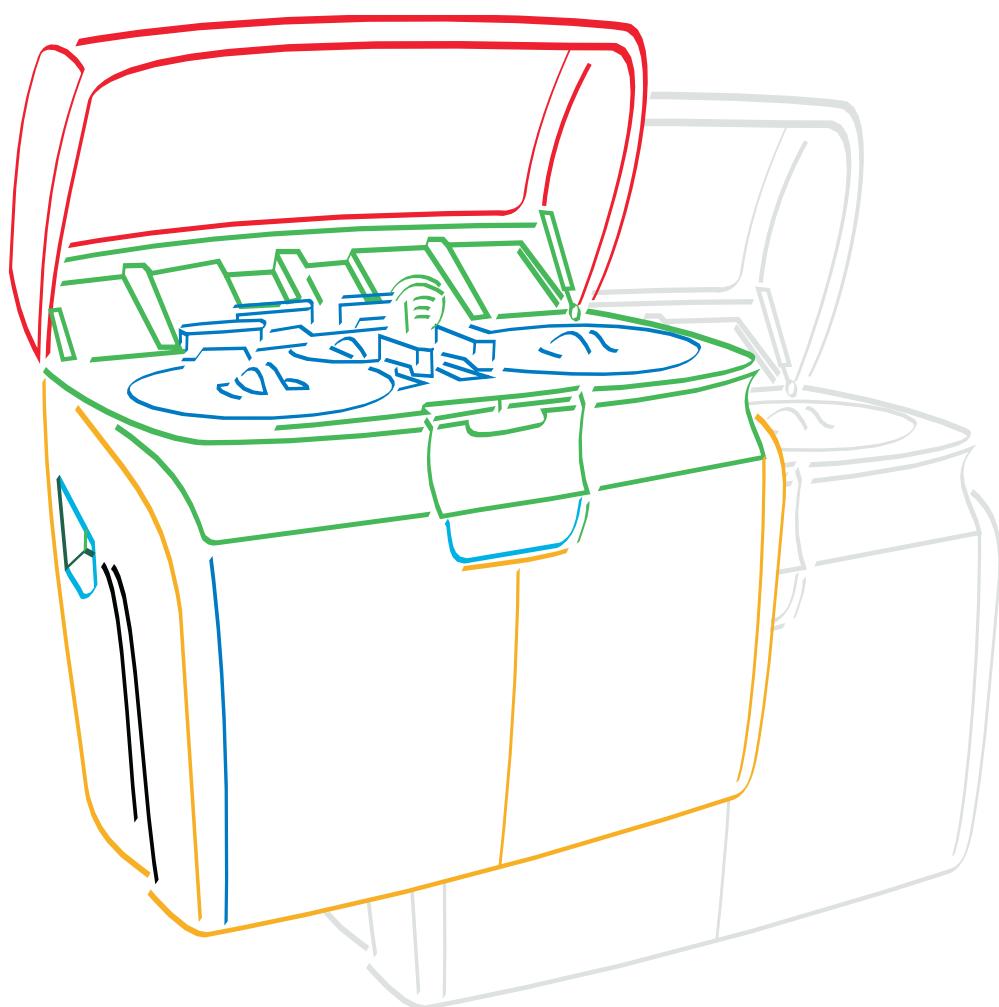




reddot award 2014
winner

BA 400
LED TECHNOLOGY



User manual

BioSystems
REAGENTS & INSTRUMENTS

*Thank you for purchasing
the BA400 biochemical
and turbidimetry analyser*

Manual version	Revision date	Modification
3.1	October 2014	Modification of the chapters: 10.3.1.1, 10.3.6, 10.3.8, 10.7.1, 14.27, 14.2.8
3.0	February 2014	Modification of chapters: 4.6, 4.11, 4.15, 9.1.4, 10.2.1, 10.4.4, 10.6.3, 14.2.3, 16.4
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1.0	June 2012	Initial version

Manual code TEUS00048-05-EN

All the necessary precautions have been taken to ensure that the information set out in this manual is correct at the time of its publication. Nonetheless Biosystems, S.A. reserves the right to make any changes that may be necessary without notice, as an inseparable part of the product's ongoing development.

Any change made to the instrument by the client will render the warranty void and without effect.

Manufacturer's address BIOSYSTEMS

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The BA400 is compliant with EU directive 98/79/EC

Table of Contents

Persons for whom this manual is intended	10
Notices and warnings	10
Software usage licence	15
1. Intended Use	16
2. Content	16
2.1. Content of the accessory box	16
3. Identification of the main components	20
4. Installation	22
4.1. Location	22
4.2. Installing the waste containers and washing solution.	23
4.2.1. Preparing the washing solution.	23
4.2.2. Emptying the high contamination waste container.	24
4.3. Purified water connection	24
4.4. Low contamination waste connection	25
4.5. Installing the sample and reagent rotors	26
4.6. Specifications of the barcode labels	26
4.7. Affixing the identification labels	27
4.8. Installing the reaction rotor	27
4.9. Connection to the mains and start-up	28
4.10. Connection to the computer	29
4.11. Installing the user program in the computer	30
4.11.1. Energy options configuration.	33
4.11.2. Configure programmes in second plane.	34
4.11.2.1. Windows update	34
4.11.2.2. Windows defender or antivirus programmes	35
4.11.2.3. Flash updates	35
4.11.2.4. Java updates	35
4.11.2.5. Operating system services configuration	36
4.12. ISE module installation (optional)	37
4.13. First steps for operating the analyser	40
4.14. Cautions during operation	41
4.15. Preanalysis and preparation of additional solutions	41
5. Transport and reshipment	42

6. Handling and storage	43
7. Operating principle	44
8. Description of the analyser	45
8.1. Cover and lids	45
8.2. Sample rotor	46
8.3. Reagent rotor	47
8.4. Reaction rotor	48
8.5. Optical system	49
8.6. Wash station	49
8.7. Stirring arm	50
8.8. Dispensing arm	50
8.9. Waste containers, purified water and washing solution	51
8.10. ISE module (optional)	52
9. Description of the software	54
9.1. Identification of the program parts	54
9.1.1. List of most frequently-used buttons.	54
9.1.2. List of fast access buttons.	55
9.1.3. List of buttons related to LIS communication.	56
9.1.4. List of action buttons.	57
10. Working procedure	58
10.1. Starting up the program	58
10.2. Setup	59
10.2.1. General setup.	59
10.2.2. Language.	61
10.2.3. Reports.	61
10.2.4. Ordering the tests.	62
10.2.5. Barcode.	63
10.2.6. LIS operation configuration.	64
10.2.6.1. Work session setup	64
10.2.6.2. LIS communication setup	65
10.2.6.3. Protocol setup	66
10.2.7. LIS mapping.	67
10.2.8. Users.	68
10.2.9. Change in user.	70
10.3. Programming	70
10.3.1. Tests.	70
10.3.1.1. Ordering of tests	71
10.3.1.2. Test parameters: general	72
10.3.1.3. Test parameters: procedure	73
10.3.1.4. Test parameters: calibration and blanks	74

<i>10.3.1.5. Test parameters: quality control</i>	76
<i>10.3.1.6. Test parameters: options</i>	77
10.3.2. Calculated tests.	79
10.3.3. Contaminations.	80
10.3.4. Profiles.	82
10.3.5. Standards.	82
10.3.6. Controls.	84
10.3.7. Patient data.	86
10.3.8. ISE module.	87
10.3.9. External tests.	88
10.4. Work session	89
10.4.1. Sample request.	90
10.4.2. Positioning in the rotor.	94
10.4.3. Creating the worklist from the sample positioning screen.	96
10.4.4. Worklist execution.	97
10.4.5. Save session.	99
10.4.6. Load session.	99
10.4.7. Delete session.	99
10.4.8. Delete virtual rotors.	99
10.5. Current status monitor	99
10.5.1. Principal.	99
10.5.2. Work session status.	101
10.5.3. Sample rotor status.	102
10.5.4. Reagent rotor status.	103
10.5.5. Reaction rotor status.	103
10.5.6. ISE module status.	104
10.5.7. List of alarms.	105
10.6. Results	106
10.6.1. Results by patient.	106
10.6.2. Results by test.	108
10.6.3. Reaction graphs.	111
10.6.4. Result repetitions.	111
10.7. Historical logs	113
10.7.1. Patient results.	113
10.7.2. Blank and calibration standard results.	114
10.7.3. Quality control results.	115
10.7.4. Accumulated quality control results.	121
<i>10.7.4.1. Accumulated daily quality control results</i>	121
<i>10.7.4.2. Accumulated results</i>	122
10.7.5. ISE Results.	125
10.7.6. Historical analyser alarm data.	126
10.8. Utilities	127
10.8.1. Rotor change.	127
10.8.2. Analyser conditioning.	128
10.8.3. ISE module functions.	128
10.8.4. LIS tools.	130
10.8.5. Technical service report.	131
10.8.6. Create a restoration point with current data.	132

10.8.7. Restore previous data.	133
10.9. Exit	133
11. List of consumables and accessories	134
12. Support and warranty	139
12.1. Warranty limits	139
12.2. Requests for components and fungible goods	139
12.3. Technical assistance	139
13. List of alarms	140
14. Maintenance and cleaning	147
14.1. Maintenance activities and frequency	147
14.2. Cleaning the analyser	148
14.2.1. General cleaning of compartments.	148
14.2.2. Emptying and cleaning the high contamination waste bottle.	148
14.2.3. Cleaning the sample and reagent rotor.	148
14.2.4. Removing of condensation water from the reagent rotor.	148
14.2.5. Cleaning the barcode reader window.	149
14.2.6. Filling the washing solution bottle.	149
14.2.7. Cleaning the stirrer paddles.	149
14.2.8. Cleaning the ISE module.	149
14.3. Maintenance	151
14.3.1. Changing the reaction rotor.	151
14.3.2. ISE module maintenance.	151
14.3.2.1. <i>Changing the electrodes</i>	151
14.3.2.2. <i>Changing the reagent kit</i>	153
14.3.2.3. <i>Changing the peristaltic pump tubes</i>	155
14.3.2.4. <i>Turning off the ISE module for a long period of time</i>	156
14.3.2.5. <i>ISE module reactivation</i>	158
14.3.3. Maintenance frequency.	158
14.3.4. End of the analyser's useful life.	159
15. Technical characteristics	160
15.1. General characteristics	160
15.2. Sample control	160
15.3. Reagent control	160
15.4. Reaction rotor	161
15.5. Cuvette washing system	161
15.6. Optical system	161
15.7. ISE module (optional)	162
15.8. Environmental requirements	162
15.9. Dimensions and weight	162

15.10. Electrical requirements	162
15.11. Fluid requirements	163
15.12. Minimum computer requirements	163
16. Measuring and calculation procedures	164
16.1. Operating sequence. Preparation and reading cycles	164
16.2. Calculation of the absorbances	165
16.2.1. Endpoint monoreagent.	166
16.2.2. Endpoint bi-reagent.	167
16.2.3. Differential switch.	168
16.2.4. Fixed time monoreagent.	168
16.2.5. Fixed time bi-reagent.	169
16.2.6. Kinetic monoreagent.	170
16.2.7. Kinetic bireagent.	171
16.3. Concentration calculation	172
16.4. Repetition criteria	174
16.5. Calculation of the ISE ion concentration	175
16.6. Internal Quality Control	177
16.6.1. Basis.	177
16.6.2. Admissible value interval.	177
16.6.3. Selection of control rules.	178
17. Summary of workflow scenarios with the LIS	180
17.1. Query by specimen and automatic start	180
17.2. Query All	181
17.3. Sending results to the LIS. Upload.	182
17.4. Repetitions	183
17.5. Reasons for rejection	183

Persons for whom this manual is intended

This manual is intended for the use of clinical laboratory professionals who will use the BA400 analyser to determine analyte concentrations.

This manual describes the characteristics and general operating concepts of the BA400 analyser. The installation, programming, execution and maintenance procedures are described in detail.

Notices and warnings

Explanation of the safety symbols located on the analyser or in this manual.

Symbol	Description
 WARNING	The symbol warns of operating risks that could cause personal injury.
 BIOHAZARD	The symbol warns of a potential biological hazard.
 CAUTION	The symbol warns of potential damage to the system or unreliable results.
 NOTE	The symbol warns that the information requires your attention.
	Risk of electric shock
	The symbol warns of a potential risk due to laser radiation emission

Explanations of the symbols used on the analyser labels and in the manual

Symbol	Description
	This product is compliant with EC directive 98/79 on medical devices for In Vitro Diagnostics.
	Medical device for In Vitro Diagnostics
	Please consult the directions for use
	Serial number
	Expiry date
	Batch code
	Catalogue number
	Temperature limit
	Manufacturer
	Irritant
	Date of installation
	Install by
	Distilled water
	Fragile, symbol used on the packaging
	Keep upright, symbol used on the packaging
	Keep dry, symbol used on the packaging

Safety precautions

Symbol	Description
	<p>Preventing electric shock To reduce the risk of electric discharges, do not remove the analyser cover. There are no parts inside that can be repaired by the user, for which reason it is necessary to contact the technical assistance service.</p>
 BIOHAZARD	<p>Preventing biological risks in handling the samples Inappropriate handling of samples, controls and calibrators could cause biological infection. Do not touch the samples, mixtures or waste with your hands. Wear gloves and protective clothing when necessary. In the event that the samples come into contact with the skin, wash immediately with abundant water and seek medical advice. It is advisable to follow good laboratory practices.</p>
 WARNING	<p>Prevention in handling reagents Handle reagents and washing solutions with care, they contain substances that could be corrosive. In the event that the reagents or washing solutions come into contact with the skin, wash immediately with abundant water and seek medical advice. Consult the reagent or washing solution adaptation sheet and follow the safety instructions. It is advisable to follow good laboratory practices.</p>
 BIOHAZARD	<p>Preventing biological risks in handling liquid waste Handle the high contamination waste container with extreme care. Wear gloves and protective clothing when handling the container. Dispose of the waste in accordance with national or local legislation for disposing of dangerous biological waste, and consult the reagent manufacturer or distributor for more details.</p>
 BIOHAZARD	<p>Preventing biological risks in handling solid waste Take care in handling parts of the analyser that are converted to waste such as the reactor rotor, sample tubes and reagent bottles. Wear gloves and protective clothing when handling such waste. Dispose of the waste in accordance with national or local legislation for disposing of dangerous biological waste, and consult the reagent manufacturer or distributor for more details.</p>
 NOTE	<p>Prevention of electro magnetic interferences The analyser complies with the requirements with respect to emissions and immunity set forth in the standard UNE -EN 61326-2-6:2006. This equipment has been designed and tested for class B of standard UNE-EN 55022:2000. In a household environment, it may cause radio interference, in which case the necessary measures must be taken to mitigate such interference. Do not use the analyser near strong electro magnetic radiation sources (such as centrifuge appliances, radio transmitters, mobile telephones), as they could interfere with its correct operation.</p>

Symbol	Description
	<p>Preventing laser light emission risks</p> <p>The analyser has two barcode readers that emit laser light. The readers only function when the analyser is in execution mode and its rotor covers are in place. In the event of a failure or during adjustment by technical maintenance staff, the light beam could be activated without the cover in place; in such cases, do not look directly at the laser beam.</p>
	<p>Prevention at the end of the analyser life cycle</p> <p>At the end of the useful life of the analyser, disposal of the product must be carried out in accordance with the environmental legislation in force in each country. If that country is an EU member state, the terms of the WEEE directive on electrical and electronic appliances will apply. In other words, when the appliance's useful life has ended, it is converted into waste and must be separated from household waste. For this purpose, contact the distributor for the correct recycling of the product.</p>

Abbreviations and units shown in the manual

Abbreviation	Definition
Ø	Diameter
ASTM	American Society for Testing and Materials (www.astm.org)
EC	European Community
EMC	Electromagnetic compatibility
CRTL	Control key on the computer keyboard
EN	European norm
F	Fast (fuse type)
FUS	Fuse
HL7	Health Level Seven (www.hl7.org)
IHE	Integrating the Healthcare Enterprise (www.ihe.net)
ISE	Ion-selective electrode
IVD	In Vitro Diagnostics
LED	Light-emitting diode
LIS	Laboratory information system
WEEE	Waste Electrical and Electronic Equipment
REF	Reference solution for the ISE unit
UPS	Uninterruptible power source
TAS	Technical assistance service
SD	Standard deviation
ES	Electrical safety
USB	Universal Serial Bus
UV	Ultraviolet

Units	Definition
"	Inch
° C	Degrees centigrade
A	Ampere / Absorbance
GB	Gigabyte
h	Hour
Hz	Hertz
kg	Kilogram
L	Litre
MB	Megabyte
m	Metre
min	Minute
mL	Millilitre
mm	Millimetre
mmol	Millimol
mv	Millivolt
nm	Nanometre
prep	Preparation
s	Second
VA	Volt-ampere
V	Volt
W	Watt
µL	Microlitre
µm	Micrometre

Software usage licence

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1. Intended Use

The BA400 analyser is used to determine analyte concentrations by in vitro biochemical, turbidimetric and electrolyte measurements of human samples of serum, urine, plasma, cephalorachidian fluid or total blood.

The BA400 analyzer is optimized to work with the BioSystems line of biochemistry, turbidimetry and electrolites reagents. Reagents not included in the BA400 validation performed in BioSystems S.A., will require thorough and detailed validation by the user or laboratory.

It is strongly recommended to validate the overall performance of the analyzer and the reagents in the laboratory setting, taking into account the preanalytical phase and any other relevant aspect.

The analyser is exclusively for professional use, i.e., for users who have the appropriate training and expertise to use it. In addition to how to install the instrument, users are instructed on how to use the analyser and the software that goes with it.

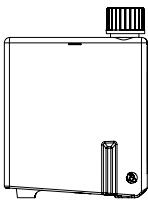
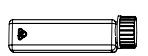
The environmental conditions for the functioning of the analyser are normal clinical analysis laboratory conditions. These conditions are described in the specifications chapter.

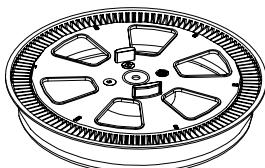
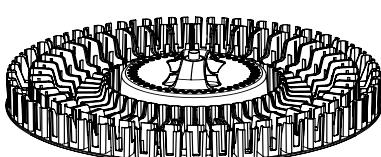
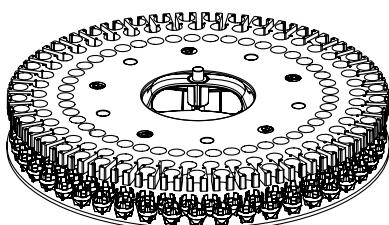
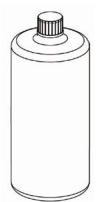
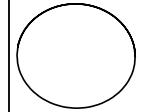
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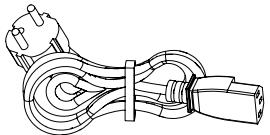
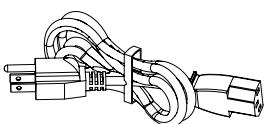
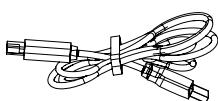
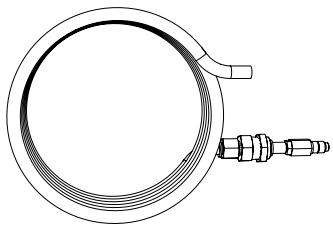
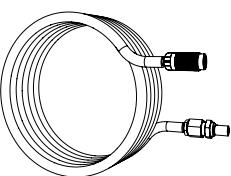
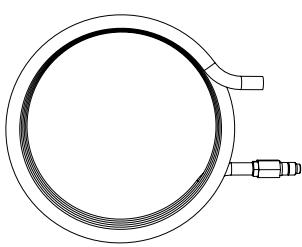
The elements that the user will find on unpacking the analyser are listed below. Make a visual check to ensure that none of the elements has suffered any apparent damage during transport.

1. Analyser.
2. Unpacking instructions sheet.
3. Analysis certificate sheet (Instrument Release Certificate).
4. Accessory box (supplied separately in a different box from the analyser).

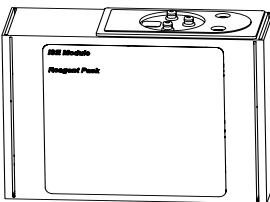
2.1. Content of the accessory box

Accessory	Description
	Empty 60mL reagent bottles (20)
	Empty 20mL reagent bottles (10)

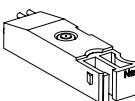
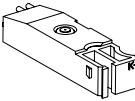
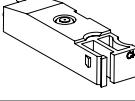
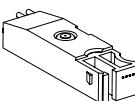
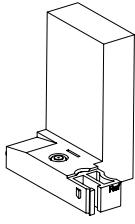
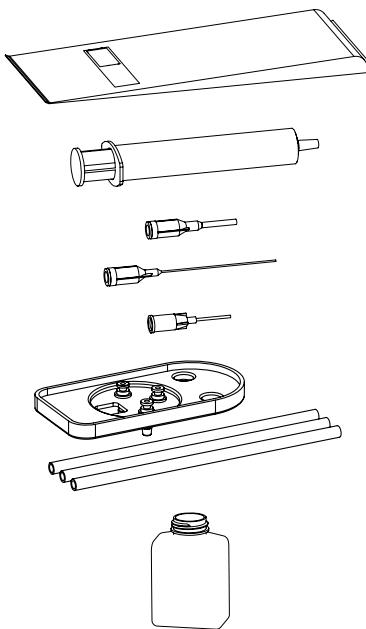
Accessory	Description
 Labels for identifying the empty bottles.	
	"Reaction Rotor" (10)
	Sample rotor
	Reagent rotor
	Sample wells (1000)
	Bottle of concentrated washing solution (500 mL)
	Acid washing solution bottle (1)
	Adapter for primary tubes (90)
	Adapter for sample wells (45)
	DVD with the user program and user manual.

Accessory	Description
	Mains connection cable, European pin
	Mains connection cable, American pin
	USB cable.
	Fuses (2).
	Connection tube with fast connector fitting for the purified water bottle. Thick blue tube (3 m).
	Connection tube for purified water bottle, thin blue tube (3 m)
	Connection tube with fast connector fitting for waste. Red tube (3 m).

ISE module accessories- Optional elements

Accessory	Description
	+Reagent kit

ISE module accessories- Optional elements

Accessory	Description
	Na ⁺ electrode. The screen printing is black.
	K ⁺ electrode. The screen printing is black.
	Cl ⁻ electrode. The screen printing is green.
	Separator electrode
	Reference electrode
	ISE washing solution kit
	ISE urine diluent
	ISE cleaning kit

3. Identification of the main components

The different component parts of the analyser are marked and numbered in the following figures and their associated lists:

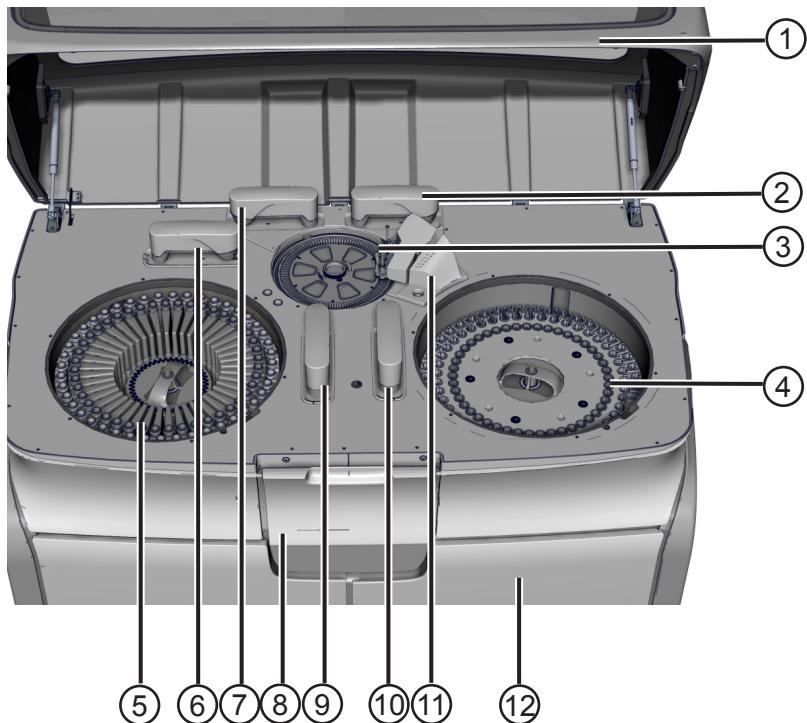


Figure 1 Main components

- | | |
|--------------------|-----------------------------|
| 1 – General cover | 8 – ISE module access cover |
| 2 – R2 stirrer | 9 – Reagent 2 arm |
| 3 – Reaction rotor | 10 – Sample arm |
| 4 – Sample rotor | 11 – Wash station |
| 5 – Reagent rotor | 12 – Bottle access doors |
| 6 – Reagent 1 arm | |
| 7 – R1 stirrer | |

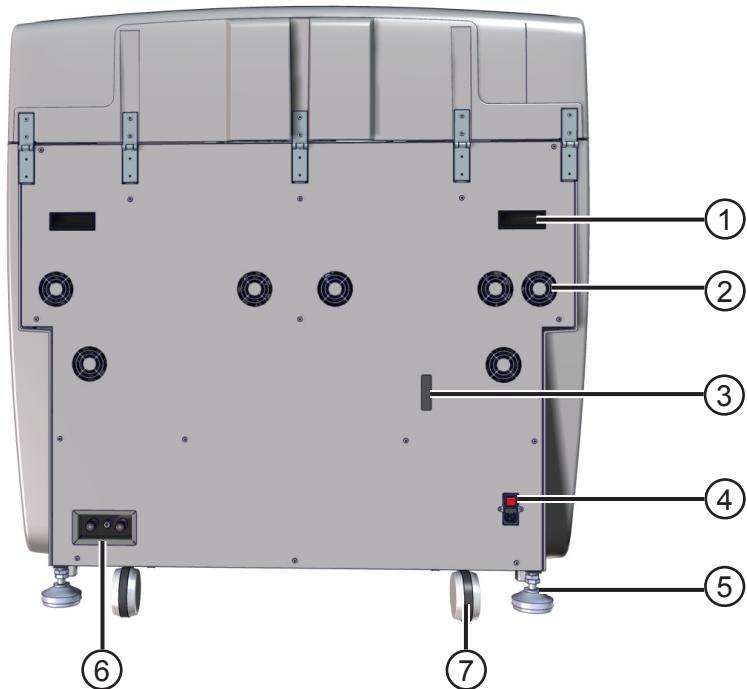


Figure 2 Rear view components

- | | |
|-------------------------------|--|
| 1 – Rear cover handle | 5 – Adjustable leg |
| 2 – Ventilation outlet | 6 – Distilled water and waste connection |
| 3 – RS-232 and USB connection | 7 – Wheel |
| 4 – Main voltage switch | |

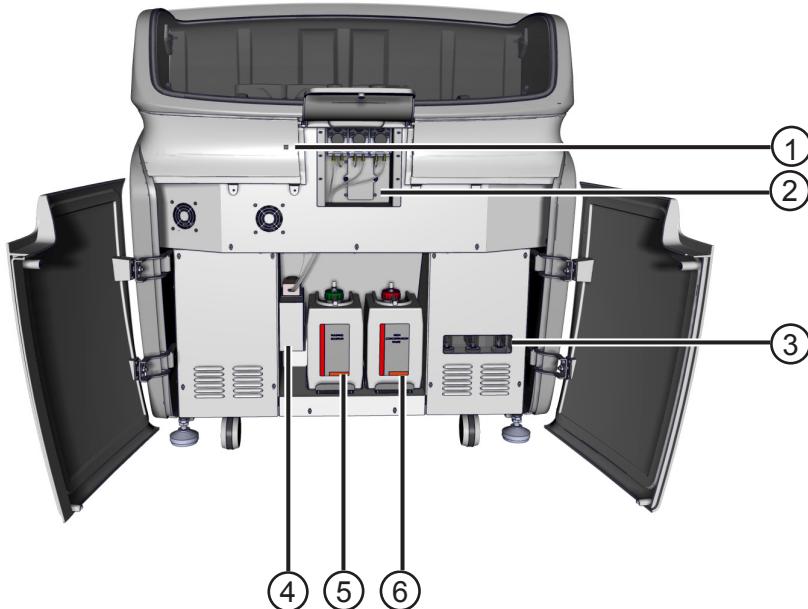


Figure 3 Internal components

- | | |
|-------------------------|-------------------------------------|
| 1 – LED status lamp | 4 – Reagent kit for ISE module |
| 2 – ISE module | 5 – Cleaning solution bottle |
| 3 – Ceramic pump viewer | 6 – High contamination waste bottle |

4. Installation

4.1. Location

- Location* Install the analyser in a large space. It occupies a minimum space of 120 cm x 72 cm.
- Leave a space of at least 50 cm at the back of the analyser to allow the air leaving the fans to circulate and the main cover to be opened.
- Leave a space of at least 60 cm above the analyser to allow the main cover to be opened.
- Leave a space of least 60 cm at the front to allow the doors to be opened for accessing the ISE module.
- Leave a space of at least 60 cm on the left side to allow room for accessing the partial and general switches.
- Environmental conditions* Install the analyser in a dry, non-corrosive environment. The relative humidity should not exceed 85%, with no condensation. It is advisable for the room temperature to be less than 35° C or 30° C in the event of using the analyser ISE module reader. Do not install the analyser in areas that are exposed to draughts.
- Lighting* Do not place the analyser below potent light sources. Keep the lighting as stable as possible and ensure that no flashing light falls directly on the analyser. Direct sunlight should also be avoided.
- Make sure* the analyser is not near any electromagnetic radiation sources (such as motors, centrifuging appliances, mobiles telephones) or heat sources.
- Anchoring* Move the analyser to its definitive location by pushing it gently. It has wheels to make it easier to move.
- Once in the final position, anchor it. Unscrew the four adjustable legs (1) until they touch the floor. (See Figure 4).
- Level the analyser by lengthening or shortening the legs, as necessary. Use a spanner to turn the nut (2) (see Figure 5) once the wheels touch the floor.
- When it is properly levelled, secure the nuts by turning the counter nut (3) to the upper limit.
- Do not turn the nut too much (3) to prevent the leg from being separated from the structure.



Figure 4 Adjustable legs

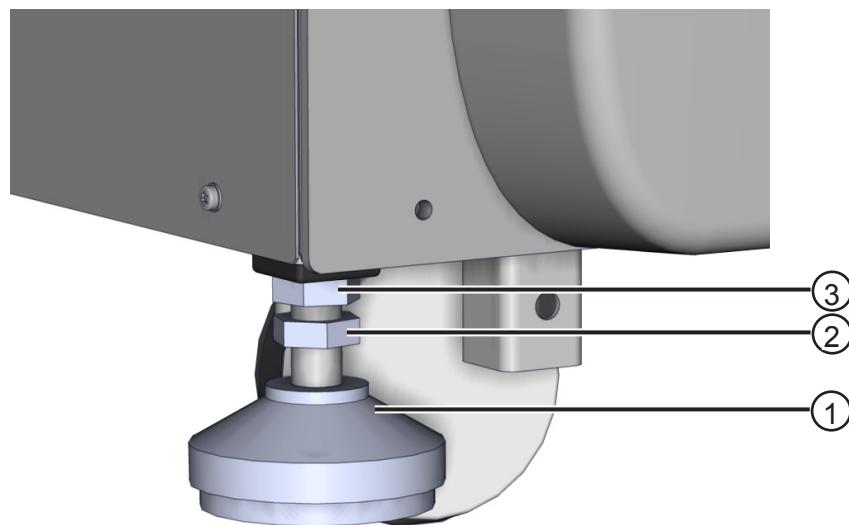


Figure 5 Securing the legs

4.2. Installing the waste containers and washing solution.

If you open both front doors, you will see two bottles inside. The one on the right is the high contamination waste bottle (6) and the one on the left contains the washing solution (7). See Figure 3.

4.2.1. Preparing the washing solution

1. Unscrew the cap of the washing solution bottle (7)
2. Fill it with 5 L of purified water.



NOTE

3. Add 25 mL of the concentrated washing solution (code AC16434) and mix gently. Take care in handling the concentration washing solution bottle, to prevent the contents from splashing or spilling. Wear gloves and protective clothing when handling it.
4. Screw on the cap with the tubes and place it in its housing inside the analyser.

4.2.2. Emptying the high contamination waste container

The high contamination waste container (6) is supplied with a fast connector fitting.

1. Press the fast connecting fitting on the cap and take the container out of the analyser.
2. Unscrew the container cap.
3. Empty the container.
4. Screw on the container cap, insert the tube with the fast connector and place in the container in its housing inside the analyser.



NOTE

Make sure that the fast connector fitting is properly inserted into the container cap. To do this, when inserting the fitting, you should hear a “click”. If not, this means it has not been properly inserted.



BIOHAZARD

Dispose of the waste in accordance with the applicable national or local government legislation governing the disposal of dangerous biological waste.

Handle the high contamination waste container with care. Wear gloves and protective clothing when handling the container.

4.3. Purified water connection

The analyser has two purified water inlets at the rear. See Figure 6.

Once the user program has been installed, configure the water inlet selection, depending on the connection made.

See water inlet selection in chapter 10.2.1

Network water inlet

This connection is used by laboratories which have a centralised purified water production system.

1. The circuit water pressure in that tube must be between 0.5 and 4 bar.
2. Connect the thick blue tube in the accessory box to the left-hand connector (1). It is marked “MAINS WATER INLET”. Connect the other end to the water mains.
3. Ensure that the central purified water system output is fitted with a filter. If it has no filter, one must be installed between the purified water production system and the analyser.



NOTE

Filter specification

Filtration < 5 µm

Tank water inlet

For laboratories which do not have a centralised purified water production system, an auxiliary tank is used to supply the purified water.

1. Place a purified water tank (60 L provide 4 h of autonomy) at the side of the equipment. This tank must be on the same level as the analyser.
2. Connect the thin blue tube supplied with the accessory box directly to the central connector (2). This connector is a fast connector. Insert the tube directly and press it slightly backwards to lock it. The connection is marked "WATER TANK INLET". Insert the other end in the base of the external tank. To remove the tube, press the external ring on the connector and pull the tube.



Figure 6 Liquid connections

- | | |
|---|------------------------------------|
| 1 – Distilled water intake from mains | 3 – Low contamination waste outlet |
| 2 – Distilled water intake from external tank | |

4.4. Low contamination waste connection



Dispose of the low contamination waste in accordance with the applicable legislation of the country in which the analyser is installed. Such waste is extremely diluted.

Connection

Insert the red tube of the accessory box into the right-hand connector of the analyser (3). See Figure 6. It is marked "LOW CONCENTRATION OUTLET". Place the other end of the tube directly in the drain if the legislation of the country in question allows this. If not, install an external tank and connect the tube inside it.

4.5. Installing the sample and reagent rotors

The sample and reagent rotors are already installed in the analyser. Check that they are in their correct positions and turn freely.

Replacing the rotors

To remove the rotor in order to easily install the sample tubes or reagent bottles, proceed as follows:

1. Remove the cover of the rotor to be accessed.
2. Press the central button on the handle to release the rotor.
3. Remove the rotor from its housing. Be careful, as if the reagent rotor is filled with bottles, it may weigh up to 5 kg.
4. When reinserting the rotor into its housing, press the release button and let the rotor descend as far as it will go. Turn it until the positioning tab coincides at the base and is correctly seated.
5. When inserting a full reagent rotor into the housing, ensure it descends slowly without falling, to prevent it from knocking against the base and the reagent bottles from splashing.
6. Place the cover of the rotor on its housing. Ensure that it is properly seated in the housing, it has only one position. Make sure that the silk-screen drawing on the cover coincides with the one on the analyser surface. The drawing helps you to put the cover in the correct position.



NOTE



NOTE

4.6. Specifications of the barcode labels

To ensure good detection with the barcode reader, the tube labels should be compliant with the following specification regarding their position.

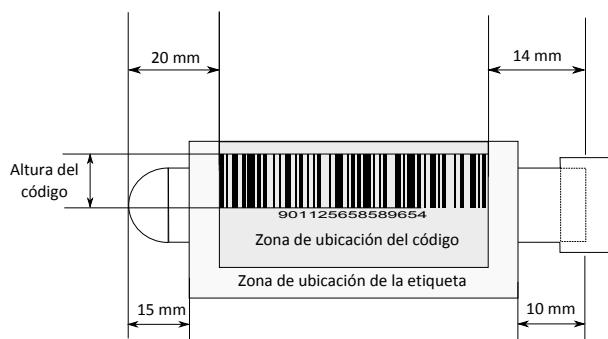


Figure 7 Positioning of the label on the primary tube

- Respect the barcode label position margins, as shown in Figure 7.
- It is advisable to have a minimum width of 3.5 mm between the edge of the label and the beginning of the barcode.
- It is advisable for the minimum barcode height to be 10 mm.

- The label is positioned with the bars perpendicular to the tube axis. The label inclination must be less than $\pm 7.5\%$ or $\pm 4.2^\circ$ with respect to the sample container axis.
- It is advisable to use CODE128 for the barcode.

4.7. Affixing the identification labels

The accessory box has identification labels that serve to identify the additional solutions. Affix them to the tubes or auxiliary reagent bottles. The following table shows the colour code and identification for each type of solution.

Label colour	Name on label	Description	Affixing the label
Blank	REAG	Auxiliary bottle	Bottle
Blue	DI H2O	Purified water	Tube / Bottle
Yellow	SAL. SOL.	Saline solution	Tube
Green	WS1	Washing solution	Bottle
Purple	ISE DET	ISE washing solution	Tube
Grey	DIL1	Diluent	Bottle

Affix each label to the reagent bottles supplied or to the tubes in accordance with the above chart. When the barcode reader scans the reagent rotor and detects an auxiliary bottle, the program will ask you to associate that bottle to a reagent in the list.

4.8. Installing the reaction rotor

1. Start up the analyser and use the rotor change function in the user programme.
☞ See how to start up the program in section 10.1
☞ See functions, rotor change in section 10.8.1
2. When the wash station is at the highest point, remove the reaction rotor cover.
3. Remove the rotor fixing screw.
4. Take a rotor from the accessory box.
5. Insert the methyl acrylate rotor into the reaction rotor, ensuring that the rotor does not touch the tips of the wash station.
6. The rotor only has one position and must be correctly fitted into the support.
7. Screw the rotor fixing screw as far as it will go.
8. Place the cover of the rotor on its housing. It only has one position.
9. Finalise the rotor change operation with the user program.

4.9. Connection to the mains and start-up

It is very important to connect the analyser and computer to an appropriate electricity system. It must be as exclusive as possible and it must have an earth connection. The analyser and computer must have the same earth connection.

Supply voltage 115 V to 230 V

Supply frequency 50 Hz or 60 Hz

Power 500 VA

The analyser automatically adapts to the mains voltage without having to select the voltage manually. Working outside the voltage range could cause the equipment to malfunction and cause damage to it. The electrical installation category must be II (surge voltage category)

Fuse The accessory box contains a set of spare fuses. The characteristics are:

Fuse	Speed
10A	F



Figure 8 Fuse location

The fuse is located in the rear main switch (1).

☞ See Figure 8.

Changing the fuses

Remove the protective cover (1) and replace both fuses with those supplied in the accessory box. Always replace both fuses at the same time.

It is advisable to use an uninterruptible power source (UPS) to protect the analyser and computer. The recommended characteristics are:

Model continuous UPS (on-line)

Power 1.5 KW

Battery capacity Over 15 min

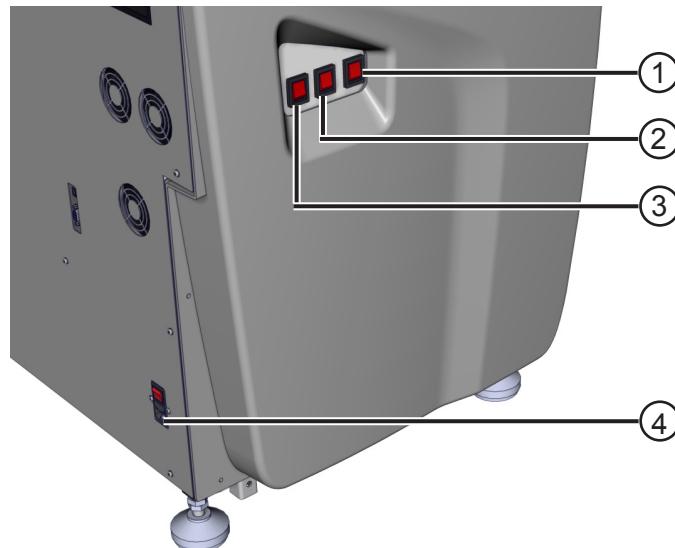


Figure 9 Analyser switches

- | | |
|-------------------------|-----------------------|
| 1 – Analyser switch | 3 – ISE module switch |
| 2 – Refrigerator switch | 4 – Main switch |

Electrical connection Proceed as follows:

1. Ensure that the three switches on the left-hand side are in the disconnected position (O) and that the general mains switch (4) is also on disconnected.
2. Connect the mains cable firstly to the appliance and secondly to the mains.
3. Put the general switch (4) to the connected position (I).
4. There are three separate switches, one for the analyser, another for the refrigerator and a third for the ISE module.
5. To turn on the analyser, put the switch (1) to the connected position (I).
6. To turn on the refrigerator raise the protective cover and put the switch (2) to the connected position (I).
7. To turn on the ISE module raise the protective cover and put the switch (3) to the connected position (I).

4.10. Connection to the computer

The computer must be fully dedicated while the analyser is in operation. No other application must be used while the analyser is operating.

The connection is made through USB.

USB connection The computer must be switched off.

Connect one end of the USB cable to the analyser and the other to a USB port in the computer.

Do not use a USB concentrator (hub) to make the connection.

 See installing the USB driver in section 4.10.

☞ See communications setup in chapter 10.2.1

RS-232 port The RS-232 port at the rear of the appliance is an auxiliary port for restricted use. This port is not used for connecting the software with the analyser.

4.11. Installing the user program in the computer

The user program must be used in a PC that is compatible with the following minimum requirements:

- Operating system: Windows® 7 64 bit (x64)
- CPU: Equivalent to Intel Core i3 @3.10 GHz or higher
- RAM memory: 4 Gbytes
- Free space of 40 Gbytes in hard disk
- DVD player
- SVGA monitor, minimum resolution 1 024 x 768
- USB serial channel connector



NOTE

Before installing the version, ensure that the user has administrator rights. Check that the user name of the account coincides with the name of the computer.

Ensure that no *Microsoft SQL server* version has been previously installed in the computer. To verify this, open the following program in *Home*:

Control panel\All Control panel elements\Programmes and characteristics

and check there is no input with the name: *Microsoft SQL server*

Before starting the installation, check that the *user account control configuration* is on: *Never notify me*. The instructions for changing it are given below:

1. Open the following screen:

Control panel\>User accounts\User accounts

2. Select the option:

Change user account control configuration

3. Select the lowest level: *Never notify me*

☞ See Figure 10

Install the program by proceeding as follows:

1. Insert the disk into the DVD drive of the computer.
2. Press *Start*, select *Execute* and write:
3. *D:\setup\setup.exe*, or the name of the DVD drive
4. Follow the steps indicated by the installer program.
5. The installer program automatically installs the application programme, the database manager and USB controller driver without the user having to intervene. During the installation process, the computer must be rebooted. Follow the steps indicated by the installer program.

6. It takes several minutes to install the program; wait until the process has been completed.
7. Configure the operating system with the following characteristics:
 - Screen resolution: 1024 x 768
 - For optimum viewing of the application do not change the default options in the operating system display settings.

Screen text size: 100%.

Customisation: windows 7 basic

See Figure 11

8. Start up the application.

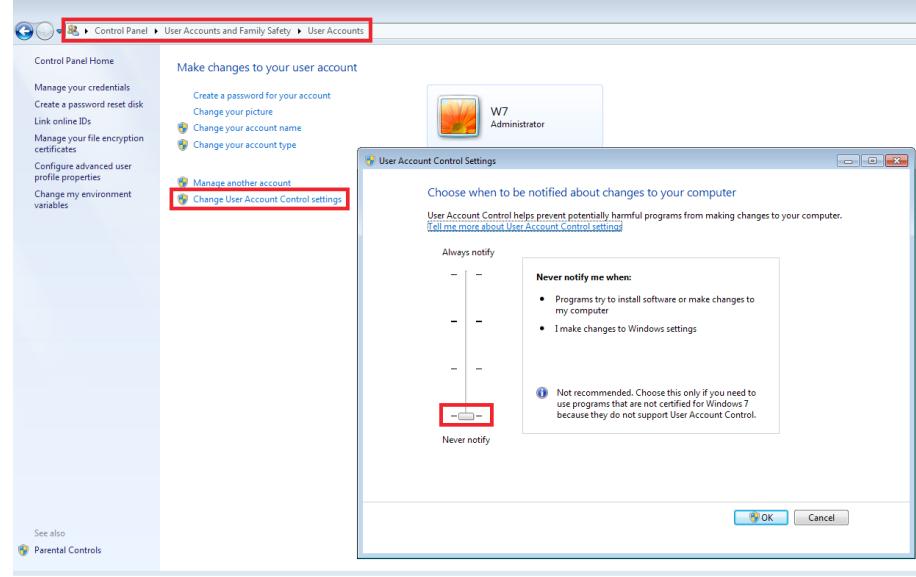


Figure 10 User account control configuration screen

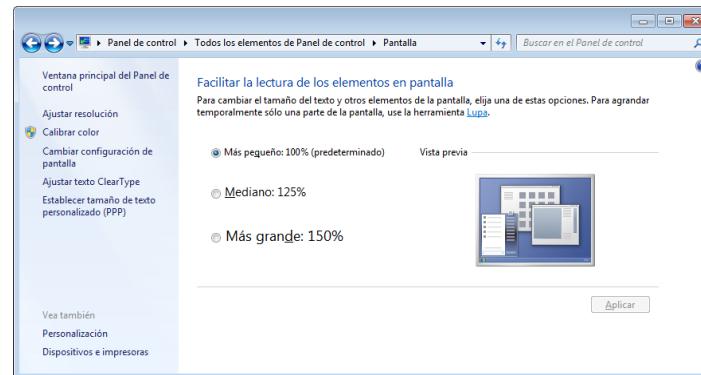




Figure 11 Text configuration screens

9. Deactivate the screen saver
 - Select the none option.
 - Deactivate the option *Show session initiation screen when restarting*

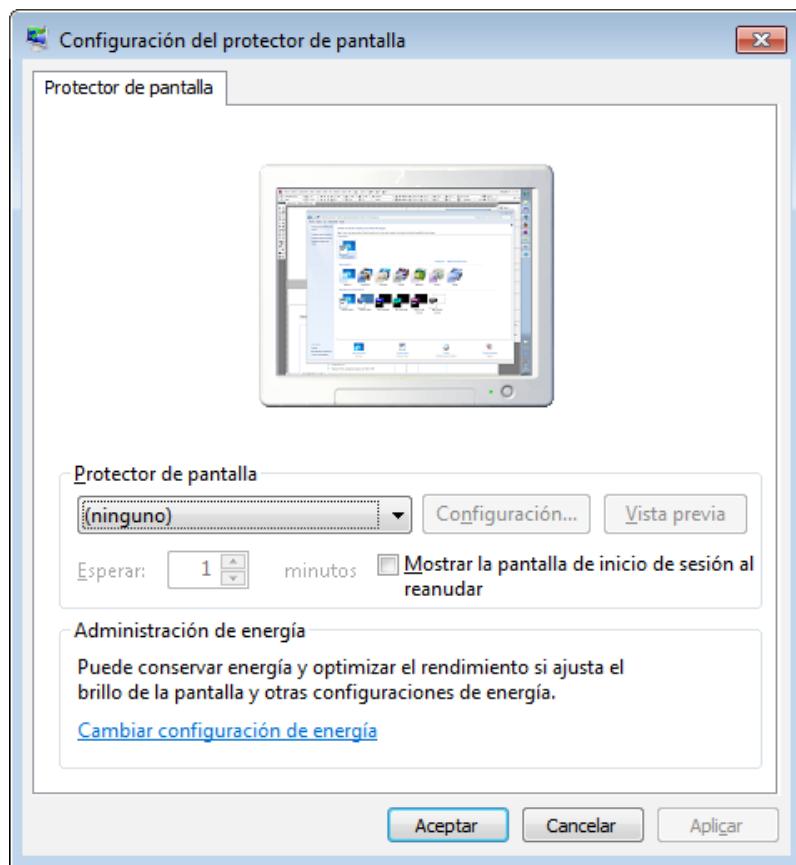


Figure 12 Screen saver options

4.11.1. Energy options configuration

1. Access *Home, Control panel*
2. Access the option *energy options*
 - Select *Change plan configuration*
 - Select *never* in the option *Put the equipment in suspension mode*
 - Select *Change advanced energy configuration*
 - Select *USB configuration*
 - Select the option *Disable* in *Selective USB/Configuration suspension configuration*
3. Save the changes

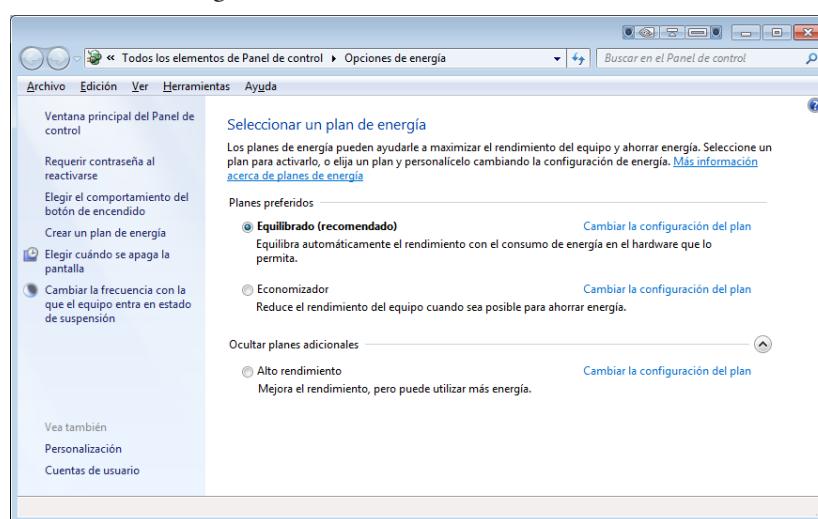


Figure 13 Energy options configuration

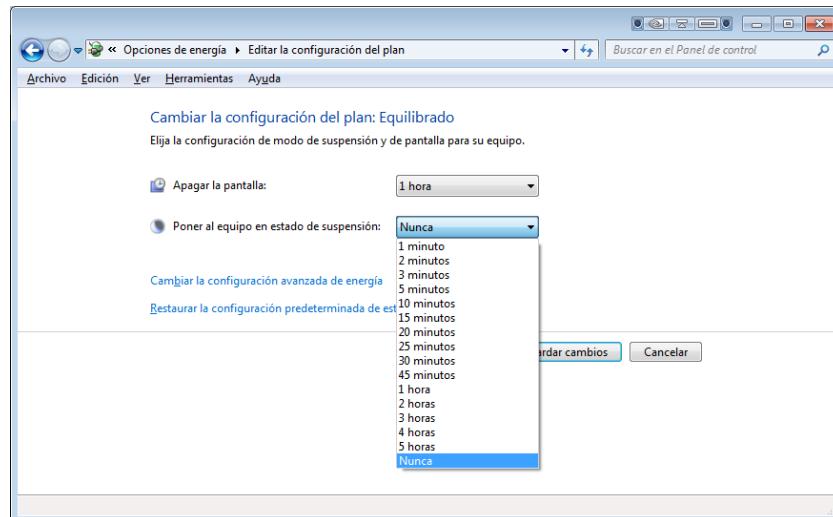


Figure 14 Change the energy options

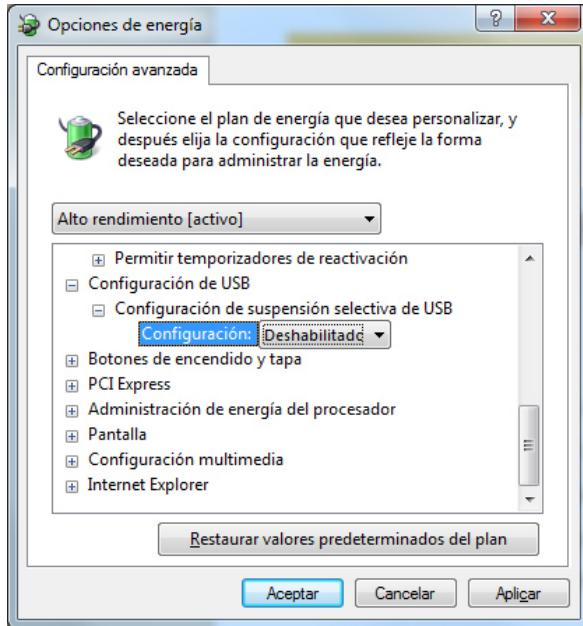


Figure 15 Change the USB energy options

4.11.2. Configure programmes in second plane

Do not execute programmes in second plane while the application is in operation. To do this, change the programming of the following programmes:

4.11.2.1. Windows update

1. Access *Home, Control panel*
2. Access *Windows Update*
3. Change the configuration for it to be activated on a day and at a time when the analyser is not operating, for example, a Saturday.

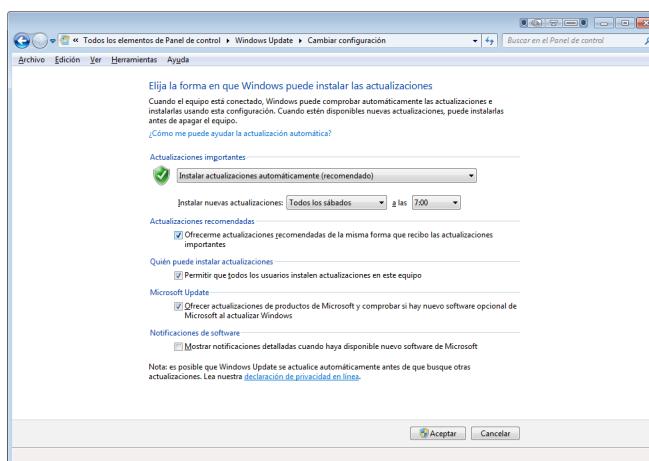


Figure 16 Windows Update configuration

4.11.2.2. Windows defender or antivirus programmes

Programme the antivirus check at a day and time when the analyser is not operating, for instance at the end of the working day.

4.11.2.3. Flash updates

1. Access *Home, Control panel*
2. Access the *flash player* icon
3. Access the *advanced* tab and select the option *Never search for updates*.

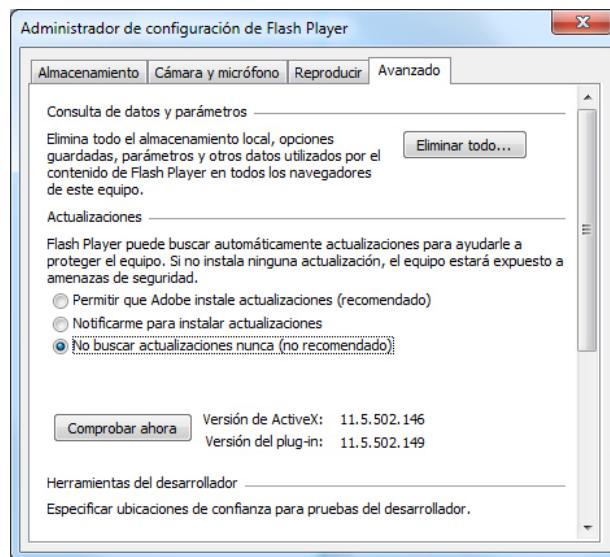


Figure 17 Flash update

4.11.2.4. Java updates

1. Access *Home, Control panel*
2. Access the *Java icon*
3. Access the *Updates* tab and uncheck the option *Check updates automatically*.

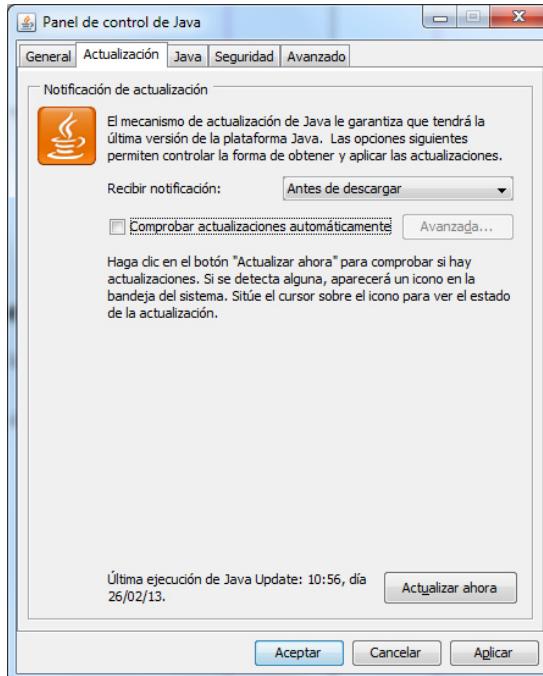


Figure 18 Java update

4.11.2.5. Operating system services configuration

Cancels unnecessary services in executing the application. Proceed as follows:

Proceed as follows to change the service options:

4. Access *Home* and execute the *msconfig* programme
5. Select the *Services* tab
6. Deactivate the following services:

Visible name	Service name
Adobe Acrobat Update Service	AdobeARMservice
Auxiliary IP application	iphlpsvc
Non-connected files	CscService
Distributed links follow-up client	TrkWks
Publication of function detection resource	FDRResPub
Diagnostic directives service	DPS
Windows Search	WSearch

7. Save the changes
8. Reboot the computer.

4.12. ISE module installation (optional)

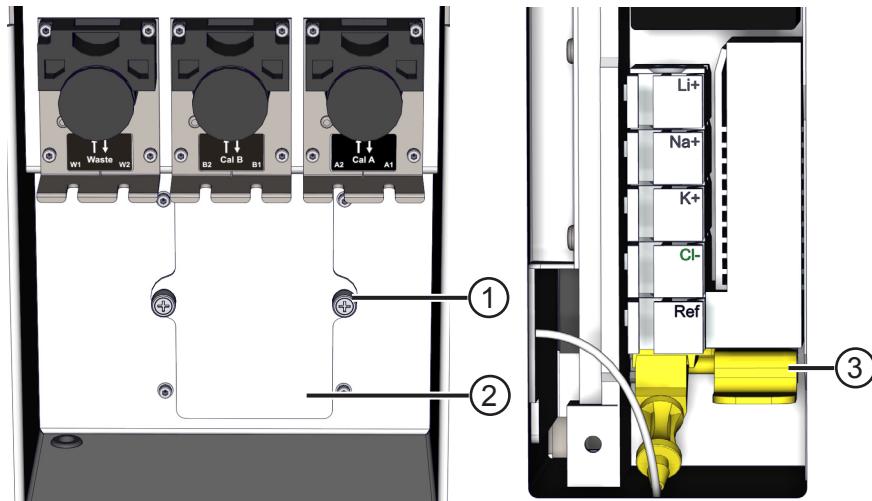


Figure 19 **Tube connection**

Electrode installation

After opening the front cover the ISE module can be directly accessed. See Figure 19.

1. Turn off the ISE module power supply using the switch.
2. Unscrew both screws by hand (1) to access the compartment (2) for positioning the electrodes.
3. Unpack each electrode. Ensure that the sealing ring (O-ring) is in position. Carefully dry any traces of liquid.
4. First put the reference electrode in position. Pull out the identification wire with a label that is connected inside the electrode circulation channel. Ensure there are no traces of salt in the channel. Keep the wire with the label in case you need to uninstall the electrode. Conserve the electrode inserting the wire into the channel.
5. To insert the reference electrode press the yellow tab downward (3) and insert it as far as it will go. Then release the tab.
6. Insert the other electrodes in the positions shown in Figure 19. Check that their sealing rings (O-rings) are correctly positioned. Carefully dry any traces of liquid.
7. Each electrode has a single position to prevent errors in putting them in place.
8. In the event of not having the Li^+ electrode, insert an empty electrode in its place (it is marked by a line of dots), to ensure continuity in the channel through which the sample passes.
9. Release the yellow button to supply pressure to all the electrodes and ensure good fluid communication.
10. To ensure that the electrodes are properly placed, press them at the front until you hear a click or they have been correctly seated.

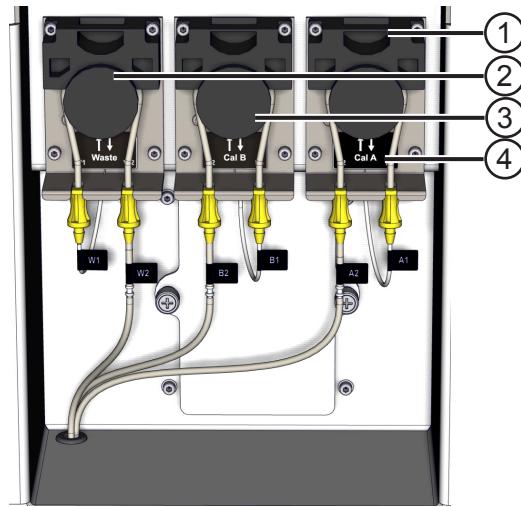


Figure 20 Order for positioning the different electrodes

Tube installation

Insert a tube into each peristaltic pump. To insert the tube into head of the peristaltic pump release the pressure on the head by pulling the clamp upward (1), see Figure 20.

Each tube has two labels. The labels help guide the tube correctly in the peristaltic pump. The number on the label of each tube must coincide with the number on the pump label.

- The tubes marked W must be installed in the pump (2). The order for putting them in place starting from the left is W1 and W2.
- The tubes marked B must be installed in the pump (3). The order for putting them in place starting from the left is B2 and B1.
- The tubes marked A must be installed in the pump (4). The order for putting them in place starting from the left is A2 and A1.

Take care when connecting the tubes of the waste pump (2) as they are connected in reverse order to the tubes of the pump for standards A (4) and B (3).

Installing the reagent kit

Unpack the kit, remove the red protective caps from the connections and the red warning label. Keep the caps in case you need to uninstall the reagent kit. Position the connector in the correct direction and press lightly until you hear a click. Write the installation date on the side of the kit.



NOTE

Do not press the sides of the box too strongly or put the reagent kit face downwards without the caps, as the reagent or waste could be spilled. It is advisable to wear gloves when performing this operation.

Place the kit in its housing.

With the user program, execute the actions in the number and order indicated in the *Installation/activation* option of the *ISE functions* section.

☞ See chapter 10.8.3

Step	Action	Repetitions	Description
1	Initialise ISE module	1	
2	Activate the reagent kit	1	If the execution icon is not activated after selecting this option, check that it is a new kit. If the kit has already been activated before, this option will not be available, but you can make a reading with the <i>Read reagent kit</i> option. In this case, go on to the next instruction. In the event that it is a new kit, check that the connector is correctly positioned, remove it again and reconnect it.
3	Read reagent kit	1	
4	Prime B	9	Remove the lower cover of the sample arm, which allows you to observe the dispensing cup. Observe the cup and check the emptying operation, i.e., that every time the module pumps dispense the liquid into the cup, it is emptied before the next dispensing operation. If the pumps do not dispense the liquid, execute the above action again. If, after repeating it several times, no liquid is dispensed, disconnect and reconnect the kit adapter and repeat the action.
5	Prime A	9	Proceed as described above
6	Date of installing the tubes	1	
7	Calibrate the pumps	1	If no satisfactory result is obtained, check that the tubes are correctly installed and execute the actions from step 4.
8	Activate the electrodes	1	Indicate the installation date. If any of the electrodes is not new, record them again with the original installation date.
9	Prime and calibrate	2	Execute this action to calibrate the electrodes with the new solution and check it is in good condition. If the result is unacceptable due to the presence of air, check that the solutions are circulating correctly and repeat steps 4 or 5, depending on the error reported. If the calibrations have ended but the results are not acceptable, repeat these instructions a couple of times.

Step	Action	Repetitions	Description
10	Wait 5 minutes	1	
11	Prime and calibrate – end	1	If the calibration of the last measurement is not acceptable, wait 5 more minutes and repeat the actions from step 9.
12	Activate the ISE module	1	

4.13. First steps for operating the analyser

1. Replenish the washing solution bottle.
2. Connect the distilled water inlet tube and the low contamination waste outlet tube.
3. Connect the electric mains cable to the analyser.
4. Install the program in the computer.
5. Install the sample and reagent rotors.
6. Install a reagent rotor.
7. Close all the covers.
8. Connect the analyser to the computer using the USB communication cable.
9. Turn on the analyser Wait until you hear a beep.
10. Select the *General Configuration* option and the *Communications configuration* tab.
11. Select the *automatic* option.
12. In the same menu, select the *Analyser* tab.
13. Select one of the two *water inlet selection* options depending on the water inlet installation.
14. Press the *initialisation* button on the analyser.
15. Perform 5 *conditionings* to ensure that the internal water tank fills and that the fluidic system is correctly primed.
16. Execute the *change rotor* function.
17. In the event of having an ISE module, install the electrodes and reagent kit.
18. Fill in the calibrator concentration fields and controls of the tests to be used.
19. Make a list of blanks, calibrators and controls.

4.14. Cautions during operation

- In analysers with the ISE module installed, you should never turn off the module switch. The module automatically performs a maintenance cycle from time to time. To turn off the ISE module, follow the steps indicated in chapter 14.2.2.4
- To keep the reagents refrigerated when the analyser is off, put the refrigerator switch at the on setting, to allow it to refrigerate.
- When the analyser is operating, do not open the main cover without first pressing the *Stop* button. In the event that the main cover opens unexpectedly, the analyser will stop any action it is performing, and the preparations already made in which the sample has not yet been dispensed will be lost.
- Ensure that the sample, reagent and reaction caps are on while the appliance is operating. The analyser will not perform any operation if any of these caps is missing.
- Keep the analyser work surface free from obstacles that could collide with the preparation or stirring arms.
- Make sure the barcode labels on the sample tubes are correctly affixed and properly centred. They must be aligned properly on the tube. If the label has a barcode with only a few digits affix it lengthwise and centred, without placing it on the top part of the tube. Position the sample tube with the barcode label facing towards the outside of the rotor.
- Take care not to duplicate any sample tube identification code on the barcode labels during the same session. If several sample tubes have the same barcode identifier while the equipment is enabled for working with LIS communications, the analyser will not automatically assign any test to those tubes and it will display a message indicating this on the screen. In the case of manual operation (without LIS communications), first the analyser will pipette the tube that is in the lowest position in the sample rotor.



NOTE



NOTE

4.15. Preanalysis and preparation of additional solutions

Primary serum tubes

For the correct operation of the analyser, carry out the sample preanalytical phase on the serum tubes as follows:

1. Obtain the sample by venous puncture in an untreated tube. Fill the tube to at least 2/3 of its total volume.
2. Let the blood stand for 20-30 min to allow the clot to form.
3. Centrifuge the tube for 10-15 min, or follow the primary tube manufacturer's instructions.

To obtain precise results, the samples must be free from clots, fibrin, etc, which could block the sample tip or ISE module reader channel.

If using a tube with serum separator gel, check it has sufficient serum volume in order to avoid inserting the sample tip into the gel layer. This could block the sample tip.

- Primary plasma tubes*
- For laboratories in which the time factor is important, plasma should be used instead of serum. Proceed with the sample preanalytical phase of the plasma tubes as follows:
1. Obtain the sample by venous puncture in a blood collection tube with an anticoagulant.
If this sample is to be used for measuring ISE determinations, heparin sodium must be used as an anticoagulant. The heparin level should not exceed 15 UI/ml of the tube volume. Do not use heparin ammonium, heparin lithium, EDTA or NaF tubes.
 2. Mix the sample by inverting the tube several times. Do not shake it.
 3. Centrifuge the sample for 10-15 min within one hour of collecting. Carefully remove the plasma layer at the top for analysis. Use a Pasteur pipette or a syringe fitted with a blunt-tipped needle for this procedure.

Also follow the plasma tube manufacturer's instructions for the preanalytical phase.

Dilution of urine for ISE

If wanting to make ISE determinations in urine, the urine must be diluted. Perform the dilution manually outside the analyser with a dilution factor of 1/10.

- The analyser uses 200 µL to make an ISE determine in urine. Prepare a larger quantity of diluted urine (for instance, prepare about 300 µL).
- Take one part of the urine and pipette it into a primary tube.
- Take nine parts of the urine diluent (it is in the ISE module accessory box) and pour it into the same primary urine tube.
- Mix it and place it in the sample rotor.

ISE washing solution

Every day in which ISE determinations are made you should wash the module to remove proteins from the fluidic canal. It is advisable to perform this washing operation at the end of the day.

The ISE module accessory box contains the ISE module washing solution kit. It has 6 bottles with washing powder (peptin) and a diluent.

- Add the diluent until the peptin bottle (12 mL) is full, shake it well and take note of the preparation date
- When it is not in use, keep it in the refrigerator.
- Discard it 4 weeks after preparing it.

5. Transport and reshipment

The analysers weights 210 kg and has wheels to allow it to be moved easily. Bear in mind that the analyser has legs to anchor it firmly to the floor. Before moving the analyser, unblock the wheels.

Only move the analyser on flat surfaces and avoid holes, dips or steps, however small they may be.

If it should be necessary to reship the analyser or move it using a haulage vehicle, the polar arms must be immobilised, and the analyser must remain in its original packaging to ensure it suffers no damage. To repack the analyser, follow the instructions on the unpacking sheet, in reverse order.

Use mechanised means (fork-lift truck or pallet jack) to transport the packaged analyser.

6. Handling and storage

In handling the analyser, remember that it is a precision instrument and must therefore be handled with special care.

If the analyser must be stored for long periods of time, heed the following recommendations:

1. Empty the high contamination waste tank and washing solution tank.
2. Remove and store the ISE module electrodes.
3. Remove the tubes from the peristaltic pumps of the ISE module
 See chapter 14.2.2 on ISE module maintenance.
4. Dispose of the reaction rotor.
5. Protect the analyser from dust and environmental aggressions, and from direct sunlight and excessive damp.

Environmental conditions for storage:

Storage temperature 10 °C to 40 °C

Humidity conditions during storage < 85% with no condensation

7. Operating principle

The analyser has various operating states: initial, standby, in operation and stopped.

Initial state (WARMING UP)

During this state the analyser initialisation process is started. It starts with the initial cleaning process and ends with the reaction rotor thermostating process.

Stand-by (STAND-BY)

In that state the analyser waits for the operating state to commence. While in this state, the user can perform maintenance tasks and/or execute the analyser functions.

Operating state (RUNING)

During this state the analyser performs several repetitive cycles to prepare the reactions and take the measurements. Each arm dispenses the substances into the different cuvettes. A reagent is preparing in the following way:

1. Suctioning of reagent 1 and dispensation in the reaction rotor.
2. Wait for 4.5 minutes to allow the reagent to cool
3. Suctioning of the sample and dispensation into the cuvette
4. Stir the reagent 1 and sample mixture.
5. Start the reading period.
6. Suctioning of reagent 2 and dispensation into the reaction cuvette 5 min. after dispensing the sample.
7. Stir the mixture with the second reagent.
8. Finalise the reading processes.
9. Wash the cuvettes.

The reading process is based on the optical absorption spectrophotometer principle. The concentration is determined by comparing the luminous intensity of a certain wavelength that passes through the cuvette when there is a reaction and when there is no reaction. In some cases the concentration is a direct function of the absorbance and in others, it is a function of the change of the absorbance over time, depending on the analysis mode.

Stopped state (SAMPLE&STOP)

During this state the analyser stops the sample and reagent dispensing process, allowing the user to access the sample and reagent rotors and add new samples or replenish reagents. During this state, the analyser continues to perform the reaction rotor reading process.

8. Description of the analyser

Each of the different parts of the analyser is described below.

The main parts of the analyser are as follows:

- Cover and lids
- Sample rotor
- Reagent rotor
- Reaction rotor
- Dispensing arms
- Stirring arms
- Wash station
- ISE module
- Electrical and communication connections
- Fluid connections
- Washing solution and high contamination waste bottles

8.1. Cover and lids

The following figure shows the different covers and lids of the analyser



Figure 21 **Covers**

- | | |
|--------------------------|-----------------------------|
| 1 – Main cover | 5 – LED status lamp |
| 2 – Reaction rotor cover | 6 – ISE module access cover |
| 3 – Sample rotor cover | 7 – Front doors |
| 4 – Reagent rotor cover | |

<i>Main cover</i>	This covers the surface of the analyser. Open this cover to access the reagent, sample or reaction rotors. To ensure the safe operation of the analyser, this cover must be kept closed. It has an open or closed casing detector. The analyser will stop executing the worklist if the cover is opened while it is operating.
<i>Sample rotor cover</i>	This allows you to access the sample rotor. The patient samples, standards and controls are placed in this rotor. The cover has a detector that enables the program to detect the presence of the cover.
<i>Reagent rotor cover</i>	This allows you to access the reagent rotor. The two types of reagent bottles are placed in this rotor. The reagent rotor is refrigerated. The cover has a detector that enables the program to detect the presence of the cover.
<i>Reaction rotor cover</i>	This allows you to access the reaction rotor. This rotor is where the reactions are made and the photometric readings are taken. This rotor is thermostatted at 37 °C. The cover has a detector to allow the program to detect the presence of the cover.
<i>Front doors</i>	These provide access to the washing solution and high contamination waste bottles, and also to the ISE module (optional unit).
<i>Led status lamp</i>	This lamp indicates the analyser state. Possible states:
Colour of LED	Description
Off	Analyser off.
Orange	Analyser in SLEEP mode.
Flashing orange	Analyser in the process of being initialised.
Green	Analyser initialised. STAND BY mode, waiting for actions-.
Flashing green	Analyser performing an action or a work session (RUNNING).
Red	Analyser with unresolved errors.
Flashing red	Analyser performing an action with unresolved errors.

Table 1 Analyser states indicated by the led lamp

Beeper states The analyser has a beeper that warns the user in the event that an alarm is triggered.

When the analyser is first switched on (supplied with power), it will carry out a series of internal checks. Once these checks have been completed, the instrument will emit a short beep, indicating that it is ready to establish connection with the User Software/Service.

While in the list execution state, if an alarm is triggered, for instance, exhaustion of reagent, samples, etc., the analyser will indicate this through a beeper that will sound until the user turns it off manually.

8.2. Sample rotor

The sample rotor consists of a removable drum with positions for inserting the sample tubes, standards and controls. The rotor has a barcode reader for the automatic identification of the samples placed in the rotor.

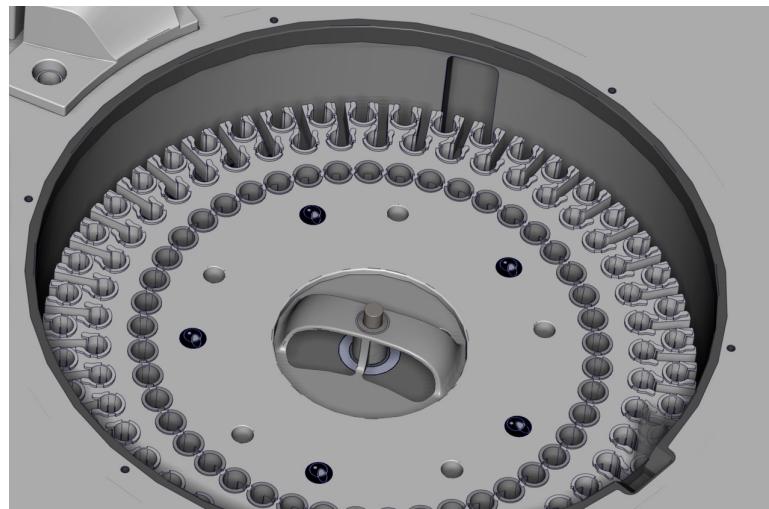


Figure 22 Sample rotor

Positions There are 135 positions in all, laid out in three rings. Each of the two outer rings have 45 positions and the inner one has 45. The sample barcodes can only be read on the two outer rings.

Tubes Tube dimensions:

- Minimum diameter: Ø12 mm
- Maximum diameter: Ø16 mm
- Minimum height: 70 mm
- Maximum height: 100 mm

Sample wells An accessory is supplied with the analyser, for inserting the sample wells into the positions.

8.3. Reagent rotor

The reagent rotor consists of a removable drum for positioning the reagents. All the reagents are refrigerated. The rotor has a barcode reader for identifying the reagent bottles.

The disk has a circular structure with 2 concentric rings with positions for inserting the reagent bottles.

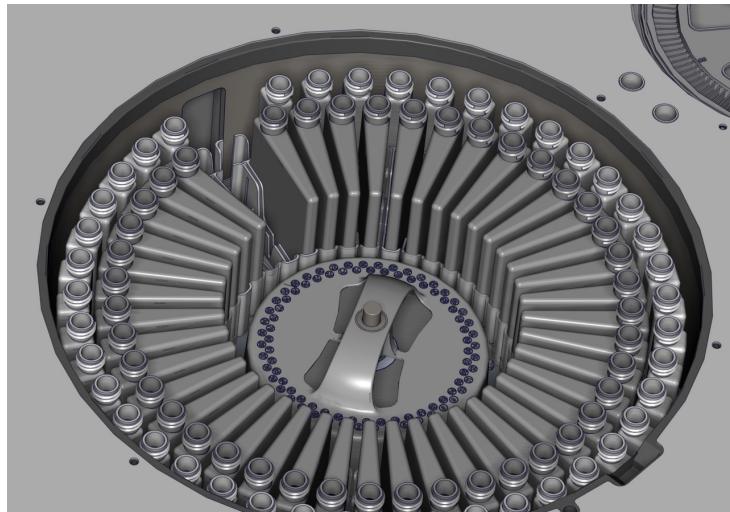


Figure 23 **Reagent rotor**

- Positions* There are 88 positions in all, laid out in two rings. The bottle barcodes can be read in both rings.
- Bottles* 2 types of bottle can be inserted. The volumes of the bottles are as follows:
- 60 mL, only for positioning in the inner ring.
 - 20 mL, for positioning in the inner and the outer ring.

Refrigeration The refrigeration system power supply is separated from that of the analyser, which means the analyser can be switched off and the refrigeration system can be left on.

8.4. Reaction rotor

The reaction rotor consists of a thermostatted channel containing an optical-quality plastic rotor that permits the transmission of UV light.

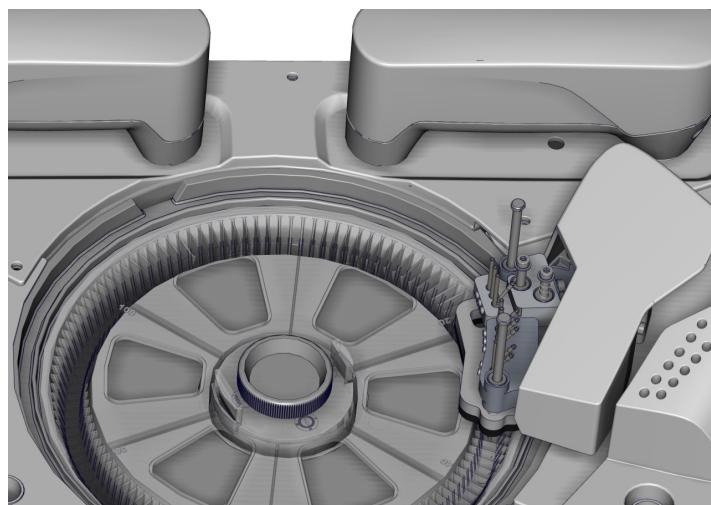


Figure 24 **Reaction rotor**

<i>Positions</i>	There are 120 positions in all. The reagent and sample are dispensed into each cuvette. While the mixture is reacting the optical reading is taken, to obtain the absorbance.
<i>Volume</i>	The reaction volume is between 180 µL and 600 µL.
<i>Temperature</i>	The rotor is maintained at a stable temperature of 37° C by a Peltier-based thermostating system.
Dispensing cycles for each of the arms:	
<ul style="list-style-type: none"> • Cycle 1: Dispensation <i>Reagent 1</i> • Cycle 31: Dispensation <i>sample</i> • Cycle 33: Stirring <i>Reagent 1 and sample</i> • Cycle 34: Initiation of photometric readings • Cycle 66: Dispensation <i>Reagent 2</i> and stirring of <i>Reagent 2</i> • Cycle 100: End of the reading processes • Cycles 101 –111: Washing of cuvettes in the wash station 	

8.5. Optical system

The optical system generates monochromatic light through the led lamps and filters unit. The reading system is comprised of two photodiodes. The reference photodiode serves to stabilise the light and the main photodiode captures the light that passes through the reaction.

The optical system is physically located in the reaction rotor, below the wash station.

<i>Wavelengths</i>	340 nm, 405 nm, 505 nm, 535 nm, 560 nm, 600 nm, 635 nm and 670 nm
<i>Measuring range</i>	From -0.2 Å to 3.5 Å
<i>Resolution</i>	0.0001 Å
The system automatically performs a blank on the cuvette before dispensing the reagent. This blank cuvette absorbance serves to correct the reaction absorbance measurements due to the aging of the cuvette. If this value exceeds a preestablished limit, the cuvette is discarded.	

8.6. Wash station

The wash station consists of an assembly with different phases, located above the reaction rotor.

Wash station cycles

- Cycle 1: Suctioning of the high contamination waste and dispensing of the washing solution.
- Cycle 2: Suctioning and dispensing of the washing solution.
- Cycle 3: Cuvette submerged in the washing solution.
- Cycle 4: Suctioning of the washing solution and dispensing of purified water.

- Cycles 5 and 6: Suctioning and dispensing of purified water.
- Cycle 7: Cuvette submerged in water.
- Cycle 8: Optical check on the cuvette.
- Cycle 9: Suctioning of purified water.
- Cycle 10: Drying.

The purified water for rinsing is thermostatted so that it does not interfere with the rotor temperature.

When the last rinse is performed an optical reading is also made on the rotor cuvette. If it is scratched or in poor conditions, the cuvette is discarded and not used for performing reactions.

If there is a large number of discarded cuvettes, the program warns of the need to replace the methacrylate rotor.

8.7. Stirring arm

The analyser has two stirring arms. These arms have a small blade that rotates inside the reaction cuvettes, to favour mixing and initiate the reaction correctly.



Figure 25 Stirring arm

Cycles Operating cycles of each arm

- Cycle 32: Stirrer 1.
- Cycle 66: Stirrer 2.

Once it has stirred the mixture the stirring arm moves to the wash station and washes the blade.

8.8. Dispensing arm

The analyser has 3 separate arms for dispensing the samples and reagents.

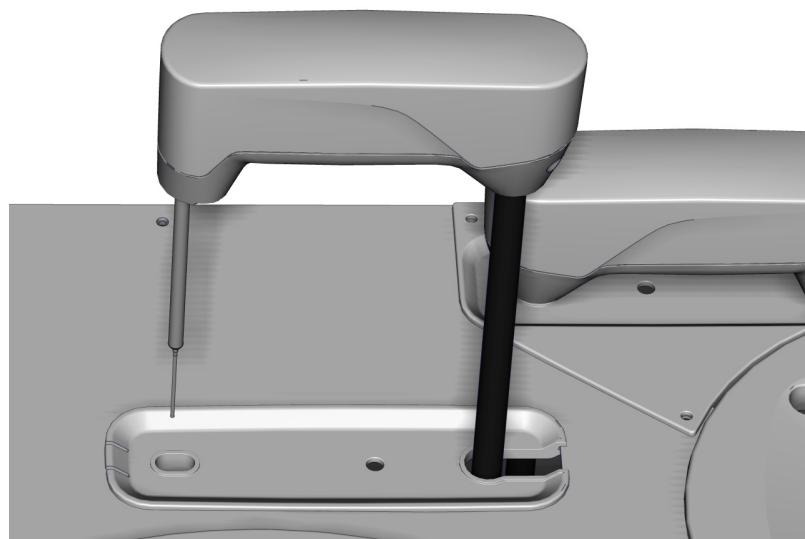


Figure 26 Dispensing arm

One arm is used to dispense the samples, and the other two arms are used to dispense reagent 1 and reagent 2, respectively.

Each arm has a wash station for washing the interior and exterior of the tip.

Dispensing volumes

Minimum and maximum volumes that can be processed by each arm:

- Sample arm: 2 µL to 40 µL
- Reagent 1 arm: 150 µL to 450 µL
- Reagent 2 arm: 40 µL to 300 µL

Detection systems

Each arm has a level detection system.

There is also a vertical collision detection system to prevent damage to the tip in the event of accidental collision.

Clot sensor

Only the sample arm has a clot sensor. This system warns the user if the tip is blocked. The blockage could be due to clotted blood remains present in the sample.

8.9. Waste containers, purified water and washing solution

The analyser has 4 containers for storing waste, purified water and washing solution. All the containers are located inside the analyser.

High contamination waste

This container is accessed from the front of the analyser. The capacity of this container is 5 L. It has 40 hours of autonomous operation. The container level is determined by its weight.

Washing solution

This is access from the front of the analyser. The capacity is 5 L. The container level is detected by its weight. It has 8 hours of autonomous operation.

Low contamination waste The low contamination waste container is located inside the analyser and cannot be accessed by the user. The container is emptied automatically. The waste leaves through the connection in the rear part of the analyser.

☞ See waste tube connection in chapter 4.4

Purified water The purified water container is located inside the analyser and cannot be accessed by the user. The container is filled and emptied automatically. The purified water enters from outside the analyser. It may come directly from a purified water inlet or from an external container with a larger capacity.

☞ See Purified water connection in section 4.3.

8.10. ISE module (optional)

The ISE ion reader module is optional and serves to determine the concentration of the Na⁺, K⁺, Cl⁻ and Li⁺ ions in serum, plasma and urine samples.

The measurements are taken using ion-selective electrodes. Figure 27 contains a diagram of the measuring system. A more detailed explanation of the calculation process is given in chapter 16.4.

The temperature of the room where the analyser with the ISE ion reading module is located should not vary more than ± 4 °C or exceed 30 °C.

The ion reading module functions in parallel, together with the biochemical determinations.

If the determining of ions is programmed in the patient programming list, the sample dispensing arm is responsible for supplying the sample to the ion module. Then the module determines the concentration of the ions and sends the results to the program.

The ion module requires a two-point calibration to function correctly. This calibration must be performed every 4h and does not require the intervention of the sample arm. The user program will send a message informing of this frequency, as a reminder.

In addition, for each determination the module measures one of the two liquids from the reagent kit: A for determinations in serum and plasma, and B for determinations in urine.

Both liquid A and liquid B are supplied with the reagent kit. That kit is connected directly to the ISE module.

The kit is supplied as an accessory and its housing is accessible through the front doors of the analyser.

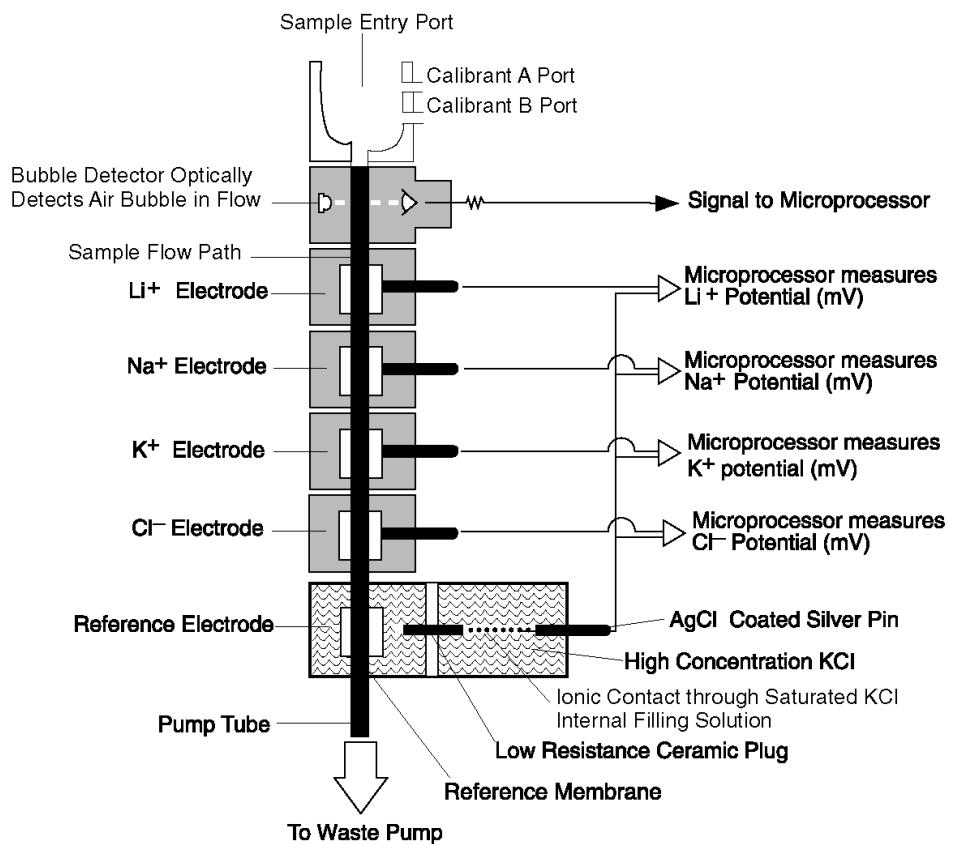
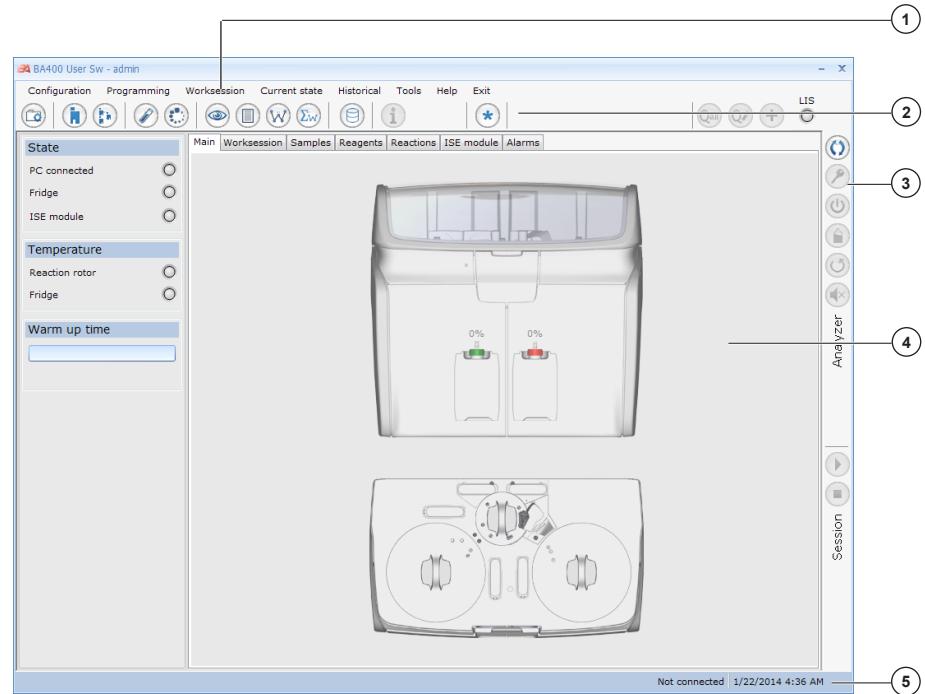


Figure 27 ISE module diagram

9. Description of the software

9.1. Identification of the program parts

Figure 28 shows the main areas of the program. These parts are common for the whole program and are always visible.



- | | |
|---|--|
| 1 – Menu bar
2 – Fast access buttons
3 – Action buttons | 4 – Main window
5 – Information bar |
|---|--|

Figure 28 Screen format

See Software installation in the installation manual

Menu bar

This gives access to the program menus.

Fast access buttons

Buttons providing fast access to the different menus.

Action buttons

Analyser operation action buttons.

Main window

Main zone where the work area is shown.

Information bar

Program zone that displays the informative and error messages. It also indicates the analyser states: WARM-UP, STAND-BY, RUNNING, SAMPLE&STOP.

9.1.1. List of most frequently-used buttons

Table 2 shows the main buttons which appear frequently in the program and their meanings.

Icon	Name	Description
	New	Allows an element to be created: test, standard, control, user, etc.
	Edit	Allows an already-created element to be edited.
	Delete	Eliminates an element.
	Print	Prints information about the element or elements selected.
	Copy	Copies the selected element.
	Save	Saves the data.
	Undo	Undoes the latest changes and retrieves the previous information on the element being edited.
	Accept	Accepts the changes and closes the window.
	Close	Cancels and closes the window.

Table 2 Description of the most frequently-used buttons

9.1.2. List of fast access buttons

The buttons on the horizontal bar are buttons that give direct access to the main program menus. Table 3 contains a description of each of the buttons.

Icon	Description of the icon
	Access to the general setup.
	Access to the test program.
	Access to the profiles program.
	Access to creation of work sessions.
	Access to the positioning of samples and reagents.
	Access to the monitor screen.
	Access to the results screen.

Icon	Description of the icon
	Access to the quality control screen
	Access to the cumulative quality control screen
	Access to the screen where information is generated for the technical service.
	Access to the information about additional functionality available in certain screens.
	Execution of the work session reset.

Table 3 Description of fast access buttons

9.1.3. List of buttons related to LIS communication

Buttons which appear on the horizontal bar and indicate the main actions that can be performed with a LIS application and the communications status with the LIS

See chapter 17 for details about LIS communications operation.

Icon	Name	Description
	LIS state	LIS connection off.
	LIS state	LIS connection established and operating.
	LIS state	LIS connection established but the LIS does not respond correctly to other actions. To solve it: check the physical connection, check that the low level LIS communication protocol is correct, check the LIS operation (response times, sending of messages in correct format, correct message flow, etc)
	LIS state	LIS connection established and operating, but the messages are delivered with delays and the message queue may be saturated (check LIS operation)
	Query All	Button for making a request to all pending LIS computers.
	Query by specimen	Button that opens the auxiliary screen for requesting orders by specimen (sample tube position in sample rotor with barcode identifier) See chapter 10.4.3
	Add orders <i>Download Orders</i>	Button that is activated when orders are received from the LIS which must be added to the work session.

Table 4 Description of the LIS communication buttons

9.1.4. List of action buttons

List of buttons that execute actions in the analyser. Only the appropriate buttons for the action being performed by the analyser are activated at any given time.

Icon	Name	Description
	Connect	Button for connecting the program with the analyser.
	Initialise analyser	Button for initialising the analyser.
	Shut down	Button for stopping and shutting down the analyser.
	Confirmation of change in bottle	Button confirming the washing solution bottle has been changed or for cancelling the high contamination waste bottle alarm.
	Recover the analyser	Button for recovering the analyser after an accidental stoppage.
	Cancel acoustic alarm	Button for cancelling the acoustic alarm; that button is activated when an alarm appears.
	Start session	Button for initiating the work session. It can also be used to restart the work session after a pause.
	Pause session	Button for executing a pause in the work session. It only appears when the session has been started. It appears in the same position as the <i>start session</i> button
	Abort session	Button for aborting or stopping the work session without being able to continue. Recommended only when the user does not wish to continue the session or if there are problems that make it impossible to execute it.

Table 5 Description of action buttons

10. Working procedure

10.1. Starting up the program



To start up the program, double click on the icon located on the desktop.

On initiating the program a welcome screen will appear and then the user identification screen (enter your login and password)



Figure 29 Home screen

The first time the program is started, the login and password to be entered are:

Parameter	Value
User name	Admin
Password	BA400

Table 6 Initial login and password



Click on the icon to change the password. You can only change the user password that was entered in the home screen.

Figure 30 shows the screen for changing the password. Enter the different values required to change the password.

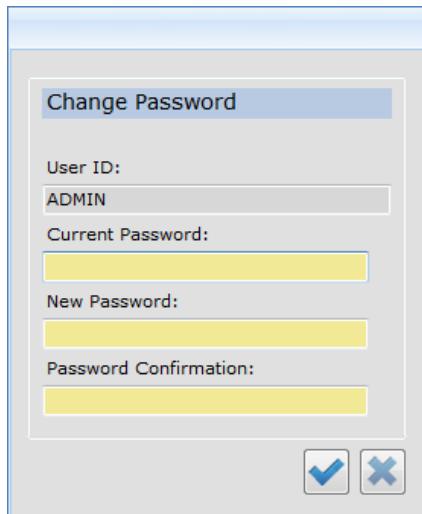


Figure 30 Screen for changing the password

10.2. Setup

In this menu you can access the different setup options:

- *General*: General program setup.
- *Languages*: Selection of the program language.
- *Reports*: Setup of the report headers and page footers.
- *Order Printing of Tests*: Selection of the test order for the patient reports.
- *Barcode*: Barcode setup.
- *LIS*: LIS communication system setup.
- Mapping for LIS
- *Users*: Generation of users for accessing the program.
- *Change User*: Change in user.

10.2.1. General setup

In this screen you can configure the general program options.



Press this button to obtain direct access to the general setup options.

Select one of the following tabs:

- *Work Session*
- *Analyser*
- *Communication Setup*

Figure 31 shows the screen with the different setup options for the work session.

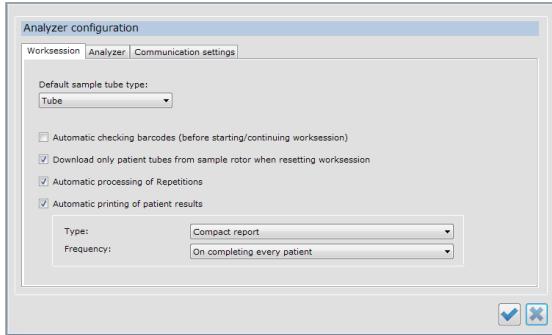


Figure 31 Work session setup

Default sample tube

Select the tube that will normally be shown when creating the list of patients. It may be: tube or sample well.

Verification of the barcode before the work session

Check this option if you want the analyser to automatically check the position of the reagent bottles and sample tubes with the barcode before starting the session.

Session reset downloads only patient tubes from the Sample Rotor

Check this option if you only want to delete the sample rotor tubes when resetting the session. The information and position of the sample wells (standards and controls) will be saved for the next session.

Automatic Repetitions process

Check this option if you want the repetitions to be made automatically. If not, they can be made manually.

Automatic printing of patient results

Check this option to automatically print out the results for a finalised patient. When this option is selected the report and frequency type options are activated.

Type

Select the type of report to be used for printing out the patient results

- *Compact* - Report with no patient header and with the results of all the patients in a continuous list with no page separations.
- *Individual* - Individual report by patient. Each report is printed out on separate pages with a patient header.

Frequency

Select the frequency to be used for printing the results.

- *On restarting the work session*
- *After completing each session*
- *After completing each patient*

Figure 32 shows the analyser setup screen.

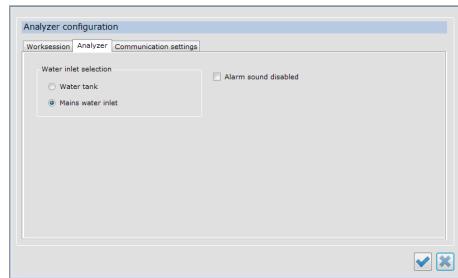


Figure 32 Analyser options setup

- Selection of the water inlet* Select the water inlet mode for the analyser.
The water may enter through different channels which are mutually exclusive:
- *Water tank*
 - *Water mains*
- ☞ See chapter 4.3 for the purified water installation.
- Alarm deactivated beeper* Check this option if you do not want the beeper to sound when an alarm is indicated.
- Figure 33 shows the communication setup screen.

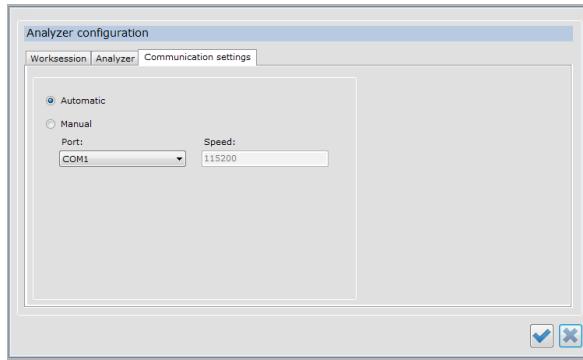


Figure 33 Communication setup

- Automatic* Select this option and the program will automatically search for the computer output port for communicating with the analyser.
- Manual* Select this option for the port to be selected manually.
Type of connection:
- RS-232 — you should normally select the COM1 port
 - USB — you should normally select the USB1 port

10.2.2. Language

This allows you to select the application language.

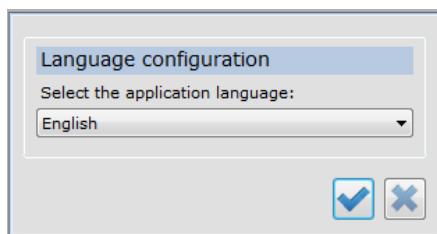


Figure 34 Screen for selecting the application language.

10.2.3. Reports

This permits the configuration of the patient report format. It allows you to change the header, footer and add logos.

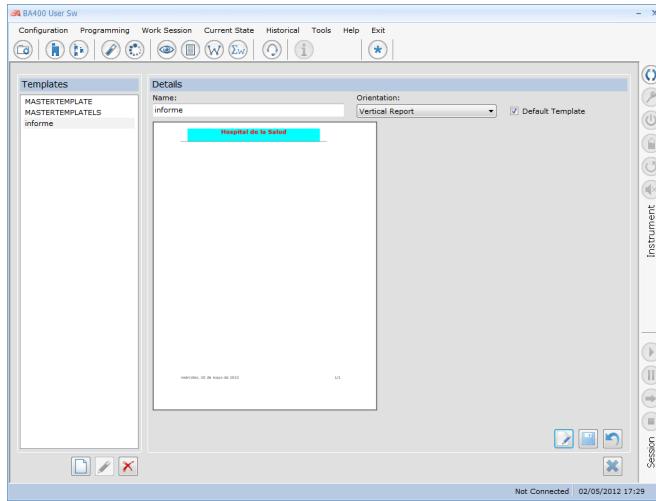


Figure 35 Patient report setup screen

There are two default design types, vertical and horizontal.

You can create as many reports as you like. When creating a report, enter the name and select the format type: horizontal or vertical.

Default template

Check this box for the program to apply the report selected from the list. There is only one horizontal report and one vertical report with this option selected.



Press this button to change to the editing mode. You will enter a screen that allows you to change the format of the header or footer of a page. You can also enter text, graphic elements and icons.

10.2.4. Ordering the tests

This allows you to order the tests that will then be shown in the same order in the patient's report.

In this screen you can select the order of the tests, calculated tests and external tests. When the patient report is drafted, the order of the tests that appears is the one selected.

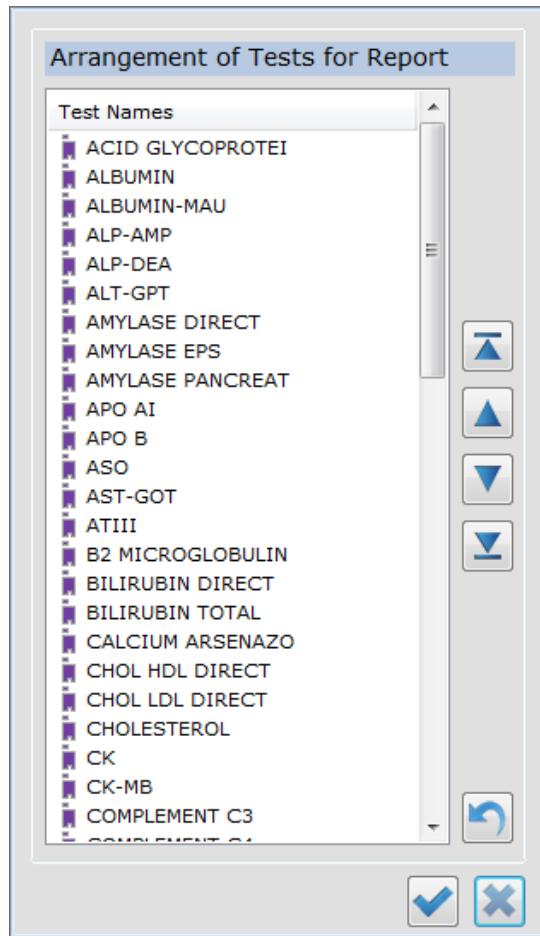


Figure 36 Screen for ordering the tests



Select a test or test group and press one of the buttons until the test is placed in the desired position.



Press this button to display the tests in alphabetical order again.

10.2.5. Barcode

Screen for configuring the barcode reader options. Figure 37 shows the screen with different options that allows the configuration to be made.

Deactivation of Barcode for reagents

Check this option to deactivate the barcode reader of the reagent rotor.

Deactivation of Barcode for samples

Check this option to deactivate the barcode reader of the sample rotor.

Type of code

Select the type of barcode for configuring the sample rotor reader. More than one barcode type can be selected. The barcode printed on the labels of the primary tubes must coincide with the code selected in the configuration.

Activation of barcode fields

If this field is not activated the barcode reader identifies the whole barcode as the sample identifier and the reader can read any code with length of between

1 and 30 characters. Codes with different lengths can be combined in the same session.

When this field is activated more details can be entered to separate different barcode identifier fields. External identifier and optionally, the type of sample in the tube. The total size of the barcode is still flexible, between 1 and 30. The following fields are enabled.

External ID Select the start and end positions of the sample identifier in the barcode. The sample identifier may coincide with the whole barcode length or the barcode may contain more information apart from the sample identifier.

Sample Type When the sample barcode contains information about the sample type, the sample type option is enabled. Select the start and end of the sample type coding in the barcode.. It also indicates how the laboratory codes each type of sample. The sample type field cannot overlap with the sample identifier.

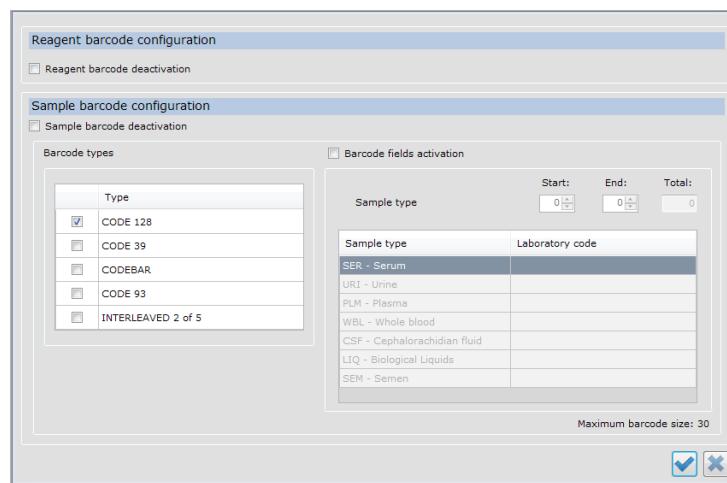


Figure 37 Barcode reader setup

10.2.6. LIS operation configuration

Screens that allow the setup of the parameters of the LIS application which the communication is to be made. These parameters can only be changed when the analyser is in the STAND-BY mode.

10.2.6.1. Work session setup

Screen showing the setup options with LIS communications that affect the work session.

Figure 38 shows the LIS options setup screen.

Host Query This allows this work mode to be activated or deactivated.

Rerun working mode (repetitions) It allows you to select who has permission to perform the repetitions: LIS, the analyser or both.

Automatic LIS query (before starting/continuing the work session) When this option is activated the Host Query process can be automated using the session start button. It is normally active when the LIS is connected and available.

<i>Maximum LIS Order waiting time</i>	Maximum LIS response waiting time. This value should be adjusted depending on the response speed of each LIS, the communication speed of each laboratory and the packet size of each query message. It is configured in the Host Query Packets option.
<i>Sending of patient results requested from the analyser</i>	When this option is activated the patient results created manually through the analyser are sent.
<i>Sending of control results requested from the analyser</i>	When this option is activated the results of controls requested manually through the analyser are sent.
<i>Sending of results on resetting session</i>	When this option is activated all the results of the session following a reset are sent. All the results requested by the LIS will be sent and when the above parameters are active, the results requested manually from the BA400 will also be sent.
<i>Automatic sending activation</i>	When this option is activated you can select the frequency with which the results are automatically sent to the LIS.

Type of on-line export	Description
At the end of each work session	At the end of a work session all the results are exported from the patient list.
After completing each patient	On completing each patient the results for that patient are automatically exported.
On completing each test on the patient	On completing a test on a patient the results are automatically exported.

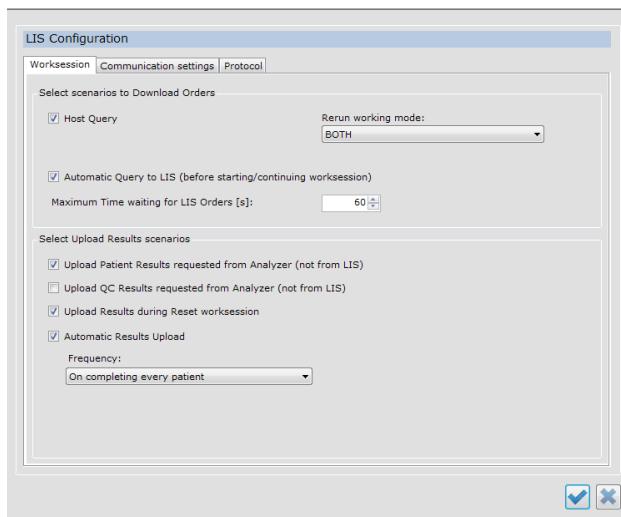


Figure 38 LIS options setup

10.2.6.2. LIS communication setup

Screen for configuring communications with a LIS system.

Lis communications activation

This allows communication with a LIS application to be activated or deactivated.

<i>Type of data transmission</i>	The transmission may be: <ul style="list-style-type: none"> • ASTM: TCPIP-Client, TCPIP-Server • HL7: TCPIP-Client, TCPIP-Server, TCPIP-transitory connection
<i>Name of host</i>	This field is only completed when the data transmission type option has been selected: TCPIP-Client. Enter the IP of the computer IP when the LIS for making the connection is executed.
<i>TCP port</i>	Number of the TCP-IP port through which the LIS connection is made When the TCPIP-Transitory HL7 Connection is selected, 2 different ports must be configured: client port and server port.
<i>Client TCP port</i>	Number of client port in a TCP connection.
<i>Server TCP port</i>	Number of server port in a TCP connection.

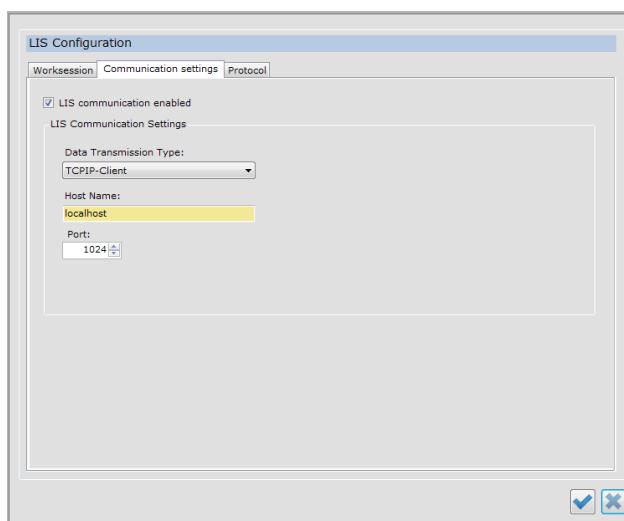


Figure 39 LIS communication setup

10.2.6.3. Protocol setup

Screen for configuring the necessary parameters for the low level LIS communication protocols

<i>Name of protocol</i>	Select the type of protocol to be used in the communications: HL7 or ASTM.
<i>Page code for transmissions</i>	Select the type of coding for messages to be sent between the analyser and the LIS. This is used in transmitting and receiving messages. You should configure the page code used by your LIS system.
<i>Server identifier</i>	Identifier used by the LIS application.
<i>Server supplier</i>	Name of the LIS application supplier.
<i>Instrument identifier</i>	Name used to identify the instrument; that field is transmitted in each message.
<i>Instrument supplier</i>	Name of the instrument supplier.
<i>Complies with IHE</i>	Select this option when the message transmission strictly follows the IHE communication standard.
<i>Host Query packet size</i>	Number of specimens sent in one Query message by specimen when using the ASTM protocol.

<i>Maximum time for sending a retry message</i>	Configuration of the maximum time during which another attempt is made to send a message to LIS when no response is received.
<i>Maximum LIS waiting time</i>	Configuration of the maximum wait time for receiving an acceptance or confirmation message from the LIS. After this time the LIS state is modified (led on red) indicating that there are problems in communication which must be solved.
<i>Delimiters</i>	Enter the delimiters to be used in transmitting and receiving messages.

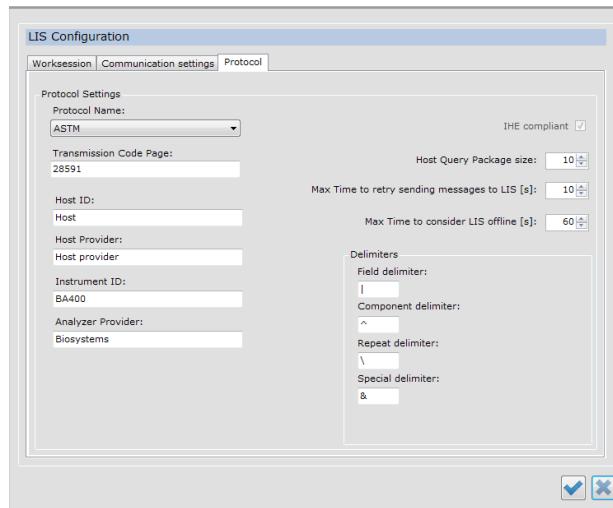


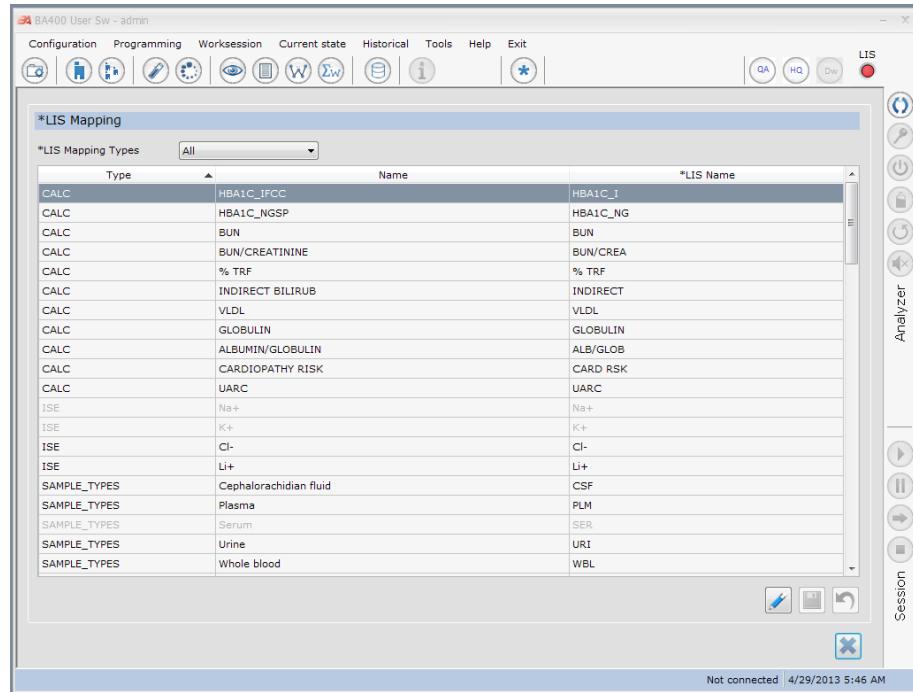
Figure 40 LIS protocol setup

10.2.7. LIS mapping

Screen for configuring the names to be used in LIS requests.

The names of the following elements should be configured: tests, ISE tests, calculated tests, external tests, sample types and units.

Caution: LIS requests with test names or sample types that have not been entered in this screen will be rejected by the analyser.

**Figure 41 LIS mapping setup screen**

The screen shows a table with different columns:

- The first column shows the type of element:

Element	Description
CALC	Calculated test
STD	Standard test
ISE	ISE test
TEST-UNIT	Units
SAMPLE_TYPE	Type of sample.
OFF-SYSTEM	External test

- The second column shows the name of the element as it appears in the analyser.
- The third column shows the name of the element used in communicating with the LIS (messages received and sent). These names must be edited in order to adapt them to each LIS. When installed, the same names as those used in the analyser will appear.

LIS mapping elements Selection box for filtering the elements shown by one of the types.

10.2.8. Users

This allows you to create, edit and delete the names of the users accessing the application.

There are three user levels. Administrator, supervisor and operator.

Level	Description
Administrator	Has complete access to the application. This user is allowed to create the supervisor user.
Supervisor	Has limited access. This user is allowed to create users with operator permits. He is permitted to change the standard and control values and create a limited number of tests.
Operator	This is the most restrictive access level. This user can only execute lists, view and print out results and consult the test parameters.

Table 7 User levels

Figure 42 shows the screen for creating and maintaining users.



Click on the icon to obtain access to creation of new users. The boxes for entering the user data are activated.

User ID

Enter a name for identifying the user in the application.

Level

Enter the level for that user: supervisor or operator. The supervisor level can only be created if the application has been accessed by an administrator user.

Name

User name.

Surname

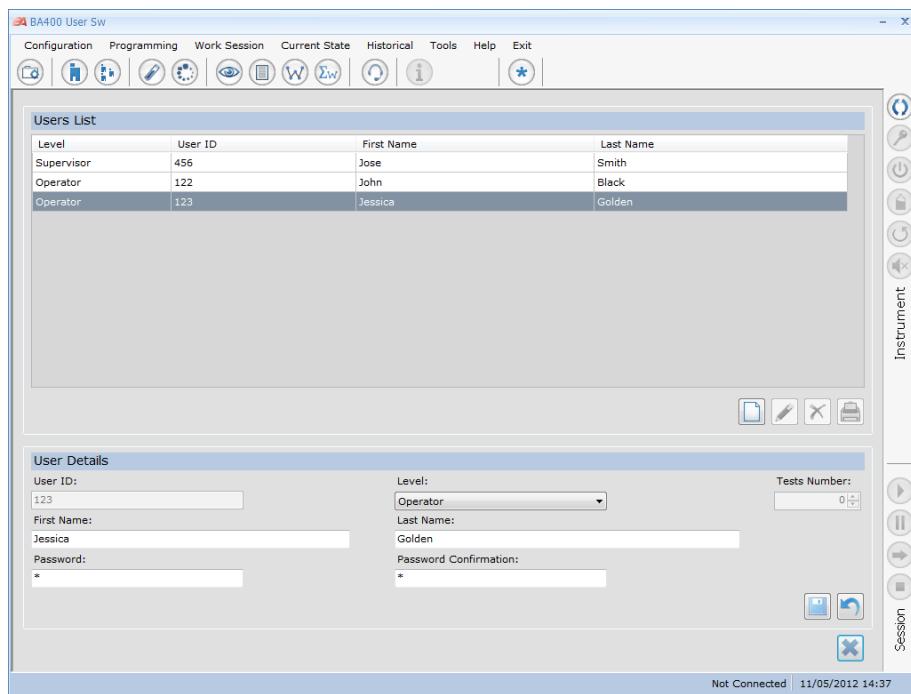
User surname.

Password

Enter a password

Confirm password

Enter the same password again to ensure it was entered correctly.

**Figure 42****User creation screen.**

10.2.9. Change in user

This screen allows you to change a user in the application without having to exit and then re-enter.

10.3. Programming

In this menu you can access the different options for programming the necessary parameters to measure the concentrations with the analyser. The different programming options are:

test parameters, tests calculated, contaminations, profiles, standards, controls, patient information, ISE tests and external tests.

10.3.1. Tests

This option in the program allows you to create, change, delete and list the tests and their parameters.

The screen is divided into two parts. The left-hand part shows a list of all the tests and the right-hand part shows the different parameters and their values. The parameters are grouped by different sections: general, procedure, calibration and blank, quality control and options.

Press on the name of the section to access each group of parameters.

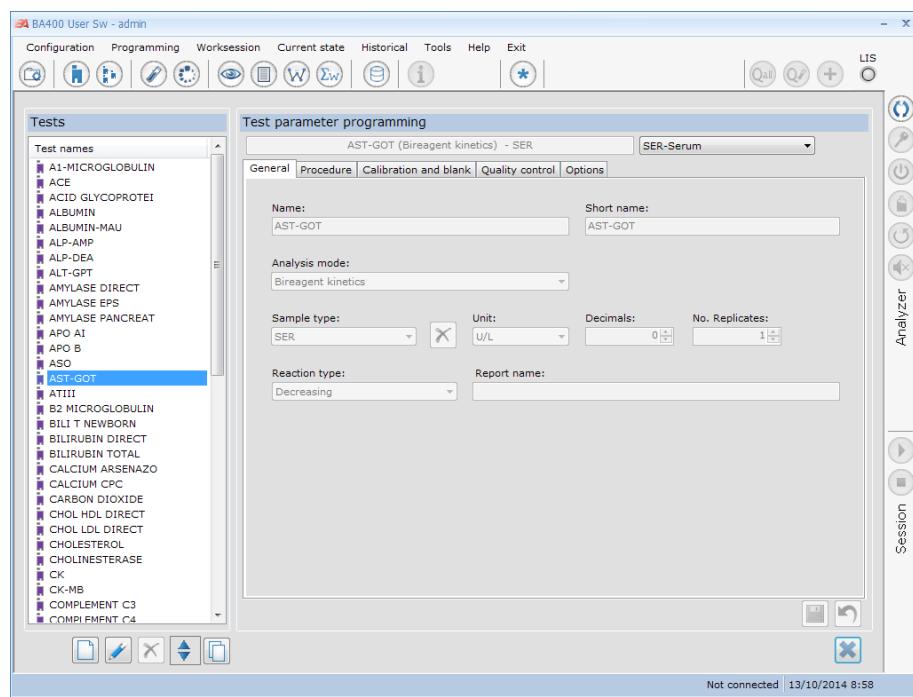


Figure 43 Test creation screen



Press the icon to create a new test. To indicate that the fields can be edited, the background colour will change to white. Some parameters will appear with default values.

-  To edit the parameters of a test already entered, first select the name of the test to be changed from the test list and then press the icon. You can also edit the test parameters by double-clicking on the name of the test in the list of tests.
 -  Select the test name and press the icon. The program will ask for confirmation before deleting it. Only the tests created by the user can be deleted (the test icon is in yellow). The original tests (with the blue icon) cannot be deleted.
 -  Press the icon to print out a list of the test parameters.
 -  You can delete or print out several tests at once, and make multiple selections from the list of tests.
 -  Press the icon to open up an auxiliary screen which allows you to cancel and order tests. The ordering and/or cancellation of tests is applied in the test selection screen.
 -  See chapter 10.3.1.1
- Non-consecutive multiple selection* Select a test and keep the CONTROL key pressed while you select the other tests.
- Consecutive multiple selection* To make a consecutive multiple selection of several tests, select the initial test, press the UPPER CASE key and select the last test. All the tests between the initial and last test will be selected.
- Ordering of tests* Press the header on the test list to show the tests in ascending order. If you press a second time, they will be shown in descending order.
-  This icon will appear when a compulsory parameter needs to be entered, or if there is an error in entering the value.

10.3.1.1. Ordering of tests

This screen allows you to order the tests in the test selection screen when creating the worklist.

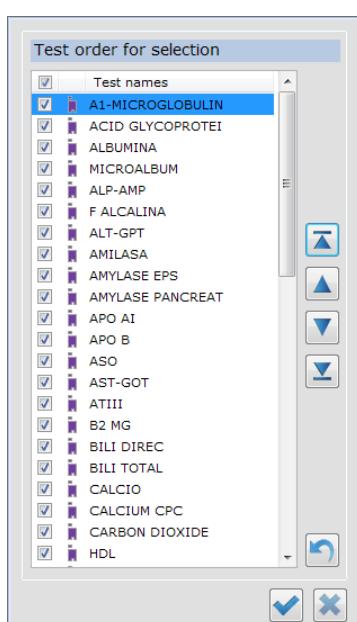


Figure 44 Screen for ordering the tests



Select a test or test group and press one of the buttons until the test is placed in the desired position.



Press this button to display the tests in alphabetical order again.



Press this icon to cancel or activate a test.

10.3.1.2. Test parameters: general

Name Test name. This name is used to identify the test in the program. The maximum length is 16 characters.

Short name Abbreviation of the test name. It must have no more than 8 characters. This field is used in the parts of the program where there is insufficient space to show the full name.

Sample type Select the type of sample, which may be:

Sample type	Description
SER	Serum
URI	Urine
PLM	Plasma
WBL	Whole blood
CSF	Cephalorachidean liquid
SEM	Semen
LIQ	Biological fluid

In creating a test, select the type of sample to which it is applied.

You can create a test with different types of sample. Display the sample type options and check the type you want to add in the options table.

In a test with more than one sample type, you can enter different test parameters for each sample type.



This icon appears when a test is programmed with several sample types.

Analysis mode The absorbance calculation depends on the analysis mode selected.

The analysis modes may be:

Analysis modes
Endpoint monoreagent
Endpoint bi-reagent
Differential bi-reagent
Fixed time monoreagent
Fixed time bi-reagent
Kinetic monoreagent
Kinetic bireagent

See how to make the absorbance calculations depending on the analysis mode in chapter 16.

Unit	Select from the list the unit that will use the test. To create a new unit enter the unit directly in the box. This value will be displayed along with the concentration results.
Decimal points	Number of decimal points for displaying the concentration values.
Number of replicates	Number of replicates performed by the analyser for each sample.
Type of reaction	Select the type of reaction: increasing or decreasing.
Report name	Name of the test which will appear in the patient report. If there is no name entered in this box, the test name will be shown in the patient report.

10.3.1.3. Test parameters: procedure

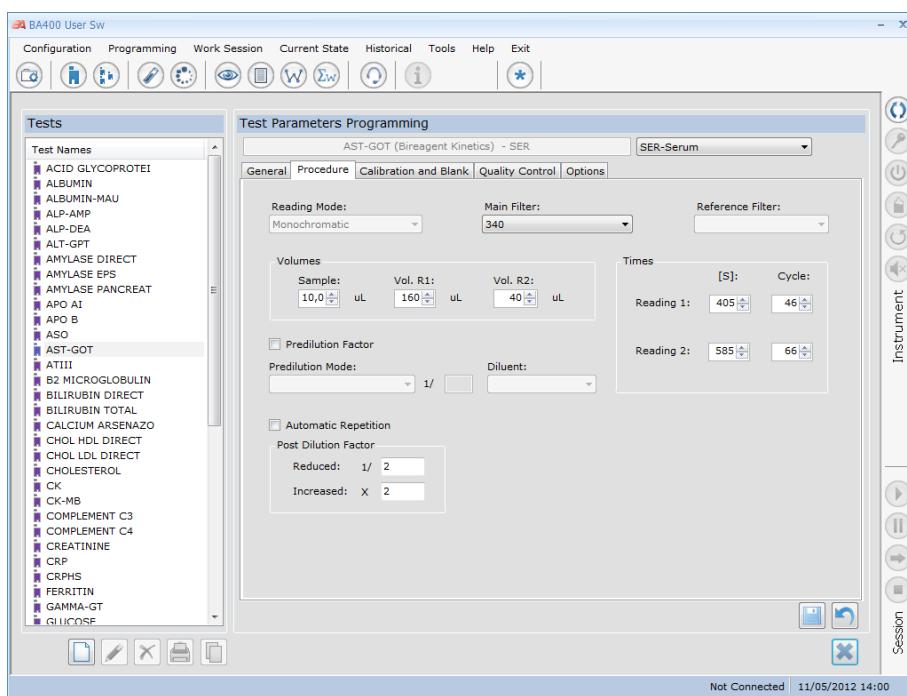


Figure 45 Test parameters, procedure screen

Reading mode	Select one of the two following options: monochromatic or bichromatic. The absorbance calculation depends on the reading mode.
	See how to perform the absorbance calculations in chapter 16.
Main filter	Select the main filter value to be used for taking the readings.
Reference filter	Select the reference filter value. This box will only be activated if the bichromatic reading mode has been selected.
Sample volume	Enter the sample volume for making the preparation. The sample volume range is from 2 µL to 40 µL. The volume can be entered in decimal fractions in µL.
Volume of reagent 1	Enter the reagent 1 volume for making the preparation. The volume range is from 150 µL to 450 µL.
Volume of reagent 2	Enter the reagent 2 volume for making the preparation. The volume range is from 40 µL to 300 µL. This box will only be activated if the bi-reagent option is selected in the analysis mode.

- Reading time 1* Enter the reading time for calculating the absorbance. This can be entered as seconds or cycles. The time ranges are from cycle 3 to 70.
- Reading time 2* Enter the time for making the last reading. This box will be activated for bi-reagent or kinetic calculation methods. The time ranges are from cycle 35 to 70. Reading time 2 must always be greater than reading time 1.
- Pre-dilution factor* Activate this option if the sample requires a pre-dilution. The pre-dilution can be made automatically with the analyser or the already-diluted sample can be placed in the sample rotor by hand. The parameters required are:

Pre-dilution parameter	Description
Analyser/user	Select who you want to make the pre-dilution: the analyser automatically or the user manually.
Factor	Enter the pre-dilution factor. The range to be entered is from 2 to 200.
Diluent	Select the diluent for preparing the dilution. Only in the event that the pre-dilution is made by the analyser.

- Automatic repetition* Activate this option if you want automatic repetitions to be made when a concentration has been obtained outside the linearity or detection limit.

Repetition factor	Description
Reduced factor	Enter the factor for the repetition concentration to be reduced without exceeding the linearity limit. The analyser changes the sample/reagent volume ratio with the programmed factor of the repeated preparation. The analyser automatically multiplies the result of the repetition concentration by the programmed factor.
Increased factor	Enter the factor for the repetition concentration to be increased and exceed the detection limit. The analyser changes the sample/reagent volume ratio with the programmed factor. The analyser automatically divides the result of the repetition concentration by the programmed factor.

10.3.1.4. Test parameters: calibration and blanks

- Type of blank* The blank can be made in different ways. Select the method for making the blank:

Type of blank	Description
Blank with Distilled Water	The analyser makes the blank with purified water.
Blank with Physiological Saline Solution	The analyser makes the blank with physiological saline solution.
Blank with Reagent Only	The analyser makes the blank only with the reagent

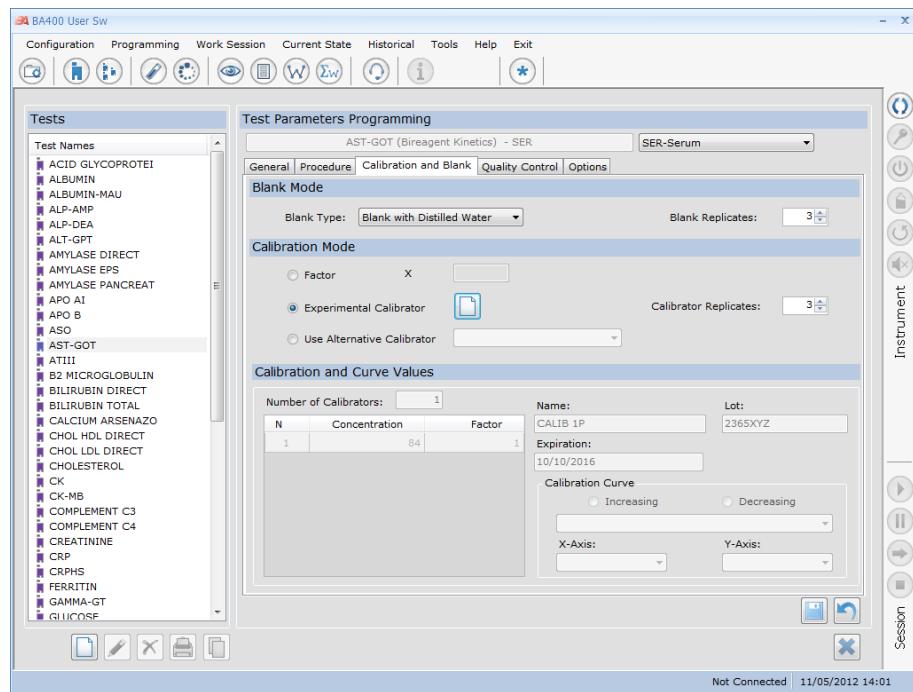


Figure 46 Test parameters, calibration and blanks screen

- Blank replicates* Number of replicates for making the blank. The range is from 1 to 3. The mean of the replicates is used to calculate the concentration.
- Factor* If the test is not calibrated enter the multiplicative factor value for calculating the concentration.
- Experimental standard* Enter the standard data and its concentration. Press the icon again to open up the calibration screen and enter the standard parameters.
☞ See how to enter the standard parameters in chapter 10.3.5
- Standard replicates* Number of replicates for making the standard. The range is from 1 to 3. The mean of the replicates is used to calculate the factor.
- Use alternative standard* If a test has several different sample types created, it is usually calibrated for one type (serum, for example) and the other sample types (such as urine) use the calibration of the first type (serum). In this box, select the type of sample from which the calibration will be obtained.
- Calibration values and curves* Shows the standard values assigned to the test. They are only shown for informative purposes. To create new standards and/or change them, edit them in the standard screen.

10.3.1.5. Test parameters: quality control

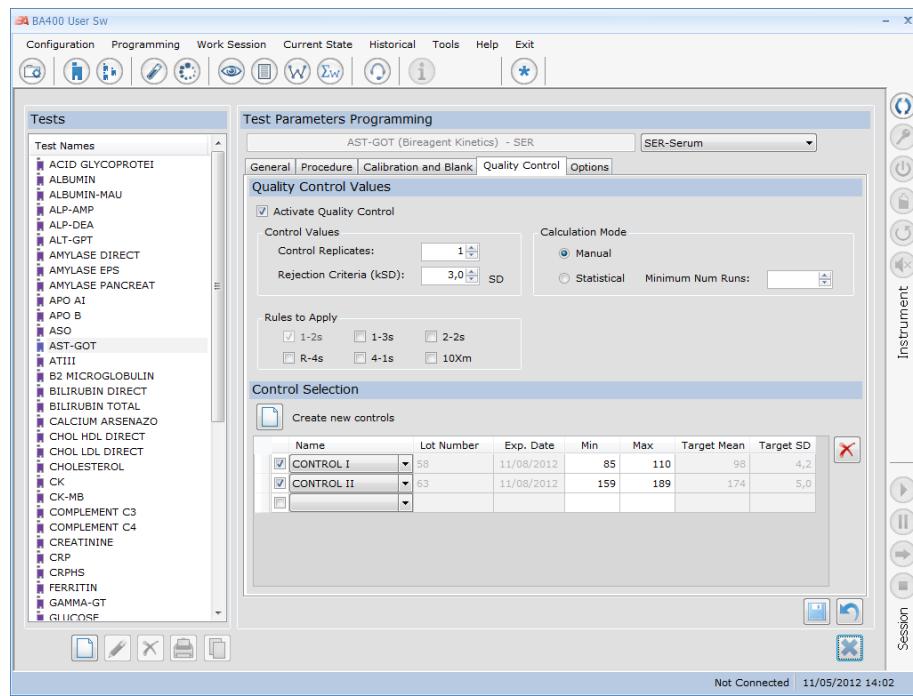


Figure 47 Test parameters, quality control screen

Active quality control

Check this option to activate the quality control for this test.

Control replicates

Number of replicates for measuring the controls. The margin is between 1 and 3.

Rejection criterion

Enter the rejection criterion for controlling the activation of alarms in quality control management. This value is calculated in standard deviations (SD). The margin is between 0.1 and 4.

Calculation mode

The calculation mode may be manual or statistical. Indicate how to calculate the ranges in order to draw the Levy-Jennings graph and activate the Westgard rules alarms.

Calculation mode	Description
Manual	Use the theoretical ranges of the serum control seating values entered when registering a control. They remain unaltered, unless new cumulative values are to be assigned. ☞ See chapter 10.7.4

Calculation mode	Description
Statistical	<p>Use the ranges calculated from the mean and SD of the above series.</p> <p>The minimum number of series indicates the number of controls measured by the analyser before starting to calculate the mean and the SD. During these first series, the manual mode is used internally. The minimum number of series to be programmed is 5.</p> <p>Different quality regulations in the laboratory make it advisable to assign 20 minimum series when starting to use a specific control batch.</p>
Applicable rules	<p>Select which Westgard rules you want to apply to the quality controls for this test.</p> <p> It serves to register the controls with their batch and concentration values.</p> <p> See how to register a control in chapter 10.3.6.</p>
Selection of controls	This table shows the different controls registered for the test. In the box, activate the controls to be used, as you may have created various controls. It can activate up to 3 controls at one time.

10.3.1.6. Test parameters: options

Screen where the limit values are programmed for issuing warnings and alarms to the user, depending on the results.

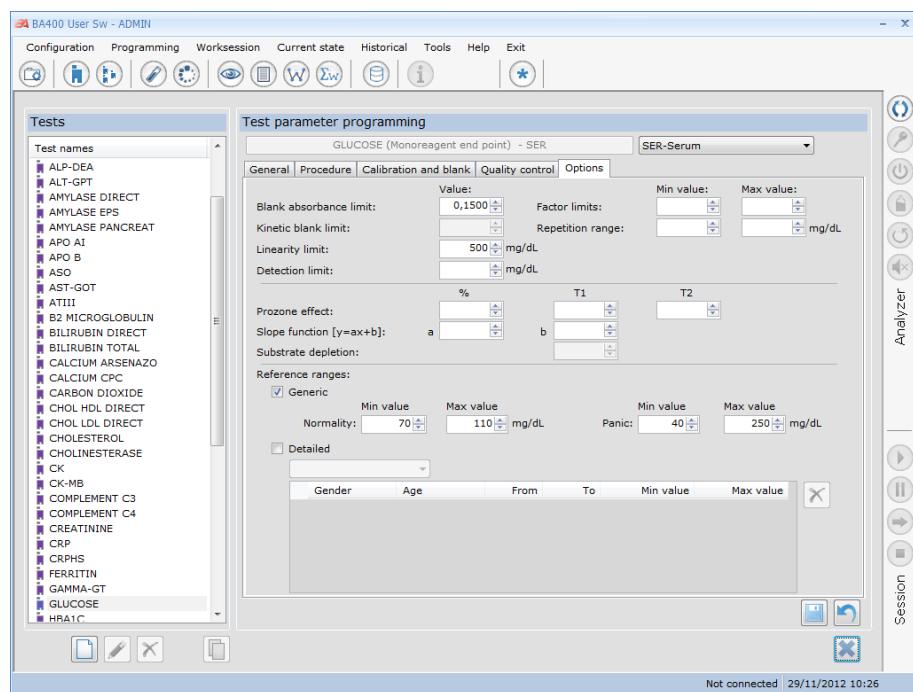


Figure 48 Test parameters, options screen

<i>Blank absorbance limit</i>	Limit value established for comparing against the result of the blank absorbance. It is used for checking the state of the reagent.
<i>Kinetic blank limit</i>	Enter the correct kinetic blank value limit. It is only applied to tests with the kinetic calculation mode.
<i>Linearity limit</i>	Enter the value for which the reagent is no longer linear. If the concentration value is higher than this value, the program will issue a warning message and if it is activated in the programme a repetition will automatically be launched.
<i>Detection limit</i>	Enter the value for which the reagent does not detect a value. If the concentration value is higher than this value, the program will issue a warning message and if it is activated in the program a repetition will automatically be launched.
<i>Factor limits</i>	Upper and lower range for verifying that the calibration factor is correct.
<i>Repetition range</i>	The analyser repeats the sample automatically if the concentration value is within the range. This range serves to confirm the result automatically.
<i>Prozone effect</i>	<p>The prozone effect may occur in tests based on the principle of the formation of antigen-antibody complexes (agglutination). This effect is usually detected in samples with a high antigen content. Excess antigen inverts the reaction direction and may cause incorrect sample measurements. To detect that effect you should activate the prozone effect option and enter the 3 parameters: Time 1, Time 2 and ratio in (%).</p> <p>The program will calculate the absorbance increases in times 1 and 2, obtain the increase quotient and compare the result against the ratio. If the quotient does not exceed the ratio, an alarm is triggered indicating that the sample could have the prozone effect, in which case the user must make a manual repetition with a dilution factor, to finally determine the exact value of the sample.</p>
<i>Slope function</i>	Enter parameters a and b of the formula $Y=aX+b$. These parameters change the value of the result concentration in a linear manner. This option is used to match the results of different analysers. Where X will be replaced by the concentration value and Y will be the changed concentration value.
<i>Consumed substrate</i>	Enter the value in absorbances. When a test in kinetic analyse mode has a point below this limit, this means it has consumed the sample substrate, and the result is thus not correct. When this alarm is activated the program automatically launches a repetition.
<i>Reference ranges</i>	Indicate the normal reference values for the population. If values are entered in the fields, the results are shown on the screen along with the patient report and the concentration result.

Reference range	Description
<i>Generic</i>	A series of common ranges for the whole population is entered in these fields.
<i>Detailed</i>	<p>In this table the specified ranges are entered by gender and/or by age.</p> <p>Enter the gender, age group and normal values in each row.</p>

Panic ranges Enter the values for which a result is pathological. The values entered must meet the following conditions:

$$\text{Minimum panic} < \text{Minimum normality} < \text{Maximum normality} < \text{Maximum panic}$$

10.3.2. Calculated tests

Screen in which the calculated tests are programmed. The result of the calculated tests is obtained by applying a formula with the concentrations of several standard tests performed previously.

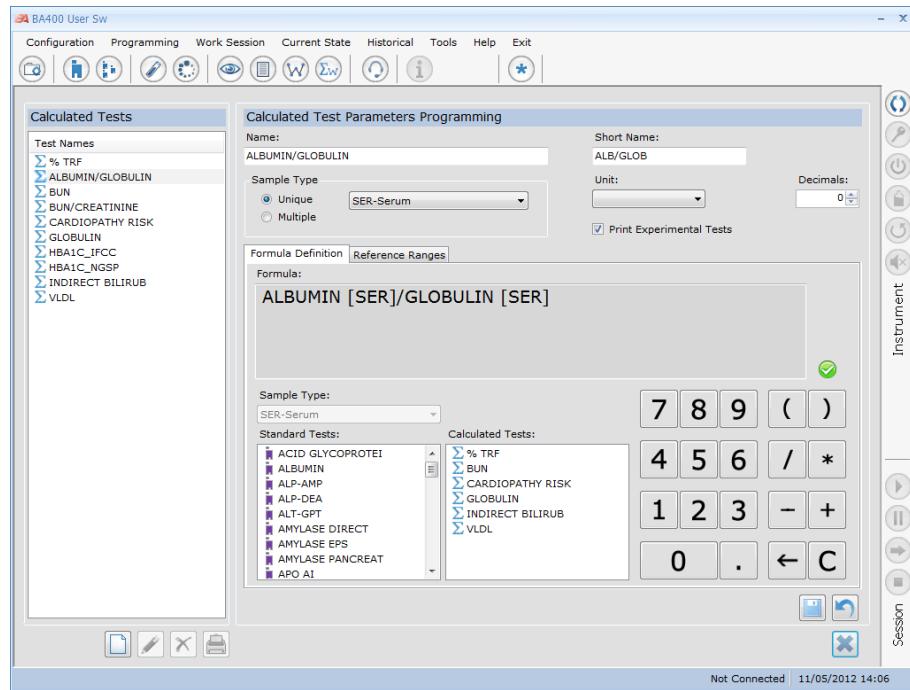


Figure 49 Screen for creating calculated tests

On the left-hand side of the screen is a list of calculated tests and on the right-hand side are the parameters to be entered for each calculated test.

☞ See functioning of creation icons, edition, deletion and printing of the test screen in chapter 10.3.1.

Name Name of the calculated test.

Short name Abbreviated name of the calculated test.

Sample type Indicates the type of sample to be used for selecting the standard tests.

Sample type	Description
Single	In this option the standard tests have only one type of sample
Multiple	In this option the standard tests may have different sample types

Unit Unit in which the results of the calculated tests will be shown. This unit may be different from that of the standard tests.

<i>Decimal points</i>	Number of decimal points for displaying the calculated test concentration values. This number of decimal places may be different from that of the standard tests.
<i>Print out experimental tests</i>	Check this option if the patient report also has to show the results of the standard tests in addition to the result of the calculated test.
<i>Formula definition</i>	Formula relating the calculated test to the standard tests. To enter the formula, select the standard tests, other calculated tests, numbers and operators. The program verifies whether the formula entered is correct and indicates this through one of the following icons:
	This icon indicates that the formula has been correctly entered with no errors.
	This icon indicates that there are errors in the formula. Change the formula until the icon disappears.
	Delete the last character entered.
	Delete the whole formula entered.

10.3.3. Contaminations

This screen is used to program contaminations between reagents and cuvette contaminations.

To eliminate the contamination, first of all the program orders the tests for a patient to avoid dispensing them in consecutive order. If it is not possible to eliminate the contamination by ordering them, an extra wash cycle is added between the contaminant test and the contaminated test, to clean the tip. If nothing is indicated in the program, the wash cycle is performed with purified water, otherwise the cycle will be executed with the programmed washing solution.

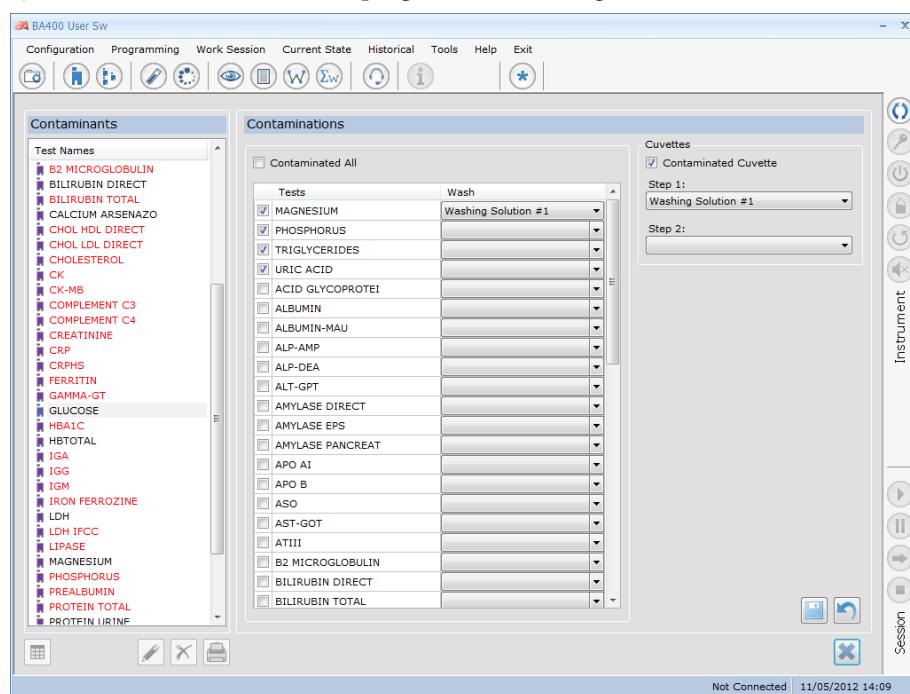


Figure 50 Contamination programming screen

In the left-hand column a list of all the potential contaminant tests is displayed. The tests for which contamination has already been programmed are marked in red.

Select a test and then press any of the following icons:



Press this icon to add the contaminated tests to the selected test. The contaminated test table will be activated for you to select the contaminated tests. The washing solution to be used by the analyser to prevent contamination can be indicated for each contaminated test.

Contamination of the cuvette

Step 1 Select this box if the contaminant test contaminates the reaction rotor cuvette.

Step 2 Enter the washing solution to be dispensed in the reaction cuvette if the contaminant is reagent 1.



Eliminate the contaminated test and cuvette programming.



Press this icon to print out a list of all the contamination pairs.



When this icon is pressed an auxiliary window emerges with a summary of all the contamination pairs and all the tests contaminating the reaction cuvettes.

☞ See Figure 51

The first column shows the contaminant tests, the second one shows the contaminated test and the third column shows the programmed washing solution. To review the programmed contaminations, you can order the tests in alphabetical order based on the *contaminant* tests column or the *contaminated* tests column. To do this press the header of either column. If you press twice, they will first be shown in ascending order and then in descending order.

Contaminations			Cuvettes		
Contaminant	Contaminated	Wash	Contaminants	Step 1	Step 2
IGG	PROTEIN TOTAL		GLUCOSE		
IGG	PROTEIN URINE		PHOSPHORUS		
IGM	PROTEIN URINE				
IRON FERROZINE	PHOSPHORUS				
IRON FERROZINE	URIC ACID				
LDH IFC	CALCIUM ARSENATO				
LIPASE	LDH IFC				
PHOSPHORUS	IRON FERROZINE				
PREALBUMIN	PROTEIN URINE				
PROTEIN TOTAL	CALCIUM ARSENATO				
PROTEIN TOTAL	IRON FERROZINE				
RF	PROTEIN URINE				
TRANSFERRIN	IRON FERROZINE				
TRANSFERRIN	PROTEIN URINE				
TRIGLYCERIDES	CHOL HDL DIRECT				
TRIGLYCERIDES	MAGNESIUM				
UREA-BUN-UV	PHOSPHORUS				
URIC ACID	MAGNESIUM				
URIC ACID	PHOSPHORUS				

Figure 51 Contamination summary screen

In the cuvette section, the contaminant test is shown, with the washing solutions to be used in step 1 and step 2.

10.3.4. Profiles

Profiles are names given to a set of tests with a diagnostic significance. They serve to help the user program create the worklist.

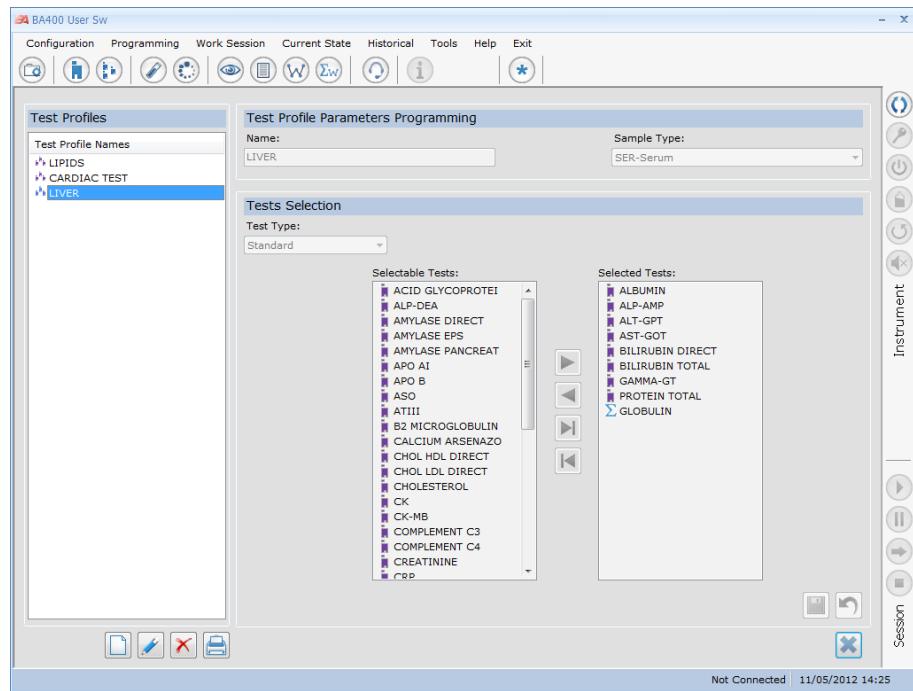


Figure 52 Screen for entering profile information

☞ See functioning of creation icons, edition, deletion and printing of the test screen in chapter 10.3.1.

Parameters to be programmed in the profiles:

Name Profile name.

Sample type Select the type of sample the profile will have.

Type of test Select the type of test, which may be: standard, calculated, ISE or external tests. It serves to filter the number of tests to be displayed in the selection column.

Select the different tests you want to form part of the profile. Use the CRTL and BLOCK CAPITALS keys to make a multiple selection.

► Add the selected tests to the profile.

◀ Eliminate a test from the profile.

► Add all the tests at one time to the profile.

◀ Eliminate all the tests at one time from the profile

10.3.5. Standards

Screen for programming the different standard parameters: name, batch, expiry date, concentration.

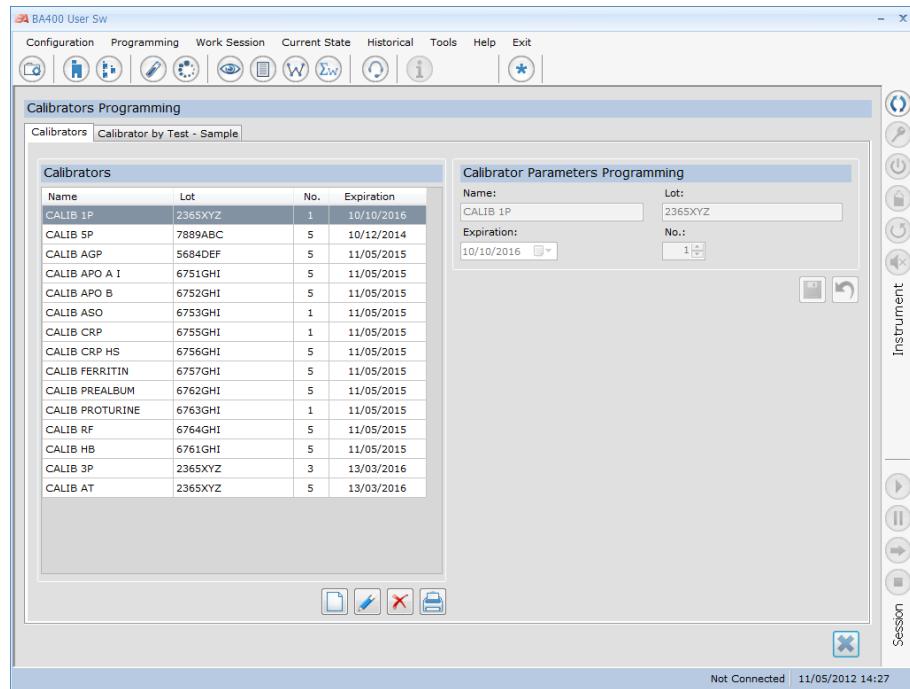


Figure 53 Entering the standard information

In the first tab enter the general information on the standard. A list of all the standards exists, with the icons new, edit and print.

The information to be entered by the user is the following:

Standard name

Enter a name for the standard

Batch

Enter the standard batch. When the batch is changed, you must reprogramme the concentrations of all the tests that use this standard. The program issues a warning, showing the tests affected.

Expiry date

Enter the days the standard will last once reconstituted.

No.

Enter the number of standards this standard has.

In the second tab the standard is assigned to the test and the concentration value is entered.

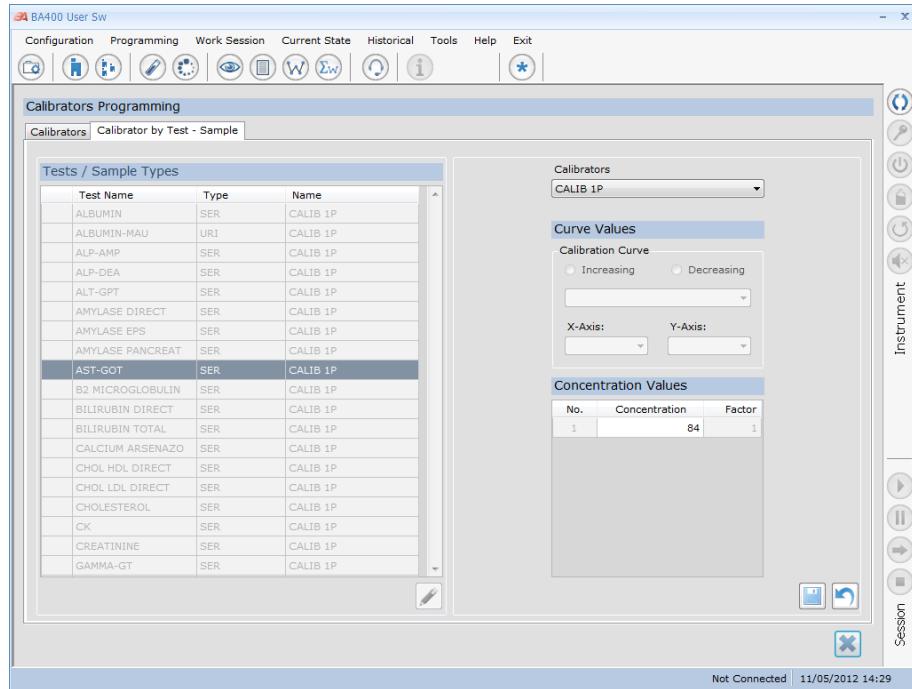


Figure 54 Entering the standard concentrations

First select the test to which you want to assign the standard and then press the edit button.

Standards Select the name of the standard you want to assign to the test.

Enter the standard values for the test.

If the standard is for a specific value, you need only enter the concentration value. In multipoint standards, you must enter the following parameters:

Ascending / descending. This indicates whether the calibration curve will be ascending or descending.

Creating the curve Enter the method for creating the calibration curve. It may be one of the following methods: polygonal, linear regression, parabolic regression or spline. Also select the axes on which you want to show the calibration curve: linear axes or logarithmic axes.

Concentration values Enter the concentration values for each standard in descending order.

Consult the programming of the test calibration in the test programming screen. You can only change the calibration value in this screen.

10.3.6. Controls

In this screen the controls to be used are registered. You can create new controls and edit, delete and print them.

You can also edit the minimum and maximum values of each test for each control level.

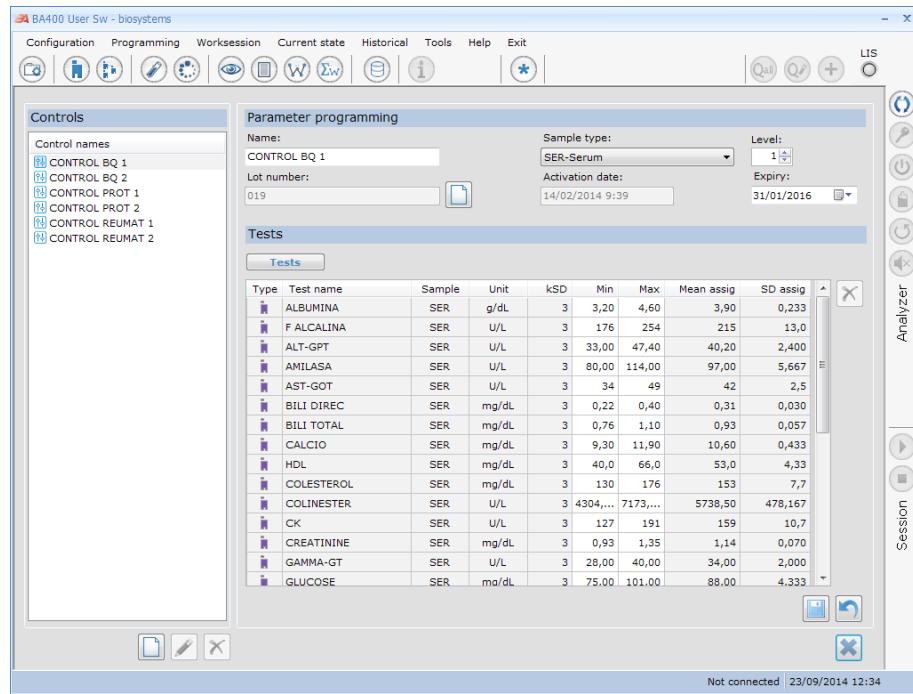


Figure 55 Screen for programming the control serums

Control name

Enter the control name.

Sample type

Enter the type of sample that will use this control.

Level

Enter the control level (1, 2 or 3). This is used to facilitate the selection of an entire level in the sample request screen.

Batch number



Press this icon to change the batch for a specific control already registered.

☞ See Figure 56.

Date activated

The date on which the control is first used.

Expiry date

Enter the expiry date. The program issues a warning when a control whose expiry date has been exceeded is used.

Tests

Press this button to assign or eliminate the tests associated to a control level. An auxiliary screen appears that contains only the tests for the same sample type, with the quality control activated (when created, the tests normally have a deactivated quality control).

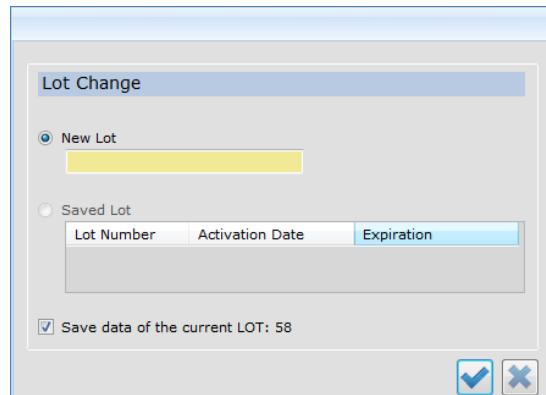


Figure 56 Screen for changing the batch of a control

10.3.7. Patient data

Screen for entering the patient data: patient code, name, gender, etc. After entering the data, a report for each patient can be generated with the analyte concentration results. Having the patient data entered makes it easier to organise and search in the historical log. In this way the results for one patient obtained during different periods can be grouped together.

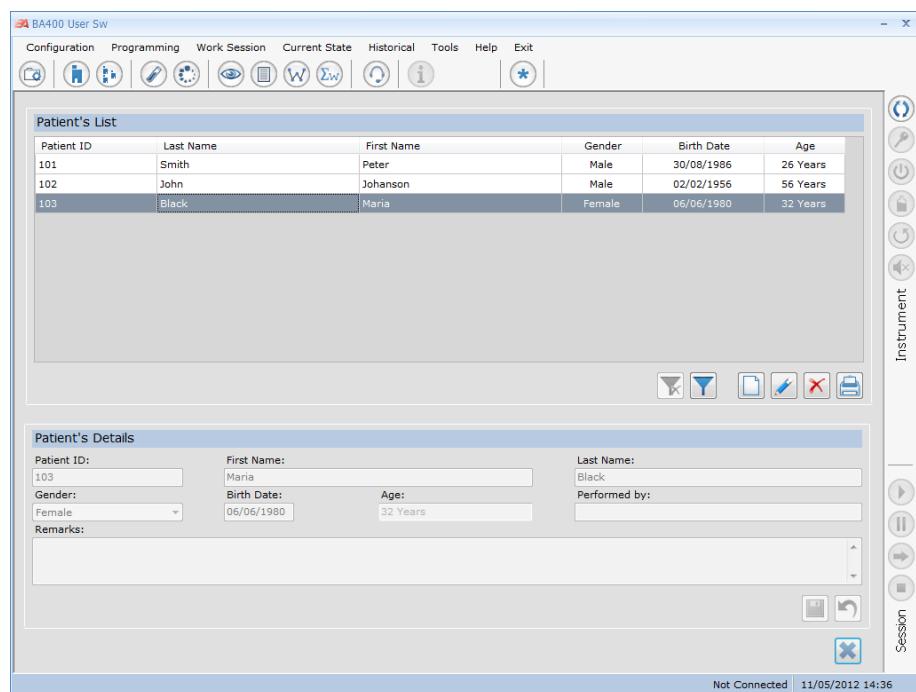


Figure 57 Screen for programming the patient data

At the top of the screen is a list with all the patients entered.

See the functioning of the creation, edition, deletion and print icons in chapter 10.3.1.

Patient identification Enter a patient identifier in order to associate the patient data to the results.

Name Enter the name of the patient.

Surname Enter the surname of the patient.

<i>Gender</i>	Enter the gender of the patient: male or female
<i>Date of birth</i>	Enter the date of birth of the patient. The age field is calculated automatically after entering the date.
<i>Analysis performed by</i>	Enter the name of the doctor
<i>Remarks</i>	Field blank for entering the opportune text.
	Press this icon to make a search for a specific patient in the patient list. When the icon is pressed an auxiliary screen will appear for you to select the search field. ☞ See Figure 58 for more information.
	Press this icon to cancel the search options and view all the patients.

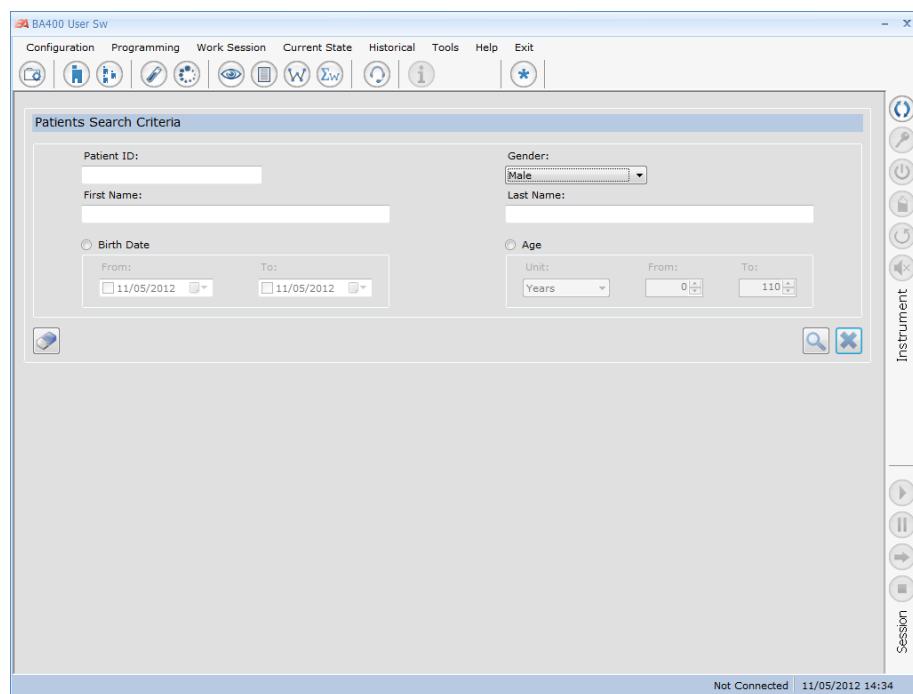


Figure 58 Screen for selecting the search options.

Complete one or more fields to enter the search criteria. For the date of birth and age fields you must enter a range of dates and ages, respectively.



Press this icon to make a search after entering the criteria.



Press this icon to delete all the search criteria. It is activated when data is entered in any field.

10.3.8. ISE module

Screen for programming the ISE module parameters. The ion-measuring module is optional. The module can measure 4 different ions: Na^+ , K^+ , Cl^- and Li^+ which are already programmed by default. No new ones can be created and they cannot be deleted. Supervisor users can change the following parameters:

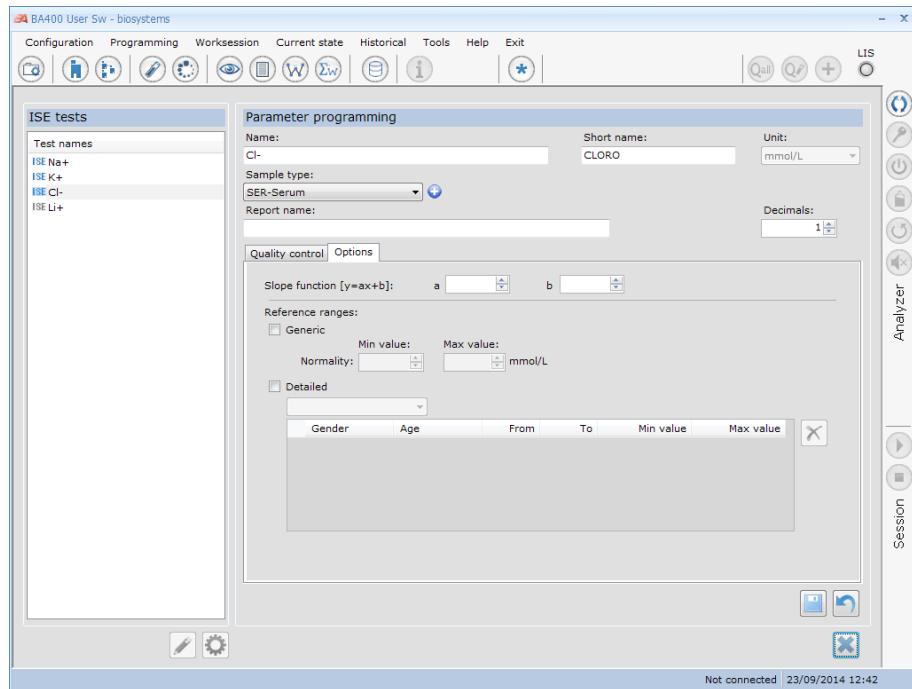


Figure 59 Screen for programming the ISE parameters

Name Test name. This name is used to identify the test in the programme. The maximum length is 16 characters.

Short name Abbreviated name with up to 8 characters for use in certain screens in the application.

Sample type Select the type of sample with which the ions will be used.

ISE test available Select this option to view the ISE test on the sample selection screen. This option is for cases in which some of the electrodes must be discarded.

Decimal Number of decimal points for displaying the concentration values.

Slope function Enter parameters a and b of the formula $Y=aX+b$. These parameters change the value of the result concentration in a linear manner. This option is used to match the results of different analysers. Where X will be replaced by the concentration value and Y will be the changed concentration value.

Quality control Enter the quality control values

☞ *The method for entering the quality control values is set out in chapter 10.3.1.5.*

Reference ranges Enter the reference values.

☞ *See how to enter the reference values in chapter 10.3.1.6.*

10.3.9. External tests

External tests are tests whose result is not measured by the analyser, but which must appear in the patient's report or in the patient's historical file. When one of these tests is assigned in the work session the results for those tests can be entered from the session screen or when viewing the results.

All the information entered in the test may be shown in the patient's report.

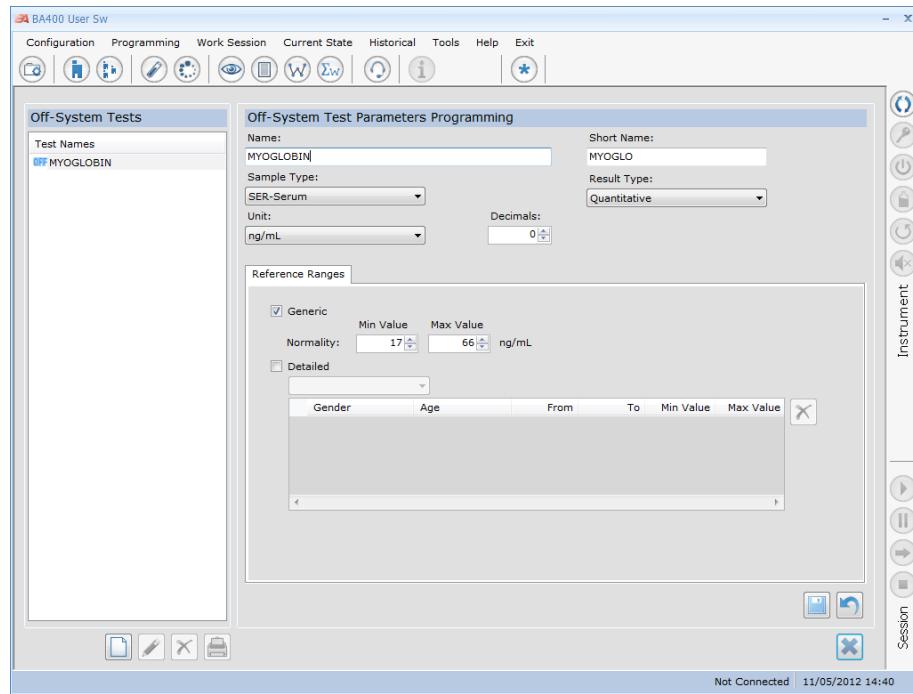


Figure 60 Screen for programming external tests

Name Enter the name of the external test

Short name Abbreviation of the test name. It must have no more than 8 characters. This field is used in the parts of the program where there is insufficient space to show the full name.

Sample type Enter the type of sample.

Type of result Enter whether the result will be: quantitative or qualitative.

Type of result	Description
Quantitative	This is a numerical result. When selecting this option the units and number of decimal places for the result are entered.
Qualitative	This is a non-numerical result. For example: a positive or negative result, a high or low result, etc.

Reference ranges Enter the reference values.

☞ See how to enter the reference values in chapter 10.3.1.5.

10.4. Work session

In this menu you can access the options for creating the work session and positioning the samples and reagents.

10.4.1. Sample request

This screen is used to create or import the work session. As the list of patients is created, the different tests to be executed are assigned. The program automatically incorporates the blanks and standards related to each test. It also incorporates the controls for the tests that have them programmed.

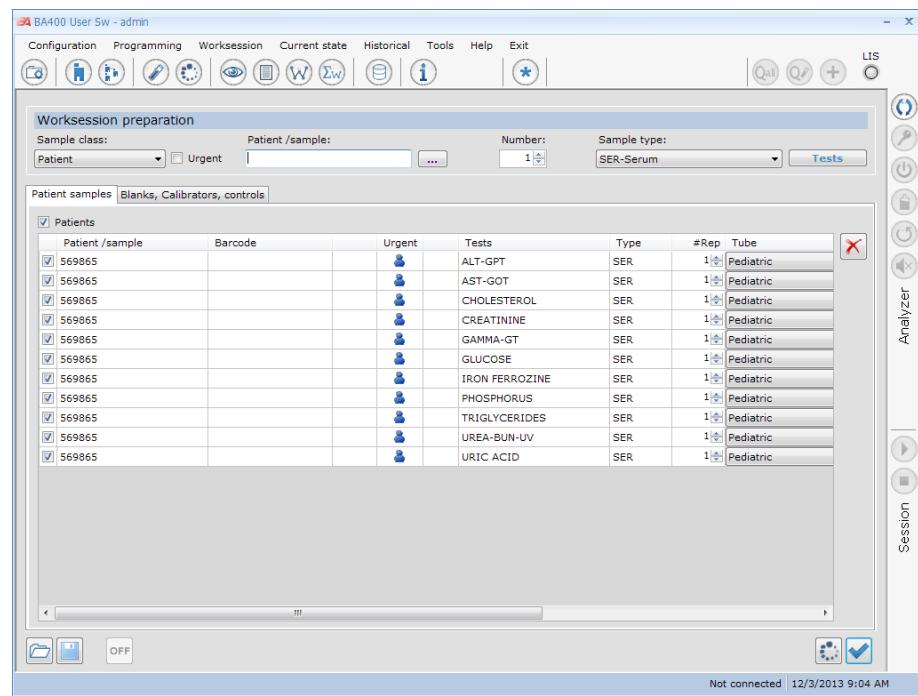


Figure 61 Screen for entering new samples

The screen has two parts. The top part contains the fields for entering the patients and tests. The patients entered are shown in list format, in the bottom part. Each individual patient and test can be edited and deleted until the list is positioned in the rotor.

Sample type This field is used to select the type of sample to be entered. The types may be: patient, blank, standard or control. It serves to make only lists of blanks and standards or only lists of controls.

Urgent This is used to indicate that the sample is urgent. Only available for patient type samples. Urgent patients are the first ones to be executed. If a work session is interrupted and urgent patients are added, they will be processed as soon as the instrument finishes the preparations in progress.

Patient/Sample Field in which the patient code is entered. This code may be alphanumerical. If no code is entered, it is generated automatically. The automatic code starts with the character #, followed by the date in numerical format and a consecutive number.



Press this button if the patient information has already been entered. When it is pressed the patient data screen will appear for you to select the patient.

Number To enter several patients with the same test profile, enter the number of patients. If the previous field has data entered, this field will be deactivated. The

patient code is automatically generated and starts with #, to distinguish it from those entered manually.

- Sample type* Select the type of sample before going to the test selection screen. Patients with several sample types will have different tubes, one for each type. (For example: for a patient with a serum sample and a urine sample, it will place both tubes in the rotor. Each tube can only be assigned the tests of the sample type selected).
In the event of determining ions in urine, dilute it manually and place the dilution in a different tube.
- Tests* Button for accessing the list of tests and assigning them to the patient. See Figure 62.

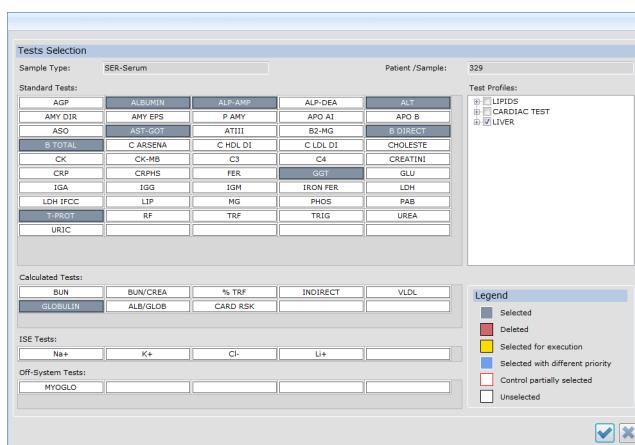


Figure 62 Test selection screen

This screen shows all the tests related to a sample type. The tests are divided into functional groups: standard tests, calculated tests, ISE tests, external tests and profiles.

Colour code for the test selection status.

Colour code	Name	Description
	Selected	Test selected
	Deleted	Test to be deleted. When accepted, this test will be eliminated from the work session along with the related blanks and standards.
	Selected for execution	Test already in use. This test cannot be deleted from the work session.
	Select. with different priority	Patient with normal and urgent tests selected.
	Partially selected control	Test created with more than one control and elimination of one control after creating the work session.
	Not selected	Test not selected

New tests can be added to a work session that has samples and reagents in position. To do this select the patient for which the tests are to be added and press the *tests* button. The program will ask the user about whether new tests are to be added, and if the answer is yes, the screen in Figure 62 appears. Samples or tests can also be added to work sessions that are already initiated.

After entering the tests for a patient, the information is shown in the list in Figure 61.

The information is separated into two tabs: patient information and information on blanks/standards/controls.

The following information is shown in the patient tab:

Column name	Description of the patient tab fields
Selected	Each patient added to the session normally appears as selected. If it is activated, when the position button is pressed the samples are sent to the positioning screen. If the selected is cancelled they are not sent and remain pending. They will not be executed.
Patient/Sample	This indicates the patient code. This code can be changed; press code and it will change to the edit mode.
Urgent	An icon indicates whether the patient is urgent or normal:  Normal patient  Urgent patient
(Empty)	This indicates whether the test is ISE or external (OFF)
Test	Test name.
Type	Type of sample.
Replicates	This indicates the number of replicates of the test to be made. The number of replicates is usually shown programmed in the test. The replicates of each sample can be changed.
Tube	This indicates the type of tube when it is to be put in position. It may be sample well or a tube. The type of tube can be changed by selecting it from the pop-up list.
Calculated tests	If the test belongs to a calculated test, this field shows the name of the calculated test.
Formula	This field is related to the above. It shows the formula of the calculated test.
Profile	If the test belongs to a profile, this field shows the name of the profile.

The following information is shown in the blanks/standards tab:

Column name	Description of the blank/standards tab fields
Selected	The blanks and standards are usually shown selected when there are no previously-memorised results. The elements selected are sent to the positioning screen. The elements not selected are not sent and remain pending (they are not included in the work session)
Type	Select the type of information, which may be: <input checked="" type="radio"/> Blank <input type="radio"/> Standard
Standard	This indicates the name of the standard used
Batch	This indicates the standard batch
No. of standards	This indicates the number of standards
Test	Test name
Type	This indicates the type of sample
Replicates	The number of replicates is usually shown programmed in the test. The replicates of the blanks and standards can be changed.
Tube	This indicates the type of tube when it is to be put in position. It may be sample well or a tube. The type of tube can be changed by selecting it from the pop-up list.
New	This indicates whether a new blank or standard is to be made during the work session. It is normally shown deactivated when there are memorised blank and/or standard results.
Absorbance	Memorised blank or standard absorbance value.
Date	Date on which the blank or standard was made.
Factor	Memorised factor value.

The following information is shown in the control tab:

Column name	Description of the control tab fields
Selected	The controls appear unselected. When the position button is pressed only the selected controls and tests are sent.
Control	Control name
Batch	Control batch
Tests	Test name
Type	This indicates the type of sample
# Rep	The number of replicates is usually shown programmed in the test. The replicates of the controls can be changed.

Column name	Description of the control tab fields
Tube	This indicates the type of tube when it is to be put in position. It may be sample well or a tube. The user can change the type of tube by selecting it from the pop-up list.
Exp. date	This indicates the control batch expiry date.

-  This button allows you to eliminate tests and samples from the work session. First select the row to be eliminated and then press the button. The blanks and standards are automatically eliminated if there is no other patient with that test. The controls can also be eliminated.
-  It allows you to save a session and retrieve it later. The program will ask you to enter a name for the session.
-  It allows you to load a previously-saved session. The program will let you select the name from a list of saved sessions.
-  Press this button to send the samples and reagents to be positioned in the rotors. The program will automatically change screen. Once the samples have been sent to the positioning screen they are marked in grey.
☞ Chapter 10.4.2 describes the procedure for positioning in the rotor.
-  Press the button to open up the screen for entering the results for all patients with external tests.

10.4.2. Positioning in the rotor

This screen indicates the positioning of the reagents and samples. The reagent and sample positioning process may be executed manually or automatically.

The screen shows the following information:

☞ See Figure 63

On the left is a list of all the reagents and samples of the work session that are to be positioned. The elements not yet positioned are shown in black, whereas the elements in position are shown in green.

In the centre, the sample and reagent rotor (in separate tabs) allows you to see the positioned elements, identified by an icon.

On the right is detailed information about the position selected in the sample and reagent rotor.

Manual positioning

Select an element from the tree and drag it with the mouse to the position in which you want it to be in the rotor. Repeat this process for each of the tree elements. First, you must have selected either the reagent or the sample rotor.



This button also positions all the patient samples, controls and standards automatically. The patient samples will be positioned starting in the first position that is empty. The standards and controls will be positioned from position 91, in the third ring. These positions have no barcode reader.



This button automatically positions the reagents. The special solution bottles (physiological saline solution, washing solution, etc) are put in place starting in the last position, in descending order of positions.



You can move the elements positioned in the rotors by dragging them to another empty position.

This button reads the barcodes of the analyser samples and reagents. The samples placed in the sample wells and elements placed in the third ring will not be scanned by the reader and the user must position them by dragging them or using the auto-position button.

If the samples have barcodes that do not correspond to the work session samples, the necessary additional information is requested: type of sample and test to be performed on each sample.

If the program detects an erroneous barcode, this is indicated by an icon over the rotor position. Erroneous barcodes can be corrected manually.

Press this button if you want the analyser to automatically position the samples and reagents by reading the barcode. It will only position the elements that have barcodes. Elements in sample wells, such as standards and controls must be positioned manually or using the auto-position button. If the reader detects an erroneous code, the program will issue a warning for the user to enter the barcode manually.

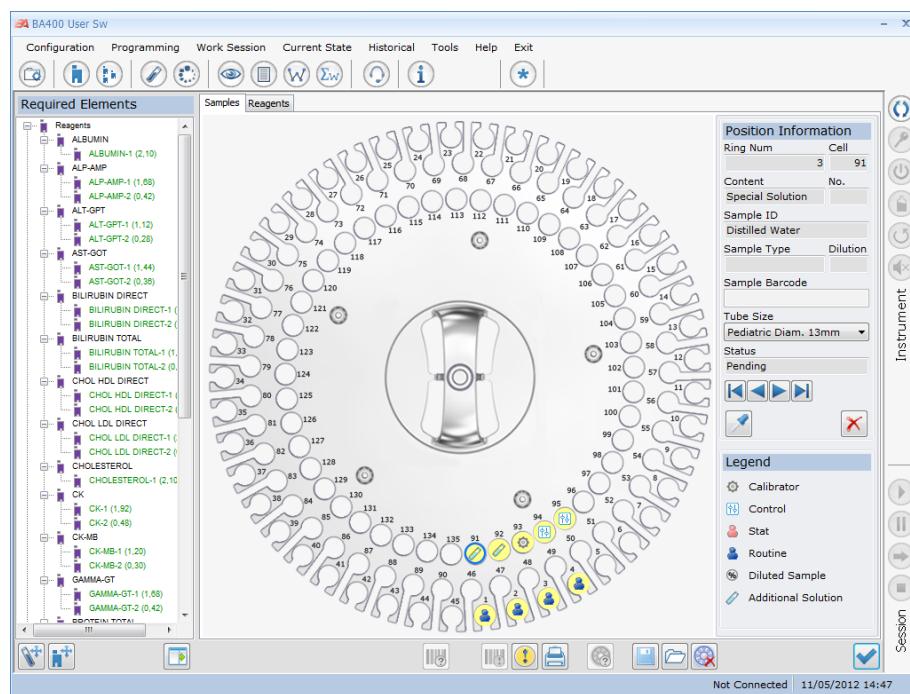


Figure 63 Screen for positioning the reagents and samples



Button for warnings related to elements required for the work session. When this button is pressed a message will appear informing you of all the elements that have still to be positioned. The same message will appear if an element has not yet been positioned when the positioning screen is closed.



Press this button to print out a report of the positions of all the elements in the current session.

-  Press this button to memorise the elements positioned in the visible rotor. The program will request a name for identifying the memorised rotor. When a session reset is made the elements positioned in the reagents rotor are maintained, but the sample rotor is emptied.
-  Press this button to load the positions of the elements of a rotor that was previously memorised.
-  Press this button to delete the visible positioning of all the rotor elements.
-  Press this button to inform the program that you have entered a sample tube, standard or control manually. Perform this action when the volume termination alarm is triggered. For reagents with barcodes you need only place a new bottle in the rotor and press the barcode reading button and the information on the volume of the new bottle will automatically be updated.

10.4.3. Creating the worklist from the sample positioning screen

When making a barcode reading of sample tubes positioned in the rotor, if there are no tests requested for any of the samples, this screen will automatically open up. It permits the work session to be completed by requesting information from the LIS through a Query by specimen or manually.

Queries made be made from that screen, or tests can be added to any sample tube positioned that is shown in grey (i.e., with no tests assigned). The same number of tubes identified with the barcode reader as there are sample tubes to which a barcode has been assigned manually.

Figure 64 Screen for creating the work list from positioning

This screen also appears when making a Host Query.

 See chapter 17 for Host Query details.

A table appears in the screen with the following information:

Column name	Description of the fields
Tic	Specimen selection.
Position	Position of the specimen in the rotor.

Column name	Description of the fields
Barcode	Information read from the specimen barcode.
Sample identifier	Sample identifier, depending on the barcode configuration it may coincide with the barcode digits.
Type	This indicates the type of specimen. Its entry comes from the worklist or the information from the LIS. In specimens containing this same information in the barcode, it is checked that the information coincides. In cases in which the sample type does not form part of the barcode and several specimens are read with the same code, a message will appear for determining the type to which each specimen belongs.
Urgent	This indicates whether the sample is urgent. Its entry comes from the worklist or the information from the LIS.
Status	Information only appears when making a Host Query. It indicates the status of requests to the LIS. It has the following states: <ul style="list-style-type: none"> • ASKING: Request sent to the LIS • PENDING: Request already sent and awaiting receipt of the worklist for the sample. • REJECTED: Request rejected by the LIS. • NO INFO: The LIS has no information about this sample.



It allows the specimens to be selected in order to request the LIS for the work order or a worklist can be created manually.



Button allowing a Query All to be made directly to the LIS from this auxiliary screen.

The bottom of the screen allows you to create the worklist manually after the specimen barcodes have been read. To do this, select the specimen or group of specimens and assign the sample type, if it is urgent, and assign tests using the TEST button. Once you have done this, press save and continue with the next specimen.

If the sample type is not coded in the barcode, the type must be assigned manually to all the specimens. To do this, select all the specimens or a group of specimens and assign the sample type from the pop-up box at the bottom of the screen.

10.4.4. Worklist execution

After creating the work session and once positioned in the rotor, the session can be executed.



Press the start button to execute the work session and the analyser will start to execute the list.

If the equipment is connected to a LIS system without a work list, press the start button directly and the analyser will read the specimen barcodes, create the work session downloaded from the LIS and start executing it.

 See chapter 17.1 to see the details regarding operation with the LIS



Press this button to stop the worklist, add samples without waiting for the session to end or to correct a session volume alarm, for instance, filling an empty reagent bottle or adding more specimens to the sample rotor. To continue with the work session in progress, press the start button again and the analyser will immediately continue executing the list at the point where it had stopped. If the analyser is connected to an LIS system, when the start button is pressed after the pause, the analyser will read the barcodes and request the LIS for the specimens and add the new preparations to the work session.



NOTE

When it is in the stopped mode it minimises the pause times. In some cases the reaction in progress may be affected by the pause, and in this case a message will appear recommending the user not to pause at that time, but to complete the critical reagent preparations.



Press this button to stop or abort the work session. Once the button has been pressed, the screen shown in Figure 65 will appear.

Select one of the two following options:

- *Stop*: This action stops the work session, ends the preparations in progress until a concentration result is given and does not prepare any more. The next action to be taken is to reset the work session.
- *Abort*: This action aborts the work session. The execution of the list stops immediately and the preparations in progress in the analyser are lost. The next action to be taken is to reset the work session.
- *Cancel*: Closes the window and continues executing the current list.

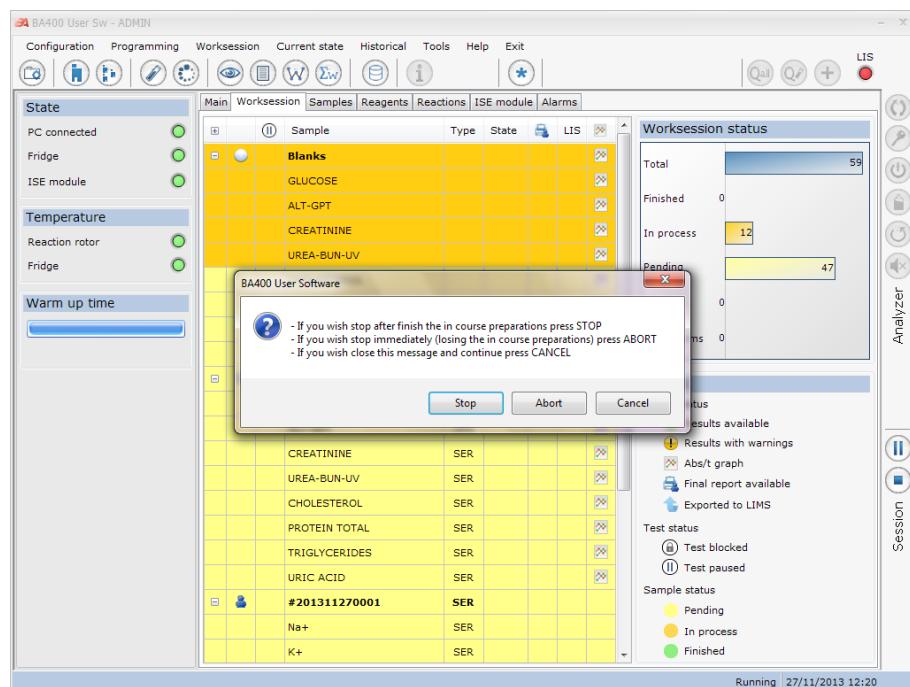


Figure 65 Screen with abort message

10.4.5. Save session

This option allows you to save the session created under a name. This function is used for saving repetitive lists, such as lists of blanks, standards and controls.

If this option is selected, a pop-up window opens. Enter a name for the session and then press the save button.

This action does not memorise the sample or reagent positions in the rotors; it only memorises the session.

10.4.6. Load session

This option allows you to load a previously memorised session. When this option is pressed a pop-window opens. Select the name and press the open button.

10.4.7. Delete session

This option allows you to delete a previously memorised session. When this option is pressed a pop-window opens. Select the name and press the delete icon.

10.4.8. Delete virtual rotors

This option allows you to delete virtual rotors memorised previously in the sample and reagent positioning screen. The virtual rotor is a name used to identify the positions of reagents or samples in a rotor. For the list of names to be displayed, the rotor must have previously been memorised in the positioning screen.

When this option is pressed a pop-window opens. Select the name of the virtual rotor and press the delete button.

10.5. Current status monitor

This allows you to see all the information about the current status of the analyser, the work session, rotors and alarms in graphic form. It enables the status of the session to be observed in real time (samples in progress, completed or with errors, or blocking actions due to the absence of a reagent or sample). It allows you to quickly view the reagent and sample volume alarms and know the current volume of the reagents. It also allows you to access the absorbance curve screen during the reception of the results and the results screen when a test has been completed.

10.5.1. Principal

Screen which informs about the status of the analyser: the analyser elements that are switched on (refrigerator, ISE module), main sensors (covers, temperatures), work session times, graphic information on alarms and information on processes being executed by the analyser.

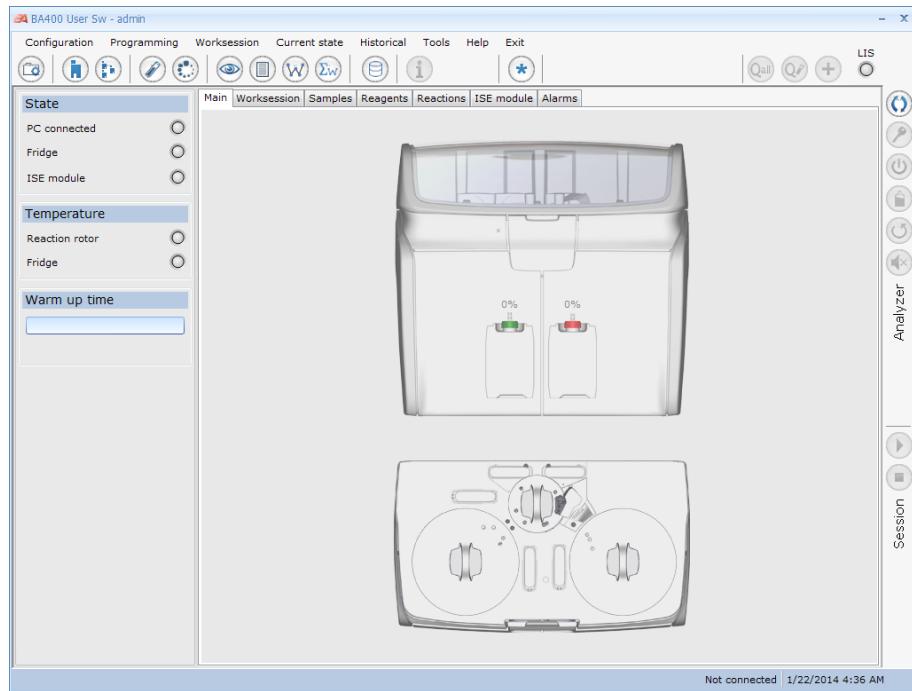


Figure 66 Monitor display

- Status* On and connected indicators:
- The analyser is on and connected to the computer when it is green.
 - The refrigerator is on when it is green.
 - The ISE module is on and correctly initialised when it is green. When it is red, this means it is on but cannot be used due to an initialisation problem. When in grey, it is not installed or off.

Temperature This indicates whether the temperature of the rotor and the refrigerator are within the established limits.

Times Shows information about the different session times.

Time indicators	Description
Total time	Indicates the total time of the session in progress.
Time passed	Indicates the time passed for the session in progress.
Time remaining	Indicates the time remaining before the session ends.
Time for accessing the reagent rotor	Indicates the time remaining for accessing the reagent rotor after pressing the <i>Stop</i> button
<i>WarmingUp</i> time	Indicates the time for ending the <i>Warm-up</i> process. A progress bar appears that remains visible until the thermostating process has ended. All the actions performed with the analyser are deactivated until the thermostating process has finished.

When an alarm is triggered a series of informative bubbles appear on the main screen indicating where the alarm was triggered in the analyser and giving a brief explanation.

 See alarm screen in chapter 10.5.7

10.5.2. Work session status

This tab displays information about the work session being performed by the analyser, the state of the samples and the state of the tests.

The information is organised in a table with all the samples and tests of the session and a graph summarising the state of the preparations.

The work session is ordered so that emergencies are always executed first. Before the patient samples the blanks, standards and controls of the tests assigned to the patients are executed.

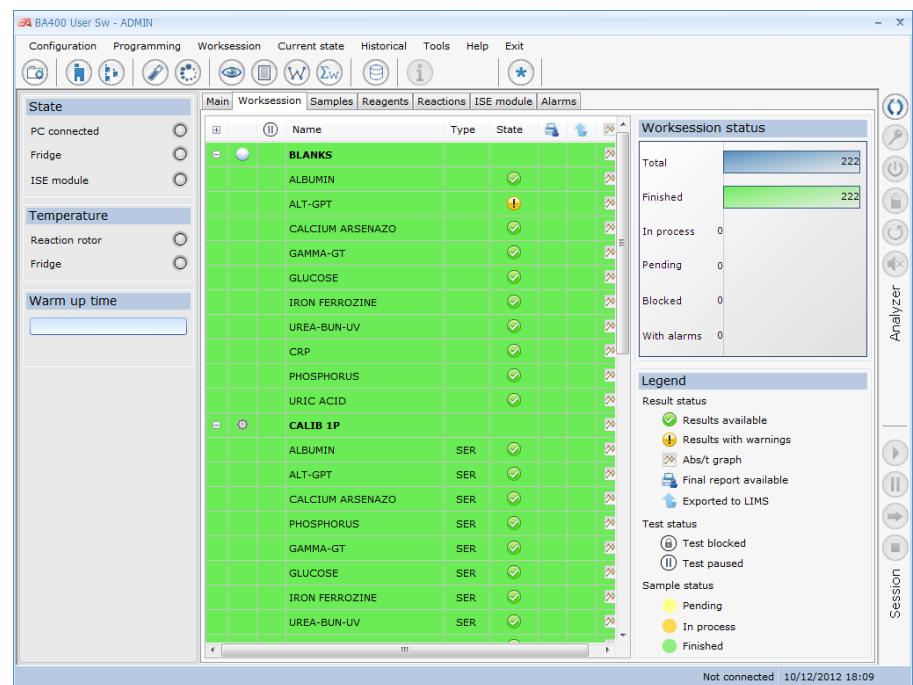


Figure 67 Work session screen

The table shows the state of the samples and tests through a colour code and additional information using icons

Colour code	Description
	State of a test that is pending preparation
	Test in progress of being prepared and read
	Test completed and with results

-  Indicates that the test or patient has been completed correctly.
 -  Indicates that the test or patient has been completed with alarms.
 -  Button for viewing the reaction curve. Viewing may be in real time or after the reaction has ended.
 -  Indicates that the user can print out the final patient report because it has been completed.
 -  Indicates that the results can be sent through the LIS system
 -  Indicates that the test or patient is blocked. This may be due to an alarm indicating the absence of a sample and/or reagent, or problems with the blank or test standard.
 -  If you double-click on the box of a test, this temporarily blocks the test and prevents it from being executed. Double click again on the same test to unblock it. It is only possible to block patient tests or complete patients in which the preparation has not yet been initiated.
- Test status* This graph informs you about the total number of preparations requested and their status: completed, in progress, pending, blocked and completed with alarms.

10.5.3. Sample rotor status

Screen with information on the status of each sample rotor tube. The user can press any tube or well to see the information in detail.

There is a colour code for identifying the status of each well.

Colour code	Name	Description of the sample identification
	Selected	Selection of a rotor position
	Not used	Sample positioned but not assigned in the work session
	Vacuum insufficient	Sample in which the analyser has detected insufficient volume. The program will block the other tests that have not yet been performed on that patient. To release the samples the user must complete it and indicate the sample position in the screen
	Pending or Blocked	Sample pending execution or blocked manually
	In progress	Sample being processed
	Completed	Sample terminated
	Error in code reading	Error in barcode reading

This screen is only for consulting the statuses and cannot be used for making changes in the sample positions or resolving volume alarms. To do this go to the Sample rotor position screen.

 See chapter 10.4.2

10.5.4. Reagent rotor status

Screen with information on the status of each reagent rotor bottle. The user can press any bottle to see the identification information.

There is a colour code for identifying the bottle status.

Colour code	Name	Description of the bottle identification
	Reagents	Reagent bottle and bottle used in the work session
	Additional solutions	Bottles of washing solution, purified water, physiological saline solution, etc
	Vacuum/insufficient	Reagent bottle in which the analyser has detected insufficient volume for making the preparation. The program will block all the subsequent preparations using that reagent. To unblock it the user must change the bottle and indicate this in the reagent position screen
	Insufficient volume	Warning that the volume in the bottle will be soon be used up.
	Not used	Reagent positioned but not used in the work session
	Error in code reading	Error in barcode reading
	Unknown	Bottle positioned but not identified
	Selected	Bottle selected

This screen is only for consulting the statuses and cannot be used for making changes in the reagent position or resolving volume alarms. To do this go to the Reagent rotor position screen.

 See chapter 10.4.2

10.5.5. Reaction rotor status

Screen informing about the status of each of the reaction cuvettes. The user can press any cuvette to see detailed information about its content or the preparation it contains. It also allows the reaction curve to be accessed when the cuvette contains a preparation.

There is a colour code for identifying the status of each cuvette.

Colour code	Name	Description of the identification of the status of the cuvette in the methacrylate rotor
	Washing	Cuvette in the washing status
	Not Used	Cuvette not used. Empty
	R1	R1 dispenser
	R1+sample	R1 dispenser and sample
	R1+sample+R2	R1 dispenser, sample and R2
	Sample dilution	Cuvette with sample dilution
	Completed	Cuvette with reaction completed
	Contaminated	Cuvette contaminated.
	Optical rejection	Cuvette optically rejected.

10.5.6. ISE module status

Screen showing detailed information about the ISE module (if installed in the analyser).

- Dates: Shows the dates of installing the reagent kit, each of the electrodes, the pump calibrations and the last cleaning operation performed.
- Consumption: Shows the estimated consumptions of standards A and B and the number of preparations made for each electrode.

When installing a new reagent kit or electrode, the installation date must be entered, and calculation of consumptions and preparations will automatically be started.

This screen also shows messages about expiry dates and changing recommendations when the electrodes are exhausted or if they have expired (installed for more than 6 months or exceeding the recommended number of preparations).

It also displays warning messages if the calibrations have incorrect results.

The program automatically checks whether there are any warnings or recommendations for changes that make it impossible to obtain correct results. In this case a reminder appears and the user can either continue or solve the problems in the ISE module.

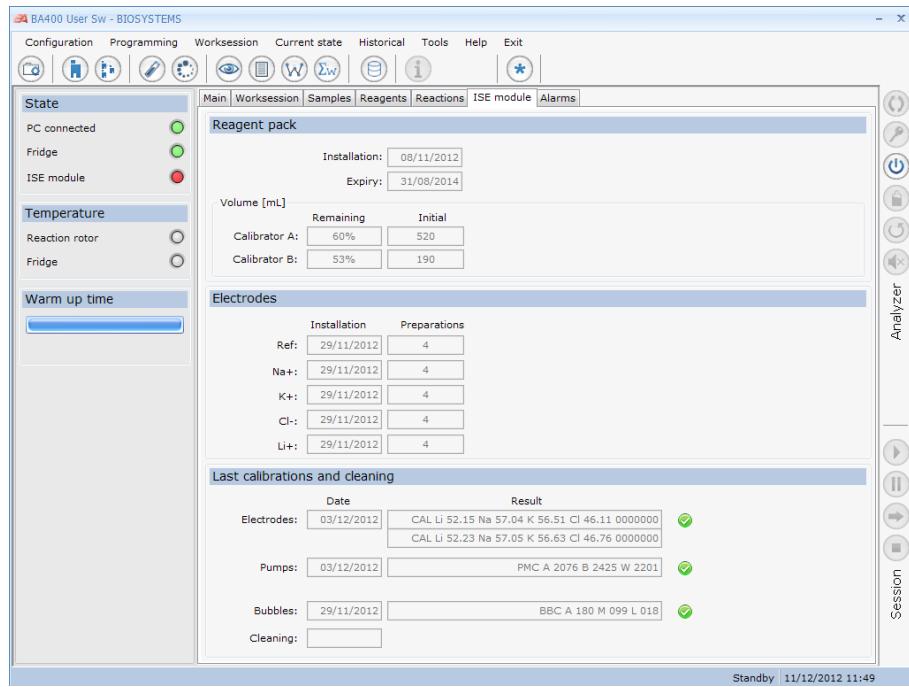


Figure 68 ISE module monitor display

10.5.7. List of alarms

Screen showing a list of all the alarms that appear while the analyser is operating. Each alarm has the following information:

- Type, indicating the severity. Serious alarms can interrupt the analyser operation.

Icons	Description
!	Warning icon. Indicates that an alarm has gone off which requires the intervention of the user. This type of alarm does not interrupt the operation of the analyse
✓	Icon indicating that the alarm has been resolved
✗	Icon indicating a serious alarm. Indicates that a serious alarm has gone off and operation is interrupted. Depending on the type of alarm, for instance, detection of a collision in one of the tips, the user will have to press the analyser recovery button to resolve the alarm.

- Date
- Time
- Alarm name
- Alarm description
- Possible solution

The alarms are ordered by date and time of arrival, but they can be ordered using any other criterion. Press the column header in which you want to order them. If pressed once, they will be ordered in ascending order, and if pressed twice, in descending order.

10.6. Results

Option in the main menu for accessing the results screen for the current session (completed or in progress).

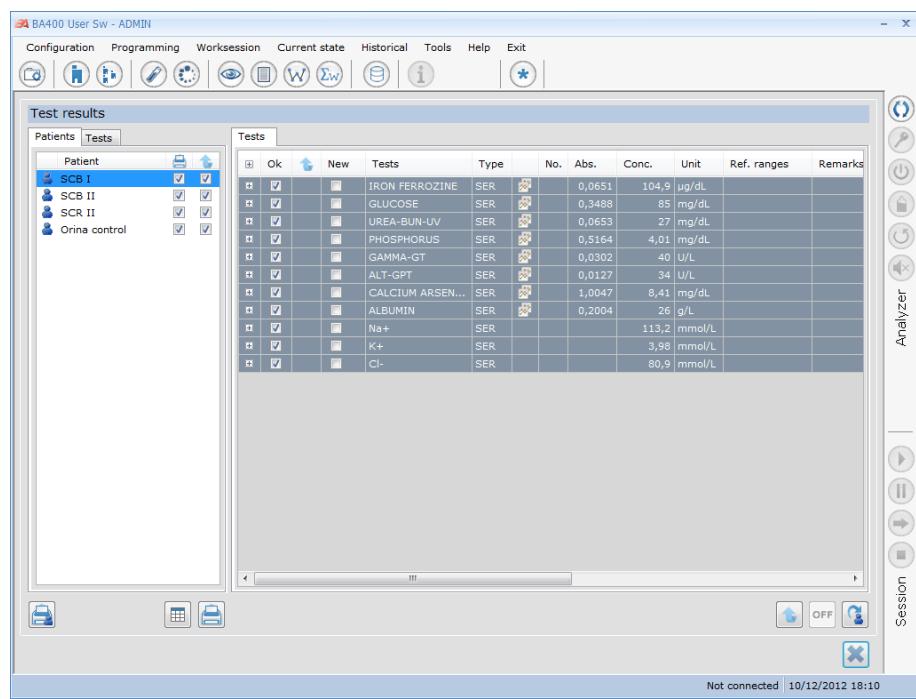


Figure 69 Results screen

On the left is a list of patients and tests performed in the session (separated into two tabs). It allows you to see all the results for each patient or all the results for each test. Select an element from the list to see the results in the tables on the right.

10.6.1. Results by patient

First select the patient tab and a list of all the patients with results will appear below in the left-hand column.

Select a patient and all the information on the result of that patient will be displayed on the right.

Patient tab

Field	Description
 	Buttons allowing you to show or hide the replicates with a result. If you press the header, icon all the patient tests will be shown or hidden. Only one of the two icons appears. Every time you press the icon, one will be changed to the other alternatively.
OK	Indicates that the result has been accepted. It will be sent to the historical file and to LIS. When repetitions are executed the last results is always accepted. If you like, you can accept various results or none.
	This indicates whether it was sent to LIS automatically or manually.
 New	This allows you to repeat a preparation. This option is deactivated if the repetition option has only been selected for LIS in the LIS setup screen.  <i>See the different repetition options in chapter 10.6.4</i>
Test	Test name
Type	Sample type
	This allows you to access the kinetic reaction graph.
Number	Indicates the replicate number, if there is more than one replicate
Absorbance	Absorbance value of the sample obtained.
Concentration	Concentration value calculated in accordance with the calculation method programmed in the test
Units	This shows the units programmed in the test.
Reference ranges	This shows the reference ranges programmed in the test. If there are patient data and demographic ranges, then it automatically selects the ranges based on the patient data.
Remarks	This displays the alarms that could appear in the results.  <i>See the possible alarms in chapter 13</i>
Date	Date on which the result was delivered
Repetition mode	This shows the mode in which the sample was repeated.



Press this icon to print out the final patient reports.



Press this icon to see a summary table of the results. A table appears with the results for all the patients and all the tests of the session in progress.



Press this icon to print out a list of the patient results.



Press this icon to manually send the selected results to a LIS laboratory information system.



Press this icon to enter the external test results. When the button is pressed, an auxiliary screen appears for you to enter the external test values.



Press this icon to send the selected samples for repetition. (I.e., tests with the New field activated)

This option is deactivated if the repetition option has only been selected for LIS in the LIS setup screen.

See the different repetition options in chapter 10.6.4

10.6.2. Results by test

Select the test tab to see the list of tests performed in the session.

Select a test from the list and four tabs will appear on the right with all the results of that test. Select the screen, depending on the information you want to see: blanks, standards, controls and patients.

All the replicates and the resulting mean are shown in the results table.

You can rule out the replicates by pressing on the row you want to eliminate. This will show the replicate that was deleted and recalculate the resulting mean without that replicate. You can reactivate it by pressing the replicate row again.

The blank results table contains the following information:

Blank tab	Field	Description
		Buttons allowing you to show or hide the replicates of a result. Only one of the two icons appears. Every time you press the icon, one will be changed to the other alternatively.
	OK	Indicates that the result has been accepted. It will be sent to the historical file and to LIS. When repetitions are executed the last results is always accepted. If you like, you can accept various results or none.
		This allows you to repeat a preparation. See the different repetition options in chapter 10.6.4
	Test	Test name
		This allows you to access the kinetic reaction graph.
	Number	Indicates the replicate number, if there is more than one replicate
	Absorbance	Blank absorbance value that will intervene in calculating the concentration.

Field	Description
Main filter absorbance	This shows the main filter blank absorbance value. Only shown in tests with bichromatic programming.
Working reagent	This shows the working reagent absorbance value. Only shown in tests with differential programming.
Blank absorbance limit	Blank limit value. This value is programmed in the test. It is used to check that the reagent is in good condition. If the absorbance value exceeds that limit, the program will issue a warning message in remarks.
Remarks	This displays the alarms that could appear in the results.  See the possible alarms in chapter 13
Date	Date on which the result was delivered
Repetition mode	This shows the mode in which the sample was repeated.

The standard results table contains the following information:

Standard tab	Field	Description
		Buttons allowing you to show or hide the replicates of a result. Only one of the two icons appears. Every time you press the icon, one will be changed to the other alternatively.
	OK	Indicates that the result has been accepted. It will be sent to the historical file and to LIS. When repetitions are executed the last results is always accepted. If you like, you can accept various results or none.
	 New	This allows you to repeat a preparation.  See the different repetition options in chapter 10.6.4
	Name	Standard name
	Batch	Standard batch
	Type	Type of sample.
		This allows you to view the kinetic reaction graph.
	Number	Indicates the replicate number, if there is more than one replicate
	Absorbance	Standard absorbance value that will intervene in calculating the factor.
	Theoretic concentration	Standard concentration value. This value comes from the test programming.
	Units	This shows the units in which the test has been programmed.

Field	Description
Factor	Value calculated based on the standard absorbance that will intervene in calculating the concentration.
Factor limits	Factor limit entered in programming the test. If the factor value is off limits, a warning message will appear in the remarks field.
Remarks	This displays the alarms that could appear in the results. ☞ See the possible alarms in chapter 13
Date	Date on which the result was delivered
Repetition mode	This shows the mode in which the sample was repeated.

The controls results table contains the following information:

Control tab	Field	Description
		Buttons allowing you to show or hide the replicates of a result. When the header icon is pressed, all the different controls of the test are shown or hidden. Only one of the two icons appears. Every time you press the icon, one will be changed to the other alternatively.
	OK	Indicates that the result has been accepted. It will be sent to the historical file and to LIS. When repetitions are executed the last results is always accepted. If you like, you can accept various results or none.
		Indicates whether it was sent to LIS automatically or manually.
		This allows you to repeat the result. ☞ See the different repetition options in chapter 10.6.4
	Name	This shows the control name.
	Batch	This shows the control batch
	Type	This shows the type
		This allows you to view the kinetic reaction graph.
	Number	Indicates the replicate number, if there is more than one replicate
	Absorbance	Absorbance value of the control obtained.
	Concentration	Calculated concentration value of the control.
	Units	This shows the units programmed in the test.
	Concentration limits	This shows the maximum and minimum limits for the controls entered in programmings the test.

Field	Description
Remarks	This displays the alarms that could appear in the results. ☞ See the possible alarms in chapter 13
Date	Date on which the result was delivered
Repetition mode	This shows the mode in which the sample was repeated.

When the patient tab is selected the information viewed is detailed in chapter 10.6.1.

10.6.3. Reaction graphs



Press this button to view the reaction kinetics graphs. A screen like the one shown in Figure 70 will appear. A single replicate or all at one time can be viewed. If there is a pause during the work session, the reaction rotor reading system continues reading. Those readings are marked with a triangle in the reaction graph.

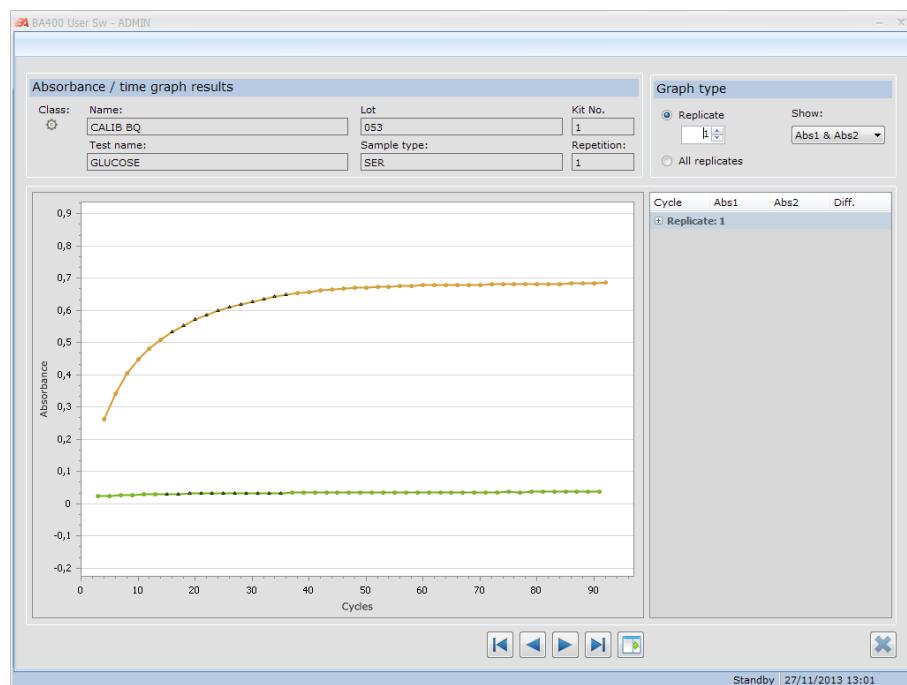


Figure 70 Reaction kinetics graph screen

10.6.4. Result repetitions

The program automatically requests repetitions of all the results off limits if the test has this repetition mode programmed.

The automatic repetition modes are the following:

Type	Repetition criterion
Linearity limit	Repetition with decrease
Detection limit	Repetition with increase
Consumed substrate	Repetition with decrease
Repetition range	Repeat with the same conditions

You can request the repetition of tests manually by selecting the *New* field in the results table.

To do this press the box again and a window will appear like the one shown in Figure 71.

You can select the repetition criterion at that time for the patient samples. The criteria are:

- Repeat with the same conditions
- Repeat with increase. This repetition changes the ratio of volumes between sample and reagent for increasing the sample absorbance. The increase factor is programmed in the test. The resulting concentration is divided by the increase factor. This repetition is used to increase the sensitivity of samples which are at the detection level limit.
- Repeat with decrease. This repetition changes the ratio of volumes between sample and reagent for decreasing the resulting sample absorbance. The decrease factor is programmed in the test. The resulting concentration is multiplied by the decrease factor. This repetition is used for samples that are outside the linearity limits or for samples that are outside the calibration curve.
- Do not repeat.

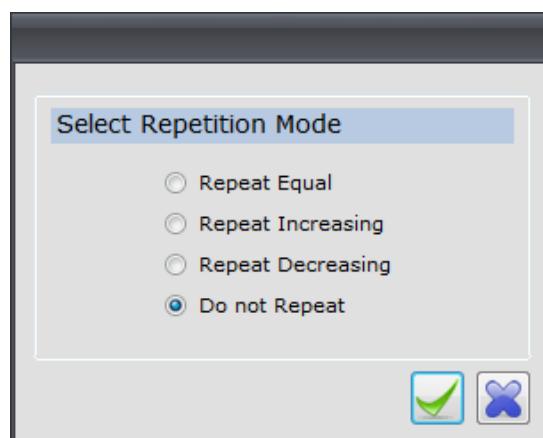


Figure 71 Screen for selecting repetitions

The blanks, standards and controls have these options deactivated, as they are always repeated with the same initial conditions.

Each row of results has an informative icon indicating the type of repetition criterion applied (for both automatic and manual repetitions). The icon also indicates whether the original result gave rise to the repetition request or whether it was a repetition result already received.

Field	Description of the icons in the results
	Indicates whether an increased repetition of a sample has been requested.
	Indicates whether a decreased repetition of a sample has been requested.
	Indicates whether a repetition with the same conditions of a sample has been requested.
	Indicates that the result comes from an increased sample.
	Indicates that the result comes from a decreased sample.
	Indicates that the result comes from a repeated sample.

10.7. Historical logs

10.7.1. Patient results

This screen displays the historical results of the patients.

At the top of the screen there are several fields that permit the entry of selection criteria for restricting the viewing of the results. More than one selection criterion may be selected at one time.



After making the selection, press the icon to execute the search and view the results at the bottom of the screen.

- | | |
|---------------------|--|
| <i>Date range</i> | Enter the start and end date for selecting the results by a date range. |
| <i>Patient</i> | Enter the patient code, name or surname to select the results by patient. All the results for a patient starting with the value entered are displayed. |
| <i>Barcode</i> | Enter a sample barcode to select the results. |
| <i>Urgent</i> | The available options are: <i>All, urgent</i> or <i>normal</i> . |
| <i>Type of test</i> | The available options are: <i>All, standard, calculated, ISE, external</i> |
| <i>Sample type</i> | The available options are: <i>All, SER, URI, PLM, WBL, CSF, SEM, LIQ</i> . |
| <i>Test name</i> | Enter the name of the test to make the selection. |

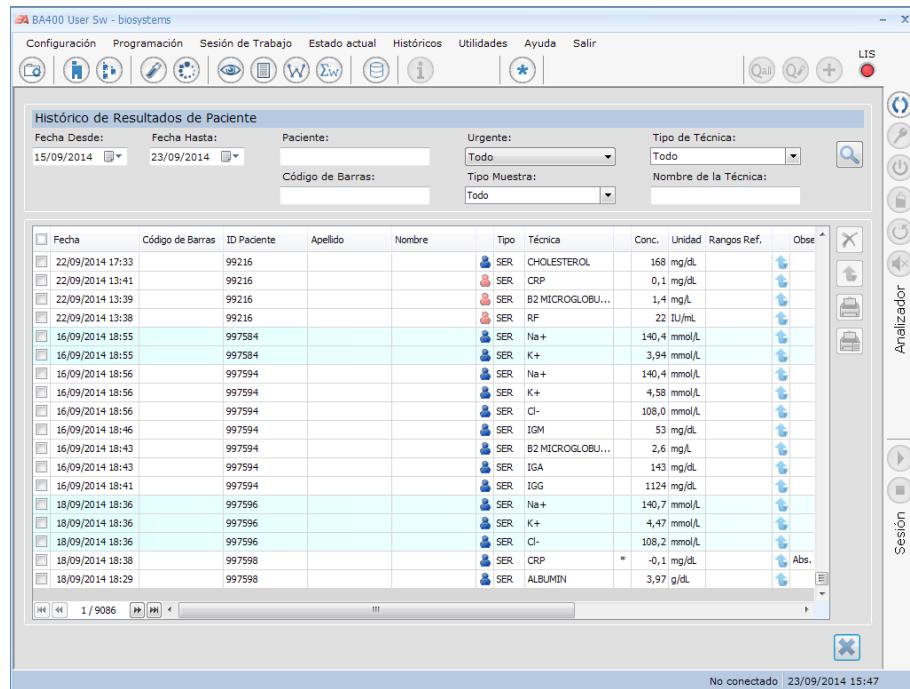


Figure 72 Screen showing historical results for patient

The results are shown in a table, ordered by date. On pressing the heading of a column in the table, the results of that column will be rearranged.

- ▶ Press this icon to display the results of the next page.
- ◀ Press this icon to display the last results.
- ◀ Press this icon to display the results of the previous page.
- ◀ Press this icon to display the first results.
- 🖨 Press this icon to print out the results that were previously selected. If you want to select all the results, press the heading selection box.
- 🖨 Select this icon to print out the results with a compact report, i.e., with no patient header and all the results shown continuously.
- 📤 Press this icon to send the selected results to a LIS laboratory information system. This is a manual export.
- ✖ Press this icon to eliminate the selected results. Once eliminated, they cannot be recovered.

10.7.2. Blank and calibration standard results

Screen for saving the blank and calibration standard results from previous sessions.

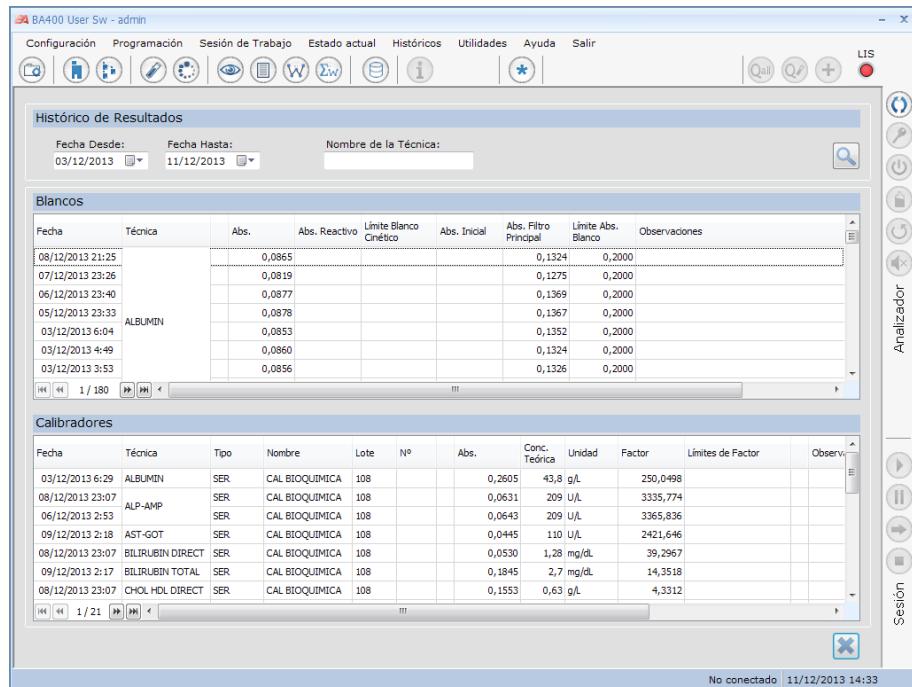


Figure 73 Screen showing historical blank and calibration standard data

At the top of the screen there are several fields that permit the entry of selection criteria for restricting the viewing of the results. More than one selection criterion may be selected at one time.



After making the selection, press the icon to execute the search and view the results at the bottom of the screen.

Date range

Enter the start and end date for selecting the results by a date range.

Test name

Enter the name of the test to make the selection.

The results will be shown in two tables, ordered by date. The first table shows the results of the blanks and the second one shows the results of the calibration standards. On pressing the date or test heading in the table, the results of that column will be rearranged.

The blank and calibration standard fields displayed are the same as the fields shown on the current session results screen, selected by test.

See chapter 10.6.2 for a description of each field in the blank and calibration standard screens.

10.7.3. Quality control results

Screen that allows you to review the current quality control results. It also allows you to change the defined calculation criteria and view the results in graphic format.

The quality control results of the active work session will not be available on the screen until the reset function has been executed.

Up to 50 results can be stored and viewed for each control and test. When resetting the active work session, this condition is verified for each control and test with quality control results in the session and in the event that the maximum has been

exceeded, a screen appear saying that the current results (except those of the work session) will be accumulated. The user can accept the warning and accumulate the results automatically, or temporarily cancel the reset and accumulate the results manually in the Accumulate daily quality control results screen.

 See chapter 10.7.4.1

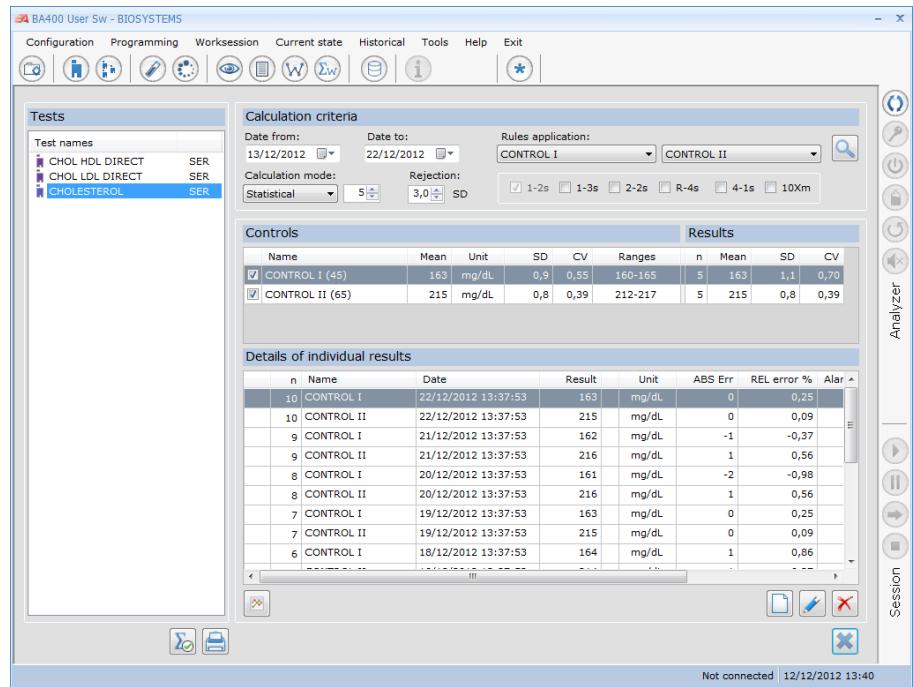


Figure 74 Screen for manual entry of quality control results

On the left is a list of tests with quality control results pending review. In selecting a test from the list, the information about its programmed and active controls is shown on the right of the screen, but only for those with at least one non-reviewed result. There are three clearly defined zones in this list area:

- **Calculation criteria.** This allows you to specify the criteria for selecting and validating the quality control results. When the normal value of any of these criteria is changed, the content of the other two list zones is emptied and you must press the search button to reload them. The values selected will also be updated in the test programme.

Date range Range of dates of the results to be viewed. The date range that is normally given displays all the results that are pending review.

Rejection criterion Number of standard deviations for determining the admissible value interval limits for the results:

$$\text{Range} = \text{Mean} \pm (\text{Rejection criterion} * \text{SD})$$

The programmed rejection criterion for the test is normally returned.

Calculation mode Indicates how to calculate the target values for each test: mean, standard deviation (SD) and coefficient of variation (CV). If the selected calculation mode is *Statistical* the number of the series that will be used for calculating the target values must also be given.

Calculation mode	Calculation method
Manual	The values programmed in the test are used for each control: $\text{Mean} = \frac{\text{Maximum value} + \text{Minimum value}}{2}$ $SD = \frac{\text{Maximum range} - \text{Minimum range}}{2 \cdot \text{Rejection criterion}}$
Statistical	The results of the n first series (n = specified series number) are used: $\text{Mean} = \frac{\sum_{i=1}^n X_i}{n}$ $SD = \sqrt{\frac{\sum_{i=1}^n (x_i - \text{Mean})^2}{n-1}}$ $CV = \frac{SD}{\text{Mean}} \cdot 100$

The programmed rejection criterion for the test is normally returned.

Application of rules

This allows you to select the rules that will apply in validating the results and controls to which they will be applied. The available set of rules are those included in the Westgard algorithm, but they may be applied optionally except in the case of the 1-2s which is always applied.

The rules selected are usually those programmed for the test. If the selected test has results for a single control, the selected rules will be applied to it. However, if the selected test has results for two controls or more, the active rules will be applied to both the selected controls.



Execute the search and validation of results applying the selected calculation criteria.

- **List of controls.** This shows the statistical information for all active controls with results pending review for the selected test. The tick activates/deactivates the viewing of the listed individual results.

The target values for each control are shown in the columns on the left: means, standard deviation (SD), coefficient of variation (CV) and admissible range of values, calculated in accordance with the selected calculation mode and rejection criteria.

The columns on the right (Results area) show the statistical values for each control, calculated based on the available results:

Results parameters	Calculation method
n	Number of results used in the calculation

Results parameters	Calculation method
Mean	Statistical mean of the results. $\text{Mean} = \frac{\sum_{i=1}^n X_i}{n}$
SD	Standard deviation of the results: $SD = \sqrt{\frac{\sum_{i=1}^n (x_i - \text{Mean})^2}{n-1}}$
CV	Coefficient of variation of the results: $CV = \frac{SD}{\text{Mean}} \cdot 100$

If the statistical calculation mode is selected, the results used for calculating the target values are not used in the calculation.

- **Listed individual results.** This shows the individual results for all the controls selected within the specified date range, validated pursuant to the indicated calculation criteria. The information displayed for each result is the following:

Parameter	Description
n	Number of series executed.
Control	Name of the control to which the result belongs
Date	Result date/time.
Result	Result value
Manual result indicator	The result changed icon is shown if: <ul style="list-style-type: none"> • the result value has been changed manually • the result has been entered manually
Unit	Result measuring unit
Absolute error	Difference between the result value and the target mean.
Relative error	Absolute percentage of error divided by the target mean.
Alarms	Alarms generated while the result is being validated. These include: <ul style="list-style-type: none"> • result outside admissible value range • infringing of rules applied. Results with alarms are shown with red lettering

In addition, if the calculation mode is statistical and the results used to calculate the target values are included in the displayed set of results, the X_m symbol is shown to the left of the number of the series executed.



This opens up the auxiliary screen for entering a new series manually, giving the date, time and value of the result for one or more of the available controls.

The added results are shown with the icon changed in the listed individual results table

 *Figure 75 shows the screen for entering new results.*



Opens the auxiliary screen for changing the value of the selected result (only the value, the date cannot be changed) or temporarily exclude it from the calculation and validation processes. An excluded result can be included later.

The Listed individual results table shows the changed results with the respective icon and the excluded results are shown deleted and on a grey background.

 *Figure 76 shows the screen for editing results.*



It allows you to permanently delete the results selected.



Opens the auxiliary screen that shows the results in graphic format. The display type can be selected: Levey-Jennings or Youden. The controls to be graphed can also be selected: between 1 and 3 for Levey-Jennings and between 1 and 2 for Youden.

In the Levey-Jenning graph the Y axis values will depend on the number of controls graphed:

- If only one control is graphed, it will display concentration values and the scale of the standard deviation in multiples.
- If several controls are graphed, it will show the values of the scale, in standard deviation multiples.

 *Figures 76 and 77 show the screens of the Levi-Jenning and Youden graphs respectively.*

Name	Lot number	Date	Hour	Result
CONTROL I	45	23/12/2012	01:37 PM	
CONTROL II	65	23/12/2012	01:37 PM	

Figure 75 Screen for entering quality control results

Test name:	CHOLESTEROL [SER]	Control:	CONTROL I
Lot number:	45	Result:	10
Remarks:			
<input type="checkbox"/> Excluded			

Figure 76 Screen for editing quality control results

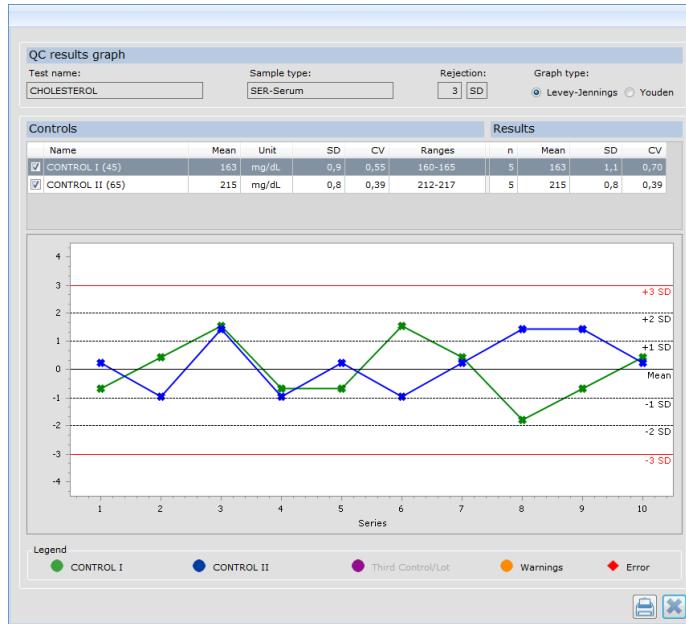


Figure 77 Screen with the Levy-Jennings graph

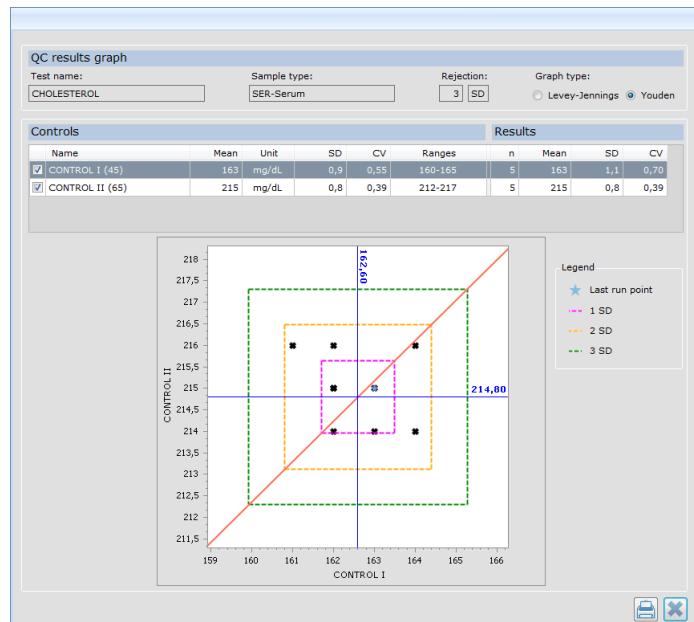


Figure 78 Screen with the Youden graph

The buttons located at the bottom of the screen are always available:

Opens the screen that allows the current quality control results to be accumulated by control and test.

See chapter 10.7.4.1

10.7.4. Accumulated quality control results

10.7.4.1. Accumulated daily quality control results

After a certain period of time during which the user has used the same working conditions, the routine control results can be accumulated with historical results from previous series and they can also be compared with future series.

Up to 50 accumulated results per control and test can be stored, for which reason once result 51 has been stored, accumulated result 1 is automatically eliminated.

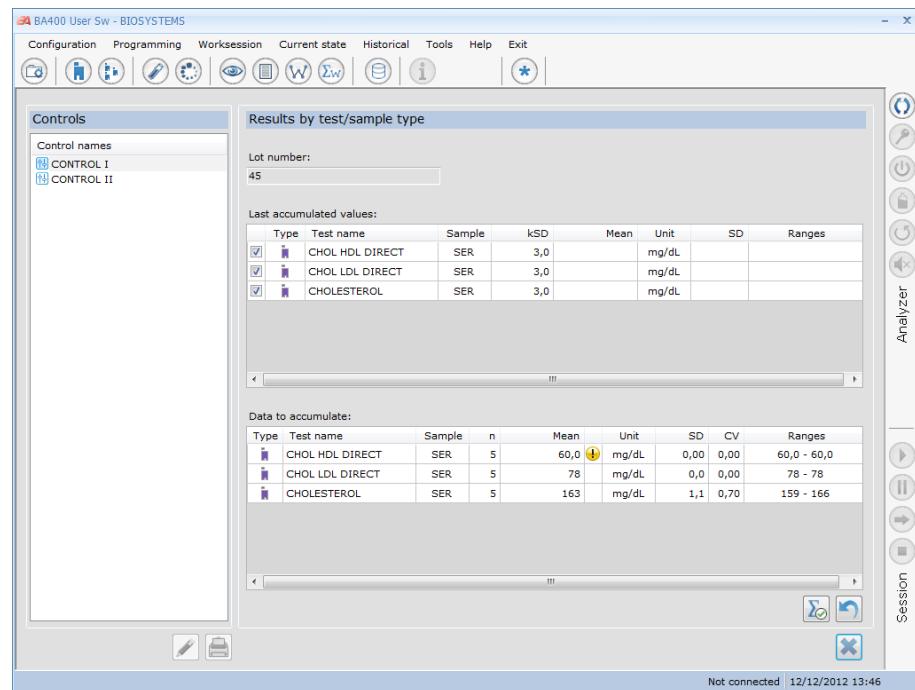


Figure 79 Screen for accumulating daily quality control results.

On the left is a list of controls with results for accumulation. In selecting a control from the list, the number of the active batch will be shown on the right of the screen, along with the list of tests with results that must be accumulated for the control.



Load the information to be accumulated for each test for the selected control. Double-click on a control in the list for this button to function.

The information of the list of tests with result to be accumulated for the control is set out in two tables:

- **Last accumulated values:** this shows the mean, standard deviation (SD) and range of values admitted for the last accumulated item for each test, if accumulated items exist previously for the selected control; otherwise the respective boxes are shown as empty. Use the tick to select/unselect the test for accumulation (the table is loaded/downloaded from Data for accumulation).
- **Data for accumulation:** only for the tests selected in the above table; it shows the calculation of the values that will be accumulated:

Parameter	Calculation method
n	Total number of values to be accumulated
Mean	Statistical mean of the results. $\text{Mean} = \frac{\sum_{i=1}^n X_i}{n}$
SD	Standard deviation of the results: $SD = \sqrt{\frac{\sum_{i=1}^n (x_i - \text{Mean})^2}{n-1}}$
CV	Coefficient of variation of the results: $CV = \frac{SD}{\text{Mean}} \cdot 100$
Ranges	Range of admissible values: $\text{Range} = \text{Mean} \pm (\text{Rejection criterion} \cdot SD)$

If the mode for calculating the test is statistical, the results used for calculating the target values are not included in the set of values to be accumulated.

Double click on a test in this table, open the Quality control results screen which displays a list of the set of results to be accumulated.

 See chapter 10.7.3



Icon indicating that the set of results to be accumulated includes one or more series with validation alarms. This icon is shown to the right of the mean.



Execute the result accumulation process for the control results of the selected tests. If all the tests are accumulated for the selected control, the control is downloaded from the controls list.

10.7.4.2. Accumulated results

Screen that allows you to review the historical log of accumulated results by test and control.

It also allows you to change the target values defined for a test and control, assigning the latest accumulated statistical values to them.

This screen shows the accumulated results. See Figures 79 and 80.

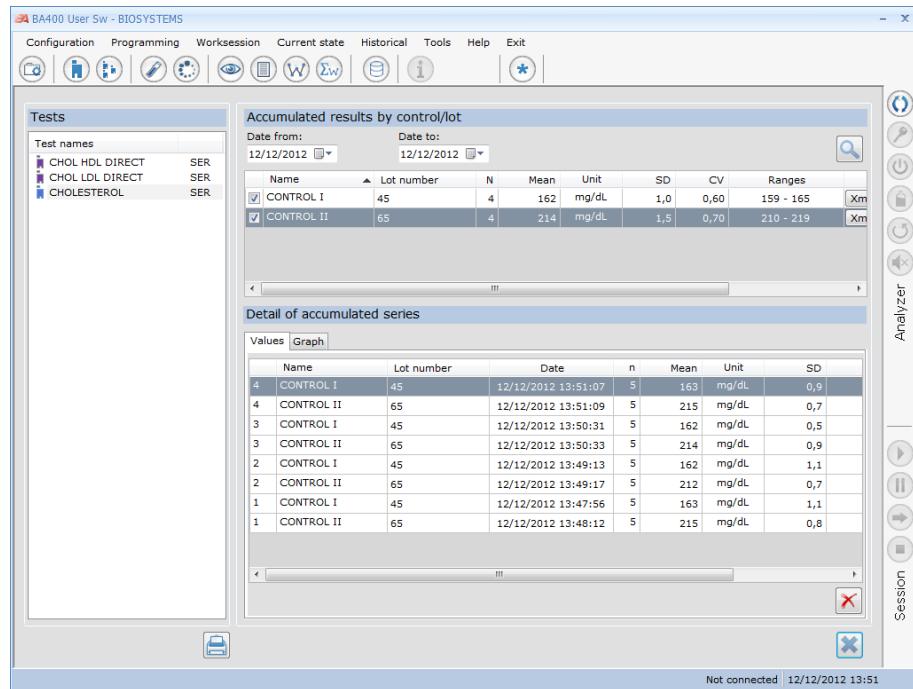


Figure 80 Quality control accumulation screen - Tabular display

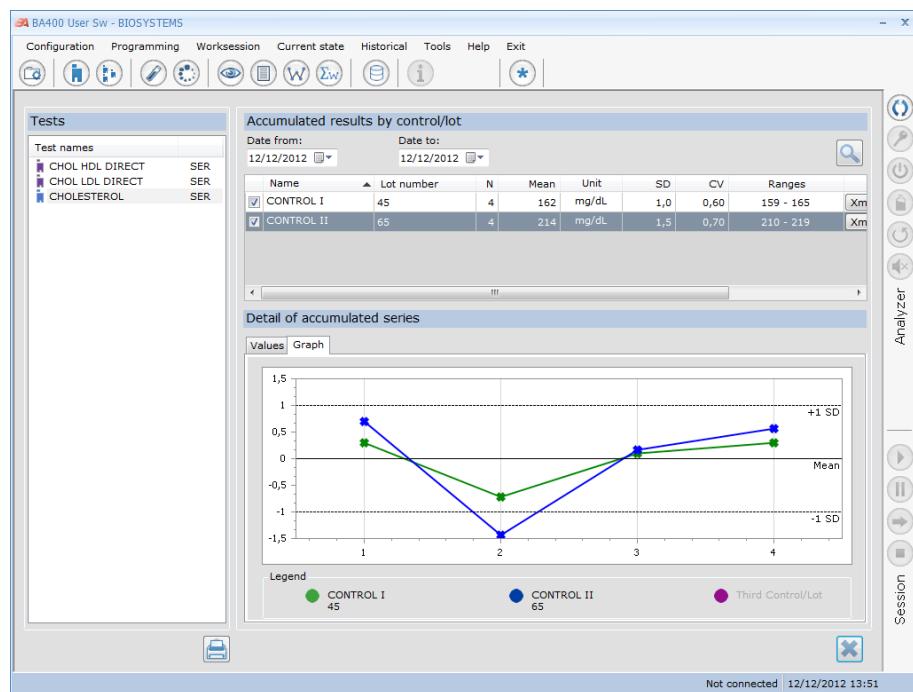


Figure 81 Quality control accumulation screen - Graphic display

On the left is a list of tests with accumulated quality control results. In selecting a test from the list the information of all the controls with accumulated results for the test appears on the right of the screen. There are two clearly defined zones in this list area:

- **Results accumulated by control/batch:** this allows you to specify the date range of the accumulated results to be consulted. In changing the date range,

the content of both list areas is emptied and it is necessary to select the search button to reload them. The information on controls with accumulated series for the test within the specified date range specified is shown in the table, with the following structure:

Parameters	Description
N	Number of accumulated series
Mean	Weighted mean of the accumulated results. Calculation method: $\text{Mean} = \frac{\sum_{i=1}^n \text{Mean}_i \cdot n_i}{\sum_{i=1}^n n_i}$ Mean _i is the mean of each accumulated series and n _i is the number of daily results used to calculate each accumulated series.
Units	Result measuring unit
SD _{obtained}	Standard deviation of the accumulated N series
CV	Coefficient of variation $CV = \frac{SD}{Mean} \cdot 100$
Range	Range of admissible values: $\text{Range} = \text{Mean} \pm (\text{Rejection criterion} \cdot SD)$
Dates	Date range in which the control measures were performed on the accumulated N series

The tick is used to activate/deactivate the accumulated series for the control/batch in the list. A maximum of 3 controls can be selected.

Date range

Range of dates of the accumulated results to be displayed. The date range that is normally given displays all the accumulated results for the selected test.



Execute the search and validation of results applying the selected calculation criteria.



Execute the updating of the target values defined for the test and control/batch selected, assigning the latest accumulated statistical values to them. Functionality only available for an active control batch and for Supervisor level users.

- **List of accumulated series:** only for the controls selected in the previous table; it shows the accumulated series list within the date range selected, in tabular and graphic format. In the tabular display, the information shown for each control is the following:

Parameter	Description
	Number of accumulated series

Parameter	Description
Control	Control name
Batch Number	Control batch number
Date	Date and time when the accumulated series was created
n	Number of individual accumulated results in the series
Mean	Statistical mean of the accumulated results in the series
Unit	Result measuring unit
SD	Standard deviation of the accumulated results in the series
CV	Coefficient of variation of the accumulated results in the series
Range	Range of admissible values for the accumulated results in the series



This allows the selected accumulated series to be permanently eliminated.
Functionality only available for supervisor level users.

When the accumulated series list is shown as a graph, the values of the Y axis will depend on the number of graphed controls:

- If only one control is graphed, it will display concentration values and the scale of the standard deviation in multiples.
- If several controls are graphed, it will show the values of the scale, in standard deviation multiples.

10.7.5. ISE Results

This screen shows the historical ISE electrode calibration standard data and the historical ISE module pump calibration standard data.

Electrodes

Select this tab to see the ISE electrode calibration standard data.

Pumps, bubbles and cleaning cycles

Select this tab to see the historical peristaltic pump calibration standards, bubble detector and cleaning cycles data.

At the top of the screen there are several fields that permit the entry of selection criteria for restricting the viewing of the results. More than one selection criterion may be selected at one time.



After making the selection, press the icon to execute the search and view the results at the bottom of the screen.

Date range

Enter the start and end date for selecting the results by a date range.

Electrodes

This option is only available in the *electrodes* tab. The available options are: Na^+ , K^+ , Cl^- and Li^+

Type

This option is only available in the *Pumps* tab. The available options are: *Pumps, bubbles and cleaning*

The results are shown in a table, ordered by date.



Press this icon to display a graph of the historical ISE electrode calibration standard results. See Figure 83

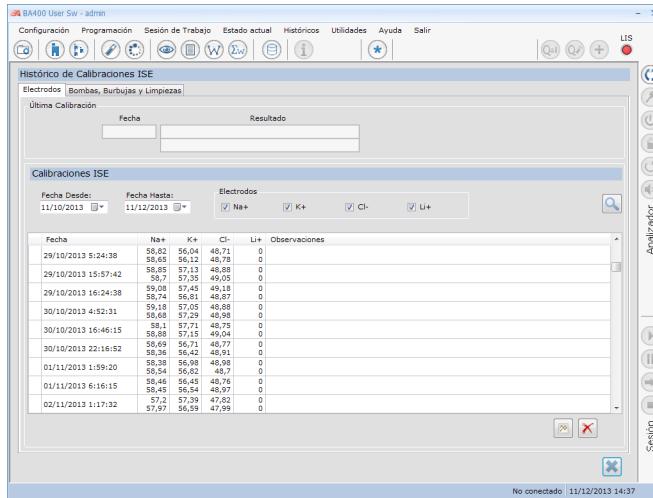


Figure 82 Screen showing historical ISE electrode calibration standard data



Figure 83 Graphic display of the calibration standards

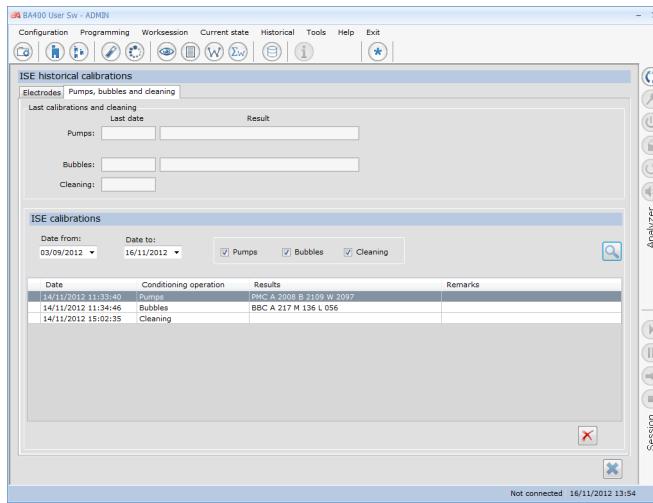


Figure 84 Screen showing the historical pump calibration standard data

10.7.6. Historical analyser alarm data

Screen showing the historical alarm data.

At the top of the screen there are several fields that permit the entry of selection criteria for restricting the viewing of the results. More than one selection criterion may be selected at one time.



After making the selection, press the icon to execute the search and view the results at the bottom of the screen.

Date range

Enter the start and end date for selecting the results by a date range.

Type

The available options are: *All*, *error* and *warnings*.

The results are shown in a table, ordered by date. On pressing the heading of a column in the table, the results of that column will be rearranged.



Press this icon to display the results of the next page.



Press this icon to display the last results.



Press this icon to display the results of the previous page.



Press this icon to display the first results.



Press this icon to eliminate the selected results. Once eliminated, they cannot be recovered.

Histórico de Alarmas					
Fecha	Descripción	Tipo	Nombre	Fecha	Hora
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:31:18
11/11/2013	- Paciente, Q04115388, Técnica: K+				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:31:18
11/11/2013	- Paciente, Q04115388, Técnica: K+				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:31:18
11/11/2013	- Paciente, Q04115388, Técnica: UREA-B-N-UV				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:31:18
11/11/2013	- Paciente, Q04115388, Técnica: CREATININE				
11/11/2013	Tubo muestra vacío			10/12/2013	10:31:18
11/11/2013	- Clase Muestra Paciente, Nombre: Q04115358, Posición: 66				
11/11/2013	Tubo muestra vacío			10/12/2013	10:30:33
11/11/2013	- Clase Muestra Paciente, Nombre: Q0411983, Posición: 65				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:30:33
11/11/2013	- Paciente, Q0411983, Técnica: Na+				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:30:33
11/11/2013	- Paciente, Q0411983, Técnica: K+				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:30:33
11/11/2013	- Paciente, Q0411983, Técnica: GLUCOSE				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:30:33
11/11/2013	- Paciente, Q0411983, Técnica: UREA-B-N-UV				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:30:33
11/11/2013	- Paciente, Q0411983, Técnica: CREATININE				
11/11/2013	Algun replicado bloqueado debido a falta de volumen	Preparación Bloqueada		10/12/2013	10:29:48
11/11/2013	- Paciente, Q0411984, Técnica: Na+				
	Algun replicado bloqueado debido a falta de volumen				

Figure 85 Historical alarm data screen

10.8. Utilities

10.8.1. Rotor change

When you want to change the rotor for preventive maintenance or because a message is displayed indicating that there are too many discarded cuvettes, use the change rotor option in the functions menu. See Figure 86.

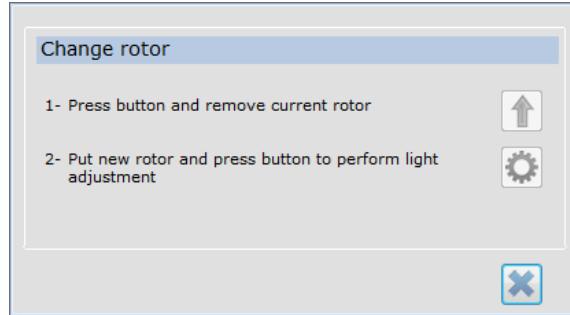


Figure 86 Rotor change

Follow the steps described below to change the rotor:

1. Open the main cover.
2. Press the button to raise the wash station.

3. Remove the reaction rotor lid.
4. Remove the screw that secures the rotor.
5. Take out the rotor and dispose of it.
6. Install a new rotor. Take care when inserting the rotor, it has only one position.
7. Screw the bolt back in place and replace on the reaction rotor lid. Close the main cover.
8. Press the button to tell the program you have changed the rotor and the wash station will be lowered and the light adjustment process will be initiated with the new rotor.


10.8.2. Analyser conditioning

Function for performing a fluidic conditioning operation on the analyser. It primes the fluidic system, among other operations.

Ensure that the rear water and waste inlets are properly connected and that the water inlet selection in the configuration screen is selected in accordance with the physical connection.

If using an external water tank, check that it is filled with water.



Press the button to start the conditioning process. That process takes a few minutes.

10.8.3. ISE module functions

To perform maintenance on the ISE module, go to the functions menu and select the *ISE functions* option.

In this menu, programme the actions for performing maintenance on the ISE module.

The following functions can be executed:

- Calibrate

- Install a reagent kit
- Install the electrodes
- Deactivate the module for a long period of time
- Change the peristaltic pump tubes
- Activate the ISE preparations

For each function several actions must be executed. Select one of the functions and show the set of actions to be executed step by step.

 See the explanation of each step in detail in chapter 14.2.2.



Select an action and press the execute button. Information about the action will appear in the results zone. It will say whether the action was successfully completed (the text is shown in black) or has errors (the text is shown in red). The results are shown in the actions that return information, such as calibrations.

In addition each of the actions is positioned in a group under the name *General*; if the user only wants to perform one of the actions, that user can launch it directly.

Action	Description
Maintenance	Empties the tubes. Only activates the waste pump. In the <i>repetitions</i> parameter indicate how many times the action must be executed.
Bleed A	It performs a priming cycle with standard A, using a volume of 100 µL. In the <i>repetitions</i> parameter indicate how many times the action must be executed.
Bleed B	It performs a priming cycle with standard B, using a volume of 100 µL. In the <i>repetitions</i> parameter indicate how many times the action must be executed.
Priming A	It performs a priming cycle with standard A, using a volume of 300 µL. In the <i>repetitions</i> parameter indicate how many times the action must be executed.
Priming B	It performs a priming cycle with standard B, using a volume of 300 µL. In the <i>repetitions</i> parameter indicate how many times the action must be executed.
Wash	It performs a wash cycle with the ISE washing solution. In the <i>sample rotor pos.</i> parameter indicate the position of the tube with the washing solution. In the <i>volume</i> parameter indicate the volume to be dispensed for washing.
Activate the reagent kit	Execute this action to activate and memorise the reagent kit in the programme. It is also used to memorise the installation date and record the consumption of the calibration standards. The program issues a warning when the standards are no longer usable.

Action	Description
Activation of electrodes	Execute this action to activate and memorise the electrodes in the programme. It is used to record the consumption of the electrodes and warn the user when they are no longer usable.
Activation of ISE preparations	Use this action to tell the program you have installed an ISE module.

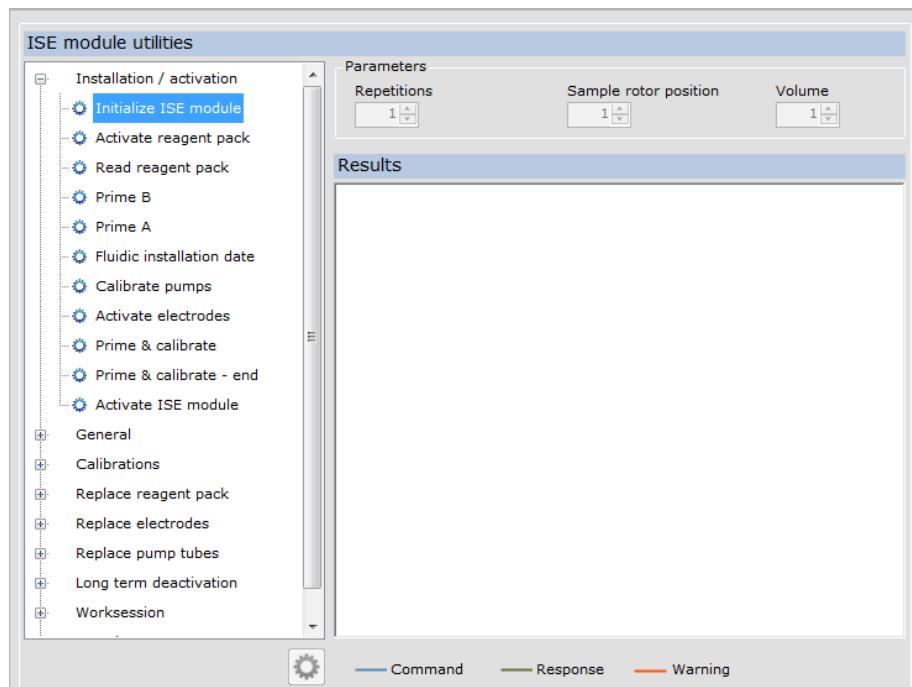


Figure 87 ISE module functions screen

10.8.4. LIS tools

In this screen certain actions can be executed to solve potential problems caused by the malfunction of the LIS program.

Deleting of non-executed LIS orders

Delete orders received from the LIS that have not been executed and are pending.

The LIS program must always send cancellations of orders sent to the BA400 if it eventually decides not to execute them. In the event of a malfunction of the LIS or the communications, the BA400 has this auxiliary tool which allows LIS orders to be eliminated. The elimination of LIS orders in this way is reported to the LIS by sending a cancelled order message; in this way the LIS can record the user and date on which this action was performed.



NOTE

The intensive use of this tool is not recommended. Formally, it must always be the LIS system that distributes orders among the laboratory instruments and reports the cancellations to each instrument.

The reasons why the LIS decides to cancel orders in the BA400 may be the following: the sample tubes do not reach the instrument, instrument alarms exist

which prevent the work from being done and the orders may be sent to another instrument.

This action is only available if the analyser is in the STAND-BY and the LIS communications are activated and free from error.

Deleting of message queue to be uploaded to the LIS

Delete the queue of messages to be uploaded to the central LIS system. If there is a communication problem with the LIS, the messages may accumulate in the queue, waiting for communications to be restored. If the user is no longer interested in sending these messages, they can be deleted using this option.

This action is only available if the analyser is in the STAND-BY mode.

Configuration of message traces

Allows the trace level to be configured for capturing information in the LOG about the operation of communications between the LIS and the BA400. This option is used to diagnose potential communication problems during the integration of LIS with the BA400.

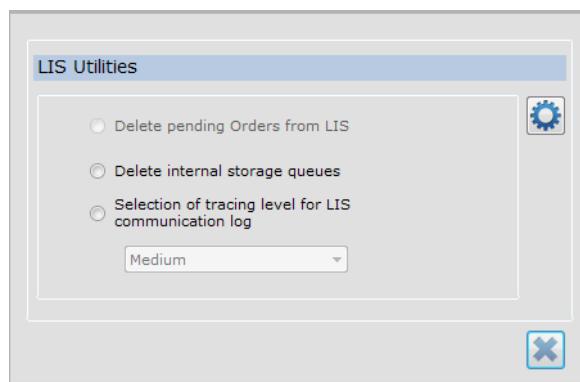


Figure 88 LIS utilities screen

10.8.5. Technical service report

If an unexpected problem arises in a program, this tool is used to help the staff implementing the programme locate the unexpected problem.

This tool generates a file with all the programme information.

If the program suddenly shuts down or performs an undesired action, execute this tool.



This tool is accessed through the *utilities/SAT report* men or or the icon on the horizontal bar. A screen opens up like the one shown in Figure 89.

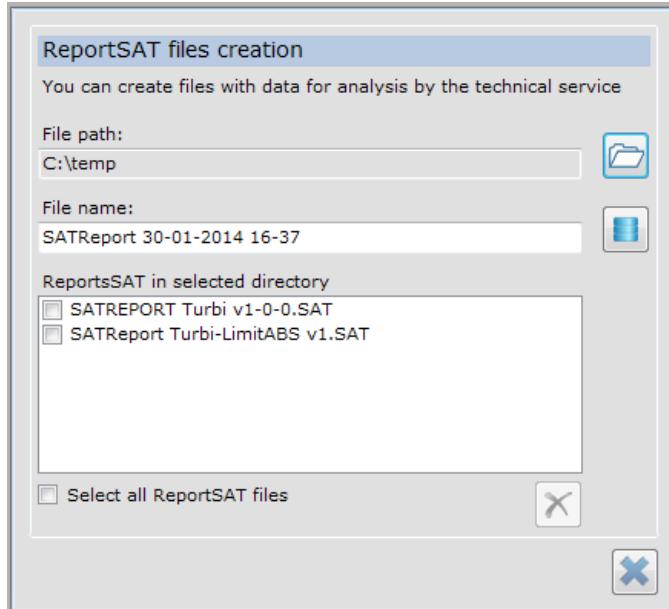


Figure 89 Screen for generating a report for the technical service.



Press the button to give the name and route where the SatReport will be stored. The desktop route usually appears, along with the name SATReport and the date.



Press the button to store the information in the SatReport.

Copy the file and send it to the technical service for analysis.

10.8.6. Create a restoration point with current data

This function is used to create a copy of the whole database. It is used to make backup copies manually.



Press the button to make the copy of the database. The file name generated by default is: RestorePoint [Date], but a different name can be entered.

The folder where that file is stored is:

C:\Program Files\BA400\User Sw\RestorePoints

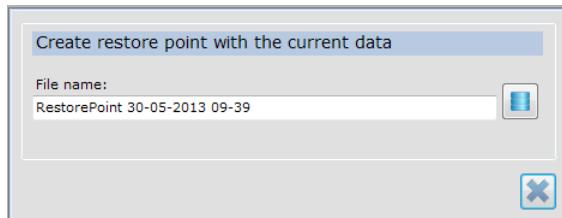


Figure 90 Screen for creating a restoration point

10.8.7. Restore previous data

This function allows you to retrieve the database saved previously at the restoration point. A window appears with all the files created in the previous restoration point. Select one and press accept.

Remember that when you restore a database file, it will replace the current database, meaning that you will lose the data generated since the last time the last restoration point was made.

It is advisable to always create a restoration point just before executing a restoration of previous data.

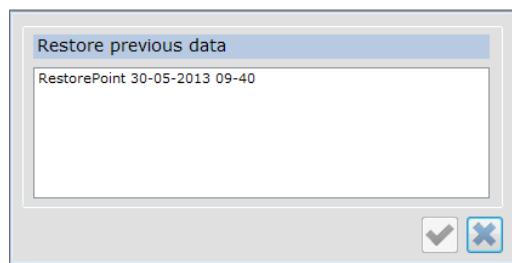


Figure 91 Screen for restoring previous data

10.9. Exit

To exit the program go to the *exit* menu and select one of the two options:

Exit and switch off the analyser

This option closes the program and tells the analyser to switch itself off and complete the closing process.

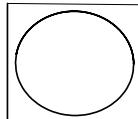
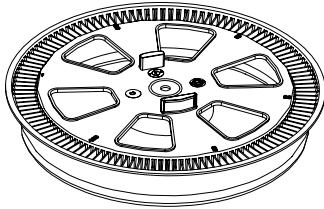
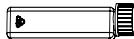
Exit without switching off the analyser

This option will only close the program and leave the analyser on and on standby.

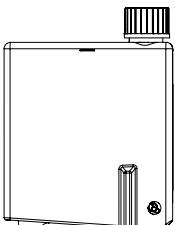
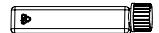
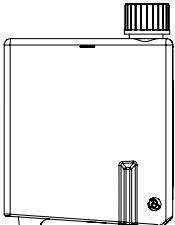
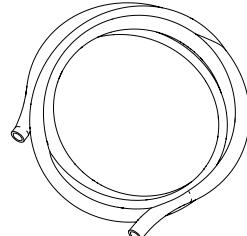
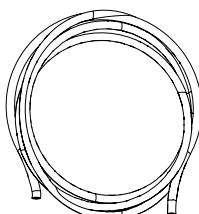
11. List of consumables and accessories

In the event of any of the analyser components being damaged or if any fungible goods are required, always use original BioSystems material.

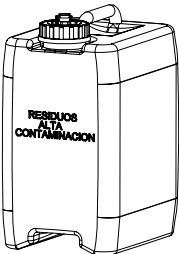
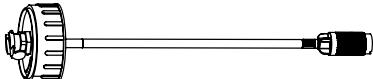
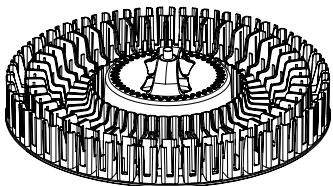
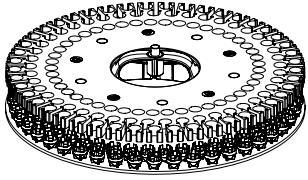
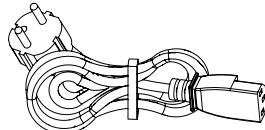
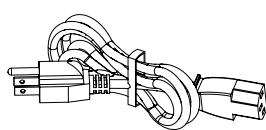
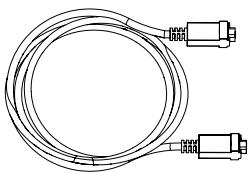
The following table shows a list of the components that might be needed. To purchase them contact your habitual distributor and ask for each element with its respective code.

Accessories list		
Code	Representation	Description
AC16359		DVD with User Program
AC11485		“Reaction Rotor” (10)
AC10770		“Sample wells” (1 000)
AC16434		500 mL bottle of concentrated washing solution
AC17201		Bottle of acid washing solution
AC16360		Open adapter for primary tubes (90)
AC16361		Closed adapter for primary tubes (45)

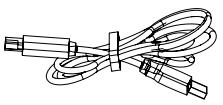
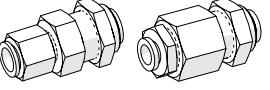
Accessories list

Code	Representation	Description
AC16362		20mL reagent bottles (60)
AC16363		20mL reagent bottles (20)
AC16364		20mL brown reagent bottles (60)
AC16365		20mL brown reagent bottles (20)
AC16366		Purified water bottle connection tubes (3 m), thin tube and thick tube.
AC16367		Connection tube for waste (3 m)
AC16368		Washing solution bottle with cap

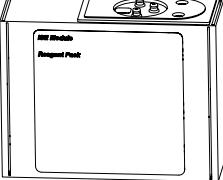
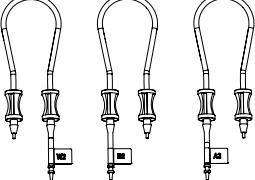
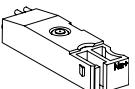
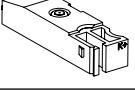
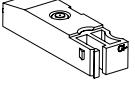
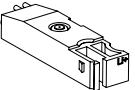
Accessories list

Code	Representation	Description
AC16369		High contamination bottle with cap
AC16748		Washing solution bottle cap
AC16749		High contamination waste bottle cap
AC16370		Reagent rotor
AC16371		Sample rotor
AC11486		Reaction rotor set screw
CA10455		European mains cable
CA10456		American mains cable
FI10466		RS-232 serial channel cable for connection to the computer

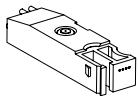
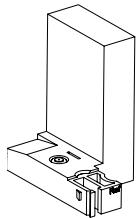
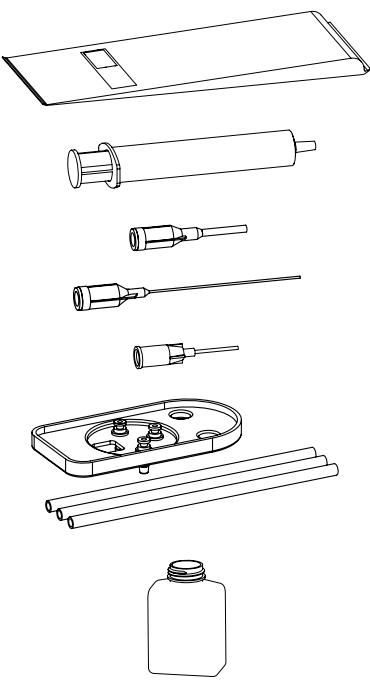
Accessories list

Code	Representation	Description
FI14226		USB USB for connection to the computer
AC16747		10 A (2) fuse
AC17097		150 µm purified water inlet filter assembly
AC16791		Water inlet filter assembly
AC16792		Spare water filter cartridge

List of ISE module accessories (optional)

Code	Representation	Description
5420		+Reagent kit
5625		Set of ISEM module tubes
5201		Na ⁺ electrode
5202		K ⁺ electrode
5207		Cl ⁻ electrode
5205		Li ⁺ electrode

List of ISE module accessories (optional)

Code	Representation	Description
5206		Separator electrode
5204		Reference electrode
5421		ISE module washing solution kit
5412		ISE module urine dilution 125 mL
AC16752	 A collection of cleaning kit components including a tray with a small container, a cylindrical tube, two long thin probes, a small tray with a central circular component, two long thin sticks, and a small bottle.	ISE cleaning kit
AC17096	 A tray containing cotton buds.	Cotton buds

12. Support and warranty

The BA400 analyser is designed to perform biochemical and turbidimetric analyses. Its operation is optimised for the BioSystems Reagents line. For information about all the available measuring procedures please contact your habitual distributor.

12.1. Warranty limits

Any improper use (falls, negligence, electrical mains conditions outside the tolerances, unsuitable environmental or location conditions, etc.) manipulation of the analyser interior by persons not authorised by Biosystems or using non-original consumables and spares (rotors, fuses, etc.) will render the warranty invalid.

12.2. Requests for components and fungible goods

In the event of any of the analyser components being damaged or if any fungible goods are required, always use original BioSystems material. The list of consumables and accessories section includes all the components that may be necessary from time to time. To purchase them contact your habitual distributor and ask for each element with its description and respective code.

12.3. Technical assistance

Contact your habitual distributor for information about:

- training in using the analyser
- After-sales Service Request Protocol
- Updating the User program

You will find more information about the product in the Biosystems website:

<http://www.biosystems.es>

13. List of alarms

Below is a list of errors shown by the program and the resolution thereof by the user:

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
Analyser alarms	Warning that the main cover of the analyser is open	The main cover of the analyser has opened while executing the work list. This action blocks the work list.	Close the cover and press the analyser recovery button. The current work list will be lost.
	Warning that the main cover of the analyser is open	The analyser cover has opened during the stopping phase. The program sends a warning that the main cover of the analyser has opened.	When the warning is active it is impossible to start or continue with the work list. Close the main cover.
	Warning that there is no washing solution	The washing solution bottle is empty. The analyser will complete the preparations already started but not dispense any more preparations.	Replenish the washing solution bottle. Press the bottle change confirmation button. The analyser will continue with the work list in progress.
	Warning that the high contamination bottle is full	The high contamination bottle is full. The analyser will complete the preparations already started but not dispense any more preparations.	Empty the high contamination bottle. Press the bottle change confirmation button. The analyser will continue with the work list in progress.
	Error due to collision of the reagent or sample arm	One of the arms has collided. This will block the arm that has collided. The analyser will try to complete the preparations in progress with the other arms.	Eliminate the cause of the collision and press the recovery button.
	Warning that there is insufficient volume of reagent R1 or R2	The program warns that there is very little reagent R1 or R2.	Insert a fresh bottle of reagent in the rotor before starting the work session.
	Warning that there is insufficient volume of reagent R1 or R2	The R1 or R2 reagent bottle is empty. The program will block the next preparations that require that reagent.	Press the pause button. When the program tells you to, access the reagent rotor and change the empty bottle. Press the continue button.
	Warning that the reagent rotor cover is open	The reagent rotor cover has opened during the stopping phase.	Close the reagent rotor cover.
	Warning that the refrigerator is off	The program warns that the refrigerator has been turned off.	Turn on the refrigerator.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	The purified water tank has been empty too long	The purified water tank has not been filled for a long time. This action blocks the work list.	Check that the water inlet setup is correct. If there is an external tank, check that it is full. Resolve the problem of the absence of water and press the bottle change confirmation button.
	Warning that the reaction rotor cover is open	The reagent rotor cover has opened during the stopping phase.	Close the reagent rotor cover.
	Warning that there is no reaction rotor	You have started a worklist without a reaction rotor.	Insert a new reaction rotor with the rotor change function.
	Error due to the reaction rotor stopping	The wash station has collided. This action stops the work list.	Check the correct positioning of the reaction rotor. Check that the wash station suspension is not blocked. Press the recovery button. If the alarm continues notify the technical service.
	Warning that a clot has been detected	The analyser has detected a blockage in the sample tip.	
		The analyser has a fluidic problem	Check the connections and the water inlet configuration. Check that there is sufficient water in the external tank.
	Warning that there is insufficient sample volume	The sample or standard volume is insufficient. The program blocks the next tests for the current patient.	Press the pause button. When the program tells you to, access the sample rotor and replenish the sample. Press the continue button.
	Warning of insufficient volume in the diluted sample	There is insufficient volume in the rotor cuvette where the sample dilution is prepared. The program blocks the diluted sample in progress.	Press the pause button. Check the sample or diluent volume. Press the continue button.
	Warning that the sample rotor cover is open	The reagent rotor cover has opened during the stopping phase.	Close the sample rotor cover.
	Error in adjusting the baseline	Baseline adjustment values off limits. This action is done with the rotor change.	Change the reaction rotor. Check that the wash stations is operating correctly. If the alarm continues notify the technical service.
	Warning message to change the reaction rotor	Too many reaction rotor cuvettes rejected. This warning does not block the execution of the work list.	Change the reaction rotor.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	Error warning in reading the barcode	There may be moisture on the barcode reading optical window	Clean the barcode reader window with a cloth.
	Erroneous automatic positioning of a sample tube read with the barcode reader	Position of sample tube in the third ring of the sample rotor with the barcode label above the surface when the first and second ring positions are empty.	The barcode label of the tubes positioned in the third ring must not be facing the reader. Always place tubes in the third ring only if the first two rings are occupied.
Warning of a failure in the analyser	Communication error	A problem has occurred with the communications between the computer and the analyser.	Check the communication cable. Press the connect button.
	Alarm saying the reaction rotor temperature is off limits	The reaction rotor temperature has been off limits for too long. This alarm will not stop the work list.	Press the recovery button. If the alarm continues notify the technical service.
	Alarm indicating that the temperature of the R1 or R2 reagent arms is off limits	The R1 or R2 reagent arm temperature has been off limits for too long. This alarm will not stop the work list.	Press the recovery button. If the alarm continues notify the technical service.
	Alarm saying the refrigerator temperature is off limits	The refrigerator temperature has been off limits for too long. This alarm will not stop the work list.	Close the reagent rotor cover. Press the recovery button. If the alarm continues notify the technical service.
	Alarm saying the wash station temperature is off limits	The washstation temperature has has been off limits for too long. This alarm will not stop the work list.	Press the recovery button. If the alarm continues notify the technical service.
	Refrigerator fans damaged	The refrigerator fans are not operating correctly.	Notify the technical service.
	The reaction rotor fans are damaged	The reaction rotor fans are not functioning properly.	Notify the technical service.
	Error in detecting the start of a motor	The motor start detection device has failed	Press the recovery button. If the alarm continues notify the technical service.
	Reinitiating an electronic board	An internal electronic board has been reinitiated	Press the recovery button. If the alarm continues notify the technical service.
ISE module alarms	ISE module status warning	ISE module installed but off	Switch on the ISE module
	ISE module status alarm	ISE module damaged	Call the technical service.
		Module off for a long period	Reactivate the module

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
Electrode alarm	Electrode not installed	Install a new electrode.	
	Electrode not correctly positioned	Check the electrode position	
	Waste pump not correctly positioned	Check the position of the peristaltic waste pump tubes	
Reagent kit alarm	Reagent kit not installed	Install the reagent kit	
	Reagent kit connector not correctly positioned	Check the reagent kit connector.	
Warning that the reagent kit has expired	The reagent kit has expired	Change the reagent kit	
	Standard A or B has been used up.	Change the reagent kit	
Warning that an electrode has expired	One of the electrodes has expired	Change the expired electrode.	
	The number of uses necessary for the correct operation of an electrode has been exceeded	Change the electrode.	
Error in dispensing the sample	Insufficient sample in the ISE module reader or air bubbles detected	Check the sample volume and repeat the sample.	
Slope value under the established limit	Non-alignment of the electrodes	Remove the electrodes. Inspect the toric joint (O-ring) Reinstall the electrodes.	
	The calibration solutions have been used up	Replace the reagent kit	
Shunt from an electrode	End of the electrode's useful life	Replace the electrodes	
	Air bubbles in the reference electrode	Remove the electrode. Tap it several times to eliminate the air bubbles. Reinstall the electrode. Recalibrate	
Air in the sample and/or standard	This may occur if the electrode is new or standard A has just been installed. If the electrode is new, it may shunt initially while rehydrating for 15 minutes.	Bleed standard A and recalibrate	
	End of the electrode's useful life	Replace the electrode	
Insufficient sample volume.	Insufficient sample volume.	Check that there is sufficient sample volume.	
		Check that the tip is not partly blocked.	

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
		Loss of fluid	Determine the leak. Call the technical service.
		Sample not in position	Electrodes not correctly sealed. Remove the electrodes. Inspect the O-ring and reinstall. Change the peristaltic pump tubes.
		Pump tubes blocked	Change the peristaltic pump tubes
		Sample intake cup dirty	Clean the cup with a cotton swab and purified water.
		Fibrin or remains of salts are blocking the electrode flow path	Apply the cleaning procedure Remove the electrodes and clean or change them. Reinstall the electrodes and recalibrate
		Air bubble detector damaged	Notify the technical service
		The waste pump is not working	Notify the technical service
Results screen alarms	Contamination determined in the protein in serum sample on the protein in urine	Very high concentration level in serum compared to urine.	Separate the serum and urine samples to ensure they are not processed consecutively.
	Principal Abs > Blank Abs limit	This message will appear for tests programmed as ascending bichromatic endpoint tests. This result indicates the status of the reagent.	Check the reagent status, it may be damaged: this may be due to the reagent expiry date being exceeded or to poor conservation of the reagent.
	Working Reagent Abs > Blank Abs Limit	This message will appear for tests programmed as ascending differential tests. This result indicates the status of the reagent.	Check the reagent status, it may be damaged: this may be due to the reagent expiry date being exceeded or to poor conservation of the reagent.
	Initial Blank Abs > Blank Abs Limit	This message will appear for tests programmed as kinetic or fixed ascending time tests. The initial blank Abs value is not used to calculate the concentration. This result indicates the status of the reagent.	Check the reagent status, it may be damaged: this may be due to the reagent expiry date being exceeded or to poor conservation of the reagent.
	Principal Abs > Blank Abs limit	This message will appear for tests programmed as descending endpoint tests. This result indicates the status of the reagent.	Check the reagent status, it may be damaged: this may be due to the reagent expiry date being exceeded or to poor conservation of the reagent.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	Working Reagent Abs > Blank Abs Limit	This message will appear for tests programmed as descending differential tests. This result indicates the status of the reagent.	Check the reagent status, it may be damaged: this may be due to the reagent expiry date being exceeded or to poor conservation of the reagent.
	Initial Blank Abs > Blank Abs Limit	This message will appear for tests programmed as kinetic or descending fixed time tests. The initial blank Abs value is not used to calculate the concentration. This result indicates the status of the reagent.	Check the reagent status, it may be damaged: this may be due to the reagent expiry date being exceeded or to poor conservation of the reagent.
	Kinetic blank > Kinetic blank limit	This message will appear for tests programmed as kinetic and fixed time tests. For descending reactions calculation of the kinetic blank will be converted into positive, to correctly compare it with the limit. It is used to check that the blank is correctly executed.	Repeat the blank.
	Incorrect curve	For an ascending calibration curve: all the absorbance points must be in ascending order as the concentration increases For a descending calibration curve: all the absorbance points must be in descending order as the concentration increases	Repeat the different calibration curve points.
	Factor calculated off limits	The factor value is outside the limits entered in programming the test	Repeat the calibration.
	Calibration factor NOT calculated	The standard absorbance is lower than the blank absorbance. It was not possible to calculate the standard absorbance. It was not possible to calculate the blank absorbance. The standard absorbance has exceeded the photometric limit >3.5	Repeat the calibration.
	CONC outside the normal range	The concentration value was outside the normal range defined in programming the test.	Repeat the test to ensure the sample is pathological.
	CONC <0	The sample absorbance is lower than the blank absorbance.	Repeat the test. If the blank value is memorised, repeat the blank.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	CONC > linearity limit	The concentration value has exceeded the linearity limit.	Repeat the test diluting the sample. The process can be automated. Activate in programming the automatic postdilution and enter a value for the linearity limit.
	CONC < detection limit	The concentration value is lower than the detection limit.	Repeat the test increasing the sample concentration. The process can be automated. Activate in programming the automatic postdilution and enter a value for the detection limit.
	CONC outside the calibration curve	Extrapolated result, the concentration Abs is outside the calibration curve.	Repeat diluting the sample.
	Conc NOT calculated	<p>It was not possible to calculate the blank absorbance.</p> <p>It was not possible to calculate the sample absorbance.</p> <p>It was not possible to calculate the factor.</p> <p>Calibration curve incorrect.</p>	Repeat the test for the sample, blank or standard, depending on the problem.
	Sample substrate consumed	<p>This message will appear for tests programmed as kinetic.</p> <p>If the message appears this means that the substrate was consumed before the reaction started. This happens in samples with very high concentrations.</p>	Repeat the test diluting the sample. The process can be automated. Activate in programming the automatic postdilution and enter a value in the consumed substrate field.
	Sample possibly affected by prozone	<p>This message will appear for tests programmed as turbidimetric.</p> <p>If the message appears it means that the sample concentration may have the prozone effect.</p>	Repeat the test diluting the sample.

14. Maintenance and cleaning

14.1. Maintenance activities and frequency

The following table shows the maintenance activities and the frequency with which they should be executed.

Activities at the start of the day	
1	Replenish the washing solution bottle
2	Start up the analyser. Perform the warm-up with the programme
3	Execute 2 conditioning cycles
4	Check the temperature of the reaction rotor and the reagent rotor
5	Check the reagent volume
6	Calibrate the ISE module peristaltic pumps
7	Calibrate the ISE electrodes

Activities at the end of the day	
1	Wash the ISE module channel with the washing solution
2	Switch off the analyser by executing the Shut-down with the programme
3	Empty the high contamination bottle
4	Remove the calibration solutions, controls and samples from the sample rotor

Activities to be executed every week	
1	Change the reaction rotor
2	Clean the working surface
3	Clean the interior of the reagent rotor vessel
4	Clean the interior of the sample rotor vessel
5	Clean the stirrer paddles with a cloth soaked in washing solution
6	Check the capacity of the ISE module reagent pack and replace it, if used up
7	Rinse the ISE module waste tubes with distilled water
8	Calibrate the ISE module air bubble detector
9	Clean the ISE module inlet cup with a cotton bud

14.2. Cleaning the analyser

14.2.1. General cleaning of compartments

Use a damp cloth and neutral soap to clean the analyser surfaces and the internal compartments of the rotors.

14.2.2. Emptying and cleaning the high contamination waste bottle

The high contamination waste container is supplied with a fast connector fitting.

1. Press the fast connecting fitting on the cap and take the container out of the analyser.
2. Unscrew the container cap.
3. Empty the container.
4. Screw on the container cap, insert the tube with the fast connector and place in the container in its housing inside the analyser.



NOTE

Make sure that the fast connector fitting is properly inserted into the container cap. To do this, when inserting the fitting, you should hear a “click”. If not, this means it has not been properly inserted.

Dispose of the waste in accordance with the applicable national or local government legislation governing the disposal of dangerous biological waste.



BIOHAZARD

Handle the high contamination waste container with care. Wear gloves and protective clothing when handling the container.

14.2.3. Cleaning the sample and reagent rotor

In the event of spills inside the rotor housing when handling the samples or reagents proceed as follows:

1. Turn off the analyser.
2. Wear gloves and protective clothing when cleaning spills.
3. Remove the sample or reagent rotor, depending on the type.
4. Mop up the spilled substance with a damp cloth.



BIOHAZARD

14.2.4. Removing of condensation water from the reagent rotor

As the reagent rotor is always connected and refrigerated, condensation may form on it. There are drainage holes to empty the water resulting from excess condensation. In the event of detecting that the reagents are not refrigerated sufficiently, mop up all excess condensation with a cloth.

14.2.5. Cleaning the barcode reader window

If the program reports a high number of errors in reading the barcodes, check the status of the barcode reading window.

1. Turn off the analyser.
2. Remove the two covers from the reagent and sample rotors.
3. Remove both the reagent and the sample rotors.
4. Wipe both windows inside the rotor housing with a damp cloth.

14.2.6. Filling the washing solution bottle

1. Unscrew the cap of the washing solution bottle
2. Fill it with 5 L of purified water.
3. Add 25 mL of the concentrated washing solution (code AC13 434). Take care in handling the concentration washing solution bottle, to prevent the contents from splashing or spilling. Wear gloves and protective clothing when handling it.
4. Screw on the cap with the tube and place it in its housing inside the analyser. Plug the fast connector into the cap and ensure it clicks into place.
5. Press the washing solution filling button that tells the analyser to prime the system.



14.2.7. Cleaning the stirrer paddles

1. Turn off the analyser by operating the switch.
2. Raise the 2 stirrer arms manually.
3. Clean the stirrer paddles with a cloth soaked in washing solution.
4. Rinse the stirrers with a cloth dampened with distilled water.
5. Lower the stirrers to their rest position.
6. Switch on the analyser and perform 2 conditioning cycles in the functions menu.

14.2.8. Cleaning the ISE module

Washing the ISE module channel The ISE module fluid transport system must be cleaned at the end of the day or after processing 50 samples.

1. With the user program in the ISE functions menu, perform 1 wash cycle.
2. Position a sample tube with at least 300 µL of washing solution (5421) in the sample rotor. Do not use any other cleaning agent such as tensoactive agents, emulsions or buffers, as they could damage the electrodes.
3. Indicate in the programme the rotor position in which you have placed the tube. Execute the instruction. The analyser will automatically dispense 300 µL into the module cup for performing the cleaning operation.

4. After completing the activity store the cleaning agent in the refrigerator.

Cleaning of sample intake

Once a month use a long cotton swab and purified water (in the accessory box there is a bag with cotton swabs). Place the swab at the module entrance and use it to rub the exterior and interior of the intake cup. To see the cup intake, remove the plastic part located at the base of the sample arm.

☞ See Figure 92

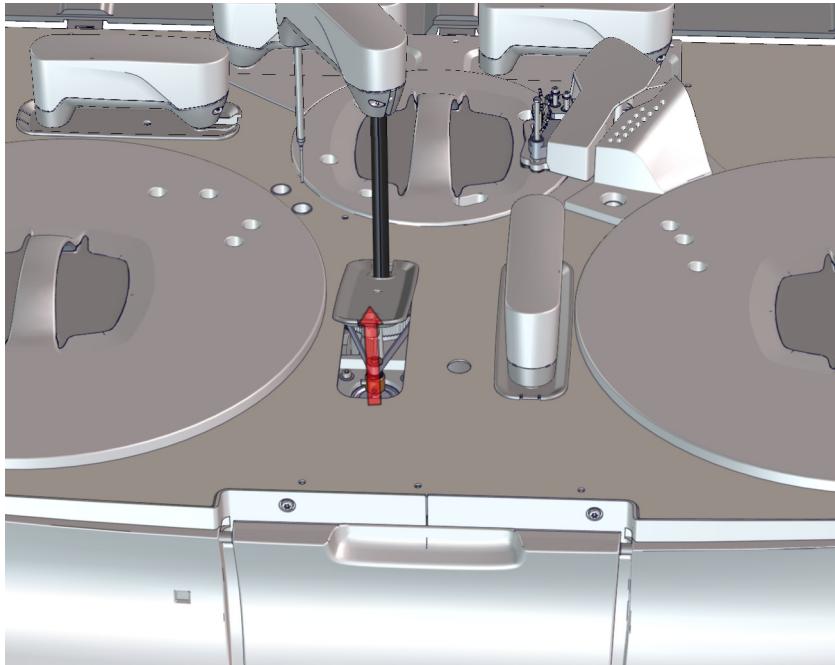


Figure 92 Access to the ISE cup

Cleaning the ISE module tubes

To prevent blockages of the ISE module waste tube due to poorly coagulating samples, proceed as follows to clean the waste tube:

1. Remove the ISE module waste tube from the peristaltic pump housing.
2. Separate the yellow L-shaped part from the bottom part of the module.
3. Use commercial bleach. Check that it has a sodium hypochlorite concentration of between 5 % and 6%.
4. Fill a syringe with 5 mL of bleach and connect it to the L-shaped connector that was previously removed.
5. Slowly inject the syringe to fill the waste tube with the bleach. Let the bleach act inside the tube for 6 minutes.
6. Remove the syringe from the L-shaped connector and fill it with distilled water.
7. Reinsert the syringe into the L-shaped connector and rinse out the waste circuit.
8. Remove the syringe from the L-shaped connector and plug the L-shaped connector into the module.
9. Replace the waste tube in the peristaltic pump.
10. Execute a couple of priming operations in CAL A.

14.3. Maintenance

14.3.1. Changing the reaction rotor

The analyser automatically makes an optical reading before using each rotor cuvette, to determine its state. If the reading exceeds certain levels, the cuvette is discarded and not used. The program informs about the cuvettes that have been discarded. If the number of cuvettes discarded is very high, it is advisable to change the reaction rotor.



NOTE

It is also advisable to change the reaction rotor every week.

Steps for changing the rotor

1. Go to the functions menu and execute the *change rotor* option. Press the button for raising the wash station in order to remove the rotor cover.
2. Remove the reaction rotor cover. Take care not to touch the tips of the wash station with the cover.
3. Remove the central screw that secures the rotor.
4. Take out the rotor. Handle it with gloves and protective clothing.
5. Treat the rotor as biological waste.
6. Take a new rotor from the accessory box.
7. Insert the rotor in its housing.
8. Tighten the screw as far as it will go.
9. Replace the reaction rotor cover.
10. Press the finalise button in the *change rotor* option of the user program.

14.3.2. ISE module maintenance

14.3.2.1. Changing the electrodes

Reference electrode

The reference electrode is submerged in saturated KCL solution. If the concentration of the reference electrode falls below 3.0 M (molar), the ISE measuring module may give erroneous results. The reference electrode tanks has a small red ball which normally floats on top of the filling solution. If the ball starts to sink the reference electrode must be replaced.

Unpack the reference electrode. Remove the wire that has a yellow label (keep the wise in case you need to turn off the module and store the electrode for a long time). Ensure that there are no accumulated salts at the ends of the measuring channel.

Other electrodes

Unpack the new electrode. Remove the adhesive tape that protects the fluid transportation channel. Check that the rubber seal in the opening is in place. If there is no rubber seal, put it back in its position. Each box of spares has pair of seals, in case one is lost.

Proceed as follows to replace the electrode (both the reference and the other electrodes)

1. With the user program in the *ISE functions* section, perform 1 *Maintenance* cycle to empty the ISE module channel.
2. Turn off the ISE module power supply.
3. Open the doors and remove the front cover of the ISE module.
4. Press the yellow button down to release the pressure in the electrodes.
5. Remove all the electrodes.
6. Discard the electrode that must be changed.
7. To put the electrodes back in position, press the yellow button down and first insert the reference electrode and then the other electrodes, in the order shown in Figure 93.
8. If there is no Li⁺ electrode, put an empty electrode in its place, to ensure continuity in the channel through which the sample flows.
9. Release the yellow button to supply pressure to all the electrodes and ensure good fluid communication.
10. To ensure that the electrodes are properly placed, press them at the front until you hear a click or they have been correctly seated.
11. Turn on the ISE module power supply.
12. Put the front cover back in position and close the doors.
13. With the user program, execute the actions in the number and order indicated in the *ISE functions, change electrodes* section.

Step	Action	Repetitions	Description
1	Priming B	1	
2	Priming A	1	If an error is shown on the results screen, perform the first two actions again. If the problem persists, check that the electrodes are properly positioned and have been correctly inserted. If necessary, take them out and put them in again. Remember that the procedure for removing them and reinserting them must be carried out with the ISE module power supply off.
3	Calibrate the pumps	1	
4	Activate the electrodes	1	Indicate the installation date. If none of the electrodes has been replaced register the old electrode again with the original installation date
5	Prime B	1	
6	Prime A	1	

Step	Action	Repetitions	Description
7	Calibrate the electrodes	1	
8	Wait 5 minutes		

Perform the last 4 actions 3 times. If the calibration is not satisfactory, wait 5 minutes and repeat the last 4 actions.

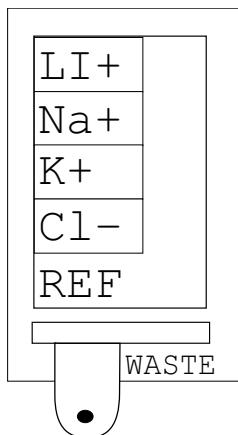


Figure 93 Order for positioning the different electrodes

14.3.2.2. Changing the reagent kit

Open the front doors and you will see the ISE module reagent kit on the left. Remove it from its housing and take the connector out of the packet. Press the yellow button to separate the kit from the connector.



Dispose of the waste in accordance with the applicable national or local government legislation governing the disposal of dangerous biological waste. Do not perforate or open the reagent kit.

Check that the new kit is from a zone with room temperature similar to that of the analyser.

Unpack the kit and remove the three red protective caps. Do not press the side of the kit after removing the caps as the solutions it contains could flow out. Have some paper at hand to dry the surface where the connector is coupled in case any liquid flows out.

Position the connector in the correct direction and press lightly until you hear a click. Write the installation date on the side of the kit.

Place the kit in its housing.

With the user program, execute the actions in the number and order indicated in the *ISE functions, change reagent kit* section.

☞ See chapter 10.8.3

Step	Action	Repetitions	Description
1	Activate the reagent kit	1	If the execution icon is not activated after selecting this option, check that it is a new kit. If the kit has already been activated before, this option will not be available, but you can make a reading with the <i>Read reagent kit</i> option. In this case, go on to the next instruction. In the event that it is a new kit, check that the connector is correctly positioned, remove it again and reconnect it.
2	Bleed B	3	Remove the lower cover of reagent arm 2, which allows you to observe the dispensing cup. ☞ See Figure 92 Observe the cup and check the emptying operation, i.e., that every time the module pumps dispense the liquid into the cup, it is emptied before the next dispensing operation. If the pumps do not dispense the liquid, execute the above action again. If, after repeating the action 4 times, no liquid is dispensed, disconnect and reconnect the kit adapter and repeat the action.
3	Bleed A	3	Proceed as described above
4	Priming B	9	Execute 9 repetitions of this instruction to ensure the solution in the new kit completely replaces the one in the previous kit throughout the whole tube and electrode circuit. Some of the error repetitions may indicate absence of liquid. Ensure that the three last priming operations have been completed correctly. If not, execute the necessary priming to achieve this.
5	Priming A	9	Proceed as described above
6	Calibrate the electrodes	2	Execute this action to calibrate the electrodes with the new solution and check it is in good condition. If the result is unacceptable due to the presence of air, check that the solutions are circulating correctly and repeat steps 2 or 3, depending on the error reported. If the calibrations have ended but the results are not acceptable, repeat these instructions a couple of times.

14.3.2.3. Changing the peristaltic pump tubes

Open the front doors and take off the front cover of the ISE module.



It empties the tubes.

- With the user program in the *ISE functions* section, perform 5 *Maintenance?* cycles, to empty the channel and the tubes.

Remove the tubes from each of the peristaltic pumps. Release the pressure from the head by pulling the clamp marked in yellow.

Separate each of the tubes at the two joints and discard them. Wear gloves when handling the tubes. Treat this material as potentially infectious. Dispose of the waste in accordance with the applicable national or local government legislation governing the disposal of dangerous biological waste.

Unpack the new tubes.

Insert a tube into each peristaltic pump. To insert the tube into head of the peristaltic pump release the pressure on the head by pulling the clamp (1) upward, see Figure 94.

Each tube has two labels. The labels help guide the tube correctly in the peristaltic pump. The number on the label of each tube must coincide with the number on the pump label.

- The tubes marked W must be installed in the pump (2). The order for putting them in place starting from the left is W1 and W2.
- The tubes marked B must be installed in the pump (3). The order for putting them in place starting from the left is B2 and B1.
- The tubes marked A must be installed in the pump (4). The order for putting them in place starting from the left is A2 and A1.

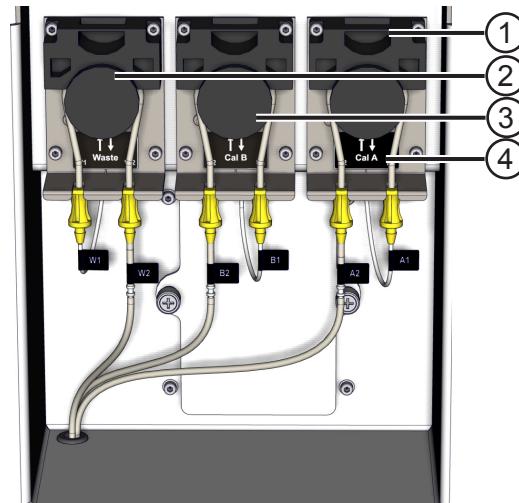


Figure 94 Connecting the peristaltic pump tubes

Take care when connecting the tubes of the waste pump (2) as they are connected in reverse order to the tubes of the pump for standards A (4) and B (3).

With the user program, execute the actions in the number and order indicated in the *ISE functions, change pump tubes* option.

See chapter 10.8.3

Step	Action	Repetitions	Description
1	Priming B	2	
2	Priming A	2	
3	Priming B	9	
4	Priming A	9	
5	Update the installation date	1	Update the tube installation date
6	Calibrate the pumps	1	Execute this action to calibrate the pumps. If the result is not acceptable due to the presence of air, check the correct installation of the tubes and repeat the indications given above.

14.3.2.4. Turning off the ISE module for a long period of time

If the analyser is not to be used for a long period of time, for instance, during the holiday period, proceed as follows to conserve each electrode, tube and reagent kit.

To leave the module inactive, uninstall the electrodes and the reagent kit and clean the tubes to prevent salts or traces of serum from blocking the circuit.

Execute the actions in the number and order indicated in the use program, in the *ISE functions* section.

☞ See chapter 10.8.3

Step	Action	Repetitions	Description
1	Filling with Cal A	3	This action dispenses 300 µl of solution A into the module cup. Use the syringe and long tip supplied with the accessories box to suction the liquid and deposit it in a well or in any other container. Repeat this action 3 times. This solution will be used to fill the electrode channel in the storage procedure. 
2	Wash	1	Place the washing solution in the well indicated in sample rotor
3	Bleed A	3	

Step	Action	Repetitions	Description
4	Install the cleaning pack	1	Remove the reagent kit and put the cleaning pack in its place, filled with purified water. The pack is comprised of the base, 3 tubes and the bottle. These elements are in the accessories box. ☞ See Figure 95 on how to install the cleaning pack.
5	Bleed A	3	
6	Bleed B	3	
7	Prime A	20	Execute these actions to wash the entire fluid circuit thoroughly with purified water.
8	Prime B	20	
9	Maintenance	1	Procedure for emptying the electrode channel and uninstalling them without damaging the module.
10	Deactivating the ISE module	1	Procedure for telling the program that the module has been disconnected.

Turn off the ISE module power supply.

Remove all the electrodes from the module, including the reference electrode. Protect them as follows:

Na⁺ and Cl⁻ electrodes

Place each electrode separately in a sealed bag.

Reference electrode

Reinsert the wire with the yellow label it into the reference electrode opening and then place it in an individual sealed bag.

K⁺ and Li⁺ electrodes

Suction a small quantity of standard A dispensed in a sample well during the first step.

Inject the appropriate quantity of standard A into the channel of the K⁺ and Li⁺ electrodes until the liquid fills the channel.

Cover the two ends of the channel (both sides of the K⁺ and de Li⁺ electrodes) with adhesive tape to hold standard A in place.

Insert the K⁺ and Li⁺ electrodes in a sealed bag.

+Reagent kit

Remove the reagent kit from the analyser and dispose of it.

Peristaltic pump tubes

Remove all the tubes from the fluids and rinse them with purified water. Use the syringe with the medium tip. 

Thin tubes

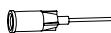
Rinse the thin tubes with purified water. Use the syringe with the small sized tip. 



Figure 95 ISE washing bottle

14.3.2.5. ISE module reactivation

- Remove all the electrodes from the sealed bags.
- Remove the tape from the K⁺ and Li⁺ electrodes and dry the electrode surface.
- If necessary, submerge the reference electrode in warm water until all salt in the electrode opening channel has been dissolved.
- Install the electrodes in the ISE module.
- Reconnect the reagent kit with the ISE module.
- Turn on the ISE module power supply.
- Perform the steps described in section 4.12

14.3.3. Maintenance frequency

The only daily maintenance required is cleaning the washing solution channel after the last sample of the day or after 50 patient samples, whichever occurs sooner. In addition, the sample input opening must be cleaned once a month with a cotton swab and deionised water.

The frequency for changing the ISE module elements is described below.

Element	Users with a low ISE sample volume	Users with a high ISE sample volume (> 100 samples/day)
Li ⁺ electrode	6 months	3000 samples
Na ⁺ electrode	6 months	10,000 samples
K ⁺ electrode	6 months	10,000 samples
Cl ⁻ electrode	6 months	10,000 samples
Reference electrode	6 months	10,000 samples

Element	Users with a low ISE sample volume	Users with a high ISE sample volume (> 100 samples/day)
Peristaltic pump tubes	6 months	6 months
Fluidic tubes	12 months	12 months

14.3.4. End of the analyser's useful life

At the end of the useful life of the analyser, disposal of the product must be done in accordance with the environmental legislation in force in each country. If that country is an EU member state, the terms of the WEEE directive on electrical and electronic appliances will apply. In other words, when the appliance's useful life has ended, it is converted into waste and must be separated from household waste for correct recycling. For this purpose, contact your habitual distributor for them to execute the recycling.

15. Technical characteristics

15.1. General characteristics

Speed	400 prep/h (without electrolytes)
ISE module speed	320 prep/h
Analysis principles	Spectrophotometry, turbidimetry. ISE module: Potentiometry (selective electrode method): Na^+ , K^+ , Cl^- (Li^+ optional)

15.2. Sample control

Sample rotor capacity	135
Barcode detector	Yes
Number of samples with barcodes	90
Size of primary tubes	Diameter 12 mm to 16 mm (max. height 100 mm)
Sample well	Sample well diameter 13.5 mm
Type of sample pump syringe	Low-maintenance ceramic piston
Piston diameter	3 mm
Dispensing volume	2 μL to 40 μL
Dispensing resolution	0.1 μL
Pre-dilution ratio	1:2 to 1:200
Level detection	Yes
Washing of tip	Interior and exterior
Clot sensor	Yes
Vertical collision detector	Yes

15.3. Reagent control

Reagent bottle volume	20 mL, 60 mL
Reagent rotor capacity	88 (44 bottles of 20 mL or 60 mL + 44 bottles of 20 mL)
Refrigerated reagents	Yes
Refrigerator temperature range	5° C to 8° C (at room temperature of 25° C)
Barcode detector	Yes
Reagent arms	2 (R1, R2)

R1 reagent volume	150 µL to 450 µL
R2 reagent volume	40 µL to 300 µL
Type of reagent pump syringe	Low-maintenance ceramic piston
Piston diameter	8 mm
Dispensing resolution	1 µL
Level detection	Yes
Washing of tip	Interior and exterior
Vertical collision detector	Yes
Thermostatted tip	Yes

15.4. Reaction rotor

Minimum reaction volume	180 µL
Maximum reaction volume	600 µL
Number of cuvettes	120
Cuvette material	UV methacrylate
Type of incubation	Dry
Dispensing time for second reagent	5 min (fixed)
Reaction cuvette temperature	37 °C
Accuracy of the temperature	±0.2 °C
Temperature stability	±0.1 °C
Stirrers	2

15.5. Cuvette washing system

Number of washing system tips	7
Number of tips with washing solution	2
Rinsing with water	3
Drying	2
Wash volume per tip	711 µL
Washing solution consumption	1.42 mL/cycle

15.6. Optical system

Light source	LED+Hard Coating Filter
No. of wavelengths	8
Wavelengths	340 – 405 – 505 – 535 – 560 – 600 – 635 – 670 nm
Filter band width	10 nm ± 2 nm
Wavelength accuracy	± 2 nm

Photometric range	-0.2 A to 3.5 A
Internal resolution	0.0001
Detector	Principal photodiode + reference photodiode
Measurement precision (for 340 nm, 405 nm and 505 nm)	CV < 1 % at 0.1 A CV < 0.1 % at 2 A

15.7. ISE module (optional)

Sample type	Serum, Plasma or Urine
Type of electrode	Na ⁺ , K ⁺ , Cl ⁻ , Li ⁺ (optional)
Sample volume	Serum: 100 µL Urine: 200 µL

15.8. Environmental requirements

Room temperature	10 °C to 35 °C 10 °C to 30 °C (with ISE module)
Relative humidity	< 85% with no condensation
Maximum altitude	< 2 500 m
Contamination grade	2
Transportation and storage temperature	0 °C to 40 °C
Transportation and storage humidity	< 85% with no condensation

15.9. Dimensions and weight

Dimensions (Width, depth and height)	1 200 mm x 720 mm x 1 258 mm
Weight	210 kg

15.10. Electrical requirements

Mains voltage	115 V to 230 V
Network frequency	50 Hz or 60 Hz
Electric power	500 VA

15.11. Fluid requirements

Water inlet	Through external tank or through direct connection
Type of water	Purification type II (NCCLS)
Water consumption	< 14 L/h
High contamination waste tank	Internal, 5 L
Washing solution tank	Internal, 5 L

15.12. Minimum computer requirements

Operating system	Windows® 7 64 bit (x64)
CPU	Equivalent to Intel Core i3 @3.10 GHz or higher
RAM memory	4 Gbytes
Hard disk	40 Gbytes or more
DVD player	Yes
Monitor:	Minimum resolution 1 024 x 768
Serial channel connector	USB

16. Measuring and calculation procedures

This chapter describes the different analysis modes of the analyser and the calculations made to obtain the analytical results, i.e., the concentration values of the different sample analytes. The different formulae used are indicated in each case. The controls are treated in the same way as the patient samples in all the calculations.

Symbols used in the formulae

Symbol	Description
ABS	Absorbance value read in one instant of the reaction.
A	Absorbance value calculated based on the chosen analysis mode.
[...] $_{\text{principal}}$ ^{λ}	Absorbance value at the main wavelength.
[...] $_{\text{reference}}$ ^{λ}	Absorbance value at the reference wavelength.
[...] _{L1}	Absorbance value in time L1
[...] _{L2}	Absorbance value in time L2
ΔABS	Increase in absorbance
V_M	Sample volume
V_{R1}	Volume of reagent 1
V_{R2}	Volume of reagent 2
C	Analyte concentration
F	Factor
A_{Blank}	Blank absorbance
A_{Standard}	Standard absorbance
A_{sample}	Sample absorbance
C_{standard}	Known standard concentration

16.1. Operating sequence. Preparation and reading cycles

Figure 96 shows the dispensing cycles, the dispensing of reagents 1 and 2 and the reading made by the analyser.

Each analyser cycle lasts for 9 seconds. The total maximum reading time for a preparation may last for 10 - 35 minutes.

The cycle for dispensing reagents 1 and 2 and the sample is fixed. All that is programmed is whether or not the second reagent is dispensed and the times for the readings or reading intervals (kinetic) L1 and L2.

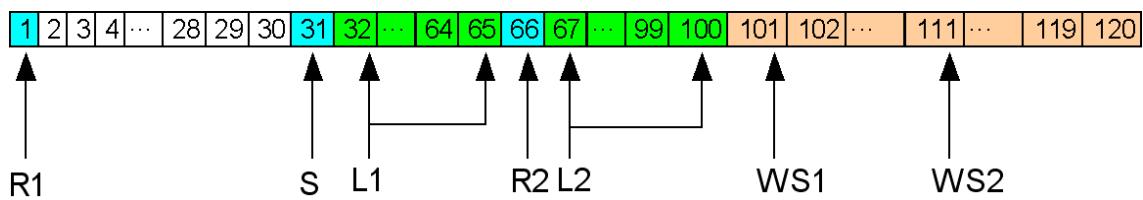


Figure 96 Analyser cycles

Abbreviations	Cycles	Description
R1	1	Dispensing of reagent 1
S	31	Dispensing of sample
M1	32	Stirring of reagent 1 and sample
L1	33-100	Reading
R2	66	Dispensing of reagent 2 (optional)
M2	66	Stirring of reagent 2
L2	67-100	Reading (L2 > L1)
WS1	101	Wash station initiation
WS2	111	Drying cycle initiation

16.2. Calculation of the absorbances

The absorbance calculation depends on the programmed analysis mode.

The analyser has the following analysis modes:

Analysis mode
Endpoint monoreagent
Endpoint bi-reagent
Differential switch
Fixed time monoreagent
Fixed time bi-reagent
Kinetic monoreagent
Kinetic bireagent

Each of the analysis modes executed by the analyser is shown below in detail, with a graphic interpretation of the dispensing and reading points and the calculation made to obtain the absorbance.

Each of the above analysis modes may be ascending or descending.

If the test is ascending, the evolution of the absorbance increases depending on the time. It has an ascending form.

If the test is descending, the evolution of the absorbance decreases depending on the time. It has a descending form. To obtain positive absorbance values using these calculation methods, the result is multiplied by -1.

16.2.1. Endpoint monoreagent

In endpoint reactions, once initiated the reaction lasts until it is balanced and then the absorbance value remains stable. The absorbance reading is programmed at this point. See Figure 97.

First reagent A is dispensed, the sample is dispensed in cycle 31 and then it is stirred and the reaction commences. Once it is balanced, the reading is taken, L1. The change in absorbance is directly proportional to the analyte concentration.

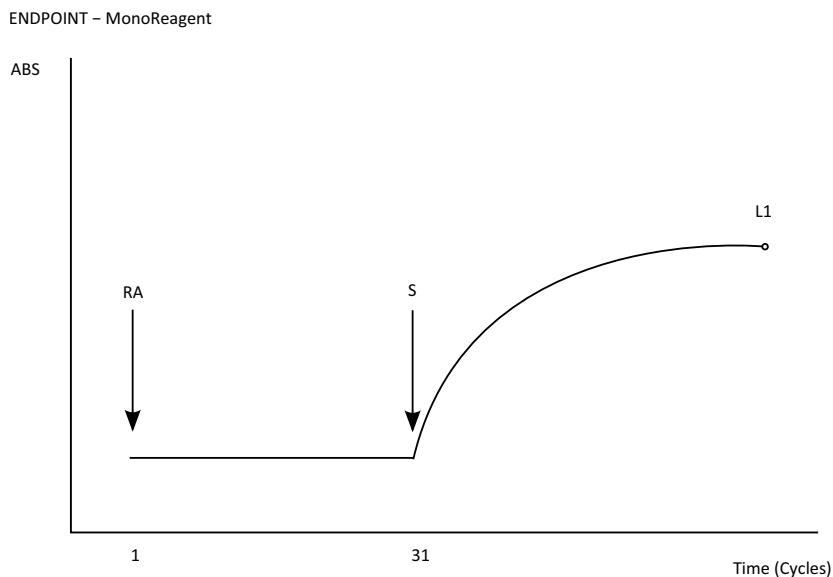


Figure 97 Endpoint monoreagent calculation method representation

The absorbance reading can be made at one wavelength (monochromatic) or two wavelengths (bichromatic).

Bichromatic readings are normally used to eliminate the influence of the cuvette in the absorbance reading.

If the reaction is monochromatic, the measurement is taken in time L1 at one wavelength.

$$A = ABS_{L1}^{\lambda, \text{main}} \quad (1)$$

If the reaction is bichromatic two readings are made in time L1. Each of the readings is made with a different wavelength. The absorbance is the difference between the two wavelengths.

$$A = ABS_{L1}^{\lambda, \text{main}} - ABS_{L1}^{\lambda, \text{reference}} \quad (2)$$

16.2.2. Endpoint bi-reagent

This operating mode is used, for example, if the working reagent stability is very short, in such a way that it is the analyser that prepares the working reagent in each preparation.

In this calculation mode a single reading is made and the reaction starts when the second reagent is dispensed.

Firstly, reagent A is dispensed, then the sample is dispensed in cycle 31, and in the next cycle it is stirred. Then reagent B is dispensed in cycle 66 and stirred and the reaction commences. Once it is balanced, the reading is taken, L1. The change in absorbance is directly proportional to the analyte concentration.

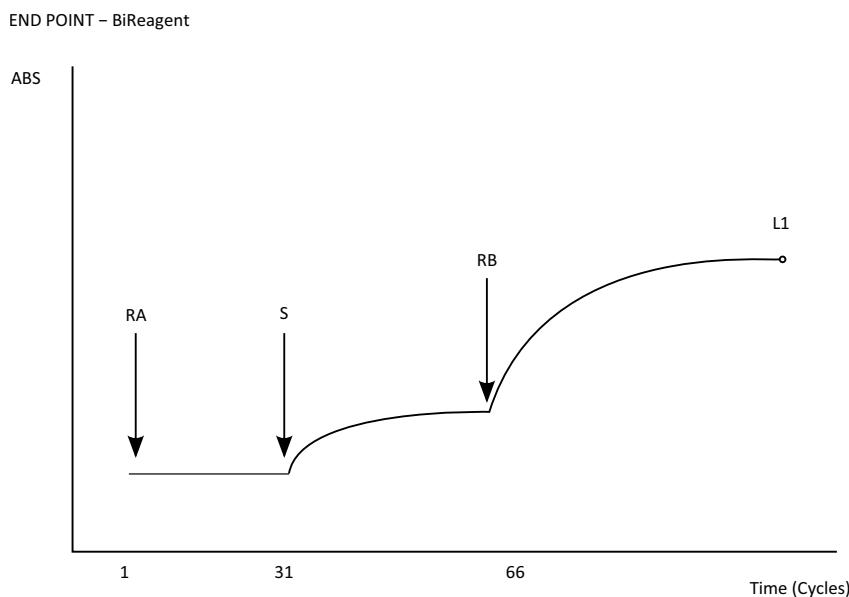


Figure 98 Endpoint bi-reagent calculation method representation

The absorbance calculation may be monochromatic or bichromatic.

If the reaction is monochromatic, the measurement is taken in time L1 at one wavelength.

$$A = ABS_{L1}^{\lambda_{main}} \quad (3)$$

If the reaction is bichromatic two readings are made in time L1. Each of the readings is made at a different wavelength. The absorbance is the difference between the two wavelengths.

$$A = ABS_{L1}^{\lambda_{main}} - ABS_{L1}^{\lambda_{reference}} \quad (4)$$

16.2.3. Differential switch

Differential tests make two readings, the first one before dispensing reagent B and the second one after the end of the reaction. These tests are used to eliminate potential turbidity effects in the sample, or eliminate the potential absorbance levels of reagent A.

First reagent A is dispensed, the sample is dispensed in cycle 31 and in the next cycle it is stirred and the reaction commences. Before dispensing reagent B, the L1 reading is taken. Reagent B is dispensed in cycle 66, and stirred in the next cycle, and the second part of the reaction commences. When the second reaction is balanced, reading L2 is taken.

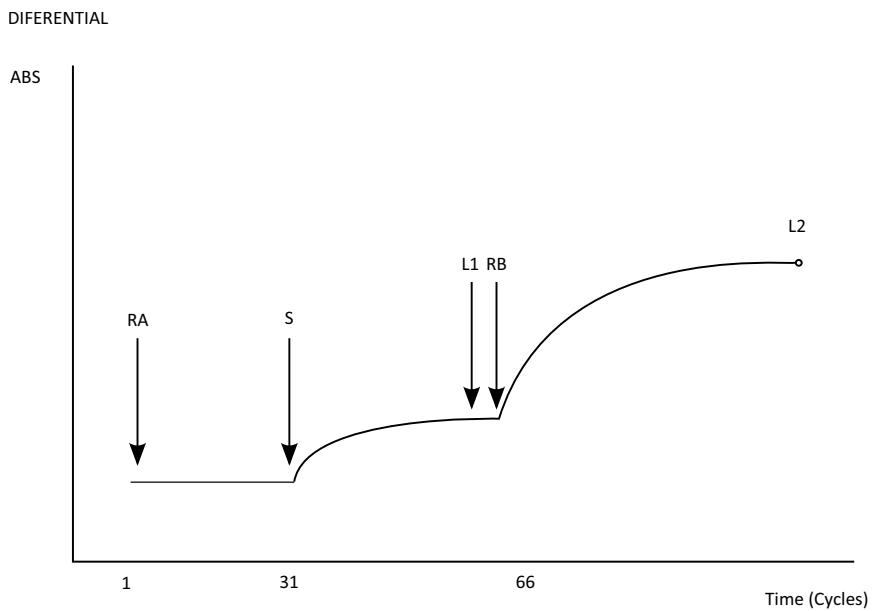


Figure 99 Differential calculation method representation

The following formula is applied in calculating the absorbance:

$$A = ABS_{L2}^{\lambda main} - ABS_{L1}^{\lambda main} * \frac{V_M + V_{R1}}{V_M + V_{R1} + V_{R2}} \quad (5)$$

16.2.4. Fixed time monoreagent

In tests programmed with the fixed time calculation method, the reaction speed is directly proportional to the consumed substrate. As the substrate is consumed the reaction speed is reduced, leading to a change in the absorbance. Thus, in a fixed time interval the change in the substrate concentration is directly proportional to the initial concentration. In the time interval, the change in absorbance is proportional to the analyte concentration.

In this calculation mode two readings are taken and the resulting absorbance is the difference between both readings.

First reagent A is dispensed, the sample is dispensed in cycle 31 and then it is stirred and the reaction commences. Reading L1 is taken and after a few cycles reading L2 is taken. The absorbance is the difference between the readings.

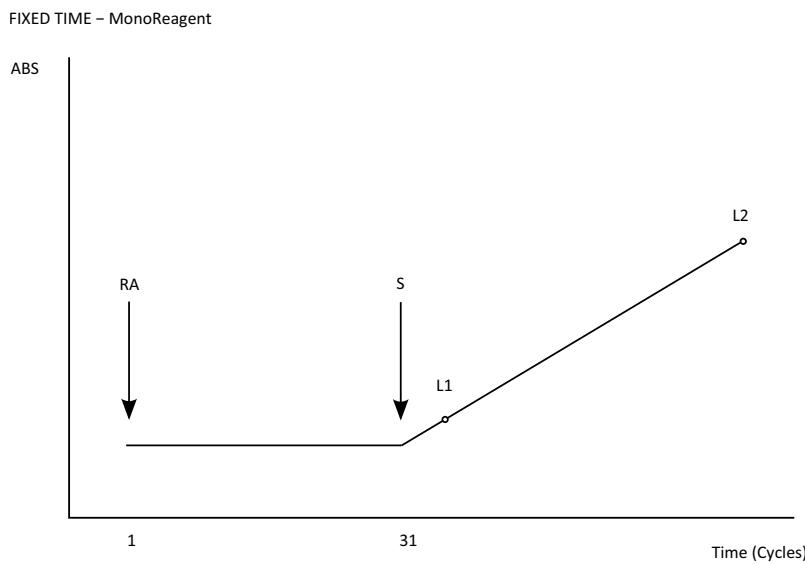


Figure 100 Fixed time monoreagent calculation method representation

The absorbance calculation may be monochromatic or bichromatic.

If the reaction is monochromatic, it is only measured at one wavelength and the absorbance calculation is performed with the following formula:

$$A = ABS_{L2} - ABS_{L1} \quad (6)$$

If the reaction is bichromatic, two readings are made at time L1 and two readings at time L2. The absorbance is the difference between the two wavelengths at each reading time.

$$A = (ABS_{L2}^{\lambda \text{ main}} - ABS_{L2}^{\lambda \text{ reference}}) - (ABS_{L1}^{\lambda \text{ main}} - ABS_{L1}^{\lambda \text{ reference}}) \quad (7)$$

16.2.5. Fixed time bi-reagent

In this operating mode it is the analyser that prepares the working reagent in each preparation.

Firstly, reagent A is dispensed, then the sample is dispensed in cycle 31, and in the next cycle it is stirred. Then reagent B is dispensed in cycle 66 and stirred and the reaction commences. Reading L1 is taken and after a few cycles reading L2 is taken. In this calculation mode two readings are taken and the resulting absorbance is the difference between both readings.

The absorbance calculation may be monochromatic or bichromatic.

If the reaction is monochromatic, it is only measured at one wavelength and the absorbance calculation is performed with the following formula:

$$A = ABS_{L2} - ABS_{L1} \quad (8)$$

If the reaction is bichromatic, two readings are made at time L1 and two readings at time L2. The absorbance is the difference between the two wavelengths at each reading time.

$$A = (ABS_{L2}^{\lambda main} - ABS_{L2}^{\lambda reference}) - (ABS_{L1}^{\lambda main} - ABS_{L1}^{\lambda reference}) \quad (9)$$

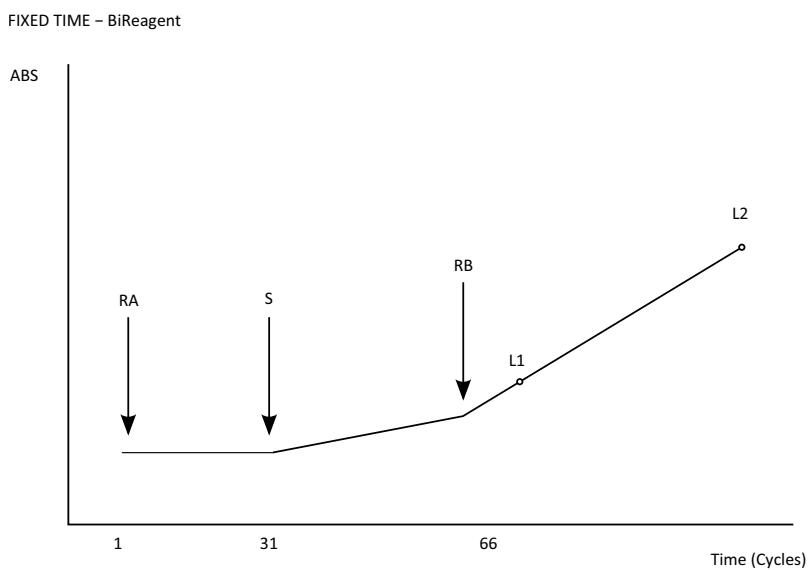


Figure 101 **Fixed time bi-reagent calculation method representation**

16.2.6. Kinetic monoreagent

In tests programmed with the kinetic calculation mode, the reaction speed is maintained constant during the reaction process. As a result the absorption of the analytes at a certain wavelength changes uniformly and the change in absorbance per minute ($\Delta ABS/min$) is directly proportional to the concentration of the analytes. The kinetic method is used to measure enzymatic activity.

For this calculation mode an initial and an end time are programmed. Between these two times several readings are taken and the linear regression of the readings is calculated. The resulting absorbance is the linear regression slope value.

In addition the linearity of the readings is checked; to do this, the correlation coefficient is calculated.

If the correlation coefficient is $\rho < 0.9$ then the program says that the result of the kinetic reaction is non-linear.

First reagent A is dispensed, the sample is dispensed in cycle 31 and then it is stirred and the reaction commences. The analyser starts to take the readings from time L1 to time L2.

The absorbance calculation is as follows:

$$A = \left[\frac{\Delta ABS}{min} \right]^{\lambda main} \quad (7)$$

KINETIC – MonoReagent

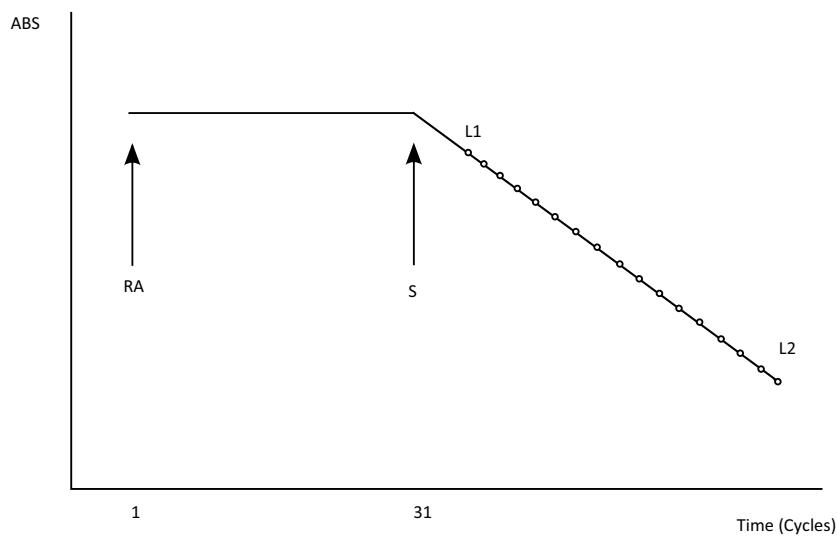


Figure 102 Kinetic calculation method representation

16.2.7. Kinetic bireagent

In this operating mode it is the analyser that prepares the working reagent in each preparation.

Firstly, reagent A is dispensed, then the sample is dispensed in cycle 31, and in the next cycle it is stirred. Then reagent B is dispensed in cycle 66 and stirred and the reaction commences. The analyser starts to take the readings from time L1 to time L2.

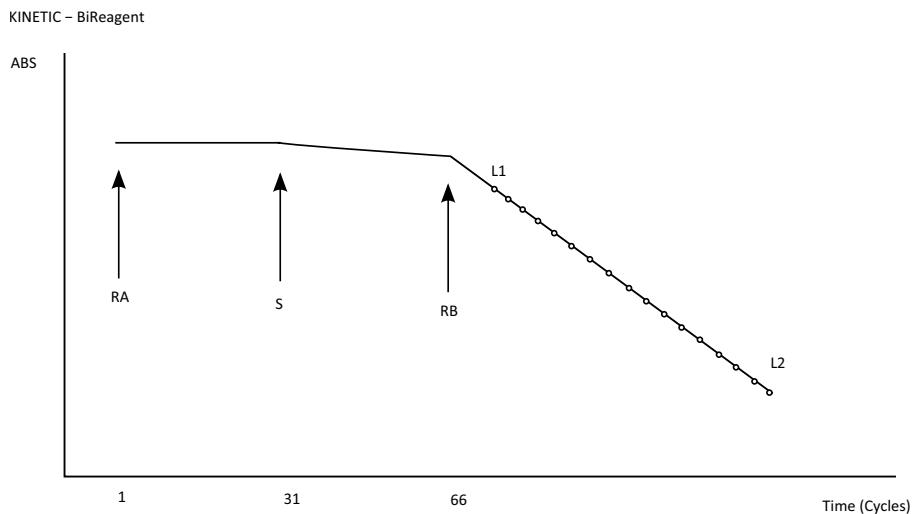


Figure 103 Kinetic calculation method representation

The absorbance calculation is as follows:

$$A = \left[\frac{\Delta ABS}{min} \right]^{\lambda_{main}} \quad (7)$$

16.3. Concentration calculation

To determine the analyte concentration of a sample, its absorbance must be calculated using any of the above analysis modes, and a calibration function must be used.

Calibration function

It establishes a ratio between the calculated absorbance values and the known sample analyte concentrations. This ratio may be linear or non-linear.

To calculate the calibration function one or several samples with a known analyte concentration are measured and a calibration curve is obtained. See Figures 103 and 104. If the ratio is linear only one standard is measured and the calibration line is calculated. If the ratio is non-linear several standards will be needed and the calibration curve will be calculated with a regression procedure. It also measures the blank that will be the signal measured by the analyser in the absence of the analyte. In the calibration curve the blank will correspond to concentration point equal to zero.

Blank

The blank is the absorbance in the absence of the analyte. It is measured using a sample that contains no analyte. In general, purified water is used as the sample, but physiological saline solution can also be used. To correctly measure the reagent blank absorbance, the same analysis mode must be used as the one used with the samples.

Standard

The standard is a sample with the known concentration of the analyte to be determined. It is a standard or reference material. To correctly measure the standard blank absorbance, the same analysis mode must be used as the one used with the samples.

If the ratio between the analyte absorbance and its concentration is linear, then the standard function is a line. So it will only be necessary to measure the blank and a standard.

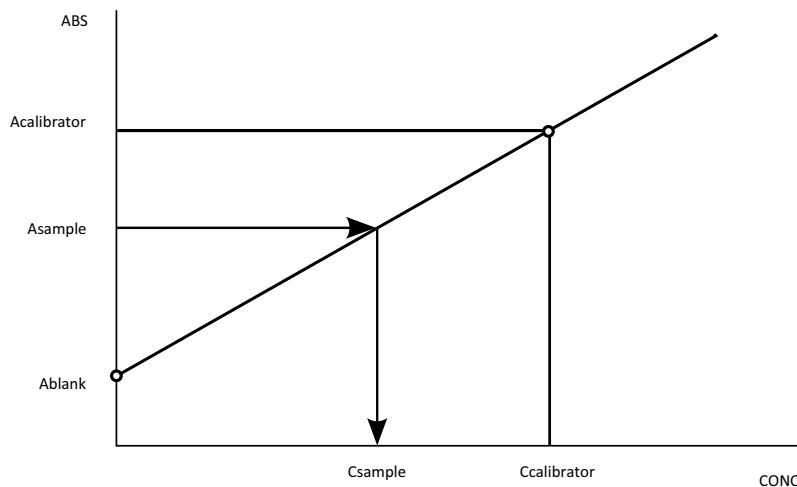


Figure 104 Linear calibration curve

For the linear standard functions the blank absorbance ordinates is taken as the source and the inverse of the factor as the slope.

The factor is calculated as follows:

$$F = \frac{C_{\text{standard}}}{A_{\text{standard}} - A_{\text{blank}}} \quad (8)$$

And the following formula is used to calculate the concentrations:

$$C_{\text{sample}} = F * (A_{\text{sample}} - A_{\text{blank}}) \quad (9)$$

For calibration functions that are non-linear several known concentration standards are used, approximating the curve with regression functions.

The following regression functions can be programmed:

Type of function	Description
Polygonal	It joins each point by a line
Linear regression	It makes a linear regression with all the points
Parabolic regression	It makes a parabolic regression with all the points
Spline	It plots a curve that passes through each point

To calculate the concentration in a non-linear curve the inverse function of the approximation curve is calculated.

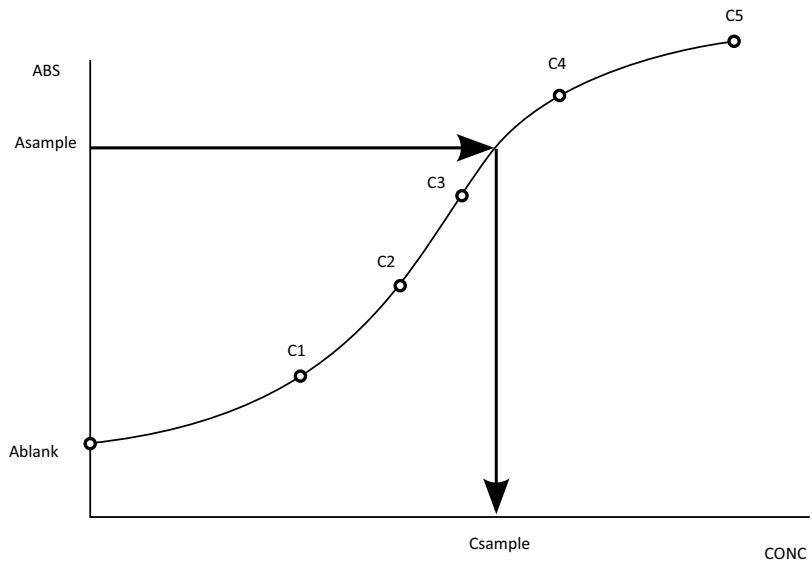


Figure 105 **Non-linear calibration curve**

16.4. Repetition criteria

To activate automatic repetitions, the following programme options must be programmed:

There is a general programme option for activating or deactivating all the automatic repetitions:

1. Select the menu: *Configuration/General/Work session*
2. Activate the option: *Automatic repetitions execution*

For each test there is an individual option for activating or deactivating the automatic repetitions.

1. Select the test you want to configure. Select the *procedure* tab
2. Activate the edition mode and activate the option *automatic repetition*, configure the dilution parameters.
3. In the *options* tab configure the parameter values for the repetitions.

Figure 106 shows the repetition criteria, depending on the programmed parameters.

Criterion	Type of repetition
Concentration result < Detection limit	Repetition with increased postdilution
Concentration result < Linearity limit	Repetition with dilution
Minimum repetition range > Concentration result > Maximum repetition range	Repeat in same way
Concentration result < Minimum repetition range	Do not repeat
Concentration result > Maximum repetition range	Do not repeat
Concentration result < Minimum panic range	Repetition with increased postdilution

Criterion	Type of repetition
Concentration result < Maximum panic range	Repetition with dilution
Minimum panic range > Concentration result >	Do not repeat
Maximum panic range	

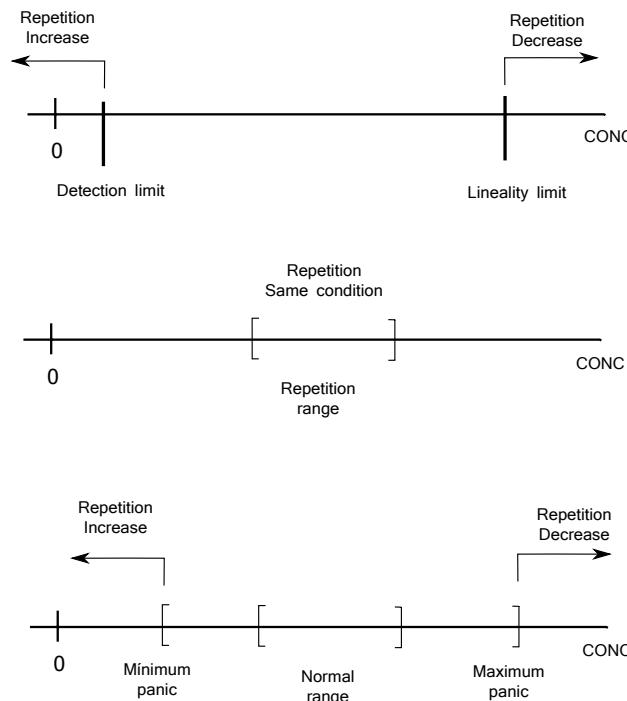


Figure 106 Repetition criteria diagram

16.5. Calculation of the ISE ion concentration

The ISE module measures the lithium, sodium, potassium and chlorine in serum, plasma and urine using ion-selective electrode technology. The continuous flow sodium electrode uses a selective membrane, specially formulated to detect sodium ions. The potassium, lithium and chlorine electrodes use a similar design with the appropriate materials for the selective membranes. The potential for each electrode is measured in relation to a fixed and a stable potential established by a reference double-union silver/silver chloride electrode. The selective ion electrode develops a voltage that varies depending on the concentration of the ion to which it responds. The ratio between the voltage developed and the detected concentration is logarithmic as expressed by the Nernst equation.

$$E_x = E_s + \frac{RT}{nF} \cdot \log(\alpha C) \quad (12)$$

Symbol	Description
E_x	Electrode potential in the sample solution
E_s	Potential developed in standard conditions

Symbol	Description
RT/nF	Constant, depending on the temperature
α	Ion coefficient of activity measured in the solution
C	Ion concentration measured in the solution

A comparative method is used for measuring. First, the ISE module measures the potentials developed by the sample when it is positioned in the electrodes. Then standard A for serum samples or standard B for urine samples is positioned in the electrodes. The difference between both measurements for each ion is proportional to the quotient logarithm between the ion concentration in the sample and in the calibration solution. The proportionality factor (S) is calculated in a previous calibration operation described below. Since the differences in potential of the ion concentrations in the calibrating solution are known, the concentration of the ions in a sample solution can be calculated, using the Nernst equation, and rewriting:

$$E_x - E_s = S \cdot \log\left(\frac{C_x}{C_s}\right) \quad (13)$$

$$C_x = C_s \cdot 10^{\frac{E_s - E_x}{S}} \quad (14)$$

Symbol	Description
E_x	ISE voltage in the sample solution
E_s	ISE voltage in the standard solution
S	Electrode slope calculated during the calibration process
C_x	Ion concentration of the sample
C_s	Ion concentration of the standard solution

“S”, slope, is determined during the calibration using standards A and B, in which the sodium, potassium and lithium levels are known.

When a two-point calibration is started, the slope is calculated based on the difference between the reading of standard A and the reading of standard B. Excessive shunt or noisy readings will be indicated and an error message will be sent to the system.

The slope is defined as:

$$\text{Slope} = \frac{E_B - E_A}{\log \frac{C_B}{C_A}} \quad (15)$$

Symbol	Description
C_A	Concentration of standard A in mmol/L

Symbol	Description
C_B	Concentration of standard B in mmol/L
E_A	Voltage measured in the ISE of standard A in mV
E_B	Voltage measured in the ISE of standard B in mV

The calibration slope value is affected by the temperature and by the aging of the electrodes. It is verified that the slope value is within certain limits.

16.6. Internal Quality Control

Many commercial materials for internal control have assigned values. Several concentration values that correspond to different measuring methods are provided for each component. In addition, each value is accompanied by an “admissible” value (Manual mode). The usefulness of these values and intervals is debatable and it is advisable not to use them for internal quality control.

Assigning values to control materials and establishing admissible value intervals for internal quality control must be carried out in the laboratory itself (Statistical mode), in its own working conditions (instruments, reagents and operators).

Internal control must be designed so that it has very little sensitivity to tolerable increases in error, while it must warn about significant errors.

16.6.1. Basis

The result obtained for a control material is compared with an admissible value interval and a decision is taken:

- The result is within the interval: It is considered that the measuring procedure maintains its accuracy within certain limits (it is stable) and the results of the series are accepted.
- The result is outside the interval: It is considered that the measuring procedure returns an error that is above tolerable levels and the results of the series are rejected.

16.6.2. Admissible value interval

The best way to obtain the admissible value interval in the control material is through a statistical estimate:

1. It is necessary to have sufficient quantity of a control material batch to meet the requirements during a long period of time.
2. Perform at least 20 measurements, each one on a different series, using the measuring procedure that must be controlled.
3. Calculate the mean value (X_m) and standard deviation (s) of the results obtained. It is recommended to review these first estimates if more results are available.

The dispersion of the results obtained is due to the imprecision of the measuring procedure between series. This dispersion must have a normal distribution characterised by the mean values and the standard deviation.

Therefore it is possible to establish a value interval with a known probability of the result being included in that interval.

As it is required that the probability be high, it is common to select intervals between $X_m \pm 2s$ and $X_m \pm 3s$. The selected criterion for establishing the admissible value interval is a decision-based criterion or a control rule.

Internal control is based on the idea that it is not very likely that a result outside the established limits will be obtained.

Control rules based on Gaussian statistics are usually represented by the expression A_{ns} , where "A" is the number of control results and "ns" is the admissible limit selected.

Different control results belonging to one control material or more than one may also be used. Likewise the control results may have been obtained in one series or in various consecutive series.

Rules that are more complex may be entered with various control results.

The ones most often used are the following:

2_{2s} Series rejected when 2 results are obtained that exceed 2s of the same type (positive or negative).

4_{1s} Series rejected if 4 results are obtained that exceed 1s of the same type.

10_X Series rejected if 10 results are obtained on the same side of the mean.

R_{4s} Series rejected if one result exceeds the +2s limit and the other exceeds the -2s limit.

The rules for several control results may also give a clue as to the possible cause of the increase in error. Rules 2_{2s} , 4_{1s} and 10_X are particularly sensitive to systemic error, whereas rule R_{4s} is better at detecting increases in imprecisions.

Another interesting option is the combination of several rules in a logical or algorithmic sequence. The best known combination is known as the Westgard algorithm or rules for two control results.

In some cases it is not possible to make a statistical estimate of the dispersion of results and apply control rules, because there are no accessible control materials or because the measuring procedure is not used very often. In such situations it is common to use a control material furnished by the supplier of the reagents or measuring system, for which an admissible value interval is indicated (Manual mode).

16.6.3. Selection of control rules

The following objectives must be considered in selecting the rules to be used in internal control:

- Simplicity: Use the least possible number of materials and control rules.
- Low probability of false rejections ($\leq 2\%$, preferably $< 1\%$).

- High likelihood of detecting important increases in error. The lower the value interval of the control rule, the greater probability there will be of detecting increases in error.

The idea is to have the lowest possible number of false alarms and guide error-detection to increases that are considered important, based on the understanding that smaller errors may occur (tolerable errors) without being detected.

17. Summary of workflow scenarios with the LIS

This chapter describes the different scenarios defining interaction between the BA400 and the information management software of a laboratory (LIS-Laboratory Information System). It describes the exchange of information between the BA400 analyser and the LIS, such as for example in receiving work orders from the laboratory for creating the worklist in the analyser and sending results from the analyser to the LIS.

The BA400 implements two types of message or protocol message flows:

- The HL7 (Health Level 7) applied pursuant to the IHE (Integrating the Healthcare Enterprise) recommendation
- The ASTM (American Society for Testing and Materials)

In this context the terminology used to describe data-transmission from the LIS to the analyser is called download and the data-transmission from the analyser to the LIS is called upload.

The specimen is the content of each patient or control tube and may be one of the types admitted (serum, urine, whole blood, etc). A patient may have two different specimens, a serum one and a urine one. The tests indicated through a worklist are performed on the specimen.

Transmission between the analyser and the LIS system is done through TCP/IP connections.

- The TCP/IP for ASTM and HL7 is established when the system is initiated and it must be permanently maintained provided the analyser is on. The communication supports two setup mode: establishing the analyser as *client* or as *server*.
- The HL7 also permits the transitory connection mode, which establishes two connections at one time: When the BA400 starts a conversation a network connection is established (a socket with an IP address and a port is opened) and all the messages related to the conversation are sent and received by the socket.

When the LIS wants to initiate a conversation, another network connection is initiated (another socket is opened with an IP address and a port) and all the messages related to this conversation are sent and received through this other socket.

17.1. Query by specimen and automatic start

A scenario in which the sample tubes to be analysed are positioned in the rotor, the barcodes of each specimen are read and the LIS is asked for the work orders for each specimen. The LIS sends the request for each specimen.

The chain of actions is as follows:

1. The user places the tubes of each specimen in the sample rotor.
2. The user presses the start button.



3. The programme automatically performs the following actions:
 - It reads the reagent rotor barcodes.
 - It reads the sample rotor barcodes.
 - It shows all the specimens read with the barcode on an auxiliary screen.
 - It requests the LIS for the Query by specimen for each of the tubes.
 - The LIS sends the work orders only for the requested specimens.
 - It closes the auxiliary information screen.
 - The work orders are downloaded, a worklist is generated and the automatic execution of the worklist is started.
4. There are some exceptional cases in which the list does not start the execution automatically.
 - When the worklist contains standards or controls that must be positioned.
 - When a reagent is missing in the worklist.
 - When an ISE test has been requested for a urine sample. This sample must be diluted and positioned manually in the rotor.
5. In exceptional cases, the programme does not start the execution and opens the positioning screen for the user to correct the reasons for the exception.



In the event of communication problems or if the LIS system is very slow, it may occur that the list is executed automatically but not all the work orders have been received; in that case the *add orders* icon is activated. The user should press the icon to add the pending orders to the worklist. If this situation occurs very often, the user can change the configuration of the LIS response times and/or the number of orders sent by message, to prevent this situation.

See chapter 10.2.6 for the LIS operation configuration



When the work session is being executed and the user presses the Query by specimen button, the programme sends a request to the LIS for all the tubes read with the barcode. This action serves to verify whether new tests have been added to already-positioned tubes or if a request to repeat a test has been made.

17.2. Query All

Scenario in which the BA400 requests the LIS for work pending before the specimens reach the analyser. In this case the LIS sends all the pending orders for that analyser.



NOTE

It is advisable for the LIS to filter orders and only send those corresponding to the analyser making the request, otherwise pending orders will remain in the analyser and the LIS will have to send cancellations when it receives results for these from another analyser.

When the specimens reach the analyser, the barcodes are read or entered manually and associated with the worklist. It may happen that there are fewer specimens than the ones programmed in the worklist, so they will remain pending execution. These pending requests are either executed through the arrival of the specimens afterwards, or cancelled by the LIS.

The chain of actions is as follows:



1. Press the *Query All* button on the bar at the top. The analyser makes a generic request for the worklist to the LIS.
2. The LIS sends all the work orders it has for the analyser. The program processes the orders and creates the worklist.
3. The user positions the sample specimens in the rotor and reads the barcodes.
4. The program assigns to each specimen the information of the work order programmed in the list.
5. The user can start the work session.
6. Once the list has been completed and the results obtained for each specimen, the analyser sends them to the LIS. The sending of results in real time is done with the frequency configured by the user. (End of Test, End of Patient, End of Work Session).
☞ See chapter 10.2.6 for the LIS operation configuration
7. The LIS must send a cancellation of all orders not executed.

17.3. Sending results to the LIS. Upload.

After completing the worklist, the results are sent to the LIS. Depending on the configuration established in the LIS setup screen, the results can be sent automatically with the following frequency:

- At the end of each work session: the results are sent at the end of the work session.
- After completing each patient: when the results of all the tests on a patient have obtained they are sent to the LIS.
- After completing each test: when a test has a result, it is sent to the LIS.

Results can also be sent to the LIS manually from the current results screen or from the historical data screen.

When the *transmission of control results requested from the analyser* is active: all the internal control results requested from the BA400 will be sent to the LIS. (With the same sending frequency configured for sending results to the LIS: automatic or manual).

When there is a LIS order related to a calculated test only the result of the calculated test is sent, and the results of partial tests are not sent, except when the LIS expressly requests orders for partial tests and also calculated order tests.

The results of the external tests (off system) are also sent to the LIS. Observations related to the results are sent to the LIS with a generic message.

On resetting the session, all the LIS orders that are pending or blocked are automatically saved in a memorised LIS session. In this case the *add orders* button appears active (indicating that there are LIS orders still to be processed in the analyser). The name of the session is the following: LIS yyyyMMdd hh:mm:ss.

These LIS orders that have not yet been processed in the analyser are automatically added to the next work LIS session by pressing the button *Add orders to LIS*. After adding them to a new session the memorised session is automatically eliminated.

To eliminate Pending LIS orders, the LIS must send the respective Cancellation messages.

In the LIS functions screen requests from the LIS that have not been processed can be eliminated.

17.4. Repetitions

The parties who can request test repetitions are established in the LIS setup screen. The options are the following:

- LIS: Patient tests can only be repeated from the LIS. Requests for repetitions are launched during the clinical validation from the LIS manager. The manual option of patient sample repetitions in the current results screen will be blocked. Blanks, standards and controls may be repeated via the analyser.
- Analyser: Patient tests can only be repeated from the analyser. Requests are launched for repetitions during the technical validation of the results. Repetition orders received from the LIS will be rejected.
- Both: All the repetition requests coming from the LIS or from the analyser are accepted.

17.5. Reasons for rejection

Below are possible reasons for rejecting messages through the BA400.

Due to actions carried out by the user

Description	Cause
The user deletes requests accepted from the LIS pending execution by the BA400	The required specimen has not been received
	Lack of reagent
	Other reasons

Due to cancellations requested by the LIS

Description	Cause
Lack of knowledge about the type of patient sample or test	The cancelled test or sample type does not exist in the BA400.
The test or sample type to be cancelled has ended	Execution of the test or sample type to be cancelled has already ended (the results have already been obtained)

Due to a request for repetitions

Description	Cause
Request from the LIS for a non-permitted repetition	The <i>repetition mode</i> in the analyser has only been selected in the BA400.
Request from LIS to repeat an internal QC control	It is not permitted to request repetitions of internal controls from the LIS.
Request from the LIS to repeat an incorrect test or sample type.	It is not permitted to make requests for repetitions of calculated tests or external tests.
Repetition request from the LIS for a different specimen identifier.	The repetition request after receiving a result was for a different specimen identifier.

Due to the incorrect field content

Description	Cause
Unknown test or sample type	The test and sample type identifier fields are known by the BA400, but the test was not programmed for the sample type.
Internal control request for an erroneous test or sample type.	An internal control was requested for a calculated test or for an external test.
Calculated test requires more than one sample type	An internal control was requested for a normal or ISE test and the quality control parameters are not programmed in the BA400.
Duplicate specimen	The calculated test is formed by tests with different sample types.
Duplicated request	The same specimen identifier was sent for different patients
	The same specimen identifier/test identifier /sample type identifier was already requested for the same patient and their result has not yet been sent.