

BA 400

SERVICE MANUAL



ENGLISH

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The BA400 analyser is compliant with European Union directive 98/79/EC

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Persons for whom this manual is intended

This manual is intended for professionals belonging to the technical service who perform preventive maintenance tasks on and repair the BA400 analyser. These professionals will have received special training enabling them to perform the above-described tasks.

This manual describes the mechanical and electronic characteristics and service software to assist technicians in performing maintenance and repair work. It also describes the steps for disassembling and changing the different elements that comprise the analyser.

Notices and warnings

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

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

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

Symbol	Description
	This product is compliant with EC directive 98/79/on medical devices for In Vitro Diagnostics.

Symbol	Description
	Medical device for In Vitro Diagnostics
	Please consult the directions for use
SN	Serial number
	Expiry date
LOT	Batch code
REF	Catalogue number
	Temperature limit
	Manufacturer
	Irritant

Safety precautions

Symbol	Description
	<p>Preventing electric shock To prevent the risk of electrocution. Do not remove any of the analyser housing elements. No user intervention makes it necessary to access the parts inside the equipment. If necessary, contact the technical assistance service.</p>
	<p>Preventing biological risks in handling the samples Inappropriate handling of samples, controls and calibrators could cause biological infection. Do not touch the samples, mixtures or waste with your hands. Wear gloves and protective clothing when necessary. In the event that the samples come into contact with the skin, wash immediately with abundant water and seek medical advice. It is advisable to follow best laboratory practices.</p>
	<p>Prevention in handling reagents Handle reagents and washing solutions with care, they contain substances that could be corrosive. In the event that the reagents or washing solutions come into contact with the skin, wash immediately with abundant water and in the event of a reaction, seek medical advice. Consult the reagent or washing solution adaptation sheet and follow the safety instructions. It is advisable to follow good laboratory practices.</p>

Symbol	Description
 BIOHAZARD	<p>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.</p>
 BIOHAZARD	<p>Preventing biological risks in handling solid waste Take care in handling parts of the analyser that are converted to waste such as the reactor rotor, sample tubes and reagent bottles. Wear gloves and protective clothing when handling such waste. Dispose of the waste in accordance with national or local legislation for disposing of dangerous biological waste, and consult the reagent manufacturer or distributor for more details.</p>
 NOTE	<p>Prevention of electro magnetic interferences The analyser complies with the requirements with respect to emissions and immunity set forth in the standard UNE -EN 61326-2-6:2006. This equipment has been designed and tested for class B of standard UNE-EN 55022:2000. In a household environment, it may cause radio interference, in which case the necessary measures must be taken to mitigate such interference. Do not use the analyser near strong electro magnetic radiation sources (such as centrifuge appliances, radio transmitters, mobile telephones), as they could interfere with its correct operation.</p>
	<p>Preventing laser light emission risks The analyser has two barcode readers that emit laser light. The readers only function when the analyser is in execution mode and its rotor covers are in place. In the event of a failure or during adjustment by technical maintenance staff, the light beam could be activated without the cover in place; in such cases, do not look directly at the laser beam.</p>
	<p>Prevention at the end of the useful life of the analyser At the end of the useful life of the analyser, the product must be disposed of in accordance with the environmental legislation in force in each country. If that country is a 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 the distributor for the product to be properly recycled.</p>

Abbreviations and units shown in the manual

Abbreviation	Definition
Ø	Diameter
EC	European Community
EMC	Electromagnetic compatibility
CRTL	Control key on the computer keyboard
EN	European norm
F	Fast (fuse type)

Abbreviation	Definition
FUS	Fuse
ISE	Ion-selective electrode
IVD	In Vitro Diagnostics
LED lamp	Light-emitting diode
LIS	Laboratory information system
WEEE	Waste Electrical and Electronic Equipment
REF	Reference solution for the ISE unit
TAS	Technical assistance service
SD	Standard deviation
ES	Electrical safety
UV	Ultraviolet

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

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Foreseen use

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

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

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

1. Introduction

The BA400 analyser is a random-access, automatic analyser that makes readings at a rate of 400 prep/h. It is specifically designed for performing clinical biochemical and turbidometric analyses and for electrolyte readings. Control of the instrument is performed *on-line* in real time from a dedicated external PC.

The analyser has 5 arms: 2 arms for handling reagents, 1 arm for handling samples and 2 arms for stirring the reagent and sample mixture.

There are two rotors, with the reagents being positioned in one and the samples in the other.

The reagent rotor is refrigerated and both rotors have barcode readers.

The reagent and sample are mixed in the third rotor or reaction rotor. It is also where the photometric readings are taken while the reaction develops. The reaction rotor is thermostatted and has a wash station for emptying the completed reactions and for washing and drying the cuvettes for the next preparation round. It therefore processes a continuous flow of preparations.

The analyser has the following built-in safety elements: vertical arm collision detector, sample tip clot detector and detectors in all the covers.

2. General description of the analyser

In mechanical terms, the analyser is divided up into subassemblies. Each subassembly has its own electronic board for controlling the individual subassembly elements.

All the subassemblies are electrically connected by the CAN bus cable. The CAN bus cable contains the power wires and the wires that transmit information between the boards.

A list of the subassemblies is given below:

- Sample rotor
- Reagent rotor
- Reaction rotor
- Pipetting arm
- Stirring arm
- Wash station
- Dispensing pumps
- Fluidic system
- Washing solution and high contamination waste bottles
- Electrical and communication connections
- ISE module (optional)

2.1. Sample rotor

The sample rotor is comprised of a drum for positioning the samples, a cover and a barcode reader.

The drum has a circular structure with 3 concentric rings in which the tubes or sample wells are placed.

Each of the 3 rings has 45 positions for tubes with diameters of between 12 and 16 mm and heights of up to 100 mm

The barcode reader can only read the primary tubes with codes located in the two outer rings.

The accessories box has some adapters for insertion in each of the positions in the event that they must contain sample wells instead of primary tubes.

The positioning of the serum in the rings is not really relevant but the following positioning is recommended:

Calibration serums, controls and special solutions (such as washing and dilution solutions) should be placed in the innermost ring, in sample wells. Samples should be placed in the two outer rings in primary tubes so that they can be read by the barcode reader.

2.2. Reagent rotor

The reagent rotor is comprised of a drum for positioning the samples, a cover and a barcode reader. The whole assembly is refrigerated.

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

Each ring has 44 positions.

The barcode reader can read the codes of the bottles positioned in both rings.

There are 2 types of bottle: some have a capacity of 60 mL and others have a capacity of 20 mL.

The 20 mL bottles can only be placed in the outer ring.

Both 60 mL and 20 mL bottles can be placed in the inner ring.

The rotor is refrigerated, and the mean temperature inside it is below 8°C. The fridge has an independent power supply system with its own switch so that when the analyser is switched off, the fridge can continue to operate.

2.3. Reaction rotor

The reaction rotor has 120 positions and a cover. The whole assembly is refrigerated.

The rotor is a single part made of PMMA and has 120 positions. The sample and reagent mixture reactions are performed on it. Different optical readings are taken during the reaction. The PMMA material filters UV radiation.

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

The reaction volumes range is from 200 µL to 600 µL.

Each arm dispenses in a different position from the rotor. The dispensing positions are:

- Cycle 1: R1 dispensation
- Cycle 31: S dispensation (sample)
- Cycle 32: R1+S stirring
- Cycle 33: Initiation of photometric readings
- Cycle 66: R2 dispensation and stirring of reagent 2
- Cycle 100: End of the reading processes
- Cycles 101 –111: Elimination of the completed reaction and cleaning of the sample well in the wash station.

2.4. Optical system

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

It is formed by a set of leds, filters, beam splitters, the reaction rotor and two photodiodes.

There is one principal reading diode and a reference photodiode that enables the correction of perturbations generated in the light source

The analyser has 8 wavelengths: 340, 405, 505, 535, 560, 600, 635, 670

The measuring range is from -0.2 Abs to 3.5 Abs.

The measuring resolution is 0.0001 Abs.

The system automatically performs a blank on the cuvette before dispensing the reagent. This blank absorbance value is used to correct the absorbance values measured in the cuvette.

If this value exceeds a preestablished limit, the cuvette is discarded.

2.5. Wash station

The wash station consists of an assembly with 7 tips located above the reaction rotor.

Each tip has a specific function and corresponds to a different execution cycle:

- Cycle 1: Suction of the high contamination waste and dispensing of the washing solution
- Cycle 2: Suctioning and dispensing of the washing solution
- Cycle 3: Washing solution rest phase

- Cycle 4: Suctioning of the washing solution and dispensing of distilled water
- Cycles 5 and 6: Suctioning and dispensing of distilled water
- Cycle 7: Distilled water rest phase
- Cycle 8: Optical scanning of cuvette
- Cycle 9: Suctioning of distilled water
- Cycle 10: Drying of cuvette

The distilled water for rinsing and the washing solution are thermostatted so that they do not interfere with the rotor temperature.

When the last rinse is made, an optical reading is taken of the rotor sample well, in order to verify the state of the well. If it is scratched or in poor condition, the well is discarded and not used for performing reactions.

In the event of there being a large number of wells in poor condition, the programme warns that the reaction rotor needs to be replaced.

2.6. Waste, distilled water and washing solution containers

The analyser has 4 containers for storing waste, distilled water and washing solution. These containers are located inside it.

The high contamination waste and washing solutions containers can be accessed from the front.

The capacity of both containers is 5 L. This capacity allows for 8 hours of continuous autonomous operation.

Detection of whether the bottle is full or empty is done by weighing.

The low contamination waste and distilled water containers are located inside the analyser, at the rear, and cannot be accessed by the user. These containers have a buoy system that informs the analyser when they are full or empty. They are automatically filled and emptied from the exterior.

The external distilled water inlet may come from a pressurised distilled water inlet or an external tank with a larger capacity.

The low contamination waste leaves the appliance through a drainage pipe that goes directly to a tank or sump.

2.7. Stirring arm

The analyser has two arms for stirring the reaction. These arms have a small blade that rotates inside the reaction cuvettes, to ensure the proper mixing of the reagent and sample.

One of the stirring arms is inserted into the cuvette after dispensing the sample and the other stirring arm is inserted after the second reagent is dispensed in reactions with two reagents.

After mixing, the arm is washed in the wash station provided for that purpose.

2.8. Dispensing arm

The analyser has 3 arms for dispensing samples and reagents.

One arm is for dispensing serum and urine samples and the other two are for dispensing the reagents. One is used to dispense reagent 1 and the other to dispense reagent 2, only in bireactive reactions.

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

The volumes dispensed by each arm are the following:

- Sample arm: from 2 µL to 40 µL

- R1 reagent arm: from 150 µL to 500 µL
- R2 reagent arm: from 40 µL to 300 µL

Each arm has a tip with an automatic level detection system. The tip descends until it reaches the reagent or sample, depending on the case, and then suctions the programmed volume. This prevents the tip from penetrating too deeply in the fluid and makes it easier to wash the tip.

Each arm has a vertical collision detection system to prevent the tips from colliding with each other and ensure they are not damaged.

The sample dispensing arm has a clot detector. This system warns the user if the tip becomes blocked when suctioning the sample. The blockage may be due to traces of fibrin or clotting present in the serum sample.

2.9. ISE module (optional)

The ISE ion module is optional, and is used to determine Na⁺, K⁺, Cl⁻ and Li⁺ ions in serum and urine samples.

The ion module is fully autonomous and functions in parallel, together with the biochemical determinations.

When ISE ion testing of patients is programmed in the list, the sample-dispensing arm is responsible for positioning the sample in the ion module.

The module has a fully sealed kit that contains the calibration standards and collects the waste. This kit is an accessory and its compartment is accessible from the front part of the analyser.

2.10. Operating mode

The analyser performs the tests patient by patient and permits the continuous input of samples. The analyser is controlled by a dedicated PC that is in permanent communication with the instrument. The application programme installed in the computer keeps the user constantly informed about the state of the analyser and the progress of the tests. As the results are obtained, the computer immediately displays them to the user.

When starting a *Worksession*, the analyser proposes the performing of the blanks, calibration standards and controls programmed for the measuring procedures it must execute. The user can decide whether or not to execute the blanks and calibration standards. If they are not executed, the analyser will use the latest data available. The controls can also be activated or not activated. During a worksession, while the analyser is operating, the user can enter new routine or urgent samples for analysis. Every time a new sample is added, the analyser automatically proposes potential new blanks, calibration standards or controls that must be executed. It is advisable to restart the session each working day.

The analyser determines the concentrations of the analytes based on optical absorbance measurements. To measure the concentration of an analyte in a sample, the analyser pipettes a specific volume of reagent, thermostats it in the same tip and dispenses it into the reaction rotor.

After 5 minutes the analyser pipettes a specific sample volume and dispenses it into the same well in which the reagent was dispensed.

During the next cycle the stirring mixes the reagent to ensure correct homogenisation and the chemical reaction is initiated. In the bireactive modes, the reaction is initiated when the analyser dispenses a second reagent into the same reaction well and it is mixed by a second stirrer.

The reactions may be biochemical or turbidimetric reactions. In both cases, the reaction or chain of reactions produced generate substances that attenuate certain light wavelengths, either by absorption or by dispersion. By comparing the luminous intensity of a certain wavelength that penetrates a well when a reaction occurs and when there is no reaction, it is possible to determine the respective analyte concentration. This comparison is quantified with the physical magnitude *absorbance*. 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.

3. Mechanical elements

In mechanical terms, the analyser has a tubular structure to which the different subassemblies and housing elements are attached.

The analyser has the following subassemblies:

- Sample rotor
- Reagent rotor
- Reaction rotor
- Pipetting arms
- Stirring arms
- Wash station
- Dosing system
- Fluidic system
- ISE module (optional)

3.1. Sample rotor

The tubes with the patient serum samples and the wells with the calibration standards and controls are placed in the sample rotor. The rotor (3) has 3 rings. Tubes with larger diameters (16 mm) are placed directly in the holes. Tubes with smaller diameters or sample wells require the use of adapters (2) to secure them in place.

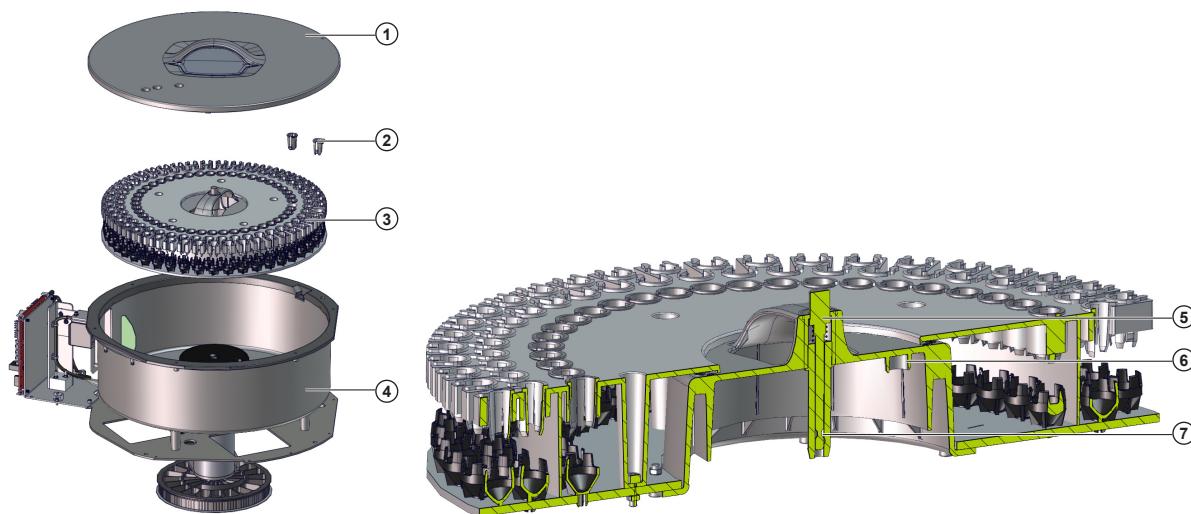


Figure 3.1 Sample rotor assembly

The rotor (3) has a single position once it has been inserted into its compartment (4). For this reason it has a centring device (6) to guide it. Once inserted, the rotor cannot be removed as it is blocked by a ball-shaped anchoring device (7). To release the rotor from the base it is necessary to press the button (5).

The rotor vessel (9) is secured to the rotor assembly support (10). The rotor (3) is connected to the rotor centring device, which in turn is connected to the pulley by a shaft (14). The belt (13) transmits the motor movement (11) to the whole assembly.

The start-up sensor (12) ensures the initial position of the sample rotor by means of a tab on the pulley.

The vessel exterior is protected by a cover (1). A Hall effect sensor (8) indicates that the cover is on the analyser.

References of figures 3.1, 3.2 and 3.3:

- | | |
|---------------------------------------|--|
| 1 – Sample rotor cover | 13 – Transmission belt |
| 2 – Adapters for tube and sample well | 14 – Pulley |
| 3 – Sample rotor | 15 – Barcode reader protective window |
| 4 – Rotor assembly | 16 – Barcode reader |
| 5 – Rotor anchoring button | 17 – CIIM00052 electronic board |
| 6 – Rotor positioning device | 18 – Set screw for angular orientation of barcode reader |
| 7 – Rotor ball-shaped anchorages | 19 – Set screw for adjusting the barcode reader height |
| 8 – Cover sensor | 20 – Set screw for barcode reader proximity adjustment |
| 9 – Rotor vessel | |
| 10 – Rotor assembly support | |
| 11 – Rotor circular movement motor | |
| 12 – Rotor start-up sensor | |

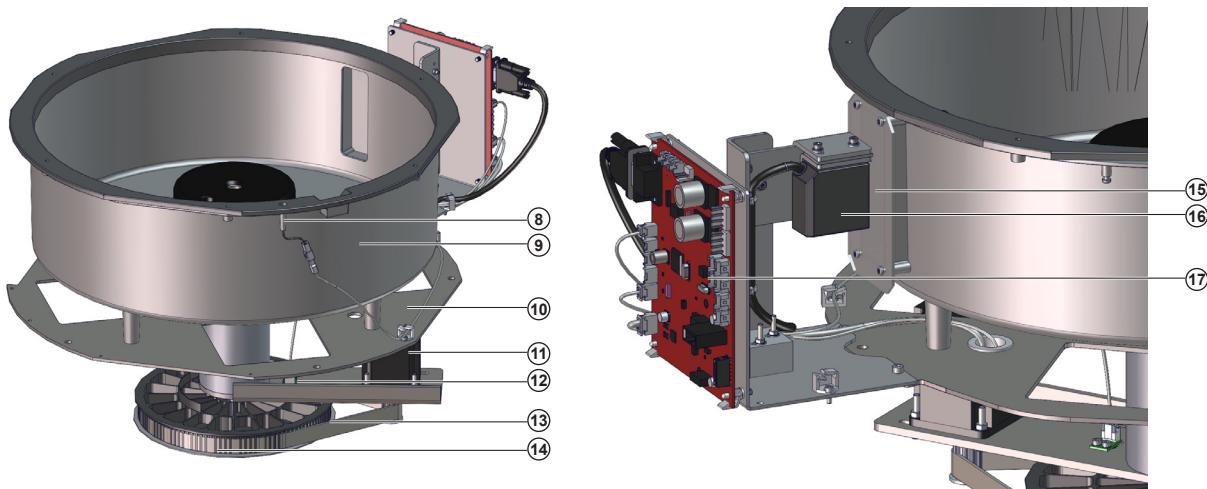


Figure 3.2 Detail of sample rotor assembly

The barcode reader (16) is secured by a support to the subassembly structure. It is positioned at the correct height for the light to correctly illuminate the tubes placed in the rotor.

There is a protective window to isolate the reader from the exterior.

The barcode reader position can be adjusted using mechanical means.

See chapter 6 for applying the service programme and reader adjustment, and Figure 3.3.

- To adjust the angular orientation, loosen the screws (18) and move the reader with your hand until you obtain a correct reading. Tighten the screws (18).
- To adjust the reader height, loosen the screws (19) and move the reader upward or downward with your hand. Once the readings are correct, tighten the screws (19).
- To adjust the reader proximity, loosen the screws (20) and move the reader forward or backward with your hand. Once the readings are correct, tighten the screws (20).

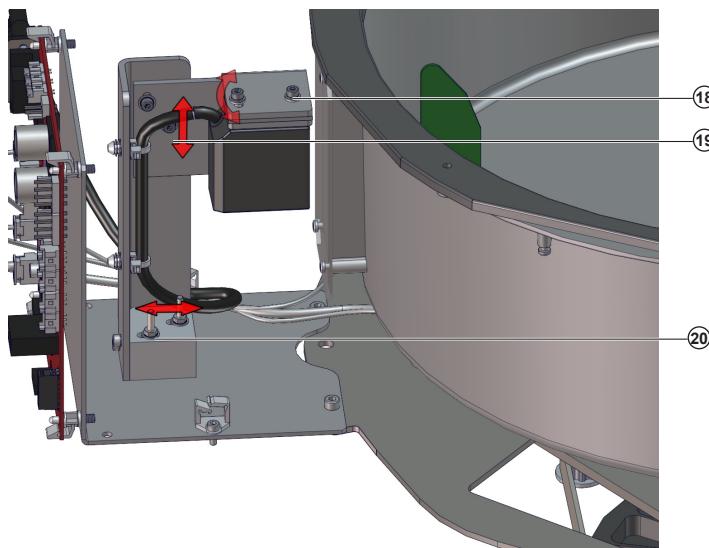


Figure 3.3 Barcode reader adjustment

3.2. Reagent rotor

The reagent bottles are placed in the reaction rotor. There are two types of bottle, one containing 60 mL and one containing 20 mL. The rotor (3) has 2 rings. Only 20mL bottles can be placed in the outer ring, and both 20mL and 60mL bottles can be placed in the inner ring. The assembly has a barcode reader that reads the codes on the bottles placed in both rings. The whole assembly is refrigerated and has a separate power supply system to maintain the refrigeration when the appliance is turned off.

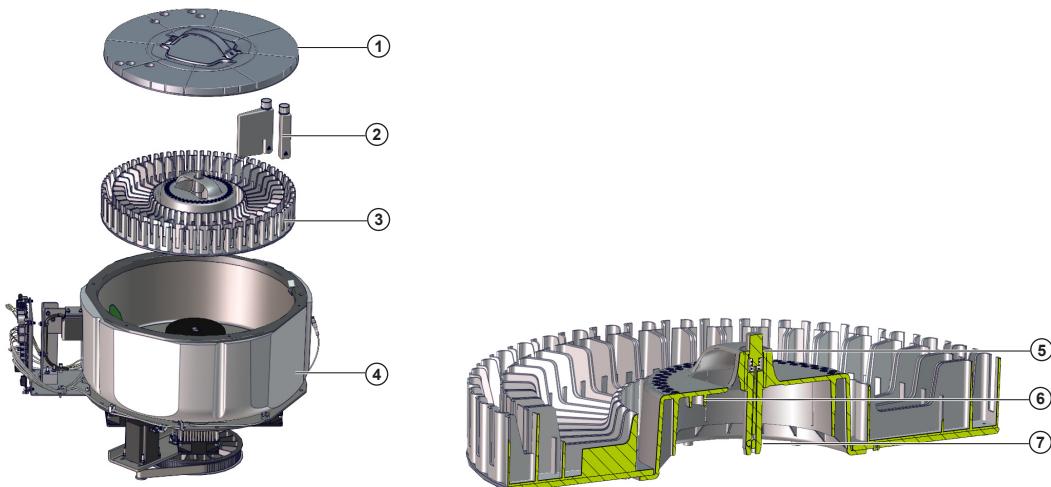


Figure 3.4 Sample rotor assembly

The rotor transmission system and the barcode reader support and adjustment are exactly the same as those of the sample rotor.

See chapter 3.1, description of the transmission system and barcode reader support.

The reagent rotor compartment is refrigerated. To maintain the temperature, the vessel is protected by an insulator (8). The cooling system is performed by 4 peltiers (10) that cool the vessel through the copper splitters (9). The heat produced by the peltiers is evacuated through the radiators (11) and fans (12).

References of figures 3.4 and 3.5:

- 1 – Reaction rotor cover
- 2 – 60mL and 20mL reagent bottles
- 3 – Reagent rotor
- 4 – Rotor assembly
- 5 – Rotor anchoring button
- 6 – Rotor positioning device

- 7 – Rotor ball-shaped anchorages
- 8 – Insulator
- 9 – Peltier splitter
- 10 – Peltier
- 11 – Radiator
- 12 – Fan

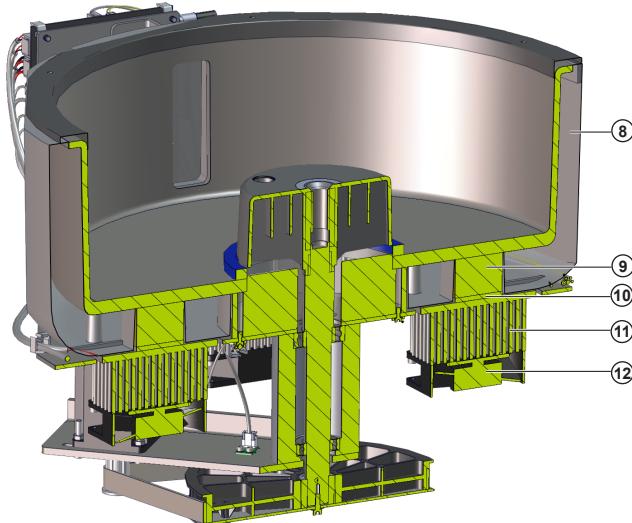


Figure 3.5 Reagent rotor cut-off

3.3. Reaction rotor

The reaction rotor is the place where the sample is mixed with the reagent. The rotor (2) has 120 PMMA wells. The rotor is installed in a heating canal (3) thermostatted at 37 **degrees C**. The entire assembly is protected by a cover (1), to maintain the temperature inside it and prevent light from entering. The system functions continuously and for this purpose, it has a wash station (4) which empties and washes the rotor wells in 10 cycles. During each cycle, the analyser reads 68 wells with the optical system (5) that is built into the assembly.

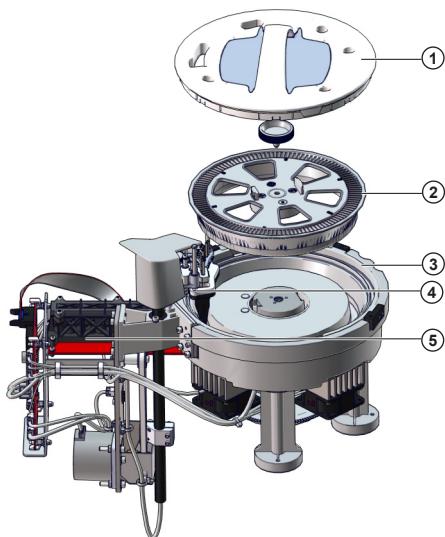


Figure 3.6 Reaction rotor assembly

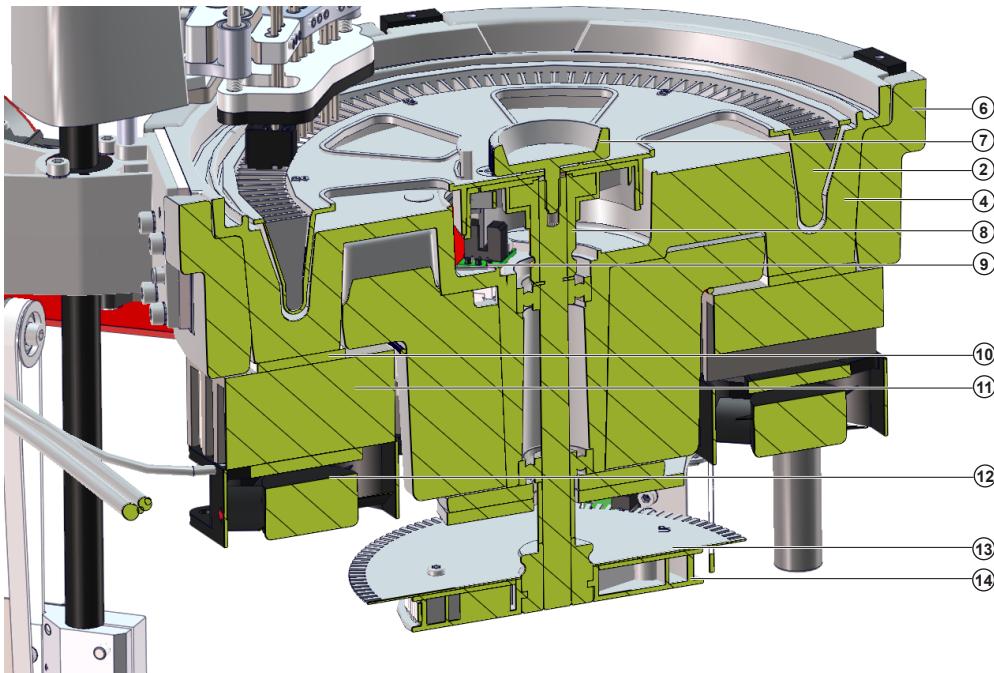


Figure 3.7 Reaction rotor cut-off

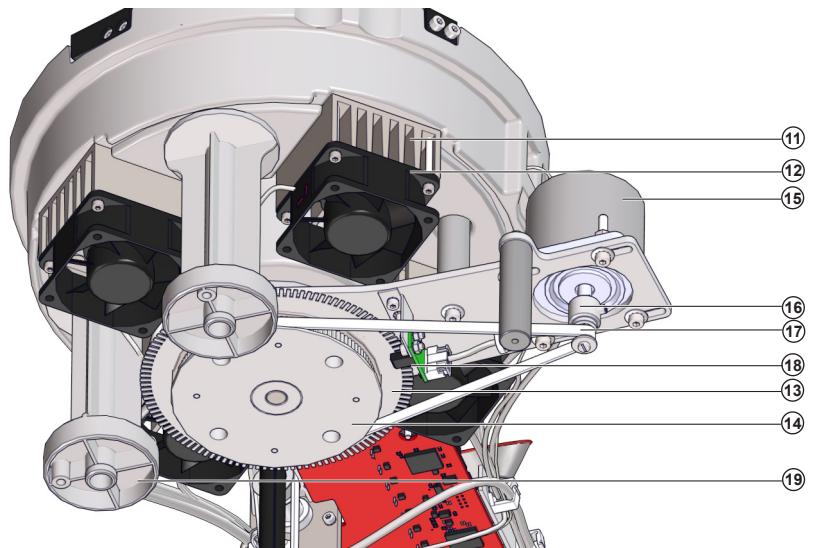


Figure 3.8 Reaction rotor transmission assembly

References of figures 3.6, 3.7 and 3.8:

- 1 – Reaction rotor cover
- 2 – Reaction rotor
- 3 – Heating canal
- 4 – Wash station
- 5 – Optical system
- 6 – Heating canal insulator
- 7 – Rotor anchoring bolt
- 8 – Rotor centring device
- 9 – Rotor start-up sensor
- 10 – Peltier

- 11 – Radiator
- 12 – Fan
- 13 – Reading encoder
- 14 – Transmission wheel
- 15 – Rotor motor operation
- 16 – Motor pinion
- 17 – Transmission belt
- 18 – Encoder photosensor
- 19 – Rotor assembly support column

The methacrylate rotor (2) is centred by means of tabs with a size that is different to that of the rotor centering device (8) and secured firmly by a bolt (7). The initiation photosensor (9) detects the initial position of the rotor.

The heating canal (4) is insulated (6). The canal is thermostatted at 37 °C by 4 peltiers (10), with their respective radiators (11) and fans (12).

The rotor shaft is connected to a pulley (14) which transmits the motor movement (15) through a belt (17) and a pinion (16). The encoder disk (13) is attached to the pulley. The photosensors (18) relays the movement of the encoder to the electronic board.

The washing operation has 10 cycles. In each cycle two tips are used. The longest is used for suctioning and the shortest for dispensing.

- Cycle 1(26): The reaction mixture is suctioned and the washing solution is dispensed. The suctioned waste is sent directly to the high contamination waste bottle.
- Cycle 2(27): The washing solution is suctioned and then dispensed again.
- Cycle 3: Wait cycle during which the wells are washed
- Cycle 4 to 6 (28): Rinsing, suctioning of liquid and dispensing of distilled water
- Cycle 7: Wait cycle
- Cycle 8: Optical checking of well
- Cycle 9(29): Suctioning of distilled water
- Cycle 10(30): Drying of well.

During the last two cycles, in the event of the tips colliding with the rotor, a sensor (21) detects this and stops the operation.

The whole tip assembly is secured mechanically with a bolt (22).

The wash station has a built-in system for blocking the entry of light through the cover vents, part (25). This part is always in a lower position, touching the cover. When the wash station is raised and lowered, part (25) is maintained in its position, making contact with the cover, by means of guide elements (23) and springs (24).

The wash station tip assembly is joined to a shaft (31). This shaft is dragged by a belt (37) through part (34). In turn, the motor (38) transmits the movement to the belt (37) through the pulley (39).

The transmission pulley is protected by part (40).

The tab (35) and photosensors (36) are used to detect the wash station start-up position.

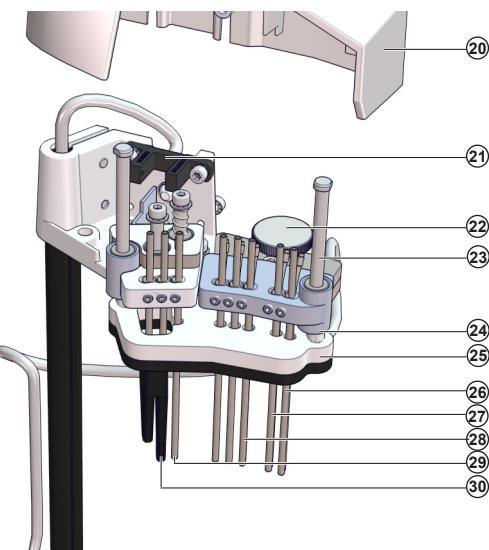


Figure 3.9 Wash station tip assembly

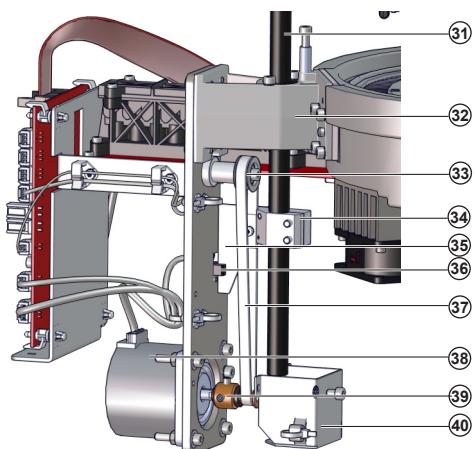


Figure 3.10 Wash station elevation system

References of figures 3.9 and 3.10:

- 20 – Wash station housing
- 21 – Tip collision sensor
- 22 – Set screw
- 23 – Pedal guide shaft
- 24 – Spring
- 25 – Pedal
- 26 – Waste aspiration
- 27 – Washing solution aspiration
- 28 – Rinsing with water
- 29 – Water aspiration

- 30 – Drying
- 31 – Wash station elevation shaft
- 32 – Wash station shaft anchoring support
- 33 – Counter pulley
- 34 – Part anchoring shaft with belt
- 35 – Start-up detection tab
- 36 – Start-up detection photosensor
- 37 – Belt
- 38 – Wash station motor
- 39 – Transmission pulley
- 40 – Transmission pulley protector

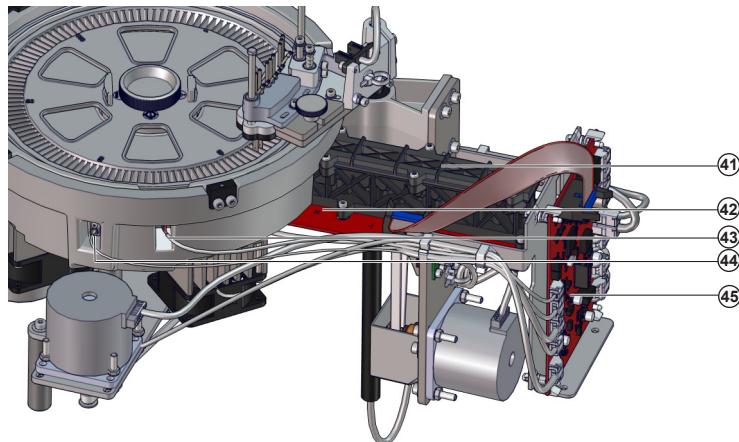


Figure 3.11 Optical bench view

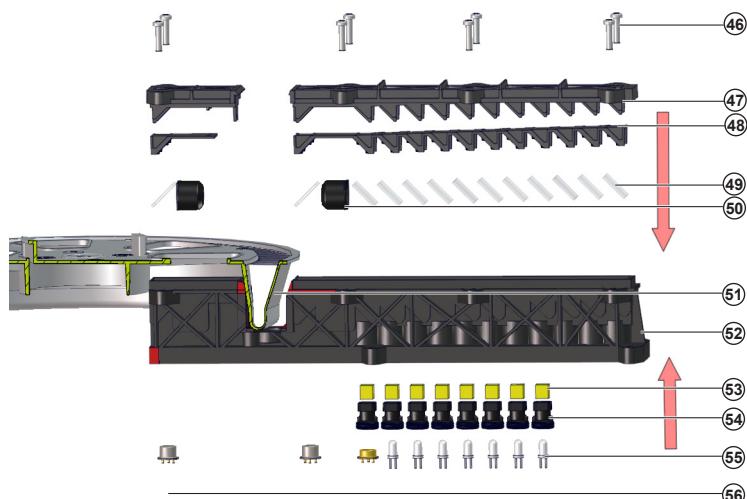


Figure 3.12 Optical bench view

References of figures 3.11 and 3.12

- 41 – Optical bench
- 42 – CIIM00051 board
- 43 – Cover sensor
- 44 – Temperature sensor
- 45 – CIIM000050 board
- 46 – Optical bench opening screws
- 47 – Optical bench cover
- 48 – Optical bench seal

- 49 – Beamsplitters for each wavelength
- 50 – Lenses and lens holder
- 51 – Rotor
- 52 – Optical bench support
- 53 – Filters for each wavelength
- 54 – Filter holder
- 55 – Leds for each wavelength
- 56 – Principal and reference photosensors

The optical bench is secured directly to board CIIM00051 (42). The different leds (55) for each wavelength and the main and reference photodiodes (56) are welded to board CIIM00051 (42). The filters (53) for each wavelength are inserted in the filter holders (54) and screwed to the optical bench support (52). To ensure that the light beam for each wavelength hits the rotor (51) there are beam splitters (49) and lenses (50). The whole assembly is sealed by a rubber joint (48) and a cover (47).

3.4. Pipetting arms

The pipetting arms are used to suction and dispense fluids. There are three arms, two for handling reagents and one for handling samples.

The pipetting arms are comprised of a housing (1) that covers the tip connections (6) and the electronic board (2). The tip and board assembly, attached to a support, is the mobile part of the arm. The assembly is raised by a guide tube (9) and the wires and tubes connected to the tip pass through this tube. The raising operation is executed with a motor (10) that transmits the movement through a pulley (11) to a belt joined to the guide tube (9). The angular movement is executed with the motor (4) by means of a belt (3) which makes the guide tube rotate (9).

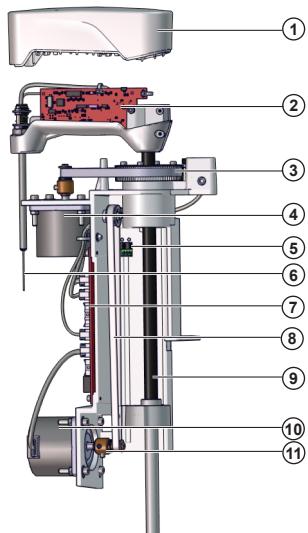


Figure 3.13 Pipetting arm assembly

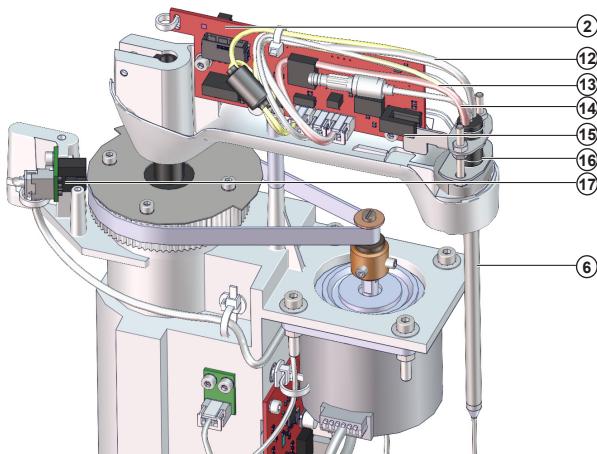


Figure 3.14 Reagent tip

References of figures 3.13 and 3.14

- | | |
|---|---|
| 1 – Housing | 10 – Elevation movement motor |
| 2 – CIIM00049 board | 11 – Elevation movement transmission pulley |
| 3 – Angular movement transmission belt | 12 – Tip thermostatting system cable |
| 4 – Angular movement motor | 13 – Tip temperature sensors cable |
| 5 – Elevation movement initiation photosensor | 14 – Tip detection system cable |
| 6 – Aspiration and dispensation tip | 15 – Collision detection photodiode |
| 7 – CIIM00048 board | 16 – Tip collision detection system |
| 8 – Elevation movement transmission belt | 17 – Angular movement initiation photodiode |
| 9 – Elevation movement guide tube | |

The only difference between the reagent and sample arms is the tip (6).

Characteristics of the reagent tip and the sample tip:

	Reagent tip	Sample tip
Inner diameter at the end	0.8 mm	0.4 mm
Maximum volume contained inside	500 µL	40 µL
Thermostatted	Yes	No
Temperature sensor	Yes	No
Fluid detection	Yes	Yes

The tip control board CIIM00049 (2) is the same for the reagent arm and the sample arm.

3.5. Stirring arm

The elevation and rotation movement assembly part is the same as the pipetting arm assembly.

☞ See section 3.4 for a detail of the assembly.

The stirrer is formed by a flat blade(5). The blade is inserted into the continuous current motor shaft (1) and pressed by a clamping nut (4). The motor (1) is attached to the head piece support (3) by an adapter (2).



Figure 3.15 Stirrer arm head

References of figure 3.15

- | |
|------------------------------|
| 1 – Continuous current motor |
| 2 – Adapter |
| 3 – Head support |
| 4 – Clamping nut |
| 5 – Stirrer blade |

3.6. Dispensing assembly

The dispensing pump assembly is comprised of three pumps. Each pump is independent and they are connected to the reagent and sample arm tips.

The pistons of the two pumps for pipetting the reagent have a diameter of 8 mm, while the piston of the sample pump has a diameter of 3 mm.

The fluidic system of the three pumps with the input electro valves is comprised of a PMMA manifold (1).

In the fluidic chamber of the sample pump the manifold has a pressure sensors that detects whether the sample tip is blocked (3).

All three pumps are identical, except for the sample pump, in which the piston has a smaller diameter. They are operated by a motor (13) attached to a multi-twisting spindle (12). The spindle raises or lowers the piston support (11) where it is attached to the piston. The suctioning chamber is sealed by a retaining element (10). The tubes are connected to the manifold by connection fittings (7).



Figure 3.16 Dispensation pump assembly

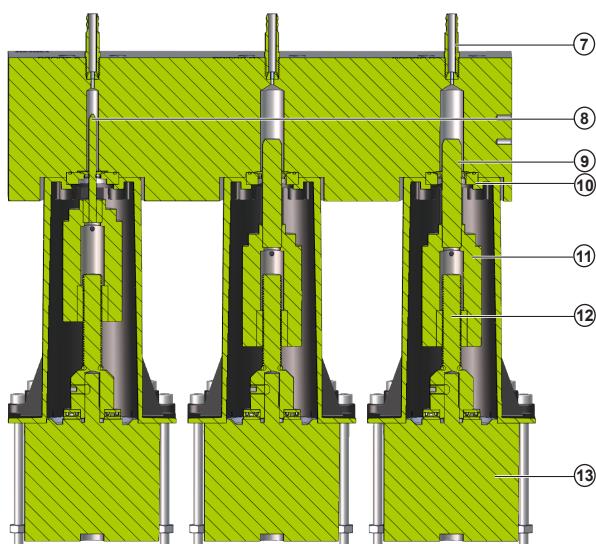


Figure 3.17 Detail of dispensation pumps

References of figures 3.16 and 3.17

- | | |
|----------------------------------|-------------------------|
| 1 – Manifold with electro valves | 8 – 3 mm sample piston |
| 2 – Board with led lamp | 9 – 8 mm reagent piston |
| 3 – Pressure sensor | 10 – Retaining element |
| 4 – Sample pump | 11 – Piston support |
| 5 – Reagent 1 pump | 12 – Pump spindle |
| 6 – Reagent 2 pump | 13 – Pump motor |
| 7 – Output connection fitting | |

3.7. Structure

Each of the analyser's subassemblies is attached to the structure (1). The sample rotor, reagent rotor, reaction rotor, sample arm, reagent arm and stirring arm subsassemblies are attached at the top. The pump and fluidic subassemblies are attached at the bottomm right-hand side. The electronics and power supplies are located on the top left-hand side.

The ISE module (2) is located in the centre, at the top, and the ISE module reagent kit (6) is located in the bottom central part. See Figure 3.18.

The washing solution bottles (5) and high contamination waste bottles (4) are located in the bottom central part. The volume in the bottles is determining by weighing. Below each bottle is a weighing scale (7).

The general fans (12), (13) are fastened directly to the structure. The fan (3) is attached to the front panel.

The wash stations for each tip and stirrer (10) are attached directly to the structure. The evacuation tubes are connected directly to the low contamination waste bottle. The distilled water bottles (14) and low contamination waste bottles (15) can be accessed from the rear bottom part. Double buoy sensors are used to detect the maximum and minimum levels of each container.

The main switch is located at the bottom right-hand side (16), and the partial switches at the side (11).

The external fluidic connections are located at the bottom left-hand side (17).

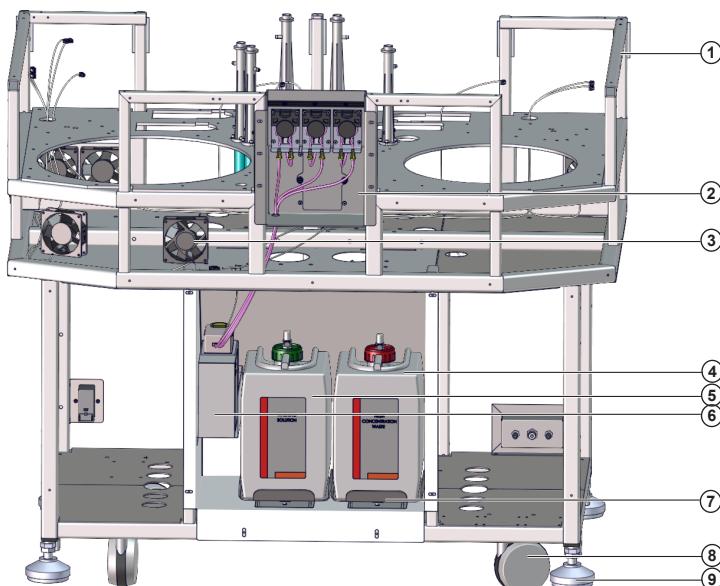


Figure 3.18 **Front view of structure**

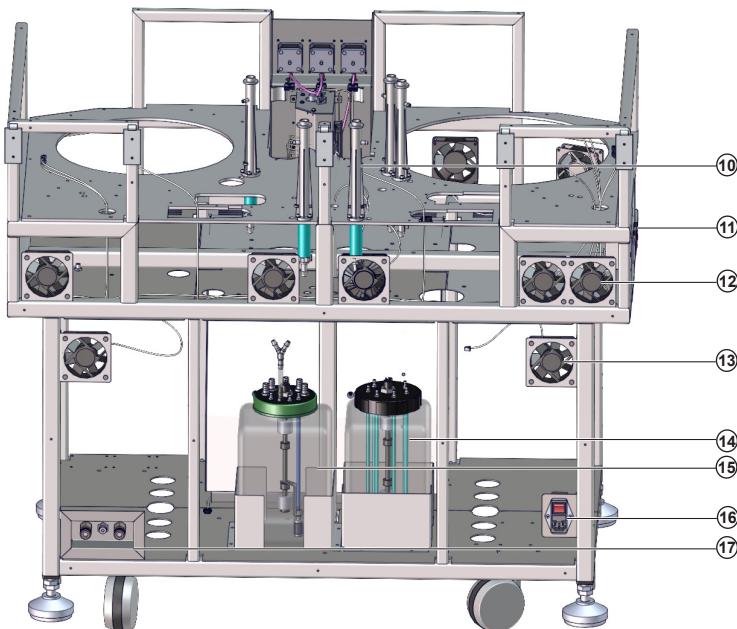


Figure 3.19 **Rear view of structure**

References of figures 3.18 and 3.19

- 1 – Structure
- 2 – ISE module (optional)
- 3 – Fridge fans
- 4 – High contamination waste bottle
- 5 – Washing solution bottle
- 6 – ISE module calibration standards kit
- 7 – Bottle weighing scales
- 8 – Wheel
- 9 – Anchoring leg

- 10 – Wash station for tips
- 11 – Lateral switches
- 12 – General fans
- 13 – Electronic compartment fans
- 14 – Distilled water bottle
- 15 – Low contamination waste bottle
- 16 – Main switch
- 17 – External fluid connections

3.8. Fluid connections

The entire fluidic system is mounted on a board located on the right-hand side of the analyser.

To facilitate the identification and monitoring of the fluidic system, the tube colour selection uses the following criterion:

- Blue: Distilled water tubes
- Red: Waste tubes
- Green: Washing solution tubes

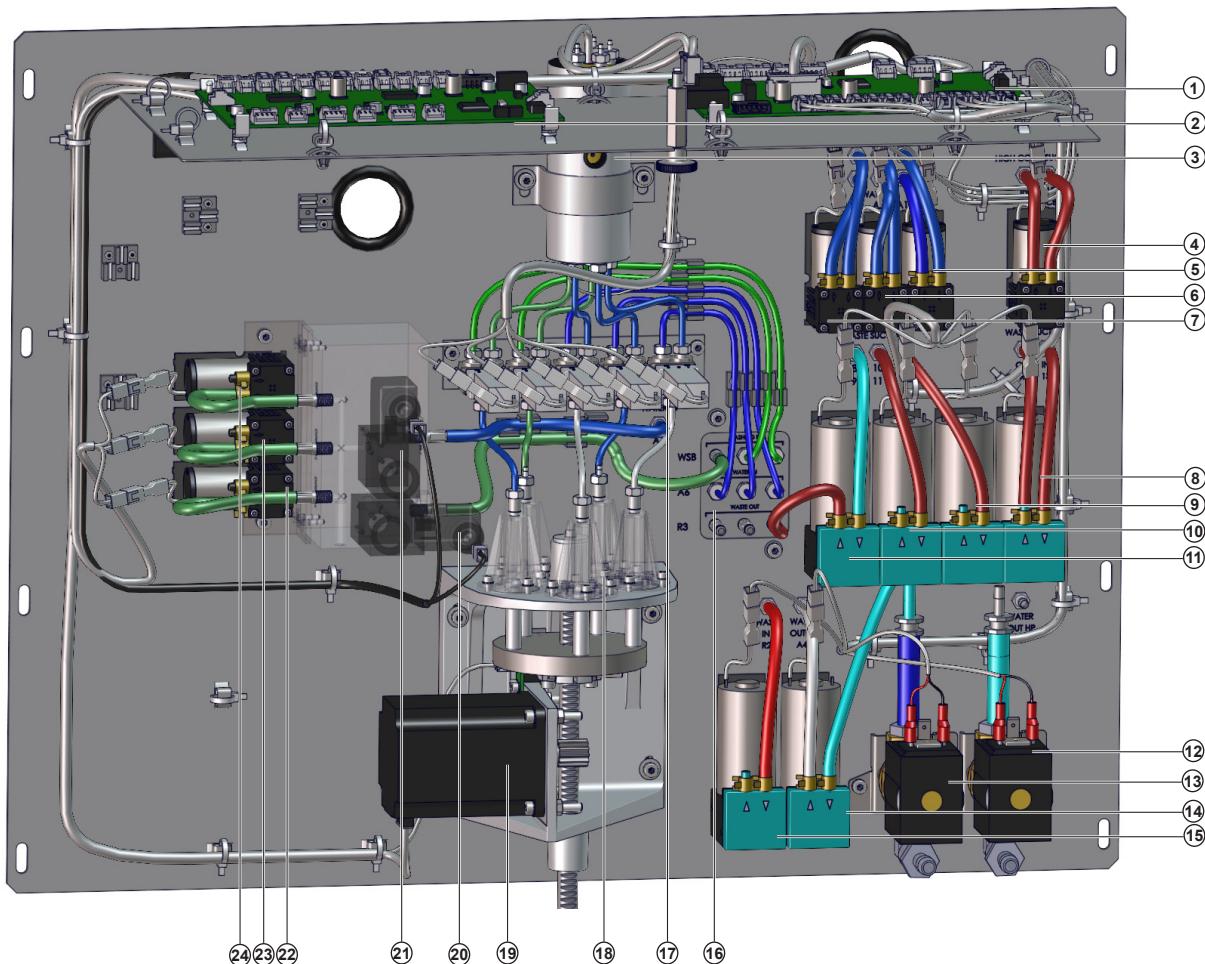


Figure 3.20 Fluidic system assembly

References of figure 3.20

- | | |
|--|----------------------------|
| 1 – SF1 board - fluidic system control | 13 – SF1-EV2 electro valve |
| 2 – JE1 board - syringe control | 14 – SF1-B4 pump |
| 3 – Wash station tube heater | 15 – SF1-B5 pump |
| 4 – SF1-B10 pump | 16 – Manifold |
| 5 – SF1-B3 pump | 17 – SF1-GE1 electro valve |
| 6 – SF1-B2 pump | 18 – Wash station pump |
| 7 – SF1-B1 pump | 19 – Wash station motor |
| 8 – SF1-B9 pump | 20 – JE1-EV4 electro valve |
| 9 – SF1-B8 pump | 21 – JE1-EV5 electro valve |
| 10 – SF1-B7 pump | 22 – JE1-B1 pump |
| 11 – SF1-B6 pump | 23 – JE1-B2 pump |
| 12 – SF1-EV1 electro valve | 24 – JE1-B3 pump |

The water can enter the analyser in two ways:

- Through a pressurised water system
- Through an external tank with a large capacity

The user programme will select the water entry method. In the first case, the programme will activate the electro valve (12) and fill the intermediate distilled water tank.

In the second case the programme will activate the electro valve (13) and the pump (14), to suction water from the external tank.

The internal distilled water tank level is controlled by a buoy system.

There is also an internal low contamination waste tank. The tank level is also controlled by a buoy system.

When the system detects that the tank is full, the programme activates the pump (15) and evacuates the water externally.

Pipetting system

Each of the tips, sample, reagent 1 and reagent 2, is connected directly to its respective ceramic pump in the manifold assembly.

When the pumps are suctioning or dispensing the samples or reagents, electro valves JE1-EV1, JE1-EV2 and JE1-EV3 will be closed.

During the internal tip washing process, these electro valves will be open and can dispense distilled water, washing solution or air, depending on the selection made in the pre-manifold.

The pre-manifold selects water, washing solution or air, depending on the state of the electro valves (20) and (21). Using the pumps (22), (23) and (24) it pumps the liquids selected by the sample, reagent 1 and reagent 2 tips, respectively.

The outsides of the tips are also washed in the wash stations. Distilled water is used for washing the insides, and it is pumped to the sample tip by pump (7), to the reagent 1 and stirring 2 tips by pump (6) and to the reagent 2 and stirrer 1 tip by pump (5).

Wash station

The rotor washing system is comprised of 10 cycles.

 See chapter 2.5 for a description of each wash station cycle.

Dispensing from each tip is executed with a pump that activates 5 pistons. The pump is operated by the motor (19). Each piston is connected to an electro valve (17) where the 2 first tips dispense washing solution and the other 3, distilled water.

The tip of the first cycle suctions the high contamination waste through pump (4) and dispenses it directly into the bottle provided for that purpose.

The tips of cycles 2 and 4 are suctioned by the same pump (11) and the suctioned material is evacuated into the low contamination waste tank.

The tips of cycles 5 and 6 are suctioned by pump (10) and also emptied into the low contamination waste tank.

The tip of cycle 9 is suctioned by pump (9) and the tip of cycle 10 executes the drying operation through pump (8). The last two pumps evacuate the suctioned material into the low contamination water tank.

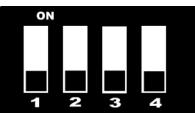
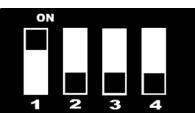
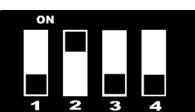
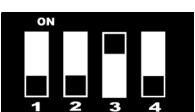
4. Electronic elements

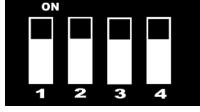
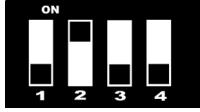
The electronics controlling the analyser are laid out in 14 independent boards. Each board controls an analyser sub-assembly. The method for transmitting the information between the boards is through a CAN communication bus.

There are 2 more boards which are used to make the CAN bus interconnection.

Some boards perform the same function and are repeated, for instance the boards that control the arms. To enable the information to be communicated through the bus and reach the correct board, the board must have a single identifier inside the analyser. For this reason each board has a series of switches so that the board identifier can be selected.

The code assigned to each board is indicated below:

Type of board	Description of board	Identification code	Selector position
Arm boards	Sample 1 arm BM1	0000	
	Reagent 1 arm BR1	1000	
	Reagent 2 arm BR2	0100	
	Stirrer 1 arm AG1	0010	
	Stirrer 2 arm AG2	1010	
Detection boards	Sample 1 detection DM1	0110	
	Reagent 1 detection DR1	1110	
	Reagent 2 detection DR2	0001	
Rotor boards	Sample 1 rotor RM1	0101	
	Reagent 1 rotor RR1	0011	

Type of board	Description of board	Identification code	Selector position
Fluidic system board	Fluidic system SF1	1111	
Syringe board	Syringes JE1	0100	

Each of the above boards has a microprocessor. To rapidly identify the microprocessor status, they have a built-in state indicator led. The information provided by the flashing of the led is the following:

Status	Description
Rapid flashing (burst)	Board start-up. After a few seconds, the flashing changes to slow.
Rapid flashing	Board in monitor mode.
Slow flashing	Board has firmware and is operating correctly.
Very rapid flashing. With no regular sequence	Firmware update process.
Not flashing	Board not supplied with power or damaged.


NOTE

The analyser chassis, and all its metallic parts are only connected to the socket ground wire. This is the electrical safety wire.

The negative reference or GND of the electrical circuit is isolated from the chassis. To measure the voltages with a multimeter or an oscilloscope, place the instrument reference at the "test points" marked GND in each board or the CAN connector reference connection.

Figure 4.21 Sources and input-AC board - CIIM00056

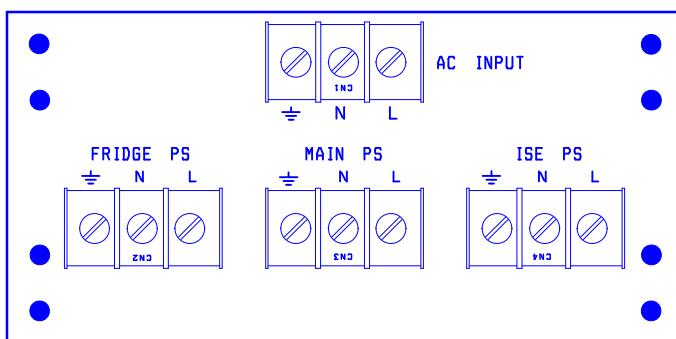


Figure 4.1 Silkscreen printing of input-AC board

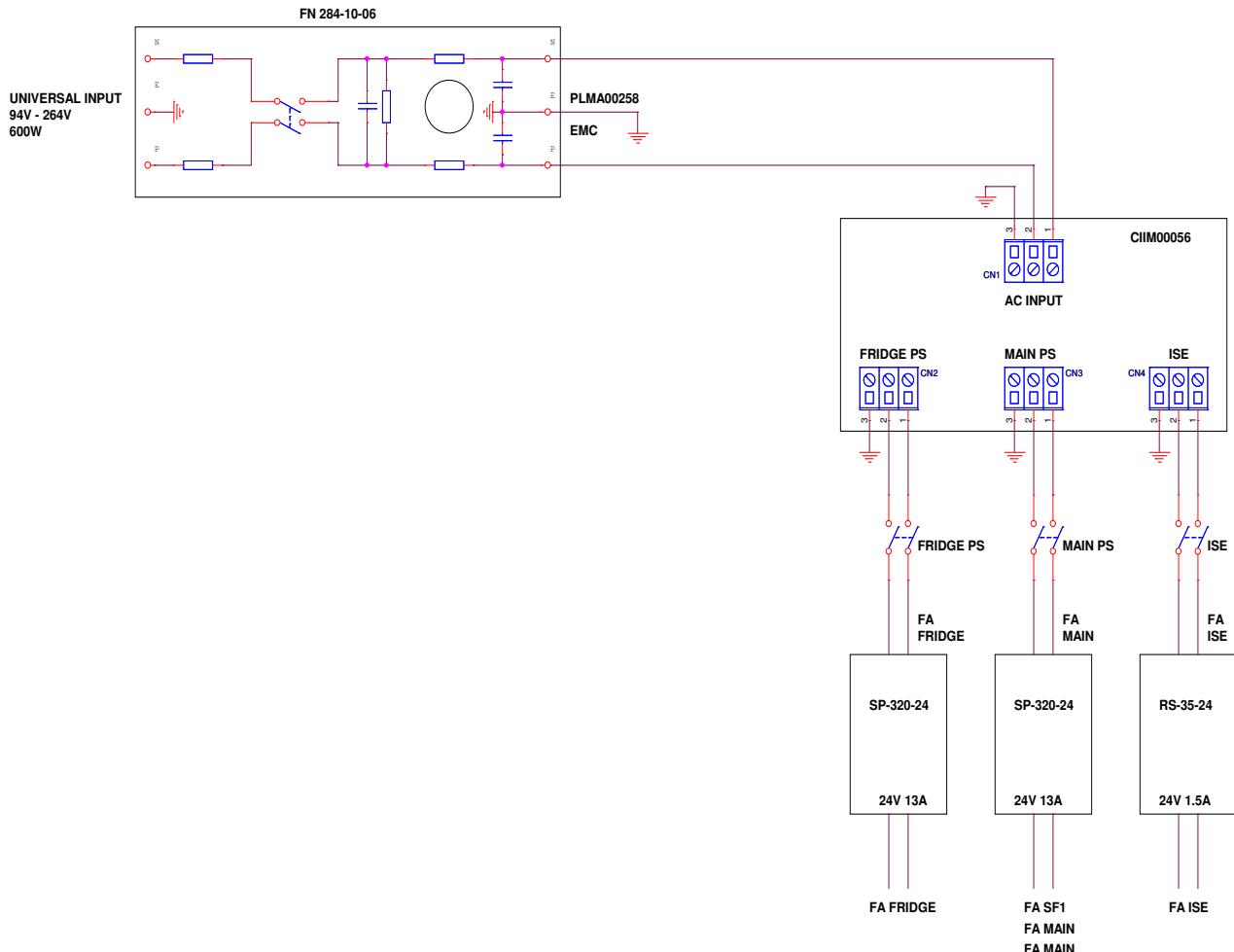


Figure 4.2 Power supply input connection diagram.

4.1. Distribution board - CIIM00047

The distribution board is responsible for making the connection for each of the different boards. The connections are made by the CAN bus. The bus cable distributes the power for each board and the CAN signals.

Both distribution boards are identical and each connector bears silk printing indicating the subassemblies to which they are connected.

Each connector has two silk prints, one of which is used for board A and the other for board B. Distribution board A is the board located in the top position, and distribution board B is located in the bottom position.

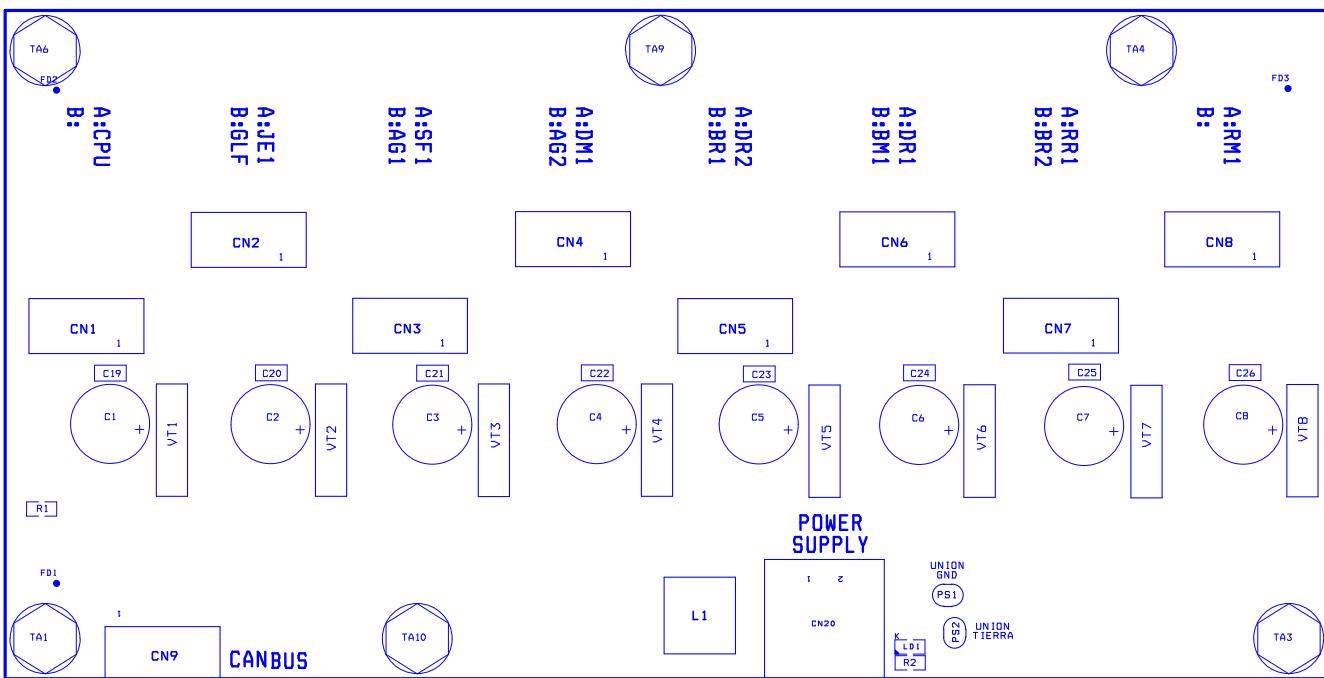


Figure 4.3 Distribution board silk printing

Connector	Function
CN1 A	Connection to the CPU board
CN1 B	
CN2 A	Connection to the JE1 board
CN2 B	Connection to the GLF board
CN3 A	Connection to the SF1 board
CN3 B	Connection to the AG1 board
CN4 A	Connection to the DM1 board
CN4 B	Connection to the AG2 board
CN5 A	Connection to the DR2 board
CN5 B	Connection to the BR1 board
CN6 A	Connection to the DR1 board
CN6 B	Connection to the BM1 board
CN7 A	Connection to the RR1 board
CN7 B	Connection to the BR2 board
CN8 A	Connection to the RM1 board
CN8 B	
CN9	Interconnection of distribution boards, only for the CAN
CN20	Connection to the power source

LEDs	Function (on condition)
LD1	Voltage of 24 V

The CAN connectors are supplied with an anchorage system to ensure their connection.

If it should be necessary to remove a CAN cable, take the following steps (see Figure 4.4):

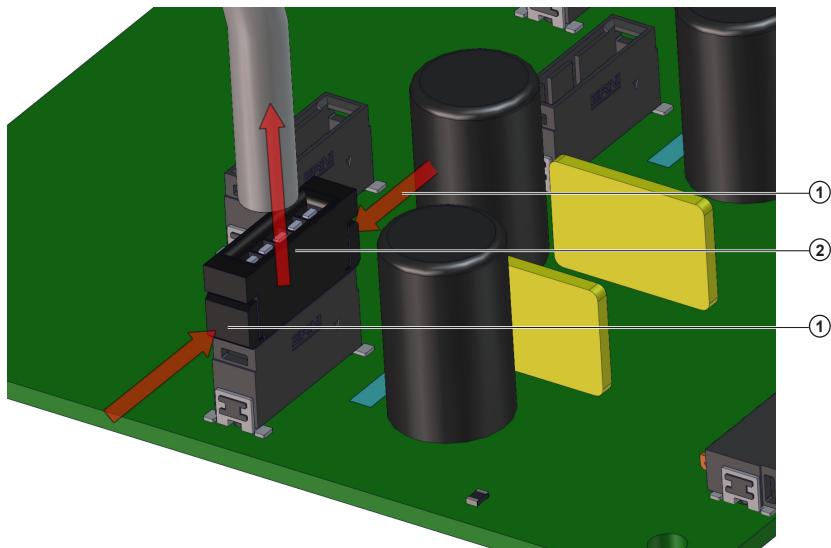


Figure 4.4 Disconnecting a CAN connector

1. Press the sides of the connector firmly (1). There are tabs on each side for insertion into the female connector.
2. Pull the connector and cable outward (2).
3. Do not pull the cable directly.
4. If you cannot remove the cable, use a pair of flat tip pliers that are wide enough to push the tabs.

All the CAN cables have three labels placed at their ends.

- One label indicates to which board it is connected and the board identifier, and is used to distinguish the cables by their lengths, given that in terms of their construction, all the cables are identical.
- The other two labels are at both ends of the cable, one is yellow and the other is white. The end with the yellow marks is the one that must be connected to the distribution board.

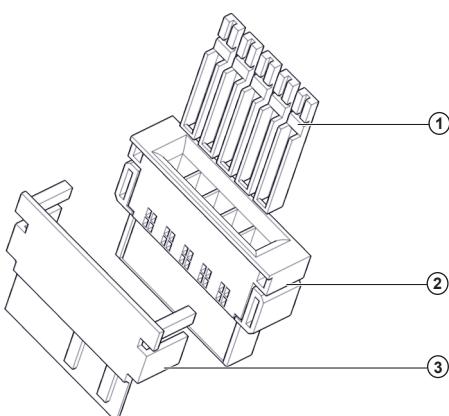


Figure 4.5 Itemised description of the CAN connector

Figure 4.5 shows a CAN connector with the pins (1), connector (2) and extra anchoring (3).

Steps for mounting a CAN connector:

1. Place each of the pins (1) so that they compress the cable in the connector compartment (2). The pins have a single position.
2. Insert the pins as far as they will go. The pins must be anchored.
3. Insert through the side of the connector (2) the extra anchoring (3) until it clicks into place.

4.2. Main board (CPU) - CIIM00046

This is the main board in which the tasks are distributed (in terms of the firmware) to each of the subassembly boards.

This board also controls the following devices:

- The computer communications through RS-232 and USB
- The analyser status lamp
- The analyser main cover sensor.
- The general fans of the analyser. These fans have two wires.
- Control in sending the commands for controlling the ISE module and receiving the results thereof.

The electronic control system for the RS-232 for communications and for the ISE module is electrically isolated from the main electronic system. To supply it with power, use a special insulated regulator (U20 and U3).

USB supplied by the computer and insulated from the equipment electronic system.

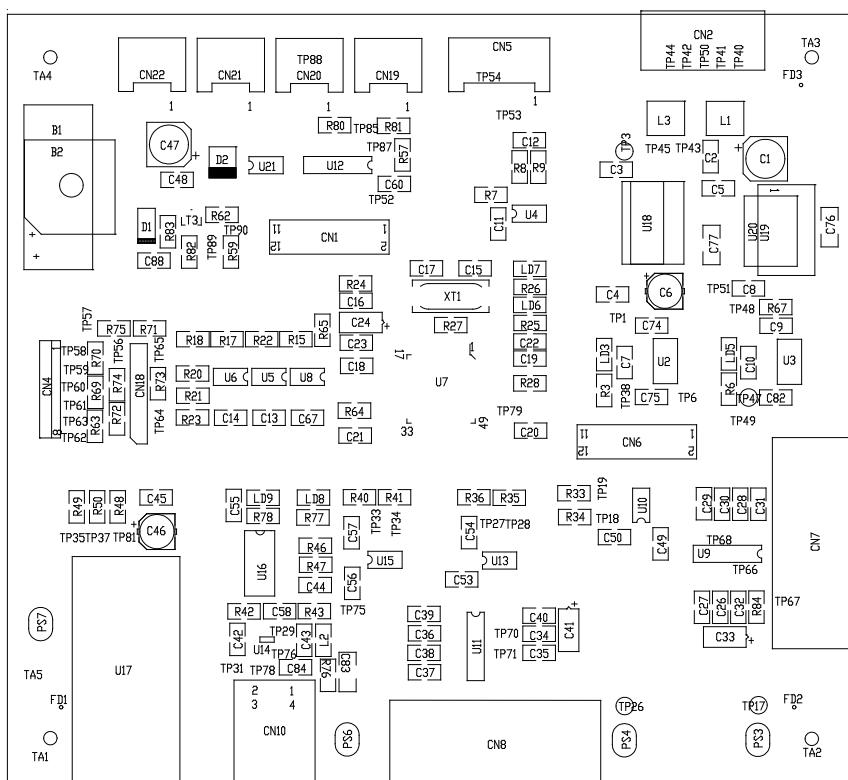


Figure 4.6 CPU board silk printing

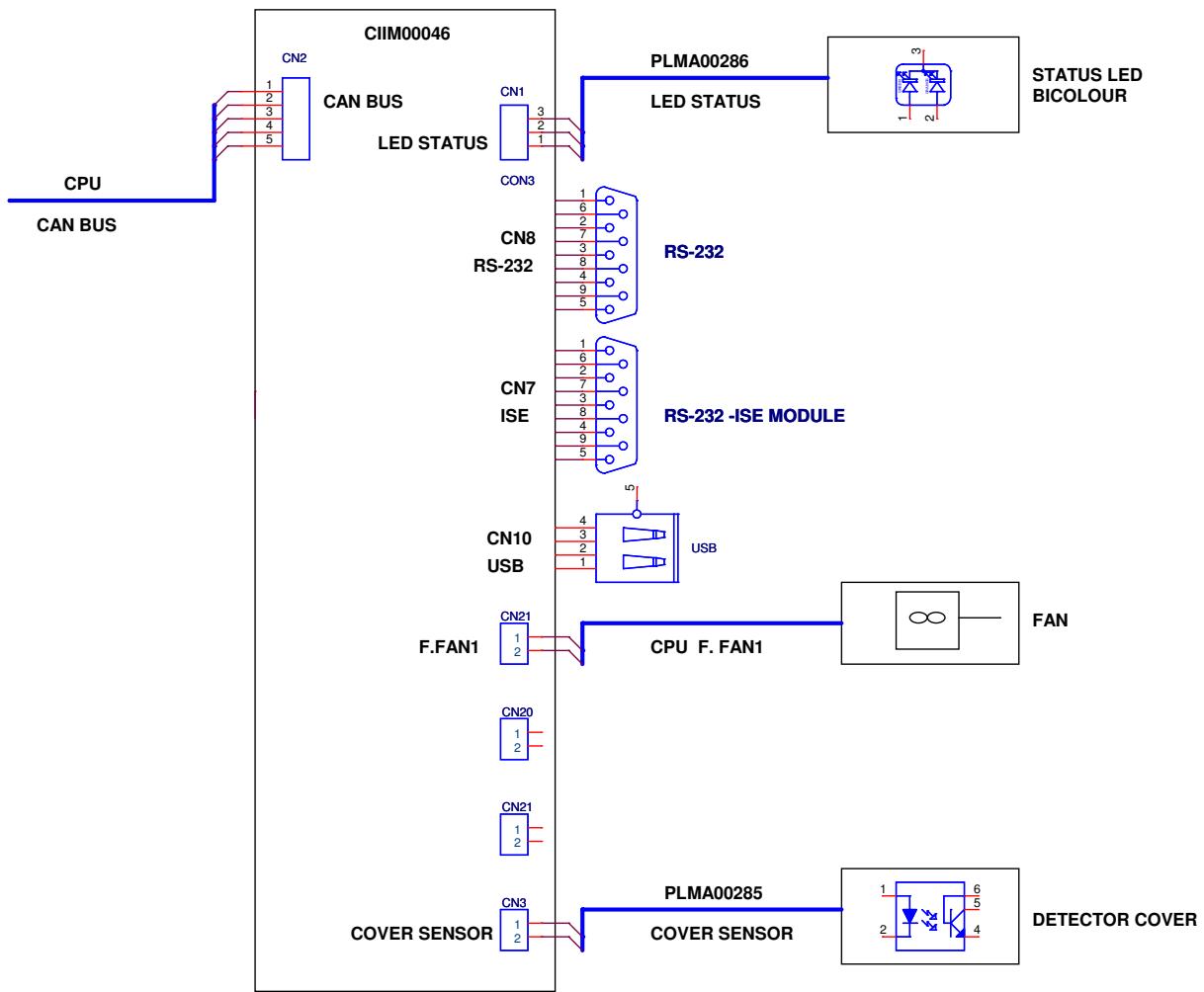


Figure 4.7 CPU board connections

Connector	Function	Pin
CN2	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN1	Led status lamp (3-coloured)	Pin 1: Activation of LED1 Pin 2: GND Pin 3: Activation of LED2
CN7	ISE module serial channel	Pin 2: Transmission Pin 3: Reception Pin 5: GND
CN8	Analyser serial channel	Pin 2: Transmission Pin 3: Reception Pin 5: GND
CN10	USB connection	Pin 1: 5 V Pin 2: USB+ Pin 3: USB- Pin 4: GND

Connector	Function	Pin
CN19	General fan	Pin 1: 24 V Pin 2: Activation
CN20	General fan	Pin 1: 24 V Pin 2: Activation
CN21	General fan	Pin 1: 24 V Pin 2: Activation
Test point	Function	
TP1	5 V	
TP7	GND ISE	
TP18	ISE transmission serial channel	
TP19	ISE reception serial channel	
TP26	GND serial channel	
TP27	Transmission serial channel	
TP28	Reception serial channel	
TP29	USB + signal	
TP31	USB - signal	
TP33	USB transmission serial channel	
TP34	USB reception serial channel	
TP38	3.3 V	
TP40	24 V	
TP41	GND	
TP42	CAN_H (bus signal)	
TP43	CAN_H	
TP44	CAN_L (bus signal)	
TP45	CAN_L	
TP48	5 V	
TP49	3.3 V	
TP50	GND	
TP51	GND	
TP52	5V	
TP76	5V USB	
TP78	5V USB	
TP87	Fan activation voltage	
TP90	Buzzer activation voltage	
LEDs	Function (on condition)	
LD3	3.3 V voltage	
LD5	Insulated 3.3 V voltage	
LD6	CPU start-up indication	
LD7	CAN start-up indication	

4.3. Arm boards - CIIM00048

These boards are located on each of the five arms.

The board has a micro controller (U1) which controls the drivers of the motors that move the arm vertically (U7) and horizontally (U8).

It also contains the electronic control system of the start-up sensors for each motor.

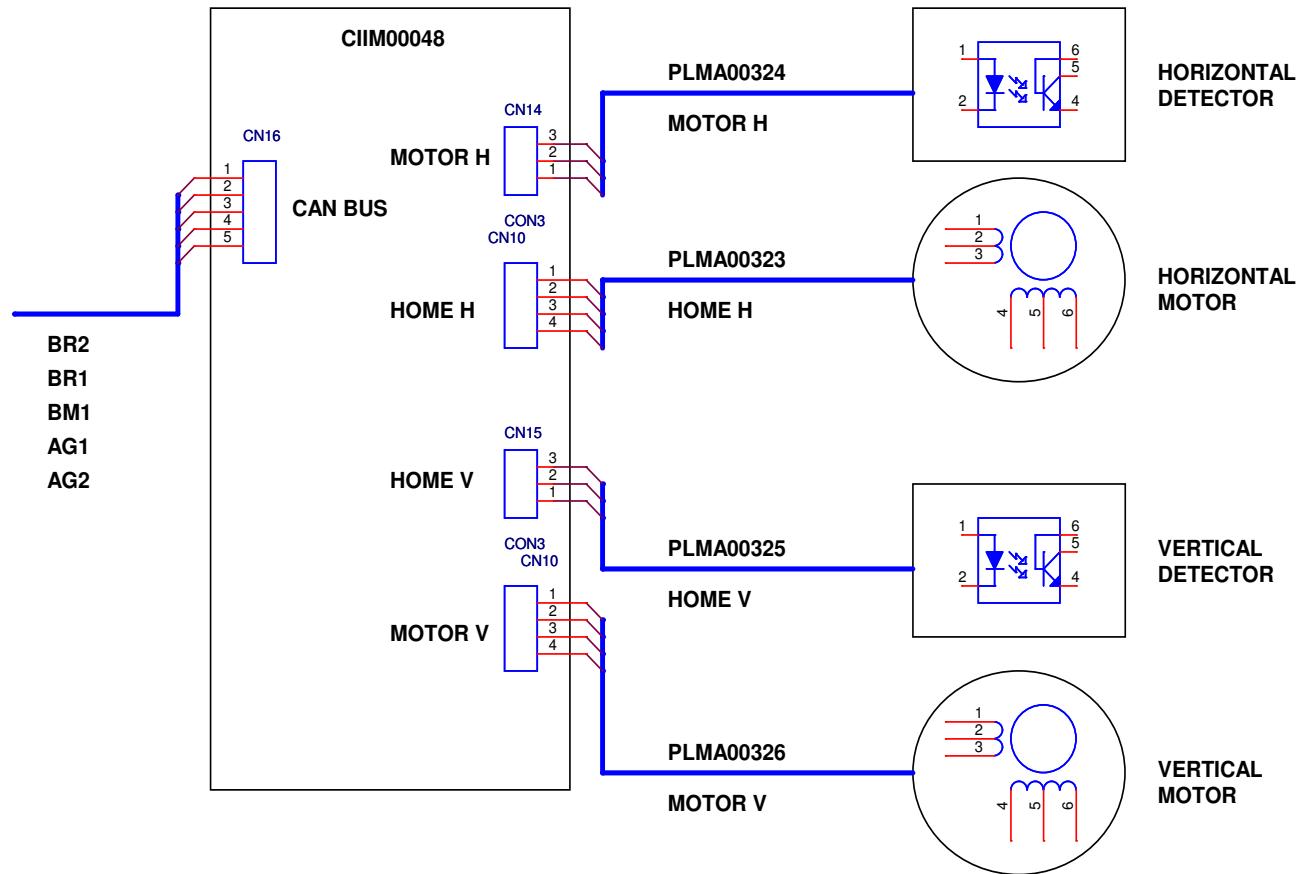


Figure 4.8 Arm board connections

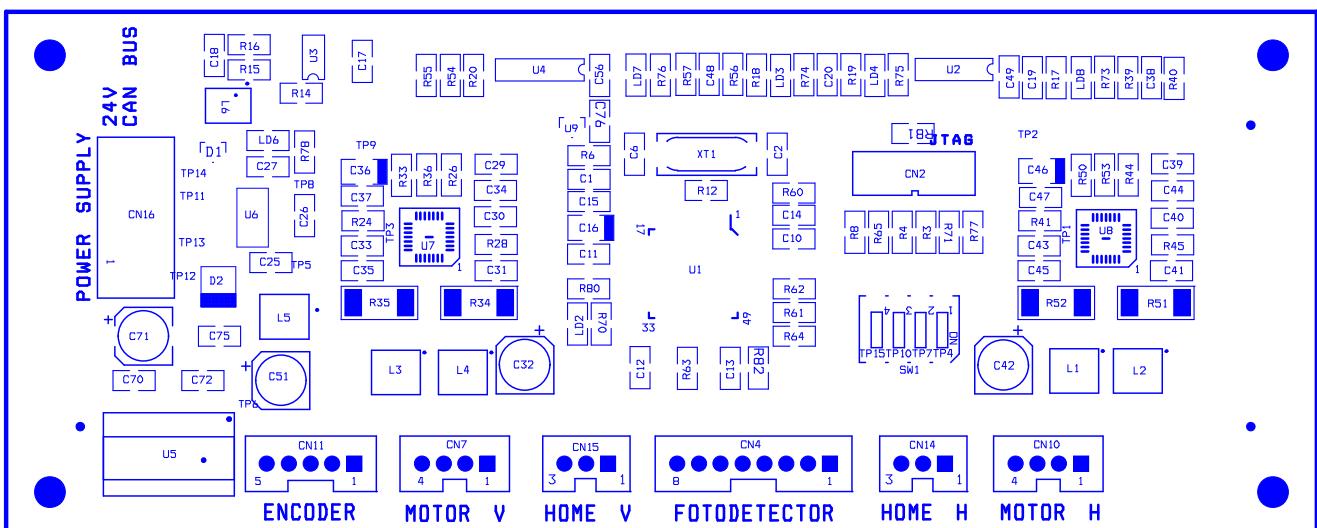


Figure 4.9 Arm board silk printing.

Connector	Function	Pin
CN16	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN7	Vertical motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN10	Horizontal motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN14	Horizontal start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN15	Vertical start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V

Test point	Function
TP1	Horizontal motor reference voltage
TP2	Horizontal stepper motor
TP3	Vertical motor reference voltage
TP4	Board selection. Direction 1
TP5	5 V
TP6	24 V
TP7	Board selection. Direction 2
TP8	3.3 V
TP9	Vertical stepper motor
TP10	Board selection. Direction 3
TP11	CAN_H (bus signal)
TP12	24 V (bus voltage)
TP13	GND (bus voltage)
TP14	CAN_L (bus signal)
TP15	Board selection. Direction 4

LEDs	Function (on condition)
LD2	Board start-up status
LD6	3.3 V voltage
LD7	Vertical arm start-up detection
LD8	Horizontal arm start-up detection

4.4. Tip detection board - CIIM00049

Board located in the upper part of the sample and reagent arms. These boards control the following elements, through a micro controller (U10):

- Fluid detection system
- Tip collision sensor
- The heating element and temperature sensor only in the reagent tips.
- Protection against ESD in the tip.

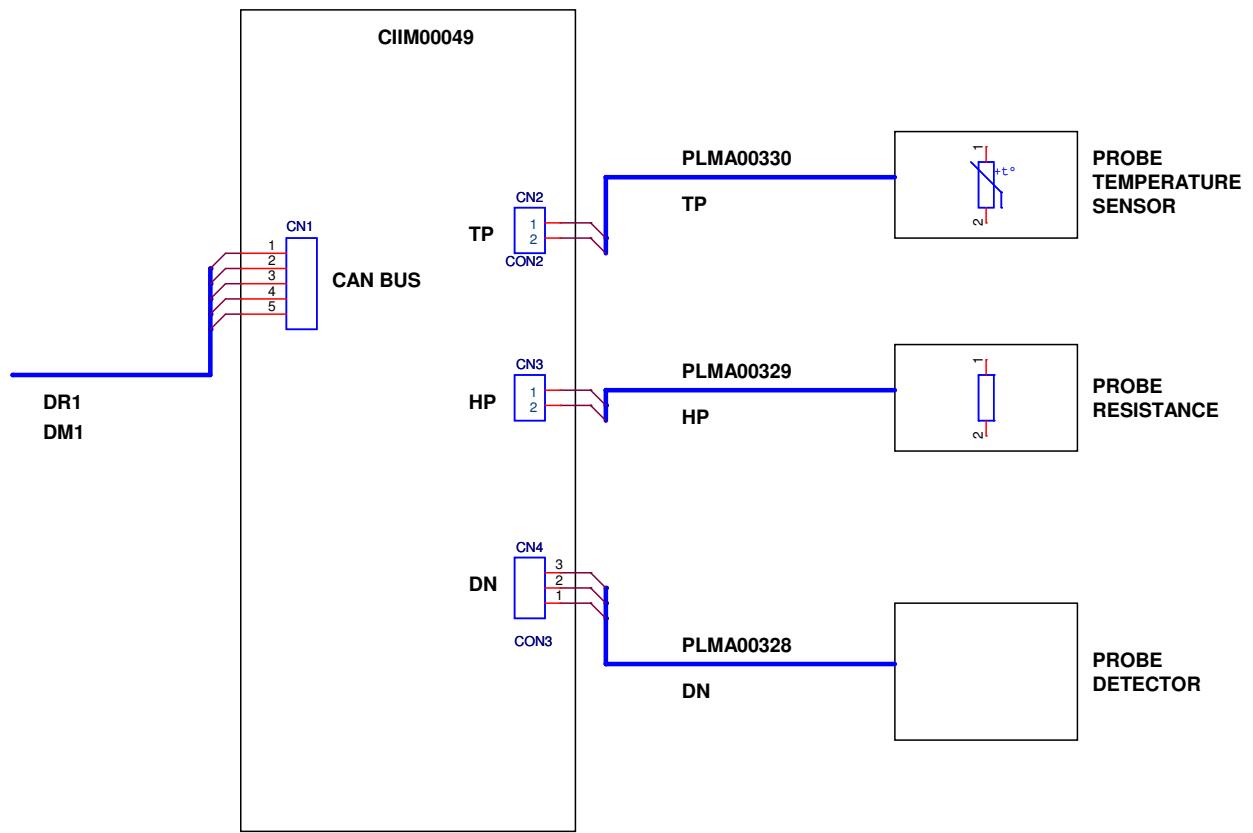


Figure 4.10 Tip board connections

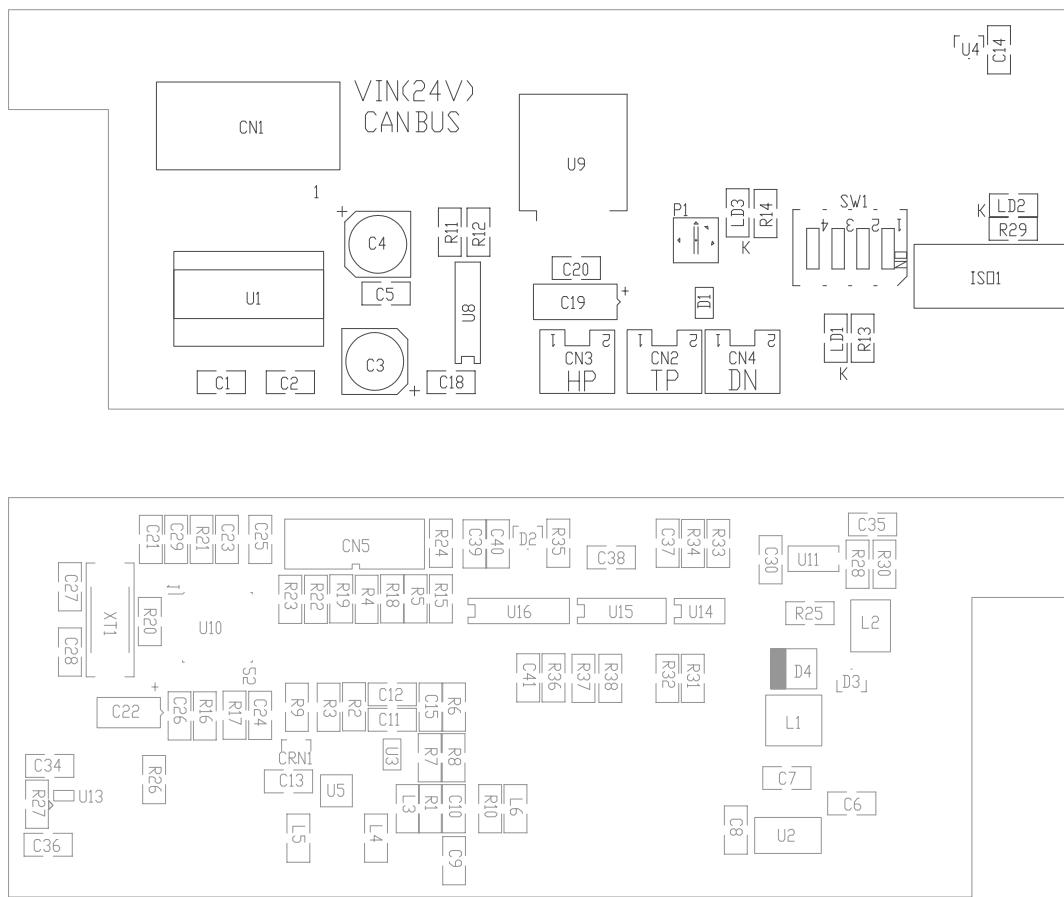


Figure 4.11 Tip board silk printing

Connector	Function	Pin
CN1	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN2	Tip temperature sensor	Pin 1: 3.3 V Pin 2: Sensor
CN3	Tip resistance	Pin 1: Resistance Pin 2: Resistance
CN4	Detection of tip	Pin 1: Detection signal Pin 2: Injection signal

Test point	Function
TP1	5 V
TP1	Board selection. Direction 1
TP2	Board selection. Direction 2
TP3	Board selection. Direction 3
TP4	Board selection. Direction 4
TP6	3.3 V
TP19	Tip collision detection

LEDs	Function (on condition)
LD1	CPU status
LD2	Collision detection
LD3	Sample detection status

4.4.1. Level detection adjustment

Material required to make the adjustment:

- plastic, flat-tip precision screwdriver. Bourns or similar trimming tool.



A plastic screwdriver must be used, to prevent perturbations in the detection signal while the power meter turns. Do not use a metal screwdrive as it will affect the signal.

The state of led LD3 indicates the detection frequency adjustment. The process must be made when the analyser is on stand-by and the tip is correctly primed.

If the led flashes or if off, this indicates that the detection frequency is not adjusted.

As the adjustment frequency is approached, the led will flash more rapidly until it remains on when the target detection frequency is reached.

The detection frequency for the sample tip is: 2M Hz

The detection frequency for the reagent tip is: 1M Hz

Steps for making the adjustment:

1. Turn on the analyser
2. Remove the cap from the tip you want to adjust
3. Insert the plastic screwdriver into the power meter (P1). Ensure that the tip is correctly primed and not touching any fluid.
4. Gently turn the power meter in the direction in which the LD3 led flashing frequency increases until it stops flashing.
5. If the frequency falls, change the direction for turning the power meter.

Potential problems in the tip detection adjustment:

Detection problem	Solution
It is impossible to achieve the stable flashing of the LD3 adjustment led	Check that the cable protective mesh is correctly compress on the connector pin. Check that the cable is not pinched.
	Check that the tip detection cable is properly attached to the board with a clamp.
	Check that the screws, nuts and parts securing the collision detection spring are properly tightened and do not move.
	Check that the tip is correctly primed.

4.5. Photometric control board- CIIM00050

Board located in the reading rotor. It contains a micro controller (U5) which controls the following elements:

- Reaction rotor cover detection (U7)
- Wash station motor (U14)
- Wash station start-up detection (U10)
- Wash station collision detection (U10)
- Photometric board connection
- Reaction rotor motor (U12)
- Reaction rotor start-up detection (U10)
- Reaction rotor encoder detection (13)
- Peltier control in thermostatting the reaction rotor (U18)
- Fan control for cooling the peltiers (U17). There are 3 fans with 3 wires.
- Reaction rotor thermostatting temperature sensor control (U15 and U16)

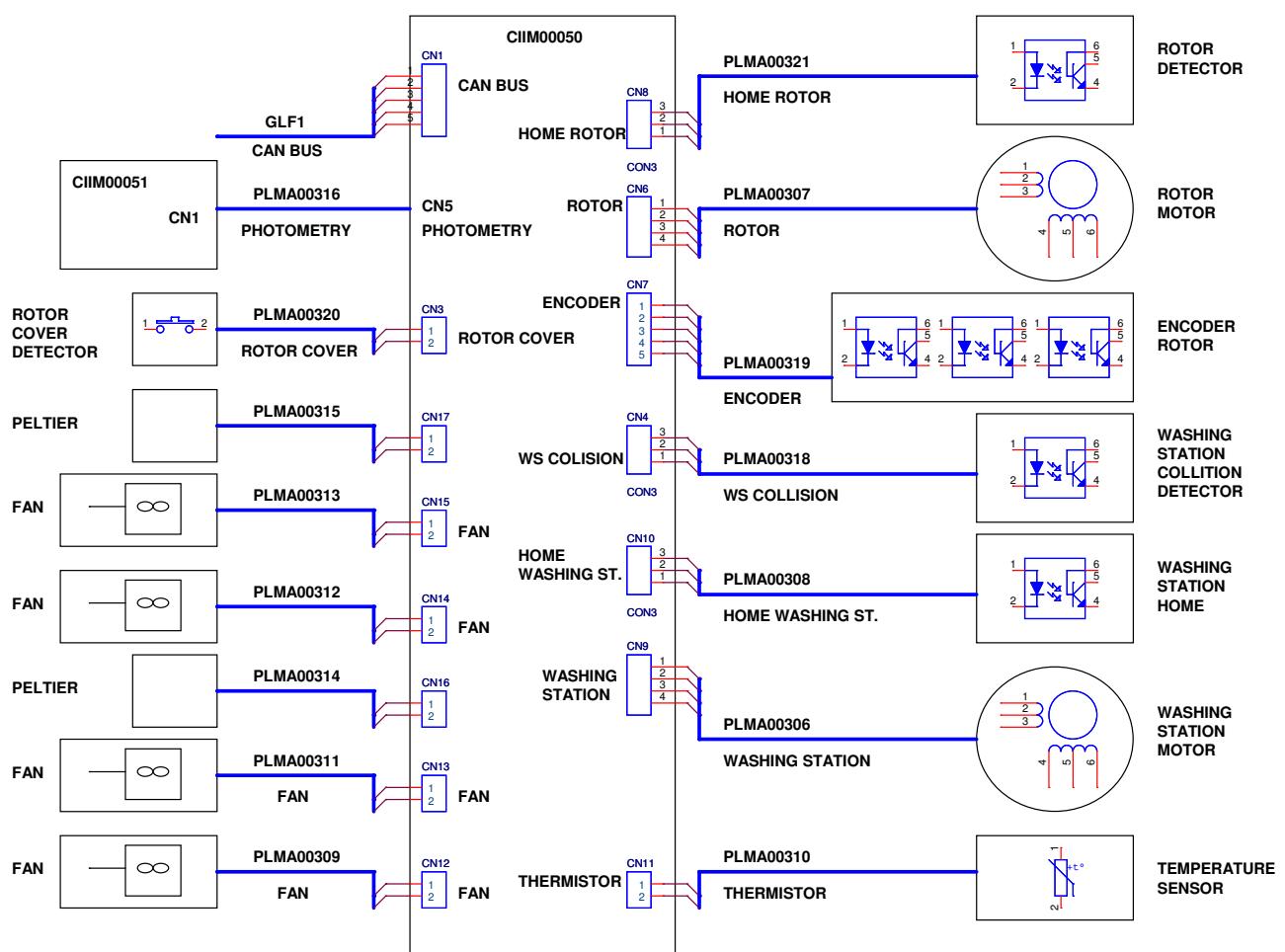


Figure 4.12 Photometric control board connections

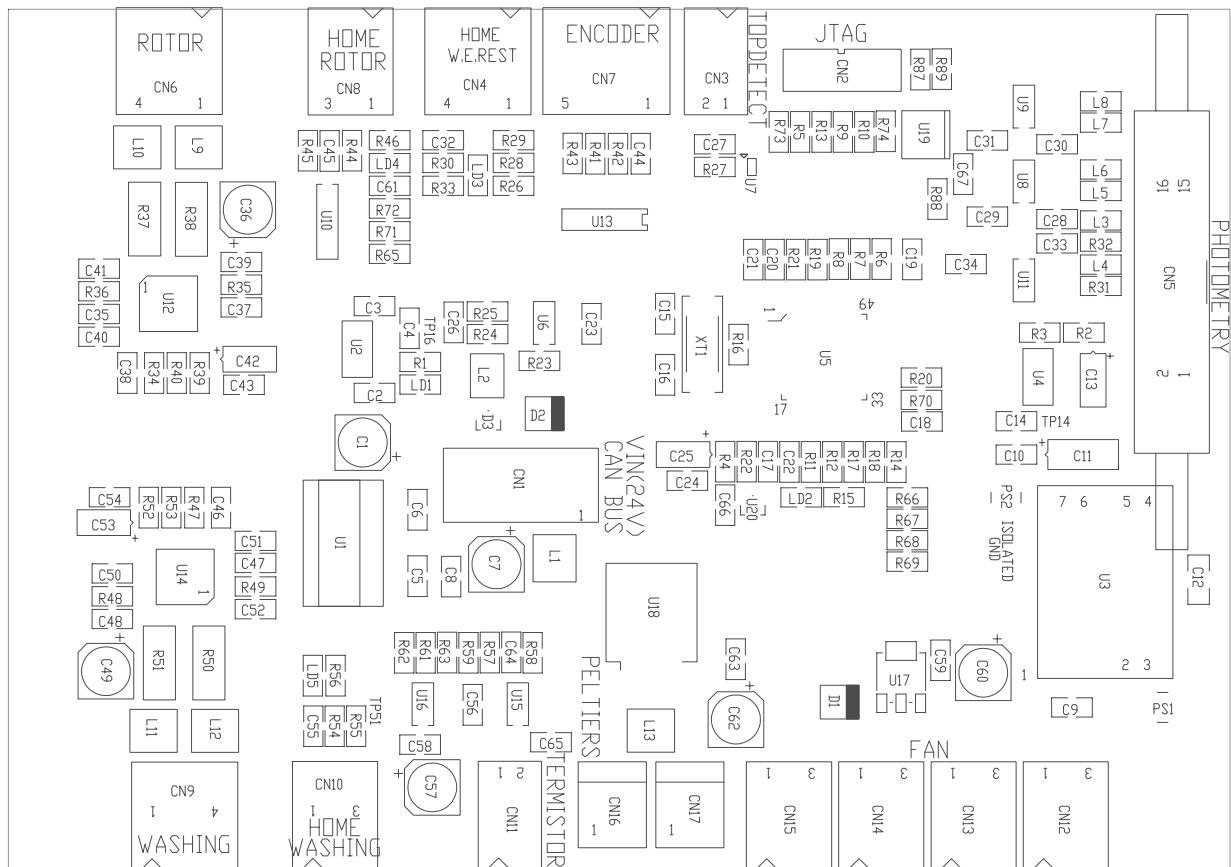


Figure 4.13 Photometric control board silk printing

Connector	Function	Pin
CN1	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN3	Rotor cover detection	Pin 1: 5V Pin 2: Cover detection
CN4	Wash station collision detection	Pin 1: GND Pin 2: Wash station detection Pin 3: GND Pin 4: Wash station collision
CN5	Photometric board connection	
CN6	Rotor motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN7	Rotor encoder	Pin 1: GND Pin 2: C channel encoder Pin 3: A channel encoder Pin 4: 5 V Pin 5: B channel encoder

Connector	Function	Pin
CN8	Rotor start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN9	Wash station motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN10	Wash station detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN11	Tip temperature sensor	Pin 1: 3.3 V Pin 2: Sensor
CN12	Fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: Activation
CN13	Fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: Activation
CN14	Fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: Activation
CN15	Fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: Activation
CN16	Peltier	Pin 2: Peltier activation Pin 3: Peltier activation
CN17	Peltier	Pin 2: Peltier activation Pin 3: Peltier activation

Test point	Function
TP1	24 V
TP2	GND
TP3	CAN_H (bus signal)
TP4	CAN_L (bus signal)
TP5	GND
TP6	GND
TP14	12 V insulated
TP16	3.3 V
TP17	5 V
TP18	24 V
TP19	GND
TP27	Rotor motor reference voltage
TP28	Stepper motor driver voltage
TP40	Wash station motor reference voltage

Test point	Function
TP41	Motor driver step voltage
TP51	Rotor temperature

LEDs	Function (on condition)
LD1	3.3 V activation
LD2	CPU start-up
LD3	Wash station rest phase detection
LD4	Rotor start-up detection
LD5	Wash station start-up detection

4.6. Photometric readings board - CIIM00051

This board is located below the optical bench in the reaction rotor assembly. The board has the leds for each wavelength and the two photosensors directly welded to it.

This board controls the switching on and off of each led. The leds are controlled through a power source (U2, U8, U9 and T13) and the led on selection is done through a decoder (U11).

The readings are made through two photodiodes (main and reference photodiodes) which are read by a double integrating ramp converter (U1, U4, U5 and U6).

All the control signals are sent to the photometric control board (CIIM00050) through an I2C channel (U7)

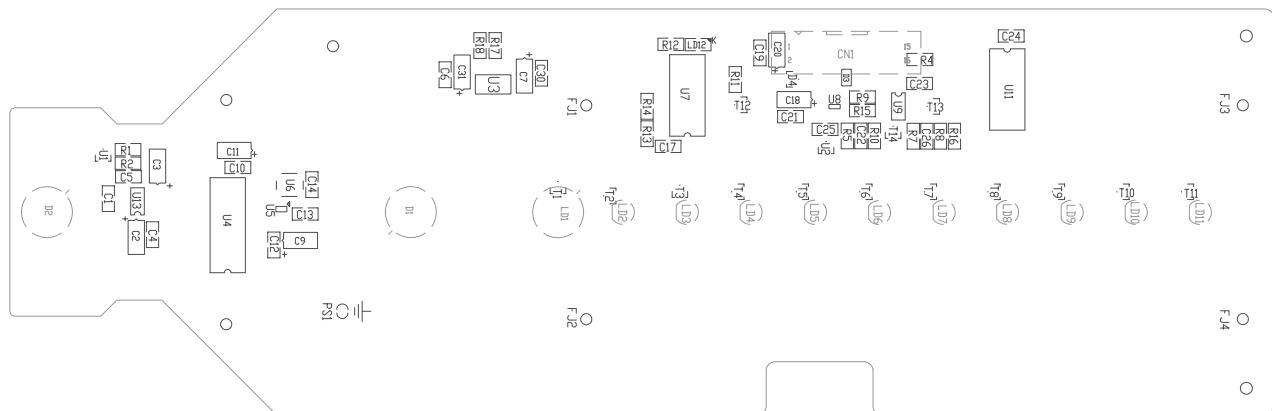


Figure 4.14 Photometric control board silk printing

Connector	Function
CN1	Photometric board connection

Test point	Function
TP3	LED voltage
TP4	LED voltage
TP6	Decoder 1

Test point	Function
TP7	Decoder 2
TP8	Decoder 3
TP9	Decoder 4
TP10	Activation of LED 1
TP11	Activation of LED 2
TP12	Activation of LED 3
TP13	Activation of LED 4
TP14	Activation of LED 5
TP15	Activation of LED 6
TP16	Activation of LED 7
TP17	Activation of LED 8
TP18	Activation of LED 9
TP19	Activation of LED 10
TP20	Activation of LED 11
TP21	Activation of LED 12

LEDs	Function (on condition)
LD1	340 nm LED
LD2	560 nm LED
LD3	670 nm LED
LD4	600 nm LED
LD5	535 nm LED
LD6	505 nm LED
LD7	635 nm LED
LD8	405 nm LED
LD9	Free position
LD10	Free position
LD11	Free position
LD12	I2C decoder indicator

4.7. Rotor boards - CIIM00052

The analyser has two CIIM00052 boards which are located in the sample and reagent rotor assemblies. Both boards have the same PCB but the fridge components have not been mounted on the sample rotor board. Each board has a different board selection switch code.

Elements that are common to both boards

- Micro controller (U5)
- Cover sensor (U3)
- Control of fans located in the structure (U3 and U6)

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- Rotor motor (U8)
- Rotor start-up detection (U3)
- Barcode reading communication (U3 and U4)

Fridge components mounted on the reagent rotor board

- Separate power supply (U16)
- Micro controller (U13)
- Reading window demisting driver (U10 and U17)
- Thermistor for controlling fridge
- Fridge peltier control (U9 and U11)
- Fridge peltier fans (U9 and U11), controlled by the same drivers as the peltiers

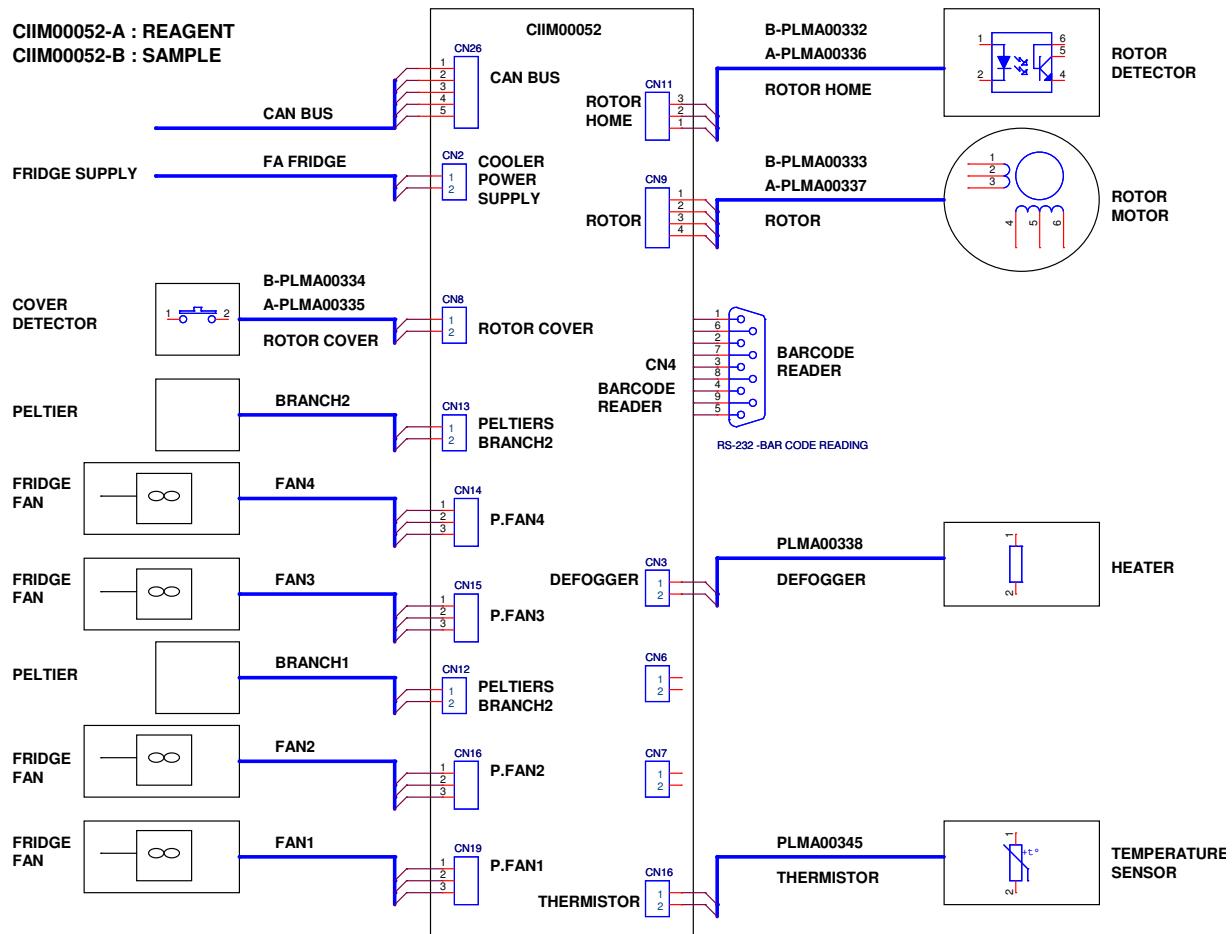


Figure 4.15 Rotor board connections

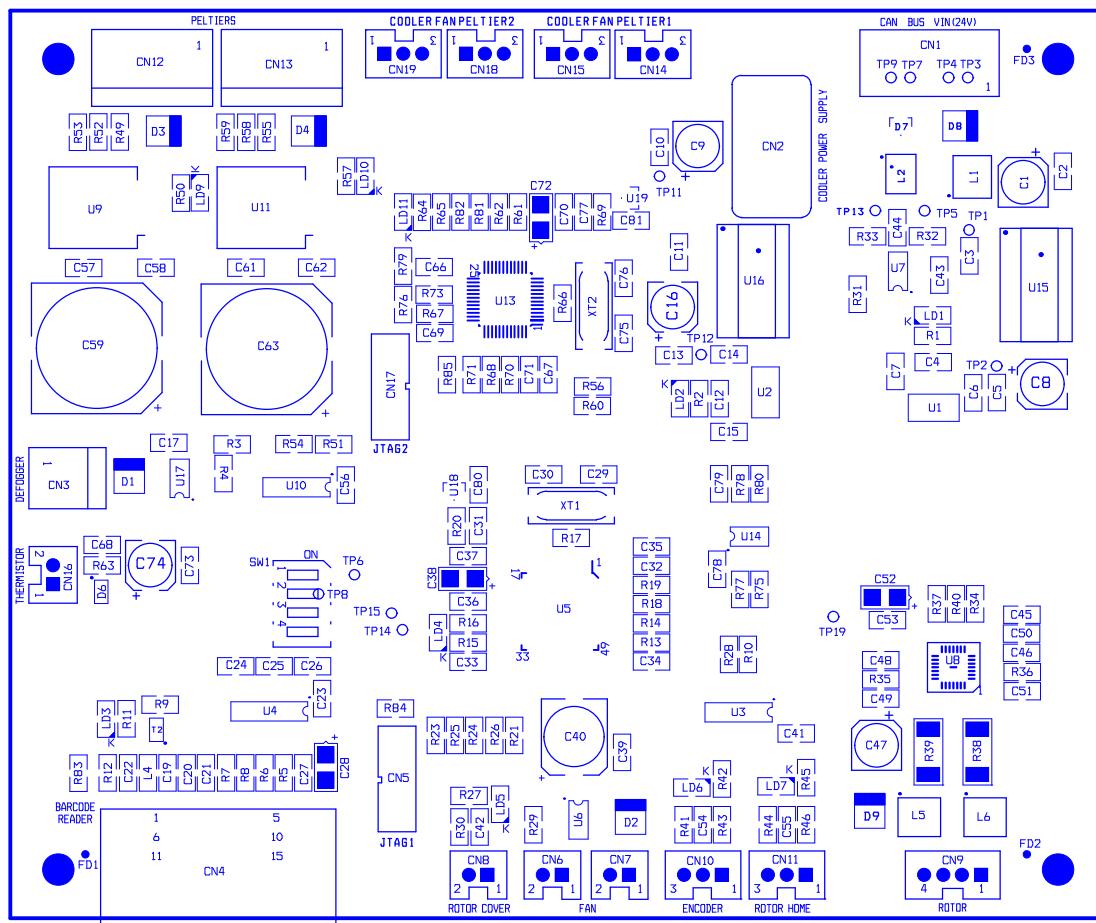


Figure 4.16 Rotor board silk printing

Connector	Function	Pin
CN1	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN2	Separate fridge power supply	Pin 1: 24 V Fridge Pin 2: GND Fridge
CN3	Demister	Pin 1: 24 V Pin 2: Activation
CN4	Barcode reader	Pin 1: Activation/deactivation Pin 2: Reading channel 1 Pin 3: Transmission1 Pin 4: GND Pin 6: Reading channel 2 Pin 9: Reading shot Pin 10: Transmission2
CN6	General fan	Pin 1: 24 V Pin 2: GND

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Connector	Function	Pin
CN7	General fan	Pin 1: 24 V Pin 2: GND
CN8	Cover sensor	Pin 1: 5V Pin 2: Detection signal
CN9	Rotor motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN11	Rotor start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN12	Peltier	Pin 1: 24 V Pin 2: Peltier diagnostic Pin 3: Peltier diagnostic Pin 4: GND
CN13	Peltier	Pin 1: 24 V Pin 2: Peltier diagnostic Pin 3: Peltier diagnostic Pin 4: GND
CN14	Fridge fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: GND
CN15	Fridge fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: GND
CN16	Temperature sensor	Pin 1: Sensor Pin 2: GND
CN18	Fridge fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: GND
CN19	Fridge fan	Pin 1: 24 V Pin 2: Detection diagnostic Pin 3: GND

Test point	Function
TP1	24 V
TP2	5 V
TP3	24 V (bus voltage)
TP4	GND (bus voltage)
TP5	CAN_H
TP6	Board selection. Direction 1
TP7	CAN_H (bus signal)
TP8	Board selection. Direction 2
TP9	CAN_L (bus signal)

Test point	Function
TP11	24 V Fridge
TP12	5 V Fridge
TP13	CAN_L
TP14	Board selection. Direction 4
TP15	Board selection. Direction 3
TP19	Rotor stepper motor

LEDs	Function (on condition)
LD1	3.3 V voltage
LD2	3.3 V voltage Fridge
LD3	Barcode reader activation
LD4	Microprocessor start-up
LD5	Cover detection
LD7	Rotor start-up detection
LD9	Fridge peltier activation
LD10	Fridge peltier activation
LD12	Fridge microprocessor start-up

4.8. Fluid control board – CIIM00053

This board is located at the top of the fluid zone.

The board controls the following elements, through a micro controller (U10):

- Stirrer driver (U18)
- Scales signal conditioning (U5 and U6) for the washing solution and high contamination waste
- Internal water and waste bottle buoy conditioning
- Driver for the wash station water heater (U1)
- Temperature sensor for controlling the thermostatting of the wash station water
- Wash station water dispensing driver
- Wash station water dispensing start-up detection

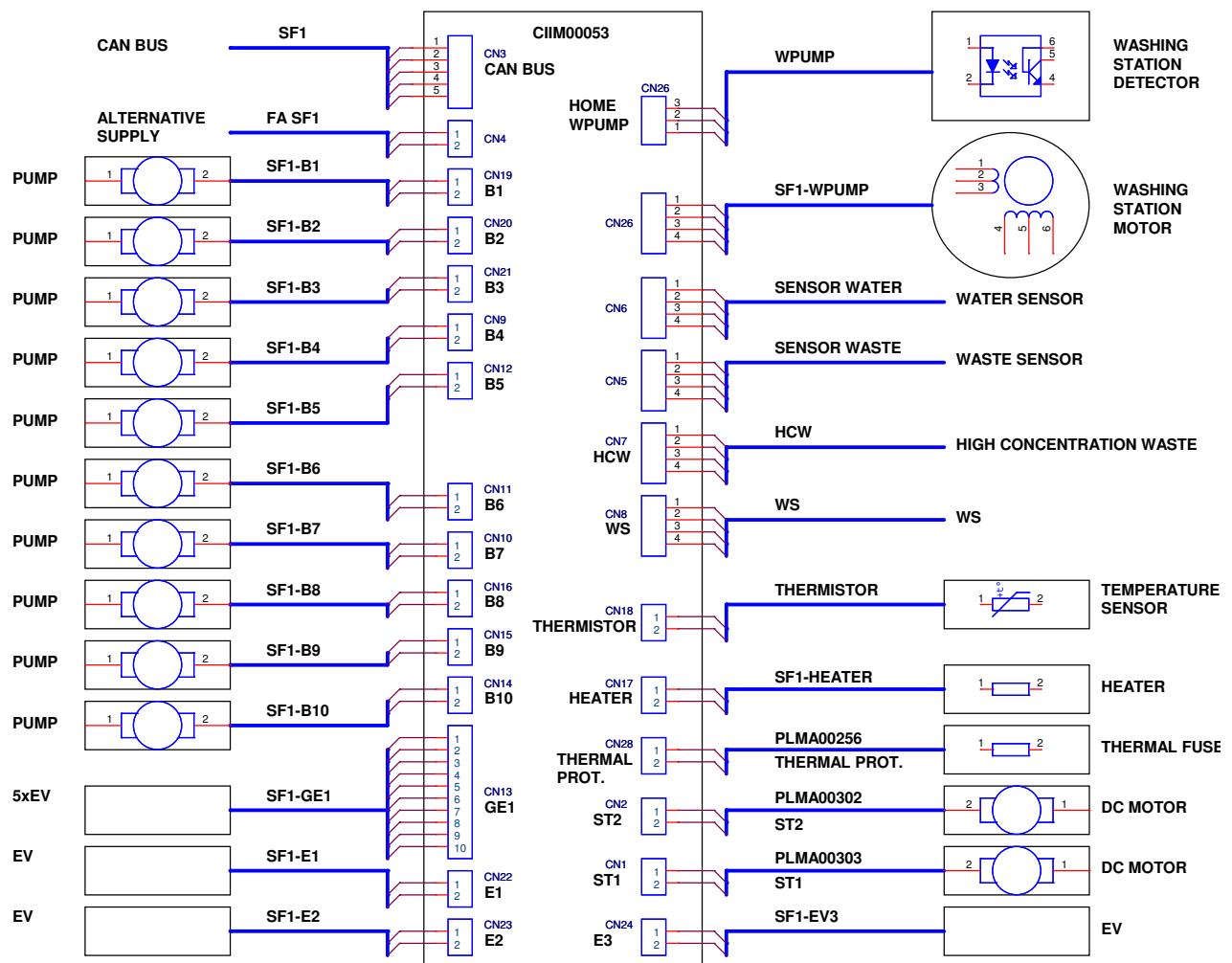


Figure 4.17 Fluid control board connections

Connector	Function	Pin
CN1	Activation stirrer 1	Pin 1: Output 1 Pin 2: Output 2
CN2	Activation stirrer 2	Pin 1: Output 1 Pin 2: Output 2
CN3	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN4	Extra power	Pin 1: 24 V Pin 2: GND
CN5	Waste bottle level detection sensor	Pin 1: GND Pin 2: Bottom sensor Pin 3: GND Pin 4: Top sensor

Connector	Function	Pin
CN6	Distilled water bottle level detection sensor	Pin 1: GND Pin 2: Bottom sensor Pin 3: GND Pin 4: Top sensor
CN7	High contamination waste bottle scales signal	Pin 1: GND Pin 2: Signal 1 Pin 3: Signal 2 Pin 4: 3.3 V
CN8	Wash station scales signal	Pin 1: GND Pin 2: Signal 1 Pin 3: Signal 2 Pin 4: 3.3 V
CN9	B4 pump	Pin 1: 24 V Pin 2: Activation signal
CN10	B7 pump	Pin 1: 24 V Pin 2: Activation signal
CN11	B6 pump	Pin 1: 24 V Pin 2: Activation signal
CN12	B5 pump	Pin 1: 24 V Pin 2: Activation signal
CN13	GE1 wash station dispensation electro valve assembly	Pin 1: 24 V Pin 2: Activation signal Pin 3: 24 V Pin 4: Activation signal Pin 5: 24 V Pin 6: Activation signal Pin 7: 24 V Pin 8: Activation signal Pin 9: 24 V Pin 10: Activation signal
CN14	B10 pump	Pin 1: 24 V Pin 2: Activation signal
CN15	B9 pump	Pin 1: 24 V Pin 2: Activation signal
CN16	B8 pump	Pin 1: 24 V Pin 2: Activation signal
CN17	Wash station water thermostatting	Pin 1: Output 1 Pin 2: Output 2
CN18	Wash station thermistor	Pin 1: 3.3 V Pin 2: sensor signal
CN19	B1 pump	Pin 1: 24 V Pin 2: Activation signal
CN20	B2 pump	Pin 1: 24 V Pin 2: Activation signal
CN21	B3 pump	Pin 1: 24 V Pin 2: Activation signal

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Connector	Function	Pin
CN22	E1 electro valve	Pin 1: 24 V Pin 2: Activation signal
CN23	E2 electro valve	Pin 1: 24 V Pin 2: Activation signal
CN24	E3 electro valve	Pin 1: 24 V Pin 2: Activation signal
CN26	Wash station water dispensation motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN27	Wash station water dispensation start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN28	Wash station water thermostatting thermostat	Pin 1: output 1 Pin 2: GND

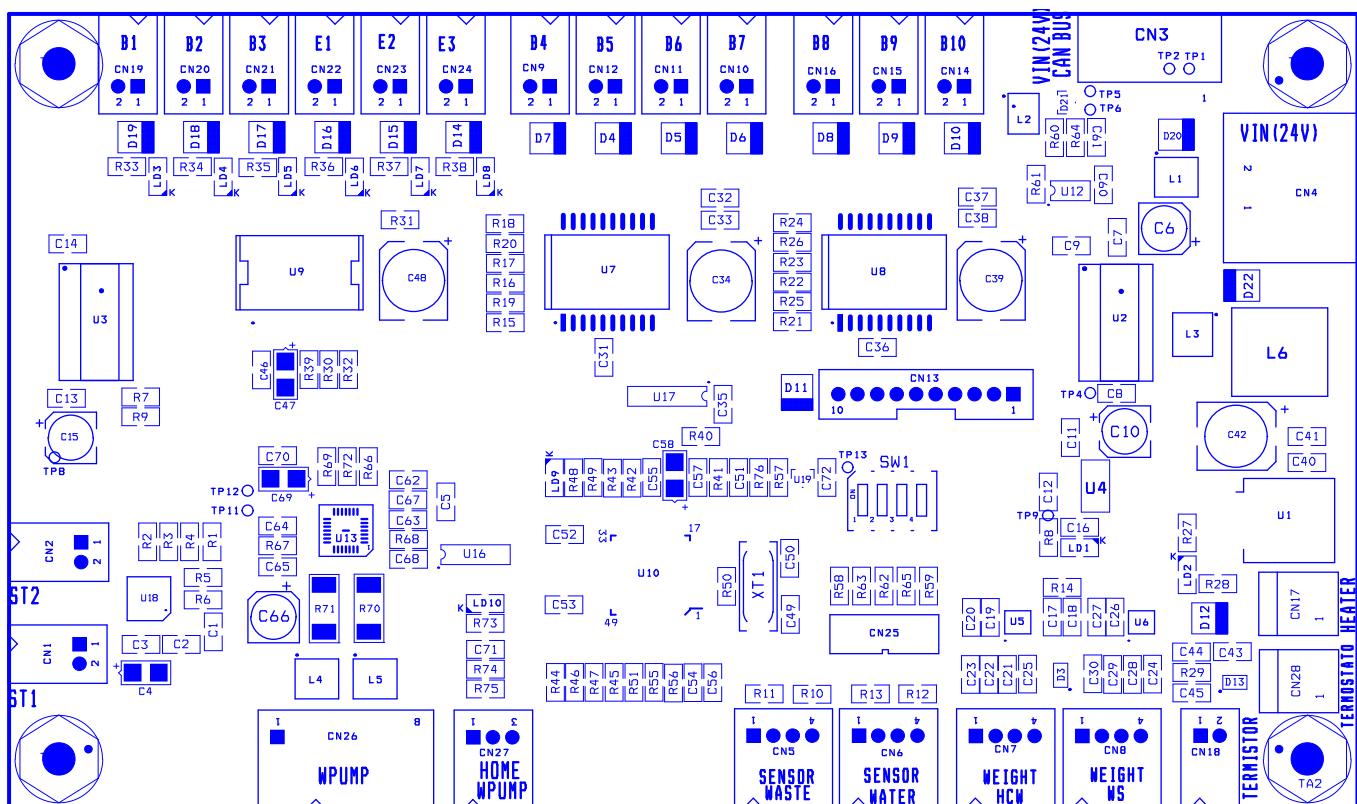


Figure 4.18 Fluid control board silk printing

Test point	Function
TP1	24 V (bus voltage)
TP2	GND (bus voltage)
TP4	5 V
TP5	CAN_H (bus signal)

Test point	Function
TP6	CAN_L (bus signal)
TP8	Stirrer DC voltage
TP9	3.3 V
TP11	Motor driver reference voltage
TP12	Stepper motor
TP13	Board selection. Direction 1

LEDs	Function (on condition)
LD1	3.3 V voltage
LD2	Heater activation
LD3	Activation of pump 1
LD4	Activation of pump 2
LD5	Activation of pump 3
LD6	Activation of electro valve 1
LD7	Activation of electro valve 2
LD8	Activation of electro valve 3
LD9	Microprocessor start-up
LD10	Motor start-up detection

4.9. Syringe control board - C1M00054

This board is located at the top of the fluid zone.

The board controls the following elements, through a micro controller (U1):

- Sample circuit pressure sensor (clot sensor)
- Manifold led power supply
- Sample dispensation motor driver
- Sample dispensation start-up sensor
- Reagent 1 dispensation motor driver
- Reagent 1 dispensation start-up sensor
- Reagent 2 dispensation motor driver
- Reagent 2 dispensation start-up sensor

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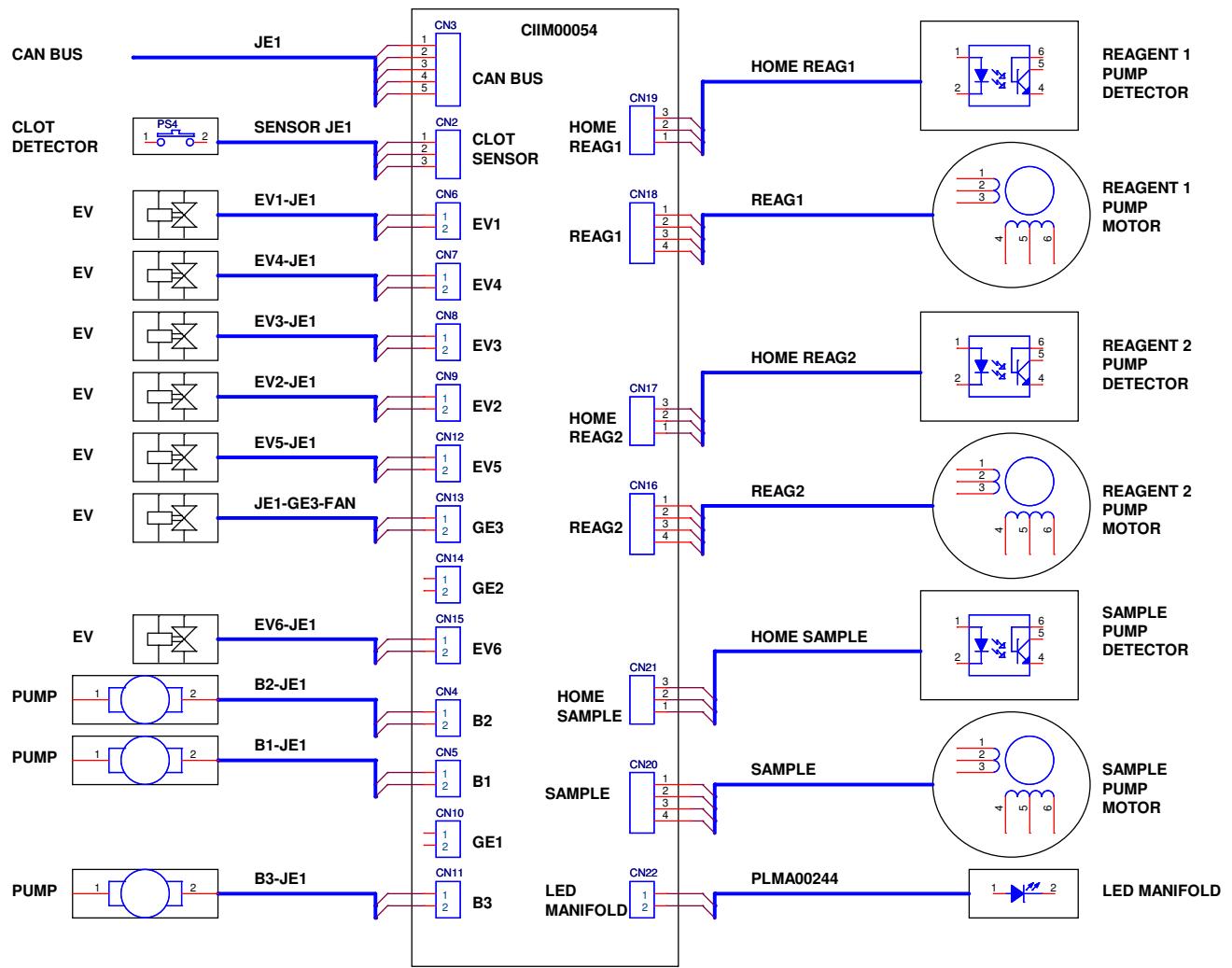


Figure 4.19 Syring control board connections

Connector	Function	Pin
CN2	Pressure sensor	Pin 1: 5 V Pin 2: Sensor Pin 3: GND
CN3	CAN bus connection	Pin 1: 24V Pin 2: GND Pin 3: NC Pin 4: CAN_H Pin 5: CAN_L
CN4	Activation of pump B2	Pin 1: 24 V Pin 2: Activation signal
CN5	Activation of pump B1	Pin 1: 24 V Pin 2: Activation signal
CN6	Activation of electro valve EV1	Pin 1: 24 V Pin 2: Activation signal
CN7	Activation of electro valve EV4	Pin 1: 24 V Pin 2: Activation signal

Connector	Function	Pin
CN8	Activation of electro valve EV3	Pin 1: 24 V Pin 2: Activation signal
CN9	Activation of electro valve EV2	Pin 1: 24 V Pin 2: Activation signal
CN10	Activation of pump GE1	Pin 1: 24 V Pin 2: Activation signal
CN11	Activation of pump B3	Pin 1: 24 V Pin 2: Activation signal
CN12	Activation of electro valve EV5	Pin 1: 24 V Pin 2: Activation signal
CN13	Activation of electro valve GE3	Pin 1: 24 V Pin 2: Activation signal
CN14	Activation of electro valve GE2	Pin 1: 24 V Pin 2: Activation signal
CN15	Activation of electro valve EV6	Pin 1: 24 V Pin 2: Activation signal
CN16	Reagent 2 dispensation motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN17	Reagent 2 start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN18	Reagent 1 dispensation motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN19	Reagent 1 start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN20	Sample dispensation motor	Pin 1: Coil 1 Pin 2: Coil 1 Pin 3: Coil 2 Pin 4: Coil 2
CN21	Sample dispensation start-up detection	Pin 1: Detection Pin 2: GND Pin 3: 5V
CN22	Manifold led	Pin 1: 5 V Pin 2: GND

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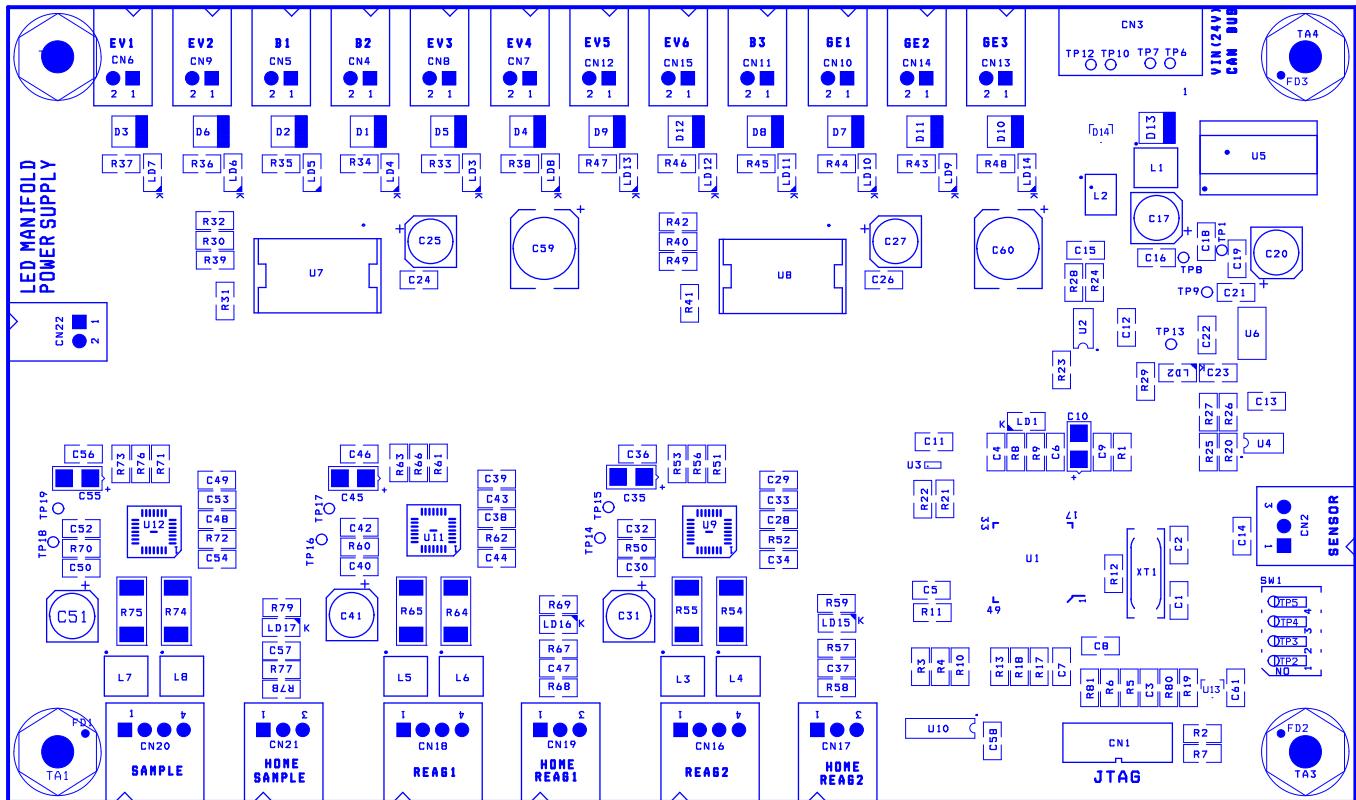


Figure 4.20 Syringe control board silk printing

Test point	Function
TP1	GND
TP2	Board selection. Direction 1
TP3	Board selection. Direction 2
TP4	Board selection. Direction 3
TP5	Board selection. Direction 4
TP6	24 V (bus voltage)
TP7	GND (bus voltage)
TP8	24 V
TP9	5 V
TP10	CAN_H (bus signal)
TP12	CAN_L (bus signal)
TP13	3.3 V
TP14	Reagent 2 motor reference voltage
TP15	Reagent 2 stepper motor driver voltage
TP16	Reagent 2 motor reference voltage
TP17	Reagent 2 stepper motor driver voltage
TP18	Sample motor reference voltage
TP19	Sample stepper motor driver voltage

LEDs	Function (on condition)
LD1	Microprocessor start-up
LD2	3.3 V voltage
LD3	Activation of pump 1
LD4	Activation of pump 2
LD5	Activation of electro valve 1
LD6	Activation of electro valve 2
LD7	Activation of electro valve 3
LD8	Activation of electro valve 4
LD9	Activation of pump 1
LD10	Activation of pump 2
LD11	Activation of electro valve 1
LD12	Activation of electro valve 2
LD13	Activation of electro valve 3
LD14	Activation of electro valve 4
LD15	Reagent 2 motor start-up detection
LD16	Reagent 1 motor start-up detection
LD17	Sample motor start-up detection

4.10>Loading of firmware

The firmware loading process is executed through the service programme.

☞ See chapter 8.6.8 Updating firmware.

A single file will be distributed, containing the individual firmware for each board. The process consists of first sending the file to the main board (CPU) which stores it in a flash drive or repository. Once it has been verified that the file sent is correct, the service programme will ask the user to confirm the start of the CPU board firmware updating process. Once the CPU board has been updated, it checks the compatibility of the versions of each of the boards against those in the repository. If any board has a version that is not compatible with the one in the repository, it updates the firmware of that board.

While the firmware file is transmitted with the service programme, the analyser status led will flash and change colour.

All the analyser adjustments are stored in the CPU board memory. When the analyser is initialised, the necessary adjustments for each board are sent.



NOTE

As a precaution, before performing any operation with the analyser it is advisable to make a backup copy of the adjustments.

☞ See chapter 8.6.9 Saving and recovering adjustments.

When the technical service has to carry out a repair and change a board, the technician will start the service programme for it to accept the firmware updating process and the adjustments for the new board.

The service programme can also be used to restore the initial adjustment values.

If that process is executed, the technician will have to readjust the analyser in full.

☞ See chapter 8.6.10 Restoring initial values

5. Fluidic elements

The analyser operates with 4 tanks for processing fluids. These tanks are: the distilled water tank, low contamination waste tank, washing solution tank and high contamination waste tank.

The distilled water and low contamination waste tanks are located at the bottom rear part of the analyser, and can only be accessed by the technical service. Full and empty level control is executed through a double-buoy system.

The washing solution and high contamination waste tanks are located at the front bottom part of the analyser. They can be accessed directly by the user.

- Once the determination has been made, the reagent and sample mixtures are sent to the high contamination waste tank. The tank has a capacity of 5 L and autonomous operation of at least 20 h.
- The tank that contains washing solution has a capacity of 5 L and autonomous operation of at least 8 h. The washing solution is used in the wash station to clean the reaction rotor and during the analyser initialisation and finalisation processes.
- All the waste from the reaction rotor wash station is deposited in the low contamination waste tank, in addition to the waste from the tip and stirrer wash stations. The tank has a capacity of 5 L and automatically empties the content outside the appliance through a buoy control process. The system uses the SF1-B5 pump to empty the tank.
- The internal distilled water tank has a capacity of 5 L. The water is used to prime the pipetting system, wash the inside and outside of the sample and reagent tips and wash the reaction rotor. The tank has two water inlets that are selected by the software. One inlet is from an external tank. For this purpose the analyser uses the SF1-EV2 and the SF1-B4 pump. The other inlet is through a water mains connection. When the water mains connection is selected, in the event that there is pressure, only one SF1-EV1 electro valve is used.

The analyser fluidic diagram is shown below.

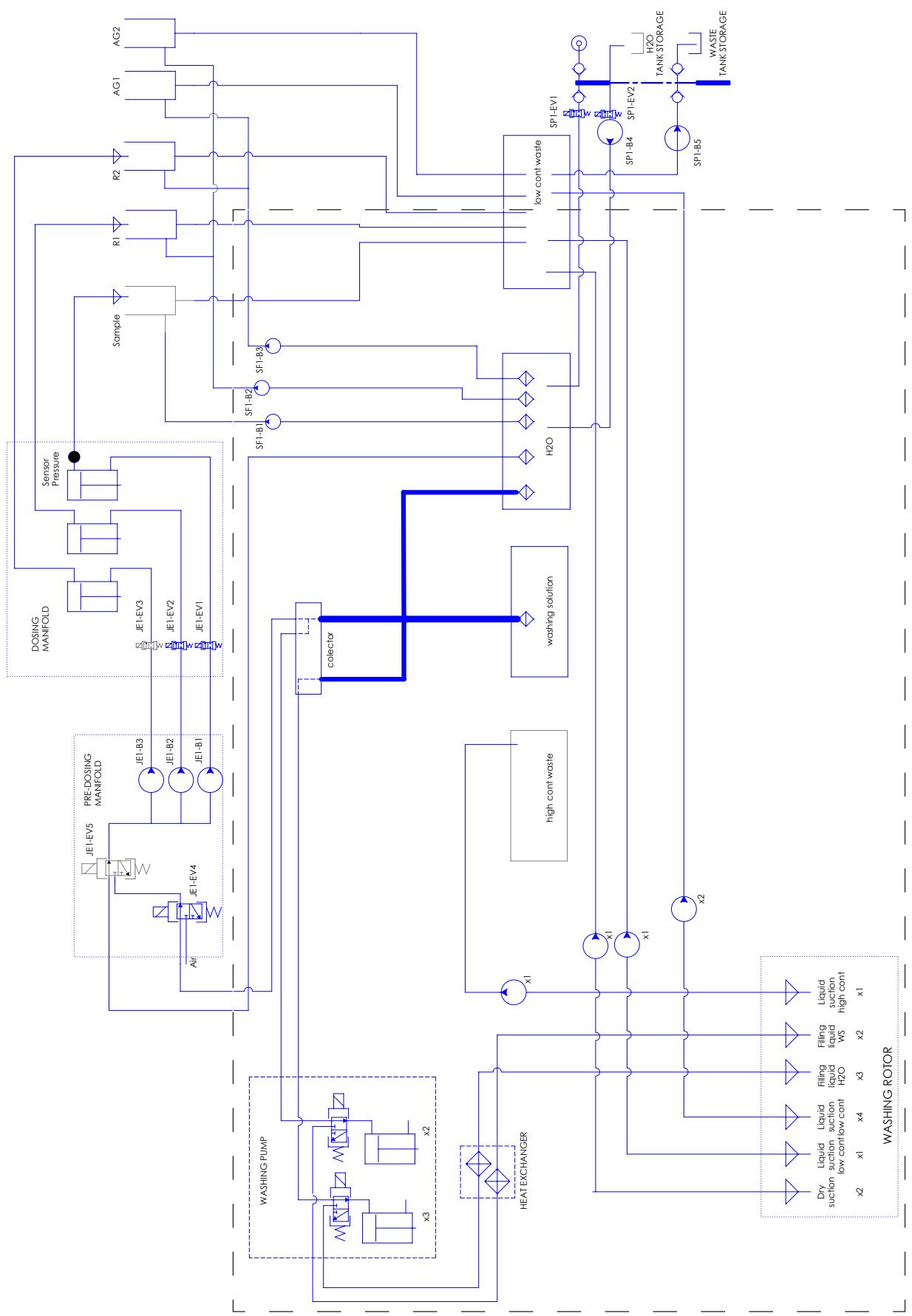


Figure 5.1 Fluidic diagram

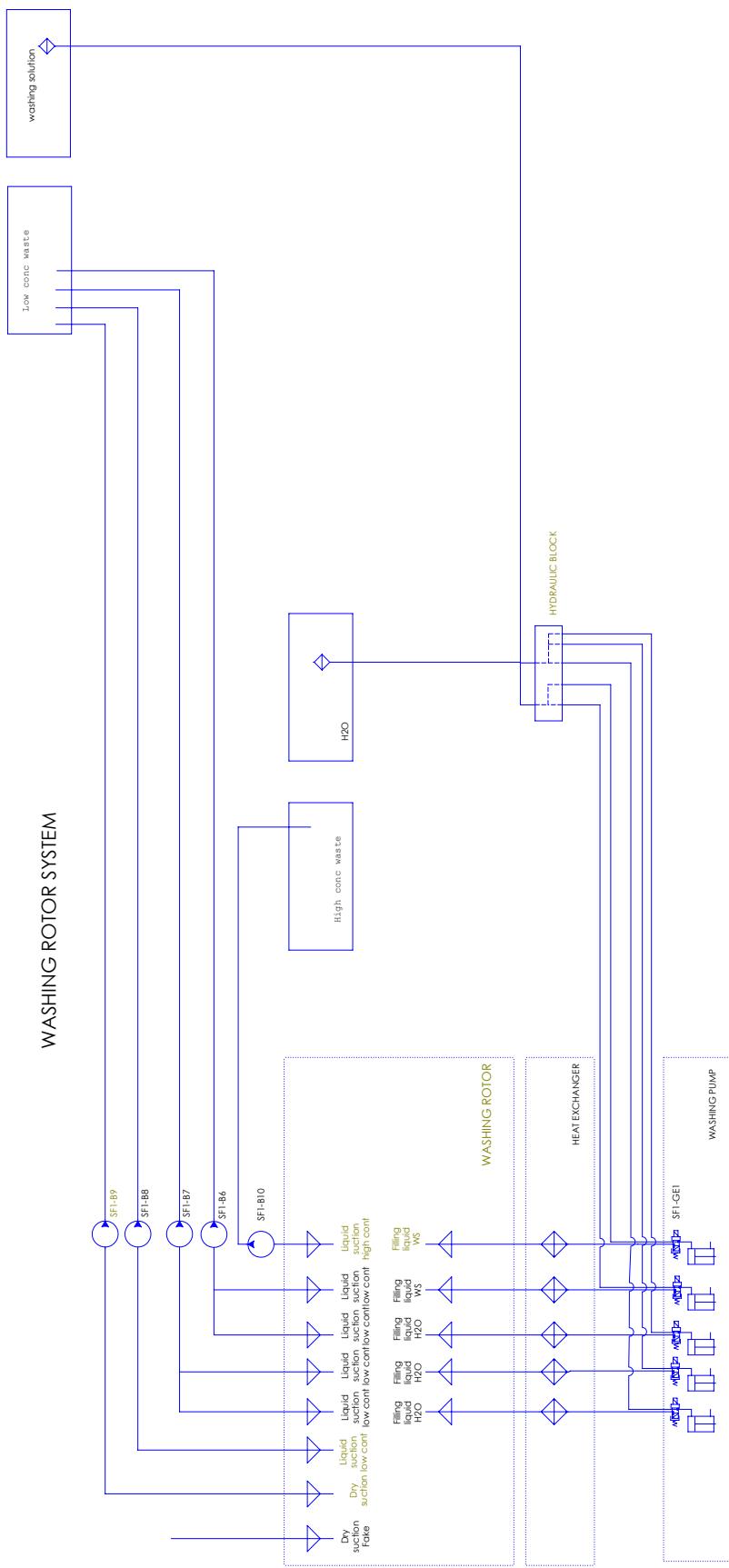


Figure 5.2 Enlarged view of the fluidic diagram

6. Service programme

The service programme enables the analyser to be adjusted and checked, and is also used to locate failures in the analyser.

6.1. Identification of the programme parts.

The programme screen has two parts which are common to all the menus. See Figure 6.1

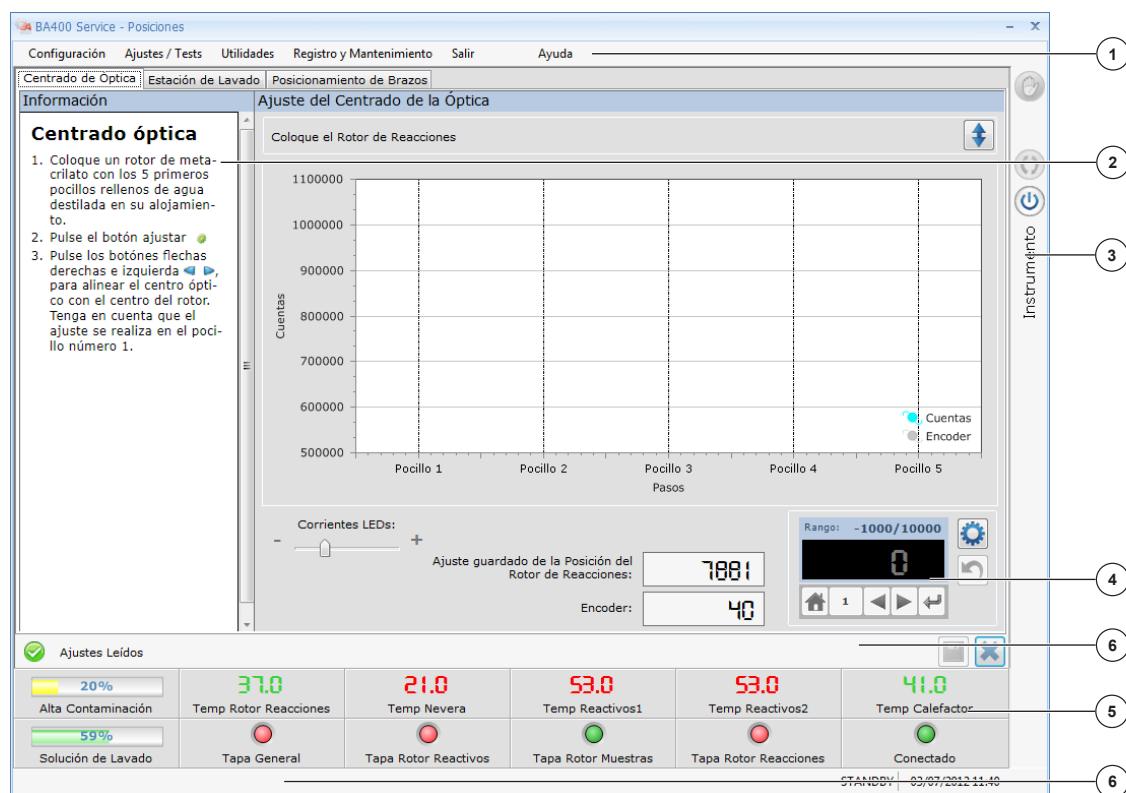


Figure 6.3 Screen format

Name	Description
Menu bar	This gives access to the programme menus.
Help panel	An incrusted help screen indicates the adjustment process for each type of adjustment on a step-by-step basis.
Lateral bar	Analyser operation icons.
Adjustment panel	Panel with different options for adjusting the positioning.
Status icons	Icons that permanently indicate the status of certain elements in the analyser.
Message line	Status line indicating messages for executing actions. The messages are shown in 2 locations.

6.1.1. List of common icons

The following chart shows the meanings of the common icons:

Icon	Name	Description
	Edit	Enables values to be edited.
	Delete	Eliminates an element.
	Adjustment	Initiates the adjustment process.
	Save	Saves the adjustment made
	Undo	Undoes and recovers the last adjustment.
	Close	Closes the window.
	Accept	Accepts the changes and closes the window.
	Print	Launches a print request.

6.1.2. Vertical bar icons list

The vertical bar icons list shows the icons that perform actions directly on the analyser. The following chart contains a description of each one.

Icon	Name	Description
	Stop	This icon is used to immediately stop an execution in course.
	Connect	This icon is used for connecting the programme with the analyser.
	Shut down	This icon is used to stop and shut down the analyser.

6.1.3. Explanation of the adjustment text box

The following text box is the same for the whole service programme.

It is used to position the mechanical elements of the analyser, such as the arms, rotors, etc



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Element	Name	Description
Range	Permitted range	Indicates the permitted range of the units displayed.
Steps	Units	Indicates the magnitude units. They are usually steps.
	Initial position	Moves the mechanical element to its initial position.
x1	Unit increments	Makes the increments one by one
x10	Increments by tens	Makes the increments by tens
x100	Increments by hundreds	Makes the increments by hundreds
	Left steps	Executes a mechanical movement to the left, one, ten or one hundred steps, depending on the above selection.
	Right steps	Executes a mechanical movement to the right, one, ten or one hundred steps, depending on the above selection.
	Upward steps	Executes a mechanical movement upward, one, ten or one hundred steps, depending on the above selection.
	Downward steps	Executes a mechanical movement downward, one, ten or one hundred steps, depending on the above selection.
	Accept value	Executes an absolute movement. A numerical value can be entered directly in the box and then the movement is excuted by pressing this button.

6.1.4. Description of the status icons

Information about the analyser appears constantly at the bottom of the screen. See Figure 6.2



Figure 6.4 Status icons

The following chart shows the meaning of each element:

Element	Description
High concentration bottle level	Indicates the high concentration waste bottle level
Reaction rotor temperature	Shows the reaction rotor temperature
Fridge temperature	Shows the fridge temperature
Reagent 1 temperature	Shows the temperature of the reagent 1 arm
Reagent 2 temperature	Shows the temperature of the reagent 2 arm
Wash station heater temperature	Shows the wash station heater temperature
New washing solution bottle	Indicates the washing solution bottle level
Main cover	Indicaets the status of the main cover of the analyser
Reagent cover	Indicates the status of the reagent cover

Element	Description
Sample cover	Indicates the status of the sample cover
Reaction cover	Indicates the status of the reaction cover
Connected	Indicates the status of the analyser connection with the programme

6.2. Programme initialisation

To start up the programme, double click on the icon located on the desktop:



or execute the programme from the following route:

Start/All Programmes/Biosystems/BA400 Service

When the programme is started a welcome screen is displayed and then the screen for identifying the user, as shown in Figure 6.3



Figure 6.5 Home screen

Enter the username and password to access the programme.

Field	Value
Username	SERVICE
Password	BA400

6.3. Description of the menus

The following chart shows the content of each programme menu

Menu Name	Description
Setup	It gives access to the different programme setup options <ul style="list-style-type: none"> • General • Language • Barcode • Users

Service Manual

Menu Name	Description
Adjustments/Test	Gives access to the different options for adjusting and checking the different analyser subassemblies <ul style="list-style-type: none">• Positioning• Photometry• Bottle level• Motors, valves and pumps• Thermostatting• Level detection• Barcode• ISE module• Clot sensor• Stress mode
Utilities	Gives access to the utilities assembly: <ul style="list-style-type: none">• Conditioning• Demo mode• Analyser information• Hardware versions• Updating of firmware
Recording and maintenance	Gives access to the report options <ul style="list-style-type: none">• Historical reports• TAS report• Preventive maintenance
Exit	Exit options <ul style="list-style-type: none">• With Shutdown• Without Shutdown
Help	Help options <ul style="list-style-type: none">• Manuals• About

6.4. Setup

6.4.1. Analyser

Enables the following options to be configured:

Selection of the water inlet: Select the water inlet mode for the analyser. The water may enter through two different channels which are mutually exclusive:

- Water tank
- Water mains

Deactivate buzzer: Check this option if you do not want the buzzer to sound when an alarm is indicated.

Deactivate other elements: Allows you to deactivate or activate the following elements separately. These values are stored in the analyser memory and applied when the user programme is executed.

- General cover of the analyser
- Reaction rotor cover
- Sample rotor cover

- Reagent rotor cover
- Clot sensor

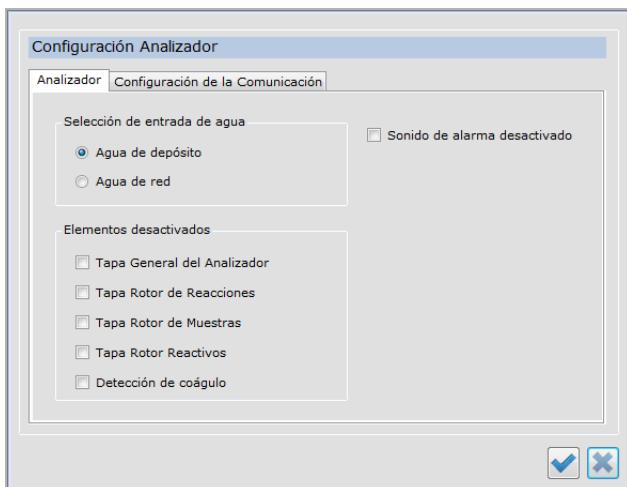


Figure 6.6 Analyser setup screen

6.4.2. Communications

Enables the configuration of the communication channel between the service programme and the analyser. Select one of the following options:

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.

Type of connection: In the manual mode, select the type of connection you want

- RS-232 — you should normally select the COM1 port
- USB — you should normally select the USB1 port

Press the button to ensure that the communications are functioning properly.

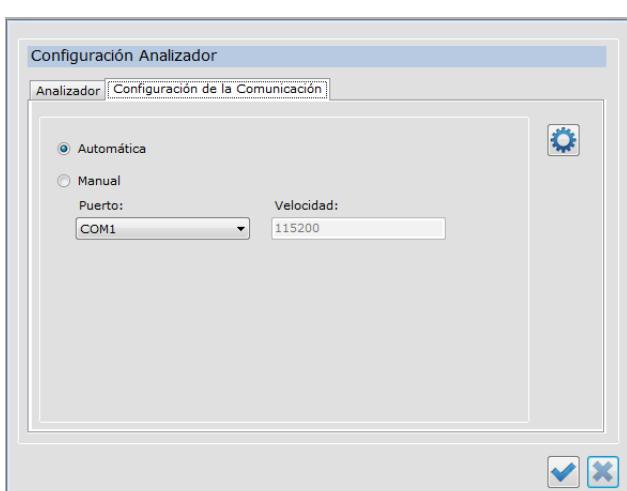


Figure 6.7 Communication setup screen

6.4.3. Language

This allows you to change the application language. There are two languages: Spanish and English.

6.4.4. Barcode

This enables the barcode readers to be activated/deactivated and the barcode options to be configured.

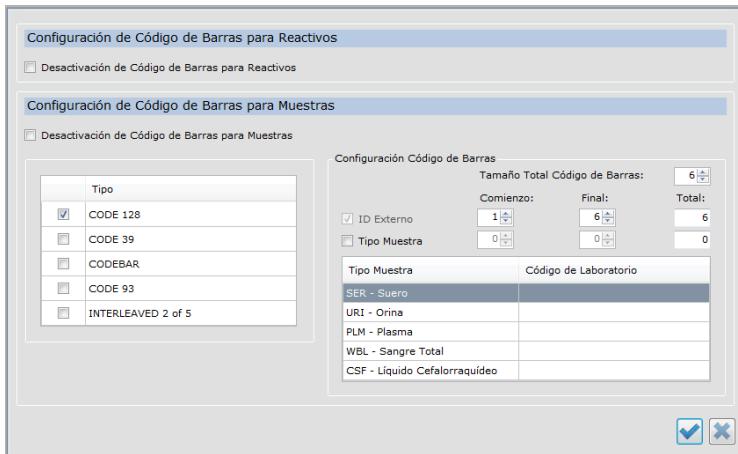


Figure 6.8 Barcode reader setup screen

- Deactivation of barcode for reagents:** Check this option to deactivate the barcode reader of the reagent rotor.
- Deactivation of barcode for samples:** Check this option to deactivate the barcode reader of the sample rotor.
- Type:** Select the barcode type used for printing the labels on the sample tubes.
- Total barcode size:** Set the total size of the barcode for the sample reader. The reader will only read the codes of the indicated size, otherwise, it will mark the reading as a code error.
- External ID:** If the barcode has more information than the patient identifier, select the start and end of the patient identifier.
- Sample Type:** If the code has the sample type information, select the sample type option, start and end inside the code and how the laboratory encodes each sample type.

6.4.5. Users

Figure 6.7 shows the screen for creating and maintaining users.

Click on the icon again 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.
- Name:** Enter the name of the user.
- Surname:** Enter the surname of the user.
- Password:** Enter a password.
- Confirm password:** Enter the same password again to ensure it was entered correctly.

Press save to save the user name or undo to rule out a user or changes.

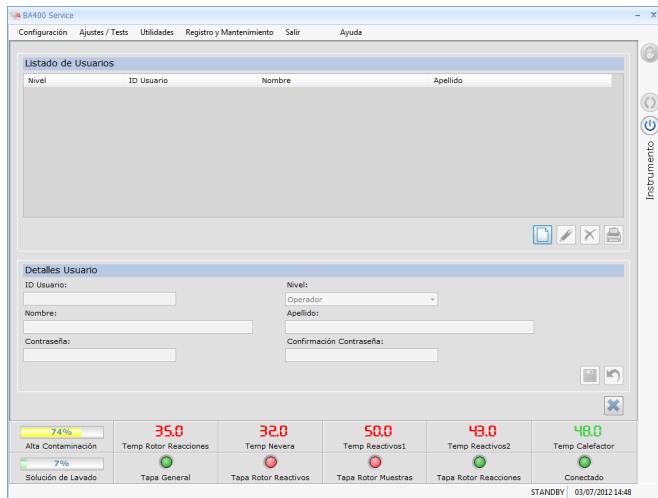


Figure 6.9 User creation screen.

6.5. Adjustments/Test

6.5.1. Adjust positioning

This menu is used to access the screens for adjusting the positions of the different mechanical elements of the analyser, such as arms, rotors, etc

To adjust some elements, a mechanical adjustment must be made as well as an adjustment in the service programme.

6.5.1.1. Optical centring adjustment

This adjustment is used to centre each well in the reading rotor with respect to the optical system light beam. The firing point used to make the reading is also adjusted with respect to the centering of the rotor.

The screen displays the reading profile of 5 wells. The *adjustment box* is used to position the vertical lines in the centre of the wells. To do this, move the rotor step by step until the reading tip is in the centre of the wells.

If a reading is saturated or has insufficient light, move the sliding led current device to increase or decrease the luminous intensity of the reading led.

1. Press the adjustment *start* button. The programme will make the optical reading of 5 wells in the rotor.
2. Step by step, move the encoder firing point with the *adjustment box* until the indicator line (4) is correctly centred with respect to the well.
3. Save this position.
4. Bear in mind that if this value is changed, all the other mechanical elements will have to be adjusted.



1 – Encoder steps
2 – Encoder reading

3 – Rotor optical reading
4 – Encoder firing adjustment

Figure 6.10 Wash station adjustment screen.

6.5.1.2. Wash station adjustment

This function is used to adjust the height of the wash station. The wash station centring must be manually adjusted beforehand.

Manual adjustment of the wash station positioning:

The manual adjustment process has two separate movements; vertical and horizontal. Each one is set using different screws.

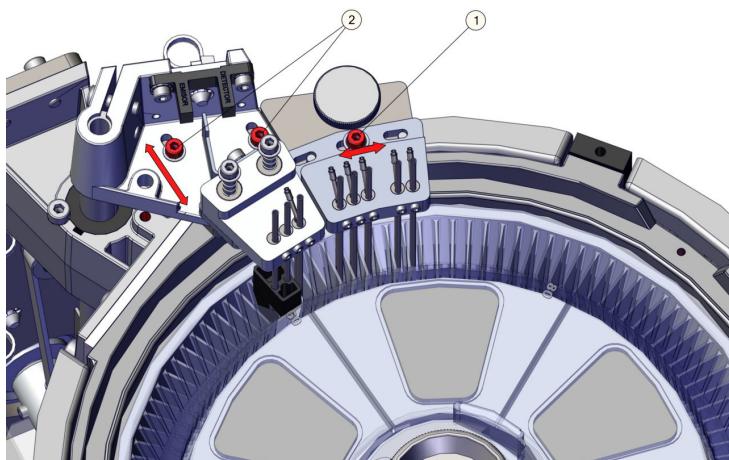


Figure 6.11 Wash station adjustment

1. Loosen the screw (1) anchoring the wash station in the vertical direction.
2. Move the wash station head until the tips are not touching the sides of the rotor.
3. Tighten the screw (1).
4. Loosen the screw (2) anchoring the wash station in the horizontal direction.

5. Move the wash station head until the tips of the station are properly centred with the rotor.
6. Tighten the screws (2).

After making the mechanical adjustment, adjust the height of the wash station with the service programme.

See Figure 6.10.

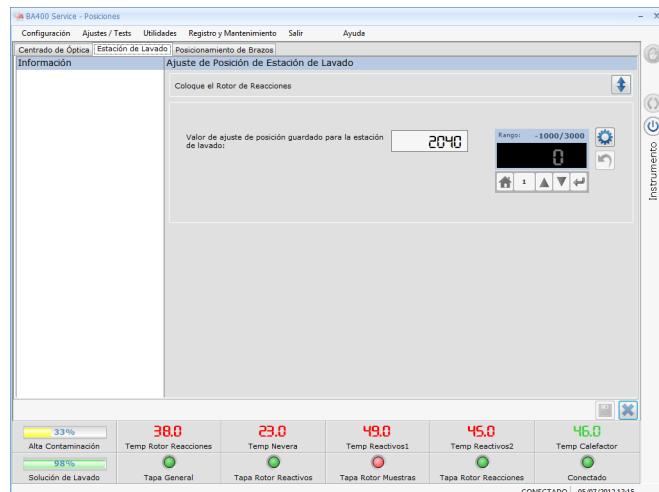


Figure 6.12 Wash station position adjustment screen

1. Press the adjustment *start* button.
2. Move the vertical positioning of the wash station using the *adjustment box*.
3. Step by step, move the wash station to lower the station tips until the tip of the dryer touches the rotor and the spring is lightly pressed (about 0.5 mm).
4. Save the positioning value.

6.5.1.3. Adjusting the arm positioning

In this screen (Figure 6.11) you can adjust the vertical positioning, height and positioning in the rotor of all five arms: sample, reagent 1, reagent 2 and stirring arms 1 and 2.

The screen shows a tab for each type of arm (1).

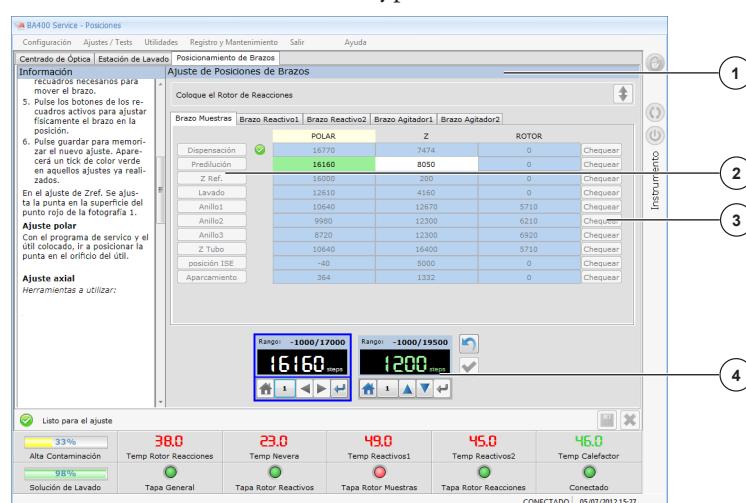


Figure 6.13 Screen for adjusting the arm positioning

Each tab contains a table with the positions that can be adjusted for each arm (2).

Depending on each position, the necessary *adjustment boxes* (4) will be activated for moving the selected element step by step.

With respect to the 3 possible values to be changed in each position: vertical, Z and rotor, not all can be memorised as adjustments. Some can be changed to facilitate the adjustment, but not memorised. The top of the table is marked in yellow, to indicate which parameters are adjustments and are memorised.

After making and saving the adjustments, an OK tick will appear at the side of the element and then the next element is automatically accessed.

It is also possible to verify the positioning of each mechanical element in this screen. To do this, press the *Checkbutton* (3). The selected element will be moved to the adjusted position.

Then the different positions that can be adjusted, depending on the arm, are displayed.

Sample arm	
Adjustment position	Description
Dispensation	Adjustment of the dispensation point in the reagent rotor
Predilution	Adjustment of the dispensation point in the reagent rotor predilution well
Z Ref.	Adjustment of the reference position for lowering the tip in the reaction rotor. To facilitate the adjustment, the reference is the rotor surface.  See Figure 6.12
Washing	Adjusting the position of the tip in the wash station.
Ring 1	Adjusting the position of the arm in ring 1 of the sample rotor. The vertical angle of the arm, arm depth and rotor angle are adjusted. The depth is adjusted for each sample well.
Ring 2	Adjusting the position of the arm in ring 2 of the sample rotor. The vertical angle of the arm, arm depth and rotor angle are adjusted. The depth is adjusted for each sample well.
Ring 3	Adjusting the position of the arm in ring 3 of the sample rotor. The vertical angle of the arm, arm depth and rotor angle are adjusted. The depth is adjusted for each sample well.
Z tube	Adjusting the depth of the tubes. This adjustment is used for the 3 rotor rings.
ISE position	Adjusting of the dispensation tip when the sample enters the ISE module.
Parking	Adjustment of the arm parking positioning.

Reagent 1 and 2 arms	
Adjustment position	Description
Dispensation	Adjustment of the dispensation point in the reagent rotor
Z Ref.	Adjustment of the reference position for lowering the tip in the reaction rotor. To facilitate the adjustment, the reference is the rotor surface.  See Figure 6.12
Washing	Adjusting the position of the tip in the wash station.
Ring 1	Adjusting the position of the arm in ring 1 of the reagent rotor. The vertical angle of the arm, arm depth and rotor angle are adjusted.
Ring 2	Adjusting the position of the arm in ring 2 of the reagent rotor. The vertical angle of the arm, arm depth and rotor angle are adjusted.
Parking	Adjustment of the arm parking positioning.

Reagent 1 and 2 arms

Adjustment position	Description
Dispensation	Adjustment of the stirring point in the reaction rotor
Z Ref.	Adjustment of the reference position for lowering the tip in the reaction rotor. To facilitate the adjustment, the reference is the rotor surface.  See Figure 6.12
Washing	Adjusting the position of the stirrer in the wash station.
Parking	Adjustment of the arm parking positioning.

 Icon appearing when stirring arms 1 and 2 are selected. When it is pressed the stirring rotation is activated and deactivated. In this way, it can be verified whether the stirrer is touching the rotor while in operation.

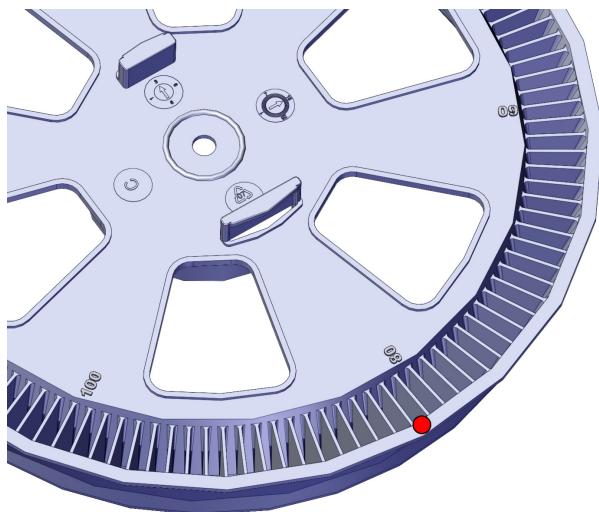


Figure 6.14 Z ref. adjustment point

6.5.2. Photometry

This menu is used to verify the led currents and for photometric verifications. The currents are adjusted every time a baseline is performed

6.5.2.1. Baseline and darkness current

This screen is used to adjust the currents for each led. See Figure 6.13.

To make the adjustment, a well must be filled with distilled water. The well can be filled automatically by the analyser or manually by the user.

1. To do this, select the desired option (1) and choose the number of the well to be filled.
2. Press the icon for raising or lowering the wash station in order to remove or insert a rotor.
3. Press the *adjust* button to start the current adjustment process for each led. This is an automatic process that changes the led current, using both photodiodes (main and reference) to make the reading. The objective is to ensure that the number of counts of the photodiode with the most light succeed is close to 900,000 without the other photodiode becoming saturated.
4. After making the automatic adjustment, the results are displayed. The required currents for each wavelength are shown in the position (2) on the screen. All values outside the pre-established ranges will be marked with a warning symbol.



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5. A bar chart is shown in position (3) of the screen with the numerical values of the results for the number of counts obtained for the main photodiode and the reference photodiode.

- !**
6. All values outside the pre-established ranges will be marked with a warning symbol.
 7. The darkness current values for the main and reference photodiodes are shown in position (4) of the screen. The darkness current is the current ready by the photodiode when there is no light.

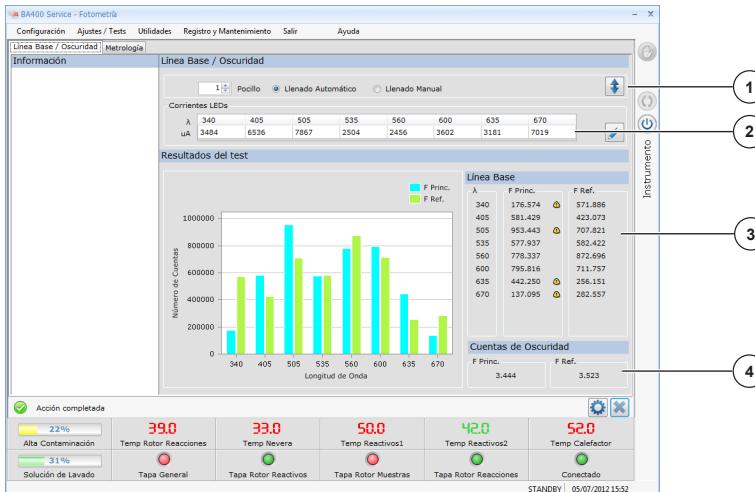


Figure 6.15 Current adjustment screen

8. Press the *edit* button to access the screen for memorising the reference currents. See Figure 6.14.
9. The reference currents are current values memorised initially and they are used for comparison with the values obtained in each baseline. This way, the changes in luminous intensity for each led can be determined. This comparison process is automatic and the user is only warned if the compared values are widely diverging.
10. Due to the long life of the leds and the “Hard Coating” filters, a warning is given only in the event of a failure. If a led or filter is damaged.
11. In the event of a failure, meaning that a filter or led must be replaced, the technician must memorise the reference current again.
12. Select the wavelength on which the operation was performed and press *save*.

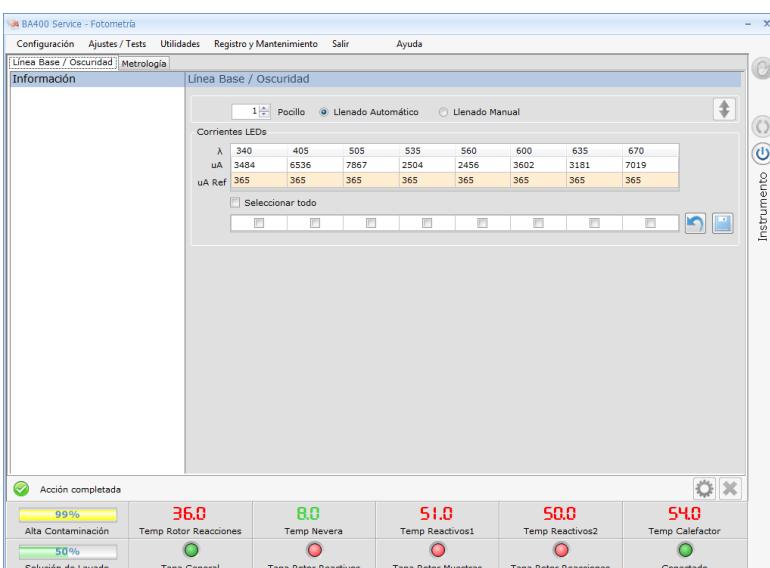


Figure 6.16 Screen for memorising the reference currents.

6.5.2.2. Metrology

This option is used to check the analyser photometry status. See Figure 6.15.

The following checks can be made:

- Repeatability of the readings.
- Stability of the readings.
- Absorbance reading.

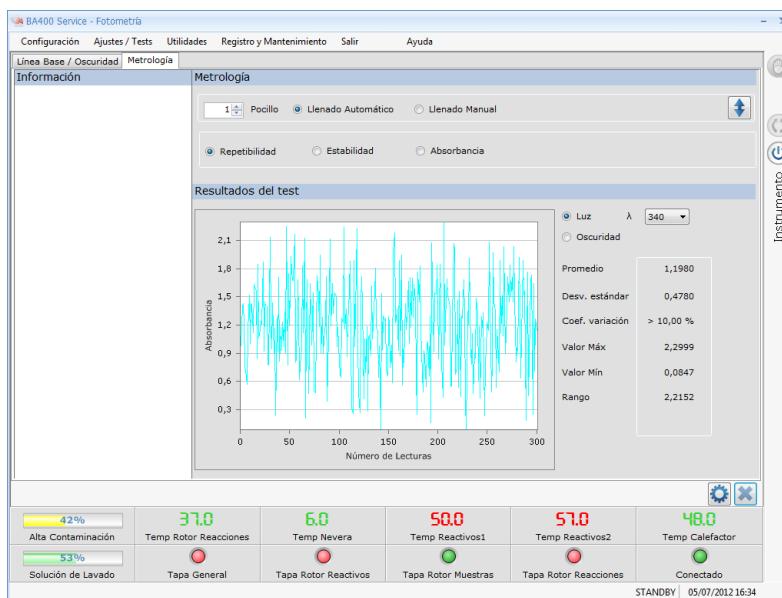


Figure 6.17 Photometric verification screen.

To make a verification the rotor must be filled with distilled water. This can be performed by the analyser or the user can do it manually.

1. Select the rotor filling mode and the well where the readings will be made
2. Press the icon for raising or lowering the wash station in order to remove or insert a rotor.
3. If you want to measure the absorbance of a specific reagent or fluid, select the manuall filling option. Dispense the fluid to be measured into a well. In the screen, select the well where the fluid was dispensed.
4. Select the type of measurement to be made.
5. Press the *adjustment* button to start the measuring process.

Repeatability

This verification takes measurements in all the wavelengths for 3 minutes. It is used to verify the repeatability of the photometric system readings

After taking the measurements it shows the following parameters for each wavelength:

- Mean
- Standard deviation of all measurements
- Coefficient of variation (CV)
- Maximim absorbance
- Minimum absorbance

See chapter AIII ranges accepted for parameters.

Stability

This verification takes measurements in all the wavelengths for 30 minutes. It is used to verify the stability of the photometric readings.

After taking the measurements it shows the following parameters for each wavelength:

- Mean
- Standard deviation of all measurements
- Coefficient of variation
- Maximum absorbance
- Minimum absorbance

Absorbance reading

This allows you to measure the absorbance of a selected well.

6.5.3. Scales, bottles and tanks

6.5.3.1. Scale adjustment for determining level.

The levels of the washing solution and high contamination waste bottles are determined by weighing. To adjust the scales, proceed as follows:

Washing solution bottle adjustment

1. Put the full washing solution bottle in place.
2. Press the FULL adjustment button.
3. Put the empty washing solution bottle in place.
4. Press the EMPTY adjustment button.
5. Save the results

High contamination waste bottle adjustment

1. Put the full waste bottle in position.
2. Press the FULL adjustment button.
3. Put the empty waste bottle in position.
4. Press the EMPTY adjustment button.
5. Save the results

Final verification of the washing solution and high contamination waste bottle levels

To verify whether the bottle level adjustment is correct, place a known level of fluid in the washing solution or waste bottle and check that the value shown on the screen (see Figure 6.16) inside the bottles matches the real bottle level.

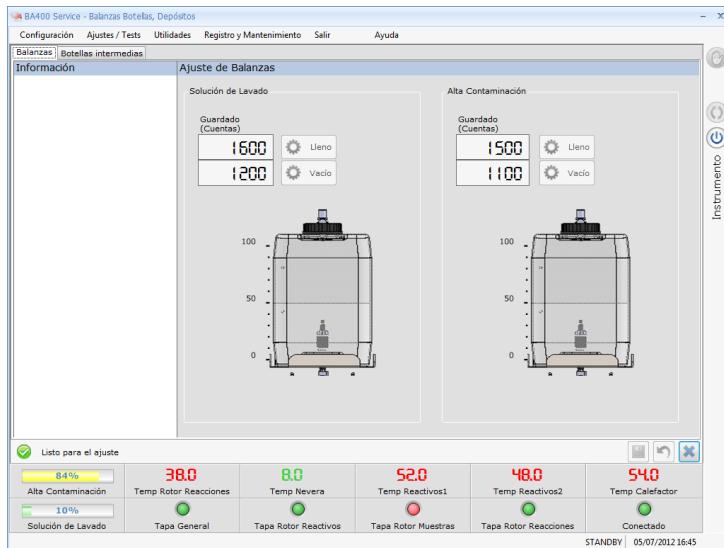


Figure 6.18 Scales adjustment screen

6.5.3.2. Internal bottle verification

Detecting the level of the internal bottles containing distilled water and low contamination waste is done through a buoy system. This means that only the analyser can detect whether a bottle is full or empty.

The programme enables the status of the buoys to be checked and indicates whether they are full or empty.

The status of the buoys for each bottle is shown on the screen (see Figure 6.17). The verification may be made manually or automatically.

Manual verification

Access the buoys of the internal bottles. To do this, access the internal bottles through the rear part of the analyser and unscrew their caps.

Move each buoy upward and downward. The status of each buoy will be constantly shown on the screen.

Automatic verification

Press the Start button for the programme to perform a full filling and emptying cycle on each bottle. The programme will constantly indicate the status of the buoys.

Bear in mind that this automatic verification process may take a few minutes.

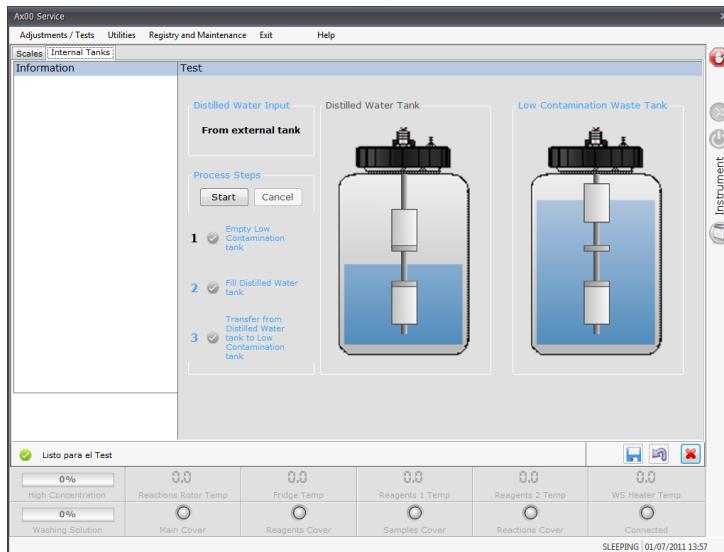


Figure 6.19 Screen for checking the internal bottles.

6.5.4. Verification of the dispensation pumps, pumps and valves.

This screen is used to verify the fluidic status of the analyser. The entire fluidic circuit is divided up into functional parts. Each part can be checked with the same buttons.

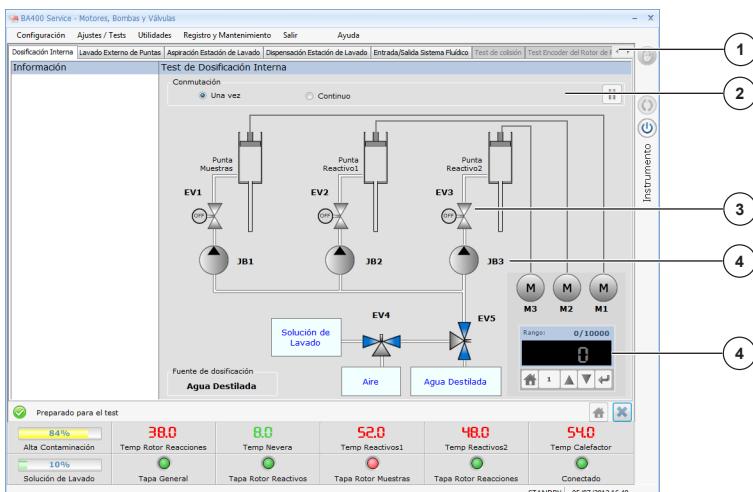


Figure 6.20 Screen for checking the pumps and electro valves

1. Select one of the circuits to be checked (1):
 - Internal dosing circuit
 - External washing circuit
 - Wash station aspiration
 - Wash station dispensation
 - Fluid input/output
2. Select whether you want to perform one cycle or continuous cycles (2)
3. Press the electro valve you want to activate. It will change from grey to green, indicating it is active (3).
4. Press the pump you want to operate, it will change from grey to green (4)
5. Enter the number of steps you want the dispensation pumps to perform in the *adjustment box*.

6. Check in the analyser that the fluids enter and leave, depending on the electro valves and pumps that are activated.
7. On exiting the test, all the electro valves and pumps that are active will be deactivated.
8. In circuits in which a pump and an electro valve are next to each other, when the pump is activated the electro valve will always be activated and when the electro valve is deactivated, the pump will be deactivated.

6.5.5. Adjusting the thermostatting systems

Screen for adjusting the thermostatting of the reaction rotor, the reagent tip assembly and for thermostatting the wash station.

6.5.5.1. Wash station thermostatting adjustment

The distilled water or washing solution dispensed by the wash station are thermostatted beforehand, to prevent interference with the rotor temperature. The thermostatting adjustment is made in this screen.

See Figure 6.19

Follow the steps to execute the adjustment process:

1. Press the adjustment button of section 1 to execute a fluidic conditioning of the system.
2. Remove the rear cover and place the thermometer sensor in the heater measuring point
 See Figure 6.20
3. Enter the value of the temperature measured with the thermometer in the box of section 2.
4. Press the adjustment button of section 3 to change the regulation system password if the value measured is out of the ranges.
 Consult chapter AIII to see the ranges accepted in making the wash station heater adjustment.
5. Save the adjustment value.

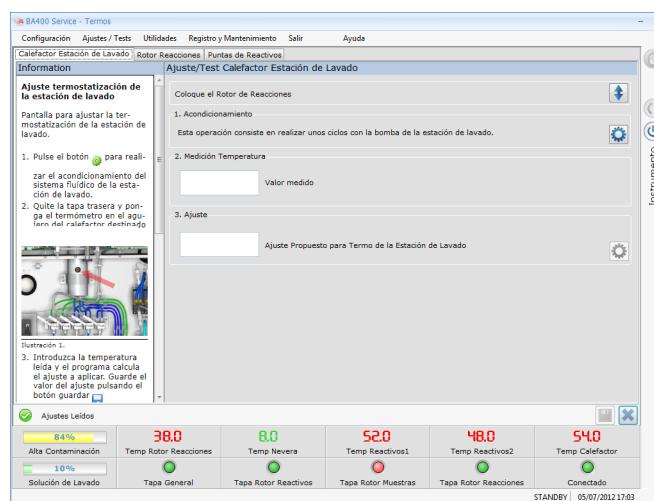


Figure 6.21 Wash station thermostatting adjustment screen

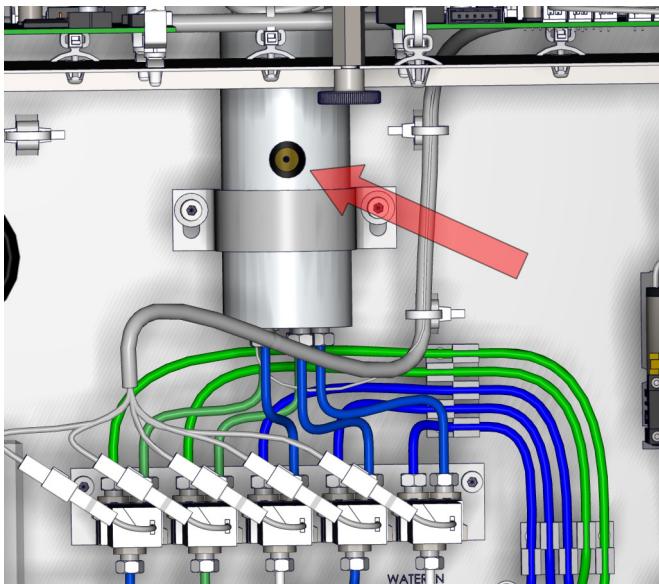


Figure 6.22 Point for measuring the wash station heater temperature

6.5.5.2. Adjusting the reaction rotor thermostatting

To perform the sample and reagent reactions correctly, the reaction rotor must be at a stable temperature. The reaction rotor thermostatting adjustment is made in this screen.

☞ See Figure 6.21

Follow the steps to execute the adjustment process:

1. Press the adjustment button of section 1 to execute a fluidic conditioning of the system. This conditioning operation takes about 5 minutes. The rotor can be filled automatically or manually.
2. Place the thermometer sensor in each of the 4 reaction rotor measuring points.
☞ Consult Figure 6.22 to see the measuring points.
3. Enter the vale of the temperature measured with the thermometer at each point in each of the boxes of section 2.
4. Press the adjustment button of section 3 to change the regulation system password if the value measured is out of the ranges.
☞ Consult AIII to see the accepted ranges in adjusting the reaction rotor.
5. Save the adjustment value.

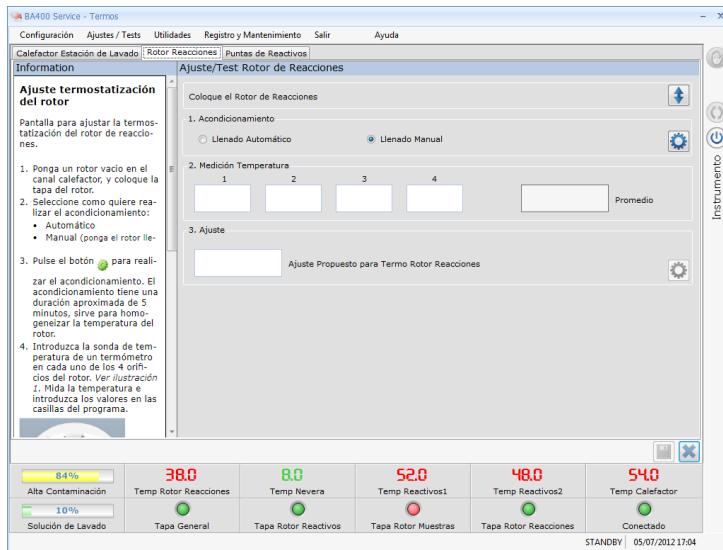


Figure 6.23 Rotor thermostating adjustment screen

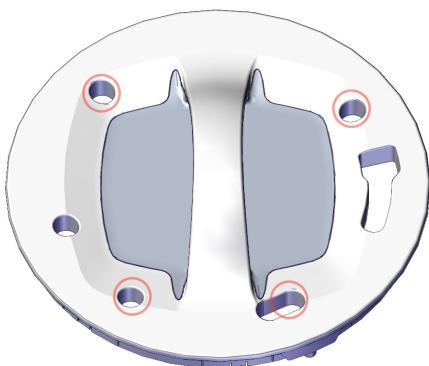


Figure 6.24 Reaction rotor measuring points

6.5.5.3. Adjusting the tip thermostating

Reagent tips R1 and R2 suction the reagents from the fridge. Before dispensing the reagent in the rotor, it is thermostatted to a temperature that is closer to that of the rotor. The thermostating of each arm is adjusted in this screen.

☞ See Figure 6.23

Follow the steps to execute the adjustment process:

1. Select the arm in which the adjustment is to be made.
2. Press the adjustment button of section 2 to execute a fluidic conditioning of the tip.
3. Place the temperature measuring tool and thermometer sensor in the tip wash station.
4. Press the adjustment button of section 3 for the analyser to dispense a volume of water in the wash station.
5. Enter the value of the temperature measured in the box of section 3. Perform several dispensation cycles to verify that the temperature is stable.
6. Press the adjustment button of section 4 to change the regulation system password if the value measured is out of the ranges.

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☞ Consult AIII to see the accepted ranges in adjusting the tip thermostatting.

7. Save the adjustment value.

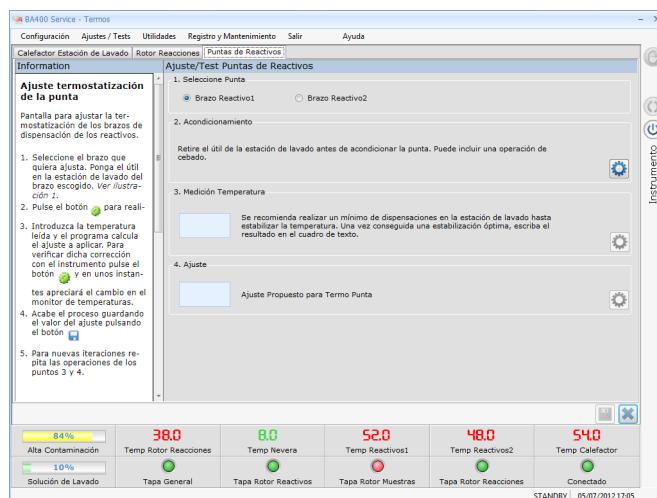


Figure 6.25 Screen for adjusting the tip thermostatting

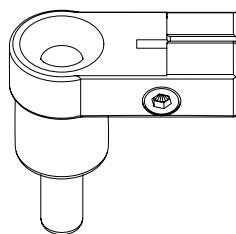


Figure 6.26 Tool for adjusting the tip thermostatting

6.5.6. Barcode reader adjustment

This screen allows you to adjust the positioning of the barcode reader.

☞ See Figure 6.25

1. First select the barcode reader you want to adjust.
2. Remove the cover and place a tube or well with a barcode in position 1 of the rotor, to obtain the reference of the beam to be adjusted.
3. Move the rotor step by step with the *adjustment box* until the reader beam is properly centred on the barcode.
4. Save the adjusted value.
5. Check in section 3 that the reader receives the readings correctly. The indicated value must be higher than 95%.
6. To perform the barcode reader test, place several tubes or bottles in the chosen reader rotor and press the test button of section 4. The table will show the codes of the bars read and the positions in which the tubes/bottles were placed.

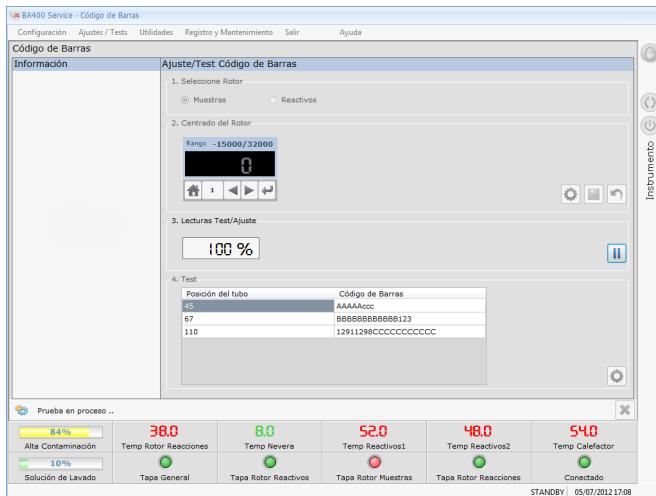


Figure 6.27 Barcode reader adjustment screen

6.5.7. ISE module

This menu is used to launch the different maintenance actions required for the ISE module.

The following functions can be executed:

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

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

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



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

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

Action	Description
Maintenance	Empties the tubes. Only activates the waste pump. In the repetitions parameter indicate how many times the action must be executed.
Bleed A	Performs a priming cycle with calibration standard A using a volume of 100 µL. In the repetitions parameter indicate how many times the action must be executed.
Bleed B	Performs a priming cycle with calibration standard B using a volume of 100 µL. In the repetitions parameter indicate how many times the action must be executed.

Action	Description
Priming A	Performs a priming cycle with calibration standard A using a volume of 300 µL. In the repetitions parameter indicate how many times the action must be executed.
Priming B	Performs a priming cycle with calibration standard B using a volume of 300 µL. In the repetitions parameter indicate how many times the action must be executed.
Wash	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.
Activate the reagent kit	Execute this action to activate and memorise the reagent kit in the programme. It is also used to memorise the installation date and record the consumption of the calibration standards. The programme issues a warning when the standards 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.

6.5.8. Stress

The stress verification test simulates the normal operating cycle of the analyser. However, instead of pipetting serum and reagent, the analyser moves the arms and pumps, but without pipetting any fluids.

The stress can be configured as global stress, i.e., performing a complete cycle or partial stress of functional parts of the analyser.

Partial stress options:

- Arms (selected separately)
- Rotors (selected separately)
- Photometry
- Syringes
- Fluids

Steps for programming stress

1. Select the stress duration by number of cycles.
2. Select whether you want the global or partial stress option.
3. Press the adjustment button to start the stress test
4. While the stress test is being executed, a status bar will appear indicating the stress duration.
5. Once the stress test has finished, the following information is displayed in the results section:
 - a) Type of stress
 - b) Total number of cycles and total stress duration time

- c) Number of cycles completed
- d) Number of restarts and cycle in which the restart was executed. This serves to verify whether a power cut occurred in the stress with very long durations.
- e) Number of errors and description of the error. After a certain number of cycles the analyser performs an internal check to detect whether there are any problems in its operation. For instance, it counts the number of steps in each motor to check that no step has been lost. If any problem is detected, this is shown in the error box.

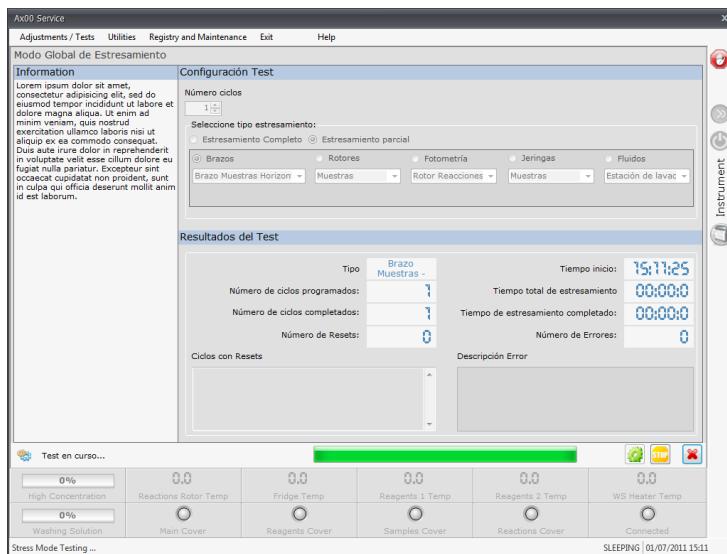


Figure 6.28 Stress screen

6.6. Utilities

6.6.1. Demo mode

Enables the analyser to be put in demo mode. This mode performs the basic pipetting and dispensation cycle, which entails a movement of the arms and rotors but no processing of fluids or photometric readings.

Press the adjustment button to start the demo mode

The analyser will continue performing the demo mode until the stop button is pressed.

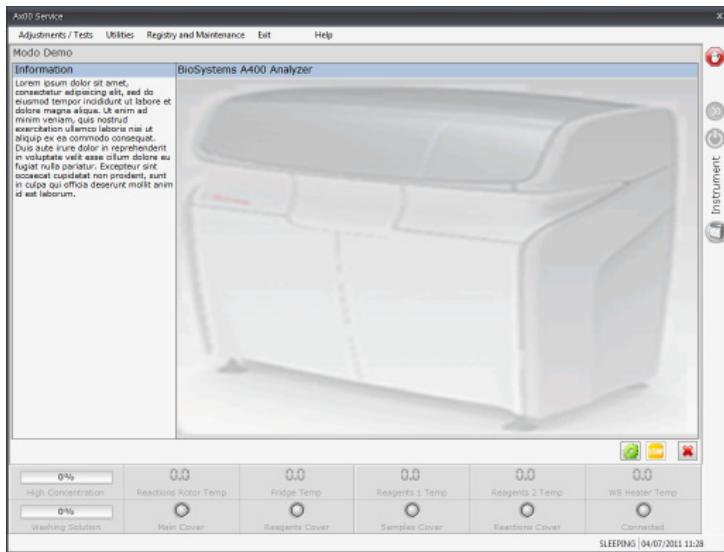


Figure 6.29 Demo mode screen

6.6.2. Analyser information

This screen allows you to input or change the analyser serial number.

Press the edit button to change the serial number.

It also performs the same verification process as the one performed by the analyser when being initialised.

Press the “*show details*” button to see the different steps executed in the verification process.

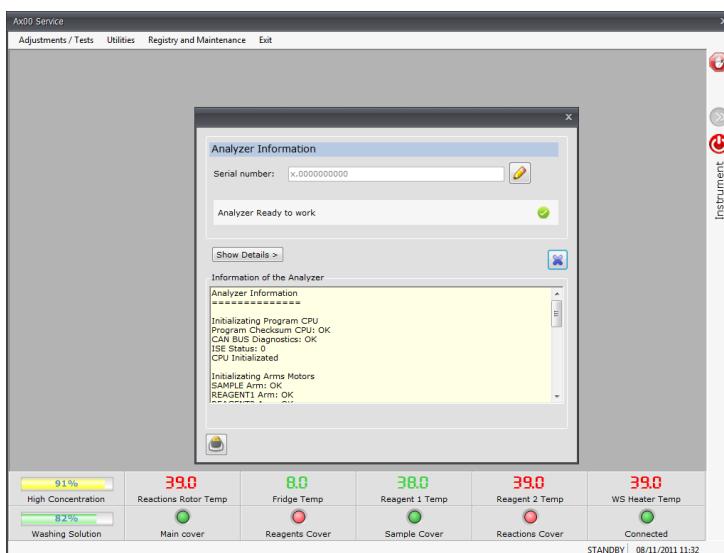


Figure 6.30 Analyser information screen

6.7. Recording and maintenance

6.7.1. Historical reports

This screen is used to consult all the actions performed with the service programme.

All the actions performed are memorised in a database. To consult the actions, select the filter fields and press search.

Filter	Description
Analyser serial number	Enter the serial number of the analyser for which the actions are to be consulted
Date	Enter the date range through which you want to filter the actions
Tasks	Select one of the possible tasks: All, Adjustments, test or utilities
Actions	A list of actions will appear, depending on the chosen task. In the event that many actions have been performed, it is used to view only the chosen action.

After selecting the filter fields, the programme displays a table with the filtered information.

The user can enter text in the comments column to make a remark about the selection action. Click the inside of the comments box to enter the text. When you have finished, press the save or undo button.

If you want to delete a historical action, select the action and press the delete button.

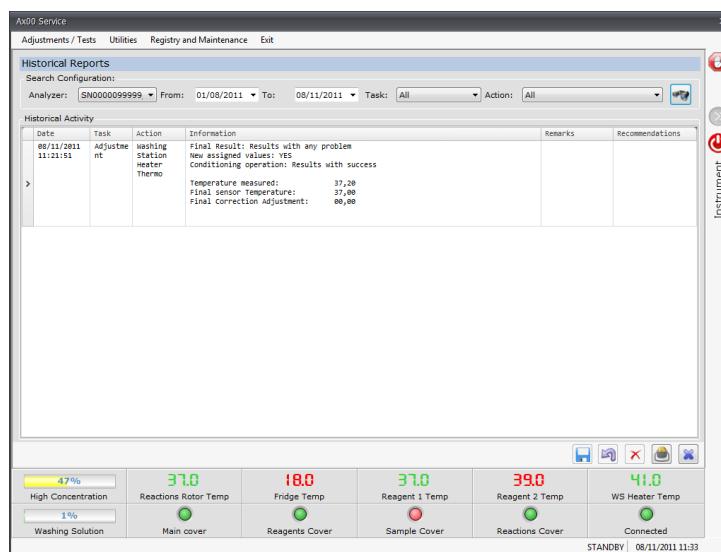


Figure 6.31 Historical information screen

6.7.2. TAS report

This screen allows you to write a report for the technical service.

Press the “save TASreport” button and a copy of the historical action database will be made automatically.

The file generated is located in the following folder:

c:\Program Files (x86)\BA400\BA400 Service\SATReports\

It also allows you to delete old TAS Reports.

6.8. Exit

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

- **Exit by switching 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.

7. Maintenance and cleaning

7.1. Cleaning

Material and tools needed to clean the appliance:

- Dry air aerosol container or air blower
- T20 torx key with a minimum length of 40 mm

7.1.1. Cleaning the interior compartments

Every time an operation is performed with the analyser, it is advisable to clean the electronic and fluidic compartments.

1. Remove the side housings
2. Remove the side panels
3. Blow the dust from the electronic boards, components and fans with dry air.

7.1.2. Checking the fluidic connections

Check that all the fluidic connections and connections to the electro valves and pumps have no leaks.

1. Remove the side housings
2. Remove the side panels
3. Touch each connection with your hand to verify that the joints are not leaking.
4. Use the service programme to open and close the electro valves and activate the pumps. Ensure there are no fluid leaks in each element when in both states.

7.1.3. Cleaning the water and low contamination waste containers

1. Remove the rear cover.
2. Remove the clamps securing the distilled water and low contamination waste bottles.
3. Empty the fluid system using the service programme.
4. Unscrew each bottle.
5. Wash the distilled water and low contamination waste containers with neutral soap and water
6. Check and replace the water inlet filters in each container.

7.1.4. Washing the outside of the tips

Wear gloves and protective clothing when handling the tips.

With the analyser off, lift the 3 tips, 2 stirrers and wash station manually.

Take care when lifting the tips.

1. Clean each tip, stirrer and the wash station tips with a cloth soaked in washing solution.
2. Repeat the process with 70 alcohol
3. Start up the analyser with the service programme and wash the tips using the washing utility.

4. Check that the wash station dryer is correctly secured and in good condition. If it is damaged, replace it with a new one.

7.1.5. Cleaning the barcode reader window

Wash the inside and outside of the barcode reader window.

1. Remove the top panel of the analyser
2. Use a damp cloth to clean the inside of the two barcode reader windows.
3. Remove the two rotors from their compartments.
4. Clean the outside of the two barcode reader windows with a damp cloth.

7.1.6. Wash the heating canal and the canal of the rotor containers

Use a damp cloth and neutral soap.

1. With the analyser switched off, lift the wash station manually.
2. Remove the covers from the 3 rotors.
3. Remove the PMMA rotor and the sample and reagent rotors.
4. Wipe the surface of the heating canal and the inside of the rotor vessel with a cloth.
5. Check that the drains are not blocked. To do this, run some water through the opening and check that the water disappears down the drain.

7.2. Maintenance

All maintenance work will be performed every 2 years or when an operation has been performed by the technical service.

Material and tools needed to perform maintenance on the appliance:

- T20 torx key with a minimum length of 40 mm
- Set of Allen keys
- SAE-40 or any equivalent lubricant

7.2.1. Checking of the wash station piston pump

1. Remove the housing on the right side
2. Remove the panel on the right side
3. Touch the fluidic connections of the 5 PMMA chambers and ensure there are no leaks.
4. Apply 2 drops of SAE40 lubricant to the linear bearings of the pump.

7.2.2. Checking of the reagent and sample arms, stirrers and wash station

Check the tension of the belts:

5. Remove the top panel of the analyser
6. Check the tension of the two belts of each arm (the 2 reagent arms, sample arm and the two stirrers). The belt tension must not be too loose or too tight.

-
7. Also check that the belt is not worn and that there are no traces of material adhering to the cogs.

Check that the anti-collision system of the reagent and sample arms is operating correctly:

1. Remove the top housings from the 3 arms.
2. Initialise the analyser with the service programme
3. Go to the anti-collision system checking option.
4. Lift each tip with your hand and check that they draw back smoothly and correctly.
5. Check that the lamp on the panel goes on every time the tip is in the raised position.
6. Check the indication that the tip is in the raised position in the service programme.

Check that the stirrers function correctly:

1. Check that the stirrer blades are properly tightened. Take care when tightening the blades, to ensure they continue to be aligned with respect to the motor shaft.
2. Use the service programme to rotate the stirrers. Check that they rotate correctly and are not eccentric.

Check the anti-collision system in the wash station

1. Remove the top housing from the wash station.
2. Initialise the analyser with the service programme
3. Go to the wash station anti-collision system checking option.
4. Lift the dryer tip with your hand and check that it draws back smoothly and correctly.
5. Check the indication that the dryer tip is in the raised position in the service programme.
6. Lift the wash station pedal system with your hand and check that it slides evenly and returns smoothly to its original position.

7.2.3. Checking the sample and reagent rotors

Check the rotor covers:

1. Initialise the analyser with the service programme.
2. Check that the cover sensor functions correctly.
3. Check that the covers fit into their housing correctly.

Check that the rotors fit into their compartments correctly:

1. Remove the two covers from the rotor assemblies.
2. Check that the anchoring of the sample and reagent rotor shaft functions correctly. If it is in position, it must not come out unless the top button is pushed and when inserting it, it must glide in smoothly.

Check the fans:

1. Check that there is no fridge or reaction rotor fan operation alarm.

7.2.4. Inspect the cover and the structure

1. Check that the general fans are functioning correctly. Put your hand on the exterior to verify that they expel air. The general fans have no automatic operation detection system.
2. Check that the wheels have no defects.
3. Check that the analyser is correctly positioned, and that the legs make contact with the floor. Tighten them with a spanner.
4. Check that the analyser is perfectly level with a levelling instrument. Tighten or loosen the legs until the analyser is completely level.

Checking the cover and legs:

1. Check that the doors open and close properly and smoothly. Check that they are correctly aligned with each other.
2. Check that the main cover is correctly supported when fully open and that when closing it, it does not fall suddenly.
3. Apply 1 drop of SAE-40 to the rear hinges of the main cover. Open and close the cover several times to help distribute the oil in the hinge.
4. Check the state of the “*bumpers*” (rubber stops for preventing the main cover from colliding), and if they are worn or damaged, replace them.

7.2.5. ISE module inspection

Replace the peristaltic pump tubes every 6 months.

Clean the ISE module sample entry opening.

Check that the tubes are not blocked.

8. Dismantling of elements

8.1. Dismantling of housing

The main cover, side housings, doors and rear panel can be removed separately, without having to dismantle the others.

To dismantle all the housings and panels, only one tool is required:

T20 torx key with a minimum length of 40 mm

To dismantle the housings and panels follow the dismantling process in reverse.

8.1.1. Removing the rear cover

To remove the rear cover, proceed as follows:

1. Remove the 14 torx screws and their washers (3).
2. Grasp the rear panel (2) using the 2 grips (1).

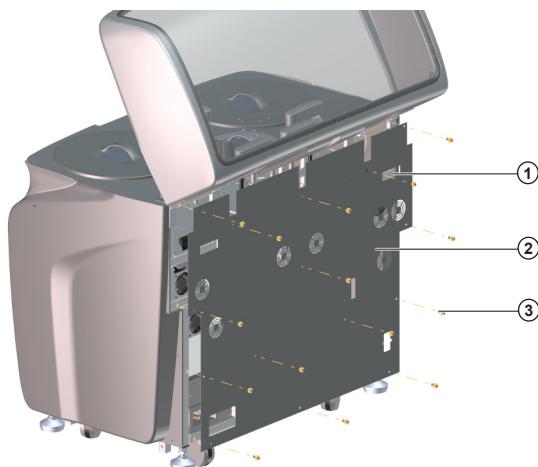


Figure 8.32 Removing the rear cover

8.1.2. Removing the top cover

To remove the top cover, proceed as follows:

1. Open the cover and remove the cover sensor tab and the 2 pistons.
2. Close the cover and turn the analyser
3. Remove the 10 torx screws and their washers from the hinges.
4. The cover can now be raised and changed.

8.1.3. Removing the side housings

To remove the housing on the right side, proceed as follows:

1. Remove the 3 screws from the rear side of the top tray () .
2. Open the right door and remove the 2 internal screws () .

3. Remove the 3 external screws () .
 4. Lift the housing slightly () and remove it from the support.
- Proceed in the same way to remove the housing on the left side.



Figure 8.33 Removing the rear cover

8.1.4. Dismantling and assembling the ISE cover

To remove the ISE cover, proceed as follows:

1. Open the ISE cover (1) to access the 2 screws that hold it in place (2).
2. Using an M4 Allen key, remove the 2 screws (2) together with their nuts, washers and the divider.
3. Remove the ISE cover.

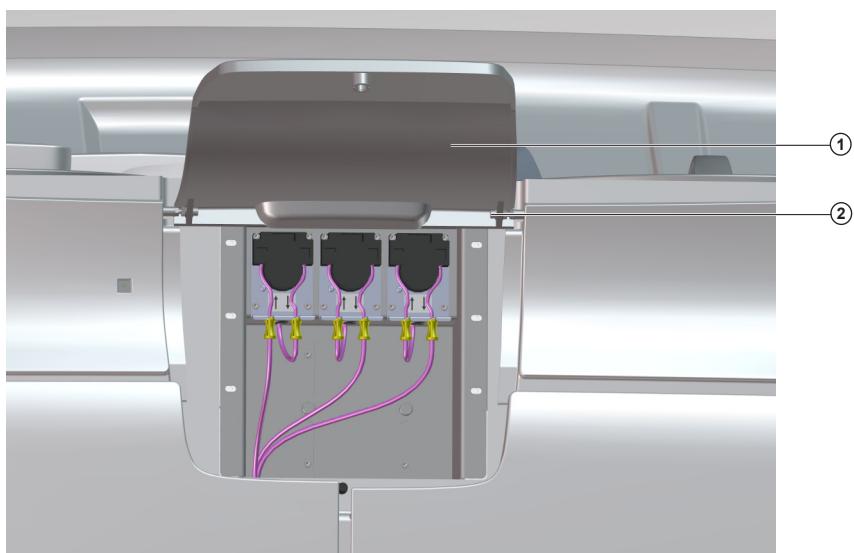


Figure 8.34 Removing the ISE cover

Proceed as follows to assemble the ISE cover (see Figure 8.4):

1. Assemble the screw, washers, nuts and divider in the cover before reassembling it again on the analyser.
2. Mount both assemblies as shown in Figure 8.4, one on each side of the ISE cover.
3. Do not tighten the nuts.
4. Position the ISE cover on the analyser and slightly tighten the screws (1) on each side.
5. Tighten one screw or the other until the ISE cover is correctly centred.
6. Secure the screw with the Allen key and tighten the nut with a Ford key (3)
7. Repeat the process with the nut (4)

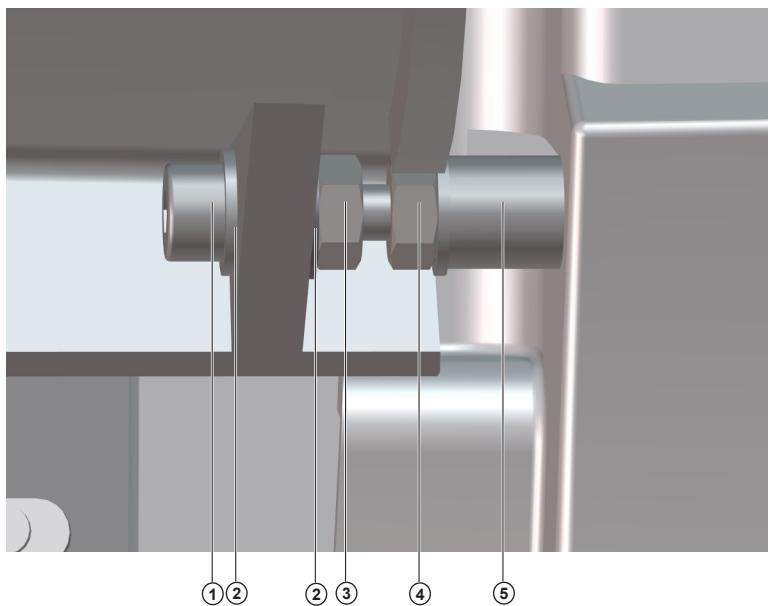


Figure 8.35 Detail of installing the ISE cover

8.1.5. Remove the top front housing

The top front housing has two parts. Proceed as follows to remove one from the other.

Follow the same process to remove the other.

1. Remove the ISE cover.
See how to remove the ISE cover in chapter 8.1.4
2. Remove the left side (to remove the left part)
3. Remove the 4 screws from the top tray.
4. Remove the 4 internal screws.
5. Remove the housing. Before removing the housing make sure you have first removed the LED indicator cable.
6. To reassemble the housing, follow the above steps in reverse order. First assembly the LED indicator cable.

8.1.6. Dismantling the top tray

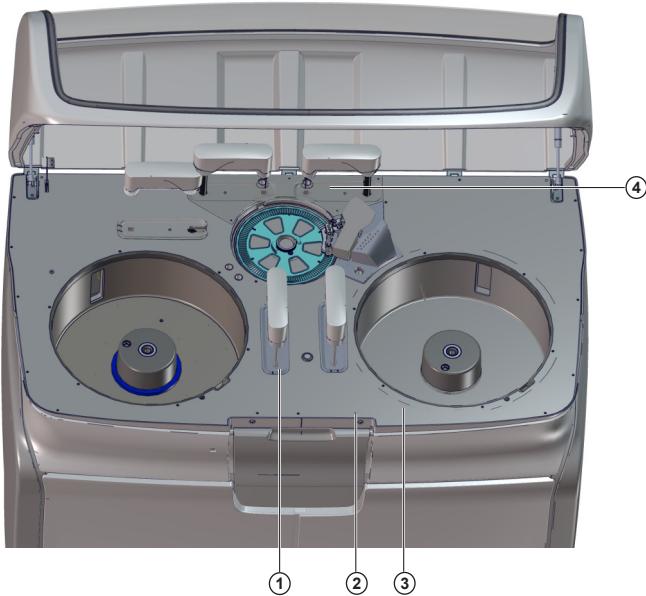


Figure 8.36 Dismantling the top cover

1. Lift all the arms and the wash station manually.
2. Remove the plastic protective caps (1) from the base of the arms.
3. Remove the plastic cap from the base of the stirrers (4).
4. Remove all the screws (2) securing the cover.
5. Lower the arms manually to the lowest level.
6. Remove the top cover(3). Take care in handling it, as it is very large.

8.2. Remove the sample and reagent arms and the stirrers

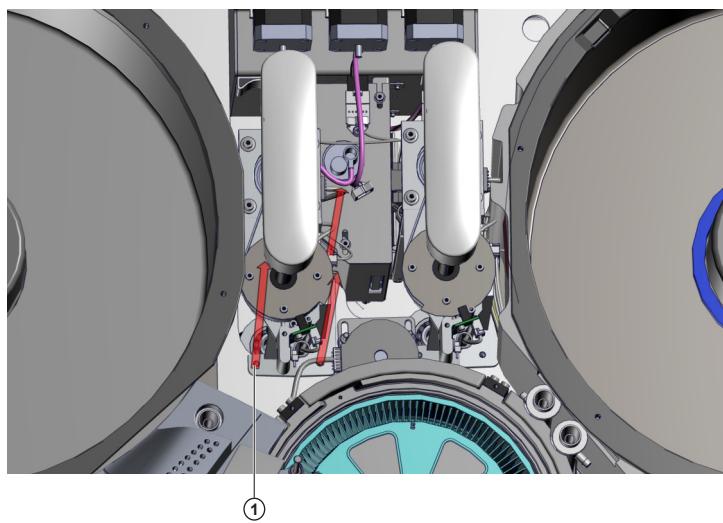


Figure 8.37 Dismantling the arm assembly

1. Remove the top cover.

☞ See chapter 8.1.6

2. Remove the rear cover, to access the interior cables.

☞ See chapter 8.1.1

3. Remove the clamps securing the cables and tubes that emerge from the lower part of the arm that you want to dismantle.
4. Remove the 3 screws (1) securing the arm assembly. Use a screwdriver and lengthener to access the screws.

8.3. Dismantling the reagent rotor

1. Remove the top cover.

☞ See chapter 8.1.6

2. Unplug the 5 fans connected to the CIIM00052 board
3. Unplug the two CAN cables connected to the CIIM00052 board
4. Remove the reagent 2 arm, to leave sufficient space for taking out the rotor.

☞ See chapter 8.2

5. Loosen the 5 screws securing the rotor assembly to the base. See Figure 8.7
6. Remove the rotor assembly and follow the steps indicated in Figure 8.8 to take the rotor out of the analyser.

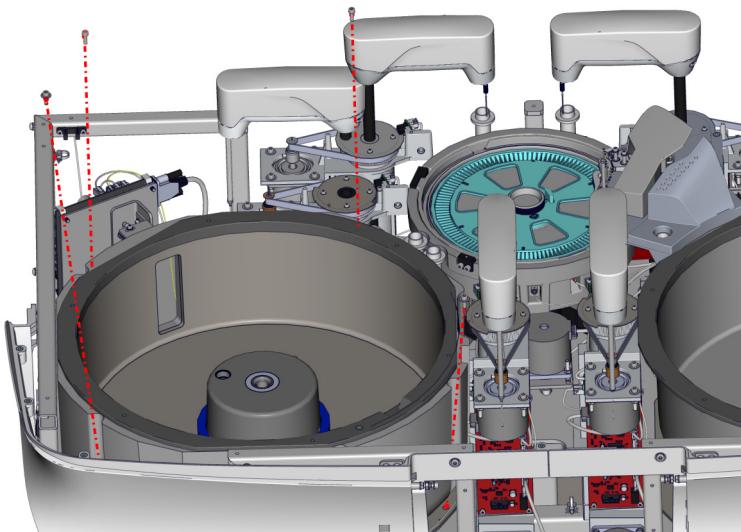


Figure 8.38 Rotor anchoring screws

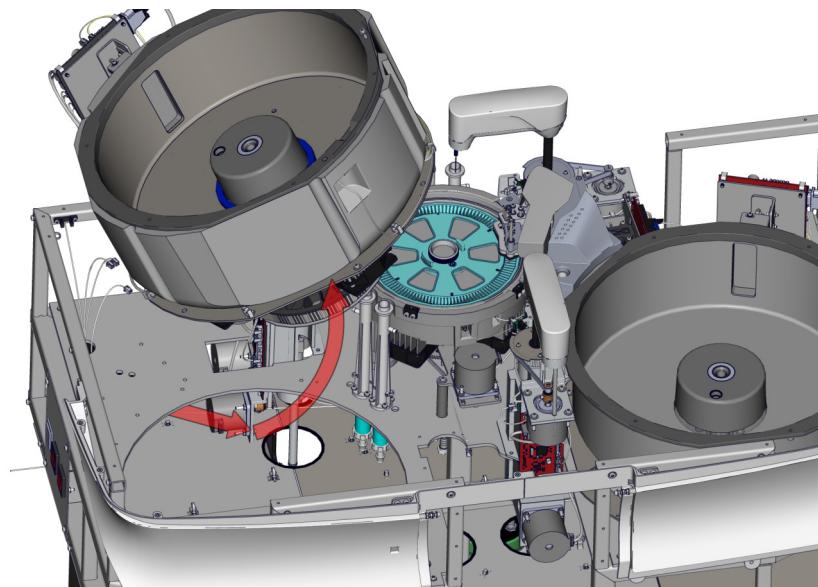


Figure 8.39 Movements required to take the rotor out of the analyser

8.4. Dismantling the sample rotor

1. Remove the top cover.
☞ See chapter 8.1.6
2. Unplug the 2 fans connected to the CIIM00052 board
3. Unplug the CAN cable.
4. Remove the sample arm
☞ See chapter 8.2
5. Loosen the 4 screws securing the rotor assembly to the base. See Figure 8.9
6. Loosen the screw that secures the wash station housing
7. Disconnect all the wash station tubes and take them from the housing
8. Remove the rotor assembly and follow the steps indicated in Figure 8.10 to take the rotor out of the analyser.

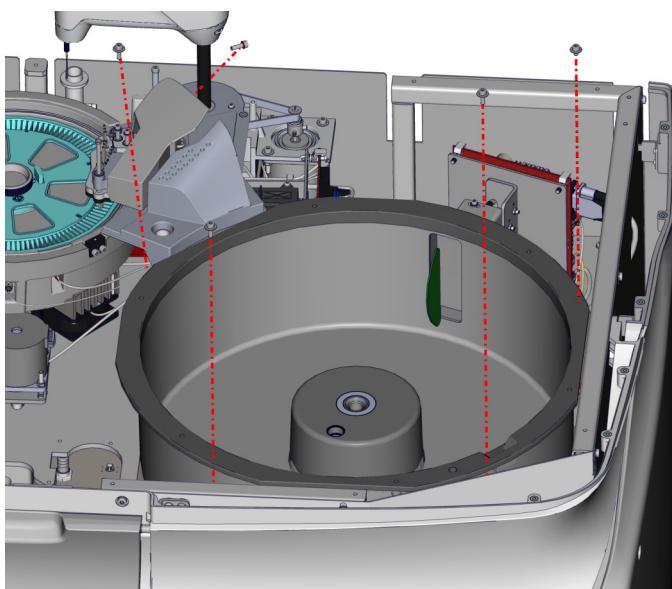


Figure 8.40 Movements required to take the rotor out of the analyser

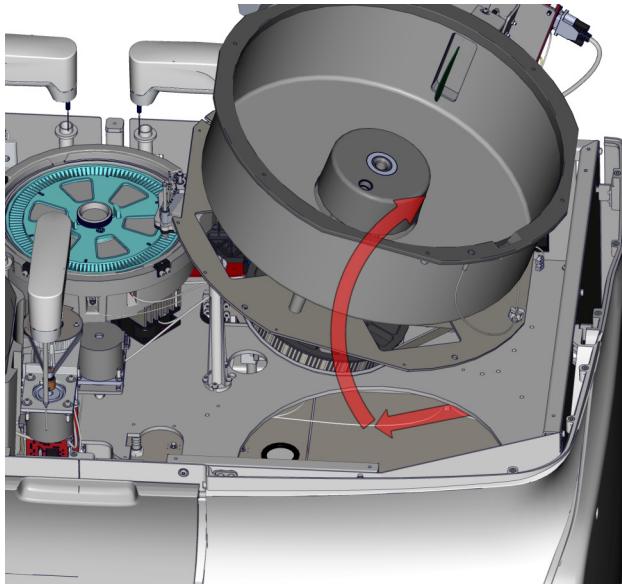


Figure 8.41 Movements required to take the rotor out of the analyser

8.5. Dismantling the reaction rotor

1. Remove the top cover.
☞ See chapter 8.1.6
2. Unplug the CAN cable.
3. Remove the stirrer 2 arm
☞ See chapter 8.2
4. Remove the sample rotor
☞ See chapter 8.4
5. Loosen the 5 screws shown in Figure 8.11
6. Take the rotor assembly out of the analyser

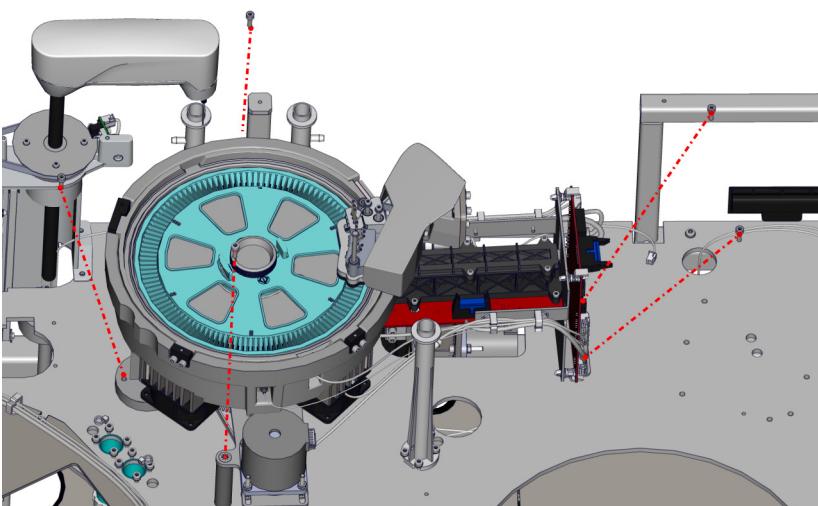
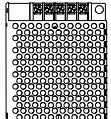
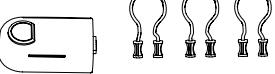
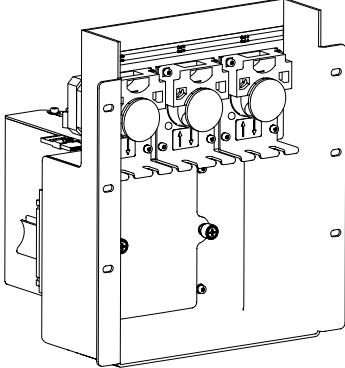


Figure 8.42 Reaction rotor anchoring screws

8.6. ISE module installation

The ISE module is optional. To install the ISE module, proceed as follows:

The spares content is as follows:

Component	Description
	Power supply
	Switch
	Cabling
	Cable gland
	Connector and tubes
	ISE module

1. Remove the side housings.
2. Remove the top cover. Remove from the cover the opening plug for dispensing the ISE module sample(8). See Figure 8.14
3. Dismantle the top front housings together with the ISE cover (7)
4. Dismantle the switch assembly (2). See Figure 8.12
5. Remove the switch cover (1)
6. Insert the ISE switch.
7. Connect the power cable to the switch.
8. Close the switch assembly with the protective cover (3) and put it back in place. See Figure 8.13.

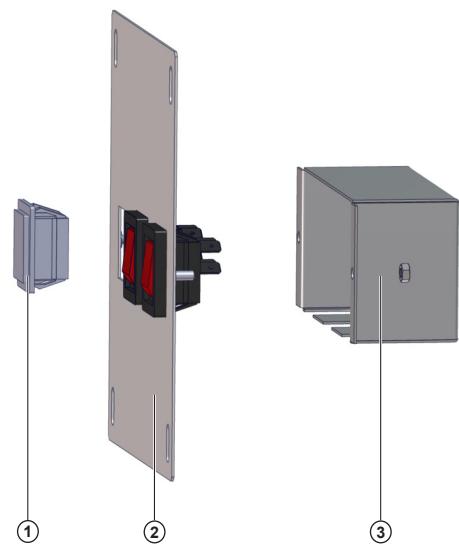


Figure 8.43 Dismantling the switch assembly

9. Lower the cabling through the analyser column (4). See Figure 8.13.
10. Install the power supply (5) as shown in the previous figure.
11. Connect one of the cable ends to the power supply.
12. Connect the other end to the AC distribution board (6).
13. Connect the module power cables to the power supply output. These cables are already installed in the analyser.
14. Insert the module in its compartment. See Figure 8.15. Use the same screws that secure the cover to screw the module in place.
15. Place the pincer (9) of the calibration standard kit in the compartment located next to the internal bottles. See Figure 8.16
16. Pass the tubes through the two openings (10) and (11) until they reach the module.
17. Consult the user manual chapter on installing the ISE module to see how to connect the different tubes and install the electrodes and standard kit.
18. Replace all the covers and housings.
19. Install the cable gland in the sample dispensing opening in the top cover

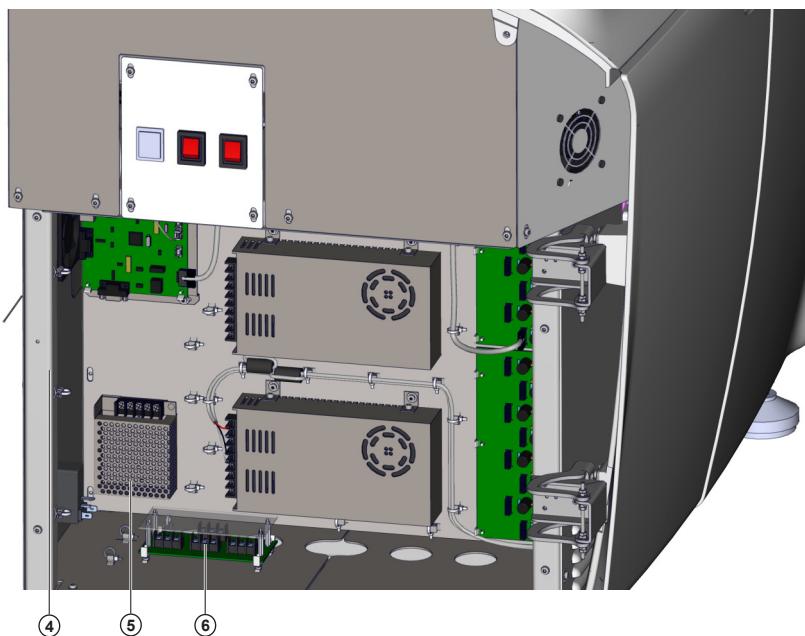


Figure 8.44 ISE module power supply installation

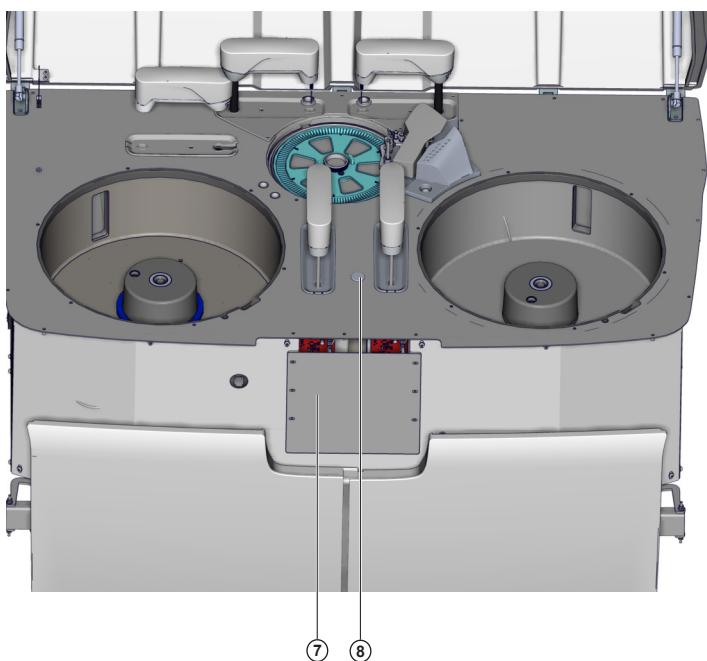


Figure 8.45 Location of the covers

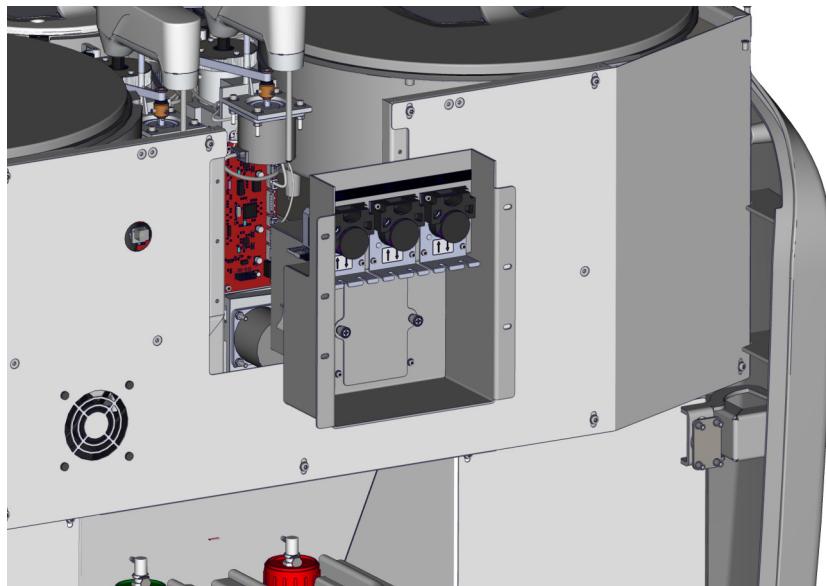


Figure 8.46 ISE module assembly

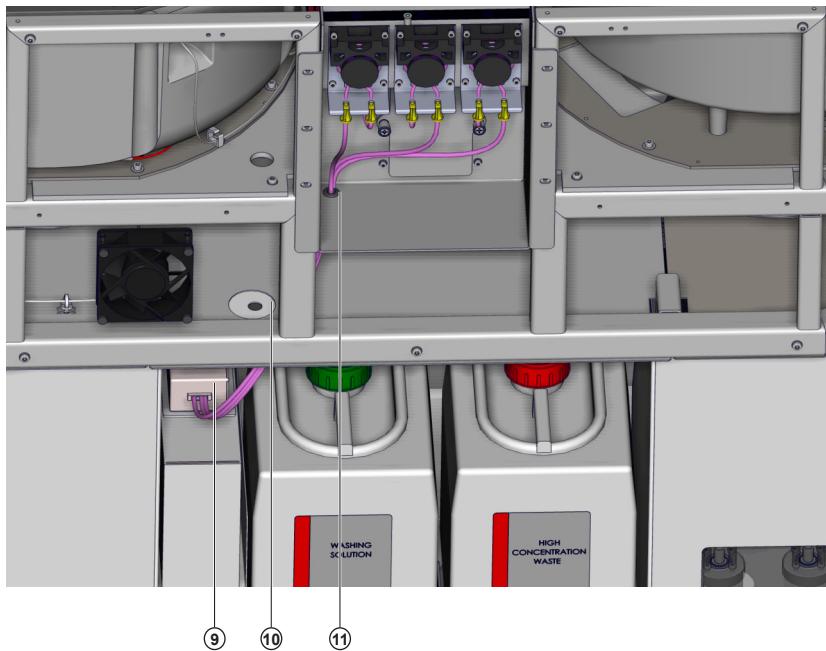


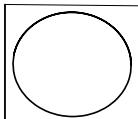
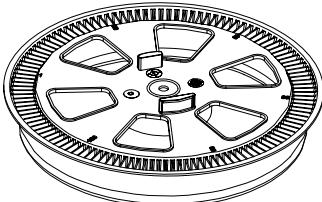
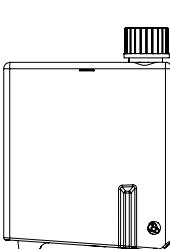
Figure 8.47 Tube installation

A1. List of accessories and spares

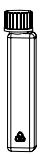
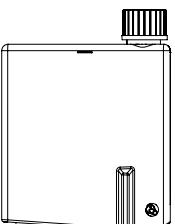
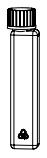
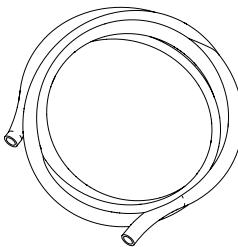
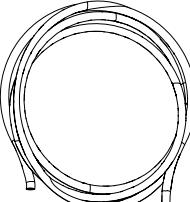
In the event of any of the analyser components being damaged or if any fungible goods are required, always use original BioSystems material.

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

LIST OF ACCESSORIES

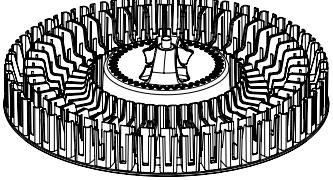
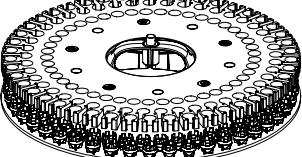
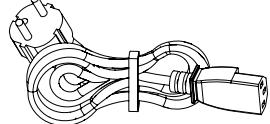
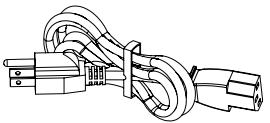
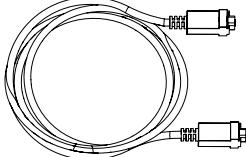
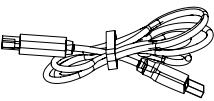
CODE	REPRESENTATION	DESCRIPTION
AC16359		DVD with User Programme
AC11485		“Reaction Rotor” (10)
AC10770		“Sample wells” (1 000)
AC16434		500 mL bottle of concentrated washing solution
AC16360		Open adapter for primary tubes (90)
AC16361		Closed adapter for sample wells (45)
AC16362		60mL reagent bottles (20)

LIST OF ACCESSORIES

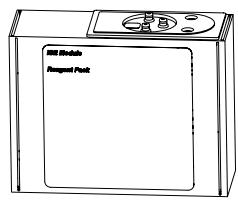
CODE	REPRESENTATION	DESCRIPTION
AC16363		20mL reagent bottles (20)
AC16364		60mL brown reagent bottles (20)
AC16365		20mL brown reagent bottles (20)
AC16366		Connection tube for distilled water bottle (3 m)
AC16367		Connection tube for waste (3 m)
AC16368		Washing solution bottle with cap
AC16369		High contamination bottle with cap

Service Manual

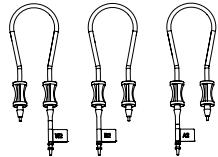
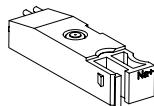
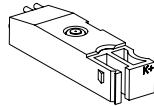
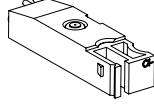
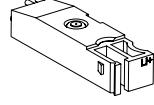
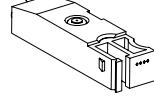
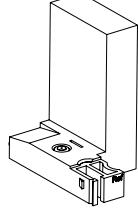
LIST OF ACCESSORIES

CODE	REPRESENTATION	DESCRIPTION
AC16370		Reagent rotor
AC16371		Sample rotor
AC11486		Reaction rotor set screw
CA10455		European mains cable
CA10456		American mains cable
FI10466		Serial channel cable for connection to PC
FI14226		USB cable for connection to PC

LIST OF ISE MODULE ACCESSORIES (OPTIONAL)

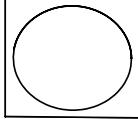
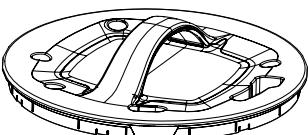
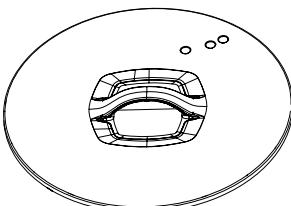
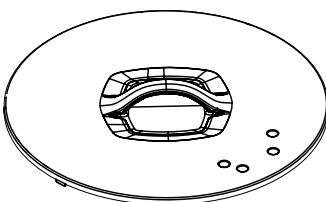
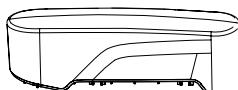
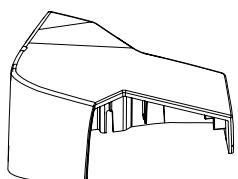
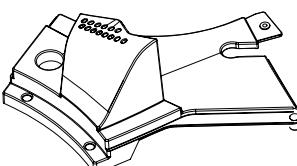
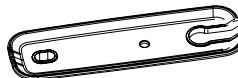
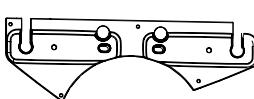
CODE	REPRESENTATION	DESCRIPTION
ME5420		Reagent pack

LIST OF ISE MODULE ACCESSORIES (OPTIONAL)

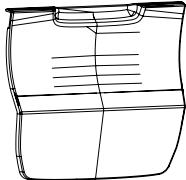
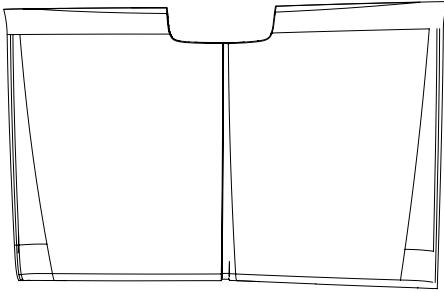
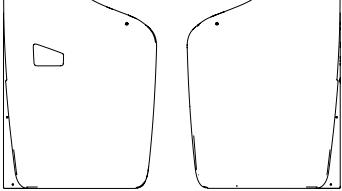
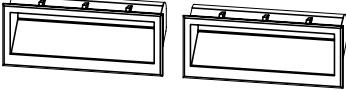
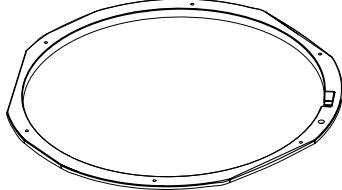
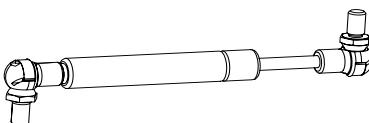
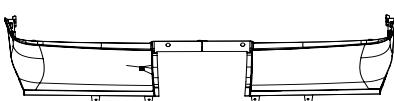
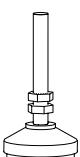
CODE	REPRESENTATION	DESCRIPTION
ME5625		Tube assembly
ME5201		Na ⁺ electrode
ME5202		K ⁺ electrode
ME5207		Cl ⁻ electrode
ME5205		Li ⁺ electrode
ME5204		Separator electrode
ME5204		Reference electrode
ME5421		ISE module washing solution KIT
ME5412		ISE 125mL urine dilution module

Service Manual

LIST OF SPARES PARTS

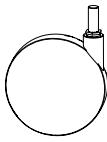
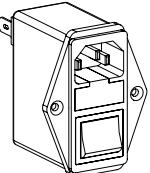
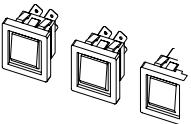
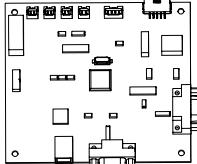
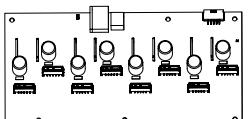
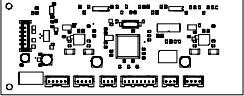
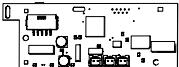
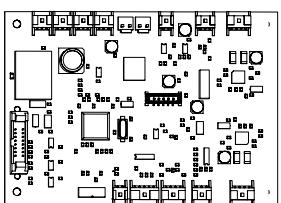
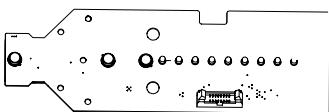
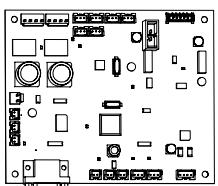
Code	Representation	Description
		DVD Service programme and Service Manual
AC16534		Reaction rotor screw
AC16535		Reaction rotor cover
AC16536		Sample rotor cover
AC16537		Reagent rotor cover
AC16538		Arm cover
AC16539		Top cover of wash station
AC16540		Lower cover of wash station
AC16541		Lower cover of arm
AC16542		Lower cover of stirrers

LIST OF SPARES PARTS

Code	Representation	Description
AC16543		ISE module cover
AC1644		Door assembly
AC16545		Lateral cover assembly
AC16546		Rear cover handles
AC16547		Reagent and sample rotor frame joint
AC16549		Hinger of general cover
AC16550		Front led frame
AC16551		Legs

Service Manual

LIST OF SPARES PARTS

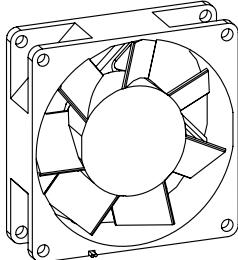
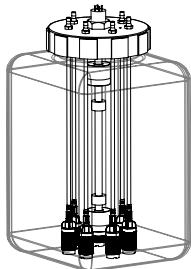
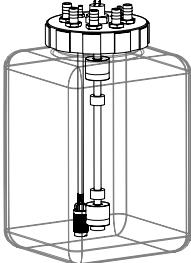
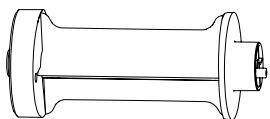
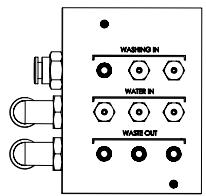
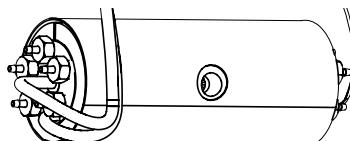
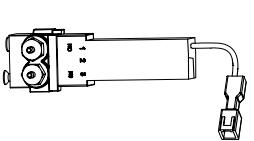
Code	Representation	Description
AC16552		Wheels
AC16553		Filter and network connector
AC16554		Switch assembly
AC16555		CPU board
AC16556		Distribution board
AC16557		Arm board
AC16558		Tip board
AC16559		Photometry Control Board
AC16560		Photometry board
AC16561		Sample rotor board

LIST OF SPARES PARTS

Code	Representation	Description
AC16562		Reagent rotor board
AC16563		Fluid board
AC16564		Syringe board
AC16565		Photobarrier board
AC16634		AC input board
AC16566		Led Manifold Board
AC16567		320 W power supply
AC16569		35 W power supply
AC16570		Load cell

Service Manual

LIST OF SPARES PARTS

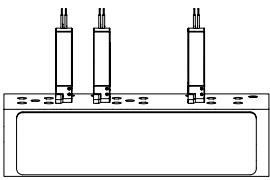
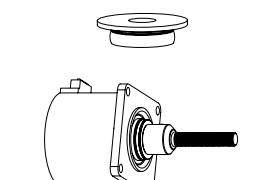
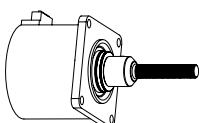
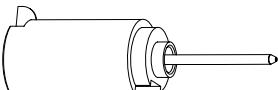
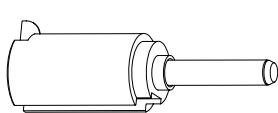
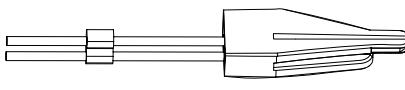
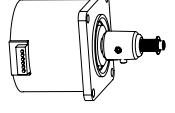
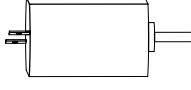
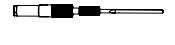
Code	Representation	Description
AC16571		General fan (2 wires)
AC16572		Distilled water bottle with cap and buoys
AC16573		Low contamination waste bottle with cap and buoys
AC16574		Tip wash station
AC16575		Reaction rotor support column
AC16576		Manifold assembly
AC16577		Wash station heater
AC16578		3-way electro valve

LIST OF SPARES PARTS

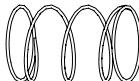
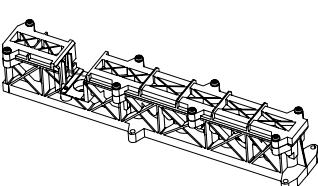
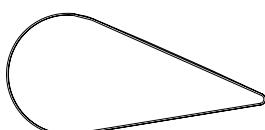
Code	Representation	Description
AC16579		Pre dose Manifold
AC16580		Water inlet valve
AC16581		Dispensing pumps
AC16582		Suction pumps
AC16583		External water inlet adapter
AC16584		Water tank inlet adapter
AC16585		Wash station pump stop + O-ring
AC16586		Wash station pump motor
AC16587		Top chamber
AC16588		Piston support + pistons

Service Manual

LIST OF SPARES PARTS

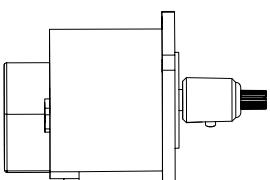
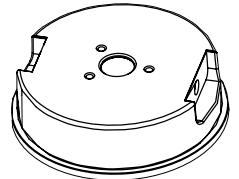
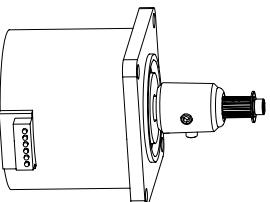
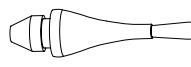
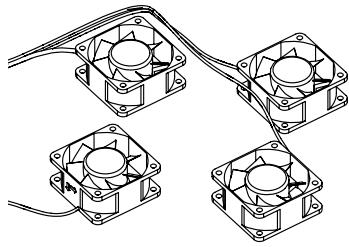
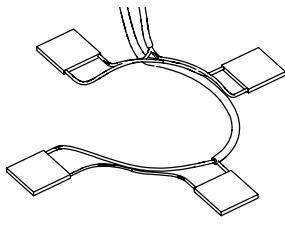
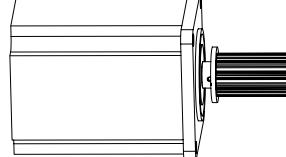
Code	Representation	Description
AC16589		Manifold
AC16590	 	Reagent piston stop
AC16591	 	Sample piston stop
AC16592		Pump motor+spindle
AC16593		Sample ceramic piston
AC16594		Reagent ceramic piston
AC16595		Wash station suction tip
AC16596		Wash station suction tip+dryer
AC16597		Wash station tip spring
AC16598		Vertical movement belt
AC16599		Polar movement belt
AC16600		Arm motor
AC16601		Continuous current stirrer motor
AC16602		Stirrer paddle

LIST OF SPARES PARTS

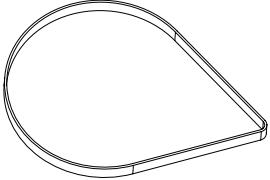
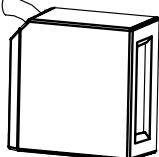
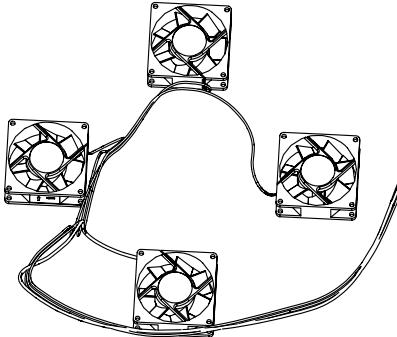
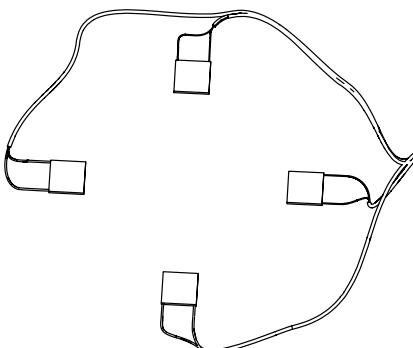
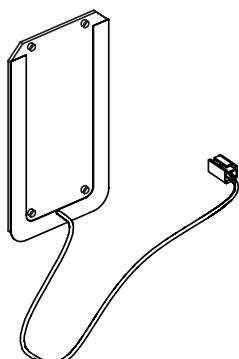
Code	Representation	Description
AC16603		Sample tip
AC16604		Reagent tip
AC16605		Tip spring
AC16606		340 Filter
AC16607		405 Filter
AC16608		505 Filter
AC16609		535 Filter
AC16610		560 Filter
AC16611		600 Filter
AC16612		635 Filter
AC16613		670 Filter
AC16614		Optical bench without filters
AC16615		Reaction rotor cogged belt

Service Manual

LIST OF SPARES PARTS

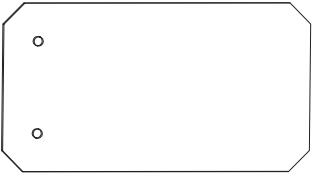
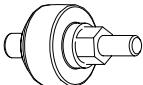
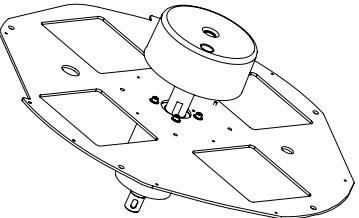
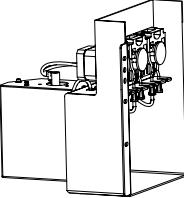
Code	Representation	Description
AC16616		Reaction rotor motor
AC16617		Rotor centring device
AC16618		Wash station elevation motor
AC16619		Wash station vertical movement belt
AC16620		Reaction rotor temperator sensor
AC16621		Reaction rotor thermostatting fan assembly (3 wires)
AC16622		Reaction rotor peltier assembly
AC16623		Reaction/sample rotor motor

LIST OF SPARES PARTS

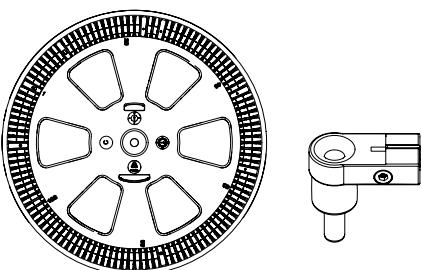
Code	Representation	Description
AC16624		Reagent rotor cogged belt
AC16625		Barcode reader
AC16626		Refrigerator fan assembly (3 wires)
AC16627		Refrigerator peltier assembly
AC16628		Barcode window heater

Service Manual

LIST OF SPARES PARTS

Code	Representation	Description
AC16629		Barcode reader window
AC16630		Cover sensor
AC16631		Refrigerator temperature sensor
AC16632		Reagent or sample rotor centring device
AC16391		ISE module

Instruments and tools

Code	Representation	Description
AC16643		Adjustment instruments
AC16644		Adjustment screwdriver for level detection
AC16645		Allen key lengthener assembly

All Technical characteristics



WARNING

The manufacturer declines all liability for damages caused by using the appliance incorrectly.

GENERAL CHARACTERISTICS

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

SAMPLE CONTROL

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

REAGENT CONTROL

Reagent bottle volume	20 mL, 60 mL
Reagent rotor capacity	88 (44 bottles of 20 mL or 60 mL + 44 bottles of 20 mL)
Refrigerated reagents	Yes
Maximum refrigerator temperature	5° C to 8° C (at room temperature of 25° C)
Barcode detector	Yes
Reagent arms	2 (R1, R2)
R1 reagent volume	150 µL to 500 µL
R2 reagent volume	40 µL to 300 µL
Type of reagent pump syringe	Low-maintenance ceramic piston
Piston diameter	8 mm

Service Manual

REAGENT CONTROL

Pipetting resolution	1 µL
Level detection	Yes
Washing of tip	Interior and exterior
Vertical collision detector	Yes
Thermostatted tip	Yes

REACTION ROTOR

Minimum reaction volume	200 µL
Maximum reaction volume	600 µL
Number of cuvettes	120
Cuvette material	UV methacrylate
Type of incubation	Dry
Fixed dispensing time for 2nd reagent	5 min (fixed)
Reaction cuvette temperature	37 °C
Temperature accuracy	±0.2° C
Temperature stability	±0.1° C
Stirrers	2

CUVETTE WASHING SYSTEM

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

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

ISE MODULE (optional)

Type of sample	Serum, Plasma or Urine
Type of electrode	Na ⁺ , K ⁺ , Cl ⁻ , Li ⁺ (optional)

ISE MODULE (optional)

Sample volume	Serum: 100 µL Urine: 200 µL
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ENVIRONMENTAL REQUIREMENTS

Room temperature	10° C to 35° C 10° C to 30° C (with ISE module)
Relative humidity	< 85% with no condensation
Maximum height	< 2500 m
Contamination grade	2
Transportation and storage temperature	0° C to 40° C
Transportation and storage humidity	< 85% with no condensation

DIMENSIONS AND WEIGHT

Dimensions (Width, depth and height)	1200 mm x 720 mm x 1258 mm
Weight	210 kg

ELECTRICITY REQUIREMENTS

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

FLUID REQUIREMENTS

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

MINIMUM COMPUTER REQUIREMENTS

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

COMPLIANCE WITH DIRECTIVES

EC-IVD Directive	98/79/EC
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III. Adjustment margin tables

Adjustment margins:

Parameter	Minimum	Maximum
Reading reference position - Well 1	7 860	7 905
Washing solution tare 0	-5	5
Washing solution tare 50	40	60
Washing solution tare 100	95	105
Washing solution tare 150	100	150
Waste tare 0	-5	5
Waste tare 50	40	60
Waste tare 100	95	105
Waste tare 150	100	150
Thermal adjustment of reaction rotor	37,0	39,0
Thermal adjustment of wash station	44,0	50,0
Thermal adjustment of reagent tip 1	50,0	55,0
Thermal adjustment of reagent tip 2	50,0	55,0
Thermal test on reaction rotor	36,8	37,2
Thermal test on wash station	45,0	50,0
Thermal test on reagent tip 1	30,0	35,0
Thermal test on reagent tip 2	30,0	35,0
Led 1 intensity reference value	6 000	25 000
Led 2 intensity reference value	14 000	30 000
Led 3 intensity reference value	12 000	30 000
Led 4 intensity reference value	4 000	30 000
Led 5 intensity reference value	3 000	15 000
Led 6 intensity reference value	6 000	25 000
Led 7 intensity reference value	6 000	20 000
Led 8 intensity reference value	4 000	15 000

Photometry margins:

Parameter	Minimum	Maximum
Dark current	3 300	4 500

Number of counts of main photodiode	Minimum	Maximum
Wavelength 340	600 000	950 000
Wavelength 405	850 000	950 000
Wavelength 505	850 000	950 000
Wavelength 535	850 000	950 000

Number of counts of main photodiode	Minimum	Maximum
Wavelength 560	550 000	950 000
Wavelength 600	750 000	950 000
Wavelength 635	850 000	950 000
Wavelength 670	450 000	950 000

Number of counts of reference photodiode	Minimum	Maximum
Wavelength 340	100 000	400 000
Wavelength 405	400 000	800 000
Wavelength 505	400 000	800 000
Wavelength 535	400 000	800 000
Wavelength 560	400 000	950 000
Wavelength 600	300 000	800 000
Wavelength 635	400 000	800 000
Wavelength 670	200 000	950 000

Measurements taken at the 505 nm wavelength	Parameter	Value
Repeatability measured at 0 Abs	Standard deviation	< 0.0002 Abs
Stability at 0 Abs	Range	< 0.0015 Abs

AIV. Software versions

Changes in the service programme versions

Date	Versions	Changes
15/05/12	1.0	First version

Changes in the user programme versions

Date	Versions	Changes
15/05/12	1.0	First version

Changes in the firmware versions

Date	Versions	Changes
15/05/12	1.0	first version

AV. Repackaging instructions

This chapter gives the instructions for repackaging and control of the marketed instruments for rental or free lease, or transferred as second hand.

General terms and conditions

- **Useful life:** There is no limit on the useful life, provided the manufacturer's instructions regarding use and maintenance set out in the User Manual are complied with and original spares are used. BioSystems will maintain the spares service up to 5 years after the manufacture of the same model of the last analyser.
- **Number of times the appliance can be repackaged:** There is no limit regarding the number of times it can be repackaged, provided the repackaging instructions described in this section are complied with and original spares are used.
- **Accessories used in repackaged appliances:** All repackaged analysers will use the accessories supplied by the manufacturer. Any remains of surplus fungibles used previously such as rotors, spare reagent or washing solution bottles, etc. will be disposed of.
- **Personnel:** The repackaging operation will be carried out by personnel authorised by Biosystems. This personnel will normally be the dealer's technical service staff or persons who have received the appropriate training.

Instructions

Cleaning and disinfecting

Users carrying out disinfection processes must wear gloves and protective apparel. All consumable materials (reaction rotor, reagent bottles, sample tubes) will be treated as potentially infectious waste.

Check whether there are any reaction rotors in their compartments or reagent bottles in the refrigerator. If there are, dispose of them.

Empty the high contamination waste tank and washing solution tank.

Wash the inside of the equipment using a damp cloth and neutral soap. If there are splashes, wash them with alcohol.

Follow the applicable national guidelines for disposing of waste that is considered potentially infectious.

Components to be replaced

Replace the following components:

- Wash station suction tubes
- Wash station dryer
- Distilled water and washing solution bottle filters
- ISE module peristaltic pump tubes

Update the firmware and software

Adjustment process

Take note of the values obtained from the adjustment in the record document at the end of the service manual.

Make the following adjustments. To make the adjustments, consult chapter 6 of the service manual.

- Verification of the LED currents.
- Thermostatting adjustment in the reagent tips
- Thermostatting adjustment in the reaction rotor

- Photometry test

Execute with the user programme.

To make the functional check, use the following BioSystems reagents and reference materials:

- Glucose reagent (12503)
- ALT reagent (12533)
- Multi-standard serum (18011)
- Level I and II control serum (18009 and 18010)

Change the following parameters in the glucose and ALT test programmes:

Number of replicates: 20

Multistandard concentration: Enter the value.

Programme the following list:

Two patients called: Level I and Level II

Programme the tests for each patient: Glucose and ALT

Execute the list. The analyser will perform the blank, standard and 20 replicates at each control serum level. Once it has finished it will display the results.

Calculate the CV for each result with the 20 replicates.

The CV is calculated as:

$$CV = \frac{SD}{Media} \cdot 100 \quad SD = \sqrt{\frac{\sum_{i=1}^n (x_i - Media)^2}{n-1}}$$

Check that the results are within the margins:

Biochemical precision	CV (%)
Control serum Level I glucose	< 2
Control serum Level II glucose	< 2
Control serum Level I ALT	< 4
Control serum Level II ALT	< 2

Check that the mean of the results for each control serum is within the margins indicated in the value entered in each control serum.

If the results are not within the above margins, the analyser is damaged. Solve the problem. Once repaired, perform the functional check again.

Finalisation

Put an indelible label on the repackaged equipment. The label should bear the following information (check the national legislation in each country):

- The company name and address and the names of the persons responsible for the execution and repackaging
- The date of the last inspection
- The number of repackaging operations carried out

- An indication that it is a renovated appliance

Useful life: no limit, provided the manufacturer's instructions regarding use and maintenance are followed.

Add a new box of accessories.

Use the original packaging. First check its state and if it is clearly damaged, replace with a new one.

Send the completed record to the Biosystems technical service (in pdf format).

REPACKAGING RECORD

BA 400

Company name:	
Serial number:	
Repackaging date:	

PART REPLACEMENT PROCESS

1. Parts to be replaced	
Replacement of parts	Ok / Not Ok
Update the firmware and software	Ok / Not Ok

ADJUSTMENT PROCESS

Points to be readjusted	Tolerances	Value
1. Thermostatting of reagent 1 tip		
Temperature set point	50,0	55,0
Temperature test	30,0	35,0
2. Thermostatting of reagent 2 tip		
Temperature set point	50,0	55,0
Temperature test	30,0	35,0
3. Thermostatting of reaction rotor		
Temperature set point	37,0	39,0
Temperature test	36,8	37,2
4. Photometry Tests		
4.1. Luminous intensity		
340 nm	6 000	25 000
405 nm	14 000	30 000
505 nm	12 000	30 000
535 nm	4 000	30 000
560 nm	3 000	15 000
600 nm	6 000	25 000
635 nm	6 000	20 000
670 nm	4 000	15 000

4.2. Number of counts of main photodiode	
340 nm	600 000
405 nm	850 000
505 nm	850 000
535 nm	850 000
560 nm	550 000
600 nm	850 000
635 nm	850 000
670 nm	450 000
4.3. Number of counts of reference photodiode	

340 nm	100 000	400 000	
405 nm	400 000	800 000	
505 nm	400 000	800 000	
535 nm	400 000	800 000	
560 nm	400 000	950 000	
600 nm	300 000	800 000	
635 nm	400 000	800 000	
670 nm	200 000	950 000	

4.4. Dark current counts	
Value	3 300
4.5. Repeatability	Tolerances CV(%)
For all the filters	< 10 %
4.6. Stability	
For all the filters	< 10 %

FINAL FUNCTIONAL CHECK

5. Biochemical precision	Tolerances CV(%)	Value
Control serum Level I Glucose	< 2	
Control serum Level II Glucose	< 2	
Control serum level I ALT	< 4	
Control serum Level II ALT	< 2	

FINALISATION

6. Completed	
Label the renovated equipment	Ok / Not Ok
Add a full box of accessories	Ok / Not Ok
Check the packaging	Ok / Not Ok

7. Acceptance of repackaging	
Rewrap OK Available for sale	Ok / Not Ok

Signed:	
Prepared by:	