USER MANUAL

BioSystems
SPICA

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USER MANUAL

Thank you for purchasing our automatic SPICA Analyser, one of the most technically advanced and most accessible analysers on the market. We are sure that its features will render it a valuable instrument for your work. Although it can be operated intuitively and simply via the menu, all users are advised to read this manual carefully prior to use. It will help ensure installation and maintenance are performed correctly and allow all users to get the maximum benefit from its many possibilities.

USER

1. INTRODUCTION

1.1 Notices and Warnings

Symbols | Safety Precautions | Abbreviations and Units

WARNING

The symbol warns of operating risks that could cause personal injury

CAUTION

The symbol warns of potential damage to the systems or unreliable results

NOTE

The symbol warns that information requires user attention

Electric shock risk

BIOHAZARD

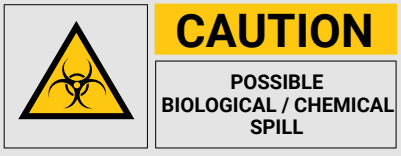
The symbol warns of a potential biohazard

The symbol warns of potential risks due to laser radiation

Irritant solution

Distilled Water

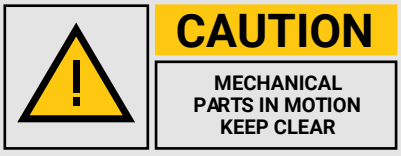
Please consult the user manual



Caution, possible Biological or Chemical spill

Caution, Exclusive use of BioSystems

Caution, Maximum Load Capacity 6 Kg



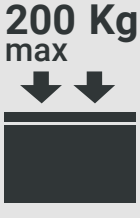
Caution, Keep clear of moving parts

USER

1. INTRODUCTION

1.1 Notices and Warnings

Symbols | Safety Precautions | Abbreviations and Units

CE	 Manufacturer
 Serial Number	 LOT Code
 Only for reference 83100BQ	
 Installation Date	 Expiry Date
 Catalog Number	
 Temperature Limit	 Packaging label. Keep upright
 Packaging label. Keep dry	
 Packaging label. Fragile	 Packaging label. Keep upright. Do not stack more than 200 Kg
 Packaging label. Heavy goods	

USER

1. INTRODUCTION

1.1 Notices and Warnings

PREVENTING ELECTRIC SHOCK

To reduce the risk of discharges, do not remove the Analyzer cover. There are no parts inside that can be repaired by the user, for which reason it is necessary to contact the technical assistance service.

PREVENTING LASER LIGTH EMISSION RISKS

The analyzer has a bar code reader that emits laser light. The laser is Class II. The reader only works when the analyzer is in the execution mode and its rotor covers are in place. In the event of a failure or during adjustment by technical maintenance staff, the light beam could be activated without the cover in place; in such cases, do not look directly at the laser beam.

WARNING

PREVENTING IN HANDLING REAGENTS

Handle reagents and washing solutions with care, they contain substances that could be corrosive. In the event that the reagents or washing solutions come into contact with the skin, wash immediately with abundant water and seek medical advice.
Consult the reagent or washing solution **safety data sheet** and follow the safety instructions. It is advisable to follow good laboratory practice.

NOTE

PREVENTING ELECTROMAGNETIC INTERFERENCES AND ELECTRICAL AND ELECTRONIC EQUIPMENT PROTECTION.

The Analyzer complies with the requirements with respect to emissions and immunity set forth in standard Electromagnetic Compatibility Directive (EMC) 2014/30, Low Voltage Directive (LVD) 2014/35, (UE) 2015/863 and 2011/65/UE RoHS Directive, Radio Equipment Directive (RED)2014/53/EU.

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 analyzer near strong electromagnetic radiation sources (such as centrifuge appliances, radio transmitters, mobile phones), as they could interfere with its correct operation.

WARNING

USE OF CONSUMABLES

Before using the consumables (cleaning solutions and systems fluids) check the expiration date. If it has expired, remove the product and use a new one with the current expiration date.

SPARE NETWORK CABLES

If you are going to use a network cable that is not supplied by the manufacturer, make sure that it supports the power of the analyzer, that it is approved and that it complies with the CE regulations.

USER

1. INTRODUCTION

1.1 Notices and Warnings

WARNING

SECURITY OPERATIONS AFTER MAINTENANCE

To proceed safely and leave the instrument in a safe state during maintenance operations, follow the steps described in the user manual for each of the operations. Be sure to place again the different protection elements that you have removed, as well as not leaving any cleaning elements in the instrument.

OPERATIONS THAT MAY COMPROMISE THE SAFETY OF THE EQUIPMENT

Any improper use negligence, non-tolerance electrical network conditions, inadequate environmental or location conditions, etc.) as well as internal manipulation of the analyzer by personnel not authorized by BioSystems orthe use of non-original consumables and spare parts (rotors, fuse, etc.) may compromise the protection assured by the analyzer.

PREVENTION AT THE END OF THE ANALYZER'S USEFUL LIFE

At the end of the useful life of the analyzer, disposal of the product must be carried out in accordance with the environmental legislation in force in each country. In EU member states, the terms of the WEEE directive on electrical and electronic appliances will apply. In other words, when the appliance's useful life has ended, it is converted into waste and must be separated from household waste for correct recycling. For this purpose, contact the distributor for the product to be properly recycled.

Use gloves to manipulate any part of the analyzer that has been in contact with biological material: tips, containers, tubes, etc.

Dispose of this material in accordance with current legislation for the disposal of hazardous biological waste from your national or local government.

NOTE

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference using one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and receiver.
- Plug the equipment into a plug on a circuit different from that to which the receiver is connected.
- Contact the dealer or an experienced radio/TV technician for help.

BioSystems S.A. has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment.

The equipment must be installed and operated at a minimum distance of 20 cm from the human body.

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1. INTRODUCTION

1.1 Notices and Warnings

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with FCC RF exposure limits and has been evaluated in compliance with mobile exposure conditions. The equipment must be installed and operated with a minimum distance of 20 cm from the human body.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a digital device, per ACMA Regulations.

ABBREVIATIONS

⌀	Diameter
ASTM	American Society for Testing and Materials (www. astm.org)
EU	European Union
EMC	Electromagnetic compatibility
CTRL	Control key on the computer keyboard
EN	European Norm
F	Fast (fuse type)
FUS	Fuse
HL7	Health Level Seven (www.hl7.org)
IHE	Integrating the Healthcare Enterprise (www.ihe.net)
LED	Light-emitting diode
LIS	Laboratory information system
WEEE	Waste Electrical and Electronic Equipment
UPS	Uninterruptible power source
TAS	Technical assistance service
SD	Standard deviation
ES	Electrical safety
USB	Universal Serial Bus
UV	Ultraviolet

UNITS

“	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	Millimole
mv	Millivolt
nm	Nanometre
s	Second
VA	Volt-ampere
V	Volt
W	Watt
µL	Microlitre
µm	Micrometer

USER

1. INTRODUCTION

1.2 End-User License Agreement

This End-User License Agreement ("EULA") is a legal agreement entered into between you and BioSystems, SA.

This EULA agreement governs your acquisition and use of BioSystems, SA SPICA software ("software"), whether acquired directly from BioSystems, SA or indirectly through a BioSystems, SA authorised reseller or distributor.

If you are entering into this EULA agreement on behalf of a company or other legal entity, you must have the authority to bind such entity and its affiliates to these terms and conditions. If you do not have such authority or disagree with the terms and conditions of this EULA agreement, do not install or use the software or enter into this EULA agreement.

This EULA agreement shall apply only to software supplied by BioSystems, SA, regardless of whether other software is referred to or described herein. These terms also apply to any BioSystems, SA updates, supplements, Internet-based services, and support services for the software, unless other terms are provided alongside the relevant items upon delivery. If so, the terms provided upon delivery shall apply.

a) License Grant

BioSystems, SA hereby grants you a personal, non-transferable, non-exclusive license to use SPICA software on your devices per the terms of this EULA agreement.

You are not permitted to:

- Edit, alter, modify, adapt, translate, or otherwise change the software, whether in whole or in part, nor permit the software to be combined or incorporated into any other software, whether in whole or in part, nor decompiled, disassembled or reverse engineered, or that any attempt be made at any such actions.
- Reproduce, copy, distribute, resell, or otherwise use the software for any commercial purpose.
- Allow any third party to use the software on behalf of or for the benefit of any third party.
- Use the Software in any way that breaches any applicable local, national, or international law.
- Rent, lease, or lend the software.
- Use the Software for any purpose that Biosystems, SA considers to be a breach of this EULA agreement.

b) Intellectual Property and Ownership

The software (and the copyright and other intellectual property rights to the software, of whatever nature, including any modifications made thereto) are and shall remain the property of BioSystems, SA.

Biosystems, SA reserves the right to grant software usage licenses to third parties.

c) Termination

This EULA agreement shall come into effect from the date on which the software is first used and shall continue until terminated. You may terminate it at any time upon written notice sent to BioSystems, SA.

It will also terminate immediately if you fail to comply with any terms of this EULA agreement. Upon such termination, the licenses granted by this EULA agreement will immediately terminate, and you agree to stop all access to and use of the software. Any provisions that, due to their nature, shall prevail or continue, will survive any termination of this EULA agreement.

1. INTRODUCTION

1.2 End-User License Agreement

USER

d) Governing Law

This EULA agreement, and any dispute arising out of or in connection with this EULA agreement, shall be governed by and construed according to the laws of Spain.

e) Applicable software licenses

• Linux kernel - https://git.kernel.org/pub/scm/linux/kernel/git/stable/linux.git/tree/COPYING?h=v5.2.5
GPL-2.0 WITH Linux-syscall-note
• Armbian - https://github.com/armbian/build/blob/master/LICENSE - GNU General Public License v2.0
• Python 3.7 - https://docs.python.org/3/license.html - PSF LICENSE AGREEMENT

- Flask - BSD - https://github.com/opentracing-contrib/python-flask/blob/master/LICENSE
- Flask-Injector - BSD - https://github.com/alecthomas/flask_injector/blob/master/COPYING
- cketIO - MIT - https://github.com/socketio/socket.io/blob/master/LICENSE
- Gevent - MIT - https://github.com/gevent/gevent/blob/master/LICENSE
- Python-escpos - MIT https://github.com/BbotLLC/python-escpos/blob/master/LICENSE
- Eventlet - MIT - https://github.com/eventlet/eventlet/blob/master/LICENSE

• Material-ui - MIT - https://github.com/mui-org/material-ui/blob/master/LICENSE
• React - MIT - https://github.com/facebook/react/blob/master/LICENSE
• Redux - MIT - https://github.com/reduxjs/redux/blob/master/LICENSE.md
• Redux-saga - MIT - https://github.com/redux-saga/redux-saga/blob/master/LIC

1.3. Intended Use

The SPICA analyser is used to determine analyte concentrations in different kinds of samples, as well as matrices, according to its intended use:

NAME	CODE	Intended use	Intended users
SPICA	83100	The **SPICA non-IVD analyser** determines analyte concentrations by taking colorimetric, turbidimetric, and electrolyte measurements of different kinds of food (for example, meat or fish) and beverage samples (for example, wines, juices, milk), veterinary samples, and/or samples of biological cultures.	For professional use in analytical laboratories only.
	83100BQ	The **SPICA IVD analyser** is used to determine analyte concentrations by taking in vitro colorimetric, turbidimetric, and electrolyte measurements of different human body fluids or samples (for example, serum, urine, plasma, cerebrospinal fluid, total blood, seminal plasma, and faecal samples).	

The SPICA Analyser is optimised to work with BioSystems Reagents. Reagents not included in the SPICA validation performed in BioSystems SA will require thorough, detailed validation by users or laboratories.

USER

2. INSTALLATION

2.1 General

The elements that the user will find upon unpacking the analyser are listed below.
Users are encouraged to carry out a visual check to ensure that none of the elements has suffered visible damage during transportation.

1. Analyzer
2. Quick Installation Guide
3. Certificate of Analysis (Instrument Release Certificate)
4. Accessory Boxes (supplied in the same box as the analyser)

2.2. Location

Install the analyser in an optimal location. It occupies a minimum area of 100 x 62 x 65cm (w x d x h).

WARNING

POSITION THE EQUIPMENT IN A WAY TO ENSURE EASY ACCESS TO THE INTERRUPTOR AND THE OUTPUTS IN THE BACK AREA OF THE EQUIPMENT.

LEAVE A SPACE OF AT LEAST 10 CM BEHIND THE ANALYZER FOR THE AIR TO CIRCULATE FROM THE FAN INLET.

ENVIRONMENTAL CONDITIONS

Air conditioning
The analyser should be installed in an air-conditioned room to ensure that temperatures and humidity remain stable. The analyser must not be placed in the direct airflow of the air conditioner.

Heat emission
Maximum of 1706 BTU/h

Temperature
The location in which the analyser is installed must be kept at temperatures between 10° C and 35° C. It is vital that operating temperatures do not vary more than 2° C/h.

Humidity
The relative humidity of the air in the room where the analyser is installed must be less than 85%, with no condensation.

Lighting
Do not place the analyser below powerful light sources. Keep lighting as stable as possible and ensure that the analyser is not exposed to any flashing light. Direct sunlight should also be avoided.

Electromagnetic radiation
Ensure the analyser is not near any electromagnetic radiation sources (such as motors, centrifuging appliances, mobile phones) or heat sources.

Leveling
Move the analyser to its permanent location by pushing it gently.
Once it is in the final position, unscrew the four adjustable feet should it need to be levelled.

USER

2. INSTALLATION

2.3. Installing distilled water, washing solution, and waste containers

3 black bottles are provided on the front of the SPICA: two with a green cap and one with a red cap. The small one on the left with the green cap is the washing solution bottle (1L). The one in the middle with the red cap is the waste bottle (3L), and the bottle on the right with the green cap contains distilled water.

NOTE

To handle the bottles safely, remove them from their position and disconnect the tubes by pressing the fast connector fitting. Once filled with (type 2) distilled water or washing solution and/or the waste has been emptied, replace the bottles and re-connect the fast connector fitting.

BIOHAZARD

Ensure that the fast connector fitting is inserted correctly into the container cap. When inserted correctly, it will produce an audible “click.” If no click is heard, reinsert.

NOTE

Preparing the washing solution:

1. Unscrew the cap of the washing solution bottle.
2. Fill with 1L of distilled water.
3. Add 5 ml of the concentrated washing solution (code AC16434) and mix gently. Take care when handling the concentrated washing solution bottle to prevent the contents from splashing or spilling. Wear gloves and protective clothing when handling.
4. Screw on the cap, connect the tubes and position it correctly inside the analyser.

Options: If the SPICA has the option of external bottles, users need only deal with the front bottles containing Washing Solution and High-Contamination Waste. These should then be connected to the mains purified water supply or purified water tank and the waste container or general waste drain.

CAUTION

If a waste or purified water tank is used, users must monitor the waste/water levels of these external tanks.

2.4 Installing the sample and reagent racks

Each rack holds 15 reagent bottles and/or samples (they can be placed in the primary tube or the sample well). Bottle and sample positioning is fully adaptable to a laboratory’s needs.

The compartments are prepared for direct placement of the reagent bottles. The 60 mL bottles must be placed in the inner ring, while the 20 mL bottles may be placed on the inner, middle, or outer ring of the racks.

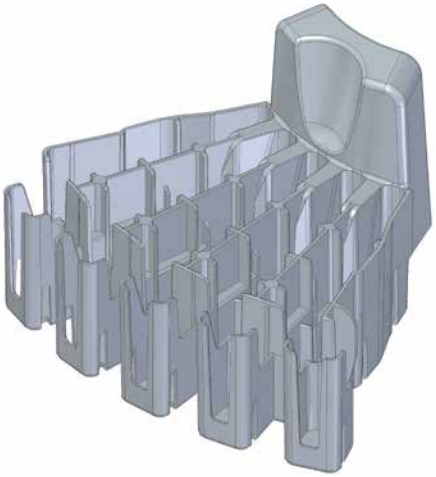
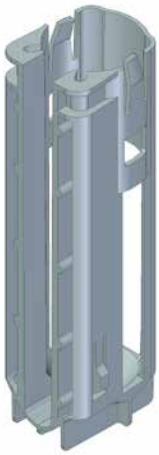
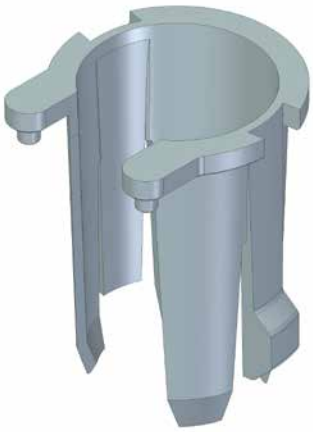
Use the adaptors to position the samples. Adapters can be placed in any position desired as long as the longitudinal opening faces outwards so as to allow for the barcode to be read by the laser scanner. When inserting, press hard until it makes an audible “click”, indicating the correct entry of the fastening tab. To remove adapters, pull outwards.

USER

2. INSTALLATION

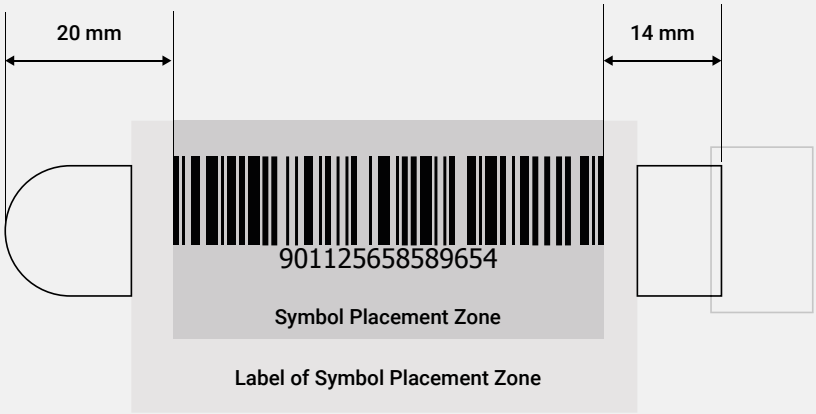
2.4 Installing the sample and reagent racks

The primary tubes with 14 mm and 15 mm diameters are inserted directly into the adapter.
To use the 13 mm diameter tubes and sample wells, the adapter must first be put in place.

RACK	MAIN ADAPTER	SAMPLE WELL ADAPTER
		

2.5 Specifications of the barcode labels

To ensure tube labels are adequately detected by the barcode reader, labels should comply with the following positioning specifications.



Positioning of the label on the primary tube

ADVICE: RESPECT THE BARCODE LABEL POSITION MARGINS.

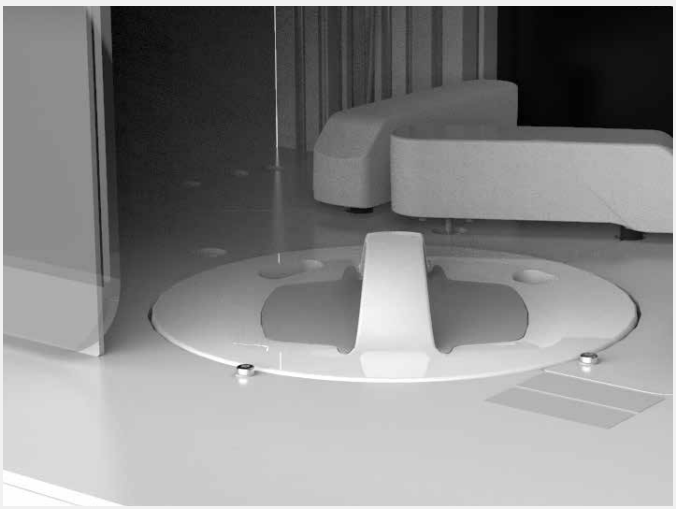
- It is advisable to leave a minimum width of 3.5 mm between the edge of the label and the beginning of the barcode.
- The minimum advisable barcode height is 10 mm.
- The label must be positioned so that the barcode is perpendicular to the tube axis. Label inclination must be less than ± 7.5% or ± 4.2 SDgr with respect to the sample container axis.
- It is advisable to use CODE128 for the barcode, but the scanner can also read CODE 39, CODEBAR, CODE 93, and INTERLEAVED 2 OF 5.

USER

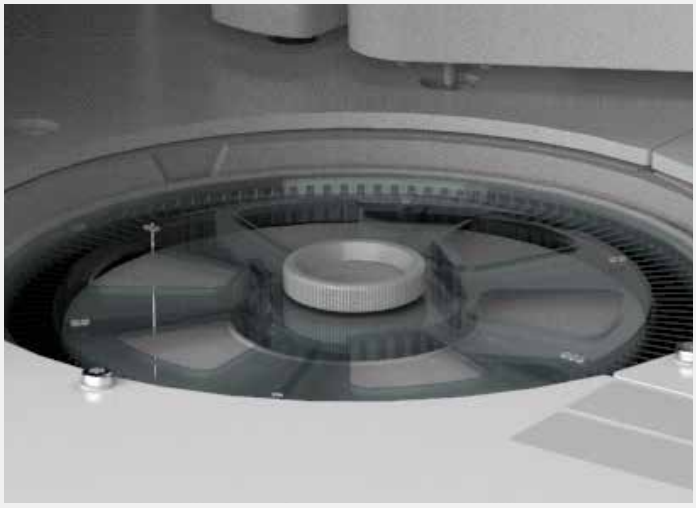
2. INSTALLATION
2.6. Installing the reaction rotor

- Install the reaction rotor before programming any operations by first switching the analyser on
- Open the main cover of the analyser and access the internal user area (**fig. 1**)
- Open the Reaction rotor Cover (**fig. 2**)
- Remove the rotor fixing screw (**fig. 3**)
- Take a rotor from the accessory box. Hold the rotor by the tabs and not the wells to avoid smudging the optical window.
- Insert the methyl acrylate rotor into the reaction rotor, ensuring that the rotor does not touch the tips of the wash station (if present in the analyser).
- The rotor can be fitted in one position only and must be correctly fitted into the support.
- Screw the rotor fixing screw as far as it will go.
- Place the cover of the rotor on its housing. There is only one correct position for the rotor.
- Finalise the rotor change operation by communicating the rotor changes to the analyser (**fig. 4**)

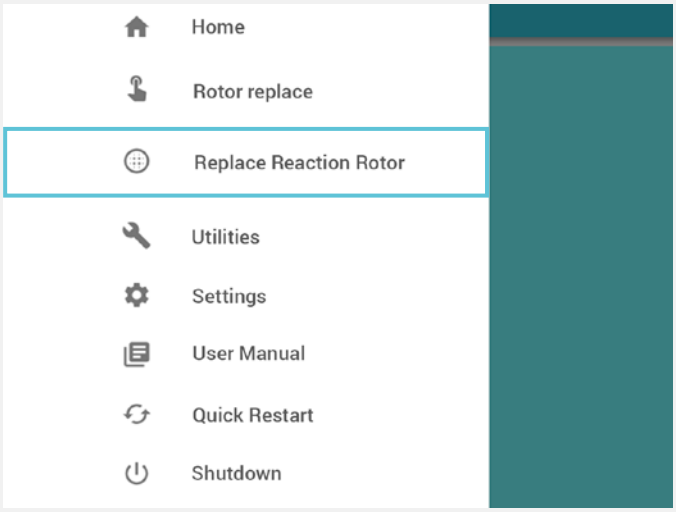
(**fig. 1**)



(**fig. 2**)



(**fig. 3**)



(**fig. 4**)

USER

2. INSTALLATION
2.7. Mains connection and start-up

Electrical Requirements

It is vital that the analyser is connected to an appropriate electricity supply. It must be as exclusive as possible and have an earth connection.

Mains plug cable: Use the mains plug cable supplied in the accessory box. Using a cable not supplied by the manufacturer may pose a safety risk.

Supply voltage: 115 V or 230 V

Supply frequency: 50 Hz or 60 Hz

Power: 450 VA

The analyser only works with the mains voltage specified on the device label.

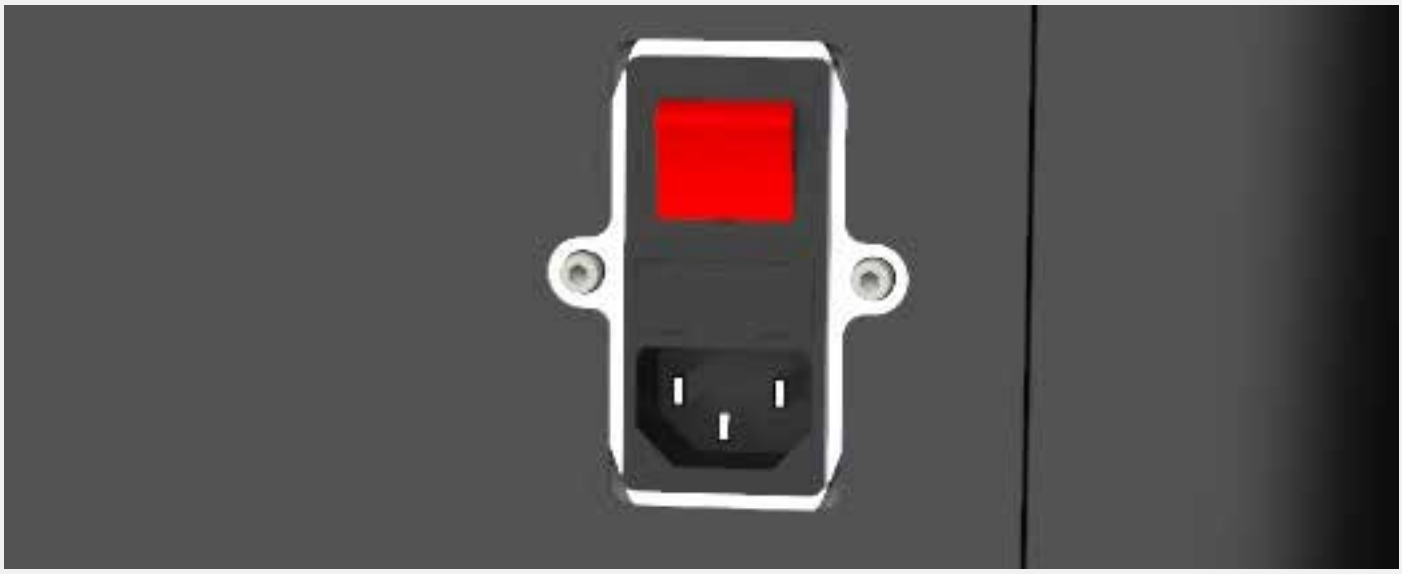
The voltage selector is located in an area to which the operator should not have access. As such, only the manufacturer or its technical service can select the voltage.

Working outside the voltage range could lead to equipment damage or malfunction. The electrical installation category must be II (surge voltage category).

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

Fuse characteristics: 6A 5x20mm CRYSTAL FAST BLOW FUSE

The fuse is located in the rear main switch:



Changing fuses: Remove the protective cover and replace both fuses with those supplied in the accessory box. Always replace both fuses at the same time.

An uninterruptible power source (UPS) is recommended so as to protect the analyser.
The recommended characteristics are:

Model: continuous UPS (on-line) | Power: 1.5 KW | Battery capacity: Over 15 min

Electrical connection: Proceed as follows

- Ensure that the main switch on the back is set to off (O).
- Connect the mains cable to the appliance first and the mains second.
- Place the switch in the on position (I).

2. INSTALLATION

USER

2.7. Mains connection and start-up

WARNING

Overvoltage and/or disturbances in the electrical network can lead to loss of functions. This may result in equipment stoppages, though these do not pose a risk to users.
In the event of a stoppage, restart the equipment.
It is the user's responsibility to ensure correct analyser electrical supply by connecting a UPS, voltage stabiliser, or similar, if necessary, to ensure normal equipment operations.

Ground connection

The analyser's ground connection is provided directly in the main power supply socket. Check that the socket's ground connection is correctly connected to the building's main ground connection.

Power sockets

Power cords are supplied with the analyser. Ensure that at least four wall sockets are available for use by the analyser.

Uninterruptible power supply (UPS)

Use of an uninterruptible power supply (UPS) is recommended in order to turn the system on safely. A UPS protects the system against micro-cuts or fluctuations in the power grid.

The minimum requirements for selecting the UPS are:

VOLTAGE	CURRENT	POWER	CAPACITY
115 V — 240 VA 50 Hz — 60 Hz	6 A	1.5 KW	Minimum of 15 min

2.8. SPICA communications

A device must be connected to allow for interactions with the SPICA analyser. Frequency Band 2.4 GHz.
• Computer • Tablet • Mobile phone

A. Wireless network:

To connect to the device for the first time you should link your device to SPICA:

Wi-Fi network: SPICA + SN (Ex: SPICA**125** for SN 83100 00**125**).
password: (12345678)
Once connected, use your device to work with the BioSystems SPICA.
Launch your **Chrome Browser and go to 172.24.1.1**

B. Ethernet Network

If connected via wi-fi, find out the BioSystems SPICA IP address. If the analyser is connected to your local network via ethernet, go to:

Home > Menu > Utilities > Show device IP

You can connect to any other device in the same local network using this IP address.

ADVICE: USERS MUST USE A CAT 5 SHIELDED ETHERNET CABLE

USER

2. INSTALLATION

2.9. First steps for operating the Analyzer

1. Replenish the washing solution and distilled water bottles on the front of the analyser. If your analyser is connected to the water mains, connect the water and waste tubes.

2. Connect the electric mains cable to the analyser.

3. Install a reaction rotor.

4. Close all covers.

5. Turn on the analyser. Wait until you hear a beep. The analyser will be warming up.

6. Select one of the two water inlet options, depending on the water inlet installation.

(should your analyser use mains water).

7. Perform 5 primes fluidics to ensure that the internal water tank fills up and that the fluid system is correctly primed when you start up the analyser for the first time.

8. Fill in the controls and calibrator fields in the Test Configuration option for the tests to be used:

Home > 04. Test Configuration - Technique > Controls | Calibrator

9. Add blanks, calibrators, and controls to your list.

Home > 01. Setup Measures > Add Calibration

2.10 Safety precautions during operations

To keep the reagents refrigerated, do not turn off the analyser (if your analyser contains a cooler system). Select sleep mode and leave the analyser switch in the ON position.

Ensure that the sample, reagent, and reaction rotor cover are ON while the appliance is operational. The analyser will not perform any operation if any of these covers are not in position.

If your analyser has a Barcode Reader, make sure the barcode labels on the sample tubes are properly affixed and centred. THEY MUST BE CORRECTLY ALIGNED ON THE TUBE. If the label barcode only has a few digits, position it lengthwise and centrally. Do not place it on the top of the tube. Position the sample tube with the barcode label facing outwards.

The equipment must be installed and operated at a minimum distance of 20 cm from the human body.

NOTE

Do not duplicate any sample tube identification code on the barcode labels during the same session.

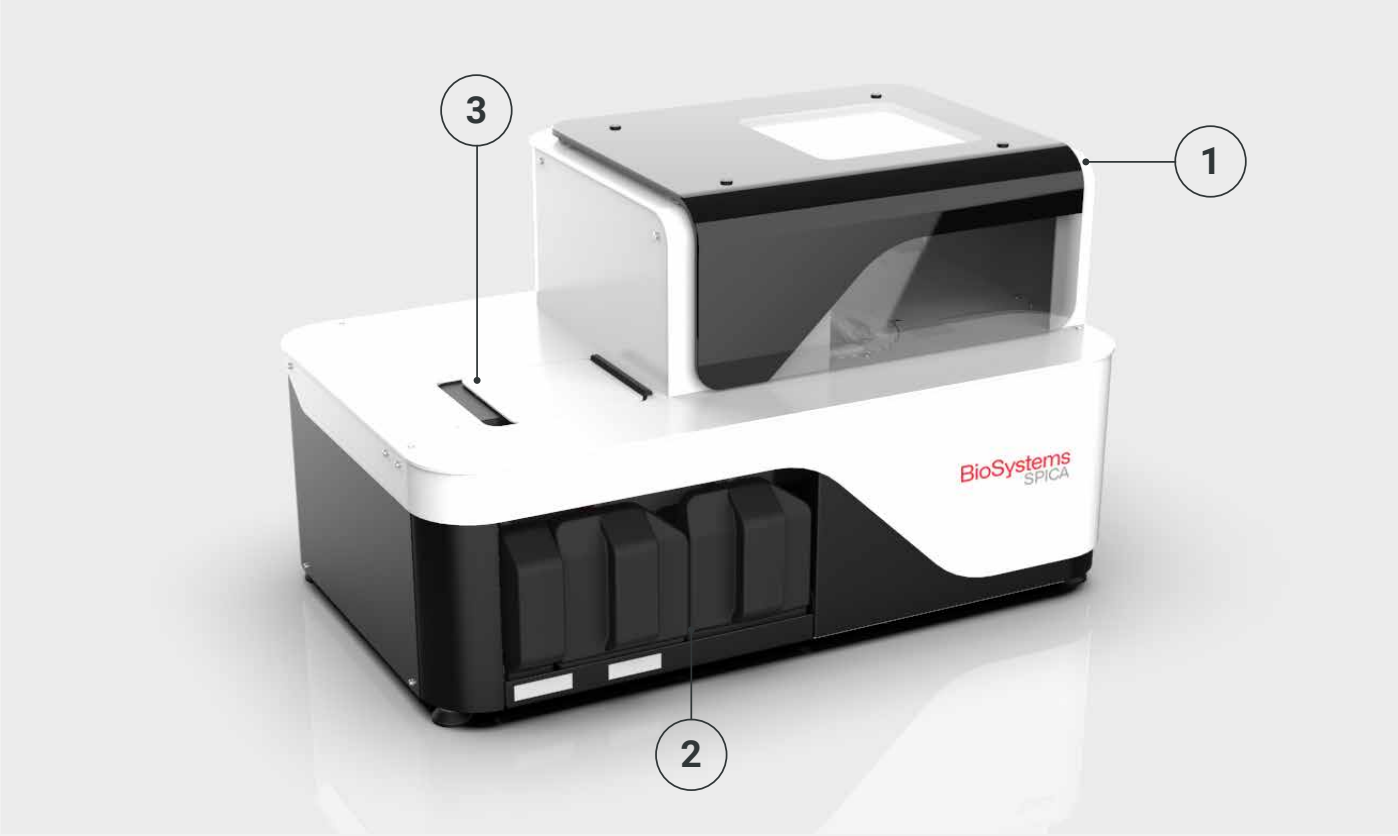
The sample tubes and reagent bottles positions must be maintained when the Automatic Barcode Verification is not being used before starting or during the work session.

USER

3. DESCRIPTION

3.1 Component Description

The SPICA analyser's various components are marked and numbered in the following figures:



1. Main cover

This covers the working surface of the analyser. Open this cover to access the reaction rotor. This cover must be kept closed to ensure safe analyser operations. It is fitted with an open or closed casing detector. The analyser will stop if the cover is removed when not in Standby mode.

2. Waste containers, distilled water, and washing solution

The analyser provides 3 containers used to store washing solution, waste, and distilled water. All containers are located and accessible on the front of the analyser.

a) WASHING SOLUTION: 1L capacity with container level detected via weight.

b) WASTE: 3L capacity with container level detected via weight.

c) DISTILLED WATER: 3L capacity with container level detected via weight.

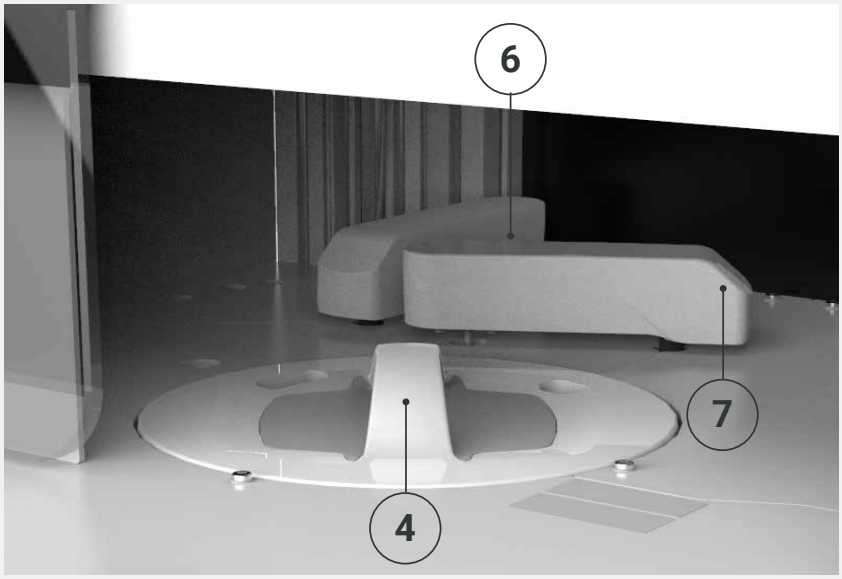
3. Sample and reagent rotor door

Provides access to the sample and reagent rotor. The cover is fitted with a detector that enables the analyser to detect whether the door is open or closed.

USER

3. DESCRIPTION

3.1 Components Description



4. Reaction rotor cover

Provides access to the reaction rotor. This rotor is where the reactions take place, and the photometric readings are taken. This rotor has a regulated temperature of 37 C°. The cover is fitted with a detector that allows the analyser to whether the cover is open or closed.

5. Reaction rotor

The reaction rotor consists of a regulated channel containing a high-quality optical plastic rotor that allows for the transmission of UV light. It can be placed in 120 positions. The reagent and sample are dispensed into each cuvette. While the mixture is reacting, an optical reading is taken to obtain the absorbance level. The reaction volume is between 180 µL and 440 µL. The rotor is maintained at a stable temperature of 37 °C by a Peltier-based thermostatic system.

6. Stirring arm

The analyser contains one arm, which is used to stir the reaction. This arm has a small blade that rotates inside the reaction cuvettes to encourage mixing and initiate the reaction correctly. Once it has stirred the mixture, the stirring arm moves to the washing station, where the blade is washed.

7. Dispensing arm

The analyser contains 1 arm used to dispense the samples and reagents. The arm contains a wash station used to wash the interior and exterior of the tip. The arm contains a level detection system. The analyser also contains a vertical collision detection system used to prevent damage to the tip in the event of an accidental collision.

If your analyser has a clot detector, the system warns if the tip is blocked. The blockage could be caused by clotted blood in the sample.

Minimum and maximum volumes dispensed by the arm:

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

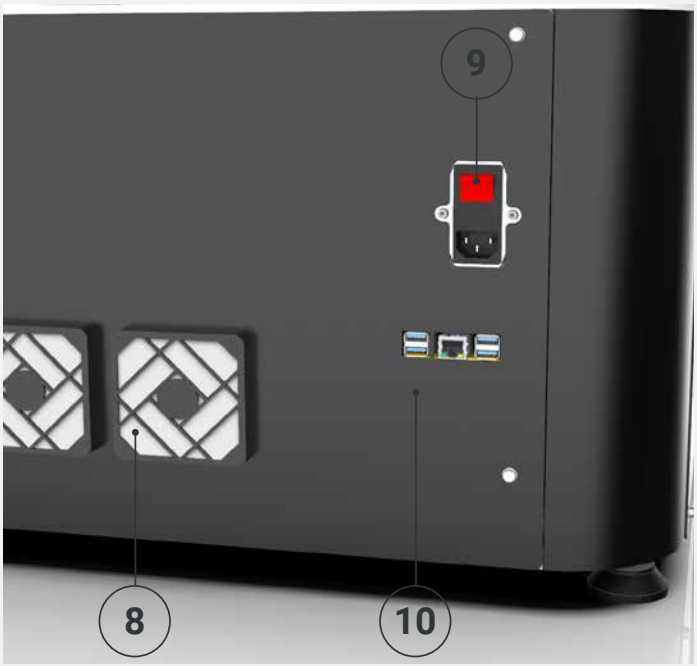
8. Fans and filters

The analyser has 2 inlet fans with filters. These fans help maintain adequate internal analyser temperatures. Air inlets must be kept free of obstacles.

USER

3. DESCRIPTION

3.1 Components Description



9. Main switch and electrical inlet

The Analyzer has one filter with the general electrical inlet and the general switch. This switch contains 2 fuses to avoid electrical damage at the analyzer.

10. CPU ports

The analyser has 4 USB type-A ports and an Ethernet port.

11. Sample and reagent rotor

The sample and reagent rotor consists of a removable set of racks containing positions into which sample tubes, calibrators, controls, and reagents can be inserted. The system is completely flexible, and samples or reagents can be inserted in any position.

SAMPLE AND REAGENT RACK
There are 7 racks:

- With 15 positions for samples or 20mL bottles
- 5 positions for 60mL and 5 positions for samples or 20ML bottles
- The reagent bottle and sample barcodes can be read in the two external rings.

POSITIONS
Various possible combinations are available. These can be configured using different rack setups:

- 105 sample positions as maximum
- 105 reagents in 20mL bottles as maximum
- 35 reagents in 60mL bottles as maximum

SAMPLE TUBES
To position the tubes, an adapter must first be inserted. Primary tube dimensions:

- Minimum diameter: ⌀ 12 mm with an extra adapter
- Maximum diameter: ⌀ 16 mm
- Minimum height: 70 mm
- Maximum height: 100 mm

USER

3. DESCRIPTION
3.1 Components Description

SAMPLE WELLS

To insert and position the sample wells, an accessory is provided with the analyser with which to adapt the diameters.

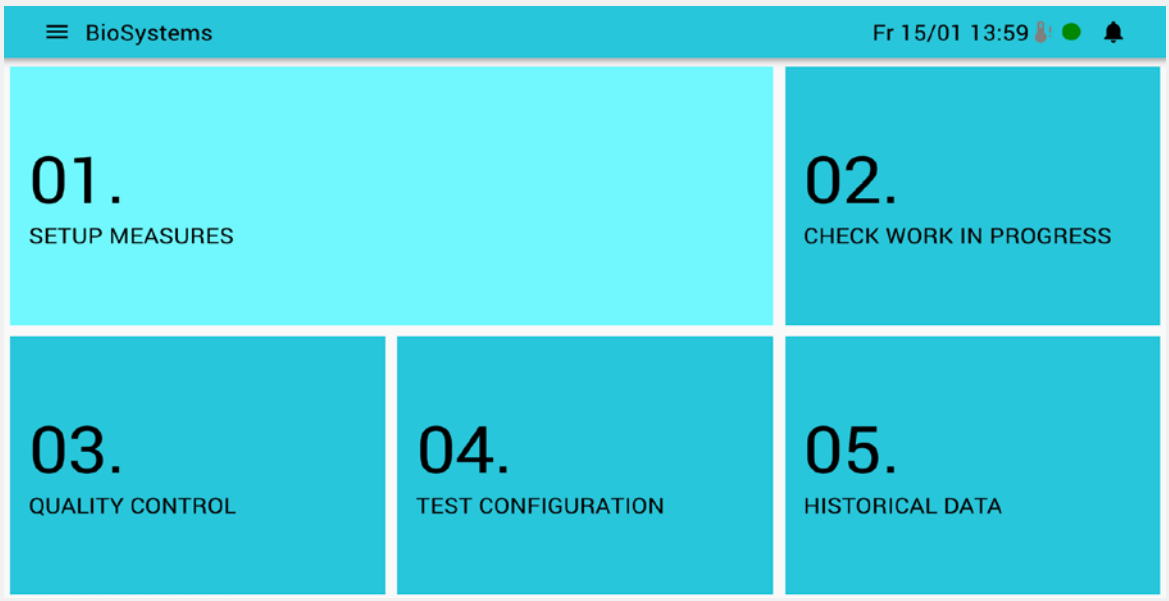
REAGENT BOTTLES

2 types of bottles can be inserted. The volumes of the bottles are as follows:

- 60 mL, to be positioned in the inner ring only.
- 20 mL, to be positioned in the inner and the outer rings.

12. APP

A simple and intuitive app enables you to access all BioSystems SPICA features.



USER

4. GENERAL OPERATING

This product can run different concentration tests. Users can follow the workflow to establish and configure the samples for analysis, place the samples and reagents into the instrument, and execute and view the result. The samples analysed can be taken from patients, quality control or calibration liquids.

The APP includes a USER MANUAL to help users understand the workflow.

5. MEASUREMENT PROCEDURES

5.1 General

This chapter describes the analyser's analysis modes and the calculations made to obtain analytical results, i.e., the concentration values of sample analytes. The various formulas used are indicated in each case. Controls are processed identically to patient samples in all calculations.

Symbols used in the formula:

SYMBOL	DESCRIPTION
ABS	Absorbance value taken in one instant of the reaction
A	Absorbance value calculated based on the analysis mode chosen
[...] **λprincipal**	Absorbance value at the main wavelength
[...] **λreference**	Absorbance value at the reference wavelength
[...] **L1**	Absorbance value in time L1
[...] **L2**	Absorbance value in time L2
DABS	Increase in absorbance
VM	Sample volume
VR1	Volume of reagent 1
VR2	Volume of reagent 2
C	Analyte concentration
F	Factor
ABlank	Blank absorbance
ACalibrator	Calibrator / Standard absorbance
Asample	Sample absorbance
Ccalibrator	Known calibrator / standard concentration

5.2 Calculation of the absorbances

The absorbance calculation depends on the analysis mode programmed.
The analyser has the following analysis modes:

ANALYSIS MODE
Endpoint mono-reagent
Endpoint bireagent
Differential mode
Fixed time monoreagent
Fixed time bireagent
Kinetic monoreagent
Kinetic bireagent

5. MEASUREMENT PROCEDURES

USER

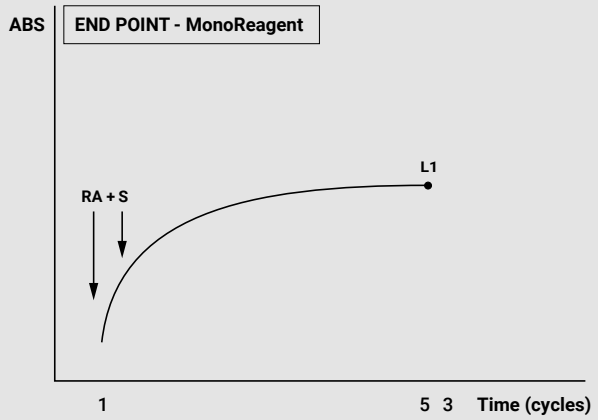
5.2 Calculation of the absorbances

This product is able to perform different concentration tests. Users can follow the workflow to establish and configure the samples for analysis, place the samples and reagents into the instrument, and execute and view the result.

Each analysis mode executed by the analyser is shown in detail below, with a graphic interpretation of the dispensing and reading points and the calculation made to obtain the absorbance. Each of the analysis modes above may be performed so that it is ascending or descending. If the test is ascending, the evolution of absorbance increases over time. It has an ascending form. If the test is descending, the evolution of the absorbance decreases over time. It has a descending form. To obtain positive absorbance values using these calculation methods, the result is multiplied by -1.

1. ENDPOINT MONO-REAGENT

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



First, reagent A is dispensed, and the sample is dispensed in cycle 1; it is stirred, and the reaction starts. Once it is balanced, the reading is taken; L1. The change in absorbance is directly proportional to analyte concentration.

Endpoint mono-reagent calculation method representation: The absorbance reading can be taken at one wavelength (monochromatic) or two wavelengths (bichromatic). Bichromatic readings are normally used to eliminate the influence of the cuvette in the absorbance reading. If the reaction is monochromatic, the measurement is taken in time L1 at one wavelength.

$$A = ABS \begin{matrix} \lambda main \\ L1 \end{matrix}$$

If the reaction is bichromatic, two readings are taken at time L1. Each of the readings is taken with a different wavelength. The absorbance value is the difference between the two wavelengths.

$$A = ABS \begin{matrix} \lambda main \\ L1 \end{matrix} \quad - \quad A = ABS \begin{matrix} \lambda reference \\ L1 \end{matrix}$$

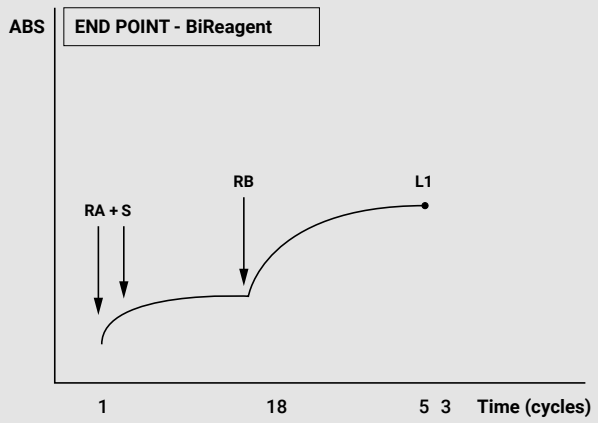
USER

5. MEASUREMENT PROCEDURES

5.2 Calculation of the absorbances

2. ENDPOINT BI-REAGENT

This operating mode is used, for example, if the working reagent stability is very short; in such a way that it is the analyzer that prepares the working reagent in each preparation. In this calculation mode, a single reading is made and the reaction starts when the second reagent is dispensed.



Firstly, reagent A is dispensed in the sample in cycle 1, and the next cycle is stirred. Then reagent B is dispensed in cycle 18 and stirred, and the reaction begins. Once it is balanced, the reading is taken, L1. The change in absorbance is directly proportional to analyte concentration.

The absorbance calculation may be monochromatic or bichromatic. If the reaction is monochromatic, the measurement is taken at time L1 at one wavelength.

$$A = ABS \begin{matrix} \lambda main \\ L1 \end{matrix}$$

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

$$A = ABS \begin{matrix} \lambda main \\ L1 \end{matrix} \quad - \quad A = ABS \begin{matrix} \lambda reference \\ L1 \end{matrix}$$

3. DIFFERENTIAL MODE

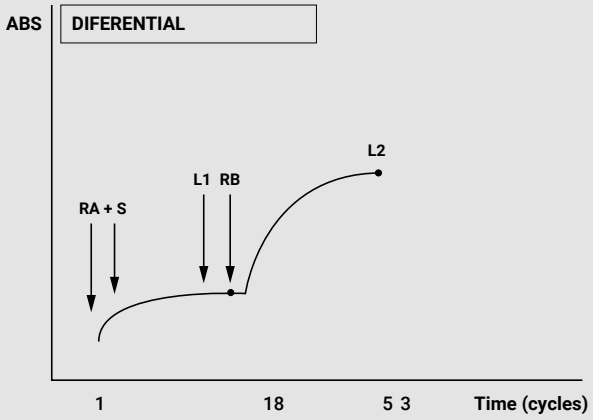
Differential tests consist of two readings being taken. The first is taken before reagent B is dispensed, and the second once the reaction is complete. These tests are used to eliminate potential turbidity effects in the sample and the potential absorbance levels of reagent A.

First, reagent A and the sample are dispensed in the initial preparation. In the next step, it is stirred, and the reaction starts. Before dispensing reagent B, the L1 reading is taken. Reagent B is dispensed a few cycles later and stirred in the next cycle when the second part of the reaction begins. When the second reaction is balanced, reading L2 is taken.

5. MEASUREMENT PROCEDURES

5.2 Calculation of the absorbances

USER

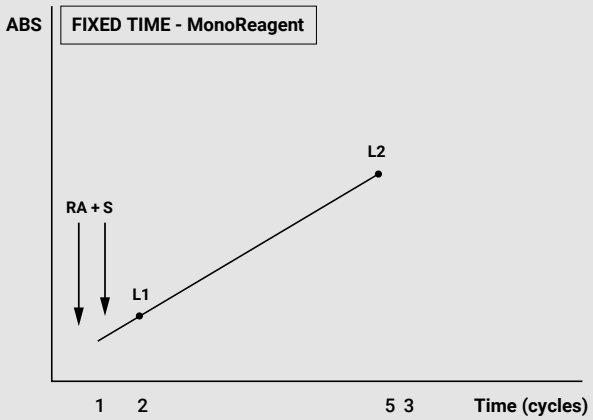


The following formula is applied to calculate the absorbance:

$$A = ABS^{\lambda main}_{L1} - ABS^{\lambda main}_{L1} * \frac{V_M + V_{R1}}{V_M + V_{R1} + V_{R2}}$$

4. FIXED TIME MONO-REAGENT

In tests programmed with the fixed time calculation method, the reaction speed is directly proportional to the substrate consumed. As the substrate is consumed, the reaction speed is reduced, leading to a change in absorbance. Thus, in a fixed time interval, the change in substrate concentration is directly proportional to the initial concentration. In the time interval, the change in absorbance is proportional to the analyte concentration. In this calculation mode, two readings are taken, and the resulting absorbance is the difference between both readings.



USER

5. MEASUREMENT PROCEDURES

5.2 Calculation of the absorbances

First, reagent A is dispensed, followed by the sample. It is stirred, and the reaction commences. Reading L1 is taken, and after a few cycles, reading L2 is taken. The absorbance is the difference between the readings.

The absorbance calculation may be monochromatic or bichromatic. If the reaction is monochromatic, it is only measured at one wavelength, and the absorbance calculation is performed using the following formula:

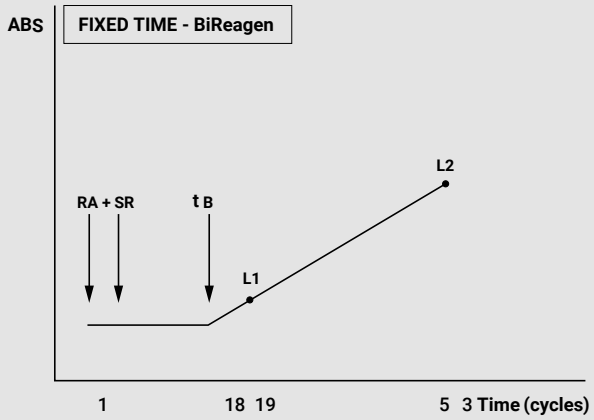
$$A = ABS_{L2} - ABS_{L1}$$

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

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

5. FIXED TIME BI-REAGENT

In this operating mode, the analyser prepares the working reagent in each preparation. Firstly, reagent A is dispensed into the sample. It is stirred in the next cycle. Then reagent B is dispensed in a few cycles and stirred, and the reaction begins. Reading L1 is taken, followed by reading L2 after a few cycles. In this calculation mode, two readings are taken, and the resulting absorbance is the difference between both readings.



The absorbance calculation may be monochromatic or bichromatic. If the reaction is monochromatic, it is only measured at one wavelength, and the absorbance calculation is performed using the following formula:

$$A = ABS_{L2} - ABS_{L1}$$

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

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

USER

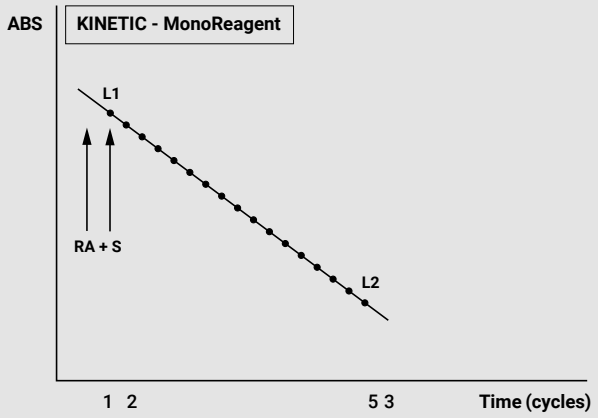
5. MEASUREMENT PROCEDURES

5.2 Calculation of the absorbances

6. KINETIC MONO-REAGENT

In tests programmed with the kinetic calculation mode, the reaction speed remains constant during the reaction process. As a result, the absorption of the analytes at certain wavelengths change uniformly. The change in absorbance per minute (DABS/min) is directly proportional to the concentration of the analytes. The kinetic method is used to measure enzymatic activity. For this calculation mode, initial and end times are programmed. Between these two times, several readings are taken, and the linear regression of the readings is calculated. The resulting absorbance is the linear regression slope value. In addition, the linearity of the readings is checked using a calculation of the correlation coefficient.

If the correlation coefficient is **r < 0.9** then the result of the kinetic reaction is non-linear.

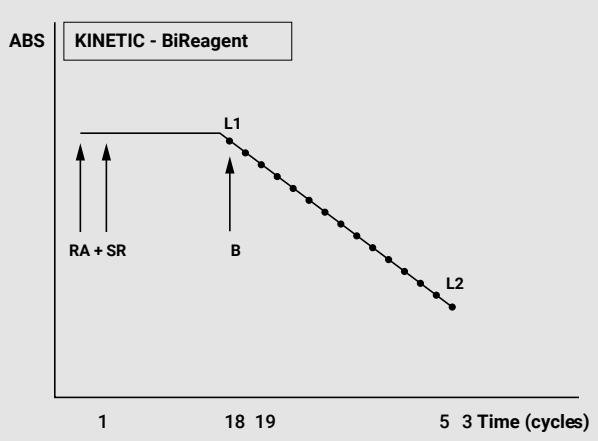


First reagent A and the sample is dispensed in cycle 1. It is stirred, and the reaction starts. The analyser starts to take the readings from time L1 to time L2. The absorbance calculation is as follows:

$$A = \left[\frac{\triangle ABS}{min} \right]^{\lambda main}$$

7. KINETIC BI-REAGENT

In this operating mode, the analyser prepares the working reagent in each test.



USER

5. MEASUREMENT PROCEDURES

5.2 Calculation of the absorbances

Firstly, reagent A is dispensed into the sample in cycle 1. It is stirred in the next cycle. Then reagent B is dispensed in a few cycles and stirred, then the reaction starts. The analyser starts to take the readings from time L1 to time L2. The absorbance calculation is as follows:

$$A = \left[\frac{\triangle ABS}{min} \right]^{\lambda main}$$

5.3 Concentration Calculation

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

1. Calibration function

Calibration function establishes the ratio between the calculated absorbance values and known sample analyte concentrations. This ratio may be linear or non-linear. One or several samples with a known analyte concentration are measured to calculate the calibration function, and a calibration curve is obtained.

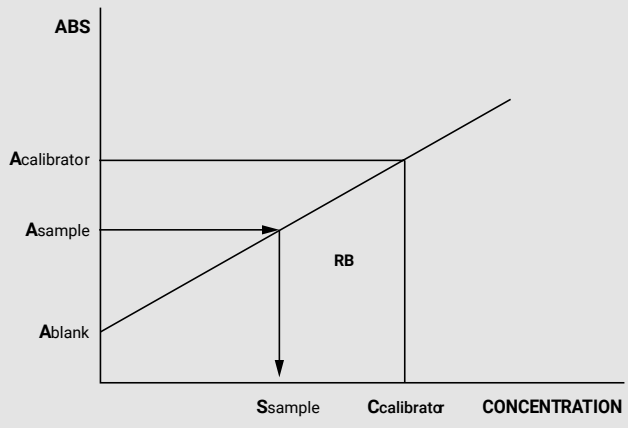
If the ratio is linear, only one calibrator is measured, and the calibration line is calculated. If the ratio is non-linear, several calibrators will be required, and the calibration curve will be calculated with a regression procedure. It also measures the blank - the signal measured by the analyser in the absence of an analyte. In the calibration curve, the blank will correspond to a concentration point equal to zero.

2. Blank

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

3. Calibrator/Standard

The calibrator is a sample with the known concentration of the analyte to be determined. It is a standard or reference material. To correctly measure the calibrator blank absorbance, the same analysis mode must be used as that used with the samples. If the ratio between the analyte absorbance and its concentration is linear, then the calibration function is a line. As such, it will only be necessary to measure the blank and a calibrator.



5. MEASUREMENT PROCEDURES

USER

5.3 Concentration Calculation

For standard linear functions, the blank absorbance ordinates coordinates are taken as the source and inverse of the factor as the slope. The factor is calculated as follows:

$$F = \frac{\mathbf{C}\text{calibrator}}{\mathbf{A}\text{calibrator} - \mathbf{A}\text{blank}}$$

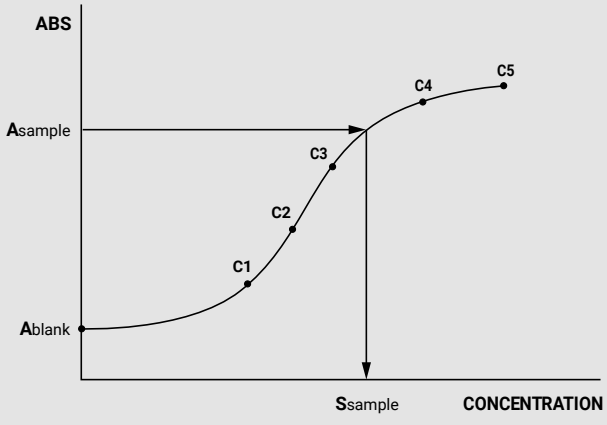
And the following formula is used to calculate the concentrations:

$$\mathbf{C}\text{sample} = F^{*} (\mathbf{A}\text{sample} - \mathbf{A}\text{blank})$$

For calibration functions that are non-linear, several known concentration calibrators are used to approximate the curve with regression functions. The following regression functions can be programmed:

TYPE OF FUCTION	DESCRIPTION
Polygonal	Joins each point by a line
Linear regression	Makes a linear regression with all the points
Parabolic regression	Makes a parabolic regression with all the points
Spline	Plots a curve that passes through each point

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



5.4 Internal Quality Control

Many commercial materials for internal control have assigned values. Several concentration values that correspond to different measuring methods are provided for each component. In addition, each value is accompanied by an “admissible” value (Manual mode).

USER

5. MEASUREMENT PROCEDURES

5.4 Internal Quality Control

1. Basis

The result obtained for a control material is compared with an admissible value interval, and a decision is made:

- The result is within the interval: It is considered that the measuring procedure maintains its accuracy within certain limits (it is stable), and the results of the series are accepted.
- The result is outside the interval: It is considered that the measuring procedure returns an error that is above tolerable levels, and the results of the series are rejected.

2. Admissible value interval

The best way to obtain the admissible value interval in the control material is through a statistical estimate:

- It is necessary to have enough of a control material to meet the requirements for a long timeframe
- Perform at least 20 measurements, each one on a different series, using a controlled measuring procedure.
- Calculate the mean value (Xm) and standard deviation (s) of the results obtained. The first estimates should be reviewed if more results are available.

Dispersed results are obtained as a result of imprecise measuring procedures between series. This dispersion must have a normal distribution characterised by the mean values and the standard deviation.

It is therefore possible to establish a value interval with a known probability of the result falling within that interval. As the probability of this being the case must be high, it is common to select intervals between Xm ± 2s and Xm ± 3s.

The criteria selected with which to establish the admissible value interval is a decision-based criterion or a control rule. Internal control is based on the idea that it is not very likely that a result outside the established limits will be obtained.

Control rules based on Gaussian statistics are usually represented by the expression Ans, where “A” is the number of control results, and “ns” is the admissible limit selected. Different control results belonging to one control material or more may also be used. Likewise, the control results may have been obtained in one series or in various consecutive series.

Rules that are more complex may be entered with various control results.
Those used most often are as follows:

- 22s Series rejected when 2 results are obtained that exceed 2s of the same type (positive or negative).
- 4-1s Series rejected if 4 results are obtained that exceed 1s of the same type.
- 10X Series rejected if 10 results are obtained on the same side of the mean.
- R4s Series rejected if one result exceeds the +2s limit and the other exceeds the –2s limit.

The rules for several control results may also provide clues as to the possible cause of increased errors. Rules 22s, 4-1s, and 10X are particularly sensitive to systemic error, whereas rule R4s are better at detecting increases in imprecisions.

Another interesting option is combining several rules in a logical or algorithmic sequence.
The best-known combination is known as the Westgard algorithm, or rules for two control results. In some cases, it is impossible to make a statistical estimate of the dispersion of results and apply control rules because no accessible control materials are available or the measuring procedure is not used very often. In such situations, it is common to use a control material provided by the supplier of the reagents or measuring system, for which an admissible value interval is indicated (Manual mode).

USER

5. MEASUREMENT PROCEDURES
5.4 Internal Quality Control

3. Selection of control rules

The following objectives must be considered when selecting the rules to be used in internal control:

- Simplicity: Use the least possible number of materials and control rules.
- Low probability of false rejections (≤ 2%, preferably < 1%).
- High likelihood of detecting significant increases in error.

The lower the value interval of the control rule, the greater the probability of detecting increased errors.

The idea is to provide for the lowest possible number of false alarms, as well as guiding error-detections considered important, based on the understanding that smaller errors may occur (tolerable errors) that are not detected.

6. MAINTENANCE
6.1 Maintenance activities and frequency

The following list shows the maintenance operations and frequency with which they should be executed:

Operations for the start of the day

1) Execute 1 prime fluidics when starting up the analyser

Operations for the end of the day

1) Switch off the analyser by initiating shutdown via the App
2) Empty the high contamination bottle

Operations to be executed weekly

1) Clean the outside of the BioSystems SPICA analyser
2) Clean the inside of the reagent and sample rotor vessel
3) Clean the stirrer paddle and the probe with a cloth soaked in washing solution

6.2 Cleaning the analyzer

GENERAL CLEANING OF COMPARTMENTS

Use a damp cloth and neutral soap to clean analyser surfaces and the rotor's internal compartments.

EMPTYING AND CLEANING THE HIGH CONTAMINATION WASTE BOTTLE

The waste container is supplied with a fast connector fitting.

- Press the fast connection fitting on the cap and take the container out of the analyser.
- Unscrew the container cap.
- Empty the container.
- Screw on the container cap, insert the tube with the fast connector and place the container in its housing inside the analyser.

Ensure that the fast connector fitting is inserted correctly into the container cap. When inserted correctly, it will produce an audible "click." If no click is heard, reinsert.

Dispose of the waste per the applicable national or local government legislation.

USER

6. MAINTENANCE

6.2 Cleaning the analyzer

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

CLEANING THE SAMPLE AND REAGENT ROTOR (ONLY IF NEEDED)

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

- Turn off the analyser.
- Wear gloves and protective clothing when cleaning spills.
- Remove all racks from the analyser by hand.
- Mop up the spilt substance with a damp cloth.

CLEANING THE BARCODE READER WINDOW

- Turn off the analyser.
- Open de Reagents and samples door and remove the racks one by one.
- Clean the interior window with a damp cloth.

FILLING THE WASHING SOLUTION BOTTLE

- Press the fast connection fitting on the cap and take the container out of the analyser.
- Unscrew the washing solution bottle cap.
- Fill with 1 L of distilled water.
- Add 5 ml of the concentrated washing solution (AC16434 code). Take care when handling the concentrated washing solution bottle to prevent the contents from splashing or spilling. Wear gloves and protective clothing when handling.
- Screw on the cap with the tube and place it in its housing inside the analyser. Plug the fast connector into the cap and ensure it clicks into place.
- Press the washing solution filling button that tells the analyser to prime the system.

NOTE

TO CLEAN THE SPICA COVERS AND VISIBLE PARTS, USE A SOLUTION OF WATER AND SOFT SOAP.

USER

7. TROUBLESHOOTING GUIDE

7.1 Pre-analysis and preparation of additional solutions

REAGENTS

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

- Before using the reagent for the first time, check the test programming against the programming supplied with the reagent.
- If content reagents must be homogenised, do so gently, without shaking them. If air bubbles have formed on the reagent surface, remove them.
- When changing the reagent lot, make sure you perform the blank and calibrate the test.
- It is recommended that a reagent blank is performed when changing the reagent bottle and/or following the frequency established by the IFU.
- Condensation could form on the reagent bottle walls, on the bottle's neck or barcode labels. If condensation is present, remove it with an absorbent paper towel.

WASHING SOLUTIONS

Three types of washing solutions are supplied with the equipment: a washing solution (WS) used for the internal washing of the tips and reaction rotor, an acid washing solution (WS1) and an alkaline washing solution (WS2) used to prevent contamination.

The washing solution (WS) is prepared in the 1L bottle located on the front left of the analyser.

The other types of washing solutions are installed in the reagent rotor. It is supplied in reagent bottles.

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

7.2 Alarms

The Biosystems SPICA App communicates all the issues that need user attendance. The user must proceed to help the analyzer to keep working.

USER

8. TRANSPORT, HANDLING, AND STORAGE

8.1 Transport and reshipment

The analyser weighs 75 kg. The analyser is supported by legs made of hard plastic, which can be slid across a smooth surface to gain access to the rear of the analyser.

If it is necessary to reship the analyser or move it using a haulage vehicle, the polar arms must be immobilised, and the analyser must remain in its original packaging to ensure it is not damaged. To repack the analyser, follow the instructions on the **quick installation guide**, in reverse order.

Use mechanised means (forklift truck or pallet jack) to transport the packaged analyser.

8.2 Handling and storage

Please note that the analyser is a precision instrument and must therefore be handled with special care.
If the analyser must be stored for long periods of time, heed the following recommendations:

- Empty the high contamination waste tank and washing solution tank.
- Dispose of the reaction rotor.
- Protect the analyser from dust and environmental damage, direct sunlight, and excessive damp.

Environmental conditions for storage:

Store in temperatures between 10 °C and 40 °C

Humidity conditions during storage < 85% with no condensation

9. WARRANTY AND LICENSE

The SPICA analyser is designed to perform biochemical and turbidimetric analyses.

Its operation is optimised for the BioSystems Reagents brand. For information about all the measuring procedures available, please contact your preferred distributor.

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

Contact your distributor for information about:

- Training on analyser use
- After-sales Service Request Protocol

10. TECHNICAL SPECIFICATIONS

USER

GENERAL CHARACTERISTICS

Speed	150 prep/h. (Monoreagent) Consider that speed may vary depending on pre-treatment procedures or whether the procedure is monoreagent or bireagent.
Analysis principles	Photometry, turbidimetry
Analyzer type	Random access continuous sample loading

SAMPLE AND REAGENT MANAGEMENT

Sample and reagent rotor capacity	105 positions (7 racks x 15 positions)
Barcode reader	Optional
Number of samples with barcodes	70
Size of primary tubes	12 mm to 16 mm diameter (max. height 100 mm)
Sample well	Sample well diameter 13.5 mm
Reagent bottle volume	20 ml, 60 ml , 10ml, 40ml
Refrigerated reagents	Optional
Refrigerator temperature range	10 °C under room temperature (at room temperature of 21 °C)
Type of sample pump syringe	Low-maintenance, ceramic piston
Piston diameter	8 mm
Dispensed sample volume	2 uL to 80 uL
Dispensing resolution	0.1 uL
Dilution ratio	1:1 to 1:400
R1 reagent volume	10 uL to 500 uL
R2 reagent volume	10 uL to 500 uL
Dispensing resolution	0.1 uL
Level detection	Yes
Washing of tip	Interior and exterior
Clot detector	Optional
Vertical collision detector	Yes
Thermostated tip	Yes

USER

10. TECHNICAL SPECIFICATIONS

REACTION ROTOR

Minimum reaction volume	180 mL
Maximum reaction volume	440 mL
Number of cuvettes	120
Cuvette material	UV methacrylate
Type of incubation	Dry
Dispensing time for second reagent	Relative to RA dispensing (Variable)
Reaction cuvette temperature	37 °C
Accuracy of the temperature	±0.2 °C
Temperature stability	±0.1 °C
Stirrers	1

OPTICAL SYSTEM

Light source	LED + Hard Coating Filter
No. of wavelengths	8 minimum
Wavelengths	Ref.83100: 280-340-405-420–505–520–560–600–620-635-750 nm Ref.83100BQ: 340-405-480–505–535–560–600–635–670-750 nm
Filter bandwidth	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

DIMENSIONS AND WEIGHT

Dimensions (Width x Depth x Height)	100 cm x 62 cm x 65cm
Weight	75 Kg

USER

10. TECHNICAL SPECIFICATIONS

ENVIRONMENTAL REQUIREMENTS

Room temperature	10 °C to 35 °C
Relative humidity	< 85% with no condensation
Maximum altitude	< 2 000 m
Contamination grade	2
Transportation, storage temperature	0 °C to 40 °C
Transportation and storage humidity	< 85% with no condensation

WIRELESS REQUIREMENTS (WIFI)

Type of Band	Band Frequency 2.4 GHz. Supports IEEE 802.11 b

ELECTRICAL REQUIREMENTS

Mains voltage	115 V or 230 V
Network frequency	50 Hz or 60 Hz
Electric power	450 VA
Fluctuations of the mains voltage	±10

FLUID REQUIREMENTS

Type of water	Purification type II (NCCLS)
Water tank	3 L
Waste tank	3 L
Washing solution tank	1 L

UNINTERRUPTIBLE POWER SUPPLY (UPS)

UPS ref. AC17262	Optional / external

OPTIONAL TABLE

Single table	AC17345

INSTALLATION GUIDE

This document provides information regarding preparation of the site for installation and information about the necessary prerequisites for correct installation and operation. Users are responsible for preparing the installation site per the instructions set out in this document, as well as for complying with the requirements relating to electricity and water supply.

1. INTRODUCTION

INSTALLATION

This Installation guide covers the following topics:

- Physical description
- Site requirements
- Electrical requirements
- Water supply requirements

For more information on special operations or questions about the site preparation procedure for installation, please contact your local BioSystems representative.

Go to http://www.biosystems.global for more details about the BioSystems Analysers and consumables and reagents. If you have any questions about the information set out in this document or any comments or suggestions for future editions, please contact your distributor.

2. PACKAGING AND DELIVERY

2.1 Number of packages

The analyser is packed in two separate boxes. The larger box contains the analyser, and the smaller one contains the accessories supplied with the analyser.

The sizes of the packages are as follows:

UNIT	**SIZE** (mm) (wxdxh)	**SIZE** (in) (wxdxh)	**WEIGHT** (**KG**)
SPICA box	1200 x 800 x 930	47,24 x 31,49 x 36,61	110
Accessories box	370 x 605 x 135	14,56 x 23,81 x 5,31	3

2.2. Necessary equipment

The Analyser box must be moved using a pallet truck or a forklift truck. The minimum pallet truck or forklift truck characteristics are as follows:

- Able to move weights of 150 kg.
- Forks with a length of at least 1150 mm.

2.3. Space for unpacking

An unoccupied area for unloading is required, which must have a surface area of 5 m2 for box unpacking and handling. The analyser is packed on a pallet.

Check the area through which the pallet will be moved and remove all obstacles.

INSTALLATION

3. DESCRIPTION

3.1 Dimensions and weight

Dimensions (**Width x Depth x Height**)	100 cm x 62 cm x 65cm
Weight	75 Kg

3.2 Space requirements

The analyser occupies a minimum space of 100 x 62 x 65 cm (W x L x H).
Install indoors, leaving a distance of at least 10 cm behind the analyser in which air may circulate from the fan inlet, and ensure easy access to ON-OFF button and outputs on the back of the machine.

3.3 Laboratory table support

The table supporting the equipment must have a minimum depth of 70 cm and should be able to withstand a minimum load of 100 kg.

The table must be level and have a maximum slope of 0.5%.
A table height of 80 cm is recommended for easy handling of the rotors and racks.

4.REQUIREMENTS REGARDING INSTALLATIONS

4.1 Electrical requirements

Refer to page 16

4.2 Fluid requirements

3 black bottles are provided on the front of the SPICA: two with a green cap and one with a red cap. The small one on the left with the green cap is the washing solution bottle (1L). The one in the middle with the red cap is the waste bottle (3L), and the bottle on the right with the green cap contains distilled water.

4.REQUIREMENTS REGARDING INSTALLATIONS

INSTALLATION

4.2 Fluid requirements

NOTE

To handle the bottles safely, remove them from their position and disconnect the tubes by pressing the fast connector fitting. Once filled with (type 2) distilled water or washing solution and/or the waste has been emptied, replace the bottles and re-connect the fast connector fitting.

BIOHAZARD

Ensure that the fast connector fitting is inserted correctly into the container cap. When inserted correctly, it will produce an audible “click.” If no click is heard, reinsert.

NOTE

Preparing the washing solution:

1. Unscrew the cap of the washing solution bottle.
2. Fill it with 1L of distilled water.
3. Add 5 ml of the concentrated washing solution (code AC16434) and mix gently. Take care when handling the concentrated washing solution bottle to prevent the contents from splashing or spilling. Wear gloves and protective clothing when handling.
4. Screw on the cap, connect the tubes and position it correctly inside the analyser.

4.3 Environmental conditions

Air conditioning: The analyser should be installed in an air-conditioned room to ensure that temperatures and humidity remain stable. The analyser must not be placed in the direct airflow of the air conditioner.

Heat emission: Maximum of 1706 BTU/h

Temperature: The location in which the analyser is installed must be kept at temperatures between 10° C and 35° C. It is vital that operating temperatures do not vary more than 2° C/h.

Humidity: The relative humidity of the air in the room where the analyser is installed must be less than 85%, with no condensation.

Lighting: Do not place the analyser below powerful light sources. Keep lighting as stable as possible and ensure that the analyser is not exposed to any flashing light. Direct sunlight should also be avoided.

Electromagnetic radiation: Ensure the analyser is not near any electromagnetic radiation sources (such as motors, centrifuging appliances, mobile phones) or heat sources.

Levelling: Move the analyser to its permanent location by pushing it gently. Once it is in the final position, unscrew the four adjustable feet should it need to be levelled.

SERVICE GUIDE

This manual has been designed to aid technicians who perform preventive maintenance tasks and repair the analyser. These professionals will have received special training enabling them to perform the tasks described in the following pages.

This manual describes the mechanical electronic characteristics and service App available to assist technicians in performing maintenance and repair work. It also describes the steps required to disassemble and change the various elements that comprise the analyser.

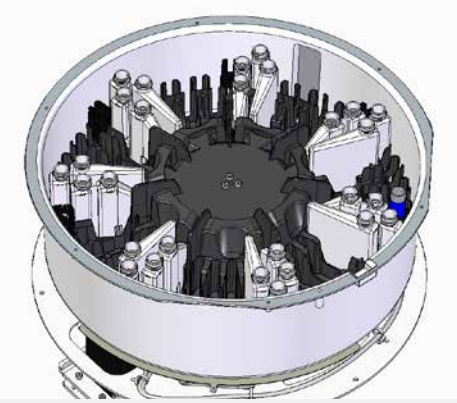
SERVICE

1. HARDWARE ELEMENTS

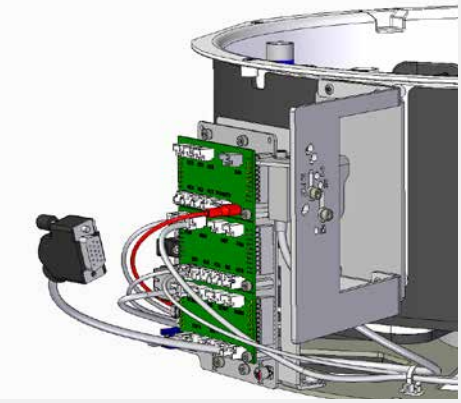
1.1 Sample and reagent rotor

All sample tubes and paediatric cups, calibrators, quality controls and reagents are placed in the same rotor.

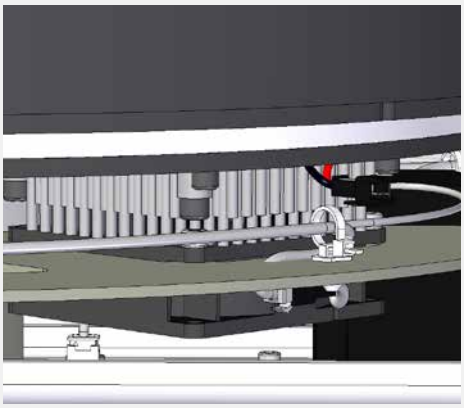
Several configurations of sample and reagent rotors are available:



Basic Option



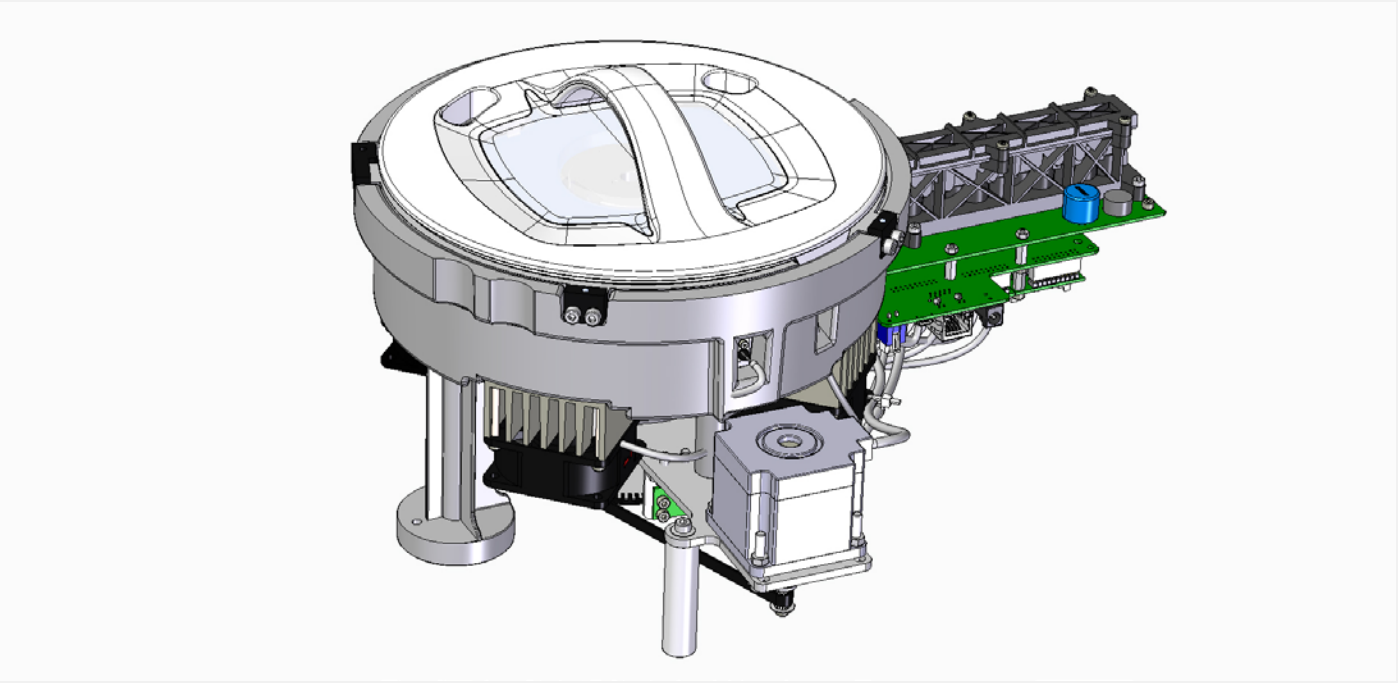
With Barcode Reader



With Cooler

1.2 Reaction Rotor

The reaction rotor is the place where the sample is mixed with the reagent. The rotor has 120 PMMA wells. The rotor is installed on a heating loop, which is maintained at 37°C and fixed in place by a bolt. The entire assembly is protected by a cover to maintain its temperature and prevent the entry of light. The assembly has a cover detector that operates via a Hall effect sensor. The system functions continuously, and as such, it is fitted with an optional wash station that empties and washes the rotor wells.

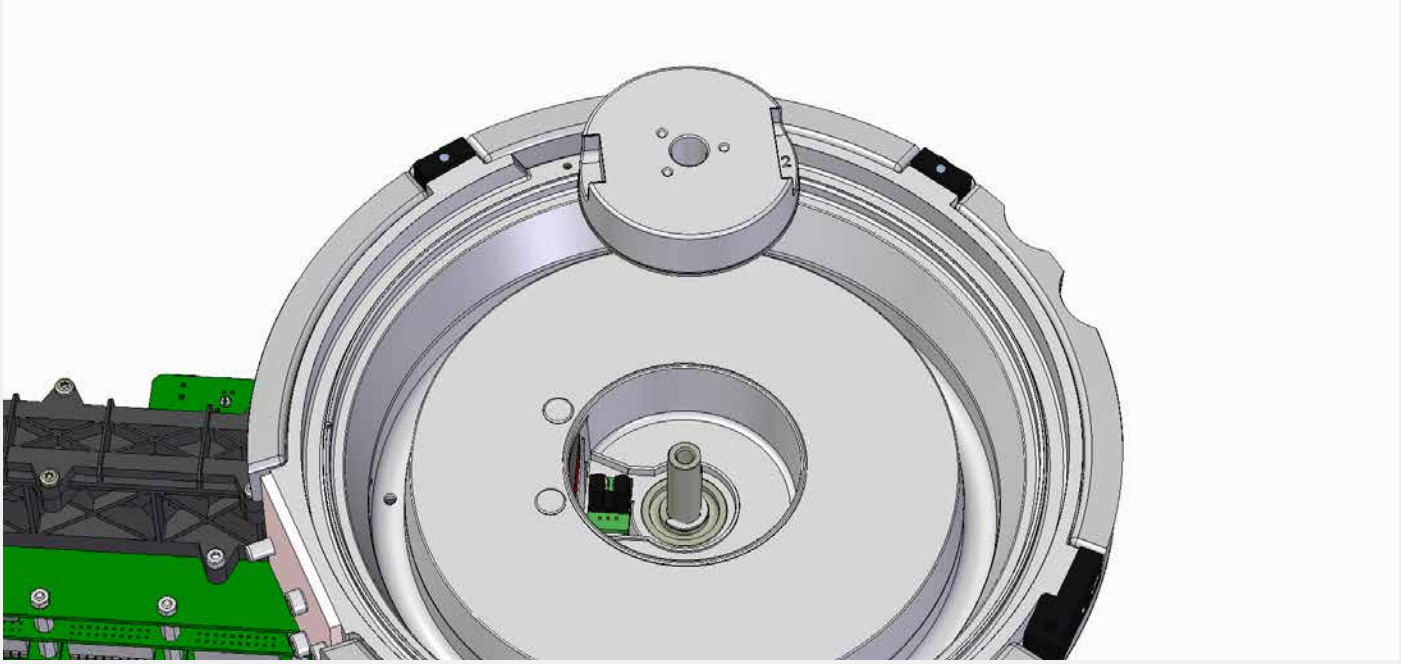


SERVICE

1. HARDWARE ELEMENTS

1.2 Reaction Rotor

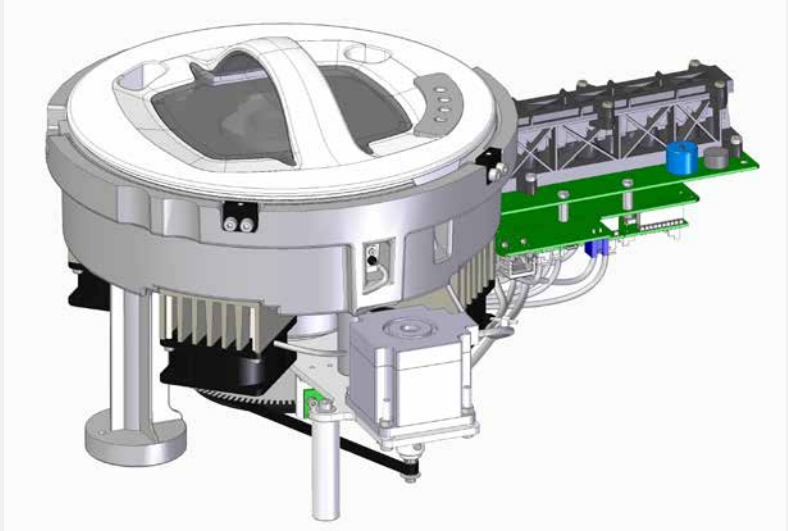
The PMMA rotor is placed on the rotor centring device and secured firmly by a bolt.
The rotor is placed on the centring device in an exact position determined by two tabs, each of a different size. The start-up photosensor detects the initial position of the rotor. The heating loop is maintained at 37°C by 4 Peltier coolers.



Resistance option for environments with room temperature lower than 15°C

To allow the **Peltier coolers** to operate, each cooler requires one radiator unit and one fan unit. To maintain the temperature, the heating loop is protected by an insulator. The temperature sensor is used to establish the loop temperature.

Resistence Option

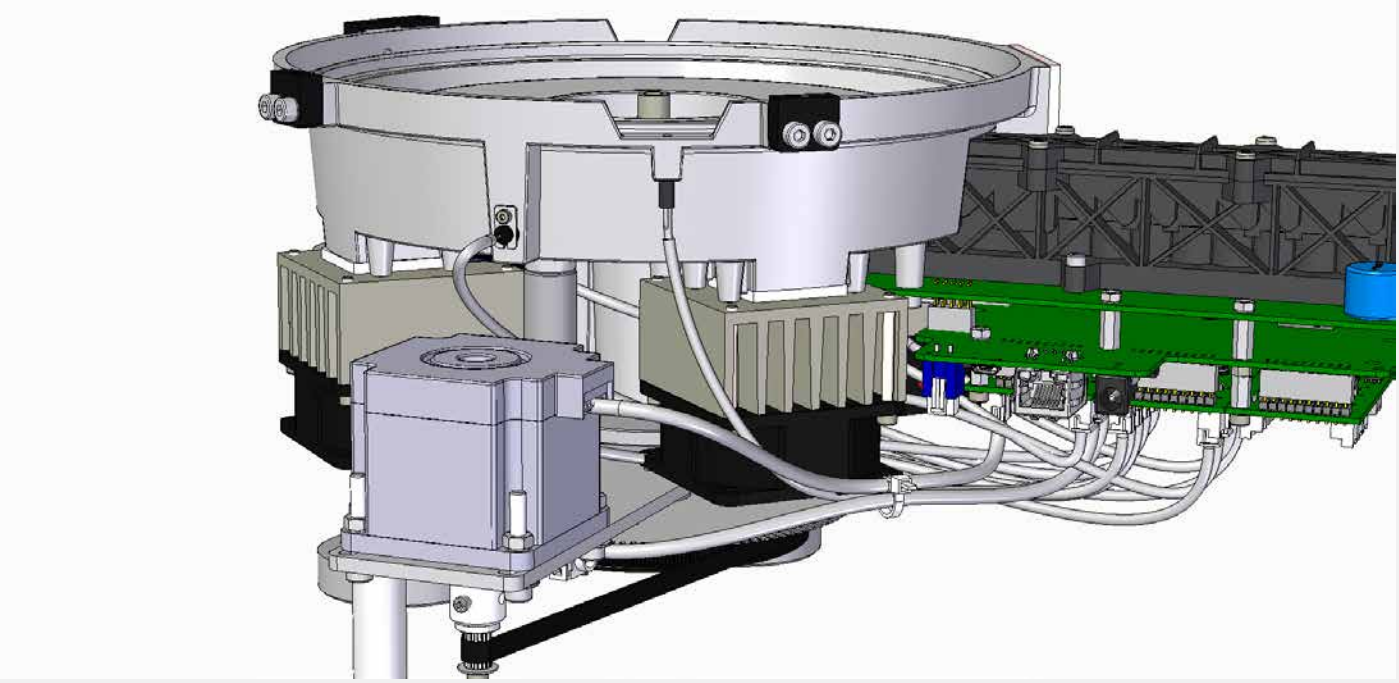


Peltier Option

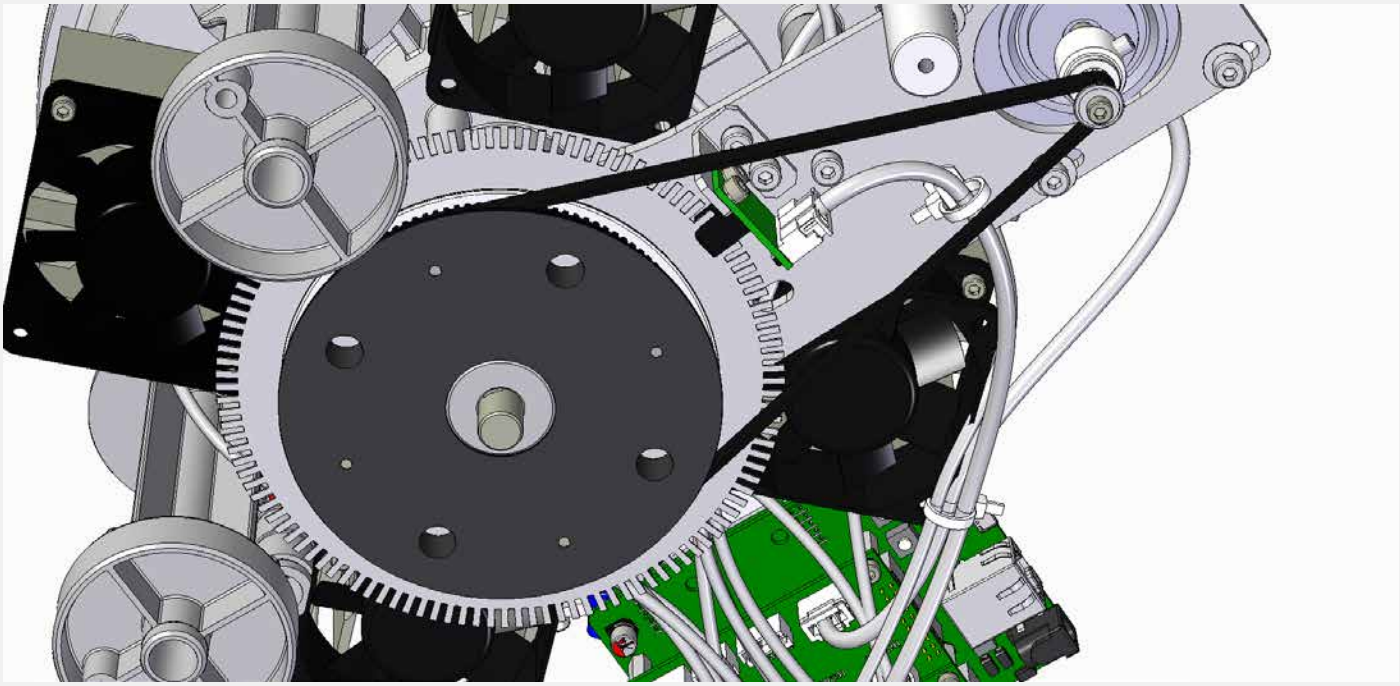
SERVICE

1. HARDWARE ELEMENTS
1.2 Reaction Rotor

The rotor centring device is connected to a shaft with a pulley at the base that transmits the motor movement through a belt and pulley.



The encoder disk is attached to the pulley. The photosensor indicates the start of the well reading.

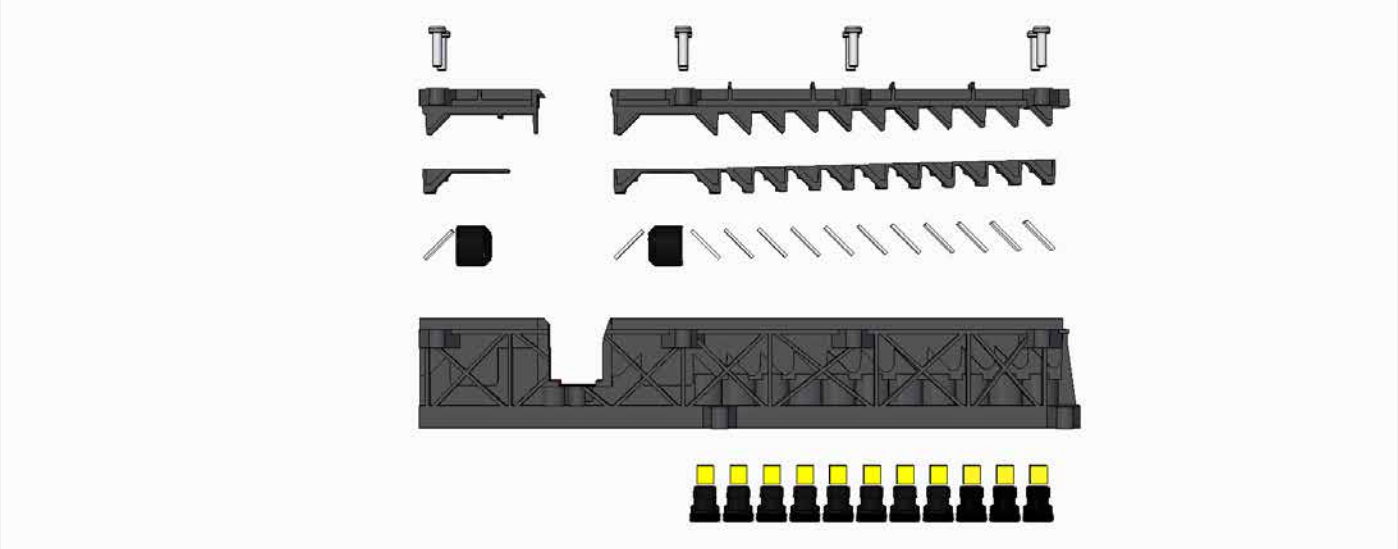


SERVICE

1. HARDWARE ELEMENTS

1.3 Optical Bench

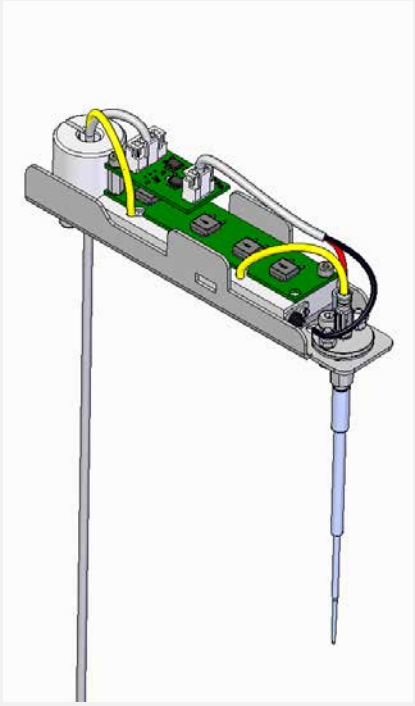
The optical bench is a sealed unit mounted on the electronic board. The different LEDs for each wavelength and the main and reference photodiodes are welded to the board. The filters for each wavelength are inserted into the filter holders and screwed to the optical bench support. Beam splitters and lenses ensure that the light beam for each wavelength hits the rotor. A rubber joint and cover seal the entire assembly.



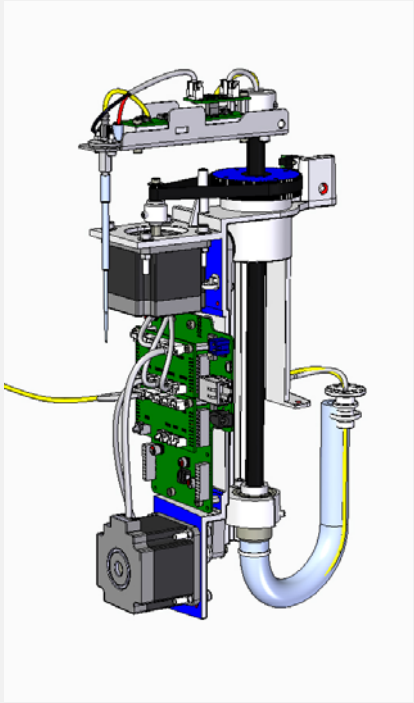
1.4 Pipetting arm

The pipetting arm is used to suction and dispense fluids. The arm is used to handle reagents and samples. The pipetting arm is comprised of housing that covers the tip connections and the electronic board. The tip and board assembly, which is the mobile part of the arm, is attached to a support (**Fig.1**).

A linear guide raises the assembly, and wires and tubes are connected to the tipped pass-through. The assembly is raised using a motor that guides the movement through a pulley to a belt joined to the linear guide. The angular movement is executed with the motor using a belt, which rotates the linear guide (**Fig.2**)



(**Fig.1**)



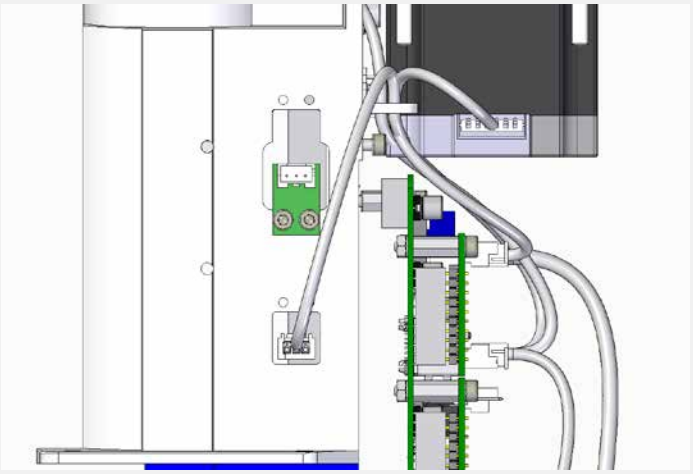
(**Fig.2**)

SERVICE

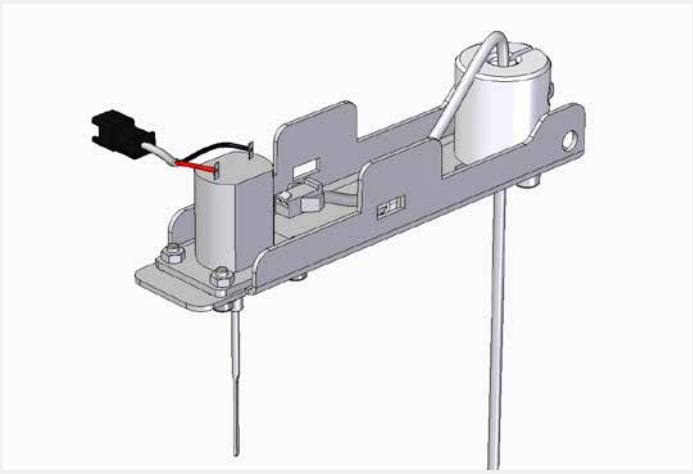
1. HARDWARE ELEMENTS
1.5 Stirring arm

The elevation and rotation movement assembly parts are the same as those in the pipetting arm.
The only difference in the arm structure of the pipetting arm and the stirrer is the start-up sensor position (**Fig.3**)

The sensor is positioned at the top of the pipetting arm and at the bottom of the stirrer.
A stirrer is made up of a flat paddle. The paddle is glued to the direct current motor shaft. The motor is attached to the headpiece supported by an adapter (**Fig.4**)



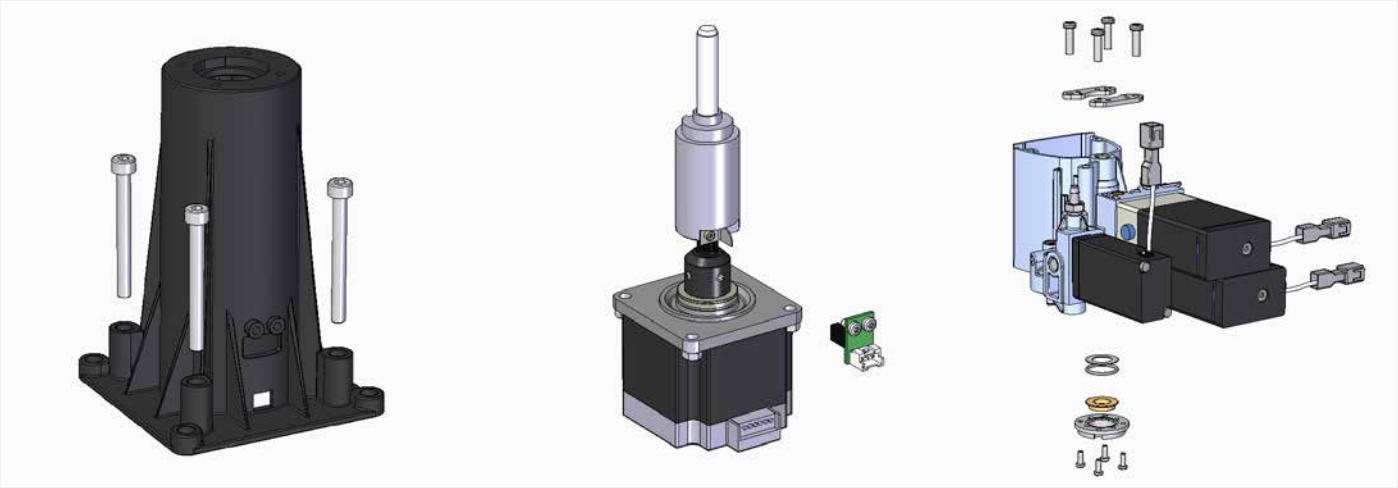
(**Fig.3**)



(**Fig.4**)

1.6 Dispensation pump assembly

The ceramic pump assembly is used to suction and dispense the samples and reagents. It is made up of a motor unit with a ceramic piston, a manifold assembly, and a diaphragm pump (**Fig.5**). The manifold outlet is a Teflon tube connected to the dispensation pump by an interconnection plate. The inlets are formed by a tube for suctioning distilled water and another for suctioning washing solution. The electro valves can be switched to select air, washing solution, or distilled water. The diaphragm pump is used to wash the inside of the dispensation circuit with distilled water or washing solution, depending on the electro valve function selected. The manifold in the pump's fluidic chamber has pressure sensors (Optional) that detect sample tip blockages.



(**Fig.5**)

1. HARDWARE ELEMENTS

1.6 Dispensation pump assembly

They are operated by a motor attached to a multi-twisting spindle. The spindle raises or lowers the piston support where the piston is attached. A stop seals the suctioning chamber. The tubes are connected to the manifold by connection fittings.

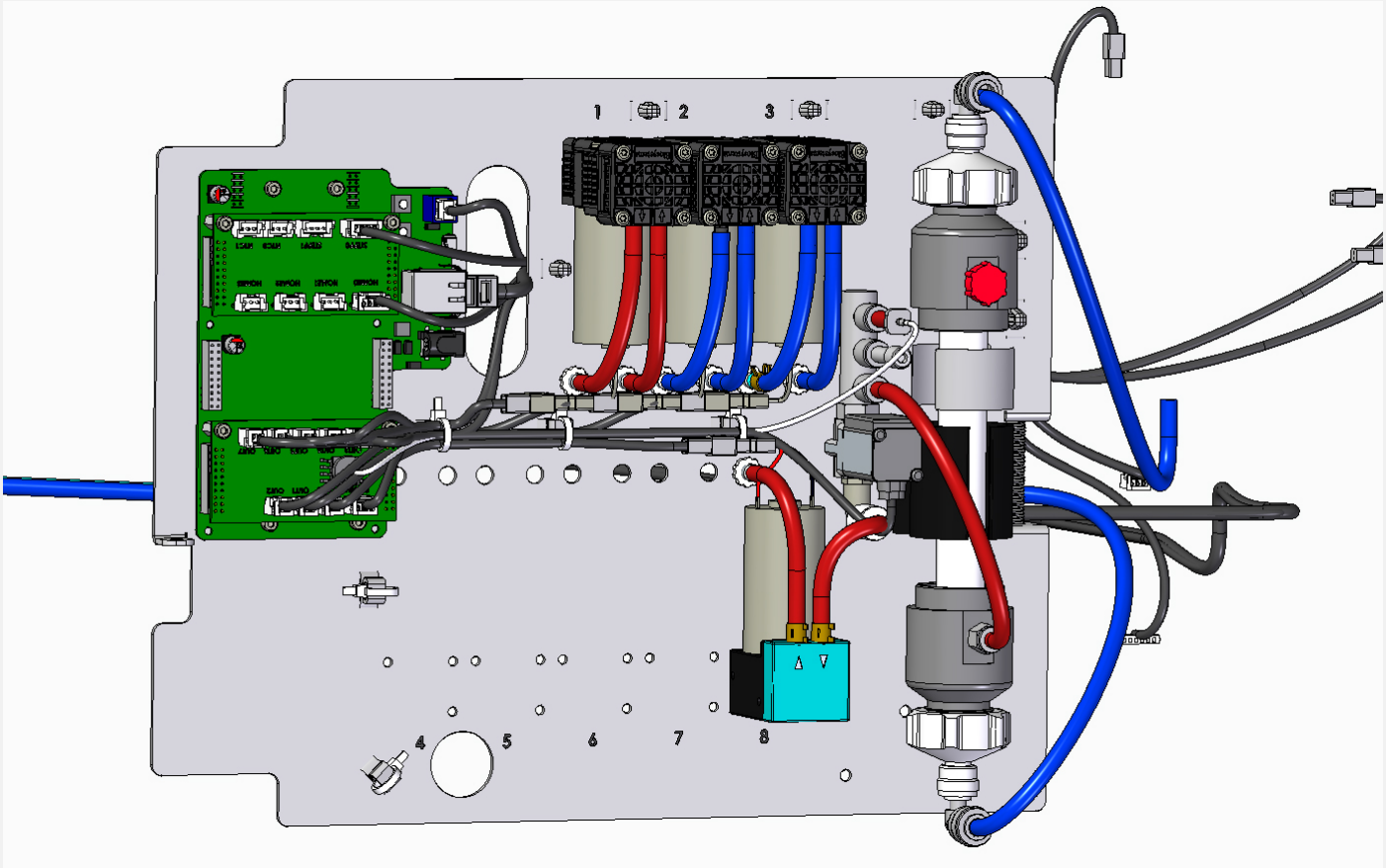
1.7 Degasser (optional)

The water used by the analyser pipetting system passes through the degassing circuit to eliminate any bubbles that may form in the water.

The system is made up of a membrane that suctions air from the water. This membrane is positioned to operate in a circuit.

To ensure the membrane functions correctly, it is operated under a vacuum, using a diaphragm pump and a control circuit to monitor the vacuum pressure.

The diaphragm pump outlet passes through a non-return valve connected through a T-shaped interconnecting fitting to the low contamination waste outlet.



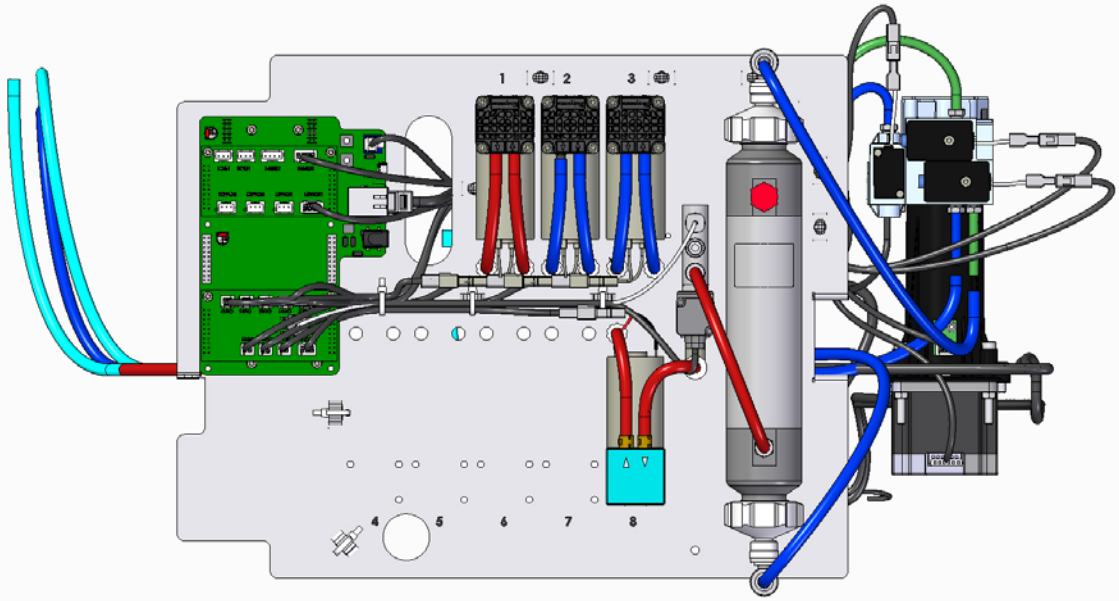
SERVICE

1. HARDWARE ELEMENTS
1.8 Fluidic system assembly

The entire fluidic system is mounted on a board located on the right-hand side of the analyser.
The water can be let into the analyser in two ways:

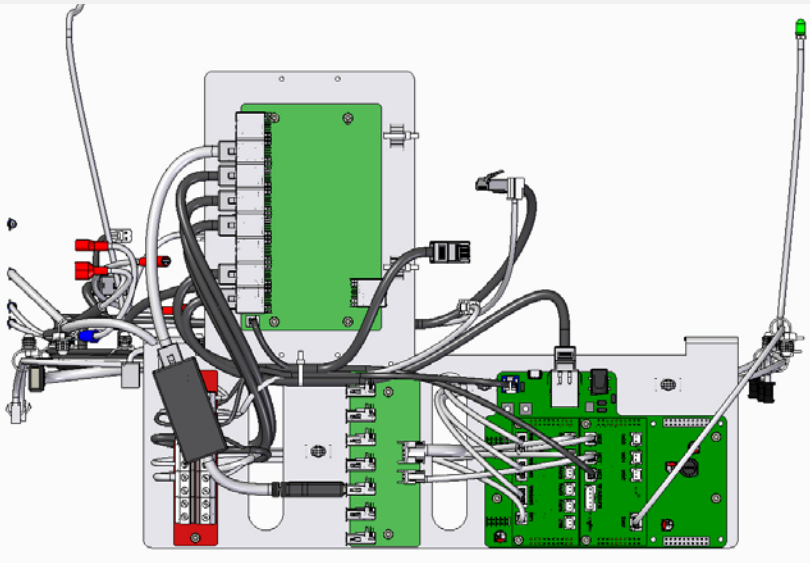
- Through a pressurised water system. (Select the option from the app)
- Through an external tank with a large capacity. (Select the option from the app)

In the absence of the rotor washing station option, water is provided through the front tanks.



1.9 Electronic assembly

Power sources for the analyser are located on the left side.
The ethernet switch, USB switch, and CPU board are also installed on the same plate.

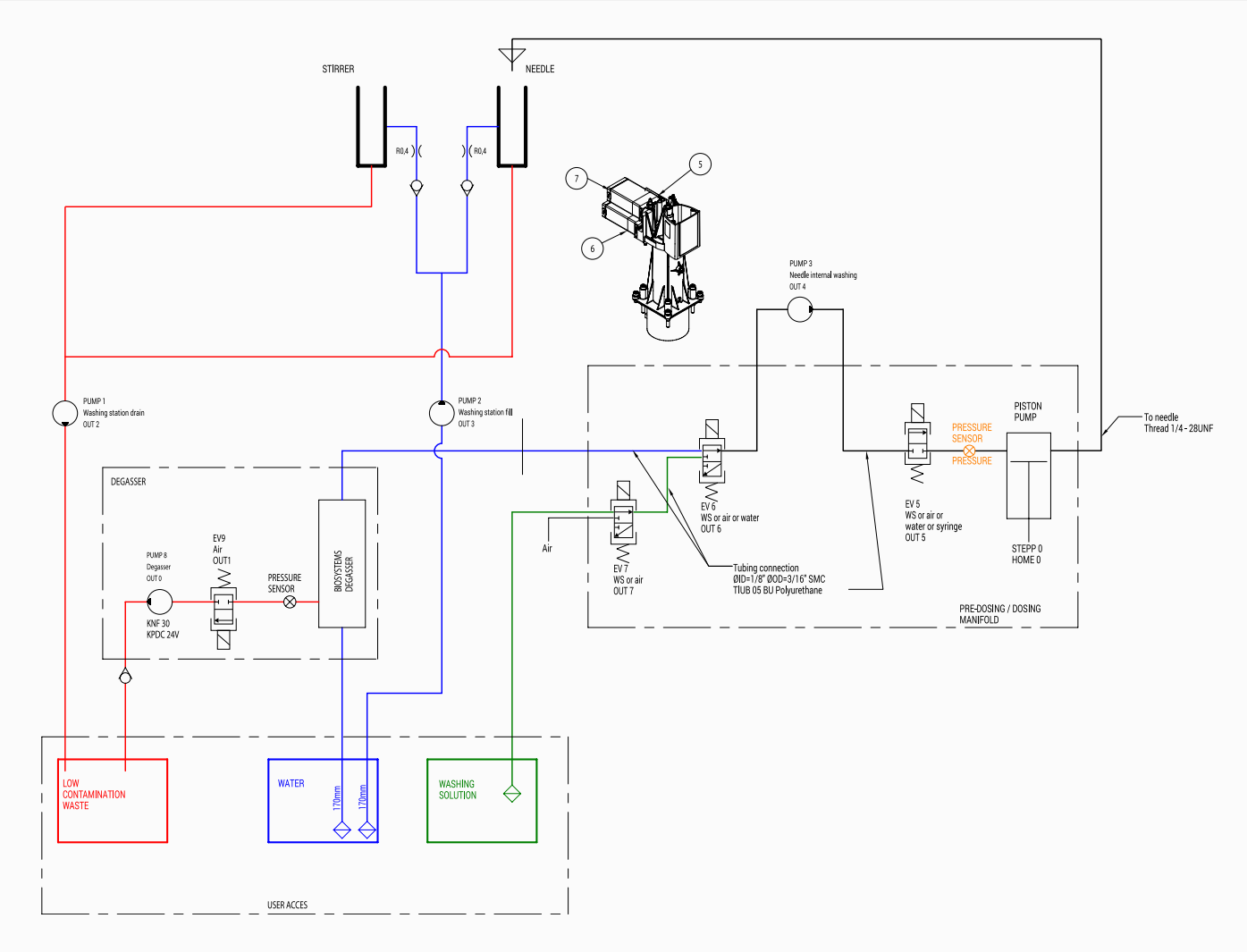


2. FLUIDICS BASIC DIAGRAM

SERVICE

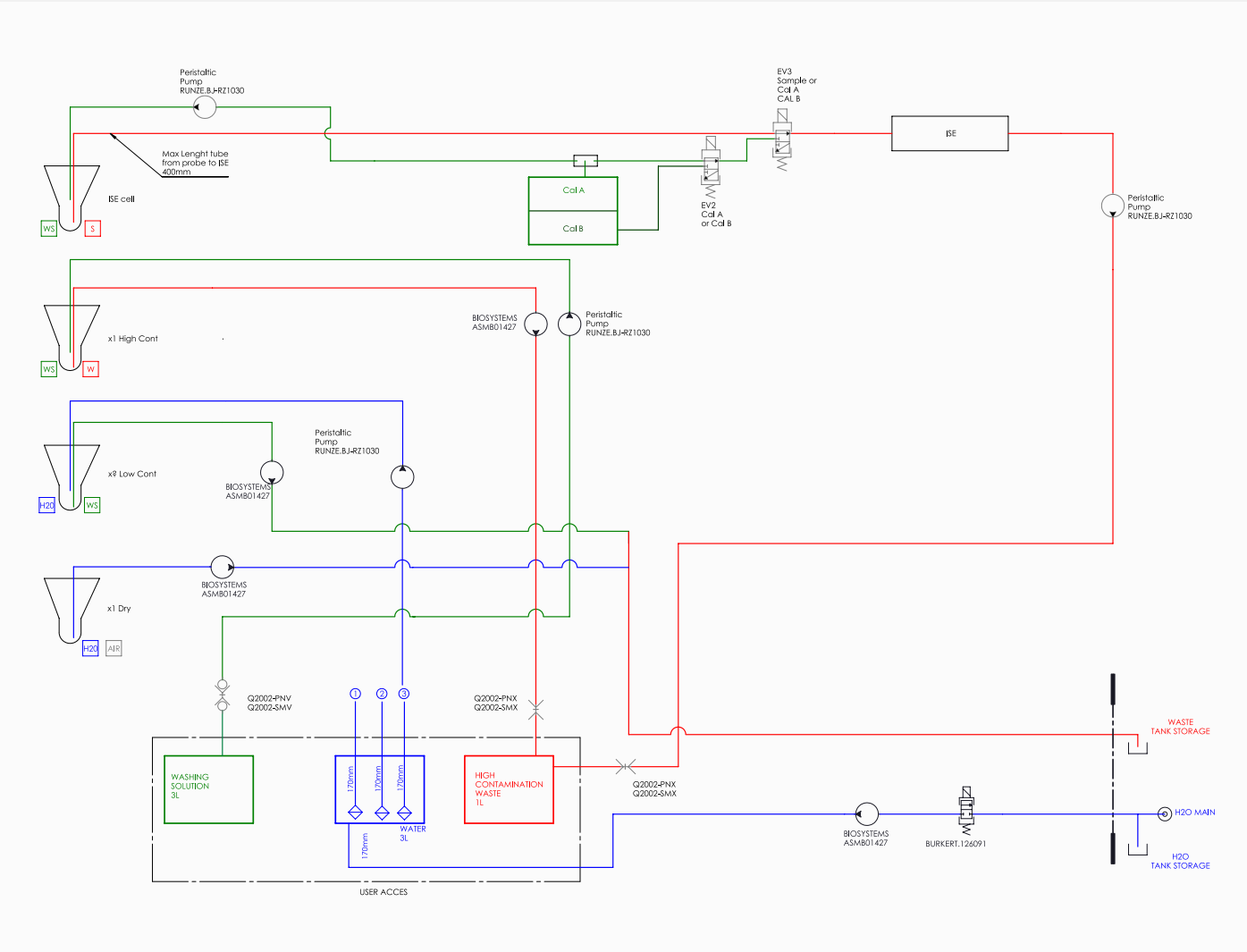
The analyser operates with 3 tanks for processing fluids. These tanks are the distilled water tank, low contamination waste tank and washing solution tank. They are located on the front of the analyser and can be accessed directly by the user.

- Once the determination has been made, the reagent and sample mixtures remain in the PMMA rotor. This is high contamination waste and must be treated carefully.
- The tank that contains the washing solution has a capacity of 1L. The washing solution is used to clean the dosing system during prime fluidics operations.
- All waste from the analyser is deposited in the low contamination waste tank. The tank has a capacity of 2.9L, and users must empty it when indicated by the App.
- The distilled water tank has a capacity of 3L. The water is used to prime the pipetting system wash the inside and outside of the tip.



2. FLUIDICS BASIC DIAGRAM

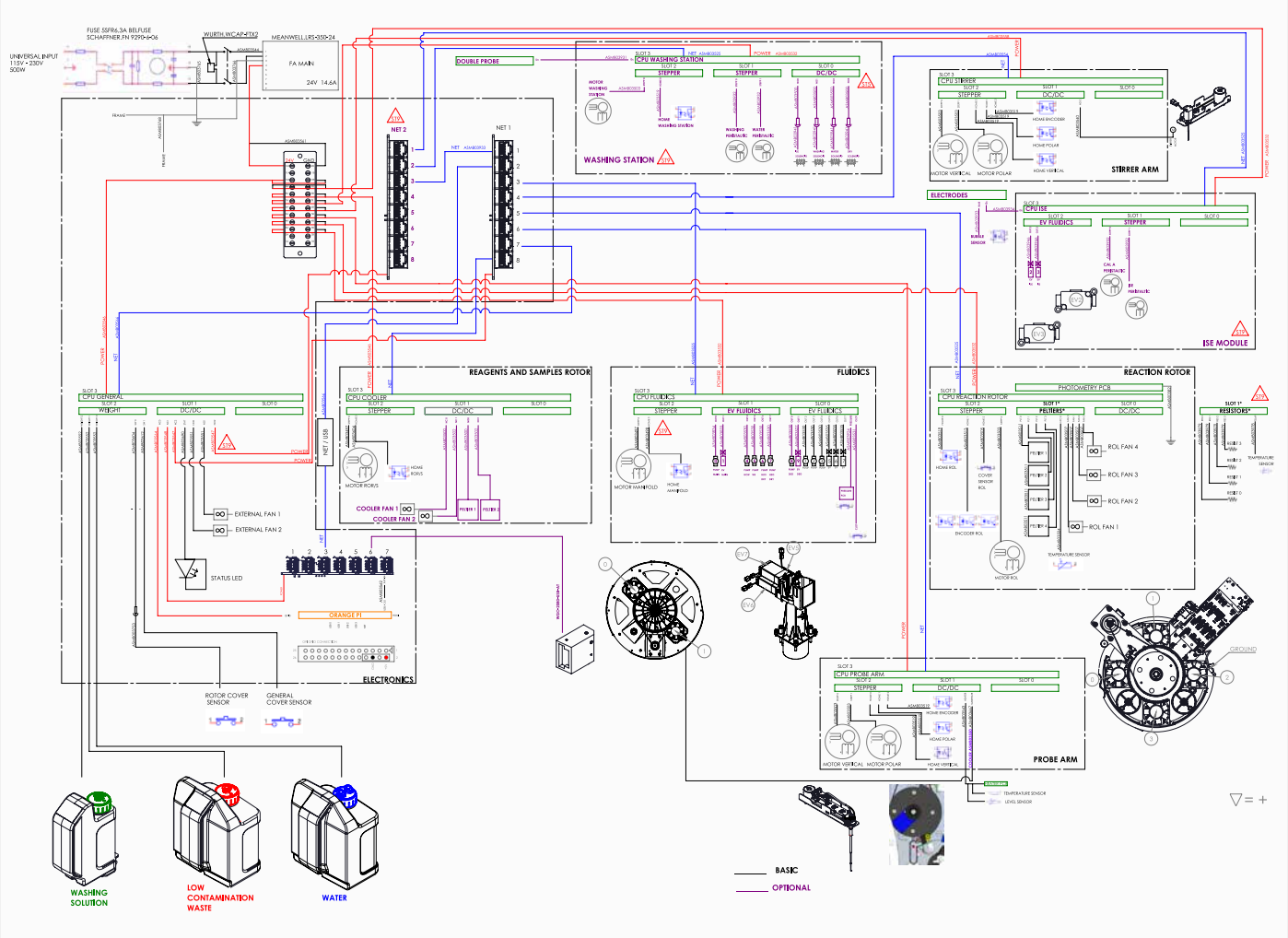
SERVICE



SERVICE

3. ELECTRONICS BASIC DIAGRAM (NO OPTIONS)

Analyser electronics contain several subsystems with the same CPU and several shield PCBs attached to configure the correct functioning of each subsystem. All PCB subsystems are connected to the Ethernet network and controlled by the PC built into the analyser.



4. MANUAL ROBOT

The manual robot is an easy tool with which to adjust and check analyser functionality. This part of the App allows users to review the analyser's full layout and issue individual commands.

Home > Utilities > Manual robot

NOTE

USERS ARE ADVISED TO COMPLETE STANDARD BIOSYSTEMS SPICA OPERATING TRAINING BEFORE USING THIS TOOL.

SERVICE

5. MAINTENANCE AND CLEANING

5.1 Maintenance activities and frequency

MAINTENANCE EVERY SIX MONTHS

- Dust the electronic board and fans.
- Check the internal fluidic connections and review possible leakages.
- Clean the distilled water and low contamination waste tank.
- Clean the exteriors of the pipetting arm, stirrer, and wash station tips with alcohol.
- Clean the barcode reader window, if applicable.

ANNUAL MAINTENANCE

- Change the degasser membrane, if applicable.
- Clean the filters inside the washing and distilled water bottles.
- Check the wash station piston pump (check for leaks and grease the bearings).
- Check arms (check the tension and wear of the belts).
- Check the friction of the stirrers in the reaction rotor.
- Check belt wear and tension in the sample and reagent rotor and reaction rotor.
- Check the position and sensor of the reagents and samples under the rotor cover and the reaction rotor cover.
- Check the adjustment and positioning of the sample and reagent rotor.
- Check the rotation of the fans, dust them and clean the filters.
- Verify analyser levelling.

BIANNUAL MAINTENANCE

- Change the vertical transmission belts in the arms.
- Change the Peltier fridge.

5.2 Cleaning

Material and tools required to clean the appliance:

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

5.3 Analyser verification process

A standard process is applied so as to verify correct instrument operations following an intervention.
This process can be applied to the following operations:

- Instrument reception (in the laboratory, before installation)
- Maintenance
- After a repair

The goal is to standardise the verification process and the acceptance criteria.

Verification process

Use a template delivered by BioSystems to calculate the results. If you don’t have this template, please contact BioSystems Customer Care.

Use the material indicated in this template to carry out this verification.

Run the session following the instructions on the template.

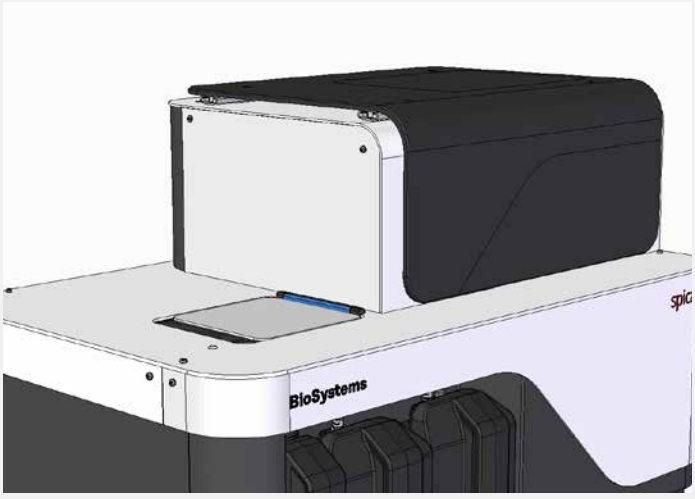
Coefficient of variation values and all concentration results must fall within the control range indicated on the template.

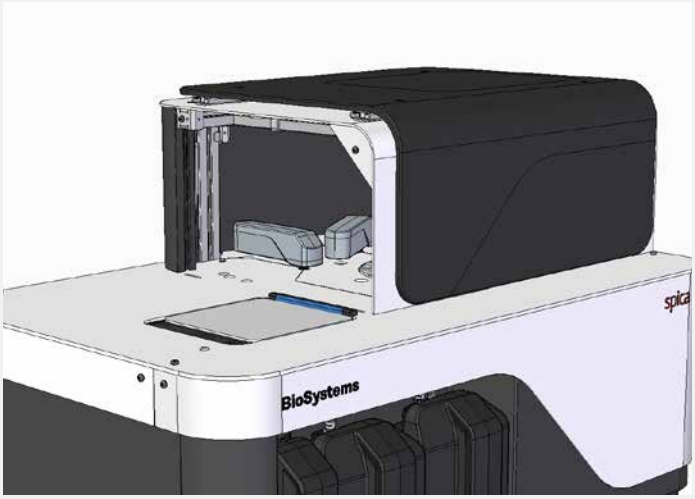
SERVICE

6. HOW TO ACCESS SUBASSEMBLIES

Step by step general description of how to access subassemblies:

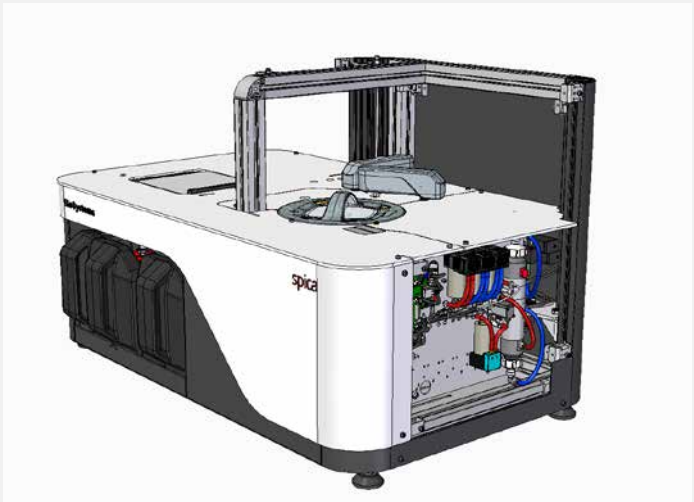
Step 1 - Remove the left panel





Step 2 - Remove the right panel to access to fluidics subsystem

Step 3 - After the first 2 steps, it is possible to remove the general cover (remove the general door sensor prior to this step)

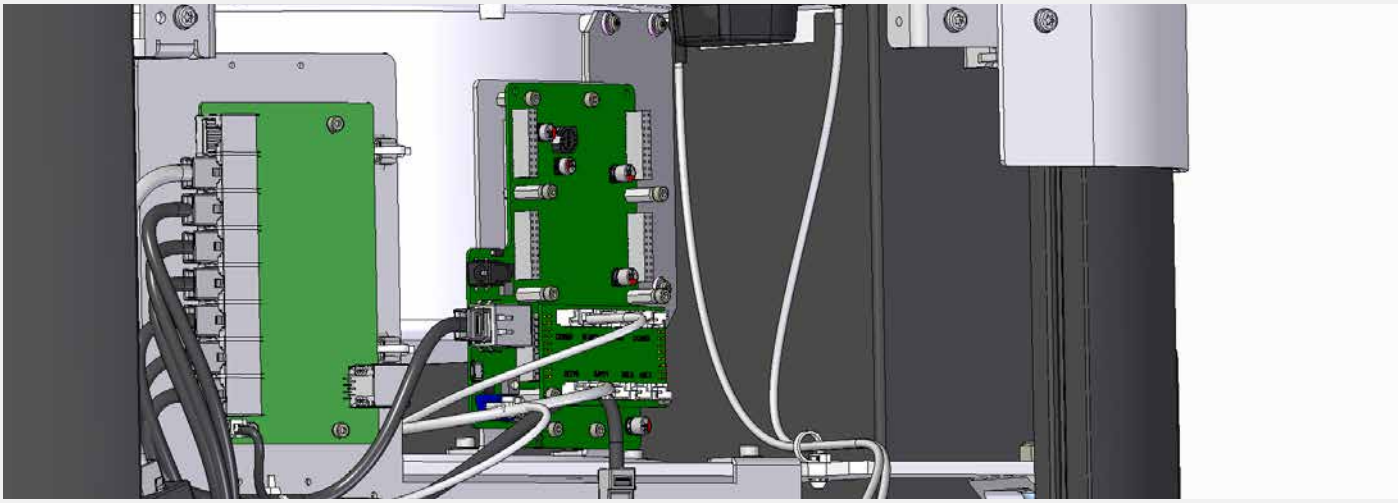


6. HOW TO ACCESS SUBASSEMBLIES

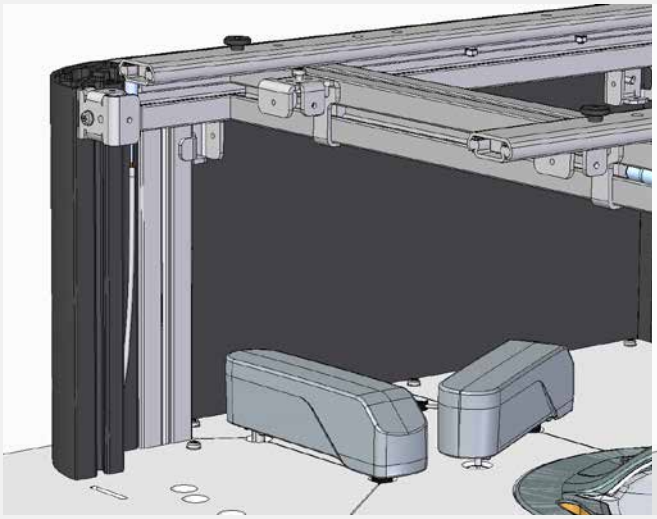
SERVICE

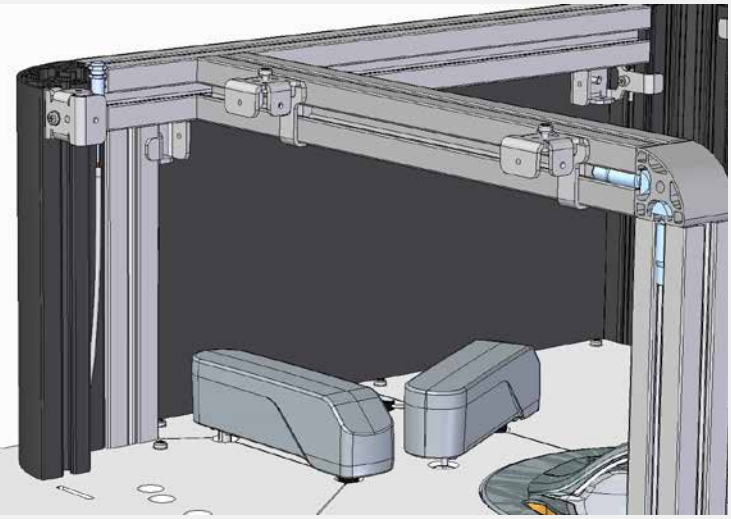
Step 4 - Remove left panel to access to electronics subsystem

Step 5 - Disconnect the door sensor to remove work surface covers



Step 6 - Raise the round black aluminium profile before removing the worksurface metal sheets:

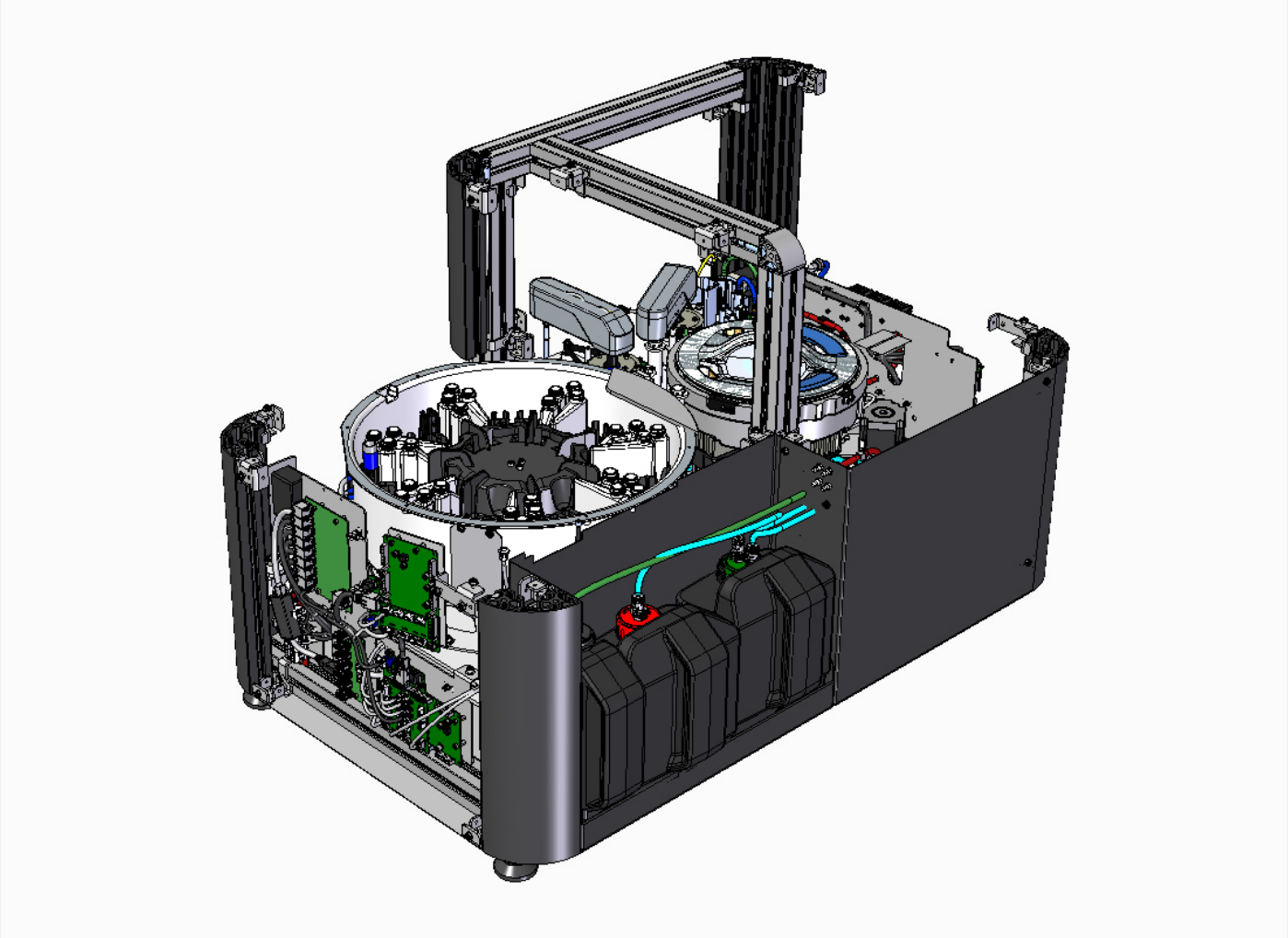




6. HOW TO ACCESS SUBASSEMBLIES

SERVICE

Step 7 - You can now remove the rest of the metal cover sheets



You now have access to all internal parts of the BioSystems SPICA. Usually, you will only need to partially remove the covers to access for repair or to carry out maintenance operations.

If you need assistance to replace any Biosystems SPICA subsystems, do not hesitate to contact BioSystems customer care.

MANUAL VERSION

All the necessary precautions have been taken to ensure that the information set out in this manual is correct at the time of its publication. Nonetheless, BioSystems, SA reserves the right to make any changes that may be necessary as part of the product's ongoing development. The changes will be communicated through the company's official communication channels.

MANUAL VERSION

MANUAL VERSION	REVISION DATE	CHANGES
1.0	February 2021	**Initial version**
2.0	February 2022	**User Guide:** 2.3 Installing distilled water, washing solution, and waste containers, 3.1 Component Description and 5.4 Internal Quality Control **Service Guide:** 2. Fluidics Basic Diagram
2.1	March 2022	**User Guide:** 1.1 Notice and Warnigns (FCC/ACMA Standard)
2.2	April 2022	**User Guide:** 1.3 Intended Use, 3.1 Components Description. **Service Guide**: 6. How to Accesss to Subassemblies
2.3	May 2022	**User Guide:** 1.1 Notice and Warnigns (FCC/ACMA Standard). **Service Guide:** 1.3 Washing station system (deleted) 1.8 Fluidic System Assembly
2.4	May 2022	**User Guide:** 1.1 Notice and Warnigns (FCC/ACMA Standard).
2.5	June 2022	**User Guide:** 1.1 Notice and Warnings (IVD icon + text Logo ACMA Standard + text) 1.3 Intended Use (all chapter review) 7.1 Pre-analysis and preparation of additional solutions/ Washing Solutions (1st paragraph) 11. Technical Specifications: General Characteristics (speed text), Sample and reagent management (Reagent bottle volume), Optical System (Wavelengths) and Wireless Requirements **Installation Guide:** 1.1 Introduction (www.biosystems.global) 3.4 Optional table

MANUAL VERSION

MANUAL VERSION	REVISION DATE	CHANGES
2.6	September 2022	**Index:** Chapters and pagination numbers actualization **User Guide:** 1.1 Notice and Warnings (FCC chapter) 8. Accessories and Spare Parts - chapter deleted
2.7	March 2024	**Technical specifications:** Bluetooth text removed **2.10 Safety precautions during operations:** Added minimum distance of operation **2.8 Spica communications:** Wireless band changed to 2.4 GHz **3.4 Optional table:** chapter removed

Manual Code UM-SPICAv2.7 -EN

NOTE

ANY CHANGE MADE TO THE INSTRUMENT BY THE CLIENT WILL RENDER THE WARRANTY VOID AND WITHOUT EFFECT.

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