cobas c 311 analyzer

Safety Guide
Software version 01-10

Roche

cobas®
Life needs answers

Publication information

Publication version	Software version	Revision date	Change description
1.0	01-09	2014-10	First version
1.1	01-10	2016-12	License information and regulatory information updated.

Revision history

Edition notice

This publication is intended for operators of the **cobas c** 311 analyzer.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **Online Help** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- A software reference
- Configuration information
- Background information

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the instrument.

The **Operator's Manual** focuses on routine operation and maintenance. The chapters are organized according to the normal operation workflow.

⚠ General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Training

Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Images

The screenshots and hardware images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty

Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative or perform such updates with their assistance.

Copyright

Trademarks

The following trademarks are acknowledged:

COBAS, COBAS C, COBAS INTEGRA, and LIFE NEEDS ANSWERS are trademarks of Roche.

All other trademarks are the property of their respective owners.

Feedback

Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals

The **cobas c** 311 analyzer meets the requirements laid down in:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the provisions of the applicable EU directives.

Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

The **cobas c** 311 analyzer complies with the emission and immunity requirements described in the standard IEC 61326-2-6 / EN 61326-2-6.

Contact addresses

Inside the European Union and EFTA member states

Manufacturer of **cobas c** 311 instrument	Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku Tokyo 105-8717 Japan
Authorized representative	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Outside the European Union and EFTA member states

Manufactured by:	Hitachi High-Technologies Corporation
Manufactured for:	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Table of contents

Preface

Use this publication together with the **cobas c** 311 Operator's Manual.

In this section

Intended use

The **cobas c** 311 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in-vitro quantitative and qualitative determination of analytes in body fluids.

The **cobas c** 311 analyzer is intended to be used by trained laboratory technicians.

The operational environment for the **cobas c** 311 analyzer are clinical laboratories, hospital laboratories and commercial hospitals, as well as private laboratories.

Symbols and abbreviations

Product names

Except where the context clearly indicated otherwise, the following product names and descriptors are used.

Product name	Descriptor
cobas c 311 analyzer	analyzer
cobas c pack	reagent pack

Product names

Symbols used in the publication

Symbol	Explanation
•	List item
	Related topics containing further information
	Tip. Extra information on correct use or useful hints.
	Start of a task
	Extra information within a task
→	Result of a user action within a task
	Frequency of a task
	Duration of a task
	Materials that are required for a task
	Prerequisites of a task

Symbols used in the publication

Symbol	Explanation
	Topic. Used in cross-references to topics.
	Task. Used in cross-references to tasks.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.
	Equation. Used in cross-references to equations.

Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
COBI	Compendium of Background Information
CSV	comma separated values
EC	European Community
EFTA	European Free Trade Association
EN	European standard
IEC	International Electrical Commission
IVD	In vitro diagnostic
LIS	Laboratory information system
n/a	not applicable
QC	Quality control
SBS	scan before sample stop
SD	Standard deviation
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6 standard. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning…

- …indicates a hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution…

- …indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

Notice...

...indicates a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is indicated with the following icon:

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

⚠ **To avoid serious or fatal injury, read and comply with the following safety precautions.**

Keep in mind that the hazard warnings in this manual, in the Operator´s Manual, in the Online Help, and on the instrument cannot cover every possible case, as it is impossible to predict and evaluate all circumstances beforehand.

Just following the given directions may, therefore, be inadequate for operation. Always be alert and use your common sense.

In this section

About operator qualification

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche Service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow standard laboratory practices, especially when you work with biohazardous material.

About safe and proper use of the system

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection with side shields
  - Fluid-resistant laboratory coat
  - Approved lab gloves
  - Face shield if there is a chance of splashing or splattering

Fatigue due to long hours of operation

Looking at the monitor over an extended time may lead to eye strain or body fatigue.

- Take a break to relax, in accordance with your local regulations.

System not used for an extended period

- Follow the decommissioning procedure if available.
- Set the power switch to OFF if you do not use the system for an extended period.
- Remove and refrigerate any remaining reagents.
- For further information, call your Roche Service representative.

Abnormal condition

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 Roche Service representative.

Non-approved parts

Use of non-approved parts or devices may result in malfunction of the system and may render the warranty null and void.

- Use only parts and devices approved by Roche Diagnostics.

About installation and deinstallation

Errors in installation

Only trained Roche Service representatives may install the system.

- Leave installation that is not described to trained Roche Service representatives.

Damage in transit

- Do not attempt to relocate or transport the system.
- Leave relocation and transportation to Roche Service representatives.

Disposal

A biohazardous system may lead to infection.

- If you must dispose of the system, read the following information.

Disposal information (37)

About operating conditions

Unsuitable operating conditions

Operation outside of the specified ranges may lead to incorrect results or malfunction of the system.

- Use the system indoors only, and avoid heat and humidity outside of the specified range.
- Make sure that the system's ventilation openings remain unobstructed always.
- To maintain the operating conditions of the system, perform maintenance in accordance with the specified intervals.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.

Power interruption

A power failure or momentary drop in voltage may damage the system or lead to data loss.

- Operate only with an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backups of results.
- Do not switch off power while the control unit accesses the hard disk or storage device.

Electromagnetic compatibility

This instrument complies with the standard IEC 61326-2-6/EN 61326-2-6. It 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 instrument.
- Do not operate this instrument in close proximity to sources of strong electromagnetic fields (for example, unshielded intentional radio frequency sources), as they may interfere with proper operations.
- Do not operate the following devices in close proximity to the instrument:
  - Mobile phones
  - Transceiver
  - Cordless phones
  - Other electrical devices that generate strong electromagnetic fields

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before operating the system, read the warning messages carefully.

In this section

Electrical safety

Electric shock

Removing the covers of electronic equipment can cause electric shock because there are high-voltage parts inside.

- Do not attempt to work in any electronic equipment.
- Do not remove any cover of the system except those covers specified in the Operator's Manual.
- Do not open the top cover and touch the ultrasonic mixing unit during operation or when the analyzer performs maintenance.
- Only Roche Service representatives may install, service, and repair the system.

Biohazardous materials

Infectious samples

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

- Follow standard laboratory practices, especially when working with biohazardous material.
- Keep all covers closed while the system is operating.
- Always switch off the system or go to maintenance mode, if available, before you work with an opened cover (for example, for cleaning or maintenance).
- Wear appropriate personal protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Sharp objects

Contact with probes or needles may result in infection.

- When you wipe probes or needles, use several layers of gauze and wipe from the top down.
- Take care not to puncture yourself.
- Wear appropriate personal protective equipment.
  Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection.

Moving parts

Contact with moving parts may result in personal injury.

- Keep all covers closed and in place while the system is operating.
- Always switch off the system or go to maintenance mode, if available, before you work with an opened cover (for example for cleaning or maintenance).
- Only trained personnel should have access to the keys to the protective covers of the instrument.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- Only load samples onto the sample disk when the green Access Sample Disk lamp next to the sample disk is on. This indicates that the sample disk will not rotate until renewed operation is actively initiated by the operator.
- During operation and maintenance, carefully follow the Operator´s Manual.

Waste

Infectious waste

Contact with waste (liquid and/or solid) may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Wear appropriate personal protective equipment.
  Take extra care when working with lab gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Waste must be treated in accordance with the relevant laws and regulations. Any substances contained in reagents, calibrators, and quality controls, which are legally regulated for environmental protection, must be disposed of according to the relevant water discharge facility regulations. For the legal regulations on water discharge, please contact the reagent supplier.

Two kinds of liquid waste are discharged by the analyzer:

- Concentrated waste solution that contains highly concentrated reaction solution. This waste must be treated as infectious waste as specified by the relevant regulations.
- Dilute waste: A non-concentrated waste solution diluted with rinsing water from cell wash or water from the incubation bath. When using NaOH-D for washing the reaction cells, alkaline concentration is 0.1 to 1.0 mmol/L.

Environmental harm

The system generates liquid and/or solid waste. This waste contains concentrated reaction solutions and is potentially biohazardous. Improper disposal may contaminate the environment.

- Treat this waste as infectious waste.
- Dispose of waste in accordance with the local regulations.

Reagents and working solutions

Skin inflammation or injury

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the Instructions for Use.
- Observe the information given in Material Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If reagents, detergents, or other cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance or checks that involve alcohol.
- When you use alcohol on or around the system, use no more than 20 mL at a time.

Incorrect results

Poor accuracy and precision

Incorrect results may lead to errors in diagnosis, posing danger to the patient.

- For proper use of the system, run QC tests and monitor the system during operation.
- Do not use reagents or consumables that have exceeded their expiry date, otherwise you may obtain inaccurate data.
- For diagnostic purposes, always assess the results with the patient's medical history, clinical examination, and results from other consultations.

Position mismatch

Putting a sample container with a manually entered ID on a wrong position may lead to incorrect results.

- Check the manually entered ID against the sample ID on the sample container.
- Be sure that the samples are loaded in the correct positions on the sample disk.

Exchange of sample positions

Exchanging of sample positions during interruption may lead to incorrect results.

- When operating in barcode mode, do not exchange any samples highlighted in green on the **Sample Tracking** screen.
- When operating in non-barcode mode, do not move or exchange any samples that are already on the disk.

Foam, clots, films, or bubbles

Incorrect results may occur due to foam, fibrin clots, films, or bubbles in reagents or samples.

- Avoid the formation of foam, clots, and bubbles in all reagents, samples, calibrators, and controls.

Contaminated samples

Insoluble contaminants, bubbles, or films in samples may cause clogging or pipetting volume shortage, leading to incorrect results.

- Make sure that the samples contain no insoluble contaminants, such as fibrin or dust.

Carryover

Traces of analytes or reagents may be carried over from one test to the next.

- Take adequate measures (for example, extra wash cycles) to avoid extra testing and potentially incorrect results.

Evaporation of samples or reagents

Evaporation of samples or reagents may lead to incorrect or invalid results.

- Sample material may evaporate if left open. Do not leave samples open for any length of time.
- Do not use improperly stored reagents. Ensure that reagents are stored according to the Instructions for Use.

Incorrect reagent volume

Incorrect reagent handling may cause an undetectable loss of reagent.

- Always store reagents according to the specified storage conditions as stated in the Instructions for Use for the test.
- Do not reuse a reagent cassette whose reagent has spilled.
- Do not use a reagent cassette for different systems.

Expired reagents or mixing reagents

Data obtained using expired reagents is not reliable. Mixing new reagents with residues of old reagents may also lead to incorrect results.

- Do not use reagents that have exceeded their expiry dates.
- Do not mix old reagents with new reagents. When a bottle is empty, replace it with a new one.

Expired calibrators or controls

Data obtained using expired calibrators or controls is not reliable.

- Perform QC and calibration only with unexpired material.
- Do not use calibrators or controls that have exceeded their expiry dates.

Missing covers of the ISE measuring system

If the cover of the ISE measuring compartment or the cover of the sipper nozzle are not reinstalled after maintenance, the temperature level or the noise level may be affected, leading to incorrect results. Touching any ISE component or opening the front doors may also affect the noise level and lower measurement precision.

- Only perform measurements if the cover of the ISE compartment system is closed.
- Do not open the front doors during measurement.
- Do not touch the ISE REF tube, the ISE unit, or the sipper nozzle cover during measurement.

Aspiration of air

Incorrect pipetting of the probes as well as incorrect adjustment of the probe position may result in aspiration of air, leading to incorrect results.

- Check the instrument performance by performing control measurements.
- Perform maintenance procedures regularly.

Incorrect mixing volume

The permissible volume of reaction solution to be mixed by the ultrasonic mixer is 100 to 250 µL. If the volume is outside this range, the reaction solution may not be mixed correctly, leading to incorrect results.

- Make sure that the volume of reaction solution stays in the range of 100 to 250 µL, especially when loading a new application onto the analyzer.
- For information on analytical parameters of each reagent, contact its manufacturer.

Low level of incubator bath

If the water supply insufficient, the incubator bath can not be filled up properly. An alarm will be issued.

- Check that the tap at the outlet of the water tank is open.
- Check that the external water supply is turned on and that the water pressure meets requirements.
- When the cause is eliminated, perform maintenance item (4) Incubation Water Exchange to refill the incubator bath.

Undetected scanning errors

Barcode scanning errors could potentially go undetected when a check digit is not used.

- Use only barcodes with check digits.
- Use only barcode labels of a good printout quality.
- Do not move any samples that have already been scanned.
- Do not add a non-barcoded sample into the position of a sample with an unreadable barcode.

Caution messages

⚠ List of caution messages

Failure to observe caution messages may result in minor or moderate injury.

- Before operating the system, read the caution messages carefully.

In this section

Mechanical safety

Top cover dropping suddenly

Be careful when opening or closing the top cover. If you let go of the handle, the top cover may drop onto your fingers.

- Always keep a firm grip on the handle and do not let go when opening or closing the top cover.
- If the top cover does not stay open properly, please contact your local Roche Service representative.

Software and data security

USB flash drives

USB flash drives can be used for several kinds of data backups and restores. Wrong handling of a USB flash drive may result in data loss or malfunction of the instrument.

- Use only USB flash drives that are tested and installed by your local Roche Service representative.
- Insert or remove a USB flash drive only when the instrument is in **Standby** status.
- At any one time only one USB device can be in use. Before inserting a USB flash drive, check that no other USB device is inserted.
- Before removing a USB flash drive, choose the **Media Eject** button.
- To prevent a virus from infecting the software, use the USB flash drive exclusively on the analyzer. Do not store other data on this USB flash drive.

Non-approved third-party software

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

- Install only approved third-party software.

Notices

⚠ List of notices

Failure to observe the notices may result in damage to the system.

- Before operating the system, read the notices carefully.

In this section

Circuit breakers and fuses

Circuit breakers and fuses

Improper use may result in damage to the system.

- If one of the circuit breakers or fuses blows, do not attempt to operate the system before contacting either your Roche Service representative or technical support.

Collision with moving parts

Collision with moving parts

Contact with moving parts may bend the probes or needles or damage some other component. If the system detects a collision, an alarm is raised, stopping the operation immediately.

- Keep all covers closed and in place during operation.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- Only load samples onto the sample disk when the green Access Sample Disk lamp next to the sample disk is on. This indicates that the sample disk will not rotate until renewed operation is actively initiated by the operator.

Spillage

Spilled liquid

Any liquid spilled on the system may result in malfunction or damage.

- Place samples, reagents, or any other liquid only at the intended positions.
  Do not place samples, reagents, or any other liquid on the covers or other surfaces of the system.
- When you remove or replace consumables, do not spill any liquid on the system.
- If liquid does spill on the system, wipe it up immediately and apply a disinfectant. Wear appropriate personal protective equipment.
  Dispose waste according to the local regulations.

Data security

Unauthorized system access and data loss

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The system is not protected against malicious software and hacker attacks.

The operators are responsible for the 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 may render the system unusable.

Roche recommends the following precautions:

- Allow connection only to authorized external devices.
- To protect all external devices, make sure that you use appropriate security software.
- To protect access to all external devices, make sure that you use appropriate security equipment. Your Roche Service representative can recommend a suitable firewall.
- Do not copy or install any software on the system unless it is part of the system software or your Roche Service representative tells you to do so.
- If extra software is required, contact your Roche Service representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless your Roche Service representative or an operating instruction tells you to do so.
- Exercise care when you use external storage devices such as USB drives, CDs, or DVDs. Do not connect to the system any external storage device that you use on public or home computers.
- Keep all external storage devices in a secure place, and make sure that only authorized personnel can access them.
- Back up your data regularly.

Safety labels on the system

In this section

List of safety labels on the system

The system has warning labels to draw your attention to areas of potential hazard. The following list explains the meanings of the labels at the locations where you find the labels.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010-2-101, IEC 61010-1, IEC 60417, ISO 7000, or ISO 15223-1.

Only Roche Service representatives may replace damaged labels. For replacement labels, contact your Roche Service representative.

Spillage
Spillage near this label may damage the system.
Do not place liquids in this area.

Infection
Touching the system mechanism may cause infection.
Do not open the covers while the system is in operation.
Stop every mechanism before you open a cover.

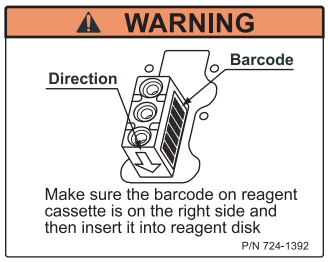
Personal protective equipment
Contact with corrosive material located near this label may harm you.
Wear appropriate personal protective equipment (such as eye protection and lab gloves).

General warning
Potential hazards located near this label may lead to death or serious injury.
Refer to the manual for instructions on safe operation.

Biohazard
Potentially biohazardous materials are used near this label.
Observe relevant laboratory procedures on safe usage.

Electrical
If you access a part of the system marked with this label, contact with electrical components may cause an electric shock.
Refer to the manual for instructions on safe operation.

Hot surface
The area near this label may be hot.
To avoid burns, do not touch this area.



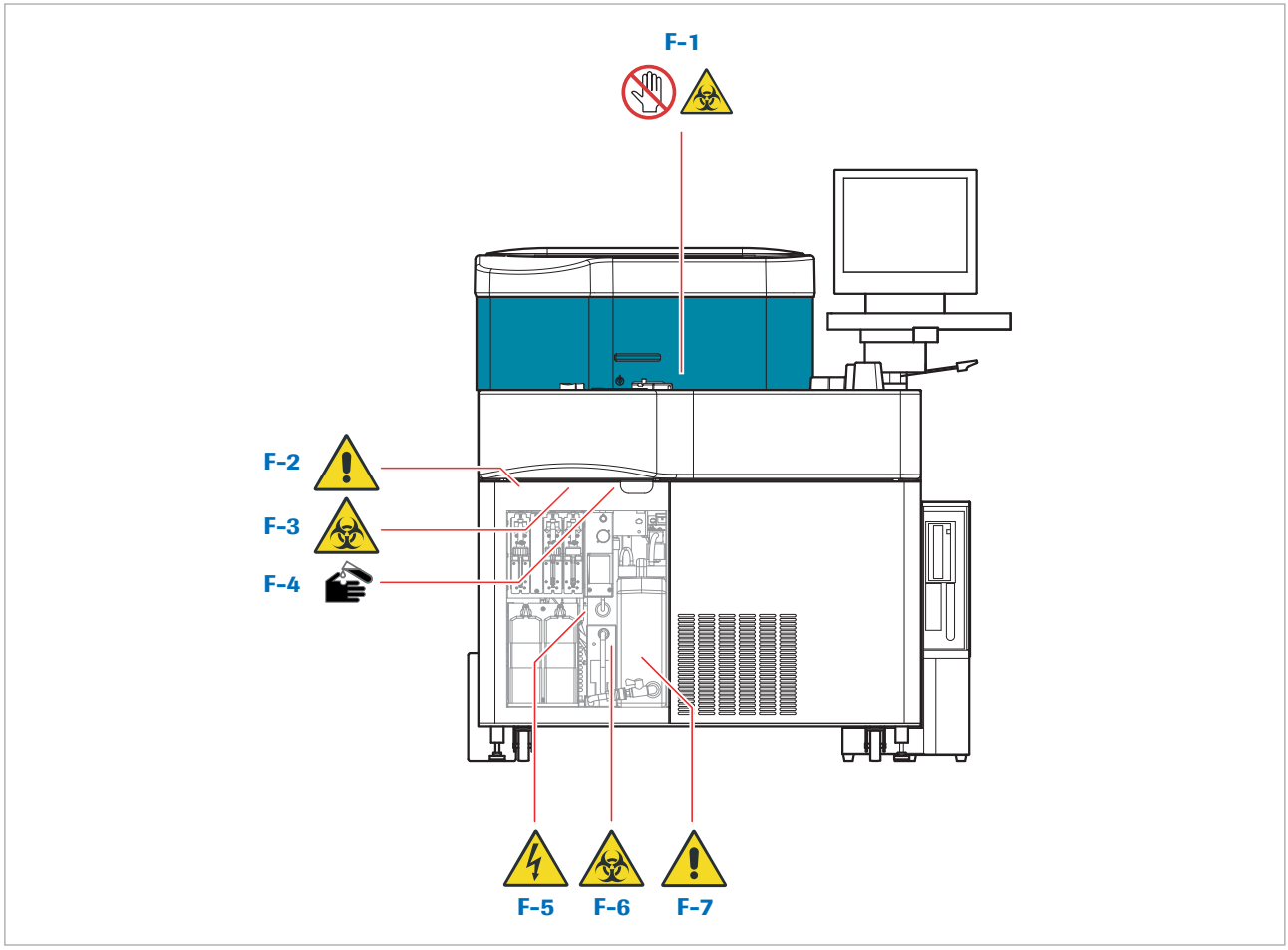
Barcode label direction
The barcode label must be on the right side when you insert the reagent pack into the reagent compartment.
To avoid damage to the system, do not insert the reagent pack the other way around.

Safety labels and safety notes

The following sections briefly describe the meaning of the safety labels at the locations where they are labeled on the system.

When working with the system, observe the safety labels on the system, the safety notes in this manual, and the safety notes in operating instructions.

Location of safety labels on the front view



Front view of the analyzer

F-1
Warning: Possibility of infection or injury due to contact with operating mechanisms!
Keep top cover closed whenever possible.

F-2
Warning: Fingers or skin may be pinched by syringe (when plunger is moving).
Do not touch any moving parts.
Caution: Loose tube connector may lower measurement precision.
After performing maintenance, tighten connector securely.

F-3
Warning: Possibility of infection due to contact with sipper syringe!
Keep front cover closed during operation.

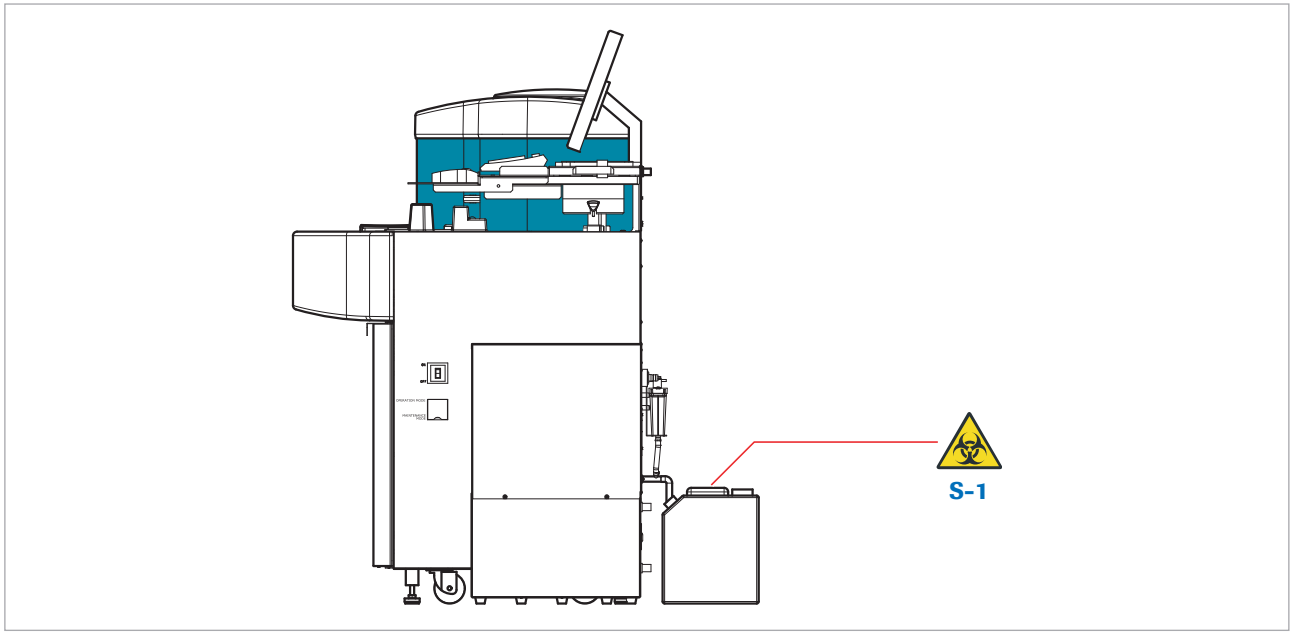
F-4
Caution: Detergent and/or reagent may cause skin irritation!
Observe safety precautions. Wear protective equipment.

F-5
Warning: Possibility of electrical shock inside the instrument.
Do not remove the cover!

F-6
Warning: Possibility of infection due to contact with waste from the vacuum tank!
Follow standard laboratory practices for working with biohazardous materials.

F-7
Caution: Malfunction due to spilled liquid
Follow all instructions for water tank maintenance carefully!

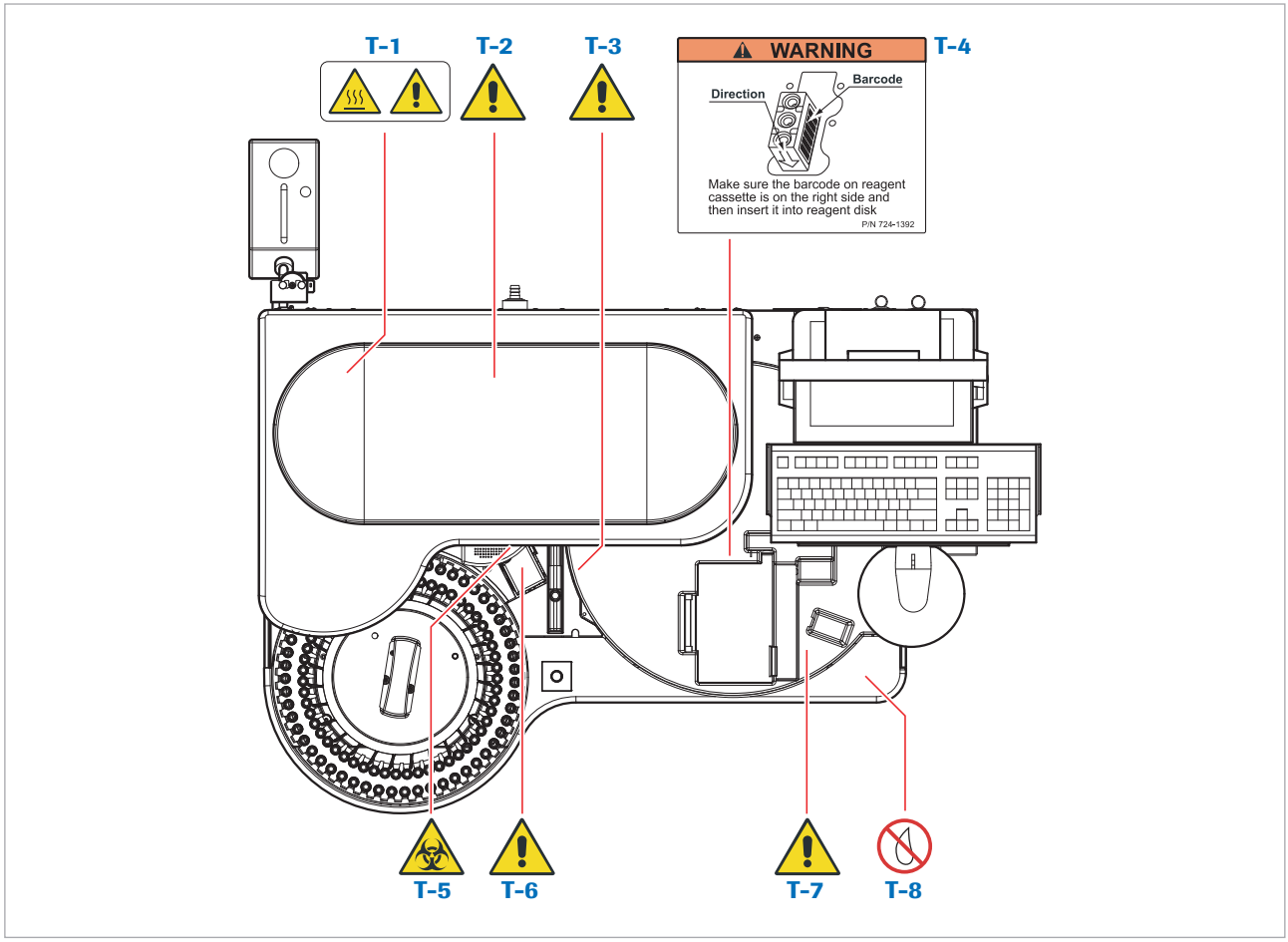
Location of safety labels on the side view



Right side of the analyzer

S-1
Warning: Possibility of infection due to contact with waste solution in waste solution tank!
Follow standard laboratory practices for working with biohazardous materials.

Location of safety labels on the top view

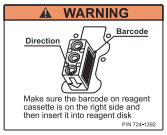


Top view of the analyzer

T-1
Warning: Possibility of burning yourself on the lamp or the lamp housing when replacing the photometer lamp!
Wait until the lamp housing has cooled down.

T-2
Warning: Possibility of injury or infection due to contact with moving mechanism!
Keep top cover closed whenever possible.

T-3
Caution: Touching the ISE Ref. tube during analysis may lower measurement precision!
Do not touch ISE Ref. tube during analysis.



T-4
Incorrect results due to incorrect placement of reagent
Make sure the **cobas c** pack is facing in the right direction when inserting cassettes!

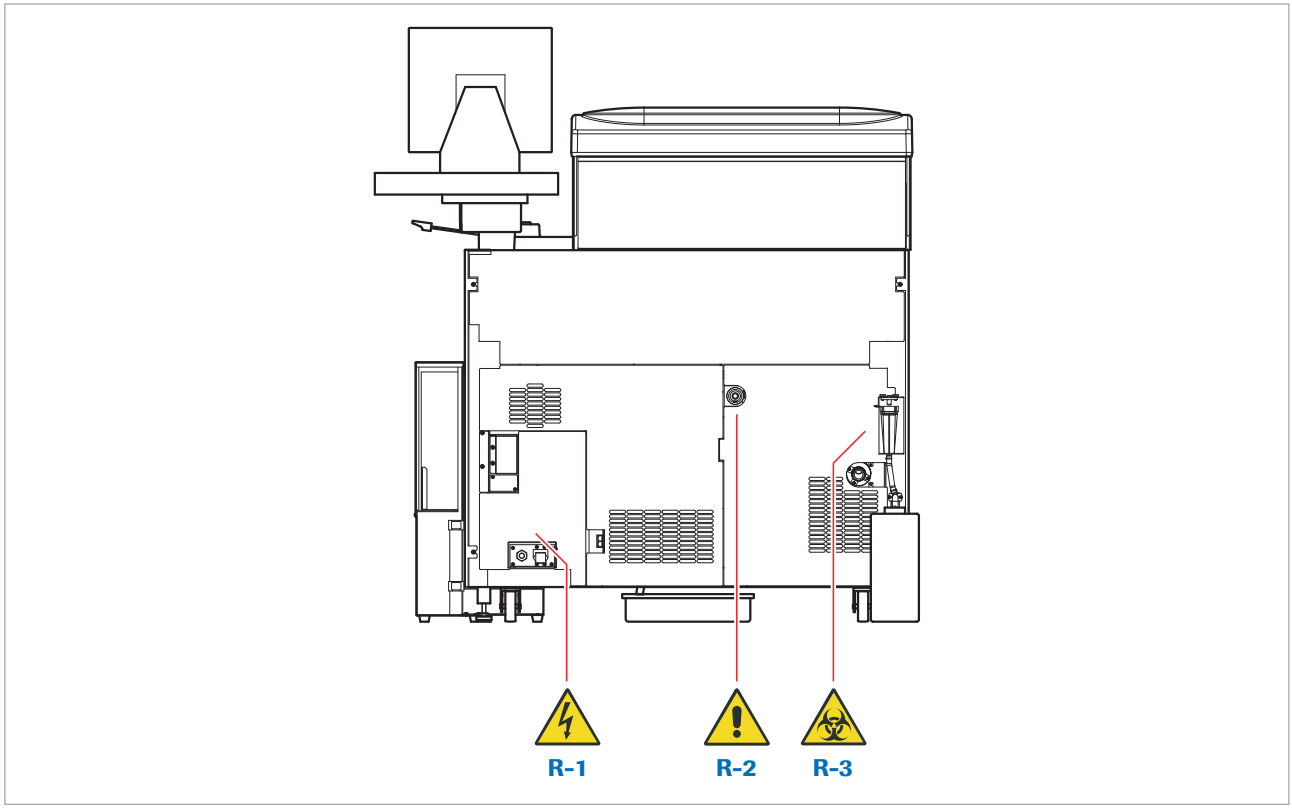
T-5
Warning: Possibility of infection due to contact with parts of the ISE measuring compartment!
Follow standard laboratory practices for working with biohazardous materials.

T-6
Caution: Opening the cover of the ISE measuring compartment may lower measurement precision!
Keep ISE cover closed during analysis.

T-7
Warning: Your fingers or hand may be pinched by the reagent disk during operation!
Do not reach into the reagent disk during operation.

T-8
Spilled liquids, e.g. samples or detergents, may cause instrument damage.
Wipe up spilled liquids immediately.

Location of safety labels on the rear view



Rear view of the analyzer

R-1
Warning: Possibility of electrical shock.
Do not remove the cover!

R-2
Caution: Incorrect results due to loose tube sockets
Follow instructions for inlet water filter maintenance carefully!

R-3
Warning: Possibility of infection due to contact with ISE waste solution!
Follow standard laboratory practices for working with biohazardous materials.

Safety information for barcode readers

The instrument uses barcode readers to scan the barcodes on samples and reagent packs.

The barcode readers use LED technology with low output power. The barcode readers and the instrument comply with the lowest laser class (Class 1).

⚠ WARNING

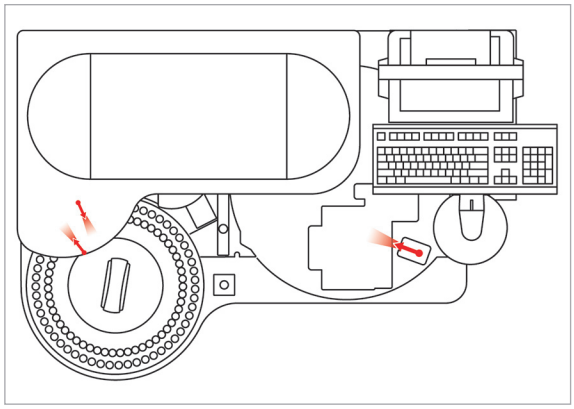
Blindness due to intense barcode reader light

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

- Do not stare into the beam of a barcode reader.
- Do not remove covers from barcode readers.
- Do not perform any maintenance actions on barcode readers. If you experience problems with the barcode readers, contact your Roche Service representative.
- Perform only the procedures described in operating instructions. Performing unauthorized procedures may result in exposure to hazardous radiation.

Position of barcode readers

The figure shows the position of the LED barcode readers and the directions of their apertures.



Position	Wavelength	Output power
Sample barcode readers at inner and outer ring	655 nm	10 µW
Reagent barcode reader	655 nm	10 µW

LED barcode readers

Safety information for disposal

Disposal information

Infection by a biohazardous system

- Treat the system as biohazardous waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the system.
- Dispose of the system according to the local regulations. For more information, contact your Roche Service representative.

Electronic equipment

Disposal of control unit components
This symbol appears on any component of your control unit (such as the computer, monitor, or keyboard) that is covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE).
You must dispose of these items through designated collection facilities appointed by government or local authorities.
Contact your city office, waste disposal service, or your Roche Service representative for more information about disposal of your old product.
Constraint:
It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat them in the same way as the system.