

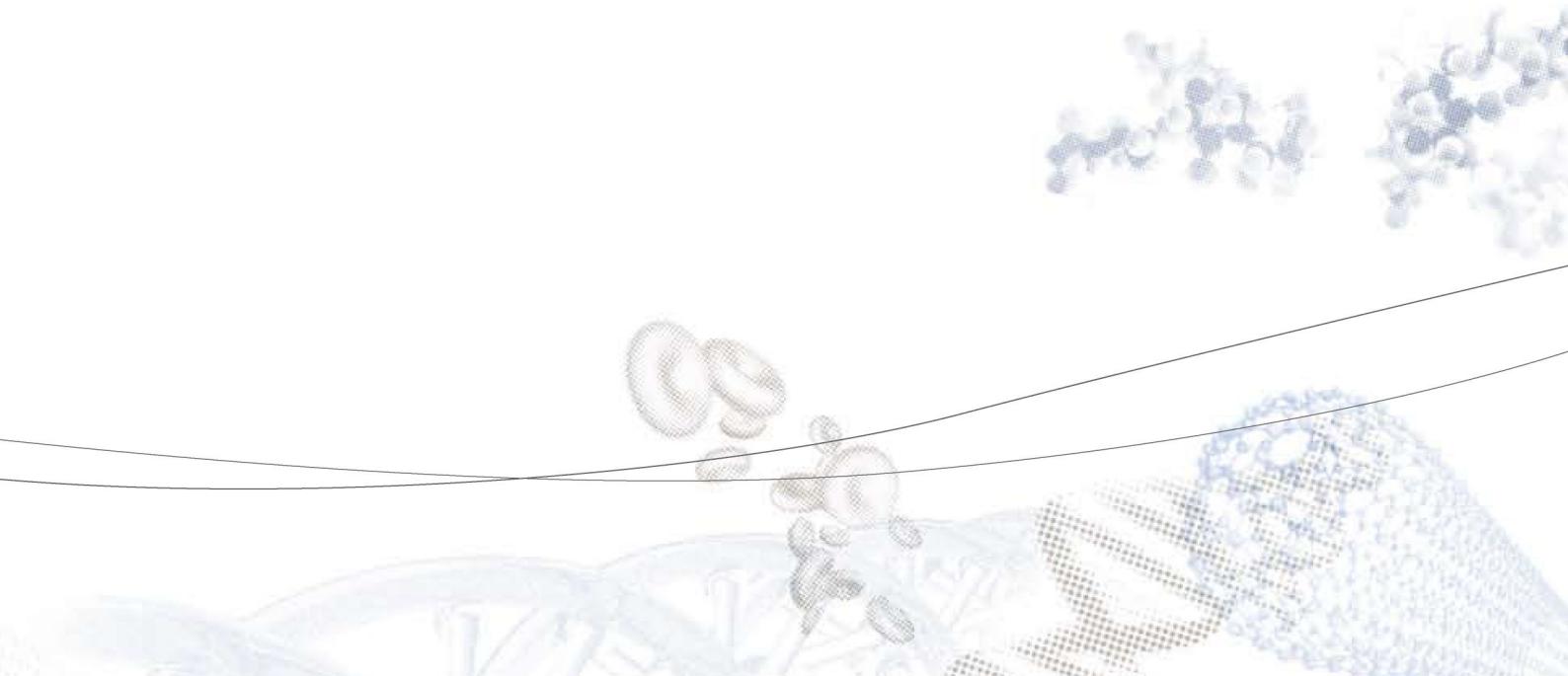


Hematology Analyzer

## Yumizen H500 OT: User Manual

Ref: 1300011897

Int. Ref. Doc.: RAB296AEN





## **Yumizen H500 OT: User Manual**

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**HORIBA ABX SAS**

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# Foreword

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# 1. Revisions

Reference	Internal Reference	Software Version	Document Date Issued
1300011897	RAB296AEN	1.0.x	April 2015

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 USB flash drive instructions**

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.

## 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](http://www.horiba-abx.com/documentation).

### 2.2. Notice of Liability

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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.

### 2.3. Trademarks

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Linux is a registered trademark of Linus Torvalds.

Other product names mentioned within this publication may be trademarks or registered trademarks of their respective owners.

### 2.4. Graphics

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

## 2.5. Document Symbols

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



Emphasizes information that must be followed to avoid hazard to either the operator or the environment, or both.

---



Emphasizes information that must be followed to avoid possible damage to the instrument or erroneous test results.

---



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.

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## 2.6. Typographical Conventions

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

Access: **Main screen > Quality Assurance > XB**

Indicates, from the main screen, the sequence of menus you have to go through to begin the procedure.

Go in **Main screen > Service > Cleaning**.

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 **XB Targets** window is displayed.

Used for windows titles, dialog boxes titles or tabs titles.

More information on [www.horiba-abx.com/documentation](http://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.

## 2.7. Copyright ® 2015 by HORIBA ABX SAS

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# Introduction

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# 1. Warning and Precautions

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

- 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](http://www.horiba-abx.com/documentation).



- The reagents and accessories stipulated by HORIBA Medical have been validated in accordance with the European Directive for *in vitro* medical devices (98/79/EC).
- The use of any other reagents and accessories 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.

## 1.1. Limited Warranty

The duration of warranty is stipulated in the Sales conditions associated with the purchase of this instrument. To validate the warranty, ensure the following is adhered to:

- The system is operated under the instructions of this manual.
- Only software or hardware specified by HORIBA Medical is installed on the instrument. This software must be the original copyright version.
- Services must be done by recommendation from HORIBA Medical, provided by an authorized technician using only approved spare parts and at least once per year or more, depending on the number of samples.
- The electrical supply of the laboratory adheres to national or international regulations.
- The system is operated according to HORIBA Medical recommendations.
- Specimens are collected and stored in normal conditions.
- Reagents used are those specified in this user manual.
- Proper tools are used when maintenance or troubleshooting operations are performed.



If this instrument has been supplied to you by anyone other than HORIBA Medical or an authorized representative, HORIBA Medical cannot guarantee this product in terms of specification, latest revision and latest documentation. Further information may be obtained from your authorized representative.

## 1.2. Safety Precautions

### 1.2.1. Electronic and Moving Parts

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

- Electrical Power supply
- 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.

On Yumizen H500 OT, the label is located near the sampling needle.



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.154](#)

## 1.3. Graphics and Symbols



Switch off position



Switch on position



Alternating current



Manufacturer



In Vitro Diagnostic medical device



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



Caution, consult accompanying documents



Biological hazard



Reagent



Up



Fragile, handle with care



Keep dry



Do not stack



Temperature limitation



Batch code



Reference Number



Use by



Consult Instruction for Use



Calibrator



Control



Content



Use no hooks



This product should be disposed of and recycled at the end of the useful life in accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and/or European Directive 2006/66/EC on batteries and accumulators.



Notice of environment-friendly use period



Packaging recycling mark



Ground



Electrostatic sensitive device



Pinch point! Be careful not to trap your hands/fingers.



Green Dot: participation in packaging recycling in Germany



RESY: cardboard recycling symbol in Germany



ERP (Enterprise Resource Planning)  
Number



Reagents identification code

## 2. Operational Conditions

### 2.1. Environment

---

The operation of the Yumizen H500 OT should be restricted to indoor location use only.

The instrument is operational at an altitude of maximum 3000 m (9840 ft).

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

---



Keep in mind that the instrument weighs approximately 23 kg (51 lbs).  
To move the instrument, two persons are required.

- Place your instrument on a clean and leveled table or workbench.
- Avoid exposure to sunlight.
- Place your instrument where it is not exposed to water or vapor.
- Place your instrument where it is not exposed to dust.
- Avoid direct exposure to air conditioner.
- Place your instrument where it is free from vibration or shock.
- 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.



The Power switch and Power supply connection should always be accessible. When positioning the system for operational use, leave the required amount of space for easy access to these items.

## 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.

The laboratory must establish a procedure to monitor a Reference Temperature in the laboratory. The system must be calibrated at this Reference Temperature. The range of acceptable Reference Temperatures is +20°C (+68°F) to +26°C (+79°F). The system is fully operational in the range of the Reference Temperature used for calibration +/-4°C (+/-7°F).

**Humidity Conditions:** Relative humidity of 30% - 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.

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.

## 2.6. Main Power Supply

---



It is recommended to install the system on UPS (Uninterruptible Power Supply).  
The UPS minimal power must be 165 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 delivered with the instrument.

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 Accessories and Consumables Disposal

Disposable used accessories 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 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and/or European Directive 2006/66/EC on batteries and accumulators.



If any doubt, please contact your local representative.

## 2.8. Storage Conditions and Transportation

**Instrument storage and transportation temperatures:** from -20°C (0°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.



Keep in mind that the instrument weighs approximately 23 kg (51 lbs).  
To move the instrument, two persons are required.

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

## 2.9. Installation

---

A representative will install your instrument and software.

### Package content:

- Yumizen H500 OT
- Power supply cable
- Safety Information booklet
- Installation kit
- Stylus
- USB External Barcode Reader (optional)
- Waste bag
- USB flash drive: user manual, daily guide, accreditation file, online help, reagents controls and calibrators leaflets and material safety data sheets.
- Diluent container opening tool
- Protective cover
- QC manufacturing certificate



Only HORIBA Medical approved accessories should be used with the Yumizen H500 OT.

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## 2.10. Package

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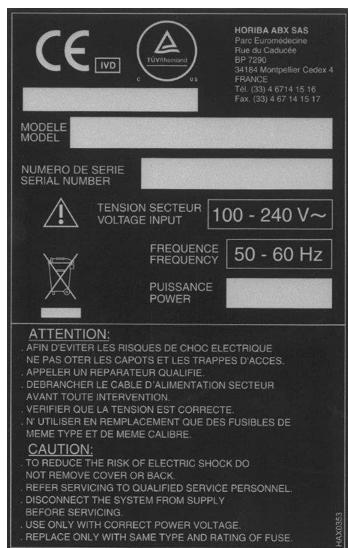
Factory package of the analyzer Yumizen H500 OT and its implements consists of firm corrugated cardboard, polyethylene foil and inner foam plastic framework. Package protects analyzer and its implements from adverse factors of outside environment.

## 3. Labels and Connections

### 3.1. Serial Number Label

---

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



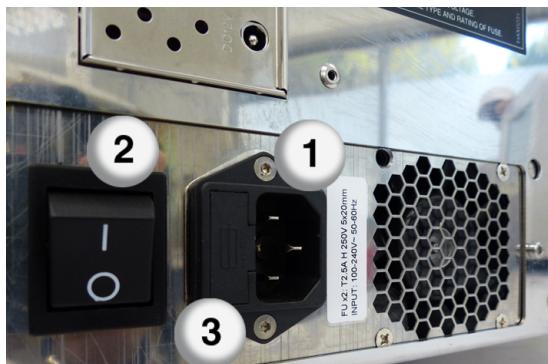
### 3.2. Power Supply Connection

---



The Power switch and Power supply connection should always be accessible. When positioning the system for operational use, leave the required amount of space for easy access to these items.

This connector is located at the back of the instrument.



- 1 = Power supply connector  
2 = ON/OFF switch  
3 = Fuses location

### 3.3. 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.

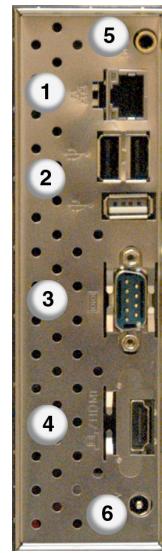
### 3.4. Peripherals Connections

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All peripheral devices should comply with relevant standards.

- 1 = Ethernet connection
- 2 = USB connections (3 connectors at the back + 1 at the front)
- 3 = RS232 (for LIS connection)
- 4 = Not used HDMI connector
- 5 = Not used optical SPDIF connector
- 6 = Not used DC12V power connector



### 3.5. Warnings and Biological Hazards Labels

---

Definition	Location	Symbol
Warning! Biological hazard	Near the waste output Near the sampling needle	
Caution, consult accompanying documents	Back of the instrument Sampling area	

## 4. Printer

Use the following printers supplied or approved by HORIBA Medical:

- M2400: USB connection only
- EPSON AL M300: USB connection only
- EPSON 4015: USB and Ethernet connections only and A4 printouts only
- HP Office Jet Pro 6230: USB and Ethernet connections only
- HP Office Jet Pro 8100: USB and Ethernet connections only
- EPSON WorkForce WF-2630: USB connection only



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

---



# Specifications

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# 1. Technical Specifications

## 1.1. Instrument Model

---

The Yumizen H500 OT is an "Open Tube" (OT) instrument. It is necessary to remove the cap from the collection tube before analyzing any sample.

Reagents are available in bottles versions and diluent in container version.

## 1.2. Intended Use

---

The Yumizen H500 OT is a fully automated hematology analyzer for *in-vitro* diagnostic use in clinical laboratories. It enumerates and identifies CBC and DIFF parameters in K2-EDTA and K3-EDTA anticoagulated whole blood samples.

## 1.3. Parameters

---

CBC Parameters	Definition
WBC	White Blood Cells
RBC	Red Blood Cells
HGB	Hemoglobin Concentration
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW-CV	Red Distribution Width
RDW-SD *	Red Distribution Width Standard Deviation
PLT	Platelets
PDW *	Platelets Distribution Width
PCT *	Plateletcrit
P-LCC *	Platelets - Large Cell Count
P-LCR *	Platelets - Large Cell Ratio
MPV	Mean Platelet Volume

DIFF Parameters	Definition
LYM#	Lymphocytes absolute value
LYM%	Lymphocytes percentage
MON#	Monocytes absolute value
MON%	Monocytes percentage
NEU#	Neutrophils absolute value
NEU%	Neutrophils percentage
EOS#	Eosinophils absolute value
EOS%	Eosinophils percentage
BAS#	Basophils absolute value
BAS%	Basophils percentage
LIC# *	Large Immature Cells absolute value
LIC% *	Large Immature Cells percentage



\* PDW, PCT, P-LCC, P-LCR, RDW-SD, LIC# and LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

## 1.4. Throughput Analyses

The throughput of Yumizen H500 OT is 50 samples per hour.

## 1.5. Computer Characteristics

- Color LCD touch screen: 12.1 in.
- Operating System: Linux™
- RS232, Ethernet, USB connections
- Capacity: 10000 results

## 1.6. Tube Identification

Tube identification can be done by using either:

- an external keyboard (optional),
- the virtual keyboard,
- an external barcode reader (optional).

## 1.7. Measurements and Computation

---

Counted parameters (measurement of impedance variation):

- RBC
- PLT
- WBC

Measured parameters:

- HGB (spectrophotometry)
- HCT (analogical integration)

Calculated parameters:

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

WBC differential (volume and absorbance measurement by the flow cytometer):

- LYM
- MON
- NEU
- EOS
- BAS
- LIC

## 1.8. Units

---

CBC Parameters	SI (international)	Conventional	mmol/L	Japan
<b>WBC</b>	$10^9/L$	$10^3/\mu L$	$10^9/L$	$10^2/\mu L$
<b>RBC</b>	$10^{12}/L$	$10^6/\mu L$	$10^{12}/L$	$10^4/\mu L$
<b>HGB</b>	g/L	g/dL	mmol/L	g/dL
<b>HCT</b>	L/L	%	L/L	%
<b>MCV</b>	fL	$\mu m^3$	fL	$\mu m^3$
<b>MCH</b>	pg	pg	fmol	pg
<b>MCHC</b>	g/L	g/dL	mmol/L	g/dL
<b>RDW-CV</b>	%	%	%	%
<b>RDW-SD *</b>	fL	$\mu m^3$	fL	$\mu m^3$
<b>PLT</b>	$10^9/L$	$10^3/\mu L$	$10^9/L$	$10^4/\mu L$
<b>PDW *</b>	fL	$\mu m^3$	fL	$\mu m^3$
<b>PCT *</b>	L/L	%	L/L	%

CBC Parameters	SI (international)	Conventional	mmol/L	Japan
P-LCC *	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>4</sup> /µL
P-LCR *	%	%	%	%
MPV	fL	µm <sup>3</sup>	fL	µm <sup>3</sup>
DIFF Parameters	SI (international)	Conventional	mmol/L	Japan
LYM#	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>2</sup> /µL
LYM%	%	%	%	%
MON#	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>2</sup> /µL
MON%	%	%	%	%
NEU#	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>2</sup> /µL
NEU%	%	%	%	%
EOS#	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>2</sup> /µL
EOS%	%	%	%	%
BAS#	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>2</sup> /µL
BAS%	%	%	%	%
LIC# *	10 <sup>9</sup> /L	10 <sup>3</sup> /µL	10 <sup>9</sup> /L	10 <sup>2</sup> /µL
LIC% *	%	%	%	%



\* PDW, PCT, P-LCC, P-LCR, RDW-SD, LIC# and LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

**Related information:**

- [To Select the Unit System, p.121](#)

## 2. Physical Specifications

### 2.1. Power Requirements

---

- Power supply: from 100 V to 240 V (+/- 10%), 50 Hz to 60 Hz
- Maximum power consumption: 165 VA
- Maximum heat output: 348 kJ/h (330 BTU/h)

**Fuses characteristics:**

Slow-blow internal fuses having the following characteristics: T2.5A H 250 V

### 2.2. Dimension and Weight

---

- Instrument dimensions: 39.7 x 47.7 x 48.3 cm (Width x Depth x Height)
- Instrument weight: 23 kg (51 lbs)

### 2.3. Sound Level

---

The maximum sound level is 53 dB (A).

### 3. Summary of Performance Data



The Documentation USB flash drive includes the latest version of the "Performance and Reference: Tools for Accreditation" document, which details necessary references and requirements relating to quality management, technical requirements and performance of the analyzer including obtained data results.

#### 3.1. Precision: Reproducibility Claims

##### Expected Precision (Reproducibility) on control samples

Parameter	Low level (%CV)	Normal level (%CV)	High level (%CV)
WBC	5	4	3
RBC	3	2.5	2.5
HGB	2.5	2	1.8
HCT	5	4	3
MCV	3	2.5	2
MCH	2.5	2.5	2.5
MCHC	3	3	3
RDW-CV	5	5	5
PLT	15	10	7
MPV	6	5	5
LYM%	8	8	8
MON%	40	25	25
NEU%	8	6	4
EOS%	30	25	15
BAS%	40	40	40

#### 3.2. Precision: Repeatability Claims

Based on ten consecutive runs without alarm of the same fresh whole blood sample:

Parameter	%CV	Nominal Values
WBC	< 3	4 - 100 X 10 <sup>9</sup> /L
RBC	< 2	3.6 - 6.2 X 10 <sup>12</sup> /L
HGB	< 1.5	120 - 180 g/L

Parameter	%CV	Nominal Values
<b>HCT</b>	< 2	0.36 - 0.54 L/L
<b>MCV</b>	< 1.5	80 - 100 fL
<b>RDW-CV</b>	< 4	10 - 16%
<b>RDW-SD</b>	< 4	37 - 49 fL
<b>PLT</b>	< 5	150 - 500 10 <sup>9</sup> /L
<b>P-LCR</b>	< 15	15 - 35% and PLT > 50 000
<b>LYM%</b>	< 5	25 - 50%
<b>MON%</b>	< 15	5 - 10%
<b>NEU%</b>	< 3.5	45 - 80%
<b>EOS%</b>	< 20	2 - 5%
<b>BAS%</b>	< 40	1 - 2%

### 3.3. Linearity Limits

---

**Linearity limits:** maximum and minimum values within which the instrument returns no dilution alarm.

**Visible range:** range values given by the instrument. These values (above linearity limits) are given as an indication. They are associated to a "D" alarm. This visible 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's instructions.

**Human blood:** linearity was also performed on human blood, using a minimum of five dilution points. The results of this study are as follows:

Parameter	Linearity Limits	Visible Range	Error Limit <sup>1</sup>
WBC (10 <sup>9</sup> /L)	0 - 300	300 - 600	+/- 0.3 or +/- 7.5%
RBC (10 <sup>12</sup> /L)	0 - 8	8 - 18	+/- 0.07 or +/- 3%
HGB (g/L)	0 - 240	240 - 300	+/- 0.3 or +/- 3%
HCT (L/L)	0 - 67	67 - 80	+/- 2 or +/- 3%
PLT (10 <sup>9</sup> /L) for HGB $\geq 15 \text{ g/L}$	0 - 2500	2500 - 4000	+/- 10 or +/- 12.5%
PLT (10 <sup>9</sup> /L) for HGB $< 15 \text{ g/L}$	0 - 4000	4000 - 5000	+/- 10 or +/- 12.5%

<sup>1</sup>: Whichever is greater

### 3.4. Carry-over

---

The following table shows carry-over for WBC, RBC, HGB and PLT. Carry-over is determined by running whole blood specimens with high target values of WBC, RBC, HGB and PLT. Each specimen is run in triplicate followed by three aspirations of whole blood specimens with low target values.

	WBC ( $10^9/L$ )	RBC ( $10^{12}/L$ )	HGB (g/L)	PLT ( $10^9/L$ )
<b>Mean low level</b>	1.24	1.11	37	24
<b>Mean high level</b>	97.3	8.26	249	1495
<b>Maximum actual carry-over (%)</b>	0.25%	0.54%	0.50%	0.37%
<b>Claimed carry-over (%)</b>	< 0.5%	< 1%	< 1%	< 0.5%

### 3.5. Reference Values

---

Parameter	Male	Female
WBC ( $10^9/L$ )	4.05 - 11	3.78 - 11.42
RBC ( $10^{12}/L$ )	4.28 - 5.79	3.93 - 5.19
HGB (g/dL)	13.4 - 16.7	11.5 - 15.1
HCT (%)	39.2 - 48.6	34.4 - 44.6
MCV ( $\mu L$ )	78 - 97	74.7 - 95.6
MCH (pg)	26.3 - 32.8	24.4 - 32.6
MCHC (g/dL)	32.4 - 36.3	31.9 - 35.8
RDW-CV (%)	12.3 - 14.3	12.4 - 15.1
RDW-SD ( $\mu L$ )	37.8 - 46.1	38.4 - 47.7
PLT ( $10^9/L$ )	161 - 398	185 - 445
MPV ( $\mu L$ )	7.4 - 10.8	7.5 - 10.9
LYM (%)	12.2 - 47.1	18.2 - 47.4
LYM (#)	1.24 - 3.91	1.24 - 3.97
MON (%)	4.4 - 12.3	4.3 - 11
MON (#)	0.23 - 0.77	0.19 - 0.71
NEU (%)	40.3 - 74.8	42.5 - 73.2
NEU (#)	1.78 - 6.95	1.69 - 7.5
EOS (%)	0 - 4.4	0 - 3
EOS (#)	0.05 - 0.63	0.04 - 0.55
BAS (%)	0 - 0.7	0 - 0.7
BAS (#)	0 - 0.1	0 - 0.09

Our reference values are based on the following sources:

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

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



Expected values will vary according to sample population and/or geographical location. It is highly recommended that each laboratory establishes its own normal ranges based on the local population.

### 3.6. Accuracy

The data show a good correlation between the results obtained on Yumizen H500 OT and the reference system:

Parameters	R (comparison of means)
WBC	> 0.97
LYM%	> 0.97
MON%	> 0.89
NEU%	> 0.97
EOS%	> 0.95
BAS%	> 0.2
RBC	> 0.97
HGB	> 0.97
HCT	> 0.97
MCV	> 0.84
RDW-CV	> 0.45
RDW-SD	> 0.70
PLT	> 0.97
MPV	> 0.84

## 4. Sample Collection and Mixing



All blood samples should be collected using proper technique.



Use established good laboratory working practice when collecting specimens. For additional information on collecting venous and capillary blood samples, refer to CLSI document H03-A6 and CLSI document H04-A6.



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, but arterial blood may also be used in extreme cases. 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.

### 4.1. Recommended Anticoagulant

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 filling 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

## 4.2. Blood 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 at low temperature

For samples stored at refrigerated temperature (between +2°C (+36°F) and +8°C (+46°F)), the post-draw stability of results is 48 hours for CBC parameters and 24 hours for DIFF parameters.

### Sample stability at room temperature

Studies are currently in progress and results will be reported in the next user manual update.

## 4.3. Microsampling

---



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.

## 4.4. Specimen Volume

---

Quantity of whole blood aspirated:

- CBC mode: 20 µL
- DIFF mode: 20 µL

**Related information:**  
■ [Sampling Principles, p.185](#)

## 4.5. Mixing

---

Blood samples must be gently and thoroughly mixed right before sampling. This ensures a homogeneous mixture for measurement.

## 5. Reagent 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**

**Parc Euromédecine - Rue du Caducée**

**B.P. 7290**

**34184 MONTPELLIER Cedex 4 - FRANCE**

**Phone: +33 (0)4 67 14 15 16**

**Fax: +33 (0)4 67 14 15 17**

Refer to the reagent notices and material safety data sheets for Yumizen H500 OT available online at [www.horiba-abx.com/documentation](http://www.horiba-abx.com/documentation).



The reagents specified for this instrument have been approved in accordance with the European Directive 98/79/EC (Annex III) for *in vitro* medical devices.



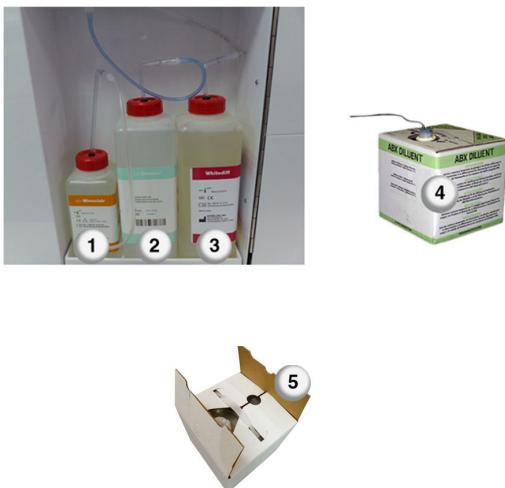
HORIBA Medical manufactures and markets reagents, calibrators and control bloods specially designed for use with this analyzer. The use of products not recommended may give erroneous results or cause instrument operation problems. For all information regarding the recommended products, please contact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

### 5.1. Reagents Location



The diluent container is installed at the same level as the instrument (on the bench).

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



## 5.2. Reagents Description

HORIBA Medical recommends that you use the following reagents on your Yumizen H500 OT:

- ABX Diluent (10 L or 20 L): for RBC/PLT dilution, sleeving and rinsing.
- ABX Cleaner (1 L, integrated): for cleaning.
- Whitediff 1L (1 L, integrated): for HGB measurement and WBC differentiation.
- ABX Minoclair (0.5 L, integrated - Optional): for concentrated cleaning procedure.



- 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.

## 5.3. Reagents Consumption

Reagent consumption is given in mL per cycle.

Cycles	ABX Diluent	Whitediff 1L	ABX Cleaner	ABX Minoclair
Startup	64.8	4.5	X	X
Analysis	21.7	1.6	X	X

Cycles	ABX Diluent	Whitediff 1L	ABX Cleaner	ABX Minoclair
Mini auto rinse *	8.2	1.6	X	X
Autoclean	23.1	1.6	X	X
Concentrated cleaning	25.9	0.6	4.2	31.9
Hydraulic initialization	26	X	X	X
Shutdown	9	X	31.1	X

\* The mini auto rinse cycle is automatically performed before an analysis if the instrument stayed inactive during at least two hours before this analysis.

## 5.4. Reagent Notices and Safety Data Sheets

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The 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](http://www.horiba-abx.com/documentation).

## 5.5. Waste Handling Precautions

---

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc.). Follow your local and/or national guidelines for biohazard waste disposal.



- 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 tubes and the liquid waste tube under any circumstance.

- 
- 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.

## 6. Limitations



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. At all times, results should be validated and communicated only once all information relating to the patient have been assessed and taken into account.

### 6.1. 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 H500 OT.



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

### 6.2. 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.

### 6.3. Known Interfering Substances

#### 6.3.1. Interferences on White Blood Cells (WBC)

**Unlysed red blood cells:** in certain cases of membrane resistance, partial lysis of red blood cells may be observed. These unlysed red blood cells may cause an erroneously high white blood cell count.

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

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

**Platelet agglutination:** the accumulation of platelets may cause an elevated white blood cell count. Platelet agglutination triggers the LYM Interference and the Background noise alarms.

**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 leucocyte count can be underestimated in patients with chronic lymphoblastic leukemia, due to the presence of abnormally small lymphocytes which may not be counted by the analyzer.

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

**Cryoglobulins:** the increased levels of cryoglobulins that may be associated with various conditions (myeloma, carcinoma, leukemia, macroglobulinemia, 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).

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

**Erythroblasts:** high concentration of erythroblasts may increase the leukocyte count. Erythroblasts trigger the LYM Interference and the Background noise alarms.

### 6.3.2. Interferences on Red Blood Cells (RBC)

**Hyperleucocytosis:** The red blood cell dilution contains all of the elements found in the blood (erythrocytes, leukocytes, and platelets). During the erythrocyte count, the platelets are not counted as they are smaller than the defined minimum threshold. In very rare cases of an extremely high leukocyte count, the erythrocyte count may be increased. It should be corrected, especially if it is very low in comparison with the leukocyte count.

**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).

### 6.3.3. 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.

#### 6.3.4. 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.

#### 6.3.5. 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.

#### 6.3.6. Interferences on the Mean Corpuscular Hemoglobin (MCH)

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

#### 6.3.7. Interferences on the Mean Corpuscular Hemoglobin Concentration (MCHC)

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

#### 6.3.8. 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.

#### 6.3.9. Interferences on Platelets (PLT)

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

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

**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.

**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.

**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.

**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 thrombocytopenia (this agglutination can also occur in the presence of citrate for less than 10% of the cases). The pseudo-thrombocytopenia due to EDTA can count up to 15% of the isolated thrombocytopenia and constitute 75-90% of the causes of pseudo-thrombocytopenia. 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 LL, and LL1 alarms.

**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.

### 6.3.10. 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 (schistocytes)** 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.

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



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

### 6.3.11. Interferences on Lymphocytes (LYM)

The presence of platelet agglutination, erythroblasts 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.

### 6.3.12. 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.

### 6.3.13. 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.

### 6.3.14. 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.

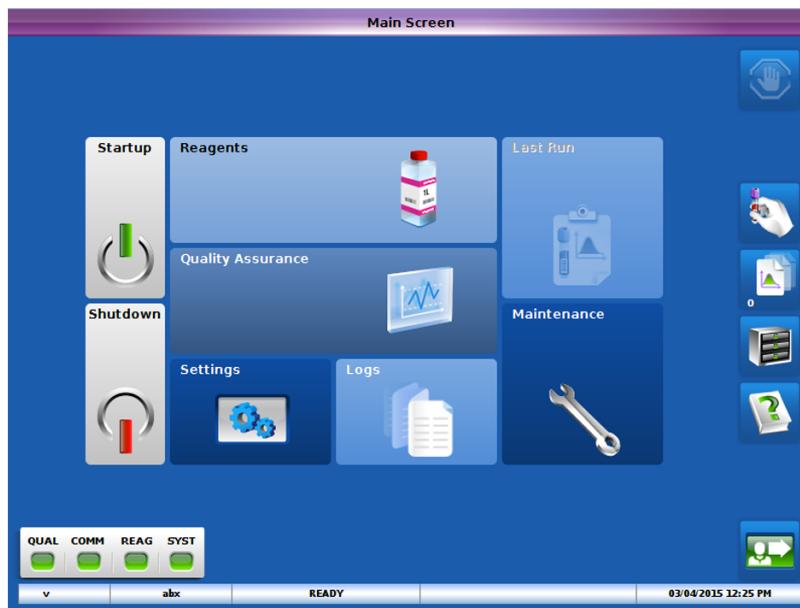


# Software

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# 1. Software Overview

The Yumizen H500 OT 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:

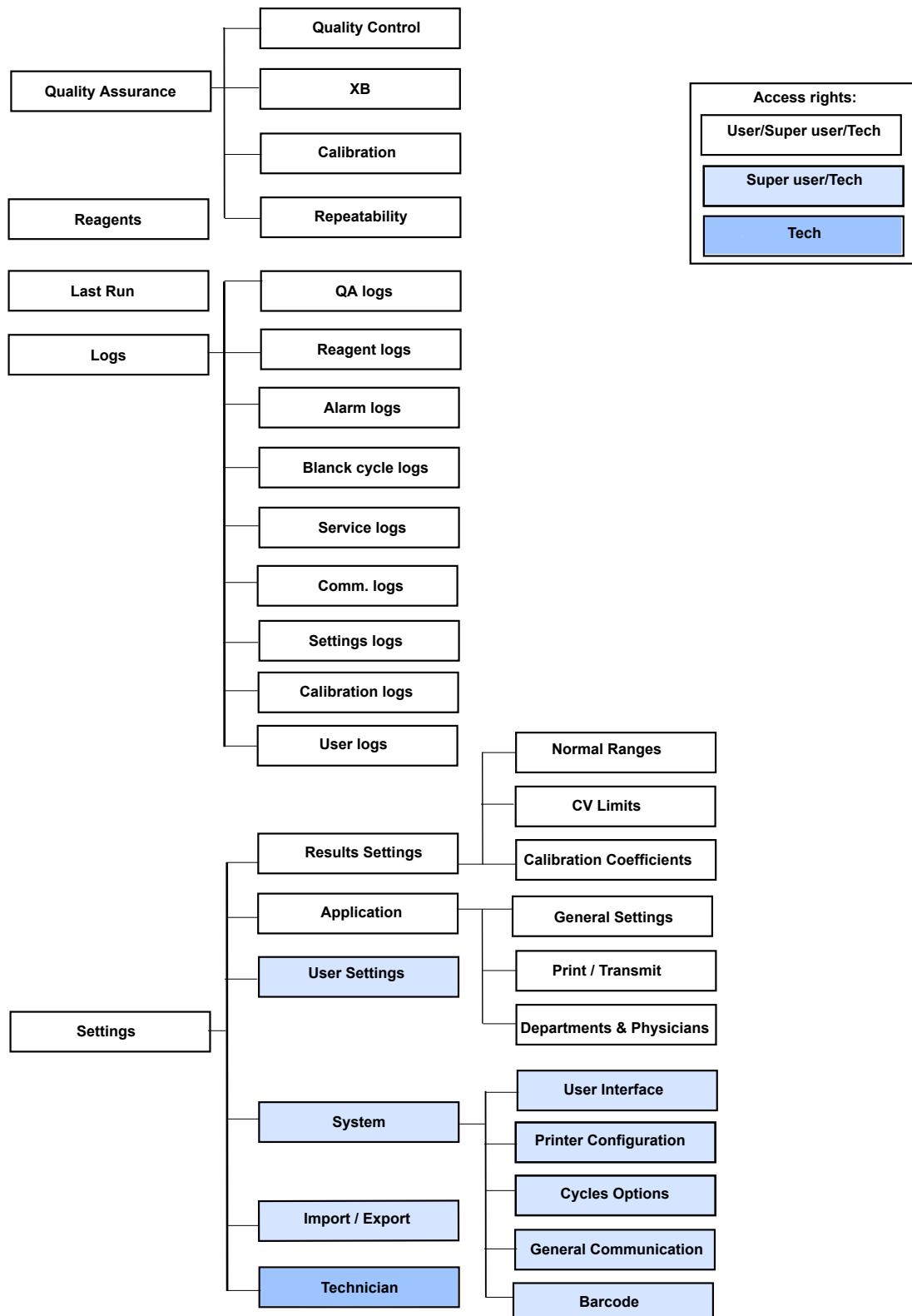
- The **contextual toolbar** (horizontal), which provides functionalities related to the screen currently displayed.
- The **function toolbar** (vertical), which provides direct access to other functionalities.
- The **main screen** buttons (center of screen), to enter the submenus.
- The **Startup** button to perform a startup cycle manually.
- The **Shutdown** button to perform a shutdown cycle manually.
- The **status bar** (next to the contextual toolbar), which gives indication on QC, communication, reagents or system problems.
- The **information bar** (bottom of screen), which gives indication on the current version, the name of the user logged in, the status of your instrument, and the date and time.

**Related information:**

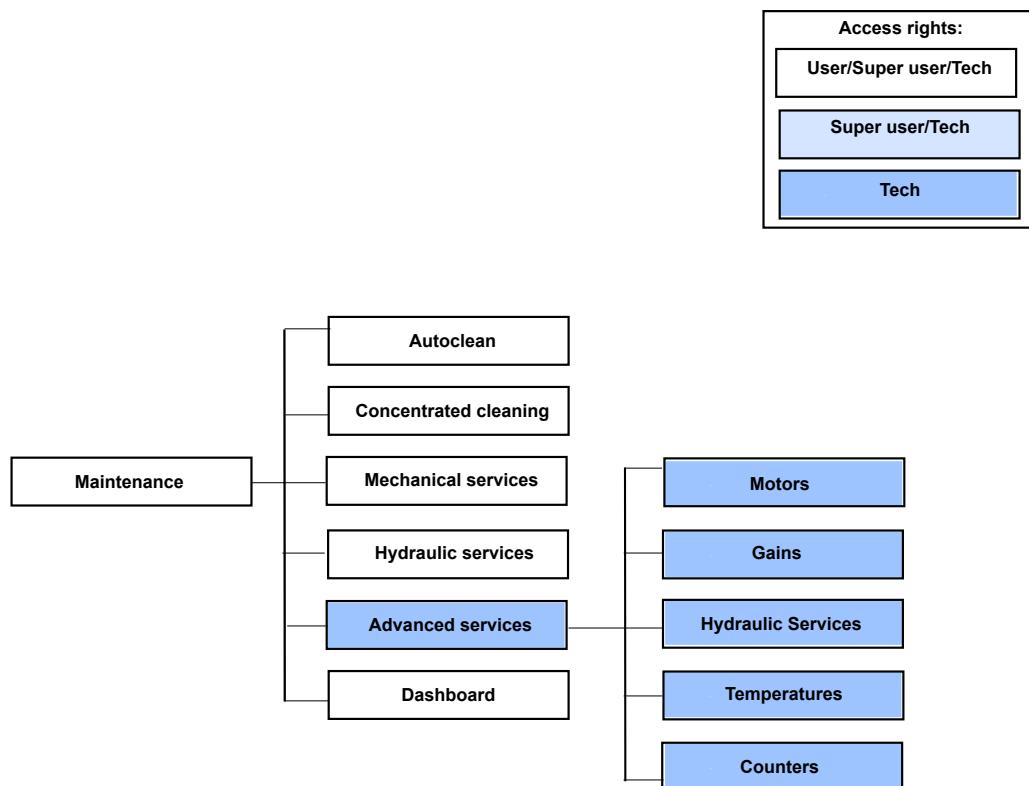
- Contextual Toolbar Description, p.52
- Function Toolbar Description, p.53
- Status Bar, p.53
- Quality Assurance Menu Buttons, p.54
- Maintenance Menu Buttons, p.54

## 2. Menus Description

### Main Menu



## 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).



**Last Run:** displays the result of the last analysis.



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



**Maintenance:** opens the maintenance menu.



**Settings:** displays the settings menu.



**Logs:** opens the instrument logs menu.

## 3.2. Contextual Toolbar Description

---

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



**Virtual Keyboard:** opens the virtual keyboard.



**Print / Send:** allows to print data or to send data to the LIS.



**Details:** displays more details about the current screen.



**Add:** allows to add new data.



**Targets:** displays QC target values.



**Delete:** deletes an item or data.



**Update:** edits the screen to modify data.



**Validate:** validates an action.



**Cancel:** cancels an action.



**Back / Exit:** goes back to the previous screen.



**Previous:** goes back to the previous item.



**Next:** goes to the next item.

### 3.3. Function Toolbar Description

---



**Stop:** stops the instrument (emergency stop).



**Stat mode:** allows you to run analyses.



**Results:** opens the list of results.



**Archives:** opens the archived results.



**Help:** opens the contextual help.

### 3.4. Status Bar

---

The status bar displays alarms regarding the four following aspects:

- Quality: invalid or failed control, XB value out of limits, etc.
- Communication: problems with the LIS or the printer.
- Reagents: empty or expired reagent, insufficient volume of reagent to perform the cycle in progress.
- System: failed cycle, mechanical problem, etc.

Each icon is green when the system operates correctly. They turn red when there is an issue. You have to click the status bar to display the **Alarms** screen.

### 3.5. 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.

### 3.6. Maintenance Menu Buttons

---



**Advanced services:** gives access to advanced maintenance.  
Reserved to HORIBA Medical approved technicians.



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



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



**Dashboard:** displays temperature, voltage, cycle counters and sensors status.



**Hydraulic services:** opens the hydraulic cycles management screen.



**Mechanical services:** opens the mechanical cycles management 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.



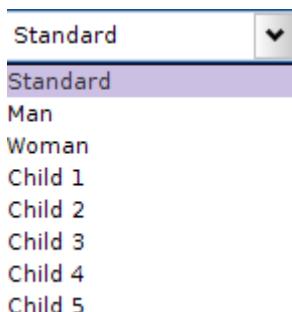
#### Tooltips

A tooltip is a short piece of information describing a button. Place your mouse pointer over a button to display a tooltip.



#### Dropdown lists

A dropdown 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.



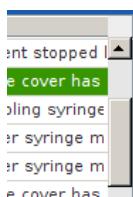
## Data fields

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



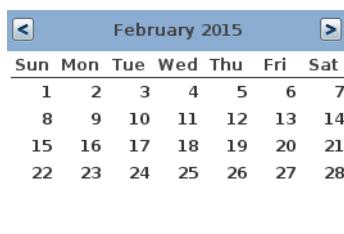
## Scroll bars

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. It is disabled when no information can be entered by the user.

The following keys have special functionalities:



Press **Valid** to validate.



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



Press **Delete** to erase text.



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



Press **Shift** to switch from uppercase to lowercase (default is uppercase).

### 4.3. Contextual Help

Help is context-sensitive. The **Help** button allows you to open a help page corresponding to the current screen.

#### Contents tab

Once you have entered the embedded help, you can navigate to find further information. In the left frame, you can expand (+) or collapse (-) the entries of the table of contents. You can also use the following buttons to navigate through the help application:



displays the table of contents.



hides the table of contents.



synchronizes the table of contents with the page currently displayed in the right frame.



displays the home page.

- ◀ goes back to the previously visited page.
- ▶ goes to the next page (based on history).
- ✖ closes the application.

### **Index tab**

The index provides an alphabetical list of terms. Each index entry is clickable and allows you to display the page relating to the subject matter.

### **Search tab**

The search functionality allows you to perform a search on all help pages. Matching results are displayed in the left frame and provide direct links to display the pages required.

# Quality Assurance

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# 1. Quality Control

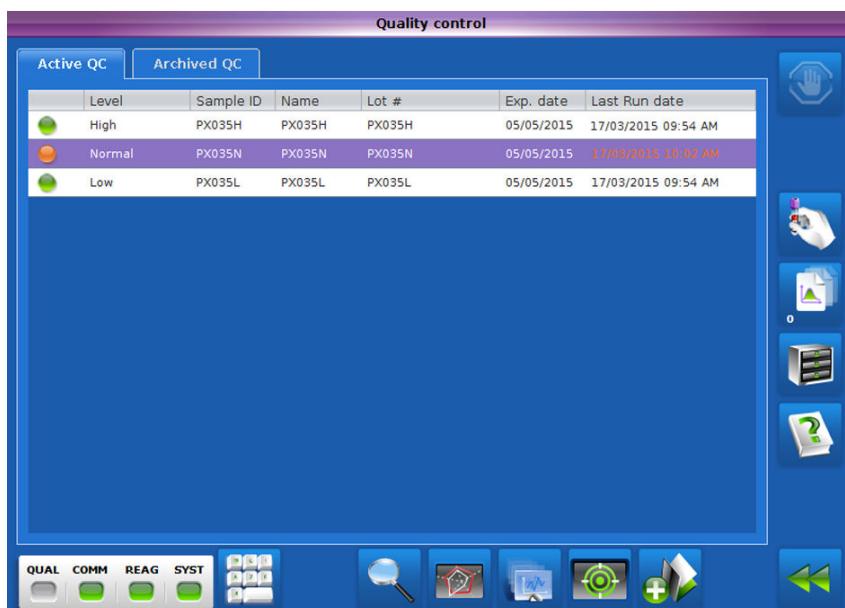
Quality Control allows the user to monitor a set of analyses based on known sample values and ranges over a period of several months. Statistical computations performed on these populations allow the extraction of qualitative information related to the stability of the instrument.

## 1.1. Quality Control Overview

---

Access: **Main Screen > 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 padlock in front of it. This padlock gives you information about the status of the control:

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



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



**FAILED:** Control blood sample results are not within the tolerance range. Analyzes 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**



Clicking **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:

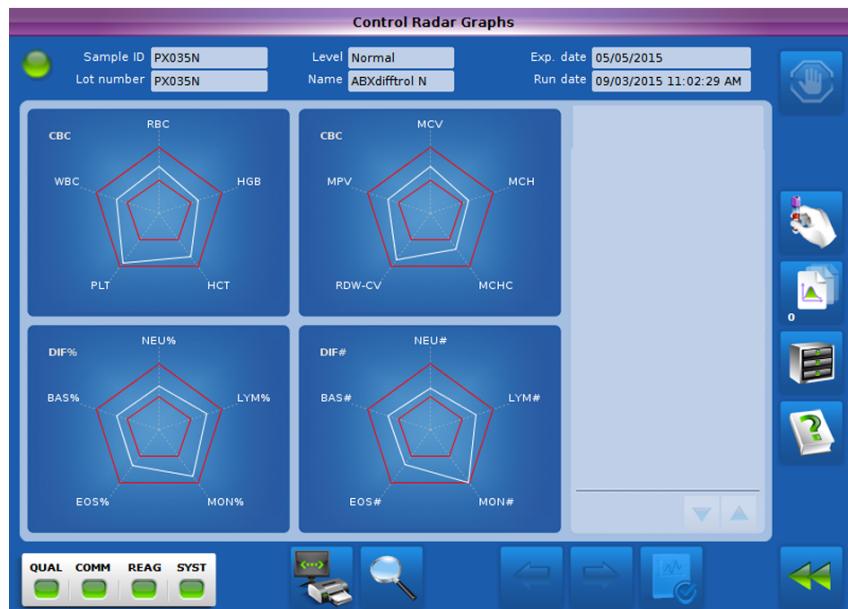
- Information about the control blood sample.
- RBC / PLT results and matrices.
- WBC results and 5 DIFF matrix.
- Alarms.

### **Control Radar Graphs**



Clicking **Radar Graphs** displays the **Control Radar Graphs** screen.

The **Control Radar Graphs** 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.

### **Quality Control Report**



Clicking **Histo Graphs** displays the **Quality Control Report** screen.

The **Quality Control Report** 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.

**Related information:**

- Controls Management, p.63
- Quality Control Results Management, p.64

## 1.2. Controls Management

---

### 1.2.1. To Create a Control Lot Manually

Access: **Main Screen > Quality Assurance > Quality control**



Control bloods have their own target values and their own ranges, defined in the leaflet provided in the container. They always have an expiration date and a maximum number of sampling.

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.

### 1.2.2. To Create a Control Lot Automatically

Access: **Main Screen > Quality Assurance > Quality control**

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

All the target values are available online at [www.horiba-abx.com/documentation](http://www.horiba-abx.com/documentation). Click **Hematology** and then **quality control target**.



Control files must have the following name format: **qctgetxxx.csv**.

The instrument downloads the first file using this name 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.

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

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 **Validate** in the contextual toolbar.

### 1.2.3. To Modify a Control Lot

Access: **Main Screen > Quality Assurance > Quality control**



Control bloods have their own target values and their own ranges, defined in the leaflet provided in the container. They always have an expiration date and a maximum number of sampling.

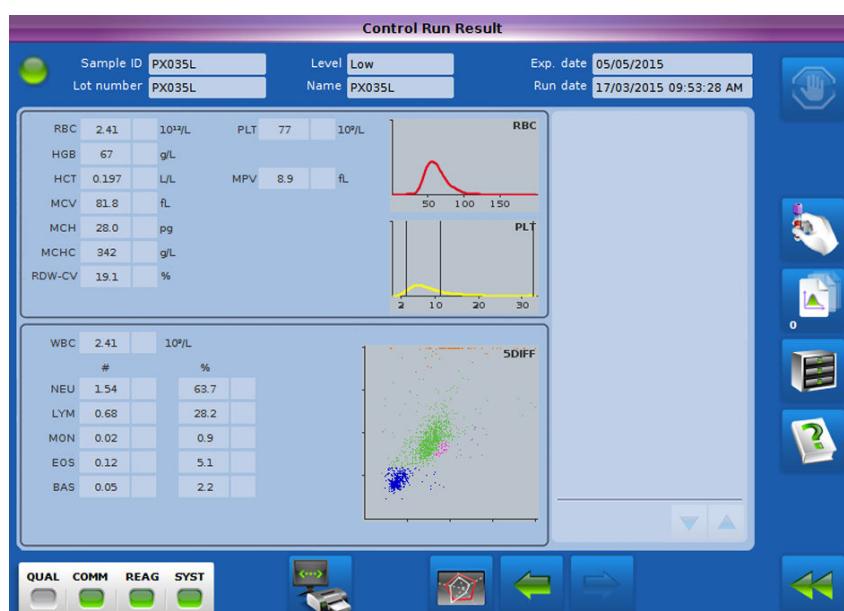
1. Select the control blood sample you want to modify.
2. Press **Targets** in the contextual toolbar.
3. Press **Update** in the contextual toolbar.
4. Modify the information you want to update.
5. Press **Validate** in the contextual toolbar.

## 1.3. Quality Control Results Management

### 1.3.1. QC Results Overview

Access: **Main Screen > 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 clicking the **Details** button.



### 1.3.2. To Manually Validate Control Results

Access: **Main Screen > 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 **Radar Graphs** 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 Print QC Results

Access: **Main Screen > Quality Assurance > Quality control**

You can print QC results from **Control Run Result**, **Control Radar Graphs** and **Quality Control Report** 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** in the contextual toolbar.
2. To print control radar graphs:
  - a. Select the data you want to print from **Active QC** or **Archived QC** areas.
  - b. Press **Radar Graphs** in the contextual toolbar.
  - c. Press **Validate** in the contextual toolbar.
3. To print quality control reports:
  - a. Select the data you want to print from **Active QC** or **Archived QC** areas.
  - b. Press **Histo Graphs** in the contextual toolbar.
  - c. Press **Print / Send** in the contextual toolbar.

### 1.3.4. To Send QC Results to the LIS

Access: **Main Screen > Quality Assurance > Quality control**

Results are automatically sent to the LIS 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.

**Related information:**

- [To Configure Results Printing and Transmission, p.118](#)

## 2. Patient Quality Control (XB)

### 2.1. Patient Quality Control (XB) Overview

Access: **Main Screen > 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 takes into account the mean of the batch as well as the previous XB value.

The XB alarm occurs if:

- a point of the graph is outside the target value +/-3%,
- three consecutive points of the graph are outside the target value +/-2%.

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

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

#### **XB**



For each parameter, a curve is displayed. A point on a curve represents the mean value of the batch (20 runs). 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 a curve.

Each parameter has a normal value, a high limit and a low limit. If the mean value of a batch is higher or lower than the limit you set up in the software, the parameter is displayed in red.

Refer to the *Settings > Instrument Default Settings > Pathological Limits* chapter.

### **XB Batch**



Clicking **Details** displays the **XB Batch** screen.

The screenshot shows the 'Quality Assurance - XB Batch' interface. At the top, there's a header with 'Batch N 2/2' and 'Batch date 17/03/2015'. Below this is a table with three rows: 'Target', 'XB' (which shows values like MCV 95.2, MCH 32.3, etc.), and 'Difference (%)'. The 'XB' row includes a red highlighted cell for MCV (-3.96). The main part of the screen is a large table with columns for 'N', 'Run date & time', and various blood parameters (MCV, MCH, MCHC, RBC, PLT, RDW-CV). The table contains 20 rows of data. At the bottom, there are buttons for 'QUAL', 'COMM', 'REAG', 'SYST', and several navigation icons.

The table displays the 20 results of the selected batch.



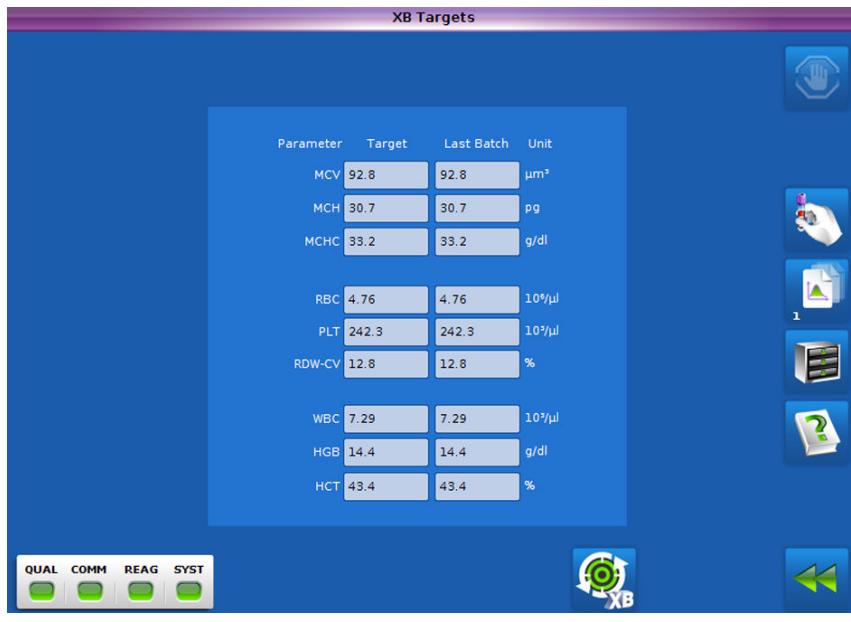
You can switch from one batch to another using the left and right arrows in the contextual toolbar.

### **XB Targets**



Clicking **Targets** displays the **XB Targets** screen.

The **XB Targets** screen allows you to reset the XB values to the current XB value or to the XB value of the next batch.



**Related information:**

- [To Initialize the XB Targets, p.68](#)
- [To Configure the XB Alarm, p.116](#)
- [Pathological Limits, p.144](#)

## 2.2. To Initialize the XB Targets

Access: **Main Screen > Quality Assurance > XB**

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

## 3. Repeatability

### 3.1. Repeatability Overview

---

Access: **Main Screen > Quality Assurance > Repeatability**

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

	WBC	RBC	HGB	HCT	PLT	MCV
Min	6.01	4.78	15.5	43.2	214.8	90.0
Max	6.16	5.00	15.9	45.3	230.8	91.2
Mean	6.08	4.94	15.7	44.7	224.3	90.4
Difference	0.15	0.22	0.4	2.1	16.0	1.3
2 SD	0.11	0.12	0.2	1.2	9.8	0.8
CV(%)	0.90	1.25	0.77	1.38	2.19	0.43

Run Date & Time	WBC 10 <sup>9</sup> /μl	RBC 10 <sup>9</sup> /μl	HGB g/dl	HCT %	PLT 10 <sup>9</sup> /μl	MCV μm <sup>3</sup>
01/04/2015 03:18:28 PM	6.02	4.97	15.7	45.3	229.1	91.2
01/04/2015 03:19:44 PM	6.03	4.95	15.8	44.9	221.6	90.7
01/04/2015 03:21:02 PM	6.15	4.97	15.6	44.9	214.8	90.5
01/04/2015 03:22:18 PM	6.03	4.97	15.7	44.7	224.6	90.0
01/04/2015 03:23:31 PM	6.07	4.94	15.7	44.5	227.3	90.1
01/04/2015 03:25:27 PM	6.09	4.78	15.6	43.2	220.0	90.4
01/04/2015 03:26:38 PM	6.08	4.96	15.7	44.9	229.0	90.5
01/04/2015 03:27:56 PM	6.01	4.92	15.5	44.3	224.3	90.0
01/04/2015 03:29:19 PM	6.16	5.00	15.7	45.1	222.1	90.3

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, p.70](#)

## 3.2. To Perform a Repeatability Test

---

Access: **Main Screen > Quality Assurance > Repeatability**

You need a fresh normal human blood sample to perform this procedure.

1. Press **Start Repeatability** in the contextual toolbar.  
If the system prompts you to create a new repeatability session, press **Validate**.
  2. Gently and thoroughly mix the sample.
  3. Open the tube and place it below the sampling needle. Lift it so that the needle can sample its content.
  4. Press the sampling bar.  
Remove the tube and put the cap back on once the needle has moved up.
- 



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

---

5. Run the blood sample ten times to obtain reliable results.
- 



You can discard the first result to obtain more reliable test results.

---

6. The instrument calculates the statistics for each parameter.
7. 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: **Main Screen > 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.



The system must be calibrated between +20°C (+68°F) and +26°C (+79°F) +/-4°C (+/-7°F).

The screenshot shows the 'Calibration' screen with the following details:

- Calibrator Information:**

Sample ID	Cx025	Name	cql	Exp. date	08/04/2015
Lot number	Cx025			Modified on	
- Coefficients:**

	WBC	RBC	HGB	HCT	PLT	MPV
New	1.097	1.059	0.971	1.097	1.135	0.850
Current	1.097	1.059	0.971	1.097	1.135	0.850
Target	9.60	4.50	135	0.370	252.0	8.6
Mean	9.31	4.27	134	0.348	251.6	8.8
CV(%)	0.64	1.30	0.40	1.06	3.42	3.06
- Selected runs (5 minimum):**

Run Date & Time	WBC ( $10^9/l$ )	RBC ( $10^{12}/l$ )	HGB (g/l)	HCT (%)	PLT ( $10^9/l$ )	MPV (fl)
09/03/2015 04:57:38 PM	9.37	4.17	135	0.341	262.6	8.9
09/03/2015 05:00:01 PM	9.34	4.27	134	0.348	254.4	9.0
09/03/2015 05:01:13 PM	9.34	4.29	135	0.350	255.0	9.1
09/03/2015 05:02:24 PM	9.27	4.30	134	0.350	245.0	8.5
09/03/2015 05:03:34 PM	9.23	4.30	134	0.349	241.1	8.6

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.72](#)
- [RDW-CV Calibration, p.76](#)
- [Calibration Results, p.75](#)
- [To Create a Calibrator Lot, p.73](#)
- [To Modify a Calibrator Lot, p.74](#)
- [To Calibrate the Instrument, p.74](#)
- [To Check the Calibration, p.76](#)
- [To Force the Calibration Coefficients, p.77](#)

## 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.

**Related information:**

- [To Make Sure the Instrument Passes the Startup, p.72](#)
- [To Check the Repeatability of your Instrument, p.73](#)

### 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 and verify that the values are within acceptable limits.

Parameter	Background count limits
WBC	$\leq 0.3 \times 10^9/L$
RBC	$\leq 0.03 \times 10^{12}/L$
HGB	$\leq 3 g/L$
PLT	$\leq 5 \times 10^9/L$



If the startup has failed refer to the *Maintenance and Troubleshooting > Troubleshooting Procedures > Operations Problems* chapter to perform the problem identification procedure.

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

**Related information:**

- [To Perform a Concentrated Cleaning, p.158](#)
- [Start of Day, p.84](#)
- [Operation Problems, p.163](#)

#### 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:**

- [To Run a Control Blood Sample, p.88](#)
- [Summary of Performance Data, p.31](#)
- [Repeatability, p.69](#)
- [Repeatability Problems, p.166](#)

#### 4.3. To Create a Calibrator Lot

Access: **Main Screen > Quality Assurance > Calibration**

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

## 4.4. To Modify a Calibrator Lot

---

Access: Main Screen > Quality Assurance > Calibration

1. Press **Targets** in the contextual toolbar.
2. Press **Update** 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: Main Screen > 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.  
If the system prompts you to create a new calibration session, press **Validate**.
  2. Prepare the calibrator according to the instructions detailed in the calibrator package insert.
  3. Gently and thoroughly mix the sample.
  4. Open the tube and place it below the sampling needle. Lift it so that the needle can sample its content.
  5. Press the sampling bar.  
Remove the tube and put the cap back on once the needle has moved up.



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.

- 
6. Sample the calibrator at least four more times.  
To obtain reliable results, it is recommended to run the sample at least five times.

7. Discard the first result from the list.  
The instrument calculates the statistical calibration factors for each parameter.
8. Press **Validate Calibration** in the contextual toolbar.  
If the coefficients are valid, press **Validate**.  
If at least one coefficient is invalid, you can force the calibration by pressing **Validate**.



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 LIS. 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 or sent to the LIS by pressing **Print / Send**.

### 4.6.1. Calibration Passed

The calibration passes if:

- The percentage difference between the target values and the mean values 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
MPV	< 2

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

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

The RDW-CV is not automatically calibrated. You have to do it manually. Refer to the *Quality Assurance > Calibration > RDW-CV Calibration* chapter for more information.

## 4.6.2. Forced Calibration

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 RDW-CV.

**Related information:**

- [RDW-CV Calibration, p.76](#)
- [To Check the Calibration, p.76](#)

## 4.7. To Check the Calibration

It is recommended to perform a check-up after calibrating your instrument. To do so, you need to:

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. RDW-CV Calibration

The RDW-CV cannot be calibrated during the automatic calibration. It has to be manually adjusted.

It is very important to calibrate it as it is used to determine erythrocyte abnormalities linked to anisocytosis. You can calculate the RDW-CV based on the mean RDW-CV value from a peer group (QCP values), on the XB mean value for RDW-CV, or using the target values of a control blood. The RDW-CV value should be 13.5 +/- 2.



Expected RDW 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.

In order to obtain the appropriate RDW-CV coefficient, use the following formula:

**New RDW-CV coefficient = Current RDW-CV coefficient X Expected RDW-CV / Calculated RDW-CV**

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



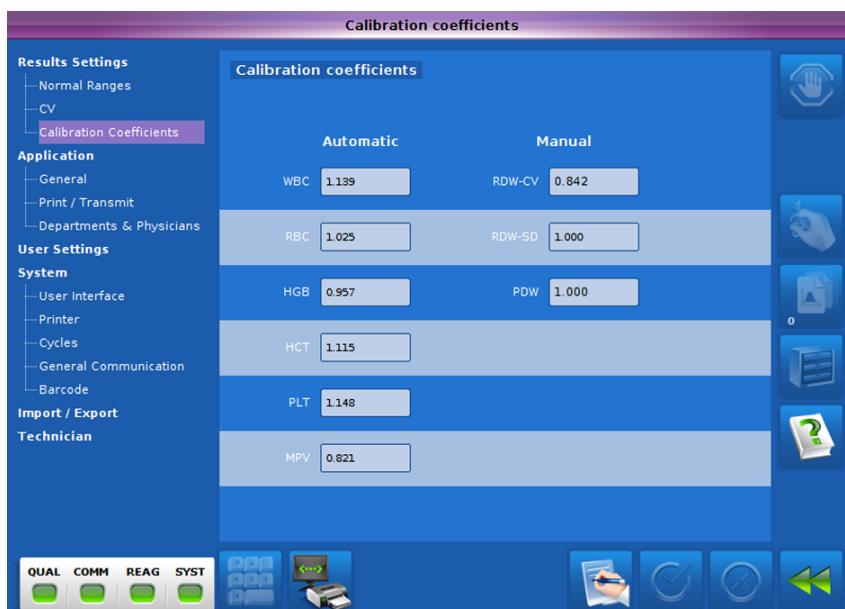
If you change the RDW-CV coefficient, you must run several fresh human blood samples and check the RDW-CV values.

## 4.9. To Force the Calibration Coefficients

**Access: Main Screen > 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.



2. Press **Validate**.

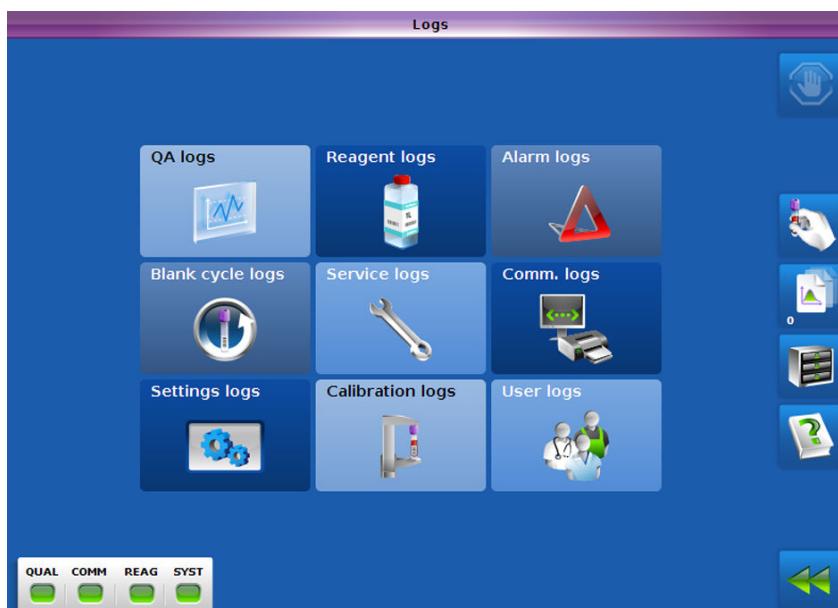


Any modification of the calibration coefficients will affect the results and is strictly the responsibility of the user.

## 5. Logs

### 5.1. Logs Overview

Access: **Main Screen > Logs**



The logs list events of your instrument for the following:



**Reagent logs:** provides information about a reagent replacement.



**Alarm logs:** provides a description of system alarms.



**Blank cycle logs:** provides information about blank cycles values.



**Service logs:** displays the list of maintenance procedures performed.



**Comm logs:** displays events related to sent or printed data.



**Settings logs:** displays comments regarding settings that have been changed on the instrument.



**Calibration logs:** displays events related to calibration.



**User logs:** displays a list of all the users who logged in to the application.



**QA logs:** displays events related to quality assurance.

## 5.2. To Add a Comment in the Logs

---

*Access: Main Screen > Logs*

It is recommended to add a comment in the logs (except in the **Comm logs**) to keep track of why it was performed.

It is recommended to add a comment after any maintenance operation.

1. Go to the appropriate logs menu.
2. Select one item in the logs.
3. Press **Add comments**.
4. Enter your comment in the text field (50 characters).
5. Press **Validate** in the contextual toolbar.

## 6. 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.

### 6.1. 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 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**.

## 6.2. To Submit your Instrument Results

---

You can submit your results from the **Detail Data** or the **Summary Data** tabs.

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

## 6.3. To Consults 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.**

All Peer Comparison															
		October 2013				Dr Jacques Meyer paris_laboratory@yahoo.fr Hospital Pitié-Salpêtrière P120DX-DIFF-Jacques									
		ABX Pentra 120, Nexus DX, DF - Diffrol - World				ABX Pentra DX 120				ABX Diffrol PX093					
		Number of Results	Level	WBC	10 <sup>9/mm<sup>3</sup></sup>	RBC	10 <sup>12/mm<sup>3</sup></sup>	HGB	g/dL	HCT	g/dL	H	%		
		Number of Results	Level	L	N	H	L	N	H	L	N	H	%		
Instruments	United States	26	55	31	26	55	31	26	55	31	26	55	31		
	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		
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	0.68	
	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

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## 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 > To Replace Reagents > To Replace the Waste Container* chapter.

---

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc.). Follow your local and/or national guidelines for biohazard waste disposal.



- 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 tubes and the liquid waste tube under any circumstance.
- 



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

---

**Related information:**

- [To Replace the Waste Container, p.172](#)

### 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.85](#)
- [Operational Conditions, p.16](#)
- [Labels and Connections, p.20](#)
- [Waste Handling Precautions, p.40](#)

### 1.3.2. To Log In to the Application

---

1. Select a user name.
2. Enter your password.
3. Press **Validate** in the contextual toolbar.



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

- 
4. Select **Reset sample ID auto-numbering** in the **Begin of Day** window, if necessary.  
This step is only necessary at the beginning of the day and if the option is selected.

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 forces 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 allows to clean the hydraulic circuit. You should not perform any action except turning off the instrument during these 10 minutes. If you try to restart the instrument during these 10 minutes, you will have to perform the shutdown cycle again.

### 1.3.3. To Control the Reagents

Access: **Main Screen > 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 do so, you need to:

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.171](#)

### 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.  
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	$\leq 0.3 \times 10^9/L$
RBC	$\leq 0.03 \times 10^{12}/L$
HGB	$\leq 3 g/L$
PLT	$\leq 5 \times 10^9/L$

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

**Related information:**  
■ [Logs Overview, p.78](#)  
■ [Startup Failed, p.164](#)

### 1.3.5. To Schedule an Automatic Startup

Access: **Main Screen > Settings > System > Cycles Options**

When you schedule an **Automatic Startup**, it is run as soon as connections with the instrument and reagents level have been checked.

1. Press **Update** in the contextual toolbar.
2. In the **Automatic Startup** area, specify the starting time.  
By default, the specified hour is 07:00 AM.
3. Select the specific days for which you require an automatic startup.
4. Press **Validate** in the contextual toolbar.

## 2. Running Control Blood Samples

### 2.1. To Run a Control Blood Sample

---

Access: **Main Screen > Quality Assurance > Quality control**

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. Enter the lot number of the control blood sample.
  5. Press **Validate** in the contextual toolbar.
  6. Gently and thoroughly mix the sample.
  7. Open the tube and place it below the sampling needle. Lift it so that the needle can sample its content.
  8. Press the sampling bar.  
Remove the tube and put the cap back on once the needle has moved up.
- 



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

**Related information:**

- [To Create a Control Lot Automatically, p.63](#)
- [To Create a Control Lot Manually, p.63](#)

### 2.2. To Check Control Results

---

Access: **Main Screen > Quality Assurance > Quality control**

1. Select a control lot.
2. Check 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.158](#)
- [To Run a Control Blood Sample, p.88](#)

### 3. Running Blood Samples

#### 3.1. To Create an Order

---

1. Press **Stat mode** in the function toolbar.
2. Enter the sample ID if necessary.
3. If your instrument is connected to a LIS, press **Query** to retrieve the analysis data for the sample.
4. If your instrument is not connected to a LIS:
  - a. Enter the physician, the department and/or comments about the sample, if necessary.
  - b. If necessary, enter the patient ID or press **Search PID** 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 which analysis to run by pressing **CBC** or **DIF**.  
You can configure which analysis is selected by default.  
For more information, refer to *Settings > Configuring the Instrument > To Select the Default Mode*.
5. Press **Validate** in the contextual toolbar.

**Related information:**  
■ [To Select the Default Mode, p.117](#)

#### 3.2. To Run a Blood Sample

---

*Make sure that you created and validated the order for the blood sample or that you received one from the LIS.*

1. Gently and thoroughly mix the sample.
2. Open the tube and place it below the sampling needle. Lift it so that the needle can sample its content.
3. Press the sampling bar.  
Remove the tube and put the cap back on once the needle has moved up.

**Related information:**  
■ [Results Management, p.91](#)

## 4. Results Management

### 4.1. Results Overview

Access: **Main Screen > Results**

The **Results** menu displays all the results of run analyzes.

This menu consists of two different screens:

- A results list screen
- A results view screen

#### Results list

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

- Run time information
- Sample information
- Patient information
- Analysis type information
- Gender information
- Print and LIS transmission information

#### Results view

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

You can also click **Last Run** from the **Main Screen** to displays the last run result.



Note that this screen automatically displays after an analysis run.



1 = Information about sample and patient. You can press the + button to obtain more information about sample and patient.

2 = Results and matrix

3 = Flags and alarms

You can consult all the results details by pressing the arrows at the bottom of the screen.

**Related information:**

- [To Print your Results, p.92](#)
- [To Send Results to the LIS, p.93](#)

## 4.2. To Print your Results

Results are automatically printed 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 from the results list.
2. Press **Print / Send** in the contextual toolbar.
3. Select one of the following options:
  - **Print all results**
  - **Print 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.118](#)

### 4.3. To Send Results to the LIS

Results are automatically sent to the LIS 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 send from the results list.
2. Press **Print / Send** in the contextual toolbar.
3. Select one of the following options:
  - **Send all results**
  - **Send only selected results**
4. Press **Validate**.

**Related information:**

- [To Configure Results Printing and Transmission, p.118](#)

## 5. Results Interpretation

### 5.1. General Alarms

---

#### 5.1.1. Parameter Reject

Reject flags occur whenever the difference between the two counts of a parameter is higher than the predefined limits. 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 occurs on every sample. Rejected results are replaced by "----" and flagged with an "\*\*\*".

Parameter Reject	Triggered when	Parameters replaced by "----" and flagged with an "***"
RBC	The two consecutive counts are different or out of ranges.	MCV, MCH, MCHC, RDW-CV and RDW-SD
PLT		PCT, PDW and MPV
HGB	Three consecutive HGB results are flagged with an ***.	HGB
WBC DIFF	The difference between the eleven consecutive counts are out of ranges. The correlation between the resistive and the optical measurements on the matrix is low (<50%). There is an optical bench light error.	DIFF parameters

#### 5.1.2. Suspicion

Results are displayed but followed by an \*\*\* 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.

##### RBC counting instability

Conditions	Parameters flagged with an ***	Action
The two consecutive counts are not enough consistent to provide a reliable result.	RBC, HCT, MCV, MCH, MCHC, RDW-CV and RDW-SD	Rerun the sample or check it using a reference method.

### Platelet counting instability

Conditions	Parameters flagged with an <b>***</b>	Action
The two consecutive counts are not enough consistent to provide a reliable result.	PLT, PCT, PDW, MPV, P-LCR and P-LCC	Rerun the sample or check it using a reference method.

### HGB measurement instability

Conditions	Parameters flagged with an <b>***</b>	Action
The two consecutive HGB blank measurements results are out of a reliable range.	HGB, MCH and MCHC	Rerun the sample or check it using a reference method.
The ten consecutive HGB measurements are not enough consistent to provide a reliable result.		

### WBC DIFF counting instability

Conditions	Parameters flagged with an <b>***</b>	Action
The eleven consecutive counts are not enough consistent to provide a reliable result.	WBC, LYM#, MON#, NEU#, EOS#, BAS# and LIC#	Rerun the sample or check it using a reference method.
The correlation between the resistive and the optical measurements on the matrix is low (<50%).	WBC, LYM#, LYM%, MON%, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, LIC# and LIC%	Rerun the sample or check it using a reference method.

**Related information:**

- [Normal and Panic Ranges, p.95](#)
- [Pathological Limits, p.144](#)

### 5.1.3. Normal and Panic Ranges

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

- **I** 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 Sample Types* chapter

**Related information:**

- [Configuring the Sample Types, p.127](#)

### 5.1.4. Out of Linearity Range Alarm

The Out of linearity range alarm is generated when the results are out of the minimum and maximum values defined for the instrument.

You must dilute the sample with ABX Diluent and rerun.

For more information, refer to the *Summary of Performance Data > Linearity Limits* chapter.

Parameter out of linearity ranges	Consequence
HGB	HGB, MCV and MCHC are flagged with an "++".
WBC	WBC, LYM#, MON#, EOS#, BAS#, NEU# and LIC# are flagged with an "++".
HCT	HCT is replaced by "---" and flagged with an "++". RBC, MCV, MCH, MCHC, RDW-CV and RDW-SD are flagged with an "++".
RBC	RBC and HCT are replaced by "---" and flagged with an "++". MCV, MCH, MCHC, RDW-CV and RDW-SD are flagged with an "++".
PLT	RBC, PLT, PCT, PDW, MPV, P-LCC and WBC are replaced by "---" and flagged with an "++". HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD and P-LCR are flagged with an "++".
WBC DIFF	WBC, LYM#, MON#, EOS#, BAS#, NEU# and LIC# are replaced by "---" and flagged with an "++".

**Related information:**  
 ■ [Linearity Limits, p.32](#)

## 5.2. Morphology Alarms

---

### 5.2.1. Platelet Alarms

The PLT 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 12 fL and 25 fL (standard area).

### 5.2.1.1. RBC PLT Interference Alarm

The RBC PLT Interference alarm is generated if the following conditions:

- An excessive number of particles on the right side of the threshold area (after 25 fL)
- The mobile threshold cannot position itself in the standard area (between 12 fL and 25 fL)
- The mobile threshold cannot be positioned because no valley is found between the PLT and RBC histograms



The PLT, PCT, PDW, MPV, P-LCC and P-LCR results are flagged with an \*\*.

This alarm indicates the possible presence of platelet aggregates or schistocytes.



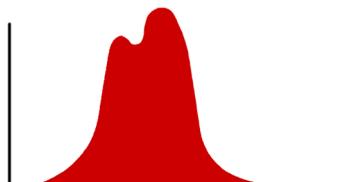
If platelet aggregates or platelet clumping are suspected, the patient sample should be redrawn in a sodium citrate tube. Do not vortex the sample.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.2. Red Blood Cells Alarms

#### 5.2.2.1. RBC Double Population Alarm

The RBC double population alarm is generated when a cells sizing difference is measured and two sub populations of RBC are detected.



The RBC, HCT, MCV, MCH, MCHC, RDW-CV and RDW-SD results are flagged with an \*\*.

This alarm may appear in case of medical treatment, blood transfusion or hemolytic anemia.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.2.2. Nucleated Cells Interference Alarm

The Nucleated cells interference alarm is generated when a large number of nucleated cells (WBC or NRBC) is detected during the RBC counts.

The RBC, HCT, MCH and MCHC results are flagged with an \*\*.

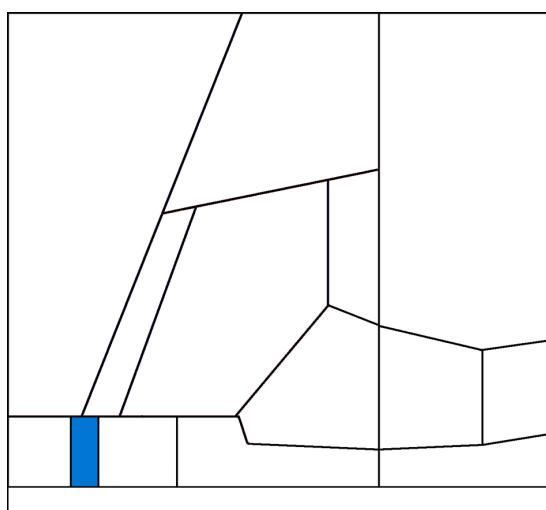
This alarm indicates the possible presence of leucocytes on the RBC curve.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.3. WBC DIFF Alarm

#### 5.2.3.1. LYM Interference Alarm

The LYM Interference alarm is generated when there is a significant large population of cells located on the left-hand side of the lymphocyte area.



This alarm appears when:

- The number of counting particles in this area is higher than the **LL** limit value or
- The percentage of counted particles in relation to the total number of lymphocytes is above the **LL1** limit value

The DIFF parameters results (in % and in #) are flagged with an \*\*.

This alarm indicates the possible presence of:

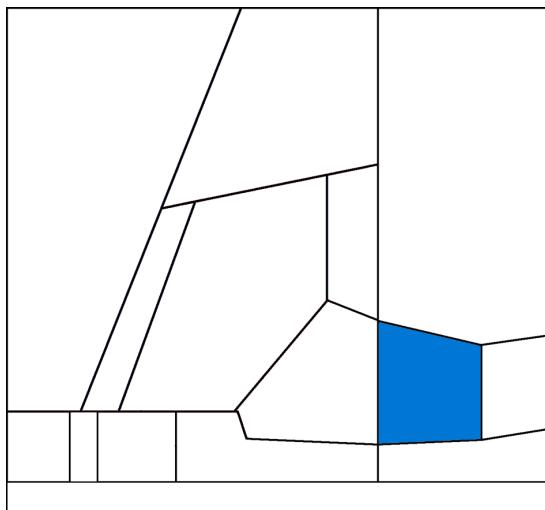
- Platelet aggregates
- Small lymphocytes
- Erythrocyte membrane resistant to lysis (stroma)
- Erythroblasts (NRBC)

The **LL** limit value is 150# and the **LL1** limit value is 16%.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.3.2. MON Interference Alarm

The MON Interference alarm is generated when there is the presence of a significant large population of cells located on the right-hand side of the monocyte area.



This alarm appears when the percentage of counted particles in relation to the total number of WBC is above the **RM** limit value.

The DIFF parameters results (in % and in #) are flagged with an \*\*.

This alarm indicates the possible presence of:

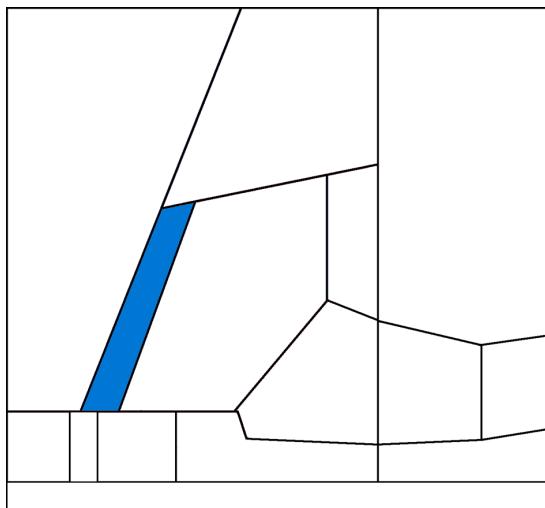
- Large monocytes
- Myelocytes
- Promyelocytes
- Hyperbasophilic monocytes
- Blasts

The **RM** limit value is 1.2%.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.3.3. Abnormal NEU Distribution Alarm

The Abnormal NEU distribution alarm is generated when there is the presence of a significant large population of cells located on the left-hand side of the neutrophil area.



This alarm appears when the percentage of counted particles in relation to the total number of neutrophils is above the **LN** limit value.

The DIFF parameters results (in % and in #) are flagged with an "++".

This alarm indicates the possible presence of the following abnormalities:

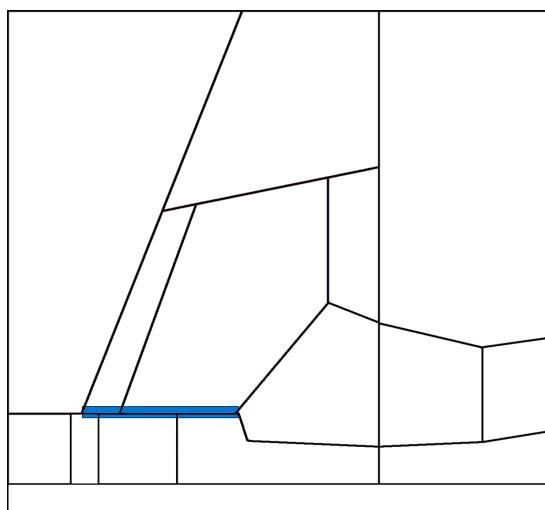
- Neutrophil destruction due to incorrect storage of the sample or old sample
- Contamination, stroma or platelet aggregates
- Erythrocyte membrane resistant to lysis (stroma)

The **LN** limit value is 15%.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

#### 5.2.3.4. Abnormal NEU/LYM Distribution Alarm

The Abnormal NEU/LYM distribution alarm is generated where there is the presence of a significant large population of cells located in the separation threshold area between lymphocytes and neutrophils.



The LYM#, LYM%, NEU# and NEU% parameters results are flagged with an "++".

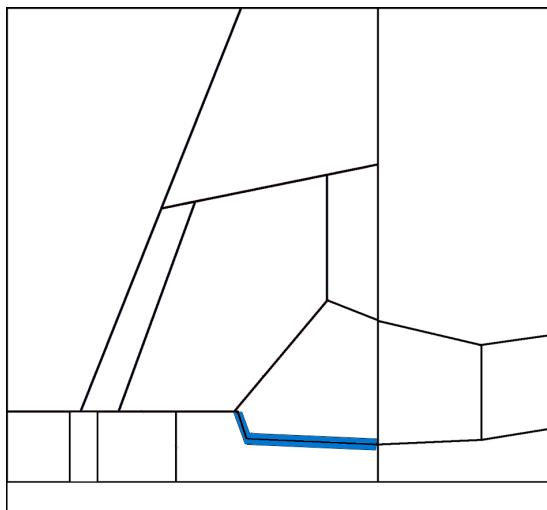
This alarm indicates the possible presence of the following abnormalities:

- Small neutrophils without granules and/or slightly segmented
- Lymphocytes with a segmented nucleus or activated lymphocytes
- Neutrophils with membrane weakness

**Related information:**  
■ [Alarm Default Levels, p.188](#)

#### 5.2.3.5. Abnormal LYM/MON Distribution Alarm

The Abnormal LYM/MON distribution alarm is generated when there is the presence of a significant large population of cells located in the separation threshold area between lymphocytes and monocytes.



The LYM#, LYM%, MON# and MON% parameters results are flagged with an \*\*.

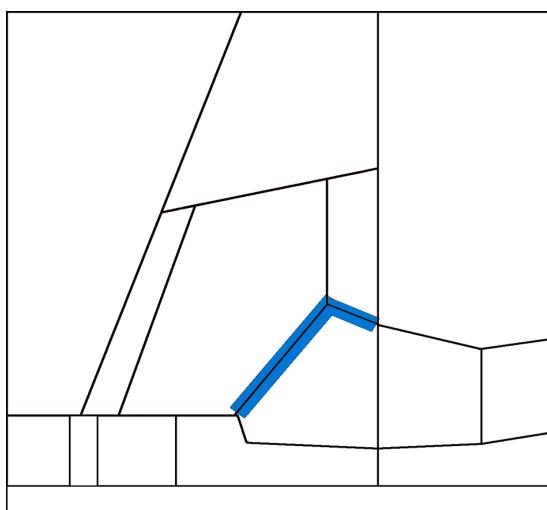
This alarm indicates the possible presence of the following abnormalities:

- Lymphocytosis
- Monocytosis
- Chronic lymphocytic leukemia (CLL)
- Acute lymphoblastic leukemia (ALL)

**Related information:**  
■ [Alarm Default Levels, p.188](#)

#### 5.2.3.6. Abnormal NEU/MON Distribution Alarm

The Abnormal NEU/MON distribution alarm is generated when there is the presence of a significant large population of cells located in the separation threshold area between monocytes and neutrophils.



The MON#, MON%, NEU# and NEU% parameters results are flagged with an \*\*.

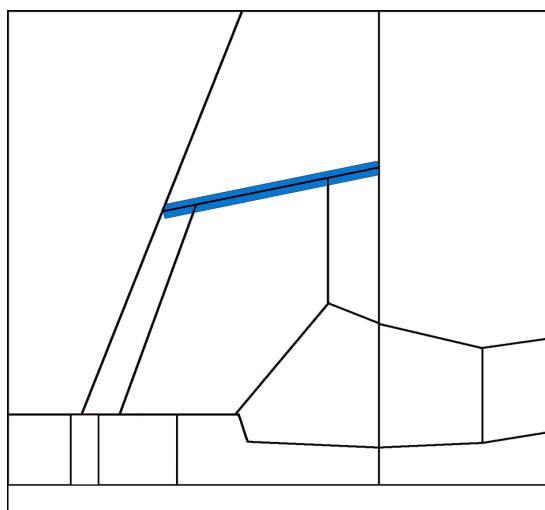
This alarm indicates the possible presence of the following abnormalities:

- Hypergranulation of monocytes or hyperbasophilic monocytes
- Young neutrophils with non-segmented nuclei (bandcells)

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.3.7. Abnormal NEU/EOS Distribution Alarm

The Abnormal NEU/EOS distribution distribution alarm is generated when there is the presence of a significant large population of cells located in the separation area between neutrophils and eosinophils because the two populations are overlapping.



The NEU#, NEU%, EOS# and EOS% parameters results are flagged with an \*\*.

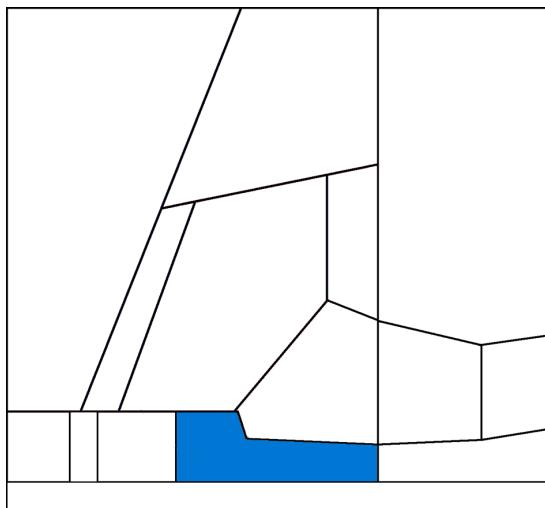
This alarm indicates the possible presence of the following abnormalities:

- Young eosinophils
- Giant hypersegmented neutrophils
- Eosinophils with low intracytoplasmic material
- Immature cells
- Neutrophils with cytotoxic granulations

**Related information:**  
■ [Alarm Default Levels, p.188](#)

### 5.2.3.8. Atypical Lymphocytes Alarm

The alarm Atypical Lymphocytes is generated when there is the presence of a significant large population of cells located on the right-hand side of the lymphocyte area.



This alarm appears when the percentage of counted particles in this area is higher than the **ALY** limit value.

The DIFF parameters results (in % and in #) are flagged with an \*\*.

This alarm indicates the possible presence of the following abnormalities:

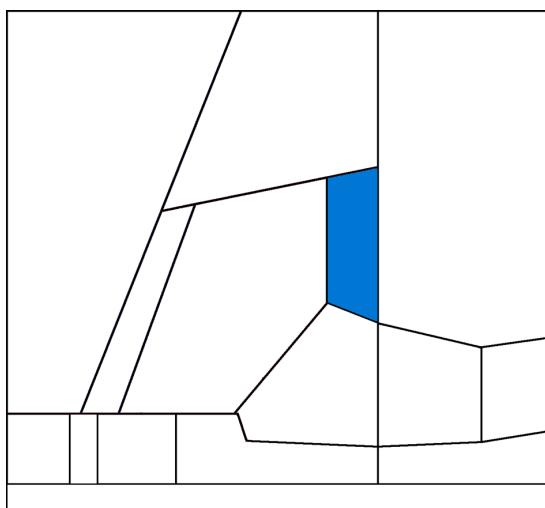
- Large lymphocytes
- Reactive lymphoid forms
- Stimulated lymphocytes
- Plasmocytes

The **ALY** limit value is 350#.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

#### 5.2.3.9. Right Neutrophils Alarm

The Right Neutrophils alarm is generated when there is the presence of a significantly large population of cells located on the right-hand side of the neutrophil area.



This alarm appears when the percentage of counted particles in relation to the total number of WBC is above the **RN** limit value.

The NEU% and NEU# parameters are flagged with an \*\*.

This alarm indicates the possible presence of the following abnormalities:

- Large neutrophils
- Immature cells from granulocytic line (metamyelocytes, myelocytes, promyelocytes, myeloblasts)

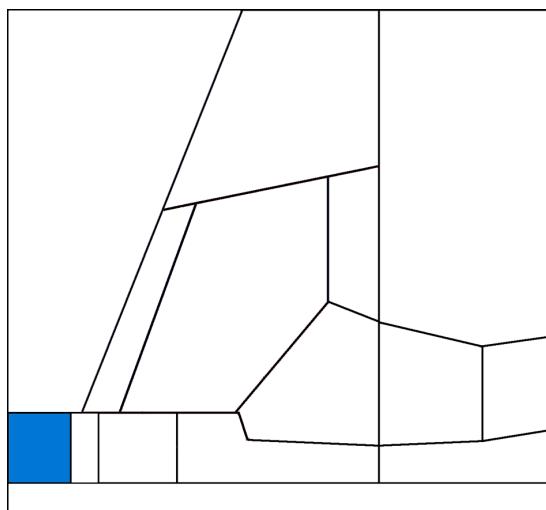
The **RN** limit value is 1.2%.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

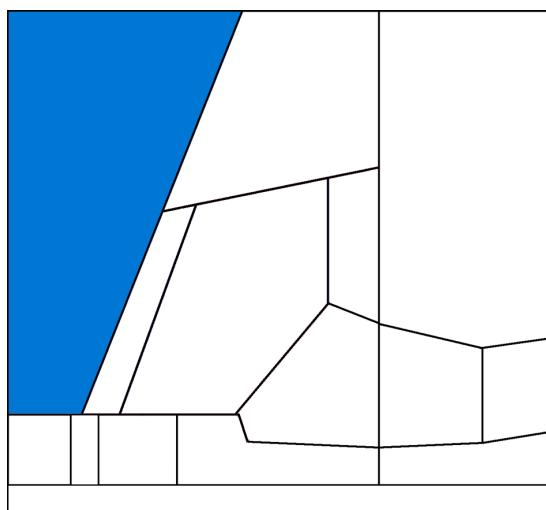
#### 5.2.3.10. Background Noise Alarm

The Background noise alarm is generated when the number of counted particles in the background noise area is higher than the limit set up in the software.

This alarm appears when the number of counting particles in the background noise low area is higher than the **BNL** limit value.



This alarm appears also when the number of counting particles in the background noise high area is higher than the **BNH** limit value.



The PLT results and the DIFF results are flagged with an \*\*.

This alarm indicates the possible presence of:

- Platelet aggregates
- Large number of platelets
- Erythrocyte membrane resistant to lysis (stroma)
- Erythroblasts (NRBC)
- Background noise

The **BNL** limit value is 25# the **BNH** limit value is 80#.

**Related information:**  
■ [Alarm Default Levels, p.188](#)

## 5.3. 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.



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. It is recommended to use known reference methods to confirm diagnoses.

### 5.3.1. WBC Messages



\* PDW, PCT, P-LCC, P-LCR, RDW-SD, LIC# and LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

Message	Triggered when
Leukocytosis	WBC > WBC <b>H</b>
Leukopenia	WBC < WBC <b>L</b>
Lymphocytosis	LYM# > LYM# <b>H</b>
Lymphopenia	LYM# < LYM# <b>L</b>
Neutrophilia	NEU# > NEU# <b>H</b>
Neutropenia	NEU# < NEU# <b>L</b>
Eosinophilia	EOS# > EOS# <b>H</b>
Monocytosis	MON# > MON# <b>H</b>
Basophilia	BAS# > BAS# <b>H</b>
Large Immature Cells	LIC# > LIC# <b>H</b> or if LIC% > LIC% <b>H</b>
Left Shift	Right Neutrophils alarm
Extrem Neutropenia	NEU# < 0.5 g/L
Pancytopenia	WBC < WBC <b>L</b> and RBC < RBC <b>L</b> and PLT < PLT <b>L</b>

### 5.3.2. RBC Messages

Message	Triggered when
Erythrocytosis	RBC > RBC L
Erythropenia	RBC < RBC H
Anemia	HGB < HGB L
Dbl pop suspicion	RBC double population alarm is triggered
Macrocytosis	MCV > MCV H
Microcytosis	MCV < MCV L
Hypochromia	MCH < MCHL
Anisocytosis	RDW-CV > RDW-CV H or RDW-SD > RDW-SD H
Poikilocytosis	Hypochromia and Anisocytosis
Cold Agglutinin	MCHC > MCHC H and RBC > $0.1 \times 10^{12}/\text{L}$ and WBC < $85 \times 10^9/\text{L}$
Pancytopenia	WBC < WBC L and RBC < RBC L and PLT < PLT L

### 5.3.3. PLT Messages

Message	Triggered when
Thrombocytosis	PLT > PLT H
Thrombocytopenia	PLT < PLT L
Macroplatelets	MPV > MPV H
Platelet Aggregates	There are six distinct conditions of activation: <ul style="list-style-type: none"><li>■ PDW &gt; 20 fL and BNL alarm and no LL alarm</li><li>■ PDW &gt; 20 fL and LL1 alarm and no LL alarm</li><li>■ MPV &gt; 10 fL and BNL alarm and no LL alarm</li><li>■ MPV &gt; 10 fL and LL1 alarm and no LL alarm</li><li>■ PLT &lt; <math>150 \times 10^9/\text{L}</math> and BNL alarm and no LL alarm</li><li>■ PLT &lt; <math>150 \times 10^9/\text{L}</math> and LL1 alarm and no LL alarm</li></ul>
ERB	LYM Interference alarm and PDW < 20 fL and MPV < 10 fL and PLT > $150 \times 10^9/\text{L}$ and no BNL alarm
Platelet Aggregates ERB	There are five distinct conditions of activation: <ul style="list-style-type: none"><li>■ BNL and LL alarms</li><li>■ BNL alarm and PDW &lt; 20 fL and MPV &lt; 10 fL and PLT &gt; <math>150 \times 10^9/\text{L}</math> and no LL1 alarm</li><li>■ LL alarm and PDW &gt; 20 fL and no BNL alarm</li><li>■ LL alarm and MPV &gt; 10 fL and no BNL alarm</li><li>■ LL alarm and PLT &lt; <math>150 \times 10^9/\text{L}</math> and no BNL alarm</li></ul>
Pancytopenia	WBC < WBC L and RBC < RBC L and PLT < PLT L

## 5.4. Analyzer Alarms

### 5.4.1. PLT Concentrate Mode

The PLT Concentrate alarm indicates the triggering of the "PLT extended linearity mode" for an HGB < 20 g/L & PLT >  $15 \times 10^9/\text{L}$ .

### 5.4.2. Incorrect Sampling

The Incorrect sampling alarm is generated when there is no counting during the analysis cycle.

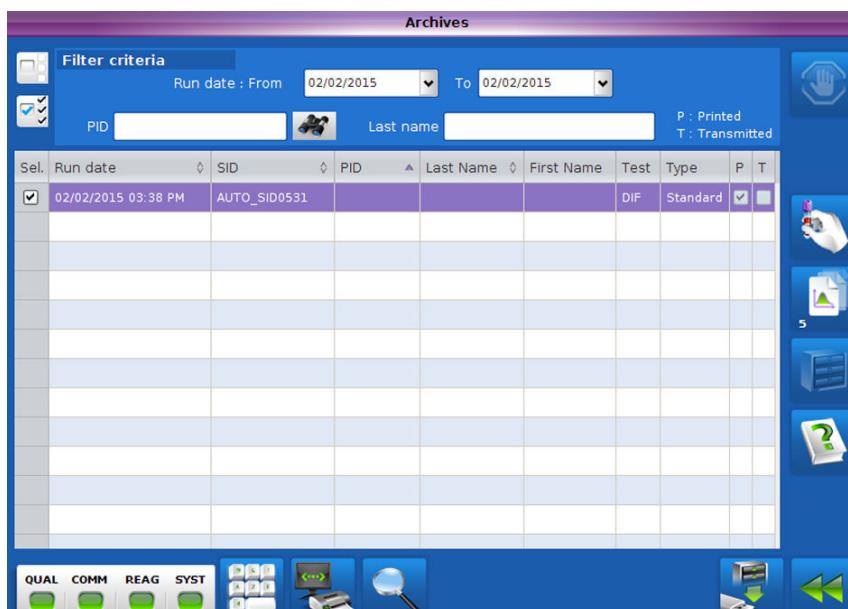
Parameter	Consequences
WBC	All the DIFF parameters are flagged with an "**".
RBC	RBC, HCT, MCV, MCH, MCHC, RDW-CV and RDW-SD are replaced by "---" and flagged with an "*".
PLT	PLT, PCT, PDW, MPV are flagged with an "**".

## 6. Archives

### 6.1. Archives Overview

Access: **Main Screen > 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 LIS transmission information

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

**Related information:**  

- [To Sort Archived Results, p.109](#)
- [To Send Archived Results to the LIS, p.109](#)
- [To Export Results, p.109](#)

## 6.2. To Sort Archived Results

---

Access: **Main Screen > Archives**

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

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

## 6.3. To Send Archived Results to the LIS

---

Access: **Main Screen > Archives**

1. Select the results you want to send from the results list.
2. Press **Print / Send** in the contextual toolbar.
3. Select one of the following options:
  - **Send all results**
  - **Send only selected results**
4. Press **Validate**.

## 6.4. To Export Results

---

Access: **Main Screen > Archives**



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

- 
1. Select the results you want to export.
  2. Press **Export Reports** in the contextual toolbar.
  3. Insert your USB flash drive.
  4. Wait during the data export.
  5. Press **Validate**.

## 7. End of Day

### 7.1. To Change Operator

---

1. Press **Back / Exit** in the contextual toolbar.
2. Press **Validate**.
3. Log in with another user name.

**Related information:**  
■ [To Log In to the Application, p.85](#)

### 7.2. Stopping the Instrument

---

#### 7.2.1. 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 allows to clean the hydraulic circuit. You should not perform any action except turning off the instrument during these 10 minutes. If you try to restart the instrument during these 10 minutes, you will have to perform 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.

### 7.2.2. To Switch the Instrument Off

1. Press **Back / Exit** to log out from the application.
2. Press **Validate**.
3. Press **Back / Exit** again 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 **Validate**.
  - b. Wait during the shutdown cycle.
  - c. Press **Back / Exit** to leave the application.
  - d. Press **Validate**.
5. If you do not want to perform a shutdown, press **Cancel** to directly leave the application.
6. Switch the instrument off.

**Related information:**

- [To Perform a Manual Shutdown, p.110](#)
- [To Schedule an Automatic Shutdown, p.125](#)

### 7.2.3. 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.

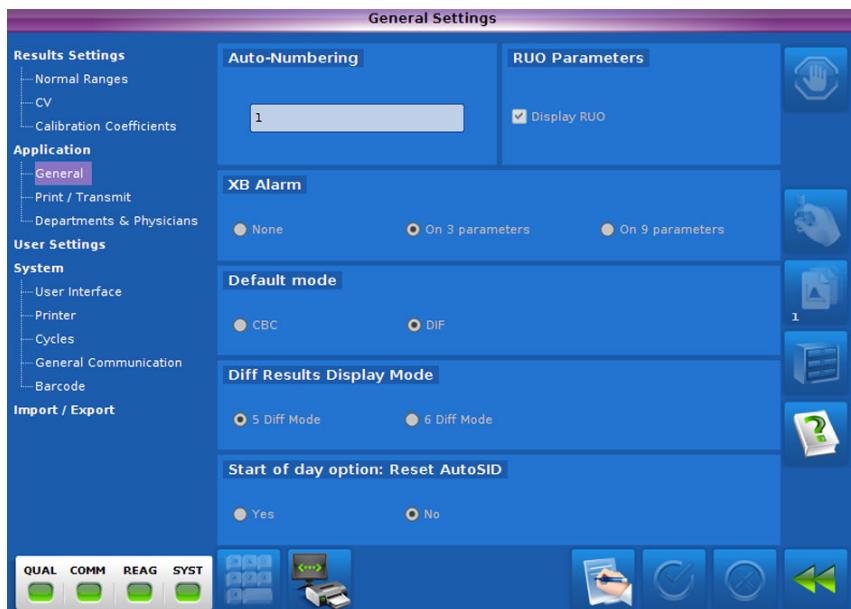


# Settings

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# 1. Configuring the Instrument

**Related information:**

- [To Modify the Sample ID Automatic Numbering, p.115](#)
- [To Activate or De-activate the RUO Parameters, p.116](#)
- [To Configure the XB Alarm, p.116](#)
- [To Select the Default Mode, p.117](#)
- [To Select the Results Display Mode, p.117](#)
- [To Reset the Sample ID Automatic Numbering, p.117](#)
- [To Configure Results Printing and Transmission, p.118](#)

## 1.1. To Modify the Sample ID Automatic Numbering

Access: **Main Screen > Settings > Application > General Settings**



Only users with the Super user 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 **Update** in the contextual toolbar.
2. Modify the **Auto-Numbering** value.

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

## 1.2. To Activate or De-activate the RUO Parameters

---

Access: **Main Screen > Settings > Application > General Settings**



*Only users with the Super user profile can perform this procedure.*

By default, the RUO parameters are displayed, printed and sent to the LIS.

1. Press **Update** in the contextual toolbar.
2. Select or deselect **Display RUO** in the **RUO Parameters** area.
3. Press **Validate** in the contextual toolbar.

## 1.3. To Configure the XB Alarm

---

Access: **Main Screen > Settings > Application > General Settings**



*Only users with the Super user profile can perform this procedure.*

1. Press **Update** 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.

## 1.4. To Select the Default Mode

Access: **Main Screen > Settings > Application > General Settings**



*Only users with the Super user profile can perform this procedure.*

1. Press **Update** in the contextual toolbar.
2. Select the default mode in the **Default Mode** area.
3. Press **Validate** in the contextual toolbar.

## 1.5. To Select the Results Display Mode

Access: **Main Screen > Settings > Application > General Settings**



*Only users with the Super user profile can perform this procedure.*

1. Press **Update** in the contextual toolbar.
2. Select the results display mode in the **Diff Results Display Mode** area.  
If you select the **5 Diff Mode** radio button, the LIC parameters are excluded from the WBC differential.  
If you select the **6 Diff Mode** radio button, the LIC parameters are included in the WBC differential.
3. Press **Validate** in the contextual toolbar.



*Note that you have to select the **5 Diff Mode** to configure the RUO parameters.*

## 1.6. To Reset the Sample ID Automatic Numbering

Access: **Main Screen > Settings > Application > General Settings**



*Only users with the Super user profile can perform this procedure.*

1. Press **Update** in the contextual toolbar.
2. Select **Yes** or **No** in the **Start of day option: Reset AutoSID** area.
3. Press **Validate** in the contextual toolbar.

## 1.7. To Configure Results Printing and Transmission

---

Access: **Main Screen > Settings > Application > Print / Transmit**

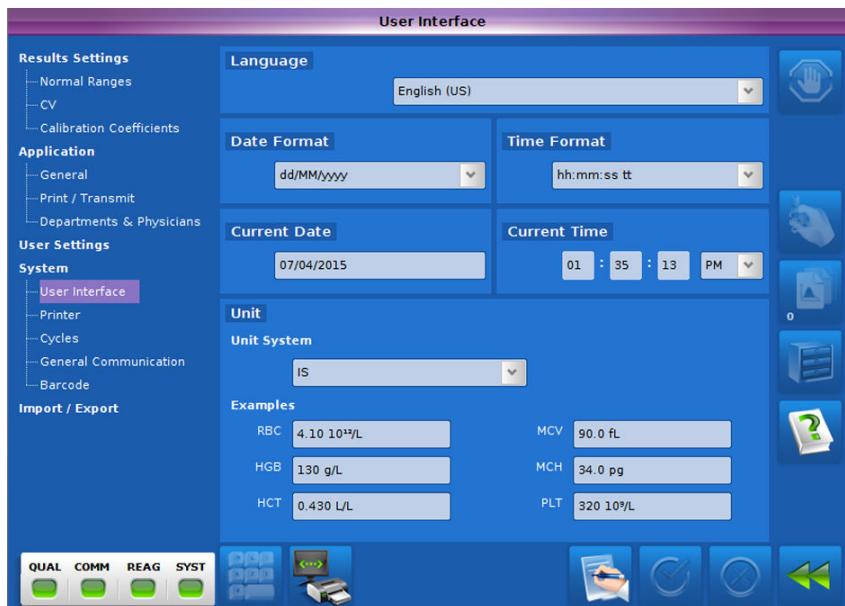


Only users with the Super user profile can perform this procedure.

---

1. Press **Update** in the contextual toolbar.
2. In the **Patients Results** area, decide if the results should be automatically printed and/or sent to the LIS.
3. In the **Control Results** area, decide if the results should be automatically printed and/or sent to the LIS.
4. Press **Validate** in the contextual toolbar.

## 2. Configuring the Interface


**Related information:**

- [To Change the Application Language, p.119](#)
- [To Change the Current Time, p.120](#)
- [To Change the Date and Time Format, p.120](#)
- [To Select the Unit System, p.121](#)
- [To Update the Contextual Help, p.121](#)
- [To Activate ISBT 128 Barcodes, p.122](#)

### 2.1. To Change the Application Language

Access: **Main Screen > Settings > System > User Interface**



Only users with the Super user profile can perform this procedure.

1. Press **Update** in the contextual toolbar.
2. Select a language from the **Language** drop-down list.  
The system prompts you to update the contextual help files.
3. Press **Validate**.
4. Press **Validate** in the contextual toolbar.



The modification becomes effective after a system restart.

## 2.2. To Change the Date and Time Format

Access: **Main Screen > Settings > System > User Interface**



Only users with the Super user profile can perform this procedure.

1. Press **Update** 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.



The modification becomes effective after a system restart.

## 2.3. To Change the Current Time

Access: **Main Screen > Settings > System > User Interface**



Only users with the Super user profile can perform this procedure.

1. Press **Update** 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.



The modification becomes effective after a system restart.

## 2.4. To Select the Unit System

Access: **Main Screen > Settings > System > User Interface**



*Only users with the Super user profile can perform this procedure.*

1. Press **Update** in the contextual toolbar.
2. Select the unit system in the **Unit System** drop-down list.
3. Press **Validate** in the contextual toolbar.



*The modification becomes effective after a system restart.*

## 2.5. To Update the Contextual Help

Access: **Main Screen > Settings > Import / Export**



*Only users with the Super user profile can perform this procedure.*

*You need to have the contextual 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 **Validate**.  
Wait for the help to be updated.
4. Press **Validate**.

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.

## 2.6. To Activate ISBT 128 Barcodes

Access: **Main Screen > Settings > System > Barcode Settings**



Only users with the Super user profile can perform this procedure.

1. Press **Update** in the contextual toolbar.
2. Select **ISBT 128** to activate ISBT 128 barcodes.
3. If necessary, select **Ignore flag characters**.
4. Press **Validate** in the contextual toolbar.

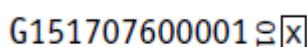
### 2.6.1. ISBT 128 Barcode Use

#### 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: =μpppyyynnnnnnff.

=	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)
pppy	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

## 2.6.2. ISBT 128 Barcode Configuration



The use of ISBT128 barcodes on the Yumizen H500 OT excludes the use of other barcode labels. It must be set by a certified HORIBA Medical technician.  
Similarly, ISBT128 barcodes cannot be used if another barcode type has been enabled.

Certified HORIBA Medical technicians 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.

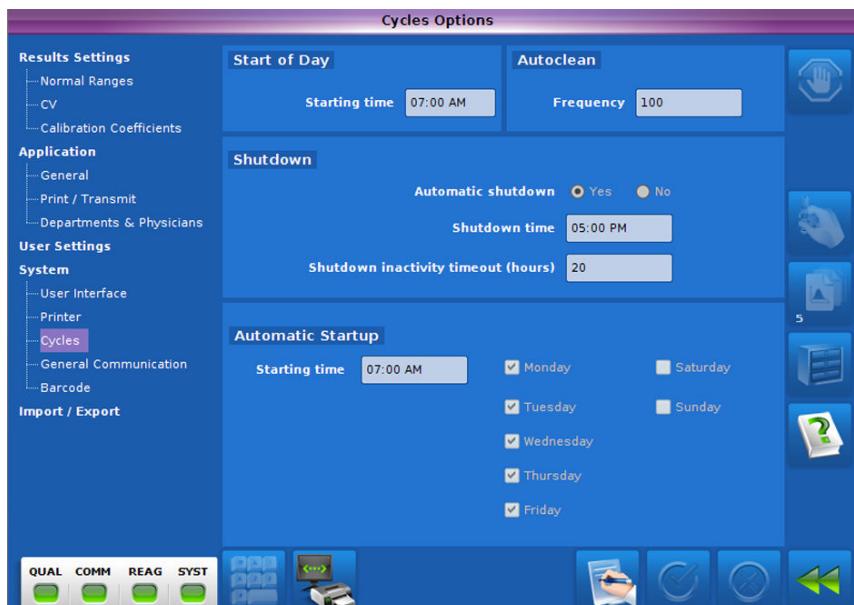
## 2.6.3. Operating With ISBT128 Barcodes

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.

### 3. Configuring the Cycles



**Related information:**

- [To Change the Starting Time of the New Session, p.124](#)
- [To Configure the Automatic Cleaning Frequency, p.125](#)
- [To Schedule an Automatic Startup, p.125](#)
- [To Schedule an Automatic Shutdown, p.125](#)

#### 3.1. To Change the Starting Time of the New Session

Access: **Main Screen > Settings > System > Cycles Options**

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 **Update** in the contextual toolbar.
2. Set the time in the **Starting Time** field.
3. Press **Validate** in the contextual toolbar.

## 3.2. To Configure the Automatic Cleaning Frequency

---

Access: **Main Screen > Settings > System > Cycles Options**

By default, an automatic cleaning is automatically run after 100 analyses.

1. Press **Update** 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.

## 3.3. To Schedule an Automatic Startup

---

Access: **Main Screen > Settings > System > Cycles Options**

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

When you schedule an automatic startup, it is run as soon as connections with the instrument and reagent levels have been checked.

1. Press **Update** 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.

## 3.4. To Schedule an Automatic Shutdown

---

Access: **Main Screen > Settings > System > Cycles Options**

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 **Update** 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.

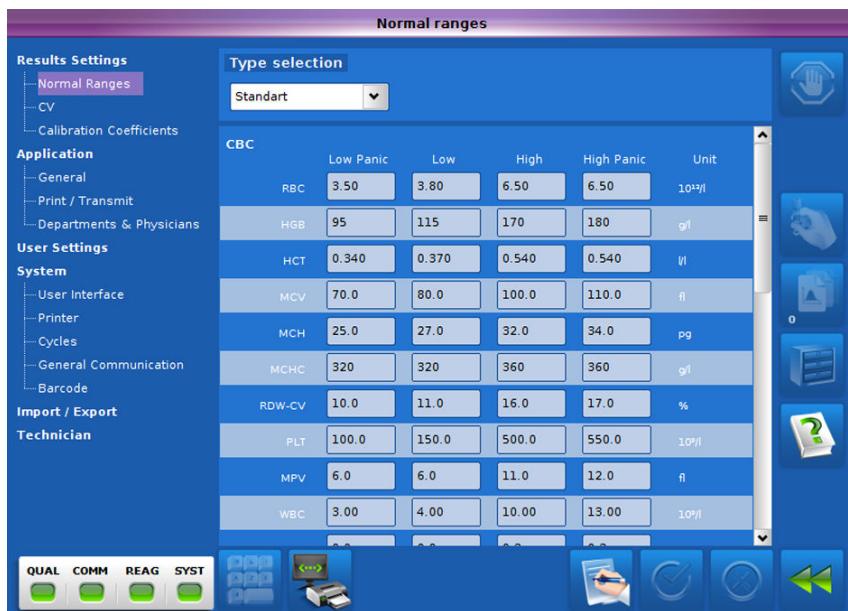


---

The shutdown cycle is efficient and valid only if the cleaner remains at least 10 minutes in the chambers after the cycle. This allows to clean the hydraulic circuit. You should not perform any action except turning off the instrument during these 10 minutes. If you try to restart the instrument during these 10 minutes, you will have to perform the shutdown cycle again.

---

## 4. Configuring the Sample Types



Eight sample types have been defined by default on the instrument:

- **Standard**
- **Man**
- **Woman**
- **Child 1:** from 1 day to 1 month old
- **Child 2:** from 1 month to 2 years old
- **Child 3:** from 2 years old to 6 years old
- **Child 4:** from 6 years old to 11 years old
- **Child 5:** from 11 years old to 14 years old



Note that you can configure the values but not the types in the software.

**Related information:**

- [To Configure the Normality Limits, p.128](#)
- [To Modify the Coefficients of Variation, p.128](#)
- [To Modify the Calibration Coefficients, p.129](#)

## 4.1. To Configure the Normality Limits

---

Access: **Main Screen > Settings > Results Settings > Normal Ranges**



*Only users with the Super user profile can perform this procedure.*

- 
1. Select a sample type from the drop-down list.
  2. Press **Update** in the contextual toolbar.
  3. Modify the values you need to update.
  4. Press **Validate** in the contextual toolbar.

## 4.2. To Modify the Coefficients of Variation

---

Access: **Main Screen > Settings > Results Settings > CV Limits**



*Only users with the Super user profile can perform this procedure.*

- 
1. Press **Update** 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.75](#)

## 4.3. To Modify the Calibration Coefficients

---

Access: **Main Screen > Settings > Results Settings > Calibration Coefficients**



*Only users with the Super user profile can perform this procedure.*

- 
1. Press **Update** in the contextual toolbar.
  2. Modify the values you need to update.
  3. 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.



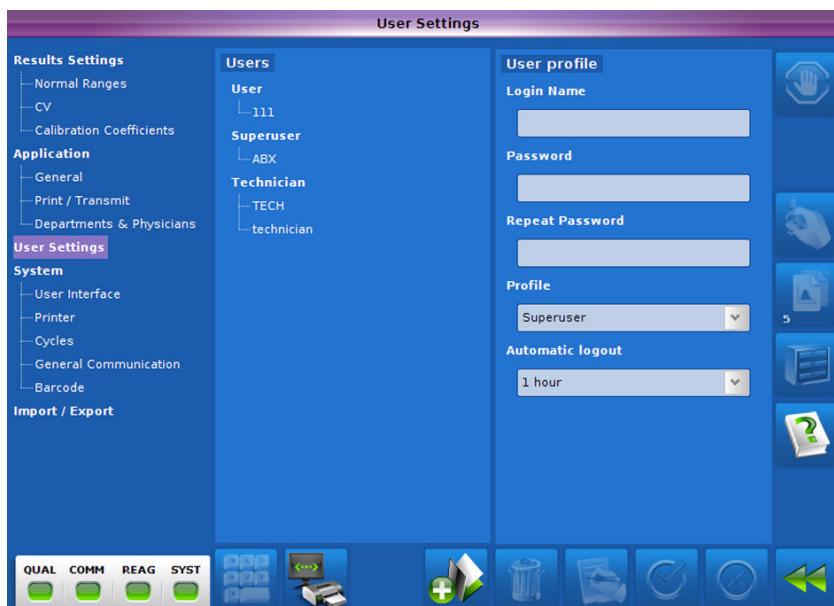
Refer to the Calibration > Calibration Results for more information about forced calibration.

**Related information:**  
■ [Calibration Results, p.75](#)

## 5. Configuring User Accounts

### 5.1. User Accounts Overview

Access: **Main Screen > 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 **Super user** profile which gives access to everything but technician menus.
- the **Technician** profile which gives access to everything.  
Reserved to HORIBA Medical approved technicians.

For each profile, you can set up an automatic logout corresponding to different security levels:

- **High security**: automatic logout after 5 minutes of inactivity.
- **Normal security**: automatic logout after 30 minutes of inactivity.
- **Low security**: automatic logout after an hour of inactivity.
- **No security**: no automatic logout.



You can only create or modify user accounts with lower access rights than yours.

## 5.2. Users Available Functions

The following table gives the available functions according to the selected user profile.

Actions	User	Super user	Technician Reserved to HORIBA Medical approved technicians.
To run a <b>Startup</b>	x	x	x
To run a <b>Shutdown</b>	x	x	x
To run patient analyzes	x	x	x
To manage control lots	x	x	x
To run control analyzes	x	x	x
To consult XB settings	x	x	x
To perform a repeatability	x	x	x
To manage a calibration		x	x
To perform a calibration		x	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 replace reagents	x	x	x
To perform cleaning cycles	x	x	x
To consult analyzes results	x	x	x
To consult control results	x	x	x
To consult logs results	x	x	x
To consult the system settings	x	x	x

## 5.3. To Create a User Account

Access: **Main Screen > Settings > User Settings**



Only users with the Super user profile can perform this procedure.

You can only create or modify user accounts with lower access rights than yours.

1. Press **Add** in the contextual toolbar.
2. Enter a login name (three to ten characters).  
Make sure it does not already exist.

3. Enter a password (three to ten characters).
4. Choose a user type from the **Profile** drop-down list.
5. Choose the level of security from the **Automatic Logout** drop-down list.
6. Press **Validate** in the contextual toolbar.

## 5.4. To Modify a User Account

---

Access: **Main Screen > Settings > User Settings**



*Only users with the Super user profile can perform this procedure.*

*You can only create or modify user accounts with lower access rights than yours.*

1. Select the user account you want to modify.
2. Press **Update** in the contextual toolbar.
3. Modify the values you need to update.
4. Press **Validate** in the contextual toolbar.

## 5.5. To Delete a User Account

---

Access: **Main Screen > Settings > User Settings**

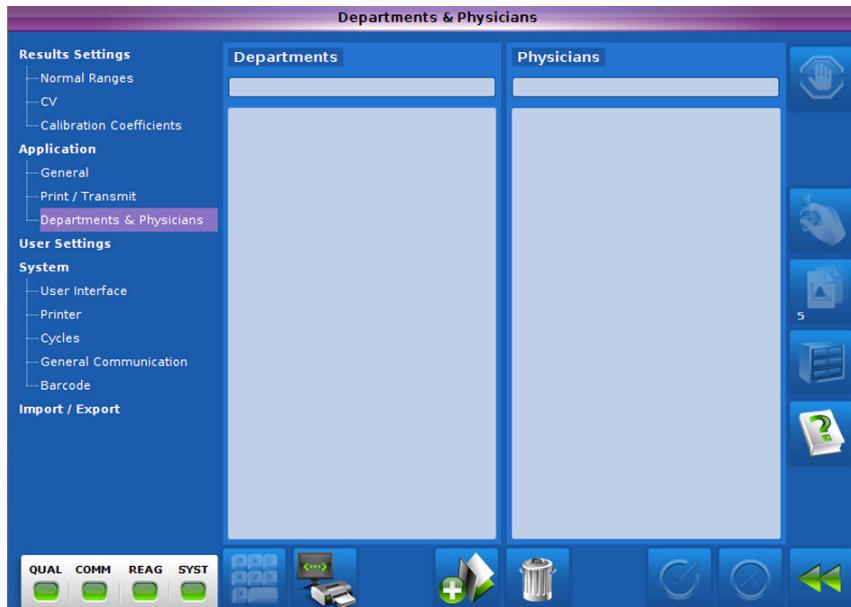


*Only users with the Super user profile can perform this procedure.*

*You can only create or modify user accounts with lower access rights than yours.*

1. Select the user account you want to delete.
2. Press **Delete** in the contextual toolbar.
3. Press **Validate**.

## 6. Configuring Departments and Physicians



### Related information:

- [To Create a Department or a Physician, p.133](#)
- [To Modify a Department or a Physician, p.134](#)
- [To Delete a Department or a Physician, p.134](#)

### 6.1. To Create a Department or a Physician

Access: **Main Screen > Settings > Application > Departments & Physicians**



Only users with the Super user profile can perform this procedure.

1. Press **Add** in the contextual toolbar.
2. Press the **Departments** area or the **Physicians** area.
3. Enter a new department or physician name in the appropriate field (20 characters maximum).
4. Press **Validate** in the contextual toolbar.

## 6.2. To Modify a Department or a Physician

---

Access: **Main Screen > Settings > Application > Departments & Physicians**



*Only users with the Super user profile can perform this procedure.*

- 
1. Press **Update** in the contextual toolbar.
  2. Press the **Departments** area or the **Physicians** area.
  3. Modify the department or physician name you want to update.
  4. Press **Validate** in the contextual toolbar.

## 6.3. To Delete a Department or a Physician

---

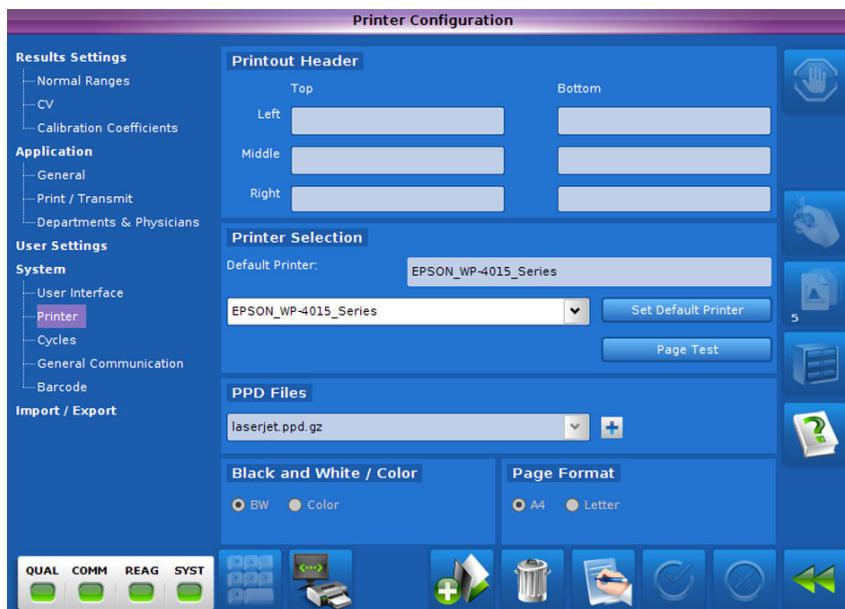
Access: **Main Screen > Settings > Application > Departments & Physicians**



*Only users with the Super user profile can perform this procedure.*

- 
1. Press **Update** in the contextual toolbar.
  2. Press the **Departments** area or the **Physicians** area.
  3. Select the department or physician name you want to update.
  4. Press **Delete** in the contextual toolbar.
  5. Press **Validate**.
  6. Press **Validate** in the contextual toolbar.

## 7. Configuring the Printer

**Related information:**

- [To Configure Printouts, p.135](#)
- [To Select a .ppd File, p.136](#)
- [To Add a Printer, p.136](#)
- [To Delete a Printer, p.136](#)
- [To Print a Test Page, p.137](#)

### 7.1. To Configure Printouts

Access: **Main Screen > Settings > System > Printer Configuration**

By default, printouts are printed in black and white on an A4 format with no headers.

1. Press **Update** 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. Select the color mode: **BW** or **Color**.
4. Select the page format: **A4** or **Letter**.
5. 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.

## 7.2. To Select a .ppd File

---

Access: **Main Screen > Settings > System > Printer Configuration**

Printers manufacturers create .ppd files (Postscript Printer Description) to describe the set of features and capabilities available for the printers.

1. To select a .ppd file from the existing list:
  - a. Press **Update** in the contextual toolbar.
  - b. Select a file from the **PPD Files** drop-down list.
  - c. Press **Validate** in the contextual toolbar.
2. To select a .ppd file from an external media:
  - a. Press the + button in the **PPD Files** area.
  - b. Select the media on which the .ppd file is stored and press **Validate**.
  - c. Select a file from the list and press **Validate**.
  - d. Go to step 1.

If you select a .ppd file, the page format and the color mode can be forced to a predefined value.

## 7.3. To Add a Printer

---

Access: **Main Screen > Settings > System > Printer Configuration**

1. Press **Add** in the contextual toolbar.
2. Select a printer from the drop-down list.
3. Press **Validate**.  
The printer is added to the list.
4. To set it as the default printer, press **Set Default Printer**.



Refer to the Introduction > Printer chapter for more information about compatible printers.

**Related information:**  
■ [Printer, p.23](#)

## 7.4. To Delete a Printer

---

Access: **Main Screen > Settings > System > Printer Configuration**

1. Select the printer to delete from the drop-down list.

2. Press **Delete** in the contextual toolbar.
3. Press **Validate**.

## 7.5. To Print a Test Page

---

Access: **Main Screen > Settings > System > Printer Configuration**

1. Select the printer in the drop-down list.
2. Press **Page Test** in the **Printer Selection** area.

## 8. Configuring the Connection to the LIS



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](http://www.horiba-abx.com/documentation).



If any doubt, please contact your local representative.

### Related information:

- [LIS Connection Configuration, p.139](#)
- [RS232 Configuration, p.139](#)
- [Network Configuration, p.139](#)
- [Analyzer Settings Configuration, p.140](#)

## 8.1. LIS Connection Configuration

---

**Access: Main Screen > Settings > System > General Communication**



Only users with the Super user profile can perform this procedure.

You need to press **Update** to select the connection mode.

Option	Function	Default function
<b>Yes</b>	Instrument is connected to the LIS	Selected
<b>No</b>	Instrument is not connected to the LIS	Not selected

## 8.2. RS232 Configuration

---

**Access: Main Screen > Settings > System > General Communication**



Only users with the Super user profile can perform this procedure.

You need to press **Update** to select the **RS232** connection mode.

Option	Function	Default value
<b>Speed</b>	Speed transmission selection	38400
<b>Parity</b>	Parity selection	NONE
<b>Stop bit</b>	Stop bit selection	1
<b>Protocol</b>	Protocol selection	NONE

## 8.3. Network Configuration

---

**Access: Main Screen > Settings > System > General Communication**



Only users with the Super user profile can perform this procedure.

You need to press **Update** to select the **Network** connection mode.

Option	Function	Default value
<b>Host IP</b>	Host IP address	Empty
<b>Port number</b>	Port number used by TCP/IP sockets	4148

## 8.4. Analyzer Settings Configuration

---

Access: **Main Screen > Settings > System > General Communication**

---



Only users with the Super user profile can perform this procedure.

---

You need to press **Update** to edit the **Analyzer Settings** data.

Option	Function	Default value
<b>Connection Mode</b>	Connection type to define	DHCP
<b>Analyzer Name</b>	DNS (Domain Name System) of the instrument	Empty
<b>IP address</b>	Instrument IP address	Empty
<b>Subnet mask</b>	Subnet mask	Empty
<b>Default gateway</b>	Default gateway	Empty

## 9. Importing and Exporting the Settings



**Related information:**

- [To Import the Settings, p.142](#)
- [To Export the Settings, p.141](#)
- [To Export the Database, p.142](#)

### 9.1. To Export the Settings

Access: Main Screen > Settings > Import / Export



Only users with the Super user 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 **Validate**.
5. When the export is complete, remove the USB flash drive and press **Validate**.

## 9.2. To Import the Settings

---

Access: Main Screen > Settings > Import / Export



Only users with the Super user 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 **Validate**.  
It can take several minutes for the import to be complete.
5. When the import is complete, remove the USB flash drive and press **Validate**.
6. Press **Back / Exit** in the contextual toolbar.  
The instrument restarts.

## 9.3. To Export the Database

---

Access: Main Screen > Settings > Import / Export



Only users with the Super user 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.

The database can only be exported.

1. Insert the USB flash drive.
2. Select **Database** in the **Import / Export** area.
3. Press **Export** in the contextual toolbar.
4. Press **Validate**.
5. When the export is complete, remove the USB flash drive and press **Validate**.

## 10. Instrument Default Settings

### 10.1. Pathological Limits

---



The pathological limits values are expressed in SI (international) units.

---

#### Standard:

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	3	4	10	13
<b>RBC</b>	3.50	3.80	6.50	6.50
<b>HGB</b>	95	115	170	180
<b>HCT</b>	0.34	0.37	0.54	0.54
<b>MCV</b>	70	80	100	110
<b>MCH</b>	25	27	32	34
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	100	150	500	550
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100
<b>NEU#</b>	1.70	2	7.50	8
<b>LYM#</b>	1	1	4	5
<b>MON#</b>	0	0.20	1	1.50
<b>EOS#</b>	0	0	0.50	0.70
<b>BAS#</b>	0	0	0.20	0.25
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.25	0.25

**Man:**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	3	4	10	13
<b>RBC</b>	3.50	3.80	6.50	6.50
<b>HGB</b>	110	130	170	180
<b>HCT</b>	0.34	0.37	0.54	0.54
<b>MCV</b>	70	80	100	110
<b>MCH</b>	25	27	32	34
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	100	150	500	550
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100
<b>NEU#</b>	1.70	2	7.50	8
<b>LYM#</b>	1	1	4	5
<b>MON#</b>	0	0.20	1	1.50
<b>EOS#</b>	0	0	0.50	0.70
<b>BAS#</b>	0	0	0.20	0.25
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.25	0.25

**Woman:**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	3	4	10	13
<b>RBC</b>	3.50	3.80	6.5	6.5
<b>HGB</b>	95	115	160	170
<b>HCT</b>	0.34	0.37	0.54	0.54
<b>MCV</b>	70	80	100	110
<b>MCH</b>	25	27	32	34
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	100	150	500	550
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100

Parameters	Panic L	Normal I	Normal h	Panic H
<b>NEU#</b>	1.70	2	7.50	8
<b>LYM#</b>	1	1	4	5
<b>MON#</b>	0	0.20	1	1.50
<b>EOS#</b>	0	0	0.50	0.70
<b>BAS#</b>	0	0	0.20	0.25
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.25	0.25

**Child 1 (from 1 day to 1 month old):**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	10	10	26	30
<b>RBC</b>	4	4	6	6
<b>HGB</b>	135	135	195	195
<b>HCT</b>	0.44	0.44	0.64	0.64
<b>MCV</b>	98	100	112	114
<b>MCH</b>	30	30	38	38
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	150	200	400	450
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100
<b>NEU#</b>	6	6	26	26
<b>LYM#</b>	2	2	11	11
<b>MON#</b>	0.40	0.40	3.10	3.10
<b>EOS#</b>	0	0	0.85	0.85
<b>BAS#</b>	0	0	0.65	0.65
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.35	0.35

**Child 2 (from 1 month to 2 years old):**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	10	10	26	30
<b>RBC</b>	4	4	6	6
<b>HGB</b>	135	135	195	195
<b>HCT</b>	0.44	0.44	0.64	0.64
<b>MCV</b>	98	100	112	114
<b>MCH</b>	30	30	38	38
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17

Parameters	Panic L	Normal I	Normal h	Panic H
<b>PLT</b>	150	200	400	450
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100
<b>NEU#</b>	6	6	26	26
<b>LYM#</b>	2	2	11	11
<b>MON#</b>	0.40	0.40	3.10	3.10
<b>EOS#</b>	0	0	0.85	0.85
<b>BAS#</b>	0	0	0.65	0.65
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.35	0.35

**Child 3 (from 2 years to 6 years old):**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	5	5	15	17
<b>RBC</b>	4.10	4.10	5.50	5.50
<b>HGB</b>	115	120	140	145
<b>HCT</b>	0.36	0.36	0.44	0.44
<b>MCV</b>	71	73	89	91
<b>MCH</b>	24	24	30	30
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	150	200	400	450
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.5	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100
<b>NEU#</b>	1.5	1.5	8.50	8.50
<b>LYM#</b>	2	2	8	8
<b>MON#</b>	0	0	0.80	0.80
<b>EOS#</b>	0	0	0.65	0.65
<b>BAS#</b>	0	0	0.20	0.30
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.35	0.35

**Child 4 (from 6 years to 11 years old):**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	4.50	4.50	13.5	15
<b>RBC</b>	4	4	5.40	5.40
<b>HGB</b>	110	115	145	150
<b>HCT</b>	0.37	0.37	0.45	0.45
<b>MCV</b>	75	77	91	93
<b>MCH</b>	24	24	30	30
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	150	200	400	450
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100
<b>NEU#</b>	1.80	1.80	8	8
<b>LYM#</b>	1.50	1.50	6.50	6.50
<b>MON#</b>	0	0	0.80	0.80
<b>EOS#</b>	0	0	0.60	0.60
<b>BAS#</b>	0	0	0.20	0.30
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.25	0.25

**Child 5 (from 11 years to 14 years old):**

Parameters	Panic L	Normal I	Normal h	Panic H
<b>WBC</b>	4.50	4.50	13.5	15
<b>RBC</b>	4	4	5.40	5.40
<b>HGB</b>	110	115	145	150
<b>HCT</b>	0.37	0.37	0.45	0.45
<b>MCV</b>	75	77	91	93
<b>MCH</b>	24	24	30	30
<b>MCHC</b>	320	320	360	360
<b>RDW-CV</b>	10	11	16	17
<b>PLT</b>	150	200	400	450
<b>MPV</b>	6	6	11	12
<b>PCT</b>	0	0.15	0.50	1
<b>PDW</b>	7	11	18	20
<b>NEU%</b>	0	0	100	100
<b>LYM%</b>	0	0	100	100
<b>MON%</b>	0	0	100	100
<b>EOS%</b>	0	0	100	100
<b>BAS%</b>	0	0	100	100

Parameters	Panic L	Normal I	Normal h	Panic H
<b>NEU#</b>	1.80	1.80	8	8
<b>LYM#</b>	1.50	1.50	6.50	6.50
<b>MON#</b>	0	0	0.80	0.80
<b>EOS#</b>	0	0	0.60	0.60
<b>BAS#</b>	0	0	0.20	0.30
<b>LIC%</b>	0	0	3	3
<b>LIC#</b>	0	0	0.25	0.25



# Maintenance and Troubleshooting

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# 1. Maintenance Procedures

## 1.1. To Remove Instrument Covers

---

*Switch the instrument off and disconnect the power supply cable.*

1. Insert an hexagonal key into the hole of the front cover and push to open.



2. Unscrew and remove the three following screws (A) at the rear of the instrument.



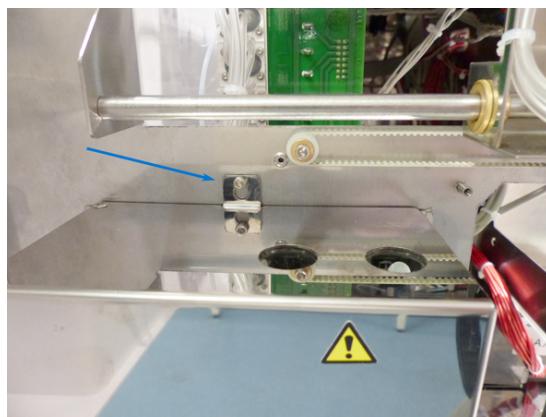
3. Loosen the two following screws (B) at the rear of the instrument.



4. Loosen the two following screws (C) on the left side and on the right side of the instrument.

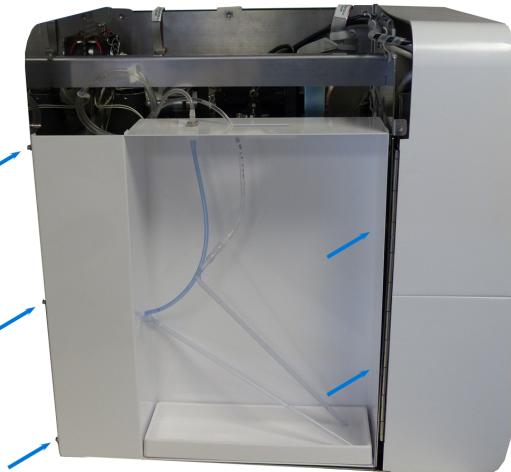


5. Remove the covers.
6. Loosen the following screw and lift the chamber cover to remove it.



Never put your fingers between the sampling needle and the chamber covers.

7. Remove the reagent bottles and loosen the five screws to remove the reagent compartment cover.



## 1.2. To Decontaminate your Instrument

### 1.2.1. To Decontaminate the Instrument Externally



- Systematically use safety gloves when cleaning the device.
- In case of liquid spillage, switch the instrument off.



- 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.

\* 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, 3rd edition" for more information.

1. Wipe all dirty surfaces thoroughly.
2. Dry all the stainless steel parts with a soft cloth.
3. Wipe the touch screen gently.
4. Dry the touch screen with a soft cloth to remove any trace of moisture.

### 1.2.2. 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.158](#)

## 1.3. To Initialize Hydraulic Assemblies

---

Access: **Main Screen > Maintenance > Hydraulic services**

The auto-control cycle resets all hydraulic assemblies to their initial position.

1. Press **Auto-control** 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: **Main Screen > 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



Perform the required maintenance cleaning cycles.

### 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	< 50 analyses per day	> 50 analyses per day
<b>Startup</b>	1 per day	1 per day
<b>Shutdown</b>	1 per day	1 per day
<b>Autoclean</b>	automatic after a predefined number of analyses <sup>1</sup>	automatic after a predefined number of analyses <sup>2</sup>
<b>Concentrated cleaning</b>	1 per week	1 or 2 per week
<b>Backflush RBC/PLT / Backflush LMNEB</b>	1 per week	1 or 2 per week

<sup>1</sup>: 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.

<sup>2</sup>: 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.86](#)
- [To Perform a Manual Shutdown, p.110](#)
- [To Perform an AutoClean Cycle, p.157](#)
- [To Configure the Automatic Cleaning Frequency, p.125](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Perform a Backflush, p.159](#)
- [To Rinse the System, p.160](#)

### 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.  
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	$\leq 0.3 \times 10^9/L$
RBC	$\leq 0.03 \times 10^{12}/L$

Parameter	Background count limits
HGB	$\leq 3 \text{ g/L}$
PLT	$\leq 5 \times 10^9 / \text{L}$

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

**Related information:**

- [Logs Overview, p.78](#)
- [Startup Failed, p.164](#)

### 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 allows to clean the hydraulic circuit. You should not perform any action except turning off the instrument during these 10 minutes. If you try to restart the instrument during these 10 minutes, you will have to perform 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 AutoClean Cycle

Access: **Main Screen > Maintenance**

1. Press **Autoclean**.
2. Wait until the cycle is over.  
An autoclean cycle takes approximately 3 minutes.

**Related information:**

- [To Configure the Automatic Cleaning Frequency, p.125](#)

### 1.5.5. To Perform a Concentrated Cleaning

Access: **Main Screen > Maintenance**

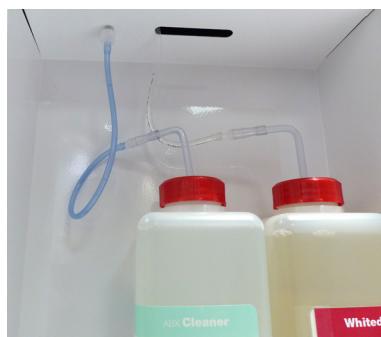
1. Press **Concentrated cleaning**.
2. When the system prompts you to, disconnect the ABX Cleaner luer connector.



3. Connect the ABX Minoclair luer connector instead.



4. Press **Validate** in the contextual toolbar.
5. Wait until the cycle is over.  
A concentrated cleaning cycle takes approximately 10 minutes.
6. When the system prompts you to, disconnect the ABX Minoclair luer connector and connect the ABX Cleaner luer connector instead.



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

*Run a startup cycle and an analysis on a control blood sample.*

**Related information:**

- [To Perform a Manual Startup, p.86](#)
- [To Run a Control Blood Sample, p.88](#)

### 1.5.6. To Perform a Backflush

Access: **Main Screen > 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: **Main Screen > 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 1L	1.35
ABX Cleaner	0.3
All	3.54

**Related information:**

- [To Replace a Reagent Bottle, p.172](#)

### 1.5.8. To Unprime a Reagent

Access: **Main Screen > 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 1L	1.35
ABX Cleaner	0.3
All	3.54

**Related information:**

- [To Replace a Reagent Bottle, p.172](#)

### 1.5.9. To Drain the System

Access: **Main Screen > 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.172](#)

### 1.5.10. To Rinse the System

Access: **Main Screen > Maintenance > Hydraulic services**

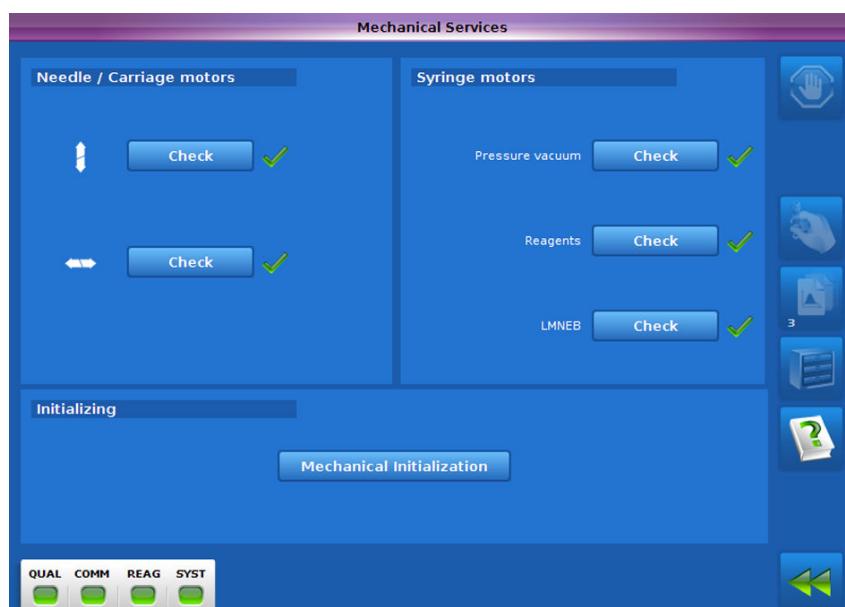
1. Press **Rinse** in the **Cleaning** area.
2. Wait until the cycle is over.  
A rinsing cycle takes approximately 40 seconds.

**Related information:**  
■ [To Decontaminate your Instrument, p.154](#)

## 1.6. To Check the Motors

Access: **Main Screen > 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. Make sure the motor movement is smooth and complete.
3. Make sure there is a green check mark next to the motor you checked.



If there is a red X mark next to the motor you checked, please contact your local HORIBA Medical representative.

4. Press **Mechanical Initialization** after checking any motor.

## 1.7. Monitoring the System

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### 1.7.1. To Check the Sensors

*Access: Main Screen > Maintenance > Dashboard*

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 Voltage

*Access: Main Screen > Maintenance > Dashboard*

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 4.7 V +/-0.5

### 1.7.3. To Check the Temperature

Access: **Main Screen > Maintenance > Dashboard**

1. In the **Temperatures** area, make sure the reagents compartment temperature is within ranges.  
The temperature should be 37°C +/-2.
2. In the **Temperatures** area, check the thermostated chamber temperature.  
The temperature should be 36°C.
3. In the **Temperatures** area, check the ambient temperature.

### 1.7.4. To Check the Draining Sensor

Access: **Main Screen > Maintenance > Dashboard**

Check the state of the draining sensor in the **Draining sensor** area.

### 1.7.5. To Check the Cycle Counter

Access: **Main Screen > Maintenance > Dashboard**

The cycle counter gives you the number of cycles run for the following cycles:

- Startup cycles
- Shutdown cycles
- Auto-clean cycles
- CBC analyses
- DIFF analyses

Check the number of cycles run in the **Cycles counters** area.

## 2. Troubleshooting Procedures

---

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:
■ <a href="#">Operation Problems, p.163</a>
■ <a href="#">Analysis Cycle Problems, p.164</a>
■ <a href="#">Repeatability Problems, p.166</a>
■ <a href="#">Flagged Results, p.168</a>

### 2.1. Operation Problems

---

#### 2.1.1. 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.

## 2.1.2. To Control the Reagents

Access: **Main Screen > 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 do so, you need to:

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.171](#)

## 2.1.3. 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.86](#)  
■ [To Replace a Reagent Bottle, p.172](#)  
■ [To Perform a Manual Startup, p.86](#)  
■ [To Perform a Concentrated Cleaning, p.158](#)

## 2.2. Analysis Cycle Problems

### 2.2.1. To Control the Mechanical Parts

Access: **Main Screen > Maintenance > Mechanical services**

Remove the covers.

1. 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.
2. Make sure the needle is not bent.
3. Replace the needle if it is bent.  
Refer to the *Maintenance and Troubleshooting > Replacement Procedures > To Replace the Sampling Needle* chapter.
4. Run an analysis on a fresh blood sample and check the results.
5. Run an analysis on a control blood sample and check the results.

**Related information:**  
■ [To Replace the Sampling Needle, p.174](#)  
■ [To Remove Instrument Covers, p.152](#)

## 2.2.2. To Control the Hydraulics

Access: **Main Screen > Maintenance > Mechanical services**

*Remove the covers.*

1. 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.
2. 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.
3. 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.
4. Run a priming cycle of Whitediff 1L in **Maintenance > Hydraulic services**.
5. Run a blank analysis.  
Make sure the results are within the ranges:

Parameter	Background count limits
WBC	$\leq 0.3 \times 10^9/L$
RBC	$\leq 0.03 \times 10^{12}/L$
HGB	$\leq 3 g/L$
PLT	$\leq 5 \times 10^9/L$



If any doubt, please contact your local representative.

**Related information:**  
■ [To Remove Instrument Covers, p.152](#)  
■ [To Check the Motors, p.160](#)

## 2.3. Repeatability Problems

### 2.3.1. Problems on all Parameters

Access: **Main Screen > 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.
  - Remove the covers.
1. 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.
  2. 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.
  3. Perform a concentrated cleaning.
  4. Run a repeatability test.

If parameters are still not repeatable, please contact your local HORIBA Medical representative.

**Related information:**

- [Analysis Cycle Problems, p.164](#)
- [To Check the Motors, p.160](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Remove Instrument Covers, p.152](#)
- [To Perform a Repeatability Test, p.70](#)

### 2.3.2. Problems on RBC, PLT and HCT

Access: **Main Screen > 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.
  - Remove the covers.
1. Run an analysis on a fresh blood sample and check the results.
  2. Visually make sure that blood is distributed in the DIL/HGB chamber.
  3. Visually check the bubbling at the bottom of the RBC/PLT chamber.
  4. 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.
  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. Perform a concentrated cleaning.

*If parameters are still not repeatable, please contact your local HORIBA Medical representative.*

**Related information:**

- [Analysis Cycle Problems, p.164](#)
- [To Check the Motors, p.160](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Remove Instrument Covers, p.152](#)
- [To Perform a Repeatability Test, p.70](#)

### 2.3.3. Problems on HGB

Access: **Main Screen > 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.
  - Remove the covers.
1. Check the expiration date and the level of the Whitediff 1L bottle.  
Replace the bottle, if necessary.
  2. Run an analysis on a fresh blood sample and check the results.
  3. Visually make sure that blood is distributed in the DIL/HGB chamber.
  4. Visually make sure that the dilution color is milky when the blood is distributed and then transparent brown when the Whitediff 1L is distributed.
  5. Make sure the HGB LED is on when the instrument is running.
  6. 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.
  7. 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.
  8. Perform a concentrated cleaning.

*If parameters are still not repeatable, please contact your local HORIBA Medical representative.*

**Related information:**

- [Analysis Cycle Problems, p.164](#)
- [To Check the Motors, p.160](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Remove Instrument Covers, p.152](#)
- [To Perform a Repeatability Test, p.70](#)

### 2.3.4. Problems on WBC DIFF

Access: **Main Screen > 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.
- Remove the covers.

1. Check the expiration date and the level of the Whitediff 1L bottle.  
Replace the bottle, if necessary.
2. Run an analysis on a fresh blood sample and check the results.
3. Visually make sure that blood is distributed in the DIL/HGB chamber.
4. Make sure the optical bench lamp is on when the instrument is running.  
Replace the lamp, if necessary.
5. Make sure there are no bubbles in the flowcell.
6. Rinse the cytometer by going to **Maintenance > Hydraulic services** and pressing **Rinse**.
7. 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.
8. 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.
9. Perform a concentrated cleaning.

*If parameters are still not repeatable, please contact your local HORIBA Medical representative.*

**Related information:**

- [Analysis Cycle Problems, p.164](#)
- [To Check the Motors, p.160](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Remove Instrument Covers, p.152](#)
- [To Perform a Repeatability Test, p.70](#)

## 2.4. Flagged Results

### 2.4.1. Flags on RBC and PLT

Access: **Main Screen > 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.
  - Remove the covers.
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. Run a priming cycle of Whitediff 1L in **Maintenance > Hydraulic services**.

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. Perform a concentrated cleaning.
6. Make sure the tubings are not too dirty.
7. 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.164](#)
- [To Check the Motors, p.160](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Remove Instrument Covers, p.152](#)
- [To Perform a Repeatability Test, p.70](#)
- [To Replace the Sampling Needle, p.174](#)

### 2.4.2. Flags on HGB

Access: **Main Screen > 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.
- Remove the covers.

1. Make sure the HGB LED is on when the instrument is running.
2. Check the expiration date and the level of the reagent bottles.



Using reagents that are not approved by HORIBA Medical can cause flagged results.

3. Run a priming cycle of Whitediff 1L in **Maintenance > Hydraulic services**.
4. Make sure the needle is not bent.
5. Replace the needle if it is bent.  
Refer to the *Maintenance and Troubleshooting > Replacement Procedures > To Replace the Sampling Needle* chapter.
6. Perform a concentrated cleaning.
7. 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.164](#)
- [To Check the Motors, p.160](#)
- [To Perform a Concentrated Cleaning, p.158](#)
- [To Remove Instrument Covers, p.152](#)
- [To Perform a Repeatability Test, p.70](#)
- [To Replace the Sampling Needle, p.174](#)

### 2.4.3. Flags on WBC DIFF

Access: **Main Screen > 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.
  - Remove the covers.
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. Run a priming cycle of Whitediff 1L in **Maintenance > Hydraulic services**.
  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. Make sure the optical bench lamp is on when the instrument is running.  
Replace the lamp, if necessary.
  6. Make sure there are no bubbles in the flowcell.
  7. Rinse the cytometer by going to **Maintenance > Hydraulic services** and pressing **Rinse**.
  8. 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.164](#)
  - [To Check the Motors, p.160](#)
  - [To Perform a Concentrated Cleaning, p.158](#)
  - [To Remove Instrument Covers, p.152](#)
  - [To Perform a Repeatability Test, p.70](#)
  - [To Replace the Sampling Needle, p.174](#)
- 170
- Yumizen H500 OT: User Manual**  
Ref: 1300011897 - Int. Ref. Doc.: RAB296AEN

## 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:** make sure a blank cycle and a control run have been performed after a reagent replacement during the day.

---

#### 3.1.1. To Replace the ABX Diluent Container

Access: **Main Screen > 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 will 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 **Validate** in the contextual toolbar.  
The system runs a prime cycle.

**Related information:**  
■ [To Control the Reagents, p.86](#)  
■ [To Prime a Reagent, p.159](#)

### 3.1.2. To Replace a Reagent Bottle

Access: **Main Screen > 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 will cause unacceptable background results especially for Platelets.

At the instrument startup, the remaining quantity of each bottle is compared to the daily workload set up by the user. If a low level is expected during the working day, a dialog box appears. You can press **Validate** and go back to running specimen until the dialog box appears again. Then, the bottle must be changed.

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 **Validate** in the contextual toolbar.  
The system runs a prime cycle.

**Related information:**  
■ [To Control the Reagents, p.86](#)  
■ [To Prime a Reagent, p.159](#)

### 3.1.3. To Replace the Waste Container

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc.). Follow your local and/or national guidelines for biohazard waste disposal.



- 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 tubes and the liquid waste tube under any circumstance.

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.84](#)

### 3.2. To Replace the Fuses

---



*Do not remove the instrument protection covers.*

---

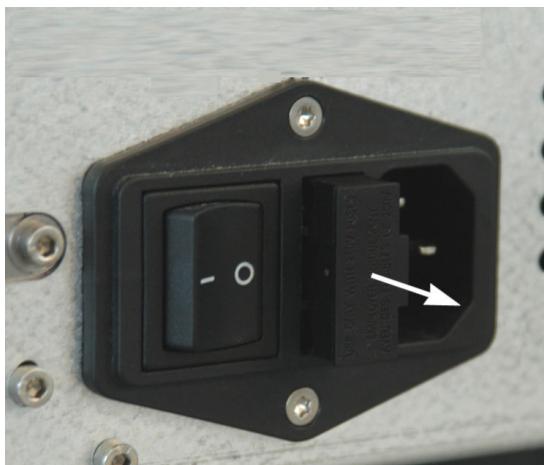


*Use only slow-blow internal fuses having the following characteristics:  
T2.5A H 250 V*

---

To replace the two fuses located on the left of the power supply connector at the back of the instrument, carry out the following procedure:

1. Switch the instrument off.
2. Disconnect the main supply cable.
3. Pull out the holding receptacle.



4. Remove the fuses from the holding receptacle.

5. Insert the new fuses in the holding receptacle.



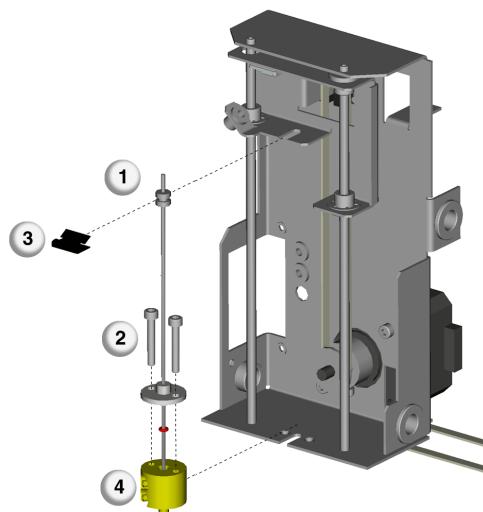
6. Insert the holding receptacle in the slot.
7. Reconnect the main supply cable.

### 3.3. To Replace the Sampling Needle

---

- *Switch the instrument off and disconnect the power supply cable.*
- *Remove the covers.*

1. Disconnect the tube from the top of the needle.  
Make sure not to bend the tube.
2. Unscrew the two screws from the needle rinsing block.
3. Remove the retaining clip.
4. Remove the rinsing block assembly.  
You do not have to disconnect tubes from the rinsing block.
5. Carefully lift the needle up and remove it.



6. Place the new sampling needle and re-assemble in reverse order.
7. Go to **Maintenance > Mechanical services**.
8. 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.
9. Run a startup cycle.  
Make sure that there are no leaks at the end of the startup cycle.
10. Run an analysis on a control blood sample and check the results.

**Related information:**

- [To Perform a Manual Startup, p.86](#)
- [To Check the Motors, p.160](#)
- [To Remove Instrument Covers, p.152](#)

### 3.4. To Replace the Optical Bench Lamp

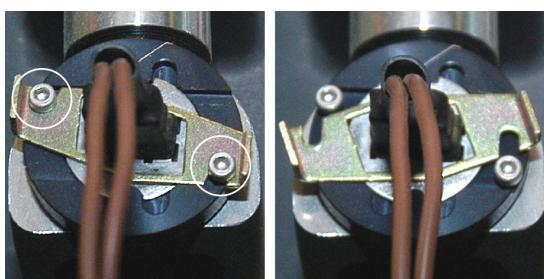
---

- *Switch the instrument off and disconnect the power supply cable.*
- *Remove the covers.*
- *Prepare a 2 mm hexagonal keys.*

1. Disconnect the lamp power supply by pressing the sides of the connector with the white cable while pulling the connector with the brown cable.



2. Loosen the lamp fixation screws.



3. Turn the lamp and remove it.
4. Replace the lamp with a new one.



Do not touch the bulb with your fingers. This will significantly reduce the shelf life of the lamp. In case of contact, clean the bulb with a solution of 90% alcohol and a soft paper towel.

5. Tighten the lamp fixation screws.
6. Reconnect the lamp to its power supply.
7. Make sure the instrument operates normally:
  - a. Reconnect the power supply cable and switch the instrument back on.
  - b. **If the lamp is on**, put the cover back.
  - c. **If the lamp is off**, check the lamp connection, remove the lamp and check its filament. Try another lamp if possible. If it still does not work, please contact your local HORIBA Medical representative.
8. Run an analysis on a fresh normal human blood sample and check the quality of the matrix.

**Related information:**

- [To Remove Instrument Covers, p.152](#)

## 4. Error Messages

### 4.1. Analyzer Error Messages

---

Message	Activation conditions	Corrective actions
Startup failed	Startup with one of the blank values out of ranges	Check blank log
Reagent syringe motor busy	Reagent syringe motor busy (outside the <b>Reagents</b> check motor command)	Run an initialization
Reagent syringe motor not reaching home	Reagent syringe motor home switch not detected after a mechanical initialization (outside the <b>Reagents</b> check motor command)	Run an initialization
Reagent syringe motor failure	Reagent syringe motor home switch still detected after a movement outside the switch (outside the <b>Reagents</b> check motor command)	Run an initialization
Reagent syringe XX step error	Reagent syringe motor loss of steps after returning back to home position (outside the <b>Reagents</b> check motor command)	Run an initialization
LMNEB syringe motor busy	LMNEB syringe motor busy (outside the <b>LMNEB</b> check motor command)	Run an initialization
LMNEB syringe motor not reaching home	LMNEB syringe motor home switch not detected after a mechanical initialization (outside the <b>LMNEB</b> check motor command)	Run an initialization
LMNEB syringe motor failure	LMNEB syringe motor home switch still detected after a movement outside the switch (outside the <b>LMNEB</b> check motor command)	Run an initialization
LMNEB syringe XX step error	LMNEB syringe motor loss of steps after returning back to home position (outside the <b>LMNEB</b> check motor command)	Run an initialization
Pressure syringe motor busy	Pressure syringe motor busy (outside the <b>Pressure Vacuum</b> check motor command)	Run an initialization
Pressure syringe motor not reaching home	Pressure syringe motor home switch not detected after a mechanical initialization (outside the <b>Pressure Vacuum</b> check motor command)	Run an initialization

Message	Activation conditions	Corrective actions
Pressure syringe motor failure	Pressure syringe motor home switch still detected after a movement outside the switch (outside the <b>Pressure Vacuum</b> check motor command)	Run an initialization
Pressure syringe XX step error	Pressure syringe motor loss of steps after returning back to home position (outside the <b>Pressure Vacuum</b> check motor command)	Run an initialization
Needle motor busy	Needle motor busy (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Needle motor not reaching home	Needle motor home switch not detected after a mechanical initialization (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Needle motor failure	Needle motor home switch still detected after a movement outside the switch (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Needle XX step error	Needle motor loss of steps after returning back to home position (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Carriage motor busy	Carriage motor busy (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Carriage motor not reaching home	Carriage motor home switch not detected after a mechanical initialization (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Carriage motor failure	Carriage motor home switch still detected after a movement outside the switch (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Carriage XX step error	Carriage motor loss of steps after returning back to home position (outside the <b>Needle / Carriage motors</b> check motor command)	Run an initialization
Electro valve XX busy	Electro valve busy (outside the check electro valves command)	Run an initialization
Reagent heater temperature sensor Out Of Order	Reagent heater temperature sensor out of order	None
Thermostatic chamber temperature sensor Out Of Order	Thermostatic chamber temperature sensor out of order	None
Ambient temperature sensor Out Of Order	Ambient temperature sensor out of order	None

**Related information:**

- [Logs Overview, p.78](#)
- [To Initialize Mechanical Assemblies, p.155](#)

## 4.2. User Error Messages

---

Message	Activation conditions	Corrective actions
Instrument stopped by user	User requires an emergency stop	Run an initialization

**Related information:**  
 ■ [To Initialize Mechanical Assemblies, p.155](#)

## 4.3. Quality Assurance Error Messages

---

Message	Activation conditions	Corrective actions
A report is not suitable for QC	Control run report has a technician alarm	Check Quality Control
No control used	No referent control profiles or empty control profiles during application start or during control profile archiving	Check Quality Control
A control report is out of ranges	At least one referent control profile accepted or failed during application start or when generating a control report	Check Quality Control
One of the XB value is upper/below 3% or the three last consecutive XB values are upper/below 2%	When an XB alarm is triggered	Check XB

**Related information:**  
 ■ [Quality Control, p.60](#)  
 ■ [Patient Quality Control \(XB\), p.66](#)

## 4.4. Reagents Error Messages

Message	Activation conditions	Corrective actions
A reagent is empty	If the level of a needed reagent is below the second low level (0-7% of the initial volume)	Check reagents status
A reagent has expired	If a needed reagent is expired	Check reagents status
A reagent remaining volume is low	If a needed reagent volume is between the first low level and the second low level (between 7% and 0-7% of the initial volume)	Check reagents status

Related information:  
■ [To Control the Reagents, p.86](#)

## 4.5. Environment Error Messages

Message	Activation conditions	Corrective actions
Embedded software error	Embedded software error	Leave the application and restart
Invalid analyzer serial number	Invalid serial number at initialization	Contact your local HORIBA Medical representative.

## 4.6. Communication Error Messages

Message	Activation conditions	Corrective actions
Field format error for the field XX of the received order	E1394 protocol error at order reception	Check <a href="#">Comm logs</a>
Order received but ignored for contextual incompatibility	Contextual issue at order reception	Check <a href="#">Comm logs</a>
Connection error	Connection error	Check <a href="#">Comm logs</a>
Low level protocol error	Low level protocol error	Check <a href="#">Comm logs</a>
High level protocol error	High level protocol error	Check <a href="#">Comm logs</a>

Related information:  
■ [Logs Overview, p.78](#)

# Description and Technology

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# 1. Yumizen H500 OT Description

## 1.1. Yumizen H500 OT Front Side

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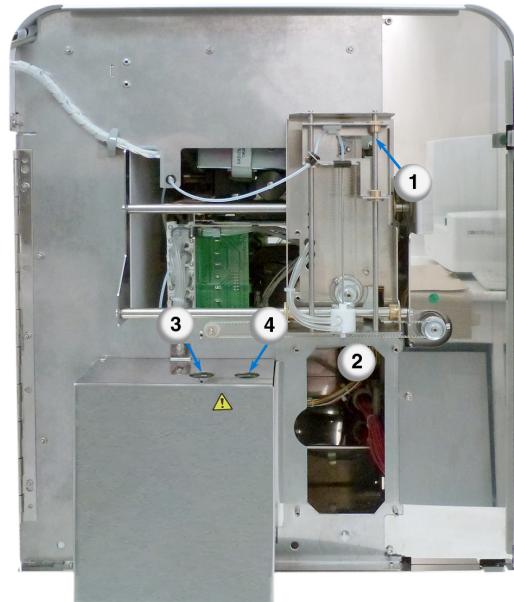
- 1 = Reagents compartment
- 2 = Sampling needle and sampling bar
- 3 = USB port
- 4 = LCD touch screen



## 1.2. Yumizen H500 OT Front Side (Covers Opened)

---

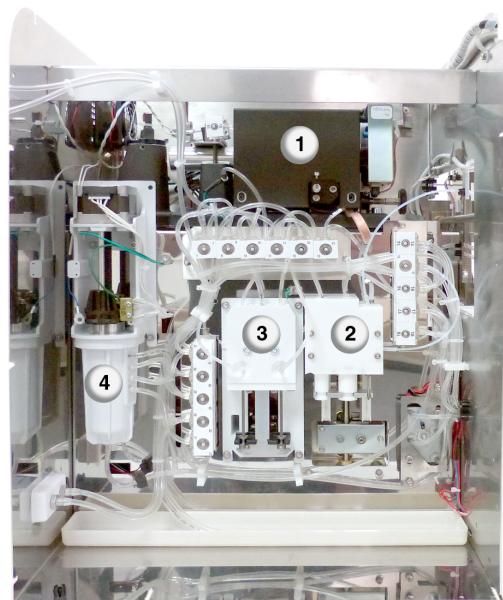
- 1 = Carriage assembly
- 2 = Sampling needle and sampling bar
- 3 = DIL/HGB chamber
- 4 = RBC/PLT chamber



## 1.3. Yumizen H500 OT Left Side

---

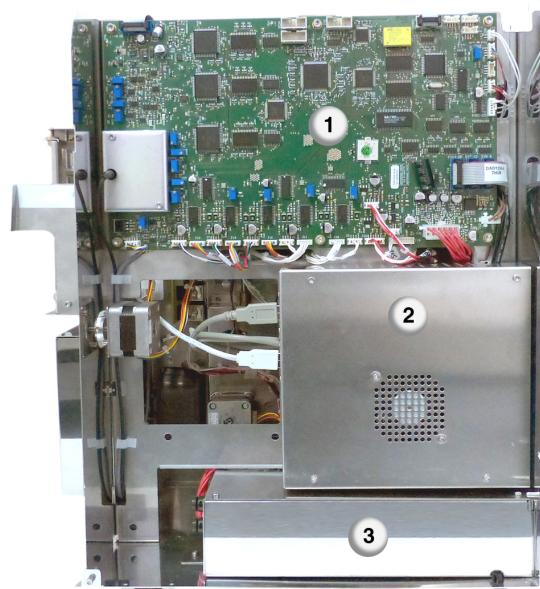
- 1 = Optical bench
- 2 = Reagent syringe assembly
- 3 = LMNEB syringe assembly
- 4 = Pressure syringe



## 1.4. Yumizen H500 OT Right Side

---

- 1 = Main board
- 2 = PC assembly
- 3 = Power supply



## 1.5. Yumizen H500 OT Rear Side

---

- 1 = Peripheral connections
- 2 = Instrument serial label
- 3 = ON/OFF button
- 4 = Power supply connection
- 5 = Diluent and waste outputs



## 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

---

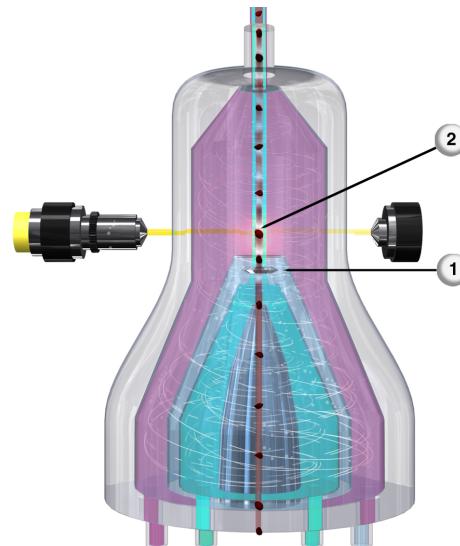
#### 2.2.1. Dilutions Description

1. 20 µL of blood is aspirated and delivered into the DIL/HGB chamber with 1 mL of ABX Diluent. The first dilution rate is 1/51.
2. 1.4 mL of Whitediff 1L is added, and the dilution incubates during 22 seconds +/- 2 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 1/121.
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 seconds 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.



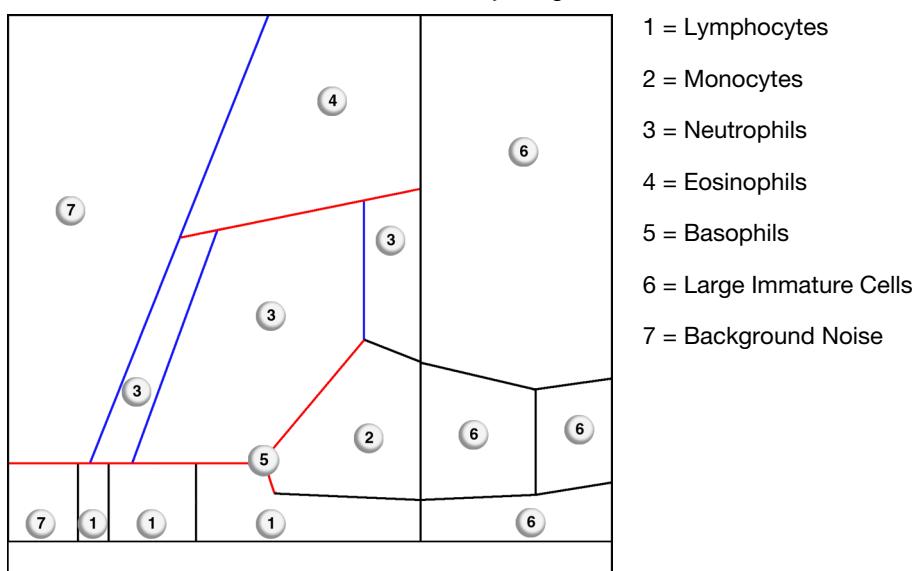
### 2.2.3. Matrix and Cells Description

#### 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 blue and the mobiles thresholds appear in red in the picture below. The black thresholds follow the red ones when adjusting the matrix.



## 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

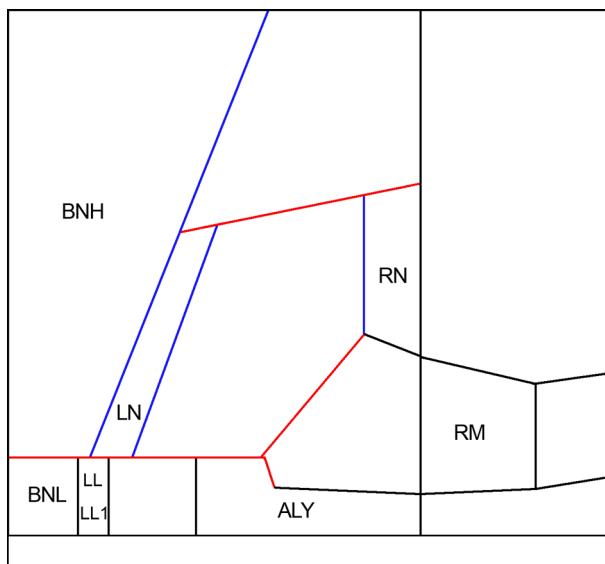
Immature granulocytic cells are detected by their larger volumes and by their increased granules which allow more light to pass through the cells, and increase the intensity of scattered light. Therefore, cells such as metamyelocytes are found at the right of the neutrophils and almost at the same level. 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.

## 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.

## 2.2.4. Alarm Default Levels

Alarms boxes 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	Level
LYM Interference	LL	150#
	LL1	16%
MON Interference	RM	1.2%
Abnormal NEU distribution	LN	15%
Atypical Lymphocytes	ALY	350#
Right Neutrophils	RN	1.2%
Background noise	BNL	25#
	BNH	80#

## 2.3. Hemoglobin Measurement

---

### 2.3.1. Dilutions Description

1. 20 µL of blood is aspirated and delivered into the DIL/HGB chamber with 1 mL of ABX Diluent. The first dilution rate is 1/51.
2. 1.4 mL of Whitediff 1L is added, and the dilution incubates during 12.5 seconds 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 1/121.

### 2.3.2. Measurement Principle

Hemoglobin is measured by spectrophotometry at a wavelength of 555 nm.

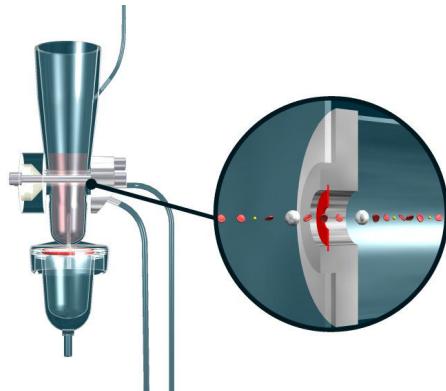
The final HGB result represents the absorbance value obtained multiplied by the coefficient of calibration.

## 2.4. Red Blood Cells and Platelets Detection

---

### 2.4.1. Dilutions Description

1. 20  $\mu$ L of blood is aspirated and delivered into the DIL/HGB chamber with 1 mL of ABX Diluent. The first dilution rate is 1/51.
2. 10  $\mu$ L 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 1/201 and the temperature of reaction is 37°C +/-2.
3. Then, the RBC and PLT are counted.

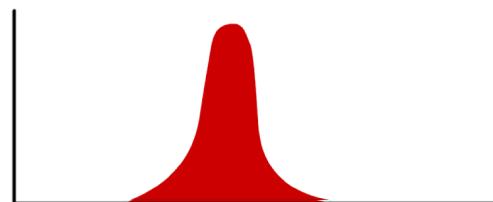
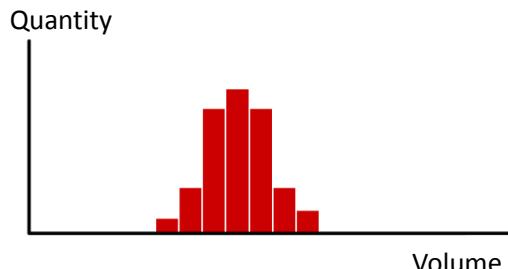


## 2.4.2. Detection Principles

### Red blood cells histogram description

The **RBC histogram** corresponds to the distribution curves on 256 channels from 30 fL to 300 fL.

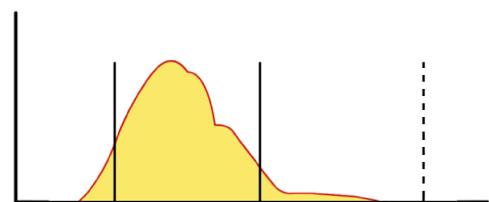
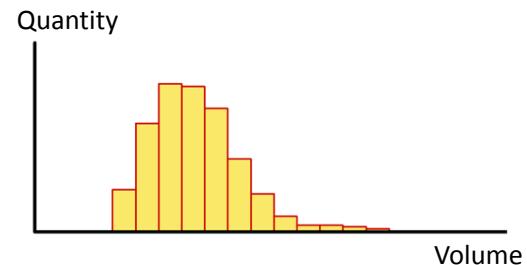
A digital analogical conversion is carried out. Then the data are integrated and the RBC distribution curve is plotted.



### 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 are 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 (Mean Cell Volume) 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**

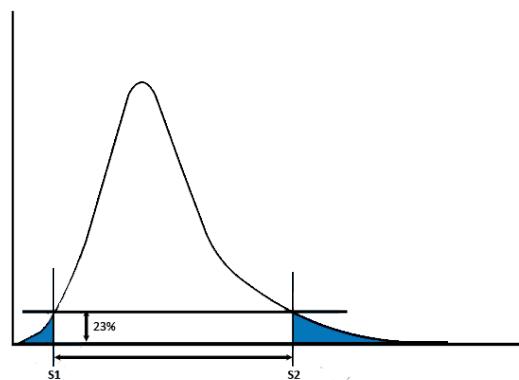
### 2.6.3. Plateletcrit Calculation

Plateletcrit (or thrombocrit) is calculated according to the formula:

$$\text{PCT} = \text{PLT} \times \text{MPV}$$

### 2.6.4. 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  $\mu\text{m}^3$ .



### 2.6.5. Large Platelets Parameters

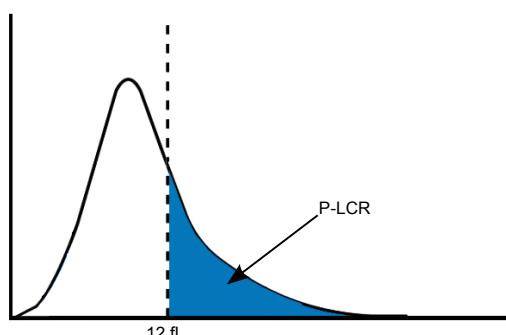
The Large Platelets parameters (P-LCC and P-LCR) allow the quantification of large-sized platelets. An increase of these parameters may indicate the presence of platelets aggregates, micro-erythrocytes and giant platelets.

#### 2.6.5.1. Platelets - Large Cell Count

The P-LCC expresses the count of large platelets that have a volume superior to 12 fL.

#### 2.6.5.2. 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 thrombocytopenia 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 H38-P).

**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.

**Reproducibility**

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 be 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).



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