BA200

LED TECHNOLOGY

User Manual

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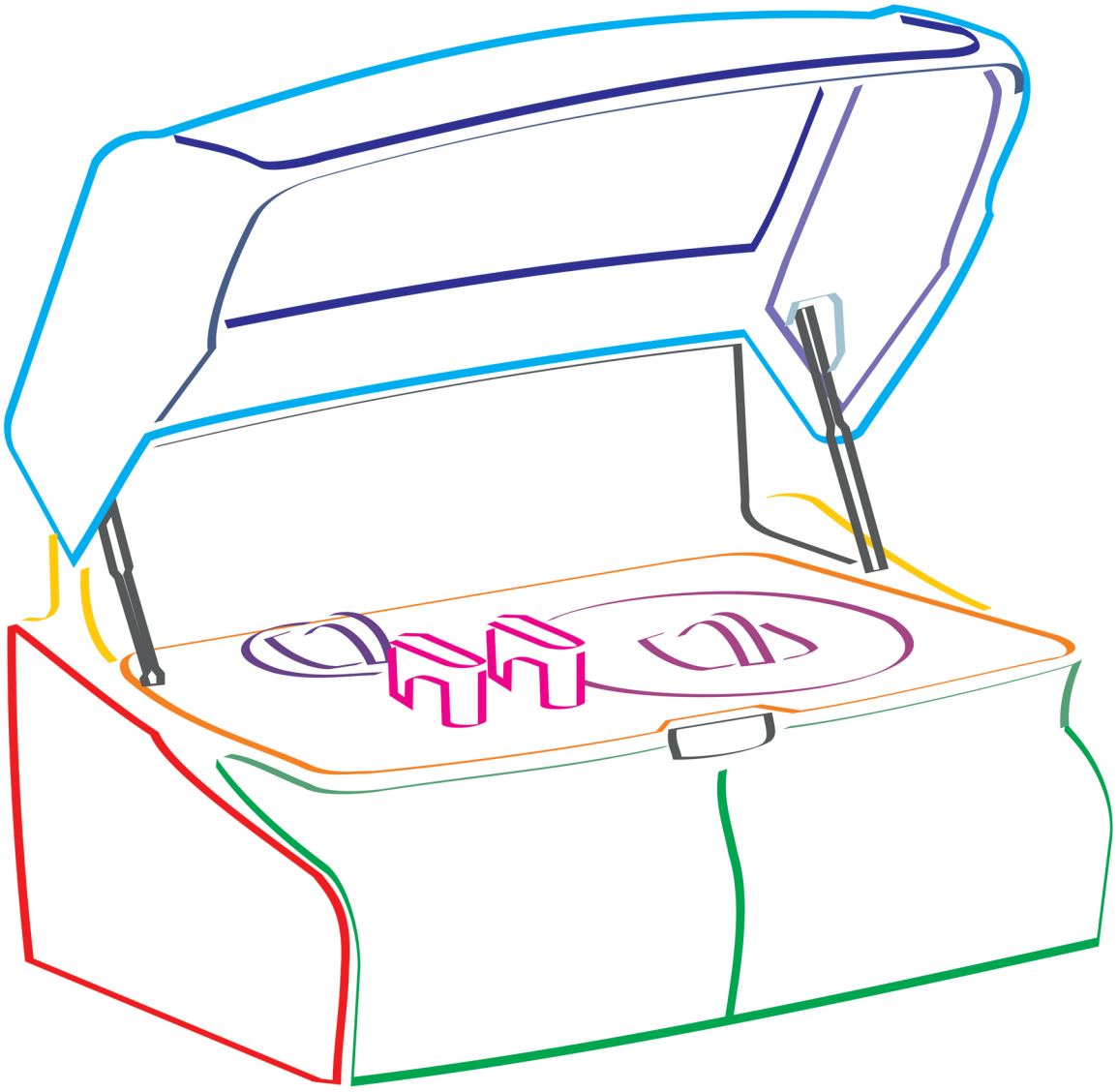

BioSystems
REAGENTS & INSTRUMENTS

Thank you for purchasing the BA200 biochemical and turbidimetric analyser

Manual version	Revision date	Changes
1.0	November 2016	Initial version

Manual code TEUS00055-01-ESP

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.

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The BA200 analyser is compliant with EU directive 98/79/EC

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Persons for whom this manual is intended

This manual is intended for the use of clinical laboratory professionals who will use the BA200 analyser to determine analyte concentrations.

This manual describes the characteristics and general operating concepts of the BA200 analyser. The installation, programming, execution and maintenance procedures are described in detail.

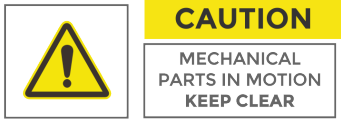
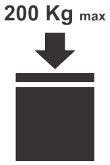
Notices and warnings

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 biohazard.
 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
CE	This product is compliant with directive 98/79/EC on medical devices for In Vitro Diagnostics.
IVD	Medical device for In Vitro Diagnostics
	Please consult the directions for use
SN	Serial number
	Expiry date
LOT	Lot code
REF	Catalogue number
	Temperature limit
	Manufacturer
	Irritant
IN Install by	Date of installation
H_2O DIST	Distilled water
	Caution, Possible biological and chemical spill
	Caution, Exclusive use of Biosystems Washing Solution
	Caution, Maximum weight 6 Kg

Symbol	Description
	Caution, Mechanical parts in motion, keep clear
	Packaging label. Keep upright
	Packaging label. Fragile
	Packaging label. Keep dry
	Packaging label. Keep vertical. Do not stack more than 200 Kg
	Packaging label. Heavy equipment

Safety precautions

Symbol	Description
	**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.
 BIOHAZARD	**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 practice.

Symbol	Description
 WARNING	**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 practice.
 BIOHAZARD	**Preventing biological risks in handling liquid waste** Handle the high contamination waste container with 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.
 BIOHAZARD	**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.
 NOTE	**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.
	**Preventing laser light emission risks** The analyser has a bar code reader that emits laser light. The reader only works when the analyser is in the 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.
	**Prevention at the end of the analyser's useful life** 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. In EU member states, 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 the distributor for the product to be properly recycled.

Screenshots The screenshots shown in this manual have a merely illustrative function. They do not necessarily reflect valid data.

Abbreviations and units shown in the manual

Abbreviation	Definition
∅	Diameter
ASTM	American Society for Testing and Materials (www.astm.org)
EC	European Community
EMC	Electromagnetic compatibility
CTRL	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
prep	Preparation
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	Time
Hz	Hertz
Kg	Kilogram
L	Litre
MB	Megabyte

Units	Definition
m	Metre
min	Minute
mL	Millilitre
mm	Millimetre
mmol	Millimol
mv	Millivolt
nm	Nanometre
s	Second
VA	Volt-ampere
V	Volt
W	Watt
µL	Microlitre
µm	Micrometre

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1. Foreseen use

The BA200 analyser is used to determine analyte concentrations by in vitro biochemical, turbidimetric and electrolyte measurements of human samples of serum, urine, plasma, cerebrospinal fluid or total blood.

The BA200 analyser is optimised to work with the BioSystems biochemical, turbidimetric and electrolyte reagents line. Reagents not included in the BA200 analyser validation performed at BioSystems SA require a full and exhaustive validation by the user or the laboratory.

We recommend a validation of the overall operation of the analyser and of the reagents by the laboratory, 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 the operation of the analyser and the software that goes with it.

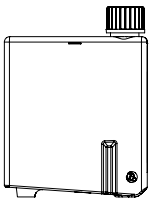
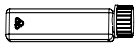
The environmental conditions for the functioning of the analyser are normal clinical analysis laboratory conditions. These conditions are described in the specifications chapter.

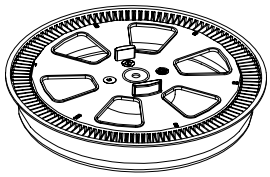
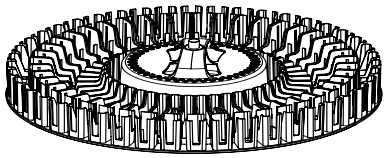
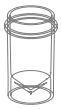
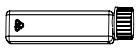
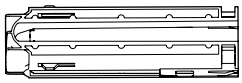
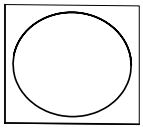
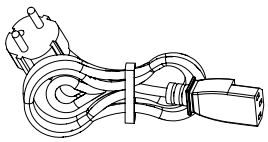
2. Contents

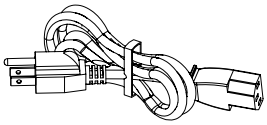
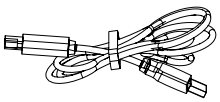
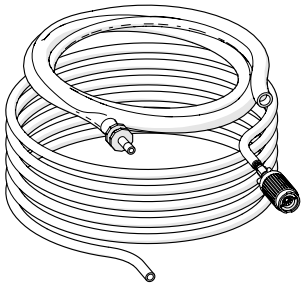
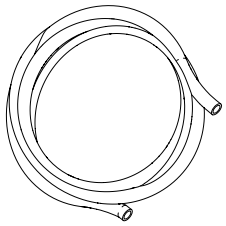
The elements that the user will find on unpacking the analyser are listed below. Make a visual check to ensure that none of the elements has suffered any apparent damage during transport.

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 60 mL reagent bottles (5)
	Empty 20 mL reagent bottles (5)

Accessory	Description
	Labels for identifying the empty bottles.
	Reaction Rotor (10)
	Reagent and samples rotor
	Lables to identify the rotor positions
	Sample wells (1000)
	Bottle of concentrated washing solution (500 mL)
	Bottle of acid washing solution (20 mL) (1)
	Paediatric adapter (50)
	Tube adapter (50)
	DVD with the user programme and user manual.
	Mains connection cable, European plug

Accessory	Description
	Mains connection cable, American plug
	USB cable.
	Fuses (2).
	Connection tube for purified water bottle (2). One thick tube and thin one coloured blue (3 m).
	Connection tube for waste. Red tube (3 m).

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:

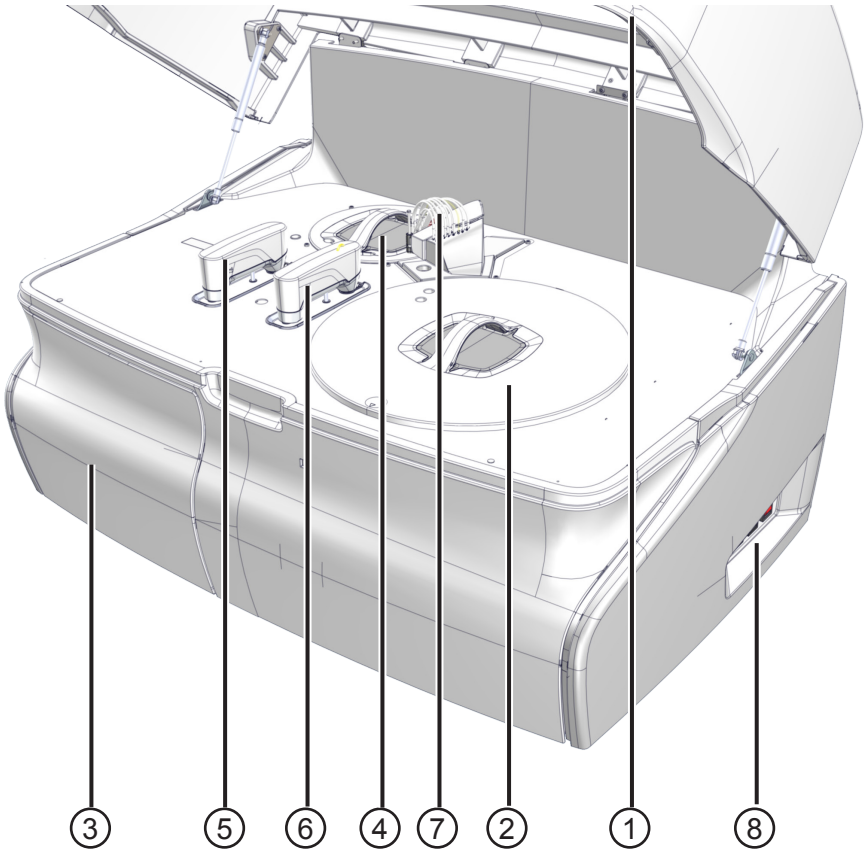


Figure 1 Main components

1 – General cover
2 – Reagent and samples rotor
3 – Bottle and ISE module access door
4 – Reaction rotor cover
5 – Stirring arm
6 – Dispensing arm
7 – Wash station
8 – Switches

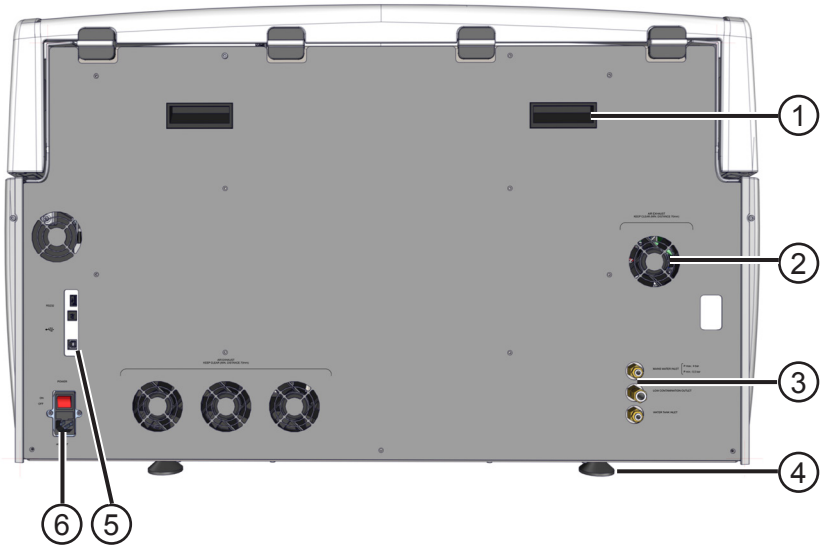


Figure 2 Rear view components

1 – Rear cover handle
2 – Ventilation outlet
3 – Distilled water and waste connection
4 – Adjustable leg
5 – USB connection
6 – Main voltage switch

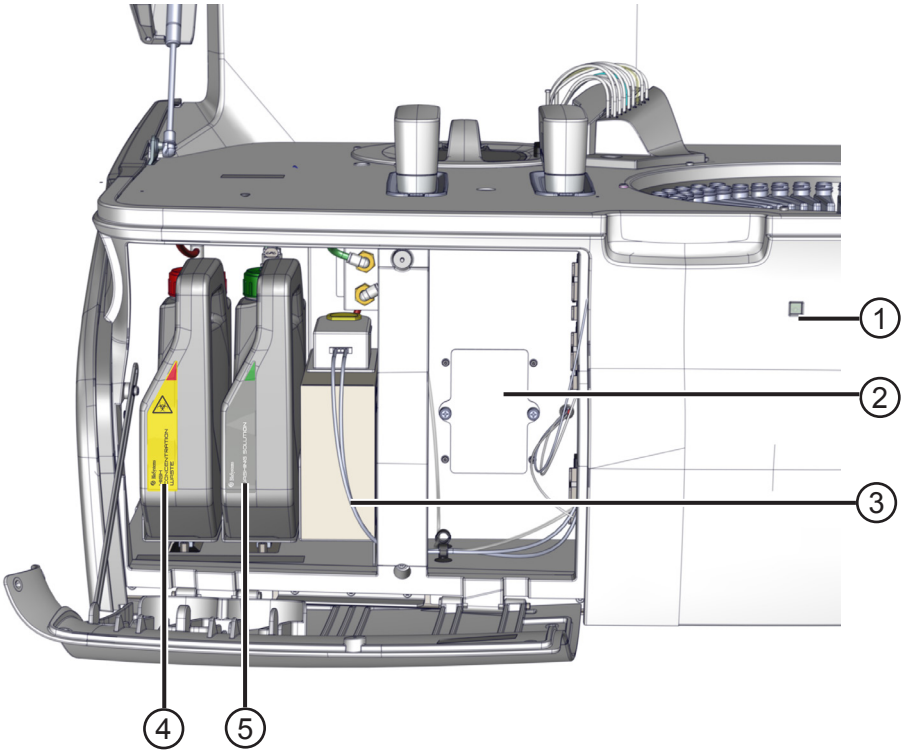


Figure 3 Internal components

1 – LED status lamp
2 – ISE module
3 – Reagent kit for ISE module
4 – High contamination waste bottle
5 – Cleaning solution bottle

4. Installation

4.1. Location

Location Install the analyser in a large space. It occupies a minimum space of 107 cm x 75 cm.

Leave a space of at least 15 cm behind the analyser for the air to circulate from the fan outlet.

Leave a space of least 70 cm above the analyser to allow the main cover to be opened.

Leave a space of least 40 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. 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.

Electromagnetic radiation 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.

Once in the final position, anchor it. Unscrew the four adjustable legs (1) until they touch the table. (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).

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.

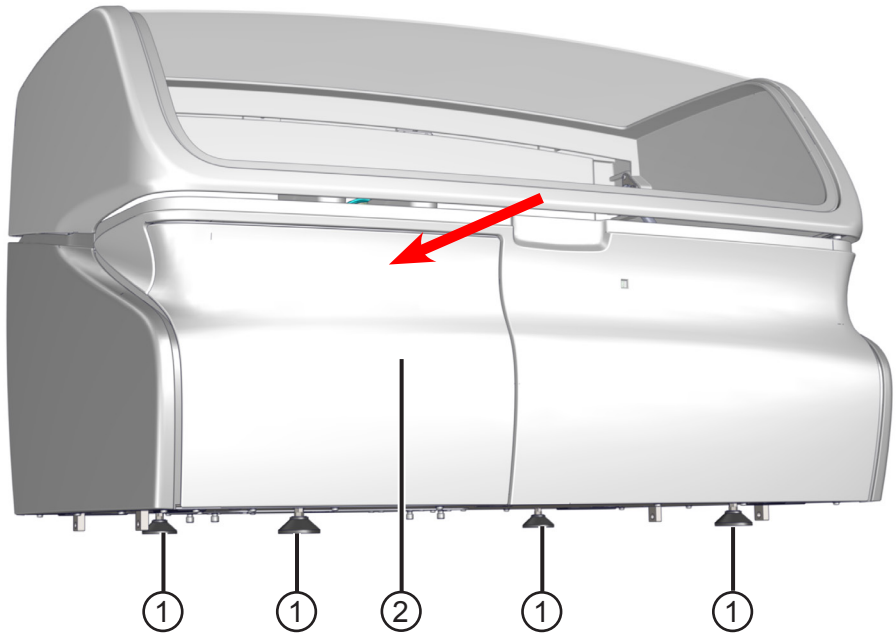


Figure 4 Adjustable legs and front cover opening

Figure 5 Securing the legs

4.2. Front door opening

The front door is located on the left side of the analyser (2). Press the front of the door with your hand to release the magnet that keeps it closed. Slide the door outwards to open it. To close the door, guide it until it touches the magnet. Then press the contact point to return the door to its original position.

☞ *See Figure 4*

4.3. Installing the waste containers and washing solution.

If you open the front door, you will see two bottles inside. The one on the left is the high contamination waste bottle (1) and the one on the right contains the washing solution (2). See Figure 6.

To handle the bottles in safety, leave them on the front door after opening it, to enable the tubes to be disconnected and connected. The door is designed to support a weight of no more than 6 kg.

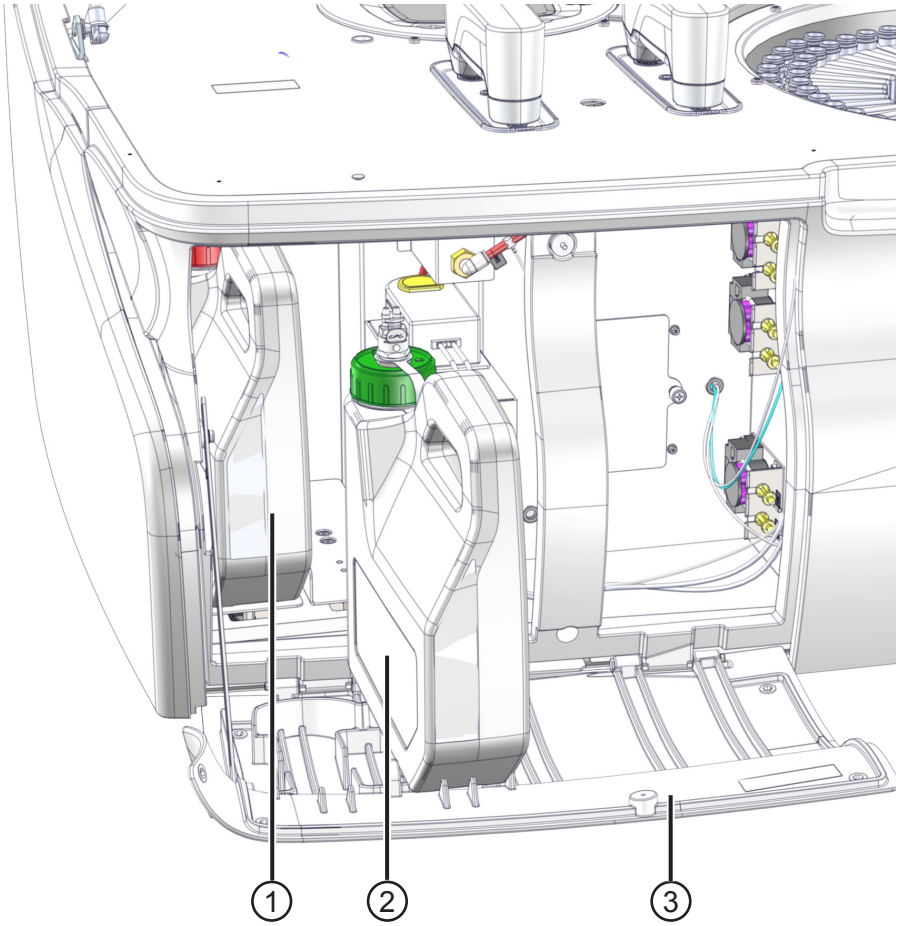


Figure 6 Location of the waste bottles and washing solution

4.3.1. Preparing the washing solution

1. Unscrew the cap of the washing solution bottle (5).
2. Fill it with 2.4 L of purified water.
3. Add 12 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.

NOTE

4. Screw on the cap, connect the tubes and place it in its housing inside the analyser.

4.3.2. Emptying the high contamination waste container

The high contamination waste container (4) is supplied with a fast connector fitting.

1. Press the fast connection 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.

4.4. Purified water connection

The analyser has two purified water inlets at the rear. See Figure 7.

Once the user programme 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 blue tube in the accessory box to the top connector (1). It is marked "MAINS WATER INLET". Connect the other end to the water mains.

NOTE

3. Ensure that the central purified water system output is fitted with a filter. If there is no filter, one must be installed between the purified water production system and the analyser.

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 6.6 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 lower connector (3). The connection is marked "WATER TANK INLET". Insert the other end in the base of the external tank. There is a connection with a weight in the accessory box. Connect it to the end of the tube to ensure the tube does not bend.

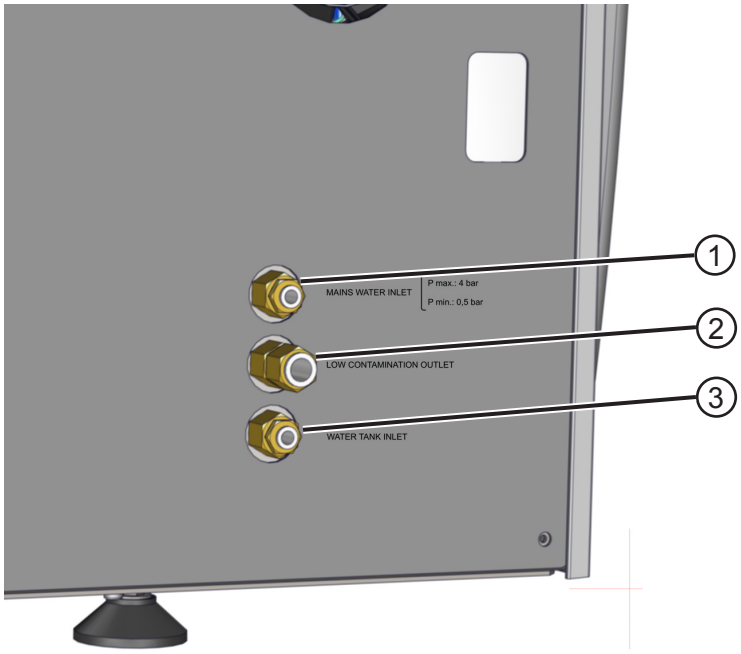


Figure 7 Liquid connections

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

4.4.1. Positioning the tubes

The analyser has a fast connector system for connecting the water and waste tubes.

☞ *See Figure 8*

Connecting the tube To connect any of the tubes, insert the tube (1) into the connector as far as it will go. Pull the tube outwards to block the nozzle (2) and ensure it is sealed.

Disconnecting the tube To disconnect the tube (1), press the nozzle inwards (2) to release the tube. Pull it to remove it.

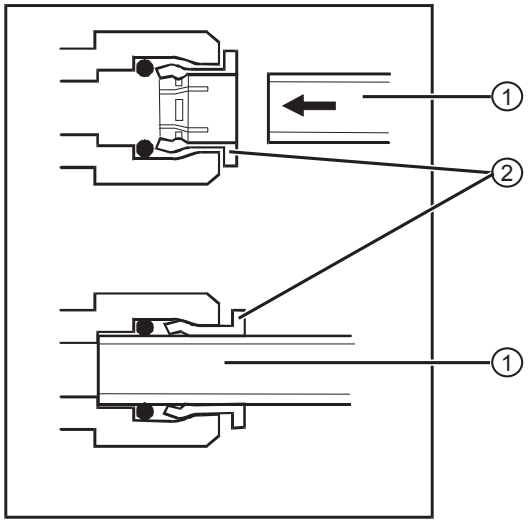


Figure 8 Tube anchoring system

4.5. Low contamination waste connection

NOTE

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 central connector of the analyser (2). See Figure 7. 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.

4.6. Installing the sample and reagent rotor

The sample and reagent rotor is in the accessory box. Remove it and place it in its position.

The rotor has an 88-position capacity for reagent bottles and/or samples (they can be placed in the primary tube or the sample well). The positioning of the bottles and samples is fully adaptable to the needs of the laboratory.

The compartments are already prepared for the reagent bottles to be placed in them directly. The 60 mL bottles must go on the inner ring, while the 20 mL bottles may be placed on the inner or outer ring.

To position the samples, first insert the tube adapters (2) in the positions in which you wish to place the samples. The adapter is positioned with the longitudinal opening facing outwards to permit the bar code laser scanner reading. Press hard until you hear a "*click*" indicating the correct entry of the fastening tab. The adapters (2) can be removed from their position by pulling them outwards.

☞ *Figure 9 shows how to place the adapters for samples.*

The primary tubes (4) with diameters of 14 mm and 15 mm are inserted directly into the adapter.

To use the 13 mm diameter tubes and sample wells the adapter must first be put in place (1).

It is advisable to place the samples on the outer ring and the reagent bottles on the inner ring. In the event of requiring a higher capacity for samples, the adapters can also be placed on the inner ring.

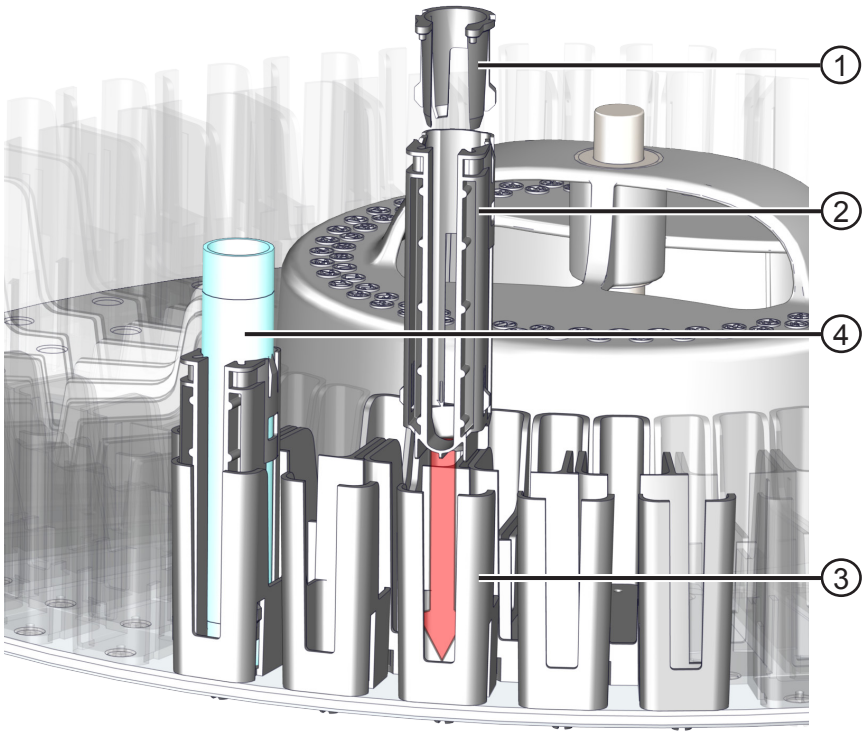


Figure 9 Placing the adapters for tubes and sample wells

Replacing the rotors

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

1. Remove the rotor cover.
2. Press the central button on the handle to release the rotor.
3. Remove the rotor from its housing. Be careful, as if the rotor is full, it may weigh up to 5 kg.

NOTE

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 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.

NOTE

4.7. 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.

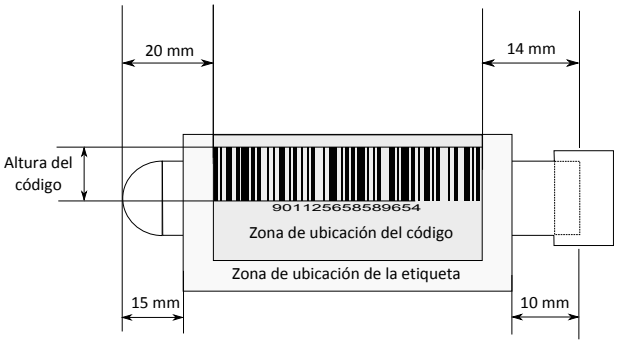


Figure 10 Positioning of the label on the primary tube

- Respect the barcode label position margins, as shown in Figure 10.
- 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 ± 7.5% or ± 4.2 ΣΔγρ with respect to the sample container axis.
- It is advisable to use CODE128 for the barcode, but the scanner can also read CODE 39, CODEBAR, CODE 93 and INTERLEAVED 2 OF 5.

4.8. 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 chart 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 H20	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 programme will ask you to associate that bottle to a reagent in the list.

4.9. 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 programme in section 10.1*

☞ *See functions, rotor change in section 10.9.1*

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. Hold the rotor by the tabs and not by the wells, to prevent the optical window from becoming dirty.
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 programme.

4.10. 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

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

☞ *See Figure 11*

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 11 Fuse location

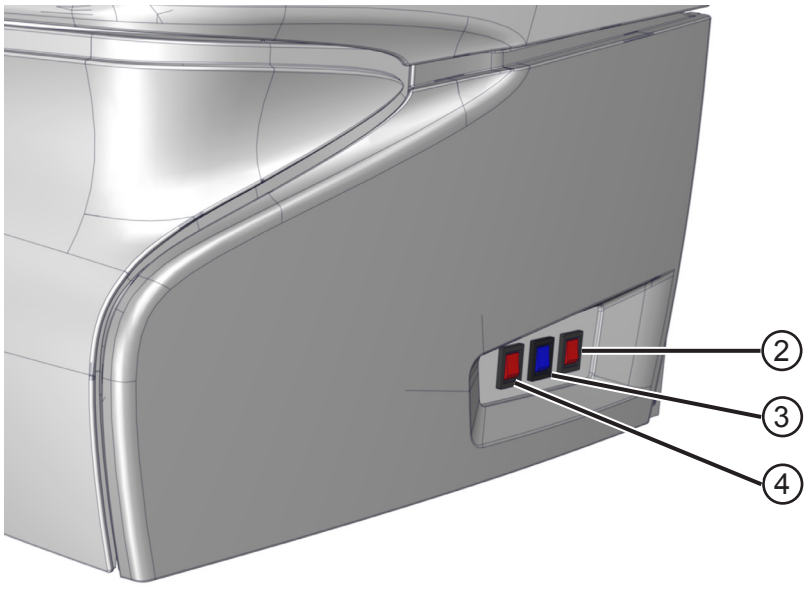


Figure 12 Analyser switches

1 – Main switch
2 – ISE module switch (optional)
3 – Refrigeration system switch
4 – Analyser switch

Electrical connection

Proceed as follows:

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

4.11. Connection to the computer

The computer must be fully dedicated to the operation of the analyser. 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*

Auxiliary USB connections

At the rear of the appliance there are 2 auxiliary ports for restricted use. These ports are not used for connecting the software with the analyser.

4.12. Installing the user programme in the computer

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

- Operating system: Windows® 7 64 bit (x64), Windows® 10 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 is different from 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 programme in *Home*:
Control panel\All Control panel elements\Programmes and characteristics

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

NOTE

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 13*

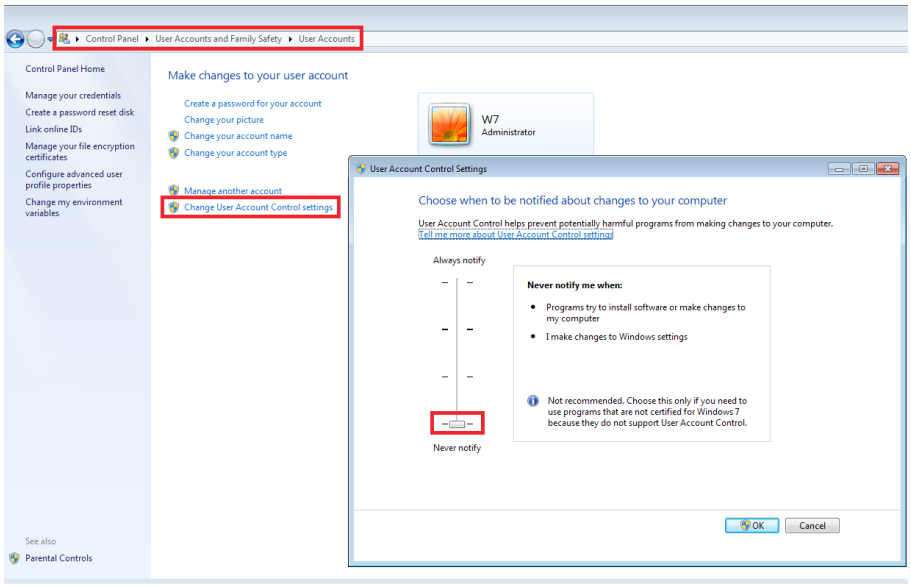


Figure 13 Change user account control configuration screen

Install the program by proceeding as follows:

1. Insert the disk into the DVD drive of the computer.
2. Press *Start*, select *Execution* and write:
3. *D:\setup\setup.exe*, or the name of the DVD unit
4. Follow the steps indicated by the installer programme.
5. The installer programme 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 programme.
6. The installer programme may last for up to one hour. Wait until the installation has finished.
7. Configure the operating system with the following characteristics:
   - Screen resolution: 1 024 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 or Windows 10

     ☞ *See Figure 15*

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

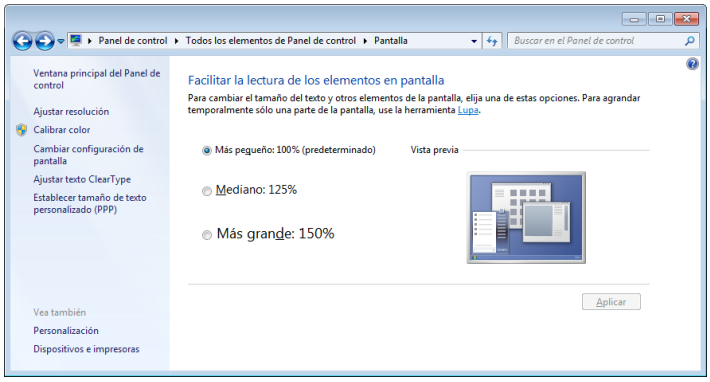


Figure 14

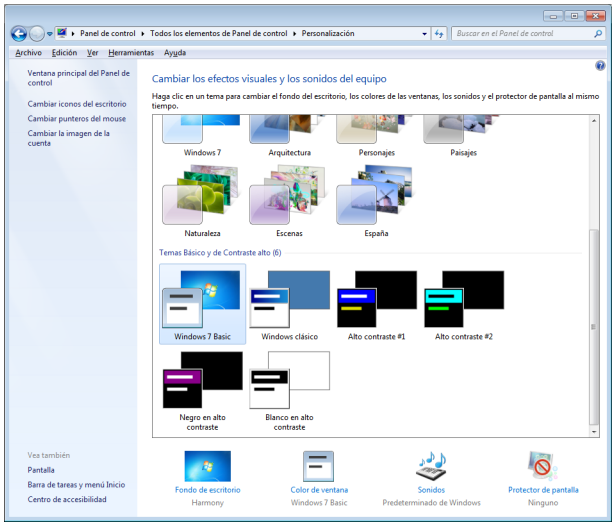


Figure 15 Text configuration screen

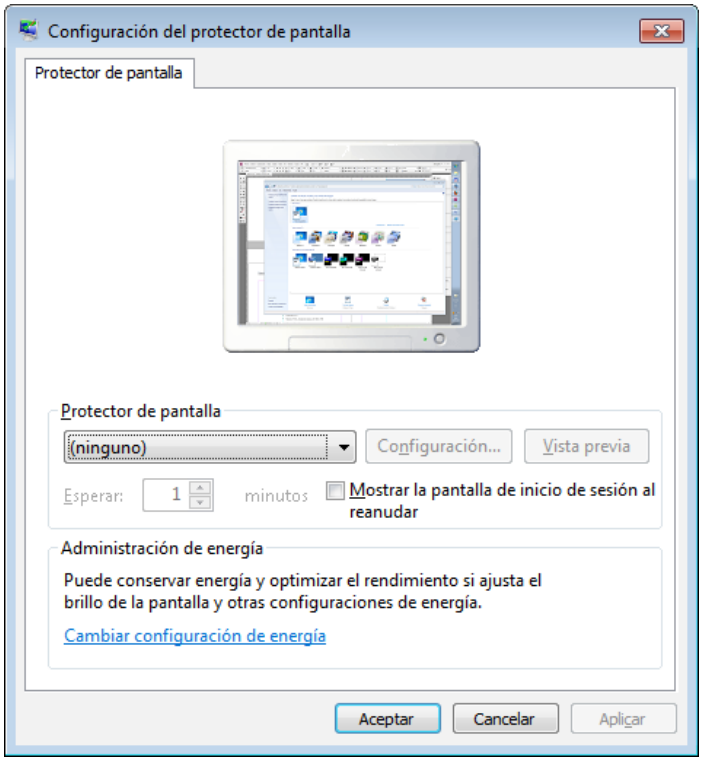


Figure 16 Screen saver options

4.12.1. 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

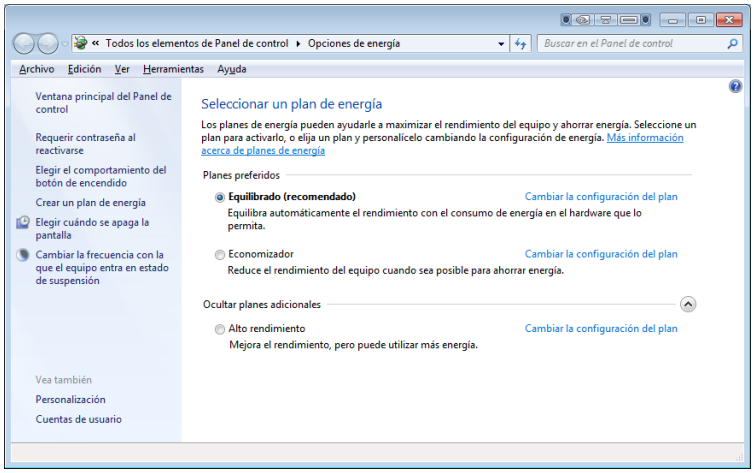


Figure 17 Energy options configuration

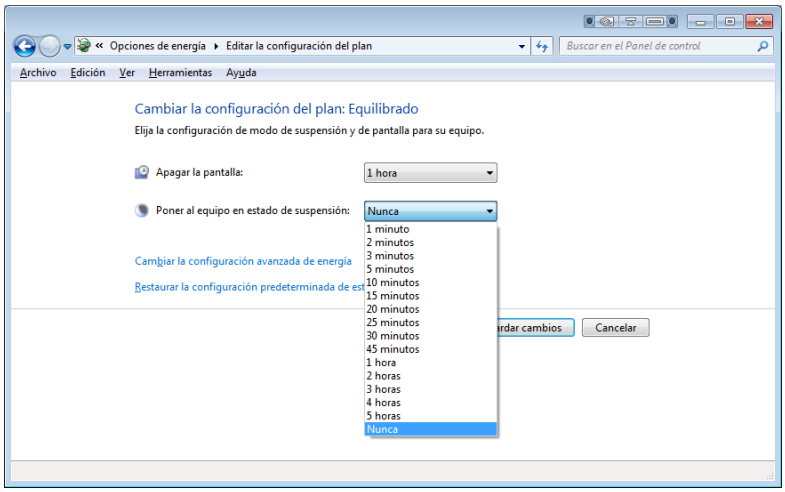


Figure 18 Change the energy options

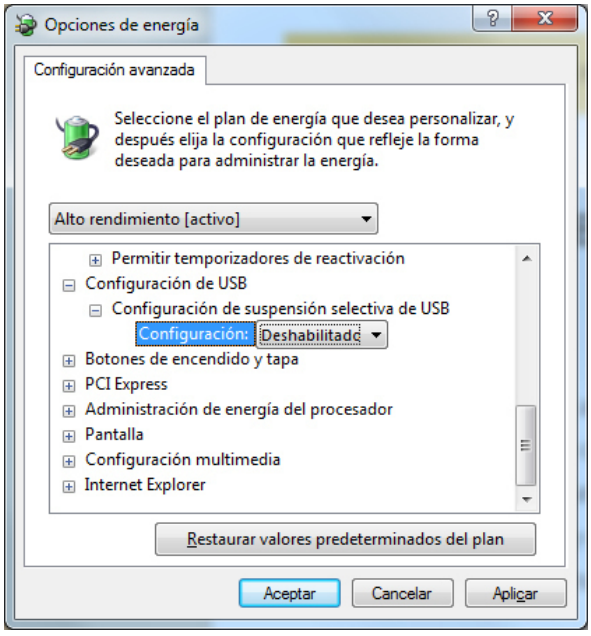


Figure 19 Change the USB energy options

4.12.2. 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:

4.12.2.1. 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 instance, a Saturday.

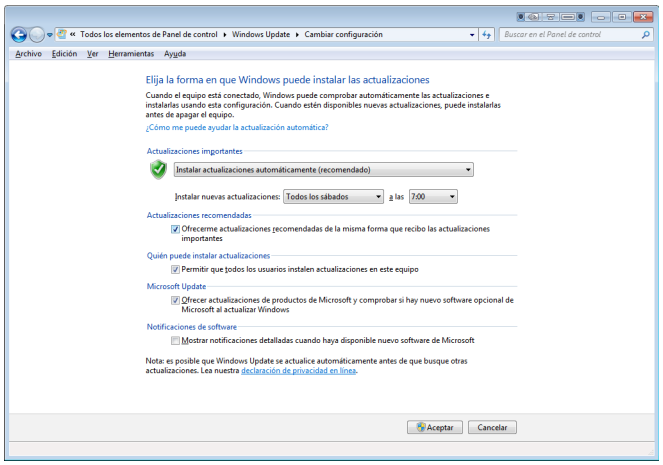


Figure 20 Windows Update configuration

4.12.2.2. 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.

Updating of Windows, antivirus programmes or other installed programmes may cause a lack of compatibility that affects the operation of the BA400 programmes: User application, Service application or LIS communication Libraries.

To rapidly resume operability, we recommend you programme the automatic and regular performing of operating system restoration points. This must always be done before the Windows or antivirus programme updates.

If you detect any problem related to compatibility after an update, immediately report the problem to your Technical Service, attaching a SATReport and the date on which the problem was detected. While Biosystems analyses the problem and designs a solution to guarantee compatibility, restore the operating system to the last date of stable operation. This will enable you to continue working.

4.12.2.3. 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*.

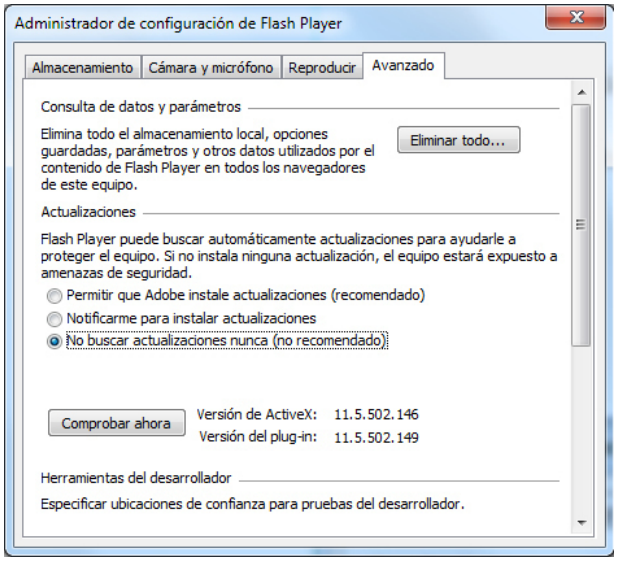


Figure 21 Flash update

4.12.2.4. Java updates

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

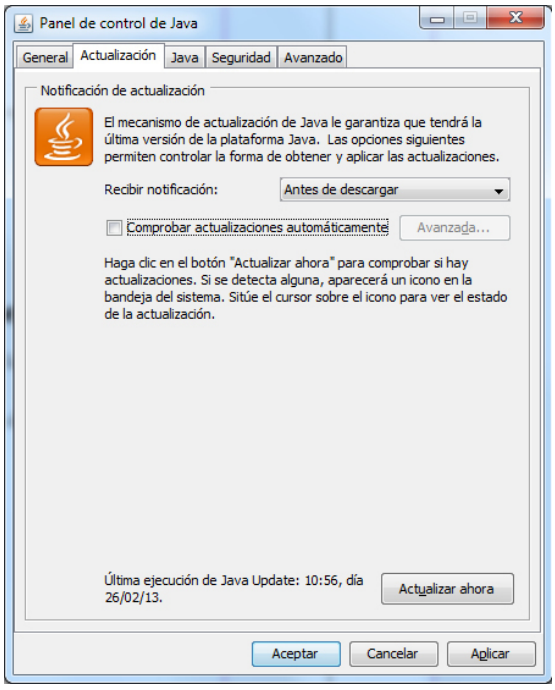


Figure 22 Java update

4.12.2.5. 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	FDResPub
Diagnostic directives service	DPS
Windows Search	WSearch

7. Save the changes.
8. Reboot the computer.

4.13. ISE module installation (optional)

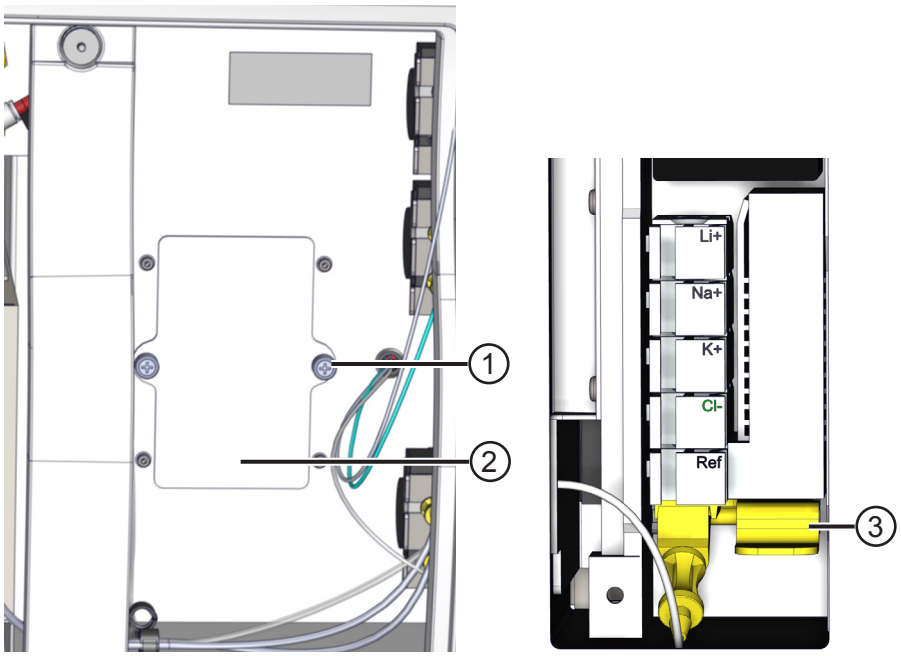


Figure 23 Order for positioning the different electrodes

Electrode installation

After opening the front cover the ISE module can be directly accessed. See Figure 23.

1. Turn off the ISE module power supply using the switch.
2. Unscrew both screws by hand (1) and remove the cover (2) to access the compartment 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.
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 23. 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 an 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.

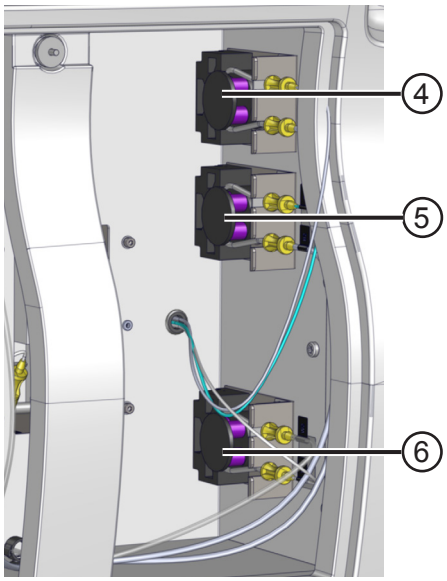


Figure 24 Tube connection

Tube installation

Insert a tube into each peristaltic pump. To insert the tube into the head of the peristaltic pump release the pressure on the head by pulling to the side of the clamp, see Figure 24.

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 (6). The order for putting them in place starting from the bottom is W1 and W2.
- The tubes marked B must be installed in the pump (5). The order for putting them in place starting from the bottom 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 bottom is A2 and A1.

Take care when connecting the tubes of the waste pump (6) as they are connected in reverse order to the tubes of the pump for calibrators A (4) and B (5).

Installing the reagent kit

Unpack the kit, remove the three 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 programme, execute the actions in the number and order indicated in the *Installation/Activation option*of the *ISE functions section*.

☞ *See chapter 10.9.3*

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 *Read reagent Kit* 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. ☞ *See chapter 14.2.9*

Step	Action	Repetitions	Description
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.
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	

4.14. First steps for operating the analyser

1. Replenish the washing solution tank.
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 rotor.
6. Install a reaction rotor.

☞ *See chapter 4.9*

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 *Communications configuration* tab in the *General* submenu of the Configuration *menu.*
11. Select the *automatic* option.
12. In the same menu select the *Analyser* tab.
13. Selection one of the two *water inlet selection* options, depending on the water inlet installation.

☞ *See chapter 10.2.1*

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.

☞ *See chapter 10.9.2*

16. In the event of having an ISE module, install the electrodes and reagent kit.

☞ *See chapter 10.9.3*

17. Fill in the calibrator concentration fields and controls of the tests to be used.

☞ *See chapters 10.3.5 and 10.3.6*

18. Make a list of blanks, calibrators and controls.

☞ *See chapter 10.5.3 and 10.5.4*

4.15. Cautions during operation

- In analysers with the ISEinstalled, you should never turn off the module switch. The module automatically performs a priming cycle from time to time. To turn off the ISE module follow the steps indicated in chapter 14.3.2.4
- To maintain the reagents refrigerated when the analyser is off, leave the refrigerator switch in the on position.

NOTE

- When the analyser is operating, do not open the main cover without first pressing the *Pause*  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 rotor 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.

NOTE

- 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

- The positions of the sample tubes and reagent bottles must be maintained when the Automatic Barcode Verification is not used before starting / continuing the work session.
- When using sample tubes of 15 mm in Ø or with a capacity of 15 mL, do not fill them to the brim with the sample. Fill them with no more than 14 mL in order to correctly detect the sample.

NOTE

- Use the positive identification of sample tubes whenever possible. That is, use the bar code to identify sample tubes. This will prevent possible errors in the placement of tubes in the rotor of samples.

4.16. Preanalysis and preparation of additional solutions

Reagents

Follow the usage and safety instructions set out in the IFU (Instructions for Use) of the reagents for their preparation and handling.

Before using the reagent for the first time, check the test programming against the programming supplied with the reagent.

In the case of reagents with contents that must be homogenised, do this gently, without shaking them. If air bubbles have formed on the reagent surface, eliminate them.

When changing the reagent lot, make sure you perform the blank and calibrate the test.

It is recommended to perform a reagent blank when changing the reagent bottle and/or in accordance with the frequency established by the IFU.

Condensation could form on the walls of the reagent bottle, on the neck of the bottle or on the barcode labels. If condensation is present, eliminate it with an absorbent paper towel.

Primary serum tubes

For the correct operation of the analyser, carry out the sample preanalytical phase on 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.

NOTE

To obtain precise results, the samples must be free from clots, fibrin, etc., which could block the sample tip or ISE module reader channel. Also check that the serum has no air bubbles.

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 tip.

Never insert samples that are extremely lipaemic and/or haemolysed.

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. The anticoagulant must be compatible with the determinations that are to be made.
   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.

NOTE

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. Make sure the cell phase is properly separately from the aqueous phase.

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 and a diluent code of 5412.

- The analyser uses 200 µL to make an ISE determination 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 or paediatric vial.
- 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.

Washing solutions

The washing solutions supplied with the equipment are of two types, the washing solution (WS) used for internal washing of the tips and reaction rotor and the acid washing solution (WS1) used to prevent contamination.

The washing solution (WS) is prepared in the 2.4 L bottle located on the left side of the front of the equipment.

The acid washing solution (WS1) is installed in the reagent rotor. It is supplied in 20 mL bottles.

Handle these solutions with care and wear the appropriate clothing and gloves. Never mix both washing solutions as they could give off dangerous gases.

5. Transport and reshipment

The analyser weighs 166 kg. The analyser has legs made of hard plastic to allow it to be moved on a smooth surface when it is necessary to access the rear part.

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 14.3.2 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.

Sleeping state (SLEEPING)

During this state the analyser is stopped and all its electronic systems are dormant, to save energy. The analyser will not perform any operation until the *warm-up*state is activated.

Initial state (WARMING UP)

During this state the analyser initialisation process is started. The initialisation process consists of the conditioning of the fluidic system and thermostating the reaction rotor so that it reaches the correct temperature and ends with the rotor baseline execution. The baseline consists of filling all the reaction rotor wells with distilled water, measuring the absorbance in each well with all the wavelengths and checking that the measurements are within the ranges. If the measurements are correct the rotor is emptied and dried. These baseline readings serve to correct the preparation reading absorbances. The whole baseline reading process takes about 20 minutes.

Stand-by state (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 (RUNNING)

During this state the analyser performs several repetitive cycles to prepare the reactions and take the measurements. The dispensing arm performs two different movements, firstly suctioning of R1 and sample and secondly, suctioning and dosing of R2. A reagent is prepared in the following way:

1. Suctioning of reagent 1 and sample, dispensation in the reaction rotor.
2. Stir the reagent 1 and sample mixture.
3. Start the reading period.
4. Suctioning of reagent 2 and dispensation into the reaction cuvette 5 min. after dispensing R1.
5. Stir the mixture with the second reagent.
6. Finalise the reading processes.
7. 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 (PAUSE)

During this state the analyser stops the sample and reagent dispensing process, allowing the user to access the sample and reagent rotors and to 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:

- Cover and lids
- Sample and reagent rotor
- Reaction rotor
- Dispensing arm
- Stirring arm
- Wash station
- ISE module (optional)
- 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

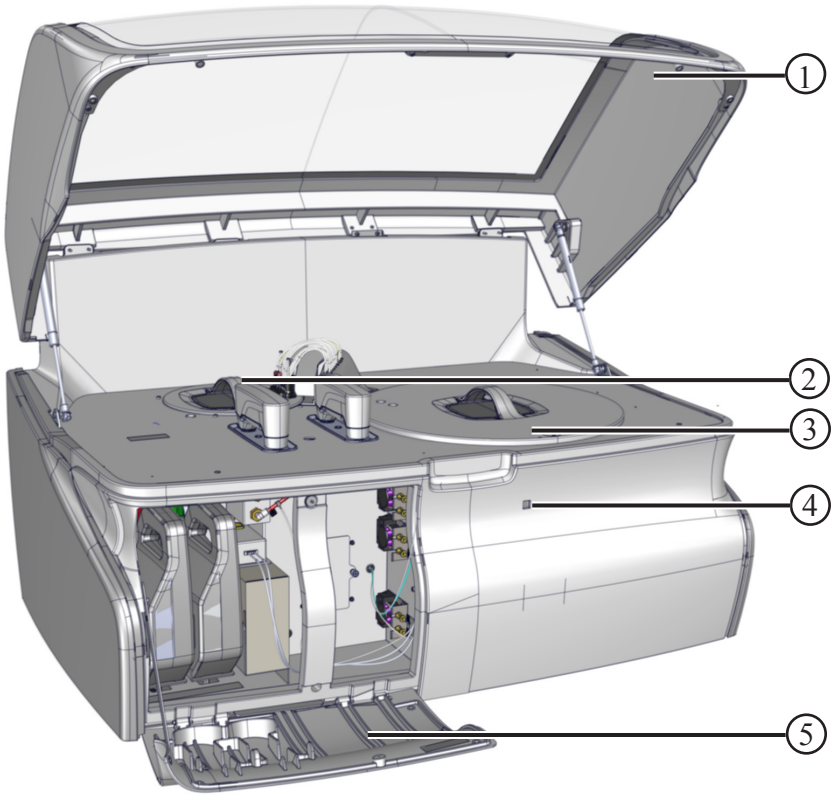


Figure 25 Covers

1 – Main cover
2 – Reaction rotor cover
3 – Sample and reagent rotor cover
4 – LED status lamp
5 – ISE module access cover and front door

Main cover 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.

Sample and reagent rotor cover This gives access to the sample and reagent rotor. The patient samples, calibrators, controls and reagents are placed in this rotor. The rotor unit is refrigerated. The cover has a detector that enables the program to detect the presence of the cover.

Reaction rotor cover 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 SDgrC. The cover has a detector to allow the programme to detect the presence of the cover.

Front door It provides access to the washing solution and high contamination waste bottles, and also to the ISE module (optional unit).

Led status lamp This lamp indicates the analyser state. Possible states:

Colour of LED	Description
Off	Analyser off.
Orange	Analyser in sleep mode (SLEEP).
Flashing orange	Analyser in the process of being initialised.
Green	Analyser initialised. Waiting for actions mode (STAND-BY).
Green light flashes slowly	Analyser performing an operation or work session (RUNNING).
Green light flashes quickly	Analyser in pause state. The user can access the sample and reagent rotor.
Red	Analyser with unresolved errors.
Flashing red	Analyser performing an action with unresolved errors.

Table 1 Analyser states indicated by 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 generate 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 and reagent rotor

The sample and reagent rotor consists of a removable drum with positions for inserting the sample tubes, calibrators, controls and reagents. The system is completely flexible and samples or reagents can be inserted in any position. The rotor has a barcode reader for the automatic identification of the samples and reagents placed on the rotor.

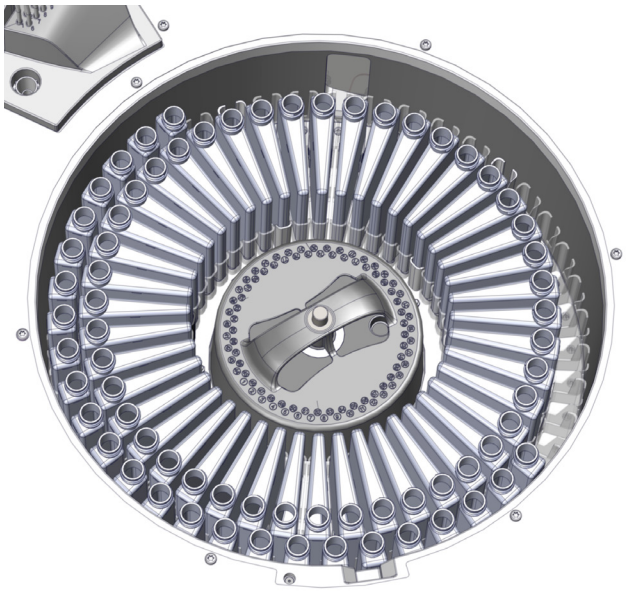


Figure 26 Reagent and samples rotor

Positions There are 88 positions in all, laid out in two rings. The bottle and sample barcodes can be read in both rings.

Sample tubes To position the tubes, an adapter must first be inserted (see chapter explaining how to position the adapter) Primary tube dimensions:

- Minimum diameter: ∅12 mm
- Maximum diameter: ∅16 mm
- Minimum height: 70 mm
- Maximum height: 100 mm

Sample wells To insert the sample wells in their positions, an accessory is supplied with the analyser for adapting the diameters. See chapter 4.6 explaining how to position the adapter.

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.

8.3. Reaction rotor

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

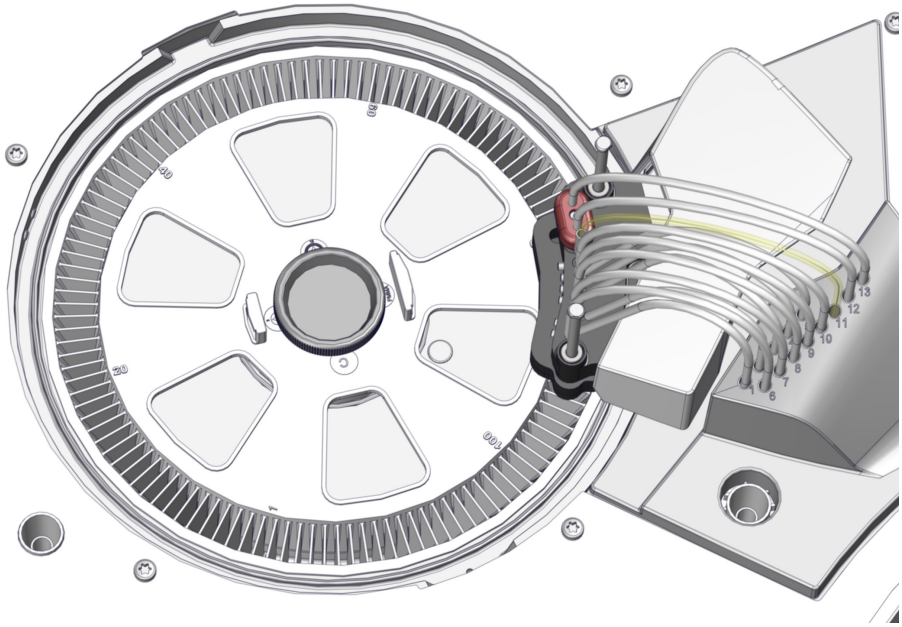


Figure 27 Reaction rotor

Positions 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.

Volume The reaction volume is between 180 µL and 600 µL.

Temperature The rotor is maintained at a stable temperature of 37 °C by a Peltier-based thermostating system.

Dispensing cycles for each of the arms:

- Cycle 1: Dispensing *Reagent 1* and *sample*
- Cycle 2: Stirring *Reagent 1* and *sample*
- Cycle 3: Initiation of photometric readings
- Cycle 18: Dispensing of *Reagent 2*
- Cycle 19: Stirring of *Reagent 2*
- Cycle 35: End of the reading processes
- Cycles 36 - 46: Washing of cuvettes in the wash station

8.4. 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.

Wavelengths 340 nm, 405 nm, 505 nm, 535 nm, 560 nm, 600 nm, 635 nm and 670 nm

Measuring range From -0.2 A to 3.5 A

Resolution 0.0001 A

The system automatically performs a cuvette blank of the whole rotor when the analyser is initialised. This cuvette blank absorbance serves to correct the reaction absorbance measurements. When the well enters the wash station, it is read again to check that it is in optimal conditions. If this value exceeds a pre-established limit, the well is rejected.

8.5. 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 programme warns of the need to replace the plastic rotor.

8.6. Stirring arm

The analyser has one arm for stirring the reaction. This arm has a small blade that rotates inside the reaction cuvettes, to favour mixing and initiate the reaction correctly.

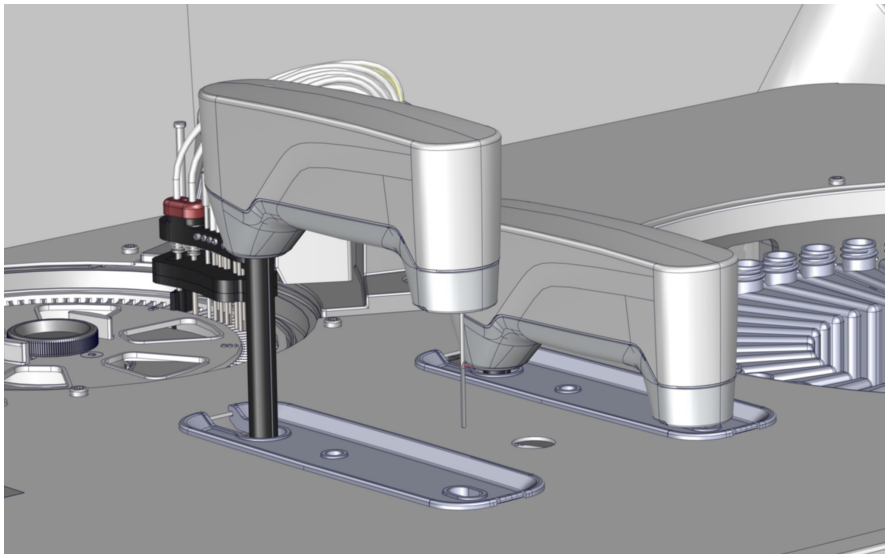


Figure 28 Stirring arm

Cycles Operating cycles of each arm

- Cycle 2: Stirring of R1 and Sample.
- Cycle 19: Stirring of R2.

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

8.7. Dispensing arm

The analyser has 1 arm for dispensing the samples and reagents.

The samples and reagents 1 and 2 are dispensed with the arm.

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

Dispensing volumes Minimum and maximum volumes that can be dispensed by the arm:

- Samples: from 2 µL to 40 µL
- Reagent 1: from 90 µL to 300 µL
- Reagent 2: from 10 µL to 100 µL

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

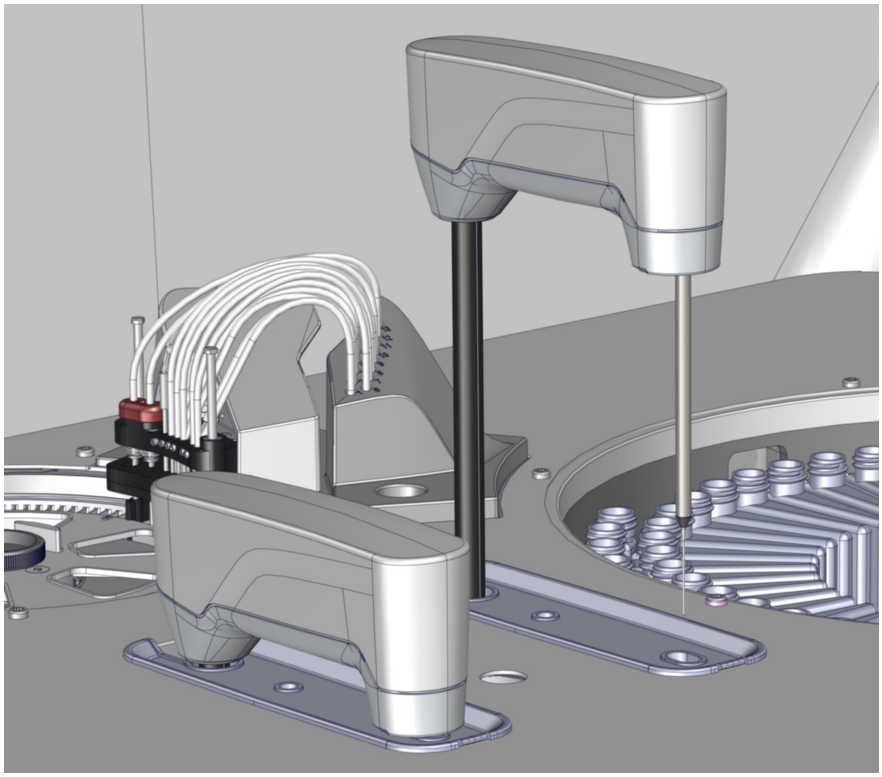


Figure 29 Dispensing arm

8.8. 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 2.4 L. It has 20 hours of autonomous operation. The container level is determined by its weight.

Washing solution It is accessible from the front part of the analyser. The capacity is 2.4 L. The container level is detected by its weight. It has about 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 4.5*

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 4.4.*

8.9. ISE module (optional)

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

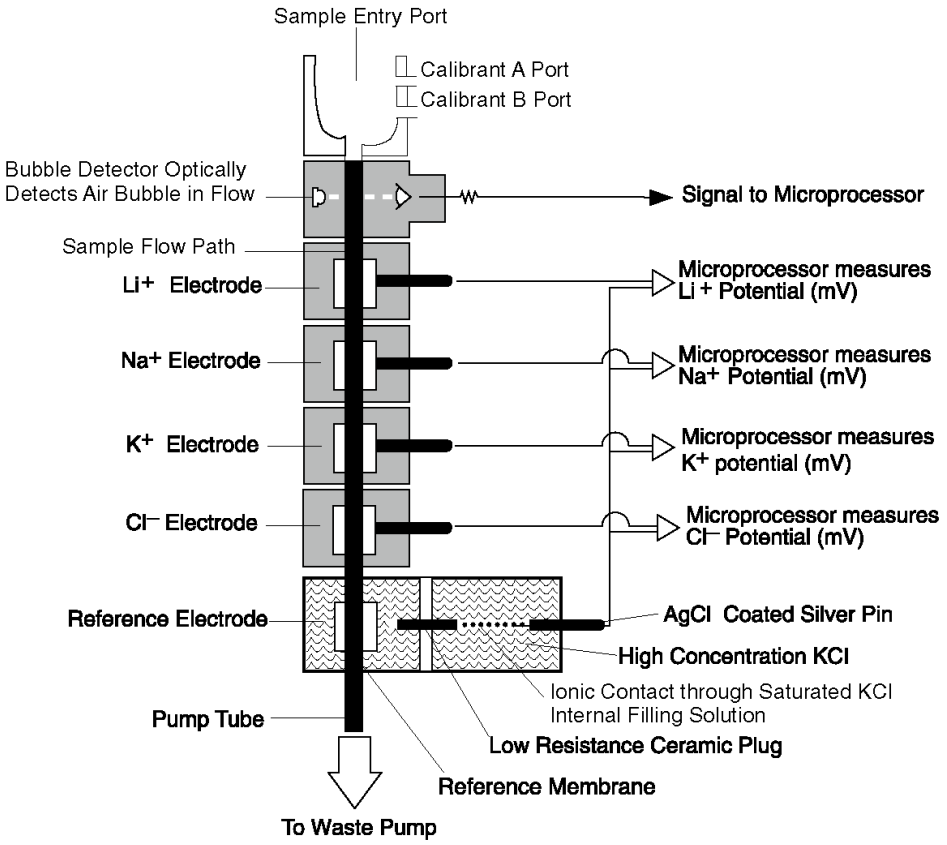


Figure 30 ISE module diagram

The measurements are taken using ion-selective electrodes. Figure 30 contains a diagram of the measuring system. A more detailed explanation of the calculation process is given in chapter 16.5.

The temperature of the room where the analyser with the ISE ion reading module is located must be between ±4 °C and 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 programme.

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 programme 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.

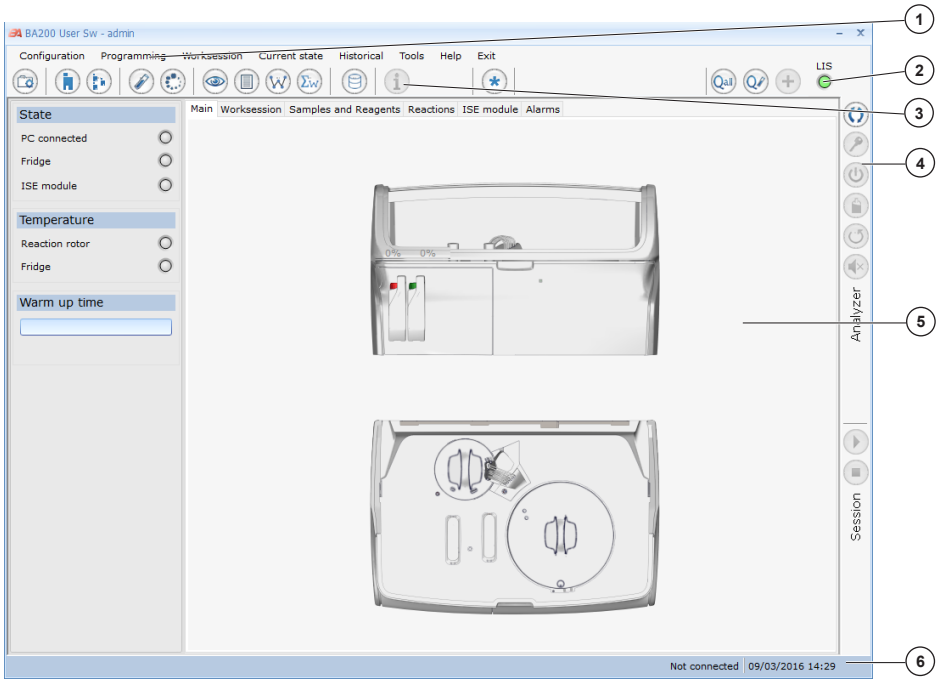
Both liquid A and liquid B are supplied with the reagent kit. That kit is connected directly to the ISE module.

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

9. Description of the software

9.1. Identification of the programme parts

Figure 31 shows the main areas of the programme. These parts are common for the whole programme and are always visible.



1 – Menu bar
2 – LIS connection buttons
3 – Fast access buttons
4 – Action buttons
5 – Main window
6 – Information bar

Figure 31 Screen format

☞ *See Software installation in the installation manual*

Menu bar This gives access to the programme 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: SLEEPING, WARM-UP, STAND-BY, RUNNING, PAUSE

9.1.1. List of most frequently-used buttons

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

Icon	Name	Description
	New	Allows an element to be created: test, calibrator, 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 programme 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 programme.
	Access to the profiles programme.
	Access to creaction 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 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. ☞ *See chapter 17.2*
	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 10.5.3*

Icon	Name	Description
	Add orders *Download Orders*	Button that is activated when orders are received from the LIS which must be added to the work session. ☞ *See chapter 17.2*

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 programme 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 *start session* 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 programme, double click on the icon located on the desktop.

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

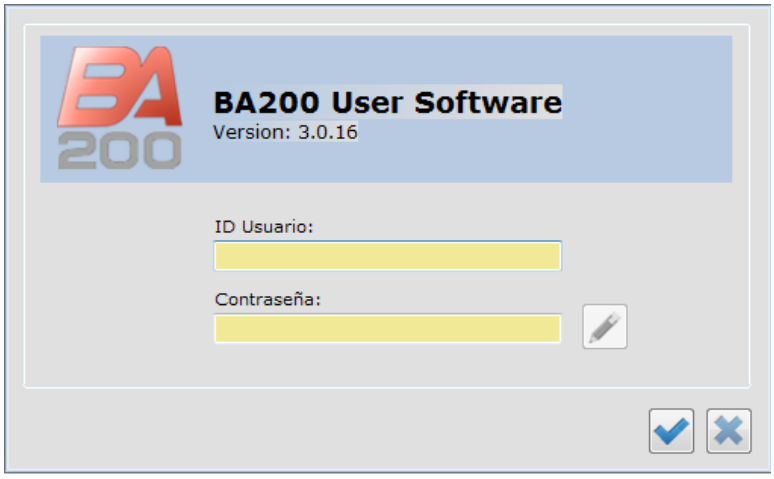


Figure 32 Home screen

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

Parameter	Value
User name	Admin
Password	BA200

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

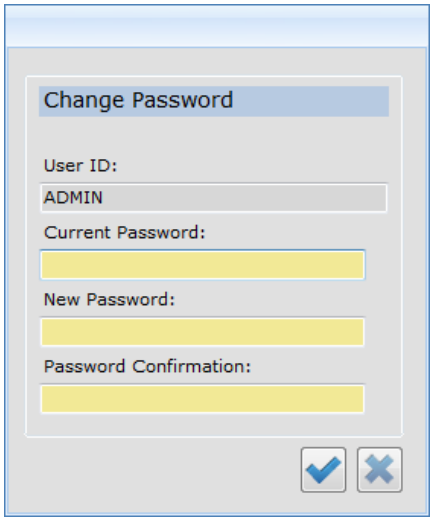


Figure 33 Screen for changing the password

10.2. Configuration

In this menu you can access the different setup options:

- *General*: General programme configuration.
- *Languages:* Selection of the programme 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 programme.
- *Change User:* Change in user.

10.2.1. General setup

In this screen you can configure the general programme 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 34 shows the screen with the different setup options for the work session.

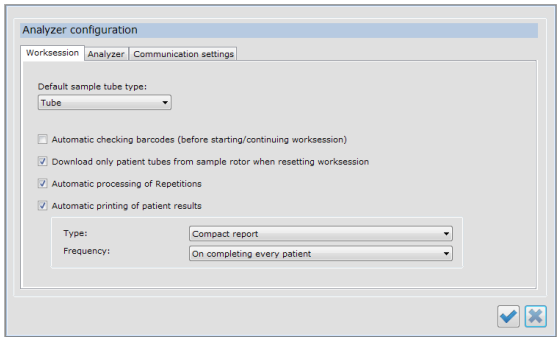


Figure 34 Work session setup

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

Reset session download only patient tubes 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 (calibrators 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 must 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 35 shows the analyser configuration screen.

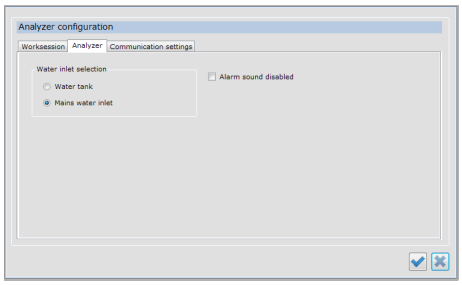


Figure 35 nalyser options setup

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 4.4 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 36 shows the communication settings screen.

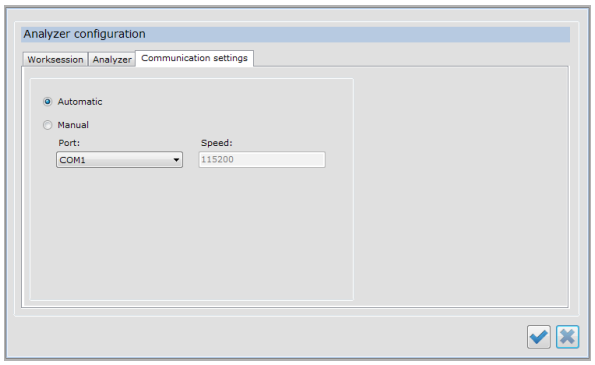


Figure 36 Communication settings

Automatic

Select this option and the programme will automatically search for the computer output port for communicating with the analyser.

Manual

Select this option for the port to be selected manually.

Port:

- Select the available COM port, the USB uses a virtual COM port.

NOTE

If no value appears in the port pop-up menu, wait a few minutes and try the connection again. The USB driver registration process may take a few minutes.

10.2.2. Language

This allows you to select the application language.

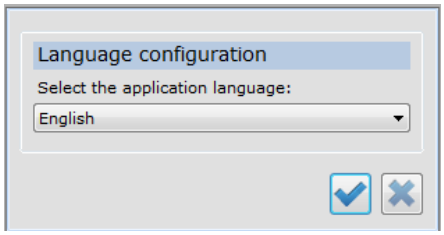


Figure 37 Screen for selecting the application language.

10.2.3. Reports

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

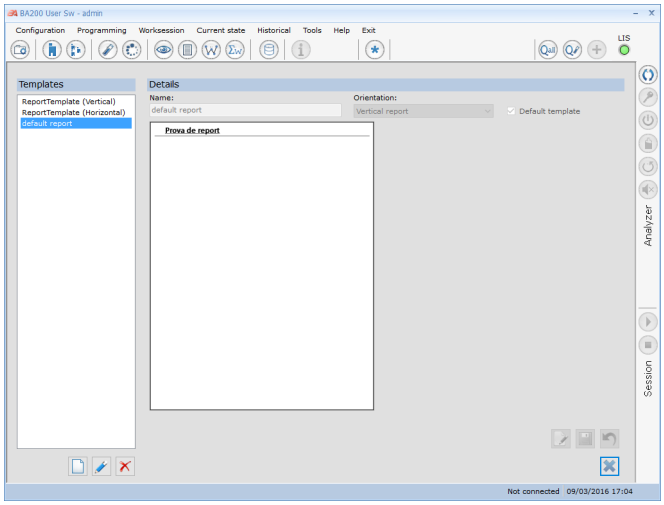


Figure 38 Patient report setup screen

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 programme 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. Arrangement of tests

This allows you to define the order in which the tests will appear in the patient 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.

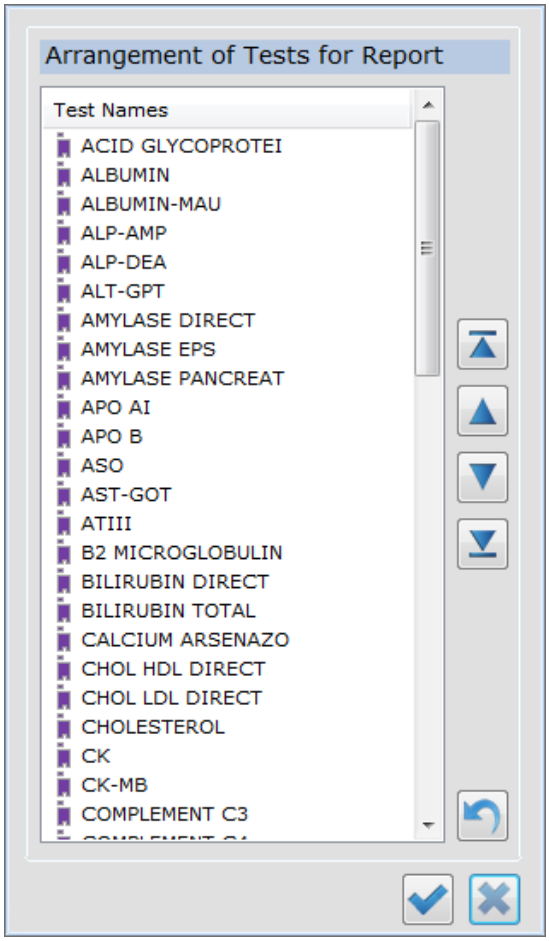


Figure 39 Screen for arranging the tests

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 40 shows the screen with different options that allows the configuration to be made.

Barcode deactivation. Select this option to disable the barcode reader.

Barcode type Select the barcode type for performing the sample barcode readings. 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, information on the sample type is provided in addition to the sample identifier. The total size of the barcode is still flexible, between 1 and 30. The following fields are enabled too.

Start and end Select the start and end positions of the sample identifier in the barcode. The sample type will always be shorter in length than the barcode type.

Sample type Table matching the sample types of the software (SER, URI, PLM, WBL, CSF, LIQ AND SEM) with the laboratory condition for identifying the different specimens.

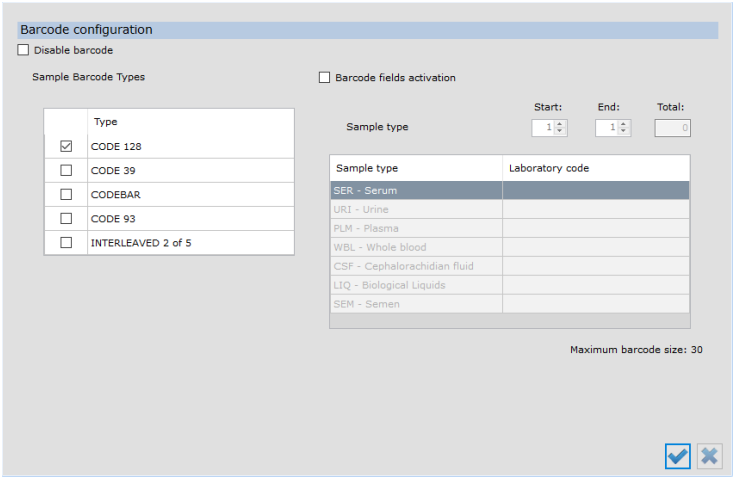


Figure 40 Barcode reader setup

10.2.6. LIS operation setup

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 41 shows the LIS configuration 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.

Maximum LIS Order waiting time 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 option *Host Query Packets*.

Sending of patient results requested by analyser — When this option is activated the patient results created manually through the analyser are sent.

Sending of control results requested by analyser — When this option is activated the results of controls requested manually through the analyser are sent.

Sending of results after resetting session — 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 BA200 will also be sent.

Automatic sending activation — 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.

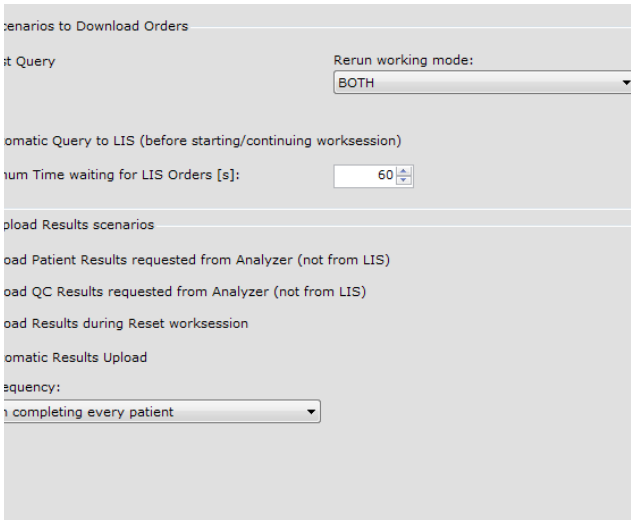


Figure 41 LIS options setup

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.

Type of data transmission — The transmission may be:

- ASTM: TCPIP-Client, TCPIP-Server
- HL7: TCPIP-Client, TCPIP-Server, TCPIP-transitory connection

Name of host 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.

TCP port 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.

Client TCP port Number of client port in a TCP connection.

Server TCP port Number of server port in a TCP connection.

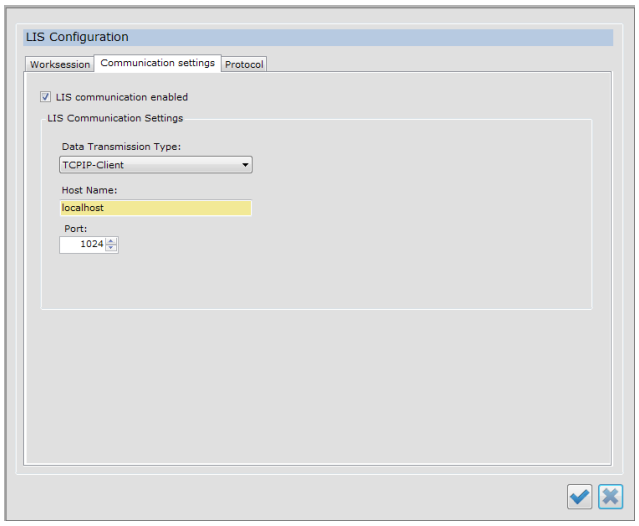


Figure 42 LIS communication settings

10.2.6.3. Protocol settings

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

Name of protocol Select the type of protocol to be used in the communications: HL7 or ASTM.

Page code for transmissions 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.

Server identifier Identifier used by the LIS application.

Server supplier Name of the LIS application supplier.

Instrument identifier Name used to identify the instrument; that field is transited in each message.

Instrument supplier Name of the instrument supplier.

Complies with IHE Select this option when the message transmission strictly follows the IHE communication standard.

Host Query packet size Number of specimens sent in one Query message by specimen when using the ASTM protocol.

Maximum time for sending a retry message Configuration of the maximum time during which another attempt is made to send a message to LIS when no response is received.

Maximum LIS waiting time 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 lamp on red) indicating that there are problems in communication which must be solved.

Delimiters Enter the delimiters to be used in transmitting and receiving messages.

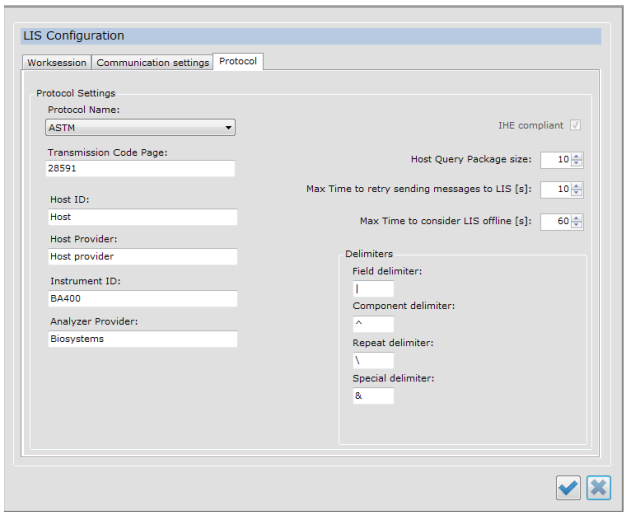


Figure 43 LIS protocol setup

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.

The screen shows a table with different columns:

- The first column shows the type of element, which may be any of the following types:
  - Calculated test
  - Standard test
  - ISE test
  - Units
  - Sample type
  - 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 each of the types.

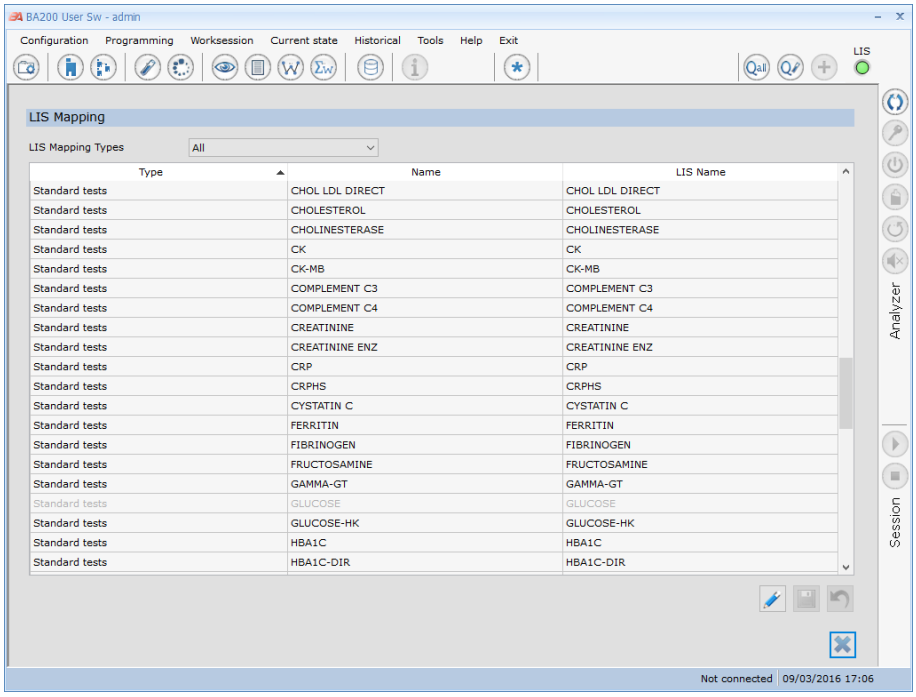


Figure 44 LIS mapping configuration screen

10.2.8. Users

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

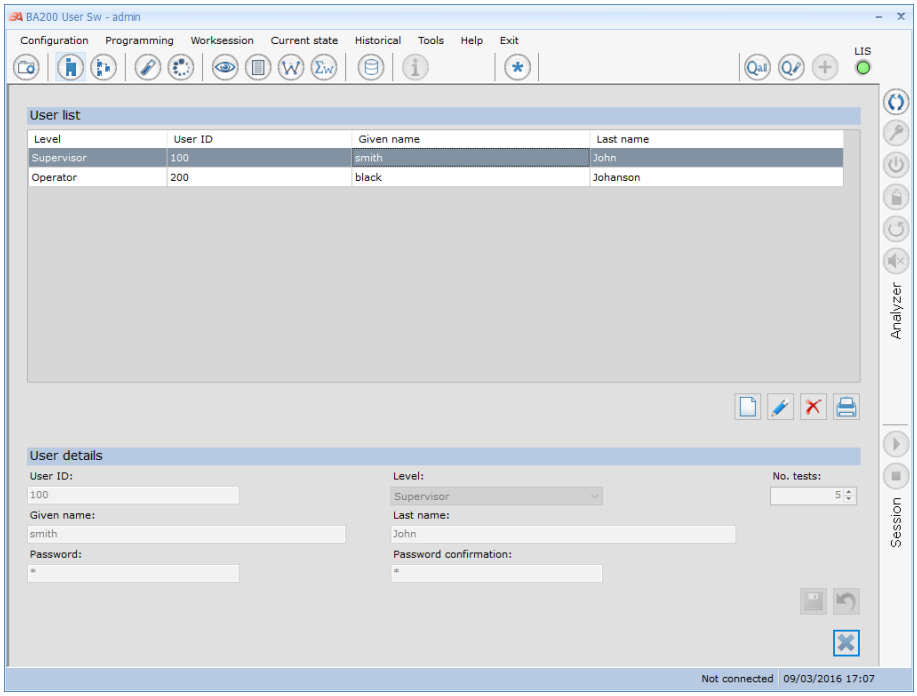


Figure 45 User creation screen.

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 and/or operator user. There is only one administrator user.
Supervisor	Has limited access. This user is allowed to create users with operator permits. He is permitted to change the calibrators and control values and create a limited number of tests established by the Administrator. Only one supervisor may be created.
Operator	This is the most restrictive access level. This user can only execute lists, view and print out results and consult the test parameters. As many users as required may be created.

Table 7 User levels

Figure 45 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.

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, calibrators, controls, patient information, ISE tests and external tests.

10.3.1. Tests

CAUTION

Check the test parameter programme against the instructions for use (IFU) values for each reagent.

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

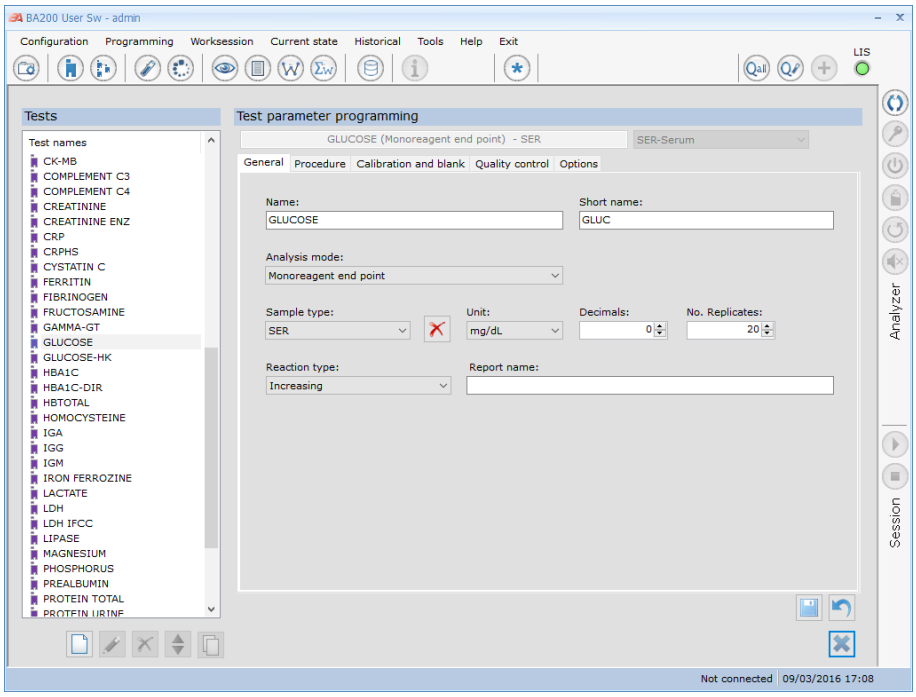


Figure 46 Test creation screen

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.

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 programme 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 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*

Press this icon to make a copy of a test. The name of the new test must be changed.

You can delete or print out several tests at once, and make multiple selections from the list of tests.

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 selec 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.

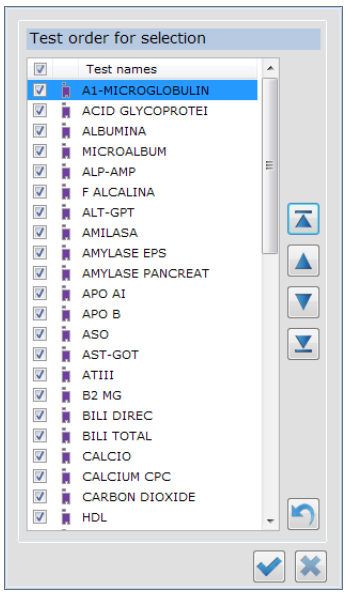


Figure 47 Screen for ordering the tests

 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 programme. 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	Cerebrospinal 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 be-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. 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

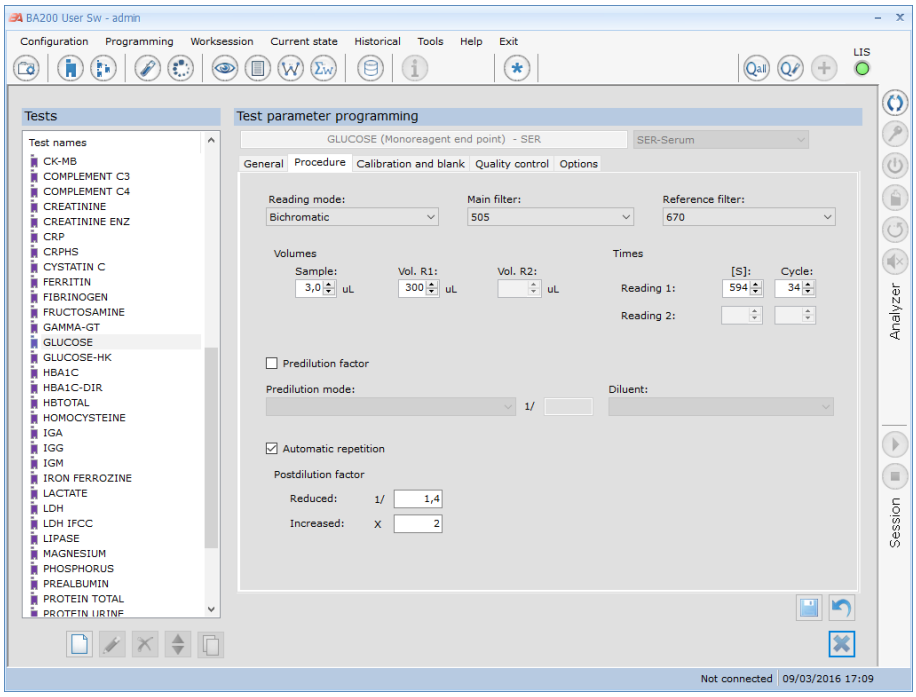


Figure 48 Test parameters, procedure screen

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 90 µL to 300 µL.

Volume of reagent 2 Enter the reagent 2 volume for making the preparation. The volume range is from 10 µL to 100 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 2 to 35.

Reading time 2 Enter the time for making the last reading. This box will be activated for kinetic or fixed-time calculation methods. The time ranges are from cycle 3 to 35. 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

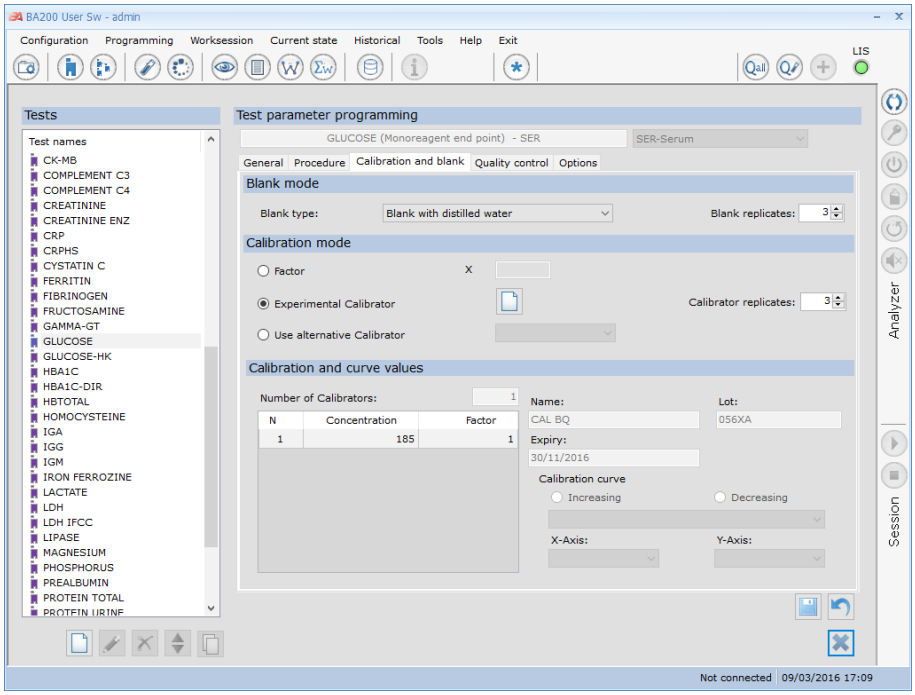


Figure 49 Test parameters, calibration and blanks screen

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 calibrator Enter the calibrator data and its concentration. Press the icon again to open up the calibration screen and enter the calibrator parameters.

☞ *See how to enter the calibrator parameters in chapter 10.3.5*

Calibrator replicates Number of replicates for making the calibrator. The range is from 1 to 3. The mean of the replicates is used to calculate the factor.

Use alternative calibrator 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 calibrator values assigned to the test. They are only shown for informative purposes. To create new calibrators and/or change them, edit them in the calibrator screen.

10.3.1.5. Test parameters: quality control

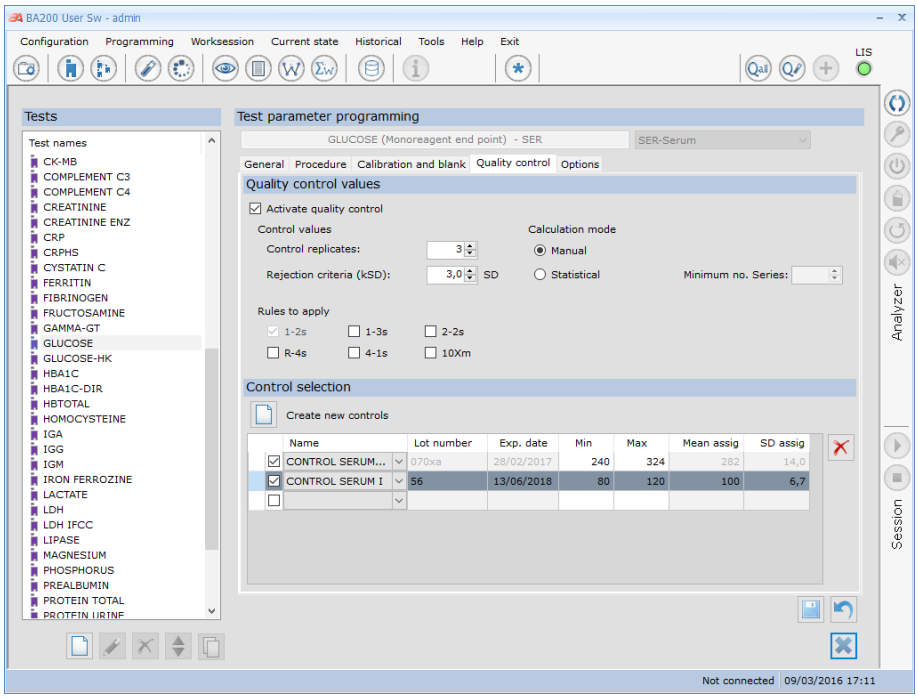


Figure 50 Test parameters, quality control

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

Control replicates Number of replicates for measuring the controls. The range 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 10.8.4*
Statistical	Use the ranges calculated from the mean and SD of the above series. 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. Different quality regulations in the laboratory make it advisable to assign 20 minimum series when starting to use a specific control lot.

Applicable rules Select which Westgard rules you want to apply to the quality controls for this test.

It serves to register the controls with their batch and concentration values.

☞ *See how to register a control in chapter 10.3.6.*

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.

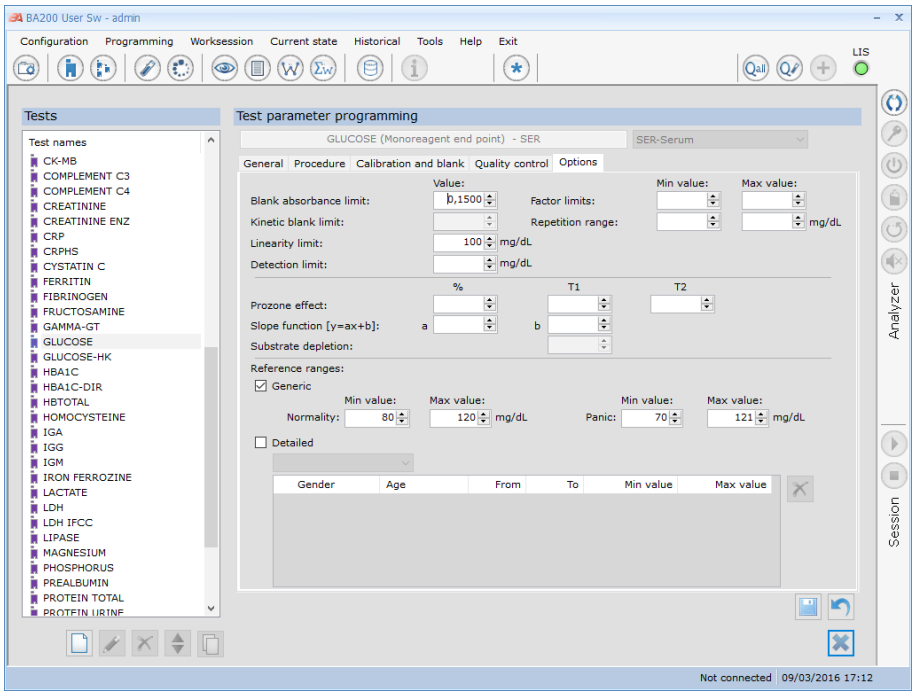


Figure 51 Test parameters, options screen

Blank absorbance limit Limit value established for comparing against the result of the blank absorbance. It is used for checking the state of the reagent.

Kinetic blank limit Enter the correct kinetic blank value limit. It is only applied to tests with the kinetic calculation mode.

Linearity limit Enter the value for which the reagent is no longer linear. If the concentration value is higher than this value, the programme will issue a warning message and if it is activated in the programme a repetition will automatically be launched.

Detection limit Enter the value for which the reagent does not detect a value. If the concentration value is lower than this value, the programme will issue a warning message and if it is activated in the programme a repetition will automatically be launched.

Factor limits Upper and lower range for verifying that the calibration factor is correct.

Repetition range The analyser repeats the sample automatically if the concentration value is within the range. This range serves to confirm the result automatically.

Prozone effect 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 (%).

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.

CAUTION

The prozone effect verification parameters must be determined by the end user. In the case of doubt in detecting the prozone, the user must make a sample dilution, to ensure the result is correct.

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 serves to proportionally correct the concentration of a sample for the same absorbance. Where X will be replaced by the concentration value and Y will be the changed concentration value.

Consumed substrate 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 programme automatically launches a repetition.

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

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

Minimum panic < *Minimum normality* < *Maximum normality* < *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.

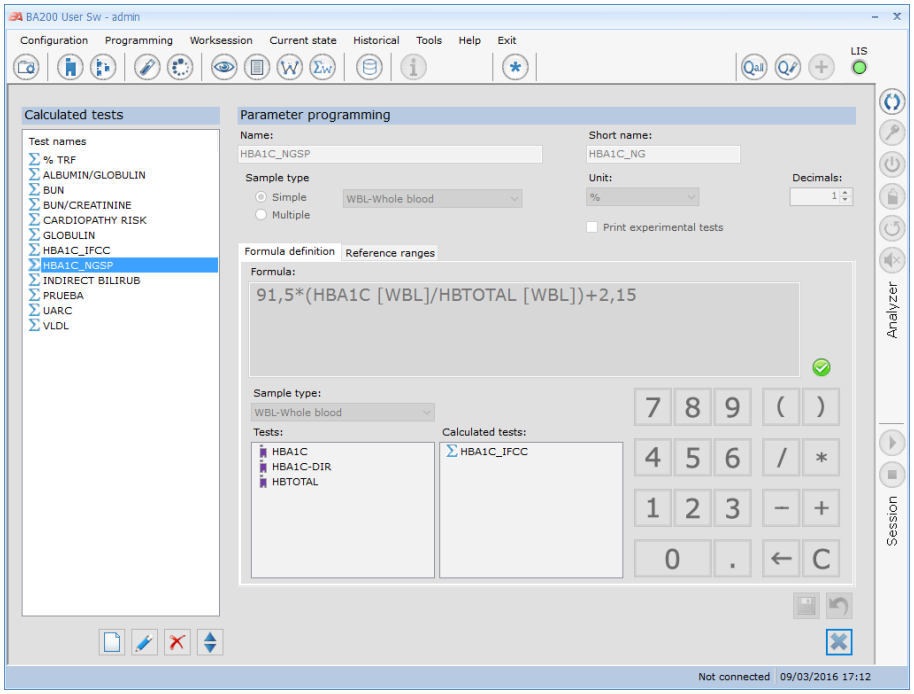


Figure 52 Screen for creating calculated tests

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.

Decimal points 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.

Print out experimental tests 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.

Formula definition Formula relating the calculated test to the standard tests. To enter the formula, select the standard tests, other calculated tests, numbers and operators. The programme 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

CAUTION

When contamination exists between programmed reagents, the process speed decreases.

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

To eliminate the contamination, first of all the programme 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 programme, the wash cycle is performed with purified water, otherwise the cycle will be executed with the programmed washing solution.

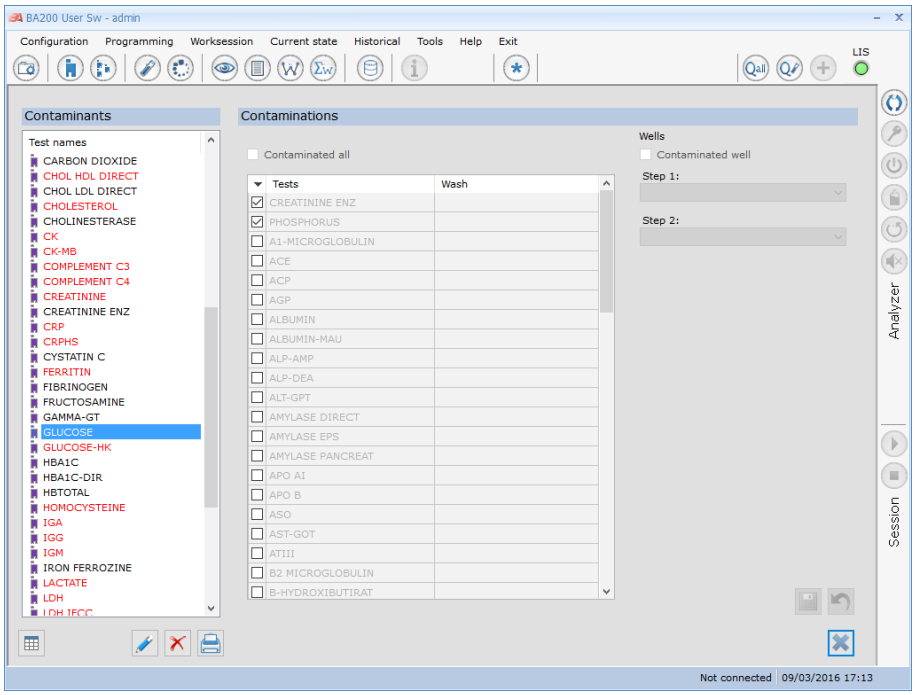


Figure 53 Contamination programming screen

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

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

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

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 54*

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 test *columns*. 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.

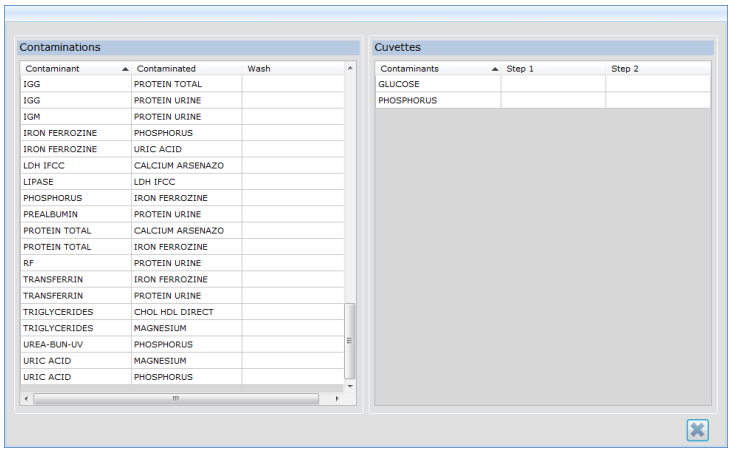


Figure 54 Contamination summary screen

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. Profiles are sets of tests that are usually requested at the same time.

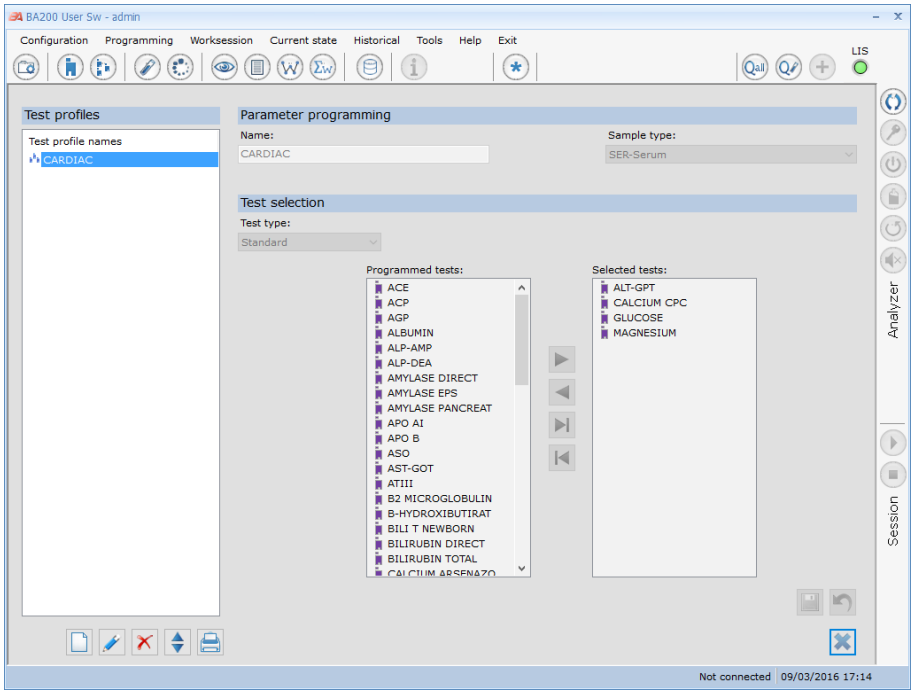


Figure 55 Screen for entering profile information

☞ *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 CTRL 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 test at one time to the profile.

 Eliminate all the tests at one time from the profile.

10.3.5. Calibrators


CAUTION

Check the calibrator concentration values entered against those of the instructions for use (IFU) values of the calibration serum. Make sure you enter the values with the test programme units.

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

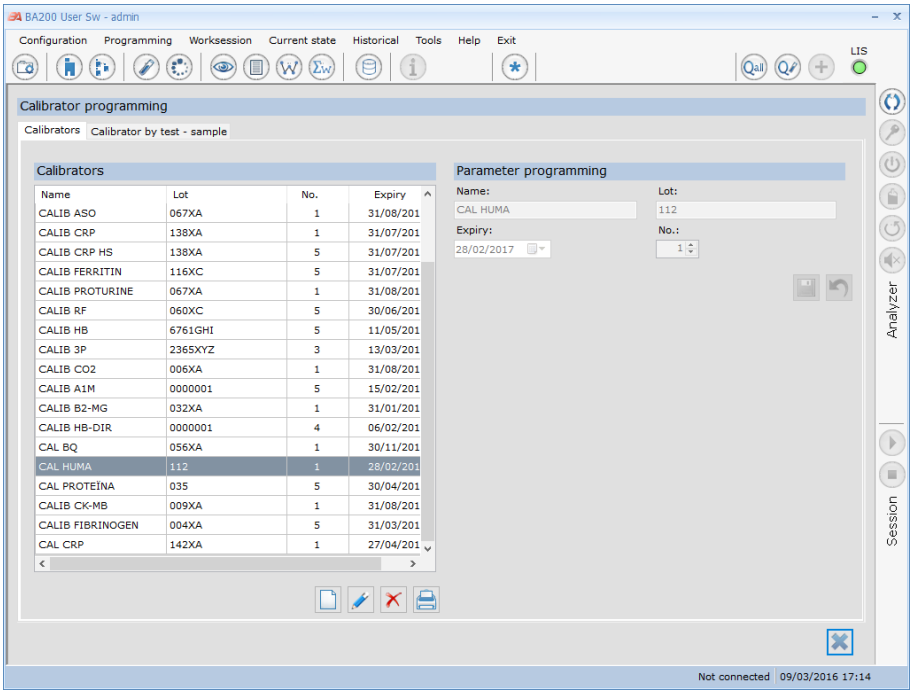


Figure 56 Entering the calibrator information

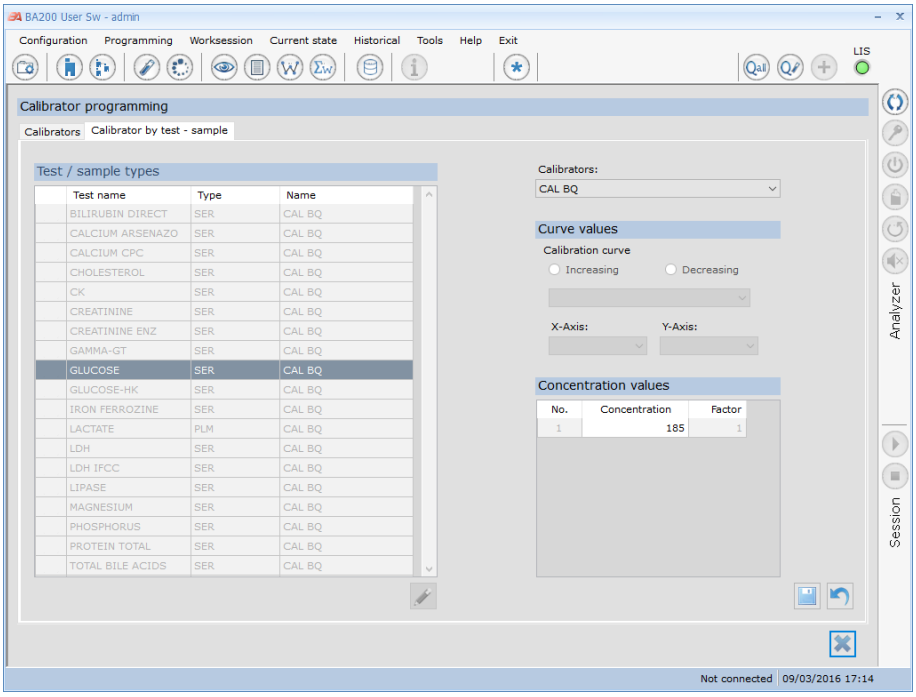


Figure 57 Entering the calibrator concentrations

In the first tab it is entered the general information on the calibrator. A list of all the calibrators exists, with the icons new, edit and print.

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

Calibrator name Enter a name for the calibrator.

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

Expiry date Enter the days the calibrator will last once reconstituted.

No. Enter the number of calibrators this calibrator has.

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

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

Calibrators Select the name of the calibrator you want to assign to the test.

Enter the calibrator values for the test.

If the calibrator is for a specific value, you only need to enter the concentration value. In multipoint calibrators, 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 calibrator in descending order. The *Factor* column on the right of the column for entering the concentration value data indicates the proportion expressed on a per unit basis with respect to the calibrator with the highest concentration (1 for the most concentrated calibrator).

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.

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 Enter the batch number of this control.

Press this icon to register a new control lot. It also allows you to retrieve the data of the last lot memorised after changing the lot. Every time you change the lot the quality control values will accumulate.

☞ *See Figure 59*

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. It appears an auxiliary screen 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).

☞ *See Chapter 10.3.1.5 to activate Quality Control*

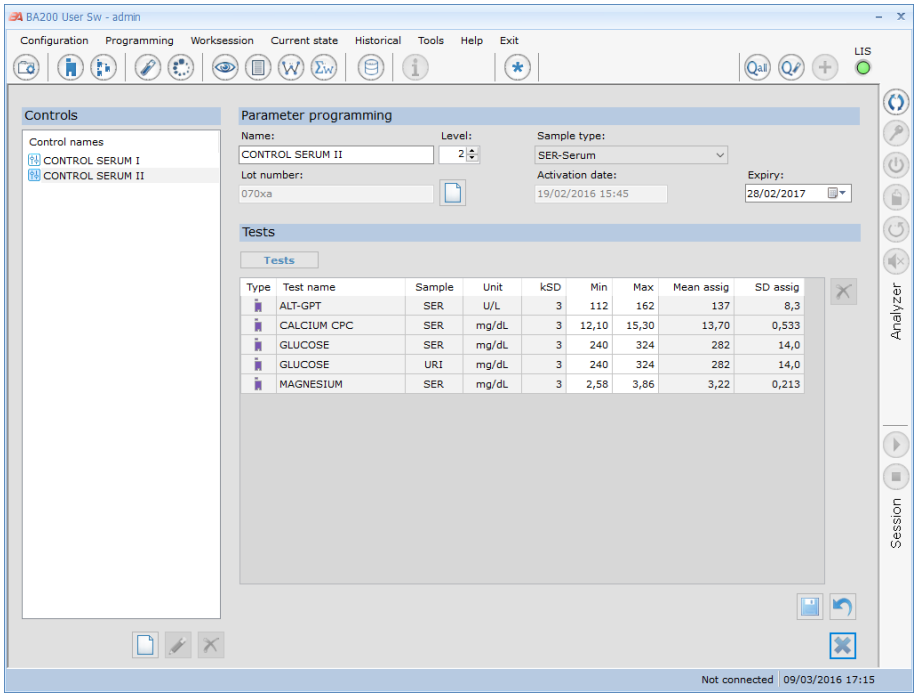


Figure 58 Screen for programming the control serums

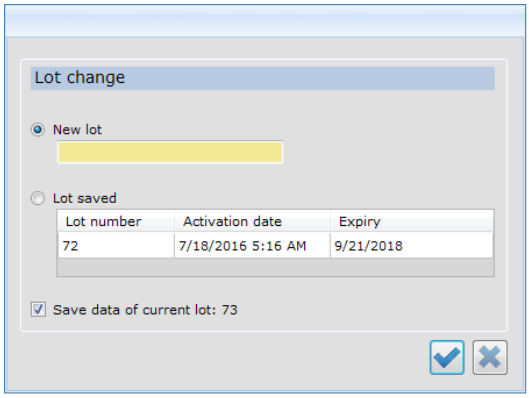


Figure 59 Screen for changing the lot of a control

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.

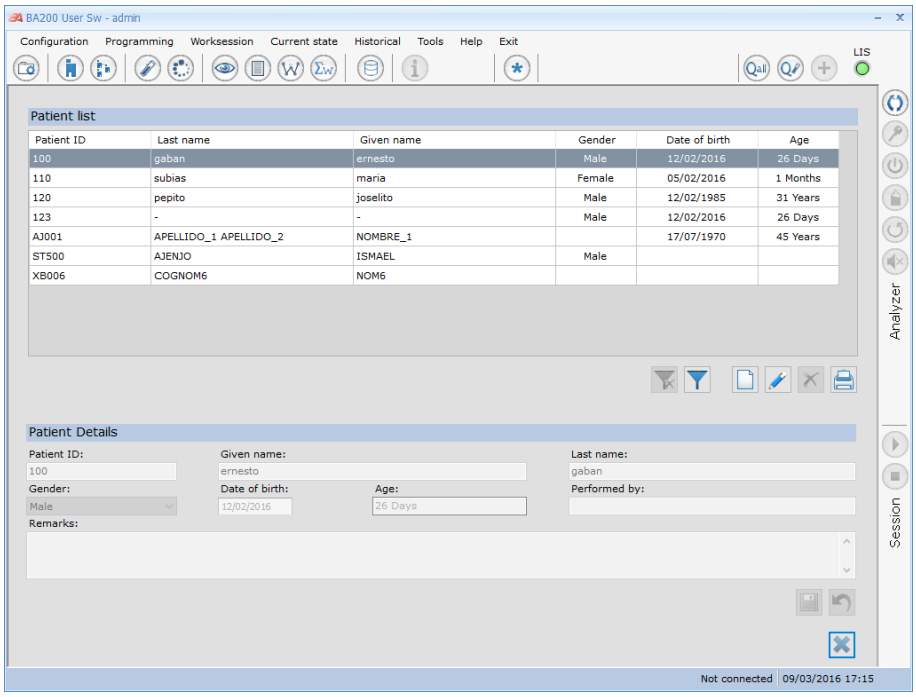


Figure 60 Screen for programming the patient data

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.

Gender Enter the gender of the patient: male or female.

Date of birth Enter the date of birth of the patient. The age field is calculated automatically after entering the date.

Analysis performed by Enter the name of the doctor.

Remarks 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 61 for more information.*

Press this icon to cancel the search options and view all the patients.

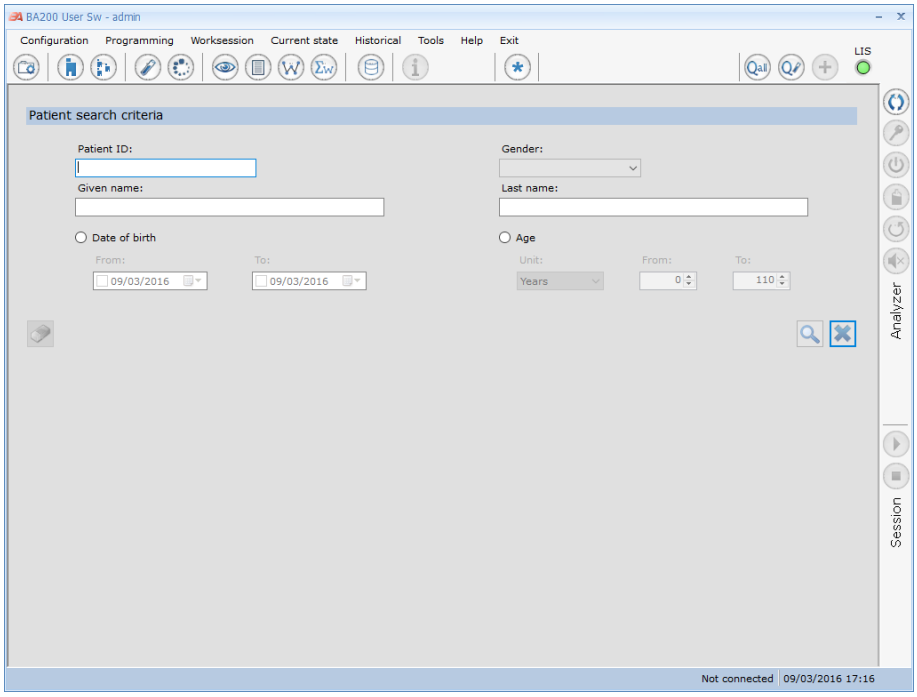


Figure 61 Screen for selecting the search options.

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 ISEmodule 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 user can change the following 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 to be used.

ISE test available Select this option to view the lithium test on the sample selection screen (option only available for Li^+).

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.

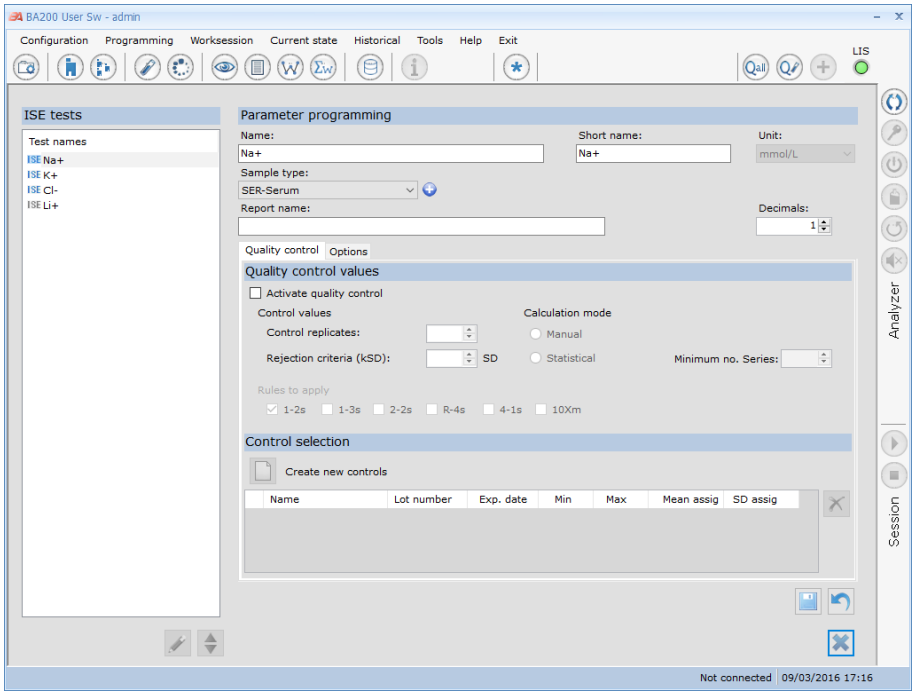


Figure 62 Screen for programming the ISE parameters

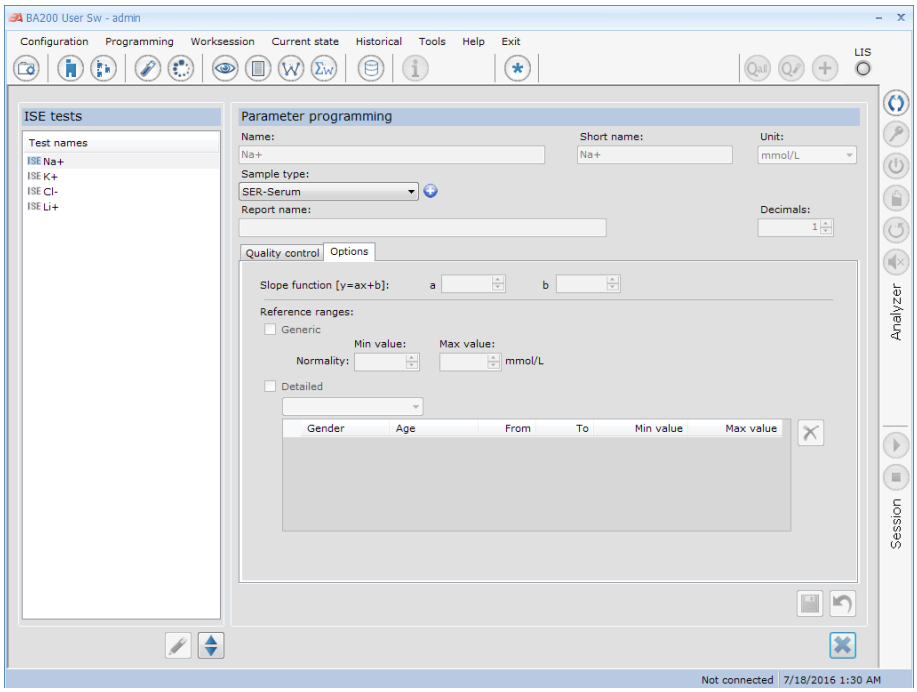


Figure 63 Screen for programming the ISE parameters

Decimal points 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 log. 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.

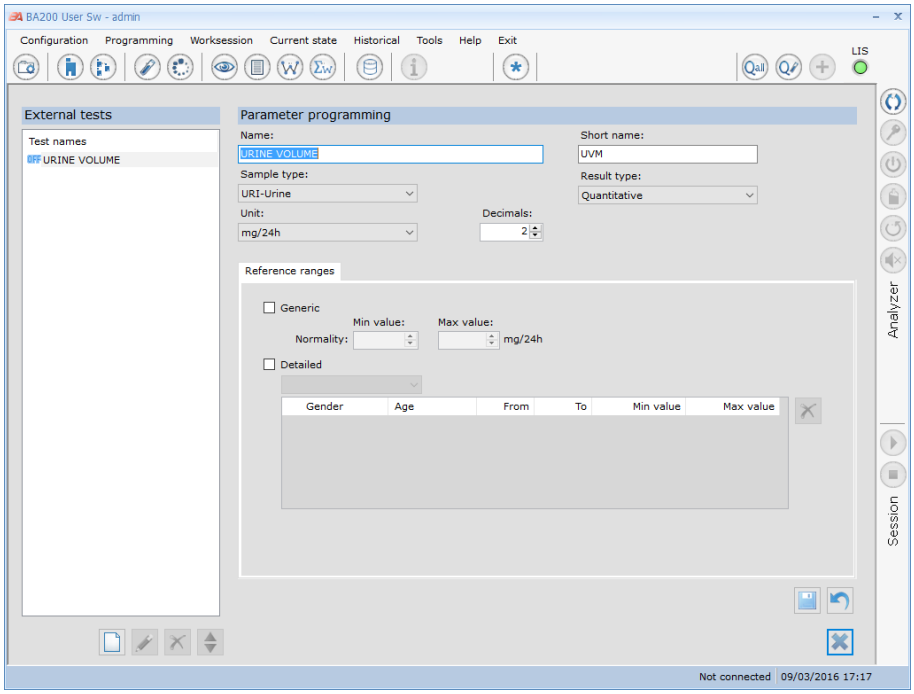


Figure 64 Screen for programming external tests

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 decimals 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 10.3.1.6.*

10.4. Initialising and switching off the analyser

The process for switching on the analyser is carried out when the main analyser switch is opened. The analyser performs its internal checks and after a short "beep" is heard, the state LED lamp turns orange, indicating that the analyser is ready to be connected with the user programme.

The user programme is initiated and the communication connections are established automatically.

If there is no communication with the analyser, check the communications setup and press the connect button.

☞ *See chapter 10.2.1*

Once connection is established the analyser is in stand by mode. In this state the user can access any part of the programme, except the parts that operate with the analyser (start worklist, change rotor, etc). Press the initialisation button to operate with it.

The initialisation process is automatic and includes the following steps:

- Process for previously checking the state of the analyser and priming the fluidic system.
- Wait 20 minutes for the reading rotor temperature to stabilise.
- Initialisation of the reading rotor baseline. This process consists of filling the 120 rotor wells with distilled water, making the photometric readings with all the wavelengths in each well and drying the reading rotor. The photometric readings will serve to compensate the determination readings. If any reading is outside the pre-established ranges, the well is discarded. If there are more than 10 discarded wells the programme recommends changing the reading rotor. This process takes about 15 minutes.

The switching off process is performed by pressing this button. In the event of processing samples with ISE determinations, the programme will ask for the ISE cup to be washed before the analyser is switched off.

☞ *See chapter 14.2.9*

Once the washing operation has been completed the analyser will automatically go off.

10.5. Work session

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

10.5.1. 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 programme automatically incorporates the blanks and calibrators related to each test. It also incorporates the controls for the tests that have them programmed.

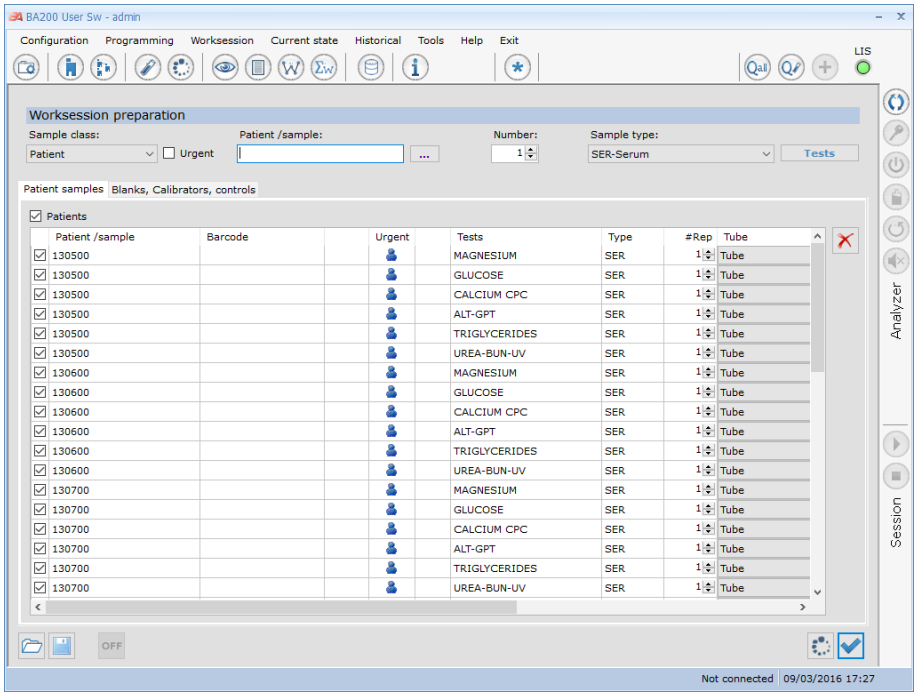


Figure 65 Screen for entering new samples

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 on the rotor.

Sample type This field is used to select the type of sample to be entered. The types may be: patient, blank, calibrator or control. It serves to make only lists of blanks and calibrators 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. The selection of a preprogrammed patient implies acquiring the identification assigned to that patient. Identification of the patient entered manually corresponds to the same identification as the sample.

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 to be created. 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 66.

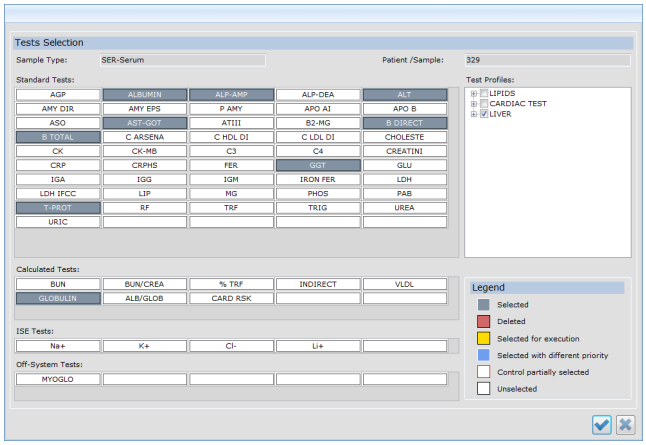


Figure 66 Test selection screen

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 calibrators.
	Selected for execution	Test already in use. This test cannot be deleted from the work session.
	Selec. with different priority	Patient with normal and urgent tests selected.
	Control partially selected	Test created with more than one control and elimination of one control after creating the work session.

Colour code	Name	Description
☐	Unselected	Unselected test

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 programme will ask the user about whether new tests are to be added, and if the answer is yes, the screen in Figure 66 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 65.

The information is separated into two tabs: patient information and information on blanks/calibrators/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	Sample type.
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 a 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/calibrators tab:

Column name	Description of the blank/calibrators tab fields
Selected	The blanks and calibrators 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)
Class	Select the type of information, which may be: Blank Calibrator
Calibrator	This indicates the name of the calibrator used
Lot	This indicates the calibrator lot
No. of Calibrators	This indicates the number of calibrators
Test	Test name
Type	This indicates the sample type
Replicates	The number of replicates is usually shown programmed in the test. The replicates of the blanks and calibrators can be changed.
Tube	This indicates the type of tube when it is to be put in position. It may be a 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 calibrator is to be made during the work session. It is normally shown deactivated when there are memorised blank and/or calibrator results.
Absorbance	Memorised blank or calibrator absorbance value.
Date	Date on which the blank or calibrator 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
Lot	Control lot
Tests	Test name
Type	This indicates the sample type
# 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 a 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 lot 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 calibrators 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 programme will ask you to enter a name for the session.

It allows you to load a previously-saved session. The programme 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 programme will automatically change screen. Once the samples have been sent to the positioning screen they are marked in grey.

☞ *Chapter 10.5.2 describes the procedure for positioning on the rotor.*

Press the button to open up the screen for entering the results for all patients with external tests.

☞ *See Figure 67*

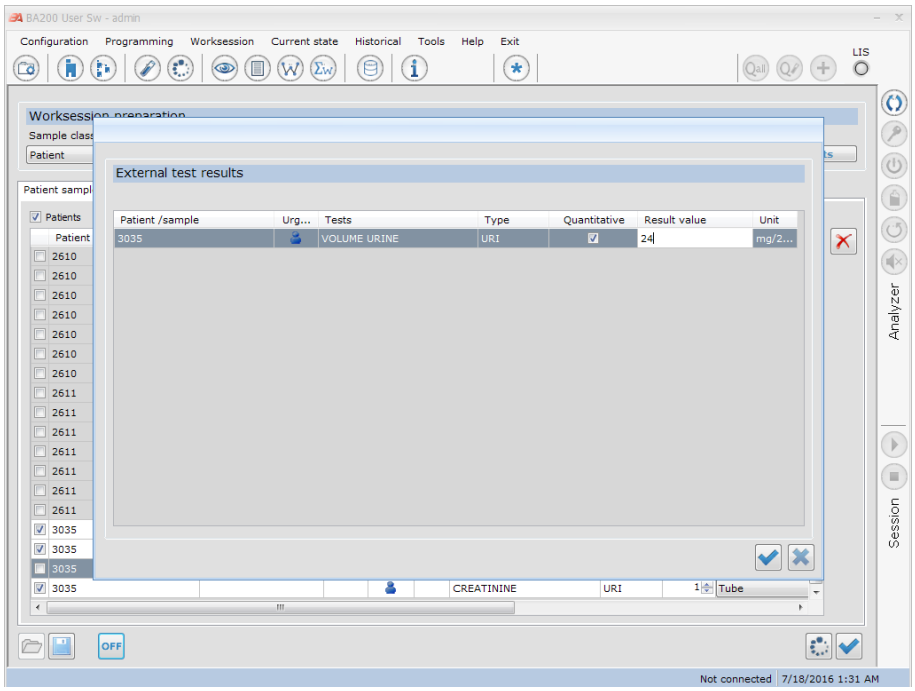


Figure 67 Screen for entering the value of external tests

10.5.2. Positioning on 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 68*

On the left there 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 allows you to see the positioned elements, identified by an icon.

On the right there 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.

This button also positions all the patient samples, controls and calibrators automatically. The patient samples will be positioned starting in the first position that is empty. The calibrators and controls can start to be positioned from position 1.

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 on the rotors by dragging them to another empty position.

This button reads the barcodes of the analyser samples and reagents. If LIS requests have been entered or received for the read samples, all the information is listed and these samples appear in yellow (ready to be executed). If any of the read samples has no tests assigned, the user can enter them in the auxiliary screen (see Figure 68) or request the tests from LIS. If information on the sample type is missing from any of the read samples, the user must enter this information.

The samples placed in sample wells will not be read by the barcode reader and the user must position them by dragging them manually or using the auto-positioning button.

In the event of automatic barcode reading, when the session start button is pressed (with Host Query activated), all the rotor positions will be read and the codes will be matched with the orders pending in LIS.

When more than one bottle with the same reagent has been positioned, the pipetting order will be the same as the order of each bottle on the rotor.

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

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

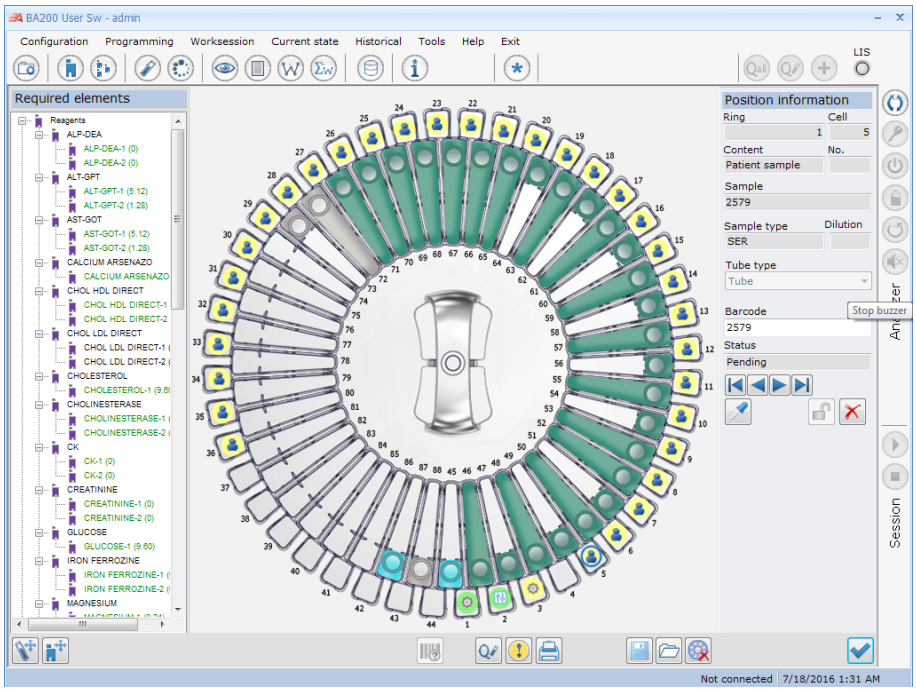


Figure 68 Screen for positioning the reagents and samples

Press this button if you want the analyser to automatically identify the session samples positioned on the rotor. These samples will be shown in yellow. The read barcodes that have not been matched with any of the requests on the list will be shown in grey, and the user can assign the tests using the screen shown in Figure 68. Elements in sample wells such as calibrators and controls will have to be positioned manually or with the auto-positioning button.

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 performing a session reset, the positioned reagents are maintained, but the samples are emptied.

Press this button to load the positions of the elements of a rotor that was previously memorised.

Press this button to delete the reagents or samples positioned on the rotor. When the button is pressed a selection menu appears for the user to select the sample or the reagent rotor.

Press this button to inform the programme that you have entered a sample tube, calibrator or control manually. Perform this action when the volume termination alarm is triggered. For reagents with barcodes you only need to place a new

bottle on the rotor and press the barcode reading button and the information on the volume of the new bottle will automatically be updated.

Press this button to release the samples and reagents shown in red due to detecting a clot or a tip collision. Before pressing it, the user must carefully check the tubes of elements in red and decide on the appropriate course of action: eliminate the clot, correct the tube size, position the tube correctly, remove the reagent bottle cap, etc.

10.5.3. Creating the worklist from the sample positioning screen

When making a barcode reading of sample tubes positioned on 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.

Host queries may 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.

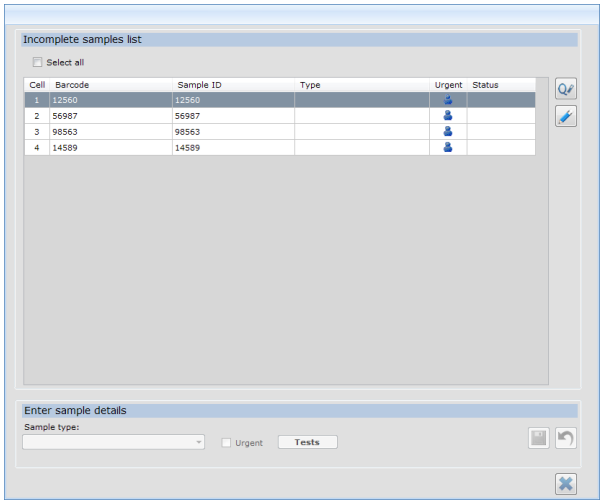


Figure 69 Screen for creating the work list from positioning

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
Cell	Position of the specimen on the rotor.
Barcode	Information read from the specimen barcode.
Sample identifier	Sample identifier, depending on the barcode configuration it may coincide with the barcode digits.

Column name	Description of the fields
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: • 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.

Select all It allows the selection of all the specimens in order to request the LIS for the work order or to manually create the worklist.

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.

10.5.4. Worklist setup

After creating the work session and once positioned on 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

specimen 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 a 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 70 will appear.

Select one of the 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.

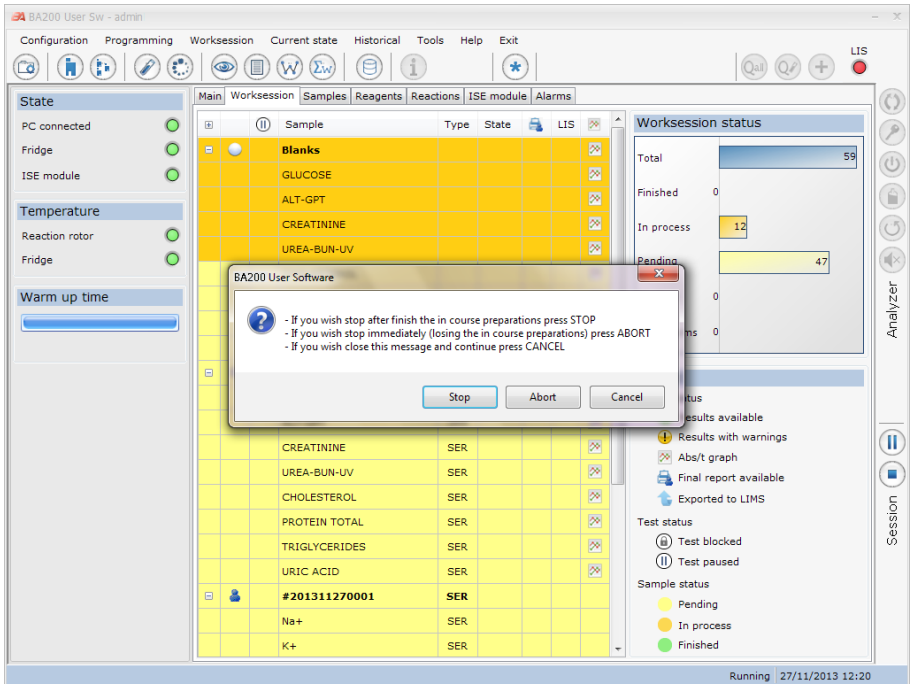


Figure 70 Screen with abort message

10.5.5. Save session

Menu option *Work session* that allows you to save the created session with a name. This function is used for saving repetitive lists, such as lists of blanks, calibrators and controls.

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

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

10.5.6. Load session

Menu option *Work session* that 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. This action may also be executed in the Sample Request Screen.

10.5.7. Delete session

Menu option *Work session* that 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.

10.5.8. Delete virtual rotors

Menu option *Work session* that 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 on 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.

10.6. 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.

10.6.1. Principal

Screen which informs about the status of the analyser: the analyser elements that are switched on (refrigeration system, ISE module), main sensors (covers, tem-

peratures), work session times, graphic information on alarms and information on processes being executed by the analyser.

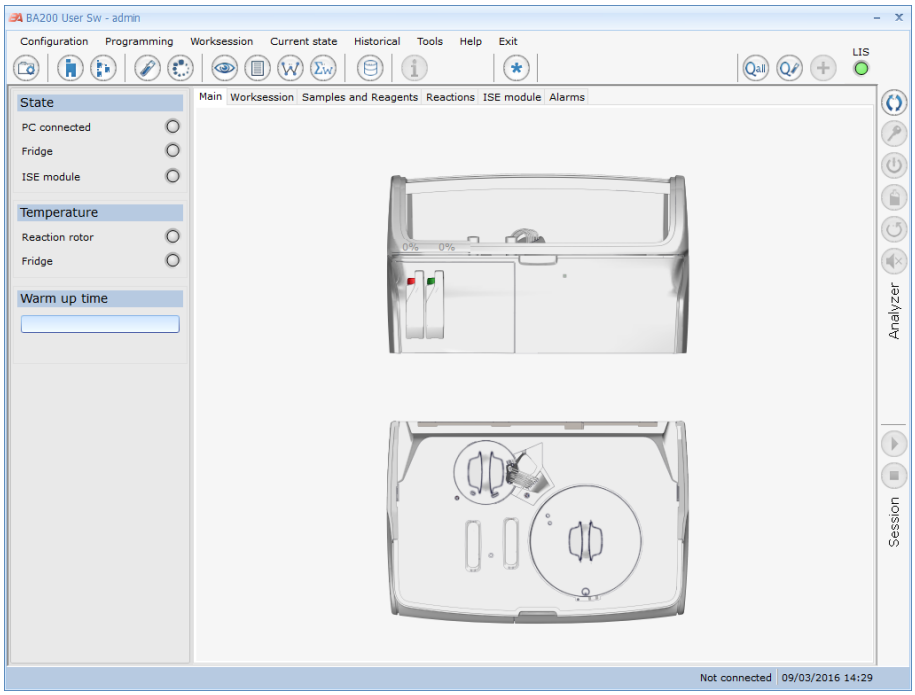


Figure 71 Monitor display

Status On and connected indicators:

- The analyser is on and connected to the computer when it is green.
- The refrigeration system 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 it is off.

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

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 10.6.6*

10.6.2. Work session

This tab displays information about the work session being performed by the analyser, the state of the samples and 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, calibrators and controls of the tests assigned to the patients are executed.

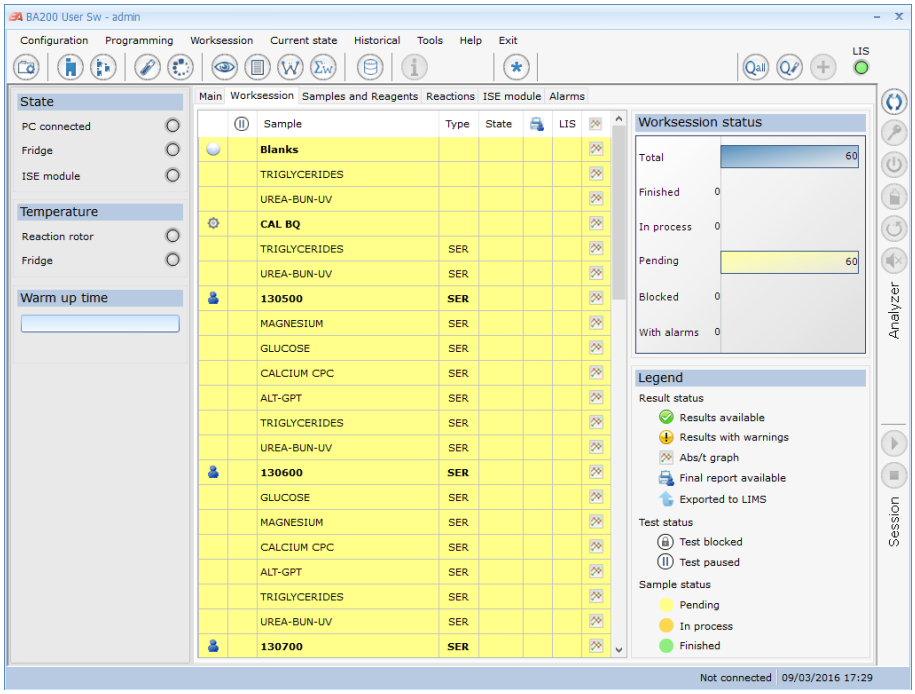


Figure 72 Work session screen

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 or remarks.

Button for viewing the reaction curve. Viewing may be in real time or after the reaction has ended.

Indicates that the final patient report has been printed because it has been completed.

Indicates that the results have been 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 calibrator.

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.

10.6.3. Sample and reagent rotor state

Screen with information about the state of each sample tube and reagent bottle. It corresponds to the sample and reagents tab of the monitor screen.

The user can press any tube, well or reagent bottle to see the information in detail.

There is a colour code for identifying the status of each sample tube or 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.
	Insufficient volume /blocked by clot or tip collision	Shows that the analyser has detected insufficient volume or a clot or collision. The programme will block the other tests that have not yet been performed on that patient. To release the samples due to insufficient volume, the user must fill the sample and press the fill button in the positioning screen. To release the samples due to detecting a clot or collision, the user must check the status of the samples and press the release button in the positioning 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.

There is a colour code for identifying the reagent bottles status.

Colour code	Name	Description of the bottle identification
	Reagents	Reagent bottle used in the work session.
	Additional solutions	Bottles of washing solution, purified water, physiological saline solution, etc.

Colour code	Name	Description of the bottle identification
	Insufficient vacuum / Blocked due to collision	Reagent bottle in which the analyser has detected insufficient volume for making the preparation. The programme will block all the subsequent preparations using that reagent. To release the bottles due to insufficient volume the user must insert a new bottle and read the barcode. To release the bottles due to a collision the user must check the positions of the bottles affected by the collision and press the release button to be able to reuse that bottle.
	Insufficient volume	Warning that the volume in the bottle will be soon 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 sample positions or resolving volume alarms. To do this go to the sample and reagent rotor position screen.

☞ *See chapter 10.5.2*

10.6.4. Reaction rotor status

Screen informing the status of each of the reaction cuvettes. It corresponds to the reactions tab of the monitor screen.

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 reaction rotor
	Washing	Cuvette in the washing status
	Not Used	Cuvette not used. Empty
	R1+sample	R1 dispenser and sample
	R1+sample+R2	R1 dispenser, sample and R2

Colour code	Name	Description of the identification of the status of the cuvette in the reaction rotor
	Sample dilution	Cuvette with sample dilution.
	Completed	Cuvette with reaction completed.
	Contaminated	Cuvette contaminated. If the cuvette contains a contaminant test, it is marked as contaminated. That cuvette will not be used during the next turn of the rotor and will enter the cleaning process to be used in the next turn of the rotor.
	Optical rejection	Cuvette optically rejected. The absorbance of each cuvette is measured in the wash station. If the absorbance levels are within the ranges, the cuvette is accepted, otherwise it is rejected and the cuvette is not used to make the determinations.

10.6.5. ISE module status

Screen showing detailed information about the ISE module (if installed in the analyser). It corresponds to the tab in the ISE module of the monitor screen.

- Dates: Shows the installation dates of the reagent kit, each of the electrodes, the pump and electrode calibrations and the last cleaning operation performed.
- Consumption: Shows the estimated consumptions of calibrators 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 programme 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.

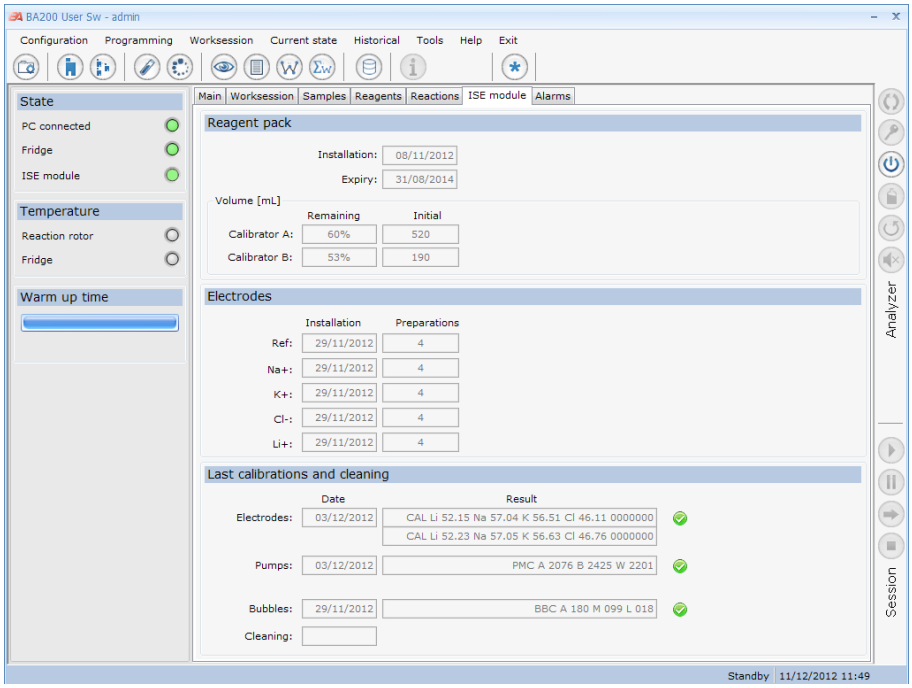


Figure 73 ISE module monitor display

10.6.6. List of alarms

Screen showing a list of all the alarms that appear while the analyser is operating. It corresponds to the alarms tab of the monitor screen.

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 analyser.
	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.

10.7. Results

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

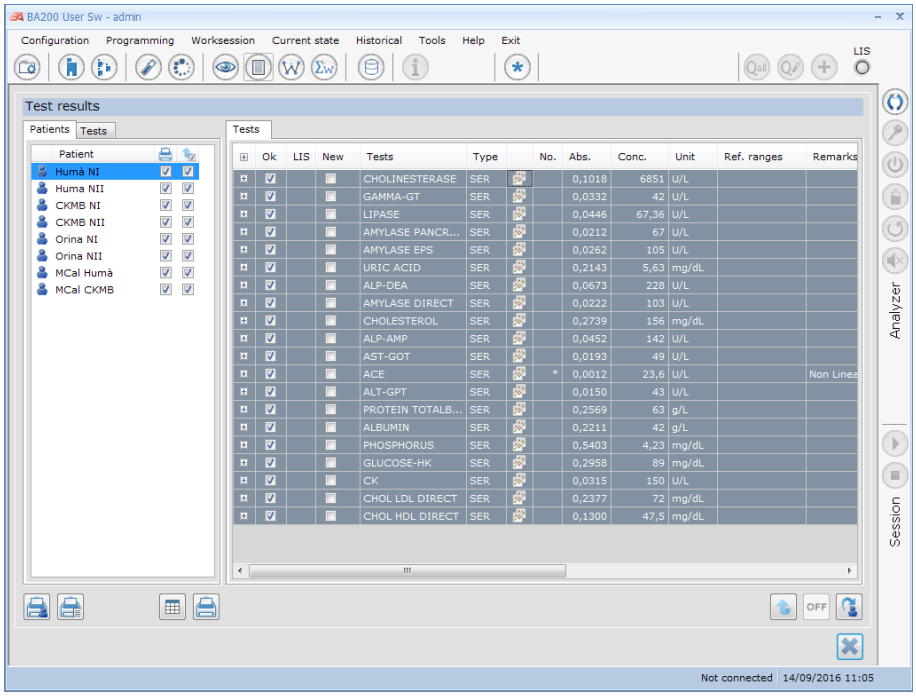


Figure 74 Results screen

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.

10.7.1. 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 log and to LIS. When repetitions are executed the last result 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 configuration screen. ☞ *See the different repetition options in chapter 10.7.4*
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. ☞ *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.

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 of all the patients and all the tests of the session in progress.

Press this icon if you want to print out a list of the patient results including the absorbance values obtained.

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 in which you can enter the external test values (the test must be selected previously for the button to be activated).

☞ *See chapter 10.3.9*

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 configuration screen.

☞ *See the different repetition options in chapter 10.7.4*

10.7.2. 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, calibrators, controls and patients.

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

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 log and to LIS. When repetitions are executed the last result 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 10.7.4*
Test	Test name
	This allows you to access the kinetic reaction graph.
Number	Indicates the replicate number, if there is more than one replicate.

Field	Description
Absorbance	Blank absorbance value that will intervene in calculating the concentration.
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 programme 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.

Calibrators tab

The calibrators results table contains the following information:

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 log and to LIS. When repetitions are executed the last result 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 10.7.4*
Name	Calibrator name
Lot	Calibrator Lot
Type	Sample type.
	This allows you to view the kinetic reaction graph.
Number	Indicates the replicate number, if there is more than one replicate.
Absorbance	Calibrator absorbance value that will intervene in calculating the factor.
Theoretic concentration	Calibrator concentration value. This value comes from the test programming.

Field	Description
Units	This shows the units in which the test has been programmed.
Factor	Value calculated based on the calibrator 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 control 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 log and to LIS. When repetitions are executed the last result is always accepted. If you like, you can accept various results or none.
	Indicates whether it was sent to LIS automatically or manually.
 New	This allows you to repeat the result. ☞ *See the different repetition options in chapter 10.7.4*
Name	This shows the control name.
Lot	This shows the control lot.
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.

Field	Description
Concentration limits	This shows the maximum and minimum limits for the controls entered in programming the test.
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 10.7.1.

10.7.3. Reaction graphs

Press this button to view the reaction kinetics graphs. A screen like the one shown in Figure 75 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.

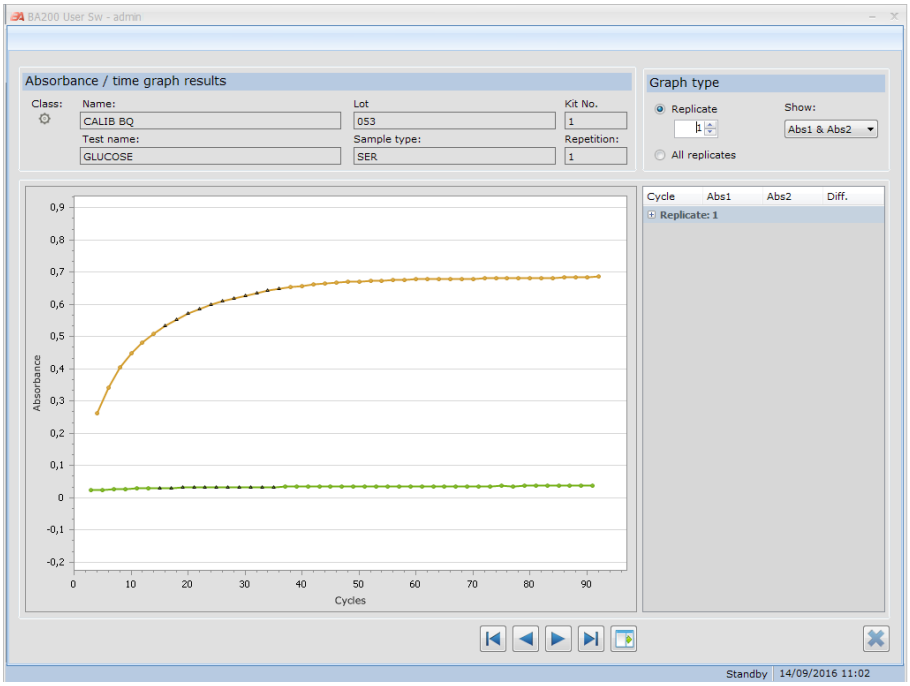


Figure 75 Reaction kinetics graph screen

The reaction graph button can be accessed in the results, work session and reactions screens.

10.7.4. Result repetitions

The programme automatically requests repetitions of all the results off limits if this 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 New field and a window like the one shown in Figure 76 will appear. For automatic repetitions, the increase/decrease factor will normally be applied in each test.

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.
- In both cases, repetition with increase or decrease, the factor will depend on the maximum reaction volume admitted, the sample: reagent ratio and the initial sample volume programmed.

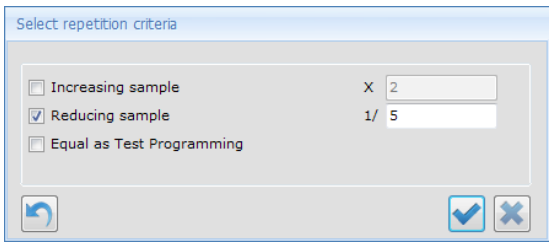


Figure 76 Screen for selecting repetitions

The blanks, calibrators 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.

10.8. Historical logs

10.8.1. 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.

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

Patient 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.

Barcode Enter a sample barcode to select the results.

Urgent The available options are: *All*, *urgent* or *normal*.

Type of test The available options are: *All*, *standard*, *calculated*, *ISE*, *external*

Sample type The available options are: *All, SER, URI, PLM, WBL, CSF, SEM, LIQ.*

Test name Enter the name of the test to make the selection.

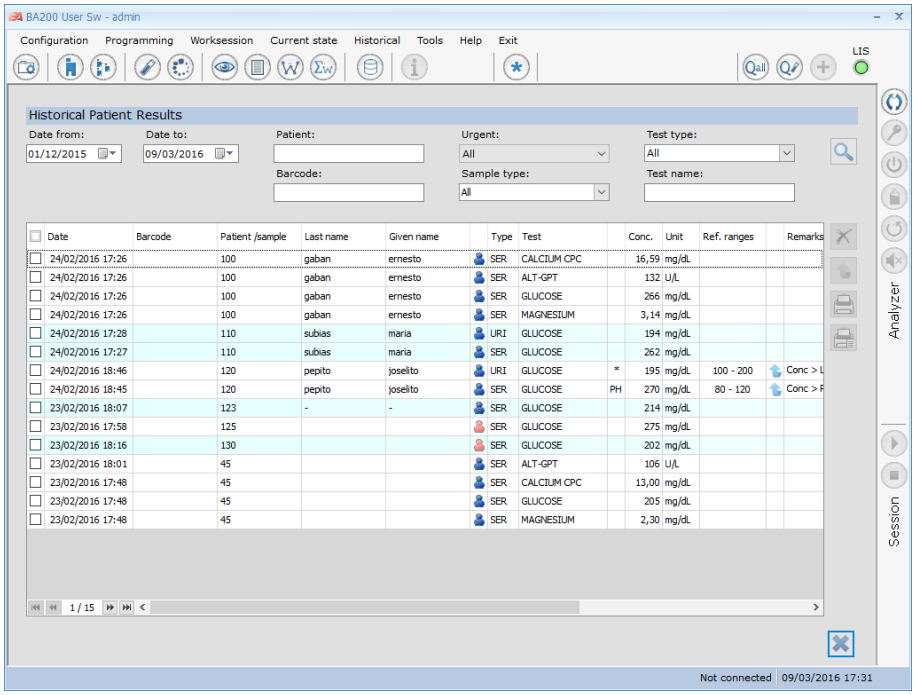


Figure 77 Screen showing historical results for patient

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.

10.8.2. Blank and calibrator results

Screen for saving the blank and calibrator results from previous sessions.

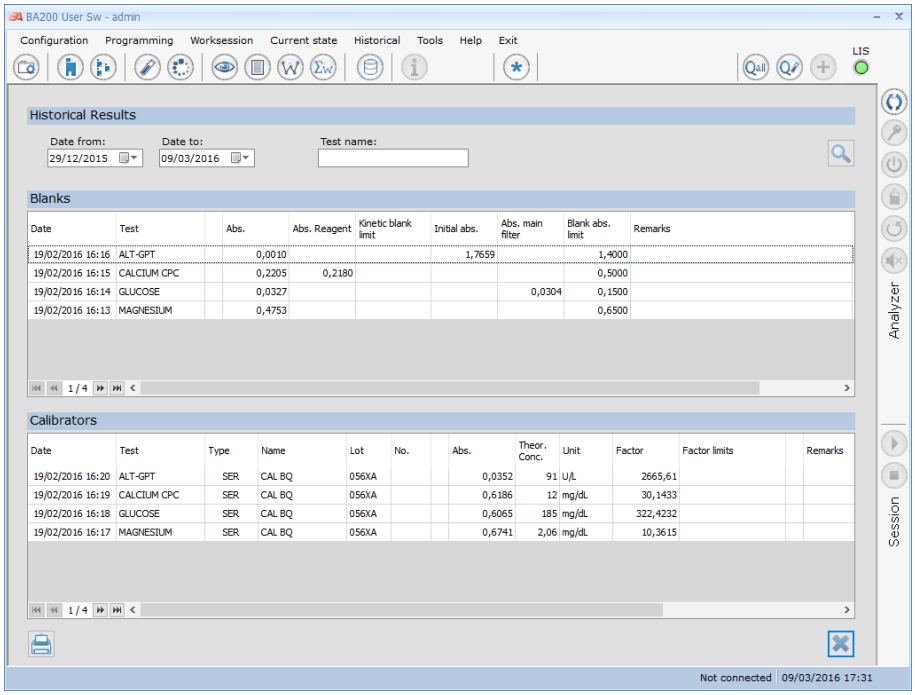


Figure 78 Screen showing historical logs of blank and calibrator data

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 calibrator fields displayed are the same as the fields shown on the current session results screen, selected by test.

☞ *See chapter 10.7.2 for a description of each field in the blank and calibrator screens.*

10.8.3. 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 daily quality control Accumulate results screen.

☞ *See the explanation of how to accumulate results in chapter 10.8.4.1.*

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 (except the selection of the Westgard rules).

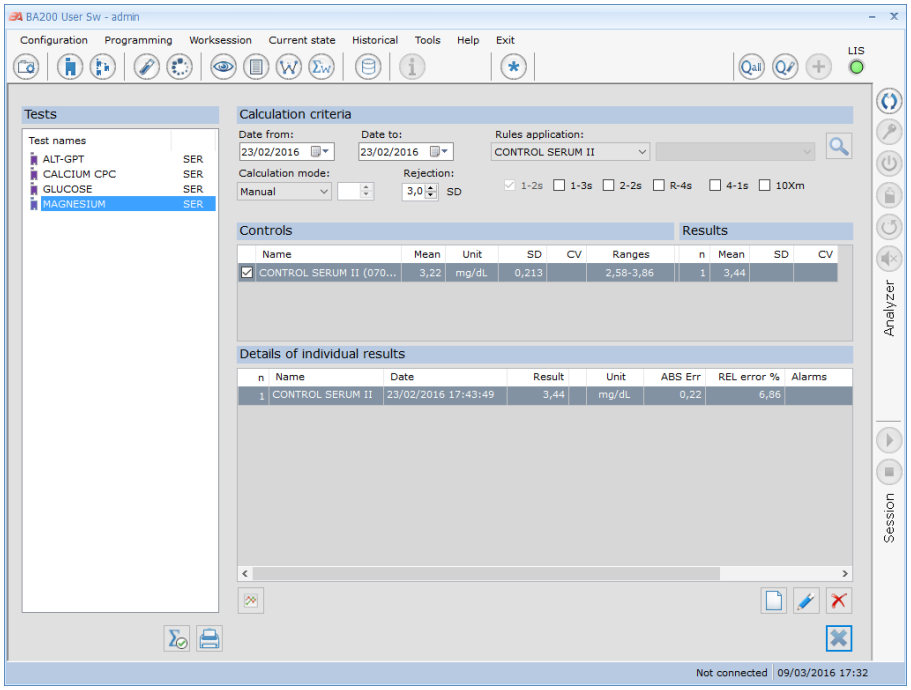


Figure 79 Screen for manual entry of quality control results

Date range Range of dates of the results to be viewed. The date range reported by default is that which allows all the results pending review to be displayed.

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

$$Range = Mean \pm (Rejection\ criterion \cdot SD)$$

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: $Mean = \frac{Maximum\ value + Minimum\ value}{2}$ $SD = \frac{Maximum\ range - Minimum\ range}{2 \cdot Rejection\ criterion}$
Statistical	The results of the n *first* series (*n* = specified series number) are used: $Mean = \frac{\sum_{i=1}^{n} X_i}{n}$ $SD = \sqrt{\frac{\sum_{i=1}^{n} (x_i - Mean)^2}{n-1}}$ $CV = \frac{SD}{Mean} \cdot 100$

The programmed calculation mode 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. $Mean = \frac{\sum_{i=1}^{n} X_i}{n}$
SD	Standard deviation of the results: $SD = \sqrt{\frac{\sum_{i=1}^{n} (x_i - Mean)^2}{n-1}}$
CV	Coefficient of variation of the results: $CV = \frac{SD}{Mean} \cdot 100$

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: • 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: • 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 results group in the displayed set of results, the symbol X_m 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 80 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 81 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 82 and 83 show the screens of the Levi-Jenning and Youden graphs respectively.*

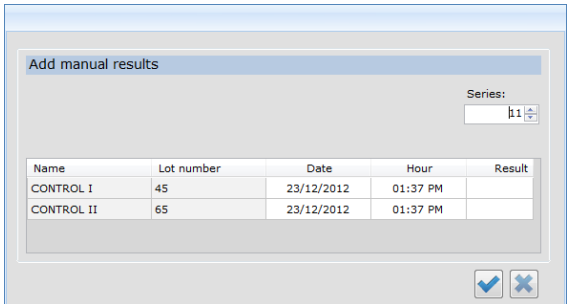


Figure 80 Screen for entering quality control results

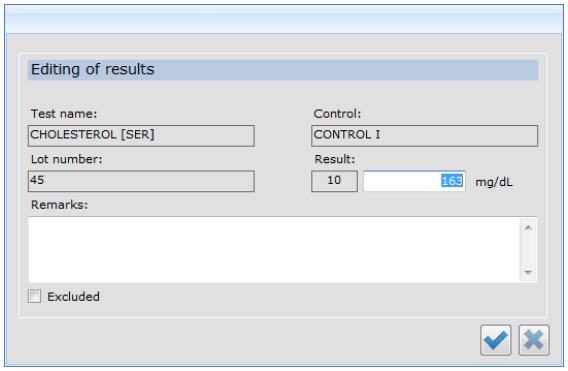


Figure 81 Screen for editing quality control results

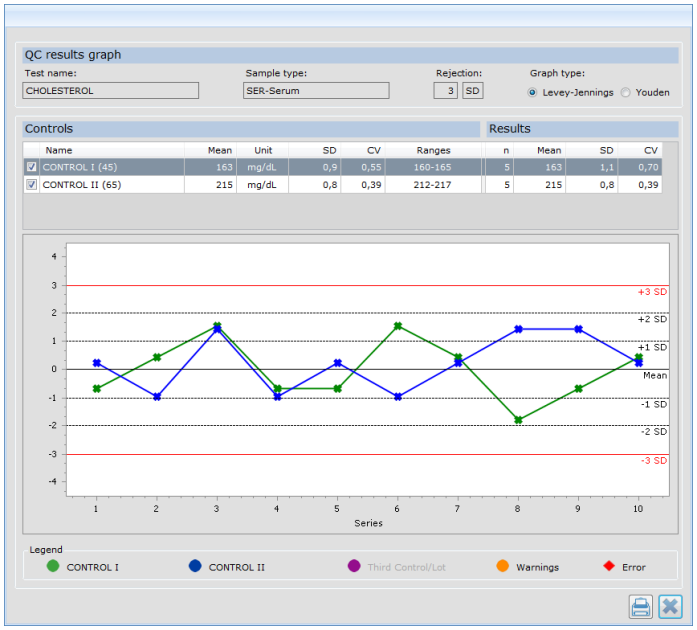


Figure 82 Screen with the Levy-Jennings graph

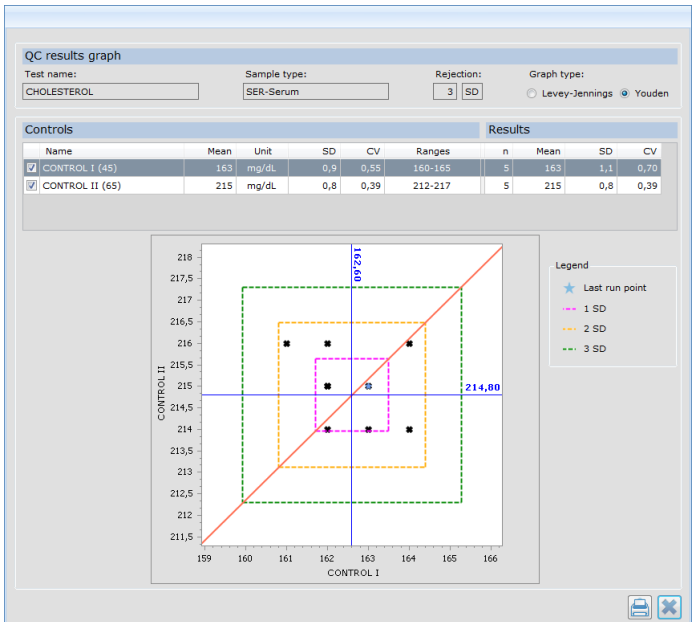


Figure 83 Screen with the Youden graph

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 10.8.4.1*

10.8.4. Accumulated quality control results

10.8.4.1. 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 to compare them with historical results from previous series and with future series.

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

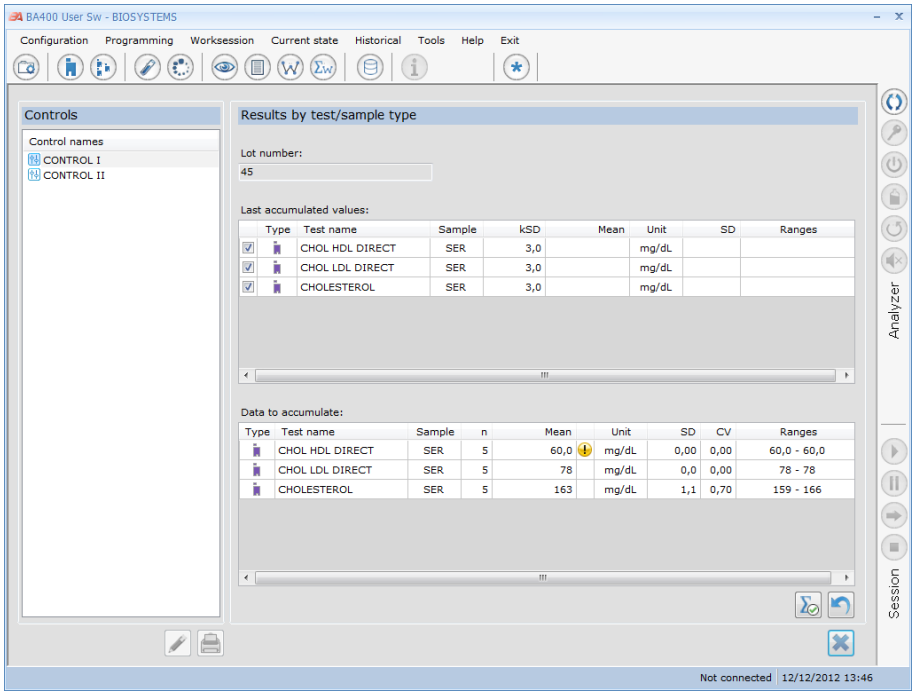


Figure 84 Screen for accumulating daily quality control results.

On the left is a list of controls with results for accumulation. In selecting a control from the list, the number of the active lot 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 results 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 to accumulate).
- **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: $Mean = \frac{\sum_{i=1}^{n} X_i}{n}$
SD	Standard deviation of the results: $SD = \sqrt{\frac{\sum_{i=1}^{n} (x_i - Mean)^2}{n-1}}$
CV	Coefficient of variation of the results: $CV = \frac{SD}{Mean} \cdot 100$
Ranges	Range of admissible values: $Range = Mean \pm (Rejection\ criterion \cdot SD)$

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 10.8.3*

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 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 control's list.

10.8.4.2. 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 85 and 86.

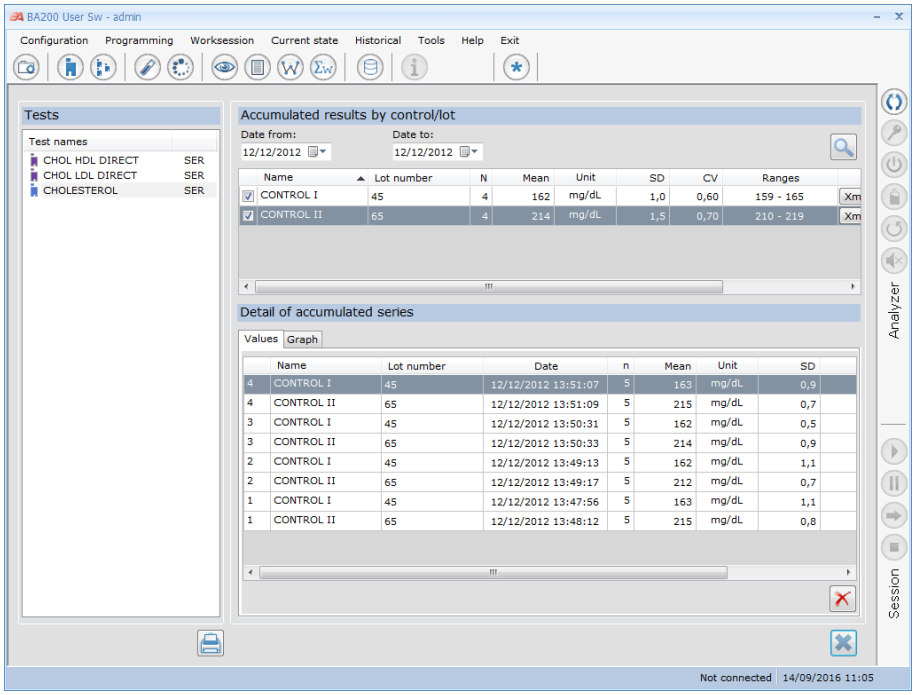


Figure 85 Quality control accumulation screen - Tabular display

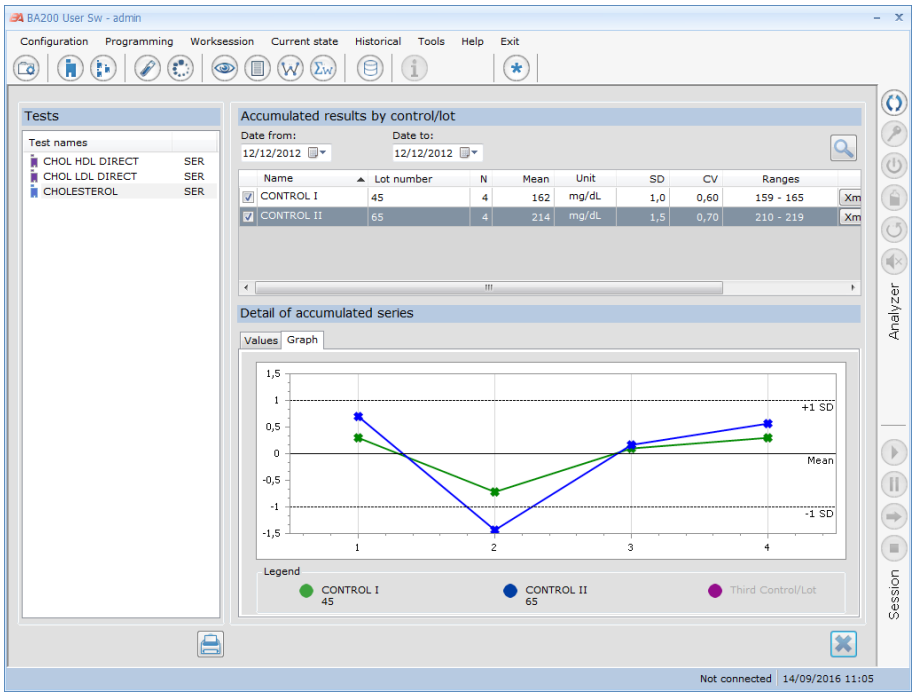


Figure 86 Quality control accumulation screen - Graphic display

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: $Mean = \frac{\sum_{i=1}^{n} Mean_i \cdot n_i}{\sum_{i=1}^{n} n_i}$ $Mean_i$ is the mean for each accumulated series and n_i is the number of daily results used to calculate each accumulated series.
Units	Results 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: $Range = Mean \pm (Rejection\ criterion \cdot SD)$
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/lot 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 lot 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 tabled and graphic format. In the tabular display, the information shown for each control is the following:

Parameter	Description
	Number of accumulated series
Control	Control name

Parameter	Description
Lot Number	Control lot 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	Results 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.

10.8.5. ISE Results

This screen shows the ISE electrode calibrations historical log and the ISE module historical pump calibrations historical log.

Electrodes Select this tab to see the ISE electrode calibrations historical log.

Pumps, bubbles and cleaning cycles Select this tab to see the historical log of the peristaltic pump calibration, bubble detector and cleaning cycles.

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 log containing the ISE electrode calibration results. See Figure 88.

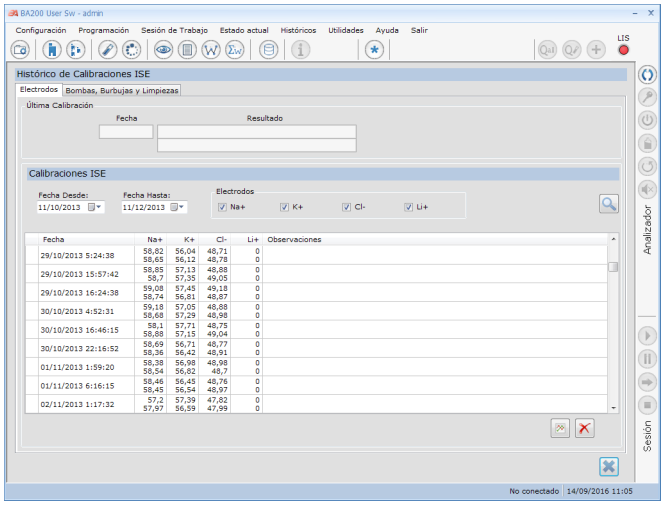


Figure 87 Screen showing ISE electrodes calibration historical log

Figure 88 Graphic display of the calibrations

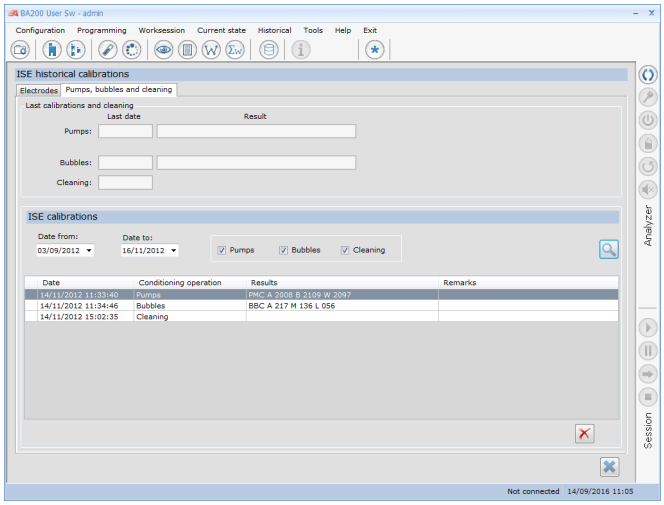


Figure 89 Screen showing the pump calibration historical log

10.8.6. Analyser alarms historical data

Screen showing the alarms historical log.

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.

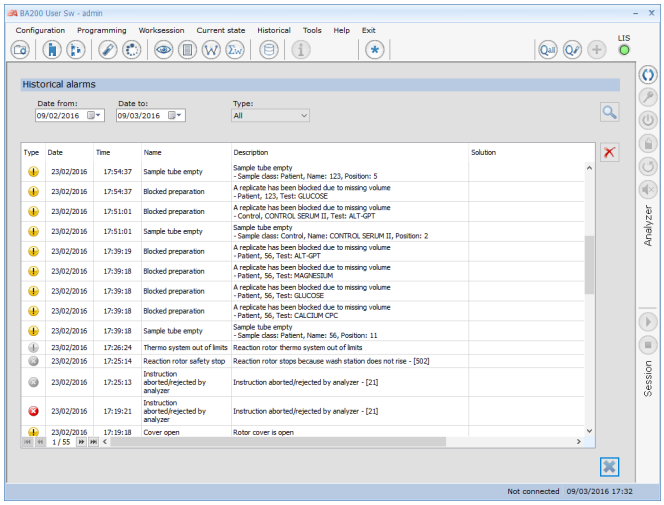


Figure 90 Alarms historical log screen

10.9. Utilities

10.9.1. 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 utilities menu. See Figure 91.

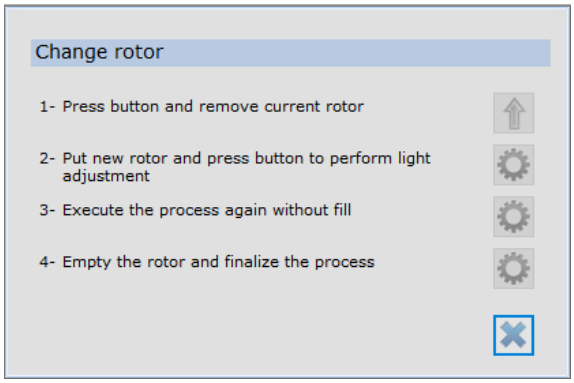


Figure 91 Rotor change

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 in step 2 to tell the programme to change the rotor.
9. The analyser will lower the wash station and start the light adjustment process with the new rotor. It will also measure the optical correction for each well. The process consists of filling each rotor well with water, measuring it with all the wavelengths and emptying it. This process takes about 20 minutes.
10. If there are values outside the ranges in the optical measurements, the utility button of step 3 is activated in order to take the measurement again without having to empty the rotor and fill it.
11. Press the button in step 4 to empty the rotor manually. You should only do this if some of the values read are outside the ranges and then repeat the reading process.

10.9.2. Analyser conditioning

Utility 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.

10.9.3. ISE module utilities

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

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

The following utilities 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 utility several actions must be executed. Select one of the utilities and show the set of actions to be executed step by step.

☞ *See the explanation of each step in detail in chapter 14.3.2.*

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 green) 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 *repetitions* parameter indicate how many times the action must be executed.
Bleed A	It performs a priming cycle with calibrator A, using a volume of 100 µL. In the *repetitions* parameter indicate how many times the action must be executed.
Bleed B	It performs a priming cycle with calibrator B, using a volume of 100 µL. In the *repetitions* parameter indicate how many times the action must be executed.
Priming A	It performs a priming cycle with calibrator A, using a volume of 300 µL. In the *repetitions* parameter indicate how many times the action must be executed.
Priming B	It performs a priming cycle with calibrator B, using a volume of 300 µL. In the *repetitions* parameter indicate how many times the action must be executed.
Wash	It performs a wash cycle with the ISE washing solution. In the *sample rotor pos.* parameter indicate the position of the tube with the washing solution. In the *volume* parameter indicate the volume to be dispensed for washing.

Action	Description
Reagent kit activation	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 calibrators. The program issues a warning when the calibrators are no longer usable.
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 programme you have installed an ISE module.

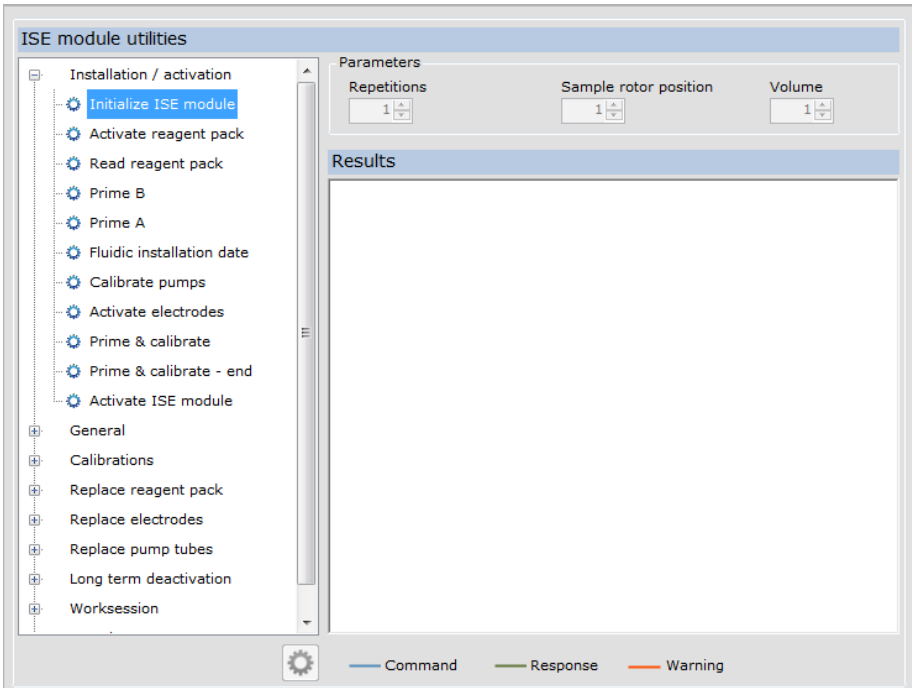


Figure 92 ISE module functions screen

10.9.4. LIS utilities

In this screen certain actions can be executed to solve potential problems caused by the malfunction of the LIS programme. This functionality is only activated if the LIS communication is activated.

Eliminate pending 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 BA200 if it eventually decides not to execute them. In the event of a malfunction of the LIS or the communications, the BA200 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 BA200 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 mode and the LIS communications are activated and free from error.

Eliminate internal storage queues

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.

Selection of LIS communication register monitoring level

Allows the trace level to be configured for capturing information in the LOG about the operation of communications between the LIS and the BA200. This option is used to diagnose potential communication problems during the integration of LIS with the BA200.

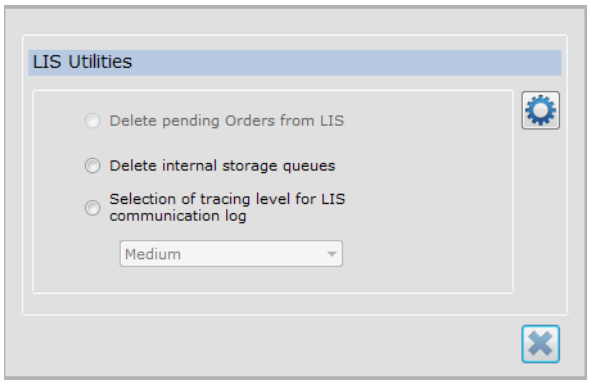


Figure 93 LIS utilities screen

10.9.5. Technical service report

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

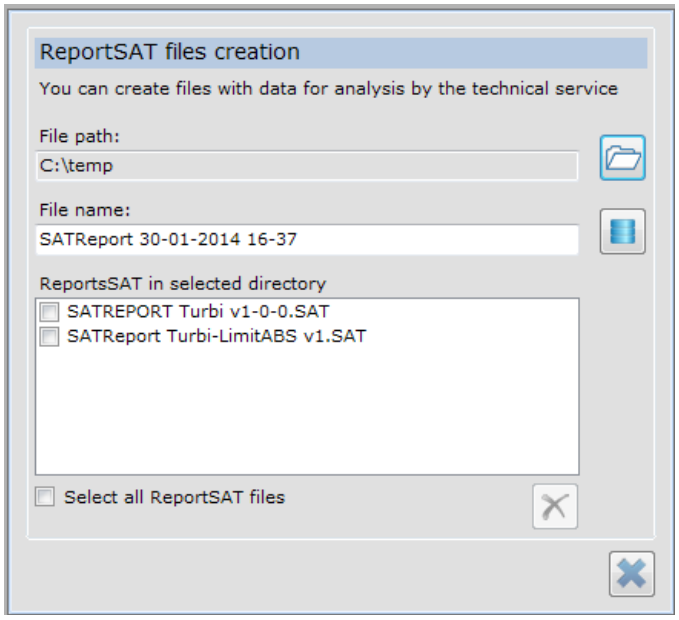


Figure 94 Screen for generating a report for the technical service.

This tool generates a file with all the programme information.

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

This tool is accessed through the *utilities/SAT report* menu or through the icon on the horizontal bar. A screen opens up like the one shown in Figure 94.

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. The file name can be edited in full by placing the cursor on the File Name field.

Press the button to store the information in the SatReport.

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

10.9.6. Create a restoration point with current data

This utility 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\BA200\User Sw\RestorePoints

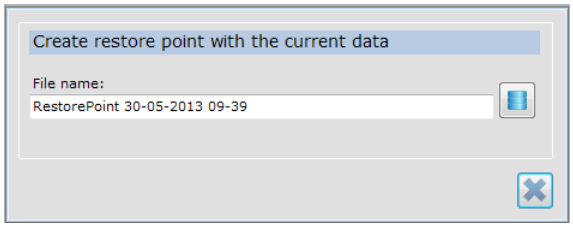


Figure 95 Screen for creating a restoration point

10.9.7. Restore previous data

This utility 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.

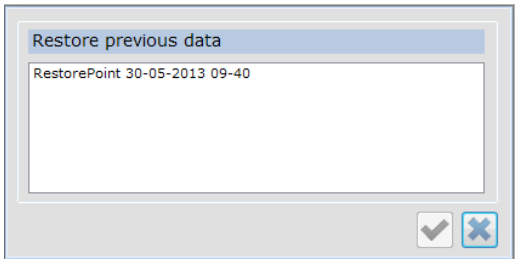


Figure 96 Screen for restoring previous data

10.10. Help

10.10.1. User manual

In this menu you can open a copy of this user manual in pdf format. The pdf reader (Reader®) can be installed directly from the DVD supplied with the equipment or it can be downloaded from the adobe® website.

10.10.2. Analyser information

This option displays the instrument serial number and firmware version installed in the analyser

10.10.3. About

This option displays the installed software version.

10.11. Exit

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

Exit and switch off the analyser — This option closes the programme and tells the analyser to switch itself off and complete the closing process.

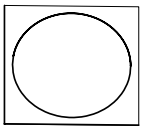
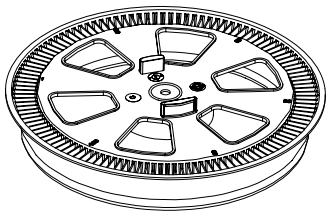
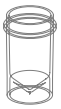
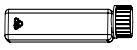
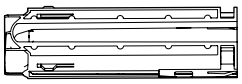
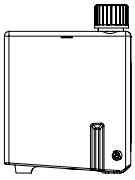
Exit without switching off the analyser — This option will only close the programme and leave the analyser on and on standby.

11. List of consumables and accessories

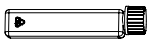
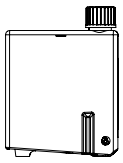
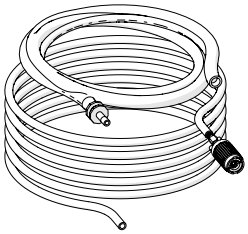
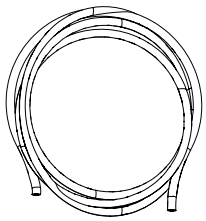
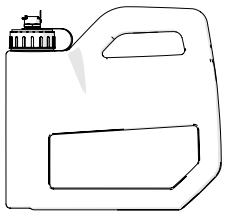
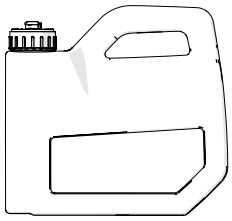
In the event of any of the analyser components being damaged or if fungible goods are required, always use original BioSystems material.

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.

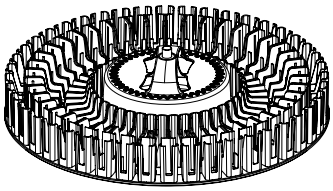
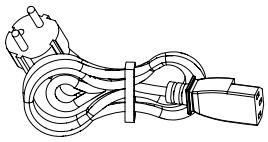
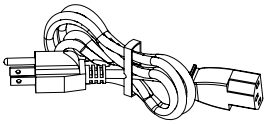
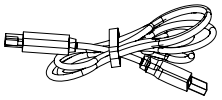
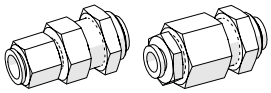
Accessories list

Code	Representation	Description
AC17274		DVD User and service programme
AC11485		Reaction Rotor (10)
AC10770		Sample wells (1000)
AC16434		500 mL bottle of concentrated washing solution
AC17201		Bottle of acid washing solution
AC16360		Open adapter for primary tubes (90)
AC17611		Tube adapter (30)
AC16362		60 mL reagent bottles (20)

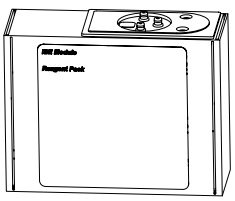
Accessories list

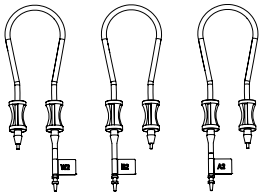
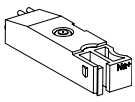
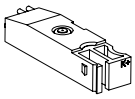
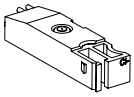
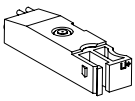
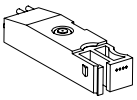
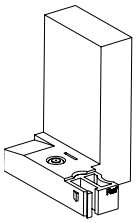
Code	Representation	Description
AC16363		20 mL reagent bottles (20)
AC16364		60 mL brown reagent bottles (20)
AC16365		20 mL brown reagent bottles (20)
AC17269		Connection tubes for purified water bottle (3 m)
AC17270		Connection tube for waste (3 m)
AC17271		Washing solution bottle with cap
AC17272		High contamination bottle with cap
AC17273		Washing solution bottle cap
AC16749		High contamination waste bottle cap

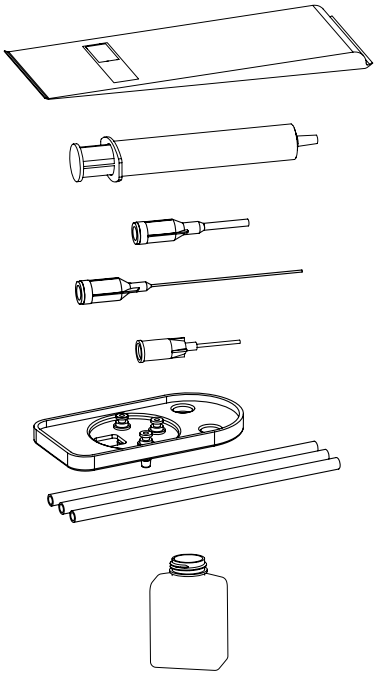
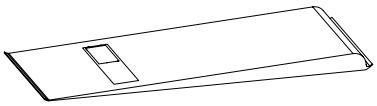
Accessories list

Code	Representation	Description
AC16370		Reagent and samples rotor
AC11486		Reaction rotor set screw
CA10455		European mains cable
CA10456		American mains cable
AC17305		USB cable for connection to the computer
AC16747		10 A (2) fuse
AC17097		150 µm purified water input filter assembly
AC16791		Water inlet filter assembly (5 µm)
AC16792		Spare water filter cartridge (5 µm)

List of ISE module accessories (optional)

Code	Representation	Description
5420		Reagent kit

List of ISE module accessories (optional)		
Code	**Representation**	**Description**
5625		Set of ISE module tubes
5201		Na^+ electrode
5202		K^+ electrode
5207		Cl^- electrode
5205		Li^+ electrode
5206		Separator electrode
5204		Reference electrode
5421		ISE module washing solution
5412		ISE module 125 mL urine dilution

List of ISE module accessories (optional)		
Code	**Representation**	**Description**
AC16752		ISE cleaning kit
AC17096		Cotton buds

12. Support and warranty

The BA200 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.) as well as and any 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 programme

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 programme 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 and sample arm	The arm has collided. This action will block the arm that has collided. The analyser recovers the arm and continues processing the preparations.	Solve the cause of the collision. Check the state of the colliding reagent bottle or sample tube.
	Warning that there is insufficient volume of reagent R1 or R2.	The programme warns that there is very little reagent R1 or R2.	Insert a fresh bottle of reagent on 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 programme 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 and samples rotor cover is open	The reagent rotor cover has opened during the stopping phase.	Close the reagent rotor cover.
	Refrigeration off warning	The programme warns that the refrigeration system is off.	Switches on the refrigeration system.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	The purified water tank has been empty for 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 configuration 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 reaction rotor cover has opened during the stopping phase.	Close the reaction 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 utility.
	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.	Centrifuge the sample again.
		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 calibrator volume is insufficient. The programme 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.
	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 station 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.
	Error warning in reading the barcode	There may be moisture on the barcode reading optical window	Clean the barcode reader window with a cloth.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
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. Check that the COM port is not being used by another programme.
	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 saying the arm temperature is off limits	The 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 and sample rotor cover. Press the recovery button. If the alarm continues notify the technical service.
	Alarm saying the wash station temperature is off limits	The wash station 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.
	Refrigerator fans damaged	The refrigerator rotor fans are not functioning properly.	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
	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

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	Warning that calibrator A or B of the reagent kit has been used up	Calibrator 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.
	Warning that the number of uses for an electrode has been exceeded	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
		End of the electrodes' 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
	Shunt from an electrode	This may occur if the electrode is new or calibrator A has just been installed. If the electrode is new, it may shunt initially while rehydrating for 15 minutes.	Bleed calibrator A and recalibrate
		End of the electrode's useful life	Replace the electrode
	Air in the sample and/or calibrator	Insufficient sample volume.	Check that there is sufficient sample volume. Check that the tip is not partly blocked.
		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 pump tubes
		Sample intake cup dirty	Clean the cup with a cotton swab and purified water.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
		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.
	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.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	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 calibrator absorbance is lower than the blank absorbance. It was not possible to calculate the calibrator absorbance. It was not possible to calculate the blank absorbance. The calibrator 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.
	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.

Type of alarm	Alarm/Error	Cause of the problem	Solution proposed
	CONC outside the calibration curve	Extrapolated result, the concentration Abs is outside the calibration curve.	Repeat diluting the sample.
	Conc NOT calculated	It was not possible to calculate the blank absorbance. It was not possible to calculate the sample absorbance. It was not possible to calculate the factor. Calibration curve incorrect.	Repeat the test for the sample, blank or calibrator, depending on the problem.
	Sample substrate consumed	This message will appear for tests programmed as kinetic. If the message appears this means that the substrate was consumed before the reaction started. This happens in samples with very high concentrations.	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	This message will appear for tests programmed as turbidimetric. If the message appears it means that the sample concentration may have the prozone effect.	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 calibrators, controls and samples from the rotor

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

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 connection 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 and reagent rotor.
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 is a drainage hole 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 programme 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 reagent and sample rotor cover.
3. Take out the rotor.
4. Clean the interior window 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 2.4 L of purified water.
3. Add 12 mL of the concentrated washing solution (AC13434 code). 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.

NOTE

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 paddle

1. Turn off the analyser by operating the switch.
2. Raise the stirrer arm manually. When moving the arms, do it gently and carefully.
3. Clean the stirrer paddle with a cloth soaked in washing solution.
4. Rinse the stirrer with a cloth dampened with distilled water.
5. Lower the stirrer to its rest position.
6. Switch on the analyser and perform 2 conditioning cycles in the functions menu.

14.2.8. Cleaning the water inlet filters

1. Turn off the analyser.
2. Access the rear part of the analyser where the water inlet filters are located.

☞ *See Figure 97*

3. Using a spanner, unscrew the water inlet filter support (1).
4. Clean the filter with water and a neutral soap (2).
5. Replace the filter and support.

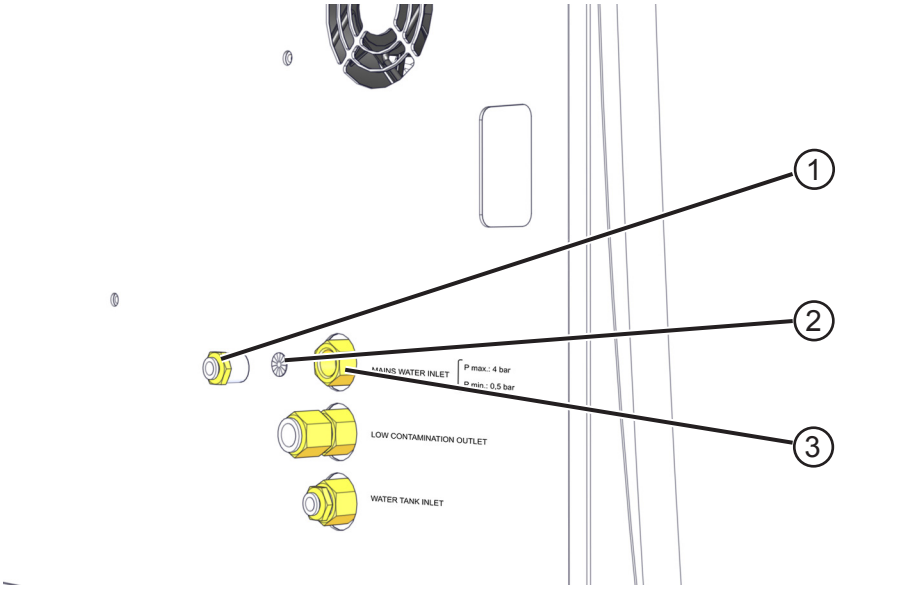


Figure 97 Dismantling the water filters

14.2.9. 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 *ISA utilities* section, 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 tensioactives, 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.

The software will also request the automatic cleaning of the ISE module after processing 50 samples.

Cleaning of sample intake

Use a cotton swab and ISE washing solution (5421) once a week.

☞ *See Figure 98 and Figure 99*

Place the swab at the module entrance and use it to rub the exterior and interior of the intake cup (2). To see the cup intake, remove the plastic part located at the base of the stirring arm (1).

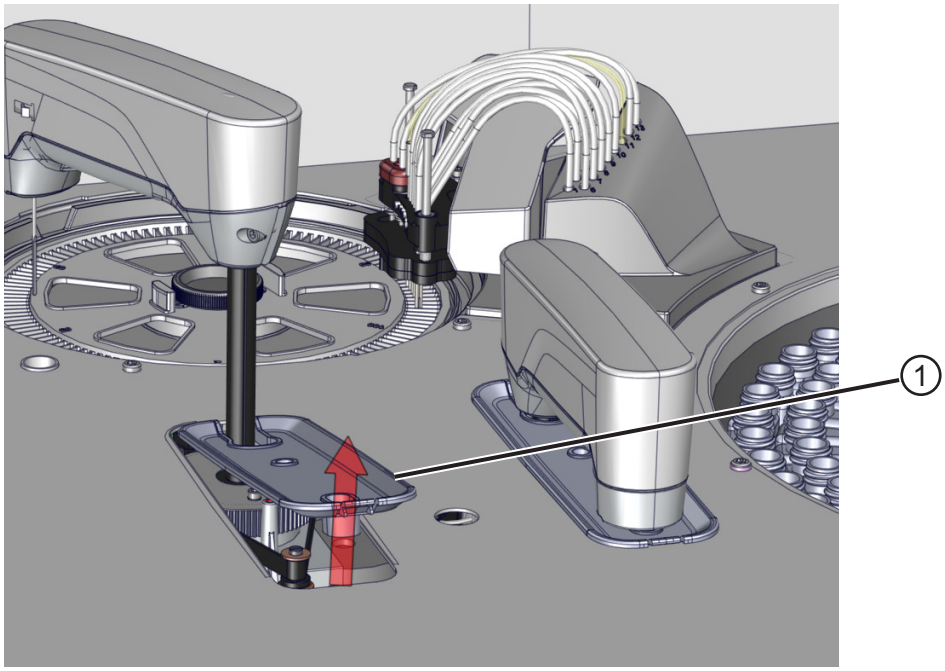


Figure 98 Access to the ISE cup

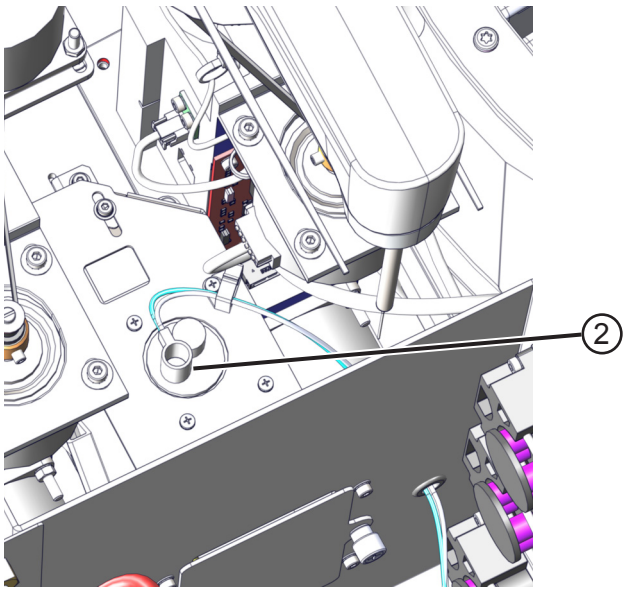


Figure 99 ISE cup

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 several cuvettes are repeatedly discarded it is advisable to change the reaction rotor.

NOTE

It is recommended to change the reaction rotor at least 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 programme.

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 programme in the *ISE utilities*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 100.
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 programme, execute the actions in the number and order indicated in the *ISE functions, change electrodes section*.

Step	Action	Repetitions	Description
1	Priming B	1	Check, through the window exposed after removing the stirrer cover, that the ISE cup is being filled and emptied in succession

Step	Action	Repetitions	Description
2	Priming A	1	Check, through the window exposed after removing the stirrer cover, that the ISE cup is being filled and emptied in succession. 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	
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.

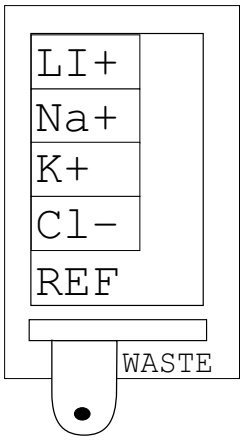


Figure 100 Order for positioning the different electrodes

14.3.2.2. Changing the reagent kit


BIOHAZARD

Open the front door 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 programme, execute the actions in the number and order indicated in the *ISE utilities, change reagent kit section*.

☞ *See chapter 10.9.3*

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 *Read reagent Kit* 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 the stirrer, which allows you to observe the dispensing cup. ☞ *See Figure 98* 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

Step	Action	Repetitions	Description
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.

1. With the user program in the *ISE utilities* 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.

BIOHAZARD

Separate each of the three 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 101.

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 A must be installed in the pump (2). The order for putting them in place starting from the bottom is A2 and A1.

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

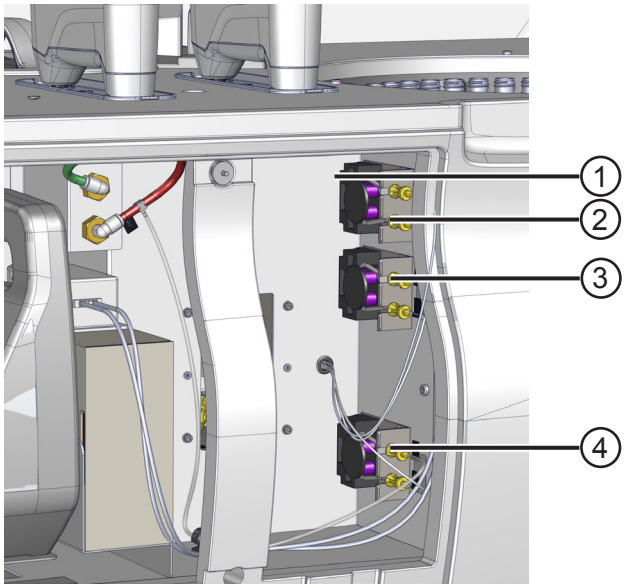


Figure 101 Connecting the peristaltic pump tubes

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

With the user programme, execute the actions in the number and order indicated in the *ISE utilities, change pump tube section*.

☞ *See chapter 10.9.3*

Step	Action	Repetitions	Description
1	Priming B	2	
2	Priming A	2	
3	Priming B	9	
4	Priming A	9	
5	Update the instal-lation 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 operations described 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 user programme, in the *ISE utilities section*.

☞ *See chapter 10.9.3*

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 sample 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 indicated sample rotor well
3	Bleed A	3	
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 102 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 programme 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 K+ and Li+ electrodes Suction a small quantity of the calibrator A dispensed in a sample well during the first step.

Inject the appropriate quantity of calibrator 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 Li^+electrodes) with adhesive tape to hold calibrator A in place.

Place 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 102 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 4.13

14.3.3. Maintenance frequency

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	3 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
Peristaltic pump tubes	6 months	6 months
Fluidic tubes	12 months	12 months

End of the analyser's useful life

At the end of the useful life of the analyser dispose of the product in accordance with the environmental legislation existing 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	200 prep/h (without electrolytes)
ISE module speed	120 prep/h with 3 channels 160 prep/h with 4 channels
Analysis principles	Photometry, turbidimetry. ISE module: Direct power meter

15.2. Sample and reagent management

Sample and reagent rotor capacity	88 (44 bottles of 20 mL or 60 mL + 44 bottles of 20 mL)
Barcode detector	Yes
Number of samples with barcodes	88
Size of primary tubes	Diameter 12 mm to 16 mm (max. height 100 mm)
Sample well	Sample well diameter 13.5 mm
Reagent bottle volume	20 mL, 60 mL
Refrigerated reagents	Yes
Refrigerator temperature range	5 °C to 12 °C (at room temperature of 25 °C)
Type of sample pump syringe	Low-maintenance ceramic piston
Piston diameter	8 mm
Dispensed sample volume	2 µL to 40 µL
Dispensing resolution	0.1 µL
Pre-dilution ratio	1:1 to 1:200
R1 reagent volume	90 µL to 300 µL
R2 reagent volume	10 µL to 100 µL
Dispensing resolution	0.1 µL
Level detection	Yes
Washing of tip	Interior and exterior
Clot detector	Yes
Vertical collision detector	Yes
Thermostatted tip	Yes

15.3. Reaction rotor

Minimum reaction volume	180 µL
Maximum reaction volume	440 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	1

15.4. 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

15.5. 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

15.6. ISE module (optional)

Sample type	Serum, Plasma or Urine
Type of electrode	Na^+, K^+, Cl^-. Li^+ (optional)

Type of measurement	Direct ISE
Sample volume	Serum: 100 µL Urine: 200 µL

15.7. 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

15.8. Dimensions and weight

Dimensions (Width, depth and height)	1077 mm x 690 mm x 680 mm
Weight	166 Kg

15.9. Electrical requirements

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

15.10. Fluid requirements

Water inlet	Through external tank or through direct connection
Type of water	Purification type II (NCCLS)
Water consumption	< 9 L/h
High contamination waste tank	Internal, 2.4 L
Washing solution tank	Internal, 2.4 L

15.11. Minimum computer requirements

Operating system	Windows® 7 64 bit (x64), Windows® 10 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.
$[...]^{\lambda principal}$	Absorbance value at the main wavelength.
$[...]^{\lambda reference}$	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
$A_{Calibrator}$	Calibrator absorbance
A_{sample}	Sample absorbance
$C_{calibrator}$	Known calibrator concentration

16.1. Operating sequence. Preparation and reading cycles

Figure 103 shows the dispensing cycles, the dispensing of reagents 1 and 2 and the reading made by the analyser.

Each analyser cycle lasts for 18 seconds. The total maximum reading time for a preparation may last for 10.2 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.

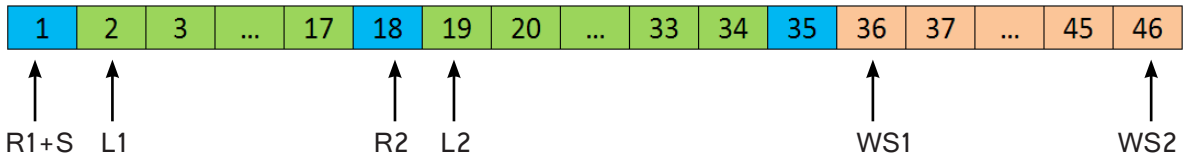


Figure 103 Analyser cycles

Abbreviations	Cycles	Description
R1+S	1	Dispensing of reagent 1 and sample
M1	2	Stirring reagent 1 and sample
L1	2-18	Reading
R2	18	Dispensing of reagent 2 (optional)
M2	19	Stirring of reagent 2
L2	18-35	Reading (L2 > L1)
WS1	36	Wash station initiation
WS2	46	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 104.

First reagent A is dispensed and the sample is dispensed in cycle 1, 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.

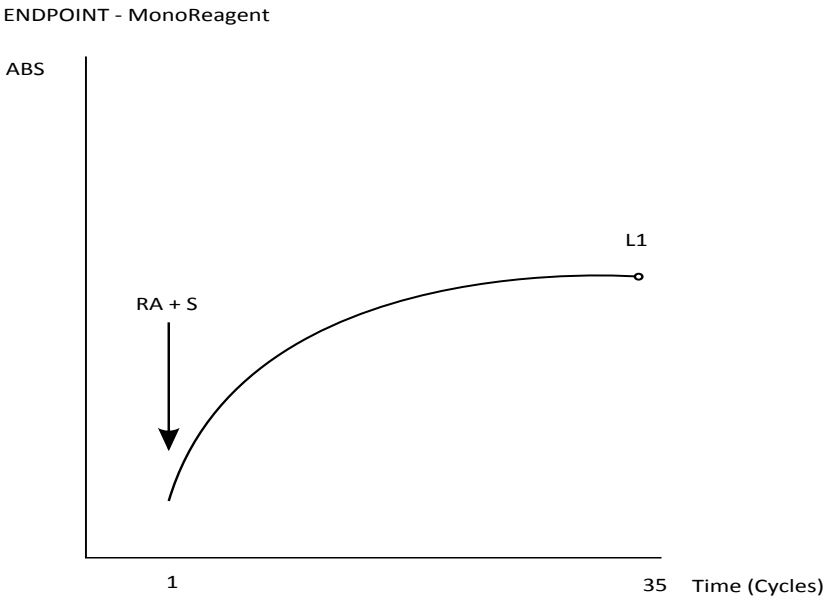


Figure 104 Endpoint monoreagent calculation method representation

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.

$$A = \mathrm{ABS}_{L1}^{\lambda main} \tag{1}$$

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.

$$A = ABS_{L1}^{\lambda main} - ABS_{L1}^{\lambda reference} \tag{2}$$

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 and the sample in cycle 1, and in the next cycle it is stirred. Then reagent B is dispensed in cycle 18 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.

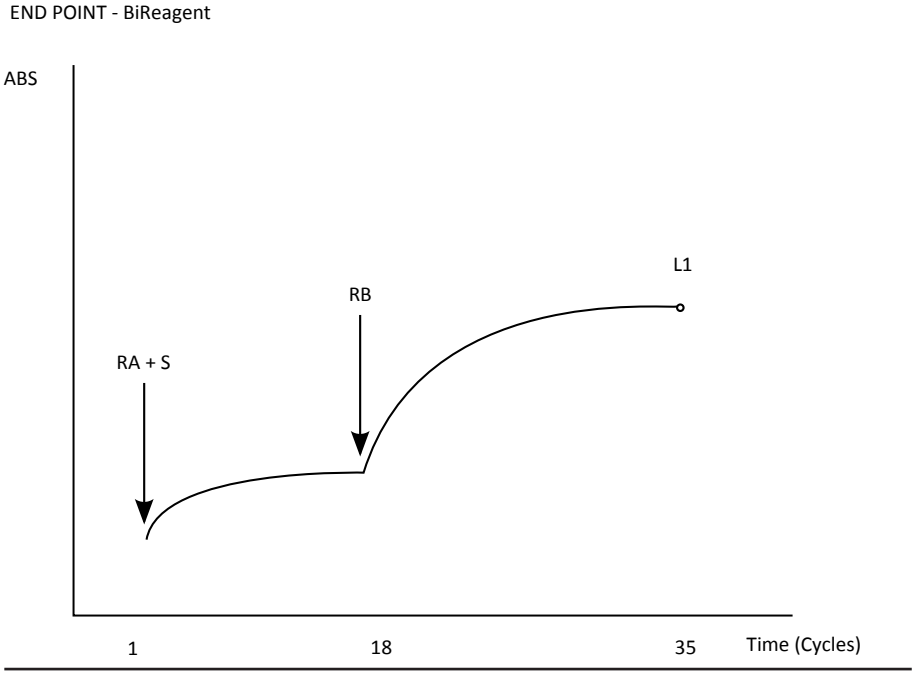


Figure 105 Endpoint bi-reagent calculation method representation

The absorbance calculation may be monochromatic or bichromatic.

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

$$A = \mathrm{ABS}_{L1}^{\lambda\, main} \tag{3}$$

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.

$$A = ABS_{L1}^{\lambda\, main} - ABS_{L1}^{\lambda\, reference} \tag{4}$$

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 and the sample in cycle 1, 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 18, and stirred in the next cycle, and the second part of the reaction commences. When the second reaction is balanced, reading L2 is taken.

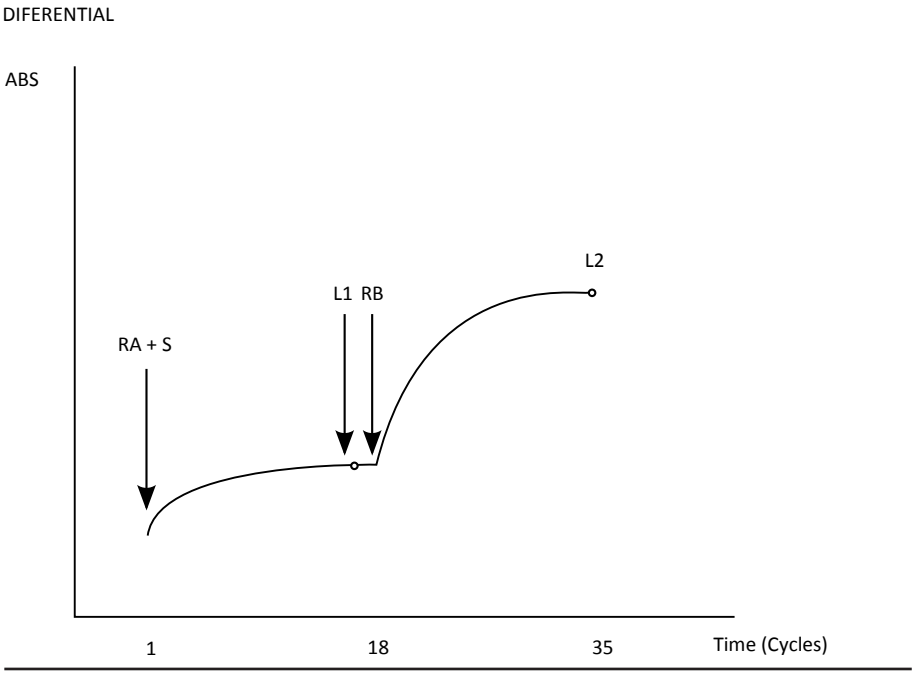


Figure 106 Differential calculation method representation

The following formula is applied in calculating the absorbance:

$$A = \mathrm{ABS}_{L2}^{\lambda main} - \left(\mathrm{ABS}_{L1}^{\lambda main} * \frac{V_M + V_{R1}}{V_M + V_{R1} + V_{R2}}\right) \quad (5)$$

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 and the sample is dispensed in cycle 1, 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.

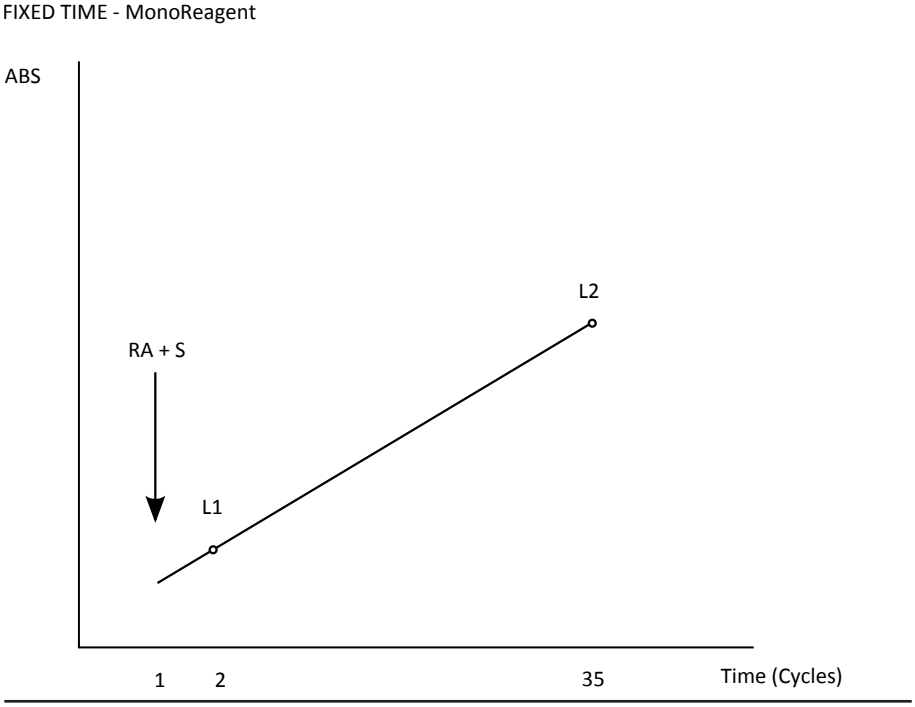


Figure 107 Fixed time monoreagent calculation method representation

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 reach reading time.

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

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 and the sample in cycle 1, and in the next cycle it is stirred. Then reagent B is dispensed in cycle 18 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 reach reading time.

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

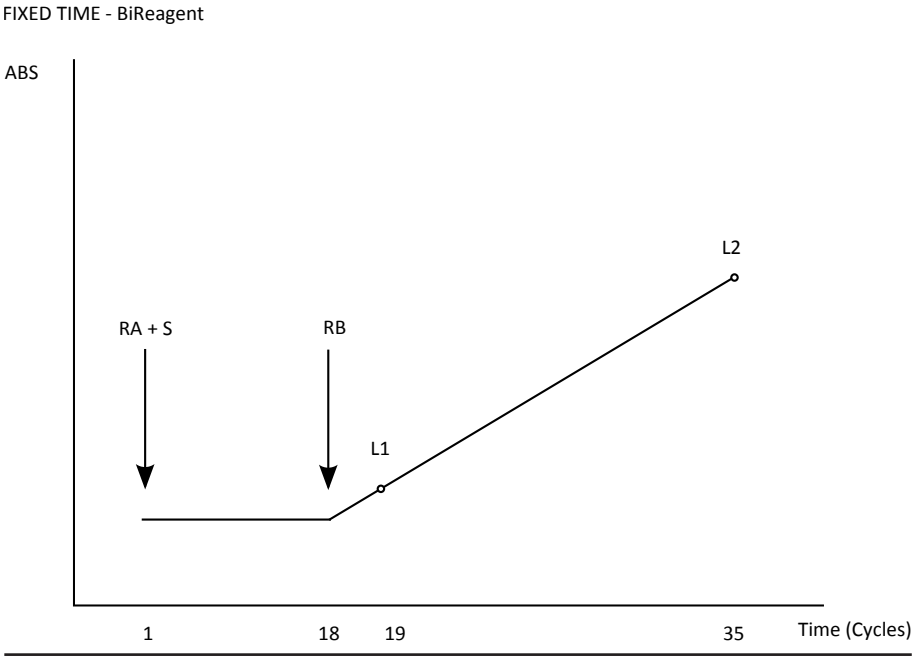


Figure 108 Fixed time bi-reagent calculation method representation

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 (ΔABS/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 ρ < 0.9 then the programme says that the result of the kinetic reaction is non-linear.

First reagent A is dispensed and the sample is dispensed in cycle 1, 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:

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

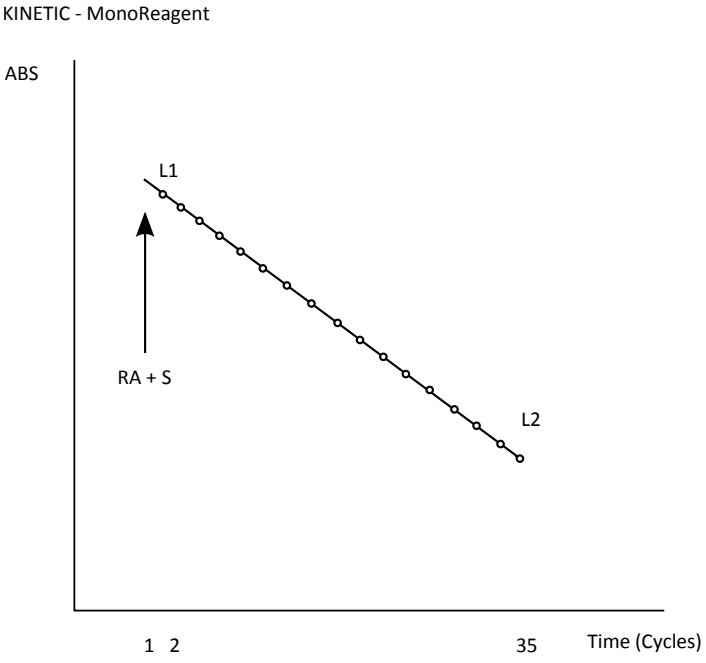


Figure 109 Kinetic calculation method representation

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 and the sample in cycle 1, and in the next cycle it is stirred. Then reagent B is dispensed in cycle 18 and stirred and the reaction commences. The analyser starts to take the readings from time L1 to time L2.

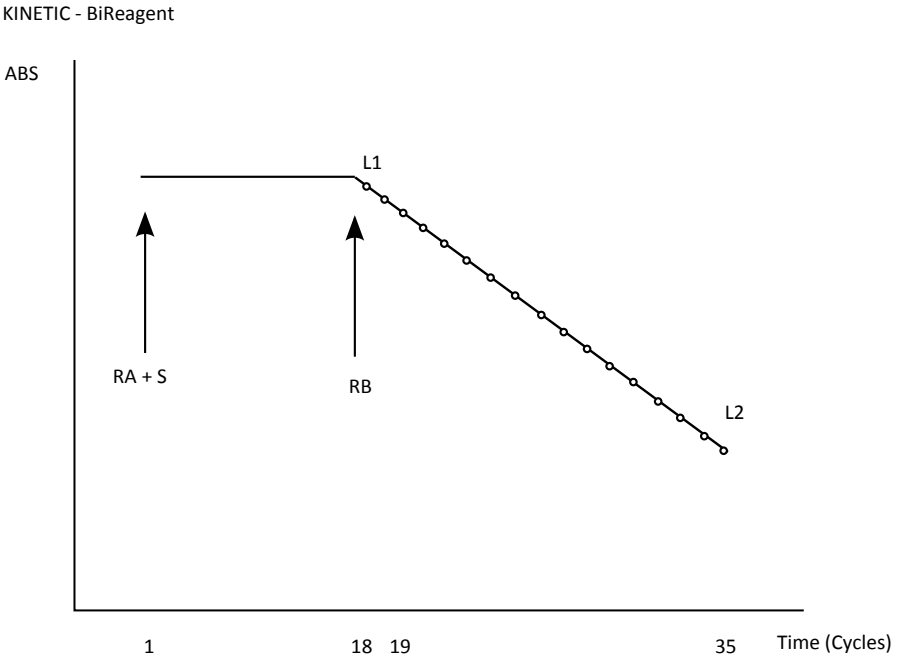


Figure 110 Kinetic calculation method representation

The absorbance calculation is as follows:

$$A = \left[\frac{\Delta\, ABS}{min} \right]^{\lambda\, main} \tag{7}$$

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 111 and 112. If the ratio is linear only one calibrator is measured and the calibration line is calculated. If the ratio is non-linear several calibrators 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.

Calibrator The calibrator is a sample with the known concentration of the analyte to be determined. It is a standard or reference material. To correctly measure the calibrator 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 calibration function is a line. So it will only be necessary to measure the blank and a calibrator.

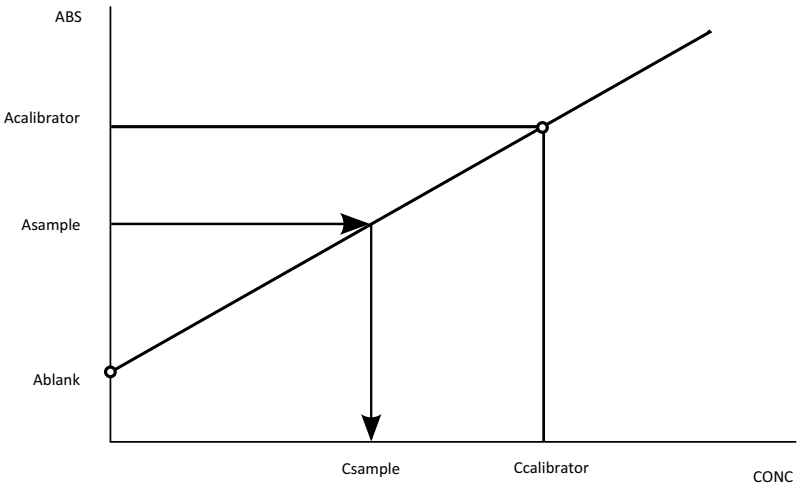


Figure 111 Linear calibration curve

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:

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

And the following formula is used to calculate the concentrations:

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

For calibration functions that are non-linear several known concentration calibrators 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.

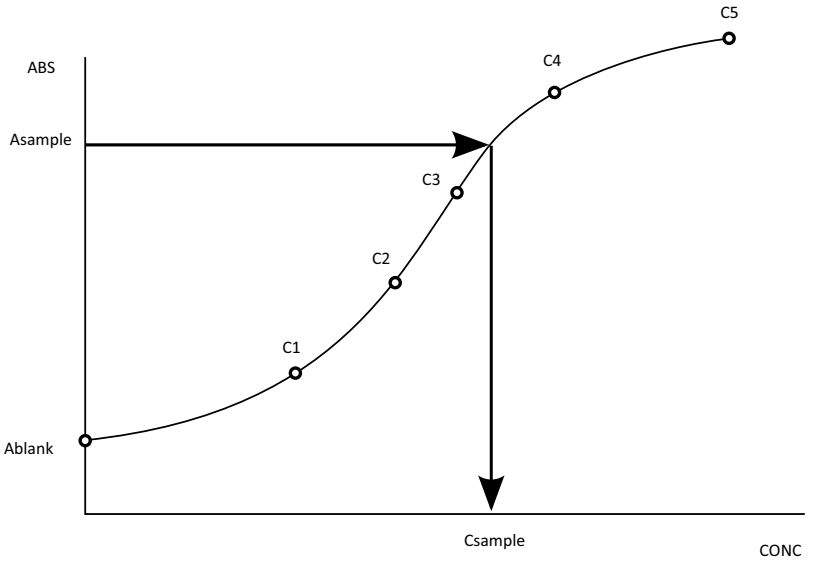


Figure 112 Non-linear calibration curve

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 113 shows the repetition criteria, depending on the programmed parameters.

Criterion	Type of repetition
Concentration result < Detection limit	Repetition with sample concentration
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	Do not repeat
Concentration result < Minimum panic range	Repetition with sample concentration

Criterion	Type of repetition
Concentration result > Maximum panic range	Repetition with dilution
Minimum panic range >Concentration result > Maximum panic range	Do not repeat

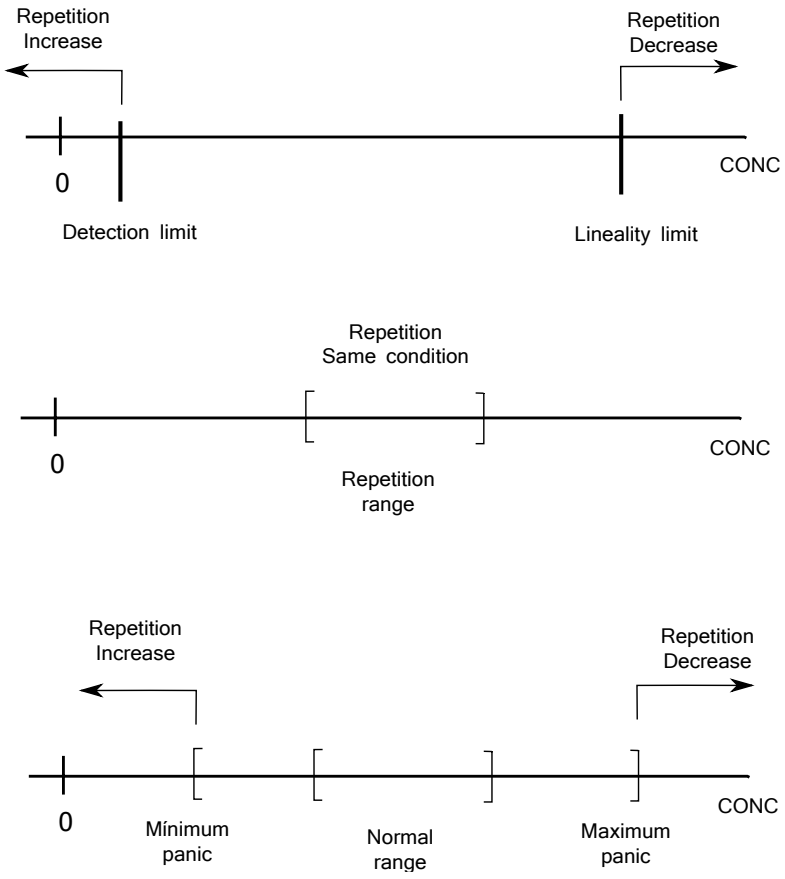


Figure 113 Repetition criteria diagram

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.

$$E_x = E_S + \frac{RT}{nF} \cdot \log(\alpha C) \tag{12}$$

Symbol	Description
E_x	Electrode potential in the sample solution
E_S	Potential developed in standard conditions
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 calibrator A for serum samples or calibrator 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:

$$E_x - E_S = S \cdot \log\left(\frac{C_x}{C_s}\right) \tag{13}$$

$$C_x = C_s \cdot 10^{\frac{E_x - E_S}{S}} \tag{14}$$

Symbol	Description
E_x	ISE voltage in the sample solution
E_S	ISE voltage in the calibrator solution
S	Electrode slope calculated during the calibration process
C_x	Ion concentration of the sample
C_S	Ion concentration of the calibrator solution

"S", slope, is determined during the calibration using calibrators 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 calibrator A and the reading of calibrator B. Excessive shunt or noisy readings will be indicated and an error message will be sent to the system.

The slope is defined as:

$$Slope = \frac{E_B - E_A}{\log \frac{C_B}{C_A}} \tag{15}$$

Symbol	Description
C_A	Concentration of calibrator A in mmol/L
C_B	Concentration of calibrator B in mmol/L
E_A	Voltage measured in the ISE of calibrator A in mV
E_B	Voltage measured in the ISE of calibrator B in mV

The calibration slope value is affected by the temperature and by the ageing 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 lot 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 (≤ 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 BA200 and the information management software of a laboratory (LIS-Laboratory Information System). It describes the exchange of information between the BA200 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 BA200 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 calledUpload.

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 modes: 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 BA200 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 on 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 calibrators 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 on 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 BA200 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 programme processes the orders and creates the worklist.
3. The user positions the sample specimens on the rotor and reads the barcodes.
4. The programme assigns to each specimen the information of the work order programmed for 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 the 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 test 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 log screen.

When the *transmission of control results requested from the analyser* is active: all the internal control results requested from the BA200 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 utilities 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 configuration 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, calibrators 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 B400.

Due to actions carried out by the user

Description	Cause
The user deletes requests accepted from the LIS pending execution by the BA200	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 BA200.
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 repetition mode *in the* analyser has only been selected in the BA200.
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 BA200, 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.
	An internal control was requested for a normal or ISE test and the quality control parameters are not programmed in the BA200.
Calculated test requires more than one sample type	The calculated test is formed by tests with different sample types.
Duplicate specimen	The same specimen identifier was sent for different patients
Duplicated request	The same specimen identifier/test identifier /sample type identifier was already requested for the same patient and their result has not yet been sent.

18. Menu tree

To access the different programme options, this is structured based on menus. To make it easy to browse in the system there are only two menu levels. The main menu has the following options:

Main menu	Description
Configuration	This menu gives access to the different programme configuration options.
Programming	This menu gives access to the different programming options permitted by the programme.
Work session	This menu gives access to the creation of the current session.
Current status	This menu gives access to the current work session status options.
Historical logs	This menu show the historical log of results and alarms.
Utilities	This menu gives access to the different programme utilities.
Help	This menu gives access to information about the system.
Exit	This menu allows the user to exit the application.

The submenu options are set out below:

Menu	Submenu	Description
Configuration	General	Selection of the different general programme options
	Language	Language selection
	Reports	Patient report configuration
	Report test order	Configuration of test order for the patient reports.
	Barcode	Configuration of the different barcode options
	LIS configuration	Configuration of LIS communication options
	LIS mapping	LIS test mapping configuration
	Users	Configuration of the different users
	Change user	Option for changing the user

Menu	Submenu	Description
Programming	Tests	Programming of test parameters
	Calculated Tests	Programming of calculated test parameters
	Contaminations	Contamination programming
	Profiles	Profile programming
	Calibrators	Programming of calibrators
	Controls	Programming of controls
	Patient data	Patient data entry
	ISE Tests	ISE test programming
	External tests	External test programming

Menu	Submenu	Description
Work Session	Sample Request	Work session programming screen
	Positioning on Rotor	Screen for positioning the work session samples and reagents
	Additional information on samples	Screen for entering the patient data for the work session
	Load session	Option for loading a previously memorised session
	Save session	Option for saving a session
	Delete session	Option for deleting a session
	Delete rotors	Option for deleting the rotor positioning

Menu	Submenu	Description
Current status	Monitor	Menu for accessing current information on the session.
	Work session results	Menu for viewing current results.

Menu	Submenu	Description
Historical logs	Patient results	Menu giving access to the historical log of patient results
	Blank and Calibrator Results	Menu giving access to the historical log of blanks and calibrators
	QC results	Menu giving access to the historical log of control results
	Cumulative QC results	Menu giving access to the historical log of cumulative control results
	ISE Results	Menu giving access to the historical log of ISE calibration results
	Analyser alarms historical data	Menu giving access to the historical log of alarms

Menu	Submenu	Description
Utilities	Change Reaction Rotor	Menu allowing the user to change the rotor
	Analyser conditioning	Menu giving access to the option of conditioning the analyser
	ISE functions	This menu gives access to the different ISE utilities
	LIS utilities	This menu gives access to the different LIS utilities
	Create SATReport	Creation of a SATreport
	Load SATreport	Loading of a previously generated SATreport
	Create a restoration point with current data	Backup copy option
	Restore previous data	Loading a previously generated backup copy file

Menu	Submenu	Description
Help	User Manual	Direct access to user manual
	Analyser information	Access to serial number information
	About	Access to programme version

Menu	Submenu	Description
Exit	With Shutdown	Option of exiting and switching off the analyser
	Without Shutdown	Option of exiting the analyser without switching it off