2.8. Storage Conditions and Transportation

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

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

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

Keep in mind that the instrument weighs approximately 22 kg (49 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 must install your instrument and software.

Package content:

- Yumizen H500 OT
- Power supply cable
- AC/DC adapter + four feet
- Documentation USB flash drive
- Safety Information booklet
- Installation kit
- USB External Barcode Reader (optional)
- Waste tank
- Diluent container opening tool
- Protective cover

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

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

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

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

HORIBA Medical recommends that barcodes with integrated check digit be used with the Yumizen H500 OT.

1.7. Measurements and Computation

Parameters counted by impedance variation measure:

- RBC
- PLT
- WBC

Parameter measured by spectrophotometry: HGB

Parameters derived from impedance measure:

- HCT
- MCV
- MCH
- MCHC
- RDW-SD
- RDW-CV
- MIC
- MAC
- PCT
- PDW

- MPV
- P-LCC
- P-LCR

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

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

1.8. Units

CBC Parameters	SI (international)	Conventional	mmol/L	Japan	China
RBC	10^{12}/L	10^{6}/mm^3	10^{12}/L	10^{4}/µL	10^{12}/L
HGB	g/L	g/dL	mmol/L	g/dL	g/L
HCT	L/L	%	L/L	%	%
MCV	fL	fL	fL	fL	fL
MCH	pg	pg	fmol	pg	pg
MCHC	g/L	g/dL	mmol/L	g/dL	g/L
RDW-SD	fL	fL	fL	fL	fL
RDW-CV	%	%	%	%	%
MIC	%	%	%	%	%
MAC	%	%	%	%	%
PLT	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{4}/µL	10^{9}/L
PCT	%	%	%	%	%
PDW	fL	fL	fL	fL	fL
MPV	fL	fL	fL	fL	fL
P-LCC	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{4}/µL	10^{9}/L
P-LCR	%	%	%	%	%
WBC	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{2}/µL	10^{9}/L

DIFF Parameters	SI (international)	Conventional	mmol/L	Japan	China
LYM#	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{2}/mm^3	10^{9}/L
LYM%	%	%	%	%	%
MON#	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{2}/mm^3	10^{9}/L
MON%	%	%	%	%	%
NEU#	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{2}/mm^3	10^{9}/L
NEU%	%	%	%	%	%
EOS#	10^{9}/L	10^{3}/mm^3	10^{9}/L	10^{2}/mm^3	10^{9}/L

2. Physical Specifications

2.1. Power Requirements

Yumizen H500 OT characteristics:

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

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

AC/DC adapter characteristics:

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

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

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

2.2. Dimension and Weight

Yumizen H500 OT

- Instrument dimensions: 39.7 x 47.7 x 48.3 cm (15.63 x 18.78 x 19.02 in.) (Width x Depth x Height)
- Instrument weight: 22 kg (49 lbs)

2.3. Sound Level

The maximum sound level is 60 dB (A).

1 = ABX Minoclair

2 = ABX Cleaner

3 = Whitediff 1L

4 = ABX Diluent

5 = Waste tank

5.2. Reagents Description

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

Yumizen H500 OT

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

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

5.3. Reagents Consumption

Reagent consumption is given in mL per cycle.

This screen contains the following information:

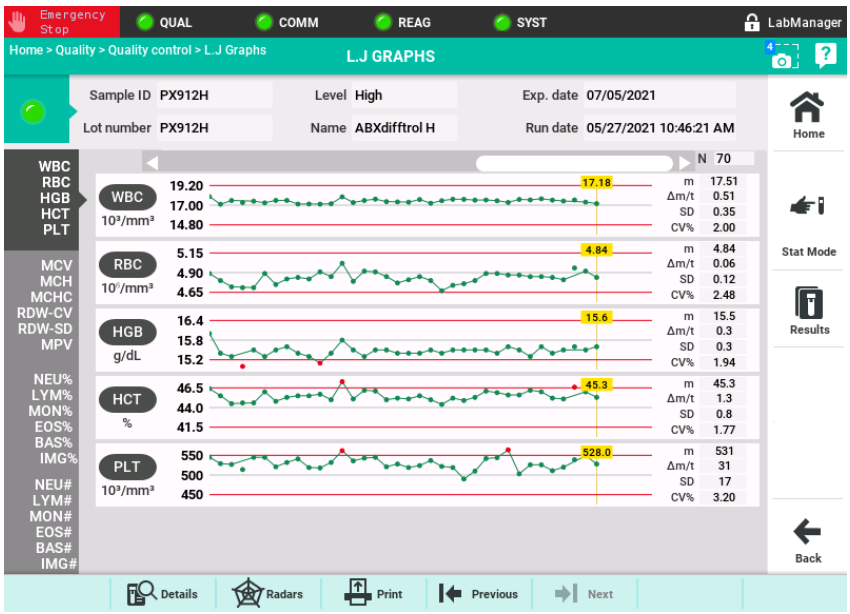
- Information about the control blood sample.
- Control blood results details for each parameter.

You can discard one or several results from the list.

L.J Graphs

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

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



This screen contains the following information:

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

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

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

Related information:

- Controls Management, p.76
- Quality Control Results Management, p.78

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

4.4. To Modify a Calibrator Lot

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

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

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

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

4.5. To Calibrate the Instrument

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

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

To calibrate the instrument, use the ABX Minocal calibrator.

1. Press **Start Calibration** in the contextual toolbar.
2. If the system prompts you to create a new calibration session, press **Confirm**.
3. Prepare the calibrator according to the instructions detailed in the calibrator package insert.
4. Gently and thoroughly mix the sample.
5. Open the tube and place it below the sampling needle. Lift it so that the needle can sample its content.
6. Press the sampling bar or press **Validate** to start sampling.
   When you hear the beep, remove the tube and put the cap back on.

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.

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

It is highly recommended to always reject failed calibrations.

4.6. Calibration Results

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

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

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

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

4.6.1. Calibration Passed

The calibration passes if:

- The percentage difference between the 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

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

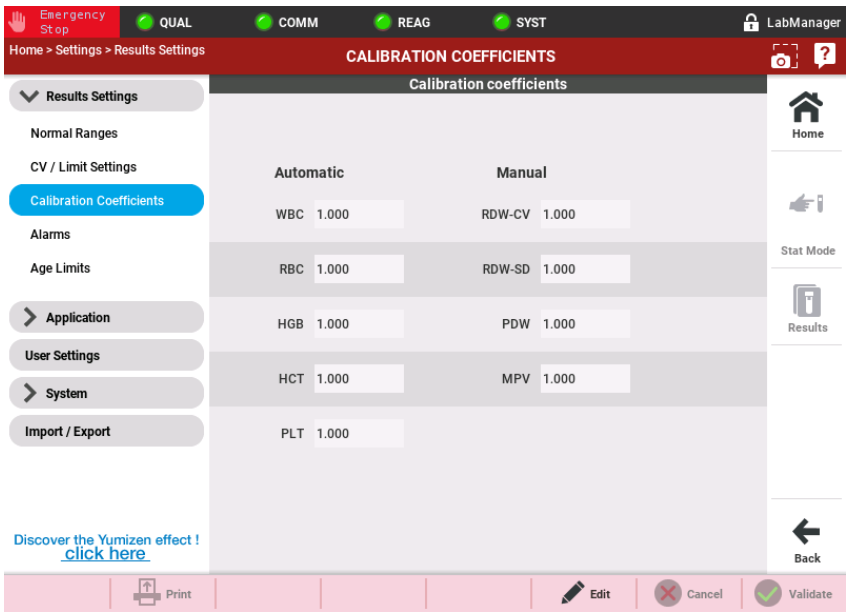
Related information:
- To Force the Calibration Coefficients, p.95

4.12. To Force the Calibration Coefficients

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

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

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



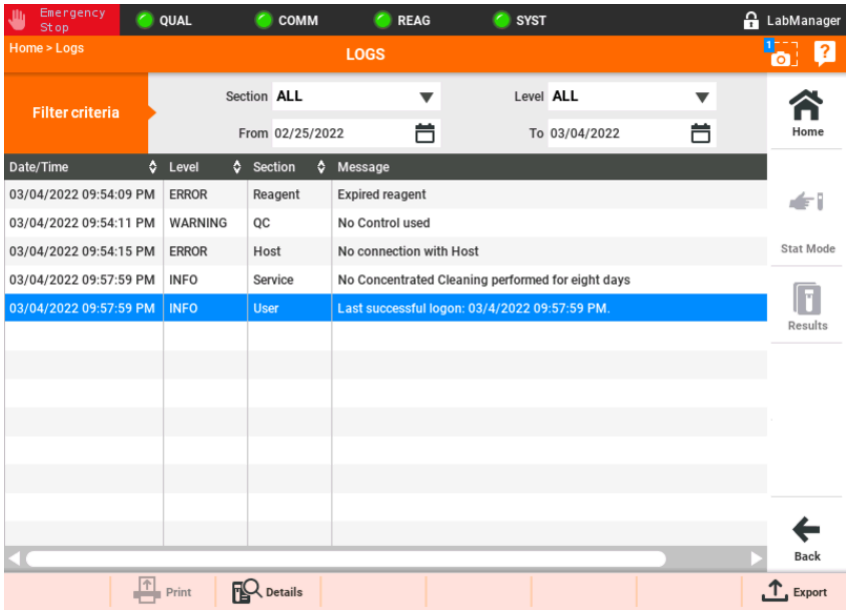
2. Press **Validate**.

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

5. Logs

5.1. Logs Overview

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



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

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

The logs are sorted according to three levels:

- **Info**: displays information about events.
- **Warning**: concerns alarming events.
- **Error**: concerns blocking events.

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

5.2. To Display Detailed Results

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

The detailed results are accessible from the following functions:

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

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

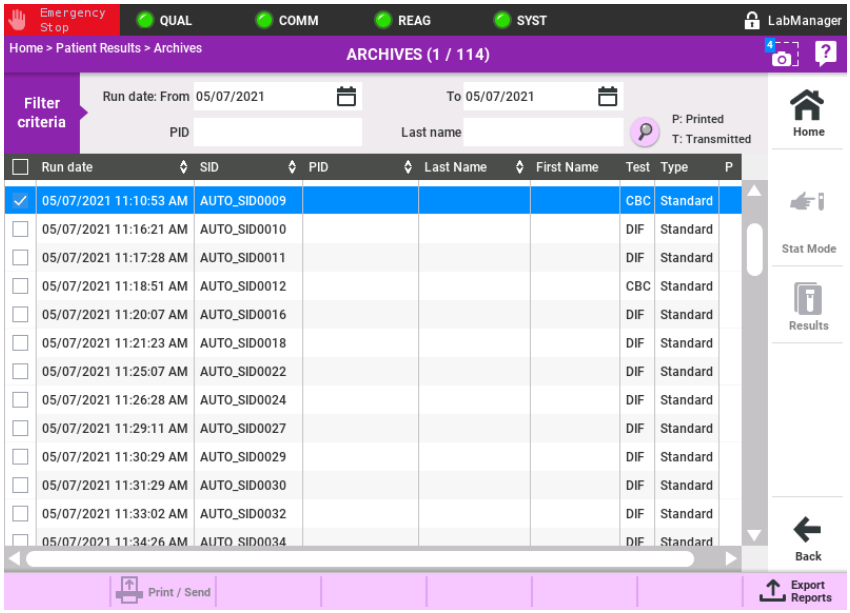
3. Verify the result status in the header of the screen (A).
   - Green: without alarm
   - Orange: hematologic alarm
   - Red: technical alarm
4. In case of alarm (orange or red), you may need to check all the parameters values and associated flags in the ***Standard*** tab (B).
   - "---": rejected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

7. Archives

7.1. Archives Overview

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

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



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

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

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

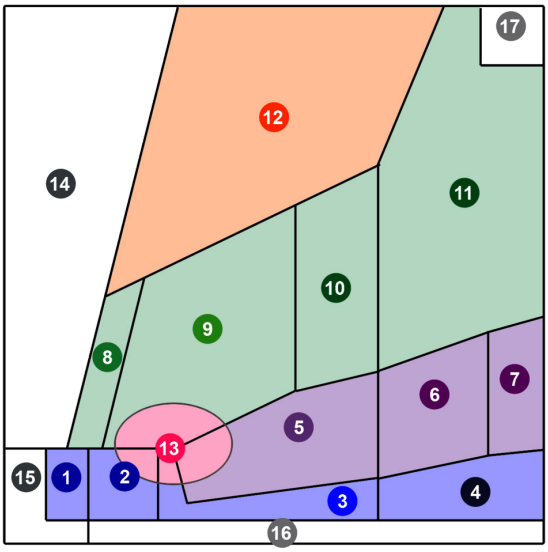
Related information:
- To Sort Archived Results, p.143
- To Send Archived Results to the Host, p.143
- To Export Results, p.120

2.6.1. To Select the 5 Diff Mode

1. Press **Edit** in the contextual toolbar.
2. Select the **5 Diff Mode** radio button in the ***Diff Results Display Mode*** area.
3. Press **Validate** in the contextual toolbar.

The WBC differential is calculated according to the following formula:

- DIFF (%): LYM% + MON% + NEU% + EOS% + BAS% = 100
- DIFF (#): LYM# + MON# + NEU# + EOS# + BAS# = WBC



LYM# = 1 + 2 + 3 + 4

MON# = 5 + 6 + 7

NEU# = 8 + 9 + 10 + 11

EOS# = 12

BAS# = 13

2.6.2. To Select the 6 Diff Mode

*The **Display RUO** check box must be selected to activate the **6 Diff Mode**.*

1. Press **Edit** in the contextual toolbar.
2. Select the **6 Diff Mode** radio button in the ***Diff Results Display Mode*** area.
3. Press **Validate** in the contextual toolbar.

The WBC differential is calculated according to the following formula:

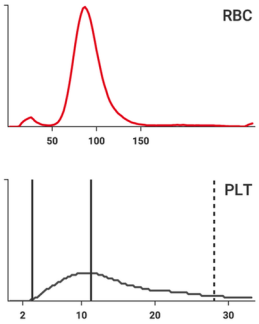
- DIFF (%): LYM% + MON% + NEU% + EOS% + BAS% + IMG% = 100
- DIFF (#): LYM# + MON# + NEU# + EOS# + BAS# + IMG# = WBC

Results

Run Date	10/03/2022 16:48:46	**Operator**	Lab Manager
Last Name		**Sample ID**	AUTO_SID0004
First Name		**Dilution**	1 / 1.00
Gender	**Age**		
Patient ID		**Department**	
		Physician	
Date of birth		**Type**	Standard
Sample comments			

CBC

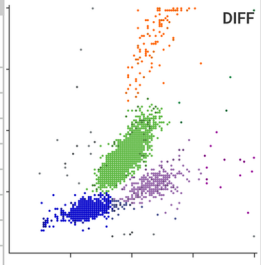
				Range
WBC	3.42	∗ℓ	10³/mm³	3.50 - 10.00
RBC	4.19		10⁶/mm³	3.80 - 6.00
HGB	14.1		g/dL	12.0 - 17.0
HCT	39.7		%	36.0 - 54.0
MCV	94.7	∗	fL	78.0 - 100.0
MCH	33.7		pg	25.0 - 34.0
MCHC	35.6	h	g/dL	32.0 - 35.0
RDW-CV	13.1	∗	%	12.0 - 18.0
RDW-SD	45.4	∗	fL	37.0 - 56.0
MIC	0.4		%	0.0 - 20.0
MAC	12.8	h	%	2.0 - 10.0
PLT	214	∗	10³/mm³	150 - 400
MPV	**12.4**	**∗H**	fL	7.4 - 12.0
PCT	0.266	∗	%	0.150 - 0.400
PDW	**26.0**	**∗H**	fL	11.0 - 20.0
P-LCC	124	∗	10³/mm³	44 - 140
P-LCR	58.1	∗h	%	18.0 - 50.0



Recommended actio 1
Slide Review
Alarms 2
No control
LMNE
Abnormal differentiation
MON Interference
WBC Interference
PLT
Schistocytes/Macro PLT?
Abnormal PDW
Synthesis WBC
LIC?
ALY?
PLT aggregates or NRBC?
Susp. Pathologies 3
Neutropenia

DIF

	%		Range	10³/mm³		Range
NEU	33.4	∗ℓ	40.0 - 75.0	**1.14**	**∗L**	1.50 - 7.00
LYM	_ . _		15.0 - 45.0	_ . _		1.00 - 4.00
MON	_ . _		4.0 - 13.0	_ . _		0.20 - 0.80
EOS	4.2	∗	0.5 - 7.0	0.14	∗	0.00 - 0.50
BAS	0.2	∗	0.0 - 2.0	0.01	∗	0.00 - 0.20
IMG	_ . _		0.0 - 2.0	_ . _		0.0 - 100.0
IMM	_ . _		0.0 - 0.5	_ . _		0.00 - 0.10
IML	_ . _		0.0 - 0.2	_ . _		0.00 - 0.05
ALY	_ . _		0.0 - 2.5	_ . _		0.00 - 0.25
LIC	_ . _		0.0 - 3.0	_ . _		0.00 - 0.20



Slide Review 4

Neutrophil	Myeloblast	Anysocytosis
Lymphocyte	Promyelocyte	Hypochromia
Monocyte	Myelocyte	Polychromasia
Eosinophil	Metamyelocyte	Poikilocytosis
Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps

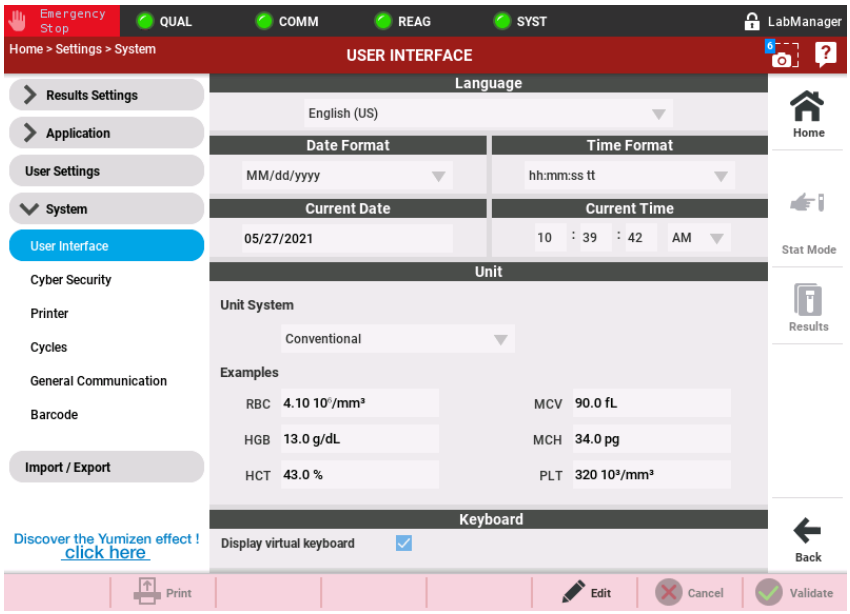
Reviewed on _____ by _____ Signature:

10/03/2022 17:10:52 **Printed by:** Lab Manager **S/N** 104YCDH03826 5 1

1 = **Recommended actions**
2 = **Quality alarms**, **Technical alarms**
3 = **Suspected pathologies**
4 = **Manual slide review**
5 = **Page footer**

4. In the ***Control Results*** area, decide if the results should be automatically printed and/or sent to the Host (LIS or Yumizen P8000).
5. Press **Validate** in the contextual toolbar.

3. Configuring the Interface



Related information:
- To Change the Application Language, p.160
- To Change the Current Time, p.161
- To Change the Date and Time Format, p.161
- To Select the Unit System, p.162
- To Configure the Virtual Keyboard, p.162
- To Update the Contextual Help, p.163
- To Activate ISBT 128 Barcodes, p.163

3.1. To Change the Application Language

*Access: **Home** > **Settings** > **System** > **User Interface***

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

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

The modification becomes effective after a system restart.

3.2. To Change the Date and Time Format

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

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

1. Press **Edit** in the contextual toolbar.
2. Select the correct date format in the **Date Format** drop-down list.
   dd stands for day, **MM** for month and **yyyy** for year.
3. Select the correct time format in the **Time Format** drop-down list.
   hh stands for hours, **mm** for minutes and **ss** for seconds.
4. Press **Validate** in the contextual toolbar.

The modification becomes effective after a system restart.

3.3. To Change the Current Time

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

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

1. Press **Edit** in the contextual toolbar.
2. Set the hours, minutes and seconds in the ***Current Time*** area.
3. For the **hh:mm:ss tt** time format, select **AM** or **PM**.
4. Press **Validate** in the contextual toolbar.

The modification becomes effective after a system restart.

Active control lots are automatically archived when changing the current time (more than two hours). Thus, you have to create the control lots and register their target values. If needed, you can recreate the same control lots.

3.4. To Select the Unit System

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

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

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

The modification becomes effective after a system restart.

3.5. To Configure the Virtual Keyboard

Access: ***Home*** > ***Settings*** > ***System*** > ***User Interface***

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

1. Press **Edit** in the contextual toolbar.
2. Select or deselect **Display virtual keyboard** in the ***Keyboard*** area.
   If the option is selected, the virtual keyboard automatically displays when you enter an editable field.
3. Press **Validate** in the contextual toolbar.

The modification becomes effective after a system restart.

3.6. To Update the Contextual Help

Access: ***Home*** > ***Settings*** > ***Import / Export***

Only users with the Lab Manager 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 **Confirm**.
   Wait for the help to be updated.
4. Press **OK**.

If the update fails, switch the instrument off and then back on, and perform this procedure again.
If the problem persists, please contact your local HORIBA Medical representative.

3.7. To Activate ISBT 128 Barcodes

Access: ***Home*** > ***Settings*** > ***System*** > ***Barcode***

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

1. Press **Edit** 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.

3.7.1. ISBT 128 Barcode Use

Specifications

The ISBT 128 system increases the level of standardization in transfusion medicine. It is an international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides a globally unique donation numbering system thanks to internationally standardized product definitions and standard data structures for bar coding and electronic data interchange.

Flag Characters

Each barcode contains two data identifier characters called "flag characters" which are embedded in the barcode. They identify the type of information coded in the barcode (e.g. ABO/Rh, Product Code), and they are followed by the specific unit information which is reproduced in an eye readable format just below the barcode.

On the example above, the flag characters are printed vertically.

Data Structure

ISBT128 barcodes have the following structure: µppppyynnnnnnff.

=	Identifier (first character)	Can be omitted in certain cases
µ	Identifier (second character): alphanumeric character {A-N; P-Z; 1-9}	Specifies the Facility Identification Number (FIN)
pppp	Four numeric characters {0-9}	
yy	Two numeric characters {0-9}	Specifies the last two digits of the year in which the product was collected
nnnnnn	Six numeric characters {0-9}	Sequence number of the donation assigned by the collection facility
ff	Two numeric characters {0-9}	Flag characters: their use must conform to national guidelines

3.7.2. 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 HORIBA Medical technical representative.
Similarly, ISBT128 barcodes cannot be used if another barcode type has been enabled.

The HORIBA Medical technical representative can either set the instrument so that flag characters are ignored, or so that they are taken into account.

Ignore Flag Characters checked

If this option is checked, the instrument manages the barcode on 13 characters instead of 15, and ignores the flag characters.

There are risks of mismatch in case two barcodes only differ in their flag characters.

Ignore Flag Characters unchecked

If this option is unchecked, the instrument manages the barcode on 15 characters, and takes the flag characters into account.

3.7.3. 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.