HORIBA Medical

Yumizen H550

Hematology Analyzer from V3.0.x

User Manual

Ref: RAB343CEN

Yumizen H550

User Manual

CE 2797

IVD

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User Manual
Ref: RAB343CEN

Contents

Foreword

1. Document Update

1.1. Revisions

Internal Reference	Software Version used for Documentation	Document Date Issued
RAB343AEN	3.0.x	05/2022
RAB343BEN	3.2.x	06/2023
RAB343CEN	4.0.x	05/2024

This document applies to the latest software version listed and higher versions.

When a subsequent software version changes the information in this document, a new electronic edition (USB flash drive and/or online help) is released and supplied by HORIBA Medical.

To update a paper document, please contact your local HORIBA Medical representative.

Documentation instructions (USB flash drive)

To view or to print the user manual or any other document included in the Documentation USB flash drive, plug it in a USB drive and follow the instructions.

Make sure the USB flash drive is free of any virus.

1.2. What's New?

Update	Chapter
IEC 60601-1-2 norm added.	Electromagnetic Environment Check
New serial number label. Manufacturing date added.	Serial Number Label
New intended use.	Intended Use
New approved printer added.	Printer
New chapter added.	Cybersecurity Description Bibliography Evaluation of Potential Interferences To Display Parameters as Suspected To Delete Patient Information
Update - Sarstedt Microvette	Compatible Tube List

Update	Chapter
Update - MAC	Precision: Repeatability Claims
Information update.	Analytical Measuring Range
Update	Environmental Protection Computer Characteristics Sound Level Reference Values Default Pathological Limit Values To Configure the Analyzer Settings To Configure Results Printing and Transmission
Possibility to create several orders with a same SID.	To Run a Blood Sample in STAT Mode
Alarm names modified.	Alarms Description To Configure the Alarms Thresholds
Children types updated.	To Configure the Age Limits for Children Types
Help format in PDF.	To Update the Help
Information addition. ■ E06 ■ M08 Update - M03	Environment Error Messages Maintenance Error Messages
User name removed.	To Create a User Account To Modify a User Account
Modification of the calibration principles of the parameters: RDW-CV / RDW-SD / MPV / PDW Replacement of the following chapters: ■ Calibration: RDW-CV ■ Calibration: RDW-SD ■ Calibration: MPV ■ Calibration: PDW	Manual Calibration with Whole Blood Specimens

2. Legal Information

2.1. Declaration of Conformity

This product complies with the Standards and Directives named in the Declaration of Conformity.

The latest version of the EC Declaration of Conformity for this product is available on www.horiba-abx.com/documentation.

2.2. Notice of Liability

The information in this manual is distributed on an "As Is" basis, without warranty. While every precaution has been taken in the preparation of this manual, HORIBA Medical will not assume any liability to any persons or entities with respect to loss or damage, caused or alleged to be caused directly or indirectly by not following the instructions contained in this manual, or by using the computer software and hardware products described herein in a manner inconsistent with our product labelling.

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The product may contain software components from third party's sources; by using those components with the product you agree that you will comply with the licences of the concerned third party for use of its concerned software components.

2.5. Graphics

All graphics including screens, printouts and photographs are for illustration purposes only and are not contractual.

2.6. Document Symbols

To alert the operator of potentially hazardous conditions, symbols described in this chapter are provided wherever necessary throughout the manual.

Emphasizes Information for Safety (IFS) that must be followed to avoid risks related to either the user, the patient, the service technician, the personal data or the environment.

Emphasizes information that must be followed to prevent the danger not linked to an IFS.

Emphasizes information that must be followed to respect the good laboratory practice (not linked to risk) or prevent damage to the instrument.

Emphasizes information that can be helpful to the operator before, during or after a specific operational function.

Gives a summary of what can be achieved if the task is performed.

2.7. Typographical Conventions

Before you start using this documentation, you should become familiar with the following typographical conventions.

Access: ***Home*** > ***Quality Assurance*** > ***XB***	Indicates, from the main screen, the sequence of menus you have to go through to begin the procedure.
Go to ***Home > Quality Assurance***.	Indicates, from the main screen, the sequence of menus you have to go through.
Press **Validate**.	Used for interface items (buttons, check boxes, fields, etc.).
The ***Batch Details*** window is displayed.	Used for windows titles, dialog boxes titles or tabs titles.
More information on www.horiba-abx.com/documentation.	External links can be used to retrieve information from a web site.
Refer to the *Workflow* > *Start of Day* chapter.	Internal links can be used when referring to related information located in another chapter.
Related information: ■ To Switch On the Printer, p.74 ■ Printer Operation Problems, p.178	The *Related information* box provides clickable internal links to navigate throughout the user manual.

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Introduction

1. Warning and Precautions

Work safety reliability and general characteristics are guaranteed by HORIBA Medical under the following conditions:

- For laboratory use only.
- User manual must be entirely read, and personnel trained by a HORIBA Medical representative before attempting to operate the instrument.
- The user always operates with full knowledge and appreciation of instrument warnings and alarms.
- Always refer to labelling and HORIBA Medical instructions in order to avoid compromising system integrity.

This instrument must be operated as instructed in the user manual. Any other use might compromise system integrity and might be hazardous for the operator.

This instrument complies with Standards and Directives named in the Declaration of Conformity. The latest version of the Declaration of Conformity for this instrument is available online at www.horiba-abx.com/documentation.

- The reagents specified for this instrument have been approved in accordance with the applicable *in vitro* medical devices European legislation in force.
- The use of any other reagents may place the performance of the instrument at risk, thus engaging user responsibility. In this case, HORIBA Medical takes no responsibility for the device nor for the results rendered.
- Disposable gloves, eye protection and lab coat must be worn by the operator.
- Local or national regulations must be applied in all the operations.
- Mobile phones should not be used in proximity of the instrument.
- All peripheral devices should comply with relevant standards.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.
- Movement and installation of the device may damage the system or affect its alignment, voiding the warranty or service contract, unless performed by the manufacturer.

1.1. Limited Warranty

Please refer to the terms and conditions expressly agreed by HORIBA Medical for the provision of the Product to know the extent of the warranty.

Nevertheless, the Warranties are conditioned on: (i) no repairs, modifications or alterations being made to the Product other than by HORIBA Medical or its authorized representatives; (ii) Buyer handling, using, storing, installing, operating and maintaining the Product in compliance with any parameters or instructions in any specifications attached herein; (iii) compliance with all generally accepted industry standards; (iv) Product not having been subjected to accident (including force majeure), alteration, abuse or misuse; and (v) Buyer not being in default of any payment obligation. The Warranties are contingent with the use of the reagents specified or recommended by HORIBA Medical. The Warranties do not apply to any equipment, parts and accessories not provided by HORIBA Medical.

Normal wear and tear is excluded, including any expendable items that comprise part of the Product (such as fuses, light bulbs and lamps). HORIBA Medical does not warrant or guarantee that any Product will be secure from cyber threats, hacking or similar malicious activity. Products that are networked, connected to the internet, or otherwise connected to computers or other devices must be appropriately protected by Buyer and/or end user against unauthorized access.

Buyer's sole and exclusive remedies for breach of the Warranties are limited, at HORIBA Medical's discretion, to repair or replacement of the Product, or its non-conforming parts, within a reasonable time period, or refund of all or part of the purchase price. The warranty on repaired or replaced parts is limited to the remainder of the original warranty period.

NOTWITHSTANDING ANYTHING IN THE TERMS AND CONDITIONS AGREED SEPARATELY TO THE CONTRARY, HORIBA Medical IS NOT LIABLE, WHETHER BASED IN CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, INDEMNITY OR ANY OTHER LEGAL OR EQUITABLE THEORY, FOR: LOSS OF USE, REVENUE, SAVINGS, PROFIT, INTEREST, GOODWILL OR OPPORTUNITY, COSTS OF CAPITAL, COSTS OF REPLACEMENT OR SUBSTITUTE USE OR PERFORMANCE, LOSS OF INFORMATION AND DATA, CLAIMS ARISING FROM BUYER'S THIRD PARTY CONTRACTS, OR FOR ANY TYPE OF INDIRECT, SPECIAL, LIQUIDATED, PUNITIVE, EXEMPLARY, COLLATERAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS OR COST OF A SIMILAR TYPE.

BUYER AGREES THAT THE ABOVE EXCLUSIONS AND LIMITATIONS WILL PREVAIL OVER ANY CONFLICTING TERMS AND CONDITIONS AND MUST BE GIVEN FULL FORCE AND EFFECT.

1.2. Safety Precautions

1.2.1. Electronic and Moving Parts

The following parts must not be handled or checked by the user:

- AC/DC adapter
- Electronic circuit boards

Operator injury may occur from an electric shock. Electronic components can shock and injure the user. Do not dismantle the instrument nor remove any components (covers, panels, etc.) unless otherwise instructed within this document.
Danger of explosion if battery is not replaced correctly! When replacing the battery, always use the same and/or equivalent type recommended by the manufacturer. Dispose of used batteries according to the manufacturer specific instructions.

Moving parts: It is strictly forbidden to disable sensors as it may cause operator injuries. Protection covers must not be opened during instrument operations.

Make sure you never touch the sampling needle during operation.

1.2.2. Biological Hazard

Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other biosafety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent biosafety procedures.

All accessible surfaces of the instrument can be potentially contaminated by human specimens. Disposable gloves and lab coat must be worn by the operator. Local and national regulations must be applied in all the operations.

The manufacturer uses disinfectant products for instrument decontamination and highly recommends it to decontaminate your instrument. Refer to the *Maintenance and Troubleshooting* > *Maintenance Procedures* > *To Decontaminate your Instrument* chapter to perform the instrument cleaning and decontamination procedure.

Related information:
- To Decontaminate your Instrument, p.224

1.3. Graphics and Symbols

Switch off position

Switch on position

Alternating current

Protective earth

Warning; Biological hazard

Manufacturer

In Vitro Diagnostic medical device

This product conforms to the EC Directives and Regulation named in the Declaration of Conformity

Caution, consult accompanying documents

Biological hazard

REAGENT Reagent	Up
Fragile, handle with care	Keep dry
Do not stack	Temperature limitation
LOT Batch code	REF Reference Number
Use by	Consult Instruction for Use
CAL Calibrator	CONTROL Control
CONT. Content	Use no hooks
This product should be disposed of and recycled at the end of the useful life in accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and/or European Directive 2006/66/EC on batteries and accumulators.	ID Reagents identification code
Packaging recycling mark	Trademark certification TUV
RESY: cardboard recycling symbol in Germany	SAP ERP (Enterprise Resource Planning) Number
Direct current	

Unique Device Identifier (UDI) code

The UDI is an international standard that enhances patient safety and improves efficiency in the healthcare supply chain.

Instrument

- (01): GTIN (Global Trade Item Number)
- (21): Instrument serial number
- (240): SAP reference

Reagent, calibrator, control and other consumables

- (01): GTIN (Global Trade Item Number)
- (10): Lot number
- (17): Expiration date
- (240): SAP reference

2. Operational Conditions

2.1. Environment

The operation of the Yumizen H550 should be restricted to indoor location use only.

In standard configuration, the instrument is operational at an altitude of maximum 3000 m (9840 ft). Above this altitude, adjustments and/or technical modifications could be necessary.

The instrument is designed for safety from voltage surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2 (IEC 61010-1).

Please contact your local representative for information regarding operation locations when it does not comply with the recommended specifications.

2.2. Location

Risk of injury when moving the instrument in case of fall.
Keep in mind that the instrument weighs approximately 35 kg (78 lbs).
To move the instrument, two persons are required.

- Place it on a clean and leveled table or workbench.
- Avoid exposure to sunlight.
- Place it where it is not exposed to water or vapor.
- Place it where it is not exposed to dust.
- Avoid direct exposure to air conditioner.
- Place your instrument where an independent power receptacle can be used.
- Use a receptacle different from the one used by a device that easily generates noise such as a centrifuge, etc.
- Provide a space of at least 20 cm (8 in.) at the back of the instrument for a proper ventilation and an easy access to connections.

The power supply connection should always be accessible. When positioning the system for operational use, leave the required amount of space for easy access to this item.

Risk of erroneous results due to vibrations.
Place your instrument where it is free from vibration or shock.

2.3. Grounding

Proper grounding is required when installing the system. Check the wall outlet ground (earth) for proper grounding to the facilities electrical ground. If you are unsure about the outlet grounding, contact your facilities engineer to verify the proper outlet ground.

2.4. Humidity and Temperature Conditions

Instrument operating temperature: from +15°C (+59°F) to +30°C (+86°F). If the instrument is stored at a temperature lower than +10°C (+50°F), it should stand for one hour at normal room temperature before use.

Risk of erroneous results due to inappropriate operating conditions. Make sure the instrument operates in the defined temperature range.

Calibration conditions: The analyzer must be calibrated at a laboratory Reference Temperature from +19°C (+66°F) to +26°C (+79°F).

The analyzer is then fully operational for blood sample analysis at this reference temperature +/-4°C (+/-7°F).

Humidity conditions: relative humidity of 80% maximum, without condensation.

2.5. Electromagnetic Environment Check

The instrument has been designed to produce less than the accepted level of electromagnetic interference in order to operate in conformity with its destination, allowing the correct operation of other instruments also in conformity with their destination.

The instrument complies with the emission and immunity requirements described in the following series of standards:

- IEC 61326-1
- IEC 61326-2-6
- IEC 60601-1-2

Do not use this instrument in close proximity to source of strong electromagnetic radiation, as these can interfere with the proper operation.

In case of suspected electromagnetic noise, make sure that the instrument has not been placed in the proximity of electromagnetic fields or short wave emissions, e.g. Radar, X-rays, Scanners, Cell phones, etc.

Do not perform analysis while cover is open or not correctly fixed. Electromagnetic noise can affect the data or disrupt a nearby instrument.

For electromagnetic (EMC) compatibilities, connect the Ethernet line with a shielded cable as CAT6A shielded twisted pair cable.

2.6. Main Power Supply

It is recommended to install the system on UPS (Uninterruptible Power Supply).
The UPS minimal power must be 180 VA.

Grounding is required. Make sure the earth wall-plug is correctly connected to the laboratory grounding system. If there is no such system, a ground stake should be used.

Use only the main supply cable and the AC/DC adapter delivered with the instrument. If a new main supply cable or a new AC/DC adapter is needed, please contact your local HORIBA Medical representative to obtain it.

Main power supply voltage fluctuations must not exceed +/- 10% of the nominal voltage.

- Always disconnect the system from the supply before servicing.
- To prevent the risk of electrical shock, do not remove the covers or the back panel.
- Connections to the supply have to be done by your local representative.

2.7. Environmental Protection

Used Materials and Consumables Disposal

Disposable used materials and consumables must be collected by a laboratory specialized in elimination and recycling of this kind of material according to the local legislation.

Instrument Disposal

This product should be disposed of and recycled at the end of the useful life in accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and/or European Directive 2006/66/EC on batteries and accumulators.

To avoid information disclosure, product decommissioning procedure must be applied to ensure data destruction.
For more detailed information, please contact your local HORIBA Medical representative.

If any doubt, please contact your local representative.

2.8. Storage Conditions and Transportation

Instrument storage and transportation temperatures: from -20°C (-4°F) to +60°C (+140°F).

Analyzer exposure to rainfall and extended sunlight must be avoided. The outdoors storage of the analyzer is prohibited.

Before the shipping of an instrument by transporter, whatever the destination, an external decontamination of the instrument must be carried out.

Risk of injury when moving the instrument in case of fall.
Keep in mind that the instrument weighs approximately 35 kg (78 lbs).
To move the instrument, two persons are required.

Be careful when moving the instrument. Hold the bottom of the instrument to lift it, one person on each side of the instrument.
Never use the tube holder cover as a grip to lift the instrument.

Before instrument removal from use, transportation or disposal, perform a general cleaning and a draining of your instrument.

2.9. Installation

A representative must install your instrument and software.

Package content:

- Yumizen H550
- Power supply cable
- AC/DC adapter + four feet
- Documentation USB flash drive
- Safety Information booklet
- Installation kit
- USB External Barcode Reader (optional)
- Racks (5)
- Waste tank
- Diluent container opening tool
- Protective cover

Risk of eye damage due to laser radiation if you use an external barcode reader not approved by HORIBA Medical.

Only HORIBA Medical approved materials should be used with the Yumizen H550.

Subject to availability and subscription:

- Yumicare
- Quality Control Program (QCP)

2.10. Package

Factory package of the analyzer Yumizen H550 and its implements consists of:

- firm corrugated cardboard
- polyethylene foil
- inner foam plastic framework

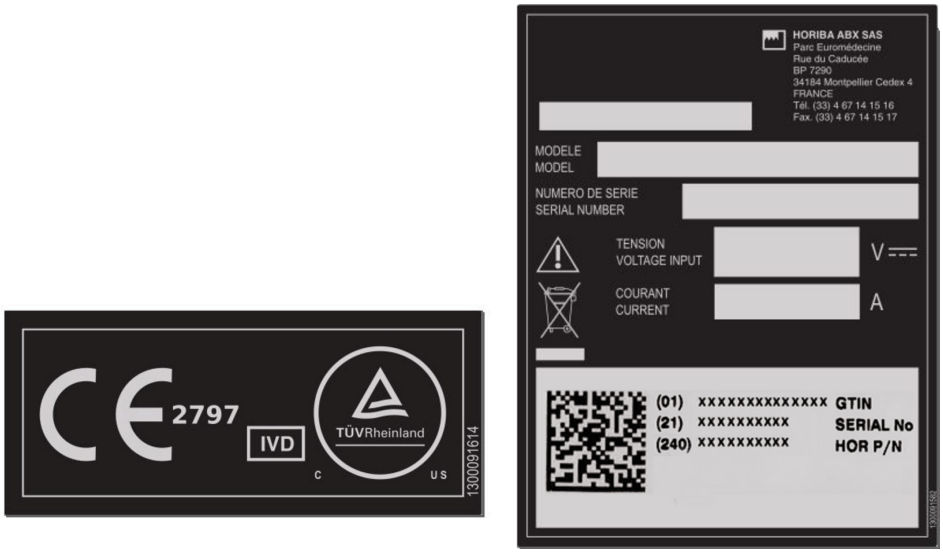
Package protects analyzer and its implements from adverse factors of outside environment.

Analyzer must be transported in its original factory package.

3. Labels and Connections

3.1. Serial Number Label

The serial label is located at the back of the instrument.



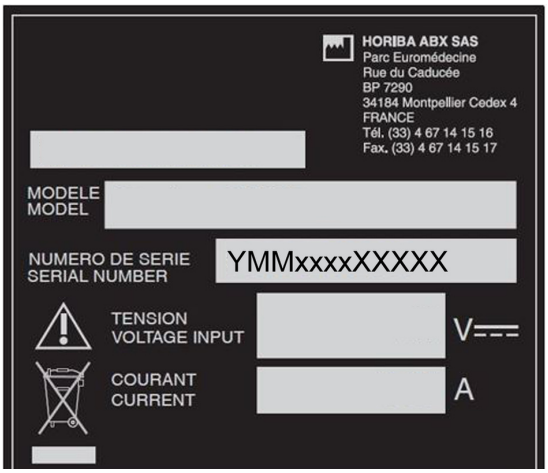
Manufacturing Date

The manufacturing date is included in the instrument serial number:

- First digit: last number of year of manufacture
- Next 2 digits: month of manufacture

Example:

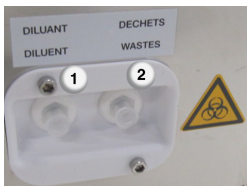
June 2022 = **206xxxxXXXXX**



3.2. Warnings and Biological Hazards Labels

Warning! Biological hazard

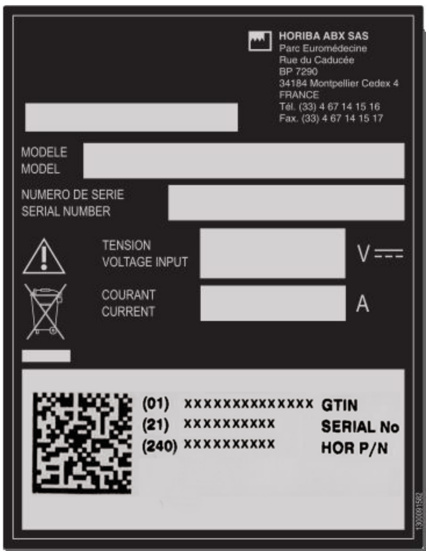
Near the waste output
Risk: the specimens, reagents, calibrators, controls, etc and waste liquids that contain human specimen extracts are potentially infectious; all accessible surfaces of the instrument can be potentially contaminated by human specimens.
How to avoid the risk: wear protective gear, gloves and lab coats, never remove the reagent and waste tubings during instrument operation.



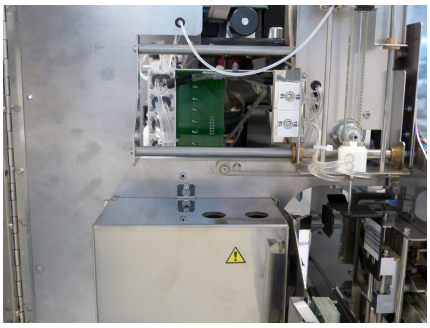
Near the tube holder
Risk: the specimens, reagents, calibrators, controls, etc and waste liquids that contain human specimen extracts are potentially infectious; all accessible surfaces of the instrument can be potentially contaminated by human specimens.
How to avoid the risk: wear protective gear, gloves and lab coats.

Caution, consult accompanying documents

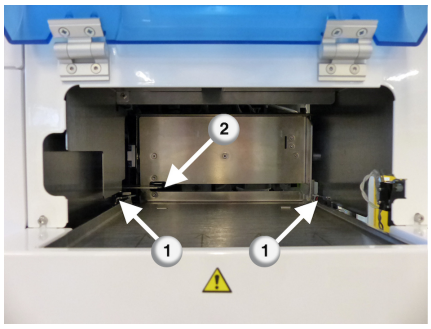
Back of the instrument
Risk: electric shock.
How to avoid the risk: do not touch electrical parts with your fingers.



On the instrument chambers' cover
Risk: sting injury, pinching risk of the fingers.
How to avoid the risk: never touch the sampling/ piercing needles during operation, never insert your fingers between the sampling/piercing needles and the chamber cover, never insert your fingers in the piercing mechanism area.



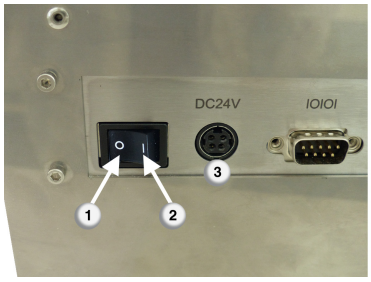
Right-hand side of the instrument
Risk: pinching risk of the fingers.
How to avoid the risk: never insert your hands through this door especially towards the sampling/piercing needles, between the grabbers for rack loading and the cover (1), between the transfer arm and the mixer (2).



3.3. Power Supply Connection

The power supply connection should always be accessible. When positioning the system for operational use, leave the required amount of space for easy access to this item.

This connector is located at the back of the instrument.



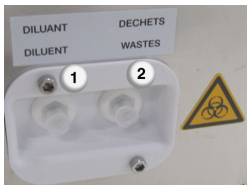
1 = Switch off position
2 = Switch on position
3 = 24 V AC/DC adapter connector
4 = AC/DC adapter
5 = Main power supply connector

Use only the main supply cable and the AC/DC adapter delivered with the instrument. If a new main supply cable or a new AC/DC adapter is needed, please contact your local HORIBA Medical representative to obtain it.

IFS

For electrical safety reasons, it is recommended to install the AC/DC adapter on the right-hand side of the instrument (on the opposite side of the reagents) and to raise it with the four provided feet in order to avoid potential hazards from fluids (diluent input, waste output, reagents location).

3.4. Diluent and Waste Connections



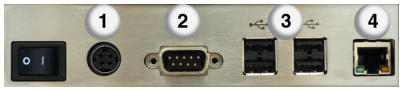
1 = ABX Diluent (10L or 20L) input

2 = Waste output

Waste must be handled according to your local and/or national regulations.

Consider waste as potentially infectious.

3.5. Instrument Peripherals Connections



1 = 24 V AC/DC adapter connector

2 = RS232 (for LIS connection)

3 = USB ports (4 ports at the back + 1 at the front)

4 = Ethernet connection (classified as Safety Extra low voltage - SELV)

All peripheral devices should comply with relevant standards.

To comply with cybersecurity requirements, HORIBA Medical recommends that you use USB port locks to lock your USB flash drive on the instrument and USB port blockers to block the unused USB ports of the instrument. USB port locks and blockers are available for order under reference 1300037849.

4. Printer

Use the following printers supplied or approved by HORIBA Medical:

Printers	Printout specifications
HP OfficeJet Pro 6230 ePrinter	USB connection only
Epson WorkForce Pro WF-C5210DW	USB and Ethernet connections only
Epson WorkForce Pro WF-C5710DWF	USB and Ethernet connections only
HP OfficeJet Pro 8218	USB and Ethernet connections only Printouts in color not available
Epson WorkForce Pro WF-4720DWF	USB and Ethernet connections only
Epson WorkForce WF-2850DWF	USB and WiFi connections only
HP LaserJet Pro M15a	USB connection only
SANEI-BL2-58	USB connection only
Epson WorkForce Pro WF-C5390DW	USB and Ethernet connections only

If you want to use another printer, contact your local HORIBA Medical representative for more information about printers compatibility.

Specifications

1. Technical Specifications

1.1. Intended Use

Yumizen H550 classifies and enumerates the following parameters in whole blood:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC, PLT, MPV, PCT, PDW, P-LCC, P-LCR, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, ALY#, ALY%, LIC#, LIC%, IML#, IML%, IMM#, IMM%, IMG#, IMG%.

Yumizen H550 provides information for *in vitro* diagnostic use in clinical laboratories.

Yumizen H550 analyzer is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.

Yumizen H550 analyzer is quantitative for parameters measurement and qualitative for alarms detection.

Yumizen H550 analyzer is intended to perform tests on the following specimens:

- venous blood
- capillary blood

collected in K2-EDTA and K3-EDTA anticoagulants.

Yumizen H550 analyzer is intended to perform tests on the following specimens:

Pediatric

- New born: from birth to 28 days
- Infant: from 29 days to 2 years
- Children: from 2 years to 12 years
- Adolescent: from 12 years to 18 years

Adult population

- Above 18 years

1.2. Parameters

LOINC Code: Logical Observation Identifiers Names & Codes

CBC Parameters	LOINC Code	Definition
RBC	789-8	Red Blood Cells
HGB	718-7	Hemoglobin Concentration
HCT	4544-3	Hematocrit

CBC Parameters	LOINC Code	Definition
MCV	787-2	Mean Corpuscular Volume
MCH	785-6	Mean Corpuscular Hemoglobin
MCHC	786-4	Mean Corpuscular Hemoglobin Concentration
RDW-SD	21000-5	Red Distribution Width Standard Deviation
RDW-CV	788-0	Red Distribution Width
MIC	X-MIC	Microcytic Red Blood Cells percentage (versus RBC)
MAC	X-MAC	Macrocytic Red Blood Cells percentage (versus RBC)
PLT	777-3	Platelets
PCT	51637-7	Plateletcrit
PDW	51631-0	Platelets Distribution Width
MPV	32623-1	Mean Platelet Volume
P-LCC	96354-6	Platelets - Large Cell Count
P-LCR	48386-7	Platelets - Large Cell Ratio
WBC	6690-2	White Blood Cells

DIFF Parameters	LOINC Code	Definition
LYM#	731-0	Lymphocytes absolute value
LYM%	736-9	Lymphocytes percentage
MON#	742-7	Monocytes absolute value
MON%	5905-5	Monocytes percentage
NEU#	751-8	Neutrophils absolute value
NEU%	770-8	Neutrophils percentage
EOS#	711-2	Eosinophils absolute value
EOS%	713-8	Eosinophils percentage
BAS#	704-7	Basophils absolute value
BAS%	706-2	Basophils percentage
IMG#	53115-2	Immature Granulocytic cells absolute value
IMG%	71695-1	Immature Granulocytic cells percentage
IMM#	X-IMM#	Immature Monocytic cells absolute value
IMM%	X-IMM%	Immature Monocytic cells percentage
IML#	X-IML#	Immature Lymphocytic cells absolute value
IML%	X-IML%	Immature Lymphocytic cells percentage
ALY#	43743-4	Atypical Lymphocytes absolute value
ALY%	42250-1	Atypical Lymphocytes percentage
LIC#	55432-9	Large Immature Cells absolute value
LIC%	55433-7	Large Immature Cells percentage

1.3. Throughput Analyses

The rate of analysis for the Yumizen H550 is 60 +/- 3 samples per hour.

1.4. Samples Management

- Autonomy: 40 tubes (four racks with a ten tubes capacity)
- Loading: continuous loading
- Mixing: automatic mixing of racks
- Tube identification: positive identification of tubes

1.5. Computer Characteristics

- Color LCD touch screen: 12.1 in.
- Operating System: Linux™
- Processor: Qseven module based on NXP i.MX 6QuadPlus
- RAM (Random Access Memory): 2 GB
- Storage Technology: 16 GB MicroSD + 4 GB eMMC Flash
- RS232, Ethernet, USB connections
- Capacity: 10000 results

1.6. Tube Identification

Tube identification can be done by using either:

- an external USB keyboard (optional)
- the virtual keyboard
- the integrated barcode reader
- an external barcode reader (optional)

Risk of erroneous diagnosis due to patient misidentification if tubes are not barcoded.
Use barcoded tubes only.

HORIBA Medical recommends that barcodes with integrated check digit be used with the Yumizen H550.

1.7. Measurements and Computation

Parameters counted by impedance variation measure:

- RBC
- PLT
- WBC

Parameter measured by spectrophotometry: HGB

Parameters derived from impedance measure:

- HCT
- MCV
- MCH
- MCHC
- RDW-SD
- RDW-CV
- MIC
- MAC
- PCT
- PDW
- MPV
- P-LCC
- P-LCR

Parameters obtained by impedance variation measure and absorbency measure inside the flow cytometer:

- LYM
- MON
- NEU
- EOS
- BAS
- IMG
- IMM
- IML
- ALY
- LIC

1.8. Units

Default unit system:
Conventional

Parameters: CBC	SI (international)	Conventional	mmol/L	Japan	China
RBC	10^{12}/L	10^{6}/mm^{3}	10^{12}/L	10^{4}/µL	10^{12}/L
HGB	g/L	g/dL	mmol/L	g/dL	g/L
HCT	L/L	%	L/L	%	%
MCV	fL	fL	fL	fL	fL
MCH	pg	pg	fmol	pg	pg
MCHC	g/L	g/dL	mmol/L	g/dL	g/L

Parameters: CBC	SI (international)	Conventional	mmol/L	Japan	China
RDW-SD	fL	fL	fL	fL	fL
RDW-CV	%	%	%	%	%
MIC	%	%	%	%	%
MAC	%	%	%	%	%
PLT	10^9/L	10^3/mm^3	10^9/L	10^4/µL	10^9/L
PCT	%	%	%	%	%
PDW	fL	fL	fL	fL	fL
MPV	fL	fL	fL	fL	fL
P-LCC	10^9/L	10^3/mm^3	10^9/L	10^4/µL	10^9/L
P-LCR	%	%	%	%	%
WBC	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L

Parameters: DIFF	SI (international)	Conventional	mmol/L	Japan	China
LYM#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
LYM%	%	%	%	%	%
MON#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
MON%	%	%	%	%	%
NEU#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
NEU%	%	%	%	%	%
EOS#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
EOS%	%	%	%	%	%
BAS#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
BAS%	%	%	%	%	%
IMG#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
IMG%	%	%	%	%	%
IMM#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
IMM%	%	%	%	%	%
IML#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
IML%	%	%	%	%	%
ALY#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
ALY%	%	%	%	%	%
LIC#	10^9/L	10^3/mm^3	10^9/L	10^2/µL	10^9/L
LIC%	%	%	%	%	%

2. Cybersecurity Description

For additional information about specifications for software, hardware, network characteristics, and security controls refer to the cybersecurity whitepaper.

For more detailed information, please contact your local HORIBA Medical representative.

2.1. Operating Environment

2.1.1. Hardware Configuration

- Color LCD touch screen: 12.1 in.
- Processor: Qseven module based on NXP i.MX 6QuadPlus
- RAM (Random Access Memory): 2 GB
- Memory capacity: 16 GB MicroSD + 4 GB eMMC Flash

2.1.2. Software Environment

Operating System: Linux™

2.1.3. Network Condition

Ethernet

2.2. Security Software

Not applicable.

2.3. Data and Equipment Interface

- USB
- RJ45

2.4. User Access Control Mechanism

Number of account types: 3

The user can only create, modify or delete user accounts with lower access rights.

User account	Method of identifying users	Access rights
Technician	Use password to authenticate users.	Everything
Manager	Use password to authenticate users.	Everything but: ■ ***Settings*** > ***Technician*** screen ■ ***Maintenance*** > ***Advanced services*** screen
User	Use password to authenticate users.	Everything but: ■ ***Quality Assurance*** > ***Calibration*** screen ■ ***Settings*** (except ***System*** > ***Printer*** and ***System*** > ***Cycles***) screens

2.5. Relevant Requirements for Software Environment

2.5.1. System Software

Linux™

2.5.2. Support Software

Not applicable.

2.5.3. Application Software

Not applicable.

2.6. Security Software Updates

Not applicable.

3. Physical Specifications

3.1. Power Requirements

Yumizen H550 characteristics:

- Nominal input voltage: 24 VDC
- Maximum input current: 6.25 A
- Maximum power consumption: 180 VA
- Maximum heat output: 378 kJ/h (358 BTU/h)

The maximum power consumption and heat output values are given with the AC/DC adapter delivered with the instrument (efficiency of approximately 90%).

AC/DC adapter characteristics:

Use only the main supply cable and the AC/DC adapter delivered with the instrument. If a new main supply cable or a new AC/DC adapter is needed, please contact your local HORIBA Medical representative to obtain it.

- Maximum input voltage range: from 100 V to 240 V (+/- 10%), 50 Hz to 60 Hz
- Nominal output voltage: 24 VDC

For both functional and electrical safety reasons, the AC/DC adapter delivered with the instrument meets the double or reinforced insulation requirements according to IEC 61010-1 and its output power is included between 150 W and 300 W.

3.2. Dimension and Weight

Yumizen H550

- Instrument dimensions: 53 x 66.8 x 62.1 cm (20.87 x 26.3 x 24.45 in.) (Width x Depth x Height)
- Instrument weight: 35 kg (78 lbs)

3.3. Sound Level

The average sound level is 57 dB (A).

3.4. Compatible Tube List

This list is not exhaustive. If the tubes in use in your laboratory are not described herein, contact your local HORIBA Medical representative.

Micro blood collection tubes can be used on STAT mode only.

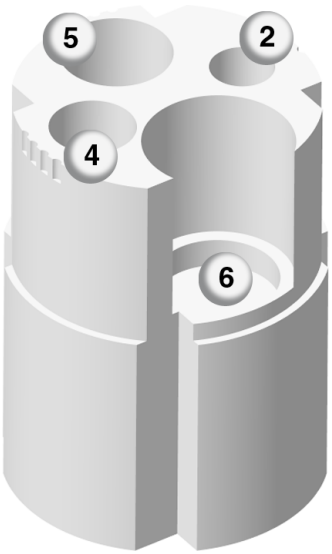
On microsampling tubes, the 100 µL volume can only be used in the following conditions:

- the tube must always be held in a vertical position,
- blood mixing must be obtained by a slight tapping on the tube. Do not rotate the tube for mixing, otherwise the blood will be spread on the tube wall, and the minimum required level will be lost.

STAT Mode

Two tube holders can be used on Yumizen H550:

- A standard tube holder for positions 2, 4, 5 and 6: 1300044084.



Tubes with Cap

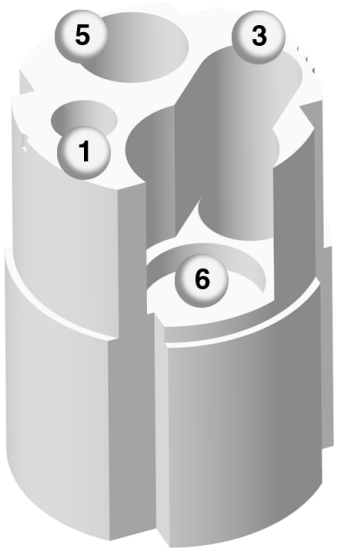
Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)	Tube holder position
Becton D Vacutainer	13	81 / 75	K2-EDTA	4	5
Greiner Vacuette	13	82 / 75	K2-EDTA K3-EDTA	2 - 4.5	5
KABE Kabevette G	12.5	81 / 72	K2-EDTA K3-EDTA	3.5	5

Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)	Tube holder position
Sarstedt Monovette	13	81 / 65	K2-EDTA K3-EDTA	2.6	5
HORIBA Medical ABX Minocal ABX Difftrol	12	81.3 / 77	None	3	5

Tubes without Cap

Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)	Tube holder position
HORIBA Medical LATEX RBC/PLT			None	3	6
Becton D Microtainer with Microgard closure	10	47 / 43	K2-EDTA	0.25 - 0.5	4
Sarstedt Microvette	10	48 / 45	K3-EDTA	0.2 - 0.5	4
Greiner MiniCollect	10	44 / 42.5	K2-EDTA	0.25 - 0.5	4
KABE GK 150	11/8	43 / 39	K2-EDTA	0.2	2

- An optional tube holder for positions 1, 3, 5 and 6: 1300063197.



Tubes with Cap

Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)	Tube holder position
Sarstedt Monovette	11.5	82.5 / 66	K2-EDTA K3-EDTA	2.7	5
KABE GK 150 with rubber membrane	11/8	43 / 39	K2-EDTA	0.2	1

The position 5 of optional tube holder is designed for the Sarstedt 2.7 mL tubes. However, please note that we recommend you to stick only one barcode label on the tube and that in case several barcode labels are stuck on the tube, this one may be blocked and not move up during sampling/piercing.
If you see that the tube is blocked in the optional tube holder and only in this particular case, you can use the position 5 of standard tube holder for the Sarstedt 2.7 mL tubes.

Tubes without Cap

Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)	Tube holder position
KABE GK 150	11/8	43 / 39	K2-EDTA	0.2	1
Becton D Microtainer MAP	13	80 / 75	K2-EDTA	0.25 - 0.5	3

Rack Mode

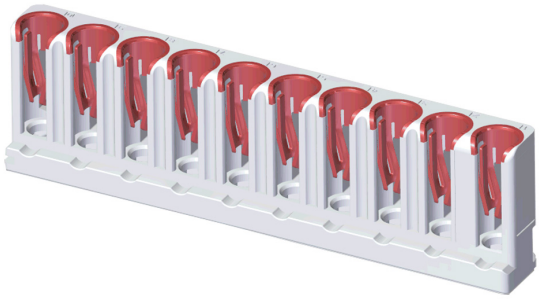
Two racks can be used on Yumizen H550:

- One standard rack with a ten tubes capacity: 1300066018.

Tubes with Cap

Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)
Becton D Vacutainer	13	81 / 75	K2-EDTA	4
Greiner Vacuette	13	82 / 75	K2-EDTA K3-EDTA	2 - 4.5
HORIBA Medical ABX Minocal ABX Difftrol	12	81.3 / 77	None	3

- One optional Sarstedt rack with a ten tubes capacity: 1300066019.



The use of Sarstedt racks requires a specific mechanical and software configuration.
For more detailed information, please contact your local HORIBA Medical representative.

Tubes with Cap

Manufact. Model	Diameter (mm)	Height (mm) With cap / Without cap	Additive	Vol. (mL)
Becton D Vacutainer	13	81 / 75	K2-EDTA	4
Greiner Vacuette	13	82 / 75	K2-EDTA K3-EDTA	2 - 4.5
KABE Kabevette G	12.5	81 / 72	K2-EDTA K3-EDTA	3.5
Sarstedt Monovette	13	81 / 65	K2-EDTA K3-EDTA	2.6
Sarstedt Monovette	11.5	82.5 / 66	K2-EDTA K3-EDTA	2.7
HORIBA Medical ABX Minocal ABX Difftrol	12	81.3 / 77	None	3

4. Summary of Performance Data

4.1. Precision: Reproducibility Claims

Expected Precision (Reproducibility) on ABX Difftrol

Parameter (Conventional Units)	Low level (%CV)	Normal level (%CV)	High level (%CV)
WBC	5	4	3
RBC	3	2.5	2.5
HGB	2.5	2	2
HCT	5	4	3
MCV	3	2.5	2
MCH	3	2.5	2.5
MCHC	3.5	3	3
RDW-CV	5	5	5
RDW-SD	6	6	6
PLT	13	8	7
MPV	6	5	5
LYM#	12	8	8
LYM%	8	8	8
MON#	30	15	15
MON%	30	15	15
NEU#	12	7	4
NEU%	8	6	4
EOS#	25	25	25
EOS%	25	25	25
BAS#	40	40	40
BAS%	40	40	40
IMG#	40	40	40
IMG%	40	40	40

4.2. Precision: Repeatability Claims

The study is based on 12 consecutive runs without alarm of the same fresh whole blood sample.

Parameter	Low level		Normal level		High level	
	CV limits % (Absolute value #)	Range Conventional Units	CV limits % (Absolute value #)	Range Conventional Units	CV limits (%)	Range Conventional Units
WBC	10% (+/- 0.3#[a])	0.2 - 4	3	4 - 10	3	10 - 300
RBC	3	0.5 - 3.6	2	3.6 - 6.2	2	6.2 - 8
HGB	1.5% (+/- 0.2#[a])	5 - 12	1.5	12 - 18	1.5	18 - 24
HCT	3	10 - 36	2	36 - 54	2	54 - 67
MCV	1.5	< 80	1.5	80 - 100	1.5	> 100
MCH	N/A[b]	N/A	2	27 - 32	N/A	N/A
MCHC	N/A	N/A	2	32 - 36	N/A	N/A
RDW-CV	N/A	N/A	4	5 - 16	4	> 16
RDW-SD	N/A	N/A	4	10 - 49	4	> 49
MIC	N/A	N/A	15	2 - 20	10	20 - 100
MAC	N/A	N/A	15	2 - 10	10	10 - 100
PLT	10% (+/- 10#[a])	10 - 180	5	180 - 500	5	500 - 1000
MPV	N/A	N/A	3	8 - 12[c]	N/A	N/A
PCT	N/A	N/A	6	0.15 - 0.4	N/A	N/A
PDW	N/A	N/A	10	11 - 20	N/A	N/A
P-LCR	10	< 15[c]	10	15 - 35[c]	20	> 35[c]
P-LCC	N/A	N/A	10	40 - 130[c]	6	130 - 500[c]
LYM#	N/A	N/A	10	0.8 - 5[d]	6	> 5[d]
LYM%	7	10 - 25[d]	5	25 - 50[d]	4	50 - 75[d]
MON#	N/A	N/A	20	0.1 - 1[d]	12	> 1[d]
MON%	N/A	N/A	15	5 - 10[d]	10	> 10[d]
NEU#	N/A	N/A	6	2 - 8[d]	4	> 8[d]
NEU%	6	0 - 45[d]	3.5	45 - 80[d]	6	80 - 90[d]
EOS#	N/A	N/A	25 +/- 0.1	0.04 - 0.5[d]	20	> 0.5[d]
EOS%	N/A	N/A	20	2 - 5[d]	15	> 5[d]
BAS#	N/A	N/A	40 +/- 0.1	0.00 - 0.25[d]	25	> 0.25[d]
BAS%	N/A	N/A	40 +/- 1	0 - 2[d]	20	> 2[d]
ALY#	N/A	N/A	40 +/- 0.1	0 - 0.25[d]	40	> 0.25[d]
ALY%	N/A	N/A	40 +/- 1	0.5 - 3[d]	40	> 3[d]
LIC#	N/A	N/A	N/A	N/A	40	> 0.2[d]
LIC%	N/A	N/A	N/A	N/A	40	> 2[d]
IML#	N/A	N/A	20 +/- 0.1	0 - 0.2[d]	20	> 0.2[d]
IML%	N/A	N/A	40 +/- 1	0.5 - 3[d]	20	> 3[d]

[a]: The notation +/- indicates a tolerance range on the returned value and not a coefficient of variation
[b]: Not Applicable
[c]: Applicable only if **PLT** > 50 $10^3/mm^3$
[d]: Applicable only if **WBC** > 4 $10^3/mm^3$

Parameter	Low level		Normal level		High level	
	CV limits % (Absolute value #)	Range Conventional Units	CV limits % (Absolute value #)	Range Conventional Units	CV limits (%)	Range Conventional Units
IMM#	N/A	N/A	20 +/- 0.1	0 - 0.2[d]	20	> 0.2[d]
IMM%	N/A	N/A	40 +/- 1	0.5 - 3[d]	20	> 3[d]
IMG#	N/A	N/A	20 +/- 0.1	0 - 0.2[d]	20	> 0.2[d]
IMG%	N/A	N/A	20 +/- 1	0.5 - 3[d]	20	> 3[d]

[a]: The notation +/- indicates a tolerance range on the returned value and not a coefficient of variation
[b]: Not Applicable
[c]: Applicable only if **PLT** > 50 $10^3/mm^3$
[d]: Applicable only if **WBC** > 4 $10^3/mm^3$

4.3. Analytical Measuring Range

Analytical measuring range (AMR): maximum values (upper limits) and minimum values (LoQ) within which the instrument returns values not associated with the following alarms: ▼ / ▲.

LoQ (Limit of Quantitation): lowest concentration at which the analyte cannot only be reliably detected but at which some predefined goals for bias and imprecision are met. It corresponds to the analytical sensitivity. The values below the LoQ are associated with a "▼" alarm.

Extended range: range values given by the instrument. These values (above AMR) are given as an indication. They are associated with a "▲" alarm. This extended range is outside manufacturer range.

Linearity kits: linearity was tested using commercially available "Low Range" and "Full Range" linearity test kits. The test kits were analyzed and data was computed according to the manufacturer instructions.

Human blood: linearity was also performed on human blood, using a minimum of five dilution points.

Parameter	Analytical Measuring Range	Error Limit		Extended range
	Conventional Units	Absolute value Conventional Units	%	Conventional Units
WBC	0.2 - 300	+/- 0.3	+/- 5	300 - 999
RBC	0.2 - 8	+/- 0.15	+/- 2	8 - 18
HGB	1 - 24	+/- 0.3	+/- 2	24 - 30
HCT	2 - 67	+/- 1	+/- 3	67 - 80
PLT (HGB > 1.5)	10 - 2500	+/- 10	+/- 8	2500 - 4000
PLT (HGB < 1.5)	10 - 4000	+/- 10	+/- 8	4000 - 5000

4.4. Carry Over

Carry-over was assessed by running a sample with low values for the following parameters three times in a row ($L_1$1, $L_1$2, $L_1$3) followed by a sample with high values, also 3 consecutive times (H1, H2, H3) and finally by running again the sample with low values three times ($L_2$1, $L_2$2, $L_2$3).

$$\text{Carry-over (\%)} = \frac{(L_2 1 - L_2 3)}{(H3 - L_2 3)} \times 100$$

Parameter	Maximum carry-over accepted (%)	Maximum Concentration of the lower level (L) Conventional Units	Minimum Concentration of the upper level (H) Conventional Units
WBC	0.6	3	90
RBC	1	1.5	6.2
HGB	1	5	22
PLT	1	30	900

4.5. Reference Values

4.5.1. Adult Reference Values

Reference values are taken from several bibliographic references listed in the *Bibliography: Reference Values* chapter.

The reference values vary according to the population and / or the region. Each laboratory is strongly advised to establish its own set of normal ranges according to the local population.

Parameter (Conventional Units)	Female	Male
RBC	3.93 - 5.19	4.28 - 5.79
HGB	11.5 - 15.1	13.4 - 16.7
HCT	34.4 - 44.6	39.2 - 48.6
MCV	74.7 - 95.6	79.6 - 97.0
MCH	26.4 - 32.6	27.3 - 32.8
MCHC	31.9 - 35.8	32.4 - 36.3
RDW-SD	37.0 - 56.0	37.0 - 56.0
RDW-CV	12.0 - 18.0	12.0 - 18.0
MIC	0.0 - 20.0	0.0 - 20.0
MAC	2.0 - 10.0	2.0 - 10.0
PLT	185 - 445	161 - 398
PCT	0.150 - 0.400	0.150 - 0.400
PDW	11.0 - 20.0	11.0 - 20.0
MPV	7.5 - 10.9	7.4 - 10.8
P-LCC	44 - 140	44 - 140
P-LCR	18.0 - 50.0	18.0 - 50.0

Parameter (Conventional Units)	Female	Male
WBC	3.78 - 11.42	4.05 - 11.0
LYM#	1.24 - 3.97	1.24 - 3.92
LYM%	15.0 - 45.0	15.0 - 45.0
MON#	0.19 - 0.71	0.23 - 0.77
MON%	4.0 - 13.0	4.0 - 13.0
NEU#	1.69 - 7.50	1.78 - 6.95
NEU%	40.0 - 75.0	40.0 - 75.0
EOS#	0.04 - 0.55	0.05 - 0.59
EOS%	0.5 - 7.0	0.5 - 7.0
BAS#	0.00 - 0.09	0.00 - 0.10
BAS%	0.0 - 2.0	0.0 - 2.0
IMG#	0.00 - 0.50	0.00 - 0.50
IMG%	0.0 - 2.0	0.0 - 2.0
IMM#	0.00 - 0.10	0.00 - 0.10
IMM%	0.0 - 0.5	0.0 - 0.5
IML#	0.00 - 0.05	0.00 - 0.05
IML%	0.0 - 0.2	0.0 - 0.2
ALY#	0.00 - 0.20	0.00 - 0.20
ALY%	0.0 - 2.5	0.0 - 2.5
LIC#	0.00 - 0.20	0.00 - 0.20
LIC%	0.0 - 3.0	0.0 - 3.0

Related information:
■ Bibliography: Reference Values, p.49

4.5.2. Pediatric Reference Values

Reference values are taken from several bibliographic references listed in the *Bibliography: Reference Values* chapter.

Parameter (Conventional Units)	0 - 30 days	1 - 6 months	6 months - 2 years	2 - 6 years
RBC	3.16 - 5.74	2.93 - 4.80	3.97 - 5.07	3.84 - 4.97
HGB	10.0 - 20.0	8.9 - 12.7	10.1 - 12.7	10.2 - 12.7
HCT	30.5 - 57.2	26.8 - 37.5	30.8 - 37.9	31.0 - 37.8
MCV	89.4 - 106.4	74.1 - 96.4	69.5 - 82.6	71.3 - 85.0
MCH	29.9 - 35.9	24.4 - 32.5	22.7 - 27.5	23.7 - 28.6
MCHC	32.7 - 35.7	31.9 - 34.9	31.6 - 34.4	31.8 - 34.7
RDW-SD	46.3 - 65.7	35.2 - 55.0	34.9 - 42.8	34.9 - 42.0
RDW-CV	14.3 - 17.3	12.2 - 16.1	12.7 - 15.6	12.4 - 14.9
MIC	ND[a]	ND	ND	ND
MAC	ND	ND	ND	ND

[a]: ND = Not defined

Parameter (Conventional Units)	0 - 30 days	1 - 6 months	6 months - 2 years	2 - 6 years
PLT	144 - 586	229 - 597	206 - 459	189 - 403
PCT	ND	ND	ND	ND
PDW	ND	ND	ND	ND
MPV	10.0 - 12.2	8.9 - 11.1	8.7 - 10.6	8.9 - 11.0
P-LCC	ND	ND	ND	ND
P-LCR	ND	ND	ND	ND
WBC	7.80 - 15.91	6.00 - 14.99	5.98 - 13.51	4.86 - 13.38
LYM#	1.75 - 8.38	2.14 - 9.14	1.52 - 8.09	1.13 - 5.77
LYM%	24.9 - 82.7	30.4 - 86.7	26.0 - 79.9	18.1 - 68.6
MON#	0.28 - 1.77	0.24 - 1.21	0.25 - 1.15	0.19 - 0.94
MON%	4.3 - 20.6	3.8 - 15.5	3.8 - 13.4	4.1 - 12.2
NEU#	1.18 - 6.75	0.83 - 7.20	1.19 - 7.21	1.54 - 8.29
NEU%	10.6 - 66.1	10.6 - 66.1	16.9 - 74.0	22.4 - 69.0
EOS#	0.06 - 0.80	0.02 - 0.74	0.02 - 0.82	0.03 - 0.53
EOS%	0.0 - 5.4	0.0 - 4.5	0.0 - 3.7	0.0 - 4.1
BAS#	0.01 - 0.11	0.01 - 0.07	0.01 - 0.06	0.01 - 0.06
BAS%	0.0 - 0.8	0.0 - 0.6	0.0 - 0.6	0.0 - 0.6
IMG#	ND	ND	ND	ND
IMG%	ND	ND	ND	ND
IMM#	ND	ND	ND	ND
IMM%	ND	ND	ND	ND
IML#	ND	ND	ND	ND
IML%	ND	ND	ND	ND
ALY#	ND	ND	ND	ND
ALY%	ND	ND	ND	ND
LIC#	ND	ND	ND	ND
LIC%	ND	ND	ND	ND

[a]: ND = Not defined

Parameter (Conventional Units)	6 - 12 years	12 - 15 years	15 - 18 years	18 - 21 years	
				Female	Male
RBC	3.90 - 5.03	3.93 - 5.29	3.93 - 5.29	3.70 - 4.87	4.18 - 5.48
HGB	10.6 - 13.4	10.8 - 14.5	10.8 - 14.5	10.6 - 13.5	11.9 - 15.4
HCT	32.2 - 39.8	33.4 - 43.5	33.4 - 43.5	32.9 - 41.2	36.2 - 46.3
MCV	74.4 - 87.6	76.7 - 90.6	76.7 - 90.6	77.7 - 93.7	80.0 - 93.6
MCH	24.8 - 29.5	24.8 - 30.2	24.8 - 30.2	25.3 - 30.9	26.5 - 31.4
MCHC	31.8 - 34.9	31.5 - 34.8	31.5 - 34.8	31.0 - 34.1	31.9 - 34.8
RDW-SD	35.1 - 41.8	36.7 - 44.2	36.7 - 44.2	38.4 - 47.7	37.8 - 46.1
RDW-CV	12.2 - 12.4	12.3 - 14.6	12.3 - 14.6	12.4 - 15.1	12.3 - 14.3
MIC	ND[(a)]	ND	ND	0.0 - 20.0	0.0 - 20.0
MAC	ND	ND	ND	2.0 - 10.0	2.0 - 10.0
PLT	199 - 369	175 - 345	175 - 345	186 - 353	151 - 304
PCT	ND	ND	ND	0.150 - 0.400	0.150 - 0.400
PDW	ND	ND	ND	11.0 - 20.0	11.0 - 20.0

[a]: ND = Not defined

Parameter (Conventional Units)	6 - 12 years	12 - 15 years	15 - 18 years	18 - 21 years	
				Female	Male
MPV	9.2 - 11.4	9.6 - 11.8	9.6 - 11.8	9.6 - 12.0	9.7 - 11.9
P-LCC	ND	ND	ND	44 - 140	44 - 140
P-LCR	ND	ND	ND	18.0 - 50.0	18.0 - 50.0
WBC	4.27 - 11.40	3.84 - 9.84	3.84 - 9.84	4.37 - 9.68	3.91 - 8.77
LYM#	0.97 - 4.28	0.97 - 3.33	0.97 - 3.33	1.16 - 3.18	0.85 - 3.00
LYM%	15.5 - 57.8	16.4 - 52.7	16.4 - 52.7	18.2 - 47.4	12.2 - 47.1
MON#	0.19 - 0.95	0.18 - 0.78	0.18 - 0.78	0.29 - 0.71	0.19 - 0.77
MON%	4.2 - 12.3	4.1 - 12.3	4.1 - 12.3	4.3 - 11.0	4.4 - 12.3
NEU#	1.63 - 7.87	1.54 - 7.47	1.54 - 7.47	2.00 - 7.15	1.82 - 7.42
NEU%	28.6 - 75.4	32.5 - 74.7	32.5 - 74.7	42.5 - 73.2	40.3 - 74.8
EOS#	0.03 - 0.52	0.02 - 0.38	0.02 - 0.38	0.03 - 0.27	0.03 - 0.44
EOS%	0.0 - 4.7	0.0 - 4.0	0.0 - 4.0	0.0 - 3.0	0.0 - 4.4
BAS#	0.01 - 0.06	0.01 - 0.05	0.01 - 0.05	0.01 - 0.05	0.01 - 0.05
BAS%	0.0 - 0.7	0.0 - 0.7	0.0 - 0.7	0.0 - 0.7	0.0 - 0.7
IMG#	ND	ND	ND	0.00 - 0.50	0.00 - 0.50
IMG%	ND	ND	ND	0.0 - 2.0	0.0 - 2.0
IMM#	ND	ND	ND	0.00 - 0.10	0.00 - 0.10
IMM%	ND	ND	ND	0.0 - 0.5	0.0 - 0.5
IML#	ND	ND	ND	0.00 - 0.05	0.00 - 0.05
IML%	ND	ND	ND	0.0 - 0.2	0.0 - 0.2
ALY#	ND	ND	ND	0.00 - 0.20	0.00 - 0.20
ALY%	ND	ND	ND	0.0 - 2.5	0.0 - 2.5
LIC#	ND	ND	ND	0.00 - 0.20	0.00 - 0.20
LIC%	ND	ND	ND	0.0 - 3.0	0.0 - 3.0

[a]: ND = Not defined

Related information:
■ Bibliography: Reference Values, p.49

4.5.3. Bibliography: Reference Values

Full Blood Count

Adults (≥ 21 years)

1	Troussard X, Vol S, Cornet E, Bardet V, Couaillac JP, Fossat C, Luce JC, Maldonado E, Siguret V, Tichet J, Lantieri O, Corberand J. Full blood count normal reference values for adults in France. Journal of Clinical Pathology (2014) **67** (4): 341-4.
2	HORIBA Medical clinical performance report

18 - 21 years

1	Soldin SJ, E.C. Wong, C. Brugnara, O.P. Soldin Pediatric Reference Intervals - Seventh Edition Washington, DC: AACC press, 2011.
2	HORIBA Medical clinical performance report

Pediatrics (0 - 18 years)

1	Soldin SJ, E.C. Wong, C. Brugnara, O.P. Soldin Pediatric Reference Intervals - Seventh Edition Washington, DC: AACC press, 2011.

4.6. Accuracy

The Accuracy performance was proven by comparing the Yumizen H550 with a recognized comparison instrument using whole blood specimens of patients, operating within normal functioning range:

Parameters Conventional Units	Maximum bias Absolute value # (%)	R claim (comparison of means)
WBC	+/- 0.3# (+/- 6%)	> 0.97
RBC	+/- 0.2# (+/- 2%)	> 0.97
HGB	+/- 0.5# (+/- 2%)	> 0.97
HCT	+/- 1# (+/- 4%)	> 0.97
MCV	+/- 3# (+/- 3%)	> 0.88
RDW-CV	+/- 2# (+/- 4%)	> 0.75
RDW-SD	+/- 5# (+/- 10%)	> 0.80
MIC	N/A[a]	> 0.89
MAC	N/A	> 0.70
PLT	+/- 10# (+/- 10%)	> 0.97
MPV	+/- 3# (+/- 25%)	> 0.84
PCT	+/- 0.08# (+/- 20%)	> 0.90
P-LCR	+/- 10# (+/- 10%)	> 0.80
P-LCC	+/- 10# (+/- 5%)	> 0.80
PDW	+/- 5# (+/- 20%)	> 0.80
LYM#	+/- 0.3# (+/- 10%)	> 0.97
LYM%	+/- 3# (+/- 10%)	> 0.97
MON#	+/- 0.2# (+/- 13%)	> 0.89
MON%	+/- 2# (+/- 13%)	> 0.89
NEU#	+/- 0.3# (+/- 9%)	> 0.97
NEU%	+/- 5# (+/- 9%)	> 0.97
EOS#	+/- 0.2# (+/- 20%)	> 0.95
EOS%	+/- 1# (+/- 20%)	> 0.95
BAS#	+/- 0.3# (+/- 35%)	> 0.65
BAS%	+/- 1.5# (+/- 35%)	> 0.45
ALY#	N/A	> 0.70
ALY%	N/A	> 0.70
LIC#	N/A	> 0.75
LIC%	N/A	> 0.75
IML#	N/A	> 0.70
IML%	N/A	> 0.70

[a]: Not Applicable

Parameters Conventional Units	Maximum bias Absolute value # (%)	R claim (comparison of means)
IMM#	N/A	> 0.70
IMM%	N/A	> 0.70
IMG#	+/- 0.5# (+/- 30%)	> 0.70
IMG%	+/- 2.5# (+/- 30%)	> 0.70

[a]: Not Applicable

5. Sample Collection and Mixing

All blood samples should be collected using proper technique.

Use established good laboratory working practice when collecting specimens. Otherwise, patient results may be impacted. For additional information on collecting venous blood samples and capillary blood samples, refer to CLSI document GP41-A7 and CLSI document GP42-A6.
Be careful of the risk of platelet clumps linked to capillary blood collection technique. There is a potential impact of the capillary collection method on results of the platelet count and MPV parameters. The laboratory should review the sample matrix information and heed any flagging regarding platelet aggregates. The laboratory should ensure that blood collection personnel follow specific instructions for drawing capillary blood, as defined by the laboratory and published guidance documents.

Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other biosafety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent biosafety procedures.

When collecting blood specimens, venous blood is recommended. Blood collection must be placed in vacuum or atmospheric collection tubes.

The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself. Any incorrectly measured blood sample collection will show a variation in results.

5.1. Recommended Anticoagulant

Blood sample

The recommended anticoagulants are K2-EDTA and K3-EDTA. Make sure you respect the blood to anticoagulant ratio specified by the tube manufacturer.

Clotted samples: Clotted samples cannot produce correct hematology results and are a cause for specimen rejection. The presence of clots in EDTA samples can be explained primarily due to increased blood to additive ratio (could be due to higher than optimal volume transferred to tubes in open collection) or improper mixing of the sample after collection. Mix the EDTA-containing blood collection tube by at least 10 complete inversions immediately after filing to prevent clotting. Microclots in whole blood could pose a major risk of erroneous results and analyzer breakdown.

Bibliographical references:

Ashavaid T. F. et al: Influence of method of specimen collection on various preanalytical sample quality indicators in EDTA blood collected for cell counting, Ind. J. Clin. Biochem. 24(4), 356-360, 2009.

Laboratory Standards (CLSI) documents: *Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - Second Edition*, CLSI document H26-A2 (ISBN 1-56238-728-6), 2010

5.2. Sample Stability

General Recommendations

Fresh whole blood specimens are recommended. Well mixed blood specimens, collected in EDTA anti-coagulant and run within eight hours after collection may provide the most accurate results for all parameters. The white cell size distribution may shift when specimens are assayed between five and twenty minutes after collection and more than eight hours after collection.

The ICSH (International Council for Standardization in Hematology) defines a fresh blood specimen as "One processed within 4 hours after collection".

Sample Stability

Parameter	Room temperature	Refrigerated temperature +2°C (+35.6°F) - +8°C (+46.4°F)
CBC	24 h	48 h
MPV	24 h	24 h
DIFF	24 h	24 h

5.3. Microsampling

Instrument manual sampling mode enables the user to work with 100 µL microsamples (for pediatrics and geriatrics).

The quantity of blood aspirated in this mode is 20 µL.

On microsampling tubes, the 100 µL volume can only be used in the following conditions:

- the tube must always be held in a vertical position,
- blood mixing must be obtained by a slight tapping on the tube. Do not rotate the tube for mixing, otherwise the blood will be spread on the tube wall, and the minimum required level will be lost.

5.4. Specimen Volume

Quantity of whole blood aspirated

- Manual analysis: 20 µL
- Rack analysis: 20 µL

Minimum specimen volume recommended

- Automatic mode (rack): 2 mL
- Manual analysis: three quarters of the nominal volume of the tube

Risk of erroneous results due to incomplete sampling if the specimen volume is too low. Do not run a blood sample which volume is less than the minimum specimen volume recommended.

Risk of erroneous results due to incomplete sampling if the specimen volume is too low. Do not run a blood sample which volume is less than the minimum specimen volume recommended.

Related information:
- Sampling Principles, p.271

5.5. Mixing

For manual mode, blood samples must be gently and thoroughly mixed right before sampling. This ensures a homogeneous mixture for measurement.

The rack mode performs an automatic mixing by rotation (up to 120°) which lasts: 30 - 40 s

5.6. Tubes Labelling Best Practices

Only one barcode label can be stuck on the tube. Risk of patient misidentification if several barcode labels are stuck on the tube.

CLSI[a] recommendations

- The length of the barcode symbol shall not exceed 60 mm including the required minimum quiet zone of 5 mm at each end of the symbol.
- The height of the barcode symbol on the collection tube shall not be less than 10 mm.
- The total size of the label may be more than 10 by 60 mm to allow for human readable information to be printed.
- The label shall be placed with the bars perpendicular to the axis of the tube. The label skew shall be less than ± 5° with respect to the axis of the sample container.
- Instrument readers shall accommodate a barcode symbol including quiet zone placed within a zone of 0 to 62 mm from rim of sample container. The label shall be applied to the cylindrical portion of the tube below the rim, skirt, or cap of the sample container.

Recommendations on Printing the Barcode Labels

Misprinted patient identification barcodes or barcodes with bad interpretation may generate incorrect patient identification numbers.

[a]Clinical Laboratory Standards Institute: Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory. LIS7-A, Vol. 23 No. 13

Caution About Partial Scans using Interleaved 2 of 5 encoded identification: It should be noted that where variable length ITF symbols are used without a check digit, there is a danger of the scanner misinterpreting a partially scanned code as a complete code. We suggest that Interleaved 2-of-5 always be used with the **Check Digit** option enabled or that you standardize on a **single character length** of Interleaved 2-of-5 barcodes.

The size of a barcode varies within certain limits depending on print conditions. The width of the symbol must be selected so that each bar corresponds to the entire number of the printer dots except when the width of the barcode bars varies within +/- 1 printer dot and especially for low printing resolution with larger size dots. The margins on the left and right sides of the barcode must always be proportional to the width of the symbol. Therefore, ensuring high quality of each barcode as well as accuracy and correct data structure.

6. Reagents Specifications

In order for the instrument to operate correctly, high-quality reagents must be used.

HORIBA Medical provides a full range of reagents.

These reagents are used for *in vitro* diagnostic.

All these reagents are manufactured by **HORIBA ABX SAS**.

Refer to the reagent notices and material safety data sheets for Yumizen H550 available online at www.horiba-abx.com/documentation.

The reagents specified for this instrument have been approved in accordance with the applicable *in vitro* medical devices European legislation in force.

HORIBA Medical manufactures and markets reagents, calibrators and controls specially designed for use with this analyzer. The use of products not recommended may give erroneous results or cause instrument operation problems. For all information regarding the recommended products, please contact your local representative.

6.1. Reagents Location

Risk of erroneous results if the diluent container is not at the same level as the instrument. The diluent container must be installed at the same level as the instrument (on the bench).

- **Diluent input tubing**: tygon 3x6 / 1 meter (40 in.) maximum
- **Waste output tubing**: cristal 4x6 / 2 meters (80 in.) maximum.

1 = ABX Minoclair

2 = ABX Cleaner

3 = Whitediff 1L

4 = ABX Diluent

5 = Waste tank

6.2. Reagents Description

- You must verify the period of stability mentioned in the reagent notices and dispose of them when they exceed the expiration date to ensure correct results.
- Make sure that your new reagents return to the operating conditions temperature before use.
- Always close your reagent container during use. Use the appropriate operational caps provided with the instrument. Put the original caps back when you remove the reagents from the machine.
- Never pour reagents into the laboratory waste water drainage system. Follow local/ national regulations for chemical waste disposal.

Yumizen H550

Our company recommends that you use the following reagents on your Yumizen H550:

Reagent name	Volume	Use
ABX Diluent	10 L[a] 20 L	Dilution, sleeving and rinsing: RBC/PLT
ABX Cleaner	1 L (integrated)	Cleaning
Whitediff 1L (cyanide free)	1 L (integrated)	Measurement: HGB Differentiation: WBC
ABX Minoclair	0.5 L (non-integrated)	Concentrated cleaning procedure

[a]: If you want to use this reagent volume, contact your HORIBA Medical technical representative.

6.3. Reagents Consumption

Reagent consumption is given in mL per cycle.

6.3.1. Analyses cycles

Cycles	ABX Diluent	Whitediff 1L	ABX Cleaner	ABX Minoclair
Automatic instrument start	66.97	1.70	8.54	X
Startup (background noise check)	18.03	1.23	X	X
Analysis	17.74	1.24	X	X
***Priming/Unpriming* - ABX Diluent**	51.22	X	X	X
***Priming/Unpriming* - Whitediff**	2.74	15.64	X	X
***Priming/Unpriming* - ABX Cleaner**	X	X	8.96	X
***Priming/Unpriming* - All reagents**	53.97	15.74	9.38	X
Shutdown	31.42	X	53.5	X

6.3.2. Maintenance cleaning cycles

Cycles	ABX Diluent	Whitediff 1L	ABX Cleaner	ABX Minoclair
Auto rinse cycle[a]	28.17	1.61	X	X
Autoclean Cycle	37.17	X	X	X
Automatic autoclean cycle[b]	21.2	X	X	X
Concentrated Cleaning Cycle	53.11	1.26	10.90	56.99
Autocontrol	48.94	0.47	8.54	X
Backflush RBC/PLT	4.85	X	X	X
Backflush LMNEB	7.4	X	X	X
Mechanical initialization	1.59	X	X	X

[a]: The auto rinse cycle is performed after one hour of inactivity or when pressing **Rinse** in the ***Hydraulic services*** menu.
[b]: The automatic autoclean cycle is automatically performed according to the frequency defined in the ***Cycles*** screen (40 by default).

6.4. Reagent Notices and Safety Data Sheets

The documentation media (USB flash drive) delivered with your instrument provides reagents, controls and calibrators leaflets and material safety data sheets. Latest versions of these documents are available online at www.horiba-abx.com/documentation.

6.5. Waste Handling Precautions

The specimens, reagents, calibrators, controls, etc. and waste liquids that contain human specimen extracts are potentially infectious; all accessible surfaces of the instrument can be potentially contaminated by human specimens.
Protective clothing must be worn (lab coat, gloves, eye protection, etc.).

- At the beginning of each day, before startup, check if the waste container needs to be emptied.
- During instrument operation, do not remove the reagent tubing and the liquid waste tubing under any circumstance.

Follow your local and/or national guidelines for biohazard waste disposal.

- If required, waste can be neutralized before being discarded. Follow your laboratory protocol when neutralizing and disposing of waste.
- Dispose of the waste container according to your local and/or national regulatory requirements.

7. Limitations

7.1. Maintenance

In the *Maintenance and Troubleshooting* section, specific maintenance procedures are listed. The maintenance procedures identified are mandatory for proper use and operation of the Yumizen H550.

Failure to execute any of these recommended procedures may result in poor reliability of the system.

7.2. Blood Specimens

Verification of any abnormal test result (including flagged results or results outside of the normal range) should be performed using reference methods or other standard laboratory procedures for conclusive verification of the results. The chapter below lists known limitations of automated blood cell counters, which use the principles of impedance and light absorbance as principles of measurement.

7.3. Known Interfering Substances

Interfering substances may cause erroneous test results. Verification of any abnormal test result (including flagged results or results outside of the normal range) should be performed using reference methods or other standard laboratory procedures.
While every effort is taken by HORIBA Medical to investigate and indicate all known interferences, it is not possible to guarantee that all interferences have been identified.

7.3.1. Evaluation of Potential Interferences

Interfering Element	May interfere with:	No interference detected on:*
Leukocytosis WBC > 100 10^3/mm^3	MCV Low MCV - WBC ≥ 33 10^3/mm^3	RBC / HGB / PLT / MPV
Platelet aggregates or **Erythroblasts**	WBC / WBC differential / PLT	-
Fragile WBC	WBC / WBC differential	-
RBC: dual population	-	MCV
RBC: fragments (schistocytes)	PLT	RBC / MCV
RBC: microcytosis MCV < 70 μm^3	PLT	-
Thrombocytosis PLT > 800 10^3/mm^3	-	WBC / RBC / HGB / MPV
Hyperbilirubinemia Total bilirubin > 825 µmol/L	-	HGB / PLT
Hyperglycemia Glucose > 65 mmol/L	-	MCV
Lipemia Triglycerides > 16.9 mmol/L	**HGB** ■ Low HGB - Triglycerides ≥ 2.5 mmol/L ■ High HGB - Triglycerides ≥ 6.7 mmol/L **PLT** ■ Low PLT - Triglycerides ≥ 5.6 mmol/L	WBC / WBC differential
Hemolysis HGB > 1 g/dL	-	WBC / WBC differential / HGB
Bacteria / Fungi / Yeasts *Saccharomyces boulardii* Concentration 500 mg/L	-	PLT

* Even if some of the tests did not show any significant effect, these known interfering elements are mentioned in the *Detailed Known Interferences* chapter.

7.3.2. Detailed Known Interferences

7.3.2.1. Interferences on White Blood Cells (WBC)

Unlysed red blood cells: in some cases of membrane resistance, partial lysis of red blood cells may be observed. This may also occur if substances in the plasma interfere with the lysing action of the reagents. These unlysed red blood cells may cause an erroneously high white blood cell count. These unlysed red cells can be detected on the WBC curve via a background noise alarm.

Hemolysis: hemolyzed specimens contain an erythrocyte stroma, which may cause elevated white blood cell counts.

Malaria: presence of malaria specimen may cause elevated white blood cell counts.

Platelet agglutination: the accumulation of platelets may interfere on white blood cell count. Platelet agglutination triggers the PLT aggregates? / PLT aggregates or NRBC? / PLT channel unstable measure alarms.

Macrothrombocytes: in excessive numbers, they may affect the leukocyte count by increasing the number of leukocytes counted.

Leukemia: leukemia can cause fragility of the leukocytes and subsequent destruction of these cells during the count, thus resulting in an abnormally low white blood cell count. These leukocytic fragments may also interfere with the various parameters of the differential white cell count. The presence of small lymphocytes, in certain cases (chronic lymphoblastic leukemia or others), may cause underestimation of the leukocyte count.

Multiple myeloma: the precipitation of immunoglobulins in patients with multiple myeloma may give elevated WBC counts.

Cryoglobulins: the increased levels of cryoglobulins that may be associated with various conditions (myeloma, carcinoma, leukemia, macroglobulinema, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, aneurysms, pregnancy, thromboembolic phenomena, diabetes, etc.), may cause an increase in the leukocyte, erythrocyte, and platelet counts and the hemoglobin concentration. The samples should be warmed to 37°C (98.6°F) in a water bath for 30 minutes, and then rerun immediately afterwards (using the analyzer or a manual method).

Erythroblasts: high concentration of erythroblasts may interfere on the leukocyte count. Erythroblasts trigger the NRBC? alarms.

Chemotherapy: cytotoxics and immunosuppressants may weaken the leukocyte membranes and result in a low leukocyte count.

7.3.2.2. Interferences on Red Blood Cells (RBC)

Agglutinated red blood cells: these may cause a falsely low RBC count. Blood samples containing agglutinated red blood cells can be identified by abnormal elevated MCH and MCHC values, and by the examination of a stained blood smear.

Cold agglutinins: IgM, which are elevated in Cold Agglutinin Disease, may lower erythrocyte and platelet counts and increase the MCV. The samples should be warmed to 37°C (98.6°F) in a water bath for 30 minutes and then rerun immediately afterwards (using the analyzer or a manual method).

7.3.2.3. Interferences on Hemoglobin (HGB)

Turbidity of the blood sample: several physiological and/or therapeutic factors may produce falsely elevated hemoglobin results. To obtain accurate results in blood samples with increased turbidity, determine the cause of the turbidity and follow the appropriate method below:

- An elevated leukocyte count: a very high leukocyte count will cause excessive diffusion of the light. In such cases, the reference methods (manual) should be used. The diluted sample should be centrifuged, and the supernatant fluid measured with a spectrophotometer.
- Elevated lipemia: elevated lipemia levels make the plasma look milky. This phenomenon can be seen in hyperlipidemia, hyperproteinemia (as in gammopathies) and hyperbilirubinemia.

Accurate hemoglobin measurement can be achieved by using reference (manual) methods, plasma blank and by plasma substitution.

Increased turbidity: this phenomenon can be seen with red blood cells that are resistant to lysis. It causes a falsely elevated HGB concentration, but can be detected with abnormal MCHC and MCH values.

Fetal blood: the mixing of fetal and maternal bloods may produce a falsely elevated hemoglobin value.

7.3.2.4. Interferences on Hematocrit (HCT)

Red blood cells agglutination: can cause an inaccurate HCT value. Red blood cell agglutination may be detected by observing abnormal elevated MCV and MCH values, and by examining a stained blood smear. In such cases, manual methods may be required to obtain an accurate hematocrit value.

7.3.2.5. Interferences on the Mean Corpuscular Volume (MCV)

Red blood cell agglutination: can cause an abnormal MCV value. Red blood cell agglutination may be detected by observing abnormal elevated MCH and MCHC values, and by examining a stained blood smear.

Excessive numbers of large platelets and/or the presence of an excessively high WBC count: may interfere with the accurate determination of the MCV value. In such cases, careful examination of a stained blood smear may reveal the error.

7.3.2.6. Interferences on the Mean Corpuscular Hemoglobin (MCH)

The interferences cited for HGB and RBC affect the MCH and may cause inaccurate results.

7.3.2.7. Interferences on the Mean Corpuscular Hemoglobin Concentration (MCHC)

The interferences cited for HGB and the HCT affect the MCHC and may cause inaccurate results.

7.3.2.8. Interferences on the Red Distribution Width (RDW-CV and RDW-SD)

The interferences cited for RBC and MCV affect the RDW parameters and may cause inaccurate results.

Red blood cell agglutination: this phenomenon may cause a falsely low erythrocyte count and an erroneous RDW. In the blood samples, red blood cell agglutination may be detected by observing abnormal elevated MCH and MCHC values, and by examining a stained blood smear.

Nutritional deficiency or blood transfusion: these phenomena may cause elevated RDW results due to iron, vitamin B12, or folate deficiencies. It is also possible to observe an elevated RDW from the bimodal distribution of red blood cells from transfused blood.

7.3.2.9. Interferences on Platelets (PLT)

Very small erythrocytes (microcytes): may interfere with the platelet count, giving falsely elevated values.

Presence of erythrocyte fragments (schizocytes) and WBC fragments: may interfere with the platelet count, giving falsely elevated values.

Hemolysis: hemolyzed samples contain a red blood cell stroma which may affect the platelet count.

RBC Inclusions: including Howell-Jolly bodies, Heinz bodies, siderotic and basophilic granules, etc., may cause falsely elevated platelet counts.

Red blood cell agglutination: may trap the platelets and cause a falsely low platelet count. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, and by examining a stained blood smear.

Platelet agglutination: A phenomenon of agglutination of platelets can result to a low platelet count. In about 1/2000 of the individuals, the presence of an antibody anti platelets acting on a cryptic site of the complex IIb/IIIa unmasked by EDTA can cause platelet aggregation that can lead to false thrombopenia (this agglutination can also occur in the presence of citrate for less than 10% of the cases). The pseudo-thrombopenia due to EDTA can count up to 15% of the isolated thrombopenia and constitute 75-90% of the causes of pseudo- thrombopenia. The quality of the sample is also a source of platelet agglutination. It is generally recommended to make an EDTA sample in parallel on a Citrate sample. Running a blood cell count on sodium citrate sample can help to reverse or confirm assuming EDTA to cause platelet aggregation. However you must be aware of the risk taken in providing platelets results obtained on sodium citrate, because they may be false like various studies* have demonstrated. It is therefore strongly advised to provide the result of a platelet count obtained on citrate in cases of absolute necessity and knowing the risk of error previously evaluated by an internal study of the risks or reported by comment.

The platelet agglutination triggers the alarms PLT aggregates? / PLT aggregates or NRBC? / PLT channel unstable measure. The quality of the sample is also a source of platelet agglutination. As discussed previously (refer to *Specifications* > *Sample Collection and Mixing*) care must be taken in collection of capillary samples due to the potential that platelet agglutination can occur. For either cause of falsely decreased platelet counts, verify by manual review the PLT result for any low results when the PLT value reported by the analyzer is below normal range and/or PLT aggregates? / PLT aggregates or NRBC? / PLT channel unstable measure alarms are triggered.

Excessive numbers of Macro platelets: this phenomenon may cause a falsely low platelet count due to the fact that these macro platelets exceed the upper threshold defined for platelets, and are therefore not counted as platelets.

Chemotherapy: cytotoxins and immunosuppressants may weaken these cells and cause a falsely low count. Manual methods may be necessary to obtain the platelet count.

Elevated lipids and/or cholesterol: may interfere with correct platelet counting. From patients undergoing parenteral nutrition with intralipids, it is noted an over-estimation of the platelet count.

Elevated bilirubine: may interfere with correct platelet counting. From patients with severe hepatic disorder, liver transplant, etc., it is noted an over-estimation of the platelet count.

Parenteral nutrition: Interference in PLT result may occur for samples from patients undergoing parenteral nutrition with injection of lipid emulsion.

7.3.2.10. Interferences on the Mean Platelet Volume (MPV)

Macro platelets: their volume exceeds the upper threshold defined for platelets and they are therefore not included in the calculation of the mean platelet volume by the analyzer. The MPV value may be falsely lowered.

Very small erythrocytes (microcytes) or presence of **red blood cell fragments (schizocytes)** and **white blood cell fragments** may interfere with the accurate determination of the mean platelet volume.

Red blood cell agglutination: may trap the platelets, causing an incorrect MPV. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, and by examining a stained blood smear.

Chemotherapy: may also affect platelet volume.

Blood samples collected in EDTA will not maintain a stable Mean Platelet Volume. Platelets collected in EDTA swell with time and temperature.

*Bibliography: "*Numération automatique des PLA sur citrate de sodium le résultat est-il exact?*", *Annales de Biologie Clinique, 2011*

7.3.2.11. Interferences on Lymphocytes (LYM)

The presence of platelet agglutination, erythroblasts, infected erythrocytes with malaria specimen and erythrocytes that are resistant to lysis may cause an inaccurate lymphocyte count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of lymphocytes.

7.3.2.12. Interferences on Monocytes (MON)

The presence of large lymphocytes, atypical lymphocytes, lymphoblasts, and excessive numbers of basophils may cause an inaccurate monocyte count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of monocytes.

7.3.2.13. Interferences on Neutrophils (NEU)

The presence of excessive numbers of eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts, and plasma cells, may cause an inaccurate neutrophil count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of neutrophils.

7.3.2.14. Interferences on Eosinophils (EOS)

The presence of abnormal granulations (degranulation of certain zones, toxic granulations, etc.) may interfere with the eosinophil count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of eosinophils.

7.3.2.15. Interferences on Basophils (BAS)

Monocytes and Blasts show large granules and may shift on the basophil counting area. This may interfere with an accurate count.

An abnormally low number of leukocytes (leukopenia) may interfere with the basophil count. The elements present in the zone of basophils are brought back on a small total quantity of leukocytes, which increases the statistical error and may cause variabilities in the percentage.

Fragile leukocyte cells shown in certain diseases (Chronic Lymphocytic Leukemia) or during anti-cancer treatment (chemotherapy) can be translated on the basophilic area by under-evaluation of the leukocytes because of their destruction and thus cause a statistical increase in the basophil ones.

During leukemia, basophils may lose their cytochemical characteristics and react abnormally with the reagent. The destruction of the basophil cytoplasm prevents their differentiation with the other leukocytes.

The basophils with very small sizes (following treatments) may interfere with leukocyte counts, as cell sizes cannot be distinguished.

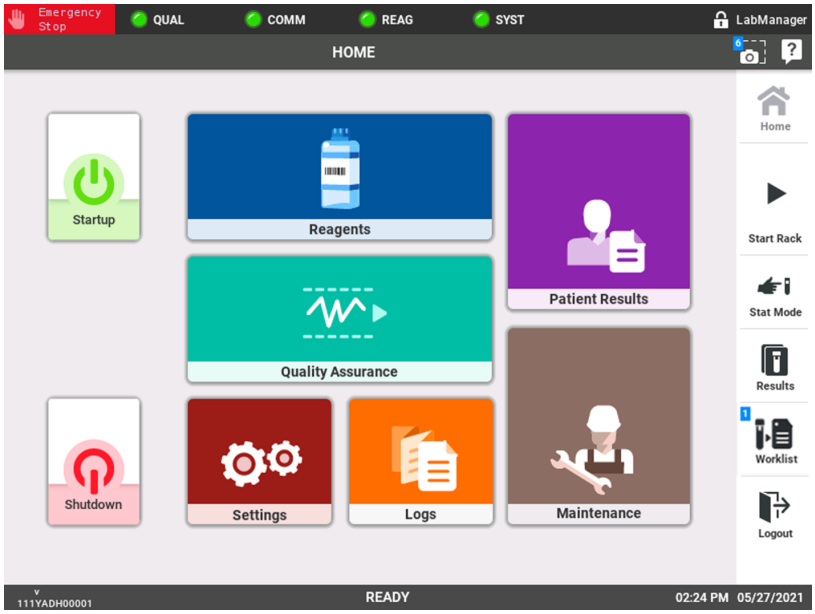
The abnormal basophils (degranulation following allergies) may interfere with leukocyte counts, because cell sizes cannot be distinguished and because they may lose their characteristic intracytoplasmic material.

Degranulation of neutrophils and hyposegmented neutrophils can be translated in the basophilic area and thus interfere with the basophil count.

Software

1. Software Overview

The Yumizen H550 includes a software application that allows you to navigate in the various screens. The touch screen allows easy and direct access to all functions via icons.

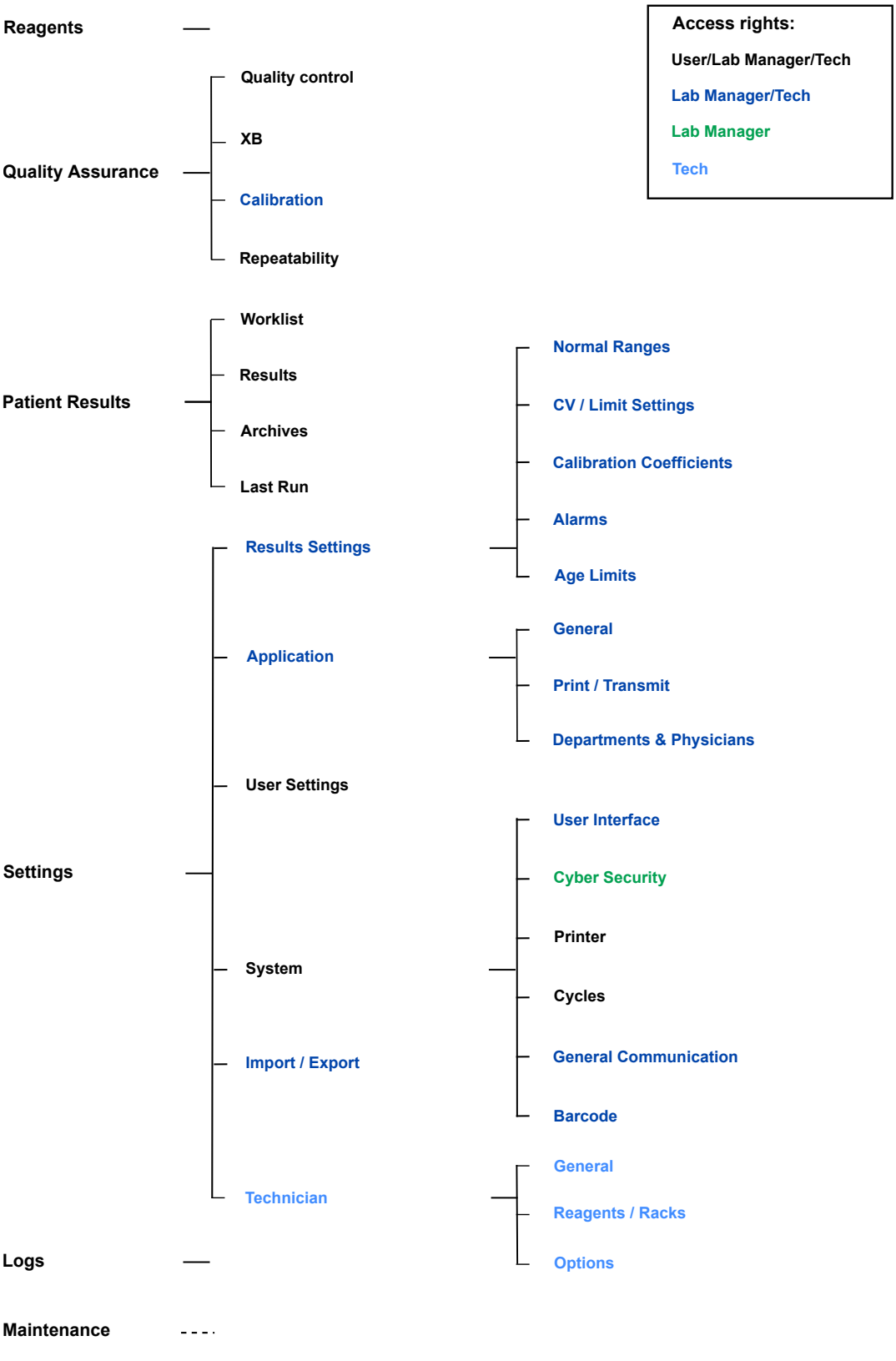


The main screen includes the following items:

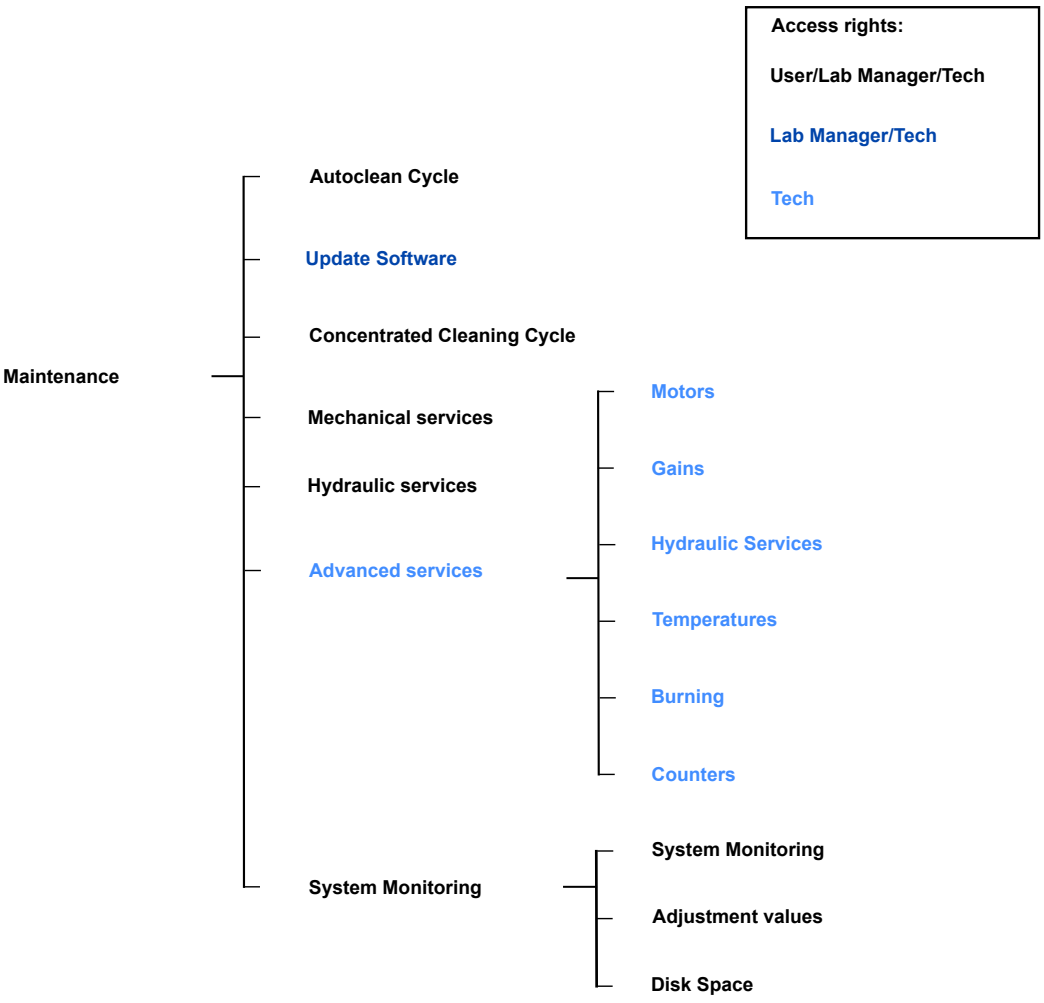
- The **main screen** buttons (center of screen), to enter the submenus.
- The **Startup** button to perform a startup cycle manually.
- The **Shutdown** button to perform a shutdown cycle manually.
- The **status bar** (top of screen), which gives indication on quality, communication, reagents or system problems. It also includes the **Emergency Stop** button to stop the instrument, the screen lock button and it displays the name of the user logged in.
- The **title** bar (top of screen), which displays the navigation path to access the screen currently displayed and the title of the screen. It also includes the **Screenshots** button and the **Help** button.
- The **function toolbar** (vertical), which provides direct access to other functionalities.
- The **contextual toolbar** (horizontal), which provides functionalities related to the screen currently displayed.
- The **information bar** (bottom of screen), which gives indication on the current version, the instrument serial number, the status of your instrument, and displays the date and time.

Related information:
- Main Screen Buttons, p.71
- Status Bar, p.72
- Title Bar Description, p.72
- Contextual Toolbar Description, p.73
- Function Toolbar Description, p.73
- Patient Results Menu Buttons, p.75
- Quality Assurance Menu Buttons, p.76
- Maintenance Menu Buttons, p.76

2. Menus Description



Maintenance menu



3. Software Buttons Description

3.1. Main Screen Buttons

Startup: runs a Startup cycle.

Shutdown: runs a Shutdown cycle.

Reagents: displays the reagents monitoring screen (level, expiration date, others).

Patient Results: gives access to the worklist, results list, archives and last run results.

Quality Assurance: gives access to QC, XB, calibration and repeatability.

Settings: displays the settings screen.

Logs: opens the instrument logs screen.

Maintenance: opens the maintenance screen.

3.2. Status Bar

The status bar displays alarms regarding the four following aspects:

- QUAL: invalid or failed control, XB value out of limits, etc.
- COMM: problems with the Host (LIS or Yumizen P8000) or the printer.
- REAG: empty or expired reagent, insufficient volume of reagent to perform the cycle in progress.
- SYST: failed cycle, mechanical problem, etc.

Each icon is green when there is no unresolved alarm. It blinks and turns red when an alarm appears. It stays red until all the alarms are resolved or checked by the user.

Press the status bar to display the ***Alarms*** screen. For more information about the alarms, refer to the Maintenance and Troubleshooting > Error Messages chapter.

It also includes the following buttons:

Emergency Stop: stops the instrument.

Lock: locks the screen.

3.3. Title Bar Description

The title bar displays the navigation path to access the screen currently displayed and the title of the screen. It also includes the following buttons:

Screenshots: takes a screenshot.

Help: opens the help.

Related information:
- Software Overview, p.68
- Main Screen Buttons, p.71
- Status Bar, p.72
- Contextual Toolbar Description, p.73
- Function Toolbar Description, p.73
- Patient Results Menu Buttons, p.75
- Quality Assurance Menu Buttons, p.76
- Maintenance Menu Buttons, p.76

3.4. Function Toolbar Description

Home: goes back to the main screen.

Start Rack: starts automatic analyses.

Stop Rack: stops the rack routine.

Stat Mode: allows you to manually run analyses.

Results: opens the list of results.

Worklist: opens the worklist.

Back: goes back to the previous screen.

Logout: allows you to log out from the application.

3.5. Contextual Toolbar Description

Depending on the screen currently displayed, buttons of the contextual toolbar may change. Buttons listed below are the most commonly displayed:

Print / **Send**: allows you to print data or to send data to the Host (LIS or Yumizen P8000).

Add: allows you to add new data.

Delete: deletes an item or data.

Edit: edits the screen to modify data.

Validate: validates an action.

Cancel: cancels an action.

Details: displays more details about the current screen.

Radars: displays the radar graphs corresponding to the control blood sample.

QC Reports: allows you to display the results table corresponding to the selected control level.

L.J. Graphs: displays the history of the control blood sample.

Targets: displays the target values of QC, XB or calibration.

Archive: allows you to archive the selected control level.

QCP export: allows you to export the QC results for the quality control program.

Export: allows you to export the settings, the database, the QA results, the logs, as well as screenshots and PDF printouts.

Import: allows you to import the settings, the database or the QC target values.

Previous: goes back to the previous item.

Next: goes to the next item.

Install: allows you to install a software version.

3.6. Patient Results Menu Buttons

Worklist: opens the worklist.

Results: opens the list of results.

Archives: opens the archived results.

Last Run: displays the result of the last analysis.

3.7. Quality Assurance Menu Buttons

Quality control: displays active and archived control blood samples.

XB: displays the XB graphs.

Repeatability: allows you to perform a repeatability test on the instrument.

Calibration: allows you to calibrate the instrument.

3.8. Maintenance Menu Buttons

Advanced services: gives access to advanced maintenance.
Reserved to HORIBA Medical technical representative.

Autoclean Cycle: runs a cleaning cycle (ABX Diluent).

Concentrated Cleaning Cycle: starts a concentrated cleaning procedure (ABX Minoclair).

System Monitoring: displays temperature, voltage, cycle counters and sensors status.

Hydraulic services: opens the hydraulic cycles management screen.

Mechanical services: opens the mechanical cycles management screen.

Update Software: opens the software update screen.

4. Using the Software

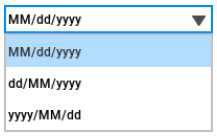
4.1. Software Functionalities

Buttons

Buttons are not always active, depending on the screen currently displayed, the instrument status or the login profile.

Drop-down lists

A drop-down list is a list of predefined items. Select one item from the list. Only one item can be selected from the list.



Check boxes

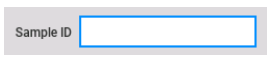
Check boxes are options you can select. Click the check box to select the option. Several options can be selected in a list of check boxes.

Radio buttons

Radio buttons are options you can select. Click the radio button to select the option. Only one option can be selected in a list of radio buttons.

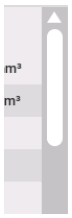
Data fields

Data fields can have a predefined format, like a date field, or can be empty. Use the keyboard to enter data.



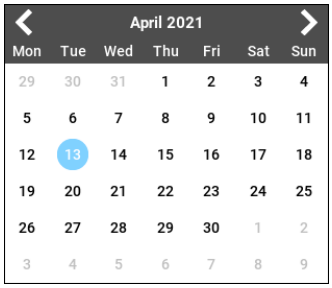
Scroll bars

Scroll bars can be either vertical or horizontal. Use them to display hidden parts of the screen or a list.



Calendars

Calendars help you to select a date. To choose a month, use the left and right arrows. Then choose the day. When done, click outside the calendar to close it.

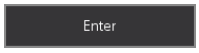


4.2. Virtual Keyboard

The virtual keyboard included in the application has the same functionalities as an external keyboard:

The keyboard type is "QWERTY" or "AZERTY", depending on the language selected. The virtual keyboard automatically displays when you enter an editable field. Refer to the *Settings* > *Configuring the Interface* > *To Configure the Virtual Keyboard* chapter.

The following keys have special functionalities:



Press **Enter** to validate.

Press **Close** to close the virtual keyboard.

Press **Backspace** to delete the character preceding the cursor.

Press **Tab** to go to the next field.

Press **Shift** to switch from lowercase to uppercase.

Press **Alt Gr** to switch from numbers and letters to special characters.

Press the **Globe** icon to switch between the different keyboards available.

Related information:
- To Configure the Virtual Keyboard, p.176

Quality Assurance

1. Quality Control

Quality Control allows the user to monitor a set of analyses based on known sample values and ranges over a period of several months. Statistical computations performed on these populations allow the extraction of qualitative information related to the stability of the instrument.

The following control type(s) should be used:

Name	Levels	Parameters
ABX Difftrol	3	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, LYM, MON, NEU, EOS, BAS, IMG

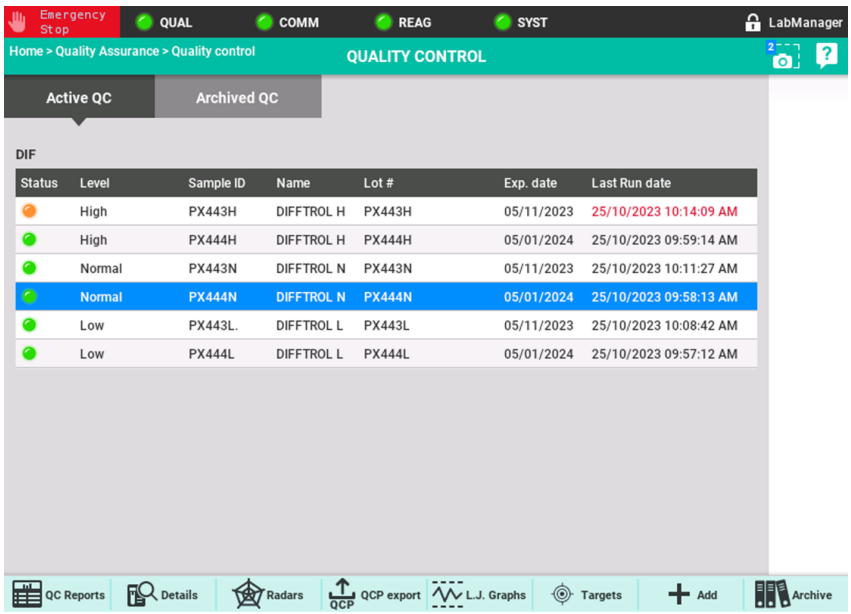
The three control levels can be simultaneously active allowing QC on three levels.

Quality control overlap allows you to configure two active control lots on the instrument.

1.1. Quality Control Overview

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

The ***Quality control*** menu is made of two tabs: one for active control blood samples, another for archived control blood samples.



In the ***Active QC*** screen, each control is displayed with a circle in front of it. This circle gives you information about the status of the control:

PASSED: Control blood sample results are within the tolerance range. Analyses can be run if all three levels have passed.

ACCEPTED: Control blood sample results were manually validated by the user. Analyses can be run if a level is accepted but the results are flagged.

FAILED: Control blood sample results are not within the tolerance range. Analyses cannot be run if at least one of the levels has failed. You can manually validate a failed control result so that it appears as accepted.

Control Run Result

Pressing **Details** displays the ***Control Run Result*** screen.

The ***Control Run Result*** screen shows you the results of the control blood sample run.

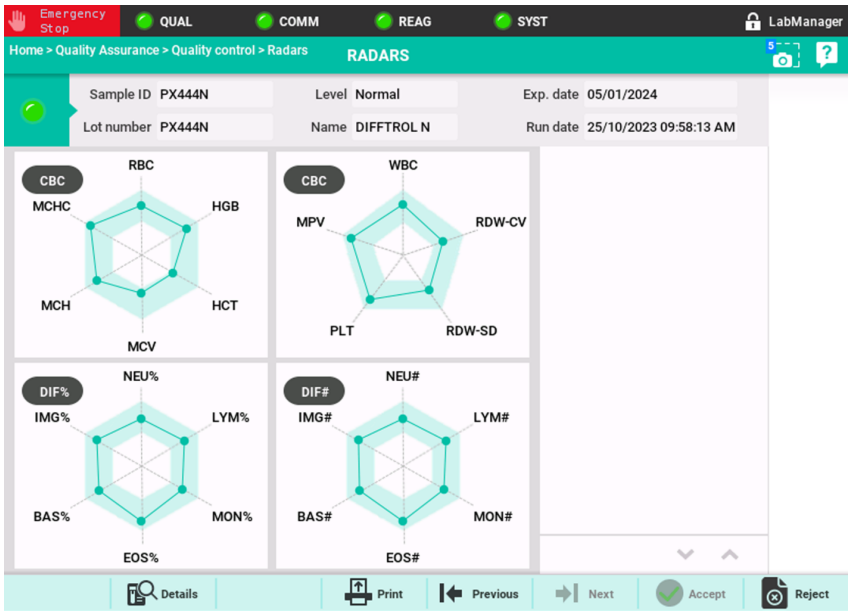
This screen contains the following information:

- Information about the control blood sample.
- Results and matrices (RBC / PLT).
- Results (WBC) and 5 DIFF matrix.
- Alarms.

Radars

Pressing **Radars** displays the ***Radars*** screen.

The ***Radars*** screen displays the radar graphs corresponding to the control blood sample.

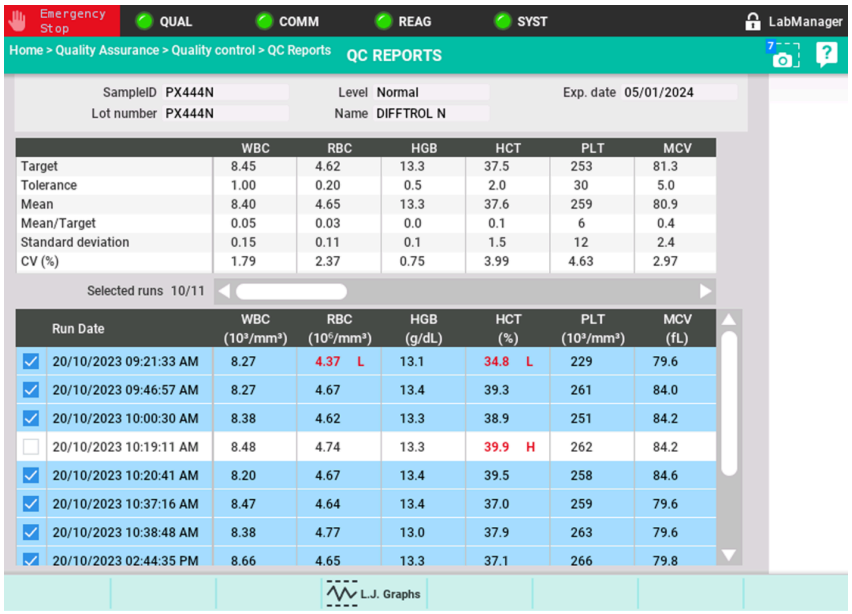


This screen contains the following information:

- Information about the control blood sample.
- Radar graphs showing which parameters are within range or out of range.
- Alarms.

QC Reports

Pressing **QC Reports** displays the results table of the selected control level.



This screen contains the following information:

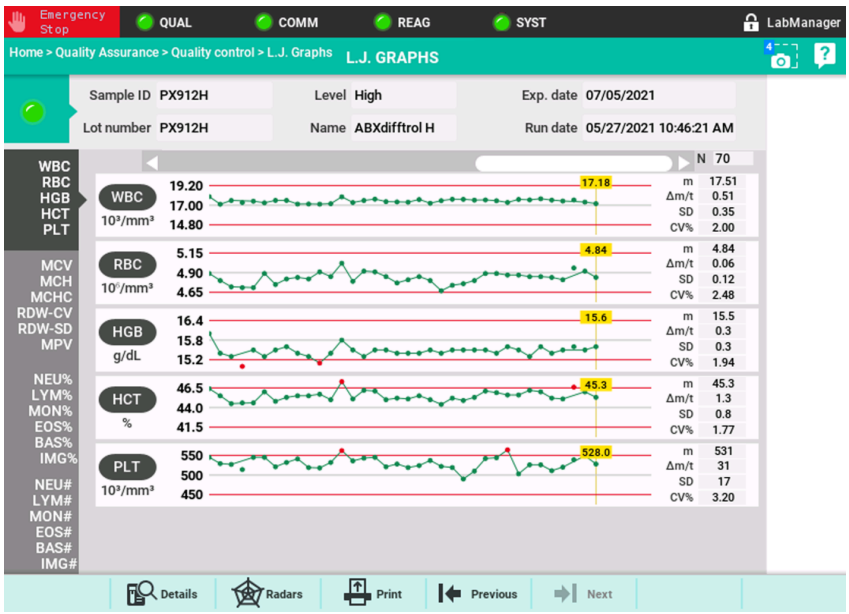
- Information about the control blood sample.
- Control blood results details for each parameter.

You can discard one or several results from the list.

L.J. Graphs

Pressing **L.J. Graphs** displays the ***L.J. Graphs*** screen.

The ***L.J. Graphs*** screen displays the history of the control blood sample.



This screen contains the following information:

- Information about the control blood sample.
- Levey-Jennings graphs showing the history of each parameter.

Control results are displayed in red when they are out of limits.

Control results which are unselected in the ***QC Reports*** table are not linked with the other selected results.

Related information:
- Controls Management, p.86
- Quality Control Results Management, p.88

1.2. Controls Management

1.2.1. To Create a Control Lot Manually

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Control blood samples have their own target values and their own ranges, defined in the leaflet. They always have an expiration date and a maximum number of samplings.

All the target values are available online at www.horiba-abx.com/documentation. Click **Hematology** and then **quality control target**.

1. Select the control level you want to create.
2. Press **Add** in the contextual toolbar.
3. Enter the control blood sample ID.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
4. Enter the lot information.
5. Enter the target values and tolerances for each parameter.
6. Press **Validate** in the contextual toolbar.
7. If two active lots are already defined, select the lot you want to archive.

1.2.2. Creating a Control Lot Automatically

You can import the control lot target values on your instrument in two ways.

Connected to Yumicare?	Yes	No
Import the target values:	with Yumicare	with a USB flash drive

1.2.2.1. To Create a Control Lot with Yumicare

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Your instrument must be connected to Yumicare.

1. Select the control level you want to create.
2. Press **Add** in the contextual toolbar.
3. Enter the control blood sample ID.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
4. Press **Yumicare** in the contextual toolbar.
5. Press **Validate** in the contextual toolbar.
6. If two active lots are already defined, select the lot you want to archive.

Related information:
■ To Configure the Connection to Yumicare, p.202

1.2.2.2. To Create a Control Lot with a USB Flash Drive

*Access: **Home** > **Quality Assurance** > **Quality control***

You need a USB flash drive containing the control lot target values.

Make sure the USB flash drive is free of any virus.

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*All the target values are available online at www.horiba-abx.com/documentation. Click **Hematology** and then **quality control target**.*

Control files must have the following name format: PX_Yumizen_xxxx.csv
The instrument downloads the first file using this format on the USB flash drive. To prevent the instrument from downloading an incorrect file, it is recommended to leave only the required file on the USB flash drive.

---

1. Select the control level you want to create.
2. Press **Add** in the contextual toolbar.
3. Enter the control blood sample ID.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
4. Insert the USB flash drive.
5. Press **Import** in the contextual toolbar.
6. Press **Confirm**.
7. Press **Validate** in the contextual toolbar.
8. If two active lots are already defined, select the lot you want to archive.

1.2.3. To Modify a Control Lot Manually

*Access: **Home** > **Quality Assurance** > **Quality control***

Control blood samples have their own target values and their own ranges, defined in the leaflet. They always have an expiration date and a maximum number of samplings.

All the target values are available online at www.horiba-abx.com/documentation. Click **Hematology** and then **quality control target**.

1. Select the control blood sample you want to modify.
2. Press **Targets** in the contextual toolbar.
3. Press **Edit** in the contextual toolbar.
4. Modify the information you want to update. If needed, you can also modify the QC matrix thresholds (Lab Manager profile only).
5. Press **Validate** in the contextual toolbar.

If you modify the target values of a control lot, the latter is automatically archived.

However, if you modify the matrix thresholds of a control lot, the latter is not automatically archived.

1.2.4. To Modify a Control Lot with Yumicare

Access: ***Home*** > ***Alarms***

Your instrument must be connected to Yumicare.

The instrument informs you when the target values of a control lot are updated by displaying the error message Q04: A review of the QC targets %s has been published..

1. Consult the error message and press **Check** to go to ***Home*** > ***Quality Assurance*** > ***Quality control***.
2. Select the control blood sample you want to modify.
3. Press **Targets** in the contextual toolbar.
4. Press **Edit** in the contextual toolbar.
5. Press **Yumicare** in the contextual toolbar.
6. Press **Validate** in the contextual toolbar.

If you modify the target values of a control lot, the latter is automatically archived.

Related information:
- To Configure the Connection to Yumicare, p.202

1.2.5. To Archive a Control Lot Level

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Control lots are automatically archived when creating a new control lot or when modifying the target values of a control lot.

You can also manually archive control lots.

1. Select the control lot you want to archive.
2. Press **Archive** in the contextual toolbar.
3. Press **Confirm**.

1.3. Quality Control Results Management

1.3.1. QC Results Overview

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

The ***Control Run Result*** screen appears automatically when a quality control analysis is complete.

You can also access the results screen by pressing the **Details** button.

1.3.2. To Manually Validate Control Results

*Access: **Home** > **Quality Assurance** > **Quality control***

You can manually validate a failed control blood result.

1. Select the control result you want to validate from the ***Active QC*** list.
2. Press **Details** or **Radars** in the contextual toolbar.
3. Press **Accept** in the contextual toolbar.
   The control result is now validated and appears in orange in the ***Active QC*** list.

1.3.3. To Delete Control Results

*Access: **Home** > **Quality Assurance** > **Quality control***

1. Select the control result you want to delete from the ***Active QC*** list.
2. Press **Details** or **Radars** in the contextual toolbar.
3. Press **Reject** in the contextual toolbar.
   The control result is now deleted and the control status is re-evaluated without this control result.

1.3.4. To Print QC Results

*Access: **Home** > **Quality Assurance** > **Quality control***

You can print QC results from ***Control Run Result***, ***Radars*** and ***L.J. Graphs*** screens.

1. To print control run results:
   a. Select the data you want to print from ***Active QC*** or ***Archived QC*** areas.
   b. Press **Details** in the contextual toolbar.
   c. Press **Print / Send** in the contextual toolbar.
   d. Press **Validate**.
2. To print control radar graphs:
   a. Select the data you want to print from ***Active QC*** or ***Archived QC*** areas.
   b. Press **Radars** in the contextual toolbar.
   c. Press **Print** in the contextual toolbar.
   d. Press **Confirm**.
3. To print quality control reports:
   a. Select the data you want to print from ***Active QC*** or ***Archived QC*** areas.
   b. Press **L.J. Graphs** in the contextual toolbar.
   c. Press **Print** in the contextual toolbar.
   d. Press **Confirm**.

1.3.5. To Send QC Results to the Host

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Results are automatically sent to the Host (LIS or Yumizen P8000) at the end of an analysis if the option is selected.

For more information, refer to the *Settings* > *Configuring the Instrument* > *To Configure Results Printing and Transmission* chapter.

You can manually send QC results from the ***Control Run Result*** screen.

1. Select the data you want to send from ***Active QC*** or ***Archived QC*** areas.
2. Press **Details** in the contextual toolbar.
3. Press **Print / Send** in the contextual toolbar.
4. Select **Send control run report** and validate.

Related information:
- To Configure Results Printing and Transmission, p.172

1.3.6. Exporting QC Results

You can export your control results in xml format to evaluate your analyzer accuracy and precision through the Quality Control Program (QCP).

You can export the control results to the QCP application in two ways.

Connected to Yumicare?	Yes	No
Export the control results:	with Yumicare	with a USB flash drive

1.3.6.1. To Export QC Results with Yumicare

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Your instrument must be connected to Yumicare.

You must have previously filled in your QCP login details on the instrument.

We recommend you to export your control results every month.

1. Select the control lot you want to export from the ***Active QC*** list.
2. Press **QCP export**.
3. Select a period for the results to export.
4. Select the **Yumicare** option.
5. Press **Validate**.
6. When the export is complete, press **OK**.

Your results are exported to the QCP application.

Related information:
- To Configure the Connection to Yumicare, p.202

1.3.6.2. To Export QC Results with a USB Flash Drive

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

---

1. Select the control lot you want to export from the ***Active QC*** list.
2. Press **QCP export**.
3. Select a period for the results to export.
4. Select the **USB** option.
5. Press **Validate**.
6. Insert the USB flash drive.
7. Press **Confirm**.
   If your USB flash drive is full, a popup message informs you that the export failed. You have to validate the message before removing your USB flash drive.
8. When the export is complete, remove the USB flash drive and press **OK**.

You can now import your results in the Quality Control Program (QCP).

Related information:
- To Submit your Instrument Results with a USB Flash Drive, p.112

2. Patient Quality Control (XB)

2.1. Patient Quality Control (XB) Overview

*Access: **Home** > **Quality Assurance** > **XB***

The Patient Quality Control (XB) is used to detect any deviation in the results using patient data only.

This monitoring can be performed on three parameters (MCV, MCH and MCHC) or on nine parameters (WBC, RBC, HGB, HCT, RDW-CV, PLT, MCV, MCH and MCHC).

XB control does not require intervention from the operator, nor control bloods. The statistics include patient results that do not contain any analysis flaw.

Each point of the graph is the XB value of a batch, calculated from 20 patient analyses and taking into account the previous XB value.

The XB target value is the XB value of the first batch, then of the ninth batch. The XB target value can be reset by the operator.

The XB alarm appears if:

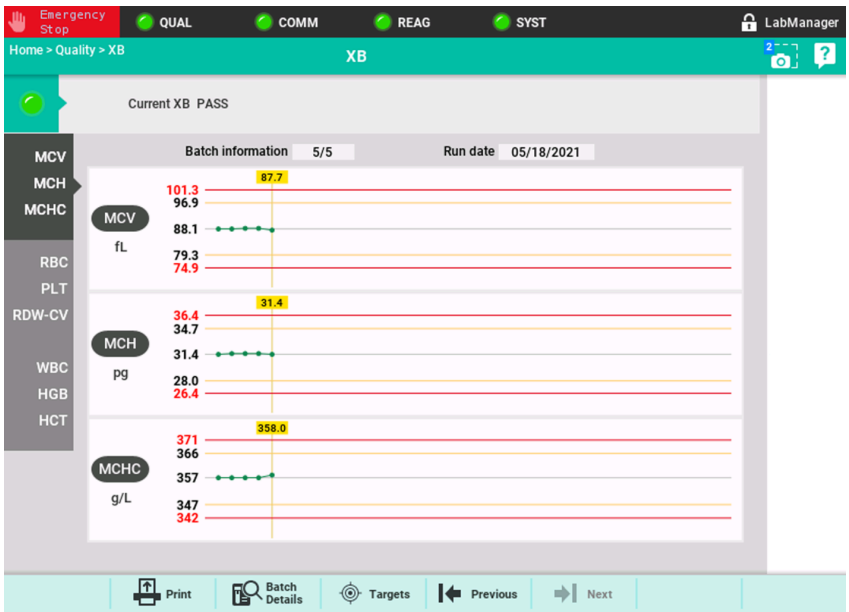
- a point of the graph is outside the target value +/- the XB limit (%) set by the operator,
- three consecutive points of the graph are outside the target value +/- 2/3 of the XB limit (%) set by the operator.

This alarm can be de-activated.

The ***XB*** menu is made of three screens:

- the ***XB*** screen,
- the ***Batch Details*** screen,
- the ***Targets*** screen.

XB



For each parameter, a curve is displayed. A point on the curve represents the XB value of a batch. It is possible to move the vertical line to switch from one batch to another. To move the line, you can either:

- use the left and right arrows of the contextual toolbar,
- press any point of the curve.

Each parameter has an XB target value (black line) and two levels of XB limits:

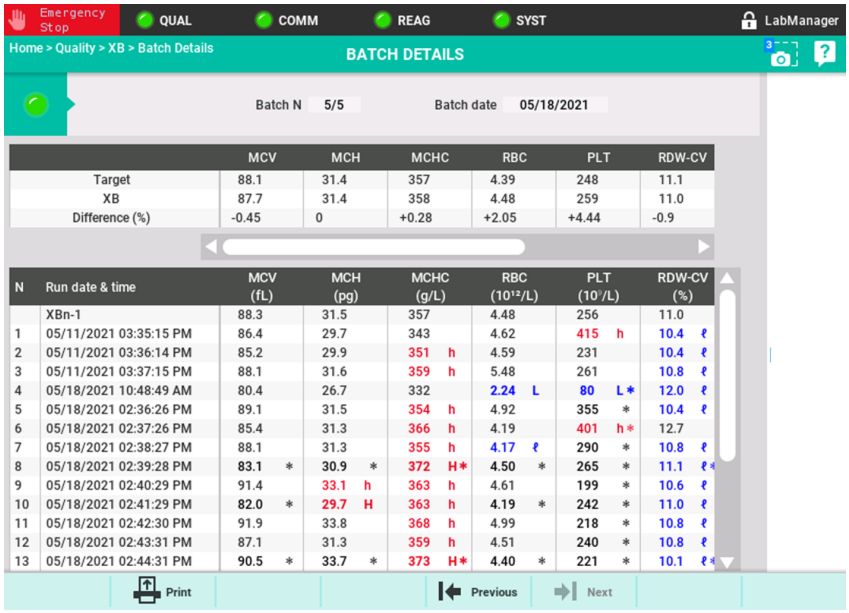
- target value +/- XB limit (%) set by the operator (red lines),
- target value +/- 2/3 of XB limit (%) set by the operator (yellow lines).

A point of the graph out of the limits is displayed in red or yellow.

Batch Details

Pressing **Batch Details** displays the ***Batch Details*** screen.

The table displays the 20 results of the selected batch and the XB value of the previous batch.



	MCV	MCH	MCHC	RBC	PLT	RDW-CV
Target	88.1	31.4	357	4.39	248	11.1
XB	87.7	31.4	358	4.48	259	11.0
Difference (%)	-0.45	0	+0.28	+2.05	+4.44	-0.9

N	Run date & time	MCV (fL)	MCH (pg)	MCHC (g/L)	RBC (10^{12}/L)	PLT (10^{9}/L)	RDW-CV (%)
	XBn-1	88.3	31.5	357	4.48	256	11.0
1	05/11/2021 03:35:15 PM	86.4	29.7	343	4.62	415 h	10.4 ₹
2	05/11/2021 03:36:14 PM	85.2	29.9	351 h	4.59	231	10.4 ₹
3	05/11/2021 03:37:15 PM	88.1	31.6	359 h	5.48	261	10.8 ₹
4	05/18/2021 10:48:49 AM	80.4	26.7	332	2.24 L	80 L*	12.0 ₹
5	05/18/2021 02:36:26 PM	89.1	31.5	354 h	4.92	355 *	10.4 ₹
6	05/18/2021 02:37:26 PM	85.4	31.3	366 h	4.19	401 h*	12.7
7	05/18/2021 02:38:27 PM	88.1	31.3	355 h	4.17 ₹	290 *	10.8 ₹
8	05/18/2021 02:39:28 PM	83.1 *	30.9 *	372 H*	4.50 *	265 *	11.1 ₹*
9	05/18/2021 02:40:29 PM	91.4	33.1 h	363 h	4.61	199 *	10.6 ₹
10	05/18/2021 02:41:29 PM	82.0 *	29.7 H	363 h	4.19 *	242 *	11.0 ₹
11	05/18/2021 02:42:30 PM	91.9	33.8	368 h	4.99	218 *	10.8 ₹
12	05/18/2021 02:43:31 PM	87.1	31.3	359 h	4.51	240 *	10.8 ₹
13	05/18/2021 02:44:31 PM	90.5 *	33.7 *	373 H*	4.40 *	221 *	10.1 ₹*

You can switch from one batch to another using the left and right arrows in the contextual toolbar.

Targets

Pressing **Targets** displays the ***Targets*** screen.

The ***Targets*** screen allows you to reset the XB values (erasing all XB values or using the last batch XB values as targets).

Related information:
- To Initialize the XB Targets, p.94
- To Configure the XB Alarm, p.168
- To Modify the XB Limits, p.184

2.2. To Initialize the XB Targets

*Access: **Home** > **Quality Assurance** > **XB***

1. Press **Targets** in the contextual toolbar.
2. Press **Initialize targets** in the contextual toolbar.
3. Select **Erase all batches (selected by default)** or **Use last batch value as target**.
4. Press **Validate** in the contextual toolbar.

3. Repeatability

3.1. Repeatability Overview

*Access: **Home** > **Quality Assurance** > **Repeatability***

The repeatability is based on a set of results obtained from consecutive analyses of the same fresh normal blood sample.

This screen contains the following information:

- Statistics for each parameter
- Results for each run

The statistics are recalculated when you select or deselect a run.

Coefficients of variation are displayed in red if they are out of the limits you defined.

Related information:
- To Perform a Repeatability Test in STAT Mode, p.96
- To Perform a Repeatability Test in Rack Mode, p.96

3.2. To Perform a Repeatability Test in Rack Mode

Access: ***Home*** > ***Quality Assurance*** > ***Repeatability***

Fresh normal human blood is needed.

1. Press **Start Repeatability** in the contextual toolbar.
   A dialog box is displayed.
2. Select the **Automatic** mode.
3. Enter the sample ID.
4. Select the number of runs to perform. It is recommended to run the sample at least 10 times.
5. Place the tube in the first position of the rack.
6. Place the rack at the start of the loading area. Be careful to push the rack inside the instrument.
7. Close the door.
8. Press **Validate** to start sampling.
9. The instrument calculates the statistics for each parameter.
10. Check the standard deviation to make sure the repeatability test is successful.
    The CV is automatically displayed in red if it is higher than the CV defined in the ***Settings*** menu.

3.3. To Perform a Repeatability Test in STAT Mode

Access: ***Home*** > ***Quality Assurance*** > ***Repeatability***

Fresh normal human blood is needed.

It is recommended to perform this procedure at a constant pace (without interruption), to mix the specimen in the same way between each analysis, to ensure there is no alarm on the results.

1. Press **Start Repeatability** in the contextual toolbar.
   A dialog box is displayed.
2. Select the **Manual** mode.
3. Enter the sample ID and press **Validate**.
4. Gently and thoroughly mix the sample.
5. Put the tube in the tube holder and close the door.

When placing your tube in the tube holder, make sure that you are using the appropriate position and that the cap can be pierced. If not, remove the cap before closing the door.

6. Press **Validate** to start sampling.

7. When the tube holder moves back to the front of the analyzer, remove the tube and put the cap back on if needed.

Risk of erroneous results if the specimen is not continuously mixed between each analysis. Keep on mixing the specimen between each analysis.

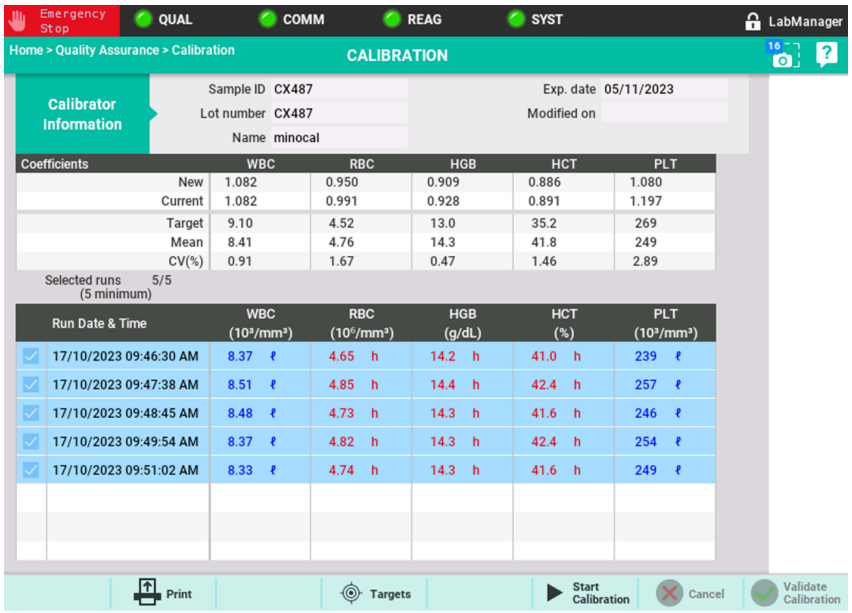
8. Run the blood sample at least 10 times to obtain reliable results.
9. The instrument calculates the statistics for each parameter.
10. Check the standard deviation to make sure the repeatability test is successful.
    The CV is automatically displayed in red if it is higher than the CV defined in the ***Settings*** menu.

4. Calibration

4.1. Calibration Overview

*Access: **Home** > **Quality Assurance** > **Calibration***

Calibration is used to determine the precision and accuracy of the analyzer using a specifically formulated product in order to recover each parameter within close tolerances of known target values and limits. Coefficients of variation and percent difference recovery must be within their specified limits.



This screen contains the following information:

- Information about the calibrator
- Statistics for each parameter
- Results for each run

The statistics are recalculated when you select or deselect a run.

Coefficients of variation are displayed in red if they are out of the limits you defined.

Related information:
- General Recommendations, p.99
- Calibration Results, p.102
- To Create a Calibrator Lot, p.100
- To Modify a Calibrator Lot, p.101
- To Calibrate the Instrument, p.101
- To Check the Calibration, p.103
- To Force the Calibration Coefficients, p.104

4.2. General Recommendations

Perform these preliminary actions before calibrating the instrument.

- Calibration is an important procedure that may be performed during specific situations such as installation, maintenance or service interventions.
- Calibration should not be performed to compensate from a drift in results due to a blockage of the instrument.
- Frequent calibration must be reported to your local technical representative to understand the actual cause and find an appropriate solution.
- After calibration, ensure the values for MCV, MCH and MCHC on patient samples match the values from normal patient population.

Calibration conditions: The analyzer must be calibrated at a laboratory Reference Temperature from +19°C (+66°F) to +26°C (+79°F).

The analyzer is then fully operational for blood sample analysis at this reference temperature +/-4°C (+/-7°F).

Related information:
- To Make Sure the Instrument Passes the Startup, p.99
- To Check the Repeatability of your Instrument, p.100

4.2.1. To Make Sure the Instrument Passes the Startup

1. Run a startup cycle.
   The startup must pass before starting any calibration.
2. Perform a concentrated cleaning procedure.
3. Perform two blank cycles.
   Make sure that the values are within acceptable limits.

Parameter	Background count limits
WBC	≤ 0.3 10^3/mm^3
RBC	≤ 0.03 10^6/mm^3

Parameter	Background count limits
HGB	≤ 0.3 g/dL
PLT	≤ 5 10^3/mm^3

If the startup has failed refer to the *Maintenance and Troubleshooting* > *Troubleshooting Procedures* > *Operations Problems* > *Startup Failed* chapter to perform the problem identification procedure.
If the problem persists, please contact your local HORIBA Medical representative.

4.2.2. To Check the Repeatability of your Instrument

1. Check the repeatability (precision) of your instrument by running a normal fresh whole blood specimen ten times with no alarms.
2. Compare the %CV with the precision claims.
   They must meet published claims.
   Refer to the *Specifications* > *Summary of Performance Data* chapter.
3. Run a control sample and check whether the results are within acceptable limits.
4. Proceed with calibration.

If your instrument shows poor repeatability (precision), refer to the *Maintenance and Troubleshooting* > *Troubleshooting Procedures* > *Repeatability Problems* chapter to perform the problem identification procedure.

If the problem persists, please contact your local HORIBA Medical representative.

Related information:
- Running Control Blood Samples, p.121
- Summary of Performance Data, p.43
- Repeatability, p.95
- Repeatability Problems, p.247

4.3. To Create a Calibrator Lot

Access: ***Home*** > ***Quality Assurance*** > ***Calibration***

1. Press **Targets** in the contextual toolbar.
2. Press **Add** in the contextual toolbar.
3. If you have already created a calibrator lot, a pop-up is displayed. Press **Confirm** to archive the existing calibration session and create a new calibrator lot.
4. Enter the lot information.
5. Enter the target values and tolerances for each parameter.
6. Press **Validate** in the contextual toolbar.

4.4. To Modify a Calibrator Lot

Access: ***Home*** > ***Quality Assurance*** > ***Calibration***

1. Press **Targets** in the contextual toolbar.
2. Press **Edit** in the contextual toolbar.
3. Modify the information you need to update.

All previous data will be lost if you replace or modify a lot. When modifying targets, make sure you use the column corresponding to your instrument on the calibration sheet.

4. Press **Validate** in the contextual toolbar.

4.5. To Calibrate the Instrument

Access: ***Home*** > ***Quality Assurance*** > ***Calibration***

Make sure you perform the steps described in the Quality Assurance > Calibration > General Recommendations chapter before calibrating the instrument.

To calibrate the instrument, use the ABX Minocal calibrator.

1. Press **Start Calibration** in the contextual toolbar.
2. If the system prompts you to create a new calibration session, press **Confirm**.
3. Prepare the calibrator according to the instructions detailed in the calibrator package insert.
4. Gently and thoroughly mix the sample.
5. Put the tube in the tube holder and close the door.

When placing your tube in the tube holder, make sure that you are using the appropriate position and that the cap can be pierced. If not, remove the cap before closing the door.

6. Press **Validate** to start sampling.
7. When the tube holder moves back to the front of the analyzer, remove the tube and put the cap back on if needed.

Always wipe any excess blood from the cap and threads of the calibrator vial with a lint-free tissue to prevent dried blood from re-entering the calibrator material. Dried blood re-entering into the vial may cause erroneous results such as alarms and sample run rejects.

Risk of erroneous results if the specimen is not continuously mixed between each analysis. Keep on mixing the specimen between each analysis.

8. Sample the calibrator at least four more times.
   To obtain reliable results, it is recommended to run the sample at least five times.
9. Discard the first result from the list.
   The instrument calculates the statistical calibration factors for each parameter.
10. Press **Validate Calibration** in the contextual toolbar.
    a. If the coefficients are valid, press **Confirm**.
    b. If at least one coefficient is invalid, you can force the calibration by pressing **Confirm**.

It is highly recommended to always reject failed calibrations.

4.6. Calibration Results

If the calibration cycle passes, the results are saved in the ***Calibration*** screen but are not sent to the Host (LIS or Yumizen P8000). They are not saved when a calibration cycle is rejected. Instead, an error message indicating that the calibration sample was rejected is displayed.

By default, all calibration cycles and all parameters are taken into account when the instrument generates the statistical calculations. It is possible to discard results or parameters using the selection check boxes. The statistical calculations are then recomputed.

A coefficient of variation is displayed in red if it is above its parameter limits. When this happens, the calibration fails.

Calibration results can be printed by pressing **Print**.

4.6.1. Calibration Passed

The calibration passes if:

- The percentage difference between the current and the new calibration factor is less than 20%.
- The coefficients of variation are within parameter limits.

Calibration coefficient	%CV
WBC	< 3
RBC	< 2
HGB	< 1.5
HCT	< 2
PLT	< 5

If the calibration passed, a message asking you to confirm the validation of new calibration coefficients appears.

Press **Confirm** to confirm the calibration. The new calibration factors are then applied.

You must then perform a check-up after calibration and calibrate the RDW-CV, RDW-SD, PDW and MPV.

Related information:
- To Check the Calibration, p.103

4.6.2. Calibration Failed

The calibration fails if:

- The percentage difference between the target values and the mean values is greater than 20%.
- The coefficients of variation are beyond parameter limits.

It is possible to calibrate the instrument even if the calibration fails, but it is then called a "forced calibration". It is up to you to either force the calibration or reject it.

It is highly recommended to always reject failed calibrations. Only force the calibration if you understand and validate the reasons of the calibration failure.

If you force the calibration, you must then perform a check-up after calibration and calibrate the following parameters:

- RDW-CV
- RDW-SD
- PDW
- MPV

Related information:
- To Check the Calibration, p.103

4.7. To Check the Calibration

It is recommended to perform a check-up after calibrating your instrument.

Risk of erroneous results if a control run has not been performed after a calibration. Always run a control blood sample after a calibration.

1. Run a control blood sample and make sure that the values are within acceptable limits. If not, run a new control blood sample.
2. Check the values of the MCV, MCH and MCHC after about 30 analyses with human blood. They have to be in conformity with the usual values of the laboratory.

4.8. Manual Calibration with Whole Blood Specimens

The calibration of the following parameters must be performed manually with 10 fresh whole blood specimens.

Parameters	Description	Normal values
RDW-CV	To determine notably erythrocyte abnormalities linked to anisocytosis.	13.5 +/- 2%
RDW-SD	To determine notably erythrocyte abnormalities linked to anisocytosis.	43.0 +/- 2.5 fL
PDW	To determine platelet abnormalities.	12.8 +/-1 fL
MPV	To determine platelet abnormalities.	9.2 +/- 1.0 fL

Expected RDW-CV values may vary with sample population and/or geographical location. It is highly recommended that each laboratory establishes its own normal ranged based on the local population.
If so, replace the target value in the following formula with your own normal range.

To obtain the appropriate coefficients, run 10 fresh normal blood specimens. Calculate the mean of the 10 values obtained for each parameter.

Make sure that no runs are invalidated.

Then, use the following formulas:

Parameters	Formulas
RDW-CV	**New RDW-CV coefficient = Current RDW-CV coefficient X 13.5 / Calculated mean RDW-CV**
RDW-SD	**New RDW-SD coefficient = Current RDW-SD coefficient X 43.0 / Calculated mean RDW-SD**
PDW	**New PDW coefficient = Current PDW coefficient X 12.8 / Calculated mean PDW**
MPV	**New MPV coefficient = Current MPV coefficient X 9.2 / Calculated mean MPV**

Refer to the *Quality Assurance* > *Calibration* > *To Force the Calibration Coefficients* chapter for more information on how to adjust calibration coefficients.

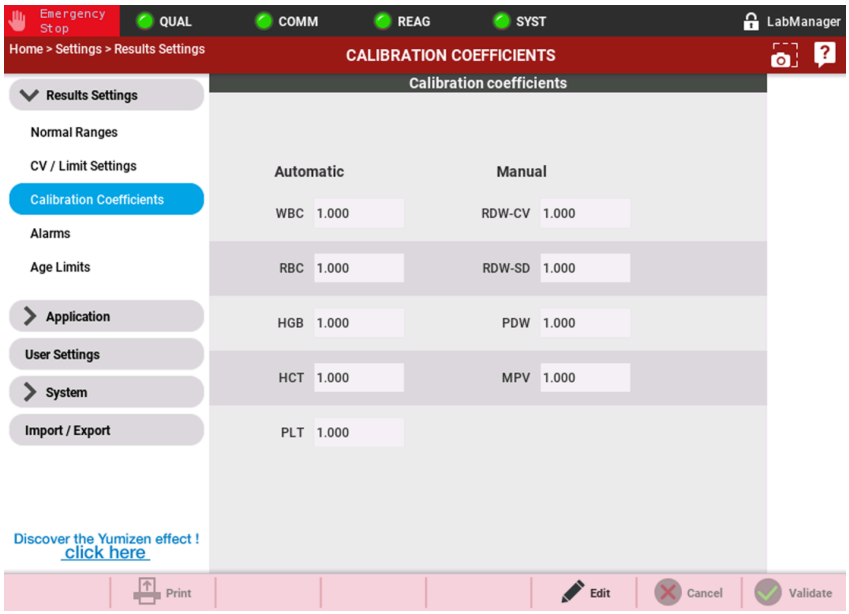
If you change the coefficients, you must run 10 normal human blood samples freshly collected and check the parameters mean value. It must comply with the given normal value.

4.9. To Force the Calibration Coefficients

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***Calibration Coefficients***

Although it is not recommended, you can force the calibration coefficients to have a specific value.

1. In the ***Calibration Coefficients*** area, modify the values you want to change.
   The calibration coefficients must be included between 0.8 and 1.2 to validate the calibration.



2. Press **Validate**.

Any modification of the calibration coefficients will affect the results and is strictly the responsibility of the user.

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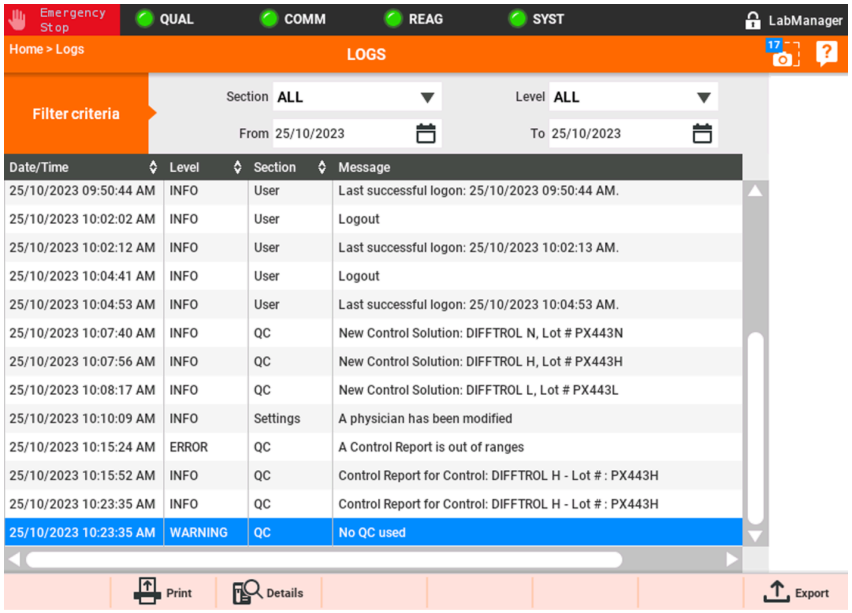
5. Logs

5.1. Logs Overview

*Access: **Home** > **Logs***



The logs record important events of the instrument. Events are sorted by categories:

- **All** (by default): displays all events.
- **Alarm**: provides a description of system alarms.
- **QC**: displays events related to quality assurance.
- **Reagent**: displays events related to reagents.
- **Blank**: provides information about blank cycles values.
- **Service**: displays events related to maintenance and adjustments.
- **Host**: displays events related to the Host (LIS or Yumizen P8000) connection.
- **Settings**: displays comments regarding settings that have been changed on the instrument.
- **Calibration**: displays events related to calibration.
- **User**: displays events related to user accounts and login.
- **Yumicare**: displays events related to the remove server connection.

The logs are sorted according to three levels:

- **INFO**: displays information about events.
- **WARNING**: concerns alarming events.
- **ERROR**: concerns blocking events.

Pressing **Details** displays more information about a specific log.

5.2. To Filter Displayed Logs

Access: ***Home*** > ***Logs***

1. Select the type of logs to display in the **Section** drop-down list.
2. Select the level to display in the **Level** drop-down list.
3. Select the period to display.

5.3. To Add a Comment

Access: ***Home*** > ***Logs***

It is recommended to add a comment in the logs to keep track of why it was performed.
It is recommended to add a comment after any maintenance operation.

1. Select the logs you want to display.
2. Select one item in the logs.
3. Press **Details** in the contextual toolbar.
4. Press **Edit** in the contextual toolbar.
5. Enter your comment in the text field (50 characters).
6. Press **Validate** in the contextual toolbar.

5.4. To Print Logs

Access: ***Home*** > ***Logs***

1. Select the logs you want to print.
2. Press **Print** in the contextual toolbar.
3. Press **Confirm**.

5.5. To Export Logs

Access: ***Home*** > ***Logs***

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

1. Select the logs you want to export.
2. Press **Export** in the contextual toolbar.
3. Insert the USB flash drive.
4. Press **Confirm**.
   If your USB flash drive is full, a popup message informs you that the export failed. You have to validate the message before removing your USB flash drive.
5. When the export is complete, remove the USB flash drive and press **OK**.

The logs are exported in xml format.

6. Quality Assurance Results

6.1. To Export the QA Results

Access: ***Home*** > ***Quality Assurance***

Only users with the Lab Manager profile can perform this procedure.

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

Quality Assurance (QA) results which are going to be exported are the calibration, control, repeatability and blank results.

1. Press **Export** in the contextual toolbar.
2. Select a period for the results to export and validate.
3. Insert the USB flash drive.
4. Press **Confirm**.
5. When the export is complete, remove the USB flash drive and press **OK**.

7. Quality Control Program (QCP)

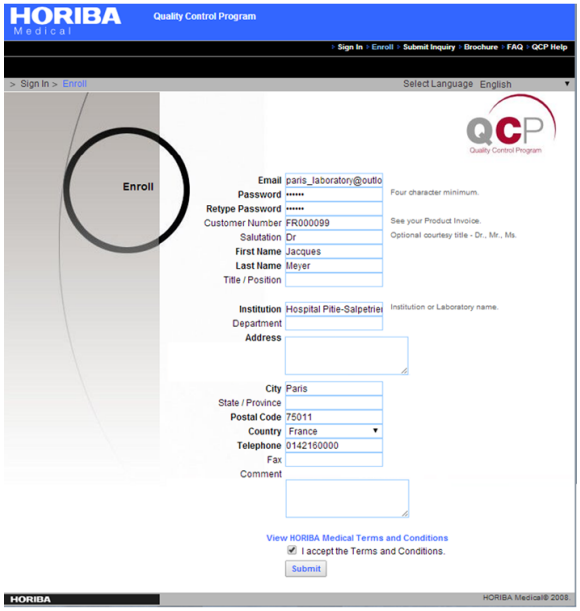
The Quality Control Program (QCP) is an online inter laboratory comparison tool.

It allows you to evaluate your analyzer accuracy and precision and obtain real time peer group statistical reports.

7.1. To Record the Instrument in the Application

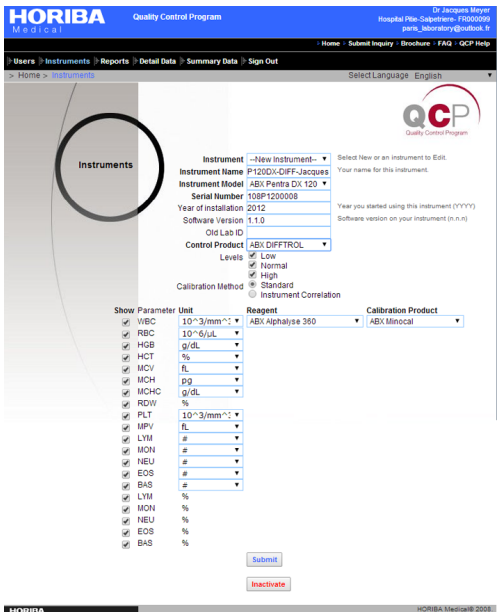
1. Go to http://qcp.horiba-abx.com/.
2. Click **Enroll** to register to the application.
3. Enter your information and then click **Submit**.

According to your location, you may already have been enrolled by your HORIBA Medical representative.



4. Enter your instrument settings.
   Make sure that the serial number is correct to ensure the proper functioning of the system.
5. Select your **Control Product** from the drop-down list.

6. Select the levels to report, calibration method, units, reagents and calibration product.



7. Click **Submit**.

If you are not yet registered, please ask your HORIBA Medical representative for a form. Fill in it and send it to HORIBA Medical. Once the registration is completed, you will receive a notification by e-mail or post.

7.2. Submitting your Instrument Results

You can submit the control results of your instrument to the QCP application in different ways:

- with Yumicare
- with a USB flash drive
- manually

7.2.1. To Export QC Results with Yumicare

*Access: **Home** > **Quality Assurance** > **Quality control***

Your instrument must be connected to Yumicare.

You must have previously filled in your QCP login details on the instrument.

We recommend you to export your control results every month.

1. Select the control lot you want to export from the ***Active QC*** list.
2. Press **QCP export**.
3. Select a period for the results to export.
4. Select the **Yumicare** option.

5. Press **Validate**.
6. When the export is complete, press **OK**.

Your results are exported to the QCP application.

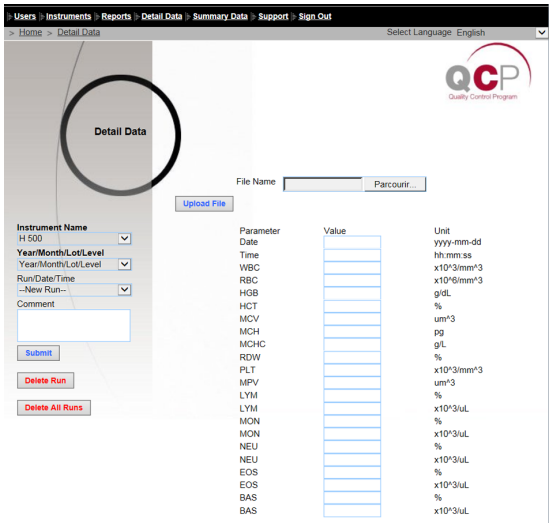
Related information:
- To Configure the Connection to Yumicare, p.202

7.2.2. To Submit your Instrument Results with a USB Flash Drive

You must have exported the control results from your instrument to a USB flash drive.

We recommend you to export your instrument results every month.

1. Insert your USB flash drive.
2. Go to the ***Detail Data*** tab.



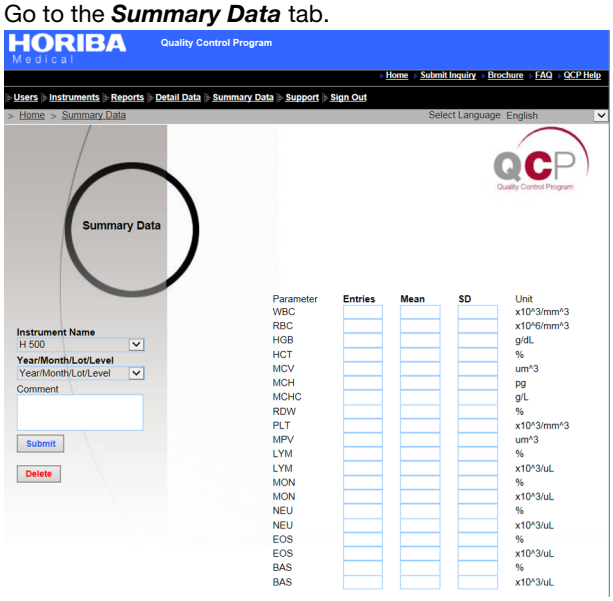
3. Select your instrument in the ***Instrument Name*** area.
4. Select your lot/level.
5. Enter the date and time.
6. Click **Browse** and select your control results file.
7. Click **Upload File**.
8. Click **Submit**.

Your instrument results are uploaded in the program.

Related information:
- To Export QC Results with a USB Flash Drive, p.91

7.2.3. To Manually Submit your Instrument Results

1. Go to the ***Summary Data*** tab.



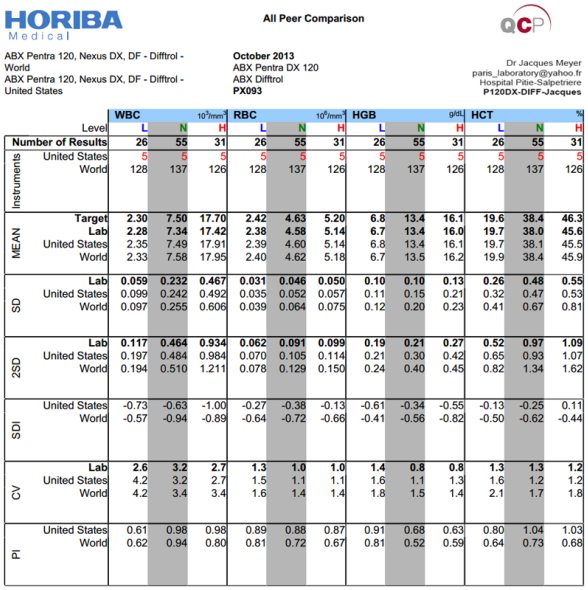
2. Select your instrument in the ***Instrument Name*** area.
3. Select your lot/level.
4. Enter the date and time.
5. Manually enter your results.
6. Click **Submit**.

7.3. To Consult the Statistical Reports

You can consult the statistical reports from the **Reports** tab.

1. Select your instrument in the ***Instrument Name*** area.
2. Select your control lot.
3. Select the peer groups and the type of report you want to consult.
4. Select the delivery method.

5. Click **View Reports**.



HORIBA Medical

All Peer Comparison

QCP

ABX Pentra 120, Nexus DX, DF - Difftrol - World
ABX Pentra 120, Nexus DX, DF - Difftrol - United States

October 2013
ABX Pentra DX 120
ABX Difftrol
PX093

Dr Jacques Meyer
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Hospital Pitie-Salpetriere
P120DX-DIFF-Jacques

		WBC			RBC			HGB			HCT		
		$10^3/mm^3$			$10^6/mm^3$			g/dL			%		
	Level	L	N	H	L	N	H	L	N	H	L	N	H
	Number of Results	**26**	**55**	**31**	**26**	**55**	**31**	**26**	**55**	**31**	**26**	**55**	**31**
Instruments	United States	5	5	5	5	5	5	5	5	5	5	5	5
	World	128	137	126	128	137	126	128	137	126	128	137	126
MEAN	**Target**	**2.30**	**7.50**	**17.70**	**2.42**	**4.63**	**5.20**	**6.8**	**13.4**	**16.1**	**19.6**	**38.4**	**46.3**
	Lab	**2.28**	**7.34**	**17.42**	**2.38**	**4.58**	**5.14**	**6.7**	**13.4**	**16.0**	**19.7**	**38.0**	**45.6**
	United States	2.35	7.49	17.91	2.39	4.60	5.14	6.8	13.4	16.1	19.7	38.1	45.5
	World	2.33	7.58	17.95	2.40	4.62	5.18	6.7	13.5	16.2	19.9	38.4	45.9
SD	**Lab**	**0.059**	**0.232**	**0.467**	**0.031**	**0.046**	**0.050**	**0.10**	**0.10**	**0.13**	**0.26**	**0.48**	**0.55**
	United States	0.099	0.242	0.492	0.035	0.052	0.057	0.11	0.15	0.21	0.32	0.47	0.53
	World	0.097	0.255	0.606	0.039	0.064	0.075	0.12	0.20	0.23	0.41	0.67	0.81
2SD	**Lab**	**0.117**	**0.464**	**0.934**	**0.062**	**0.091**	**0.099**	**0.19**	**0.21**	**0.27**	**0.52**	**0.97**	**1.09**
	United States	0.197	0.484	0.984	0.070	0.105	0.114	0.21	0.30	0.42	0.65	0.93	1.07
	World	0.194	0.510	1.211	0.078	0.129	0.150	0.24	0.40	0.45	0.82	1.34	1.62
SDI	United States	-0.73	-0.63	-1.00	-0.27	-0.38	-0.13	-0.61	-0.34	-0.55	-0.13	-0.25	0.11
	World	-0.57	-0.94	-0.89	-0.64	-0.72	-0.66	-0.41	-0.56	-0.82	-0.50	-0.62	-0.44
CV	**Lab**	**2.6**	**3.2**	**2.7**	**1.3**	**1.0**	**1.0**	**1.4**	**0.8**	**0.8**	**1.3**	**1.3**	**1.2**
	United States	4.2	3.2	2.7	1.5	1.1	1.1	1.6	1.1	1.3	1.6	1.2	1.2
	World	4.2	3.4	3.4	1.6	1.4	1.4	1.8	1.5	1.4	2.1	1.7	1.8
PI	United States	0.61	0.98	0.98	0.89	0.88	0.87	0.91	0.68	0.63	0.80	1.04	1.03
	World	0.62	0.94	0.80	0.81	0.72	0.67	0.81	0.52	0.59	0.64	0.73	0.68

Workflow

1. Start of Day

1.1. To Check the Waste Container Level

1. Check the level of waste in the container.
2. If it needs to be emptied, refer to the *Maintenance and Troubleshooting* > *Replacement Procedures* > *Replacing Reagents* > *To Replace the Waste Container* chapter.

The specimens, reagents, calibrators, controls, etc. and waste liquids that contain human specimen extracts are potentially infectious; all accessible surfaces of the instrument can be potentially contaminated by human specimens.
Protective clothing must be worn (lab coat, gloves, eye protection, etc.).

- At the beginning of each day, before startup, check if the waste container needs to be emptied.
- During instrument operation, do not remove the reagent tubing and the liquid waste tubing under any circumstance.

Follow your local and/or national guidelines for biohazard waste disposal.

Related information:
- To Replace the Waste Container, p.255

1.2. To Switch the Printer On

Start and check the printer at the beginning of the day.

Make sure that the printer has enough paper for daily operations. If not, add some paper following the instructions of the printer user guide.

Check the alignment of the paper if the printer used is a tractor feed printer.

1. Press the **ON/OFF** switch.
2. Wait during printer initialization.
3. Make sure that the control LEDs are on.

If the printer does not work properly, refer to its user guide.

1.3. Starting the Instrument

1.3.1. To Switch the Instrument On

Before switching the instrument on, you need to:

- Check the operational conditions described in the *Introduction* > *Operational Conditions* chapter.
- Check all instrument connections. To learn more about connections, refer to the *Introduction* > *Labels and Connections* chapter.
- Check if the waste container needs to be emptied. Follow the instructions in the *Specifications* > *Reagent Specifications* > *Waste Handling Precautions* chapter.

1. Switch the instrument on.
2. Wait during initialization.
   A startup cycle begins, if scheduled by default.
3. Log in to the application.
   Refer to the *Workflow* > *Start of Day* > *Starting the Instrument* > *To Log In to the Application* chapter.

Related information:
- To Log In to the Application, p.118
- Operational Conditions, p.17
- Labels and Connections, p.22
- Waste Handling Precautions, p.60

1.3.2. To Log In to the Application

If an error message is displayed during initialization or if the application does not start properly, please contact your local HORIBA Medical representative.

1. Select your user name.
2. Enter your password.
3. Press **Validate** in the contextual toolbar.
   - If your user account is locked (you have reached the maximum number of failed attempts), wait 15 minutes before trying again.
   - If your user account is disabled, ask your Lab Manager to reactivate it.
4. Select **Reset sample ID auto-numbering** in the ***Start of day*** window, if necessary.
   This step is only necessary at the beginning of the day and if the option is selected.
5. Select **Erase worklist** in the ***Start of day*** window, if necessary.
   This step is only necessary at the beginning of the day and if the option is selected.
6. Select **Export patient results before data deletion** if necessary.
   This option is available if 10000 results are detected in the system.
7. Press **Validate**.
   A dialog box indicates the date of your last login and the number of failed attempts since your last login. If your password expires soon, the dialog box also informs you that you have to change your password.

8. Press **OK**.

If a reagent is expired, the software informs you when you log in.

If the shutdown cycle has not been performed at the end of the previous day, the system force you to perform a shutdown cycle before the startup.

The shutdown cycle is efficient and valid only if the cleaner remains at least 10 minutes in the chambers after the cycle. This cleans the hydraulic circuit.

You must not perform any actions during these 10 minutes at the risk of performing the shutdown cycle again.

Related information:
- To Reactivate a User Account, p.191

1.3.3. To Control the Reagents

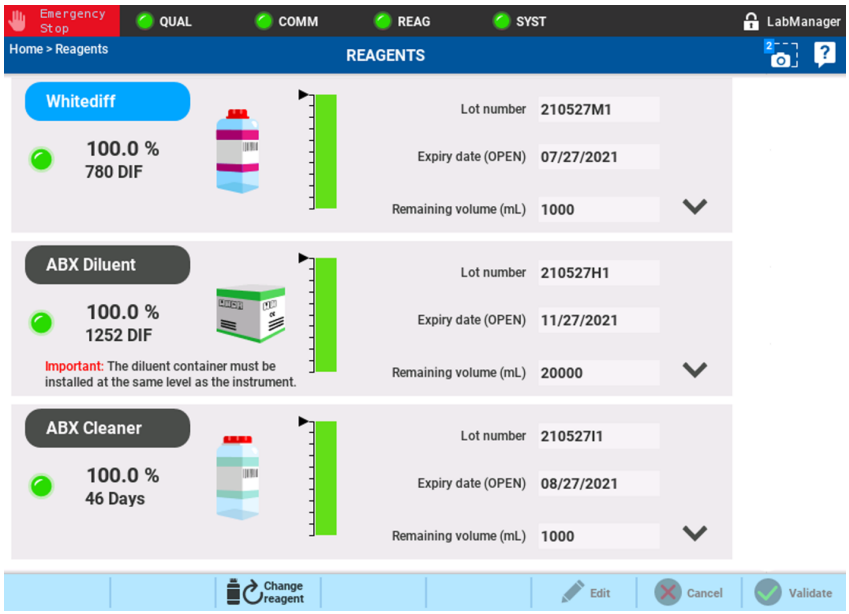
*Access: **Home** > **Reagents***

The system can manage HORIBA Medical reagents automatically (levels and expiration date). It informs the user about the reagents status at the end of the instrument start, or displays an alarm message in the ***Reagents*** screen if a reagent runs low or has expired.

IFS However, it is recommended to check the reagent levels and expiration date before starting the system to avoid risk of erroneous results.

---

1. Check the level of the reagent bottles from the software.



2. Visually check the lot number and expiration date on the reagent bottles.

3. If a reagent bottle has to be changed, refer to the *Maintenance and Troubleshooting* > *Replacement Procedures* > *Replacing Reagents* chapter.

Related information:
- Replacing Reagents, p.253

1.3.4. To Perform a Manual Startup

1. Press **Startup**.
2. Wait until the cycle is over.
   A startup cycle takes approximately one minute.
   LED voltage is checked and blank cycles (cycles without any blood specimen) are performed during the startup cycle. The startup passes if the background counts are within acceptable limits:

Parameter	Background count limits
WBC	≤ 0.3 x 10^3/mm^3
RBC	≤ 0.03 x 10^6/mm^3
HGB	≤ 0.3 g/dL
PLT	≤ 5 x 10^3/mm^3

You can consult the startup results in the **Blank** logs.

Related information:
- Logs Overview, p.106
- Startup Failed, p.242

1.3.5. To Schedule an Automatic Startup

Access: ***Home*** > ***Settings*** > ***System*** > ***Cycles***

For the automatic startup to work:

- *the instrument and the printer must be switched on 24/7*
- *a shutdown cycle must have been performed at the end of the previous work day*
- *the shutdown lasts 10 minutes and it should not be interrupted during this time*

When you schedule an automatic startup, it is run as soon as connections with the instrument and reagent levels have been checked. By default, the starting time is 07:00 AM.

1. Press **Edit** in the contextual toolbar.
2. Enter the startup time in the ***Starting Time*** field of the ***Automatic Startup*** area.
3. Select the days on which the automatic startup must be performed.

2. Running Control Blood Samples

2.1. To Run a Control Blood Sample in Rack Mode

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Make sure you have created the control lot before running it so that it is not run like a blood sample.

1. Prepare your control blood according to the specific instructions detailed in the control blood package insert.
2. Place the tube in the rack.
   Make sure that the barcode label is visible for the internal barcode reader.
3. Place the rack at the start of the loading area. Be careful to push the rack inside the instrument.

4. Close the door.
5. Press **Start Rack** in the function toolbar.
6. When the rack is ejected, remove it from the unloading area.

Related information:
- Creating a Control Lot Automatically, p.86
- To Create a Control Lot Manually, p.86
- Warnings and Biological Hazards Labels, p.23

2.2. To Run a Control Blood Sample in Stat Mode

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

Make sure you have created the control lot before running it so that it is not run like a blood sample.

1. Prepare your control blood according to the specific instructions detailed in the control blood package insert.
2. Press **Stat Mode** in the function toolbar.
3. Enter the sample ID of the control blood sample.
4. Press **Validate** in the contextual toolbar.
5. Gently and thoroughly mix the sample.
6. Put the tube in the tube holder and close the door.

When placing your tube in the tube holder, make sure that you are using the appropriate position and that the cap can be pierced. If not, remove the cap before closing the door.

7. Press **Validate** to start sampling.
8. When the tube holder moves back to the front of the analyzer, remove the tube and put the cap back on if needed.

Risk of erroneous results if the specimen is not continuously mixed between each analysis. Keep on mixing the specimen between each analysis.

Related information:
- Creating a Control Lot Automatically, p.86
- To Create a Control Lot Manually, p.86

2.3. To Check Control Results

Access: ***Home*** > ***Quality Assurance*** > ***Quality control***

1. Select a control lot.
2. Make sure that the results are within control target values range.
3. If results are out of range, perform a concentrated cleaning and rerun the control blood.

If results are still out of range, please check your reagents and your control blood stability and then contact your local HORIBA Medical representative.

Related information:
- To Perform a Concentrated Cleaning, p.231
- Running Control Blood Samples, p.121

2.4. To Run an External Control Blood Sample

1. Prepare your control blood according to the specific instructions detailed in the control blood package insert.
2. Press **Stat Mode** in the function toolbar.
3. Enter the sample ID of the control blood sample.
4. Select the analysis type.
5. Select the analysis mode from the **Analysis mode** drop-down list.
   - **EQC Control Mode**: the control blood sample is run in control mode.
   - **EQC Patient Mode 1**: the control blood sample is run in patient mode with corrected WBC count (cellular interferences removal).
   - **EQC Patient Mode 2**: the control blood sample is run in patient mode without corrected WBC count.

It is recommended to run external control blood samples with the **EQC Control Mode** analysis mode unless otherwise instructed in the control blood package insert.

6. Press **Validate** in the contextual toolbar.
7. Gently and thoroughly mix the sample.
8. Put the tube in the tube holder and close the door.

When placing your tube in the tube holder, make sure that you are using the appropriate position and that the cap can be pierced. If not, remove the cap before closing the door.

9. Press **Validate** to start sampling.
10. When the tube holder moves back to the front of the analyzer, remove the tube and put the cap back on if needed.

Risk of erroneous results if the specimen is not continuously mixed between each analysis. Keep on mixing the specimen between each analysis.

11. Wait until the analysis is over and check the results.

3. Worklist

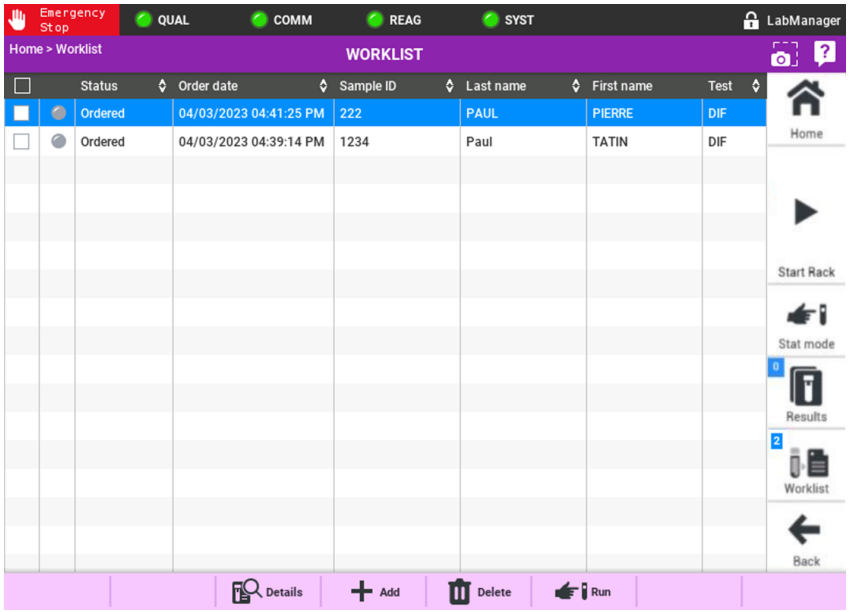
3.1. Worklist Overview

*Access: **Home** > **Patient Results** > **Worklist***

*Access: **Home** > **Worklist***

The worklist allows you to:

- create orders,
- provide all the patient data,
- specify the test to carry out,
- directly run samples.



The worklist displays the orders list with their status:

- ***Ordered***: the order is asked
- ***In Progress***: analysis is in progress

Orders disappear as soon as they have been run.

3.2. To Create an Order

*Access: **Home** > **Patient Results** > **Worklist***

*Access: **Home** > **Worklist***

1. Press **Add** in the contextual toolbar.
2. Enter the ***Sample ID*** and press another field so that the software checks if the SID is already known.

It is possible to create several orders with a same SID for different analysis types.

3. If your instrument is connected to a Host (LIS or Yumizen P8000), press **Query** to retrieve the analysis data for the sample and acknowledge the tube presence.

4. If your instrument is not connected to a Host:
   a. Enter the physician, the department and/or comments about the sample, if necessary.
   b. If necessary, enter the patient ID or press **Search** to select it.
   c. Enter the name, the gender and the date of birth of the patient, if necessary.
      The sample type is automatically determined based on the demographic data you entered.
      Normal and panic ranges differ from one blood sample type to another.
   d. Select the analysis type.
      You can configure which analysis is selected by default.
      For more information, refer to *Settings* > *Configuring the Instrument* > *To Select the Default Mode*.
5. If you have diluted the sample before the analysis, enter the dilution factor (from 1 to 10) so that the factor is taken into account in the results rendered.

Be aware that if you have diluted the sample before the analysis, some alarms can be falsely not triggered only due to the pre-dilution.

6. Press **Validate** in the contextual toolbar.

The order appears in the worklist in ***Ordered*** status.

Related information:
- To Select the Default Mode, p.168

3.3. To Sort Orders

*Access: **Home** > **Patient Results** > **Worklist***

In the worklist, you can sort the analyses according to various criteria.

1. Press the column header once to obtain an increasing order.
2. Press the column header twice to obtain a decreasing order.
3. Press the header of a column three times to restore default order.

3.4. To Delete Orders

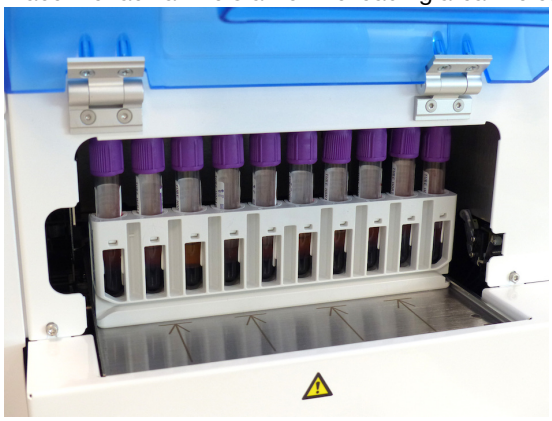
Access: ***Home*** > ***Patient Results*** > ***Worklist***

1. Select the orders you want to delete from the list.
2. Press **Delete** in the contextual toolbar.
3. Press **Confirm**.

4. Running Blood Samples

4.1. To Run a Blood Sample in Rack Mode

1. Prepare your worklist.
2. Place the tube in the rack.
   Make sure that the barcode label is visible for the internal barcode reader.
3. Place the rack at the start of the loading area. Be careful to push the rack inside the instrument.



4. Close the door.
5. Press **Start Rack** in the function toolbar.
6. When the rack is ejected, remove it from the unloading area.

In case of rerun, it is recommended to run the sample in stat mode and to remove the cap before closing the door.

The stat mode can be used while analyses in rack mode are running. In this case, the analyses in the rack are paused and the sample in stat mode is run in priority.

Related information:
- Warnings and Biological Hazards Labels, p.23
- Worklist, p.124

4.2. To Run a Blood Sample in STAT Mode

1. Press **Stat Mode** in the function toolbar.
   If analyses in rack mode are running, they are stopped and the **Start Rack** button blinks.
2. Enter the ***Sample ID*** and press another field so that the software checks if the SID is already known.
3. If your instrument is connected to a Host (LIS or Yumizen P8000), press **Query** to retrieve the analysis data for the sample and acknowledge the tube presence.

4. If your instrument is not connected to a Host, enter all the information related to the blood sample and the patient.
5. If you have different orders associated with a same SID, the ***Run analysis*** window displays.
6. Select the analysis type.
7. If you have diluted the sample before the analysis, enter the dilution factor (from 1 to 10) so that the factor is taken into account in the results rendered.

Be aware that if you have diluted the sample before the analysis, some alarms can be falsely not triggered only due to the pre-dilution.

8. Press **Validate** in the contextual toolbar.
9. Gently and thoroughly mix the sample.
10. Put the tube in the tube holder and close the door.

When placing your tube in the tube holder, make sure that you are using the appropriate position and that the cap can be pierced. If not, remove the cap before closing the door.

11. Press **Validate** to start sampling.
12. When the tube holder moves back to the front of the analyzer, remove the tube and put the cap back on if needed.
13. Press **Start Rack** to return back to the rack mode if needed.

In case of rerun, it is recommended to remove the cap before closing the door.

4.3. To Run a Blood Sample from the Worklist

Access: ***Home*** > ***Worklist***

An order must be created.

1. Select the order to be run.
2. Press **Run** in the contextual toolbar.
   A dialog box displays.
3. Check patient information and follow the instructions on screen.
4. Press **Validate** to start sampling.
5. When the tube holder moves back to the front of the analyzer, remove the tube and put the cap back on if needed.

Related information:
- To Create an Order, p.125

4.4. To Interrupt Analyses in Rack Mode

Analyses in rack mode are running.

1. Press **Stop Rack** in the function toolbar.
   The analysis of the tube in progress is complete. The rack is ejected without processing the pending tubes.
2. When the rack is ejected, remove it from the unloading area.

5. Results Matching

5.1. Sample Identification

5.1.1. Sample Identification using Barcode Label

Identifying a sample allows the instrument to automatically match an order to a sample, or the operator to manually match an order to a sample.

The sample can be identified through the barcode identification.

The ***Sample ID*** field must be filled with the barcode number. When you run an analysis, orders and samples are matched, and there are virtually no risks of mismatch.

Note that it is not possible to select a position in the rack during sampling identification.

5.1.2. Automatic Numbering

When a sample tube does not have an ID, the instrument automatically generates an ID. This ID is made of two parts: "*AUTO_SID*" followed by a number which is incremented every time a new ID is generated, e.g. *AUTO_SID001*.

This happens for example:

- when a tube is not barcoded
- when the barcode label cannot be read
- if you do not manually assign an ID to the tube

Related information:
- To Modify the Sample ID Automatic Numbering, p.167

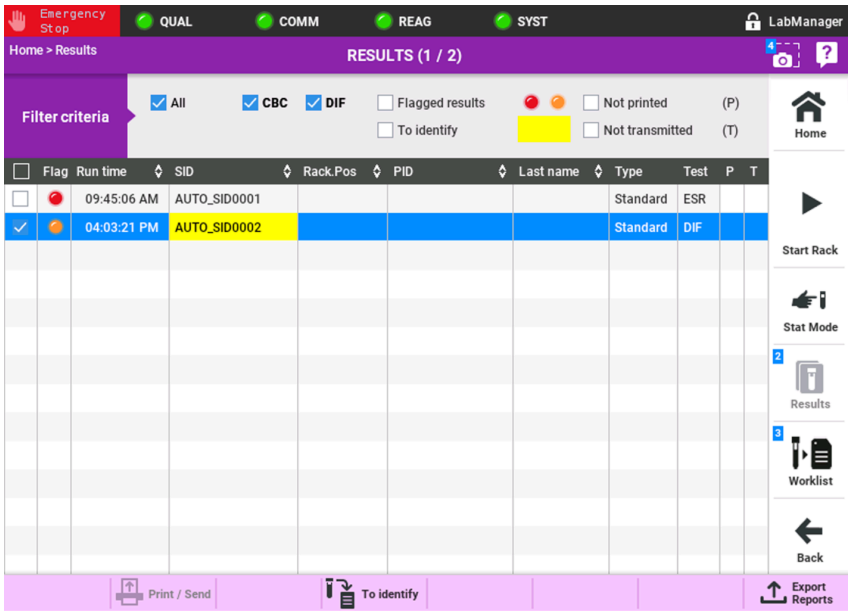
5.2. Manual Match Overview

Access: ***Home*** > ***Results*** > ***To identify***

The ***Association*** screen is only available if you selected the **Do not send AUTO_SID** option in the ***Print / Transmit*** settings.

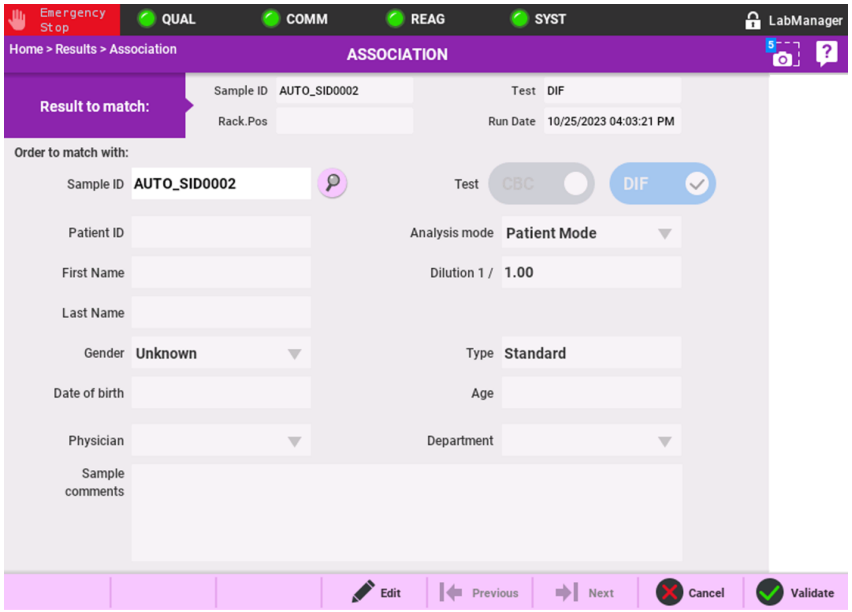
When a sample is run in AUTO_SID, the result is not matched with an order.

In this case, the **Results** button blinks and the ***Sample ID*** appears in yellow in the list.



Pressing **To identify** allows you to reach the ***Association*** screen.

This screen allows you to manually match results and orders in case of unmatched results.



Related information:
- To Configure Results Printing and Transmission, p.172

5.3. To Manually Match Results

Access: ***Home*** > ***Results*** > ***To identify***

You can match results only at the end of the analysis cycle.

1. If you want to retrieve the order in the worklist:
   a. Press the **Search** button.
   b. Select the order from the list.
   c. Press **Validate** in the contextual toolbar.
2. If you want to retrieve the analysis data of the sample from the Host (LIS or Yumizen P8000):
   a. Press the **Query** button.
   b. Wait for the software to retrieve the sample ID.
3. If you want to manually enter the sample information:
   a. Press **Edit** in the contextual toolbar.
   b. Manually enter information about sample and patient.
4. Press **Validate** in the contextual toolbar.
5. Press **Confirm** to confirm the result matching.

If you change the following data, flags for the result are re-evaluated, to take into account the thresholds:

- ***Gender***
- ***Date of birth***
- ***Type***
- ***Age***

Each result matching is saved in the user logs.

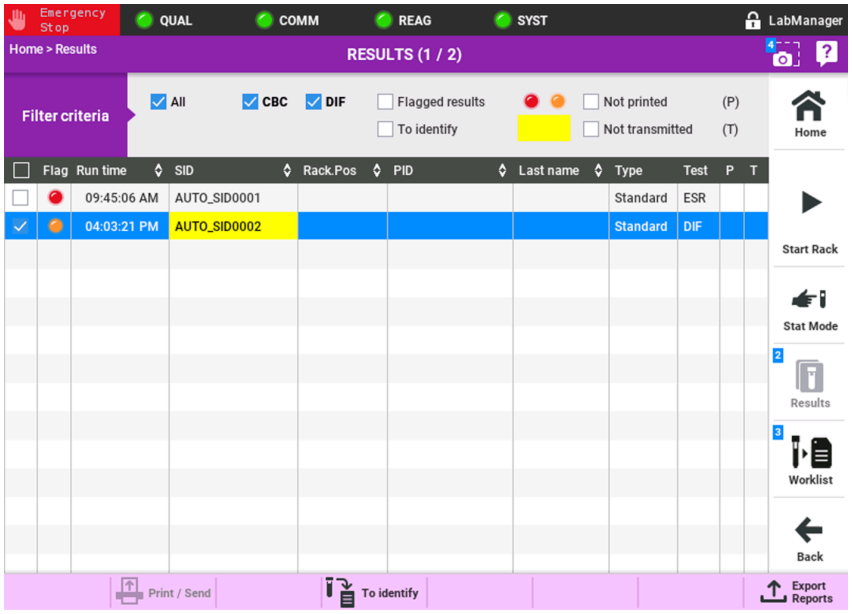
Related information:
- Logs Overview, p.106

6. Results Management

6.1. Results Overview

*Access: **Home** > **Results***

This screen displays the list of results obtained during the current session (non archived results).



The results list allows you to consult the status of all the results. You can see:

- Result status: green (without alarm), orange (hematologic alarm), red (technical alarm)
- Run time information
- Sample information
- Patient information
- Analysis type information
- Print and Host (LIS or Yumizen P8000) transmission information

6.2. To Display Detailed Results

*Access: **Home** > **Results***

The detailed results are accessible from the following functions:

- **Results**
- **Archives**

1. Open one of the above functions.
2. Press a row to display the detailed results.

3. Verify the result status in the header of the screen (A).
   - Green: without alarm
   - Orange: hematologic alarm
   - Red: technical alarm
4. In case of alarm (orange or red), you may need to check all the parameters values and associated flags in the ***Standard*** tab (B).
   - "_._": rejected result
   - Parameter associated with an "*": suspected result
   - Blue parameter associated with L: result < panic limits.
   - Blue parameter associated with ℓ: result < normal limits.
   - Blue parameter associated with ▼: result < linearity limits
   - Red parameter associated with h: result > normal limits.
   - Red parameter associated with H: result > panic limits.
   - Red parameter associated with ▲: result > linearity limits
   - Parameter associated with +++: result > visibility limits
5. You can also check the alarm panel (C) which displays:
   - Recommended actions
   - Alarms
   - Suspected pathologies
   - NLR ratio value

6. If you have diluted the sample before the analysis and entered the dilution factor in the order, the message *Prediluted sample* is displayed in the information panel (D).

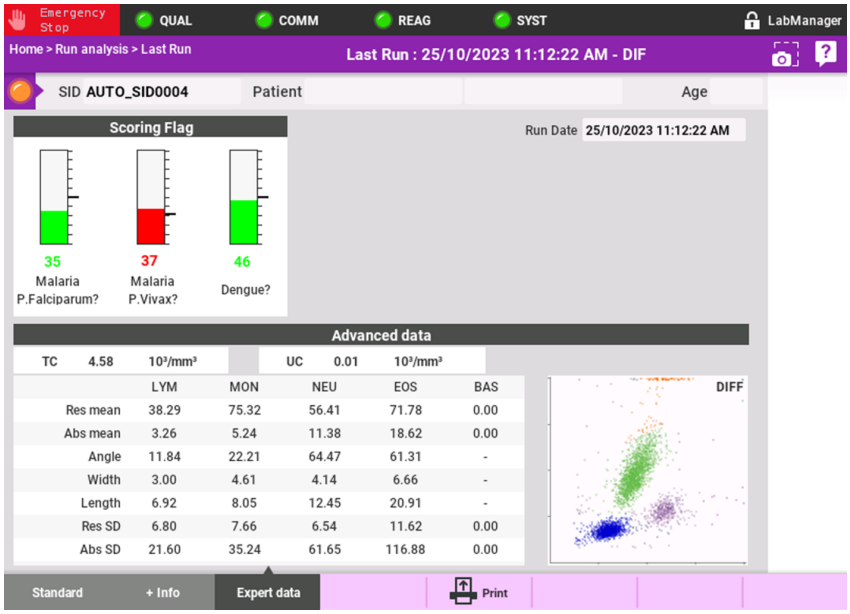
Be aware that if you have diluted the sample before the analysis, some alarms can be falsely not triggered only due to the pre-dilution.

7. Press ***+ Info*** in the contextual toolbar if you need to display more information on patient and sample.

6.3. To Display Advanced Data

Access: ***Home*** > ***Results***

1. Select a result.
2. Press ***Expert data*** in the contextual toolbar if you need to display more data on the results.
   a. For results (DIFF) the following information displays:



Scoring Flag: 3 graduated gauges indicate the Malaria and Dengue scores of the sample.

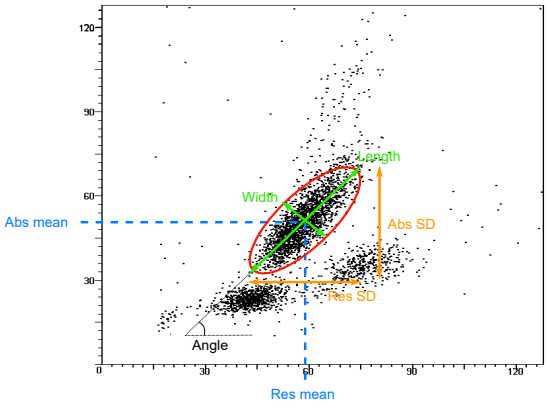
- Green: The sample score is lower than the threshold set up in the software.
- Red: The sample score is higher that the threshold set up in the software. This triggers the corresponding suspected pathology.

The ***Scoring Flag*** is only displayed with the Malaria mode activated (available as an option).

Advanced data: WBC cells measurement data for investigation use and/or extensive diagnosis interpretation.

- **TC** (Total Cells): total number of counted particles on the DIFF matrix including the WBC and extra cells such as platelet aggregates, erythrocyte membrane resistant to lysis (stroma), erythroblasts (NRBC), infected erythrocytes, ...
- **UC** (Unclassified Cells): **TC** - WBC
- The following data is given for each population: LYM, MON, NEU, EOS, BAS.

Item	Description
Res mean	Resistive mean
Abs mean	Absorbance mean
Angle	Angle of the scatter plot
Width	Width of the scatter plot
Length	Length of the scatter plot
Res SD	Resistive standard deviation
Abs SD	Absorbance standard deviation



6.4. To Print or Send your Results

Results are automatically printed at the end of an analysis if the option is selected.

Results are automatically sent to the Host (LIS or Yumizen P8000) at the end of an analysis if the option is selected.

For more information, refer to the *Settings* > *Configuring the Instrument* > *To Configure Results Printing and Transmission* chapter.

1. Select the results you want to print or send from the results list.
2. Press **Print / Send** in the contextual toolbar.
3. Select **Print only selected results** or **Send only selected results**.
4. Press **Validate**.

The raw values are automatically printed for users with a Technician profile.

Related information:
- To Configure Results Printing and Transmission, p.172

6.5. To Export Results

Access: ***Home*** *>* ***Patient Results***

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

You can export patient results from the **Results** screen or the **Archives** screen.

1. Select the results you want to export.
2. Press **Export Reports** in the contextual toolbar.
3. Select the export format.
   - **XML**
   - **XML (expert mode)** if you need to export more data on the results (Malaria and Dengue scores of the sample, advanced data on the DIFF matrix)
   - **PDF**
4. Select **Anonymize data**, if necessary.
   This step is only necessary if you want to hide the patient information in the export file.
5. Insert the USB flash drive.
6. Press **Validate**.
7. When the export is complete, remove the USB flash drive and press **OK**.

If patient data is not hidden, the export file is zipped and protected by the PHI key as password.

7. Results Interpretation

7.1. General Flags

7.1.1. Parameter Reject

Rejected results are replaced with "_._".

Results are rejected whenever the difference between several counts or measurements for a parameter is out of the predefined limits.

It also appears when there is an instrument technical issue.

They indicate that the results for the flagged parameters are not validated, and that they should be investigated for the manual rerun status, and/or an instrument malfunction if the flag appears on every sample.

7.1.2. Suspicion

Results with suspicion are displayed but followed by an "*".

This indicates that displayed results are not reliable.

Suspicions appear when the analyzer detects a possible anomaly during the count or a potential abnormality linked to an alarm. The reason of the suspicion must be understood and the sample rerun.

7.1.3. Normal and Panic Ranges

Results that exceed the normal or panic limits are identified with an alarm:

- ℓ means normal lower limits
- h means normal upper limits
- L means panic lower limits
- H means panic upper limits

If an L alarm or an H alarm is triggered, you must be particularly careful when validating the results. Make sure you check the anteriority of the patient and rerun the sample if there is no clinical specificity.

To change these limits, refer to the *Settings* > *Configuring the Results Settings* chapter.

Related information:
- Configuring the Results Settings, p.183

7.1.4. Parameters Out of Linearity Range

Results out of linearity limits defined for the instrument are identified with a flag:

- ▼: result below LoQ
- ▲: result above linearity range. You can dilute the sample with ABX Diluent and rerun.

7.2. Alarms Description

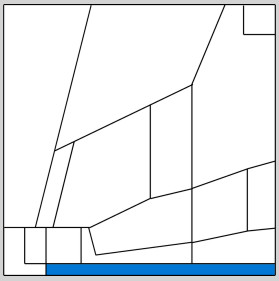
7.2.1. Alarms Type Definitions

Alarm type	Definition
Sample Alarm	Anomaly detected on the sample, the system warns the user. For example: platelet aggregates, icteric blood, interferences, etc.
Device Alarm	Anomaly detected on the analyzer, the system warns the user. For example: instability count, bubbling, clogging, etc. A rerun on the same analyzer or on another HORIBA Medical analyzer could solve the issue.

7.2.2. Analytical Alarm Messages (Device Alarm)

WBC

Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC Analytical error DIFF channel unstable measure	Unstable resistive measure Two of the 11 consecutive counts are not acceptable (different or out of ranges).	**Consequence** The following parameters results are flagged (*): WBC, LYM#, MON#, NEU#, EOS#, BAS#, IMG#, IMM#, IML#, ALY#, LIC# **Recommended action** Rerun
WBC Analytical error DIFF channel unstable measure	■ Correlation between the resistive and optical measurements on the matrix is too low (< 90%). ■ No cells are counted in the flowcell.	**Consequence** The following parameters results are flagged (*): WBC The following parameters results are rejected: LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Rerun
WBC Analytical error DIFF channel clog?	No cells are counted in the flowcell.	**Consequence** The following parameters results are rejected: WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Rerun

Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC Analytical error DIFF channel clog?	Counted number is abnormally low for: WBC	**Consequence** The following parameters results are flagged (*): WBC The following parameters results are rejected: LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Rerun
WBC Analytical error DIFF channel light beam error	Measure of the light intensity out of tolerance	**Consequence** The following parameters results are flagged (*): WBC The following parameters results are rejected: LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Rerun
WBC Analytical error DIFF channel bubble?	The percentage of counted particles in the low optical correlation (LOC) area in relation to the total number of white blood cells is too high. 	**Consequence** The following parameters results are rejected: LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Rerun

RBC

Alarms	Triggered if...	Consequence / possible causes / recommended action
RBC Analytical error RBC channel unstable measure	Unstable resistive measure Two of the 12 consecutive counts are not acceptable (different or out of ranges).	**Consequence** The following parameters results are rejected: RBC, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC **Recommended action** Rerun
RBC Analytical error RBC channel clog?	■ No cells are counted in the counting head. ■ Counted number is abnormally low for: RBC	**Consequence** The following parameters results are rejected: RBC, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC **Recommended action** Rerun
RBC Analytical error RBC/HGB channel balance	■ Result value is > 50 for: MCH ■ Result value is > 50 for: MCHC	**Consequence** The following parameters results are rejected: RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC, PLT, PCT, PDW, MPV, P-LCC, P-LCR **Recommended action** Rerun

HGB

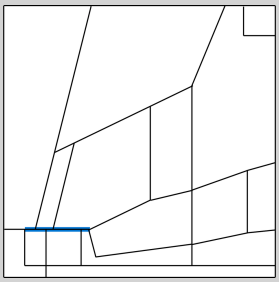
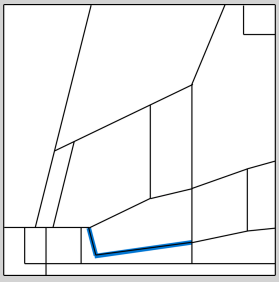
Alarms	Triggered if...	Consequence / possible causes / recommended action
HGB Analytical error HGB channel unstable measure	■ Intensity instability during the 9 measurements ■ Intensity instability during the 3 blank measurements ■ The different blank measurements are out of intensity ranges	**Consequence** The following parameters results are rejected: HGB, MCH, MCHC **Recommended action** Rerun

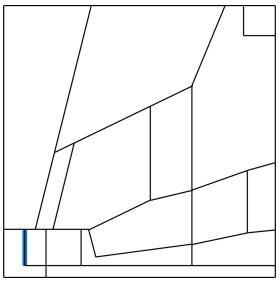
PLT

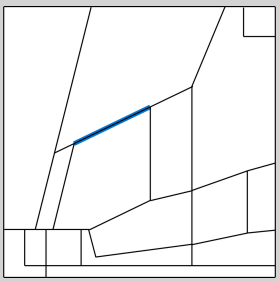
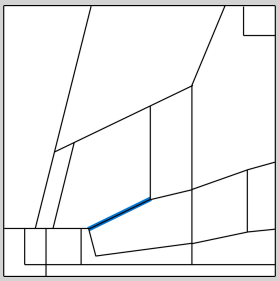
Alarms	Triggered if...	Consequence / possible causes / recommended action
PLT Analytical error PLT channel unstable measure	■ Unstable resistive measure Two of the 12 consecutive counts are not acceptable (different or out of ranges). ■ Abnormal pulses width ■ The percentage of counted small cells in relation to the total number of platelets is too high.	**Consequence** The following parameters results are rejected: PLT, PCT, PDW, MPV, P-LCC, P-LCR **Recommended action** Rerun
PLT Analytical error PLT channel unstable measure	The number of particles not counted, as they are smaller than the defined minimum threshold, is too high.	**Consequence** The following parameters results are rejected: PLT, PCT, PDW, MPV, P-LCC, P-LCR **Possible causes** ■ Platelet aggregates ■ Erythrocyte membrane resistant to lysis (stroma) ■ Erythroblasts (NRBC) ■ Electronic noise **Recommended action** Rerun
PLT Analytical error PLT channel clog?	■ No cells are counted in the counting head. ■ Counted number is abnormally low for: PLT	**Consequence** The following parameters results are rejected: PLT, PCT, PDW, MPV, P-LCC, P-LCR **Recommended action** Rerun
PLT Analytical error PLT channel clog?	Counted number is abnormally low for: PLT	**Consequence** The following parameters results are flagged (*): PLT The following parameters results are rejected: PCT, PDW, MPV, P-LCC, P-LCR **Recommended action** Rerun

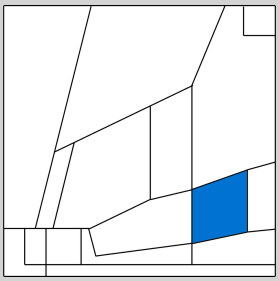
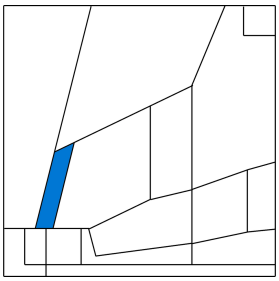
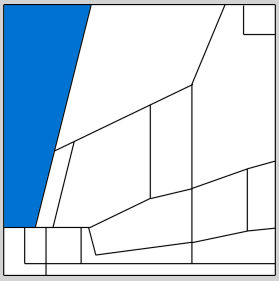
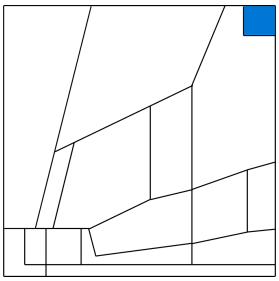
7.2.3. Clinical Alarm Messages (Sample Alarm)

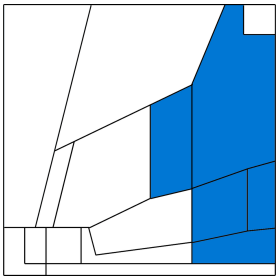
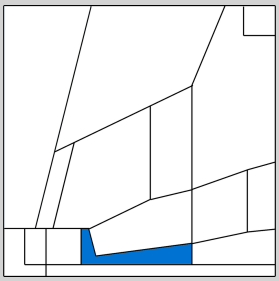
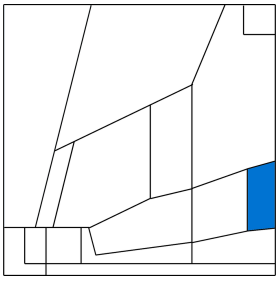
WBC

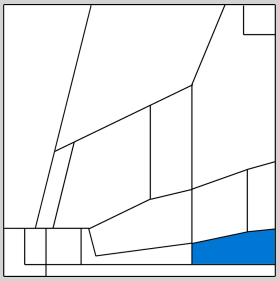
Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC abn. matrix TNC interference	Abnormally low number of: WBC	**Consequence** The following parameters results are flagged (*): WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Low leukocyte count ■ Background noise **Recommended action** Slide Review
WBC abn. matrix LYM/NEU	The separation threshold is not found between the lymphocytes and neutrophils areas. 	**Consequence** The following parameters results are flagged (*): LYM#, LYM%, NEU#, NEU%, BAS#, BAS%, IMM#, IMM%, IMG#, IMG%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Small neutrophils without granules and/or slightly segmented ■ Lymphocytes with a segmented nucleus or activated lymphocytes ■ Neutrophils with membrane weakness **Recommended action** Slide Review
WBC abn. matrix LYM/NEU	The number of counted particles in the separation area between lymphocytes and neutrophils in relation to the total number of cells in the lymphocytes and neutrophils areas is above the limit value. The default value is: 0.19	**Consequence** The following parameters results are flagged (*): BAS#, BAS% The following parameters results are rejected: LYM#, LYM%, NEU#, NEU%, IMG#, IMG%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Small neutrophils without granules and/or slightly segmented ■ Lymphocytes with a segmented nucleus or activated lymphocytes ■ Neutrophils with membrane weakness **Recommended action** Slide Review
WBC abn. matrix LYM/MON	The separation threshold is not found between the lymphocytes and monocytes areas. 	**Consequence** The following parameters results are flagged (*): LYM#, LYM%, MON#, MON%, BAS#, BAS%, IMM#, IMM%, IMG#, IMG%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Lymphocytosis ■ Monocytosis ■ Chronic lymphocytic leukemia (CLL) ■ Acute lymphoblastic leukemia (ALL) **Recommended action** Slide Review

Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC abn. matrix LYM/MON	The number of counted particles in the separation area between lymphocytes and monocytes in relation to the total number of cells in the lymphocytes and monocytes areas is above the limit value and the percentage of lymphocytes is: > 45% The default value is: 0.02	**Consequence** The following parameters results are flagged (*): BAS#, BAS% The following parameters results are rejected: LYM#, LYM%, MON#, MON%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Lymphocytosis ■ Monocytosis ■ Chronic lymphocytic leukemia (CLL) ■ Acute lymphoblastic leukemia (ALL) **Recommended action** Slide Review
WBC abn. matrix LYM/MON	The monocyte population extends to the left-hand side of the monocyte area.	**Consequence** The following parameters results are flagged (*): LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** Small monocytes **Recommended action** Slide Review
WBC abn. matrix LYM/NRBC	The number of counted particles in the separation area between the background noise low and lymphocytes areas in relation to the total number of cells in the background noise low and lymphocytes areas is above the limit value. The default value is: 0.14 	**Consequence** The following parameters results are flagged (*): WBC The following parameters results are rejected: LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Platelet aggregates ■ Erythroblasts (NRBC) ■ Infected erythrocytes ■ Small cell elements that may interfere with the lymphocyte count **Recommended action** Slide Review

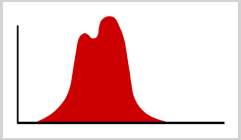
Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC abn. matrix NEU/EOS	■ The separation threshold is not found between the eosinophils and neutrophils areas. ■ Presence of significant large population of cells located in the separation area between neutrophils and eosinophils because the 2 populations are overlapping. 	**Consequence** The following parameters results are flagged (*): NEU#, NEU%, EOS#, EOS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Immature eosinophils ■ Giant hypersegmented neutrophils ■ Eosinophils with low intracytoplasmic material ■ Immature cells ■ Neutrophils with cytotoxic granulations **Recommended action** Slide Review
WBC abn. matrix NEU/EOS	The number of counted particles in the separation area between neutrophils and eosinophils in relation to the total number of cells in the neutrophils and eosinophils areas is above the limit value. The default value is: 0.018	**Consequence** The following parameters results are flagged (*): BAS#, BAS% The following parameters results are rejected: NEU#, NEU%, EOS#, EOS%, IMG#, IMG%, LIC#, LIC% **Possible causes** ■ Immature eosinophils ■ Giant hypersegmented neutrophils ■ Eosinophils with low intracytoplasmic material ■ Immature cells ■ Neutrophils with cytotoxic granulations **Recommended action** Slide Review
WBC abn. matrix MON/NEU	The separation threshold is not found between the monocytes and neutrophils areas. 	**Consequence** The following parameters results are flagged (*): MON#, MON%, NEU#, NEU%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Hypergranulation of monocytes or hyperbasophilic monocytes ■ Immature neutrophils with non-segmented nuclei (bandcells) or degranulated neutrophils **Recommended action** Slide Review
WBC abn. matrix MON/NEU	The number of counted particles in the separation area between monocytes and neutrophils in relation to the total number of cells in the monocytes and neutrophils areas is above the limit value and the percentage of monocytes is: > 15% The default value is: 0.10	**Consequence** The following parameters results are flagged (*): BAS#, BAS% The following parameters results are rejected: MON#, MON%, NEU#, NEU%, IMG#, IMG%, IMM#, IMM%, LIC#, LIC% **Possible causes** ■ Hypergranulation of monocytes or hyperbasophilic monocytes ■ Immature neutrophils with non-segmented nuclei (bandcells) or degranulated neutrophils **Recommended action** Slide Review

Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC abn. matrix MON/IMM	The percentage of counted particles on the right-hand side of the monocyte area in relation to the total number of white blood cells is above the limit value. The default value is 2.5% 	**Consequence** The following parameters results are flagged (*): MON#, MON%, NEU#, NEU%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, LIC#, LIC% **Possible causes** ■ Hyperbasophilic monocytes ■ Large monocytes ■ Myelocytes ■ Promyelocytes ■ Blasts **Recommended action** Slide Review
WBC abn. matrix NEU/Noise	Presence of a significant large population of cells located on the left-hand side of the neutrophil area. The default value is 15% 	**Consequence** The following parameters results are flagged (*): LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Neutrophil destruction due to incorrect storage of the sample or old sample ■ Contamination, stroma or platelet aggregates ■ Erythrocyte membrane resistant to lysis (stroma) **Recommended action** Slide Review
WBC abn. matrix NEU+EOS/Noise	The number of counted particles in the background noise area is higher than the limit set up in the software. ***Background Noise High*** default value: 80# 	**Consequence** The following parameters results are flagged (*): WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Large number of platelets ■ Erythrocyte membrane resistant to lysis (stroma) ■ Background noise **Recommended action** Slide Review
WBC abn. matrix Background noise	Presence of bubbles in the flowcell is detected in the background noise bubbles area. 	**Consequence** This alarm does not invalidate the results. However, the rack routine is stopped if this alarm is triggered consecutive times. **Recommended action** None

Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC abn. matrix PLT aggregates or NRBC?	■ The following platelet parameters results are not flagged (*) but noise is detected in the background low area. There is a significant large population of cells located on the left-hand side of the lymphocytes area. ■ The platelet parameters results are flagged (*). There is a significant large population of cells located on the left-hand side of the lymphocytes area but no noise is detected in the background low area.	**Consequence** The following parameters results are flagged (*): PLT, PCT, PDW, MPV, P-LCC, P-LCR, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Platelet aggregates ■ Erythroblasts (NRBC) **Recommended action** Slide Review
WBC abn. matrix LIC?	Presence of a significant large population of cells in the large immature cells area. 	**Consequence** This alarm does not invalidate the results. **Possible causes** Immature cells **Recommended action** None
WBC abn. matrix ALY?	Presence of a significant large population of cells in the atypical lymphocytes area. This alarm does not invalidate the results. 	**Consequence** This alarm does not invalidate the results. **Possible causes** Atypical Lymphocytes **Recommended action** None
WBC abn. matrix IMM?	Presence of a significant large population of cells in the middle part of the large immature cells area. 	**Consequence** This alarm does not invalidate the results. **Possible causes** Immature cells medium granulometry **Recommended action** None

Alarms	Triggered if...	Consequence / possible causes / recommended action
WBC abn. matrix IML?	Presence of a significant large population of cells in the lower part of the large immature cells area. 	**Consequence** This alarm does not invalidate the results. **Possible causes** Immature cells low granulometry **Recommended action** None
WBC abn. matrix NRBC?	The platelet parameters results are not flagged (*). No noise is detected in the background low area, but there is a significant large population of cells located on the left-hand side of the lymphocytes area.	**Consequence** The following parameters results are flagged (*): LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Erythroblasts (NRBC) ■ Small lymphocytes **Recommended action** Slide Review
WBC abn. matrix Blasts?	The percentage of counted particles in one of the following areas in relation to the total number of white blood cells is too high: ■ atypical lymphocytes area ■ monocyte area ■ right-hand side of the neutrophil area ■ far right of the matrix	**Consequence** The following parameters results are flagged (*): LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** Immature cells **Recommended action** Slide Review
WBC abn. matrix WBC interference	The level of interference is too high to provide a reliable value for: WBC	**Consequence** The following parameters results are flagged (*): WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Possible causes** ■ Platelet aggregates ■ Small lymphocytes ■ Erythrocyte membrane resistant to lysis (stroma) ■ Erythroblasts (NRBC) ■ Infected erythrocytes **Recommended action** Slide Review
WBC abn. matrix Abnormal NEU	Neutrophil population has abnormally shifted to the right.	**Consequence** The following parameters results are flagged (*): NEU#, NEU%, BAS#, BAS%, IMG#, IMG%, LIC#, LIC% **Possible causes** ■ Large neutrophils ■ Immature cells from granulocytic line (metamyelocytes, myelocytes, promyelocytes, myeloblasts) **Recommended action** Slide Review

RBC

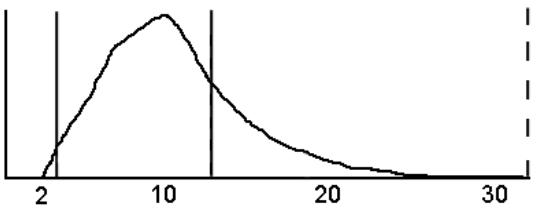
Alarms	Triggered if...	Consequence / possible causes / recommended action
RBC abn. histogram RBC/WBC interference	Large number of nucleated cells (WBC or NRBC) during counts for: RBC	**Consequence** The following parameters results are flagged (*): RBC, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC **Recommended action** None
RBC abn. histogram Double population?	Cell sizing difference is measured and 2 subpopulations are detected for: RBC 	**Consequence** The following parameters results are flagged (*): MCV, RDW-SD, MIC, MAC The following parameters results are rejected: RDW-CV **Possible causes** ■ Medical treatment ■ Blood transfusion ■ Hemolytic anemia
RBC abn. histogram Abnormal distribution	Abnormality is detected on the distribution curve for: RBC	**Consequence** The following parameters results are flagged (*): RDW-SD, RDW-CV, MIC, MAC **Possible causes** Large red blood cells with a low level of hemoglobin or very small erythrocytes with a high level of hemoglobin.
RBC abn. histogram Interference?	The result value is higher than the ***Max MCHC Suspicious*** limit set up in the software for: MCHC The default value is: 36.5	**Consequence** The following parameters results are flagged (*): RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC, PLT **Possible causes** ■ Sample interferences ■ Sampling issue **Recommended action** Check Sample/Rerun/Standard operation procedure

HGB

Alarms	Triggered if...	Consequence / possible causes / recommended action
HGB measurm. bias HGB/WBC interference	An elevated leukocyte count interferes on the measurement for: HGB	**Consequence** The following parameters results are flagged (*): HGB, MCH, MCHC **Recommended action** Rerun

PLT

The platelet histogram contains 256 channels between 2 fL and 30 fL. A mobile threshold (at 25 fL by default) moves according to the microcyte population present in the platelet analysis area.



This mobile threshold looks for a valley between the platelet and RBC populations.

Alarms	Triggered if...	Consequence / possible causes / recommended action
PLT abn. histogram RBC/PLT	■ The mobile threshold cannot position itself due to an excessive number of particles on the right side of the threshold area. ■ The result (PLT) is too low and the mobile threshold position is lower than the limit set up in the software. The default value is: 102 (10 fL)	**Consequence** The following parameters results are flagged (*): PLT, PCT, PDW, MPV, P-LCC, P-LCR **Possible causes** ■ Platelet aggregates ■ Schistocytes If platelet aggregates or platelet clumping are suspected, the patient sample should be redrawn in a sodium citrate tube. Do not vortex the sample. **Recommended action** Check Sample/Rerun/Standard operation procedure
PLT abn. histogram Schistocyte / Macro PLT?	■ High number of schistocytes ■ Percentage of counted schistocytes in relation to the total number of platelet is too high	**Consequence** The following parameters results are flagged (*): RDW-SD, RDW-CV, PLT, PCT, PDW, MPV, P-LCC, P-LCR, MCV **Possible causes** ■ Schistocytes ■ Macro platelets ■ Microcytes **Recommended action** Check Sample/Rerun/Standard operation procedure
PLT abn. histogram Abnormal PDW	Result is out of normal ranges for: PDW	**Consequence** The following parameters results are flagged (*): PLT, PCT, PDW, MPV, P-LCC, P-LCR **Possible causes** ■ Platelet aggregates ■ Schistocytes ■ Microcytes ■ Macro platelets **Recommended action** Slide Review
PLT Interference PLT aggregates?	The platelet parameters results are flagged (*) and noise is detected in the background low area or there is a significant large population of cells located on the left-hand side of the lymphocytes area.	**Consequence** The following parameters results are flagged (*): PLT, PCT, PDW, MPV, P-LCC, P-LCR **Possible causes** Platelet aggregates **Recommended action** Slide Review
PLT Concentrate Mode	It indicates the triggering of the "PLT extended linearity mode" for an hemoglobin < 1.5 g/dL with presence of platelets.	**Recommended action** None

7.2.4. Out of Range Alarm Messages (Sample Alarm)

WBC

Alarms	Triggered if...	Consequence / Recommended action
WBC out of range High visibility	Result out of visibility range	**Consequence** Flag +++ (above limit of visibility) on: WBC, LYM#, MON#, NEU#, EOS#, BAS#, IMG#, IMM#, IML#, ALY#, LIC# The following parameters results are flagged (*): LYM%, MON%, NEU%, EOS%, BAS%, IMG%, IMM%, IML%, ALY%, LIC% **Recommended action** Dilute and Rerun

RBC

Alarms	Triggered if...	Consequence / Recommended action
RBC out of range High visibility	Result out of visibility range	**Consequence** Flag +++ (above limit of visibility) on: RBC The following parameters results are rejected: HCT The following parameters results are flagged (*): MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC **Recommended action** Dilute and Rerun
HCT out of range High visibility	Result out of visibility range	**Consequence** Flag +++ (above limit of visibility) on: HCT The following parameters results are flagged (*): MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC **Recommended action** Dilute and Rerun

HGB

Alarms	Triggered if...	Consequence / Recommended action
HGB out of range High visibility	Result out of visibility range	**Consequence** Flag +++ (above limit of visibility) on: HGB The following parameters results are rejected: MCH, MCHC **Recommended action** Dilute and Rerun

PLT

Alarms	Triggered if...	Consequence / Recommended action
PLT out of range High visibility	Result out of visibility range	**Consequence** Flag +++ (above limit of visibility) on: PLT The following parameters results are flagged (*): RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PDW, MPV, P-LCR, WBC, LYM#, MON#, NEU#, EOS#, BAS#, IMG#, IMM#, IML#, ALY#, LIC# The following parameters results are rejected: P-LCC, PCT **Recommended action** Dilute and Rerun
PLT concent. mode	Platelet extended linearity mode detected when hemoglobin is < 1.5 g/dL with presence of platelets.	**Consequence** The following parameters results are flagged (*): RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC, WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** None

Parameters out of linearity ranges

Flag: ▼

Parameter	Triggered if...	Consequence / Recommended action
HGB	Result out of LoQ (Limit of Quantitation)	**Consequence** Flag ▼ (below limit of quantitation) on: HGB The following parameters results are flagged (*): HGB The following parameters results are rejected: MCH, MCHC **Recommended action** Check Sample/Rerun/Standard operation procedure
WBC	Result out of LoQ (Limit of Quantitation)	**Consequence** Flag ▼ (below limit of quantitation) on: WBC The following parameters results are flagged (*): WBC The following parameters results are rejected: LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Check Sample/Rerun/Standard operation procedure

Parameter	Triggered if...	Consequence / Recommended action
RBC	Result out of LoQ (Limit of Quantitation)	**Consequence** Flag ▼ (below limit of quantitation) on: RBC The following parameters results are flagged (*): RBC, HCT, MCV The following parameters results are rejected: MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC **Recommended action** Check Sample/Rerun/Standard operation procedure
HCT	Result out of LoQ (Limit of Quantitation)	**Consequence** Flag ▼ (below limit of quantitation) on: HCT The following parameters results are flagged (*): HCT, MCV The following parameters results are rejected: MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC **Recommended action** Check Sample/Rerun/Standard operation procedure
PLT	Result out of LoQ (Limit of Quantitation)	**Consequence** Flag ▼ (below limit of quantitation) on: PLT The following parameters results are flagged (*): PLT The following parameters results are rejected: PCT, PDW, MPV, P-LCC, P-LCR **Recommended action** Check Sample/Rerun/Standard operation procedure

Flag: ▲

Parameter	Triggered if...	Consequence / Recommended action
HGB	Result out of linearity range	**Consequence** Flag ▲ (above limit of linearity) on: HGB The following parameters results are flagged (*): HGB, MCH, MCHC **Recommended action** Dilute and Rerun
WBC	Result out of linearity range	**Consequence** Flag ▲ (above limit of linearity) on: WBC The following parameters results are flagged (*): WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC% **Recommended action** Dilute and Rerun
RBC	Result out of linearity range	**Consequence** Flag ▲ (above limit of linearity) on: RBC The following parameters results are flagged (*): RBC, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC **Recommended action** Dilute and Rerun

Parameter	Triggered if...	Consequence / Recommended action
HCT	Result out of linearity range	**Consequence** Flag ▲ (above limit of linearity) on: HCT The following parameters results are flagged (*): HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC **Recommended action** Dilute and Rerun
PLT	Result out of linearity range	**Consequence** Flag ▲ (above limit of linearity) on: PLT The following parameters results are flagged (*): PLT, PCT, PDW, MPV, P-LCC, P-LCR, RBC, WBC, LYM#, MON#, NEU#, EOS#, BAS#, IMG#, IMM#, IML#, ALY#, LIC# **Recommended action** Dilute and Rerun

7.3. Suspected Pathologies

"Suspected Pathologies" messages can be displayed and/or printed out. The triggering conditions are linked to the laboratory limits set by the user.

Suspected Pathology messages are only intended for use in a clinical laboratory and are not for patient diagnosis. Suspected pathology messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data.

These messages indicate a possible pathological disorder and should be used to assist with quick and efficient screening of abnormal samples, along with detection of certain conditions that lead to specific diagnoses. You must always confirm diagnoses by using reference methods.

7.3.1. WBC Messages

Message	Triggered when
Leukocytosis	WBC > WBC H
Leukopenia	WBC < WBC L and Pancytopenia = false
Lymphocytosis	LYM# > LYM# H
Lymphopenia	LYM# < LYM# L
Neutrophilia	NEU# > NEU# H
Neutropenia	NEU# < NEU# L
Extrem neutropenia	NEU# < 0.5 10^3/mm^3
Eosinophilia	EOS# > EOS# H
Monocytosis	MON# > MON# H
Basophilia	BAS# > BAS# H

Message	Triggered when
Large Immature Cells	LIC# > LIC# H or LIC% > LIC% H
Atypical Lymphocytes	ALY# > ALY# H or ALY% > ALY% H
Pancytopenia	WBC < WBC L and RBC < RBC L and PLT < PLT L
Aplasia	WBC < 1 $10^3/mm^3$

7.3.2. RBC Messages

Message	Triggered when
Erythrocytosis	RBC > RBC H
Anemia	HGB < HGB L
Macrocytosis	MCV > MCV H
Microcytosis	MCV < MCV L
Pancytopenia	WBC < WBC L and RBC < RBC L and PLT < PLT L
Hypochromia	MCH < MCH L and RDW-CV < RDW-CV H
Anisocytosis	RDW-CV > RDW-CV H and MCH > MCH L
Poikilocytosis	MCH < MCH L and RDW-CV > RDW-CV H
Cold agglutinins	MCHC > MCHC H and RBC > 0.1 $10^6/mm^3$ and WBC < 85 $10^3/mm^3$

7.3.3. PLT Messages

Message	Triggered when
Thrombocytosis	PLT > PLT H
Thrombopenia	PLT < PLT L and Pancytopenia = false
Pancytopenia	WBC < WBC L and RBC < RBC L and PLT < PLT L

7.3.4. Infectious Screening Messages

Malaria and Dengue suspicion messages

The Malaria and Dengue suspicion messages are only displayed with the Malaria mode activated (available as an option). Please contact your local HORIBA Medical representative.

When the Malaria mode is activated, the Malaria and Dengue scores are calculated and displayed on the **Results** screen.

The Malaria and Dengue suspicion messages are triggered when one of these scores is higher than the limit set up in the software.

Message	Default value
Malaria P. falciparum?	Score > 0.50
Malaria P. vivax?	Score > 0.31
Dengue?	Score > 0.50

The infectious suspicion messages aim at providing a screening flag for triggering out suspected Malaria and Dengue infections. Only for intended use in a clinical laboratory and not for patient diagnosis. The user must confirm the Malaria or Dengue diagnosis by using reference method in compliance with Standard Operating Procedure of its laboratory.

The Malaria and Dengue suspicion messages are combined with patient analyses in DIFF mode and these results performance could be affected with the below interfering conditions:

- Aging specimens; fresh blood specimens are required (processed within 4 hours after collection)
- Hemolyzed specimens
- Lipemic specimens
- Platelet aggregates
- Erythroblasts (NRBC)
- Children aged less than 12 years old for Dengue detection

Scoring Threshold Set Up as per Diseases Prevalence

The default cut off values have been determined for a high infectious disease rate during the rainy season.

When the pathogens are less present into the samples pool, the clinical performance of flags are different and cut off values can be adjusted depending on the prevalence of the diseases.

You'll find in the table below the optimized scoring values which can be set up depending on the infectious diseases rate for the 3 different pathogens:

Prevalence (positive samples rate)	1%	5%	10%	15%	20%	25%	30%	40%	50%
Optimized Score for: *Plasmodium falciparum*	0.88	0.88	0.88	0.88	0.83	0.55	0.43	0.30	0.19
Optimized Score for: *Plasmodium vivax*	0.96	0.96	0.89	0.66	0.42	0.31	0.25	0.19	0.13
Optimized Score for: Dengue	0.87	0.87	0.87	0.87	0.87	0.83	0.77	0.61	0.52

Neutrophil-to-Lymphocyte Ratio (NLR)

The Neutrophil-to-Lymphocyte Ratio (NLR) provides the ratio value of neutrophils to lymphocytes absolute counts (NEU# / LYM#). The NLR can be used as an indicator of inflammation and combined to other clinical markers, can be also used as a prognosis factor of some pathological disorders and infections.

The NLR ratio value is displayed on the **Results** screen on condition that NEU# > 0 and LYM# > 0.

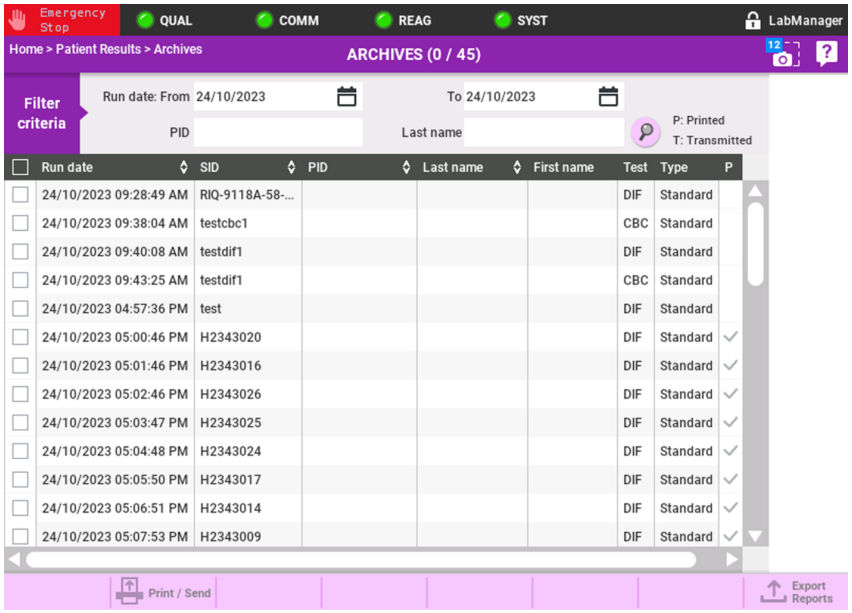
Related information:
- To Configure the Alarms Thresholds, p.187

8. Archives

8.1. Archives Overview

*Access: **Home** > **Patient Results** > **Archives***

At the beginning of each day, all the results of the previous day are automatically archived in the system memory.



The **Archives** screen allows you to consult the status of all the archived results. You can see:

- Run time information
- Sample information
- Patient information
- Analysis type information
- Gender information
- Print and Host (LIS or Yumizen P8000) transmission information

When you select a result, the **Results** screen appears.

Related information:
- To Sort Archived Results, p.157
- To Send Archived Results to the Host, p.157
- To Export Results, p.137

8.2. To Sort Archived Results

Access: ***Home*** > ***Patient Results*** > ***Archives***

You can sort archived results according to the following criteria: date, patient ID and name.

1. Press the column header once to obtain an increasing order.
2. Press the column header twice to obtain a decreasing order.

8.3. To Send Archived Results to the Host

Access: ***Home*** > ***Patient Results*** > ***Archives***

1. Select the results you want to send from the results list.
2. Press **Print / Send** in the contextual toolbar.
3. Select **Send only selected results**.
4. Press **Validate**.

8.4. To Export Results

Access: ***Home*** > ***Patient Results***

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

You can export patient results from the **Results** screen or the **Archives** screen.

1. Select the results you want to export.
2. Press **Export Reports** in the contextual toolbar.
3. Select the export format.
   - **XML**
   - **XML (expert mode)** if you need to export more data on the results (Malaria and Dengue scores of the sample, advanced data on the DIFF matrix)
   - **PDF**
4. Select **Anonymize data**, if necessary.
   This step is only necessary if you want to hide the patient information in the export file.
5. Insert the USB flash drive.

6. Press **Validate**.
7. When the export is complete, remove the USB flash drive and press **OK**.

If patient data is not hidden, the export file is zipped and protected by the PHI key as password.

8.5. To Delete Patient Information

Access: ***Home*** > ***Patient Results*** > ***Archives***

Only users with the Lab Manager profile can perform this procedure.

A patient may request the deletion of personal data.

1. In the filter area, press the **Search** button.
   The ***Patient Search*** screen displays.
2. Search the patient you want to delete from the database with **PID** or **Last name** (case sensitive).
3. Press **Delete** in the contextual toolbar.
4. Press **Confirm**.

Patient results are not deleted, but they are no longer linked to the patient since all personal data is deleted.

9. End of Day

9.1. To Change Operator

1. Press **Logout** in the contextual toolbar.
2. Press **Confirm**.
3. Log in with another user name.

Related information:
■ To Log In to the Application, p.118

9.2. Stopping the Instrument

9.2.1. To Perform a Manual Shutdown

A shutdown cycle has to be performed every 24 hours.

1. Press **Shutdown**.
2. Wait during the shutdown cycle.
   The shutdown cycle takes approximately 3 minutes.

The shutdown cycle is efficient and valid only if the cleaner remains at least 10 minutes in the chambers after the cycle. This cleans the hydraulic circuit.

You must not perform any actions during these 10 minutes at the risk of performing the shutdown cycle again.

If the system is not used for a period superior to 36 hours, it is mandatory to power it down. This eliminates startup problems, as well as the possibility of the dilution chambers evaporating.

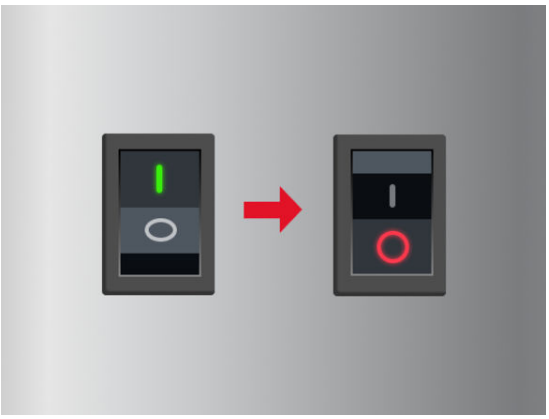
9.2.2. To Switch the Instrument Off

1. Press **Logout** to log out from the application.

2. Press **Confirm**.
3. Press **Exit** to leave the application.
   The system asks you to perform a shutdown.
   It is highly recommended to perform a shutdown cycle before switching the instrument off.

A shutdown cycle has to be performed every 24 hours.

4. If you want to perform a shutdown:
   a. Press **Confirm**.
   b. Wait during the shutdown cycle.
   c. Press **Exit** to leave the application.
   d. Press **Confirm**.
   The shutdown cycle is efficient and valid only if the cleaner remains at least 10 minutes in the chambers after the cycle. This cleans the hydraulic circuit.
   You must not perform any actions during these 10 minutes at the risk of performing the shutdown cycle again.
   Wait 10 minutes minimum before restarting the instrument.
5. If you do not want to perform a shutdown, press **Cancel** to directly leave the application.
6. Wait a few minutes for the application closure without switching the instrument off.
7. When the application is closed, switch the instrument off.



Related information:
- To Perform a Manual Shutdown, p.159
- To Schedule an Automatic Shutdown, p.182

9.2.3. To Switch the Printer Off

Switch the printer off at the end of the day.

1. Make sure that no printout has been launched.
2. Switch the printer off.

Settings

1. Configuring the Passwords

1.1. To Modify the Default User Account Password

Only users logged with the LabManager user name can perform this procedure.

A user account having a Lab Manager profile is created by default on the instrument.

For safety reasons, you have to change the initial password from the login screen at the first connection.

1. Select the LabManager user name.
2. Enter the initial password: LabM1.
3. Press **Validate** in the contextual toolbar.
   A popup appears forcing you to enter a new password.
4. Enter your new password twice.
   The password must comply with the defined password policy.
5. Press **Validate**.
6. Enter your new password in the login screen.
7. Press **Validate** in the contextual toolbar.
   A popup appears to change the initial PHI key.
8. Enter a new key in the **PHI Key** field.
   The new key must be between 4 and 20 characters without any space and must include one special character (!, $, #, %).
9. Press **OK**.
   A popup appears to configure the security questions.
10. Select the two security questions you want to answer and enter the corresponding answers.
11. Press **OK**.

Related information:
- To Configure the Password Policy, p.165

1.2. To Modify Your Password

You can modify the password of your own account only.

However, users with the Lab Manager profile can set a default password when reactivating a user account.

When you log in to the application, you have to change your password from the login screen:

- at the first connection
- in case of account reactivation
- if your password is expired

Later, you can modify your password from the ***User Settings*** screen.

1. Select your user name.
2. Enter your password.
3. Press **Validate** in the contextual toolbar.
   A popup appears forcing you to enter a new password.
4. Enter your new password twice.
   The password must comply with the defined password policy.
5. Press **Validate**.
6. Enter your new password in the login screen.
7. Press **Validate** in the contextual toolbar.
   If you have not configured your security questions yet, a popup appears to do it.
8. Select the two security questions you want to answer and enter the corresponding answers.
9. Press **OK**.

Related information:
- To Configure the Password Policy, p.165
- To Reactivate a User Account, p.191
- To Modify a User Account, p.191

1.3. To Reset Your Password

You can reset the password of your own account only.

However, users with the Lab Manager profile can set a default password when reactivating a user account.

If you forget your password, you can reset it by answering one of the two security questions.

1. Select your user name.
2. Press **Reset password**.
3. Select the security question you want to answer and enter the corresponding answer.
4. Press **OK**.
5. Enter your new password twice.
   The password must comply with the defined password policy.
6. Press **Validate**.
7. Enter your new password in the login screen.
8. Press **Validate** in the contextual toolbar.

Related information:
- To Configure the Password Policy, p.165
- To Reactivate a User Account, p.191

1.4. To Unlock the Access in Case of Password Loss

Only users with the Lab Manager profile can perform this procedure.

If you forget your password and you are not able to reset it by answering one of the two security questions, you can reset it by means of an unlocking code.

If you are logged with a User profile, you must ask your Lab Manager to unlock the access.

Your instrument current date has to be up to date to unlock the access.

1. Contact your HORIBA Medical representative to obtain an unlocking code.
2. Select your user name.
3. Press **Reset password**.
4. Press **Reset**.
5. Enter the code provided by your HORIBA Medical representative.
   This code is valid during seven days to allow you changing your password.
6. Press **Validate**.
7. Enter your new password twice.
   The password must comply with the defined password policy.
8. Press **Validate**.
9. Enter your new password in the login screen.
10. Press **Validate** in the contextual toolbar.

Related information:
- To Configure the Password Policy, p.165

1.5. To Configure the Password Policy

Access: ***Home*** > ***Settings*** > ***System*** > ***Cyber Security***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.

2. Configure the ***Password Policy*** options.

Option	Function	Value range	Default value
Minimum Length (maximum length for password is 64 characters)	Password minimum length	4 - 20	14
Requires Lower Case Alpha	If selected, lowercase alpha characters (a - z) are required.	**Yes** / **No**	**Yes**
Requires Upper Case Alpha	If selected, uppercase alpha characters (A - Z) are required.	**Yes** / **No**	**Yes**
Requires Numeric	If selected, numeric characters (0 - 9) are required.	**Yes** / **No**	**Yes**
Requires Special Characters	If selected, special characters (!, $, #, %, @) are required.	**Yes** / **No**	**Yes**
Expiration (in days)	Password expiration time limit (in days)	0, 20 - 180	90
Prevent Reuse (last ones)	Number of previous passwords that cannot be reused	0 - 6	3
Max Login attempts	Number of authorized password attempts before the account is locked for 15 minutes	0 - 20	10

3. Press **Validate** in the contextual toolbar.

1.6. To Modify the PHI Key

Access: ***Home*** > ***Settings*** > ***System*** > ***Cyber Security***

Only users with the Lab Manager profile can perform this procedure.

To comply with data protection requirements, patient information is encrypted by means of a PHI (Protected Health Information) key when exporting results.

For safety reasons, you have to create the initial PHI key from the login screen at the first connection. Later, you can modify the PHI key from the ***Cyber Security*** screen.

Please note that in case the PHI key is lost or modified, the patient information encrypted with the previous PHI key will not be accessible anymore.

1. Press **Edit** in the contextual toolbar.
2. Enter a new key in the **PHI Key** field.
   The new key must be between 4 and 20 characters without any space and must include one special character (!, $, #, %).
3. Press **Validate** in the contextual toolbar.

2. Configuring the Instrument

2.1. To Modify the Sample ID Automatic Numbering

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

By default, the value is set to 1. In this case, the first automatic sample ID is "AUTO_SID001". The following sample IDs are then incremented.

1. Press **Edit** in the contextual toolbar.
2. Modify the **Auto-Numbering** value.
3. Press **Validate** in the contextual toolbar.

The modification becomes effective at the next beginning of the day (when you select the **Reset sample ID auto-numbering** option).

2.2. To Display the Full or Restricted Parameters

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

By default, the following parameters not validated for a clinical diagnostic use in some countries are displayed, printed and sent to the Host (LIS or Yumizen P8000): RDW-SD, MIC, MAC, PCT, P-LCC, P-LCR, PDW, IML#, IML%, IMM#, IMM%, ALY#, ALY%, LIC# and LIC%.

By default the **Full parameters** option is selected. Follow the procedure below to hide them.

1. Press **Edit** in the contextual toolbar.
2. Select **Restricted parameters** in the ***Display*** area to hide these parameters.
3. Press **Validate** in the contextual toolbar.

2.3. To Activate or De-activate the Neutrophil-to-Lymphocyte Ratio (NLR)

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select **Display NLR** to display the NLR value on the **Results** screen.
   The Neutrophil-to-Lymphocyte Ratio (NLR) is de-activated by default.
3. Press **Validate** in the contextual toolbar.

2.4. To Configure the XB Alarm

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select the alarm mode:
   - **None**: the XB alarm is not triggered.
   - **On 3 parameters**: the XB alarm is triggered on MCV, MCH and MCHC.
   - **On 9 parameters**: the XB alarm is triggered on WBC, RBC, HGB, HCT, RDW-CV, PLT, MCV, MCH and MCHC.
3. Press **Validate** in the contextual toolbar.

2.5. To Select the Default Mode

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

This procedure allows you to choose the analysis to run by default in manual and rack mode.

1. Press **Edit** in the contextual toolbar.
2. Select the required mode in the drop-down lists of the ***Default mode*** area.
3. Press **Validate** in the contextual toolbar.

2.6. To Manage the Rack Routine Errors

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

This procedure allows you to choose if the rack routine should stop or not when alarms are triggered.

1. Press **Edit** in the contextual toolbar.
2. Select **Yes** or **No** in the ***Rack routine*** area.
3. Press **Validate** in the contextual toolbar.

If you selected **Yes**, the rack routine is stopped if one of the following alarms is triggered three consecutive times:

- HGB Analytical error - HGB channel unstable measure
- PLT Analytical error - PLT channel unstable measure
- WBC abn. matrix - NEU+EOS/Noise
- WBC abn. matrix - Background noise
- WBC Analytical error - DIFF channel unstable measure
- WBC Analytical error - DIFF channel light beam error

2.7. To Select the Results Display Mode

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

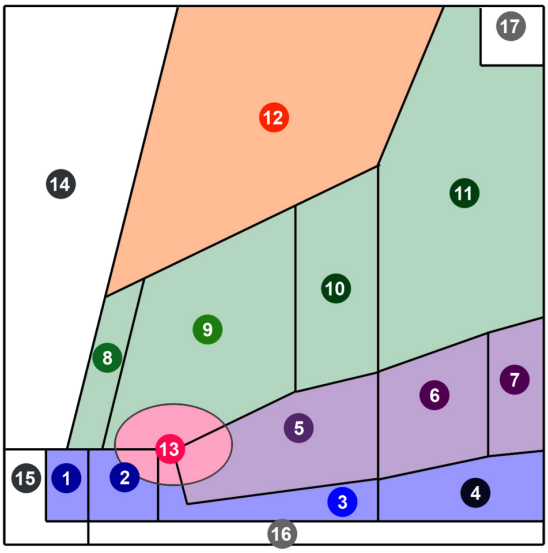
Only users with the Lab Manager profile can perform this procedure.

2.7.1. To Select the 5 Diff Mode

1. Press **Edit** in the contextual toolbar.
2. Select the **5 Diff Mode** radio button in the ***Diff Results Display Mode*** area.
3. Press **Validate** in the contextual toolbar.

The WBC differential is calculated according to the following formula:

- DIFF (%): LYM% + MON% + NEU% + EOS% + BAS% = 100
- DIFF (#): LYM# + MON# + NEU# + EOS# + BAS# = WBC



LYM# = 1 + 2 + 3 + 4

MON# = 5 + 6 + 7

NEU# = 8 + 9 + 10 + 11

EOS# = 12

BAS# = 13

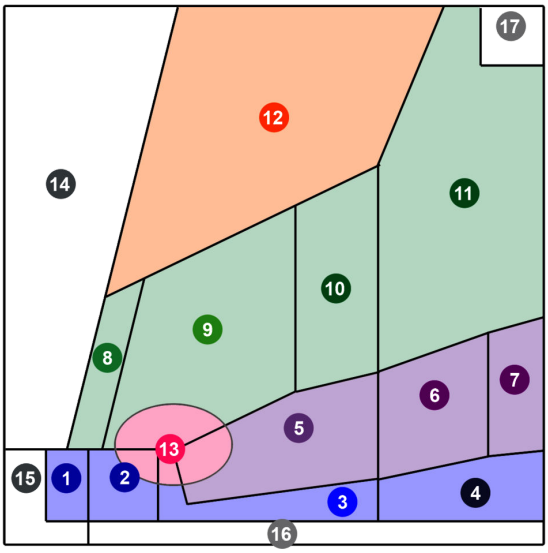
2.7.2. To Select the 6 Diff Mode

*The **Full parameters** radio button must be selected to activate the **6 Diff Mode**.*

1. Press **Edit** in the contextual toolbar.
2. Select the **6 Diff Mode** radio button in the ***Diff Results Display Mode*** area.
3. Press **Validate** in the contextual toolbar.

The WBC differential is calculated according to the following formula:

DIFF (%)	LYM% + MON% + NEU% + EOS% + BAS% + IMG% = 100
DIFF (#)	LYM# + MON# + NEU# + EOS# + BAS# + IMG# = WBC



LYM# = 1 + 2 + 3 + 4

MON# = 5 + 6 + 7

NEU# = 8 + 9

EOS# = 12

BAS# = 13

IMG# = 10 + 11

2.8. To Set the Start of Day Options

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. In the ***Start of day options*** area, select:
   a. To reset or not the sample ID automatic numbering.
   b. To erase or not the worklist.
3. Press **Validate** in the contextual toolbar.

2.9. To Activate or De-activate the Suspected Pathologies

Access: ***Home*** > ***Settings*** > ***Application*** > ***General***

Only users with the Lab Manager profile can perform this procedure.

By default, the suspected pathologies messages are displayed, printed and sent to the Host (LIS or Yumizen P8000).

1. Press **Edit** in the contextual toolbar.
2. Choose if you want to display or not the suspected pathologies messages.
3. Press **Validate** in the contextual toolbar.

2.10. To Configure Results Printing and Transmission

Access: ***Home*** > ***Settings*** > ***Application*** > ***Print / Transmit***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. In the ***Automatically Print*** area, select the results to be automatically printed.
3. In the ***Automatically Transmit*** area, select the results to be automatically sent to the Host (LIS or Yumizen P8000).
4. Select **Do not send AUTO_SID** if you want to block printing and sending of results with an AUTO_SID identifier.
   In this case you have to manually associate results with orders in the ***Association*** screen before printing and/or sending.
5. In the ***Print Patient Report Content*** area, deselect the content you want to remove from the patient report printout.

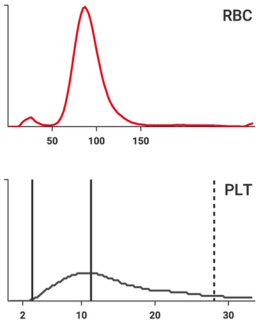
   If you remove quality alarms and technical alarms, the patient report is printed in duplicate: with and without alarms.

Results

Run Date	10/03/2022 16:48:46	**Operator**	Lab Manager
Last Name		**Sample ID**	AUTO_SID0004
First Name		**Dilution**	1 / 1.00
Gender	**Age**		
Patient ID		**Department**	
		Physician	
Date of birth		**Type**	Standard
Sample comments			

CBC

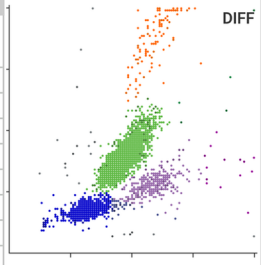
				Range
WBC	3.42	∗ℓ	10³/mm³	3.50 - 10.00
RBC	4.19		10⁶/mm³	3.80 - 6.00
HGB	14.1		g/dL	12.0 - 17.0
HCT	39.7		%	36.0 - 54.0
MCV	94.7	∗	fL	78.0 - 100.0
MCH	33.7		pg	25.0 - 34.0
MCHC	35.6	h	g/dL	32.0 - 35.0
RDW-CV	13.1	∗	%	12.0 - 18.0
RDW-SD	45.4	∗	fL	37.0 - 56.0
MIC	0.4		%	0.0 - 20.0
MAC	12.8	h	%	2.0 - 10.0
PLT	214	∗	10³/mm³	150 - 400
MPV	**12.4**	**∗H**	fL	7.4 - 12.0
PCT	0.266	∗	%	0.150 - 0.400
PDW	**26.0**	**∗H**	fL	11.0 - 20.0
P-LCC	124	∗	10³/mm³	44 - 140
P-LCR	58.1	∗h	%	18.0 - 50.0



Recommended actio 1
Slide Review
Alarms 2
No control
LMNE
Abnormal differentiation
MON Interference
WBC Interference
PLT
Schistocytes/Macro PLT?
Abnormal PDW
Synthesis WBC
LIC?
ALY?
PLT aggregates or NRBC?
Susp. Pathologies 3
Neutropenia

DIF

	%		Range	10³/mm³		Range
NEU	33.4	∗ℓ	40.0 - 75.0	**1.14**	**∗L**	1.50 - 7.00
LYM	_ . _		15.0 - 45.0	_ . _		1.00 - 4.00
MON	_ . _		4.0 - 13.0	_ . _		0.20 - 0.80
EOS	4.2	∗	0.5 - 7.0	0.14	∗	0.00 - 0.50
BAS	0.2	∗	0.0 - 2.0	0.01	∗	0.00 - 0.20
IMG	_ . _		0.0 - 2.0	_ . _		0.0 - 100.0
IMM	_ . _		0.0 - 0.5	_ . _		0.00 - 0.10
IML	_ . _		0.0 - 0.2	_ . _		0.00 - 0.05
ALY	_ . _		0.0 - 2.5	_ . _		0.00 - 0.25
LIC	_ . _		0.0 - 3.0	_ . _		0.00 - 0.20



Slide Review 4

Neutrophil	Myeloblast	Anysocytosis
Lymphocyte	Promyelocyte	Hypochromia
Monocyte	Myelocyte	Polychromasia
Eosinophil	Metamyelocyte	Poikilocytosis
Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps

Reviewed on _____ by _____ Signature:

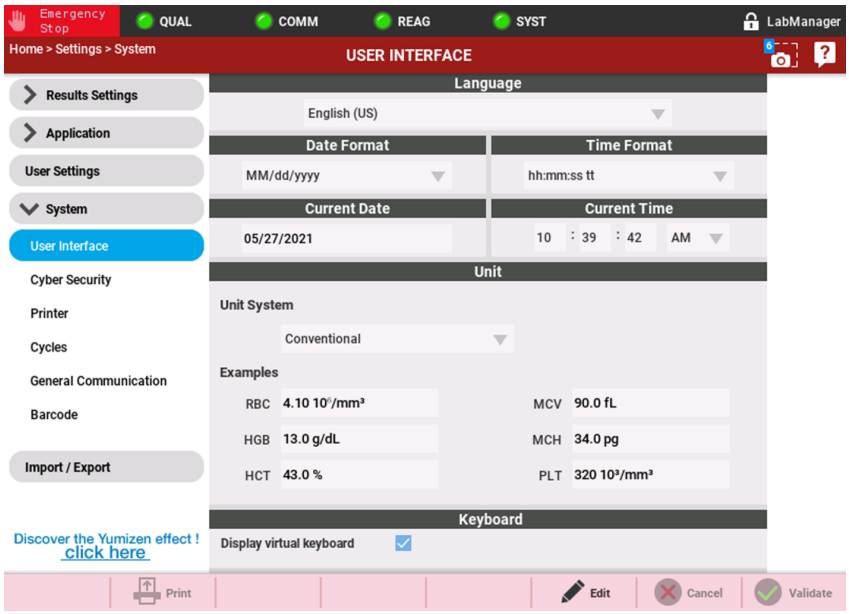
10/03/2022 17:10:52 **Printed by:** Lab Manager **S/N** 104YCDH03826 5 1

1 = **Recommended actions**
2 = **Quality alarms / Technical alarms**
3 = **Suspected pathologies**
4 = **Manual slide review**
5 = **Page footer**

6. Press **Validate** in the contextual toolbar.

Related information:
- Manual Match Overview, p.130

3. Configuring the Interface



Related information:
- To Change the Application Language, p.174
- To Change the Current Time, p.175
- To Change the Date and Time Format, p.175
- To Select the Unit System, p.176
- To Configure the Virtual Keyboard, p.176
- To Update the Help, p.176
- To Configure Barcodes, p.177
- To Activate ISBT 128 Barcodes, p.178

3.1. To Change the Application Language

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select a language from the **Language** drop-down list.
3. Press **Validate** in the contextual toolbar.
   The system prompts you to update the help files.

4. Press **OK**.
5. Press **Reboot**.

3.2. To Change the Date and Time Format

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select the correct date format in the **Date Format** drop-down list.
   dd stands for day, **MM** for month and **yyyy** for year.
3. Select the correct time format in the **Time Format** drop-down list.
   hh stands for hours, **mm** for minutes and **ss** for seconds.
4. Press **Validate** in the contextual toolbar.
5. Press **Reboot**.

3.3. To Change the Current Time

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Set the hours, minutes and seconds in the ***Current Time*** area.
3. For the **hh:mm:ss tt** time format, select **AM** or **PM**.
4. Press **Validate** in the contextual toolbar.
5. Press **Reboot**.

Active control lots are automatically archived when changing the current time (more than 2 h). Thus, you have to create the control lots and register their target values. If needed, you can recreate the same control lots.

3.4. To Select the Unit System

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select the unit system in the **Unit System** drop-down list.
3. Press **Validate** in the contextual toolbar.
4. Press **Reboot**.

3.5. To Configure the Virtual Keyboard

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select or deselect **Display virtual keyboard** in the ***Keyboard*** area.
   If the option is selected, the virtual keyboard automatically displays when you enter an editable field.
3. Press **Validate** in the contextual toolbar.
4. Press **Reboot**.

3.6. To Update the Help

Access: ***Home*** > ***Settings*** > ***Import / Export***

Only users with the Lab Manager profile can perform this procedure.

You need to have the help files available on a USB flash drive.

Make sure the USB flash drive is free of any virus.

1. Insert the USB flash drive.
2. Press **Update Help**.
3. Press **Confirm**.
   Wait for the help to be updated.
4. Press **OK**.

If the update fails, switch the instrument off and then back on, and perform this procedure again.

If the problem persists, please contact your local HORIBA Medical representative.

3.7. To Configure Barcodes

Access: ***Home*** > ***Settings*** > ***System*** > ***Barcode***

Only users with the Lab Manager profile can perform this procedure.

Note that if you change the configuration from **ISBT 128** to another barcode type and conversely:

- The settings are recorded
- The worklist is emptied
- All the current session results are archived
- The current session closes and a new session has to be created

If the **ISBT 128** barcode is selected, you cannot select another available barcode.

1. Press **Edit** in the contextual toolbar.
2. Select one or several barcodes from the ***Available Barcodes*** list:
   - **Code 39** (with or without check digit)
   - **Interleaved 2 of 5** (with or without check digit)
   - **Codabar**
3. Press **Validate** in the contextual toolbar.

3.8. To Activate ISBT 128 Barcodes

Access: ***Home*** > ***Settings*** > ***System*** > ***Barcode***

Only users with the Lab Manager profile can perform this procedure.

Note that if you change the configuration from **ISBT 128** to another barcode type and conversely:

- The settings are recorded
- The worklist is emptied
- All the current session results are archived
- The current session closes and a new session has to be created

If another available barcode is selected, you cannot select the **ISBT 128** barcode.

1. Press **Edit** in the contextual toolbar.
2. Select **ISBT 128** to activate ISBT 128 barcodes.
3. If necessary, select **Ignore flags characters**.
4. Press **Validate** in the contextual toolbar.

3.8.1. ISBT 128 Barcode Use

Specifications

The ISBT 128 system increases the level of standardization in transfusion medicine. It is an international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides a globally unique donation numbering system thanks to internationally standardized product definitions and standard data structures for bar coding and electronic data interchange.

Flag Characters

Each barcode contains two data identifier characters called "flag characters" which are embedded in the barcode. They identify the type of information coded in the barcode (e.g. ABO/Rh, Product Code), and they are followed by the specific unit information which is reproduced in an eye readable format just below the barcode.

On the example above, the flag characters are printed vertically.

Data Structure

ISBT128 barcodes have the following structure: µppppyynnnnnnff.

=	Identifier (first character)	Can be omitted in certain cases
μ	Identifier (second character): alphanumeric character {A-N; P-Z; 1-9}	Specifies the Facility Identification Number (FIN)
pppp	Four numeric characters {0-9}	
yy	Two numeric characters {0-9}	Specifies the last two digits of the year in which the product was collected
nnnnnn	Six numeric characters {0-9}	Sequence number of the donation assigned by the collection facility
ff	Two numeric characters {0-9}	Flag characters: their use must conform to national guidelines

3.8.2. ISBT 128 Barcode Configuration

The use of ISBT128 barcodes on the Yumizen H550 excludes the use of other barcode labels. It must be set by a HORIBA Medical technical representative.
Similarly, ISBT128 barcodes cannot be used if another barcode type has been enabled.

The HORIBA Medical technical representative can either set the instrument so that flag characters are ignored, or so that they are taken into account.

Ignore Flag Characters checked

If this option is checked, the instrument manages the barcode on 13 characters instead of 15, and ignores the flag characters.

There are risks of mismatch in case two barcodes only differ in their flag characters.

Ignore Flag Characters unchecked

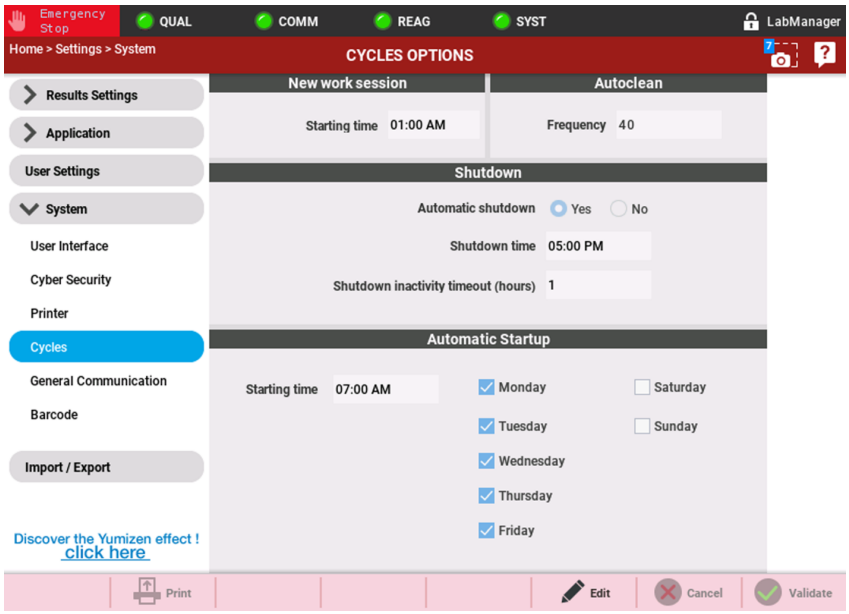
If this option is unchecked, the instrument manages the barcode on 15 characters, and takes the flag characters into account.

3.8.3. Operating With ISBT128 Barcodes

Operating with ISBT128 barcodes is the same as with other types of barcodes when you enter the sample ID using the external barcode reader in the worklist. When you enter the sample ID manually, you need to either type 13 characters if the **Ignore Flag Characters** option is set, or 15 characters if the option is unchecked.

- Sample results cannot be validated if the barcode does not match the ISBT128 standards.
- The instrument cannot match orders automatically if the barcode format is not properly read or entered.

4. Configuring the Cycles



This screen gives you an example to configure the cycles on your instrument.

With the configuration below:

Option	Setting	Consequence	Condition
Shutdown inactivity timeout (hours)	1 h	The instrument inactivity timeout before shutdown starts is defined.	The instrument must be idle for the defined timeout before shutting down.
Automatic shutdown	05:00 PM	If the instrument is not operating from 04:00 PM, it shuts down at the defined time.	The defined inactivity timeout before shutdown must be respected (1 h in the example). If not, the shutdown is delayed until the inactivity timeout is respected. Example: if a sample is run around 04:30 PM, the instrument shuts down at 05:30 PM. Shutdown must not be interrupted.
New work session	01:00 AM	A new session starts at the defined time. Results of previous session are archived.	The new work session must be scheduled before the automatic startup.

Option	Setting	Consequence	Condition
Automatic Startup	07:00 AM **Monday** - **Friday**	The instrument starts up at the defined time on scheduled days.	The new work session must be scheduled.
Autoclean	40	Automatic cleaning is run after 40 analyses.	Frequency must be adjusted according to your routine throughput.

Related information:
- To Change the Starting Time of the New Session, p.181
- To Configure the Automatic Cleaning Frequency, p.181
- To Schedule an Automatic Startup, p.120
- To Schedule an Automatic Shutdown, p.182

4.1. To Change the Starting Time of the New Session

Access: ***Home*** > ***Settings*** > ***System*** > ***Cycles***

The starting time is the hour at which a new session of work begins. By default, the starting time is 07:00 AM.

1. Press **Edit** in the contextual toolbar.
2. Set the time in the ***Starting Time*** field.
3. Press **Validate** in the contextual toolbar.

4.2. To Configure the Automatic Cleaning Frequency

Access: ***Home*** > ***Settings*** > ***System*** > ***Cycles***

By default, an automatic cleaning is run after 40 analyses.

It is recommended to configure the automatic cleaning frequency to your routine throughput. You should run an automatic cleaning minimum once a day on regular activity of 80 analyses per day.

1. Press **Edit** in the contextual toolbar.
2. Set the automatic cleaning frequency in the **Frequency** field.
   The frequency must be between 10 and 120 analyses.
3. Press **Validate** in the contextual toolbar.

4.3. To Schedule an Automatic Startup

Access: ***Home*** > ***Settings*** > ***System*** > ***Cycles***

For the automatic startup to work:

- *the instrument and the printer must be switched on 24/7*
- *a shutdown cycle must have been performed at the end of the previous work day*
- *the shutdown lasts 10 minutes and it should not be interrupted during this time*

When you schedule an automatic startup, it is run as soon as connections with the instrument and reagent levels have been checked. By default, the starting time is 07:00 AM.

1. Press **Edit** in the contextual toolbar.
2. Enter the startup time in the ***Starting Time*** field of the ***Automatic Startup*** area.
3. Select the days on which the automatic startup must be performed.

4.4. To Schedule an Automatic Shutdown

Access: ***Home*** > ***Settings*** > ***System*** > ***Cycles***

The instrument and the printer must be switched on 24/7 for the automatic shutdown to work.

In automatic shutdown mode, the shutdown runs automatically every day at a predefined hour.

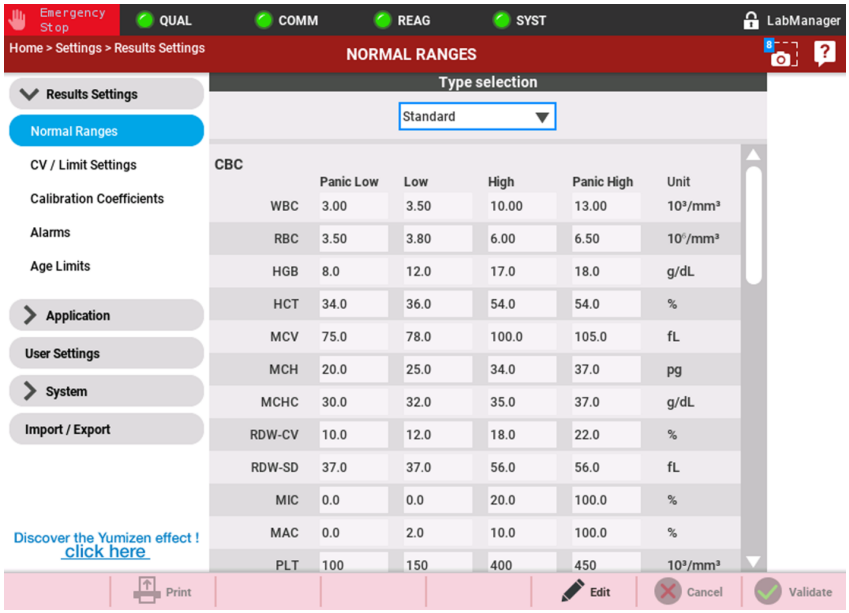
A shutdown cycle has to be performed every 24 hours.

1. Press **Edit** in the contextual toolbar.
2. Set **Automatic shutdown** to **Yes** in the ***Shutdown*** area.
3. Enter the shutdown time in the **Shutdown time** field.
4. Enter the duration of the inactivity timeout in the **Shutdown inactivity timeout (hours)** field.
   The instrument automatically shuts down after **x** hours of inactivity after the specified shutdown time.
   The default value is 1 hour.

The shutdown cycle is efficient and valid only if the cleaner remains at least 10 minutes in the chambers after the cycle. This cleans the hydraulic circuit.

You must not perform any actions during these 10 minutes at the risk of performing the shutdown cycle again.

5. Configuring the Results Settings



Related information:
- To Configure the Normality Limits, p.183
- To Modify the Coefficients of Variation, p.184
- To Modify the Calibration Coefficients, p.185
- To Configure the Alarms Thresholds, p.187
- To Configure the Age Limits for Children Types, p.188
- To Modify the XB Limits, p.184

5.1. To Configure the Normality Limits

*Access: **Home** > **Settings** > **Results Settings** > **Normal Ranges***

Only users with the Lab Manager profile can perform this procedure.

Note that you can configure the limit values and the children types in the software.

HORIBA Medical cannot guarantee the results obtained if the results settings have been modified without the approval of a HORIBA Medical representative.

1. Select a sample type from the drop-down list.
2. Press **Edit** in the contextual toolbar.
3. Modify the values you need to update.
4. Press **Validate** in the contextual toolbar.

5.2. To Modify the Coefficients of Variation

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***CV / Limit Settings***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Modify the values you need to update.
3. Press **Validate** in the contextual toolbar.

The calibration passes only if the coefficients of variation are within the parameters limits. Refer to the Calibration > Calibration Results for more information.

Related information:
- Calibration Results, p.102

5.3. To Modify the XB Limits

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***CV / Limit Settings***

Only users with the Lab Manager profile can perform this procedure.

The XB limits are expressed as a percentage (%) and can be modified for each parameter.
The default limits are the following:

Parameters	Limits
MCV	15
MCH	16
MCHC	4

Parameters	Limits
RBC	19
PLT	66
RDW-CV	17
WBC	64
HGB	20
HCT	19

1. Press **Edit** in the contextual toolbar.
2. Modify the values you need to update.
3. Press **Validate** in the contextual toolbar.

When the XB limits are modified, all XB batches are erased.

5.4. To Modify the Calibration Coefficients

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***Calibration Coefficients***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Modify the values you need to update.
   The calibration coefficients must be included between 0.8 and 1.2 to validate the calibration.
3. Modify the values you need to update.
4. Press **Validate** in the contextual toolbar.

We highly recommend that you run a control blood sample after modifying the calibration coefficients. Make sure all three levels of the control blood sample are within the ranges specified and that no alarm is triggered.

Refer to the Calibration > Calibration Results for more information about forced calibration.

Related information:
- Calibration Results, p.102

5.5. To Display Parameters as Suspected

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***Alarms***

Only users with the Lab Manager profile can perform this procedure.

If preferred, it is possible to change reject flag "_._" into suspicion flag "*" on parameters for some alarms triggered. The result value is displayed as suspected and not masked as it is the case for rejected results.

The setting is not retroactive. Results rejected when the option was not selected are still rejected, even after the option has been activated.

Impacted alarms and parameters:

Alarm	Parameters displayed as suspected instead of rejected
WBC abn. matrix LYM/MON	LYM#, LYM%, MON#, MON%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC%
WBC abn. matrix LYM/NEU	LYM#, LYM%, NEU#, NEU%, IMG#, IMG%, IML#, IML%, ALY#, ALY%, LIC#, LIC%
WBC abn. matrix MON/NEU	MON#, MON%, NEU#, NEU%, IMG#, IMG%, IMM#, IMM%, LIC#, LIC%
WBC abn. matrix NEU/EOS	NEU#, NEU%, EOS#, EOS%, IMG#, IMG%, LIC#, LIC%
WBC abn. matrix LYM/NRBC	LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC%
RBC abn. histogram Double population?	RDW-CV
RBC Analytical error RBC/HGB channel balance	RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, MIC, MAC, PLT, PCT, PDW, MPV, P-LCC, P-LCR
▼ - HGB	MCH, MCHC
▼ - HCT	MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC
▼ - PLT	PCT, PDW, MPV, P-LCC, P-LCR
▼ - RBC	MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC
▼ - WBC	LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%, IMM#, IMM%, IML#, IML%, ALY#, ALY%, LIC#, LIC%
HGB out of range High visibility	MCH, MCHC
PLT out of range High visibility	P-LCC, PCT
RBC out of range High visibility	HCT

1. Press **Edit** in the contextual toolbar.
2. Select **Display as suspected parameter** in the ***Display parameter*** area.
   The option is deselected by default.
3. Press **Validate** in the contextual toolbar.

The rejected results are now displayed as suspected.

5.6. To Configure the Alarms Thresholds

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***Alarms***

Only users with the Lab Manager profile can perform this procedure.

You can configure the following alarm levels according to the percentage or absolute value. The alarm are triggered when results exceed these values.

1. Press **Edit** in the contextual toolbar.
2. Modify the values you need to update.

Field	Alarm	Default value
Background Noise High	WBC abn. matrix NEU+EOS/Noise	80#
Background Noise Low	WBC abn. matrix ■ PLT aggregates? ■ NRBC? ■ PLT aggregates or NRBC?	25#
LYM Interference (dots)	WBC abn. matrix	150#
LYM Interference (ratio)	■ PLT aggregates? ■ NRBC? ■ PLT aggregates or NRBC?	16%
Right MON (ratio)	WBC abn. matrix MON/IMM	2.5%
Max MCHC Suspicious	RBC abn. histogram Interference?	36.5
High threshold Abnormal MCH	RBC Analytical error RBC/HGB channel balance	50
Low threshold Abnormal MCHC		26
High threshold Abnormal MCHC		50
Left NEU (ratio)	WBC abn. matrix NEU/Noise	15%
RBC/PLT Interference (channel)	PLT abn. histogram RBC/PLT	102
Density separation LYM/NEU	WBC abn. matrix LYM/NEU	0.19
Density separation MON/NEU	WBC abn. matrix MON/NEU	0.10 and MON% > 15%
Density separation NEU/EOS	WBC abn. matrix NEU/EOS	0.018
Density separation LYM/MON	WBC abn. matrix LYM/MON	0.02 and LYM% > 45%
Density separation Nrbc/LYM	WBC abn. matrix LYM/NRBC	0.14
Malaria P. Falciparum	Suspected pathology: Malaria P. falciparum?	0.50

Field	Alarm	Default value
Malaria P. Vivax	Suspected pathology: Malaria P. vivax?	0.31
Dengue	Suspected pathology: Dengue?	0.50

The Malaria and Dengue settings are only displayed with the Malaria mode activated (available as an option).

3. Press **Validate** in the contextual toolbar.

Related information:
- Matrix and Cells Description, p.272

5.7. To Configure the Age Limits for Children Types

Access: ***Home*** > ***Settings*** > ***Results Settings*** > ***Age Limits***

Only users with the Lab Manager profile can perform this procedure.

Number of sample types defined by default on the instrument: 12

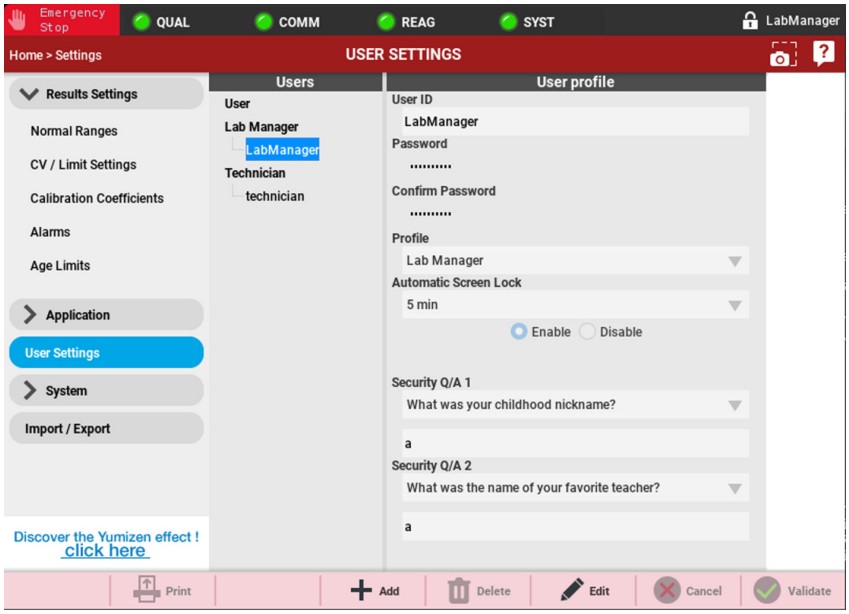
- **Standard**
- **Man**
- **Woman**
- **Child 1:** 0 - 30 days
- **Child 2:** 30 days - 6 months
- **Child 3:** 6 months - 2 years
- **Child 4:** 2 - 6 years
- **Child 5:** 6 - 12 years
- **Child 6:** 12 - 15 years
- **Child 7:** 15 - 18 years
- **Child 8:** (**Woman** / **Man**) 18 - 21 years

1. Press **Edit** in the contextual toolbar.
2. Modify the age limits for the children types you need to update.
   The values must be included between 1 and 30 and configured in ascending order.
3. Press **Validate** in the contextual toolbar.

6. Configuring User Accounts

6.1. User Accounts Overview

*Access: **Home** > **Settings** > **User Settings***



There are three types of user accounts:

- the **User** profile which gives access to everything but advanced settings and technician menus.
- the **Lab Manager** profile which gives access to everything but technician menus.
- the **Technician** profile which gives access to everything but patient data.
  Reserved to HORIBA Medical technical representative.

For each profile, you can set up an automatic screen lock corresponding to different security levels:

- **Very high security**: automatic screen lock after 5 minutes of inactivity.
- **High security**: automatic screen lock after 15 minutes of inactivity (default).
- **Normal security**: automatic screen lock after 30 minutes of inactivity.
- **Low security**: automatic screen lock after an hour of inactivity.
- **No security**: no automatic screen lock.

6.2. Users Available Functions

The following table gives the available functions according to the selected user profile.

Actions	User	Lab Manager	Technician
To run a **Startup**	x	x	x
To run a **Shutdown**	x	x	x
To run patient analyses	x	x	x
To manage control lots	x	x	x
To run control analyses	x	x	x
To consult XB settings	x	x	x
To perform a repeatability	x	x	x
To manage a calibrator lot		x	x
To perform a calibration		x	x
To configure security policy		x	
To configure users settings		x	x
To configure the reagents mode			x
To configure quality control settings		x	x
To perform technical adjustments			x
To update the software		x	x
To replace reagents	x	x	x
To perform cleaning cycles	x	x	x
To monitor the system	x	x	x
To consult analyses results	x	x	x
To consult control results	x	x	x
To consult logs	x	x	x
To consult the system settings	x	x	x
To delete patient data		x	

6.3. To Create a User Account

Access: ***Home*** > ***Settings*** > ***User Settings***

Only users with the Lab Manager profile can perform this procedure.

You can only create user accounts with the User or Lab Manager profiles.

1. Press **Add** in the contextual toolbar.
2. Enter a login name in the **User ID** field (four to twenty characters).
   Make sure it does not already exist.
3. Enter a password twice.
   The password must comply with the defined password policy.

4. Choose a user type from the **Profile** drop-down list.
5. Choose the level of security from the **Automatic Screen Lock** drop-down list.
6. Press **Validate** in the contextual toolbar.

Related information:
- To Configure the Password Policy, p.165

6.4. To Modify a User Account

Access: ***Home*** > ***Settings*** > ***User Settings***

1. Select the user account you want to modify.
2. Press **Edit** in the contextual toolbar.
3. Modify the values you need to update.

This table indicates the editing rights according to the logged in user.

Field	User	Lab Manager	Technician
User ID			
Password	X For your own account only	X For your own account only or in case of reactivation of an account with the User or Lab Manager profiles	X For your own account only or in case of reactivation of an account with the Technician profile
Profile		X Except for your own account or accounts with the Technician profile	
Automatic Screen Lock		X	
Account status		X Except for your own account	X For accounts having the Technician profile only Except for your own account
Security questions	X For your own account only	X For your own account only	

4. Press **Validate** in the contextual toolbar.

6.5. To Reactivate a User Account

Access: ***Home*** > ***Settings*** > ***User Settings***

Only users with the Lab Manager profile can perform this procedure.

You can only reactivate user accounts having the User or Lab Manager profiles except your own account.

1. Select the user account you want to reactivate.
2. Press **Edit** in the contextual toolbar.
3. Change the account status from **Disable** to **Enable**.
4. Enter a password twice.
   The password must comply with the defined password policy.
5. Press **Validate** in the contextual toolbar.

After reactivation of the user account, the user must log in and change his password within seven days.

Related information:
- To Configure the Password Policy, p.165

6.6. To Delete a User Account

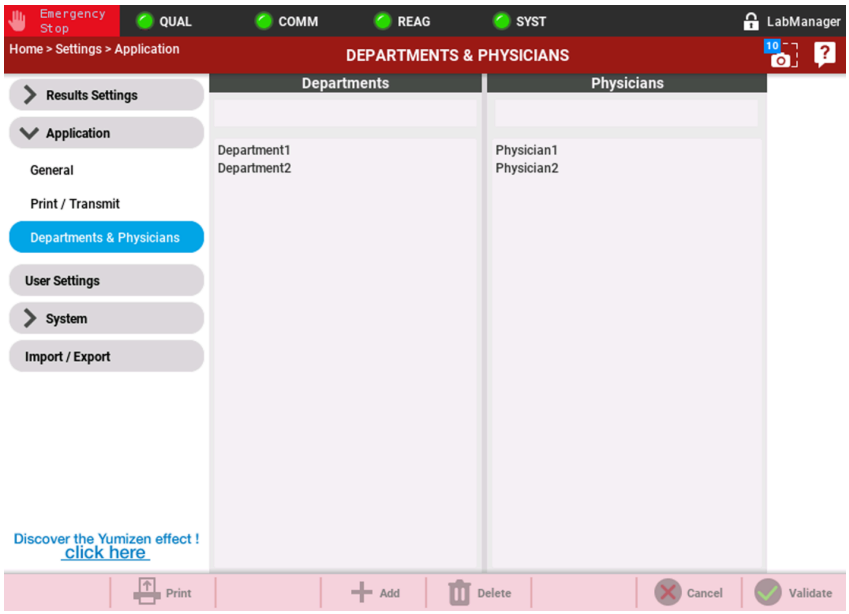
Access: ***Home*** > ***Settings*** > ***User Settings***

Only users with the Lab Manager profile can perform this procedure.

You can only delete user accounts having the User or Lab Manager profiles except your own account.

1. Select the user account you want to delete.
2. Press **Delete** in the contextual toolbar.
3. Press **Confirm**.

7. Configuring Departments and Physicians



Related information:
- To Create a Department or a Physician, p.193
- To Delete a Department or a Physician, p.194

7.1. To Create a Department or a Physician

Access: ***Home*** > ***Settings*** > ***Application*** > ***Departments & Physicians***

Only users with the Lab Manager profile can perform this procedure.

1. Press the ***Departments*** area or the ***Physicians*** area.
2. Press **Add** in the contextual toolbar.
3. Enter a new department or physician name in the appropriate field (20 characters maximum).
4. Press **Validate** in the contextual toolbar.

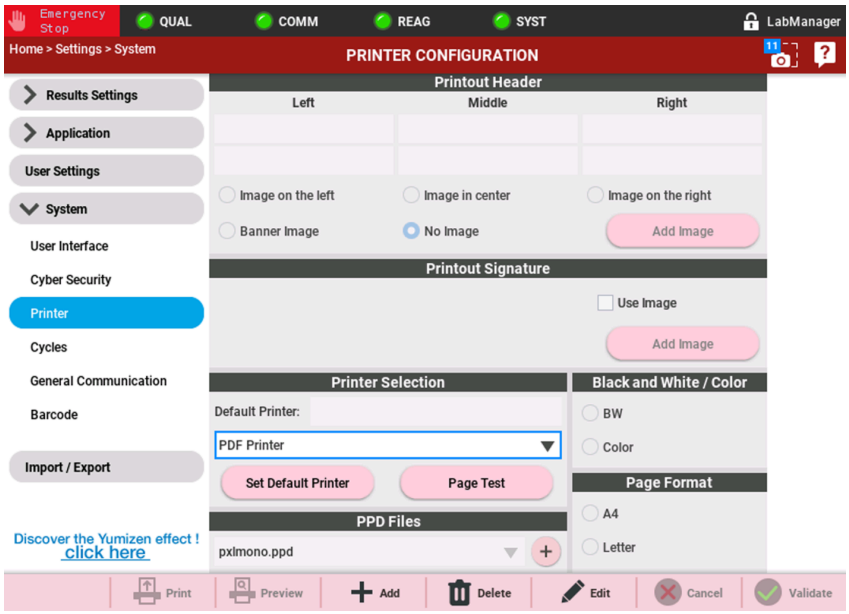
7.2. To Delete a Department or a Physician

Access: ***Home*** > ***Settings*** > ***Application*** > ***Departments & Physicians***

Only users with the Lab Manager profile can perform this procedure.

1. Press the ***Departments*** area or the ***Physicians*** area.
2. Select the department or physician name you want to update.
3. Press **Delete** in the contextual toolbar.
4. Press **Validate**.

8. Configuring the Printer



Related information:
- To Configure Printouts, p.195
- To Select a .ppd File, p.196
- To Add a Printer, p.196
- To Delete a Printer, p.197
- To Print a Test Page, p.197
- To Configure the PDF Printer, p.197

8.1. To Configure Printouts

*Access: **Home** > **Settings** > **System** > **Printer***

By default, printouts are printed in black and white on an A4 format with no header or footer.

1. Press **Edit** in the contextual toolbar.
2. Enter text in the ***Printout Header*** area to customize the header (laboratory name, address, etc). Each field can contain up to 20 characters.
3. To set a logo in the header:
   a. Press **Add Image** in the ***Printout Header*** area.
   b. Insert the USB flash drive containing the logo (.png or .jpg file) and validate.
   c. Select your image, choose its position and size, then validate.
   d. Remove the USB flash drive and validate.

4. To set a banner in the footer:
   a. Press **Add Image** in the ***Printout Signature*** area.
   b. Insert the USB flash drive containing the banner (.png or .jpg file) and validate.
   c. Select your image and validate.
   d. Remove the USB flash drive and validate.

If you set a banner in the footer, the **Manual slide review** area is removed from the patient report printout.

5. Select the color mode: **BW** or **Color**.
6. Select the page format: **A4** or **Letter**.
7. Press **Validate** in the contextual toolbar.

If you select a .ppd file, the page format and the color mode can be forced to a predefined value.

8.2. To Select a .ppd File

Access: ***Home*** > ***Settings*** > ***System*** > ***Printer***

Printers manufacturers create .ppd files (Postscript Printer Description) to describe the set of features and capabilities available for the printers.

1. If needed, import a .ppd file from a USB flash drive:
   a. Press the **+** button in the ***PPD Files*** area.
   b. Insert the USB flash drive containing the .ppd file and press **Confirm**.
   c. Select the file and press **Validate**.
2. Press **Edit** in the contextual toolbar.
3. Select a file from the drop-down list in the ***PPD Files*** area.
4. Press **Validate** in the contextual toolbar.

If you select a .ppd file, the page format and the color mode can be forced to a predefined value.

8.3. To Add a Printer

Access: ***Home*** > ***Settings*** > ***System*** > ***Printer***

1. Connect the printer to the instrument.
2. Switch the printer on.
3. Press **Add** in the contextual toolbar.
4. Select the printer from the drop-down list.
5. Select the .ppd file corresponding to the printer.
   The printer does not correctly work if the wrong .ppd file is associated.
6. Press **Validate**.
   The printer is added to the list.

7. Press **Set Default Printer** to initialize the printer and make it available for the application.

Refer to the Introduction > Printer chapter for more information about compatible printers.

Related information:
- Printer, p.27

8.4. To Delete a Printer

Access: ***Home*** > ***Settings*** > ***System*** > ***Printer***

1. Select the printer to delete from the drop-down list.
2. Press **Delete** in the contextual toolbar.
3. Press **Confirm**.

8.5. To Print a Test Page

Access: ***Home*** > ***Settings*** > ***System*** > ***Printer***

1. Select the printer in the drop-down list.
2. Press **Page Test** in the ***Printer Selection*** area.

8.6. To Configure the PDF Printer

Access: ***Home*** > ***Settings*** > ***System*** > ***Printer***

1. Select the PDF printer from the drop-down list in the ***Printer Selection*** area.
2. Press **Set Default Printer** to set it as the application default printer.

All printouts, either manual (using the **Print** button) or automatic, are in PDF format. You can then export the PDF printouts.

Related information:
- To Export PDF Printouts, p.208

9. Configuring the Connection to the Network

9.1. To Configure the Analyzer Settings

Access: ***Home*** > ***Settings*** > ***System*** > ***General Communication*** > ***Network***

Only users with the Lab Manager profile can perform this procedure.

The instrument network settings must be configured when you use an ethernet connection to connect your instrument to the Host (LIS or Yumizen P8000), to Yumicare or to a network printer.

1. Press **Edit** in the contextual toolbar.
2. Select the **DHCP** or **Static IP** connection mode.
3. If the **DHCP** connection mode is selected, fill in the following fields:
   - ***Analyzer Name***
   - ***IP address***
4. If the **Static IP** connection mode is selected, fill in the following fields:
   - ***Analyzer Name***
   - ***IP address***
   - ***Subnet mask***
   - ***Default gateway***
   - ***Primary DNS*** (Option)
   - ***Secondary DNS*** (Option)
5. Press **Validate** in the contextual toolbar.

10. Configuring the Connection to the Host

The communication configuration must be performed by a qualified technician using the *Output Format* documentation. This document is available on the documentation database at www.horiba-abx.com/documentation.

For more detailed information, please contact your local HORIBA Medical representative.

Related information:
- ASTM Connection Configuration, p.199
- To Configure the Analyzer Settings, p.198
- To Configure the HL7 Connection, p.200

10.1. ASTM Connection Configuration

10.1.1. To Configure the RS232 Connection Mode

Access: ***Home*** > ***Settings*** > ***System*** > ***General Communication*** > ***Host***

Only users with the Lab Manager profile can perform this procedure.

1. Press **Edit** in the contextual toolbar.
2. Select the **ASTM** connection format.
3. Configure the options:
   - **Anonymous patient**: if selected, patient identification data is not sent to the Host (LIS or Yumizen P8000).
   - **Send curves and matrix**: if selected, results curves and matrix are sent to the Host.
4. Select the **RS232** connection mode.
5. Configure the ***RS232 Settings*** data.

Option	Function	Default value
Speed	Speed transmission selection	38400
Parity	Parity selection	None

Option	Function	Default value
Stop bit	Stop bit selection	1
Protocol	Protocol selection	None

6. Press **Validate** in the contextual toolbar.

10.1.2. To Configure the Network Connection Mode

*Access: **Home** > **Settings** > **System** > **General Communication** > **Host***

Only users with the Lab Manager profile can perform this procedure.

You must have configured the instrument network settings.

Refer to the Settings > Configuring the Connection to the Network > To Configure the Analyzer Settings chapter.

1. Press **Edit** in the contextual toolbar.
2. Select the **ASTM** connection format.
3. Configure the options:
   - **Anonymous patient**: if selected, patient identification data is not sent to the Host (LIS or Yumizen P8000).
   - **Send curves and matrix**: if selected, results curves and matrix are sent to the Host.
4. Select the **Network** connection mode.
5. Configure the IP address and the port number where the Host is awaiting connection in the ***Host Settings*** area.
6. Press **Validate** in the contextual toolbar.

Related information:
- To Configure the Analyzer Settings, p.198

10.2. To Configure the HL7 Connection

*Access: **Home** > **Settings** > **System** > **General Communication** > **Host***

Only users with the Lab Manager profile can perform this procedure.

You must have configured the instrument network settings.

Refer to the Settings > Configuring the Connection to the Network > To Configure the Analyzer Settings chapter.

1. Press **Edit** in the contextual toolbar.

2. Select the **HL7** connection format.
   The **Network** connection mode is automatically selected.
3. Configure the options:
   - **Anonymous patient**: if selected, patient identification data is not sent to the Host (LIS or Yumizen P8000).
   - **Send curves and matrix**: if selected, results curves and matrix are sent to the Host.
4. Configure the IP address and the port number to send results to the Host in the ***Host Interface 1 (Results)*** area.
5. Configure the IP address and the port number to receive orders from the Host in the ***Host Interface 2 (Orders)*** area.
6. Configure the ***Message Header*** data.

Option	Function	Default value
Receiving Facility	This area defines the facility to receive the message. It is unique to each installation. The other application should use the same ID to send messages to the interface.	Empty
Receiving Application	This area uniquely identifies the receiving application among all other applications within the network enterprise.	Empty

7. Press **Validate** in the contextual toolbar.

Related information:
- To Configure the Analyzer Settings, p.198

11. Configuring the Connection to Yumicare

11.1. To Configure the Connection to Yumicare

Access: ***Home*** > ***Settings*** > ***System*** > ***General Communication*** > ***Yumicare***

Only users with the Lab Manager profile can perform this procedure.

The Yumizen H550 can be connected to Yumicare: the HORIBA Medical remote connected support.

Connecting your instrument to Yumicare helps you to:

- import and update the control lot target values
- export your control results to the Quality Control Program (QCP)
- update the instrument software
- monitor your hematology activity

Contact your HORIBA Medical technical representative to connect your instrument to Yumicare.

1. Press **Edit** in the contextual toolbar.
2. Select the connection corresponding to your instrument configuration in the ***Connection*** area.
   - **Direct connection**: if you connect the instrument through the laboratory network.
   - **Through the router**: if you connect the instrument through the router.
3. If **Direct connection** is selected, you have to configure the instrument network settings from the **Network** tab.
   Refer to the *Settings* > *Configuring the Connection to the Network* > *To Configure the Analyzer Settings* chapter.
4. Press **Validate** in the contextual toolbar.
5. Go to ***Home*** > ***Logs*** and select **Yumicare** in the **Section** drop-down list to check the connection status.

Related information:
- To Configure the Analyzer Settings, p.198

11.2. To Fill in your QCP Login Details

Access: ***Home*** > ***Settings*** > ***System*** > ***General Communication*** > ***Yumicare***

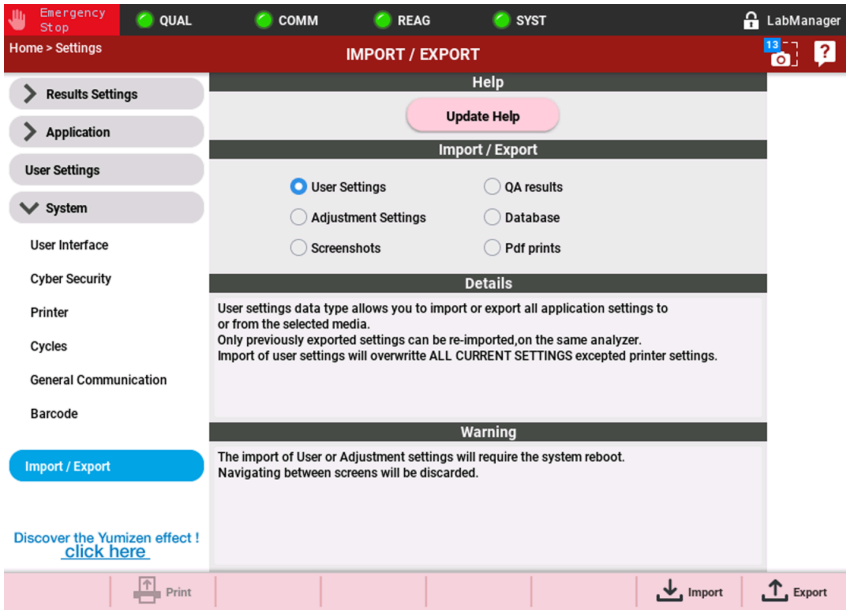
Only users with the Lab Manager profile can perform this procedure.

You can export your control results to the Quality Control Program (QCP) with Yumicare. In this case, the control results are exported to the QCP application without using a USB flash drive.

This requires to connect your instrument to Yumicare and to fill in your QCP login details on the instrument.

1. Press **Edit** in the contextual toolbar.
2. Enter your login, password and instrument name registered on the QCP application in the ***QCP Export*** area.
3. Press **Validate** in the contextual toolbar.

12. Importing and Exporting the Settings



Related information:
- To Import the Settings, p.205
- To Export the Settings, p.204
- To Export the Database, p.206
- To Import the Database, p.206
- To Export the QA Results, p.207
- To Export Screenshots, p.207
- To Export PDF Printouts, p.208

12.1. To Export the Settings

*Access: **Home** > **Settings** > **Import / Export***

Only users with the Lab Manager profile can perform this procedure.

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

You can export both user settings and technical adjustment settings.

1. Insert the USB flash drive.
2. Select **User Settings** or **Adjustment Settings** in the ***Import / Export*** area.
3. Press **Export** in the contextual toolbar.
4. Press **Confirm**.
5. When the export is complete, remove the USB flash drive and press **OK**.

12.2. To Import the Settings

Access: ***Home*** > ***Settings*** > ***Import / Export***

Only users with the Lab Manager profile can perform this procedure.

You need to have the settings you previously exported from the same instrument available on a USB flash drive.

Make sure the USB flash drive is free of any virus.

You can import both user settings and technical adjustment settings. When you import both types of settings, all current settings are overwritten, except printer settings.

1. Insert the USB flash drive.
2. Select **User Settings** or **Adjustment Settings** in the ***Import / Export*** area.
3. Press **Import** in the contextual toolbar.
4. Press **Confirm**.
   It can take several minutes for the import to be complete.
5. When the import is complete, remove the USB flash drive and press **OK**.

The modification becomes effective after a system restart.

12.3. To Export the Database

Access: ***Home*** > ***Settings*** > ***Import / Export***

Only users with the Lab Manager profile can perform this procedure.

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

This procedure allows you to back up the complete database of the instrument in order to restore it in case of software reinstallation (same version). The database includes results, user settings, adjustment settings, calibration coefficients, QC target values, etc.). It is advisable to export the database on a regular basis.

1. Insert the USB flash drive.
2. Select **Database** in the ***Import / Export*** area.
3. Press **Export** in the contextual toolbar.
4. Press **Confirm**.
5. When the export is complete, remove the USB flash drive and press **OK**.

12.4. To Import the Database

Access: ***Home*** > ***Settings*** > ***Import / Export***

Only users with the Lab Manager profile can perform this procedure.

You need to have the database you previously exported from the same instrument available on a USB flash drive.

Make sure the USB flash drive is free of any virus.

1. Insert the USB flash drive.
2. Select **Database** in the ***Import / Export*** area.

3. Press **Import** in the contextual toolbar.
4. Press **Confirm**.
   It can take several minutes for the import to be complete.
5. When the import is complete, remove the USB flash drive and press **OK**.

The modification becomes effective after a system restart.

12.5. To Export the QA Results

Access: ***Home*** > ***Settings*** > ***Import / Export***

Only users with the Lab Manager profile can perform this procedure.

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

1. Select **QA results** in the ***Import / Export*** area.
2. Press **Export** in the contextual toolbar.
3. Select a period for the results to export and validate.
4. Insert the USB flash drive.
5. Press **Confirm**.
6. When the export is complete, remove the USB flash drive and press **OK**.

12.6. To Export Screenshots

Access: ***Home*** > ***Settings*** > ***Import / Export***

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

1. Go to the screen you want to capture and press the **Screenshots** button at the top-right corner of the screen.
   The **Screenshots** button displays the number of screenshots taken.
2. Take the screenshots you need, then go to ***Home*** > ***Settings*** > ***Import / Export***.
3. Select **Screenshots** in the ***Import / Export*** area.
4. Press **Export** in the contextual toolbar.
5. Insert the USB flash drive.
6. Press **Confirm**.
7. When the export is complete, remove the USB flash drive and press **OK**.

12.7. To Export PDF Printouts

Access: ***Home*** > ***Settings*** > ***Import / Export***

You need a USB flash drive to perform this procedure.

Make sure the USB flash drive is free of any virus.

You must have previously set the PDF printer as the application default printer.

1. Select **Pdf prints** in the ***Import / Export*** area.
2. Press **Export** in the contextual toolbar.
3. Insert the USB flash drive.
4. Press **Confirm**.
5. When the export is complete, remove the USB flash drive and press **OK**.

Related information:
- To Configure the PDF Printer, p.197

13. Default Pathological Limit Values

13.1. Default (unknown age and sex)

Default values are taken from several bibliographic references listed in the *Bibliography: Reference Values* and *Bibliography: Critical Values* chapters.

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.93	5.79	5.79
HGB	7.0	11.5	16.7	18.7
HCT	33.0	34.4	48.6	70.0
MCV	74.7	74.7	97.0	105.0
MCH	26.4	26.4	32.8	34.0
MCHC	30.0	31.9	36.3	37.0
RDW-SD	-	37.0	56.0	-
RDW-CV	-	12.0	18.0	22.0
MIC	-	0.0	20.0	-
MAC	-	2.0	10.0	-
PLT	100	161	445	600
PCT	-	0.150	0.400	-
PDW	-	11.0	20.0	22.0
MPV	7.0	7.4	10.9	12.0
P-LCC	-	44	140	-
P-LCR	-	18.0	50.0	-
WBC	3.00	3.78	11.42	30.00
LYM#	-	1.24	3.97	5.00
LYM%	-	15.0	45.0	-
MON#	-	0.19	0.77	1.50
MON%	-	4.0	13.0	-
NEU#	1.00	1.69	7.50	20.00
NEU%	-	40.0	75.0	-
EOS#	-	0.04	0.59	2.00
EOS%	-	0.5	7.0	-
BAS#	-	0.00	0.10	0.50
BAS%	-	0.0	2.0	3.0
IMG#	-	0.00	0.50	-
IMG%	-	0.0	2.0	-
IMM#	-	0.00	0.10	-
IMM%	-	0.0	0.5	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
IML#	-	0.00	0.05	-
IML%	-	0.0	0.2	-
ALY#	-	0.00	0.20	-
ALY%	-	0.0	2.5	-
LIC#	-	0.00	0.20	-
LIC%	-	0.0	3.0	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.2. Men (≥ 21 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	4.28	5.79	5.79
HGB	7.0	13.4	16.7	18.7
HCT	33.00	39.2	48.6	70.0
MCV	75.0	79.6	97.0	105.0
MCH	27.0	27.3	32.8	34.0
MCHC	30.0	32.4	36.3	37.0
RDW-SD	-	37.0	56.0	-
RDW-CV	-	12.0	18.0	22.0
MIC	-	0.0	20.0	-
MAC	-	2.0	10.0	-
PLT	100	161	398	600
PCT	-	0.150	0.400	-
PDW	-	11.0	20.0	22.0
MPV	7.0	7.4	10.8	12.0
P-LCC	-	44	140	-
P-LCR	-	18.0	50.0	-
WBC	4.00	4.05	11.00	30.00
LYM#	-	1.24	3.92	5.00
LYM%	-	15.0	45.00	-
MON#	-	0.23	0.77	1.50
MON%	-	4.0	13.00	-
NEU#	1.00	1.78	6.95	20.00
NEU%	-	40.0	75.0	-
EOS#	-	0.05	0.59	2.00
EOS%	-	0.5	7.0	-
BAS#	-	0.00	0.10	0.50
BAS%	-	0.0	2.0	3.0
IMG#	-	0.00	0.50	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
IMG%	-	0.0	2.0	-
IMM#	-	0.00	0.10	-
IMM%	-	0.0	0.5	-
IML#	-	0.00	0.05	-
IML%	-	0.0	0.2	-
ALY#	-	0.00	0.20	-
ALY%	-	0.0	2.5	-
LIC#	-	0.00	0.20	-
LIC%	-	0.0	3.0	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.3. Women (≥ 21 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.93	5.19	5.50
HGB	7.0	11.5	15.1	18.7
HCT	33.0	34.4	44.6	70.0
MCV	74.7	74.7	95.6	105.0
MCH	26.4	26.4	32.6	34.0
MCHC	30.0	31.9	35.8	37.0
RDW-SD	-	37.0	56.0	-
RDW-CV	-	12.0	18.0	22.0
MIC	-	0.0	20.0	-
MAC	-	2.0	10.0	-
PLT	100	185	445	600
PCT	-	0.150	0.400	-
PDW	-	11.0	20.0	22.0
MPV	7.0	7.5	10.9	12.0
P-LCC	-	44	140	-
P-LCR	-	18.0	50.0	-
WBC	3.00	3.78	11.42	30.00
LYM#	-	1.24	3.97	5.00
LYM%	-	15.0	45.0	-
MON#	-	0.19	0.71	1.50
MON%	-	4.0	13.0	-
NEU#	1.00	1.69	7.50	20.00
NEU%	-	40.0	75.0	-
EOS#	-	0.04	0.55	2.00
EOS%	-	0.5	7.0	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
BAS#	-	0.00	0.09	0.50
BAS%	-	0.0	2.0	3.0
IMG#	-	0.00	0.50	-
IMG%	-	0.0	2.0	-
IMM#	-	0.00	0.10	-
IMM%	-	0.0	0.5	-
IML#	-	0.00	0.05	-
IML%	-	0.0	0.2	-
ALY#	-	0.00	0.20	-
ALY%	-	0.0	2.5	-
LIC#	-	0.00	0.20	-
LIC%	-	0.0	3.0	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.4. Men Pediatrics (≥ 18 < 21 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	4.18	5.48	5.50
HGB	7.0	11.9	15.4	18.7
HCT	33.0	36.2	46.3	70.0
MCV	75.0	80.0	93.6	105.0
MCH	26.5	26.5	31.4	34.0
MCHC	30.0	31.9	34.8	37.0
RDW-SD	-	37.8	46.1	-
RDW-CV	-	12.3	14.3	22.0
MIC	-	0.0	20.0	-
MAC	-	2.0	10.0	-
PLT	100	151	304	600
PCT	-	0.150	0.400	-
PDW	-	11.0	20.0	22.0
MPV	7.0	9.7	11.9	12.0
P-LCC	-	44	140	-
P-LCR	-	18.0	50.0	-
WBC	3.00	3.91	8.77	30.00
LYM#	-	0.85	3.00	5.00
LYM%	-	12.2	47.1	-
MON#	-	0.19	0.77	1.50
MON%	-	4.4	12.3	-
NEU#	1.00	1.82	7.42	20.00

Parameters	Panic L	Normal ℓ	Normal h	Panic H
NEU%	-	40.3	74.8	-
EOS#	-	0.03	0.44	2.00
EOS%	-	0.0	4.4	-
BAS#	-	0.01	0.05	0.50
BAS%	-	0.0	0.7	3.0
IMG#	-	0.00	0.50	-
IMG%	-	0.0	2.0	-
IMM#	-	0.00	0.10	-
IMM%	-	0.0	0.5	-
IML#	-	0.00	0.05	-
IML%	-	0.0	0.2	-
ALY#	-	0.00	0.20	-
ALY%	-	0.0	2.5	-
LIC#	-	0.00	0.20	-
LIC%	-	0.0	3.0	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.5. Women Pediatrics (≥ 18 < 21 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.70	4.87	5.50
HGB	7.0	10.6	13.5	18.7
HCT	32.9	32.9	41.2	70.0
MCV	75.0	77.7	93.7	105.0
MCH	25.3	25.3	30.9	34.0
MCHC	30.0	31.0	34.1	37.0
RDW-SD	-	38.4	47.7	-
RDW-CV	-	12.4	15.1	22.0
MIC	-	0.0	20.0	-
MAC	-	2.0	10.0	-
PLT	100	186	353	600
PCT	-	0.150	0.400	-
PDW	-	11.0	20.0	22.0
MPV	7.0	9.6	12.0	12.0
P-LCC	-	44	140	-
P-LCR	-	18.0	50.0	-
WBC	4.00	4.37	9.68	30.00
LYM#	-	1.16	3.18	5.00
LYM%	-	18.2	47.4	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
MON#	-	0.29	0.71	1.50
MON%	-	4.3	11.0	-
NEU#	1.00	2.00	7.15	20.00
NEU%	-	42.5	73.2	-
EOS#	-	0.03	0.27	2.00
EOS%	-	0.0	3.0	-
BAS#	-	0.01	0.05	0.50
BAS%	-	0.0	0.7	3.0
IMG#	-	0.00	0.50	-
IMG%	-	0.0	2.0	-
IMM#	-	0.00	0.10	-
IMM%	-	0.0	0.5	-
IML#	-	0.00	0.05	-
IML%	-	0.0	0.2	-
ALY#	-	0.00	0.20	-
ALY%	-	0.0	2.5	-
LIC#	-	0.00	0.20	-
LIC%	-	0.0	3.0	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.6. Pediatrics (≥ 15 < 18 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.93	5.29	5.50
HGB	7.0	10.8	145	18.7
HCT	33.0	33.4	43.5	70.0
MCV	75.0	76.7	90.6	105.0
MCH	24.8	24.8	30.2	34.0
MCHC	30.0	31.5	34.8	37.0
RDW-SD	-	36.7	44.2	-
RDW-CV	-	12.3	14.6	22.0
MIC	-	-	-	-
MAC	-	-	-	-
PLT	100	175	345	600
PCT	-	-	-	-
PDW	-	-	-	22.0
MPV	7.0	9.6	11.8	12.0
P-LCC	-	-	-	-
P-LCR	-	-	-	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
WBC	3.00	3.84	9.84	30.00
LYM#	-	0.97	3.33	5.00
LYM%	-	16.4	52.7	-
MON#	-	0.18	0.78	1.50
MON%	-	4.1	12.3	-
NEU#	1.00	1.54	7.47	20.00
NEU%	-	32.5	74.7	-
EOS#	-	0.02	0.38	2.00
EOS%	-	0.0	4.0	-
BAS#	-	0.01	0.05	0.50
BAS%	-	0.0	0.7	3.0
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.7. Pediatrics (≥ 12 < 15 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.93	5.29	5.50
HGB	7.0	10.8	14.5	18.7
HCT	33.0	33.4	43.5	70.0
MCV	75.0	76.7	90.6	105.0
MCH	24.8	24.8	30.2	34.0
MCHC	30.0	31.5	34.8	37.0
RDW-SD	-	36.7	44.2	-
RDW-CV	-	12.3	14.6	22.0
MIC	-	-	-	-
MAC	-	-	-	-
PLT	100	175	345	600
PCT	-	-	-	-
PDW	-	-	-	22.0

Parameters	Panic L	Normal ℓ	Normal h	Panic H
MPV	7.0	9.6	11.8	12.0
P-LCC	-	-	-	-
P-LCR	-	-	-	-
WBC	3.00	3.84	9.84	30.00
LYM#	-	0.97	3.33	5.00
LYM%	-	16.4	52.7	-
MON#	-	0.18	0.78	1.50
MON%	-	4.1	12.3	-
NEU#	1.00	1.54	7.47	20.00
NEU%	-	32.5	74.7	-
EOS#	-	0.02	0.38	2.00
EOS%	-	0.0	4.0	-
BAS#	-	0.01	0.05	0.50
BAS%	-	0.0	0.7	3.0
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.8. Pediatrics (≥ 6 < 12 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.90	5.03	5.50
HGB	7.0	10.6	13.4	18.7
HCT	32.2	32.2	39.8	70.0
MCV	74.4	74.4	87.6	105.0
MCH	24.8	24.8	29.5	34.0
MCHC	30.0	31.8	34.9	37.0
RDW-SD	-	35.1	41.8	-
RDW-CV	-	12.2	14.4	22.0
MIC	-	-	-	-
MAC	-	-	-	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
PLT	100	199	369	600
PCT	-	-	-	-
PDW	-	-	-	22.0
MPV	7.0	9.2	11.4	12.0
P-LCC	-	-	-	-
P-LCR	-	-	-	-
WBC	4.00	4.27	11.40	30.00
LYM#	-	0.97	4.28	7.00
LYM%	-	15.5	57.8	-
MON#	-	0.19	0.85	3.00
MON%	-	4.2	12.3	-
NEU#	1.00	1.63	7.87	20.00
NEU%	-	28.6	74.5	-
EOS#	-	0.03	0.52	2.00
EOS%	-	0.0	4.7	-
BAS#	-	0.01	0.06	0.50
BAS%	-	0.0	0.7	3.0
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.9. Pediatrics (≥ 2 < 6 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.84	4.97	5.50
HGB	7.0	10.2	12.7	18.7
HCT	31.0	31.0	37.8	70.0
MCV	71.3	71.3	85.0	105.0
MCH	23.7	23.7	28.6	34.0
MCHC	30.0	31.8	34.7	37.0
RDW-SD	-	34.9	42.0	-

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RDW-CV	-	12.4	14.9	22.0
MIC	-	-	-	-
MAC	-	-	-	-
PLT	100	189	403	600
PCT	-	-	-	-
PDW	-	-	-	22.0
MPV	7.0	8.9	11.0	12.0
P-LCC	-	-	-	-
P-LCR	-	-	-	-
WBC	4.00	4.86	13.38	30.00
LYM#	-	1.13	5.77	7.00
LYM%	-	18.1	68.6	-
MON#	-	0.19	0.94	3.00
MON%	-	4.1	12.2	-
NEU#	1.00	1.54	8.29	20.00
NEU%	-	22.4	69.0	-
EOS#	-	0.03	0.53	2.00
EOS%	-	0.0	4.1	-
BAS#	-	0.01	0.06	0.50
BAS%	-	0.0	0.6	3.0
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.10. Pediatrics (≥ 6 months < 2 years)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	3.50	3.97	5.07	5.50
HGB	7.0	10.1	12.7	18.7
HCT	30.8	30.8	37.9	70.0
MCV	69.5	69.5	82.6	105.0

Parameters	Panic L	Normal ℓ	Normal h	Panic H
MCH	22.7	22.7	27.5	34.0
MCHC	30.0	31.6	34.4	37.0
RDW-SD	-	34.9	42.8	-
RDW-CV	-	12.7	15.6	22.0
MIC	-	-	-	-
MAC	-	-	-	-
PLT	100	206	459	600
PCT	-	-	-	-
PDW	-	-	-	22.0
MPV	7.0	8.7	10.6	12.0
P-LCC	-	-	-	-
P-LCR	-	-	-	-
WBC	4.00	5.98	13.51	30.00
LYM#	-	1.52	8.09	11.00
LYM%	-	26.0	79.9	-
MON#	-	0.25	1.15	3.00
MON%	-	3.8	13.4	-
NEU#	1.00	1.19	7.21	20.00
NEU%	-	16.9	74.0	-
EOS#	-	0.02	0.82	2.00
EOS%	-	0.0	3.7	-
BAS#	-	0.01	0.06	0.50
BAS%	-	0.0	0.6	3.0
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.11. Pediatrics (≥ 1 < 6 months)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	2.93	2.93	4.80	5.50
HGB	7.0	8.9	12.7	18.7
HCT	26.8	26.8	37.5	70.0
MCV	74.1	74.1	96.4	105.0
MCH	24.4	24.4	32.5	34.0
MCHC	30.0	31.9	34.9	37.0
RDW-SD	-	35.2	55.0	-
RDW-CV	-	12.2	16.1	22.0
MIC	-	-	-	-
MAC	-	-	-	-
PLT	100	229	597	600
PCT	-	-	-	-
PDW	-	-	-	22.0
MPV	7.0	8.9	11.1	12.0
P-LCC	-	-	-	-
P-LCR	-	-	-	-
WBC	4.00	6.00	14.99	30.00
LYM#	-	2.14	9.14	11.00
LYM%	-	30.4	86.7	-
MON#	-	0.24	1.21	3.00
MON%	-	3.8	15.5	-
NEU#	0.83	0.83	7.20	20.00
NEU%	-	10.6	66.1	-
EOS#	-	0.02	0.74	2.00
EOS%	-	0.0	4.5	-
BAS#	-	0.01	0.07	0.50
BAS%	-	0.0	0.6	3.0
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.12. Pediatrics (≥ 0 < 30 days)

Default limits values (Conventional Units)

Parameters	Panic L	Normal ℓ	Normal h	Panic H
RBC	-	3.16	5.74	-
HGB	7.0	10.0	20.0	-
HCT	-	30.5	57.2	-
MCV	-	89.4	106.4	-
MCH	-	29.9	35.9	-
MCHC	-	32.7	35.7	-
RDW-SD	-	46.3	65.7	-
RDW-CV	-	14.3	17.3	-
MIC	-	-	-	-
MAC	-	-	-	-
PLT	100	144	586	-
PCT	-	-	-	-
PDW	-	-	-	-
MPV	-	10.0	12.2	-
P-LCC	-	-	-	-
P-LCR	-	-	-	-
WBC	4.00	7.80	15.91	30.00
LYM#	-	1.75	8.38	-
LYM%	-	24.9	82.7	-
MON#	-	0.28	1.77	-
MON%	-	4.3	20.6	-
NEU#	-	1.18	6.75	-
NEU%	-	10.6	66.1	-
EOS#	-	0.06	0.80	-
EOS%	-	0.0	5.4	-
BAS#	-	0.01	0.11	-
BAS%	-	0.0	0.8	-
IMG#	-	-	-	-
IMG%	-	-	-	-
IMM#	-	-	-	-
IMM%	-	-	-	-
IML#	-	-	-	-
IML%	-	-	-	-
ALY#	-	-	-	-
ALY%	-	-	-	-
LIC#	-	-	-	-
LIC%	-	-	-	-

Related information:
- Bibliography: Reference Values, p.49
- Bibliography: Critical Values, p.222

13.13. Bibliography

13.13.1.Bibliography: Reference Values

Full Blood Count

Adults (≥ 21 years)

1	Troussard X, Vol S, Cornet E, Bardet V, Couaillac JP, Fossat C, Luce JC, Maldonado E, Siguret V, Tichet J, Lantieri O, Corberand J. Full blood count normal reference values for adults in France. Journal of Clinical Pathology (2014) **67** (4): 341-4.
2	HORIBA Medical clinical performance report

18 - 21 years

1	Soldin SJ, E.C. Wong, C. Brugnara, O.P. Soldin Pediatric Reference Intervals - Seventh Edition Washington, DC: AACC press, 2011.
2	HORIBA Medical clinical performance report

Pediatrics (0 - 18 years)

1	Soldin SJ, E.C. Wong, C. Brugnara, O.P. Soldin Pediatric Reference Intervals - Seventh Edition Washington, DC: AACC press, 2011.

13.13.2.Bibliography: Critical Values

1	Consensus Guidelines - International Society for Laboratory Hematology (islh.org)
2	Revue microscopique du frottis sanguin : propositions du groupe Francophone d'hématologie cellulaire (GFHC). VOL LVI N° 317 - MARS 2014.
3	Consolidated Comparison of Hematology and Coagulation Performance Specifications - Westgard (westgard.com)

Maintenance and Troubleshooting

1. Maintenance Procedures

1.1. To Decontaminate your Instrument

1.1.1. To Decontaminate the Instrument Externally

Systematically use safety gloves when cleaning the device.

You need the following elements to perform this procedure:

- *disinfectant product*
- *soft cloth*

Disinfectant product must have the following microbiological properties:

- Bactericidal
- Fungicidal
- Active on Aspergillus fumigatus
- Active on Mycobacterium tuberculosis (BK)
- Antiviral (HIV, HBV and rotavirus)

Product example recommended by HORIBA Medical: ANIOS detergent disinfectant; Wip'Anios.

See also the WHO (World Health Organization) guidelines: "*Laboratory Biosafety Manual, 4th edition*" for more information.

- Never use alcohol or disinfectant product containing alcohol on painted covers.
- Never use bleach.
- Never use scrubbing sponge on any surfaces.
- Never spill liquid onto any cover or external surfaces.
- Never use any soaked material i.e. sponge, soft cloth, towel, etc. to clean/rinse external surfaces.

1. Switch the instrument off and disconnect the power supply cable.
2. Clean all accessible surfaces such as covers, etc.
   a. Wipe dirty surfaces thoroughly.
      Replace wipes whenever necessary.
   b. Allow surfaces to dry for at least 5 minutes.
3. Clean stainless steel parts.
   a. Wipe dirty surfaces thoroughly.
      Replace wipes whenever necessary.
   b. Dry with a soft cloth.
4. Clean the screen.
   a. Gently wipe the screen.
   b. Dry with a soft cloth to remove any trace of moisture.

1.1.2. To Decontaminate the Instrument Internally

1. Perform a concentrated cleaning procedure to clean the counting chambers, hydraulic parts and sampling needle.
   Refer to the *Maintenance and Troubleshooting > Maintenance Procedures > Hydraulic Maintenance > To Perform a Concentrated Cleaning* chapter.
2. Prepare a solution of Sodium Hypochlorite with 13% of active chlorine to 100 mL/L.
3. Fill a 5 mL tube with this solution.
4. Run five analyses on bleach.

Related information:
- To Perform a Concentrated Cleaning, p.231

1.2. To Clean the Instrument

Prepare disinfectant product and a soft cloth.*

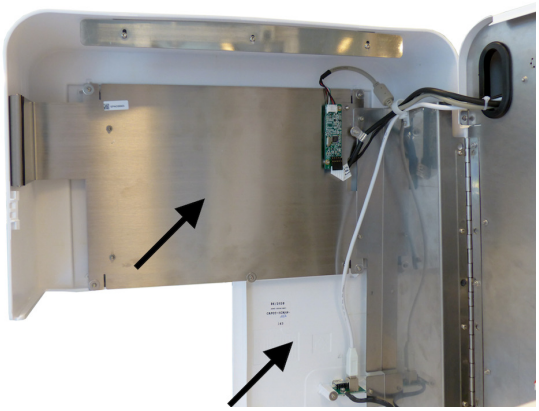
Disinfectant product must have the following microbiological properties:

- Bactericidal
- Fungicidal
- Active on Aspergillus fumigatus
- Active on Mycobacterium tuberculosis (BK)
- Antiviral (HIV, HBV and rotavirus)

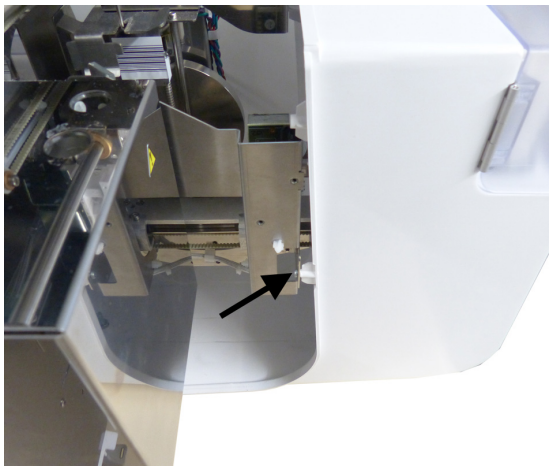
Product example recommended by HORIBA Medical: ANIOS detergent disinfectant; Wip'Anios.

1. Switch the instrument off.
2. Disconnect the AC/DC adapter from the wall outlet first, then from the instrument.
3. Insert an hexagonal key into the hole of the front cover and push to open.

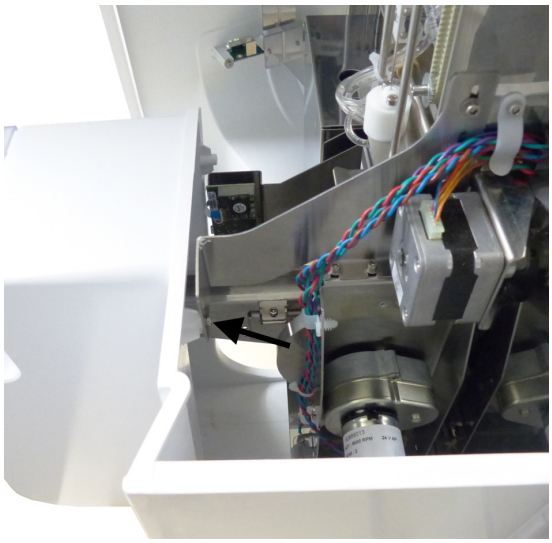
4. Wipe the back of the front cover thoroughly, then dry it with a soft cloth.



5. Loosen the following screw behind the tube holder assembly.



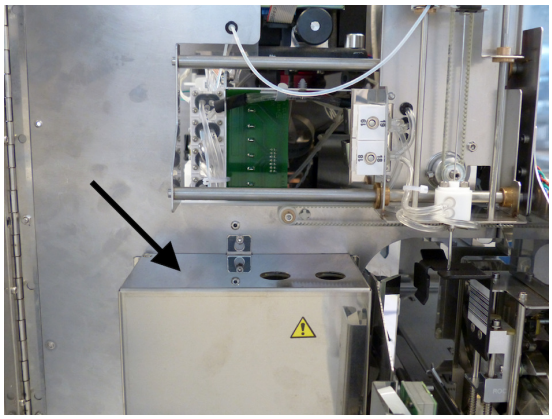
6. Loosen the following screw behind the tube holder assembly.



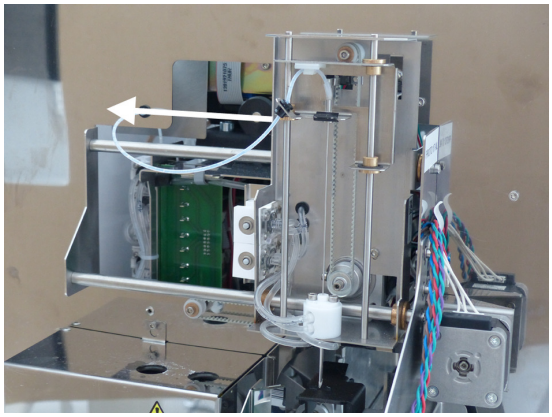
7. Remove the tube holder cover.

8. Wipe the chamber cover thoroughly, then dry it with a soft cloth.

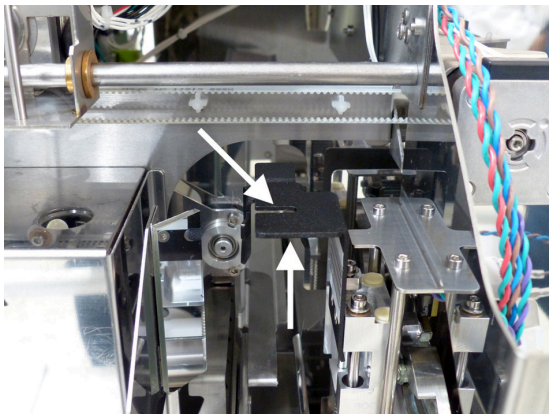
Take care that no debris fall into the chambers.



9. Manually move the sampling carriage to the left.

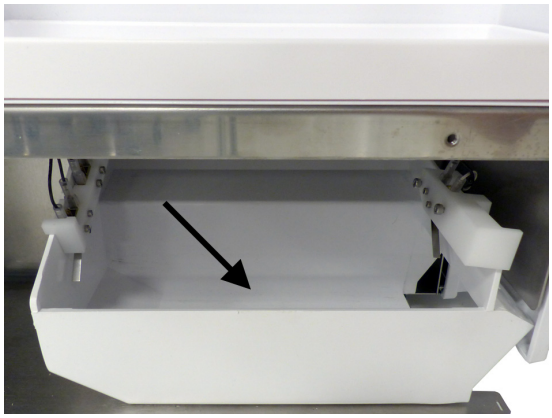


10. Wipe the upper plate of the piercing carriage, particularly inside the notch and under the plate. Then, dry it with a soft cloth.



11. Remove the two following fixation screws to remove the left panel.

12. Wipe the rack unloading area thoroughly, then dry it with a soft cloth. Take care not to damage the switches.



13. Reinstall the covers.
14. Connect the AC/DC adapter to the instrument first, then to the wall outlet.
15. Switch the instrument on.

1.3. To Initialize Hydraulic Assemblies

Access: ***Home*** > ***Maintenance*** > ***Hydraulic services***

The auto-control cycle resets all hydraulic assemblies to their initial position.

1. Press **Autocontrol** in the ***Initializing*** area.
2. Wait until the cycle is over.
   The auto-control cycle takes approximately 2 minutes and a half.

1.4. To Initialize Mechanical Assemblies

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

1. Press **Mechanical Initialization** in the ***Initializing*** area.
2. Wait until the cycle is over.
   A mechanical initialization takes approximately 12 seconds.

1.5. Hydraulic Maintenance

1.5.1. Cleaning Frequency

One of the main factors contributing to accurate and reliable results is to have a well-maintained instrument. Several maintenance functions are available for the user to clean and check the instrument. Follow the cycle frequencies indicated in the table below:

Cycles	< 80 analyses per day	> 80 analyses per day
Startup	1 per day	1 per day
Shutdown	1 per day	1 per day
Autoclean Cycle	automatic after a predefined number of analyses[a]	automatic after a predefined number of analyses[b]
Concentrated Cleaning Cycle	1 per week	1 or 2 per week

[a]: You need to have at least one Autoclean cycle per day. Set the Autoclean frequency value as the total number of analyses per day divided by 2.
[b]: You need to have at least two Autoclean cycles per day. Set the Autoclean frequency value as the total number of analyses per day divided by 3.

Related information:
- To Perform a Manual Startup, p.120
- To Perform a Manual Shutdown, p.159
- To Perform an Automatic Cleaning, p.230
- To Configure the Automatic Cleaning Frequency, p.181
- To Perform a Concentrated Cleaning, p.231
- To Rinse the System, p.232

1.5.2. To Perform a Manual Startup

1. Press **Startup**.
2. Wait until the cycle is over.
   A startup cycle takes approximately one minute.

LED voltage is checked and blank cycles (cycles without any blood specimen) are performed during the startup cycle. The startup passes if the background counts are within acceptable limits:

Parameter	Background count limits
WBC	≤ 0.3 x 10^3/mm^3
RBC	≤ 0.03 x 10^6/mm^3
HGB	≤ 0.3 g/dL
PLT	≤ 5 x 10^3/mm^3

You can consult the startup results in the **Blank** logs.

Related information:
- Logs Overview, p.106
- Startup Failed, p.242

1.5.3. To Perform a Manual Shutdown

A shutdown cycle has to be performed every 24 hours.

1. Press **Shutdown**.
2. Wait during the shutdown cycle.
   The shutdown cycle takes approximately 3 minutes.

The shutdown cycle is efficient and valid only if the cleaner remains at least 10 minutes in the chambers after the cycle. This cleans the hydraulic circuit.

You must not perform any actions during these 10 minutes at the risk of performing the shutdown cycle again.

If the system is not used for a period superior to 36 hours, it is mandatory to power it down. This eliminates startup problems, as well as the possibility of the dilution chambers evaporating.

1.5.4. To Perform an Automatic Cleaning

Access: ***Home*** > ***Maintenance***

1. Press **Autoclean Cycle**.
   The cycle starts after user confirmation.
2. Wait until the cycle is over.
   An autoclean cycle takes approximately three minutes.

Related information:
- To Configure the Automatic Cleaning Frequency, p.181

1.5.5. To Perform a Concentrated Cleaning

Access: ***Home*** > ***Maintenance***

1. Press **Concentrated Cleaning Cycle**.
   The cycle starts after user confirmation.
2. Wait until the cycle is over.
   A concentrated cleaning cycle takes approximately 10 minutes.
3. Press **OK**.

Run a startup cycle and an analysis on a control blood sample.

Related information:
- To Perform a Manual Startup, p.120
- Running Control Blood Samples, p.121

1.5.6. To Perform a Backflush

Access: ***Home*** > ***Maintenance*** > ***Hydraulic services***

1. Press **Backflush RBC/PLT** to backflush the RBC/PLT aperture.
2. Wait until the cycle is over.
   The backflush takes approximately 35 seconds.
3. Press **Backflush LMNEB** to backflush the flowcell.
4. Wait until the cycle is over.
   The backflush takes approximately one minute.

1.5.7. To Prime a Reagent

Access: ***Home*** > ***Maintenance*** > ***Hydraulic services***

1. Select the reagents you want to prime in the ***Priming/Unpriming*** area.
2. Press **Prime**.
3. Wait until the cycle is over.

Reagent	Cycle time (in minutes)
ABX Diluent	3.40
Whitediff	1.35
ABX Cleaner	0.3
All reagents	3.54

Related information:
- To Replace a Reagent Bottle, p.254

1.5.8. To Unprime a Reagent

Access: ***Home*** > ***Maintenance*** > ***Hydraulic services***

1. Disconnect and remove the bottles of the reagents you want to unprime.
2. Select the reagents you want to unprime in the ***Priming/Unpriming*** area.
3. Press **Unprime**.
4. Wait until the cycle is over.

Reagent	Cycle time (in minutes)
ABX Diluent	3.40
Whitediff	1.35
ABX Cleaner	0.3
All reagents	3.54

Related information:
■ To Replace a Reagent Bottle, p.254

1.5.9. To Drain the System

Access: ***Home*** > ***Maintenance*** > ***Hydraulic services***

1. Disconnect and remove the reagent bottles.
2. Press **Drain system** in the ***Draining*** area.
3. Wait until the cycle is over.
   The draining cycle takes approximately 4 minutes.

Related information:
■ To Replace a Reagent Bottle, p.254

1.5.10. To Rinse the System

Access: ***Home*** > ***Maintenance*** > ***Hydraulic services***

1. Press **Rinse** in the ***Cleaning*** area.
2. Wait until the cycle is over.
   A rinsing cycle takes approximately 40 seconds.

Related information:
■ To Decontaminate your Instrument, p.224

1.6. Mechanical Parts Check

1.6.1. To Check the Motors

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

1. Press the button corresponding to the motor you want to check in the ***Needle / Carriage motors*** area and in the ***Syringes motors*** area.
2. Press **Check** in the ***Tube holder*** area.
3. Make sure the motor movement is smooth and complete.
4. Make sure there is a check mark next to the motor you checked.
   If there is a cross mark next to the motor you checked, please contact your local HORIBA Medical representative.
5. Press **Mechanical Initialization** after checking any motor.

1.6.2. To Check the Barcode Reader

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

1. Press **Mechanical Initialization** in the ***Initializing*** area.
2. Place a rack with:
   - Tubes with barcodes
   - Tubes without barcodes
   - Empty positions
3. Press **Check** in the ***Barcode reader check*** area.
4. Make sure that the rack barcode is correctly read.
5. For tubes with barcodes, make sure that the circle becomes green and the barcode is read.
6. For tubes without barcodes, make sure that the circle becomes green.
7. For empty positions, make sure that the circle remains red.
8. Press **Mechanical Initialization** in the ***Initializing*** area.

1.6.3. To Check the Rack Transfer

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

1. Press **Load rack** to check the correct rack loading.
2. Press **Mix rack** to check the correct rack mixing.
3. Press **Pos1 sampling pos** to check if the first tube of the rack is correctly placed in sampling position.
4. Press **Tube holder sampling position** to check if the tube holder is correctly placed in sampling position.
5. Press **Piercing up down** to check the piercing mechanism.
6. Press **Eject rack** to check the correct rack ejection.

7. Press **Mechanical Initialization** in the ***Initializing*** area.

1.7. Monitoring the System

1.7.1. To Check the Sensors

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***System Monitoring***

1. Make sure there is a green circle next to each sensor in the ***Motor sensors*** area.
2. If there is a red circle next to a sensor, make sure that the corresponding motors operate normally in ***Maintenance*** > ***Mechanical services***.
3. If not, please contact your local HORIBA Medical representative.

1.7.2. To Check the Rack Transfer Sensors

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***System Monitoring***

1. Check the sensors states for rack transfer in the ***Other*** area.
2. If the states are not correct, make sure that the corresponding motors operate normally in ***Maintenance*** > ***Mechanical services***.
3. If not, please contact your local HORIBA Medical representative.

1.7.3. To Check the Voltage

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***System Monitoring***

1. In the ***Voltages*** area, make sure the optical bench current voltage is within ranges.
   The voltage value should be 7.5 V +/-1.
2. In the ***Voltages*** area, make sure the spectrophotometer current voltage is within ranges.
   The voltage should be 3.1 V +/- 0.02.

1.7.4. To Check the Temperature

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***System Monitoring***

1. In the ***Temperatures*** area, check the thermostated chamber temperature.
   The temperature should be 36°C.
2. Check the ambient temperature.
3. Check the reagents temperature.
   The temperature should be 40°C.

1.7.5. To Check the Draining Sensor

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***System Monitoring***

Make sure that the value displayed in the ***Pressure sensor*** area is close to 0 mbar.

1.7.6. To Check the Cycle Counter

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***System Monitoring***

The cycle counter gives you the number of cycles run for the following cycles:

- Startup cycles
- Shutdown cycles
- Analyses (CBC)
- Analyses (DIFF)
- Autoclean cycles
- Concentrated cleaning cycles (ABX Minoclair)
- Analyses since the last maintenance

Check the number of cycles run in the ***Cycle counters*** area.

1.7.7. To Check the Adjustment Values

Access: ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***Adjustment values***

1. The ***Sampling depth / Tube holder top (mm)*** area displays the sampling depth for each position. Your HORIBA Medical technical representative may ask you those adjustment values for troubleshooting purposes.
2. The ***Gains (%)*** area displays the gains for the measurements:
   - ***Optical***
   - ***Resistive***
   - ***RBC***
   - ***PLT***
   - ***HGB***

   Your HORIBA Medical technical representative may ask you those adjustment values for troubleshooting purposes.

1.8. Updating the Software

1.8.1. To Import a Software Version

Access: ***Home*** > ***Maintenance*** > ***Update Software***

Only users with the Lab Manager profile can perform this procedure.

You need to have the software version available on a USB flash drive.

Make sure the USB flash drive is free of any virus.

To install a software version, a new Operating System (OS) version or a new application version must be available on the instrument.

- If your instrument is connected to Yumicare, the new versions are automatically downloaded on your instrument.
- If your instrument is not connected to Yumicare, you need to import the new versions by means of a USB flash drive.

This procedure allows you to upload a new software version to the instrument before installing it.

1. Press **Import** in the contextual toolbar.
2. Insert the USB flash drive.
3. Press **Confirm**.
   The software version is imported.
4. When the import is complete, remove the USB flash drive and press **OK**.

You can now install the software version.

Related information:
- To Configure the Connection to Yumicare, p.202
- To Install a Software Version, p.236

1.8.2. To Install a Software Version

Access: ***Home*** > ***Maintenance*** > ***Update Software***

Only users with the Lab Manager profile can perform this procedure.

To install a software version, a new Operating System (OS) version or a new application version must be available on the instrument.

Before installing a software version, it is advisable to export both user settings and technical adjustment settings as well as the database.

This procedure allows you to update the software when a new version is available.

1. Select a new OS version or a new application version.
2. Press **Install** in the contextual toolbar.
3. Press **Confirm** to confirm the installation.
4. When the prerequisites are verified, press **Confirm** again.
   The software update starts, it can take several minutes.
   A dialog box informs you that the update is in progress. Do not switch the instrument off.
5. When the security patch is installed, press **OK** to proceed.
   A dialog box informs you that the update is in progress. Do not switch the instrument off.
6. When the update is complete, press **OK** to restart the system.

Related information:
- To Import a Software Version, p.236
- To Export the Settings, p.204
- To Export the Database, p.206

1.8.3. To Delete a Software Version

Access: ***Home*** > ***Maintenance*** > ***Update Software***

Only users with the Lab Manager profile can perform this procedure.

1. Select the software version you want to delete.
2. Press **Delete** in the contextual toolbar.
3. Press **Confirm** to confirm the deletion.
4. Press **OK**.

2. Troubleshooting Procedures

For technical assistance, you can call +33 (0)4 67 14 15 16.

Whatever the issue occurring on your instrument, a series of controls can be performed in the following logical order before attempting to carry out any intervention:

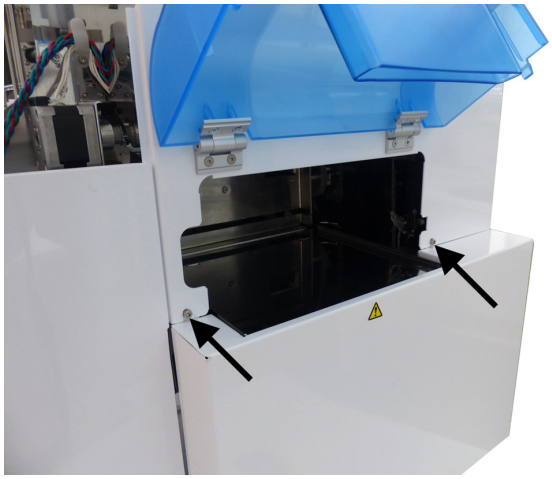
1. Is there an instrument or peripheral operating issue? If there is no obvious doubt regarding the system operation, move on to the next question. In case of any possible issue, please check the user manual corresponding procedures.
2. Are there mechanical, sampling or dilution problems while the analysis cycle is running? If there is no obvious doubt regarding the analysis cycle operations, move on to the next question. In case of any possible issue, please check the user manual corresponding procedures.
3. Are there incorrect results on all parameters or only on some parameters? If there is no obvious doubt regarding the results given by the instrument, move on to the next question. In case of any possible issue, please check the user manual corresponding procedures.
4. Are there a lot of alarms, pathology messages or technical alarms? In case of any possible issue regarding the alarms given by the instrument, please check the user manual corresponding procedures.

Related information:
- Operation Problems, p.241
- Analysis Cycle Problems, p.246
- Repeatability Problems, p.247
- Flagged Results, p.249

2.1. To Remove Instrument Covers

1. Switch the instrument off.
2. Disconnect the AC/DC adapter from the wall outlet first, then from the instrument.
3. Insert an hexagonal key into the hole of the front cover and push to open.

4. Loosen the two following screws on the right side of the instrument.

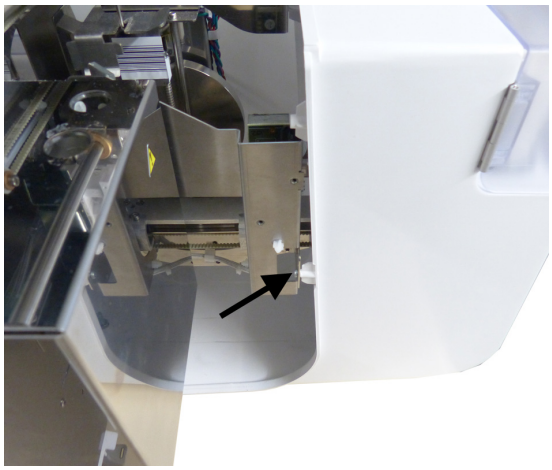


5. Unscrew and remove the following screws at the rear of the instrument.

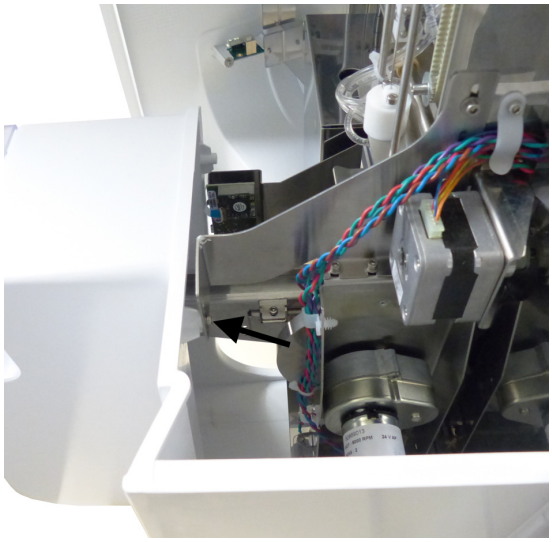
6. Loosen the two following screws at the rear of the instrument.

7. Loosen the following screw on the left side of the instrument.

8. Loosen the following screw behind the tube holder assembly.

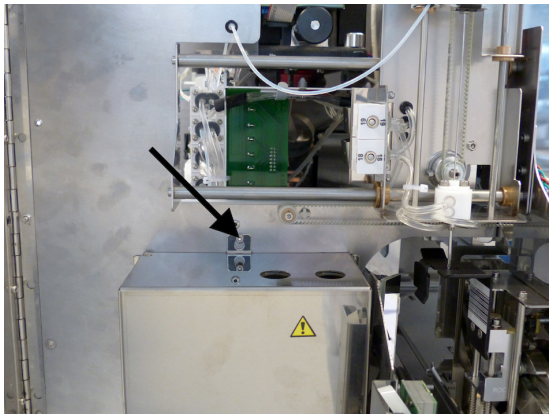


9. Loosen the following screw behind the tube holder assembly.



10. Remove the covers.

11. Loosen the following screw and lift the chamber cover to remove it.



12. Remove the reagent bottles and loosen the five screws to remove the reagent compartment cover.

2.2. Operation Problems

2.2.1. Printer Operation Problems

1. Make sure that the printer power cord is properly connected.
2. Switch the printer on and off.
3. Check the paper feed.
4. Refer to your printer user manual.

If the problem persists, please contact your local HORIBA Medical representative.

2.2.2. To Control the Reagents

Access: ***Home*** *>* ***Reagents***

The system can manage HORIBA Medical reagents automatically (levels and expiration date). It informs the user about the reagents status at the end of the instrument start, or displays an alarm message in the ***Reagents*** screen if a reagent runs low or has expired.

However, it is recommended to check the reagent levels and expiration date before starting the system to avoid risk of erroneous results.

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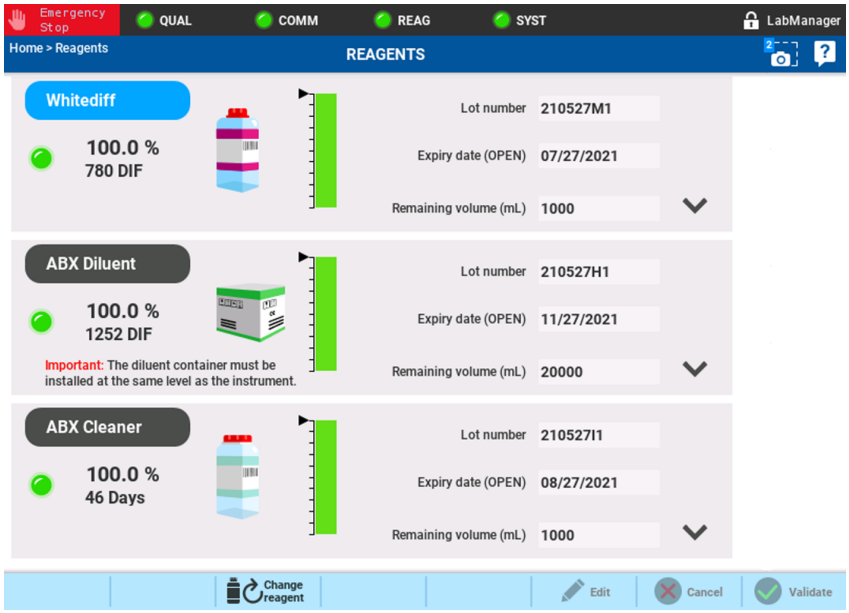
1. Check the level of the reagent bottles from the software.



2. Visually check the lot number and expiration date on the reagent bottles.
3. If a reagent bottle has to be changed, refer to the *Maintenance and Troubleshooting > Replacement Procedures > Replacing Reagents* chapter.

Related information:
■ Replacing Reagents, p.253

2.2.3. Startup Failed

1. Check the expiration date of each reagent.
2. Check the level of each reagent.
3. Replace the expired or empty reagent bottles, if necessary.
4. Rerun a startup.

5. If the startup fails again, perform a concentrated cleaning.

Related information:
- To Control the Reagents, p.119
- To Replace a Reagent Bottle, p.254
- To Perform a Manual Startup, p.120
- To Perform a Concentrated Cleaning, p.231

2.2.4. To Unblock a Rack

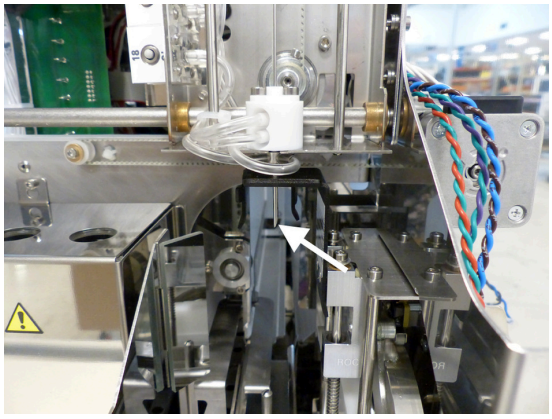
1. Remove the two following fixation screws to remove the left panel.

2. Remove the rack.

3. Reinstall the left panel.

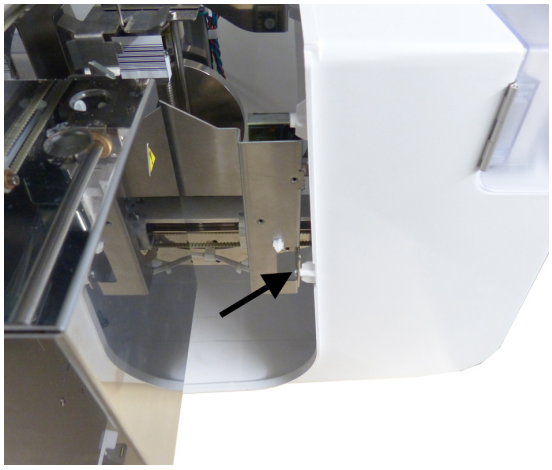
2.2.5. To Unblock the Piercing Carriage Finger

Take care not to touch the sampling/piercing needles to prevent risk of sting injury.

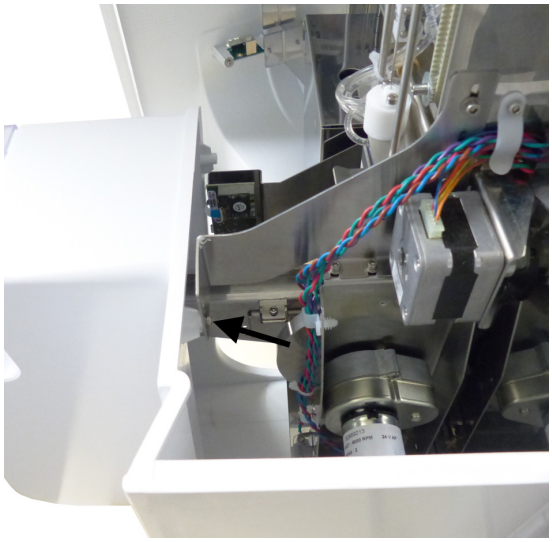


1. Switch the instrument off.
2. Disconnect the AC/DC adapter from the wall outlet first, then from the instrument.
3. Insert an hexagonal key into the hole of the front cover and push to open.

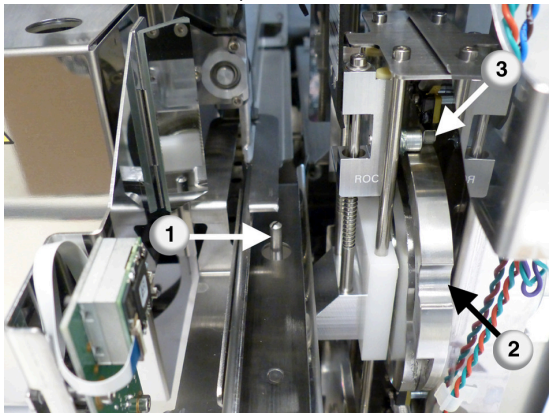
4. Loosen the following screw behind the tube holder assembly.



5. Loosen the following screw behind the tube holder assembly.



6. Remove the tube holder cover.
7. Manually turn the wheel from bottom to top to move the finger down (the switch must be in the notch of the wheel).



1 = Finger

2 = Wheel notch

3 = Switch

8. Reinstall the covers.
9. Connect the AC/DC adapter to the instrument first, then to the wall outlet.

10. Switch the instrument on.

2.3. Analysis Cycle Problems

2.3.1. To Check the Mechanical Parts

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

1. Open the instrument front cover.
2. Check the up and down movement and the left and right movement of the needle and the carriage by pressing the two **Check** buttons of the ***Needle / Carriage motors*** area.
   The movements must be smooth and regular.
3. Make sure the needle is not bent.
4. Replace the needle if it is bent.
   Refer to the *Maintenance and Troubleshooting > Replacement Procedures > To Replace the Sampling Needle* chapter.
5. Close the instrument front cover.
6. Run an analysis on a fresh blood sample and check the results.
7. Run an analysis on a control blood sample and check the results.

Related information:
- To Replace the Sampling Needle, p.255
- To Remove Instrument Covers, p.238

2.3.2. To Check the Hydraulics

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

1. Open the instrument front cover.
2. Remove the reagent bottles and the reagent compartment cover.
3. Press the **Pressure vacuum Check** button in the ***Syringes motors*** area to check the motion of the pressure vacuum syringe.
   The movements must be smooth and regular.
4. Press the **Reagents Check** button in the ***Syringes motors*** area to check the motion of the reagents syringe.
   The movements must be smooth and regular.
5. Press the **LMNEB Check** button in the ***Syringes motors*** area to check the motion of the LMNEB syringe.
   The movements must be smooth and regular.
6. Install the reagent compartment cover and the reagent bottles.
7. Close the instrument front cover.
8. Run a priming cycle of Whitediff 1L in ***Maintenance*** > ***Hydraulic services***.

9. Perform a blank cycle and make sure that the values are within acceptable limits.

Parameter	Background count limits
WBC	≤ 0.3 x 10^3/mm^3
RBC	≤ 0.03 x 10^6/mm^3
HGB	≤ 0.3 g/dL
PLT	≤ 5 x 10^3/mm^3

If any doubt, please contact your local representative.

Related information:
- To Remove Instrument Covers, p.238
- To Check the Motors, p.233

2.4. Repeatability Problems

2.4.1. Problems on all Parameters

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Perform a concentrated cleaning.
2. Run a repeatability test.

If parameters are still not repeatable, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96

2.4.2. Problems on RBC, PLT and HCT

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Open the instrument front cover.

2. Remove the chambers cover.
3. Run an analysis on a fresh blood sample and check the results.
4. Visually make sure that blood is distributed in the DIL/HGB chamber.
5. Visually check the bubbling at the bottom of the RBC/PLT chamber.
6. Install the chambers cover.
7. Close the instrument front cover.
8. Perform a concentrated cleaning.

If parameters are still not repeatable, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96

2.4.3. Problems on HGB

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Check the expiration date and the level of the Whitediff 1L bottle.
   Replace the bottle, if necessary.
2. Open the instrument front cover.
3. Remove the chambers cover.
4. Run an analysis on a fresh blood sample and check the results.
5. Visually make sure that blood is distributed in the DIL/HGB chamber.
6. Visually make sure that the dilution color is milky when the blood is distributed and then transparent brown when the Whitediff 1L is distributed.
7. Make sure the HGB LED is on when the instrument is running.
8. Install the chambers cover.
9. Close the instrument front cover.
10. Perform a concentrated cleaning.

If parameters are still not repeatable, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96

2.4.4. Problems on WBC DIFF

Access: ***Home*** > ***Maintenance*** > ***Mechanical services***

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Check the expiration date and the level of the Whitediff 1L bottle.
   Replace the bottle, if necessary.
2. Open the instrument front cover.
3. Remove the chambers cover.
4. Remove the instrument upper cover.
5. Remove the optical bench cover.
6. Run an analysis on a fresh blood sample and check the results.
7. Visually make sure that blood is distributed in the DIL/HGB chamber.
8. Make sure the optical bench LED is on when the instrument is running.
   In case of problem, please contact your local HORIBA Medical representative.
9. Make sure there are no bubbles in the flowcell.
10. Rinse the cytometer by going to ***Maintenance*** > ***Hydraulic services*** and pressing **Rinse**.
11. Make sure that the flowcell is not obstructed.
12. Perform a backflush going to ***Maintenance*** > ***Hydraulic services*** and pressing **Backflush LMNEB**.
13. Reinstall the covers.
14. Close the instrument front cover.
15. Perform a concentrated cleaning.

If parameters are still not repeatable, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96

2.5. Flagged Results

2.5.1. Flags on RBC and PLT

Access: ***Home*** > ***Maintenance***

Perform this procedure if the same alarm is triggered several times on different blood samples.

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Check the expiration date and the level of the reagent bottles.

Using reagents that are not approved by HORIBA Medical can cause flagged results.

2. Open the instrument front cover.
3. Remove the chambers cover.
4. Run a priming cycle of ABX Diluent in ***Maintenance*** > ***Hydraulic services***.
5. Visually make sure that ABX Diluent is distributed in the RBC/PLT chamber.
6. Make sure the needle is not bent.
7. Replace the needle if it is bent.
   Refer to the *Maintenance and Troubleshooting > Replacement Procedures > To Replace the Sampling Needle* chapter.
8. Perform a concentrated cleaning.
9. Make sure the tubing is not too dirty.
10. Install the chambers cover.
11. Close the instrument front cover.
12. Rerun the blood sample and check the results.

If parameters are still flagged, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96
- To Replace the Sampling Needle, p.255

2.5.2. Flags on HGB

Access: ***Home*** > ***Maintenance***

Perform this procedure if the same alarm is triggered several times on different blood samples.

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Check the expiration date and the level of the reagent bottles.

Using reagents that are not approved by HORIBA Medical can cause flagged results.

2. Open the instrument front cover.
3. Remove the chambers cover.
4. Make sure the HGB LED is on when the instrument is running.
5. Run a priming cycle of Whitediff 1L in ***Maintenance*** > ***Hydraulic services***.
6. Visually make sure that Whitediff 1L is distributed in the DIL/HGB chamber.
7. Make sure the needle is not bent.
8. Replace the needle if it is bent.
   Refer to the *Maintenance and Troubleshooting* > *Replacement Procedures* > *To Replace the Sampling Needle* chapter.
9. Install the chambers cover.
10. Close the instrument front cover.
11. Perform a concentrated cleaning.
12. Rerun the blood sample and check the results.

If parameters are still flagged, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96
- To Replace the Sampling Needle, p.255

2.5.3. Flags on WBC DIFF

Access: ***Home*** > ***Maintenance***

Perform this procedure if the same alarm is triggered several times on different blood samples.

Make sure you check the mechanical parts and the hydraulics first. Refer to the Maintenance and Troubleshooting > Troubleshooting Procedures > Analysis Cycle Problems chapter.

1. Check the expiration date and the level of the reagent bottles.

   Using reagents that are not approved by HORIBA Medical can cause flagged results.

2. Open the instrument front cover.
3. Remove the chambers cover.
4. Remove the instrument upper cover.
5. Remove the optical bench cover.
6. Run a priming cycle of Whitediff 1L in ***Maintenance*** > ***Hydraulic services***.
7. Visually make sure that Whitediff 1L is distributed in the DIL/HGB chamber.
8. Make sure the needle is not bent.

9. Replace the needle if it is bent.
   Refer to the *Maintenance and Troubleshooting* > *Replacement Procedures* > *To Replace the Sampling Needle* chapter.
10. Make sure the optical bench LED is on when the instrument is running.
    In case of problem, please contact your local HORIBA Medical representative.
11. Make sure there are no bubbles in the flowcell.
12. Rinse the cytometer by going to ***Maintenance*** > ***Hydraulic services*** and pressing **Rinse**.
13. Make sure that the flowcell is not obstructed.
14. Perform a backflush going to ***Maintenance*** > ***Hydraulic services*** and pressing **Backflush LMNEB**.
15. Reinstall the covers.
16. Close the instrument front cover.
17. Rerun the blood sample and check the results.

If parameters are still flagged, please contact your local HORIBA Medical representative.

Related information:
- Analysis Cycle Problems, p.246
- To Check the Motors, p.233
- To Perform a Concentrated Cleaning, p.231
- To Remove Instrument Covers, p.238
- To Perform a Repeatability Test in STAT Mode, p.96
- To Replace the Sampling Needle, p.255

3. Replacement Procedures

3.1. Replacing Reagents

We recommend you to always keep a reagent bottle or container in advance close to your instrument. It allows you to replace empty reagents by new ones which are already at operating conditions temperature.

Verification after a reagent replacement: risk of erroneous results if a control run has not been performed after a reagent replacement during the day.

3.1.1. To Replace the ABX Diluent Container

Access: ***Home*** > ***Reagents***

Be careful not to bend the tubing when replacing a reagent.

Risk of erroneous results if a used reagent is poured into a new reagent container.
Never pour a reagent from one container into another. Particles at the bottom of the old container can contaminate the new reagent and cause unacceptable background results especially for platelets.

1. Press **ABX Diluent**.
2. Press **Change reagent**.
3. Enter the barcode 1 which corresponds to the LOT number.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
4. Enter the barcode 2 which corresponds to the ID of the reagent.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
5. Press **Validate** in the contextual toolbar.
6. Unplug the old container and plug the new one.

   Properly dispose of the empty reagent container. Follow your local regulations for reagent disposal.

7. Press **Confirm**.

8. If you need to replace another reagent, select the reagent you want to replace and repeat the same procedure.
9. If you do not need to replace another reagent, press **Back** in the contextual toolbar.
   The system primes the reagents that have been replaced and automatically performs a startup cycle.

Related information:
- To Control the Reagents, p.119
- To Prime a Reagent, p.231

3.1.2. To Replace a Reagent Bottle

Access: ***Home*** > ***Reagents***

Risk of erroneous results if a used reagent is poured into a new reagent container.
Never pour a reagent from one container into another. Particles at the bottom of the old container can contaminate the new reagent and cause unacceptable background results especially for platelets.

At the instrument startup, the remaining quantity of each bottle is compared to the low threshold (7% of the initial volume) and the empty threshold (4% of the initial volume).

If the level is under the low threshold, an information alarm is triggered. If the level is under the empty threshold, the bottle is considered as empty and you have to replace it.

Be careful not to bend the tubing when replacing a reagent.

1. Select the reagent you want to replace.
2. Press **Change reagent**.
3. Enter the barcode 1 which corresponds to the LOT number.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
4. Enter the barcode 2 which corresponds to the ID of the reagent.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.
5. Press **Validate** in the contextual toolbar.
6. Unplug the old reagent bottle and plug the new one.
7. Press **Confirm**.
8. If you need to replace another reagent, select the reagent you want to replace and repeat the same procedure.
9. If you do not need to replace another reagent, press **Back** in the contextual toolbar.
   The system primes the reagents that have been replaced and automatically performs a startup cycle.

Related information:
- To Control the Reagents, p.119
- To Prime a Reagent, p.231

3.1.3. To Replace the Waste Container

The specimens, reagents, calibrators, controls, etc. and waste liquids that contain human specimen extracts are potentially infectious; all accessible surfaces of the instrument can be potentially contaminated by human specimens.
Protective clothing must be worn (lab coat, gloves, eye protection, etc.).

- At the beginning of each day, before startup, check if the waste container needs to be emptied.
- During instrument operation, do not remove the reagent tubing and the liquid waste tubing under any circumstance.

Follow your local and/or national guidelines for biohazard waste disposal.

1. Make sure no cycle is in progress.
2. Replace the full waste container by an empty new one.
3. Close the old container with the new container cap and follow your local and/or national guidelines for biohazard waste disposal.

Related information:
- To Check the Waste Container Level, p.117

3.2. To Replace the Sampling Needle

For more detailed information, please contact your local HORIBA Medical representative.

1. Switch the instrument off.
2. Disconnect the AC/DC adapter from the wall outlet first, then from the instrument.
3. Open the instrument front cover.
4. Remove the retaining clip.
5. Carefully lift the needle up and remove it.
6. Disconnect the tube from the top of the needle.
   Make sure not to bend the tube.
7. Place the new sampling needle and reassemble in reverse order.
8. Connect the AC/DC adapter to the instrument first, then to the wall outlet.
9. Switch the instrument on.
10. Go to ***Maintenance*** > ***Mechanical services***.
11. Check the up and down movement and the left and right movement of the needle by pressing the two **Check** buttons of the ***Needle / Carriage motors*** area.
    The movements must be smooth and regular.
12. Close the instrument front cover.
13. Run a startup cycle.
    Make sure that there are no leaks at the end of the startup cycle.
14. Run an analysis on a control blood sample and check the results.

A complete adjustment of the new needle must be performed by a HORIBA Medical technical representative.

Related information:
- To Perform a Manual Startup, p.120
- To Check the Motors, p.233
- To Remove Instrument Covers, p.238

4. Error Messages

4.1. Analyzer Error Messages

4.1.1. Cleanliness Check Failure

Code	Message	Activation conditions	Corrective actions
A00	Startup failed	Startup with one of the blank values out of ranges	Check **Blank** logs.

Related information:
- Logs Overview, p.106

4.1.2. Motors Management Failure

Code	Message	Activation conditions	Corrective actions
A01	Reagent syringe motor busy	Reagent syringe motor busy (outside the **Reagents** check motor command)	Run an initialization
A02	LMNEB syringe motor busy	LMNEB syringe motor busy (outside the **LMNEB** check motor command)	Run an initialization
A03	Pressure syringe motor busy	Pressure syringe motor busy (outside the **Pressure vacuum** check motor command)	Run an initialization
A04	Needle motor busy	Needle motor busy (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A05	Carriage motor busy	Carriage motor busy (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A06	Transfer motor busy	Transfer motor busy (outside the ***Autoloader check*** command)	Run an initialization
A07	Loader motor busy	Loader motor busy (outside the ***Autoloader check*** command)	Run an initialization
A08	Mixing motor busy	Mixing motor busy (outside the ***Autoloader check*** command)	Run an initialization

Related information:
- To Initialize Mechanical Assemblies, p.229

4.1.3. Position Error

Code	Message	Activation conditions	Corrective actions
A11	Reagent syringe motor not reaching home	Reagent syringe motor home switch not detected after a mechanical initialization (outside the **Reagents** check motor command)	Run an initialization
A21	Reagent syringe motor failure	Reagent syringe motor home switch still detected after a movement outside the switch (outside the **Reagents** check motor command)	Run an initialization
A31	Reagent syringe #%s step error	Reagent syringe motor loss of steps after returning back to home position (outside the **Reagents** check motor command)	Run an initialization
A12	LMNEB syringe motor not reaching home	LMNEB syringe motor home switch not detected after a mechanical initialization (outside the **LMNEB** check motor command)	Run an initialization
A22	LMNEB syringe motor failure	LMNEB syringe motor home switch still detected after a movement outside the switch (outside the **LMNEB** check motor command)	Run an initialization
A32	LMNEB syringe #%s step error	LMNEB syringe motor loss of steps after returning back to home position (outside the **LMNEB** check motor command)	Run an initialization
A13	Pressure syringe motor not reaching home	Pressure syringe motor home switch not detected after a mechanical initialization (outside the **Pressure vacuum** check motor command)	Run an initialization
A23	Pressure syringe motor failure	Pressure syringe motor home switch still detected after a movement outside the switch (outside the **Pressure vacuum** check motor command)	Run an initialization
A33	Pressure syringe #%s step error	Pressure syringe motor loss of steps after returning back to home position (outside the **Pressure vacuum** check motor command)	Run an initialization
A14	Needle motor not reaching home	Needle motor home switch not detected after a mechanical initialization (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A24	Needle motor failure	Needle motor home switch still detected after a movement outside the switch (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A34	Needle #%s step error	Needle motor loss of steps after returning back to home position (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A15	Carriage motor not reaching home	Carriage motor home switch not detected after a mechanical initialization (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A25	Carriage motor failure	Carriage motor home switch still detected after a movement outside the switch (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization

Code	Message	Activation conditions	Corrective actions
A35	Carriage #%s step error	Carriage motor loss of steps after returning back to home position (outside the ***Needle / Carriage motors*** check motor command)	Run an initialization
A16	Transfer motor not reaching home	Transfer motor home switch not detected after a mechanical initialization (outside the ***Autoloader check*** command)	Run an initialization
A26	Transfer motor failure	Transfer motor home switch still detected after a movement outside the switch (outside the ***Autoloader check*** command)	Run an initialization
A36	Transfer #%s step error	Transfer motor loses steps after returning back to home position (outside the ***Autoloader check*** command)	Run an initialization
A17	Loader motor not reaching home	Loader motor home switch not detected after a mechanical initialization (outside the ***Autoloader check*** command)	Run an initialization
A27	Loader motor failure	Loader motor home switch still detected after a movement outside the switch (outside the ***Autoloader check*** command)	Run an initialization
A37	Loader #%s step error	Loader motor loses steps after returning to home (outside the ***Autoloader check*** command)	Run an initialization
A18	Mixing motor not reaching home	Mixing motor home switch not detected after a mechanical initialization (outside the ***Autoloader check*** command)	Run an initialization
A28	Mixing motor failure	Mixing motor home switch still detected after a movement outside the switch (outside the ***Autoloader check*** command)	Run an initialization
A38	Mixing #%s step error	Mixing motor loses steps after returning to home (outside the ***Autoloader check*** command)	Run an initialization

Related information:
- To Initialize Mechanical Assemblies, p.229

4.1.4. Software Error

Code	Message	Activation conditions	Corrective actions
A101	Reagent syringe motor software error %s	The software is unable to perform the requested movement.	Run an initialization
A102	LMNEB syringe motor software error %s	The software is unable to perform the requested movement.	Run an initialization
A103	Pressure syringe motor software error %s	The software is unable to perform the requested movement.	Run an initialization
A104	Needle motor software error %s	The software is unable to perform the requested movement.	Run an initialization
A105	Carriage motor software error %s	The software is unable to perform the requested movement.	Run an initialization
A106	Transfer motor software error %s	The software is unable to perform the requested movement.	Run an initialization

Code	Message	Activation conditions	Corrective actions
A107	Loader motor software error %s	The software is unable to perform the requested movement.	Run an initialization
A108	Mixing motor software error %s	The software is unable to perform the requested movement.	Run an initialization

Related information:
■ To Initialize Mechanical Assemblies, p.229

4.1.5. Draining Errors

Code	Message	Activation conditions	Corrective actions
A40	Drain sensor time-out	Draining sensor timeout	Run an initialization
A41	Drain sensor out of order	Draining sensor out of order	Run an initialization
A42	Drain sensor calibration failed	Draining sensor cannot be calibrated during the initialization	Run an initialization Contact your local HORIBA Medical representative.

4.1.6. Electrovalves Management Failure

Code	Message	Activation conditions	Corrective actions
A50	ElectroValve #%s busy	Electrovalve busy (outside the electrovalves check command)	Run an initialization
A51	ElectroValve #%s not released	Electrovalve not released	Run an initialization
A52	Electrovalve #%s out of order	Electrovalve is out of order	Run an initialization Contact your local HORIBA Medical representative.

#%s stands for the electrovalve number

Related information:
■ To Initialize Mechanical Assemblies, p.229

4.1.7. Temperature Management Failure

Code	Message	Activation conditions	Corrective actions
A95	Reagent heater temperature sensor out of order	Reagent heater temperature sensor out of order	Contact your local HORIBA Medical representative.
A96	Thermostatic chamber temperature sensor out of order	Thermostatic chamber temperature sensor out of order	Contact your local HORIBA Medical representative.
A97	Ambient temperature sensor out of order	Ambient temperature sensor out of order	Contact your local HORIBA Medical representative.
A98	Temperature sensor	Temperature sensor functional	Run an initialization

Code	Message	Activation conditions	Corrective actions
A85	Unable to control reagent temperature	Reagent heater system out of order	Run an initialization
A86	Unable to control thermostatic chamber temperature	Thermostatic chamber out of order	Run an initialization

Related information:
- To Initialize Mechanical Assemblies, p.229

4.1.8. Piercing System Management Failure

Code	Message	Activation conditions	Corrective actions
A62	Piercing movement failed	Tube holder up movement failure after an up movement, holder up sensor is not active (outside the ***Tube holder*** check motor command)	Run an initialization
A63	Piercing Switch Fault	Piercing mechanism failure	Contact your local HORIBA Medical representative.
A64	Post-piercing movement failed	Tube holder down movement failure after a down movement, holder down sensor is not active (outside the ***Tube holder*** check motor command)	Run an initialization

4.1.9. Barcode Reader

Code	Message	Activation conditions	Corrective actions
A66	Barcode reader error	Barcode reader communication fails on command	Run initialization

4.1.10. Rack Management

Code	Message	Activation conditions	Corrective actions
A70	Loading area door opened	Loading area door is opened on rack loading	None
A71	Unloading area full	Unloading area is full during a rack routine	None
A72	Loading area empty	No rack is loaded on routine start	None
A73	Unknown rack	Rack barcode is unknown or cannot be read	None
A75	Tube mismatch%C	First tube barcode reading does not correspond to second tube barcode reading	None
A76	Unloading area full	Unloading area is full on rack ejection at first initialization	Run an initialization
A77	Sample ID #%C doesn't match with waited format	The format of the SID field does not match the ISBT128 format	None

Code	Message	Activation conditions	Corrective actions
A78	Sample ID #%C Already in Progress	The Sample ID of the tube to be sampled is already in progress	None
A79	3 consecutive inconsistent results	The same problem happens three consecutive times during a rack routine	None
A80	Sample ID #%C is too long	The sample ID on the barcode label is too long	None

4.2. User Error Messages

Code	Message	Activation conditions	Corrective actions
U00	Instrument stopped by user	User requires an emergency stop	Run an initialization

Related information:
- To Initialize Mechanical Assemblies, p.229

4.3. Quality Assurance Error Messages

Code	Message	Activation conditions	Corrective actions
Q01	A result is invalid for QC	Control run report has a technical alarm	Check QC
Q02	No QC used	No referent control profiles or empty control profiles during application start or during control profile archiving	Register QC lot and run QC sample
Q03	A Control Result is out of range	At least one referent control profile accepted or failed during application start or when generating a control report	Check QC Accept or delete the result from the ***Control Run Result*** screen
Q04	A review of the QC targets %s has been published.	Target values of the control lot have been updated %s stands for the control lot	Check QC Check the control lot and update the target values
X01	One XB value is outside target value +/- XB limit(%) or three consecutive points are outside target value +/- 2/3 XB limit (%)	When an XB alarm is triggered	Check XB

Related information:
- Quality Control, p.82
- Patient Quality Control (XB), p.92

4.4. Reagents Error Messages

Code	Message	Activation conditions	Corrective actions
R01	A reagent is empty	If the level of a reagent is below the empty threshold (4% of the initial volume) If the remaining volume of the cleaner reagent is lower than the required volume for the shutdown cycle	Check reagents status
R02	A reagent has expired	If a reagent has expired	Check reagents status
R03	A reagent remaining volume is low	If the level of a reagent is below the low threshold (7% of the initial volume)	Check reagents status
R04	A reagent remaining volume is low to start rack routine	At rack routine start, if the level of a reagent is not sufficient to perform all the analyses on the tubes in the rack.	Check reagents status
R05	ABX Minoclair prime failed	Unable to prime the product at the beginning of the concentrated cleaning cycle	Check the ABX Minoclair bottle and replace it if needed Run an initialization

Related information:
■ To Control the Reagents, p.119

4.5. Environment Error Messages

Code	Message	Activation conditions	Corrective actions
E00	Software Error (#%s)	Software Error (#%s)	Leave application and restart
E01	Data management Software Error (#%s)	Data purge failed	Leave application and restart
E02	Not Enough Memory	Not enough memory available to operate correctly	Leave application and restart
E03	Several system files are corrupted	Several system files are corrupted	Contact your local HORIBA Medical representative.
E04	Internal connection lost	The internal Ethernet cable is disconnected or damaged	Leave application, check the internal connection and restart
E06	Storage device error	Errors detected on the storage device	Leave application and restart If the problem persists, please contact your local HORIBA Medical representative.
E11	Invalid analyzer serial number	Invalid serial number at initialization	Contact your local HORIBA Medical representative.
E12	Inconsistent hardware configuration	Invalid hardware configuration	Contact your local HORIBA Medical representative.

4.6. Communication Error Messages

Code	Message	Activation conditions	Corrective actions
H01	Frame format error %S in the received Order (SID: %C)	Protocol error at order reception %S stands for the error type %C stands for the sample ID	Check **Host** logs
H02	Order received but ignored for contextual incompatibility (SID: %C)	Contextual issue at order reception %C stands for the sample ID	Check **Host** logs
H03	Connection error (%C)	Connection error %C stands for the error type	Check **Host** logs
H04	Low Level protocol error (%C)	Low level protocol error %C stands for the error type	Check **Host** logs
H05	High Level protocol error (%C)	High level protocol error %C stands for the error type	Check **Host** logs
H06	Sending Validation error (%C)	Protocol error at sending %C stands for the error type	Check **Host** logs
H07	Host Software Error (%C)	Host software error %C stands for the error code	Run an initialization

Related information:
- Logs Overview, p.106

4.7. Maintenance Error Messages

Code	Message	Activation conditions	Corrective actions
M01	No Concentrated Cleaning cycle since eight days	At the beginning of the day, if the date of the last concentrated cleaning cycle is greater than or equal to 8 days.	Perform a concentrated cleaning cycle with ABX Minoclair
M02	New patch available	At login, if a new software version is available.	Install the new software version from the ***Update Software*** screen
M03	Free disk space is insufficient	The remaining free disk space is lower than 90%.	Go to ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***Disk space*** to purge the required data.
M04	Update has failed. Software has been successfully rolled back and the instrument is operational.	The software update failed.	Reinstall the software version from the ***Update Software*** screen
M05	Software update and restoration failure	The software update and the software recovery failed.	Contact your local HORIBA Medical representative.
M06	The software update is successful	When the update is complete and successful.	None

Code	Message	Activation conditions	Corrective actions
M07	Maintenance to do	The maintenance must be performed by a HORIBA Medical technical representative.	Contact your local HORIBA Medical representative.
M08	Free disk space is full	The disk is full.	Go to ***Home*** > ***Maintenance*** > ***System Monitoring*** > ***Disk space*** to purge the required data.

Related information:
- To Perform a Concentrated Cleaning, p.231
- To Install a Software Version, p.236
- To Delete a Software Version, p.237

Description and Technology

1. Instrument Description

1.1. Yumizen H550 Front Side

1 = Reagents compartment

2 = Rack loading area

3 = USB port

4 = LCD touch screen

5 = Rack unloading area

6 = Tube holder door

1.2. Yumizen H550 Front Side (Covers Opened)

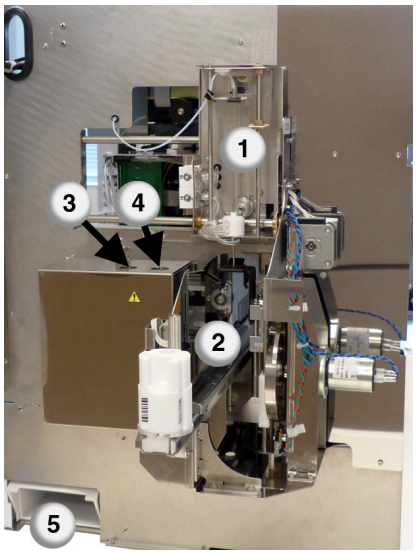
1 = Carriage assembly

2 = Rack mode and STAT mode sampling areas

3 = DIL/HGB chamber

4 = RCB/PLT chamber

5 = Rack unloading area



1.3. Yumizen H550 Left Side

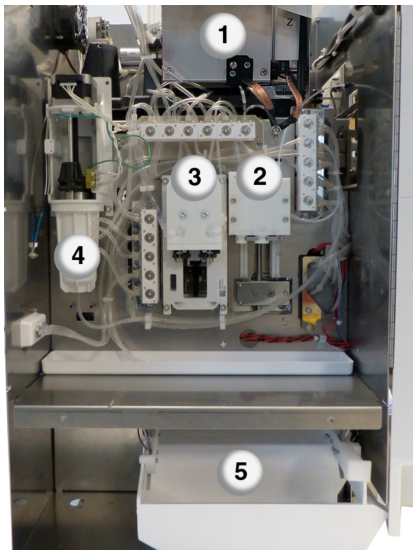
1 = Optical bench

2 = Reagent syringe assembly

3 = LMNEB syringe assembly

4 = Pressure syringe

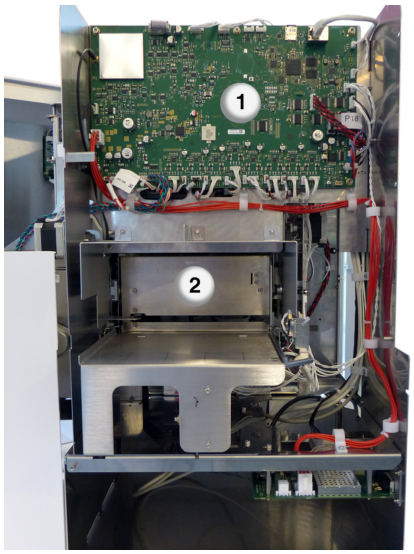
5 = Rack unloading area



1.4. Yumizen H550 Right Side

1 = Main board

2 = Rack loading area



1.5. Yumizen H550 Rear Side

1 = Peripheral connections

2 = Instrument serial label

3 = ON/OFF button

4 = Power supply connection

5 = Diluent input and waste output

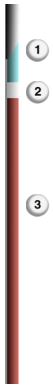
2. Measurement Principles

2.1. Sampling Principles

In CBC and DIFF modes, 20 µL of blood is aspirated as follows:
1 = Diluent

2 = Air

3 = 20 µL of blood



2.2. White Blood Cells Count and Differential

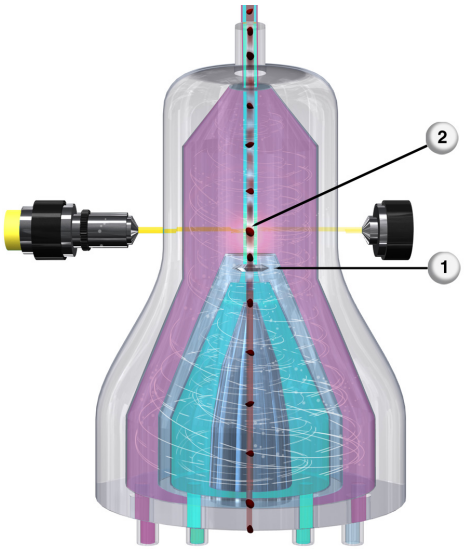
2.2.1. Dilutions Description

1. 20 µL of blood is aspirated and delivered into the DIL/HGB chamber with 795 µL of ABX Diluent. The first dilution rate is 1/41.
2. 1.24 mL of Whitediff 1L is added, and the dilution incubates during 10.5 s +/-1 at 37°C +/-2. Whitediff 1L destroys the RBC membrane and stabilizes WBC to prepare the cells for identification in the cytometer. The Final dilution rate is 1/97.
3. 93.25 µL of final dilution is injected in the cytometer to analyze the volume and absorbance of each cell.

2.2.2. White Blood Cells Differential Principle

The WBC detection principle is based on the Double Hydrodynamic Sequential System "DHSS" which allows a linear flow of the cells through the light path (HORIBA Medical patent).

1. Cells go through a 60 µm aperture to be counted during 11 X 1 s and measured by electrical current (impedance changes).
2. The transmitted light at a 0° angle is measured to allow a measured response according to the internal structure of each cell and its absorbance, as unabsorbed light passes through the spaces in the nuclear material of each cell. This is known as diffused light.



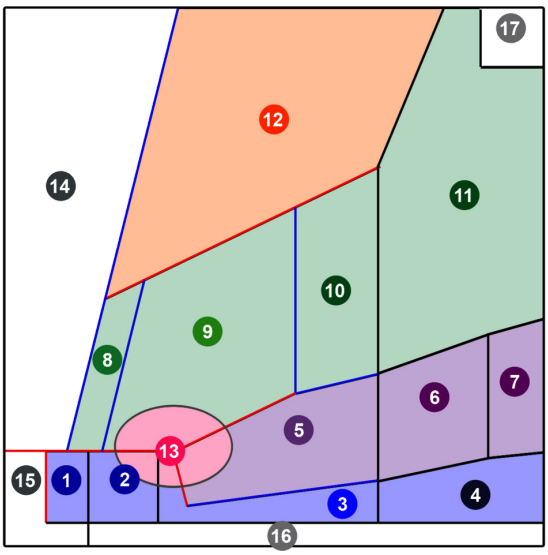
2.2.3. Matrix and Cells Description

Results

From the absorbance and resistive measurements of the leukocytes, a matrix is developed with cell volumes on the X-axis and optical transmission on the Y-axis. Study of the matrix image allows a clear differentiation of leukocyte populations.

Most of the cell population thresholds are fixed and give the normal limits for the normal leukocyte morphologies. Changes in the morphology of a specific population will be indicated on the matrix by a shift in the corresponding population.

The fixed thresholds appear in black and the mobiles thresholds appear in red in the picture below. The blue thresholds follow the red ones when adjusting the matrix.



LYM# = 1 + 2 + 3 + 4

MON# = 5 + 6 + 7

NEU# = 8 + 9 + 10 + 11

EOS# = 12

BAS# = 13

IMG# = 10 + 11

IMM# = 7

IML# = 4

ALY# = 3

LIC# = 4 + 6 + 7 + 10 + 11

Background Noise = 14 + 15

Low Optical Correlation = 16

Background Noise Bubbles = 17

Corrected WBC Count

Also called leukocytes, the White Blood Cells (WBC) are the cells of immune system and are commonly classified into five sub-populations: Lymphocytes, Monocytes, Neutrophils, Eosinophils and Basophils (currently named 5 Diff). On Yumizen H550, the Immature Granulocytic cells (IMG) are differentiated as a 6th population group (currently named 6 Diff).

The WBC count is automatically recounted by removing the cellular interferences of infected erythrocytes (Malaria), erythroblasts (NRBC), platelet aggregates. The WBC interference alarm is triggered if the WBC and Differential counts are not enough reliable and are displayed as suspected results with "*".

Lymphocytes

Lymphocytes are very small, round shaped cells with a condensed cytoplasm and a large nucleus. These cells are normally positioned in the lower part of the Y-axis, as well as in the left part of the X-axis because of their small size.

Monocytes

Monocytes are very large, irregular shaped cells with a large convoluted nucleus. The nucleus contains folds and sometimes vacuoles. The cytoplasm is also large with non-granular intra-cellular material. They are positioned in the lower part of the Y-axis. Because monocytes are large cells, they are positioned on the right side of the X-axis.

Neutrophils

Neutrophils are medium size cells. They contain granular material in their cytoplasm along with a segmented nucleus. Due to these cellular features, more light will pass through neutrophils in the flowcell. As a result, neutrophils are placed in the middle of the Y-axis, and spread along the middle part of the X-axis according to their maturity. Hyper-segmentation and increased granules place this population higher along the Y-axis.

Eosinophils

Eosinophils are somewhat like neutrophils. They contain granular material and a segmented nucleus within the cytoplasm. Due to the action of the reagent, eosinophils are placed in the highest part of the Y-axis. Hyper-segmentation and increased granules place this population in the top-right area of the matrix.

Basophils

Basophils are located between the population of lymphocytes, monocytes and neutrophils. Basophils are medium size cells with averaged absorbance value, that allow their identification.

Large Immature Cells

The large immature cells are placed in the right part of the X-axis on the matrix.

- The **IML**, located in the lower part of the large immature cells area, are more representative of the presence of the immature lymphoid lineage.
- The **IMM**, located in the middle part of the large immature cells area, usually contain immature elements of the monocytic lineage.
- The "Right Monocytes", located in the middle part of the large immature cells area and between the monocytes and the IMM areas, contain the large monocytes and the hyperbasophilic monocytes.
- The **IMG**, in the upper part of the large immature cells area, usually contain immature forms of granulocytic cells that have a high potential of light scattering (complex intracellular content). Immature granulocytic cells are detected by their larger volumes and by their increased quantity of granules which allow more light to pass through the cells, and increase the intensity of scattered light. Therefore, cells such as metamyelocytes are found at the right of the neutrophils and almost at the same level. Myelocytes and promyelocytes are found on the far right of the matrix, in the

saturation position. Metamyelocytes, myelocytes, and promyelocytes are all classed as LIC, and their given results is included in the neutrophil value.

The Blast cells are generally located at the right of the monocyte population and, as such, increase the LIC count. A Blasts? alarm is generated from increased counts within the LIC area.

Atypical Lymphocytes

Large lymphocytes are usually detected in the ALY area (right box #3), where reactive lymphoid forms, stimulated lymphocytes, and plasmocytes are also found.

Background Noise

Alarms are generated when platelet aggregates and debris from RBC cell fragments are found in the background noise area, at the bottom-left corner of the matrix.

Low Optical Correlation

Resistive measurements which are not correlated with optical measurements are found in the low optical correlation area, at the bottom of the matrix.

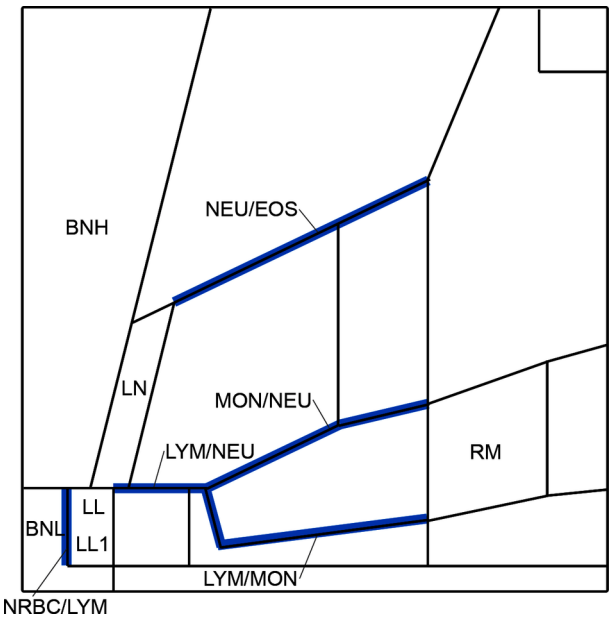
They can be due to electronic noise or LED noise.

Background Noise Bubbles

The presence of bubbles in the flowcell can be detected in the background noise bubbles area, at the top-right corner of the matrix.

2.2.4. Alarm Default Levels

Alarms boxes and thresholds are located on the matrix as follows:



If the results exceed the default levels of morphology alarms set in the software, an alarm is triggered and displayed in the **Results** screen.

Alarm	Box or threshold	Level
WBC abn. matrix NEU+EOS/Noise	BNH	80#
WBC abn. matrix ■ PLT aggregates? ■ NRBC? ■ PLT aggregates or NRBC?	BNL	25#
WBC abn. matrix ■ PLT aggregates? ■ NRBC? ■ PLT aggregates or NRBC?	LL	150#
	LL1	16%
WBC abn. matrix MON/IMM	RM	2.5%
WBC abn. matrix NEU/Noise	LN	15%
WBC abn. matrix LYM/NEU	LYM/NEU	0.19
WBC abn. matrix MON/NEU	MON/NEU	0.10 and MON% > 15%
WBC abn. matrix NEU/EOS	NEU/EOS	0.018
WBC abn. matrix LYM/MON	LYM/MON	0.02 and LYM% > 45%
WBC abn. matrix LYM/NRBC	NRBC/LYM	0.14

2.3. Hemoglobin Measurement

2.3.1. Dilutions Description

1. 20 µL of blood is aspirated and delivered into the DIL/HGB chamber with 795 µL of ABX Diluent. The first dilution rate is 1/41.
2. 1.24 mL of Whitediff 1L is added, and the dilution incubates during 9.5 to 11.5 s at 37°C +/-2. Whitediff 1L destroys the RBC membrane and releases hemoglobin. All the heme iron is oxidized and stabilized. The Final dilution rate is 1/97.

2.3.2. Measurement Principle

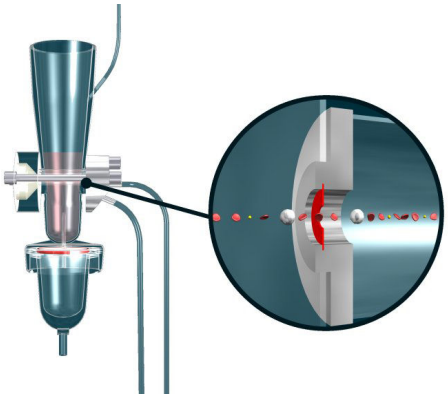
Hemoglobin is measured by spectrophotometry at a wavelength of 555 nm.

The final HGB result represents the absorbance value obtained multiplied by the coefficient of calibration.

2.4. Red Blood Cells and Platelets Detection

2.4.1. Dilutions Description

1. 20 µL of blood is aspirated and delivered into the DIL/HGB chamber with 795 µL of ABX Diluent. The first dilution rate is 1/41.
2. 9 µL of blood is aspirated from the first dilution, and delivered into the RBC/PLT chamber with 2 mL of ABX Diluent. The Final dilution rate is 1/9116 and the temperature of reaction is 35°C +/-2.
3. Then, the RBC and PLT are counted.

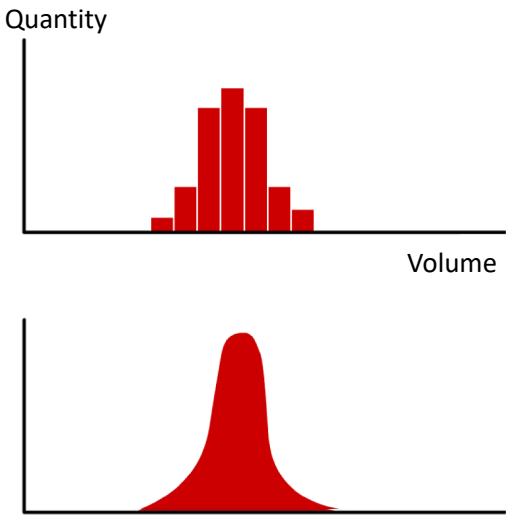


2.4.2. Detection Principles

Red blood cells histogram description

The **RBC histogram** corresponds to the distribution curves on 256 channels from 30 fL to 300 fL.

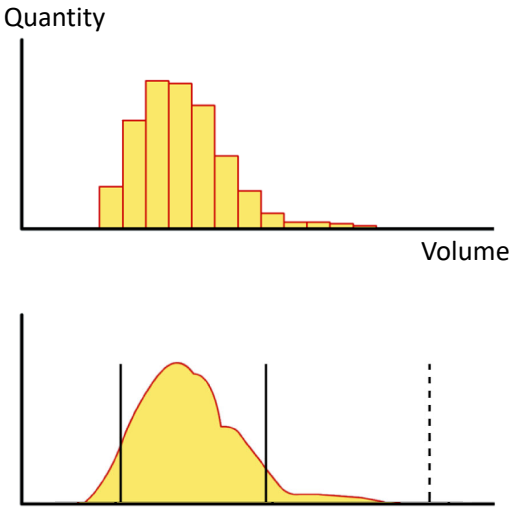
A digital analogical conversion is carried out. Then the data is integrated and the RBC distribution curve is plotted.



Platelets histogram description

The **PLT histogram** corresponds to the distribution curves on 256 channels from 2 fL to a mobile threshold. This threshold moves according to the microcyte population present in the analysis area.

Then the data is integrated and the PLT distribution curve is plotted.



2.5. Measurements

2.5.1. Hematocrit Measurement

All the RBC pulses are grouped into various sizes. Each group pulse height is then averaged. All the pulse height averages are then averaged one final time for a mean average of all the RBC pulse heights. This function is a numeric integration of the MCV.

The HCT results are given as a percentage of this integration.

2.5.2. Mean Platelet Volume Measurement

The MPV (Mean Platelet Volume) is directly derived from the analysis of the platelet distribution curve.

2.6. Calculations

2.6.1. Red Blood Cells Distribution Parameters Calculation

The Red Blood Cells distribution width parameters (RDW-CV and RDW-SD) are indexes of the distribution of red blood cells volume. They allow the quantification of anisocytosis and contribute to the characterization of erythrocyte morphological abnormalities.

The RDW-CV (%) expresses the Coefficient Variation of red cells volume distribution calculated from the Standard Deviation and Mean Corpuscular Volume.

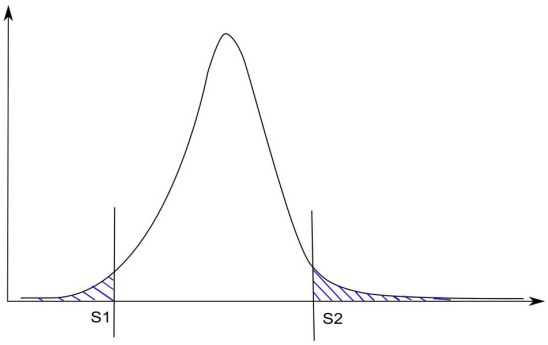
The RDW-SD (fL) is derived from the Standard Deviation of red cells volume from the red blood cell distribution curve and is independent of Mean Corpuscular Volume.

2.6.2. MCV, MCH, MCHC Calculation

- The MCV is calculated directly from the entire RBC histogram.
- The MCH (Mean Cell Hemoglobin) is calculated from the HGB value and the RBC count. The mean hemoglobin weight in each RBC is given by the formula:
  MCH (pg) = HGB / RBC X 10
- The MCHC (Mean Corpuscular Hemoglobin Concentration) is calculated according to the HGB and HCT values. The mean hemoglobin concentration in the total volume of RBC is given by the formula:
  MCHC (g/dL) = HGB / HCT X 100

2.6.3. MIC and MAC Calculation

MIC and MAC are calculated from the RBC histogram. Their value is expressed in fL. They are profile dependent.
The **S1** point is the value minimum defined in the software. Below this value we consider there are MIC.
The **S2** point is the value maximum defined in the software. Above this value we consider there are MAC.



- **MIC Calculation**
  Microcytic Red Blood Cells % (per 100 RBC)
- **MAC Calculation**
  Macrocytic Red Blood Cells % (per 100 RBC)

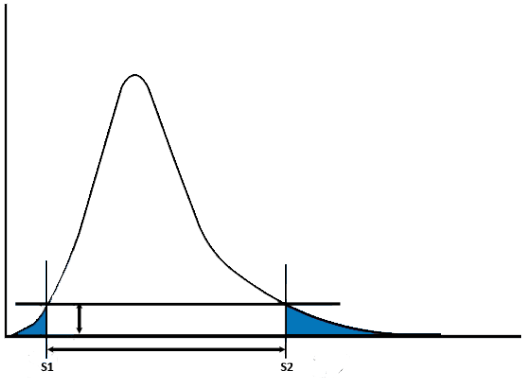
2.6.4. Plateletcrit Calculation

Plateletcrit (or thrombocrit) is calculated according to the formula:

PCT = PLT X MPV / 10^6

2.6.5. Platelet Distribution Width Calculation

PDW (Platelet Distribution Width) is calculated from the PLT histogram.
The Y axis corresponds to the number of cells and the X axis corresponds to the volume of cells.
The PDW is derived from the standard deviation, calculated between the **S1** and **S2** thresholds defined at 23% of the maximum height of the distribution curve.
The PDW is expressed in fL or μm^3.



2.6.6. Large Platelets Parameters

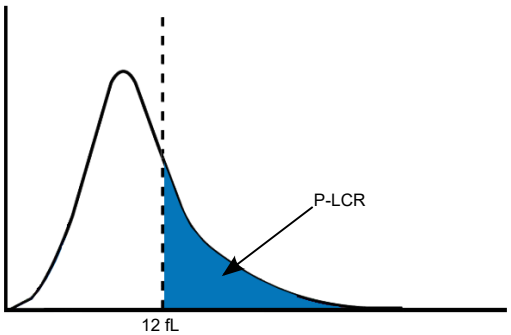
The Large Platelets parameters (P-LCC and P-LCR) allow the quantification of large-sized platelets. An increase of these parameters may indicate the presence of platelets aggregates, micro-erythrocytes and giant platelets.

2.6.6.1. Platelets - Large Cell Count

The P-LCC expresses the count of large platelets that have a volume superior to 12 fL.

2.6.6.2. Platelets - Large Cell Ratio Calculation

The P-LCR expresses the percentage of large platelets that have a volume superior to 12 fL.



The MPV, the PDW and the P-LCR can contribute to the characterization of immune thrombopenia and inherited giant platelets disorder.

Glossary

Accuracy
Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value.

Analysis (Field of)
Interval of concentrations (or other quantities) of an analyte for which the technique is applicable without modification. Its evaluation requires the establishment of linearity limits and (possibly) of the detection limit of the technique. Synonym: “Field of measurement, range of measurement”.

Analyte
Component, substance, material to be measured in a possibly complex environment.

Analytical sensitivity
In compliance with the Common Technical Specifications (CTS), the "analytical sensitivity" refers to the limit of detection, i.e. the smallest quantity of target marker that can be detected with precision.

Analytical specificity
The capacity of the method to determine only the target marker.

Background count
Measure of the amount of electrical or particle interference.

Bias (ISO 3534-1)
Difference between the mathematical prediction of the results of the analysis and the accepted reference value.

Calibration
Set of operations to establish, under specified conditions, the relationship between the values of the quantity indicated by a measuring instrument or a measurement system or the values represented by a materialized measurement or by a reference material, and the corresponding values of the quantity given by standards.

Calibration factors
Multiplication factors that the system uses to fine-tune instrument accuracy.

Calibrator
A (reference) material (e.g., solution, suspension) or device of known quantitative/qualitative characteristics (e.g., concentration, activity, intensity, reactivity) used to calibrate, graduate, or adjust a measurement procedure or to compare the response obtained with the response of a test specimen/sample (CLSI H26-A2).

Carry-over
Amount of blood cells remaining in diluent following the cycling of a blood sample (in percent).

Certified reference material
Reference material, accompanied by a certificate, of which one (or several) value(s) of the property(ies) is (are) certified by a procedure that establishes its association with an exact undertaking of the unit in which the property values are expressed and for which each certified value is accompanied by an uncertainty with a known level of confidence.

Chemical specificity, specificity

Property of an analytical method to selectively determine the concentration of the component(s) that it is designed to measure.

Coefficient of variation (CV) ISO 3534-1

For a non-negative character, ratio of the standard deviation to the mean.

Contaminant (Effect)

Undesirable effect, resulting from contamination. Most commonly, this is the effect exerted by a serum on that which follows or precedes it. It may also arise from contaminating effects between reagents.

Control

Substance used for monitoring the performance of an analytical process or instrument.

Correction

Value that is algebraically added to the raw result of a measurement to compensate for a systematic error.

- the correction is equal to the opposite of the estimated systematic error
- since the systematic error cannot be precisely known, the compensation cannot be complete.

Correlation coefficient

Quotient of the covariance of two characteristics by the product of their standard-deviations. It expresses the possible relationship between two variables that are known to be independent. Its value must only be tested in comparison with zero according to a chosen risk. It is usually of no interest in technical comparisons.

Default settings

Original factory settings.

Detection limit (CLSI H26-A2)

The smallest quantity of an analyte to be examined in a sample that can be detected and considered as being different from the value of the blank (with a given probability), but not necessarily quantified. Two risks need to be taken into account:

- the risk of considering the substance present in the sample when in fact its quantity is nil.
- the risk of considering a substance absent when in fact its quantity is not nil.

Deviation

Value minus its reference value.

Drift

Slow variation over time of a metrological characteristic of a measuring instrument.

Error

Result of a measurement minus a true value of the measurand (Bias).

Exactitude (Precision)

Closeness of the agreement between the result of a measurement and the true value of the measurand.

Femtoliter (fL)

One quadrillionth (10^{-15}) of a liter.

Linearity (CLSI H26-A2)
Capacity of a method of analysis, within a certain interval, to provide a value of information or results proportional to the quantity of analyte to be assayed in the laboratory sample. This proportionality is expressed using a previously defined mathematical expression. The limits of linearity are the experimental limits of quantities between which a linear standard model can be applied with a known level of confidence (generally taken as being equal to 1%).

LIS
Laboratory Information System

Lot Number
Manufacturer code that identifies a batch of product (either reagents, controls or calibrators).

Matrix
Environment that is used to display the differential of the WBC population.

Mean, m
The sum of observations divided by their number. Unless otherwise indicated, the term “mean” designates the arithmetic value.

Measurand
Specific quantity subjected to measurement.

Measurement
A series of operations whose aim is to determine a value of a quantity.

Noise
Corresponds to random variations of the measurement signal for a given level. It is measured by the standard deviation of a series of at least 30 measurements of the signal, at the level in question.

Operating range
Range of results over which the instrument displays, prints and transmits data.

Parameter
Component of blood that the instrument measures and reports.

Performance criteria
Parameters characterizing the analytical procedure (linearity, repeatability, trueness, etc.)

Platelet concentrate
Labile blood product, composed of platelets, produced by blood bank centers and intended for transfusion.

PRP (Platelet Rich Plasma)
Cellular suspension in the plasma, high platelet concentration obtained by sedimentation from a whole blood sample.

Quality control (QC)
Comprehensive set of procedures that a laboratory establishes to ensure that the instrument is working accurately and precisely.

Quantitation limit (CLSI H26-A2)
The smallest quantity of an analyte to be analyzed in a sample that can be determined quantitatively under the experimental conditions described in the method with a defined variability (determined coefficient of variation).

Reference material (Calibrator, reference values)
Material or substance of which one (or several) values of the properties are sufficiently homogeneous and well-defined to enable it to be used to calibrate a piece of equipment, evaluate a measuring method, or attribute values to materials.

Reference values
Results obtained for a given component in a reference population whose individuals are exempt from disease or treatments that may alter their values. The reference values may vary, notably according to the geographic origin, sex, and age of individuals. They are usually expressed as a function of lower and upper limits that have been determined via statistical studies. They may be established by the biologist, according to the analytical techniques used, or possibly verified when data from scientific publications is used. The expression "reference value" is preferable to "usual value" or "normal value".

Reliability (Precision)
Aptitude of a measuring instrument to give very similar indications during the repeated application of the same measurand under the same measurement conditions.

Repeatability
Closeness of the agreement between the results of successive measurements of the same measurand, measurements undertaken entirely in the same conditions of measurement.

Reproducibilty
Closeness of the agreement between the results of measurements of the same measurand, measurements undertaken under a variety of measurement conditions.

Result of a measurement
Value attributed to a measurand, obtained by measurement.

Shutdown cycle
Cleans the instrument’s fluidic lines and apertures to help prevent residue build-up.

Specimen
To avoid any confusion with the term sample (in the following context: group of individuals from a population), it is preferable to use the term specimen to designate a biological sample (blood specimen, urine specimen, etc.).

Standard
Materialized measurement, measuring apparatus, reference material or measurement system designed to define, undertake, store, or reproduce a unit or one or several values of a quantity to serve as a reference.

Standard Deviation (SD)
Measurement of variation within a group samples or within a population.

Standard uncertainty
Uncertainty of the result of a measurement expressed as a standard deviation.

Startup cycle
Ensures that the instrument is ready to run; includes performing a background test.

Trueness
Aptitude of a measuring instrument to give results that are exempt from systematic error.

Uncertainty
Parameter associated with the result of a measurand that characterizes the dispersion of values that could reasonably by attributed to the measurand.

Validation (analytical and biological)

This is the set of procedures used to ensure that a technique has the required reliability to meet the quality control requirements in the state of the art. The validation generally comprises two stages: a technical validation and a biological validation. The first consists, following a series of assays, of verifying with appropriate controls that the principal errors have been maintained within acceptable limits. The second involves ensuring the coherence of the result in its clinical context, by comparing it with any previous results and with the results of other analyses requested for exploring the same function.

Validation (validation of methods)

Verification process that involves comparing the values of performance criteria, as determined during the characterization study or experimentation phase (test phase) of the analytical method, to those initially expected or assigned (acceptable limits, objectives to be attained), and then to declare whether the method of analysis is valid or not (see definition of the standard EN ISO/CEI 17025, §5.4.5.1).

Verification (EN ISO 10012)

Confirmation by examination and establishment of proofs that the specified requirements have been met.

Whole blood

Non-diluted blood (blood and anticoagulant only).