in the Material Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

Incorrect results due to incorrect reagent volume

Application faults may cause an undetectable loss of reagent.

- Store reagents always according to specified storage conditions.
- Do not reuse a **cobas c** pack or other cassette whose reagent has been spilled.
- Do not use a single **cobas c** pack for different instruments.



Correct handling of reagents and other working solutions

- Reagents, calibrators and controls must be handled, stored and disposed of according to the instructions given in the instructions for use.
- Samples and chemicals must be handled, stored and disposed of on your own responsibility and in accordance with the appropriate standards.

Insoluble contaminants in samples



Incorrect results and interruption of analysis due to contaminated samples

Insoluble contaminants in samples and bubbles or film inside a sample container may cause clogging or pipetting volume shortage and deterioration in measurement accuracy.

When loading samples on the instrument, make sure that samples contain no insoluble contaminants such as fibrin, dust or bubbles.

Evaporation of samples



Incorrect results due to evaporation of samples

Evaporation of samples may lead to incorrect results

Do not leave a sample that has been pipetted into a sample container uncooled for a long time.

Loading of samples and reagents



Loading of samples and reagents

Be sure to load samples and reagents only into the specified positions on the instrument.

Cross contamination of samples



Incorrect results due to carryover

Traces of analytes or reagents may be carried over from one test to the next. Take adequate measures to safeguard additional testing and to avoid potentially false results.

- ☞ For more information about avoiding carryover and cross-contamination between tests, see *Special Wash* on page B-234.

Spillage



Malfunction due to spilled liquid

Any liquid spilled on the instrument may result in malfunction of the instrument. If liquid does spill on the instrument, wipe it up immediately and apply disinfectant. Be sure to wear protective equipment.

Biohazardous materials



Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Follow standard laboratory practices, especially when working with biohazard material.
- Be sure to wear appropriate protective equipment, including, but not limited to, safety glasses with side shields, fluid resistant lab coat, and approved disposable gloves.
- Wear a face shield if there is a chance of splash or splatter.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or waste solution comes into contact with your skin, wash it off immediately with soap and water and apply a disinfectant. Consult a physician.

Infection and injury due to sharp objects

When wiping probes, use several layers of gauze and wipe from the top down.

- Be careful to not puncture yourself.
- Be sure to wear appropriate protective equipment, for example gloves. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.

Waste**WARNING****Infection by waste solution**

Contact with waste solution may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-6, F-7, F-19, S-1.

Contamination by waste solution and solid waste

The waste of the system is potentially biohazardous.

The system discharges two kinds of waste solutions:

- Concentrated waste solution, that contains highly concentrated reaction solution. This waste must be treated as infectious waste.
- Diluted waste: Rinsing water from cell wash or water from the incubator bath.

When disposing of any waste generated by the system, do so according to the appropriate local regulations.

Miscellaneous safety precautions**Operation over an extended period of time****CAUTION****Fatigue due to long hours of operation**

Looking at the monitor screen over an extended period of time may lead to fatigue of your eyes or body. Take a rest for 10 to 15 minutes every hour to relax. Avoid spending more than 6 hours per day looking at the monitor screen.

Instrument unused for a long period of time**CAUTION****Instrument unused for a long period of time**

If the instrument is not used for a long period of time, the main circuit breaker switch must be set to OFF. Remove, cap and refrigerate any remaining reagents. For further information, call technical support.

**CAUTION****Start up the instrument after a long period of time**

When the instrument was not in use for a period longer than 8 days, call technical support. The necessary procedure is performed by your technical support.

Power interruption**CAUTION****Data loss or damage to the system due to voltage drop**

By a power failure or momentary voltage drop the operation unit or software of this system may get damaged or data loss may occur. Use only uninterruptible power supply.

Data security**Unauthorized access and data loss due to malicious software and hacker attacks**

Portable storage media can be infected with and transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The cobas® 6000 analyzer series is not protected against malicious software and hacker attacks.

The customers are responsible for IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or render the cobas 6000 analyzer unusable.

Roche recommends the following precautions:

- Allow connection to authorized external devices only.
- Ensure that all external devices are protected by appropriate security software.
- Ensure that access to all external devices is protected by appropriate security equipment. Roche strongly recommends the use of a **cobas IT Firewall**.
- Do not copy or install any software on the cobas 6000 analyzer unless it is part of the system software or you are instructed to do so by a Roche service representative.
- If additional software is required, contact your Technical support to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless you are instructed to do so by official user documentation or a Roche service representative.
- Exercise utmost care when using external storage devices such as USB flash drives, CDs, or DVDs. Do not use them on public or home computers while connecting to the cobas 6000 analyzer.
- Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.

Electromagnetic devices**Malfunction of instrument and incorrect results due to interfering electromagnetic fields**

This instrument has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The electromagnetic environment should be evaluated prior to operation of the device.

Devices that emit electromagnetic waves may cause the instrument to malfunction. Do not operate this instrument in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources).

Do not operate the following devices in the same room where the instrument is installed:

- Mobile phone
- Transceiver
- Cordless phone
- Other electrical devices that generate electromagnetic fields

Safety precautions

Approved parts



CAUTION

Malfunction of instrument and incorrect results due to nonapproved parts

Use of nonapproved parts or devices may result in malfunction of the instrument and may render the warranty null and void. Only use parts and devices approved by Roche Diagnostics.

Third-party software



CAUTION

Malfunction of instrument and incorrect results due to third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior of the system. Do not install any nonapproved software.

Safety labels of the system

Warning labels have been placed on the analyzer to draw your attention to areas of potential hazards. The labels and their definitions are listed below according to their location on the instrument.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010, IEC 60417, or ISO 7000.



If the labels are damaged, they must be replaced by your local technical support. For replacement labels, contact your local technical support.



Spillage warning

This label indicates the instrument may be damaged if a spillage occurs within the vicinity of this label. Do not place liquids in this area.



Protective equipment warning

This label indicates protective goggles and gloves should be worn when working within the vicinity of this label as there is a danger of coming into contact with corrosive material.



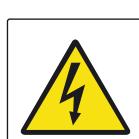
Warning

This label indicates there is a danger of hazardous situations within the vicinity of this label, which may result in death or serious injury. Refer to the Operator's Manual for safety operation.



Biohazard warning

This label indicates there are potential biohazards within the vicinity of this label. The relevant laboratory procedures on safe use must be observed.



Electrical warning

This label indicates there is a danger of coming into contact with electrical components when gaining access to parts of the system marked with this label.



Mechanical parts warning

This label indicates there is a danger of coming into contact with moving mechanical parts within the vicinity of this label.



Sharp object warning

This label indicates there is a danger of coming into contact with sharp objects which may result in injuries.

Safety labels of the system**Hot surface warning**

This label indicates the area within the vicinity of this label may be hot. Do not touch this area as you may be burned.

**Maximum weight**

This label indicates the maximum weight. Do not place anything heavier than the specified weight on the label.

INDICATION	NOTE
Light OFF	Bottle in use DO NOT REPLACE
Light ON	Stand-by bottle (full) DO NOT REPLACE
Light FLASHING	Bottle empty SAFE TO BE REPLACED

Green button light states

This label indicates the meaning of the status of the green button lights. DO NOT perform an action unless the correct state is indicated.

The following sections describe the meaning of the safety labels on the instrument in a short form.

- ☛ For more information about the safety labels on the instrument, see:

Front view on page A-15

Side view on page A-17

Top view on page A-18

Rear view on page A-20

Safety information for barcode readers on page A-21

In addition to *safety labels* on the instrument there are *safety notes* in the corresponding parts of the Operator's Manual and Online Help.

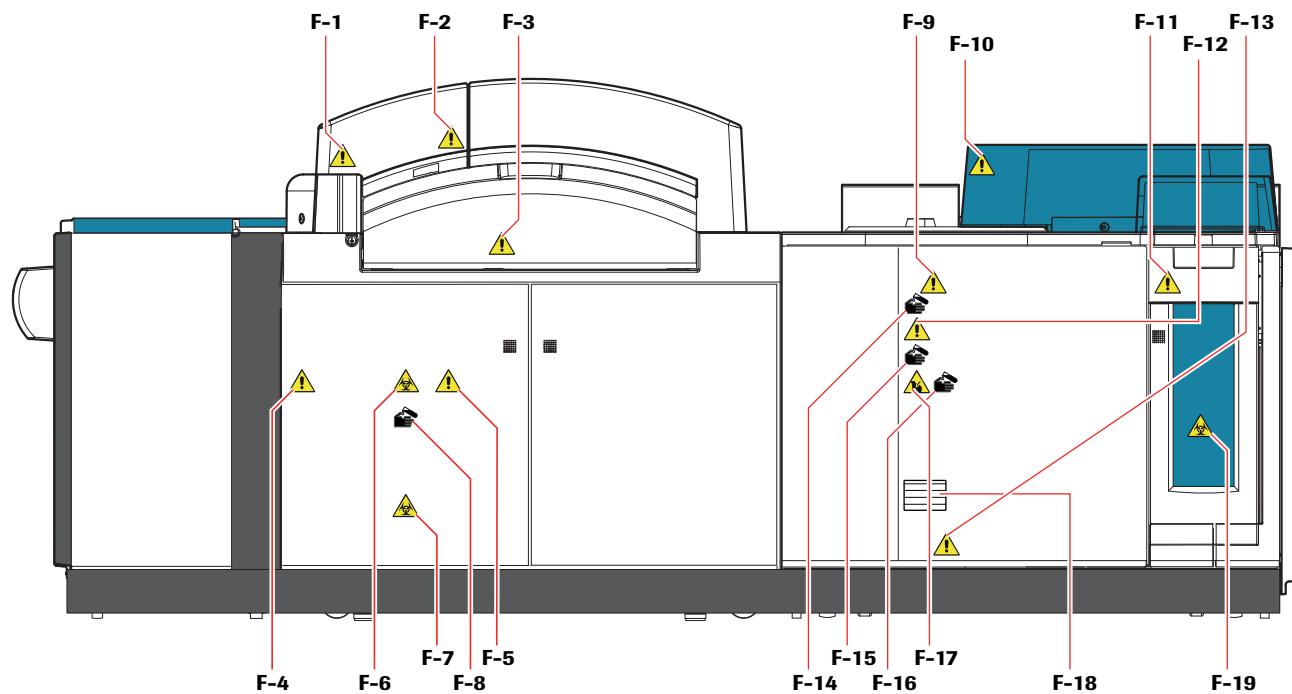
- ☛ For more information, see:

Part Operation on page B-1

Part Maintenance on page C-1

These safety notes give more detailed information about potentially hazardous situations in the context of all kinds of working procedures.

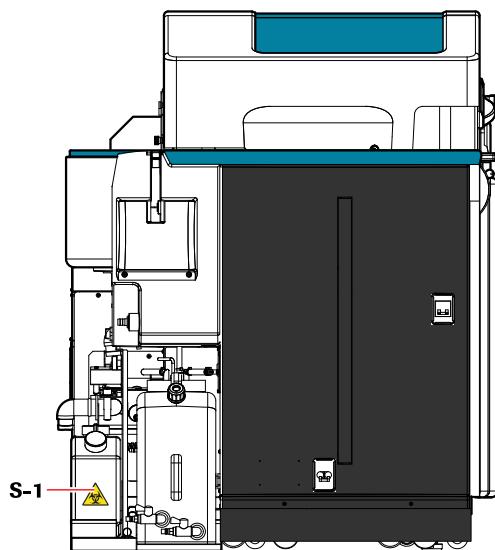
When working with the analyzer be sure to observe both safety labels on the instrument and safety notes in the Operator's Manual and Online Help.

Front view**Figure A-1** Front view of the analyzer

F-1		Attention to interlock!
F-2		Caution against contact with pierce pin!
F-3		Caution against contact with mechanism!
F-4		Caution against pinch by syringe!
F-5		Caution against false result due to loose tube connector!
F-6		Caution against infection due to contact with sipper syringe!
F-7		Caution against infection due to contact with waste from the vacuum tank!
F-8		Caution against irritation by detergent and/or reagent!
F-9		Caution against pinch by syringe

Safety labels of the system

F-10		Caution against injury and infection due to contact with mechanical parts!								
F-11		Attention to handling the magazine drawer!								
F-12		Attention to auxiliary reagent setting!								
F-13		Attention to auxiliary reagent misplacement!								
F-14		Caution against irritation by detergent and/or reagent!								
F-15		Caution against irritation by detergent and/or reagent!								
F-16		Caution against irritation by detergent and/or reagent!								
F-17		Caution against injury by contact with needle!								
F-18	<table border="1"><thead><tr><th>INDICATION</th><th>NOTE</th></tr></thead><tbody><tr><td>Light OFF</td><td>Bottle in use DO NOT REPLACE</td></tr><tr><td>Light ON</td><td>Stand-by bottle (full) DO NOT REPLACE</td></tr><tr><td>Light FLASHING</td><td>Bottle empty SAFE TO BE REPLACED</td></tr></tbody></table>	INDICATION	NOTE	Light OFF	Bottle in use DO NOT REPLACE	Light ON	Stand-by bottle (full) DO NOT REPLACE	Light FLASHING	Bottle empty SAFE TO BE REPLACED	Attention to the status of the green lights!
INDICATION	NOTE									
Light OFF	Bottle in use DO NOT REPLACE									
Light ON	Stand-by bottle (full) DO NOT REPLACE									
Light FLASHING	Bottle empty SAFE TO BE REPLACED									
F-19		Caution against infection due to contact with tips and AssayCups!								

Side view**Figure A-2** Right side of the analyzer**S-1****Caution against infection due to contact with waste solution in waste solution tank!**

Safety labels of the system

Top view

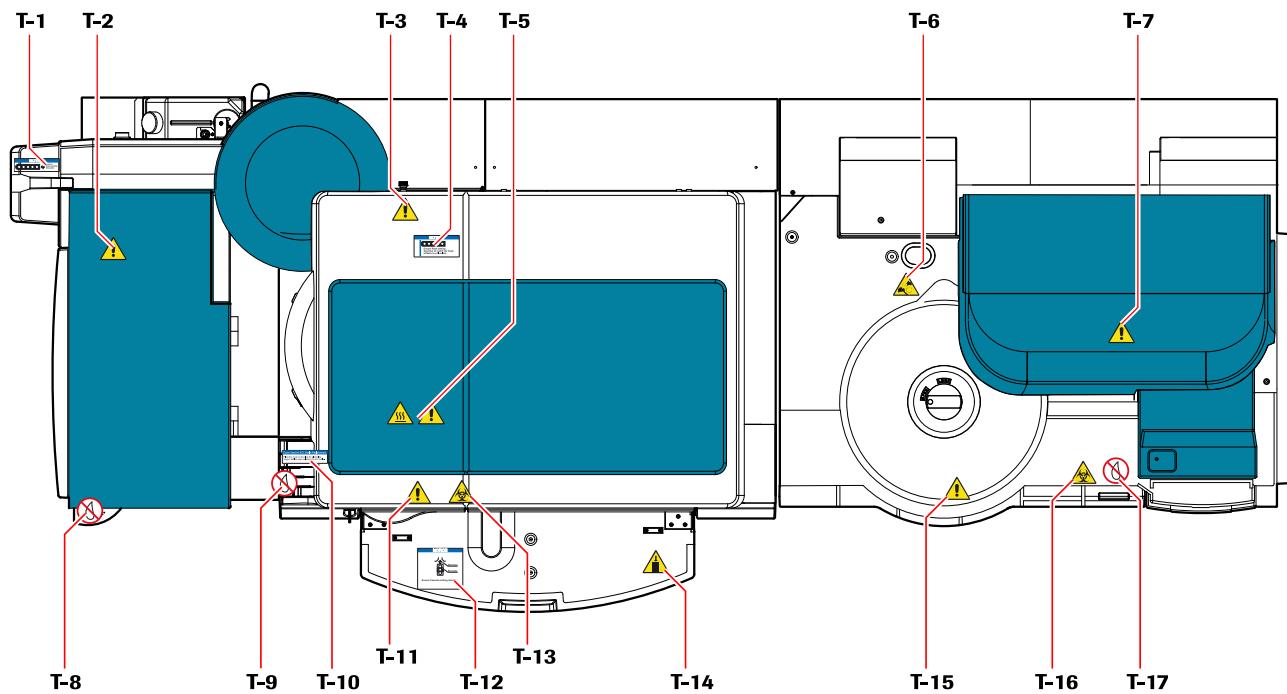
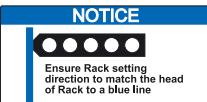
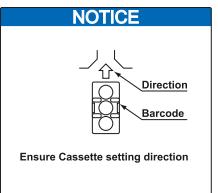


Figure A-3 Top view of the analyzer

T-1		Attention to rack direction when loading racks at the STAT port!
T-2		Attention to sampler cover!
T-3		Caution against pinch by rotor mechanism!
T-4		Attention to rack direction when loading racks at the backup operation port!
T-5	 	Caution against burn at photometer lamp replacement!
T-6		Caution against entanglement by reagent disk!
T-7		Attention during incubator maintenance!
T-8		Instrument damage by water!
T-9		Instrument damage by water!

T-10	 Place this cover on the slots for electrolyte reagent bottles when replacing the KCL bottle.	Reminder to use cover for KCL bottle replacement
T-11		Attention when opening or closing ISE cover!
T-12	 Direction Barcode Ensure Cassette setting direction	Attention to cassette direction when loading cassettes!
T-13		Caution against infection due to contact with parts of the ISE compartment!
T-14	 2 kg Max.	Attention to cassette table maximum weight!
T-15		Attention when opening or closing reagent disk cover!
T-16		Caution against infection due to contact with mechanism!
T-17		Instrument damage by water!

Safety labels of the system

Rear view

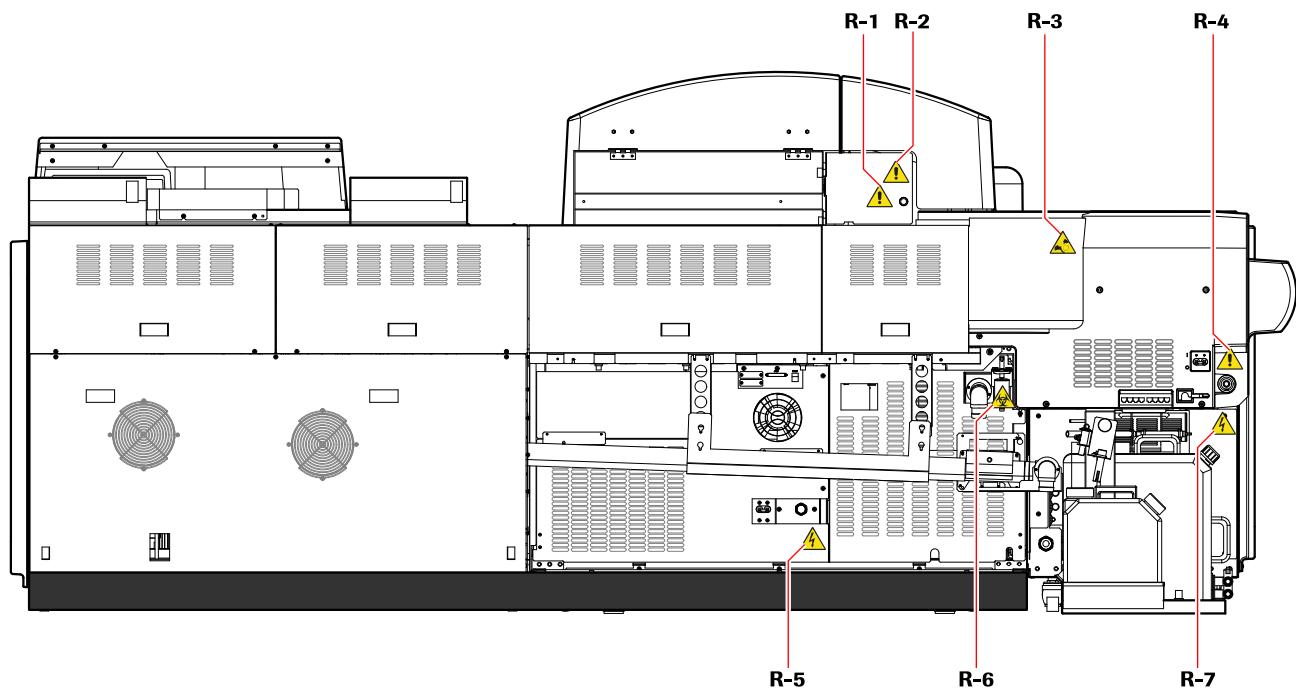


Figure A-4 Rear view of the analyzer

R-1		Caution against contact with mechanism!
R-2		Attention to cover with a key!
R-3		Caution against entanglement by rack rotor!
R-4		Attention during water filter maintenance!
R-5		Attention to electric shock at the back side of the instrument!
R-6		Caution against infection due to contact with ISE waste solution!
R-7		Attention to electric shock at the lower part of the rack sampler unit!

Safety information for barcode readers



Loss of sight

The intense light of a LED barcode reader may severely damage your eyes or result in hazardous radiation exposure.

- Do not stare into the LED barcode reader.
- Do not perform maintenance work on the barcode reader. If problems concerning the barcode reader occur, contact your local technical support.
- Do not perform other maintenance work than described in Chapter 18 *Maintenance c 501 with ISE* and Chapter 19 *Maintenance e 601*.

The following figure shows the position of the barcode readers and the directions of the LED apertures used by the cobas® 6000 analyzer series:

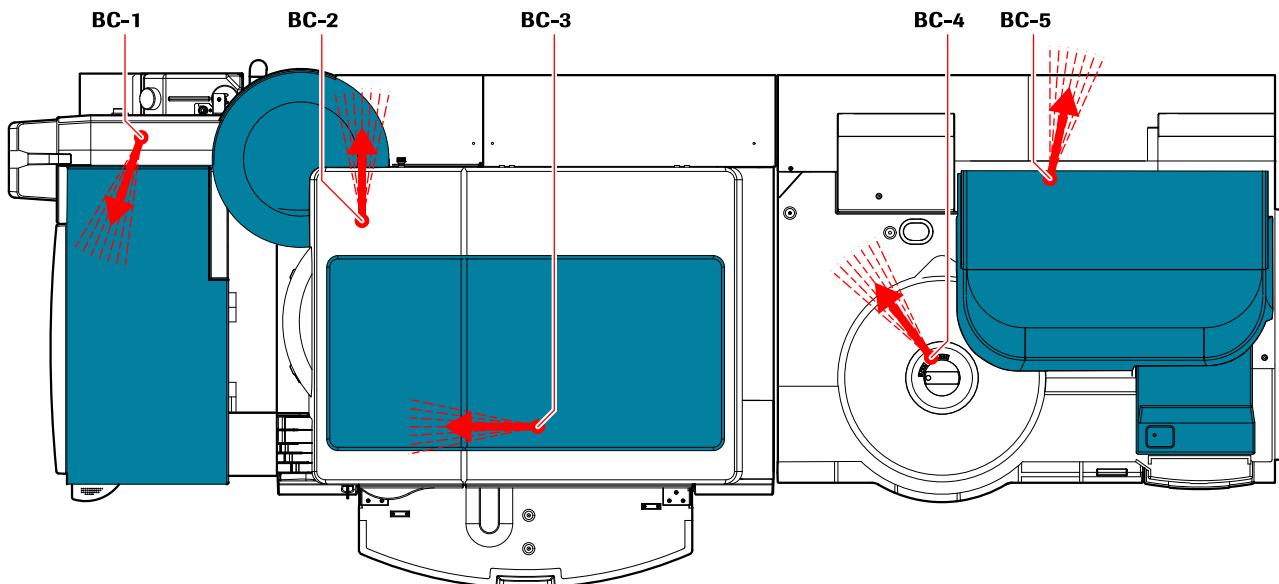


Figure A-5 Top view of the analyzer - localization of barcode readers

The following table gives technical information about the intensity of the barcode readers:

Barcode no.	Module	Barcode reader used for	Maximum LED radiation output power	LED class / Classified standard
BC-1	cu 150	Rack ID and sample ID	10 µW	Class 1 LED product
BC-2	c 501	Rack ID and sample ID	10 µW	IEC 60825-1, +A2:2001
BC-3		Reagent	10 µW	
BC-4	e 601	Reagent	102.92 µW	
BC-5		Rack ID	10 µW	

Table A-1 Barcode readers of the cobas® 6000 analyzer series

Overview modules

This chapter provides an overview of all modules of the cobas® 6000 analyzer series. As well as system specifications and environmental conditions, a description of possible configurations is also provided.

In this chapter

Chapter **2**

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Modules of the cobas® 6000 analyzer series	A-25
Control unit and cobas link	A-26
Core unit	A-27
c 501 module	A-28
Photometric unit	A-28
ISE unit	A-29
e 601 module	A-30

Overview

The cobas® 6000 analyzer series is a fully automated, software-controlled system for clinical chemistry and immunoassay analysis. It is designed for both quantitative and qualitative in vitro determinations using a large variety of tests for analysis. It is ready to use 24 hours per day. The cobas® 6000 analyzer series:

- is fully automated
- is modular
- is computerized
- uses serum/plasma, urine, CSF, supernatant and whole blood sample types
- performs in vitro quantitative and qualitative tests on a wide range of analytes
- performs photometric assays and ion-selective electrode measurements on c 501 modules as well as electrochemiluminescence assays on e 601 modules

Modules of the cobas® 6000 analyzer series

The cobas® 6000 analyzer series comprises of a control unit, core unit cu 150 and the following hardware units, which can be combined in various combinations:

- c 501 module
- e 601 module



Figure A-6 The cobas® 6000 analyzer series

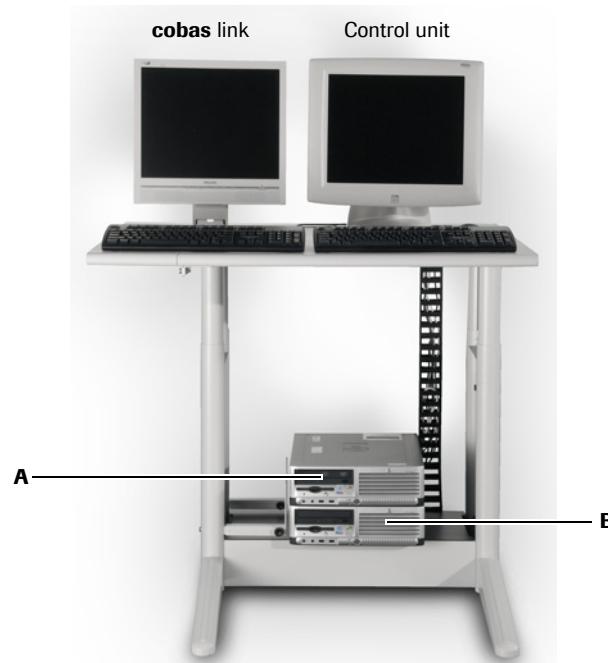
The modularity of the system allows for up to seven combinations of the above hardware units and thus provides tailored solutions for all medium workload requirements:

Clinical chemistry	< c > < c c >	Up to 2000 tests/h (photometric and ISE) for a <cc> system Up to 1000 test/h for a single <c> system Up to 60 cobas c packs per c 501 module
ECL technology	< e > < e e >	Up to 340 tests/h for a <ee> system Up to 170 test/h for a single <e> system Up to 25 cobas e packs per e 601 module
Hybrid combinations	< c e > < c c e > < c e e >	Up to 2170 tests/h Up to 145 reagent packs

Control unit and cobas link

The control unit uses a graphical user interface to control all instrument functions. The cobas link data station is used as the gateway for retrieving and distributing information - such as important notes and test- and lot-specific analyzer settings - from Roche TeleService-Net to cobas analyzers.

The following figure shows the control unit together with the cobas link data station:



A cobas link data station **B** Control unit computer

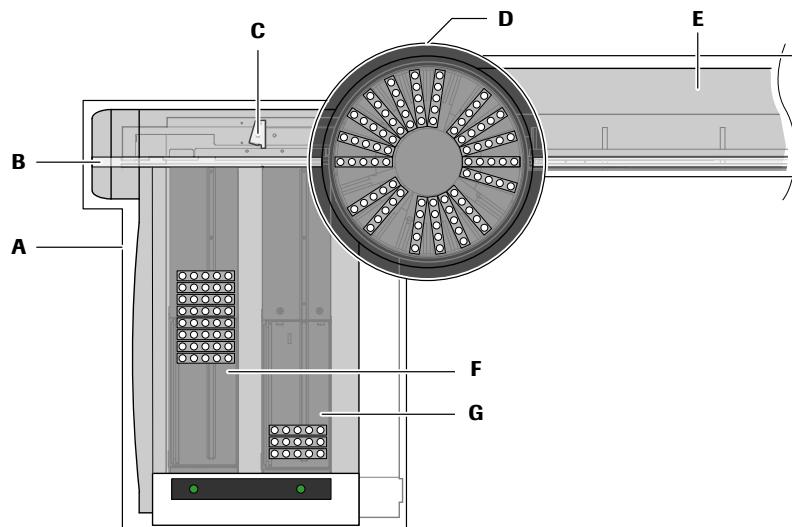
Figure A-7 Control unit and cobas link data station



Any component of the control unit is subject to change without prior notice.

Core unit

The core unit comprises several components that manage the conveyance of samples to each assigned analytical module. Therefore, the actual composition depends on the current module configuration of the analyzer.



- | | | | |
|----------|-------------------|----------|---|
| A | Rack sampler unit | E | Conveyor line (depending on system configuration) |
| B | STAT port | F | Rack loader |
| C | Barcode reader | G | Rack unloader |
| D | Rack rotor | | |

Figure A-8 Core unit cu 150

Other core module components (installed into the rack sampler unit) are:

- Water supply
- System interface port
- Power switches
- Main circuit breaker

c 501 module

The c 501 module comprises a photometric unit and an ISE unit (for ion-selective electrode [ISE] determinations).



Figure A-9 **c 501 module**

Photometric unit

The photometric unit provides the analyzer with a flexible photometric method of assaying up to 600 in vitro tests per hour on a wide range of analytes. The following are the main components of the c 501 module:

- Sampling system
- Reagent system
- Reaction disk system

Sampling system

The sampling system is composed of a sample pipetter (consisting of a pipetter arm and the sample probe), a sample syringe, and a rinse station for internal and external rinsing of the sample probe.

Reagent system

The reagent system is composed of a refrigerated reagent compartment consisting of two storage rings for reagent cassettes, and a reagent pipetting system with two rinse stations for internal and external rinsing of the reagent probes.

Another integral part of the reagent system is the cassette management system, which provides a fully automated management of reagent cassettes—from the point of loading of new cassettes all the way to the disposal of empty cassettes.

Reaction disk system

The reaction disk system is composed of a reaction disk, immersed in a incubator bath, three ultrasonic mixing units, a photometric measuring system, and a cell rinse unit for cleaning the reaction cells once test measurement is complete.

ISE unit

Moreover, the c 501 module has an integrated ISE unit, which provides the analyzer with a potentiometric method for assaying sodium, potassium and chloride samples. The ISE unit can process up to 200 samples per hour. The following are the main components of the ISE unit:

- ISE measuring compartment with measuring cartridges for Cl⁻, K⁺, Na⁺ and Reference cartridge
- ISE pipetter
- ISE sipper
- IS bath
- ISE reagent compartment

e 601 module

The e 601 module is a multi-test immunoassay analyzer with random access with a capacity of up to 170 tests per hour. The cobas® 6000 analyzer series can be configured with up to two e 601 modules.



Figure A-10 e 601 module

The following are the main components of the e 601 module:

- Reagent area
- Measuring area
- Consumables area
- Pre-wash area

Reagent area

The reagent area comprises the left side of the analyzer and consists of a reagent disk, a barcode reader, a cap open/close mechanism, a microbead mixer, a reagent probe and two rinse stations.

Measuring area

The measuring area is in the middle of the analyzer and consists of an incubator, a sample probe, two sipper probes, two sipper rinse stations, and the two detection units (measuring channels).

Pre-wash area

The Pre-wash station, located in the middle at the back of the analytical module, carries out a pre-wash step to remove special contents of serum from the reaction solution before measuring if required by the assay protocol. It consists of a Pre-wash gripper, Pre-wash sipper, Pre-wash dispenser, rinse station, separation stations, and the vortex mixing station.

Consumables area

The consumables area is on the right side of the e 601 and consists of the gripper, the mixing station, the AssayTip station, the magazine lifter trays, two solid waste containers, the magazine waste compartment, and the auxiliary reagents and cleaning solutions.

Control unit, cobas link and core unit

This chapter provides a detailed description of the control unit, the **cobas** link platform, and the core unit. The description of the core unit includes the rack sampler unit, the rotor, and the conveyor line, as well as line movements within these components. The sample containers, sample racks, and the rack identification are also described in this chapter.

In this chapter

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Control unit

The control unit uses a graphical user interface to control all instrument functions. The following figure shows the control unit together with the **cobas** link data station:

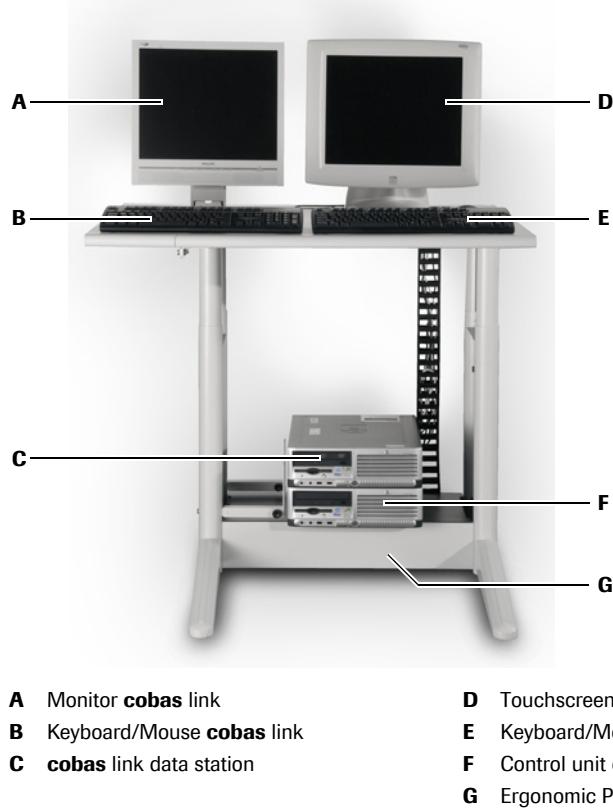


Figure A-11 Control unit and **cobas** link data station

Keep the touchscreen, computer and any disks away from magnetic fields as this may cause damage.



Control unit computer

The control unit computer monitors the system functions, and operational modes for all modules.

- A hard disk drive is used to store the operating system, the analyzer software, the Online Help system and data, for example patient data, calibration data, QC data and system parameters.
- A 3 1/2 inch floppy disk drive is available for reading and writing parameters and other information for backup purposes.
- A CD or a DVD drive is available for loading software updates.

Touchscreen Monitor

The system uses a 17" SVGA with color monitor touchscreen adapter to:

- Display information
- Navigate through the software
- Initiate instrument functions

To use a touchscreen, touch what you want to request or change directly on the screen. Most of the items within the software can be accessed using the touchscreen. Touch the item desired (for example, menu bar, list box, text box, button, etc.) to complete your task. For example, to display the **Data Review** screen in the **Workplace** menu, touch **Workplace**, then the **Data Review** tab.



When touching the screen, be sure to “tap”, not “press”. The tap must be of short duration. When touching the screen, you can use your finger or a pointing device.

Selecting Items

To select a consecutive range of items in a list, press <Shift> and touch the first item in the range. While continuing to press <Shift>, touch the last item in the range. All items, including the first and last items touched in the range, are highlighted. You may also touch the first item in the list and drag your finger to the last item in the list.

To select multiple, nonconsecutive items, press <Ctrl>, then touch the desired items.

Keyboard

A 101-key enhanced keyboard is used to navigate through the software and to enter information.

Most items that can be accessed via the touchscreen can also be accessed via the keyboard.

For more information, see *Shortcut Keys* on page B-14

Mouse

A mouse is available to navigate through the software.

The mouse can be used to select items on the screen and to place the cursor at an insertion point in a text box. To select an item using the mouse, move the mouse over the item and then click.

Printer

The system uses a graphics-capable printer. Patient results can be printed in report format (long) or in monitor format (short). The printer can be ordered as an optional accessory.

See *Report Format* on page B-243.

cobas® link

Overview

cobas link platform

The **cobas** link platform is the gateway for retrieving and distributing information - such as instructions for use, value sheets, important notes, and test- and lot-specific analyzer settings - from Roche TeleService-Net to **cobas** analyzers in the laboratory. **cobas** link is an integral and mandatory part of the **cobas** modular platform analyzers.

TeleService-Net (TSN)

TeleService-Net is the technical infrastructure to provide **cobas** analyzers and operators with important product information from Roche Diagnostics. TeleService-Net offers several applications to manage and display data and information of remotely connected instruments.

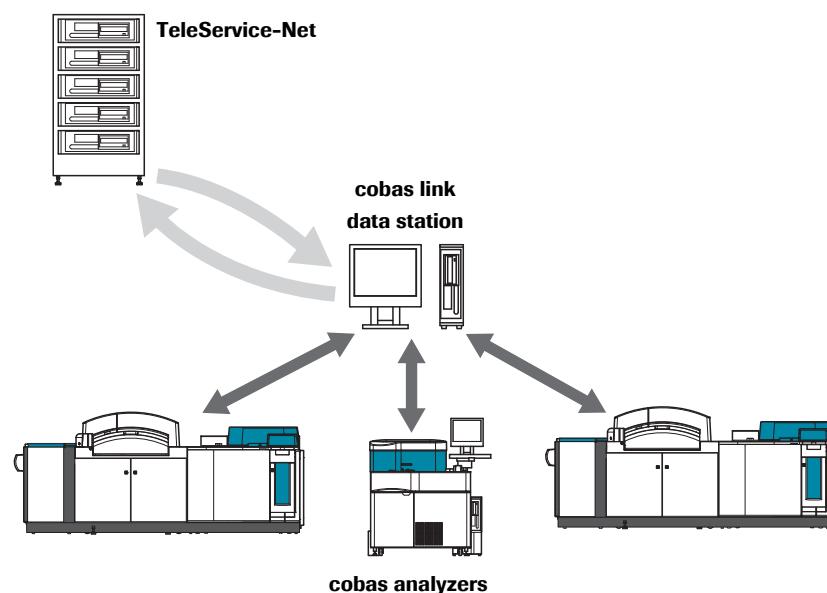


Figure A-12 The **cobas** link platform

cobas link data station

The **cobas** link data station is a dedicated desktop computer with keyboard, mouse, monitor, and printer.

cobas e-library

The **cobas** e-library (e-library) is the user interface for working with **cobas** link on the **cobas** link data station.

The main application on **cobas** link for the operator is the **cobas** e-library, consisting of e-package inserts and e-barcodes. This application is used for searching, reviewing, and printing of e-package inserts.

There is a separate Operator's Manual for the **cobas** e-library available.

- ☞ For more information on working with the e-library, refer to the **cobas** e-library Operator's Manual.

cobas link update process

cobas link receives data from TSN about the applications, calibrators, and controls used on **cobas** analyzers. This ensures that the most up-to-date product information is always available in the laboratory. All information relevant for the analyzer can be downloaded from **cobas** link.

cobas link

cobas link is updated daily via an automatic download if connected to the internet or a phone line. The **cobas** link data station connects to TSN, typically overnight, depending on the customer's requirements (configured by your local technical support during installation). While connected, all newly available data are downloaded from the TSN to your **cobas** link data station.

If your laboratory does not have an online connection to TSN, the TSN data is provided on a CD, distributed by your local technical support.

- ☛ For more information on working with CD, refer to the **cobas** e-library Operator's Manual.

Main functions

From the operator's point of view the main functions of **cobas** link are:

Analyzer control unit

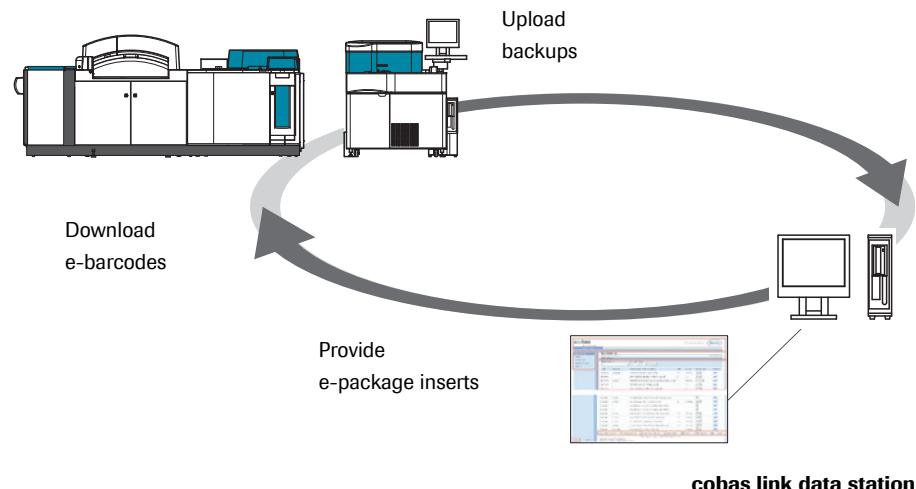


Figure A-13 **cobas** link - main functions

e-package inserts

- The **cobas** e-library stores many documents (e-package inserts) such as the instructions for use for the applications, information on controls, calibrators, and announcements.

☛ See *Using e-package inserts* on page A-38

e-barcodes

- Providing e-barcodes (e-BC) like application parameters to be downloaded from **cobas** link to the analyzer by the operator. e-BCs are instrument readable only.

☛ See *Using e-barcodes via download* on page A-37

Backup function

- Providing the possibility of important data backup for the **cobas** 6000 analyzer series.

☛ See *Using the backup function* on page A-38

Working with cobas link functions

This section explains the working principles of the main cobas link functions.

Using e-barcodes via download

The operator downloads the required e-barcodes from the cobas link data station to the analyzer.

The following types of e-barcodes are available:

- Application data
- Calibrator data
- Control data

The following figure gives an overview of the installation process.

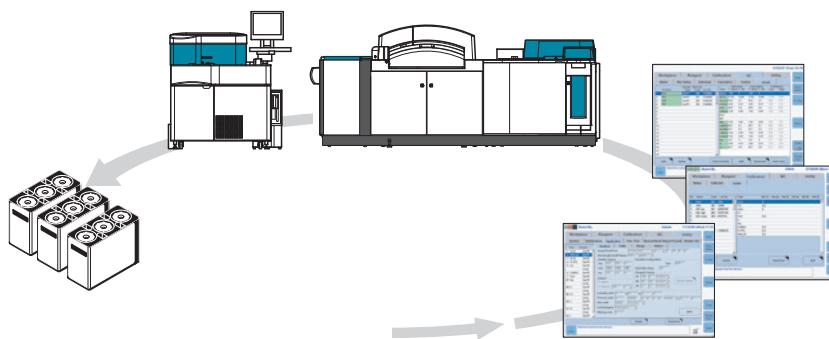


Figure A-14 Installation process of a new cobas application

If the data of a particular application (application parameters, calibrator data, and control data) is not available on the analyzer, it has to be downloaded from cobas link.

- ☛ For more information, see:
Loading or updating new applications on page B-192



Reassigned calibrator or control values have to be downloaded manually!

If calibrator or control values for a particular calibrator or control have been reassigned, you are informed by means of the e-library. In this case you have to start the download process for the particular calibrator or control manually to update the calibrator or control data.

A detailed description for installing new applications, calibrators, and controls is given in the corresponding chapters.

- ☛ For a more detailed description see:
To download application parameters from cobas link on page B-192
To download calibrator data from cobas link on page B-147
To download control data from cobas link on page B-182

Using the backup function

Instrument and process related data can be stored to the hard disk of the **cobas** link data station for disaster recovery. In order to initiate this backup function it is necessary to include the **cobas** link upload function (*Smart. Com Essential information upload*) in a maintenance pipe that is carried out daily (e.g., the Power On pipe).

This item can only be performed in a Maintenance Pipe.



- For more information, see
 - Defining and editing maintenance pipes* on page C-15
 - Recommended maintenance pipes* on page C-35
 - Smart. Com Essential information upload* on page C-44



Perform daily backups to preserve the operational availability of the analyzer!

Include the **cobas** link upload function (*Smart. Com Essential information upload*) into a maintenance pipe that is executed daily. If a hard disk error on the control unit occurs, the last backup can be restored from the **cobas** link data station.

Using e-package inserts

You can view and print package inserts as required through the e-library. The following electronic documents are provided via the e-library:

- e-package inserts (e-PI)
 - Instructions for use
 - Value sheets of calibrators and controls
 - Important notices (for example reassigned control values)
 - Announcements of the local technical support



Check your cobas e-library daily to obtain important information!

It is important to check your **cobas** e-library daily because important information that is necessary for analysis—like reassigned control values—is announced through the **cobas** e-library.

Brief introduction to the cobas e-library

The following section explains how to start the e-library application and gives an overview over the user interface.

► To start the e-library

- 1 Log on to the **cobas** link data station, by entering the user name and password for the e-library.
- 2 Confirm with OK.

The start screen of the e-library is displayed (New Entries).



Overview of the user interface

The screen in Figure A-15 is for illustrative purposes only. It shows the New Entries for an analyzer with clinical chemistry and immunological modules.

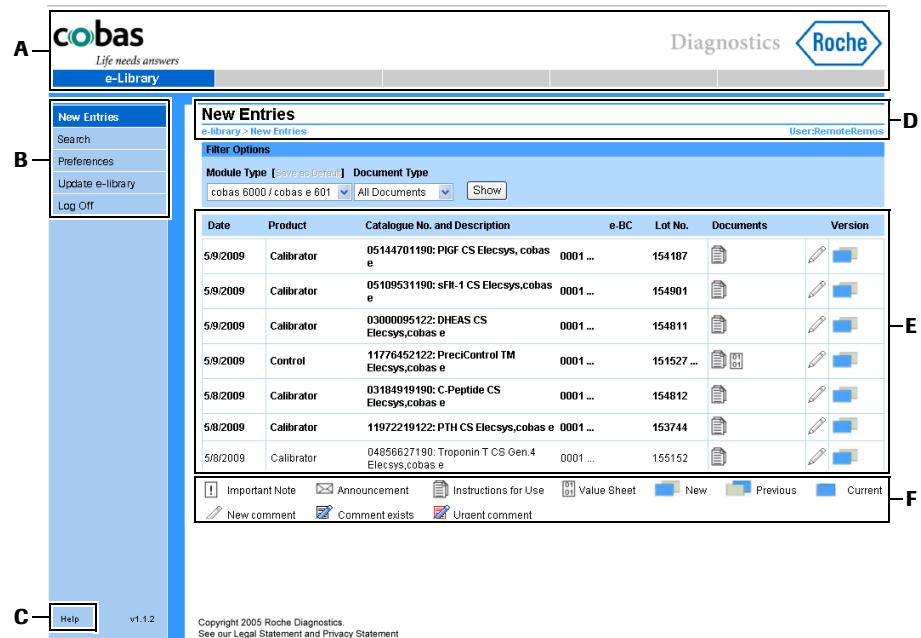


Figure A-15 Introduction to the cobas e-library user interface

The e-library user interface comprises the following components:

- A Navigation bar** has a tab for the e-library application. Links to other applications can also appear in this bar. The e-library application opens by default.
- B Navigation menu** provides links to the e-library application screens.
- C Online Help** accesses the context-sensitive online help. A quick and convenient way to find information, such as explanations of screens and dialog boxes and how to perform particular processes.
- D Screen header** displays the path of your active screen. The active operator name is displayed on the right hand side of the Screen header.
- E Message List** displays the list of important notes, announcements, instructions for use and value sheets.
- F Footer** explains the icons used in the document and version columns.

The e-library offers the following important functions:

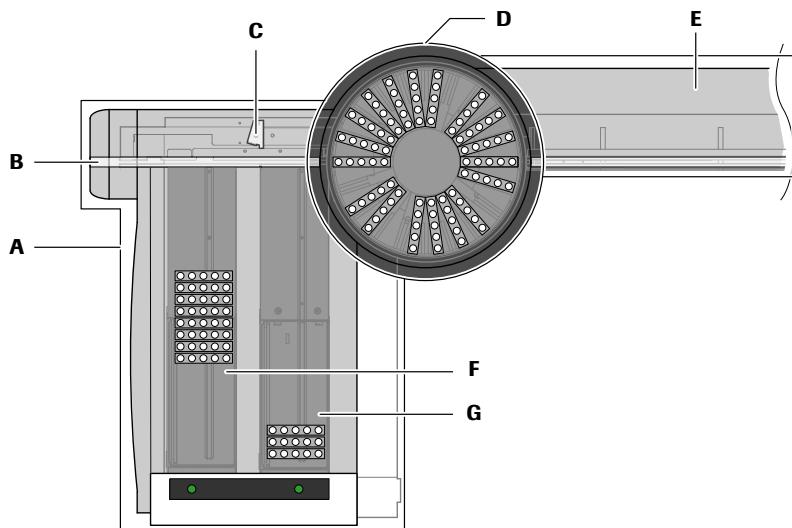
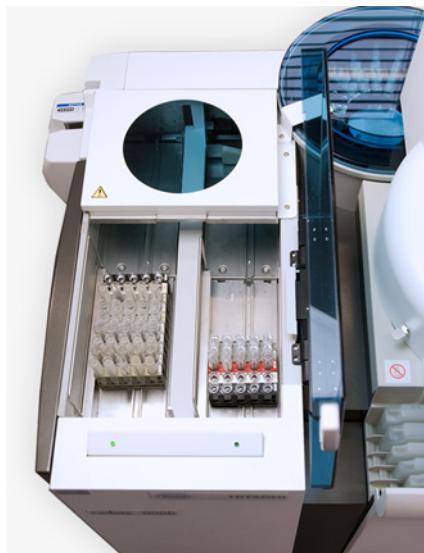
- Show new e-library documents (New Entries screen), based on **Preferences** screen
- Search for documents in the e-library archive (**Search** screen)
- Specify applications, calibrators, and controls currently used on the system (**Preferences** screen)



- Check the New Entries screen on a daily basis to make sure that you receive all important information from your local technical support.
 - Whenever you load a new application, make sure that you always add it to your Preferences. Only the items you have selected in Preferences will be displayed on the New Entries screen.
 - If the **cobas** link data station is not connected to TeleService-Net, you have to update regularly via CD (Update e-library screen).
-
- For more information on working with the e-library, refer to the **cobas** e-library Operator's Manual.

Core unit cu 150

The core unit comprises several components that manage the conveyance of samples to each assigned analytical module. Therefore, the actual composition depends on the current module configuration of the analyzer. The core unit comprises at least the rack sampler unit and one rack rotor as main components. Conveyor line(s) and second rack rotor are possible extensions.



- | | | | |
|----------|-------------------|----------|---|
| A | Rack sampler unit | E | Conveyor line (depending on system configuration) |
| B | STAT port | F | Rack loader |
| C | Barcode reader | G | Rack unloader |
| D | Rack rotor | | |

Figure A-16 Core unit cu 150

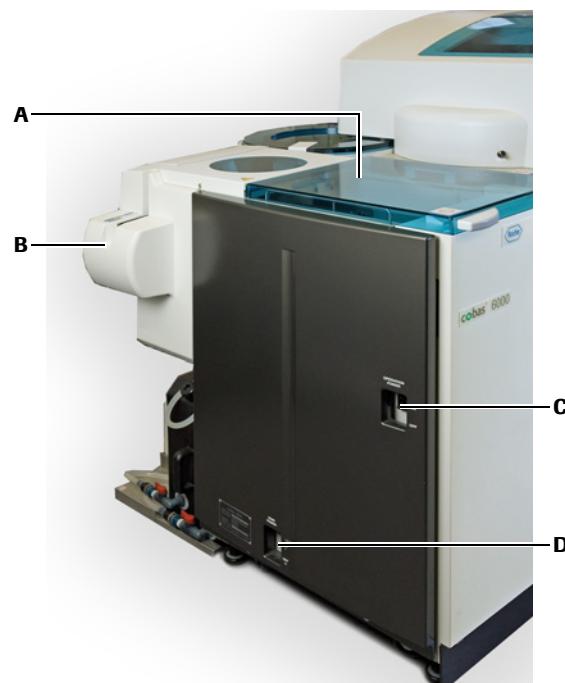
The following are main components of the core unit:

- Rack sampler unit
- Rack rotor(s)
- (Conveyor line[s])

Other core unit components (installed into the rack sampler unit) are:

- Rack loader/unloader
- STAT port
- Barcode reader (for racks and samples)
- Water supply
- System interface port
- Power switches
- Main circuit breaker

Rack sampler unit



A Rack loader/unloader
B STAT port

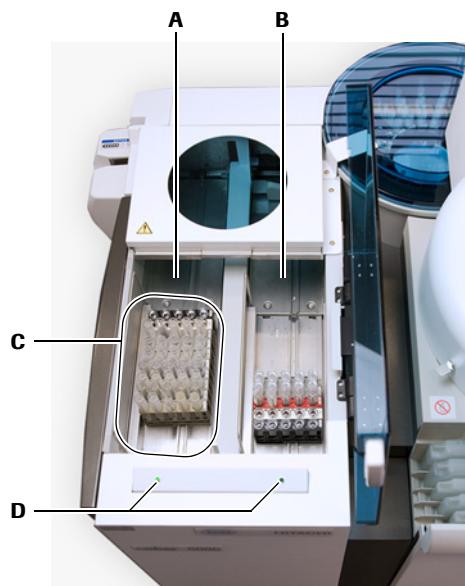
C Operation power switch
D Main circuit breaker

Figure A-17 Rack sampler unit

All central control and supply functions of the core unit are installed into the rack sampler unit.

The following subsections describe the rack loader/unloader, STAT port, barcode reader, and power switches. Then, we turn to the rear of the rack sampler unit and discuss the system interface and the water supply.

Rack loader/unloader



A Rack loader
B Rack unloader

C Rack tray (with racks)
D Green LED

Figure A-18 Rack loader/unloader

Viewed from above, the rack sampler unit features two lanes where sample racks (or rack trays with sample racks) are to be inserted; the left lane is the rack loader, the right lane is the rack unloader. Both the loader and the unloader have a capacity of 150 samples, corresponding to 30 racks each. The racks are supplied on rack trays.

Make sure the rack barcode label is on the right side when placing a rack on a tray. The barcode label can be read only when racks are supplied in correct orientation.



The rack loader is designed for continuous loading. That is, the operator can load new samples while others are still being processed. When the analyzer is in operation, the green LEDs indicate when a rack tray can be exchanged, that is, when new sample racks can be inserted or when a rack tray can be removed from the unloader.

When the analyzer is in operation, rack loading proceeds automatically. When the analyzer is in standby, rack loading initiates after the operator starts the run.

Rack loading

The rack loader automatically pushes the sample racks forward. One after another, the racks are pushed onto a feeder, which transports each rack into the rack rotor. When transporting the racks into the rack rotor, a barcode reader scans the barcode and a sensor checks the height of each sample container. From the rack rotor, the racks move to the analytical unit where their samples are analyzed.

After analysis, the racks move from the analytical unit via the rack rotor to the unloader. The unloader collects the processed sample racks up to a maximum of 30 racks.

STAT port**Figure A-19** STAT port

Use the STAT port to send any racks directly onto the rack rotor, bypassing all racks on the trays of the rack loader. A rack loaded through the STAT port will be processed with higher priority than other racks in rack rotor

- ☞ To locate the STAT port on the rack sampler unit, see Figure A-17 on page A-42.

Make sure the rack barcode label is on the right side when inserting a rack into the STAT port. The barcode label can be read only when racks are supplied in correct orientation.



Any rack can be put into the processing track at any time by using the STAT port. However, when operating in non-barcode mode, routine (gray) racks must not be put into the processing track by using the STAT position! Doing so would disrupt the predefined sample sequence and lead to sample mismatch for all subsequent samples.

- ☞ For information on the different types of racks, see *Sample racks* on page A-48.

Barcode reader / cup sensor

When racks are loaded onto the analyzer, either via rack loader or via STAT port, they pass by a barcode reader before they enter the rack rotor. This barcode reader performs the following tasks:

- Scans rack barcode of each sample rack
- Detects if there is a sample in each of the five rack positions
- Detects the type of sample tube or cup present
- Scans barcodes on each sample within a rack

Power switches

There are two types of power switches: Superordinate power switches and power switches for each module.

Superordinate power switches (on the left of the rack sampler unit):

- Operation power switch
- Main circuit breaker

 To locate the superordinate power switches, see Figure A-17 on page A-42.

Power switches for each module (at the rear of each module):

- Module power switch for the rack sampler unit
- Module power switch for the **c 501** module and the **e 601** module

Power switch	Dependent components
Operation power switch	Whole analyzer except for cooling unit
Main circuit breaker	Whole analyzer including the cooling unit
Module power switch for the rack sampler unit	Rack sampler unit (including rack rotor)
Module power switch for the c 501 module and the e 601 module	c 501 module, e 601 module

Table A-2 Power switches and dependent components

System interface port

The following components take part in the data communication within the analyzer and its network environment:

- Rack sampler unit
- Connected analytical modules
- **cobas** link
- Host computer

There are two devices to accomplish the data communication: A serial port for bidirectional communication with the Host computer and a hub for network connections. The hub is located on the PC stand.

 For technical information about the serial interface, see *System interface* on page A-101



Incorrect results or damage to the analyzer due to wrong installation

- The connection between **cu 150** unit and analyzer units (**c 501**, **e 601**) must be done by your local technical support only.
- Do not use connection cables other than the cables provided by your local technical support.

Water supply

- A** Joint with water supply filter inside
B System interface port
C Water tank
- D** Tap for water tank
E High concentration waste container

Figure A-20 Water supply

The deionized water supply system consists of the water tank, located behind the rack sampler unit, connecting tubing, and a series of electronic valves. Water is automatically added to the water tank when necessary. Water from this source is supplied directly to the cell rinse unit, to the rinse stations, and to the incubator bath.

- For more information about water consumption and specifications, see:
Water requirements on page A-100

Rack rotor



Figure A-21 Rack rotor

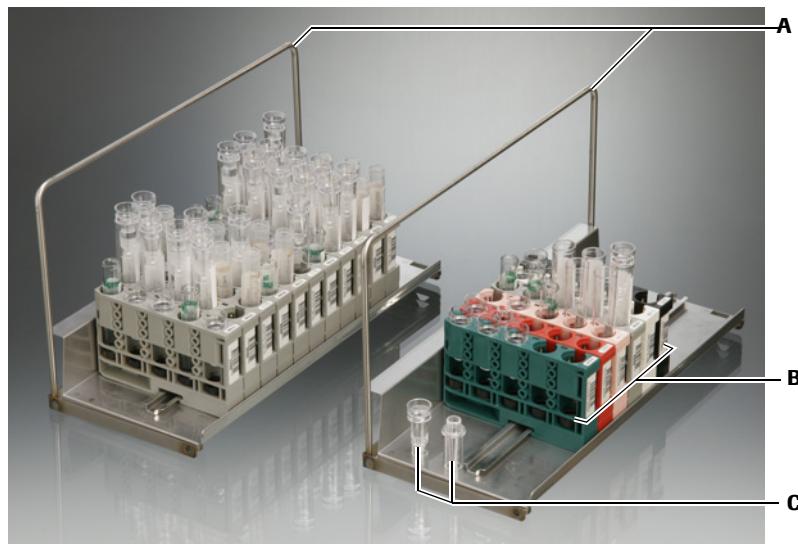
The rack rotor is located at the rear between the rack sampler unit and analytical module (c 501 or e 601, depending on system configuration). The rotor has 20 positions for sample racks. It receives sample racks from the rack loader, passes them on to the c 501 module or the conveyor line, receives sample racks from the c 501 module after pipetting or from the conveyor line, and passes them on to the unloader.

In addition, the rack rotor can hold special racks (auto QC) readily available, as well as reserve special positions for STAT racks. Any of the 20 positions are freely definable for STAT or auto QC.

If your **cobas** 6000 analyzer is equipped with two c 501 modules, then the second c 501 module is provided with a second rack rotor.

Trays, racks, tubes, and cups

This section describes the different containers and components used to transport samples.



A Rack Trays

B Sample racks with different tubes, cups and cup on tube

C Standard cup, micro cup

Figure A-22 Trays, racks, tubes, and cups

Samples are supplied to the analyzer in sample tubes or cups. These sample containers are inserted in sample racks, which are placed on rack trays.

Rack trays

Rack trays are used to transport sample racks to and from the rack loader/unloader. Each tray has a capacity of 15 racks. This corresponds to a number of 75 samples that can be loaded onto the analyzer with one tray.

Sample racks

The analyzer distinguishes the following categories of samples:

- Patient samples
 - Routine samples
 - STAT samples
 - Rerun samples
- Calibrators
- Quality controls.

Each sample category has its own type of sample rack. Each sample rack holds a maximum of five samples. To load sample racks, they are either inserted at the STAT port or placed on a tray and the tray is placed into the rack loader.



Make sure the rack barcode label is on the right side, when inserting a rack into the STAT port or when placing a rack into the rack loader. The barcode label can be read only when racks are supplied in correct orientation.



Figure A-23 Sample racks

Sample racks are color-coded and equipped with a barcode label and a label with a unique rack number. Each rack is identified and registered when its barcode label is scanned by the barcode reader of the rack sampler unit.

The following table explains the different types of racks, their color codes and numbers:

Rack type	Rack color	Display in software	Label on rack
Routine rack	Gray	N00001-N03999	001-3999
STAT rack	Red	E00001-E00999	S001-S999
Rerun rack ^(a)	Pink	R00001-R00999	R001-R999
Calibrator rack	Black	S00001-S00999	C001-C999
QC rack	White	C00001-C00999	Q001-Q999
Wash rack	Green	W00999	W999

Table A-3 Rack types

(a) Rerun racks are used for manual reruns in non-barcode mode only.

The table shows that each type of sample rack has its specific range of rack numbers. The software allows to subdivide the range of rack numbers of routine, rerun, and STAT racks according to sample types (such as Ser/Pl, Urine, CSF...). This assignment of sample types to rack numbers is displayed in the **Rack Assignment** area on **Utility > System**.



The rack numbers displayed in the software differ from those printed on the racks.

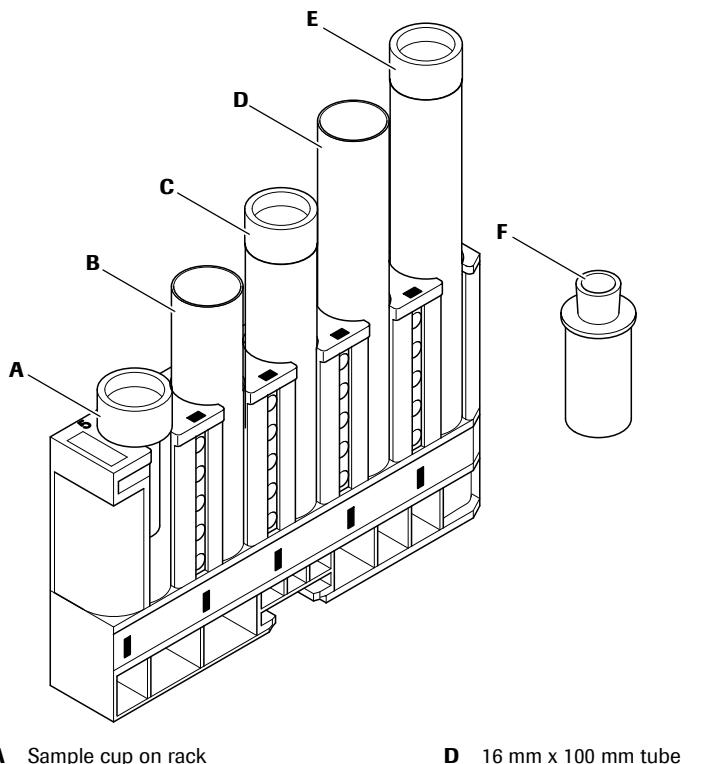
Sample containers

There are three general kinds of sample containers: Sample tubes, sample cups, and calibrator or control vials.

Sample tubes and cups

Sample tubes are 13 mm or 16 mm in diameter and 75 mm or 100 mm in length. Sample cups (both standard and micro cups) can be inserted into 16-millimeter sample tubes (*cup on tube*) or they can be used without tubes.

 For sample container specifications, see *Sample cups and tubes* on page A-104.



- | | | | |
|----------|----------------------------------|----------|-----------------------------------|
| A | Sample cup on rack | D | 16 mm x 100 mm tube |
| B | 16 mm x 75 mm tube | E | Sample cup on 16 mm x 100 mm tube |
| C | Sample cup on 16 mm x 75 mm tube | F | Micro cup |

Figure A-24 Sample container heights



Restrictions for the use of micro cups

- Do not use micro cups on e 601 modules.
- Do not use micro cups for calibrators and controls.



Non-standard tubes

Sample tubes with the following dimensions can also be used:

- Length between 73 mm - 102 mm
- Outer diameter between 12 mm - 16 mm

Non-standard tubes and false bottom tubes can be used for patient samples and controls. Please contact your technical support for more information about the use of non-standard tubes and other sample containers.

Sample identification

When operating in barcode mode, each sample's barcode label is scanned by the barcode reader of the rack sampler unit. The sample barcode label provides the sample ID, which is used for sample identification and test selection purposes.

 For label dimensions and placement specifications, see *Barcode types* on page A-102.

The combination of the sample ID and the rack identification number provides tracking for the system. To track samples by means of the software, select **Sample Tracking** from the **System Overview** screen.

When operating in non-barcode mode, samples are identified by a sequence number, the rack number, and their position in the sample rack. This assignment has to be done on the **Workplace > Test Selection** screen.

**Incorrect results due to sample mismatch**

If samples are not placed in the proper position, incorrect measurement results may occur.

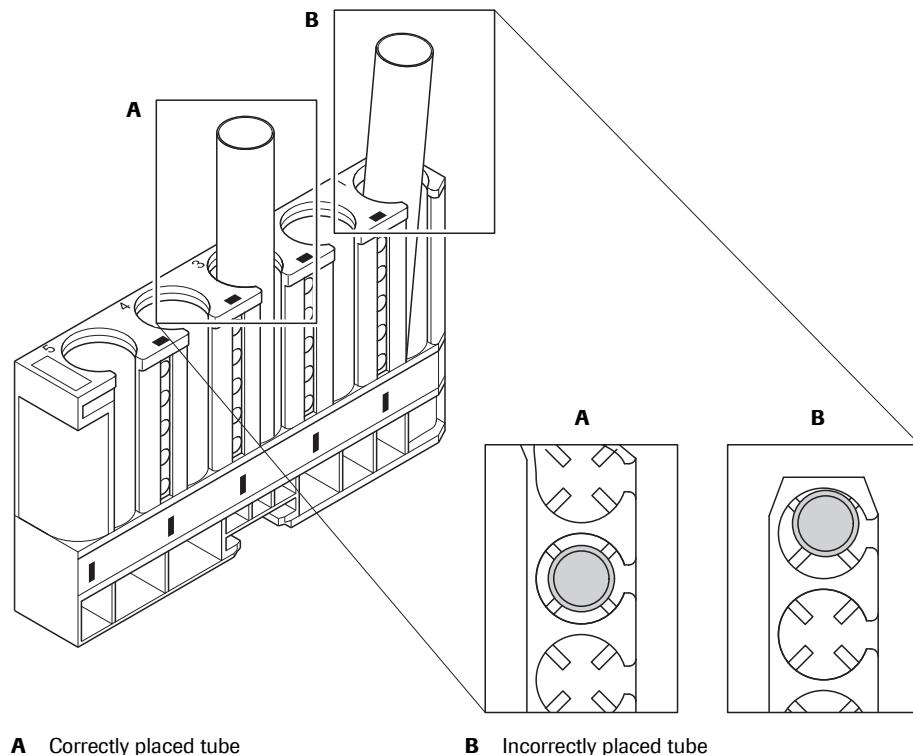
When manually assigning positions, ensure the position is not already assigned.

Correct placement of sample tubes on a rack

Take special care to place sample tubes correctly on the rack. This is especially important for 13 mm tubes, which are narrower and more likely to tilt if placed incorrectly. If the tubes are not correctly seated in an upright position on the rack, the sample probe may attempt to sample outside the tube or the sample probe may short sample if the probe hits the side of the tube, causing errors and incorrect results.

Correct placement without Cup-Adapters

The following figure illustrates correct and incorrect placement of a sample tube on the rack. The tube should be seated correctly in the rack so that the tube is vertical.



A Correctly placed tube

B Incorrectly placed tube

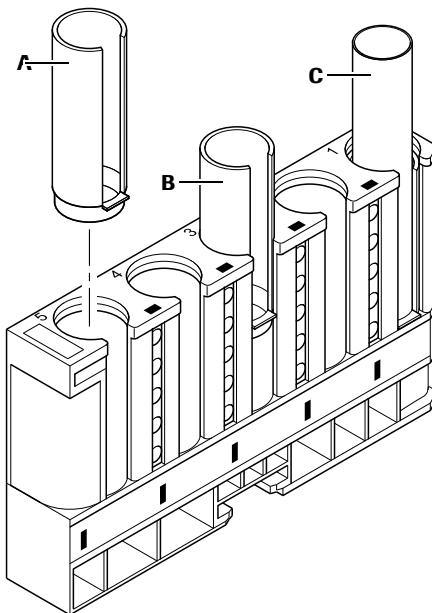
Figure A-25

Correct placement of a sample tube on the rack

Trays, racks, tubes, and cups

Correct placement with
Cup-Adapters

To improve the alignment of 13 mm tubes on the rack, Roche recommends that the Roche Cup-Adapters are used. Cup-Adapters are placed as an insert to the standard rack, as shown in the following figure.



A Roche Cup-Adapter **C** 13 mm tube inserted in a Cup-Adapter
B Insert Cup-Adapter into rack

Figure A-26 Fitting a Cup-Adapter to a 5-position standard rack

The Roche Cup-Adapters should be used only for the sample tubes specified for use with the **cobas** 6000 analyzer. Tubes with an outer diameter greater than 13mm should not be used in combination with Cup-Adapters, because the barcode label might be damaged.

c 501 module

This chapter provides a detailed description of the c 501 module, its hardware components and technical specifications.

In this chapter

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Overview

The c 501 module is a fully automated, discreet, computerized analyzer for in vitro tests on a wide range of analytes. It is designed to use serum/plasma, urine, CSF, supernatant and whole blood sample types. The c 501 module performs photometric assays as well as ion-selective electrode (ISE) determinations. The throughput is up to 1000 tests per hour for a combination of photometric and ISE tests.



Figure A-27 **c 501 module**

This chapter describes the c 501 module. The rack rotor and rack sampler unit belong to the core unit.

- ☞ For a detailed description of the core unit, see Chapter 3 *Control unit, cobas link and core unit*.

System characteristics

- 131 onboard pre-programmable applications
- STAT sample processing within less than 2 min.
- Automatic reagent cassette loading and unloading
- Automated maintenance functions
- Automatic rerun capability
- Automatic calibration notification
- Automatic sample dilution capabilities
- Non-contact ultrasonic mixing
- Reduced water consumption
- HbA1c whole blood support
- Backup solution for core unit

Components of the c 501 module

The c 501 module contains an ISE unit and a photometric unit. Figure A-28 sketches the different areas from a top -view perspective:

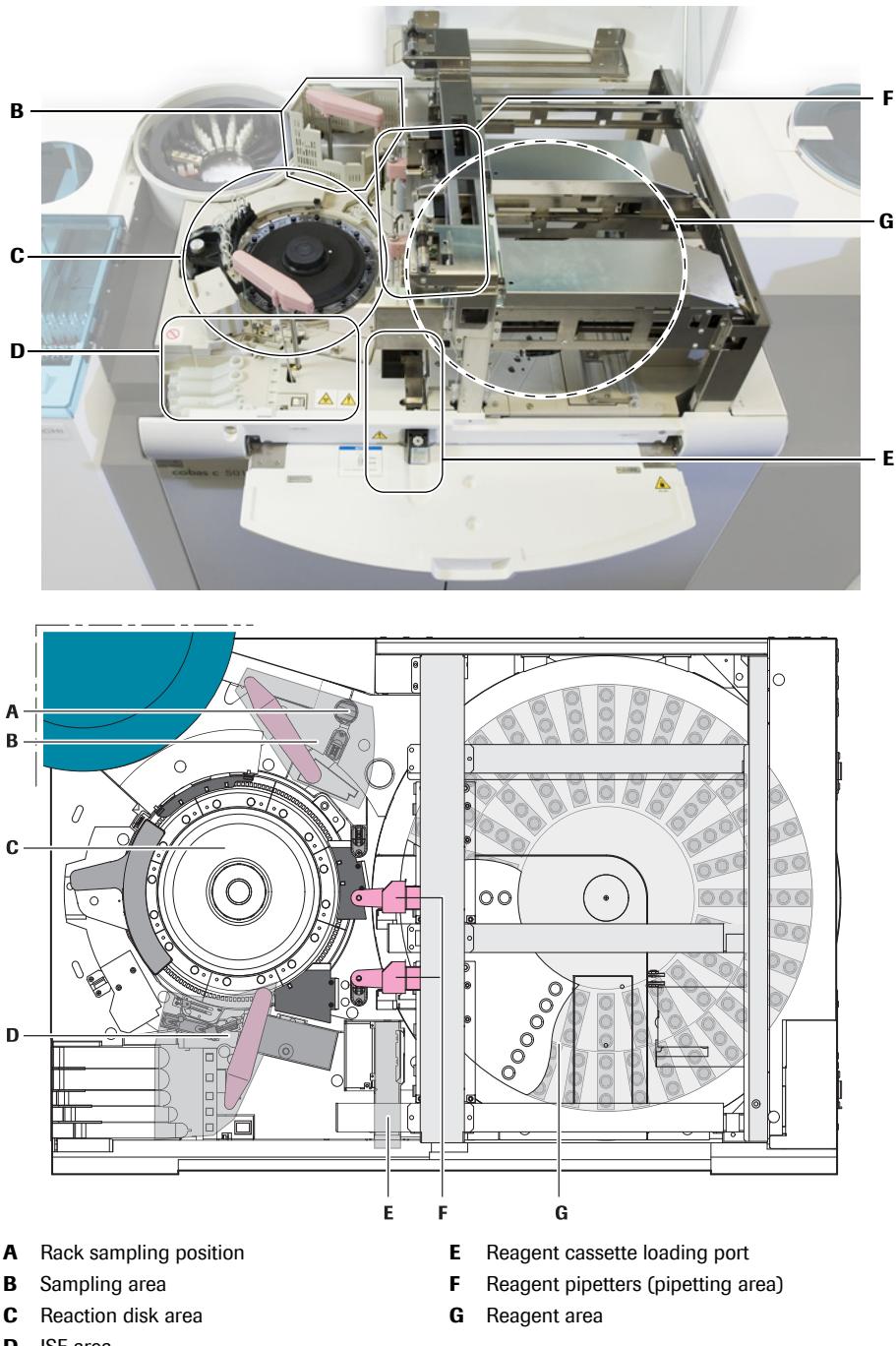
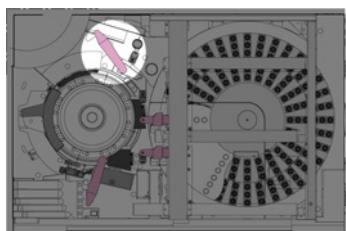


Figure A-28 Areas of the c 501 module

The c 501 module can be subdivided into the following areas

- **Sampling area**
  See *Sampling area components* on page A-58.
- **Reagent area**
  See *Reagent area components* on page A-60.
- **Reaction disk area**
  See *Reaction disk area components* on page A-65.
- Behind the front doors
  See *Behind the front doors* on page A-75.
- Rear side
  See *Rear view* on page A-76.
- **ISE area**
  See *ISE area components* on page A-77.

Sampling area components



The sampling area of the c 501 module consists of the following components:

- A rack sampling position.
 - A sample pipettor (consisting of pipettor arm and probe) for pipetting samples from the sample tubes to the reaction cells on the reaction disk.
 - A rinse station for internal and external rinsing of the sample probe.



A	Pipetter arm	D	Drying cylinder
B	Sample probe	E	Sample probe rinse station
C	Shield pipe (against electrostatic noise)		

Figure A-29 Sample pipetting system

Sample pipetter

The sample pipetter consists of the pipetter arm and the sample probe. When a rack is in the sampling position, the pipetter transports sample liquid from the sample tube to a reaction cell. When aspirating, liquid level detection is accomplished by a highly sensitive capacitance measurement, as well as a clot detection by means of pressure measurements.

To protect the probe against electrostatic noise, which would interfere with the capacitance measurement, a metal shield pipe is mounted over the sampling position.



The sample probe is equipped with an extra sensitive level detection and a clot detection. That is, it is not identical in construction and therefore not exchangeable with the ISE pipettor probe.

After sample has been aspirated, the probe is raised from the sample and is moved to the reaction disk. The sample probe arm lowers the probe into the reaction cell at the sample dispense position. Sample is dispensed while the beveled sample probe tip is in contact with the bottom of the reaction cell. This ensures that a precise volume of sample is deposited into the bottom of the cell even when using a low dispense volume. The sample probe is spring-mounted on the arm to avoid damage to the probe or reaction cell.

Sample probe rinse station

The sample probe rinse station is located between the sample aspiration position at the sample tubes in the sample racks and the sample dispense position at the reaction disk. To prevent carryover, the sample probe is rinsed here with deionized water both externally and internally before aspirating from a new sample.

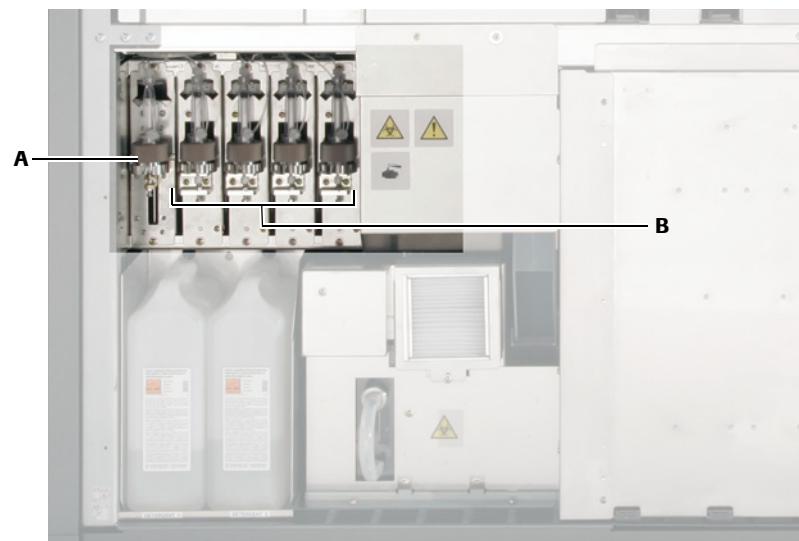


The sample probe stops at the drying cylinder only when whole blood is pipetted for HbA1c tests.

The rinse station is the home position for the sample probe when the pipettor is in standby.

Sample syringe

The sample pipettor is connected by tubing to the sample syringe, which controls the pipetting action.



A Sample syringe

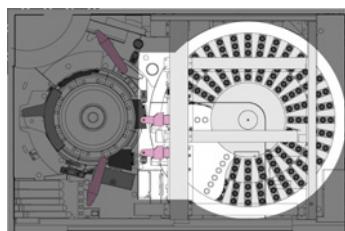
B Reagent syringes

Figure A-30 Sample syringe

The sampling syringe, which is located behind the left front door of the module, is filled with degassed and deionized water. The syringe uses positive displacement to aspirate and dispense samples via the sample probes.

The syringe motor retracts the plunger within the chamber of the syringe, and sample is aspirated into the tip of the sample probe. The pipettor arm moves the sample probe to the reaction disk. The sample probe lowers into the reaction cell and the syringe motor reverses to dispense the sample. The pipettor arm lifts the sample probe from the reaction cell and moves it to the sample probe rinse station.

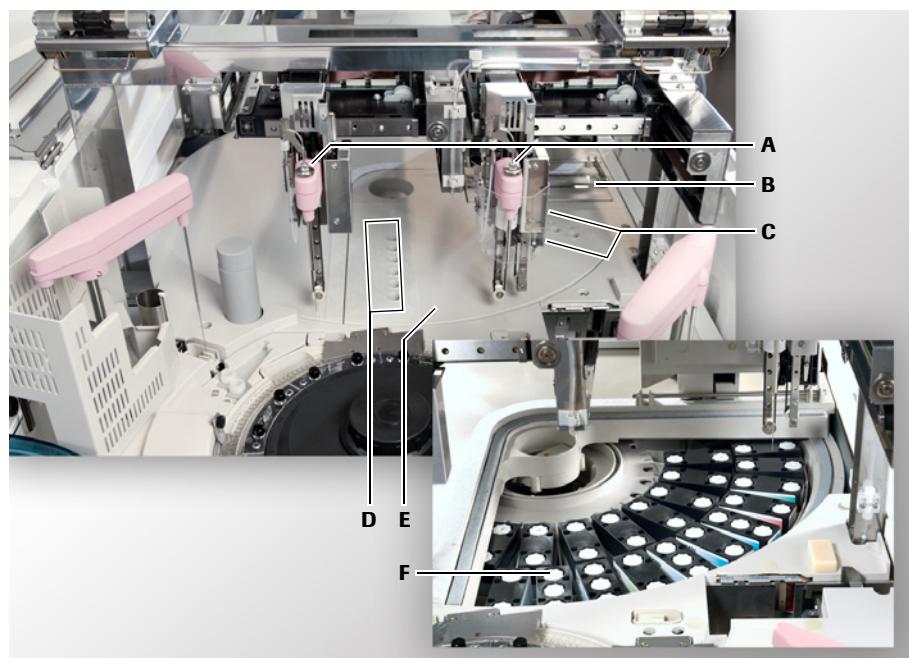
Reagent area components



The reagent area of the c 501 module consists of the following components:

- A refrigerated reagent compartment for storing up to 60 reagent cassettes.
- Two reagent pipettors for aspirating and dispensing reagents from the reagent compartment to the reaction cells on the reaction disk.
- Two rinse stations for internal and external rinsing of the reagent probes.
- A fully automated cassette management system

Reagent storage compartment



- | | |
|--|--|
| A Reagent pipettors | D Cutouts for R2 reagent pipettor probe |
| B Shutter | E Reagent compartment (cover closed) |
| C Cutouts for R1 reagent pipettor probe | F Reagent compartment (cover opened) |

Figure A-31 Reagent storage compartment

Reagent cassettes are stored in a closed, temperature-controlled (5-12°C) compartment containing two concentric rings with a total of 60 positions for reagent cassettes. There are 24 positions on the inner and 36 positions on the outer ring.

To prevent reagents from evaporating, the reagent compartment is equipped with a cover. By design, this cover is not meant to be opened or removed. Cassettes are placed into and removed from the compartment by way of the shutter and cutouts in the cover allow reagent probes to access the reagents.

Reagent pipetting system

The reagent pipetting system is composed of two reagent pipetters—R1 and R2—and two reagent syringes. The pipetters are mounted on two independent x-y-motion mechanisms.

Reagent pipetters

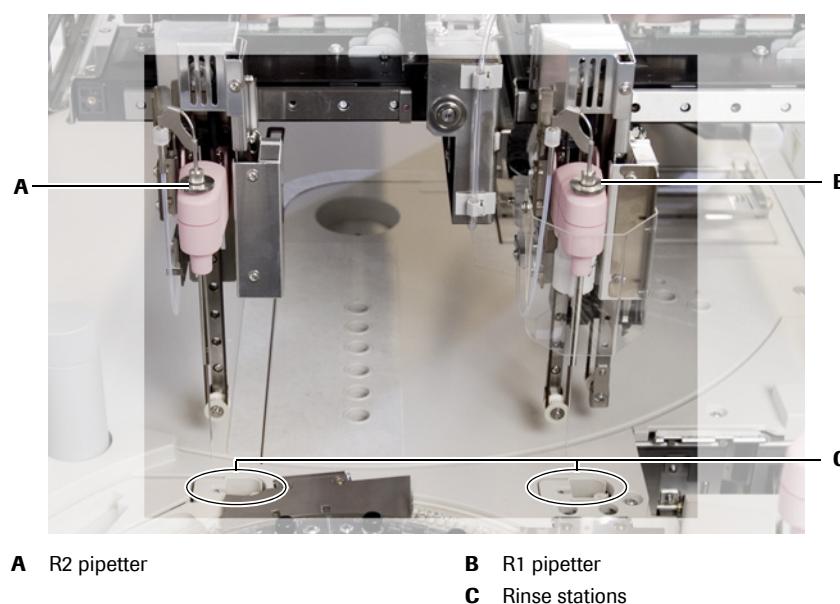


Figure A-32 Reagent pipetters

Two reagent pipetters, which are mounted above the reagent disk, transport the reagents from the reagent compartment to the reaction disk.

Before each pipetting, the reagent probes are externally and internally rinsed with deionized water and dried. After reagent has been aspirated, the probe moves from the reagent compartment to the reaction disk. There, the reagent volume is dispensed into a reaction cell containing the sample. Unlike the sample probe, the reagent probes are not lowered into the reaction cell. Reagent is dispensed from the top of the reaction cell.

The mechanical cycle of the c 501 module allows for three different reagent timings: R1, R2, and R3. The R1 pipetter pipettes reagents at R1 timing. The R2 pipetter pipettes reagents at R2 and R3 timing.

In contrast to R2, the R1 reagent probe is equipped with a level detector. This detector works with a pressure sensor and is used when a new cassette is loaded and checked at the preparation station. Moreover, the gripper and the piercer are mounted on the same x-y-motion mechanism as the R1 reagent probe.

See *Cassette preparation station* on page A-63.

Reagent syringes



A R1 syringe

B R2 syringe

Figure A-33 Reagent syringes

The reagent syringes are located behind the left front door of the module. They are filled with degassed and deionized water, using positive displacement to aspirate and dispense reagents.

Reagent probe rinse stations

The reagent probe rinse stations are located between the reagent compartment and the reaction disk. After each reagent dispense, water is flushed through the probes and onto their outside surfaces. The probes are then dried at a drying cylinder.

The rinse stations are the home position for the reagent probes when the module is in standby.

Cassette management system

Reagents for all Roche Diagnostics applications are provided in reagent cassettes. These cassettes contain one to three specially designed reagent vials and carry barcode labels with detailed reagent and test related information.

From the time of check-in until an empty cassette is discharged the c 501 manages the registration, internal transportation, and placement fully automatically. This rules out any possibility of misplacement or usage of inappropriate reagents. The cassette management system consists of the following components:

- Cassette loading port
- Cassette preparation station
- Piercer and Gripper
- Cassette disposal

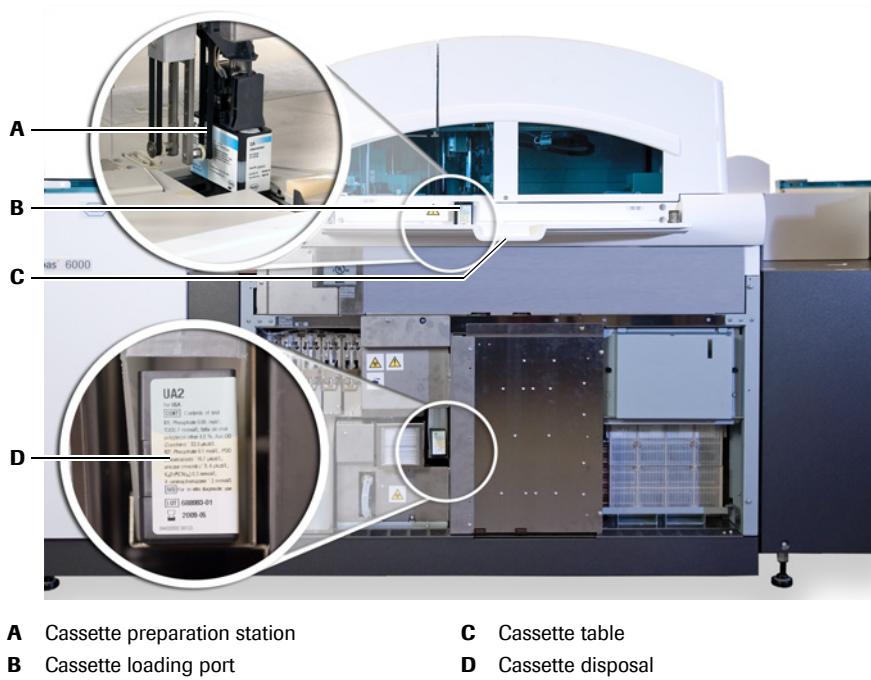


Figure A-34 Components of the cassette management system

Cassette loading port

The cassette loading port is located behind the reagent cassette table at the front of the c 501 module. It is used for loading reagent cassettes onto the module.

When loading a reagent cassette, it is important that its **barcode label is facing to the right**.

After loading, the system handles the cassette without any further intervention of the operator: The cassette is pulled in to the preparation station where a barcode reader scans the cassette's barcode label and checks its integrity.



A cassette is rejected and not loaded but pushed out of the loading port again in the following cases:

- The cassette's barcode is unreadable
- The cassette has been on the analyzer before and it was previously dumped (discarded) by the system

Cassette preparation station

The cassette preparation station is located directly behind the cassette loading port. When a new cassette is pulled in to the preparation station, a barcode reader scans the following data from the cassette's barcode label:

- System-ID (for example, 07-3755-0)
- Lot number
- Production date
- Cassette number (serial number, for example, 01983)
- Expiration date
- Bottle configuration information

In case, the current cassette has been registered before, the shutter of the reagent compartment opens and the gripper loads the cassette.

If the current cassette is new, the system proceeds with the following actions while the cassette is at the preparation station:

- By reading the cassette barcode, the system checks the availability of the corresponding test application.
- The piercer pierces the reagent bottle caps.

Now, the cassette is ready to be transported to the reagent compartment by the gripper.

Piercer and Gripper

The piercer and gripper are mounted—together with the R1 pipetter—on a x-y-z motion mechanism. When a cassette is ready to be transported to the reagent compartment, the gripper lowers down on the cassette, grips it, lifts it, and moves it to the shutter. The shutter automatically opens and the cassette is placed in a registered position in the reagent compartment.



Injury or damage to the analyzer due to contact with instrument mechanism

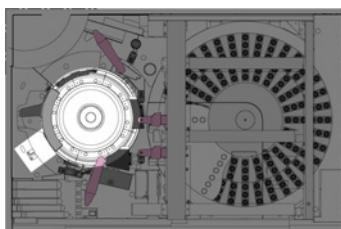
Do not touch piercer and gripper during instrument operation.

Cassette disposal

Empty reagent cassettes are automatically transported to the cassette disposal. With the aid of gravity, the cassettes drop down the cassette disposal shaft at the end of which they can be removed by the operator. The cassette disposal has a capacity of 10 cassettes.

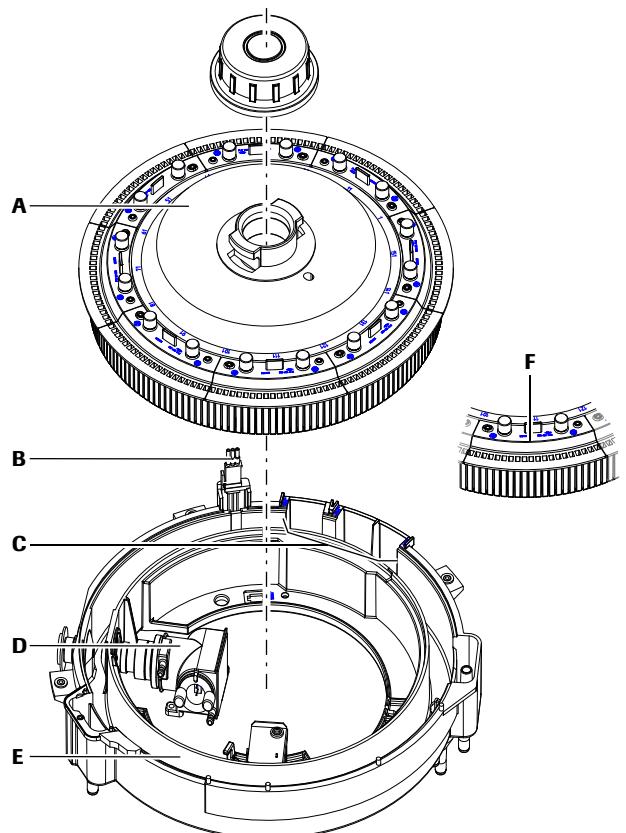
☞ To locate the cassette disposal, see Figure A-34 on page A-63.

Reaction disk area components



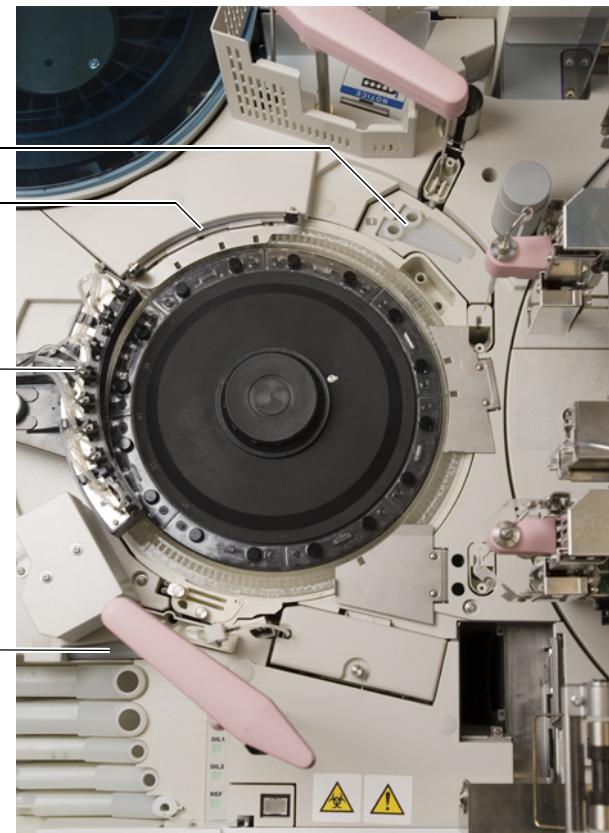
The reaction disk area of the c 501 module consists of the following components:

- A reaction disk with the reaction cells, which are immersed in the incubator bath.
- Three ultrasonic mixing units for non-contact mixing of reaction mixtures (15 levels).
- A photometric measuring system which continually measures the absorbance of the reaction mixture in each of the reaction cells.
- A cell rinse unit for cleaning the reaction cells once test measurement is complete.
- The auxiliary reagents SMS (acid wash), Multiclean (basic wash), and Hitergent.



- A** Reaction disk
B Water level sensor
C Ultrasonic mixing units

- D** Photometric unit
E Incubator bath
F Reaction cell segment



- G** (1) Multiclean (basic wash)
(2) SMS (acid wash)
H Reaction cell rinse unit
I Hitergent

Figure A-35 Reaction disk area

Reaction disk

The reaction disk of the c 501 module carries 160 reusable plastic reaction cells (cuvettes). These reaction cells are grouped together in eight segments with 20 cells each. All reaction cells are seated in a controlled-temperature bath. This incubator bath maintains the cells at the required temperature of 37°C.



The reaction cells should be replaced once a month since they gradually deteriorate over long use. Carry out cell blank measurement once a week after rinsing the reaction system to check the integrity of all cells.

See *To perform a cell blank measurement* on page C-77.

Ultrasonic mixers

The ultrasonic mixing units mix the reagents within each of the reaction cells to ensure a homogeneous distribution of reactants. Corresponding to the three reagent timings R1, R2, and R3, there are three independent mixing units.

To avoid spillage, the water level of the incubator bath is checked before mixing by calculating the volume. If the liquid level is too low or too high, an alarm (Mix.E) is issued and mixing is not performed.

Contamination on the surface of the ultrasonic mixing units will cause inadequate mixing. It should be cleaned at least once every three months. The ultrasonic output intensity is continually monitored. If the intensity falls below a certain limit, an alarm (<Mix) is issued, and replacement of the ultrasonic mixing unit is required. Contact your technical support for the replacement.

See *Cleaning the ultrasonic mixers* on page C-116.

Incubator bath

The circular incubator bath, positioned beneath the reaction disk, maintains the reaction mixtures in the reaction cells at a temperature of 37°C. Water in the incubator bath is circulated by a pump through a refrigeration unit where it is cooled and then onto the heater where it is heated, as necessary, to maintain the temperature ($\pm 0.1^\circ\text{C}$).

Two glass windows (inner and outer) are positioned in opposite walls of the incubator bath. These windows permit light from the photometer lamp to pass through the incubator bath water and through the reaction cells in the bath. The light beam emerges from the outer window of the incubator bath and enters the instrument photometer.

A liquid level sensor detects the water level of the bath. Deionized water is automatically added to the incubator bath, as determined by the liquid level sensor, to compensate for evaporation. This occurs even in standby.

Hitergent

Hitergent is a non-ionic, bacteriostatic detergent automatically added to the incubator bath by the ISE pipetter whenever the water is exchanged. It acts as a surfactant to minimize the formation of bubbles that could potentially interfere with the photometer readings. Hitergent is located between the ISE reagent compartment and the reaction disk.

To locate the reagent bottle for Hitergent, see Figure A-35 on page A-65.

Photometer

The c 501 module is equipped with a photometer to measure the absorbencies of the reaction mixtures in the reaction cells.

The photometer lamp is located against the inner ring of the incubator bath beneath the reaction disk. The detector is outside the incubator bath ring, behind the ISE reagent compartment.

To locate the photometer unit, see Figure A-35 on page A-65.

Measurements are taken of all the 160 reaction cells, as the reaction disk is turning.

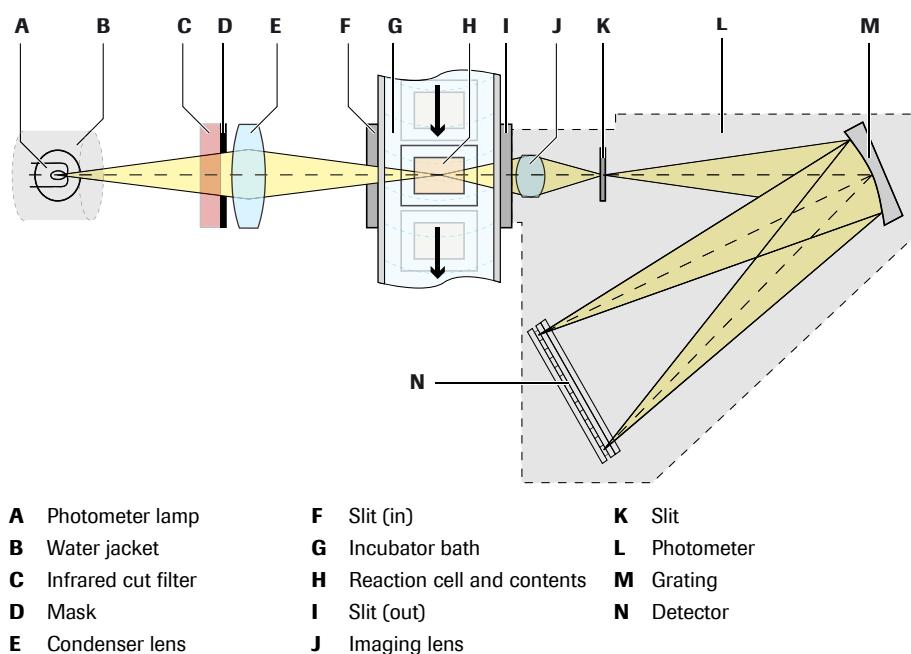


Figure A-36 Illustration of light path through photometer components

Photometer lamp

The photometer lamp beneath the reaction disk, is encased in a constant-temperature water jacket, which helps to maintain a constant energy output from the lamp, and also extends the lamp life.

For more information about replacing the photometer lamp, see *Replacing the photometer lamp* on page C-116.

Light path

The light from the photometer lamp passes through the following main components:

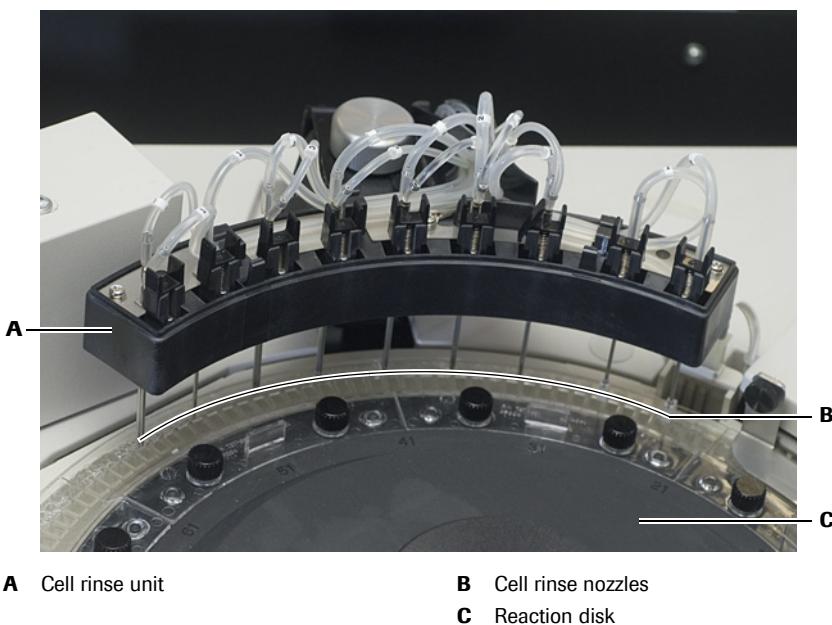
- Inner incubator bath window
- Incubator bath water
- Reaction cell and its contents
- Incubator bath water
- Outer incubator bath window
- ...and into the photometer

When the light beam enters the photometer, it strikes a diffraction grating. This separates the light into its constituent wavelengths and reflects them onto a fixed array of 12 photodiodes. Each photodiode is permanently positioned to detect light at a different wavelength.

The computer uses the available assay parameter information to select the wavelengths and the times at which a reaction mixture's absorbance is read and results are calculated.

The instrument computer keeps track of which test is being performed in each reaction cell. It also knows when each reaction cell passes through the photometer light path. The computer uses this tracking ability and the programmed read instructions to obtain test results.

Cell rinse unit



A Cell rinse unit

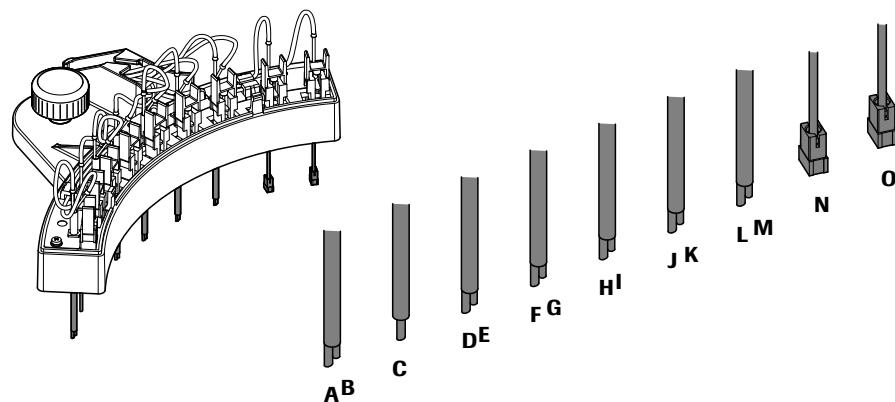
B Cell rinse nozzles

C Reaction disk

Figure A-37 Reaction cell rinsing system

The cell rinse unit is located to the left of the reaction disk. It cleans, rinses, and dries the reaction cells once the chemical reaction of the reaction mixture has been measured. To ensure cell integrity (optical characteristics), a photometric reading of a cell containing water is performed during the cleaning process (cell blank) and compared with the previous cell blank reading.

Cell rinse sequence The following sequence reflects the order in which cleaning, rinsing, and cell blanking of the reaction cells takes place.



1. L: Liquid aspiration at end of reaction
M: Rinse water discharge
2. J: Rinse water aspiration
K: Cell wash I discharge
3. H: Cell wash I aspiration
I: Cell wash II discharge
4. F: Cell wash II aspiration
G: Rinse water discharge
5. D: Rinse water aspiration
E: Rinse water discharge
6. C: Rinse water aspiration
7. A: Water blank discharge
B: Water blank overflow aspiration
8. N: Water blank aspiration (nozzle tip)
O: Water blank aspiration (nozzle tip)

Figure A-38 Flow of the cell rinse mechanism

Flow of photometric analysis

The following two figures help to understand the flow of photometric analysis:

- Figure A-39 on page A-70 shows the main functions and their positions on the reaction disk area.
- Figure A-40 on page A-71 shows the main steps of photometric analysis flow
- Table A-4 on page A-72 explains the operating principle and the photometric analysis flow.

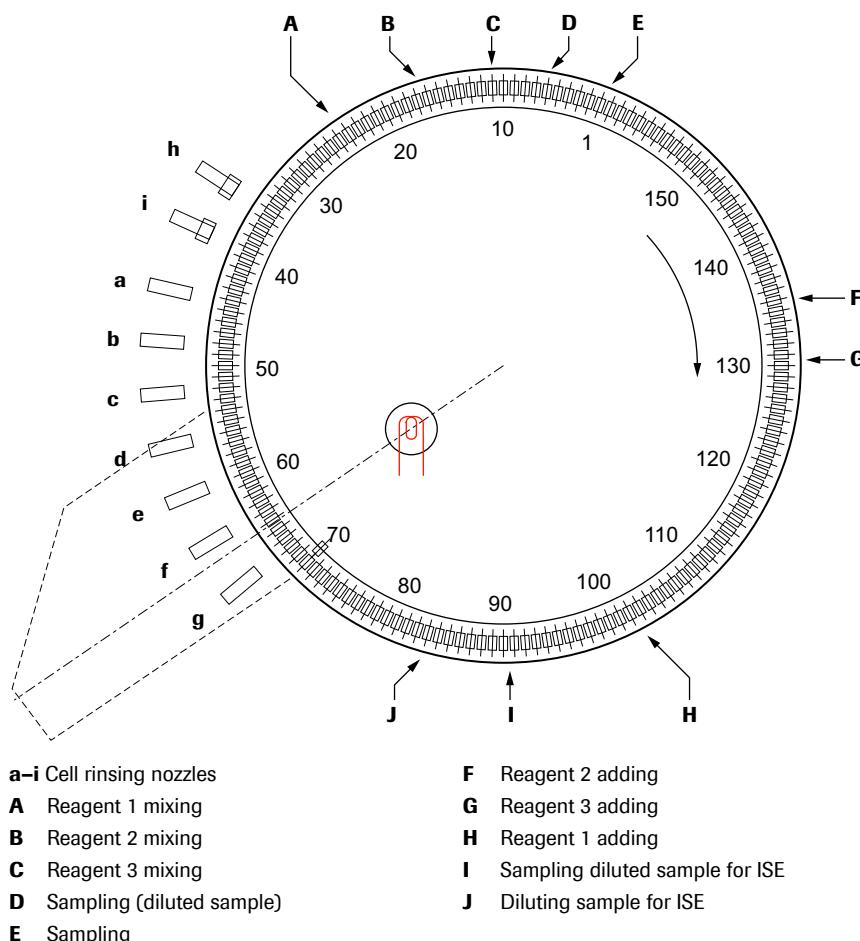


Figure A-39 Main functions and their positions on the reaction disk area

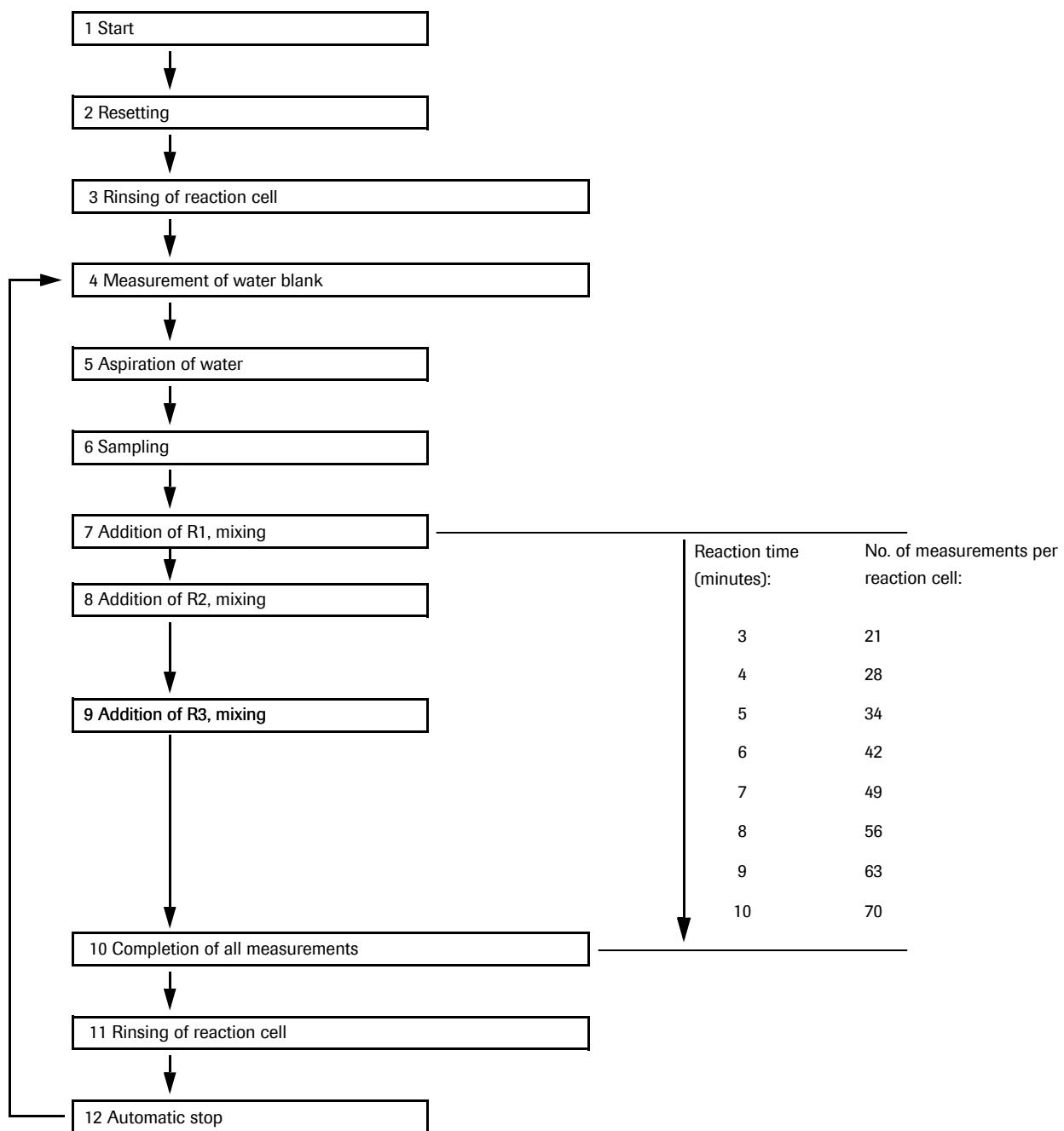


Figure A-40 Flow chart of the photometric analysis

Step	Action
1–2	<p>Upon start, the instrument resets the mechanisms, and then starts rinsing the reaction cell.</p> <p>In a single cycle (6.0 s), the reaction disk rotates by 60 reaction cells, stops temporarily, and rotates by a distance of 59 reaction cells. Therefore, the reaction disk rotates 3 turns minus 4 reaction cells in 4 cycles (24.0 s)</p>
3	<ul style="list-style-type: none"> Using the rinsing nozzle a in the rinsing mechanism, reaction solution is aspirated and the reaction cell is rinsed with deionized water. Then, after 4 cycles, the reaction cell is washed with rinsing nozzle b in the rinsing mechanism using Cell wash I. Then, after 4 cycles, the reaction cell is washed with rinsing nozzle c in the rinsing mechanism using Cell wash II. Using the rinsing nozzle d and the rinsing nozzle e, the reaction cell is rinsed again with deionized water. After deionized water is aspirated with nozzle f, rinse water is discharged with nozzle g.
4	<p>Then a water blank is measured 3 times.</p> <p>If the water blank value differs by 0.1 or more from the cell blank value, that cell will not be used for analysis.</p>
5–6	<p>After the water blank measurement, the water is aspirated (using rinsing nozzles h and i) and the cells are dried and ready for measurement.</p> <p>Sampling is carried out in the order starting from the sample with the test that will take the longest reaction time in order to shorten the time needed for completion of data output.</p>
7–9	<p>Reagents R1, R2, and R3 are usable, and will be added at the determined positions and time points (0, 1.5 and 5 minutes), respectively.</p> <p>After one of the reagents R1, R2, and R3 has been added, the liquid in the cuvette will be mixed at the corresponding mixing position by means of the ultrasonic mixer.</p>
10	<p>Sampling is carried out every 6 s (1 cycle), and measurement is performed once in one full turn, that is 70 times in 10 minutes. On completion of measurement, the concentration is calculated by use of the absorbance at the specified photometric point.</p>
11	The instrument discharges the reaction solution with the rinsing mechanism and conducts washing with detergent and rinsing with water.
12	Then the instrument goes into standby.

Table A-4 Flow of photometric analysis

Reaction monitoring

The c 501 module adopts the entire reaction monitoring system, which measures the absorbance of reaction solution intermittently during reaction time. The reaction disk rotates 3 turns in 24 seconds and during this time, the absorbance is measured and stored for all of reaction cuvettes that go across the optical path of the photometer. For each reaction cuvette, water blank (absorbance 0) is measured, and then photometry is performed about every 8 seconds, or 70 times in 10 minutes. Therefore, photometry which is less affected by passage of time can be performed. Analysis method can be set flexibly by using arbitrary photometric points for concentration calculation.

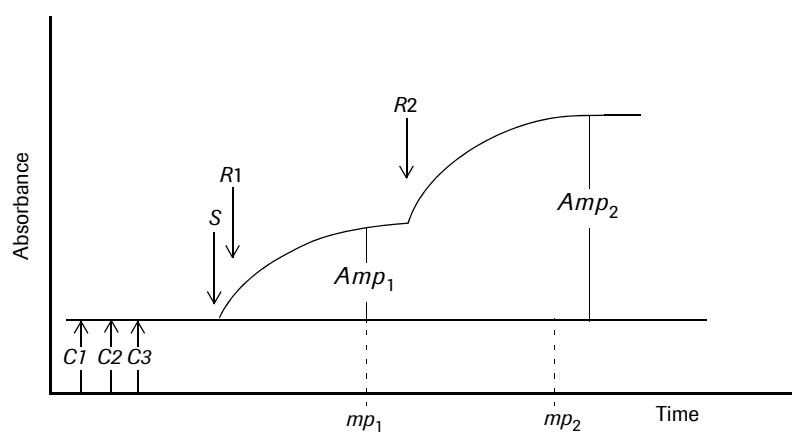


Figure A-41 Reaction course

Maintenance key

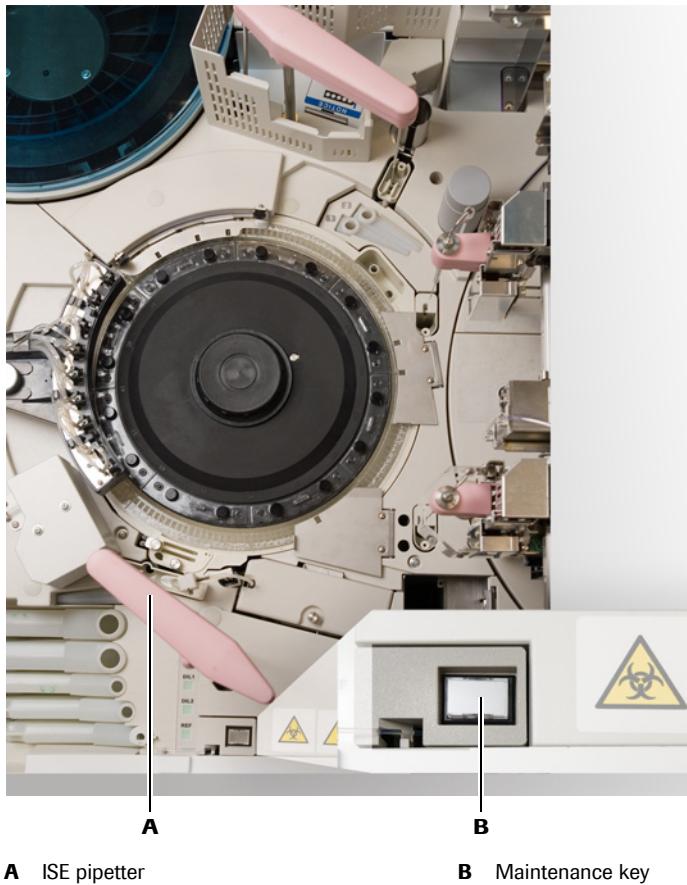


Figure A-42 Maintenance key

The maintenance key is located to the right of the ISE reagent compartment, in front of the ISE pipetter.



Maintenance key must be used by specially trained operators only!

This key is used to move a previously selected pipetter to various predefined positions. This is important to verify the horizontal probe alignment.

- ☞ For more information about the maintenance key refer to the *Interlock function cobas c 501 with ISE manual*.

Behind the front doors

Figure A-43 provides a front view of the c 501 module and lists the main components behind the front doors of the module.

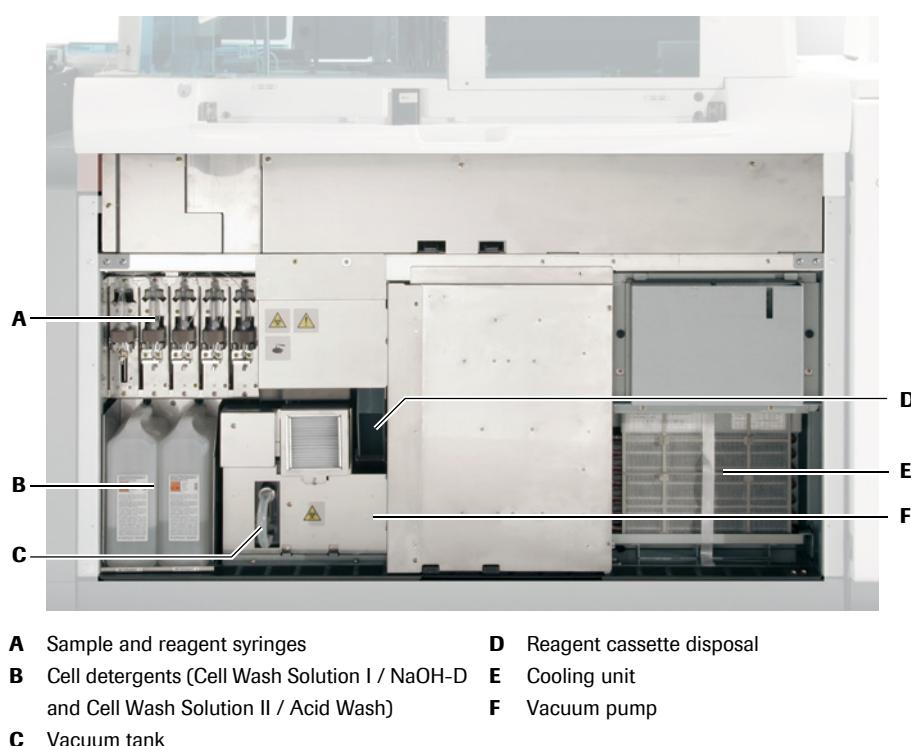


Figure A-43 c 501 module with open front doors

Auxiliary reagents and cleaning solutions

Auxiliary reagents of the c 501 module are located both behind the front door and in the reaction disk area:

- Two large bottles with detergents for the cell rinse process are located behind the left front door of the c 501. They contain Cell Wash Solution I / NaOH-D (Cell wash I) and Cell Wash Solution II / Acid Wash (Cell wash II).
 - Two small bottles (70 mL) containing Multiclean and SMS are located close to the sample pipetter, and one bottle of Hitergent is located close to the ISE pipetter.
 - Multiclean and SMS are used for cleaning the sample probe.
 - Hitergent is an additive to the incubator bath to reduce surface tension and microbial proliferation.
- ☞ See Figure A-35 on page A-65 (**G, I**).
- ☞ For more information about auxiliary reagents, see *Auxiliary reagents* on page B-94

Rear view

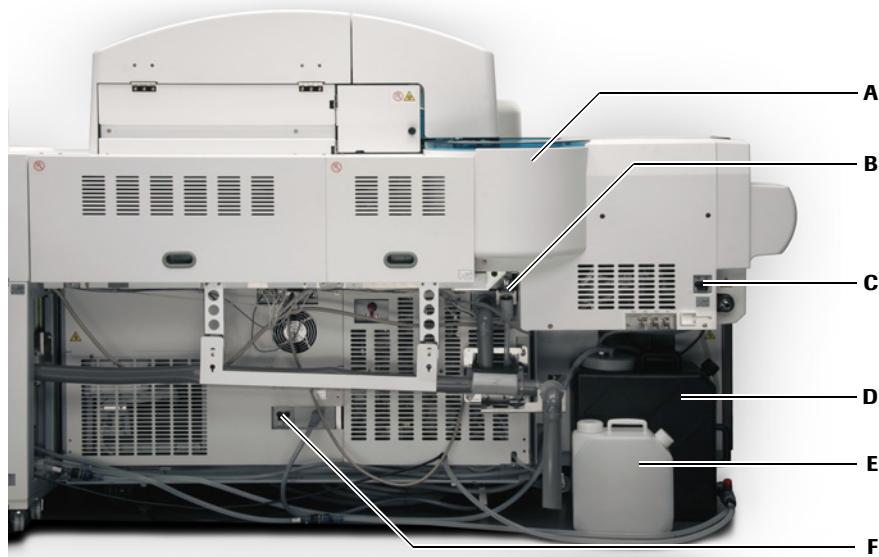
Vacuum system

The vacuum system is located at the front of the module. It consists of vacuum pump, vacuum tank, vacuum sensors, and connecting tubing. The vacuum system aspirates reaction mixture waste from the reaction cells to the reaction waste container and removes reaction cell rinse water from the module through the main drain line.

☞ To locate the vacuum system, see Figure A-43 on page A-75.

Rear view

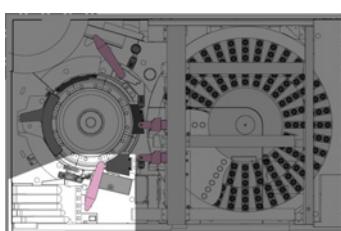
Figure A-44 provides a rear view of the c 501 module assembled with a cu 150 core unit. The legend lists the main components on the back of the analyzer.



- | | | | |
|----------|--|----------|-------------------------|
| A | Rack rotor | D | Water tank |
| B | Drain port (connected to the drain pipe) | E | High concentrated waste |
| C | Core unit module switch | F | c 501 module switch |

Figure A-44 **c 501 rear view**

ISE area components



The ISE unit provides an electronic method for measuring sodium, potassium, and chloride ion activities in samples. It is designed to process up to 600 tests or 200 samples per hour. The ISE unit of the c 501 module consists of the following components:

- ISE pipetting system
- Internal standard bath (IS bath)
- ISE sipper mechanism
- ISE measuring system
- ISE rinse station
- ISE reagent compartment

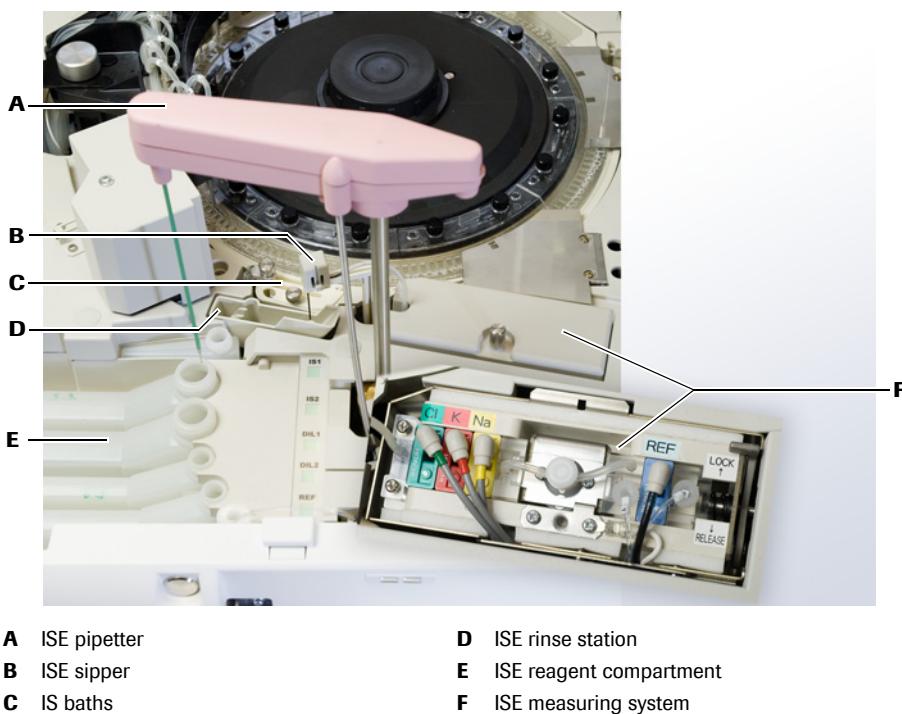


Figure A-45 c 501 ISE unit

The ISE area of the c 501 module comprises the following components:

- One internal standard bath with two chambers (IS bath)—for heating internal standard (ISE IS) to measuring temperature (37°C)
- ISE pipetting system
- ISE sipper mechanism—for aspirating ISE IS and sample solution into the measuring system
- ISE reagent compartment—containing bottles for ISE IS, ISE Dil., and ISE Ref. (KCl)
- ISE measuring system

ISE pipetting system

The ISE pipetting system is composed of a pipetter (consisting of pipetter arm and probe), a syringe, and the ISE rinse station. The pipetter is connected by tubing to the syringe, which controls the pipetting action.

- ISE pipetter probe* The ISE pipetter probe is equipped with a level detector (capacitance method). These features are similar to the sample probe, however, ISE and sample probes are not equal in construction and cannot be exchanged.
- ISE syringe* The ISE syringe is located behind the left front door of the c 501 module. It is the fourth syringe (from left to right), between the R2 and the sipper syringe.
- ISE rinse station* The ISE rinse station is located between the IS bath and the reagent compartment. This rinse station is used for both ISE pipetter probe and sipper probe.

Internal standard bath

Internal standard bath (IS bath) has two chambers for heating internal standard (ISE IS) to measuring temperature (37°C). The use of two chambers allows for an optimized flow of the analysis: While the content of one chamber is ready for use, fresh ISE IS is pipetted into the other chamber where it is given time to heat up for the next measurement.

ISE sipper mechanism

The ISE sipper mechanism consists of a sipper nozzle and a sipper syringe.

- Sipper nozzle* The sipper nozzle lowers either into ISE IS solution in the IS bath or into sample solution in a reaction cell to aspirate the respective solution into the measuring flow path.
- Sipper syringe* The sipper syringe is positioned behind the left front door of the c 501 module. It is the rightmost syringe (to the right of the ISE reagent syringe). The syringe not only provides the negative pressure for the sipper but also aspirates ISE Ref. from its container and into the reference cartridge flow path.

ISE measuring system

The ISE measuring system is—together with the IS bath—contained in a temperature-controlled compartment. It is composed of three channelled sample/ISE IS measurement cartridges and one reference cartridge.

Measurement cartridges

Three cartridges, each containing an ion-selective electrode, are directly connected to form a flow path for the diluted sample and the ISE IS solutions. The electrode potentials are measured in the color-coded cartridges as follows:

Red	Potassium	K ⁺
Yellow	Sodium	Na ⁺
Green	Chloride	Cl ⁻

Reference cartridge

The reference cartridge contains the reference electrode. ISE Ref. is aspirated through the cartridge and a reference electrode potential is registered.

The difference between the potentials at the reference electrode and the ion-selective electrode equals the electromotive force (EMF). For every test, the EMF of both ISE IS and diluted sample solution are measured for each sort of ions (Cl⁻, K⁺, and Na⁺). From these EMF values the results are calculated.

ISE rinse station

At the ISE rinse station both ISE pipetter probe and sipper probe are rinsed with deionized water. To avoid contamination, clean the rinse station at least once a week.

☞ See *Cleaning the rinse stations* on page C-80.

ISE reagent compartment

The ISE reagent compartment provides five positions for reagent bottles: Two positions for ISE IS, two for ISE Dil., and one for ISE Ref. bottle.

The reagent compartment is equipped with position sensors for each reagent bottle (reflection type).

A green indicator lamp (next to the reagent position) lights up if no reagent bottle is present or if the liquid level falls below the limit where the bottle needs to be replaced. In this case the ISE probe pipettes from the second bottle of the reagent (changeover reagent). If the second bottle of ISE IS is used as changeover reagent, a changeover calibration is automatically recommended by the system.

☞ For more information on level detection and ISE reagent registration, see:

ISE pipetting system on page A-78

ISE reagent registration on page B-97

Flow of an ISE analysis

Upon start of an electrolyte analysis, the sample pipetter pipettes a sample into a reaction cell. Then, into this cell, ISE Dil. is pipetted by the ISE pipetter and mixing is carried out with the ultrasonic mixing unit. Next, the ISE pipetter dispenses ISE IS solution into the IS bath where it is heated up to 37°C.

After heating, the ISE IS solution is aspirated into the measuring flow path to perform an ISE IS measurement (single-point calibration). The residual ISE IS solution is aspirated through the vacuum nozzle to make the IS bath chamber empty. Then, the sipper aspirates diluted sample from the reaction cell and the sample measurement is performed.

For every ISE measurement, the analyzer measures three electromotive force values (EMF); for chloride, potassium, and sodium, where EMF denotes the difference in potential between the respective ion-selective electrode and reference electrode.

Finally, the results are calculated from the electromotive forces of ISE IS and diluted sample. The ISE system is now ready for the next analysis. In case there are no more samples to be analyzed, the ISE unit performs a final ISE IS measurement and stops. Table A-5 on page A-80 summarizes the flow of an ISE analysis:

Step	Actor	Action
Preparation of measurement		
1	Sample pipetter	Pippettes sample (9.7 µl) to cell
2	ISE pipetter	Aspirates 348 µl and pippettes ISE Dil. (291 µl) to cell
3	Ultrasonic mixing unit	Mixes sample and ISE Dil.
4	ISE pipetter	Pippettes 450 µl ISE IS to IS bath
5	IS bath	ISE IS heats to measuring temperature (37°C)
Internal standard (ISE IS) measurement		
6	Sipper	Aspirates ISE IS to Cl/K/Na cartridges (400 µl)
7	Sipper syringe via tubing	Aspirates ISE Ref. from the ISE Ref. bottle to reference cartridge (65 µl)
8	Electrodes	Measure ISE IS
Diluted sample measurement		
9	Sipper	Aspirates sample to Cl/K/Na cartridges (250 µl)
10	Sipper syringe via tubing	Aspirates ISE Ref. from the ISE Ref. bottle to reference cartridge (65 µl)
11	Electrodes	Measure sample
12		Result calculation and output If there are more samples to be analyzed, go to step 1. If there are no more samples, repeat 6-8 and stop.

Table A-5 Flow of ISE analysis

e 601 module

This chapter provides a detailed description of the e 601 module, its components and technical specifications. In addition, an overview of the reagents used on the e 601 module is provided.

In this chapter

Chapter 5

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Measuring area components	A-88
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Overview

The **e 601** module is a fully automated analyzer for immunoassay analysis. It is designed for both quantitative and qualitative in vitro determinations using a large variety of tests for analysis. Samples are transported to the **e 601** module by the core unit of the **cobas** 6000 system.



Figure A-46 **e 601** module

This chapter describes the **e 601** module. The rack rotor and rack sampler unit belong to the core unit.

- ☞ For a detailed description of the core unit, see Chapter 3 *Control unit, cobas link and core unit*.

System characteristics

- Heterogeneous immunoassays with ECL technology
- Ready to use 24 hours per day
- Reagent barcode capability
- 2 ECL measuring cells
- 170 tests/hour throughput on one e 601 module
- Temperature regulated storage for 25 cobas e packs on one e 601 module
- 100/200 tests per cobas e pack
- 1008 disposable plastic AssayCups and tips on one e 601 module (12 trays of 84 AssayCups and 84 AssayTips)
- Disposable tips for sample pipetting to prevent carry over
- Incubator disk with 54 incubator positions (37°C)
- Stainless steel pipetter probes for reagents and microbeads
- Liquid level detection and clot detection
- Non-invasive vortex mixer
- Automated maintenance functions
- Automatic rerun capability
- Automatic calibration notification
- Automatic sample dilution capabilities

Components of the e 601 module

Figure A-47 shows the different areas of the e 601 module from a top-view perspective:

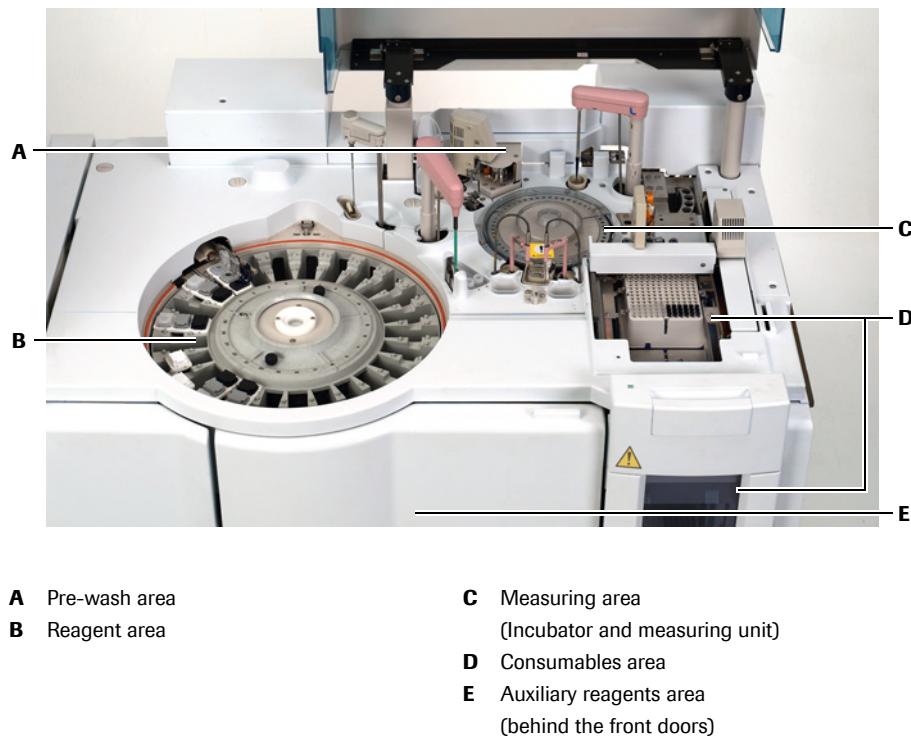


Figure A-47 e 601 module: top view

The e 601 module can be subdivided into the following areas

- **Reagent area**
 eye See *Reagent area components* on page A-86.
- **Measuring area**
 eye See *Measuring area components* on page A-88.
- **Pre-wash area**
 eye See *Pre-wash area components* on page A-90.
- **Consumables area**
 eye See *Consumables area components* on page A-92.
- **Auxiliary reagents area (behind the front doors)**
 eye See *Auxiliary reagents and cleaning solutions* on page A-94.

Reagent area components

The reagent area is on the left side of the analytical module and consists of the following components:

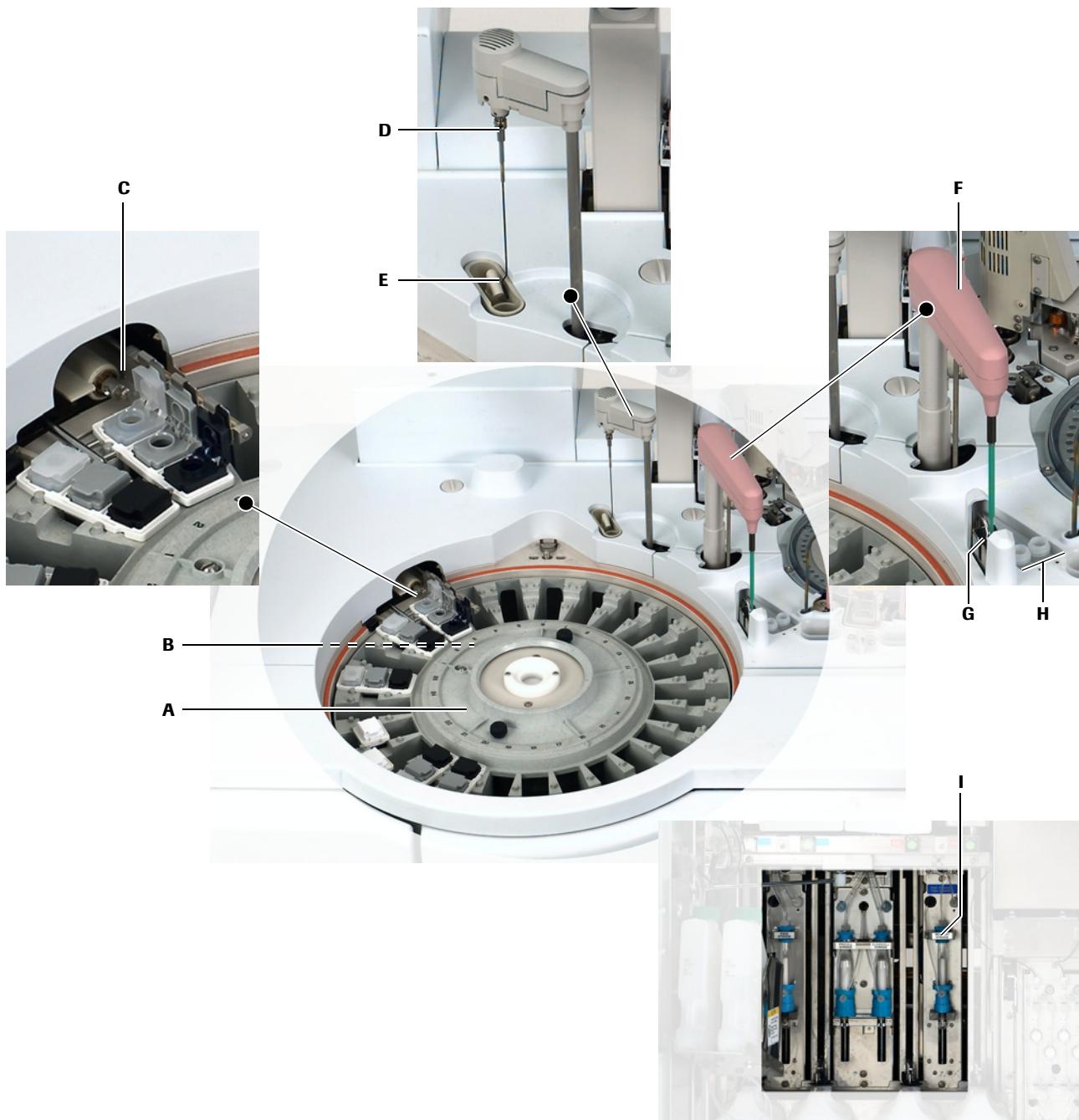
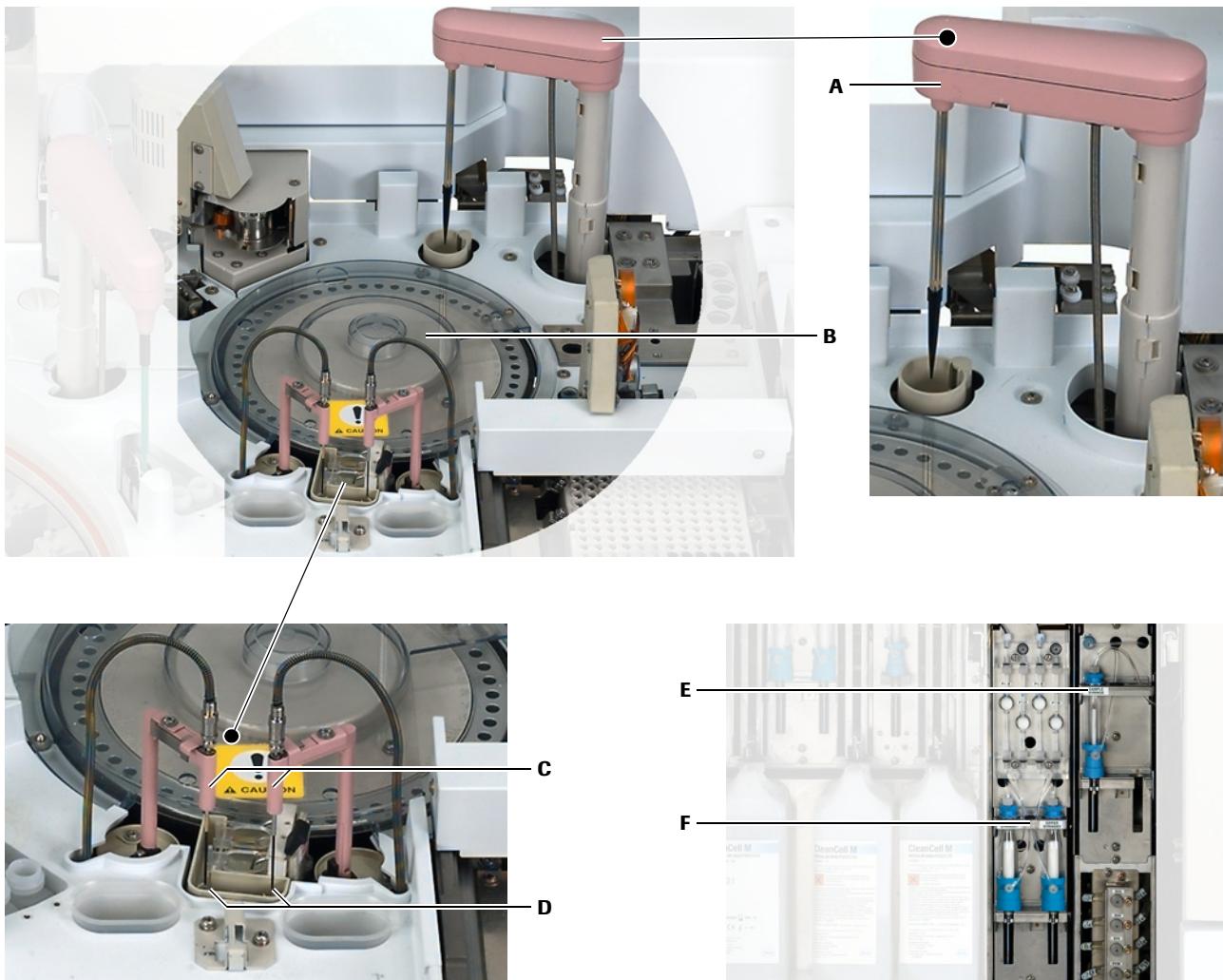


Figure A-48 Reagent area components

<i>Reagent disk</i>	The reagent disk is located on the left side of the analytical module and contains 25 positions for assay, diluent or pretreatment cobas e packs. The reagent disk is temperature controlled at $20 \pm 3^\circ\text{C}$.
	Diluent or pretreatment reagents can be placed in ANY position on the reagent disk. More than one cobas e pack can be loaded on the reagent disk for each test at any time.
<i>Barcode reader</i>	The barcode reader is located in the center of the reagent disk and reads the 2D matrix barcode on the cobas e packs.
<i>Reagent Cap Open/Close mechanism</i>	To prevent reagents from evaporating, and for ease of use, the reagent disk utilizes a reagent cap open/close mechanism during reagent pipetting. The mechanism is located on the back wall of the reagent disk compartment and emerges when cobas e packs need to be opened or closed. The system can be configured to open caps prior to pipetting or mixing the specific reagent (e.g., M, R1 or R2) and close them again afterwards, or to leave the cap open during operation.
<i>Microbead mixer with rinse station</i>	<p>The microbead mixer, located beside the reagent disk, mixes the microbeads to ensure a homogeneous suspension before aspiration.</p> <p>The microbead mixer rinse station rinses the microbead mixer with deionized water each time it has been used.</p>
<i>Reagent probe with rinse station</i>	<p>The reagent pipetter, located between reagent disk and incubator, aspirates reagent from the cobas e packs on the reagent disk and dispenses it into the AssayCups in the incubator. To prevent reagent carryover, the reagent probe is rinsed after each pipetting operation at the rinse station. The reagent probe also has liquid level sensing for accurate pipetting.</p> <p>The reagent probe rinse station rinses the reagent probe externally and internally with deionized water between aspirations.</p>
<i>ProbeWash station</i>	The ProbeWash station, located on the analytical module near the reagent probe, consists of two bottles of ProbeWash. ProbeWash is used to wash the inside of the reagent probe to prevent carryover.
<i>Reagent syringe</i>	The reagent syringe is located on the right behind the front door of the analytical module. The syringe is filled with deionized water and uses positive displacement to aspirate and dispense from the reagent probe.

Measuring area components

The measuring area is in the middle of the analytical module and consists of the following components:



A Sample probe

B Incubator disk

C Sipper probes

D Sipper probe rinse stations

E Sample syringe

F Sipper syringes

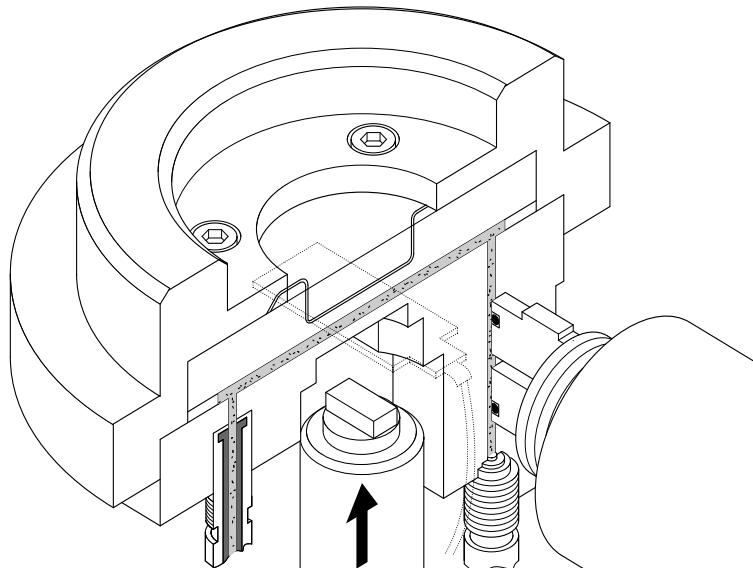
Figure A-49 Measuring area components

Sample probe The sample probe is located at the back of the analytical module near the core unit. The sample probe transports the sample, calibrator or control fluids from the sample tubes in the racks at the sampling position into the AssayCups in the incubator. The probe uses a new disposable tip for every pipetting sequence to prevent carryover and has liquid level and clot detection for accurate pipetting. Liquid level detection is accomplished by capacitance measurement. Clot detection is accomplished by a pressure transducer.



Do not touch the surface of the sample probe with bare hands as this leaves residues on the probe which seriously affect the probe's performance. If you do touch the probe, wipe it immediately with gauze soaked in alcohol followed by gauze soaked in deionized water.

<i>Sample syringe</i>	The sample syringe is located on the right behind the front door of the analytical module. The syringe is filled with deionized water and uses positive displacement to aspirate and dispense from the sample probe.
<i>Incubator disk</i>	The incubator disk contains 54 positions for AssayCups and is located approximately in the center of the analyzer unit. It is maintained at a temperature of $37.0 \pm 0.3^\circ\text{C}$ to ensure/facilitate reaction between the sample and the reagents that have been dispensed into an AssayCup. When an assay is ready for measurement, the incubator rotates, moving the AssayCup to the various positions in the assay protocol process. It transports each AssayCup to the position where the appropriate unit performs its respective task.
<i>Sipper probes with rinse stations</i>	There are two sipper probes located in front of the incubator (one probe for measuring channel 1 and the other probe for measuring channel 2). These aspirate the reaction mixture from the AssayCup in the incubator into the measuring channels as well as the ProCell and CleanCell from their respective cups in front of the sippers. One rinse station for each sipper probe is located next to the sipper probes. The sipper probes move between measurements to their rinse stations and are washed externally with deionized water. In standby mode, the sipper probes are located directly above their rinse stations.
<i>Sipper syringes</i>	The sipper syringes are located on the right behind the front door of the analytical module. The pipetters are filled with deionized water and use positive displacement to aspirate and dispense from the sipper probes.

Detection cell**Figure A-50** Detection Cell

The two detection cells, which are located inside the analytical module, are the central components of the measuring channels of the e 601 module for the determination of samples. Each unit contains a photomultiplier tube, peltier, flow-through measuring channel, magnet drive assembly and an amplifier circuit board.

Pre-wash area components

The Pre-wash station, located in the middle at the back of the analytical module, carries out a pre-wash step to remove special contents of serum from the reaction solution before measuring if required by the assay protocol.

It consists of the following components:

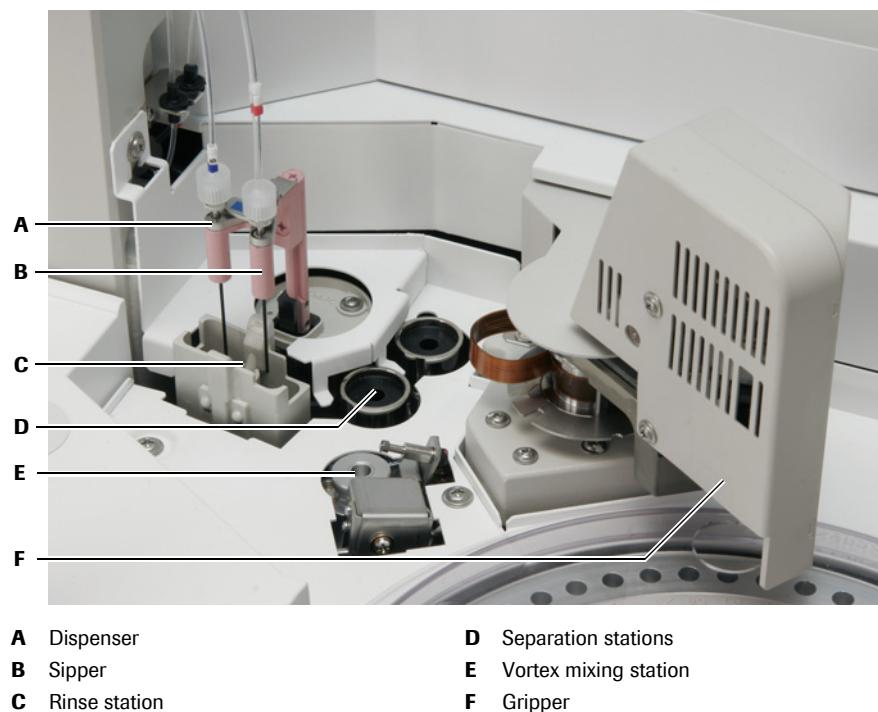


Figure A-51 Components of the Pre-wash area

<i>Pre-wash gripper</i>	The Pre-wash gripper is located at the back and on the left of the incubator and can move between the incubator and the Pre-wash area. It is equipped with gripping fingers for gripping AssayCups which are filled with the reaction solution in the incubator and transporting them to the separation stations in the Pre-wash area and back. The gripper also transports the AssayCups from the separation stations to the vortex mixer.
<i>Pre-wash sipper</i>	The sipper is located at the back and on the left of the Pre-wash area, beside the dispenser. It aspirates the reaction solution from the AssayCup positioned in one of the separation stations.
<i>Pre-wash dispenser</i>	The dispenser is located at the back and on the left of the Pre-wash area, beside the sipper. It dispenses PreClean solution (a phosphate buffer) into the AssayCup after the sipper has drained the reaction solution.
<i>Rinse station</i>	The rinse station for sippert and dispenser probes is located beside the sippert and dispenser. It rinses the corresponding probe after each aspiration or dispensing procedure with deionized water.
<i>Separation stations</i>	Two separation stations (AssayCup holders) are located in front of the sippert and dispenser, which are in the middle of the Pre-wash area. The separation stations are permanent magnets used to capture the microbeads in the AssayCup as the reaction solution is being aspirated by the sippert.
<i>Vortex mixing station</i>	The vortex mixing station is located between the gripper and the separation stations. After the wash procedure, the AssayCup is positioned here by the gripper to resuspend microbeads in the PreClean solution.

Consumables area components

The components of the consumables are located on the right of the analytical module.



Figure A-52 Consumables area components

Gripper The gripper is located on the right of the analytical module and can move in 3 directions:

- X (left and right)
- Y (forward and back)
- Z (up and down)

It is equipped with gripping fingers for gripping tips or AssayCups. The gripping fingers grip an AssayCup from the magazine and transport it to the incubator or from the incubator to the vortex mixing station. After the AssayCup has been used, the gripper transports it to the cup disposal opening. The gripper also transports tips from the tip tray to the tip buffer where the sample probe picks them up for the next sampling.

During operation, the gripper is supplied with tips and AssayCups from the magazine lifter, which transport the magazines to the surface of the analytical module. Empty magazines are discarded automatically to the magazine waste inside the analytical module.

Vortex mixing station

The vortex mixing station, located between the gripper and the tip buffer, mixes the reaction solution after reagent delivery. AssayCups are transported here from the incubator by the gripper.

Assay tip buffer station with disposal openings

The AssayTip buffer station with disposal openings is located between the vortex mixing station and the sample probe. The gripper transports new tips here as required by the sample probe. The sample probe takes the new tip and, after pipetting samples, discards the used tip at the disposal opening into the active solid waste container.

AssayCup disposal openings

Used AssayCups are discarded by the gripper in the AssayCup disposal openings, located between the incubator and the vortex mixing station. The used cups pass into the active solid waste container.

AssayCup and tip magazine lifter

The magazine lifter is located behind the right front door of the analytical module and is the first compartment of the magazine drawer. It consists of the magazine lifter, the magazine waste and the solid waste containers. The magazine lifter transports the full magazines to the surface of the analytical module as required. The lifter can be loaded with magazines by opening the transparent door of the magazine drawer. The magazines can be loaded on the magazine lifter only when the green indicator lamp is permanently illuminated.

Magazine waste compartment

The magazine waste compartment contains the empty magazines. It is located behind the right front of the analytical module and the middle part of a magazine drawer, which consists of the magazine lifter, the magazine waste and the solid waste containers. The magazine waste can be emptied by pulling out the magazine drawer. The magazine drawer can be pulled out only when the green indicator lamp is permanently illuminated.

Solid waste containers

The solid waste containers are located behind the right front of the analytical module and they are the third compartment of a magazine drawer that consists of the magazine lifter, the magazine waste and the solid waste containers. The 2 containers are used alternately. When one becomes full, the other becomes active. The full waste container can be emptied only when the green indicator lamp on the magazine drawer is permanently illuminated (i.e., the magazine drawer can be pulled out). The green button corresponding to the container should be pressed after the container has been emptied.

Green indicator lamp

The indicator lamp is located on the top of the right front door and indicates when the magazine drawer and door can be opened.

Green indicator lamp On	Drawer safe to open
Green indicator lamp flashing	About to operate—DO NOT open

Auxiliary reagents and cleaning solutions

The auxiliary reagent bottles of ProCell and CleanCell (two each) are located behind the front door of the e 601 module, and two bottles of PreClean are mounted on the inside of the door itself.



A PreClean bottles

B ProCell bottles (in keyed positions)

C CleanCell bottles (in keyed positions)

Figure A-53 Auxiliary reagents behind the front door

PreClean bottles

Two bottles of PreClean are located in the inner side of the front door of the module. Each bottle has a volume of 600 mL. Two bottles of each reagent allow bottle changeover without interrupting operation. The system monitors the amount of PreClean available by counting the number of pipetting actions. In addition, liquid short sensors are available in case of inaccurate counting due to incorrect loading of PreClean bottles.

 See *Replacing PreClean (e 601)* on page B-112.



Avoid putting your hand into the PreClean bottle holders as the needles are sharp and could cause injury.

ProCell and CleanCell bottles

Two bottles of ProCell and two bottles of CleanCell are located in special, keyed positions behind the front door:

- ProCell is a buffer solution containing tripropylamine (TPA). These bottles are identified with white caps.
- CleanCell is a solution of potassium hydroxide (KOH) which is used to clean the measuring channel after measurement. CleanCell bottles are identified with black caps.

The ProCell and CleanCell bottle positions are keyed to ensure the correct reagent is placed in the proper position. Each bottle has a volume of 2 liters, which is sufficient reagent for 1000 determinations prior to initial priming. Two bottles of each reagent allow bottle changeover without interrupting operation.

 See *Replacing ProCell and CleanCell (e 601)* on page B-110.



If a ProCell bottle is replaced, the lot number of the new bottle must be entered in to the system.

Specifications

This chapter gives an overview of the specifications of the cobas® 6000 analyzer series and its modules.

In this chapter

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General system specifications

The following specifications apply to the cobas® 6000 analyzer series.

Dimensions

Dimension	Module	International (Europe)	US
Depth	Max.	1040 mm	41.0 in
Height	c 501 module	1300 mm	51.2 in
	e 601 module	1140 mm	44.9 in
Length	rack sampler unit of cu 150	690 mm	27.2 in
	c 501 module	1200 mm	47.2 in
	e 601 module	1200 mm	47.2 in
Weight	c 501 module	330 kg	730 lb
	cu 150 incl. rack sampler unit and rack rotor	180 kg	400 lb
	e 601 module	360 kg	795 lb

Table A-6

Dimensions of the cobas® 6000 analyzer series

Operating conditions

The power distribution panel and the water supply and drainage facilities must be available within 5 m of the system.

Water requirements

Bacteria-free, deionized water	< 10 cfu/mL
Conductivity	1.0 µS/cm or less
Water pressure	50-340 kPa
Water supply volume	<ul style="list-style-type: none"> • typical water consumption: <ul style="list-style-type: none"> • <c> system: 10 L/h • <e> system: 12 L/h • <cc> system: 20 L/h • <ce> system: 22 L/h • <ee> system: 24 L/h • <cce> system: 32 L/h • <cee> system: 34 L/h • max. water consumption per c 501 module: 40 L/h^(a) • max. water consumption per e 601 module: 30 L/h^(a)

(a) These max. water consumptions are theoretical values that may occur temporarily in service mode. Thus, the water supply of the laboratory must provide the max. water consumption of the system, for example 110L/h for a <cce> system.

Electric power supply

Power rating	Single phase AC 200/208/220/230/240V 50/60Hz
Power supply fluctuation	No significant power supply fluctuation (max. power supply change: ± 10 %)
Oversupply category	II
Pollution degree	2
Power consumption	max. power consumption during Operation: <ul style="list-style-type: none"> • <c> system: 1.8 kVA • <e> system: 1.4 kVA • <cc> system: 2.6 kVA • <ce> system: 2.4 kVA • <ee> system: 2.6 kVA • <cce> system: 3.7 kVA • <cee> system: 3.6 kVA

The power supply must be grounded. The system can only be connected to a power supply source with the specified mains cable and only by authorized personnel.



WARNING

Environmental conditions

The following environmental conditions should be followed in order to ensure correct operation of this system:

Ambient temperature	During operation: <ul style="list-style-type: none"> • 18 to 32°C (64.4-89.6°F) with changes < ± 2°C/h (± 3.6°F/h) During transportation and storage: <ul style="list-style-type: none"> • -20 to 50°C (-4 to 122°F)
Ambient humidity	During operation: <ul style="list-style-type: none"> • 30-85% (non-condensing)^(a) During transportation and storage: <ul style="list-style-type: none"> • 5-95%
Altitude	< 2000m
Electromagnetic interference	<ul style="list-style-type: none"> • No equipment generating electromagnetic waves in the near vicinity (e.g., cell phones, transceivers, cordless phones, etc.) • No machines discharging ultrahigh frequencies (e.g., electric discharger)
Noise levels	< 65 dB for surrounding
Other environmental conditions	<ul style="list-style-type: none"> • Dust-free environment with adequate ventilation • No direct sunlight • No perceptible vibration • Indoor use only
Floor condition	Level (angle: less than 1/200); strong enough to hold the weight of the instrument ^(b)

(a) Only valid for systems with appropriate hardware update.

(b) See *Dimensions* on page A-99.

System interface

The instrument can be bidirectionally interfaced with a Host.

System interface	RS-232C serial interface
 All data processing equipment connected to the system must comply with the relevant standards of IEC, UL and CSA.	

System start

System start-up time	12 min (power on to standby) for a <ce> system
-----------------------------	--

Barcode types

Barcodes used with the cobas® 6000 analyzer series must be in compliance with one of the following standards:

- NW7 (Codabar)
- Code 39
- ITF
- Code 128



Incorrect results due to barcode reading error

Use only barcodes with check digits. Barcode reading errors could potentially go undetected when a check digit is not used.

Sample barcodes

The following specifications apply to the various barcode types:

Reading method	Scanning with CCD sensor	
Used barcode symbol	NW7 (Codabar), Code 39, ITF, Code 128	
Check digit	Must be used to prevent scanning errors.	
Number of ID digits	NW7	3-13 digits + 1 digit (with check digit)
	Code 39	3-13 digits + 1 digit (with check digit)
	ITF	3-13 digits + 1 digit (with check digit)
	Code 128	4-12 digits + 2 digits (with check digit)
Characters usable for ID	NW7	0 to 9, -, /, ., \$, :, + ^(a)
	Code 39	0 to 9, A to Z, -, ., [], /, +, \$, %
	ITF	0 to 9
	Code 128	Alpha numerics (excluding those assigned to functions and communications)
Check digit	NW7	Modulus 16, Modulus 11, Modulus 10/2 weight, Modulus 10/3 weight, 7 check DR, weighted Modulus 11, Modulus 10/2 weight A
	Code 39	Modulus 43
	ITF	Modulus 10/3 weight

(a) For more information about usable characters and check digit characterization, refer to the common specifications for the different barcode types.

Sample rack barcodes

The following barcode types are used for sample racks:

Barcode, number of digits	ITF	5 digits + check digit
----------------------------------	-----	------------------------

Scan range for sample barcodes

Confirm that the barcode zone starts at a minimum of 20 mm above the bottom of the tube. The barcode must be within the zone of 63 mm and must have a blank area of ≥ 5 mm at both ends of the barcode zone, as shown in the figure below. Stick the label in exact alignment with the centerline of the sample tube in order to prevent scanning errors.

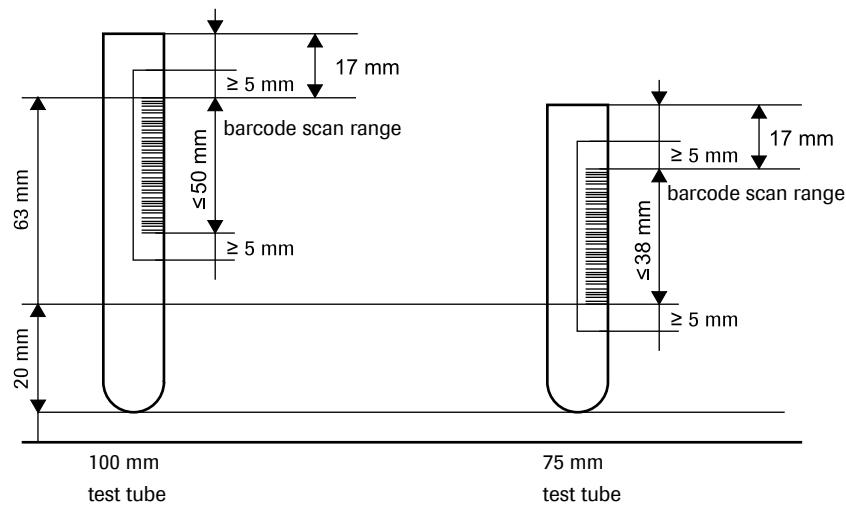


Figure A-54 Scan range of sample barcode reader

Sample cups and tubes

Container	Diameter × length	Comment	Dead volume
Primary sample tube	16 mm × 100 mm	Use for <i>cup on tube</i>	1000 µL
	16 mm × 75 mm	Use for <i>cup on tube</i>	1000 µL
Primary sample tube	13 mm × 100 mm		500 µL
	13 mm × 75 mm		500 µL
Hitachi standard cup directly on the sample rack or on top of a 16 mm diameter tube		2.5 mL	100 µL
Hitachi micro cup ^(a)		1.5 mL	50 µL
Calibrator/control vial ^(b)			200 µL
Non standard tube	12-16 mm × 73-102 mm		
RD Standard False Bottom Tube ^(c) (Roche Diagnostics)	12 mm × 75 mm	c 501 e 601 with cup adapter e 601 without cup adapter	100 µL 100 µL 200 µL
Other false bottom tubes ^(c)	12-16 mm × 73-102 mm		

Table A-7 Sample containers

- (a) Only to be used on c 501 modules. Not to be used for calibrators and controls.
If you use micro cups, you have to select micro cups on **Test Selection** screen as **Sample Cup**. Only in this case the dead volume for Hitachi micro cups is valid.
- (b) Only to be used on the e 601modules.
- (c) Only one type of false bottom tube (RD or other) is definable.

Sample cups (both standard and micro cups) can be inserted into 16-millimeter sample tubes (*cup on tube*) or they can be used without tubes.

 For more information, see *Sample containers* on page A-50

Sample racks

Rack type	Rack color	Display in software	Label on rack
Routine rack	Gray	N00001-N03999	001-3999
STAT rack	Red	E00001-E00999	S001-S999
Rerun rack ^(a)	Pink	R00001-R00999	R001-R999
Calibrator rack	Black	S00001-S00999	C001-C999
QC rack	White	C00001-C00999	Q001-Q999
Wash rack	Green	W00999	W999

Table A-8 Rack types

- (a) Rerun racks are used for manual reruns in non-barcode mode only.

Control unit

Computer	Computer with Windows operating system
Monitor	17" TFT color monitor
Input devices	Mouse, touch screen, keyboard
Computer stand	Optional, ergonomic (UL, CE, GS, TÜV)
 <i>Data storage capacity</i>	
Sample data (routine/STAT)	10 000 samples (including reruns)
Reaction process data	10 000 tests
Calibration data	> 1000 tests
Quality control data	Individual: 100 control materials, 2500 results per c module, 2500 results per ISE module, 2500 results per measuring cell (e module) Cumulative: 100 control materials, 500 points

Core unit cu 150

The following specifications apply to the rack sampler unit of the core unit **cu 150**.

Rack transfer	120 racks/h
Rack loader	30 racks (150 samples) (15 racks / tray + a buffer for 15 racks)
Rack unloader	30 racks (150 samples) (15 racks / tray + a buffer for 15 racks)
Rack rotor	20 positions, definable for STAT and auto QC
Rerun buffer	Up to 20 racks (100 samples) for automatic rerun possible
Reflex testing	Automatic reflex is supported by the system, reflex request to be provided by PSM or LIS

c 501 module

The following specifications apply to the c 501 module.

Reaction system (c 501)

Applications	Up to 131 applications: <ul style="list-style-type: none">• 117 photometric applications can be registered, max. 86 applications can be assigned per module• 3 electrolyte applications• 8 calculated tests• 3 serum indices
Number of simultaneous tests	Up to 60
Throughput	1000 tests/h (photometric and ISE)
Reaction volume	100-250 µL
Reaction temperature	37 ± 0.1°C (98.6 ± 0.2°F) circulating incubator bath
Reaction disk	Turntable system with 160 reaction cells
Reaction cells	8 segments of 20 reaction cells each (semi-disposable cuvettes for photometry)
Reaction times	3-10 min, in 1-minute steps
Pipetting cycle	6 s
Mixing method	Non-contact ultrasonic mixing



Processing capacity varies depending on measuring conditions, test selection and system configuration

Sampling system (c 501)

Sample types	Serum/plasma, whole blood, urine, CSF, supernatant (hemolysate)
Sample pipetting volume	1.5-35 µL, in 0.1 µL increments
Detection of sample clogging	Pressure sensitive clot detection system
Liquid level sensor	Capacitance sensing technology

For more information, see *Sample cups and tubes* on page A-104

Reagent system (c 501)

Reagent identification	Automatic identification, automatic placement
Reagent pipetting volume	5-180 µL, in 1 µL increments (5-19 µL + 20 µL water)
Reagent pipetting timing	3 timings possible (R1: 3.2 s; R2: 90.2 s; R3: 300.2 s)
Reagent storage	Refrigerated compartment for up to 60 reagent cassettes
Reagent vials	4 different configurations available with up to 3 reagent vials/cassette: <ul style="list-style-type: none"> • COBAS INTEGRA cassette: Pos. A: 22.6 mL, Pos. B/C: 11.0 mL • cobas c pack: vials of 20 mL, 40 mL, or 60 mL: (20/40/20 ml, 40/40 ml, 60/20 ml)
Reagent cooling	5-12°C (41-53,6°F)
Remaining reagent volume control	Automatic test countdown with each pipetting
Capacity of cassette disposal	10 reagent cassettes

Photometric measuring system

Light source	Halogen lamp, 12 V / 50 W
Photometer	Multiple wavelength spectrophotometer
Wavelengths	12 wavelengths available: 340, 376, 415, 450, 480, 505, 546, 570, 600, 660, 700, 800 nm
Optical path length	5.6 mm
Optical range	0.0000-3.3000 absorbance
Linearity	Up to 2.5 absorbance
Optical mode	Monochromatic and bichromatic

ISE unit

Applications	Na ⁺ , K ⁺ , Cl ⁻ in serum and urine
Detection system	Ion-selective electrode system
Throughput	200 samples/h (corresponding to 600 tests/h)
Sample pipetting volume	9.7 µL (normal sample volume) 6.5 µL (decreased sample volume for urine)
Reagent pipetting volume	Dil 348 µL/sample (291 µL is dispensed into the cuvette to get a dilution to 1/31) ISE IS 590 µL/sample (measurements in succession) 1180 µL/sample (single measurement)
	KCl 130 µL/sample
Measuring range (serum)	Na ⁺ 80-180 mmol/L K ⁺ 1.5-10.0 mmol/L Cl ⁻ 60-140 mmol/L
Measuring range (urine)	Na ⁺ 10-250 mmol/L K ⁺ 1-100 mmol/L Cl ⁻ 10-250 mmol/L
Measuring temperature	37° ± 2°C (98,6° ± 3,6°F) (during operation ± 0.5°C/0,9°F)
Cycle time	18 s
Liquid level sensor	Capacitance sensing technology
Mixing method	Non-contact ultrasonic mixing

e 601 module

The following specifications apply to the e 601 module:

Reaction system (e 601)

Applications	60 heterogeneous immunoassays
Test principals	Competitive tests, sandwich tests
Reaction volume/test	Nominal: approx. 200 µL Real: approx. 160 µL
Throughput	Up to 170 tests/h
Reaction disk	54 positions Carryover-free reaction as AssayCups only used once
Incubator temperature	37 ± 0.3°C (98.6 ± 0.5°F)
Reaction times	9, 18 and 27 min assays
Cycle time	21 s per module, 42 s per channel
Mixing method	Non-invasive vortex mixers

Sampling system (e 601)

Sample types	Serum, plasma, urine
Sample pipetter principle	Conductive disposable tip handling Carryover-free pipetting as AssayTips only used once
Sample pipetting volume	Nominal: 10-50 µL Real: 8-40 µL
Sample detection	Liquid level detection (LLD) and clot detection
AssayTips	84 tips / magazine
AssayCups	84 cups / magazine
Magazine loading capacity	Up to 12 loaded magazines are possible with 1008 AssayCups and 1008 AssayTips

 For more information, see *Sample cups and tubes* on page A-104

Reagent system (e 601)

Reagent disk temperature	20 ± 3°C (68 ± 5.4°F)
Reagent disk capacity	25 cobas e packs in 25 positions
Reagent pipetting volume	Nominal: 40-64 µL/test dependent upon the assay
Microbead consumption	Nominal: 24-40 µL/test dependent upon the assay
ProCell consumption	≤ 2.0 mL/cycle
CleanCell consumption	≤ 2.0 mL/cycle (CleanCell is used less than ProCell)
PreClean consumption	≤ 550 µL/Pre-wash
Reagent volume control	Liquid level detection (LLD)
Positive reagent identification	2-dimensional barcode (PDF417)
Automatic dilution	Available
Evaporation protection	Reagents are automatically opened and closed
Inventory control	Available

<i>Waste handling (e 601)</i>	
Liquid waste handling	Optional: Two waste containers (20 L)
Solid waste handling	Two waste boxes for used AssayTips and AssayCups (max. 672 per box) and the magazine waste section for magazine waste (max. 12 magazines).

ECL measuring system

Measuring method	Integral measuring of an electrochemiluminescence (ECL) signal
Measuring cells	2 individually calibrated ECL measuring cells
Calibration mode	two-point calibration
Test protocols	26 test methods
Auxiliary reagents temperature	28° ± 2°C (82.4 ± 4°F)
Detection unit temperature	28° ± 0.3°C (82.4 ± 0.5°F)
Pre-wash station temperature	20° ± 1°C (68 ± 2°F)

Operation

B

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Safety information for operation

This section describes potential hazards that may occur during the daily operation procedures.

Before working with the analyzer, particular attention must be taken of the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury.



Electrical shock by electronic equipment

Removing the covers marked with this symbol can cause electric shock, as there are high voltage parts inside. In addition, opening the top cover and touching the ultrasonic mixing mechanism during operation can also cause electric shock.

- Do not remove any cover of the instrument, other than specified in this Operator's Manual
- Do not open the top cover and touch the ultrasonic mixing unit during operation or when the analyzer performs maintenance.

Infection by contact with sample or waste solution

Contact with sample or waste solution may result in infection. All materials and mechanical components associated with the reaction system and the waste systems are potentially biohazardous.

- Be sure to wear protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Personal injury by the touching the fan

Contact with the cooling fan during operation of the instrument may result in personal injury.

- Do not touch the cooling fan during operation.
- Before cleaning the fan, be sure to shutdown the instrument.

Personal injury due to contact with instrument mechanism

Contact with sampling mechanism or other mechanisms may result in personal injury and infection.

- Before starting operation or maintenance, be sure to close and lock the top cover.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-2, F-3, F-4, F-9, F-10, F-11, F-12, T-2, T-3, T-6, R-1, R-2, R-3.

Personal injury due to contact with cleaning solutions or reagents

Contact with cleaning solutions of the system or reagents may cause skin damage or inflammation.

- Be sure to wear protective equipment.
- Observe the cautions given on the bottles and cassettes and the instructions for use.
- If cleaning solution comes into contact with your skin, wash it off immediately with water. Consult a physician.



CAUTION

Interrupt of the analysis run due to interlock system of c 501

The interlock system of c 501 senses top cover opening and immediately stops the analysis run by cutting off the power.

- Before starting operation or maintenance, be sure to close and lock the top cover.
- Do not open the top cover during operation.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-1.

Incorrect results and interruption of analysis due to contaminated samples

Insoluble contaminants in samples and bubbles or films inside a sample container may cause clogging or pipetting volume shortage and deterioration in measurement accuracy.

When loading samples on the instrument, make sure that samples contain no insoluble contaminants such as fibrin, dust or bubbles.

Incorrect results due to evaporation of samples

Evaporation of samples may lead to incorrect results

Do not leave a sample that has been pipetted into a sample container uncooled for a long time.

Incorrect results due to incorrect definition of sample volume

If you use standard and micro sample cups the correct sample volume has to be defined when ordering samples manually or via Host system.

If the sample volume is defined incorrectly, the sample pipetting will be inaccurate and thus lead to inaccurate measurement results.

Incorrect results due to sample mismatch

When operating in non-barcode mode, make sure to load the samples according to the Requisition list as provided by the analyzer.

- Avoid empty positions within the racks. Do not place nonregistered samples in any empty rack position.
- Do not insert any gray rack into the STAT port when operating in non-barcode mode because the predefined sequence of samples will be disrupted by the routine rack inserted through the STAT-port.

Incorrect results due to missing cover of the ISE measuring compartment

If the cover of the ISE measuring compartment is not reinstalled after maintenance, the temperature may become inaccurate, leading to incorrect results.

- Only perform measurement, when the cover of the ISE measuring compartment is closed.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-11.

Incorrect results due to missing covers of the e 601 reagent compartment or the incubator

If the covers of the reagent compartment or the incubator are not reinstalled after maintenance, the temperature may become inaccurate, leading to incorrect results.

- Only perform measurement when the covers are closed.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-15.

**CAUTION**

Incorrect results due to foam on the surface of the e 601 ProCell/CleanCell reservoirs

Before start of analysis, check that no foam has been accumulated on the surface of the e 601 ProCell/CleanCell reservoirs.

If foam has been accumulated, clean the ProCell/CleanCell reservoirs.

See *Cleaning ProCell/CleanCell nozzles and replace reservoirs* on page C-125

Damage to the analyzer

Sample or reagent spilled on the analyzer may damage the circuit boards.

- Do not place samples or reagents on the analyzer
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-8, T-9, T-17.

Excessive weight on the cassette table of the c 501 may lead to damage.

- Do not place anything other than reagent cassettes upon the table.
- Maximum load of the table is 2 kg.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-14.

Excessive weight on the magazine drawer of the e 601 may lead to damage.

- Do not open the front door of the magazine drawer and do not pull out the magazine drawer when the indicator lamp is off or blinking.
- Pull out the magazine drawer gently and do not lean on the magazine drawer.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-11.



Data loss due to erroneous operation or instrument troubles

Data may get lost due to aging of the hard disk or due to a hard disk failure because of electric power failure.

Back up your data (measurement results and system parameters) at regular intervals.

See *Using the backup function* on page A-38



During operation, always check for any abnormal sound, water leakages or other abnormal condition. If a trouble occurs, take suitable safety measures according to the condition and contact your technical support.

Software basics

This chapter is an introduction to the basic operational procedures for the cobas® 6000 analyzer series.

In this chapter

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General description of the user interface



The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid results.

The screen of the PC is divided into different sections. Some of these sections do not change and some differ according to the currently active function. Following is an example of a screen showing the different areas.

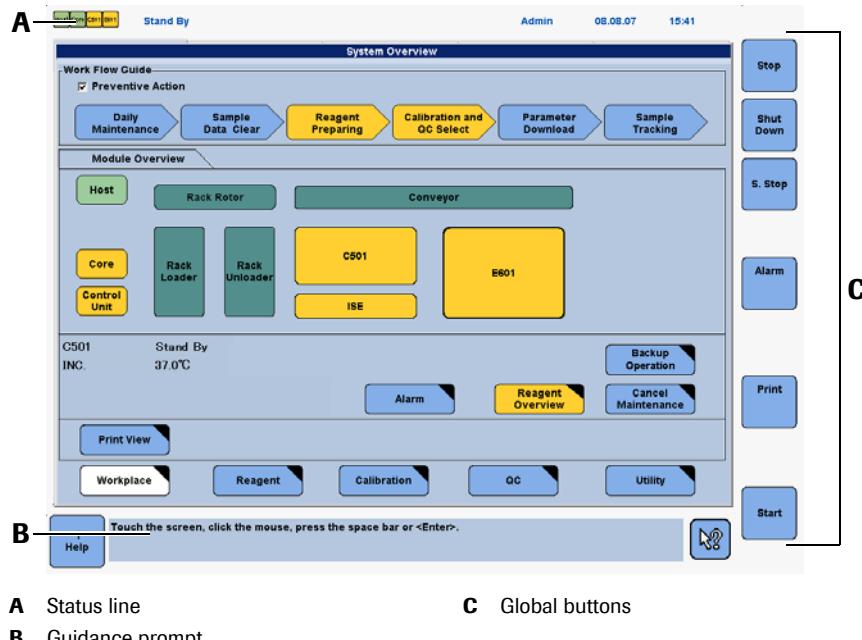


Figure B-1 Screen configuration

Status line

The status line appears across the top of each screen.

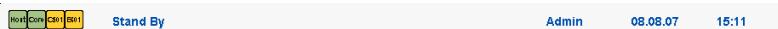


Figure B-2 Status line

The status line displays the current operational mode, operator ID, date and time, and the time remaining when performing maintenance. The icon on the left displays the current statuses of the system modules. Touching this icon displays the **System Overview** screen with information of the selected item/module.

The following describes the colors from the lowest to the highest priority:

- Light green indicates Standby mode.
- Light blue indicates statuses other than Standby (for example, maintenance).
- Purple indicates that the number of tests remaining for a reagent or a reagent volume is less than the Purple alarm level specified on the **Utility > System** (Page 2/4) > **Reagent Level Check** window.
- Yellow indicates an instrument alarm with a caution level or the number of tests remaining for a reagent is less than the Yellow alarm level specified on the **Reagent Level Check** window.
- Red indicates an instrument alarm of **Stop**, **S.Stop** or **E.Stop** or the number of tests for a reagent is zero.
- Dark green indicates that a module has been inactivated on the **Utility > Module Set > Module Setting** window.
- An “X” on the module indicates the module is masked on the **Start Conditions > Masking > Module Masking** window.

Guidance prompt

The guidance prompt is shown in the lower left of each screen.



Figure B-3 Guidance prompt

In this area, the software prompts you as to what kind of information to type and what format to use when typing that information. The guidance prompt may also tell what action to take, such as touching a button or pressing a key. For example, “Touch screen or press <Enter>”. Each prompt is specific to the location of the cursor.

Menu tabs

The menu tabs are displayed below the status line.



Figure B-4 Menu tabs

The menu tabs are used to select screens and windows that are grouped together and perform related tasks. The menu tabs are accessible from every screen, except the global screens. This makes the software navigation within the menus and between menus very easy.

The menu tabs are only for the 5 menus: **Workplace**, **Reagent**, **Calibration**, **QC** and **Utility**. The menu tabs can be selected by touchscreen, mouse or keyboard.

List boxes

List boxes display a list of choices. If there are more choices than can fit in the box, a scroll bar is displayed.

1. Touchscreen: Touch the desired area within the list box on the screen. If a scroll bar is displayed next to the list box, touch the scroll bar above or below the current display position, or touch the arrows on the scroll bar to move up or down the list.
2. Keyboard: The <Arrow> keys can be used to move quickly through the list. Press the <Arrow> key that points in the direction you want to move. The currently selected choice is indicated by the selection cursor, which appears as a highlight. The Home, End, Page Up and Page Down keys can also be used to move through the list. When the desired item is highlighted, press <Enter>.

Text boxes

Text boxes are used to type information. When you move to an empty text box, the box is highlighted.

1. Touchscreen: Move to a text box by touching it on the screen. The text box highlights when you touch it.
2. Keyboard: Move to a text box by pressing the <Tab> key. The text box highlights when you move to it.

Press the <Enter> key to accept information typed. The cursor then moves to the next field.

Options

Options are used to select a particular function. Sometimes when an option is selected, other fields become available.

An option is selected when a black circle is displayed within the white circle for the option. Only one option can be selected at a time.

1. Touchscreen: Move to the option by touching it on the screen. The option displays a black circle within the white circle when you touch the option.
2. Keyboard: Move to the option by pressing the <Tab> key or press the letter which is underlined. If multiple options are available, the up and down arrow keys move to the different options.

Check boxes

Check boxes are used to select a particular function. Sometimes when an option is selected, additional fields become available. Multiple check boxes can be selected in the same area of the screen.

1. Touchscreen: Move to the check box by touching it on the screen. A check mark appears in the check box when it is selected. When the check box is blank, it is not selected.
2. Keyboard: Move to the check box by pressing the <Tab> key or press the letter which is underlined. If multiple check boxes are available, the up and down arrow keys move to the different check boxes.

Buttons

Buttons are used for execution of functions, confirmation of entries and selections, and displaying pop-up windows. The available buttons depend on the menu or tab that is active. For example, the **Demographics** button on the **Workplace > Test Selection** screen displays a window that is used for the entry of demographic patient information.

The black triangle in the upper right-hand corner of a button indicates that touching this button displays another window. The black triangle in the lower left corner of a button indicates that touching this button performs the specified function and closes the window.

If a button is shaded, the button is not available in the current mode.

1. Touchscreen: Choose a button by touching it on the screen.
2. Keyboard: Press the <Arrow> keys, <Tab> key or press the letter which is underlined to highlight a button. Press the <Enter> key to initiate the action.

In addition, each software button on screen or window has an action key: the letter underlined in the button name (e.g., the action key for “OK” is O). While pressing the <Alt> key, press the letter key corresponding to the button to activate the button.

Standard buttons

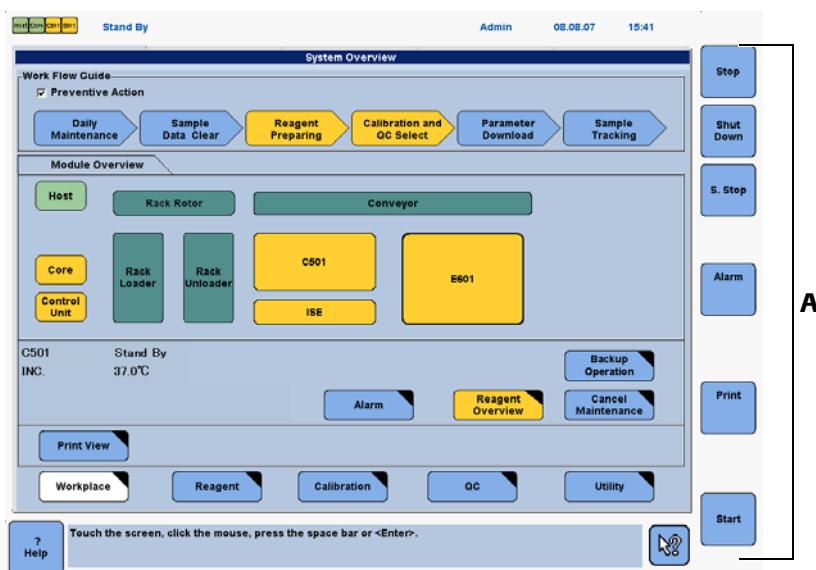
The following buttons are used throughout the software. These buttons are explained below and will not be explained again with each individual screen.

- | | |
|--------|---|
| OK | Touch this button to accept the changes and entries made on a window and to close the window. |
| Cancel | Touch this button to close the window without saving the changes and entries made on a window |
| Yes | Touch this button to accept the changes made on a window, execute the action of the window (e.g., Delete) and close the window. |
| No | Touch this button to close the window without saving the changes made on a window or without executing the function of the window (e.g., Delete). |
| Close | Touch this button to close the window. |

- Save* When changes have been made, this button turns yellow. Touch this button to save any changes made to the screen/window currently displayed.
- Update* When changes have been made, this button turns yellow. Touch this button to update any changes made to the screen/window currently displayed.
- Execute* Touch this button to accept the changes made on a window, to execute the action of the window and to close the window.
- Page buttons* The **Utility > System** screen displays page buttons that can be used to display additional buttons to display new screens. These page buttons are numbered (X/4), to indicate which page you are on.
-
-  The page buttons only change the displayed buttons and not the entire appearance of the screen.

Global buttons

Use the global buttons to display screens that are used for specific functions. The global buttons are accessible from every screen and appear on the right side of the screen (except for the **Help** button which appears on in the lower left corner of the screen). The global buttons include: **Stop**, **Shut down**, **S. Stop**, **Alarm**, **Print**, **Start** and **Help**. The **Stop**, **S. Stop** and **Start** buttons are also the system control buttons. The global buttons can be selected by touchscreen, mouse or keyboard.



A Global buttons

Figure B-5 Global buttons

Windows

Windows contain additional information that pops up over existing screens/windows.

Windows function similar to screens. Information on a window can be entered or edited through list boxes, text boxes, options and check boxes. Action buttons are also available.

Confirmation window Many functions require confirmation prior to their execution (e.g., **Delete**).

Confirmation windows are used to confirm these functions. Touch **Yes** to confirm the function and to close the confirmation window, or touch **No** to close the confirmation window without carrying out the function.

Screen accessibility

Some screens are not accessible with the operator level logon, or can be viewed with a supervisor level logon but not edited. Some fields are viewed only at the administrator level logon.

Shortcut Keys

All functions can be initiated via the keyboard or the touchscreen for selection of screen items.

All special keys and their functions are described below.

Shortcut	Description
<F1>	Use this key to display the Online Help.
<F2>	Use this key to display the Start Conditions screen.
<F3>	Use this key to display the Sample Stop screen.
<F4>	Use this key to display the Stop screen.
<F5>	Use this key to display the Workplace menu. This key does not work if you are in a global screen.
<F6>	Use this key to display the Reagent menu. This key does not work if you are in a global screen.
<F7>	Use this key to display the Calibration menu. This key does not work if you are in a global screen.
<F8>	Use this key to display the QC menu. This key does not work if you are in a global screen.
<F9>	Use this key to display the Utility menu. This key does not work if you are in a global screen.
<F11>	Use this key to display the Alarm screen.
<F12>	Use this key to display the System Overview screen.
<Print/Print Screen>	Use this key to display the Print screen. Press <Shift + Print Screen> simultaneously to print the current screen.
<Scroll Lock>	Use this key to display the Cancel Print window.
<Pause/Break>	Use this key to display the Logoff screen.
<Esc>	Use this key to exit a window or global screen.

Table B-1

Shortcut Keys (Sheet 1 of 2)

Shortcut	Description
<Tab>	Use this key to move to the next field in a window or screen. To go from a field to the previous one, press <Shift + Tab> simultaneously.
<Enter>	Use this key to confirm an entry.
<Shift>	Simultaneously pressing <Shift> and a character key generates a capital letter or a special character, for example <Shift> + <>, generates the character ">".
<Backspace>	Use this key to delete a character to the left of the cursor.
<Space>	Use this key to generate a space.
<Delete>	Use this key to delete a character to the right of the cursor.
<Home>	Use this key to place the cursor at the beginning of a list or text box.
<End>	Use this key to place the cursor at the end of a list.
<Page Up>	Use this key to scroll upward in a list, one page at a time.
<Page Down>	Use this key to scroll downward in a list, one page at a time.
<Arrow>	Use these keys to move the cursor to the right, left, upwards or downwards within a text box.
<Caps Lock>	Use this key to lock the letter keys into the upper case mode.
<Num Lock>	Use the numerical key pad for entry of numbers and mathematical operators such as +, -, /, *.

Table B-1

Shortcut Keys (Sheet 2 of 2)

Online Help system

The cobas® 6000 analyzer series has a context sensitive online help feature to aid in operating the instrument. “Context sensitive” means that wherever you are located within the cobas 6000 software, choosing the **Help** feature displays information relating to your current location in the software. The online Help offers a quick and convenient way to find information, such as explanations of screens and dialog boxes and how to perform particular processes.

**A** F1 Help**Figure B-6** Online Help buttons

F1 Help

There are two main entry points for the online Help: a context sensitive entry via the **Help** buttons in the software or F1 on the keyboard, or the main entry via the **Help** icon in the bottom left of the screen. The context sensitive entry displays information relating to your current location in the software.

Main menus

Main menus

The graphical user interface used by the control unit consists of 6 main screens, **System Overview**, **Workplace**, **Reagent**, **Calibration**, **QC** and **Utility**, and 6 global screens. Through these screens all instrument functions are controlled.

Access to some screens, especially those of the **Utility** menu, is confined to the access level of the user. For this reason, the screen may not appear exactly as shown here.

System Overview

The **System Overview** screen has a central role within the **cobas 6000** software. From here the user has an overview of the whole system at any given time. It displays the status of each module, and the modules can be prepared for daily routine operation.

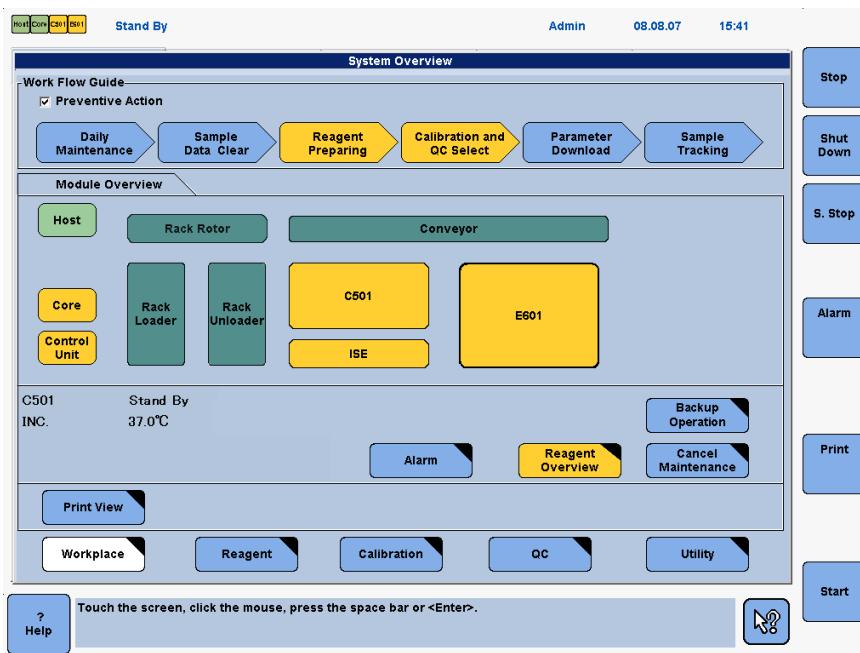


Figure B-7 System Overview screen

- 👁 For more information, see:
System Overview screen on page B-31

Workplace

The **Workplace** menu consists of three screens: **Test Selection**, **Data Review** and **Calib Review**. Use the **Test Selection** screen to make test selections, specify patient demographics, and assign patient IDs and rack positions to samples. Use the **Data Review** screen to review, backup, edit, delete and send data to the Host. Use the **Calib Review** screen to review the status of the calibrators that are currently processing and the status of the calibrations.

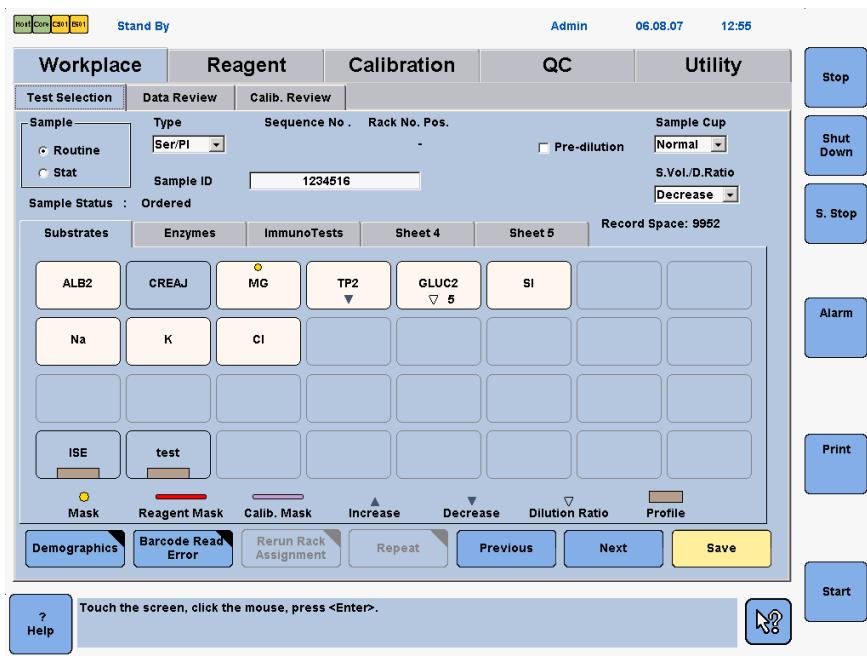


Figure B-8 Workplace menu

- 🕒 For more information, see:
 - Test Selection screen* on page B-68
 - Data Review screen* on page B-75
 - Calib. Review screen* on page B-81

Main menus

Reagent

The **Reagent** menu consists of two screens: **Setting** and **Status**. These screens are used to view detailed reagent information and to perform operation related to reagent management.

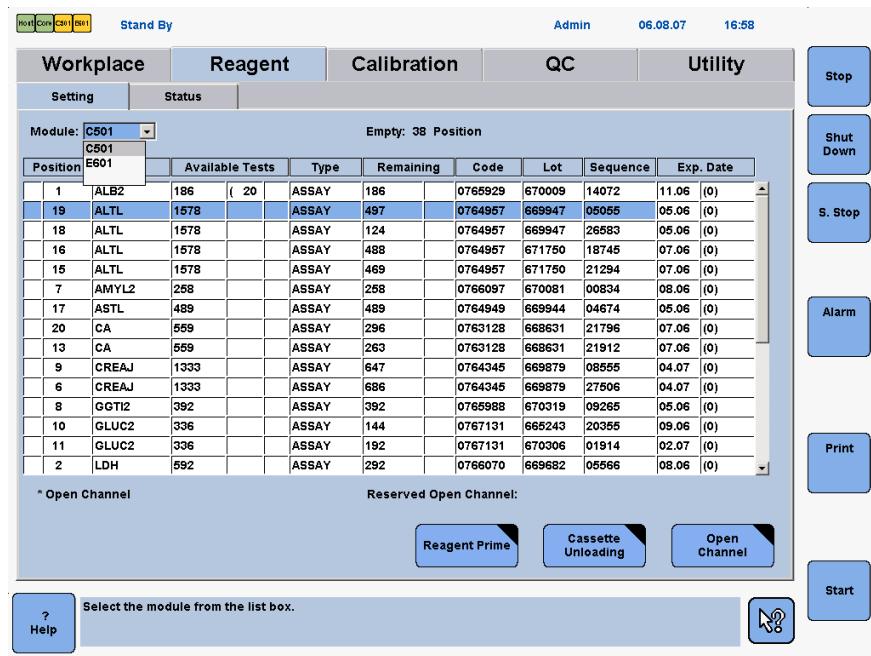


Figure B-9 Reagent menu

- 🕒 For more information, see:
 - Reagent Setting screen* on page B-103
 - Reagent Status screen* on page B-108

Calibration

The **Calibration** menu consists of three screens: **Status**, **Calibrator** and **Install**. These screens are used to request calibrations, define calibrators and view the reaction curves for calibrators installed on the system.

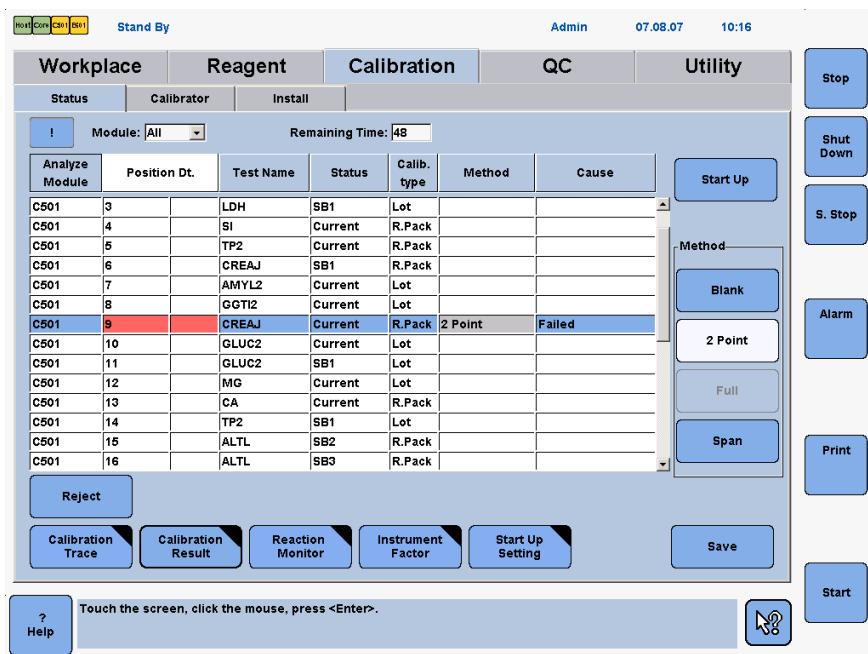


Figure B-10 Calibration menu

- 🕒 For more information, see:
 - Calibration Status screen* on page B-136
 - Calibration Install screen* on page B-146
 - Calibration Calibrator screen* on page B-152

Main menus

QC

The QC menu consists of 6 screens: **Status**, **Run Status**, **Individual**, **Cumulative**, **Control**, and **Install**. Use these screens to install, view and edit controls, and to manage quality control results.

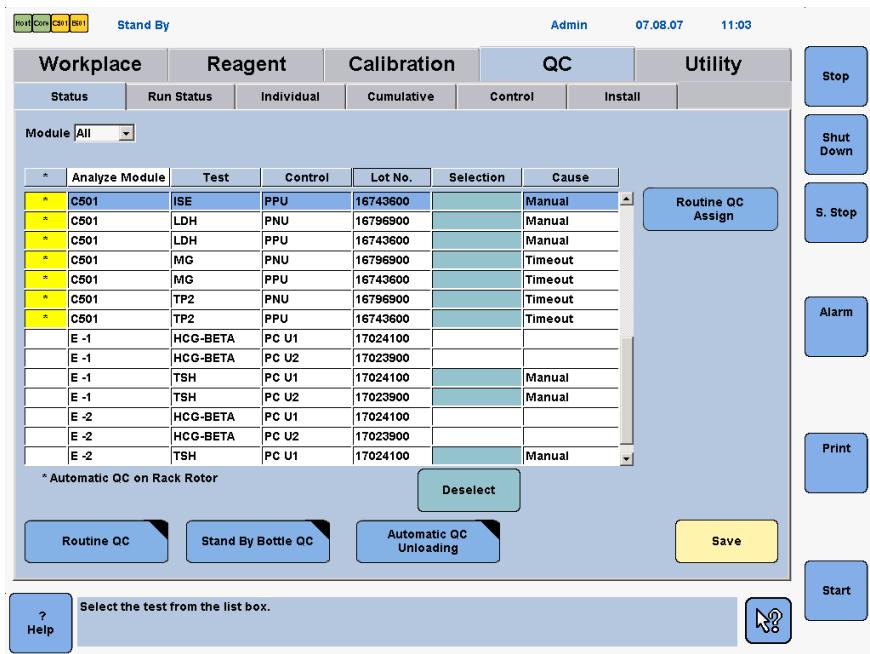


Figure B-11 QC menu

- 🕒 For more information, see:
 - QC Status screen* on page B-164
 - QC Run Status screen* on page B-168
 - QC Individual screen* on page B-170
 - QC Cumulative screen* on page B-178
 - QC Control screen* on page B-179
 - QC Install screen* on page B-181

Utility

The **Utility** menu consists of 7 screens: **System**, **Maintenance**, **Application**, **Calculated Test**, **Special Wash**, **Report Format**, and **Module Set**. These screens are used to enter system parameters, application parameters, maintenance settings and system settings.

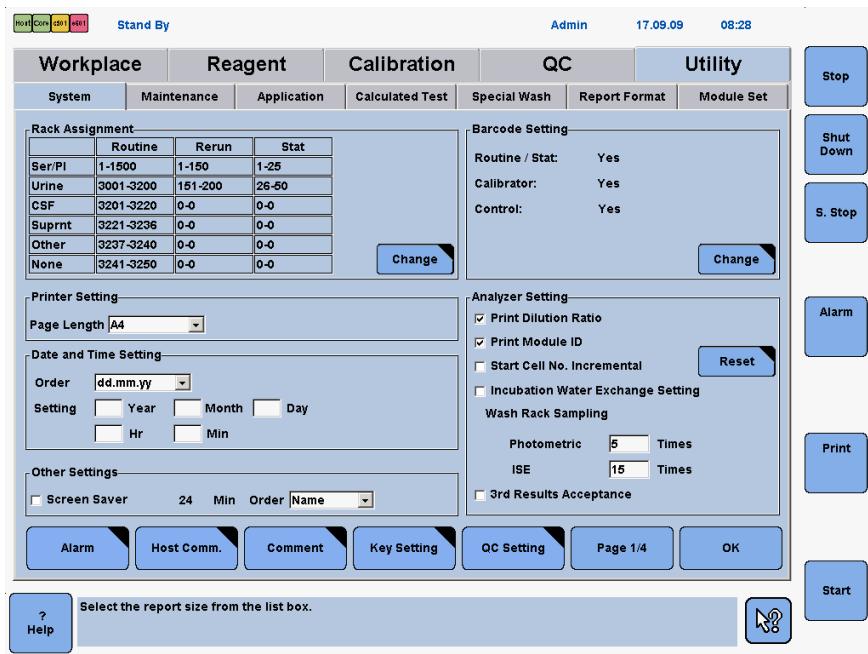


Figure B-12 Utility menu

- 🕒 For more information, see:
 - System configuration* on page B-213
 - Performing maintenance items or pipes* on page C-16
 - Application* on page B-191
 - Calculated Tests* on page B-229
 - Special Wash* on page B-234
 - Report Format* on page B-243
 - Module Set* on page B-221

Main menus

Daily operation

This chapter provides a description of the everyday tasks which are required for running the cobas 6000 analyzer. Common procedures that are performed as part of the daily workflow are also described here.

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Overview

Daily operation encompasses the routine tasks that are required to prepare the analyzer, analyze samples, and maintain the analyzer. The layout of the **System Overview** screen gives the operator an intuitive guide for the tasks required for routine operation.

The following diagram gives an overview of daily operation.

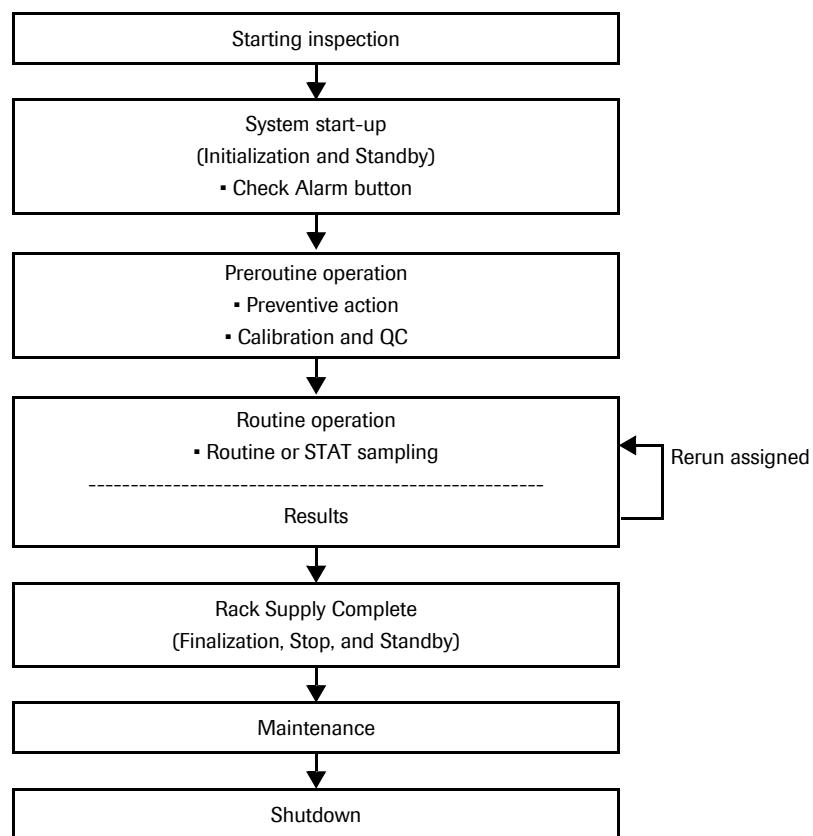


Figure B-13 Workflow diagram

Starting the analyzer

Before you can start routine operation, you must prepare the analyzer for operation.

- ☞ For more information, see:
 - Work Flow Guide* on page B-35
 - Preventive action* on page B-35

Starting inspection

Before start-up, it is important that the following conditions of the analyzer are checked. Take the necessary action if a condition is not as listed below.



Before performing this action, observe the following safety precautions:

- *Infection by contact with sample or waste solution* on page B-3
 - *Personal injury due to contact with instrument mechanism* on page B-3
 - *Personal injury due to contact with cleaning solutions or reagents* on page B-36
-

- | | |
|--|---|
| <i>Control unit</i> | <ul style="list-style-type: none">• There is no floppy disk; CD or DVD in the corresponding drive.• There is sufficient paper in the printer. |
| <i>Core unit</i> | <ul style="list-style-type: none">• The water supply is switched on.• Container for high concentrated waste is empty, clean and placed in the correct position.• All connections and fittings of tubes and containers are connected properly and leak-proof.• There are no racks on the rack loader, unloader, rack rotor, or conveyor line. |
| <i>Analytic modules</i> | <ul style="list-style-type: none">• All surfaces are clean and clear of loose articles.• No tubing is pinched or bent.• Syringes are not leaking.• Auxiliary reagents (cleaning solutions) required for start-up pipes are loaded. |
| <i>c 501 module – ISE unit</i> | <ul style="list-style-type: none">• All electrode cables and tubings are correctly connected. Tubing is not leaking. |
| <i>c 501 module – photometric unit</i> | <ul style="list-style-type: none">• All reagent cassettes are removed from the cassette disposal.• Top cover of the c 501 module is closed and locked. |
| <i>e 601 module</i> | <ul style="list-style-type: none">• The amount of ProbeWash solution (near the reagent probe) is sufficient.• The magazine door and drawer are closed. |

If any problems arise, refer to the module-specific maintenance and troubleshooting chapters.



If the analyzer has been set for automatic start-up, it is important that the above checks are done as part of the maintenance at the end of the previous working session; otherwise, problems may occur.

Start-up

The analyzer can be started manually or automatically. The analyzer (**c 501, e 601, and control unit**) performs initialization and then enters standby mode (time approximately 12 min).

Automatically starting up the analyzer allows the analyzer to perform initialization before the beginning of a working session. When the operator arrives, the analyzer is ready for operation. To automatically start up the analyzer you have to do two things:

1. Configure the **Power Up pipe** function (set a wake-up time).
2. Put the analyzer in sleep mode at the end of the previous working session.

☞ For more information, see:

Power Up Pipe function on page C-18

Analyzer shutdown on page B-62.

Preparatory maintenance

Certain preparatory maintenance items are recommended to be executed after each analyzer start-up and before the start of analysis. To automate this preparatory maintenance use maintenance pipes in connection with the **Power Up pipe** or **Start Up pipe** functions.

☞ For more information, see:

Maintenance pipes on page C-14

Daily maintenance on page C-26

Recommended maintenance pipes on page C-35

If you do not use maintenance pipes in connection with the **Power Up pipe** or **Start Up pipe** functions, you have to execute the maintenance items manually.

☞ See *Performing maintenance items or pipes* on page C-16

Visual checks

Even though you can automatically execute preparatory maintenance pipes using the **Power Up pipe** or **Start Up pipe** functions, some maintenance items require visual checks by the operator. Be sure to perform these checks prior to routine operation.

☞ See *Visual checks at start-up* on page C-27.

► **To automatically start up the analyzer**

The analyzer can be programmed to start up automatically. If the analyzer was put in sleep mode at the end of the previous working session and a wake-up time was set, the following occurs:

- 1 The analyzer starts up automatically at the set time. While the analyzer is performing initialization, the **log-on** screen is displayed.
 - If the **Alarm** button on the right of the screen is flashing, check the **Alarm** screen for important system notifications.
☞ See *To review the Alarm screen* on page B-30.
 - If the **Alarm** button is not flashing, go to step 2.

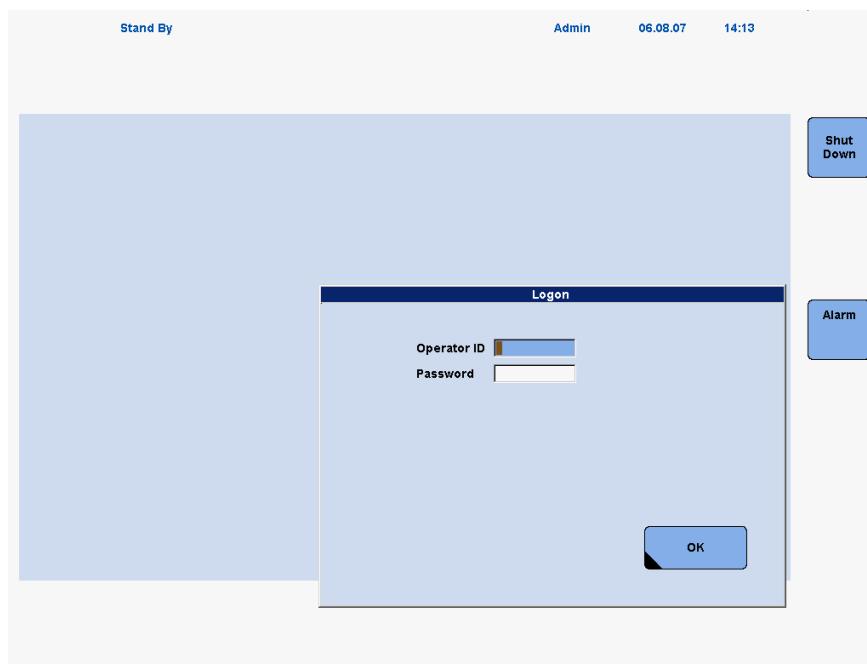


Figure B-14 Logon screen

- 2 Enter your **Operator ID** and password to log on.
- 3 Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.



If no automatic start-up has been set, use the following procedure to start up the analyzer.



If the logon mode is not activated (**Utility > System (Page 3/4) > Operator ID**), the software opens at the **System Overview** screen.

► **To manually start up the analyzer**

- 1 Switch on the operation power switch, located on the left side of the rack sampler unit.

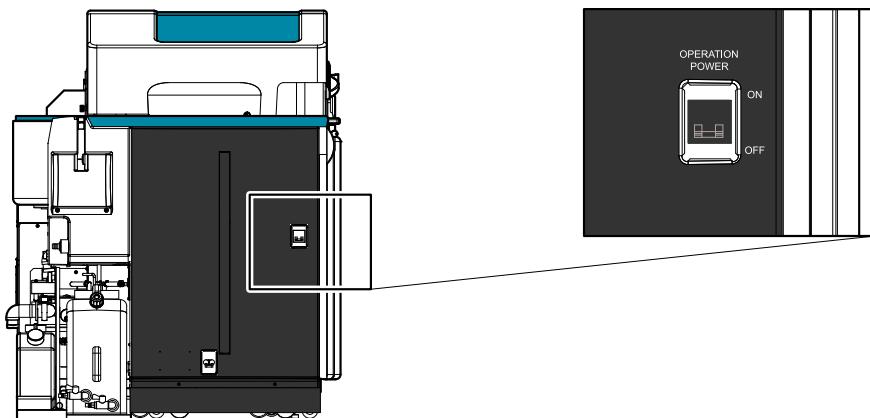


Figure B-15 Operation power switch

- 2 Switch on each power switch of the computer, printer, and monitor.

The analyzer starts the initialization routine (time for c 501, e 601, and control unit approximately 12 min).

While the analyzer is performing initialization the **Logon** screen is displayed.

- 3 Enter your **Operator ID** logon and password to log on.
- 4 Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.

■



Interrupt of the analysis run due to interlock system of c 501

The interlock system of c 501 senses top cover opening and immediately stops the analysis run by cutting off the power.

- Before starting operation or maintenance, be sure to close and lock the top cover.
- Do not open the top cover during operation.

Check system alarms



If an alarm was issued, the **Alarm** global button flashes. In this case, it is necessary to open the **Alarm** screen to view the alarm. The **Alarm** screen identifies any system alarm conditions.

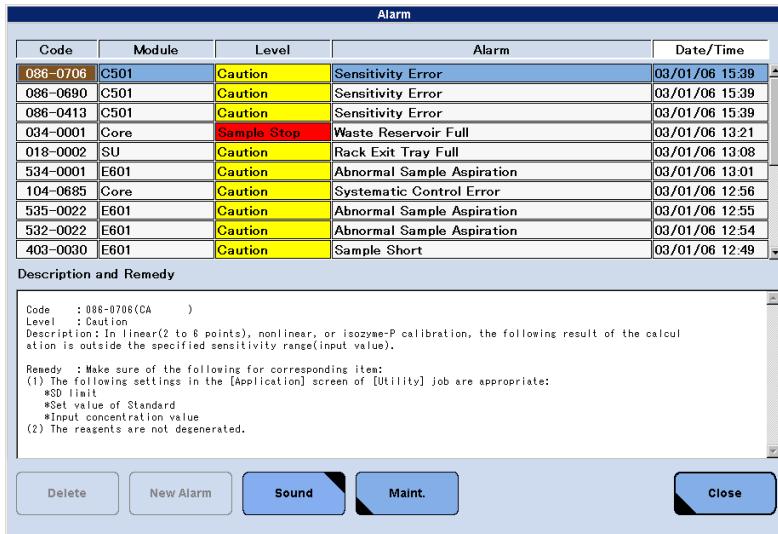


Figure B-16 Alarm screen

► To review the **Alarm** screen

- 1 Choose **Alarm** (global button) to display the **Alarm** screen.
- 2 Select each alarm to view the description and remedies (displayed in the lower half of the screen).
- 3 Correct any alarm conditions by following the remedies.
If any problems arise, refer to the module specific troubleshooting chapter.
- 4 Choose **Close** to close the **Alarm** screen.



System Overview screen

The **System Overview** screen has a central role within the **cobas 6000** software. From here the operator has an overview of the whole system at any given time and the modules can be prepared for daily routine operation (via the **Work Flow Guide**).

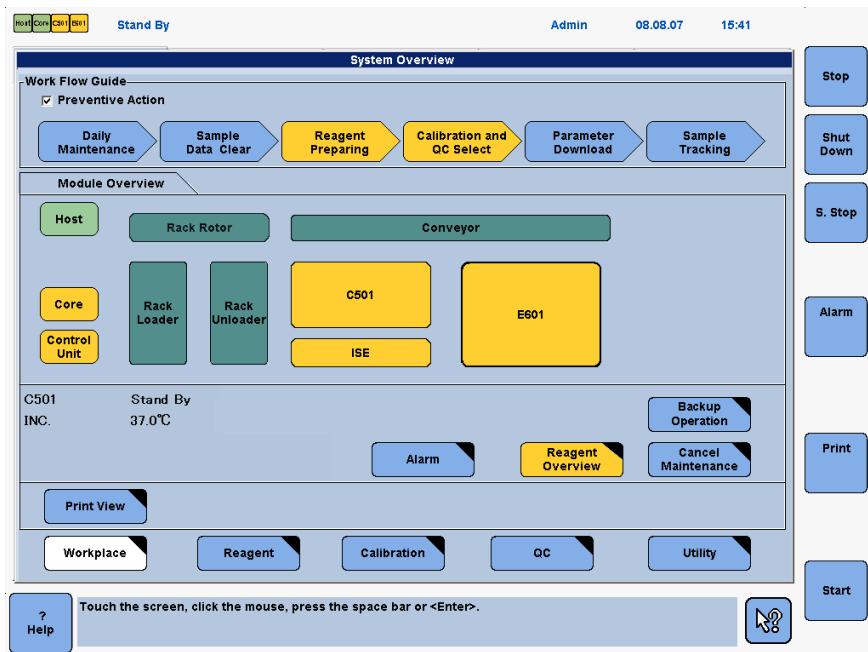


Figure B-17 System Overview screen



From any point in the software—**Workplace**, **Reagent**, **Calibration**, **QC**, or **Utility**—it is possible to display the **System Overview** screen by choosing the icon in the top left corner of the screen or by pressing F12.

Work Flow Guide area

The **Work Flow Guide** area at the top of the **System Overview** screen guides you through the preroutine operation.

Module Overview area

The **Module Overview** area provides a view of the current status of the modules and components (for example, rack loader, unloader, c 501 module, and e 601 module) of the **cobas 6000** system.

The lower section of the **Module Overview** area displays information relevant to the module or component currently selected such as incubator temperature (INC.).



Before performing any measurements, check that the temperature of the incubator is within $37 \pm 0.1^\circ\text{C}$ ($98.6 \pm 0.2^\circ\text{F}$).

- Select each module on the **System Overview** screen to display the temperature of the incubator bath of the selected module.
- A wrong temperature may result in incorrect measurement results and lead to incorrect results for the photometer check (maintenance (3) Photometer Check).
- Depending on the ambient temperature, it can take up to 30 minutes to reach the correct temperature after switching on the analyzer or after exchange of incubation water (maintenance item (5) Incubation Water Exchange).

Temperature (e 601)

Choose this button to display the **Temperature** window. This window displays actual, target and control temperatures for the e 601 module currently selected.

Starting the analyzer

Alarm This button displays the color corresponding to the highest priority alarm of the currently selected module or component. Use this button to display the global **Alarm** screen. The alarm(s) corresponds to the module or component currently selected.

 For a detailed description of the **Alarm** screen, refer to the *Online Help*.

Reagent Overview Choose this button to display an overview of the reagents loaded on the module currently selected.

 See *Reagent Overview button* on page B-115.

Backup operation In case of problems with the rack sampler unit, the backup operation mode allows to continue sample measurement on c 501 modules.

 See *Backup operation* on page B-225.

Cancel Maintenance Use this button to force all maintenance items running on the currently selected module to stop after confirmation.



Some maintenance items performed on the analyzer cannot be stopped once they have begun.

Color scheme of the System Overview screen

The **System Overview** screen uses a color scheme to display the status of the analyzer.

The following table describes the meaning of the color scheme for each button/module on the **System Overview** screen.

Colors in the Work Flow Guide



Figure B-18 Work Flow Guide area of the System Overview screen

Button in Work Flow Guide area	Color	Meaning
Daily Maintenance	■ Red	A maintenance item has expired.
	■ Yellow	A maintenance item is about to expire.
Sample Data Clear	■ Red	The database is full, 10 000 records. No additional samples can be processed until database (Routine view) is cleared.
	■ Yellow	The database is nearly full (more than 9400 records).
Reagent Preparing	■ Red	Reagent for at least one test or detergent required for the test is not on board (mandatory) or is empty.
	■ Yellow	The number of tests remaining for a reagent is less than the yellow alarm level.
	■ Purple	The number of tests remaining for a diluent, test reagent or detergent volume is less than the purple alarm level (daily requirement) - only applicable when Preventive Action check box is selected.
Calibration and QC Select	■ Yellow	The system has recommended a calibration or quality control.
Parameter Download	■ Red	A reagent cassette, calibrator, or QC was loaded onto the analyzer, which has not been installed before. New information for applications, controls, and calibrators must be downloaded from cobas link .

Table B-2 Color scheme Work Flow Guide area

Starting the analyzer

Colors in the Module Overview

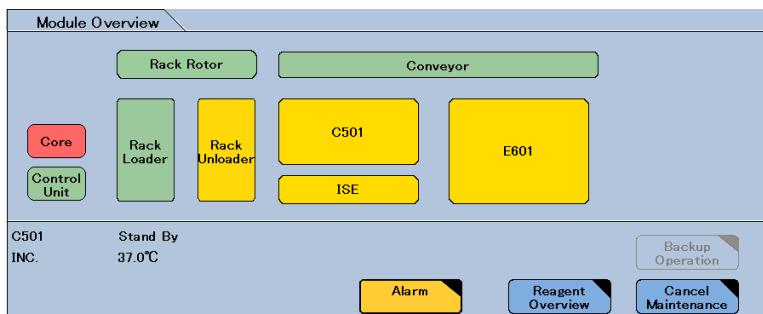


Figure B-19 Module Overview area of the System Overview screen

Button in Module Overview	Color	Meaning
Rack Rotor, Conveyor, Core, Control Unit, Rack Loader, Rack Unloader, C501, ISE, E601	■ Red	An instrument alarm of Stop , S.Stop or E.Stop level.
	■ Yellow	An instrument alarm with a caution level.
	■ Light blue	Indicates a status other than standby (e.g., Operation or Maintenance).
	■ Light green	Indicates standby mode.
Module	■ Red	Indicates an instrument alarm of Stop , S.Stop or E.Stop level or a reagent is empty and there is no second cobas c pack or cobas e pack on this particular module, or a mandatory reagent is not on board.
	■ Yellow	Indicates an instrument alarm with a caution level or the number of remaining tests is less than the yellow alarm level.
	■ Purple	Indicates the number of tests remaining for a diluent, test reagent or detergent volume is less than the purple alarm level (daily requirement) - only applicable when Preventive Action check box is checked.
	■ Light blue	Indicates a status other than standby (e.g., Operation or Maintenance).
	■ Light green	Indicates standby mode.
	■ Dark green	Indicates an administrator has inactivated the module.
	■ Black	Indicates the module is powered off.
X in a module		Indicates the module is masked.
\ in a module		Indicates the module is service masked.
Reagent Overview	■ Red	A reagent is empty and there is no second reagent cassette or cobas e pack on this particular module, or a mandatory reagent is not on board.
	■ Yellow	The number of tests remaining for a reagent is less than the yellow alarm level.
	■ Purple	The number of tests remaining for a reagent is less than the purple alarm level.
Alarm	■ Red	Indicates an instrument alarm of Stop , S.Stop or E.Stop level
	■ Yellow	Indicates an instrument alarm with a caution level

Table B-3 Color scheme Module Overview area

Work Flow Guide

The **Work Flow Guide** area at the top of the **System Overview** screen guides you through the preroutine operation.

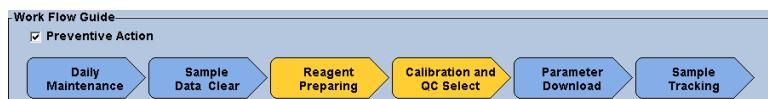


Figure B-20 Work Flow Guide

The **Work Flow Guide** area consists of 6 buttons: **Daily Maintenance**, **Sample Data Clear**, **Reagent Preparing**, **Calibration and QC Select**, **Parameter Download**, and **Sample Tracking**. The first 4 buttons are placed in the suggested sequence of preventive action. If a button remains blue, that action is not necessary.

The **Sample Tracking** button is used for searching samples on the analyzer. This is possible during operation as long as no samples have been removed from the unloader and no new run has been started.

- 🕒 For more information about the meaning of the colors, see: *Color scheme Work Flow Guide area*, Table B-2 on page B-33
- 🕒 For more information about the different buttons, see:
 - Preventive action* on page B-35
 - Daily Maintenance button* on page B-36
 - Sample Data Clear button* on page B-37
 - Reagent Preparing button* on page B-37
 - Calibration and QC Select button* on page B-42
 - Sample Tracking button* on page B-50

Preventive action

Preventive action is a look ahead at what might be required during the daily routine. When activated, preventive action triggers the following items:

- Reagent purple alarm (diluent, test reagent or detergent volume is less than the daily requirement).
- Recommended calibration for tests with calibrations due within the **Remaining Time** set on the **Calibration Status** screen.

At wake up or power on, the **Preventive Action** check box on the **System Overview** screen is automatically selected and therefore active.

It is recommended to deselect the **Preventive Action** check box after all recommended reagents are loaded and recommended calibrations are performed.

Preroutine operation

Preroutine operation involves the following tasks:

- Performing maintenance actions
- Preparation of reagent
- Calibration
- Measurement of quality controls

The **Work Flow Guide** area at the top of the **System Overview** screen guides you through the preroutine operation.

Daily Maintenance button

Requirements: Define maintenance types

The **Daily Maintenance** button indicates when maintenance is about to expire. However this function is available only if maintenance intervals for maintenance items are defined.

- ☞ For more information, see
Color scheme Work Flow Guide area, Table B-2 on page B-33.
Maintenance types—scheduling and tracking maintenance items on page C-13.

Choosing **Daily Maintenance** on the **Work Flow Guide** area displays the **Maintenance** screen. Use the **Maintenance** screen to execute maintenance actions or maintenance pipe functions.

- ☞ See *Performing maintenance items or pipes* on page C-16.

Define a power up pipe

For a proper use of the analyzer Roche Diagnostics recommends performing some maintenance items regularly. We recommend automating these maintenance items by means of maintenance pipes.

- ☞ See *Recommended maintenance pipes* on page C-35



Daily maintenance items may be programmed as a power up pipe and then performed automatically when powering on the analyzer or as a daily pipe if you do not shut down the analyzer daily.

To backup the data of your **cobas** 6000 system to **cobas** link we recommend including the maintenance item Smart. Com Essential information upload into the power up pipe or in the daily pipe.

- ☞ For more information, see:
Power Up Pipe function on page C-18
Start Up pipe function on page C-19

Sample Data Clear button

Use the **Sample Data Clear** button to delete the contents of the database (**Workplace > Data Review > Routine View**).

- ⦿ For more information, see Table B-2 on page B-33

If **Sample Data Clear** is executed, all records of the samples are deleted and QC data is moved to the **QC View**. Less sample data in the database allows faster access to the data. Backing up on a periodic basis is recommended. If your system is connected to a Host, make sure that all data has been uploaded before performing the **Sample Data Clear**.

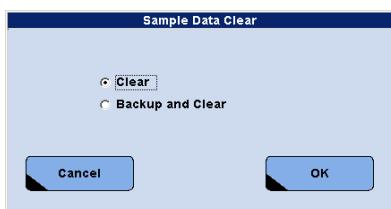


Figure B-21 Sample Data Clear window

- ⦿ For more information on saving data, see
Archiving patient data on page B-77
Handling of QC results on page B-162.



Operation of the analyzer may slow down and become error-prone

If the database for patient results or QC results is overloaded, the operation of the analyzer software may slow down and become error-prone.

- It is strongly recommended to delete the contents of the database daily.
- Make sure that the results are transferred to the Host or saved on external storage media before deleting the contents of the database.

Reagent Preparing button

Requirements: Define reagent warning levels and mandatory tests

The **Reagent Preparing** button indicates insufficient amount of reagent. However, this function is available only if the volumes for the reagent level check and the mandatory tests were defined.

- ⦿ For more information, see:
Table B-2 on page B-33
Assigning a test to a module on page B-222

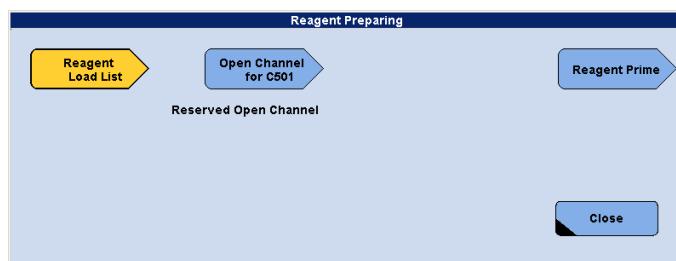


Figure B-22 Reagent Preparing window

Print Reagent Load List

The **Reagent Load List** displays the **cobas c** packs, **cobas e** packs, auxiliary reagents and other consumables that need to be replenished on the analyzer.

► **To print a Reagent Load List/Unload List**

- 1 Choose Reagent Preparing on the System Overview screen.
- 2 Choose Reagent Load List on the Reagent Preparing window.
A confirmation window appears.
- 3 Choose Yes to print the Reagent Load List/Unload List.

Now, remove and replace any required reagent, diluent, detergent or wash solution according to the **Reagent Load List/Unload List**.

Ensure that reagents have not exceeded their expiration dates. Check the expiration status on the **Reagent Overview** screen.

 For more information, see:

Reagent Overview c 501 module on page B-115

Reagent Overview e 601 module on page B-120



WARNING



CAUTION



CAUTION

Before performing the following actions, observe the following safety precautions:

- *Infection by contact with sample or waste solution* on page B-3
- *Personal injury due to contact with cleaning solutions or reagents* on page B-3

Incorrect results due to expired reagents

- Data obtained using expired reagents are not reliable. Do not use reagents that are expired.

Incorrect results due to incorrect reagent volume

- To avoid undetectable loss of reagent store cassettes always according to specified storage conditions.
- Do not reuse a reagent cassette or **cobas e** pack whose reagent has been spilled.
- Do not use a single **cobas c** pack or **cobas e** pack for different **cobas** 6000 analyzers.

c 501 – ISE unit

ISE IS, ISE Ref., and ISE Dil. are stored in reagent bottles in the ISE reagent compartment. A green indicator lamp (next to the reagent position) lights up if no reagent bottle is present or if the liquid level falls below the limit where the bottle needs to be replaced. In this case the ISE probe pipettes from the second bottle of the reagent (changeover reagent). If the second bottle of ISE IS is used as changeover reagent, a changeover calibration is automatically recommended by the system.



When replacing an ISE reagent bottle, the remaining volume is reset. Before starting a measurement, reagent level is detected by using the ISE reagent probe to check the remaining volume of reagent so that the number of available tests can be controlled.

 *ISE reagent registration* on page B-97.



CAUTION

Injury due to contact with ISE mechanical parts when replacing ISE reagents

- Do not insert your hands or fingers into the inner side of the top cover when replacing ISE reagents.

► **To replace ISE IS or ISE Dil.**

The green indicator lamp lights up at the position where the bottle needs to be replaced.



Replacement is allowed only in the position where the green LED is lit.

Replacement of ISE IS and ISE Dil. can be done with the top cover closed.

1 Remove the empty bottle from the position where the green indicator lamp lights up.

2 Place a new bottle into the reagent position.

Reagent registration is performed automatically when a new bottle is placed.



► **To replace ISE reference solution (ISE Ref.)**

1 Put the module in standby.

2 Unlock and open the top cover of the module.

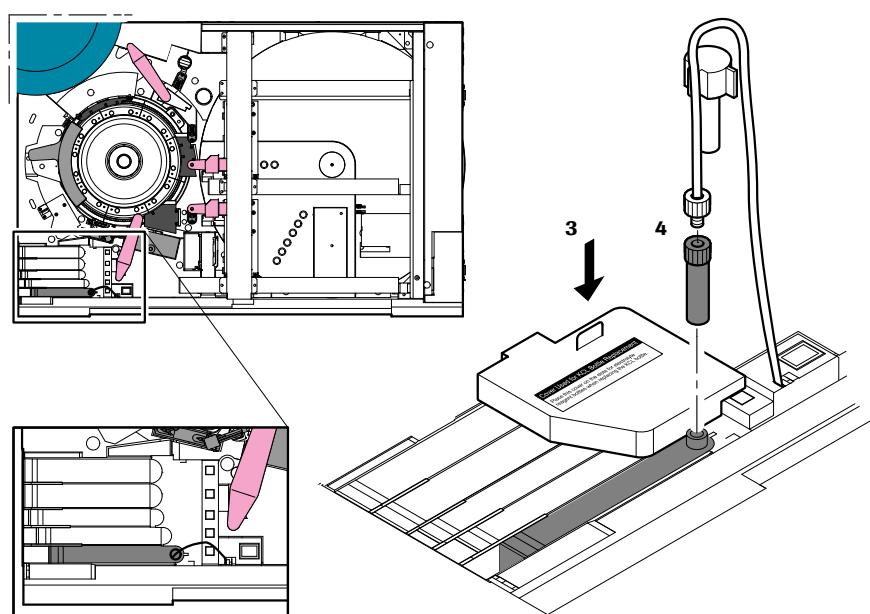


Figure B-23 Cleaning the ISE Ref. aspiration filter

3 Place the dedicated cover over the ISE reagent bottles.



Incorrect results due to mixing or misplacement of ISE reagents

If the dedicated cover for the ISE reagent bottles is not placed correctly when replacing the ISE Ref. bottle, liquid from the tip of the tube may drop into another ISE reagent bottle, leading to incorrect results.

- Before replacing the ISE Ref. bottle or when cleaning the filter, attach the dedicated cover for the ISE reagent bottles.
- Take care to place the ISE reagent bottles in the correct positions as labelled.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-10.

- 4 Remove the tubing from the ISE Ref. bottle and clean the ISE Ref. aspiration filter.
☞ See *Cleaning the ISE Ref. (KCl) aspiration filter* on page C-83.
- 5 Replace the ISE Ref. bottle, and place the tubing into the new bottle. Make sure that the end of the tube touches the bottom of the bottle. Otherwise, reagent may not be pipetted properly.
The indicator lamp of the ISE Ref. bottle turns off.
- 6 Remove the dedicated cover from the ISE reagent bottles.
- 7 Close the top cover of the module and lock it.
Reagent registration is performed automatically when a new bottle is placed.



After replacing the ISE Ref. bottle, it is necessary to perform a **Reagent Prime**.

► **To perform a Reagent Prime**

- 1 From the **System Overview** screen, choose **Reagent Preparing**.
- 2 Choose **Reagent Prime** on the **Reagent Preparing** window.
- 3 Select a module. Selected modules are highlighted.
- 4 Choose **Ref** in the **ISE** area.
- 5 Choose **Execute**.
The prime is complete when the analyzer returns to standby.

After the **Reagent Prime**, recalibrate the ISE unit before you resume routine operation.

- ☞ For details on how to recalibrate the ISE unit, see *Calibration and QC Select button* on page B-42.

c 501 – photometric unit

Replace all required reagent cassettes and auxiliary reagents as indicated by the **Reagent Load List**. Ensure that reagents have not exceeded their expiration date.

Replacing auxiliary reagents

- ☞ For instructions how to replace auxiliary reagents, see:
To replace a cell detergent bottle on page B-109
To replace a sample probe detergent bottle or Hitergent on page B-109

Replacing reagent cassettes

The **c 501** module automatically unloads empty reagent cassettes to the cassette disposal, which is located behind the left front door of the **c 501** module. It is also possible to unload reagent cassettes manually from the **Reagent > Setting** screen (only possible in standby).

- ☞ For details see *Unloading reagent cassettes* on page B-105.

To load a new reagent cassette, follow the procedure below:

► To load a cobas c pack

- 1 Fold the cassette table at the front of the c 501 module downward to get access to the cassette loading port.
☞ To locate the cassette loading port, see *Cassette loading port* on page A-63.
- 2 Place the **cobas c** pack right in front of the loading port with its **barcode label facing to the right**.
- 3 Slide the **cobas c** pack all the way into the loading port until you sense a resistance.

From this point on the analyzer handles the **cobas c** pack without any further intervention of the operator: The **cobas c** pack is pulled in to the preparation station where the module automatically performs the reagent registration.



Injury due to contact with cassette loading mechanism

The instrument may recognize your hands or fingers as a reagent cassette if you insert your hands or fingers into the cassette loading port. An unloaded cassette may hit your hands or fingers when the instrument is unloading cassettes.

- The **c 501** module cover must be closed and locked when loading cassettes.
- Leave the cassette table closed, except when registering reagent cassettes or when manually unloading cassettes from the **Reagent > Setting** screen.
- Do not insert anything other than cassettes into the cassette loading port.



If a cassette barcode is facing the wrong direction or the barcode is unreadable, a label reading error occurs and the cassette is not registered. In this case the cassette is rejected and will not be loaded but pushed out of the loading port.

e 601

Replace all required **cobas e** packs, auxiliary reagents and consumables on the respective modules as indicated by the **Reagent Load List**. Ensure that **cobas e** packs have not exceeded their expiration date.



If both bottles of ProCell, CleanCell or PreClean solution are empty, or if the AssayCups/AssayTips magazines are empty on a **e 601** module, the corresponding module turns red on the **System Overview** screen and is not used for sample processing. If your **cobas 6000** system is equipped with another **e 601** module, sample processing is performed on the second module.



Incorrect results due to incorrect reagent temperature

cobas e packs taken directly from the refrigerator may result in incorrect results.

- Only insert **cobas e** packs of the correct temperature of $20 \pm 3^\circ\text{C}$ ($68 \pm 5.4^\circ\text{F}$)



Incorrect results due to reagent barcode read error (e 601 module)

If due to a barcode read error a **cobas e** pack was manually assigned to a reagent rotor position, thoroughly check reagent information after replacement of this **cobas e** pack and a new occurrence of a barcode read error.

Illuminating indicators The e 601 uses illuminating indicators to show when it is safe for you to replace an auxiliary reagent. The nature of the indicator may differ for the individual reagents, but the meaning of the states is consistent:

Light off	The bottle is in use, do not replace it.
Light on	This is a standby bottle, do not replace it.
Light flashing	The bottle is empty, it is safe to be replaced.

► To load cobas e packs

- 1 Make sure, that the system is in standby.



Risk of personal injury and damage to the analyzer

- If you open the reagent disk cover during operation, your fingers may crash moving parts or get entangled in the reagent disk and cause you injury.
- Do not open the reagent disk cover while the module is in operation.

- 2 Lift off the lid of the reagent disk.

☞ See *Reagent disk* on page A-87.

- 3 Place the required reagents in the reagent disk. Ensure that the cobas e packs are placed in the reagent disk in the correct orientation.

- 4 Close the lid of the reagent disk. A reagent scan is activated and the **Reagent Overview** window (*System Overview > Reagent Overview*) is updated.

■

Replacing auxiliary reagents

- ☞ For instructions how to replace auxiliary reagents, see:
Replacing auxiliary reagents (e 601) on page B-110
Replacing consumables and emptying solid waste (e 601) on page B-113

Calibration and QC Select button

It is necessary to calibrate all applications and measure quality control (QC) samples regularly to verify the stability of reagents and the entire system. Make sure calibration has been completed successfully and all QC results are OK before you start routine operation.

The intervals of calibration and QC vary with each application and therefore each application has its individual configuration. According to this configuration, the system automatically recommends calibrations and QC measurements for all registered applications.

For details about calibration and QC intervals refer to the instructions for use of the corresponding test.

Each time the system recommends a calibration it is indicated by the **Calibration and QC Select** button turning yellow.

The following sections explain how a recommended calibration is executed. The instructions are given assuming that all configurations for calibration and QC are already set.

- ☞ For general information on calibration, see:
Calibration concept on page B-127
Causes for automatic calibration recommendations on page B-128

- For information on calibration settings, see:
Description of application parameters - Calib. tab on page B-201
To select tests for start-up calibration on page B-145

The entire calibration and QC process comprises the following parts:

1. Requesting calibration and QC and printing load lists
2. Measuring calibrators and controls
3. Validating calibration and QC results

The following explains each of these parts. However, some details depend on your laboratory's decision on a specific calibration workflow (for example, time-triggered calibration or QC-triggered calibration).

Requesting calibration and QC and printing load lists

Use the **Calibration and QC Select** button to select calibrations and QC to be performed. Choose this button to display the **Calibration and QC Select** window from which calibration and quality controls are selected and calibrator and QC load lists can be printed.



Calibration and QC measurements can be requested only for applications which have their corresponding **cobas e** packs and **cobas c** packs loaded.

Use the following procedure to request the recommended calibrations and controls. If you need to select additional calibrations manually, select these from the **Calibration > Status** screen.

- See *Requesting and cancelling calibrations manually* on page B-137.

► To request calibration and QC

- 1 Choose **Calibration and QC Select** in the **Work Flow Guide** area.

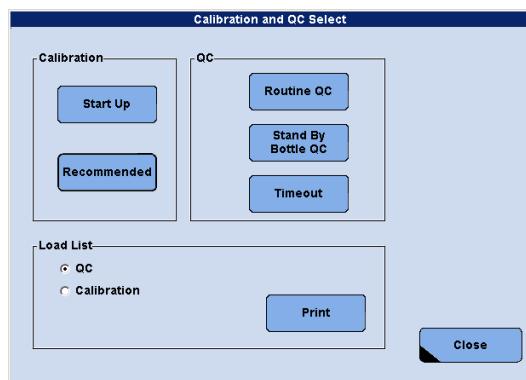


Figure B-24 Calibration and QC Select window

- 2 Choose the buttons that are yellow in both the **Calibration** area and the **QC** area to select the suggested calibrations and controls for measurement.



In case there are reagents with less than 10 tests on board, a confirmation window opens and it is possible to cancel the calibration or QC request for these reagents.

- 3 Select the list you want to print from the **Load List** area:

- **QC** comprises all requested QCs including QC after calibration.
- **Calibration** comprises all requested calibrations.

- 4 Choose **Print** to print the selected load list.

The **QC Load List** and the **Calibration Load List** respectively displays all controls and calibrators that are needed to perform the requested measurements.



If you need to run QC for standby cassettes, do one of the following:

- Choose **Stand By Bottle QC** to request a QC for all standby reagents.
- Choose **QC > Status > Stand By Bottle QC**, select individual tests from the list, and choose **OK**.

See *Requesting QC measurements* on page B-166.

- 5 Load the calibrators and controls on the analyzer as directed by the **Calibration Load List** and the **QC Load List**.

See *To load required calibrators and controls* on page B-46.



Calibration Load List					07/10/08 09:24
NAME	LOT	R.NO.	EVENT	VOLUME	
H2O	99999900		-----	-----	
CFAS	17715200		-----	-----	
ISELOW	69906400	S0002-1	-----	-----	
ISEHIGH	69631400	S0002-2	-----	-----	
ISECOMP	18191800	S0002-3	-----	-----	
TSH-L1	182423		2	196.0	
TSH-L2	182423		2	196.0	

Figure B-25 Calibration Load List report

QC Load List					27/11/08	16:59
<hr/>						
System Specific Rack						
AUTOMATIC	QC RACK RANGE	0000 - 0000				
NAME	LOT	EVENT	VOLUME	R.NO.		
PPU	17628700	----	-----	C0001-2		
PNU	17683000	----	-----	C0001-1		
<hr/>						
QC After Calib.						
NAME	LOT	EVENT	VOLUME	R.NO.		
PC U2	15041800	2	22.0			
PC U1	18067700	2	22.0			
PC CARD1	18269000	4	60.0	C0005-1		
PC CARD2	18269100	4	60.0	C0005-2		
<hr/>						
Module Specific Rack						
MODULE E1	RACK RANGE	5- 10				
NAME	LOT	EVENT	VOLUME	R.NO.		
PC U2	15041800	2	22.0			
PC U1	18067700	2	22.0			
PC CARD1	18269000	4	60.0			
PC CARD2	18269100	4	60.0			

Figure B-26 QC Load List report

► **To load required calibrators and controls**

- 1 Using the load list as a guide, prepare all required calibrator and control materials according to the manufacturer's instructions.



Before placing calibrators and controls on the loader, check that no bubbles or foam are visible on the liquid surface.

- 2 Load calibrators and controls onto the racks (calibrators onto black racks, controls onto white racks) and place the racks on the loader.

Two or more calibrator racks are to be measured as one group, so do not put other racks between them. When you carry out QC after calibration, QC racks have to follow calibrator racks directly. Do not set other racks with the calibrator and QC racks.



CAUTION

Calibration or QC failure

- If a calibrator or QC vial (or another sample container) needs to be manually assigned (for example, due to an unreadable barcode) do not place any vials or other sample containers with barcodes on the same rack. If manually assigned vials and barcoded vials are on the same rack, the requested calibrations are not measured and the requests are deleted.
- Do not use micro cups for calibrators and controls.



CAUTION

Incorrect results due to expired calibrators or controls

Data obtained using expired calibrators or controls are not reliable. Do not use calibrators or controls that are expired.



CAUTION

Incorrect results due to concentrated ISE calibrators

- The concentration of the ions increases due to evaporation, this may result in an incorrect calibration, and thus incorrect results.
- For ISE calibrations ensure that the calibrator is opened immediately before the calibration is performed.



- For more information, see:

To load calibrator vials on page B-154

To assign calibrator positions on page B-153

- For an explanation of the colors of the racks, see *Sample racks* on page A-48.

Measuring calibrators and controls

Once calibrations and QCs are requested and the calibrators and controls placed on the loader, the measurements can be started.

► To measure calibrators and controls

- 1 Choose **Start** (global button).

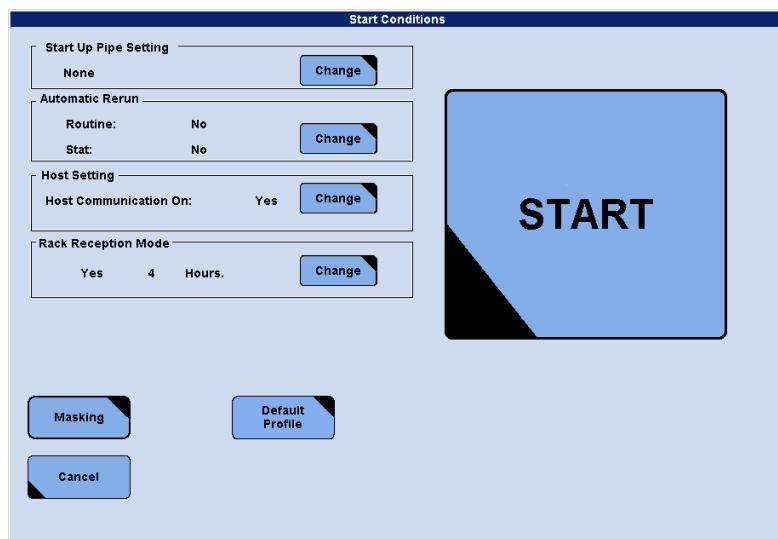


Figure B-27 Start Conditions screen

- 2 Choose **Start** on the **Start Conditions** screen. The **Start** screen closes and the calibration and control run begins.



If automatic printout is selected on **Utility > System (Page 4/4) > Auto. Print**, the **Calibration Monitor** and **Control Result Monitor** report is automatically printed when the measurements are completed; calibration and QC results can also be viewed choosing **Print (global button) > View**.



Validating calibration and QC results

It is important to verify that calibrations and QC results are valid before measuring routine samples. Validation can be performed either at the Host or on the cobas 6000 system. For routine operation it is sufficient to validate calibrations and QC by means of the **System Overview** screen:

- A failed or newly recommended calibration is indicated on the **System Overview** screen by the **Calibration and QC Select** button turning yellow.



Information on the status of the calibrators that are currently processing can be viewed on the **Workplace > Calib. Review** screen.

☞ See *Calib. Review screen* on page B-81.

Detailed information on calibration results can be viewed on the **Calibration > Status** screen.

☞ See *Calibration Status screen* on page B-136.

Detailed information on quality control results can be viewed on **QC > Individual** screen.

☞ See *QC Individual screen* on page B-170.

If the automatic printout of calibration or QC results is configured (under **Utility > System** (Page 4/4) > **Automatic Printout**), it is also possible to use these printouts for validation.

If calibration or QC failed...

If a calibration fails or a QC result falls out of the expected range, check for data alarms on the **Workplace > Calib. Review** screen or on the printouts.

Data alarms are issued when measurement values or results are in any way unusual or unexpected. Data alarms appear on screen and on reports as short strings (up to six characters) also referred to as data flags. Look up the meaning of each data flag and possible remedies in the troubleshooting part of this manual.

☞ See Chapter 20 *Data alarms*.

After taking the necessary measures, repeat the calibration or QC before you begin routine analysis.



If a realtime QC rule is violated, the system issues a realtime QC alarm. Ensure you check the results of the QC to see if you accept the values.

Quality control results

The results of QC measurements are saved in the database and displayed on the **Data Review** screen as well as on the **QC > Run Status** screen and **QC > Individual** screen. It is important to regularly accumulate these results for long term quality control data storage (**QC > Cumulative**).

Parameter Download button

The **Parameter Download** button turns red if there is missing information for applications, calibrators, and controls. For example if a calibrator barcode is read by the barcode reader and calibrator data of this lot has not been downloaded.

Choose **Parameter Download** in the **System Overview** screen to open the **To Do List** window.

- ☛ For an overview of downloading parameters from **cobas** link, see:
Loading or updating new applications on page B-192.

► To download new information

- 1 Choose **Parameter Download** in the **Work Flow** guide area

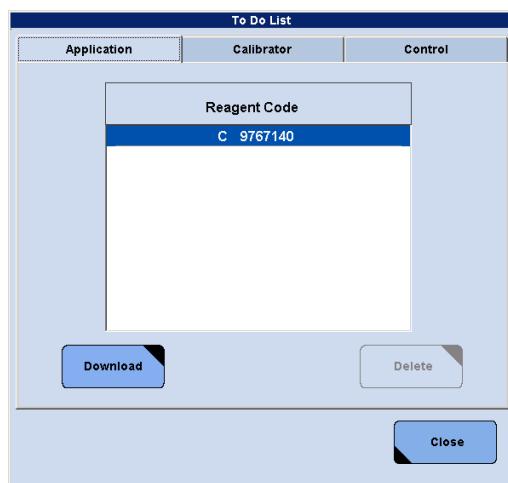


Figure B-28 To Do List window

- 2 Choose the tab of the corresponding items you want to download.
- 3 Select an item from the list and choose **Download**.

The corresponding screen will be opened, e.g. the **Utility > Application** screen for application parameters.

- 4 Choose the **Download** button to open the **Download** window.

- ☛ The following steps are described in the corresponding chapters:
Loading new application parameters on page B-192
Loading calibrator data on page B-147
Loading control data on page B-182



Sample Tracking button

Sample Tracking allows the operator to search for any sample on the analyzer (as soon as it is registered by the analyzer) and provides an overview of the samples in the unloader.

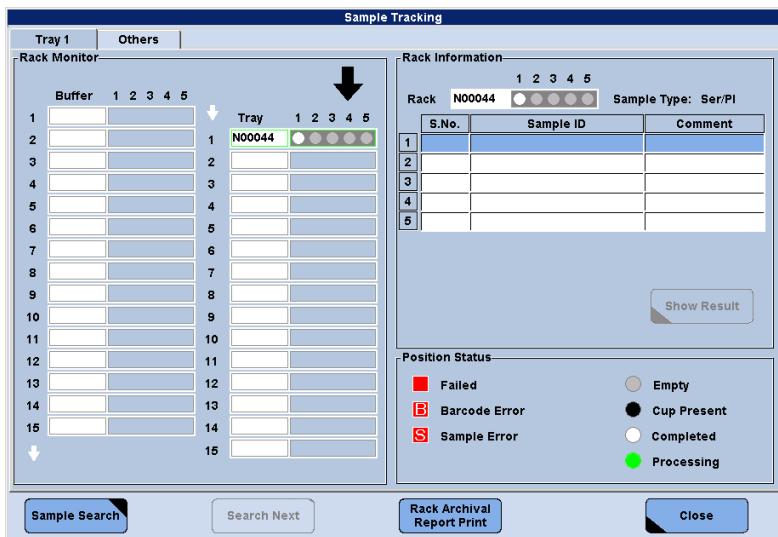


Figure B-29 Sample Tracking window

- 🕒 For more information, see:
Sample tracking on page B-59
Tracking samples on the analyzer on page B-83.

Routine operation

Before continuing with routine operation, clear the **Preventive Action** check box on the **System Overview** screen. Otherwise, the system will issue purple and other irrelevant alarms in the course of routine operation.

Routine operation involves the following items:

1. Processing routine samples
2. Processing STAT samples
3. Processing reruns
4. Checking results
5. Sampling Stop

The way in which routine operation works varies depending on the following system settings and sample properties:

- Whether routine or STAT samples are being analyzed
- Whether the analyzer operates in barcode mode or not (set in the **Barcode Setting** area under **Utility > System**)
- Whether the analyzer operates in connection with a Host computer



CAUTION

Before performing the following actions, observe the following safety precautions:

- *Infection by contact with sample or waste solution* on page B-3
 - *Incorrect results and interruption of analysis due to contaminated samples* on page B-4
 - *Incorrect results due to sample mismatch* on page B-4
 - *Interrupt of the analysis run due to interlock system of c 501* on page B-4
-



CAUTION

Injury due to contact with rack loader mechanism

Only load samples onto the rack loader when the green light on the rack loader is on.



Restrictions for the use of micro cups

- Do not use micro cups on e 601 modules.
 - Do not use micro cups for calibrators and controls.
-



Sample preparation

When preparing samples, always ensure that the preanalytical requirements are fulfilled according to good laboratory practice and tube manufacturer recommendations.

Processing routine samples

In this section, we describe the workflow for an analyzer that operates in connection with a Host and is set to process routine samples in barcode mode. Processing samples always includes the following three steps:

1. Test selection
2. Loading samples
3. Starting the measurement

☞ For more information on ordering samples, see Chapter 10 *Orders and results*.

Test selection

Test selections for routine samples are downloaded from the Host. However, these test selections can manually be changed—regardless of the mode (**Standby**, **Stop**, **Operation**, or **Sample Stop**) the analyzer is in.

☞ For information on manual test selections, see *Requesting a test manually* on page B-71.

Loading routine samples

Once test selections have been made on your Host system or on the analyzer, load the samples onto the rack loader observing the notes below. If needed, print a requisition list from **Print** (global button) > **Workplace** > **Requisition List**.

☞ For more details on printing the **Requisition List**, refer to the *Online Help*.

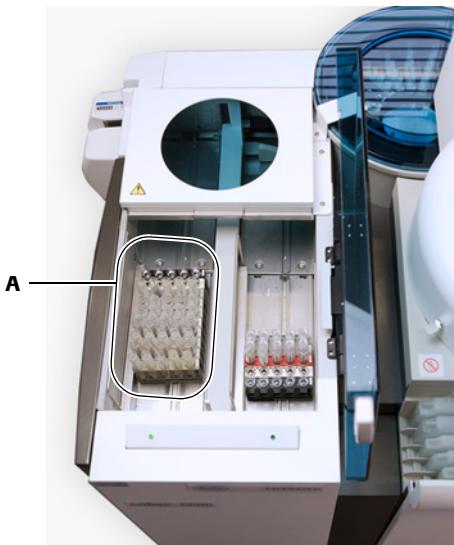


Injury or damage to the analyzer due to contact with instrument mechanism

- Rack transfer mechanism may hurt you and lead to personal injury.
- Do not insert your hands or fingers into the inner side of the cover of the rack loader/unloader.
- Keep all covers closed and in place while the instrument is operating.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-2.

► To load patient samples

- 1** Prepare sample racks with the correct color and rack numbers according to sample types (such as Ser/Pl, Urine, CSF...).
 - For all routine samples use gray racks.
 - To verify the correct rack numbers for each sample type refer to the **Rack Assignment** area on the **Utility > System** screen.
- 2** Place the samples in the prepared sample racks. Ensure the sample barcodes are facing the open slot in the rack so the barcode reader can scan them.
 For more information, see *Correct placement of sample tubes on a rack* on page A-51

**A** Rack loader**Figure B-30** Loading patient samples

- 3** Place the routine sample racks onto a rack tray in the correct orientation: The barcode labels of the sample racks have to be on the right side when placing the tray into the rack loader. The rack loader is on the left side.

*Starting the measurement*

Before starting a run, ensure that all test selections have been made and all necessary samples, calibrators, and controls have been loaded.

► **To start processing**

- 1 Choose **Start** (global button).

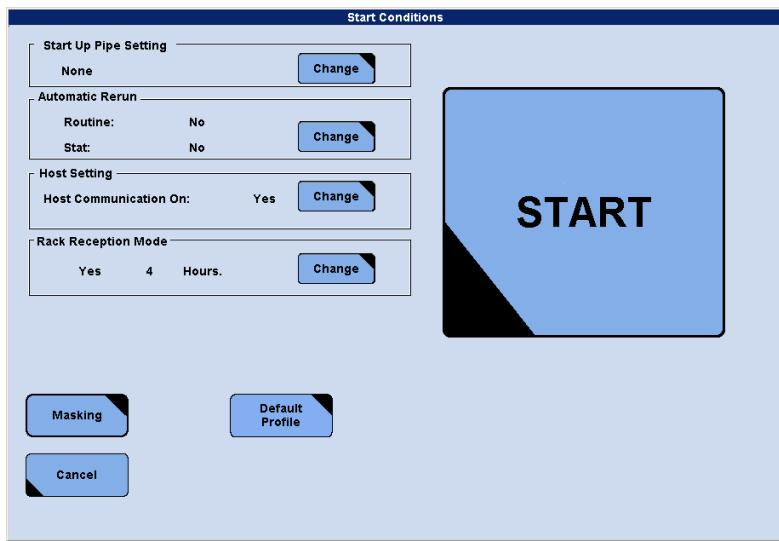


Figure B-31 Start Conditions screen

- 2 Verify the settings on the **Start Conditions** screen.
 - For more information on setting the start conditions, see:
 - Start Up pipe function* on page C-19
 - To activate the automatic rerun function* on page B-57
 - Rack Delivery button* on page B-219
- 3 Choose **Start** (on the **Start Conditions** screen). The analyzer performs preparation routine and then begins to process the samples.

■

Processing additional samples

Additional samples can be loaded onto the analyzer at any time. There are two priority levels: STAT (emergency) and routine, where the first takes priority over the second. In either case, test selections for additional samples are downloaded from the Host in realtime.

- For information on manual test selections, see *Requesting a test manually* on page B-71

► **To process additional samples**

- 1 Load the additional samples either from the STAT port or on the rack loader (racks placed on a rack tray).
 - If the analyzer is in operation, samples are processed without any further action.
 - If the analyzer is not already in operation, go to step 2.
- 2 Choose **Start** (global button).
- 3 Choose **Start** on the **Start Conditions** screen to initiate the run.



Samples loaded from the STAT port are processed before those on the rack loader.

- For unloading specific racks, see: *To unload specific racks* on page B-85

Processing STAT samples

In this section, we describe the workflow for an analyzer that operates in connection with a Host and is set to process STAT samples in barcode mode.



Reserve rack rotor positions for STAT samples

To ensure that a STAT sample can be processed immediately, reserve positions on the rack rotor for STAT samples on the **Rack Delivery** window (**Utility > System** (Page 3/4) > **Rack Delivery**).

Otherwise all positions might be used by routine samples.

For more information, see *Rack Delivery button* on page B-219

Test selection

Test selection for STAT samples is the same as for routine samples. That is, test selections for samples are downloaded from the Host in realtime but can still be changed from the analyzer's control unit.

For information on changing test selections, see *Requesting a test manually* on page B-71.

Loading STAT samples

Once test selections have been made on your Host system or on the analyzer, load the STAT samples onto the analyzer using the STAT port observing the notes below.



Incorrect results due to sample mismatch

Do not insert any gray rack into the STAT port when operating in non-barcode mode because the predefined sequence of samples would get disrupted by the STAT-port inserted routine rack.

► To load STAT samples

- 1 Prepare sample racks with the correct color and rack numbers according to sample types (such as Ser/Pl, Urine, CSF...).
 - For all STAT samples use red racks.
 - To verify the correct rack numbers for each sample type refer to the **Rack Assignment** area on the **Utility > System** screen.



If a barcode read error has occurred and the rack position has been manually assigned, be sure not to place another barcoded sample in that position.

- 2 Set the samples in the prepared sample racks. Ensure the sample barcodes are facing the open slot in the rack so the barcode reader can scan them.



Figure B-32 Loading STAT samples

- 3 Place the STAT rack in the STAT port carefully observing its correct orientation:
The open slots in the racks must point to the rear of the rack sampler unit; The side of the STAT rack with the barcode label must point to the analyzer.
■
 For unloading specific racks, see: *To unload specific racks* on page B-85

Processing reruns

Rerun samples can be processed in two ways, as automatic reruns or as manual reruns.

For information on manual test selections, see *Requesting a test manually* on page B-71.

Automatic reruns

Automatic reruns are performed depending on whether the **Automatic Rerun** check box on **Utility > Application > Range** is selected or not. If it is, the test is automatically requested for rerun and remeasured each time a result is flagged with a data alarm. Selection of the **Automatic Rerun** check box is an application-specific setting; that is, it has to be set for each individual application.

See *Automatic Rerun* on page B-207.

In addition to the application-specific setting, there is a system-wide setting for the automatic rerun function. It is displayed in the **Automatic Rerun** area on the **Start Conditions** window:

See Figure B-31 on page B-54.

- If **Automatic Rerun** is set to **YES**, the application-specific settings are applied; the automatic rerun function is activated.
- If **Automatic Rerun** is set to **NO**, reruns are to be processed manually (regardless of application-specific settings).



When processing reruns automatically, sample racks are kept in the rack rotor until all samples' results are available.

► **To activate the automatic rerun function**

- 1 Verify the settings of the **Automatic Rerun** check box on **Utility > Application > Range** (application-specific).
- 2 Choose **Start** (global button).
- 3 Choose **Change** in the **Automatic Rerun** area.



Figure B-33 Automatic Rerun window

- 4 Choose the **Routine** check box, **Stat** check box, or both to process reruns without operator intervention. **Routine** and **STAT** reruns are selected separately.
- 5 Choose **OK** to save the rerun setting.

■

Manual reruns

If **Automatic Rerun** is set to **NO** in the **Start Conditions** window, all reruns are to be processed manually (regardless of application-specific settings). This is of advantage when you aim for an optimized throughput because no racks will have prolonged rotor times while waiting for the last test results before they are transferred to the unloader.

To manually rerun samples *in barcode off mode* use pink sample racks for the sample containers. To rerun samples *in barcode mode* use gray sample racks for the sample containers. In case you predilute a sample before you reload it onto the analyzer, make sure to select the **Pre-dilution** check box on **Workplace > Test Selection**.

☞ See *Prediluted samples* on page B-58.

Reruns with diluted samples

Tests that need to be rerun can be measured with normal, decreased, or increased sample volumes or with diluted samples.

	c 501 module, photometric unit	c 501 module, ISE unit	e 601 module
Decreased sample volume	✓	✓ ^(a)	-
Increased sample volume	✓	-	-
Diluted sample	✓	-	✓

Table B-4 Availability of dilutions for reruns

(a) available only for urine samples as a manual rerun

These dilutions, performed by the analyzer, can either be programmed to be performed automatically, they can be requested manually by the operator or they can be requested by the Host.

- ☞ Refer to the instructions for use of the respective application for recommended dilutions.



Make sure that sufficient module-specific diluents are loaded for the analyzer to dilute samples.

Automatic dilutions

Individual tests can be configured with a dilution for the first run and/or rerun. Dilutions defined in the **cobas** 6000 software are automatically performed and calculated by the system. Administrator access is required to define these dilution parameters.

- ☞ For more information, see:

Sample Volume area on **Utility > Application** screen (photometric tests)
Dilution ratios (e 601) on page B-200

Manually requested dilutions

Dilutions can be requested by the operator. Choose the **Sample Volume / Dilution** box on **Workplace > Test Selection** and select **Decrease**, **Increase**, or a dilution ratio (1:1, 1:2, ...1:400).

- ☞ For more information, see *Requesting a test manually* on page B-71.

Request from Host

Dilutions can also be requested by a Host computer. In this case, the samples are in the unloader and have to be reloaded and processed again.

Prediluted samples

Manually prediluted samples are samples which have been prediluted before they were put on the analyzer. (These are not to be confused with manually *requested* dilutions.)



Samples which have been manually prediluted can be measured, but the corresponding dilution factors are NOT taken into consideration when the results are calculated by the system. It is the operator's responsibility to calculate the final results.

For manually prediluted samples, make sure that you first select the **Pre-dilution** check box on **Workplace > Test Selection**. When the **Pre-dilution** check box is selected, results are flagged with "P" on the printed monitor report and there is a check mark in the **Pre-dilution** check box on **Workplace > Data Review > Test Review**, too. Pre-dilution is also indicated in the results sent to the host.

Checking results

As results are generated on the instrument, they are saved in the database located on the internal hard disk of the control unit. When all results for all the tests requested for a sample are available, the analyzer sends them to the Host where they can be validated.

To view or edit results on the analyzer, use the **Workplace > Data Review** screen; all test results in the database are displayed here.

- ⦿ For more information, see:
 - Chapter 10 Orders and results*
 - Data Review screen* on page B-75
 - Archiving patient data* on page B-77
 - Editing or deleting sample data* on page B-78
 - Tracking samples on the analyzer* on page B-83

When checking results, it can become necessary to locate a certain sample for further inspection. If a sample is still on the analyzer, use **System Overview > Sample Tracking** to locate it.

Sample tracking

The **Sample Tracking** window allows the operator to search for any sample on the analyzer from the moment of registration (the sample has passed the barcode reader) to the moment when the sample reaches the rack unloader (Tray 1).

The **Sample Tracking** window also allows the operator to search for samples and subsequently unload them.



The location of a sample is indicated by the **Sample Tracking** window only when the sample tray has not been removed from the unloader and no new run has been started yet.

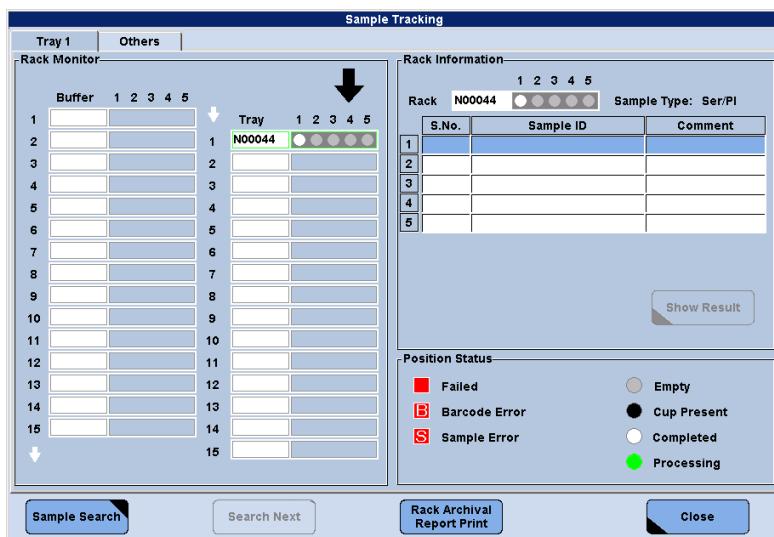


Figure B-34 Sample Tracking window

The **Sample Tracking** window has two tabs, the **Tray 1** tab and the **Others** tab.

Routine operation

Tray 1 tab The **Tray 1** tab provides an overview of all racks in the unloader. The **Rack Information** area on the right side of the screen displays detailed information about each sample in the rack selected on the **Tray 1** tab.

Statuses displayed in the **Sample Tracking** window comprise the following:

	Failed	Measurement is completed and one or more results have a data alarm, or a test could not be processed.
	Barcode Error	The barcode is unreadable (displayed in barcode mode only).
	Sample Error	Possible reasons for sample error are: <ul style="list-style-type: none">• Sample short• Air bubbles (only for e-module)• Sample clot
	Empty	The selected rack position is empty.
	Cup Present	A cup is present but no request has been made.
	Completed	The sample is completed with no flags.
	Processing	The sample is being processed.

For more information, see *Tracking samples on the analyzer* on page B-83

Others tab The **Others** tab provides information about racks and samples that are already registered by the analyzer (have passed the barcode reader) but have not yet reached the unloader.



In the **Others** tab the status *Cup present* is used instead of *Processing*, *Completed* or *Failed*.

For detailed information about the statuses, see *Tray 1 tab* on page B-60.

For more information about the Sample Tracking window, see *Tracking samples on the analyzer* on page B-83.

Printing sample information

Sample information in the database can be printed if necessary. The **Data Monitor/Report** displays all test information about a sample ID, tests performed and results measured, for example.

► To print a Data Monitor/Report report

- 1 Choose **Workplace > Data Review**.
- 2 Select a single sample, a range of samples or nonconsecutive samples to be printed from the sample list on the left side of the screen.
- 3 Choose **Print** (global button).



Figure B-35 Workplace Print screen

- 4 Choose **Data Monitor/Report** in the report list.
- 5 Select the desired print format, **Monitor** or **Report**, from the **Print Format** area.
- 6 Select the appropriate result option, **1st**, **Rerun**, **Both** or **Chosen**, from the **Run Type** area.
- 7 Choose **All** in the **Print Data** area to print all results on the currently selected sample(s) or choose **Edited** to select printing of only edited results of the currently selected sample(s).
- 8 You can display the currently selected report on the screen without printing or you can print the report:
 - To display a preview of the currently selected report, choose **Preview** and then **View**.
 - To print the report, choose **Print**.

Sampling Stop

After all test requests are completed, sampling stops. After the last result is calculated, the analyzer remains in **Rack Reception** mode for a set span of time. Thereafter, finalization for the e 601 is performed and then the entire analyzer goes into standby.

The span of time between operation and standby is specified under **Utility > System (Page 3/4) > Rack Delivery**. If the **Rack Reception Mode** check box is cleared, the analyzer goes into standby immediately after the last result is calculated.

- ☞ For more information, see *Rack Reception Mode* on page B-219

Shutting down the analyzer

This section discusses the tasks to be performed at the end of analysis. It gives a detailed description of the analyzer shutdown including both the complete shutdown and the sleep mode.

Maintenance before shutdown

At the end of routine operation, it is important that all required maintenance is performed. In addition to the routine daily maintenance, this could also include other scheduled maintenance—for example, weekly and monthly maintenance.

- ☞ For information about maintenance items to be performed, refer to your laboratory maintenance schedule and see the following maintenance chapters:
Chapter 16 *General maintenance*
Chapter 18, *Maintenance schedule* on page C-65
Chapter 19 *Maintenance e 601*

Analyzer shutdown

After routine operation is finished and all required maintenance has been performed, the analyzer can be shut down. There are two options for the analyzer shutdown:

- Entering sleep mode
- The complete shutdown

Entering sleep mode provides the possibility of an automatic analyzer start-up on the next day. Thus, the analyzer can perform initialization in the absence of an operator, before the beginning of a working session. When the operator arrives, the analyzer is ready for operation.

- ☞ For more information on automatic start-up, see *Start-up* on page B-27.

Perform one of the following procedures to shut down the analyzer after all required maintenance has been performed.

► To enter sleep mode

- 1 Check that sufficient reagents and auxiliaries are on board for the next start-up.

Choose the wake-up time and select any **Power Up pipe** function required (**Utility > System** (Page 2/4) > **Power Up Pipe Setting**).

☞ See *Power Up Pipe function* on page C-18.

- 2 Choose **Shut Down** (global button) to display the **Shut Down** window.

- 3 Select the **Sleep** option and choose **Execute**. The **Sleep** window is displayed.

- 4 Select one of the following options:

- Select **Regulation** to let the system wake up at the preset time.
- Select **exception** and enter the date and time when the system should wake up

The instrument is put in sleep mode until the wake-up time. The wake-up time is displayed.

- 5 Perform the regular checks after shutdown.

☞ See *Checks after shutdown* on page B-64.



For **cobas** 6000 systems, the complete shutdown procedure should be performed at least once a week.

► To shut down the analyzer

- 1 Choose **Shut Down** (global button) to display the **Shut Down** window.

- 2 Select the **Shut Down** option, choose **Execute** and confirm the shutdown.

- 3 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.

Damage to the control unit or data loss due to improper switch-off

If power to the analyzer is switched off prior to the complete shutdown of the computer, the instrument may not start up properly when power is supplied again.

Before switch-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

- 4 Switch off the operation power switch on the left side face of the rack sampler unit.

- 5 Turn off the water supply.



After shutting down the analyzer, check individual parts of the instrument according to the given maintenance recommendations.

☞ See *Checks after shutdown* on page B-64.



Checks after shutdown

The checks and maintenance actions after shutdown correspond to the analyzer conditions that are to be checked before start-up.

 See *Starting inspection* on page B-26.

Especially if the analyzer has been set for automatic start-up, it is important that the checks before start-up are done at the end of the previous working session; otherwise, problems may occur.

Laid out below is the list of analyzer conditions that are to be checked before start-up:

- Control unit*
 - There is no floppy disk in drive A.
 - There is sufficient paper in the printer.
- Core unit*
 - The water supply is switched on.
 - Container for high concentration waste is empty.
 - There are no racks on the rack loader, unloader, rack rotor, or conveyor line.
- Analytic modules*
 - All surfaces are clean and clear of loose articles.
 - No tubing is pinched or bent.
 - Syringes are not leaking.
 - Auxiliary reagents (cleaning solutions) required for start-up pipes are loaded.
- c 501 module - ISE unit*
 - All electrode cables and tubings are correctly connected. Tubing is not leaking.
- c 501 module - photometric unit*
 - All reagent cassettes are removed from the cassette disposal.
 - Top cover is closed and locked.
- e 601 module*
 - The magazine door and drawer are closed.

Orders and results

This chapter provides descriptions of special tasks that are not usually part of the daily workflow. It is meant to complement the chapter Daily operation, where everyday tasks and common procedures for running the cobas 6000 analyzer are described.

In this chapter

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Overview

The following sections describe tasks and data that can be accessed by the screens under the **Workplace** menu. The **Workplace** menu comprises three screens: The **Workplace > Test Selection** screen, the **Workplace > Data Review** screen and the **Workplace > Calib. Review** screen.

Workplace > Test Selection screen

Use this screen to enter test selections and demographics for a sample. The available fields for sample identification vary, depending whether STAT or routine test selections are being entered and whether the analyzer is operating in barcode mode or not.

- ☞ For information on special operation procedures, see:
Requesting a test manually on page B-71
Entering unreadable sample barcodes on page B-73
Assigning or deleting a rerun rack manually on page B-74

Workplace > Data Review screen

Use this screen to perform tasks related to reviewing and editing routine and STAT results. Control results can also be viewed here. Other tasks that can be performed from this screen include editing demographic information, sending data to the Host, deleting data individually or in batches, backing up data and editing data.

- ☞ For information on special operation procedures, see:
Archiving patient data on page B-77
Editing or deleting sample data on page B-78
Displaying archived patient data on page B-80
Tracking samples on the analyzer on page B-83

Workplace > Calib. Review screen

Use this screen to review the status of the calibrators that are currently processing and the status of the calibrations.

- ☞ For information on special operation procedures, see:
Deleting a calibrator or a calibration test on page B-82
- ☞ For a complete description of all fields and commands under the **Workplace** menu, refer to the Online Help.

Test Selection screen

Test Selection screen

To display this screen, choose **Workplace > Test Selection**.

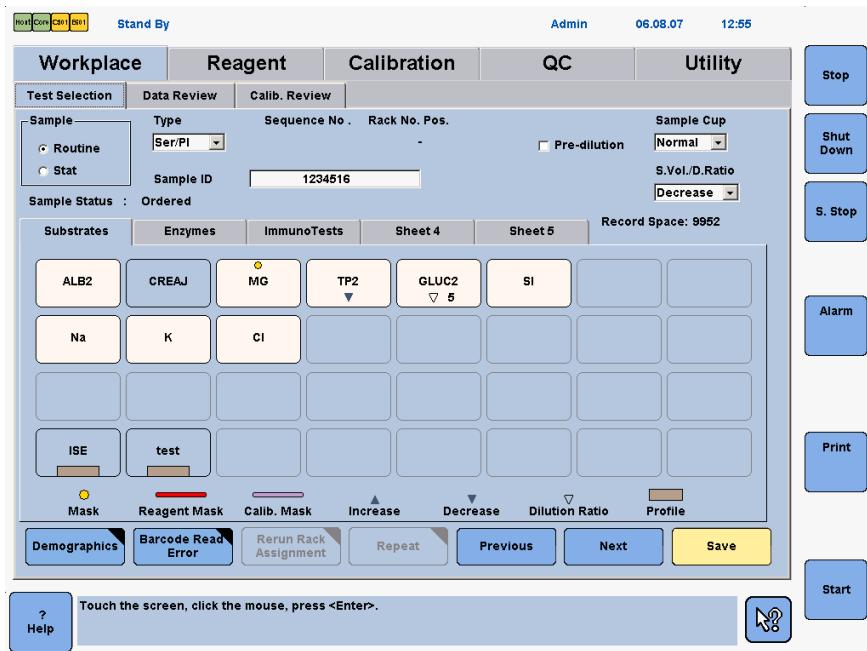


Figure B-36 Test Selection screen

Use this screen to enter test selections and demographics for a sample. The available fields for sample identification vary, depending whether STAT or routine test selections are being entered and whether the analyzer is operating in barcode mode or not.

Fields	Barcode mode		Non-barcode mode	
	Routine	Stat	Routine	Stat
Sequence No.	–	–	✓	–
Rack No. / Pos.	–	–	–	✓
Sample ID	✓	✓	✓	–

Table B-5 Test Selection screen – available fields for sample identification

If test selections are downloaded from a Host, this screen is commonly not used.

- ☞ For more information about the different sample information fields and the buttons on this screen, refer to the *Online Help* of the particular field or button.
- ☞ For information about the test selection matrix, see *Test selection matrix* on page B-69
- ☞ For information on special operation procedures, see:
 - Requesting a test manually* on page B-71
 - Entering unreadable sample barcodes* on page B-73
 - Assigning or deleting a rerun rack manually* on page B-74

Test selection matrix

A maximum of 160 test keys can be programmed on the system. The test matrix has 32 keys in each group and up to 5 groups of test keys can be programmed on **Utility > System (Page 1/4) > Key Setting**. One group at a time is displayed on the Test Selection screen. Use the tabs above the test matrix to switch between the groups. Group names are defined on **Utility > System (Page 1/4) > Key Setting**.

 For more information about Key Setting, refer to the *Online Help*.

Substrates	Enzymes	ImmunoTests	Sheet 4	Sheet 5	Record Space: 9952
ALB2	CREA1J	MG	TP2	GLUC2 ▼ 5	SI
Na	K	Cl			
ISE	test				
 Mask	 Reagent Mask	 Calib. Mask	 Increase	 Decrease	 Dilution Ratio
					

Figure B-37 Test matrix

Colors

The test keys display different colors to indicate the status of the test for the sample ID in the **Sample ID** text box. The following colors are available:

- | | |
|---|--|
|  | This test has been selected. |
|  | This test has been performed, a result is available, and can be reordered again. |
|  | A rerun has been performed for this test and the result is available. |

Markings

One test or profile can be assigned to each key. The test keys display special markings depending on the test's status or programming. The different markings and their meanings are outlined below:



Blank test key indicates no test is assigned.



Test key with a test or profile name and no masking indicators can be requested, further settings are not required. The reagent is on board and registered.



Test mask

- Test manually masked on the Masking window (**Start** (global button) > **Masking, P- or T-mask**)
- Module is deactivated

The test can be requested. However, the test is performed only after the test is manually unmasked.



Reagent mask (no reagent available)

Test is automatically masked by the system. The volume of a reagent (**cobas c pack** or **cobas e pack**), or detergent cassette, that is required for the respective test is either insufficient or the reagent is not present on the analyzer. The test can be requested; however, the test is performed only if a new reagent is placed on the analyzer.

If a diluent cassette or other wash solutions are empty or missing (Multiclean, SMS, or ProbeWash), the corresponding reagent is not masked.



Calibration mask (calibration failed)

Test is automatically masked by the system due to a failed calibration and the test requires a cassette / **cobas e pack** or lot calibration, or a new application was added to the system without performing a calibration.

The purple bar will not be displayed on the test key if:

- Calibration auto masking setting for the individual test is not selected on **Utility > Application > Calib**.
- Calibration auto masking setting for the analyzer is not selected on **Utility > System (Page 2/4) > Calib Mask Setting**.



Increased sample volume (**c 501** module only)

- Test will run with an increased sample volume set on the **Utility > Application > Analyze** screen.



Decreased sample volume

- Test will run with the decreased sample volume set on the **Utility > Application > Analyze** screen.



Dilution

- Test will run with a dilution. The number after the triangle indicates the ratio of the dilution (for example, 2 is 1:2).



Profile

- A brown bar on the key indicates the key has been assigned a profile. When selected, all tests assigned to that profile are highlighted.



If the reagent for a test is not on board, the corresponding test key is marked with test mask, reagent mask, and the calib mask.

Requesting a test manually

Tests can be manually selected for STAT and routine samples when the analyzer is in either barcode or non-barcode mode.



Incorrect results due to sample mismatch

When operating in non-barcode mode, make sure to load the samples according to the Requisition list as provided by the analyzer. Avoid empty positions within the racks. Do not place nonregistered samples in any empty rack position.

Do not insert any gray rack into the STAT port when operating in non-barcode mode because the predefined sequence of samples will be disrupted by the routine rack inserted through the STAT-port.



- Application-specific dilutions are performed automatically by the system.
- Not all dilution ratios are available.
- If you choose a dilution ratio in the **S. Vol./D.Ratio** field, this selection will overwrite the pre-programmed dilution ratio indicated in the **Utility > Application > Analyze** screen.
If for example the test has a pre-programmed dilution ratio of 1:5 and you select a dilution ratio of 1:2 for **S. Vol./D.Ratio**, the test is processed with a dilution of 1:2.
- For **c 501**, if the sample volume of a test is higher than 20 µL, a manual dilution request is not accepted and a pop-up window is displayed.
- The **e 601** cannot pipette increased sample volume.
- For **e 601** assays there is a recommended dilution described in the instructions for use. Only these dilutions should be used.



All manual selections such as sample type and dilution ratio remain as selected, within and between samples, until they are manually reset.



Micro cups are not to be used on the **e 601**.

► To request a STAT sample

- 1 Select the **Stat** option from the **Sample** area on the top left of the **Test Selection** screen.
 - In non-barcode mode the cursor moves to the **Rack ID** text box. Go to step 2.
 - In barcode mode the cursor moves to the **Sample ID** text box. Go to step 4.
- 2 Type in the rack ID of the sample in the **Rack ID** text box and press **<Enter>**. The cursor moves to the **Pos. No.** text box.
- 3 Type in the position number of the sample in the Position Number text box and press **<Enter>**. The cursor moves to the **Sample ID** text box.
- 4 Type in the sample ID of the sample in the **Sample ID** text box and press **<Enter>**. The cursor moves to the **Pre-dilution** check box.
- 5 Select the **Pre-dilution** check box if the sample has already been diluted and press **<Enter>**. The cursor moves to the **Sample Cup** box.
- 6 Select the sample container type and press **<Enter>**.
The cursor moves to the **Sample Volume / Dilution** box.
- 7 Select the necessary dilution, if any, for the sample and press **<Enter>**. The cursor moves to the test key matrix.

Test Selection screen

- 8 Select the test, combination of tests, or test profiles for the sample. Selected tests and profile keys appear white.
- 9 Choose **Save** to save the test selection.
■

► **To request a routine sample**

- 1 Choose **Workplace > Test Selection**.
- 2 Select the **Routine** option from the **Sample** area on the top left of the **Test Selection** screen.
 - In non-barcode mode the cursor moves to the **Sequence No.** text box. Go to step 3.
 - In barcode mode the cursor moves to the **Sample ID** text box. Go to step 4.
- 3 Type in the sequence number for the sample in the **Sequence No.** text box and press <Enter>. The cursor moves to the **Sample ID** box.
- 4 Type in the sample ID of the sample in the **Sample ID** box and press <Enter>. The cursor moves to the **Pre-dilution** check box.
- 5 Select this check box if the sample has already been diluted and press <Enter>. The cursor moves to the **Sample Cup** box.
- 6 Select the sample container type and press <Enter>. The cursor moves to the **Sample Volume / Dilution** box.
- 7 Select the necessary dilution, if any, for the sample and press <Enter>. The cursor moves to the test key matrix.
- 8 Select the test, combination of tests or test profiles for the sample. Selected tests and profile keys appear white.
- 9 Choose **Save** to save the test selection.
■

Entering unreadable sample barcodes



The **Barcode Read Error** screen is only available in barcode mode.

► To enter an unreadable sample barcode

- 1 Choose Workplace > Test Selection.
- 2 Choose Barcode Read Error.

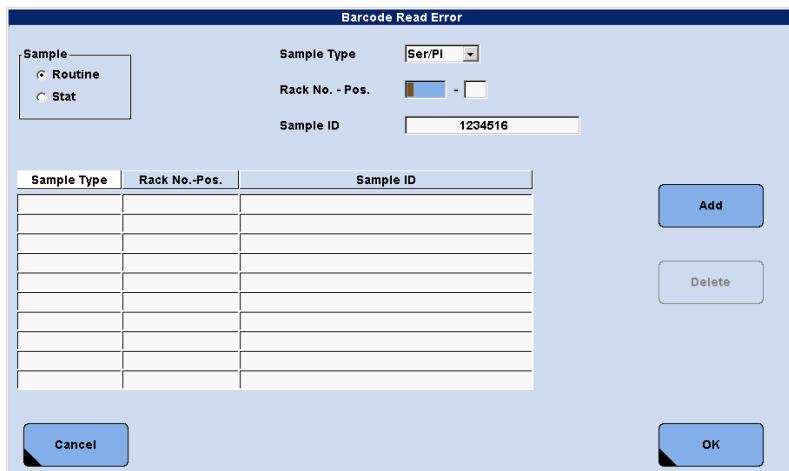


Figure B-38 Barcode Read Error window

- 3 Select the sample type (**Stat** or **Routine**) in the **Sample** area and press <Enter>.
- 4 Select the sample material from the **Sample Type** list box and press <Enter>.
- 5 Type the rack no. and position in the **Rack No. - Pos.** text boxes and press <Enter>.
- 6 Type the sample ID of the sample in the **Sample ID** text box and press <Enter>.
- 7 Choose **Add**. The sample type, rack number and position, and sample ID are displayed.
- 8 Repeat steps 3 to 7 for any further samples with a barcode read error.
- 9 Choose **OK**.



The non-read position assignments are deleted once the rack(s) to which samples are assigned are scanned by the rack ID reader. Therefore, once the rack is read it can be re-used for different samples. If it is necessary to run these samples again, the position assignment must be re-entered.

Assigning or deleting a rerun rack manually

Samples requested for a rerun are only manually assigned to a rack when the analyzer is in non-barcode mode. Use the pink rerun racks for reruns in non-barcode mode.

► To assign a rerun rack

- 1 Choose **Workplace > Test Selection**.
- 2 Type the sample ID of the sample in the **Sample ID** text box or type the sequence number of the sample in the **Sequence No.** text box.



If any changes have to be made to the test selection and/or sample dilution, they can be done at this time.

- 3 Choose **Rerun Rack Assignment** to display the **Rerun Rack Assignment** window.



Figure B-39 Rerun Rack Assignment window

- 4 Check that the details displayed on the **Rerun Rack Assignment** window are correct.
- 5 Type the rack No. and position of the pink rerun rack in the **Rack No.-Pos.** text boxes.
- 6 Choose **OK**.



► To delete a rerun rack



To reassign a rerun, the old assignment must be first deleted, and then the new rack ID and position entered.

- 1 Select the sample that you need to reassign from **Workplace > Test Selection**.
- 2 Choose **Rerun Rack Assignment**.
- 3 Choose **Delete** to delete the rack assignment after confirmation.
- 4 Choose **Cancel** to close the **Rerun Rack Assignment** window.



Data Review screen

To display this screen, choose **Workplace > Data Review**.

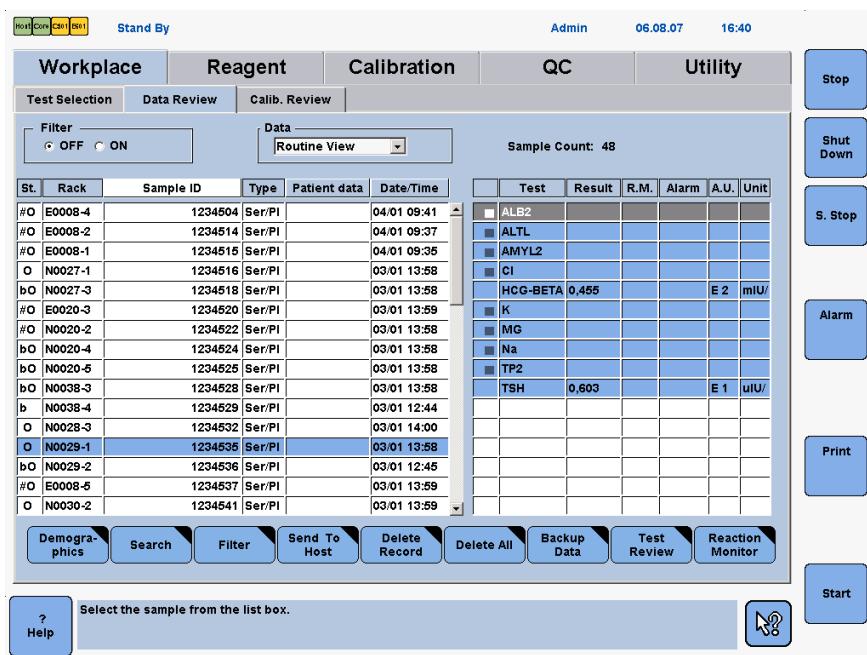


Figure B-40 Data Review screen (barcode mode)

Use this screen to perform tasks related to reviewing and editing routine and STAT results. Control results can also be viewed here.

Other tasks that can be performed from this screen include editing demographic information, sending data to the Host, editing, searching, filtering, and deleting data individually or in batches, and backing up data.

- ⦿ For more information about the different sample information fields and the buttons on this screen, refer to the *Online Help* of the particular field or button.
- ⦿ For information on special operation procedures, see:
 - Archiving patient data* on page B-77
 - Editing or deleting sample data* on page B-78
 - Displaying archived patient data* on page B-80
 - Tracking samples on the analyzer* on page B-83

Sample selection list The list on the left side of the screen displays the patient and control samples registered by the system. Its content varies depending on whether barcode mode, or non-barcode mode is selected on **Utility > System**.

The St. column displays the sample status codes:

O (Ordered)	Sample registered by user or Host.
P (Processing)	Sample ID or rack ID has been read by barcode reader.
I (Incomplete)	Samples processed, but a data alarm is present.
No symbol (Complete)	Sample successfully processed. All test results are available without a data alarm.
H (Sent to Host)	Sample results have been sent to the Host.
#	Sample has been processed on c 501.
b	Sample has been processed on c 501. A special wash for the sample probe of the c 501 has been performed before the sample was pipetted.

- ☞ For more information about special washes, see: *Programming a special wash for e 601* on page B-240



The status of Ordered is not applied to control samples.

Test results list The list on the right side of the screen displays the results of the tests performed on the sample currently selected in the sample selection list.

A symbol for the volumes to be used is displayed to the left of the test name.

	(Dark blue): indicates a test to be run with normal sample volume.
	(Dark blue): indicates a test is marked to be run with an increased sample volume. This applies to photometric assays (c 501 module) only.
	(Dark blue): indicates a test is marked to be run with a decreased volume. This applies to photometric assays and ISE tests (c 501 module) only. For ISE tests only urine samples can be run with decreased volume.
	(White): indicates a test is marked to be run with a dilution.
#	A hash (#) indicates a test with potential carry over. The sample has been processed on a c 501 in the first run. After this additional tests are requested and the sample is run again with test requests that need a special wash for the sample probe, or with high priority e 601 tests. The hash (#) appears as a warning for a potential carry over together with the <i>Samp.O</i> alarm.



- Additional tests with the same sample ID are displayed as open requests (ordered) and a blue square in the first column to the left of the **Test** column is displayed.
- As soon as a result is available, it is displayed in this Test Result list
- If a test has already run twice and a third request is made, the result of the second run is replaced by the result of the third run. An additional run (3rd., 4th., and so on) is only possible, if the previous result has been uploaded to the Host.
- If Host communication is not available, it is not possible to use 3rd Results Acceptance.
- Please note the number of runs (1st., Rerun) is tests-oriented, not sample-oriented.

- ☞ For more information about 3rd Results Acceptance, see *Generating multiple results for a single test* on page B-215

Archiving patient data

Patient data can only be archived when the system is in standby.

► To archive patient data

- 1 Choose **Workplace > Data Review**.
- 2 Select the samples for which data is to be backed up from the list on the left of the **Data Review** screen.
- 3 Choose **Backup Data** to display the **Backup Data** window.

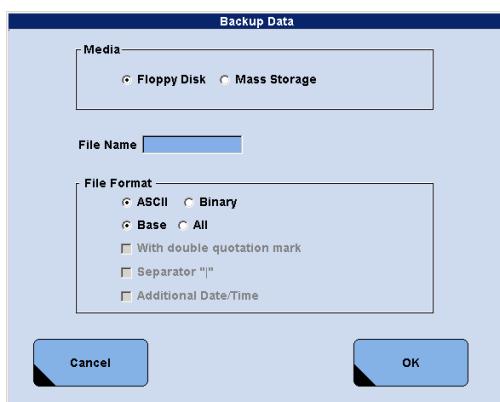


Figure B-41 Backup Data window

- 4 Select the medium to which the data will be written, for example **Floppy Disk**, from the **Media** area.
 - 💡 If only one medium is available, for example, floppy disk, the **Media** area is not active.
 - Mass Storage denotes the DVD disk.
- 5 Insert the chosen medium into the corresponding disk drive.
- 6 Type the name to be given to the file in the **File Name** text box.
- 7 Select the format in which the data is to be written, **ASCII** or **Binary**, and select **Base** or **All** option in the **File Format** area.
 - 💡 ASCII files can be read by other PC systems, but cannot be reloaded in to the **cobas** 6000 system.
 - Binary files can be reloaded in to the **cobas** 6000 system but cannot be read by other PC systems.
 - When the **Base** option is selected, no data from **e 601** tests are saved.
- 8 Choose **OK** to back up the selected data after confirmation. The **Save Data** window is displayed. This closes after the data has been backed up.
 - 💡 If a confirmation window with the message *Mass storage media is full or Floppy disk is full* is displayed during backup, no data is stored on the media.
 - Insert an empty medium and repeat the backup process

- For more information about the different backup options, refer to the *Online Help of Backup Data window*.
 - For more information on using DVD disks, see *Preparing a DVD disk* on page B-87

Editing or deleting sample data

Sample data displayed on the **Data Review** screen can be edited or deleted if required. Use the following procedures to edit or delete sample data.

► **To select a result to be edited or deleted**

- 1 Choose **Workplace** > **Data Review**.
 - 2 Select **Routine View** from the **Data** list box.



QC View is also available as an option in the list box in the **Data** area, but this view displays only QC data.

- ☛ For information on using a **Backup Disk**, see *Displaying archived patient data* on page B-80.
 - 3 Select a sample from the list on the left of the screen. The results, 1st and Rerun, of the tests performed on this sample are displayed in the list on the right of the screen.
 - 4 Choose **Test Review** to display the **Test Review** window. This window displays more information on the test results.

Figure B-42 Test Review window

- 5** Select the test result in the **Data** column. The result is activated (blue background) and highlighted white.



The **St.** column displays the status code of the test result.

O (Ordered)	Test requested by user or Host.
P (Processing)	Test ID or rack ID has been read by core.
I (Incomplete)	Test processed, but a data alarm is present.
No symbol (Complete)	Test successfully processed.
H (Sent to Host)	Test results have been sent to the Host.
M (Masked Test)	Test has been masked due to an abnormality during processing. Displayed only on Workplace > Data Review > Test Review .
E (Edited Test)	Test results have been manually edited on Workplace > Data Review > Test Review .



The status of Ordered, Masked and Edited Test is not applied to control samples.

► To edit sample data

- 1 Select the test result to be edited.
- 2 Enter the new result (the old result is overwritten) and press <Enter>. The **Updated** button turns yellow.
- 3 Choose **Update** to save the changes or **Cancel** to reset the entry to the original value.



Edited test results are flagged with an *Edited* data flag.

► To delete sample data

- 1 Select the test result to be deleted.
- 2 Choose **Delete Test** to delete the test after confirmation.



► To delete a sample from the Data Review screen

- 1 Choose **Workplace > Data Review**.
- 2 Select an individual sample, or a number of samples, to delete from the list on the left of the screen.
- 3 Choose **Delete Record** to delete the sample(s) selected after confirmation.



The **Sample Count** is unchanged after a record has been deleted. To delete all records, use **Delete All**. This will reset the sample count to 0.

Displaying archived patient data

Only data saved in binary format can be reloaded onto the analyzer.

 Archiving patient data on page B-77

Reloaded data can only be viewed on the **Data Review** screen.

► To display archived patient data

- 1 Select **Backup Disk** from the **Data** list box on the **Workplace > Data Review** screen to display the **Read Back Up Disk** window.

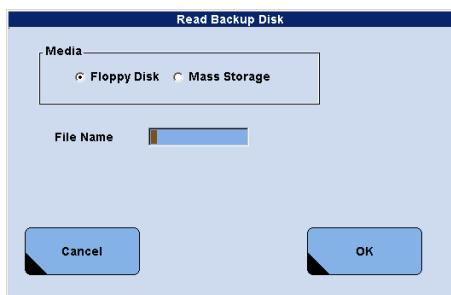


Figure B-43 Read Backup disk window

- 2 Select the medium from which the data will be read, for example **Floppy Disk**, from the **Media** area.



If only one medium is available, for example, floppy disk, the **Media** area is not active.

- 3 Insert the chosen medium into the corresponding disk drive.
- 4 Type the file name in which the data is saved in the **File Name** text box.
- 5 Choose **OK**. The saved data is displayed on **Workplace > Data Review**.



Calib. Review screen

To display this screen, choose **Workplace > Calib. Review**.

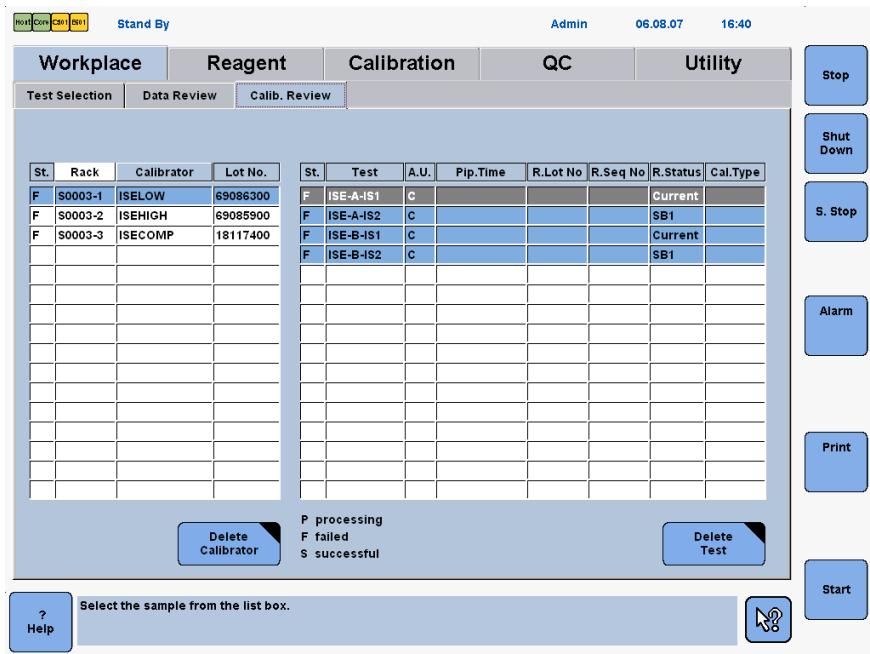


Figure B-44 Calib. Review screen

Use this screen to review the status of the calibrators that are currently processing and the status of the calibrations.

- For more information about the different sample information fields and the buttons on this screen, refer to the *Online Help* of the particular field or button.
 - For information on special operation procedures, see:
Deleting a calibrator or a calibration test on page B-82

Calibrator selection list The list on the left side of the screen displays the calibrators registered by the analyzer.

The **St.** column displays the calibrator status codes:

P (Processing)	The calibrator is registered by the analyzer (barcode is already read).
F (Failed)	At least one of the calibrations performed with this calibrator could not generate a valid calibration.
S (Successful)	Calibrator successfully processed. All calibrations performed with this calibrator have generated valid results.

Calib. Review screen

- Test results list* The list on the right side of the screen displays detailed information for the tests performed with the calibrator currently selected in the calibrator selection list.
The **St.** column displays the calibration status codes:

P (Processing)	The calibrator for the test is registered by the analyzer (barcode is already read) and at least one calibration is requested for this calibrator. If the calibrator has already been pipetted by the analyzer, a pipetting date and time is available.
F (Failed)	No valid calibration has been generated for the test.
S (Successful)	A valid calibration has been generated for the test.

- For more information about the calibration status, see *Calibration Status screen* on page B-136

Deleting a calibrator or a calibration test

Calibrator data displayed on the **Calib. Review** screen can be deleted if required. Use the following procedures to delete the status of a calibrator or a test.

► To delete a calibrator

- 1 Choose **Workplace > Calib. Review**.
- 2 Select a calibrator, to delete from the list on the left of the screen.
The calibrator is highlighted in blue.
- 3 Choose **Delete Calibrator** to delete the calibrator after confirmation.



► To delete a test

- 1 Choose **Workplace > Calib. Review**.
- 2 Select a test, to delete from the list on the right of the screen.
The calibration test is highlighted in blue.
- 3 Choose **Delete Test** to delete the calibration test after confirmation.



Tracking samples on the analyzer

The **Sample Tracking** window allows the operator to search for any sample on the analyzer from the moment of registration (the sample has passed the barcode reader) to the moment when the sample reaches the rack unloader (Tray 1).

 See *To track a sample on the analyzer* on page B-83

The **Sample Tracking** window also allows the operator to search for samples and subsequently unload them.

 See *To unload specific racks* on page B-85



- Only STAT and routine samples can be searched for in the **Sample Tracking** window.
- The location of a sample is indicated by the **Sample Tracking** window only when the sample tray has not been removed from the unloader and no new run has been started yet.

► To track a sample on the analyzer

- Choose Sample Tracking on the System Overview screen.

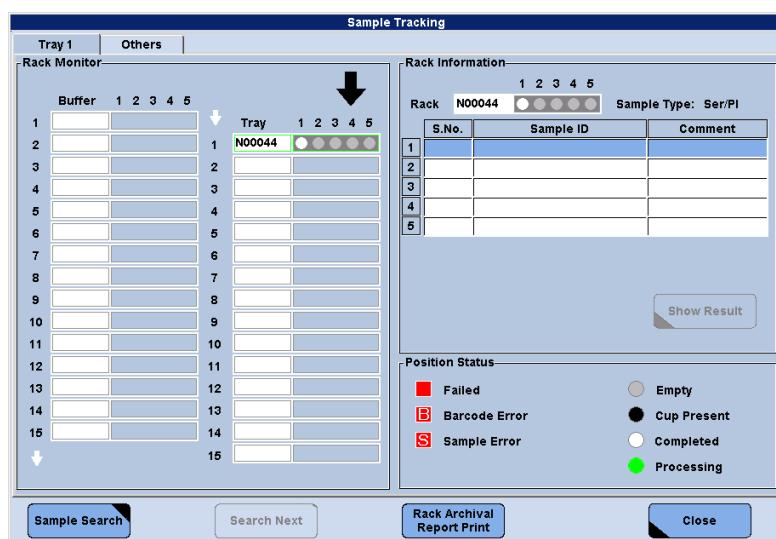


Figure B-45 Sample Tracking window

2 Choose Sample Search to display the Sample Search window.

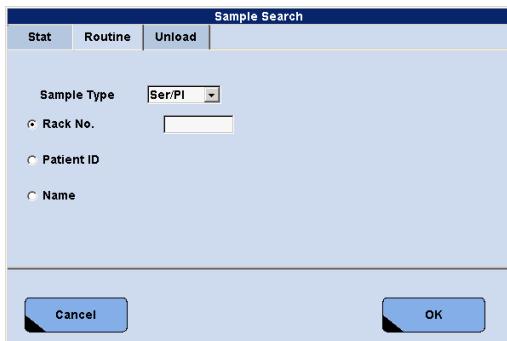


Figure B-46 Sample Search window - barcode mode

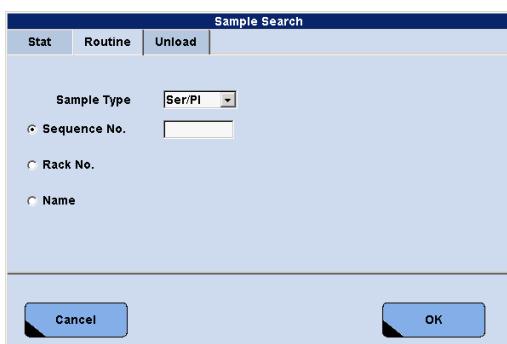


Figure B-47 Sample Search window - non-barcode mode

- If searching for a STAT sample choose the **STAT** tab.
 - If searching for a routine sample choose **Routine**.
 - ☞ For using the **Unload** tab, see *To unload specific racks* on page B-85
- 3** Choose the sample type.
- 4** Select the required search criterion.
- 5** Enter the data you are searching for in the corresponding text field.
- 6** Choose **OK**.
 - If the sample is in the Unloader the sample is highlighted in the **Rack Information** area and the rack is highlighted in the **Rack Monitor** area.
 - If the sample is not in the Unloader a short message is displayed under the **Others** tab indicating the location of the sample.



The **Others** tab shows samples that are being processed, but are not yet unloaded. Thus, it can only show information when the analyzer is in Operation mode.

- ☞ For more information, see:
Sample tracking on page B-59
 or refer to the Online Help of the particular window.

► **To unload specific racks**

- 1 Choose Sample Tracking on the System Overview screen.

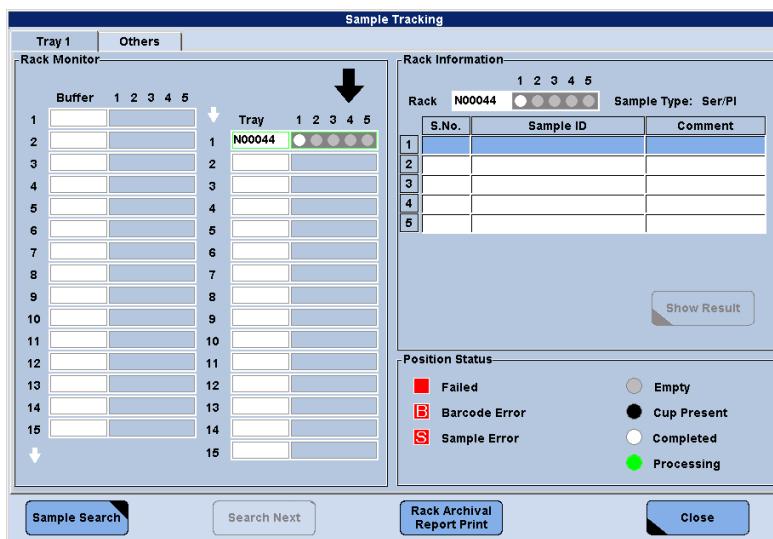


Figure B-48 Sample Tracking window

- 2 Choose Sample Search > Unload.

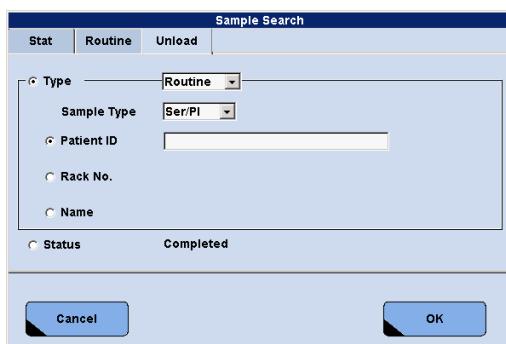


Figure B-49 Sample Search window - barcode mode

The **Unload** tab can be used to search for specific routine or STAT samples to be unloaded.

- 3 Select the required option, **Type** or **Status**.
 - Select **Type** to search for samples according to the criteria in the **Type** area (for example, **Sample Type**, **Patient ID**, **Rack No.**).
 - Select **Status** to search for samples with a specific sample status. Possible statuses are: **Completed**, **Failed**, **Barcode Error**, **Sample Error**
- 4 Select the required search criteria.
- 5 Enter the data you are searching for in the corresponding text field.

Tracking samples on the analyzer

6 Choose OK.

A list of racks that meet the search criteria is displayed in the **Rack Monitor** area of the **Sample Tracking > Others** window.

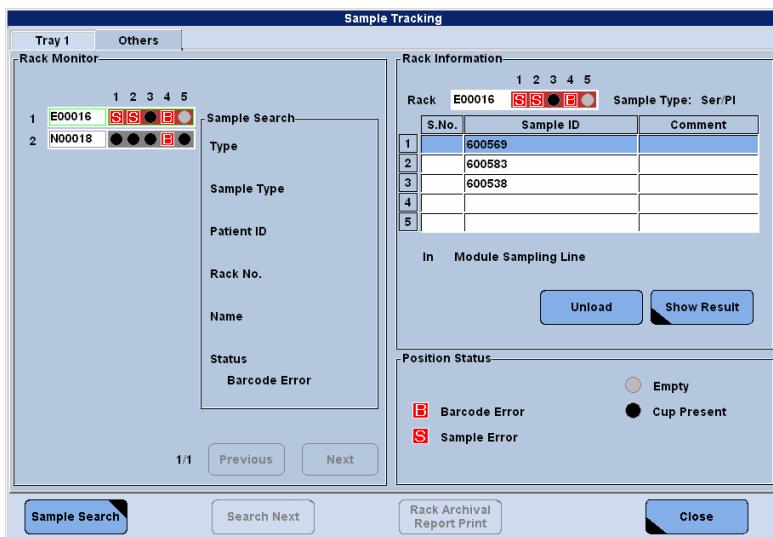


Figure B-50 Sample Tracking window - search results

7 Select the rack to be unloaded.

8 Choose **Unload in the **Rack Information** area and confirm the unloading process.**

The rack is transferred to the rack unloader.



Incorrect results due to sample mismatch

If unloaded racks are reloaded in non-barcode mode, sample mismatch may occur.

Do not reload an unloaded rack, when working in non-barcode mode. In non-barcode mode, pink racks have to be used to reload samples.



- If the rack is in the pipetting position, on the module rack buffer (e 601) or already scheduled to one of the modules pipetting of all samples on the rack will be finished, before the rack is transferred to the rack unloader.
- Only routine and STAT racks can be unloaded, no calibrator and QC racks.
- A STAT rack can only be unloaded after it was processed once at any module.
- If a rack is unloaded after pipetting, the result for the samples will be processed.



- For more information, see:
Sample tracking on page B-59
 or refer to the Online Help of the particular window.

Preparing a DVD disk

cobas 6000 control unit computers are optionally equipped with a DVD disk drive. The DVD disk drive can be used for installing software updates and backing up and restoring data.

 See *Archiving patient data* on page B-77

The following DVD formats can be used:

- DVD-R
- DVD+R
- DVD-RW
- DVD+RW

DVD disks require formatting before use.

 See *Formatting a DVD disk* on page B-87

If you want to use the DVD disk on another computer than the **cobas** 6000 control unit computer, the DVD disk must be made compatible to be able to read the data.

 See *Making a DVD disk compatible* on page B-88



- The DVD disk is formatted with UDF (Universal Disk Format). The DVD disk can not be read on computers that do not support UDF.
- The procedure for formatting a DVD disk may differ, depending on the configuration of your system.
- Only format DVD disks on the **cobas** 6000 control unit computer. The **cobas** 6000 control unit computer may not be able to read DVD disks formatted on any other computer.

Formatting a DVD disk

DVD-R and DVD+R disks can be formatted once only. DVD-RW and DVD+RW disks can be formatted several times.



Danger of data loss

Formatting a DVD-RW or DVD+RW disk deletes all data on the disk.

- Before formatting a DVD disk, make sure that no important data is stored on the disk.

► To format a DVD disk

- 1 Make sure the analyzer is in standby.
- 2 Insert a new DVD disk into the DVD drive.
- 3 Press <Ctrl>+<F7> to display the Format window.
- 4 Choose **Quick (erase)** or **Full** from the Format type area.

Depending on the type of DVD disk only **Full** is available.

- 5 Choose **Start** and confirm the formatting process with **OK**.

The DVD disk is formatted. This may take several minutes.

- 6 After formatting is finished confirm with **OK**.

The DVD disk is ready for a data backup now.



Making a DVD disk compatible

If you want to use the DVD disk on another computer than the **cobas** 6000 control unit computer, the DVD disk must be made compatible (*finalized* or *closed*).

Finalizing a DVD-R or DVD+R disk After making the DVD disk compatible, no more data can be stored on the DVD-R or DVD+R disk. The disk is *finalized*.

Closing a DVD-RW disk A DVD-RW can store additional data after being made compatible. The disk is not finalized, it is only *closed*. After storing additional data on the DVD-RW disk, the disk needs to be closed again.

A DVD+RW disk can be used on other computers without being made compatible.

► To make a DVD disk compatible

- 1 Make sure the analyzer is in standby.

- 2 Insert the DVD disk into the DVD drive.

- 3 Press <Ctrl>+<F8> to display the Compatibility window.

- 4 Choose **Start** and confirm the process with **OK**.

The DVD disk is made compatible. This may take several minutes.

- 5 After making compatible is finished confirm with **OK**.

The DVD disk is ready to be used on other computers.



Reagents

This chapter describes all types of reagents used on the cobas® 6000 analyzer series. It provides information about the system's reagent management as well as detailed information on how the operator can monitor the status of loaded reagents (operator-related reagent management).

In this chapter

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Reagent concept – c 501

This section provides information about reagents used on the c 501 module, how they are used for ISE applications and photometric applications. It describes the reagent containers used on this module and explains how the system registers new reagents and how it monitors reagent consumption.

Reagents for ISE applications

This section describes all reagents necessary to run the c 501 module's ISE unit and the reagents that are specific for each available ISE application. Available ISE applications are the following:

ISE applications	ISE applications
Potassium serum/plasma	Potassium urine
Sodium serum/plasma	Sodium urine
Chloride serum/plasma	Chloride urine

Table B-6 List of ISE applications

Reference information for ISE reagents

The following table compiles reference information for all ISE reagents, such as auxiliary reagents, calibrators, and controls.

Product name	Short name ^(a)	Containers on the analyzer	Localization or code
ISE Internal Standard Gen.2	ISE IS	2 bottles of 600 mL	ISE reagent compartment
ISE Diluent Gen.2	ISE Dil.	2 bottles of 300 mL	
ISE Reference Electrolyte	ISE Ref.	1 bottle of 300 mL	
ISE Standard low ^(b)	ISE Low	Sample tube or cup	502
ISE Standard high ^(b)	ISE High	on calibrator rack	503
ISE Compensator ^(b) (global use)	ISE Comp.		504
<i>ISE Standard high^(b) (compensated) (use in US only)</i>	<i>ISE High (compensated) (use in US only)</i>		763
Precinorm U or Precinorm U plus	PNU	Sample tube or cup	300
Precipath U or Precipath U plus	PPU	on QC rack	301
ISE Cleaning Solution	SysClean	Sample tube or cup	Position 2
Activator	Activator	on green wash rack	Position 3

Table B-7 c 501 (ISE) auxiliary reagents

(a) used in this documentation

(b) The calibration interval is 24 hours for all ISE applications.

Reagents for measurements Each ISE measurement uses the following reagents:

- Internal standard (ISE IS), used for one-point calibrations performed before and after each sample determination
- Reference solution (ISE Ref.), used for reference electrode measurements
- Diluent (ISE Dil.)

ISE auxiliary reagents (ISE IS, ISE Ref., ISE Dil.) are supplied in reagent bottles and do not use a barcode for registration. Two bottles can be set for each of ISE IS and ISE Dil.. Replacement of ISE IS and ISE Dil. reagent bottles can be performed regardless of instrument status. ISE Ref., however, is to be replaced only when the analyzer is in standby. After replacement of ISE Ref., a Reagent Prime is required.

 For more information on routine operations, see Chapter 9 *Daily operation*.

Calibrators ISE calibrators are used without barcodes. The following calibrators are used for two-point calibrations and full calibrations:

- ISE Low [Std(1)]: water-based solution, used for two-point calibrations and for full calibrations
- ISE High [Std(2)]: water-based solution, used for two-point calibrations and for full calibrations
- ISE Comp. [Std(3)] (global use): serum-based solution, used for blank calibrations, full calibrations
- *ISE High (compensated) [Std(3)]: use in US only, used for full calibrations*

The calibration interval for all ISE applications is 24 hours.

Quality controls The following products are used for quality controls:

- PNU
- PPU

Quality controls can be used either with or without barcodes. If necessary change the corresponding settings (**Barcode Setting** area on **Utility > System**).



- Do not use barcoded control vials on the same rack as assigned for non-barcoded control vials.
- If working with non-barcoded controls, correct position of the controls must be checked, otherwise incorrect measurement result may occur.

 For more information on ISE reagents, see:
ISE reagent registration on page B-97.

Reagents for photometric applications

This section describes all reagents necessary to run the c 501 module's photometric unit. It provides an overview of diluents, auxiliary reagents (such as basic and acid detergents), as well as calibrators and controls.

Diluents

Cassette short name	Cassette long name	Comment	Application code
NaCl	NaCl 9%	Diluent for photometric tests	951

Table B-8 Diluents for photometric tests

For photometric applications, either water or an NaCl solution is used as diluent. The water is deionized water from the analyzer's water tank. NaCl solution is supplied in cobas c packs *NaCl 9%*. The following general rules apply:

- Water is used for all blank calibrations.
- NaCl solution is used for all sample dilutions. Whenever used as diluent, the 9% solution from the cassette is diluted with water to a concentration of 0.9% by the analyzer.



Make sure you have sufficient amounts of NaCl diluent on the c 501—especially if a higher demand of diluent can be expected.

To monitor the remaining amount of NaCl diluent, set a reagent warning level.

Auxiliary reagents

The c 501 module uses the following auxiliary reagents:

Product name	Short name^(a)	Description	Containers on the analyzer	Localization
Cell Wash Solution I/NaOH-D	Cell wash I	NaOH-D, used for rinsing and cleaning reaction cells	1 large bottle	Behind the left front door
Cell wash Solution II/Acid Wash	Cell wash II	Acid wash, test specific, used for rinsing and cleaning reaction cells	1 large bottle	
Multiclean	Multiclean	Sample probe wash solution 1, NaOH	1 bottle of 70 mL	Reaction disk area
SMS/Acid Wash	SMS	Sample probe wash solution 2, acid wash,	1 bottle of 70 mL	
Hitergent	Hitergent	Surfactant for incubator bath to prevent algae proliferation and foaming	1 bottle of 70 mL	
NaOHD	NaOH-D	Detergent 1 for reagent probe wash and cell wash (Maintenance item (7) Wash Reaction Parts)	1 cassette ACN 947	Cassette on Reagent rotor
SMS	SMS	Detergent 2 for reagent probe wash and cell wash	1 cassette ACN 948	
SCCS	SCCS	Special Cell Cleaning Solution. Additive, used for reaction cell carry over evasion in long HbA1c batches.	1 cassette ACN 949	

Table B-9 **c 501 auxiliary reagents**

(a) used in this documentation

- ☞ To locate these auxiliary reagents on the analyzer, see:
Behind the front doors on page A-75
Figure B-132 on page B-239

Remaining volume control

The remaining volumes of the auxiliary reagents are monitored by countdown, starting from a given initial volume. The remaining volumes are displayed on the **Reagent > Status** screen. Whenever a reagent bottle is replaced, the operator has to reset the initial volume. Reagent registration is *not* performed automatically when a new bottle is placed.

- ☞ For more information on monitoring the reagent status, see:
Reagent Status screen on page B-108
To reset initial volumes of auxiliary reagents (c 501) on page B-109

For NaOH-D, SMS and SCCS cassettes, the volumes are tracked using the cassette barcode.

- ☞ For more information, see *Remaining volume control (c 501)* on page B-98

Calibrators and controls

For photometric applications, there are universal calibrators and special calibrators available. The same universal calibrator is used for a large number of applications whereas a special calibrator covers only a few or only one application.

Universal calibrators for c 501 applications are Cf as (without diluent), Cf as Proteins, or Cf as Proteins Urine/CSF.

- ☞ For information about calibrators and quality control reagents for specific applications, refer to the corresponding instructions for use.

Likewise, there are universal and special controls.

Universal quality controls are PNU and PPU.

- ☞ For information about quality controls for specific applications, refer to the corresponding instructions for use.

Usually, calibrators and controls have to be reconstituted and pipetted into cups or tubes. For measurement place calibrators onto black calibrator racks and controls on white QC racks.

cobas c packs and other reagent cassettes

Apart from various reagent bottles for auxiliary reagents, the principal reagent containers for the c 501 modules are reagent packs. The following sections describe these reagent containers as well as their labels and barcodes.

For third party reagents, there is the **cobas c pack MULTI**, which is an empty cassette kit (empty but assembled and barcoded cassettes). These kits are used for development channels.

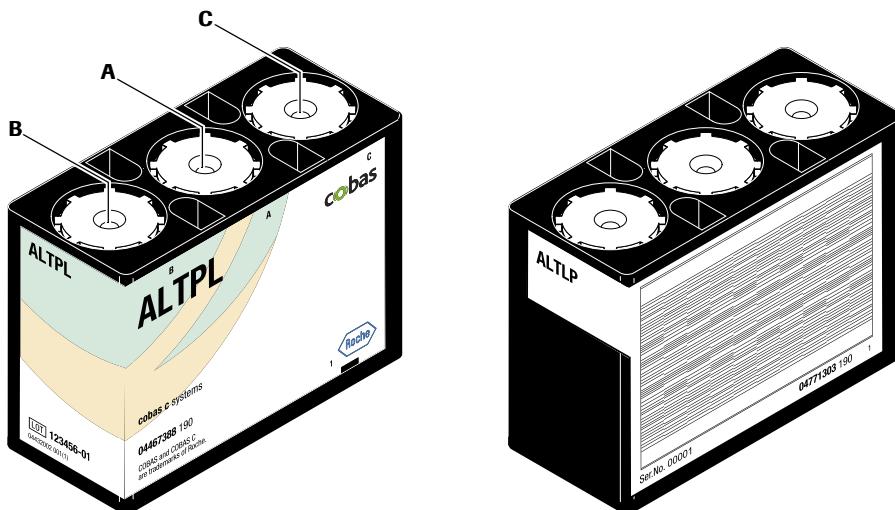


Figure B-51 **cobas c pack with position designations**

The **cobas c** packs contain up to three reagent vials. The center position is position **A**. With the barcode facing to the rear, the left position is position **B** and the right position is position **C**. Pipettings at different timings (R1, R2, or R3) are not restricted to any position.

System-related reagent management (c 501)

This section describes how the analyzer registers reagents and how it keeps track of the remaining volumes of reagents in the course of their consumption. The unloading and reloading of reagent cassettes is explained and finally there is a section about carryover evasion.

ISE reagent registration

ISE IS, ISE Ref., and ISE Dil. are stored in reagent bottles in the ISE reagent compartment. At analyzer startup, the remaining volume is checked for the current bottle of ISE IS, ISE Ref., and ISE Dil. There is a bottle sensor at each of the reagent positions of the ISE reagent compartment. By means of a light beam, the sensor detects the presence of a reagent bottle. In addition to this, the ISE pipetter probe is equipped with a level detector (capacitance method), which monitors the liquid level in the reagent bottles.

When you replace a reagent bottle, always use full bottles.

A green indicator lamp (next to the reagent position) lights up if no reagent bottle is present or if the liquid level falls below the limit where the bottle needs to be replaced. For ISE IS and ISE Dil., the analyzer performs an automatic bottle changeover when a reagent shortage is detected. Thus, the reagent replacement does not interrupt the continuous analytical process flow of the ISE unit.

When the number of available tests is “0” as a sum of the remaining volumes in two bottles, all ISE tests will be masked and thus no subsequent measurement is possible.

☞ For instructions on how to replace ISE reagents, see *c 501 – ISE unit* on page B-38.

cobas c pack registration

New cobas c packs are registered at the cassette preparation station after they have been loaded at the cassette loading port.

☞ For more information on the cassette preparation station and the cassette loading port, see *Cassette management system* on page A-62.

The cobas c pack registration comprises the following items:

- By reading the cassette barcode, the system checks the availability of the corresponding test application.
- The piercer pierces the reagent bottle caps.

Note, only new cassettes are registered in this way. If the system recognizes a cassette that has been on the analyzer before, it is transported directly to the reagent compartment.

Remaining volume control (c 501)

After a **cobas c** pack has been registered, the system counts every pipetting out of this cassette. Thus, the cassette's initial number of available test is counted down. When the number of available tests (total number of tests available for an application on one module) is lower than a defined limit, an alarm is issued (yellow or purple alarm, according to configuration under **Utility > System > Reagent Level Check**). When the number of available tests becomes zero, an alarm is issued (red alarm) and the test is masked—unless another **cobas c** pack is available on a second module.

- ☞ For more information on monitoring the reagent status, see:
Reagent Status screen on page B-108

Unloading and reloading cobas c packs

The system counts down each cassette's initial number of available tests with every pipetting out of that cassette. The number of available tests is stored by the system for up to 3000 cassettes. If you unload a **cobas c** pack and reload it later, the system recognizes the cassette and continues the test count at the point where the cassette was unloaded. It is assumed that the cassette's reagent volumes remain unchanged while the cassette is not on the analyzer.



Incorrect results and interruption of analysis due to false reagent volumes

Reload a reagent cassette only if you are sure the reagent volumes remained unchanged while the cassette was not on the analyzer.

Never load a used reagent cassette onto another analyzer.

- ☞ For further instructions, see *To unload a reagent cassette* on page B-105

Carryover evasion

Even though all pipetter probes and reaction cells are washed and rinsed thoroughly after each use, it could be possible that traces of sample or reagent remain on contacted parts (probes or reaction cells) and are carried over at the next pipetting.

By means of the special wash function, the system prevents traces of sample or reagent from being carried over and bias the results.

- ☞ For more information on programming special washes for c 501, see:
Reagent probe wash on page B-235
Cell wash on page B-237
Sample probe wash on page B-238

Reagent concept – e 601

This section provides information about all reagents used on the e 601 including auxiliary reagents, calibrators, and controls. It also describes the reagent containers used on this module.

Reagents for e 601 applications

This section describes all reagents necessary to run the e 601 and the reagents that are specific for each available e 601 application. The available applications are divided into different groups:

- Thyroid
- Cardiac markers
- Hormones
- Tumor markers
- Bone markers
- Anemia
- Infectious diseases
- Miscellaneous

Diluents

For most applications where dilution may be necessary, use Universal Diluent or MultiAssay as diluent. However, some applications require specific diluents.

- ☞ For information on required diluents and recommended dilution factors, refer to the respective assay reagent instructions for use.

Auxiliary reagents

The e 601 uses the following auxiliary reagents:

Product name	Short name ^(a)	Description	Containers on the analyzer	Localization
ProCell M	ProCell	<ul style="list-style-type: none"> • Conditioning of the electrodes • Transport of the assay reaction mixture • Washing of the streptavidin-coated microbeads • Signal generation 	2 bottles of 2 L	Behind the front doors
CleanCell M	CleanCell	<ul style="list-style-type: none"> • Cleaning of tubing system and measuring cell after every measurement • Conditioning of the electrodes 	2 bottles of 2 L	
PreClean M	PreClean	<ul style="list-style-type: none"> • To remove potentially interfering substances before signal generation—the final step of the analytical procedure. • Required only for certain assays. Its use is indicated under <i>Materials required (but not provided)</i> in the respective assay reagent instructions for use. 	2 bottles of 600 mL	
ProbeWash M	ProbeWash	<ul style="list-style-type: none"> • Cleaning the reagent probe during analysis and at the end of the day. 	2 bottles of 70 mL	Near the reagent probe
SysClean	SysClean	<ul style="list-style-type: none"> • Sodium hypochlorite solution used for cleaning of the measuring cells (every two weeks). 		Not on the analyzer

Table B-10 e 601 auxiliary reagents

(a) used in this documentation

Calibrators and controls

There are specific calibrators for each e 601 application. As for quality controls, there are both, controls covering multiple applications and controls that are specific for only a single application.

- ☞ For information on required calibrators and controls, refer to the respective assay reagent instructions for use.

To get information about what calibrator and controls are currently needed for calibration or QC, print a **Calibration and QC Load List** from the software.

- ☞ For information on how to print a **Calibration and QC Load List**, see *Calibration and QC Select button* on page B-42.

cobas e packs

The principal reagent container for cobas e 601 modules is the **cobas e pack**.

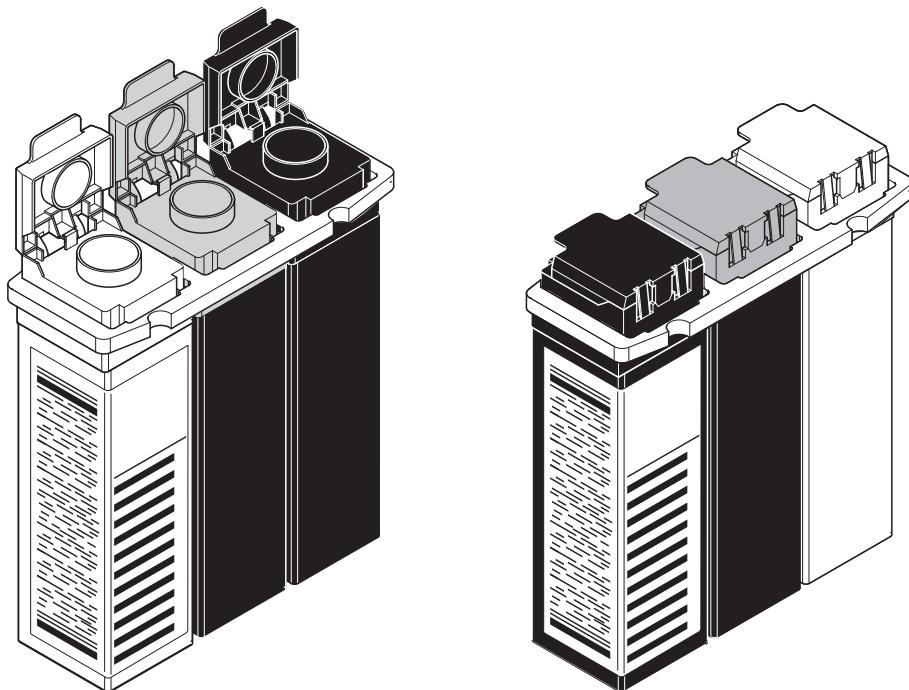


Figure B-52 **cobas e pack for cobas e systems**

A **cobas e pack** consist of three separate, capped reagent containers. e 601 modules are capable of opening and closing these caps automatically. For each e 601 application, there is an individual **cobas e pack** available.

Each **cobas e pack** is equipped with a barcode label. The barcode label contains reagent, control, and calibration information.



Priority of cobas e packs and diluents within an e 601 module

If there are multiple **cobas e** packs for one application on an **e 601** module, a **cobas e** pack becomes the active reagent pack in the following order:

1. Current **cobas e** pack
2. **cobas e** pack with the same lot number as the last current **cobas e** pack
3. **cobas e** pack lot which expires first
4. Within the same lot: The **cobas e** pack with the oldest registration date
5. Within the same lot: The **cobas e** pack with the least remaining volume
6. Within the same lot: The **cobas e** pack on the lowest position on the reagent disk

Carryover evasion

Heterogeneous immunoassays are very sensitive tests. Some combinations of these assays are especially sensitive against carryover. To prevent such carryover, program a special wash cycle on **Utility > Special Wash > Immune**.

☞ For more information, see *Programming a special wash for e 601* on page B-240.

Operator-related reagent management

The following sections describe tasks and data that can be accessed by the screens under the **Reagent** menu. The **Reagent** menu comprises two screens: The **Reagent > Setting** screen and the **Reagent > Status** screen. In addition, the **Reagent Overview** button on the **System Overview** screen as well as windows accessed via this button are explained.

Reagent > Setting screen

The **Reagent > Setting** screen provides detailed information about each test reagent and position for each installed module. The compiled data include reagent codes, lot numbers, expiration dates (shelf life) as well as on board stability of reagents (in days). Tasks that can be performed from this screen are:

- Priming reagents (ISE and e 601)
- Unloading cobas c packs (c 501 only)
- Manually registering cobas e packs (e 601 only)
- Open channel (c 501 only)
- Loading a cobas c pack MULTI for a Development Channel application (**Open Channel - c 501 only**)

Reagent > Status screen

The **Reagent > Status** screen provides all important data about test reagents to monitor the reagent status on the analyzer. The data are sorted according to the names of the applications and displayed either for all modules or for one specified module. Moreover, there is an additional list, which provides information about auxiliary reagents. Tasks that can be performed from this screen are:

- Resetting the remaining volume control for auxiliary reagents (c 501 only)
- Entering ProCell lot numbers (e 601 only)
- For a complete description of all fields and commands under the **Reagent** menu, refer to the Online Help.
- For more information, see:
 - Reagent Setting screen on page B-103
 - Reagent Status screen on page B-108

System Overview screen > Reagent Overview button

By changing its color, the **Reagent Overview** button indicates potentially insufficient amounts of reagent on the module currently selected in the **Module Overview** area. Choose this button to view details about the status of loaded reagents.

- See *Reagent Overview button* on page B-115.

Reagent Setting screen

To display this screen, choose **Reagent > Setting**.

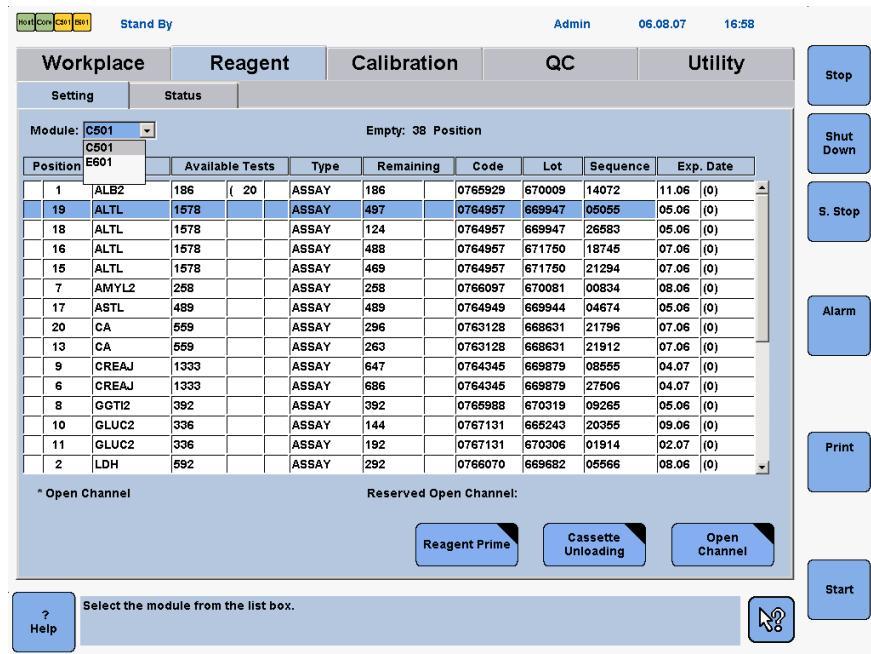


Figure B-53 Reagent Setting screen

This screen comprises a **Module** box (on the top left), a large test list, and several buttons. The buttons available as well as the view of the test list change according to the module selected from the **Module** box.

- ☞ For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

*Manual Registration
(e 601 only)*

Use this button to manually register a **cobas e** pack; that is, to manually enter a **cobas e** pack barcode number.

- ☞ For more information, see *Manual reagent registration* on page B-104.

Reagent Prime

Use this button to prime reagents either of the **e 601** (ProCell, CleanCell, PreClean) or of the ISE unit (ISE IS, ISE Ref.).

- ☞ For more information on the **e 601** auxiliary reagents, see: *Auxiliary reagents* on page B-100.
- ☞ For more information on replacing and priming ISE reagents, see: *Reagent Preparing button* on page B-37
To perform a Reagent Prime on page B-40.

Cassette Unloading (c 501 only)

Use this button to unload a reagent cassette either to the cassette loading port or to the cassette disposal.

- ☞ For more information, see *Loading and unloading of reagent cassettes (c 501)* on page B-105.

Manual reagent registration

A manual reagent registration for the c 501 is not available. The c 501 automatically registers all new reagent cassettes. The initial reagent volume is counted down with each pipetting.

The e 601 automatically registers all new **cobas e** packs. In case the automatic registration fails (if system is unable to read the barcode), you can manually register a **cobas e** pack from the **Manual Registration (e 601)** window.

► To manually register a **cobas e** pack

- 1 Select an e 601 from the **Module** box on the **Reagent > Setting** screen.
- 2 Choose **Manual Registration** to open the **Manual Registration (e 601)** window.
- 3 Type the barcode of the **cobas e** pack to be registered.
- 4 Choose **OK**.



Incorrect results

If due to a barcode read error a **cobas e** pack was manually assigned to a reagent rotor position, please thoroughly check reagent information after replacement of this **cobas e** pack and a new occurrence of a barcode read error.



It is only possible to manually register a **cobas e** pack if at least one **cobas e** pack of the same lot was scanned in before.

Loading and unloading of reagent cassettes (c 501)

Loading reagent cassettes

Load reagent cassettes at the loading port behind the arched drop side at the front of the c 501 module. When loading, make sure the cassette's barcode label is facing to the right. Reagent registration is performed automatically when a new reagent cassette is loaded.

 For more details, see *Replacing reagent cassettes* on page B-40.

Unloading reagent cassettes

The c 501 module automatically unloads empty reagent cassettes to the cassette disposal. If you need to manually unload a reagent cassette, you have the choice either to send it to the cassette loading port (option **Unload**) or to send it to the cassette disposal (option **Dump**). In case you intend to reload the reagent cassette, choose **Unload**.



If you use the option **Dump** for unloading a cassette, the cassette cannot be reloaded.

► To unload a reagent cassette

- 1 Put the module in standby.
- 2 Select a c 501module from the **Module** box on **Reagent > Setting**.
- 3 Select the position of the reagent cassette that is to be unloaded.
- 4 Choose **Cassette Unloading** to open the **Cassette Unloading** window.
- 5 Choose either **Unload** (to send the cassette to the cassette loading port) or **Dump**.
- 6 Choose **Execute**.



Reagent reloading (e 601)

Reagent reloading is a function that automatically starts a reagent reloading process on a particular module. It is separately selectable for each application on that module.



Incorrect results due to reagent barcode read error (e 601)

If due to a barcode read error a **cobas e** pack was manually assigned to a reagent rotor position, thoroughly check reagent information after replacement of this **cobas e** pack and a new occurrence of a barcode read error.

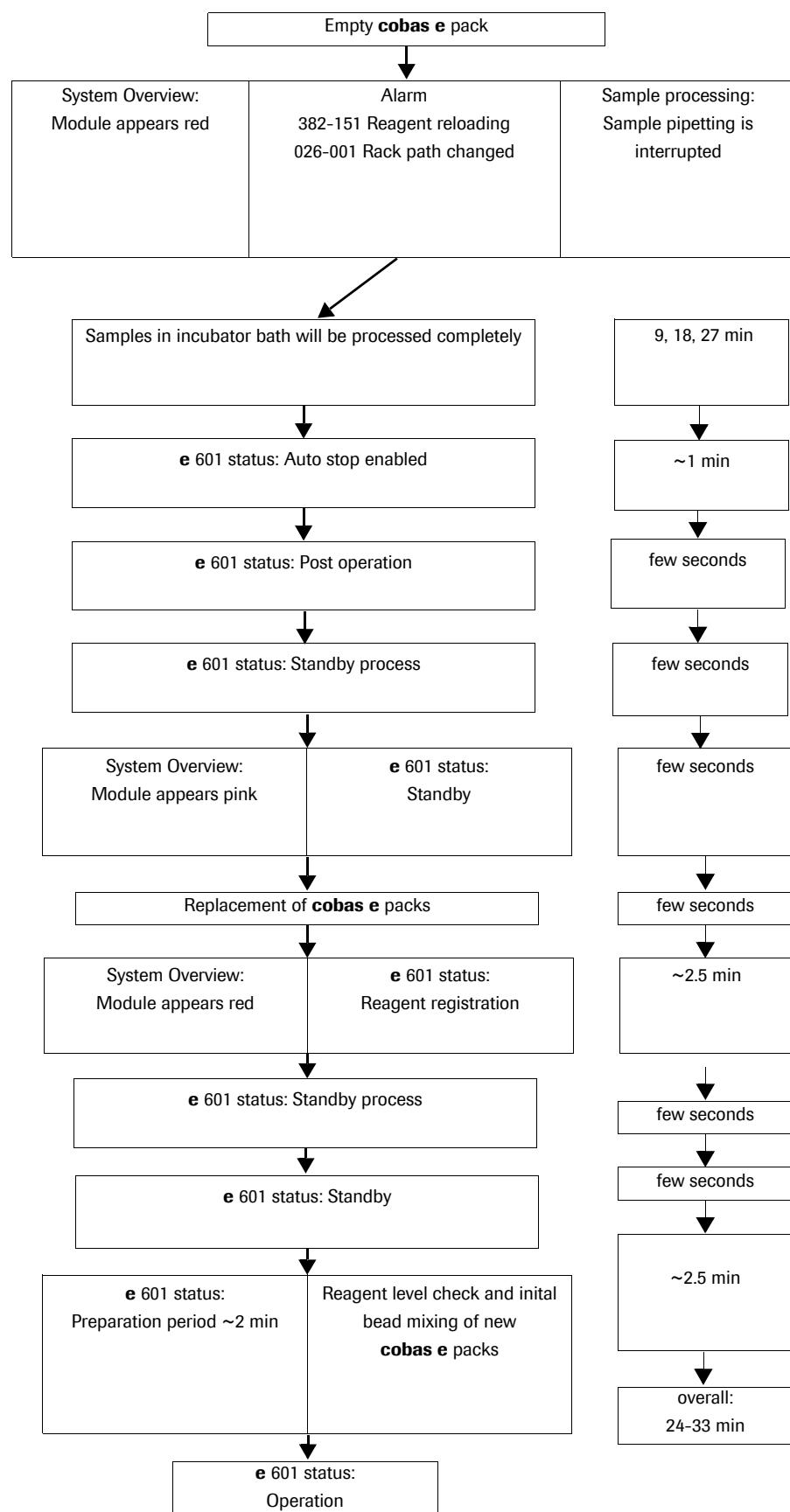
Reloading process

If selected, the reloading process starts when the number of remaining tests for the respective application and measuring channel becomes zero.

For more information, see: *To assign a test to an e 601 module* on page B-223.

The reloading process comprises the following items:

1. The following caution-level alarm (yellow) is issued: Reagent reloading. The alarm code is within the range of 381-xxx through 386-xxx, where the subcode xxx indicates the affected application: xxx corresponds to the number in the test list on **Utility > Application**.
2. The module automatically stops pipetting. The racks in the siding line are transported to their destination (other modules, rack rotor, or rack unloader). Other racks which have already passed the barcode reader are no longer transported into this particular module. All samples which are in process are measured.
3. After the results are available, the module turns to standby. Reagents can be reloaded.
Standby and reload possibility is indicated on the **System Overview** screen by the module being displayed in pink color.
4. After closing the reagent cover, reagent registration is automatically performed. For e modules, liquid level detection and initial bead mixing is performed as well for the newly inserted **cobas e** packs (Preparation).
5. Finally, the module returns to operation.

**Figure B-54** Reagent reloading process (e 601)

Reagent Status screen

To display this screen, choose **Reagent > Status**.

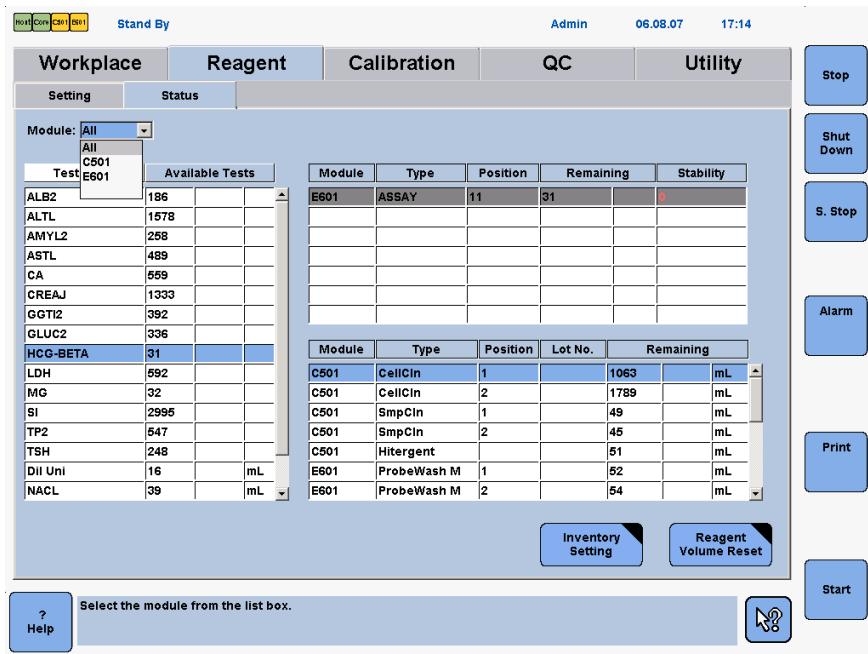


Figure B-55 Reagent Status screen

The **Reagent > Status** screen displays reagent data for all tests on the analyzer. The screen comprises a **Module** box (on the top left), a test list, a detailed reagent list (on the top right), and auxiliary reagent list (on the bottom right).

- For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Replacing auxiliary reagents (c 501)

When replacing auxiliary reagent bottles (such as cell detergent or sample probe detergent bottles), you have to manually reset the software's reagent volume count.



Personal injury due to contact with instrument mechanism

Contact with the syringes may result in personal injury.

- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-4, F-6.



Only reset the reagent volume count in the software after a new reagent bottle has been placed.

Follow the procedures below to replace auxiliary reagent bottles and reset their volume count:

► **To replace a cell detergent bottle**

- 1 Put the system in standby.
- 2 Open the front door of the module.
- 3 Replace required reagent bottle and clean the aspiration filter.
☞ See *Cleaning the detergent aspiration filters* on page C-94.



Incorrect results due to incorrect insertion of aspiration tube

If the aspiration tube is not inserted correctly, the detergent may not be dispensed properly. This may lead to incorrect results.

- Insert the aspiration tube so that the end of the tube touches the bottom of the bottle.
- Do not bend the aspiration tube.

- 4 Reset the volume count under **Reagent > Status > Reagent Volume Reset**.

☞ See *Resetting initial volumes of auxiliary reagents (c 501)*.



► **To replace a sample probe detergent bottle or Hitergent**

- 1 Put the analyzer in standby.
- 2 Unlock and open the top cover of the module.



Improper aspiration of detergent due to foam or air bubbles

If you shake the new detergent bottles before placing them on the analyzer, the detergent may foam or air bubbles.

- Do not shake the detergent bottles before placing them on the analyzer.

- 3 Replace required reagent bottle

- 4 Reset the volume count under **Reagent > Status > Reagent Volume Reset**.

☞ See *Resetting initial volumes of auxiliary reagents (c 501)*.



Resetting initial volumes of auxiliary reagents (c 501)

The remaining volumes of cell detergents and other auxiliary reagents are monitored by counting down from the initial volume of a full reagent bottle. When you place a new reagent bottle, you always have to manually reset this volume countdown.

► **To reset initial volumes of auxiliary reagents (c 501)**

- 1 Select a c 501 from the **Module** box on the **Reagent > Status** screen.
- 2 Select the reagent from the auxiliary reagents list (on the bottom right) whose volume needs to be reset.
- 3 Choose **Reagent Volume Reset**.
- 4 Choose **OK** to confirm the reset.



Replacing auxiliary reagents (e 601)

The e 601 module uses an illuminating indicator to show when it is safe for you to replace a reagent. The nature of the indicator may differ for the individual reagents, but the meaning of the states is consistent. Refer to the stickers explaining the meaning of the indicators on the e 601 module.

- ☞ For more information, see
 - Auxiliary reagents and cleaning solutions* on page A-94
 - Reagents for e 601 applications* on page B-99



Personal injury due to contact with instrument mechanism

Contact with the syringes may result in personal injury.

- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-9.



Malfunction of instrument and incorrect results

Only replace a bottle if the green button is flashing.

- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-18.



False results due to misplacement of ProCell/CleanCell or PreClean bottles

ProCell and CleanCell bottles are different in shape to fit the keyed position of the bottle stand. This is done to ensure the correct positions. Measurements cannot be performed if the bottle stand is not present. Ensure the bottle stand is present before placing the ProCell and CleanCell bottles.

- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-13.

If you do not properly load the PreClean bottles, or load them without checking, the volume available for pipetting may be less than expected by the system and therefore cause deterioration in measurement accuracy.

- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-12.

Replacing ProCell and CleanCell (e 601)

Two bottles of ProCell and two bottles of CleanCell are located behind the front door of the e 601 module. Whenever you place a new bottle of ProCell of a new lot, enter its lot number according to the following instruction:

- ☞ For more information, see *ProCell and CleanCell bottles* on page A-95.

► **To replace ProCell (PC)/CleanCell M (CC)**

- 1 Open the middle door of the e 601.

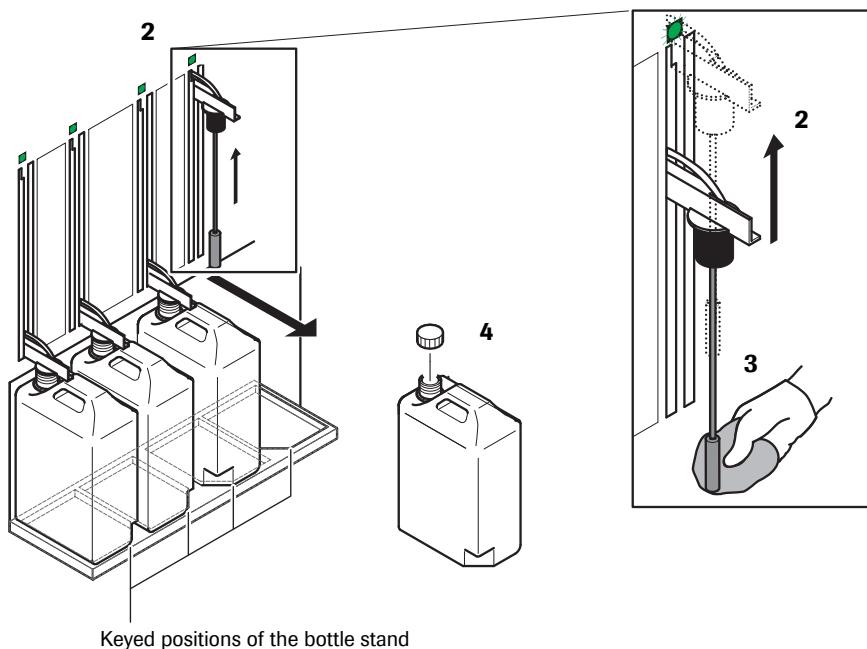
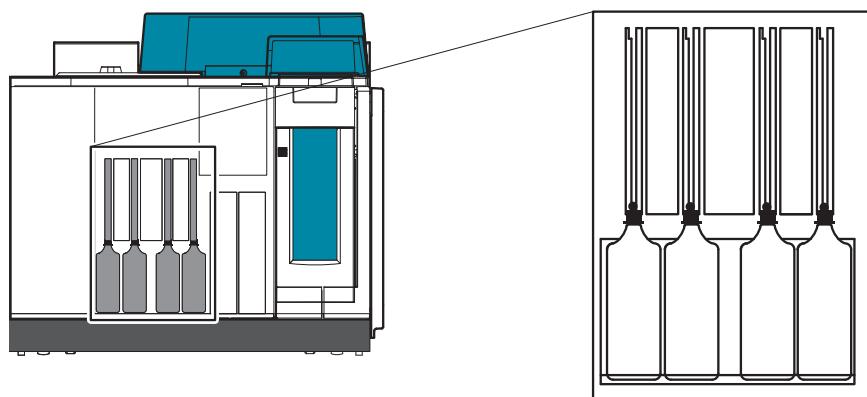


Figure B-56 Replacing ProCell/CleanCell bottles



Only replace a bottle if the green button is flashing.

- 2 Pull the aspiration tubes up and to the left to secure them on their respective notches.
- 3 Absorb the liquid with lint-free gauze squares.
- 4 Remove the empty bottle, indicated by the flashing green button, and replace it with a full bottle ensuring that it is firmly in place.

- 5 Lower the aspiration tube into the new bottle.

NOTICE

Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

- 6 Press the flashing green button corresponding to the position in which the new bottle has been placed to inform the system that a new bottle was loaded. The button will be illuminated indicating that this is a standby bottle.
- 7 Close the middle door of the e 601.
- 8 If a ProCell bottle with a new lot number was loaded, enter the lot number on the **Reagent > Status > Inventory Setting**.
 - Choose **Inventory Setting** to open the **Inventory Setting** window.
 - Type the new lot number into the box for ProCell Position 1 or 2, respectively.
 - Choose **Execute**.

*Replacing PreClean (e 601)*

2 bottles of PreClean are located in the inner side of the front door of the module.

☞ For more information, see *PreClean bottles* on page A-95.

**Personal injury due to contact with PreClean needles**

Contact with the PreClean needles may cause personal injury.

- Do not put your hands into the PreClean bottle holder.
- Do not replace a bottle if the green button is not flashing.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-17, F-18.

► To replace PreClean

- 1 Open the middle door at the front of the required module.
- 2 Remove the empty bottle, indicated by the flashing green button. Replace it with a full bottle ensuring that it is firmly in place and that the needle has pierced the bottle. Loosen the cap to allow air into the bottle.
- 3 Press the flashing green button corresponding to the position in which the new bottle has been placed to inform the system that a new bottle has been loaded. The button will be illuminated indicating that this is a standby bottle.

NOTICE

Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

- 4 Close the middle door of the e 601.



Replacing ProbeWash (e 601) 2 bottles of ProbeWash are located on the analytical module near the reagent probe.

See *ProbeWash station* on page A-87.

► To replace ProbeWash

The 2 ProbeWash bottles can simply be replaced when necessary, as the reagent probe is equipped with a liquid level detector (LLD) which senses the remaining volume.

- 1 Remove the empty ProbeWash bottle.
 - 2 Remove the cap from the new ProbeWash bottle.
 - 3 Place the new ProbeWash bottle in the module.
 - 4 The level is checked and the inventory is automatically updated.
-



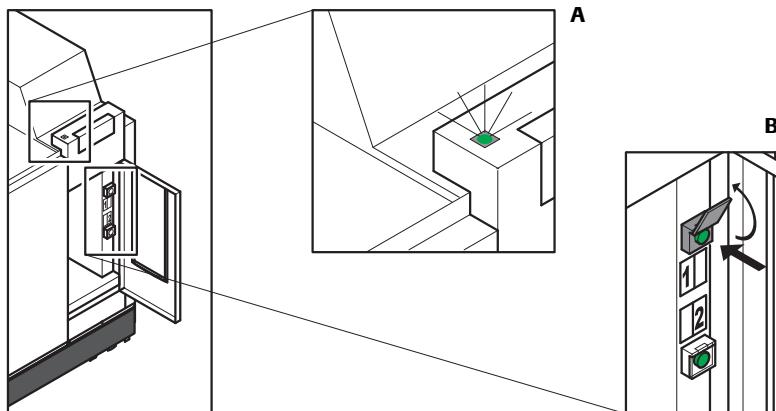
ProbeWash can only be replaced when the affected module is masked or the analyzer is in standby mode.

Replacing consumables and emptying solid waste (e 601)

All consumables (AssayCups and AssayTips) and solid waste are located in the magazine drawer, which consists of the magazine lifter, the magazine waste and the solid waste compartments.

- The lifter can be loaded with new AssayCup and AssayTip magazines.
 - The magazine waste compartment contains the empty magazines.
 - The solid waste compartment has solid waste containers.
- See *Consumables area components* on page A-92.

The green indicator lamp on the top of the magazine drawer indicates when the magazine drawer and door can be opened. In addition, two green buttons to the right of the magazine lifter indicate when the waste containers can be accessed.



A Indicator lamp of the magazine drawer

B Indicator lamps of the waste containers

Figure B-57

Indicator lamps of the magazine drawer and waste containers

Indicator lamp state	Indicator lamp (A) (magazine drawer)	Indicator lamp (B) (waste container)
Off		Waste container in use DO NOT replace
On	Drawer safe to open	standby container (empty) DO NOT replace
Flashing	About to operate DO NOT open	Container full, safe to be replaced Empty it immediately

Table B-11 Indicator lamp states of the magazine drawer and waste containers**Damage to the analyzer**

Excessive weight on the magazine drawer of the e 601 may lead to damage.

- Do not open the front door of the magazine drawer and do not pull out the magazine drawer when the indicator lamp is off or blinking.
- Pull out the magazine drawer gently and do not lean on the magazine drawer.

► **To replace AssayCup and AssayTip magazine**

- 1 Pull out the drawer on the right hand side of the module fully.
- 2 Empty the magazine waste and refill the magazine lifter as required.
- 3 Close the drawer, ensuring that it is fully closed.
- 4 The level is checked and the inventory is automatically updated the next time the analyzer changes the magazine.



Ensure that the door at the front of the drawer is closed. Otherwise, the magazine lifter will detect the open door the next time it operates and the analyzer will stop.



► **To empty solid waste**

- 1 Pull out the drawer on the right hand side of the module fully.
- 2 Remove the waste container liners and replace with fresh ones as required.
- 3 Close the drawer, ensuring that it is fully closed.
- 4 Open the door at the front of the drawer.

NOTICE

Only press the green button after you have emptied a container. Do not press the green button under any other circumstances.

- 5 Press the flashing green button (to the right of the AssayCup and AssayTip tray magazine) corresponding to the container(s) emptied to update the system.
- 6 Close the door ensuring that it is fully closed.



Ensure that the door at the front of the drawer is closed. Otherwise, the magazine lifter will detect the open door the next time it operates and the analyzer will stop.



Reagent Overview button

By changing its color, the **Reagent Overview** button indicates potentially insufficient amounts of reagent on the module currently selected in the **Module Overview** area. It also indicates when QC results are out of range and if there is no valid calibration available:

Button in Module Overview area	Color	Meaning
Reagent Overview	Red	A reagent is empty and there is no second cobas c pack or cobas e pack on this particular module.
	Yellow	The number of tests remaining for a reagent is less than the yellow alarm level.
	Purple	The number of tests remaining for a reagent is less than the purple alarm level.

Table B-12 Colors of Reagent Overview button in Module Overview area

Choose this button to display the **Reagent Overview** window. This window displays an overview of the consumables loaded on the module currently selected.

Reagent Overview c 501 module

Select a **c 501** module in the **Module Overview** area of the **System Overview** screen and choose **Reagent Overview** to display this screen. It consists of 3 areas, the **Reagent** area, **Inventory** area, and **ISE** area.

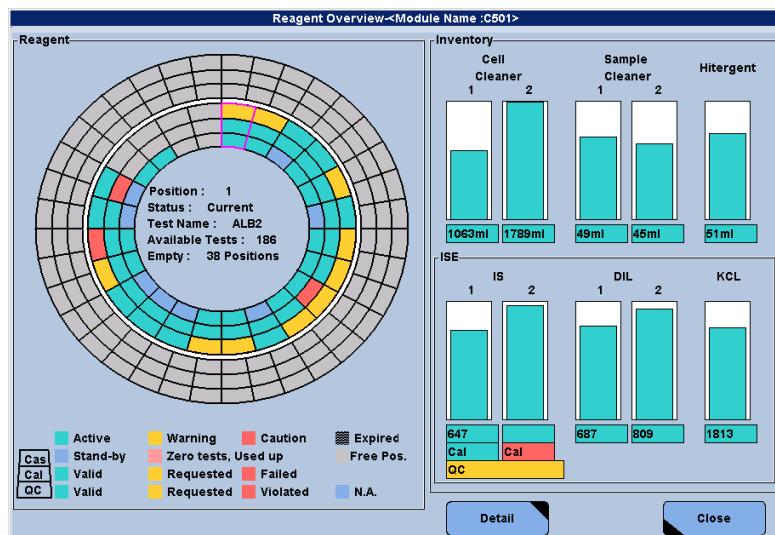


Figure B-58 Reagent Overview window (**c 501** module)



A reagent mandatory message is displayed on the **Reagent Overview** screen if a mandatory reagent is not on board.

This function is available only if the test of the missing reagent has been defined as mandatory under the **Utility > Module Set > Test Assignment**.

Reagent area

Use this area to view the status of the **cobas c** packs, loaded on the module. This area comprises a graphic representing the reagent disk and a legend.

The graphic is divided into 2 large rings. The 24 segments of the inner large ring and the 36 segments of the outer large ring represent the 60 **cobas c** packs positions within the reagent compartment.

Each of the large rings is subdivided into 3 subrings:



- Cas: Reagent status (inner subring)
- Cal: Calibration status (middle subring)
- QC: QC status (outer subring)

Choosing a segment displays detailed information about the **cobas c** pack (**Position**, **Status**, **Test Name** and **Available Tests**) in the center of the graphic.

Legend The legend at the bottom of the **Reagent** area explains the colors represented in the segments of the reagent disk graphic.

1. Inner subring: Cas (Cassette = **cobas c** pack)

	Active	This cassette is currently in use.
	Warning	Remaining tests in this cassette set below yellow alarm level (Utility > System (Page 2/4) > Reagent Level Check).
	Zero tests, Used up	The cassette has been used up and is empty. There is still reagent available in another cassette on this module.
	Caution	There is no more reagent available for this assay on this module.
	Stand-by	This cassette is currently not in use. Standby cassettes are already on board but not in use at present.
	Free Pos.	There is no cassette in this channel.
	Expired	The cassette has exceeded its expiration date.

2. Middle subring: Cal (Calibration)

	Valid	A valid calibration is available.
	Requested	A calibration has been requested.
	Failed	The calibration of the cassette has failed.

3. Outer subring: QC (Quality Control)

	Valid	QC result is within the confidence limits.
	Requested	A QC has been requested.
	Violated	QC result is not within the confidence limits.
	N.A.	Not applicable.

Reagent information In the middle of the reagent disk, information about the selected cobas c pack is displayed.

The following information is provided:

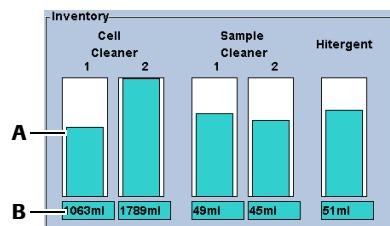
Position	Position of the cassette in the reagent disk.
Status	Indicates whether the cassette is active or standby.
Test Name	Name of the application using this reagent.
Available Tests	Total number of determinations that can be measured with the currently available cassettes (including the standby cassettes). If a cassette contains diluent or cleaner, the total volume is displayed in ml.
Empty	Number of empty positions on the reagent disk.



For diluent and cleaner cassettes, only the inner subring (Cas) contains information.

Inventory area

The **Inventory** area displays the amount of auxiliary reagents on the module previously selected on the **System Overview** screen.

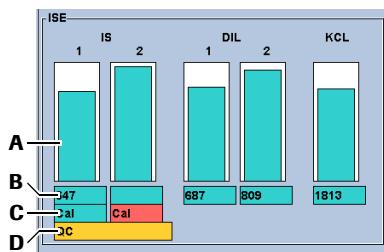


- A** Bar-chart for the remaining volume
B Color-coded bar

Figure B-59 Inventory area of Reagent Overview window

Abbreviation	Unit	Color	Description
Cell Cleaner 1/2	mL	Yellow	Cell wash I and Cell wash II
		Red	Volume ≤ 50 mL
Sample Cleaner 1/2	mL	Yellow	Multiclean and SMS
		Red	Volume < yellow alarm level
Hitergent	mL	Yellow	Hitergent
		Red	Volume < yellow alarm level
			Bottle empty

Table B-13 c 501 module reagent types

ISE area

- A** Bar-chart for the remaining number of tests
B Color-coded bar for the remaining volume of ISE reagents
C Color-coded bar for the calibration status
D Color-coded bar for the QC status

Figure B-60 ISE area of Reagent Overview window

The ISE area displays the amount of reagents using bar-charts (**A**). The first bar (**B**) below each bar-chart indicates the remaining number of tests for each ISE reagent. The second and the third bar below the bar-charts provide additional, color-coded information on the statuses of calibration (**C**) and QC (**D**).



If this field is empty after changing an ISE reagent bottle, the analyzer has not checked the remaining volume yet.

For information about remaining volume check, see *ISE reagent registration* on page B-97

Abbreviation	Unit	Description
IS	test	Internal standard solution
DIL	test	Diluent
KCL	test	Reference solution (ISE Ref.)

Table B-14 c 501 (ISE) reagent types

Two color-coded bars below the IS 1 and IS 2 bar-charts provide additional information on the statuses of calibration and QC.

1. First colored bar (directly below volume indication field): Calib

	Valid	A valid calibration is available.
	Requested	A calibration has been requested.
	Failed	The calibration of the bottle has failed.

2. Second colored bar: QC

	Valid	QC result is within the confidence limits.
	Requested	Requested for QC measurement.
	Violated	QC result is not within the confidence limits.
	N.A.	Not applicable.

Detail window

Choose the **Detail** button to display the **Detail** window. This window displays more detailed information about the selected cassette, namely: **Reagent Type**, **Test Name**, **Remaining Tests**, **Calibration Date**, **Calibration Type**, **Reagent Lot No.**, **Reagent Sequence Number**, **First Registration Date And Time** And **Reagent Expired**.



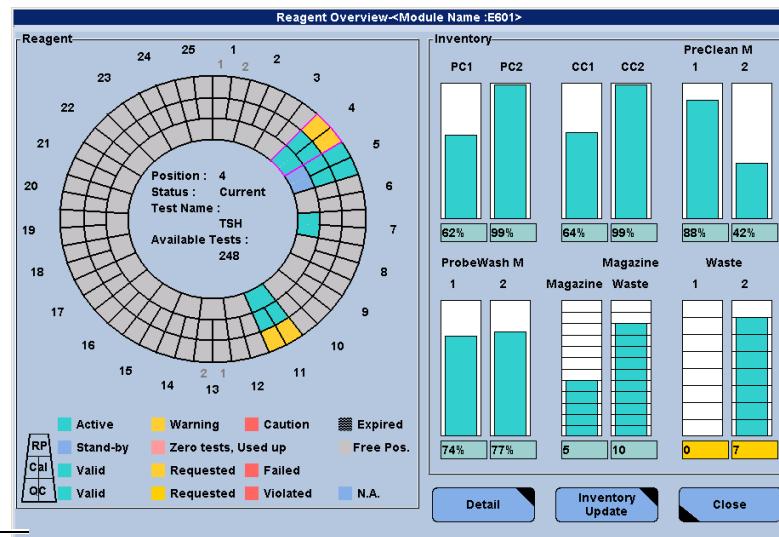
Figure B-61 Detail window

☞ For more information about the **Detail** window, refer to the *Online Help* of this window.

Reagent Overview button

Reagent Overview e 601 module

Select a e 601 module in the **Module Overview** area of the **System Overview** screen and choose **Reagent Overview** to display this screen. It consists of 2 areas, the **Reagent** area and the **Inventory** area.



A Reagent mandatory message

Figure B-62 Reagent Overview window (e 601 module)



A reagent mandatory message is displayed on the **Reagent Overview** screen if a mandatory reagent is not on board. This may occur if a reagent is not loaded or not available.

This function is available only if the test of the missing reagent has been defined as mandatory under the **Utility > Module Set > Test Assignment**.

Reagent area

Choosing a segment of the Reagent Disk graphic displays detailed information of the **cobas e** pack in the center of the graphic. The following information is displayed:

- **Position**
- **Status**
- **Test Name**
- **Available Tests**

The color of each segment corresponds to the status of the respective **cobas e** pack (inner ring), the status of the calibration (middle ring), and the status of the QC (outer ring). Segments of the middle and outer ring are subdivided in two subsections corresponding to the two measuring channels.

The legend at the bottom of the **Reagent** area explains the colors represented in the segments of the reagent disk graphic.



If the **e 601** test is not assigned to both measuring cells, the subsection for the unassigned measuring cell is displayed in gray.

1. Inner ring: RP (**cobas e** pack)

	Active	cobas e pack currently in use for this test.
	Warning	Remaining tests in this cobas e pack below yellow alarm level (Utility > System (Page 2/4) > Reagent Level Check).
	Caution	There is no more reagent available for this assay on this module.
	Stand-by	This is a standby cobas e pack.
	Zero tests, Used up	The cobas e pack has been used and is empty. There is still reagent available in another cobas e pack on this module.
	Free Pos.	There is no cobas e pack in this position.
	Expired	The reagent has exceeded its expiration date.

2. Middle ring: Cal (Calibration)

	Valid	A valid calibration is available.
	Requested	The reagent is requested for calibration.
	Failed	Calibration of the reagent has failed.

3. Outer ring: QC (Quality Control)

	Valid	QC result is within the confidence limits.
	Requested	Requested for QC measurement.
	Violated	QC result is not within the confidence limits.
	N.A.	Not applicable.

Inventory area

This area displays the amount of auxiliary reagents, magazines, magazine waste and solid waste. The abbreviations have the following meanings:

Abbreviation	Unit	Description
PC1/PC2	%	ProCell bottle 1 and 2 First bottle \leq 20% \Rightarrow number box turns yellow Second bottle \leq 20% \Rightarrow number box turns red
CC1/CC2	%	CleanCell bottle 1 and 2 First bottle \leq 20% \Rightarrow number box turns yellow Second bottle \leq 20% \Rightarrow number box turns red
PreClean M 1/2	%	PreClean bottle 1 and 2 One bottle empty \Rightarrow number box turns yellow Both bottles empty \Rightarrow number box turns red
ProbeWash M 1/2	%	ProbeWash bottle 1 and 2 One bottle empty \Rightarrow number box turns yellow Both bottles empty \Rightarrow number box turns red
Magazine	Actual number (max 12)	Full magazine with AssayTips and AssayCups. Each full magazine \Rightarrow 1 blue box One magazine remaining \Rightarrow box turns yellow No magazines remaining \Rightarrow box turns red
Magazine waste	Actual number (max 12)	Empty magazine Each space available for empty magazine \Rightarrow 1 blue box
Waste 1/2	Actual number in magazines	Solid waste for AssayTips and AssayCups. Each empty magazine \Rightarrow 1 blue box

Table B-15 Reagent and consumable types

Detail window

Choose the **Detail** button to display the **Detail** window.

This window displays more detailed information about the selected cobas e pack, namely: **Position**, **Reagent Type**, **Test Name**, **Reagent Lot No.**, **Reagent Sequence Number**, **First Registration Date And Time**, **Reagent Expired**, **Remaining Tests**, **Calibration Date**, and **Calibration Type** (for each Channel).

Detail	
Position	4
Reagent Type	ASSAY
Test Name	TSH
Reagent Lot No.	00173048
Reagent Sequence Number	040569
First Registration Date And Time	13.12.05 11:39
Reagent Expired	06.06
Remaining Tests	56
On Board Stability Time	0 ;
Calibration Date Of Ch.1	02.01.06 12:25
Calibration Type Of Ch.1	Reagent Pack
Calibration Date Of Ch.2	02.01.06 12:26
Calibration Type Of Ch.2	Reagent Pack

Detail	
Position	15
Reagent Type	PRE
Test Name	B12
Reagent Lot No.	00181823
Reagent Sequence Number	175704
First Registration Date And Time	06/10/08 11:21
Remaining Tests	57

Figure B-63 Detail window of an assay and a pretreatment

☞ For more information about the Detail window, refer to the *Online Help* of this window.

Reagent Overview button

Inventory Update window

Use the **Inventory Update** button to execute an inventory update for an **e 601** module.

This button is a short cut to the **Inventory Update** maintenance window.

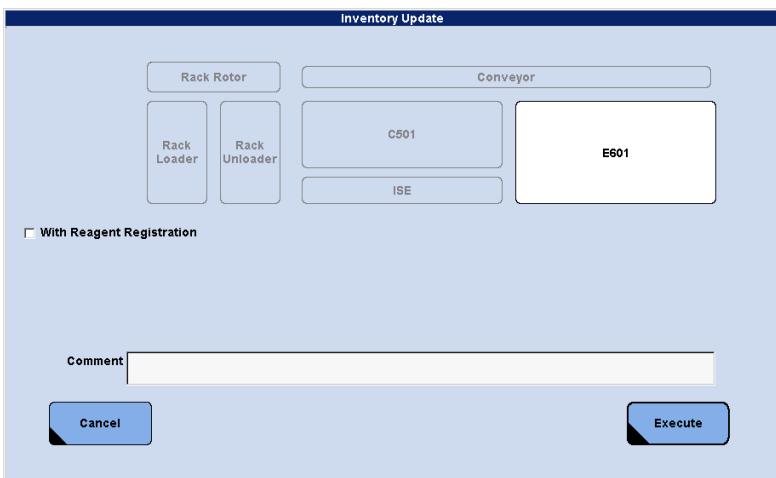


Figure B-64 Inventory Update window

If inventory update is executed the following actions are performed:

- Update the number of magazines in the magazine lifter
- Update the number of magazines on the magazine waste
- Check and update of ProbeWash solutions 1 & 2



The inventory update function is only available for **e 601** module.

With Reagent Registration

Select this check box to initiate a reagent registration as part of the inventory update.

Calibration

This chapter provides descriptions of special tasks that are not usually part of the daily workflow. It is meant to complement the chapter Daily operation, where everyday tasks and common procedures for running the cobas 6000 analyzer are described.

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Calibration concept

The following section gives an overview of the calibration concept applied by the cobas® 6000 analyzer series; it provides you with a basic understanding of the various calibration functionalities implemented on the analyzer and its software.

- ☞ For instructions on how to perform calibrations, see *Calibration and QC Select button* on page B-42.

What is calibration?

Calibration is the process that establishes a relation between measurement values (such as absorbance values or ECL signals) and corresponding results (concentration of an analyte).

This process may comprise the complete setting up of a new calibration curve or it is only the update of one or two parameters of an existing calibration curve.—In either case the term *calibration* is appropriate.

Automatic calibration

The relation between measurement values and results is subject to various environment and reagent conditions and may drift in the course of time. Therefore it is necessary to repeat calibrations regularly. To keep the resulting calibration management simple and efficient the system automatically recommends calibrations.

To get an overview of the functionalities provided by the cobas® 6000 analyzer series for automating calibration refer to the following section.

- ☞ See *Causes for automatic calibration recommendations* on page B-128.

Validation of calibration

After a calibration is performed, it needs to be validated. The system performs this task by means of automatic calibration checks. Whenever it detects an irregular condition or result, the calibration is classified as failed, a calibration alarm is issued, and the calibration gets recommended to be repeated.

- ☞ For a list of calibration alarms and for an overview of application-specific calibration quality criteria, see: *Calibration quality criteria for e 601* on page B-134

Information on the status of the calibrators that are currently processing can be viewed on the **Workplace > Calib. Review** screen.

- ☞ See *Calib. Review screen* on page B-81.

Calibration masking

If a calibration fails one or more quality criteria applied in the validation process, tests should no longer be performed with the affected reagent. This is achieved automatically by means of the auto masking function.

- ☞ For more information, see *Calibration masking* on page B-134.

Causes for automatic calibration recommendations

For automating the calibration process, the **cobas** 6000 system provides the following features:

- Automatic calibration at start-up of the analyzer (Start-up calibration).
- Automatic calibration at change of reagents (Changeover calibration):
 - Calibration at **cobas c** pack or **cobas e** pack change
 - Calibration at lot change
- Automatic calibration without reagent change:
 - Calibration in regular intervals (Timeout)
 - Calibration in combination with Preventive action (Calib Now)
 - Calibration due to failed QC (QC-triggered calibration (QC Violation))
- Automatic recommendation for recalibration when a calibration failed (Failed)

The different calibration functions can be combined. For automatic calibration without reagent change you have to decide on one workflow: Timeout calibration or QC violation.

Start-up calibration

With this function you can select a predefined set of tests which are calibrated automatically at the start of an analysis run or when you order a start-up calibration manually. The tests for Start up calibration are defined on **Calibration > Status > Start Up Setting**.

 See *To select tests for start-up calibration* on page B-145.

The further calibration settings are defined on the **Utility > Application > Calib.** screen.

 See *Description of application parameters - Calib. tab* on page B-201.

Changeover calibration

Calibrations also have to be performed when certain physical events occur. These include:

- A change in reagent lot (of **cobas c** packs or **cobas e** packs)
- A change in a **cobas c** pack or **cobas e** pack (regardless of the lot)
- A installation of new test on the system

Timeout

Calibrations are performed at regular intervals to compensate for changes over time in reagents and in the measurement systems. Timeout calibrations can be performed for lot timeout and for cassette timeout.

QC-triggered calibration (QC Violation)

Calibration will be initiated if the QC results are outside the confidence limit. Three different controls can be defined.

For each application you have to decide whether calibration should be performed timer-triggered (Timeout) or QC-triggered (QC violation).



It is recommended to decide for one calibration workflow—timer-triggered or QC-triggered—for all applications.

When a new application is loaded, timer-triggered calibration is preselected and the intervals recommended by Roche Diagnostics are predefined. If you prefer a workflow with QC-triggered calibration you have to activate **QC Violation**.

 For information on the necessary QC violation settings, see *Auto Calibration* on page B-203.

- Calib Now* This automatic calibration function is active only if **Preventive Action** is activated. When a calibration times out during the period specified in the **Remaining Time** box on the **Calibration > Status** screen, the system recommends a calibration indicating *Calib Now* as calibration cause.

Calibration concept c 501

Types of calibration curves There are six different types of calibration curves possible on c 501 modules. One of six different types of mathematical functions is used to describe the relation between a measured value and a result.

In this document and in the user interface (UI), these types of calibration curves are called calibration types. The names of the calibration types are:

Linear	RCM2T1	Spline
RCM	RCM2T2	Line Graph

Table B-16 Calibration types for photometric tests

Each calibration type corresponds to one type of mathematical function. For example, *Linear* corresponds to a linear equation, *RCM2T2* to an exponential function.

☞ For more details, refer to the *COBI CD*.

Calibration curve parameters A specific calibration curve is defined by its calibration type (mathematical function) and its parameters. The names of these parameters in the user interface are:

- S1Abs., K, A, B, and C.

A Linear calibration curve, for example, is defined by two parameters (S1Abs. and K), an RCM calibration curve is defined by four, and a Spline can require up to six parameters. When the system performs a calibration, it redetermines these parameters by fitting the calibration curve to the newly measured values.

Calibration methods

Calibrations are performed with varying numbers of calibrators. Up to six calibrators are used for a full calibration of certain photometric tests. However, not all calibrators available for a test need to be used in every calibration. To define which calibrators are used there is a choice of up to four different calibration methods.

The availability of calibration methods depends on the kind of test to be calibrated. The Table B-17 on page B-130 displays all calibration methods and the corresponding calibrators.

	Photometric tests	ISE tests
Blank	Std (1) ^(a) is used	Only ISE Comp. [Std (3)] is used <i>(not recommended in US)</i>
Span	Only one calibrator out of Std (2)-Std (6) ^(b) is used	Not available
2 Point	Std (1) and a second calibrator are used	ISE Low [Std (1)] and ISE High [Std (2)] are used
Full	All calibrators [Std (1)-Std (6)] are used (for nonlinear calibration types)	ISE Low [Std(1)], ISE High [Std(2)], and ISE Comp. [Std (3)] are used <i>(global use)</i> <i>ISE Low [Std(1)], ISE High [Std(2)], and ISE High (compensated) [Std (3)] are used (in US only)</i>

Table B-17 Calibration methods on c 501 module

- (a) Std (1) is the first standard solution, that is, the calibrator of the lowest analyte concentration. For many photometric applications water is used as a blank calibrator.
- (b) Std (2)-Std (6) refer to calibrators assigned to an application under **Utility > Application > Others**.

Calibration rules for c 501

- Calibration is best done as a part of the daily preroutine operation. However, it can be done at any time during operation as well.
- Multi-calibrators are usually used. Calibrator data are downloaded via cobas link.
- If expired calibrators are used, no alarm is issued.
- Calibrations are carried out in duplicate.
- Barcoded calibrators:
Roche calibrators are always supplied with barcode labels (inserted in the calibrator kit). The labels must be placed on a tube.
- Non-barcoded calibrators can be used as well. In this case calibrator vials have to be assigned to specific racks and positions (rack assignment).
- Calibrators can be used several times for calibrations.

ISE calibration concept

Full calibration Full calibration for Na⁺, K⁺, and Cl⁻ requires the following 3 calibrator solutions:

- ISE Standard 1 (ISE Low)
- ISE Standard 2 (ISE High)
- ISE Standard 3 (ISE Comp.)
- *For US only, ISE High (compensated) is used instead of ISE Comp.*

The slope of the calibration curve is calculated from ISE Standards 1 and 2. ISE Low and ISE High are aqueous standards. ISE Comp. / ISE High (compensated) is designed to reduce matrix effects.



Incorrect results due to concentrated ISE calibrators

- The concentration of the ions increases due to evaporation, this may result in an incorrect calibration, and thus incorrect results.
- For ISE calibrations ensure that the calibrator is opened immediately before the calibration is performed.



A full calibration is required every 24 hours.

One-point calibration

The ISE internal standard (ISE IS) is measured before and after each routine sample (only one measurement for sample analyses in succession). These measurements are used to correct for system-related drifts (junction potential differences, differences in electrode conditions, and the like).

The ISE IS is measured during calibration as well.

Sample type specific ISE calibration curves

It is possible to set up and use two independent sets of calibration curves (**Type A** and **Type B**) for different sample types for Na⁺, K⁺, and Cl⁻.

If only one calibration curve is used for the different sample types, only one calibration is performed.

- ☞ For information on configuration and assignment of calibrations, see
Setting up individual calibration curves for each ISE sample type on page B-212
ISE calibration on page B-151

Lot and cassette calibrations for c 501

Lot calibration

Lot calibration data are reagent lot specific for the test. Lot calibration data are transferred to other cassettes belonging to the same reagent lot. This means, lot calibration data generated for a **cobas c** pack are applied to result calculations of all patient samples and controls using **cobas c** packs of the same lot.

A lot calibration can only be generated from a *fresh* cassette, which means that the calibration must be performed within 24 hours after the cassette has been loaded on the system.

Cassette calibration

Cassette calibration data are cassette-specific. If the cassette was loaded on the system more than 24 hours ago and this cassette is used for calibration for the first time, a cassette calibration is generated.

Newest calibration

Newest calibration is a function that permits to replace empty cassettes during operation without performing a calibration.

For a reagent cassette for which no applicable calibration data exists, the newest calibration result is transferred at the time of reagent registration. This function is used to avoid the following situation: A cassette of a new lot, that was loaded on the system, does not have any calibration data. Always the newest calibration data (the data of the last valid lot calibration) are transferred.

Calibration concept e 601

Calibration is the process that establishes a relation between measurement values (such as ECL signals) and corresponding results (concentration of an analyte). This relation depends on both analyzer conditions and reagent conditions. For this reason, Roche Diagnostics supplies a master calibration curve for each application (generated during production of the reagent kit) and—at customer site—the analyzer generates an update of this master calibration curve under the local routine laboratory conditions. A calibration curve thus updated is also referred to as working curve.

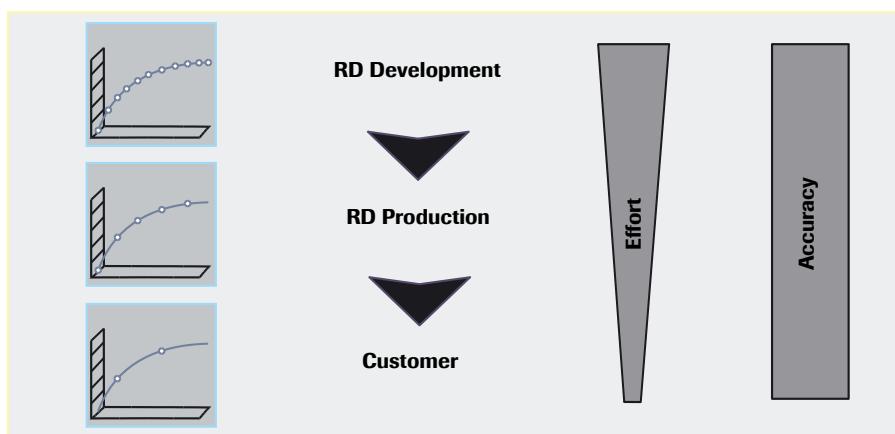


Figure B-65 Calibration concept e 601

Calibration rules for e 601

General calibration rules

- Calibration is best done as a part of the daily preroutine operation. However, it can be done at any time during operation as well.
- Elecsys test-specific calibrators are used. Calibrator data are downloaded via cobas link or they are encoded within the cobas e pack barcode.
- Calibrations are carried out in duplicate.
- Calibrations for both channels are automatically carried out from the same calibrator set if both channels are to be calibrated.
- Expired calibrators cannot be used.
- If calibration is recommended due to QC violation because of improper placement of controls (reversed order), the control material can be run again. If the controls recur within their confidence limits, the calibration request is removed.

- For lyophilized calibrators:* Carefully dissolve the contents of a bottle according to the instructions for use. Carefully mix avoiding the build up of foam. Transfer the dissolved calibrator to the empty, labeled CalSet vials using the additional vials and labels provided.
- For liquid e 601 calibrators:* If the total volume is not required for calibration on the e 601, divide the ready-to-use calibrator in the CalSet vials using the additional vials and labels provided. Store the reserved calibrator portion according to the instructions for use.
- Positioning of calibrators* Calibrators are placed in calibrator racks (black racks).
- Calibrator vials of the same set are to be placed next to each other in the racks. Calibrators for different tests can be placed in any order. Important: Do not separate the vials of a calibration set.
 - In order to process calibrations in parallel on two e modules, the calibration racks can be sequenced for the individual modules.

Lot and reagent pack calibrations for e 601

- Lot calibrations* Every new reagent lot must be calibrated. A lot calibration is generated if a calibration is carried out within 24 hours (from first registration of the cobas e pack on the e 601 module) and all calibration criteria are met.
- Calibrations are channel-specific, that is, each channel is calibrated separately.
 - Once a lot calibration has been accepted, it is automatically used for all cobas e packs of the same lot.
- Reagent pack calibrations* A calibration automatically becomes a reagent pack calibration if the cobas e pack has been on the module for longer than 24 hours.
- The generated calibration curve is only valid for the cobas e pack from which it was measured (cobas e pack number specific).
 - **Note:** Expired cobas e packs can only generate a reagent pack calibration.
-  For more information about Lot and reagent pack calibrations for e 601, refer to the COBI CD.

Calibration quality criteria for e 601

Calibration measurements are automatically checked against various quality criteria. The assessment is different for qualitative and quantitative assays. The following table shows which criteria are used for quantitative assays and which are used for qualitative assays.

Results of the calibration checks are displayed on the **Calibration Result** (Immune) window. To open this window select an e 601 test from the **Calibration > Status** screen and choose **Calibration Result**.

Quantitative assays	Qualitative assays
Missing values	Missing values
Monotony of curve	Slope
Minimum signal	Minimum signal
	Maximum signal
Minimum difference	Minimum acceptable difference
Deviation of duplicate measurement	Deviation of duplicate measurement
System error	System error
Calibration factor	

Table B-18 Quality criteria for quantitative and qualitative assays

☞ For explanation of these calibration quality criteria for e 601, refer to the COBI CD.

Calibration masking

Automatic calibration masking is a function which masks a **cobas c pack** or **cobas e pack** for a module or measuring cell when no valid calibration is available for this particular module or measuring cell. This function is activated (or deactivated) for the entire system under **Utility > System (Page 2/4) > Calib Mask Setting**. When activated, the function can be selected individually for each application on the **Calib.** tab of the **Utility > Application** screen.

Failed calibrations

When a calibration is successful, the calibration data are available for the measurement of patient samples and controls. When a calibration fails one or more quality criteria, this calibration gets the status *Failed*. *Failed* calibration data is not available for the corresponding **cobas c pack** or **cobas e pack**.

If automatic calibration masking is activated, the corresponding test with the *Failed* calibration data is masked. If automatic calibration masking is not activated, the test is not masked but data alarms are attached to the results.

The *Failed* calibration can be *rejected* by the operator (**Reject** button on **Calibration > Status**) so that the latest successful calibration, if it exists, is recalled for the samples and controls. However, the calibration recommendation still remains for the **cobas c pack** or **cobas e pack**.

Overview

The calibration menu comprises three screens: **Calibration > Status**, **Calibration > Calibrator**, and **Calibration > Install**. This chapter describes important commands accessed via these screens as well as various information displayed on them. However, this chapter does not cover all possible commands. For a complete description of all fields of the software's user interface, refer to the *Online Help*.

- ☞ For more information about the calibration menu, refer to the *Online Help*.

Calibration Status screen

The following sections explain certain tasks associated with the **Calibration > Status** screen. Not all tasks are described, but the most important ones are discussed here.

- For a complete description of all elements of the user interface, refer to the *Online Help*.

To display this screen choose **Calibration > Status**.

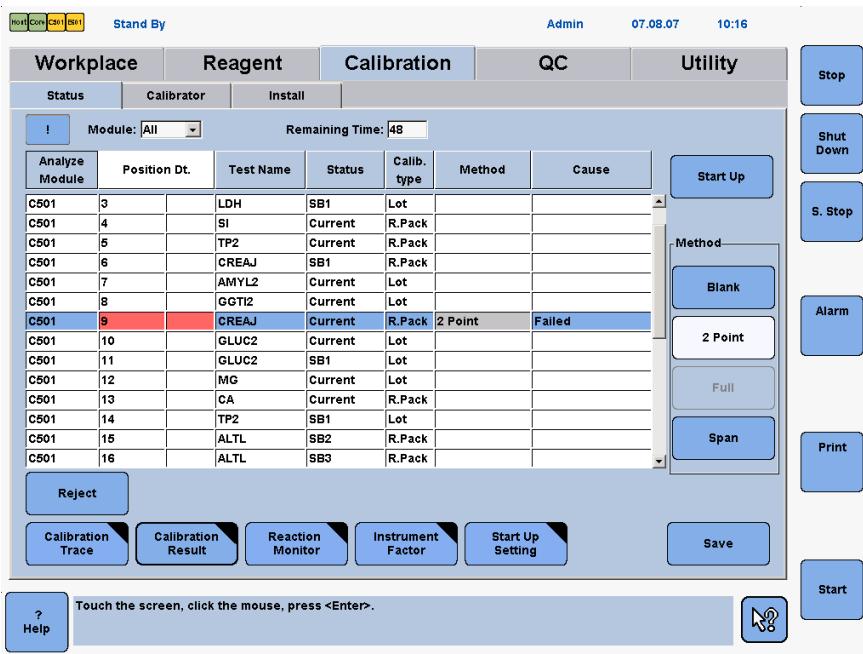


Figure B-66 Calibration > Status screen

This screen shows detailed information about the calibration status of the tests on the modules selected in the **Module** list box. This screen is used to select tests for start up, timeout, changeover or manual calibrations.

- For more information about the calibrator status during calibration, see *Calib. Review screen* on page B-81

Exclamation Point button

This button turns yellow if the displayed status list should be updated. The displayed information may be out-of-date, for example, if a calibration has been performed in the meantime. Choose the **Exclamation Point** button to update the status list.

- For information about particular tasks associated with this screen, see:
 - Requesting and cancelling calibrations manually* on page B-137
 - Reviewing calibration data* on page B-138
 - Calibration factors* on page B-144
 - Selecting tests for start-up calibrations* on page B-145
- For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Requesting and cancelling calibrations manually

According to the intended use, calibrations are automatically recommended by the system and requested by the operator via the **System Overview** screen.

- ☛ See *Calibration and QC Select button* on page B-42

Regardless of these system recommendations calibrations can be manually selected and deselected as well.

► To request calibration for a test manually

- 1 Choose **Calibration > Status**.
- 2 Select the test and reagent (**Current** or **SBx**) that needs to be calibrated from the list.
The selected line is highlighted in blue.
- 3 Select the appropriate button in the **Method** area for a **Blank**, **2 Point**, **Full**, or **Span** calibration.

The selected option appears in the **Method** column highlighted in green, the **Cause** column indicates **Manual**, and the **Save** button turns yellow.

- 4 To request calibrations for additional reagents and tests repeat steps 2 and 3.
- 5 Choose **Save** to save the changes.

All listed tests and reagents that have an entry in the **Method** column highlighted in green correspond to a requested calibration.



Incorrect results due to concentrated ISE calibrators

- The concentration of the ions increases due to evaporation, this may result in an incorrect calibration, and thus incorrect results.
 - For ISE calibrations ensure that the calibrator is opened immediately before the calibration is performed.
-

► To cancel a calibration request manually

- 1 Choose **Calibration > Status**.
- 2 Select the reagent and test for which the calibration request is to be cancelled.

The selected line is highlighted in blue, the entry in the **Method** column is highlighted in green, and the corresponding button in the **Method** area is highlighted in white.

- 3 Select the highlighted button in the **Method** area.
The entries in the **Method** and **Cause** column for this reagent disappear and the **Save** button turns yellow.
- 4 To cancel further calibration requests repeat steps 2 and 3.
- 5 Choose **Save** to save the changes.



Reviewing calibration data

After a calibration is completed it should be reviewed. Details for each calibration performed on any of the analyzer's modules can be retrieved from the **Calibration > Status** screen. The following sections describe the possibilities to check calibration data according to the different kinds of test calibrated.

- ☛ For further information, see:

Checking calibrations of photometric tests on page B-138

Checking calibrations of ISE tests on page B-141

Checking calibrations of e 601 tests on page B-142

Checking calibrations of photometric tests

For each successful calibration of a photometric test, the following information is available:

- **Calibration Factor:** Parameters that determine the position and shape of the calibration curve.
☛ See *Calibration factors* on page B-144.
- **Calibration curve:** Mathematical relation between the measured signal (for example, absorbance or rate of change in absorbance) and the corresponding concentration value for the concerned analyte.
- **Reaction monitor:** A graph showing the measured absorbance in the course of a test measurement.
- **Calibration trace:** A graph used to review the measurements of the 50 most recent calibrations for a specific test. It shows signal values for both, the Std (1) calibrator and the calibrator with the maximum concentration on one plot.

► **To review calibration data**

- 1 Choose Calibration > Status.
- 2 Select a photometric test from the list on Calibration > Status.
- 3 Choose Calibration Result to display the Calibration Result window.

Calibration Result (Photometry)									
Calibration Type									
Linear		Lot No.		Seq. No.		Pos.			
		669879		08555		9			
Test	Module	S1 Abs.	K	A	B	C	L	H	I
CA	C501	803	857						
CREAJ	C501	2	8308						
CREAJ	C501	4	8419						
GGTI2	C501	1	4995						
GLUC2	C501	111	146						
GLUC2	C501	81	146						
S1 Abs. K		4 8419							
Cancel		Working Information		Calibration Factor		Update		OK	

Figure B-67 Calibration Result (Photometry) window

This window gives information about the most recent calibrations for the displayed photometric test.

- To display the calibration curve of a selected test choose **Working Information**.
- To display the calibration factors for the cassette calibration, lot calibration, and currently valid calibration of a selected test choose **Calibration Factor**.
 - ☞ For more details, see *Calibration factors* on page B-144.

► **To review measurement details of the most recent calibration**

- 1 Choose Calibration > Status.
- 2 Select a photometric test from the list on Calibration > Status.
- 3 Choose Reaction Monitor to display the Reaction Monitor window.

This window displays reaction graphs for each of the duplicate measurements of each calibrator used for the calibration selected.

- 4 Use the drop-down list above the graph to select a specific measurement. The extensions *1st* and *2nd* in the list correspond to the first and second measurement of each calibrator, respectively.
 - ☞ For a complete description of all fields and buttons, refer to the *Online Help*.



Reaction monitor data of a calibration can be printed out: First, select a test from the **Calibration > Status** screen, then, choose **Print** (global button), select **Reaction Monitor** from the list on the left, and choose **Print**.

Calibration Status screen

► **To review results of previous calibrations**

- 1 Choose **Calibration > Status**.
- 2 Select a photometric test from the list on **Calibration > Status**.
- 3 In order to review the results of previous calibrations of the selected test, choose **Calibration Trace**.

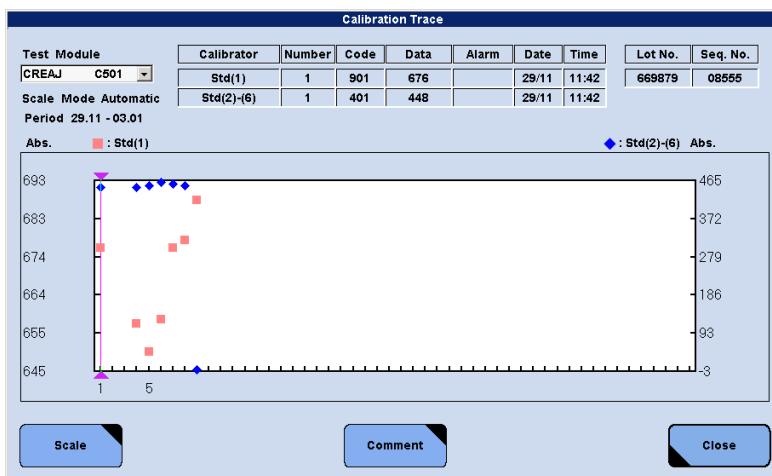


Figure B-68 Calibration Trace window

The graph shows calibration results for the selected photometric test. It displays the measured absorbance values for both the Std (1) calibrator and the calibrator with the maximum concentration Std (2)-Std (6) on one plot.

The left and right y-axes are scaled independently:

- The left axis refers to the Std (1) calibrator represented by ■.
 - The right axis refers to the maximum calibrator Std (2)-Std (6) represented by ◆.
- For a complete description of all fields and buttons, refer to the *Online Help*.

The calibration trace can be printed out. First, select a test from the **Calibration > Status** screen, then, choose **Print** (global button), select **Calibration Trace** from the list on the left, and choose **Print**.

Checking calibrations of ISE tests

For each successful calibration of an ISE test, the following information is available:

- Working Information (ISE): Results from the most recent successful ISE calibration for the test selected.
- Calibration trace: A graph used to review the measurements of the 50 most recent calibrations for a specific test. It shows both the measured data for the selected test's compensator ISE Comp. (in mmol/L) and slope values (in mV) on one plot.

For US only, ISE High (compensated) is used instead of ISE Comp.

► To review calibration data

- 1 Choose Calibration > Status.
- 2 Select an ISE test from the list on Calibration > Status.



The entries ISE-A and ISE-B refer to two different calibration curves that can be assigned to different sample types. For example, ISE-A is assigned to serum/plasma and ISE-B to urine samples. This assignment is set on **Utility > System (Page 3/4) > ISE Calib Setting**.

- 3 Choose Calibration Result to display the Calibration Result (ISE) window.

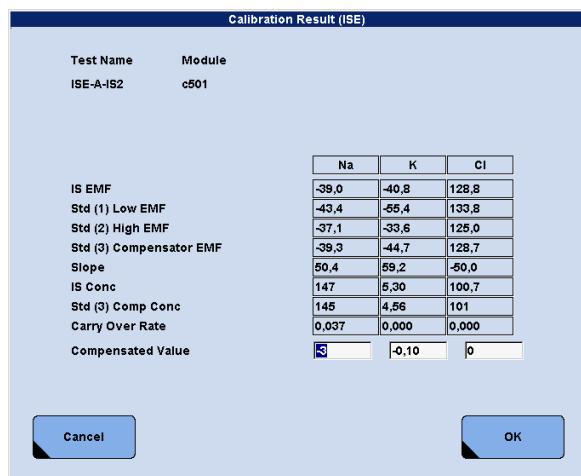


Figure B-69 Calibration Result (ISE) window

This window displays information about the most recent successful ISE calibration: Electromotive force (EMF), slope, and target concentration values.

The three **Compensated Value** text boxes display the difference between the target value of [ISE Std (3)] (ISE Comp.) and its measured values for Na^+ , K^+ , and Cl^- . This difference is added to all measured routine samples and controls.

The slope of the calibration curve is calculated from ISE Standards 1 and 2. ISE Comp. is designed to reduce matrix effects. It only affects the intercept and not the slope.

For US only, ISE High (compensated) is used instead of ISE Comp.

► **To review results of previous ISE calibrations**

- 1 Choose **Calibration > Status**.
- 2 Select an ISE test from the list on **Calibration > Status**.
- 3 Choose **Calibration Trace** to open the **Calibration Trace** window.
- 4 Select a test from the drop-down list on the top left of the window.

The graph shows calibration results for the selected ISE test. The left and right y-axes are scaled independently:

- The left axis refers to the measured concentration values of the ISE compensator [ISE Std (3)] represented by ■.
- The right axis refers to the calculated slope values represented by ◆.
- For a complete description of all fields and buttons, refer to the *Online Help*.



Checking calibrations of e 601 tests

For each successful calibration of an e 601 test, the following information is available:

- Calibration results (Immune): A list showing target and signal values for the test selected on the **Calibration > Status** screen.
- Calibration trace: A graph used to review the measurements of the 50 most recent calibrations for a specific test. It shows signal values for both calibrators [Std(min) and Std(max)] on one plot.

► **To review calibration data**

- 1 Choose **Calibration > Status**.
- 2 Select an e 601 test from the list on **Calibration > Status**.
- 3 Choose **Calibration Result** to display the **Calibration Result** window.

Calibration Result (Immune)							
Test	Module	Calibration Type	Unit	Date Time	Calibrator Lot	Lot	Seq. No.
TSH	E-1	Rodbard	uIU/mL	02.01.06 12:25:52	171927	00173048	040569
L-Calib. Could not be generated! Released as R-Calib. by System							
	Level 1	Level 2	Level 3	Level 4	Level 5		
Target	0,000	1,48					
Signal 1	1005	25485					
Signal 2	956,5	25712					
Signal 3							
Signal 4							
Monotony	--	--					
Diff.	--	--					
Dupl.	--	--					
Sys. Err.	--	--					
Factor	1,00						
Close							

Figure B-70 Calibration Result (Immune) window

This window displays information relating to the calibration currently used for the selected heterogeneous immunology test (signal levels, calibration criteria).



► **To review results of previous calibrations**

- 1 Choose **Calibration > Status**.
- 2 Select an e 601 test from the list on **Calibration > Status**.
- 3 Choose **Calibration Trace** to open the **Calibration Trace** window.
- 4 Select a test from the drop-down list on the top left of the window.

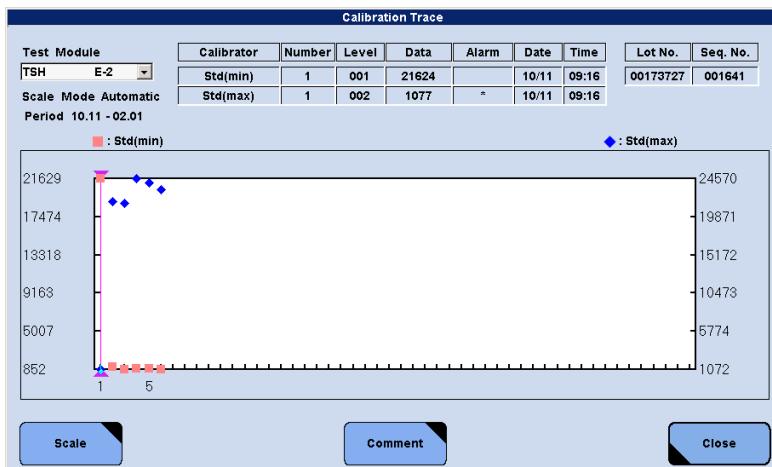


Figure B-71 Calibration Trace window for e 601 tests

The graph shows calibration data for the selected test; it displays the measured signal values for both the low concentration calibrator, Std(min), and the high concentration calibrator, Std(max), on one plot.

The left and right y-axes are scaled independently:

The left axis refers to the Std(min) calibrator, represented by ■.

The right axis refers to the Std(max) calibrator, represented by ♦.

For a complete description of all fields and buttons, refer to the *Online Help*.



The calibration trace can be printed out. First, select a test from the **Calibration > Status** screen, then, choose **Print** (global button), select **Calibration Trace** from the list on the left, and choose **Print**.

Calibration factors

The term calibration factors refers to coefficients (S1Abs, K, A, B, C) used for setting up calibration curves for photometric tests. The system stores calibration factors for each calibration curve of all registered reagent cassettes.

The following kinds of calibration factors are available: **Cassette**, **Lot**, and **Newest**.

 For more information, see *Lot and cassette calibrations for c 501* on page B-131

► To check calibration factors

- 1 Choose **Calibration > Status**.
- 2 Select a photometric test from the test list.
- 3 Choose **Calibration Result**.
- 4 On the **Calibration Result** window, choose **Calibration Factor**.

The **Calibration Factor** window opens. On the **Calibration Factor** window you can see which calibration is currently used for calculating the results. The following data is displayed:

Cassette	Lot No.	Newest
S1 Abs.	111	S1 Abs.
K	414	K

Table B-19 Example for calibration factors



Cassette The factors of the selected **cobas c** pack which are used for calculating the results are displayed.

If a cassette calibration is used for calculating the results, the factors of cassette differ from the factors of the lot calibration.

If a lot calibration is used, the factors of cassette are the same as the factors of the lot calibration.

Lot No. The factors of the lot calibration are displayed.

Newest The factors used for the newest calibration is displayed. Always the last valid lot calibration is used as the newest calibration.

The newest calibration is transferred to a cassette for which no valid lot calibration exists and that has not been calibrated since loading.

Selecting tests for start-up calibrations

The start-up calibration function serves to treat a whole set of tests collectively:

- Tests selected for start-up calibration will be automatically recommended for calibration each time the system is started.
- You can also manually request a start-up calibration by choosing **Calibration > Status > Start Up**: For all tests selected for start-up calibration a calibration request will be issued.

The set of tests that are calibrated in a start-up calibration, including the respective calibration methods, is defined on the **Start Up Setting** window.

► To select tests for start-up calibration

- 1 Choose **Calibration > Status > Start Up Setting**.

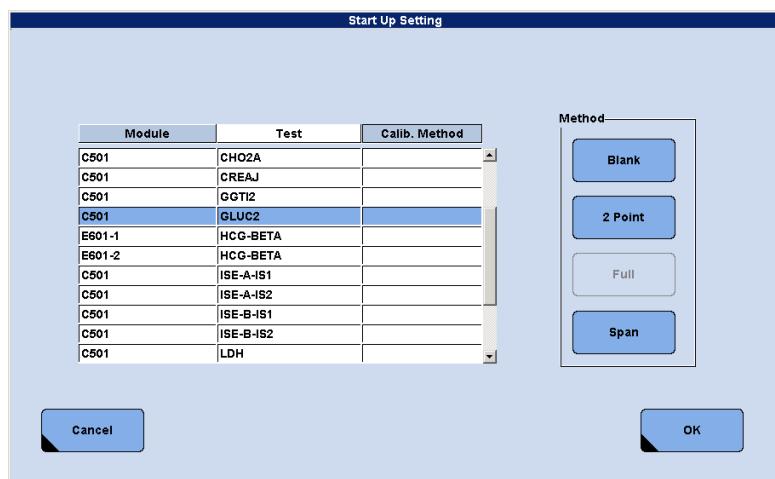


Figure B-72 Start Up Setting window

- 2 Choose a test in the list to select it.
- 3 Choose a method in the **Method** area to request it for the selected test. The **OK** button turns yellow indicating you have made a change.



- For **e** 601 tests, only **Full** is available as an option.
- For **c** 501 tests, for all non linear calibrations all methods are available. According to the instructions for use, a full calibration must be performed.

- 4 Choose **OK** to save the start-up calibration settings and close the **Start Up Setting** window.
- 5 Choose **Start Up** on the **Calibration > Status** Screen to activate the selected calibrations.
- 6 Choose **Save** to confirm the start-up calibrations.



Calibration Install screen

The following sections explain certain tasks associated with the **Calibration > Install** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **Calibration > Install**.

If you need to update a clinical chemistry calibrator, choose the **Chemistry** tab. If you need to update an immunology calibrator, choose the **Immune** tab.

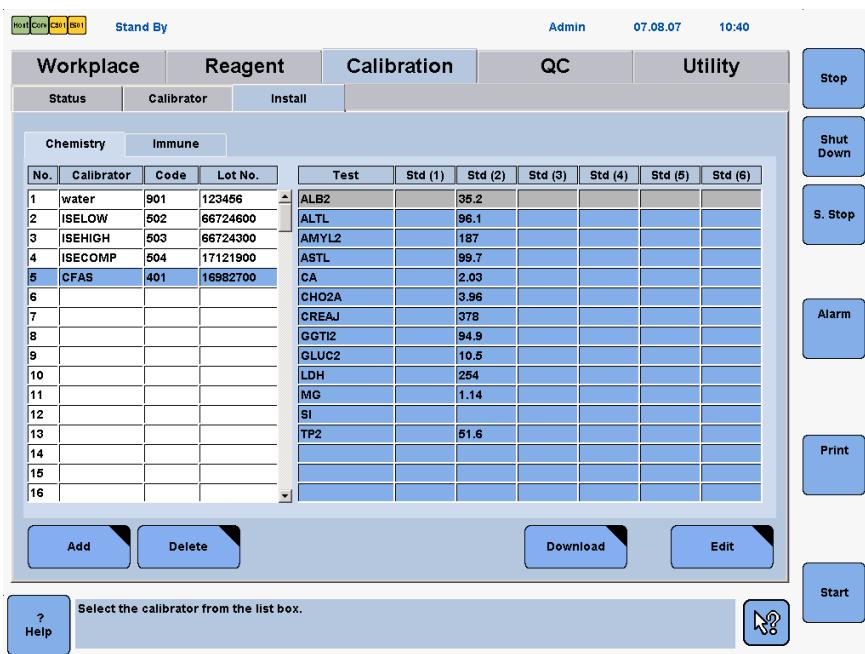


Figure B-73 Chemistry tab on Calibration > Install

The **Calibration > Install** screen is used to review information about already registered calibrators, to update calibrator information, and to install new calibrators.

- 🕒 For information about particular tasks associated with this screen, see:
 - Checking information about already installed calibrators* on page B-147
 - Loading calibrator data* on page B-147
 - Editing concentration values* on page B-149
- 🕒 For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Checking information about already installed calibrators

Information regarding calibrator codes, lot numbers, expiration dates, and concentration values can be downloaded to the system using **cobas** link.

This section describes how to check registered calibrator information.

► To check registered calibrator information

- 1 Choose **Calibration > Install**.
- 2 Select a calibrator from the list on the left.

The list on the right displays the registered concentration values for this calibrator.

- 3 In order to look up a calibrator's calibrator code, lot number, or expiration date choose **Calibration > Calibrator**.



Loading calibrator data

Information regarding calibrator codes, lot numbers, expiration dates, and concentration values can be downloaded to the system using **cobas** link. An operator ID of supervisor level or higher is required for this operation.

- ☞ For instructions on entering calibration information manually, see *Editing concentration values* on page B-149

How to download new or update existing calibrator data from **cobas** link is described in the following procedure.

► To download calibrator data from **cobas** link

- 1 Put the analyzer in standby.
- 2 Choose **Calibration > Install > Download** to open the **Download** window.

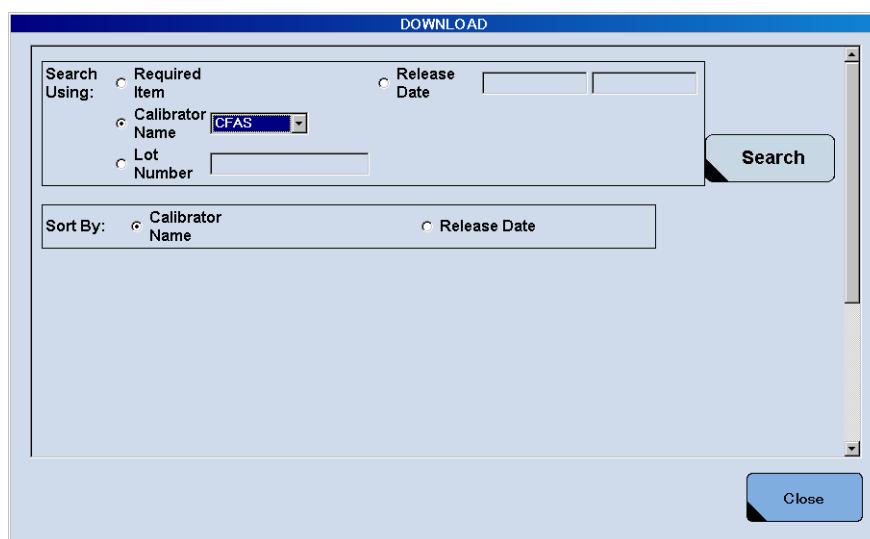


Figure B-74 Download window

- 3 Select one of the available search conditions (required item, calibrator name, lot number, or release date).
 - The option **Release Date** refers to the date when the calibrator was released by the QA department.
 - The option **Required Item** refers to calibrator information that have not been found on the system at the time the calibrator rack passed the barcode reader of the rack sampler unit.
- 4 Choose **Search**. A list of items that meet the given search conditions appears.

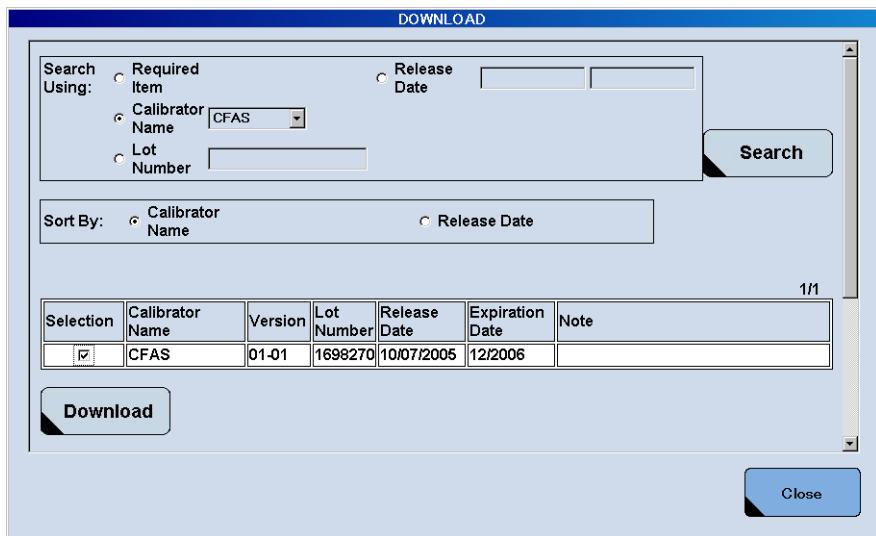


Figure B-75 Download window with search results

To change the order of the list select the option **Calibrator Name** or **Release Date**.

- 5 Select the check box of each list item to be downloaded.
- 6 Choose **Download** and confirm with **OK**.
- 7 Choose **Close** to return to the **Calibration > Install** screen and verify the downloaded information has been registered correctly.

Editing concentration values

The concentration value of a calibrator can be edited on the **Calibration > Install** screen (c 501 module only).

- To enter or edit concentration values of a calibrator

- 1 Choose **Calibration > Install**.
 - 2 On the **Chemistry** tab select the calibrator to be edited from the list on the left.
 - 3 Choose **Edit**. The **Edit Calibrator** window opens.

Edit Calibrator

Name : CFAS	Code : 401	Lot No. : 16982700					
Test	Std (1)	Std (2)	Std (3)	Std (4)	Std (5)	Std (6)	Std Concentration
ALB2	35,2						Std(1) <input type="text"/>
ALTL	56,1						Std(2) <input type="text"/> 35,2
AMYL2	187						Std(3) <input type="text"/>
ASTL	99,7						Std(4) <input type="text"/>
CA	2,03						Std(5) <input type="text"/>
CHO2A	3,96						Std(6) <input type="text"/>
CREAJ	378						
GGT12	94,9						
GLUC2	10,5						
LDH	254						
MG	1,14						
SI							
TP2	51,6						

Unit of Measure g/L

Figure B-76 Edit Calibrator window

- 4** Select a test (analyte) from the list whose calibrator concentration value is to be entered or edited.
 - 5** Select a box in the **Std Concentration** area and type the appropriate concentration value(s). Observe the respective unit of measure displayed below the **Std Concentration** area.

Std (1) is used for the blank calibrator. Std (2) through Std (6) are used for all other calibrators.



The number of decimal places used for Std (1) defines the number of decimal places used for reportable data. This is only valid for c 501 tests.

It is recommended to select the number of decimal places at the time of installing the application.

- 6** After all necessary values are entered, complete the input by choosing **Update**.
 - 7** If you need to edit additional tests, repeat steps 4 through 6.
 - 8** Choose **OK** to save all changes and close the window.



- To change the decimal places or calibrator target values for a previously calibrated application



Incorrect results due to wrong calibration

You can change the decimal places or calibrator target values after an application has been installed. However, if the decimal places or calibrator target values are changed after the test in question has already been calibrated, we strongly recommend deleting that test application and reinstalling it.

After changing the calibrator target values or the number of decimal places for Std (1), the calibration is immediately updated, that is, even before the actual calibration measurement is performed

- After changing the decimal places or calibrator target values, always recalibrate and run controls in order to ensure no incorrect results are reported.
- Make sure to perform the calibration measurement prior to any other determinations

1 Backup the database and delete patient data (**System Overview > Sample Data Clear > Backup and Clear**).

If Sample data clear is executed, all the records of the samples are deleted and QC data are moved to the **QC View**.

☞ For details see *Sample Data Clear button* on page B-37.

2 Unload all the cobas c packs for this test (**Reagent > Setting > Cassette Unloading**).

☞ For details see *Unloading reagent cassettes* on page B-105.

3 Delete the test application (**Utility > Application**).

4 Reinstall the test application (**Utility > Application > Download**).

☞ For details see *Loading or updating new applications* on page B-192.

5 Load new cobas c packs.

☞ For details see *To load a cobas c pack* on page B-41.



Any cobas c packs for this test that were already in use on a c 501 module cannot be reloaded onto the c 501 module after the test has been deleted.

6 Install the calibrator values for this test under **Calibration > Install > Download**.

☞ For details see *Loading calibrator data* on page B-147.

7 Change the decimal places of calibrator 1 (Std (1)) (**Calibration > Install > Edit**).

8 Install the control values for this test under **QC > Install > Download**.

☞ For details see *Loading control data* on page B-182.

9 Calibrate the test and perform control measurements.

☞ For details see *Requesting calibration and QC and printing load lists* on page B-43.



ISE calibration

ISE calibrators are used without barcode. Therefore you have to register the calibrators, assign rack number and positions, and enter the relevant concentration values for each calibrator as described above.

If the system configuration is done, use a (black) calibrator rack for the three calibrators used in an ISE calibration—ISE Low, ISE High, and ISE Comp.—and put these in positions according to the rack assignment.

For US only, ISE High (compensated) is used instead of ISE Comp.

☞ For details, see *Editing concentration values* on page B-149.

Sample type specific ISE calibration curves

For ISE tests it is possible to apply one of two independent calibration curves. After installation and assignment, the respective calibrator values are displayed under **Type A** and **Type B** on **Utility > Application > Other**.

The assignment of one or the other calibration curve to a certain sample type is set on **Utility > System (Page 2/4) > ISE Calib Setting**.

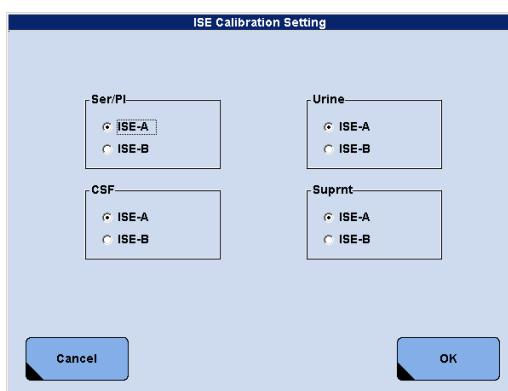


Figure B-77 Utility > System (Page 2/4) > ISE Calib Setting window

☞ For more information, see *Setting up individual calibration curves for each ISE sample type* on page B-212

Calibration Calibrator screen

The following sections explain certain tasks associated with the **Calibration > Calibrator** screen. Not all tasks are described, but the most important ones.

To display this screen choose **Calibration > Calibrator**.

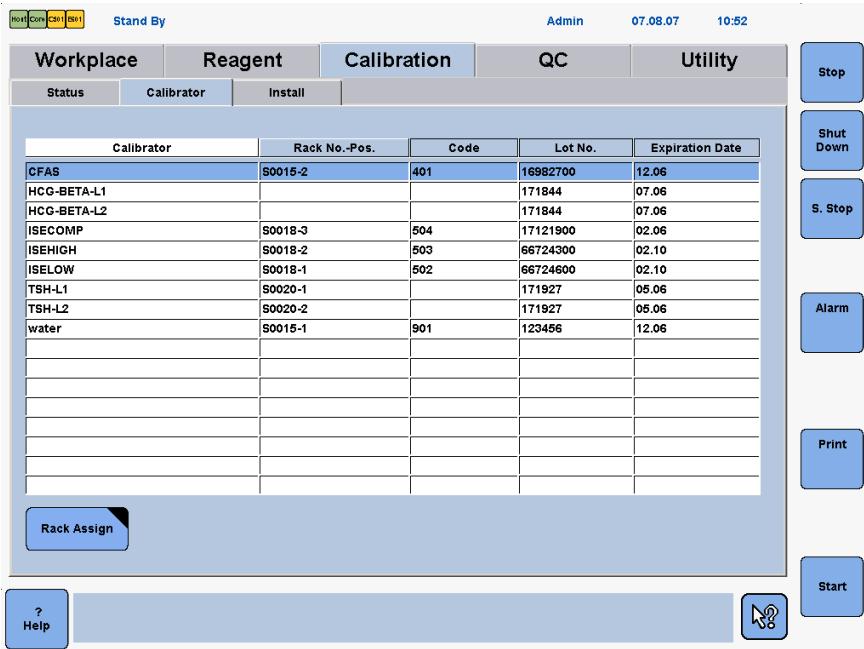


Figure B-78 Calibration > Calibrator window

The **Calibration > Calibrator** screen is used to review information about already registered calibrators and to assign calibrators to specific racks and positions. The rack assignment is necessary for calibrators that are used without barcode identification.

- For information about particular tasks associated with this screen, see:
Assigning calibrator positions on page B-153
Loading calibrator vials for e 601 tests on page B-154
 - For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Assigning calibrator positions

Use the following procedure to assign a rack number and position to a calibrator if you are using cups without a barcode, or if the system cannot read the barcode on the calibrator vial.



Do not use barcoded calibrator vials on racks that have been assigned for non-barcoded calibrator vials.

- In this case the instrument generates an alarm and no calibration is performed. The rack is passed to the output buffer.
 - If you have to manually assign a calibrator vial to a calibrator rack, for example, due to an unreadable barcode, place this calibrator vial on the assigned rack in the correct position.

► To assign calibrator positions

- ## **1 Choose Calibration > Calibrator > Rack Assignment.**

Rack Assignment				
Calibrator	Code	Lot No.	Rack-Pos.	Calibrator
				Code
CFAS	401	16982700	S0015-1	water
HCG-BETA-L1		171844	S0015-2	CFAS
HCG-BETA-L2		171844	S0015-3	
ISECOMP	504	17121900	S0015-4	
ISEHIGH	503	66724300	S0015-5	TSH-L1
ISELOW	502	66724600	S0016-1	TSH-L2
TSH-L1		171927	S0016-2	
TSH-L2		171927	S0016-3	
water	901	123456	S0016-4	
			S0016-5	
			S0017-1	ISECOMP
			S0017-2	ISEHIGH
			S0017-3	ISELOW
			S0017-4	
			S0017-5	

Figure B-79 Rack Assignment window

- 2** Select the calibrator to be assigned to a rack ID and position from the list on the left.
 - 3** Select a rack ID and position from the list on the right:
 - The position selected for the assignment has to be an empty line in the list.
 - On e 601 modules the calibrator vials must be assigned to consecutive positions on the same rack.
 - On c 501 modules the calibrator vials can be in different racks.
 - 4** Choose **Assign** to assign the selected calibrator to the selected position.
To undo the assignment choose **Remove** or choose **Cancel** to leave the **Rack Assignment** window without saving any changes.
 - 5** To assign further calibrators repeat steps 2 to 4.
 - 6** After all necessary assignments are completed, choose **OK** to save the changes.



Loading calibrator vials for e 601 tests

The calibrators used for the calibration of e 601 tests come in barcoded vials. To ensure correct pipetting from these vials it is important that they are placed correctly in the calibration racks.



- Before placing calibrators and controls on the loader, check that no bubbles or foam are visible on the liquid surface.
- Barcoded calibrator vials for e 601 modules can be used for a maximum of 4 calibration events.

► To load calibrator vials

- 1 Place both calibration vials of a CalSet in a black calibrator rack according to the figure below.

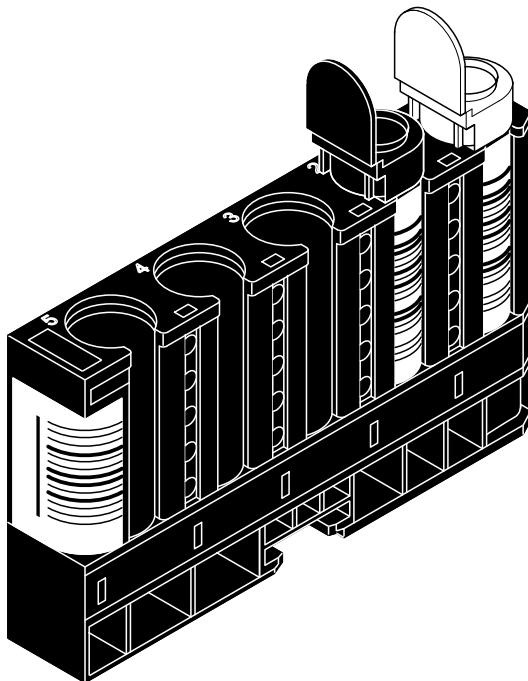


Figure B-80 Loaded vial on calibrator rack

- 2 Open the lid of the calibrator vials ensuring that they are perpendicular to the rack (see figure above).
- 3 Load the calibration rack into the loader.



System Overview screen

The following section explains calibration tasks associated with the **System Overview** screen.

Choose the graphical icon representing the configuration in the status line (top left of the screen), or press <F12> to display the **System Overview** screen.

Calibrating tests during operation

Calibration is usually performed at the beginning of routine operation before sample processing begins. However, it can be done anytime during routine operation as well.

The procedure for calibrating tests during operation is essentially the same as the calibration at the beginning of routine operation:

► **To perform calibrations during operation**

- 1 Request the recommended calibrations via the **Calibration and QC Selection** button (highlighted yellow) on the **System Overview** screen.
 - 2 Print the load list.
 - 3 Prepare the calibrator(s).
 - 4 Place the calibrator rack(s) on the loader.
 - 5 Start the calibration measurement.
- ☞ For a detailed description of the calibration process at the beginning of routine operation, see *Calibration and QC Select button* on page B-42.



QC

This chapter provides descriptions of the basic QC concepts as well as of special tasks that are not usually part of the daily workflow. It is meant to complement the chapter Daily operation, where everyday tasks and common procedures for running the cobas 6000 analyzer are described.

In this chapter

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QC concept

Regularly perform QC measurements to continually monitor the instrument performance. After measurement of QC samples, data can either be transferred to and processed on a Host or they can be processed on the analyzer.

QC methods

The following QC methods are available on a cobas 6000 system: Individual (intraday) QC, cumulative (long-term) QC, and realtime QC.

Individual and cumulative QC

All results of QC measurements can be viewed on the **QC > Run Status** screen and the **QC > Individual** screen. It is recommended to transfer QC data at the end of a day from the individual QC to the cumulative QC. Under cumulative QC you find all the long-term quality control information stored on the system.

- ☞ For more information, see:
 - QC Run Status screen* on page B-168
 - QC Individual screen* on page B-170
 - QC Cumulative screen* on page B-178
- ☞ For more details on the accumulation of QC data (from individual to cumulative QC), see:
 - Accumulation methods for QC measurement data* on page B-161
 - Accumulation of QC results* on page B-177.

Realtime QC

Independent of individual and cumulative QC, the realtime QC function allows the evaluation of QC measurement immediately after their results become available (realtime) utilizing the Westgard algorithm.

Realtime QC for one test always uses two kinds of controls and compares QC results against the controls' known standard deviation (SD) and mean values.

- ☞ For more information on realtime QC, see *Configuring and using realtime QC* on page B-173.

System implementations for QC measurements

In addition to the QC *methods* explained above, there are six *types* of implementations which are available to manage the measurement of QC samples:

- Routine QC
- Standby reagent QC
- Timeout QC
- Automatic QC
- QC after calibration
- Manual QC

Routine QC Each test has one or more controls assigned to it. Moreover, a test must be not only *assigned* to a control but also *activated* for that control to make a QC measurement possible. Routine QC comprises all activated tests of all installed controls. You can request a QC measurement for all of these tests—for example, at the beginning of a work shift—with one single command (**System Overview > Calibration and QC Select > Routine QC**).

- ☞ For more information about routine QC, see:
Requesting QC measurements on page B-166
To perform controls for active reagents on page B-166

Standby reagent QC QC measurements can be requested individually for standby reagents. Standby reagents are **cobas c** packs and **cobas e** packs already on board but not in use at present.

- ☞ For more information about standby reagent QC, see:
Requesting QC measurements on page B-166
To perform controls for standby reagents on page B-167

Timeout QC QC measurements can be performed at predefined (test-specific) time intervals. When the time interval has elapsed, the system issues a recommendation for a QC measurement. This is indicated by the **Calibration and QC Select** button on the **System Overview** screen lighting up in yellow.
In case an automatic QC rack is standing by in the rack rotor, this rack is transferred to the sample line and measurements are performed fully automatically.

- ☞ See *Timeout QC* on page B-165.

Automatic QC It is possible to keep frequently used controls in the rack rotor—ready to be used any time before or during routine operation. Thus, in combination with Timeout QC, the system is able to perform QC measurements without any intervention by the operator.

- ☞ See *Automatic QC measurement* on page B-187.

QC after calibration For this kind of QC measurements no special settings are needed. Whenever a calibrator rack(s) (black) is immediately followed by a QC rack (white), QC measurements are performed for all calibrated tests without explicit requests from the operator.



If you use *QC after calibration*, the QC results are always calculated with this new calibration curve.

- Manual QC* This function allows you to measure QCs of any items based on your judgment.
- ☞ See *Requesting QC measurements* on page B-166.

Accumulation methods for QC measurement data

At the end of daily operation, QC measurement data should be accumulated. When accumulating QC results, the corresponding data are deleted from the **QC > Individual** screen and transferred to the **QC > Cumulative** screen.

Two accumulation methods There are two accumulation methods available: **Mean-R** and **X-R**. The choice for one or the other method is made under **Utility > System (Page 1/4) > QC Setting**.

- **X-R** transfers only **one** QC result from individual QC to cumulative QC. Therefore you must specify a measurement when accumulating QC data.
- **Mean-R** calculates cumulative QC data on the basis of **all** individual QC results being accumulated.

Two calculation methods If **Mean-R** is set as accumulation method, two methods are available for the calculation of mean values and SD values in cumulative QC: **DayToDay** and **Overall**.

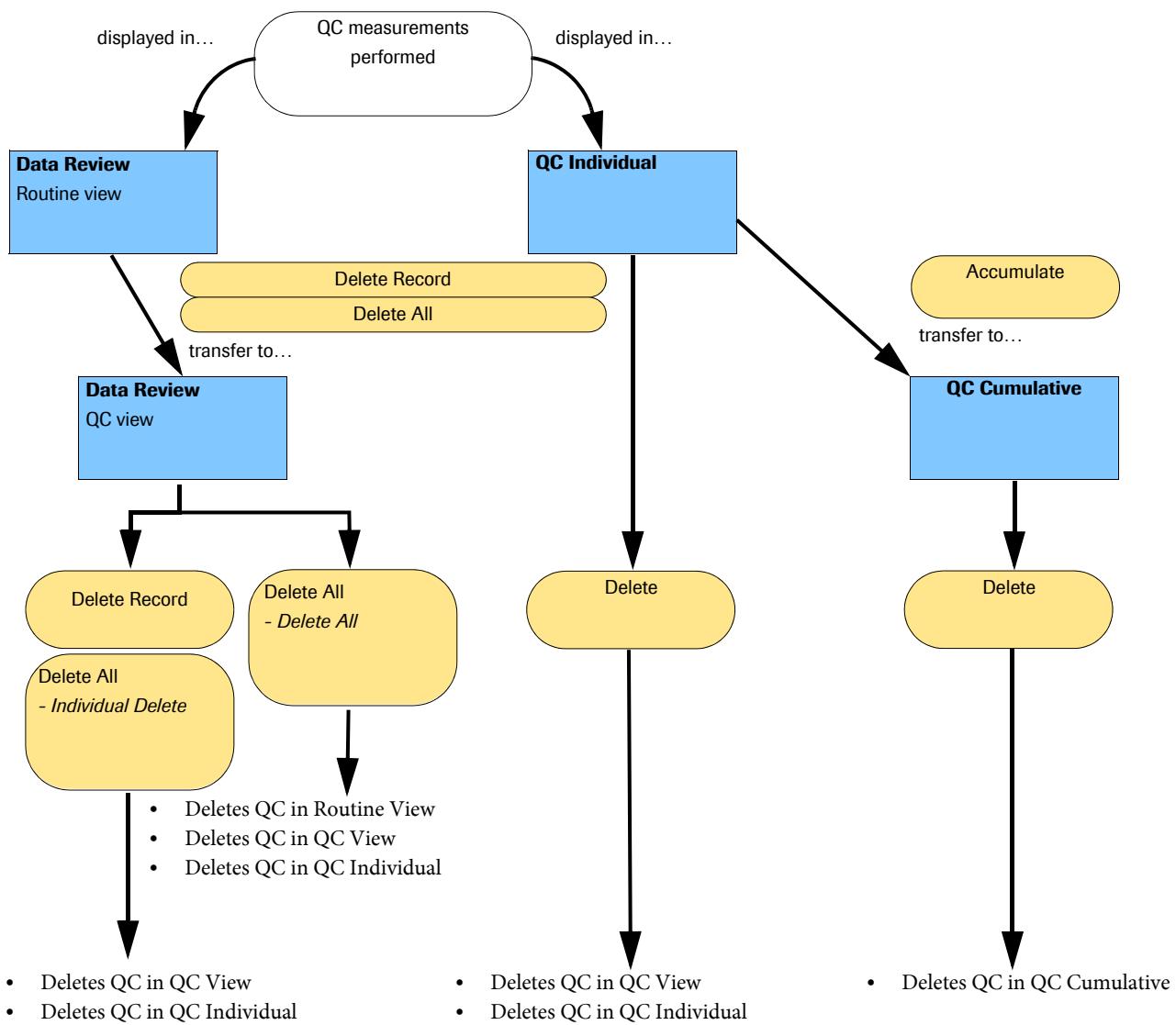
- The **Overall** method uses a weighting factor for each accumulated set of data.
- In the **DayToDay** calculation method all accumulations have the same weight.

The calculation method is selected under **Utility > System (Page 1/4) > QC Setting**.

- ☞ For more information on the different calculations of mean and SD values according to the DayToDay or Overall method, see *Accumulation of QC results* on page B-177.

Handling of QC results

The following chart shows the handling of QC results starting with the measurement of QC samples and ending with the deletion of QC results. It shows the different screens that display QC results, and shows the particular action that moves (deletes, accumulates) the results from one screen to another screen.



Recommendation

Workflow for handling QC results in order to keep as little QC data as possible

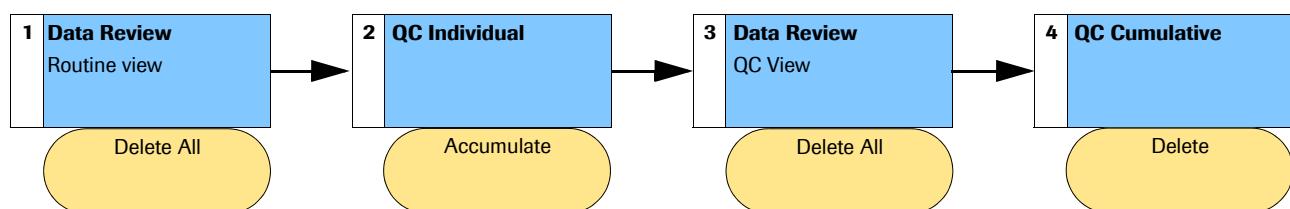


Figure B-81 Workflow for handling QC results

Summary **QC View** is linked with the QC individual database. If a QC result is deleted in the **QC View** database, it is as well deleted in the QC individual database and vice versa. Therefore it is recommended to first accumulate individual QC results before deleting QC data on **Data Review > QC View**.

QC data of the QC cumulative database should only be deleted, if the particular data is no longer required.

Working in barcode or non-barcode mode

On the **Utility > System** screen under **Barcode Setting**, you can verify or change whether the system uses barcodes for controls or not.

When working with barcodes, controls are automatically identified. In case controls are processed in non-barcode mode, it is necessary to assign a rack number and rack position for each control.

The current rack assignment is listed on the **QC > Control** screen. To provide additional assignments or remove existing assignments choose **Rack Assignment**.



- For assigned controls (without barcode), be sure to use the specified racks and positions. A misplacement would go undetected by the system and yield completely invalid results.
- Do not use barcoded controls on a QC rack that is assigned for non-barcoded controls.

For more information, see **QC Control screen** on page B-179.

QC Status screen

The following sections explain certain tasks associated with the **QC > Status** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **QC > Status**.

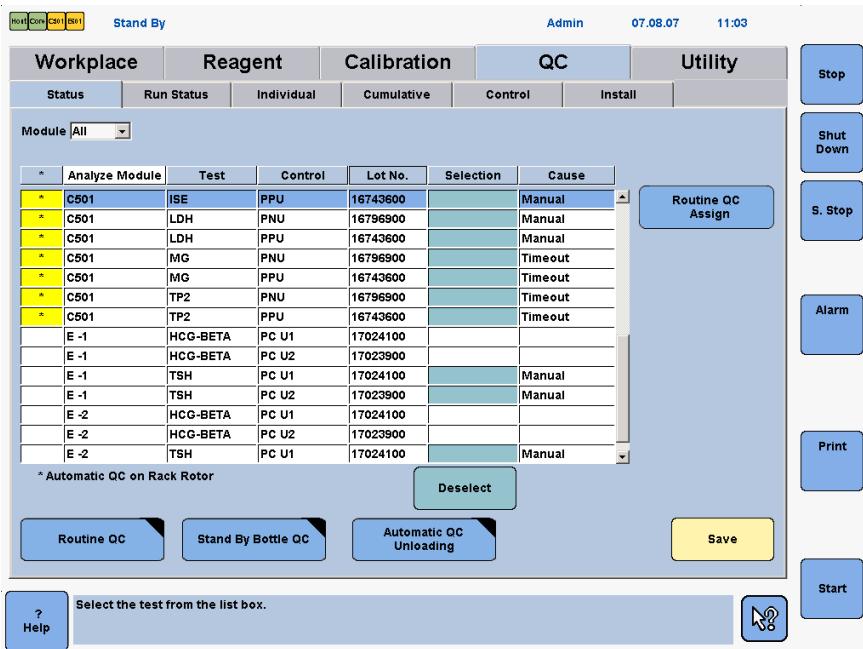


Figure B-82 QC > Status screen

The **QC > Status** screen displays all installed controls with the corresponding assigned and activated tests for each module and channel.

The test display can be sorted by module, test name (alphabetical order), control name (alphabetical order), QC test selection, or QC cause. Tests can be selected with the **Select/Deselect** button. Selected tests are highlighted in green. A control test selection is made for the subsequent control run. The control test selections of the status list are deleted after the control is measured.



Only the test selection of pipetted control tests are deleted. If a test is requested but the control vial is not inserted, the QC request remains.

An asterisk (*) in the first column of the **QC > Status** screen denotes which control is used as automatic QC.

For more information, see *Automatic QC measurement* on page B-187.

Routine QC Assign

The **Routine QC Assign** button selects all Routine QC tests (current reagents only) for a control measurement. Routine QC tests are all activated tests for all installed controls.

Tests that are not to be measured can be deselected on the **Status** screen: Highlight the concerned line(s) on the status list and then use the green Deselect button.

For more information, see *To perform controls for active reagents* on page B-166.

Direct access from System Overview screen

From the **System Overview** screen, select the **Calibration and QC Select** button and then the **Routine QC** button in the **QC** area on the right. This is essentially the same as selecting the **Routine QC Assign** button on **QC > Status**.

For more information, see *To request calibration and QC* on page B-43.

Automatic QC Unloading

Use this button to unload auto QC racks from the rack rotor. In the **Automatic QC Unloading** window select the rack(s) to be unloaded and choose **Select**. Then choose **Execute**.

For more information, see *Automatic QC measurement* on page B-187.

For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Timeout QC

A control interval in hours can be defined for each application on the **Range** tab on **Utility > Application**. Select the **Control Interval Time** check box and type the appropriate time in the adjacent text box.

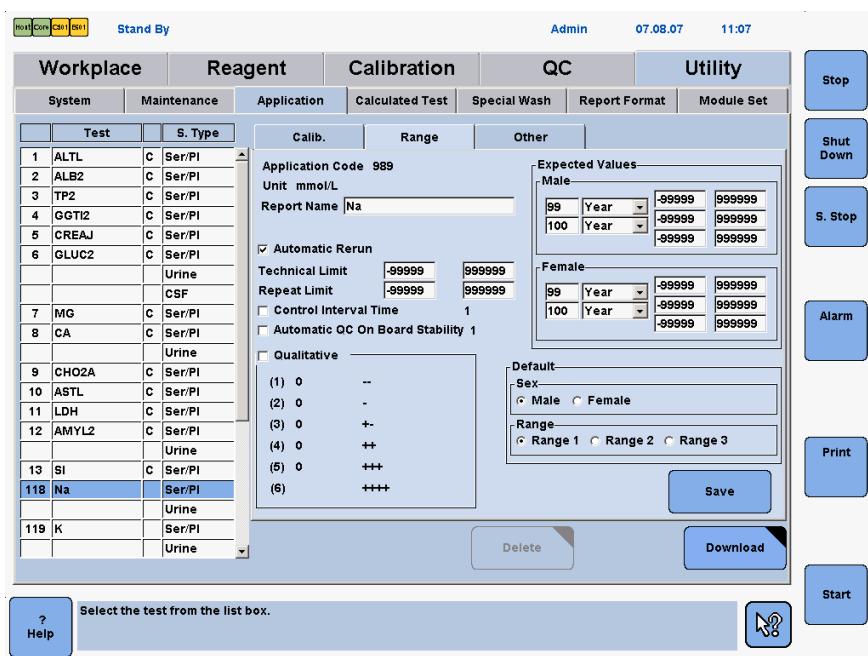


Figure B-83 Range tab on Utility > Application

The system checks the timeout every 30 minutes. When the specified time has elapsed, a QC request is triggered. This QC request is indicated on the **QC > Status** screen by the word **Timeout** in the **Cause** column.

If there is an auto QC rack in the rack rotor with a suitable control, the system performs an automatic QC.

The control is measured with the active (in use) **cobas c pack** or **cobas e pack**.

Requesting QC measurements

QC measurements can be requested individually for active and standby reagents. Active reagents are **cobas c** packs and **cobas e** packs currently in use. Standby reagents are **cobas c** packs and **cobas e** packs already on board but not in use at present.



- Expired controls are possible to be used on **c 501** modules and **e 601** modules. No alarm is issued.
- Do not use barcoded control vials on the same rack as assigned for non-barcoded control vials.



Only load racks onto the loader when the green light is on.

- For more information about requesting QC measurements according to the intended use, see *Requesting calibration and QC and printing load lists* on page B-43.
- For more information about requesting QC manually, see:
 - To perform controls for active reagents* on page B-166
 - To perform controls for standby reagents* on page B-167
 - To perform QC after calibration* on page B-167

► To perform controls for active reagents

- 1 On **QC > Status** select the module where the QC is to be performed from the **Module** box.
- 2 If routine QC is to be performed, choose **Routine QC** to select all tests that are currently loaded on the system and activated for QC.
If individual tests are to be selected, go to step 3.
- 3 Choose the appropriate test, control and measuring channel, if applicable.
Multiple tests, controls and measuring channels can be highlighted.
- 4 Choose **Select**. A blue bar appears in the Selection column. Manual is displayed in the **Cause** column.
The **Select** button toggles to **Deselect**.
- 5 Choose **Save** to request the selected controls for measurement.
- 6 Print a QC load list and load controls onto the system.
 - Choose **Print** (global button) > **QC** and select **QC Load List**.



You can also print a QC load list from **System Overview > Calibration and QC Select**. Select the **QC Only** option in the **Load List** area and choose **Print**.



- Choose **Print**. The System prints a **QC Load List**.
- Place the controls in white racks and load them onto the loader.

Routine QC does not include QC measurement for standby reagents. To perform controls for standby reagents, QC measurement has to be requested separately.



► To perform controls for standby reagents



- **Stand By Bottle QC** can not be requested, when the analyzer is in operation. Before requesting QC measurement for standby reagents, put the analyzer into **S.Stop**.
- Additional steps may be necessary if your **cobas** 6000 system is connected to a preanalytical system.

- 1 On **QC > Status** choose **Stand By Bottle QC** to display the **Stand By Bottle QC** window.

Analyze Module	Reagent Position	Status	Test	Control	Lot No.	Selection
C501	14	SB1	TP2	PPU	16743600	
C501	15	SB2	ALTL	PNU	16796900	
C501	15	SB2	ALTL	PPU	16743600	
C501	16	SB3	ALTL	PNU	16796900	
C501	16	SB3	ALTL	PPU	16743600	
C501	19	SB1	ALTL	PNU	16796900	
C501	19	SB1	ALTL	PPU	16743600	
E -1	5	SB1	TSH	PC U1	17024100	
E -1	5	SB1	TSH	PC U1	17024100	
E -1	5	SB1	TSH	PC U2	17023900	
E -1	5	SB1	TSH	PC U2	17023900	
E -2	5	SB1	TSH	PC U1	17024100	

Figure B-84 Stand By Bottle QC window

- 2 Select the appropriate test, control, and measuring channel if applicable. Multiple tests, controls, and measuring channels can be highlighted.
- 3 Choose **Select**. A blue bar appears in the **Selection** column. Manual is displayed in the **Cause** column.
The **Select** button toggles to **Deselect**.
- 4 Choose **OK** to request the selected controls for measurement.
- 5 Print a **QC Load List** and load controls onto the system.

■

► To perform QC after calibration

A calibration request automatically triggers a QC request for that reagent (current and standby reagents). A QC rack has to directly follow the calibrator rack.

■

QC Run Status screen

To display this screen choose **QC > Run Status**

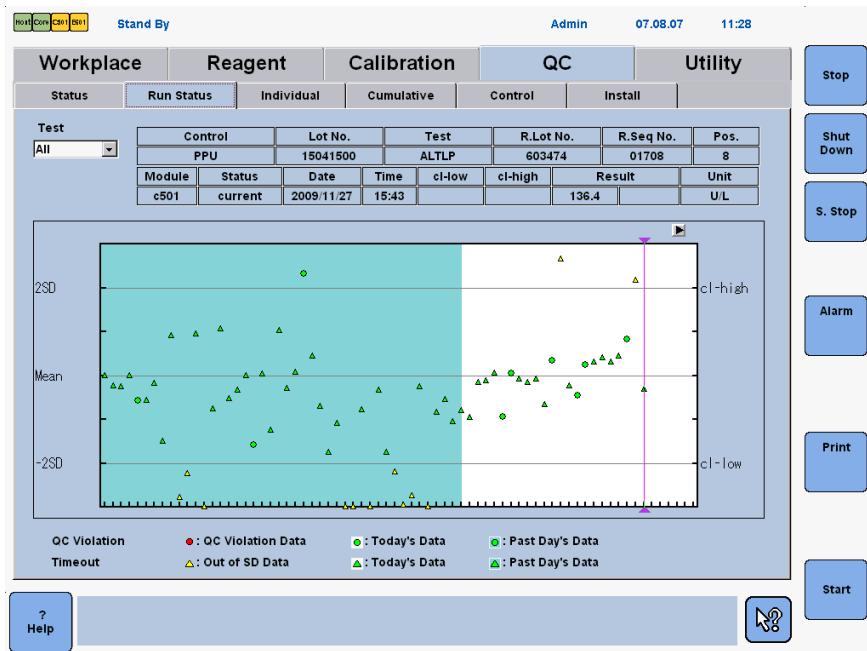


Figure B-85 QC > Run Status screen

Use the **Run Status** screen to get an overview of the last 500 quality control (QC) measurements performed on the analyzer or to view the most recent QC measurements for one particular test specified.

Use the **Test** box to select all tests or one specific test to be displayed on the chart. Use the arrows at the top right of the chart to move the focus from one result to the next.

- For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

QC run status details

The **Run Status** screen consists of a details area in the upper part of the screen and a run status chart in the center of the screen. The details area displays information that relates to the QC measurement selected on the run status chart. The chart in the center of the **Run Status** screen displays up to 500 results of QC measurements.

Chart background

A white background refers to today's measurements. A blue background refers to past days' measurements.

Chart symbols **Shape:** Circles are used when **QC Violation** is activated; otherwise triangles are used.

- For more information on **QC Violation**, see *QC-triggered calibration (QC Violation)* on page B-128.

Color: Red and yellow denote a QC result falls out of confidence limits or 2 SD limits, respectively. Green symbols are used for results within the relevant limits.

	Displayed if QC violation is activated	QC result exceeds confidence limit (right axis of chart). A calibration is automatically recommended for the affected test.
	Displayed if QC violation is activated	QC result within confidence limits
	Displayed if QC violation is not activated and confidence limits are not checked	QC result falls outside ± 2 SD (left axis of chart)
	Displayed if QC violation is not activated	QC result within ± 2 SD



The confidence limit for all Elecsys PreciControls is $+/- 3$ SD. However, in the software and on the print out control results are flagged if the 2 SD interval is exceeded. This range may be altered by the operator to meet the $+/- 3$ SD range.

Special fields in the details area

Status: This field displays a reagent's status of precedence. Possible values are **Current**, **SB1**, **SB2**, **SB3**...

Current	Reagent (that is, cobas c pack or cobas e pack) currently in use
SB1	(Standby reagent 1) The reagent which will be used after the current reagent
SB2	(Standby reagent 2) The reagent which will be used after SB1 reagent



The order of precedence of standby reagents within the same lot is assessed by the reagents' time of registration; the oldest reagent is used first.

cl-low / cl-high: These fields display the confidence limits specified for the selected test. If the selected test is not configured for QC violation but for timeout calibration, the fields under **cl-low** and **cl-high** are blank.

QC Individual screen

The following sections explain certain tasks associated with the **QC > Individual** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **QC > Individual**



Figure B-86 QC > Individual screen

The **QC > Individual** screen lists all non-accumulated QC results.

The list can be sorted by test name, module, and control name. The table below explains the most important columns of the list.

Reagent Lot No.	cobas e pack number (for e 601 only)
Control	Name of the control
Control Lot No.	Lot number of control material
Target Mean	Control target mean
Target SD	Control target standard deviation
N	Number of QC runs carried out on this control since the last accumulation
Mean	Calculated mean of N measurement results
SD	Standard deviation calculated from N control measurements
CV [%]	Coefficient of variation calculated from the mean value
Result	Most recent QC result of this control

- ⦿ For information about particular tasks associated with this screen, see: *Excluding an individual QC point or adding a comment* on page B-172
- ⦿ For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

On the **QC > Individual** screen, choose **Chart** to open the **Individual QC Chart** window.

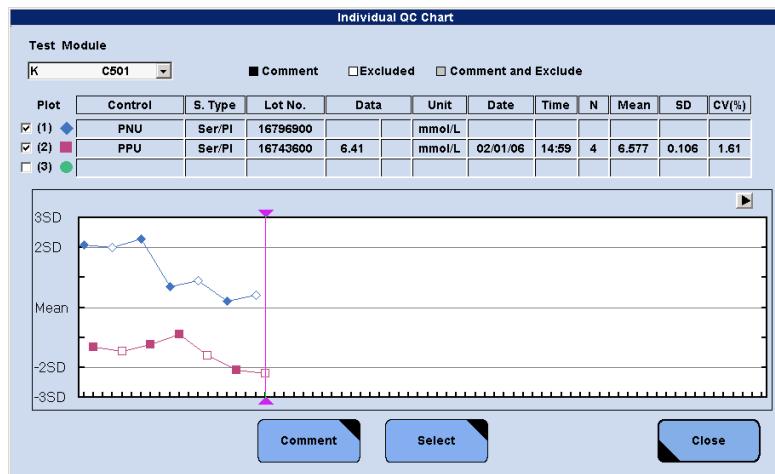


Figure B-87 Individual QC Chart window

This window displays all non-accumulated QC results for the selected test in a Levey-Jennings chart. A Levey-Jennings chart provides a visual method of monitoring trends in QC results. The result values are scaled to the standard deviation (SD) of the respective test.

Up to three controls for one test can be selected (**Select** button) and displayed on one chart.



If for one test different sample types are defined (**S. Type**), for example serum and urine, then the corresponding control within the QC chart must be selected, based on the sample type.

Example:

For serum samples select **PNU** and **PPU**. For urine samples select **Biorad 1** and **Biorad 2**.

Excluding an individual QC point or adding a comment

Individual QC points on a QC chart can be excluded from QC calculations if required. It is also possible to annotate individual QC points.

► To exclude an individual QC point and add a comment

- 1 Choose QC > Individual > Chart.
- 2 Select the QC point to be excluded from QC calculations.
- 3 Choose Comment on the **Individual QC Chart** window to display the **Comment** window.
- 4 If necessary type a comment (max. 20 characters) in the **Comment** box.
- 5 Choose **Exclude**. The window is closed after confirmation.

This removes the point from statistics but continues to display the information on the chart.

- A comment is attached to this point
- The point is excluded
Also results from a standby **cobas c pack/cobas e pack** are shown as excluded.
- The point is excluded and a comment is attached

Excluded points cannot be included later.

- 6 Choose OK.



Configuring and using realtime QC

In realtime QC the system uses the Westgard algorithm to evaluate QC measurements. The Westgard algorithm is based on a multi-rule Shewhart-type method and applies a set of rules to each QC. These rules are selected from **QC > Individual > Realtime QC > Select Rules** for each test.

Quality control by the Shewhart method

The instrument measures two control samples (X and Y) in pairs, whose mean value (\bar{X}) and standard deviation (SD) are known for each test. Each QC result is processed according to the judgment standard (multi-rule) and it is judged whether it can be reported or not.—When the algorithm yields an error, an alarm is generated indicating whether the error is random error, QC error, or systematic error.

The kinds of realtime QC samples are 100 at a maximum. Figure B-88 shows an illustration of the multi-rule chart.

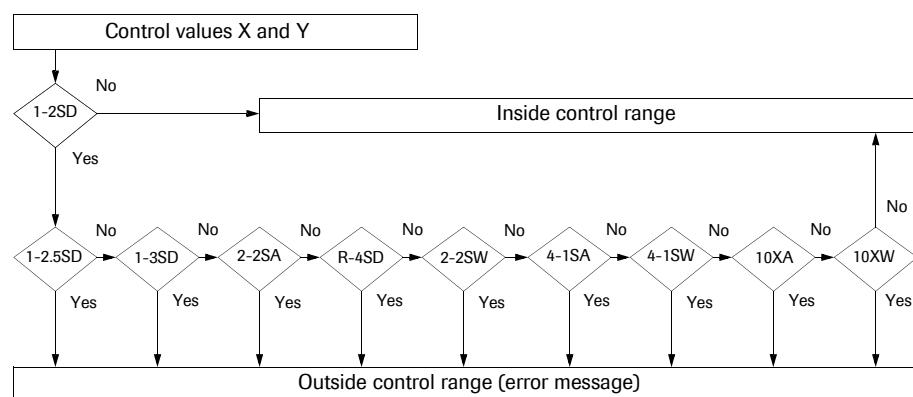


Figure B-88 Application of multi-rule Shewhart-type method in realtime QC

Configuration of realtime QC

Configure realtime QC in **Realtime QC** window (**QC > Individual > Realtime QC**): Choose **Select** to specify control (X) and control (Y) for each relevant test. Then, choose **Rules** to select the rules.



Only QC results of currently used **cobas c** packs and **cobas e** packs are evaluated.

For more details see *Configuring realtime QC* on page B-176.

The following table briefly explains all rules that are selectable for realtime QC and lists the corresponding alarms.

For more details, refer to the COBI CD.

Rule	Order	Judgement	Judgment area	Alarm
1-2SD	1	Either X or Y data value is above +2SD or below -2SD.		None
1-2.5SD	2	Either X or Y data value is above +2.5SD or below -2.5SD.		Q2.5SD
1-3SD	3	Either X or Y data value is above +3SD or below -3SD.		Q3SD
2-2SD	4	Both of X and Y data values are above +2SD or below -2SD.		S2-2Sa
	6	The last two X or Y data values are above +2SD or below -2SD.		S2-2Sw

Table B-20

QC evaluation by Shewhart multi-rule method and corresponding alarms

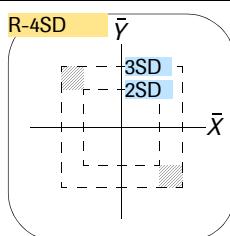
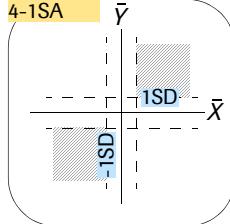
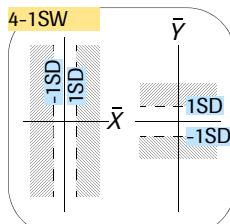
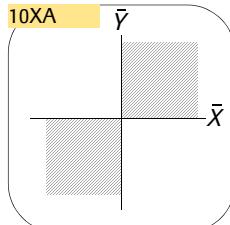
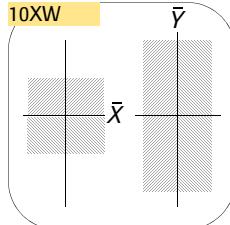
Rule	Order	Judgement	Judgment area	Alarm
R-4SD	5	One of X and Y data value is above +2SD and the other is below -2SD.		R-4SD
4-1SD	7	The last two X and Y data values are above +1SD or below -1SD. (Total 4 values)		S4-1Sa
	8	The last four X or Y data values are above +1SD or below -1SD.		S4-1Sw
10X	9	The last five X and Y data values fall on the + or - side of the mean value. (Total 10 values)		S10Xa
	10	The last ten X or Y data values fall on the + or - side of the mean value.		S10Xw

Table B-20

QC evaluation by Shewhart multi-rule method and corresponding alarms

Configuring realtime QC

Choose QC > Individual > Realtime QC to display the Realtime QC window.

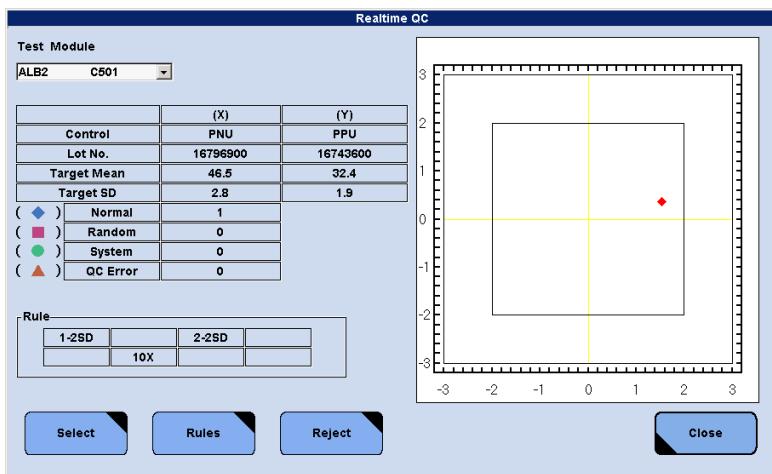


Figure B-89 Realtime QC window

This window shows a diagram with the QC results for a selected test and a selected pair of controls. The diagram is scaled to the target SD of control (X) and control (Y), respectively. The newest QC result is shown in red.

Select Choose this button to assign two controls—control (X) and control (Y)—to be evaluated by the multi-rule method.

Rules Choose this button to select rules used to evaluate the QC results. A pair of controls is compared against a known standard deviation (SD) and mean. If one or both of the controls fail a rule, the system continues applying the testing criteria for all selected rules. When at least one rule violation is found, the corresponding data alarm is issued.

The following symbols are used in the realtime QC plot:

- ◆ Normal: Without QC errors
- Random: Random QC errors
- ◆ System: System QC errors
- ▲ With intermediate QC errors

Reject Choose this button to reject realtime QC results that have specific data alarms attached. Affected result points are removed from the plot.

Accumulation of QC results

At the end of daily operation, QC measurement data should be accumulated. There are two accumulation methods available: **Mean-R** and **X-R**. The choice for one or the other method is made under **Utility > System (Page 1/4) > QC Setting**.

- ☛ For an explanation of the two accumulation methods, see
Accumulation methods for QC measurement data on page B-161.

System settings for QC accumulation

Choose **Utility > System (Page 1/4) > QC Setting** to display the **QC Setting** window.

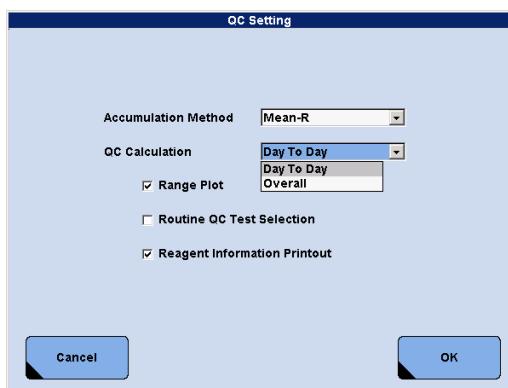


Figure B-90 Utility > System (Page 1/4) > QC Setting window

Accumulation Method Select one of the two accumulation methods, **Mean-R** or **X-R**, from this box.

- ☛ See *Accumulation methods for QC measurement data* on page B-161.

QC Calculation If the accumulation method is **Mean-R**, select one of the two calculation methods, **DayToDay** or **Overall**, from this box to specify how mean and SD values are calculated in the cumulative QC.

This box is not available if **X-R** is selected in the **Accumulation Method** box.

- ☛ For more information on system settings, see:
System configuration on page B-213

Accumulating QC results

► To accumulate QC data

- 1 Select the data to be accumulated from the list on the **QC > Individual** screen.
- 2 Choose **Accumulate**.
- 3 If **Mean-R** is set as accumulation method, go to step 4.

If **X-R** is set as accumulation method, type the consecutive number of the QC result to be used for the accumulation in the box or type 0 (zero) to transfer the mean value; then choose **OK**.

- 4** In the confirmation window choose **Yes** to accumulate the selected data.

After accumulation the corresponding data are deleted from the **QC > Individual** screen and a new standard deviation (SD) and mean value is calculated and displayed on **QC > Cumulative**.

QC Cumulative screen

To display this screen choose **QC > Cumulative**

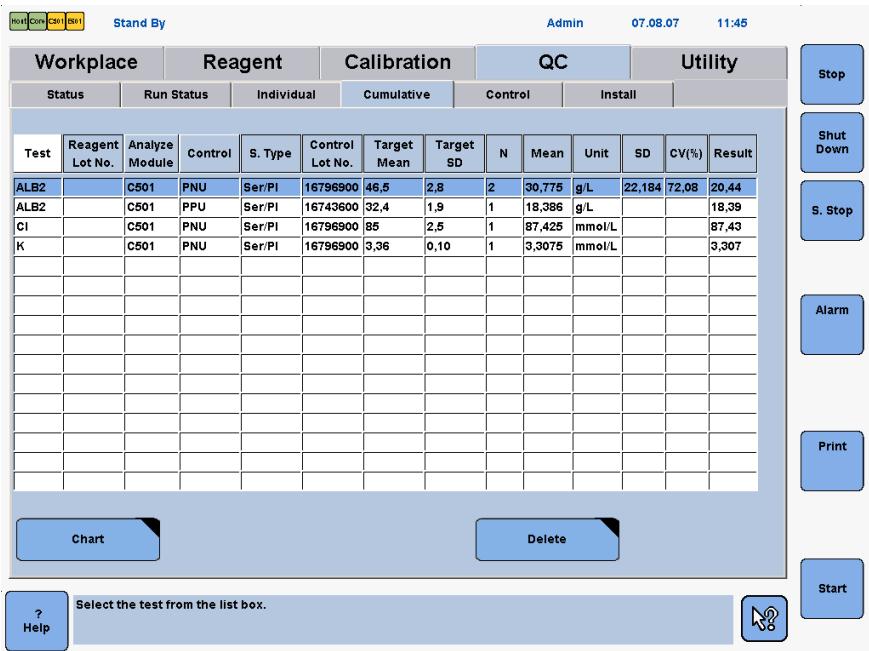


Figure B-91 QC > Cumulative screen

The **QC > Cumulative** screen lists all accumulated QC results.

The list can be sorted by test name, module, and control name. The table below explains columns whose meaning is different from that on the QC > **Individual** screen:

N	Number of accumulations (max. 500)
Mean	Accumulated mean for each test (using the accumulation method selected on Utility > System > QC Setting)

-  For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

QC Control screen

The **QC > Control** screen provides an overview of all controls that are either scanned in by the barcode reader or manually assigned by the operator.

When working with barcodes, controls are automatically identified. In case controls are processed in non-barcode mode, it is necessary to assign a rack number and rack position for each control. The current rack assignment is listed on the **QC > Control** screen.

Choose **QC > Control** to display this screen.

The screenshot shows the 'QC > Control' screen with the following details:

- Header:** Shows 'Stand By' status, 'Admin' user, date '07.08.07', and time '11:48'.
- Navigation:** Buttons for 'Stop', 'Shut Down', 'S. Stop', 'Alarm', 'Print', and 'Start'.
- Table Headers:** Workplace, Reagent, Calibration, QC, Utility.
- Table Rows:**

Control	Rack	S. Type	Lot No.	Exp. Date
Biorad		Ser/PI	12345678	01.06
PC U1	C0002-1	Ser/PI	17024100	01.07
PC U2	C0002-2	Ser/PI	17023900	01.07
PNU	C0001-1	Ser/PI	16796900	01.07
PNU	C0004-1	Ser/PI	16796900	01.07
PNU	C0012-1	Ser/PI	16796900	01.07
PNU	C0014-1	Ser/PI	16796900	01.07
PPU	C0001-2	Ser/PI	16743600	10.06
PPU	C0004-2	Ser/PI	16743600	10.06
PPU	C0012-2	Ser/PI	16743600	10.06
PPU	C0014-2	Ser/PI	16743600	10.06
PPU		Ser/PI	16800900	10.06
- Buttons:** 'Rack Assignment' button at the bottom left, and a 'Help' button with a question mark icon at the bottom center.

Figure B-92 QC > Control screen

To provide additional assignments or remove existing assignments follow the procedure on the following page.

► **To assign a control to a specific rack and position**

- ## **1 On QC > Control choose Rack Assignment.**

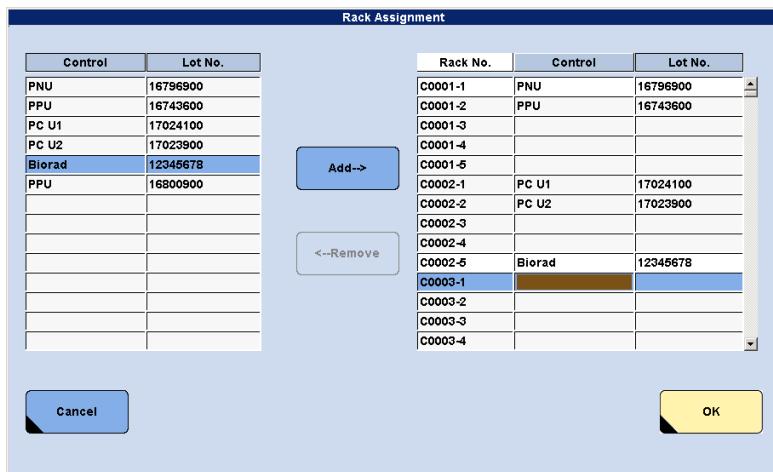


Figure B-93 QC > Control > Rack Assignment window

- 2** On the **Rack Assignment** window select the control from the list on the left and an unassigned rack number and position from the list on the right.
 - 3** Choose **Add** to register the new assignment.
 - 4** To remove an existing assignment select the concerned rack number and position from the list on the right and choose **Remove**.
 - 5** Choose **OK** to save the changes and close the window.

1

QC Install screen

The following sections explain certain tasks associated with the QC > Install screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose QC > Install

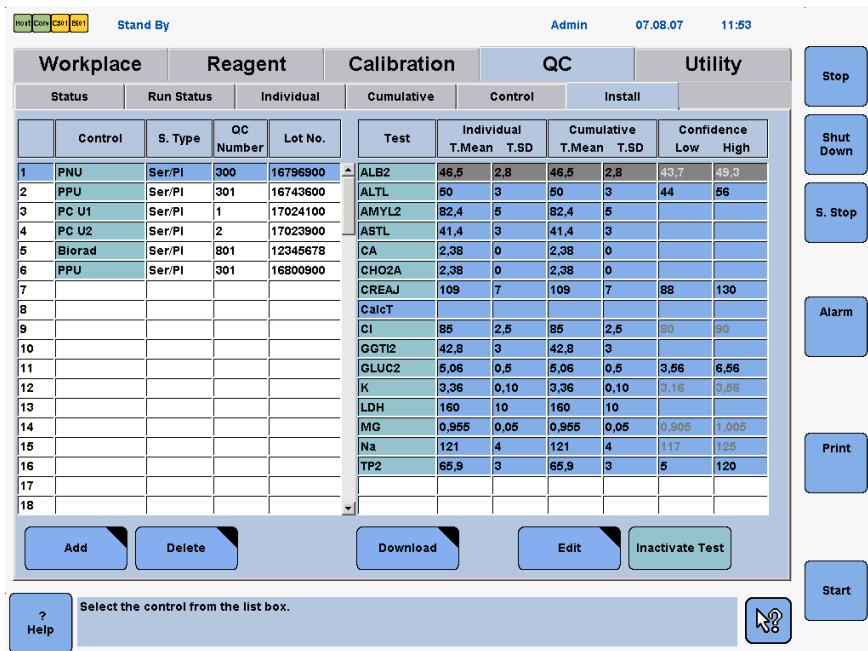


Figure B-94 QC > Install screen

Use this screen to add, delete or download controls from the system and to assign or edit control values.

The list on the left of the screen displays all controls that are installed on the system. For all installed controls the control name is highlighted in green. Up to 100 controls can be installed on the system.

The list on the right of the screen displays details about the tests assigned to the control selected from the control list on the left.

Also calculated tests are available. Calculated tests are only displayed for Roche controls that are used by the tests in the calculation formula or for Non-Roche controls. For calculated tests, the control values must be determined and entered manually.

- ⦿ For information about particular tasks associated with this screen, see:
 - Loading control data* on page B-182
 - Editing control values* on page B-184
 - Activating control tests* on page B-186
 - Programming calculated tests* on page B-229
- ⦿ For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Loading control data

Controls may be installed on the system but the control tests are not run until they are activated from **QC > Install**.

☞ See *Activating control tests* on page B-186.

To install a Roche control, you have to download control data from cobas link.

☞ See *To download control data from cobas link* on page B-182.

To install a Non-Roche control, you add the control manually.

☞ See *To add controls manually* on page B-183.

► To download control data from cobas link

- 1 On the **QC > Install** screen choose **Download**.

The appropriate **Download** window is displayed.

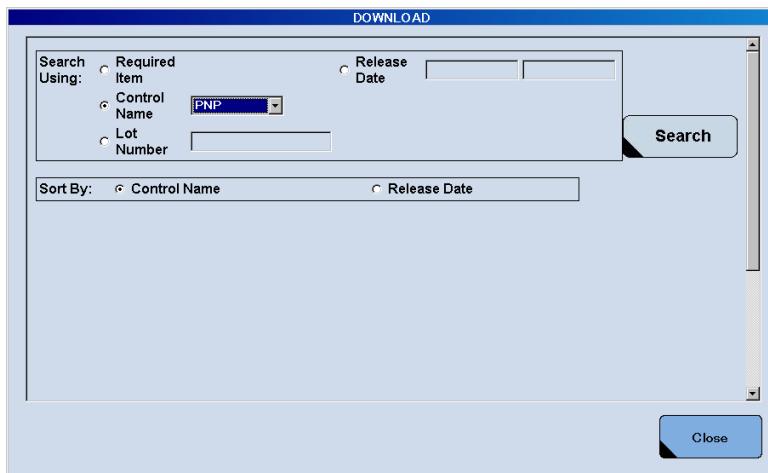


Figure B-95 Download window (tentative screen proposal)

- 2 In the **Search Using** area select a search option.
- 3 Choose **Search** to start searching for the selected criteria.
The search results are displayed.
- 4 Select the check box(es) in the **Selection** column to download the necessary control information and choose **Download**.
- 5 Confirm the message on the confirmation windows to start the download.
All necessary information, such as applications covered by the control, target mean values, and target SD values, is automatically stored by the system.

To run control tests with a newly installed control it is necessary to activate these tests.

☞ See *Activating control tests* on page B-186.

If necessary it is possible to edit the downloaded target values and/or confidence limits.

☞ See *Editing control values* on page B-184.

► **To add controls manually**

- 1 Select a blank line from the control list on the QC > **Install** screen.
- 2 Choose **Add**.
- 3 Type all necessary data in the **Add Control** window.

The **Material No** range is from 801-999.

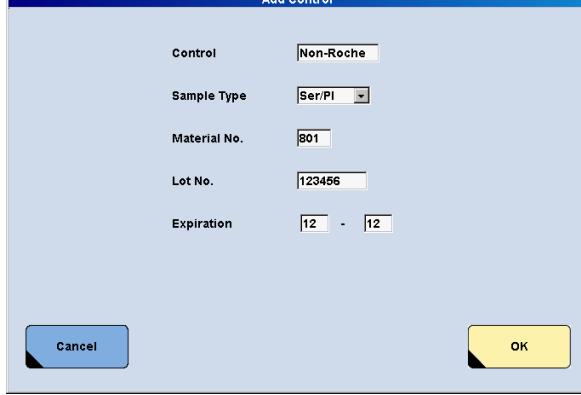


Figure B-96 Add Control window

- 4 Choose **OK**. The new control appears on the control list.

To run control tests with the newly installed controls, it is necessary to manually enter the target values for each test and then to activate these tests.

- 5 Choose **Edit** to enter target mean, target SD, and confidence limits if necessary. Then choose **Active Test** to activate the tests for the new control.

☞ For more details see:

Editing control values on page B-184

Activating control tests on page B-186



Editing control values

► To edit control values

- 1 On the QC > Install screen choose the name of the control to be edited in the **Control** list on the left-hand side of the screen.
- 2 Choose **Edit** to display the **Edit Control** window.

The screenshot shows the 'Edit Control' window. At the top, it displays 'Control PNU' and 'Lot No. 16796900'. Below is a table with columns: Test, Reagent Lot No., Individual T.Mean, Individual T.SD, Cumulative T.Mean, Cumulative T.SD, Confidence Low, and Confidence High. The table contains data for various tests like ALB2, ALT, AMYL2, etc. To the right of the table are three text boxes: 'Individual' (T. Mean: 46,5, T. SD: 2,8), 'Cumulative' (T. Mean: 46,5, T. SD: 2,8), and 'Confidence Limit' (High: 49,3, Low: 43,7). Below these are 'Calculate' and 'Update' buttons. At the bottom are 'Cancel' and 'OK' buttons. A note at the bottom says 'Unit of Measure g/L'.

Figure B-97 Edit Control window

- 3 Select the test to be edited from the list.
- 4 Type the new target mean and SD (standard deviation) values, cumulative and individual, in the appropriate text boxes.
If the test uses this control for its QC Violation assessment, the **Calculate** button is active; if not skip step 5.
 - ☞ For more information on QC violation, see *QC-triggered calibration (QC Violation)* on page B-128.
- 5 Choose **Calculate** to recalculate the confidence limits on the basis of the edited target and SD values and the QC violation rule (set under **Utility > Application > Calib.**).
- 6 Choose **Update** to update the window.
- 7 Repeat steps 3 to 6 for all tests assigned to this control that need to be edited.
- 8 Choose **OK** to save the changes and close the **Edit Control** window.

■

 In case target and SD values are edited or entered manually the calculation of confidence limits is achieved by choosing the **Calculate** button. However, the confidence limits can also be typed directly in the text boxes under **Confidence Limit**.

The **Calculate** button and the boxes High and Low are not available if the selected test is not configured for QC Violation.

Reassignment of control values

In case of a reassignment of control values, the control values of the **cobas** 6000 system have to be updated.

- At the **c** 501 the new control values can be downloaded, or manually updated.
- At the **e** 601 the new control values are automatically updated via **cobas e** pack barcode, or can be manually updated.



Manual entry has the highest priority in the software, this means that even if another version of control values is downloaded for **c** 501 or read in for **e** 601 the manual input will not be overwritten.

Updating the control values via **cobas e** pack barcode

The barcode of a **cobas e** pack contains the control values for the reagent lot and control lot information and it will be only used, if this lot combination is used on the system. If the lot of the **cobas e** pack is newer than the installed controls, the reassigned control values are updated automatically via the barcode of a **cobas e** pack.

Updating the control values manually

If both the **cobas e** pack and the control are already in the field, and reassigned control values are established, then the customer has to update these values manually in the software. The customer will be informed about this task by the Important Note on the **cobas** link.

► To reassign control values for **c 501** via download

- 1 Download the control values for controls that need to be reassigned.

See *Loading control data* on page B-182



► To reassign control values manually

- 1 Enter the control values for controls that need to be reassigned on the **Edit Control** window.

See *Editing control values* on page B-184

The new control values are communicated via product bulletin and Important Note on the **cobas** link.



Activating control tests

Tests can only be activated when the system is in standby.

► To activate control tests

- 1 On the QC > Install screen choose the appropriate control name in the list box on the left side of the screen.
- 2 Choose the test to be activated in the list on the right of the screen.
- 3 Choose **Activate Test**. The test name highlights in green when the test is activated.
- 4 Repeat step 2 and 3 for all tests to be activated for that control.



To activate a test, it must have target and SD values entered for the control.

 See *Editing control values* on page B-184.

Automatic QC measurement

When a control interval time is specified on **Utility > Application > Range** for an application, it is possible to let the system automatically perform necessary QC measurements with controls that permanently reside in the rack rotor.

Configuring automatic QC measurement

► To program auto QC measurements

- 1 Select the **Control Interval Time** check box on the **Range** tab of **Utility > Application** for the relevant tests and specify a control interval from 1 to 1000 hours.
- 2 Reserve one or more rack rotor positions for control racks under **Utility > System (Page 3/4) > Rack Delivery**.

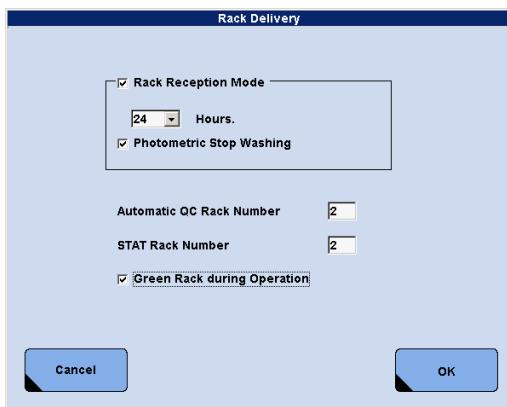


Figure B-98 Rack Delivery window

- 3 Assign a rack range for control racks that are to be used for auto QC measurements:
 - Choose **Utility > System > Change (Rack Assignment area)**.
 - In the **Rack Assignment** window, choose the **Module Setting** tab and enter the rack range in the **Rotor** text fields.

■ When loaded onto the analyzer, the assigned control racks remain in the rack rotor and get used whenever a QC measurement is requested and the auto QC rack holds the appropriate control material.

An asterisk (*) in the first column of the **QC > Status** screen denotes which control is used as automatic QC.

Unloading auto QC racks from the rack rotor

► To unload auto QC racks from the rack rotor

- 1 Choose QC > Status > Automatic QC Unloading.
- 2 In the **Automatic QC Unloading** window select the rack(s) to be unloaded and choose **Select**.
- 3 Choose **Execute**.



Expired controls in auto QC racks

- If you use auto QC racks and a control expires (the onboard stability set on the **Utility > Application > Range** tab is exceeded), the system issues a yellow alarm. Additionally on the **QC > Status** screen, the first column of the corresponding control turns yellow.
- Unload the concerned auto QC rack, replace all controls, and reload the rack onto the analyzer.
- If you do not replace an expired control, the analyzer continues to use this control, which results in unreliable quality controls.



Priority within control materials of the same kind

- When there is more than one control available for a QC measurement, the system uses the control with the longest onboard stability.
- If for example, an automatic QC rack is loaded for QC after calibration and this rack holds a control that is already present in an auto QC rack in the rack rotor, the auto QC control is not used if the additionally loaded control has a later expiration date.

Configuration

This chapter describes the configuration of the cobas® 6000 analyzer series for customers.

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Application

When the system was installed by your technical support all required applications were installed. This section explains how to add new applications and configure specific application parameters.

Overview

General information for photometric tests

Up to 117 photometric applications can be registered (test numbers 1-117), max. 86 applications can be assigned per module. The following test numbers are fixed:

Test number	Test name
118	Na
119	K
120	Cl
121	Serum index L
122	Serum index H
123	Serum index I

Table B-21 Fixed test numbers

General information for immunological tests

Up to 60 heterogeneous immunoassays can be installed, independent of the number of modules. An application can be programmed for each module and measuring cell (E1-1, E1-2 and E2-1, E2-2) individually.



A description for loading Development Channel applications is available on **cobas** link. Refer to the *Instructions for Use* for the **cobas c** pack MULTI. Please contact your technical support for more information.

Loading a new application

Before you can load a **cobas c** pack, another cassette, or a **cobas e** pack of a new application on to the system the application parameters have to be loaded via **cobas** link. Otherwise, the cassette will be rejected by the system and the **cobas e** pack test will not be displayed correctly on different screens of the **Reagent**, **Calibration** and the **Utility** menu.

- ☞ Refer to the following sections to get information about:
 - Loading new application parameters* on page B-192
 - Description of application parameters* on page B-198

Loading or updating new applications

To be able to utilize a new application on the system, you have to perform the following installation procedures:

1. Loading application parameters, customize the default parameters if necessary
 - ☛ For more information, see:
Loading new application parameters on page B-192
Description of application parameters on page B-198
2. Loading calibrator data
 - ☛ See *Loading calibrator data* on page B-147
3. Loading control data
 - ☛ See *Loading control data* on page B-182
4. Assigning rack positions for calibrator and controls (only necessary when working with non-barcoded calibrators or controls)
 - ☛ For more information, see:
Assigning calibrator positions on page B-153
To assign a control to a specific rack and position on page B-180
To assign a test or a profile to a key on page B-217
5. Loading **cobas c** packs or **cobas e** packs

Loading new application parameters

This procedure can be performed by an operator with administrator level password only.

► **To download application parameters from cobas link**

- 1 Choose **Utility > Application** to display the **Application** screen.
- 2 Choose **Download** to start the download of information about additional applications.

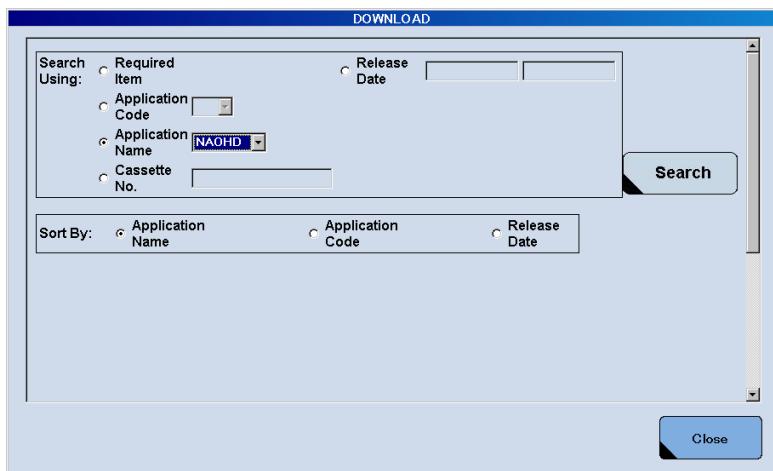


Figure B-99 Download window (application)

- 3** Select the search condition in the area **Search Using:**
- **Required item:** An item that has not been found in the instrument at the time of reagent barcode reading. For measurement necessary parameters must be downloaded.
 - **Application Code, Application Name:** Select the Application from the list box.
 - **Cassette No.:** Enter the Cassette number in the text box.
- 4** Choose **Search** to start searching for the selected criteria. The search results are displayed.

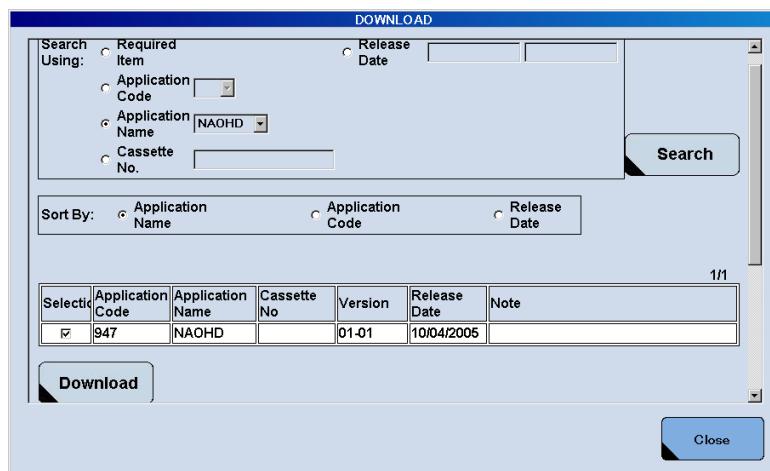


Figure B-100 Download window (application)

In the **Notes** column you can find additional information about the application such as reason for change.

- 5** Mark the check box in the column **Selection** to download the corresponding application and choose **Download**.

- 6 Confirm the message on the confirmation windows to start the download.

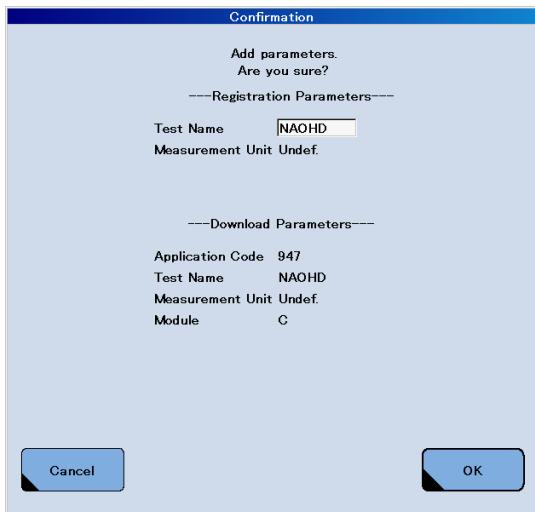


Figure B-101

The short test name assigned to the application automatically displays in the **Test Name** box. However, it is possible to assign a different test name (up to 5 characters) if needed.



Once the application has been downloaded, the test name cannot be changed. In order to change the test name, the application needs to be deleted and downloaded again.

- 7 Choose OK to read all parameter information.

The application parameters of the downloaded application are displayed on the **Application** screen. Some parameters are user-definable.

See *Description of application parameters* on page B-198.



Installing the HbA1c application

This section describes the necessary steps to utilize HbA1c application on the system.

Information on the general installation procedure for a new application is given in the previous section.

See *Loading or updating new applications* on page B-192

Overview

Necessary applications To obtain results for HbA1c (%), the following applications are necessary:

Application/Reagent	Short name	Application code (ACN)
Hemolyzing Reagent	A1CD2	952
Hemoglobin	Hb-W2	870
Hemoglobin A1c	A1-W2	880
% Ratio of Hemoglobin/Hemoglobin A1c	RWI2	890

Table B-22

Applications and reagents of the HbA1c (%) application

Reaction course The following figure shows the reaction course of the application:

1 Sample pipetting

For pipetting EDTA whole blood sample, the sample probe lowers down to 70% of the filling volume.

2 Hemolyzing process

EDTA whole blood sample is pipetted into predilution cuvette and is hemolyzed with hemolyzing reagent (A1CD2).

3 Hemoglobin analysis

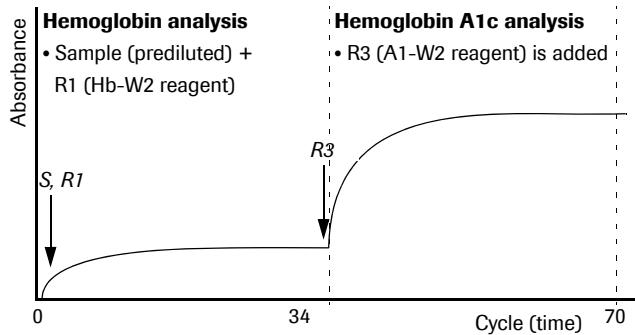
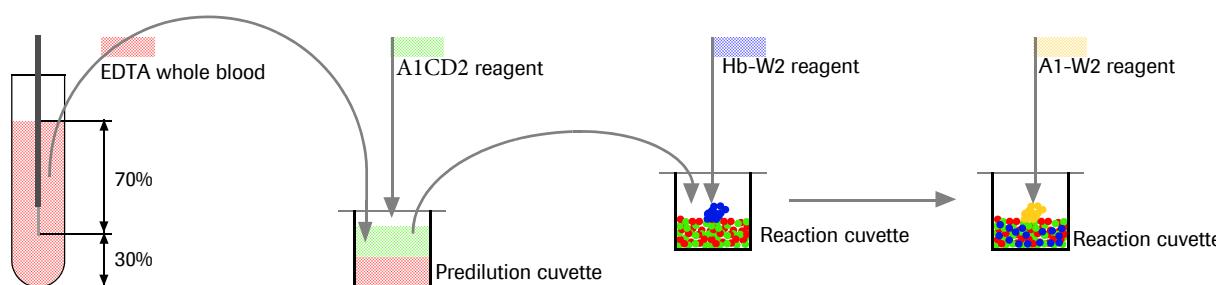
Hemolyzed (prediluted) sample and R1 (Hb-W2 reagent) is pipetted.

- 1 Point assay
- Cycle 1-34

4 Hemoglobin A1c analysis

R3 (A1-W2 reagent) is added.

- 2 Point assay
- Cycle 34-70

**Figure B-102** Reaction course of the HbA1c application

Result calculation The result for the Hemoglobin A1c analysis is calculated according to IFCC standardization:

$$\text{Equation B-1} \quad RWI2 = \frac{A1-W2}{HB-W2} \cdot 100\% \quad (\text{that means } HbA1c \% = \frac{HbA1c}{Hb} \cdot 100\%)$$

This calculated test can be downloaded as application RWI2 (Application code 890)

Installing and configuring the application

To be able to utilize the HbA1c application on the system, you have to perform the following installation procedures:

1. Loading application parameters for the following applications:
 - Hemoglobin (Hb-W2, ACN 870)
 - Hemoglobin A1c (A1-W2, ACN 880)
 - % Ratio of Hemoglobin/Hemoglobin A1c (RWI2, ACN 890)
 - Hemolyzing Reagent (A1CD2, ACN 952)
☞ See *Loading new application parameters* on page B-192
2. Loading calibrator data for the following calibrator:
 - C.f.a.s HbA1c (674)
☞ See *Loading calibrator data* on page B-147
3. To improve the fit of nonlinear HbA1c calibration curve, a constant and lot independent offset of 0.6 g/dl was added to all calibrator values. This offset is already included in the assigned HbA1c calibrator target values and finally needs to be subtracted from the obtained Hemoglobin A1c results.
Please ensure that b = -0.6 is assigned for A1-W2 in **Calibration > Status > Instrument Factor**.
4. Loading control data for the following controls:
 - HbA1c Control N (357)
 - HbA1c Control P (358)
☞ See *Loading control data* on page B-182
5. Setting the decimal places of the calculated test RWI2:

Roche recommends reporting the results with one decimal place.

☞ For more information on configuring the decimal places of a calculated test, see:
To set range parameters on page B-231
6. Loading cassettes for the following applications:
 - A1C-2: Hemoglobin (Hb-W2, ACN 870)/Hemoglobin A1c (A1-W2, ACN 880)
 - A1CD2: Hemolyzing Reagent (A1CD2, ACN 952)

Notes for the use of the application

Result calculation according to DCCT/NGSP reporting range

Roche provides the application RWI2 (Application code 890) to calculate the Hemoglobin A1c% results according to IFCC reporting range.

To report the results according to DCCT/NGSP reporting range, you have to configure the calculated test ACN 890 (Formula tab of the **Calculated Test Formula** window):

$$\text{Equation B-2} \quad RWD2 = \frac{A1-W2}{HB-W2} \cdot 87.6 \% + 2.27$$

Loading control data for DCCT/NGSP reporting range

Control data for HbA1c Control N (357) and HbA1c Control P (358) are downloaded with values for the IFCC reporting range. The control data must be manually updated to the DCCT/NGSP reporting range values. These values can be obtained from the control value sheets.

 See *Editing control values* on page B-184

Sample container, sample pipetting

For processing the HbA1c whole blood application only standard tubes with the following specifications can be used:

- 13 mm x 75 mm
- 13 mm x 100 mm
- 16 mm x 75 mm
- 16 mm x 100 mm

For HbA1c whole blood QC measurements, sample cups directly placed on a control rack can be used.



For the use of blood collection systems as sample tubes, please contact your technical support.

Clot detection

Clot detection is automatically deactivated when pipetting whole blood samples.

Description of application parameters

It is possible to change some of the default parameters installed with an application to suit individual laboratory practice. These procedures can be performed by an operator with administrator level password only.

- ⦿ For instructions on changing default application parameters on the **Analyze** tab, see:
To define application dilution ratios (e 601) on page B-200
- ⦿ For instructions on changing default application parameters on the **Calib.** tab, see:
To define calibration timeouts on page B-204
To define application duplicate limit (e 601) on page B-202
- ⦿ *To define application auto masking* on page B-202
- ⦿ For instructions on changing default application parameters on the **Range** tab, see:
To define application measuring units on page B-206
To define application report name on page B-207
To change technical limit (photometric tests) on page B-208
To change repeat limit on page B-208
To change qualitative fields on page B-209
To change expected values on page B-210
To change default settings on page B-210

Description of application parameters - Analyze tab

The following sections explain certain settings associated with the **Analyze** tab on **Utility > Application** screen. Not all settings are described, but the most important ones are discussed here.

To display this screen choose **Utility > Application > Analyze**.

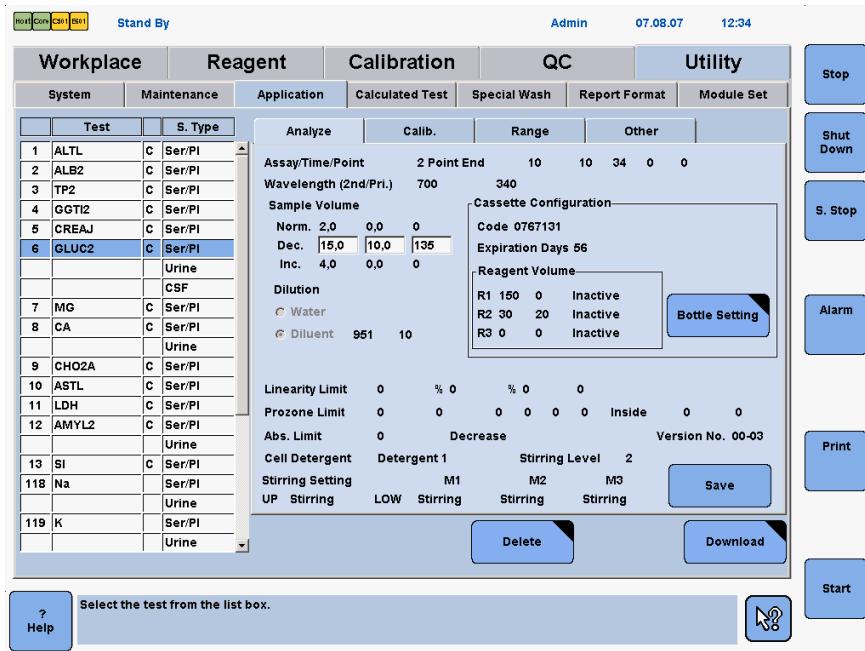


Figure B-103 Analyze tab on Utility > Application screen (photometric tests)

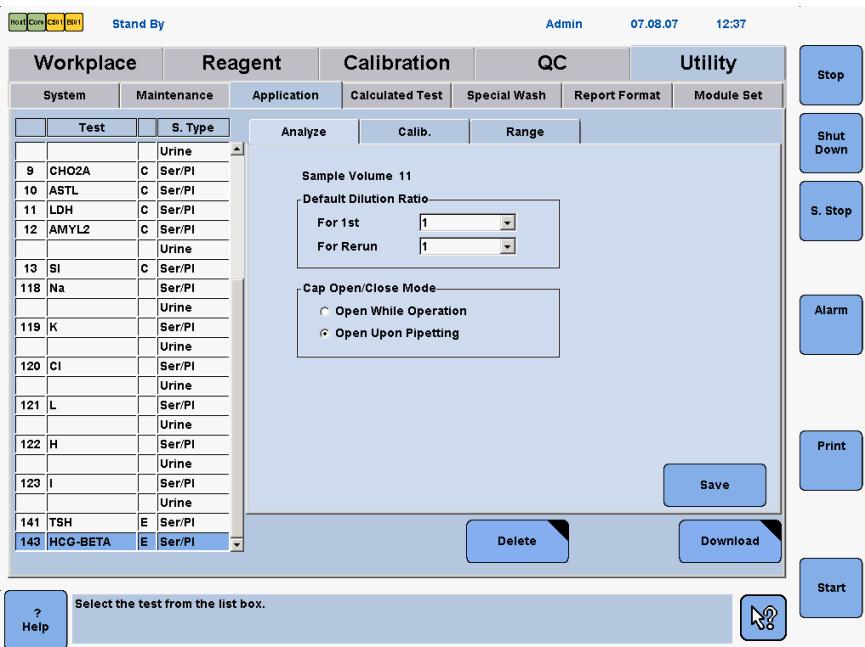


Figure B-104 Analyze tab on Utility > Application screen (immunological tests)

Dilution ratios (e 601)**► To define application dilution ratios (e 601)**

- 1** Choose Utility > Application > Analyze.
- 2** Select the test to be edited from the Test list on the left.
- 3** Select the required dilution for the first run in the For 1st list box and for reruns in the For Rerun list box of the Default Dilution Ratio area.

 - A **2** selected from the list box represents a 1:2 dilution.
 - A **cobas e** pack must be registered for the test, before the **Default Dilution Ratio** can be entered.

- 4** Repeat steps 2 and 3 for all necessary tests.
- 5** Choose Save to save the changes made.



Description of application parameters - Calib. tab

The following sections explain certain settings associated with the **Calib.** tab on **Utility > Application** screen. Not all settings are described, but the most important ones are discussed here.

To display this screen choose **Utility > Application > Calib.**

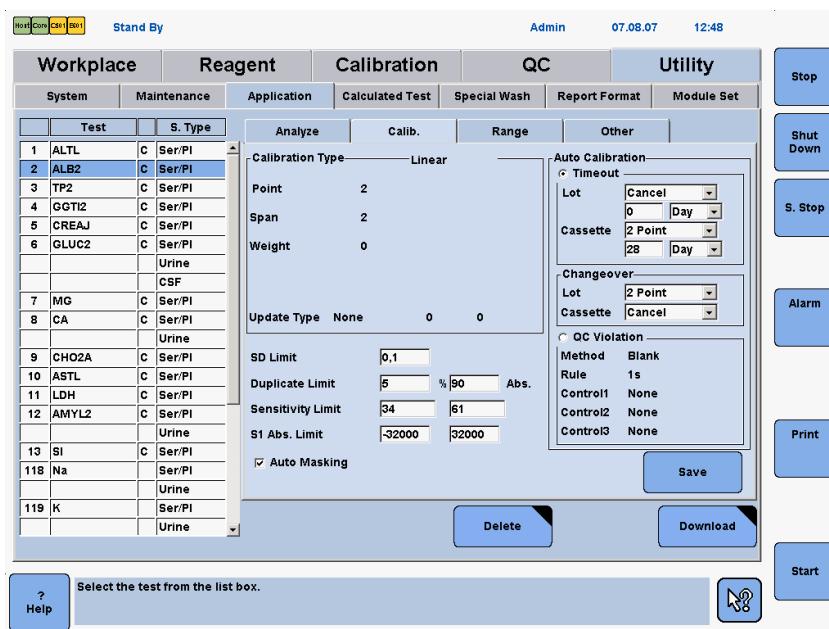


Figure B-105 Calib. tab on Utility > Application screen (Photometric test)

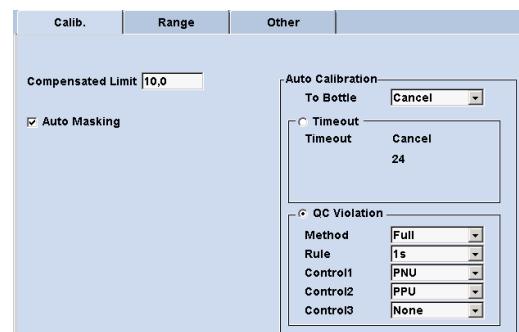


Figure B-106 Calib. tab on Utility > Application screen (ISE test)

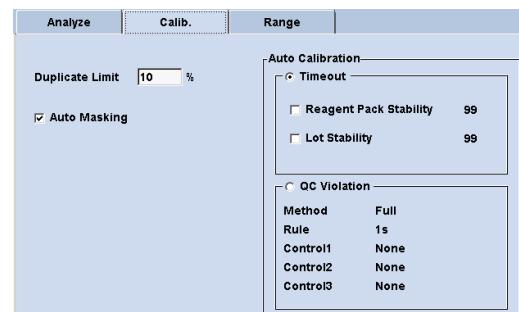


Figure B-107 Calib. tab on Utility > Application screen (Immunological test)

- For instructions on changing default application parameters on the **Calib.** tab, see:
To define application auto masking on page B-202
To define calibration timeouts on page B-204
To define application duplicate limit (e 601) on page B-202

Duplicate limit (e 601)

All Roche e 601 calibrators have a default duplicate limit of 10%. For some applications it is necessary to change the duplicate limit value.

► To define application duplicate limit (e 601)

- 1 Choose Utility > Application > **Calib.**
- 2 Select the test to be edited from the **Test** list on the left.
- 3 Type the required duplicate limit (0-64), expressed as a percentage (%), in the **Duplication** text box.
- 4 Repeat steps 2 and 3 for all necessary tests.
- 5 Choose **Save** to save the changes made.



Auto masking

If **Auto Masking** is selected, the particular test requiring calibration due to a failed calibration will be masked automatically.

► To define application auto masking

- 1 Choose Utility > Application > **Calib.**
- 2 Select the test to be edited from the **Test** list on the left.
- 3 Check the **Auto Masking** check box to select the test for auto masking.
- 4 Repeat steps 2 and 3 for all necessary tests.
- 5 Choose **Save** to save the changes made.



To activate the auto masking function, select the **Auto Masking** check box on **Utility > System (Page 2/4) > Calib. Mask Setting**.

Auto Calibration

Calibration can be requested automatically in the following cases:

- **Timeout:** If the calibration time period for a reagent cassette, cobas e pack or the reagent lot has expired.
- **Changeover** (Cassette or lot change—only c 501): If a new reagent cassette or the reagent lot is loaded on the analyzer.
- **QC Violation:** If a QC measurement has violated a defined rule.

When you load a new application onto the system, the time-triggered calibration (Timeout) is activated by default. If you intend to work with QC-triggered calibration, you must configure the QC violation parameters and activate QC-triggered calibration (**QC Violation**).

 For more information, see:

To activate QC violation on page B-203

To define calibration timeouts on page B-204

► To activate QC violation

- 1 On the **Calib.** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2 Select **QC Violation**.
- 3 Select the Calibration update **Method** (**Blank**, **Span**, **2 Point**, or **Full**) from the first list box.
- 4 Select the rule for checking the QC measurement from the **Rule** list.

Calibration will be recommended if a QC result falls out of the specified range (expressed in multiples of one standard deviation)

- 5 Select the controls that should trigger a calibration

Up to three controls can be assigned. If any of the QC results falls out of the specified range, a new calibration is recommended

For each of the assigned controls, an individual confidence interval must be specified. The confidence interval can be calculated automatically using the standard deviation selected in the **Rule** field or it can be entered manually.

 For more information, see *Editing control values* on page B-184.



Important notes for QC violation:

- At least one control must be selected for Control 1, 2, or 3.
- If a control is deleted, the setting will be changed to **None** automatically.
- Make sure that at least one control selection for QC violation is other than **None**. Otherwise the QC violation function remains activated if the corresponding radio button is selected but can not be carried out.
- If calibration is recommended due to QC violation because of improper placement of controls (reversed order), the control material can be run again. If the controls recur within their confidence limits, the calibration request is removed.

 For more information about calibration, see:

Causes for automatic calibration recommendations on page B-128

Calibration rules for c 501 on page B-130

Calibration rules for e 601 on page B-132

► **To define calibration timeouts**

- 1 On the **Calib.** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.



For e 601 applications:

Before selecting the check box **Timeout** and defining timeout periods, please check the instructions for use. If the check box is not selected, the default values read from the **cobas e** pack barcodes are used (in most cases 7 days for **cobas e** pack stability and 28 days for lot stability).

- 2 Select **Timeout**.

- 3 Define the required calibration method and the timeout period:

- For **c 501** module applications:
 - Select the calibration method for lot calibration from the corresponding list box.
 - Type the required timeout period for lot calibration in the corresponding text box and select the time unit from the corresponding list box.
 - Repeat the last two steps for cassette calibration.
- For **ISE** applications:
 - Select the calibration method from the corresponding list box.
 - Type the required timeout period for ISE calibration, in days, in the corresponding text box.
- For **e 601** applications:
 - Select the **Reagent Pack Stability** check box and type the required timeout period for reagent pack calibration, in days, in the corresponding text box.
 - Select the **Lot Stability** check box and type the required timeout period for lot calibrations, in days, in the corresponding text box.



If you don't want to use timeouts, select both check boxes and enter 0 in the text boxes.

- 4 Choose **Save** to save the changes made.



Description of application parameters – Range tab

The following sections explain certain settings associated with the **Range** tab on **Utility > Application** screen. Not all settings are described, but the most important ones are discussed here.

To display this screen choose **Utility > Application > Range**.

The screenshot shows the software interface with the following details:

- Top Bar:** Host, Copy, Cut, Paste, Stand By, Admin, 07.08.07, 14:27.
- Navigation:** Workplace, Reagent, Calibration, QC, Utility.
- Sub-Navigation:** System, Maintenance, Application, Calculated Test, Special Wash, Report Format, Module Set.
- Test List:** A table listing various tests (e.g., ALT, ALB, TP2, GGT12, CREAJ, GLUC2) with their corresponding S. Type (e.g., C Ser/PI, Urine).
- Range Tab Content:**
 - Application Code:** 413, **Unit:** g/L, **Report Name:** ALB2.
 - Data Mode:** Active, **Automatic Rerun:** checked.
 - Technical Limit:** 0, 30.
 - Repeat Limit:** 1, 15.
 - Control Interval Time:** 1.
 - Automatic QC On Board Stability:** 2.
 - Qualitative:** A table with rows (1) through (6) and columns L, H, I. Values include: (1) 0, --; (2) 0, -; (3) 0, +-; (4) 0, ++; (5) 0, +++; (6) 0, +++. L values: 650, 1000, 60. H values: 15, 1000. I values: 15, 60.
 - Expected Values:** Male and Female tables for Year ranges 99 and 100. All values are set to 99999.
 - Default:** Sex (Male selected), Range (Range 1 selected).
 - Buttons:** Save, Delete, Download.
- Help:** Select the test from the list box.
- Buttons on the right:** Step, Shut Down, S. Stop, Alarm, Print, Start.

Figure B-108 Range tab on Utility > Application screen (Photometric test)

The screenshot shows the software interface with the following details:

- Top Bar:** Calib., Range, Other.
- Application Code:** 989, **Unit:** mmol/L, **Report Name:** Na.
- Checkboxes:** Automatic Rerun, Control Interval Time (unchecked), Automatic QC On Board Stability (unchecked).
- Technical Limit:** 99999, 99999.
- Repeat Limit:** 99999, 99999.
- Qualitative:** A table with rows (1) through (6) and columns L, H, I. Values include: (1) 0, --; (2) 0, -; (3) 0, +-; (4) 0, ++; (5) 0, +++; (6) 0, +++. L values: 2000, 1000. H values: 1000, 1000. I values: 60, 60.
- Expected Values:** Male and Female tables for Year ranges 99 and 100. All values are set to 99999.
- Default:** Sex (Male selected), Range (Range 1 selected).
- Buttons:** Save.

Figure B-109 Range tab on Utility > Application screen (ISE test)

The screenshot shows the software interface with the following details:

- Top Bar:** Analyze, Calib., Range.
- Application Code:** 1, **Unit:** µIU/mL, **Report Name:** TSH.
- Checkboxes:** Automatic Rerun, Control Interval Time (unchecked), Automatic QC On Board Stability Time (unchecked).
- Repeat Limit:** 99999, 99999.
- Text Fields:** Test Priority (Normal), Result Message Border Range (0).
- Expected Values:** Male and Female tables for Year ranges 99 and 100. All values are set to 99999.
- Default:** Sex (Male selected), Range (Range 1 selected).
- Buttons:** Save.

Figure B-110 Range tab on Utility > Application screen (Immunological test)

- ⦿ For instructions on changing default application parameters on the Range tab, see:
To define application measuring units on page B-206
To define application report name on page B-207
To define application automatic rerun on page B-207
To change technical limit (photometric tests) on page B-208
To change repeat limit on page B-208
To change qualitative fields on page B-209
To define serum indices on page B-209
To change expected values on page B-210
To change default settings on page B-210

Measuring units

The unit of measure can be selected in this field. Up to four units can be displayed. Changing the unit also recalculates the concentration based application data, for example, repeat limit, expected value.

► To define application measuring units

- 1 On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2 Select the required measurement units from the **Unit** list box.
- 3 Choose **Save** to save the changes made.



► To change the unit of measure for a previously calibrated application



Incorrect calibration and QC results

You can change the unit of measurement after an application has been installed. However, if the unit is changed after the test in question has already been calibrated, we strongly recommend deleting that test application and then reinstalling it.

After changing the unit of measurement, always recalibrate and run controls in order to ensure no incorrect results are reported.

- 1 Backup the database and delete patient data (**System Overview > Sample Data Clear > Backup and Clear**).

If Sample data clear is executed, all the records of the samples are deleted and QC data are moved to the QC view.

⦿ For details see *Sample Data Clear button* on page B-37.

- 2 Unload all the **cobas c** packs for this test (**Reagent > Setting > Cassette Unloading**).

⦿ For details see *Unloading reagent cassettes* on page B-105.

- 3 Delete the test application (**Utility > Application**).

- 4 Reinstall the test application (**Utility > Application > Download**).

⦿ For details see *Loading or updating new applications* on page B-192.

- 5 Change the unit of measure (**Utility > Application > Range**).

6 Load new **cobas c** packs.

☞ For details see *To load a cobas c pack* on page B-41.



Any **cobas c** packs for this test that were already in use on a **c 501** module cannot be reloaded onto the **c 501** module after the test has been deleted.

7 Install the calibrator values for this test under **Calibration > Install > Download**.

☞ For details see *Loading calibrator data* on page B-147.

8 Install the control values for this test under **QC > Install > Download**.

☞ For details see *Loading control data* on page B-182.

9 Calibrate the test and perform control measurements.

☞ For details see *Requesting calibration and QC and printing load lists* on page B-43.

**Report name**► **To define application report name**

- 1** On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2** Type the desired report name for the test in the **Report Name** text box.
- 3** Choose **Save** to save the changes made.

**Automatic Rerun**► **To define application automatic rerun**

- 1** On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2** Select **Automatic Rerun**.
- 3** Choose **Save** to save the changes made.



☞ For more information, see
Processing reruns on page B-56
Rerun list on page D-62



- If automatic rerun is selected, the sample remains on the rack rotor until the results of the sample are available.
- To perform automatic reruns, the automatic rerun function must be selected (**Start** (global button) > **Automatic Rerun**).

Technical limit (c 501 only)► **To change technical limit (photometric tests)**

- 1 On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2 In the first **Technical Limit** box, type the lower limit.
In the second box, type the upper limit.
- 3 Choose **Save** to save the changes.

■

Repeat limit

For each test a clinically relevant range can be typed in here. If the test result is outside this limit but inside the **Technical Limit** of the application, the test is repeated using the same sample volume and dilution as in the first run.

► **To change repeat limit**

- 1 On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2 In the first **Repeat Limit** box, type the lower limit of the range.
In the second box, type the upper limit of the range.
- 3 Choose **Save** to save the changes.

■



The concentration range of the **Repeat Limit** must lie within the **Technical Limit**.

- ☞ For more information, see
Processing reruns on page B-56

Control Interval Time

This check box and the corresponding text box is used to define the time period (1 to 1000 hours) to run repeatedly controls for the selected test. At the end of the time period a QC measurement is automatically requested (Cause: Timeout) by the system or an auto QC measurement is triggered.

Automatic QC On Board Stability

This check box and corresponding text box is used to define the on board stability (1 to 1000 hours) for the control material on the rack rotor for the selected test. If AutoQC racks are used and a the control material stability expires (On Board stability exceeded), the system displays the yellow alarm. Please refer to the instructions for use of the application and the control to find out the on board stability time of the control material.

Qualitative fields (c 501 only)

This function is important for DAT (drugs of abuse testing) especially. Qualitative reporting can be chosen instead of quantitative reporting for each photometric test. In the text boxes of the first column (1-5) the upper limit concentration range has to be entered. Any result less than or equal to the value defined here will be printed with the text defined in the second box.

If a result is higher than range (5) the text defined in text box (6) is taken.

► To change qualitative fields

- 1 On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
 - 2 Select the **Qualitative** check box to activate the qualitative fields.
 - 3 Type the correct information in the first qualitative text box for (1).
 - 4 Type the symbol that prints on the report in the second text box for (1).
 - 5 Repeat steps 3 to 4 for numbers (2) to (6).
 - 6 Choose **Save** to save the changes.
-

☞ For correct upload setting refer to the Host Interface Manual.

L, H, I (serum index, c 501 only)

The serum index function can be defined individually for each photometric and ISE test. In the serum index fields **L** (lipemic), **H** (hemolytic), **I** (icteric) the ranges that are loaded with the application are displayed.

Limits for H, I and L index are implemented in conventional units in all application settings. When using international units for H, I and L index the respective serum index limits have to be changed in all applications.

If at least one serum index field has a value other than 0, serum indexes are calculated. If 0 is entered, the corresponding serum index is not calculated.

► To define serum indices

- 1 On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.
- 2 Select the text box of the corresponding serum index **L**, **H**, or **I**.
- 3 Enter the recommended values from the instructions for use of the corresponding test.

Remember to enter the values in the same unit as those used for the test results (conventional units or international units).

■



To use the serum index function, the serum index application must be installed and the serum index requested on the **Workplace > Test Selection** screen.

☞ For more information on serum indices:
refer to the Online Help of the **Range** tab of the **Utility > Application** screen or
refer to the COBI CD.

Expected values

Expected Values area is used to define the reference range for men and women in three different age groups. If the result for this test falls outside the ranges entered here, the system issues a data alarm (H, L). The last row of the field does not allow an age limit to be defined. These expected values include patients older than the upper limit of the second age group.

► To change expected values

- 1 On the **Range** tab of the **Utility > Application** screen select the test to be edited from the **Test** list on the left.

Now, you can change the settings in the **Expected Values** area.



► To change expected values ranges and corresponding age

- 1 In the **Expected Values** area, choose the first text box and enter a patient age for cutoff of the first expected value range. Then select the unit (**Day**, **Month**, **Year**) for that age in the list box.
- 2 Type the lower and upper reference values for males in the **Male** area in the last 2 text boxes in the row for the specified test.
- 3 Repeat steps 1 and 2 for the second age cutoff in the second row of text boxes in the **Male** area.
- 4 In the third row of text boxes, type the lower and upper reference values for males of all ages above the second age cutoff.
- 5 Repeat steps 1 to 4 for female age cutoff ranges.

Now, you can change the default settings.



► To change default settings

- 1 In the **Default Sex** area, select either the **Male** or **Female** option as the default if no sex is specified.
- 2 In the **Default Range** area, select the default age range (**Range 1**, **Range 2** or **Range 3**) to be used if no age range is specified.
- 3 Choose **Save** to save the changes.



Description of application parameters - Others tab for ISE tests

The following section explains how to set up two independent sets of calibration curves for different sample types for each ISE test Na⁺, K⁺, and Cl⁻.

To display this screen choose **Utility > Application > Others**.

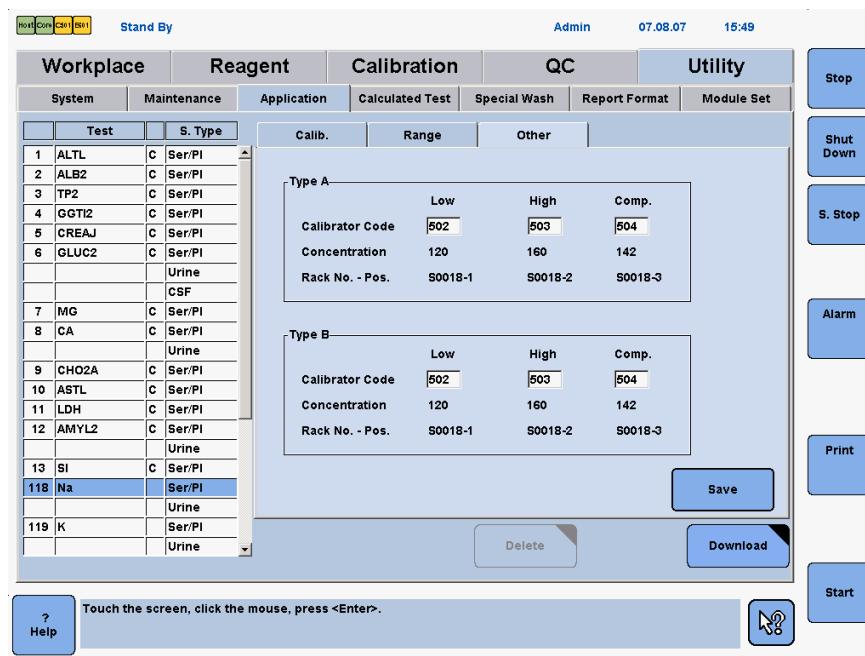


Figure B-111 Others tab on Utility > Application screen (ISE test)

Use the **Other** tab to set up two independent sets of calibration curves for different sample types for each ISE test Na⁺, K⁺, and Cl⁻. Choose an ISE test from the test list to display calibrator codes, concentration values, and rack position numbers.

Setting up individual calibration curves for each ISE sample type

The **Other** tab of the Na, Cl and K contains two areas, **Type A** and **Type B**, where each area relates to one of the two independent calibration curves.

To use these calibration curves for a specific sample type, the following settings have to be done:

- Set the calibrators used for generating the calibration curve type A and B.
- Assign an ISE calibration curve for each sample type.

► To set the calibrators for calibration curve type A and B

- 1 On the **Other** tab of the **Utility > Application** screen select the ISE test to be edited from the **Test** list on the left.
- 2 Enter the codes of the calibrators used for generating the calibration curve type A in the corresponding text boxes for each calibrator, **Low**, **High** and **Comp**.
- 3 Repeat steps 2 for calibration curve **Type B**.
- 4 Choose **Save** to save the changes made.



If only one calibration type is used—if you use the same calibration curve for all sample types—then you must enter the same calibrator codes for **Type A** and **Type B**. It is not possible to deactivate one of the calibrator curves.

► To assign an ISE calibration curve for each sample type

- 1 Choose **Utility > System (Page 3/4) > ISE Calib Setting**.
- 2 Select the calibration curve type (**ISE-A** or **ISE-B**) for each sample type.
- 3 Choose **Save** to save the changes made.



👁 For more information, see:
ISE calibration concept on page B-131
ISE calibration on page B-151



If a field is grayed out, the field is read only for the password level logged onto the system. At an administrator level, if the field is not grayed out, it can be edited.

System configuration

This section explains how to perform certain tasks associated with the **Utility > System** menu.



The entire module set (module configuration, test assignment) should be performed before the other settings (control, calibrator settings)

For more information on configuring the modules, see *Module Set* on page B-221

To display this screen, choose **Utility > System**.

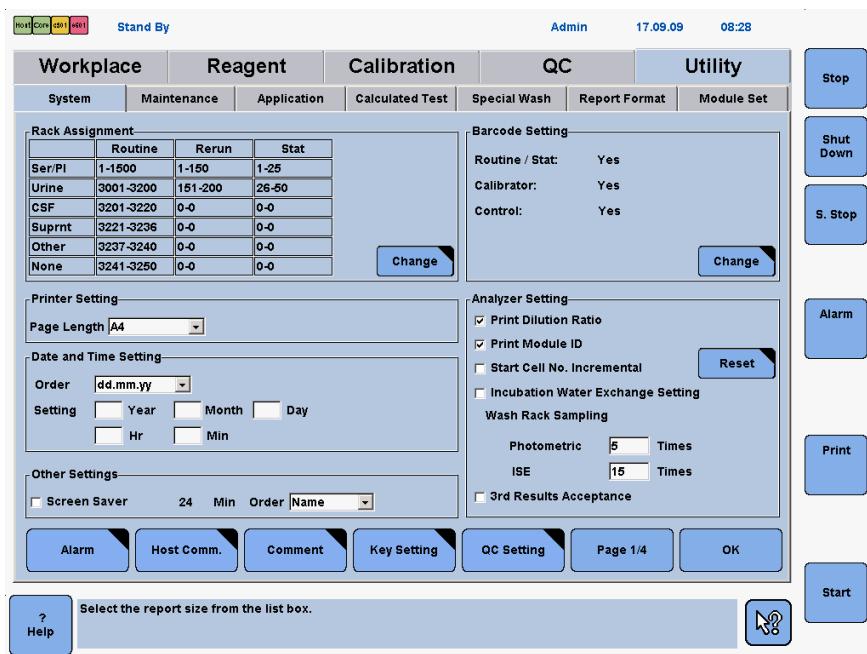


Figure B-112 Utility > System screen

For information about particular tasks associated with this screen, see: *Programming system parameters* on page B-213

Programming system parameters

Many system parameter settings can be customized according to your laboratory's needs. Your technical support programs these according to your specifications during installation.

You can adjust the following system parameter settings.



After (re)programming system parameters, it is strongly recommended that you make a backup disk. However, some items cannot be saved to disk.

System parameter	screen/window
Assign Rack Numbers	Utility > System
Set the Printer Page Size	Utility > System
Set Date and Time	Utility > System
Set The Screen Saver	Utility > System
Order (Name/Test No.)	Utility > System
Set The Barcode Mode	Utility > System
Print Dilution Ratio	Utility > System
Print Module ID	Utility > System
Start Cell No. Incremental	Utility > System
Wash Rack Sampling	Utility > System
3rd Results Acceptance	Utility > System
Define Alarm Settings	Utility > System (Page 1/4) > Alarm
Define Host Communication Settings	Utility > System (Page 1/4) > Host Comm.
Define Comment Titles	Utility > System (Page 1/4) > Comment
Assign Test Keys	Utility > System (Page 1/4) > Key Setting
Define Test Group Names	Utility > System (Page 1/4) > Key Setting
Add/Edit A Profile	Utility > System (Page 1/4) > Key Setting > Profile Setting
Define QC Settings	Utility > System (Page 1/4) > QC Setting
Activate Host Communication Setting	Start (global button)
Program Default Profiles	Start (global button) > Default Profile
Define Reagent Level Check Alarms	Utility > System (Page 2/4) > Reagent Level
Activate Calibration Mask Settings	Utility > System (Page 2/4) > Calib. Mask Setting
Maintenance Settings	Utility > System (Page 2/4) > Maintenance Setting
Pipe Settings	Utility > System (Page 2/4) > Pipe Setting
Power Up Pipe Settings	Utility > System (Page 2/4) > Power Up Pipe Setting
Assign Operator IDs	Utility > System (Page 3/4) > Operator ID Setting
Define Check Digit Settings - Barcode Mode	Utility > System (Page 3/4) > Check Digit Setting
Define ISE Calib Setting	Utility > System (Page 3/4) > ISE Calib Setting
Define Rack Delivery Setting (and Rack Reception Mode)	Utility > System (Page 3/4) > Rack Delivery
Check Diluents and Cleaners	Utility > System (Page 3/4) > Dil. + Cln.
Activate Automatic Printout	Utility > System (Page 4/4) > Automatic Printout
Review By Exception	Utility > System (Page 4/4) > Review By Exception
Activate Automatic Rerun	Start (global button)
Set Alarm Sounds	Alarm (global button) > Sound

Table B-23 System parameters

Generating multiple results for a single test

It is always possible to generate 2 results for each test: 1st run and rerun. Select the **3rd Results Acceptance** check box on **Utility > System** to expand the ability to generate multiple results for a single test.

Description of 3rd Results Acceptance

When **3rd Results Acceptance** is activated, it is possible to request a test more than two times after confirming a safety warning. Any third or subsequent result will overwrite the previous rerun result.



Incorrect results due to sample mismatch

Be aware that in non-barcode mode there is a risk of sample mismatch.

Do not exchange or remove samples.

The repeated rerun is only performed if the previous rerun result has been sent to the Host. In case the previous result is not transmitted prior to the repetition request, the sample is not pipetted.

Preconditions for 3rd Results Acceptance

Before activating **3rd Results Acceptance** it is necessary to check the following conditions.

► **To activate 3rd Results Acceptance**

- 1 Choose **Start** (global button) to open the **Start Conditions** window.
- 2 Verify if in the **Host Setting** area, that the Host communication is enabled. If not, choose **Change**, select the **Communication On** check box, and choose **OK**.
If Host communication is not available, it is not possible to use **3rd Results Acceptance**.
- 3 Choose **Workplace > Data Review > Send To Host** and send all results to the Host. Then delete all data from the database by choosing **Delete All**.
- 4 Choose **Utility > System**.
- 5 Select the **3rd Results Acceptance** check box in the **Analyzer Setting** area.
- 6 Choose **OK** and confirm the warning message.

With this confirmation you allow the system to overwrite rerun results by third and subsequent results.



Assigning tests or profiles to test keys

► To display the Key Setting window

- 1 Choose Key Setting on Utility > System (Page 1/4)

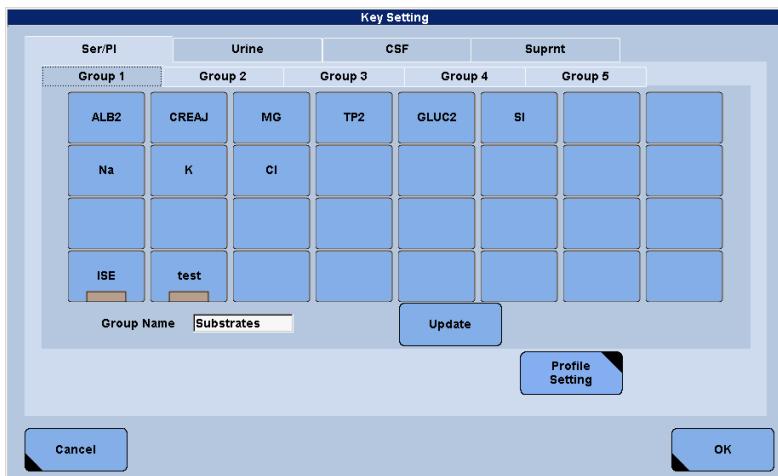


Figure B-113 Key Setting window

This window is used to assign tests or profiles to test keys. One test or profile can be assigned to each test key. Tests can be assigned for up to 5 groups of 32 keys per sample type. In total 160 test keys are available for each sample type.

► To define a group name

The group name can be defined individually, for example, hormones, thyroids, tumor marker

- 1 Choose the sample type tab, for example, Ser/PL
- 2 Select the **Group** tab (Group 1 - 5).
- 3 Type the name of the group in the **Group Name** box.

 The group name is not displayed on the **Key Setting** window. It is displayed in the **Test Selection** screen.

► **To assign a test or a profile to a key**

- 1 Choose a key on the **Key Setting** window. The available tests and profiles are displayed.

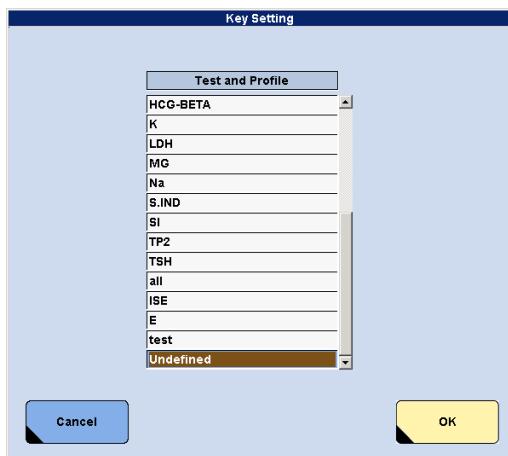


Figure B-114 Key Setting window

- 2 Select a test or a profile from the list and choose **OK**.
💡
 - If you want to delete a test key assignment, select **Undefined** at the end of the list.
 - Before you can select a profile, the profile has to be defined.
- 3 Repeat step 1 and 2 to select a key for other tests.
- 4 Choose **Update** on the **Key setting** window to update the new information.
- 5 Then choose **OK** to close the window.
■

► **To define a profile**

Profiles are sample type specific, this means the sample type has to be selected.

- 1 Choose the tab of a sample type, for example, Ser/Pl.
- 2 Choose **Profile Setting** on the **Key Setting** window. The **Profile Setting** window is displayed.

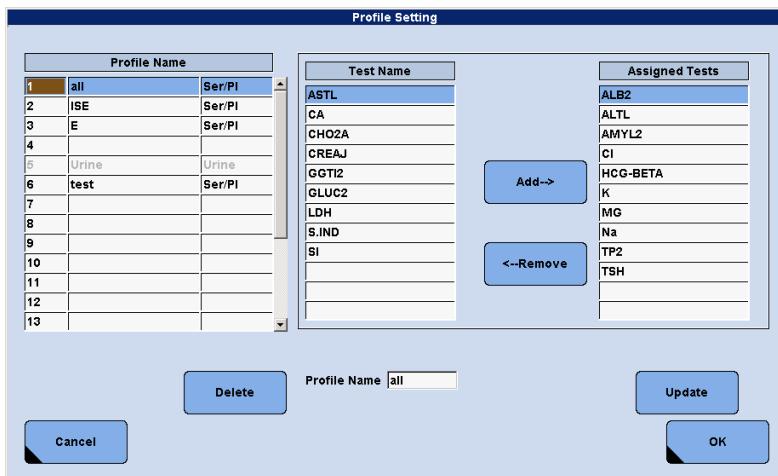


Figure B-115 Profile Setting window

A maximum of 20 profiles in total can be defined in the **Profile Name** list.

- 3 Select an empty line in the **Profile Name** list.
- 4 Type in the profile name in the **Profile Name** box.
- 5 Add the tests that should be included in the profile to the **Assigned Test** list.



When adding the serum index tests, (L, H, I) to a profile, select the **S.IND** test name. Do not add the SI or S-SI2 tests to a profile.

- 6 Choose **Update** to update the information and choose **OK** to save the profile settings.
- 7 If a profile is assigned to a key, the key on the **Test Selection** screen is marked with a brown bar.



Maintenance / Pipe Setting / Power Up Pipe buttons

Configuration of Maintenance related items is described in the corresponding maintenance chapters.

👁 For information, see:

Defining and editing maintenance types on page C-21

Defining and editing maintenance pipes on page C-15

Power Up Pipe function on page C-18

Rack Delivery button

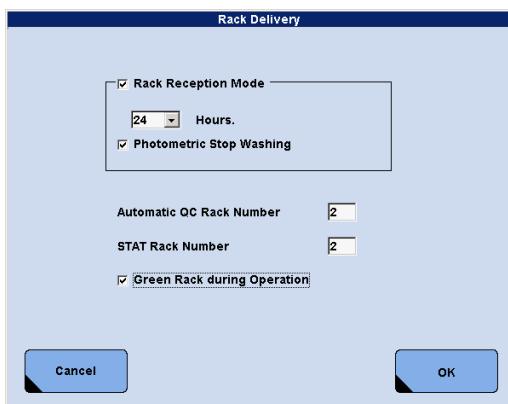


Figure B-116 Rack Delivery window

Use this window to make the following settings:

- Activate or cancel **Rack Reception mode**, set the time period. The following periods are available: 1, 2, 4, 8, 12 and 24 hours.
- Activate or cancel **Photometric Stop Washing**.
- Set the number of rack rotor positions that are reserved for automatic QC and STAT racks
- Activate or cancel **Green Rack during Operation**.

Rack Reception Mode

Select this check box to activate and configure the rack reception mode (RRM). When the rack reception mode is activated, you can choose this mode on the **Start Conditions** screen.

See *Start Conditions screen* on page E-175.

Use the **Hours** list box to specify the duration of the rack reception mode. The following periods are available: 1, 2, 4, 8, 12 and 24 hours. The count down for the remaining time starts, when the system changes to operation mode. The remaining time for RRM is shown in the status line.

See *Start Conditions screen* on page E-175.

For an analysis started without RRM, the system automatically turns to Stand By after the last available sample is processed.

For an analysis started with active RRM, the system remains in operation after the last available sample is processed and until one of the following occurs:

Action	Result
Specified time is elapsed	System goes into standby
S.Stop button is chosen	System goes into standby
Stop button is chosen	System goes into standby
An red alarm is issued	System goes into standby
A wash rack is loaded	The wash rack is processed and then the system goes into standby (only if Green Rack during Operation is not selected)

Table B-24 Stopping the system in rack reception mode

If there are still samples to be processed after the RRM time has elapsed, the system finishes these samples and goes to Standby afterwards.

If you want to stop the RRM before the specified time is elapsed, proceed as follows:

► **To interrupt the Rack Reception mode**

- 1 Choose **Start** (global button).
- 2 Choose **Change** in the **Rack Reception Mode** area.
- 3 Clear the **Rack Reception Mode** check box and confirm with **OK**.
The **Rack Reception Mode** is stopped. The system goes into standby.
- 4 Choose **Cancel** to close the **Start Conditions** screen.



- The remaining time for RRM is shown in the status line.
- Changes to the duration of the rack reception mode can only be done in standby.
- If a e 601 module was in rack reception mode or operation mode for 12 hours or more and has not been returned to standby, initial bead mixing has to be performed. Initial bead mixing is carried out automatically after the module is started from standby.
- The system goes into standby after 24 hours if 24 hours is specified as the duration of the rack reception mode.

**Photometric Stop Washing
(c 501)**

During operation and rack reception mode the reaction cells of the c 501 module are continuously washed. To disable the washing function, select the **Photometric Stop Washing** check box. In this case washing stops, after the last sample is processed.

Cell washing is automatically enabled when the next analysis is started.

This check box is available only if rack reception mode is selected.

**Automatic QC Rack number /
STAT Rack number**

Set the number of slots for each rotor that will be reserved for **Automatic QC** and **STAT** racks during operation.

The reserved number of slots will be used by the automatic QC or STAT racks. The number of slots reserved for automatic QC should correspond with the specified rack range for automatic QC racks.

☞ See *Automatic QC measurement* on page B-187.



At least one position should be reserved for a STAT rack!

If no position is reserved for a STAT rack and all positions are occupied by other racks, the STAT rack can not be processed until a rack is removed from the rack rotor.

Green Rack during Operation

Select this check box to activate the **Green Rack during Operation** function. When this function is activated, you can load a green wash rack during operation. The analyzer will not go into standby after processing of the green wash rack. Therefore a continuous processing of samples is possible.



CAUTION

Incorrect results due to wrong calibration

After processing a green wash rack all ISE tests must be calibrated.

Do not load samples with ISE requests before you have checked the calibration and QC results for ISE.

☞ See *Processing green wash rack* on page C-67.

Module Set

This section explains how to perform certain tasks associated with entire modules rather than specific samples or tests.

- ☛ Refer to the following procedures to get information about:
 - Assigning a test to a module* on page B-222
 - Inactivating a module* on page B-224



The entire module set (module configuration, test assignment) should be performed before the other settings (control, calibrator settings)

To display this screen, choose **Utility > Module Set**.

This screen can be accessed by an operator with administrator level password only.

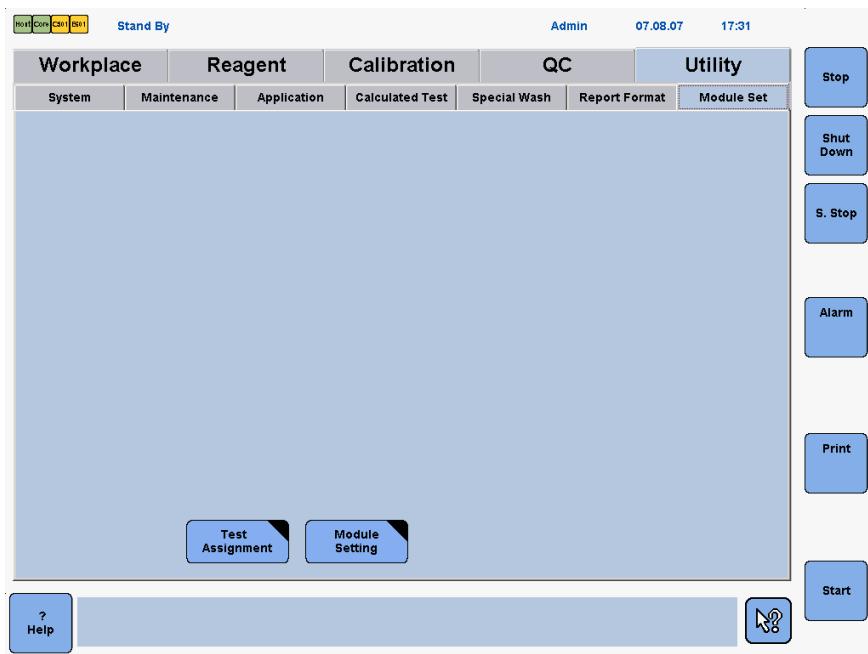


Figure B-117 Utility > Module Set screen

This screen is used to access the **Module Configuration**, **Test Assignment** and **Module Setting** windows

Assigning a test to a module

► To assign a photometric or an ISE test to a c 501 module

- 1 Choose Test Assignment on the Utility > Module Set screen.
- 2 Choose the button of the c 501 module to which you want to assign the test. The module specific Test Assignment window is displayed.

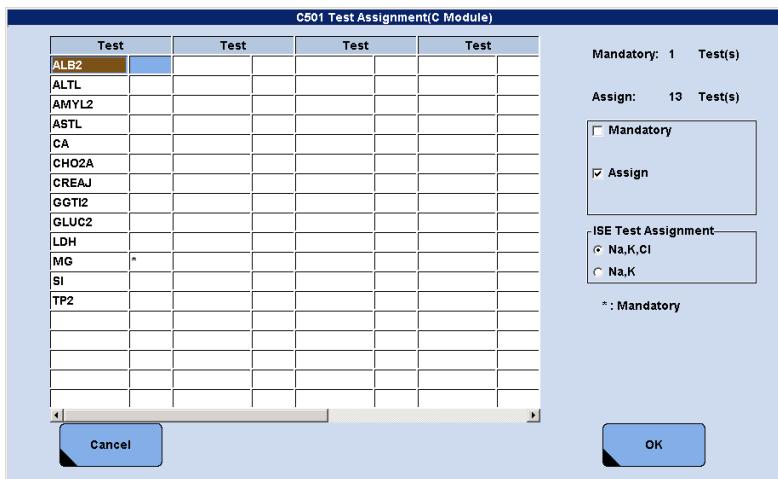


Figure B-118 Test Assignment window – c 501

- 3 Select a test in the Test list of the Test Assignment window.
 - 4 Select the Assign check box.
 - 5 Select the Mandatory check box if the reagent has to be on board all the time.
 - 6 Select Na, K, Cl or Na, K.
 - **Na, K, Cl:** This option allows sodium (Na^+), potassium (K^+) and chloride (Cl^-) ion testing on this ISE module.
 - **Na, K:** This option allows only sodium (Na) and potassium (K) testing on this ISE module.
 - 7 Choose OK.
-



If the **cobas c** pack of a mandatory test is not available on the system, the corresponding module is displayed in red on the **System Overview** screen. Nevertheless operation of the module can start.

► **To assign a test to an e 601 module**

- 1 Choose Test Assignment on the Utility > Module Set screen.
- 2 Choose the button of the e 601 module to which you want to assign the test. The module specific Test Assignment window is displayed.

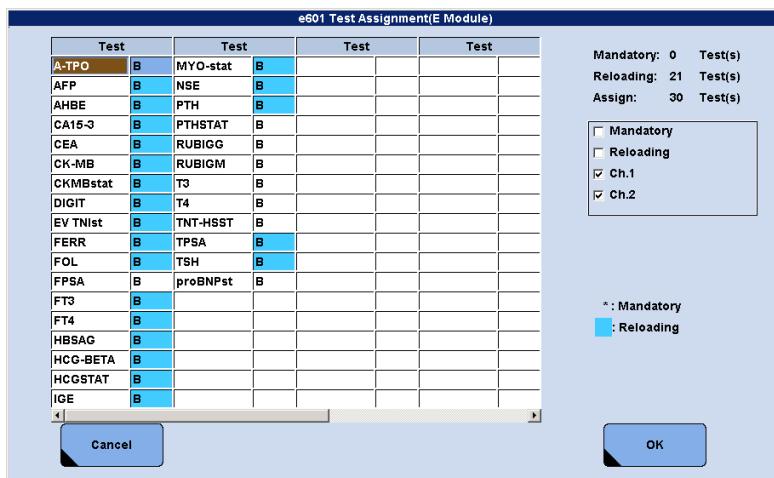


Figure B-119 Test Assignment window – e 601

- 3 Select a test in the **Test** list of the **Test Assignment** window. Check either the **Ch.1**, **Ch.2** or both check boxes to assign the test to measuring channel 1, 2, or both respectively.
- 4 Select the **Mandatory** check box if the reagents for the selected test must be available on the module all the time.
- 5 The **Test** list is updated immediately.
Unassigned tests are grayed out. Tests assigned to an e 601 module are followed by a **1**, **2** or **B** indicating they have been assigned to measuring channel 1, 2 or both.
- 6 Select the **Reloading** check box in order to initiate the reloading process if the selected test runs out of reagent during operation.

For more information, see *Reagent reloading (e 601)* on page B-106.

- 7 Choose **OK**.



- If the **cobas e** pack of a mandatory test is not available on the system, the corresponding module is displayed in red on the **System Overview** screen and operation of the analyzer can not start.
- A test that is not assigned to any of the channels must not be loaded on the system.

Inactivating a module

Use this procedure to deactivate one or more modules. A module cannot perform any automated maintenance functions when it is inactive.



The system must be in standby to activate or deactivate a module.

► To deactivate a module

- 1 Choose **Module Setting** on the **Utility > Module Set** screen.

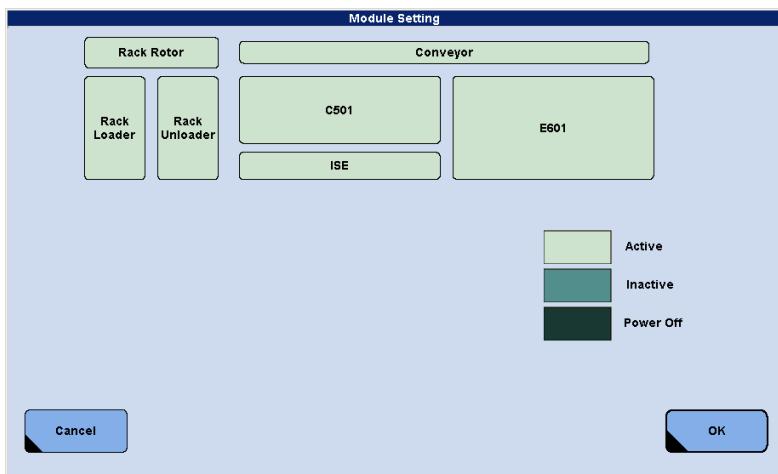


Figure B-120 Module Setting window

This window is used to activate/deactivate or power off modules.

The window displays a system layout diagram from which the module to be activated or deactivated is selected. Choosing a module changes its state successively from active, to inactive, to power OFF, and back. The current status of the module is shown by different colors explained on the window.

- 2 Choose the appropriate module to toggle between **Active**, **Inactive**, and **Power Off**.
- 3 Choose **OK** and confirm with **Yes** to apply the assigned settings.



If you want to use the **Backup Operation** function, you have to deactivate the rack rotor.

- ☞ For more information about the **Backup Operation** function, see:
Backup operation on page B-225.

Backup operation

The backup operation mode can be useful if the rack loader/unloader or the rack rotor can not convey any samples. This mode enables sample measurement on c 501 modules to continue.

In backup operation mode, only routine and STAT samples can be processed (including rerun samples).



- Backup operation mode is available only if barcode mode is selected and only on one c 501 module at a time.
- Backup operation mode is only available when the rack loader/unloader, rack rotor and the conveyor have been inactivated (**Utility > Module Set**).
- Backup operation mode is not available on e 601 modules.

Activating backup operation mode

Before using the backup operation mode, the rack rotor needs to be inactivated in the analyzer software.

► To deactivate the rack rotor

- 1 Choose **Utility > Module Set**.
- 2 Choose **Module Setting**.
- 3 Choose **Rack Rotor** to deactivate the rack rotor. The color of the **Rack Rotor** and **Conveyor** buttons changes to dark green.

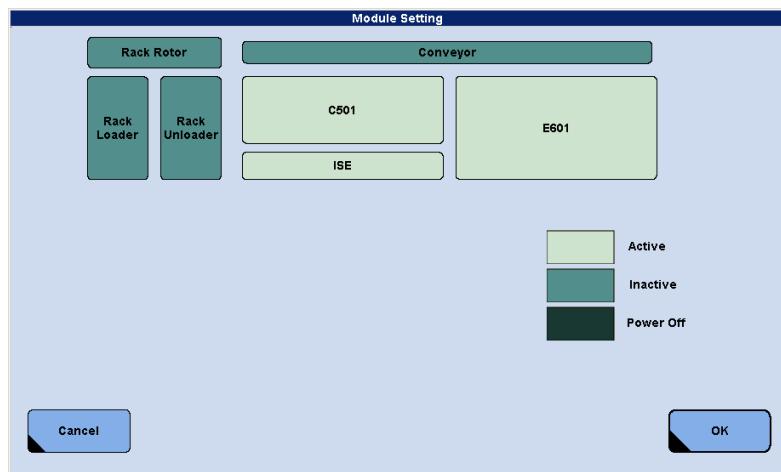


Figure B-121 Module Setting window

- 4 Choose **OK** to save the changes.



► **To activate the backup operation mode**

- 1 On the **System Overview** screen, select the c 501 module on which the samples should be processed.

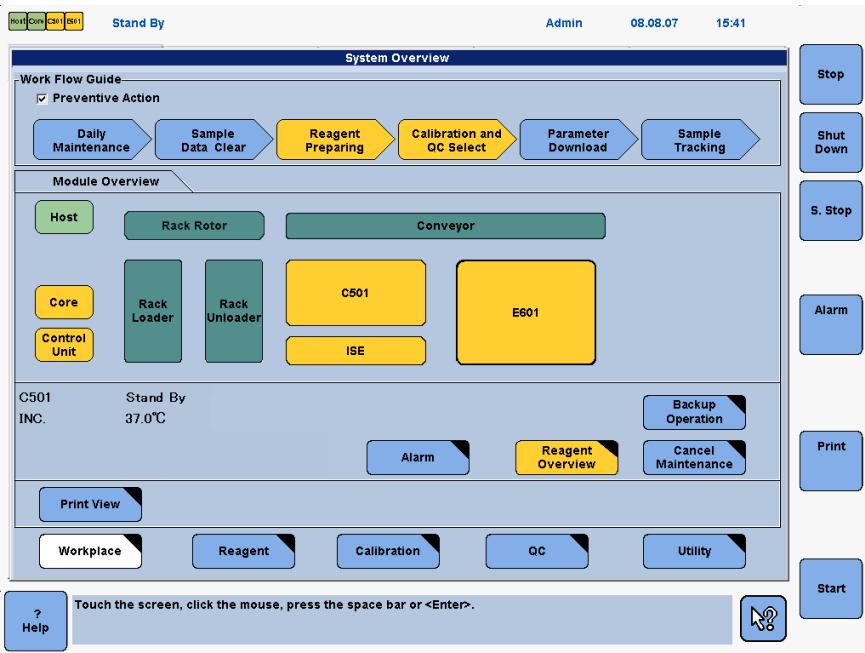


Figure B-122 System Overview window

- 2 Choose **Backup Operation**.
- 3 Choose **Start** on the **Backup Operation** window.
- 4 When the instrument goes into *Backup Wait For Rack Setting* status, the instrument is ready to measure samples.

☞ See *Measuring samples in backup operation mode* on page B-227



Measuring samples in backup operation mode

Tests can be selected similar to routine operation, either from the **Test Selection** screen or via Host.

In this mode, you have to place the sample racks through a door at the back of the c 501 module into the backup operation port.



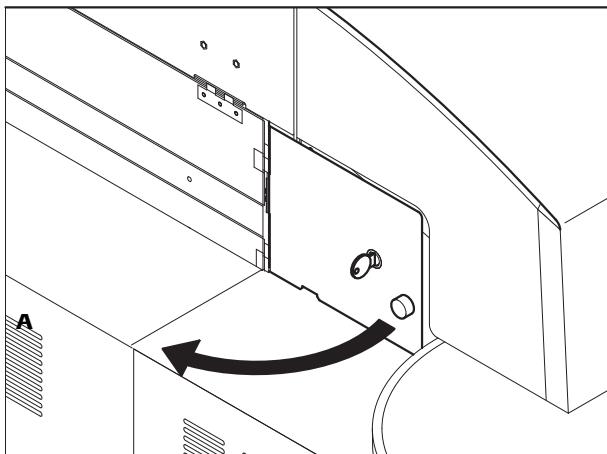
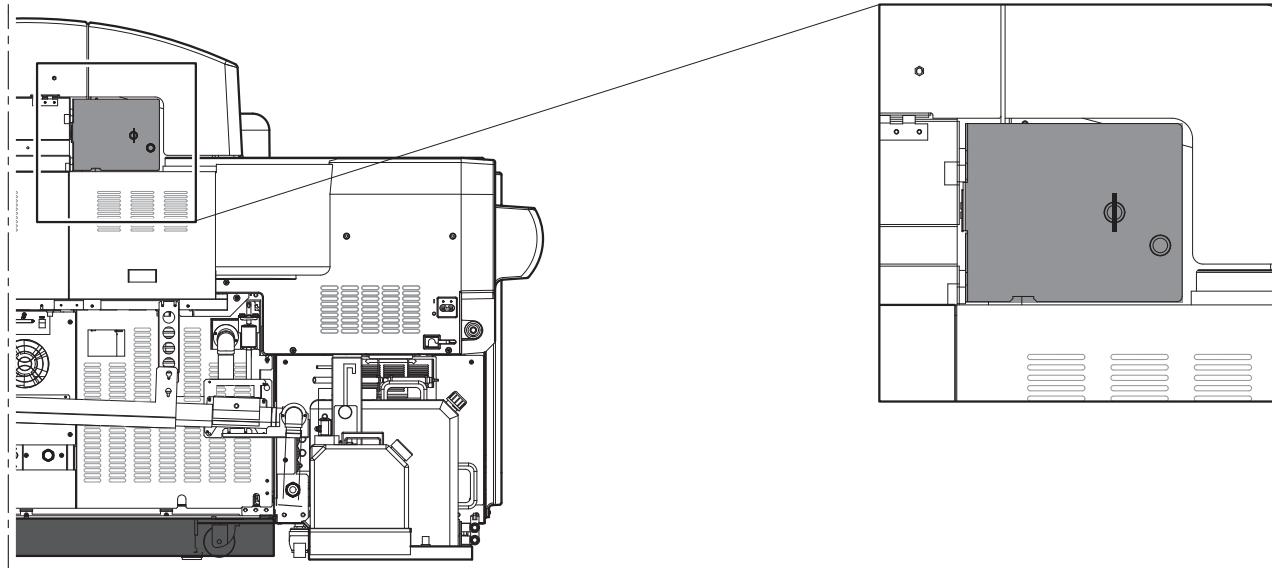
Before performing the following actions, observe the following safety precautions:

- *Infection by contact with sample or waste solution* on page B-3
 - *Personal injury due to contact with instrument mechanism* on page B-3
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: R-1, R-2, R-3.
 - *Incorrect results and interruption of analysis due to contaminated samples* on page B-4
-

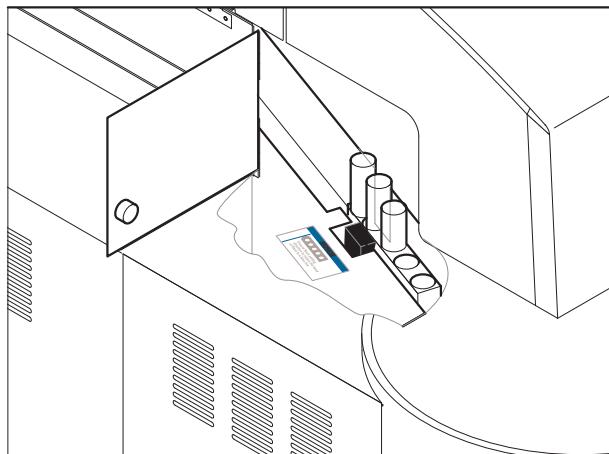
► **To measure samples in backup operation mode**

- 1 Activate the backup operation mode.

See *Activating backup operation mode* on page B-225



A Back door



B Correct position of the rack

Figure B-123 Placing a rack into the backup operation port

- 2 Unlock and open the back door.
- 3 Place a rack containing barcoded samples into the backup operation port.

- 4 Check the position and direction of the rack:

- Align the left side of the rack with the blue line on the label.
- The sample barcodes must be oriented towards the instrument.

If the rack position or direction is wrong, an alarm will be issued.

- 5 Close and lock the back door.

NOTICE

Ensure Rack setting direction to match the head of Rack to a blue line

- 6 After sample pipetting is completed and the instrument is in Standby or in *Backup Wait For Rack Extraction* status, remove the rack through the back door. To perform continuous measurement, remove the rack during *Backup Wait For Rack Extraction* status, place the next rack to be measured, and choose **Start**.
 - 7 Repeat steps 1 to 6 until all sample racks are measured.
-

Calculated Tests

This section explains how to program calculated tests and compensated tests.



Calculated tests and compensated tests can be programmed for **c 501** tests only.

To display this screen choose **Utility > Calculated Test**.

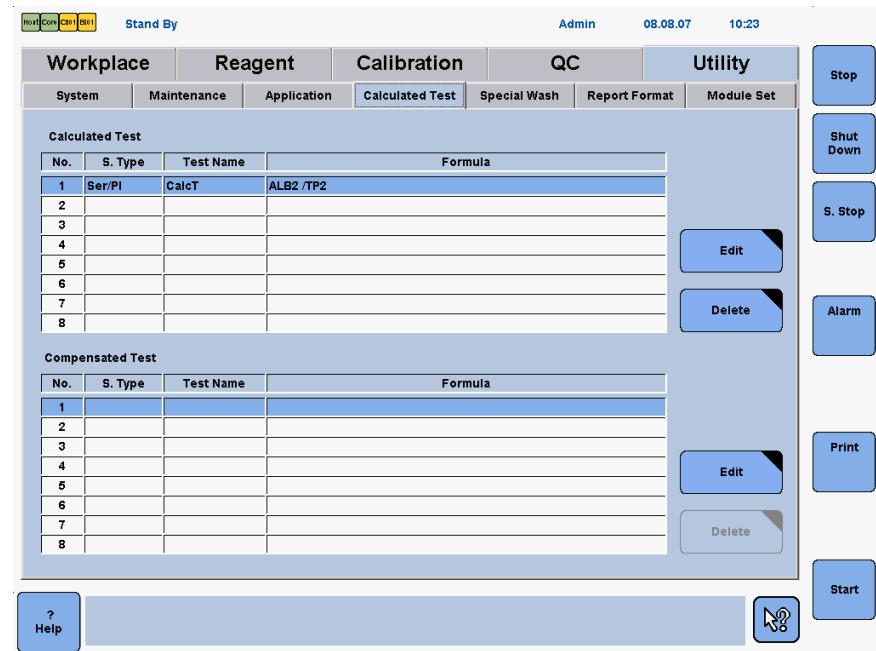


Figure B-124 Calculated Test screen

Programming calculated tests

Calculated test results are not performed on the system but are derived from applying a test formula to the results of clinical chemistry tests performed on the system.

A calculated test will be automatically added to the installed controls in **QC > Install** screen. The QC result for the calculated test is visible on the **QC > Individual** screen and **Individual QC Chart**.

- 👁 For more information, see
 - QC Install screen* on page B-181
 - QC Individual screen* on page B-170



Real Time QC and QC Run Status is not available for calculated tests.

If test data to be used in the calculation is unavailable, the program does not perform the calculation. Calculated test results cannot be edited. Use the following procedures to add, edit or delete a calculated test formula.



If a calculated test formula is edited, the calculated test result displayed on **Data Review** is modified.

► To program a calculated test and enter a calculated test formula

- 1 Choose Utility > Calculated Test.
- 2 Select an empty line from the Calculated Test list at the top of the screen.
- 3 Choose Edit. The Calculated Test Formula window is displayed.

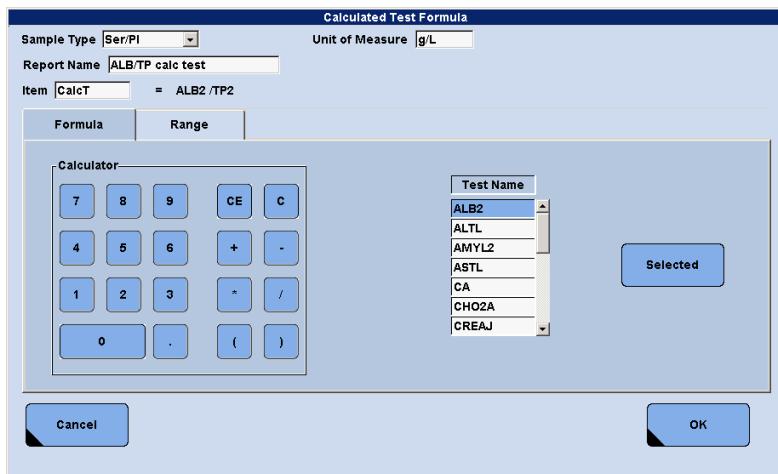


Figure B-125 Calculated Test Formula window

- 4 Select the type of sample (**Ser/Pl**, **Urine**, **CSF**, **Suprnt**) for which the calculated test formula is being created from the **Sample Type** list.
- 5 Type the unit of measure in the **Unit of Measure** box.
- 6 Type a name for the calculated test as it should appear on the report in the **Report Name** box.
- 7 Type the short name of the calculated test in the **Item** box.
Only alphabetic and numerical characters can be used.
- 8 Enter the formula (the formula appears to the right of the **Item** text box, after the equal sign):
 - To add a test to the formula, select the test that is part of the formula from the **Test Name** list and choose **Selected**.
 - To add mathematical operators and numerals, use the **Calculator** area in the window to enter these in the correct sequence along with test names until the formula is complete.
- 9 Now, set the range parameters.



► **To set range parameters**

- 1 Choose the **Range** tab.

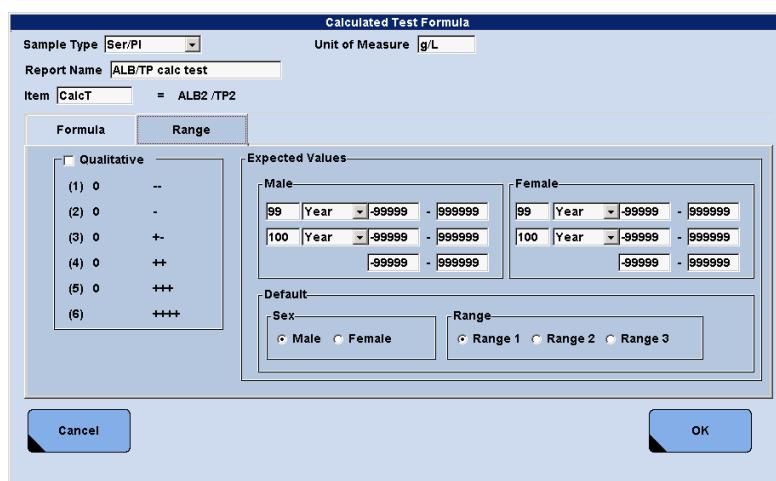


Figure B-126 Calculated Test Formula - Range tab

- 2 Type the expected value ranges or the qualitative parameters in the **Range** area, if needed. Select the **Default Setting**, if needed.
- 3 Choose **OK** to save the new formula and close the **Calculated Test Formula** window. The new formula is shown in the **Calculated Test** list box at the top of the **Calculated Test** screen.



The number of digits displayed to the right of the decimal in the calculated test result is determined by the number of digits entered to the right of the decimal for the first Male Expected Value field on the **Range** tab of the **Calculated Test Formula** window.

- 4 Choose **Utility > Report Format**.
- 5 Select the defined test in the **Print Order** area.
- 6 Type an unused line number into the **Line** field.
- 7 Choose **Update** and **Save** to save the changes.



► **To edit a calculated test formula**

- 1 Choose Utility > Calculated Test.
- 2 Select the calculated test formula to be edited from the **Calculated Test** list box at the top of the screen.
- 3 Choose **Edit** to display the **Calculated Test Formula** window.
- 4 Use **C** in the **Calculator** area of the window to clear the entire formula or **CE** to clear components of the formula one at a time from right to left.
- 5 Enter the formula (the formula appears to the right of the **Item** text box, after the equal sign):
 - To add a test to the formula, select the test that is part of the formula from the **Test Name** list and choose **Selected**.
 - To add mathematical operators and numerals, use the **Calculator** area in the window to enter these in the correct sequence along with test names until the formula is complete.
- 6 Choose the **Range** tab. Type the expected value ranges or the qualitative parameters in the **Range** area, if needed. Change the **Default** settings, if needed.
- 7 Choose **OK** to save the formula programming and close the **Calculated Test Formula** window. The revised formula appears in the **Calculated Test** list box at the top of the **Calculated Test** screen.

■

► **To delete a calculated test formula**

- 1 Choose Utility > Calculated Test.
- 2 In the **Calculated Test** list box, select the calculated test to be deleted.
- 3 Choose **Delete** to the right of the **Calculated Test** list box. A confirmation window appears.
- 4 Choose **Yes** to delete the calculated test and close the window.

■

Programming compensated tests

Clinical chemistry test results can be processed on the system and adjusted by applying a compensated test formula. Use the following procedures to add, edit or delete a compensated test formula.

► To enter a compensated test formula

- 1 Choose Utility > Calculated Test.
- 2 Select an empty line in the **Compensated Test** list box at the bottom of the screen.
- 3 Choose **Edit** to display the **Compensated Test Formula** window.

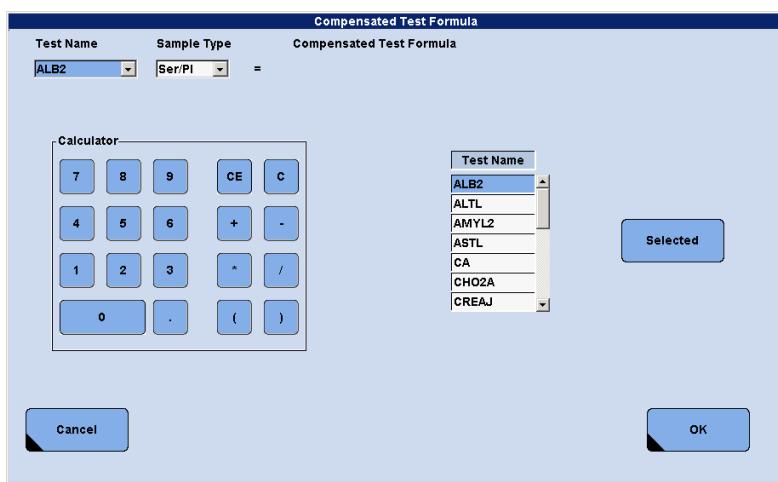


Figure B-127 Compensated Test Formula window

- 4 Select the test and sample type to be compensated from the **Test Name/Sample Type** list box in the upper left corner of the window.
- 5 Enter the formula (the formula appears to the right of the **Sample Type** list box, after the equal sign):
 - To add a test to the formula, select the test that is part of the formula from the **Test Name** list and choose **Selected**.
 - To add mathematical operators and numerals, use the **Calculator** area in the window to enter these in the correct sequence along with test names until the formula is complete.
- 6 Choose **OK** to save the new formula and close the **Compensated Test Formula** window. The new formula is shown in the **Compensated Test** list box at the bottom of the **Calculated Test** screen.



► **To edit a compensated test formula**

- 1 Choose Utility > Calculated Test.
- 2 Select the compensated test formula to be edited from the **Compensated Test** list.
- 3 Choose **Edit** to display the **Compensated Test Formula** window.
- 4 Choose **C** in the **Calculator** area of the window to clear the entire formula, or **CE** to clear components of the formula, one at a time, from right to left. Use the **Test Name** list to select any test that is part of the formula. Choose **Select** after selecting the test to add it to the formula, which is shown at the top of the window. Use the **Calculator** area to enter mathematical operators and numerals in the correct sequence with test names.
- 5 Choose **OK** to save the formula programming and close the **Compensated Test Formula** window. The revised formula appears in the **Compensated Test** list box at the bottom of the **Calculated Test** screen.

■



CAUTION

Even if a compensated test formula is edited, the already calculated test result displayed on **Data Review** is not modified.

► **To delete a compensated test formula**

- 1 Choose Utility > Calculated Test.
- 2 Select the compensated test formula to be deleted from the **Compensated Test** list.
- 3 Choose **Delete**. A confirmation window is displayed.
- 4 Choose **Yes** to delete the compensated test and close the window.

■

Special Wash

The cobas® 6000 analyzer series is a random access system. Therefore, reagent probes and reaction cells may cause carryover and thus interferences between tests, and the sample probe may cause sample carryover.

To avoid carryover and cross-contamination between tests use the special wash function. This function allows you to preset combinations of reagents or samples that may cause carryover so that washing will be carried out between them when the combination is encountered during analysis.

☞ The following sections explain how to set the carryover avoiding function.

Programming a special wash for c 501 modules on page B-235

Programming a special wash for e 601 on page B-240

Programming a special wash for c 501 modules

Reagent probe, sample probe or cell washes may be required due to potential interference from other reagents or samples. These special washes maintain reagent and sample integrity.

Reagent probe wash

The reagent probes dip into the reagents when aspirating. To evade a reagent carryover, program a special wash cycle for the reagent probe.

► To program a reagent probe wash

- 1 Choose Utility > Special Wash > Chemistry.



Figure B-128 Special Wash > Chemistry tab

- 2 Select an empty line in the **Reagent Probe** list to add a reagent probe wash. To edit an existing reagent probe wash, select the corresponding line

- 3** Choose **Edit**, on the right of the **Reagent Probe** area, to display the **Edit Reagent Probe Wash** window.

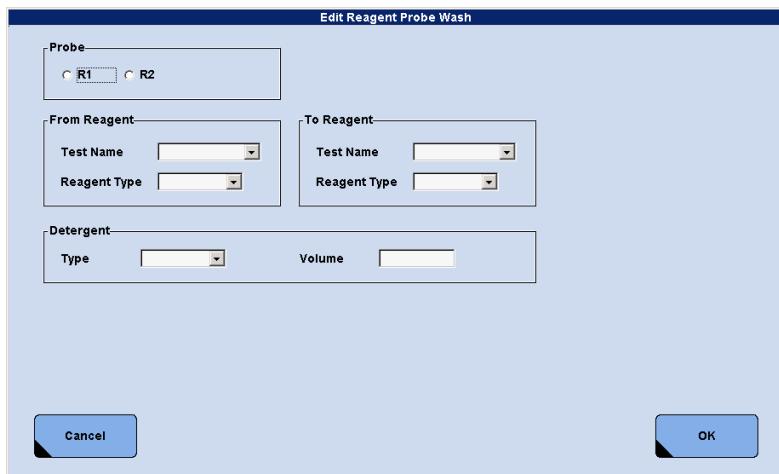


Figure B-129 Edit Reagent Probe Wash window

- 4** In the **Probe** area, choose **R1** or **R2** to designate which reagent probe is to be washed.
- 5** In the **From Reagent** area you have to make the settings for the test from which contamination could be carried over to another test.
- Select the name of the test from the **Test Name** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **To Reagent** area is pipetted afterwards.
 - Select the appropriate reagent type (**R1**, **R2**, or **R3**) in the **Reagent Type** list box.



Individual wash steps must be programmed before the **all tests** wash steps.

- 6** In the **To Reagent** area you have to make the settings for the test to which contamination could be carried over from another test.
- Select the name of the test from the **Test Name** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **From Reagent** area was pipetted before.
 - Select the appropriate reagent type (**R1**, **R2**, or **R3**) in the **Reagent Type** list box.
- 7** In the **Detergent Type** list box select the detergent used for washing. These solutions are used for washing the reagent probe of the c 501 module.
- D1 (NaOH-D)
 - D2 (SMS)
 - D3 (SCCS)
 - Water
- 8** Then type the wash solution volume (from 20 to 180 µL) in the **Volume** text box.
- 9** Choose **OK** to add the new special wash to the list on the **Special Wash** screen and close the window.

- 10** Check the amount of the appropriate detergent cassette on the instrument on the **Reagent > Status** screen



► **To delete a reagent probe wash**

- 1** Choose **Utility > Special Wash > Chemistry**.
- 2** Select the line in the **Reagent Probe** list to be deleted.
- 3** Choose **Delete** located on the right of the **Reagent Probe** area to delete the reagent probe wash after confirmation.



Cell wash

To evade the carryover of traces of the test mixture of one test to the next test measured in that same reaction cell, program a special wash cycle for the reaction cell. In this case a special wash is carried out *before* the corresponding test is performed.

For the HbA1c application (HB-W2, A1-W2) this window shows the **After Sampling** area additionally. In this area you can define special washes for the reaction cell in which the HB-W2 test or the A1-W2 test was performed. In this case a special wash is carried out *after* the corresponding test was performed.

► **To program a cell wash**

- 1** Choose **Utility > Special Wash > Chemistry**.
- 2** Select an empty line in the **Cell** list to add a cell wash. To edit an existing cell wash, select the corresponding line.
- 3** Choose **Edit** located below the **Cell** area to display the **Edit Cell Wash** window.

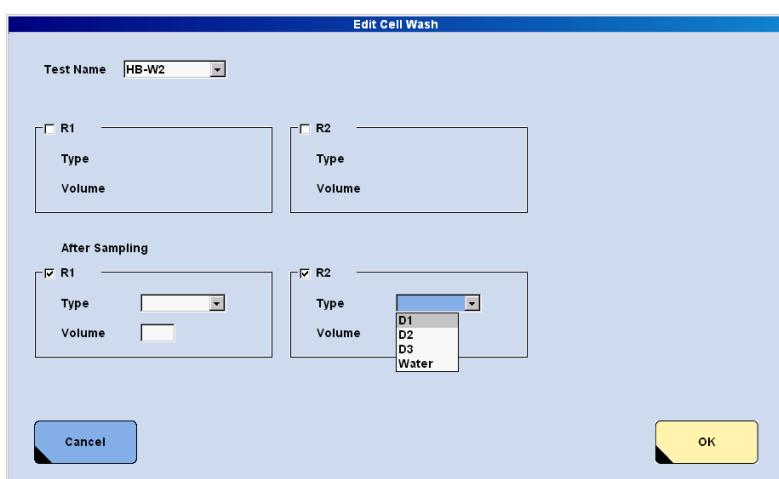


Figure B-130 Edit Cell Wash window

- 4** Select a test from the **Test Name** list box that may cause carry over.
- 5** Designate the reagent probe(s) (**R1** or **R2**) that will dispense the detergent by choosing the **R1** and/or **R2** check boxes.

- 6 In the **Type** list box select the detergent used for washing.

These solutions are used for washing the cells of the c 501 module.

- D1 (NaOH-D)
- D2 (SMS)
- D3 (SCCS)
- Water

- 7 Type the cell wash solution volume (from 20 to 180 µL) in the **Volume** text box for each reagent probe selected.

- 8 Choose **OK** to save the settings, add the programming to the **Cell** list box and close the window.

- 9 Check the amount of the appropriate detergent cassette on the instrument on the **Reagent > Status** screen.



► To delete a cell wash

- 1 Choose **Utility > Special Wash > Chemistry**.

- 2 Select the test to be deleted from the **Cell** list.

- 3 Choose **Delete** located below the **Cell** list box to delete the cell wash after confirmation.



Sample probe wash

The sample probe dips into the sample when it aspirates sample liquid. To evade a carryover of sample liquid into a test that is sensitive for sample residual, program a special wash cycle for the sample probe.

► To program sample probe wash

- 1 Choose **Utility > Special Wash > Chemistry**.

- 2 Select an empty line in the **Sample Probe** list to add a sample probe wash. To edit an existing sample probe wash, select the corresponding line.

- 3** Choose **Edit** located below the **Sample Probe** area to display the **Edit Sample Probe Wash** window.

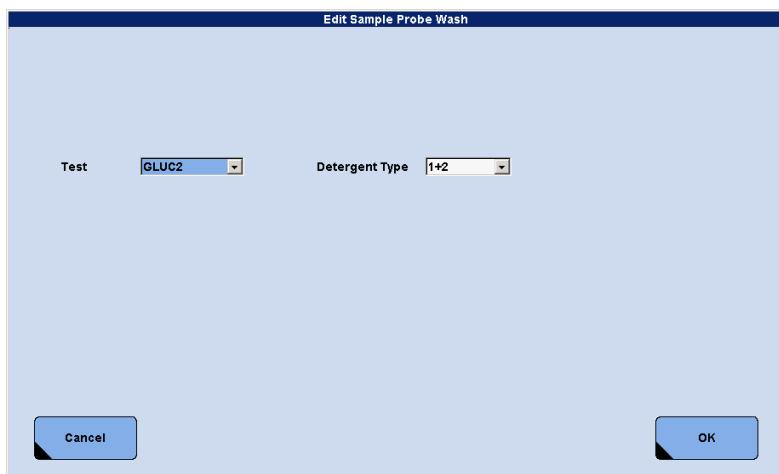


Figure B-131 Edit Sample Probe Wash window

- 4** Select a test from the **Test** list box that is sensitive for sample residual.
- 5** In the **Detergent Type** list box select the detergent used for washing.
These solutions are used for washing the sample probe of the c 501 module.
- 1 (Multiclean)
 - 2 (SMS)
 - 1+2 (Multiclean + SMS)
 - Water
- The detergent aspiration volume is 45 µl
- 6** Choose **OK** to save the settings.



When a sample probe wash is performed prior to sample aspiration for a sample, a *b* appears in the status column on **Workplace > Data Review**. The solutions used to clean the sample probe are listed in the **Carryover Evasion** field on the **Workplace > Data Review > Test Review** screen.

- 7** Check that the appropriate wash solution is placed on the instrument in the correct position.

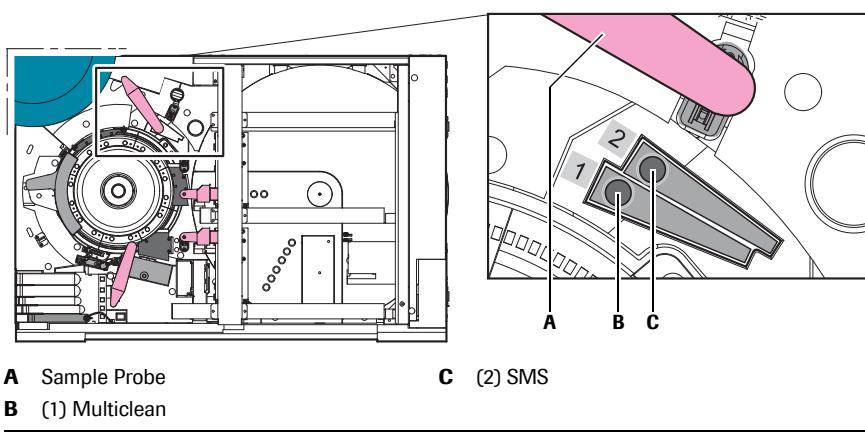


Figure B-132 Sample probe cleaners

- 8** Check the amount of the appropriate detergent on the **Reagent > Status** screen.

■

► **To delete a sample probe wash**

- 1** Choose Utility > Special Wash > Chemistry.
- 2** Select the test to be deleted from the **Sample Probe** list.
- 3** Choose **Delete** located below the **Sample Probe** list to delete the sample probe wash after confirmation.

■

Programming a special wash for e 601

Use special wash programs for the e 601 reagent probe to avoid potential carryover of reagents or samples to other assays. Special washes maintain reagent and sample integrity.

Reagent probe wash

The reagent probes dip into the reagents when aspirating. To evade a reagent carryover, program a special wash cycle for the reagent probe.

► **To program a reagent probe wash**

- 1** Choose Utility > Special Wash > Immune.

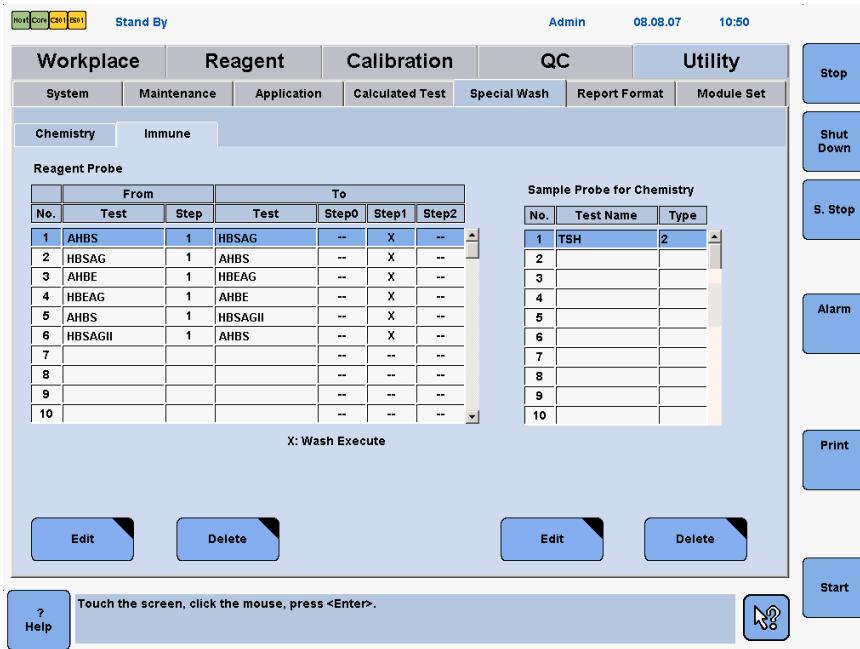


Figure B-133 Special Wash > Immune tab

- 2** Select an empty line in the **Reagent Probe** list to add a reagent probe wash. To edit an existing reagent probe wash, select the corresponding line.

- 3 Choose **Edit** located below the **Reagent Probe** area to display the **Edit Reagent Probe Wash** window.

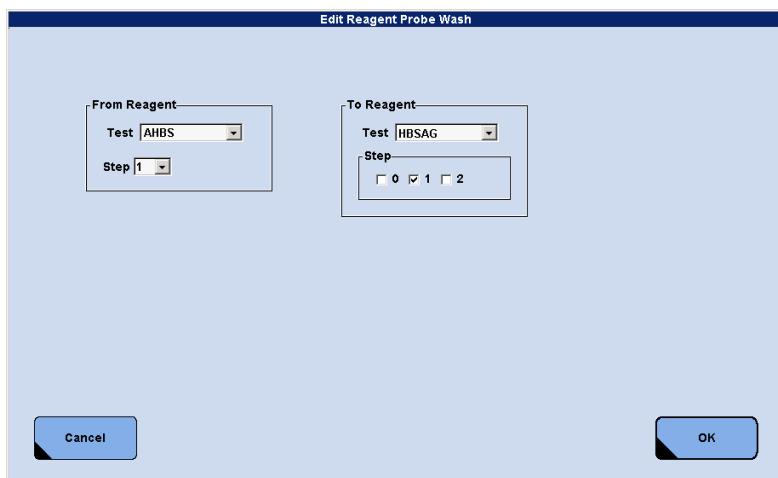


Figure B-134 Edit Reagent Probe Wash window

- 4 In the **From Reagent** area you have to make the settings for the test from which contamination could be carried over to another test.
- Select the name of the test from the **Test** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **To Reagent** area is pipetted afterwards.
 - Select the pipetting step (0, 1 or 2) from the **Step** list box.
 - Step 0 is used for pretreatment or diluent.
 - Step 1 is the pipetting step before the first incubation.
 - Step 2 is the pipetting step before the second incubation.
- 5 In the **To Reagent** area you have to make the settings for the test to which contamination could be carried over from another test.
- Select the name of the test from the **Test** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **From Reagent** area was pipetted before.
 - Select which pipetting steps are affected (0, 1 or 2) from the **Step** check boxes.
- 6 Choose **OK** to save any changes made.

■

Sample probe wash

In the context of e 601 special wash, the term *sample probe* refers to the sample probe of the c 501, not to the e 601 sample probe.

Prior to pipetting the c 501 test, the sample probe of the c 501 is washed with the specified detergent if afterwards the e 601 test (specified on the **Edit Sample Carry Over Evasion** window) is requested.



If a sample has been processed on c 501 before an e 601 assay is performed and a special wash for the sample probe of the c 501 has been performed, a b-flag is added to the result on the **Data Review** screen.

► To program a sample probe wash

- 1 Choose Utility > Special Wash > Immune.
- 2 Select an empty line in the **Sample Probe for Chemistry** list to add a sample probe wash. To edit an existing sample probe wash, select the corresponding line.
- 3 Choose **Edit** located below the **Sample Probe** area to display the **Edit Sample Carry Over Evasion** window.

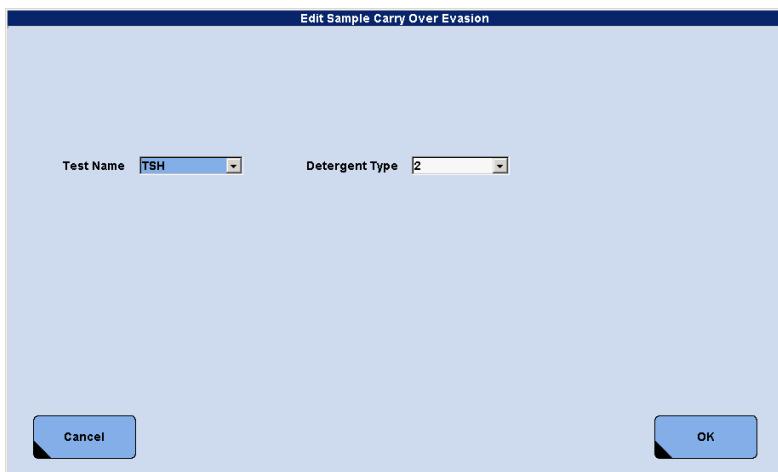


Figure B-135 Edit Sample Carry Over Evasion window

- 4 In the **Test Name** list box select the test.
- 5 In the **Detergent Type** list box select the detergent used for washing.
These solutions are used for washing the sample probe of the c 501 module.
 - 1 (Multiclean)
 - 2 (SMS)
 - 1+2 (Multiclean + SMS)
 - Water

The detergent aspiration volume is 45 µl

- 6 Choose **OK** to save any changes made.



Report Format

This section explains how to customize the report format of the patient report.

The patient report (**Print** (global button)> **Workplace> Data Monitor/Report**) can be printed in two formats: **Monitor** format or **Report** format. Only the **Report** format can be customized.

Customizing patient report format

► **To customize patient report format**

- 1 Choose Utility > Report Format.

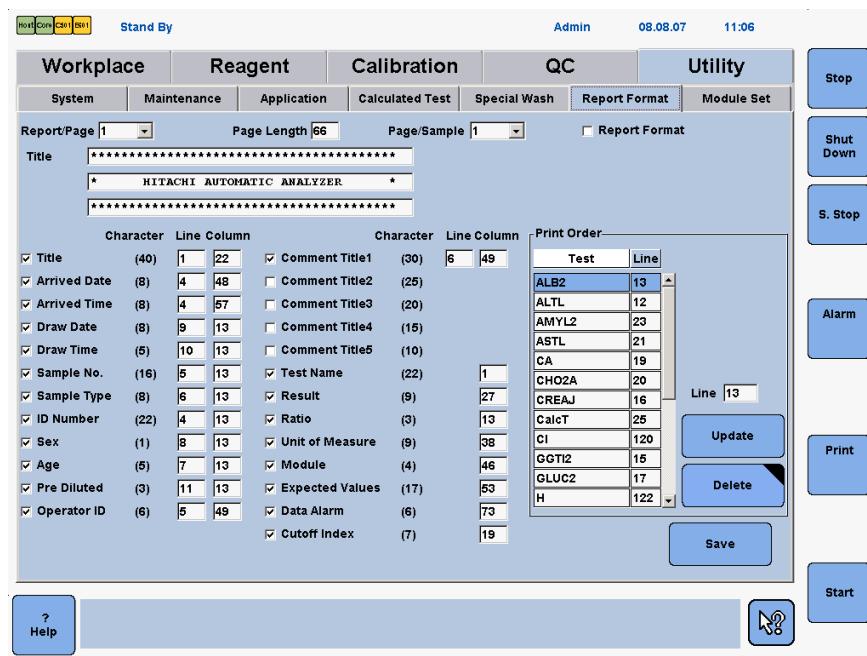


Figure B-136 Report Format screen

Customizing the report format of the patient report consists of the following steps:

- Choose the page layout.
☞ *To choose the page layout* on page B-244
- Define the title, the positions of all other items, and the print order.
☞ *To define the title and the positions of all other items* on page B-244
- Choose **Save** to save the changes.

► To choose the page layout

- 1 Select the number of reports per page (1 or 2) from the **Report/Page** list.
- 2 Type the page length in lines in the **Page Length** box.
 - for US letter (8 1/2 "x 11") type 66
 - for A4 (21cm x 29,7 cm) type 72
- 3 Select the number of pages per sample (1 or 2) from the **Page/Sample** list.
- 4 Select the **Report Format** check box to print patient reports in report format or deselect it to print in monitor format.

If automatic printout is activated (**Utility > System** (Page 4/4) > **Automatic Printout**) the patient report (only STAT samples) is printed in the selected format (report format or monitor format).

If you print the patient report from the **Data Monitor/Report** screen (**Print** (global button)> **Work Place**> **Data Monitor/Report**) you can select the format regardless of the setting on the **Print Format** screen.

**► To define the title and the positions of all other items**

- 1 Type the title to be used for the report header (up to 3 lines of 40 characters each) in the **Title** text boxes.
- 2 Assign a print line and column to each of the items of report information, as appropriate.



When assigning a print column, allow for the maximum character length for the item if assigning more than one demographic item to a line. For example, if the arrived date is assigned to line 4, column 47 and the arrived time is also assigned to line 4, it must be assigned to column 56 or higher since the character length for the arrived date is 8. If the second item is assigned to a column that is used by the first item, one of the items does not print or only partially prints.

► **To alter the print order**

**CAUTION****Results may not be displayed**

- If there is no print order defined, the result is not printed out or displayed in the **Print/View** screen, although the test itself is measured.
 - For each test, a print order number has to be defined.
 - The setting of print order corresponds to the test order in the printout. Ensure that print order lines are not used from the information fields.
-

1 In the **Print Order** area, select the test from the list.

2 Type the line number on which the test is to print in the **Line** text box.

**WARNING****Results may not be displayed**

- Do not assign the same print line number to a test that is assigned to any demographic information in step 1 from *To define the title and the positions of all other items*.
 - If a print order is assigned to a line already used, the result may be overwritten by the other information.
-

3 Choose **Update** to update the print order information.

4 Choose **Save** to save the changes.



To check the report setup, print a report example from **Print** (global button) > **Utility** > **Report Example**.

Comparison of data monitor format and report format

Data Monitor/Report (monitor format)

Data Monitor						19/07/08	16:30
Ser/Pl	N	00014-2		000434			
19/07/08		CREA (C)	ALB2 (C)	CHOL (C)	TG (C)	TP2 (C)	
16:15:44		6.76	3.27	186	194	80.0	
admin			>Test				
		HCG-BETA (E-1)		TSH (E-2)			
		33,00		1,00			

Figure B-137 Data Monitor report (monitor format)

Data Monitor/Report (report format)

* HITACHI AUTOMATIC ANALYZER *							

ID		000434	DATE	18/09/08	17:05:23		
S.NO.	N	00014-2	OPERATOR ID	admin			
S.TYPE	Ser/Pl		Name				
AGE							
SEX							
DRAW DATE							
DRAW TIME							
PPEDILUTED	NO						
TEST	RATIO	COI/MES	RESULT	UNIT	MODULE	EXPECTED VALUE	ALARM
TOTAL PROTEIN			49.6	g/dL	C	(-99999- 999999)	
Chol			174	mg/dL	C	(-99999- 999999)	
Crea			1.18	mg/dL	C	(-99999- 999999)	
Na			125	mmol/L	C	(-99999- 999999)	
K			3.5	mmol/L	C	(-99999- 999999)	
Cl			87	mmol/L	C	(-99999- 999999)	
ALB			33	g/L	C	(-99999- 999999)	

Figure B-138 Data Monitor report (report format)

☞ For more information, refer to the Online-Help information of the Data Monitor/Report

Maintenance

C

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17	<i>Maintenance cu 150</i>	C-47
18	<i>Maintenance c 501 with ISE</i>	C-63
19	<i>Maintenance e 601</i>	C-119

Safety information for maintenance

This chapter describes potential hazards that may occur during maintenance of the cobas 6000 analyzer.

Before performing maintenance, particular attention must be taken of the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury.



Electrical shock by electronic equipment

Removing the covers marked with this symbol can cause electric shock, as there are high voltage parts inside. In addition, opening the top cover of the c 501 module and touching the ultrasonic mixing mechanism during operation can also cause electric shock.

- Do not remove any cover of the instrument, other than specified in this Operator's Manual
- Do not open the top cover and touch the ultrasonic mixing unit during operation or when the analyzer performs maintenance.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: R-5, R-7.

Infection due to contact with sample or waste solution

Contact with sample or waste solution may result in infection. All materials and mechanical components associated with the reaction system and the waste systems are potentially biohazardous.

- Be sure to wear protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-6, F-7, F-10, T-13, T-16, R-6, S-1.

Contamination by waste solution and solid waste

The waste of the system is potentially biohazardous.

The system discharges two kinds of waste solutions:

- Concentrated waste solution that contains high concentrated reaction solution. This waste must be treated as infectious waste.
- Diluted waste: Rinsing water from cell wash or water from the incubator bath.

When disposing of any waste generated by the system, do so according to the appropriate local regulations.



Personal injury due to contact with instrument mechanism

Contact with sampling mechanism or other mechanisms may result in personal injury and infection.

- Before starting operation or maintenance, be sure to close and lock the top and back covers whenever possible.
 - Do not open the top cover of a module while the analyzer is performing maintenance.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-3, F-4, F-9, F-10, T-2, T-3, T-6, R-3.
-

Personal injury due to contact with pierce pin

A pierce pin for reagent cassettes is located adjacent to the reagent probe R1. Contact with the pierce pin may result in personal injury.

- Do not touch the pierce pin during cleaning.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-2.
-

Infection and injury due to sharp objects

When wiping probes, use several layers of gauze and wipe from the top down.

- Be careful to not puncture yourself.
 - Be sure to wear appropriate protective equipment, for example gloves. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
-

Personal injury due to contact with cleaning solutions or reagents

Contact with cleaning solutions of the system or reagents may cause skin damage or inflammation.

- Be sure to wear protective equipment.
 - Observe the cautions given on the bottles and cassettes and the instructions for use.
 - If cleaning solution comes into contact with your skin, wash it off immediately with water. Consult a physician.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-8, F-14, F-15, F-16.
-

Fire and burns due to the use of alcohol

Alcohol is a flammable substance.

- Keep flammables away from the analyzer when conducting maintenance or checks using alcohol.
 - When using alcohol on or around the instrument, use no more than 20 mL at a time.
-

**CAUTION**

Malfunction due to spilled liquid

Any liquid spilled on the instrument may result in malfunction of the instrument. If liquid does spill on the instrument, wipe it up immediately and apply disinfectant. Be sure to wear protective equipment.

Incorrect results due to missing cover of the ISE measuring compartment

If the cover of the ISE measuring compartment is not reinstalled after maintenance, the temperature may become inaccurate, leading to incorrect results.

- Only perform measurement, when the cover of the ISE measuring compartment is closed.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-11.
-

Incorrect results due to missing covers of the e 601 reagent compartment or the incubator

If the covers of the reagent compartment or the incubator are not reinstalled after maintenance, the temperature may become inaccurate, leading to incorrect results.

- Only perform measurement, when the covers are closed.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-15.
-

Damage to the analyzer due to remaining tools during maintenance

If the instrument power is turned ON when performing manual maintenance, parts or tools may contact the instrument mechanisms and damage the instrument.

- Make sure no maintenance is being performed before supplying power to the instrument.
-

Damage to the e 601 module due to the use of acid or alkaline solutions for cleaning

Do not use an acid solution or an alkaline solution to clean the Pre-wash mixer, the incubator, and the AssayCup vortex mixer. It is made of aluminum and these solutions degrade the metal.

- Use deionized water to clean these parts of the analyzer.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-7.
-

General maintenance

This chapter provides general information about maintenance for the cobas® 6000 analyzer series. Concepts, such as maintenance pipes, maintenance types, parallel and background maintenance are described as well as instrument care. In addition, a combined maintenance schedule for all cobas 6000 modules is provided.

In this chapter

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Overview



WARNING

Injury or damage to the analyzer due to non-observance of safety information

- Before performing maintenance for any part of the instrument, observe the safety notes for the corresponding maintenance item in the module-specific maintenance chapters.
- The system must be provided with proper care and maintenance to ensure consistent and accurate functioning. Modifying or omitting the maintenance procedures may result in the loss of performance or reliability of the system which is the responsibility of the operator.

The part Maintenance contains information about the following topics:

- General maintenance

This chapter contains an overview of maintenance on the analyzer and describes how maintenance is managed.

- Module specific maintenance actions

The module-specific maintenance actions are described in separate chapters.

☞ For more information, see:

Maintenance cu 150 on page C-47

Maintenance c 501 with ISE on page C-63

Maintenance e 601 on page C-119

All of the software screens shown in this part are used as examples only. Your screens may vary depending on your system setup.

General information on performing maintenance for the cobas 6000 analyzer

For most maintenance actions, either a module has to be in standby or the analyzer has to be in shutdown status. This section explains what shutdown status is, how to put the analyzer in shutdown status, how to restart the analyzer, and how to release the analyzer in standby status after interlock function has generated an error message.

Make sure to put the analyzer in shutdown status or in an appropriate maintenance mode (for example, incubator bath cleaning mode) before replacing parts.

Keep the top cover of the analytical unit closed for maintenance carried out with the system powered on. If a check or maintenance requires open covers, be careful not to touch any other than the aimed-at parts.

Operator time and System time

In the chapters of part C Maintenance the operator time and the system time for each maintenance item are mentioned.

The *operator time* is the estimated time that a trained person requires to perform this maintenance item.

The *system time* is the approximate time that the system requires to perform the required maintenance items. As most maintenance items can be performed in standby or shutdown status, the system time for shutdown of the analyzer (approximately 3 minutes) and for switching on the analyzer (approximately 12 minutes) is not included in the calculation of the system time.

 *List of maintenance items* on page C-41

Interlock function during standby status

If you open the top cover of the c 501 module during standby status, the interlock function stops all moving parts immediately. If you want to continue operation or perform a maintenance item, you have to release the analyzer in standby status.

► To release the analyzer in standby status after interlock

- 1 Close the top cover of the c 501 module and lock it.
- 2 If an error message is displayed that the top cover was opened, delete this error message.
- 3 Choose **Utility > Maintenance**.
- 4 Select **Maintenance (1)** from the **Maintenance Type** list on the left.
- 5 Select **(1) Reset** from the **Maintenance Items** list on the right.
- 6 Choose **Select** to open the **Reset** window. Select the c 501 module to be reset.
- 7 Choose **Execute**.

■

Shutdown status

Shutdown status is the condition where analytical module(s) and control unit are disconnected and the operation power switch is switched off. Power for keeping the reagents cool, however, is still supplied.

► To shutdown the analyzer

System time approximately 3 minutes

- 1 Choose **Shut Down** (global button) to display the **Shut Down** window.
- 2 Select the **Shut Down** option, choose **Execute** and confirm the shutdown.
- 3 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.
- 4 Switch off the operation power switch on the left of the rack sampler unit.



If the power of the analyzer is switched off prior to the complete shutdown of the computer, the instrument may not start up properly when power is supplied again.

- Make sure the monitor indication has changed from shutdown to a state where nothing is displayed.
- Then, switch off the analyzer power switch.

► To switch on the analyzer

System time approximately 12 minutes

- 1 Switch on the analyzer's operation power switch located on the left of the rack sampler unit.

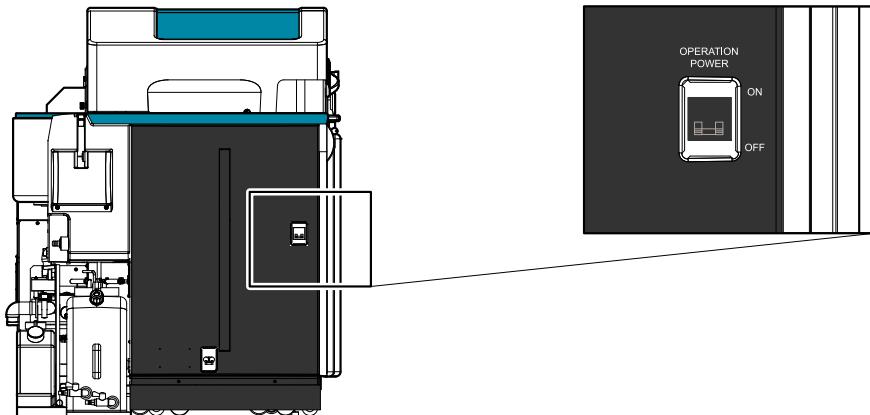


Figure C-1 Operation power switch

The system starts the initialization routine.

- 2 Switch on the computer of the control unit, the monitor, and the printer.
- 3 After initialization, the Logon screen displays. Enter your operator ID and password to log on.
- 4 Choose **OK** to gain access to the software and begin system operation.



If the logon mode is not activated (**Utility > System** (Page 3/4) > **Operator ID**), the software opens at the **System Overview** screen.

Definitions

<i>Maintenance items</i>	A single maintenance procedure ☞ For a list of maintenance items see <i>List of maintenance items</i> on page C-41
<i>System-controlled (automatic) maintenance</i>	Maintenance items that are performed without operator interaction (such as (6) Air Purge)
<i>Operator-controlled (interactive) maintenance</i>	Maintenance items that require operator interaction (such as (10) Incubator Bath Cleaning).
<i>User-definable (manual) maintenance</i>	Users may define maintenance items specific for their laboratory (such as Cleaning Sample Probe). User-definable maintenance items are always maintenance actions that have to be performed manually.
<i>Maintenance pipe</i>	A combination of sequential maintenance items programmed into a fully automated procedure, which can be performed by the analyzer without operator intervention.
<i>Maintenance pipe function</i>	A function that automatically starts a maintenance pipe at a particular time (e.g., at power-up).
<i>Maintenance type</i>	A set of maintenance items (system-controlled, operator-controlled and user-definable) and maintenance pipes grouped according to certain functions (such as daily or weekly maintenance).

Maintenance concept

This section explains how the analyzer supports the operator when performing maintenance.

<i>Performing maintenance items manually</i>	Maintenance items can be performed manually on the Utility > Maintenance screen. Operator-controlled and user-definable maintenance items cannot be part of a maintenance pipe. Thus, they have to be performed manually.
--	---

☞ See *Performing maintenance items or pipes* on page C-16

<i>Maintenance pipes—performing maintenance items automatically</i>	A maintenance pipe is a set of system-controlled maintenance items (batch set). You can use a maintenance pipe so that certain maintenance items occur in a certain sequence.
---	---

Before usage, maintenance pipes must be defined under **Utility > System (Page 2/4) > Pipe Setting**. They comprise up to ten maintenance items including parameters belonging to them.

Maintenance pipes can be executed in two different ways:

- Manually by the user
- Automatically by means of *maintenance pipe functions* at those events:
 - At power up of system (**Power Up Pipe** function)
 - Before start of analysis (**Start Up Pipe** function)
 - Before entering sleep mode (**Sleep Pipe** function)

☞ For more information on maintenance pipes, see:
Defining and editing maintenance pipes on page C-15

<i>Maintenance types—scheduling and tracking maintenance items</i>	<p>Maintenance items and maintenance pipes can be assigned to a maintenance type according to certain functions (such as daily or weekly maintenance).</p> <p>Within a maintenance type you can assign maintenance intervals (Period) and warning levels to each maintenance item and maintenance pipe. Thus, you can create and customize a maintenance schedule for any periodic maintenance tasks.</p> <p>If a maintenance item or a maintenance pipe has been scheduled, you can track its status (date of last execution and warning level) on the Maintenance screen. The status of maintenance types is also displayed on the System Overview screen.</p> <p>Maintenance types are configured in Utility > System (Page 2/4) > Maintenance Setting.</p> <p class="list-item-l1">⦿ For more information on defining and using maintenance types, see: <i>Defining and editing maintenance types</i> on page C-21 <i>Tracking maintenance</i> on page C-24</p>
<i>Maintenance report—recording maintenance</i>	<p>The analyzer records the execution of maintenance items in the Maintenance Report.</p> <p>The Maintenance Report is requested through Print (global button) > Utility > Maintenance Report.</p> <p class="list-item-l1">⦿ See <i>Maintenance report</i> on page C-25.</p>
<i>Parallel and background maintenance</i>	<p>Various maintenance procedures can be performed in parallel, meaning that one module can be performing a maintenance item while another module is performing a different maintenance item. Maintenance procedures may also be performed in background while the system is in the Operation mode.</p> <p class="list-item-l1">⦿ See <i>Background and parallel maintenance</i> on page C-37.</p>

Maintenance pipes

A maintenance pipe is a set of system-controlled maintenance items (batch set). Using maintenance pipes saves time by allowing the system to perform a series of maintenance items without operator intervention.

Be sure to note the relation between *maintenance pipes* and *maintenance pipe functions*:

Maintenance pipes

Before usage, maintenance pipes must be defined under **Utility > System (Page 2/4) > Pipe Setting**. The name of a pipe is freely definable, e.g. **Power On pipe**.

Roche Diagnostics recommends using maintenance pipes for automating instrument care, but there are no pre-defined pipes on the system by default.

For more information, see:

Defining and editing maintenance pipes on page C-15

Recommended maintenance pipes on page C-35

Maintenance pipes can be executed manually by the user. Alternatively, they can be executed automatically by means of *maintenance pipe functions*.

Maintenance pipe functions

A maintenance pipe function triggers the system to start a maintenance pipe at one of those three particular times (events):

- At power-up or wake up (**Power Up Pipe** function)
- Before start of analysis (**Start Up Pipe** function)
- Before entering sleep mode after the last maintenance item is completed (**Sleep Pipe** function)

See *Maintenance pipe function* on page C-12

Example

The **Power On pipe** contains multiple maintenance items (Figure C-2). It can be executed manually or be assigned e.g., to the **Power Up Pipe** function. In the latter case, the pipe function will automatically start the maintenance pipe at power-up.

Maintenance pipe:

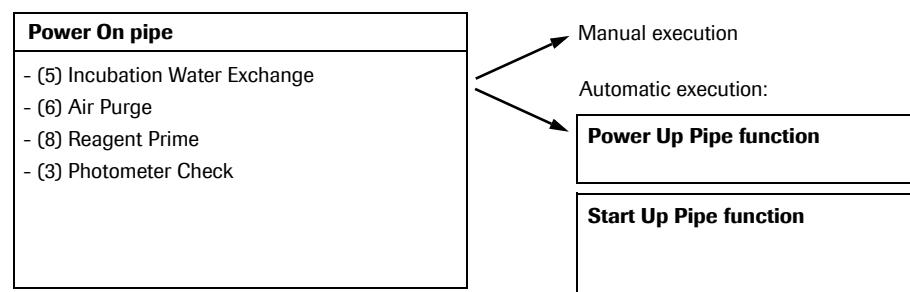


Figure C-2 Example of maintenance pipes and maintenance pipes functions



Note that:

- **Power On** is used as a name for a maintenance pipe. (This name is freely definable.)
- **Power Up Pipe** is a fixed name of a maintenance pipe function.

The following sections describe how maintenance pipes are defined, executed, and deleted.

Defining and editing maintenance pipes

Use the following procedure to program a series of maintenance items into a specific maintenance pipe. Up to ten items can be defined in each pipe. These items are performed one after the other. When a maintenance item is performed as part of a pipe, an asterisk appears on the left side of the date on the **Maintenance Report**.

 See *Maintenance report* on page C-25.

► To edit a maintenance pipe or to define a new pipe

- 1 Choose **Utility > System (Page 2/4) > Pipe Setting** to display the **Maintenance Pipe Setting** window.

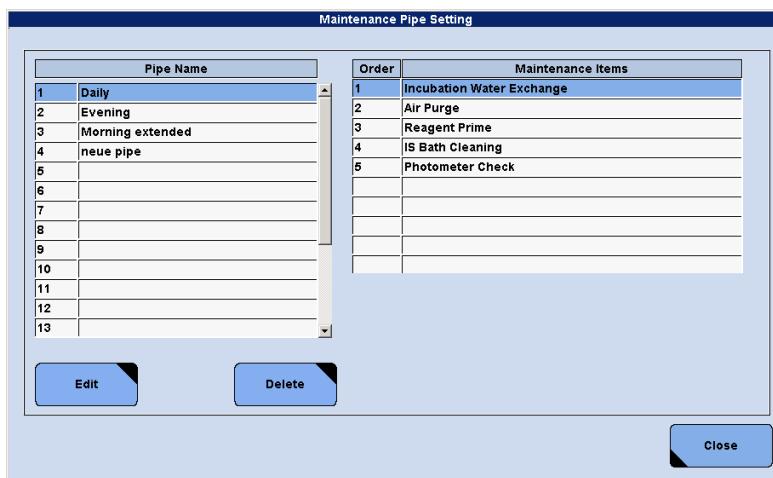


Figure C-3 Maintenance Pipe Setting window

- 2 Choose an existing pipe in the **Pipe Name** list to edit the pipe or choose the first blank line to define a new pipe. Choose **Edit** to display the **Edit Pipe** window.

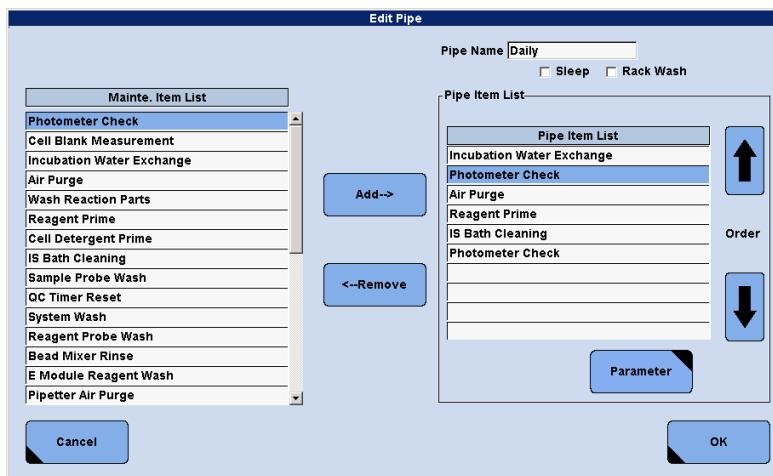


Figure C-4 Edit Pipe window

- 3 Type an unused name for the new pipe in the **Pipe Name** text box or edit the name of the existing pipe if you want to change its name.

To carry out washing with a green wash rack, select **Rack Wash**. Set the green wash rack in the rack loader. The maintenance pipe will be performed after the washing procedure.

- 4 Add a maintenance item to the **Pipe Item List** by choosing the maintenance item on the **Maintenance Item List**, then choose **Add**.
- 5 Choose **Parameter** to select or deselect specific modules or define the number of cycles performed depending on the maintenance item highlighted.
 - ☞ For more information about the parameters of the different maintenance items, refer to the *Online Help* of the particular window.
- 6 Choose **OK** to save the settings and return to the **Edit Pipe** window.
- 7 Repeat steps 4 to 6 for all items that are to be included in the pipe.
- 8 Delete items from the pipe by choosing the appropriate item on the **Pipe Item List**, then choose **Remove**.



Items must be listed in the sequence that they are to be performed by the system. If the items are not in the desired order, choose the item to be reordered to highlight it, then choose the appropriate arrow to move the item up or down in the list.

- 9 Choose **OK** when the pipe settings are complete. The pipe then appears in the **Pipe Name** list in the **Maintenance Pipe Setting** window and as an option on **Utility > System (Page 2/4) > Power Up Pipe Setting**.



Deleting maintenance pipes

► To delete a maintenance pipe

- 1 Choose **Utility > System (Page 2/4) > Pipe Setting**.
- 2 In the **Pipe Name** list, choose the name of the pipe to be deleted to highlight it.
- 3 Choose **Delete** and confirm with **Yes** to delete the maintenance pipe.



Performing maintenance items or pipes

Maintenance pipes are normally performed automatically by the system as a power up pipe or a start up pipe. But they can also be performed manually. Maintenance pipes can only be performed if they are part of a maintenance type.

To manually perform a maintenance pipe, it must be configured as an item of a maintenance type.

☞ See *Defining and editing maintenance types* on page C-21

If a single maintenance item is not part of a maintenance pipe, it can only be performed manually.

► **To execute a maintenance item or pipe**

- 1 Choose Utility > Maintenance to display the **Maintenance** screen.



Figure C-5 Maintenance screen

- 2 Choose an entry from the **Maintenance Type** list.
 - The entries **Maintenance** and **Check** are predefined. They include only maintenance items, but no pipes.
 - A self-defined maintenance type can include both: Maintenance items and maintenance pipes.
- 3 Select the maintenance item or pipe to be performed from the **Maintenance Item** list.



A maintenance pipe can only be selected, if it was configured as an item of a maintenance type.

- 4 Choose **Select**.

- 5 Define any parameters required.

- 6 Choose **Execute**.



The maintenance pipe or item is performed. The date of the maintenance pipe or item is updated.

If the pipe is defined as a Sleep pipe, the system will enter in sleep mode after the pipe has been performed.

If the green wash rack (Rack Wash) is processed with the pipe, you have to load the green wash rack on the system before executing the pipe.

See *Sleep Pipe function with green wash rack* on page C-20.

Using maintenance pipe functions

Maintenance pipes can be performed automatically by the system by means of maintenance pipe functions. The system provides three maintenance pipe functions, which are described in the following.

Power Up Pipe function

Use the **Power Up Pipe** function to select a pipe to be performed at power up of the system. In addition, you can set a wake up time when the power up of the system—and thus the selected pipe—is performed. However, the wake-up time takes effect only if the system was put in sleep mode before (and not put to shutdown status).

► To activate the Power Up pipe function

- 1 Choose Utility > System (Page 2/4) > Power Up Pipe Setting.

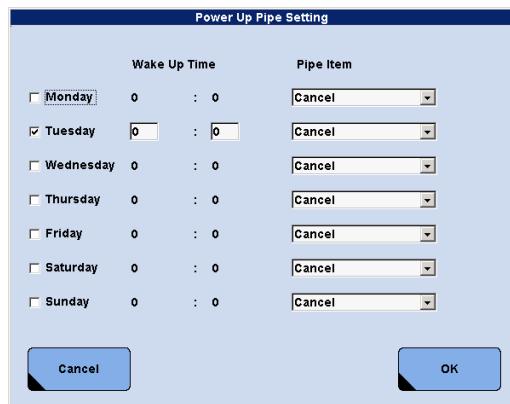


Figure C-6 Power Up Pipe window

- 2 Select the pipe to be performed at power up from the drop-down list box for each day of the week.
- 3 In case you want to set a wake-up time do the following:
 - Select the check box to the left of the weekday for which you want to set a wake-up time.
 - Set the time in the two boxes to the right of the check box.
- 4 Choose OK.



Start Up pipe function

The **Start Up Pipe** function is used to automatically perform a selected pipe before the start of analysis.

► To activate the Start Up pipe function

- 1 Choose **Start** (global button) or press the F2 key.

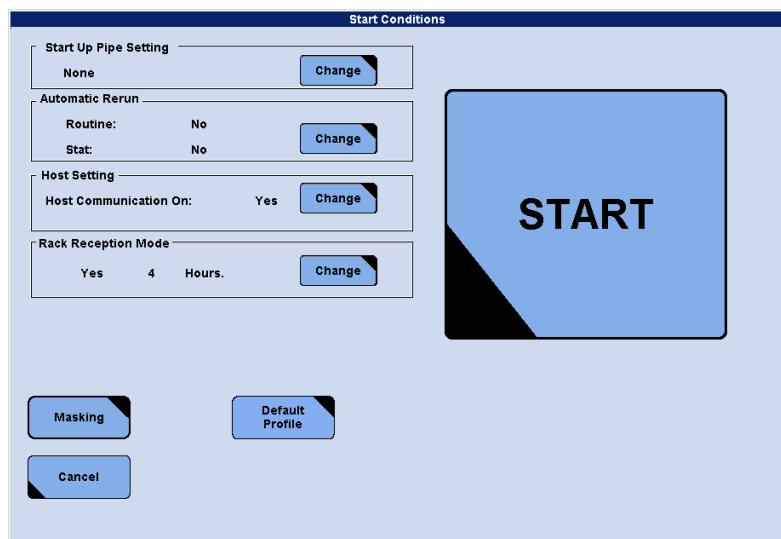


Figure C-7 Start Conditions screen

The **Start Up Pipe Setting** area displays the maintenance pipe currently selected as **Start Up pipe**. If no maintenance pipe is selected, None is displayed.

- 2 Choose **Change** in the **Start Up Pipe Setting** area.
- 3 Select the desired start up pipe from the list box on the **Pipe Function** window.
- 4 Choose **OK** to accept the change.

■



Once the start up pipe begins, the setting defaults to None.

Sleep Pipe function with green wash rack

The **Sleep Pipe** function enables the system to enter in sleep mode after a pipe has been performed. If the **Sleep Pipe** function is not activated (**Sleep** check box is not selected), the system turns to standby when a pipe is completed.

► To activate the Sleep Pipe function

- 1 Choose Utility > System (Page 2/4) > Pipe Setting to display the Maintenance Pipe Setting window.
- 2 Choose the pipe in the **Pipe Name** list to be performed as a sleep pipe.
- 3 Choose **Edit** to display the **Edit Pipe** window.

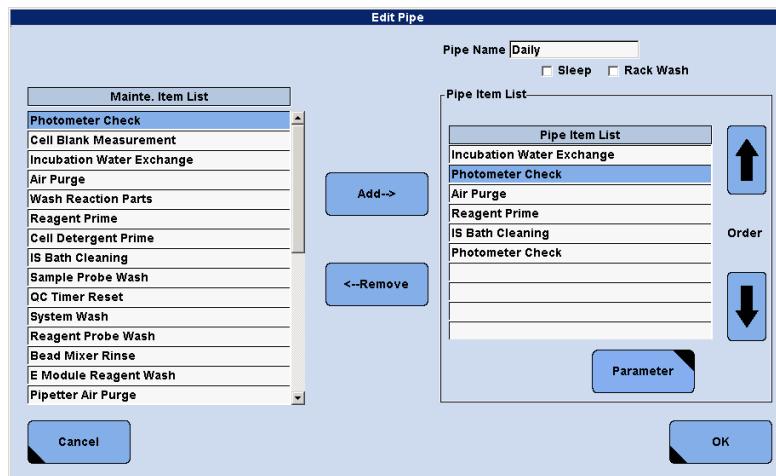


Figure C-8 Edit Pipe window

- 4 Select the **Sleep** check box to activate the **Sleep Pipe** function.

The system automatically turns to Sleep mode after the pipe is completed.

See *Performing maintenance items or pipes* on page C-16

- 5 Select the **Rack Wash** check box in order to carry out washing with a green rack before pipe operation.
- 6 Choose **OK** to save the settings and return to the Maintenance Pipe Setting window.



Maintenance types

Maintenance items and maintenance pipes can be assigned to a maintenance type according to certain functions (such as daily, weekly, or monthly maintenance).

By means of maintenance types you can create a maintenance schedule. A maintenance interval can be assigned to each maintenance item and maintenance pipe within a maintenance type.

Two Maintenance types are predefined: **Maintenance** and **Check**.

Maintenance Contains all available maintenance items except check routines.

Check Contains all check routines.

Defining and editing maintenance types

Use the following procedure to assort a series of maintenance items into a specific maintenance type.

► **To edit a maintenance type or define a new type**

- 1 Choose Utility > System (Page 2/4) > Maintenance Setting.

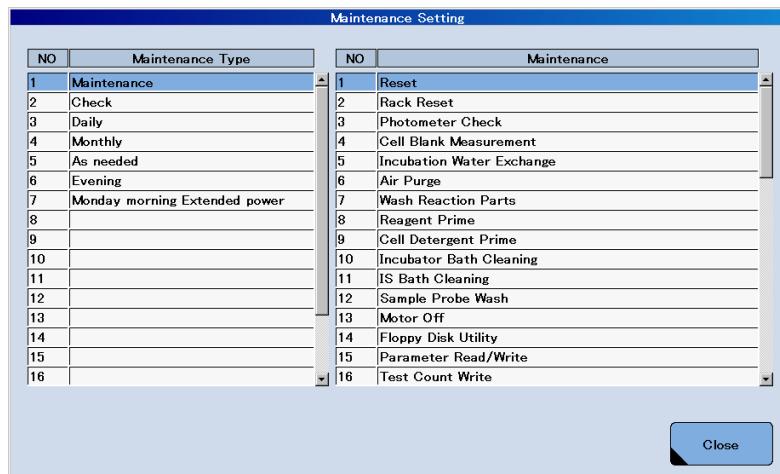


Figure C-9 Maintenance Setting window

Maintenance types

- 2** If a new Maintenance Type is to be defined, select a free line from the **Maintenance Type** list, choose **Edit**, and proceed with step 3.
 If an existing Maintenance Type is to be edited, select the appropriate line from the **Maintenance Type** list, choose **Edit**, and proceed with step 4.

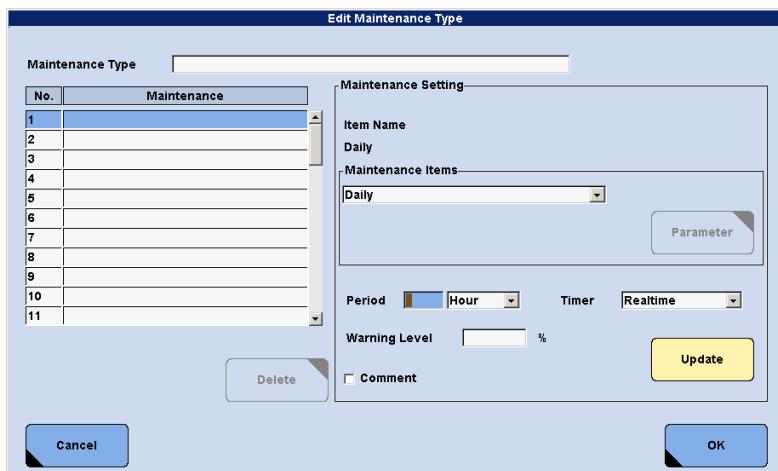


Figure C-10 Edit Maintenance Type window

- 3** Enter a name for the maintenance type in the text box at the top of the window.
4 Select an item from the **Maintenance Items** list box.

This list includes both maintenance items and user defined maintenance pipes.



The entry **User Definable** in this list can be used to define a new maintenance item that is not automated by the system (for example, clean instrument surfaces, check detergent level, etc.).

- 5** Choose **Parameter** to display the **Maintenance Parameter** window for the selected maintenance item, if available. Use this window to define parameters for the selected maintenance item.
- For more information about the different **Maintenance Parameter** windows, refer to the *Online Help* of the particular window.
- 6** For maintenance tracking, enter the frequency in the text box and select the time period (**Hour**, **Day** and **Month**) from the **Period** list box.
- 7** Select a timer function from the **Timer** list box:
- **Realtime:** The actual time
 - **Power On:** Cumulative power-on time of the analyzer (excluding sleep time)
 - **Operation:** Cumulative operation time
- Power On time and Operation time are both listed on the **Maintenance Report** (**Print > Utility > Maintenance Report**).
- See *Maintenance report* on page C-25
- 8** Enter the warning level (%) in the **Warning** level text box.
- Example:**
 If you define a period of 10 hours in real time and a warning level of 90%, the analyzer will remind you to perform the maintenance item after 9 hours.

- 9 Select the **Comment** check box to display the **Comment** field on the appropriate maintenance item window and to print the comment on the **Maintenance Report**.
- 10 Choose **Update** to add the item to the **Maintenance Items** list.
- 11 Repeat steps 3 to 10 for all maintenance items for the maintenance type.
- 12 Choose **OK** to save the collection and its settings and close the **Edit Maintenance Type** window.



Tracking maintenance

If you have assigned a maintenance interval to a maintenance item or a maintenance pipe within a maintenance type, the analyzer reminds you when a maintenance item or pipe has to be performed.

Maintenance tracking is done on the **Maintenance** screen. The status of maintenance actions is also displayed on the **System Overview** screen.

► To display the maintenance status

- 1 Choose **Utility > Maintenance** to display the **Maintenance** screen.



Figure C-11 Maintenance screen

The following information is displayed:

- The maintenance type is highlighted in yellow or red if any item or pipe for this maintenance type exceeds its warning level or its maintenance interval.
 - The date the maintenance item or pipe was last performed.
 - The date in the item list is highlighted in yellow if the maintenance item or pipe exceeds its warning level.
 - The date in the item list is highlighted in red if the maintenance item or pipe exceeds its maintenance interval.
- 2 If you need more information about the maintenance status of a particular maintenance type, select a maintenance type and then a maintenance item or pipe from the **Maintenance** Item list.
 - 3 Choose **Monitor** to view the status of the selected maintenance item or pipe.
 - For more information about the **Maintenance Monitor** window, refer to the *Online Help* of the particular window.

Maintenance report

The analyzer records the execution of maintenance items in the **Maintenance Report**.

The **Maintenance Report** is requested through **Print** (global button) > **Utility** > **Maintenance Report**.

			Maintenance Report	02/02/06	14:27
POWER ON TIME		984	HOURS		
OPERATION		24	HOURS		
MAINTENANCE TYPE:	Maintenance			Page	1
MODULE:	E				
MAINTENANCE					
DATE	TIME	OP.ID	COMMENTS		
Cell Wash					
Reagent Line Purge					
Wash Reaction Parts					
Reagent Flowpath Wash					
System Wash					
02/01/10 13:45		admin			
01/12/17 12:14		admin			
Photometer Check					
Cell Blank Measurement					
Incubation Water Exchange					
Air Purge					
Reset					
02/01/31 11:36		admin			
02/01/25 09:56		admin			
02/01/25 09:54		admin			
02/01/25 09:52		admin			
02/01/24 15:08		admin			
02/01/22 11:03		admin			
02/01/10 15:03		admin			
02/01/08 10:09		admin			
01/12/19 14:45		admin			

Figure C-12 Maintenance report

- ☞ For more information about the **Maintenance Report**, refer to the *Online Help* of the particular window.

Maintenance schedules

The following section provides you with an overview of the maintenance actions required for proper instrument care. The information is sorted according to the frequency in which the actions must be performed and includes the module and type of actions required.



Precautions for continuous operation

The intervals for maintenance and checkup recommended in this document are based on a usage of the analyzer for 5 hours a day, 25 days a month. If the instrument is used continuously (without shutdown) for 24 hours or longer—for example, for STAT measurements at night—reset all maintenance intervals to meet the actual running hours of your system and use customized maintenance types to schedule your maintenance tasks.

See *Maintenance types* on page C-21.



Precaution for operation after longtime-shutdown

If the analyzer has been shut down for a week or more, check its performance before starting operation. For details of check, consult your local technical support.



Spare parts

For proper instrument care use only original spare parts provided by Roche.

- The necessary spare parts are listed in the description of the corresponding maintenance action.
- For ordering the spare parts, please contact your technical support.

Daily maintenance

The following tables provide you with an overview of the maintenance actions that must be performed on a daily basis.

Checks before start-up of the analyzer

There are various conditions that need to be checked before a system start-up. Therefore it is important to inspect the system prior to switching on the analyzer.

For more information, see *Starting inspection* on page B-26.

Maintenance items that can be performed in a Power on pipe

Laid out below is a list of maintenance items that are suitable to be used in connection with the **Power Up Pipe** function or the **Start Up Pipe** function.

- 🕒 For more information, see
 - Maintenance pipes* on page C-14
 - Power Up Pipe function* on page C-18
 - Start Up pipe function* on page C-19

Visual checks at start-up Note that even though a maintenance pipe can be executed automatically some maintenance items require visual checks by the operator.



If a green wash rack is processed in the Power On pipe, it is not necessary to perform the maintenance items **(8) Reagent Prime** and **(11) IS Bath Cleaning**.

Item	Action type: Power On pipe with visual checks	Module
(5) Incubation Water Exchange	<i>Check the temperature of the incubator bath on the System Overview screen before starting analysis.</i>	c 501
(6) Air Purge	<i>Check the syringes and the tubing system against leakage and air bubbles.</i>	c 501
(8) Reagent Prime	<i>ISE: All</i>	c 501 (ISE)
(11) IS Bath Cleaning	<i>Check against solid residual at the upper part of the IS baths.</i>	c 501 (ISE)
Smart. Com Essential information upload	<i>Backup function; configuration settings and patient data are uploaded from the flash memory of the analyzer to the cobas link data station.</i>	c 501 e 601
(3) Photometer Check	<i>Check the photometer values on the Print View window.</i>	c 501

Table C-1 Instrument care - daily (Power On)

Maintenance items before shutdown

Item	Action type: Cleaning	Module	Page
Processing green wash rack	Position 1: Multiclean (cycles: 5) Position 2: SysClean (cycles: 15) Position 3: Activator (cycles: 15) The cycles are set in the Wash Rack Sampling area of the Utility > System screen: <ul style="list-style-type: none"> • <i>Photometric</i> refers to Position 1 • <i>ISE</i> refers to Position 2 and 3. <i>Can be included in a sleep pipe.</i>	c 501	C-67
Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle	Clean the probes, shield pipe and the ISE sipper with alcohol (e.g. isopropyl alcohol or ethanol). <i>Upon detection of abnormal sample aspiration caused by a clot, the sample probe is washed automatically by the analyzer.</i>	c 501	C-72
Cleaning the drain port for high concentrated waste	Apply deionized water to the waste solution nipple at the rear of the c 501 to rinse off crystals.	c 501 (ISE)	C-75
Emptying and cleaning the concentrated waste tank	Empty the concentrated waste tank at the rear of the analyzer. <i>Wear protective gloves when performing this procedure. Contents of the waste solution reservoir are potentially biohazardous.</i>	cu 150	C-50
Cleaning cell rinse nozzles	Clean the cell rinse nozzles with deionized water.	c 501	C-74

Table C-2 cu 150 module-specific and c 501 module-specific instrument care - daily before shutdown

Maintenance schedules

Item	Action type: Cleaning	Module	Page
Cleaning probes and sippers:	Wipe the outer surfaces of the probe and probe tip with a gauze pad soaked in deionized water. If the probe still appears dirty, wipe the outer surfaces with a gauze pad soaked in alcohol (e.g. isopropyl alcohol or ethanol). Then with deionized water again.	e 601	C-122
Sample probe			
Cleaning probes and sippers:	Wipe the outer surfaces of the probe with a gauze pad soaked in alcohol. Then with deionized water again.	e 601	C-122
Reagent probe			
Cleaning probes and sippers:	Wipe the outer surfaces of the probe with a gauze pad soaked in alcohol. Then with deionized water again.	e 601	C-122
Sipper probes for measuring channels 1 and 2			
Cleaning probes and sippers:	Wipe the outer surfaces of the probe with a gauze pad soaked in alcohol. Then with deionized water again.	e 601	C-122
Pre-wash sipper and dispenser probe			

Table C-3 e 601 module-specific instrument care - daily before shutdown**Daily maintenance - only if last run has been interrupted**

Item	Action	Module	Page
Finalization	The system is primed with water and the measuring cells are filled with ProCell. Finalization must be performed if analyzer did not complete Post Operation at the end of the day, for example, due to a system stop.	e 601	C-156

Table C-4 Instrument care e 601 module - daily if last run interrupted

Weekly maintenance

The following tables provide you with an overview of the maintenance actions that must be performed on a weekly basis.

Item	Action	Module	Page
Cleaning the reaction system	Perform maintenance item (7) Wash Reaction Parts to clean sample probe with Multiclean (1.8 mL) and reagent probes and reagent cells with reagent from NaOH-D cassette (application code 947).	c 501	C-76
(7) Wash Reaction Parts			
(4) Cell Blank Measurement	Perform maintenance item (4) Cell Blank Measurement to obtain new photometric reference.	c 501	C-77
Cleaning the rinse stations	• Clean rinse stations using cotton swabs moistened with 2% Hitergent solution. Inject 2% Hitergent solution and deionized water.	c 501	C-80
Sample probe			
Reagent probes	• Clean the drying cylinder of the sample probe rinse station with cotton swabs moistened with alcohol (e.g. isopropyl alcohol or ethanol).		
ISE probe			
Removing and manually cleaning the IS bath	Put the analyzer in shutdown status or the module in standby and remove the IS bath. Wash away any crystals or contamination in the IS bath with deionized water.	c 501 (ISE)	C-82
Cleaning the cell covers (metal plates)	Wipe front and rear faces of cell covers using a gauze pad moistened with alcohol. Wipe openings of cell covers using a cotton swab.	c 501	C-78

Table C-5 c 501 module-specific instrument care - weekly

Item	Action	Module	Page
Cleaning ProCell/CleanCell nozzles and replace reservoirs	Wipe the ProCell/CleanCell reservoir filling nozzle and electrodes with a cotton swab soaked in deionized water. Lift the sipper supply unit and exchange the reservoirs. Clean the inside of reservoir positions by wiping them with a cotton swab soaked in deionized water. Place new reservoirs in the reservoir positions and push the sipper nozzle unit back into place.	e 601	C-125
Cleaning mixing station and separation stations of the Pre-wash area	Wipe the surfaces of all components with a gauze pad soaked in deionized water. Afterwards, dry it with gauze pads and cotton swabs. Ensure that the Pre Wash Mixer, Pre Wash separation stations and their holes are not clogged. Check also that incubator holes are not clogged.	e 601	C-129
Cleaning incubator			C-131
Cleaning vortex mixing station			C-133
Cleaning microbead mixer	Very carefully wipe the microbead mixer paddle with a lint-free gauze square soaked in alcohol (e.g. isopropyl alcohol or ethanol) from top to bottom. Then use a brush to clean the 4 propeller plates with alcohol. Repeat the procedure using deionized water instead of alcohol.	e 601	C-135
Cleaning rinse stations	Clean the inside of each rinsing station using a cotton tipped applicator stick soaked in alcohol, followed by a cotton tipped applicator stick soaked in deionized water.	e 601	C-137
Sipper station			
Mixer station			
Reagent station	Fill a 50 mL syringe (with tubing attached) with Hitergent. Inject the cleaning solution (empty the syringe) into the drain hole of the rinse bath. Fill a 50 mL syringe with deionized water. Inject the deionized water (empty the syringe) into the drain hole of the rinse bath.		

Table C-6 e 601 module-specific instrument care - weekly

Every two weeks maintenance

The following table provides you with an overview of the maintenance actions that must be performed at least once every two weeks.

Item	Action	Module	Page
Liquid flow path cleaning	Fill SysClean cups with SysClean to the lower limits (approx. 9 mL/cup) and perform maintenance item (27) Liquid Flow Cleaning . System time: approx. 30 min <i>This function will clean the sipper probe, tubings, and measuring cells.</i> <i>Perform liquid flow path cleaning at least every two weeks or after 2500 to 3000 determinations per channel, whichever comes first.</i>	e 601	C-140

Table C-7 Instrument care - every two weeks

Monthly maintenance

The following table provides you with an overview of the maintenance actions that must be performed on a monthly basis.

Item	Action	Module	Page
Cleaning the water tank	<ul style="list-style-type: none"> Shut down the analyzer and disconnect the water tank. Wipe float assembly with gauze pads. Rinse tank thoroughly with deionized water. <p>If water tank is considerably contaminated, clean with 0.5% sodium hypochlorite solution using a brush. Rinse tank thoroughly with deionized water.</p>	cu 150	C-53
Replacing reaction cells	<p>Put the module in shutdown or motor off status.</p> <ul style="list-style-type: none"> Remove reaction cells. Clean incubator bath and its drain filter (see below). Install new reaction cells. Perform maintenance item (7) Wash Reaction Parts then perform maintenance item (4) Cell Blank Measurement. 	c 501	C-86
Cleaning the incubator bath	<p>Put the module in shutdown status or in Incubator bath cleaning status. In case the analyzer is already in shutdown status, drain incubator bath water. Otherwise, perform maintenance item (10) Incubator Bath Cleaning.</p> <ul style="list-style-type: none"> Detach cell rinse unit and reaction cells. Clean incubator bath and photometer windows using lint-free gauze pads. Clean and rinse the filter with deionized water. Reattach reaction cells and cell rinse unit. Refill the bath with ~ 500 mL deionized water and start up the analyzer performing maintenance item (5) Incubation Water Exchange or—if (10) Incubator Bath Cleaning is used—choose Continue to release the incubator bath cleaning mode. <p>Perform maintenance items (7) Wash Reaction Parts and (4) Cell Blank Measurement (see above).</p>	c 501	C-87
Cleaning the detergent aspiration filters	<p>Clean aspiration filters, which are attached to the tube ends, each time you replace a reagent bottle or at least once a month.</p> <ul style="list-style-type: none"> Remove the filter from the tube end. Clean and rinse the filter with deionized water. Perform maintenance item (9) Cell Detergent Prime. 	c 501	C-94
Cleaning the ISE Ref. (KCl) aspiration filter	<p>Clean aspiration filter each time you replace the ISE Ref. bottle or at least once a month.</p> <ul style="list-style-type: none"> Remove the filter from the tube end. Clean and rinse the filter with deionized water. Perform maintenance item (8) Reagent Prime with the Ref option selected. 	c 501 (ISE)	C-83
Cleaning the filters behind the front doors	Remove dust from filter with a vacuum cleaner	c 501	C-96
Cleaning the filter of the rack sampler unit	Remove dust from filter with a vacuum cleaner	cu 150	C-57

Table C-8 Instrument care - monthly

Every three months maintenance

The following table provides you with an overview of the maintenance actions that must be performed at least once every three months.

Item	Action	Module	Page
Cleaning the ultrasonic mixers	<p>Include this maintenance in the monthly cleaning of the incubator bath. If the ultrasonic mixers were used for more than three months, or after 225.000 tests, whatever comes first.</p> <ul style="list-style-type: none"> Wipe surface of ultrasonic mixers with cotton swabs moistened with 2% Hiertgent solution. Wipe off the detergent with cotton swabs moistened with deionized water. At the end of the maintenance, perform maintenance check (7) Cuvette Mixing. 	c 501	C-98
Replacing e 601 pinch valve tubing	<ul style="list-style-type: none"> Perform maintenance item (26) MC Exchange before removing the tubes, to avoid dripping off fluid on the valves. Shut down the system or put the e 601 module into standby mode. Remove all 4 pinch valve tubings from the fittings. Use a dry gauze pad to absorb liquid which drains from the acrylic block or from the tubing. Take new pinch valve tubing and insert it through the pinch valve. Slide the ends of the tubing over each fitting. Perform maintenance item (24) Sipper Air Purge and (25) MC Preparation before resuming operation. 	e 601	C-143

Table C-9 Instrument care - every three months

Every six months maintenance

The following table provides you with an overview of the maintenance actions that must be performed at least every six months.

Item	Action	Module	Page
Cleaning the inlet water filter	<ul style="list-style-type: none"> Put the analyzer in shutdown status. Place a 500 mL beaker beneath the inlet water manifold. Disconnect the inlet water hose. Clean the filter thoroughly with deionized water, then reinstall the filter. 	cu 150	C-58
Cleaning the cooling fans	<ul style="list-style-type: none"> Put the analyzer in shutdown status. Remove dust from filter with a vacuum cleaner or use a brush. 	cu 150	C-60
Replacing the syringe seals	<p>Shut down the system and remove the syringe.</p> <ul style="list-style-type: none"> Replace the syringe seals and reattach the syringe. Perform maintenance item (6) Air Purge and check all connections. 	c 501	C-102
Replacing the photometer lamp	<p>Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.</p> <ul style="list-style-type: none"> If any of the current photometer check data exceeds 14000, check light path for contamination or scratches. Check that cell no. 1 is at least half filled with water. Replace the photometer lamp if necessary. Wait 30 min for the photometer lamp to stabilize, then, perform maintenance item (4) Cell Blank Measurement (necessary to compensate for a change in light intensity). 	c 501	C-109

Table C-10 Instrument care - every six months

As needed maintenance

The following table provides you with an overview of the maintenance actions that must be performed as needed.

Item	Cause	Action	Module	Page
Emptying the concentrated waste tank	In spite of emptying the tank at the beginning of the day, it can get full in the course of a working session. An alarm is issued when the concentrated waste tank gets full.	<ul style="list-style-type: none"> Empty the concentrated waste tank at the rear of the analyzer. Wear protective gloves when performing this procedure. Contents of the waste tank are potentially biohazardous. 	cu 150	
Cleaning the detergent aspiration filters	When replacing cell detergents (Cell wash I, Cell wash II) behind the front doors. An alarm is issued on the System Overview screen when a detergent bottle gets empty (Reagent Preparing > Reagent Load List in the Work Flow Guide)	<ul style="list-style-type: none"> Remove the filter from the tube end. Clean and rinse the filter with deionized water. Perform maintenance item (9) Cell Detergent Prime. 	c 501	C-114
Cleaning the ISE Ref. (KCl) aspiration filter	When replacing ISE Ref. bottle. An alarm is issued on the System Overview screen when the ISE Ref. bottle is empty (Reagent Preparing > Reagent Load List in the Work Flow Guide)	<ul style="list-style-type: none"> Remove the filter from the tube end. Clean and rinse the filter with deionized water. Perform maintenance item (8) Reagent Prime with the Ref option selected. 	c 501 (ISE)	C-114
Cleaning the ultrasonic mixers	If the ultrasonic mixers were used for more than three months, or after 225.000 tests, whatever comes first.	<ul style="list-style-type: none"> Wipe surface of ultrasonic mixers with cotton swabs moistened with 2% Hitergent solution. Wipe off the detergent with cotton swabs moistened with deionized water. At the end of the maintenance, perform maintenance check (7) Cuvette Mixing. 	c 501	C-116
Replacing the syringe seals	If the syringe seals were used for more than six months, or after 225.000 tests, whatever comes first.	<ul style="list-style-type: none"> Shut down the system and remove the syringe. Replace the syringe seals and reattach the syringe. Perform maintenance item (6) Air Purge and check all connections. 	c 501	C-116
Replacing the photometer lamp	If the photometer lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.	<ul style="list-style-type: none"> If any of the current photometer check data exceeds 14000, check light path for contamination or scratches. Check that cell no. 1 is at least half filled with water. Replace the photometer lamp if necessary. Wait 30 min for the photometer lamp to stabilize, then, perform maintenance item (4) Cell Blank Measurement (necessary to compensate for a change in light intensity). 	c 501	C-116

Table C-11

cu 150 module-specific and c 501 module-specific instrument care - as needed (Sheet 1 of 2)

Maintenance schedules

Item	Cause	Action	Module	Page
Replacing nozzle tips on cell rinse nozzles	If the nozzle tips are worn but latest after 225.000 tests.	<ul style="list-style-type: none"> Put the analyzer in Maintenance mode or Shutdown status. Remove the cell rinse unit. Replace nozzle tip. Attach the cell rinse unit. Check the alignment of the new nozzle tip. Perform a (3) Mechanism Check (10 cycles). 	c 501	C-114
Draining the vacuum tank	Alarm (Liquid in Vacuum Tank) is issued.	<ul style="list-style-type: none"> Remove the cap holding the drain tube of the vacuum tank. Drain the waste solution into a beaker. 	c 501	C-117
Cleaning instrument surfaces	Spills on the instrument surface could be potentially biohazardous and damage the material.	<ul style="list-style-type: none"> Clean up spills immediately using a paper towel moistened with disinfectant. 	cu 150 c 501	C-61 C-118

Table C-11 cu 150 module-specific and c 501 module-specific instrument care - as needed (Sheet 2 of 2)

Item	Action	Module	Page
Cleaning ProCell/CleanCell stand and aspiration tubes	If crystallization is observed, wipe the aspiration tubes and stand for the ProCell/CleanCell bottles with a lint-free gauze pad soaked in deionized water. Then dry them with dry gauze pads.	e 601	C-146
Cleaning ProCell/CleanCell aspiration tube filters	If the filters are blocked, unscrew the filters and clean with deionized water and then dry it. Operator time: approx. 5 min. System time: 15 min	e 601	C-148
Cleaning reagent disk and compartment	If the disk appears dirty, use a lint-free gauze pad soaked with alcohol (e.g. isopropyl alcohol or ethanol). Then use gauze pads soaked with deionized water. Afterwards, dry with cloth or lint-free towels.	e 601	C-151
Cleaning solid waste compartment	Pull out the draw unit. Remove both waste liners. Wipe the containers (inside and outside) with gauze pads soaked in disinfectant. Then wipe with gauze pads soaked with deionized water. Place a new Waste Liner M into each waste container and updated it.	e 601	C-153
Finalization	The system is primed with water and the measuring cells are filled with ProCell. Finalization must be performed if analyzer did not complete Post Operation at the end of the day, for example, due to a system stop.	e 601	C-156
Cleaning instrument surfaces	Spills on the instrument surface could be potentially biohazardous and damage the analyzer. Clean up spills immediately using a paper towel moistened with disinfectant.	e 601	C-155

Table C-12 e 601 module-specific instrument care - as needed

Automating instrument care with maintenance pipes

A maintenance pipe is a set of system-controlled maintenance items.

Maintenance pipes can be executed manually by the user. Alternatively, they can be executed automatically by means of maintenance pipe functions.

Moreover, maintenance pipes can be programmed to automatically put the analyzer in sleep mode after the last maintenance item is completed (**Sleep Pipe** function).

Maintenance pipes are configured under **Utility > System (Page 2/4) > Pipe Setting**.

 For more information on defining and using maintenance pipes, see:

Defining and editing maintenance pipes on page C-15

Power Up Pipe function on page C-18

Start Up pipe function on page C-19

Sleep Pipe function with green wash rack on page C-20

List of maintenance items on page C-41

Recommended maintenance pipes

This section shows the maintenance pipes that Roche Diagnostics recommends for proper use of the analyzer. The maintenance items must be programmed in the order listed here for the pipe to be performed correctly.

 For more information on defining and using maintenance pipes, see:

Defining and editing maintenance pipes on page C-15



If a green wash rack is processed in the Power On pipe, it is not necessary to perform the maintenance items **(8) Reagent Prime** and **(11) IS Bath Cleaning**.

Power ON

Maintenance Item	Module
(5) Incubation Water Exchange	c 501
(6) Air Purge	c 501
(8) Reagent Prime (ISE)	c 501
(11) IS Bath Cleaning	c 501
Smart. Com Essential information upload	c 501, e 601
(3) Photometer Check	c 501

Table C-13 Maintenance pipe Power ON

 For more information on, see:

Power Up Pipe function on page C-18

Start Up pipe function on page C-19

Sleep

Maintenance Item	Module
Processing green wash rack	c 501

Table C-14 Maintenance pipe Sleep

 For more information, see *Sleep Pipe function with green wash rack* on page C-20.

Automating instrument care with maintenance pipes

Weekly shutdown

Maintenance Item	Module
(7) Wash Reaction Parts	c 501
(4) Cell Blank Measurement	c 501

Table C-15 Maintenance pipe Weekly shutdown

Extended power ON (1-2 days - only e 601)

Execute this maintenance pipe when the system is idle for one to two days, for example, after weekends. After more than one day the e 601 measuring cell needs to be conditioned; therefore, maintenance item (25) MC Preparation is integrated in this maintenance pipe.

Maintenance Item	Cycles
(37) System Air Purge (E Module)	10
(8) Reagent Prime (Pre-wash Probe)	5
(25) MC Preparation	5

Table C-16 Maintenance pipe Extended power ON (1-2 days)

Extended power ON (2-7 days - only e 601)

Execute this maintenance pipe when the system is idle for two to seven days. In comparison to the maintenance pipe Extended power ON (1-2 days - only e 601) this recommendation includes priming the e module reagent lines.

Maintenance Item	Cycles
(24) Sipper Air Purge	5
(23) Pipetter Air Purge	10
(8) Reagent Prime (Pre-wash Probe)	5
(8) Reagent Prime (Reagent)	2
(25) MC Preparation	30

Table C-17 Maintenance pipe Extended power ON (2-7 days)

Extended power OFF (2-7 days - only e 601)

Execute this maintenance pipe before shutting down the system for two to seven days.

Maintenance Item	Cycles
(8) Reagent Prime (Pre-wash Probe)	5
(8) Reagent Prime (Reagent)	5
(33) Empty PC/CC Reservoir	-
(31) Pre-wash Sipper Air Purge	10

Table C-18 Maintenance pipe Extended power OFF (2-7 days)

Background and parallel maintenance

Background Maintenance Background maintenance is used to perform maintenance functions on one or more modules while the system is still in Operation mode. In Background maintenance one or more modules are masked.

Parallel Maintenance You may use parallel maintenance to perform different maintenance items on different modules while the system is in the standby mode.

Pipe functions can also be performed as background maintenance. Background maintenance can be stopped using **Cancel Maintenance** on the **System Overview** screen. However, not all maintenance items can be stopped once started.

☞ For more information, see:

Performing background maintenance on page C-38

Performing parallel maintenance on page C-40

The following tables display the maintenance items and checks and indicate in which operation mode they can be performed.

✓ This item can be performed

Maintenance Item	c 501			e 601		
	Standby	Background	Parallel	Standby	Background	Parallel
(1) Reset	✓	✓	✓	✓	✓	✓
(2) Rack Reset	✓			✓		
(3) Photometer Check	✓	✓	✓			
(4) Cell Blank Measurement	✓	✓	✓			
(5) Incubation Water Exchange	✓	✓	✓			
(6) Air Purge	✓	✓	✓			
(7) Wash Reaction Parts	✓	✓	✓			
(8) Reagent Prime	✓	✓	✓	✓	✓	✓
(9) Cell Detergent Prime	✓	✓	✓			
(10) Incubator Bath Cleaning	✓	✓	✓			
(11) IS Bath Cleaning	✓	✓	✓			
(12) Sample Probe Wash	✓	✓	✓			
(19) System Wash				✓	✓	✓
(20) Reagent Probe Wash				✓	✓	✓
(21) Bead Mixer Rinse				✓	✓	✓
(22) E Module Reagent Wash				✓	✓	✓
(23) Pipetter Air Purge				✓	✓	✓
(24) Sipper Air Purge				✓	✓	✓
(25) MC Preparation				✓	✓	✓
(26) MC Exchange				✓	✓	✓
(27) Liquid Flow Cleaning				✓	✓	✓
(28) Inventory Update				✓	✓	✓
(29) Manual Cleaning				✓	✓	✓
(30) Pre-wash Sipper Rinse				✓	✓	✓

Table C-19 Available operation modes for Maintenance items (Sheet 1 of 2)

Background and parallel maintenance

Maintenance Item	c 501			e 601		
	Standby	Background	Parallel	Standby	Background	Parallel
(31) Pre-wash Sipper Air Purge				✓	✓	✓
(32) Finalization				✓	✓	✓
(33) Empty PC/CC Reservoir				✓	✓	✓
(34) Initial Bead Mixing				✓	✓	✓
(35) Reagent Capping				✓	✓	✓
(36) AssayCup Discarding				✓	✓	✓
(37) System Air Purge (E Module)				✓	✓	✓
(38) System Prime (E Module)				✓	✓	✓
(39) Change Light Source Lamp	✓	✓	✓			

Table C-19 Available operation modes for Maintenance items (Sheet 2 of 2)

Maintenance Check	c 501			e 601		
	Standby	Background	Parallel	Standby	Background	Parallel
(2) ISE Check	✓	✓	✓			
(3) Mechanism Check	✓	✓	✓	✓	✓	✓
(4) Sample Barcode Reader Check	✓			✓		
(5) Reagent Barcode Reader Check	✓	✓	✓	✓	✓	✓
(6) Cassette Loading Check	✓	✓	✓			
(7) Cuvette Mixing	✓	✓	✓			
(8) Reagent Short Sensor Check				✓	✓	✓
(9) Sample Pipetting Check				✓	✓	✓
(10) Reagent Pipetting Check				✓	✓	✓
(11) Cap Opener Check				✓	✓	✓
(12) Bead Mixer Check				✓	✓	✓
(13) Gripper Check				✓	✓	✓
(14) Magazine Exchange Check				✓	✓	✓
(15) Sipper Check				✓	✓	✓
(16) Pre-wash Probe Check				✓	✓	✓
(17) Pre-wash Gripper Check				✓	✓	✓

Table C-20 Available operation modes for Maintenance checks

Performing background maintenance

Use the following procedure to perform maintenance on one analytical module while the system is in operation.



Personal injury due to contact with instrument mechanism

Contact with sampling mechanism or other mechanisms may result in personal injury and infection.

- Before starting background maintenance, be sure to mask the correct module and to wait until the masked module is in standby.
- When performing maintenance actions on the masked module, ensure that nobody unmasks and starts the module.

► **To perform background maintenance**

- 1 Choose **Start** (global button) to display the **Start Conditions** screen.
- 2 Choose **Masking** to display the **Masking** window.
- 3 Choose **Module Masking** to display the **Module Masking** window.

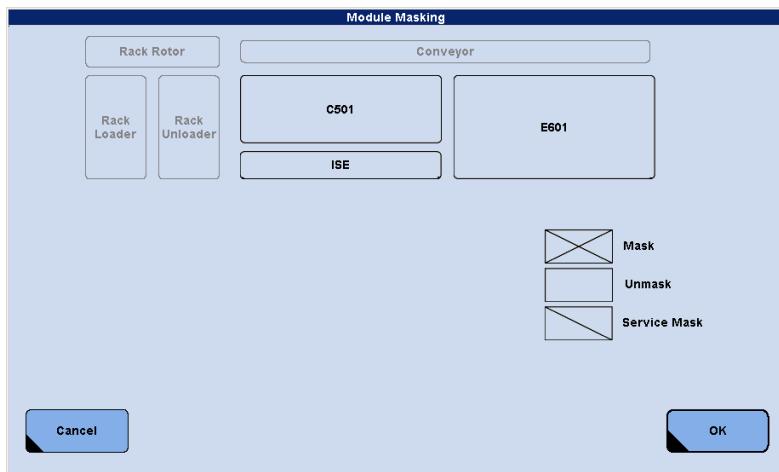


Figure C-13 Module Masking window

- 4 Choose the modules to be masked. When a module is masked, it appears crossed out on the display.
- 5 Choose **OK** to save the changes.
- 6 Choose **Yes** on the confirmation window.
- 7 Allow the module to go to standby mode. The module completes any samples assigned to it prior to masking, goes to **Sampling Stop** mode and then to standby mode.
- 8 You may now perform any of the maintenance procedures listed in the background maintenance table.
☞ See *Background and parallel maintenance* on page C-37.

■ The module can be masked/unmasked when the system is in standby or operation mode.



Using maintenance pipes for background maintenance

A maintenance pipe can be performed during background maintenance on the following conditions:

- The maintenance pipe must only contain maintenance items for the masked module.
- The analyzer is in operation mode.
- The masked module is in standby

Performing parallel maintenance

You may use parallel maintenance to perform different maintenance items on different modules while the system is in the standby mode.

Pipe functions cannot be performed as parallel maintenance; you must perform all maintenance items individually.

For example, you can select maintenance item (4) **Cell Blank Measurement** on c 501 and maintenance item (21) **Bead Mixer Rinse** on e 601.

 See *Background and parallel maintenance* on page C-37.

If you need to stop a maintenance procedure while the other modules are in operation, use the following steps.

Stopping background and parallel maintenance

Use the following procedure to stop background or parallel maintenance.



Do not choose **Stop** (global button) to end background maintenance. This will stop all functions on all modules.

► To stop background maintenance

- 1 Choose **System Overview**.
- 2 Select the module performing the function you want to stop.
- 3 Choose **Cancel Maintenance** to stop the action after confirmation.



List of maintenance items

The following section lists all maintenance items, on which module they can be performed, and a brief description of their function. The time period in brackets denotes the system time of the maintenance item in (min:sec).

c 501: Denotes that a function applies to both units, the photometric unit and the ISE unit.

c 501 (ISE): Denotes that a function applies to the ISE unit of the **c 501** module only.

c 501 (P): Denotes that a function applies to the photometric unit of the **c 501** module only.

(1) *Reset* **c 501 (0:24), e 601 (0:40):** Mechanical parts are reset to their home positions.

cu 150: Mechanical parts are reset to their home positions, all racks are transported to the unloader.

(2) *Rack Reset* **cu 150:** Mechanical parts are reset to their home positions, all racks including STAT racks are transported to the unloader. When there is a rack for automatic QC in the rack rotor, it will remain in the rotor unless the check box (**With Automatic QC Rack**) is selected.

(3) *Photometer Check* **c 501 (P) (3:53):** Photometer output is checked by measuring a water blank of cell no. 1. Perform this maintenance item daily. To view report, choose **Print** (global button) > **View**. Measurement results must be below 14000. If results are higher, check the light path, if necessary replace the photometer lamp, then perform cell blank measurement.

Before performing this maintenance item, check that the temperature of the incubator bath water is within $37 \pm 0.1^\circ\text{C}$ ($98.6 \pm 0.2^\circ\text{F}$). Depending on the ambient temperature it can take up to 30 minutes after switching on the analyzer or after maintenance item (5) **Incubation Water Exchange** for the incubator to reach the correct temperature.

(4) *Cell Blank Measurement* **c 501 (P) (19:42):** Water blanks of all cells are measured. If there is a difference greater than 0.1 absorbance units in the results for one cell compared to cell no. 1, that cell number is written to the **Abnormal Cell List**. To view this report choose **Print** (global button) > **View**.

(5) *Incubation Water Exchange* **c 501 (P) (4:41):** Incubator bath water is exchanged and Hitergent (approx. 4 ml) is added. Perform this maintenance item daily. If the **Incubation Water Exchange Setting** check box (**Utility** > **System**) is activated, the incubator bath water is exchanged five times and approx. 8 ml Hitergent is added. This takes 17:30 min.

After this maintenance item has been performed, check that the temperature of the incubator is within $37 \pm 0.1^\circ\text{C}$ ($98.6 \pm 0.2^\circ\text{F}$) before performing maintenance item (3) **Photometer Check**. Depending on the ambient temperature it can take up to 30 minutes for the incubator to reach the correct temperature.

(6) *Air Purge* **c 501 (0:52):** Air is purged from sample and reagent pipetters. Perform this maintenance item daily.

(7) *Wash Reaction Parts* **c 501 (P) (35:00):** All cells and reagent probes are washed. The sample probe is washed with Multiclean (approx. 1 ml) from the 70 mL detergent bottle. The reagent probes and cells are washed with detergent from a detergent cassette (approx. 58 ml NaOH-D, application code 947).

List of maintenance items

(8) *Reagent Prime* **c 501 (ISE):** Reagents are primed according to the chosen option (IS, Ref, or All).

Options	System time	Description	Reagent consumption
IS	4:35	ISE IS is aspirated through the sipper to prime the measurement cartridges.	ISE IS: 6.6 mL ISE Ref.: 0.8 mL
Ref	2:34	ISE Ref. is aspirated through the reference cartridge to prime the reference electrode.	ISE IS: 0 mL ISE Ref.: 9.0 mL
All	6:44	Both ISE IS and ISE Ref. are primed.	ISE IS: 6.6 mL ISE Ref.: 9.8 mL

Table C-21 **c 501 reagent prime options**

e 601: If **Reagent** is selected the tubings of ProCell and CleanCell are primed and air bubbles are washed out of the system by emptying the reservoirs and refilling them. If Pre-wash Sipper is selected the PreClean tubings are primed and air bubbles are washed out of the system.

(9) *Cell Detergent Prime* **c 501 (P) (7:30):** Reagent lines for Cell wash I and Cell wash II are primed (30 times); reagent lines are purged of air and cells are filled up and emptied by vacuum.

(10) *Incubator Bath Cleaning* **c 501 (P):** Performs transition to incubator bath cleaning mode: The photometer lamp is switched off and the incubator bath water is automatically drained. Cleaning of ultrasonic mixers or incubator bath is possible without complete system shutdown. Choose **Continue** on the **Utility > Maintenance >Incubator Bath Cleaning** window to end the incubator bath cleaning mode; the incubator bath is automatically refilled with water and Hitergent (approx. 4 ml).

(11) *IS Bath Cleaning* **c 501 (ISE) (1:35):** The IS bath is rinsed. Perform this maintenance daily. However, this is not necessary after processing a green rack (flow path washing) because IS bath cleaning is already included in that maintenance.

(12) *Sample Probe Wash* **c 501:** The sample probe is washed with Multiclean. This item can be used in case of a clogged probe.

(13) *Motor Off* **c 501:** The motors of the **c 501** module are switched off. Use this item to manually move different parts, such as reagent gripper or reaction disk, without having to shut down the analyzer. If you open the top cover of the **c 501** module, the motors of the module are also switched off.

For more information, see *Interlock function during standby status* on page C-10

(14) *Floppy Disk Utility* **Control unit:** A floppy disk inserted into the floppy disk drive will be formatted after confirmation.

(15) *Parameter Read/Write* **Control unit: Parameter** settings are read from or written to a floppy disk.

(16) *Test Count Write* **c 501, e 601:** Test count for all modules and measuring channels is written to a floppy disk.

(17) *QC Timer Reset* **c 501 (P), e 601:** Resets the control interval timer.

For example, the control interval timer is set to 10 hours. When 5 hours are left, the user can reset the timer to 10 hours.

(18) Probe Check	c 501: Puts the c 501 module in probe adjust mode: In this mode, a probe—selected in the Probe Adjust window—can be moved to designated positions using the maintenance key. This maintenance item should only be used by specially trained operators to verify alignment of the probe. ☞ For more information refer to the separate maintenance manual: <i>Interlock function cobas c 501 with ISE</i>
(19) System Wash	e 601: Combination of maintenance items (20) Reagent Probe Wash, (21) Bead Mixer Rinse, and (22) E Module Reagent Wash is performed as many times as specified.
(20) Reagent Probe Wash	e 601: Both the inside (by aspirating the ProbeWash solution) and outside of the reagent pipetter probe is washed as many times as specified.
(21) Bead Mixer Rinse	e 601: The microbead mixer is rinsed as many times as specified.
(22) E Module Reagent Wash	e 601: The auxiliary reagent flow paths and the reservoirs for both ProCell and CleanCell are rinsed. That is, remaining liquid is aspirated from the reservoirs and discharged to the washing stations. Then, the auxiliary reagent flow paths and reservoirs are filled with water. The sippers aspirate liquid in the reservoirs and discharge it to the washing stations as many times as necessary to drain the whole liquid of the reservoirs. Afterwards (38) System Prime (E Module) and (32) Finalization should be performed.
(23) Pipetter Air Purge	e 601: Sample pipetter and reagent pipetter flow paths are purged of air as many times as specified.
(24) Sipper Air Purge	e 601: Sipper flow paths are purged of air as many times as specified.
(25) MC Preparation	e 601: Measuring cells are conditioned as many times as specified.
(26) MC Exchange	e 601: Sipper flow paths are rinsed with water as many times as specified and then emptied to be prepared for a measuring cell exchange.
(27) Liquid Flow Cleaning	e 601: Sipper flow paths are washed with SysClean. Liquid flow path cleaning must be performed at least once every two weeks or after 2500 to 3000 determinations per measuring channel.
(28) Inventory Update	e 601: The number of magazines with AssayTips and AssayCups in the loading area and empty magazines in the waste area are updated.
(29) Manual Cleaning	e 601: Sample pipetter, reagent pipetter, microbeads mixer, and sippers are reset and move to positions where manual cleaning of these parts can be done. The instrument stays in the maintenance function Manual Cleaning until the Stop (global button) or Cancel Maintenance on System Overview screen is chosen.
(30) Pre-wash Sipper Rinse	e 601: Pre-wash Sippers are rinsed in the wash station as many times as specified.
(31) Pre-wash Sipper Air Purge	e 601: Pre-wash Sipper flow paths is purged of air.
(32) Finalization	e 601 (5:30): Finalization routine is carried out on sample pipetter, reagent pipetter, sippert and detection unit.
(33) Empty PC/CC Reservoir	e 601 (2:40): The liquid in the ProCell and CleanCell reservoirs is drained.

List of maintenance items

- (34) *Initial Bead Mixing* e 601: Microbeads are mixed in all occupied positions on the reagent rotor.
- (35) *Reagent Capping* e 601: All open cobas e packs on the reagent rotor are closed.
- (36) *AssayCup Discarding* e 601: All AssayCups are taken out of the incubator and discharged to the waste by the gripper.
- (37) *System Air Purge (E Module)* e 601: The following maintenance functions are performed:
• (23) Pipetter Air Purge
• (24) Sipper Air Purge
• (31) Pre-wash Sipper Air Purge.
- (38) *System Prime (E Module)* e 601: ProCell, CleanCell, and both Pre-wash lines are primed at the same time.
- (39) *Change Light Source Lamp* c 501 (P): The photometer lamp is switched off. Use this item to exchange the photometer lamp without having to shut down the analyzer.
- Smart. Com Essential information upload* c 501, e 601: Backup function; configuration settings and patient data are uploaded from the flash memory of the analyzer to the cobas link data station. The five most recent backups are stored on the cobas link and allow for restoring parameter backup files to the flash memory of the analyzer.
It is recommended to perform this maintenance item every day. This maintenance item can only be performed in a maintenance pipe. Therefore it can only be selected on the **Edit Pipe** window under **Utility >System >Pipe Setting > Edit**.
 For more information, see:
Defining and editing maintenance pipes on page C-15
Recommended maintenance pipes on page C-35

List of Maintenance checks

The following section lists all maintenance checks, on which module they can be performed, and a brief description of their function.

(1) *Check Disk* Files on hard disk or floppy disk are checked by the control unit. A result list is available in the print buffer afterwards. This list is not automatically printed. The hard disk check can also be used to save a log file (Backup data file) and to determine the software version.

(2) *ISE Check* c 501(**ISE**): The electrode output of ISE cartridges ($\text{Cl}^-/\text{K}^+/\text{Na}^+$ and ISE reference cartridge) is measured with ISE IS and a listing of EMF values is printed out.

(3) *Mechanism Check* The option **All** performs a functional check of mechanical parts of the entire sample line and each module. Make sure to place some racks in the rack loader.

The option **Rack Sampler** performs a functional check of mechanical parts of the rack sampler unit. Make sure to place some racks in the rack loader.

The option **Analyze Module** performs a mechanical check for selected modules according to entered number of cycles.

If the check box **With Photo Interrupter** check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Choose **S. Stop** to end this maintenance check and to move all racks to the unloader.

(4) *Sample Barcode Reader Check* The barcode on a sample tube is scanned. After pressing **Stop**, the data is displayed in the print preview for verification. There is no automatic printout. After pressing **Stop** a system reset has to be performed.

c 501: Check the function of the sample barcode reader:

- Set a rack with barcoded tubes in the rack loader and start the sample barcode reader check.

The rack moves first to the barcode reader in the rack feeder line. After reading the relevant positions the rack moves to the barcode reader in the sampling line of the selected modules.

According to the selected cycles the rack moves to the unloader or back to the rack feeder line.

The reading results are shown in the print view screen.

(5) *Reagent Barcode Reader Check* The reagent barcode reader is checked according to input cycle (minimum is 5 cycles).

c 501: After starting the **Reagent Barcode Reader Check** a reagent cassette must be inserted in the cassette loading port. The gripper retracts the cassette automatically and the barcode reader reads in the barcode information on the cassette 5 times. Finally the results are shown in the print view screen. The cassette is ejected to the loading port and can be removed.

e 601: The barcodes of the loaded **cobas e** packs are read.

(6) *Cassette Loading Check* c 501: A check for cassette loading, gripper and piercer movement is performed according to input cycle (minimum: 5 cycles).

List of Maintenance checks

- (7) Cuvette Mixing **c** 501: Performs a functional check on the ultrasonic mixers (1:32)—optionally with cell wash (system time with cell wash: 19:26).
The reagent probe pipettes deionized water in the corresponding cell (cuvette) for R1, R2 and R3 mixer. Then the cuvette turns to the mixing position and ultra sonic mixing is executed. The proper operation of the corresponding mixer can be checked visually—the water in the cuvette is vibrating when the mixer is operating.
- (8) Reagent Short Sensor Check **e** 601: The sensors in the lines of the PreClean, ProCell and CleanCell bottles will be checked.
- (9) Sample Pipetting Check **e** 601: The movement of the sample pipetter is checked and its liquid level detection function.
- (10) Reagent Pipetting Check **e** 601: The movement of the reagent pipetters is checked.
- (11) Cap Opener Check **e** 601: The movement of the cap opener is checked.
- (12) Bead Mixer Check **e** 601: The movement of the microbead mixer is checked.
- (13) Gripper Check **e** 601: The movement of the gripper and its tip and AssayCup handling function is checked.
- (14) Magazine Exchange Check **e** 601: The movement of the magazine exchange is checked.
- (15) Sipper Check **e** 601: The movement of the sippers and their liquid level detection function is checked.
- (16) Pre-wash Probe Check **e** 601: The movement and function of the Pre-wash sipper is checked. The Pre-wash sippere and syringe will aspirate and discharge PreClean during this procedure.
• Manually add cups to the separation stations.
- (17) Pre-wash Gripper Check **e** 601: The movement of the Pre-wash Gripper is checked as well as its AssayCup handling function.
• Make sure to place AssayCups on the following positions before you start this procedure:
 - Pre-wash Gripper position on the incubator (position 6)
 - Vortex mixer position
 - First position in the Pre-wash station

Maintenance cu 150

This chapter describes the maintenance actions required for correct and efficient running of the **cu 150**. The schedule of required periodic maintenance actions (daily, weekly, monthly...) is provided as well as maintenance actions that are performed as needed.

In this chapter

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Maintenance schedule

The recommended intervals for maintenance and checkup are based on a usage of the analyzer for 5 hours a day, 25 days a month. Maintenance and checkup should be conducted in accordance with the list. All maintenance actions are listed in descending frequency.

PO	Power OFF (shut down status)
SB	Standby

	Procedure	Mode	Operator time (min)	System time (min)	Page
Daily	Emptying and cleaning the concentrated waste tank	PO	2		C-50
Monthly	Cleaning the water tank	PO	5		C-53
	Cleaning the filter of the rack sampler unit	SB/PO	5		C-57
Every 6 months	Cleaning the inlet water filter	PO	5		C-58
	Cleaning the cooling fans	PO	5		C-60
As needed	Cleaning instrument surfaces	SB/PO	5		C-61

Table C-22 Maintenance schedule cu 150

Create a maintenance schedule, which is customized to your laboratory's individual requirements. We recommend letting the analyzer's software remind the operator of all periodic maintenance tasks. You can do this by configuring maintenance types (from **Utility > System (Page 2/4) > Maintenance Setting**). Within a maintenance type, you can assign maintenance intervals (**Period**) and warning levels to each maintenance item and maintenance pipe.

- ☛ For more information on scheduling maintenance tasks, see *Maintenance types—scheduling and tracking maintenance items* on page C-13.

Daily maintenance

In this section you find all maintenance for the cu 150 module that is to be performed every day.

Emptying and cleaning the concentrated waste tank

The system issues an alarm if the concentrated waste tank requires emptying. To prevent disruption to the daily routine, empty the concentrated waste tank at the end of the day before shutdown and clean the tank if necessary.

Operator time approximately 2 minutes

- Materials required*
- Water
 - Laboratory disinfectant (no bleach)
 - Paper towels



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-



Harmful fumes due to combination of bleach with content of the waste tank

The combination of bleach with the content of the waste tank can cause potentially harmful fumes.

Do not use bleach to clean the waste tank.

NOTICE

Damage to the waste tank

Do not use alcohol or bleach to clean the waste tank as this may damage the waste tank.

► **To empty and clean the concentrated waste tank**

- 1 Locate the concentrated waste tank at the rear of the rack sampler unit.

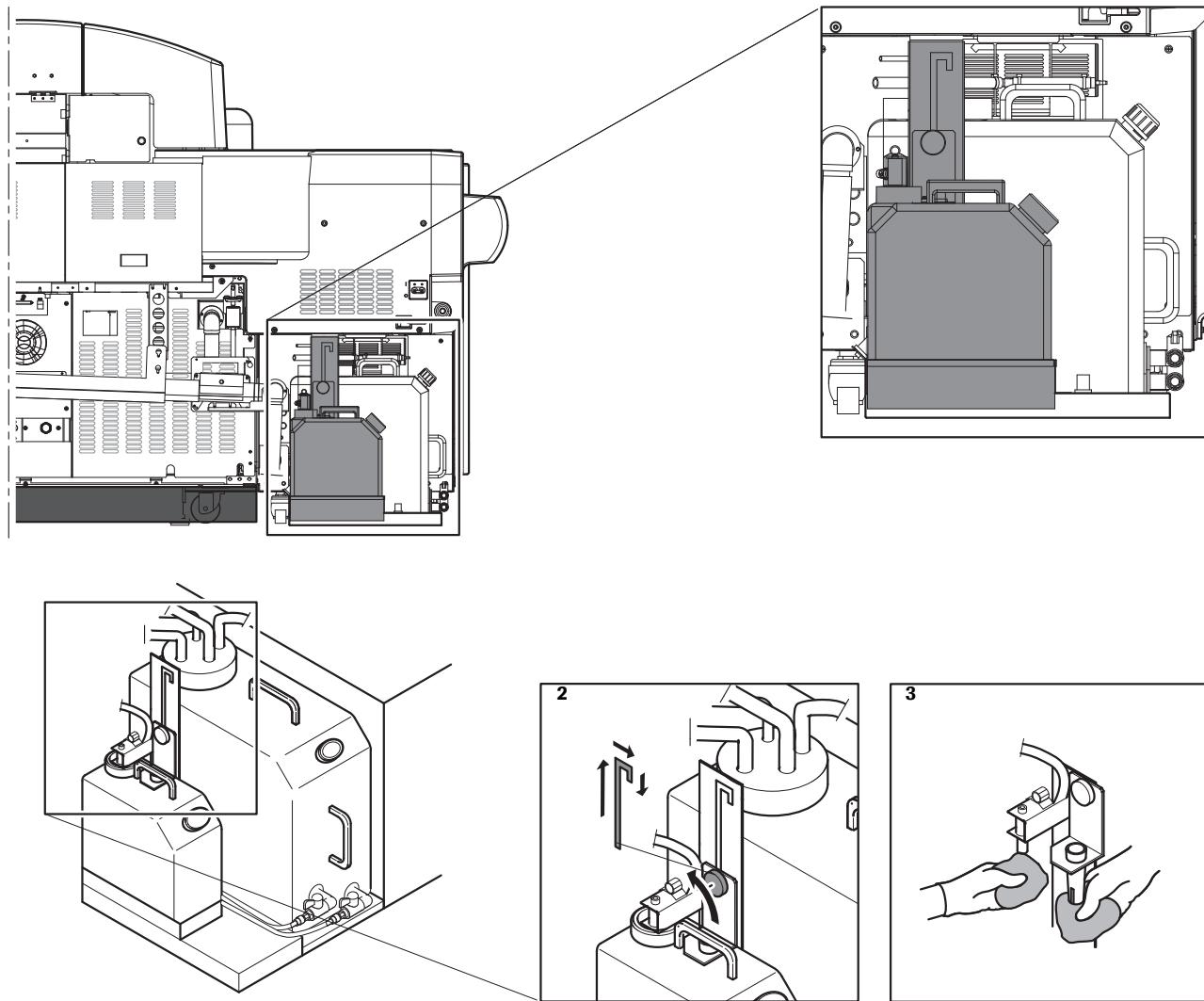


Figure C-14 Emptying and cleaning the concentrated waste tank

- 2 Lift the liquid level sensor assembly from the waste tank and secure it on the notch.

- 3** Clean the concentrated waste drain and the liquid level sensor and place paper towels below them.

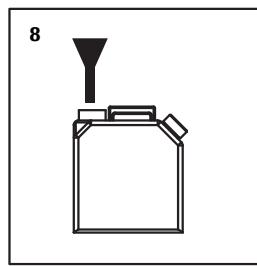
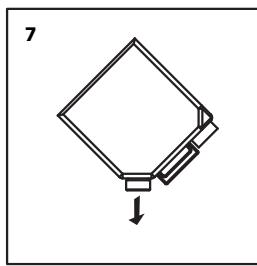
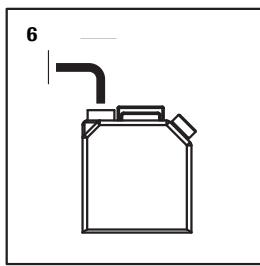
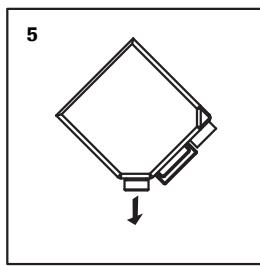
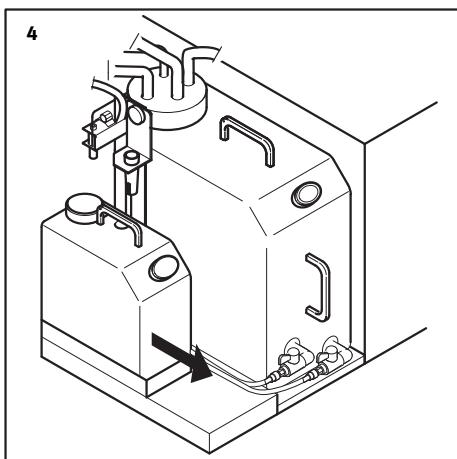


Figure C-15 Emptying and cleaning the concentrated waste tank

- 4** Remove the waste tank.
- 5** Dispose of the contents of the waste tank according to your laboratory's biohazardous waste disposal regulations.
- 6** Rinse the waste tank thoroughly with water
- 7** Dispose of the rinse water in the same manner.
- 8** Prepare the disinfectant according to the manufacturers' instructions and pour the disinfectant into the waste tank.
- 9** Place the waste tank back in its original position.
- 10** Place the liquid level sensor assembly back in the waste tank.
- 11** Dispose of the paper towels according to your laboratory's biohazardous waste disposal regulations and disinfect the area where you were working.

■

Monthly maintenance

In this section, you find all maintenance for the cu 150 that is to be performed at least once a month.

Cleaning the water tank

Contamination inside the tank will result in contamination of the entire flow path and adversely affect all measurements. Check the water tank at least once a month and clean the tank if necessary.

Operator time approximately 5 minutes

- Materials required*
- 0.5% sodium hypochlorite solution
 - Deionized water
 - Lint-free gauze pads
 - Paper towels
 - Brush



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► **To disconnect the water tank**

- 1 Put the analyzer in shutdown status.
☞ See *To shutdown the analyzer* on page C-11.
- 2 Locate the water tank at the rear of the rack sampler unit.

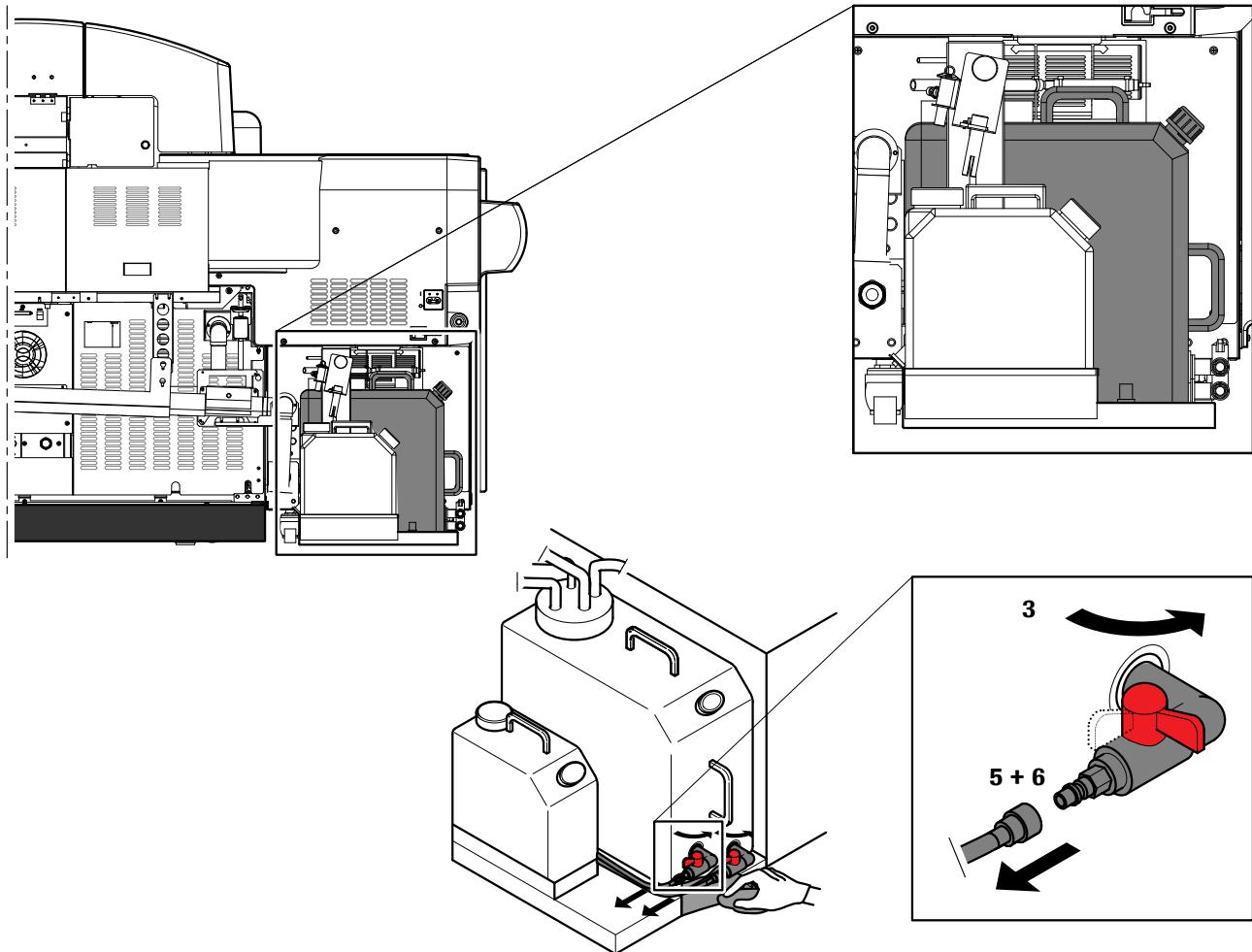


Figure C-16 Disconnecting the two joints of the water tank

- 3 Close the taps at the outlet of the water tank.
- 4 Place paper towels under the hose unit to absorb extra water.
- 5 Disconnect the quick release connector by rotating the release collar until it lines up with its key.

- 6** Pull back the spring-loaded collar to separate the water hose from the tank.



Personal injury due to heavy water tank

The water tank, when filled with water, is heavy. Handle the tank accordingly.

If the tank is too heavy, pour out sufficient water until the tank becomes light to carry.

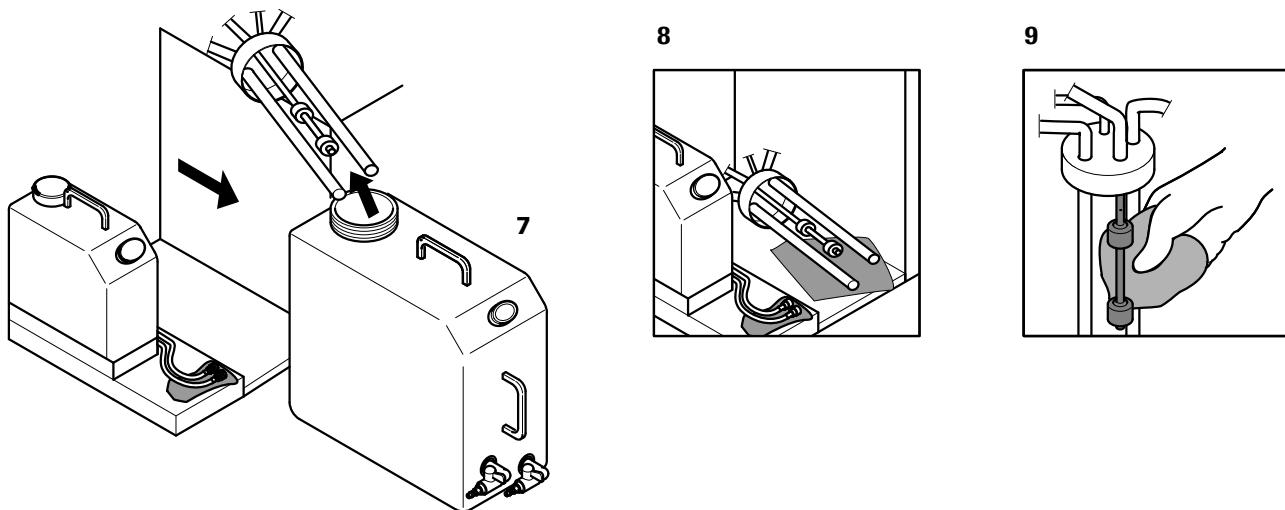


Figure C-17 Cleaning the liquid level sensor assembly of the water tank

- 7** Pulling the water tank sideways, remove the liquid level sensor assembly from the tank and place it on a paper towel, then empty the water from the tank.
- 8** Wipe the liquid level sensor assembly with gauze pads soaked with deionized water.
- 9** Rinse the water tank thoroughly with deionized water three times.
If the water tank is considerably contaminated, follow the procedure below: *To thoroughly clean the water tank*. Otherwise, proceed as follows:
- 10** Fill the tank at least 1/3 full with deionized water.
- 11** Reattach the liquid level sensor assembly and place the tank to its original position.
- 12** Reconnect the water hose to the water tank and open the taps.
- 13** Ensure main water supply is on.



► **To thoroughly clean the water tank**

- 1 Rinse the tank thoroughly with 0.5% sodium hypochlorite solution. For thorough cleaning use a brush to clean the interior surface. Then wash with tap water to eliminate the detergent.
- 2 Rinse the tank thoroughly with deionized water 3 times.
- 3 Fill the tank at least 1/3 full with deionized water.
- 4 Reattach the liquid level assembly and place the tank to its original position.
- 5 Reconnect the water hose to the water tank and open the taps.
- 6 Ensure main water supply is on.
- 7 Switch on the analyzer.

■



Slip hazard due to leaking water

If the joints of the water tank are not connected properly, water may leak.

Ensure that all joints are connected properly.

Cleaning the filter of the rack sampler unit

Clean the filter at the rear of the rack sampler unit at least once a month to prevent dust or dirt accumulation.

Operator time approximately 5 minutes

Materials required Vacuum cleaner



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3

► To clean the filter of the rack sampler unit

1 Put the analyzer in shutdown or standby status.

☞ See *To shutdown the analyzer* on page C-11

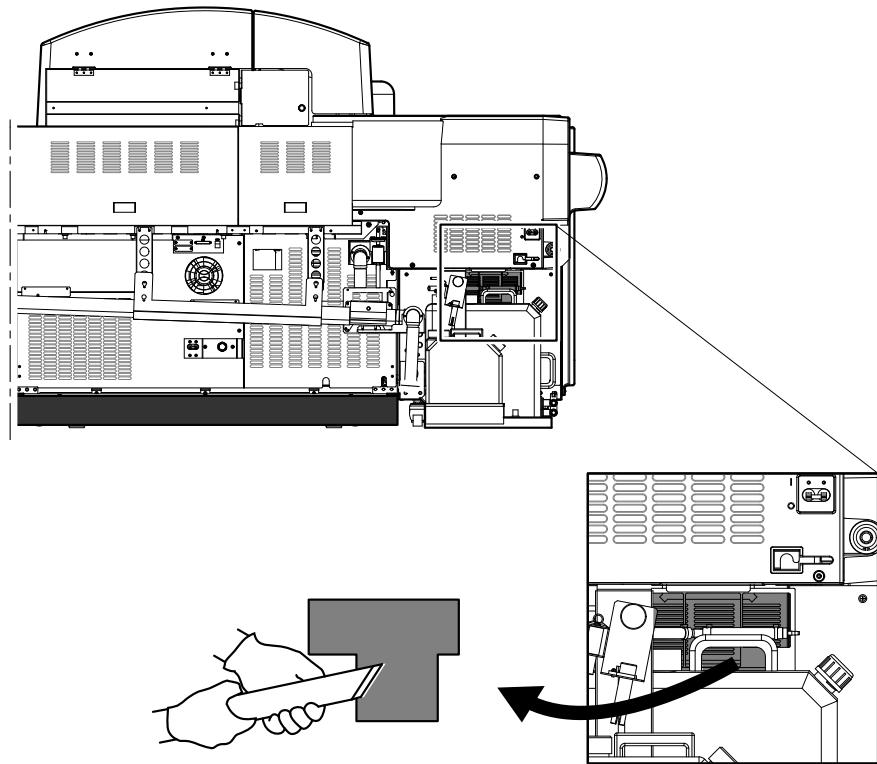


Figure C-18 Cleaning filter of rack sampler unit

- 2 Remove the filter of the rack sampler unit.
- 3 Vacuum dirt and other debris from the filter of the rack sampler unit.
- 4 Reattach the filter of the rack sampler unit.
- 5 Switch on the analyzer.



Every six months maintenance

In this section, you find all maintenance for the cu 150 that is to be performed at least once every six months.

- ☛ This section discusses the following maintenance actions:
 - Cleaning the inlet water filter* on page C-58
 - Cleaning the cooling fans* on page C-60

Cleaning the inlet water filter

Clean the inlet water filter at least once every six months to prevent clogging of the water system.

Operator time approximately 5 minutes

Materials required Inlet water filter (in case replacement is required)
 Beaker, 500 mL
 Deionized water



Incorrect results due to loose tube sockets

If the water supply filter is clogged or the inlet water hose is not reconnected to the inlet water manifold accurately, it may cause instrument malfunction and result in inaccurate measurement.

- Clean the filter regularly.
- Reconnect the inlet water hose to the inlet water manifold accurately.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: R-4.

► **To clean the inlet water filter**

- 1 Put the analyzer in shutdown status.
- 2 Close the water tap and halt the supply of water from the external deionized water supply.

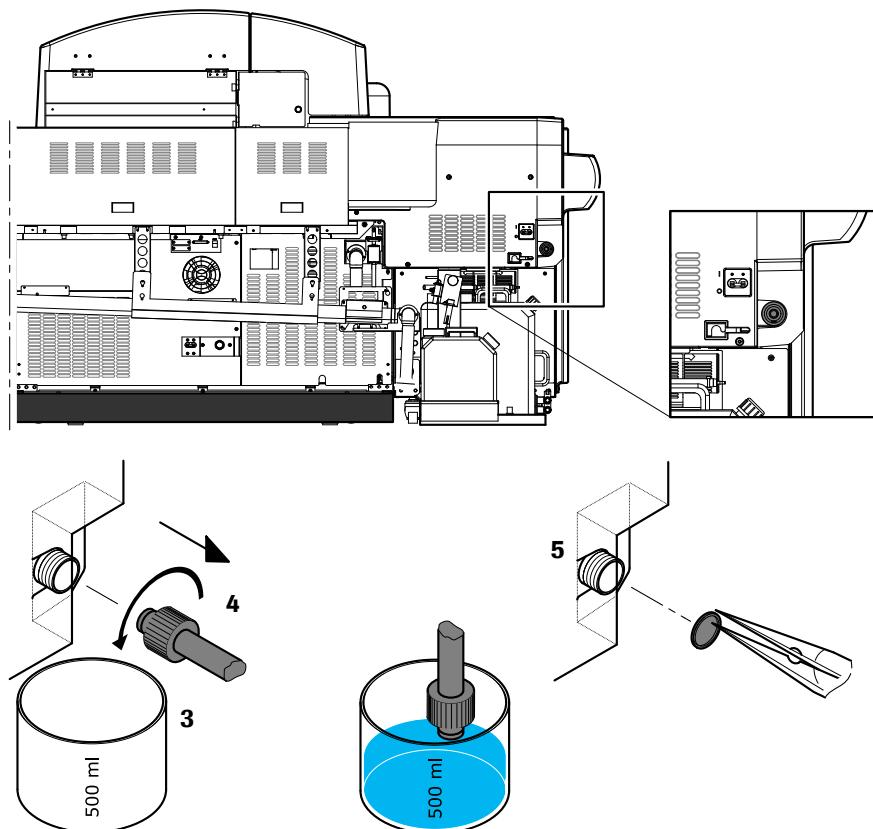


Figure C-19 Disconnecting inlet water hose and removing inlet water filter

- 3 Place a 500 mL beaker (or a similar type container) beneath the inlet water manifold.
- 4 Turn the knurled ring on the water filter cap counterclockwise and disconnect the inlet water hose.
- 5 Remove the water filter and place the hose in the beaker. Be careful not to tip the beaker.
- 6 Clean the filter thoroughly with deionized water, then reinstall the filter.
If necessary, replace the inlet water filter.



After cleaning, tighten the filter cap securely and make sure there is no water leakage.

- 7 Reconnect the inlet water hose to the inlet water manifold.
- 8 Ensure the water supply is on, before you start up the analyzer again.



Every six months maintenance

Cleaning the cooling fans

Clean the cooling fans at the rear of the **c 501** and **e 601** modules to remove dust and dirt.

Operator time approximately 5 minutes

Materials required Vacuum cleaner
 Brush

► To clean a cooling fan

- 1 Put the analyzer in shutdown status.



Injury by touching the fan

If the fan is cleaned with the analyzer not in shutdown status, there is a danger of injury.

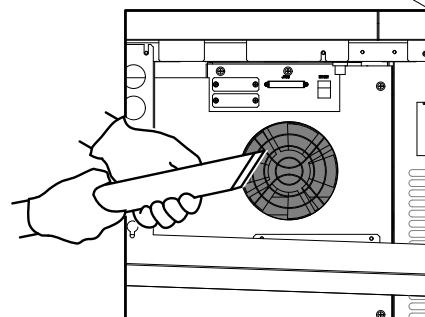
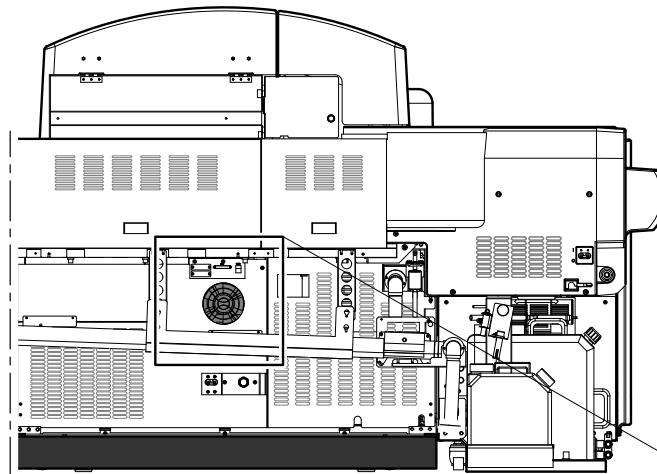


Figure C-20 Cleaning the cooling fans

- 2 Vacuum or brush dust, dirt, and other debris from all cooling fans on the back of each module.
- 3 Start up the analyzer.



As needed

In this section, you find all maintenance for cu 150 that is to be performed as needed and is not subject to a regular time schedule.

Cleaning instrument surfaces

Spills on the instrument surface could be potentially biohazardous and damage the surface.

Operator time approximately 5 minutes

Materials required Cloth or paper towels
 Laboratory disinfectant (no bleach)



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

NOTICE

Damage to the instrument surface

Do not use alcohol or bleach to clean the instrument surfaces as this may damage the finish.

► **To clean instrument surfaces**

- 1 Put the analyzer in shutdown status or in standby.
 ☞ See *To shutdown the analyzer* on page C-11.
 - 2 Clean the module surfaces using a cloth or paper towel moistened with disinfectant.
 Clean up all spills immediately. Use this procedure to ensure that surfaces are clean.
-

As needed

Maintenance c 501 with ISE

This chapter describes the maintenance actions required for correct and efficient running of the c 501 module. The maintenance of both ISE unit and photometric unit is discussed. The schedule of required periodic maintenance actions (daily, weekly, monthly...) is provided as well as maintenance actions that are performed as needed.

Further maintenance actions, that can only be performed by specially trained operators, are required for a correct and efficient running of the c 501 module. These maintenance actions are described in a separate manual: *Interlock function cobas c 501 with ISE*.

In this chapter

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Maintenance schedule

The recommended intervals for maintenance and checkup are based on a usage of the analyzer for 5 hours a day, 25 days a month. Maintenance and checkup should be conducted in accordance with the list. All maintenance actions are listed in descending frequency.

PO	Power OFF
SB	Standby
CIB	Cleaning Incubator Bath
CLSL	Change Light Source Lamp

Interval	Procedure	Mode	Operator time (min)	System time (min)	Page
Daily	Processing green wash rack		5	15 ^(a)	C-67
	Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle	SB/PO	2		C-72
	Cleaning cell rinse nozzles	SB/PO	2		C-74
	Cleaning the drain port for high concentrated waste	SB/PO	1		C-75
Weekly	Cleaning the reaction system	SB	2	55	C-76
	Cleaning the cell covers	SB/PO	5		C-78
	Cleaning the rinse stations	SB/PO	5		C-80
	Removing and manually cleaning the IS bath	SB/PO	5		C-82
Monthly	Cleaning the ISE Ref. (KCl) aspiration filter	SB/PO	5	3	C-83
	Replacing reaction cells	CIB/SB/PO	10	55	C-86
	Cleaning the incubator bath	CIB/PO	15	25	C-87
	Cleaning the detergent aspiration filters	SB/PO	5	7	C-94
	Cleaning the filters behind the front doors	SB/PO	10		C-96
Every 3 months	Cleaning the ultrasonic mixers ^(c)	CIB	6	7	C-98
Every 6 months^(b)	Replacing the syringe seals	PO	15	7	C-102
	Replacing the photometer lamp ^(d)	CLSL/PO	5	20	C-109
As needed^(b)	Cleaning the ISE Ref. (KCl) aspiration filter	SB/PO	5	3	C-114
	Cleaning the detergent aspiration filters	SB/PO	5	7	C-114
	Replacing nozzle tips on cell rinse nozzles	SB/PO	6		C-114
	Replacing the photometer lamp ^(d)	CLSL/PO	5	20	C-116
	Replacing the syringe seals	PO	15	7	C-116
	Cleaning the ultrasonic mixers ^(c)	CIB	6	7	C-116
	Draining the vacuum tank	SB/PO	5		C-117
	Cleaning instrument surfaces	SB/PO	5		C-118

Table C-23 Maintenance schedule c 501

(a) When **Green Rack during Operation** is enabled for a 24 hour shift

(b) All maintenance actions described as 6 monthly or as needed can be covered by appropriate service contract actions.

(c) Every 3 months or after 225.000 tests (whatever comes first)

(d) Every 6 months, after 750 hours or if the photometer check value exceeds 14000 (whatever comes first)

Periodic replacement of parts

Create a maintenance schedule, which is customized to your laboratory's individual requirements. We recommend letting the analyzer's software remind the operator of all periodic maintenance tasks. You can do this by configuring maintenance types (from **Utility > System (Page 2/4) > Maintenance Setting**). Within a maintenance type, you can assign maintenance intervals (**Period**) and warning levels to each maintenance item and maintenance pipe.

- ⦿ For more information on scheduling maintenance tasks, see *Maintenance types—scheduling and tracking maintenance items* on page C-13.

Periodic replacement of parts

Some parts require periodic replacement for preventive maintenance. Replace these parts regularly and in accordance with your workload and the recommendations given in this document.

<i>ISE unit</i>	Item	2 months	3 months	6 months	As needed	Reference
	ISE measuring cartridges ^{(a)(b)} (Na ⁺ , K ⁺ , Cl ⁻)	x			x	
	ISE reference cartridge ^(a)			x		
	ISE sipper tubing ^{(a)(c)}		x		x	
	ISE pinch valve tubing ^{(a)(c)}		x		x	
	Syringe seals of ISE pipettor and ISE sipper ^(d)		x		x	

Table C-24 Periodic replacement of parts for c 501 ISE unit

- (a) Can only be done by specially trained operators.
- (b) Every 2 months or after 9000 samples (whatever comes first)
- (c) Every 6 months or after 75.000 samples (whatever comes first)
- (d) Every 6 months or after 75.000 tests (whatever comes first)

<i>Photometric unit</i>	Item	Monthly	3 months	6 months	As needed	Reference
	Reaction cells	x				C-86
	Photometer lamp ^(a)		x	x		C-109
	Syringe seal of sample probe and reagent probes ^(b)		x	x		C-102

Table C-25 Periodic replacement of parts for c 501 photometric unit

- (a) Every 6 months or after 750 hours, or if the photometer check exceeds 14000 (whatever comes first)
- (b) Every 6 months or after 225.000 tests (whatever comes first)



Incorrect results due to improper spare parts

For proper instrument care use only original spare parts provided by Roche.

- The necessary spare parts are listed in the description of the corresponding maintenance action.
- To order spare parts, please contact your technical support.

Daily maintenance

In this section, you find all maintenance for the c 501 module that is to be performed every day.

- ☛ This section discusses the following maintenance actions:

Processing green wash rack on page C-67

Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle on page C-72

Cleaning cell rinse nozzles on page C-74

Cleaning the drain port for high concentrated waste on page C-75

Cleaning instrument surfaces on page C-118

Contamination of flow paths or pipettor probes may cause incorrect measurement results or clogging. Therefore, make sure to regularly perform the stated maintenance procedures.

Processing green wash rack

A green wash rack containing detergents and Activator must be processed once every 24 hours as described below.

Normally the green wash rack is processed at the end of analysis each day.

- ☛ See *At the end of analysis each day* on page C-70

If your cobas 6000 analyzer operates continuously during a 24-hour shift, the green wash rack must be processed once every 24 hours.

- ☛ See *During a continuous 24-hour shift* on page C-70

Operator time approximately 5 minutes

System time approximately 15 minutes during a 24-hour shift

- Materials required*
- Green rack (wash rack)
 - Multiclean, 400 µL (5 cycles) per c 501 module
 - SysClean, 300 µL (15 cycles) per c 501 module
 - Activator, 300 µL (15 cycles) per c 501 module

Daily maintenance

ISE reagent consumption Approximately 18 mL internal standard (ISE IS)

Approximately 7 mL diluent (ISE Dil.)

Approximately 2 mL reference electrode solution (ISE Ref.)



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
-



CAUTION

Incorrect patient results due to shortage of ISE conditioning solution (Activator) or ISE cleaning solution (SysClean)

If the amount of Activator or SysClean is not sufficient or the sample cup containing the Activator or SysClean is missing or in an incorrect position, the conditioning or cleaning of the ISE can not be completed.

- Fill a sufficient amount of Activator and SysClean into sample cups.
 - Place the sample cups in the correct position of the green wash rack.
 - If an alarm due to insufficient volume of these solutions is issued, all ISE samples measured after the alarm must be rerun.
-



CAUTION

Incorrect results due to wrong calibration

After processing a green wash rack all ISE tests must be calibrated.

- Do not load samples with ISE requests before you have checked the calibration and QC results for ISE.
-

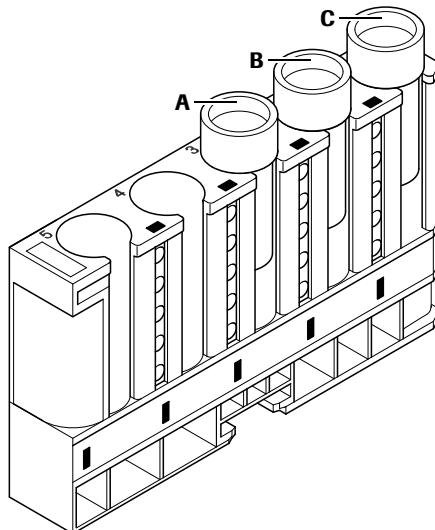


If the processing of the green wash rack is interrupted for some reason, perform the following maintenance items:

- **(7) Wash Reaction Parts**
 - **(8) Reagent Prime (All)**
-

Preparing the wash rack and checking the number of cycles**► To prepare the wash rack**

- 1 Place sample cups at positions 1 to 3 on a green rack (wash rack) and fill suitable amounts of Multiclean, ISE cleaning solution (SysClean), and Activator into the sample cups as shown in the figure below.



- A** Activator (for conditioning)
B SysClean
C Multiclean

Figure C-21 Green rack with reagents for daily ISE maintenance

- Position 1: Multiclean, 400 µL (5 cycles) per c 501 module
- Position 2: ISE cleaning solution (SysClean), 300 µL (15 cycles) per c 501 module
- Position 3: Activator 300 µL (15 cycles) per c 501 module



Unless sample cups are positioned as instructed, neither sampling nor rinsing will be conducted.

- 2 Check the number of cycles for detergent pipetting:

- Choose **Utility > System**
- If necessary, change the number of cycles for both Photometric and ISE under **Wash Rack Sampling** (recommended are 5 cycles for Photometric and 15 for ISE).
- Choose **OK** to save the settings.



At the end of analysis each day**► To clean sample flow paths and ISE electrodes**

- 1 Place the wash rack on the rack loader.
 - 眼界 For more information, see *To prepare the wash rack* on page C-69
- 2 Choose **Start** (global button) and **Start** on the **Start Conditions** screen. If the analyzer is already in operational status, skip this step.
- 3 Perform a full calibration of the ISE unit.
 - 眼界 For details on how to calibrate the ISE unit, see:
Requesting and cancelling calibrations manually on page B-137.



For labs not running 24 hours per day, Roche recommends performing the cleaning of the flow paths and conditioning of the electrodes within a sleep pipe. Then the system will go to sleep mode after the sleep pipe with green wash rack is performed.

眼界 See *Sleep Pipe function with green wash rack* on page C-20

During a continuous 24-hour shift

The analyzer offers a function to process a green wash rack in operation during a continuous 24-hour shift.

The **Green Rack during Operation** function is activated under **Utility > System (Page 3/4) > Rack Delivery**.

眼界 See *Green Rack during Operation* on page B-220

**Notes for working with the Green Rack during Operation function**

- The analyzer must not be in standby to process a green wash rack when this function is activated.
- Since the analyzer is still processing samples, it is possible to load any other rack together with the green wash rack. In this case only photometric and immunological tests are processed on the **c 501** module or the **e 601** module.
- Therefore during processing of the green wash rack do not load any sample with ISE requests because ISE tests are P-masked. If you load samples with ISE requests, the ISE requests can not be processed until the green wash rack is finished.
- Samples with open ISE requests that were registered before masking the ISE tests will be unloaded after masking the ISE tests. You have to reload these samples after processing the green wash rack.
- It is recommended to process the green wash rack immediately before your periodic calibration during a continuous 24-hour shift.

► **To process a green wash rack on a analyzer with one c 501 module**

- 1 P-mask the ISE tests on the **Masking** window (**Start** (global button) > **Masking**)
- 2 Request a full calibration for all ISE tests on the **Calibration Status** screen.
☞ See *Requesting and cancelling calibrations manually* on page B-137.
- 3 Place the racks in the following sequence on the rack loader:
 - Green wash rack.
☞ For more information, see *To prepare the wash rack* on page C-69
 - Calibrator rack containing the ISE calibrators.
 - QC rack containing the QCs for ISE tests.
- 4 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.
- 5 Check the results for calibration and QC.
- 6 If the analyzer has generated a valid calibration and the QC results are okay, unmask the ISE tests.

■

The analyzer is ready to process routine samples.

► **To process a green wash rack on a analyzer with two c 501 modules**

- 1 P-mask the ISE tests for both c 501 modules on the **Masking** window (**Start** (global button) > **Masking**)
- 2 Request a full calibration for both c 501 modules for all ISE tests on the **Calibration Status** screen.
☞ See *Requesting and cancelling calibrations manually* on page B-137.
- 3 Place the green wash rack on the rack loader.
☞ For more information, see *To prepare the wash rack* on page C-69
- 4 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.
- 5 Wait until the green wash rack is in the rack unloader.
 - Load a calibrator rack containing the ISE calibrators.
 - Load a QC rack containing the QCs for ISE tests.
- 6 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.
- 7 Check the results for calibration and QC.
- 8 If the analyzer has generated a valid calibration and the QC results are okay, unmask the ISE tests.

■

The analyzer is ready to process routine samples.



If you load the ISE calibrator and QC racks before the green wash rack is in the rack unloader, the green wash rack is processed on the first c 501 module. The calibrator and QC racks are processed on the second c 501 module previous to the green wash rack.

The thus obtained calibration is no longer valid, after the green wash rack has been processed on the second c 501 module.

Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle

At the end of analysis each day, clean the outside of the pipettor probes (sample probe, reagent probes, ISE probe) and of the ISE sipper to remove residual solution and precipitation. This is a combined maintenance procedure for both ISE and photometric unit.

When sample aspiration error occurs frequently or if an alarm for clogging of the sample probe occurs and is not reset after cleaning (maintenance item **(12) Sample Probe Wash**), the sample probe must be detached and clogging must be eliminated.



Pipettor probes must be replaced, when they are bent or damaged. Detaching the sample probe and elimination of sample clogging must only be done by specially trained operators. Positional adjustment is required after reattaching the probe.

- ☞ For more information refer to the separate maintenance manual:
Interlock function cobas c 501 with ISE.

Operator time

approximately 2 minutes

Materials required

- Alcohol (e.g. isopropyl alcohol or ethanol)
- Lint-free gauze pads



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Personal injury due to contact with pierce pin* on page C-4
- *Infection and injury due to sharp objects* on page C-4
- *Fire and burns due to the use of alcohol* on page C-4



Damage to the probes

Do not bend or damage the lower end of the probes during cleaning. Move the arm gently. Do not move it up and down.

► To clean the outside of sample probe, reagent probes, ISE probe and ISE sipper nozzle

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

- ☞ For a description of the analyzer parts referred to in this section, see:
Figure C-22 on page C-73.

The pipettor probes (**A, C, F**) and sipper nozzle (**E**) can be easily moved by hand to an accessible position.



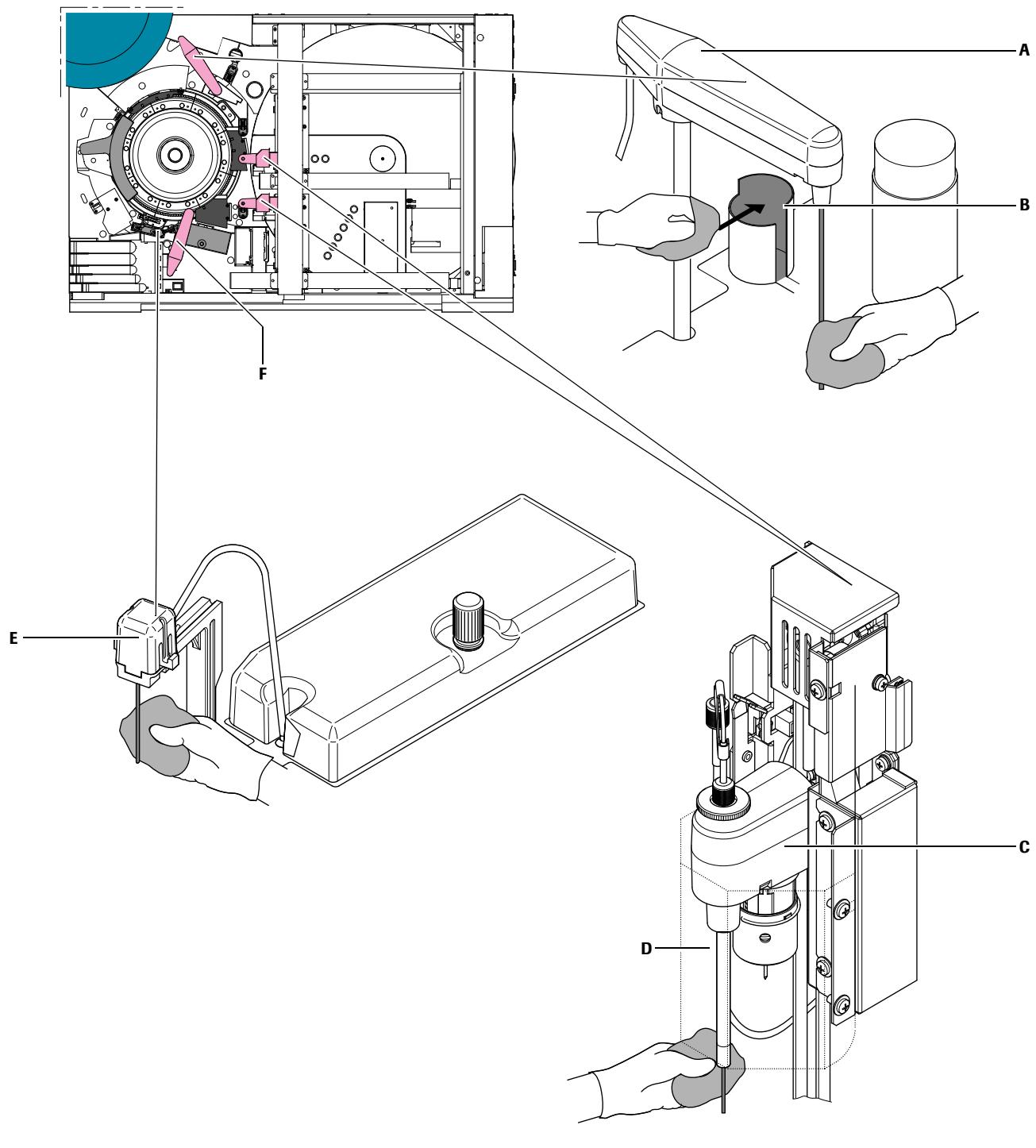
Use a new lint-free gauze pad for each probe to prevent cross contamination.

3 Wipe (from top to bottom) the outsides of the sample, reagent and ISE probes and the sipper nozzle with gauze pads moistened with alcohol.

4 Also wipe the inside of the shield pipe (**B**) with a gauze pad moistened with alcohol.

5 Close the top cover of the module and lock it.

6 Switch on the analyzer, if the analyzer is in shutdown status.



A Sample probe
B Shield pipe

C Reagent 1/2 probe
D Plexiglas cover

E ISE sipper
F ISE probe

Figure C-22 Cleaning the outside of sample probe with shield pipe, reagent probe, ISE probe and sipper

Cleaning cell rinse nozzles

At the end of analysis each day, clean the cell rinse nozzles. Regular cleaning prevents contamination, crystal formation, and clogging.

Operator time approximately 2 minutes

Materials required

- Deionized water
- Lint-free gauze pads
- Cleaning wire of 0.5 mm diameter (stainless steel)



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Personal injury due to contact with cleaning solutions or reagents* on page C-4

► **To clean the cell rinse nozzles**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of the module.

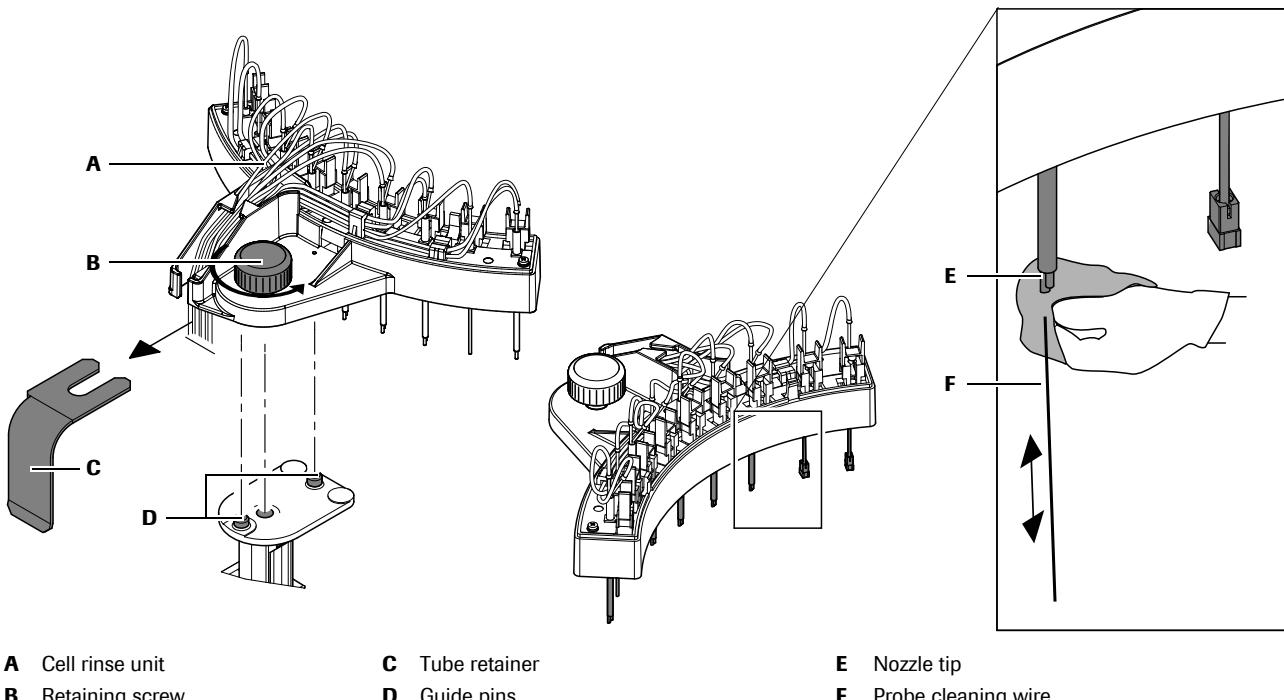


Figure C-23 Dismount the cell rinse unit and clean the cell rinse nozzles

- 3 Loosen the retaining screw (B) of the cell rinse unit and lift off the entire unit (A).
- 4 Moisten a lint-free gauze pad with deionized water and gently wipe all tips (E) of the cell rinse unit nozzles in a downward motion.
- 5 If a nozzle is clogged, insert the probe cleaning wire (F) (stainless steel wire, 0.5 mm diameter) into the tip of the nozzle and eliminate the clogging.

- 6 Align the pin holes of the cell rinse unit with the guide pins (**D**) and attach the rinse unit.
 - 7 Fix the tube retainer (**C**) below the screw and then tighten the retaining screw.
 - 8 Close the top cover of the module and lock it.
 - 9 Switch on the analyzer, if the analyzer is in shutdown status.
-

Cleaning the drain port for high concentrated waste

At the end of analysis each day, clean the outlet of the drain port for high concentrated waste. Regularly perform this maintenance to prevent the accumulation of crystals and clogging of the drain port.

Operator time approximately 1 minute

Materials required

- Cotton swabs
- Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Contamination by waste solution and solid waste* on page C-3
-

► **To clean the outlet of the drain port for high concentrated waste**

- 1 Put the analyzer in shutdown status or the module in standby.
 - 2 Apply deionized water to the outlet of the drain port at the rear of the module and rinse off crystals using cotton swabs.
 - 3 Switch on the analyzer, if the analyzer is in shutdown status.
-

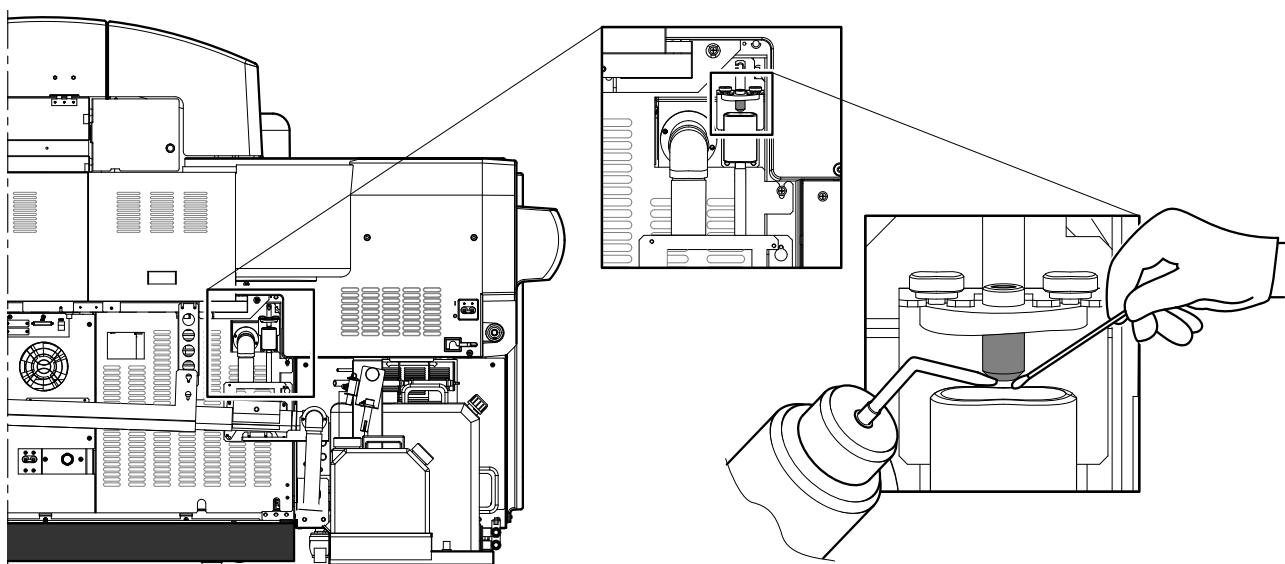


Figure C-24 Cleaning the drain port for high concentrated waste
Roche Diagnostics

Weekly maintenance

In this section you find all maintenance for the c 501 module that is to be performed at least once a week.

- ⦿ This section discusses the following maintenance actions:
 - Cleaning the reaction system* on page C-76
 - Cleaning the cell covers* on page C-78
 - Cleaning the rinse stations* on page C-80
 - Removing and manually cleaning the IS bath* on page C-82

Cleaning the reaction system

Contamination of the reaction cells or the waste solution flow path will result in incorrect measurement results. Wash the reagent probe and reaction cells at least once a week.

- ⦿ For instructions on how to remove reaction cells, see *Replacing reaction cells* on page C-86.

After rinsing the reaction system, perform a cell blank measurement to monitor the condition of the reaction cells.

Operator time approximately 2 minutes

System time approximately 55 minutes

This maintenance comprises the following procedures and maintenance items:

1. To rinse the reaction system (maintenance item **(7) Wash Reaction Parts**)
2. To perform a cell blank measurement (maintenance item **(4) Cell Blank Measurement**)
3. To view the cell blank measurement results



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► **To rinse the reaction system**

- 1 Put the module in standby.
- 2 Select the c 501 module on the **System Overview** screen and choose **Reagent Overview**.
- 3 On the **Reagent > Status** screen, check the remaining amounts of detergents for reaction cells, reagent probe and sample probe. If inadequate, add a new detergent bottle or cassette.

Detergent	Reagent	Consumption
Sample probe detergent	Multiclean	approximately 1 mL
Reagent probe and reaction cell detergent	NaOH-D cassettes (application code 947)	approximately 58 mL

Table C-26 Detergent consumption

- 4 Choose **Utility > Maintenance**.
- 5 Choose **Maintenance (1)** on the **Maintenance Types** list on the left.
- 6 Choose **(7) Wash Reaction Parts** on the **Maintenance Items** list on the right.
- 7 Choose **Select** to open the **Wash Reaction Parts** window.
- 8 Select a module. Selected modules are highlighted.
- 9 Choose **Execute**.

The procedure is finished when the module returns to standby.

Now, proceed with the cell blank measurement.



► **To perform a cell blank measurement**

- 1 Choose **Utility > Maintenance**.
- 2 Choose **(4) Cell Blank Measurement** on the **Maintenance Items** list on the right.
- 3 Choose **Select**, to open the **Cell Blank Measurement** window.
- 4 Select a module. Selected modules are highlighted.
- 5 Choose **Execute**.



Weekly maintenance

► **To view the cell blank measurement results**

After performing a cell blank measurement, the corresponding report can be viewed directly on the **Print View** window.

- 1 Choose **Print** (global button).
- 2 Choose **View** to display the **Print View** window.

This window shows a short form of the **Cell Blank Measurements** report. In this short report, the cell blank values of the first cuvette are shown. This indicates that the cell blank was successful.

If an abnormal cell list is displayed below the cell blank values of the first cuvette, the cell blank failed. The cells listed did not compare to cell 1. These cells need to be inspected and the Cell Blank must be performed again



Cell Blank Measurements												04/12/08	18:25
MODULE	C1	ABORMAL CELL LIST											
27/11/08	17:03	-----											
CELL NO.	340	376	415	450	480	505	546	570	600	660	700	800	
001	10392	9806	9625	9393	9388	9230	9065	9075	8988	8838	8716	8543	
002	10422	9817	9639	9408	9403	9244	9079	9085	8997	8847	8726	8554	
003	10429	9843	9660	9425	9421	9262	9099	9107	9021	8872	8749	8568	
004	10522	9917	9721	9481	9472	9310	9139	9142	9053	8898	8772	8588	
005	10379	9798	9612	9382	9380	9222	9060	9068	8981	8833	8711	8532	
006	10421	9827	9641	9408	9404	9244	9079	9084	8998	8848	8725	8549	
007	10400	9817	9628	9395	9392	9233	9068	9076	8990	8840	8719	8540	
008	10503	9894	9694	9452	9440	9277	9105	9110	9020	8865	8741	8558	
009	10500	9896	9692	9449	9437	9274	9102	9108	9017	8863	8737	8551	
010	10509	9898	9703	9461	9452	9289	9119	9122	9033	8878	8753	8573	

Figure C-25 Cell Blank Measurements report

- ☞ For more information, see *To replace reaction cells* on page C-86 and refer to the Online Help of the Cell Blank Measurements report (Print > Utility > Cell Blank)

Cleaning the cell covers

Clean the cell covers of the reaction cells at least once a week. The cell covers serve to prevent contamination by reagent and reaction solution. If reagent adheres to the front or rear face of a cell cover, the analytical accuracy may decrease.

Operator time approximately 5 minutes

Materials required

- Cotton swabs
- Lint-free gauze pads
- Alcohol (e.g. isopropyl alcohol or ethanol)

**Before performing this maintenance action, observe the following safety precautions:**

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Fire and burns due to the use of alcohol* on page C-4

► To clean the cell covers

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

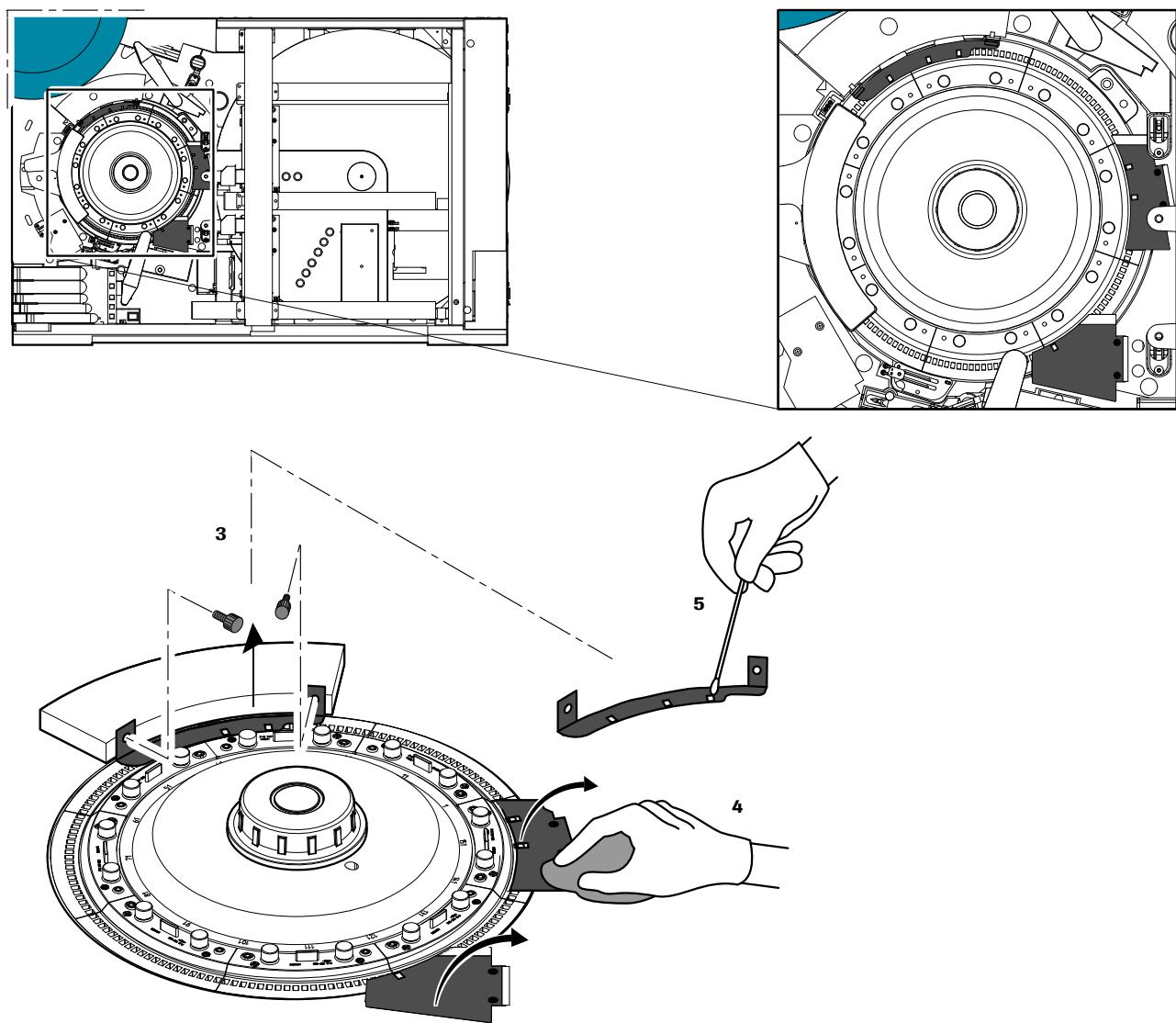


Figure C-26 Cleaning the cell covers

Weekly maintenance

- 3 Loosen the screws and remove the cell cover above the ultrasonic mixers.
- 4 Wipe the front and rear faces of the cell covers using a gauze pad moistened with alcohol.
- 5 Wipe the openings of cell covers using a cotton swab moistened with alcohol.



Be careful not to splash alcohol in the reaction cells.

- 6 Return the cell cover above the ultrasonic mixers.
- 7 Close the top cover of the module and lock it.
- 8 Switch on the analyzer, if the analyzer is in shutdown status.



Cleaning the rinse stations

Clean the rinse stations of the sample probe, reagent probes, ISE probe and ISE sipper nozzle at least once a week, to prevent bacterial growth or precipitation that may clog the rinse stations.

Operator time approximately 5 minutes

Materials required

- Wash bottle
- Cotton swabs
- 2% Hitergent solution
- Deionized water
- Alcohol (e.g. isopropyl alcohol or ethanol)



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Personal injury due to contact with pierce pin* on page C-4
- *Personal injury due to contact with cleaning solutions or reagents* on page C-4
- *Fire and burns due to the use of alcohol* on page C-4

► **To clean the rinse station**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of the module.

- 3** Move the sample probe, reagent probes, ISE probe and ISE sipper nozzle to positions that leave the rinse stations easily accessible.

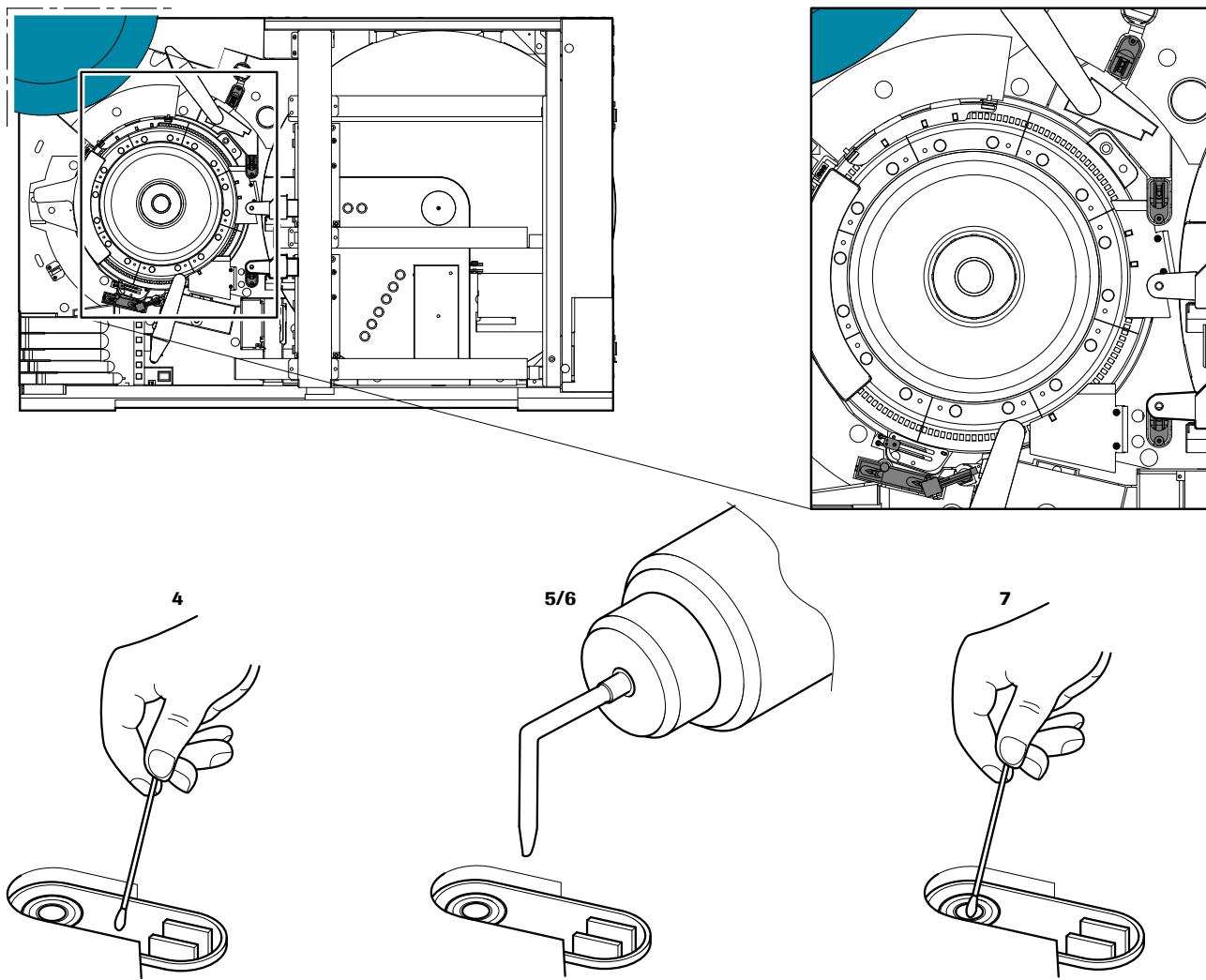


Figure C-27 Cleaning rinse stations of sample probe, reagent probe, and ISE probe

- 4** Using cotton swabs moistened with 2% Hitergent solution, clean the inside of each rinse station.

- 5** Inject about 10 mL of 2% Hitergent solution to each of the rinse stations.



Be careful not to splash water on the drying cylinder (for vacuum suction).

- 6** Inject about 100 mL of deionized water to each of the rinse stations to rinse them.

- 7** Wipe the drying cylinder (used for vacuum suction in the sample probe rinse station) with cotton swabs moistened with alcohol.

- 8** Close the top cover of the module and lock it.

- 9** Switch on the analyzer, if the analyzer is in shutdown status.



Removing and manually cleaning the IS bath

Crystals may remain on the upper part of the IS bath even after daily automatic rinsing. Therefore, remove and manually clean the IS bath once a week.

We recommend combining this maintenance with the monthly cleaning of the incubator bath. This allows the incubator bath to be cleaned below the IS bath.

☞ See *Cleaning the incubator bath* on page C-87

Operator time approximately 5 minutes

Materials required □ Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3

► **To remove and manually clean the IS bath**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of analyzer.

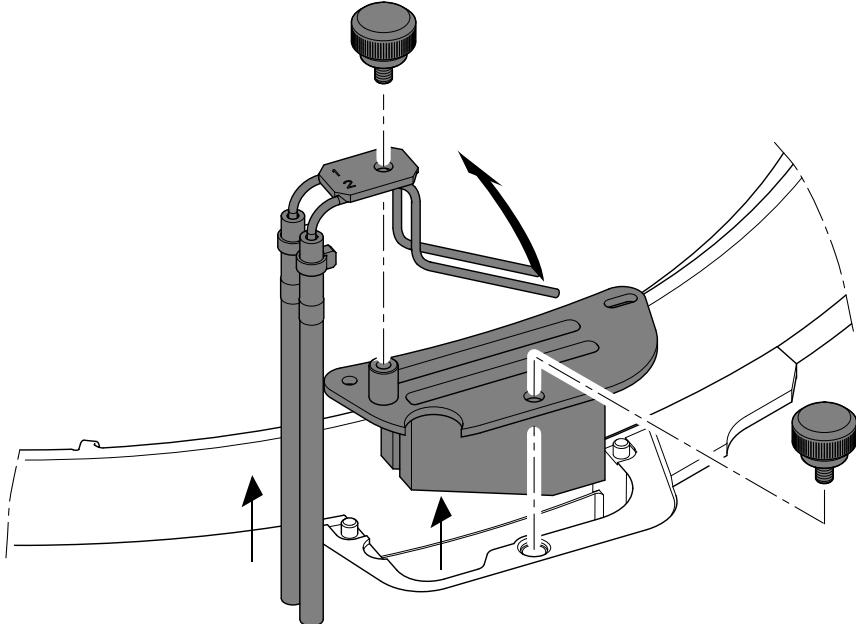


Figure C-28 Removing and cleaning the IS bath

- 3 Loosen the screws and remove the IS bath.
- 4 Wash away any crystals or contamination in the IS bath with deionized water.
- 5 Drain the water from the IS bath and then attach it in the analyzer.
- 6 Close the top cover of the module and lock it.
- 7 Switch on the analyzer, if the analyzer is in shutdown status.

■

Monthly maintenance

In this section, you find all maintenance for the c 501 module that is to be performed at least once a month.

- ⦿ This section discusses the following maintenance actions:
 - Cleaning the ISE Ref. (KCl) aspiration filter* on page 83
 - Replacing reaction cells* on page C-86
 - Cleaning the incubator bath* on page C-87
 - Cleaning the detergent aspiration filters* on page C-94
 - Cleaning the filters behind the front doors* on page C-96

Cleaning the ISE Ref. (KCl) aspiration filter

Inspect the ISE Ref. aspiration filter, which is attached to the tube end in the ISE reference solution bottle. Clean the filter each time you replace the bottle but at least once a month. Clogging of the filter will reduce the accuracy of ISE Ref. aspiration and data reliability.

This maintenance comprises the following procedures and maintenance items:

1. To clean the ISE Ref. aspiration filter
2. To prime the ISE Ref. tubing

Operator time approximately 5 minutes

System time approximately 3 minutes

Materials required
 Deionized water
 Paper towel



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
-

**Incorrect results due to mixing of ISE reagents**

If the dedicated cover for the ISE reagent bottles is not attached when replacing the ISE Ref. bottle, liquid from the tip of the tube may drop into another ISE reagent bottle, leading to incorrect results.

- Before replacing the ISE Ref. bottle or when cleaning the filter, attach the dedicated cover for the ISE reagent bottles.
 - Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-10.
-

► **To clean the ISE Ref. aspiration filter**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of the module.

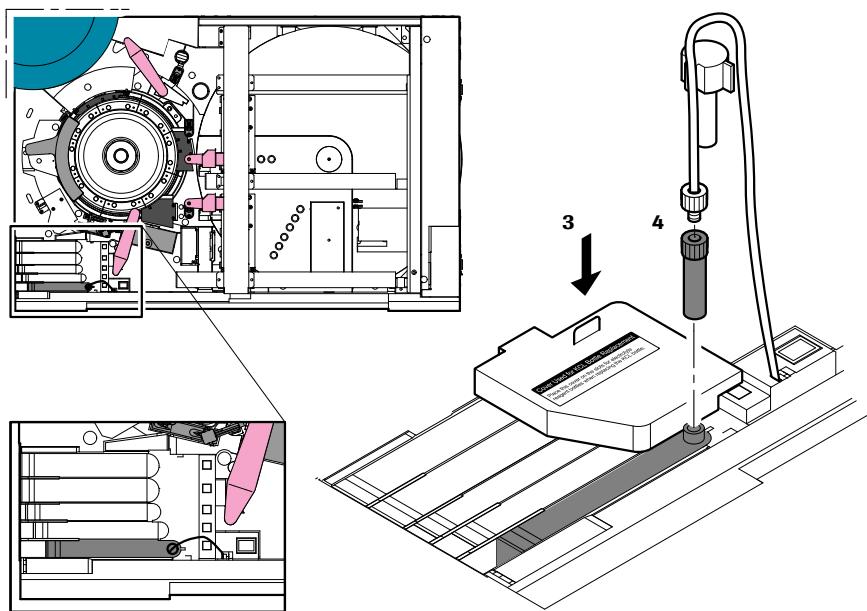


Figure C-29 Cleaning the ISE Ref. aspiration filter

- 3 Attach the dedicated cover.
- 4 Remove the tubing from the ISE Ref. bottle and unscrew the filter from the tube end.
- 5 Clean and rinse the filter with deionized water.
- 6 Finally, screw the filter on the tube end and place it back into the bottle.
Make sure that the end of the tube touches the bottom of the bottle. Otherwise, reagent may not be pipetted properly.
- 7 Clean any spills of ISE Ref. from the surface of the instrument, using paper towels.



Damage to the ISE probe

If the dedicated cover for the ISE reagent bottles is attached during operation, the ISE pipetter probe will be damaged.

- Before starting operation, remove the dedicated cover for the ISE reagent bottles.

- 8 Close the top cover of the module and lock it.

- 9 Switch on the analyzer, if the analyzer is in shutdown status.

After replacing the ISE Ref. aspiration filter, it is important to perform a reagent prime (maintenance item (8) Reagent Prime) for the ISE Ref. tubing.



► **To prime the ISE Ref. tubing**

- 1 Choose Utility > Maintenance.
- 2 Select Maintenance (1) from the Maintenance Type list on the left.
- 3 Select (8) Reagent Prime from the Maintenance Items list on the right.
- 4 Choose Select to open the Reagent Prime window.

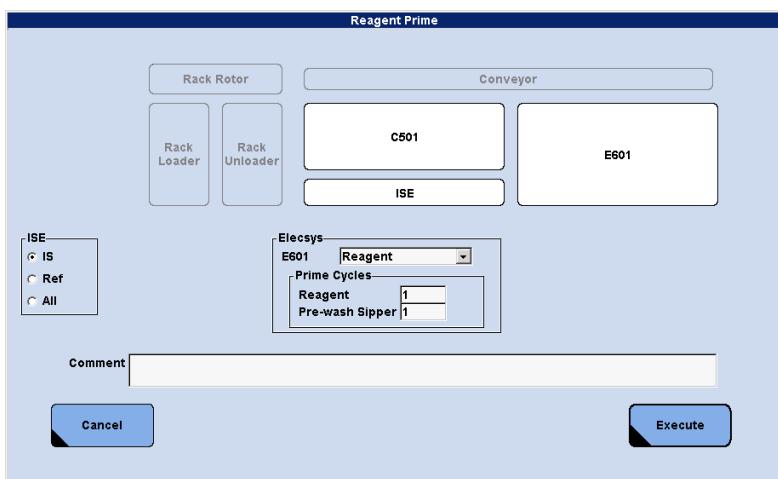


Figure C-30 Reagent Prime window

- 5 Select a module. Selected modules are highlighted.
 - 6 Choose Ref in the ISE area and choose Execute.
- The prime is complete when the system returns to standby.



Replacing reaction cells

Replace the reaction cells once a month because they gradually deteriorate over long use. We recommend cleaning the incubator bath and incubator bath filter at the same time.

Replacing reaction cells can be performed with the analyzer being in one of the following states:

- Shutdown status or standby (all mechanical parts can be moved by hand)
- If this maintenance is performed in combination with cleaning the incubator bath, reaction cells are replaced in incubator bath cleaning mode.
☞ *Cleaning the incubator bath* on page C-87

The decision which status or mode to choose depends on the analyzer's current status and on other maintenance actions that are to be performed.

Materials required Reaction cells

Operator time approximately 10 minutes

System time approximately 55 minutes ((7) Wash Reaction Parts, (4) Cell Blank Measurement)



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
 - *Malfunction due to spilled liquid* on page C-5
-

► **To replace reaction cells**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of the module.

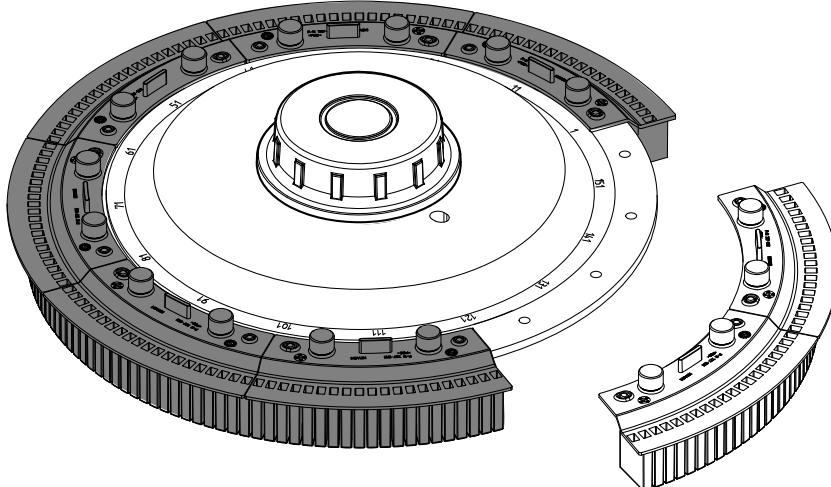


Figure C-31 Removing reaction cells

- 3 On each section of reaction cells, loosen and remove the thumbscrews and lift the reaction cells out of the reaction disk.
- 4 Discard the used reaction cells.

- 5 Remount new sections of reaction cells aligning them with the guide pins. Be careful not to touch the optical surfaces.
- 6 Switch on the analyzer, if the analyzer is in shutdown status.

After replacing reaction cells, perform the maintenance item (7) Wash Reaction Parts and then perform maintenance item (4) Cell Blank Measurement to verify the integrity of the reaction cells.



- ☞ For detailed instructions, see:
To rinse the reaction system on page C-77
To perform a cell blank measurement on page C-77

Cleaning the incubator bath

Contamination inside the incubator bath or on the photometric window will reduce the reproducibility of measurement results. Clean the incubator bath and photometric window at least once a month.

We recommend combining this maintenance with the weekly cleaning of the IS bath, the monthly replacement of reaction cells and with the quarterly cleaning of the ultrasonic mixers.

- ☞ For more information, see
Removing and manually cleaning the IS bath on page C-82
Replacing reaction cells on page C-86
Cleaning the ultrasonic mixers on page C-98

Cleaning of the incubator bath can be performed either with the analyzer in shutdown status or with the module in incubator bath cleaning mode. These two states require different steps to be performed for this maintenance; these steps are described in two separate procedures in the remainder of this section.

- ☞ For more information, see
To clean the incubator bath (in incubator bath cleaning mode) on page C-88.
To clean the incubator bath (in shutdown status) on page C-90.

Operator time approximately 15 minutes

System time approximately 25 minutes

Materials required

- Deionized water
- Cotton swabs
- Lint-free gauze pads



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
 - *Malfunction due to spilled liquid* on page C-5
-

► **To clean the incubator bath (in incubator bath cleaning mode)**

- 1 Put the analyzer in incubator bath cleaning mode:
 - Choose Utility > Maintenance.
 - Select Maintenance (1) from the Maintenance Type list on the left.
 - Select (10) Incubator Bath Cleaning from the Maintenance Items list on the right.
 - Choose Select to open the Incubator Bath Cleaning window.
 - Select the appropriate module. Selected modules are highlighted.
 - Choose Execute.

The analyzer enters incubator bath cleaning mode and water is drained from the incubator bath.

- Choose OK to confirm the message of the confirmation window.
- Choose Monitor to open the Maintenance Monitor window.
- Wait until the message *Incubation Bath Cleaning (Wait Restart)* is displayed.



Do not open the top cover of the module until the corresponding message is displayed on the Maintenance Monitor.

If the top cover is opened before the message is displayed, an alarm is issued and maintenance is stopped.

- 2 Unlock and open the top cover of the module.

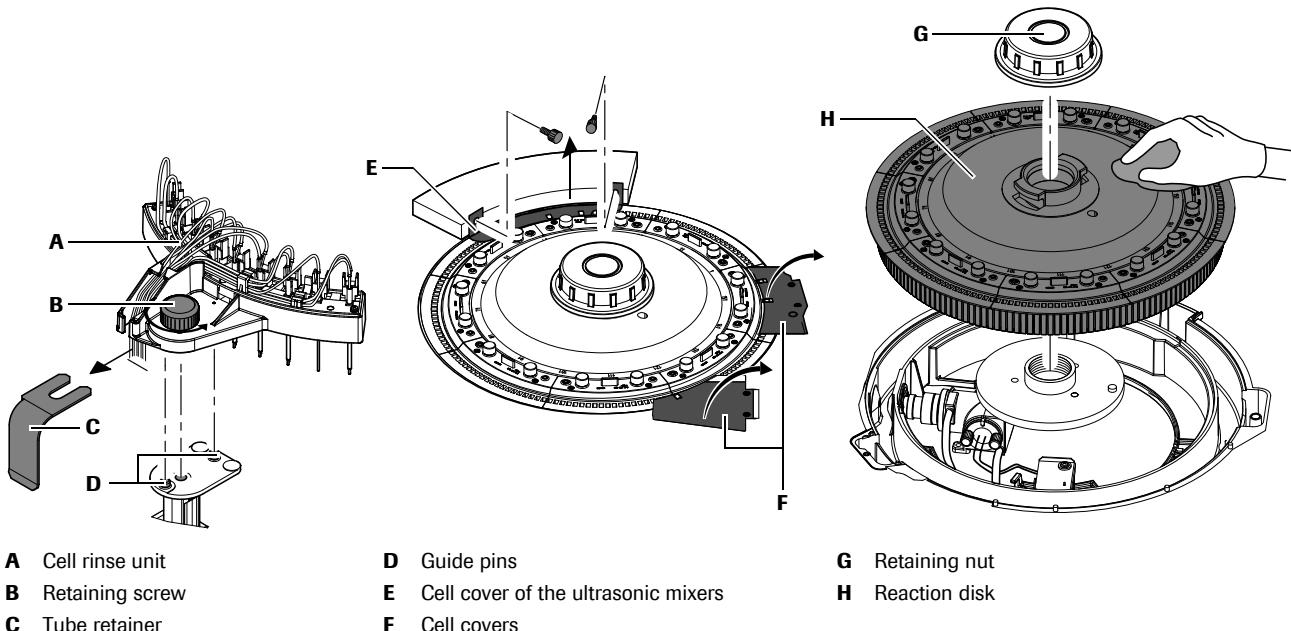


Figure C-32 Dismount the cell rinse unit and the reaction cells

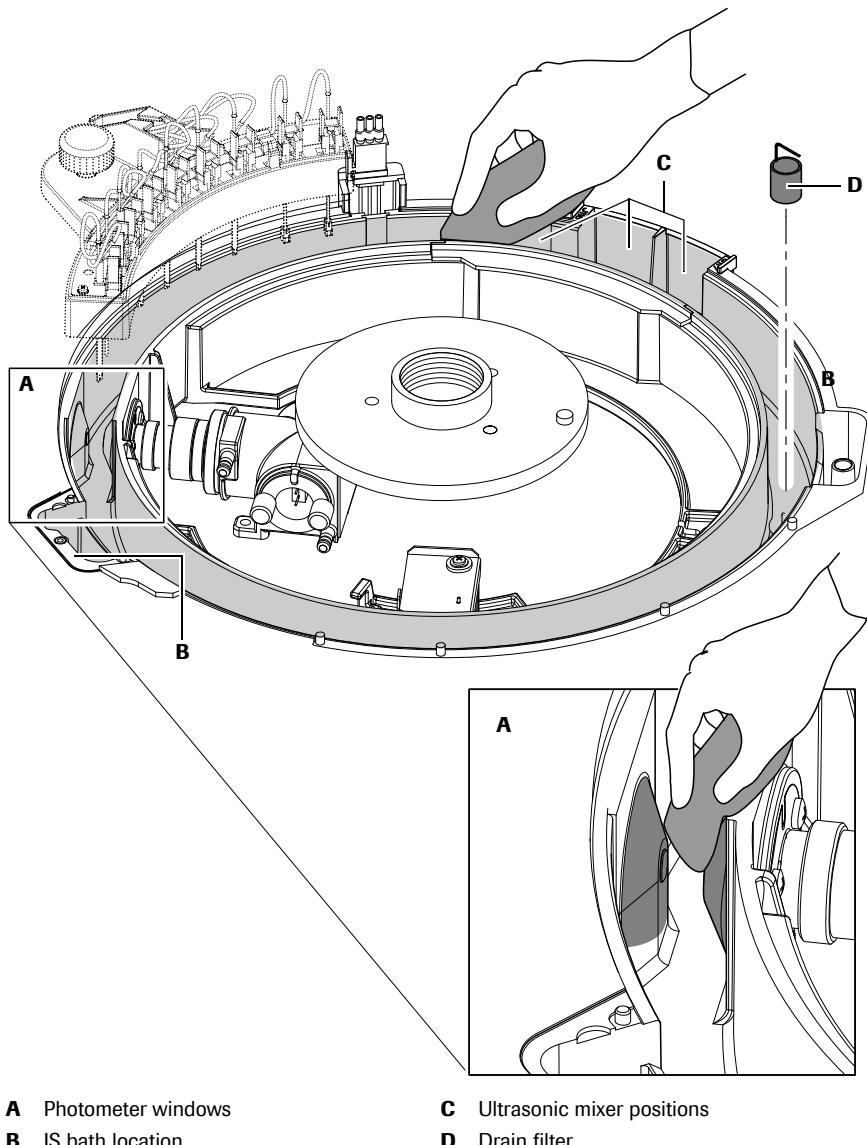
- 3 Loosen the retaining screw (B) of the cell rinse unit and lift off the entire unit (A).
- 4 Remove the cell cover above the ultrasonic mixers (E). Lift the cell covers (F) and leave them vertical.

- 5** Loosen the retaining nut (**G**) and remove the reaction disk (**H**) inclusive reaction cells from system. Be careful not to touch the optical surfaces.



Damage to the photometer windows

Do not scratch the photometer windows when cleaning. Use only gauze pads moistened with deionized water.



A Photometer windows **C** Ultrasonic mixer positions
B IS bath location **D** Drain filter

Figure C-33 Wipe the inside surfaces of the incubator bath

- 6** Carefully wipe the photometer windows (**A**) using a clean lint-free gauze pad moistened with deionized water.
- 7** If you combine this maintenance action with the weekly maintenance action *To remove and manually clean the IS bath*, remove and manually clean the IS bath.
 ☺ For instructions, see: *To remove and manually clean the IS bath* on page C-82.
- 8** Wipe the inside surfaces of the incubator bath, using a clean lint-free gauze pad. Wipe the indented part near the ultrasonic mixers (**C**) with a cotton swab.
 ☺ For instructions, see: *To clean the surface of the ultrasonic mixer* on page C-99

Monthly maintenance

- 9 Remove the incubator bath drain filter (D). Grasp the filter by the handle and pull up to remove.
- 10 Clean and rinse the filter with deionized water and return it in place.
- 11 If you combine this maintenance action with the maintenance action *Replacing reaction cells*, replace all sections of reaction cells against new reaction cells.
 See: *To replace reaction cells* on page C-86
- 12 Reinstall the reaction disk (inclusive reaction cells), the cell cover of the ultrasonic mixer and the cell rinse unit.
- 13 Turn down the cell covers for the reagent probes.
- 14 Close the top cover of the module and lock it.
- 15 Choose Continue on the **Utility > Maintenance >Incubator Bath Cleaning** window to end the incubator bath cleaning mode.

The incubator bath is filled with water and the analyzer returns to standby.

- 16 Perform maintenance item (4) Cell Blank Measurement.



Perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity after the cleaning of the photometric windows and replacing the reaction cells.

 For instructions, see *To perform a cell blank measurement* on page C-77.



► To clean the incubator bath (in shutdown status)

- 1 Put the analyzer in shutdown status.
- 2 Unlock and open the top cover of the module.
- 3 Loosen the retaining screw of the cell rinse unit and lift off the entire unit.
- 4 Remove the cell cover above the ultrasonic mixers. Lift the other cell covers and leave them vertical.



Do not let all the water drain. Leave a small amount of water to just cover the bottom of the incubator bath. Close the drain by moving the tap to the Operation position.

- 5 Turn the tap located on the rear of the analyzer to the DRAIN position and drain the incubator bath. After draining, turn the tap back to its OPERATION position.

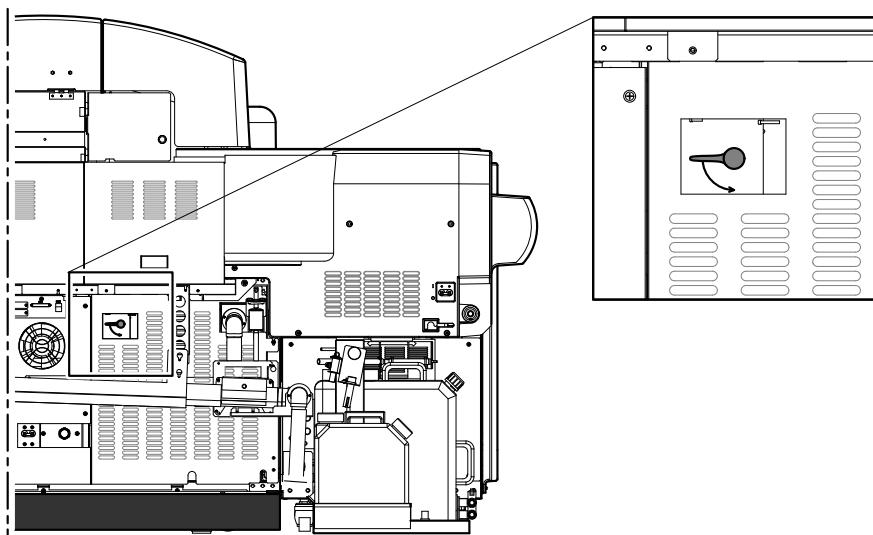


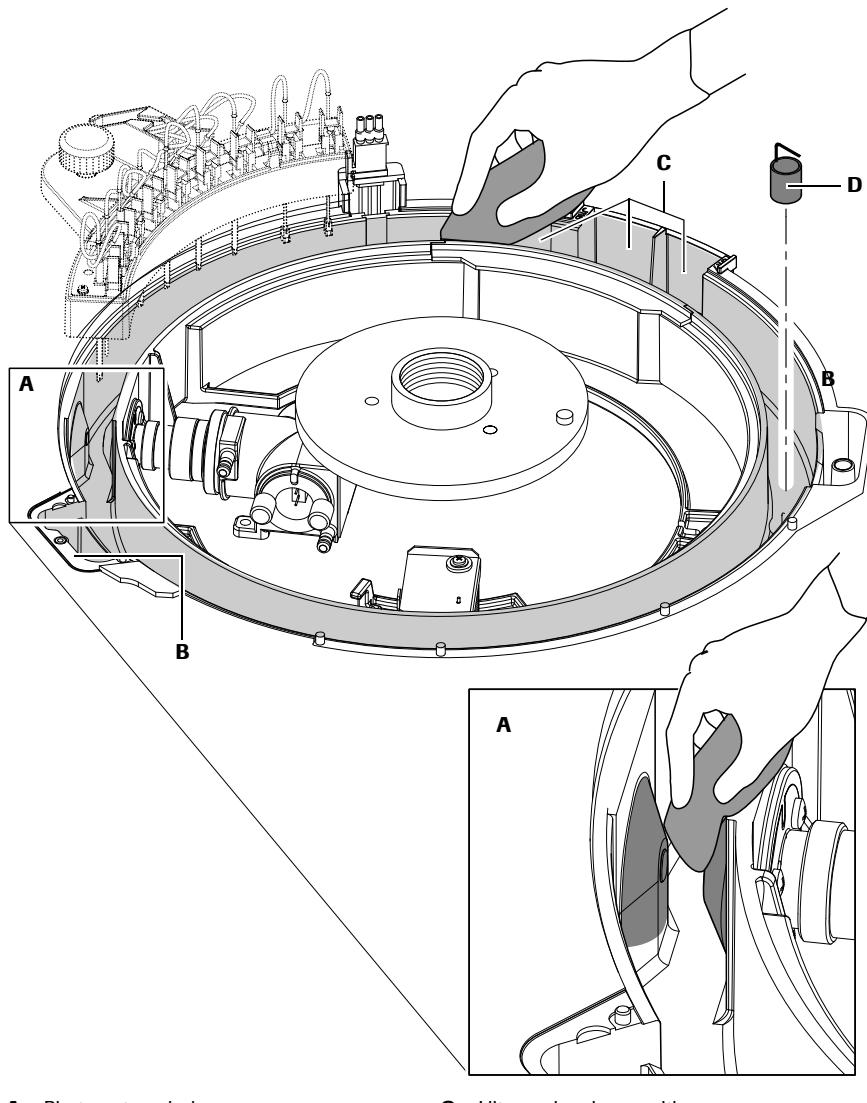
Figure C-34 Tap for manually draining the incubator bath

Monthly maintenance

- 6** Loosen the retaining nut and remove the reaction disk inclusive reaction cells from system. Be careful not to touch the optical surfaces.

**Damage to the photometer windows**

Do not scratch the photometer windows when cleaning. Use only gauze pads moistened with deionized water.



A Photometer windows **C** Ultrasonic mixer positions
B IS bath location **D** Drain filter

Figure C-35 Wipe the inside surfaces of the incubator bath

- 7** Carefully wipe the photometer windows (**A**) using a clean lint-free gauze pad moistened with deionized water.
- 8** If you combine this maintenance action with the weekly maintenance action *To remove and manually clean the IS bath*, remove and manually clean the IS bath.
 ☺ For instructions, see: *To remove and manually clean the IS bath* on page C-82.
- 9** Wipe the inside surfaces of the incubator bath, using a clean lint-free gauze pad. Wipe the indented part near the ultrasonic mixers (**C**) with a cotton swab.
 ☺ For instructions, see: *To clean the surface of the ultrasonic mixer* on page C-99

- 10 Remove the incubator bath drain filter (**D**). Grasp the filter by the handle and pull up to remove.
- 11 Clean and rinse the filter with deionized water and return it in place.
- 12 If you combine this maintenance action with the maintenance action *Replacing reaction cells*, replace all sections of reaction cells against new reaction cells.
 See: *To replace reaction cells* on page C-86
- 13 Reinstall the reaction disk (inclusive reaction cells) and the cell rinse unit.
- 14 Reinstall the cell cover of the ultrasonic mixer and **remove one** section of reaction cells.
- 15 Turn down the cell covers for the reagent probes.
- 16 Gradually pour about 500 mL of deionized water into the incubator bath and mount the missing section of reaction cells. Be careful not to allow water to overflow from the incubator bath.
- 17 Close the top cover of the module and lock it.
- 18 Start up the analyzer.
- 19 Perform maintenance items (5) Incubation Water Exchange and (4) Cell Blank Measurement.



Make sure to perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity after the cleaning of the photometric windows.

 For instructions, see *To perform a cell blank measurement* on page C-77.



Cleaning the detergent aspiration filters

Inspect the detergent aspiration filters, which are attached to the tube end in the cell detergent bottles. The cell detergent bottles (Cell wash I and Cell wash II) are located behind the left front door of the c 501 module. Clean the filter each time you replace a bottle but at least once a month. Clogging of the filter will reduce the accuracy of detergent aspiration and will lead to insufficient cell cleaning.

This maintenance comprises the following procedures and maintenance items:

1. To clean the detergent aspiration filters
2. To perform a cell detergent prime

Operator time approximately 5 minutes

System time approximately 7 minutes

Materials required

- Deionized water
- Paper towel



Before performing this maintenance action, observe the following safety precautions:

- *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► **To clean the detergent aspiration filters**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Open the front doors of the module and take out the detergent bottle(s).

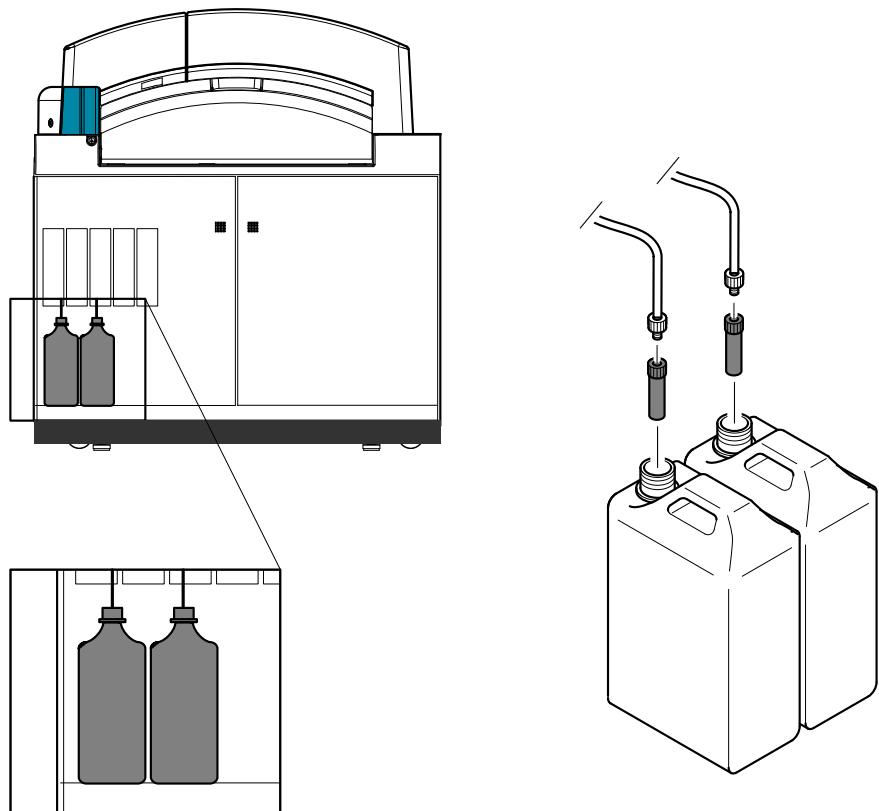


Figure C-36

Cleaning the detergent aspiration filters

- 3 Remove the tubing from the detergent bottle(s) and unscrew the filter from the tube end.
- 4 Clean and rinse the filter with deionized water.
- 5 Screw the filter on the tube end and place it back into the bottle.



Incorrect results due to incorrect insertion of aspiration tube

If the aspiration tube is not inserted correctly, the detergent may not be dispensed properly. This may lead to incorrect results.

- Insert the aspiration tube so that the end of the tube touches the bottom of the bottle.
- Do not bend the aspiration tube.

- 6 Close the front doors.
- 7 Switch on the analyzer, if the analyzer is in shutdown status.
- 8 Perform maintenance item (9) Cell Detergent Prime.



► To perform a cell detergent prime

- 1 Choose Utility > Maintenance.
- 2 Choose (9) Cell Detergent Prime on the Maintenance Items list on the right.
- 3 Choose Select to open the Cell Detergent Prime window.

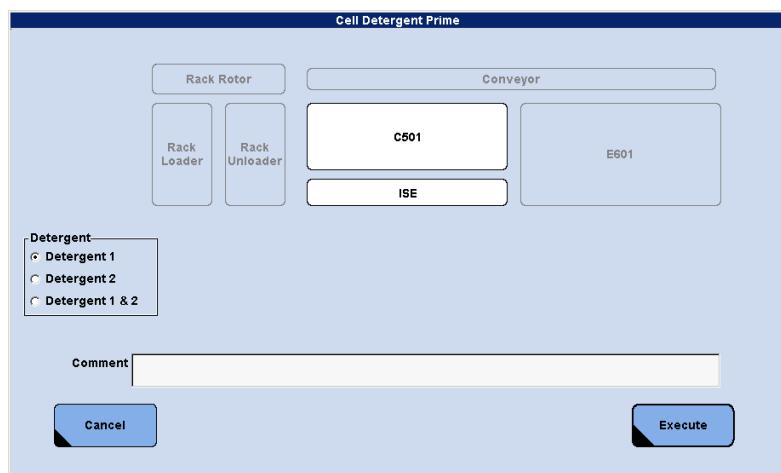


Figure C-37 Cell Detergent Prime window

- 4 Select a module. Selected modules are highlighted.
- 5 Select an option in the **Detergent** area to specify which line is to be primed.
Detergent 1 corresponds to Cell wash I (basic).
Detergent 2 corresponds to Cell wash II (acid).
- 6 Choose Execute.



Cleaning the filters behind the front doors

Clean the radiator filter, the power supply filter and the filter of the circuit board rack at least once a month to prevent dust or dirt accumulation. Clogging of the filter may cause temperature rise and faulty temperature control of the analyzer.

Operator time approximately 10 minutes

Materials required

- Paper towels
- Water for rinsing
- Vacuum cleaner

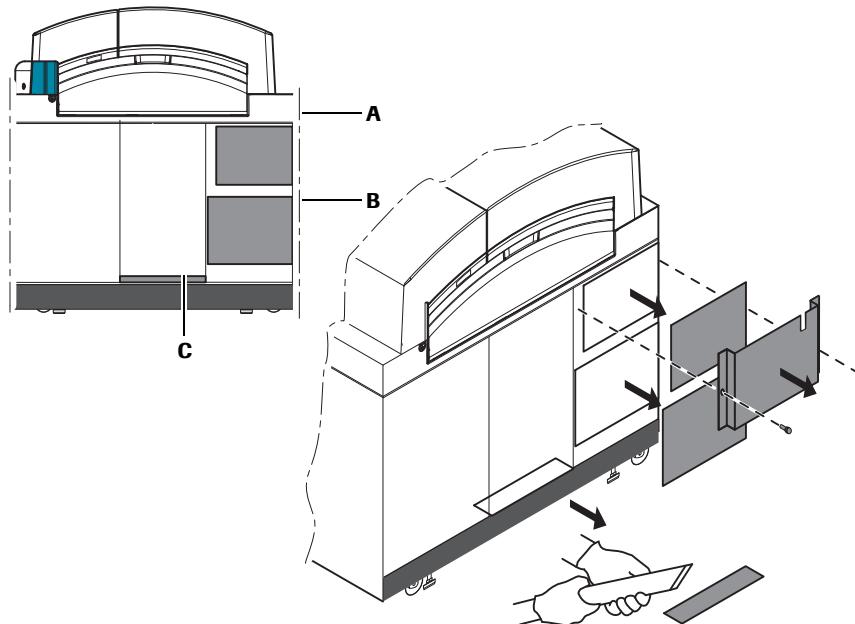
► To clean the filters behind the front doors

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Open the front doors.



Burns due to contact with the radiator of the refrigerator

You may get burned by touching the radiator. Avoid touching the radiator when removing the filter.



A Power supply filter

B Radiator filter

C Filter of the circuit board rack

Figure C-38 Cleaning power supply filter, the radiator filter and the filter of the circuit board rack

3 Remove the filters:

- Loosen the thumbscrews of the cover plate of the power supply filter (**A**) and remove the plate.
- Remove the power supply filter (**A**) and the radiator filter (**B**) by pulling it forward from the retaining brackets.
- Remove the filter of the circuit board rack (**C**) by pulling it out from underneath the circuit board rack.

- 4 Vacuum the filters. If it is conspicuously contaminated, rinse the filters with water and blot dry with paper towels.
- 5 Reinstall the filters:
 - To reinstall the radiator filter (**B**), first insert the bottom of the filter. Then, push the top of the filter into the brackets.
 - Return the power supply filter (**A**) and the filter of the circuit board rack (**C**) to their original positions.
 - Return the cover plate of the power supply filter and tighten the thumbscrews.
- 6 Close the front doors of the module.
- 7 Switch on the analyzer, if the analyzer is in shutdown status.



Every three months maintenance

Every three months maintenance

In this section, you find all maintenance for the c 501 module that is to be performed at least once every three months.

- ⦿ This section discusses the following maintenance actions:
Cleaning the ultrasonic mixers on page C-98

Cleaning the ultrasonic mixers

Clean the ultrasonic mixers every 3 months or after 225.000 tests (whatever comes first). Contamination and precipitation on the surface of the ultrasonic mixers may cause inadequate mixing and thus lead to inaccurate results.

If the ultrasonic mixer cleaning coincides with the monthly incubator bath cleaning, the procedure can be performed together.



Replacement of ultrasonic mixer

The ultrasonic output intensity is continually monitored during measurement. If the data alarm <Mix occurs frequently, replacement of the ultrasonic mixer is required. Contact your technical support for the replacement.

This maintenance comprises the following procedures and maintenance items:

1. To clean the surface of the ultrasonic mixer
2. To check the intensity of the ultrasonic output

Operator time approximately 6 minutes

System time approximately 7 minutes

Materials required

- 2% Hitergent solution
- Deionized water
- Cotton swabs



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Electrical shock by electronic equipment* on page C-3
- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4

► To clean the surface of the ultrasonic mixer

- 1 Put the analyzer in incubator bath cleaning mode:
 - Choose **Utility > Maintenance**.
 - Select **Maintenance (1)** from the **Maintenance Type** list on the left.
 - Select **(10) Incubator Bath Cleaning** from the **Maintenance Items** list on the right.
 - Choose **Select** to open the Incubator Bath Cleaning window.
 - Select the appropriate module. Selected modules are highlighted.
 - Choose **Execute**.

The analyzer turns to incubator bath cleaning mode and water is drained from the incubator bath.

- Choose **OK** to confirm the message of the confirmation window.
- Choose **Monitor** to open the **Maintenance Monitor** window.
- Wait until a message about the Incubator bath cleaning mode is displayed.



Do not open the top cover of the module until the corresponding message is displayed on the Maintenance Monitor.

If the top cover is opened before the message is displayed, an alarm is issued and maintenance is stopped.

Every three months maintenance

- 2 Unlock and open the top cover of the module.

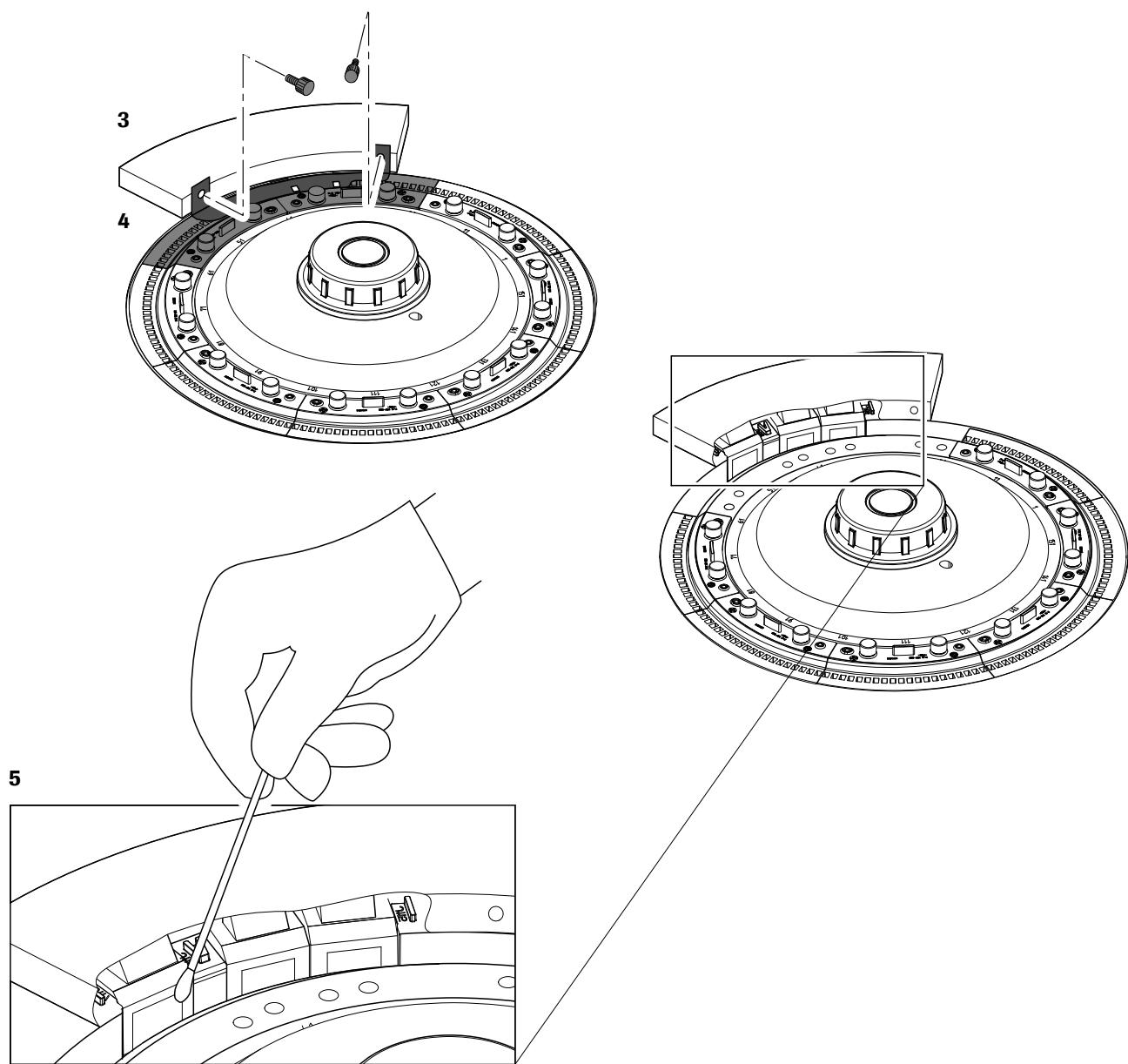


Figure C-39 Cleaning surface of ultrasonic mixer with cotton swabs

- 3 Remove the cell cover.
- 4 Loosen and remove the thumbscrews on two or three sections of reaction cells near the ultrasonic mixers. Lift the reaction cells out of the reaction disk. Be careful not to touch the optical surfaces.
- 5 Gently wipe the surface of the ultrasonic mixers with cotton swabs moistened with 2% Hitergent solution. Then, wipe off the detergent with cotton swabs moistened with deionized water.
- 6 Return the removed sections of reaction cells.

- 7 Return the cell cover.
- 8 Close the top cover of the module and lock it.
- 9 Choose **Start** (global button) > **Start** to release the incubator bath cleaning mode.
Water is poured into the incubator bath.

■

► **To check the intensity of the ultrasonic output**

- 1 Choose **Utility** > **Maintenance**.
- 2 Select **Check (2)** from the **Maintenance Type** list on the left.
- 3 Select (7) **Cuvette Mixing** from the **Maintenance Items** list on the right.
- 4 Choose **Select**, to open the **Cuvette Mixing** window.
- 5 Select a module (selected modules are highlighted), and verify the **Cell Wash** check box is not selected.
Selecting the **Cell Wash** check box would rinse all reaction cells prior to the actual intensity check.
- 6 Choose **Execute**.

■

Every six months maintenance

In this section, you find all maintenance for the c 501 module that is to be performed at least once every six months.

- ⦿ This section discusses the following maintenance actions:
Replacing the syringe seals on page C-102
Replacing the photometer lamp on page C-109

Replacing the syringe seals

The syringe seals have to be replaced after 225,000 tests or after six months, whatever comes first. When the syringe seals get worn out, this may cause leakage and inaccurate pipetting. This is a combined maintenance procedure for both ISE and photometric unit.

There are five syringes behind the left front door of the c 501 module: The first on the left is the sample syringe, then follow R1, R2, ISE pipetter syringes and the ISE sipper syringe (from left to right). The procedure for replacing the syringe seals is the same for all syringes. Note, however, there are different spare parts for sample and reagent syringes.

In the remainder of this section, figures and screen shots refer to the ISE reagent syringe as an example.

This maintenance comprises the following procedures and maintenance items:

1. To remove the syringe
2. To replace the syringe seals
3. To reattach the syringe
4. To perform an air purge and check connections

Operator time approximately 15 minutes

System time approximately 7 minutes

Materials required

- Seals and spacer
- Spanner wrench
- Lint-free gauze pads
- Cotton swabs
- Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
-

NOTICE

Damage to the syringe tubes by alcohol, grease or detergent.

Alcohol, grease or detergent that adheres to the syringe tubes may damage the tubes.

- Avoid to apply alcohol, grease or detergent to the syringe tubes.
-

► **To remove the syringe**

- 1 Put the analyzer in shutdown status.
- 2 Open the left front door of the c 501 and locate the syringes.

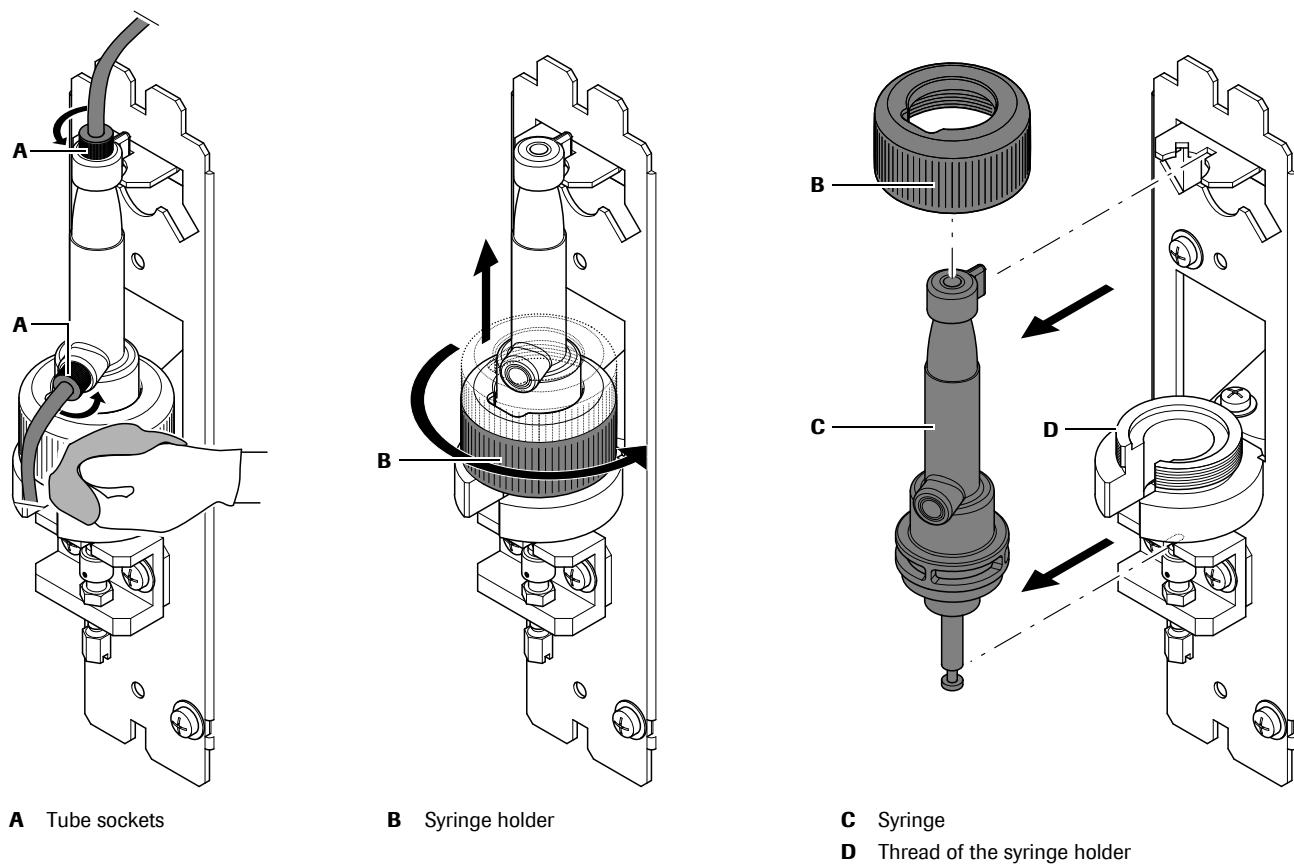
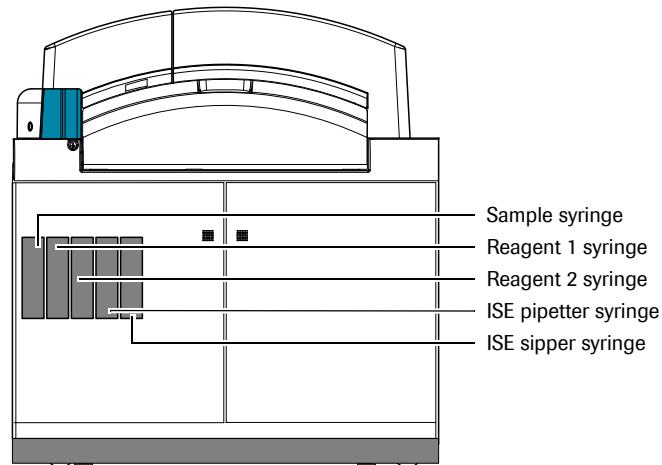


Figure C-40 Remove syringes

Every six months maintenance

- 3** To disconnect the tubing at the top and bottom of the syringe, loosen and remove the upper and lower tube sockets (**A**). Use a dry gauze pad to absorb any liquid leaking from the tubing or syringe.
- 4** Loosen the syringe holder (**B**) and lift it up for about 1 cm (lift it up over the thread (**D**) of the syringe holder).
- 5** Remove the syringe (**C**) carefully toward you.
- 6** Place the removed syringe on a dry gauze pad.



► To replace the syringe seals

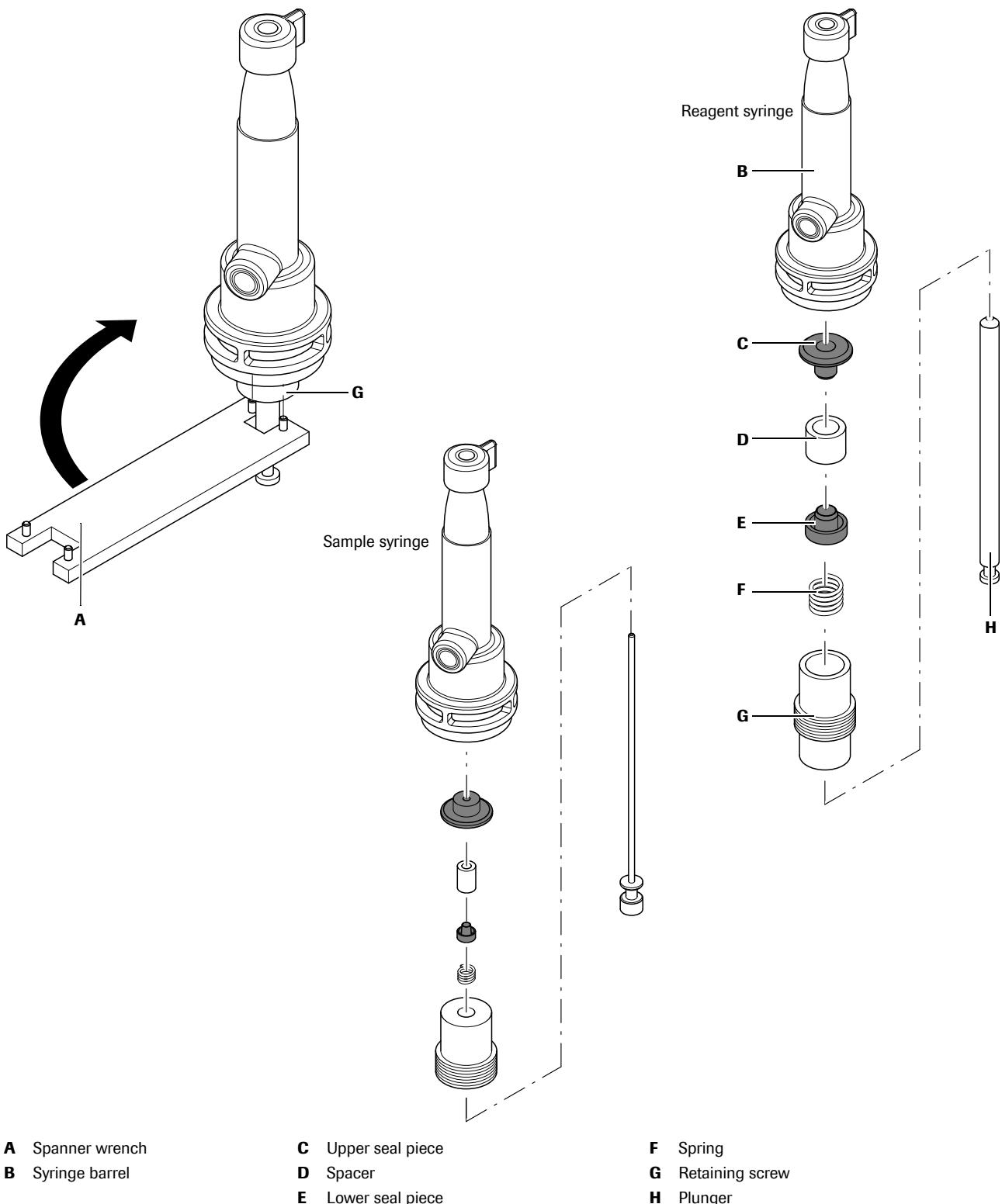


Figure C-41 Replace the syringe seals

1 Loosen the retaining screw (**G**) with the spanner wrench (**A**).



Be careful not to bend the plunger!

Every six months maintenance

- 2 Carefully remove the plunger (**H**) together with retaining screw (**G**) and syringe seals (**C, E**) from the syringe barrel.
- 3 Remove the upper seal piece (**C**), spacer (**D**), lower seal piece (**E**), and the retaining screw (**G**) from the plunger (**H**).
Wipe the plunger, syringe or spacer with a gauze pad or cotton swab moistened with deionized water.
- 4 Mount the retaining screw, spring, new lower seal piece, spacer, and new upper seal piece onto the plunger as shown in Figure C-41.



- Be careful not to mistake the orientation of syringe seals and spacer!
- The seals are different in shape depending on the kind of syringe. Check the part numbers before mounting.



CAUTION

Damage to the syringe seals

Do not overtighten the retaining screw. If the retaining screw is overtightened, the syringe seals wear out quickly and the plunger may bend or break, requiring replacement.

- 5 Place the plunger (**H**) in the syringe barrel (**B**). Check that the spring (**F**) is centered on the lower seal piece (**E**). If the spring is not centered, it could be damaged during tightening. Tighten the retaining screw with the spanner wrench.



► To reattach the syringe

- 1 To reattach the syringe, follow the instructions for removing in the reverse order.

To remove the syringe on page C-103

Finally, it is important to check the connections. To do this you must first perform either maintenance item (6) Air Purge or (8) Reagent Prime (ISE > All).

- If you work at the ISE sipper syringe, perform maintenance item (8) Reagent Prime.
- If you work at any syringe other than the ISE sipper syringe (that is, sample syringe, R1 syringe, R2 syringe, or ISE reagent syringe), perform an air purge and check connections following the instructions below:

See *To perform an air purge and check connections* on page C-107.

During the reagent prime or air purge check the following conditions:

- The plunger moves vertically.
- There is no leakage from any of the connections.
- There are no air bubbles in the syringe barrel.

- 2 Switch on the analyzer.



► **To perform an air purge and check connections**

- 1** Choose Utility > Maintenance.
- 2** Select Maintenance (1) from the Maintenance Type list on the left.
- 3** Select (6) Air Purge from the Maintenance Items list on the right.
- 4** Choose Select to open the Air Purge window.
- 5** Select a module. Selected modules are highlighted.
- 6** Choose the syringe to be purged of air in the Syringe area and choose Execute.

The respective pipetter will operate.

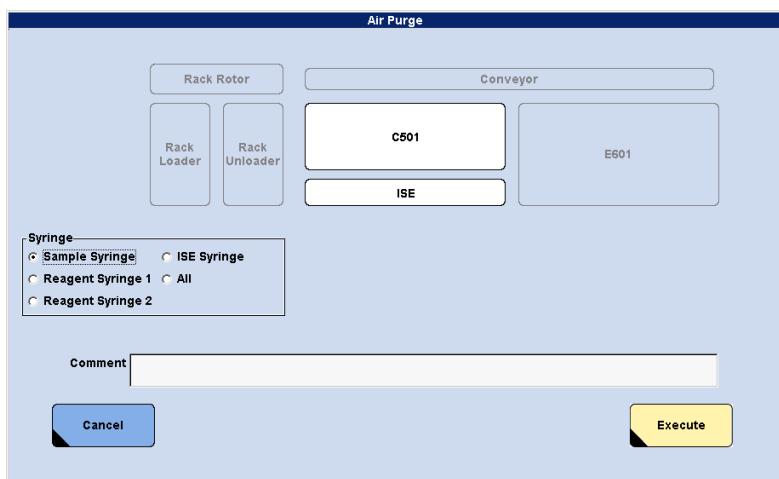


Figure C-42 Air Purge window



Incorrect results due to loose tube sockets

A loose tube socket may cause insufficient pipetting and result in inaccurate measurement.

- Tighten the tube socket securely and make sure there is no liquid leakage.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: F-5.

Every six months maintenance

- 7 Inspect the syringe to ensure that no air remains in the syringe and no leaks are visible at any of their fittings.
- If leakage is found at the syringe holder or tube socket, try to retighten.
 - If leakage is found at the bottom of the syringe, try to attach again.
 - If there are air bubbles in the syringe, remove them by lightly tapping or vibrating the syringe with liquid flowing. If bubbles cannot be removed, wipe the plunger with gauze moistened with deionized water.

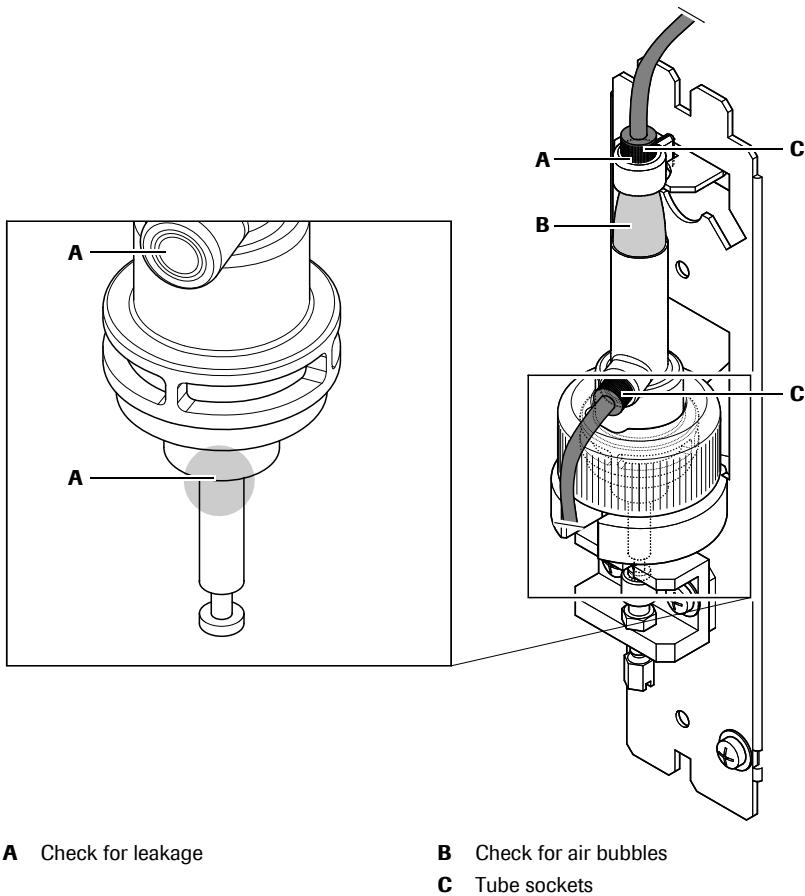


Figure C-43 Check syringe for leakage and air bubbles

Replacing the photometer lamp

The reproducibility of measurement will decrease if the photometer lamp deteriorates. Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.

We recommend combining this maintenance with the monthly cleaning of incubator bath.

This maintenance comprises the following procedures and maintenance items:

1. To check the light intensity
2. To remove the photometer lamp
3. To install a new photometer lamp

Operator time approximately 5 minutes

System time approximately 20 minutes

Materials required

- Alcohol (e.g. isopropyl alcohol or ethanol)
- Lint-free gauze pads
- Photometer lamp

► To check the light intensity

- 1 Choose Utility > Maintenance.
- 2 Select Maintenance (1) from the Maintenance Type list on the left.
- 3 Select (3) Photometer Check from the Maintenance Items list on the right.
- 4 Choose Select to open the Photometer Check window.
- 5 Select a module. Selected modules are highlighted.
- 6 Select Execute.
Water is injected from the rinsing mechanism into reaction cell no. 1 and the absorbance of the water is measured for each available wavelength.
- 7 After the photometer check select Print (global button) to open the Print window.
- 8 Select Print to print a Photometer Check report and check the absorbance values of the current photometer check.



Every six months maintenance

Photometer Check				8:20	
-----PREVIOUS DATA-----			-----CURRENT DATA-----		
c501	DATE	05/12/1	8:20	DATE	
340 nm	10386			340 nm	10386
376 nm	10358			376 nm	10358
415 nm	9534			415 nm	9534
450 nm	9275			450 nm	9275
480 nm	9195			480 nm	9195
505 nm	9130			505 nm	9130
546 nm	8984			546 nm	8984
570 nm	8967			570 nm	8967
600 nm	8929			600 nm	8929
660 nm	8676			660 nm	8676
700 nm	8657			700 nm	8657
800 nm	8594			800 nm	8594

Figure C-44 Photometer check report

If the current data exceed 14000, check the following points and then replace the photometer lamp:

- Verify there are no contamination or bubbles in incubator bath or photometric windows.
- Verify reaction cell no. 1 is not scratched, cracked or damaged.

If the current data value is quite different from the previous one, check for the cause!



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Fire and burns due to the use of alcohol* on page C-4



Burns due to hot surface!

You may be burned if you touch any part of the photometer lamp unit.

- Wait about 30 minutes after turning off lamp power.
- Check that the photometer lamp unit has cooled down before replacing the lamp.
- Observe the system safety labels illustrated from page A-15 to A-20 and in particular the following: T-5.

► **To remove the photometer lamp**

- 1 Put the analyzer in shutdown status.

 See *To shutdown the analyzer* on page C-11.

Alternatively, cut off the photometer lamp's power supply by executing the maintenance item (39) Change Light Source Lamp from the **Maintenance Items** list on **Utility > Maintenance**.

Alternatively, you can combine the incubator bath cleaning with the changing of the photometer lamp.

Wait about 30 minutes for the lamp and lamp housing to cool down.

- 2 Unlock and open the top cover of the module.

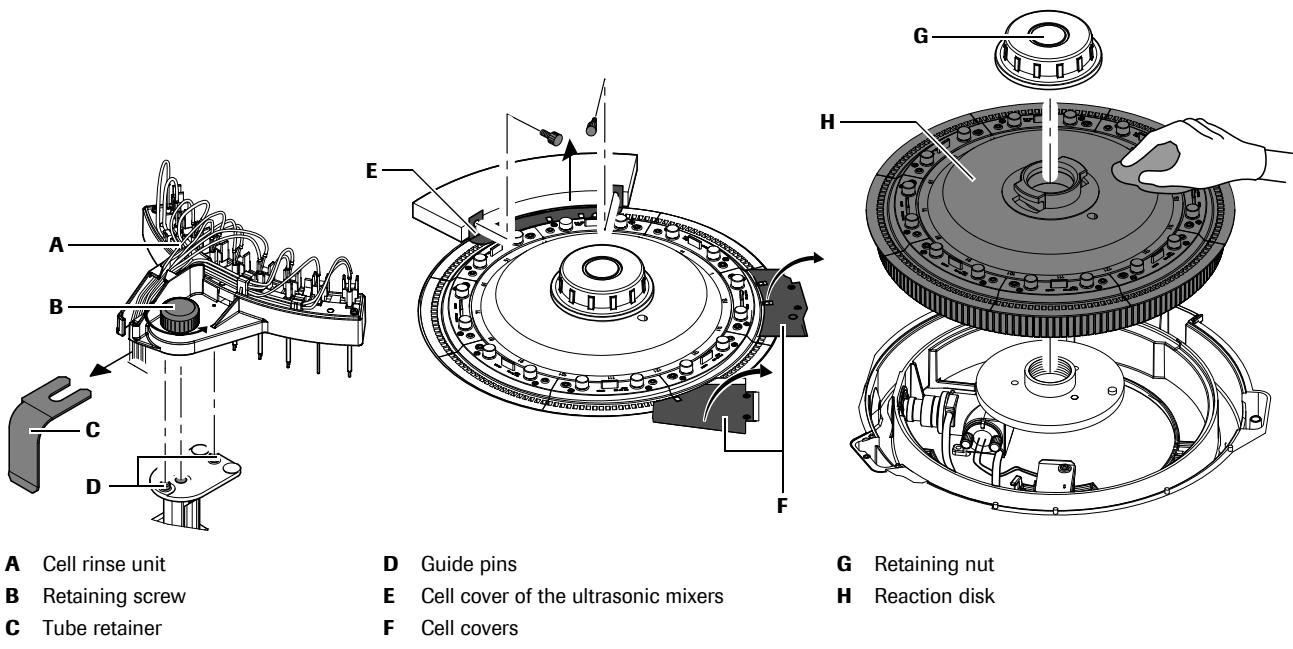


Figure C-45 Dismount the cell rinse unit and the reaction cells

- 3 Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).
- 4 Remove the cell cover above the ultrasonic mixers (**E**). Lift the cell covers (**F**) and leave them vertical.

Every six months maintenance

- 5** Loosen the retaining nut (**G**) and remove the reaction disk (**H**) inclusive reaction cells from system. Be careful not to touch the optical surfaces.



If the reaction disk is detached with the reaction cells left in place, water drops adhering to the outside of the reaction cells may drip onto the detector, causing an alarm to be issued.

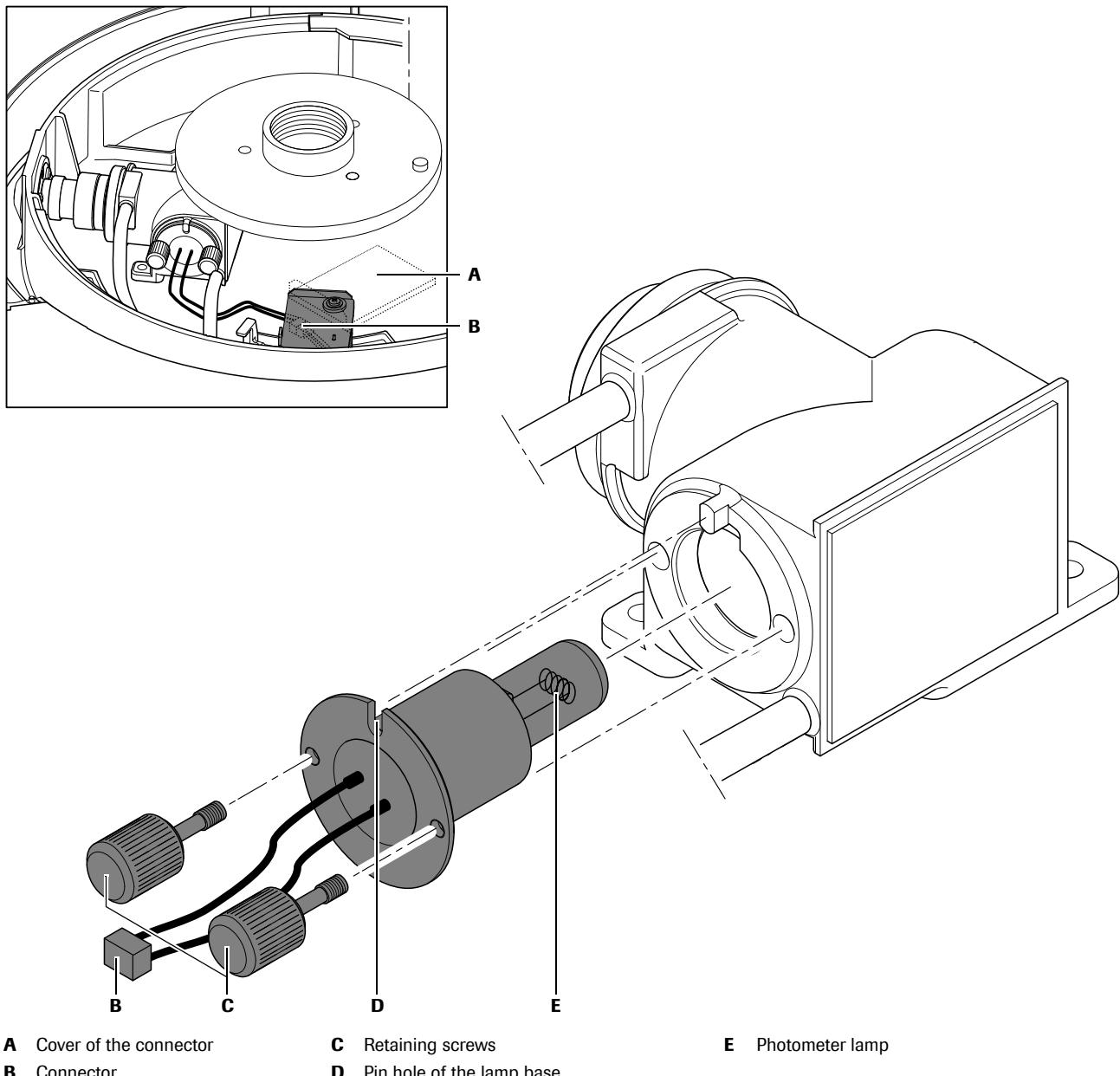


Figure C-46 Replacing photometer lamp

- 6** Rotate the connector cover (**A**) and disconnect the connector (**B**) of the lamp wire.
- 7** Loosen two lamp retaining screws (**C**) and pull out the photometer lamp (**E**).
When the screws become easy to turn, the lamp can be detached.
- 8** Carefully remove the retaining screws from the lamp base. These are needed to install the new lamp.



► To install a new photometer lamp

- 1 Insert the retaining screws in the new lamp.
- 2 Insert the new photometer lamp:
 - Align the pin hole (**D**) in the lamp base with the guide pin of the lamp housing
 - Tighten the two lamp retaining screws (**C**).



If you have touched the glass part of the new photometer lamp, wipe it off with a gauze pad moistened with alcohol.

- 3 Connect the connectors of the lamp wires.
Do not let the lamp wires float up from the unit.
- 4 Reinstall the reaction disk with the reaction cells and close the cell covers.
- 5 Mount the cell rinse unit to its original position.
- 6 Close the top cover of the module and lock it.
- 7 Start up the analyzer again or—if maintenance item (39) Change Light Source Lamp has been executed without shutting down the analyzer—choose **Cancel Maintenance** on the **System Overview** screen.
- 8 Wait about 30 minutes for the photometer lamp to stabilize.

Finally, perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity.

For instructions, see *To perform a cell blank measurement* on page C-77.



As needed maintenance

In this section, you find all maintenance for c 501 module that is to be performed as needed and is not subject to a regular time schedule.

- ☛ This section discusses the following maintenance actions:
 - Replacing nozzle tips on cell rinse nozzles* on page C-114
 - Draining the vacuum tank* on page C-117

Cleaning the ISE Ref. (KCl) aspiration filter

Inspect the ISE Ref. aspiration filter, which is attached to the tube end in the ISE reference solution bottle. Clean the filter each time you replace the bottle but at least once a month. Clogging of the filter will reduce the accuracy of ISE Ref. aspiration and data reliability.

- ☛ *Cleaning the ISE Ref. (KCl) aspiration filter* on page C-83

Cleaning the detergent aspiration filters

Inspect the detergent aspiration filters, which are attached to the tube end in the cell detergent bottles. The cell detergent bottles (Cell wash I and Cell wash II) are located behind the left front door of the c 501 module. Clean the filter each time you replace a bottle but at least once a month. Clogging of the filter will reduce the accuracy of detergent aspiration and will lead to insufficient cell cleaning.

- ☛ *Cleaning the detergent aspiration filters* on page C-114

Replacing nozzle tips on cell rinse nozzles

Replace the nozzle tips on the cell rinse nozzles if they are worn but latest after 225.000 tests. The replacement cycle is typically one to two years depending on conditions of use.

Replace a nozzle tip if its corner or bottom is worn so that water remains in the reaction cell.

Operator time approximately 6 minutes

Materials required Needle-nose pliers
 Nozzle tip



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
-

► **To replace the cell rinse nozzle tips**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of the module.

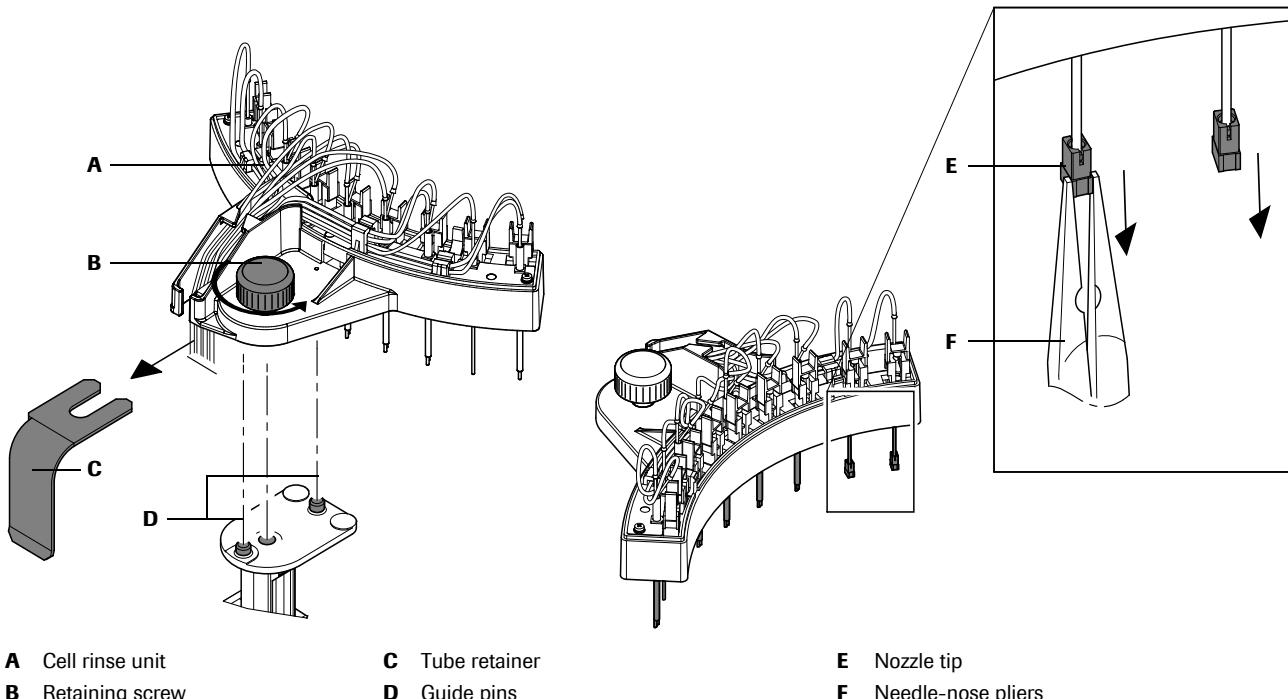


Figure C-47 Dismount the cell rinse unit and replace the nozzle tips

- 3 Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).
- 4 Grasp the sides of the nozzle tip (**E**) with needle-nose pliers (**F**) and pull it out.

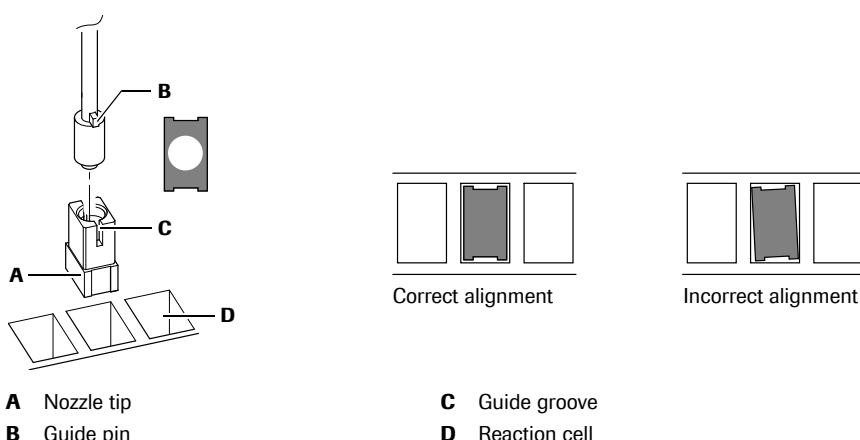


Figure C-48 Alignment of a nozzle tip in relation to reaction cells

- 5 Insert a new nozzle tip (**A**) by hand aligning it with the guides (**B, C**).
- 6 Align the pin holes of the cell rinse unit with the guide pins (**D**, Figure C-47) and attach the rinse unit.
- 7 Fix the tube retainer (**C**, Figure C-47) below the screw and then mount the unit.

As needed maintenance

- 8 Make sure the nozzle tip is not at a slant relative to the reaction cell.
- 9 Close the top cover of the module and lock it.
- 10 Switch on the analyzer, if the analyzer is in shutdown status.



Cleaning the ultrasonic mixers

Clean the ultrasonic mixers every 3 months or after 225.000 tests (whatever comes first). Contamination and precipitation on the surface of the ultrasonic mixers may cause inadequate mixing and thus lead to inaccurate results.

Cleaning the ultrasonic mixers on page C-98

Replacing the photometer lamp

The reproducibility of measurement will decrease if the photometer lamp deteriorates. Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.

Replacing the photometer lamp on page C-109

Replacing the syringe seals

The syringe seals have to be replaced after 225,000 tests or after six months, whatever comes first. When the syringe seals get worn out, this may cause leakage and inaccurate pipetting. This is a combined maintenance procedure for both ISE and photometric unit.

Replacing the syringe seals on page C-102

Draining the vacuum tank

An alarm is issued (Liquid in vacuum tank) when there is water or waste solution in the vacuum tank. If this alarm appears, the vacuum tank must be drained. In case this happens frequently, contact the technical support.

Operator time approximately 5 minutes

Materials required Beaker



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Contamination by waste solution and solid waste* on page C-3

► **To drain the vacuum tank**

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Open the front doors of the c 501 and locate the vacuum tank.

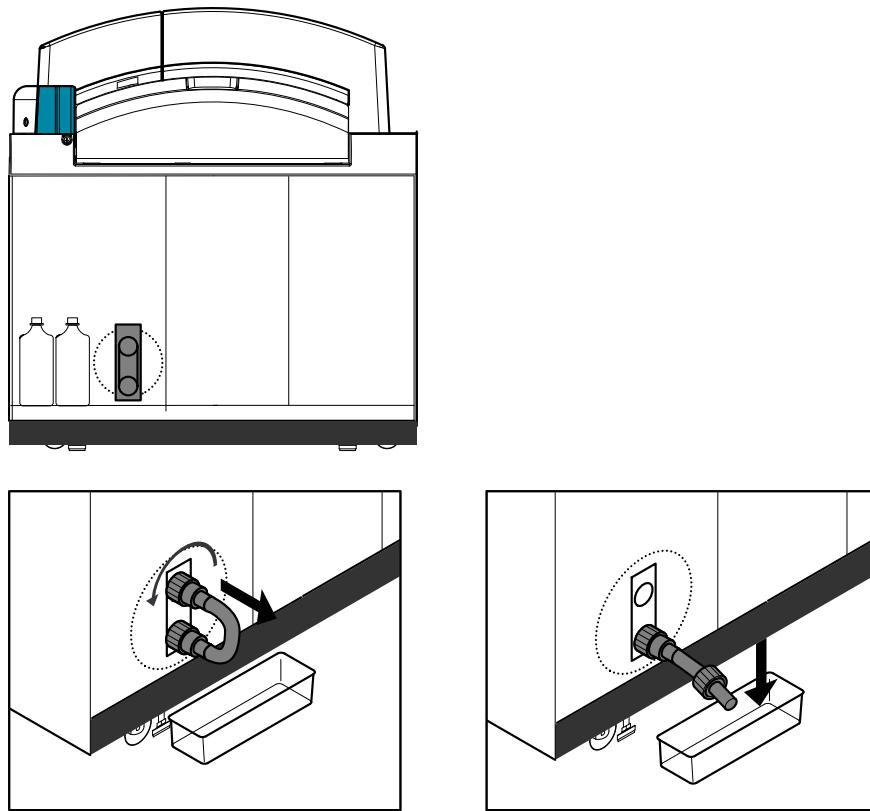


Figure C-49 Draining the vacuum tank

- 3 Remove the cap holding the drain tube of the vacuum tank.
- 4 Drain the waste solution into a beaker.

As needed maintenance

- 5 Replace the drain tube and reattach the cap to secure the drain tube.
- 6 Close the front doors of the module.
- 7 Switch on the analyzer, if the analyzer is in shutdown status.



Cleaning instrument surfaces

Spills on the instrument surface could be potentially biohazardous and damage the surface.

Operator time approximately 5 minutes

Materials required

- Cloth or paper towels
- Laboratory disinfectant (no bleach)



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

NOTICE

Damage to the instrument surface

Do not use alcohol or bleach to clean the instrument surfaces as this may damage the finish.

► To clean instrument surfaces

- 1 Put the analyzer in shutdown status or the module in standby.
- 2 Unlock and open the top cover of the module.
- 3 Clean the module surfaces using a cloth or paper towel moistened with disinfectant.
Clean up all spills immediately. Use this procedure to ensure that surfaces are clean. If necessary, move the probes or units manually to clean the surface.
- 4 Close the top cover and lock it with the key.



Maintenance e 601

This chapter describes the maintenance actions required for correct and efficient running of the e 601 module. The required schedule of the maintenance actions, for example, daily, weekly, and quarterly is provided as well as actions that are performed as needed.

In this chapter

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Maintenance schedule

All maintenance actions are listed in descending frequency.

PO	Power OFF
SB	Standby
MM	Module Masked
MC	Manual Cleaning

Procedure	Mode	Operator Time (min)	System Time (min)	Page
Daily				
Cleaning probes and sippers	MC	5		C-122
Weekly	Cleaning ProCell/CleanCell nozzles and replace reservoirs	MC	8	15
	Cleaning mixing station and separation stations of the Pre-wash area	MC	5	C-129
	Cleaning incubator	MM	10	C-131
	Cleaning vortex mixing station	MC	2	C-133
Every 2 weeks	Cleaning microbead mixer	MC	2	C-135
	Cleaning rinse stations	MC	5	C-137
	Liquid flow path cleaning	SB	5	30
	Replacing e 601 pinch valve tubing	SB/PO	5	30
As Needed	Cleaning ProCell/CleanCell stand and aspiration tubes	SB	5	15
	Cleaning ProCell/CleanCell aspiration tube filters	SB	5	15
	Cleaning reagent disk and compartment	MM	10	C-151
	Cleaning solid waste compartment	MM	5	C-153
	Cleaning instrument surfaces	MM	5	C-155
	Finalization	SB		C-156
	Extended Power OFF procedures	SB		C-158

Table C-27 Maintenance schedule

Daily maintenance

Cleaning probes and sippers

Clean the reagent probe, sample probe, sipper probes and Pre-wash sippers to remove residual solution and precipitation. Impurities on the sample probe may cause problems and affect results. After cleaning the probe, its discharge and operation should be checked. When cleaning, take care not to bend or damage the probes or sippers.

Operator time approximately 5 minutes

- Materials required*
- Lint-free gauze squares
 - Alcohol (e.g. isopropyl alcohol or ethanol)
 - Deionized water
 - Paper towel



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Fire and burns due to the use of alcohol* on page C-4
-

NOTICE**Damage to the instrument surface**

Do not place alcohol pads on the instrument surfaces as alcohol may damage the finish.

Damage to the probes

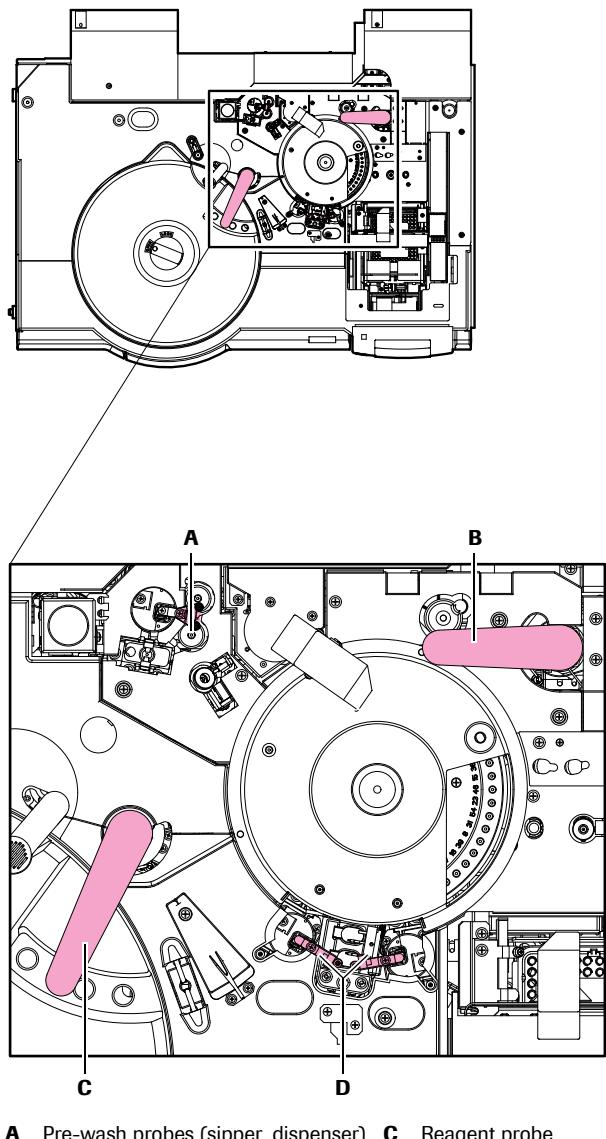
- Do not bend or damage the lower end of the probes during cleaning. Move the arm gently. Do not move it up and down.
 - Use a new lint-free gauze square for each probe to prevent cross contamination.
 - Do not bend the electrode for LLD inside the reservoir. If they are bent, contact the technical support.
-

► To position probes for maintenance

- 1 Choose Utility > Maintenance.
 - 2 Choose Maintenance on the Maintenance Type list.
 - 3 Choose (29) Manual Cleaning on the Maintenance Items list.
 - 4 Choose Select to display the Manual Cleaning window.
 - 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
 - 6 Choose Execute. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.
-

► **To clean probes**

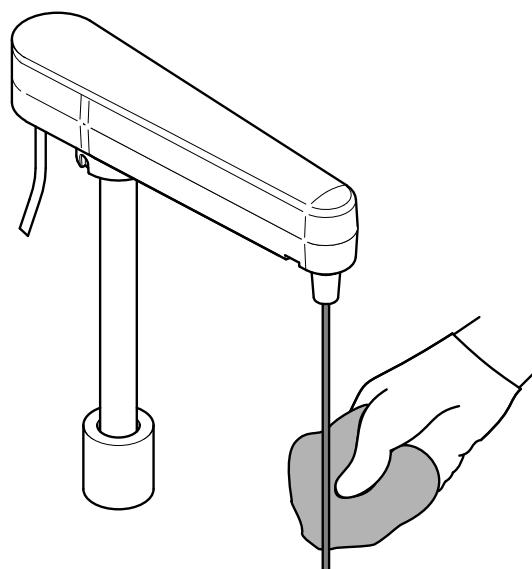
- 1 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.
- 2 Open the top cover.
- 3 To ensure no alcohol drops into the module, place a paper towel underneath the probe.



A Pre-wash probes (sipper, dispenser) **C** Reagent probe
B Sample probe

D Sipper probes for measuring channels
1 and 2

Figure C-50 Cleaning probes and sippers



4 Clean the probes and sippers using the following procedures.

- Sample probe

Wipe the probe from top to bottom in a downward motion with a lint-free gauze square soaked in deionized water.

If the probe still appears dirty, wipe the outer surface with a lint-free gauze square soaked in alcohol, then immediately with deionized water.

- Reagent probe
- Sipper probes for measuring channels 1 and 2
- Pre-wash sipper and dispenser probe

Wipe each of the probes from top to bottom in a downward motion with a lint-free gauze square soaked in alcohol, followed by a lint-free gauze square moistened with deionized water.

5 Remove the paper towels from the module.

6 Close top cover and lock it with the key.

7 Choose **Stop** (global button) once cleaning has been completed.

8 Choose **Yes** to stop maintenance after confirmation.



► **To return probes to standby positions**

1 Choose **Utility > Maintenance**.

2 Select **Maintenance** on the **Maintenance Type** list.

3 Select **(1) Reset** on the **Maintenance Items** list.

4 Choose **Select** to display the **Reset** window.

5 Select the appropriate e 601 module and deselect all other modules and units.
Selected modules are highlighted in white.

6 Choose **Execute**. The probes on the selected module(s) return to their standby positions.



Weekly maintenance

Cleaning ProCell/CleanCell nozzles and replace reservoirs

As ProCell dries, crystals are formed. To prevent problems, the ProCell/CleanCell filling nozzles and electrodes must be cleaned and the reservoirs must be replaced regularly.

This maintenance is divided into 5 procedures and must be performed in the order specified:

- Procedure 1 - To empty ProCell/CleanCell reservoirs
- Procedure 2 - To clean nozzles and electrodes
- Procedure 3 - To replace ProCell/CleanCell reservoirs
- Procedure 4 - To perform Reagent Prime
- Procedure 5 - To perform Finalization

Operator time approximately 8 minutes

System time approximately 15 minutes

Materials required

<input type="checkbox"/>	Cotton tipped applicator sticks
<input type="checkbox"/>	Deionized water
<input type="checkbox"/>	2 ProCell/CleanCell reservoirs



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► **Procedure 1 - To empty ProCell/CleanCell reservoirs**

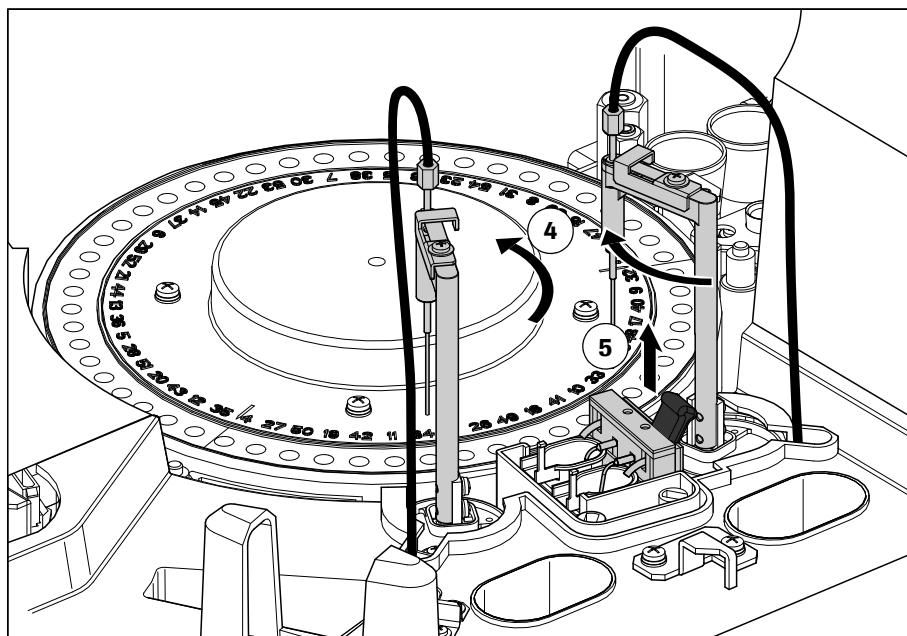
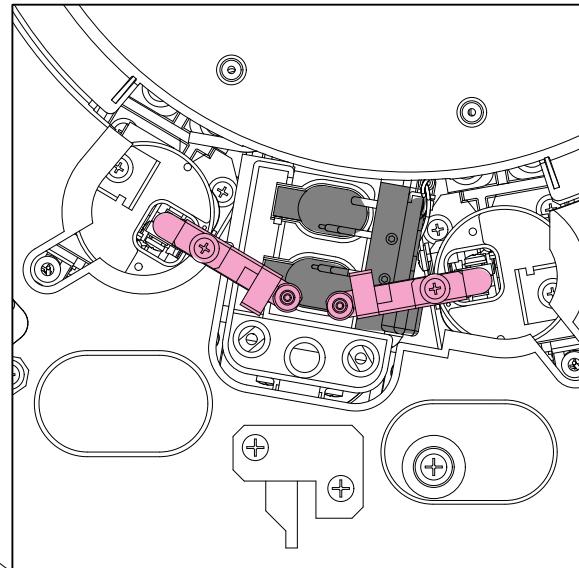
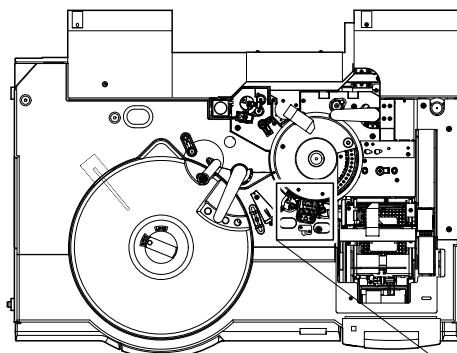
- 1 Choose Utility > Maintenance.
 - 2 Select Maintenance from the Maintenance Type list.
 - 3 Select (33) Empty PC/CC Reservoir from the Maintenance Items list.
 - 4 Choose Select to display the Empty PC/CC Reservoir window.
 - 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
 - 6 Choose Execute. The PC/CC reservoirs are emptied.
 - 7 After the procedure has been completed, the e 601 module goes into standby mode.
-

► Procedure 2 - To clean nozzles and electrodes

- 1 Make sure that the module is in standby.
- 2 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.
- 3 Open the top cover.

**Damage to the sipper probes**

- Do not bend or damage the lower end of the sipper probes during cleaning. Move the arm gently. Do not move it up and down.
- Do not bend the electrode for LLD inside the reservoir. If they are bent, contact the technical support.

**Figure C-51** Move the sipper probes over the incubator

- 4 Manually move the sipper probes over the incubator.
- 5 Pull up the unit containing the PC/CC supplier nozzles and the electrodes using the black handle gently to the stop/hold position.

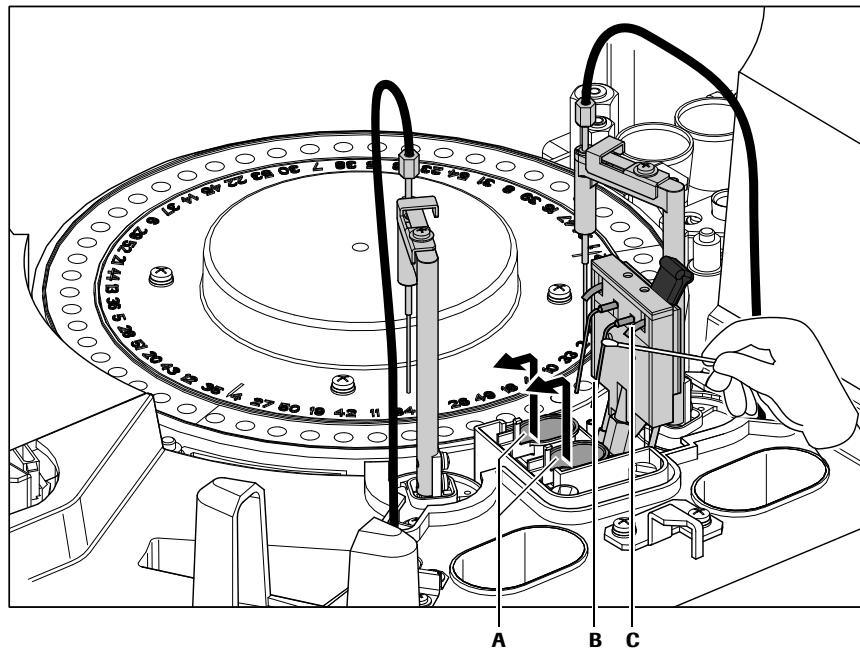


Figure C-52 Cleaning ProCell/CleanCell reservoir filling nozzle
A Reservoirs B Reservoir filling nozzle
C Electrodes

- 6 Clean the ProCell/CleanCell reservoir filling nozzle (**B**) and electrodes (**C**) by wiping them with a cotton tipped applicator stick soaked in deionized water.

■

► Procedure 3 - To replace ProCell/CleanCell reservoirs

- 1 Carefully remove the ProCell/CleanCell reservoirs (**A**) (upward /left direction) making sure the electrodes are not bent.
- 2 Clean the inside of the reservoir positions by wiping them with a cotton tipped applicator stick soaked in deionized water.
- 3 Place new reservoirs in the reservoir positions and push the sipper nozzle unit back into place.
- 4 Close the top cover and lock it with the key.
- 5 Choose **Stop** (global button) once cleaning is complete.
- 6 Choose **Yes** to stop maintenance after confirmation.

■

► **Procedure 4 - To perform Reagent Prime**

- 1 Choose Utility > Maintenance.
- 2 Choose (8) Reagent Prime in the Maintenance Items list.
- 3 Choose Select to display the Reagent Prime window.

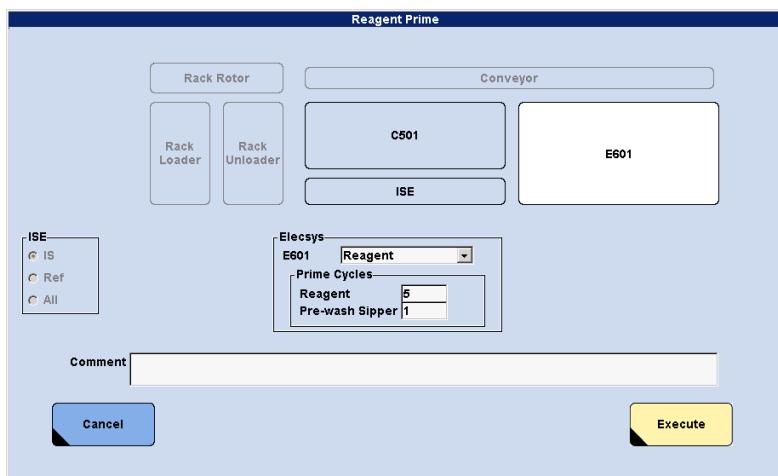


Figure C-53 Reagent Prime window

- 4 Deselect the c 501 module and select the e 601 module.
- 5 In the Elecys area select Reagent from the e 601 list box. In the Prime Cycles area enter 1 for the Reagent
- 6 Choose Execute to start reagent priming.
- 7 Wait until the reagent prime is completed and the instrument enters standby mode, then start finalization.



If, after the maintenance is performed, the instrument is to be powered off or in standby for an extended period of time then a finalization must be performed.

If further samples are to be processed then finalization is not necessary.

► **Procedure 5 - To perform Finalization**

- 1 Choose Utility > Maintenance.
- 2 Choose (32) Finalization in the Maintenance Items list.
- 3 Choose Select to display the Finalization window.
- 4 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white. Channel 1+2 is activated.
- 5 Choose Execute to start finalization. The procedure is complete when the system returns to standby.

Cleaning mixing station and separation stations of the Pre-wash area

Spills on the mixing station and the separation stations could cause gripper movement alarms.

Operator time approximately 5 minutes

Materials required

- Cotton tipped applicator sticks
- Lint-free gauze squares
- Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Damage to the e 601 module due to the use of acid or alkaline solutions for cleaning* on page C-5
-

► **To clean Pre-wash mixer and separation station**

- 1 Choose Utility > Maintenance.
- 2 Choose Maintenance on the Maintenance Type list.
- 3 Choose (29) Manual Cleaning on the Maintenance Items list.
- 4 Choose Select to display the Manual Cleaning window.
- 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 6 Choose Execute. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.
- 7 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

Weekly maintenance

- 8 Open the top cover of the e 601 module to be cleaned.



Damage to the probes

Do not bend or damage the lower end of the sipper and dispenser probes during cleaning.

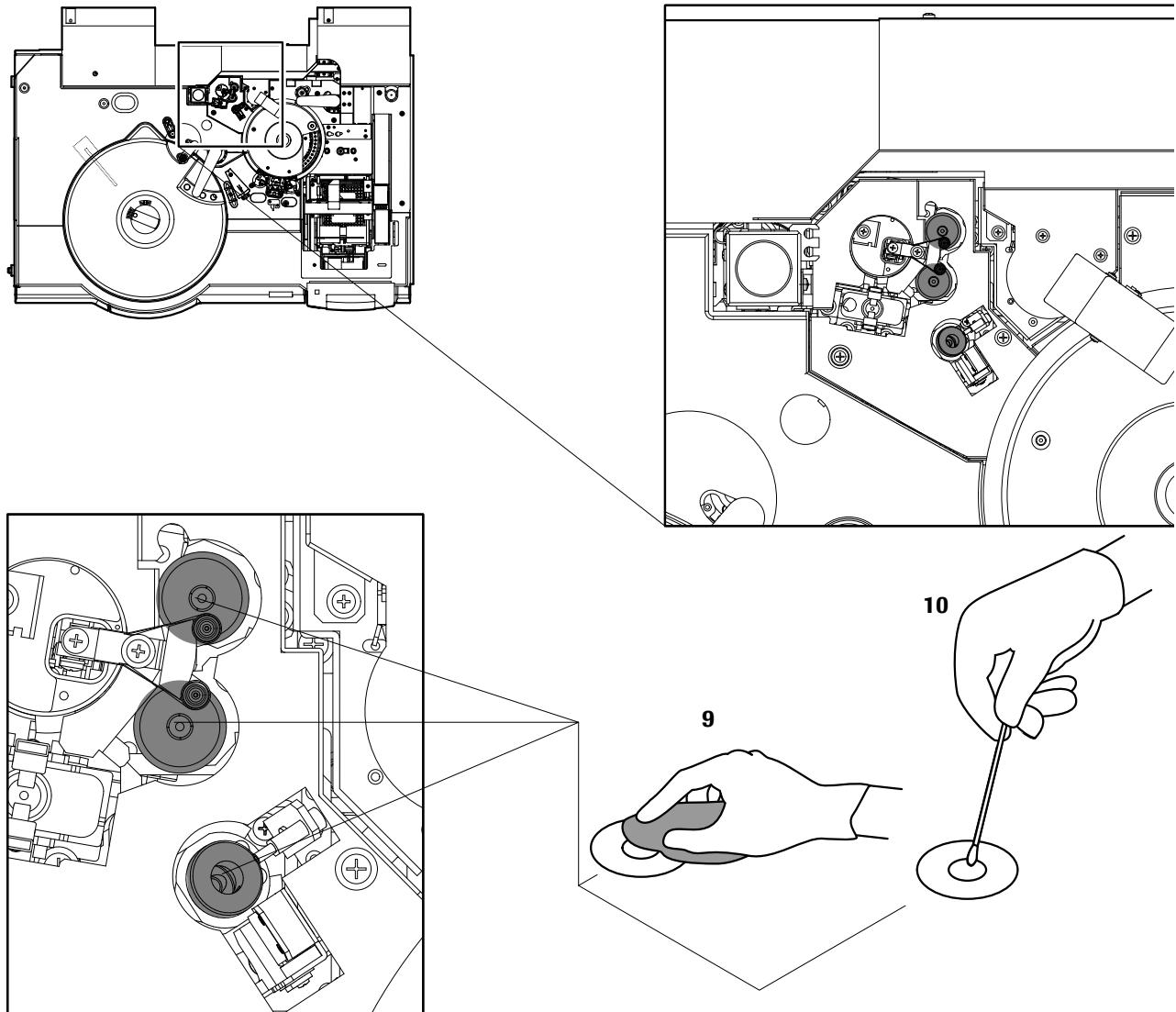


Figure C-54 Cleaning mixing station and separation station

- 9 Clean the surface of the mixing station and the separation stations with lint-free gauze squares dampened with deionized water. If the mixing station and the separation stations appear dirty, use a slight scrubbing motion with the water-soaked lint-free gauze squares.
- 10 Next, wet cotton tipped applicator sticks with deionized water and swab the openings on the mixing station and the separation stations.

- 11** Dry the mixing station and the separation stations with dry lint-free gauze squares and cotton tipped applicator sticks when cleaning is completed.



Ensure that the surface and the openings of the mixing station and the separation stations are dry and not clogged or the gripper may experience problems when operation is resumed.

- 12** Close the cover and lock it with the key.

- 13** Choose **Stop** (global button) once cleaning has been completed.

- 14** Choose **Yes** to stop maintenance after confirmation.



► **To return mechanical parts to standby position**

- 1** Choose **Utility > Maintenance**.
- 2** Select **Maintenance** from the **Maintenance Type** list.
- 3** Select **(1) Reset** from the **Maintenance Items** list.
- 4** Choose **Select** to display the **Reset** window.
- 5** Select the appropriate **e 601** module and deselect all other modules and units. Selected modules are highlighted in white.
- 6** Choose **Execute**. Mechanical parts on the selected **e 601** module move to their standby positions.



Cleaning incubator

Spills on the incubator could cause gripper movement alarms.

Operator time approximately 10 minutes

Materials required

- Lint-free gauze squares
- Cotton tipped applicator sticks
- Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Damage to the e 601 module due to the use of acid or alkaline solutions for cleaning* on page C-5

► **To clean the incubator**

- 1** Choose **Start** (global button) > **Masking > Module Masking** to display the **Module Masking** screen.
- 2** Select the **e 601** module you wish to mask and choose **OK**. The selected **e 601** module is now masked and goes into standby mode.

Weekly maintenance

- 3 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.
- 4 Open the top cover and move the gripper manually if necessary, to allow the incubator cover to be removed.

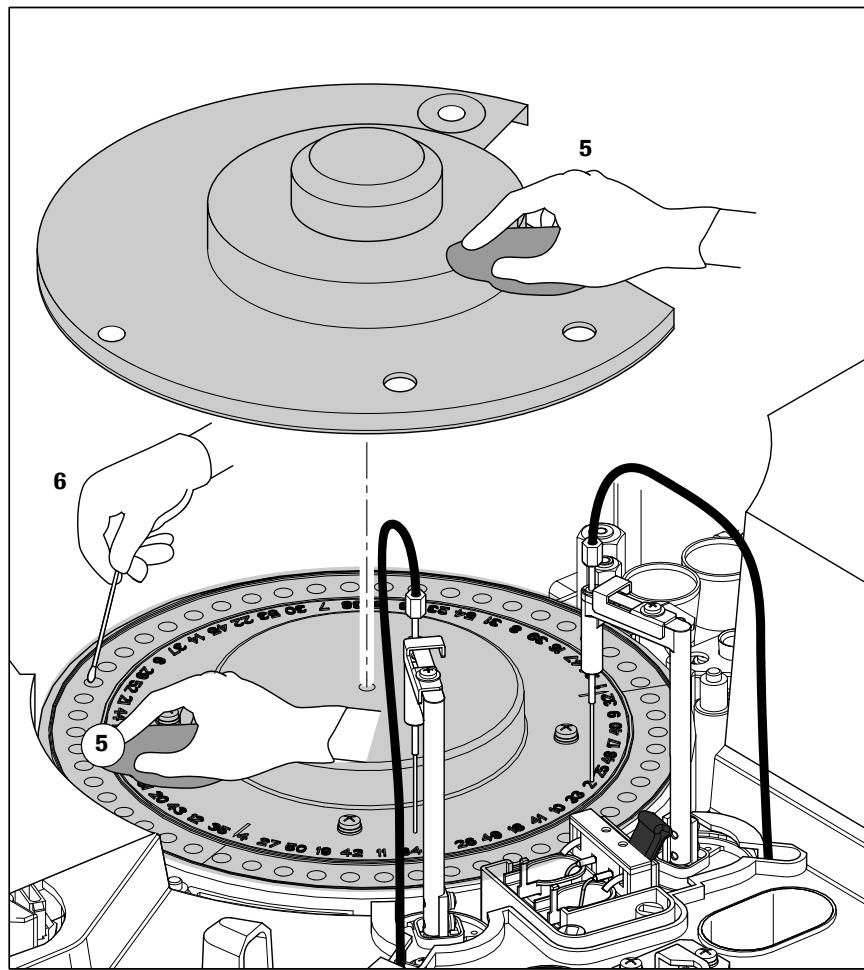


Figure C-55 Cleaning incubator

- 5 Clean the incubator cover and the top of the incubator with lint-free gauze squares dampened with deionized water. If the incubator or the cover appears dirty, use a slight scrubbing motion with the water-soaked lint-free gauze squares.
- 6 Next, wet a cotton tipped applicator stick with deionized water and swab each of the 54 positions on the incubator.
- 7 Dry the incubator with dry lint-free gauze squares and cotton tipped applicator sticks when cleaning is completed.



Ensure that the incubator and its positions are dry and not clogged or the gripper may experience problems when operation is resumed.

- 8 Replace the incubator cover, close the top cover and lock it with the key.
- 9 Unmask the module at **Start** (global button) > **Masking** > **Module Masking**.



Cleaning vortex mixing station

Spills on the vortex mixing station for AssayCups could cause gripper movement alarms.

Operator time approximately 2 minutes

Materials required

- Lint-free gauze squares
- Cotton tipped applicator sticks
- Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Damage to the e 601 module due to the use of acid or alkaline solutions for cleaning* on page C-5
-

► **To clean the vortex mixing station**

- 1 Choose Utility > Maintenance.
- 2 Choose Maintenance on the Maintenance Type list.
- 3 Choose (29) Manual Cleaning on the Maintenance Items list.
- 4 Choose Select to display the Manual Cleaning window.
- 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 6 Choose Execute. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.

Weekly maintenance

- 7** Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

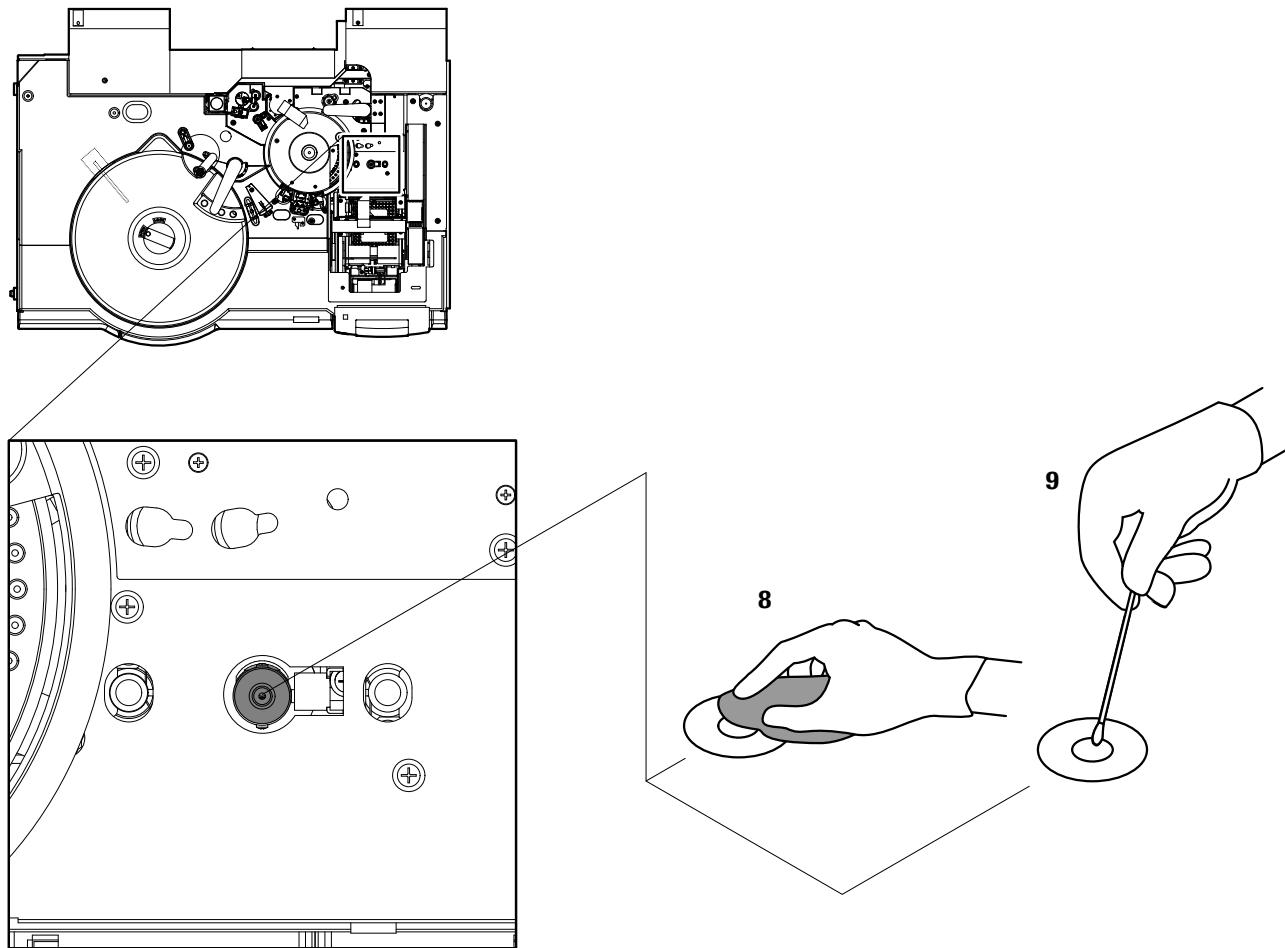


Figure C-56 Cleaning vortex mixing station

- 8** Clean the surface of the vortex mixing station with lint-free gauze squares dampened with deionized water. If the vortex mixing station appears dirty, use a slight scrubbing motion with the water-soaked lint-free gauze squares.
- 9** Wet a cotton tipped applicator stick with deionized water and swab the opening of the vortex mixing station.
- 10** Dry the vortex mixing station with dry lint-free gauze squares and cotton tipped applicator sticks when cleaning is completed.



Ensure that the vortex mixing station and its opening are dry and not clogged or the gripper may experience problems when operation is resumed.

- 11** Close the top cover and lock it with the key.
- 12** Choose **Stop** (global button).
- 13** Choose **Yes** to stop maintenance after confirmation.



► **To return probes to standby positions**

- 1 Choose Utility > Maintenance.
- 2 Select Maintenance from the Maintenance Type list.
- 3 Select (1) Reset from the Maintenance Items list.
- 4 Choose Select to display the Reset window.
- 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 6 Choose Execute. The probes on the selected e 601 module move to their standby positions.



Cleaning microbead mixer

Impurities on the microbead mixer may cause problems, and affect results.

Operator time approximately 2 minutes

Materials required

- Lint-free gauze squares
- Alcohol (e.g. isopropyl alcohol or ethanol)
- Deionized water
- Small Brush



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Fire and burns due to the use of alcohol* on page C-4
-

► **To clean the microbead mixer**

- 1 Choose Utility > Maintenance.
- 2 Choose Maintenance on the Maintenance Type list.
- 3 Choose (29) Manual Cleaning on the Maintenance Items list.
- 4 Choose Select to display the Manual Cleaning window.
- 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 6 Choose Execute. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.
- 7 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

8 Open the top cover.

**Damage to the microbead mixer**

- Do not bend the microbead mixer during cleaning.
- Look and make sure the microbead mixer is not bent.

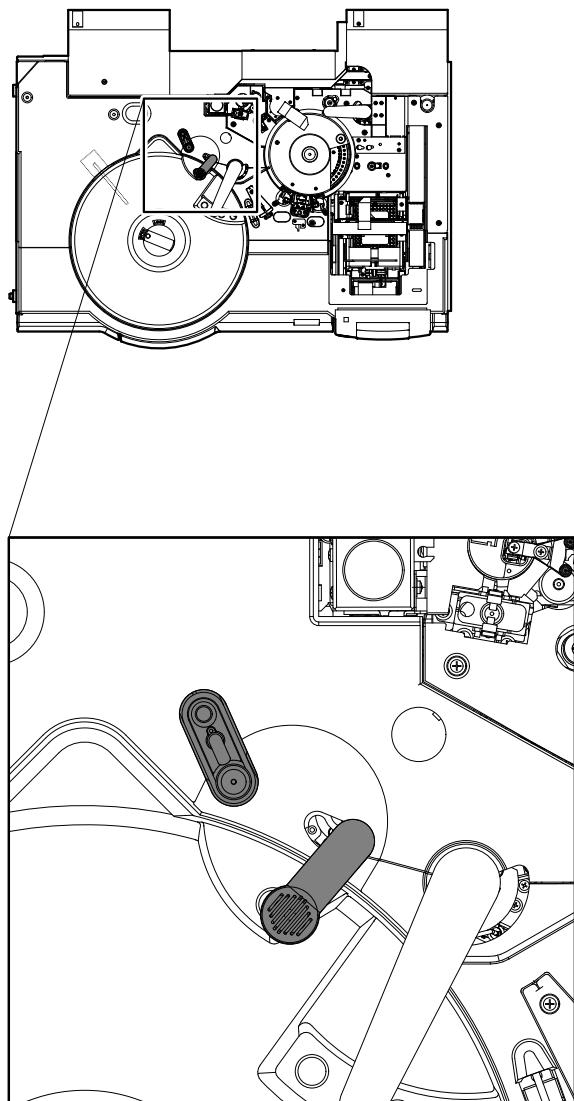


Figure C-57 Cleaning microbead mixer

9 Very carefully wipe the microbead mixer paddle with a lint-free gauze square soaked in alcohol from top to bottom.

10 Use a brush to clean the 4 propeller plates with alcohol.

11 Repeat the procedure using deionized water instead of alcohol.

12 Choose **Stop** (global button).

13 Choose **Yes** to stop maintenance after confirmation.



► **To return probes to standby positions**

- 1 Choose Utility > Maintenance.
- 2 Select Maintenance from the Maintenance Type list.
- 3 Select (1) Reset from the Maintenance Items list.
- 4 Choose Select to display the Reset window.
- 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 6 Choose Execute. The probes on the selected e 601 module move to their standby positions.



Cleaning rinse stations

Contamination in the rinse stations for the Pre-wash probes, the reagent probe, the microbead mixer, and the sipper probes can cause problems.

Operator time approximately 5 minutes

Materials required

- Cotton tipped applicator sticks
- Alcohol (e.g. isopropyl alcohol or ethanol)
- 2% Hitergent
- 50 mL syringe with tubing attached



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
 - *Fire and burns due to the use of alcohol* on page C-4
-

► **To clean rinse stations**

- 1 Choose Utility > Maintenance.
- 2 Choose Maintenance on the Maintenance Type list.
- 3 Choose (29) Manual Cleaning on the Maintenance Items list.
- 4 Choose Select to display the Manual Cleaning window.
- 5 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 6 Choose Execute. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.
- 7 Touch any screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

8 Open the top cover.

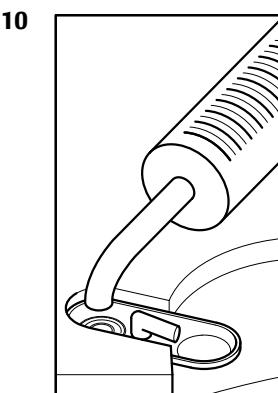
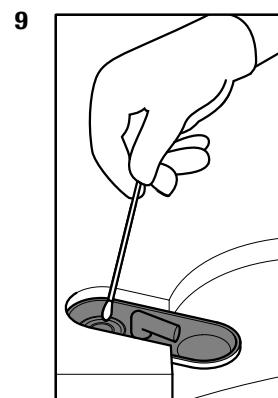
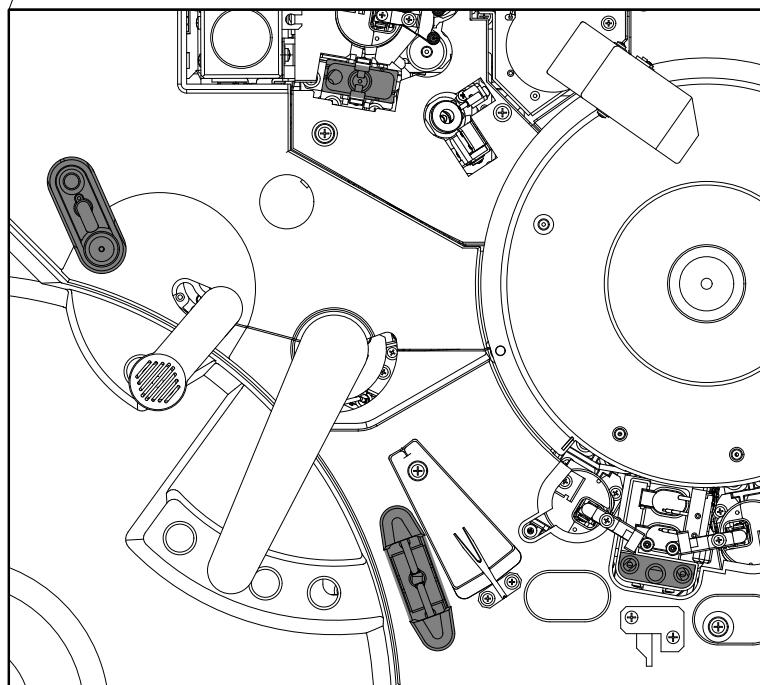
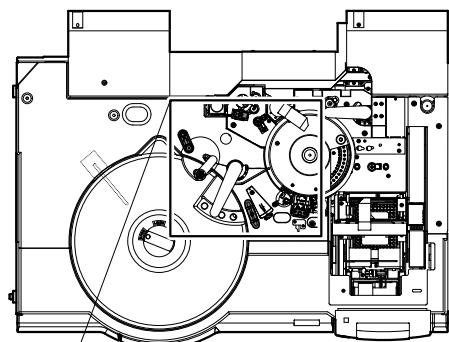


Figure C-58 Cleaning Pre Wash rinse station

- 9** Clean the inside of each rinse station using a cotton tipped applicator stick soaked in alcohol, followed by a cotton tipped applicator stick soaked in deionized water.
- 10** Fill a syringe (with tubing attached) with 50 mL of 2% Hitargent.
- 11** Inject the Hitargent solution (empty the syringe) into the drain hole of the rinse bath.
- 12** Fill a syringe with 50 mL deionized water.
- 13** Inject the deionized water (empty the syringe) into the drain hole of the rinse bath.
- 14** Repeat step 1-13 for all of the probe and stirrer rinse baths on each e 601 module.

15 Choose **Stop** (global button).

16 Choose **Yes** to stop maintenance after confirmation.



► **To return probes to standby positions**

1 Choose **Utility > Maintenance**.

2 Select **Maintenance** from the **Maintenance Type** list.

3 Select **(1) Reset** from the **Maintenance Items** list.

4 Choose **Select** to display the **Reset** window.

5 Select the appropriate **e 601** module and deselect all other modules and units.
Selected modules are highlighted in white.

6 Choose **Execute**. The probes on the selected **e 601** module move to their reset positions.



Every two weeks maintenance

Every two weeks maintenance

Liquid flow path cleaning

Contamination in the sippert system could cause problems. To keep the flow paths of the sippers clean and maintain the integrity of the measuring cell, perform liquid flow path cleaning at least every two weeks or after 2500 to 3000 determinations per channel, whichever comes first.

Operator time approximately 5 minutes

System time approximately 30 minutes

Materials required 2 SysClean Adapter M
 SysClean solution



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► **To prepare Liquid Flow Path Cleaning**

- 1 Open the top cover.

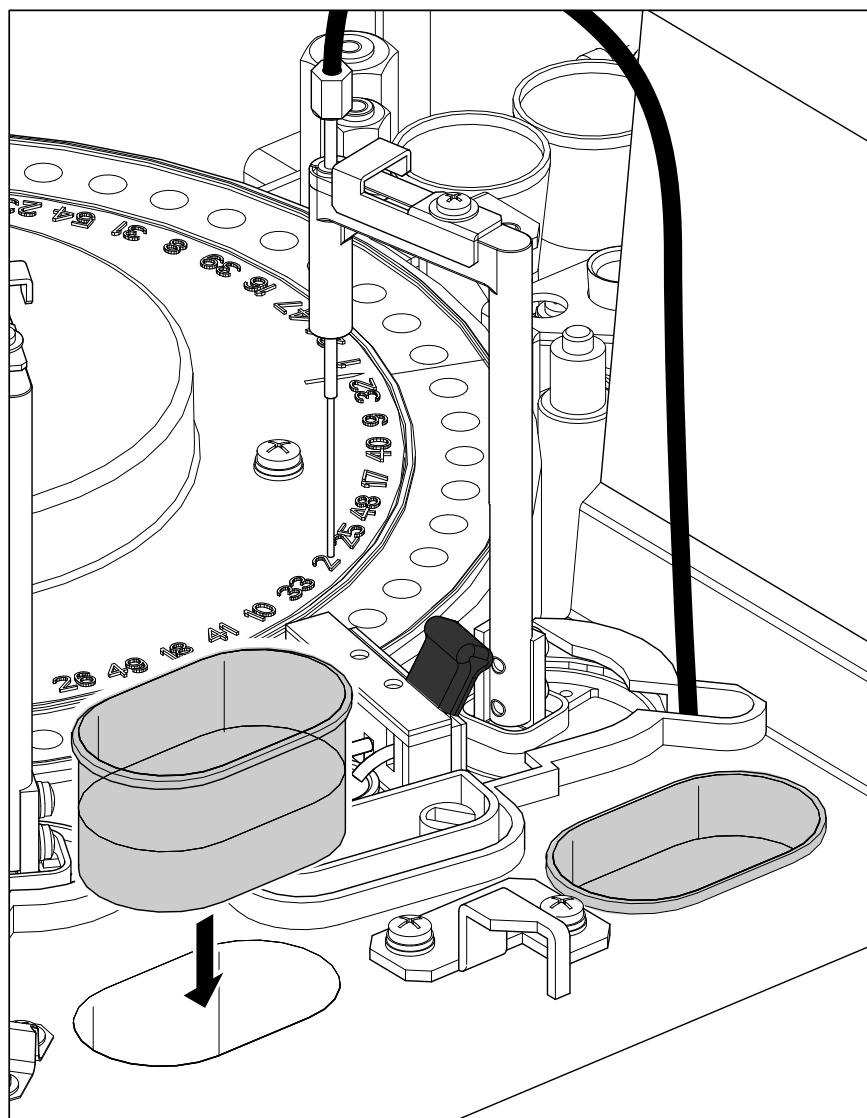


Figure C-59 Placing SysClean Adapter M

- 2 Fill the SysClean Adapter M with SysClean solution to the lower line (approximately 9 mL/cup).
- 3 Carefully, insert the filled SysClean cups into the position located in front of the sipper unit to be cleaned.
- 4 Close the top cover.

■

Every two weeks maintenance

► **To initiate Liquid Flow Path Cleaning**

- 1 Choose Utility > Maintenance.
- 2 Select Maintenance from the Maintenance Type list.
- 3 Select (27) Liquid Flow Cleaning from the Maintenance Items list.
- 4 Choose Select to display the Liquid Flow Path Cleaning window.
- 5 Select the appropriate e 601 module and deselect all other modules. Selected modules are highlighted in white.
- 6 Select the Ch1,2 option and enter 1 in the Cycles text box and choose Execute.

■

► **Post-cleaning steps**

- 1 Open the top cover.
- 2 Remove the SysClean Adapter M.
- 3 Dispose of any remaining SysClean solution. Rinse the SysClean Adapter M(s) thoroughly with deionized water.

■

Every three months maintenance

Replacing e 601 pinch valve tubing

Pinch valve tubings wear out in the course of time. To rule out the risk of defective tubings replace e 601 pinch valve tubings every 3 months or after measuring 25,000 tests per measuring cell.

Operator time approximately 5 minutes

System time approximately 30 minutes

Materials required

- Pinch valve tubing
- Lint-free gauze pads
- Protective equipment (gloves, paper towels)



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► To replace e 601 pinch valve tubings

- 1 Perform maintenance item (26) MC Exchange before removing the tubes, to avoid dripping of fluid on the valves.
- 2 Shut down the system or put the e 601 module into standby mode.

Every three months maintenance

- 3** Locate the e 601 pinch valve tubings behind the front door of the e 601 module.

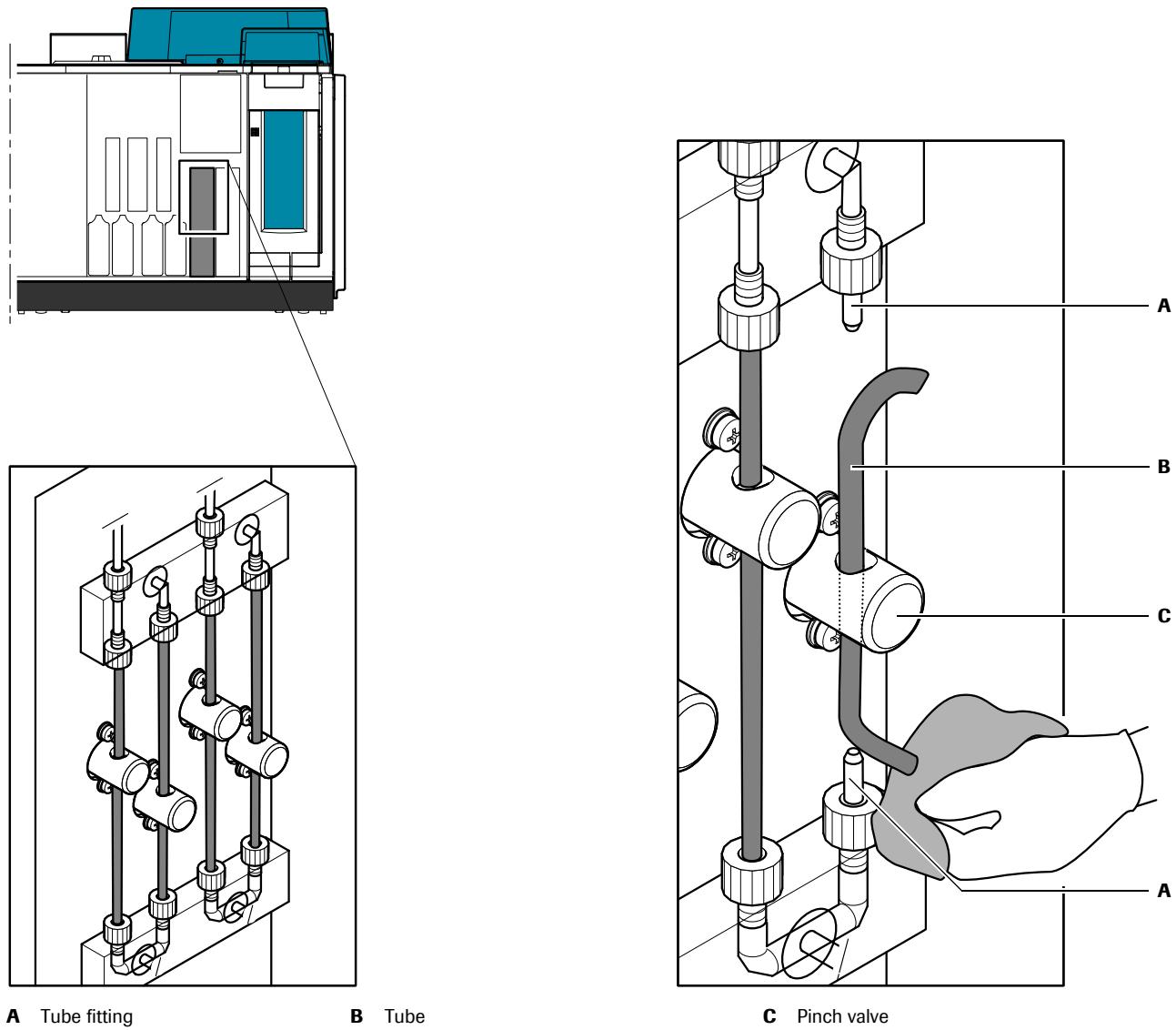


Figure C-60 Replacing e 601 pinch valve tubing

- 4** Carefully remove (pull) all 4 pinch valve tubings (**B**) from the fittings (**A**).
 - 5** Use a dry gauze pad to absorb liquid which drains from the acrylic block or from the tubing.
 - 6** Take new pinch valve tubing and insert it through the pinch valve (**C**).
 - 7** Carefully slide the ends of the tubing over each fitting (**A**).
-

After replacement of the e 601 pinch valve tubing it is necessary to perform 2 maintenance items before resuming operation:

- (24) Sipper Air Purge
- (25) MC Preparation

► To perform Sipper Air Purge

- 1 Start up the instrument.
- 2 After initialization is finished, choose **Utility > Maintenance**.
- 3 Select **(24) Sipper Air Purge** from the **Maintenance Items** list on the right and choose **Select** to display the Sipper Air Purge window.
- 4 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 5 Enter 10 in the Cycles box and choose **Execute** to initiate the Sipper Air Purge.

While the air purge is executed, inspect the syringe to ensure that no air remains in the syringe and no leaks are visible at any of its fittings. Also check that the sufficient amount of water is discharged from the sipper probe.

**► To perform MC Preparation**

- 1 After Sipper Air Purge is finished, select **(25) MC Preparation** from the **Maintenance Items** list on **Utility > Maintenance**.
- 2 Choose **Select** to display the **MC Preparation** window.
- 3 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white.
- 4 Under Channel select Ch1,2. If only one tube has been replaced, choose the appropriate measuring channel.
- 5 Enter 10 in the Cycles box and choose **Execute** to initiate the maintenance function.

Again, check for leaks at the fittings and on the tubings while the system is performing the maintenance function.



As needed

As needed

Cleaning ProCell/CleanCell stand and aspiration tubes

Clean ProCell and CleanCell stand and aspiration tubes if crystallization is observed.

Operator time approximately 5 minutes

System time 15 minutes

- Materials required*
- Lint-free gauze squares
 - ProCell/CleanCell bottle caps
 - Paper towels
 - Deionized water



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
-

► **To clean ProCell/CleanCell stand and aspiration tubes**

- 1 Open the middle door of the e 601 module to be cleaned.

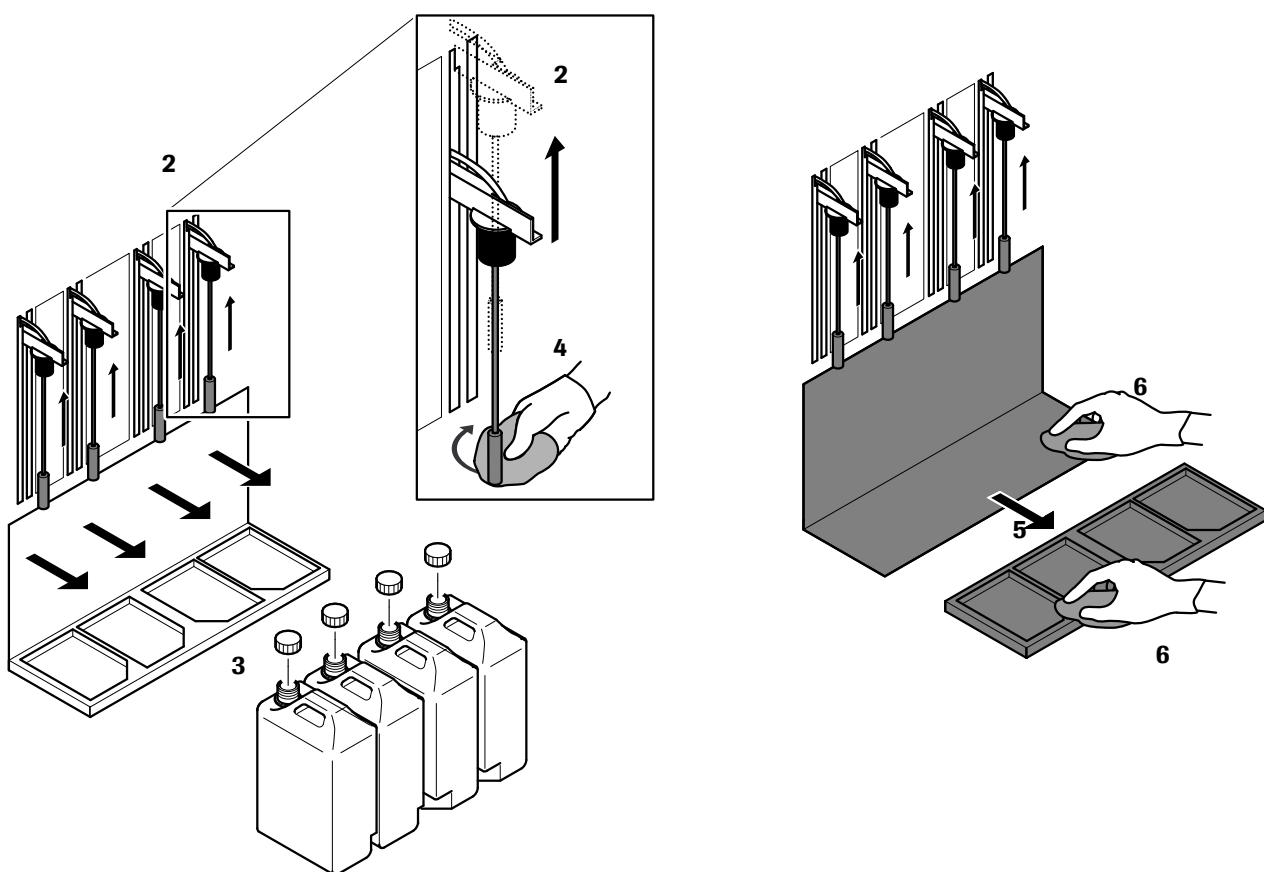
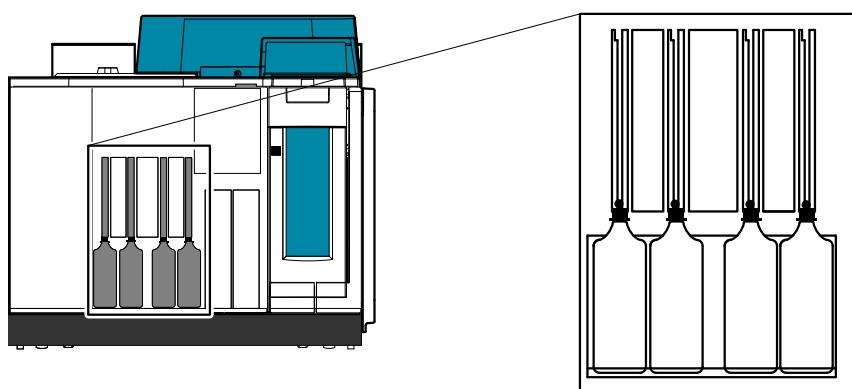


Figure C-61 Cleaning ProCell/CleanCell stand and aspiration tubes

- 2 Pull the aspiration tubes up and to the left to secure them on their respective notches.
- 3 Cap the ProCell and CleanCell reagent bottles and remove them from the e 601 module.



Droplets of ProCell and CleanCell may drip when ProCell and CleanCell bottles are removed. If this occurs, use paper towels to wipe up the liquid.

As needed

- 4 Wipe the aspiration tubes with lint-free gauze squares soaked with deionized water and then dry them with dry lint-free gauze squares.
- 5 Remove the ProCell and CleanCell stand from the module.
- 6 Clean the stands with lint-free gauze squares soaked with deionized water and then dry them with dry lint-free gauze squares.
- 7 It may be necessary to clean inside the instrument surface. Use a lint-free gauze square with water and dry after.
- 8 Replace the ProCell and CleanCell stand in the module.



False results due to ProCell/CleanCell bottle misplacement.

ProCell and CleanCell bottles are different in shape to fit the keyed position of the bottle stand. This is done to ensure the correct positions. Measurements cannot be performed if the bottle stand is not present. Ensure the bottle stand is present before placing the ProCell and CleanCell bottles.

- 9 Replace the ProCell and CleanCell reagent bottles in their original positions and remove the caps.
- 10 Guide the aspiration tubes into the bottles.
- 11 Close the middle door of the e 601 module.



Cleaning ProCell/CleanCell aspiration tube filters

Clean the ProCell and CleanCell aspiration tube filters if they are blocked.

Operator time approximately 5 minutes

System time 15 minutes

Materials required

- Lint-free gauze squares
- ProCell/CleanCell bottle caps
- Deionized water



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Personal injury due to contact with cleaning solutions or reagents* on page C-4
- CleanCell causes severe burns!**
-

► **To clean ProCell/CleanCell aspiration tube filters**

- 1 Open the middle door of the e 601 module to be cleaned.

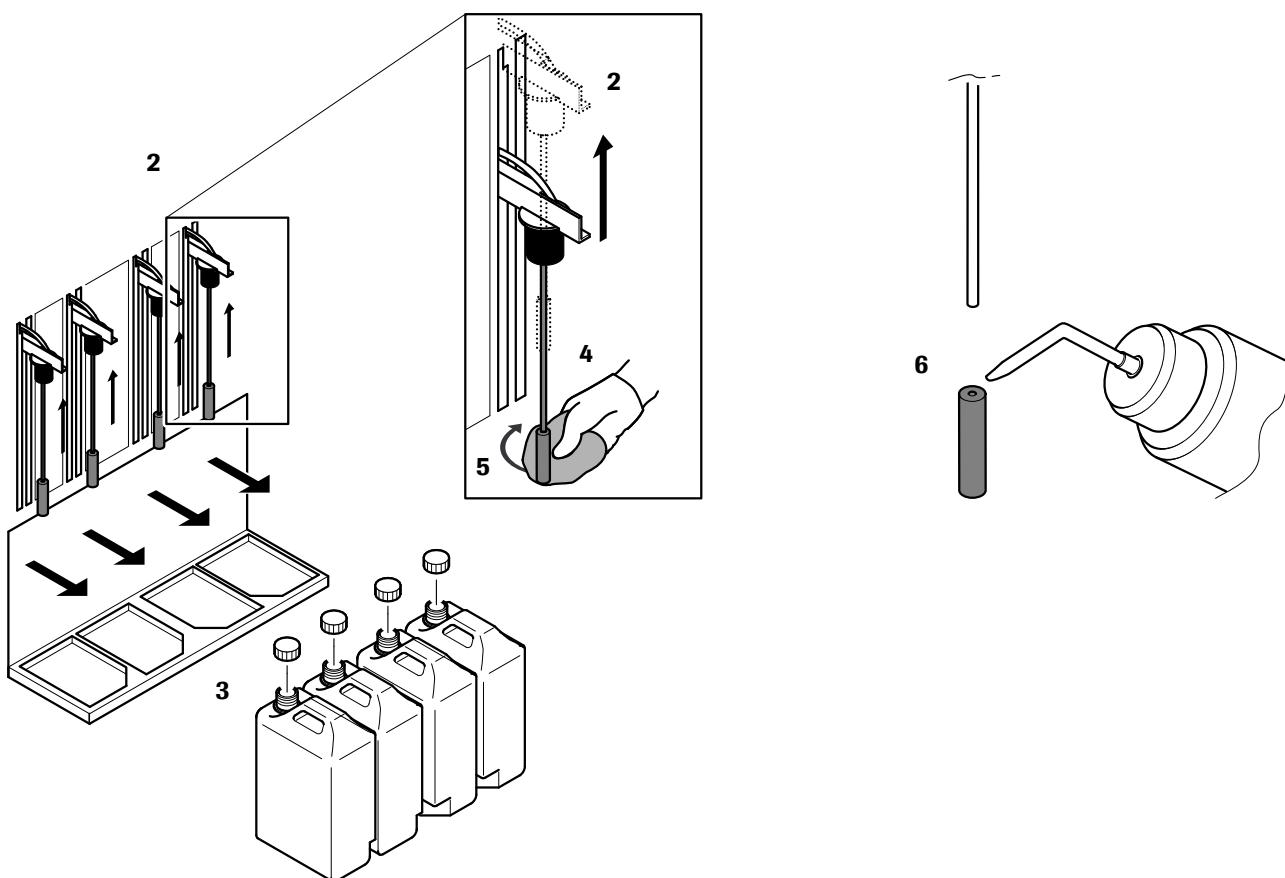
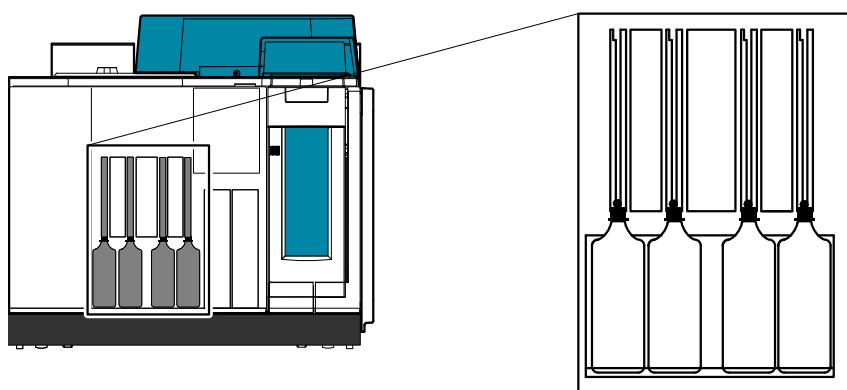


Figure C-62 Cleaning ProCell/CleanCell aspiration tube filters

- 2 Pull the aspiration tubes up and to the left to secure them on their respective notches.
- 3 Cap the ProCell and CleanCell reagent bottles and remove them from the module.
- 4 Wipe the aspiration tube filters with lint-free gauze squares soaked with deionized water and then dry them with dry lint-free gauze squares.
- 5 Unscrew the filters from the aspiration tubes.

As needed

- 6** Clean the filters with deionized water, dry them with a lint-free gauze square and then replace them.



False results due to ProCell/CleanCell bottle misplacement.

ProCell and CleanCell bottles are different in shape to fit the keyed position of the bottle stand. This is done to ensure the correct positions. Measurements cannot be performed if the bottle stand is not present. Ensure the bottle stand is present before placing the ProCell and CleanCell bottles.

- 7** Replace the ProCell and CleanCell reagent bottles in their original positions and remove the caps.
8 Guide the aspiration tube filters into the bottles.
9 Close the middle door of the e 601 module.



After replacing the ProCell and CleanCell bottles back on the analyzer, it is important to perform a reagent prime to ensure there are no air bubbles in the fluidics system. Continue the procedure to perform a reagent prime.

► **To perform Reagent Prime**

- 1** Choose Utility > Maintenance.
- 2** Choose (8) Reagent Prime in the Maintenance Items list.
- 3** Choose Select to display the Reagent Prime window.

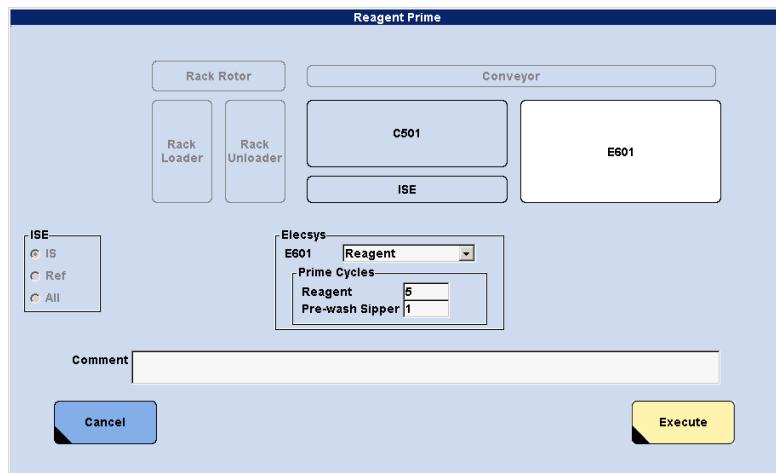


Figure C-63 Reagent Prime window

- 4** Deselect the c 501 module and select the e 601 module.
- 5** In the Elecsys area select Reagent from the e 601 list box. In the Prime Cycles area enter 1 for the Reagent.
- 6** Choose Execute to start reagent priming.
- 7** Wait until the reagent prime is completed and the instrument enters standby mode, then start finalization.



► To perform Finalization

- 1 Choose Utility > Maintenance.



Always start finalization in combination with reagent prime. Never repeat finalization alone.

- 2 Choose (32) Finalization in the **Maintenance** Items list.
- 3 Choose **Select** to display the **Finalization** window.
- 4 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white. Channel 1+2 is activated.
- 5 Choose **Execute** to start finalization. The procedure is complete when the system returns to standby.



Cleaning reagent disk and compartment

Clean reagent spills as they occur. Clean the reagent disk as needed.

Operator time approximately 10 minutes

- Materials required*
- Lint-free gauze squares
 - Alcohol (e.g. isopropyl alcohol or ethanol)
 - Deionized water
 - Cloth or lint-free towels



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Personal injury due to contact with instrument mechanism* on page C-4
 - *Fire and burns due to the use of alcohol* on page C-4
-

As needed

► **To remove reagent disk and clean the reagent disk and compartment**

- 1 Ensure the system is in standby.



Damage to the microbead mixer

- Do not bend the microbead mixer when cleaning the reagent disk compartment.
- Look and make sure the microbead mixer is not bent.

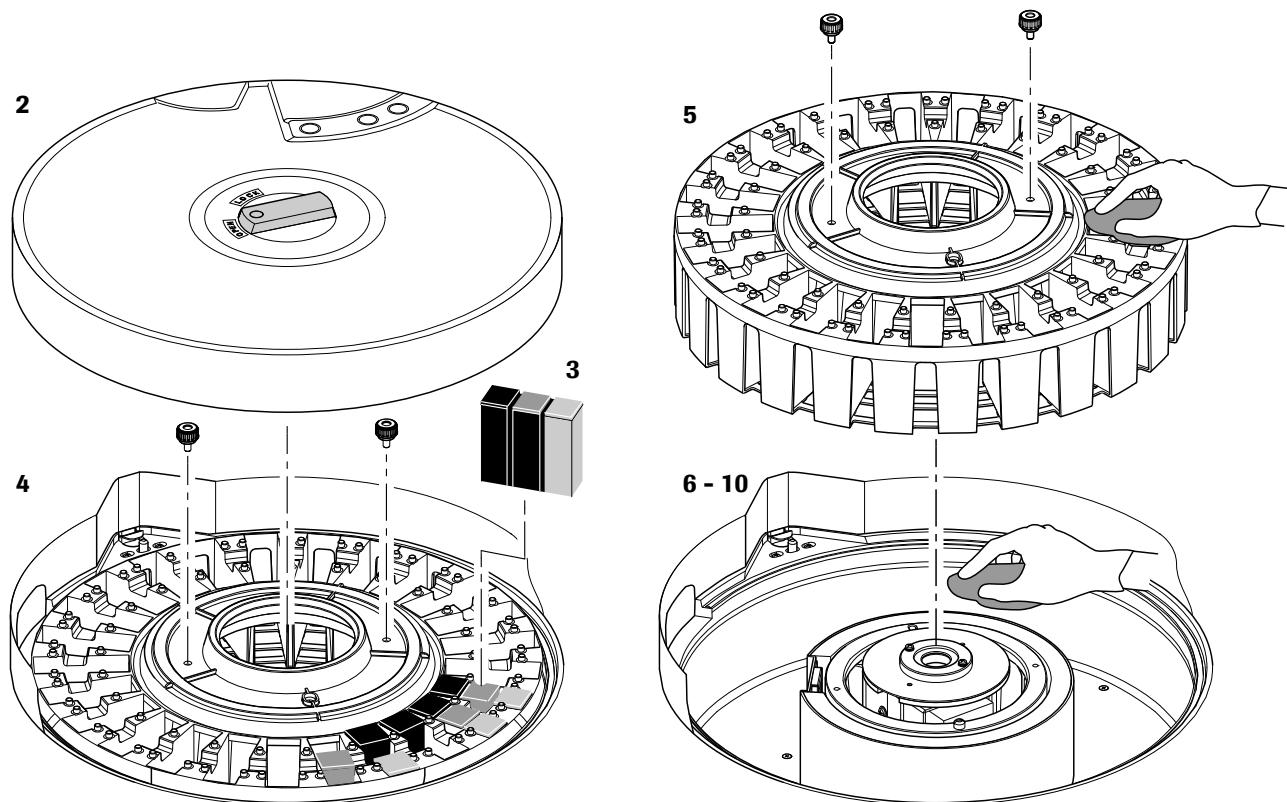


Figure C-64 Cleaning reagent disk and compartment

- 2 Remove the cover from the reagent disk.
- 3 Completely close the **cobas e** pack caps and remove all the **cobas e** packs from the reagent disk.
- 4 Loosen and remove the black thumbscrews.
- 5 Remove the reagent disk from the compartment.
- 6 Wipe the inside and outside of the reagent disk with lint-free gauze squares soaked with deionized water.
- 7 If the disk appears dirty, use lint-free gauze squares soaked with alcohol to clean the disk. Follow with lint-free gauze squares soaked with deionized water.
- 8 Dry the reagent disk with a cloth or lint-free towels. Set the reagent disk aside.



Do not scratch or smear the barcode reader window as this may cause barcode reading errors.

- 9 Wipe the reagent disk compartment with lint-free gauze squares soaked with deionized water.

If the compartment appears dirty, use lint-free gauze squares soaked with alcohol to clean the compartment. Follow with lint-free gauze squares soaked with deionized water.

- 10 Dry the reagent disk compartment with a cloth or lint-free towels.



► **To reinstall reagent disk**

- 1 Return the reagent disk to the compartment. Make sure that the alignment pin on the center plate is aligned with the opening on the disk.
- 2 Securely reinstall the thumbscrews.
- 3 Place the cobas e packs back into the reagent disk.
- 4 Replace the reagent disk cover and lock.



Cleaning solid waste compartment

Check the waste compartment when emptying the solid waste containers. If the compartment is dirty and requires cleaning, follow the procedures below.

Operator time approximately 5 minutes

Materials required

- Lint-free gauze squares
- Laboratory disinfectant (no bleach)
- Deionized water
- WasteLiner M



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
 - *Contamination by waste solution and solid waste* on page C-3
-



CAUTION

Damage to the solid waste compartment

Do not use alcohol or bleach to clean the solid waste compartment as this may damage the compartment.

► **To clean the solid waste compartment**

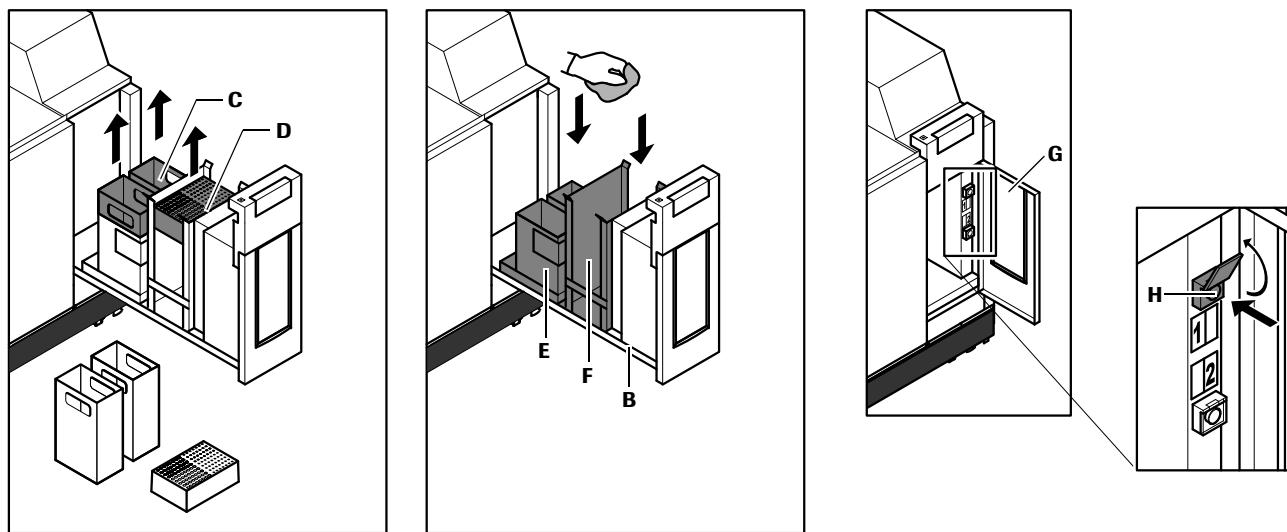
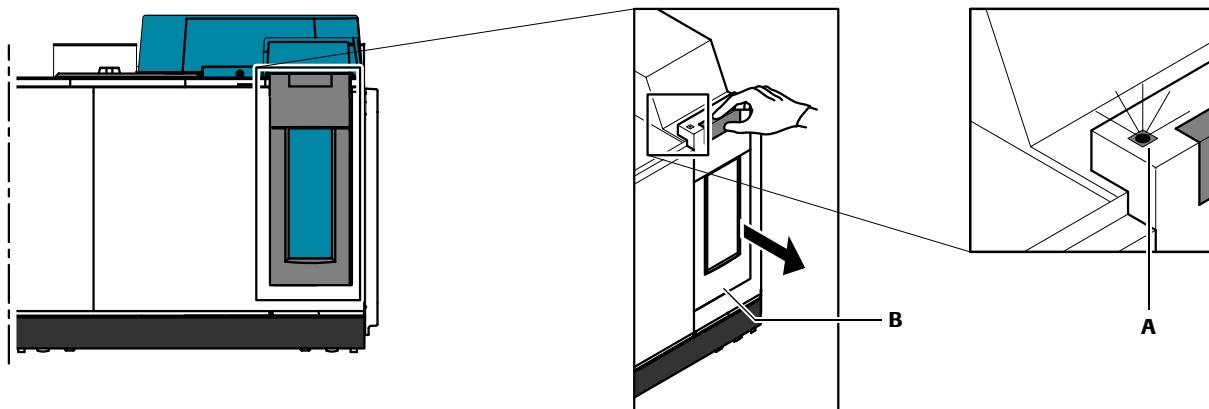
- 1 Choose Start (global button) > Masking > **Module Masking** to display the **Module Masking** screen.
- 2 Select the e 601 module which is to be cleaned and choose **OK**. The selected e 601 module is now masked and goes into **Module Masking**.



Masking a module prior to performing maintenance ensures that the system does not allocate samples to this module and therefore that the module does not operate. In this state, the operator can clean the instrument surface safely.

As needed

- 3** Wait until the green indicator lamp (**A**) on the top of the drawer is illuminated, then open the magazine drawer on the right of the module.

**A** Indicator lamp**B** Magazine drawer**C** WasteLiners**D** Empty magazines**E** Solid waste containers**F** Magazine waste compartment**G** Drawer door**H** Green button (for inventory update)**Figure C-65** Consumables area components

- 4** Open the magazine drawer (**B**) on the right of the module.
- 5** Remove both WasteLiners (**C**) from the solid waste containers and the empty magazines (**D**) from the magazine waste compartment.
- 6** Wipe the inside and outside of the solid waste container (**E**) and the magazine waste compartment (**F**) with lint-free gauze squares soaked with disinfectant.
- 7** Wipe the inside and outside of the solid waste container (**E**) and the magazine waste compartment (**F**) again, this time using lint-free gauze squares soaked with deionized water.



If the area surrounding the waste containers appears to be dirty, it should also be cleaned using the same procedure.

- 8** Place new WasteLiners into the waste containers.

- 9 Close the drawer, ensuring that it is fully closed.
- 10 Open the transparent door (**G**) at the front of the drawer.
- 11 Press the green button (**H**) corresponding to the container(s) emptied to update the inventory. These buttons flash for a moment and then light green.
- 12 Close the door ensuring that it is fully closed.



- Ensure that the door at the front of the drawer is closed. Otherwise, the magazine lifter detects the open door the next time it operates and the system stops.
- The inventory is updated and displayed on the **Reagent Overview** window.

Cleaning instrument surfaces

Spills on the instrument surface could be potentially biohazardous and damage the surface.

Operator time approximately 5 minutes

System time 0 minutes

Materials required

- Cloth or paper towels
- Laboratory disinfectant (no bleach)



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Personal injury due to contact with cleaning solutions or reagents* on page C-4

NOTICE

Damage to the instrument surface

Do not use alcohol or bleach to clean the instrument surfaces as this may damage the finish.

► To clean instrument surfaces

- 1 Choose **Start** (global button) > **Masking** > **Module Masking** to display the **Module Masking** screen.
- 2 Select the **e 601** module you wish to mask and choose **OK**. The selected **e 601** module is now masked and goes into module masking mode.
- 3 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.
- 4 Open the top cover of the module.
- 5 Clean the module surfaces using a cloth or paper towel moistened with disinfectant. Clean up all spills immediately. Use this procedure to ensure that surfaces are clean. If necessary, move the probes or units manually to clean the surface.

As needed

- 6 Close the top cover and lock it with the key.
- 7 Unmask the module at **Start** (global button) > **Masking > Module Masking**.
-

Finalization

Finalization allows the module to stand unused for several hours (for example, overnight). The system is primed with water, the measuring cells are filled with ProCell, and the sipper probes are cleaned with water.

Before going into standby mode, the system automatically performs finalization maintenance. Finalization must be manually initiated if finalization was not performed automatically (due to emergency stop, for example) or did not complete (alarm is issued) and the system will stand unused for several hours.



Always start finalization in combination with reagent prime. Never perform finalization alone.

**WARNING**

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4

► **To perform Reagent Prime**

- 1 Choose **Utility > Maintenance**.
- 2 Choose **(8) Reagent Prime** in the **Maintenance Items** list.
- 3 Choose **Select** to display the **Reagent Prime** window.

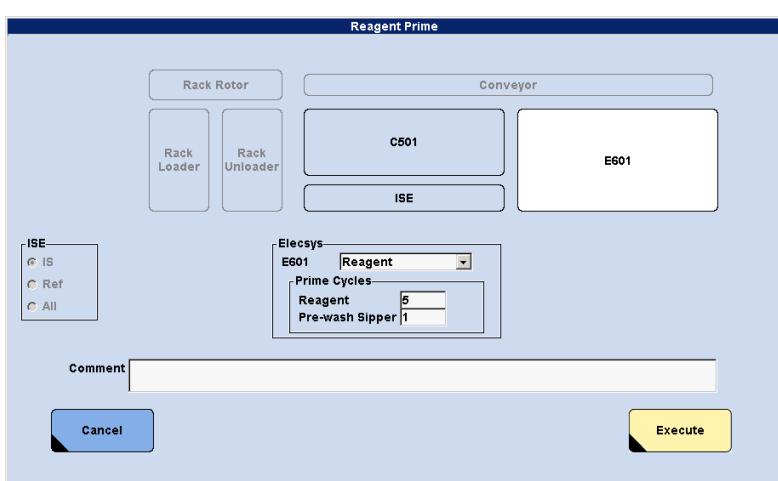


Figure C-66 Reagent Prime window

- 4 Deselect the **c 501** module and select the **e 601** module.
- 5 In the **Elecys** area select **Reagent** from the **e 601** list box. In the **Prime Cycles** area enter 1 for the Reagent.

- 6 Choose **Execute** to start reagent priming.
- 7 Wait until the reagent prime completes and the instrument enters standby, then start finalization.

■

► **To perform Finalization**

- 1 Choose **Utility > Maintenance**.
- 2 Choose (32) Finalization in the **Maintenance Items** list.
- 3 Choose **Select** to display the **Finalization** window.
- 4 Select the appropriate e 601 module and deselect all other modules and units. Selected modules are highlighted in white. Channel 1+2 is activated.
- 5 Choose **Execute** to start finalization.
- 6 After the procedure has been completed, the system goes into standby.

■

As needed

Extended Power OFF procedures

If the system is not used for an extended period of time, it is important to ensure that the system is properly prepared and that the correct shut down maintenance has been performed.

Time period (Days)	Power OFF procedure	Power ON procedure
1 to 2	Power OFF 1	Power ON 1
3 to 7	Power OFF 2	Power ON 2
8 or more	When the instrument was not in use for a period longer than 8 days, call technical support. The necessary procedure is performed by your technical support.	

Table C-28 Extended power OFF procedures

Power OFF procedures



Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Contamination by waste solution and solid waste* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Personal injury due to contact with cleaning solutions or reagents* on page C-4

Power OFF 1 Use this procedure if the instrument will not be in use for 1 to 2 days (e.g., a weekend).

► **Power OFF 1**

- 1 Choose Shut down (global button) to display the **Shut Down** window.
- 2 Select the **Shut Down** option and choose **OK** to confirm the shutdown.
- 3 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.



Damage to the control unit or data loss due to improper switch-off

If power to the analyzer is switched off prior to the complete shutdown of the computer, the instrument may not start up properly when power is supplied again.

Before switch-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

- 4 Switch off the operation power switch on the left side face of the rack sampler unit.
- 5 Turn off the water supply.



Power OFF 2 Use the following procedure if the instrument will not be used for 3 to 7 days.

System time approximately 45 minutes



The maintenance items listed in this procedure can be programmed as a maintenance pipe.

See *Recommended maintenance pipes* on page C-35.

► To perform Liquid Flow Path Cleaning

For a detailed description of this procedure, see *Liquid flow path cleaning* on page C-140

- 1 Open the top cover.
- 2 Fill the SysClean Adapter M with SysClean solution to the lower line (approximately 9 mL/cup).
- 3 Carefully, insert the filled SysClean cups into the position located in front of the sipper unit to be cleaned.
- 4 Close the top cover.
- 5 Choose **Utility > Maintenance**.
- 6 Select **Maintenance** from the **Maintenance Type** list.
- 7 Select **(27) Liquid Flow Cleaning** from the **Maintenance Items** list.
- 8 Choose **Select** to display the **Liquid Flow Path Cleaning** window.
- 9 Select the appropriate e 601 module and deselect all other modules. Selected modules are highlighted in white.
- 10 Select the Ch1,2 option and enter 1 in the Cycles text box and choose **Execute**.



Ensure the system has returned to standby mode before continuing.

► To remove reagents and consumables

- 1 Remove the reagent cover and press the caps of each cobas e pack down to close them. Remove all cobas e packs from the reagent disk(s). Refrigerate them in the same manner as unused cobas e packs. The cobas e packs can be used again.
- 2 Remove all magazines from the magazine lifter, and magazine waste. Ensure that no AssayTips or AssayCups are present on the module.
- 3 Choose **Utility > Maintenance**.
- 4 Select **Check** from the **Maintenance Type** list.
- 5 Select **(14) Magazine Exchange Check** from the **Maintenance Items** list.
- 6 Enter 1 in the cycle text box. A caution alarm is issued because there are no AssayTips or AssayCups available.
- 7 Remove the WasteLiners and replace with fresh ones.
- 8 Remove the ProbeWash, ProCell, CleanCell and PreClean bottles. Replace them with new bottles filled with deionized water.
- 9 Remove the SysClean Adapters from the instrument.



As needed

► **To perform Reagent Prime**

- 1 Choose Utility > Maintenance.
- 2 Choose (8) Reagent Prime in the Maintenance Items list.
- 3 Choose Select to display the Reagent Prime window.

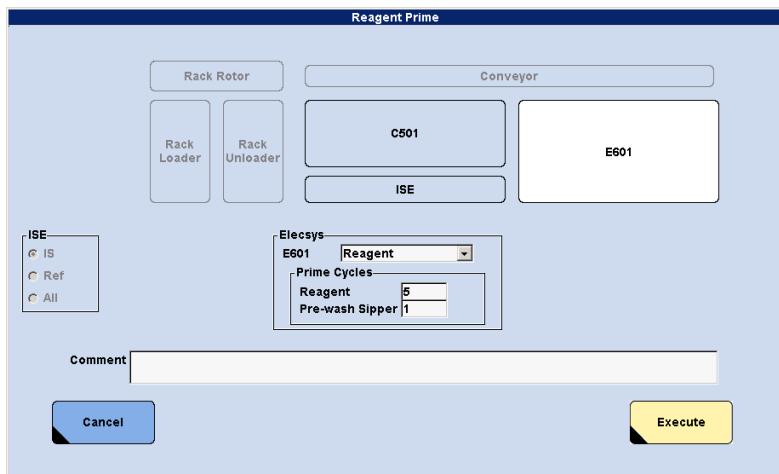


Figure C-67 Reagent Prime window

- 4 Deselect the c 501 module and select the e 601 module.
- 5 In the Elecsys area select **Reagent** from the e 601 list box. In the Prime Cycles area enter 5 for the Reagent.
- 6 Choose **Execute** to start reagent priming.
- 7 Display the Reagent Prime window a second time

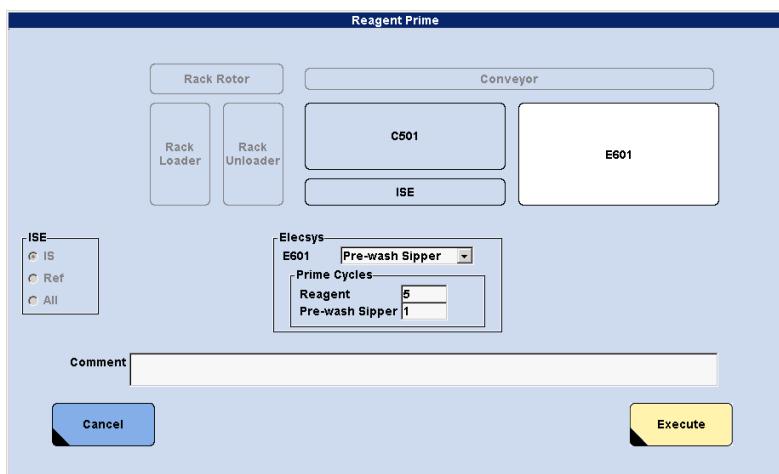


Figure C-68 Reagent Prime window

- 8 In the Elecsys area select **Pre-wash Sipper** from the e 601 list box. In the **Prime Cycles** area enter 5 for the Pre-wash Sipper
- 9 Choose **Execute** to start reagent priming.



► **To empty PC/CC reservoirs**

- 1 Select (33) Empty PC/CC Reservoir from the **Maintenance** Items list on **Utility > Maintenance**. Choose **Select** to display the Empty PC/CC Reservoir window.
- 2 Select the appropriate e 601 module and deselect all other modules. Selected modules are highlighted in white.
- 3 Choose **Execute**. The PC/CC reservoirs are emptied.

■

► **To perform Sipper Air Purge**

- 1 Select (24) Sipper Air Purge from the **Maintenance** Items list on **Utility > Maintenance**. Choose **Select** to display the **Sipper Air Purge** window.
- 2 Select the appropriate e 601 module and deselect all other modules. Selected modules are highlighted in white.
- 3 Enter 10 in the Cycles text box and choose **Execute** to perform the Sipper Air Purge.
- 4 Remove the ProCell and CleanCell reservoir cups.

■

► **To perform daily and weekly maintenance items and finish Power OFF**

- 1 Perform all Daily and Weekly maintenance items excluding Reagent Prime and Finalization.
 - ☞ For more information, see:
Daily maintenance on page C-122
Weekly maintenance on page C-125
- 2 Choose Shut down (global button) to display the **Shut Down** window.
- 3 Select the Shut down option and choose **OK** to confirm the shutdown.
- 4 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.



Damage to the control unit or data loss due to improper switch-off

If power to the analyzer is switched off prior to the complete shutdown of the computer, the instrument may not start up properly when power is supplied again.

Before switch-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

- 5 Switch off the operation power switch on the left side face of the rack sampler unit.
- 6 Turn off the water supply.

■

As needed

Power ON procedures (after Extended Power OFF)



WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page C-3
- *Contamination by waste solution and solid waste* on page C-3
- *Personal injury due to contact with instrument mechanism* on page C-4
- *Personal injury due to contact with cleaning solutions or reagents* on page C-4

Power ON 1

The procedures below correspond to *Power OFF 1*, an extended Power OFF Procedure applied if the instrument will not be in use for 1 to 2 days (for example, a weekend).



The maintenance items listed in this procedure can be programmed as a maintenance pipe.

See *Recommended maintenance pipes* on page C-35.

► To start the system

- 1 Switch on the water supply of the system.
- 2 Switch on the operation power switch, located on the left side of the rack sampler unit.
The analyzer starts the initialization routine (time for c 501, e 601, and control unit approximately 12 min).
- 3 Switch on each power switch of the computer, printer, and monitor. While the analyzer is performing initialization the Logon screen is displayed.
- 4 Enter your Operator ID logon and password to log on.
- 5 Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.
- 6 Perform the maintenance items listed below in the specified order to prepare the System for routine operation.



► **To prepare the system for routine operation**

- 1 Select (37) **System Air Purge (E Module)** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **System Air Purge (E Module)** window.
- 2 Select the Ch1,2 option and enter 5 in the Cycles text box and choose **Execute** to perform this maintenance item 5 times.
- 3 Select (8) **Reagent Prime** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **Reagent Prime** window.

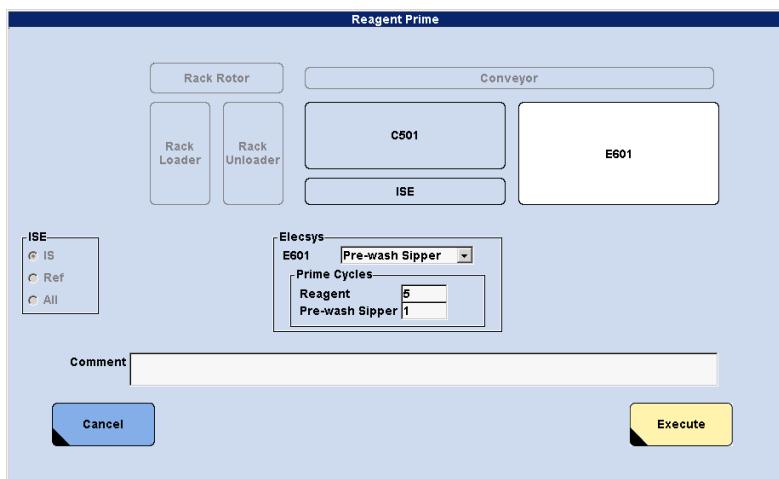


Figure C-69 Reagent Prime window

- 4 In the **Elecsys** area select **Pre-wash Sipper** from the **e 601** list box. In the **Prime Cycles** area enter 5 for the Pre-wash Sipper
- 5 Choose **Execute** to start reagent priming.
- 6 Select (25) **MC Preparation** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **MC Preparation** window.
- 7 Select the Ch1,2 option and enter 5 in the Cycles text box and choose **Execute** to initiate the MC preparation.

The system is now ready for routine operation.



As needed

- Power ON 2** The procedures below correspond to *Power OFF 2*, an extended Power OFF Procedure applied if the instrument will not be used for 3 to 7 days.



The maintenance items listed in this procedure can be programmed as a maintenance pipe.

See *Recommended maintenance pipes* on page C-35.

► **To reload consumables and start the system**

- 1** Return the removed cobas e packs to the reagent disk prior to power ON.
- 2** Discard the ProbeWash, ProCell, CleanCell and PreClean bottles filled with deionized water. Place new ProbeWash, ProCell, CleanCell and PreClean bottles.
 See *Reagent reloading (e 601)* on page B-106.
- 3** Refill magazine lifter and place new ProCell and CleanCell reservoir cups on the instrument.
- 4** Switch on the water supply of the system.
- 5** Switch on the operation power switch, located on the left side of the rack sampler unit.

The analyzer starts the initialization routine. While the analyzer is performing initialization (time for c 501, e 601, and control unit approximately 12 min), the Logon screen is displayed.

- 6** Enter your Operator ID logon and password to log on.
- 7** Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.



Update all system consumables by pressing the corresponding indicator lamps.

- 8** Perform the maintenance items listed below in the specified order to prepare the System for routine operation.



► **To prepare the system for routine operation**

- 1 Select (37) **System Air Purge (E Module)** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **System Air Purge (E Module)** window.
- 2 Select the Ch1,2 option and enter 5 in the Cycles text box and choose **Execute** to perform this maintenance item 5 times.
- 3 Select (8) **Reagent Prime** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **Reagent Prime** window.

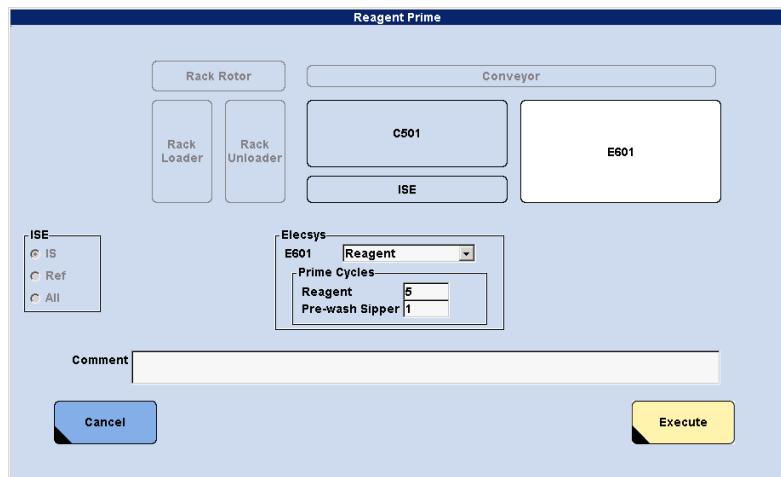


Figure C-70 Reagent Prime window

- 4 Deselect the c 501 module and select the e 601 module.
- 5 In the **Elecsys** area select **Reagent** from the **e 601** list box. In the **Prime Cycles** area enter 5 for the **Reagent**.
- 6 Choose **Execute** to start reagent priming.
- 7 Select (25) **MC Preparation** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **MC Preparation** window.
- 8 Select the Ch1,2 option and enter 30 in the Cycles text box to perform MC preparation 30 times on each channel. Choose **Execute** to initiate the MC preparation.
- 9 Select (8) **Reagent Prime** from the **Maintenance Items** list on **Utility > Maintenance**. Choose **Select** to display the **Reagent Prime** window.
- 10 In the **Elecsys** area select **Pre-wash Sipper** from the **e 601** list box. In the **Prime Cycles** area enter 5 for the **Pre-wash Sipper**.
- 11 Choose **Execute** to start reagent priming.

The system is now ready for routine operation.



As needed

Troubleshooting

D

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Data alarms

This chapter contains the data alarms generated by the **cobas** 6000 system. In addition to a description of the cause of each alarm and remedy, the analytical module of origin and automatic rerun conditions are described here.

In this chapter

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Introduction

If any abnormality occurs while the system is switched on, the system notifies the operator of the potential problem by issuing an alarm. These alarms comprise data alarms (referring to irregular measuring results or conditions) and instrument alarms (referring to irregular system conditions). Alarms are classified into five levels:

<i>Alarm levels</i>	
	Data alarm
	This alarm is attached to the results of calibrations or to measurement results of QC or patient samples. If a data alarm occurs at calibration or QC sample measurement and if it will affect subsequent measurements, an instrument alarm of the warning level occurs at the same time. The analyzer does not stop operation.
	Warning
	This alarm is generated by data alarms or troubles on the instrument. If this alarm occurs during operation, the analyzer does not stop operation. The operator must judge whether to continue or interrupt measurement.
	Sampling stop
	This alarm concerns troubles on the instrument. For the pipetted sample, measurement is continued.
	Stop
	This alarm concerns troubles on the instrument. The analyzer stops operation within one cycle (6 seconds). For the sample under measurement, no result data are obtained and the measurement must be repeated.
	Emergency stop
	This alarm concerns troubles on the instrument. The analyzer immediately stops operation. For the sample under measurement, no result data are obtained and the measurement must be repeated.

Alarm indication

Data alarms are indicated on the **Workplace > Data Review** screen, on the **Test Review** window (**Workplace > Data Review > Test Review**), and on printed reports. If a data alarm occurs, an abbreviation (also referred to as flag) is attached to the measurement result. These flags are strings of three to six characters, which are all explained in this chapter.

Instrument alarms are indicated by the **Alarm** button (global button) on the **System Overview** screen as well as by an audible alarm. If an alarm occurs, the **Alarm** button lights up. Its color indicates the alarm level: Yellow indicates warning level, red indicates sampling stop or emergency stop.

In case of an alarm choose the **Alarm** button to open the **Alarm** window. This window provides an alarm list and descriptions and remedies for each listed alarm.

Automatic rerun

If a data alarm occurs on a test for which automatic rerun is selected (check box on **Utility > Application > Range**), a rerun is automatically requested. For execution of the automatic rerun during measurement, however, automatic rerun needs to be activated on the Start Conditions screen as well.

 For more information, see *Rerun list* on page D-62

For QC and patient samples, a data alarm consists of an alarm message and a result message. The result messages are specific to the cobas 6000 tests.

Data alarm list

The following table displays the data alarms applicable to ISE tests, c 501 tests, e 601 tests, and their presentation (flag) on screens and reports.

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601
>AB	AB level range over (Assay Buffer=ProCell)	-	-	✓
AB.E	AB level check error	-	-	✓
>Abs	ABS over	-	✓	-
ADC.E	ADC abnormal	✓	✓	✓
Cal.E (Sample flag)	Calibration result abnormal (Sample flag)	✓	✓	✓
Calc.?	Calculation not possible	✓	✓	✓
CarOvr	Potential microbeads carry over	-	-	✓
Cell.T	Measuring cell temperature out of range	-	-	✓
ClcT.E	Calculated test error	✓	✓	-
Clot.E	Clot pressure abnormal	-	-	✓
CmpT.?	Unable to calculate compensated test	✓	✓	-
CmpT.E	Data error in compensated test	✓	✓	-
>Curr	Current range over	-	-	✓
Curr.E	Current range check error	-	-	✓
>Cuvet	Cell blank abnormal	-	✓	-
Det.S	Carry over detergent short	-	✓	-
Edited	Edited test	✓	✓	✓
Inc.T	Incubator temperature	-	-	✓
>Index	Serum index check	✓	✓	-
>I.xxx	Serum index check	✓	✓	-
ISE.E	ISE voltage level error	✓	-	-
ISE.N	ISE noise error	✓	-	-
>Kin	Prozone error 2 / Kinetic unstable	-	✓	-
>Lin	Linearity abnormal	-	✓	-
Mix.E	Ultrasonic mixing error	✓	✓	-
<Mix	Mixing power low level	✓	✓	-
Over.E	Overflow	✓	✓	✓
>Proz	Prozone error 1	-	✓	-
Q2.5SD	1-2.5SD (QC error 2)	✓	✓	✓
Q3SD	1-3SD (QC error 1)	✓	✓	✓
R4SD	R-4S (Random error in realtime QC)	✓	✓	✓
>React	Reaction limit over (substrate depletion)	-	✓	-
Reag.Ex	Reagent expired	-	✓	✓
Reag.F	Reagent film detected	-	-	✓
Reag.H	Reagent hovering	-	-	✓
Reag.S	Reagent short	✓	-	✓
Reag.T	Reagent disk temperature	-	-	✓

Table D-1 Data alarm list

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601
>Rept / <Rept	Repeat limit over (upper / lower)	✓	✓	✓
S2-2Sa	2-2SA (Syst. error 1 - 2 results)	✓	✓	✓
S2-2Sw	2-2SW (Syst. error 2 - 2 samples / 4 results)	✓	✓	✓
S4-1Sa	4-1SA (Syst. error 3 - 4 results)	✓	✓	✓
S4-1Sw	4-1SW (Syst. error 4 - 4 samples / 8 results)	✓	✓	✓
S10Xa	10XA (Syst. error 5 - 10 results)	✓	✓	✓
S10Xw	10XW (Syst. error 6 - 10 samples / 20 results)	✓	✓	✓
Samp.?	ABS maximum over (non-lin curve)	-	✓	-
Samp.B	Sample air bubble	-	-	✓
Samp.C	Sample clot	✓	✓	✓
Samp.H	Sample hovering	-	-	✓
Samp.O	Potential carry over during processing of the rerun measurement	-	✓	✓
Samp.S	Sample short	✓	✓	✓
<SigL	Low signal level	-	-	✓
SLLD.E	Sample LLD abnormal	-	-	✓
SLLD.N	Sample LLD noise	-	-	✓
SysR.S	Auxiliary reagent short	-	-	✓
SysR.T	Auxiliary reagent temperature	-	-	✓
<>Test	Sample range over	✓	-	-
>Test / <Test	Upper/Lower technical Limit	✓	✓	✓
WB.S	Washing buffer short (PreClean)	-	-	✓
WB.T	Washing buffer temperature (PreClean)	-	-	✓

Table D-1

Data alarm list

Data alarms c 501 (ISE)

ADC.E

Alarm ADC abnormal

Description The analog/digital converter does not work normally.

Cause Numerical conversion of the electromotive force is abnormal.

- Remedy*
- 1 If other instrument alarm exist, correct those alarms and resume operation.
 - 2 Choose **Utility > Maintenance** and perform maintenance item (1) Reset. If the alarm recurs call technical support.



Calc.?

Alarm Calculation not possible

Description The denominator becomes zero in calculation.

1. During calculation the denominator became zero.
2. An overflow occurred in logarithmic or exponential calculation.
3. Result was left blank.

Cause Internal calculation error has occurred.

- Remedy*
- 1 Check the test that is flagged with an error message in the calculation. Dilute the sample and rerun the sample.
 - 2 Check the calibration type list box on **Utility > Application > Calib.**
 - 3 Resume operation. If alarm recurs, call technical support.



Cal.E (Sample flag)

<i>Alarm</i>	Calibration result abnormal (Sample flag)
<i>Description</i>	No calibration data or previous calibration data used.
	Cal.E appears on each QC and patient sample for the affected test until the problem is resolved.
<i>Cause</i>	Any alarm, for example, Std.E, ISE.E, ISE.N, ..., occurred during calibration.
<i>Remedy</i>	<p>1 Correct the condition causing the alarm that occurred during the latest calibration.</p> <p>2 Recalibrate.</p> <p>■</p>

ClcT.E

<i>Alarm</i>	Calculated test error
<i>Description</i>	Calculation error has occurred.
<i>Cause</i>	A data alarm has occurred for a test needed in the calculation. This is not valid for the following errors and alarms:
	<ul style="list-style-type: none"> • Calculation not possible (Calc.?) • Test-to-test compensation disabled (CmpT.E)
<i>Remedy</i>	<p>1 Correct the data alarm of the test to be used on the calculation.</p> <p>2 Recalibrate.</p> <p>■</p>

CmpT.?

<i>Alarm</i>	Unable to calculate compensated test
<i>Description</i>	During test-to-test compensation calculation, the denominator became zero. Blank space is left in the report.
<i>Cause</i>	<ol style="list-style-type: none"> 1. The test used for test-to-test compensation has not been measured yet. 2. Any test used for test-to-test compensation has data alarm calculation not possible (Calc.?) or test-to-test compensation error (CmpT.E). 3. Any test used in the compensation formula has a data alarm that leaves the result blank (for example, Samp.S, Reag.S).
<i>Remedy</i>	Correct the data alarm of the test to be used for compensation. Rerun the sample.

CmpT.E

Alarm Data error in compensated test

- Description*
1. In test-to-test compensation calculation, a data alarm other than those shown below is indicated for the compensation test data.
 2. Calculation not possible, test-to-test compensation disabled, overflow, random error, systematic error, QC error and outside of expected value.

Cause The test to be used for compensation has a data alarm.

Remedy Correct the data alarm on the test to be used for compensation. Rerun the sample.

Edited

Alarm Edited test

Description An edited first result or replaced rerun result is marked with an *Edited* alarm on the **Data Review** screen. This also prints on the patient report.

Cause The result data has been edited.

Remedy Check the result of measurement.

>Index

Alarm Serum index check

Description The L (lipemic), H (, hemolytic), or I (icteric) result is greater than the specified value (**Utility > Application > Range**).

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

>I.xxx

Alarm Serum index check

Description The L (lipemic), H (hemolytic), or I (icteric) result is greater than the specified value (**Utility > Application > Range**).

Possible >I.xxx alarms are:

- >I.L
- >I.H
- >I.I
- >I.LH
- >I.LI
- >I.HI
- >I.LHI

The combination of L, H, I indicates which serum index value is exceeded. For example, the data alarm >I.LH indicates, that the serum index values of L and H are exceeded.

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

ISE.E

Alarm ISE voltage level error

Description During measurement of internal reference, the EMF was not within the following ranges (ISE IS):

Na⁺	-90.0 to -10 mV
K⁺	-90.0 to -10 mV
Cl⁻	80.0 to 160 mV

- Cause*
- The reference electrode is deteriorated.
 - Insulation is poor due to liquid leakage from the reference electrode mounting section.
 - ISE IS is deteriorated.

- Remedy*
- 1 Set the reagent and perform maintenance item (8) Reagent Prime for the ISE unit.
 - 2 Replace the electrode and perform maintenance item (8) Reagent Prime for the ISE unit.
 - 3 Make sure that the O-ring is attached to the electrode joint and then perform maintenance item (8) Reagent Prime for the ISE unit.
 - 4 Set the internal standard solution properly and perform maintenance item (8) Reagent Prime for the ISE unit.
 - 5 Check that the electrode cords are correctly connected.



ISE.N

Alarm ISE noise error

Description In ISE measurement, the fluctuation in electromotive force exceeds the following value:

Na⁺	0.7 mV
K⁺	1.0 mV
Cl⁻	0.8 mV

- Cause*
- Entry of air bubbles for lack of reagent
 - Entry of air bubbles due to improper attachment of electrode
 - Entry of air bubbles through sipper tube
 - Poor insulation of waste solution block
 - Poor insulation due to liquid leakage from sipper pipetter

- Remedy*
- 1 Check for sufficient reagent volume, make sure the tubing sits correctly in the ISE Ref. bottle, and perform maintenance item (8) Reagent Prime for the ISE unit (All).
 - 2 Make sure that the O-ring is attached to the electrode joint and perform maintenance item (8) Reagent Prime for the ISE unit (All).
 - 3 Replace the sipper tube and perform maintenance item (8) Reagent Prime for the ISE unit (All).
 - 4 Eliminate deposits.
 - 5 Carry out cleaning, checkup, and maintenance of the sipper syringe.



<Mix

Alarm Mixing power low level

For more information, see <Mix on page D-26.

Mix.E

Alarm Ultrasonic mixing error

For more information, see Mix.E on page D-26.

Over.E

<i>Alarm</i>	Overflow
<i>Description</i>	Display is not possible because the output figure exceeds 6 digits
<i>Cause</i>	<ul style="list-style-type: none">The data is obtained in more than six digits including a negative sign and decimal places.
<i>Remedy</i>	<ul style="list-style-type: none">Minimize the difference in concentration between the sample and calibrator.Obtain the result data with six characters including negative sign and decimal places.

Reag.S

<i>Alarm</i>	Reagent short
<i>Description</i>	There is insufficient ISE reagent volume when alarm is associated with sodium, potassium and chloride values.
<i>Cause</i>	There is not enough reagent in the reagent bottle.
<i>Remedy</i>	<ol style="list-style-type: none">Verify adequate reagent volumes. Replace low reagent, as necessary. Prime new reagent and recalibrate.If adequate reagent volumes are present, verify volumes on the Reagent screen. Rerun the sample.Resume operation. If alarm recurs, call technical support.
	■

>Rept / <Rept

<i>Alarm</i>	Repeat limit over (upper / lower)
<i>Description</i>	The result falls outside the repeat limit range programmed on Utility > Application > Range .
<i>Cause</i>	The sample concentration is higher or lower (>Rept / <Rept) than the set value.
<i>Remedy</i>	This alarm can be activated on Utility > System (Page 1/4) > Alarm . If activated, the system can also be programmed to automatically repeat this test with normal sample volume.

Samp.S

Alarm Sample short

Description The liquid level cannot be detected in the sample container.

Cause 1. The sample volume is insufficient in the sample container.

Remedy 1 Add sample and rerun.
2 Resume operation. If alarm recurs, call technical support.



Samp.C

Alarm Sample clot

Description The specified volume of sample is not aspirated.

Cause A clot is detected.

Remedy 1 Perform maintenance item (12) Sample Probe Wash.
2 Check if there are clots in the sample.
3 If necessary remove the clots from the sample and rerun.
4 If alarm recurs, call technical support.



< >Test

Alarm Sample range over

Description If the data is out of the following ranges, Sample range over is issued:

Na⁺ 10-250 mmol/L

K⁺ 1-100 mmol/L

Cl⁻ 10-250 mmol/L

Cause • The electrode is deteriorated.

• The flow path is contaminated.

• Sample concentration is too high or too low.

Remedy 1 Are controls in range?

If Yes, go to 2.

If No, go to 3.

2 Continue with routine analysis. Continue with step 3 at the end of the day.

3 Replace the appropriate cartridge.



Replacing ISE cartridges must only be done by specially trained operators.

☞ For more information refer to the separate maintenance manual:

Interlock function cobas c 501 with ISE.

4 Resume operation.

If alarm recurs, call technical support.



>Test / <Test

Alarm Upper/Lower technical Limit

Description The sample concentration is outside the technical range entered on **Utility > Application > Range**.

- Over the technical limit: Value is greater than the upper limit (>Test).
- Under the technical limit: Value is less than the lower limit (<Test).

Cause Sample concentration is too high or too low.

Remedy 1 Manually dilute and rerun the diluted sample until the measured concentration is within the specified range. Be sure to calculate the original concentration from the measured value, using the correct dilution factor.

In case of urine samples with a >Test alarm, a manual rerun can be performed with decreased volume (6.5 µL instead of normal volume).

2 Perform maintenance item (12) Sample Probe Wash.

3 Clean the outside of the sample probe manually.

If alarm recurs, call technical support.



Data alarms c 501 (P)

>Abs

Alarm ABS over

Description The absorbance value to be used for calculation after cell blank correction exceeded 33000.

- Cause*
- The sample concentration is too high or the sample is lipemic.
 - The reagent has not been stored or handled properly.
 - Obstructions are in the optical path of the photometer.

- Remedy*
- If only one sample is affected: Check whether the sample is grossly lipemic or has an extremely high value. Follow your laboratory protocol for this situation.
 - If only one application is affected: Check reagent storage and handling for that test.
 - If all samples are affected:
 - Remove any obstructions in the optical path of the photometer. Make sure the lamp is on.
 - Choose **Utility > Maintenance** and perform maintenance item (5) Incubation Water Exchange
 - Clean the incubator bath if it is contaminated.
 - ⦿ For further instructions, see:
Replacing reaction cells on page C-86
Cleaning the incubator bath on page C-87
 - Choose **Utility > Maintenance** and perform maintenance item (3) Photometer Check.
 - Check the Photometer Check results on the printout (Abs < 14000).
 - Replace the photometer lamp, if necessary.
 - Resume operation. If alarm recurs, call technical support.
 - If all samples are affected intermittently:
 - If any reaction cell is scratched, replace the cell.
 - ⦿ For further instructions, see:
Replacing reaction cells on page C-86
Cleaning the incubator bath on page C-87

ADC.E

Alarm ADC abnormal

Description The analog-digital converter does not work normally.

- Cause*
1. Numerical conversion is abnormal.
 2. The cell count is abnormal.

Remedy 1 If other instrument alarms exist, correct those alarms and resume operation.

2 Choose **Utility > Maintenance** and perform maintenance item (1) Reset.

3 If the alarm recurs, remove the reaction disk and check for water droplets or dust on sensors. Clean if necessary.

4 If the alarm recurs call technical support.



Calc.?

Alarm Calculation not possible

Description The denominator becomes zero in calculation.

- During calculation the denominator became zero.
- An overflow occurred in logarithmic or exponential calculation.
- Result was left blank.

Cause Internal calculation error has occurred.

Remedy 1 Check the test that is flagged with an error message in the calculation. Dilute the sample and rerun the sample.

2 Check the calibration type list box on **Utility > Application > Calib.**

3 Resume operation. If alarm recurs, call technical support.



ClcT.E

<i>Alarm</i>	Calculated test error
<i>Description</i>	Calculation error has occurred.
<i>Cause</i>	A data alarm has occurred for the test needed in the calculation. This is not valid for the following data alarms: <ul style="list-style-type: none">• Calculation not possible (Calc.?)• Test-to-test compensation disabled (Calc.?)
<i>Remedy</i>	<ol style="list-style-type: none">1 Correct the data alarm of the test to be used on the calculation.2 Recalibrate. <p>■</p>

Cal.E

<i>Alarm</i>	Calibration result abnormal (Sample flag)
<i>Description</i>	No calibration data or previous calibration data used.  Cal.E appears on each QC and patient sample for the affected test until the problem is resolved.
<i>Cause</i>	Any alarm (for example, Std.E) occurred during calibration.
<i>Remedy</i>	<ol style="list-style-type: none">1 Correct the condition causing the alarm that occurred during the latest calibration.2 Recalibrate. <p>■</p>

CmpT.?

<i>Alarm</i>	Unable to calculate compensated test
<i>Description</i>	During test-to-test compensation calculation, the denominator became zero. Blank space is left in the report.
<i>Cause</i>	<ol style="list-style-type: none">1. The test used for test-to-test compensation has not been measured yet.2. Any test used for test-to-test compensation has data alarm calculation not possible (Calc.?) or test-to-test compensation error (CmpT.E).3. Any test used in the compensation formula has a data alarm that leaves the result blank (for example, Samp.S, Reag.S).
<i>Remedy</i>	Correct the data alarm of the test to be used for compensation. Rerun the sample.

CmpT.E

<i>Alarm</i>	Compensation Error Between Tests
<i>Description</i>	<ol style="list-style-type: none">1. In test-to-test compensation calculation, a data alarm for the compensation test data is indicated.2. Calculation not possible, test-to-test compensation disabled, overflow, random error, systematic error, QC error and outside of expected value.
<i>Cause</i>	The test to be used for compensation has a data alarm.
<i>Remedy</i>	Correct the data alarm on the test to be used for compensation. Rerun the sample.

>Cuvet

<i>Alarm</i>	Cell blank abnormal
<i>Description</i>	The cell blank value used for measurement exceeds the reference value by more than 0.1Abs.
<i>Cause</i>	Reaction cells are contaminated or damaged.
<i>Remedy</i>	<ol style="list-style-type: none">1 Check that the reaction cell is not contaminated or cracked.2 Choose Utility > Maintenance and perform maintenance item (7) Wash Reaction Parts.3 Ensure that there is no excessive foaming or particles in the incubator bath.4 Wipe the outside of the reaction cells with a gauze pad moistened with incubator bath water.5 Resume operation. If alarm recurs, ensure there is adequate rinse water and cell blank water from the rinse mechanism. The cells must be completely filled.6 Choose Utility > Maintenance and perform maintenance item (5) Incubation Water Exchange7 Resume operation. If alarm recurs, choose Utility > Maintenance and perform maintenance item (4) Cell Blank Measurement.<ul style="list-style-type: none">• If cells are out of specification, replace the cells.• If the results for the first cell are greater than 14000 or if the deviation of the cells is ± 1000 or more, replace the cells and repeat the cell blank measurement. ☞ For further instructions, see: <i>Replacing reaction cells</i> on page C-86 <i>Cleaning the incubator bath</i> on page C-878 Resume operation. If alarm recurs, call technical support.

Det.S

<i>Alarm</i>	Carry over detergent short
<i>Description</i>	If a special wash for the reagent probe is defined, the reagent probe immerses into the specified detergent cassette. This alarm occurs, if the test is carried out even though the detergent volume is insufficient.
<i>Cause</i>	The residual volume of the special wash detergent is insufficient.
<i>Remedy</i>	<ol style="list-style-type: none">1 Load a new detergent cassette.2 Check the results of the measurement and rerun the sample if necessary.
	■

Edited

<i>Alarm</i>	Edited test
<i>Description</i>	An edited first result or replaced rerun result is marked with an <i>Edited</i> alarm on the Data Review screen. This also prints on the patient report.
<i>Cause</i>	The result data has been edited.
<i>Remedy</i>	Check the result of measurement.

>Index

<i>Alarm</i>	Serum index check
<i>Description</i>	The L (lipemic), H (, hemolytic), or I (icteric) result is greater than the specified value (Utility > Application > Range).
	The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.
<i>Cause</i>	A highly lipemic, hemolytic, or icteric sample has been measured.
<i>Remedy</i>	Check the result of measurement.

>I.xxx

Alarm Serum index check

Description The L (lipemic), H (hemolytic), or I (icteric) result is greater than the specified value (**Utility > Application > Range**).

Possible >I.xxx alarms are:

- >I.L
- >I.H
- >I.I
- >I.LH
- >I.LI
- >I.HI
- >I.LHI

The combination of L, H, I indicates which serum index value is exceeded. For example, the data alarm >I.LH indicates, that the serum index values of L and H are exceeded.

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

>Kin

Alarm Prozone error 2 / Kinetic unstable

Description The prozone check value exceeds the specified limit value. (Reaction rate method)

Cause

- The sample concentration is too high. The monotone kinetic check value exceeds the specified limit for other tests.
- The limit value is not set properly.

Remedy

- 1 Dilute and rerun the sample or rerun the sample with a decreased sample volume.
- 2 To avoid check, set [0] [0] [0] [0] [0] [Inside] [0] [0] for Prozone Limit (on **Utility > Application > Analyze**).



>Lin

Alarm Linearity abnormal

Description In rate assay, the reaction linearity exceeds the specified limit value.

- Cause*
- The photometer lamp is deteriorated.
 - The linearity check value is not set properly.
 - The sample is extremely lipemic.
 - The ultrasonic mixers are defective.
 - Debris are in the incubator bath.

Remedy

- 1 Check the photometer lamp.

- 2 Dilute and rerun the sample.

- 3 Choose **Utility > Application > Analyze** to check the Linearity Limit.

- 4 Choose **Utility > Maintenance > Check** (on **Maintenance Type** list) and perform maintenance check (7) Cuvette Mixing to check the ultrasonic mixing mechanisms.

- 5 Ensure the incubator bath is free of debris. Clean the incubator bath, if necessary.

☞ See *Cleaning the incubator bath* on page C-87.

- 6 Resume operation. If alarm recurs, call technical support.



Mix.E

Alarm Ultrasonic mixing error

Description There is no ultrasonic output for mixing.

- Cause*
- The water level in the incubator bath is too low.
 - The water level sensor of the incubator bath is abnormal.

Remedy Supply water to the incubator bath.

<Mix

Alarm Mixing power low level

Description The ultrasonic monitor value is lower than the reference value.

- Cause*
- The ultrasonic mixer is deteriorated.

Remedy

- 1 Clean the surface of the ultrasonic mixers.

☞ See *Cleaning the ultrasonic mixers* on page C-98.

- 2 Call technical support.



Over.E

Alarm Overflow

Description Display is not possible because the output figure exceeds 6 digits

- Cause*
- The K factor has more than six digits due to the use of a wrong calibrator decimal place.
 - The data is obtained in more than six digits including a negative sign and decimal places.

- Remedy*
- Reduce the number of decimal places used for the calibrator 1.
 - Obtain the result data with six characters including negative sign and decimal places.

>Proz

Alarm Prozone error 1

Description The prozone check value exceeds the specified limit value. (Antigen readdition method)

- Cause*
- The sample concentration is too high for immunological test.
 - The limit value is not set properly.

- Remedy*
- 1 Check the reagent preparation.
 - 2 Dilute and rerun the sample or rerun the sample with decreased sample volume.
 - 3 Choose **Utility > Application > Analyze** to check the upper prozone limit.
 - 4 Resume operation. If the alarm recurs, call technical support.



>React

Alarm Reaction limit over (substrate depletion)

Description In a rate assay, the rate of change in main wavelength absorbance exceeds the specified limit value.

- Cause*
- The sample concentration is too high.
 - The reagent has been prepared improperly or deteriorated.
 - On **Utility > Application > Analyze** there is an improper setting in the Increase/Decrease box in the Abs. Limit line.

- Remedy*
- 1 Verify the setting in the Increase/Decrease box on **Utility > Application > Analyze**.
 - 2 Dilute and rerun the sample or rerun the sample with a decreased sample volume.
 - 3 Prepare the reagent newly.



ReagEx

<i>Alarm</i>	Reagent expired
<i>Description</i>	The alarm indicates that an expired reagent was used; the test result is not guaranteed. The alarm can be inactivated under Utility > System > Alarm .
<i>Cause</i>	The system detected an expired reagent onboard the analyzer.
<i>Remedy</i>	<ol style="list-style-type: none">1 Check the Reagent Overview screen for expired reagents. ☞ For more information, see <i>Reagent Overview</i> button on page B-115.2 Exchange expired reagents.
	■

>Rept / <Rept

<i>Alarm</i>	Repeat limit over (upper / lower)
<i>Description</i>	The result falls outside the repeat limit range programmed on Utility > Application > Range .
<i>Cause</i>	The sample concentration is higher (>Rept) or lower (<Rept) than the set value.
<i>Remedy</i>	This alarm can be activated on Utility > System (Page 1/4) > Alarm . If activated, the system can also be programmed to automatically repeat this test with normal sample volume.

Samp.?

<i>Alarm</i>	ABS maximum over (non-lin curve)
<i>Description</i>	The absorbance of a sample is found equal or greater than the theoretical maximum absorbance (for infinite analyte concentration). The result field will be left blank on the report and Data Review screen. This blank result is transmitted, together with the alarm code "46" to the Host.
<i>Cause</i>	The sample concentration is too high.
<i>Remedy</i>	Dilute the sample, if required, and rerun. If automatic rerun is programmed, the sample will be rerun with a decreased sample volume.

Samp.C

<i>Alarm</i>	Sample clot
<i>Description</i>	The specified volume of sample is not aspirated.
	☞ For more information, see <i>Samp.C</i> on page D-17.

Samp.O

<i>Alarm</i>	Potential carry over during processing of the rerun measurement
<i>Description</i>	If a sample probe wash is defined for a photometric test and this test is requested for a sample that has been already measured, the Samp.O flag is attached to the test result. ☞ For information about defining a sample probe wash for photometric tests, see <i>Sample probe wash</i> on page B-238
<i>Cause</i>	Required measurement condition does not correspond to sample probe wash configuration for this test.
<i>Remedy</i>	Repeat measurement with a new sample aliquot.

Samp.S

<i>Alarm</i>	Sample short
<i>Description</i>	The liquid level cannot be detected in the sample container. ☞ For more information, see <i>Samp.S</i> on page D-17.

>Test / <Test

<i>Alarm</i>	Upper/Lower technical Limit
<i>Description</i>	The sample concentration is outside the technical range entered on Utility > Application > Range . <ul style="list-style-type: none">• Over the technical limit: Value is greater than the upper limit (>Test).• Under the technical limit: Value is less than the lower limit (<Test).
<i>Cause</i>	Sample concentration is too high or too low.
<i>Remedy</i>	<ol style="list-style-type: none">1 Manually dilute and rerun the diluted sample until the measured concentration is within the specified range. Be sure to calculate the original concentration from the measured value, using the correct dilution factor.2 Perform maintenance item (12) Sample Probe Wash.3 Clean the outside of the sample probe manually. <p>If alarm recurs, call technical support.</p> <p>■</p>

Data alarms e 601 module

>AB

<i>Alarm</i>	AB level range over (Assay Buffer=ProCell)
<i>Description</i>	During run preparation, the ProCell signal level is out of range.
<i>Cause</i>	ProCell is evaporated or may be contaminated.
<i>Remedy</i>	Check for air bubbles in the ProCell reservoir. Replace with a new ProCell bottle.

AB.E

<i>Alarm</i>	AB level check error
<i>Description</i>	The ProCell level check failed.
<i>Cause</i>	ProCell liquid level check failed. The ProCell Volume is inadequate for run preparation.
<i>Remedy</i>	Replace the low volume bottle with a new bottle.

ADC.E

<i>Alarm</i>	ADC abnormal
<i>Description</i>	The analog-digital converter does not work normally.
<i>Cause</i>	<ul style="list-style-type: none">• Numerical conversion is abnormal.• The cell count is abnormal.
<i>Remedy</i>	<ol style="list-style-type: none">1 If other instrument alarms exist, correct those alarms and resume operation.2 Choose Utility > Maintenance and perform maintenance item (1) Reset.3 If the alarm recurs, remove the reaction disk and check for water droplets or dust on sensors. Clean if necessary.4 If the alarm recurs call technical support.
	■

Calc.?

Alarm Calculation not possible

Description The denominator becomes zero in calculation.

Cause Internal calculation error occurred.

Remedy Rerun the sample.

Cal.E (Sample flag)

Alarm Calibration result abnormal (Sample flag)

Description No calibration data or previous calibration data used.

 *Cal.E* appears on each QC and patient sample for the affected test until the problem is resolved.

Cause

- There is no valid calibration stored in the system.
- The attempted calibration has failed.

Remedy

- 1 Correct the condition causing the alarm that occurred during the latest calibration.
- 2 Repeat the calibration.
- 3 Replace with new calibrators and a **cobas e** pack. Repeat the calibration.

■

CarOvr

Alarm Potential microbeads carry over

Description The signal level of this sample is low.

Cause Microbeads carry over from the previous sample may have occurred.

Remedy

- Rerun the sample.

Exception: Do not rerun the sample if either qualitative assays are negative or quantitative assays are below the lower limit of the clinical decision.

■

Cell.T

<i>Alarm</i>	Measuring cell temperature out of range
<i>Description</i>	Measuring cell temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.
<i>Cause</i>	<ul style="list-style-type: none">The reagent disk cover is open. Radiation of heat does not work normally.The room temperature is out of range.
<i>Remedy</i>	<ol style="list-style-type: none">Verify the temperature of ProCell/CleanCell. Check the fans at the rear part of the module are operating normally and are free of obstructions.Check that room temperature is between 18°C and 32°C (64,4°F and 89,6°F). <p>■</p>

Clot.E

<i>Alarm</i>	Clot pressure abnormal
<i>Description</i>	In checking of the pressure sensor, overflow data is detected.
<i>Cause</i>	There are air bubbles in the water flow tube.
<i>Remedy</i>	<p>Choose Utility > Maintenance and perform maintenance item (23) Pipettor Air Purge (10 cycles).</p> <p>Resume measurement. If the alarm recurs, contact the technical support.</p>

>Curr

<i>Alarm</i>	Current range over
<i>Description</i>	The measuring cell current is out of range when checked during run preparation.
<i>Cause</i>	Abnormal measuring cell condition. <ul style="list-style-type: none">There are air bubbles in the ProCell reservoir.The electrode of the measuring cell is contaminated or deteriorated.
<i>Remedy</i>	<ol style="list-style-type: none">Check for air bubbles in the ProCell reservoir. Replace with a new ProCell bottle.Choose Utility > Maintenance and perform maintenance item (27) Liquid Flow Cleaning. <p>■</p>
	During operation: <ol style="list-style-type: none">Choose Utility > Maintenance and perform maintenance item (25) MC Preparation (10 cycles).Rerun the sample. If alarm recurs immediately, call technical support. <p>■</p>

Curr.E

<i>Alarm</i>	Current range check error
<i>Description</i>	The measuring cell current check failed.
<i>Cause</i>	ProCell liquid level check failed. The ProCell Volume is inadequate for run preparation.
<i>Remedy</i>	Replace the low volume bottle with a new bottle.

Edited

<i>Alarm</i>	Edited test
<i>Description</i>	An edited first result or replaced rerun result is marked with an <i>Edited</i> alarm on the Data Review screen. This also prints on the patient report.
<i>Cause</i>	The result data has been edited.
<i>Remedy</i>	Check the result of measurement.

Inc.T

<i>Alarm</i>	Incubator temperature
<i>Description</i>	Incubator temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.
<i>Cause</i>	<ul style="list-style-type: none">• Radiation of heat does not work normally.• The room temperature is out of range
<i>Remedy</i>	<ol style="list-style-type: none">1 Check the fans at the back of the module are operating normally and are free of obstructions.2 Check that room temperature is between 18°C and 32°C (64,4°F and 89,6°F). <p>■</p>

Over.E

<i>Alarm</i>	Overflow
<i>Description</i>	Display is not possible because the output figure exceeds 7 digits
<i>Cause</i>	<ul style="list-style-type: none">• The display of the data result is not possible due to more than 7 digits.
<i>Remedy</i>	<ul style="list-style-type: none">• Check the decimal places of the target value of the calibrator 1.• Repeat the calibration.

ReagEx

<i>Alarm</i>	Reagent expired
<i>Description</i>	The alarm indicates that an expired reagent was used; the test result is not guaranteed. The alarm can be inactivated under Utility > System > Alarm .
<i>Cause</i>	The system detected an expired reagent onboard the analyzer.
<i>Remedy</i>	<ol style="list-style-type: none">1 Expired reagents are listed on the reagent unload list with the ReagEx alarm.2 Exchange expired reagents.
	■

Reag.F

<i>Alarm</i>	Reagent film detected
<i>Description</i>	The reagent probe detects a film or air bubbles on the reagent.
<i>Cause</i>	There are bubbles in the reagent bottle.
<i>Remedy</i>	Remove bubbles with an applicator stick.

Reag.H

<i>Alarm</i>	Reagent hovering
<i>Description</i>	The reagent probe hovers over the reagent disk.
<i>Cause</i>	A premature LLD signal is detected during reagent pipetting.
<i>Remedy</i>	<ol style="list-style-type: none">1 Dry the lids on the affected cobas e pack. Check for bubbles in the affected cobas e pack.2 Choose Utility > Maintenance and perform maintenance item (1) Reset.
	■

Reag.T

Alarm Reagent disk temperature

Description Reagent disk temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

- Cause*
- Radiation of heat does not work normally.
 - The room temperature is out of range.

Remedy

- 1 Verify that the reagent disk cover is securely in place.
- 2 Check the fans at the back of the module are operating normally and are free of obstructions.
- 3 Check that room temperature is between 18°C and 32°C (64,4°F and 89,6°F).



Reag.S

Alarm Reagent short

Description The liquid level cannot be detected in the **cobas e** pack.

- Cause*
- There is no reagent in the **cobas e** pack.
 - The lead wire for the liquid level sensor is disconnected.

Remedy

- 1 Replace with a new **cobas e** pack.
- 2 Connect the lead wire.



>Rept / <Rept

Alarm Repeat limit over (upper / lower)

Description The result is larger than the specified upper limit value (>Rept) or smaller than the lower limit value (<Rept).

- Cause*
- The sample concentration is higher than the set value (>Rept).
 - The sample concentration is lower than the set value (<Rept).
 - An improper repeat limit range is specified.

Remedy

- 1 Rerun the sample and check the measured value. Or rerun the sample with its dilution.
- 2 Rerun the sample and check the measured value.
- 3 Specify a proper range for Repeat Limit (test parameter).



Samp.B

Alarm Sample air bubble

- Description*
- The sample probe detects air bubbles on the sample.
 - Air bubble is detected in the sample syringe flow path when the sample is aspirated.



While pipetting samples, the e 601 module checks if there are bubbles on the surface of the sample liquid. This check, however, is performed only if the pipetting volume is more than 10 µL.

- Cause*
- There are bubbles in the sample container.
 - There are air bubbles in the water flow tube.

- Remedy*
- 1 Remove bubbles from sample tube with an applicator stick.
 - 2 Choose **Utility > Maintenance** and perform maintenance item (6) Air Purge (10 cycles).



Samp.C

Alarm Sample clot

Description A sample clot is detected during aspiration.

- Cause*
- The sample volume is insufficient.
 - There are clots in the sample.

- Remedy*
- 1 Fill the required volume in the sample container.
 - 2 Check sample for fibrin. Remove any clots.



Samp.H

Alarm Sample hovering

Description The sample probe hovers over the sample.

Cause A premature LLD signal is detected during sample pipetting.

- Remedy*
- 1 Check for bubbles in the sample.
 - 2 Choose **Utility > Maintenance** and perform maintenance item (1) Reset.



Samp.O

- Alarm* Potential carry over during processing of the rerun measurement
- Description* If a sample probe wash is defined for a e 601 test and this test is requested for a sample that has been already measured, the Samp.O flag is attached to the test result.
☞ For information about defining a sample probe wash for photometric tests, see *Sample probe wash* on page B-242
- Cause* Required measurement condition does not correspond to sample probe wash configuration for this test.
- Remedy* Repeat measurement with a new sample aliquot.

Samp.S

- Alarm* Sample short
- Description* The liquid level cannot be detected in the sample container.
- Cause* The sample volume is insufficient in the sample container.
- Remedy* **1** Add sample and rerun.
2 Resume operation.
3 If alarm recurs, call technical support.
■

<SigL

- Alarm* Low signal level
- Description* The signal level is extraordinarily low.
- Cause* • The volume of the reaction mixture in the AssayCup is insufficient
• Reaction mixture contain clots
- Remedy* • Rerun the sample
- Cause* • Extremely high sample concentration for a competitive assay
- Remedy* • Rerun manually diluted sample.
- Cause* • Abnormal MC condition of detection unit (sipper/tubing/MC)
- Remedy* • If alarm recurs, call technical support.

SLLD.E

Alarm Sample LLD abnormal

Description The sample probe does not start LLD or LLD is not completed.

Cause

1. The tip of the sample probe is dirty.
2. The tip of the sample probe is wet.

Remedy

- 1 Clean the tip of the sample probe and resume measurement. If the alarm recurs, call technical support.
- 2 Dry the tip of the sample probe and resume measurement. If the alarm recurs, call technical support.

**SLLD.N**

Alarm Sample LLD noise

Description The sample probe detects air bubbles on the sample.

Cause

1. The sample volume is insufficient.
2. There are bubbles in the sample container.

Remedy

- 1 Check sample volume.
- 2 Remove the bubbles with an applicator stick.

**SysR.S**

Alarm Auxiliary reagent short

Description The counted remaining number becomes 0, liquid short signal is detected, or the liquid level cannot be detected in the ProCell reservoir.

Cause There is no reagent in the reagent bottle.

Remedy Replace with new ProCell/CleanCell bottles.

Sys.R.T

<i>Alarm</i>	Auxiliary reagent temperature
<i>Description</i>	ProCell/CleanCell temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.
<i>Cause</i>	<ol style="list-style-type: none"> 1. Radiation of heat does not work normally. 2. The room temperature is out of range.
<i>Remedy</i>	<ol style="list-style-type: none"> 1 Check the fans at the rear part of the module are operating normally and are free of obstructions. 2 Check that room temperature is between 18°C and 32°C (64,4°F and 89,6°F). <p>■</p>

>Test / <Test

<i>Alarm</i>	Upper/Lower technical Limit
<i>Description</i>	<ul style="list-style-type: none"> • Upper technical limit exceeded: The measured value is higher than the measuring range (>Test) coded in the cobas e pack barcode. • Lower technical limit exceeded: The measured value is lower than the measuring range (<Test) coded in the cobas e pack barcode.
<i>Cause</i>	<ul style="list-style-type: none"> • The sample concentration is above the upper limit of the measuring (reportable) range (>Test). • The sample concentration is below the lower limit of the measuring (reportable) range (<Test).
<i>Remedy</i>	<ol style="list-style-type: none"> 1 If >Test, rerun using the recommended dilution and check the measured value. 2 If <Test, report the result as less than the lower detection limit of the assay. Rerun is not requested. <p>■</p>

WB.S

<i>Alarm</i>	Washing buffer short (PreClean)
<i>Description</i>	The remaining volume for PreClean is 0, or liquid short signal is detected.
<i>Cause</i>	There is no reagent in the reagent bottle.
<i>Remedy</i>	Replace with a new PreClean bottle.

WB.T

Alarm Washing buffer temperature (PreClean)

Description PreClean temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

- Cause*
1. Radiation of heat does not work normally.
 2. The room temperature is out of range.

Remedy

- 1 Check the fans at the rear part of the module are operating normally and are free of obstructions.
- 2 Check that room temperature is between 18°C and 32°C (64,4°F and 89,6°F).



Data alarms for calibrations

The following table displays all calibration data alarms applicable to ISE tests, c 501 tests, e 601 tests, and their presentation (flag) on screens and reports.

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601
Cal.E	CALIB error (Calib flag – c 501 (ISE))	✓	–	–
Cond.E	Conditioning (ISE) abnormal	✓	–	–
Diff.E	Minimum acceptable difference	–	–	✓
Dup.E	Duplicate error (c 501)	–	✓	✓
IStd.E	Internal standard concentration abnormal	✓	–	–
Mono.E	Monotony of curve	–	–	✓
Prep.E	Preparation abnormal	✓	–	–
Rsp1.E	Response (ISE) abnormal 1	✓	–	–
Rsp2.E	Response (ISE) abnormal 2	✓	–	–
S1A.E	S1ABS abnormal	–	✓	–
SD.E	SD limit error	–	✓	–
Sens.E	Sensitivity error	–	✓	–
>Sig	Maximum signal	–	–	✓
<Sig	Minimum signal	–	–	✓
Sig.E	Minimum/Maximum signal	–	–	✓
Slop.E	ISE slope abnormal	✓	–	–
Std.E	Standard error	✓	✓	–
Sys.E	System error	–	–	✓

Table D-2

Data alarm list

Cal.E

Alarm CALIB error (Calib flag – c 501 (ISE))

Displayed in **Calibration > Status > Calibration Trace**.

Description The current calibrator concentration value or slope value differs from the previous one by more than the specified Compensated Limit. The Compensated Limit is a limit for the difference | previous value – current value | expressed as percentage of the average (previous value + current value)/2.



The Cal.E alarm is a warning only, not necessarily indicative of a problem with the calibration. Check the test's control recovery before accepting the new calibration result.

Cause

- The standard solution or reagent is not placed in proper position.
- The reagent has deteriorated or the standard solution has become concentrated due to evaporation.

Remedy

- Correct any other instrument and/or data alarms.
- Check standards, reagents, and controls. If controls are in range, and standards and reagents are acceptable, resume operation. Otherwise, correct abnormalities and recalibrate.
- Check Compensated Limit on **Utility > Application > Calib**.

Cond.E

Alarm Conditioning (ISE) abnormal

Description The slope value is 68.1 mV or greater for Na⁺ or K⁺ electrodes, or it is -68.1 mV or less for the Cl⁻ electrode. The conditioning is inadequate.

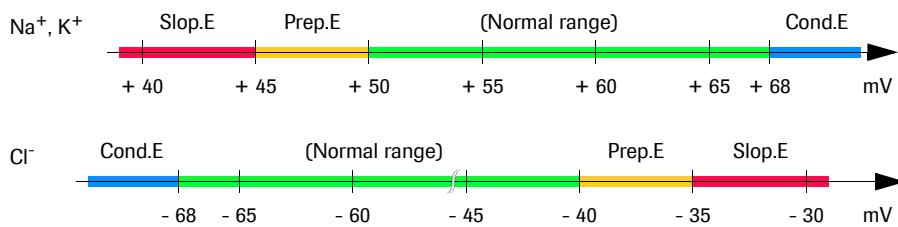


Figure D-1 ISE data alarms and corresponding slope values (EMF values)

Cause

- Conditioning of a new electrode is unsatisfactory.
- The concentration of standard solution LOW/HIGH is improper.

Remedy

- Run 10 dummy samples of human serum.
- Pour fresh calibrator ISE Low [Std(1)], ISE High [Std(2)], and ISE Comp. [Std (3)], place on calibration rack and recalibrate the ISEs.
For US only, ISE High (compensated) is used instead of ISE Comp.
- Resume operation. If alarm recurs, call technical support.



Diff.E

<i>Alarm</i>	Minimum acceptable difference
<i>Description</i>	The difference of the signals between each level of calibrators is below the permissible value.
<i>Cause</i>	<ul style="list-style-type: none">• The ProCell or calibrator is expired.• The calibrator does not reach room temperature.
<i>Remedy</i>	<ol style="list-style-type: none">1 Replace ProCell.2 Set the calibrator appropriately. <p>■</p>

Dup.E

<i>Alarm</i>	Duplicate error (c 501)
	Displayed in Calibration > Status > Calibration Trace .
<i>Description</i>	The difference between the first and second measurement (absorbance) of a calibrator is outside the specified range. The following steps describe how a decision is made to flag a calibration for violating the duplicate limit. <ol style="list-style-type: none">1. The absorbance for a calibrator (N) is measured twice.2. The % of error and absorbance error are computed.3. Is the absorbance error < Duplicate Limit Abs. that appears on Utility > Application? If no, go to step 5. If yes, go to step 4.4. Continue with result calculations. No Dup.E alarm is issued.5. Is the % error < the % Duplicate Limit? If no, go to step 6. If yes, go to step 4.6. Dup.E alarm is issued for this result.
<i>Cause</i>	The difference between the first and second measurement (absorbance) of a calibrator is greater than Duplicate Limit Abs and greater than the % Duplicate Error.
<i>Remedy</i>	<ol style="list-style-type: none">1 Recalibrate.2 Check reagent storage, handling and expiration date. Replace the reagent if necessary and recalibrate.3 If alarm recurs, call technical support.
	If this alarm occurs, a Std.E alarm is issued. The Std.E alarm prevents updating of calibration for the affected test.

Dup.E

Alarm Duplicate error (e 601)

Displayed in **Calibration > Status > Calibration Result**.

Description The difference between the first and second measured signal of the calibrator is out of the range specified in the assay.

- Cause*
- Air was aspirated during the first determination due to air bubbles on the corresponding calibrator. During the second determination no air was aspirated.
 - Consequence: The signal values of the first and second determination differ more than the specified percentage.

Remedy

- 1 Verify that there are not air bubbles on the surface of the calibrator and perform a new calibration.



IStd.E

Alarm Internal standard concentration abnormal

Displayed on **Calibration > Status > Calibration Trace**

Description The concentration of the internal standard solution (ISE IS) was not within the following ranges:

Na⁺ 120.0-160.0 mmol/L

K⁺ 3.0-7.0 mmol/L

Cl⁻ 80.0-120.0 mmol/L

- Cause*
- The flow path is contaminated.
 - The reagent has deteriorated.

Remedy

- 1 If the EMF of ISE IS is abnormal on the calibration report, check the ISE IS reagent volume. If necessary, perform a reagent prime and recalibrate.
- 2 If the EMF of ISE IS is normal on the calibration report, check ISE reagent syringe. The EMF of ISE IS lies ideally midway between the low and the high standard. The ideal ISE IS concentrations values are: Na⁺: 140 mmol/L; K⁺: 5 mmol/L; Cl⁻: 100 mmol/L.
- 3 Resume operation. If alarm recurs, call technical support.
- 4 Perform maintenance item (8) Reagent Prime for the ISE unit to wash the flow path.
- 5 Replace the internal standard solution and recalibrate.



Mono.E

<i>Alarm</i>	Monotony of curve
<i>Description</i>	The working curve is not monotonically increasing or monotonically decreasing.
<i>Cause</i>	<ul style="list-style-type: none"> • The ProCell or calibrator is expired. • The calibrator did not reach room temperature.
<i>Remedy</i>	<ol style="list-style-type: none"> 1 Replace ProCell. 2 Place the calibrator appropriately. <p>■</p>

Prep.E

<i>Alarm</i>	Preparation abnormal
	Displayed on Calibration > Status > Calibration Trace .
<i>Description</i>	The slope value is within the following range: 45.0 to 49.9 mV for Na ⁺ or K ⁺ electrodes, -39.9 to -35.0 mV for the Cl ⁻ electrodes.

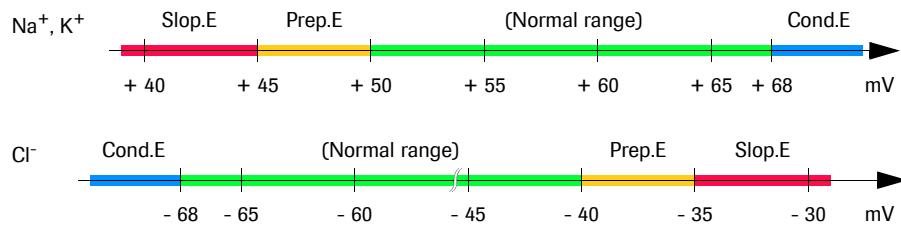


Figure D-2 ISE data alarms and corresponding slope values (EMF values)

<i>Cause</i>	<ul style="list-style-type: none"> • The electrode is deteriorated. • The flow path is contaminated.
<i>Remedy</i>	<ol style="list-style-type: none"> 1 Replace the electrode.



Replacing ISE cartridges must only be done by specially trained operators.

☞ For more information refer to the separate maintenance manual:
Interlock function cobas c 501 with ISE.

<i>2</i>	Perform maintenance item (8) Reagent Prime to prime the lines.
	■

Rsp1.E

Alarm Response (ISE) abnormal 1

Description The compensation factor is over the limits (narrower range).

- Cause*
- The flow path is contaminated.
 - The electrode is contaminated or deteriorated.

- Remedy*
- 1 Check ISE controls for correct levels.
 - 2 If incorrect, go to step 3 before continuing routine analysis. If correct, go to step 3 after finishing routine analysis at the end of the day.
 - 3 Choose **Utility > Maintenance** and perform maintenance item (19) System Wash for ISE to wash the flow path.
 - 4 Run 10 dummy samples of human serum.
 - 5 Prepare fresh calibrator; place on calibration rack and recalibrate the ISEs.
 - 6 Resume operation. If alarm recurs, repeat steps 3 through 5 a maximum of two times. If alarm recurs, replace the ISE cartridges.



Rsp2.E

Alarm Response (ISE) abnormal 2

Description The compensation factor is over the limits (wider range).

- Cause*
- The flow path is contaminated.
 - The electrode is contaminated or deteriorated.

- Remedy* See Rsp1.E on page D-46.

S1A.E

Alarm S1ABS abnormal

Displayed in **Calibration > Status > Calibration Trace**.

Description During calibration, expected absorbance is outside the S1 Abs Limit. S1 is read bichromatically for endpoint assays, monochromatically for rate assays.

- Cause*
- The reagent has been stored or handled improperly or has deteriorated.
 - An improper absorbance range is specified for calibrator 1.

Remedy

- 1 Check reagent storage and handling and calibrator preparation, if applicable.
- 2 Recalibrate.
- 3 Check S1 Abs. Limit values on **Utility > Application > Calib**.
- 4 Resume operation. If alarm recurs, call technical support.



SD.E

Alarm SD limit error

Description During nonlinear or multipoint linear calibration, the SD value was larger than the SD limit programmed on **Utility > Application**.



The result of the calibration is not updated.

- Cause*
- The calibrator is not placed at a correct position.
 - An improper SD limit value is specified.

Remedy

- 1 Check calibrator positions on **Calibration > Calibrator**
- 2 Choose **Utility > Application > Calib**. to check the SD limit.
- 3 Check reagent storage and handling and calibrator preparation. Recalibrate the affected test.
- 4 Check the standard concentrations on **Calibration > Install**. For a calibration with automatic standard dilution; check whether the ratio between concentration, sample, diluent volume and diluted sample is correct on **Utility > Application > Others**.
- 5 Resume operation. If alarm recurs, call technical support.



Sens.E

Alarm Sensitivity error

Sensitivity is checked for linear (2 to 6 points), nonlinear, or isozyme-P calibration. This alarm is indicated if the sensitivity value obtained in a calibration falls out of the sensitivity limits specified on **Utility > Application > Calib.**

A sensitivity value is calculated from the measured absorbance values (*Abs*) and given concentration values (*Conc*) of the blank calibrator (S_1) and the calibrator S_N :

$$|Abs(S_N) - Abs(S_1)| / |Conc(S_N) - Conc(S_1)|, \text{ where}$$

S_N = Std 2 for 2 Point calibrations and span calibrator for multipoint calibrations



For span calibration, the previous S1 Abs (linear) or previous mean absorbance (nonlinear) of calibrator (1) is used for the sensitivity check.

Cause • The calibrator is not placed at a proper position.

- The reagent has been prepared improperly or has deteriorated.

An improper sensitivity limit is specified.

Remedy 1 Check preparation and expiration dates of calibrators and reagents. Recalibrate the affected test.

2 Check sample pipetter for leaks and recalibrate the affected test.

3 Choose **Utility > Application > Calib.** to check the sensitivity limit and recalibrate the affected test.

4 Resume operation. If alarm recurs, call technical support.



>Sig

Alarm Maximum signal

Description The calibrator signal is larger than the specified upper limit value coded in the **cobas e** pack barcode. Only for qualitative assays.

Cause • The ProCell calibrator is expired.

- The calibrator does not reach room temperature.

Remedy 1 Replace ProCell.

2 Place the calibrator appropriately.



<Sig

Alarm Minimum signal

Description The calibrator signal is lower than the specified lower limit value coded in the cobas e pack barcode. For qualitative and quantitative assays.

- Cause*
- The ProCell or calibrator is expired.
 - The calibrator does not reach room temperature.

Remedy **1** Replace ProCell.

2 Place the calibrator appropriately.



Sig.E

Alarm Minimum/Maximum signal

Description The measured signal of a calibrator for a qualitative test should fall between the designated minimum and maximum signal. If one or more values falls out of the allowable minimum/maximum signal range, the calibration fails.

- Cause* The measured signal of a calibrator for a qualitative test lies outside the designated minimum/maximum signal range.

Remedy **1** Check the calibrators and reagents and repeat the calibration.

2 Set new calibrators and a cobas e pack if necessary, and repeat calibration.



Slop.E

Alarm ISE slope abnormal

Displayed on **Calibration > Status > Calibration Trace**.

Description The slope value is less than 45.0 mV for Na⁺ or K⁺ electrodes, or greater than -35 mV for the Cl⁻ electrode.

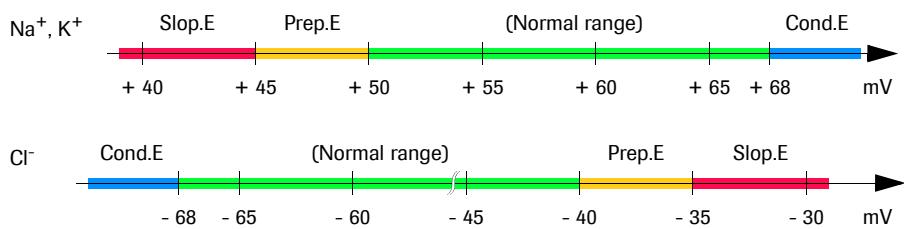


Figure D-3 ISE data alarms and corresponding slope values (EMF values)

- Cause**
- The electrode is deteriorated.
 - Standard solutions Low and High are not placed in the proper positions.
 - The sample probe is clogged.

- Remedy**
- 1 Replace the appropriate ISE cartridge before continuing routine analysis.



Replacing ISE cartridges must only be done by specially trained operators.

☞ For more information refer to the separate maintenance manual:
Interlock function cobas c 501 with ISE.

- 2 Run 10 dummy samples of human serum.
- 3 Prepare fresh calibrator; place on calibration rack and recalibrate the ISEs.
- 4 Resume operation. If alarm recurs, call technical support.



Std.E**c 501 (ISE)**

Alarm Standard error

Description 1. During ISE calibration, any one of the following alarms was encountered:

Data alarm	Data flag
ADC abnormal	ADC.E
Calculation not possible	Calc.?
ISE voltage level error	ISE.E
ISE noise error	ISE.N
Mixing power low level	<Mix
Ultrasonic mixing error	Mix.E
Sample short	Samp.S

Table D-3 Data alarms giving rise to an Std.E alarm when occurring in calibration

2. During calibration, calculation was disabled.



The calibration is not updated if this alarm is issued; i.e. the prior calibration remains in effect.

- Cause*
- The reagent is empty and has to be replaced.
 - The concentration of calibrator is improper or the calibrator is not placed in the proper position.
 - An improper check value is specified.

- Remedy*
- 1 Correct any other instrument and/or data alarms.
 - 2 Prepare fresh calibrator; place on the rack and recalibrate.
 - 3 Replace reagent, prime, and recalibrate.
 - 4 Choose **Utility > Application** to check the calibration parameters.
 - 5 Resume operation. If alarm recurs, call technical support.



c 501 (P)

Alarm Standard error

- Description* 1. During photometric calibration, any one of the following alarms was encountered:

Data alarm	Data flag
ABS over	>Abs
ADC abnormal	ADC.E
Calculation not possible	Calc.?
Cell blank abnormal	>Cuvet
Duplicate error (c 501)	Dup.E
Linearity abnormal	>Lin
Mixing power low level	<Mix
Ultrasonic mixing error	Mix.E
Prozone error 1, Prozone error 2 / Kinetic unstable	>Proz, >Kin ^(a)
Reaction limit over (substrate depletion)	>React
Reagent short	Reag.S
S1ABS abnormal	S1A.E
Sample short	Samp.S

Table D-4 Data alarms giving rise to an Std.E alarm when occurring in calibration

(a) Not for Std.1

2. During calibration, calculation was disabled.
3. During nonlinear calibration, an extreme value appeared.



The calibration is not updated if this alarm is issued; i.e. the prior calibration remains in effect.

- Cause*
- The reagent has not been stored or handled properly or is empty and has to be replaced.
 - The concentration of calibrator is improper or the calibrator is not placed in the proper position.
 - An improper check value is specified.

Remedy 1 Correct any other instrument and/or data alarms.

2 Prepare fresh calibrator; place on the rack and recalibrate.

3 Replace reagent and recalibrate.

4 Choose **Utility > Application** to check the calibration parameters.

5 Resume operation. If alarm recurs, call technical support.



Sys.E

Alarm System error

Description An error occurs on the system during measurement.

Cause Check the **Alarm** screen.

Remedy Eliminate problems with the instrument, referring to the **Alarm** screen.

Data alarms for controls

Q3SD

Alarm 1-3SD (QC error 1)

Description In Realtime QC, the control X or control Y data value is above 3 SD or below -3 SD.

- Cause*
- Reagent is deteriorated
 - Poor precision due to leakage of the pipetter joint
 - Proper control values (mean value, standard deviation) are not specified.



This check is performed only when RULE 1-3 SD is selected.

- Remedy*
- 1 Check that calibrators, controls and reagents are properly prepared, positioned, and stored.
 - 2 Check that the mean and SD for the specified assays are entered correctly on **QC > Install**.
 - 3 Check that calibrator values are correct, if available, on **Calibration > Install**.
 - 4 Register a new reagent cassette or **cobas e pack**.
 - 5 Check the pipetter (**Maintenance Check**).



Q2.5SD

Alarm 1-2.5SD (QC error 2)

Description In Realtime QC, the control X value or control Y data value is above 2.5 SD or below -2.5 SD.

- Cause*
- The reagent is deteriorated (linearity of working curve degraded).
 - One control is concentrated or deteriorated.



This check is performed only when RULE 1-2.5SD is selected.

- Remedy*
- 1 Register new reagent cassette or replace with a new **cobas e pack**.
 - 2 Prepare a new control. Prepare control X together with control Y and use them for a given period of time.



R4SD

Alarm R-4S (Random error in realtime QC)

Description On Realtime QC, one of X and Y data values is above 2 SD and the other is below -2 SD.

- Cause*
- The control X and control Y are not set at proper positions.
 - Reagent is deteriorated.



This check is performed only when RULE R-4SD is selected. N = run size entered on **Select Rules** window.

Remedy

- 1 Check that calibrators, controls, and reagents are properly prepared and stored.
- 2 Check that calibrators and controls are properly positioned on the system.
- 3 Check proper lot number and expiration dates of calibrators, controls and reagents.
- 4 Check that the mean and SD for the specified assay are entered correctly on **QC > Install**.
- 5 Check that calibrator values are correct on **Calibration > Install**.
- 6 Resume operation. If alarm recurs, call technical support.



S2-2Sa

Alarm 2-2SA (Syst. error 1 - 2 results)

Description The control X and Y values are above 2 SD or below -2 SD.

- Cause*
- The calibrators or controls are not properly prepared.
 - The controls are not properly positioned on the system.



This check is performed only when RULE 2-2SD is selected.

Remedy

- 1 Check that calibrators, controls, and reagents are properly prepared and stored.
- 2 Check that calibrators and controls are properly positioned on the system.
- 3 Check proper lot number and expiration dates of calibrators, controls and reagents.
- 4 Check that the mean and SD for the specified assay are entered correctly on **QC > Install**.
- 5 Check that calibrator values are correct on **Calibration > Install**.
- 6 Resume operation. If alarm recurs, call technical support.



S2-2Sw

Alarm 2-2SW (Syst. error 2 - 2 samples / 4 results)

Description The last two control X or last two control Y values were above 2 SD or below -2 SD.

- Cause*
- The calibrators or controls are not properly prepared.
 - The reagents are not properly prepared.



This check is performed only when RULE 2-2SD is selected.

Remedy See *Remedy* of S2-2Sa on page D-55.

S4-1Sa

Alarm 4-1SA (Syst. error 3 - 4 results)

Description On realtime QC the last two X and Y data values are above +1 SD or below -1 SD.

- Cause*
- The calibrators or controls are not properly prepared.
 - The reagents are not properly prepared.



This check is performed only when RULE 4-1SD is selected.

Remedy See *Remedy* of S2-2Sa on page D-55.

S4-1Sw

Alarm 4-1SW (Syst. error 4 - 4 samples / 8 results)

Description The last four control X or last four control Y values are above 1 SD or below -1 SD.

- Cause*
- The calibrators or controls are not properly prepared.
 - The reagents are not properly prepared.



This check is performed only when RULE 4-1SD is selected.

Remedy See *Remedy* of S2-2Sa on page D-55.

S10Xa

Alarm 10XA (Syst. error 5 - 10 results)

Description On realtime QC the last five X and Y data values fall on the + or - side of the mean value.

- Cause*
- The calibrators or controls are not properly prepared.
 - The reagents are not properly prepared.



This check is performed only when RULE 10X is selected.

Remedy See *Remedy* of S2-2Sa on page D-55.

S10Xw

Alarm 10XW (Syst. error 6 - 10 samples / 20 results)

Description The last 10 control X or last 10 control Y values are positive-above the mean value or negative-below the mean value.

- Cause* The mean value specified for one control is improper.



This check is performed only when RULE 10X is selected.

Remedy See *Remedy* of S2-2Sa on page D-55.

Data problems without alarm

Drift of result data

- Cause*
- Concentration or deterioration of sample
 - The calibrator is concentrated or deteriorated.
 - The reagent flow path is contaminated. (ISE unit)
- Remedy*
- 1 Avoid leaving the sample in the sample cup for a long time.
 - 2 Perform maintenance item (19) System Wash.
-

Erroneous operation

- Cause*
- Neglect of preliminary or periodical check(s).
 - Carryover between tests.
 - Fibrin contained in sample or dust contained in reagent.
 - The sample container that was used, was not recommended.
- Remedy*
- 1 Carry out preliminary and/or periodical check according to the specified procedure.
 - 2 Change the channel, use the wash program, or take any other measure after consulting with the reagent manufacturer.
 - 3 Eliminate fibrin or dust. Be sure to check the sample and reagent before setting them.
 - 4 Perform maintenance item (12) Sample Probe Wash.
 - 5 Use the recommended sample container.
-

Poor reproducibility

- Cause*
- A maintenance item is overdue.
 - Deterioration of reagent or precipitation of insoluble matter.
 - Deterioration of ProCell, CleanCell, or PreClean.
 - Poor deionized water quality.
 - Reagent handling was not done as recommended.
 - Test parameters are not set properly.
- Remedy*
- 1 Carry out daily checks and periodical maintenance according to the specified maintenance procedure.
 - 2 Replace with a new reagent cassette or cobas e pack. Do not add or mix old and new reagent.
 - 3 Replace with new ProCell/CleanCell or PreClean bottles.
 - 4 The water quality must be 1 µS/cm (microsiemens per cm) or less.
 - 5 Use the recommended reagent handling.
 - 6 Check the completeness of the special wash list. If necessary, install the special wash list according to the recommendation of the manufacturer.
 - 7 Check the application setting of the Open/Close mode in **Utility > Application > Range**. The usage of the Cap Open/Close mode *open upon pipetting* is recommended for all tests in order to guarantee a maximum reagent stability.



Result data at high level

- Cause*
- Concentration of control or sample.
 - Deterioration of calibrator.
 - Deterioration of ProCell or CleanCell (e 601).
 - The reagent, control and standard handling was not done as recommended.
- Remedy*
- 1 Avoid leaving the sample or control in the sample cup for long time.
 - 2 Avoid leaving the calibrator cup open for a long time.
 - 3 Replace with new ProCell/CleanCell bottles.
 - 4 Use the recommended reagent, control and calibrator handling.



Result data at low level

- Cause*
- Concentration of calibrator.
 - Reagent storage or handling was not done as recommended.
 - The test parameters are not set properly.
 - Deterioration of ProCell or CleanCell (e 601).
- Remedy*
- 1 Use the calibrator immediately after opening the cap of the vial.
 - 2 Replace the reagent.
 - 3 Set the concentration of calibrator properly (not for e 601).
 - 4 Replace with new ProCell/CleanCell bottles.
-

Trouble attributed to characteristics of reagent

- Cause*
- Cross contamination (high value, low value)
 - Coloring matter adheres to the reaction cell.
- Remedy*
- 1 Perform maintenance item (7) Wash Reaction Parts.
 - 2 Check whether the special wash list is complete. Install the special wash list according to the recommendations of the manufacturer.
☞ *Special Wash* on page B-234
-

Trouble for each test

- Cause*
- Improper preparation or management of calibrator or control (high value, low value).
 - Improper management of reagent (low value).
- Remedy*
- 1 Prepare a new calibrator or control.
 - 2 Replace with a new reagent cassette or **cobas e** pack.
 - 3 Set the test parameters properly according to the setting table given by the reagent manufacturer.
-

Trouble on each analytical module

- Cause*
- Air bubbles in the sample or reagent syringe (poor reproducibility).
 - Liquid leakage from sample or reagent syringe (poor reproducibility).
 - Deterioration of ProCell, CleanCell, or PreClean (e 601).

- Remedy*
- 1 Carry out maintenance and inspection.
 - 2 Replace with new ProCell/CleanCell or PreClean bottles.

■

Trouble on each channel in same module

- Cause*
- Air bubbles in the sipper syringe (poor reproducibility).
 - Liquid leakage from sipper syringe (poor reproducibility).
 - The electrode of the measuring cell is contaminated or deteriorated (high value or low value).

- Remedy*
- 1 Call technical support.
 - 2 Perform maintenance item (27) Liquid Flow Cleaning according to the specified procedure.

■

Rerun list

The following table indicates whether a rerun is automatically *requested* by the system when a data alarm is attached to a result. The rerun conditions are displayed under c 501 (ISE unit, Photometric unit) and e 601 module, respectively. The automatic rerun column indicates whether a rerun is automatically *performed* by the system.

 For more information on performing reruns, see *Processing reruns* on page B-56

Increase	Sample is rerun at an increased sample volume
Normal	Sample is rerun at same sample volume (repeat)
Decrease	Sample is rerun at a decreased sample volume
No rerun	No rerun is performed on this module

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601	Auto rerun
>AB	AB level range over (Assay Buffer=ProCell)	-	-	Normal	Yes
AB.E	AB level check error	-	-	Normal	Yes
>Abs	ABS over	-	Decrease	-	Yes
ADC.E	ADC abnormal	Normal	Normal	Normal	Yes
Cal.E	Calibration result abnormal (Sample flag)	Normal	Normal	Normal	No
Calc.?	Calculation not possible	Normal	Normal	Normal	Yes
CarOvr	Potential microbeads carry over	-	-	Normal	Yes
Cell.T	Measuring cell temperature out of range	-	-	Normal	Yes
ClcT.E	Calculated test error	No rerun	No rerun	-	No
Clot.E	Clot pressure abnormal	-	-	Normal	Yes
CmpT.?	Unable to calculate compensated test	Normal	Normal	-	Yes
CmpT.E	Data error in compensated test	Normal	Normal	-	Yes
>Curr	Current range over	-	-	Normal	Yes
Curr.E	Current range check error	-	-	Normal	Yes
>Cuvet	Cell blank abnormal	-	Normal	-	Yes
Det.S	Carry over detergent short	-	Normal	-	No
Edited	Edited test	No rerun	No rerun	No rerun	No
Inc.T	Incubator temperature	-	-	Normal	Yes
>Index	Serum index check	No rerun	No rerun	-	No
>I.xxx	Serum index check	No rerun	No rerun	-	No
ISE.E	ISE voltage level error	Normal	-	-	Yes
ISE.N	ISE noise error	Normal	-	-	Yes
>Kin	Prozone error 2 / Kinetic unstable	-	Decrease	-	Yes
>Lin	Linearity abnormal	-	Normal	-	Yes
Mix.E	Ultrasonic mixing error	Normal	Normal	-	Yes
<Mix	Mixing power low level	Normal	Normal	-	Yes
Over.E	Overflow	No rerun	No rerun	No rerun	No
>Proz	Prozone error 1	-	Decrease	-	Yes

Table D-5 Rerun list (Sheet 1 of 2)

(a) For urine: Decrease sample volume can only be requested manually.

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601	Auto rerun
>React	Reaction limit over (substrate depletion)	-	Decrease	-	Yes
ReagEx	Reagent expired	-	No rerun	No rerun	No
Reag.F	Reagent film detected	-	-	Normal	Yes
Reag.H	Reagent hovering	-	-	Normal	Yes
Reag.S	Reagent short	Normal	Normal	Normal	No
Reag.T	Reagent disk temperature	-	-	Normal	Yes
>Rept / <Rept	Repeat limit over (upper / lower)	Normal	Normal	Normal	Yes/No due to setting
Samp.?	ABS maximum over (non-lin curve)	-	Decrease	-	Yes
Samp.B	Sample air bubble	-	-	Normal	Yes
Samp.C	Sample clot	Normal	Normal	Normal	No
Samp.H	Sample hovering	-	-	Normal	Yes
Samp.O	Potential carry over during processing of the rerun measurement	-	Normal	Normal	Yes
Samp.S	Sample short	Normal	Normal	Normal	No
<SigL	Low signal level	-	-	Normal	Yes
SLLD.E	Sample LLD abnormal	-	-	Normal	Yes
SLLD.N	Sample LLD noise	-	-	Normal	Yes
SysR.S	Auxiliary reagent short	-	-	Normal	Yes
SysR.T	Auxiliary reagent temperature	-	-	Normal	Yes
<>Test	Sample range over	Normal	-	-	Yes
>Test	Upper/Lower technical Limit	For urine: Decrease (a) For other sample types: Normal	Decrease	Decrease	c 501: Yes e 601: Yes
< Test	Upper/Lower technical Limit	Normal	Increase	No rerun	c 501: Yes e 601: No
WB.S	Washing buffer short (PreClean)	-	-	Normal	Yes
WB.T	Washing buffer temperature (PreClean)	-	-	Normal	Yes

Table D-5 Rerun list (Sheet 2 of 2)

(a) For urine: Decrease sample volume can only be requested manually.

Rerun list

Troubleshooting

This chapter provides general information about troubleshooting problems on the cobas 6000 system.

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General troubleshooting

This chapter provides general information about troubleshooting problems on the cobas 6000 system.

Troubleshooting procedures

To identify and isolate problems effectively, you must understand the theory of operation, operating procedures, emergency procedures and test reaction descriptions covered in this manual. The following areas are covered:

- | | |
|-----------------------------|---|
| <i>Application problems</i> | <ul style="list-style-type: none">• Photometric, immunoassay or ISE• Reagents• Samples, controls or calibrators• Operator error. |
| <i>Instrument problems</i> | <ul style="list-style-type: none">• Electrical/electronic• Mechanical• Operator error |
| <i>Computer problems</i> | <ul style="list-style-type: none">• Problems during download procedure, incorrect parameters• System parameter reading• Operator error |
| <i>Facility problems</i> | <ul style="list-style-type: none">• Heat• Humidity• Power supply• Water supply• Drain |

Operator's primary responsibility

- Reagent, calibrator and control preparation and storage
- Sample preparation
- Instrument mechanical alignments and adjustments
- Computer parameters and general computer input/output operations
- Basic component replacement
- Basic operator technique, including computer operation
- Maintenance



The basic operator is not responsible for troubleshooting electrical problems except as covered in this part of the Operator's Manual: Do not attempt removal of printed circuit boards unless specifically instructed to do so by your local technical support.

When troubleshooting, observe and record the alarms and isolate the problem to the area denoted by the alarms. In many cases, you may be able to find the problem, correct it and then resume processing. The remainder of this chapter provides instructions and guidelines to aid in isolating problems.

Calling technical support

If it becomes necessary to consult technical support to troubleshoot a test or instrument problem, be prepared with the following information:

- ⦿ The items are divided into the following categories:

Chemistry problem on page D-68

Immunoassay problem on page D-68

Instrument problem on page D-68

Chemistry problem

- account number/customer ID number
- instrument serial number
- module type, serial number, and software version
- test(s) affected and other tests on board
- special wash programming
- description of the problem including relevant alarm(s) and alarm code numbers
- catalog number, lot numbers and expiration dates of reagents
- catalog number, lot numbers and expiration dates of calibrators and controls
- lot number of ISE cartridges
- calibration absorbance values from the last few calibrations performed
- control results from the last few controls performed
- patient results (with correlation results, if relevant)
- **Reaction Monitor** report for affected test(s).

Immunoassay problem

- account number/customer ID number
- instrument serial number and software version
- module serial number
- if problem module or channel specific
- one assay or more assays affected and other assays on board
- special wash programming
- description of the problem including relevant alarm(s) and alarm code numbers
- when problem first occurred
- catalog numbers, lot numbers and expiration dates of reagents
- catalog numbers, lot numbers and expiration dates of calibrators and controls
- calibration results from the last few calibrations performed
- control results from the last few controls performed
- patient results (with correlation results, if relevant)

Instrument problem

- account number/customer ID number
- instrument serial number and software version
- description of the problem including relevant alarm(s) and alarm code numbers
- other instrument or maintenance related information.

Instrument troubleshooting

This chapter provides information about troubleshooting procedures for the system as a whole. Procedures for troubleshooting general instrument problems as well as problems during power up are described.

Troubleshooting at Power Up

Conditions that can affect instrument power up are presented in the table below.

To troubleshoot a problem, determine the category below that best describes the problem, and follow the recommended remedy. If all remedies are unsuccessful, call technical support.

Troubleshooting instrument Power Up

PROBLEM: The instrument does not power up when the operation power switch (on the left side of the rack sampler unit) is pressed.

Cause or description	Remedy
1. Instrument is unplugged.	Plug instrument power cord into socket.
2. Main circuit breaker (bottom left of rack sampler unit) in OFF position.	Switch main circuit breaker to the ON position.
3. Module power switch for the c 501 or e 601 module is switched off.	Switch on the module power switch.
4. The circuit breaker for the instrument power line in your facility is in the OFF position.	Have your facility electrician check the appropriate circuit breaker.
5. Control unit workstation power cable is unplugged.	Plug the power cable into the socket. If the instrument still does not power up, call technical support.

Table D-6

Troubleshooting at power up

General instrument troubleshooting

General mechanical problem isolation

The control unit controls and monitors all mechanical functions of the instrument. When a mechanical problem arises within the instrument, it is immediately recognized by the system. The alarm indicator on the global **Alarm** button lights, alerting you to the problem. Touch **Alarm** (global button) to display the **Alarm** screen with the specific alarm code, date and time the alarm occurred and a description of the alarm. Touch a specific alarm to display the alarm details and appropriate remedy.

For certain problems affecting the instrument's performance, the system terminates the operation mode and enters the sampling stop or stop mode. In the sampling stop mode, the system allows completion of the samples in process unaffected by the failure. If the problem affects all samples in process, the computer immediately terminates the operation mode with a stop or emergency stop.



Certain instrument problems may arise that the system does not monitor. If this is the case, no alarm will be issued to alert the operator. Such problems may include worn parts, air leaks in the syringe system, reagent contamination, etc. When you encounter these types of problems, you must decide whether to continue to process samples or to terminate the operation, depending on the possibility of causing damage to the system or reporting erroneous test results.

Electrical power not available

If you are having problems powering the analyzer on, follow the steps below:

- 1** Are the operation ON/OFF switch and circuit breaker switched OFF?
 - If yes, then go to step 2.
 - If no, then go to step 3.
- 2** Switch on both power switches.
- 3** Is the power cable plug disconnected at either the instrument or the outlet?
 - If yes, then go to step 4.
 - If no, then go to step 5.
- 4** Firmly connect the power cable.
- 5** Is the main power outlet working?
 - If yes, then go to step 8.
 - If no, then go to step 6.
- 6** Check the circuit breaker in the laboratory distribution box.
- 7** Ensure line voltage is adequate.
- 8** If you are still experiencing problems, call technical support.



Cannot access another software screen

If you are unable to access another software screen, follow the steps below:

- 1** Power OFF the analyzer at the circuit breaker.
- 2** Check the cabling between the touchscreen and the analyzer.
- 3** Power ON the analyzer at the circuit breaker. If you are still unable to access another screen, then call technical support.

**Touchscreen does not come on**

If you are having problems with the touchscreen, follow the steps below:

- 1** Is the operation ON/OFF switch on the front of the touchscreen switched OFF?
 - If yes, then go to step 2.
 - If no, then go to step 3.
- 2** Switch the operation switch ON.
- 3** Is the cable between the touchscreen and the instrument disconnected?
 - If yes, then go to step 4.
 - If no, then go to step 5.
- 4** Firmly connect the cable.
- 5** If you are still experiencing problems, call technical support.

**Touchscreen is difficult to see**

If the content of the touchscreen is difficult to see, follow the steps below:

- 1** Is the touchscreen dirty?
 - If yes, then go to step 2.
 - If no, then go to step 3.
- 2** Gently wipe the surface with a dry cloth.
- 3** Is the ambient lighting too bright?
 - If yes, then go to step 4.
 - If no, then go to step 5.
- 4** Either reduce the brightness of the ambient lighting or change the direction of the monitor.
- 5** If you are still experiencing problems, call technical support.



Probes do not descend to liquid surface

If the sample probes do not descend to the liquid surface, follow the steps below:

- 1** Are there bubbles on the liquid surface?
 - If yes, then go to step 2.
 - If no, then go to step 3.
- 2** Eliminate the bubbles in the sample container with an applicator stick.
- 3** Did the probe tip touch something during descent? If yes, remove the obstacle.
■

Bubbles in syringes

If you see bubbles in either the reagent and/or sample syringe, follow the steps below:

- 1** Perform Reagent Prime (8 on **Maintenance** Items list) from **Utility > Maintenance**. From the ISE area select All, from the Elecsys area select the appropriate working solution line (Reagent or Pre-wash) and enter 5 cycles.
- 2** If there are still bubbles in the syringe, repeat this process for the appropriate syringe.
■

If bubbles remain in the syringe after the second pipettor prime, call technical support.

c 501 (ISE) troubleshooting

This chapter provides information about troubleshooting procedures specific to the ISE module.

ISE, all results are erratic, excessive air in sipper syringe

For problems with erratic ISE results where there is excessive air in the sipper syringe, follow the steps below:

- 1** Check reagent volumes in reagent bottles. Are reagent volumes sufficient and is the ISE Ref. reagent line in the solution?

If not, replace reagent. Make sure the ISE Ref. reagent line is at the bottom of the bottle. Perform an ISE prime of the relevant reagent(s).

- 2** Is the system leaking?

If yes, check all tubings and connections for leaks. Tighten loose fittings. Check seals of the ISE and sipper syringes.

Choose **Utility > Maintenance** and perform **(8) Reagent Prime** on the ISE unit (Ref).

- 3** Check position of the measuring cartridges. Are measuring cartridges placed properly?

If no, place cartridge in correct position. Choose **Utility > Maintenance** and perform **(8) Reagent Prime** on the ISE unit (Ref).

- 4** Check reference cartridge placement. Is the reference cartridge placed properly?

If no, place cartridge in its proper position. Choose **Utility > Maintenance** and perform **(8) Reagent Prime** on the ISE unit (Ref).

- 5** If problem recurs, call technical support.



ISE, results are erratic

For problems with erratic ISE results, follow the steps below:

- 1 Is the ISE Ref. reagent line correctly placed in the bottle?
If no, check line placement, prime reagents and rerun samples.
- 2 Is there salt buildup on electrodes or syringes or are there any loose connections?
If yes, tighten any loose or leaky connections, then clean all salt buildup with wet gauze and rerun samples.
- 3 Check sipper line tubing for kinks or occlusions and remove them.
- 4 Perform maintenance check (2) *ISE Check*. The Ref. EMF is allowed to be within -7 mV to +7 mV. The maximum deviation for the entire cycle range should be no more than ± 2 mV for Ref. EMF. The measurement-to-measurement difference within the 30 cycle interval should not be larger than 0.2 mV for Na, K, and Cl.
If results are not within range, replace ISE reference cartridge. Choose **Utility > Maintenance** and perform (8) *Reagent Prime* on the ISE unit (Ref). Then, recalibrate and rerun samples.
- 5 Are there air bubbles in the sipper line?
If yes, replace seal in the sipper syringe and prime the ISE IS reagent. Choose **Utility > Maintenance** and perform (8) *Reagent Prime* on the ISE unit (IS).
 - See *Replacing the syringe seals* on page C-102.
- 6 Verify microbial growth is not present in the reagent system. If necessary, clean the ISE reagent flow path.
 - See *Processing green wash rack* on page C-67.
- 7 If problem recurs, call technical support.



ISE, high internal standard values

For problems with high/low ISE internal standard values, follow the steps below:

- 1** Is the ISE IS EMF value and the ISE IS concentration value higher than normal?

The internal standard EMF deviated ± 2 mV maximum from the mean value between the Standard Low and Standard High. The concentration of the internal standard ideally lies at:

Na^+ : 140 mmol/L

K^+ : 5 mmol/L

Cl^- : 100 mmol/L

- If yes, go to step 2.
- If no, go to step 5.

- 2** Check that the ISE IS is correctly placed on the system.

Replace ISE reagents if required.

☞ For information about replacing ISE reagents, see:

Figure A-45 on page A-77

c 501 – ISE unit on page B-38

- 3** Check that fresh ISE calibrators are used and that they are placed in the correct positions of the calibrator rack.

Replace ISE calibrators if required.

- 4** Check the ISE sipper syringe assembly. Are there leaks?

If yes, replace the seals and prime the ISE IS.

☞ For more information, see *Replacing the syringe seals* on page C-102

- 5** Perform maintenance check (2) ISE Check. The EMF of the reference electrode must be between -7 mV and +7 mV. The maximum deviation for the entire cycle range should be no more than ± 2 mV.

- If all values (Na^+ , K^+ , and Cl^-) are too high or too low, replace the reference cartridge. An ISE.E data alarm is displayed in the printout adjacent to the respective EMF if the following limits are exceeded:

Na^+ : -90 to -10 mV;

K^+ : -90 to -10 mV

Cl^- : 80 to 160 mV

- If only single values (Na, K or Cl) are outside the range, replace the respective electrode.

- 6** If problem recurs, call technical support.



ISE, high sodium or low chloride values

For problems with high sodium and low chloride values, follow the steps below:

- 1 Were fresh low and high calibrators used?

If no, recalibrate with fresh calibrators and rerun the samples.

- 2 Prepare fresh ISE IS and ISE Dil. reagents.

- Replace the old ISE IS and ISE Dil. reagents with the fresh reagent.
- Perform a wash: Choose **Utility > Maintenance** and perform (7) *Wash Reaction Parts*.
- Prime the fresh reagent: Choose **Utility > Maintenance** and perform (8) *Reagent Prime* on the ISE unit (IS).
- Recalibrate two times with fresh ISE IS.
- Rerun the sample.

- 3 If problem recurs, call technical support.



Low ISE values

For problems with low ISE values, follow the steps below:

- 1 Were fresh low and high calibrators used?

If no, recalibrate with fresh calibrators and rerun the samples.

- 2 Were fresh ISE reagents used?

If no, prepare fresh ISE IS and ISE Dil.

- Replace the old ISE IS and ISE Dil. reagents with the fresh reagent.
- Perform a wash: Choose **Utility > Maintenance** and perform (7) *Wash Reaction Parts*.
- Prime the fresh reagent: Choose **Utility > Maintenance** and perform (8) *Reagent Prime* on the ISE unit (IS).
- Recalibrate two times with fresh ISE IS.
- Rerun the sample.

- 3 Is the correct compensator value (ISE Comp.) entered under **Calibration > Install > Chemistry**?

For US only, ISE High (compensated) is used instead of ISE Comp.

If no, correct the compensator value.

- 4 If problem recurs, call technical support.



c 501 (P) troubleshooting

This chapter provides information about troubleshooting procedures specific to the c 501 module.

High test results

The following may cause high test results on the c 501 module. Identify which module or modules are giving high test results and troubleshoot according to the steps below:

- 1** Incubator bath temperature is incorrect.
 - If the bath temperature does not read $37 \pm 0.1^\circ\text{C}$, call technical support.
- 2** Poor calibration results.
 - Check calibrator preparation.
 - Check proper calibration programming and calibration results. Repeat calibration if necessary.
- 3** Calibrators were not properly prepared.
 - Check calibrator preparation and calibration results. Repeat calibration.
- 4** Evaporation of sample, calibrator or control.
 - Repeat analysis with fresh sample, calibrator and/or control.
If calibrators and controls have been loaded on the racks for more than 2 hours, evaporation of calibrator may lead to lower results for patient samples.
- 5** Reagents were not properly prepared.
 - Check reagent preparation and expiration date.
- 6** Information is not correct **Calibration > Install**.
 - Verify the calibration points on **Calibration > Install** and compare the displayed data with the documentation for a specific test.
 - Verify the calibration sample volume in the application parameters.
- 7** Incorrect sampling or dilution of sample.
 - Check correct assembly of sample probe and pipetter parts.
 - Check all fittings for leaks.
 - Replace O-rings and seals.
- 8** Insufficient reagent volume.
 - Check reagent pipetting system for leaks.
 - Replace reagent cassette and repeat analysis.
- 9** If you are still experiencing problems, call technical support.



Low test results

The following may cause low test results on the c 501 module. Identify which module or modules are giving low test results and troubleshoot according to the steps below:

- 1** Reagents are expired.
 - Prepare new reagents (see instructions for use for stability of the prepared reagent).
- 2** Reagents were not properly stored.
 - Prepare new reagents (see instructions for use for proper storage).
- 3** Reagents were not properly prepared.
 - Prepare new reagents (see instructions for use for proper preparation instructions).
- 4** Incubator bath temperature is incorrect.
 - If the bath temperature does not read $37 \pm 0.1^\circ\text{C}$, call technical support.
- 5** Calibrators were not properly prepared.
 - Check calibrator preparation and repeat the calibration with fresh calibrators.
- 6** Information is not correct on **Calibration > Install**.
 - Check **Calibration > Install** and compare the displayed data with the documentation for a specific test.
 - Verify the calibration sample volume in the application parameters.
- 7** Ensure there is sufficient sample in the container. Check instrument specifications for minimum sample volumes.
- 8** Check sample for fibrin clotting.
- 9** Check sample pipetting systems for leaks and air bubbles.
- 10** Check sample probe for contaminants and obstructions.
- 11** Repeat analysis with appropriate sample volume.
- 12** If you are still experiencing problems, call technical support.



Erratic test results

The following may cause erratic test results on the c 501 module. Identify which module or modules are giving erratic test results and troubleshoot according to the steps below:

- 1** Fibrin clot in 1 sample container or in sample probe (if low values printed for several samples).
 - Check sample for fibrin clot; remove fibrin and repeat analysis.
 - Check sample probe for fibrin clot; clean probe (perform maintenance item (12) *Sample Probe Wash*) and perform an air purge.
 - ☛ See also *Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle* on page C-72.
 - Replace sample probe and sample probe seal.
- 2** Sample probe does not reach the bottom of the reaction cell when dispensing sample.
 - Perform mechanism check and verify that the probe reaches the bottom of the cell.
 - Check the spring mechanism to make sure the probe moves up and down freely.
 - The sample probe tip may be damaged. Replace the sample probe.
- 3** Maintenance was not performed properly or at the recommended frequency on sample or reagent pipetters or probes.
 - Check the **Maintenance** screen and perform any overdue maintenance functions.
 - If maintenance was recently performed on the sample probe(s), reagent probe(s), rinse nozzles, or any pipetters:
 - Was an air purge performed after maintenance?
 - Were all parts correctly assembled?
 - Have all tubings and seals been checked for air leaks?
 - Were sample and reagent probe seals replaced?
- 4** Insufficient sample volume.
 - Repeat analysis with sufficient sample.
- 5** Contaminated incubator bath.
 - Check for particles in the incubator bath. If particles exist, perform the incubation cleaning procedure
 - ☛ See: *Cleaning the incubator bath* on page C-87
 - Check for foaming, perform incubation water exchange.
 - Check for sufficient Hittergent on the module. Perform incubation water exchange.
- 6** Check for sufficient volumes of cell cleaning detergents.
- 7** Check the cell rinse unit for contamination and clean the nozzles if necessary.
 - ☛ For more information, see *Cleaning cell rinse nozzles* on page C-74
- 8** If you are still experiencing problems, call technical support.



Erratic or biased test results

For problems with erratic or biased test results on c 501 module, identify which module or modules are having problems and troubleshoot according to the steps below:

- 1 Verify that the deionized water supply is free from contamination.
- 2 Check calibrators used on all modules.
 - Calibrators were not properly prepared. Repeat calibration with fresh calibrator.
 - Check calibrator preparation.
- 3 Information is not correct on **Calibration > Install**.
 - Verify the calibration points on **Calibration > Install** and compare the displayed data with the documentation for a specific test.
 - Check that the calibration sample volume in the application parameters is correct.
- 4 Check sample for fibrin clotting.
- 5 Ensure there is sufficient sample in the container. Check instrument specifications for minimum sample volumes.
 - Repeat analysis with appropriate sample volume.
- 6 If you are still experiencing problems, call technical support.



Single sample or control

For problems with a single sample or control on the c 501 module, identify which module or modules are having problems and troubleshoot according to the steps below:

- 1 Verify samples and controls are placed in the proper rack and positions. If necessary, correct the sample or control placement and rerun the sample.
- 2 Verify the control value ranges and lot numbers entered on **QC > Install** are correct. If necessary, correct the control value range or lot number on **QC > Install**.
- 3 Verify the sample and/or control volume is sufficient. Verify the selected sample cup on **Workplace > Test Selection**.
- 4 Verify the sample integrity is acceptable (fibrin, lipemia, hemolysis, icterus). If necessary, collect fresh sample and rerun.
- 5 Verify the appropriate sample type is selected (serum/plasma, CSF, urine, supernatant, other) and the specimen was collected appropriately. If necessary, correct the sample type; check the instructions for use for acceptable specimen types. Check the specimen collection; check the instructions for use for acceptable specimen collection methods.
- 6 Verify the collection time and date of the sample are correct. If necessary, collect fresh sample.
- 7 Verify correct test selections were made on **Workplace > Test Selection**. If necessary, correct any selections and rerun the sample.

- 8** If you are still experiencing problems, call technical support.

■

Single test (1 reagent)

For repeated or consistent problems with a single test on the c 501 module, identify which module is having problems and troubleshoot according to the steps below:

- 1** Verify that reagents have not expired, or are not contaminated. If necessary, insert a new reagent cassette.
- 2** Verify the correct calibrator code and setpoints are used. If necessary, correct the calibrator code and setpoints and repeat the calibration.
- 3** Verify the special wash programming, if applicable.
- 4** If you are still experiencing problems, call technical support.

■

Tests with more than 1 calibration point

For problems with tests with more than 1 calibration point on the c 501 module, identify which module or modules are having problems and troubleshoot according to the steps below:

- 1** Verify calibrators were properly prepared and stored. If necessary, prepare new calibrators and recalibrate.
- 2** Verify the assigned calibrators are in the correct positions. If necessary, place calibrator(s) in correct position(s), recalibrate and rerun samples. Verify that required diluents are on board.
- 3** If you are still experiencing problems, call technical support.

■

Multiple photometric tests (more than 1 reagent)

For problems with multiple photometric tests on the c 501 module, follow the steps below:

- 1** Verify there are sufficient volumes of special wash solutions and detergents. If necessary, replace needed special wash solutions, detergent and rerun samples.
- 2** Check the reagent probes for barbs, obstructions or leaks.
- 3** Verify the R1 system is not leaking. Perform an air purge. If the system is leaking, check connections in the R1 probe arm and check connections in the reagent 1 syringe(s).
- 4** Verify the incubator bath is free of debris and foam. If necessary, perform incubator bath maintenance.
- 5** Perform a photometer check. Verify the Photometer Check report is within acceptable limits (< 14000). If it is not, replace the photometer lamp. Perform a cell blank. Calibrate all photometric tests.

- 6 Verify the Reagent 2 probe is aligned properly. If necessary, perform a reagent probe check.
- 7 Verify the R2 probe system is not leaking. Check connections in the R2 delivery system. Check syringe connections. Perform an air purge.
- 8 If you are still experiencing problems, call technical support.

■

All photometric tests

For problems with all photometric tests on the c 501 module, identify which module or modules are having problems and troubleshoot according to the steps below:

- 1 Verify the sample probe is not blocked or does not have barbs at the tip. If necessary, clean the probe. Perform an air purge.
- 2 Verify the sample system is not leaking. If necessary, check tubings and connections. Perform an air purge and check if there are air bubbles in the syringe.
- 3 Verify controls/calibrators were properly prepared and stored. If necessary, prepare new controls/calibrators.
- 4 Check that ultrasonic mixers operate properly.
- 5 If you are still experiencing problems, call technical support.

■

Biased enzyme results

For problems with biased enzymes on the c 501 module, identify which module or modules are having problems and troubleshoot according to the steps below:

- 1 Verify the incubator bath level is above the photometer lens.
- 2 Verify the incubator bath temperature displayed on the **System Overview** screen is $37 \pm 0.1^\circ\text{C}$. Verify there is no Incubator Bath Temperature alarm present.
If the temperature is out of range, perform an incubation water exchange, allow the temperature to stabilize and recheck the bath temperature. If the temperature is still unacceptable, call technical support.
- 3 Verify the sample and reagent syringe seals are in good condition. If necessary, change the syringe seals.
- 4 Verify the syringe fittings are not loose. If necessary, correct any loose fittings.
- 5 Verify controls were prepared using volumetric pipettes. If not, prepare new controls using a volumetric pipette.
- 6 Perform a full calibration or blank update.
- 7 Perform a Photometer Check. Verify the Photometer Check report is within acceptable limit (< 14000). If not, replace the photometer lamp. Perform a cell blank. Calibrate all photometric tests.
- 8 If you are still experiencing problems, call technical support.

■

e 601 troubleshooting

This chapter provides information about troubleshooting procedures specific to the e 601.

Reagent disk cover does not open/close

If you are having problems opening or closing the reagent disk cover, follow the steps below:

- 1** The reagent disk cover is keyed. Is the reagent disk cover properly oriented for placement?
 - If yes, then go to step 3.
 - If no, then go to step 2.
- 2** Make sure that the reagent disk cover fits into the key before locking.
- 3** Is there an obstacle around the cover?
 - If yes, then go to step 4.
 - If no, then go to step 5.
- 4** Remove the obstacle.
- 5** If you are still experiencing problems, call technical support.



Trouble replacing ProCell/CleanCell

If you are having problems replacing a ProCell or CleanCell reagent bottle, follow the steps below:

- 1** The auxiliary reagent bottles are keyed for proper placement. Are you placing the bottle in its appropriate position?
 - If yes, then go to step 3.
 - If no, then go to step 2.
- 2** Remove the bottle and check the position before placing the reagent into its proper place.
- 3** Is there an obstacle beneath the auxiliary reagent bottle?
 - If yes, then go to step 4.
 - If no, then go to step 5.
- 4** Remove the obstacle.
- 5** If you are still experiencing problems, call technical support.



Trouble placing PreClean

- 1 Ensure PreClean bottles are fully inserted.
- 2 Ensure the caps have been slightly opened after insertion.



Drift

Control or sample shows drift over a period of time

Possible causes

- Evaporation or incorrect storage conditions of **cobas e** packs.
- **cobas e** packs are not at the proper temperature.
- Recommended calibration frequency not used.
- Recommended handling of controls and/or samples not followed (stability and evaporation).

Actions/Prevention

- Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Erratic test results

Possible causes

- Foam on sample
- Foam on assay reagents
- Foam on controls
- Not-recommended sample container used

Actions/Prevention

- Have you handled the reagents, samples and controls according to instructions for use?
- Have you performed the recommended maintenance?
- If you are still experiencing problems, call technical support.

Assay calibration

Calibration cannot be performed

Possible causes

- Calibrator vial previously used on the instrument.
- cobas e pack or calibrator not on board.
- Missing diluent, for example for CA15-3.
- Calibration not activated in the software.
- Calibrator expiration date exceeded.
- Invalid or unreadable calibrator vial barcode, or calibrator lot specific data not downloaded.
- Data link not available for combination cobas e pack and CalSet.
- CalSet 1 and CalSet 2 not on same rack or empty space between CalSets.

Actions/Prevention

- Check barcode of calibrator vial and cobas e pack (barcode damaged?, correct position of the barcode?).
- Check if calibrator lot specific data has been downloaded.
- Wipe off the dust on the surface of the barcode reader.
- Dry the calibrator vial if it is wet.
- Check calibrator position.
- If you are still experiencing problems, call technical support.

Calibration not released

 For more information, see:

Duplicates out of limits on page D-85

Monotony not fulfilled on page D-85

Missing values on page D-86

Values out of limits on page D-86

Calibration factor out of limits on page D-87

Duplicates out of limits

Possible causes

- Foam on calibrator or assay reagents.

Actions/Prevention

- Have you handled the reagents and calibrators according to the instructions for use?
- Perform a new assay calibration (new CalSet).
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Monotony not fulfilled

Possible causes

- Calibrators not transferred to the correct barcoded calibrator vials.

Actions/Prevention

- Have you handled the reagents and calibrators according to the instructions for use?
- Perform a new assay calibration (new CalSet).

Missing values

Possible causes

- Empty calibrator.
- Insufficient volume of calibrator or calibrators.

Actions/Prevention

- Have you handled the reagents and calibrators according to the instructions for use?
- Perform a new assay calibration (new CalSet).
- If you are still experiencing problems, call technical support.

Values out of limits

Values below minimum signal or signal difference between CalSet 1 and CalSet 2 or maximum signal out of limits (latest criteria valid for qualitative assays only).

Possible causes

- Possible causes in connection with reagent handling:
 - cobas e pack not at correct temperature.
 - cobas e pack not within allowed stability after opening.
 - cobas e pack expiration date exceeded.
 - cobas e pack stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
 - Foam on assay reagents.
- Possible causes in connection with Calibrator handling:
 - Calibrator not at correct temperature.
 - Foam on calibrator
 - Calibrator handling not as recommended.
 - Calibrator transferred to the incorrect calibrator vial. For example, CalSet 1 transferred to CalSet 2 vial.
 - Calibrators not within allowed stability after opening and/or reconstitution.

Actions/Prevention

- Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
- Perform a new assay calibration (new cobas e pack or new CalSet).
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Calibration factor out of limits

Only valid for quantitative assays.

Possible causes

- Possible causes in connection with reagent handling:
 - cobas e pack not at correct temperature.
 - cobas e pack not within allowed stability after opening.
 - cobas e pack expiration date exceeded.
 - cobas e pack stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
 - Foam on assay reagents.
- Possible causes in connection with Calibrator handling:
 - Calibrator not at correct temperature.
 - Foam on calibrator
 - Calibrator handling not as recommended.
 - Calibrator transferred to the incorrect calibrator vial. For example, CalSet 1 transferred to CalSet 2 vial.
 - Calibrators not within allowed stability after opening and/or reconstitution.

Actions/Prevention

- Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
- Perform a new assay calibration (new cobas e pack or new CalSet).
- Have you performed recommended maintenance?

If you are still experiencing problems, call technical support.

Recovery of controls

Control values out of range

Possible causes

- Possible causes in connection with Control handling:
 - Controls not at correct temperature.
 - Control not within allowed stability after opening or reconstitution.
 - Control expiration date exceeded.
 - Foam on controls.
 - Control handling not as recommended.
- Possible causes in connection with reagent handling:
 - cobas e packs not at correct temperature.
 - cobas e packs not within allowed stability after opening.
 - cobas e pack expiration date exceeded.
 - cobas e packs stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
 - Foam on assay reagents or auxiliary reagents.
- Possible causes in connection with Calibrator handling:
 - Recommended calibration frequency not followed.

Actions/Prevention

- Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
- Use another control vial.
- Perform a new assay calibration (new cobas e pack and CalSet).
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Intra assay precision

Intra assay precision out of expected range

Possible causes

- Foam on assay reagents.
- cobas e packs and/or sample not at correct temperature.
- cobas e packs stressed (storage or transport conditions not as recommended, for example, temperature, upright position).

Actions/Prevention

- Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Inter assay precision (including both channels within 1 module)

Inter assay precision out of expected range

Possible causes

- cobas e packs and/or sample not at correct temperature.
- Foam on assay reagents.
- cobas e pack stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
- Calibration not carefully carried out.
- Recommended calibration frequency not followed.

Actions/Prevention

- Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Module to module variance

Deviation of control and samples when measured with different modules.

Possible causes

- Recommended handling of assay, auxiliary reagents and calibrators, controls not followed (for example, stability, evaporation).
- Calibration not carefully carried out.

Actions/Prevention

- Have you handled the reagents, auxiliary reagents, calibrators, and/or controls according to the instructions for use?
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Method comparison

Deviation of method comparison when compared with competitors (internal, external)

Possible causes

- Different standardizations (reference material).
- Different antibodies (for example, HCG on Elecsys/ES).
- Different methods (RIA/ELISA etc.).
- Different units (conversion factor between units sometimes different from competitor to competitor).
- Different sample material +/- anticoagulants.
- Recommended calibration frequency not followed.
- Calibration handling not as recommended.
- The number of samples is too small, and/or all results are within a very limited range compared to the measuring range of the assay.
- Reagent lot to reagent lot variance.
- System to system variance.

Actions/Prevention

- Have you handled the reagents and calibrators according to the instructions for use?
- Have you performed recommended maintenance?
- If you are still experiencing problems, call technical support.

Appendix

E

Glossary

F

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Glossary

This glossary is a compendium in which to look up the meaning of technical terms used in conjunction with the cobas® 6000 analyzer series.

Numbers

2-dimensional barcode A type of barcode on cobas e packs, calibrators, and control barcode cards or sheets. These matrix barcodes, which use PDF417 symbology, contain more information than traditional linear barcodes.

A

absorbance (Abs) The instrument displays an absorbance by ten-thousandfold value.

aspiration station A position on the e 601 module located next to the incubator where an AssayCup containing the reaction mixture is placed for aspiration into the measuring cell by the sipper probe.

assay 1. A specific test.
2. The process of measuring a substance.

AssayCup A plastic vessel that is used to hold the assay reaction mixture. An alternative term is reaction vessel.

AssayTip A disposable pipette tip made of black, conductive plastic. AssayTips are used by the sample probe.

assigned value (Roche-defined) Roche-defined concentration for calibrator material that is encoded on the calibrator barcode card or e-barcode. See also *target value*.

automatic calibration 1. Automatic timeout calibration. A calibration of a parameter performed if a specified time interval expires. The calibration can be defined for each method separately.
2. Automatic calibration after a cassette or a cassette of a new lot is registered. The calibration can be defined for each method separately.
3. Automatic calibration on QC failure. A calibration request is generated by the system if a QC value is outside a predefined range.

Automated Download (ADL) A service that provides the information necessary for analysis, for example analytical parameters or concentration information from the data center. ADL is a cobas TeleService application. See also *cobas TeleService*.

automatic QC A quality-control function that automatically samples QC material, test-specifically according to defined time intervals.

automatic rerun The repetition, without operator intervention, of tests that have results with data alarms.

auxiliary reagent A non-test specific reagent that is needed to perform testing on an analyzer.

B

backup 1. The saving of data onto supplementary storage media such as disks or DVDs. If such data is required but is no longer available from the main storage (instrument hard disk), it can be restored from a backup copy.
2. An internal instrument-specific process to establish the data for a backup; only used in a case of routine instrument break down.

backup operation A software function that allows to place routine racks with barcoded samples manually on the c 501 module. Intended to be used when trouble occurs in the rack sampler and a rack cannot be conveyed.

barcode mode The operational mode when a system is configured to operate using barcoded samples.

barcode type Typical sample barcode types used in the IVD industry are Code39, NW7 (Codabar), ITF, and Code 128.

bichromatic measurement The measured absorbance of the primary wavelength and the secondary wavelength.

blank cell Calibration procedure for ECL instruments performed by Roche Diagnostics service staff.

bound/free separation - calibrator code

bound/free separation The physical separation of reagent or sample that is bound to a solid phase (the microbeads) from free reagent or sample. With ECL systems this step occurs in the measuring cell.

Bracketing A mode of operation in which patient results have to be surrounded by successful control results before they are released.

bridging principle One of three test principles that can be applied to ECL immunoassays. It is used to detect antibodies (such as IgG, IgM, or IgA) in the sample. See also *competitive principle, sandwich principle*.

C

calculated result See calculated test.

calculated test A test result calculated from different individual analytical methods with a given formula such as ratio A/B.

calibration The process that establishes the relation between measured signals (e.g. from a photometer, photomultiplier, or ion-selective electrodes) and corresponding concentration values of a calibrator.

calibration curve A plot of measured signal values (determined during calibration) versus known concentration values of calibrators.

calibration factor 1. In ECL systems (e 601), one of the six calibration quality criteria used to verify the validity of a calibration. This criterion is only used for reagent pack calibrations. It is derived by comparing two different calibrations. A factor of 1.0 is achieved when two calibrations are equal. A successful calibration has a factor of 0.8-1.2.
2. In photometric systems (c 501) the K factor and S1Abs (linear calibration), and factors A, B, C for non-linear calibration curves.

calibration frequency A specified interval at which an assay should be calibrated. Also referred to as calibration stability. It is implemented in the application parameters which are downloaded via **cobas** link or encoded in the reagent barcode of cobas e packs.

calibration function The type of calibration (for example, Rodbard function, linear function, or cutoff function). A mathematical model that describes the relationship between a signal and a concentration in the calibration curve. See calibration curve.

calibration masking A function that masks a cobas c pack or cobas e pack for a module or measuring channel when no valid calibration is available for this particular module or measuring channel.

calibration monitor A function that prints the measured absorbance of the standard solution and the calibration factors, at the time of calibration, for every measurement item.

calibration NOW A system-generated recommendation to carry out calibration within a forthcoming defined time interval (Remaining time on Calibration > Status screen).

calibration quality criteria Calibration checks applied to the auto-validation of every calibration on the analyzer.

calibration trace A graph used to review the measurements of the 50 most recent calibrations for a specific test.

calibration type 1. In clinical chemistry: One of the following: Linear, RCM, RCM2T1, RCM2T2, Spline, Line Graph. Each calibration type corresponds to one specific type of mathematical function. See calibration function.
2. For ECL systems: Lot calibration (L-Cal) or reagent pack calibration (R-Cal).
3. In clinical chemistry: Lot calibration or cassette calibration.

calibration validation Analysis, performed by software, to check a calibration data set against specific criteria. Calibration validation results are: successful or failed.

calibration verification The assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument kit or test system has remained stable throughout the laboratory's reportable range for patient test results (for example, Elecsys CalChecks).

calibrator A material of known concentration of the parameter that can be presented to the analytical instrument for calibration purposes. Also referred to as standard.

calibrator code The identification number of the standard solution in calibration measurement.

capacitance An electrical property that provides the basis for liquid level detection in sample probes. The probes carry a high-frequency, low-voltage electrical charge. Frequency and electrical charge characteristics are altered and sensed when the probe touches liquid.

carryover Contamination of a reaction mixture of one assay by reagents or sample material of another assay.

cassette The integrated reagent carrier consisting of two or three reagent bottles and barcoded labels. The term cassette, on cobas systems, is related to different reagent carriers, namely INTEGRA cassettes, cobas c packs, or cobas c pack MULTI.

cell blank The process of measuring the absorbance of all reaction cells, filled with water, at all wavelengths. The cell blank values are stored on the hard disk. By periodic cell blank measurement, reaction cells can be screened for contamination or damage.

cell holder A container holding the electrode in the electrode measurement unit.

cell rinse units A device for cleaning the reaction cells with detergent and water and for dispensing and aspirating cell blank water.

channel 1. The number of reagent positions on an analytical instrument.
2. A specific reagent position.
3. The two measuring cells on the e 601 are sometimes referred to as channel one and channel two.

check digit A verification number used in barcodes and software.

check sum The result of a mathematical procedure to validate the integrity of a set of data.

circuit breaker The main power switch on the instrument. It controls the power supply including the power to the Peltier elements. Consequently it controls the temperature in each reagent disk, incubator, and detection unit.

cleaning solution See wash solution.

client/server A network in which computer processing is distributed among many individual PCs (clients) and a more powerful, central computer (server).

clot detection 1. A device built into the pipetting system to detect clots and to avoid false pipetting.
2. The procedure of detecting a clot.

cobas® The "umbrella brand name" for a broad range of products and services for use in professional IVD laboratories and physician's office settings.

cobas c pack The name given to a reagent cassette used on cobas c systems and COBAS INTEGRA® systems.

cobas c pack MULTI The name given to an empty, but assembled and barcoded, cassette that can be used for Roche or non-Roche reagents. The word multi in this name stands for multi-purpose.

cobas e pack The name given to a reagent pack used on cobas e systems and Elecsys® systems.

cobas link The infrastructure of network connections that enables cobas TeleService to exchange information between the Roche service network and a customer's laboratory.

cobas link data station A specific desktop computer, located in the laboratory, that has been configured to act as a gateway between Roche systems and the Internet. As well as providing a communication link, the data station also stores data and documentation for assay processing and can provide a data archive.

cobas TeleService The set of software applications that use cobas link to exchange service information between Roche service network and a customer's laboratory. cobas TeleService provides remote monitoring and diagnosis, hotline support, and software and documentation updates.

Code39 A barcode type for sample tubes that can be read by the barcode reader.

coefficient of variation A statistical measure used to describe imprecision. Often abbreviated to CV.

compensated test A test that has the result modified by a formula that takes account of known or defined interference factors.

competitive principle One of three test principles that can be applied to ECL immunoassays. It is used to detect analytes of low molecular weight (for example, FT3). See also *bridging principle*, *sandwich principle*.

conditioning The process of letting serum-type liquid flow through the flow path before electrolyte measurement.

consumables A generic term for items that are used during test processing and must be replaced on a regular basis by the operator. Examples of consumables include AssayCups, printer paper, and reaction cells.

consumables area The area of an analyzer where the consumables, such as AssayCups and AssayTips, are stored.

continuous loading/access Instrument function that allows loading of samples and reagents during operation.

control ID The abbreviated name for a control material, for example PC U1 or PC TSH. Control IDs are used on software screens and windows where limited space prevents the use of longer names.

control material A material used to assess the performance of an analytical procedure or part of an analytical procedure. Also called the control sample.

control name The name of a control material, for example PreciControl Universal.

control SD value The acceptable variation SD value of a quality control sample.

control unit An external PC or printer by which an analytical system is controlled. The control unit also serves as the user interface.

core unit The backbone of modular instruments for sample transportation.

correction item A function that corrects the measurement result of one item by using figures or the measurement result of other tests.

cumulative QC The accumulated data and associated statistics of individual QC data.

cup disposal opening Openings where used AssayCups are disposed into the solid waste.

cup-on-tube The placement of a smaller secondary sample container (for example a Hitachi Cup) on top of a primary sample tube

cycle The instrument time interval during which pipetting or measurement can be carried out.

cyclic QC Controls run at fixed intervals.

D

data alarm Printed or displayed notification that occurs if a result (including calibration or QC results) is unexpected or abnormal; an indication of unusual reaction or instrument conditions, for example, insufficient sample or reagent.

data flag See data alarm.

database A defined section of the computer memory where all instrument, assay, and patient-relevant data are processed and stored.

database management system A software system that provides the necessary procedures and programs to collect, create, organize, store, retrieve, and maintain databases or data files with security and integrity.

dead volume See minimum sample volume.

default profile A predefined set of tests that the analyzer automatically applies to a sample unless the operator specifies a different set of tests.

demographics Patient-related data such as name, date of birth, and gender.

detection unit A hardware unit comprising a photomultiplier tube, Peltier elements, flow-through measuring cell, magnet drive assembly, and an amplifier circuit board.

deviation of duplicate measurements See duplicate limit.

Diagnostics The status that is required to perform system diagnostics and hardware error tracking actions. The field service engineer may request a system to go to Diagnostics mode to perform such procedures. The system may require initialization afterwards to resume normal operation.

dilute waste solution A waste solution resulting after rinsing with water.

dilution factor A software preset or manually assigned dilution ratio that is used by the analyzer to perform a requested dilution.

disk position A dedicated position on the reagent or sample disk.

down time The period of non-operation between an instrument failure and the resumption of operation.

dual value method A mode of expression of the control chart in real-time quality control. For X-axis and Y-axis, measure simultaneously the average and the standard deviation of control of a low value and a high value, and display them by X and Y coordinates, respectively.

duplicate limit A calibration quality criterion. For a successful calibration, duplicate measurements must be within a specified limit.

dynamic range The reportable range of an assay. This range extends from the lower detection limit to the limit of linearity.

E

emergency stop An instrument alarm level that immediately stops all instrument functions.

electromotive force (EMF) The physical principle that provides the basis for electrolyte measurement.

endpoint assay An analytical technique taking measurements after a reaction is completed or has been halted. See also *rate assay*.

error handling A process during which the analyzer attempts to recover from an error condition (for example, an AssayTip is not picked up from the magazine). If the analyzer cannot successfully recover from error, an alarm is issued and the instrument is halted.

E-stopped A status indicating that the system has performed an emergency stop (E. Stop). This could be due to hardware failure or because any of the safety devices have requested an emergency stop. The system requires either complete power off, or at least initialization, to resume normal operation.

expected range The predefined range of test result values expected for a defined group of healthy patients or materials. Also known as "reference" range.

expected value A value for a test result that can be considered as a "normal" result.

expiration date Also called the expiry date. The end of a period until which Roche Diagnostics guarantees product claims for its reagents, calibrators, and controls.

extended dynamic range The measuring range for an assay at its highest dilution.

F

filter A process that sorts data for viewing, documenting, or printing according to pre-defined criteria

first registration The date and time when a reagent or sample was successfully recognized by the barcode reader for the very first time

functional sensitivity The concentration of an analyte at which a predefined level of imprecision is obtained.

G

global button A button that allows access to the global software screens and that can be used at any time.

gripper A technical device that transports AssayCups and AssayTips to their required destination on the analyzer (for example, to the incubator). The gripper moves in three directions (X, Y, and Z).

H

hard disk (HD) A computer component on which data can be written, stored, and retrieved by the means of magnetization.

H detergent 1. A detergent, with antibacterial properties, that can be added to the incubator bath where it acts as a surfactant, reducing the formation of foam.
2. A surfactant diluted for use in some cleaning procedures.

homogeneous immunoassay (HIA) An analytical technique employing antigens and antibodies. An HIA uses assay protocols similar to clinical chemistry without a bound-free separation (for example, latex assays).

Host computer 1. A computer used for overall management and control of the computer network.
2. A clinical laboratory computer that stores and processes patient requests and results. A Host is able to communicate with analytical instruments.

Host communication Data exchange with a clinical laboratory information system (LIS).

Host interface protocol A technical description that defines data transfer between a Host computer and an analytical system.

I

ID reader Typically an optical device that reads the identification code of a patient sample or sample rack (ID) and transfers it to the instrument database.

increased volume rerun A rerun performed after increasing the amount of sample used for the determination.

incubator bath A temperature-controlled, water-filled reservoir that surrounds the reaction cells and keeps the reaction cells at a defined temperature (37°C).

incubator A temperature-controlled aluminum block for AssayCups on cobas and Elecsys instruments.

initial BlankCell procedure The calibration procedure for ECL instruments performed by Roche Diagnostics service staff when setting up an ECL-based analyzer for the first time.

Initialization The operational mode of an analyzer that occurs immediately after power on and during which the instrument prepares itself for operation.

input buffer A section of an analyzer where samples are loaded by using a rack or rack tray. See also *rack loader*.

instrument alarm A displayed alarm that indicates an unusual instrument condition such as an abnormal incubator bath temperature or a mechanical malfunction.

Instrument Manager Typically, PC-based software that controls or supervises one or more analytical instruments.

internal reference solution An internal standard solution, assayed between every ISE sample, that compensates for electronic drift.

inventory control The real-time monitoring of the quantities of all consumable items (liquid and solid) on an analyzer.

ISE check A maintenance function for checking whether electrolyte analysis can be performed correctly.

ISE prime A procedure that fills the ISE reagent lines and syringes with reagent.

K

K factor The reciprocal of the slope of the calibration curve. A factor used in conversion of absorbance values to concentration values or activities.

L

linear barcode A conventional one-dimensional barcode with limited data capacity.

liquid level detection (LLD) The ability of an analytical instrument to sense liquid by using the sample or reagent probes.

liquid waste container A reservoir for liquid waste generated by an analyzer; its size and location vary between instruments.

loader See *rack loader*.

loading capacity The maximum number of samples that can be loaded onto the input buffer.

local area network (LAN) A computer network covering a limited area, such as an office or a home.

log file A set of data, typically stored in the control unit, that traces instrument-related or operator-related activities such as maintenance.

lot calibration (L-cal) A calibration when a new lot of reagents is introduced to an analytical instrument and calibrated within 24 hours.

M

maintenance item A maintenance procedure performed by the system or the operator.

maintenance key A button for position movement, used for a probe position check.

maintenance pipe A combination of sequential maintenance items programmed into a fully automated procedure, which can be performed by the analyzer without operator intervention.

maintenance procedure A procedure that must be performed on a regular basis (for example daily, weekly, monthly, or every three months) to secure reliable operation of the analyzer.

manual dilution An off-system, preanalytical step performed by laboratory staff to reduce the analyte concentration in a sample.

manual rerun A retest function. Although a list of samples required for a rerun is created by following data alarms, rerun is not carried out automatically. After organizing the rerun sample list, the operator directs the rerun.

masking A function that temporarily suspends the measurement or calibration of a specific test, depending on the condition of the instrument or reagent. Tests can be masked completely, or just for individual modules or channels. There are two possibilities to mask a test: If T-mask is selected, no patient samples, no controls, and no calibrations can be performed. If P-mask is selected, the test is masked for patient samples only—calibration and QC can be performed. Masking can also be applied to entire modules (module masking) so maintenance can be performed on the masked module while the other modules are still processing samples.

master calibration A reference standardization that uses master test kit reagents and certified reference standard material (for example, World Health Organization reference material) measured at Roche Diagnostics. The resulting reference standard curve, typically using 10 to 12 points, is the basis for the production of in-house master calibrators.

master curve A lot-specific master calibration curve ($n=5$ or 6) measured at Roche Diagnostics using lot-specific test-kit reagents and master calibrators. The shape of the lot-specific master curve is characterized by a four-parameter Rodbard function. The data characterizing this curve is stored in the lot-specific reagent barcode. Lot-specific, calibrator-assigned values (CalSet-assigned values) are read from the lot-specific master calibration curve and encoded in the CalSet calibrator barcode transfer sheet.

Material Safety Data Sheets (MSDS) Documents that list components of chemical solutions and precautions for the handling and disposal of the solutions.

measure point Time at which absorbance reading is taken and used to calculate results.

measuring cell A flow-through device that is used to generate light during the ECL detection process.

measuring channel The entire pathway that is passed by the reaction mixture during the ECL measuring cycle (including tubing, heat pipe, measuring cell, photo multiplier, and so on).

measuring range See reportable range.

message In computing, a defined set of alphanumeric data that transfers information from computer to computer or from an analytical instrument to the operator.

microbead Paramagnetic streptavidin-coated microparticles used as the solid phase for heterogeneous immunoassays in ECL systems.

Microcup A secondary sample cup made by Hitachi with a small dead (residual) volume

microbead mixer A paddle or propeller that thoroughly mixes the microbead reagent to ensure resuspension before use.

minimum sample volume The amount of residual sample material plus the volume required for assaying all requested tests to ensure faultless sample aspiration.

minimum signal In ECL assays, a calibration quality criterion. A predefined, assay-specific signal level that must be achieved to establish a valid calibration.

missing value In ECL assays, a calibration quality criterion. All calibrator values must be available for a successful calibration.

mode Defined states of operation of an analyzer.

module An analytical unit that can be combined with others to form larger systems.

monotony of curve A calibration quality criterion. All measured calibrator values must fall in either ascending (sandwich or bridging principle) or descending (competition principle) order for a successful calibration.

multi-wavelength spectrophotometer A spectrophotometer in which detectors are placed at multi-wavelength positions to enable simultaneous light reception.

N

non-barcode mode A mode of instrument operation during which the instrument identifies samples by using the rack and position numbers.

O

onboard 1. A technical device or function that is part of the analytical instrument and can be used by the instrument at any time.
2. The availability of reagents and consumables on an analytical instrument for use at any time.

one-way serial processing Sample flow and processing along a single, serial process lane that allows no bypass function and no rerun.

Online Help On-screen documentation that a user can request in a context-sensitive manner and search for any given term.

online support A service that supports the preparation for analysis and maintenance management by exchanging information over networks. See also *cobas TeleService*.

open request An ordered test that has not yet been performed or completed. Results for a sample may be partially available while some tests are not yet completed.

Operate The operational mode during which the instrument processes samples.

operator ID An alphanumeric ID that a system uses to identify a particular operator. There are several levels including operator, supervisor, and administrator.

order Also called a request. A test selected for a specific sample or control.

order date/time A field used to maintain the arrival date and time of an order in the laboratory. The date/time data may be entered manually or transmitted by LIS protocols.

order ID The sample order identification refers to a number of sample tubes (one or more specimen types) of a given patient collected for a panel of different tests. Typically, the sample order identification is printed on order sheets.

output buffer A section of an analyzer to which samples are moved on completion of the analytical process and from which they can be unloaded. See also *rack unloader*.

P

P-mask See Patient mask.

paramagnetic A property of materials that do not exhibit magnetic forces themselves but are capable of becoming magnetic in the presence of a magnetic field. Magnetic property of microbeads used with ECL technology.

patient ID A set of alphanumeric data that unmistakably identifies a particular patient. For example, a social security number and a sample number.

Patient mask There are two possibilities to mask a test: Test mask (T-mask) and Patient mask (P-mask). If T-mask is selected, no patient samples, no controls, and no calibrations can be performed. If P-mask is selected, the test is masked for patient samples only—calibration and QC can be performed.

pending requests See open request.

photometer A device that measures the intensity of light.

photometric assay An assay in which analytes are measured by a photometer.

photometric window A window that enables light to pass from the light source lamp and into the incubator bath.

photomultiplier A light-sensitive tube that collects and amplifies emitted photons from the ECL reaction and converts them into an electric signal.

photon A quantum of electromagnetic energy, having both particle and wave behavior, that carries the light emitted from the ECL reaction.

pinch valve A valve that pinches the suction tube and switches the flow path.

piercer A punch on the reagent transfer arm that pierces the reagent bottle seals during cassette preparation.

pipe See maintenance pipe.

pipetter A device used for pipetting (aspirating and dispensing) a fixed amount of sample or reagent from a sample or reagent container to reaction vessel.

plunger A rod that connects with the drive arm and moves up or down, depending on the pipetting amount.

post-analytical The sample management process, typically storage and archiving, after results have been reported.

potentiometric assay An assay in which analytes (for example Na, K, or Cl) are measured in millivolts by ion-selective electrodes.

Power Up The system status while it is loading programs, performing self-checks, and so on.

pre-analytical The sample management process before the analytical phase. Preanalytical processing typically involves actions such as sorting and aliquoting.

precision The closeness of agreement between independent test results obtained under prescribed conditions.

PreClean A phosphate buffer used to wash and resuspend the microbeads during the pre-wash step.

pre-dilution A dilution step performed before samples are analytically processed on the analyzer.

preventive action A series of actions, suggested by the system, that the operator should perform before daily operation to ensure sufficient inventory during the day (for example, the replenishment of reagents and consumables).

Pre-wash dispenser A technical device that dispenses PreClean into the AssayCups in the Pre-wash station.

Pre-wash sipper Sipper of the PreClean station, which aspirates reaction mixture and PreClean solution from AssayCups.

primary tube The original tube containing the sample that has been drawn from the patient.

ProbeWash An auxiliary reagent used to wash the reagent probe during special wash steps.

ProCell An auxiliary reagent that transports the reaction mixture from an AssayCup into the measuring cell and aids the ECL detection technology.

processing lane The section of an analytical module where sample racks are moved for pipetting.

profile A user-defined set of test requests.

protocol 1. A convention or standard that controls or enables the connection, communication, and data transfer between two computing end points. Protocols can be implemented by hardware, software, or a combination of the two.
2. A set of rules that guides how an activity should be performed.

prozone The antigen/antibody complex formation is predictable as long as an excess of reagent (antibody) exists. However, in patient samples with very high levels of antigen, the reaction may begin to reverse (deagglutination) because of the effect of the excess antigen. This is called a prozone effect, and without checking for this phenomenon, abnormally high samples may give incorrect or even false normal results. There are two prozone check methods available: Antigen readdition method and reaction rate method.

Q

QC error An alarm generated in realtime QC when either a low value or a high value exceeds the limit of 3SD (QC error 1) or 2.5 SD (QC error 2).

qualitative assay An assay that does not allow the determination of the concentration of an analyte, but yields a classification of the sample, such as reactive/nonreactive or positive/negative, with regard to a certain analyte.

quantitative assay An assay that allows the determination of the quantity (concentration or activity) of an analyte.

query download A communication process between instrument PC and LIS by which a predefined data set is transmitted upon request of the analytical instrument.

R

rack A sample carrier device that holds sample cups or primary sample tubes (including those for routine samples, standard and washing solutions, quality control, STAT, and rerun samples). The rack enables easy transportation on analytical systems and modules. Different rack types can be distinguished by their differing colors.

rack ID A barcode (one-dimensional or binary) at the end of the rack that unmistakably identifies the rack.

rack loader Area where the sample racks to be measured are set. 15 racks can be placed on the rack tray and 15 racks on the input buffer.

rack pusher arm An arm, located on the loader, for pushing racks.

rack rotor A device that performs the rotation movement of the sample rack from the rack feed unit, or STAT sample inlet, to the conveyance position on the sample line. The structure can hold up to twenty racks waiting for rerun or for automatic QC.

rack tray A device for carrying and handling racks. It holds up to 15 racks and is placed directly in the rack loader or unloader of the analyzer.

rack unloader Area that holds the sample racks whose measurements have completed. Fifteen racks can be stored on the rack tray and 15 racks on the output buffer.

random access The ability of an analytical instrument to process requests from a patient sample in any order.

rate assay A determination in which measurements are taken as the reaction proceeds. The rate of the reaction is proportional to the sample component being analyzed. Also known as a kinetic assay.

raw data The unprocessed values obtained during the analytical process on an instrument (for example mVolt or absorbance).

reaction bath See also *incubator bath*.

reaction cell A plastic cuvette into which sample and reagents are pipetted for the chemical or immunological reactions.

reaction disk A rotatable disk that holds the reusable reaction cells used for photometric measurement.

reagent cap open/close mechanism A mechanism that prevents evaporation by automatically opening and closing the cobas e pack caps before and after reagent pipetting or operation.

reagent compartment A temperature-controlled section on an analyzer that holds reagents and diluents.

reagent disk The device in the reagent compartment into which the cobas c packs or cobas e packs are placed.

reagent mask A function that automatically stops analysis of the current test when a required reagent (cobas c pack or cobas e pack) is empty or not present on the system. A red bar appears on the test key in the test selection screen.

reagent pack A complete set of physically combined and ready-to-use reagent bottles for Elecsys assays. The components of a reagent pack cannot be interchanged with another reagent pack. See also *cassette*, *cobas c pack*, and *cobas e pack*.

reagent pack calibration (R-cal) The calibration performed when a reagent has been onboard the analyzer more than 24 hours. A reagent pack calibration is valid for one specific reagent pack only.

reagent pack number A unique number on the reagent bottle label that identifies each reagent pack.

reagent probe Probe used to transfer reagents from the reagent bottles to the reaction cells.

reagent probe rinse station An area located between the reagent disks and reaction disk where reagent probes are rinsed both internally and externally with water.

reagent scan A scan of the reagent disk to read information from the reagent barcode into the analyzer and to update the inventory.

real time The display of information on the monitor at the very moment a change to such information occurs.

realtime QC Real-time quality control. A method in which two quality control samples of low and high values are measured, the quantitative values are judged in real time, and an alarm is generated if necessary.

recalibration The repetition of a calibration.

S

reference electrode 1. Electrode through which the reference solution flows to provide a reference potential for ISE measurements (also called reference cartridge).
2. A part of the measuring cell used to control the electrochemical process of the ECL reaction.

reference range See *expected range*.

reference solution A KCl solution aspirated through the ISE reference cartridge. Also known as the REF, ISE Ref. or reference electrode solution. See reference electrode (1.).

reflex testing A request for additional testing based on customer-defined algorithms or rules and previous test results.

repeat limit A user-definable limit at which a test is run again under unchanged conditions.

reportable range The range of results that can be reported for the assay. It stretches from the lower detection limit to the high end of the calibration curve.

request See order.

rerun The performance of the same test on a sample again under the same or changed conditions.

rerun – concentrated The performance of the same test with a less diluted sample, either by decreasing the diluent or by increasing the sample volume.

Reset Operational mode during which the analyzer sets and aligns all mechanical parts to their home positions.

Result Date/Time The instrument fills the result date and time after the result calculation is finished. It may be maintained by work area management systems for information purpose.

rinse bath See rinse station.

rinse nozzle A nozzle that supplies or drains detergent or water used for rinsing reaction cells.

rinse station A technical device that cleans probes or disposable tips with deionized water or cleaning solutions to avoid contamination and carryover.

Rodbard function A mathematical function used to convert measured signals into concentrations. It uses four parameters to define the shape and position of calibration curves.

S.Stop Abbreviation for sampling stop. A system operating mode in which no new samples are pipetted, but samples already pipetted will be completed without interruption or loss.

S1Abs The absorbance of standard solution 1. The displayed value is 10 000 times greater than the actual measured absorbance.

sample blank The absorbance of the sample plus reagent 1 of a photometric test. The sample blank is subtracted from the actual absorbance reading to obtain the absorbance value relevant for the result calculation.

sample cup A small container that is used for samples and also for calibrator and control material. A sample cup can be placed either on specific racks, other inserts, or on sample tubes. Compared to a sample tube, a sample cup allows the use of smaller liquid volumes and so reduces the dead volume.

sample ID A set of alphanumeric data that unmistakably identifies a particular sample. See also *patient ID*.

sample probe Pipetter probe used to transfer sample material from sample containers to reaction cells.

sample rack See rack.

sample tray See rack tray.

sample tube A glass or plastic container for liquid samples to be used with the system. It may or may not have a barcode label, which may be used for positive sample identification. A sample tube contains sample of one specific specimen (sample) type.

sample type One of four types of sample that can be analyzed: serum/plasma, urine, cerebrospinal fluid (CSF), or supernatant. The sample volume and normal value are settable for each type.

sampling stop An instrument alarm level that indicates a problem with the sampling system. See also *S.Stop*.

sandwich principle One of three test principles that can be applied to ECL immunoassays. It is used to detect higher molecular weight analytes, such as TSH. See also *bridging principle, competitive principle*.

secondary tube A sample container of variable size into which aliquots are transferred

sequence number A number automatically assigned to each sample by the analyzer and used to track samples and orders.

serum index A function by which the absorbance characteristics of the samples are described to assess the presence of lipemia, hemolysis, and icterus.

serum work area (SWA) The section of a clinical laboratory where all CC, HIA, and HetIA tests (including preanalytical and postanalytical work) are processed.

Service System status that is required to perform a maintenance action. See maintenance item, maintenance procedure.

shutter A door, located on the lid of the reagent disk, that is used to load and unload cobas c packs (reagent cassettes).

sipper A device to aspirate liquid from a vessel into a flow path, for example, ISE measuring flow path. In ECL systems, a device that aspirates the reaction mixture out of the AssayCup as well as ProCell and CleanCell from their reservoirs into the measuring channel.

Sleep mode Also called sleeping. A mechanical and electrical status of an analytical instrument during which no immediate processing can be initiated by the operator.

slider A device for raising and lowering the aspiration nozzles from the ProCell and CleanCell bottles.

solid waste container A metal waste container holding a liner that collects discarded solid waste.

standard Traceable reference material used to create a (master) calibration curve. Also referred to as calibrator.

standard deviation A statistic used as a measure of the dispersion or variation in a distribution of data.

standard rack A standardized transportation device for a maximum of five sample containers on Roche Diagnostics/Hitachi High-Technologies instruments.

Standby An operational mode of the analyzer during which power is on but no sample analysis or maintenance procedures are being performed.

standby reagent QC The measurement of a quality control sample from a reagent that is on board the analyzer but not presently in use for routine testing.

Start up An operational mode of an analyzer, following power-on, during which the instrument prepares itself for operation.

STAT application A special test application (for example, reduced incubation time) for STAT or emergency samples to achieve faster result reporting.

STAT port Special entry area for STAT samples, which will be processed with priority.

STAT sample Emergency sample. Results should be available within shortest possible time.

SysClean An auxiliary reagent used for the periodic cleaning of the measuring cell.

system cleaning solution See wash solution.

system error 1. A calibration quality criterion that originates from a hardware failure while a calibration measurement is performed.
2. The general term for a case of instrument-related problems.

systematic error An error that is generated by a cause giving deviation to measured values. An alarm generated when control of a low value or a high value is changed in the same direction in realtime quality control.

SysWash A system-specific agent used to avoid reagent carryover. It also prevents bacterial growth.

T

T-mask See Test mask.

target range The allowed range of recovery for an analyte in a control material.

target value The mean of all participant responses after removal of outlying values.

technical limit The dynamic range of an assay.

test code The abbreviated name for a test. This code is displayed on test buttons shown on software screens or windows.

Test mask There are two possibilities to mask a test: Test mask (T-mask) and Patient mask (P-mask). If T-mask is selected, no patient samples, no controls, and no calibrations can be performed. If P-mask is selected, the test is masked for patient samples only—calibration and QC can be performed.

test principle A technique that serves as the basis for designing an assay to detect or quantify analytes.

test protocol The sequence of test steps used to perform an assay (for example, volumes and timings).

ticket master A part of the instrument software that controls the flow of racks on the analyzer.

timeout calibration An instrument mode that automatically generates a calibration request after a predefined interval.

timeout QC A function that measures the quality control sample for the specified item at certain time intervals.

tip See AssayTip.

tip eject station An opening in the instrument housing through which AssayCups and AssayTips are discarded.

tray indication light A light, at the front of the rack loader and unloader that indicates the mode of operation.

tripropylamine (TPA) One of two electrochemically active substances used in the ECL reaction.

turn-around-time 1. The time between the decision to perform a test and the time when the doctor receives the result and can act on it.
2. Inside the laboratory (Lab-TAT): Time between receiving a sample and sending out the validated result.

V

validation The process of checking results or data against defined rules or ranges in clinical laboratories. Validation can be against technical or clinical criteria.

W

wash solution 1. A solution used to wash reaction cells. The unused solution is stored in a detergent bottle in the instrument.
2. A solution used to wash the reagent probes as specified in the Utility > Special Wash screen.

waste solution reservoir Container that collects reaction waste.

water level sensor A sensor that monitors the water level of temperature-controlled water.

water supply tank A tank used to store ion-exchanged water.

water supply tube A tube for connecting a water supply tank and an analyzer.

workarea consolidation The combination of separate workstations to produce one physical or logical workarea in a laboratory. This combination can be achieved through mechanics (a conveyor, for example), facilitated sample transfer (racks or trays), and data management.

U

ultrasonic mixer A mechanical unit, in a waterproof pack, that generates ultrasound used to stir samples.

unloader An unloader holds sample racks after the completion of the analytical process.

upload The process of sending data to Roche by a network link.

workarea consolidation - workarea consolidation

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