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# ABX MICROS ES60 OT/CT

User Manual



P/n: RAB237AEN





#### **Revisions**

Part number	Technical note	Software version	Section	Date
RAB237AEN		V1.1.X	All	13/02/09

- ◆ This document applies to the latest software version as indicated above.
- ◆ When a subsequent software version is released, only the electronic version (CD-ROM and/or online help) of this user manual is updated and supplied by HORIBA ABX. To update a paper document, please contact your local HORIBA ABX Technical Support Representative.

#### Intended use

◆ The ABX Micros ES60 OT/CT is a fully automated (microprocessor controlled) hematology analyser used for in-vitro diagnostics testing of whole blood specimens and whole blood component concentrates.



Important: when analyzing whole blood component concentrates, you must consider the linear range of the component parameter and its associated parameters if any. These concentrates may prematurely pollute the counting aperture when analyzing them. It is suggested that you perform 3 backflushes and/or a concentrated cleaning after analyzing the concentrates.

- ◆ The ABX Micros ES60 OT/CT is available in 16 and 18 parameters. These parameters are noted according to the system setup.
- ◆ The rate of determination is approximately 60 samples per hour\* in the optimum configuration. The system is totally automated, including an internal dilution system, and a graphic printer for recording all test results including flags and graphics.
- \*Throughput performance is reachable in optimized conditions with an admitted margin for variation of 10%.

#### **Notice of liability**

◆ The Information in this manual is distributed on an "As Is" basis, without warranty. While every precaution has been taken in the preparation of this manual, HORIBA ABX 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 labeling.

#### **Declaration of conformity**

◆ The ABX Micros ES60 OT/CT responds to the Standards and directives named in the Declaration of Conformity. The latest version of the CE declaration of conformity for this system is available on www.horiba-abx.com.

#### **Potential hazards**

◆ To alert the operator of potentially hazardous conditions, one of the bold captioned headings which are described below is provided wherever necessary throughout this text.



Flags a procedure that if not followed properly, can prove to be extremely hazardous to either the operator or the environment or both.



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



Emphasizes important information especially helpful to the operator before, during or after a specific operational function.

#### **Graphics**

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### 1. Warning and precautions

#### 1.1. Recommendations

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

- User manual must be entirely read and personnel trained by HORIBA ABX before attempting to operate instrument.
- The user always operates with full knowledge and appreciation of instrument warnings, alarms and flags.
- Always refer to labelling and HORIBA ABX instructions to avoid compromising system integrity.

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

- ◆The reagents and accessories stipulated by HORIBA ABX have been validated in accordance with the European Directive for in-vitro medical devices (98/79/CE).
- ◆The use of any other reagents and accessories may jeopardize the performance of the instrument, engaging the users' responsibility. In this case, HORIBA ABX takes no responsibility for the device nor for the results rendered.



- **◆Local** or national regulations must be applied to all the operations.
- ◆Cell phones should not be used in the proximity of the instrument.
- ◆All peripheral devices should comply with relevant standards.

#### 1.2. Limited guarantee

- ◆ The duration of guarantee is stipulated in the sales conditions associated with the purchase of this instrument. To validate the guarantee, ensure the following is adhered to:
- 1- The system is operated under the instructions of this manual.
- 2- Only software or hardware specified by HORIBA ABXis installed on the instrument. This software must be the original copyrighted version.
- 3- Services and repairs are provided by an HORIBA ABX authorised technician, using only HORIBA ABX approved spare parts.
- 4- The electrical supply of the laboratory adheres to national or international regulations.
- 5- Specimens are collected and stored in normal conditions.
- 6- Reagents used are those specified in this user manual.
- 7- Proper tools are used when maintenance or troubleshooting operations are performed.



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

### 1.3. Safety Precautions

#### 1.3.1. 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 tamper with the instrument and do not remove any components (covers, doors, panels and so on) unless otherwise instructed within this document.



- Moving parts: it is strictly forbidden to disable sensors as it may cause operator injuries. Protection covers must not be opened during instrument operations.
- ◆The battery may explode if it is not replaced correctly! Ask your local HORIBA ABX Technical Support Representative, replace only with the same or equivalent type recommended by the manufacturer. Dispose of used batteries according to the battery manufacturer's instructions.
- ◆ The ABX Micros ES60 OT/CT responds to IEC61010-1 (2002).

#### 1.3.2. Biological risks



Consider all specimens, reagents, calibrators, controls, etc. that contain human blood or serum 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 bio-safety procedures.

◆ If need be, use disinfectant product for instrument decontamination (including touch screen). See Section 7, 3.1. General cleaning of the instrument, page 7-5.

### 2. Operational conditions

#### 2.1. Environment

- ◆ The operation of the ABX Micros ES60 OT/CT should be restricted to indoor location use only. This instrument is operational at an altitudes of maximum 3000 meters (9800 feet) in bottle version and 3000 meters (9800 feet) in pack version.
- ◆ The ABX Micros ES60 OT/CT is designed for safety from voltage surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2 (IEC 61010-1 (2002)).



Please contact your local HORIBA ABX Technical Support Representative if use conditions do not comply with the recommended specifications.

#### 2.2. Location

- ◆ The ABX Micros ES60 OT/CT should be placed on a clean and leveled table or workbench.
- Please note that the instrument, integrated printer and reagents weigh approximately 20 kilograms (44 lbs).
- Avoid exposure to sunlight.
- ◆ Place your instrument in a well-ventilated area.
- ◆ Place your instrument where it is not exposed to water or vapor.
- ◆ 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...
- Provide a space of at least 20 cm (8 inches) at the back of the instrument for arranging the power cable and tubings.



The power switch and input voltage supply connection should always be accessible. When positioning the system for operational use, leave the required amount of space for easy accessibility 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 of the outlet grounding, contact your facilities engineer to verify the proper outlet ground.

### 2.4. Humidity/temperature conditions

- ◆ The ABX Micros ES60 OT/CT must operate between temperatures of 16°C to 30°C (61°F to 86°F). Maximum relative humidity 85% for temperatures up to 30°C (86°F) without condensation.
- ◆ If it is stored at a temperature less than 10°C (50°F), the instrument should stand for 1 hour at the correct room temperature before use.

### 2.5. Electromagnetic environment check

- ◆ The ABX Micros ES60 OT/CT 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 the case of suspected electromagnetic noise, check that the instrument has not been placed in the proximity of electromagnetic fields or short wave emissions, (i. e. Radar, X-rays, Scanners, Cell phones, etc...)

### 2.6. Main supply

- Grounding is required. Check that 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 main supply cable delivered with the ABX Micros ES60 OT/CT.
- ◆ Main supply voltage fluctuations must not exceed +/-10% of the nominal voltage.

Voltage input: ..100V to 240V (+/-10%) Frequency: ......50Hz to 60HZ

### 3. Environmental protection

#### 3.1. Disposal of 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.

#### 3.2. Disposal of ABX Micros ES60 OT/CT instrument

◆ It should be disposed of, in accordance with local legislation, and should be treated as being contaminated with blood. The appropriate biological precautions should be taken.



If any doubt, please contact your local HORIBA ABX Technical Support Representative.

#### 3.3. European Legislation

In accordance with the European Directive (2002/96/CE, known also as W.E.E.E) instruments having this symbol and sold into a European country by HORIBA ABX or an authorised representative must be disposed of and recycled correctly at the end of its useful life.



Due to the local changing regulations in each country, please contact your local representative for detailed and up-to-date information on how to appropriately dispose of the instrument.

#### 3.4. Transportation and storage conditions

◆ Condition for storage and transportation: Temperature from -20°C to +65°C (-4°F to 122°F).



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

## 4. Graphics and symbols



Switch off position



Alternating current



In Vitro Diagnostic Medical Device



Caution, consult accompanying documents



Reagent



Fragile, handle with care



Do not stack



Batch code



Use by



Calibrator



Content



Ground



Packaging recycling mark



Switch on position



Manufacturer



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



Biological risks



Up



Keep dry



Temperature limitation



Catalogue number



Consult Instructions for Use



Control



This product should be disposed of and recycled at the end of the useful life in accordance with the WEEE Directive (2002/96/CE)



Notice of environment-friendly use period

### 5. Labels

#### 5.1. Instrument rear view labels

Diag.1-1 ABX Micros ES60 OT/CT rear view



- 1- Identification label
- 2- Output label
- 3- Supply module label
- 4- Diluent and waste connection labels

#### 5.1.1. Identification label

Diag.1-2 ABX Micros ES60 OT

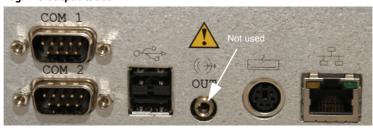


Diag.1-3 ABX Micros ES60 CT



#### 5.1.2. Output label

Diag.1-4 Output label



#### 5.1.3. Supply module label

Diag.1-5 Supply module label



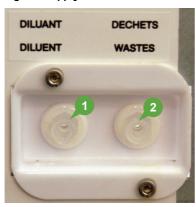
- 1- ON/OFF switch
- 2- Fuses location
- 3- Power supply connector

To replace the 2 fuses located on the left of the power supply connector on the back of the analyser, carry out the following procedure:

- ◆ Do not remove the instrument protection cover.
- Switch the instrument off.
- ◆ Disconnect the main power cable from the back power cord receptacle on the instrument.
- ◆ Pull the little flap marked "250V fuse".
- ◆ Remove the fuses from their holding receptacle
- Check for the correct ohm value on each fuse.
- ◆ Use only "Slow-blow" internal fuses.
- ◆ Use only fuses having the following characteristics: for 100/240Vac supply: F1-F2 T2AL250V

#### 5.1.4. Diluent and waste connection label

Diag.1-6 Supply module label



- 1- Diluent input connector
- 2- Waste output connector

**Waste:** connect the waste output line to the (waste position) fitting. Note the waste label for waste output "Only".

**Diluent:** connect the diluent input line to the (diluent position) fitting. Note the diluent label for diluent input "Only".

### 5.2. "Biological risks" label

◆ This label is located on the reagent compartment cover (See 1.3.2. Biological risks, page 1-4).

Diag.1-7 Biological risk label



#### 5.3. Internal label

◆ This label is located on the WBC chamber cover (main covers must be opened to reach it).
Diag.1-8 ESD label



**Electrostatic Sensitive Device (ESD).** 



The reagent and chambers are susceptible to cause ESD damage to the instrument motherboard when they are handled without ESD safe handling tools.

Make contact with the instrument ground (cover screw for example) before proceeding onto the chambers to prevent electrostatic discharges.

### 6. Presentation

The ABX Micros ES60 OT/CT, which is small in size, has 8 main parts:

- ◆ The electrical supply,
- ◆ The electronic main board,
- ◆ The dilution pneumatics,
- ◆ The control panel, including the touch screen,
- ◆ A reagent compartment,
- ◆ A printer that prints out results and distribution curves,
- ◆ A USB port for quality control result records and patient result records,
- ◆ A barcode reader (optional on ABX Micros ES60 OT) for a direct entry of the alphanumerical identifications.



The internal barcode reader allows the reading of barcodes with a resolution higher than or equal to 0.15mm.

ABX Micros ES60 models available:

- ◆ The ABX Micros ES60 CT: this model is a "Closed Tube" unit. This unit has a blood collection tube cap-piercing mechanism which allows the operator to place the tube directly into the analyser for analysis, without removing the cap.
- ◆ The ABX Micros ES60 OT: this model is an "Open Tube" unit. The operator must remove the cap from the blood collection tube before analyzing any sample.



- ◆OT and CT are indicated in the instrument serial number that identifies the unit and model.
- ◆These models are available in pack or bottles version.

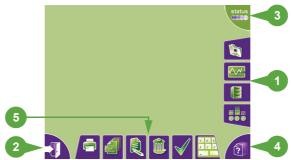
### 7. Software overview

#### 7.1. Generic screen

The generic screen is composed of:

- 1- Menu access buttons: See 7.2. Menu access buttons description, page 1-12.
- 2- Exit button: See 7.3. "Exit" button and "Exit" screen, page 1-12.
- 3- Status area: See 7.4. "Status" button description, page 1-13.
- 4- Contextual help button: See 7.5. "Contextual help" button description, page 1-14.
- 5- Contextual toolbar: See 7.6. Contextual toolbar, page 1-14.

Diag.1-9 Generic screen



#### 7.2. Menu access buttons description

◆ Menu access buttons are located on the right-hand side of the screen. These buttons allow the user to access the main functions of the system.

Button	Name	Action
	Sample identification	Launches "Sample identification" menu
	QC	Launches "Quality control" menu
	Result history	Launches "Result history" menu
	Maintenance	Launches "Maintenance" menu

◆ When a menu is selected, the active button is shown by a yellow line. The user always knows in which menu he is located.

#### 7.3. "Exit" button and "Exit" screen

◆ The "Exit" button is located on the bottom left corner of the screen (Diag.1-10).

#### Diag.1-10 Exit button



- ◆ It allows to change the user, to restart or shutdown the instrument.
- ◆ When the "Exit" button is pressed, the "Exit" screen is displayed (Diag.1-11).

Diag.1-11 Exit screen



- 1- Press radio button corresponding to the action to perform (See Tab.1-1 Exit screen icons description, page 1-13).
- 2- Press "OK" button.

Tab.1-1 Exit screen icons description

Button	Name	Description
9	Logout	Disconnects current user and displays the "Login" screen.
U	Restart	Restart the analyser.
<u>(1)</u>	Shutdown	Shutdown the analyser with or without "Parking" option.



"Parking" option is the first step to prepare the instrument for transport or is used when the instrument will not be used for a long time.

To activate this option, press "Shutdown" radio button then check the "Parking" check box.

#### 7.4. "Status" button description

- ◆ The "Status" button allows to display the "Status" area. This screen informs the user on general system state, locks and actions to perform to unlock the instrument (See Section 4, 1.5. Status area, page 4-7).
- ◆ The "Status" button has different colors according to the instrument status (Tab.1-2).

#### Tab.1-2 Instrument status

Status	Colour	Description
status	Green	The instrument is running correctly.
status	Orange	An alarm has been raised but does not lock the instrument. Analysis can be run.
status	Red	An alarm has been raised and locks the instrument. Analysis cannot be run except QC.

◆ The "Status" button blinks when a new alarm is raised.

Press "Status" button (Diag.1-12) to display the "Status" area.

Diag.1-12 Status button



### 7.5. "Contextual help" button description

◆ The "Contextual help" button (Diag.1-13) opens the help file corresponding to the current screen (context sensitive help). If no help topic is available for the current screen, the following message is displayed: "No help available for this screen."

Diag.1-13 Contextual help button





When the online help is displayed, user auto-disconnection is not active. It is reactivated when the online help is closed.

#### 7.6. Contextual toolbar

◆ Contextual toolbar is located at the lower part of the screen. It contains action buttons that are dedicated to the displayed screen.

#### 7.6.1. Action buttons

#### Tab.1-3 Action buttons description

Button	Name	Action
	Edit	Edits/modifies data
	ОК	Validates an action. In creation screens ("Control Modification", "Calibration creation", etc.), the " <b>OK</b> " button will be available only when all mandatory fields will be correctly filled.
×	Cancel	Cancels an action
	Reset	Resets the entered fields (sample identification, archives status, etc.).
	Delete	Deletes the selected item (user account, reagent, etc.)
	Back	Returns to the previous displayed screen.
	View	Displays additionnal information.

#### 7.6.2. Virtual keyboard

- ◆ A virtual QWERTY keyboard (upper case letter only) is provided by the application.
- This virtual keyboard has the same functionalities as a generic one and allows users to enter values in text fields.
- ◆ Virtual keyboard is disable when no information can be entered by the user.
- ◆ Press "Virtual keyboard" button (Diag.1-14) to access the virtual keyboard.

Diag.1-14 Virtual keyboard button



Tab.1-4 Virtual keyboard specific keys

Button	Name	Action	Description
Valid	Valid	Validation	It validates entry and moves to the next text field.
Del.	Delete	Deletion	It allows to delete entries.
<b>(</b>	Previous	Navigation	It moves the pointer backward (to the left) in the selected text field. [Only for sample identification]
<b>→</b>	Next	Navigation	It moves the pointer forward (to the right) in the selected text field. [Only for sample identification]
×	Close	Closing	It closes virtual keyboard and returns to previous screen.

◆ See Section 4, 4.2. Sample identification using the virtual keyboard, page 4-15 for more information.

#### 7.7. Data transmission buttons

◆ The buttons below allow the user to send data to the peripheral devices.

Button	Name	Action	Description
	Print	Printing	Prints data (integrated or external printer).
	Send	Sending	Sends data to the Laboratory Information System (LIS).



Some printings (LJ statistics for example) require an external printer. If this one is not configured, the "Print" button is disable.

#### 7.8. Miscellaneous

#### 7.8.1. Navigation buttons

#### **Arrows**

◆ The four arrow buttons described hereafter, allow the user to scroll between table lines and pages.

Button	Name	Description
	Up	Scrolls the upper line of the table.
	Down	Scrolls the next line of the table.
	Page up	Scrolls the previous page of the table.
<b>\rightarrow</b>	Page down	Scrolls the next page of the table.

#### "Previous" and "Next" buttons

- ◆ At the top of each result screen (patient, QC, archived results) the "Previous" and "Next" buttons allow the user to navigate between results.
- ◆ The displaying order of the result screens depends on the way that the results are sorted in the archived results list.

Button	Name	Description
	Previous	Displays the previous results screen.  If pressed, the result displayed corresponds to the result located above the selected result in the archived results list.
	Next	Displays the next results screen.  If pressed, the result displayed corresponds to the result located below the selected result in the archived results list.

◆ If no previous or next result is available, the corresponding button ("Previous" or "Next") is disable.

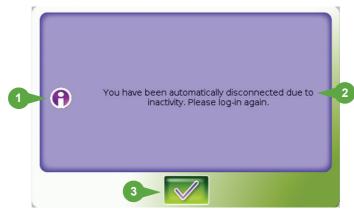
#### 7.8.2. Dialog box

- Application uses dialog boxes either to inform user about happening events (errors, confirmation, etc.) or to inform user about the next action to perform.
- Dialog boxes are modal, they must be closed prior to any other action.

#### Dialog boxes are composed of:

- 1- An icon to inform user about the message context (See Dialog box icons description, page 1-17).
- 2- The message.
- 3- Action buttons (See Dialog box action buttons, page 1-17).

Diag.1-15 Dialog box



#### Dialog box icons description

Button	Name	Description
0	Information	Displays an information message: Press ${}^{\rm H}{\rm O}{\rm K}{}^{\rm H}$ button to close the dialog box.
0	Action	Press " <b>OK</b> " button to confirm.
	Confirmation	Ask user confirmation for an action: Press $"OK"$ button to continue or $"Cancel"$ button to cancel the action.
	Error	Displays an error message: Press ${}^{\text{O}}\mathbf{K}{}^{\text{m}}$ button to close the dialog box.
0	Warning	Displays a warning message: Press " <b>OK</b> " button to close the dialog box.

#### Dialog box action buttons

◆ "OK" button: confirms an action and closes the dialog box (Diag.1-16).

Diag.1-16 OK button



◆ "Cancel" button: cancels an action and closes the dialog box (Diag.1-17).

Diag.1-17 Cancel button



◆ "Emergency stop" button: stops a cycle in progress (Diag.1-18).

Diag.1-18 Emergency stop button



#### 7.8.3. Check box

Check boxes allow to activate or de-activate software options (multiple choice):

- ◆ When it is not checked, the option is inactived (Diag.1-19).
- ◆ When it is checked, the option is activated (Diag.1-20).

Diag.1-19 Inactive

Diag.1-20 Active



◆ To use check box, the application must be in edition mode: if not, press "Edit" button.

#### **7.8.4. Combo box**

◆ A combo box is composed of a field and up and down buttons (Diag.1-21). The user can scroll between a list of values defined for the combo box.

Diag.1-21 Combo box



#### 7.8.5. Radio button

Radio buttons allow to select a software option (single choice):

- ◆ When it is not selected, the option is inactived (Diag.1-22).
- ◆ When it is selected, the option is activated (Diag.1-23).

Diag.1-22 Inactive

Diag.1-23 Active

0



### 7.8.6. Text field

◆ Text fields allow to type alphanumerical characters. Edit the text field by pressing it (Diag.1-24).

Diag.1-24 Text field



◆ To use text field, the application must be in edition mode: if not, press "Edit" button.

### 8. Installation



An HORIBA ABX representative will install your instrument.

#### 8.1. Package contents

#### 8.1.1. Package contents check

A thorough inspection is carried out on the instrument before sending it. We, nevertheless, recommend checking the total system as soon as it is received to report any anomalies to the carrier. Verify that all of the parts from the package list are present.

The ABX Micros ES60 OT/CT boxes contain the following parts:

- ◆ Instrument
- ◆ User manual CDROM: RAXO61
- ◆ Reagents, controls & calibrators CD ROM: RAX055
- Software version CDROMDaily guide: RAB238
- ◆ Installation kit (Bottle or Pack)
- ◆ Touch screen pen
- ◆ Power cable (European): DACO11A or power cable (US): DACO12A
- ◆ Paper rolls for integrated printer
- ◆ Waste tank (bottle version only)
- ◆ External barcode reader (optional)

#### 8.1.2. ABX Micros ES60 "Bottle" installation kit

The ABX Micros ES60 "bottle" installation kit (XEC001A) includes:

#### Tab.1-5 Installation kit XEC001A

Part number	Qty	Designation
DAR006A	1	Fuse, 0.8A (5x20) T 250V
DAR012A	2	Fuse, 2A (5x20) T 250V
DAR013A	2	Fuse, 2.5A (5x20) T 250V
DAR023A	1	Fuse, 4A (5x20) T 250V
EAB032A	1	Fitting "T" 1.6mm T210-6
EAE007A	2 ML	Tubing, Tygon 1.52 (0.060")
EAE009A	2 ML	Tubing, Tygon 2.29 (0.090")
FAA017A	1	0'ring 30, 8x3, 6 NIT 70SH
FAA029A	1	0'ring, 15x1, 5 NIT 70SH
FAA036A	2	0'ring, 6x1, 5 SILIC 60SH
GBC337A	1	Dust sheet
MAB001A	1	Tool, hexagonal key 2mm
MAB002A	1	Tool, hexagonal key 2.5mm
MAB003A	1	Tool, hexagonal key 1.5mm
MAB069A	1	Tool, hexagonal screwdriver 2.5
MAB090A	1	Tool, Torx key T10
XEA019A	1	Grease silicon container KM1011
XEA821A	1	Grease oil Vactra 100ml
GBG138A	1	Door, key for T° room P60

Part number	Qty	Designation
EAC019A	2	Diluent/Waste male connector
EAE011A	4 ML	Tubing, Crystal 3x6
FBL001A	1	Rubber stopper 2 holes
XDA566A	2	Red reagent bottle stopper
XEA017A	3	Reagent straw L=270mm

#### 8.1.3. ABX Micros ES60 "Pack" installation kit

The ABX Micros ES60 "pack" installation kit (XEC002A) includes:

Tab.1-6 Installation kit XEC002A

Part number	Qty	Designation
DAR006A	1	Fuse, 0.8A (5x20) T 250V
DAR012A	2	Fuse, 2A (5x20) T 250V
DAR013A	2	Fuse, 2.5A (5x20) T 250V
DAR023A	1	Fuse, 4A (5x20) T 250V
EAB032A	1	Fitting "T" 1.6mm T210-6
EAE007A	2 ML	Tubing, Tygon 1.52 (0.060")
EAE009A	2 ML	Tubing, Tygon 2.29 (0.090")
FAA017A	1	0'ring 30, 8x3, 6 NIT 70SH
FAA029A	1	0'ring, 15x1, 5 NIT 70SH
FAA036A	2	O'ring, 6x1, 5 SILIC 60SH
GBC337A	1	Dust sheet
MAB001A	1	Tool, hexagonal key 2mm
MAB002A	1	Tool, hexagonal key 2.5mm
MAB003A	1	Tool, hexagonal key 1.5mm
MAB069A	1	Tool, hexagonal screwdriver 2.5
MAB090A	1	Tool, Torx key T10
XEA019A	1	Grease silicon container KM1011
XEA821A	1	Grease oil Vactra 100ml
GBG138A	1	Door, key for T° room P60

### 8.2. Reagent installation

See Section 7, 3.5. Reagent installation, page 7-13.

#### 8.3. Instrument connectors

The following connectors are located on the rear side of the ABX Micros ES60 OT/CT. See Diag.1-25 ABX Micros ES60 OT/CT connectors, page 1-21.

- 1- 2 RS232 ports:
  - 1 to connect to the LIS (COM 1, top)
  - 1 available (COM 2, bottom)
- 2- 2 USB ports: to connect to an external printer, an external keyboard, an external barcode reader



Never type data with the external keyboard when reading barcode label with the external barcode reader. Risk of erroneous data entries!



Do not connect any printer which has not been recommended by an HORIBA ABX qualified engineer.



- ◆External barcode reader on USB port validated by HORIBA ABX is Datalogic Touch 65/90 Pro.
- ◆The external barcode reader must be configurated by HORIBA ABX.
- 3- 1 PS2 port: to connect to an external keyboard



- ◆ <u>Never</u> use a PS2 external keyboard at the same time as the external barcode reader (connected on the USB port). Risk of erroneous data entries!
- ◆ Never connect external barcode reader on PS2 port.
- 4- 1 RJ45 port: to connect to LAN Network
- 5- 1 Power supply connector
- 6- 1 Diluent input connector (not used in pack version)
- 7- 1 Waste output connector (not used in pack version)

Diag.1-25 ABX Micros ES60 OT/CT connectors



#### 8.4. Printer

#### 8.4.1. Integrated ticket printer

ABX Micros ES60 OT/CT includes an integrated ticket printer:

◆ It allows printing of results, QC tab and XB statistics. All the printouts are in grey levels.

#### Tab.1-7 Printer button

Button	Name	Action	
	Feed paper	Enable user to load paper into the printer.	
<b>*</b> + <b>*</b>	Printer self test	Press both button simultaneously and start the instrument with the "ON/OFF" button to start a printer self test.  When printer self test is completed, press Feed paper button to start the printer.	



<u>Integrated ticket printer accepts "latin characters" only</u>. Please use an external printer when non "latin characters" are used.

#### 8.4.2. External printer (optional)

An external printer can be set up and used instead of the integrated ticket printer. The external printer can be used:

- ◆ Locally (connected to the USB port)
- ◆ Remotely (connected to laboratory network)
  - ◆User must check his printer compatibility with ABX Micros ES60 OT/CT.
  - ◆ A non exhaustive list of printers that can be used with the instrument can be found on the website: http://www.horiba-abx.com/documentation: Other/printers/instrument printer list/abx micros es60.



◆ For more detailed information, please contact your local HORIBA ABX Technical Support Representative.

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## 1. Specifications

### 1.1. Introduction

- ◆ WBC, RBC and PLT histograms
- ◆ Quantitative flags
- ◆ Parameter selection by software settings



The ABX Micros ES60 OT/CT performs automated blood counts and requires no manual operations for aspirating blood, dilutions, measuring, calculations, print-outs and computer transfer of data. The parameters are given according to the internal setup.

#### 1.2. Parameters

#### Tab.2-1 16 parameters

Parameter	Definition
WBC	White Blood Cells
LYM%	Lymphocyte percentage
LYM#	Lymphocyte absolute value
MON%	Monocyte percentage
MON#	Monocyte absolute value
GRA%	Granulocyte percentage
GRA#	Granulocyte absolute value
RBC	Red Blood Cells
HGB	Hemoglobin
НСТ	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red cell Distribution Width
PLT	Platelets
MPV	Mean Platelet Volume
WBC, RBC and PLT Distribution Curves	

Tab.2-2 18 parameters

Parameter	Definition
WBC	White Blood Cells
LYM%	Lymphocyte percentage
LYM#	Lymphocyte absolute value
MON%	Monocyte percentage
MON#	Monocyte absolute value
GRA%	Granulocyte percentage
GRA#	Granulocyte absolute value
PDW*	Platelet Distribution Width
PCT*	Plateletcrit
RBC	Red Blood Cells

Parameter	Definition		
HGB	Hemoglobin		
НСТ	Hematocrit		
MCV	Mean Corpuscular Volume		
MCH	Mean Corpuscular Hemoglobin		
MCHC	Mean Corpuscular Hemoglobin Concentration		
RDW	Red cell Distribution Width		
PLT	Platelets		
MPV	Mean Platelet Volume		
WBC, RBC and PLT Distribution Curves			



PDW and PCT have not been established as indications for this product, in the United States. The use of PDW and PCT should be restricted to research and Investigational measurements only.

### 1.3. Instrument specifications

Tab.2-3 Instrument specifications

ABX Micros ES60 CT/ABX Micros ES60 OT				
Throughput analysis*	OT: 60 samples/hour CT: 50 samples/hour			
Minimum sample volume	Minimum blood sample requirement: 50μl Analyser sample volume: 10μl			
Dilution ratios	WBC: approximately 1/260 RBC/PLT: approximately 1/15000			
Measurements and computation	Impedance change for WBC, RBC, PLT. Spectrophotometry for HGB. Numeric integration for HCT. Impedance change for LYM%, MON%, GRA%. Computation from stored data that was directly measured for MCV, MCH, MCHC, RDW, MPV, LYM#, MON#, GRA#, PCT, PDW.			
Counting aperture diameter	WBC: 80μm. RBC: 50μm.			
Hemoglobin measurement	Performed in the WBC/HGB chamber. Light source LED (Light Emiting Diode) at wavelength 550nm.			
Statistics and quality control	Extended quality control package.			
Calibration	Automatic calibration procedure. Direct entering of calibration coefficients. Calibrator: ABX Minocal (2mL) Ref. 2032002			
Reagents**	3 reagents or 1 pack of reagents:  Diluent: ABX Minidil LMG (10L) Ref. 0802010  Cleaner: ABX Miniclean (1L) Ref. 0403010, ABX Cleaner (0.5L) Ref. 0903011  Lyse: ABX Minilyse LMG (1L) Ref. 0702010, ABX Alphalyse 360 (0.36L) Ref. 0906014, ABX Alphalyse (0.4L) Ref. 0906004  Pack all reagents: ABX Minipack LMG (4.2L) Ref. 0602050			
Controls	ABX Minotrol 16 Twin Pack: 2N Ref. 2042202 ABX Minotrol 16 Twin Pack: 1H/1B Ref. 2042204			
Wastes	Automatic disposal Waste handling according to local/national regulations			

<sup>\*</sup> Throughput performance is reachable in optimized conditions with an admitted margin for variation of 10%.



\*\* The CD-ROM RAX055 delivered with your instrument provides reagent, control and calibrator leaflets/msds. Latest versions of these documents are available on www.horiba-abx.com/documentation.

## 1.4. Technical specifications

#### Tab.2-4 Technical specifications

	ABX Micros ES60 CT/ABX Micros ES60 OT
Software	Designed by HORIBA ABX, installed on a Flash EPROM
Memory capacity	1000 results
Display	Operated touch screen, LVDS screen: 8"4, 640x480, 256000 colours
Outputs	Hard copy printing (integrated or external printer) External output (RS232)
Barcode reader	C 39, C 128, ISBT C128, ITF (2of5), CODABAR with or without Checksum. External barcode reader is optional.
Integrated ticket printer	
Power requirements	Power supply: 100V, 240V (+/- 10%) 50/60Hz.  Power consumption:  Maximum: 150VA (-30%, +10%)  In use: 100VA (-30%, +10%)  Stand-by mode: 35 VA (-30%, +10%)  Heat output: 293kJ/h (280BTU/h)
Sound pressure level	53 dB (A)
Dimensions	Height: approximately 430mm (16.9 inches) Width: approximately 360mm (14.2 inches) Depth: approximately 360mm (14.2 inches)
Weight	Weight (without reagents): CT: approximately 17kgs (37.5 lbs) OT: approximately 14kgs (30.9 lbs)

## 2. Summary of performance data

### 2.1. Precision (Reproducibility)

- ◆ The ABX Micros ES60 OT/CT was initially calibrated with Minocal calibrator (lot N° MCAL058).
- ◆ Three levels of ABX Minotrol 16 control material (lot N°: MX058) were run in duplicate twice daily for 20 days. The results were used to quantify within run precision, SD of the run means, SD of the daily means and the total imprecision with the NCCLS EP-5 Guidelines.

#### **Precision SD**

Tab.2-5 Precision SD (ABX Micros ES60 OT)

Parameters	MINOTROL 16 Control	Within run SD	SD of runs means	SD of daily means	Total imprecision (SD)
	MX058 High	0.27	0.19	0.20	0.31
WBC	MX058 Normal	0.12	0.09	0.08	0.13
	MX058 Low	0.06	0.04	0.04	0.07
	MX058 High	0.06	0.05	0.05	0.08
RBC	MX058 Normal	0.04	0.03	0.05	0.06
	MX058 Low	0.02	0.03	0.03	0.04
	MX058 High	0.09	0.12	0.10	0.15
HGB	MX058 Normal	0.07	0.10	0.10	0.13
	MX058 Low	0.05	0.09	0.06	0.10
	MX058 High	0.61	0.38	0.46	0.68
HCT	MX058 Normal	0.29	0.29	0.37	0.47
	MX058 Low	0.16	0.13	0.23	0.27
	MX058 High	0.32	0.58	0.26	0.54
MCV	MX058 Normal	0.27	0.62	0.30	0.57
	MX058 Low	0.22	0.59	0.22	0.50
	MX058 High	14.23	9.27	6.92	13.86
PLT	MX058 Normal	7.20	5.40	5.15	8.19
	MX058 Low	4.96	3.09	3.44	5.38
	MX058 High	0.29	0.18	0.12	0.27
GRA%	MX058 Normal	0.51	0.39	0.40	0.61
	MX058 Low	1.03	0.62	0.61	1.05
	MX058 High	0.27	0.20	0.10	0.26
LYM%	MX058 Normal	0.48	0.41	0.41	0.61
	MX058 Low	1.08	0.83	0.76	1.23
	MX058 High	0.17	0.15	0.11	0.19
MON%	MX058 Normal	0.26	0.18	0.17	0.28
	MX058 Low	0.63	0.50	0.44	0.72

# **Specifications**

Tab.2-6 Precision SD (ABX Micros ES60 CT)

Parameters	MINOTROL 16 Control	Within run SD	SD of runs means	SD of daily means	Total imprecision (SD)
	MX058 High	0.19	0.16	0.22	0.28
WBC	MX058 Normal	0.09	0.09	0.09	0.13
	MX058 Low	0.04	0.05	0.04	0.06
	MX058 High	0.06	0.04	0.06	0.08
RBC	MX058 Normal	0.05	0.04	0.05	0.06
	MX058 Low	0.03	0.02	0.04	0.05
	MX058 High	0.12	0.09	0.20	0.23
HGB	MX058 Normal	0.08	0.10	0.17	0.19
	MX058 Low	0.06	0.05	0.14	0.16
	MX058 High	0.56	0.40	0.48	0.68
HCT	MX058 Normal	0.39	0.35	0.35	0.51
	MX058 Low	0.22	0.21	0.25	0.33
	MX058 High	0.30	0.68	0.35	0.63
MCV	MX058 Normal	0.27	0.72	038	0.67
	MX058 Low	0.34	0.56	0.34	0.57
	MX058 High	10.69	7.39	7.23	11.69
PLT	MX058 Normal	6.67	6.53	5.20	8.41
	MX058 Low	4.24	2.57	2.86	4.53
	MX058 High	0.29	0.25	0.14	0.31
GRA%	MX058 Normal	0.49	0.46	0.42	0.63
	MX058 Low	1.08	0.54	0.59	1.04
	MX058 High	0.17	0.16	0.14	0.22
LYM%	MX058 Normal	0.26	0.20	0.20	0.31
	MX058 Low	0.63	0.56	0.46	0.75
	MX058 High	0.27	0.23	0.17	0.30
MON%	MX058 Normal	0.47	0.47	0.43	0.64
	MX058 Low	1.16	0.78	0.76	1.25

#### **Precision CV%**

Tab.2-7 Precision CV% (ABX Micros ES60 OT)

Parameters	MINOTROL 16	Within run	CV% of run	CV% of daily	Total imprecision
	Control	CV%	means	means	(CV%)
	MX058 High	1.35%	0.97%	1.01%	1.55%
WBC	MX058 Normal	1.56%	1.25%	1.05%	1.76%
	MX058 Low	2.96%	2.17%	2.03%	3.29%
	MX058 High	1.13%	0.86%	0.94%	1.38%
RBC	MX058 Normal	0.78%	0.71%	1.00%	1.25%
	MX058 Low	0.98%	1.12%	1.40%	1.75%
	MX058 High	0.51%	0.66%	0.55%	0.80%
HGB	MX058 Normal	0.49%	0.70%	0.77%	0.98%
	MX058 Low	0.86%	1.44%	0.96%	1.53%
	MX058 High	1.20%	0.76%	0.90%	1.35%
HCT	MX058 Normal	0.78%	0.76%	1.00%	1.26%
	MX058 Low	0.95%	0.79%	1.39%	1.65%
	MX058 High	0.36%	0.66%	0.30%	0.61%
MCV	MX058 Normal	0.34%	0.77%	037%	0.70%
	MX058 Low	0.31%	0.82%	0.31%	0.69%
	MX058 High	2.97%	1.94%	1.45%	2.90%
PLT	MX058 Normal	2.97%	2.23%	2.12%	3.38%
	MX058 Low	6.44%	4.02%	4.47%	6.98%
	MX058 High	0.36%	0.22%	0.15%	0.34%
GRA%	MX058 Normal	0.86%	0.64%	0.67%	1.01%
	MX058 Low	3.66%	2.18%	2.15%	3.70%
	MX058 High	1.89%	1.36%	0.71%	1.80%
LYM%	MX058 Normal	1.45%	1.24%	1.25%	1.84%
	MX058 Low	1.76%	1.36%	1.24%	2.01%
	MX058 High	3.80%	3.35%	2.45%	4.34%
MON%	MX058 Normal	3.69%	2.62%	2.40%	4.00%
	MX058 Low	5.92%	4.77%	4.11%	6.77%

Tab.2-8 Precision CV% (ABX Micros ES60 CT)

Parameters	MINOTROL 16	Within run	CV% of run	CV% of daily	Total imprecision
raiailleteis	Control	CV%	means	means	(CV%)
	MX058 High	0.95%	0.82%	1.08%	1.40%
WBC	MX058 Normal	1.22%	1.25%	1.15%	1.69%
	MX058 Low	2.06%	2.58%	1.97%	3.05%
	MX058 High	1.03%	0.66%	0.96%	1.29%
RBC	MX058 Normal	0.97%	0.85%	1.02%	1.37%
	MX058 Low	1.27%	1.07%	1.66%	2.04%
	MX058 High	0.67%	0.50%	1.13%	1.27%
HGB	MX058 Normal	0.58%	0.70%	1.27%	1.43%
	MX058 Low	1.04%	0.84%	2.34%	2.52%
	MX058 High	1.10%	0.78%	0.93%	1.33%
HCT	MX058 Normal	1.01%	0.91%	0.92%	1.33%
	MX058 Low	1.31%	1.29%	1.50%	1.99%
	MX058 High	0.34%	0.78%	0.39%	0.72%
MCV	MX058 Normal	0.34%	0.89%	0.47%	0.82%
	MX058 Low	0.46%	0.78%	0.47%	0.79%
	MX058 High	2.24%	1.55%	1.51%	2.45%
PLT	MX058 Normal	2.75%	2.70%	2.15%	3.47%
	MX058 Low	5.57%	3.38%	3.76%	5.95%
	MX058 High	0.36%	0.30%	0.17%	0.38%
GRA%	MX058 Normal	0.81%	0.77%	0.70%	1.06%
	MX058 Low	3.85%	1.92%	2.11%	3.70%
	MX058 High	3.98%	3.70%	3.23%	5.02%
LYM%	MX058 Normal	3.80%	2.94%	2.86%	4.44%
	MX058 Low	6.15%	5.38%	4.44%	7.29%
	MX058 High	1.90%	1.59%	1.17%	2.11%
MON%	MX058 Normal	1.42%	1.42%	1.30%	1.92%
	MX058 Low	1.88%	1.27%	1.23%	2.02%

Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guidelines, NCCLS document EP-5 (ISBN 1-56238-145-8) 1999.

### **Expected precision on control samples**

Parameters	Low level	Normal level	High level
WBC	7%	5%	4%
RBC	4%	3%	3%
HGB	5%	4%	3%
HCT	5%	4.5%	4%
MCV	4%	3%	2.5%
RDW	5%	5%	5%
PLT	15%	10%	7%
GRA%	12%	4%	3%
LYM%	8%	8%	8%
MON%	15%	14%	11%

### 2.2. Precision (Repeatability)

♦ Based on 10 consecutive samplings from 1 fresh normal whole blood, without any alarms.

Tab.2-9 Precision (Repeatability)

Precision table: N=10 Parameters	ABX Micros ES60 OT	ABX Micros ES60 CT
WBC	1.48%	1.65%
RBC	0.96%	1.19%
HGB	0.51%	1.00%
нст	1.07%	1.38%
PLT	3.2%	3.23%
LYM %	2.23%	2.64%
MON %	4.67%	7.54%
GRA %	1.37%	1.42%

Tab.2-10 Precision claims

Precision table: N=10 Parameters	%CV	Range
WBC	<2.5%	4-10.0 x 10 <sup>3</sup> /μl
RBC	<2.0%	4-7 x 10 <sup>6</sup> /μl
HGB	<1.5%	12-18 g/dl
НСТ	<2.0%	36-54 %
PLT	<5.0%	200-500 x 10 <sup>3</sup> /μl
LYM %	<10%	25-50%
MON %	<20%	2-10%
GRA %	<4%	50-87%

### 2.3. Linearity

- ◆ Linearity range: the manufacturer's tested linearity zone of the instrument using linearity kits and/or human blood.
- ◆ Linearity limits: maximum and minimum values within 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 given associated with a "D" flag. This visible range is outside manufacturer's range.
- ◆ Linearity kits: linearity was tested using 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 obtained on human blood, using a minimum of 5 dilution points. The results of this study are as followed.

Tab.2-11 Linearity

Parameters	Linearity range	Linearity limits	Visible range		or limit er is greater)
WBC $(10^3/\text{mm}^3)$	0.4 - 106.6	0 - 100	100 - 150	±0.3	±5%
RBC $(10^6/\text{mm}^3)$	0.2 - 8.1	0 - 8	8 - 18	±0.07	±3%
PLT (10 <sup>3</sup> /mm <sup>3</sup> ) ( <b>A</b> )	13 - 2777	0 - 2200	2200 - 6000	±10	±10%
PLT (10 <sup>3</sup> /mm <sup>3</sup> ) ( <b>B</b> )	13 - 4856	0 - 4000	4000 - 6000	±10	±10%
HGB (g/dl)	0.68 - 26	0 - 26*	26 - 30	±0.3	±3%
HCT (%)	2.0 - 80	0 - 55 56 - 80*	80 - 90	±2.0 ±2.0	±3% ±5%

A: for HGB>2g/dl (normal mode)

**B**: for HGB<2g/dl (Concentrated platelets mode)

### 2.4. Carry-over

◆ Carry-over effects were evaluated by assaying a sample with high cell concentrations 3 times (h1-3), followed immediately by testing a diluted sample consecutively 3 times (l1-3). Carry-over is then:

Carry-over = (l1-l3)/(h3-l3)x100

Tab.2-12 Carry-over (ABX Micros ES60 OT)

Parameters units	WBC (10 <sup>3</sup> /mm <sup>3</sup> )	RBC (10 <sup>6</sup> /mm <sup>3</sup> )	HGB (g/dl)	PLT (10 <sup>3</sup> /mm <sup>3</sup> )
Mean Low level	0.98	0.98	3.30	38.17
Mean High level	52.48	6.89	21.22	933.33
% Carry-over (actual)	0.0%	0.17%	0.0%	0.23%
% Carry-over (claimed)	<2%	<2%	<2%	<2%

Tab.2-13 Carry-over (ABX Micros ES60 CT)

Parameters units	WBC (10 <sup>3</sup> /mm <sup>3</sup> )	RBC (10 <sup>6</sup> /mm <sup>3</sup> )	HGB (g/dl)	PLT (10 <sup>3</sup> /mm <sup>3</sup> )
Mean Low level	0.90	0.98	3.12	32.17
Mean High level	52.07	7.02	20.95	907.83
% Carry-over (actual)	0.1%	0.25%	0.0%	0.14%
% Carry-over (claimed)	<2%	<2%	<2%	<2%

### 2.5. Normal ranges

◆ See Section 6, Default values of analysis limits, page 6-12.

#### 2.6. Accuracy

◆ The accuracy performance was proven by analyzing approximately 98 patient specimens on the ABX Micros ES60 OT/CT along with a commercially available reference analyzer. The following table summarizes the data:

Tab.2-14 Accuracy

		ABX Micros ES60 OT		ABX Micro	s ES60 CT
Parameters		n	R <sup>2</sup>	n	R <sup>2</sup>
WBC	10 <sup>3</sup> /mm <sup>3</sup>	98	0.997	98	0.996
RBC	$10^6/\text{mm}^3$	98	0.992	98	0.987
HGB	g/dl	98	0.995	98	0.989
HCT	%	98	0.992	98	0.990
MCV	$\mu m^3$	98	0.988	98	0.990
PLT	$10^3/\text{mm}^3$	98	0.983	98	0.986
Lymphocytes	%	77	0.997	77	0.989
Monocytes	%	77	0.920	77	0.868
Granulocytes	%	77	0.990	77	0.989
Reference anal	yzers	ABX Mi	cros 60	ABX Mi	cros 60

n: number of specimens analyzed.

<sup>\*</sup> In the US version, the instrument will trigger the D flag on HGB and HCT parameters according to the following high linearity values: HGB = 24, HCT = 70.

**R**<sup>2</sup>: correlation coefficient from the regression curve Reference/ABX Micros ES60.

### 3. Limitations



Whilst every effort is taken by HORIBA ABX to investigate and indicate all known interferences, it is by no means 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 has been assessed and taken into account.

#### 3.1. Maintenance

◆ In this manual, specific start-up, shutdown and maintenance procedures are listed (See Section 7, 2. Daily maintenance, page 7-3). The maintenance procedures listed in this manual are mandatory for the proper use and operation of the ABX Micros ES60 OT/CT (See Section 7, 3. Maintenance procedures, page 7-5).



Failure to execute any of these maintenance procedures may result in "Decreased Reliability" of the system. High emphasis on maintaining the system is strongly suggested.

### 3.2. Blood specimens

◆ All blood samples should be collected using proper technique.

Consider all specimens, reagents, calibrators, controls, etc. that contain human blood or serum as potentially infectious.



Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses or face shields and follow other biosafety practices as specified in OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

#### 3.2.1. Sample collection and mixing

◆ 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 sample collection tubes. .



(For USA only). For additional information on collecting venous and capillary samples, refer to NCCLS document H3-A4 and NCCLS document H4-A4 (sept.1999).



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

#### 3.2.2. Sample stability

- ◆ Fresh whole blood specimens are recommended. The ICSH (International Council for Standardization in Hematology) defines a fresh blood specimen as "One processed within 4 hours after collection".
- ◆ Well mixed whole blood specimens, collected in EDTA anti-coaqulant and run within eight hours after collection, provide the most accurate results for all parameters. The white cell size distribution may shift when specimens are assayed between 5 and 20 minutes after collection and more than 8 hours after collection.

#### 3.2.3. Anti-coagulants and their effects (on whole blood)

This is a list of commonly used anti-coagulants used for whole blood collections:

- Heparin Causes an increase in cell clumping (WBCs and PLTs) and modifies cytoplasmic color with Romanowsky staining (blue background). An increase in HCT and MCV with high heparin concentrations > 7.5μL /capillary tube.
- ◆ Trisodium Citrate Because the anti-coagulant is liquid, it includes a dilution estimated at 10/11 when filling 5ml tubes with whole blood. This anti-coagulant is used in coagulation. It is sometimes used in hematology when an EDTA induced Pseudothrombocytopenia is suspected.
- Acid Citrate Dextrose (ACD) and Citrate Phosphate Dextrose with Adenine (CPDA) The most commonly used anti-coagulants for cell concentrates (in particular platelet concentrates) is normally not used for cell counting. There is no seriously known interference.



Anti-coagulants used in blood collection may vary in the effects of changing the characteristics of the blood components. Caution is advised when selecting an anti-coagulant for analysis on the ABX Micros ES60 OT/CT.

- ◆ EDTA Amoung the EDTA salts, EDTA K2 (USA and Japan), EDTA K3 (USA and Europe) and sometimes NA2 EDTA are used. EDTA K2 and EDTA K3 are the most frequently used anti-coagulants for Hematology testing Worldwide. Mainly because they have been recommended by ICSH since 1993. The other EDTA salts are acceptable as well. EDTA can include Pseudothrombocytopenia (estimated frequency: 1/800) through platelet clumping.
- ◆ Fluoride Was used before EDTA replaced it. No side effects as known so far.

#### 3.2.4. Sample collection tube caps (ABX Micros ES60 CT)

Some sample collection tube caps are more adaptable to "Cap-piercing" sampling systems. Obviously, plastic caps cannot be used. Rubber caps can have a variation of materials that they are made from. It is highly recommended to use the best quality of material in order to avoid any rubber particles entering the sample tube when piercing the tube. It is also recommended to use caps specifically designed to avoid any blood retention in the upper portion of the cap.

### 3.3. Known interfering substances



Verification of any "Abnormal" test result (including flagged results or results outside their normal range) should be performed using reference methods or other standard laboratory procedures for the conclusive verification of these abnormal results. The section hereafter starts the list of the known limitations of automated blood cell counters which use the principle of impedance.

#### 3.3.1. WBC White Blood Cells (Leukocytes)

- ◆ WBC results that exceed the linearity limits of the system will require a dilution of the blood sample. Re-assaying the diluted blood sample will help to obtain the correct assay value. As in some Leukemia patients.
- ◆ NRBC Immature (Nucleated Red Blood Cells) will be counted in the WBC (White Blood Cell) parameter. If the number of nucleated red blood cells is sufficient enough to activate an "L1 alarm", such interference will be detected. However, a manual differential white blood cell count, performed on a stained blood smear, will confirm the presence of NRBCs.
  - When NRBCs are present in the WBC count, the formula for correcting the WBC parameter is as followed: Corrected WBC = (Counted WBCs  $\times$  100) / [100 + (# of NRBCs/100 WBC)]
- ◆ Non-lysed Red Cells In particularly rare instances, the erythrocytes in the blood sample may not completely lyse when lysing reagent is added in the WBC chamber. These non-lysed red blood cells may be detected on the WBC Histogram with an "L1 alarm" or as an elevated baseline on the left leading edge of the lymphocytes population in the WBC Histogram. Non-lysed erythrocytes will also cause a falsely elevated WBC count.
  - Following the manual differential white blood cell count, the WBC assay value must be corrected to subtract the NRBCs from the total white blood cell count. This will give a true and correct count of the actual WBCs.

- Multiple myeloma The precipitation of proteins in multiple myeloma patients may give elevated WBC counts.
- ◆ Hemolysis Hemolyzed specimens contain red cell stroma which may elevate WBC counts.
- ◆ Leukemia A very low WBC count may result in this disease state because of possible increased fragility of the leukocytes leading to some destruction of these cells during counting. These white cell fragments will also interfere with the white cell partial differential parameters: LYM% and #, MON% and #, GRA% and #. A suspiciously low WBC count may also be seen in patients with lymphocytic leukemias due to the presence of abnormally "Small" lymphocytes which may not be counted by the instrument.
- Chemotherapy Cytotoxins and immunosuppressive drugs may increase the fragility of the leukocytes which may cause low WBC counts.
- ◆ Cryoglobulins Increased levels of cryoglobulins that may be associated with myeloma, carcinoma, leukemia, macroglobulineima, lymphoproliferative disorders, mestastic turmors, auto-immune disorders, infections, idiopathic disease, aneurism, pregnancy, thromboembolic phenomena, diabetes, etc... which can elevate the WBC, RBC and PLT counts along with the HGB value. The specimen can be warmed up to 37°C and re-analyzed immediately. If warming the specimen has no effect on the count, a manual WBC, RBC, and or PLT count can be performed.
- ◆ Increased turbidity May also be seen in cases where the red blood cells are resistant to the lysing action. This condition will cause a falsely elevated hemoglobin result, but may be detected by observing the abnormal MCH and MCHC values, also the increased baseline on the left leading edge of the WBC histogram. Erroneous hemoglobin results will also cause the results of the MCH and MCHC to be erroneous as well.

#### 3.3.2. RBC Red Blood Cells (Erythrocytes)

- ◆ The red blood cell dilution contains all the formed elements in the blood: erythrocytes, leukocytes and platelets. During the counting of the RBCs, platelets are below the RBC size minimum threshold, therefore they are not counted as RBCs.
- ◆ Leukocytes (white blood cells) on the other hand, are included in the RBC count. However, since the normal ratio between red blood cells and white blood cells is so extreme, the influence of counting the WBCs during the RBC count is negligible.
- High WBCs In rare cases where the WBCs are extremely high, the RBC count may be corrected, especially if the RBC count is extremely low in comparison to the high WBC count.
- ◆ Agglutinated red blood cells May cause a falsely low RBC count. Blood samples containing the agglutinated red blood cells may be identified by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear.
- ◆ Cold agglutinins IgM Immunoglobulins which are elevated in cold agglutinins disease, may lower RBC and PLT counts and increase the MCV.

#### 3.3.3. HGB (Hemoglobin)

- ◆ Turbidity of the blood sample Any number of physiologic and/or therapeutic factors may produce falsely elevated hemoglobin results. To obtain accurate HGB results when increased turbidity of the blood sample occurs, determine the cause of the turbidity and follow the appropriate method below:
- 1- Elevated WBC: an extremely elevated WBC will cause excessive light scatter from the L.E.D. In these cases, use reference (manual) methods. The diluted sample should be centrifuged and the supernatant fluid measured with a spectrophotometer.
- 2- Elevated Lipids: elevated lipids in the blood will give the plasma a "milky" appearance. This condition can occur with hyperlipidemia, hyperproteinemia (as in gammapathies) and hyperbilirubinemia. Accurate hemoglobin measurement can be achieved by using reference (manual) methods and a plasma blank.

Increase in turbidity may also be seen in cases where the red blood cells are resistant to the lysing action. This condition will cause a falsely elevated HGB result, but may be detected by observing the abnormal MCH and MCHC values and the increased baseline on the left leading edge of the WBC histogram. Erroneous HGB results will cause the results of the MCH and MCHC to be erroneous as well.

 Fetal bloods - The mixing of fetal and maternal bloods may produce a falsely elevated hemoglobin value.

#### 3.3.4. HCT (Hematocrit)

◆ Red Blood cell Agglutination - May produce erroneous HCT and MCV values. Red blood cells agglutination may be detected by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear in such cases. Manual laboratory methods may be required to obtain an accurate HCT value.

#### 3.3.5. MCV (Mean Corpuscular Volume)

- Red blood cell Agglutination May produce an erroneous MCV value. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear. In such cases, manual methods may be required to obtain an accurate MCV value.
- ◆ 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. Careful examination of a stained blood smear may reveal the error.

#### 3.3.6. MCH (Mean Corpuscular Hemoglobin)

◆ The MCH is determined, according to the HGB value and the RBC count. The limitations listed for HGB and RBC will have an effect on the MCH and may cause erroneous values.

#### 3.3.7. MCHC (Mean Corpuscular Hemoglobin Concentration)

◆ The MCHC is determined, according to the HGB and HCT values. The limitations listed for HGB and HCT will have an effect on the MCHC and may cause erroneous values.

#### 3.3.8. RDW (Red cell Distribution Width)

- ◆ The red blood cell distribution width is determined, according to the RBC count. The red blood cells pass through a micro-aperture that will generate electronic pulses, as the cells pass through it. These pulses are then grouped according to size, thresholded and calculated to form a histogram (distribution curve). This distribution curve is then used to calculate the distribution of the red blood cells as a percentage of the curve. This curve is then used in determining the RBC size abnormalities as in anisocytosis.
- Agglutinated red blood cells May cause a falsely low RBC count and erroneous RDWs. Blood samples containing the agglutinated RBCs may be detected by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear.
- Nutritional deficiency or blood transfusion May cause elevated RDW results due to iron, vitamin B12, or folate conditions. High RDWs may also be present from bi-modal RBC distribution from transfused blood. This will be detected by the RBC Histogram showing 2 distinctive peaks on the distribution curve.

#### 3.3.9. PLT (Platelets)

- Very small erythrocytes Microcytes, erythrocytes fragments schistocytes and WBC fragments
  may interfere with the proper counting of platelets and cause elevated platelet counts.
- Agglutinated red blood cells May trap platelets, causing an erroneously low platelet count. The presence of agglutinated RBCs may be detected by observing abnormal MCH and MCHC values and by careful exmination of a stained blood smear.
- Giant platelets in excessive numbers May cause an erroneously low platelet count since these
  large platelets may exceed the upper threshold limit for platelets and are not counted as platelets.
- Chemotherapy Cytotoxic and immunosuppressive drugs may increase the fragility of these cells
  which may cause low platelet counts. Reference (manual) methods may be necessary to obtain an
  accurate platelet count.
- Hemolysis Hemolyzed specimens contain red blood cell stroma which may cause elevated platelet counts.
- A.C.D. blood Blood anti-coagulated with acid-citrate-dextrose may contain platelet aggregates
  which could give falsely low platelet counts.
- ◆ RBC inclusions Erythrocyte inclusions such as Howell-Jolly bodies, Heinz bodies, siderotic and basophilic granules, etc... may produce considerably elevated platelet counts.

- ◆ Platelet agglutination Clumped platelets due to poor collection techniques or platelet satellitosis caused by EDTA activation of immunoglobulins may cause a low platelet count and/or an elevated WBC count.
- ◆ These types of specimens should be re-collected in sodium-citrate anticoagulant and re-analyzed "For Platelets Only"!

#### 3.3.10. MPV (Mean Platelet Volume)

◆ Giant platelets - That exceed the upper thresholding of the platelet channels, may not be counted as platelets. Consequently, these larger platelets will not be included in the instrument's calculations of the mean platelet volume.



Blood samples collected in EDTA will not maintain a stable mean platelet volume. Platelets collected in EDTA will swell with time and temperature

- Agglutinated red blood cells May trap platelets, causing an erroneous MPV result. The presence of aggultinated erythrocytes may be detected by observing abnormal MCH and MCHC values and by careful examination of a stained blood smear.
- ◆ Very small erythrocytes Microcytes, erythrocyte fragments schistocytes and white blood cell fragments may interfere with the proper sizing and counting of the platelets.
- ◆ **Chemotherapy** May also affect the sizing of platelets.

#### 3.3.11. LYM# (lymphocyte count absolute value)

◆ The lymphocyte count is derived from the WBC count. The presence of nucleated red blood cells (NRBC), certain parasites and erythrocytes that are resistant to the lysing action, may interfere with an accurate LYM# count. Limitations listed for the WBC count pertain to the LYM# count as well.

#### 3.3.12. LYM% (lymphocyte percentage)

◆ The lymphocyte percentage is determined, according to the WBC count and the number of lymphocytes. The presence of NRBCs, certain parasites and erythrocytes that are resistant to the lysing action, may interfere with an accurate LYM% count. Limitations listed for the WBC count pertain to the LYM% count as well.

#### 3.3.13. MON# (monocyte count absolute value)

The mononuclear cell count is derived from the WBC count. The percentage of large lymphocytes, atypical lymphocytes, lymphoblasts and an excessive number of basophils may interfere with an accurate monocyte count.

#### 3.3.14. MON% (monocyte percentage)

◆ The monocyte percentage is determined, according to the WBC count and the number of monocytes. The presence of large lymphocytes, atypical lymphocytes, lymphoblasts and an excessive number of basophils may interfere with an accurate monocyte % count.

#### 3.3.15. GRA# (granulocyte count absolute value)

◆ The granulocyte cell count is derived from the WBC count. The excessive presence of eosinophils, metamyelocytes, myelocytes, promyelocytes, myeloblasts and plasma cells may interfere with an accurate granulocyte # count.

#### 3.3.16. GRA% (granulocyte percentage)

◆ The granulocyte percentage is determined, according to the WBC count and the number of granulocytes. The excessive presence of eosinophils, metamyelocytes, myelocytes, promyelocytes, myeloblasts and plasma cells may interfere with an accurate granulocyte % count.

### 4. Reagent

### 4.1. Reagent specifications

◆ Do not use the instrument operational caps when reagents are left off the instrument.



HORIBA ABX manufactures reagents, calibrators and quality control bloods specially designed for use with the ABX Micros ES60 OT/CT analyser. The use of products not recommended by HORIBA ABX may give erroneous results or instrument operation problems. Contact your local HORIBA ABX Technical Support Representative for all information regarding the recommended products.

- ◆ The HORIBA ABX reagents specified for this instrument have been approved in accordance with the European Directive 98/79/CE (Annex III) for in-vitro medical devices.
- ◆ Refer to reagent leaflets for all reagent specifications.



The CD-ROM RAX055 delivered with your instrument provides reagent, control and calibrator leaflets/msds. Latest versions of these documents are available on www.horiba-abx.com/documentation.

- ◆ Allow your reagents to return to room temperature before use, to avoid gas bubble emissions.
- Never pour the remaining quantity of a reagent previously used into the new reagent replacing it. This will eliminate any cross contamination to the new reagent.
- Never leave a reagent container open during use. Use the appropriate caps provided with the instrument. Order new reagent caps if lost or misplaced.
- Check with your shipping company and verify that your reagent shipment has not encountered important temperature differences during transportation.
- Clean any reagent spillage with water as soon as possible to prevent crystallization of the reagent and oxidation of the metal parts of the instrument.
- Never pour reagents into the laboratory waste water drainage system. Follow local/national regulations for chemical waste disposal. Apply neutralization procedures when necessary.
- ◆ It is necessary to flush the reagent lines with distilled water, then dry them when the instrument is going to be shipped to any location or will be left without operating for an extended period of time. Contact your local HORIBA ABX Technical Support Representative for more information about this procedure.
- ◆ These reagents are used for Invitro diagnostics.

#### 4.2. Reagent consumption

 Reagent consumption is given in millimiters (ml). It has been calculated according to a specific software version.

Tab.2-15 Reagent consumption on ABX Micros ES60 CT (software version V1.1.X)

Cycle	Diluent	Lyse	Cleaner	ABX Minoclair
Startup	23.5	0.5	-	-
Shutdown	-	-	14.4	-
Analysis	16.8	0.5	1.0	-
Prime all reagents	26.4	10.3	5.4	-
Automatic cleaning	16.3	0.5	13.8	-
Concentrated cleaning	16.3	0.5	1.9	6.0
Cal photometer	16.3	0.5	1.6	-
Backflush	-	-	-	-

Tab.2-16 Reagent consumption on ABX Micros ES60 OT (software version V1.1.X)

Cycle	Diluent	Lyse	Cleaner	ABX Minoclair
Startup	23.2	0.5	-	-
Shutdown	-	-	13.0	-
Analysis	15.2	0.5	0.8	-
Prime all reagents	26.8	10.3	4.9	-
Automatic cleaning	16.1	0.5	12.6	-
Concentrated cleaning	16.1	0.5	1.7	6.0
Cal photometer	16.1	0.5	1.5	-
Backflush	-	-	-	-

## 5. Waste handling procedure

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



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.

# Description & Technology

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## 1. ABX Micros ES60 OT/CT description

### 1.1. ABX Micros ES60 CT description

#### 1.1.1. Overview

Diag.3-1 ABX Micros ES60 CT



- 1- LCD display & touchscreen
- 2- Cap piercing mechanism & tube holder
- 3- Reagent compartment
- 4- Printer
- 5- Barcode reader
- 6- USB port

### 1.1.2. Front view (covers opened)

Diag.3-2 ABX Micros ES60 CT front side



- 1- Carriage assembly
- 2- Tube holder
- 3- WBC/HGB chamber
- 4- RBC/PLT chamber

1.1.3. Left side view (covers opened)

Diag.3-3 ABX Micros ES60 CT left hand side



- 1- Diluent temperature sensor
- 2- Liquid syringe
- 3- Valve blocks
- 4- Vacuum/waste chamber

# **Description & Technology**

### 1.2. ABX Micros ES60 OT description

#### 1.2.1. Overview

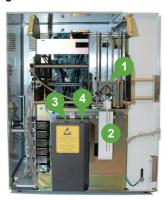
Diag.3-4 ABX Micros ES60 OT



- 1- LCD display & touchscreen
- 2- Manual sampling needle
- 3- Reagent compartment
- 4- Printer
- 5- USB port

#### 1.2.2. Front view (door opened)

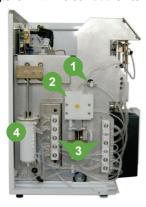
Diag.3-5 ABX Micros ES60 OT front side



- 1- Carriage assembly
- 2- Sampling needle and manual sample bar
- 3- WBC/HGB chamber
- 4- RBC/PLT chamber

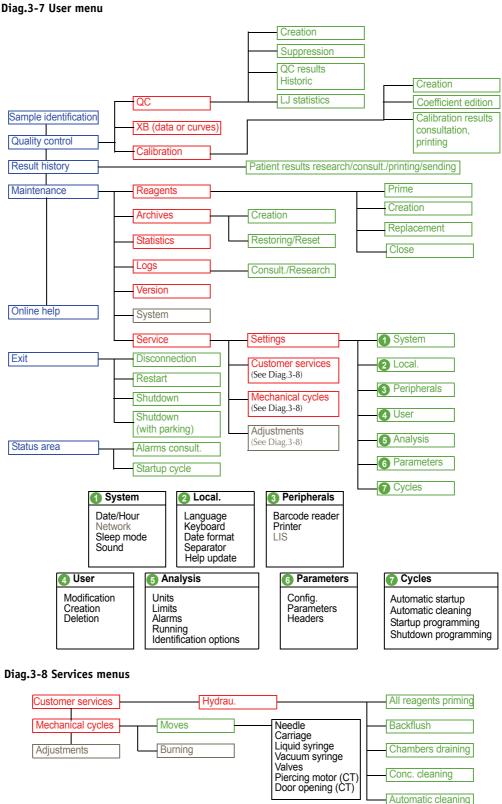
1.2.3. Left side view (covers opened)

Diag.3-6 ABX Micros ES60 OT left hand side



- 1- Diluent temperature sensor
- 2- Liquid syringe
- 3- Valve blocks
- 4- Vacuum/waste chamber

## 2. Software menus description



## 3. Technology

### 3.1. Sampling

#### 3.1.1. ABX Micros ES60 CT

- 1- Blood collection tube is placed into the tube holder.
- 2- The tube holder door is then closed by the operator.
- 3- The cap-piercing mechanism moves the tube holder up and pierces the sample tube.
- 4- Aspiration of 10µl of blood.
- 5- Needle carriage assembly moves to the left, over the WBC/HGB chamber.
- 6- Internal and external cap-piercing needle rinses. External sampling needle rinses.
- 7- Blood sample is delivered into the WBC chamber for the first dilution.
- 8- Aspiration of 28.3µl of diluted blood from the WBC chamber.
- 9- Needle carriage assembly moves to the right, over the RBC/PLT chamber.
- 10- Internal and external cap-piercing needle rinses. External sampling needle rinses.
- 11- Diluted blood sample is delivered into the RBC chamber for the RBC/PLT measurement.

#### 3.1.2. ABX Micros ES60 OT

- 1- Blood collection tube cap must be removed.
- 2- The tube is placed beneath the sampling needle.
- 3- The tube is moved upwards and the sampling needle enters into the blood.
- 4- The manual sample bar is pressed and aspiration of 10μl of blood occurs.
- 5- Needle carriage assembly moves to the left, over the WBC/HGB chamber.
- 6- The external sampling needle rinses.
- 7- Blood sample is delivered into the WBC chamber for the first dilution.
- 8- Aspiration of 28.3µl of diluted blood from the WBC chamber.
- 9- Needle carriage assembly moves to the right, over the RBC/PLT chamber.
- 10- The external sampling needle rinses.
- 11- Diluted blood sample is delivered into the RBC chamber for the RBC/PLT measurement.

#### 3.2. Dilutions

#### 3.2.1. WBC/HGB

#### Tab.3-1 WBC/HGB dilution

WBC/HGB dilution	
Initial blood volume	10.0µl
Volume of ABX Minidil LMG	2.1ml
Volume of ABX Lyse	0.5ml
Final dilution ratio	1/260

#### Tab.3-2 WBC measurement

WBC measurement	
Method	Impedance
Aperture diameter	80µm
Count vacuum	200mb
Count period	2 (or 3) x 6 seconds
Temperature reaction	Ambient

#### Tab.3-3 HGB measurement

HGB measurement		
Method	Photometry	
Wavelength	550nm	
Count period	2x5 seconds	
Temperature reaction	Ambient	

- ♦ 10µl of blood sample contained in the sampling needle is pushed with 1.2ml of ABX Minidil LMG along with 0.5ml of ABX Minidil LMG from the outer needle into the WBC/HGB chamber.
- ♦ 0.4ml of ABX Minidil LMG is added into the WBC/HGB chamber making the diluent volume 2.1ml.
- ◆ 0.5ml of ABX Lyse is added to the mixture.
- ◆ This makes the total dilution for WBC/HGB.

#### 3.2.2. RBC/PLT

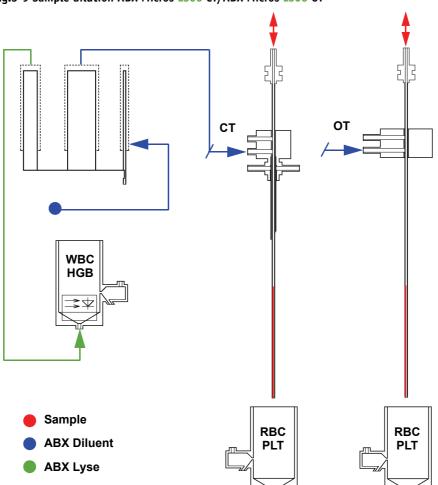
#### Tab.3-4 RBC/PLT dilution

RBC/PLT dilution	
Initial diluted blood volume	28.3µl: rate 1/170
Volume of ABX Diluent	2.5ml
Final dilution ratio	1/15 000

#### Tab.3-5 RBC/PLT measurement

RBC/PLT measurement	
Method	Impedance
Aperture diameter	50µm
Count Vacuum	200mb
Count period	2 (or 3) x 6 seconds
Temperature reaction	Ambient

- ◆ 28.3µl of diluted blood is aspirated from the WBC chamber. The needle carriage assembly moves to the right over the RBC/PLT chamber.
- ◆ 2.0ml of ABX Minidil LMG and the 28.3µl of diluted blood is injected into the RBC/PLT chamber from the inner sample needle.
- ◆ 0.5ml of ABX Minidil LMG is added to the dilution in the chamber from the outer sample needle. This makes the total dilution for the RBC/PLT.



Diag.3-9 Sample dilution ABX Micros ES60 CT/ABX Micros ES60 OT

### 3.3. CBC measurement principles

#### 3.3.1. RBC/PLT

- ◆ The RBCs and PLTs are measured by an electronic impedance variation principle. This means that an electronic field is generated around the micro-aperature in which the blood cells pass through. The cells create a resistance in the electronic field as they pass through the calibrated micro-aperture. This in turn causes an electronic pulse to be generated which is amplified, measured and then mathematically calculated to create a numerical value.
- ◆ Firstly, the 28.3µl diluted blood sample is diluted in an electrolytic diluent (electronic current conducting fluid), mixed, then pulled through a calibrated micro-aperture. There are two electrodes placed on each side of the aperture and a constant electronic current passes between them.
- ◆ As the blood cells pass through the aperture, they create resistance (impedence) in the electronic field between the two electrodes. Since the current is constant and remains unchanged, the larger the cell is, the "more" resistance it has. The smaller the cell is, the "less" resistance it has. The voltage which measures the cells is proportional to the cell size. The larger the cell, the higher the voltage will be. The smaller the cell, the lower the voltage will be.
- These electronic voltages vary in pulse size as cells pass through the aperture. The pulses are then channeled according to pulse size. The pulses are then thresholded, grouped, then mathematically calculated to create a numerical value for the determination of RBCs and PLTs.

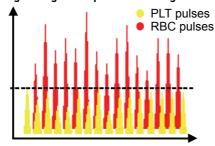
#### Results

◆ A certain amount of cells will pass through the calibrated micro-aperture within a specific time frame. They are then measured by pulse height, thresholded, grouped by size and mathematically calculated along with the calibration coefficient to give a final numerical value for both RBCs and PLTs.

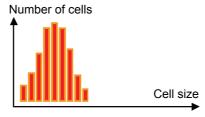
#### **RBC** and **PLT** histograms

◆ The RBC and PLT histograms are determined by thresholding of the electronical pulses. These pulses are then grouped according to size by channeling the pulses into the correct size category. The electronic pulses are smoothed mathematically and plotted on a graph.

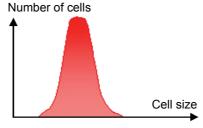
Diag.3-10 Cells passsing through the aperture creating electronic pulses



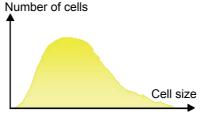
Diag.3-11 RBC Pulses grouped according to the number and the size of the cells



Diag.3-12 RBC Pulses electronically calculated and smoothed: RBC distribution curve



Diag.3-13 PLT pulses electronically calculated and smoothed: PLT distribution curve



- RBC histogram: is an electronic distribution and mathematical calculation of the RBCs placed into 256 channels of volumetric sizing from 30fl to 300fl.
- ◆ PLT histogram: is an electronic distribution and mathematical calculation of the PLTs placed into 128 channels of volumetric sizing from 2fl to a mobile threshold between the high end platelets and the low end red blood cell thresholds.
  - (fl = femtoliters) A microscopic volumetric unit of measurement. This is a 3-dimentional measurement used to determine the volume of microscopic particles.

# **Description & Technology**

#### 3.3.2. HGB

- ◆ The hemoglobin measurement is based on a startup cycle. This cycle includes an hemoglobin blank test sequence which includes 2 hemoglobin blank measurements. Each analysis cycle run after start-up also has a HGB blank measurement which is compared to the initial start-up HGB blank. Each analysis cycle run thereafter compares the HGB blank reading to the previous cycle HGB blank reading.
- ◆ During the WBC analysis cycle, 0.5ml of ABX Lyse reagent is added to 2.05ml of diluted blood in the WBC chamber. The Lyse reagent contains potassium ferricyanide [Fe(Cn)]K, and potassium cyanide [KCN]. This lysing reagent breaks down the RBC cell membrane and releases the hemoglobin within the RBC.
- ◆ The hemoglobin then combines with the potassium cyanide to form a chromogenous cyanmethemoglobin compound. This chemical compound is measured by spectrophotometry, through the optical pathway in the WBC chamber. The light wavelength of measurement is at 550nm.

**Results**: HGB results are given as such:

HGB = Log(Blank value/Sample value) x Calibration Coefficient.

#### 3.3.3. HCT

◆ The hematocrit is a combination measurement of electronic pulses and mathematical calculations. 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 is a function of the numeric integration of the MCV. Results are given as a percentage of this integration.

#### 3.3.4. MCV, MCH & MCHC

- ◆ MCV (Mean Cell Volume), is calculated directly from the entire RBC histogram.
- MCH (Mean Cell Hemoglobin), is calculated from the hemoglobin value and the RBC count. Calculations are as follows:

 $MCH(pg) = HGB/RBC \times 10$ 

(pg) Picograms

 MCHC (Mean Corpuscular Hemoglobin Concentration), is calculated according to the hemoglobin and hematocrit values. Calculations are as follows:

 $MCHC(g/dl) = HGB/HCT \times 100$ 

#### 3.3.5. RDW

◆ The RDW (Red cell Distribution Width) is used to determine erythrocyte abnormalities linked to anisocytosis. The RDW will enable you to follow the evolution of the width of the RBC histogram in relation to the number of cells and their average volume. This is also a calculation of the RBC histogram. Calculations are as follows:

RDW (%) =  $K \times SD/MCV$ 

K: Calibration coefficient for RDW.

SD: Standard Deviation according to statistical studies on cell distribution.

MCV: (Mean Cell Volume) of the erythrocytes.

#### 3.3.6. MPV

◆ The MPV (Mean Platelet Volume), is directly calculated from the platelet histogram distribution curve. This calculation is almost the same as the MCV.

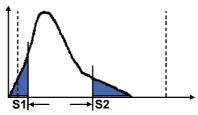
#### 3.3.7. PCT

◆ Thrombocrit (Plateletcrit), is calculated according to the formula:  $PCT\% = PLT (10^3/mm^3) \times MPV (\mu m^3) / 10 000$ 

#### 3.3.8. PDW

- ◆ The PDW (Platelet Distribution Width) is calculated from the platelet histogram/distribution curve.
- ◆ The PDW is represented by the width of the curve between 15% of the number of platelets starting from the low threshold 2fl (S1) and 15% of the number of platelets beginning with the variable high threshold (S2). The PDW determination area is shown by the distribution curve below.

Diag.3-14 Platelet distribution curve





PDW and PCT have not been established as indications for this product, in the United States. The use of PDW and PCT should be restricted to research and Investigational measurements only.

#### 3.3.9. WBC

◆ The WBC measurement principles are based upon the same as the RBC/PLT measuring principles. The WBC count is performed in the WBC/HGB chamber. The electronic signal processing device places an electronic threshold between the WBCs and the PLTs. The electronic pulses are then placed into 256 channels according to pulse size. The pulses are then thresholded, grouped, then mathematically calculated to create a numerical value for the determination of WBCs.

#### **WBC** histogram

◆ The WBC histogram is a distribution study that reveals the following 3 types of white blood cell sub-populations: lymphocytes, monocytes and granulocytes. The diluent and lyse of the ABX Micros ES60 OT/CT play a very important part when sizing the WBC subpopulations in the WBC distribution curve.

#### **Differential measuring principles**

#### Diluent and lysing action

- ◆ The diluent preserves and prepares the WBC cell membrane for the differential reaction. The lysing reagent has a differential mode of action on the WBC cytoplasmic membranes.
- When the ABX Lyse reagent reacts with the lymphocytes, the cytoplasm and the membrane are destroyed. At the end of the lysing action, it only remains the nucleous, who has a small volume.
- ◆ When the ABX Lyse reagent reacts with the monocyte cytoplasmic membrane, it has an intermediate reaction who empties cytoplasm from the cell. At the end of the lysing action, the monocyte cells obtained have an intermediate size between the lymphocytes and the granulocytes.
- ◆ When the ABX Lyse reagent reacts with the granulocytes, it has a limited reaction due to a molecule in their cytoplasmic structure which protects them from the shrinking action of the lyse. This in turn makes the granulocytes the larger of the WBC sub-populations in the cell differentiation.
- ◆ After the differential lysing action, the ABX Micros ES60 OT/CT analyses the height of each electronic pulse as the WBCs pass through the micro-aperture. The pulses are then channeled, thresholded, grouped according to their size from 30fl to 450fl and calculated mathematically to create the WBC distribution curve which inturn is known as the WBC histogram.
- ◆ The 3 sub-populations of WBCs are placed accordingly as to the number of cells and size of the cells in each group.
- ◆ The distribution of the WBC sub-populations are as followed: The lymphocytes are between 30 - 100fl.

The monocytes are between 100 - 150fl.

The granulocytes are between 150 - 450fl.

◆ This in turn creates the term (LMGs) for a 3 part WBC differential on the ABX Micros ES60 OT/CT.

# **Description & Technology**

The granulocytes subpopulation of the WBC's contains 3 sub-populations within itself, which are somewhat the same in nature.

They all contain cytoplasmic granuler material which stain various colors. when viewed microscopically. These 3 sub-populations are as followed:



- **♦** Neutrophils
- **◆**Eosinophils
- **♦** Basophils

The distribution of these cells depends on the pathological and physiological conditions of the individuals analyzed.



Pathological cells will, of course, place themselves in different zones within the WBC distribution curve. Mobile and fixed alarm flags will alert the lab operator of the presence of these pathological elements.

#### Results

◆ The lymphocyte, monocyte and granulocyte results are given as a percentage of the entire WBC count, along with absolute numbers, as well, to reflect on the actual WBC count itself. They are presented as follows:

LYM% LYM# MON% MON# GRA% GRA#

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## 1. Checks and startup

### 1.1. Reagent level checks

#### 1.1.1. Bottle units

- ◆ The system manages automatically the HORIBA ABX reagents (reagent level and expiry date). If this function is configured, you will be informed on the reagents status at the end of instrument startup. See Section 7, 4.2. Reagent management, page 7-21 to set this function.
- ◆ If this function is not set, it is required to check the levels of each reagent before operating the system. If a reagent level is "Low", replace the reagent (See Section 7, 4.2.2. Reagent creation, page 7-22 and 3.5. Reagent installation, page 7-13).



Never pour reagent from one container into another! Any type of contamination present in the old reagent would affect the new reagent. Unacceptable background counts will most likely occur especially for PLT's. Always use the reagents caps provided with the instrument to prevent reagent pollution or oxidation.

#### 1.1.2. Pack unit

All reagents and a waste bladder are contained in one reagent pack - Configure your pack for an automatic management (See Section 7, 4.2. Reagent management, page 7-21). When a reagent pack runs low, the instrument will display a message stating that the reagent pack is low. This warning message is given according to the number of cycles left in the pack. Replace the pack (See Section 7, 4.2.2. Reagent creation, page 7-22 and 3.5. Reagent installation, page 7-13).

### 1.2. Printer power and on-line checks

- Prior to instrument startup, always check the printer integrated or external (optional) to verify that the power is turned "ON" and that the LEDs are in the ready state.
- Check that the printer has sufficient paper for the daily operations.
- ◆ Check the alignment of the paper if your printer is a tractor feed printer.

### 1.3. Instrument startup

#### Power on

- ◆ Switch the instrument on by pressing the ON/OFF switch, located on the back of the instrument.
- ◆ The instrument performs an initialization phase for the internal electronics. Please wait.

#### Startup cycle

◆ Once the initialization phase is complete, the ABX Micros ES60 OT/CT will automatically run a startup cycle, if and only if the instrument has been programmed for an automatic startup cycle (See Section 6, 8.2.1. Settings startup cycle, page 6-17). This function is activated by default.



If the ABX Micros ES60 OT/CT does not automatically run a startup cycle after the initialization phase is completed, press "Startup" button in the "Status" area (See 1.5. Status area, page 4-7) to initiate a startup cycle.

◆ The ABX Micros ES60 OT/CT will perform a startup cycle which primes all the reagents, checks the fluidic and mechanical movements.



If an error occurs in fluidic or mechanic movements, the startup is stop before blank counting. The "Startup cycle failed" message is displayed and blank results for each parameter are replaced by "----".

Press "Cancel" button to close the dialog box and consult status area for more detailed information.

- Then, the instrument will perform a blank cycle for a reference blank count (an analysis cycle based on reagents without any blood sample).
  - A dialog box is displayed to indicate the startup cycle progress. This dialog box also contains an "Emergency stop" button to stop the startup cycle if necessary.
- ◆ The instrument displays and prints out the blank cycle results if this function is activated (See Section 6, 6.5. Analysis running, page 6-14). This function is activated by default.

#### **Reference blank limits:**

- 1- Check and verify that the reference blank counts do not exceed the following parameter limits:
  - WBC  $< 0.3 \times 10^3 / \text{mm}^3$
  - $RBC < 0.02 \times 10^6 / mm^3$
  - HGB < 0.3g/dl
  - $PLT < 10x10^3/mm^3$
- 2- Press "OK" button to validate blank results.

The user identification screen is displayed (See 1.4. User identification, page 4-4).

◆ If the reference blank count is above any of the parameter limits, the ABX Micros ES60 OT/CT will automatically perform another startup cycle. The cycle progress bargraph restarts at the beginning. If the problem persists after 3 consecutive cycles, a message will be displayed stating "Startup cycle failed". See Section 7, 5. Troubleshooting, page 7-31 for identifying and resolving the problem.



If any analysis cycles are run prior to a startup cycle, the following message is displayed: "Do you want to execute a startup cycle before analysis?". Press "OK" button to execute the startup cycle or "Cancel" button to continue without startup cycle.



When the ABX Micros ES60 OT/CT has not been used within 4 hours (default value, to set it: See Section 6, 8.2.1. Settings startup cycle, page 6-17) of the last cycle, the following error message is displayed: "4 hours elapsed since last analysis". It is necessary to perform a startup cycle before running an analysis cycle.

#### 1.4. User identification

#### 1.4.1. User profile selection

- ◆ Select user profile by pressing the appropriate icon (Tab.4-1).
  - The "Lab tech" corresponds to the laboratory technician who runs the analyses.
  - The "Scientist" correponds to the person in charge of the laboratory. He manages the system.



The "Technician" profile is dedicated to the HORIBA ABX local representative technician only.

◆ The following table gives the function available according to the user profile selected.
Tab.4-1 User profiles

#### **User actions** Lab tech Instrument startup and shutdown Χ Χ Χ Χ Χ Χ Displaying alarms in "Status" area Running patient analysis Χ Χ Χ Χ Running control analysis Displaying and printing patient results Χ Χ Χ (current and history) Sending patient results Χ Χ Χ

User actions	Lab tech	Scientist	Technician
Displaying and printing control results	Χ	Χ	X
Sending control results	Χ	Χ	X
Managing quality controls	Χ	Χ	Χ
Managing calibration		X	X
Managing reagents and control solutions (creation, deletion, priming)	X	Х	X
Consulting archive status	Χ	Χ	X
Reset archive alarms	Χ	Χ	Χ
Saving logs, analysis and control results	Χ	X	X
Saving and restorating of settings		X	Χ
Saving and restoring of instrument adjustments		X	Χ
Displaying statistics		X	Χ
Displaying and printing logs	Χ	X	Χ
Displaying instrument software version	Χ	X	Χ
Running service cycles (priming, backflush, draining, cleaning)	Х	Х	X
Checking mechanical movements (in "Moves" tab)	Х	Х	Χ
Settings: System - Date and time - Network - Sleep mode - Sound	X X X	X X X	X X X
Settings: Localization (language, keyboard, date format, separator, update help)		Х	Х
Settings: Peripherals (barcode reader, printer, LIS)	X (except LIS)	X (except LIS)	X
Settings: User profiles		Χ	Χ
Settings: Analysis (system units, analysis limits, alarm sensitivity, analysis running, identification option)		Х	X
Settings: Parameters (config. results, parameters, report header)		Х	X
Settings: Cycles (startup & cleaning cycles, instrument startup & shutdown)		Х	X
Printing settings	Χ	Χ	X
Displaying online help	X	X	X

- ◆ The user password is requested (See 1.4.2. Entering user password, page 4-6).
  - ◆For the default "Lab tech" profile the password is not mandatory. If it has been selected the "Sample identification" menu can be automatically displayed by pressing the "Valid" key of the virtual keyboard.



- ◆For each "Scientist" profile connection, a password will be required. Ask your local HORIBA ABX Technical Support Representative to know the default "Scientist" password.
- ◆ The user identification screen also allows to create a work session (See 1.4.3. Creating a work session, page 4-6).

# 1.4.2. Entering user password

- 1- Once the user profile login button is pressed the login password screen is displayed.
- 2- Enter password into the "Password" field using the keyboard or the virtual keyboard and press "Valid" key.
  - ◆When an erroneous password is entered the following error message is displayed: "Invalid password. Please try again."



- ◆When a user logs in for the first time, a new password is required (except for "Lab tech" created without password. See Section 6, 5. User settings, page 6-9.).
- 3- Once logged in the "Sample identification" menu is displayed (See 4. Sample identification menu, page 4-12).



If an alarm is detected, the "Status" button is blinking. Before running an analysis, enter "Status" area to know instrument status and eventual operation to perform (See 1.5. Status area, page 4-7).

# 1.4.3. Creating a work session

- The user is able to begin a new day of work by checking the "New Session" check box in the login password screen.
- ◆ A new session is then created and the previous session is archived.
- A new session cleans up the SID history.
- ◆ In one session, a sample ID is linked to the same patient. If the user enters a sample ID that has already been used, the system considers it as a rerun of the same sample. The following message will be displayed: "Are you sure you want to rerun this sample?".

Press "**OK**" button to rerun the sample or press "**Cancel**" button.



Sample rerun cannot be done if the automatic identification option is activated (See Section 6, 6.6. Identification option, page 6-14).

- ◆ To re-use the same sample ID for another patient, a new session must be created.
  - ◆Each entered Patient ID associated with its patient demography is saved in the instrument database. Patient IDs are unique. They are not cleared when a new session is created.



◆ Patient demography is managed only by filling in the "Patient ID" field. If it is not filled in, the patient name, first name and date of birth entered are not traited as patient demography but only as additional information on patient.



The "Result history" menu allows to consult the result of the current session or the archived results of the previous sessions.

See 6.5. Result history, page 4-26.

# 1.5. Status area

#### 1.5.1. Introduction

◆ The "Status" button (Diag.4-1) is blinking to indicate that an alarm has been raised. Press the "Status" button.

#### Diag.4-1 Status button



◆ The "Status" area (Diag.4-2) is displayed showing automatically the category concerned by the alarm.

Diag.4-2 Status area



- ◆ The "Status" area contains:
- 1- 5 category buttons representing the functions checked by the instrument in real-time. (See 1.5.2. Functions checked by the instrument, page 4-8).
- 2- Status icon showing the status of each category checked. (See Tab.4-2 Status description, page 4-7).

Tab. 4-2 Status description

Status	Icon	Description
ОК		No alarm has been detected in this category.
ALARM	1	An alarm has been detected in this category on at least 1 element checked by the instrument: the instrument is not locked. Analysis can be run.
LOCK	8	A locking alarm has been detected in this category on at least 1 element checked by the instrument: the instrument is locked. Analysis cannot be run except QC.

Thus, the status of each category will determine the color of the "Status" button:

- if all the categories have an OK status, the "Status" button is green
- if at least one category has an ALARM status, the "Status" button is orange
- if at least one category has a LOCK status, the "Status" button is red
- 3- System alarm messages sorted by time. The displayed system alarm messages correspond to the category selected by pressing one of the category buttons. When the category is selected, the button is surrounded by a yellow line.

4- Help message corresponding to the system alarm message selected in the table above. This help message gives corrective actions to perform (See Section 7, 6.1. System alarms, page 7-37).



System alarm messages are displayed in the "Status" area until the problem is solved.

- 5- A "Startup" button to run a startup cycle if necessary.
- ◆ Press "OK" button to close the "Status" area and enter "Sample identification" menu (See 4. Sample identification menu, page 4-12).

# 1.5.2. Functions checked by the instrument

- This chapter describes all the functions checked by the instrument. These checks will determine the status (OK, ALARM or LOCK) for each category.
- ◆ The analyser functional status is thus determined. It depends on 3 elements:
  - the system alarm level
  - the user connected (variable according to user profile)
  - the locking alarm options set in the "**Settings**" menu (See Section 6, 6.5. Analysis running, page 6-14).
- The following pages will give for each category the analyser functional status and the color of the "Status" button. This information is sorted by system alarms triggered according to:
  - the profile of the user connected
  - the locking alarm options set in the "Settings" menu

#### **Instrument status**

◆ To select the instrument category, press the "Instrument status" button Diag.4-3.

## Diag.4-3 Instrument status button



Tab.4-3 Instrument category alarm messages

System alarm message	Status accouser profil	•	Locking alarm user profil	-	
	Lab tech	Scientist	options	Lab tech	Scientist
Cycle cancelled by user	LOCK	LOCK	N/A		
Critical cycle error	LOCK	LOCK	N/A		
Startup cycle failed	LOCK	LOCK	N/A		
Invalid startup cycle	ALARM	ALARM	Automatic lock on analyser alarm	LOCK	ALARM
Analyser connection failed	LOCK	LOCK	N/A		
Analyser communication failed	LOCK	LOCK	N/A		
Reagent temperature error	ALARM	ALARM	Automatic lock on analyser alarm	LOCK	ALARM

Follow the indications displayed in help messages to perform corrective actions. For more detailed information: See Section 7, 6.1.1. Instrument alarms, page 7-37.

# **QC** status

◆ To select the QC category, press the "QC status" button Diag.4-4.

## Diag.4-4 QC Status button



Tab.4-4 QC category alarm messages

Alarm message	Status according to user profile		Locking alarm	Status according to user profile	
	Lab tech	Scientist	options	Lab tech	Scientist
XB drift	ALARM	ALARM	N/A		
Inter QC time limit "lot number"	ALARM	ALARM	Automatic lock on QC alarm	LOCK	ALARM
Invalid QC "lot number"	ALARM	ALARM	Automatic lock on QC alarm	LOCK	ALARM

◆ Follow the indications displayed in help messages to perform corrective actions. For more detailed information: See Section 7, 6.1.2. QC alarms, page 7-38.

## **Reagent status**

◆ To select the reagent category, press the "Reagent status" button Diag.4-5.

# Diag.4-5 Reagent status button



Tab.4-5 Reagent category alarm messages

Alarm message	Status acc user profil		Locking alarm options	Status according to user profile	
	Lab tech	Scientist	options	Lab tech	Scientist
Reagent empty	LOCK	LOCK	N/A		
Reagent LYSE expired	ALARM	ALARM	Automatic lock on reagent alarm	LOCK	ALARM
Reagent DILUENT expired	ALARM	ALARM	Automatic lock on reagent alarm	LOCK	ALARM
Reagent CLEANER expired	ALARM	ALARM	Automatic lock on reagent alarm	LOCK	ALARM
Reagent PACK expired	ALARM	ALARM	Automatic lock on reagent alarm	LOCK	ALARM
Low reagent level LYSE	ALARM	ALARM	N/A		
Low reagent level DILUENT	ALARM	ALARM	N/A		
Low reagent level CLEANER	ALARM	ALARM	N/A		
Low reagent level PACK	ALARM	ALARM	N/A		

<sup>◆</sup> Follow the indications displayed in help messages to perform corrective actions. For more detailed information: See Section 7, 6.1.3. Reagent alarms, page 7-38.

## **Archive status**

◆ To select the archive category, press the "Archive status" button Diag.4-6.

#### Diag.4-6 Archive status button



Tab.4-6 Archive category alarm messages

Alarm message	Status according to user profile		Locking alarm	Status according to user profile	
	Lab tech	Scientist	options	Lab tech	Scientist
settings archive should be archived	ALARM	ALARM	N/A		
analyser archive should be archived	ALARM	ALARM	N/A		
logs archive should be archived	ALARM	ALARM	N/A		
qc archive should be archived	ALARM	ALARM	N/A		
analyse archive should be archived	ALARM	ALARM	N/A		

<sup>◆</sup> Follow the indications displayed in help messages to perform corrective actions. For more detailed information: See Section 7, 6.1.4. Archive alarms, page 7-39.

#### **Application status**

◆ To select the application category, press the "Application status" button Diag.4-7.

Diag.4-7 Application status button



Tab.4-7 Application category alarm messages

Alarm message	Status according to user profile		Locking alarm	Status according to user profile	
	Lab tech	Scientist	options	Lab tech	Scientist
Barcode reader error	ALARM	ALARM	N/A		
Ticket printer error	ALARM	ALARM	N/A		
Application error	LOCK	LOCK	N/A		
LIS connection failed	ALARM	ALARM	N/A		
Printer queue full	LOCK	LOCK	N/A		
Print error	ALARM	ALARM	N/A		

<sup>◆</sup> Follow the indications displayed in help messages to perform corrective actions. For more detailed information: See Section 7, 6.1.5. Application alarms, page 7-40.

# 2. Daily quality control

# 2.1. General recommendations

- Before analyzing any patient blood samples, it is recommended that the operator performs quality control analysis on 3 levels of control blood material (low, normal and high) to verify that the instrument is performing within the specified ranges of the quality control material.
- ◆ Check control status (See Section 5, 2.3.1. Control status icons, page 5-4). If necessary, create a control (See Section 5, 2.3.2. Control creation, page 5-5).

# 2.2. Running control blood (ABX Minotrol 16)

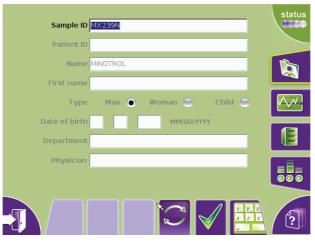
- 1- Enter "Sample identification" menu to identify the control.
- 2- Press "Sample ID" field to select it.
- 3- Read the contol label by means of barcode reader or type the control lot number (displayed in the "QC" tab) using virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).



To be recognized, ensure that the typed control lot number has the same case (lower or upper case) as the control lot number entered in the "Control Modification" screen. If it is correctly entered, "MINOTROL" will be displayed in the "Name" field.

The control name is automatically displayed in the "Name" field and all other fields become disabled.

Diag.4-8 Control identification



- 4- Press "Close key to close the virtual keyboard if it is opened.
- 5- Press  ${}^{\mathsf{n}}\mathbf{OK}{}^{\mathsf{m}}$  button to validate the control identification.
- 6- Follow the indications displayed in the "Sample analysis" dialog box and start the analysis. For more detailed information on sample running: See 5. Running analysis, page 4-16.
- 7- The analysis cycle will begin. It will take approximately 60 seconds.
- 8- At the end of the cycle, the result prints out if this function is activated (See Section 6, 7.2. Result settings, page 6-15). The "Sample analysis" dialog box is closed and results are displayed (See Section 5, 2.4. QC results, page 5-9 to have detailed information on control results).

If any results are out of their acceptable ranges, perform the following steps:

- 1- Clean the system (See Section 7, 3.3.5. Concentrated cleaning, page 7-9).
- 2- Perform a repeatability and a calibration (See Section 5, 4.2. Calibration procedure, page 5-22).
- 3- Re-run the control blood.
- 4- Open a new vial of control material.
- 5- If the problem persists, call your local HORIBA ABX Technical Support Representative.

# 3. Blood sample collection

- ◆ See Section 2, 3.2. Blood specimens, page 2-12 for collection requirements. Blood samples must be gently and thoroughly mixed with a rocking or tilting motion just before placing the sample into the tube holder for the analysis cycle.
- ◆ All blood samples should be collected using proper technique.
  - 1- When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Samples must be placed in a vacuum or atmospheric collection tubes.

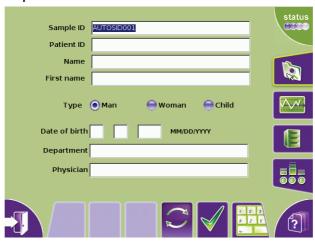


- 2- For additional information on collecting venous and capillary blood samples, refer to NCCLS document H3-A4 (June 1998) and NCCLS document H4-A5 (June 2004).
- 3- The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself. Any incorrectly measured blood sample collections will show a possible variation in the results.

# 4. Sample identification menu

◆ Once user is logged in, the "Sample identification" menu is displayed.

Diag.4-9 Sample identification menu



- The "Sample identification" menu is composed of text fields intended for entering sample information.
- ◆ The patient type is selected by using radio buttons. "Man" is selected by default.
- ◆ If there is unwanted data already entered into those fields, press "Reset" button (Diag.4-10) to delete this information. All fields will be cleared except "Sample ID" if automatic identification option is activated (See Section 6, 6.6. Identification option, page 6-14).

Diag.4-10 Reset button



If "R

If "Reset" button is pressed, a sampling needle reinitialization is also carried out (up and down movement).

In "Closed Tube" version, this button also allows to open the tube holder door if it was unawares closed and remains blocked.

◆ The "OK" button is used to validate sample identification. If the instrument is locked, this button is disable.

# 4.1. Entering patient sample information

# 4.1.1. Sample ID

- ◆ Sample ID is the sample identification number (16 alphanumeric characters maximum).
- ◆ It is a mandatory field. If it is not entered, the "OK" button is disable.
- ◆ It could be entered as follows:
- 1- Press "Sample ID" field to select it
- 2- Read sample ID label by means of barcode reader or use virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).



If the automatic identification option is activated, "AUTOSID" prefix cannot be used.

- ◆ The sample ID could also be generated automatically by the instrument. For this, check the "Automatic identification" option in the "Settings" menu (See Section 6, 6.6. Identification option, page 6-14). The SID number (16 alphanumeric characters maximum) is then displayed in the "Sample ID" field. This number is composed of:
  - the prefix "AUTOSID" (not modifiable)
  - the counter which raises at each sample identification (from 1 to 999).



Reminder: the Sample ID is unique in the same session.

#### 4.1.2. Patient ID

- ◆ The Patient ID is the patient identification number (16 alphanumeric characters maximum).
- ◆ Patient ID number may be the same as the sample ID number (its up to the laboratory).
- ◆ To enter patient ID:
- 1- Press "Patient ID" field to select it.
- 2- Use virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).
- When patient ID is entered, the instrument automatically searches, in its patient results database, for the patient demographic information (patient name, first name and date of birth). If found, all information on patient is displayed in the "Sample identification" menu.
- Patient demography is managed only by filling in the "Patient ID" field. If it is not filled in, the patient name, first name and date of birth entered are not traited as patient demography but only as additional information on patient.



The patient type is not included in the patient demography. It is necessary to select it manually.

◆ The patient demography could be modified. If changed, a confirmation message will be displayed. Press "OK" button to validate. A message indicating that patient demography has been modified is added in logs (in analysis category).

# 4.1.3. Patient name

- ◆ The patient name has up to 20 alphabetic characters maximum.
- ◆ To enter patient name, press "Name" field to select it and type in the patient name using the virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).



If you want that the patient name will be traited as an element of patient demography, the patient ID field has also to be filled in.

## 4.1.4. Patient first name

- ◆ The patient first name has up to 20 alphabetic characters maximum.
- ◆ To enter patient first name, press "First name" field to select it and type in the patient first name using the virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).



If you want that the patient first name will be traited as an element of patient demography, the patient ID field has also to be filled in.

## 4.1.5. Patient type

- ◆ 3 patient types are defined: man, woman or child. "Man" is selected by default.
- ◆ In the "Type" area press radio button corresponding to the patient type.

#### 4.1.6. Patient date of birth

- ◆ To enter patient date of birth, press "Date of birth" field to select it and type in the patient date of birth using the virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).
- ◆ If you want that the patient date of birth will be traited as an element of patient demography, the patient ID field has also to be filled in.



◆ Patient date of birth format is set in the "Settings" menu (See Section 6, 3.4. Date format setting, page 6-5).

## 4.1.7. Department name

- ◆ The department name is 20 alphanumeric characters maximum, it corresponds to the medical department where patient receives treatment.
- ◆ To enter the department name, press "Department" field to select it and type in the department name using the virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).

# 4.1.8. Physician name

- ◆ The physician name is 20 alphanumeric characters maximum, it corresponds to the physician who ordered the patient analysis.
- ◆ To enter the physician name, press "**Physician**" field to select it and type in the physician name using the virtual keyboard (See 4.2. Sample identification using the virtual keyboard, page 4-15) or an external keyboard (if one is connected).

# 4.2. Sample identification using the virtual keyboard

Press "Virtual keyboard" button to open the virtual keyboard (Diag.4-11).
 Diag.4-11 Virtual keyboard button



- ◆ Press the text field (located above the virtual keyboard) corresponding to the requested item
- ◆ Use "Previous" and "Next" keys to move backward or forward in the selected text field Diag.4-12).
  Diag.4-12 Previous/Next keys



◆ Use virtual keyboard to enter the text (if needed use the "**Del.**" key for correction Diag.4-13).

Diag.4-13 Del. key



• Press "Valid" key to validate each field (Diag.4-14), the next text field is automatically selected.
Diag.4-14 Valid key



◆ Once you have completed, press "Close" key to close virtual keyboard (Diag.4-15) and return to the "Sample identification" menu (See 4. Sample identification menu, page 4-12).

Diag.4-15 Close key



# 5. Running analysis



A patient analysis cannot be run if the instrument is locked. The "Status" button is red and the "OK" button is disable.

1- Press "**OK**" button to validate sample identification.

If a blank counting has to be done, the following message is displayed: "A reference cycle hemoglobin has to be carried out, press the manual sample bar to run this cycle." (OT) or "A reference cycle hemoglobin has to be carried out, close the door to run this cycle." (CT):

- Press the manual sample bar or close the tube holder door and wait until the end of the blank counting cycle.

If the startup is invalid, the following message is displayed: "Warning! Startup is not valid. Do you want to execute a startup cycle?":

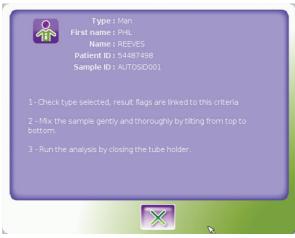
- Press "OK" button and wait until the end of the startup cycle.
- In the "Reference blank counting" screen, press "OK" button to validate blank results.
- Press "OK" button in the "Sample identification" menu.



If an analysis is run with an invalid startup, the "Invalid startup" alarm will be displayed on the result.

◆ The "Sample analysis" dialog box is displayed.

Diag.4-16 Sample analysis dialog box (ABX Micros ES60 CT)



◆ The "Sample analysis" dialog box gives a summary of the sample identification parameters: Patient type, Patient name and first name, Patient ID and Sample ID and gives instructions to run the analysis.



Press "Cancel" button to cancel the sample analysis.

2- Follow the indications displayed in the "Sample analysis" dialog box to run the analysis.

# ▼ ABX Micros ES60 CT:

- ◆ Select the position of the tube holder (See Tube holder selection:, page 4-17).
- Mix the sample gently and thoroughly.
- ◆ Place the sample in that position of the tube holder.
- Close the tube holder door.

#### Tube holder selection:

The sample tube holder has 4 positions according to the sample tube characteristics. The required position is selected when it is at the 12:00 o'clock position inside the sampling compartment. Turn the tube holder either "Right" or "Left". A "Clicking" sound will be heard once it is correctly placed. The tube holder is associated with 3 switches located on the inside "Right-hand" side of the piercing mechanism. These switches detect the position of the tube holder. A different configuration of "notches" on the side of the tube holder gives the switches the ability to detect the position desired. The 4 positions can be used for the following sample tubes with the standard tube holder:

- ◆ Position 2 : Micro sample collection device up to 0.5ml
- ◆Position 4 : Mini Vacutainers up to 3ml
- ◆Position 5 : Vacutainers up to 5ml
- ◆ Position 6: ABX Control, Calibrator, and Latex Vials only up to 2ml

#### V ABX Micros ES60 OT:

- ◆ Mix the sample gently and thoroughly.
- ◆ Remove the cap from the sample tube.
- ◆ Place the sample beneath the sampling needle.
- Raise up the tube so that the sampling needle lowers into the blood and press the manual sample bar.
- 3- The analysis cycle will begin. When the analysis is in progress, the menus are not accessible. Follow the indications in the different dialog box displayed.
- 4- When the analysis is completed, the "**Sample analysis**" dialog box is closed and results are displayed in the "**Result display**" menu (See 6. Results, page 4-18 to have detailed information on patient results).

# 6. Results

# 6.1. Results from analyser

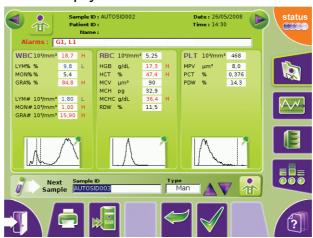
- Once analysis is completed, the data are treated by the instrument calculation software which allows the display of results in accordance with the instrument settings (parameters, units, curves, alarms, etc.).
- ◆ These results are associated with analysis limits specified in the instrument settings.
- ◆ Thus, morphological flags may be determined.

# 6.2. Displaying results

# 6.2.1. Result display screen

◆ The results are automatically displayed in the "Result display" screen.

Diag.4-17 Result display



◆Use "Previous" and "Next" buttons, located at the top of the result screens, to navigate between patient result screens of the same session (See Section 1, "Previous" and "Next" buttons, page 1-16).



- ◆Use the "Result history" menu to display all stored results (See 6.5. Result history, page 4-26).
- ◆Use the "Back" button to return to the "Sample identification" menu.
- ◆ A patient result screen gives the following information:
  - the patient information: See 6.2.2. Patient information, page 4-19.
  - the alarms if any were reported: See 6.2.3. General alarms, page 4-19.
  - the patient results and associated flags: See 6.2.4. Results and associated flags, page 4-19.
- ◆ It allows to display detailed results of one paramater family: See 6.2.5. Detailed results, page 4-20.



To display RUO parameters (PCT and PDW), the function "With RUO data" must be activated in the "Settings" menu (See Section 6, 6.5. Analysis running, page 6-14).

- ◆ To print or send results to the LIS: See 6.3. Results sending and transmitting, page 4-21.
- ◆ A result screen also allows to run analysis with simplified identification: See 6.4. Analysis run with the simplified identification, page 4-25.

## 6.2.2. Patient information

- ◆ A summary of patient information is displayed at the top of the "Result display" screen: sample ID, patient ID, patient name, analysis date and time.
- ◆ More detailed information on the patient can be displayed by pressing the "Patient identification" button located at the top of the result screen (Diag.4-18).

## Diag.4-18 Patient identification button



◆ A dialog box is displayed containing the following information (press "OK" button to close the dialog box):

Sample ID Patient first name Patient date of birth Department name
Patient ID Patient name Patient type Physician name

# 6.2.3. General alarms

The general alarms are displayed in the "Alarms" field located below the patient information.

#### Analysis alarms

- ◆ MIC, SCH, SCL. See 7. Flags, page 4-28.
- ◆ L1, M2, G1, G2, G3. See 7. Flags, page 4-28.
- ◆ "CPLT"= Concentrated platelets: indicates the triggering of the PLT extended linearity mode for an HGB<2g/dL (See Section 2, Tab.2-11 Linearity, page 2-10).</p>

## Analyser alarms

- ◆ "STi"= Invalid startup.
- ◆ "T°"= Reagent temperature out of range.
- ◆ "Rex"= Expired reagent (See Section 7, 4.2. Reagent management, page 7-21).

#### QC alarms

- "QCi"= Invalid QC: one of the QC parameters is out of range.
- ◆ "XB"= XB drift: one of the XB parameters is out of range or if less than 20 QC results have been archived (See Section 5, 3. Patient Quality Control (XB), page 5-19).
- ◆ "QCtl"= Inter QC time limit: time between two QC control runs has expired.

# 6.2.4. Results and associated flags

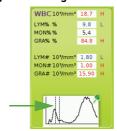
The "Result display" screen displays for each parameter:

- Parameter name.
- ◆ Parameter unit: to set units (See Section 6, 6.2. System units settings, page 6-11).
- Parameter value:
  - if a parameter result has a "H" flag set, its value is displayed in red.
  - if a parameter result has a  $\ensuremath{^{\text{L}}}\xspace$  flag set, its value is displayed in blue.
- ◆ Parameter flags: D, H, L, \$, \*, ! (See 7. Flags, page 4-28).
- ◆ The histograms present in the result.

## 6.2.5. Detailed results

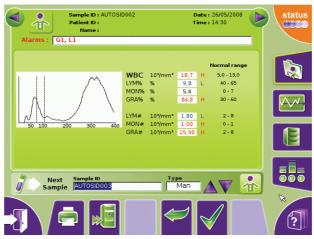
◆ To display detailed results of one parameter family, press the corresponding histogram area.

Diag.4-19 Histogram area



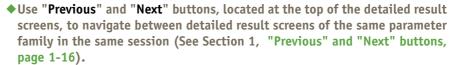
◆ The "Detailed results" screen is displayed.

Diag.4-20 Detailed results



It gives for each parameter of the selected family the following information:

- ◆ Parameter name.
- ◆ Parameter unit: to set units (See Section 6, 6.2. System units settings, page 6-11).
- ◆ Parameter value:
  - if a parameter result has a "H" flag set, its value is displayed in red.
  - if a parameter result has a "L" flag set, its value is displayed in blue.
- ◆ Parameter flags: D, H, L, \$, \*, ! (See 7. Flags, page 4-28).
- ◆ The normal range for each parameter: to set normal range (See Section 6, 6.3. Analysis limits, page 6-12).
- ◆ The histograms present in the result.



◆Use the "Back" button to return to the "Result display" screen.



# 6.3. Results sending and transmitting

# 6.3.1. Printing results

Results can be printed:

- ◆ Automatically: See Section 6, 7.2. Result settings, page 6-15 to set this option.
- Manually.



<u>Integrated printer accepts "latin characters" only</u>. Please use an external printer when non "latin characters" are used.

- 1- In the results screen, press "Print" button to print results manually.
- 2- The following printing progress message is displayed: "Analysis results printing in progress."

# 6.3.2. Result printouts



The analysis limits can only be printed on an external printer.

- ◆ Results are printed in the format defined by the printout criteria set in the "Settings" menu: See Section 6, 7.4. Report header settings, page 6-16.
- ◆ To select which paramaters will be printed: See Section 6, 7.3. Parameter settings, page 6-15.
- ◆ Examples of result printouts are given in the following pages: See Result printout on external printer, page 4-22.

See Result printout on integrated ticket printer, page 4-23.

#### Result printout on external printer

#### A result printout on external printer contains (Diag.4-21)

- 1- Headers set in the "Settings" menu.
- 2- Patient demography and analysis information (date, operator).
- 3- Analyser and analysis alarms, if any were reported.
- 4- WBC parameters and associated results.
- 5- WBC flags, if any were reported (See 7. Flags, page 4-28).
- 6- WBC units.
- 7- WBC parameter limits (See 7.2. Normal limits, page 4-28).
- 8- WBC distribution curve (histogram).
- 9- RBC parameters and associated results.
- 10- RBC flags, if any were reported (See 7. Flags, page 4-28).
- 11- RBC units.
- 12- RBC parameters limits (See 7.2. Normal limits, page 4-28).
- 13- RBC distribution curve (histogram).
- 14- PLT parameters and associated results.
- 15- PLT flags, if any were reported (See 7. Flags, page 4-28).
- 16- PLT units.
- 17- PLT parameters limits (See 7.2. Normal limits, page 4-28).
- 18- PLT distribution curve (histogram).
- 19- Printout information (date, user name, analyser reference).

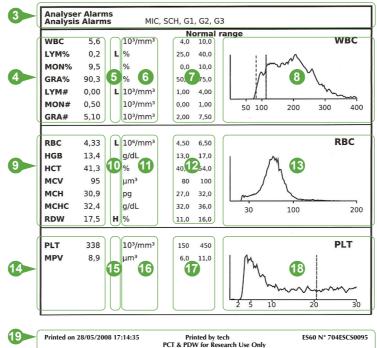
## Diag.4-21 Result printout on external printer (example)



rue du caducée

montpellier

# Sample ID AUTOSID021 Analysis Date 27/05/2008 17:13:52 Physician Department

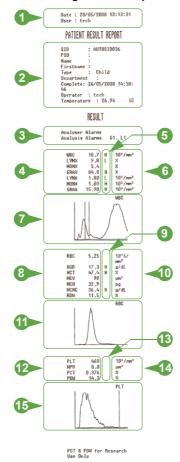


# Result printout on integrated ticket printer

## A result printout on integrated ticket printer contains (Diag.4-22)

- 1- Printout information (date, user name)
- 2- Patient demography and analysis information (date, operator).
- 3- Analyser and analysis alarms, if any were reported.
- 4- WBC parameters and associated results.
- 5- WBC flags, if any were reported (See 7. Flags, page 4-28).
- 6- WBC units.
- 7- WBC distribution curve (histogram).
- 8- RBC parameters and associated results.
- 9- RBC flags, if any were reported (See 7. Flags, page 4-28).
- 10- RBC units.
- 11- RBC distribution curve (histogram).
- 12- PLT parameters and associated results.
- 13- PLT flags, if any were reported (See 7. Flags, page 4-28).
- 14- PLT units.
- 15- PLT distribution curve (histogram).

Diag.4-22 Result on integrated ticket printer (example)



# 6.3.3. Sending results



The instrument can be linked to the LIS using an ABX or an ASTM format.

Results can be sent to the LIS:

◆ Automatically: See Section 6, 7.2. Result settings, page 6-15 to set this option.

The automatic sending of results is blocked if the following alarms and flags are triggered:



- ◆Alarms: "QCtl" (Inter QC time limit), "QCi" (Invalid QC), "STi" (Invalid startup), "T°" (Reagent temperature), "Rex" (Expired reagent), "CPLT" (Concentrated platelets).
- **♦** Flags: \$, !, \*, D.
- Manually.



To select which paramaters will be sent: See Section 6, 7.3. Parameter settings, page 6-15.

To send results manually:

◆ In the results screen, press "Send" button (Diag.4-23).

Diag.4-23 Send button



- ◆ A LIS connection is established.
- ◆ A message is displayed to inform user on the connection and sending progress.

# 6.4. Analysis run with the simplified identification

Simplified identification allows to run a control blood or a patient analysis directly from the result screen and without entering all the sample information in the "Sample identification" menu.

Diag.4-24 Simplified identification



- ◆ User only has to enter the sample ID and the patient type (for patient sample). In the results menu (main or detailed):
- 1- Press "Sample ID" field to select it.
- 2- Read sample ID label by means of barcode reader or type sample ID using an external keyboard.



If the automatic identification option is activated, the next sample ID number is automatically displayed in the "Sample ID" field.

The patient type displayed in the "**Type**" list corresponds to the default type: Man. If needed, modify it:

- 3- Use arrow buttons to select patient type in the "Type" list.
- 4- Press "OK" button to validate the sample identification.
- 5- Follow the indications displayed in the "Sample analysis" dialog box and start the analysis. For more detailed information on sample running: See 5. Running analysis, page 4-16.
- ◆ To access the "Sample identification" menu again to identify (in detail) another sample, press "Sample identification menu" button (Diag.4-25).

Diag.4-25 Sample identification menu button



# 6.5. Result history

# 6.5.1. Result history menu description

◆ To access the "Result history" menu, press "Result history menu" button (Diag.4-26).
Diag.4-26 Result history menu button



◆ The "Result history" menu displays all stored results.

## Diag.4-27 Result history



- 1- The "**Result history**" menu allows to display the results of the current session or archived results of the previous sessions:
  - To display results of the current session, press "Current Session" radio button
  - To display results of the previous sessions, press "Archive Results" radio button.

### 2- Result list:

Results are sorted by date/hour by default.

Press one of the 3 following items: "Date/Hour", "Sample ID" or "Name" to sort results by this item.

To scroll up and down the table pages and lines use the following buttons:

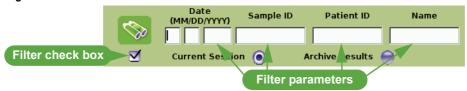


- "Page up" button goes to the previous result page
- ◆ "Page down" button goes to the next result page
- ◆"Up" button goes to the upper line of the selected result
- ◆"Down" button goes to the under line of the selected result
- 3- At the bottom of the "**Result history**" menu, the following information of the selected result is displayed:
  - Analysis date
  - Sample ID
  - Patient ID
  - Patient name
  - Patient first name
- 4- The "Result history" menu also allows to filter the results: See 6.5.2. Filtering results with the filter check box, page 4-27.
- 5- To access detailed result: See 6.5.3. Accessing detailed results, page 4-27.

## 6.5.2. Filtering results with the filter check box

- ◆ The results can be filtered by 4 different items: "Date", "Sample ID", "Patient ID" and/or "Name".
- 1- Check the filter check box (Diag.4-28).

#### Diag.4-28 Filter check box



2- Enter date in the "Date" fields and/or sample ID in the "Sample ID" field and/or patient ID in the "Patient ID" field and/or patient name in the "Name" field using the virtual keyboard or an external keyboard (if one is connected).



- Only one character can be typed in. For example: only the month or the year for the date, the first letter of the patient name, etc.
- ◆The system will recognized a name with the same case than the case entered in the sample identification.
- 3- Press "Filter" button (Diag.4-29).

Diag.4-29 Filter button



◆ The results are filtered according to filter parameters set.



To deactivate filter function, uncheck the filter check box. All results are re-displayed.

## 6.5.3. Accessing detailed results

◆ In the table, select the result to display and press "View" button (Diag.4-30).

## Diag.4-30 View button



◆ The "Result display" menu is displayed (See 6.2. Displaying results, page 4-18).

Use "Previous" and "Next" buttons, located at the top of the result screens, to navigate between patient result screens (See Section 1, "Previous" and "Next" buttons, page 1-16).



The previous or next result screen displayed is linked to selected filter option:

- ◆If "Current Session" is selected, the displayed results corresponds to the results of the current session.
- ◆If "Archive Results" is selected, the displayed results corresponds to archived results of previous session sorted by chronological order.
- ◆ Use the "Back" button to return to the "Result history" menu.

# 7. Flags

# 7.1. Introduction

These instrument flags can be classified into 3 different groups:

- 1- Results exceeding normal limits: See 7.2. Normal limits, page 4-28.
- 2- Flags linked to results that exceed the linear range of the instrument or leading to "Rejected Analysis": See 7.3. Flags linked to linearity range and rejected analysis, page 4-28.
- 3- Flags linked to the morphology of a blood cell population: See 7.4. Morphology flags, page 4-29.

# 7.2. Normal limits

- ◆ The "H" flag located next to a parameter result indicates that the value is "Above" the upper limit of the analysis limits set by the operator: See Section 6, 6.3. Analysis limits, page 6-12.
- ◆ The "L" flag located next to a parameter result indicates that the value is "Below" the lower limit of the analysis limits set by the operator: See Section 6, 6.3. Analysis limits, page 6-12.

# 7.3. Flags linked to linearity range and rejected analysis

These flags are shown in different ways as indicated:

- ◆ See 7.3.1. Results exceeding linear range, page 4-28.
- ◆ Results associated with an asterisk (\*): See 7.3.2. Results rejected, page 4-28.
- ◆ Dollar sign (\$): See 7.3.3. Result comparison, page 4-28.
- ◆ Exclamation mark for HGB (!): See 7.3.4. HGB blank reference, page 4-29.



When D, !, \*, \$ flags are triggered, result cannot be sent automatically.

## 7.3.1. Results exceeding linear range

Tab.4-8 Displayed, printed and host transmitted results

Parameters	Linearity limits	Visible range	> Visible range
WBC $(x10^3/mm^3)$	"result"	"result"+"D"	+ D
RBC (x10 <sup>6</sup> /mm <sup>3</sup> )	"result"	"result"+"D"	+ D
PLT $(x10^3/mm^3)$ HGB > 2g/dl PLT $(x10^3/mm^3)$ HGB < 2g/dl	"result" "result"	"result"+"D" "result"+"D"	+ D + D
HGB (g/dl)	"result"	"result"+"D"	+ D
HCT (%)	"result"	"result"+"D"	+ D



Whole blood parameter results within visible range will still give a result value with a "D" indication. These results require a dilution (or PRP analysis for PLT) of the sample with the instrument diluent.

# 7.3.2. Results rejected

- ◆ A "Reject" flag, shown by an asterisk (\*) following the parameters WBC, RBC, HCT, or PLT indicates that the ABX Micros ES60 OT/CT has analyzed that parameter for a maximum of 3 counts. All 3 counts were outside the system precision limits for that specific parameter.
- ◆ The results should be verified by re-running the sample.

# 7.3.3. Result comparison

- ◆ A reportable result shown by a dollar sign (\$) following the parameters WBC, RBC, HCT or PLT indicates that the ABX Micros ES60 OT/CT has analyzed that parameter for a maximum of 3 counts. Two out of three counts were within the system precision limits for that specific parameter.
- ◆ The results can be reported, but the parameter should be monitored for the next sample analyzed.

## 7.3.4. HGB blank reference

- ◆ A suspicious flag, shown by an exclamation mark (!) located next to the hemoglobin result shows that the HGB blank carried out during the analysis differs from the previous cycle's HGB blank. This (!) means that both HGB blanks were outside the instrument precision limits.
- ◆ This result can be reported, but the parameter should be monitored for the next sample analyzed.
- ◆ The MCH and MCHC may also be affected by this (!) flag depending on the severity of the results.



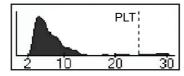
If the suspicious flag (!) occurs more than 3 times on consecutive sample runs, troubleshoot the HGB (See Section 7, 5. Troubleshooting, page 7-31).

# 7.4. Morphology flags

# 7.4.1. Flags on PLT distribution curve

◆ The PLT histogram has 128 channels between 2fl and 30fl. A mobile threshold (positioned to 25fl by default) moves according to the microcyte population present in the platelet analysis area.

Diag.4-31 PLT distribution curve

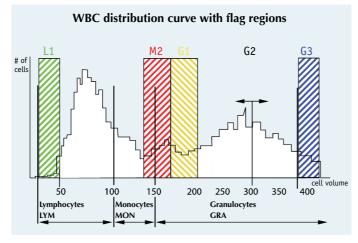


- ◆ The PLT flags are as follows:
- 1- An excessive presence of cells to the right of the threshold area (25fl) will trigger the "MIC" (microcytes) flag. The mobile threshold looks for a valley between the 25fl (standard value) and 18fl.
- 2- When there is no valley between PLT and RBC populations, a reject PLT (\*) flag is triggered. PLT results are not reliable and must be verified by a manual platelet count.
- 3- If the number of particles between 18fl and 25fl are too high, the "**SCH**" (schistocytes) flag will be triggered. Suspected abnormalities include:
  - Presence of schistocytes.
  - Presence of platelet aggregates: verify the platelet results on a stained blood smear.
- 4- The "SCL" (small cells) flag indicates the presence of small cells in the 2fl to 3fl zone.

## 7.4.2. Flags on WBC distribution curve

◆ The ABX Micros ES60 OT/CT has a system of WBC differential flags alerting the operator to the possible presence of pathological cells, abnormal volume distribution histograms, or abnormal elevated populations such as the excessive presence of eosinophils and basophils.

Diag.4-32 WBC distribution curve with flagging regions



1- Flag **"L1"** indicates an abnormal number of cells, in comparison with the lymphocytes, in the 30fl to 60fl zone. The pathological elements which may be found in this area will include:

- Platelet aggregates
- ◆ Nucleated red blood cells
- This flag corresponds to the number of cells counted in the first channels, out of the total number of lymphocytes.
- 2- The "M2" flag indicates an excessive number of cells in the 130fl to 160fl zone. The pathological elements which may be found in this area will include:
- Lymphoblasts
- Myelocytes
- Abnormal lymphocytes
- Basophilia (too many basophils)
- ◆ This flag corresponds to the number of cells counted in the detection zone in comparison to the total number of granulocytes.
- 3- The "G1" flag indicates an excessive number of cells in the 160fl to 220fl zone. The pathological elements which may be found in this area will include:
- Eosinophilia (too many eosinophils).
- Myelocytes
- Neutrophil polynucleose
- ◆ This flag corresponds to the number of cells counted in the detection zone in comparison to the total number of granulocytes.
- 4- The "G2" flag indicates an excessive number of cells in the 220fl to 250fl zone. This flag makes it possible to follow an abnormal granulocyte peak displacement. Some of the cell variances will include:
- ◆ Anomalies in the cell membrane of the granulocytes.
- Possible lyse flow error.
- ◆ Fluidic errors.
- ◆ Old blood (after 6 to 8 hours) unrefrigerated.
- ◆ Granulocyte cell size less than 250fl.
- 5- The "G3" flag indicates an excessive number of cells larger than 400fl. The pathological elements which may be found in this area will include:
- Metamyelocytes.
- Many types of large immature cells.
- ◆ This flag corresponds to the number of cells counted in the detection zone in comparison to the total number of granulocytes. This cell count will be higher than the set level.

All anomalies and/or abnormal distribution flags given by the instrument should be manually verified by the examination of a stained peripheral blood smear for the presence of pathological elements. As a result of the differential resistance of cytoplasmic membranes in the different cell types, pathological elements can be found in a number of different zones. This also applies to the presence of normal or nonpathological cells that have been subjected to chemotherapy or some other form of treatment which affects the alarm zones. These types of treatment will result in "False" alarms.



# Quality assurance

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# 1. "Quality control" menu

- ◆ The Quality Control allows 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.
- Three control levels are available for each test. The three controls can be simultaneously active allowing QC on three levels.
- ◆ Press "Quality control menu" button (Diag.5-1) to access the "Quality control" menu.
  Diag.5-1 Quality control button



The " ${\bf Quality\ control"}$  menu is composed of three tabs:

- ◆ "QC" tab: See 2. QC tab, page 5-3.
- ◆ "XB" tab: See 3. Patient Quality Control (XB), page 5-19.
- ◆ "Cal" tab: See 4. Calibration, page 5-21

# 2. QC tab

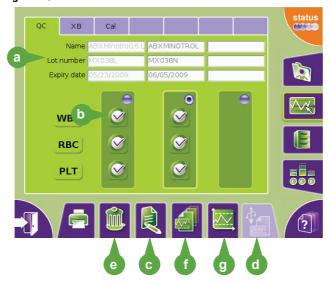
# 2.1. Introduction

- ◆ The "QC" tab is the control blood management menu: lot information and status, QC results, and statistical results.
- ◆ The "QC" tab displays a succinct view of all activated controls.

To access the "QC" tab:

- 1- Press "Quality control menu" button (Diag.5-1) to access the "Quality control" menu.
- 2- Press "QC" tab.

#### Diag.5-2 QC tab



- a- Control lot information: See 2.2. "QC" tab description, page 5-4.
- b- Control status: See 2.3.1. Control status icons, page 5-4.
- c- For control creation: See 2.3.2. Control creation, page 5-5.
- d- For control importation: See Control importation, page 5-5.
- e- For control closing: See 2.3.3. Control closing, page 5-8.
- f- QC result hitory: See 2.4.3. QC result history, page 5-15.
- g- LJ screen access: See 2.5. Levey Jennings graphs, page 5-16.

#### The "QC" tab can be printed:

- 1- In the "QC" tab, press the "Print" button.
  A message is displayed asking to choose between printing the QC tab or the results of the selected control.
- 2- Press the "**Print the QC matrix**" radio button then press "**OK**" button.

  The following printing progress message is displayed: "**QC matrix printing in progress.**"

The "QC" tab printout gives the following information on the selected control: the control lot number, the control name, the control expiration date and the control status (passed or invalid).

# 2.2. "QC" tab description

The "QC" tab is composed of the following elements:

- ◆ 3 fields, located at the top of the tab, give information on the selected control:
  - the "Name" field displays the control name.
  - the "Lot number" field displays the control lot number.
  - the "Expiry date" field displays the control expiration date.
- ◆ 3 frames containing 1 radio button to select control (See 2.3. Control management, page 5-4). It is recommended to use the left frame for the low level control, the middle frame for the normal level control and the right frame for the high level control. When the user selects a control, the corresponding control frame is highlighted.
- ♦ 9 icons give the QC results status of each family (See 2.3.1. Control status icons, page 5-4).

# 2.3. Control management

This chapter gives information on control status and how to manage them.

- ◆ See 2.3.1. Control status icons, page 5-4.
- ◆ See 2.3.2. Control creation, page 5-5.
- ◆ See 2.3.3. Control closing, page 5-8.

#### 2.3.1. Control status icons

◆ 4 different icons inform the user on the control status: See Tab.5-1 Control status icons, page 5-4. Tab.5-1 Control status icons

Icon	Name	Description
	QC expired	The control blood expiration date is reached. Analysis cannot be run on the expired control but patient samples can be analysed. The control is expired but its result is valid (until the time limit between two control runs has not been exceeded).
<u></u>	Inter QC time limit	The inter QC time limit set has been exceeded between two control runs. Patient samples can be analysed but the "QCtl" (QC time limit) alarm will be triggered on the result.  Run an analysis for this control (See Section 4, 2.2. Running control blood (ABX Minotrol 16), page 4-11).  The instrument automatic lock on Inter QC time limit alarm could be set in the "Settings" menu (See Section 6, 6.5. Analysis running, page 6-14).
•	Invalid QC	The QC is invalid: - In a parameter family, at least one parameter QC result is out of range. or - QC is invalid because flag D, *, \$ or ! is triggered. The instrument automatic lock on invalid QC alarm could be set in the "Settings" menu (See Section 6, 6.5. Analysis running, page 6-14).
	QC passed	The QC has passed.

### 2.3.2. Control creation

#### Introduction

- A new lot of control blood can be created by two different ways:
- ◆ Importation of control information from USB key: See Control importation, page 5-5.
- ◆ Creation with the "Control Modification" screen: See Control creation, page 5-6.

# **Control importation**

The control file imported from USB key contains control lot number, name, expiration date and target values.

- 1- First import control file on a USB key (See Control file downloading, page 5-6).
- 2- Press "Quality control menu" button to access the "Quality control" menu.
- 3- In the "QC" tab, select an empty frame where no control has been created by pressing the corresponding radio button located on the top right corner of the frame.
- ◆ If no frame is available, a place will be freed up when a control will be closed manually (See 2.3.3. Control closing, page 5-8).
- 4- The selected frame is highlighted, press "Import QC" button (Diag.5-3).

#### Diag.5-3 Import QC button



- ◆ The following message is displayed: "Please insert your USB key into the front slot of the instrument. Select 'OK' to continue QC controls targets import."
  - ◆Control files must have the following name format: "qctgetxxxxx.csv".



- ◆The instrument takes the first file with this name format on the USB key. To guarantee that only the required file will be used, it is recommended to leave only one control file on the key.
- 5- Insert USB key in the front slot of the instrument, then press "**OK**" button.
- 6- In the "QC Name" list, select the control lot to import then press "Import QC" button.



Never remove the USB key from the front slot before the progress indication window closes.

- When importation is complete, control information is displayed in the "Control Modification" screen.
- 7- Check the control information.
- 8- "InterQC timelimit" is not imported from USB key. By default is 24 hours. See Control setting, page 5-7 to modify it.
- 9- Press "OK" button.
- 10- Check the control target values by pressing the "Targets" button (Diag.5-6). If needed modify them (See Entering control target values, page 5-7).
- 11- Press "Back" button twice to return to the "QC" tab.

## **Control file downloading**

- 1- Connect to HORIBA ABX website: http://www.horiba-abx.com/documentation: hematology/quality control target.
- 2- In the "quality control target" page, click the control name ("minotrol 16" for example ).
- 3- In the control page, click the instrument name "micros es 60".
- 4- In the "micros es 60" page, click the control lot number ("mx038" for example).
- 5- In the "Control Target Files" page, click the control target file in "Download Target values" (Diag.5-4).

Diag.5-4 Target file screen



6- Download control target file on a USB key.

#### **Control creation**

To add a new lot of control blood, follow the steps below:

- ◆ See Accessing the "Control Modification" screen, page 5-6.
- ◆ See Control identification, page 5-7.
- ◆ See Control setting, page 5-7.
- ◆ See Control creation validation, page 5-7.
- ◆ See Entering control target values, page 5-7.

#### Accessing the "Control Modification" screen

- 1- Press "Quality control menu" button to access the "Quality control" menu.
- 2- In the "QC" tab, select an empty frame where no control has been created by pressing the corresponding radio button located on the top right corner of the frame.
- ◆ If no frame is available, a place will be freed up when a control will be closed manually (See 2.3.3. Control closing, page 5-8).
- 3- The selected area is highlighted, press "**Edit**" button.
- ◆ The "Control Modification" screen is displayed.

Diag.5-5 Control modification screen



4- Now, the control can be identified: See Control identification, page 5-7.

#### **Control identification**

- 1- Press "Lot number" field to select it and enter the control lot number.
- 2- Read the control label by means of barcode reader or type the control lot number using the virtual keyboard or an external keyboard (if one is connected).
- 3- Press "Name" field to select it and enter the control name.
- 4- Type the control name in the "Name" field using the virtual keyboard or an external keyboard (if one is connected).
- 5- Once the control blood is identified, it has to be set: See Control setting, page 5-7.

#### Control setting

In the "Control Modification" screen:

- 1- Press "Expiry date" field to select it to set the control blood expiration date.
- 2- Type the control blood expiration date in the "**Expiry date**" field using the virtual keyboard or an external keyboard (if one is connected).
- ◆ The expiration date must be given as a date with the date format set in the "Settings" menu (See Section 6, 3.4. Date format setting, page 6-5).
- 3- Press "InterQC timelimit" field to select it and set the maximum time allowed between 2 control runs using the virtual keyboard or an external keyboard (if one is connected). By default is 24 hours.
- ◆ The time between two control runs is given in hours.
- 4- To validate the control creation: See Control creation validation, page 5-7.

#### Control creation validation

- 1- Press "Close" key to close the virtual keyboard if it is opened.
- 2- Press "OK" button in the "Control Modification" screen.
- ◆ The new control is created. It can be modified as long as no control analysis is running on it.
- ◆ Your own target values need to be entered.
- 3- To enter control target values: See Entering control target values, page 5-7.

## **Entering control target values**

In the "Control Modification" screen.

1- Press "Targets" button (Diag.5-6).

Diag.5-6 Target button



◆ The "Target Modification" screen is displayed.

Diag.5-7 Target modification screen



- 2- Press "Edit" button.
- 3- Press corresponding radio button to select a parameter family.

- 4- Enter "Target" and "Tolerance" values for each parameter in the corresponding fields:
  - Press value fields to select them.
  - Type the control target values in the fields using the virtual keyboard or an external keyboard (if one is connected).



When using the virtual keyboard, values can be entered only for one parameter family at a time. Close the virtual keyboard, then press corresponding radio button to select another parameter family.

- Press "Close" key to close the virtual keyboard if it is opened.
- In the "Target Modification" screen, press "OK" button.
- Press "Back" button to return to the "Control Modification" screen.

## 2.3.3. Control closing

- 1- Press "Quality control menu" button to access the "Quality control" menu.
- 2- Press corresponding radio button to select the control to close.
- 3- Press "Delete" button.

Diag.5-8 Delete button



- ◆ The following confirmation message is displayed: "Are you sure to want to close this control?"
- 4- Press "OK" button.

Closed control lots are kept for one year on the analyser.



Once a control is closed, the "Status" button blinks. The "Status" area informs the user that this control can be archieved by using a USB key (See Section 7, 4.3.2. Archives creation, page 7-26).

Once archived, the control results can be consulted on an external computer.

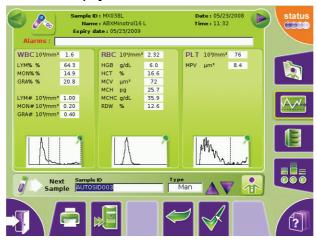
# 2.4. QC results

- ◆ Results are compared with the entered target values (See Entering control target values, page 5-7) to establish if the QC run is passed or invalid (See 2.4.1. Displaying QC results, page 5-9).
- ◆ The current QC results can be printed and sent to the LIS: See 2.4.2. QC results printing and transmitting, page 5-11.
- ◆ The 100 latest QC are listed in the "QC result history" menu: See 2.4.3. QC result history, page 5-15.

# 2.4.1. Displaying QC results

◆ Once the QC analysis cycle is finished, the results are automatically displayed in the "QC result display" screen.

Diag.5-9 QC result display



◆Use "Previous" and "Next" buttons, located at the top of the result screens, to navigate between QC result screens of the same control (See Section 1, "Previous" and "Next" buttons, page 1-16).



- ◆Use the "History" button to display QC results history for the selected control (See 2.4.3. QC result history, page 5-15).
- ◆Use the "Back" button to return to the "Sample identification" menu.
- ◆ A QC result screen gives the following information:
  - the control information: See Control information, page 5-10.
  - the alarms if any were reported: See Section 4, 6.2.3. General alarms, page 4-19.
  - the QC results and associated flags: See Section 4, 6.2.4. Results and associated flags, page 4-19.
- ◆ It allows to display detailed QC results of one paramater family: See Detailed QC results, page 5-10.
- ◆ To print or send results to the LIS: See 2.4.2. QC results printing and transmitting, page 5-11.
- ◆ It also allows to run analysis with simplified identification: See Section 4, 6.4. Analysis run with the simplified identification, page 4-25.

#### **Control information**

- ◆ A summary of control information is displayed at the top of the "QC result display" screen: sample ID (= QC lot number), control name, control expiration date, analysis date and time.
- ◆ The "Control information" button (located at the top of the screen, Diag.5-10) allows to display a dialog box containing the following information (press "OK" button to close the dialog box): Sample ID (= QC lot number) and control name.

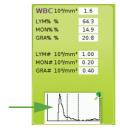
Diag.5-10 Control information button



## **Detailed QC results**

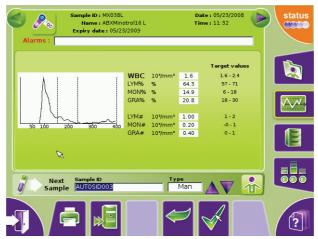
◆ To display detailed QC results of one parameter family, press the corresponding histogram area.

Diag.5-11 QC histogram area



◆ The "Detailed QC results" screen is displayed.

Diag.5-12 Detailed QC results



It gives for each parameter of the selected family the following information:

- Parameter name.
- ◆ Parameter unit: to set units (See Section 6, 6.2. System units settings, page 6-11).
- ◆ Parameter value.
- ◆ Parameter flags: See Section 4, 7. Flags, page 4-28.
- ◆ The control lot target values.
- ◆ The histograms present in the result.



- ◆Use "Previous" and "Next" buttons, located at the top of the detailed result screens, to navigate between detailed QC result screens of the same control (See "Previous" and "Next" buttons, page 1-16).
- ◆Use the "Back" button to return to the "QC result display" screen.

## 2.4.2. QC results printing and transmitting

## **Printing QC results**

- QC results can be printed:
- ◆ Automatically: See Section 6, 7.2. Result settings, page 6-15 to set this option.
- Manually.



<u>Integrated printer accepts "latin characters" only</u>. Please use an external printer when non "latin characters" are used.

- 1- In the QC results screen, press "Print" button to print results manually.
- 2- A printing progress message is displayed.

## **QC** result printouts

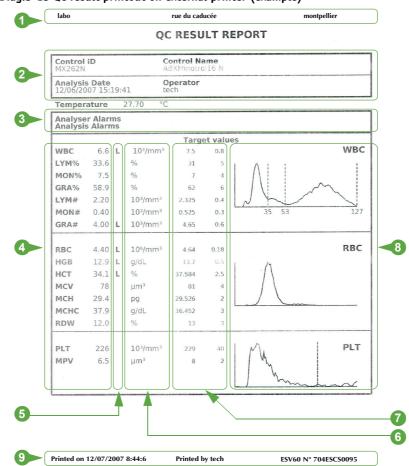
- ◆ Control results are printed in the format defined by the printout criteria set in the "Settings" menu: See Section 6, 7.4. Report header settings, page 6-16.
- ◆ To select which paramaters will be printed: See Section 6, 7.3. Parameter settings, page 6-15.
- ◆ Examples of control result printouts are given in the following pages:
  - See QC result printout on an external printer, page 5-12.
  - See QC result printout on integrated ticket printer, page 5-13.

## QC result printout on an external printer

#### A result printout contains (Diag.5-13)

- 1- Headers set in the "Settings" menu.
- 2- Control ID, control name and analysis information (date, operator).
- 3- Analyser and analysis alarms, if any were reported.
- 4- Parameters and associated results.
- 5- WBC, RBC and PLT flags, if any were reported (See Section 4, 7. Flags, page 4-28).
- 6- Units.
- 7- WBC, RBC and PLT target values.
- 8- WBC, RBC and PLT distribution curves (histograms).
- 9- Printout information (date, user name, analyser reference).

#### Diag.5-13 QC result printout on external printer (example)

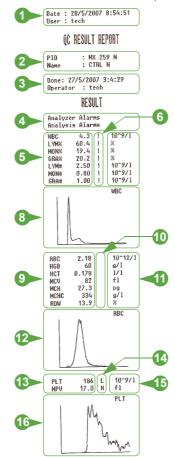


## QC result printout on integrated ticket printer

#### A result printout on integrated ticket printer contains (Diag.5-14)

- 1- Printout information (date, user name)
- 2- Control ID, control name
- 3- Analysis information (date, operator).
- 4- Analyser and analysis alarms, if any were reported.
- 5- WBC parameters and associated results.
- 6- WBC flags, if any were reported (See Section 4, 7. Flags, page 4-28).
- 7- WBC units.
- 8- WBC distribution curve (histogram).
- 9- RBC parameters and associated results.
- 10- RBC flags, if any were reported (See Section 4, 7. Flags, page 4-28).
- 11- RBC units.
- 12- RBC distribution curve (histogram).
- 13- PLT parameters and associated results.
- 14- PLT flags, if any were reported (See Section 4, 7. Flags, page 4-28).
- 15- PLT units.
- 16- PLT distribution curve (histogram).

Diag.5-14 QC result on integrated ticket printer (example)



## **Sending results**



The instrument can be linked to the LIS using an ABX or an ASTM format.

QC results can be sent to the LIS:

◆ Automatically: See Section 6, 7.2. Result settings, page 6-15 to set this option.

The automatic sending of results is blocked if the following alarms and flags are triggered:



- ◆Alarms: "QCtl" (Inter QC time limit), "QCi" (Invalid QC), "STi" (Invalid startup), "T°" (Reagent temperature), "Rex" (Expired reagent), "CPLT" (Concentrated platelets).
- ◆Flags: \$, !, \*, D.
- Manually.



To select which paramaters will be sent: See Section 6, 7.3. Parameter settings, page 6-15.

To send QC results manually:

◆ In the "QC result display" menu, press "Send" button (Diag.5-15).

Diag.5-15 Send button



- ◆ A LIS connection is established.
- ◆ A message is displayed to inform user on the connection and sending progress.

## 2.4.3. QC result history

◆ The "QC" tab allows to display the 100 latest QC results.

## Accessing the "QC result history" screen

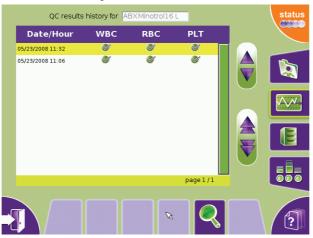
- 1- Press "Quality control menu" button to access the "Quality control" menu.
- 2- Press corresponding radio button to select the control.
- 3- Press "History" button (Diag.5-16).

#### Diag.5-16 History button



The "QC result history" screen is displayed.

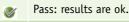
Diag.5-17 QC result history screen

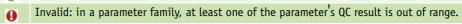


#### "QC result history" screen description

◆ The 100 latest QC results are displayed sorted by date and time (latest to oldest).

An icon shows the status of the parameter family:





◆Use "Up", "Down", "Page up" and "Page down" buttons to scroll up and down table content if it does not fit into the screen (See Section 1, 7.8.1. Navigation buttons, page 1-16).



Results are sorted from the most recent to the oldest by default. To change this order press "Date/Hour" at the top of the table.

To display QC results of the selected control:

- 1- Press the corresponding line to select one result in the table.
- 2- Press "View" button.



- ◆In the QC result screen, press "Back" button to return to the "QC result history" screen.
- ◆Use the "Quality control" button to return to the "QC" tab.

## 2.5. Levey Jennings graphs

Levey Jennings (LJ) curves are graphical representations of Quality control data based on the daily value for each control parameter, its target value and range that are plotted on a graph for periodic review.

## 2.5.1. Accessing the "Levey Jennings" screen

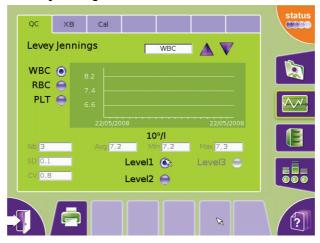
- 1- Press "Quality control menu" button to access the "Quality control" menu.
- 2- Select one control by pressing the corresponding radio button.
- 3- Press "LJ display" button (Diag.5-18).

#### Diag.5-18 LJ display button



◆ The "Levey Jennings" screen is displayed.

Diag.5-19 Levey Jennings screen



#### 2.5.2. Displaying the Levey Jennings curves

- 1- Press the corresponding radio button to select the parameter family to display: "WBC" or "RBC" or "PLT".
- 2- In the combo box, select the parameter to display.
- 3- It is possible to display the LJ curves of the 3 controls levels directly from this screen:
  - Press "**Level 1**" radio button to display LJ curve of the low level control (created in left frame of in the "**QC**" tab)
  - Press "Level 2" radio button to display LJ curve of the normal level control (created in middle frame of in the "QC" tab)
  - Press "Level 3" radio button to display LJ curve of the high level control (created in right frame of in the "QC" tab)

The LJ curve corresponding to the selected parameter control is drawn.

The target value, the upper limit and the lower limit are displayed on the LJ graph.

The following values are also displayed:

- ◆ In the "Nb" field: the number of results used to calculate the average, the standard deviation and the coefficient of variation.
- ◆ In the "Avq" field: the average of N results.
- ◆ In the "Min" field: the minimum value.
- ◆ In the "Max" field: the maximum value.
- ◆ In the "SD" field: the standard deviation value.
- ◆ In the "CV" field: the coefficient of variation value.



Use the "Quality control" button to return to the "QC" tab.

# Quality assurance

## 2.5.3. Printing Levey Jennings statistics



To print LJ statistics, an external printer must be configured as default printer. If integrated printer is selected, the "Print" button is not available. To configure printer: See Section 6, 4.3.2. Printer settings, page 6-8.

- 1- Press the "**Print**" button to print the LJ statistics.

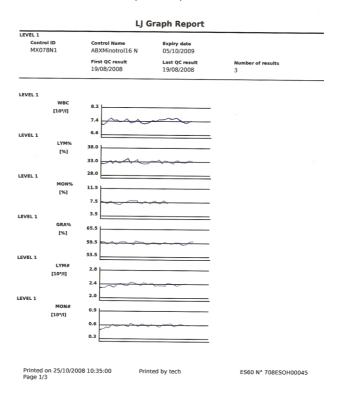
  A message is displayed asking to choose between printing the LJ Report (= LJ data) or the LJ graphs Report (= LJ curves) or both.
- 2- Check the check box corresponding to your choice then press "**OK**" button. A printing progress message is displayed.

See Diag.5-20 LJ data printout (example), page 5-17 and Diag.5-21 LJ graphs printout (example), page 5-18.

#### Diag.5-20 LJ data printout (example)

	LJ REPORT																
LEVEL 1 Control ID		Contro	ol Name			Expiry	date										
MX078N1			linotrol1 <b>QC resul</b> /2008				05/10/ <b>Last Q</b> 19/08/	C result			Numb 3	er of res	sults	ults			
	WBC	LYM%n	MON%	GRA%	LYM#	MON#	GRA#	RBC	HGB	нст	MCV	мсн	мснс	RDW	PLT	MPV	
Unit.	[10 <sup>9</sup> /l]	[%]	[%]	[%]	[10 <sup>9</sup> /l]	[10 <sup>9</sup> /l]	[10 <sup>9</sup> /l]	[10 <sup>12</sup> /l]	[g/l]	[1/1]	[fl]	[pg]	[g/l]	[%]	[10 <sup>9</sup> /l]	[fl	
UpperLimits	8.2	38	11.5	65.5	2.80	0.90	5	4.73	14	39.35	85	31.2	39	15.4	285	9.	
Targetvalues	7.4	33	7.5	59.5	2.40	0.60	4.40	4.55	13	36.85	81	29.2	36	12.4	245	7.	
LowerLimits	6.6	28	3.5	53.5	2	0.30	3.80	4.37	13	34.35	77	27.2	33	9.4	205	5.5	
Mean	7.2	32.3	7.6	60.1	2.30	0.50	4.43	4.53	134	0.361	80	29.7	372	12.1	246	7.3	
MeanTargetDiff	0.2	0.7	-0.1	-0.6	0.10	0.10	-0.03	0.02	-121	36.49	1	-0.4	-336	0.3	-1	0.2	
Min	7.2	32.3	7.5	59.9	2.30	0.50	4.40	4.52	133	133	79	29.4	371	11.6	243	7.3	
Max	7.3	32.4	7.7	60.2	2.30	0.50	4.50	4.55	135	0.363	80	29.9	374	12.4	250	7.4	
SD	0.1	0.1	0.1	0.2	0	0	0.06	0.02	1	0.002	1	0.3	2	0.4	4	0.1	
CV	0.8	0.2	1.3	0.3	0	0	1.30	0.34	9	0.006	1	0.8	4	3.6	2	3.0	
19/08/2008	7.30	32.30	7.50	60.20	2.30	0.50	4.50	4.52	13.30	35.90	79	29.40	37.10	11.60	243	7.30	
19/08/2008	7.20	32.40	7.70	59.90	2.30	0.50	4.40	4.53	13.50	36.20	80	29.90	37.40	12.40	250	7.40	
19/08/2008	7.20	32.30	7.60	60.10	2.30	0.50	4.40	4.55	13.50	36.30	80	29.70	37.20	12.30	244	7.30	
Printed on 25/1 Page 1/1	0/2008	10:34:53	3			Printe	d by tecl	h				ES60 1	N° 708ES	6OH000	)45		

Diag.5-21 LJ graphs printout (example)

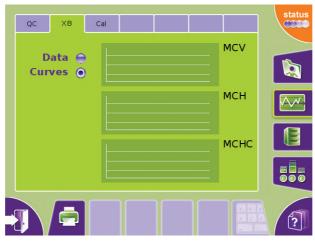


# 3. Patient Quality Control (XB)

## 3.1. Introduction

- ◆ The (XB) Patient Quality Control is used to detect any change in the quality of results by using patient data only.
- This data monitoring is performed without any user intervention and is applied to 3 parameters: MCV, MCH and MCHC.

Diag.5-22 XB screen



- ◆ When a total of 20 results are archived (only valid parameters) an XB batch is computed.
- ◆ The batch data computed is the mean result for all 20 analyses contained in that specific batch.

#### This chapter gives some information about:

- ◆ See 3.2. XB tab access and description, page 5-19.
- ◆ See 3.3. XB printing, page 5-20.

## 3.2. XB tab access and description

To access the "XB" tab:

- 1- Press "Quality control menu" button to access the "Quality control" menu.
- 2- Press "XB" tab.
- ◆ The "XB" tab contains two radio buttons for switching between XB curves and XB data screens.
- ◆ The "XB curves" screen is displayed by default.

#### XB curves screen contains:

◆ 3 drawing areas: one for each XB parameter (MCV, MCH and MCHC).

#### XB data screen contains a table displaying:

- ◆ 3 columns: one for each XB parameters (MCV, MCH and MCHC).
- lacktriangle 20 rows: for the 20 XB points representing the computed averages for each point and parameter.
- ◆ If a parameter result is upper than the limit set in the "**Settings**" menu (See Section 6, 6. Analysis settings, page 6-11), its value is displayed in red.
- ◆ If a parameter result is lower than the limit set in the "Settings" menu (See Section 6, 6. Analysis settings, page 6-11), its value is displayed in blue.

## 3.3. XB printing

- ◆ XB statistics can be printed on the integrated ticket printer or on an external printer.
- ◆ It depends on which printer is selected by default. To set the default printer: See Section 6, 4.3.2. Printer settings, page 6-8.



<u>Integrated printer accepts "latin characters" only</u>. Please use an external printer when non "latin characters" are used.

- ◆ Press "**Print**" button.
- ◆ The following printing progress message is displayed: "XB printing in progress."
- ◆ Examples of XB printouts are given below: See Diag.5-23 XB Printout on external printer, page 5-20 and See Diag.5-24 XB printout on integrated ticket printer, page 5-20.

## XB printout on external printer

#### Diag.5-23 XB Printout on external printer

XB REPORT								
MCV	MCH	MCHC						
[fl]	[pg]	[g/l]						
88.4	29.875	337.65						
98.2	30.285	309.55						
91.75	28.73	313.15						
94.5	28.23	298.95						
Printed on 28/5/2007 8:48:57	Printed by ted	ch	N° 704ESCS00095					

## XB printout on integrated printer

## Diag.5-24 XB printout on integrated ticket printer

Date : 28/05 User : tech	5/2007 8:50:17	
Oser . tech	XB REPOR	т
MCV	мсн	мснс
[fl]	[pg]	[g/l]
88.4	29.875	337.65
98.2	30.285	309.55
91.75	28.73	313.15
94.5	28.23	298.95

## 4. Calibration

## 4.1. General recommendations

General recommendations on calibration:

◆The calibration on HORIBA ABX instruments is an exceptional procedure, which must be carried out, particularly in the case of certain technical interventions (installation, maintenance, service intervention).



- ◆The calibration should not be carried out to compensate a drift on a result due for example to clogging of the instrument.
- ◆If the frequency of re-calibration is too important, it may be the sign of the beginning of a problem (technical, reagents, etc.)

### Calibration principle:

- ◆ Running the calibrator at least 4 times without taking into account the values of the first result (See 4.2. Calibration procedure, page 5-22).
- ◆ Calibrating the instrument on the average of the last three results according to indications of the manual (See 4.4. Calibration passed, page 5-27).
- ◆ Running the calibrator 3 times again to check the values.
- Confirming the calibration while running a control blood, the values have to be returned within acceptable limits.
- After about thirty numeration analyses of the day, checking that values of MCV, MCH and MCHC are in conformity with the usual values of the laboratory.

## 4.2. Calibration procedure

## 4.2.1. Startup cycle

◆ Run a startup cycle from the "**Status area**" before calibration creation. The startup cycle must be successfully run before starting any calibration.

## 4.2.2. Repeatability check

- ◆ Before carrying out a calibration, it is essential to make sure that the instrument is in perfect operating condition and to follow the steps bellow:
- 1- Carry out a concentrated cleaning procedure (See Section 7, 3.3.5. Concentrated cleaning, page 7-9).
- 2- Perform two blank cycles to check the cleanliness of the instrument.
- 3- Check the repeatability of the instrument by running a fresh normal whole blood sample 11 times with no alarm. Discard the first result and calculate the CV on the remaining 10 runs.
- 4- Check that the CV calculated using the remaining 10 runs meets or exceeds the specifications: See Section 2, Tab.2-10 Precision claims, page 2-10.
- 5- Run a control blood and check that the values are within the acceptable limits. If not, run a new control blood.
- 6- If the values are still out of the acceptable limits and the instrument is clean (blank cycles in conformity with the values given in the manual) and repeatability is correct (acceptable CV values), carry out the calibration (See 4.2.3. Running calibration, page 5-22).

## 4.2.3. Running calibration

## Accessing the "Creation" screen

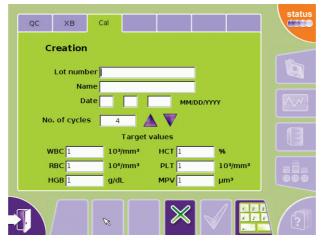
- 1- Press "Quality control menu" button (Diag.5-1) to access the "Quality control" menu.
- 2- Press "Cal" tab.
- 3- Press "Calibration creation" button (Diag.5-25).

#### Diag.5-25 Calibration creation button



◆ The "Creation" screen is displayed.

Diag.5-26 Calibrant creation screen



#### Calibrator identification

- 1- Enter the calibrator lot number:
- ◆ Press "Lot number" field to select it.
- ◆ Type the calibrator lot number using the virtual keyboard or an external keyboard (if one is connected).
- 2- Enter the calibrator name:
- ◆ Press "Name" field to select it.
- ◆ Type the calibrator name in the "Name" field using the virtual keyboard or an external keyboard (if one is connected).
- 3- Enter the calibrator expiration date:
- Press "Date" field to select it.
- ◆ Type the calibrator expiration date in the "Date" field using the virtual keyboard or an external keyboard (if one is connected).
  - The expiration date must be given as a date with the date format set in the settings menu (See Section 6, 3.4. Date format setting, page 6-5).
- 4- Select the number of calibration cycles in the "No. of cycles" combo box using arrows.
- ◆ The number of samples you can run for calibration is a minimum of 3 and a maximum of 11. In order for the instrument to provide the best mathematical data for a good calibration, a minimum of 6 sample runs is highly recommended for quality statistical calibration data.
- 5- Enter the calibrator target values for each parameter (WBC, RBC, HGB, HCT, PLT, MPV):
- ◆ In "Target values", press value fields to select them.
- ◆ Type the calibrator target values in the fields using the virtual keyboard or an external keyboard (if one is connected).
- 6- Press "Close" key to close the virtual keyboard if it is opened.
- 7- Press "OK" button.

#### **Running calibration**

1- A prime cycle is launched first. The following message is displayed: "Calibration cycle initialisation in progress, please wait."

Once the prime cycle is finished, the following message is displayed: "Please insert your sample and launch the 1/X analysis of the calibration procedure." ("X" represents the total number of calibration cycles).



If "Cancel" button is pressed, the calibration procedure will be cancelled. In this case, to rerun calibration, it will be necessary to run a startup cycle and to identify the calibrator again.

2- Run calibration cycle:

#### ABX Micros ES60 CT:

- ◆ Select the tube holder position for the calibrator vial and rotate it to the 12:00 o'clock position.
- Gently and thoroughly mix the calibrator material as indicated on the instruction sheet that comes with the calibrator.



Remove the cap from the calibrator vial before placing it into the sample tube holder. Severe sampling needle damage will occur if the cap remains on the vial.

- Place the calibrator into the tube holder.
- Close the tube holder door.

The cycle will begin and the sample will be aspirated. During the cycle, the tube holder door will open so the calibrator vial can be removed for the next sample.

## ABX Micros ES60 OT

- Gently and thoroughly mix the calibrator material as indicated on the instruction sheet that comes with the calibrator.
- Place the calibrator beneath the sampling needle and raise the vial upwards so that the sampling needle enters into the blood.
- ◆ Press manual sample bar. The cycle will begin and the sample will be aspirated.



Wipe any excess blood from the cap and threads of the calibrator vial with a lint-free tissue to prevent any dried blood from re-entering into the calibrator material. Dried blood re-entering into the vial may give error flags and reject the sample runs.

3- At the end of the cycle, a dialog box displays the calibration sample run results. Press "**OK**" button to validate results or press "**Cancel**" button to refuse results.

If a calibration sample run result is refused by the user, the following message is displayed: "You refused the result obtained. You can start your analysis again.".



Press "OK" button. The following message is displayed: "Last result refused. Please insert your sample and launch the 1/X analysis of the calibration procedure.". Launch the calibration cycle.



Calibration results having error flags such as (\$, \*, or ! for HGB) will automatically be rejected! The system will automatically re-set itself to rerun that sample. If you acquire 3 rejects continuously on the same number sample, abort calibration and contact your local HORIBA ABX Technical Support Representative!

- 4- Place the cap back onto the vial, gently and thoroughly mix the material for the next calibration sample run.
- 5- Run the remaining calibrator samples (See Running calibration, page 5-23).

## 4.3. Calibration results

• When the last sample result has been validated, the instrument calculates the statistical calibration factors for each parameter. These statistical calculations include the average, target, coefficient of variation, percent difference between the target value and the average, previous calibration coefficients and the new calibration coefficients.

See "Calibration result" screen description, page 5-25.

- ◆ If the new calibration coefficients are valid (See 4.4. Calibration passed, page 5-27), they are displayed and the user can decide to apply or ignore those coefficients. If new coefficients are ignored, the previous coefficients will remain unchanged.
- ◆ When the instrument fails calibration (See 4.5. Calibration failed, page 5-27), the calibration coefficients are rejected and the previous coefficients will remain unchanged in memory.



When the calibration fails, the operator may restart the calibration again or call local HORIBA ABX Technical Support Representative for further instructions.

## "Calibration result" screen description

To access "Calibration result" screen:

- 1- Press "Quality control menu" button (Diag.5-1) to access the "Quality control" menu.
- 2- Press "Cal" tab.

The "Calibration result" screen is displayed.

Diag.5-27 Calibration result screen



## The "Calibration result" screen contains:

- 1- Four fields giving information on the last calibration: date, user name, lot number and name of the calibrator used for the calibration.
- 2- A combo box which allows to choose the type of result consultation: summary or detailed. By default the summary view is displayed. Use arrow buttons to display detailed view.
- 3- A table displaying calibration results:
- ◆ In summary view (Diag.5-28), the result table displays for each parameter (WBC, RBC, HGB, HCT, PLT and MPV):
  - the statistics: average, target, coefficient of variation and balance (in %).
  - the calibration coefficients:
  - the "Old" line displays the previous coefficients.
  - the "Auto" line displays the new coefficients at the end of the calibration procedure when they are validated by the user.

the "Manu" line allows the user to enter coefficients manually (See 4.7.1. Changing calibration coefficients, page 5-29).

Diag.5-28 Calibration result summary view

Stat	WBC	RBC 10%mm³	HGB g/dL	HCT %	PLT 10³/mm³	MPV
Average	7.1	4.33	13.9	37.3	225	7.5
Target	7.5	4.64	13.7	37.6	229	8.0
CV	1.4	0.5	1.2	0.6	2.8	1.7
%BAL	5.5	6.7	1.2	0.9	1.7	6.7
Coef						
Old	1.00	0.81	1.10	1.04	1.20	0.94
Auto	1.06	0.87	1.09	1.05	1.22	1.01
Manu						

◆ In detailed view (Diag.5-29), the result table displays for each parameter (WBC, RBC, HGB, HCT, PLT and MPV) the analysis results of the last calibration procedure. The first line is faded. It corresponds to the first analysis not taken into account for the statistic calculation.

Diag.5-29 Calibration result detailed view

Run	WBC	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	HCT %	PLT 10³/mm³	MPV μπ³
1		4.33	14.2	37.4		
2	7.1	4.34	14.0	37.4	226	7.6
3	7.0	4.30	13.7	37.0	232	7.4
4	6.9	4.31	13.7	37.1	217	7.5
5	7.2	4.36	14.1	37.6	231	7.2
6	7.1	4.32	13.8	37.2	219	7.6
7						
8						
9						
10						
11						

## 4.4. Calibration passed

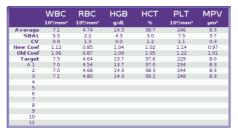
- ◆ For the instrument to pass calibration, the data must meet the statistical criteria which has 2 conditions:
- 1- The coefficient of variations must be within their limits (See Tab.5-2 Coefficient of variation limits, page 5-27).
- 2- The difference between the target value and the average for each parameter calibrated, must be less than 20%.

Tab.5-2 Coefficient of variation limits

Parameters	WBC	RBC	HGB	НСТ	PLT	MPV
CV%	< 2.5	< 2.0	< 1.5	< 2.0	< 5.0	< 3.0

◆ Passed calibration is as follows:

Diag.5-30 Passed calibration



## 4.5. Calibration failed

- ◆ For the instrument to fail calibration, the data must meet the statistical criteria which has 2 conditions:
- 1- The coefficient of variations are out of their specified limits (See Tab.5-2 Coefficient of variation limits, page 5-27).
- 2- The difference between the target value and the average for each parameter that failed calibration, is greater than 20%.
- ◆ Invalid coefficients are displayed in red.
- ◆ Failed calibration is as follows:

Diag.5-31 Failed calibration

	MBC	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	HCT %	PLT 10³/mm³	MPV μπ³
Average	7.4	4.58	13.4	37.0	221	7.9
%BAL	1.7	23.7	1.9	1.5	3.4	0.7
cv	1.2	0.5	0.5	0.5	0.3	0.6
New Coef	1.14	1.11	1.06	1.03	1.18	0.98
Old Coef	1.12	0.85	1.04	1.02	1.14	0.97
Target	7.5	6.00	13.7	37.6	229	8.0
A1	7.3	4.49	13.5	36.4	221	8.1
2	7.5	4.56	13.5	36.9	221	7.9
3	7.3	4.60	13.4	37.2	222	8.0
4						
5						
6						
7						
8						
9						
10						
11						

## 4.6. RDW calibration

#### Introduction

- ◆ The RDW calibration is a separate calibration outside the calibration menu.
- ◆ The RDW calibration coefficient default value is normally set at 1.00.

The RDW calibration is normally performed by taking blood samples from 100 healthy, normal and drug free individuals. These blood samples are then analyzed on the instrument that has been calibrated for RDW determination. The mean and standard deviation are then calculated from that population analyzed. The same 100 samples are then analyzed on the ABX Micros ES60 OT/CT. A population mean is calculated and then compared to the known calculated mean from the comparison instrument. The RDW calibration coefficient for the ABX Micros ES60 OT/CT is then calculated from the difference of the two mean values.



Expected RDW values may vary with sample population and/or geographical location. It is highly recommended that each laboratory establish its own normal ranges based on the local population.

#### RDW calibration using a quality control standard

◆ The RDW may also be calibrated by using a known quality control standard.



DEFINITION: A quality control standard is defined as a commercial blood product which has been specifically developed and assayed with set parameter target values and ranges. This product is designed to measure precisely the accuracy and linearity of the analyser.

- 1- Take the controls and bring them to room temperature. Gently and thoroughly mix the control material as indicated on the instruction sheet that comes with the control kit.
- 2- Run the normal level control 6 times, as a regular patient analysis. When the cycles are complete, note only the RDW results. Write down these results for future reference use.
- 3- Calculate the mean value for all 6 results and write it down for future reference use.
- 4- Take the control assay sheet that comes with the control kit and note only, the normal control mean assay value for RDW.
- 5- Calculate the new RDW coefficient as follows:

  Take the normal control mean assay value for RDW. Divide it by the mean value of the normal control ran 6 times as a sample, times the current RDW calibration coefficient. This will equal the new RDW calibration coefficient.
- 6- To enter this new value See 4.7.1. Changing calibration coefficients, page 5-29.
- 7- Now take all 3 levels of controls (low, normal, high) and run them 1 time each as a regular patient analysis. When the cycles are complete, note only the RDW results and compare them to the control assay values for RDW, on the assay sheet. Verify that the RDW results are somewhat close to the mean assay values and within the ranges as specified for all 3 Levels.
- $8 ext{-}$  The RDW calibration is now complete. Be sure to monitor your RDW results and verify that they fall within your patient population.
- 9- Verify that normal RDW results will be within the established ranges set in the settings menu. See Section 6, 6.3. Analysis limits, page 6-12.



Certain pathological conditions will affect the RDW results. See Section 2, 3.3.8. RDW (Red cell Distribution Width), page 2-15.

## 4.7. Calibration coefficients

◆ The operator has the option of editing the current calibration coefficients.



The ABX Micros ES60 is an accurate and reliable instrument when properly maintained. Should any variation of quality control results outside the assayed ranges occur after calibration, it is highly recommended that you contact your local HORIBA ABX Technical Support Representative before manually editing the calibration coefficients!

## 4.7.1. Changing calibration coefficients

In the "Calibration result" screen:

- 1- Display the summary view.
- 2- Press "Edit" button.
- 3- Enter the new coefficients using virtual keyboard or an external keyboard (if one is connected)...
- 4- Press "Close" key to close the virtual keyboard if it is opened.
- 5- Press "OK" button.

The new coefficients are displayed in the "Manu" line.



RDW and PDW can be modified but they are not printed or displayed in the "Calibration result" screen.

#### New coefficient calculation

New parameter coeff. = (Parameter target value/Parameter mean value) x Current parameter coeff.

- ◆ After manually editing the calibration coefficients, it is highly recommended to run quality control. Verify that all levels of control material are within their specified parameter ranges. Verify that there are no error flags (H, L, \*, \$, ! for HGB) associated with all levels of quality control results.
- ◆ Calibration coefficients are: WBC/RBC/HGB/HCT/PLT/MPV/RDW/PDW.



PDW and PCT have not been established as indications for this product, in the United States. The use of PDW and PCT should be restricted to research and Investigational measurements only.

#### 4.7.2. Calibration coefficient limits

◆ After any calibration has been performed on the instrument, verify that all parameter calibration coefficients are within their specified ranges as indicated (Tab.5-3).

#### Tab.5-3 Calibration coefficient limits

	Coefficient limits							
Parameters	WBC	RBC	HGB	HCT	PLT	MPV	RDW	PDW
Minimum	0.89	0.73	0.83	0.87	0.99	0.75	0.75	0.75
Mean	1.09	0.89	1.11	1.08	1.20	0.94	1.00	1.00
Maximum	1.29	1.05	1.39	1.29	1.41	1.13	1.25	1.25



PDW and PCT have not been established as indications for this product, in the United States. The use of PDW and PCT should be restricted to research and Investigational measurements only.

◆ If any of the calibration coefficients are out of their specified ranges after calibrating the instrument, contact your local HORIBA ABX Technical Support Representative.

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# 1. Accessing the "Settings" menu

1- Press "Maintenance menu" button to access the "Maintenance" menu (Diag.6-1).

Diag.6-1 Maintenance button



- 2- Press "Serv." tab.
- 3- Press "Settings" button (Diag.6-2).

Diag.6-2 Settings button



The "Settings" menu is displayed.

Diag.6-3 Settings menu



# 2. System settings

## 2.1. System tab description

◆ Enter menu "Maintenance\Serv.\Settings\Syst."

The "Syst." tab allows to set:

- ◆ System date and time: See 2.2. System date/time settings, page 6-3.
- ◆ Sleep mode: See 2.3. Sleep mode settings, page 6-4.
- ◆ Sound: See 2.4. Sound settings, page 6-4.



At any time, the "Cancel" button allows to cancel modifications and reset all fields with previous values.

## 2.2. System date/time settings

◆ The "Date/Hour" screen allows to change date and time of the system.



If modified, the system takes the changes into account immediately.

In the "Syst." tab:

- 1- Press "Date/Hour" radio button.
- 2- Press "Edit" button.
- 3- Modify the system date (See System date changing, page 6-3) and the system time (See System time changing, page 6-3).
- 4- Once all changes have been carried out, press "OK" button.

#### System date changing

- 1- Type the year in the "**Year**" field, the month in the "**Month**" field and the day in the "**Day**" field using the virtual keyboard or an external keyboard (if one is connected).
- 2- Press "Close" key to close the virtual keyboard if it is opened.

## System time changing

#### To modify the time format

1- Press corresponding radio button: "12H" or "24H". "24H" is factory set by default.

#### To modify the hour

- 1- Press "Hour" field to select it.
- 2- Use the "+" and "-" buttons to modify the hour (Diag.6-4).

#### To modify the minutes

- 1- Press "Min" field to select it.
- 2- Use the "+" and "-" buttons to modify the minutes (Diag.6-4).

Diag.6-4 + and - buttons



## 2.3. Sleep mode settings

- ◆ The "Sleep" screen allows to set the inactivity time from which the sleep mode is activated and the screen contrast level during sleep mode.
  - ◆ During sleep mode, the analyser reduces the screen luminance.



- ◆The sleep mode does not stop cycles programmed or in progress.
- **◆**To deactivate sleep mode, press touch screen.

In the "Syst." tab:

- 1- Press "Sleep" radio button.
- 2- Press "Edit" button.
- 3- Use arrow buttons to decrease or increase "**Inactivity time**". The inactivity time can be set between 0 to 240 minutes (by 30 minute steps). "**30**" minutes is factory set by default.
- 4- Use arrow buttons to decrease or increase "Contrast". The contrast can be set between 10 to 50 % (by 10 % steps). "20" % is factory set by default.
- 5- Press "**OK**" button.

## 2.4. Sound settings

◆ The "Sound" screen allows to set alarm sound and when sounds will be emitted (cycle end, screen key).

In the "Syst." tab:

- 1- Press "Sound" radio button.
- 2- Press "Edit" button.
- 3- Set alarm sound (See Alarm sound settings, page 6-4).
- 4- Set sound emission (See Sound emission settings, page 6-4).
- 5- Press "OK" button.

#### **Alarm sound settings**

- 1- Check the "Alarms sound" check box.
- 2- In "Associated sound" list, use arrow buttons to select the sound type associated with alarms.
- 3- Press "Sound test" button to hear the selected sound (Diag.6-5).

### Diag.6-5 Sound test button



## Sound emission settings

- 1- Check the "**Enable for end of cycle**" check box to activate/deactivate sound emission at the end of a cycle. It is activated by default.
- 2- Check the "**Enable for selected key**" check box to activate/deactivate sound emission when a screen key is pressed. It is activated by default.

# 3. Localization settings



Localization settings can only be done by a user with a "Scientist" profile.

## 3.1. Localization tab description

◆ Enter menu "Maintenance\Serv.\Settings\Local.".

The "Local." tab allows to set:

- ◆ The system language: See 3.2. Language setting, page 6-5.
- ◆ The external keyboard layout: See 3.3. External keyboard layout setting, page 6-5.
- ◆ The date and time format: See 3.4. Date format setting, page 6-5.
- ◆ The numerical data format: See 3.5. Numerical data format setting, page 6-5.
- ◆ This tab also allows to update the contextual help system: See 3.6. Update contextual help, page 6-6.
  - ◆All these items could be set at the same time or separetely. If it is at the same time: apply all your modifications then press "OK" button to validate.



- ◆If modified, the system takes the changes into account on next instrument startup.
- ◆At any time, the "Cancel" button allows to cancel modifications and reset all fields with previous values.

## 3.2. Language setting

The "Local." tab contains the list of available languages, shown by their country flag:

- 1- Press "Edit" button.
- 2- In "Language": press radio button associated with the country flag to select the corresponding language.
- 3- Press "OK" button.

## 3.3. External keyboard layout setting

The "Local." tab contains the list of available keyboard layouts, shown by their country flag:

- 1- Press "Edit" button.
- 2- In "**Keyboard**": press radio button associated with the country flag to select the corresponding keyboard layout.
- 3- Press "OK" button.

## 3.4. Date format setting

In the "Local." tab:

- 1- Press "Edit" button.
- In "Date format", there are 3 available date formats for international use:
- ◆ DD/MM/YYYY (factory set by default.)
- MM/DD/YYYY
- ◆ YYYY/MM/DD (USA default settings)
- 2- Select the date format that corresponds to your national date format.
- 3- Press "OK" button.

## 3.5. Numerical data format setting

In the "Local." tab:

- 1- Press "Edit" button.
- 2- In "**Separator**": press corresponding radio button to select the character ([.] or [,]) to be used with decimal numbers. [.] is factory set by default.
- 3- Press "OK" button.

## 3.6. Update contextual help

Help files are provided on a CD-ROM and have to be pasted onto your USB key. Please contact your local HORIBA ABX Technical Support Representive to have detailed information on procedure to follow.

Once help files are pasted onto your USB key:

1- In the "Local." tab, press "Update help" button (Diag.6-6).

Diag.6-6 Update help button



- ◆ A dialog box is displayed: "Please insert your USB key in the front slot of your instrument. Select 'OK' to continue help update."
- 2- Insert USB key in the front slot of the instrument.
- 3- Press "OK" button. The following message is displayed during contextual help update: "Help update in progress. Please wait..."



Never remove the USB key from the front slot before the progress indication window closes.

◆ The help language installed corresponds to the language sets in the "Local." tab (See 3.2. Language setting, page 6-5).

## 4. Peripheral settings

## 4.1. Peripheral tab description

Enter menu "Maintenance\Serv.\Settings\Periph.".

The "Periph." tab allows to set the following device:

- ◆ Barcode reader: See 4.2. Barcode reader (optional), page 6-7.
- ◆ Printer: See 4.3. Printer, page 6-7.



At any time, the "Cancel" button allows to cancel modifications and reset all fields with previous values.

## 4.2. Barcode reader (optional)

The "Barcode" screen allows to set the different types of barcode handled by the reader.

- 1- In the "Periph." tab, press "Barcode" radio button.
- 2- Press "Edit" button.
- 3- Use arrow buttons to select barcode reader in the "Model" list. "None" is displayed by default.
- 4- Check "Interleaved 2 of 5" or "Code 39" or "Code 128" or "Codabar" or "ISBT 128" check box to select the barcode type.

Use with or without check digit for Code 128, Codabar and ISBT 128 are factory set and cannot be modified:



- ◆Code 128 is used with check digit.
- ◆Codabar is used without check digit.
- ◆ISBT 128 is used with check digit.
- 5- For "Interleaved 2 of 5" or "Code 39" types: check the corresponding "Check digit" check box to activate/deactivate this option.
- 6- Press "OK" button.

#### 4.3. Printer

## 4.3.1. Printer tab description

The "Printer" tab allows to select which printer will print results and settings information (integrated or external): See 4.3.2. Printer settings, page 6-8.

- ◆User must check his printer compatibility with the ABX Micros ES60 OT/CT.
- ◆ A non exhaustive list of printers that can be used with the instrument can be found on the website: http://www.horiba-abx.com/documentation: Other/printers/instrument printer list/abx micros es60.
- ◆ For more detailed information, please contact your local HORIBA ABX Technical Support Representative.

## 4.3.2. Printer settings

In the "Periph." tab:

- 1- Press "Printer" radio button.
- 2- Press "Edit" button.
- 3- Press one of the three radio buttons to select "Internal", "Local" or "Remote" printer. "Internal" printer (integrated ticket printer) is selected by default.
- 4- If "Local" or "Remote" is selected, use arrow buttons to select printer in the "Printer" list.
- 5- If "Remote" printer is selected, it needs to enter identification sentence: See Remote printer identification, page 6-8.
- 6- Press "Close" key to close the virtual keyboard if it is opened.
- 7- Press "OK" button.

### **Remote printer identification**

- ◆ The identification sentence will allow access to remote printer.
- It should give, at least, the remote printer IP address, while some printers need additional information like username or printername.
- ◆ Please refer to your network administrator for "remote printer access" syntax.
- ◆ Syntax examples: 192.168.3.25 or laser@192.168.4.5 or username@192.168.5.12
- ◆ If the printer is shared on a remote computer on the network, the identification sentence format is: ShareName@ComputerIPaddress. ex: share@192.168.3.25
- Type the identification sentence in the "IP address" field using the virtual keyboard or an external keyboard (if one is connected).



Use an external keyboard to have lower case letters.

# 5. User settings



User settings can only be done by a user with a "Scientist" profile.

## 5.1. User tab description

- ◆ Enter menu "Maintenance\Serv.\Settings\User".
- ◆ The "User" tab contains list of user accounts created on the system.
- ◆ A maximum of 18 user accounts can be created. They are sorted by login name.

When one user profile is selected:

- ◆ The user name is displayed in the "Login name" field.
- ◆ The user profile is represented with the correponding icon: Lab tech, Scientist or Technician (for HORIBA ABX technician only). See Section 4, 1.4.1. User profile selection, page 4-4.

This tab allows to create, delete or modify a user account:

- ◆ See 5.2. User account creation, page 6-9.
- ◆ See 5.3. User account modification, page 6-10.
- ◆ See 5.4. User account deletion, page 6-10.



At any time, the "Cancel" button allows to cancel modifications and reset all fields with previous values.

## 5.2. User account creation

In the "User" tab:

1- Press "New user" button (Diag.6-7).

Diag.6-7 New user button



- ◆ The "User profile" screen is displayed.
- 2- Select user profile in the combo box (Lab tech or Scientist) using arrows. "Lab tech" is selected by default.
- 3- Enter the user name (between 3 and 10 characters):
- ◆ Press "Login name" field to select it.
- ◆ Type a user name using the virtual keyboard or an external keyboard (if one is connected).
- 4- Enter the user password (between 3 and 10 characters):
- ◆ Press "Password" field to select it.
- ◆ Type a user password using the virtual keyboard or an external keyboard (if one is connected).
- ◆ Type exactly the same password in both "Password" fields.



For "Lab tech" profile, the password is not mandatory.

- 5- Press "Close" key to close the virtual keyboard if it is opened.
- 6- Use arrows to set the auto-disconnection duration in the "Time out" combo box.
  - For Lab tech profile, the auto-disconnection duration can be from Never to 240 min.
  - "Never" is factory set by default.
  - For Scientist profile, the auto-disconnection duration can be from 5 min to 240 min.
  - "5 min" is factory set by default.
- 7- Press "OK" button.

## 5.3. User account modification

In the "User" tab:

- 1- Press a user account in the table to select it.
- 2- Press "Edit" button.
- 3- It is possible to:
- Ask for a new password on next user connection using the "Change password" check box. If this option is selected, when the user logs for the first time on the instrument, a new password is required.
- ◆ Set the auto-disconnection duration in the "Time out" combo box using arrows.
- 4- Press "OK" button.

## 5.4. User account deletion

In the "User" tab:

- 1- In the table: press user account to delete in order to select it.
- 2- Press "Delete" button:

Diag.6-8 Delete button



- 3- A dialog box opens displaying the following message: "Are you sure to want to delete user? {xxx}"
- 4- Press "OK" button.

# 6. Analysis settings



Analysis settings can only be done by a user with a "Scientist" profile.

## 6.1. Analysis tab description

- ◆ Enter menu "Maintenance\Serv.\Settings\Analys."
- The "Analys." tab allows to set:
- ◆ Units: See 6.2. System units settings, page 6-11.
- ♦ High and low limits of all parameters for each patient type: See 6.3. Analysis limits, page 6-12.
- ◆ Alarm sensitivity: See 6.4. Alarm sensitivity settings, page 6-13.
- ◆ Analysis running modes: See 6.5. Analysis running, page 6-14.
- ◆ Identification options: See 6.6. Identification option, page 6-14.
  - ◆At any time, the "Cancel" button allows to cancel modifications and reset all fields with previous values.
  - ◆ Laboratory limits are also known as normal patient ranges. These limits will vary with population and/or geographical location. The default limits set on the instrument were based on a study that included normal, healthy and drug-free individuals. Your limits may vary based upon the applications for intended use.
  - ◆Before changing any of the laboratory limits, printout the manufacturer limits set on the instrument and select any, all, or none of the parameter limits to be modified.

## 6.2. System units settings

- ◆ The "Unit." screen contains the list of unit systems convertion tables available on the system. In the "Analys." tab:
- 1- Press "Unit." radio button.
- 2- Press "Edit" button.
- 3- Use arrow buttons to select unit system in the list. 4 unit systems are available: Japan, Standard, mmol, International (See Tab.6-1 System unit values, page 6-11). "Standard" is factory set by default.
- 4- Once a unit system is selected, the corresponding values are displayed in the table.
- 5- Press "OK" button.

Tab.6-1 System unit values

	Japan	Standard	mmol	International
WBC	$10^2/\text{mm}^3$	$10^3/\text{mm}^3$	10 <sup>9</sup> /L	10 <sup>9</sup> /L
LYM%	%	%	%	%
LYM#	$10^2/\text{mm}^3$	$10^3/\text{mm}^3$	10 <sup>9</sup> /L	10 <sup>9</sup> /L
MON%	%	%	%	%
MON#	$10^2/\text{mm}^3$	$10^3/\text{mm}^3$	10 <sup>9</sup> /L	10 <sup>9</sup> /L
GRA%	%	%	%	%
GRA#	$10^2/\text{mm}^3$	$10^3/\text{mm}^3$	10 <sup>9</sup> /L	10 <sup>9</sup> /L
RBC	10 <sup>4</sup> /mm <sup>3</sup>	10 <sup>6</sup> /mm <sup>3</sup>	10 <sup>12</sup> /L	10 <sup>12</sup> /L
HGB	g/dL	g/dL	mmol/L	g/L
HCT	%	%	l/L	l/L
MCV	$\mu\text{m}^3$	$\mu\text{m}^3$	fl	fl
MCH	pg	pg	fmol	pg
MCHC	g/dL	g/dL	mmol/L	g/L

	Japan	Standard	mmol	International
RDW	%	%	%	%
PLT	10 <sup>4</sup> /mm <sup>3</sup>	$10^3/\text{mm}^3$	10 <sup>9</sup> /L	10 <sup>9</sup> /L
MPV	μm <sup>3</sup>	μm <sup>3</sup>	fl	fl
PCT*	%	%	10 <sup>-2</sup> /L	10 <sup>-2</sup> /L
PDW*	%	%	%	%



PDW and PCT have not been established as indications for this product, in the United States. The use of PDW and PCT should be restricted to research and Investigational measurements only.

## 6.3. Analysis limits

- ◆ The "Limits" screen allows to set low and high limits of all parameters for each patient type.
- ♦ To know the analysis limits factory set by default: See Default values of analysis limits, page 6-12.

In the "Analys." tab:

- 1- Press "Limits" radio button.
- 2- Use arrow buttons to select patient type in the list (man, woman or child).

The table content is updated with high and low limits of the selected patient type.

3- Press "Edit" button.

The virtual keyboard is displayed.

- 4- Type the new values using the virtual keyboard then press "Valid" key to valid the entries.
- 5- Press "Close" key to close the virtual keyboard.
- 6- Press "OK" button.



Use the scroll bar, "Up", "Down", "Page up" and "Page down" buttons to scroll up and down table content if it does not fit in the screen (See Arrows, page 1-16).

## **Default values of analysis limits**

Parame	Parameters		Man		man	Child (male, 4-10 years)		
		Low	High	Low	High	Low	High	
WBC	$(10^3/\text{mm}^3)$	4.0	10.0	4.0	10.0	4.3	11.9	
RBC	$(10^6/\text{mm}^3)$	4.5	6.5	3.8	5.8	4.2	5.3	
HGB	(g/dl)	13.0	17.0	11.5	16.0	11.6	14.8	
HCT	(%)	40.0	54.0	37.0	47.0	35.0	46.0	
MCV	$(\mu m^3)$	80.0	100.0	80.0	100.0	76.0	88.0	
MCH	(pg)	27.0	32.0	27.0	32.0	23.0	35.0	
MCHC	(g/dl)	32.0	36.0	32.0	36.0	30.0	36.0	
PLT	$(10^3/\text{mm}^3)$	150.0	500.0	150.0	500.0	203.0	484.0	
RDW	(%)	11.0	16.0	11.0	16.0	11.0	16.0	
MPV	$(\mu m^3)$	6.0	11.0	6.0	11.0	6.0	11.0	
PCT	(%)	0.15	0.5	0.15	0.5	0.15	0.5	
PDW	(%)	11.0	18.0	11.0	18.0	11.0	18.0	
LYM#	$(10^3/mm^3)$	1.0	5.0	1.0	5.0	1.9	7.1	
MON#	$(10^3/\text{mm}^3)$	0.2	1.5	0.2	1.5	0.0	1.3	
GRA#	$(10^3/\text{mm}^3)$	2.0	9.0	2.0	9.0	1.3	10.3	

Bibliography for man and woman:
 AIDE MEMOIRE D'HEMATOLOGIE (1998)
 Prof: C. SULTAN / M. GOUAULT - HELMANN / M. IMBERT
 Service Central d'Hématologie de l'Hôpital Henri Mondor
 Faculté de médecine de Créteil (Paris XII)

Bibliography for child (male, from 4 to 10 years old):
 Lecture critique de l'hémogramme: valeurs seuils à reconnaitre comme probablement pathologique et principales variations non pathologiques.

ANAES: Agence Nationale d'Accréditation et d'Evaluation en Santé

◆PDW and PCT have not been established as indications for this product, in the United States. The use of PDW and PCT should be restricted to research and Investigational measurements only.



◆There is no study for the LMG 3Diff formula. A 5Diff formula study has been taken into account to establish these default values. Thus, the granulocytes are defined as follows: GRA = NEU + BAS + EOS.



Expected values will vary with sample population and/or geographical location. It is highly recommended that each laboratory establish its own normal ranges based upon the local population!

## 6.4. Alarm sensitivity settings

- ◆ The "Alarms" screen allows to set the alarms sensitivity for platelet, WBC and XB alarms. In the "Analys." tab:
- 1- Press "Alarms" radio button.
- 2- Use arrow buttons to select alarm type in the list.
- 3- Set the platelet alarms (See Platelet alarm settings, page 6-13), the morphological WBC alarms (See WBC alarm settings, page 6-13) and the XB statitstics alarms (See XB alarm settings, page 6-13).
- 4- Press "Close" key to close the virtual keyboard if it is opened.
- 5- Press "OK" button.

#### **Platelet alarm settings**

- 1- Press "Edit" button.
- 2- Type platelet alarms using the virtual keyboard or an external keyboard (if one is connected):
- ◆ Enter the SCL value in the "SCL threshold" field. "8" % is factory set by default.
- ◆ Enter the SCH value in the "SCH threshold" field. "8"% is factory set by default.
- ◆ Enter the MIC value in the "MIC threshold" field. "8"% is factory set by default.

#### **WBC** alarm settings

- 1- Press "Edit" button.
- 2- Type WBC alarms using the virtual keyboard or an external keyboard (if one is connected):
- ◆ Enter the L1 value in the "L1" field. "8" % is factory set by default.
- ◆ Enter the M2 value in the "M2" field. "8" % is factory set by default.
- ◆ Enter the G1 value in the "G1" field. "15" % is factory set by default.
- ◆ Enter the G2 value in the "G2" field. "15" % is factory set by default.
- ◆ Enter the G3 value in the "G3" field. "8" % is factory set by default.

#### XB alarm settings

- 1- Press "Edit" button.
- 2- Type the MCV min. and max. values in the "MCV" fields, the MCH min. and max. values in the "MCH" fields and the MCHC min. and max. values in the "MCHC" fields using the virtual keyboard or an external keyboard (if one is connected).

Tab.6-2 Default values of XB alarms

Alarm	Min. value	Max. value
MCV (µm3)	80	100
MCH (pg)	27	32
MCHC (g/dl)	32	36

## 6.5. Analysis running

◆ The "Running" screen allows to set analysis running modes.

In the "Analys." tab:

- 1- Press "Running" radio button.
- 2- Press "Edit" button.
- 3- Check the "With RUO data" check box to activate/deactivate RUO data. It is activated by default (except for US version).
- 4- Check the "Automatic lock on analyser alarm" check box to activate/deactivate instrument locking on analyser alarms (reagent temperature, invalid startup). It is deactivated by default (except for US version).
- 5- Check the "Automatic lock on reagent alarm" check box to activate/deactivate instrument locking on reagent alarms. It is deactivated by default (except for US version).
- 6- Check the "Automatic lock on QC alarm" check box to activate/deactivate instrument automatic locking on QC alarms (inter QC time limit or invalid QC). It is deactivated by default (except for US version).
- 7- Check the "Display startup results" check box to activate/deactivate displaying (at the end of startup cycle) results of blank cycle runs during the startup. It is activated by default.
- 8- Check the "Print startup results" check box to activate/deactivate automatic printing results of blank cycle runs during the startup. It is activated by default.
- 9- Press "OK" button.

## 6.6. Identification option

◆ The "Identifi." screen allows to activate or not automatic identification. This option allows the instrument to generate automatically sample ID.

In the "Analys." tab:

- 1- Press "Identifi." radio button.
- 2- Press "Edit" button.
- 3- Check the "Automatic identification" check box to activate/deactivate automatic identification. It is deactivated by default.
- 4- Press "OK" button.

# 7. Parameter settings



Parameter settings can only be done by a user with a "Scientist" profile.

## 7.1. Parameters tab description

◆ Enter menu "Maintenance\Serv.\Settings\Param."

The "Param." tab allows to set:

- ◆ Which results can be printed and/or uploaded: See 7.2. Result settings, page 6-15.
- ♦ Which parameter can be printed and/or uploaded: See 7.3. Parameter settings, page 6-15.
- Which information will be displayed on header result reports: See 7.4. Report header settings, page 6-16.

## 7.2. Result settings

◆ The "Config." screen allows the user to select the results that will be printed or sent.

In the "Param." tab:

- 1- Press "Config." radio button.
- 2- Press "Edit" button.
- 3- Set the following items: normal range (See Normal range, page 6-15), curves (See Curves, page 6-15), patient results (See Automatic patient result, page 6-15), QC results (See Automatic QC result, page 6-15) and temperature (See Temperature, page 6-15).
- 4- When results have been set: press "OK" button.

#### Normal range

• Check the corresponding "Print" check box to allow analysis limits printing. The analysis limits can only be printed on an external printer.

#### **Curves**

- ◆ Check the corresponding "**Print**" check box to allow curves printing.
- ◆ Check the corresponding "Upload" check box to allow curves sending.

#### Automatic patient result

- ◆ Check the corresponding "Print" check box to activate automatic printing of patient results.
- Check the corresponding "Upload" check box to activate automatic sending of patient results.

#### **Automatic QC result**

- ◆ Check the corresponding "**Print**" check box to activate automatic printing of QC results.
- ◆ Check the corresponding "Upload" check box to activate automatic sending of QC results.

## **Temperature**

◆ Check the corresponding "Print" check box to activate automatic printing of analyser temperature.

## 7.3. Parameter settings

◆ The "Parameters" screen allows to set which parameters can be printed or sent.

In the "Param." tab:

- 1- Press "Parameters" radio button.
- 2- Press "Edit" button.
- 3- For each parameter:
- ◆ Check the corresponding "**Print**" box to allow the parameter printing.
- ◆ Check the corresponding "Upload" box to allow the parameter sending.

◆Use the scroll bar, "Up", "Down", "Page up" and "Page down" buttons to scroll up and down table content if it does not fit in the screen (See Arrows, page 1-16).



- ◆The RUO parameters (PCT and PDW) can only be set if the "With RUO data" has been activated (See 6.5. Analysis running, page 6-14).
- 4- Press "OK" button.

## 7.4. Report header settings

◆ The "Headers" screen allows to set the result printings (headers, number of copies, logo).

In the "Param." tab:

- 1- Press "Headers" radio button.
- 2- Import a logo:
- On a USB key, paste a logo with the following name "report-logo.gif" (max. 300px width x 78px heigh).
- ◆ Press "Import logo" button (Diag.6-9).

#### Diag.6-9 Import logo button



A dialog box is displayed: "Insert USB key."

- ◆ Insert USB key in the front slot of the instrument.
- ◆ Press "**OK**" button.



Never remove the USB key from the front slot before the progress indication window closes.

- 3- Press "Edit" button.
- 4- Type information in the "**Left**", "**Centre**" and "**Right**" fields using the virtual keyboard or an external keyboard (if one is connected). Maximum 30 characters for each field.
- 5- Use arrow button to select the logo position.
- 6- Use arrow button to select the number of copies to print.
- 7- Press "Close" key to close the virtual keyboard if it is opened.
- 8- Press "OK" button.

## 8. Analyser settings



Analyser settings can only be done by a user with a "Scientist" profile.

### 8.1. Cycles tab description

◆ Enter menu "Maintenance\Serv.\Settings\Cycles".

The "Cycles" tab allows to:

- ♦ set the automatic run of startup and cleaning cycles: See 8.2. Startup and cleaning cycles settings, page 6-17.
- ◆ program instrument startup and shutdown: See 8.3. Instrument startup and shutdown programming, page 6-18

## 8.2. Startup and cleaning cycles settings

#### 8.2.1. Settings startup cycle

- ◆ The startup cycle is used daily, prior to any normal operation to ensure that detergent from the shutdown cycle is completely rinsed out of the system.
- ◆ It includes a reference blank count which must be verified prior to any analysis of samples. This is necessary to ensure that there are "No" extraneous interferences that may be detected as background noise which will affect the cell count. See Section 4, 1.3. Instrument startup, page 4-3 for more information regarding startup.

In the "Cycles" tab:

- 1- Press "Cycles" radio button.
- 2- Press "Edit" button.
- 3- Check the "Automatic startup cycle" check box to activate/deactivate automatic running of startup cycle. It is activated by default.
- 4- In the "Startup cycle alarm after inactivity" list, use arrow button to set the inactivity time (between 2 and 8 hours, by 1 hour step) after which the alarm startup is triggered. This alarm informs the user that a startup cycle run is mandatory before running an analysis cycle.
- "4" hours is factory set by default.
- 5- Press "OK" button.

### 8.2.2. Setting autocleaning frequency

- ◆ This function allows the operator to change the cycle frequency of the automatic cleaning cycle which occurs when the cycle number programmed, has been reached.
- ◆ This automatic cleaning cycle involves the use of the solution ABX Miniclean which is an enzymatic cleaner. This solution breaks down protein buildup in the counting chambers and apertures.

In the "Cycles" tab:

- 1- Press "Cycles" radio button.
- 2- Press "Edit" button.
- 3- In the "Automatic cleaning cycle after" list, use arrow button to set the number of analysis cycles which can be run before running a cleaning cycle (from 1 to 100 analyses, by 1 analysis step). "50" analysis cycles is factory set by default.
- 4- Press "OK" button.

## 8.3. Instrument startup and shutdown programming



The time programming is the same for each selected day.

### 8.3.1. Instrument startup programming

In the "Cycles" tab:

- 1- Press "On / Off" radio button.
- 2- Press "Edit" button.
- 3- In "Starting", set the instrument startup time:
- Press "Hour" field to select it then enter the hour using the virtual keyboard or an external keyboard (if one is connected).
- Press "Min" field to select it then enter the minutes using the virtual keyboard or an external keyboard (if one is connected).
- 4- Check the corresponding check box(es) to select the day(s) when programmed startup will be performed.
- 5- Press "OK" button.

### 8.3.2. Instrument shutdown programming

In the "Cycles" tab:

- 1- Press "On / Off" radio button.
- 2- Press "Edit" button.
- 3- In "Exit", set the instrument shutdown time:
- Press "Hour" field to select it then enter the hour using the virtual keyboard or an external keyboard (if one is connected).
- ◆ Press "Min" field to select it then enter the minutes using the virtual keyboard or an external keyboard (if one is connected).
- 4- Check the corresponding check box(es) to select the day(s) when programmed shutdown will be performed.
- 5- Press "OK" button.

## 9. Printing settings



To print settings, an external printer must be set as default printer: See 4.3.2. Printer settings, page 6-8.

- ◆ Settings printout contains all the settings.
- ◆ If integrated ticket printer is selected, the "**Print**" button is not available.

In the "Settings" tab:

- 1- Press "Print" button.
- 2- The following message is displayed: "Settings printing in progress."



Passwords of user account are not printed.

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## 1. Introduction

• One of the principal factors contributing to accurate and reliable results is a well-maintained instrument. The ABX Micros ES60 OT/CT is designed to keep this maintenance automatically to a minimum providing that the operator is aware of its schedule. This section of the manual will describe the daily and periodic maintenance procedures.

## 2. Daily maintenance

◆ These cleaning procedures are required daily to maintain optimum performance of your ABX Micros ES60 OT/CT.



Failure to perform any of these recommended cleaning procedures can result in decreased reliability of your system. It is important that you monitor your analyser for the types of specimens that may cause premature cleaning other than routine.

## 2.1. Startup and shutdown cycles

#### Startup

- ◆ At the beginning of each working day, a startup cycle must be performed. This can be done either automatically or manually depending how the system has been set up for (See Section 6, 8.2.1. Settings startup cycle, page 6-17).
- 1- Switch the instrument on by pressing the  $\ensuremath{\mathsf{ON/OFF}}$  switch.
- 2- When the instrument is on, press the "Status" button (Diag.7-1) to display the "Status" area.

Diag.7-1 Status button



3- Press "Startup" button to run manually a startup cycle (Diag.7-2).

Diag.7-2 Startup button



#### Shutdown

- ◆ At the end of each working day, a shutdown cycle must be performed.
- 1- Press "Exit" button (Diag.7-3).

#### Diag.7-3 Exit button



- ◆ The "Exit" screen is displayed.
- 2- Press "Shutdown" radio button (Diag.7-4).

#### Diag.7-4 Shutdown icon



- 3- Press "OK" button.
- 4- Once the shutdown cycle is complete switch the instrument off.



The shutdown mode introduces ABX Miniclean into the chambers for the enzymatic cleaning of protein build-up on the counting chambers and apertures. This shutdown cycle is a very important step in daily maintenance.

## 2.2. Automatic cleaning

- ◆ Automatic cleaning cycle is automatically performed when a programmable number of analysis cycles has been reached. It is recommended to perform at least one automatic cleaning cycle during a day. Setup the frequency according to the workload of the laboratory (See Section 6, 8.2.2. Setting autocleaning frequency, page 6-17).
- ◆ To run an automatic cleaning, See 3.3.6. Automatic cleaning, page 7-10.

## 3. Maintenance procedures

## 3.1. General cleaning of the instrument

#### Instrument external cleaning

- The external surfaces of the instrument must be decontaminated considering the biological environment.
  - ◆ Never spill liquids on the instrument.
  - ◆ Never use disinfectant product that contains alcohol.
  - ◆ Never use solvants or abrasive materials.



- ◆Wipe off any trace of blood spillage as soon as possible.
- ◆Always disconnect the main electrical supply before cleaning the exterior of the analyser.
- ◆ Make sure that the instrument is completely dry before re-connecting the electrical power.

#### All contaminated surfaces

◆ Slightly wet a sponge with disinfectant product\* and wipe the dirty surfaces.

#### Stainless steel

- ◆ Slightly wet a sponge with disinfectant product\* and wipe the dirty surfaces. Dry with a soft cloth.
- \* Products having the following microbiological properties:
  - Bactericidal
  - Fungicidal
  - Active on Aspergillus fumigatus
  - Active on Mycobacterium tuberculosis (B.K)
  - Antiviral (VIH, HBV and rotavirus)

Product example validated by HORIBA ABX:

ANIOS detergent disinfectant; WIP'ANIOS; ref: 1316.424



Please also refer to the W.H.O (World Health Organization) guidelines: "Laboratory Biosafety Manual, 2nd edition", for further information.

#### Instrument internal cleaning

#### Concentrated cleaning

◆ Counting chambers and hydraulics parts are decontaminated by using the "Concentrated cleaning" function (See 3.3.5. Concentrated cleaning, page 7-9).

#### Sampling needle

- ◆ Sampling needle must be decontaminated as follows:
- 1- Prepare a solution of sodium hypochlorite to 100ml/L.
- 2- Fill a 5ml tube with this solution.
- 3- Run 5 analyses on bleach.

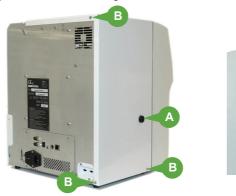


Please also refer to the W.H.O (World Health Organization) guidelines: "Laboratory Biosafety Manual, 2nd edition", for further information.

## 3.2. Cover dismantling

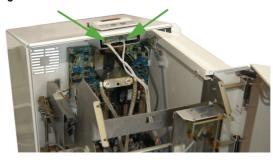
◆ Using the key from the installation kit, turn the locker (Diag.7-5-A) to open the pneumatic protection door.

Diag.7-5 Cover dismantling



- ◆ Unscrew the 3 cover fixation screws (Diag.7-5-B) and loosen the 2 screws (Diag.7-5-C) under the reagent flap.
- ◆ Disconnect the integrated printer connectors when removing the cover (Diag.7-6).

Diag.7-6 Printer connectors



 $\ \, \bullet \,$  Remove the cover: pull it backward and lift it up to the rear of the instrument.

### 3.3. Service

### 3.3.1. Service menu description

◆ Several service functions are available for the operator to clean and check the instrument. See "Service" menu overview (Tab.7-1).

Tab.7-1 Service menu

Service menu	Sub-menus level 1	Sub-menus level 2	
Settings (See Section 6, Setup, page 6-2)			
Customer services	Hydrau.	All reagents priming	
		Backflush	
		Chambers draining	
		Concentrated cleaning	
		Automatic cleaning	
Mechanical cycles	Moves	Needle	
		Carriage	
		Liquid syringe	
		Vacuum syringe	
		Valves	
		Piercing motor (CT only)	
		Door opening (CT only)	
	Burning (for Technician only)		
Adjustments (for Technician only)			

- ◆ To access the "Service" menu:
- 1- Press "Maintenance menu" button to access the "Maintenance" menu (Diag.7-7).

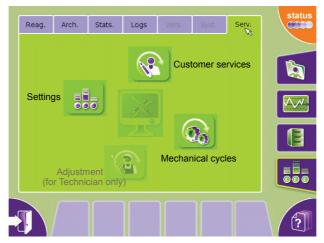
### Diag.7-7 Maintenance button



2- Press "Serv." tab.

The "Service" menu is displayed.

Diag.7-8 Service menu



#### 3.3.2. Prime

- ◆ This service function will allow the operator to prime all reagents or pack.
- 1- In "Service" menu, press "Customer services" button (Diag.7-9).

#### Diag.7-9 Customer services button



The "Hydrau." tab is displayed.

Diag.7-10 Hydrau. tab



- 2- Press "All reagents priming" radio button.
- 3- Press "Start cycle" button (Diag.7-11).

Diag.7-11 Start cycle button



4- When priming reagents or pack, verify that reagent is being primed. View the chambers for reagent priming. Verify that reagent is coming in and draining out of the chambers when a cycle is initiated. Verify that there are no air bubbles in the reagent lines when priming.

#### 3.3.3. Backflush

- ◆ This service function will allow the operator to clean the counting chamber apertures in case of blockage.
- 1- In "Service" menu, press "Customer service" button (Diag.7-9). The "Hydrau." tab is displayed.
- 2- Press "Backflush" radio button.
- 3- Press "Start cycle" button (Diag.7-11).
- 4- Open the instrument door and verify that liquid is being pulled through the apertures. Watch for a few micro-bubbles in the count tubing, coming from the counting head. When the backflushing starts, verify that liquid is being pushed back through the apertures (watch for a few micro-bubbles coming into the chambers from the counting head).
- ◆ If you cannot see any micro-bubbles moving through tubing or in the chambers, the aperture may still be blocked. In this case, perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9).

### 3.3.4. Chambers draining

- This service function will allow the operator to check for proper chamber draining and to maintain some of the parts of the hydraulic manifold as it flushes waste out of the instrument.
- 1- In "Service" menu, press "Customer services" button (Diag.7-9). The "Hydrau." tab is displayed.
- 2- Press "Chambers draining" radio button.
- 3- Press "Start cycle" button (Diag.7-11).
- 4- Verify the proper draining of the waste through the waste tubing located on the back of the instrument. If it is not flushing waste sufficiently, check the waste tubing connection and verify that there is no blockage or crimping of the tubing. Verify that both the WBC and RBC chambers are draining properly, not slow but fairly rapid. If not, view the troubleshooting (See 5. Troubleshooting, page 7-31).

#### 3.3.5. Concentrated cleaning

- This service function allows the operator to perform a very strong cleaning of the WBC and RBC counting chambers and apertures.
- This service function is used when frequent parameter and/or morphology flags are present on normal patient results.
- 1- Prepair the following solutions: ABX Minoclair or bleach containing 12% active chlorine.
- 2- In "Service" menu, press "Customer services" button (Diag.7-9). The "Hydrau." tab is displayed.
- 3- Press "Concentrated cleaning" radio button.
- 4- Press "Start cycle" button (Diag.7-11) and follow the steps that appear on screen.
- 5- When the message "Open the front cover and validate to continue." is displayed:
- ◆ Open the main cover door of the instrument (See 3.2. Cover dismantling, page 7-6).
- ◆ Press "OK" button.
- 6- When the message "Put 3ml of MINOCLAIR in WBC tank and validate to continue." is displayed:
- Dispense the bleach solution you choose into the WBC chamber (or into the hole on the top of the cover so that it goes into the chamber).
- ◆ Press "OK" button.
- 7- When the message "Put 3ml of MINOCLAIR in RBC tank and validate to continue." is displayed:
- Dispense the bleach solution you choose into the RBC chamber (or into the hole on the top of the cover so that it goes into the chamber).
- ◆ Press "**OK**" button.
- 8- When the message "Close the front cover and validate to continue." is displayed:
- ◆ Close the main cover door of the instrument.
- ◆ Press "OK" button.
- 9- The cleaning cycle will begin and a cleaning time will be displayed.
- This concentrated cleaning cycle involves different cycles, backflush, aspiration, rinsing, which allow a good cleaning of the chambers and apertures.
- 10- After this procedure is complete, perform a startup cycle to verify that the reference blank parameters are within their limits.
- Press "Status" button to open "Status area".
- ◆ Press "Startup" button.

Once the startup cycle has passed, sample analysis may begin.

#### 3.3.6. Automatic cleaning

- Provides an automatic cleaning cycle to run at any time when the operator wishes to clean the instrument.
- 1- In "Service" menu, press "Customer services" button (Diag.7-9). The "Hydrau." tab is displayed.
- 2- Press "Automatic cleaning" radio button.
- 3- Press "Start cycle" button (Diag.7-11).
- ◆ This auto clean cycle is a short cycle and may not provide enough cleaning action for fibrin clots in the apertures and/or chambers. If this is the case, a concentrated cleaning is highly recommended (See 3.3.5. Concentrated cleaning, page 7-9).

#### 3.3.7. Mechanics

#### Mechanical movements check

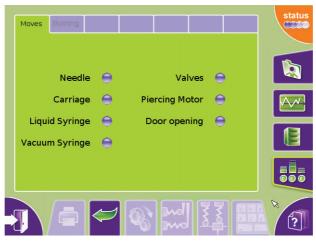
- ◆ This service function will allow the operator to check mechanical movements of the instrument mechanisms (needle, syringes, valves, etc.). If the operator suspects a specific mechanical failure, he may then verify it in this menu.
- ◆ If needed, dismantle the covers (See 3.2. Cover dismantling, page 7-6).
- 1- In "Service" menu, press "Mechanical cycles" button (Diag.7-12).

#### Diag.7-12 Mechanical cycles button



The "Moves" tab is displayed.

Diag.7-13 Moves tab



- 2- Select between the 7 functions below:
  - Needle: this allows the operator to check the up and down movement of the sampling needle.
  - Carriage: this allows the operator to check the left to right movement of the sample carriage.
  - Liquid syringe: this allows the operator to check the up and down movement of the syringes.
  - Vacuum syringe: this allows the operator to check the vacuum/waste syringe for complete movement up and down.
  - Valves: this allows the operator to operate all valves on the analyser in sequencial order from 1 to 13
  - Piercing motor (for CT only): this allows the operator to view the sampling needle depth on any position in the tube holder.
  - Door opening (for CT only): this allows the operator to check the tube holder opening movement.
- 3- Press "Start cycle" button (Diag.7-11).

#### Sensor state check

The "Moves" tab also allows to know the state of needle and carriage sensors.

#### To know the needle sensor state:

- 1- Press "Needle" radio button.
- 2- Press "Needle sensor" button (Diag.7-14).

#### Diag.7-14 Needle sensor button



A dialog box displays the needle sensor state (See Tab.7-2 Needle sensor state description, page 7-11). Tab.7-2 Needle sensor state description

State	Description	
ON	The sensor is activated. The needle presence is detected.	
OFF TO	The sensor is not activated. The needle presence is not detected.	

3- Press "**OK**" button to close the dialog box.

### To know the carriage sensor state:

- 1- Press "Carriage" radio button.
- 2- Press "Carriage sensor" button (Diag.7-15).

Diag.7-15 Carriage sensor button



A dialog box displays the carriage sensor state (See Tab.7-3 Carriage sensor state description, page 7-11). Tab.7-3 Carriage sensor state description

State	Description	
ON	The sensor is activated. The carriage presence is detected.	
OFF 3	The sensor is not activated. The carriage presence is not detected.	

3- Press "OK" button to close the dialog box.

## 3.4. Extended concentrated cleaning

#### Concerns:

- ◆ RBC/PLT chamber and aperture cleaning
- ◆ WBC/HGB chamber and aperture cleaning

#### Required tools:

◆5ml or 10ml syringe

#### Required products:

◆ ABX Minoclair 0.5L (P/n: 0401005) or bleach containing 12% active chlorine

#### Intervention time:

Approximately 30 minutes

#### Specific kits or consumable products:

None

#### Procedure:

- 1- Perform 3 backflush cycles (See 3.3.3. Backflush, page 7-8).
- 2- Drain the chambers (See 3.3.4. Chambers draining, page 7-9).
- 3- Open the main door (See 3.2. Cover dismantling, page 7-6).
- 4- Locate the opening on the top of the chamber (shield or not).
- 5- Fill both chambers with 5mL of the ABX Minoclair.
- 6- Let the solution set for 10 minutes in the chambers.
- 7- After 10 minutes, run a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9).
- 8- Once the cleaning cycle is complete, perform 3 backflush cycles (See 3.3.3. Backflush, page 7-8).
- 9- Press "Status" button to open "Status" area.
- 10- Press "**Startup**" button to run a startup. Verify that reference blank results are within their limits.
- 11- Re-run quality control and verify that the results are within the assay limits listed on the control assay sheet that comes with the controls.
- ◆ If the problem still persists, repeat steps <1> through <11> again.
- If the problem still persists after the second cleaning, call your local HORIBA ABX Technical Support Representative.

### 3.5. Reagent installation

◆ Make sure that a blank cycle and control run will be carried out after the change of a reagent in the course of day.



◆Before reagent installation, register reagent pack or bottles in the "Reag." tab (See 4.2.2. Reagent creation, page 7-22).

### 3.5.1. Bottle connections

◆ Lyse and cleaning reagents are placed inside the reagent compartment (Diag.7-16).

#### Diag.7-16 Reagent bottles



- 1- Install the reagent straws and the bottle stoppers on the reagent bottles.
- 2- Connect the blue tube to the ABX Cleaner bottle and the white tube to the ABX Minilyse LMG bottle.
- 3- Close the compartment cover.
- 4- See 3.3.2. Prime, page 7-8 to run the priming of the replaced reagent.

### 3.5.2. Alphalyse 360

#### **Required products:**

- ◆ Lyse straw (P/n: G0166740). Contact your local HORIBA ABX Technical support to order it.
- 1- Open the pack pulling the flap A and open the level window B (Diag.7-17).

Diag.7-17 Opening



2- Replace the rigid straw by the Lyse straw and install the Alphalyse 360 as shown on Diag.7-18.

Diag.7-18 Alphalyse 360 installation



### 3.5.3. Reagent pack connection

1- Remove the 3 reagent output protections (Diag.7-19).

Diag.7-19 Reagent output protections



2- Install the pack into the compartment of the instrument (Diag.7-20). Push the pack down in order to plug correctly the pack onto the male connectors.

Diag.7-20 Pack installation



3- Cut the seal then remove the waste input protection (Diag.7-21).

Diag.7-21 Pack protection





4- The free male connector must be plugged onto the pack upper valve in order to receive the waste liquids (Diag.7-22).

Diag.7-22 Waste connector





It is recommended not to remove the pack several times before the reagents are totally used to avoid leak problems.

5- See 3.3.2. Prime, page 7-8 to run the priming after the pack replacement.

### 3.5.4. ABX Diluent & waste connections (Bottle version only)

◆ Connect the ABX Diluent container using the diluent straw and a 3x6 cristal tube (1 meter maximum) on the diluent input (located at the bottom of the instrument rear panel) and place the waste container below the instrument level (under the bench).

Diag.7-23 Rear connections





Always follow the recommended procedures for waste disposal. Never connect the instrument wastes directly to the laboratory drain pipes.



The ABX Diluent container will be located on the bench at the same level as the instrument.

## 3.6. Integrated ticket printer paper changing

1- Lift the lever (Diag.7-24-A) then the printers cover (Diag.7-24-B).

Diag.7-24 Printer's cover opening



- 2- Remove the old roll.
- 3- Load the new paper roll (Diag.7-25).

Diag.7-25 Paper roll loading



4- Close the printer by pressing simultaneously on both sides of the cover (Diag.7-26).

Diag.7-26 Printer's paper closing



## 3.7. Unblocking sampling needle

#### Concerns:

◆ Unblocking sampling needle in case of fibrin clot.

#### Instrument response/problem type:

- ◆ Low results on all parameters in any analysis mode
- ◆ No results on all parameters in any analysis mode
- ◆ Possible high reference blanks on startup

#### **Required Tools:**

- ◆5mL or 10mL syringe
- Absorbant paper
- ◆ 5 inch small diameter tubing
- ◆ Small vial

#### **Required Products:**

◆ ABX Minoclair 0.5L (P/n: 0401005) or bleach containing 12% active chlorine

#### **Intervention time:**

◆ Approximately 15 minutes

#### Frequency:

◆ As needed, in case of partially blocked needle

#### Specific kits or consumable products:

None

#### Procedure on ABX Micros ES60 CT:

- 1- Close the tube holder door.
- 2- Open the main door (See 3.2. Cover dismantling, page 7-6).
- 3- Enter menu "Maintenance\Serv.\Mechanical cycles.
- 4- Press "Door opening" radio button.
- 5- Press "Start cycle" button (Diag.7-11) to open the tube holder door.
- 6- Remove the tube holder.
- 7- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle downwards until you can see the top of the needle and sample tubing.
- 8- Remove the tubing from the top of the sampling needle.
- 9- Place the small vial just below the piercing needle, where the tube holder was. Directly below the sampling needle.
- 10- Connect a piece of tubing to the tip of the syringe and aspirate the ABX Minoclair.
- 11- Place the free end of the syringe tubing on the top end of the sampling needle and flush the needle. Verify that the solution is flowing directly into the small vial.



If the sampling needle is free from blockage, the solution stream will appear to be straight. If a blockage is present, the solution stream will appear to be flared and/or at an angle. Flush the needle until the stream is straight.

- 12- Once the sampling needle is free from blockage, carefully remove the small vial.
- 13- Re-connect the sample tubing to the top of the needle so that it is air tight.
- 14- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle upwards until the tip of the sampling needle is inside the piercing needle.
- 15- Press "Status" button to open "Status" area.
- 16- Press "Startup" button to run a startup. Verify that background results are within their limits.
- 17- Re-run the Quality Controls to verify correct results.

#### **Procedure on ABX Micros ES60 OT:**

- 1- Open the main door (See 3.2. Cover dismantling, page 7-6).
- 2- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle downwards until you can see the top of the needle and sample tubing.
- 3- Remove the tubing from the top of the sampling needle.
- 4- Place the small vial just below the end of the sampling needle.
- 5- Connect a piece of tubing to the tip of the syringe and aspirate the ABX Minoclair.
- 6- Place the free end of the syringe tubing on the top end of the sampling needle and flush the needle. Verify that the solution is flowing directly into the small vial.



If the sampling needle is free from blockage, the flow will appear to be straight. If a blockage is present, the flow will appear to be flared and/or at an angle. Flush the needle until the flow is straight.

- 7- Once the sampling needle is free from blockage, carefully remove the small vial.
- 8- Re-connect the sample tubing to the top of the needle so that it is air tight.
- 9- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle upwards until the tip of the sampling needle is about 1 inch below the rinsing block.
- 10- Press "Status" button to open "Status" area.
- 11- Press "Startup" button to run a startup. Verify that reference blank results are within their limits.
- 12- Re-run the Quality Controls to verify correct results.

## 3.8. Replacing sampling needle

#### Concerns:

◆ Replacing sampling needle.

#### Instrument response/problem type:

- ◆ Low results on all parameters in any analysis mode
- ◆ No results on all parameters in any analysis mode
- ◆ Possible high reference blanks on startup

#### Required tools:

None

#### Required products:

None

#### Intervention time:

◆ Approximately 15 minutes

#### Frequency:

◆ Bent needle

#### Specific Kits or Consumable products:

- ◆ ABX Micros ES60 CT sampling needle (P/n: GBC052AS)
- ◆ ABX Micros ES60 OT sampling needle (P/n: GBC069AS)

#### Procedure on ABX Micros ES60 CT:

- 1- Close the tube holder door.
- 2- Open the main door (See 3.2. Cover dismantling, page 7-6).
- 3- Enter menu "Maintenance\Serv.\Mechanical cycles.
- 4- Press "Door opening" radio button.
- 5- Press "Start cycle" button (Diag.7-11) to open the tube holder door.
- 6- Remove the tube holder.
- 7- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle downwards until you can see the top of the needle and sample tubing.
- 8- Remove the tubing from the top of the sampling needle.
- 9- Remove the sampling needle retaining clip (pull the clip out horizontally towards the front of the analyser).
- 10- Hold the sampling needle mounting bracket on the upper right edge and move the sample upwards until the top of the needle is just below the front panel.
- 11- Very carefully pull the sampling needle slightly out of its retaining slot.
- 12- Now hold the sampling needle around the retaining collar, very carefully lift up the needle so that it is free from the white needle guide.



The sampling needle is fragile and may bend if not inserted into the needle guide correctly. Be careful when placing the needle. Try to maintain a vertical position of the needle when inserting it into the white needle guide.

- 13- Place the new sampling needle in the white needle guide.
- 14- Place the retaining collar of the needle into its slot.
- 15- Place retaining clip back onto the mounting bracket. (Leave a 3mm gap between the needle and clip. This will ensure that the sampling needle will move freely, when moving up and down through the needle guide).
- 16- Re-connect the sample tubing to the top of the needle so that it is air tight.
- 17- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle upwards until the tip of the sampling needle is inside the piercing needle.
- 18- Press "Status" button to open "Status" area.
- 19- Press "Startup" button to run a startup. Verify that background results are within their limits.
- 20- Re-run the Quality Controls to verify correct results.

#### Procedure on ABX Micros ES60 OT:

- 1- Open the main door (See 3.2. Cover dismantling, page 7-6).
- 2- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle downwards until you can see the top of the needle and sample tubing.
- 3- Remove the tubing from the top of the sampling needle.
- 4- Remove the sampling needle retaining clip (pull the clip out horizontally towards the front of the analyser).
- 5- Hold the sampling needle mounting bracket on the upper right edge and move the sample upwards until the top of the needle is just below the front panel.
- 6- Very carefully pull the sampling needle slightly out of its retaining slot.
- 7- Now hold the sampling needle around the retaining collar, very carefully lift up the needle so that it is free from the white needle guide.



The sampling needle is fragile and may bend if not inserted into the needle guide correctly. Be careful when placing the needle. Try to maintain a vertical position of the needle when inserting it into the white needle guide.

- 8- Place the new sampling needle in the white needle guide.
- 9- Place the retaining collar of the needle into its slot.
- 10- Place retaining clip back onto the mounting bracket. (Leave a 3mm gap between the needle and clip. This will ensure that the sampling needle will move freely, when moving up and down through the needle guide).
- 11- Re-connect the sample tubing to the top of the needle so that it is air tight.
- 12- Hold the sampling needle mounting bracket on the upper right edge and move the sampling needle upwards until the tip of the sampling needle is about 1 inch below the rinsing block.
- 13- Press "Status" button to open "Status" area.
- 14- Press "Startup" button to run a startup. Verify that reference blank results are within their limits.
- 15- Re-run the Quality Controls to verify correct results.

## 4. Service functions

### 4.1. Maintenance menu description

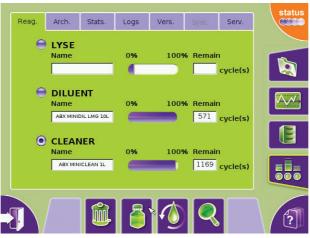
◆ To access the "Maintenance" menu: press "Maintenance menu" button (Diag.7-27).

Diag.7-27 Maintenance menu button



The "Maintenance" menu is displayed.

Diag.7-28 Maintenance menu



The "Maintenance" menu allows to:

- ◆ Manage reagents: See 4.2. Reagent management, page 7-21.
- ◆ Create or restore archives: See 4.3. Archives management, page 7-25.

It also displays:

- ◆ Instrument statistics: See 4.4. Instrument statistics, page 7-28.
- ◆ Logs: See 4.5. Logs, page 7-29.
- ◆ Version numbers: See 4.6. Version, page 7-30.

### 4.2. Reagent management

- ◆ ABX Micros ES60 OT/CT offers an automatic reagent management if HORIBA ABX reagents are configured.
- ◆ The management of reagents is carried out through the Reagent tab.
- ◆ To access the Reagent tab: See 4.2.1. Reagent tab access and description, page 7-21.

Reagents can be:

- ◆ Created: See 4.2.2. Reagent creation, page 7-22.
- ◆ Replaced: See 4.2.3. Reagent replacement, page 7-23.
- ◆ Primed: See 4.2.4. Reagent priming, page 7-24.
- ◆ Closed: See 4.2.5. Reagent closing, page 7-24.

### 4.2.1. Reagent tab access and description

◆ Enter menu "Maintenance\Reag."

The "Reag." tab is displayed.

In bottle mode:

- ◆ It contains radio buttons linked to the different reagent types used by the system: "LYSE", "DILUENT" and "CLEANER".
- Only one reagent of each type may exist at the same time on the system.

For each reagent type, it displays the following information:

- ◆ The reagent name in the "Name" field.
- ◆ A graphical representation of the reagent level (in percentage).
- ◆ The number of remaining cycles in the "Remain" field.

In pack mode:

It displays the following information:

- ◆ The pack name in the "Name" field.
- ◆ A graphical representation of the reagent level (in percentage).
- ◆ The number of remaining cycles in the "Remain" field.

#### 4.2.2. Reagent creation

#### **Bottle unit**

In the "Reag." tab:

- 1- Press corresponding radio button ("LYSE", "DILUENT" or "CLEANER") to select the reagent type to create.
- 2- Press "View" button (Diag.7-29).

#### Diag.7-29 View button



The "Edit reagent" screen is displayed.

- 3- Press "Edit" button.
- 4- Press "Lot" field to select it.
- 5- Read the reagent label by means of barcode reader or type the reagent lot number using the virtual keyboard or an external keyboard (if one is connected).
- 6- Press "Close" key to close the virtual keyboard if it is opened.

The instrument searches reagent information in the reagent database.

To know the reagents recognized by the instrument: See Tab.7-4 List of recognized reagents, page

### Tab.7-4 List of recognized reagents

Reagent designation	Reagent type
ABX Alphalyse 360 (0.36L)	LYSE
ABX Alphalyse (0.4L)	LYSE
ABX Minilyse LMG (1L)	LYSE
ABX Minipack LMG (4.2L)	LYSE, CLEAN, DIL
ABX Minidil LMG (10L)	DIL
ABX Cleaner (0.5L)	CLEAN
ABX Miniclean (1L)	CLEAN

When reagent information is found, it is displayed as follows:

- ◆ The reagent name in the "Name" field.
- ◆ The reagent expiration date in the "Expiry date" field.
- ◆ The reagent volume in the "Initial volume" field.
- 7- If necessary, the reagent volume can be modified:
- ◆ Type the reagent volume value in the "Initial volume" field using the virtual keyboard or an external keyboard (if one is connected).
- ◆ Press "Close" key to close the virtual keyboard if it is opened.
- 8- Press "OK" button to validate.
- 9- Press "Back" button to return to previous screen.
- 10- Install the reagents on the instrument (See Section 7, 3.5. Reagent installation, page 7-13).
- 11- Run a prime cycle (See Section 7, 4.2.4. Reagent priming, page 7-24).

#### Pack unit

In the "Reag." tab:

1- Press "View" button (Diag.7-29).

The "Edit reagent" screen is displayed.

- 2- Press "Edit" button.
- 3- Press "Lot" field to select it.
- 4- Read the reagent pack label by means of barcode reader or type the reagent pack lot number using the virtual keyboard or an external keyboard (if one is connected).
- 5- Press "Close" key to close the virtual keyboard if it is opened.

The instrument searches reagent pack information in the reagent database.

When reagent pack information is found, it is displayed as follows:

- ◆ The reagent pack name in the "Name" field.
- ◆ The reagent pack expiration date in the "Expiry date" field.
- ◆ The reagent volume in the "Initial volume" field.
- 6- If necessary, the reagent volume can be modified:
- ◆ Type the reagent volume value in the "Initial volume" field using the virtual keyboard or an external keyboard (if one is connected).
- ◆ Press "Close" key to close the virtual keyboard if it is opened.
- 7- Press "OK" button to validate.
- 8- Press "Back" button to return to previous screen.
- 9- Install the pack on the instrument (See Section 7, 3.5. Reagent installation, page 7-13).
- 10- Run a prime cycle (See Section 7, 4.2.4. Reagent priming, page 7-24).

When a reagent is created, the following information is displayed in the "Logs" tab in the "Reagent" category:



- the date/hour of the reagent creation
- the user who has created the reagent

### 4.2.3. Reagent replacement

#### **Bottle unit**

In the "Reag." tab:

- 1- Press corresponding radio button ("LYSE", "DILUENT" or "CLEANER") to select the reagent type to replace.
- 2- Press "Replace" button (Diag.7-30).

Diag.7-30 Replace button



- ◆ The following message is displayed: "Are you sure you want to replace this reagent / pack?"
- 3- Press "OK" button.

The "Edit reagent" screen is automatically displayed.

4- Edit a new reagent (See 4.2.2. Reagent creation, page 7-22).

#### Pack unit

In the "Reag." tab:

- 1- Press "Replace" button (Diag.7-30).
- ◆ The following message is displayed: "Are you sure you want to replace this reagent / pack?"
- 2- Press "OK" button.

The "Edit reagent" screen is displayed.

3- Edit a new reagent pack (See 4.2.2. Reagent creation, page 7-22).



When a reagent is replaced, the following information is displayed in the "Logs" tab in the "Reagent" category:

- the date/hour of the reagent replacement
- the user who has replaced the reagent

#### 4.2.4. Reagent priming

This function primes all reagents of the pack in pack mode and the selected reagent in the bottle mode.

In the "Reag." tab:

1- Press "Prime" button (Diag.7-31).

Diag.7-31 Prime button





A priming cycle must be done after each reagent installation (creation or replacement).

### 4.2.5. Reagent closing

A reagent has to be closed when a reagent is expired.

#### **Bottle unit**

In the "Reag." tab:

- 1- Press corresponding radio button ("LYSE", "DILUENT" or "CLEANER") to select the reagent to close.
- 2- Press "Delete" button (Diag.7-32).

Diag.7-32 Delete button



- ◆ The following message is displayed: "Are you sure you want to close the selected reagent?"
- 3- Press "OK" button.

#### Pack unit

In the "Reag." tab:

- 1- Press "Delete" button (Diag.7-32).
- ◆ The following message is displayed: "Are you sure you want to close the selected reagent?"
- 2- Press "OK" button.

All the reagents of the pack are closed.



When a reagent is closed, the following information is displayed in the "Logs" tab in the "Reagent" category:

- the date/hour of the reagent closing
- the user who closed the reagent

## 4.3. Archives management

### 4.3.1. Archives tab access and description

- ◆ Enter "Maintenance\Arch".
- ◆ For each kind of archive, the last archiving operation date is displayed.
- ◆ One icon, for each type of archive, displays the archive status:



No archive needed.



Data needs to be archived. An archive is required when the last archive of a category dates from more than 1 month or according to different criteria for each category.

The "Arch." tab allows to create or restore (settings and analyser only) archives for:

- ◆ Settings: See Settings archives, page 7-25.
- ◆ Analyser: See Analyser archives, page 7-25.
- ◆ Logs: See Logs archives, page 7-26.
- ◆ QC: See QC archives, page 7-26.
- ◆ Analyses: See Analyse archives, page 7-26.

#### **Archives description**

- Archives can be:
  - Full: full archives contain all the data present in the system even if they have already been archived.
  - Partial: partial archives contain only the new data saved until last archive done.
- ◆ At the beginning of each archive file the following information is displayed:
  - The instrument network name
  - The archive creation date and time
  - The login of the user who has generated the archive
  - The instrument version
  - The instrument serial number
- ◆ The archives are exported on a USB key on a file with the following name format:

#### "ar-serial-category-yyyyMMddhhmmss".

- "ar": Means archive
- "serial": represents the instrument serial number from which archive comes.
- "category": represents the archive type.
- "yyyyMMdd": represents the archive date.
- "hhmmss": represents the archive time.
- ◆ The QC result archives are .xml files. An .xml file contains all the QC results archived.

  The patient results archives are .tar files containing an .xml file for each result stored.

  Thus, the QC and patient results can be consulted on an external computer using a spreadsheet (type Microsoft Excel) or a specific viewer (See 4.3.3. Consulting result archives on external computer, page 7-27).

### **Settings archives**

- ◆ Settings archives correspond to the instrument settings. They can be created or restored (See 4.3.2. Archives creation, page 7-26 and 4.3.4. Restoring archive, page 7-28).
- ◆ A setting archive is always full. It is required at each instrument settings modification.

#### **Analyser archives**

- ◆ Analyser archives correspond to the instrument adjustments. They can be created or restored (See 4.3.2. Archives creation, page 7-26 and 4.3.4. Restoring archive, page 7-28).
- ◆ An analyser archive is always full. It is required at each instrument adjustment modification.

#### Logs archives

◆ Logs archives can only be created (See 4.3.2. Archives creation, page 7-26). A log archive can be full or partial. It is required when the last logs archive dates from more than 1 month.

#### QC archives

- ◆ QC archives correspond to the closed control results. They can only be created (See 4.3.2. Archives creation, page 7-26).
- ◆ A QC archive can be full or partial. It is required at each control closing.

#### **Analyse archives**

- ◆ Analyse archives correspond to the patient results. They can only be created (See 4.3.2. Archives creation, page 7-26).
- A result archive can be full or partial. It is required when more than 990 results are present in the historic.

#### 4.3.2. Archives creation

- ◆ The archives creation consists in saving instrument settings ("Settings"), instrument adjustments ("Analyser"), logs ("Logs"), closed control results ("QC") or patient results ("Analyses") on an USB key.
- Archives can be created anytime.
- However, the instrument informs the user when archives are required. A message is displayed in the "Status" area.

When an archive requirement message is displayed, the user can:

- ◆ Create an archive (See Creating an archive, page 7-26).
- Press "Reset" button in the "Arch." tab if user does not want to create an archive at this time (Diaq.7-33).

#### Diag.7-33 Reset button



◆ The archive requirement message is deleted in the status area.

#### Creating an archive



"Settings" and "Analyser" archives can only be done by user with a "Scientist" profile.

In the "Arch." tab:

- 1- Press one of the five radio buttons: "Settings", "Analyser", "Logs", "QC" or "Analyses" to select the category to archive.
- 2- User has two options:
- ◆ To create a full archive of the selected category: press "Complete" button (Diag.7-34).

#### Diag.7-34 Complete button



◆ To create a partial archive of the selected category: press the "Incremental" button (Diag.7-35).

#### Diag.7-35 Incremental button



- ◆ A dialog box is displayed: "Please insert your USB key into the front slot of the instrument. Select 'OK' to continue."
- 3- Insert USB key into the front slot of the instrument and press "OK" button.



Never remove the USB key from the front slot before the progress indication window closes.

During the archive creation, the following message is displayed: "Archive creation in progress. Please wait."

### 4.3.3. Consulting result archives on external computer

#### Consulting result with a spreadsheet application

- 1- Paste the result archive files on your external computer.
- 2- For patient results:
- ◆ Double-click on the .tar file.
- ◆ The list of .xml files is displayed. They have the following name format "yyyyMMddhhmmss.xml".
  - "yyyyMMdd": represents the archive date (year, month, day).
  - "hhmmss": represents the archive time (hour, minute, second).
- ◆ Select the .xml files to extract, then press "Extract" button.
- ◆ Right-click on the .xml file to consult then open it with a spreadsheet application.
- 3- For QC results: right-click on the .xml file to consult then open it with a spreadsheet application.

#### Consulting result with a specific viewer

- 1- First, install the viewer on your computer (if it has not been already installed). See Viewer installation, page 7-27.
- 2- Paste the result archive files on your external computer.
- 3- Double-click on the viewer icon (with .jar extension) located on the computer desktop.
- 4- An opened window is displayed. It allows to select the archive file to open on your computer:
- ◆ For patient results:
  - select the .tar file to open.
  - the list of .xml files is displayed in the viewer. Click on one .xml file to display it in the viewer.
- ◆ For QC results:
  - select the .xml file to open.
  - to open another .xml file press the "Open file" button (Diag.7-36) located at the bottom of the viewer window.

#### Diag.7-36 Open file button



#### Viewer installation

- 1- Insert the User manual CDROM (RAX061) in your computer CDROM drive.
- 2- Select the language.
- 3- Press "View html" button (Diag.7-37)

#### Diag.7-37 View html button



- 4- Press "Install viewer" button.
- 5- Press "Save" button and follow the instructions displayed to install the viewer.
- 6- Once the viewer installation is ended, the viewer icon is displayed in your computer desktop.

#### 4.3.4. Restoring archive



- ◆Only "Settings" and "Analyser" archives can be restored.
- ◆Archives can only be restored by user with a "Scientist" profile.

In the "Arch." tab:

- 1- Press "Settings" or "Analyser" radio button.
- 2- Press "Restore" button (Diag.7-38).

Diag.7-38 Restore button



- ◆ A dialog box is displayed: "Please insert your USB key into the front slot of the instrument. Select 'OK' to continue archive restoration."
- 3- Insert USB key into the front slot of the instrument and press "**OK**" button.
- ◆ A window opens containing the archive files list.
- ◆ The archives are sorted out by date and time. The latest archive file is selected by default.
- 4- Select the archive file to restore. Use "Up" and "Down" buttons to scroll up and down the list.



If selected archive is a setting archive containing settings for a previous application version, all unknown settings are ignored.

- 5- Press "Restore" button.
- During the restoring of archive, the following message is displayed: "Archive restoration in progress. Please wait."
- ◆ Before the restoring, the following confirmation message is displayed: "Warning: all current settings will be lost! Are you sure to want to restore settings from USB archive file?"
- 6- Press "OK" button.



Never remove the USB key from the front slot before the progress indication window closes.

◆ When the archive file is restored, the instrument restarts automatically.

### 4.4. Instrument statistics

◆ Enter "Maintenance\Stats".



This tab is not available for user logged in as "Lab tech".

The "Stats." tab contains all statistics for the following items:

- ◆ Number of analyser startups
- Number of analyser shutdowns
- Number of analyses
- Number of reagents used
- Number of settings changed
- Number of log-ons
- Number of startup cycles
- ◆ Number of shutdown cycles
- Number of service cycles

### **4.5. Logs**

#### 4.5.1. Logs tab access and description

- Enter menu "Maintenance\Logs."
- ◆ The "Logs" tab contains all of the notifications made automatically by the software while instrument is in operation.

Each log contains the following information:

- ◆ The date and time of the event.
- ◆ The user signed on during the event.
- The event message.

Press one of the 3 following items: "Date/Hour", "User" or "Message" to sort results by this item.

The logs can be:

- ◆ Filtered by category or by date: See 4.5.2. Logs filtering, page 7-29.
- ◆ Printed: See 4.5.3. Logs printing, page 7-29.
- ◆ Archived: See 4.3. Archives management, page 7-25.

### 4.5.2. Logs filtering

To display the list of a log category:

- 1- Use arrow button to select the desired category in the "Category" list.
- ◆ The available log categories are "Configuration", "Connections", "QC", "Analysis", "Maintenance", "Alarms", "Errors", "Startup" and "Reagent".

The logs are sorted by date/hour by default.

1- Press one of the 3 following items at the top of the table: "Date/Hour", "User" or "Message" to sort results by this item.

To filter logs by date:

- 1- Check the "Date" check box.
- 2- Type the date in the "**Date**" fields using the virtual keyboard or an external keyboard (if one is connected).
- ◆ Only one charater can be typed in. For example: only the month or the year.
- ◆ The date format corresponds to the format set in the "Settings" tab (See Section 6, 3.4. Date format setting, page 6-5).
- 3- Press "Filter" button (Diag.7-39).

#### Diag.7-39 Filter button



- ◆ Logs are sorted by date according to the selected log category.
  - ◆Use the scroll bar, "Up", "Down", "Page up" and "Page down" buttons to scroll up and down table content if it does not fit in the screen (See Section 1, Arrows, page 1-16).



◆To deactivate filter function, uncheck the "Date" check box. All logs are redisplayed.

#### 4.5.3. Logs printing



To print logs, an external printer must be configured as a default printer. If integrated ticket printer is selected, the "Print" button is not available.

To configure printer: See Section 6, 4.3.2. Printer settings, page 6-8.

Press "Print" button, the following printing progress message is displayed: "Log printing in progress."

## 4.6. Version

- ◆ Enter menu "Maintenance\Vers."
- ◆ The "Vers." tab contains all of the version numbers (application, analyser, help, etc.).

## 5. Troubleshooting



Before coming to the conclusion that the instrument has malfunctioned and needs repair, check the following points of operation. After checking these points and verifying that the problem still occurs, contact your local HORIBA ABX Technical Support Representative for further assistance.

- ◆ Is the power cable correctly connected to the instrument?
- ◆ Does an ERROR message display in the status area?

#### 5.1. Overview

Your ABX Micros ES60 OT/CT may occasionally require troubleshooting if:

- System operations are faulty.
- ◆ The background count is unacceptably high.
- Your quality control values are out-of-range, or patient results are suspicious (e.g. consistently high RBC counts, or the inability to verify results by manual methods).
- Precision is poor.
- Calibration is drifting.

#### 5.2. Problem identification

The first step in any troubleshooting session is to identify the source of the system malfunction:

- System operation
- Precision
- ◆ Quality control
- Calibration
- ◆ These steps should be carried out in sequence as described below.

#### **5.2.1. System operations**

- ◆ The ABX Micros ES60 OT/CT software identifies most of the mechanical or hydraulic problems. A mechanical problem gives an alarm message and stops the current cycle in progress.
- ◆ A hydraulic problem can be noted by parameter and/or morphology flags. The waste sensor also gives an error message if a hydraulic problem exists.
- ◆ If this is the case, power OFF then ON the system and run a startup.
- ◆ If the problem persists during or after startup, identify the source of the malfunction and initiate the appropriate troubleshooting procedures.

#### 5.2.2. Reagents

- ◆ If your background count is unacceptable, quality control values are out-of-range, or your patient results are suspicious, reagent deterioration or contamination may be suspected.
- ◆ Replace your reagents (See 3.5. Reagent installation, page 7-13) and perform a concentrated cleaning procedure (See 3.3.5. Concentrated cleaning, page 7-9).
- ◆ If the background count is acceptable, but the quality control values are still out-of-range or patient results are still suspicious, continue with the indentification procedure. If replacing the reagents performing a concentrated cleaning procedure does not correct the background count problem, call your local HORIBA ABX Technical Support Representative for further instructions.

#### 5.2.3. Precision

- ◆ In order to verify the precision of the instrument, it is recommended to run a fresh, normal whole blood sample 10 times, mixing between each analysis cycle.
- ◆ After all 10 runs are complete, calculate the coefficient of variation percentage (CV%).
- ◆ Compare the CV% results with those listed (See Section 2, Tab.2-9 Precision (Repeatability), page 2-10)
- ◆ If the precision of any parameter is not within these specifications, identify the out-of-range parameter(s) and initiate appropriate troubleshooting procedures.

### Diag.7-40 Calculation factors for CV% determination

 $\overline{X} = \sum \frac{xi}{n}$   $\Rightarrow \overline{X} = \text{the calculated Mean}$   $\Rightarrow n = \text{the total number of samples}$   $\Rightarrow Xi = \text{the individual parameter value}$   $\Rightarrow SD = \text{Standard Deviation}$   $\Rightarrow CV\% = (SDx100)/X$ 

◆ Once the CV%s have been calculated, compare them to the specified limits.

#### 5.2.4. Calibration

◆ If the system seems to be operating properly, fresh uncontaminated reagents are being used and the precision is within the specifications but the problem still occurs, the ABX Micros ES60 OT/CT may need calibration (See Section 5, 4. Calibration, page 5-21).

## 5.3. Troubleshooting parameters

- ◆ The procedures described below should be performed whenever the precision of a parameter is not within its CV specifications or the parameter is incorrect or suspicious.
- When all parameters are affected, it is necessary to look for a common cause (e.g. vacuum, pressure, sample aspiration, chamber filling and draining correctly, common reagent pollution, etc....).
- ◆ When only one parameter is affected, it is necessary to look for a cause in this specific area of analysis. The different tables listed, give the noted problems for the parameter in question, possible cause of the problem and the necessary user action to correct the problem.

### 5.3.1. Problems on all parameters

#### Tab.7-5 Problems on all parameters

Problem noted	Possible cause	Corrective action
	Out of reagent(s)	Check and/or replace reagent(s) if necessary (See 3.5. Reagent installation, page 7-13)
Startup failed	Contaminated reagent(s)	Check and/or replace reagent(s) if necessary (See 3.5. Reagent installation, page 7-13)
	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun startup
	Blocked sampling needle	Remove and flush out sampling needle (See 3.7. Unblocking sampling needle, page 7-17)
No results in analysis	Sampling needle depth not adjusted correctly Possible defective Pre-amp on main board	Contact your local HORIBA ABX Technical Support Representative for assistance
	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Possible partial blocked sampling needle	Remove and flush out sampling needle (See 3.7. Unblocking sampling needle, page 7-17)
Suspicious patient results	Possible leakage from syringe blocks	Check syringe block for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible fibrin clot in "T" fitting below WBC chamber possible tube cap debris in "T" fitting below WBC chamber	Contact your local HORIBA ABX Technical Support Representative

Problem noted	Possible cause	Corrective action
Alouer Flores on most	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
Alarm flags on most parameters	Possible fibrin clot in "T" fitting below WBC chamber possible tube cap debris in "T" fitting below WBC chamber	Contact your local HORIBA ABX Technical Support Representative
	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), re-run sample
QC outside acceptable	Possible leakage from syringe block	Check syringe block for leakage and contact your local HORIBA ABX Technical Support Representative
limits	Possible fibrin clot in "T" fitting below WBC chamber possible tube cap debris in "T" fitting below WBC chamber	Contact your local HORIBA ABX Technical Support Representative
	Poor calibration	Recalibrate and rerun QC (See 4. Calibration, page 5-21).
	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
Poor repeatability	Possible leakage from syringe block	Check syringe block for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible fibrin clot in "T" fitting below WBC chamber possible tube cap debris in "T" fitting below WBC chamber	Contact your local HORIBA ABX Technical Support Representative
Poor Chamber draining	Possible fibrin clot in "T" fitting below WBC chamber possible tube cap debris in "T" fitting below WBC chamber	Contact your local HORIBA ABX Technical Support Representative
	Possible vacuum/waste syringe malfunction	Check syringe correct operation (See 3.3.7. Mechanics, page 7-10).

### 5.3.2. Problems on RBC/PLT parameters only

#### Tab.7-6 Problems on RBC/PLT parameters only

Prot	olem noted	Possible cause	Corrective action
Startup failed	Possible dirty aperture Possible dirty chamber	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample	
	Possible partial blockage in sampling needle	Remove and flush out sampling needle (See 3.7. Unblocking sampling needle, page 7-17)	
	Possible leakage from syringe block	Check syringe block for leakage and contact your local HORIBA ABX Technical Support Representative	
	Possible contaminated reagent(s)	Check and/or replace reagent(s) if necessary	

Problem noted	Possible cause	Corrective action
No results in analysis	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
NO TESULES III allatysis	Has diluent been delivered correctly into RBC chamber?	Check for diluent delivering into chamber, contact your local HORIBA ABX Technical Support Representative
	Possible dirty aperture	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
Suspicious patient results	Possible leakage from syringe blocks	Check syringe blocks for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible dirty chamber	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Possible dirty aperture	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
QC outside acceptable limits	Possible leakage from syringe blocks	Check syringe blocks for leakage and contact your local HORIBA ABX Technical Support Representative
	Poor calibration	Recalibrate and rerun QC (See Section 5, 4. Calibration, page 5-21)
Poor repeatability	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible partial blockage in sampling needle	Remove and flush out sampling needle (See 3.7. Unblocking sampling needle, page 7-17)
	Possible dirty chamber	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Incorrect sample mixing	Mix sample just before placing into the tube holder for each sample (CT). Mix sample just before pressing the manual sample bar for each sample (OT).

### 5.3.3. Problems on WBC/HGB parameters only

Tab.7-7 Problems on WBC/HGB parameters only

Problem noted	Possible cause	Corrective action
	Possible dirty aperture	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Possible partial blockage in sampling needle	Remove and flush out sampling needle (See 3.7. Unblocking sampling needle, page 7-17)
Startup failed	Possible leakage from syringe block	Check syringe block for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible contaminated reagent(s)	Check and/or replace reagent(s) if necessary (See 3.5. Reagent installation, page 7-13)
	Possible bad HGB blank reference voltage	Contact your local HORIBA ABX Technical Support Representative for assistance
	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
No results in analysis	Has diluent been delivered correctly into WBC chamber?	Check for diluent delivering into chamber, contact your local HORIBA ABX Technical Support Representative
	Possible lyse flow error	Check and/or replace Lyse reagent (See 3.5. Reagent installation, page 7-13)
Very high results on WBC/HGB	Possible fibrin clot in "T" fitting below WBC chamber Possible tube cap debris in "T" fitting below WBC chamber	Contact your local HORIBA ABX Technical Support Representative
	Possible dirty aperture	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
Suspicious patient results	Possible leakage from syringe blocks	Check syringe blocks for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible dirty chamber	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
QC outside acceptable limits	Possible dirty aperture Possible dirty chamber	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and contact your local HORIBA ABX Technical Support Representative
	Poor calibration	Recalibrate and rerun QC (See Section 5, 4. Calibration, page 5-21).

Problem noted	Possible cause	Corrective action
Poor repeatability	Possible dirty apertures	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and contact your local HORIBA ABX Technical Support Representative
	Possible dirty chamber	Perform a concentrated cleaning (See 3.3.5. Concentrated cleaning, page 7-9), rerun sample
	Incorrect sample mixing	Mix sample just before placing into the tube holder for each sample (CT). Mix sample just before pressing the manual sample bar for each sample (OT).
	Possible partial blockage in sampling needle	Remove and flush out sampling needle (See 3.7. Unblocking sampling needle, page 7-17)
	Possible sampling needle bent	Replace sampling needle (See 3.8. Replacing sampling needle, page 7-19)

## **5.4.** Troubleshooting system operations

Tab.7-8 Troubleshooting system operations

Problem noted	Possible cause	Corrective action
No power to the unit	Unit is powered off and/or power cord is disconnected from power source	Power on unit and/or plug in power cord to power source
	Possible blown power fuses	Contact your local HORIBA ABX Technical Support Representative for assistance
No display on LCD screen	Possible disconnection of cable to display	Contact your local HORIBA ABX Technical Support Representative for instructions on re- connection of cable
Motor errors on any motor	Possible motor failure	Check motor operation (See 3.3.7. Mechanics, page 7-10)
	Possible disconnected cable to motor on main board	Remove main cover of the unit, check all connectors, contact your local HORIBA ABX Technical Support Representative for assistance

## 6. Alarms and error messages

This chapter will describe different alarms or errors which could be generated. It also explains actions to perform in order to solve the detected problem:

- ◆ See 6.1. System alarms, page 7-37.
- ◆ See 6.2. Logs, page 7-41.

### 6.1. System alarms

◆ When a system alarm is triggered on the instrument, the status button blinks. Press "Status" button (Diag.7-41) to display the "Status" area.

Diag.7-41 Status button



The system alarms are sorted by 5 categories.
 Press the corresponding category button to display the system alarm messages.

#### 6.1.1. Instrument alarms

Diag.7-42 Instrument status button



System alarm message	Help message	Possible cause / Corrective action
Startup cycle failed	Run a Startup cycle directly from this status screen.	The cycle has not been able to be completely performed or no result received or no previous result to display: - Run a startup cycle by pressing the "Startup" button.
Invalid startup cycle	Run a Startup cycle directly from this status screen.	The startup cycle has correctly carried out, but the result of the blank cycle is out of acceptable limits or the delay between 2 analyses (X hours adjustable) is exceeded or the technician asks for a restart without Shutdown: - Run a startup cycle by pressing the "Startup" button.
Cycle cancelled by user	Run a Startup cycle directly from this status screen.	- Run a startup cycle by pressing the "Startup" button Consult "Logs" tab (See 4.5.2. Logs filtering, page 7-29).
Critical cycle error	Run a Startup cycle directly from this status screen.	- Run a startup cycle by pressing the "Startup" button.
Analyser connection failed	Restart the analyser (Logout screen / Shutdown / Restart).	Connection not initialized between analyser and application (analyser do not answer or analyser version is not compatible with the application version):  - Restart the instrument.  - Check version numbers (See 4.6. Version, page 7-30).  - Contact your local HORIBA ABX Technical Support Representative for assistance.
Analyser communication failed	Run a Startup cycle directly from this status screen.	A communication error with the analyser occurred: - Run a startup cycle by pressing the "Startup" button.
Reagent temperature error.	Run a Startup cycle directly from this status screen.	A reagent is not at the operating temperature: - Run a startup cycle by pressing the "Startup" button Replace the reagent or the pack. See 4.2. Reagent management, page 7-21

## 6.1.2. QC alarms

#### Diag.7-43 QC status button



System alarm message	Help message	Possible cause / Corrective action
Invalid QC "lot number"	Check the last QC "lot number" result in QC menu and rerun the appropriate control if necessary.	A QC analysis is out of normality limits:  - Check the last control results.  - Run an analysis for this control (See Section 4, 2.2. Running control blood (ABX Minotrol 16), page 4-11).  - Replace the control lot (See Section 5, 2.3. Control management, page 5-4).
Inter QC time limit "lot number"	Inter QC "lot number" time set elapsed. You should run the appropriate control.	The inter QC time limit set for a control is elapsed: - Run an analysis for this control (See Section 4, 2.2. Running control blood (ABX Minotrol 16), page 4-11).
XB drift	Check XB data in QC menu/XB screen.	A statistic dot is out of limits: - Check XB data.

## 6.1.3. Reagent alarms

Diag.7-44 Reagent status button



System alarm message	Help message	Possible cause / Corrective action
Reagent LYSE expired.	Check LYSE expiration date in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent by another lot number, run priming cycle from reagent screen and run a Startup cycle.	- Replace the LYSE reagent. See 4.2. Reagent management, page 7-21
Reagent DILUENT expired.	Check DILUENT expiration date in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent by another lot number, run priming cycle from reagent screen and run a Startup cycle.	- Replace the DILUENT reagent. See 4.2. Reagent management, page 7-21
Reagent CLEANER expired.	Check CLEANER expiration date in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent by another lot number, run priming cycle from reagent screen and run a Startup cycle.	- Replace the CLEANER reagent. See 4.2. Reagent management, page 7-21
Reagent PACK expired.	Check PACK expiration date in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent by another lot number, run priming cycle from reagent screen and run a Startup cycle.	- Replace the reagent pack. See 4.2. Reagent management, page 7-21
Low reagent level LYSE	Check LYSE level in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent, run priming cycle from reagent screen and run a Startup cycle.	LYSE reagent is almost empty (counter of tests lower than 10): - Replace the LYSE reagent. See 4.2. Reagent management, page 7-21

System alarm message	Help message	Possible cause / Corrective action
Low reagent level DILUENT	Check DILUENT level in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent, run priming cycle from reagent screen and run a Startup cycle.	DILUENT reagent is almost empty (counter of tests lower than 10): - Replace the DILUENT reagent. See 4.2. Reagent management, page 7-21
Low reagent level CLEANER	Check CLEANER level in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent, run priming cycle from reagent screen and run a Startup cycle.	CLEANER reagent is almost empty (counter of tests lower than 10): - Replace the CLEANER reagent. See 4.2. Reagent management, page 7-21
Low reagent level PACK	Check PACK level in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent, run priming cycle from reagent screen and run a Startup cycle.	Reagent pack is almost empty (counter of tests lower than 10): - Replace the reagent pack. See 4.2. Reagent management, page 7-21
Reagent empty	Check level in Maintenance menu / Reagent screen. If necessary, replace the appropriate reagent, run priming cycle from reagent screen and run a Startup cycle.	- Replace the pack or the empty reagent. See 4.2. Reagent management, page 7-21

#### 6.1.4. Archive alarms

Diag.7-45 Archive status button



System alarm message	Help message	Possible cause / Corrective action
settings archive should be archived.	Archive the settings category in the Maintenance menu / Archives screen by connecting a USB key on the analyser.	- Create archive for the software settings. See 4.3. Archives management, page 7-25
analyser archive should be archived.	Archive the analyser category in the Maintenance menu / Archives screen by connecting a USB key on the analyser.	- Create archive for the Analyser settings. See 4.3. Archives management, page 7-25
logs archive should be archived.	Archive the logs category in the Maintenance menu / Archives screen by connecting a USB key on the analyser.	- Create archive for the Logs. See 4.3. Archives management, page 7-25
qc archive should be archived.	Archive the qc category in the Maintenance menu / Archives screen by connecting a USB key on the analyser.	- Create archive for the QC. See 4.3. Archives management, page 7-25
analysis archive should be archived.	Archive the analysis category in the Maintenance menu / Archives screen by connecting a USB key on the analyser.	- Create archive for the Patient results. See 4.3. Archives management, page 7-25

## 6.1.5. Application alarms

#### Diag.7-46 Application status button



System alarm message	Help message	Possible cause / Corrective action
Barcode reader error	Restart the analyser (Logout screen / Shutdown / Restart).	- Check barcode reader settings (See Section 6, 4.2. Barcode reader (optional), page 6-7) Restart the instrument.
Ticket printer error	Restart the analyser (Logout screen / Shutdown / Restart).	<ul> <li>Check if ticket printer is online. If not, switch it on.</li> <li>Check if there is enough paper.</li> <li>Check printer setting (See Section 6, 4.3. Printer, page 6-7).</li> <li>Restart the instrument.</li> </ul>
Application error	Restart the analyser (Logout screen / Shutdown / Restart).	A software problem occurs during data saving or file opening for example: - Restart the instrument.
LIS connection failed	Check the connection with the LIS or its availability or its configuration.	A result cannot be translated to the LIS:  - Check if LIS connection cable is correctly plugged.  - Restart the instrument.  - Contact your local HORIBA ABX Technical Support Representative for assistance.
Printer queue full	More than 3 print jobs pending. Please wait or check the status of your printer.	- Check if printer is on line. If not, switch it on.
Print error	An error occured during the last print job. Check the status of your printer and consult the error log.	<ul> <li>Check if instrument and printer cables are correctly plugged.</li> <li>Check if printer is on line. If not, switch it on.</li> <li>Check if there is enough paper.</li> <li>Check printer settings (See Section 6, 4.3. Printer, page 6-7).</li> </ul>

### **6.2. Logs**

- When the instrument detects an error, the status button turns orange and the error message is displayed in the "Logs" tab.
- ◆ To access the "Logs" tab:
- 1- Press "Maintenance menu" button (Diag.7-27).

#### Diag.7-47 Maintenance menu button



- 2- Press "Logs" tab.
- ◆ The log messages are sorted by category:
  - See 6.2.1. Alarms logs, page 7-41.
  - See 6.2.2. Errors logs, page 7-42.
  - See 6.2.3. QC logs, page 7-47.
  - See 6.2.4. Maintenance logs, page 7-47.
  - See 6.2.5. Startup logs, page 7-47

#### 6.2.1. Alarms logs

Message	Possible cause/Corrective action
Startup cycle failed	The cycle has not been able to be completely performed or no result received or no previous result to display: - Run a startup cycle by pressing the "Startup" button.
Invalid startup cycle	The startup cycle has correctly carried out, but the result of the blank cycle is out of acceptable limits or the delay between 2 analyses (X hours adjustable) is exceeded or the technician asks for a restart without Shutdown:  - Run a startup cycle by pressing the "Startup" button.
Printing blank report failed	Print error or report generation error: - Check if printer is on line. If not, switch it on Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16 Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Analyser communication failed	A communication error with the analyser occurred: - Run a startup cycle by pressing the " <b>Startup</b> " button.
Analyser connection failed	Connection not initialized between analyser and application (analyser do not answer or analyser version is not compatible with the application version):  - Restart the instrument.  - Check version numbers (See 4.6. Version, page 7-30).  - Contact your local HORIBA ABX Technical Support Representative for assistance.
Critical cycle error	- Run a startup cycle by pressing the "Startup" button.
Application error	A software problem occurs during data saving or file opening for example: - Restart the instrument.
Reagent temperature error	A reagent is not at the operating temperature: - Run a startup cycle by pressing the "Startup" button Replace the reagent or the pack. See 4.2. Reagent management, page 7-21

Message	Possible cause/Corrective action
Cannot print result	During the automatic result printout: impossible to convert in current units or error during report creation or error during printout:  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Cannot upload result	LIS sending error: - Check if LIS connection cable is correctly plugged Restart the instrument Contact your local HORIBA ABX Technical Support Representative for assistance.
Invalid QC "lot number"	A QC analysis is out of normality limits:  - Check the last control results.  - Run an analysis for this control (See Section 4, 2.2. Running control blood (ABX Minotrol 16), page 4-11).  - Replace the control lot (See Section 5, 2.3. Control management, page 5-4).
XB drift	A statistic dot is out of limits: - Check XB data Replace the control lot (See Section 5, 2.3. Control management, page 5-4).
Barcode reader error	<ul> <li>Check barcode reader settings (See Section 6, 4.2. Barcode reader (optional), page 6-7).</li> <li>Restart the instrument.</li> </ul>
Ticket printer error	<ul> <li>Check if ticket printer is online. If not, switch it on.</li> <li>Check if there is enough paper.</li> <li>Check printer setting (See Section 6, 4.3. Printer, page 6-7).</li> <li>Restart the instrument.</li> </ul>

### 6.2.2. Errors logs

#### Software, connection and communication

Message	Possible cause/Corrective action
Software internal error, try to restart the application.	Reception of an analysis result instead of a QC result or conversely.  Internal read/write error.  - Restart the instrument.  - Contact your local HORIBA ABX Technical Support Representative for assistance.
Internal read command failure, try to restart the application.	Internal communication error: - Restart the instrument Contact your local HORIBA ABX Technical Support Representative for assistance.
Internal write command failure, try to restart the application.	Internal communication error: - Restart the instrument Contact your local HORIBA ABX Technical Support Representative for assistance.
Read write / error on history file, the application must be reinstalled, contact your local technical support.	Error during "result historic", or "QC list", or "LJ graphic", or "LJ save", or «result save» or «result in historic save» recuperation.  - Contact your local HORIBA ABX Technical Support Representative for assistance.

Message	Possible cause/Corrective action
Cannot update XB statistics, the application must be reinstalled, contact your local technical support.	Error during XB loading or No parameter for XB calculation or Corrupted datas or Recording error - Contact your local HORIBA ABX Technical Support Representative for assistance.
Cannot send calibration factors, try to restart the application.	Internal communication error Restart the instrument.
<pre>Internal command error, try to restart the application.: (code = %s)</pre>	Internal communication error Restart the instrument.
Read / write error on history file, the application must be reinstalled, contact your local technical support.	Error of historic result reading during purge Contact your local HORIBA ABX Technical Support Representative for assistance.
Error cannot read QC controls files, the application must be reinstalled, contact your local technical support.	QC files repository does not exist or QC files have been corrupted during QC purge Contact your local HORIBA ABX Technical Support Representative for assistance.
Read / write error on settings file, the application must be reinstalled, contact your local technical support.	The setting file exists but its format is not correct Contact your local HORIBA ABX Technical Support Representative for assistance.
Error cannot read QC controls files, the application must be reinstalled, contact your local technical support.	Internal read/write error. The files cannot be load Contact your local HORIBA ABX Technical Support Representative for assistance.
Read error on history file, the application must be reinstalled, contact your local technical support.	Internal read/write error. Error during historic results recovery Contact your local HORIBA ABX Technical Support Representative for assistance.
Read / write error on reagents file, the application must be reinstalled, contact your local technical support.	The reagent list has not been loaded during starting Contact your local HORIBA ABX Technical Support Representative for assistance.
Read / write error on XB file, the application must be reinstalled, contact your local technical support.	XB files loading (opening) error Contact your local HORIBA ABX Technical Support Representative for assistance.
Read / write error on settings file, the application must be reinstalled, contact your local technical support.	The setting file do not exist Contact your local HORIBA ABX Technical Support Representative for assistance.
Read/write error on LJ file, the application must be reinstalled, contact your local technical support.	Files loading (opening) error Contact your local HORIBA ABX Technical Support Representative for assistance.
Critical error, the application must be reinstalled, contact your local technical support.	Internal error Contact your local HORIBA ABX Technical Support Representative for assistance.
Get user list failed (unable to open the file), the application must be reinstalled, contact your local technical support.	Internal read/write error Contact your local HORIBA ABX Technical Support Representative for assistance.
Read error on QC file, the application must be reinstalled, contact your local technical support.	Error on QC list import Contact your local HORIBA ABX Technical Support Representative for assistance.
Internal connection failure, please contact your local technical support.	Internal communication error or Serial port opening error Contact your local HORIBA ABX Technical Support Representative for assistance.

Message	Possible cause/Corrective action
- Tressage	- Check if LIS connection cable is correctly plugged.
	- Restart the instrument.
Send result failed.	- Contact your local HORIBA ABX Technical Support
	Representative for assistance.
	Internal read/write error.
Minor error (key not found in %s).	- Contact your local HORIBA ABX Technical Support
rimor error (key not round in 763).	Representative for assistance.
	Internal read/write error.
Invalid patient type, software internal	- Contact your local HORIBA ABX Technical Support
error.	Representative for assistance.
	Internal read/write error.
Unexpected error (%ld)	- Contact your local HORIBA ABX Technical Support
onexpected error (with)	Representative for assistance.
	Internal read/write error.
Settings file not found	- Contact your local HORIBA ABX Technical Support
Sections the not round	Representative for assistance.
	Setting file is corrupted.
Settings file corrupted	- Contact your local HORIBA ABX Technical Support
Settings file confupted	Representative for assistance.
	Setting file is missing.
Settings file not found : Translations	- Contact your local HORIBA ABX Technical Support
Settings the not found. Transtations	Representative for assistance.
	- Contact your local HORIBA ABX Technical Support
Incompatible EPROM version.	Representative for assistance.
Archive restoration failed	Internal read/write error.
Archive restoration railed	- Contact your local HORIBA ABX Technical Support Representative for assistance.
	USB key removal during reading.
Online help installation failed, check	Missing or corrupted files on USB key:
the help file on your USB key.	- Check the help files on your USB key.
	- Check if LIS connection cable is correctly plugged.
	- Restart the instrument.
LIS connection failed	- Contact your local HORIBA ABX Technical Support
	Representative for assistance.
	Internal read/write error.
	- Restart the instrument.
Error while deleting user.	- Contact your local HORIBA ABX Technical Support
	Representative for assistance.
	Internal read/write error.
Backup of current default reagents	- Restart the instrument.
configuration files failed	- Contact your local HORIBA ABX Technical Support
3	Representative for assistance.
	Internal read/write error.
Tourist and the second of the second	- Restart the instrument.
Invalid reagents import file format	- Contact your local HORIBA ABX Technical Support
	Representative for assistance.
	Internal read/write error.
Compared default was south files fail 1	- Restart the instrument.
Copy of default reagents files failed	- Contact your local HORIBA ABX Technical Support
	Representative for assistance.
	Internal read/write error.
Tourist default	- Restart the instrument.
Invalid default reagents import file	- Contact your local HORIBA ABX Technical Support
	Representative for assistance.

#### **Printer**

Message	Possible cause/Corrective action
Printing calibration report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing LJ report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing log report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing QC report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing QC matrix report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing result report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing settings report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Printing XB report failed.	No report, missing printer, no printer selected, printer initialization error.  - Check if printer is on line. If not, switch it on.  - Check if there is enough paper. If not, See 3.6. Integrated ticket printer paper changing, page 7-16.  - Check printer settings (See Section 6, 4.3. Printer, page 6-7).
Ticket printer comm. port initialisation failed, try to restart the application.	Error on serial port opening: - Restart the instrument.

Message	Possible cause/Corrective action
Ticket printer do not answer (timeout)	<ul><li>Check if ticket printer is online. If not, switch it on.</li><li>Check if there is enough paper.</li><li>Restart the instrument.</li></ul>
Ticket printer initialisation failed.	<ul><li>Check if ticket printer is online. If not, switch it on.</li><li>Check if there is enough paper.</li><li>Restart the instrument.</li></ul>

### Analyser

Message	Possible cause/Corrective action
Analyser connection failed (internal RS232).	Internal communication error: - Contact your local HORIBA ABX Technical Support Representative for assistance.
Analyser com port initialisation failed	Internal communication error: - Contact your local HORIBA ABX Technical Support Representative for assistance.

### QC

Message	Possible cause/Corrective action
Previous invalid QC result automatic deletion.	Invalid QC result is deleted when directly followed by a QC passed result.
QC file write error.	Internal read/write error: - Contact your local HORIBA ABX Technical Support Representative for assistance.
QC control not found	Impossible to found a QC with this ID Check the control lot number.

#### Barcode reader

Message	Possible cause/Corrective action
Bar code reader initialisation failed	Barcode reader initialization failure in the sample identification screens.  Restart the instrument  Contact your local HORIBA ABX Technical Support Representative for assistance.
Cannot configure bar code reader.	Error during the barcode reader serial port opening - Restart the instrument - Contact your local HORIBA ABX Technical Support Representative for assistance.
Cannot connect to bar code reader.	Error during the barcode reader initialization.  - Restart the instrument  - Contact your local HORIBA ABX Technical Support Representative for assistance.
Bar code reader cannot read.	Error during the barcode reader functionning.

### Mechanical and service cycles

Message	Possible cause/Corrective action
Carriage positioning mechanic cycle failed	Error during carriage motion check cycle - Manually check the mechanical movement - Run a startup cycle by pressing the "Startup" button.
Diluter positioning mechanic cycle failed	Error during diluter motion check cycle - Manually check the mechanical movement - Run a startup cycle by pressing the "Startup" button.

Message	Possible cause/Corrective action
Door opening mechanic cycle failed	Error during door opening check cycle - Manually check the mechanical movement - Run a startup cycle by pressing the " <b>Startup</b> " button.
Needle positioning mechanic cycle failed	Error during needle motion check cycle - Manually check the mechanical movement - Run a startup cycle by pressing the " <b>Startup</b> " button.
Tube piercing mechanic cycle failed	Error during tube piercing motion check cycle - Manually check the mechanical movement - Run a startup cycle by pressing the " <b>Startup</b> " button.
Valve positioning mechanic cycle failed	Error during valves check cycle - Restart the instrument.
Waste piston positioning mechanic cycle failed	Error during waste piston motion check cycle - Manually check the mechanical movement - Run a startup cycle by pressing the "Startup" button.
Cleaning service cycle failed	<ul><li>Check cleaner level.</li><li>Restart the instrument.</li><li>Run a startup cycle by pressing the "Startup" button.</li></ul>
Concentrated cleaning service cycle failed	<ul><li>Check cleaner level.</li><li>Restart the instrument.</li><li>Run a startup cycle by pressing the "Startup" button.</li></ul>
Draining service cycle failed	<ul><li>Restart the instrument.</li><li>Run a startup cycle by pressing the "Startup" button.</li></ul>
All reagents prime service cycle failed	<ul> <li>View the chambers for reagent priming.</li> <li>Verify that the reagent is coming in and draining out of the chambers when a cycle is initiated.</li> <li>Verify that there are no air bubbles in the reagent lines when priming.</li> </ul>

## **6.2.3. QC logs**

Message	Possible cause/Corrective action
Cannot open control configuration file, the application must be reinstalled, contact your local technical support.	QC list recovery impossible Contact your local HORIBA ABX Technical Support Representative for assistance.

## 6.2.4. Maintenance logs

Message	Possible cause/Corrective action
Cannot save closed reagent, please contact your local technical support.	Internal read/write error: - Contact your local HORIBA ABX Technical Support Representative for assistance.
Software internal error, please contact your local technical support.	- Contact your local HORIBA ABX Technical Support Representative for assistance.

### 6.2.5. Startup logs

Message	Possible cause/Corrective action
Invalid startup cycle (wbc/rbc/hgb/	Parameters WBC , RBC , HGB & PLT > startup limits
plt)	- Run a startup cycle by pressing the "Startup" button.

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