INSTALLATION REPORT AND CHECKLIST

For analyzer	CY014 - CYANVision

Distributor	*(Company name)*
Coordinates	*(Country, city)* *(Telephone and E-mail)*
Maintenance engineer	*(Name)* *(Telephone and E-mail)*

Institution	*(Laboratory name)*
Coordinates	*(Country, city)* *(Telephone and E-mail)*
Lab manager	*(Name)* *(Telephone and E-mail)*

Installation report	
Serial number	
Delivery date	
Installation date	
Content packing list verified	☐ Yes ☐ No
Installation checklist completed (see page 2)	☐ Yes ☐ No
User training given	☐ Yes ☐ No
Warranty activated (see page 2)	☐ Yes ☐ No Warranty end date:

The installation report of the laboratory equipment is approved and signed by:

	Laboratory manager	**Maintenance engineer**
First and last name:	_____	_____
Date:	_____	_____
Signature:		

This form is a compulsory requirement for ISO certification, laboratory accreditation, good laboratory practices and the legal requirements in many countries. Fill it out and be future ready.

P.S. Keep a copy

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Register now at: https://diagnostics.be/warranty

Checklist for installation (detailed instructions in chapter 3 of the user manual)	
Ensure optimal operation	
☐	Verify the location specifications
☐	Check the electronical current requirements. If necessary, use: ☐ Electronic stabilizer ☐ UPS
Installation of accessories on the CYANVision analyzer	
☐	Install the peripherals
☐	Install the waste bottle
☐	Connect the power cord to a suited power supply
Checking the CYANVision analyzer	
☐	Perform washing and cleaning after start-up
☐	Check the aspiration and hydraulic circuit by performing a pump calibration
☐	Check the optical system by performing an auto zero measurement
☐	Reset the maintenance timers
Adaptation of the system to the customer	
☐	System setup: language, date format, printer setup, report setup, contact information, create user accounts
☐	Customize the programs and create profiles
☐	Give extensive information on daily use and maintenance to the user
☐	Register the instrument to activate its warranty

Warranty activation:

Link: https://diagnostics.be/warranty

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MAINTENANCE INSTRUCTIONS

Analyzer	CY014 - CYANVision
Serial number	

To be performed by	Period	Code	Must log	Activity description
Laboratory Technician	Daily	D	/	Perform auto zero measurement
				Wash between methods
				Clean the flow cell with detergent
				Clean outside of the instrument
	Weekly	W-1	/	Disinfect the flow cell with hypochlorite
		W-2	✓	Perform a pump calibration
Laboratory Technician or Maintenance Engineer	Upgrade notice	UN	✓	Install the latest software version
	6 months	M	✓	Replace the pump cassette
Maintenance Engineer	1 year	Y-1	✓	Replace: • Inlet tubing flow cell (incl. connector & internal protection) • External protection aspiration inlet • Tube from flow cell to pump • Waste tube
	3 years	Y-2	✓	Replace: • Inlet connector pump tube • Outlet connector pump tube
	Problems	P	✓	Consult the CYANVision Helper (https://diagnostics.be/cyanvision)
				Perform reparation

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MAINTENANCE LOGBOOK

Date	Code	Activity performed	Performed by

Need more prints?

Link: https://www.diagnostics.be/Log

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CE

CYPRESS DIAGNOSTICS

CY014

English

CYANVision

User Manual

For a clear and precise diagnose

link: https://diagnostics.be/cyanvision

ISO 13485-2016

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Please read the user manual before operating the instrument and make sure the installation is performed correctly.

If the installation, usage and maintenance directions given in this manual, are not followed correctly and/or safety indications are not respected, Cypress Diagnostics cannot guarantee the correct functioning of the instrument. Misuse can compromise the safety of the operator and his surroundings and will void the warranty. Consumables are not included in the warranty.

The symbols listed below indicate hazards associated with operating the analyzer. See chapter 2 Safety information for all recommended precautions.

WARNING:
Risk of personal injury. The analyzer contains electrical components. Please do not attempt to disassemble the analyzer to avoid electric shock.

BIOHAZARD:
Risk of contamination. Carefully manipulate all the consumables and the waste produced during the analysis routines. Always wear personal protective equipment.

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1 INTRODUCTION

The next-generation CYANVision biochemistry analyzer is designed to achieve unprecedented measurement performance. With guidance and advice, the operating system helps deliver precise and accurate results.

Key advantages of using the CYANVision semi-automated biochemistry analyzer are:

Cost savings

- Minimum reaction volume of 500 µl results in a decreased cost per test
- Limited consumables required
- Extra consumables included at delivery (five paper rolls)
- Integrated printer, pump and flow cell
- Long-life optical system
- Robustness of the analyzer with minimal daily maintenance
- Analyzer guides the user and thereby reduces mistakes

Flexibility

- Onboard printer for automatic or on-request printing
- Eight wavelengths (340, 405, 450, 510, 546, 578, 620 & 670 nm filter) cover all clinical diagnostic applications
- Five calculation methods (absorbance, endpoint, two-point, kinetic, bichromatic) and three calibration methods (factor, calibrator and multi-point calibration) provide plenty of processing options with one system
- Three blank options (sample blank, reagent blank and water) provide background correction of the reagent and sample coloration

Convenience

- All Cypress Diagnostics biochemistry reagents are pre-programmed at delivery
- 100 open channels are programmable to allow unrestricted testing
- Memory for up to 100 000 sample results
- Large font size pleases the eye and reduced the effort
- Multilingual capability
- On-screen keyboard possibilities for touch screens
- Automatic upload of calibrator and control information by an (optional) barcode scanner
- Automatic update of the programming by an (optional) barcode scanner
- Build-in quality control possibility for every program.
- Minimal daily maintenance which is automatically followed-up in the software
- Easy exportation of diagnostic information
- Back-up and restore possibilities of patient information and results

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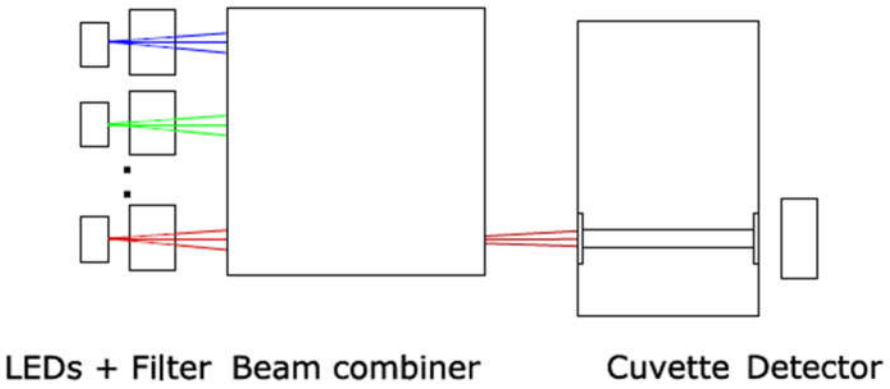
1.1 PRINCIPLE OF MEASUREMENT

The CYANVision is a semi-automated biochemical analyzer. Samples are prepared manually outside the instrument and after an incubation period (in- or outside the instrument) the samples are measured in the flow cell and the analyzer calculates the result.

A LED emits light which passes through a filter selecting the required wavelength. The light is then focused through the sample in the flow cell. The sample will transmit or reflect the fractions of the light. The detector will measure how much light was reflected from/transmitted through the sample. This measurement is then amplified and converted to a digital number for further calculations. These calculations can be performed because there is a relationship between how much light is reflected/transmitted and the concentration of the substances in a sample.



1.2 INTENDED USE

The CYANVision semi-automatic analyzer is an ***in vitro*-diagnostic** medical device for professional use only. **(Semi-) automatic biochemistry analyzers** are widely applied in hospitals and research institutes for the **quantitative determination** of different biochemical substances and other characteristics in various biological samples. Evaluation of these measured properties of blood and other fluids may be useful in the **diagnosis of disease**.

The type of ***in vitro*** **diagnostic tests** that can be performed on this analyzer includes enzyme levels (such as many of the liver function tests), ion levels (e.g. sodium and potassium), and other tell-tale chemicals (such as glucose, serum albumin, or creatinine). Enzymes may be measured by the rate they change one colored substance to another; in these tests, the results for enzymes are given as an activity, not as a concentration of the enzyme. Other tests use colorimetric changes to determine the concentration of the chemical in question. Turbidity may also be measured.

The automation of laboratory testing does not remove the need for human expertise, but it does minimize the potential human errors, resulting in **higher precision and accuracy**. Furthermore, it reduces the necessary sample and reagent volumes and increases the speed of the testing compared to measurements with a spectrophotometer.

For the best results, we advise using **Cypress Diagnostics reagents**. The analyzer is delivered with all Cypress Diagnostics biochemistry test methods pre-programmed. These methods have been extensively verified and optimized. In the **application sheets,** you can find detailed information on the preparation of the samples and the execution of the tests for all Cypress Diagnostics kits. Using these pre-programmed methods and following the preparation instructions correctly, Cypress Diagnostics guarantees the accuracy and precision as stated in the kit's insert. Upon registering to our website (www.diagnostics.be) you can find the latest application sheets under 'Products → Analyzers → CYANVision'.

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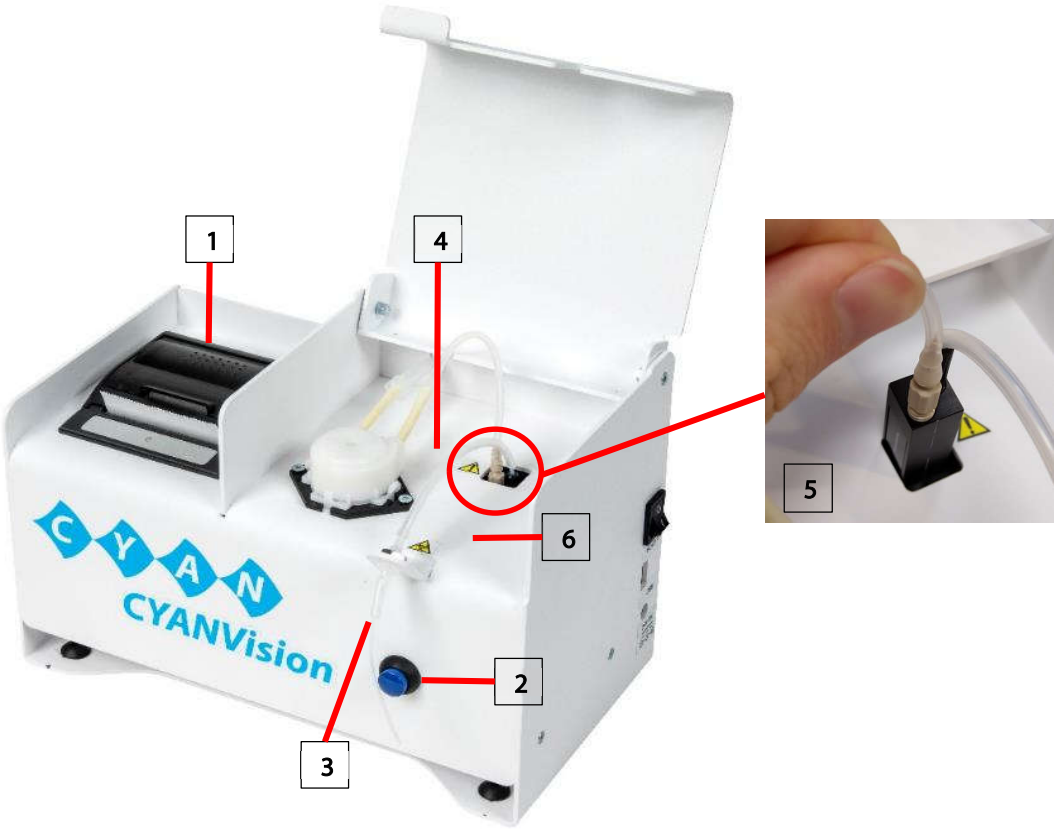
1.3 System Description

The CYANVision is a microcomputer-based independent unit, controlling several systems: built-in thermal printer, optical detection system with flow cell and aspiration system.



1	Thermal printer
2	Aspiration button
3	Aspiration inlet
4	Hydraulic system
5	Flow cell correctly positioned in holder (beige connector in lower left corner, black connector in upper right corner)
6	Cover with the optical system underneath it

After a certain time of inactivity (programmable in the system setup), the instrument will go into a power-saving « Standby » mode, causing the external monitor to turn black.

1.3.1 Thermal carbon printer

The CYANVision is equipped with a built-in thermal printer. The text or graph is printed on coated Long-life paper. This paper is selectively heated when passing over the thermal printing head, and thereby the coating on these places turns black, producing an image. One of the big advantages of a thermal printer over a normal printer is that it does not require expensive consumables like a toner.

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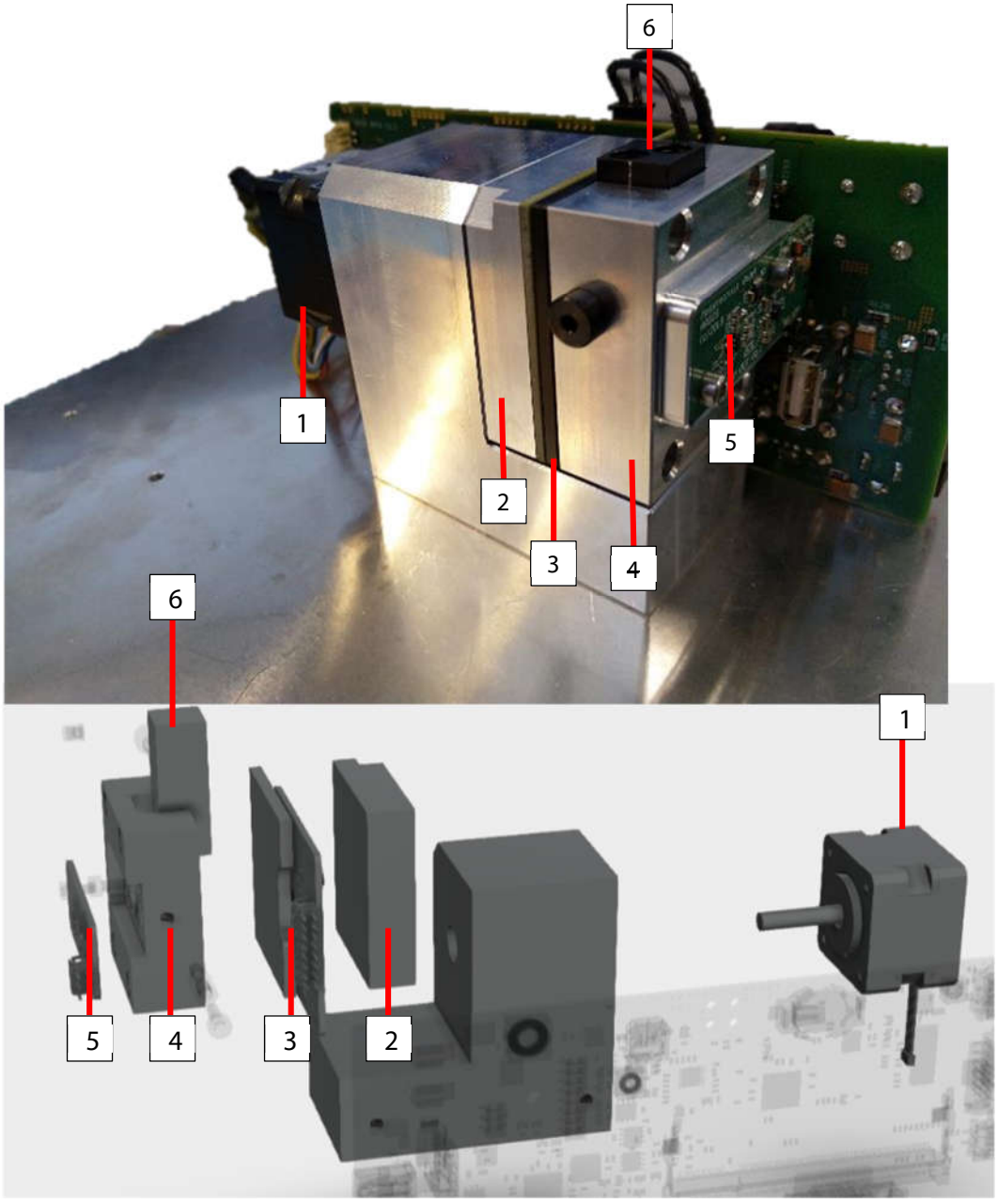
1.3.2 Optical assembly

The optical system is the functional key compound of the instrument. It contains the light sources, filters for wavelength selection, flow cell with heating mechanism and a PC board that contains the photodiode detector. This pre-amplifier board also converts the light detection from an analog to a digital signal for further processing on the mainboard. Eight LEDs and a filter cover are mounted on the illumination PCB. The light is sent towards a mirror which focusses the light to the flow cell, which has a light path of 10 mm. The flow cell is heated with a Peltier element to 25°C, 30°C or 37°C and the heating is regulated by a temperature sensor. Ultimately, the light is detected by a silicon photodiode on the pre-amplifier board. This photodetector has a range of 300-900 nm. These eight wavelengths cover all clinical diagnostic applications: 340, 405, 450, 510, 546, 578, 620 & 670 nm filter. The wavelength accuracy is ± 10 nm.



1	Stepper motor
2	Filter holder
3	Illumination PCB incl. LEDs
4	Flow cell holder
5	Detector board
6	Flow cell

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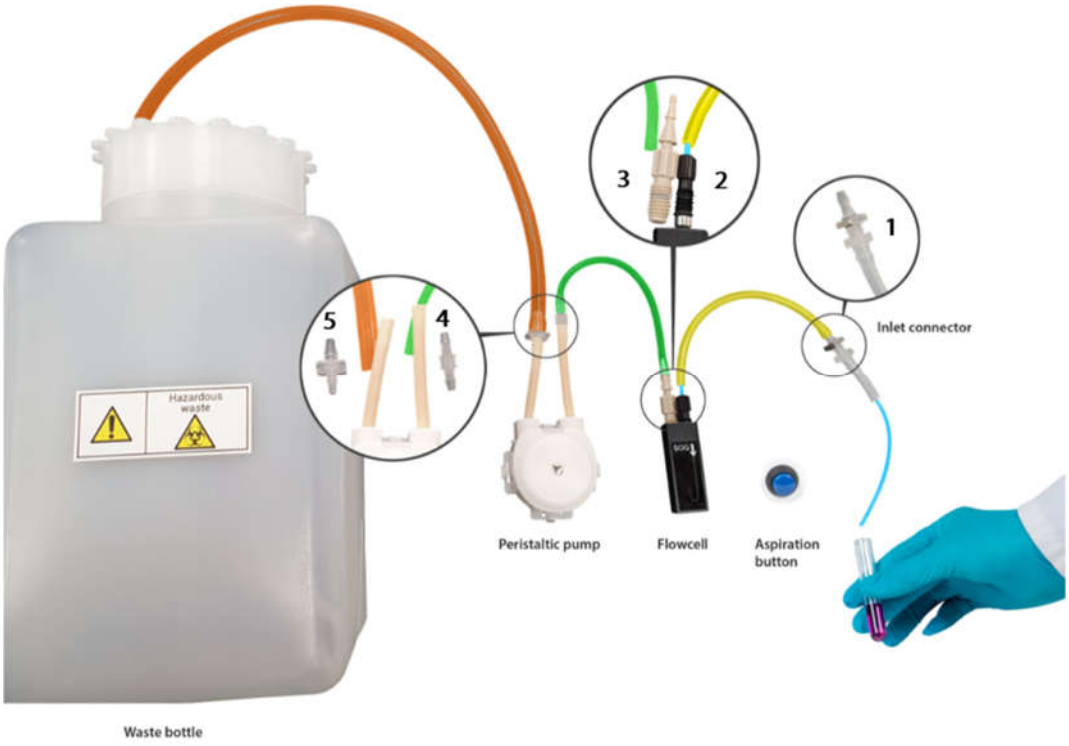
1.3.3 Hydraulic and aspiration system

The peristaltic pump is situated on top of the analyzer. It can be activated by:

- The "Aspirate" button in the software
- Pushing the aspiration button in front of the analyzer

Upon activation of the peristaltic pump, a quantitative volume is aspirated by the hydraulic system. This is a continuous line consisting of various tubes, connectors, the flow cell and ending in the waste bottle.



Tubes	Item code	Item name
	Part of CY014-S02	Inlet tubing flow cell (internal)
	Part of CY014-S04	External protection aspiration inlet
	Part of CY014-S02	Inlet tubing flow cell (external)
	CY014-S05	Tube from flow cell to pump
	CY014-S08	Peristaltic pump cassette
	CY014-S10	Waste tube
Connectors	**Item code**	**Item name**
1	Part of CY014-S04	External protection aspiration inlet connector (incl. screw)
2	Part of CY014-S02	Inlet tubing flow cell connector
3	CY014-S03	Flow cell outlet connector
4	CY014-S06	Inlet connector pump tube
5	CY014-S09	Outlet connector pump tube

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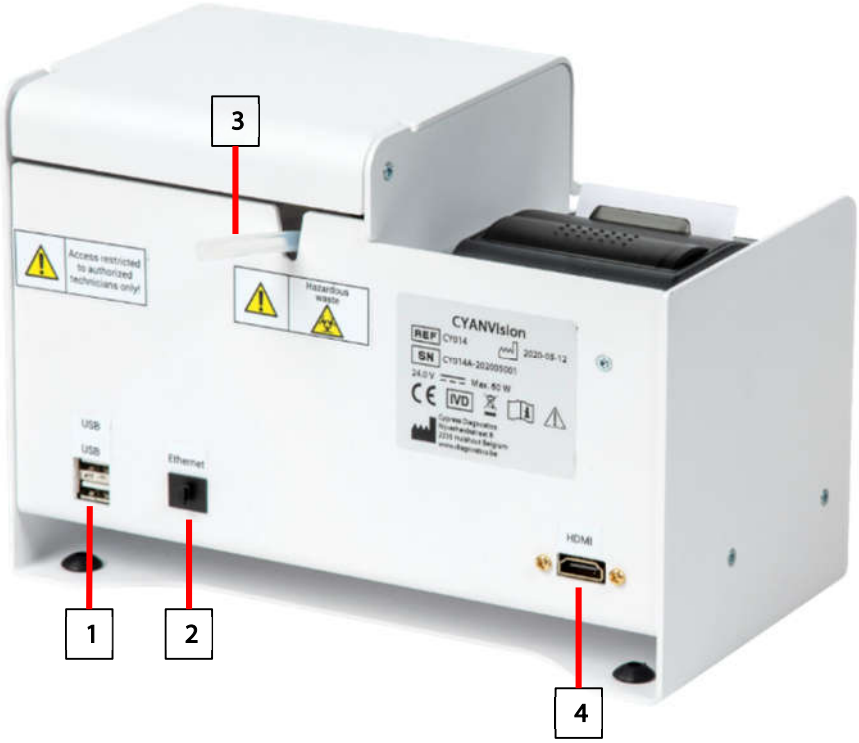
1.3.4 Side panel

On the side panel of the CYANVision the ON / OFF button, a USB connection and the DC Power inlet can be found.

1	ON / OFF Button
2	USB connection
3	DC Power inlet

1.3.5 Rear panel

The rear panel of the CYANVision holds 2 USB ports as well as 1 Ethernet and HDMI port. The tube towards the waste is also visible.



1	USB / USB
2	Ethernet
3	Waste tube
4	HDMI connection

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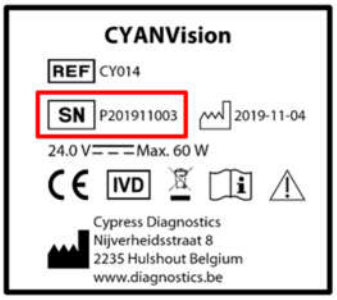
1.4 LABELS AND SYMBOLS

Every instrument has its own serial number, which can be found on the back label and can also be found in the 'About - Instrument' menu. Please mention this serial number in every communication with technical support.



Symbols which can be found on the cover of the analyzer:

Symbol	Explanation
	**Attention:** Read the instructions in the user manual before use. See chapter 2 for detailed descriptions.
	**Warning, Potential biohazards**. Carefully manipulate all the consumables and the waste produced during the analysis routines. Disposal of waste must be done in compliance with the locally applicable regulation. It is recommended to periodically/daily check the level in the waste container, in order to avoid overflow.
REF	The **reference number** of the analyzer: CY014
SN	**Serial number**
	The **manufacturing date** of the analyzer
	**Address** of the manufacturer
	**Carefully read the instructions in the user manual before use**
	**Direct current**. The input of power supply
	On-indicator. Power switch, indicating that the instrument is switched ON.
	**Off-Indicator**. Power switch, indicating that the instrument is switched OFF.
CE	**CE mark**
IVD	***In vitro* diagnostic medical device**
	**Separate collection for electrical and electronic equipment**

Symbols which can be found on the outer packaging:

	**This way up.** To indicate correct upright position of the transport package.
	**Fragile, handle with care.** To indicate that the content of the transport package is fragile and the package shall be handled with care.

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1.5 TECHNICAL AND OPERATIVE SPECIFICATIONS

Measurement system

• Min. reaction volume	500 µL per test
• Incubation time	0 - 999 seconds
• Reading time	2 - 999 seconds
• Blank options	Sample blank, reagent blank, air, and distilled water
• Calculation methods	Absorbance, endpoint, two-point, kinetic, bichromatic
• Calibration methods	Use of calibrator, standard or factor Single point or multi-point calibration
• Temperature choices	25 °C, 30 °C or 37 °C (by default: 37°C)

Optical system

• Light source	Light Emitting Diodes (LEDs)
• Photo detector	Silicon based detector (range 300 - 900 nm)
• Flow cell	Quartz glass, 32 µl, 10 mm light path Temperature controlled (PID) +/- 0.5 °C, accurate to +/- 1 °C
• Measurement range	0,000 Abs – 3,000 Abs
• Onboard wavelengths	340, 405, 450, 510, 546, 578, 620 & 670 nm
• Wavelength selection	Small bandwidth LED's + Filter
• Optical repeatability (CV)	≤ 2%

Hydraulic system

• Peristaltic pump cassette	Convenient cartridge system
• Tubing	Ultrashort, directly accessible
• Waste bottle included	

Software

• Reference ranges	Per age (adult - child), per sample (serum, plasma, urine,…), per sex (male, female, unknown) and per species (only in veterinary mode)
• Quality control	Automated import of values (QR code) Multiple controls programmable Separate QC result menu with Levey-Jennings graphs
• Calibration	Automated import of values (QR code) Separate calibration menu
• Maintenance	Digital logbook
• Methods	100 closed (Cypress methods pre-programmed at delivery) 100 open
• Data storage	100 000 results
• Data exchange	Export data and system copy to USB LIS: HL7 bi-directional connectivity Ethernet (RJ45) connection
• Languages	English, French, Russian, Spanish and Portuguese

User interface

• Connectivity	USB: External keyboard, mouse, barcode reader, QR code Reader (none included) HDMI: HD screen or HD touchscreen (none included)
• Printer	Built-in thermal printer Automatic or on-demand printing 24 characters per line Prints graphs

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Power supply

- External power supply unit: Auto-ranging 100 - 240 V AC, 50/60 Hz
Grounding required
Advised: voltage regulator & UPS
- Analyzer: Power save / Standby mode
Input voltage 24 V DC, 2,5 A, 60 W max

Weight and dimensions

- Instrument: 4 kg
23,5 x 13,0 x 17,0 cm (LxWxH)

Environmental requirements

- Optimal operational temperature: 25 °C
- Operational temperature: 18 °C - 30 °C
- Operational relative humidity: 30% - 70%
- Operational max. altitude: 2000 m

1.6 LIMITATIONS OF USE

- After turning on the instrument, pay attention not to spill liquids on the surface around the instrument. Keep the instrument away from children.
- Operate the instrument on a level, stable surface and away from excessive humidity.
- Bright sunlight or strong incandescent light can reduce the linear performance range of the instrument.
- Measurement values may be affected by extraneous particles (such as dust) in the flow cell. A clean work area is necessary to ensure accurate readings.
- When operated in a safe environment according to the instructions in this document, there are no known hazards associated with the instrument. However, the operator should be aware of certain situations that could result in serious injury; these vary depending on the instrument type. See Hazards and Precautions.
- Clinical Diagnosis of the patient should not be made on a single test result. It should integrate clinical and other laboratory data.
- No operation by (color) blind people is allowed.

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1.7 Regulatory Compliances

Based on the testing described below and information contained herein, this instrument bears the CE mark

- See the Declaration of Conformity for more information

1.7.1 Directive 2004/108/EC: electromagnetic Compatibility

- Emissions – Class A

This equipment has been designed and tested by an independent, accredited testing laboratory and found to meet the requirements of EN61326-1: Class A for Radiated emissions and Line Conducted Emissions. Verification of compliance was conducted to the limits and methods of EN 55011 – CISPR 11, Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference

- Immunity

This instrument has been type-tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1 and EN61326-2-6 for Immunity. Verification of compliance was conducted to the limits and methods of the following standards:

- EN 61000-4-2, Electrostatic Discharge
- EN61000-4-3, Radiated immunity
- EN61000-4-4, Burst
- EN 61000-4-6, Common Mode Immunity

1.7.2 Directive 2006/95/EC: Low Voltage (Safety)

This system has been type-tested by an independent testing laboratory and was found to meet the requirement of this directive. Verification of compliance was conducted to the limited and methods of the following standards:

- EN 61010-1; "Safety requirement for electrical equipment for measurement, control and laboratory use. Part 1, General requirements".
- EN 61010-2-101: "Safety requirements for electrical equipment for measurement, control and laboratory use - Particular requirements for *in vitro* diagnostic (IVD) medical equipment"

1.7.3 Directive 2012/19/EU: Waste Electrical and Electronic Equipment

This instrument contains printed circuit boards and wiring with lead solder. Dispose the instrument according to Directive 2012/19/EU- "on waste electrical and electronic equipment (WEEE)" or local ordinances, contact your dealer or supplier for further information.

For disposal in countries outside of the European Union: this symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

1.7.4 Directive 98/79/CE for *In Vitro* Diagnostic Devices (if labeled for this use)

- Product registration with competent authorities (Currently Pending)
- EN61010-2-101, "Particular requirements for *In Vitro* Diagnostic (IVD) medical equipment

1.7.5 Directive 2011/65/EU amended by 2015/863/EU on the restriction of the use of certain hazardous substances (RoHS III) in electrical and electronic equipment

The device has no intentional addition of certain hazardous components defined in the directive. Any trace impurities of these substance are below the threshold limits as specified by the RoHS directive or part of the exemption subject to Annex III or IV of the directive.

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1.8 NOTICES

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2235 Hulshout, Belgium

1.8.1 All Rights Reserved

1.8.2 Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Cypress Diagnostics. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Cypress Diagnostics for the use or reliability of software

1.9 CONSUMABLES AND ACCESSORIES SUBJECTED TO WEAR AND USE

These consumables and accessories are not included in the warranty:

Code	*Description*	*Quantity*
CY014-S02	Inlet tubing flow cell (incl. connector)	1
CY014-S03	Flow cell outlet connector	1
CY014-S04	External protection aspiration inlet	1
CY014-S05	Tube from flow cell to pump	1
CY014-S06	Inlet connector pump tube	1
CY014-S08	Peristaltic pump cassette	1
CY014-S09	Outlet connector pump tube	1
CY014-S10	Waste tube	1
CY014-S11	Waste bottle	1

2 SAFETY INFORMATION

This information summarizes the established guidelines for handling laboratory biohazard. Use this summary for general information only. It is not intended to replace or supplement your laboratory's or hospital's biohazard control procedures.
By definition, a biohazard condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood, blood products, and other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- Needles.
- Hand-to-mouth contact.
- Hand-to-eye contact.
- Direct contact with superficial cuts, open wounds, and other skin conditions may permit adsorption into subcutaneous skin layers.
- Splashes or aerosol contact with skin and eyes.

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have been in contact with body fluids such as a serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a non-contaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation is possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the system sample-path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.
- Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand.

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2.1 HAZARDS

The following hazard warnings are provided to help avoid injury:

Warning! Power Rating. The instrument's power supply must be connected to a power receptacle that provides voltage and current within the specified rating for the system. The use of an incompatible power receptacle may produce electrical shock and fire hazards.

Warning! Service. Only qualified technical personnel should perform service procedures on internal components.

Warning! Accessories. Only accessories that meet the manufacturer's specifications shall be used with the instrument.

Warning! Liquids. Avoid spilling liquids on the instrument; fluid seepage into internal components creates a potential for shock hazard or instrument damage. If a spill occurs while a program is running, abort the program and turn the instrument off. Wipe up all spills immediately. Do not operate the instrument if internal components have been exposed to the fluid.

Warning! Unspecified Use. Failure to operate this equipment according to the guidelines and safeguards specified in this manual could result in a hazardous condition.

Warning! Software Test parameters. The operator must follow the manufacturer's reagent kit instructions when modifying software parameters and establishing test parameters (Methods & Programs).

Warning! Software data Reduction & quality control The built-in software will flag properly defined quality controls when they are out of range. Failure to conduct quality control checks could result in erroneous test data. The software will display the data with an error flag for the operator to verify the outcome. It's the user's responsibility to correctly interpret these flags.

Warning! Host connection. All information exported to the host connection must be thoroughly analyzed by the operator on the analyzer before sending it to the host. If a rerun or other verification is required, this should be performed before sending the result to the host.

Warning: Internal Battery: This product contains a coin/button cell battery. Keep new and used batteries away from children. If you think the battery might have been swallowed or placed inside any part of the body, seek immediate medical attention. Before disposal always cover the battery in plastic tape to avoid possible short-circuit. If the battery compartment does not close securely, stop using the product and keep it away from children.

Warning! Potential Biohazards. Carefully manipulate all the consumables and the waste produced during the analysis routines. Always wear appropriate protective equipment, such as chemically resistant rubber gloves and apron. Disposal of waste must be done in compliance with the locally applicable regulation. It is recommended to periodically/daily check the level in the waste container, in order to avoid overflow.

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2.2 PRECAUTIONS

The following precautions are provided to help avoid damage to the instrument:

Caution: Service. The instrument should be serviced by Cypress Diagnostics authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.

Caution: Spare Parts. Only approved spare parts should be used for maintenance. The use of unapproved spare parts and accessories may result in a loss of warranty and potentially impair instrument performance or cause damage to the instrument.

Caution: Environmental Conditions. Do not expose the instrument to temperature extremes. For proper operation, ambient temperatures should remain within the range listed in the *Specifications* section. Performance may be adversely affected if temperatures fluctuate above or below this range. Storage temperature limits are broader.

Caution: Sodium Hypochlorite. Do not expose any part of the instrument to the recommended diluted sodium hypochlorite solution (bleach) for more than 10 minutes. Prolonged contact may damage the instrument surfaces. Be certain to rinse and thoroughly wipe all surfaces.

Caution: Power Supply. Only use the power supply shipped with the instrument. Operate this power supply within the range of line voltages listed on it.

Caution: Disposal. This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to Directive 2002/96/EC, "on waste electrical and electronic equipment (WEEE)" or local ordinances.

Caution: Warranty. Failure to follow preventive maintenance protocols may void the warranty.

Caution: Electromagnetic Environment. Per IEC 61326-2-6 it is the user's responsibility to ensure that a compatible electromagnetic environment for this instrument is provided and maintained in order that the device will perform as intended.

Caution: Electromagnetic Compatibility. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper orientation.

Caution: Internal Battery: Risk of explosion if the battery is replaced by an incorrect type, disposal of a battery into fire or a hot oven, or mechanically crushing or cutting can result in an explosion of the battery. Leaving the battery in an extremely high temperature surrounding environment can result in an explosion or the leakage of flammable liquid or gas of the battery. If the battery subjected to extremely low air pressure it may result in an explosion or the leakage of flammable liquid or gas of the battery"

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3 INSTALLATION

Please carefully read and follow all the instructions described below to ensure the correct installation and functioning of the CYANVision semi-automatic biochemistry analyzer .

3.1 TRANSPORT AND STORAGE

The packing has been expressly studied and designed to ensure maximum protection of the contents during shipping and handling. It is therefore extremely important that the box is carefully examined upon delivery in order to assure integrity. All visible external damage (for example holes, dents, rips or tears, watermarks, etc.) must be noted on the delivery note. Please make photos of the damage. This will simplify matters in the event of any future claims for damages.

NOTE:
Once the carrier has taken possession of the system for transportation from the factory, the carrier takes total responsibility until delivery. All claims for damage due to transportation must be filed against the carrier as soon as these damages are noticed.

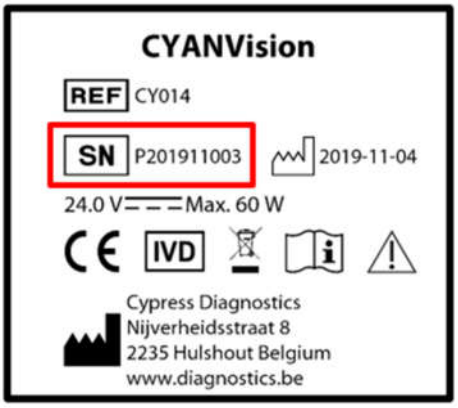
The CYANVision should **always be handled with care!** Dropping or another improper handling of the instrument will disturb calibrated mechanic and electronic components and/or cause damage. Store the analyzer in its original packaging in an environment with a temperature range of 5 – 50 °C, relative humidity not more than 70%, well ventilated and indoors. Storage should be away from toxic, harmful and corrosive substances. Make sure the box is in the upright position (arrows on the box).

3.2 UNPACKING/PACKING LIST

WARNING! Do NOT discard the carton box or protection material! If you need to ship the instrument (for example for service), be sure to use the original packing materials. Other forms of commercially available packing are not recommended and can void the warranty.

Open the box and carefully take out the analyzer and accessories:

1. Makes sure the serial number (SN on the back label) is in accordance with the delivery note.



2. Check that all the items of the following list are undamaged and included in the carton box.
   If the instrument is damaged or items are missing, contact your local distributor/importer immediately for assistance. Make sure to document with photos.

Code	*Description*	*Quantity*
CY014	CYANVision Analyzer	1
-	User manual including application sheets	1
CY014-S11	Waste bottle	1
CY014-S40	Power supply (incl. EU power cord)	1
CY001-S01	Thermal print paper (57 mm width)	5

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3.3 INSTALLATION GUIDE

The CYANVision is an easy to operate instrument with integrated user-friendly software. In order to fully guarantee the performance of the CYANVision, it is extremely important that it is correctly installed.

If the installation, usage and maintenance directions, given in this manual, are not followed correctly and/or safety indications are not respected, Cypress Diagnostics cannot guarantee the correct functioning of the instrument. Misuse can compromise the safety of the operator and his surroundings and will void the warranty. Consumables are not included in the warranty.

At installation, we strongly recommend filling in the **installation report and checklist** (provided with the instrument). It contains essential information and provides a short checklist of all installation requirements.

Procedure:
1. Verify the location specifications.
2. Install any peripheral.
3. Mount the pump cassette on the pump motor.
4. Install the waste bottle.
5. Install printing paper.
6. Connect the power cord to a suited power supply.
7. Switch on the instrument.
8. Verify the instrument.
9. Adaptation of the system to the end customer.

3.3.1 Location specifications

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance. Please take note of the following conditions required for the location of the installation:

- Placed on a stable, horizontal surface, free from vibrations.
- Clean, dust-free environment.
- Room temperature between 18 – 30 °C. Optimal operational temperature: 25 °C.
- Not in direct sunlight, this could affect the operating temperature and the quantity of light measured by the instrument.
- Avoid draughts, and do not place under/up/ besides air conditioning or heat sources.
- Do not use this device proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.
- Select a location near a suitable power source.
- Leave 10 cm around and at the back of the instrument for air circulation and cooling.
- Humidity between 30 – 70%.
- Max. altitude 2000 m.
- Atmospheric pressure between 860 hPa – 1060 hPa.

3.3.2 Install any peripheral

The CYANVision offers 3 USB sockets (2 on the rear panel, 1 on the side panel), 1 HDMI and 1 Ethernet port for connecting additional external peripheral devices (**not provided** with the analyzer).

Note:

- Make sure the power is in the **OFF** state before connections (external HDMI screen, external keyboard or mouse, barcode reader, …) are made. Carefully read all literature accompanying the peripheral instrument and its accessories.
- It is **NOT** possible to connect the CYANVision to a laptop, computer or any other device on which software is running by default.

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3.3.2.1 External HDMI screen (not included)

It is possible to connect a Full HD screen or HD touchscreen with a HDMI cable to the HDMI port at the back of the instrument.

Note:

- The external screen must have an HDMI port or a suitable adapter.
- The external screen should have a minimal resolution of 1920 x 1080 (Full HD)
- The HDMI cable can have a maximum length of 1,8 m. Longer cables are not supported.

3.3.2.2 Keyboard or USB connection of touchscreen (optional)

The CYANVision supports connecting an external USB keyboard (or external touchscreen with USB adapter) to facilitate data entry. Remove the protection from an USB A port at the back of the instrument to allow connection.

WARNING! Do NOT discard the protection cap! If the keyboard is removed the cap should be repositioned over the USB connection for safety reasons.

Note:

- The external keyboard must have an USB port or a suitable adapter.
- In case an HDMI touchscreen is used, an on-screen keyboard can be enabled in the software (see chapter 4.7.2: Regional settings).

3.3.2.3 Mouse (optional)

An USB mouse can be connected to one of the USB A ports at the back of the instrument. First remove the protection from the USB A port.

Warning! Do NOT discard the protection cap! If the mousse is removed the cap should be repositioned over the USB connection for safety reasons.

Note:

- The external mouse must have an USB port or a suitable adapter.

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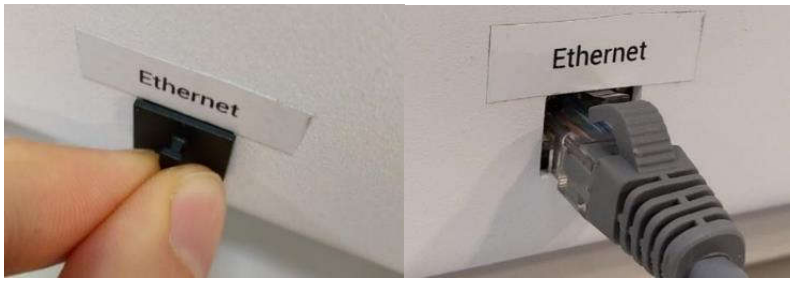
3.3.2.4 Ethernet for LIS connection (optional)

The analyzer can be connected to the local network by Ethernet cable (not included). Remove the protection from the Ethernet (RJ45) socket at the back of the instrument to attach the Ethernet cable.

Warning! Do NOT discard the protection cap! If the ethernet cable is removed, the cap should be repositioned over the ethernet connection for safety reasons.



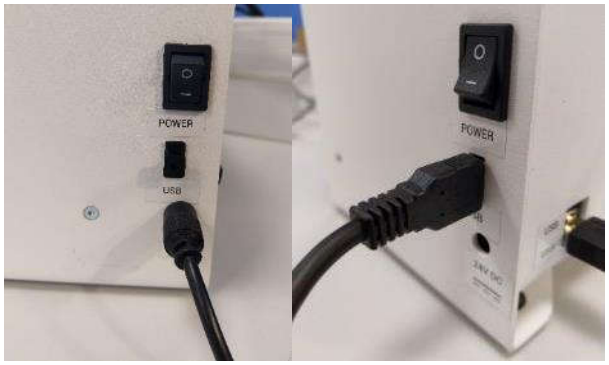
Note:

- Ethernet cable must have an RJ45 connection or a suitable adapter.
- Ethernet cable can have a maximum length of 30 m.

3.3.2.5 Barcode reader (optional)

An USB barcode reader can be connected to the CYANVision analyzer. Remove the protection from the USB connection on the side of the instrument to attach the USB connection of the barcode reader.

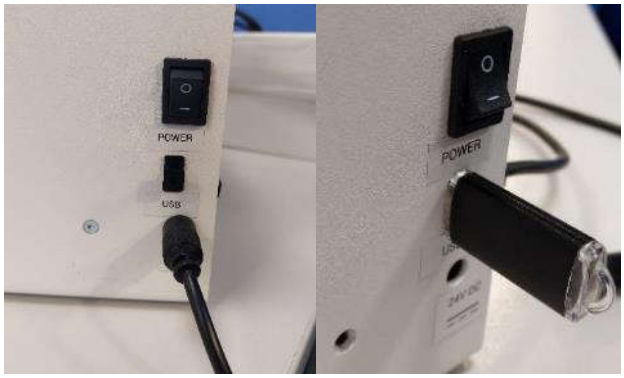
Warning! Do NOT discard the protection cap! If the USB barcode reader is removed, the cap should be repositioned over the USB connection for safety reasons.



3.3.2.6 USB flash drive (optional)

An USB flash drive can be connected to save reports and database or system content. Remove the protection from the USB connection on the side of the instrument to allow inserting the USB flash drive.

Warning! Do NOT discard the protection cap! If the USB flash drive is removed the cap should be repositioned over the USB connection for safety reasons.



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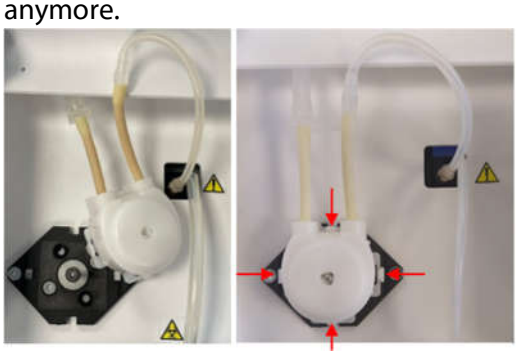
3.3.3 Mount the pump cassette on the pump motor

Upon delivery of the analyzer, the pump cassette is dismounted from the pump motor to avoid deformation of the pump tubes due to pressure on the pump rollers.
Mount the pump cassette on the pump motor and apply slight pressure until you hear the pump cassette clicking in place. All clips on the sides (indicated in red) should be in position, the cassette cannot be moved anymore.



3.3.4 Install the waste bottle

Waste must be collected in a separate container which is delivered with the instrument.

Procedure:

1. Lift the cover of the hydraulic system.
2. Slide the waste tube through the slit at the back of the instrument.

3. Remove the cap of the waste bottle and remove the internal cap.
4. Screw the external cap back on the waste bottle. Keep the internal cap, this can be used to discard the waste and clean the bottle to prevent spillage of liquid.
5. Slide the waste tube through the hole in the waste bottle.

ATTENTION:

Place the waste tube deep enough to avoid it slipping out during measurements but avoid inserting it too deep so it does not reach the waste liquid level. This could cause poor draining and increases the risk of tube contamination!

Warning! Potential Biohazards. Carefully manipulate all the consumables and the waste produced during the analysis routines. Always wear appropriate protective equipment, such as chemically resistant rubber gloves and apron. Disposal of waste must be done in compliance with the locally applicable regulation. It is recommended to periodically/daily check the level in the waste container, in order to avoid overflow.

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3.3.5 Install printing paper

To correctly install the thermal printing paper, follow the procedure below.

Procedure:

1. Open the printer cover of the instrument (pull the lid upwards by using the handle).
2. Remove any left-over of the old print paper roll.
3. Take a new paper roll and place it in the right direction (see attention point below) into the paper slot.
4. Roll off the print-paper so that the 'starting edge' is coming towards you from down under.
5. Close the lid, making sure that the paper is captured between the lid and the front of the printer.

ATTENTION:

Only the coated side can be used to print. If the paper is installed in the wrong direction the paper will move through the printer, but nothing will be printed. To verify the printable side of the paper, the operator can scratch the paper. Only one side will become slightly greyish (see picture above), this is the side that can be used for printing and thus should contact the printing bar.

3.3.6 Connect the power cord to a suited power supply

The CYANVision is delivered with an approved power supply and power cord. Proper use of the power cord assures adequate grounding of the system. The electromagnetic environment should be evaluated prior to the operation of the device. The power outlet connection MUST be grounded. Environmental and electrical characteristics provide the accuracy and precision of the instrument and maintain a high level of operational safety for lab personnel.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Procedure:

1. Place the instrument on a flat surface in the designated work area, near an appropriate AC wall outlet.
2. Before connecting the power cord, check that the AC wall outlet corresponds to the value that is stated on the power supply.
3. Connect the power plug to a grounded AC wall outlet, preferably one that is not shared with other electric appliances and with low fluctuation of line voltage.
4. Make sure that your AC mainline has an efficient ground line. If the AC wall outlet is not properly grounded, please connect the ground or earth wire to the external grounding connector on the back of the analyzer.
5. Keep the instrument away from other appliances that generate high-frequency electrical noises (e.g. radiological instruments). To ensure proper instrument functioning, the manufacturer strongly advises using a stable tension supply outlet (± 10%). If this cannot be guaranteed, use of the following supplementary devices is necessary:
   a. **Electronic Stabilizer**
      This is used to stabilize the electric voltage in the laboratory. Any stabilizer, currently available on the market, with a power potential of at least 0,2 KW can be used.
   b. **No Break module UPS (Uninterrupted Power Supply).**
      This module provides two important functions:
      - Stabilizes the main-line power
      - Supplies current to the instrument in case of a main-line power failure.

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Notes:

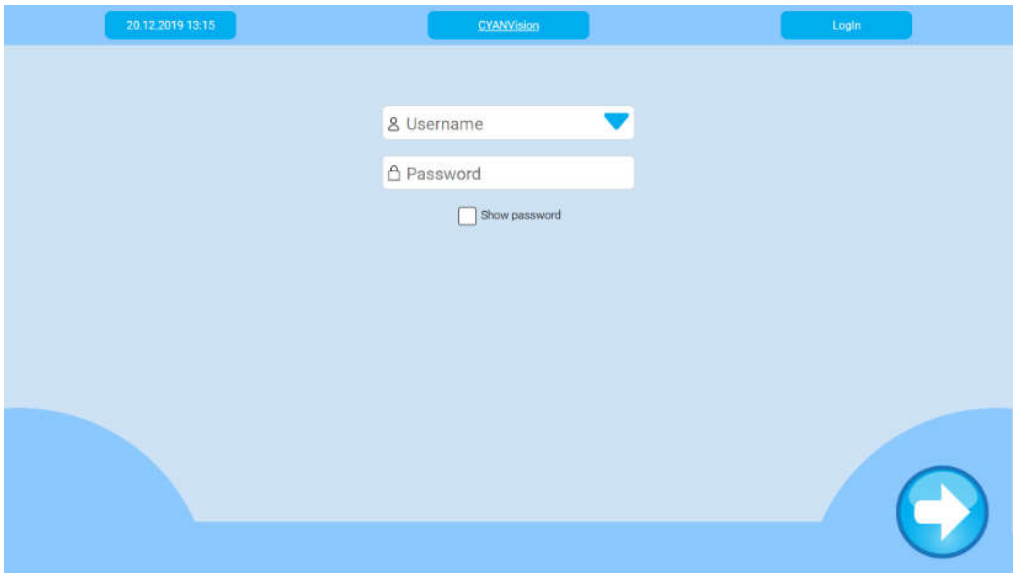
- Improper grounding of the analyzer bypasses important safety features, compromises analysis results and damages the instrument.
- Prior to initial operation, allow the instrument to reach room temperature (approximately two hours). Rapid temperature changes in an operating unit can lead to water condensation, which may damage electronic parts, and cause malfunction.
- The power supply unit and internal electronic boards must NOT be opened or serviced by the user!

3.3.7 Switch on the analyzer

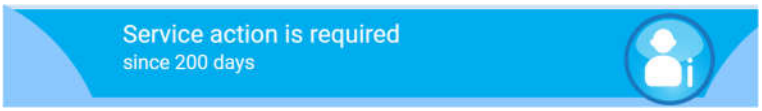
At start-up, the instrument will perform an initialization, then the login screen will appear.

Procedure:

1. Press the "ON/OFF" switch on the side of the analyzer.
2. Select the username from the dropdown menu and insert the corresponding password.



3. Ignore the following Service action pop-up, the necessary actions will be performed when verifying the instrument (chapter 3.3.8).



4. Press the "Continue" button, the main menu will appear.

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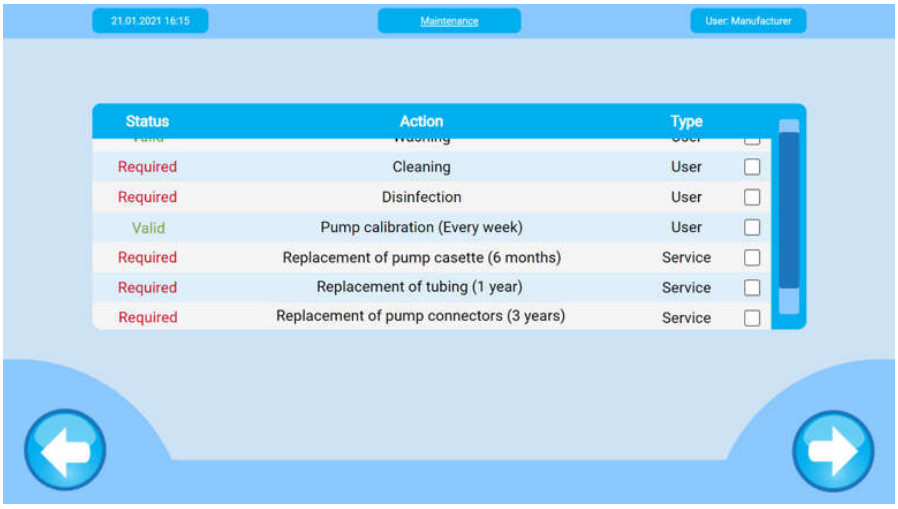
3.3.8 Verification of the instrument

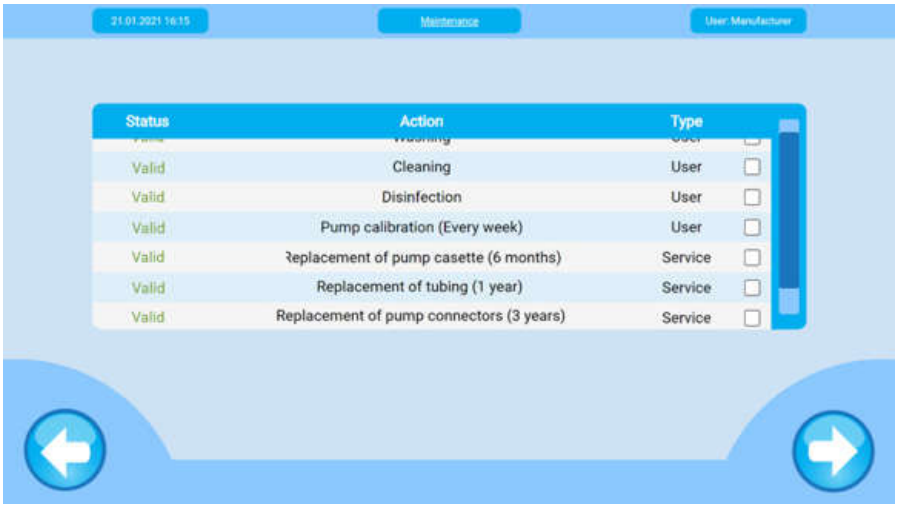
Before using the instrument for sample measurements, validate its performance by executing the actions below.

Procedure:

1. During start-up, the instrument will automatically perform an initialization.
2. Perform a washing and external surface cleaning.
   During packing and transport, dirt can get in the tubes and on the instrument. It is thus recommended to perform washing of the tubes (see 7.2.1 point b) and to clean the outside of the instrument (see 7.2.2).
3. Perform a pump calibration to verify the aspiration and hydraulic system (see 4.5.3).
4. Perform an Auto Zero to verify the optical system (see 4.5.2).
5. Reset the timer for the maintenance actions, to allow warnings to be emitted starting from the first use of the instrument:
   a. Navigate to "Maintenance - Overview".
      Due to the default manufacturing settings, some maintenance actions will be shown as required.



   b. Reset the user maintenance actions by performing the "Cleaning" and "Disinfection" one by one. Check the boxes, press "Continue" and follow the described steps in the software.
   c. Reset the service actions one by one by checking the corresponding boxes, pressing "Continue" and confirming the tubing and connector replacements (without actually changing the items).
   d. When all actions have been executed, the maintenance actions will be shown as valid.



   Warnings will now be shown once the maintenance actions are due following a specific schedule (see details in chapter 7: Maintenance).

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3.3.9 Personalization of the system

Upon installation of the CYANVision analyzer, modify the system settings and customize the programs to the needs of the end customer.

Procedure:

1. Modify the system info:
   a. Adjust the regional settings such as the language, date format and set the date & time (see 4.7.2).
   b. Define the report settings to the customer's needs (see 4.7.3).
   c. Insert the name of the hospital or laboratory where the instrument is installed as well as the name of the distributor who is responsible for the maintenance of the analyzer (see 4.8.1).
   d. Create user accounts (see 4.8.4).
2. Customize the programs:
   a. Adjust the report name (see 4.6.2.1).
   b. Select the requested measurement unit (see 4.6.2.1).
   c. Adjust the normal ranges for each profile for your region, if necessary (see 4.6.5).
   d. Create test profiles (see 4.6.6).

3.3.10 Give an extensive explanation to the user

Thoroughly explain the procedure for routine analysis (patient entries, patient results, calibration, QC measurements). Teach how to run the tests by using the application sheets and check the results. Always perform some tests together with the user (see chapter 5: Daily routine).
Also, explain the user maintenance (see chapter 7: Maintenance) and make an appointment for service maintenance. Leave the user manual in the laboratory. It contains essential, daily instructions to execute the tests.

3.4 PREPARE THE CYANVISION FOR SHIPMENT

If you need to send the CYANVision for service or repair, use the original packing materials. Other forms of commercially available packing materials are not recommended and can void the warranty. If the original materials have been damaged or lost, contact Cypress Diagnostics or your local distributor for replacements.

Note:
Failure to properly pack the analyzer increases the likelihood of damage to the analyzer during shipping. The packaging system stabilizes the CYANVision mechanical components, which would otherwise be free to move around during shipment.

Procedure:

1. Launch the "**Disinfection"** procedure from the "Maintenance - Overview" menu before repacking the analyzer. See chapter 7.2.1 for detailed instructions.
2. Turn off the analyzer and unplug the power supply.
3. Remove any installed peripherals and the waste bottle.
4. Disconnect the pump cassette from the pump motor.
5. Place the analyzer on its side, place it in the plastic bag and attach the protective caps.
6. Close the box firmly. Write the complaint number, the correct coordinates and shipping address on the outside of the box.

Warning! If the analyzer has been exposed to potentially hazardous material, decontaminate it to minimize the risk to all who come in contact with the CYANVision during shipping, handling and servicing. Decontamination prior to shipping is required by local regulations.

3.5 OPENING THE INSTRUMENT FOR INSPECTION

The CYANVision is a high precision laboratory analyzer. There are no user serviceable parts inside this instrument. Adjustments or repair of internal components should only be performed by qualified service personnel. For service maintenance and in case of malfunction, contact your local certified distributor.

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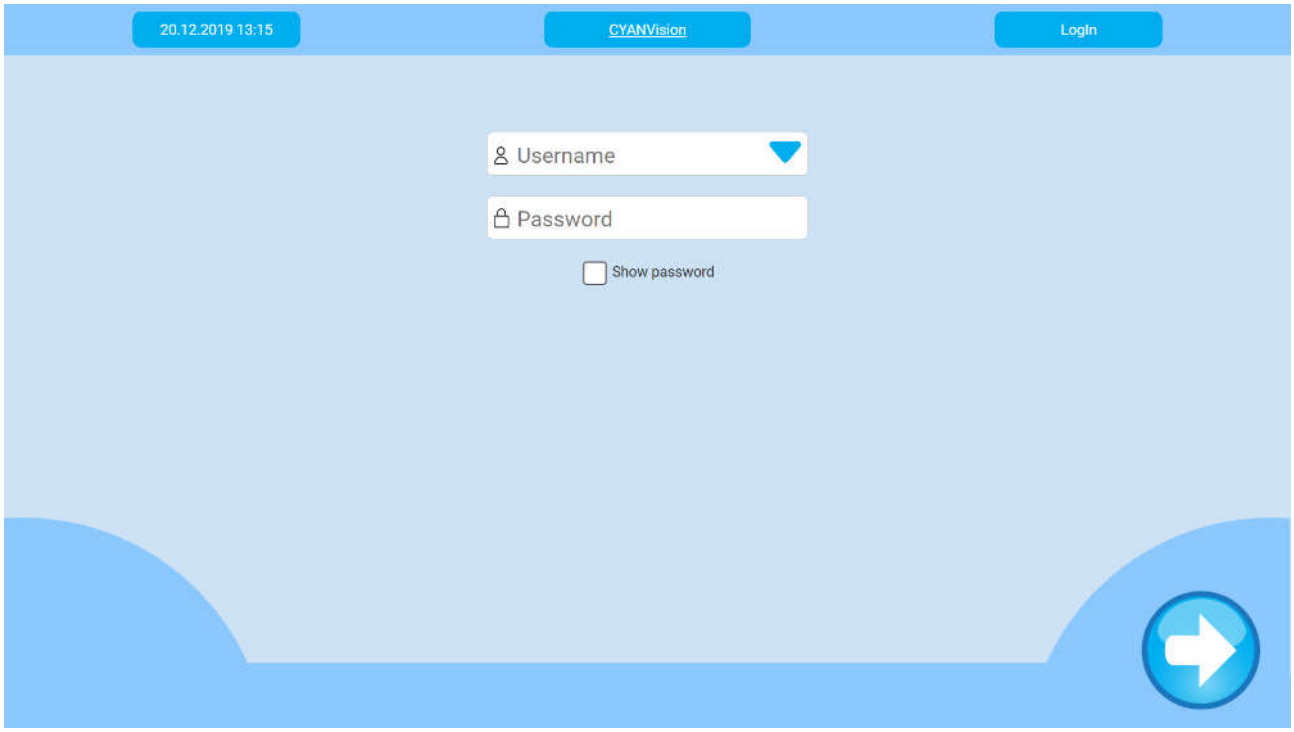
4 SOFTWARE DESCRIPTION

4.1 LOGIN

Switch on the instrument using the power switch located on the right side of the instrument. During start-up, the instrument will perform an initialization. After the start-up system test has been performed successfully, the log-in screen will appear.



Field or button	Function
Username	Select the user login name from the dropdown menu. In case no accounts have been created at installation, choose 'Lab_Head'.
Password	Upon selection of this box, an on-screen keyboard will appear to insert the password of the selected user (for the 'Lab Head' user account, the password is 'Cypress1').
Show password	To display the entered password.
	Press "Continue/Next" after filling in the "Username" and "Password" to enter the main menu. **Note:** If the password does not correspond to the login name, an error will be shown.

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4.2 MAIN MENU

The main menu consists of 6 specific menus. Select one of the buttons to navigate to that specific menu.

The different menus have the following functions:

Button	Function
	Perform test: To measure samples for a certain method.
	Results: To (re)view, print or delete the sample and quality control result database. Also view QC statistical information.
	Maintenance: To perform the punctuational and periodical maintenance of the instrument.
	Parameters: To set up the parameters for each test method.
	Options: Software information, regional settings, report settings, temperature settings, filter test, other settings.
	About: Contains the contact information, test counter, instrument diagnose and account management.

In the footer of the screen, the following buttons are displayed:

Button	Function
	Log out, to end your user session without turning the analyzer OFF. The login screen will then appear.
	Tube wash, to activate the peristaltic pump to rinse the hydraulic system (tubes + flow cell).

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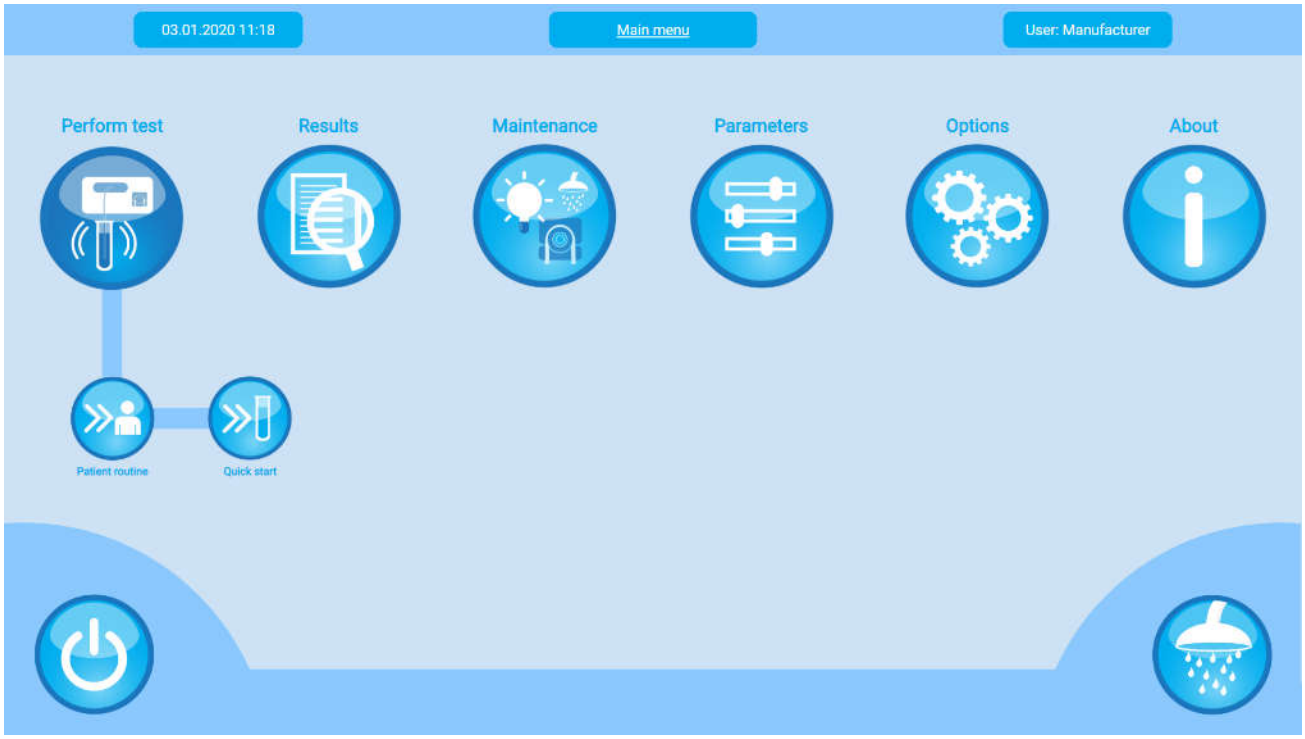
4.3 PERFORM TEST

The "Perform test" menu contains 2 submenus:
- **Patient Routine:** To manage the worklist, to program the patient's personal data and required tests.
- **Quick Start:** To immediately start with a specific method.

Note:

- Once you have entered these submenus, the blue aspiration push button in front of the device can be used to easily navigate to the next page in the software.
- Returning to the main menu can be achieved by pressing the middle, underlined button in the header.



For the best results, we advise using Cypress Diagnostics reagents. The analyzer is delivered with all Cypress Diagnostics biochemistry test methods pre-programmed. These methods have been extensively verified and optimized. In the **application sheets,** you can find detailed information on the preparation of the samples and the execution of the tests for all Cypress Diagnostics kits. Using these pre-programmed methods and following the preparation instruction correctly, Cypress Diagnostics guarantees the accuracy and precision as stated in the kit's insert.

For the best use of our kits on a Cypress Diagnostics analyzer we kindly advise following the application sheets of the respective analyzer (NOT the kit insert). Upon registering to our website (www.diagnostics.be) you can find the latest application sheets under analyzers.

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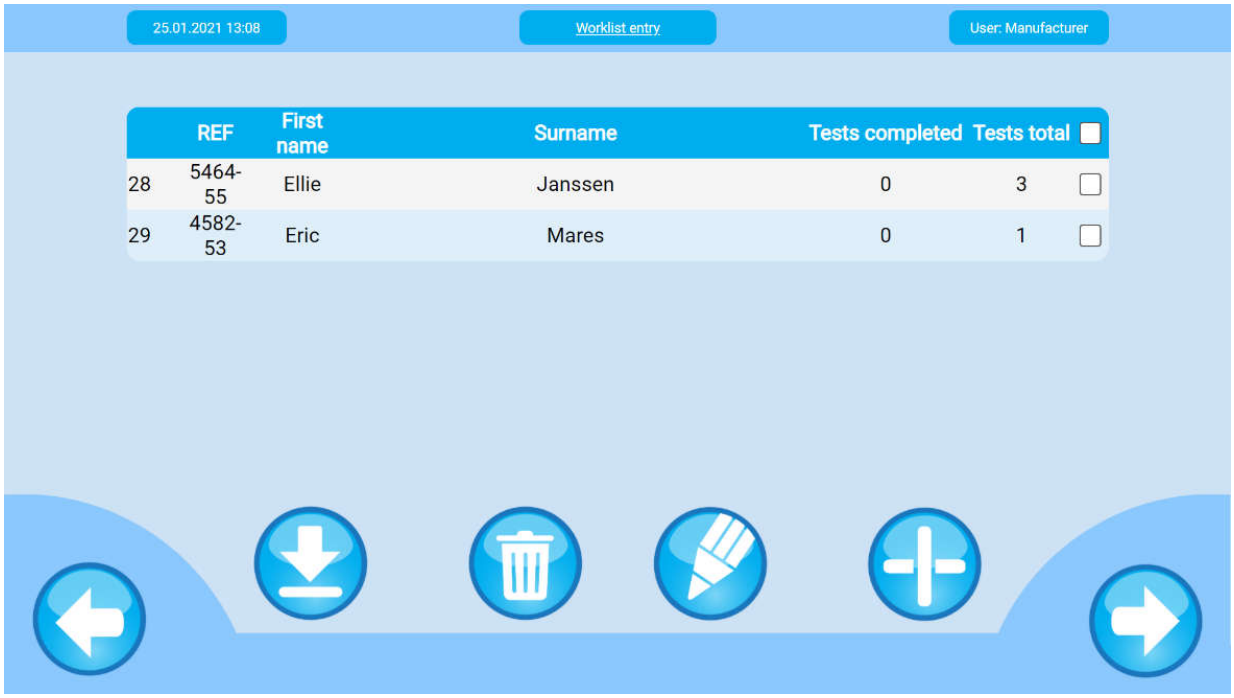
4.3.1 Patient Routine

This window allows managing the worklist with the programmed patients and their requested tests. For an optimal workflow, this programming phase is recommended before proceeding to the execution of the tests.



Field or button	Function
REF	The unique identifier of the specific request. This can be a unique Sample ID, Request ID or Patient ID depending on the internal workflow of the lab.
First name	The patient's first name (given name).
Surname	The patient's surname (family name).
Tests completed	The number of executed programs for the specific requests.
Tests total	The total number of required tests for the specific requests.
	Return, to go back to the main menu.
	Continue, to proceed to the program selection. Alternatively, the push button in front of the device can be used.
	Load, this command allows to activate and then automatically receive data transmission from the host. The worklist is automatically updated. (If LIS-communication (Host connection) is enabled see 4.7.6).
	Delete, to delete the selected requests.
	Edit, to edit the selected request.
	Add, to add a new request.

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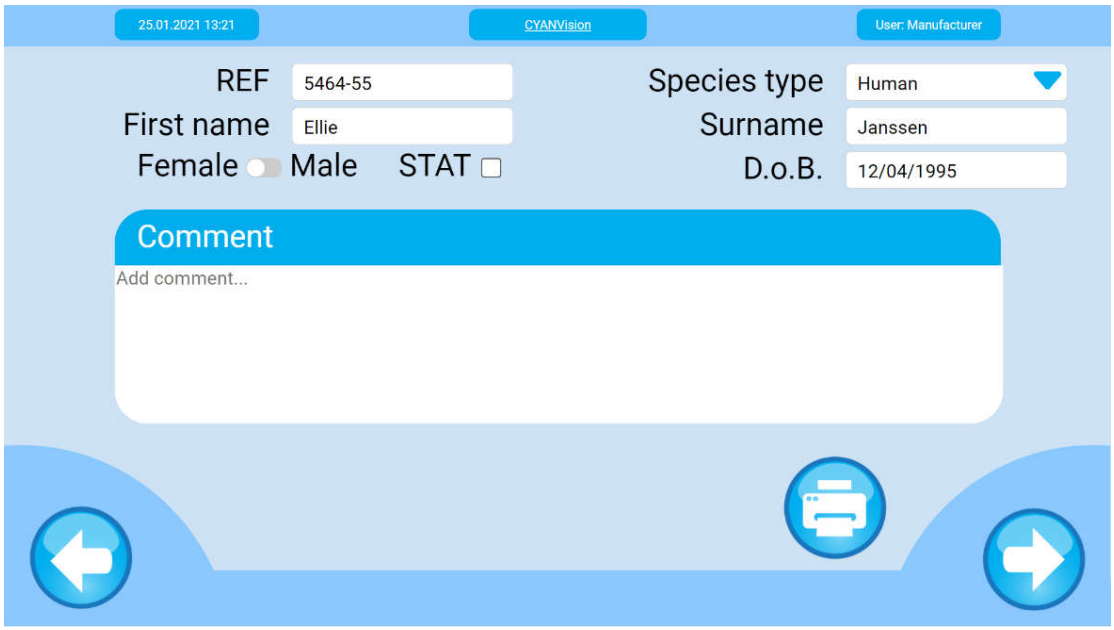
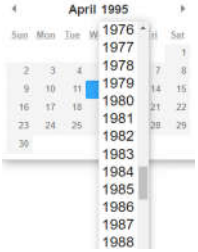
4.3.1.1 Add or modify a patient

Pressing "Add" or "Edit" allows to manage the different properties of a specific patient. This window allows inserting data regarding the patient and their requested tests. Change the properties by pressing the individual fields. For an optimal workflow, this programming phase is recommended before proceeding to the execution of the tests.



Field or button	Function
REF	The unique identifier of the specific request. This can be a unique Sample ID, Request ID or Patient ID depending on the internal workflow of the lab. **Note:** If the REF is fully inserted and matches an existing REF a pop-up shall appear to approve the autocompletion of the first name, last name, D.O.B., sex, and species type. It remains possible to modify this information.
Species type	Only if veterinary use is activated (see 4.7.6) The species type is used to evaluate the patient result with the correct reference values. After sample running, it is not possible to modify this patient property.
First name	The patient's first name (given name).
Surname	The patient's surname (family name).
Sex	The sex of the patient is a required field. Press the button to change between male and female. Male is the default setting. The sex is used to evaluate the patient result with the correct reference values. After sample running, it is not possible to modify this patient property.
STAT	Abbreviation for "Short Turn-around Time". This indicates that the sample is **urgent** and will be performed first.
DOB	Patient's date of birth. The date can be inserted manually using a keyboard or by using the calendar picker. 
Comment	Any information deemed important or useful (max. 200 characters).

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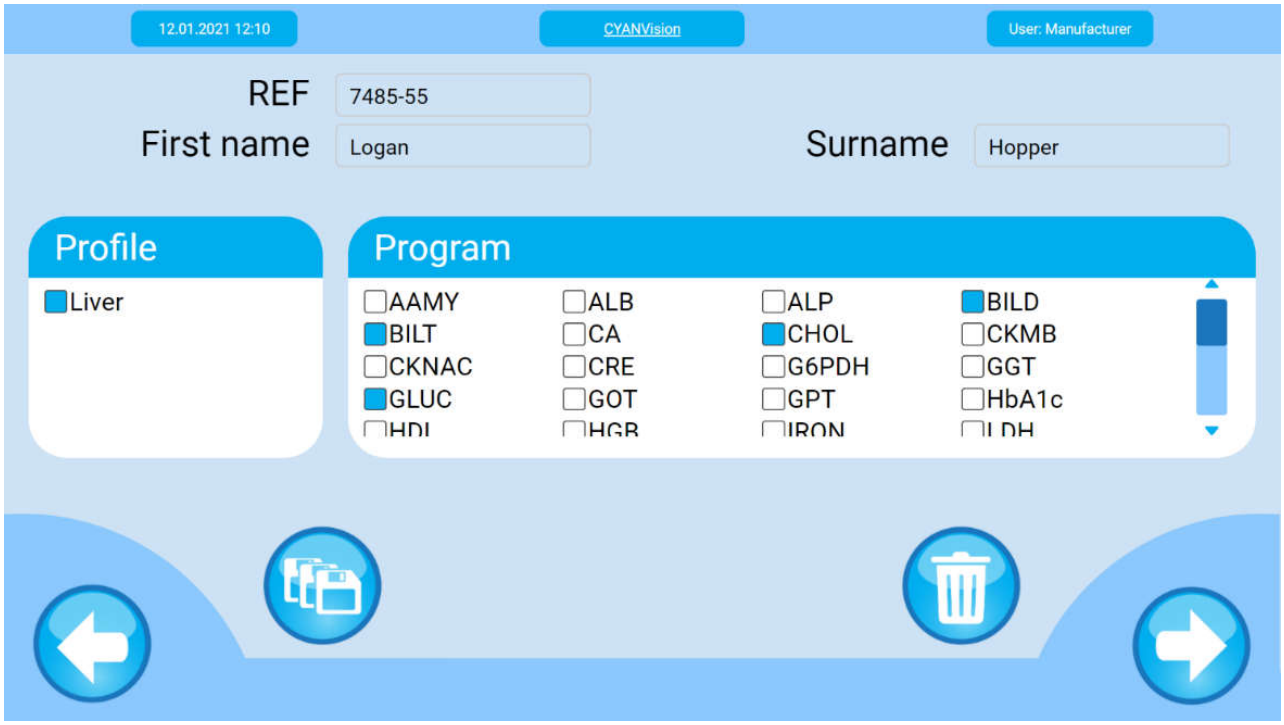
Field or button	Function
	Return, to go back to the worklist overview.
	Next, to proceed with the selection of the specific programs. Alternatively, the push button in front of the device can be used.
	To print the specific patient information.

4.3.1.2 Selecting patient specific tests

Pressing "Continue" allows to program specific tests or selecting a profile for patients.



Field or button	Function
Profile	When a profile is selected in the profile tab, all the tests that are programmed in that profile (see 4.6.6) will be automatically selected and the checkbox will appear blue in the program tab. When a profile is deselected in the profile table, all the tests part of the specific profile are automatically deselected.
Program	Select the checkboxes to assign the requested program for that patient. The checkbox will be marked blue.
	Return, to go back to the previous screen.
	Next, to save the changes and return to the worklist entry overview. Alternatively, the push button in front of the device can be used.
	Save for, to save this specific programming for more than one patient. The following dialog box will appear:

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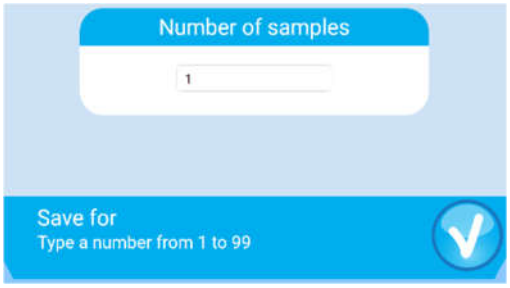
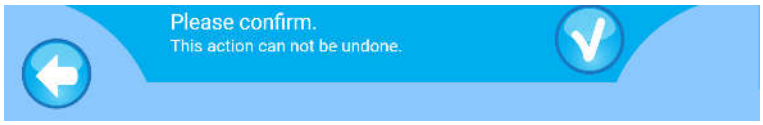


Insert the number of patients for whom the data must be programmed, within the maximum available number of 99. Click "Yes", to confirm and complete the operation. Click "Return" to cancel the operation.

Note:

- If the REF was inserted, all the patients will receive the same REF.
- After saving it is possible to add personal information for a specific patient. Select the SID on the position list, add the personal information and save again.

Delete, to delete the displayed request. The following warning will appear:



Click "Yes", to confirm the deletion. Click "Return" to cancel the request and return to the request.

Note:

If a partially analyzed sample is deleted, the remaining tests are no longer performed.

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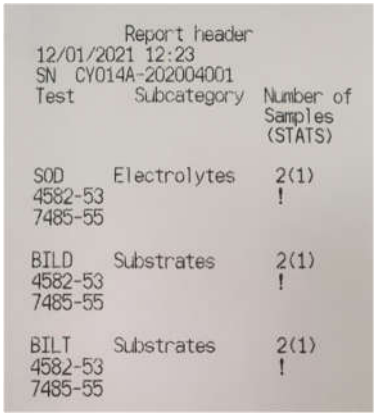
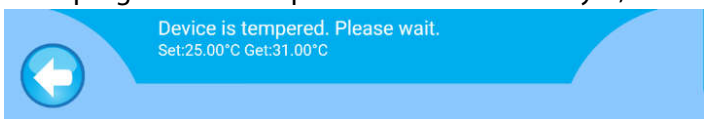
4.3.2 Program selection

After the worklist entry or when pressing the “Perform test - Quick start” button on the home screen, a list with the programs will appear. Select the desired program by clicking on the corresponding checkbox. The programs with the most STATs (Short Turn Around Time, priority samples) are displayed above all other programs. The program without any requests is displayed below all other programs.

Button	Function
	Return, to go back to the previous screen.
	Next, proceed with the selected program to the kit selection. **Note:** The first program is always selected by default.
	Print, to print the worklist order. In case a specific test contains a STAT sample, the REF is marked with an “!”. 

Note:

If the programmed temperature is not reached yet, the following warning will appear:



After start-up, the instrument should reach the default temperature (37 °C) within 5 minutes. A stable temperature is required for an accurate measurement. It is thus strongly recommended to NOT proceed if the temperature has not yet reached the set temperature.

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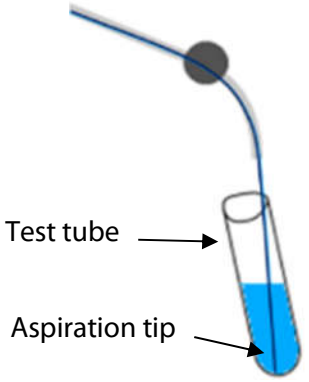
The following screens will guide the user through the test procedure. The software will inform the operator what to perform: Auto Zero, blank, standard, calibrator, control or sample measurement and will indicate the acceptable range to facilitate the decisions the user has to make. The different menus will now be explained using the endpoint test "Glucose Liquid". If differences exist for the other method types, these are explained in chapter 6 - Specific program instruction and formulas.

Operating tips: how to aspirate liquids into the flow cell

Under the aspiration inlet, the aspiration button can be found. Upon pressing the aspiration button (for no more than half a second), the peristaltic pump is activated and the correct amount of liquid volume (according to the method settings 500 – 1000 µL) is aspirated in the flow cell, where it will be measured.
To reduce interference, carryover and the risk of contamination, an air gap will be automatically aspirated between the samples.

Instruction for a correct aspiration:

1. Prepare disposable test tubes with the correct amount of reagent and sample volume according to the method.
2. Position the aspiration tip inside the test tube, be sure that the aspiration tip is in the lower corner of the test tube (see figure).
3. Press the aspiration button, the sample will be aspired automatically.
4. After aspiration is completed (no more pump motor sound), remove the aspiration tip from the liquid, so air can be aspirated (= air gap).



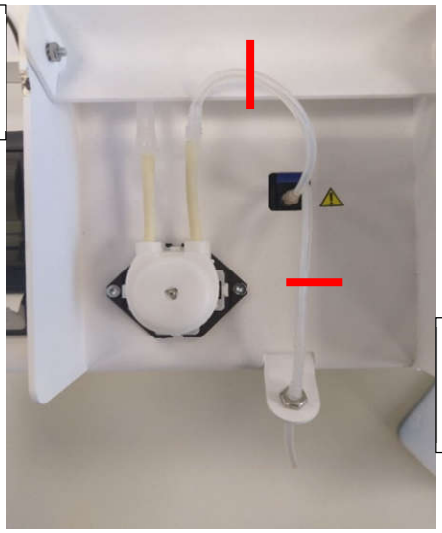
To ensure correct measurement, the flow cell should be filled with liquid and free of air bubbles. This filling can be easily checked by opening the cover. Check the tubes going to and from the flow cell:

- The aspiration tube must be completely filled with liquid and free of air bubbles from the fastening screw to the flow cell.
- The tube from the flow cell to the pump tube should be filled with liquid and free of air bubbles until the peristaltic pump tube connector.

If these tubes are filled with liquid until the limits indicated below and are free of air bubbles, the flow cell is correctly filled. Otherwise, check 4.5.3: Pump calibration.

ATTENTION:
Close the optical cover for further measurements. Background light can interfere with the measurements!

Tube from flow cell to pump, air bubbles only visible after the 5 cm limit



Aspiration tube completely filled with liquid, no air bubbles

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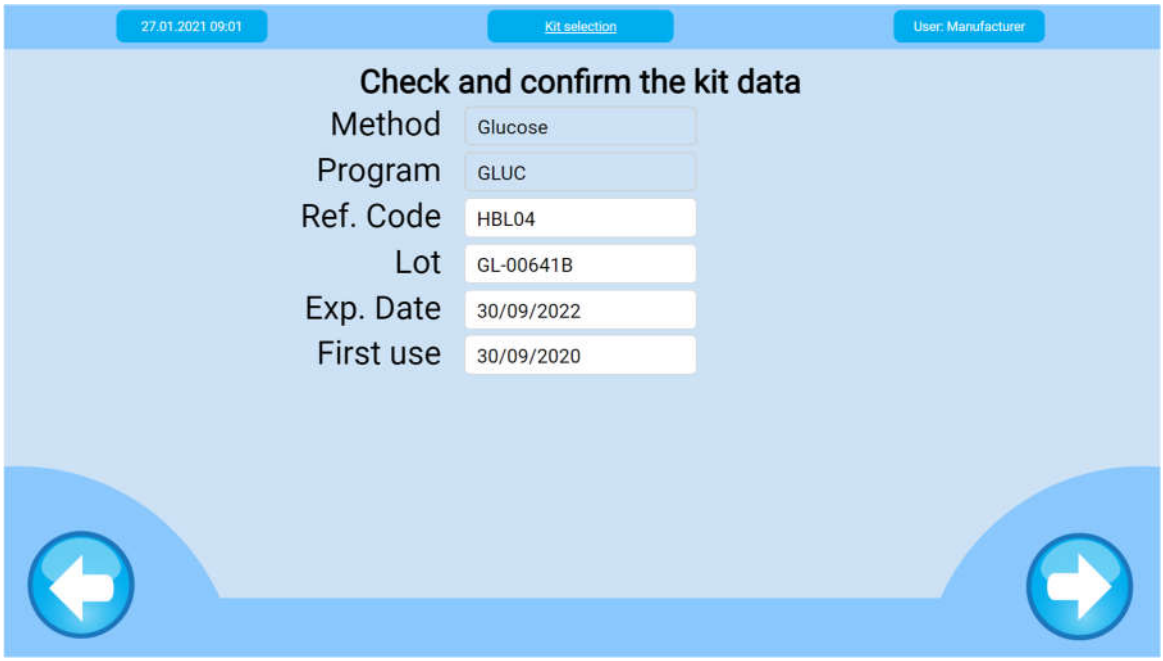
4.3.3 Kit selection

The first step in the test procedure is to fill in the reagent kit information. The most recently used reagent kit information will be displayed. Adjust the information when a new reagent bottle or a new lot of reagent is used. This can be done manually or by scanning the barcode on the kit. When using the barcode platform verify if the selected program matches the used reagent kit and if the most recent programming is used, if not a warning appears. In case a new lot of reagent is inserted the operator will have to perform a new blank measurement.



Field or Button	Function
Ref. Code	Reference code of the reagent kit (see kit label).
Lot	Lot number of the reagent kit (see kit label).
Exp. Date	Expiration date of the selected kit (see kit label). **Note:** In case the kit is expired a warning will appear.
First use	Date when this specific kit was used for the first time.
	Return, to go back to the previous screen.
	Next, proceed with the selected reagent kit and perform an autozero.
	Scan the barcode code on the reagent kit the information is automatically loaded. **Note:** This is only applicable for supported Cypress Diagnostics reagent kits.

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4.3.4 Autozero

Before the measurements can start an auto zero is performed to initialize the optical system. This measurement is always performed with distilled water.

Note:
To have a correct reference measurement, it is essential that the hydraulic system (tubes and flow cell) is clean. Verify the maintenance overview (see 4.5.1) and make sure the required cleanings are performed.

Button	Function
	Return, to go back to the previous screen.
	Wash, to activate the pump and rinse the flow cell.
	Skip, to skip the Auto zero measurement. **Note:** The skip button is not available when: - The last Auto zero is executed more than 4 hours ago. - After a start-up or standby.
	Print, to print the result of the AD Auto zero. 
	Aspirate, to activate the pump. The measurement is automatically started after the sample is aspirated.

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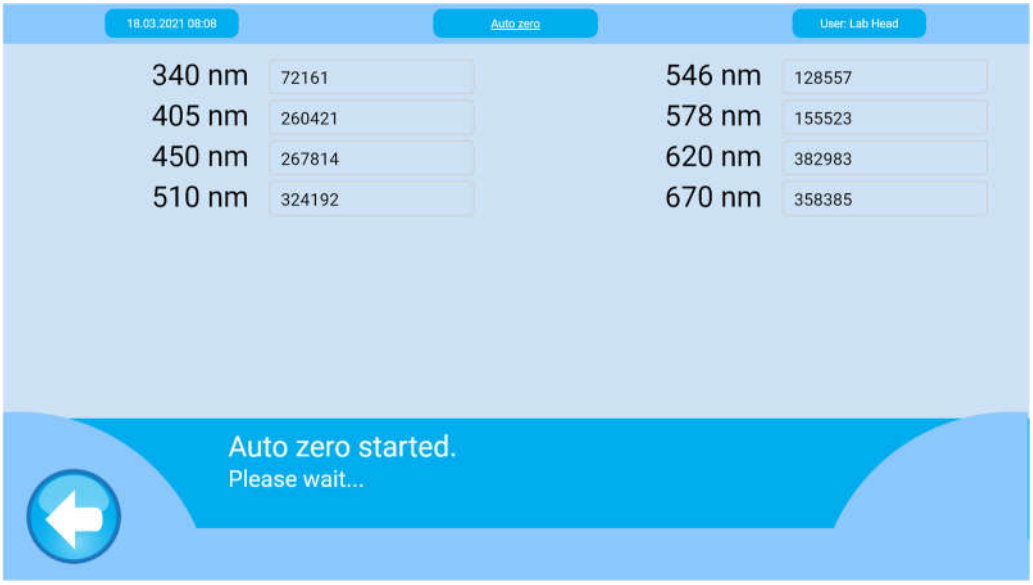
Procedure:

1. Position distilled water under the aspiration inlet and press the “Aspirate” button.
2. The distilled water will be aspirated in the flow cell and the instrument will perform the auto zero measurements.



3. When the measurement is finished, the full signal measurement will be displayed (and printed if the print button is pressed).

4. The full signal value should be higher than **50 000**.
   a. If the full signal is above 50 000, no error is displayed. Press “Next” to proceed.
   b. If the full signal is below 50 000, the error “◆” will be displayed behind the value. Press “Rerun” to repeat the measurement. Do NOT continue measuring if the full signal is outside the acceptable range!

ATTENTION!

If after 2 reruns the value is still outside the acceptable range, perform the following checks:

- Rinsing with 15 mL distilled water (see 7.2.1).
- Cleaning with detergent and/or 5% hypochlorite (see 7.2.1).
- Pump calibration and verify that the flow cell is filled with distilled water and free of air bubbles (see 4.5.3).

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4.3.5 Reagent Blank

The reagent blank (RBL) measurement is essential in the calculation of endpoint tests but will also provide an indication of the reagent deterioration or the cleanliness of the instrument. Check the application sheets to determine which reagents needs to be measured and for the number of blank measurements that are recommended to be performed. The last 10 measurements for the specific program are displayed on a graph with an indication of the high and low limit.

We recommend to perform the RBL measurement to guarantee that the reagent is fit for the purpose. This step is required for each new (working) reagent lot.

Button	Function
	Return, to go back to the previous screen.
	Continue, to proceed with the RBL measurement.
	Skip, to skip the Reagent Blank measurement. **Note:** The skip button is **not** available when: - A new lot of reagent is used. - A new working reagent is used. - When it is the first time the program is executed. - When the reagent blank is mandatory by the programming.
	Renew working reagent, to press when a new working reagent is prepared. The reagent age will be reset (only for working reagents).

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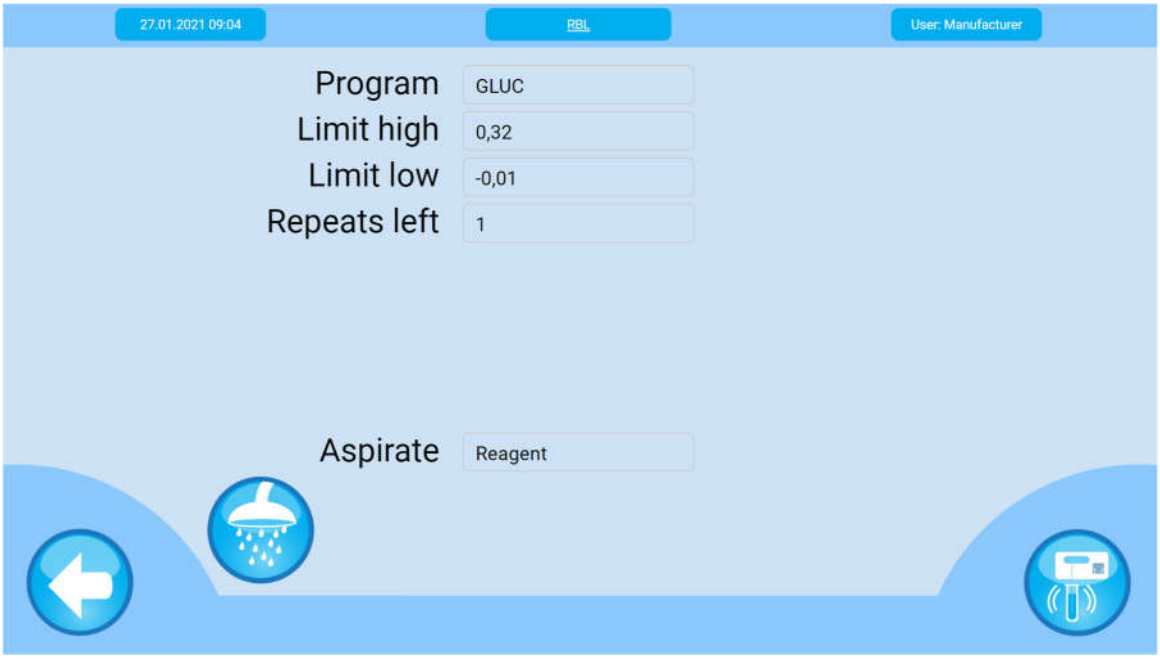
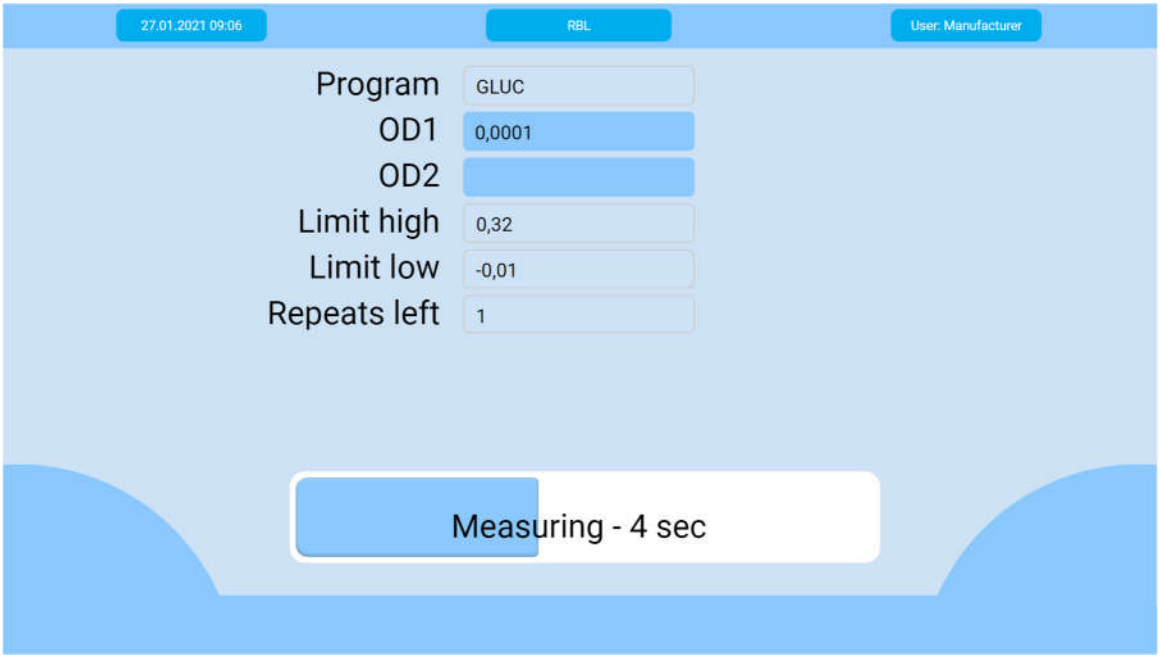
Procedure:

1. The first screen shows the RBL OD value obtained during the last blank measurement.
2. Press "Next" to perform a new blank measurement. It is strongly recommended to measure a new blank every time you perform a test.
   If "Skip" is pressed, the instrument will use (and print) the last blank value to calculate the result of the measurements.
3. Position the test tube containing the blank (reagent, distilled water or air) under the aspiration inlet and press the aspiration button. "Repeats left" shows how many times this reagent blank should still be measured.



4. The blank will be aspirated in the flow cell and the instrument will perform the measurement.



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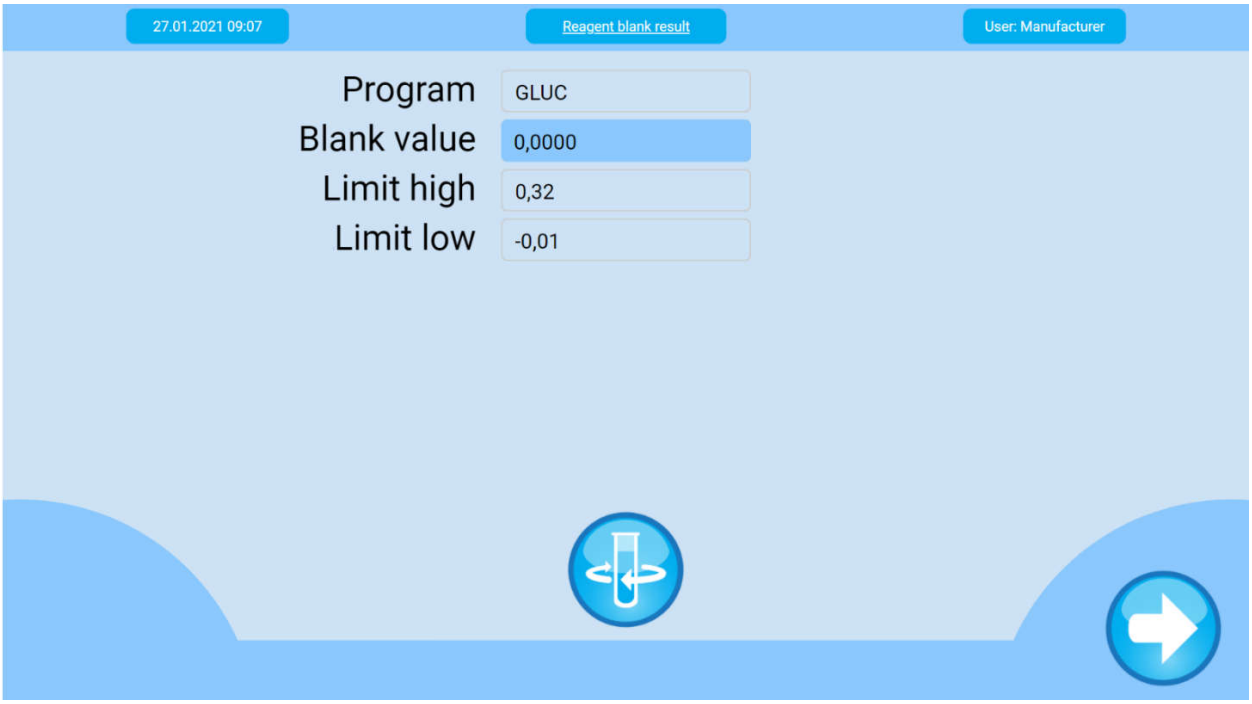
5. When the measurement is finished, the absorbance of the blank (OD value) will be displayed with its limits.



Note: For some programs, it is recommended to perform multiple blank measurements. The request to aspirate will re-appear until the programmed number of blanks have been measured. Then all (up to 3) measurement results will be displayed (and printed).

6. The Blank OD value should be between the range mentioned for "Limit Low" and "Limit High".
   a. If the OD value is within range, press "Continue" to proceed to the next screen.
   b. If the OD value is out of range, the error "  "or "  " will be displayed behind the value.
   Do **NOT** continue measuring if the OD value is outside the acceptable range!

   Press "Rerun"  to repeat the measurement.

ATTENTION!

If after 2 reruns the value is still outside the acceptable range, perform the following checks:

→ **Water** as blank:
- Clean and then rinse the instrument abundantly with distilled water and restart the test.

→ **Reagent** as blank:
- Check (working) reagent preparation.
- The reagent is deteriorated, check storage conditions (expiration date and opening date), open new kit or vial and restart the test.

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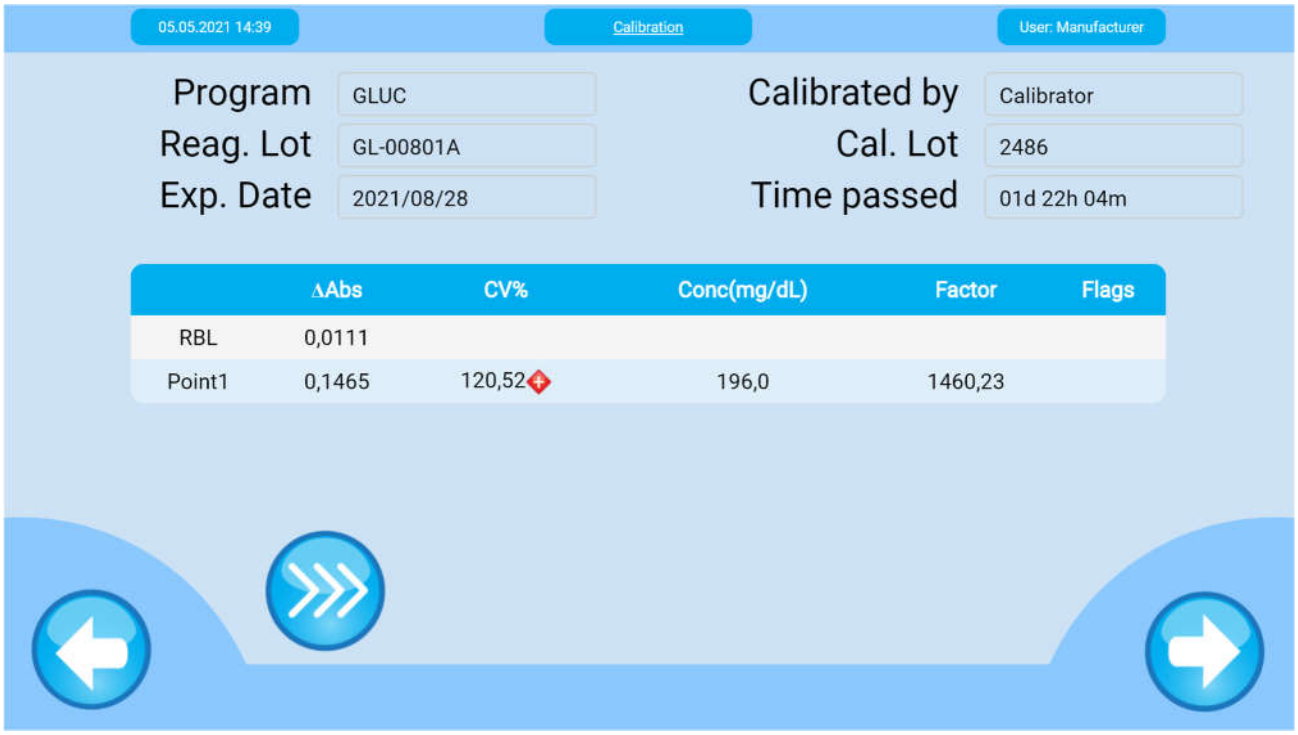
4.3.6 Test standard/calibrator

The standard or calibrator measurement is essential for the determination of the factor and thus in the calculation of all sample test results. Check the application sheets if a standard, calibrator or factor should be used. Only the calibrator which is not expired and has a determined value for the specifically used method is displayed. If the test allows a calibration by a factor, the software will not ask to measure a standard or calibrator and immediately proceed to the quality control (QC) measurements.



Button	Function
	Return, to go back to the previous screen.
	Continue, to proceed with the standard/calibration measurement. Alternatively, the push button in front of the device can be used.
	Skip, to skip the calibration measurement. **Note:** The skip button is not available when: - A new lot of reagent is used, or a new working reagent is used. - When it is the first time the program is executed. - When calibration is mandatory by the programming.

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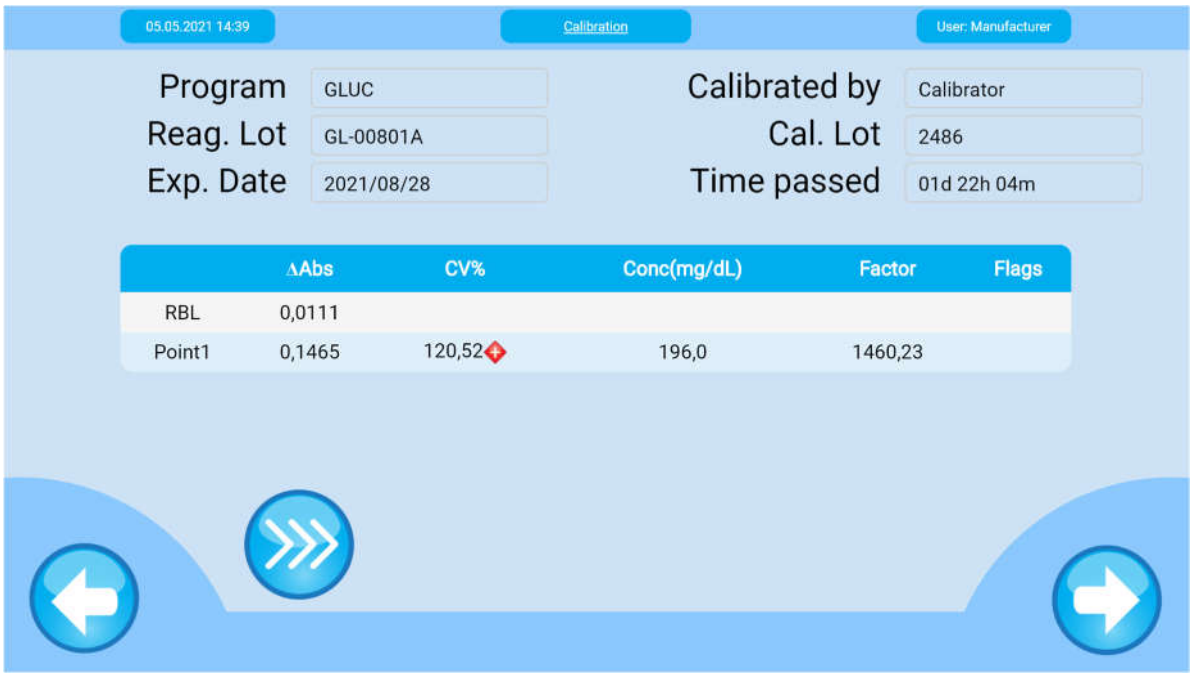
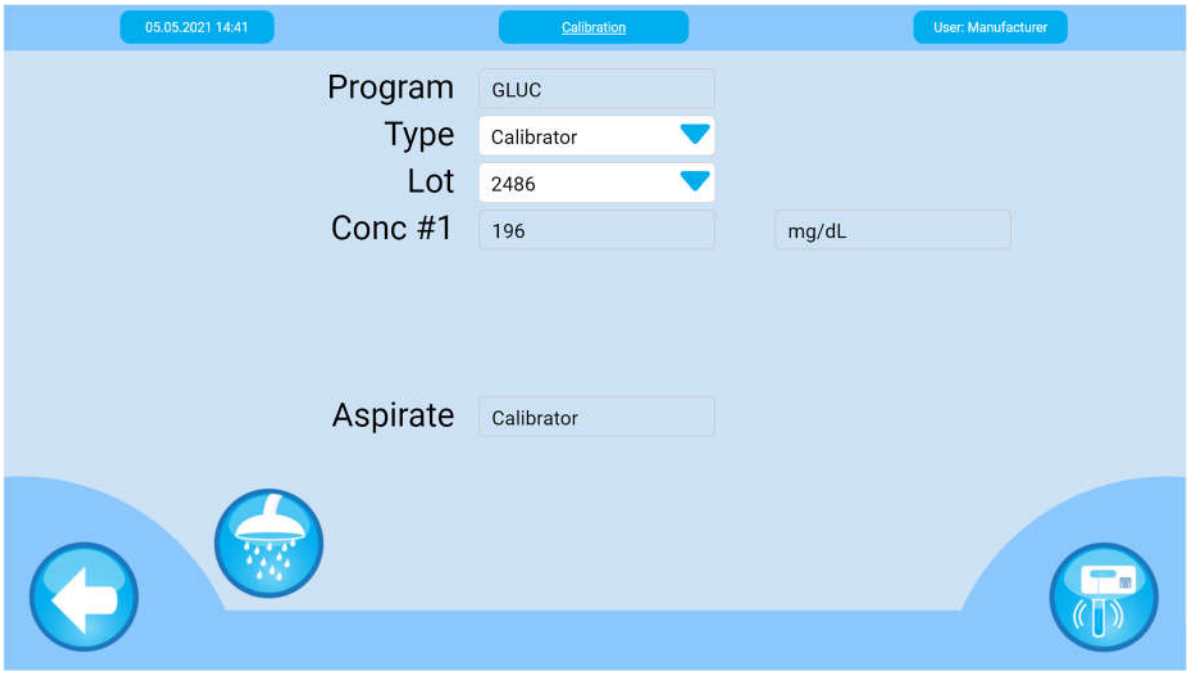
Procedure:

1. The first screen shows the factor obtained during the last calibration of that method.



2. Press "**Continue**" to perform a new standard measurement. A new calibration should be performed:
   - The first time you perform the test method.
   - When using a new lot number of reagent or a new working solution.
   - When the QC measurement is out of range.

   Press "**Skip**" to keep (and print) this factor and immediately proceed to the QC measurements.
3. Select the calibration method by clicking the "**Type**" dropdown menu.
   a. In case of a **calibrator**, select the lot number of the specific calibrator. If no valid calibrator is available, first insert the calibration values of the new calibrator (see 4.6.3).



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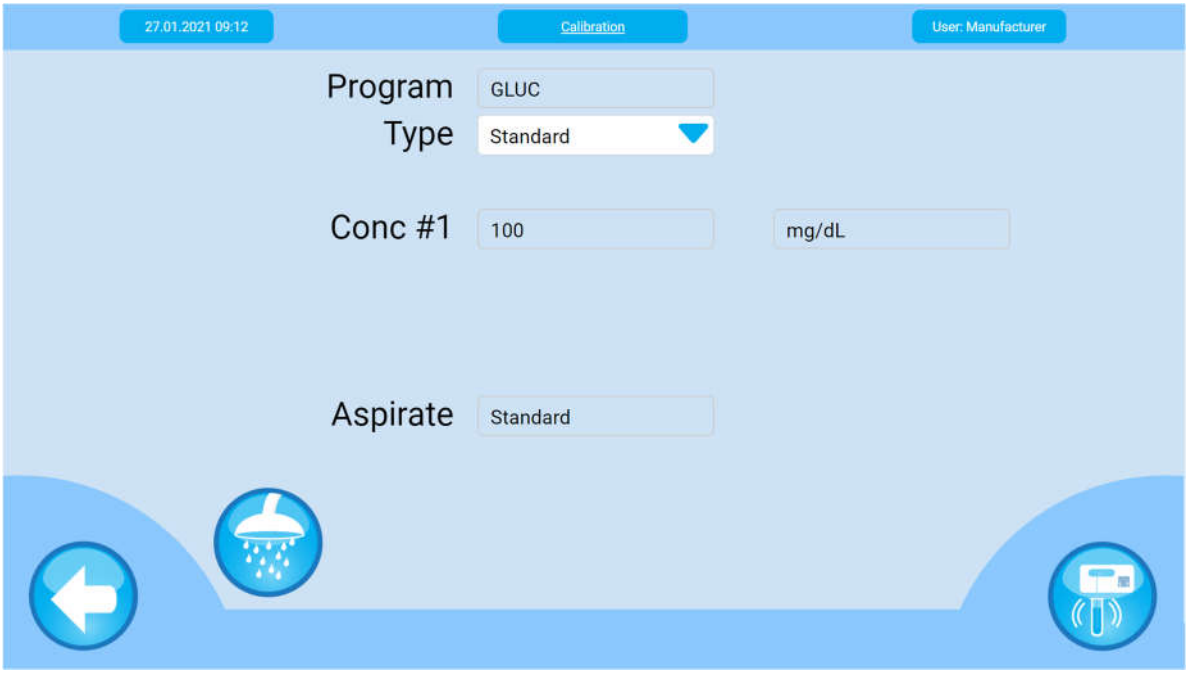
b. In case of a **standard**, the concentration values set in the programming will be used (see 4.6.2). In case of a **variable standard**, the concentration can be adjusted directly in this window.



c. Calibration by **factor** uses the factor defined in the programming. This type of calibration is only available in the dropdown menu if the programming allows it (see 4.6.2). When calibration by factor is selected, the pre-programmed factor will automatically appear. You can use this factor if the quality control (QC) measurements are within range. However, for the most accurate results, it is recommended to use a calibrator (see application sheets and 4.6.3.1).

4. Position the test tube containing the standard/calibration preparation under the aspiration inlet and press the aspiration button.

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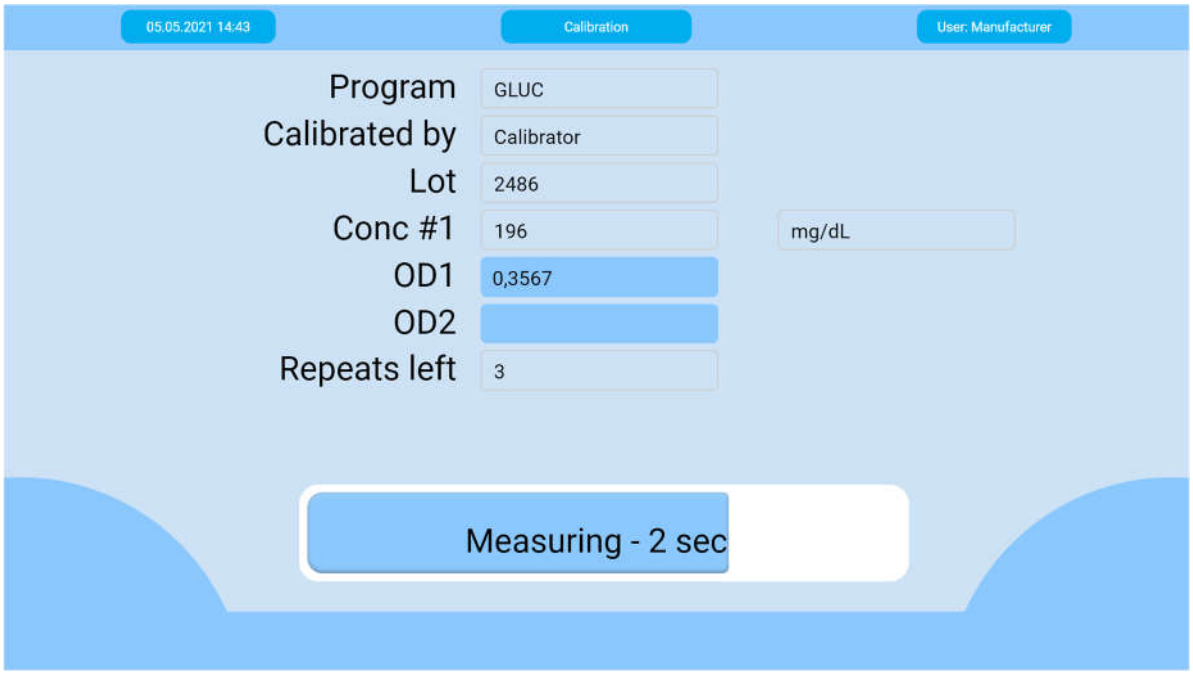
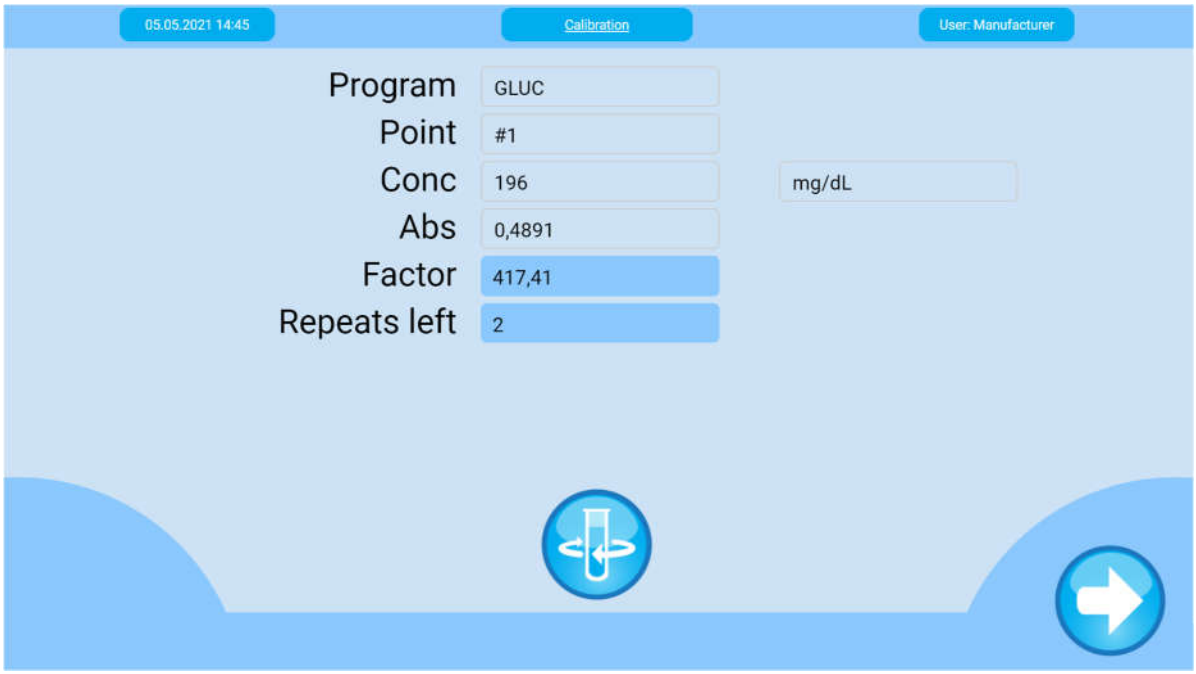
5. The standard or calibrator preparation will be aspirated in the flow cell and the instrument will perform the measurement.



6. When the measurement is finished, the measured OD will be displayed (and printed). Considering the programmed concentration of the standard/calibrator, the instrument will calculate, display (and print) the new calibration factor. In case repeats are left, continue to proceed with these measurements.



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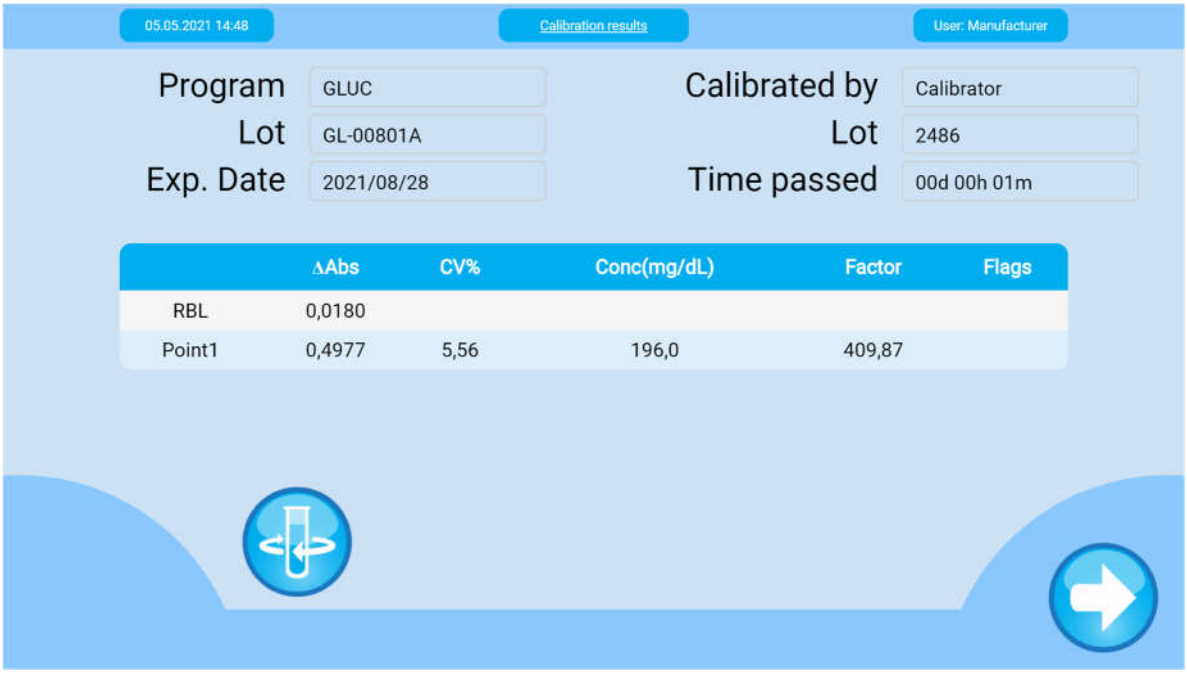
7. Press "**Continue**" to proceed to the next screen. An overview of the calibration is displayed.



a. Press "**Continue**" when no flags are displayed.

b. Press "**Rerun**" to repeat the measurement in case the concentration is lower "<" or higher ">" than specified (which indicates an error in the programming or an error during the manual insertion of the value) or when the CV% is higher "+" than specified.

Note:

- Some standards and (almost) all calibrators have a **lot dependent concentration**. Make sure the correct concentration is programmed in the methods!
  → For a variable standard:
  The standard concentration can be changed in the calibration window itself.
  → For a calibrator:
  Go to "Parameters → CAL values → Add or view" (see 4.6.3.1).
- Some methods do not have a standard included in the kit. For these methods, a factor is pre-programmed. You can use this factor if the quality control (QC) measurements are within range. However, for the most accurate results, it is recommended to use a calibrator (see application sheets) (see 4.6.3.1)
- If after recalibration with the standard included in the kit, the QC measurements remain out of range, it is recommended to use a calibrator to perform a more accurate calibration (see application sheets).
- In case of a **multi-standard**, aspirate the standards from the lowest to the highest concentration. This should also be programmed this way in the "Programming" menu. The result screen will show the graph obtained for these measurements instead of a single factor.

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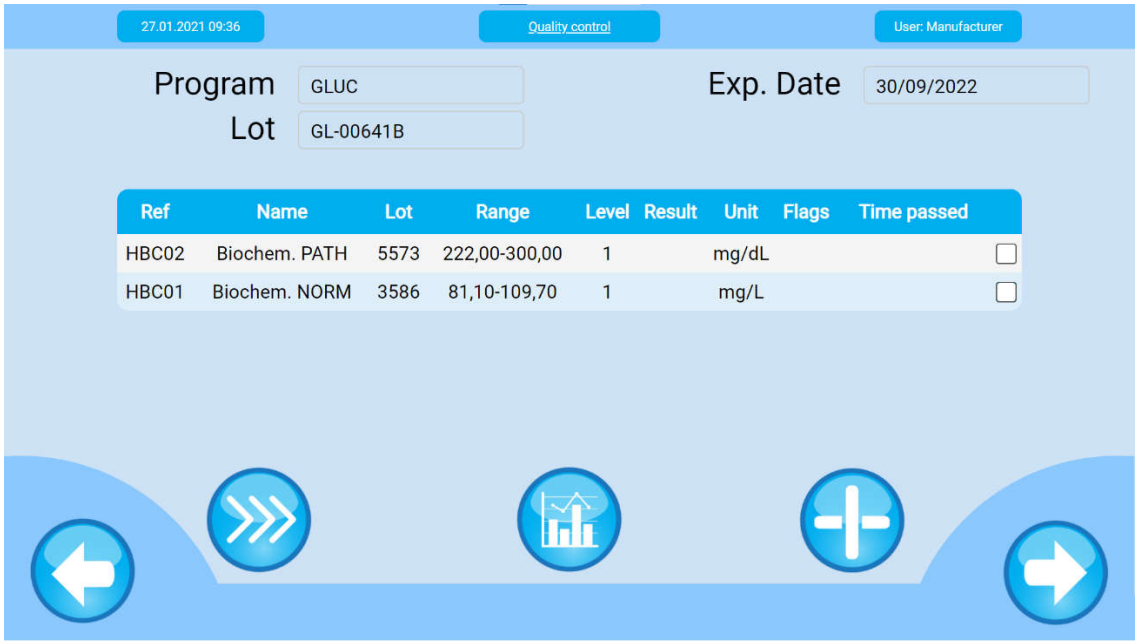
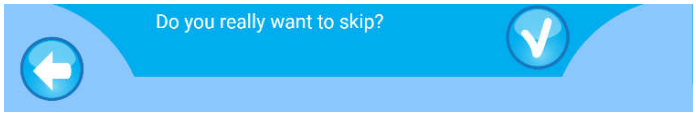
4.3.7 Test quality control

Performing quality control measurements is the only way to ensure that the results you obtain are accurate. If the QC measurements are within range, you can be sure the correct procedure is used (pipetting, storage, contamination,...), that the analyzer is clean and correctly functioning, that the reagent is not deteriorated, and that the calibration is performed correctly. This will result in more accurate results, thereby less false negative and positive results and thus exclusion of false diagnosis. This will also eliminate the need to duplicate a test because you are not sure of the result. All advantages for the patient, laboratory and doctor. It is strongly recommended to perform a Quality Control (QC) by measuring **both normal control** and **pathological control** serum. Check the application sheets to determine which control sera should be used.



Button	Function
	Return, to go back to the previous screen.
	Continue, to perform the selected quality control measurement. After performing 2 quality control (normal and pathological) measurements, pressing continue will take you to the patient sample measurements.
	Skip, to skip the quality control measurement. A warning will appear press “Yes” to confirm.  **Note:** QC measurements should at least be performed: - When a new lot of reagent is used, or a new working reagent is used. - When it is the first time the program is executed. - Once a week.
	To display the Levey-Jennings Control Chart. Press the table icon to exit the Levey-Jennings Control chart.
	To add new quality controls for this specific program.

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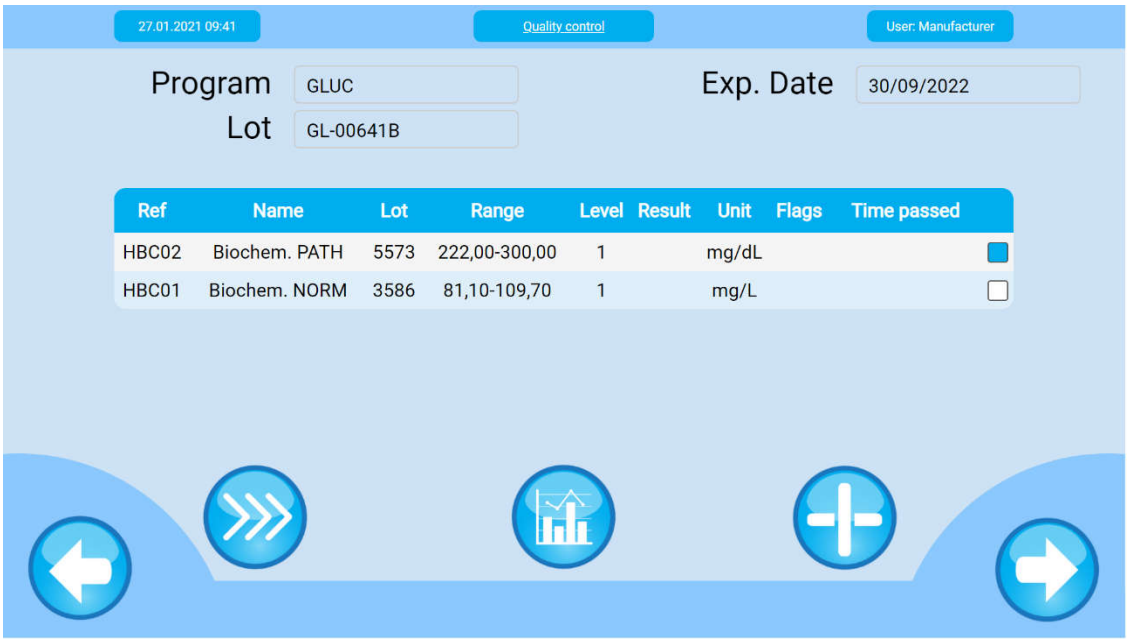
Procedure:

1. Select the first quality control to be measured and press "**Next**". Ideally, 2 controls (Normal and Pathological) are measured every time you perform a test. Thus, after executing one quality control the overview screen will appear again to allow you to select and measure a second quality control.
   QC measurements should at least be performed:
   - The first time you perform the test method.
   - When using a new lot number of reagent or a new working solution.
   - Once a week.

   Press "**Skip**" when it is not possible to perform Quality Control measurements to immediately proceed to the patient sample measurements.



2. Position the test tube containing the QC preparation under the aspiration inlet and press the aspiration button.

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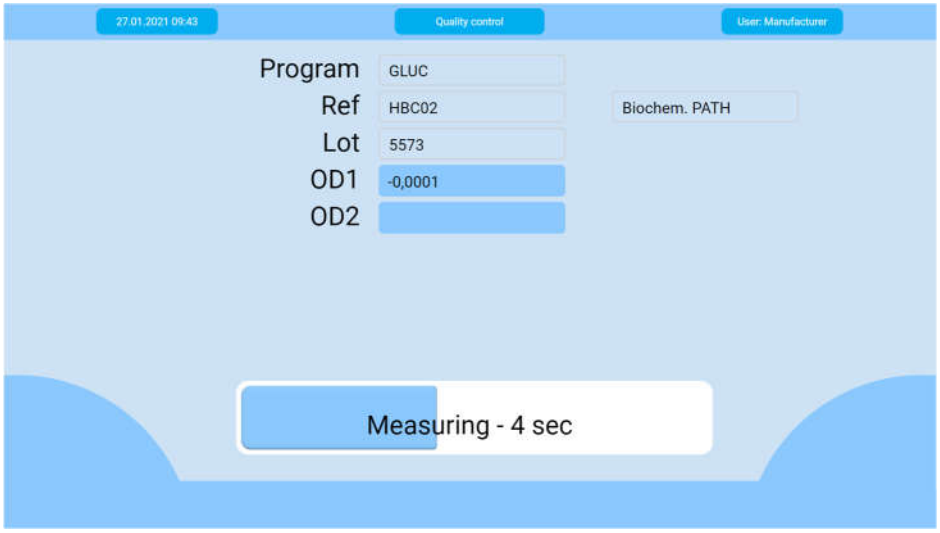
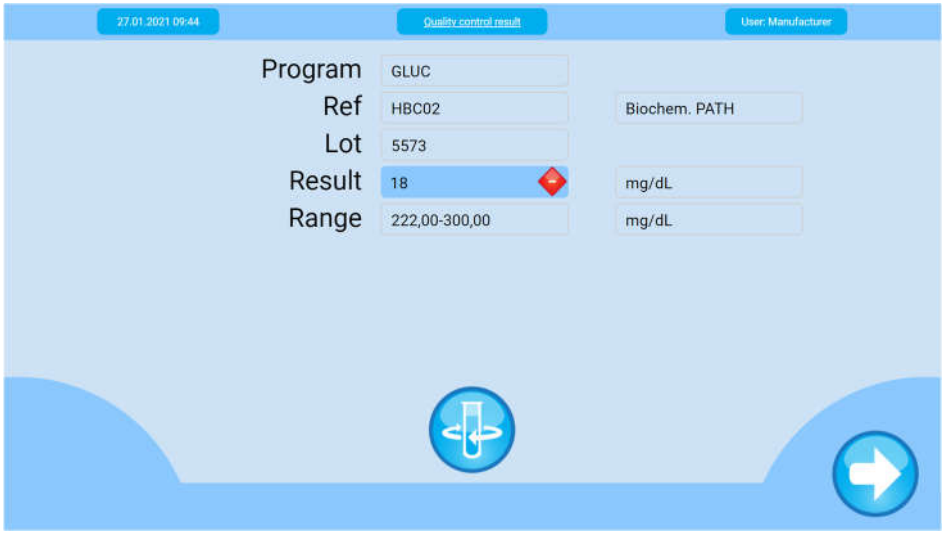
3. The QC preparation will be aspirated in the flow cell and the instrument will perform the measurement.



4. When the measurement is finished, the calculated concentration will be displayed (and printed).



5. Check if the QC concentration is within the target control range.
   a. If the concentration is within range, press "**Continue**" to proceed to the next step.
   b. If NOT within range, the error "⊖"or "⊕" will be displayed behind the value. Do NOT continue measuring if the concentration is outside the acceptable range!
   If Press "**Rerun**" to repeat the measurement.

Note:
- Quality controls have a **lot dependent concentration**. Make sure the correct range is programmed in the methods! Check or modify in "Parameters → QC values → Add or view" (See 4.6.4.1).
- If after recalibration with the standard included in the kit, the QC measurements remain out of range, it is recommended to use a calibrator to perform a more accurate calibration (see application sheets).

6. If only one QC has been performed, the next screen will allow you to repeat these steps for a second quality control (recommended).
7. When the two controls are in range press "**Continue**" to proceed to the patient sample measurements.

Attention! If after the rerun the value is still outside the acceptable range, perform the following checks:
- Verify the preparation instructions (application sheets): stability, volumes, and times should be strictly followed.
- Rinse with 15 mL distilled water (see 7.2.1).
- Cleaning with detergent and/or hypochlorite (see 7.2.1).
- Perform pump calibration and verify that the flow cell is completely filled with distilled water and free of air bubbles (see 4.5.3).
- Repeat the measurement and include a new calibration!

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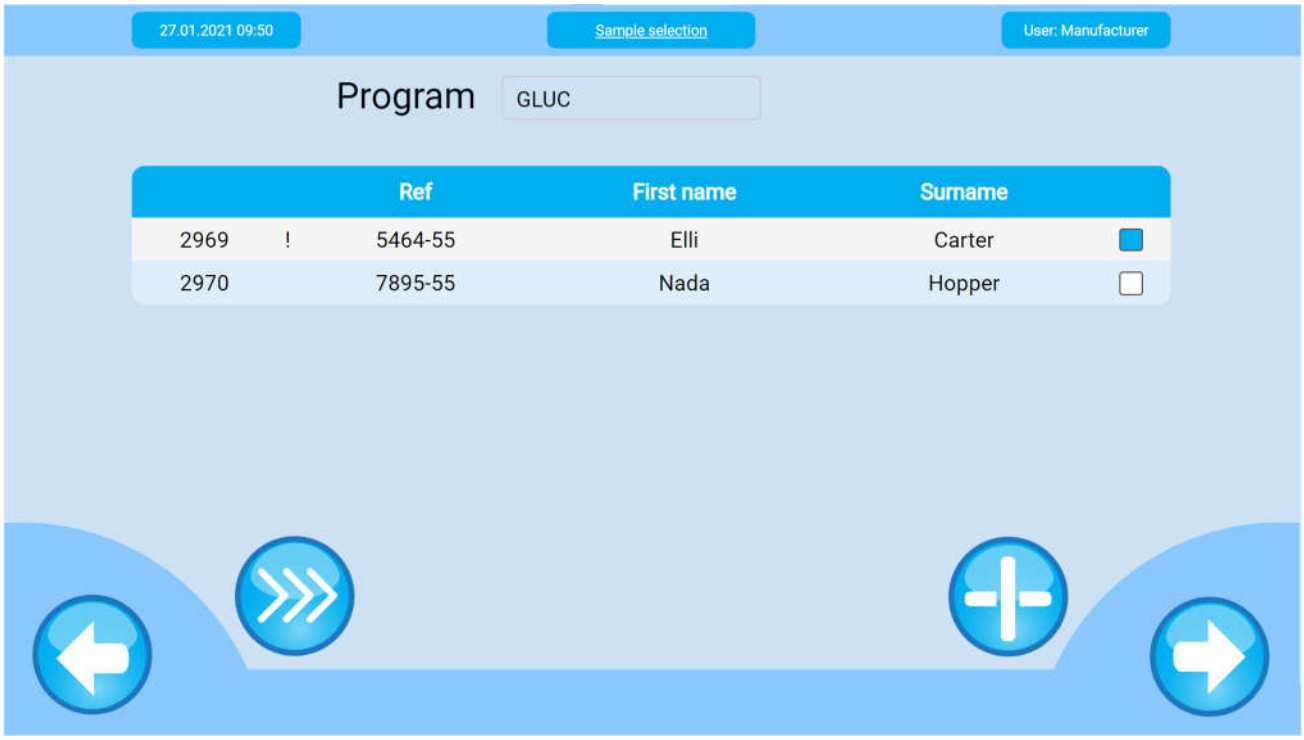
4.3.8 Sample measurement

If the autozero, reagent blank and QC are successful, you can proceed with the sample measurements. The first screen "Sample selection" will show an overview of the samples which need to be executed for the specific program. It is possible to measure a specific sample by selecting the sample, adding new samples for the specific program or continue to the program selection.



Field or button	Function
Nr	Unique (unchangeable) sequence number of the sample measurements.
!	This indicates that the sample is **urgent** (STAT sample) and it will be recommended to perform first.
Ref	Reference name/number for the sample.
First Name	The patient's first name (given name).
Surname	The patient's family name.
	Return, to go back to the previous screen.
	Continue, to proceed with the sample analysis.
	Skip this program, to proceed to the program selection (see 4.3.2).
	Add sample, to add a sample for the specific program (see 4.3.1.1)

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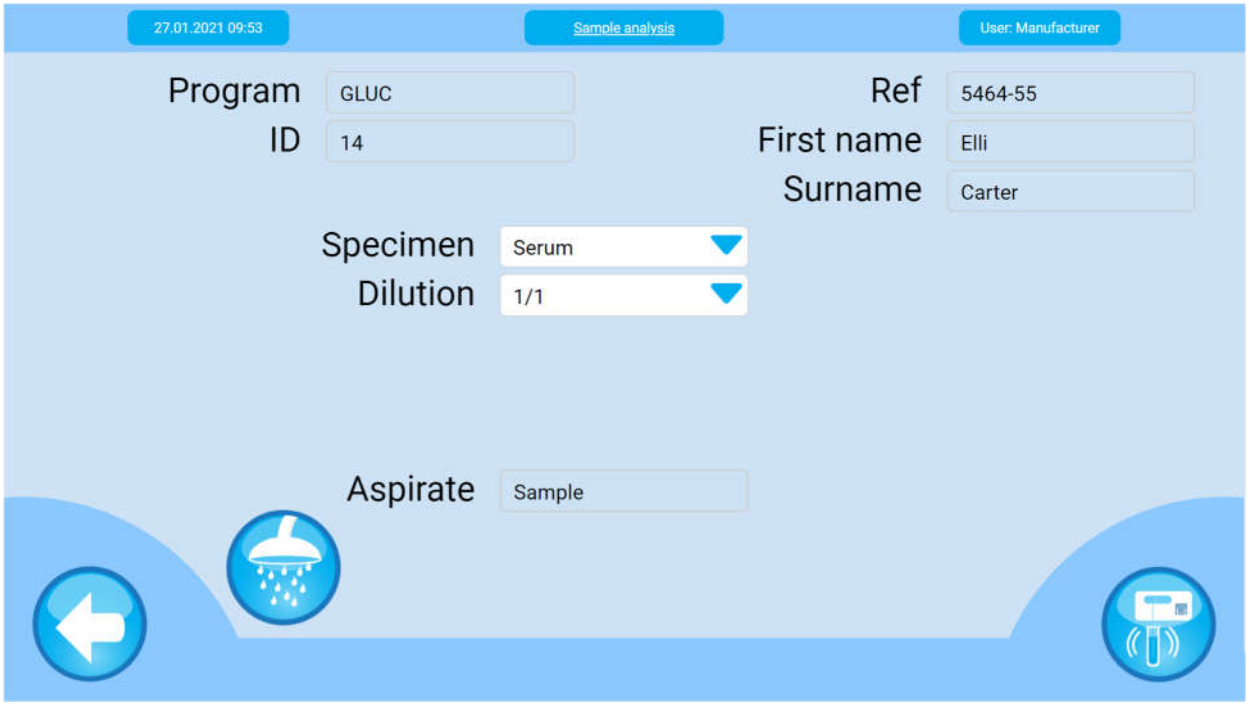
Procedure:

1. First assign the specimen type and dilution ratio, make a selection from the dropdown menus.



Field or button	Function
Program	The program name
Program ID	The ID of the selected program
Ref	Reference name/number for the sample.
First Name	The patient's first name (given name).
Surname	The patient's family name.
	Return, to go back to the previous screen.
	Aspirate, to start the measurement by aspirating a sample. Alternatively, the push button in front of the device can be used.
	Rinse, to activate the pump. **Note:** It is not necessary to rinse the instrument **between different samples** for the same method. However: • In case of a high risk of cross-over, you could pre-rinse the flow cell by aspirating distilled water, followed by air (to avoid dilution) between the samples. • In the case of a strongly colored reagent, it might be necessary to pre-rinse the flow cell with (working) reagent before aspirating the first sample. Otherwise, the first measurement could be influenced by the distilled water used to zero the instrument.

2. Position the test tube containing the selected patient sample preparation under the aspiration inlet and press the aspiration button. It will be aspirated in the flow cell and the instrument will perform the measurement.
3. When the measurement is finished, the OD value and calculated concentration will be displayed.

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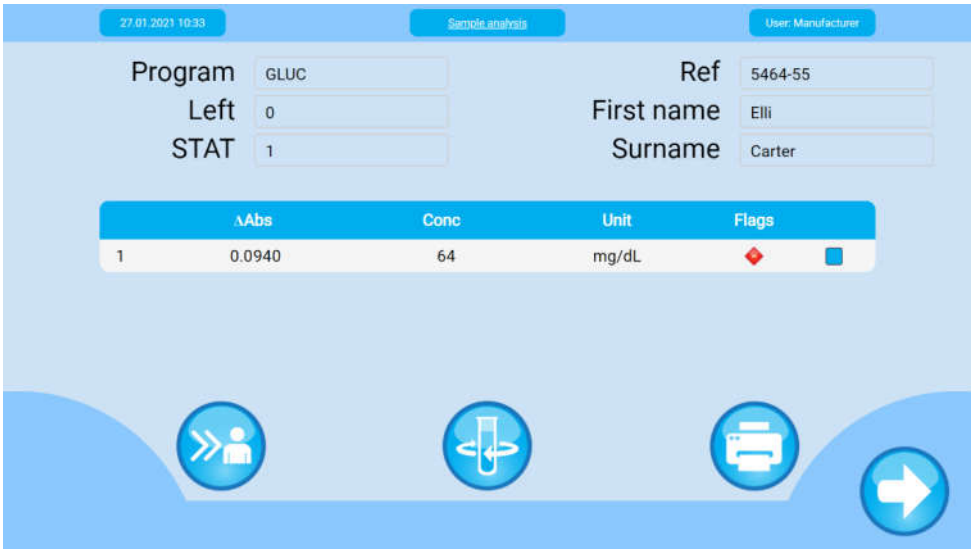
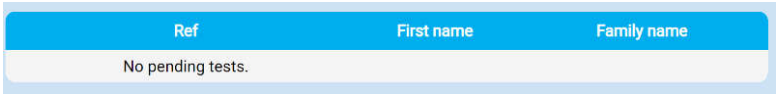


Field or button	Function
Program	The program name.
Left	The number of remaining samples for the specific program.
STAT	The number of remaining STAT samples for the specific program.
Ref	Reference name/number for the sample.
First Name	The patient's first name (given name).
Surname	The patient's family name.
	Continue, to prepare the next sample measurement or program.
	Continue with the patient, to change the program to stick to the requested tests for this patient. **Note:** This is recommended in case of a STAT, to ensure all STATs for the specific program are executed.
	Rerun, to re-execute the specific sample.
	Print, to create a print-out of the sample result (see 4.7.3).

4. Evaluate the measurement result.
   a. If no flag is displayed behind the result, press "**Continue**" to proceed with the next sample measurement or program.
   b. A flag "  "or "  " will be displayed behind the value in case the calculated concentration is outside the **normal reference range** (lower or higher, respectively). Customize the normal ranges for each type of patient (see 0) to allow these flags to appear.

      The flags "  " or "  " will be displayed when the programmed linearity_min or linearity_max have been exceeded.

      Only press "**Rerun**" to repeat the measurement in case it is suspected something went wrong during the measurement (air bubbles, not enough sample volume, …), or when a direction or fit error "  " is displayed.
5. Press "**Continue**" to proceed with the next sample, until all samples are analyzed.



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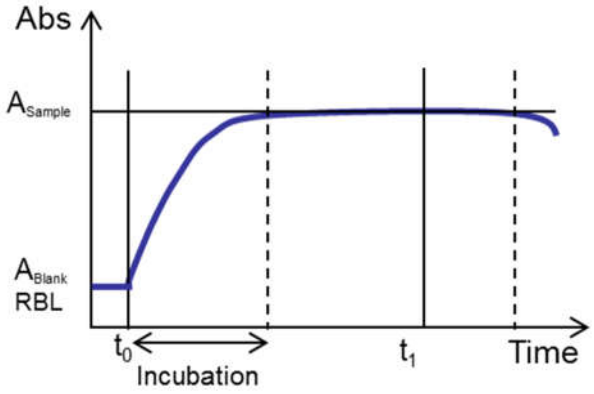
4.3.9 Specific program instructions and formulas

In the application sheets, you can find detailed information on the preparation of the samples and the execution of the tests for all Cypress Diagnostics kits.

This chapter considers the practical implications to perform the test, a more detailed theoretical background about the methodologies can be found in **Chapter 6 - Methods**.

4.3.9.1 Endpoint methods

After a certain incubation time, this type of reaction reaches an absorbance that remains stable for a specific period. Within this stable period (at time t_1), the measurement of the sample is performed. Before the addition of a sample (at time t_0), the reagent already has a certain absorbance. To correct for this absorbance, the reagent is measured as blank and the difference in absorbance between sample and blank is calculated.



Calculation formula:

$$Conc_{\ sample} = F * (Abs_{T1} - RBL)$$

with factor F: $F = \frac{Con_{CAL}}{Abs_{CAL} - RBL}$

Implications for performing endpoint tests:

- Incubation time is performed **outside** the instrument.
- You can prepare several samples simultaneously. Mix and incubate for the specified time at the specified temperature. After the incubation time, aspirate and measure all the samples within the specified stable period after preparation.
- For some endpoint tests, the incubation time needs to be exact. A special time scheme can be used to prepare several samples 'simultaneously' if you respect the times mentioned!
  E.g. Bilirubin direct and total, LDL cholesterol, HbA1c, Hemoglobin, Phosphorus…
- The correct measurement of the (reagent) blank is very important!

Note:

For an endpoint test where the absorbance of the sample itself can affect the analytical result, it is necessary to measure and correct for the sample blank. This correction can be done by choosing one of the following methodologies according to the specific need:

- Sample blank: absolute correction
- Bichromatic: partial correction

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4.3.9.2 Sample blank

Calculation formula:

$$Conc_{\ sample} = F * \left(\left(Abs_{Sample} - RBL \right) - VCF * \left(ABS_{Sample_{Blank}} - RBL_{Blank} \right) \right)$$

With factor F: $$F = \frac{Con_{CAL}}{\left(Abs_{CAL} - RBL \right) - VCF * \left(ABS_{CAL_{Blank}} - RBL_{Blank} \right)}$$

Implications for performing the sample blank correction:

- For every measurement, you need to prepare 2 test tubes: one for measuring the sample blank (background absorbance) and one for measuring the real sample absorbance. Both are measured on the same wavelength.
- The above is valid for patient samples, but also for the standard/calibrator and control preparations.
- When the sample blank correction is activated, the blank is measured before every sample.

Procedure:

1. Aspirate distilled water to adjust the instrument to zero (AD value).
2. In the blank menu aspirate (working) reagent (see application sheets):
   i. Used for the sample blank measurement (Sample blank) → RBL_Blank
   ii. Used for the sample measurement → RBL
3. In the standard/sample menu:
   i. First: "Aspirate Standard/Calibrator/Sample Blank" → Abs_Standard/Calibrator/Sample_Blank
   ii. Secondly: "Aspirate Standard/Calibrator/ Sample" → Abs_Standard/Calibrator/ Sample

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4.3.9.3 Bichromatic

This type of methodology is applicable to endpoint reactions that require correction due to the biological liquid's properties of the sample (turbidity, icteric and hemolysis). The correction on the matrix is not absolute, but relative. The bichromatic calculation requires measurement at two wavelengths: the main filter and a subfilter.

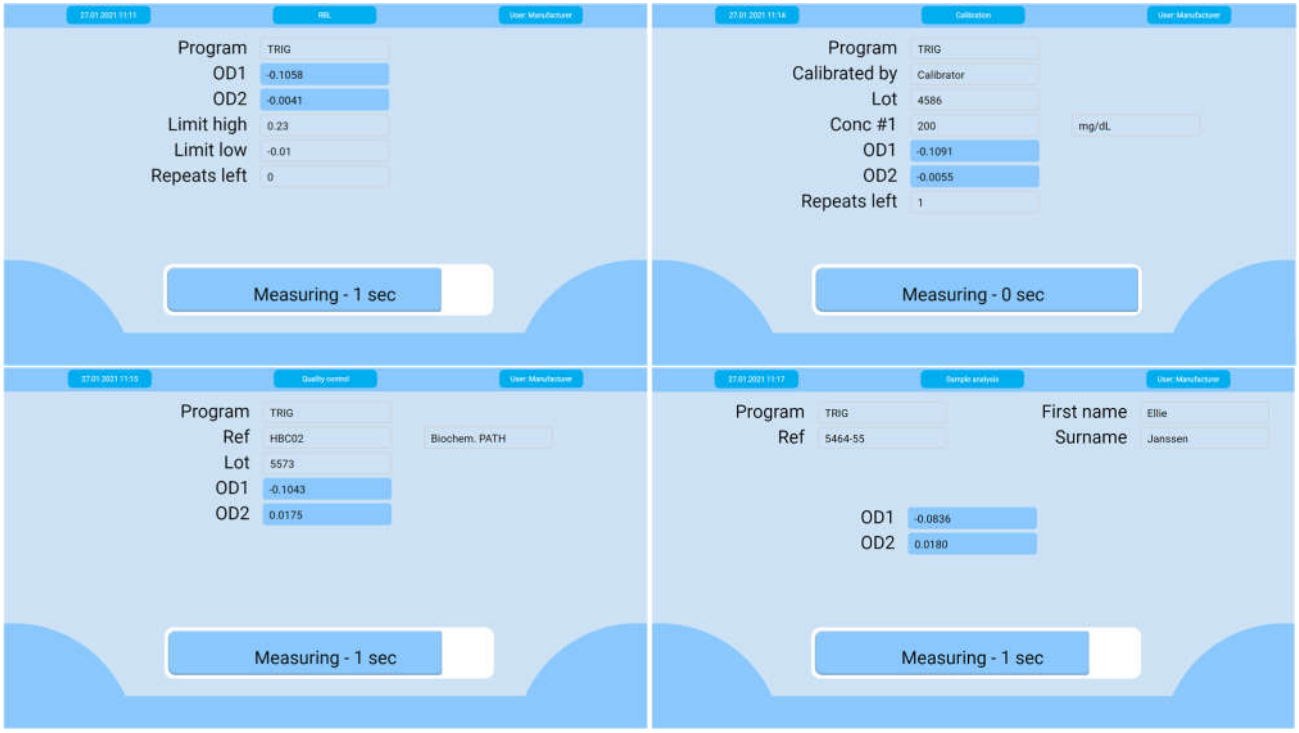
Calculation formula:

$$Conc_{\ sample} = F\ x\ \Big((Abs_{F1} - RBL_{F1}) - \big(Bic.Fact.x\ (ABS_{F2} - RBL_{F2})\big)\Big)$$

with factor F: $F = \frac{Con_{CAL}}{(Abs_{CAL_{F1}} - RBL_{F1}) - (Bic.Fact.x\ (ABS_{CAL_{F2}} - RBL_{F2}))}$

Implications for performing the bichromatic correction:

For every measurement (blank, standard, QC and samples), the instrument will perform measurements with both the main and subfilter and display the results (OD1 = main and OD2 = sub).



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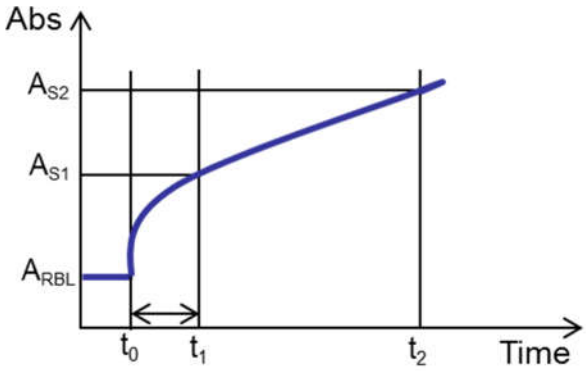
4.3.9.4 Two points (fixed time) methods

After a certain incubation time, this type of reaction has linear progress. For each measurement/aspiration, the instrument will carry out two readings within this linear time period, respectively at the times t_1 and t_2. The analytical result can be calculated using Δ Abs (delta) = difference in absorbance at the times t_2 and t_1.



During the RBL measurement the mobility of the reagent is monitored and calculated, the RGT-rate. This can be used in the calculation of the calibration factor and sample concentration.

$$RGTR = ABS_{RBL_{T_2}} - ABS_{RBL_{T_1}}$$

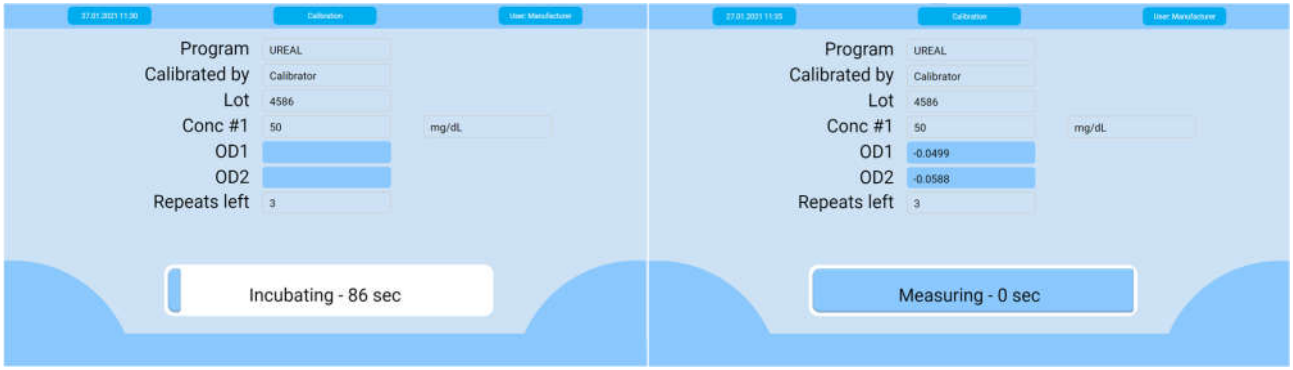
Calculation formula:

$$Conc_{\ sample} = F * \left(\left(Abs_{Sample_{T_2}} - ABS_{Sample_{T1}}\right) \pm RGTR\right)$$

with factor F: $F = \frac{Con_{CAL}}{\left(Abs_{CAL_{T2}} - ABS_{CAL_{T1}}\right) \pm RGTR}$

Implications for performing two point methods:

- Incubation time is performed **inside** the instrument.
- You need to prepare, mix and measure one sample at a time. Aspirate the mixture in the CYANVision immediately after the addition of the (working) reagent to the sample/standard/control.
- It is thus essential that the CYANVision is ready for the aspiration. This is when the CYANVision displays the "aspirate" symbol. Press the "Aspirate" button or the push button in front of the analyzer.
- Wait with the preparation of the next sample until the CYANVision is finished with measuring the previous one.
- The above is valid for the patient samples, but also for the standard/calibrator and QC preparations.
- The correct temperature is very important since temperature influences the rate of a reaction.



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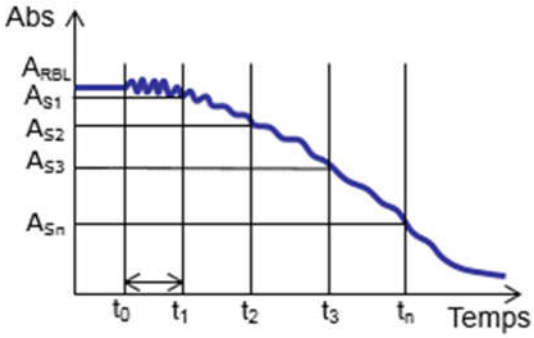
4.3.9.5 Kinetic methods

This methodology type is used to determine enzyme activity. For each measurement/aspiration, the system carries out several readings. From all the reading points taken during the reading time, the slope of a theoretical straight line is determined, using the criteria of minimum squares. The slope is used to calculate the analytical result. Furthermore, for every measurement, the instrument will display the linear correlation coefficient (COR). This could be used as a control parameter for kinetic reactions. The closer to one, the more perfect the fit resembles a straight line. The COR should be ≥ 0.95.



During the RBL measurement the mobility of the reagent is monitored and calculated, the RGT-rate. This is used in the calculation of the calibration factor and sample concentration.

$$RGTR = \frac{\triangle Abs_{Reagent}}{\Delta min} = slope_{reagent}$$

Calculation formula:

$$Conc_{\ sample} = F * \left(\triangle Abs \frac{CAL}{min} \pm RGTR\right)$$

With F = fixed factor or $F = \frac{Con_{CAL}}{\left(\triangle Abs \frac{CAL}{min} \pm RGTR\right)}$

Implications for performing kinetic methods:

- Incubation time is performed **inside** the instrument.
- You need to prepare, mix and measure one sample at a time. Aspirate the mixture in the CYANVision, immediately after the addition of the (working) reagent to the sample/calibrator/control.
- It is thus essential that the CYANVision is ready for the aspiration. This is when the CYANVision displays the "aspirate" symbol, press the "Aspirate" button or the push button in front of the analyzer.
- Wait with the preparation of the next sample until the CYANVision is finished with measuring the previous one.
- The above is valid for the patient samples, but also for the standard/calibrator and QC preparations.
- The correct temperature is very important since temperature influences the rate of a reaction and the activity (factor).

Procedure:

1. Press the aspiration button to aspirate the sample.
2. The CYANVision will display the measurement result and reaction curve expressed as absorbency in real-time during the testing.
3. At the end of the measurement the absorbance rate, correlation, and concentration will be displayed, and the results will be printed.

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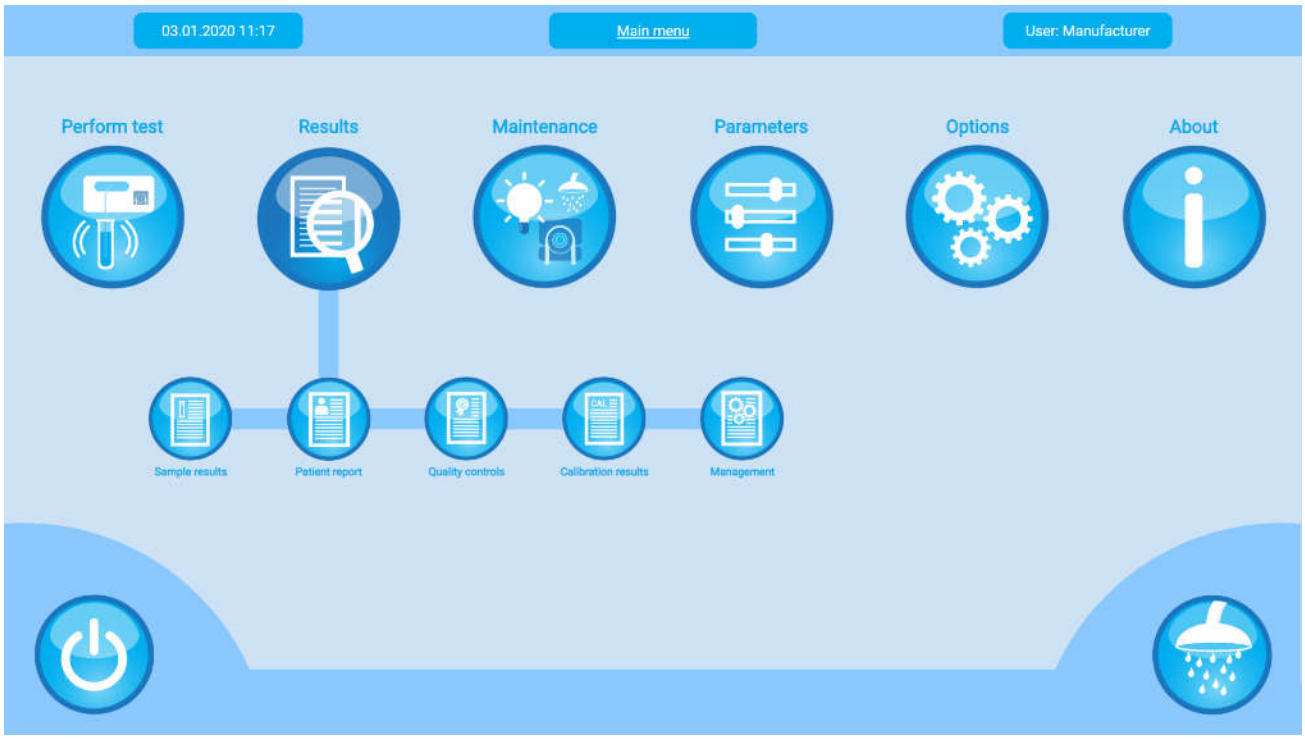
4.4 RESULTS

After selecting the "Results" button in the main menu, the user can review the sample results, make a patient report or manage the data (delete, export,…). Specific submenus with all quality control and calibration results are also available.



4.4.1 Sample results

Pressing the samples results button will give you the list of all stored sample results. The instrument can store up to 100 000 test results. All results receive a unique sequence number and are stored chronologically. Once the memory is full (> 100 000 test results or less than 50 MB free memory), the system will give a warning. Print or export the results you require and delete results to clear the memory.

Note: Program names can have a "D-" as prefix, indicating this program is deleted or not active anymore.

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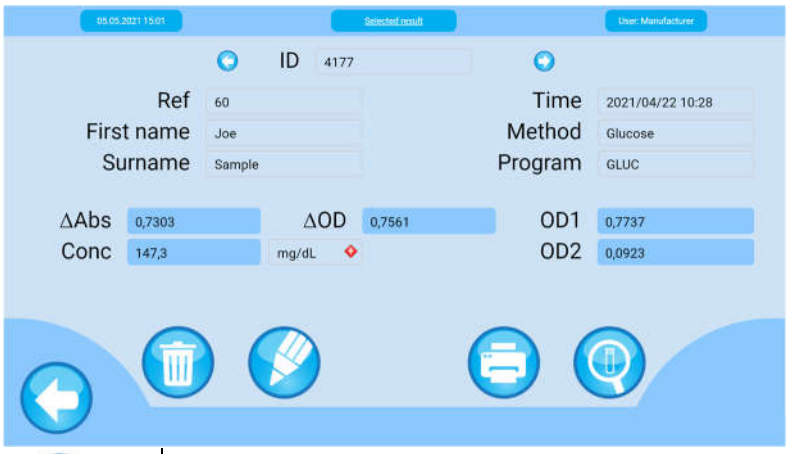
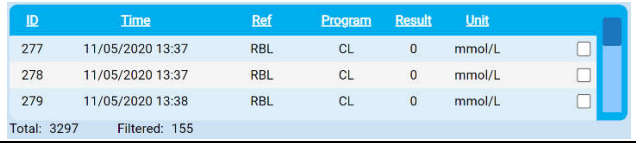
Field or button	Function
ID	The automatic increasing number of the measurement ID.
Time	Date & time of execution.
Ref	Assigned reference name or number for the sample.
Program	The program name.
Result	The measured outcome of the test.
Unit	The unit of the result.
	Return, to return to the previous screen.
	Delete, to delete the selected result. Press "Yes" to confirm the action. 
	Upload to LIS, see 4.7.6 – Host connection for more information.
	Print, to create a print-out of the sample result (see 4.7.3).
	To view the details of the measurement. 
	Return, to return to the sample results.
	Delete, to remove the result from the database.
	Edit, to modify the Ref, First Name and Surname of the sample result.
	Print, to create a print-out of the sample result (see 4.7.3).
	View more details about the result, such as the date of birth, sex, specimen type, species type and measurement range.
	To filter all the records that correspond to your search criteria and return to the table view. The table view will now only display the records that correspond to the search criteria. At the bottom of the screen, it will be indicated that the filter is on. 

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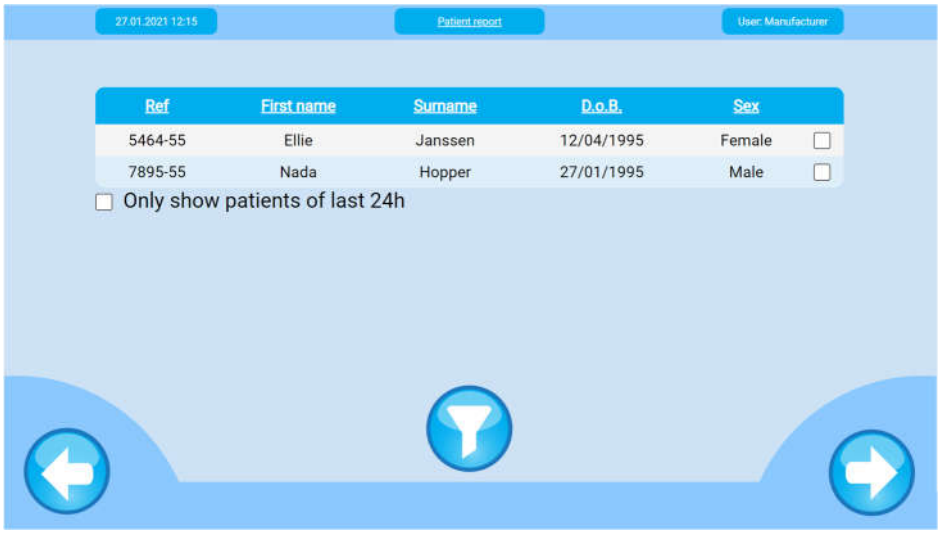
4.4.2 Patient report

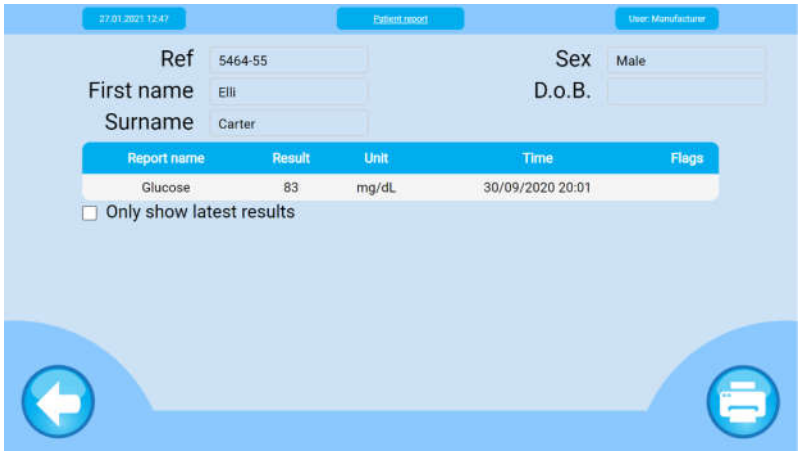
This function enables to print a patient report, this includes the test results of a certain reference (name/number) performed on a certain date. Upon entering this menu, an overview of the available patients is displayed.

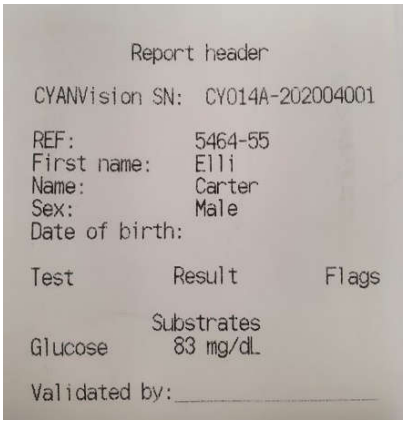


Button	Function
	Return, to return to the previous screen.
	Continue, to view result details of the selected patient.
	Filter, to restrict the view to a range of patient results. Alternatively, check the box "Only show patients of the last 24h" to only have an overview of tests performed for patients during the last 24h. 

Filter and select the correct patient, press "Continue", and the test results are displayed. Press "Print" to create a print-out.

A flag "  "or "  " will be displayed behind the value in case the calculated concentration is outside the **normal reference range** (lower or higher, respectively). The flags "  " or "  " will be displayed when the programmed linearity_min or linearity_max have been exceeded.





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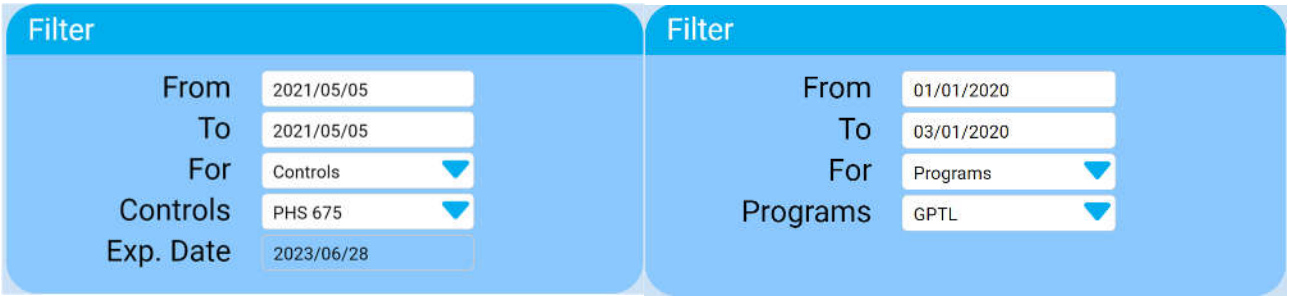
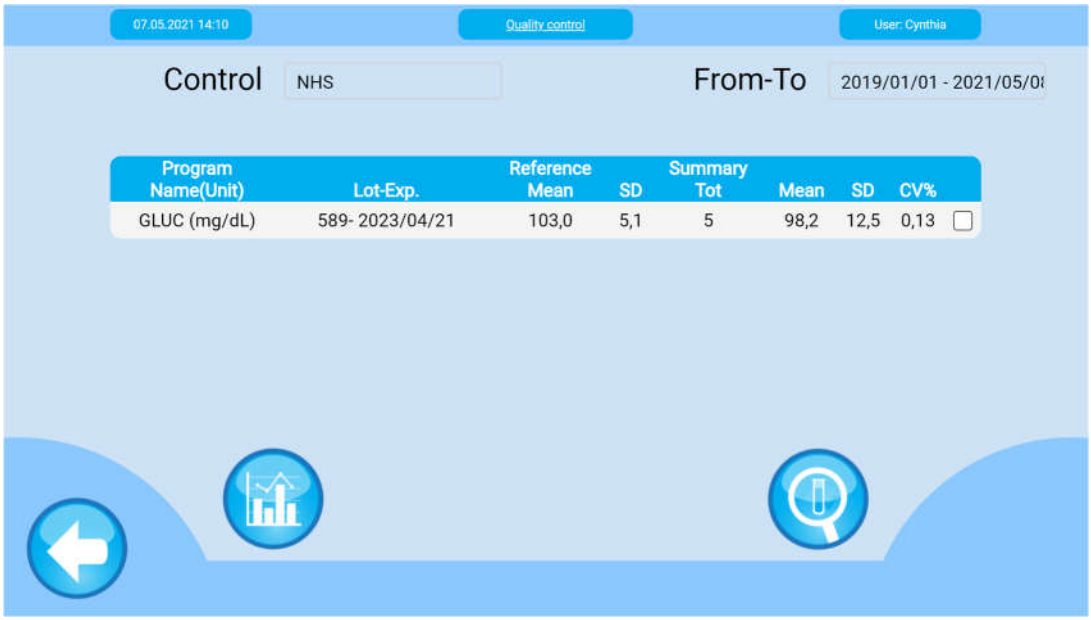
4.4.3 Quality controls

In this menu, you can review the results and statistics for the quality control measurements. Upon entering this menu, it will be necessary to filter using specific dates (From - To) and defining for which controls or programs you want to view more information.



Confirm and the system will search in the memory and then display all the matching quality controls (different view depending on the selection of control or program).



The statistics include the program name, the normal range for the control, number of measurements performed (Tot), the average (Mean) of the measurements, the standard deviation (SD) and the coefficient of variation (CV%).

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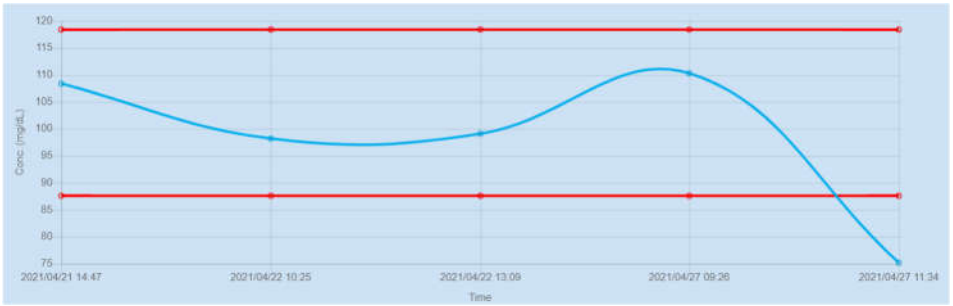
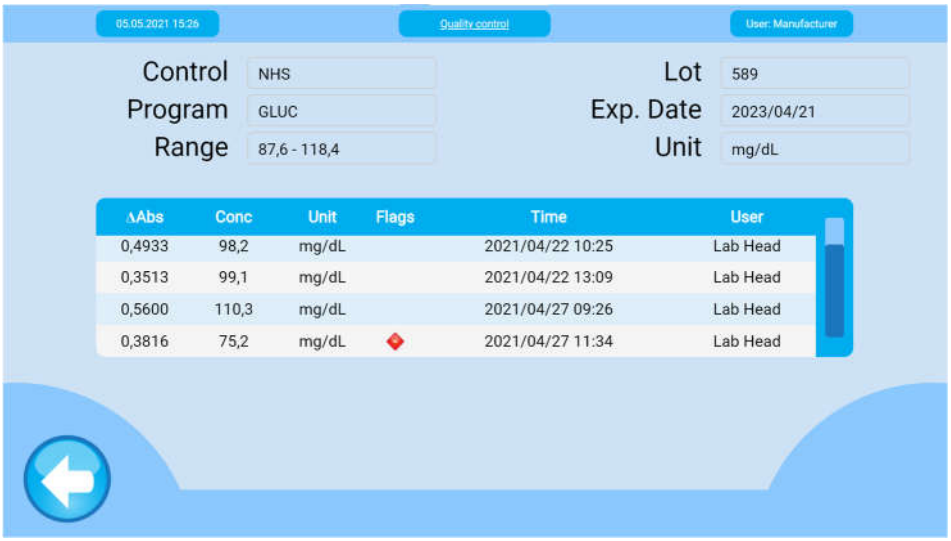
Button	Function
	Return, to return to the previous screen.
	Display Levey-Jennings chart with quality control data to give a visual indication of whether a laboratory test is working well. The limits of the quality control are indicated in red. 
	To view the details for the selected program and control. The required range, unit, absorbance value, and calculated concentration are displayed. 

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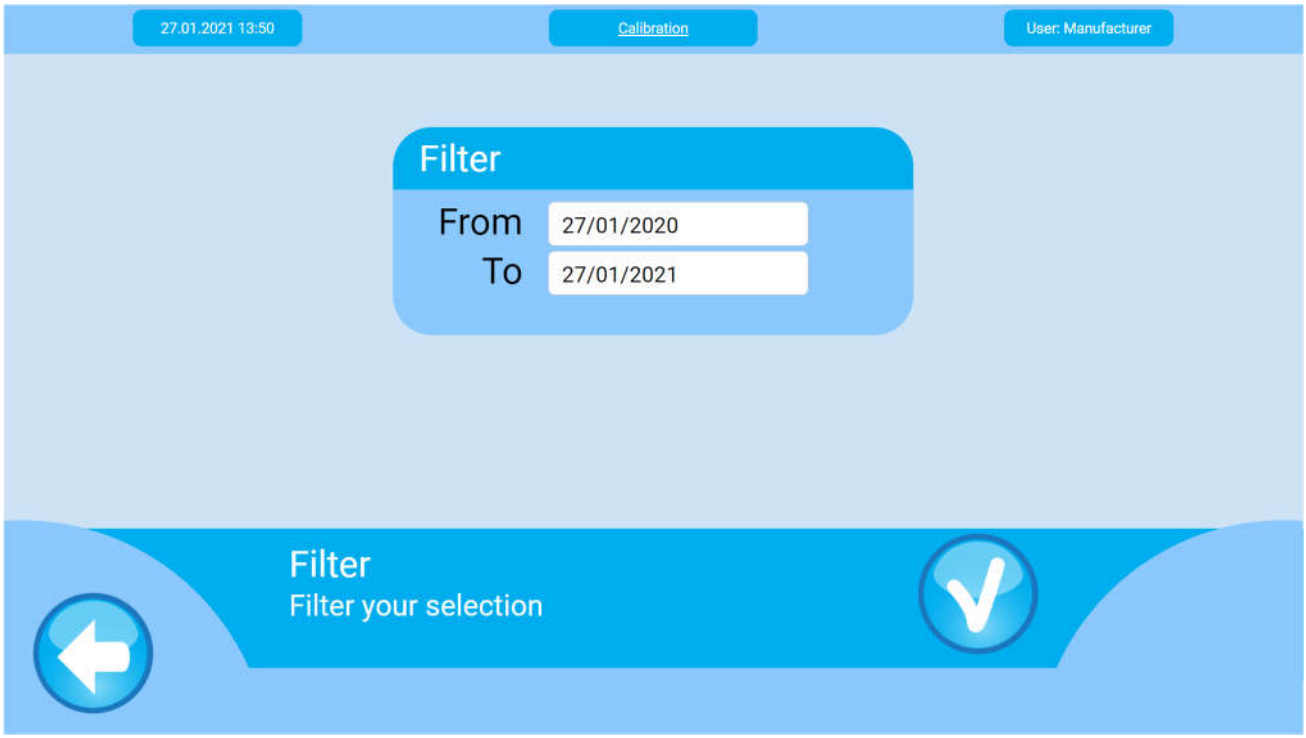
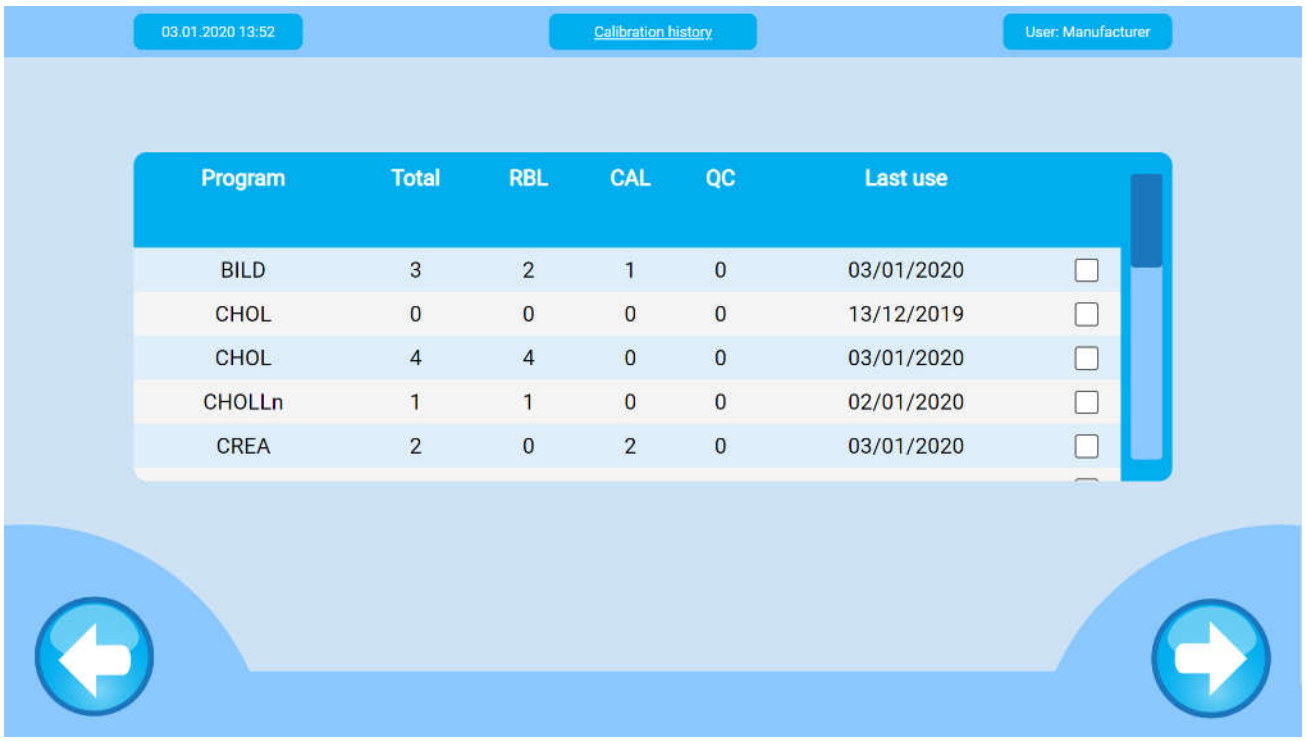
4.4.4 Calibration results

Select “Results” and from the options listed “Calibration Results”. This window allows viewing the data of previously performed calibrations. Upon entering this menu, a specific date range (From - To) needs to be filled in. Press “OK” to confirm the selection. The software will filter all the data contained in the result database that match the entered criteria. To cancel the selection press “Return”.



The requested information is sorted by the program type. Select the desired program and press “Continue” to display the calibration details for the specific program.



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The calibration details for the specific program are displayed. Linearity flags " " or " " will be displayed when the programmed concentrations have been exceeded. In case of problems with the fit or direction, a " " flag will be displayed.

Button	Function
	Return, to go back to the previous screen.
	To view the details for the selected measurement. It is possible to create a print-out of this single result. 
	Print, to create a print-out of the calibration result (see 4.7.3).

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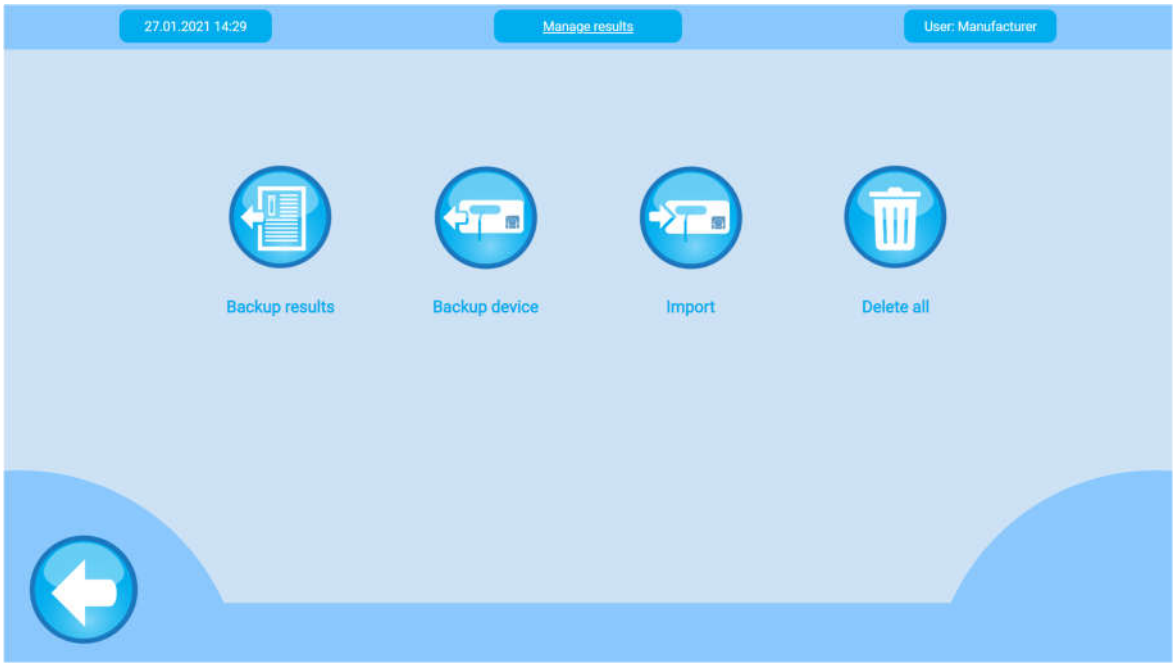
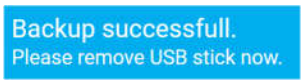
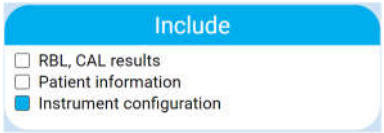
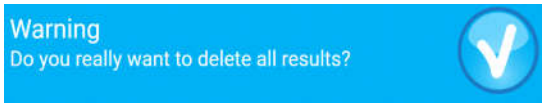
4.4.5 Management

The management submenu allows the user to perform the following actions:
- Make a back-up of the measurement results.
- Make a back-up of the full device.
- Import data from an external data storage device to the instrument archive.
- Delete all results from the memory.



Button	Function
	Return, to go back to the main menu.
	Back-up results, to make a copy of the results to an external data storage device. Do not remove the external data storage device until the following message appears:  A zipped folder will be saved on the external data storage device, containing .backup and .header format records, which can only be read by a CYANVision analyzer.
	Back-up device, to make a copy of the full device to an external data storage device. Do not remove the external data storage device until the following message appears:  A zipped folder will be saved on the external data storage device, containing .backup and .header format records, which can only be read by a CYANVision analyzer.
	Import, to place data back in the archive from an external data storage device. Select the specific information which needs to be imported: RBL, CAL results or patient information. **Note**: Always include the instrument configuration. Confirm twice by pressing “OK”. 
	Delete, to delete all results in the archive. A warning will appear, press “Yes” to confirm. 

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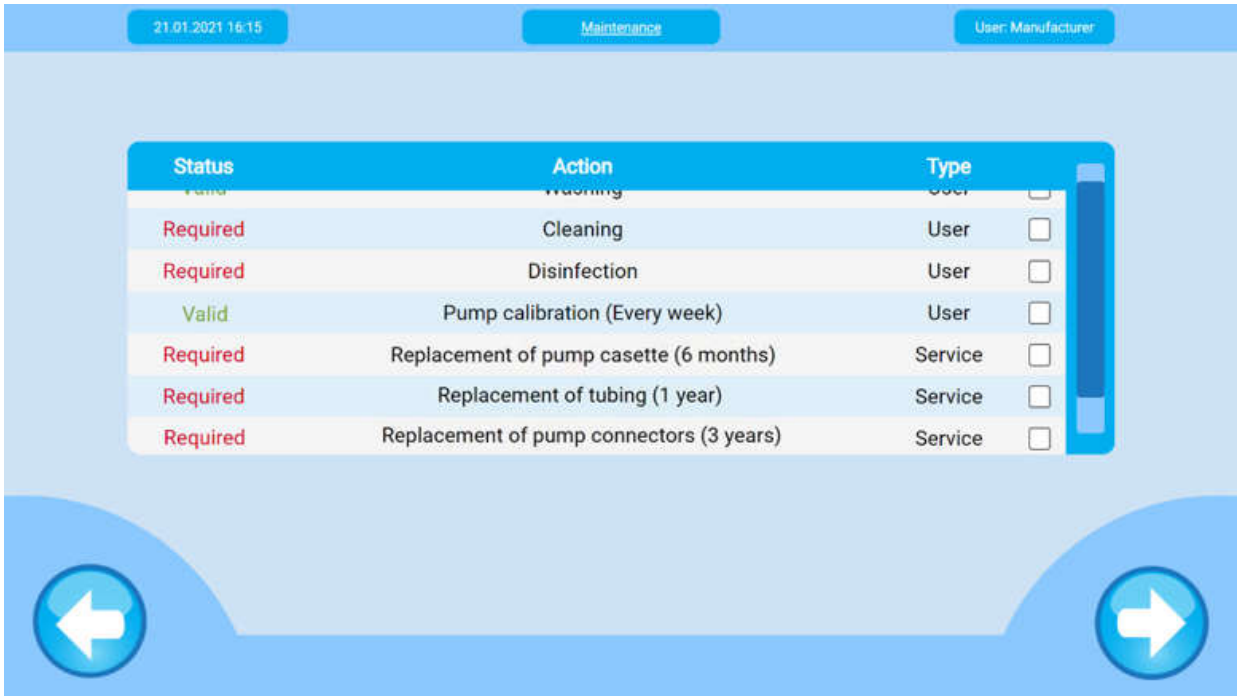
4.5 MAINTENANCE

After selecting the "Maintenance" button in the main menu, the user can get an overview of the maintenance status of the CYANVision, perform an auto zero and execute a pump calibration.

4.5.1 Overview

In this window, an overview of the required maintenance actions can be consulted.



Field or button	Function
Status	Status of the maintenance action: - **Required:** To guarantee precise and accurate results it is required to execute this specific maintenance action. - **Advised**: User can continue working, although it is recommended to perform the specific maintenance action. - **Valid**: No maintenance action required.

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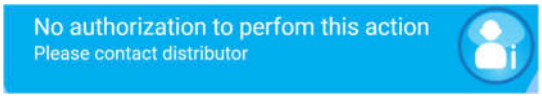
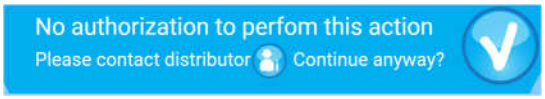
Action	The description of the specific maintenance action see 7.3 for more information. Select the action to proceed.
Type	The person allowed to perform the specific maintenance action: - **Lab User**: May only perform the User maintenance actions, no Service actions. A warning is emitted when a Service action is selected.  - **Lab Head**: May perform all maintenance actions, but a warning will be emitted for Service maintenance actions, with the recommendation to contact the distributor (see 7.3 for more information). Confirm to register the action has been performed anyway.  - **Service**: May perform all maintenance action without warning. Confirm to register the action has been performed. 
	Return, to return to the main menu.
	Next, to proceed to the next step after selecting a specific maintenance action.

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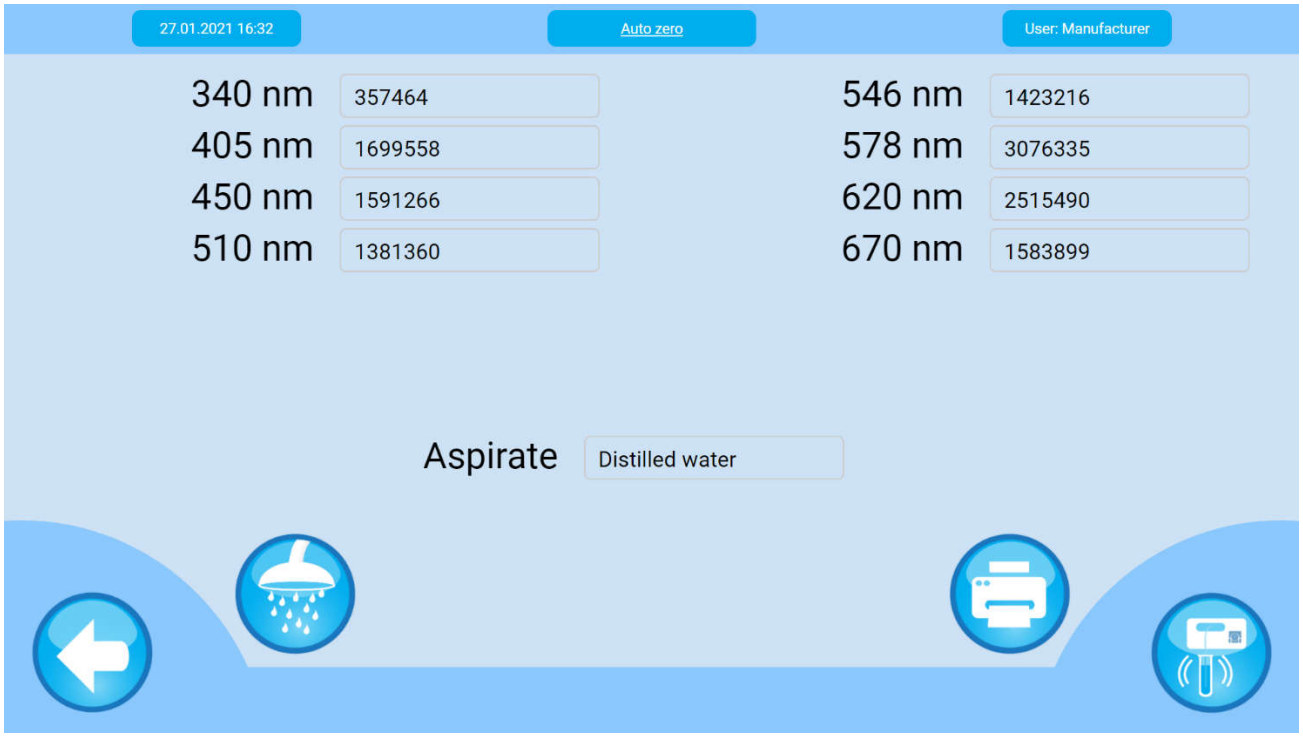
4.5.2 Auto zero

Before the measurements can start the auto zero is required to initialize the optical system. This measurement is always performed with distilled water.

Note: To have a correct reference measurement, it is essential that the hydraulic system (tubes and flow cell) is clean and the required maintenance is performed. Verify the maintenance overview (see 4.5.1) and make sure the required cleanings are performed.



Button	Function
	Return, to return to the main menu.
	Wash, to activate the pump and rinse the flow cell.
	Print, to print the result of the AD Auto zero. 
	Aspirate, to activate the pump, the measurement is automatically started after the sample is taken.

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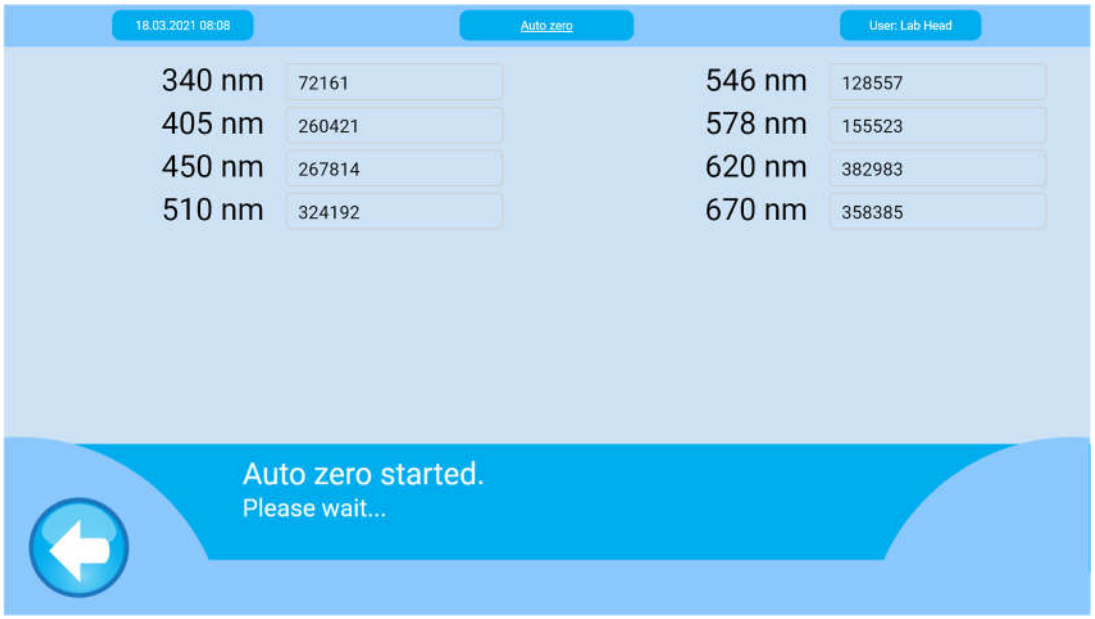
Procedure:

1. Position distilled water under the inlet pipe and press the "Aspirate" button.
2. The distilled water will be aspirated in the flow cell and the instrument will perform the auto zero measurements.



3. When the measurement is finished, the full signal measurement will be displayed (and printed if the print button is pressed).

4. The full signal value should be higher than **50 000**.
   a. If the full signal above 50 000, no error will be displayed. Press "Next" to return to the main menu.
   b. If the full signal is below 50 000, the error "◆" will be displayed behind the value. Press "Re-run" to repeat the measurement. Do NOT continue measuring if the AD value is outside the acceptable range!

ATTENTION! If after 2 reruns the value is still below the acceptable limit, perform the following actions:

- Rinsing with 15 mL distilled water (see 7.2.1).
- Cleaning with detergent and/or 5% hypochlorite (see 7.2.1).
- Pump calibration and verify that the flow cell is filled with distilled water and free of air bubbles (see 4.5.3)

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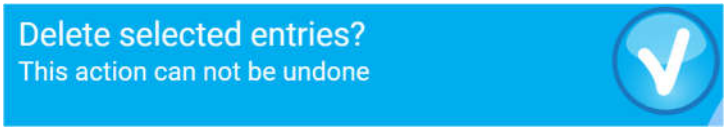
4.5.3 Pump Calibration

The peristaltic pump tube is placed underneath the lid and driven by a DC motor. This menu enables the user to calibrate the peristaltic pump, to determine how long the motor should be ON to aspirate a certain volume. To ensure precise and accurate sample aspiration, it is strongly recommended to **calibrate the pump once a week.**

Before performing a pump calibration, it is essential to check that:

- There is no leakage or blockage in the hydraulic system (flow cell + tubes).
- The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water (see 7.3.2)
- The pump tube is installed and connected correctly (see 7.3.4)

Button	Function
	Return, to return to the main menu.
	Wash, to activate the pump and rinse the hydraulic system. **Note:** After activation of the pump and the aspiration of 3 mL distilled water, allow the system to aspirate air (automatically) before continuing with the next tube!
	To delete a single, selected pump calibration execution. **Note:** It is recommended to store a pump calibration based on three, successful executions. If one execution is removed, perform an additional execution. 
	Save, to store the obtained pump calibration results.

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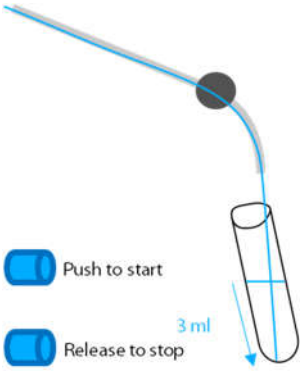
Procedure:

1. Select the "Pump Calibration" menu. The amount of time the pump was on during the last pump calibration is shown.



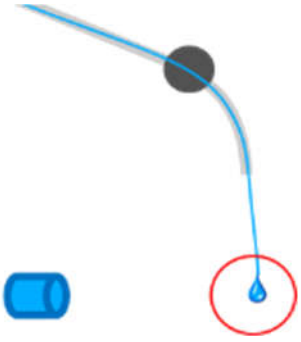
2. Pipette **exactly 3 ml of distilled water** into a test tube.
3. Position the aspiration inlet inside the test tube, be sure that aspiration tip is in the lower corner of the test tube (see figure), so all liquid can be aspirated.
4. Press the aspiration button in the software to start the aspiration.
5. Immediately and exactly when the tube is empty, release the button again to stop the aspiration.
6. The number of steps performed by the motor is displayed. The value should be **between 3500 and 9000.**

   Note: It is strongly recommended to **perform this procedure at least 3 times**. All obtained values should be within this range and the **difference** between the obtained values should be **smaller than 1000 steps**.
7. After three executions the save button will appear. By pressing "save" the software will exit the submenu. The software will ask "Sure to save?" Click "Yes" to save and use this calibration as a reference to intake any quantity of sample. Click "No" to discard this calibration.

If the obtained values are **outside the range** or the difference between the replicates is more than **1000** steps:

a) Verify the pipette used and its precision/accuracy. Perform a pipette calibration if necessary.
Note: For a higher precision we advise to use CYANPipettes. Ask your distributor for more information about the CYAN product range.

b) Verify that after the aspiration of distilled water, there is no big drop formation at the tip of the aspiration tube. Drop formation indicates the presence of leakage or blockage in the hydraulic system (tubes or flow cell):



- A leak in one of the tubes or the flowcell:
  ➔ Replacement is necessary, contact your service engineer.
- Blockage in one of the tubes can be caused by:
  ➔ Squashing of the tube, for example by the case, replace the tube if damaged, contact your service engineer.
  ➔ Sticking together of the pump tube. To prevent this, it is recommended to unhook the pump tube if the instrument is not used for more than one week.
  ➔ Accumulation of dirt in the tubes. Perform a cleaning with hypochlorite (7.2.1), replace if cleaning is not sufficient, contact your service engineer.
- Blockage in the flow cell:
  ➔ Accumulation of dirt in the flow cell. Perform a cleaning with hypochlorite (7.2.1), replace if cleaning is not sufficient, contact your service engineer.

c) Verify there is no lubricant on the rotor axis. Lubricant can make the rollers of the cassette slip and increase amount of time the pump is activated. Clean and remove the lubricant if necessary.

d) If after these verifications, the values remain outside the ranges, please contact a service engineer. Do **NOT** continue measuring with the instrument if the AD zero is out of range!

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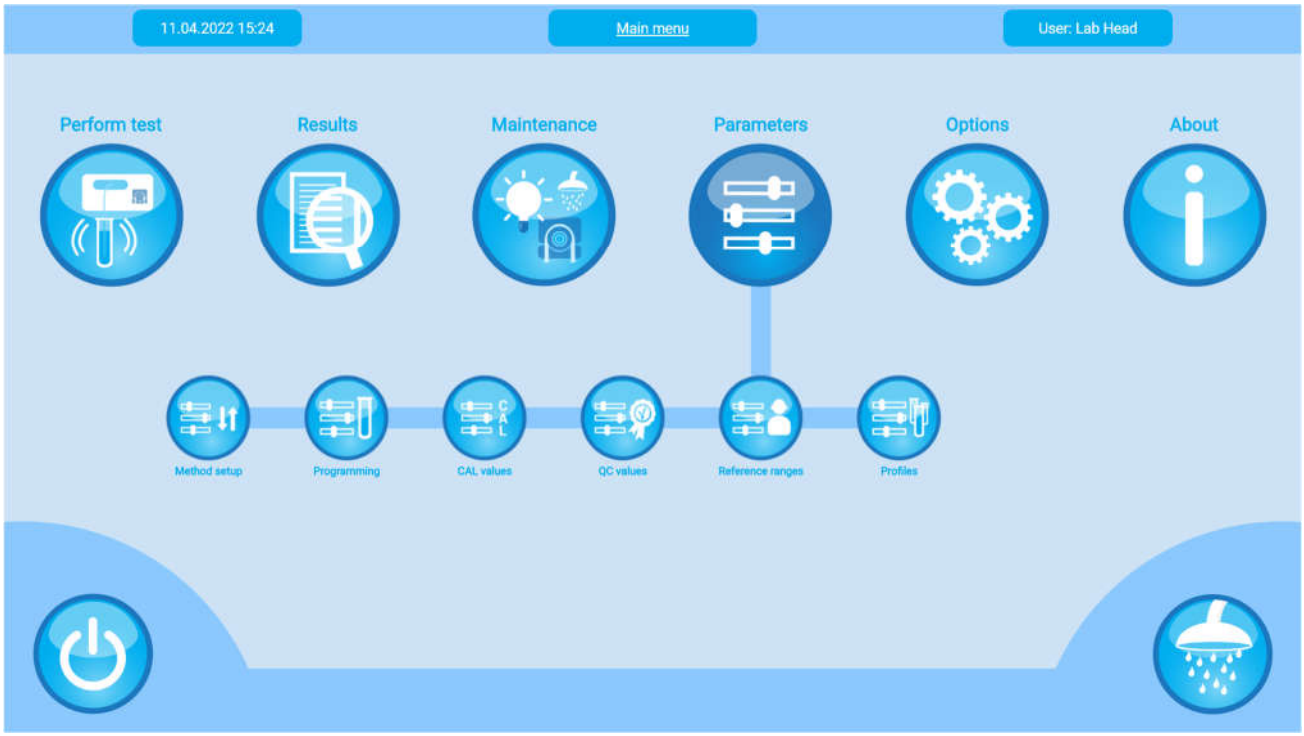
4.6 PARAMETERS

In the “Parameters” menu, 7 submenus with the following functions can be found:
- **Method setup:** To set-up the available methods which define the quality controls and calibrators.
- **Programming:** To set-up the detailed programming for the different methods.
- **CAL values:** To program the calibrators, along with their relevant tests.
- **QC values:** To program the quality controls and their relevant tests.
- **Reference ranges:** To program the reference ranges for the available programs.
- **Profiles:** To set up the profiles with their respective tests.



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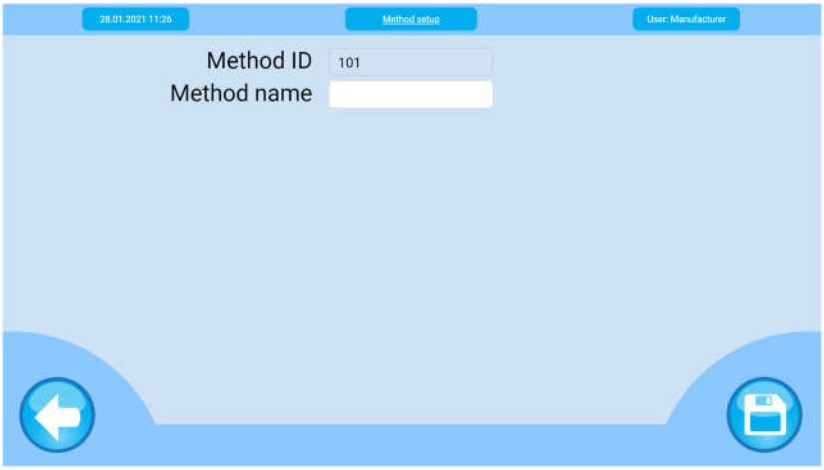
4.6.1 Method setup

After selecting “Method Setup”, you can add or modify a method. Methods are used to define the calibrators and quality controls and to group programming of tests that use the same calibrators and control values.

Button	Function
	Return, to return to the main menu.
	Edit, to edit the selected method.
	To delete the selected method.
	Add, to create a new method. The following screen will appear. The method ID will automatically appear, assign a method name. Press “Save” to store. 

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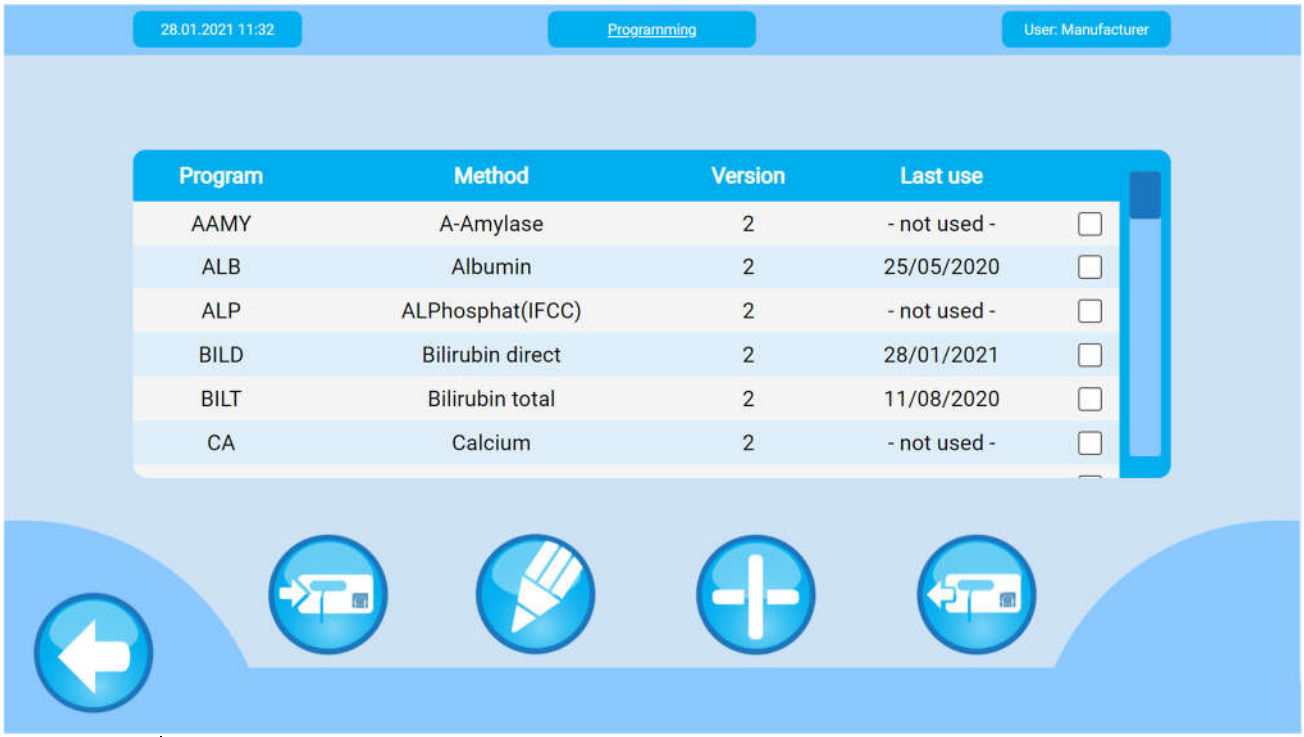
4.6.2 Programming

The instrument is delivered with all Cypress Diagnostics biochemistry programs already pre-programmed and ready to use. These closed (not modifiable) programs contain optimized parameters, which can always be reviewed using the application sheet. Up to 100 open programs can be added and modified to your choice. In total, the instrument can store up to 200 programs.



Button	Function
	Return, to return to the previous screen.
	Export, to create a back-up of the current programming and transfer it to an external USB.
	Edit, to edit the selected method (see 4.6.2.1)
	Add, to create a new programming.
	Import, to restore a back-up of the programming from an external USB.

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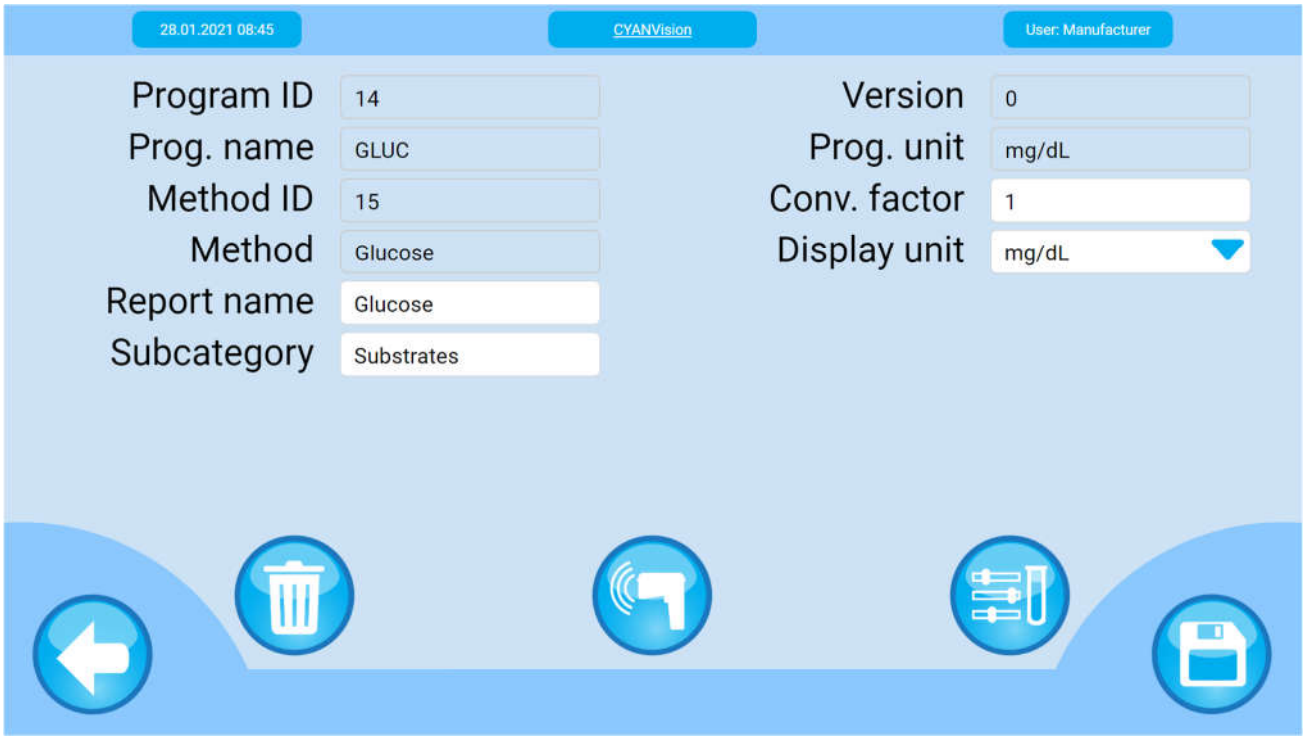
4.6.2.1 Edit a programming

From the programming menu, select the checkbox behind one of the programs and press the "Edit" button. The following screen with lab-depending parameters will appear. The **lab head** can change these parameters in case it concerns an open program (not the pre-programmed programs).



Field or button	Function
Program ID	The program number automatically assigned by the software.
Program Name	Use the keyboard to insert the desired name.
Method ID	A unique number to identify the method, which automatically appears when assigning a method.
Method	Select the required Method in the pull-down menu. If the correct method is not available, first define the method in "Method Setup" (see 4.6.1).
Report Name	The name which should appear on the report (automatic fill in from Method name).
Subcategory	Use the keyboard to insert the category under which the test should appear. Example: Liver, Lipids, …
Version	The version of the specific programming. Automatically assigned for the closed programs. For the open programs, this number automatically increases when a change is applied.
Program Unit	Choose a program unit from the pull-down menu. This unit will automatically appear in all the fields of the parameters with unit dependent values. **Note:** If the value on the patient report should appear in another unit, change the display unit!
Conv. Factor	The conversion factor between the program unit and the display unit. Insert the value using the numeric keyboard. Examples: 1. Conversion mg/dL to mmol/L The conversion factor needed can be found on the insert. This value is different for every method! Glucose liquid: the method is originally programmed in mg/dL, the desired unit is mmol/L. The conversion factor (mentioned in the insert): mg/dL x **0,0555** = mmol/L.

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	2. Conversion mg/dL to g/L First you need to calculate/ find the conversion factor 1 mg = 0,001 g and 1 dL = 0,1 L → 1 mg/dL = 0,001/0,1 g/L = 0,01 g/L. Conversion factor: mg/dL * **0,01** = g/L **Note:** • For enzymatic reactions like GOT or GPT, concentrations will always be given in « U/L ». Therefore, it is not advised to change the units. It is recommended to keep the program unit as display unit for Cypress Diagnostics reagents.
Display Unit	Choose a display unit from the pull-down menu. The display unit corresponds to the unit which appears on the report. When -free text- is chosen, one can manually enter the desired unit in the comment field.
	Return, to go back to the previous screen.
	Delete, to remove the programming.
	Scan, to automatically update the programming by scanning the QR code mentioned in the application sheets. **Note:** • Only Cypress Diagnostics kits are supported by the barcode platform. • Upon registering to our website (www.diagnostics.be) you can find the latest application sheets under the CYANVision product page.
	**Test parameters**, to manage the detailed test parameters of the specific programming.
	Save, to apply the changes. When adding a program, the save button will only appear once all the parameters have been filled in.

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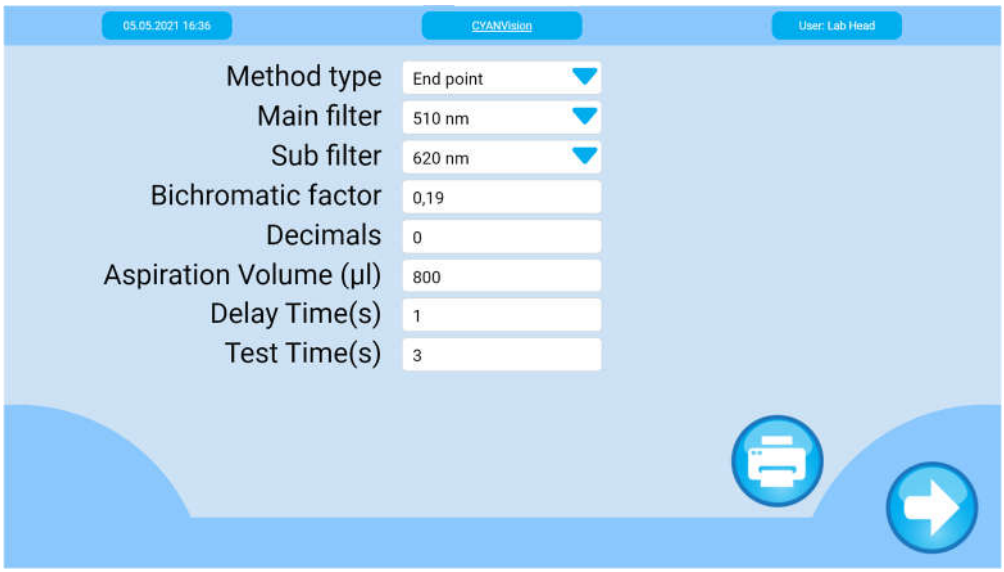
Pressing the "**Test parameters**" will open the first page of the program setup folder. Fill in all the fields manually or use the drop-down menus.



Field	Function
Method Type	Select the required test method: Endpoint, Two-point or Kinetic.
Main Filter	Select the required filter from the drop-down menu.
Sub Filter	This option is only available when the **End Point** method is selected. Otherwise, the field is not displayed. Select the required reference filter. If a filter different from "-none-" is selected, the **Bichromatic calculation** model is used (see 6.3.3).
Bichromatic factor	The bichromatic factor allows the user to correlate the sample absorbance reading with the subfilter (Filter 2) to the main filter (Filter 1) (see 6.3.3). This option is only available for an endpoint method with two filters defined (= Bichromatic methodology).
Decimals	The number of decimal places expressed in the results and patient report. Insert a value between 0 and 4 using the numeric keyboard.
Aspiration volume (µL)	Insert the required volume using the numeric keyboard.
Delay Time (s)	This is the incubation time inside the flow cell. Insert the required time using the numeric keyboard. The limits are 0 - 999 seconds.
Test time (s)	This is the measuring time. Insert the required time using the numeric keyboard. The limits are 3 - 999 seconds.

Press "**Continue**" to proceed to the second page.

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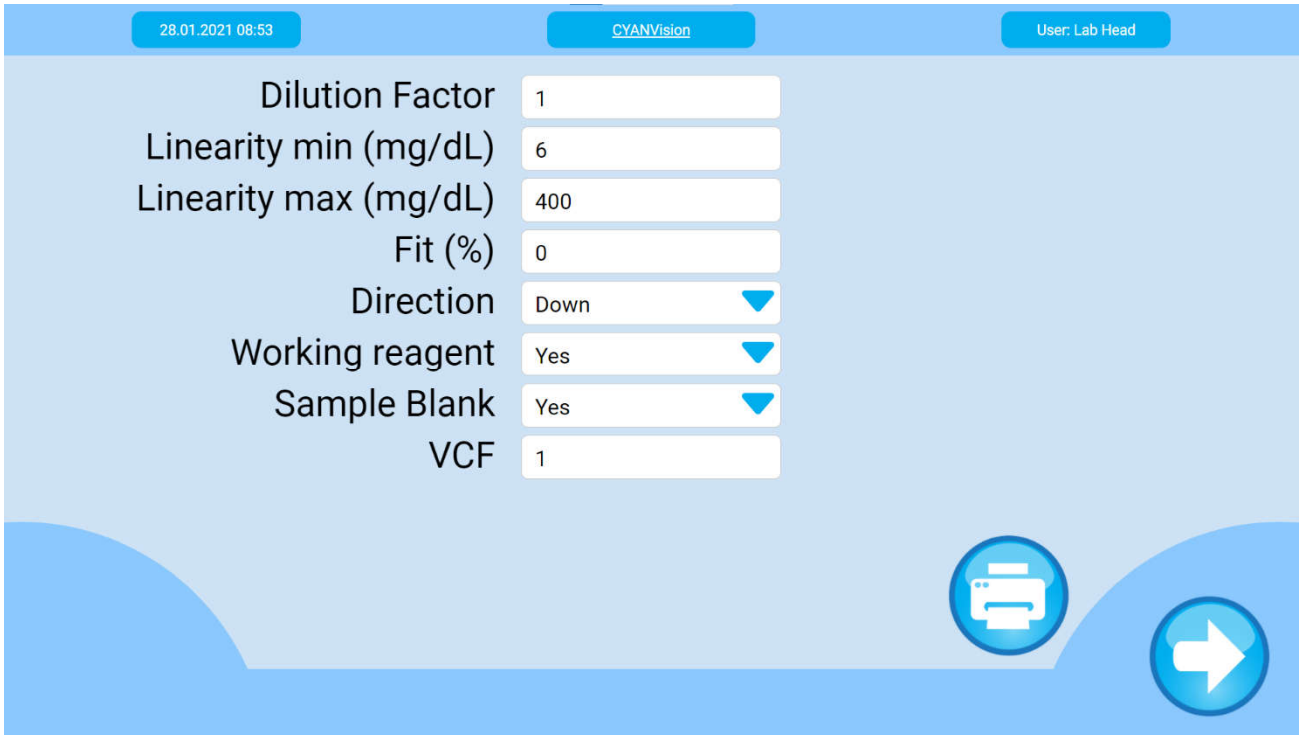

Field	Function
Dilution factor	If samples are diluted manually prior to measurement, the dilution ratio can be inserted here. This factor will then be taken into account in the calculation of the result. The default is 1 (no dilution).
Linearity Min	The lower limit for linearity, expressed in concentration. If the patient result is below this range, the result will be flagged "<". The measurement should be repeated with a new or more concentrated sample. **Attention!** Insert the value corresponding to the program unit!
Linearity Max	The upper limit for linearity, expressed in concentration. If the patient result is above this range, the result will be flagged ">". The measurement should be repeated with a diluted sample. **Attention!** Insert the value corresponding to the program unit!
Fit	The value introduced into this field indicates the limit of variation of the reading points compared to the calculated regression line, and within which the reaction is considered stable. If the value is outside of this parameter, even by only one reading point, it will be flagged. This specific parameter is applicable only when using the "Kinetics" methodology.
Direction	Defines the direction of the reaction: absorbance increase = direction "Up" or absorbance decrease = direction "Down". Select the required direction from the drop-down menu.
Working reagent	Defines the reagent reconstitution, if a working reagent is used = "Yes", if no select "No". This will control the possibility to skip the Reagent blank measurement. Skipping the reagent blank measurement for new working reagents is not allowed.
Sample blank	This selection permits to the system to subtract the absorbance value of the sample (matrix effect). This specific parameter is only applicable when using the "End Point" Methodology. Press the arrow to select the correct property.
VCF	Volume Correction Factors. This factor is automatically calculated by the system and is introduced to compensate for the dilution ratio resulting from the addition of the second reagent. Insert the value using the numeric keyboard.

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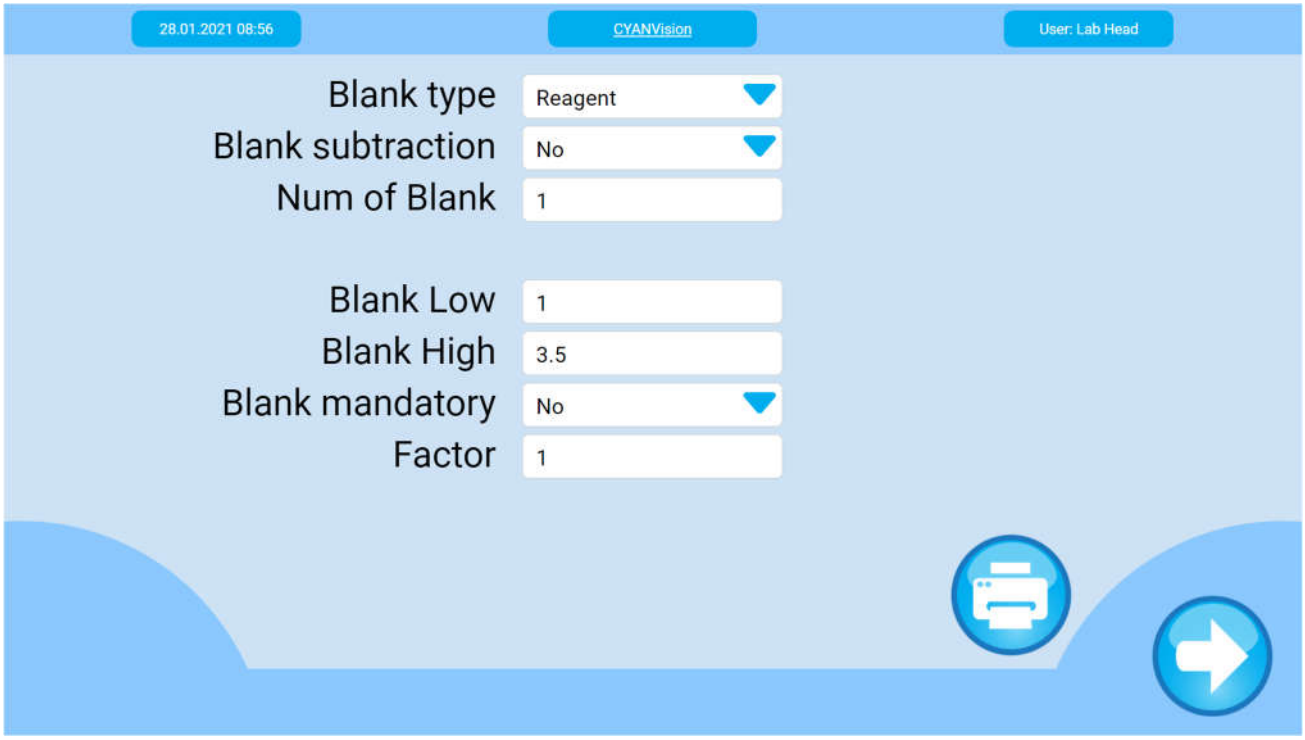
Press "**Continue**" to proceed to the next page.



Field	Function
Blank Type	Press the arrow and select the required blank method: water (bi-distilled), air, reagent or no blank. The sample blank measurement can only be performed for an endpoint method.
Blank subtraction	Select if a blank subtraction is required ("Yes"), or not ("No").
Num of Blank	Insert the required number of replicates. The limits are 1-3.
CV% of blank	Only if the Num of blank is higher than 1. The value introduced into this field indicates the maximum acceptable coefficient of variation percentage (CV%) among the replicates of RBL measurements. Results outside this value will automatically be flagged and discarded from the calculations when there are more than 2 measurements. Insert the value using the numeric keyboard.
Blank Low	The lowest acceptable absorbance value for the blank measurement. Blank measurements below this value will automatically be flagged "". If the reagent is measured as blank, a value below this limit could give an indication of reagent deterioration (especially for downward reactions).
Blank High	The highest acceptable absorbance value for the blank measurement. Blank measurements above this value will automatically be flagged "". If water is measured as blank, a value above this limit could give an indication of contamination of the water or of the hydraulic system of the instrument. If the reagent is measured as blank, a value above this limit could give an indication of reagent deterioration (especially for upward reactions).
Blank Mandatory	Choose if skipping of the blank is allowed: skipping is not allowed = Blank mandatory "Yes", skipping of the blank is allowed = Blank mandatory "No".
Factor	In this area, the calibration factor can be inserted when the calculation model is defined as "Factor". Combining a factor with another calculation model is not applicable and will create errors in the sample results. Insert the value using the numeric keyboard.

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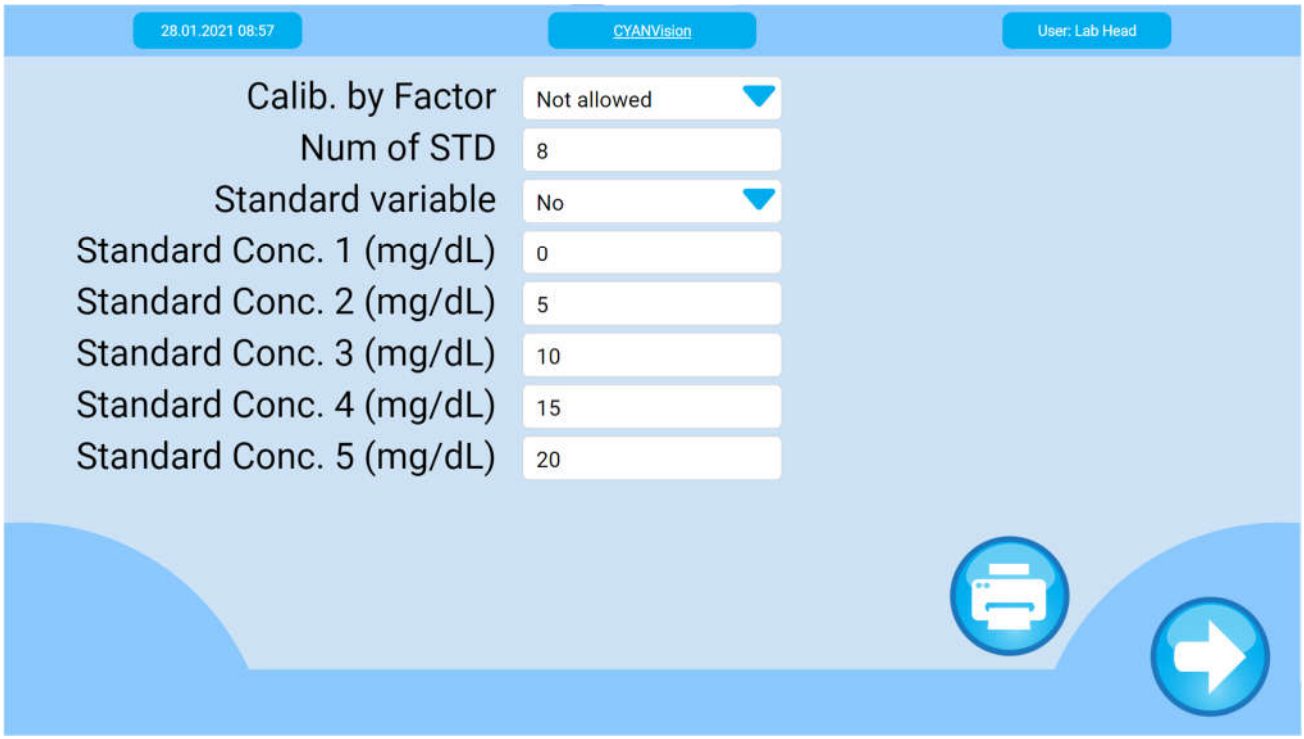
Press "**Continue**" to proceed to the next page.



Field	Function
Calib. by factor	Select if a calibration by factor is allowed or not
Num of STD	Insert the numbers of standards using the numeric keyboard. In case of calibration by means of a factor, insert 0 and proceed with inserting the factor. Insert a value ranging from 1 - 8, in case of a single or multi-point calibration.
Standard variable	Select if the standard is variable "Yes", or not variable "No". If the standard is variable and changes from lot to lot, the operator can change the standard concentrations directly during the calibration measurement process.
Standard Conc. # (unit)	The concentration of the standard corresponding to the number displayed in STD. Insert the concentration using the numeric keyboard. In the case of a multi-calibration, the standard concentrations must be entered from the **lowest to the highest** value. **Attention!** • Insert the value corresponding to the units of this method programming! • For some standards, the value is lot dependent, thus it needs to be adjusted for a new lot number.

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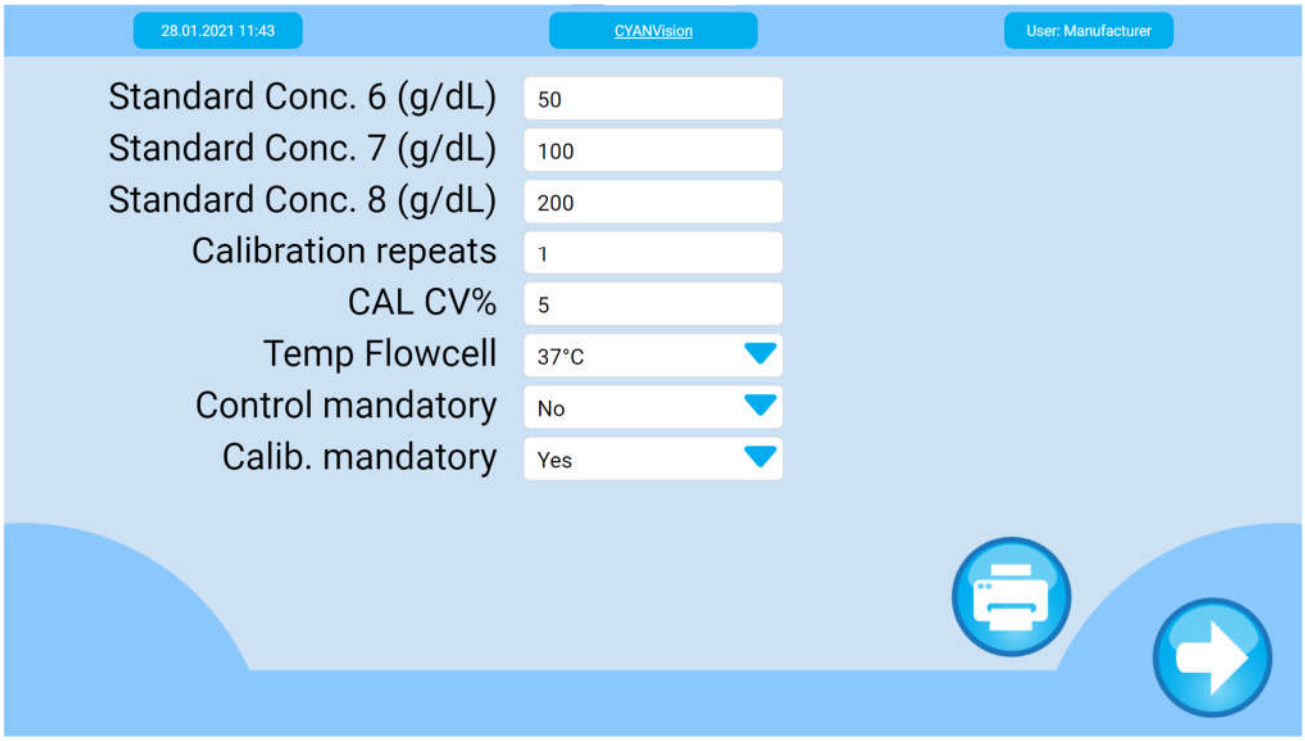
Press "**Continue**" to proceed to the next page.



Field	Function
Standard Conc. # (unit)	The concentration of the standard corresponding to the number displayed in STD. Insert the concentration using the numeric keyboard. In the case of a multi-calibration, the standard concentrations must be entered from the **lowest to the highest** value. **Attention!** • Insert the value corresponding to the units of this method programming! • For some standards, the value is lot dependent, thus it needs to be adjusted for a new lot number.
Calibration repeats	This field permits to define the number of calibrations requested, from 1 (single) to 10. Insert the value using the numeric keyboard.
CAL CV%	The value introduced into this field indicates the maximum acceptable coefficient of variation percentage (CV%) among the replicates of calibration measurements. Results outside this value will automatically be flagged. Insert the value using the numeric keyboard.
Cuvette Temp	Press the arrow and select the required flow cell temperature: 25 °C, 30 °C or 37 °C. For all Cypress Diagnostics methods, 37 °C must be selected. **Note:** The temperature of the flow cell should be higher than the room temperature (°C).
Control Mandatory	To determine if skipping of the QC measurement is allowed: skipping is not allowed = Control mandatory "Yes", skipping is allowed = Control mandatory "No".
Calibration Mandatory	To determine if skipping of the calibration measurement is allowed: skipping is not allowed = calibration mandatory "Yes", skipping is allowed = calibration mandatory "No".

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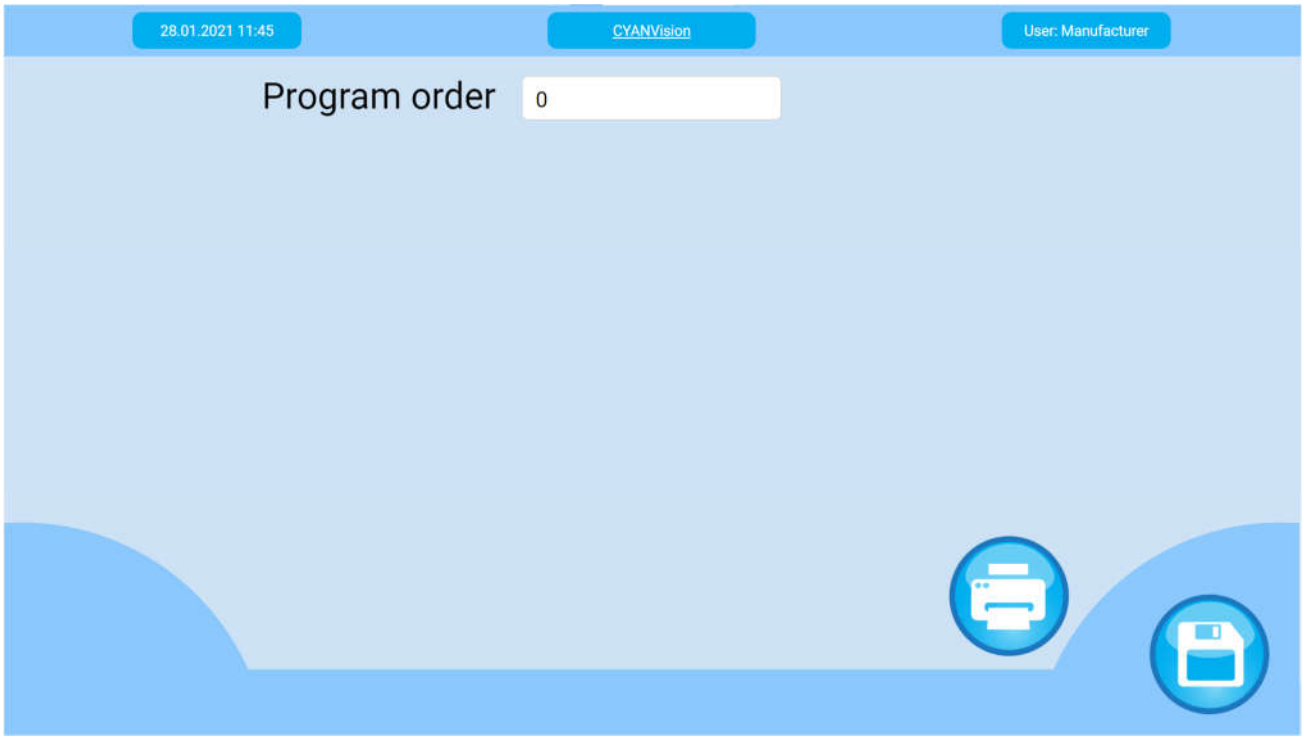
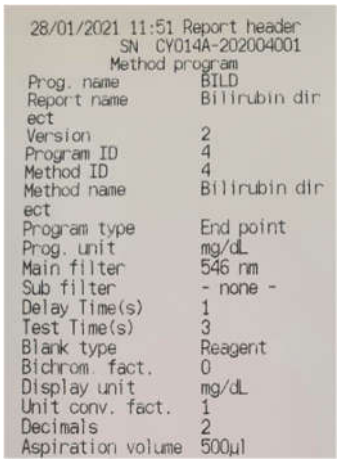
Press "**Continue**" to proceed to the next page.



Field	Function
Program order	The value introduced in this field indicates the sample order of the tests which have to be performed. Programs will receive 0 (= no priority) by default. 1 is the highest number (= priority). Insert the value using the numeric keyboard. **Note:** Programs with STATs (Priority samples) will always have a higher priority than programs without STATs.
	Print, to create a print-out of the entire programming. 
	Save, to store the applied changes and return to the program list. Leaving the page by pressing on the header button will prompt a warning that the changes will not be saved. 

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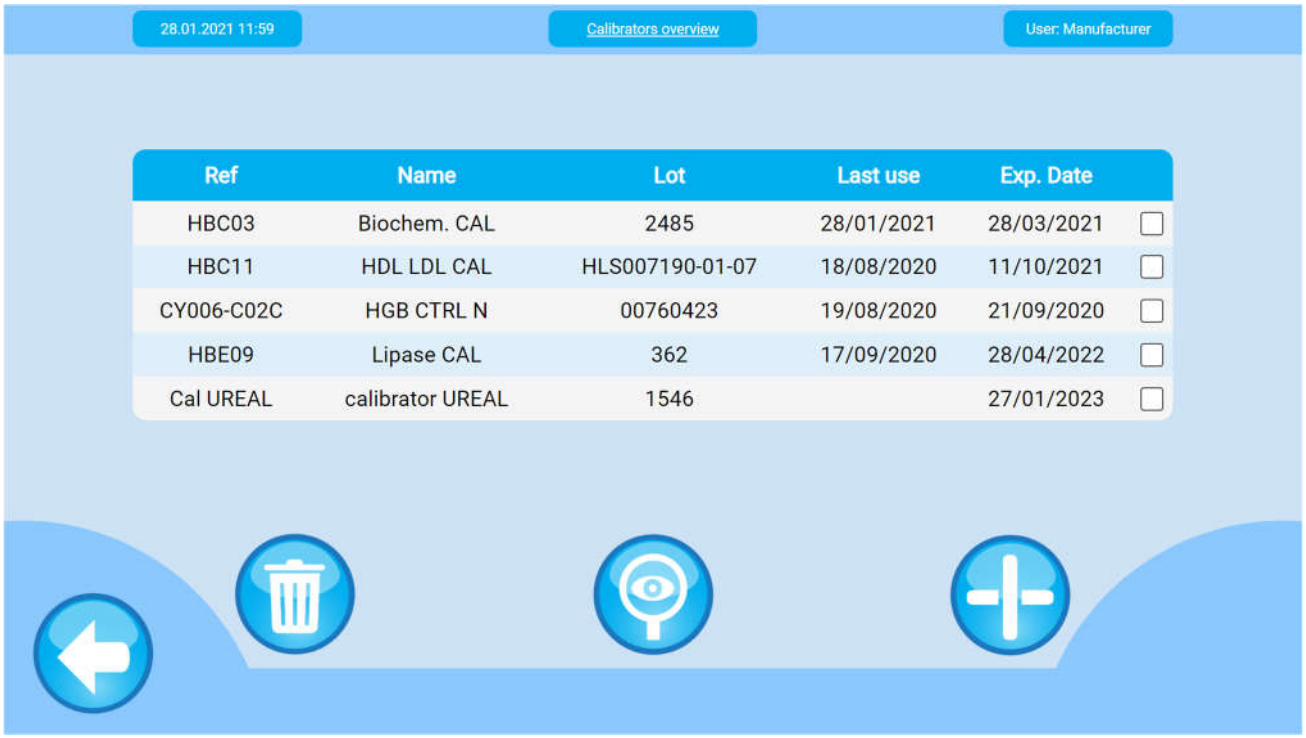
4.6.3 CAL values

This menu allows the user to program the calibrators along with the relevant methods.
Select “Parameters” and from the options listed, click “CAL values”. An overview of the available calibrators will appear.



Button	Function
	Return, to go back to the previous screen.
	Delete, to remove the selected calibrator.
	View details, to manage the programmed values for the selected calibrator. The following screen will appear.  Press the “Edit” button to modify, delete or add programs to the calibrator.

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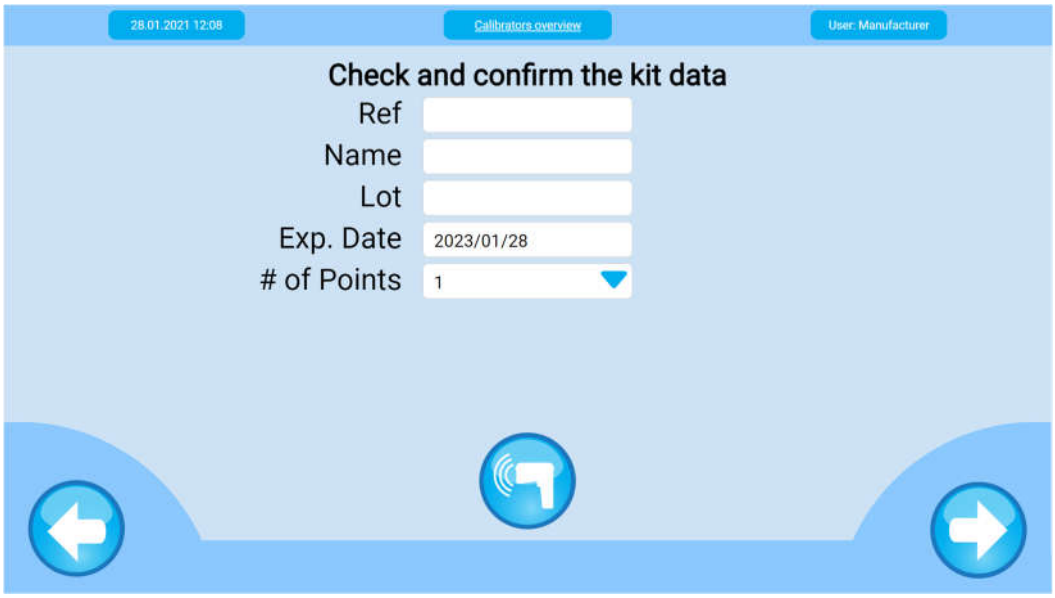
Add, to add a new calibrator to the list of calibrators. The following screen will appear.



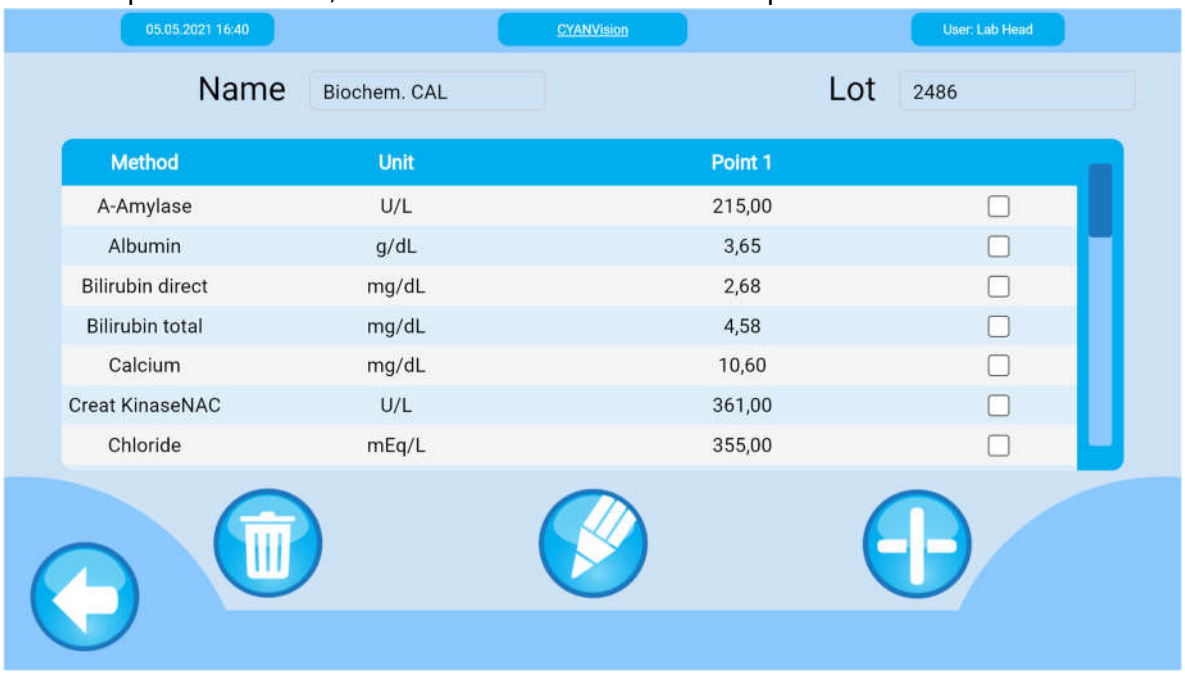
Field	Function
Ref	Reference of the calibrator
Name	Name of the calibrator
Lot	The lot number of the calibrator
Exp. Date	The expiration date of the calibrator.
# of points	Number of points of the calibrator (from 1 to 8)

Use the "**Scan**" feature to scan the QR code on the calibrator insert to automatically upload the calibrator information.

Note: The scan feature is only applicable for supported Cypress Diagnostics reagent kits.

4.6.3.1 Manage a calibrator

To edit a specific calibrator, select it from the overview list and press "View details → Edit".



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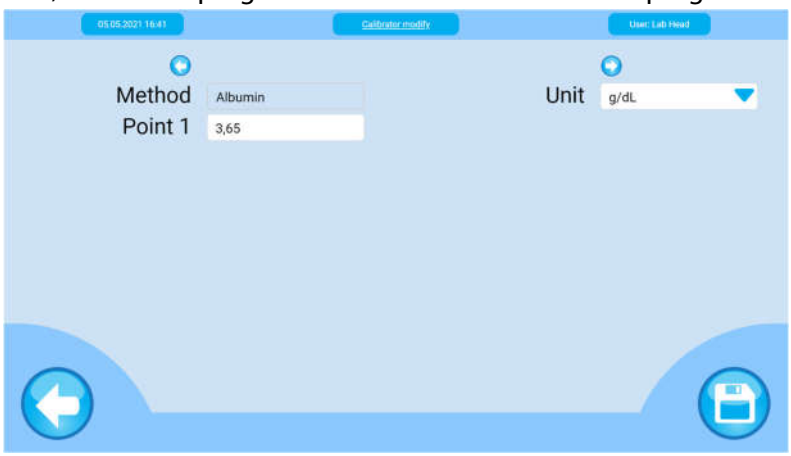
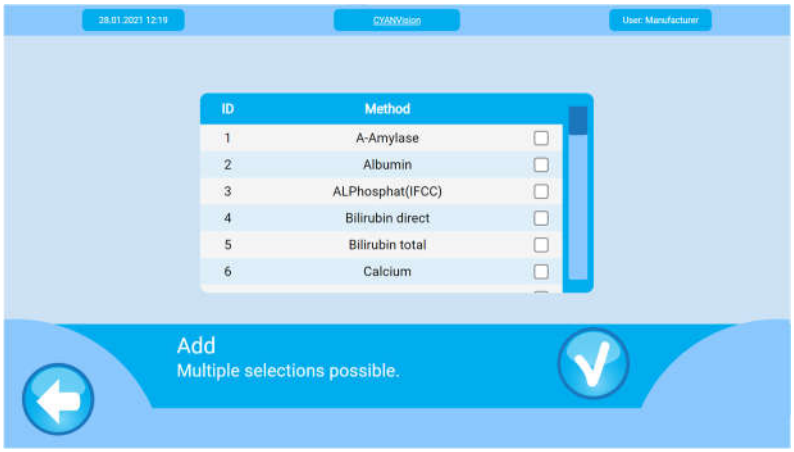
Button	Function
	Return, to return to the previous screen.
	Delete, to remove the selected method.
	Edit, to edit the programmed values for the selected program. 
	Add, to add methods to the calibrator. When pressing the “Add” button the following screen will appear. Select the required methods and press “Confirm”. The different “Methods” will be added to the programming. 

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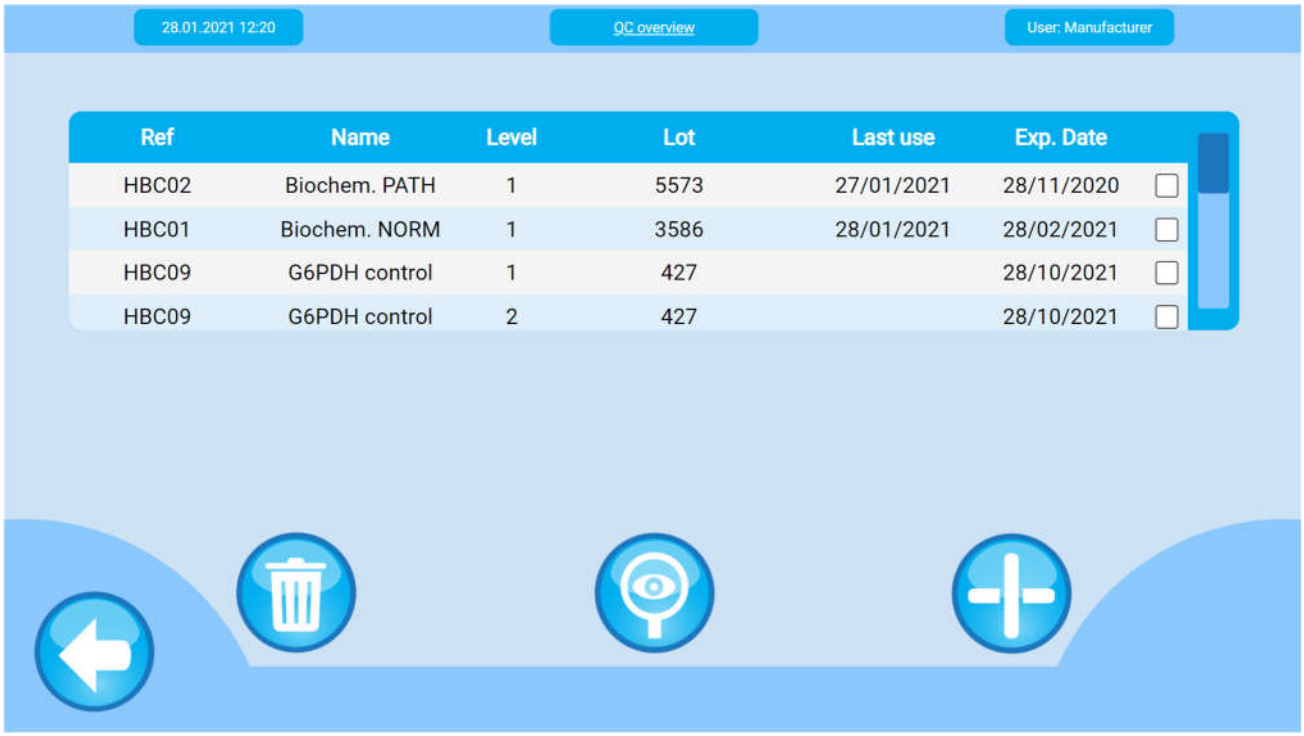
4.6.4 QC values

This menu allows the user to program the quality controls along with the relevant methods.
Select "Parameters" and from the options listed, click "QC values". An overview of the available quality controls appears.



Button	Function
	Return, to return to the main menu.
	Delete, to remove the selected quality control.
	View details, to manage the programmed values for the selected quality control. The following screen will appear.  Press the "Edit" button to modify, delete or add programs to the quality control.
	Add, to add a new quality control to the list of quality controls.

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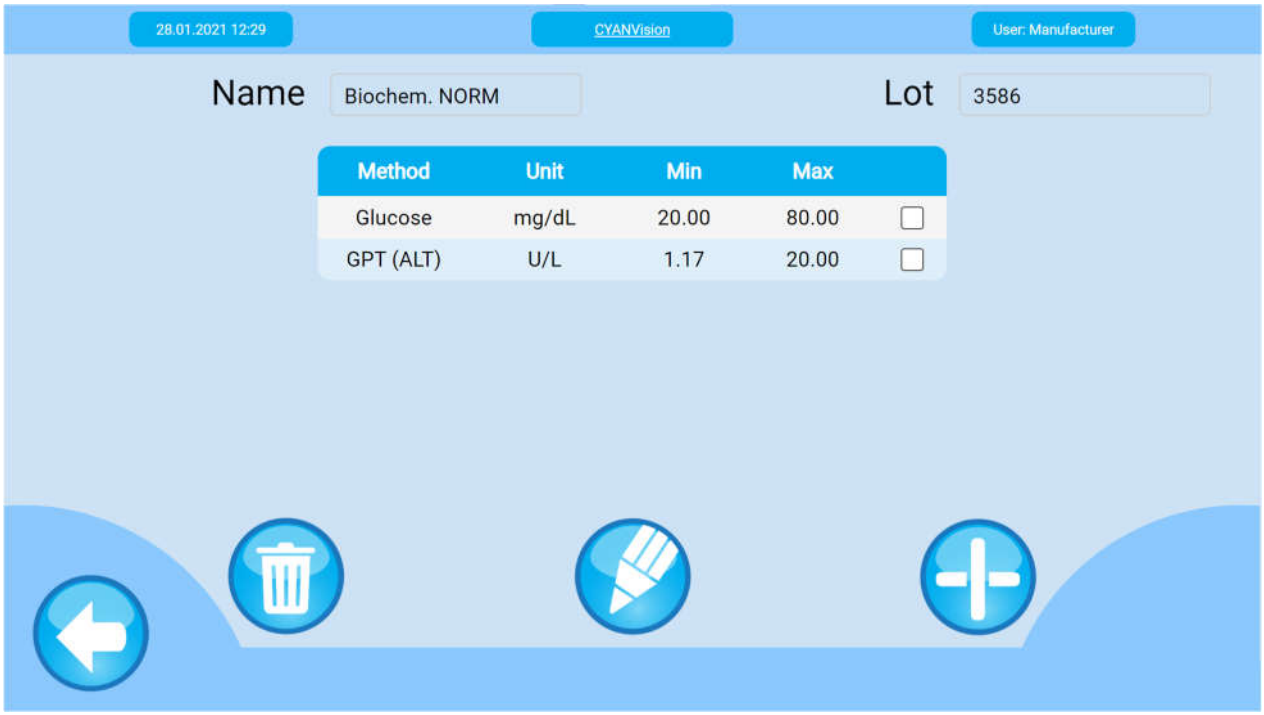
Field	Function
Ref	Reference of the quality control
Name	Name of the quality control
Lot	The lot number of quality control
Level	The level of quality control
Exp. Date	The expiration date of the quality control.

Use the "**Scan**" feature to scan the QR code on the quality control insert to automatically upload quality control information.
Note: This scan feature is only applicable for supported Cypress Diagnostics reagent kits.

4.6.4.1 Manage quality control

To edit a specific quality control, select it from the overview list and press "View details → Edit".



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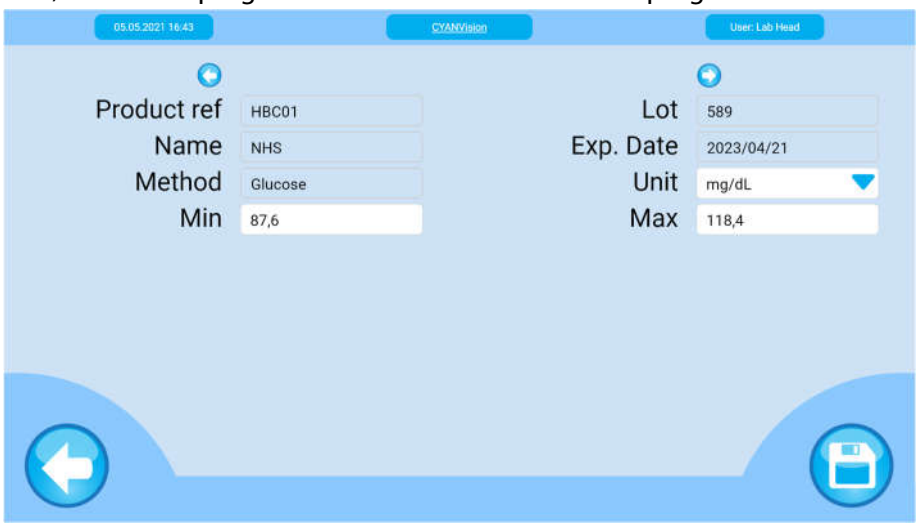
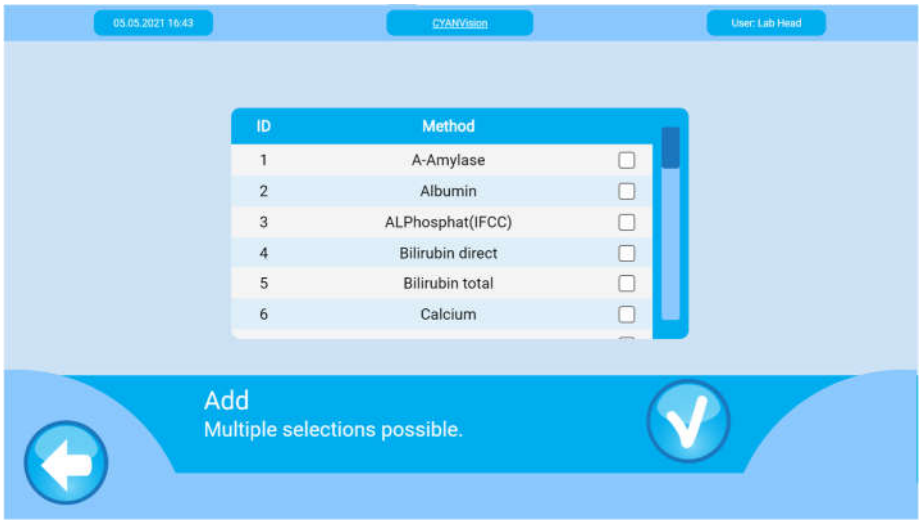
Button	Function
	Return, to return to the previous screen.
	Delete, to remove the selected method.
	Edit, to edit the programmed values for the selected program. 
	To add methods to the quality control. When pressing the “Add” button the following screen will appear. Select the required methods and press “Confirm”. The different “Methods” will be added to the programming. 

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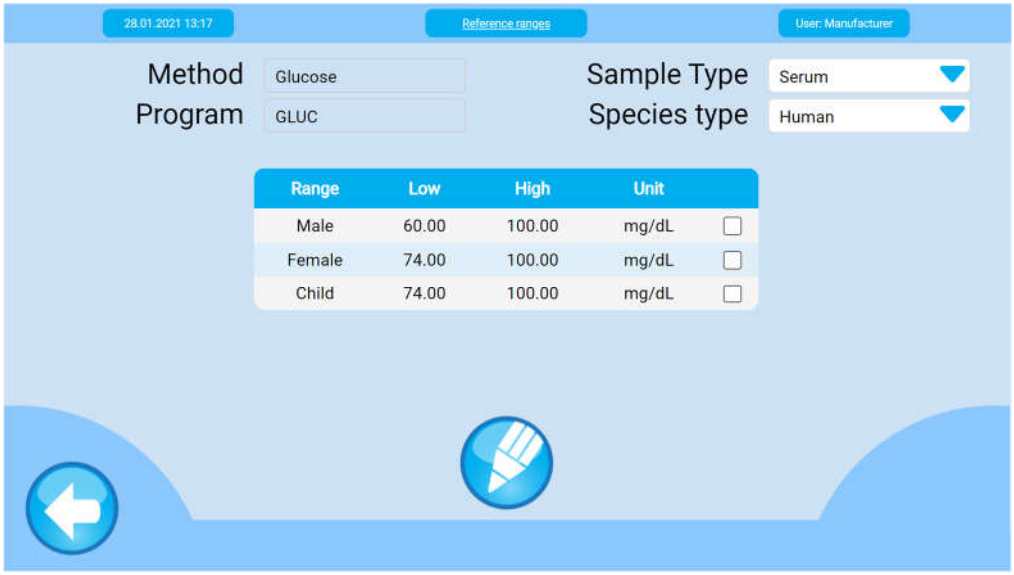
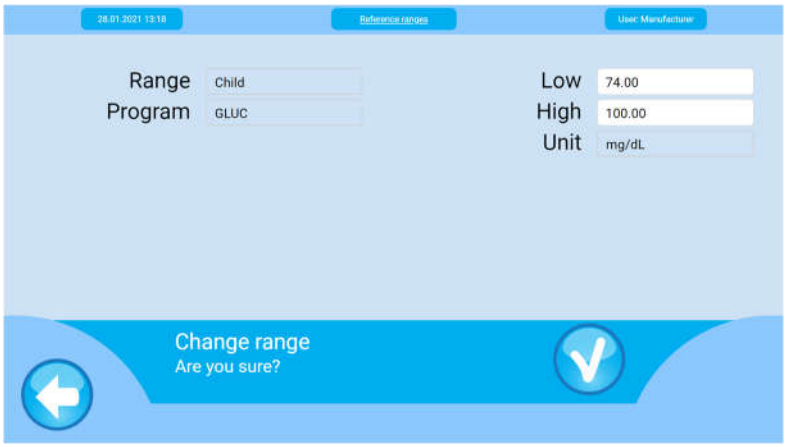
4.6.5 Reference ranges

This menu is used to program the limits for the normal range or reference range for every program, sample type, specimen and each profile (Men, Female and Child) separately. In the perform test menu the sample type and specimen can be set for every individual sample (see 4.3.1.1 & 4.3.8). When the measured result is outside these limits, a flag "  "or "  " highlights that the parameter is respectively higher or below the range.

Select "Parameters" and from the options listed, click "Reference ranges", a list of the available programs will appear. Select the required program and press "Edit". The following screen will appear.



Note: At delivery, there are values pre-programmed in the instrument. These are for orientation purposes. Each laboratory should establish its own reference range.

Field or button	Function
Sample type	Select the sample type for which reference values need to be defined from the drop-down menu .
Species type	Press the arrow and select the species type to define the reference values
Decimals	The number of decimals. Insert the value by using the numeric keyboard.
	Return, to return to the program list.
	Edit, to modify the selected reference ranges. 
	Save, to store the applied changes.

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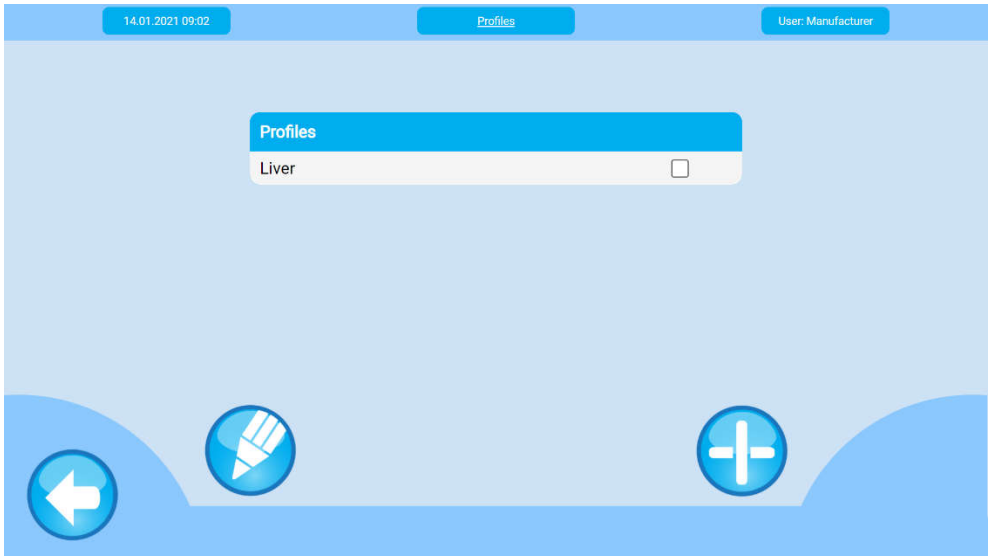
4.6.6 Profiles

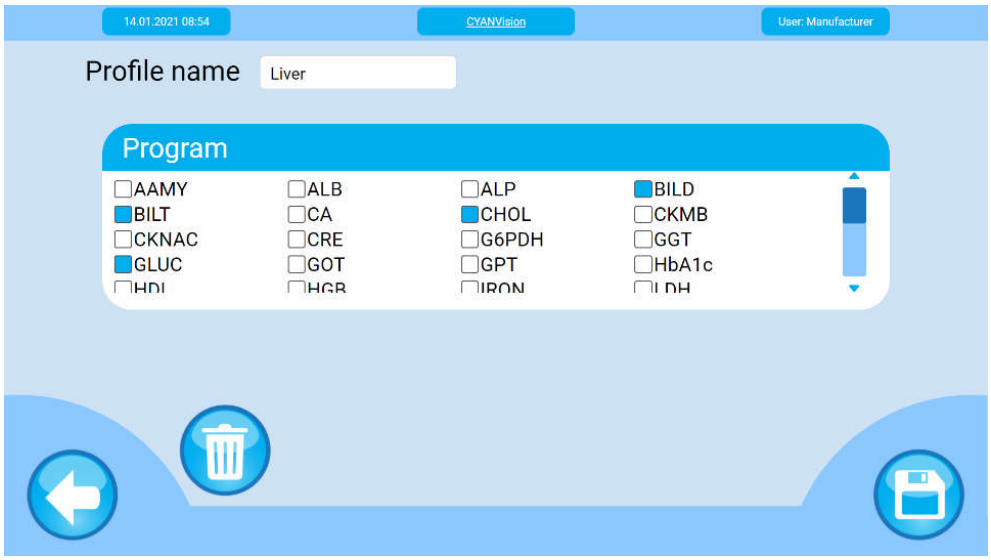
This function allows programming test profiles, (i.e. predetermined group of tests to be carried out together). There is no limit on the number of profiles the user can define.
Select "Parameters" and from the options listed, click "Profiles". An overview of the defined profiles appears.



Button	Function
	Return, to return to the main menu.
	Edit, to modify the selected profile.
	Add, to create a new profile to the profiles list. **Note**: A lab user can not edit or modify profiles, a lab head account is necessary to perform these actions.

4.6.6.1 Manage a profile

Whenever the lab head selects a profile from the "Profiles list" and presses "Edit" the following screen appears. The profile name can be adapted and the different programs for this profile can be selected. Other actions include saving changes or deleting the selected profile.



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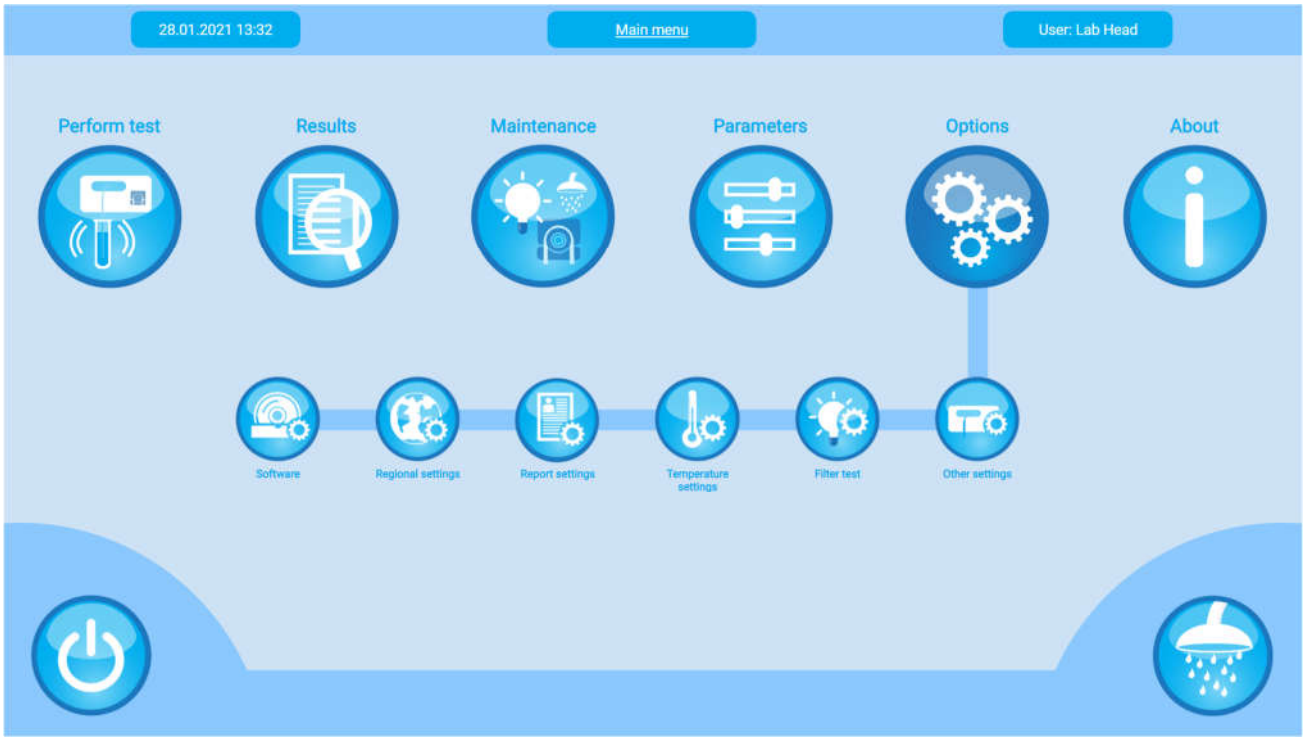
4.7 OPTIONS

In the "Options" menu, 6 submenus with the following functions can be found:

- **Software:** To manage the installed software version.
- **Regional settings:** To manage the region depending settings.
- **Report settings:** To define the report names and report options.
- **Temperature settings:** To manage the temperature settings.
- **Filter test:** To perform an OD test or absorbance measurement.
- **Other settings:** Settings reserved for the Lab head or service engineer during the installation.



4.7.1 Software

Select "Options" and from the options listed, click "Software". The software version of the CYANVision can be found here. This is useful information for the service engineer or support technicians and should be included in the repair report.

Software updates (on an external data storage device) can be launched using the update button  .
Press the "Return" button to exit the menu.

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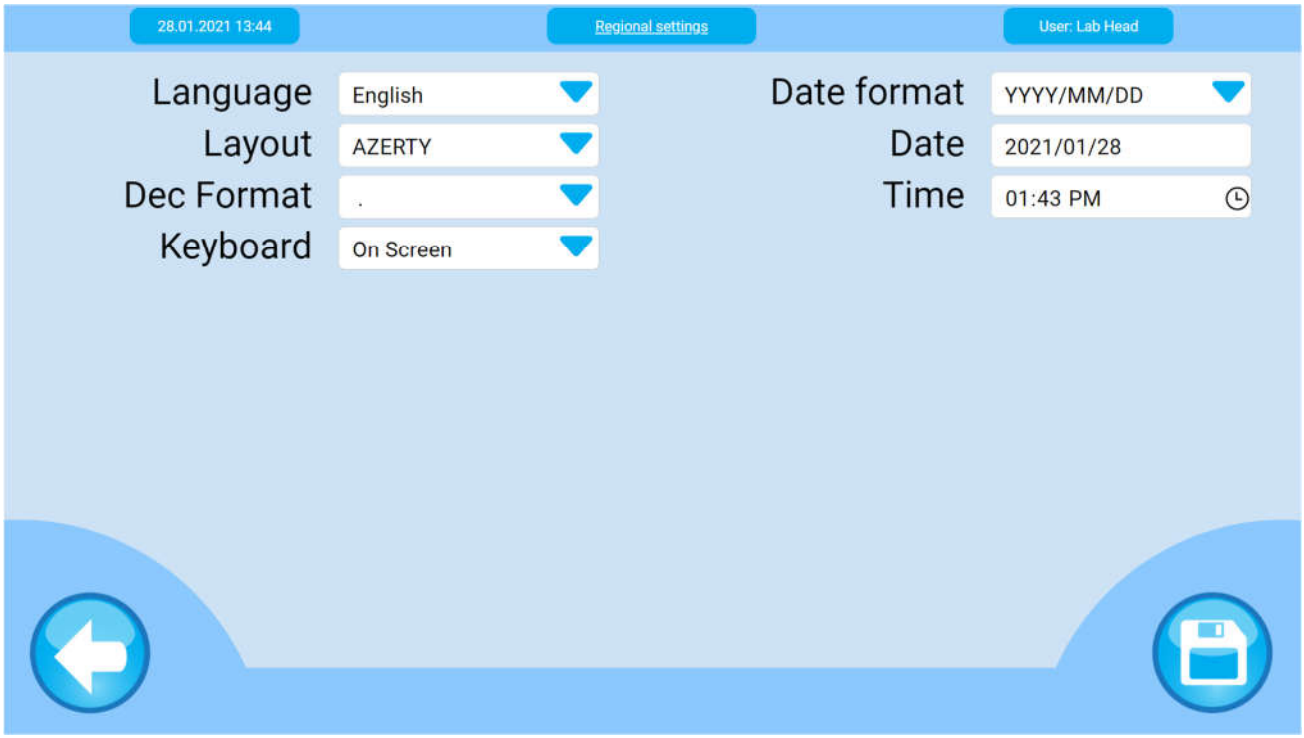
4.7.2 Regional settings

Select "Options" and from the options listed, click "Regional settings". The regional settings of the CYANVision can be found here. This information should be configured by the service engineer during installation. Press the "Return" button to exit the menu.



Field or button	Function
Language	The current version of the CYANVision software is available in English and in French. Select the desired language from the drop-down menu.
Layout	This feature enables you to select the desired keyboard layout format: Qwerty, Qwertz or Azerty.
Dec format	This feature enables you to select the desired decimal format: "," or ".".
Keyboard	To activate the on-screen keyboard layout format, choose 'On screen' from the drop-down menu.
Date format	Select the desired date format: YY-MM-DD, DD-MM-YY or MM-DD-YY.
Date & Time	This feature enables you to input the correct time and date according to the format selected under the menu Date Format. Setting the correct date & time is essential if you wish to re-find results in the archives because the data is stored chronologically.
	Return, to go back to the main menu.
	Save, to store the applied changes.

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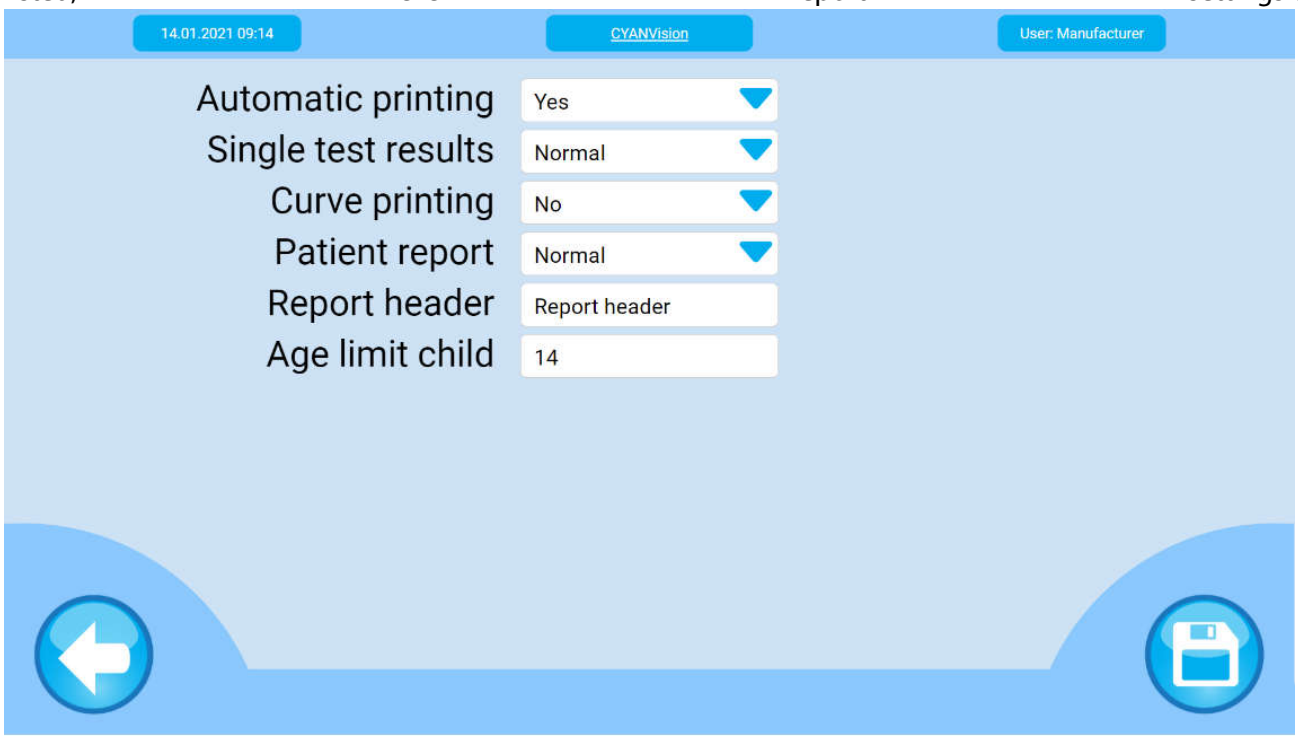
4.7.3 Report settings

The feature enables you to configure the build-in printer settings. Select "Options" and from the options listed, click "Report settings".



Field or button	Function
Automatic printing	Select "Yes" or "No" from the drop-down menu. When this option is enabled, the instrument will print all results automatically upon finishing a measurement. All "on-demand" printing in the menus "Programming", "Results" or "AD Zero" are not influenced by the choice in this option.
Single test results	Print single test results in normal or extended mode (choose from the drop-down list). In the extended mode, the ranges for the blank, QC and samples will be printed. The normal printing mode is more economic printing and uses less paper than the extended mode.
Curve printing	Select "Yes" or "No" from the drop-down menu. When this option is enabled, the curves obtained during the performance of a kinetic test will be printed [This feature will be enabled in the upcoming software releases].
Patient report	Print patient reports in normal or extended mode (choose from the drop-down menu). In the extended mode, the ranges for the blank, QC and samples will be printed. The normal printing mode is more economic printing and uses less paper than the extended mode.
Report header	This menu enables the user to add a personalized heading (name of the hospital or laboratory) on the printed reports.
Age limit child	Insert an age limit in this field to define from which age on a patient as either Adult or Child. This age limit will be used by the program when the normal values range is interpreted.
	Return, to go back to the previous screen.
	Save, to store the applied changes.

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4.7.4 Temperature settings

This menu enables to verify if the temperature of the flow cell (cuvette) measured by the instrument corresponds to the set temperature. Select "Options" and from the options listed, click "Temperature settings". The temperature is expressed in degrees Celsius (°C). Press the "Return" button to exit the menu.

Field or button	Function
Set	The set temperature corresponds to the temperature setting of the last executed program, which is by default 37 °C.
Measured	To currently measured temperature in the flow cell. The measured temperature should be the set temperature ± 0.5 °C. If not, see 8 – Troubleshooting & errors.
	Return, to go back to the main menu.
	To perform a temperature calibration. This menu is used by the service engineer to re-calibrate the temperature settings of the flow cell and incubator. If necessary, contact a service engineer.

Note:

- After start-up, the instrument should reach the default temperature (37 °C) **within 5 minutes**.
- If upon entering the perform test menu and selecting a program, the programmed temperature for the flow cell is not yet reached, the instrument will display a warning to inform the user of this discrepancy.

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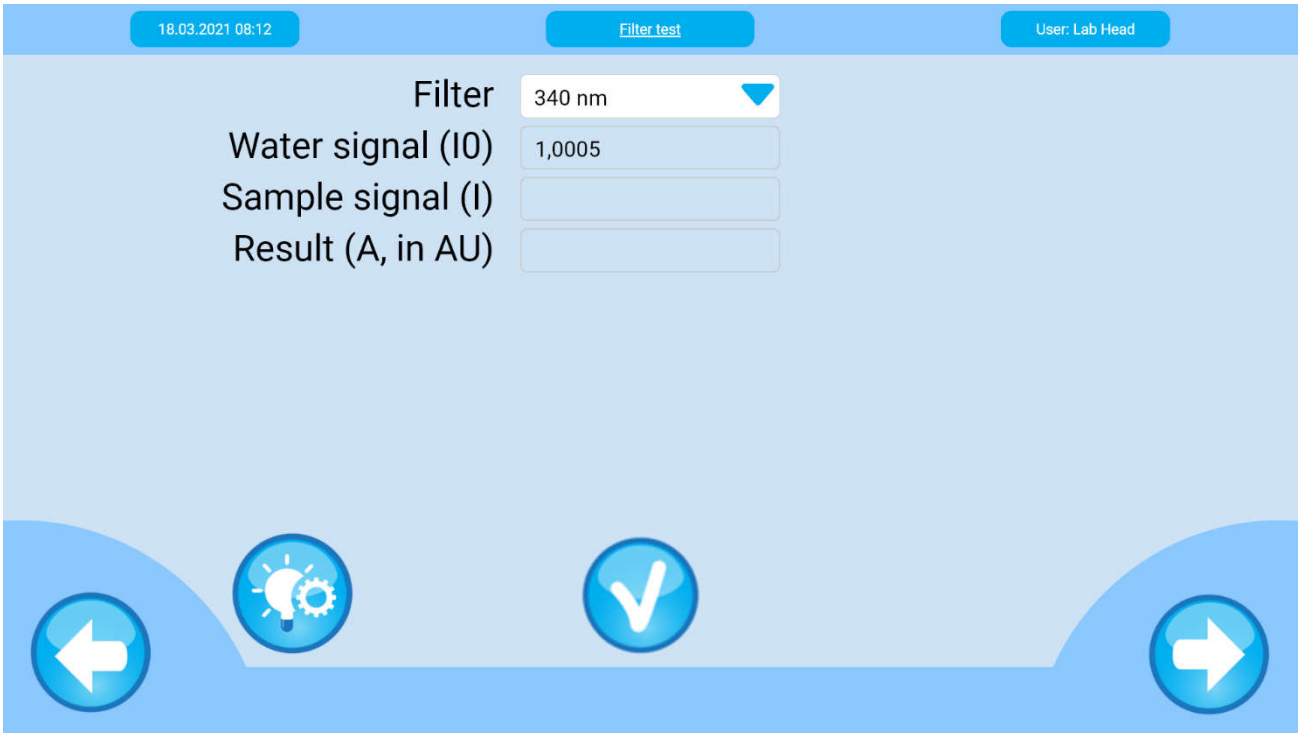
4.7.5 Filter test

This menu can be used to perform an OD test or absorbance measurement. It is also used by the service engineer during checking of the individual wavelengths and the optical sensor.

Before performing a filter test, it is **essential** to check that:

a) The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water.
b) The flow cell is filled with distilled water and without any air bubbles.
c) The instrument is ON for at least 5 minutes, this time is necessary for the flow cell to obtain the correct temperature.
d) The AD Zero is performed and within the acceptable ranges.



Field or button	Function
Filter	Drop-down menu with all the available filters with a certain wavelength (nm).
Water signal (I_0)	The amount if initial light (100% signal transmission)
Sample signal (I)	The amount of light transmitted by the sample.
Result (A, in AU)	Absorbance value A, which measures the ability of a medium to absorb light passing through it. Calculation formula: $A = \frac{I_0}{I}$
	Return, to return to the main menu.
	Confirm the measurement, to fix the value for the Water Blank.
	To assign a filter with a certain wavelength (nm) to a position. Only modifiable by the Service engineer.
	Aspirate, to activate the pump, the measurement is automatically started after the sample is taken.

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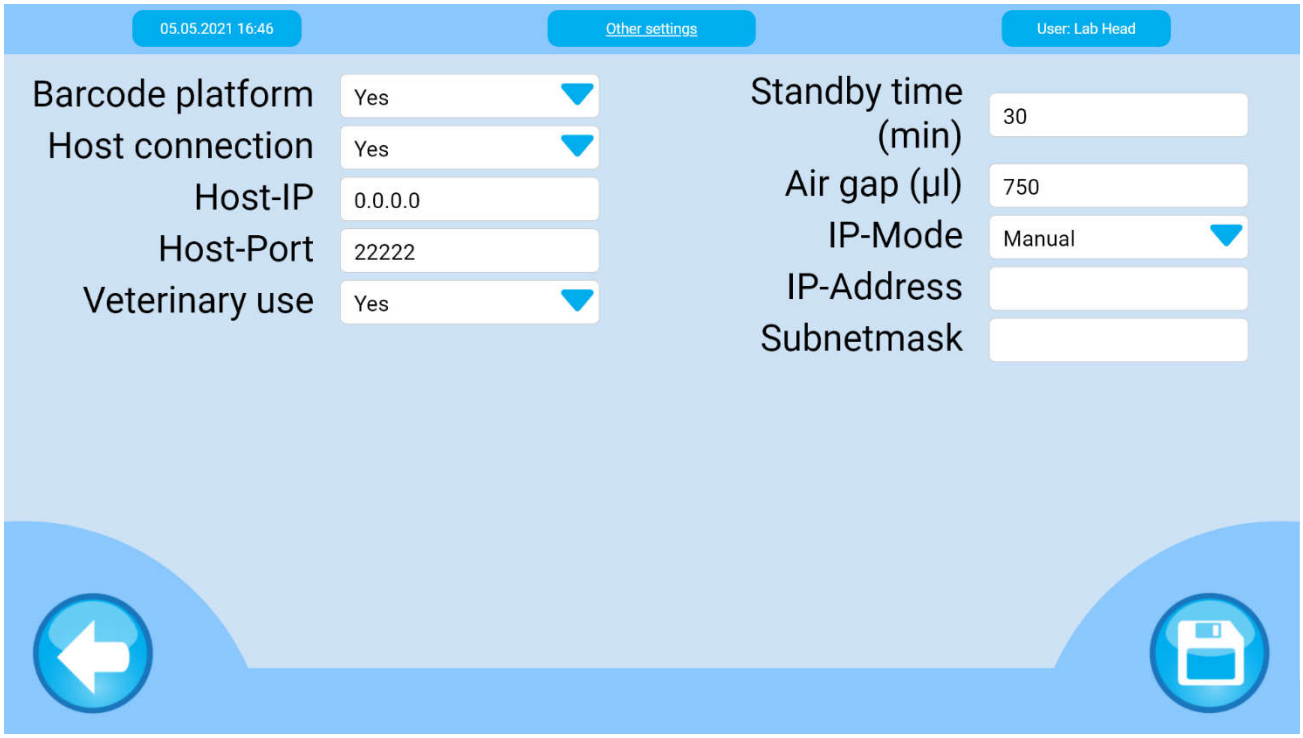
4.7.6 Other settings

Properties related to the barcode platform, the LIS and network connection, the veterinary mode, the standby time and air gap settings can be found in this submenu.



Field or button	Function
Barcode platform	This feature enables you to activate the barcode mode, it will enable you to add the calibrator and quality control information by scanning the QR barcode on the respect kit. Select "Yes" or "No" to (de)activate the barcode platform.
Host connection	This feature enables the host connection. A detailed procedure for host connection is available, contact your service engineer for more information.
Veterinary use	To activate the veterinary mode of the CYANVision. Besides the human species, it is possible to assign a species type for every sample and assign species reference values. Choose "Yes" to activate this mode or select "No" to leave inactive.
Standby time (min)	In this menu, you can select the preferred time (in min) after which the instrument will go into a standby mode. The user will be logged out automatically.
Air gap (µL)	During an aspiration cycle, the programmed volume of the sample is aspirated in the flow cell and measured. When the measurement is finished, an air gap is aspirated to prevent cross-contamination with/of the next sample. Then the instrument will indicate it is ready to aspirate the next sample. This feature enables you to input the air gap. Use the keyboard to insert the air gap in µL. The advised volume is 750 µL. **Attention!** If the air gap is too big, air bubbles will flow into the flow cell during measurement, given false results and if the air gap is too small, there is increased risk of cross-contamination.
	Return, to return to the main menu.
	Save, to store the applied changes.

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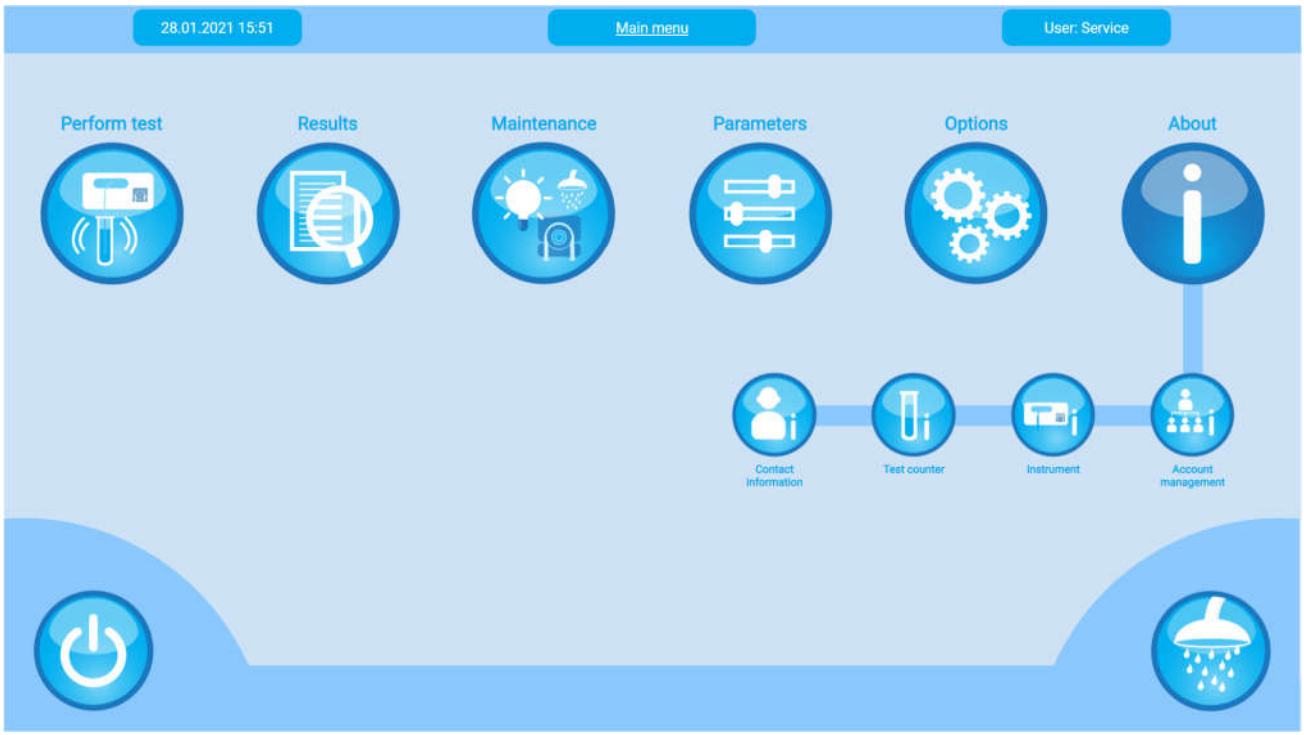
4.8 ABOUT

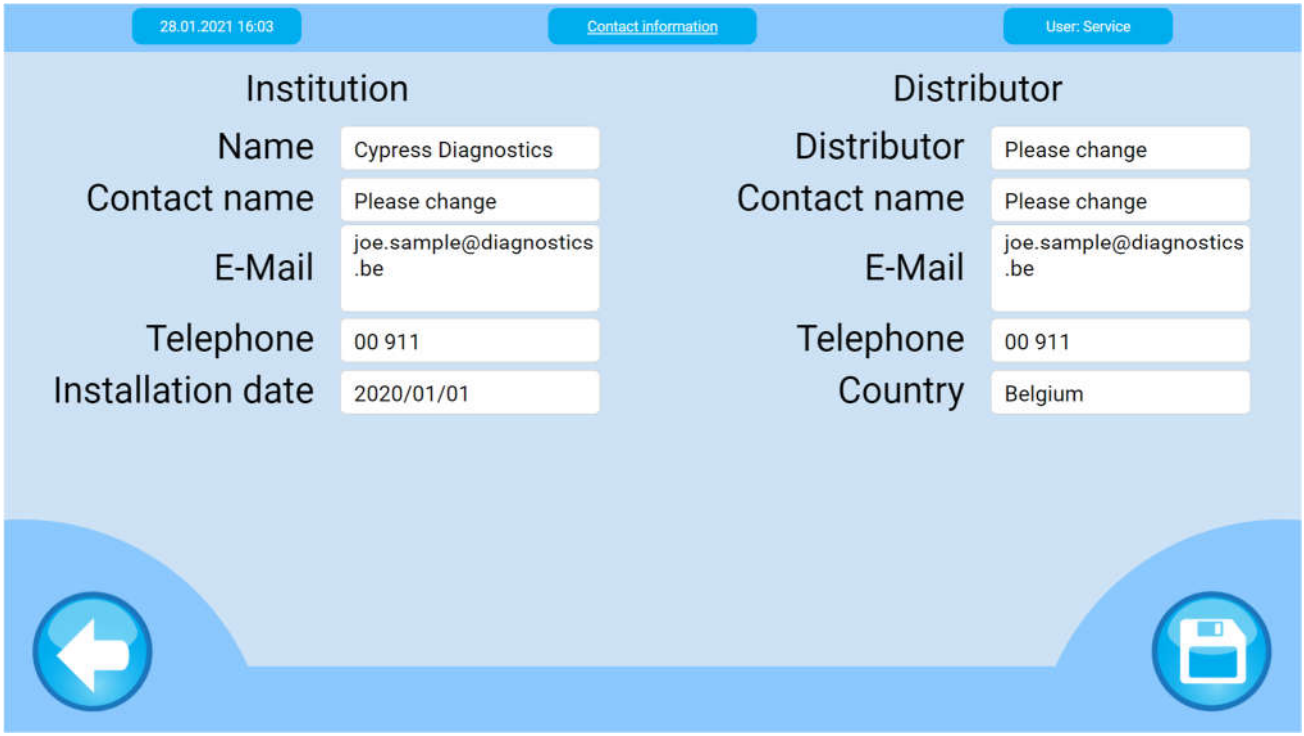
This menu contains general information about the CYANVision analyzer, divided in 4 submenus:

- **Contact information**
- **Test Counter**
- **Instrument**
- **Account management**



4.8.1 Contact information

Select "About" and from the options listed, click "Contact information". This menu gives you an overview of the contact details of the responsible distributor and the coordinates of the installation location. This information is filled in by the service engineer during installation.



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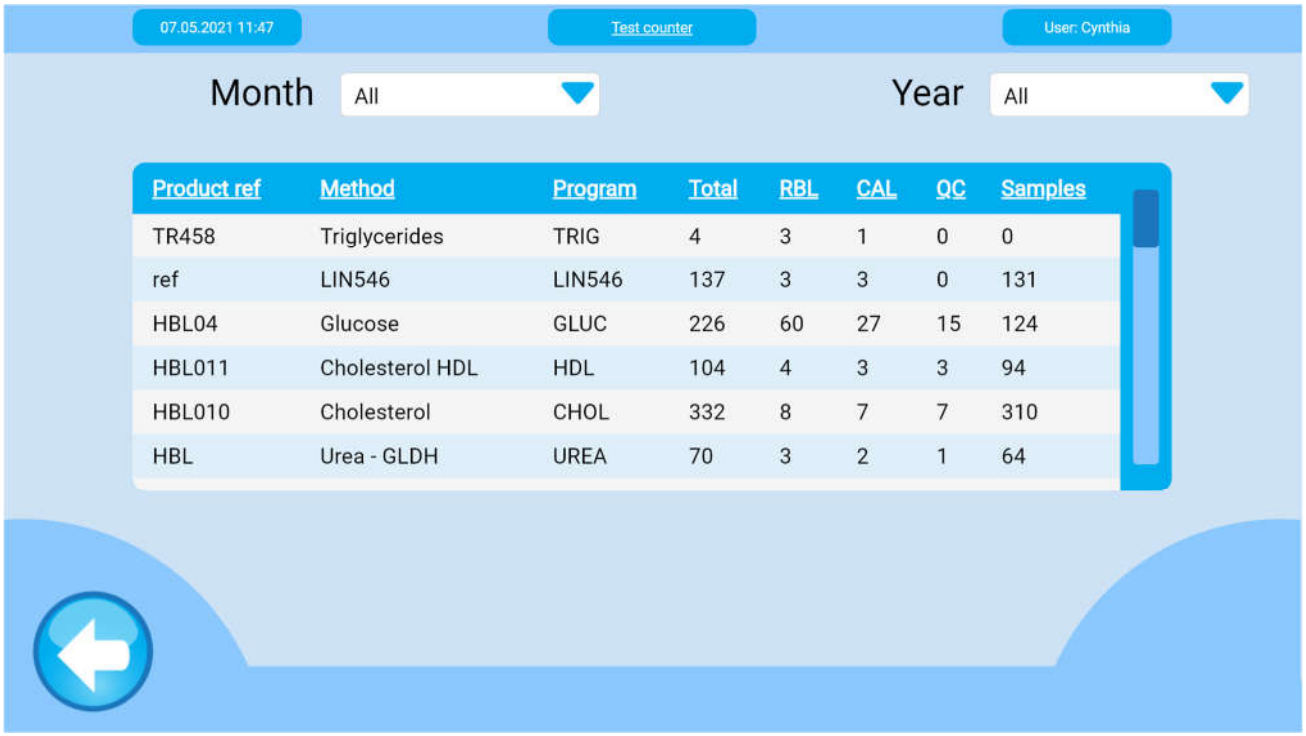
4.8.2 Test Counter

Select "About" and from the options listed, click "Test Counter". The displayed table provides information regarding all tests which were carried out, subdivided into groups (RBL, CAL, CTRL and Samples). It presents the sum of all the test performed in a specified date range. Press "Delete" to delete all entries.



4.8.3 Instrument

Select "About" and from the options listed, click "Instrument" to enter the instrument information menu.

Use the export diagnose button  to make a copy of the results and diagnostics information on an external data storage device (USB drive). Forward this information to your local distributor for support (see 4.8.1 for the contact information).

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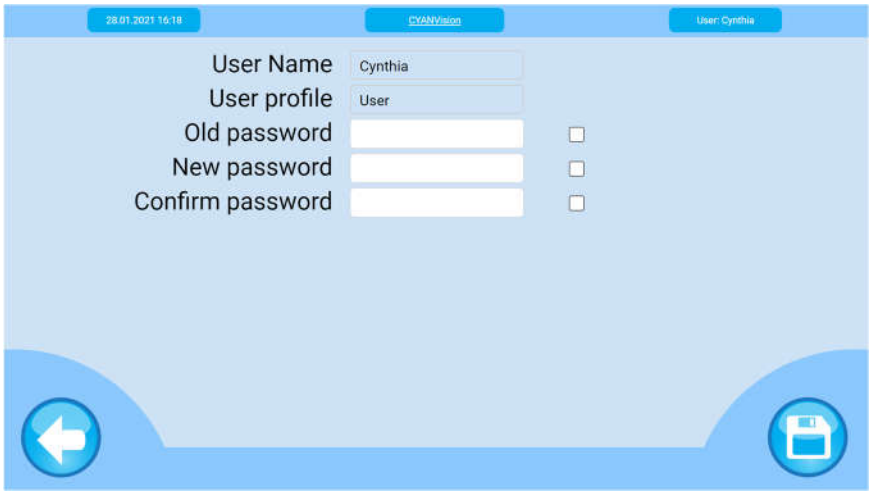
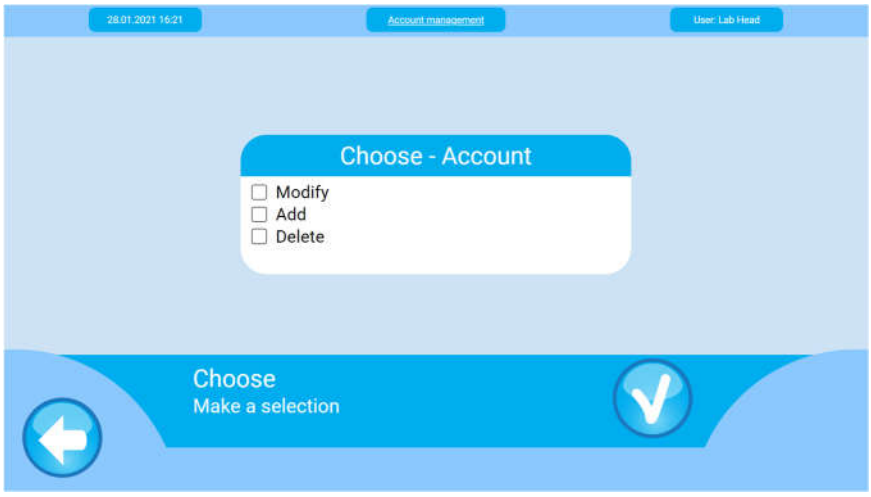
4.8.4 Account Management

It is possible to operate the instrument in a multi-user environment where different users can log in with their own password and have different access levels. As a laboratory user, you only have access to change your password. Enter your old password, followed by your new password and confirm the new one. Press "Save" to store the changes.



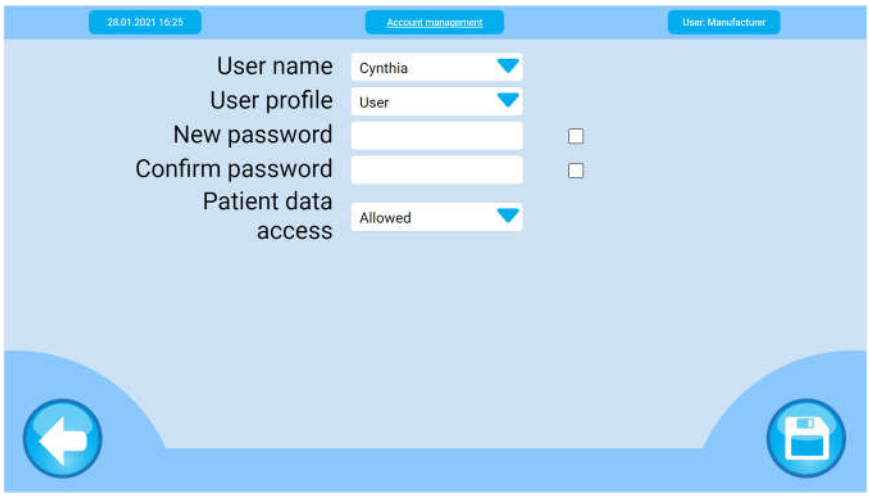
Only lab heads (with an account) and service engineer (your distributor) have full access to all menus.



To add new user accounts or change the login settings, please contact your distributor or lab head.

4.8.4.1 Modify an account

To view or edit any user's profile. When logged in as Lab Head or Service, you can view and edit all programmed user profiles. Click on any field to edit the information. Press "Save" to store the changes.



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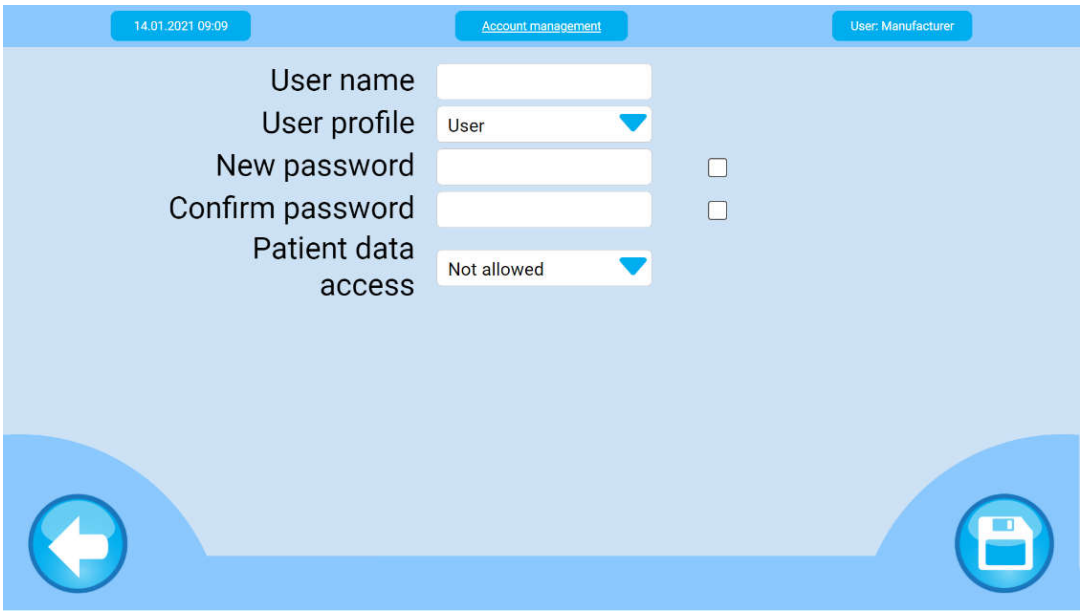
4.8.4.2 Add an account

Use this menu to add a new user.



Field or button	Function
User name	The name of the user. This field is mandatory.
User profile	Select the desired user type from the drop-down menu: user or lab head. • User: the basic user type has no access to the settings menu • The lab head has full access to all menus. **Note:** This field cannot be changed by a laboratory user. Only the lab head or service engineer can change this field.
New password	Enter a password. The user can always change his own password after login.
Confirm password	Enter the password a second time. If the password is not the same as in the above field, an error will be shown.
Patient access	To allow user-patient access. Patient access needs to be granted to create a user. If the user is not allowed to access the patient data, it is not possible to create an account for that specific user.
	Return, to return to the previous screen without saving changes.
	Save, to confirm and create a user profile with the programmed settings and to return to the previous menu.

4.8.4.3 Delete an account

To remove an existing user. Select the username to be deleted from the drop-down menu and confirm the action.

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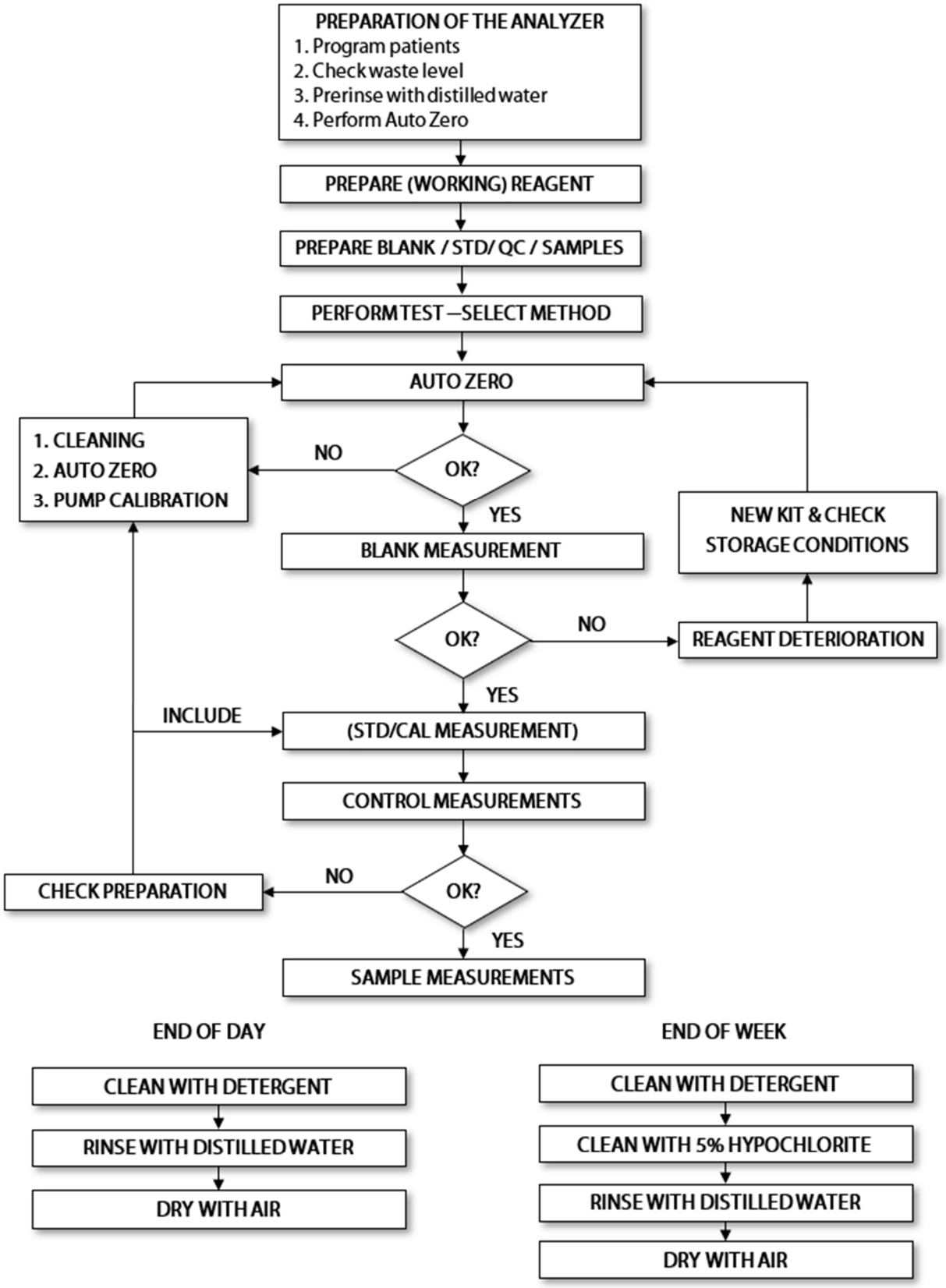
5 DAILY ROUTINE

The daily routine is made to help the operator know which tasks to perform on a daily basis and in what order. This will allow the best performance of the analyzer and produce the most accurate results.

5.1 DAILY ROUTINE SCHEME



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5.2 PREPARATIVE WORK

5.2.1 Preparation of the analyzer

1. Switch ON the CYANVision. After a short system initialization, the login screen is shown.
2. Enter the username and corresponding password to enter the main menu.
3. Wait around **5 minutes** to allow the instrument to reach the **optimal working temperature** before proceeding to the test measurements. In the meantime, you can perform the preparative work.
4. Check the liquid level of the waste container (empty if necessary).

Warning! Potential Biohazards. Carefully manipulate all the consumables and the waste produced during the analysis routines. Always wear appropriate protective equipment, such as chemically resistant rubber gloves and apron. Disposal of waste must be done in compliance with the locally applicable regulation. It is recommended to periodically/daily check the level in the waste container, in order to avoid overflow.

5. Perform a washing of the hydraulic tubes of the analyzer (see 7.2.1)

5.2.2 Perform an AD zero

An auto zero is performed to initialize the optical system. This measurement is always performed with distilled water.

Attention! When performing AD Auto Zero, make sure that:

- The flow cell is washed and sufficiently rinsed with distilled water.
- The flow cell is completely filled with distilled water and free of air bubbles (~ pump calibration).
- The obtained values are within the ranges.

Procedure:

1. Position distilled water under the aspiration inlet and press the "Aspirate" button in the software or push the aspiration button in front of the analyzer.
2. The distilled water will be aspirated in the flow cell and the instrument will perform the auto zero measurements.
3. After the measurement, the results will appear automatically. The full signal value should be higher than **50 000**.
    a. If the full signal is above 50 000, no error will be displayed. Press "Continue" to return to the main menu.
    b. If the full signal is below 50 000, the error "  " will be displayed behind the value. Press "Repeat" to restart the measurement. Do NOT continue measuring if the AD value is outside the acceptable range!

Attention! If after 2 reruns the value is still below the limit, perform the following actions:

- Rinsing with 15 mL distilled water (see 7.2.1).
- Cleaning with detergent and/or 5% hypochlorite (see 7.2.1).
- Pump calibration and verify that the flow cell is filled with distilled water and free of air bubbles (see 4.5.3)

5.2.3 Preparation of the reagent

For certain methods, it is necessary to prepare a working solution. Check the application sheets at the end of the user manual for specific requirements for each reagent. In case a new working reagent is prepared, press the "Reset" button during the measurement of the reagent blank (see 4.3.5)

5.2.4 Preparation of the samples

1. Prepare the blank as described in the application sheets.
2. Prepare the standard/calibrator and sample(s) as described in the application sheets.
3. Prepare the quality controls in the same way as the samples:
    a. Take the same amount of control serum as indicated for the sample.
    b. Respect the incubation times and use the same measuring procedure.

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5.3 INSERT PATIENT INFORMATION

1. Go to "Perform Test", press "Patient routine".
2. Click "Add" patient and insert the Patient information (see 4.3.1.1) press "Continue".
3. Select the requested analysis by checking the required profiles or programs, press "Continue".
4. Add a 2nd patient by clicking the "Add" button or press "Continue" to proceed to the program selection.

5.4 START SAMPLE ANALYSIS

1. Press "Continue" in the patient worklist or go to "Perform Test" and select "Quickstart", an overview of the required tests are displayed.
2. Select the test of your choice from the program list.
3. Follow the workflow as displayed on the screen and in the daily routine schematics: If the programmed temperature is not yet reached, "Device is tempered. Please wait" will appear when opening the method. Do NOT proceed if the temperature has not reached 37 °C!

5.4.1 Reagent kit information

1. Scan or manually insert the reagent kit information (Ref. Code, Lot number, Exp. Date, First use).
2. Press "Continue" to proceed to the Auto Zero.

5.4.2 Full signal value (Auto zero)

Before the measurements can start an auto zero is performed to initialize the optical system. This measurement is always performed with distilled water.

Note: Execution of the Auto Zero is required every 4 hours or after start-up/stand-by. If the previous Auto Zero is executed less than 4 hours ago it is possible to skip this step.

Procedure:

1. Position distilled water under the inlet pipe and press the "Aspirate" button in the software or push the aspiration button in front of the analyzer.
2. The distilled water will be aspirated in the flow cell and the instrument will perform the auto zero measurements.
3. After the measurements, the results will appear automatically. The full signal value should be higher than **50 000**.
   a. If the full signal is above 50 000, no error will be displayed. Press "Continue" to proceed with the blank measurement.
   b. If the full signal is below 50 000, the error "  " will be displayed behind the value. Press "Re-run" to repeat the measurement. Do NOT continue measuring if the AD value is outside the acceptable range!

Attention! If after 2 reruns the value is still below the limit, perform the following actions:

- Rinsing with 15 mL distilled water (see 7.2.1).
- Cleaning with detergent and/or 5% hypochlorite (see 7.2.1).
- Pump calibration and verify that the flow cell is filled with distilled water and free of air bubbles (see 4.5.3)
- If after several washing and cleaning procedures the values remain out of range, see chapter 8 troubleshooting guide.

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5.4.3 Blank measurement

The reagent blank (RBL) measurement is essential in the calculation of endpoint tests but will also provide an indication of the reagent deterioration or the cleanliness of the instrument.

Note: Execution of the Blank measurement is required:

- With a new lot of reagent,
- With a new working reagent,
- The first time the program is executed,
- When skipping the blank measurement is not allowed by the programming.

Procedure:

1. The first screen will show an overview of the historical RBL values with the upper and lower limit.
2. Select "Continue" to proceed with the blank measurement. It is strongly recommended to measure a new blank every time you perform a test.
3. Position the test tube containing the blank under the aspiration inlet and press the aspiration button.
4. The sample will be aspirated in the flow cell and the measurement is automatically started.
5. The Blank OD value should be between the range mentioned for "Limit low" and "Limit high".
   a. If the OD value is within range, press "Continue" to proceed to the next screen.
   b. If the OD value is NOT within range, the error "  "or "  " will be displayed behind the value. Press "Rerun" to repeat the measurement. Do NOT continue measuring if the OD value is outside the acceptable range!

Attention! If after the 2 reruns the value is still outside the acceptable range, perform the following checks:

→ **Water** as blank:
- Clean and then rinse the instrument abundantly with distilled water and restart the test.

→ **Reagent** as blank:
- Check (working) reagent preparation.
- The reagent is deteriorated, check storage conditions (expiration date and opening date), open new kit or vial and restart the test.

5.4.4 Standard/calibrator measurement

The standard or calibrator measurement is essential for the determination of the factor and thus in the calculation of all sample test results.

Note: Execution of a calibration is required:

- The first time you perform the test method,
- When using a new lot number of reagent or a new working solution,
- When QC measurement is out of range (see the following point),
- When skipping of the calibration measurement is not allowed by the programming.

Procedure:

1. Check the application sheets if a standard, calibrator or factor should be used. If Calibrator is selected select the lot number of the used calibrator. If the test allows a calibration by a factor, the software will not ask to measure a standard or calibrator and immediately proceed to the quality control (QC) measurements.
2. Position the test tube with the standard/calibrator preparation under the inlet pipe and press the aspiration button.
3. The measurement will start automatically after aspiration of the preparation in the flow cell. Afterwards, the new factor will be automatically calculated and stored in method programming.

Note:

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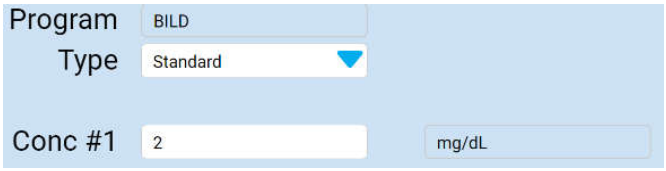
- In case the standard concentration is lot dependent and thus variable, it is allowed to change the concentration of the standard in the calibration menu.



- Some methods do not have a standard included in the kit. For these methods, a factor is pre-programmed. You can use this factor if the QC measurements are within range. However, for the most accurate results, it is recommended to use a calibrator (see application sheets) to calculate the factor. See 4.6.3.1 for instructions to add a new calibrator.

5.4.5 Quality control measurement

Performing quality control measurements is the only way to ensure that the results you obtain are accurate. If the QC measurements are within range, you can be sure the correct procedure is used (pipetting, storage, contamination ...), that the analyzer is clean and correctly functioning, that the reagent is not deteriorated and that the calibration is performed correctly. This will result in more accurate results, thereby less false negative and positive results and thus exclusion of false diagnosis. This will also eliminate the need to duplicate a test because you are not sure of the result. All advantages for the patient, laboratory and doctor. It is strongly recommended to perform a Quality Control (QC) by measuring **both normal control** and **pathological control** serum.

Note: QC measurements should be performed:

- When a new lot of reagent is used, or a new working reagent is used,
- When it is the first time the program is executed,
- Recommended **every time you perform that method or at least once a week.**

Procedure:

1. Check the application sheets to determine which control sera should be used. For the optimal guarantee of results, always measure **both normal control** and **pathological control** serum.
2. Select the available QC (if no QC is available, add a QC first, see 4.6.4), press "Continue".
3. Position the test tube with the QC preparation under the inlet pipe and press the aspiration button.
4. The preparation will be aspirated in the flow cell and the measurement will start.
5. Afterwards, check if the concentration is within the target control range.
   a. If the concentration is within range, press "Continue" to proceed to the next screen.
   b. If NOT within range, the error "  "or "  " will be displayed behind the value. Press "**Rerun**" to repeat the measurement. Do NOT continue measuring if the concentration is outside the acceptable range!

   Attention! If after the rerun the value is still outside the acceptable range, perform the following checks:
   - Preparation instructions (application sheets): stability, volumes, and times should be strictly followed.
   - Quality controls have a **lot dependent concentration**. Make sure the correct range is programmed in the QC values submenu (see 4.6.4)!
   - Rinsing 10 times with 15 mL distilled water (see 7.2.1).
   - Cleaning with detergent and/or hypochlorite (see 7.2.1).
   - Perform pump calibration and verify that the flow cell is completely filled with distilled water and free of air bubbles (see 4.5.3).
   - Restart the measurement and include a new calibration!
   - If after recalibration with the standard included in the kit, the QC measurements remain out of range, it is recommended to use a calibrator to perform a more accurate calibration (see application sheets).

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5.4.6 Sample measurement

If the AD value, blank and QC are OK, you can proceed with the sample measurements:

1. Select the patient samples and press "Continue".
2. If necessary, select the sample type and/or dilution ratio.
3. Position the test tube with the first sample preparation under the aspiration inlet and press the aspiration button.
4. The measurement will start automatically after the sample has been aspirated in the flow cell.
5. Press "Continue" to proceed with the next sample and proceed this way until all the samples are analyzed.

5.5 END OF TEST

1. Press the header to exit the test method and confirm.
2. Go to the "Maintenance Overview", select "Washing" and follow the required steps to rinse with 15mL distilled water.

5.6 EVALUATE THE RESULTS

1. The results (OD and concentration value) can be printed with a built-in thermal printer.
2. In the results menu, review the sample results that can be reviewed, edited (addition of reference), printed or deleted and a patient print report can be made.
3. The calibration and control results (and related statistics) are stored in a separate menus (Results → Quality Controls or Calibration).

5.6.1 Flags

The CYANVision has various ways to indicate something is abnormal about the measurements.

Parameter	Evaluation and flag	Which measurement?
Linearity_min or max	Concentration is lower "<" or higher ">" than specified	Calibration, QC and patient samples
Fit	Fit is lower than specified "*"	Calibration, QC and patient samples (only with **kinetic** tests)
Direction	Direction is not as specified "*"	Calibration, QC and patient samples (only with **2-point** and **kinetic** tests)
CV%	CV% higher than specified "+"	Blank or calibration with repeats
Absorbance	Absorbance (OD value) is lower "-" or higher "+" than specified	Only blank measurements
Concentration	Concentration is lower "-" or higher "+" than specified	QC and patient samples

5.7 SHUT DOWN - END OF THE DAY

1. Wash the instrument with a **detergent** (CYAN Washing Solution CY001-WS or 5% Tween 20).
    a. Select "Maintenance", "Overview" and from the options listed, click "Cleaning".
    b. Position the detergent solution under the inlet pipe and press "Aspirate".
    c. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
    d. Repeat this operation using 15 mL **distilled water** to rinse the system.
    e. Repeat this operation using **air** to dry the hydraulic system and avoid microbiological contamination.
2. Switch OFF the CYANVision.
3. Clean the external surface of the instrument, with a cloth and some detergent.

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5.8 WEEKLY VERIFICATIONS

1. Perform a pump calibration (Maintenance → Pump calibration) and make sure to:
   - Pipet exactly 3 mL of distilled water in each test tube.
   - Press and hold the aspiration button and release immediately after all the liquid has been aspirated.
   - Perform in triplicate (3 repetitions).
   - Obtain values between **3500 and 9000** and the difference between repetitions **< 1000**.
2. Disinfect the hydraulic system (tubes and flow cell) with **5% Hypochlorite (bleach)**.
   a. Go to "Maintenance", select "Overview", check "Disinfection" and press "Continue".
   b. Position the **detergent solution** under the inlet pipe and press "Aspirate".
   c. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
   d. Repeat this operation using 15 mL **distilled water.**
   e. Repeat this operation using **air** to make an air gap between the distilled water and the hypochlorite solution.
   f. Position **the hypochlorite solution** under the inlet pipe and press "Aspirate".
   g. Incubate the hypochlorite in the flow cell for about 10 minutes (no longer!).
   h. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
   i. Repeat this operation using 15mL **distilled water**.
   j. Repeat this operation using **air** to dry the hydraulic system.

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6 METHODS

6.1 INTRODUCTION

The three principal groups of analysis are:

1. Endpoint
2. 2-point (or fixed time)
3. Kinetic

Remark:

- In case the dilution factor is different from 1, the obtained concentration values for the samples are multiplied with the dilution factor.
- In case the results are displayed in another unit (display unit) then the program unit all concentration values (incl. standard & calibrator concentration) are multiplied with a unit conversion factor. This results in another concentration factor as the concentration factor is unit dependent.
- RBL: averaging of multiple executions is a possibility when a higher accuracy for the RBL needs to be obtained
- Multipoint calibration: multiple calibration measurements at different concentration levels are executed in case a multiple point calibration is requested. The used factor depends on the absorbance range.

6.2 INITIALIZATION

To obtain a correct absorbance value the digital signal (counts) received by the detector is compared to the digital signal (counts) received during the fast AD autozero.

$$Abs = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL,STD,CAL\ or\ Sample}}}\right)$$

6.3 ENDPOINT

For each "Endpoint" test the instrument carries out 1 reading. The analytical result is obtained using the Abs(T1) – RBL value. The RBL value is taken during the calibration phase and Abs(T1) is taken during the analysis phase. In "Endpoint" methodologies the absorbance of the sample itself can affect the analytical result, it is always necessary to evaluate the sample blank. This correction can be done by choosing one of the following according to the specific need:

1. Classical RBL measurement
2. Sample blank correction
3. Bi-chromatic correction

6.3.1 Classical RBL measurement

1) Reagent Blank

The reagent blank is measured – immediately after aspiration - at the beginning of every method calibration.

$$RBL = ABS_{RBL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL}}}\right)$$

2) Calibration

The calibration step is used to calculate the factor which is necessary to convert absorbance values into concentration values. The absorbance of the calibrator/standard – reagent mixture is measured immediately after aspiration.

- For single-point calibration:
  - Only one measurement ($Conc_{CAL}$, Abs_{CAL})

$$F = \frac{Con_{CAL}}{Abs_{CAL} - RBL}$$

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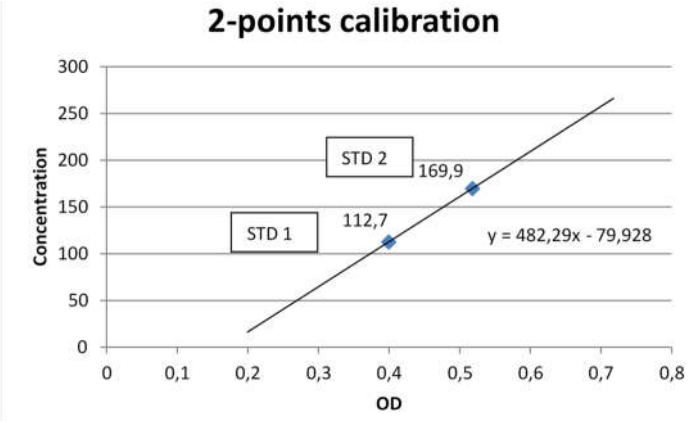
- For multipoint calibration:
  - Two calibrator measurements (C1, OD1) & (C2, OD2)
    - 2-points calibrator: linear fit
    - Independent if ODx below OD1, ODx between OD1 and OD2 or ODx above OD2, the calculation should be a linear fit following the next calculation:

$$Cx = \frac{C2 - C1}{OD2 - OD1} ODx + \frac{C1 * OD2 - C2 * OD1}{OD2 - OD1}$$

    - Example:

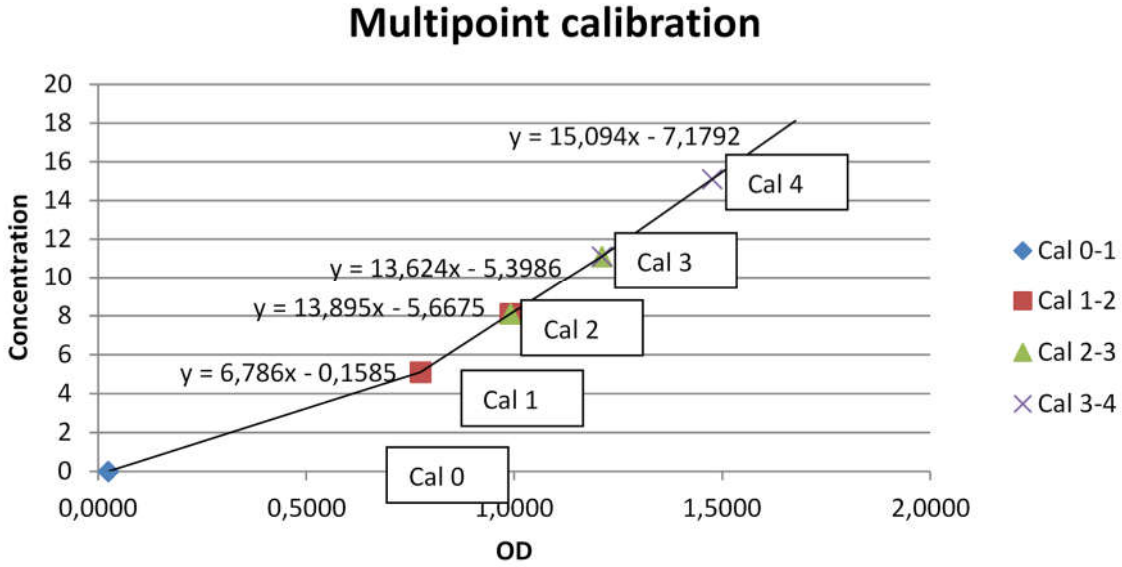


- 3- or more calibrator measurements (Cal 0 (C0, OD0), CAL1 (C1, OD1), CAL2 (C2, OD2), CAL3 (C3, OD3), …):
  - 3 or more point calibration: point-to-point fit
  - The concentration calculation of a sample depends on the absorbance measurement of the sample

$$C_x = C_{si-1} + (C_{si} - C_{si-1}) * \frac{A_x - A_{si-1}}{A_{si} - A_{si-1}}$$

Low OD range limit	High OD range limit	C_{si-1}	C_{si}	A_{si-1}	A_{si}	Note
0	OD0	0	C0	0	OD0	Flag the results
OD0	OD1	C0	C1	OD0	OD1	
OD1	OD2	C1	C2	OD1	OD2	
OD2	OD3	C2	C3	OD2	OD3	
OD3	OD4	C3	C4	OD3	OD4	
OD4	Infinity	C3	C4	OD3	OD4	Flag the results

    - Example :



Note:

- RBL subtraction (- RBL) is optional
- The factor is unit dependent (see remark Introduction 6.1)

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3) Samples

After the calibration step, QC samples or human samples are measured and compared to the target or reference range. The absorbance of the sample – reagent mixture is measured immediately after aspiration.

- For single-point calibration:

$$Analytical\ result\ = F * (\ Abs_{T1} - RBL)$$

- For multipoint calibration:
  - 2-point calibrator: see point 2
  - 3 point or more calibrator: see point 2

Note:

- RBL subtraction (- RBL) is optional
- The factor is unit dependent (see remark Introduction 6.1)

6.3.2 Sample blank correction

This type of methodological approach is used for the resolution of the problems posed by the "sample blank" and is always usable. Most importantly, this is decisively the most valid approach:
However, the operative disadvantages due to this type of methodology are the following:

1. You need to prepare two test tubes with a sample (more sample used)
2. You need to prepare two test tubes with reagent (more reagent use)
3. For the one result, you need to perform 2 measurements (decrease of max. workload)

1) Reagent blank

Besides the normal reagent blank (the mixture of your reagents you add to your sample) you also need a reagent blank of your sample blank. This is the absorbance of the reagent you add to your sample during the sample blank measurement.

➔ Reagent Blank Sample Blank = RBL_{Blank} (= reagent used for sample blank measurement)

$$RBL_{Blank} = ABS_{RBL_{Blank}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL_{Blank}}}}\right)$$

➔ Reagent Blank = RBL (= reagent used for sample measurement)

$$RBL = ABS_{RBL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL}}}\right)$$

2) Calibration

The calibration step is used to calculate the factor which is necessary to convert absorbance values into concentration values. The absorbance of the calibrator/standard (Abs_{Cal}) – reagent mixture is measured immediately after aspiration. Just before this measurement also the sample blank (Abs_{CAL_Blank}) is measured.

➔ Sample blank Calibration measurement

$$ABS_{CAL_{Blank}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CAL_{Blank}}}}\right)$$

➔ Calibration measurement

$$ABS_{CAL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CAL}}}\right)$$

$$F = \frac{Con_{CAL}}{(Abs_{CAL} - RBL) - VCF * \left(ABS_{CAL_{Blank}} - RBL_{Blank}\right)}$$

VCF = Volume correction factor. This factor is included in the method programming and is introduced to compensate for the dilution ratio introduced with the addition of the additional reagent.
VCF = Total volume during sample blank measurement / total volume during sample measurement.

Note:

- RBL subtraction (-RBL & - RBL_{Blank}) is optional
- The factor is unit dependent (see remark Introduction 6.1)

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- In case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by OD_x – $VCF*OD_{x, blank}$

3) Samples

After the calibration step, QC samples or human samples are measured and compared to the target or reference range. The absorbance of the sample – reagent mixture is measured immediately after aspiration (Abs_{Sample}), just before this measurement also the sample blank ($Abs_{SampleBlank}$) is measured.

➔ Sample blank measurement

$$ABS_{Sample_{Blank}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{Sample_{Blank}}}}\right)$$

➔ Sample measurement

$$ABS_{Sample} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{Sample}}}\right)$$

$$Analytical\ result\ = F * \left(\left(Abs_{Sample} - RBL\right) - VCF * \left(ABS_{Sample_{Blank}} - RBL_{Blank}\right)\right)$$

VCF = Volume correction factor. This factor is included in the method programming and is introduced to compensate for the dilution ratio introduced with the addition of the additional reagent. VCF = Total volume during sample blank measurement / total volume during sample measurement.

Note:

- RBL subtraction (-RBL & - RBL_{Blank}) is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by OD_x – $VCF*OD_{x, blank}$

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6.3.3 Bi-chromatic measurement

This type of methodology is applicable to the endpoint reactions, which require a reading of the "sample blank'. The correction on the matrix is not absolute, but relative.

The bichromatic method requires the following:

1. A secondary wavelength (filter 2) useful for the evaluation of the absorbance due only to the **biological liquid's properties** (turbidity, icteric, and hemolysis).
2. A bichromatic correction factor (see below).

Determination of the second filter:
As the absorbance spectrum of the interfering substance varies (turbidity, icteric or hemolysis), the best choice of the second wavelength will vary in function of the interfering substance that has to correct.

The secondary filter choice is made with the following criteria:

1. A significant indication of the interfering absorbance to be taken into consideration
2. Minimum evaluation in terms of chromogenic absorbance

The choice can be made by the observation of the absorbance spectrum of the chromogen of the interfering substances, using a scansion spectrophotometer. If it is not possible to use a spectrophotometer, an alternative can be found by coupling the following historical indications:

Reaction type	Interference	F1	F2
NADH dependent reactions	Turbidity	340	380
405 nm + Chromogen Paranitrophenol, Paranitroaniline	Icteric	405	492 (460/500)
Trinder	Hemolysis	510	578 (560/580)
All reactions	Turbidity	see note (*)	620 (600/700)

* One of the 8 available wavelengths, depending on the reaction type.

Determination of the bichromatic correction factor:
It is provided with the method programming. By default, 1, needs to be determined on a large number of different matrices (30):

1) AD Autozero

To receive a correct absorbance value the digital signal (counts) received by the detector is compared to the digital signal (counts) received during the fast Auto Zero. As in a bi-chromatic measurement absorbance measurements on two different wavelengths are performed you need to perform initialization on those two wavelengths.

➔ Filter 1: $AD_{Value_{Autozero_{F1}}}$

➔ Filter 2: $AD_{Value_{Autozero_{F2}}}$

2) Reagent blank:

➔ Filter 1:

$$RBL_{F1} = ABS_{RBL_{F1}} = Log10\left(\frac{AD_{Value_{Autozero_{F1}}}}{AD_{value_{RBL_{F1}}}}\right)$$

➔ Filter 2:

$$RBL_{F2} = ABS_{RBL_{F2}} = Log10\left(\frac{AD_{Value_{Autozero_{F2}}}}{AD_{value_{RBL_{F2}}}}\right)$$

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3) Calibration

The calibration step is used to calculate the factor which is necessary to convert absorbance values into concentration values. The absorbance of the calibrator/standard – reagent mixture is measured immediately after aspiration.

➔ Filter 1:

$$ABS_{CAL_{F1}} = Log10\left(\frac{AD_{Value_{Autozero_{F1}}}}{AD_{value_{F1}}}\right)$$

➔ Filter 2:

$$ABS_{CAL_{F2}} = Log10\left(\frac{AD_{Value_{Autozero_{F2}}}}{AD_{value_{F2}}}\right)$$

$$F = \frac{Con_{CAL}}{\left(Abs_{CAL_{F1}} - RBL_{F1}\right) - \left(Bic.Fact.x\left(ABS_{CAL_{F2}} - RBL_{F2}\right)\right)}$$

Note:

- RBL subtraction (-RBL_{F1} & - RBL_{F2}) is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In the case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by (ODx, $_{F1}$ – RBL_{F1}) – Bic. Fact *($OD_{x,F2}$ – RBL_{F2})

4) Samples

After the calibration step, QC samples or human samples are measured and compared to the target or reference range. The absorbance of the sample – reagent mixture is measured immediately after aspiration.

➔ Filter 1:

$$ABS_{F1} = Log10\left(\frac{AD_{Value_{Autozero_{F1}}}}{AD_{value_{F1}}}\right)$$

➔ Filter 2 :

$$ABS_{F2} = Log10\left(\frac{AD_{Value_{Autozero_{F2}}}}{AD_{value_{F2}}}\right)$$

$$Analytical\ result\ = F\ x\ \left(\left(Abs_{F1} - RBL_{F1}\right) - \left(Bic.Fact.x\ \left(ABS_{F2} - RBL_{F2}\right)\right)\right)$$

Note:

- RBL subtraction (-RBL_{F1} & - RBL_{F2}) is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In the case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by (ODx, $_{F1}$ – RBL_{F1}) – Bic. Fact *($OD_{x,F2}$ – RBL_{F2})

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6.4 2 – POINT (OR FIXED TIME)

This methodology type does not need any correction referring to the possible interference due to the sample (matrix), since the results are calculated with variations of absorbance (ΔAbs), and not with absolute values of absorbance.

1) Reagent Blank

The reagent blank is measured – immediately after aspiration - at the beginning of every method calibration. The RBL value is used to evaluate if the reagent is ready for use, but it is not used in the reagent calculation.

$$ABS_{RBL_{T1}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL_{T1}}}}\right)$$

$$RBL = ABS_{RBL_{T2}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL_{T2}}}}\right)$$

During the RBL measurement the mobility of the reagent is monitored and calculated, the RGT-rate. This can be used in the calculation of the calibration factor and sample concentration.

$$RGTR = ABS_{RBL_{T2}} - ABS_{RBL_{T1}}$$

2) Calibration

The calibration step is used to calculate the factor which is necessary to convert absorbance values into concentration values. The absorbance of the calibrator/standard – reagent mixture is measured immediately after aspiration.

$$F = \frac{Con_{CAL}}{\left(Abs_{CAL_{T2}} - ABS_{CAL_{T1}}\right) \pm RGTR}$$

Note:

- RGT Rate correction is negative or positive according to the direction of the reaction, respectively upwards or downwards.
- RGTR subtraction is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by ($OD_{x,T2}$ - $OD_{x,T1}$) ± RGTR

3) Samples

After the calibration step, QC samples or human samples are measured and compared to the target or reference range. The absorbance of the sample – reagent mixture is measured immediately after aspiration.

$$Analytical\ result\ = F * \left(\left(Abs_{Sample_{T2}} - ABS_{Sample_{T1}}\right) \pm RGTR\right)$$

Note:

- RGT Rate correction is negative or positive according to the direction of the reaction, respectively upwards or downwards.
- RGTR subtraction is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by ($OD_{x,T2}$ - $OD_{x,T1}$) ± RGTR

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6.5 KINETIC

This methodology type is used to determine enzyme activity. It does not need any correction to possible sample (matrix) interference, since the results are calculated with variations of absorbance per minutes (ΔAbs x min), and not with absolute absorbance values.

1) Reagent Blank

The reagent blank is measured at the beginning of every method calibration. The RBL value of the reagent at the end of the measurement cycle is used to evaluate if the reagent is ready for use, but it is not used in the reagent calculation.

$$RBL = ABS_{RBL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL_{Last\ measurement}}}}\right)$$

During the RBL measurement the mobility of the reagent is monitored and calculated, the RGT-rate. This is used in the calculation of the calibration factor and sample concentration.

$$RGTR = \frac{\triangle\ Abs_{Reagent}}{\Delta min} = slope_{reagent}$$

2) Calibration

The calibration step is used to calculate the factor which is necessary to convert absorbance values into concentration values. The absorbance of the calibrator/standard – reagent mixture is measured immediately after aspiration.

$$F = \frac{Con_{CAL}}{\left(\triangle\ Abs\frac{CAL}{min} \pm RGTR\right)}$$

Note:

- RGT Rate correction is negative or positive according to the direction of the reaction, respectively upwards or downwards.
- RGTR subtraction is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In the case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by (△Abs CAL/min ± RGTR

3) Samples

After the calibration step, QC samples or human samples are measured and compared to the target or reference range. The absorbance of the sample – reagent mixture is measured immediately after aspiration.

$$Analytical\ result\ = F * \left(\triangle\ Abs\frac{CAL}{min} \pm RGTR\right)$$

Note:

- RGT Rate correction is negative or positive according to the direction of the reaction, respectively upwards or downwards.
- RGTR subtraction is optional
- The factor is unit dependent (see remark Introduction 6.1)
- In the case of multipoint calibration: see point 6.3.1 – Multipoint calibration with OD_x replaced by (△Abs CAL/min ± RGTR

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6.6 EXAMPLES

Example 1: Endpoint with reagent blank

1) Aspiration of water
2) Reading of AD value count (AD Value autozero)

RBL:

3) Aspiration of reagent
4) Immediately reading of AD value count (AD Value RBL)
5) Calculation of Abs_RBL

$$RBL = ABS_{RBL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL}}}\right)$$

Calibration:

6) Aspiration of calibrator – reagent mixture
7) Immediately reading of AD value count (AD Value CAL)
8) Calculation of Abs_CAL & Factor

$$ABS_{CAL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CAL}}}\right)$$

$$F = \frac{Con_{CAL}}{Abs_{CAL} - RBL}$$

QC/Sample:

9) Aspiration of the sample – reagent mixture
10) Immediate reading of AD value count
11) Calculation of analytical result in concentration

$$Analytical\ result\ = F * (\ Abs_{T1} - RBL)$$

Example 2: Endpoint with sample blank

1) Aspiration of water
2) Reading of AD value count (AD Value autozero)

RBL:

3) Aspiration of blank reagent. The reagent used during the sample blank measurement.
4) Immediately reading of AD value count (AD Value RBL Blank)
5) Calculation of Abs_RBL_Blank

$$RBL_{Blank} = ABS_{RBL_{Blank}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL_{Blank}}}}\right)$$

6) Aspiration of reagent
7) Immediately reading of AD value count (AD Value RBL)
8) Calculation of Abs_RBL

$$RBL = ABS_{RBL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL}}}\right)$$

Calibration:

9) Aspiration of calibrator – sample blank reagent
10) Immediately reading of AD value count (AD Value CAL_Blank)
11) Calculation of Abs_CAL_Blank

$$ABS_{CAL_{Blank}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CAL_{Blank}}}}\right)$$

12) Aspiration of calibrator – reagent mixture
13) Immediately reading of AD Value count (AD Value CAL)
14) Calculation of Abs_CAL

$$ABS_{CAL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CAL}}}\right)$$

15) Calculation of factor

$$F = \frac{Con_{CAL}}{(Abs_{CAL} - RBL) - VCF * (ABS_{CAL_{Blank}} - RBL_{Blank})}$$

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QC & Samples:

16) Aspiration of sample – reagent blank mixture
17) Immediate reading of AD Value count (AD Value Sample_Blank)
18) Calculation of Abs_Sample_Blank

$$ABS_{Sample_{Blank}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{Sample_{Blank}}}}\right)$$

19) Aspiration of the sample – reagent mixture
20) Immediately reading of AD Value count (AD Value Sample)
21) Calculation of Abs_Sample

$$ABS_{Sample} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{Sample}}}\right)$$

22) Calculation of analytical result in concentration

$$Analytical\ result\ = F * \left(\left(Abs_{Sample} - RBL\right) - VCF * \left(ABS_{Sample_{Blank}} - RBL_{Blank}\right)\right)$$

Example 3: Endpoint with Bichromatic correction

1) Aspiration of water
2) Reading of AD value count (AD Value autozero) at F1

$$AD_{Value_{Autozero_{F1}}}$$

3) Reading of AD value count (AD Value autozero) at F2

$$AD_{Value_{Autozero_{F2}}}$$

RBL:

4) Aspiration of blank reagent. The reagent used during the sample blank measurement.
5) Immediately reading of AD value count (AD Value RBL Blank) at F1
6) Calculation of RBL at F1

$$RBL_{F1} = ABS_{RBL_{F1}} = Log10\left(\frac{AD_{Value_{Autozero_{F1}}}}{AD_{value_{RBL_{F1}}}}\right)$$

7) Immediately reading of AD value count (AD value RBL Blank) at F2
8) Calculation of RBL at F2

$$RBL_{F2} = ABS_{RBL_{F2}} = Log10\left(\frac{AD_{Value_{Autozero_{F2}}}}{AD_{value_{RBL_{F2}}}}\right)$$

Calibration:

9) Aspiration of calibrator – sample blank reagent
10) Immediately reading of AD value count (AD Value CAL_F1) at F1
11) Calculation of Abs_CAL_F1

$$ABS_{CAL_{F1}} = Log10\left(\frac{AD_{Value_{Autozero_{F1}}}}{AD_{value_{F1}}}\right)$$

12) Immediately reading of AD value count (AD Value CAL_F2) at F2
13) Calculation of Abs_CAL_F2

$$ABS_{CAL_{F2}} = Log10\left(\frac{AD_{Value_{Autozero_{F2}}}}{AD_{value_{F2}}}\right)$$

14) Calculation of factor

$$F = \frac{Con_{CAL}}{\left(Abs_{CAL_{F1}} - RBL_{F1}\right) - \left(Bic.Fact.x\left(ABS_{CAL_{F2}} - RBL_{F2}\right)\right)}$$

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QC & Samples:

15) Aspiration of the sample – reagent mixture
16) Immediate reading of AD Value count (AD Value Sample_F1) at F1
17) Calculation of Abs_Sample_F1

$$ABS_{F1} = Log10\left(\frac{AD_{Value_{Autozero_{F1}}}}{AD_{value_{F1}}}\right)$$

18) Immediately reading of AD Value count (AD Value Sample_F2) at F2
19) Calculation of Abs_Sample_F2

$$ABS_{F2} = Log10\left(\frac{AD_{Value_{Autozero_{F2}}}}{AD_{value_{F2}}}\right)$$

20) Calculation of analytical result in concentration

$$Analytical\ result\ = F\ x\ \left((Abs_{F1} - RBL_{F1}) - \left(Bic.Fact.x\ (ABS_{F1} - RBL_{F2})\right)\right)$$

Example 4: two-point (Fixed time)

1) Aspiration of water
2) Reading of AD value count (AD Value autozero)

RBL:

3) Aspiration of reagent
4) Reading of AD value count (AD Value RBL_T1)

$$ABS_{RBL_{T1}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL\_T1}}}\right)$$

5) Incubation time is executed. The reagent remains in the flowcell
6) A second reading of the AD value count is performed (AD Value RBL_T2)

$$RBL = ABS_{RBL_{T2}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{RBL\_T2}}}\right)$$

7) Calculation of the RGT rate:

$$RGTR = ABS_{RBL_{T2}} - ABS_{RBL_{T1}}$$

Calibration:

8) Aspiration of calibrator – reagent mixture
9) Reading of AD value count (AD Value CAL_T1)
10) Calculation of ABS_CAL_T1:

$$ABS_{CAL_{T1}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CALT1}}}\right)$$

11) Incubation time is executed. The reagent-CAL remains in the flowcell
12) A second reading of the AD value count is performed (AD Value CAL_T2)

$$ABS_{CAL_{T2}} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{CALT2}}}\right)$$

13) Calculation of the factor

$$F = \frac{Con_{CAL}}{\left(Abs_{CAL_{T2}} - Abs_{CAL_{T1}}\right) \pm RGTR}$$

QC/Sample:

14) Aspiration of the sample – reagent mixture
15) Immediate reading of AD value count
16) Calculation of analytical result in concentration

$$Analytical\ result\ = F * \left(\left(Abs_{Sample_{T2}} - ABS_{Sample_{T1}}\right) \pm RGTR\right)$$

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Example 5: Kinetic test

1) Aspiration of water
2) Reading of AD value count (AD Value autozero)

RBL:

3) Aspiration of reagent
4) Incubation time is executed. The reagent remains in the flowcell
5) A continuous reading of the AD value count is performed (Multiple AD Value's)
6) Calculation of ABS_RBL

$$RBL = ABS_{RBL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{value_{Last\ AD\ measurement}}}\right)$$

7) Calculation of the RGT rate:

$$RGTR = \frac{\triangle\ Abs_{reagent}}{\Delta min} = slope_{reagent}$$

Calibration:

8) Aspiration of calibrator – reagent mixture
9) Reading of AD value count (AD Value CAL) over time
10) Calculation of ABS:

$$ABS_{CAL} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{Value_{CAL}}}\right)$$

$$\frac{\triangle\ Abs_{reagent}}{\Delta min}$$

11) Calculation of the factor

$$F = \frac{Conc_{CAL}}{\left(\frac{\triangle\ Abs_{CAL}}{\Delta min} \pm RGTR\right)}$$

QC/Sample:

12) Aspiration of the sample – reagent mixture
13) Immediate reading of AD value count over time
14) Calculation of ABS

$$ABS_{Sample} = Log10\left(\frac{AD_{Value_{Autozero}}}{AD_{Value_{Sample}}}\right)$$

$$\frac{\triangle\ Abs_{reagent}}{\Delta min}$$

15) Calculation of analytical result in concentration

$$Analytical\ result\ = F * \left(\frac{\triangle\ Abs_{reagent}}{\Delta min} \pm RGTR\right)$$

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7 MAINTENANCE

This chapter contains all routine operations concerning instrument maintenance. The procedures, listed and described below, should be carefully followed in order to guarantee the manufacturers quality specifications and the perfect working conditions of the instrument over time.

The CYANVision requires three levels of maintenance:

- **Punctual** maintenance: at special moments such as at installation.
- **Routine** maintenance: to maintain the level of precision day in day out.
- **Special** maintenance: replacement of specific parts.

Please consult the maintenance form for an overview of the different maintenance actions. In case of repair, please register all undertaken actions in the repair form to keep track of the interventions.

Caution: Spare Parts. Only approved spare parts should be used for maintenance. The use of unapproved spare parts and accessories may result in a loss of warranty and potentially impair instrument performance or cause damage to the instrument.

7.1 PUNCTUAL MAINTENANCE

The punctual maintenance should be effectuated at installation, before or after a long period of duty.
The following points of attention should be considered:

- Check the installation instructions.
- Check all tubes visually for leaking or squashing. Pay special attention to the pump tube. Replace if necessary.
- Washing the flow cell with a **detergent** (CYAN Wash Solution CY001-WS or 5% Tween 20) and rinse the flow cell with distilled water.
- Disinfect the flow cell with **5% Hypochlorite solution** and rinse the flow cell with distilled water.
- Check the pump calibration.
- Check the AD auto zero.
- In case the instrument will not be used for a long period:
  - Remove all liquid inside the instrument by aspirating air.
  - Disconnect the pump cassette from the pump motor by pressing the clips on the side.
    This will avoid deformation of the pump tubes.

7.2 ROUTINE MAINTENANCE

Frequency	What	Cleaning solution
Between methods	Washing	Distilled water
End of the day	Internal cleaning	Detergent + rinse with distilled water + dry with air
	External surface cleaning	Detergent
Every week	Disinfection	Detergent + sodium hypochlorite (diluted 5%) + rinse with distilled water + dry with air
Every morning	Verification	Auto Zero
Every week		Pump calibration

7.2.1 Washing

1. Rinsing (between tests)

It is not necessary to rinse the instrument **between different samples** for the same method. However:

- In case of the high risk of cross-over, you could pre-rinse the flowcell by aspirating distilled water, followed by air (to avoid dilution) between the samples.

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- In case of a strongly colored reagent, it might be necessary to pre-rinse the flowcell with (working) reagent before aspirating the first measurement. Otherwise, the first measurement could be influenced by the distilled water used to zero the instrument.

2. Washing (between methods)

Between methods, always rinse the flow cell with distilled water, to avoid contamination problems.

a. Select "Maintenance", "Overview" and from the options listed, click "Washing".
b. Position the **distilled water** under the inlet pipe and press "Aspirate".
c. Repeat this operation using **air** to dry the hydraulic system to dry the system.

3. Daily internal cleaning

At the end of each working day, wash the instrument with a neutral **detergent** (CYAN Washing Solution CY001-WS or 5% Tween 20):

a. Select "Maintenance", "Overview" and from the options listed, click "Cleaning".
b. Position the detergent solution under the inlet pipe and press "Aspirate".
c. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
d. Repeat this operation using 15mL of **distilled water** to rinse the system.
e. Repeat this operation using **air** to dry the hydraulic system and avoid microbiological contamination.
f. Clean the external surface of the instrument, with a tissue and detergent.

4. Weekly disinfection

After a week of work disinfect the hydraulic system (tubes and flowcell) with **5% Hypochlorite (bleach)**.

a. Select "Maintenance", "Overview" and from the options listed, click "Disinfection".
b. Position the **detergent solution** under the inlet pipe and press "Aspirate".
c. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
d. Repeat this operation using 15 mL **distilled water.**
e. Repeat this operation using **air** to make an air gap between the distilled water and the hypochlorite solution.
f. Position **the hypochlorite solution** under the inlet pipe and press "Aspirate".
g. Incubate the hypochlorite in the flowcell for about 10 minutes (no longer!).
h. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
i. Repeat this operation using 15mL **distilled water**.
j. Repeat this operation using **air** to dry the hydraulic system.

Note:

- In case of air bubbles (visible during Auto Zero or perform the test) rinse with diluted sodium hypochlorite (5 to 10%), then rinse with plenty of distilled water, followed by a few washing cycles with air.
- This diluted sodium hypochlorite is on the market available. Please use only good trademarks. Cheap ones contain contaminating solutions.
- **Always dilute the sodium hypochlorite for 5 to 10%, never use it undiluted! This will damage the instrument.**
- **Do not use corrosive detergents to wash the instrument.**

7.2.2 External surface cleaning

Please notice that the instrument, especially the optical system and the electrical circuit, is sensitive to dust. Avoid using the instrument in dusty spaces. Keep the printer and flow cell cover closed during use.
At the end of each working session, dampen a tissue with a non-abrasive detergent and wipe the outside of the instrument.

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7.2.3 Verifications

1. Daily

Perform an Auto zero measurement (see 4.5.2).

2. Weekly

Perform a pump calibration (see 4.5.3).

7.3 REPLACEMENT OF SPECIFIC PARTS

Any laboratory instrument that has been used for research or clinical analysis is considered a biohazard and requires decontamination prior to handling. Decontamination minimizes the risk to all who come into contact with the instrument during shipping, handling, and servicing. Persons performing the decontamination process must be familiar with the basic setup and operation of the instrument.

	Cypress Diagnostics recommends the use of the following decontamination solutions and methods based on our knowledge of the instrument and recommendations of the WHO (World Healthcare Organization). Neither Cypress Diagnostics nor the WHO assumes any liability for the adequacy of these solutions and methods. Each laboratory must ensure that decontamination procedures are adequate for the Biohazard(s) they handle.
	Wear prophylactic gloves when handling contaminated instruments. Gloved hands should be considered contaminated at all times; keep gloved hands away from eyes, mouth, nose, and ears. Eating and drinking while decontaminating instruments is not advised. Mucous membranes are considered prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosol contamination. Intact skin is generally considered an effective barrier against infectious organisms; however, small abrasions and cuts may not always be visible. Wear protective gloves when performing the decontamination procedure. The bleach solution is caustic; wear gloves and eye protection when handling the solution.

7.3.1 External surface cleaning

Use an antibacterial and antiviral detergent.

Procedure:

1. Spray the solution all over the instrument.
2. Allow the solution to stand for approximately 30 minutes.
3. Wipe the solution off the instrument using a tissue dampened with distilled water.

7.3.2 Internal washing

First wash with 15 mL detergent and then disinfect the hydraulic system (tubes and flow cell) with **5% Hypochlorite (bleach)**.

Procedure:

1. Select "Maintenance", "Overview" and from the options listed, click "Disinfection".
2. Position the **detergent solution** under the aspiration inlet and press "Aspirate".
3. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
4. Repeat this operation using 15 mL **distilled water.**
5. Repeat this operation using **air** to make an air gap between the distilled water and the hypochlorite solution.
6. Position **the hypochlorite solution** under the aspiration inlet and press "Aspirate".
7. Incubate the hypochlorite in the flow cell for about 10 minutes (no longer!).
8. Repeat this operation using **air** to make an air gap between the detergent and the distilled water, press "Aspirate".
9. Repeat this operation using 15mL **distilled water**.
10. Repeat this operation using **air** to dry the hydraulic system.

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7.3.3 Replacement schedule

Some spare parts should be replaced after a fixed period of time to ensure the good performance of the analyzer. Please check the table below:

Frequency	Action	Executor
6 months	Replace peristaltic pump cassette	Service Engineer
1 year (or in case of leaking, obstruction, discoloration)	Replace all tubing of the hydraulic system	Service Engineer
3 years	Replace pump tube connectors	Service Engineer

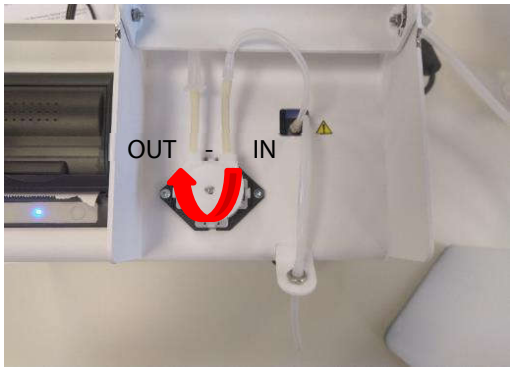
7.3.4 Replacement of peristaltic pump cassette

Every 6 months, the peristaltic pump cassette (CY014-S08) needs to be replaced. This action can be performed by lab users or the service engineer.

Procedure:

1. Aspirate air to make sure all tubes are dry and will not leak upon disconnection.
2. Turn OFF the CYANVision analyzer.
4. Lift the cover above the hydraulic circuit.
5. To change the pump cassette, remove it from the peristaltic pump rotor by pressing the two clips on the side of the rotor.

6. Disconnect the pump tube from the 2 connectors (one attached to the waste tube and one attached to the tube from the flow cell to the pump tube) by gently pulling them out.
7. Re-attach the connector with waste tube and the connector with tube from flow cell in the correct direction. The tube coming from the flow cell need to be connected to the right pump cassette tube and the tube going to the waste on the left pump cassette tube. **The tubings may not cross!**



8. Place the new peristaltic pump motor back on the peristaltic pump motor. Make sure it is completely clicked on.
9. Turn ON the CYANVision analyzer and log in.
10. Select “Maintenance” and from the options listed, click “Overview”. Select the “Replacement of pump cassette (6 months)”, press “Next” and press “Confirm”. The maintenance action is registered.

Attention!

- Make sure the pump tube connectors are completely inserted into the new pump tube.
- After replacing any part of the hydraulic circuit, you must **recalibrate the peristaltic pump aspiration** volume! Select “Maintenance” and from the options listed, click “Pump Calibration”.

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8 TROUBLESHOOTING & ERRORS

8.1 OPERATIONAL

Trouble	Diagnosing and solution:
Auto zero out of range for all filters	**Check if:** - The flow cell is in the correct direction (windows to front and back). - The flow cell is completely inserted to the bottom of the flow cell holder. - The optical cover is closed during measurement. - The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water. ➔ Perform washing and rinsing (see 7.2). - The windows of the flow cell are clean (no dirt/fingerprints on the outside). ➔ Clean with wipes for glasses. - The flow cell is filled with distilled water and without any air bubbles. ➔ Verify the pump calibration and the absence of leakages, cracks in tubes & flow cell. If after these verifications, the problems remain, please contact a service engineer.
Auto zero out of range for one or few filters	**Check if:** - The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water. ➔ Perform washing and rinsing (see 7.2). - The windows of the flow cell are clean (no dirt/fingerprints on the outside). ➔ Clean with wipes for glasses. - Verify the 2 points above even more thorough if (only) the 340 nm filter is out of range because this filter is the most sensitive to dirt are insufficient rinsing. - The flow cell is filled with distilled water and without any air bubbles. ➔ Verify the pump calibration and the absence of leakages, cracks in tubes & flow cell. If after these verifications, the problems remain, please contact a service engineer.
OD values are near zero	**Check if:** - The flow cell is in the correct direction (windows to front and back). - The flow cell is completely inserted to the bottom of the flow cell holder. - The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water. ➔ Perform washing and rinsing (see 7.2). - The windows of the flow cell are clean (no dirt/fingerprints on the outside). ➔ Clean with wipes for glasses. - The flow cell is filled with distilled water and without any air bubbles. ➔ Verify the pump calibration and the absence of leakages, cracks in tubes & flow cell. - The reagents are deteriorated (reagent blank values out of range). - Preparation of the (working reagent) and the samples. - The method has been programmed correctly. If after these verifications, the problems remain, please contact a service engineer.
The concentrations are zero	**Check if:** - The OD values are (near) zero. ➔ See the point above. - Restart the measurement and include a (new) calibration! ➔ The first time you perform a method, it is essential that you perform a calibration, so the instrument can determine the factor for the calculation of the concentration. ➔ Check the application sheets if a standard, calibrator or factor should be used. Some standard and (almost) all calibrators have a **lot dependent concentration**! Make sure the correct concentration is programmed in the methods!

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Blank is out of range	**Check if:** - The method programming is consistent with the latest application sheets: distilled water or reagent, the number of blank measurements and the blank limits. - The flow cell is filled with distilled water and without any air bubbles. ➔ Verify the pump calibration and the absence of leakages, cracks in tubes & flow cell. - Blank is distilled water. ➔ Perform washing and rinsing (see 7.2) then restart the test. - Blank is reagent. ➔ Verify the preparation of the (working) reagent. ➔ The reagent is deteriorated, check storage conditions (expiration date and opening date), open new kit or vial and restart the test. If after these verifications, the problems remain, please contact a service engineer.
QC is out of range or bad accuracy of results	**Check if:** - The reagent is deteriorated, check storage conditions (expiration date and opening date) ➔ Open a new kit or vial. - The preparation instructions of the (working reagent), blank, (standard) and the controls have been followed strictly: stability, volumes, times (application sheets). - The method programming is consistent with the latest application sheets. Quality controls have a **lot dependent concentration**! Make sure the correct range is programmed in the methods! - The flow cell is filled with distilled water and without any air bubbles. ➔ Verify the pump calibration and the absence of leakages, cracks in tubes & flow cell. - Restart the measurement and include a new calibration! • Check the application sheets if a standard, calibrator or factor should be used. • Some standard and (almost) all calibrators have a **lot dependent concentration**! Make sure the correct concentration is programmed in the programs! • Some methods do not have a standard included in the kit. For these methods, a factor is pre-programmed. You can use this factor if the QC measurements are within range. However, for the most accurate results, it is recommended to use a calibrator (see application sheets) to calculate the factor. If after these verifications, the problems remain, please contact a service engineer.
Bad repeatability of results	**Check if:** - No power problem (see below). - The optical cover is closed during measurement. - The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water. ➔ Perform washing and rinsing (see 7.2). - The flow cell is filled with distilled water and without any air bubbles. ➔ Verify the pump calibration and the absence of leakages. - The reagents are not deteriorated. - The pipette for manual handling has been correctly calibrated and the tips are compatible. If after these verifications, the problems remain, please contact a service engineer.

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8.2 TECHNICAL

Trouble	Diagnosing and solution:
Power problem	**Check if:** - The original power cord supplied with the instrument is used. - The connection of the power is correct and firm. - Placed on a stable, horizontal surface, free from vibrations. - Placed away from other appliances that generate electrical noise or magnetic fields (e.g. radiological instruments, X-ray, radio…). - Connected to a suited and **grounded AC wall outlet**, preferably one that is not shared with other electric appliances and with low fluctuation of line voltage: 90 to 264 VAC. - If the AC wall outlet is not properly grounded, please connect the ground or earth wire to the bottom plate of the analyzer. - If the fluctuation is >10% use of the following supplementary devices is strongly recommended: ➔ Electronic Stabilizer. ➔ No Break module UPS – (Uninterrupted Power Supply). If after these verifications, the problems remain, please contact a service engineer.
Temperature problem	**Check if:** - Not in direct sunlight, this could affect the operating temperature. - Not in a draught or under/up/ beside air conditioning or heat sources. - Leave 10 cm around and at the back of the instrument for air circulation and cooling. - Room temperature between 18 °C – 30 °C. - The instrument is on for at least 5 minutes. - In the temp display (system settings, see 4.7.4): the measured temperature for the flow cell is the set temperature ± 0,5 °C. If after these verifications, the measured temperatures do not correspond to these specifications, contact a service engineer.
Aspiration problem	**Check if:** - The hydraulic system (flow cell + tubes) is clean and rinsed with distilled water (see 7.2.1). - Verify that after the aspiration of distilled water, there is no big drop formation at the tip of the aspiration tube. Drop formation indicates the presence of leakage or blockage in the hydraulic system (tubes or flow cell): - A leak in one of the tubes or the flow cell: ➔ Replacement is necessary, contact a service engineer. - Blockage in one of the tubes can be caused by: ➔ Squashing of the tube, for example by the lid, replace the tube if damaged, contact a service engineer. ➔ Accumulation of dirt in the tubes → perform cleaning with hypochlorite (see 7.2.1), replace if cleaning is not sufficient. - Blockage in the flow cell: ➔ Accumulation of dirt in the flow cell → perform cleaning with hypochlorite (see 7.2.1), replace if cleaning is not sufficient. - The pump tube is installed and connected correctly (see 7.3.4). - The peristaltic pump is correctly calibrated. - The peristaltic pump motor is turning smoothly. If after these verifications, the problems remain, please contact a service engineer.
Printing problem	**Check (user):** - There is a thermal paper inserted. - The paper is inserted in the correct direction (prints only on one side). - The result print is enabled in the print setup. If after these verifications, the problems remain, please contact a service engineer.
The screen is not readable	**Check (user):** - If the screen is powered, and the HDMI cable is well connected - If replacing the screen by another screen solves the issue If after these verifications, the problems remain, please contact a service engineer.

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CYANVision CONSUMABLES

Item Code	Item name	Photo	Comments	Consumable for one year		Suggested stock 10 sold instruments
Accessories & Consumables						
CY001-S01	Thermal print paper (57mm width)			Y	user dependent	user dependent
CY001-WS	CYAN Washing solution			Y	4	5
Optical Assembly						
CY014-S02	Inlet tubing flowcell (Incl. connector & internal protection)		Replace every year	Y	1	5
CY014-S34	Main CPU battery			(Y)		1
Hydraulic & aspiration assembly						
CY014-S04	External protection aspiration inlet		Replace every year	Y	1	10
CY014-S05	Tube from flowcell to pump		Replace every year	Y	1	10
CY014-S06	Inlet connector pump tube		Replace every 3 years	Y		4
CY014-S08	Pump casette		Replace every 6 months	Y	2	20
CY014-S09	Outlet connector pump tube		Replace every 3 years	Y		4
CY014-S10	Waste tube		Replace every year	Y	1	10

Register now at: https://diagnostics.be/warranty

To all Healthcare Professionals,

Thank you for your interest. We appreciate it!

Hello, I am Thomas, Managing Director of Cypress Diagnostics. I have been at Cypress Diagnostics for more than 15 years. Cypress Diagnostics is one of Belgium's biggest diagnostic manufacturers, with more than 67,7 million tests sold yearly! We pride ourselves on providing quality products you can trust.

Together with my colleague Liesbeth, our marketing manager, we have crafted this brochure with minute detail to present to you our CYANVision.

Interested?
Please read on.

Kind regards,

The Cypress Diagnostics Team

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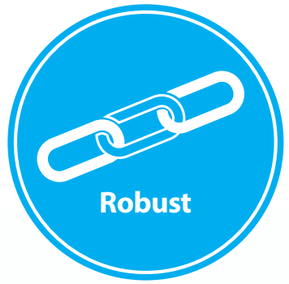
CYANVision Highlights

A next-generation biochemistry analyzer
Based on our 25-year experience in *in-vitro* diagnostics, we created the CYANVision to excel in three different areas: clinical performance, user convenience, and robustness.



Clinical performance
The clinical performance of the CYANVision is the result of advanced optical engineering and software capabilities. The software helps with improved Reagent Blank (RBL) corrections, multipoint calibration, integrational and differential calculation.
The photometer uses a reference detector to remove signal noise and to correct for light intensity fluctuations. By design, the CYANVision has exceptional linearity of absorbance measurements. Additionally, we work with high-resolution responsive detectors, specific LEDs, and very narrow spectral half-width filters. Compared with previous generations of biochemistry analyzers, the light intensity is 4 to 5 times higher.
Because of these design features, the CYANVision gives you excellent repeatability and accuracy.

Convenience
The CYANVision operating system is powerful and convenient because it is icon-based, intuitive, and automated. It also assists and advises the operator. This makes your work more enjoyable and efficient.

Robustness
Robustness is essential because it means lower costs of ownership for the lab. Typically, a CYANVision owner will save on maintenance, spare parts, and work disruptions. Additionally, you benefit from a long-lasting device. We selected reputable subcontractors for quality components, and we work with durable materials.

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Other distinguishing features

With our new and innovative CYANVision, we set the benchmark for the industry.
This super-compact analyzer uses light-emitting diodes (LED) to achieve unprecedented measurement performance.
With guidance and advice, the operating system helps you deliver precise and accurate results.

Any screen
A distinguishing feature of the CYANVision is your freedom to use any HDMI connectable screen. You choose the size. Our vector-based operating system adapts automatically.

Certified
The CYANVision is officially registered as IVD-CE by the Belgian MOH (FAGG) and is produced under strictly controlled protocols according to ISO13485:2016. This biochemistry analyzer is designed to meet and excel in national and international regulatory standards.

Data back-up
Take a USB drive, click, and you are done.
If you like, you can even create a system copy to clone all your data to a different CYANVision analyzer. This way, you make an exact copy of your device.

Maintenance
The software will inform you of the required interventions and deadlines in advance so that you can plan them at your convenience.

Multiple reference ranges
The operating system enables you to save different reference values for each method. These references are sample, sex, and age-dependent. In practice, this means that a male adult serum sample can have different flags from an infant plasma sample.

Patient report
All the results (regardless of the number of tests or types of samples) are printed out in one patient report. The report even comes with user-defined titles like “Lipids” or “Electrolytes”!.
This way your work is more professional.

Scanning
You can program lot-specific quality control or calibrator values by scanning their QR codes.
You won’t need to type a digit!
This feature is industry-leading in convenience.

Test counter
The CYANVision shows you how many tests, blanks, calibrations, and controls were run. You can filter per month, year, and test.

Veterinary mode
The veterinary mode enables you to define and select multiple animal species. You can even define different reference values for each animal and method. These references are sample, sex, and age dependent. In practice, this means that a dog serum sample can have different flags from a horse plasma sample.

Is the CYANVision unique?

In practice, yes!
On paper our competition advertises optical specifications that cannot be reproduced on sold models.
We do things differently. Our quality policy consists of delivering on our promises. Try it!
That is why we also offer validation fluids for each wavelength (8) in 6 different concentration levels.

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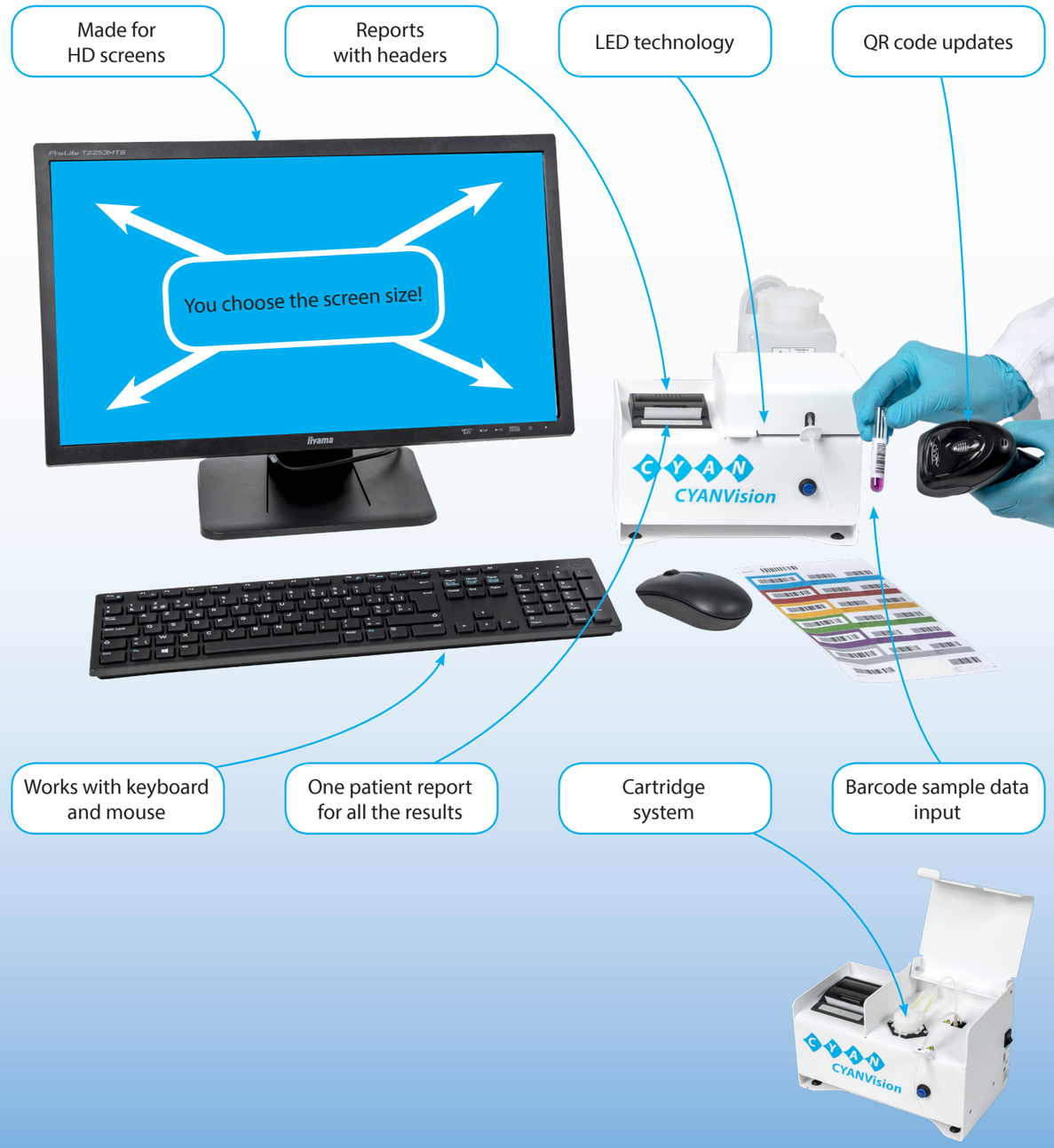
What is the benefit of an external screen?

Freedom of choice.
With the CYANVision, you choose the screen size. It can be a computer screen, a television, a projector of even a touchscreen!
To save place on your lab bench or improve user ergonomics, you can attach the screen to the wall.
It is all up to you!
Just ensure that your choice is full HD and has an HDMI connection.



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Why work with LEDs?

The life span of LEDs is many times longer than of halogen lamps. Because of this, you can perform 100.000 tests without the need for a lamp replacement. For the lab, this equals to lower costs of ownership.

LEDs also come to full brightness immediately with no delay. The CYANVision is, therefore, on standby 24/7.

LEDs generate minimal heat. This, together with other design features, eliminates the need for cooling by mechanical ventilation. Consequently, no ventilator is needed, and a significant source of dust pollution is eliminated.
The CYANVision, therefore, consumes less energy and stays dust-free for longer.

Technical specifications

Application
- Clinical diagnostics
- Veterinary diagnostics

Connectivity
- External keyboard (USB)*
- Mouse (USB)*
- Barcode reader (USB)*
- QR code reader (USB)*
- HD screen (HDMI)*
- HD touchscreen (HDMI)*

** not included*

Data exchange
- Data backup (USB)
- Ethernet (RJ45)
- LIS: HL7 bi-directional connectivity
- System copy (USB)

Data Storage
- 100 000 results
- 8 GB of data

Environmental conditions
- Optimal operational temperature: 25 °C
- Operational temperature: 18 °C – 30 °C
- Operational relative humidity: 30% - 70 %
- Operational max altitude: 2000 m

Flow cell
- Light path: 10 mm
- Quartz glass
- Temperature controlled (PID), +/- 0,5 °C
- Volume: 32 µL

Hydraulic system
- Convenient cartridge system
- Directly accessible
- Peristaltic pump
- Ultrashort
- Waste bottle included

Languages
- English
- French
- Russian
- Spanish
- Portuguese

Measurements
- 100 closed methods
- 100 open methods
- 18,3 billion possible method configurations
- Blank options: air, reagent blank, sample blank, water blank
- Calculation methods: absorbance, bichromatic, endpoint, kinetic, two-points
- Calibration methods:
  1. Single point
  2. Multipoint (up to 8)
  3. Use of calibrator, standard, or factor
- Incubation time between 0 and 999 s
- Min. reaction volume: 500 µL per test
- Optional reagent blank correction
- Reading time between 2 and 999 s
- Temperature choices: 25 °C, 30 °C, 37 °C

Optical system
- Light-emitting diodes (LED) light source
- Reference detector (double beam)
- Photo detector: Silicon based (range 300 – 900 nm)
- Measurement range: 0,000 – 3,000 Abs
- Onboard wavelengths (8): 340, 405, 450, 510, 546, 578, 620 & 670 nm
- Optical accuracy:

Absorbance ranges (Abs)	0,2 – 0,5	0,5 – 1,0	1,0 – 1,8	1,8 – 3,0
Max error (+/-)	5 %	4 %	2 %	5%

- Max. drift (20 minutes at 340 nm at 0 Abs): 0,005 Abs
- Optical repeatability (CV): ≤ 2 %

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Power
- External power supply unit (auto-ranging 100 – 240 VAC, 50/60 Hz)
- Grounding required
- Advised: voltage regulator & UPS
- Analyzer power input: 24 VDC, 2,5 A, 60 W max

Printer
- Automatic or on-demand printing
- Built-in thermal printer
- 24 characters per line
- Prints results, and patient reports

Quality control
- Automated import of values (QR code on controls and calibrator)
- Separate QC result menu
- Levey-Jennings graphs

Reagents
- For best results, use Cypress Diagnostics reagents
- Cypress Diagnostics reagents are preprogrammed
- QR code method update

Reference ranges
- Specific ranges per age (adult – child)
- Specific ranges per sample (serum, plasma, urine…)
- Specific ranges per sex (male, female, unknown)
- In veterinary mode, specific ranges per animal (species)

Screen
- HD screen or HD touchscreen
- HDMI connectivity

Software
- Clear identification of emergency tests
- Digital maintenance logbook
- Icon-based user interface
- Unique 16-digit patient or sample identifier (ID)
- Vector-based design to fit to any HD screen
- Workflow optimization suggestions

Weight and dimensions
- 4 kg
- 23,5 x 13,0 x 17,0 cm (LxWxH)

Order code
- CY014 CYANVision

Ancillary products
- CC-BC Barcode reader (for QR/2D codes)
- CY001-S01 Thermal print paper (57mm width)
- CY001-WS CYANWashing solution

Notes
- Specifications are subject to change
- The CYANVision is only available for selected distributors who excel in their after sales support and outperform defined sales targets.

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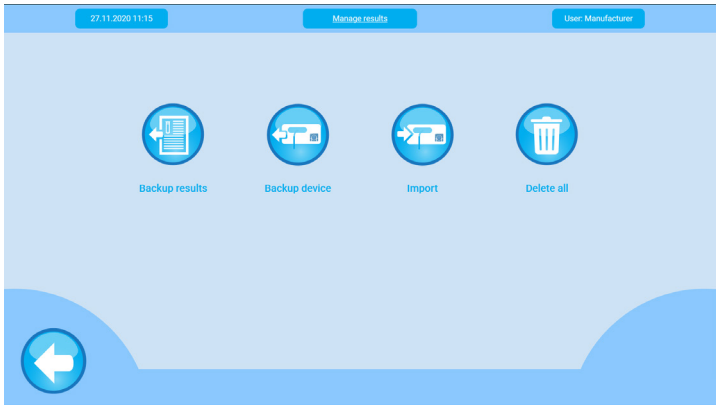
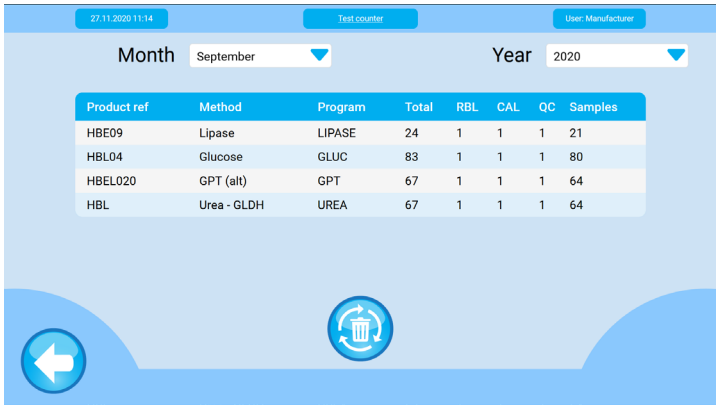
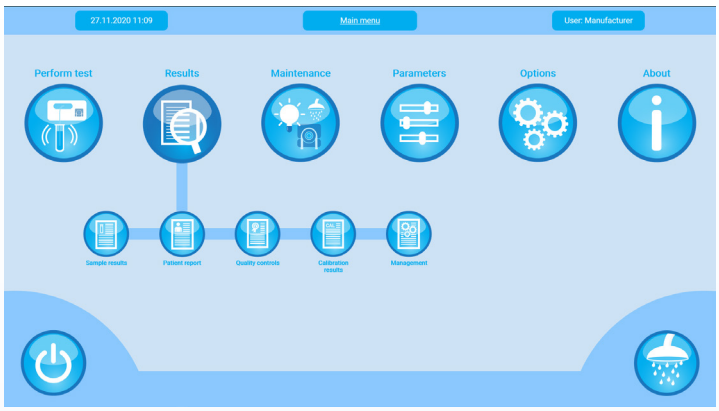


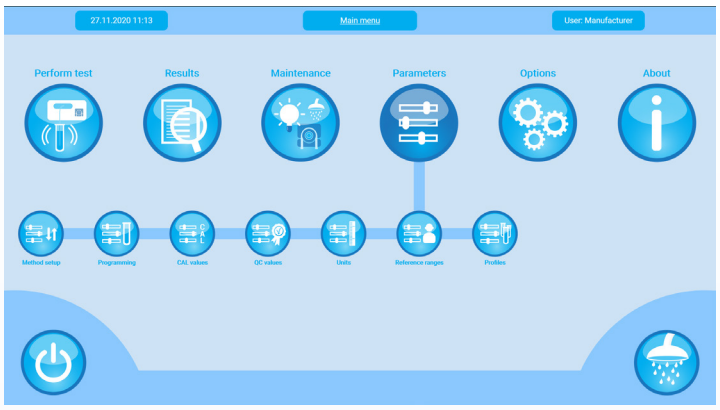
The back-up options



The test counter



The results menu



The parameters menu

The patient worklist overview

The suggested maintenance overview

Conclusion

This super-compact analyzer uses light-emitting diodes (LED) to achieve unprecedented measurement performance. The CYANVision is ideal for quality-conscious laboratories looking for a performant device. It is built to take the leading role in biochemistry and turbidimetric measurements. It shows you are a professional.

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URL: www.diagnostics.be

Your Distributor

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