

ABX Pentra **XL**₈₀

User Manual



P/n: RAB131GEN



HORIBA ABX
B.P. 7290
34184 MONTPELLIER Cedex 4 - FRANCE

HORIBAABX
Diagnostics

This section includes the following:

1. Revisions
2. List of modifications

1. Revisions

Index	Technical note	Software revision	Section	Date
RAB131AA	RAH981AA	V 1.0.0	All	17/06/03
RAB131BA	RAH986AA	V1.0.0 + CE Ivd labelling corrections	All	15/09/03
RAB131C	RAN002	V1.1.0 Software version	See V1.1.0 Software improvements and corrections , page 4	15/03/04
RAB131D	RAN136A	v1.4.0 Software version + Company name change	See V1.4.0 Software improvements and user manual updates , page 5	27/01/05
RAB131EEN	RAN165a	v1.5.0 Software version	See V1.5.0 Software improvements and user manual updates , page 6	08/06/05
RAB131FEN	RAN229A	v1.6.0 Software version	Cancelled	28/08/06
RAB131GEN	RAN229B	v1.6.1 Software version	See v1.6.1 Software improvements and user manual updates , page 7	15/03/07

- ◆ This document applies to the latest higher software version.
- ◆ When a subsequent software version is released, only 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 representative.

▼ Declaration of conformity

Latest version of the CE declaration of conformity for this instrument is available on www.horiba-abx.com

▼ 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.

▼ Trademarks

- ◆ Microsoft and Windows are registered trademarks of Microsoft Corporation
- ◆ Other product names mentioned within this publication may be trademarks or registered trademarks of other companies.

▼ Graphics

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

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

▼ Copyright © 2007 by HORIBA ABX

All rights reserved. No part of this book may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of **HORIBA ABX**.

HORIBA ABX

Parc Euromédecine

Rue du caducée

B.P. 7290

34184 MONTPELLIER Cedex 4 - FRANCE

Tel: (33) (0)4 67 14 15 16

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

2. List of modifications

2.1. V1.1.0 Software improvements and corrections

XB Limits defaults values	Chap 3-19
Worklist printing option: Light mode	Chap 4-21
Button "Expanded" DIFF instead of "Extended"	Chap 4-56
Translation: "History" instead of "Anteriority"	Chap 4-60
Report printing options: Light mode	Chap 4-66
Archive Printing options: Light mode	Chap 4-72
Max CV default values	Chap 5-14
Rerun conditions default settings	Chap 5-18
Defaults settings for Printer Properties	Chap 5-31
Update of the Printer properties	Chap 5-34
Day by day exportation of the deleted files	Chap 5-39
User login while PXL80 software running	Chap 5-41
Defaults settings associated to the V1.1.0 version release	Chap 5-51
Correction of the WBC counting thresholds	Chap 6-17
Instrument Rinse procedure	Chap 7-6
Lyse instead of Alphalyse in the Prime Cycles menu	Chap 7-32

2.2. V1.4.0 Software improvements and user manual updates

CDR mode validation (RAM189)	Chap 2-13
CDR Mode (RAM189)	Chap 4-31
Automatic validation on Plt suspicion (RAM174)	Chap 5-16
CDR mode validated dilution (RAM189)	Chap 5-18
network settings modification (RAM174)	Chap 5-30
Begin of day screen with new logo	Chap 5-39
CDR mode validation (RAM189A)	Chap 8-2

2.3. V1.5.0 Software improvements and user manual updates

input/output labels modification	Chap 1-5
reagent and waste label addition	Chap 1-6
biological risk label warning addition	Chap 1-7
Correction error: "contextual" toolbar instead of "generic"	Chap 1-14
Reagent consumption modification	Chap 2-6
Standardisation Linearity and Error limit	Chap 2-10
Modifying control lot action	Chap 3-10
Automatic printout and deletion of the results after calibration	Chap 3-29
Plt suspicion flags addition	Chap 4-33
Differential suspicion flag addition if HGB>17,5 g/dL	Chap 4-34
LIC and GCI standard values	Chap 4-40
Modification of concentrated cleaning (pour minoclaire into WBC/Baso chamber) ...	Chap 7-35
LMNE lamp error message addition	Chap 7-46
Addition error message on rack movement	Chap 7-47

2.4. v1.6.1 Software improvements and user manual updates

Update of the revision table	Chap 0 - Page 2
Declaration of Conformity is removed	Chap 0 - Page 2
WEEE directive addition	Chap 1 - Page 4
PC connection label update	Chap 1 - Page 8
Correction in the safety requirements standard.....	Chap 1 - Page 9
Installation kit update.....	Chap 1 - Page 11
diluent installation at altitude over 1000 meters	Chap 1 - Page 12
Main menu new design	Chap 1 - Page 14
Internet link to printer Information.....	Chap 1 - Page 26
10L ABX diluent availability.....	Chap 2 - Page 4
Heat output	Chap 2 - Page 5
Reagent consumption modification.....	Chap 2 - Page 6
CD ROM RAX055 instead of reagent leaflets	Chap 2 - Page 15
Known interferences due to chemotherapy	Chap 2 - Page 16
Interferences in the platelet counting (Elevated lipids and bilirubine)	Chap 2 - Page 18
Interferences in the basophil count	Chap 2 - Page 20
Calibration general recommendations.....	Chap 3 - Page 25
Recommendations on the analysis mode selection.....	Chap 4 - Page 26
Addition of transmitted flag according to linearity limits	Chap 4 - Page 31
Message "platelet concentrate mode"	Chap 4 - Page 31
Plt suspicion flags modification	Chap 4 - Page 33
LMNE and WBC suspicion flag modification	Chap 4 - Page 34
Modification on RBC suspicion flag	Chap 4 - Page 34
Recommendations on CBC mode: L1 flag.....	Chap 4 - Page 41
CBC mode limitations (WBC Balance).....	Chap 4 - Page 44
"Platelet aggregate" message conditions	Chap 4 - Page 49
Raw counts printing conditions.....	Chap 4 - Page 67
Raw counts printing conditions.....	Chap 5 - Page 32
Secondary dilution principle modification	Chap 6 - Page 4
Blank cycle and control run after reagent change.....	Chap 7 - Page 9
Sampling probe replacement procedure modified	Chap 7 - Page 17
Secondary dilution principle modification	Chap 7 - Page 40
New Hydraulic diagram	Chap 7 - Page 43
Compatible tube list	Chap 8 - Page 6
"Greiner Minicollect" sample tube homologation.....	Chap 8 - Page 7

ABX Pentra **XL** 80

User manual content

User manual content and revisions

1. Revisions	0-2
2. List of modifications	0-4

Section1: Introduction

1. Warning and precautions	1-2
2. Labels.....	1-5
3. Operational conditions.....	1-9
4. Software overview	1-14
5. Workflow overview	1-22
6. Printer	1-26

Section 2: Specifications

1. Technical specifications	2-2
2. Physical specifications.....	2-5
3. Summary of performance data.....	2-7
4. Reagent specifications	2-15
5. Limitations.....	2-16

Section 3: Quality Assurance and Logs

1. Quality control	3-4
2. Patient Quality Control (XB)	3-14
3. Within run.....	3-21
4. Calibration	3-25
5. Logs.....	3-32

Section 4: Workflow

1. Workflow	4-3
2. Worklist description	4-15
3. Sample collection & mixing.....	4-25
4. Running specimen.....	4-26
5. Run results and associated Flags.....	4-27
6. Report	4-51
7. Archives	4-70
8. Status.....	4-77

Section 5: Settings

1. Menu «Settings» overview	5-3
2. Soft parameters.....	5-5
3. Quality assurance settings	5-12

4. Rules.....	5-15
5. System	5-23
6. Save and restore.....	5-36
7. User profiles.....	5-40
8. Sample Types.....	5-43

Section 6: Description & Technology

1. Pentra XL 80 description	6-2
2. Automatic mode principles	6-7
3. Measuring principles.....	6-11

Section 7: Maintenance & Troubleshooting

1. Maintenance & Troubleshooting procedures	7-3
2. Replacement procedures.....	7-9
3. Instrument panels & cover Removals.....	7-19
4. Service menu description	7-22
5. Troubleshooting.....	7-37
6. Hydraulic diagram	7-43
7. Error messages	7-44

Section 8: Annex

1. CDR mode.....	8-2
2. Reagent Leaflets	8-5
3. Compatible tube list.....	8-6

Section 9: Index & Glossary

1. Glossary.....	9-2
2. Index.....	9-4

Contents

1. Warning and precautions	1-2
1.1. Limited guarantee	1-2
1.2. Safety Precautions	1-3
1.3. graphics and symbols	1-4
2. Labels	1-5
2.1. Input/Output Labels	1-5
2.2. PC connection label	1-8
3. Operational conditions	1-9
3.1. Environment	1-9
3.2. Location	1-9
3.3. Grounding	1-10
3.4. Humidity/Temperature conditions	1-10
3.5. Electromagnetic environment check	1-10
3.6. Environmental protection	1-10
3.7. Transportation and storage conditions	1-11
3.8. Installation	1-11
3.9. Interconnections	1-12
3.10. Racks	1-13
4. Software overview	1-14
4.1. Contextual toolbar description	1-15
4.2. Generic toolbar description	1-16
4.3. Main Menu description	1-17
4.4. Miscellaneous	1-18
5. Workflow overview	1-22
5.1. Order and Worklist overview	1-22
5.2. Runs & Report overview	1-23
6. Printer	1-26

This section provides important information to get you started with Pentra XL 80

- 1. **Warning and precautions**, page 1-2
- 2. **Labels**, page 1-5
- 3. **Operational conditions**, page 1-9
- 4. **Software overview**, page 1-14
- 5. **Workflow overview**, page 1-22
- 6. **Printer**, page 1-26

1. Warning and precautions

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 labeling and **HORIBA ABX** instructions in order to avoid to compromise system integrity.

The Pentra XL 80 responds to the Standards and directives named in the Declaration of Conformity added at the beginning of this manual.



- ◆ 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 place at risk 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.
- ◆ Disposal gloves, eyes protection and lab coat must be worn by the operator. Local or national regulations must be applied in all the operations
- ◆ Portable/mobile telephones should not be used in proximity of the instrument.
- ◆ All peripheral devices should be IEC compatible.

1.1. 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 ABX** is installed on the instrument. This software must be the original copyrighted version.
- 3 - Services and repairs are provided by an **HORIBA ABX** authorized technician, using only **HORIBA ABX** approved spare parts.
- 4 - The electrical supply of the laboratory follows the national 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 (See Section 7: Maintenance & Troubleshooting, **1.2. Maintenance procedures**, page 7-3).



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.

1.2. Safety Precautions

1.2.1. Electronic and moving parts

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

- ◆ electrical Power supply.
- ◆ electronic circuit boards.

Danger of explosion if battery is not replaced correctly!

When replacing the battery, always use the same and/or equivalent type recommended by the manufacturer. Dispose of used batteries according to the manufacturer's specific instructions.

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

1.2.2. 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 bio-safety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent bio-safety procedures.

HORIBA ABX uses disinfectant product for instrument decontamination (including touch screen) and highly recommends it to decontaminate your instrument (refer to Section 7, **1.3. Instrument general cleaning**, page 7-4, to perform the instrument decontamination procedure).

1.3. graphics and symbols



Switch off position



Switch on position



Alternating current



Manufacturer



In Vitro Diagnostic Medical Device



This product conforms to the EEC Standards and Directives named in the Declaration of Conformity.



Caution, consult accompanying documents



Biological risk



Reagent



Up



Fragile, handle with care



Keep dry



Do not stack



Temperature limitation



Batch code



Catalogue number



Use by



Consult Instructions for Use



Calibrator



Control



Content



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

2. Labels

2.1. Input/Output Labels



Fig. 1-1 Rear panel labels

2.1.1. Identification label



Fig. 1-2 Serial number label

2.1.2. Reagent and waste connection labels

- ◆ **Waste output:** Connection used for Waste output tubing (on Waste position).
- ◆ **Waste level detection:** Connection used for Waste level detection (on Waste Alarm position)
- ◆ **Diluent input:** Connection used for Diluent input tubing (on Diluent position).



Fig. 1-3 Reagent and waste label

2.1.3. Biological risk label

(see Fig. 1–3, page 1-6)



Consider all instrument accessible surfaces as potentially contaminated with blood.
Use protective gloves to operate instrument.

2.1.4. Output label

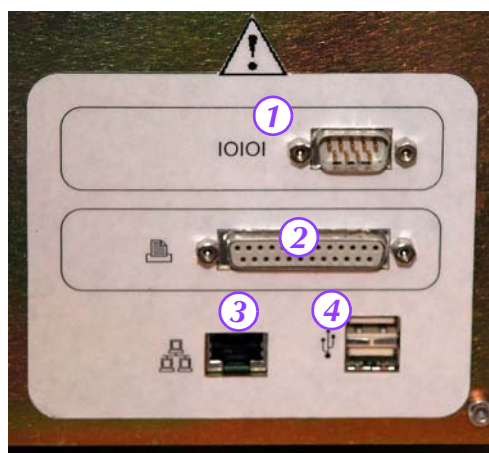


Fig. 1–4 Output Label

- 1- RS 232 output: LIS (Laboratory Information System) connection.
- 2- Printer connection: Do not connect any printer which has not been recommended by an **HORIBA ABX** qualified engineer.
- 3- Ethernet connection: This network output is classified as «Safety extra low voltage SELV»
- 4- USB connection

2.2. PC connection label

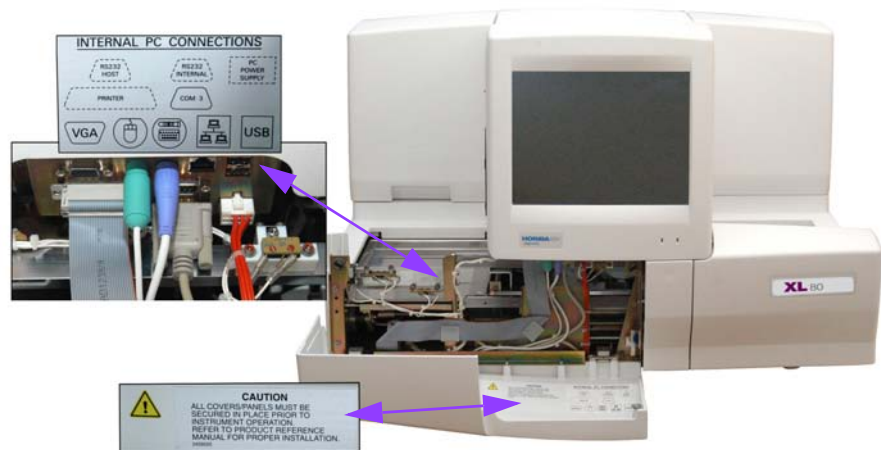


Fig. 1-5 Internal PC connections



Caution label: It is strictly forbidden to remove protection covers during instrument operations.

Refer to **3.9. Interconnections**, page 1-12, for other peripheral connections.

3. Operational conditions

- 3.1. **Environment**, page 1-9
- 3.2. **Location**, page 1-9
- 3.3. **Grounding**, page 1-10
- 3.4. **Humidity/Temperature conditions**, page 1-10
- 3.5. **Electromagnetic environment check**, page 1-10
- 3.6. **Environmental protection**, page 1-10
- 3.7. **Transportation and storage conditions**, page 1-11
- 3.8. **Installation**, page 1-11
- 3.9. **Interconnections**, page 1-12
- 3.10. **Racks**, page 1-13

3.1. Environment

The operation of the Pentra XL 80 should be restricted to indoor location use only! Operation of the instrument at altitudes of over 3000 Meters (9800 feet) is not recommended. The instrument is designed for safety from voltages surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2 (IEC 61010-1).

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

3.2. Location

The Pentra XL 80 should be placed on a clean and leveled table or workbench.

Please note that the Pentra XL 80 and printer weigh approximately 55 kilograms (121 lbs).

Avoid exposure to sunlight.

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 generate 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



Fig. 1-6 Power ON/OFF switch

3.3. 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!

3.4. Humidity/Temperature conditions

The Pentra XL 80 must operate between temperatures of 16 to 34°C (61 to 93°F). Maximum relative humidity should be 80% for temperatures up to 31°C (88°F) and decreasing linearly to 50% relative humidity at 40°C (104°F). If the system is kept at a temperature of 10°C (50°F) or less, it must be allowed to sit at room temperature for 1 hour before it can be used for operation.

3.5. Electromagnetic environment check

- ◆ The Pentra XL 80 has been designed to produce less than the accepted level of electromagnetic interference in order to operate in conformity with its destination, allowing the correct operation of other instruments also in conformity with their destination.
- ◆ In case of suspected electromagnetic noise, 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.)

3.6. Environmental protection

▼ Disposal 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.

▼ Disposal Pentra XL 80 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 **HORIBA ABX** representative service department.

3.7. Transportation and storage conditions

Storage temperature: -20°C +50°C.



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

3.8. Installation

An **HORIBA ABX** representative will install your instrument, software, and printer.

▼ Package contents

Verify that all of the parts from the package list are present:

Part Number	Quantity	Designation
XEA785B	1	Installation kit Pentra XL 80
XBA453B	1	Barcode reader
GBD072A	4	Lifting handles
GBL0280	10	Rack 10 vials 13x82
XBA322B	1	Waste sensor
CBK048A	1	Computer Mouse
GBL0250	1	Keyboard drawer
CBK043A (or CBK045A)	1	Qwerty (or Azerty) keyboard
	1	Printer
7001020	1	Empty waste container + cap
DAC011A (or DAC012A in USA)	1	Power supply cable
HAN524A	1	Mouse pad
RAB156	1	Daily guide
RAX055	1	Reagents, Controls & Calibrators CD ROM
RAX040	1	User manual and Help on screen CD ROM

Tab. 1-1: Package list table

3.9. Interconnections

3.9.1. Electrical & Computer connections

(see [2.2. PC connection label](#), page 1-8)

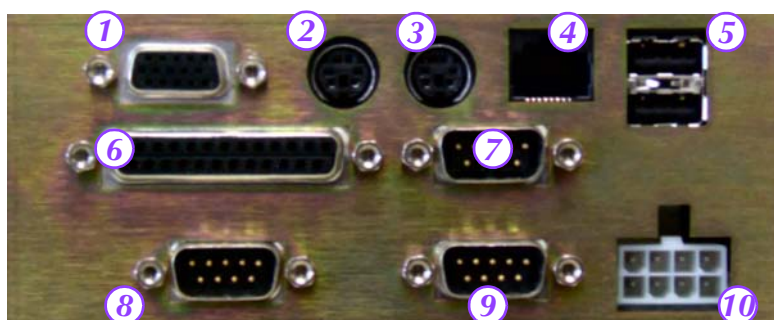


Fig. 1-7 Computer connections

- | | | |
|-------------|-----------------------------------|--------------------------|
| 1. VGA | 5. 2 X USB | 8. COM2: Labo Link |
| 2. Mouse | 6. Printer | 9. COM1: To Mother Board |
| 3. Keyboard | 7. COM3: External Bar Code Reader | 10. Power |
| 4. LAN | | |

3.9.2. Printer connection

(see [2.1.4. Output label](#), page 1-7)

3.9.3. Reagent connections



It is mandatory to install the diluent container at the same level than the instrument (on the bench) when the ABX Pentra XL 80 is operated at altitudes over 1000 Meters (3280 feet).

(See Section 7: Maintenance & Troubleshooting, [2.1.1. Reagent locations and connections](#), page 7-9)

3.10. Racks

The Pentra XL 80 racks are identified on the system by means of Barcode labeling. These labels must be placed on the racks in the following manner:

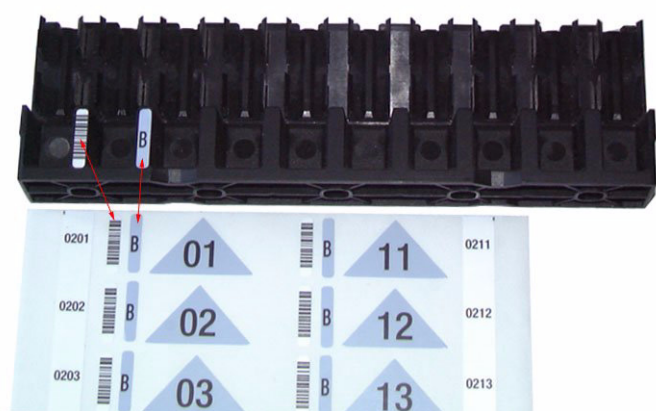


Fig. 1-8 Rack barcode Identification and Rack type (Front side)

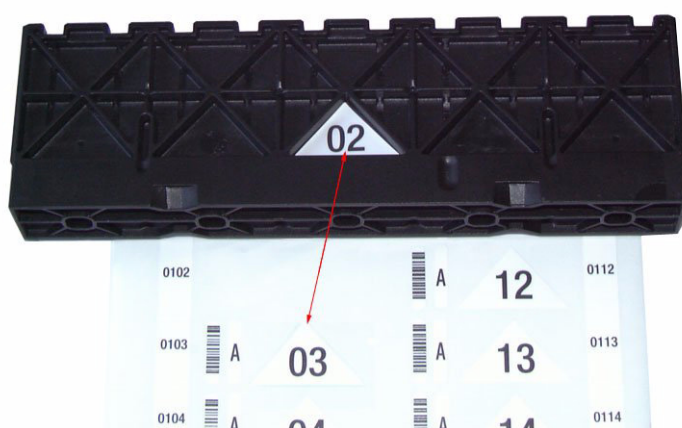


Fig. 1-9 Rack Identification Number (Back side)

4. Software overview

The Pentra XL 80 includes a control station which software, designed by **HORIBA ABX**, is installed on a loading PC with a twelve inch 800 x 600 operated touch screen.

The Main Menu of the system includes two-menu selection bars located on the lower horizontal and right vertical portions of the touch screen,

- 1- The **Contextual toolbar** (see [4.1. Contextual toolbar description](#), page 1-15) is located on the bottom of the screen
- 2- The **Generic toolbar** (see [4.2. Generic toolbar description](#), page 1-16) on the right,
- 3- The Main menu access keys (see [4.3. Main Menu description](#), page 1-17) are featured in the center portion of the touch screen.
- 4- Startup and Shutdown operation keys are also featured in the center portion of the touch screen.



Fig. 1-10 Main Menu



- ◆ A Status Bar is also located at the bottom of the screen which indicates the Date, Time, Software version, Operator Code, and the Cycle Bar Graph (Startup, Shutdown, and Calibration).
- ◆ Either pressing on the screen with a finger or making the selection with the Mouse activates all Toolbar and Menu keys.
- ◆ To modify, edit or review data in screens and tabs refer to [4.4. Miscellaneous](#), page 1-18

4.1. Contextual toolbar description

This toolbar that located at the bottom of the screen, contains the same selections regardless of what initial menu is open.

	Name	Function	Description
	Help	Help	Brings up the help file
	Details	Details	Details/displays supplementary information
	Insert	Insertion	Inserts new data
	Edit	Modification	Edits/Modifies data
	OK	Validation	Validates an action
	Cancel	Cancel	Cancels an action
	Delete	Delete	Deletes data
	Print	Print	Prints data
	Return	Return	Quits the current menu
	Quit	Quit	Quits the ASP02 software

Tab. 1–2: Contextual toolbar Keys

4.2. Generic toolbar description

The Generic toolbar function keys are accessed from the toolbar located on the right side of the screen. These function keys are the most frequently used besides the Main Cycle Launch keys.

	Name	Action	Indicator
	Stop	Stops the analyzer	
	Alarm	Launches «Alarm» menu	Flashes when an alarm is triggered (See Section 7: Maintenance & Troubleshooting, 7. Error messages , page 7-44)
	Worklist	Opens Worklist	Displays the number of orders (See Section 4: Workflow, 2. Worklist description , page 4-15)
	Start Rack	Runs the automatic mode	See Daily Guide: RAB156C
	Stat	Runs the manual mode	See Daily Guide: RAB156C
	Reports	Opens reports menu	Displays the number of reports (See Section 4: Workflow, 6. Report , page 4-51)
	Archives	Opens Archives menu	(See Section 4: Workflow, 7. Archives , page 4-70)

Tab. 1–3: Generic toolbar keys

4.3. Main Menu description

Access to the main functions of the system:

	Name	Action	Indicator
	Startup	Runs the startup cycle	The gauge on the bottom status bar progresses at the same time as the cycle. Flashes when the «Startup» cycle has to be performed.
	Shutdown	Runs the shutdown cycle	The gauge on the bottom status bar progresses at the same time as the cycle.
	Logs	Launch the «Logs» menu	Section 3, 5. Logs , page 3-32
	Quality Assurance	Launches the «Quality Assurance» menu	Section 3, 5. Logs , page 3-32
	Run in Progress	Launches the «Run in Progress» menu	See Daily Guide: RAB156C
	Status	Launches the reagent «Status» menu	See Daily Guide: RAB156C
	Services	Launches the «Services» menu	Section 7, 4. Service menu description , page 7-22
	Settings	Launches the «Settings» menu	Section 5: Settings , page 5-3

Tab. 1–4: Main menu function keys

4.4. Miscellaneous

4.4.1. Software arborescence and Hints

- ◆ keys, Tabs, Function keys can be enabled or disabled according to the instrument or software status:



Enabled



Disabled

- ◆ Menu headings are displayed at the top of the screen when a menu is selected
- ◆ Hints can be displayed by moving and holding the cursor on menus keys (see [Fig. 1-11](#), page 1-18).

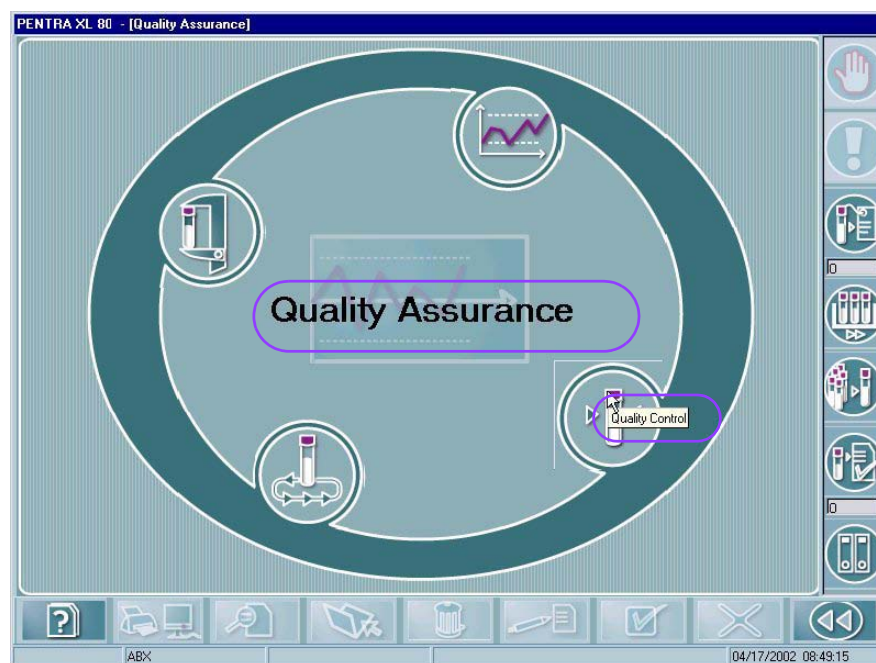


Fig. 1-11 Software arborescence and Hints

4.4.2. Tabs description

Tabs are used to group similar functions that pertain to a specific menu.

Press a Tab or click once with the mouse to access that specific function Menu.

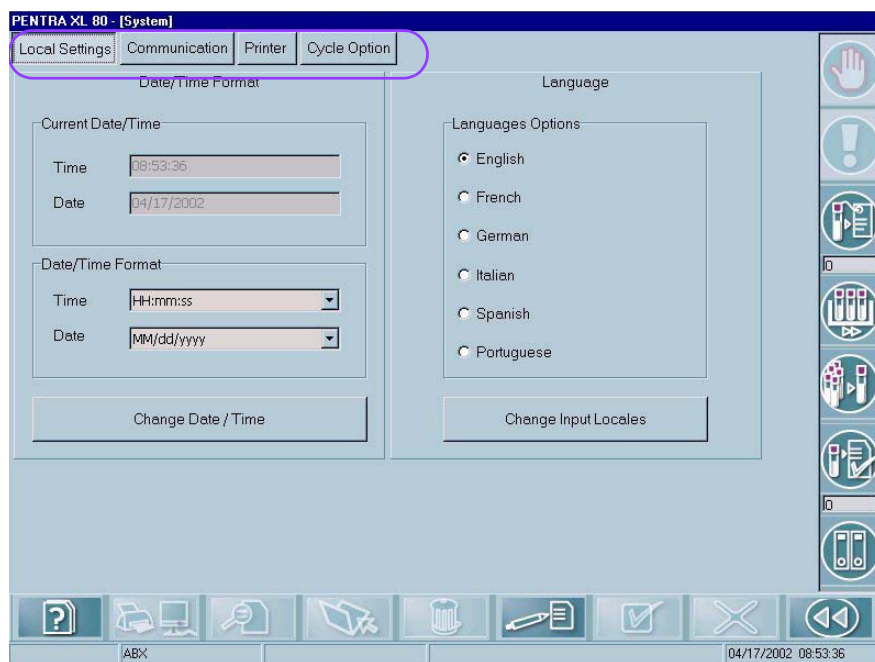


Fig. 1-12 Menu tabs

4.4.3. Scrolling list

These small menus include a list of options, and sometimes include a «Free Field» to enter or edit data within the menu.



The «Edit» key must be selected to access a «Scrolling list».

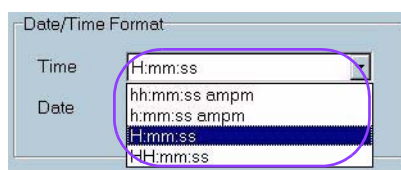


Fig. 1-13 Scrolling list

4.4.4. Checked box

A Checked Box will enable or disable an option in a specific menu. Placing a «Check Mark» within the box will enable the option. Removing a «Check Mark» from the box will disable the option.



The «Edit» key must be selected to modify the «Checked Box».

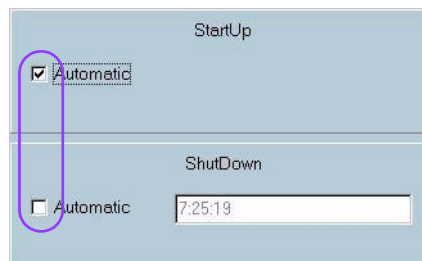


Fig. 1-14 Checked box

4.4.5. Radio button

Selection between options excluding each other

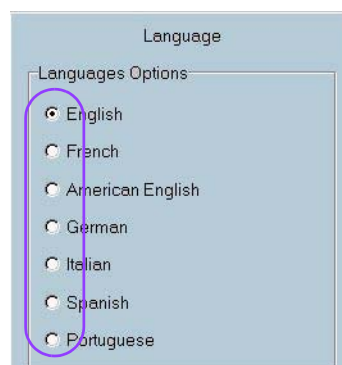


Fig. 1-15 Radio button



The «Edit» key must be selected to modify the «Radio button».

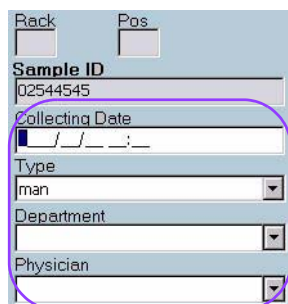
4.4.6. Data Fields

These fields are rectangular areas within a specific menu that are used to display, input, or edit specific information within each field. For example Name, Date, Time, etc....

Some fields have predefined formats: Date, Number, Text, etc....

These data fields may be modified when they appear in «WHITE».

Use the «Tab» key to move the cursor from one field to the next



Rack Pos

Sample ID

Collecting Date

Type

Department

Physician

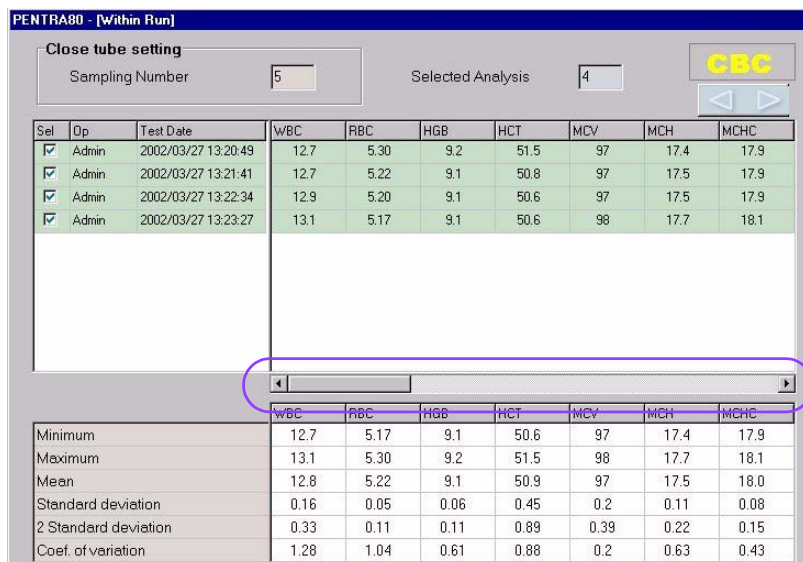
Fig. 1–16 data Fields



The «Edit» key must be selected to modify a «data field».

4.4.7. Sliders

When data can not be displayed within the same window, a horizontal or vertical slider will appear. Drag it or click the arrows to move through all the data.



PENTRA80 - [Within Run]

Close tube setting 5 Selected Analysis 4 **CBC**

Sel	Op	Test Date	WBC	RBC	HGB	HCT	MCV	MCH	MCHC
☒	Admin	2002/03/27 13:20:49	12.7	5.30	9.2	51.5	97	17.4	17.9
☒	Admin	2002/03/27 13:21:41	12.7	5.22	9.1	50.8	97	17.5	17.9
☒	Admin	2002/03/27 13:22:34	12.9	5.20	9.1	50.6	97	17.5	17.9
☒	Admin	2002/03/27 13:23:27	13.1	5.17	9.1	50.6	98	17.7	18.1

Minimum

WBC	RBC	HGB	HCT	MCV	MCH	MCHC
12.7	5.17	9.1	50.6	97	17.4	17.9

Maximum

WBC	RBC	HGB	HCT	MCV	MCH	MCHC
13.1	5.30	9.2	51.5	98	17.7	18.1

Mean

WBC	RBC	HGB	HCT	MCV	MCH	MCHC
12.8	5.22	9.1	50.9	97	17.5	18.0

Standard deviation

WBC	RBC	HGB	HCT	MCV	MCH	MCHC
0.16	0.05	0.06	0.45	0.2	0.11	0.08

2 Standard deviation

WBC	RBC	HGB	HCT	MCV	MCH	MCHC
0.33	0.11	0.11	0.89	0.39	0.22	0.15

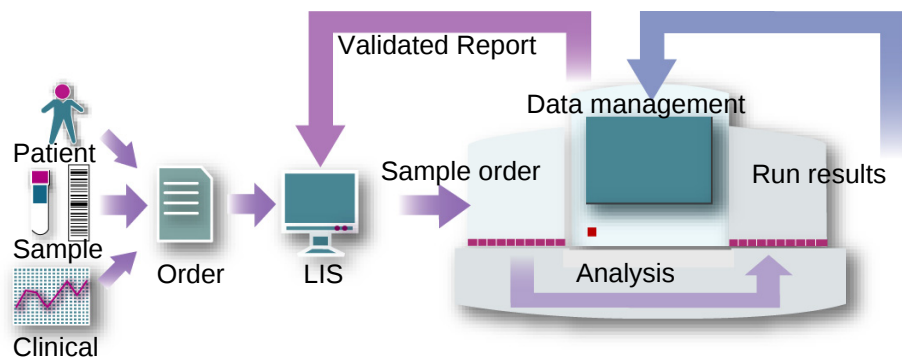
Coef. of variation

WBC	RBC	HGB	HCT	MCV	MCH	MCHC
1.28	1.04	0.61	0.88	0.2	0.63	0.43

Fig. 1–17 Sliders

5. Workflow overview

Pentra XL 80 introduces the «Biotechnical validation» which purpose is to provide one unique Report for each analysis request (Order, see [5.1. Order and Worklist overview](#), page 1-22), even when Rerun of the sample has been performed.



5.1. Order and Worklist overview

An order is the set of data, which is used for requesting an analytical process. The order includes 3 data areas of intervention as followed:

▼ The patient information:

- ◆ Patient ID
- ◆ Patient name
- ◆ Birthdate
- ◆ Sex

▼ The sample information:

- ◆ Sample Id (barcode or other)
- ◆ Sample type (Child, Male, female..)
- ◆ Sample test (Complete Blood Count or Differential)

▼ The clinical information:

- ◆ Sample collection date
- ◆ Department requesting the Order
- ◆ Physician requesting the Order

Orders can be received from the LIS or manually entered by the operator in the Pentra XL 80.

The Worklist is the list of **orders** generated on a daily basis (See Section 4: Workflow, [2. Worklist description](#), page 4-15). **Orders** are removed from the Worklist after Report validation.

5.2. Runs & Report overview

5.2.1. Runs

Analytical processes and obtained results are defined as «Runs». Runs are constituted of 4 hematological parameter groups: RBC, PLT, WBC, Differential.

5.2.2. Reports

Sample «Reports» are determined from runs, automatic reruns and manual entries required for an order.

Here following the Pentra XL 80 report production schemes:

▼ One report for each run

Each run is automatically or manually validated because all parameters are within operator defined criteria. The report includes the copy of the Run results.

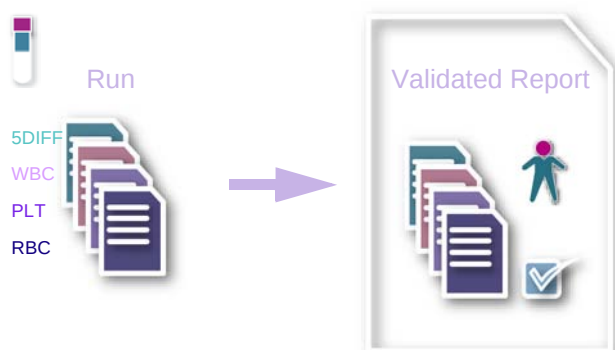


Fig. 1–18 One report for each run

▼ One report = Run or Rerun

An automatic Rerun has been performed. The operator validates either Run or Rerun. This validation can also be automatic. The report includes either Run or Rerun results.

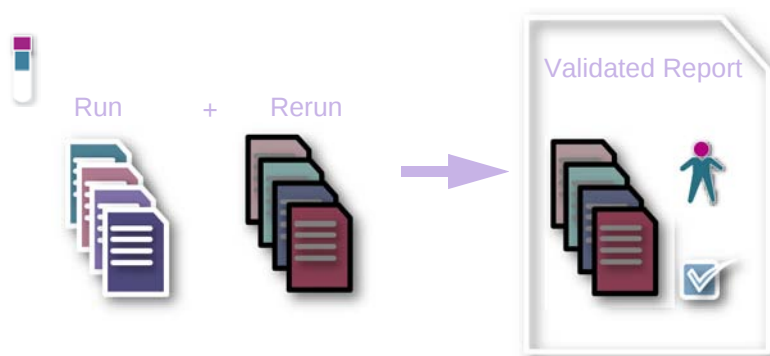


Fig. 1–19 One report = Run or Rerun

▼ One report = Run + Manual entry

On request, the report can be determined by modifying run results (microscopic examination): the operator performs a «Manual entry».

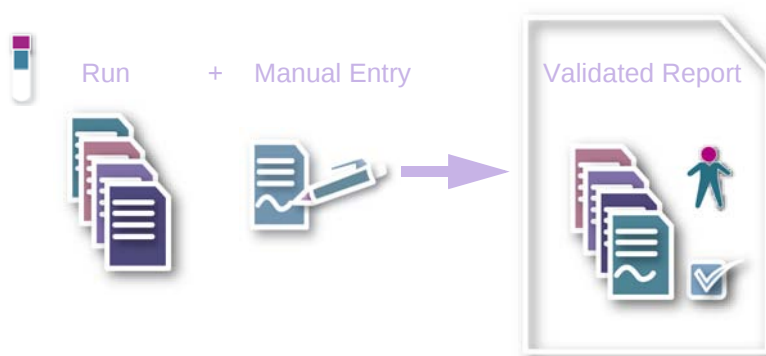


Fig. 1-20 One report = Run + Manual entry

▼ One report = Run + Rerun

Report can be created from the selection of different groups of parameters (RBC, PLT, WBC, differential), issued of several run results of the same sample.

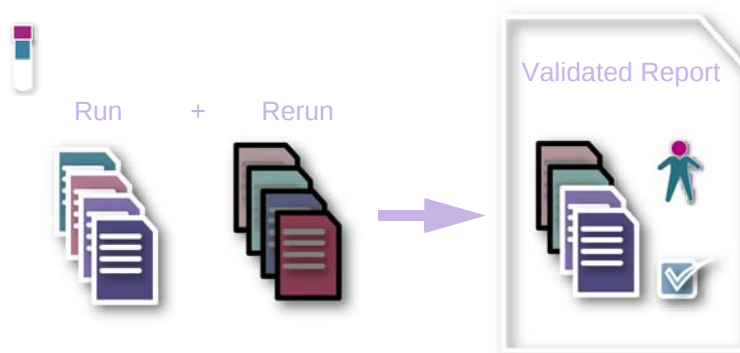


Fig. 1-21 One report = Run + Rerun

▼ One report = Run + Rerun + Manual entry

In that case the report has been created from the selection of different groups of parameters (RBC, PLT, WBC, differential), issued of several run results of the same sample. A «manual entry» has also been done for at least one of the parameter group.

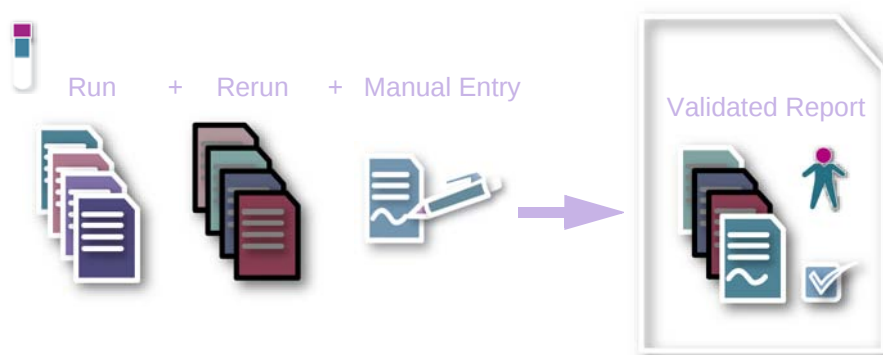


Fig. 1–22 One report = Run + Rerun + Manual entry

▼ Unconditional validation

All the runs are automatically validated. Several reports can be produced for the same order.

6. Printer

Use the printer supplied or approved by **HORIBA ABX**



Latest printer information as well as consumable part numbers are available on www.horiba-abx.com/documentation.

Contents

1. Technical specifications	2-2
1.1. Intended Used	2-2
1.2. Parameters	2-2
1.3. Throughput Analyses	2-3
1.4. Tube identification	2-4
1.5. Reagents	2-4
1.6. Internal Computer	2-4
1.7. Methods and technologies	2-4
2. Physical specifications	2-5
2.1. Power requirements	2-5
2.2. Operating temperature and humidity	2-5
2.3. Dimension and weight	2-5
2.4. Minimum specimen volume	2-5
2.5. dilution ratios	2-5
2.6. HGB measurement	2-5
2.7. Counting aperture diameters	2-6
2.8. Reagent consumption (ml)	2-6
2.9. Compatible tube list	2-6
3. Summary of performance data	2-7
3.1. Precision (Reproducibility)*	2-7
3.2. Precision (Repeatability)*	2-8
3.3. Linearity	2-9
3.4. Carryover*	2-10
3.5. Normal Ranges	2-11
3.6. Accuracy*	2-11
3.7. Leukocyte differential count*	2-12
3.8. Sample stability study*	2-12
3.9. CDR Mode specifications	2-13
4. Reagent specifications	2-15
5. Limitations	2-16
5.1. Maintenance	2-16
5.2. Blood specimens	2-16
5.3. Known interfering substances	2-16

Pentra XL 80 specifications includes the following:

1. **Technical specifications**, page 2-2
2. **Physical specifications**, page 2-5
3. **Summary of performance data**, page 2-7
4. **Reagent specifications**, page 2-15
5. **Limitations**, page 2-16

1. Technical specifications

1.1. Intended Used

Pentra XL 80 system is a fully automated hematology analyzer used for the in vitro diagnostic testing of whole blood specimens.

1.2. Parameters

WBC	White Blood Cell
RBC	Red Blood Cell
HGB	Hemoglobin Concentration
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Distribution Width
PLT	Platelets
PDW	Platelets Distribution Width
MPV	Mean Platelet Volume
PCT	Plateletcrit

Tab. 2-1: CBC Parameters



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

WBC	White Blood Cell
LYM	Lymphocytes % and #
MON	Monocytes % and #
NEU	Neutrophils % and #
EOS	Eosinophils % and #
BAS	Basophils % and #
LIC	Large Immature Cell % and #
ALY	Atypical Lymphocytes % and #
RBC	Red Blood Cell
HGB	Hemoglobin Concentration
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Distribution Width
PLT	Platelets
PDW	Platelets Distribution Width
MPV	Mean Platelet Volume
PCT	Plateletcrit

Tab. 2–2: DIFF parameters



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

1.3. Throughput Analyses

- ◆ 80 samples per hour.

1.4. Tube identification

- ◆ By means of Keyboard, internal and external Barcode.

1.5. Reagents

- ◆ **ABX Diluent** (20 or 10 Litres).
- ◆ **ABX Cleaner** (1 Litre, Integrated).
- ◆ **ABX Eosinofix** (1 Litre, Integrated).
- ◆ **ABX Basolyse II** (1 Litre, Integrated).
- ◆ **ABX Alphalyse** or **ABX Lysebio** (0.4 Litre, Integrated).

1.6. Internal Computer

- ◆ Capacity: 10 000 results + graphics
- ◆ Color LCD touch screen: 12 inches.
- ◆ Industrial PC board Windows XP[™].
- ◆ Processor frequency Celeron 566 MHz.
- ◆ RAM 256 Mb.
- ◆ Hard drive 10 Gb mini.
- ◆ Floppy disk.
- ◆ CD ROM drive.
- ◆ RS 232C, Ethernet, USB.
- ◆ Keyboard.
- ◆ Mouse.

1.7. Methods and technologies

- ◆ Multi Distribution Sampling System: «MDSS»
- ◆ Customised Dilution Ratio: «CDR»

▼ Measurements and computations

- ◆ Impedance for WBC, PLT, RBC, BAS.
- ◆ Photometry for HGB.
- ◆ Impedance and light scattering for LYM, MON, NEU, EOS, ALY and LIC.
- ◆ Computation from stored data that was directly measured for HCT, MCV, MCH, MCHC, RDW, MPV, PCT and PDW.

2. Physical specifications

2.1. Power requirements

- ◆ Power supply.....from 100 Vac to 240 Vac +/- 10%
..... 50 Hz to 60 Hz.
- ◆ Power consumption Maximum 230 VA.
- ◆ Heat output..... Max 670 Kjoules/h (635 BTU/h)
- ◆ Printer Depends on printer model
.....(See printer's manual).

2.2. Operating temperature and humidity

- ◆ 16 - 34°C (61-93°F) room temperature.
- ◆ Maximum relative humidity 80% for temperature up to 31°C (88°F) decreasing linearly to 50% relative humidity at 40°C (104°F).

2.3. Dimension and weight

- ◆ Dimensions82 x 57 x 54 cm.
.....32.3 x 22.4 x 21.5 in.
- ◆ Weight55 Kg.
.....122 lbs.

2.4. Minimum specimen volume

- ◆ CBC Mode (**CBC**)..... 30µL.
- ◆ CBC + 5DIFF Mode (**DIFF**) 53µL.

2.5. dilution ratios

- ◆ WBC/BAS..... 1/200.
- ◆ LMNE 1/80.
- ◆ RBC/PLT 1/10000.
- ◆ HGB..... 1/250.

2.6. HGB measurement

- ◆ HGB chamber, LED 555 nm.
- ◆ Modified Drabkin method (cyanmethemoglobin).
- ◆ Light source..... Electroluminescent diode.
- ◆ Wavelength..... 550nm +/- 10nm.

2.7. Counting aperture diameters

- ◆ WBC/BAS 80µm.
- ◆ LMNE..... 60µm.
- ◆ RBC/PLT 50µm.

2.8. Reagent consumption (ml)

Cycles	Estimated duration	Diluent (ml)	Eosinofix (ml)	Basolyse II (ml)	Cleaner (ml)	Lyse (ml)
CBC/DIFF	0'45"	27.6	1.0	2.1	1.1	0.41
CBC	0'45"	27.6	-	2.0	1.1	0.41
Prime Diluent	3'00"	47.6	-	-	-	-
Prime Eosinofix	1'34"	1.6	23.7	-	-	-
Prime Basolyse 2	1'25"	1.7	-	23.7	1.0	-
Prime Cleaner	1'24"	1.7	-	-	24.7	-
Prime Lyse	1'31"	2.7	-	-	-	8.4
Prime all	7'13"	47.6	24.0	24.0	25.0	8.4
Startup (1 blank cycle)	3'35"	61	2.0	5.1	2.1	1.0
Shut Down	4'00"	33.5	1.0	1.0	19.1	0.5
Rinse Cytometer	1'30"	5.0	-	-	-	-
Autoclean	1'33"	28.2	1.0	1.0	1.0	0.5
Miniclean	0'38"	10.9	1.0	2.0	1.0	0.33
Concentrated cleaning	7'12"	39.1	1.0	1.0	1.0	0.5
Backflush	0'35"	-	-			

Tab. 2-3: Reagent consumption (software version v1.6.1)



STARTUP cycle estimated duration and consumptions are given for one blank cycle control. It could be a maximum of three cycles.

2.9. Compatible tube list

See Section 8: Annex, **3. Compatible tube list**, page 8-6

3. Summary of performance data

3.1. Precision (Reproducibility)*

The Pentra XL 80 was initially calibrated with ABX MINOCAL (lot Number: MCAL321).

Three levels of PENTRA 5D Hematology Control (ABX Diffrol) material (Lot No: PX52) 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 Total Imprecision in accordance with the NCCLS EP 5-A Guidelines.

Parameter	Pentra 5D Hematology control	Within Run SD	SD of run Means	SD of Daily Means	Total Imprecision (SD)
WBC	PX052 High	0.67	0.53	0.53	0.81
	PX052 Normal	0.11	0.1	0.12	0.16
	PX052 Low	0.06	0.04	0.04	0.07
RBC	PX052 High	0.06	0.04	0.05	0.07
	PX052 Normal	0.06	0.04	0.04	0.06
	PX052 Low	0.03	0.02	0.03	0.04
HGB	PX052 High	0.12	0.07	0.09	0.13
	PX052 Normal	0.08	8	0.07	0.11
	PX052 Low	0.05	0.05	0.04	0.06
HCT	PX052 High	0.76	0.61	0.65	0.95
	PX052 Normal	0.62	0.62	0.62	0.88
	PX052 Low	0.28	0.34	0.37	0.48
PLT	PX052 High	16.29	8.32	10.6	16.72
	PX052 Normal	9.01	5.2	8.64	11.35
	PX052 Low	3.61	3.87	4.69	6
Neutro%	PX052 High	1.73	1.2	1.34	2
	PX052 Normal	0.76	0.53	0.41	0.77
	PX052 Low	0.97	0.8	0.72	1.14
Lympho%	PX052 High	1.79	1.27	1.54	2.19
	PX052 Normal	0.86	0.67	0.55	0.94
	PX052 Low	1.24	0.72	0.78	1.28
Mono%	PX052 High	0.32	0.25	0.14	0.32
	PX052 Normal	0.18	0.09	0.12	0.18
	PX052 Low	0.21	0.13	0.08	0.19
Eosino%	PX052 High	0.24	0.14	0.17	0.26
	PX052 Normal	0.32	0.29	0.21	0.37
	PX052 Low	1.05	0.83	0.48	1.06
Baso%	PX052 High	0.1	0.08	0.09	0.13
	PX052 Normal	0.05	0.05	0.03	0.06
	PX052 Low	0.1	0.07	0.07	0.11

Tab. 2–4: Reproducibility (Standard deviation)

Parameters	PENTRA 5D Hematology Control	Within Run CV%	CV% of run Means	CV% of Daily Means	Total Imprecision (CV%)
WBC	PX052 High	4.04	3.16	3.18	4.83
	PX052 Normal	1.54	1.44	1.61	2.19
	PX052 Low	2.52	1.64	1.78	2.78
RBC	PX052 High	1.27	0.79	1.02	1.47
	PX052 Normal	1.2	0.93	0.87	1.38
	PX052 Low	1.38	0.88	1.16	1.64
HGB	PX052 High	0.76	0.42	0.56	0.83
	PX052 Normal	0.59	0.57	0.55	0.8
	PX052 Low	0.81	0.73	0.61	0.99
HCT	PX052 High	1.67	1.35	1.44	2.09
	PX052 Normal	1.58	1.57	1.58	2.23
	PX052 Low	1.54	1.83	2.02	2.63
PLT	PX052 High	3.29	1.68	2.14	3.38
	PX052 Normal	3.34	1.93	3.2	4.2
	PX052 Low	4.94	5.3	6.42	8.22
Neutro%	PX052 High	3	2.07	2.32	3.47
	PX052 Normal	1.06	0.74	0.57	1.08
	PX052 Low	1.58	1.31	1.17	1.86
Lympho%	PX052 High	4.96	3.51	4.27	6.05
	PX052 Normal	3.67	2.87	2.35	4.05
	PX052 Low	4.52	2.61	2.83	4.65
Mono%	PX052 High	7.95	6.28	3.52	7.98
	PX052 Normal	7.34	3.95	4.92	7.67
	PX052 Low	13.82	8.88	5.25	12.75
Eosino%	PX052 High	11.38	6.51	8.13	12.33
	PX052 Normal	10.65	9.65	7.1	12.4
	PX052 Low	10.73	8.51	4.86	10.84
Baso%	PX052 High	3.27	2.54	3.03	4.21
	PX052 Normal	1.32	1.21	0.89	1.55
	PX052 Low	3.29	2.18	2.34	3.64

Tab. 2-5: Reproducibility (CV%)

Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline, NCCLS document EP5-A (ISBN 1-56238-145-8) 1999.

*source 510K submission #K024002

3.2. Precision (Repeatability)*

Three normal blood are tested 10 times running, one in CBC mode, one in diff mode and one in open tube

The average, the variation ratio, together with the standard deviation of the measure, for each sample, will be calculated.

Parameters	Manual CV (%) (Open tube)	Rack CBC CV (%)	Rack Diff CV (%)
WBC	1,24	1,16	1,22
RBC	0,51	0,86	1,00
HGB	0,34	0,38	0,54
HCT	0,53	0,78	1,03
PLT	1,51	2,25	1,66
LYM	2,20	---	2,27
MONO	4,69	---	6,18
NEU	1,37	---	0,77
EOS	6,28	---	9,41
BASO	11,11	---	16,62

Tab. 2-6: Repeatability table N=10

▼ Precision claims

Parameters	%CV	Range
WBC	< 2.0%	4 – 10 x 10 ³ /μL
RBC	< 2.0%	3.6 – 6.2 x 10 ⁶ /μL
HGB	< 1.0%	12 – 18 g/dl
HCT	< 2.0%	36 – 54 %
PLT	< 5.0%	150 – 500 x 10 ³ /μL

Tab. 2-7: Precision claims

*source 510K submission #K024002

3.3. 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 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:

Parameters	Linearity Range	Linearity Limits*	Visible Range*	Error Limit (which ever is greater)	
WBC (10 ³ /mm ³)	0.45 - 124	0 - 120	120 - 150	± 0.3	± 7,5%
RBC (10 ⁶ /mm ³)	0.22 - 8.9	0 - 8.0	8.0 - 18.0	± 0.07	± 3 %
HGB (g/dl)	1.3 - 26	0 - 24	24 - 30	± 0.3	± 3%
HCT (%)	1.9 - 72	0 - 67	67 - 80	± 2.0	± 3%
PLT (10 ³ /mm ³) for HGB>2 g/dL	7 - 2087	0 - 1900	1900 - 2800	± 10	± 12,5%
PLT (10 ³ /mm ³) for HGB<2 g/dL, PLT>15X10 ³ /mm ³	5 - 2792	0 - 2800	2800 - 3200	± 10	± 12,5%

Tab. 2–8: Linearity

*source 510K submission #K024002

3.4. Carryover*

Carry-over effects were evaluated by assaying a sample with high cell concentrations three consecutive times (i1-3), followed immediately by testing a diluted sample consecutively 3 times (j1-3).

Carry-over % is then:

$$\text{Carryover} = \frac{j1 - j3}{i3 - j3} \times 100$$

The overall results gave the following :

	WBC	RBC	HGB	PLT
Mean low levels	0,78	1,047	4,09	28,67
Mean high levels	43,64	8,56	25,94	739,00
Carry over %	-0,070%	-0,268%	0,046%	0,286%

Tab. 2–9: Carry over table

This is the method as described in *Guidelines for the Evaluation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications*. ISLH, 14 January, 1994.

▼ Carry-over Claims

	WBC	RBC	HGB	PLT
Claims	< 2,0%	< 2,0%	< 2,0%	< 2,0%

Tab. 2–10: Carry over claims

*source 510K submission #K024002

3.5. Normal Ranges

Parameters	Male	Female
WBC ($10^3/\text{mm}^3$)	4 - 10	4 - 10
RBC ($10^6/\text{mm}^3$)	4.50 - 6.50	3.80 - 5.80
HGB (g/dl)	13.0 - 17.0	11.5 - 16.0
HCT (%)	40.0 - 54.0	37.0 - 47.0
MCV (μm^3)	80 - 100	80 - 100
MCH (pg)	27.0 - 32.0	27.0 - 32.0
MCHC (g/dl)	32.0 - 36.0	32.0 - 36.0
RDW (%)	11.0 - 16.0	11.0 - 16.0
PLT ($10^3/\text{mm}^3$)	150 - 500	150 - 500
MPV (μm^3)	6 - 11	6 - 11
PCT (%)	0.15 - 0.50	0.15 - 0.50
PDW (%)	11 - 18	11 - 18
NEU (%)	50 - 80	50 - 80
LYM (%)	25 - 50	25 - 50
MON (%)	2 - 10	2 - 10
EOS (%)	0 - 5	0 - 5
BAS (%)	0 - 2	0 - 2

Tab. 2-11: Normal ranges table¹



Important: 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!

3.6. Accuracy*

The Accuracy performance was proven by comparing the Pentra XL 80 with a recognised comparison instrument using 200 patient whole blood specimens, operating within the instrument normal functioning range:

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

Parameter	R ² (Comparison of means)	Accuracy Claims
WBC	0,99	>0,95
PLT	0,99	>0,95
RBC	0,95	>0,95
HGB	0,99	>0,95
HCT	0,96	>0,95
Lympho	0,94	-
Neutro	0,97	-
Mono	0,81	-
Eosino	0,96	-
Baso	0,4	-

Tab. 2-12: Accuracy table

*source 510K submission #K024002

3.7. Leukocyte differential count*

Data from 200 samples for Leukocyte Differentiation was collected in accordance with the recommended NCCLS guidance documents:

	Lympho %	Neutro %	Mono %	Eosino %
AGREEMENT (%)	92,5	85,5	74	97
FALSE POSITIVE RATIO (%)	2,3	2,2	20,6	1,6
FALSE NEGATIVE RATIO (%)	44	41,9	47,5	33,3

Tab. 2-13: Leukocyte differentiation table

Laboratory Standards (NCCLS) documents: Reference Leukocyte *Differential (Proportional) and Evaluation of Instrumental Methods, Approved Standard*, NCCLS document H20-A (ISBN 1-56238-131-8), 1992.

*source 510K submission #K024002

3.8. Sample stability study*

In accordance with the ICSH guidance, 10 samples were collected from the routine laboratory workload (5 normal samples and 5 abnormal samples). The samples were divided into 2 aliquots, one of which was stored at room temperature, and one at 4 degrees centigrade. Sample stability was assessed over a 72 hour period.

The following results were obtained :

	Room Temperature				4 °Celsius			
	0 hrs	24 hrs	48 hrs	72 hrs	0 hrs	24 hrs	48 hrs	72 hrs
% Deviation WBC #	0	1,44	1,85	7,19	0	0,41	0,1	9,87
% Deviation RBC #	0	1,42	1,4	3,06	0	0,55	0,7	6,41
% Deviation HGB	0	1,42	0,71	3,3	0	0,87	0,69	2,83
% Deviation HCT	0	0,93	0,53	0,03	0	0,42	0,37	1,11
% Deviation PLT #	0	5,73	5,81	4,95	0	8,87	11,58	12,23
% Deviation Lympho %	0	9,49	22,36	29,95	0	8,61	0,15	19,53
% Deviation Neutro %	0	4,38	6,79	6,10	0	1,18	9,85	23,78
% Deviation Mono %	0	1,71	18,75	39,52	0	10,28	25,40	19,86
% Deviation Eosino %	0	5,38	12,11	24,22	0	22,83	11,66	8,52
% Deviation Baso %	0	6,52	0,00	18,48	0	9,78	7,61	210,87

Tab. 2–14: Sample stability study

Guidelines for the evaluation of blood cell analysers including those used for differential leukocyte and reticulocyte counting and cell marker applications International Council for Standardization in Hematology; Clin. Lab. Haemat.1994, 16, 157-174

▼ Sample Stability Conclusion

The results conclude with a relative sample stability claim of 48 hour period at 4°C and at room temperature.

*source 510K submission #K024002

3.9. CDR Mode specifications

The CDR mode technique of dilution has been specifically validated through tests using commercially available «Full range» Linearity test kits. The test kits were analyzed and data computed according to the manufacturer instruction. Each kit includes 6 levels and 1 level was used as the reference value. Each level was analyzed 4 times.

Dilution Ratio Visible Range: This range is a range that is beyond the Dilution Ratio Value of the instrument. These ranges are indications.

Parameters values within will have a "D" flag associated with the value.

Parameters	Validated Dilution Ratio	Dilution Ratio Value*	Dilution Ratio Visible Range	Error Limit (which ever is greater)	
WBC ($10^3/\text{mm}^3$)	1/3	120 - 360	360 - 550	± 0.3	$\pm 15\%$
RBC ($10^6/\text{mm}^3$)	1/2	0 - 8.0	8.0 - 18.0	± 0.07	$\pm 3\%$
HGB (g/dl)	1/2	0 - 24	24 - 30	± 0.3	$\pm 3\%$
HCT (%)	1/2	0 - 67	67 - 80	± 2	$\pm 3\%$
PLT ($10^3/\text{mm}^3$) for HGB > 2 g/dl	1/2	1 900 - 3 800	3 800 - 5 500	± 10	$\pm 25\%$
PLT ($10^3/\text{mm}^3$) for HGB < 2 g/dl, PLT > $15 \times 10^3/\text{mm}^3$	1/2	2 800 - 5 600	5 600 - 7 500	± 10	$\pm 25\%$

Tab. 2-15: Results Obtained on CDR mode with validated dilution ratio

* to be validated according to local Good Laboratory Practices requirements.

(See Section 8: Annex, **1. CDR mode**, page 8-2)

4. Reagent specifications



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.

The CD ROM RAX055 delivered with your instrument provides Reagents, Controls and Calibrators leaflets/msds.

Latest versions of these documents are available on «www.horiba-abx.com/documentation»

▼ Waste handling precautions



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

If required, waste can be neutralized before being discarded. Follow your laboratory's protocol when neutralizing and disposing of waste.

Dispose of the waste container according to the local or national regulatory requirements

5. Limitations



While every effort is taken by HORIBA ABX to investigate and indicate all known interference's, it is by no means possible to guarantee that all interference's 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.

5.1. Maintenance

In Section 7: Maintenance & Troubleshooting, **1. Maintenance & Troubleshooting procedures**, page 7-3, specific maintenance procedures are listed. The maintenance procedures identified are mandatory for proper use and operation of the Pentra XL 80.



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

5.2. Blood specimens

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

5.3. Known interfering substances

WBC:

- ◆ **White Blood Cells (Leukocytes):** WBC results that exceed the linearity limits of the system will require dilution of the blood sample (Leukemia sample followed by a leukopenia). Re-assaying the diluted sample will help to obtain the correct assay value.
- ◆ **Unlysed Red Cells** - In some rare instances, the erythrocytes in the blood sample may not be completely lysed. These non-lysed red blood cells may be detected on the WBC histogram with an L1 alarm or as an elevated baseline on the side (leading edge) of the lymphocytes population. Non-lysed erythrocytes will cause a falsely elevated WBC count.
- ◆ **Multiple myeloma** - The precipitation of proteins in multiple myeloma patients may give high WBC counts.
- ◆ **Leukemia** - A very low WBC count may result from this disease because of possible increased fragility of the leukocytes leading to destruction of some of these cells during counting. These white cell fragments will also interfere with the white cell differential parameters. 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** - Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocyte membranes which may cause low WBC counts. In these particular cases, CBC mode must not be used as WBC balance alarm (see Section 4: Workflow, **5.3.9. WBC balance**, page 4-44) is disabled. It is recommended to run these samples in DIFF mode.

- ◆ **Cryoglobulins** - Increased levels of cryoglobulin that may be associated with myeloma, carcinoma, leukemia, macroglobulinemia, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, aneurism, pregnancy, thromboembolic phenomena, diabetes, etc, which can increase the WBC, RBC or PLT counts and the HGB concentration. The specimen must be warmed up to 37°C (99°F) in a bain marie for 30 minutes and analyzed again immediately after (analyzer or manual method).
- ◆ **Macrothrombocytes** - in excessive numbers may affect and increase Leukocyte numeration.

RBC:

- ◆ **Red Blood Cells (Erythrocytes)**: The red blood cell dilution contains all the formed elements in the blood: erythrocytes, leukocytes and platelets. During erythrocytes counting (red blood cells), platelets are not counted as their size falls below the minimum threshold.
- ◆ **Agglutinated erythrocytes** - May cause a low incorrect RBC count. Blood samples containing the agglutinated red blood cells may be suspected by elevated MCH and MCHC values and shown by examination of the stained blood film.
- ◆ **Cold agglutinins** - IgM immunoglobulins which are high in cold agglutinin disease may cause lower RBC and PLT counts and increase MCV.

HGB (Hemoglobin):

- ◆ **Turbidity of the blood sample** - Any number of physiological and/or therapeutic factors may produce high incorrect HGB results. To obtain accurate hemoglobin results when increased turbidity of the blood sample occurs, determine the cause of the turbidity and follow the appropriate method below:
- ◆ **High WBC**: An extremely high WBC will cause excessive light scatter. In these cases use reference (manual) methods. The diluted sample should be centrifuged, and the supernatant fluid measured with a spectrophotometer.
- ◆ **High lipid concentration**: A high concentration of lipids in the blood sample will give the plasma a «milky» appearance. This condition can occur with hyperlipidemia, hyperproteinemia (as in gammopathies) and hyperbilirubinemia. Accurate hemoglobin determinations can be achieved by using reference (manual) methods and a plasma blank.
- ◆ **Increased turbidity** may also be seen in cases where the red blood cells are resistant to lysing. This condition will cause an incorrect high HGB result, but may be detected by observing the abnormal MCH, MCHC values, and the increased baseline on the leading edge of the WBC histogram. Erroneous hemoglobin results will cause the results of the MCH and MCHC to be incorrect as well.
- ◆ **Fetal bloods** - The mixing of fetal and maternal bloods may produce a high inaccurate HGB value.

HCT (Hematocrit):

- ◆ **Red blood cells agglutination** - May produce an inaccurate HCT and MCV values. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film. In such cases, manual methods may be required to obtain an accurate HCT value.

MCV (Mean Corpuscular Volume):

- ◆ **Red blood cell agglutination** - May produce an inaccurate MCV value. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film. 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. In such cases, careful examination of the stained blood film may reveal the error.

MCH (Mean Corpuscular Hemoglobin):

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

MCHC (Mean Corpuscular Hemoglobin Concentration):

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

RDW (Red blood cell Distribution Width):

- ◆ The red blood cell distribution width is determined according to the RBC count.
- ◆ **Nutritional deficiency or blood transfusion** - May cause high RDW results due to iron and/or cobalamin and /or folate deficiency.

PLT (Platelets):

- ◆ **Elevated lipids and/or cholesterol:** may interfere with correct platelet counting. From patients undergoing parenteral treatment with intralipids brought, it is noted an over-estimate of the platelet counting which can mask a thrombopenia in DIFF mode. In this case, sample re-run should be done in CBC mode.
- ◆ **Elevated bilirubine** : may interfere with correct platelet counting. From patients with severe hepatic disorder, liver transplant...it is noted an over-estimate of the platelet counting which can mask a thrombopenia.
- ◆ **Very small erythrocytes** (microcytes), erythrocyte fragments (schistocytes) and WBC fragments may interfere with the proper counting of platelets and cause elevated PLT counts.
- ◆ **Agglutinated erythrocytes** - May trap platelets, causing an erroneously low platelet count. The presence of agglutinated erythrocytes may be detected by observation of abnormal MCH and MCHC values and by careful examination of the stained blood film.
- ◆ **Giant platelets in excessive numbers** - may cause a low inaccurate platelet count as these large platelets may exceed the upper threshold for the platelet parameter and are not counted.
- ◆ **Chemotherapy** - Cytotoxic and immunosuppressive drugs may increase the fragility of these cells which may cause low PLT counts. Reference (manual) methods may be necessary to obtain an accurate platelet count.

- ◆ **Hemolysis** - Hemolysed specimens contain red cell stroma which may increase platelet counts.
- ◆ **A.C.D. blood** - Blood anticoagulated with acid-citrate-dextrose may contain clumped platelet which could decrease the platelet count.
- ◆ **Platelet agglutination** - Clumped platelets may cause a decreased platelet count and/or a high WBC count. The specimen should be recollected in sodium citrate anticoagulant to ensure the anticoagulated character depending on agglutination and reanalyzed only for the platelet count. The final PLT result must be corrected for the sodium citrate dilution effect. However, these platelet clumps do trigger flags L1, LL and LL1.

MPV (Mean Platelet Volume):

- ◆ **Giant platelets** that exceed the upper threshold of the Platelet parameter may not be counted as platelets. Consequently, these larger platelets will not be included in the instrument's calculation of Mean Platelet Volume.
- ◆ **Very small erythrocytes** (microcytes), erythrocytic fragments (schistocytes) and white blood cell fragments may interfere with the proper counting and sizing of Platelets.
- ◆ **Agglutinated erythrocytes** - May trap Platelets, causing an incorrect MPV result. The presence of agglutinated erythrocytes may be detected by observation of abnormal MCH and MCHC values and by careful examination of the stained blood film.
- ◆ **Chemotherapy** - May also affect the sizing of PLTs.



Blood samples collected in EDTA will not maintain a stable Mean Platelet Volume. Platelets collected in EDTA swell depending on the time post-collection and storage temperature.

LYM# (Lymphocyte count absolute value), LYM% (Lymphocyte percentage):

- ◆ The Lymphocyte count is derived from the WBC count. The presence of erythroblasts, certain parasites and erythrocytes that are resistant to lysis may interfere with an accurate LYM count. Limitations listed for the WBC count pertain to the LYM # and % counts as well.

MON# (mononuclear cell count absolute), MON% (Mononuclear percentage):

- ◆ The mononuclear cell count absolute is derived from the WBC count. The presence of large lymphocytes, atypical lymphocytes, blasts and an excessive number of basophils may interfere with an accurate monocyte count.
- ◆ Limitations listed for the WBC count pertain to the MON # and % counts as well.

NEU# (neutrophil count absolute), NEU% (Neutrophil percentage):

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

EOS# (Eosinophil cell count absolute), EOS% (Eosinophil percentage):

- ◆ The eosinophil cell count is derived from the WBC cell count. The presence of abnormal granules (degranulated areas, toxic granules...) may interfere with the eosinophil counting.

BAS# (Basophil cell count absolute), BAS% (Basophil percentage):

- ◆ The Basophil cell count is derived from the WBC cell count.

▼ Over evaluation in the Basophil count:

Excessive number of leukocytes (leukocytosis) can cause artificial rise in the number of counted basophils due to the shifting of the leukocytes population in the zone of the basophil ones.

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

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

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

▼ Under evaluation in the Basophil count:

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

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

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

Contents

1. Quality control	3-4
1.1. Access to the Quality Control Menu	3-4
1.2. L.J. Graphs	3-6
1.3. QC data screen grid	3-7
1.4. Graphics screen	3-8
1.5. Print, send or delete results	3-9
1.6. New blood control setup	3-10
1.7. Running control blood	3-13
2. Patient Quality Control (XB)	3-14
2.1. Access to the XB menu	3-15
2.2. XB Graphs	3-16
2.3. XB Data Grid screen	3-17
2.4. Batch content	3-18
2.5. XB limits	3-19
3. Within run	3-21
3.1. Accessing the Within Run Data Grid	3-21
3.2. Closed tube sample setting	3-22
3.3. Running cycles	3-22
4. Calibration	3-25
4.1. General recommendations	3-25
4.2. Accessing the Calibration Main Menu	3-26
4.3. Target values	3-27
4.4. Running calibration	3-28
5. Logs	3-32
5.1. Accessing the «Logs» function	3-32
5.2. Calibration logs	3-34
5.3. Quality control logs	3-34
5.4. Reagent logs	3-35
5.5. Settings logs	3-35
5.6. Maintenance logs	3-35
5.7. Error logs	3-35

5.8. Host logs.....	3-35
5.9. Blank cycle logs.....	3-35
5.10. Patient logs	3-36
5.11. Logs by Date.....	3-36

The «Quality Assurance» menu is accessible by selecting the Quality Assurance key from the Main Menu screen.



Fig. 3-1 Quality Assurance access key

Four functions are available in this menu:

- ◆ Quality Control (see [1. Quality control](#), page 3-4)
- ◆ XB (see [2. Patient Quality Control \(XB\)](#), page 3-14)
- ◆ Within Run (see [3. Within run](#), page 3-21)
- ◆ Calibration (see [4. Calibration](#), page 3-25)

Logs are described in [5. Logs](#), page 3-32

1. Quality control

- ◆ The Quality Control allows the monitoring of a set of analyses based on known samples 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.
- ◆ A total of 24 Control lots can be saved in Quality control.

All QC functions are described in the following sections:

- **1.1. Access to the Quality Control Menu**, page 3-4
- **1.2. L.J. Graphs**, page 3-6
- **1.3. QC data screen grid**, page 3-7
- **1.4. Graphics screen**, page 3-8
- **1.5. Print, send or delete results**, page 3-9
- **1.6. New blood control setup**, page 3-10
- **1.7. Running control blood**, page 3-13

1.1. Access to the Quality Control Menu

Press the «Quality Control» key

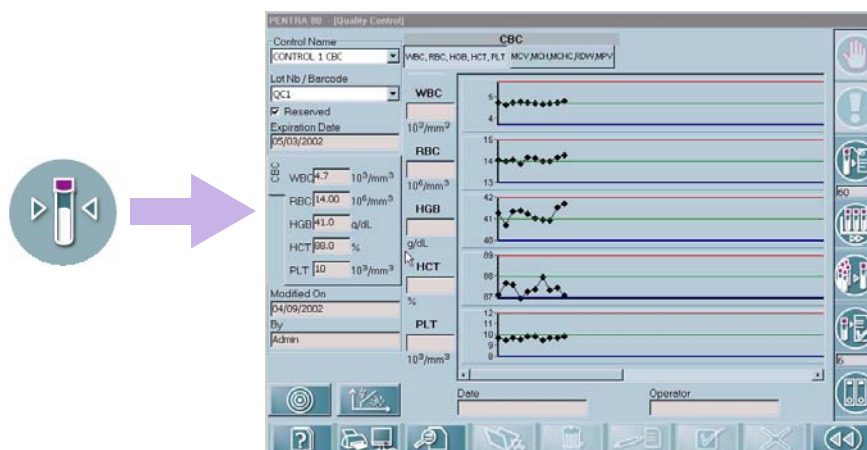
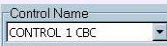
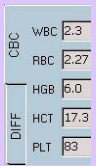


Fig. 3-2 Quality Control access key

▼ Quality Control Key

Key	Name	Function
	Details	Switches from LJ Graph to Data Grid window (see 1.3. QC data screen grid , page 3-7)
	Target	Access to the Target values window (see 1.6. New blood control setup , page 3-10)
	Matrix	Displays the last QC run in a full screen mode (see Graphics screen , page 3-8)
	Control Name	Selection of a new control lot (see Selection of a control # , page 3-10) 24 controls can be saved (12 in CBC, 12 in DIF)
	Tab DIFF/CBC	Switches from CBC target display to DIFF target display.
	Print/Transmit	In Data screen Grid: - Selected or all results, or statistics only (see Print, send or delete results , page 3-9) - Send to the host selected or all results In L.J. graphs: Printing with 100 full points
	Delete	Delete selected/Unselected or all results (see Print, send or delete results , page 3-9)

Tab. 3-1: Quality Control Keys

1.2. L.J. Graphs

This is the graphical representation 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.

A total of 100 points per parameter can be displayed on the screen and on the printout.

The hematology parameters are displayed in groups of 5. Two or four views can be accessed depending on the analysis mode, CBC or DIFF. Changing the parameter view can be made by selecting the parameter tabs «WBC, RBC, HGB, HCT, PLT», «MPV, MCV, MCHC, HCT, MCH», and «NEU, EOS, BAS, LYM, MON» (see Fig. 3-3, page 3-6)

1- Indicates the target value, shown by the centerline in the parameter field

2- Indicates the Maximum Target value, shown by the upper line in the parameter field

3- Indicates the Minimum Target value, shown by the lower line in the parameter field

4- Individual parameter value points, as indicated by the cursor

Blue indicates a value that is lower than the low limit

Red indicates a value that is higher than the upper limit.

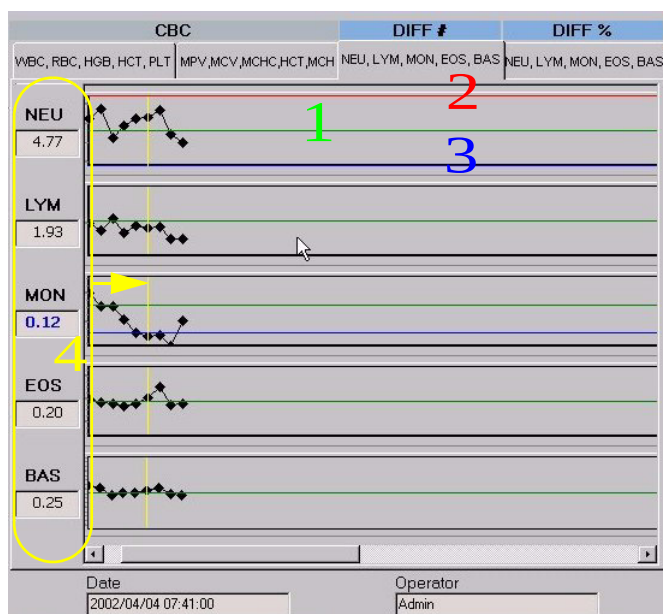


Fig. 3-3 L.J. graphs

The date displayed is the date of the control run which is indicated by the cursor.

1.3. QC data screen grid

From the L.J. graphs screen, use the «Details» key to display the «QC data screen grid».

▼ Analyses results

1- Check boxes: select/deselect QC data.

2- Operator that processed the control runs

3- Date and time that the QC run was processed

4- Filter: (DIFF, CBC or All parameters)

5- Use sliders to view all parameters

6- This field will display all comments associated with the specific QC run (Click on the individual results line so that it will display it in «Grey»)

Sc	Op	Test Date	WBC	RBC	HGB	HCT	MCV	MCH
☒	Admin	2002/04/03 15:28:16	7.4	4.74	13.8	39.0	82	29.1
☒	Admin	2002/04/03 15:32:21	7.4	4.80 H	14.1	39.7 H	83	29.3
☒	Admin	2002/04/04 06:48:57	7.1	4.71	13.8	40.0 H	85 H	29.2
☒	Admin	2002/04/04 07:10:58	7.0	4.73	13.7	40.1 H	85 H	28.9
☒	Admin	2002/04/04 07:38:02	7.3	4.70	14.0	39.7 H	84 H	29.8
☒	Admin	2002/04/04 07:41:00	7.3	4.67	13.8	39.5 H	85 H	29.7
☒	Admin	2002/04/04 08:02:09	7.5	4.61	13.9	38.8	84 H	30.1
☒	Admin	2002/04/04 10:04:53	6.7	4.66	13.9	38.2	82	29.8
☒	Admin	2002/04/04 10:07:47	6.6	4.68	14.0	38.7	83	29.9

Filter	
☒ All	Comment
☐ CBC	
☐ DIFF	
Selected Analysis	

	WBC	RBC	HGB	HCT	MCV	MCH
Upper limits	8.2	4.80	14.4	39.1	84	31.8
Target values	7.2	4.65	13.9	37.1	80	29.8
Lower limits	6.2	4.50	13.4	35.1	76	27.8
Mean	7.1	4.70	13.9	39.3 H	84	29.5
Mean/target diff	0.1	0.05	0.0	2.2	4	0.3
Standard deviation	0.3	0.06	0.12	0.65	1.19	0.42
Coef. of variation	4.17 H	1.21	0.85	1.65	1.42	1.41

Fig. 3-4 QC grid screen

7- This field shows the number of QC runs selected from the Check boxes

Results are displayed in **red** when they are greater than the upper limits, in **blue** when they are lower than the lower limits.



Rejected analyses are not stored in QC! A notification of rejection is entered in the logs

▼ Statistics

For selected results:

- ◆ Mean values are displayed in **red** when they are greater than the upper limits, in **blue** when they are lower than the lower limits.
- ◆ The coefficients of variation are displayed in **red** when they are greater than the coefficients set by the operator (See Section 5: Settings, **3.4. Coefficients of variation ranges**, page 5-13)
- ◆ When a Quality Control parameter is out of range, a QC alarm is activated (See Section 4: Workflow, **5.3.13. Statistical function flags**, page 4-50)



- ◆ One or more results may be excluded from the CV calculations by using the check boxes for selection or deselection of QC results. Statistical calculations are re-computed after each selection/deselection of results.
- ◆ There is not limit on the number of results to be saved for a specific blood control lot.

1.4. Graphics screen

From the L.J. Graphs or Data screen grid, select the «Matrix» key to display the last QC result.

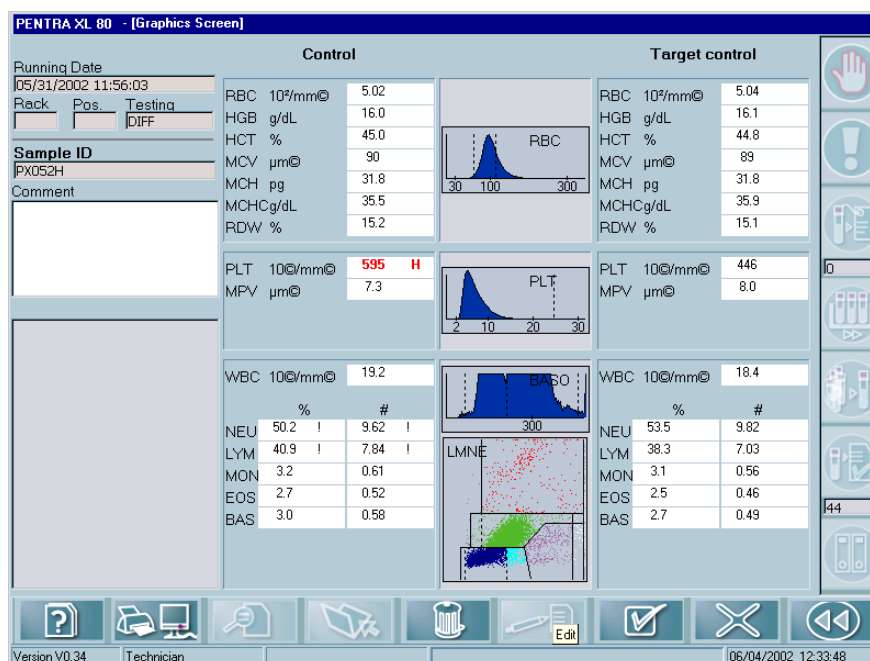


Fig. 3-5 QC graphics screen

Flag and alarm definitions are described in detail in Section 4: Workflow, [5.3. Flags](#), page 4-30.

▼ Entering a comment

Comments can be entered into the "Comment" field when in the QC Graphics screen. A Maximum of 50 characters may be entered.

Select the "Comment" field and enter your comments.

Press the «OK» key once you have finished your entry. These comments can be displayed in the QC data grid (see [Fig. 3-4](#), page 3-7).

1.5. Print, send or delete results

1.5.1. Printing results

▼ Graphics screen

Results are printable from the «Graphics screen» (see [Fig. 3-5](#), page 3-8) in a full screen mode. .

Select the «Print/Send» key.

Then select the «OK» key.

▼ QC Data Grid

From the «Data Grid» screen, Selected, Unselected, and ALL results can be printed by selection choice as indicated in [Fig. 3-6](#), page 3-9.

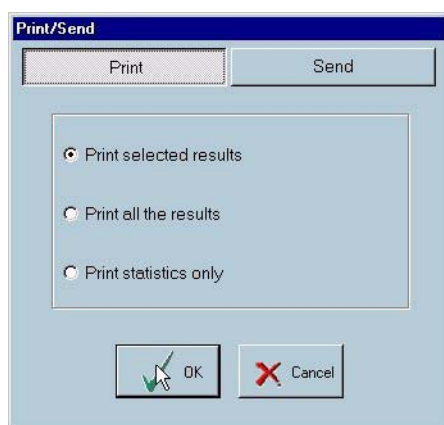


Fig. 3-6 QC print options

▼ L.J. graphs

L.J. graphs can also be printed from the «L.J. Graphs» screen.

When in this screen, select the data to be printed then select the «Print/Send» key.

1.5.2. Sending results to the LIS

Enter into the «Data Grid» screen, (see [Fig. 3-4](#), page 3-7).

Select the «Print/Send» key and choose an option (Selected or All results),

Now select the «Send» key. Selected results will now be sent to the host computer.

1.5.3. Deleting results

▼ Graphics screen

You can only delete the last QC result from the «Graphics» screen.

Select the «Delete» key (see [Fig. 3-5](#), page 3-8), using the «Delete» key.

▼ QC Data Grid

Multiple results can be selected and deleted from the «QC Data Grid». Once the grid has been opened, the «Delete» window becomes available (see [Fig. 3-7](#), page 3-10)

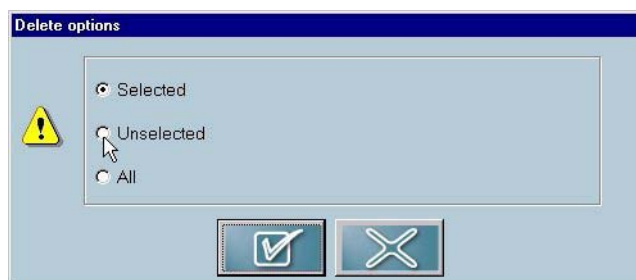


Fig. 3-7 QC delete options

1.6. New blood control setup

It is most necessary to enter all required information related to a new lot of control blood before any QC analysis can take place on such a lot. Target values, Parameter ranges, Alarm levels, 5DIFF Matrix thresholds, and other control blood characteristics should be entered prior to the analysis of the new lot.

▼ Selection of a control

Select the «Target» key (see [Tab. 3-1: Quality Control Keys](#), page 3-5) in order to open the «Target modify» window.

Scroll through the «Control name» list and select the control # you would like to modify (From 1 to 12 reserved to CBC control, from 13 to 24 reserved to DIFF).

If you need to modify the target values or lot #, proceed as described in [Target initialization by floppy](#), page 3-10, or in [Manual target value entry](#), page 3-11.

▼ Target initialization by floppy

Each order of Blood controls (ABX DIFFTROL) comes with a floppy disk so that the operator can insert the disk and update the new control lots without any manual entry of data. Lot #, Target values and Ranges, Alarms and Thresholds, and Expiration Date are included on the floppy disk for each level of control.

Select the «Target» key (see [Tab. 3-1: Quality Control Keys](#), page 3-5) in order to open the «Target modify» window.

Now select the «Edit» key.



When modifying a control lot, analyses from the previous lot must be either erased or saved. A Warning message will be displayed.

- ◆Selecting the «Yes» key, will delete all previous control lot information.
- ◆Selecting the «No» key will recalculate previous Control quality statistics according to the new lot targets.



Fig. 3-8 Floppy access key

- ◆ Insert the floppy disk into the drive.
- ◆ Select the «Edit» key, then the «Floppy disk» key (see **Fig. 3-8**, page 3-11)
- ◆ Now select the level of control you want to load.

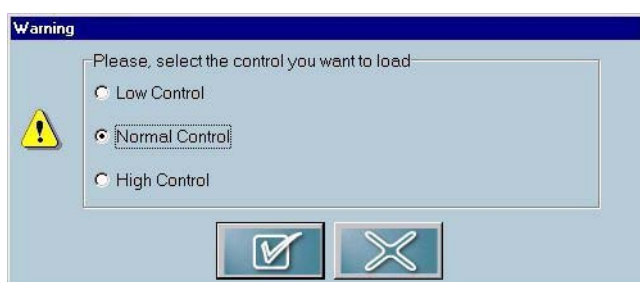


Fig. 3-9 Load control window



If you use a control blood with a Barcode label, make sure that the «reserved» box has been checked (see **Fig. 3-11**, page 3-12)

- ◆ Confirm by selecting the «OK» key

▼ Manual target value entry

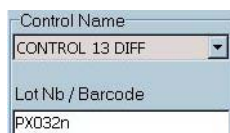


Fig. 3-10 Control Lot #

- ◆ Select the «Target» key (see **Tab. 3-1: Quality Control Keys**, page 3-5) to open the «Target modify» window.
- ◆ select the «Edit» key.
- ◆ Select the barcode field (twice to keep the previous lot #)

- ◆ Read the label with the external Barcode reader or manually type in the lot #
- ◆ Use the «Tab» key to move to the next field or entry.
- ◆ Confirm your entry by selecting the «OK» key.



If you use the control blood with a barcode label, make sure that the «reserved» box has been checked (see **Fig. 3-11**, page 3-12)



◆ Use the scrolling box key to open a calendar and select the expiration date.

◆ Modify or enter target values by selecting the area in which you want to replace the value.

Fig. 3-11 Control expiration date

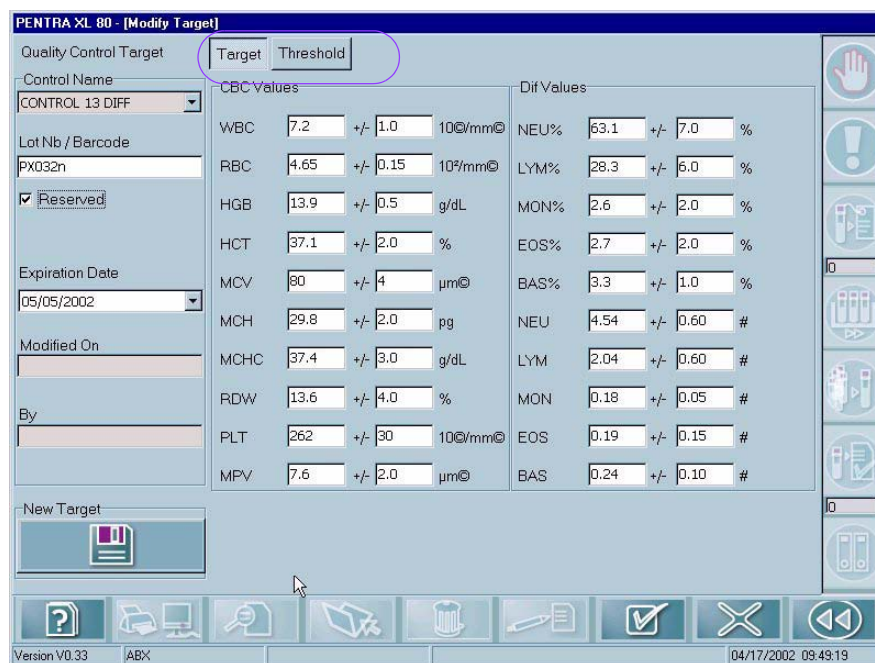


Fig. 3-12 Manual entry of target value

By selecting the tab «Threshold», you can also modify threshold and Alarm levels.

1.7. Running control blood

1.7.1. Running in STAT mode

Verify that the lot of control blood has been entered as described in **1.6. New blood control setup**, page 3-10.

Prepare the Blood control according to the specific instructions detailed in the blood control package insert (temperature, mixing...).

Select the «Stat» key: the tube holder door will open.

Read the lot # with the external barcode reader (or manually type the Lot #)

Select the «OK» key

Place the vial into the appropriate position and close the door to the backwards position.

When the analysis is complete, the QC results will automatically be saved in the QC menu for that specific lot #.

1.7.2. Running in Rack mode (With barcode label identification)

Verify that the lot of control blood has been entered as described in **1.6. New blood control setup**, page 3-10.

Prepare the Blood control according to the specific instructions detailed in the blood control package insert (temperature, mixing...).

Position the blood control in any rack (verify that the Barcode label will be readable by the internal barcode reader).

Place the rack in the rack loader and select the «Start Rack» key.

When the analysis is complete, the QC results will automatically be saved in the QC menu for that specific lot #.

2. Patient Quality Control (XB)

The (XB) Patient Quality Control is used to detect any change in the quality of results by use of patient data only. This data monitoring is performed without any user intervention and can be applied to a set of 9 parameters (WBC, RBC, HGB, HCT, RDW, PLT, MCV, MCH, MCHC) or 3 parameters (MCV, MCH, and MCHC). The operator makes the selection of parameters based on their own population studies (See Section 5: Settings, **3.2. XB options**, page 5-12).

The XB data can be processed as follows:

All the analyses associated to a patient (*analysis that is not associated with a Calibrator or a Quality Control blood, and in the Standard, Male, Female or Child types*) which:

- ◆ have neither «Reject»,
- ◆ nor null value on a parameter
- ◆ nor «DIL» flags on WBC or HCT
- ◆ nor Invalidities
- ◆ nor SCL, MIC, or SCH flags and PLT result.

When a total of 20 results are archived, an XB batch is computed.

The batch data commutated, is the mean result for all 20 analyses contained in that specific batch.

The date of computation of the batch values is noted as the «batch date».

An (XB) alarm occurs when the calculation of the last batch shows a point located outside of the limits set by the operator (see **2.5. XB limits**, page 3-19). The operator can disable this alarm.

A maximum of 60 batches can be stored within the software.

▼ XB section includes

- ◆ **2.1. Access to the XB menu**, page 3-15
- ◆ **2.2. XB Graphs**, page 3-16
- ◆ **2.3. XB Data Grid screen**, page 3-17
- ◆ **2.4. Batch content**, page 3-18
- ◆ **2.5. XB limits**, page 3-19

2.1. Access to the XB menu

From the «Quality Assurance Menu» (see [Fig. 3-1](#), page 3-3), select the «XB» key.

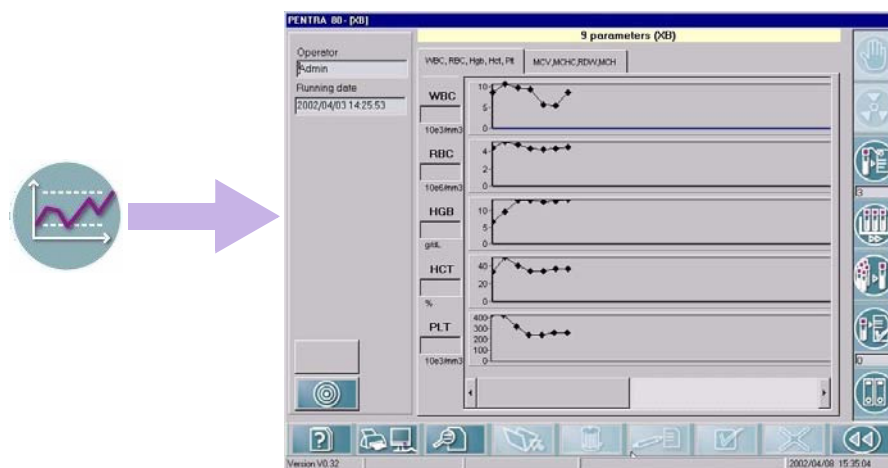


Fig. 3-13 XB Graphic screen

▼ XB Keys

Key	Name	Function
	Details	Switches from LJ Graph to Data Grid screen (see 2.3. XB Data Grid screen , page 3-17)
	Target	Access to XB limit modifying screen (see 2.5. XB limits , page 3-19)
	XB	Displays the content of results of the selected batch (see 2.4. Batch content , page 3-18).
	Print/Transmit	In XB Data grid: prints a list of Batch (see Printing XB Data grid , page 3-17) In XB graphs mode: prints graphs with 60 full points

Tab. 3-2: XB keys

2.2. XB Graphs

The XB Graphs (see Fig. 3-14, page 3-16) are a representation of each batch parameter and their limits plotted on a graph, up to 60 batches. All 60 batches will be displayed on the screen and on the printout (see 2.5. XB limits, page 3-19).

- ◆ Use the “Parameter Tab” keys to select between parameter groups.
- ◆ For the XB limit values, the **Red** line indicates the Maximum limit, the **Green** line indicates the Target value, and the **Blue** line indicates the Minimum limit.
- ◆ The **Yellow** cursor can be positioned by the operator to select a specific batch.
- ◆ Parameter values of a selected batch are displayed in **Red** if greater than the upper limit, in **Blue** if lower than the lower limit.

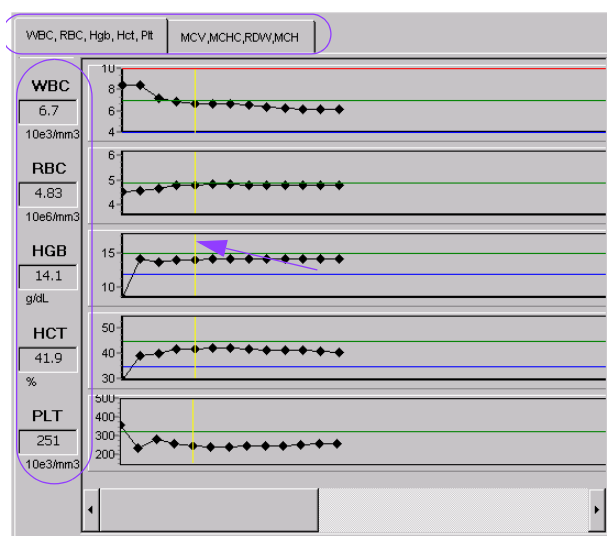


Fig. 3-14 XB Graphs

▼ Print XB graphs

Use the «Print/Transmit» key to print out XB graphs (60 total points)

2.3. XB Data Grid screen

From the «XB graphs» menu (see Fig. 3-14, page 3-16), select the «Details» key to open the «XB Data Grid» screen (see Fig. 3-15, page 3-17)

PENTRA XL 80 - [XB]									
9 parameters (XB)									
Operator	N°	Op	Test Date	WBC	RBC	HGB	HCT	MCV	MCH
Admin	1	Admin	2002/04/05 11:51:32	8.4	4.54	8.5 L	29.6 L	63 L	11
Running date	2	Admin	2002/04/08 11:09:22	8.4	4.60	14.2	39.2	84	3
2002/05/28 14:29:34	3	Admin	2002/05/27 17:16:23	7.2	4.66	13.8	40.0	86	2
	4	Admin	2002/05/28 11:22:34	6.9	4.83	14.0	41.9	86	2
	5	Admin	2002/05/28 14:29:34	6.7	4.83	14.1	41.9	86	2
	6	Admin	2002/05/28 15:22:31	6.7	4.85	14.2	42.2	86	2
	7	Admin	2002/05/29 12:18:14	6.7	4.85	14.2	42.2	87	2
	8	Admin	2002/05/30 11:42:15	6.5	4.81	14.2	41.9	87	2
	9	Admin	2002/05/30 16:03:53	6.4	4.80	14.2	41.6	87	2
				WBC	RBC	HGB	HCT	MCV	M
Upper limits				10.0	6.20	18.0	55.0	98	
Target values				7.0	4.90	15.0	45.0	88	
Lower limits				4.0	3.60	12.0	35.0	78	
Mean				6.8	4.77	13.7	40.4	84	
Mean/target diff				0.2	0.13	1.3	4.6	4	
Standard deviation				0.77	0.1	1.58	3.36	6.35	
Coef. of variation				11.25	2.1	11.49	8.31	7.57	

Fig. 3-15 XB Data grid screen

The XB data grid contains the individual hematology data as well as the batch number. The running date and limit values are also included.

The Statistical data includes the mean of all the batches, Standard deviation and Coefficients of variation. When the Batch values and/or Means are not within their specific limits (see 2.5. XB limits, page 3-19), they will be displayed in **Red** if they are greater than their upper limit, in **Blue** if they are lower than their lower limit.

Select the «XB» key to display the contents within a specific batch.

▼ Printing XB Data grid

Select the «Print/Transmit» key to print a list of the batches.

2.4. Batch content

When selecting the XB Batch content, this will display all 20 results within that specific batch.

From the «XB Data Grid» screen (see Fig. 3-15, page 3-17) or from the «XB Graphs» (see Fig. 3-14, page 3-16), select the «XB» key to open specifically selected batch contents.

PENTRA XL 80 - [Batch Contains]

Batch Number: Batch Date:

Selected Analysis:

Sel	N°	Op	Test Date	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT
☒	1	Admin	2002/05/28 13:49:12	7.3	5.20	15.3	45.9	88	29.4	33.2	11.5	319
☒	2	Admin	2002/05/28 13:55:51	7.3	5.30	15.3	46.6	88	28.8	32.8	11.8	312
☒	3	Admin	2002/05/28 13:57:45	5.1	5.12	15.1	44.4	87	29.5	34.0	12.6	215
☒	4	Admin	2002/05/28 13:59:07	5.0	5.15	15.1	44.7	87	29.4	33.8	12.5	215
☒	5	Admin	2002/05/28 14:01:00	8.2	4.67	12.8	38.8	83	27.5	33.1	14.4	245
☒	6	Admin	2002/05/28 14:02:53	5.6	4.86	14.0	41.4	85	28.7	33.7	12.5	212
☒	7	Admin	2002/05/28 14:04:40	5.1	5.27	14.6	44.0	83	27.8	33.3	12.6	207
☒	8	Admin	2002/05/28 14:06:34	4.4	4.68	14.3	42.2	90	30.5	33.9	12.7	216
☒	9	Admin	2002/05/28 14:08:30	4.9	4.96	14.7	43.1	87	29.7	34.2	12.9	266
☒	10	Admin	2002/05/28 14:10:19	4.7	5.32	15.2	44.7	84	28.5	34.0	14.7	238
☐	11	Admin	2002/05/28 14:12:22	7.9	5.68	16.7	49.8	88	29.3	33.5	11.7	227
☒	12	Admin	2002/05/28 14:14:18	5.5	4.55	13.7	40.3	89	30.2	34.1	12.5	213
☒	13	Admin	2002/05/28 14:16:14	6.8	5.42	15.8	47.0	87	29.2	33.7	12.4	323
☒	14	Admin	2002/05/28 14:18:05	5.3	4.72	12.8	38.8	82	27.2	33.1	13.8	252
☒	15	Admin	2002/05/28 14:19:52	7.0	4.41	12.6	37.7	86	28.5	33.3	12.5	275
☒	16	Admin	2002/05/28 14:22:01	7.6	4.64	13.3	39.6	85	28.6	33.5	12.1	299
☒	17	Admin	2002/05/28 14:23:52	6.6	5.15	15.1	44.3	86	29.4	34.2	13.2	245
☒	18	Admin	2002/05/28 14:25:43	1.2	1.14	3.6	10.6	93	32.0	34.5	11.6	41
☒	19	Admin	2002/05/28 14:27:35	6.6	4.86	14.6	43.5	90	30.1	33.5	13.8	195
☒	20	Admin	2002/05/28 14:29:34	11.5	4.56	13.5	41.2	90	29.7	32.9	12.2	199

Version V0.32 2002/06/05 11:54:13

Fig. 3-16 XB Batch content

A Maximum of 5 results may be de-selected from the last batch only! Select the «Check Boxes» to de-select results to be excluded from the statistical calculations.

The number of analyses included in the batch values is shown in the square, located to the right of «Selected Analysis». When results are de-selected from the batch, the statistical values are automatically re-calculated.

▼ Printing XB batch content

Use the «Print/Transmit» key to print out the displayed contents of the selected batch.

2.5. XB limits

From the «XB Data Grid» screen (see Fig. 3-15, page 3-17) or from the «XB Graphs» (see Fig. 3-14, page 3-16), select the «Target» key to open the «XB Limits» screen (see Fig. 3-17, page 3-19).

Parameter	Value	Target Range	Unit
WBC	7.0	+/- 3.0	10 ³ /mm ³
RBC	5.00	+/- 1.00	10 ⁶ /mm ³
HGB	14.0	+/- 3.0	g/dL
HCT	45.0	+/- 5.0	%
PLT	320	+/- 100	10 ³ /mm ³
MCV	90	+/- 10	μm ³
MCH	29.0	+/- 2.0	pg
MCHC	34.0	+/- 2.0	g/dL
RDW	14.0	+/- 2.0	%

Fig. 3-17 XB limits screen

Select the «Edit» key to modify the limit values then select the value that you want to edit.

Use the «Tab» key to move to the following field.

Press the «OK» key to confirm the new values entries.

If any XB parameter within the last batch is out of its limits, an «XB Alarm» will occur Section 4: Workflow, **5.3.13. Statistical function flags**, page 4-50.

If the printer is selected, a message «XB» is printed out. This flag can also be transmitted via the data output if it has been activated from the «RS output format».

If a printer is configured with the system, a message stating «XB» will be noted on the print-out. The «XB» flag can also be transmitted to a host computer if it has been selected in the «RS232 Output Format». This alarm occurs when the last batch statistical calculations are complete, no matter which operational screen the operator is in.

The values that are presently displayed in the «XB limits» screen are factory Default values. These values can be edited for a specific group or patient population, to detect any possible drift in calculations.

Parameters	Value	Tolerance
WBC	7	3
RBC	5	1
HGB	14	3
HCT	45	5
PLT	320	100
MCV	90	10
MCH	29	2
MCHC	34	2
RDW	14	2

Tab. 3–3: XB limits ranges

▼ Printing XB Limits

Use the «Print/Transmit» key to print out the XB limits.

3. Within run

The Within Run is based on results that are obtained by consecutive analyses of the **same blood sample**.

▼ Sections detailed in Within Run:

- ◆ 3.1. Accessing the Within Run Data Grid, page 3-21
- ◆ 3.2. Closed tube sample setting, page 3-22
- ◆ 3.3. Running cycles, page 3-22

3.1. Accessing the Within Run Data Grid

From the «Quality Assurance Menu» (see Fig. 3-1, page 3-3), select the «Within Run» key.

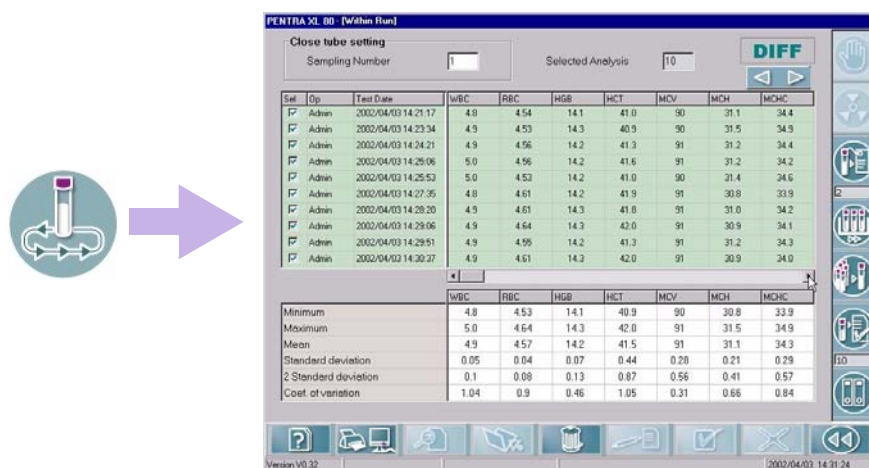


Fig. 3-18 Within Run Data Grid

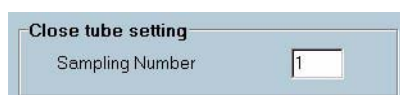
▼ Within Run Keys

Key	Name	Function
	Delete	Deletes Unselected/Selected or All results (see 3.3.4. Print/Transmit or delete Results, page 3-23)
	Print/Transmit	Prints: selected or all results or Statistics only Sends: selected or all results (see 3.3.4. Print/Transmit or delete Results, page 3-23)
	CBC/DIFF	Switches from CBC to DIFF test (see 3.3. Running cycles, page 3-22)

Tab. 3-4: Within Run keys

3.2. Closed tube sample setting

The operator is allowed to run within run samples in both Manual Mode and Rack Mode.



Enter the number of sample takes to be performed on the sample tube for Rack mode.

Fig. 3-19 Closed tube mode setting



◆The «Within Run Data Grid» must be opened when performing a sample repeatability cycle!

◆Each tube of the rack is analysed the number of times specified by the «sampling number».

3.3. Running cycles

The Within Run test must be done on a fresh normal whole blood sample.

3.3.1. Manual mode

Open the «Within Run Data Grid» screen (see [Fig. 3-18](#), page 3-21).

Select the test (CBC or DIFF) by pressing the CBC/DIFF key of the grid (see [Tab. 3-4: Within Run keys](#), page 3-21).

Select the «STAT» key of the generic toolbar Section1: Introduction, [4.2. Generic toolbar description](#), page 1-16.

Once the «STAT» key has been selected, the tube holder door opens. Place the sample tube in the appropriate position of the tube holder.

Close the tube holder on the rear position; the analysis cycle begins.

Rerun the sample several times.

The Within Run is complete once the operator exits the «Within Run Data Grid» screen.

3.3.2. Rack mode

Position the tube in any rack.



If there is more than one sample tube placed in the rack, each tube will be analyzed the number of times specified by the «Sampling Number».

Open the «Within Run Data Grid» screen (see [Fig. 3-18](#), page 3-21).

Select the test (CBC or DIFF) by pressing the CBC/DIFF key of the grid (see [Tab. 3-4: Within Run keys](#), page 3-21).

Place the rack in the Rack Loader.

Select the «Start Rack» key Section1: Introduction, [4.2. Generic toolbar description](#),

page 1-16.

The rack is loaded and the results will automatically appear in the grid.

3.3.3. Results

PENTRA XL 80 - [Within Run]

Close tube setting
Sampling Number: 1
Selected Analysis: 15
DIFF

Sel	Op	Test Date	WBC	RBC	HGB	HCT	MCV	MCH	MCHC
☒	Admin	2002/04/03 14:28:20	4.9	4.61	14.3	41.8	91	31.0	34.2
☒	Admin	2002/04/03 14:29:06	4.9	4.64	14.3	42.0	91	30.9	34.1
☒	Admin	2002/04/03 14:29:51	4.9	4.55	14.2	41.3	91	31.2	34.3
☒	Admin	2002/04/03 14:30:37	4.9	4.61	14.3	42.0	91	30.9	34.0
☒	Admin	2002/04/03 15:15:41	5.1	4.52	13.9	40.7	90	30.8	34.2
☒	Admin	2002/04/03 15:16:50	5.1	4.56	14.1	41.1	90	30.9	34.3
☒	Admin	2002/04/03 15:17:44	5.0	4.55	14.1	41.1	90	30.9	34.3
☒	Admin	2002/04/03 15:18:34	5.2	4.47	14.1	40.4	90	31.6	35.0
☒	Admin	2002/04/03 15:19:21	4.7	4.50	13.9	40.8	91	30.9	34.1
☒	Admin	2002/04/03 15:20:22	5.1	4.51	14.1	41.0	91	31.4	34.5

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC
Minimum	4.7	4.50	13.9	40.7	90	30.8	33.9
Maximum	5.1	4.64	14.3	42.0	91	31.5	34.9
Mean	4.9	4.56	14.2	41.3	91	31.1	34.3
Standard deviation	0.11	0.04	0.12	0.45	0.33	0.21	0.24
2 Standard deviation	0.22	0.08	0.24	0.89	0.67	0.42	0.48
Coef. of variation	2.21 H	0.91	0.85	1.08	0.37	0.67	0.7

Version V0.32
2002/04/09 15:16:22

Fig. 3-20 Within run results

This grid includes statistical data for each parameter (maximum, minimum, mean, standard deviation). The coefficient of variation will be displayed in red, if it is greater than the upper limit established by the operator Section 5: Settings, 3.4. Coefficients of variation ranges, page 5-13.

Results can be excluded from the statistical data, by using the «check boxes» to de-select the analyses.

3.3.4. Print/Transmit or delete Results

▼ Print or Transmit

Open the «Within Run Data Grid» screen

Using the «Print/Transmit» key (see Tab. 3-4: Within Run keys, page 3-21),

Select either «Print» or «Send» depending which action you would like to create

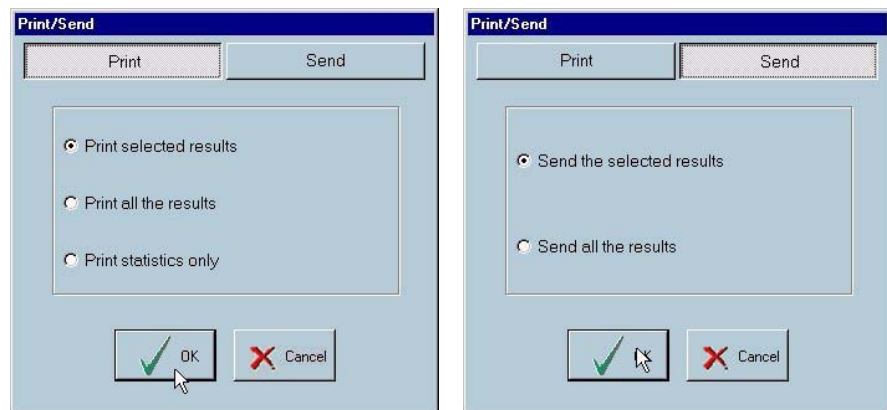


Fig. 3-21 Print/Send Within run results

▼ Delete results

Open the «Within Run Data Grid» screen

Using the «Delete» key (see [Tab. 3-4: Within Run keys](#), page 3-21), discard the unselected, selected or all results from the grid:

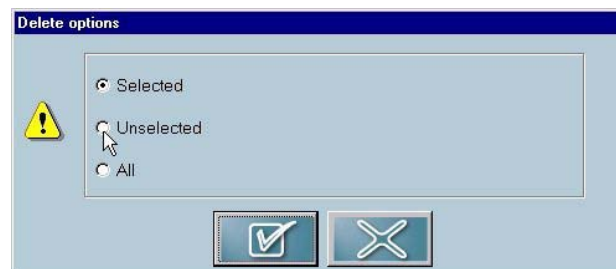


Fig. 3-22 Delete Within Run Results

4. Calibration

The Calibration function is used to determine the Precision and Accuracy of the analyzer with use of a specifically formulated product to recover each parameter within close tolerances of known target values and limits. Coefficients of variation and percent difference recovery must be within their specified limits.

▼ Sections detailed in Calibration:

- ◆ 4.1. General recommendations, page 3-25
- ◆ 4.2. Accessing the Calibration Main Menu, page 3-26
- ◆ 4.3. Target values, page 3-27
- ◆ 4.4. Running calibration, page 3-28

4.1. General recommendations

The calibration on HORIBA ABX instruments is an exceptional procedure, which must be carried out particularly in 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 a clogging of the instrument.

4.1.1. Preliminaries

Before carrying out a calibration, it is essential to make sure that the instrument is in perfect condition of operation, and to follow the following steps:

- 1- Carry out a Concentrated cleaning procedure (See Section 7: Maintenance & Troubleshooting, [4.3.5. Concentrated cleaning, page 7-34](#)).
- 2- Perform two blank cycles to check the cleanliness of the instrument (other cycles Blank cycle,) and check the results are within the following values (If not contact your Horiba ABX representative):
 - WBC < $0.3 \times 10^3/\text{mm}^3$
 - RBC < $0.03 \times 10^6/\text{mm}^3$
 - HGB < 0.3 g/dl
 - PLT < $7 \times 10^3/\text{mm}^3$
 - LMNE < 0.30
- 3- Check the repeatability of the instrument by running 6 times a normal human blood without taking account of the first result (See Section 3: Quality Assurance and Logs, [3. Within run, page 3-21](#))
- 4- Deselect the first result from the results table and check that the CV obtained out on the other 5 results are lower than: WBC: 2%, RBC: 2%, HGB: 1%, HCT: 1%, PLA: 5%
- 5- Run a control blood and check that the values are within the acceptable limits. If not, run a new control blood.

If the values are still out of the acceptable limits and 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 as described in Section 3: Quality Assurance and Logs, **4.1.2. Calibration procedure, page 3-26.**

4.1.2. Calibration procedure

6- Run at least 4 times Calibrator without taking the values of the first result into account (See Section 3: Quality Assurance and Logs, **4.4. Running calibration, page 3-28).**

7- Calibrate the instrument on the average of the last three results according to indications of the manual (See Section 3: Quality Assurance and Logs, **4.4.1. Calibration passed, page 3-29)**

8- Run 3 times again Calibrator to check the values.

9- Confirm the calibration while passing a control blood, the values have to be returned within acceptable limits.

10- After about thirty numerations analyses of the day, check that values of MCV, MCH and MCHC are in conformity with the usual values of the laboratory.

4.2. Accessing the Calibration Main Menu

From the «Quality Assurance Menu» (see **Fig. 3-1**, page 3-3), select the «Calibration» key

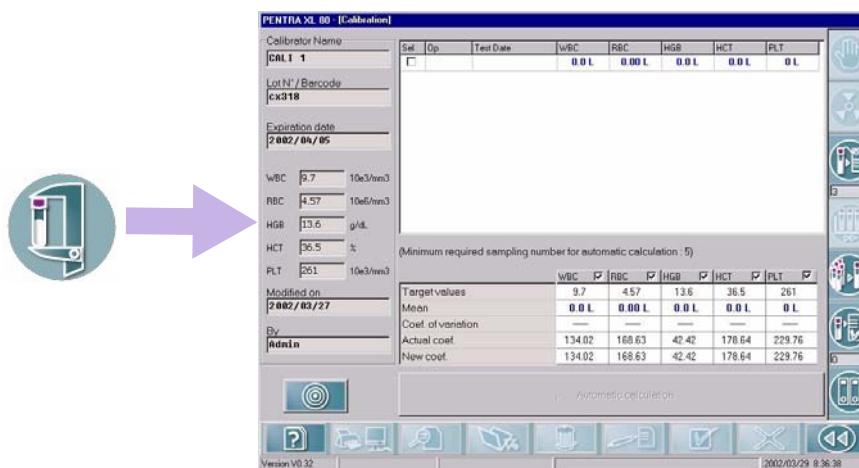


Fig. 3-23 Calibration Access Key

▼ Calibration Key

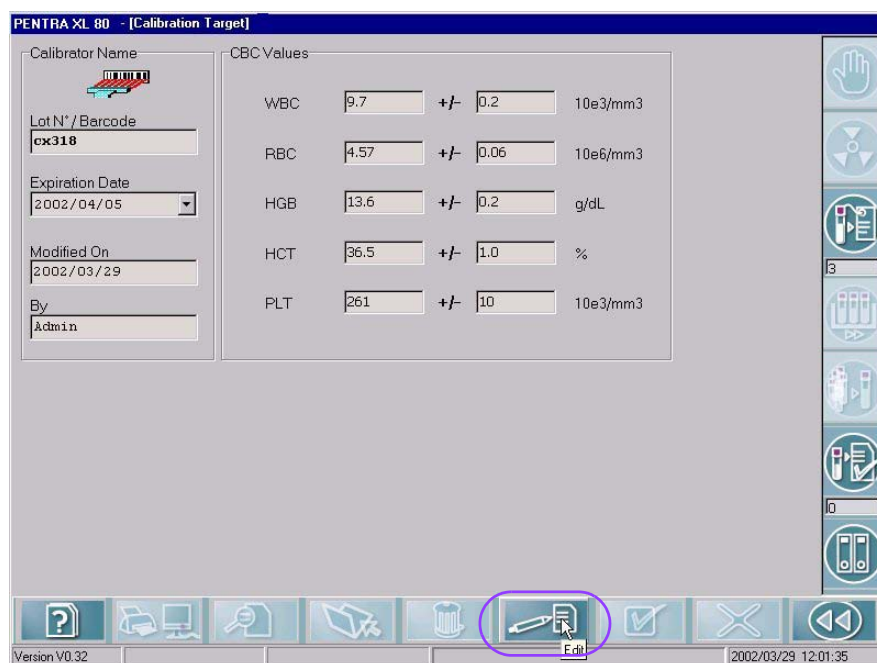
Key	Name	Function
 Automatic calculation	Automatic Calculation	Runs an automatic calculation of the new coefficients (see 4.4.1. Calibration passed , page 3-29). This key is enabled only if a minimum of 5 runs on calibrator has been performed
	Target	Access to the Target values window (see 4.3. Target values , page 3-27)

Tab. 3-5: Calibration Grid Keys

If the Calibrator lot is different than the current calibrator material being used for calibration, proceed with the following as described in [4.3. Target values](#), page 3-27.

4.3. Target values

From the Calibration grid, select the «Target» key (see [Tab. 3-5: Calibration Grid Keys](#), page 3-27) to open the «Calibration Target» screen for editing.



PENTRA XL 80 - [Calibration Target]

Calibrator Name: 

Lot N° / Barcode:

Expiration Date:

Modified On:

By:

CBC Values

WBC	9.7	+/-	0.2	10e3/mm3
RBC	4.57	+/-	0.06	10e6/mm3
HGB	13.6	+/-	0.2	g/dL
HCT	36.5	+/-	1.0	%
PLT	261	+/-	10	10e3/mm3

Version V0.32 | 2002/03/29 12:01:35

Fig. 3-24 Editing the target values

Select the «Edit» key to edit the target fields.

Read the barcode label on the calibrator with the external Barcode Reader or type in all the calibrator information using the calibrator Assay sheet that comes with the calibrator kit.

Once all entries have been made, select the «OK» key to save the information

Exit the «Target values» menu by selecting the «Return» key.

4.4. Running calibration

If Quality control check procedure has failed (see **1.7. Running control blood**, page 3-13),

- 1- Verify that the reagents are sufficient, fresh, and uncontaminated.
- 2- Run a system «Startup» and verify that the Backgrounds are at their lowest possible limits.
- 3- Run «Within Run» and verify that the Coefficients of variation are within their limits.

Use a **Minocal** calibrator to calibrate Pentra XL 80. Follow the calibrator package insert for proper instructions on mixing and handling of the product.

If a new lot needs to be entered into the system, follow the procedure as described in **4.3. Target values**, page 3-27.

Open the «Calibration Grid» as described in **Accessing the Calibration Main Menu**, page 3-26.

Select the «Stat Mode» key

Gently mix the calibrator and place it into the appropriate position in the tube holder.

Now close the tube holder door to run the analysis.

When the tube holder door opens, remove and recap the vial for pre-mixing of the next cycle.



Calibration results may be erroneous if the calibrator is not mixed properly between each analysis cycle.

Once the analysis is complete, the first result is displayed in the «Results Grid».

Run the calibrator 4 more times. (*The Minimum number of sampling is 5 for good statistical calculations*). The calibrator may be run from 1 to 99 times if needed. Section 5: Settings, **3.3. Number of calibration runs**, page 5-13.

PENTRA XL 80 - [Calibration]

Calibrator Name: **CALI 1**

Lot N° / Barcode: **cx318**

Expiration date: **2002/04/05**

WBC: 9.7 10e3/mm3

RBC: 4.57 10e6/mm3

HGB: 13.6 g/dL

HCT: 36.5 %

PLT: 261 10e3/mm3

Modified on: **2002/03/29**

By: **Admin**

Sel	Op	Test Date	WBC	RBC	HGB	HCT	PLT
☐	Admin	2002/04/02 15:03:20	9.6	4.67 H	13.7	37.2	256
☒	Admin	2002/04/02 15:04:16	9.6	4.56	13.6	36.4	263
☒	Admin	2002/04/02 15:05:12	9.7	4.59	13.5	36.7	269
☒	Admin	2002/04/02 15:06:08	9.7	4.58	13.5	36.8	269
☒	Admin	2002/04/02 15:08:57	9.7	4.64 H	13.7	37.1	268
☒	Admin	2002/04/02 15:09:50	9.8	4.62	13.8	37.1	279 H

(Minimum required sampling number for automatic calculation : 5)

	WBC	RBC	HGB	HCT	PLT
Target values	9.7	4.57	13.6	36.5	261
Mean	9.7	4.60	13.6	36.8	270
Coef. of variation	0.79	0.65	0.87	0.8	2.07
Actual coef.	135.94	171.65	43.19	182.22	258.82
New coef.	135.8	170.67	43.15	180.7	250.49

Automatic calculation

Version V0.32 2002/04/02 15:12:50

Fig. 3-25 Calibration result grid



- ◆ When calibration results are received on the display, they are saved as calibration data and not received as sample results.
- ◆ Calibration results are not transmitted to a host computer, they are kept in the calibration "Results Grid".
- ◆ If a calibration cycle is rejected, it will not be displayed or stored. An error message will be displayed on the screen indicating that the calibration sample was rejected.

To remove results from the statistical calculation, select the check box (see **Fig. 3-25**, page 3-29) to remove the mark.

To remove Parameters from the Coefficient calculations, select the check box (see **Fig. 3-25**, page 3-29) to remove the mark.

When a Coefficient of variation is displayed in **Red**, it is above its limit and that parameter will fail calibration.

4.4.1. Calibration passed

There are only 2 passing criteria for calibration!

- 1- The Coefficients of variation must be within their limits Section 5: Settings, **3.4. Coefficients of variation ranges**, page 5-13.
- 2- The percent differences between the Target value and the Mean values must be less than 20%.

Instrument allows you to select an automatic calibration. Press the «Automatic calculation» key.

A message is displayed to confirm the Autocalibration. Selecting the «ok» key will automatically print the results and then erase them from the «Result grid».

4.4.2. «Forced» calibration

This is an indication that the current calibration analysis is not within the acceptable limits.

1- The Coefficients of variation are greater than their limits.

2- The percent difference between the Target value and the Mean values is greater than 20%. The calibration is called «Forced» and a warning message shall request confirmation to continue.

When running calibration, a warning message appears on the screen stating a «Forced» calibration has been detected, another message will appear asking you if you wish to continue the calibration.

You have the option of continuing or rejecting the calibration at this time.

4.4.3. Coefficients of calibration ranges

Check that the coefficients of calibration are within the following acceptable limits. Or else, please contact your **HORIBA ABX** representative department.

Coefficients of calibration	Minimum	Standard	Maximum
WBC	90	137	200
RBC	100	225	300
HCT	100	220	300
HGB	25	40	55
PLT	130	290	400
RDW	0.1	0.35	1
MPV	0.1	1.0	2
LMNE	0.5	0.86	1.5

4.4.4. Printing, sending or deleting calibration results

▼ Printing and sending calibration results

Calibration results can be printed out and/or sent to a host computer by selecting the «Print/Send» key. Specific results and parameters may be included or excluded from statistical calculations by selection of the Check Boxes in the «Calibration Results Grid» (see **Fig. 3-26**, page 3-31).

Press the «Print» key of the Contextual Toolbar to open it.

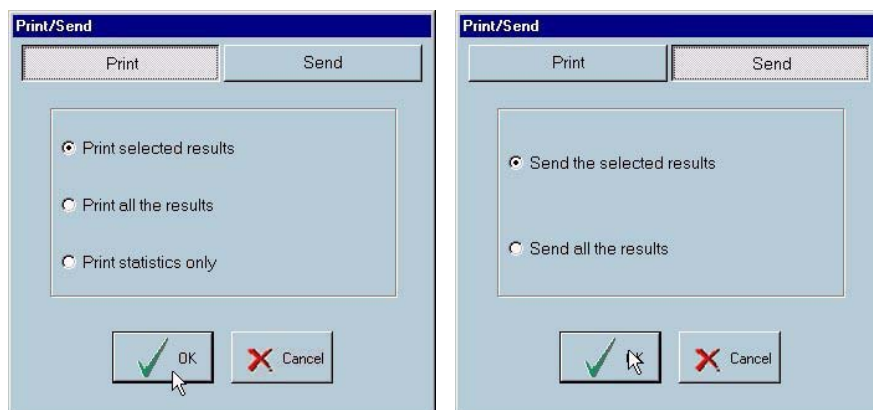


Fig. 3–26 Print and send windows

Calibration: List View													
TARGET													
Calibrator Name		Lot N° / Barcode		Expiration date		Modified on		Modified by					
CALI 1		cx318		2002/04/05		2002/03/29		Admin					
WBC		RBC		HGB		HCT		PLT					
9.7+/- 0.2		4.57+/- 0.06		10e6/mm3		13.6+/- 0.2 g/dL		36.5+/- 1.0 %		261+/- 10 10e3/mm3			
ANALYSES													
Sel	Operator	Test Date	WBC	RBC	HGB	HCT	PLT						
☒	Admin	2002/04/02 15:04:16	9.6	4.56	13.6	36.4	263						
☒	Admin	2002/04/02 15:05:12	9.7	4.59	13.5	36.7	269						
☒	Admin	2002/04/02 15:06:08	9.7	4.58	13.5	36.8	269						
STATISTICS													
Intermediate values			WBC	RBC	HGB	HCT	PLT						
Target values			9.7	4.57	13.6	36.5	261						
Mean			9.7	4.58	13.5	36.6	267						
Coef. of variation			0.77	0.37	0.24	0.5	1.24						
Actual coef.			135.94	171.65	43.19	182.22	258.82						
New coef.			136.26	171.39	43.42	181.65	252.76						

Fig. 3–27 Calibration printout

▼ Deleting calibration results

For deleting results from the «Calibration Results Grid», select the Check Boxes to select or de-select results and parameters, then select the «Delete» key from the Contextual Toolbar and select «Selected», «Unselected», or «ALL» for deletion (see Fig. 3–28, page 3-31).

Now confirm your selection



Fig. 3–28 Delete options

5. Logs

These are the event logs for the Pentra XL 80. They contain all of the notifications made automatically by the software while the Pentra XL 80 is in operation

«Logs» functions are described in:

- ◆ 5.1. Accessing the «Logs» function, page 3-32
- ◆ 5.2. Calibration logs, page 3-34
- ◆ 5.3. Quality control logs, page 3-34
- ◆ 5.4. Reagent logs, page 3-35
- ◆ 5.5. Settings logs, page 3-35
- ◆ 5.6. Maintenance logs, page 3-35
- ◆ 5.7. Error logs, page 3-35
- ◆ 5.8. Host logs, page 3-35
- ◆ 5.9. Blank cycle logs, page 3-35
- ◆ 5.10. Patient logs, page 3-36
- ◆ 5.11. Logs by Date, page 3-36

5.1. Accessing the «Logs» function

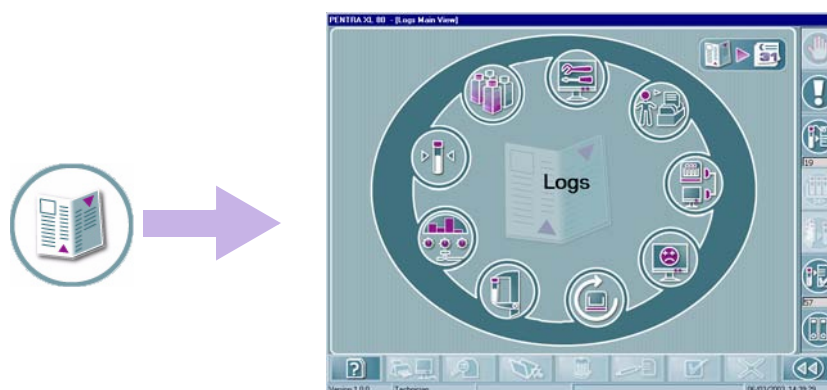


Fig. 3-29 Logs main screen

Press the «Logs» key of the main screen.

▼ Logs access keys

Key	Name	Function
	Calibration	Launches calibration log screen (see 5.2. Calibration logs , page 3-34)
	Quality Control	Launches Quality control log screen (see 5.3. Quality control logs , page 3-34)
	Reagent	Launches Reagent log screen (see 5.4. Reagent logs , page 3-35)
	Settings	Launches settings log screen (see 5.5. Settings logs , page 3-35)
	Maintenance	Launches Maintenance log screen (see 5.6. Maintenance logs , page 3-35)
	Error	Launches error log screen (see 5.7. Error logs , page 3-35)
	Host	Launches Host log screen (see 5.8. Host logs , page 3-35)
	Blank cycle	Launches Blank cycle log screen (see 5.9. Blank cycle logs , page 3-35)
	Patient	Launches Data handling log screen (see 5.10. Patient logs , page 3-36)
	Logs by Date	Launches Logs by Date screen (see 5.10. Patient logs , page 3-36)

Tab. 3–6: Log access keys

▼ Logs function key

Key	Name	Function
	Add comments	Opens a comment window. The user can enter a comment to associate to the «Logs» entry on which he is positioned
	Print/send	permits to the user to print the current logs as a list, between two dates

Tab. 3–7: Logs function keys

5.2. Calibration logs

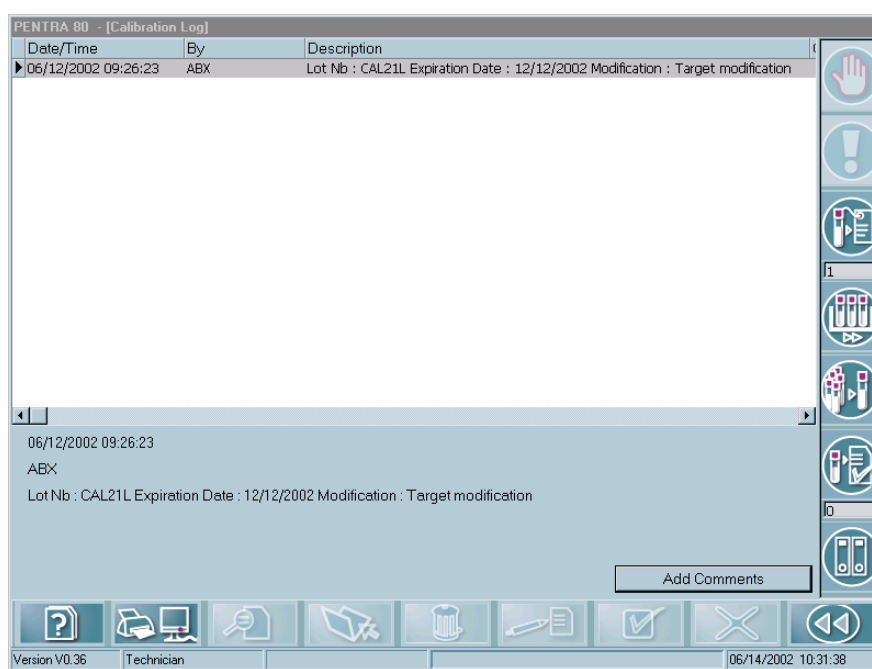


Fig. 3–30 Calibration logs

- ◆ For every calibration, a notification is done in this log (new coefficients display).
- ◆ For a LMNE channel calibration, a notification is done.
- ◆ For every target change a notification is done.
- ◆ For every rejected analysis in calibration, a notification is done.
- ◆ When an analysis is launched with an expired calibrator, a notification is done.

5.3. Quality control logs

- ◆ Every time that the QC targets are changed, a notification is done.

- ◆ Every time that an analysis made on a QC is rejected, a notification is done.

5.4. Reagent logs

- ◆ For every reagent change, a notification is done.

5.5. Settings logs

- ◆ At every modification in the settings, a notification is done.

5.6. Maintenance logs

- ◆ For every maintenance, a notification shall be done by the user or technician in this screen. After any maintenance operation, open the «Maintenance» logs screen. Press the «Insert» key in order to enter an action, the duration and a comment about this action. Press «ok» key to save the new entry.

5.7. Error logs

- ◆ A notification shall be done when an alarm is displayed

5.8. Host logs

- ◆ Each time a file from the Host is rejected, a notification is done. This rejection is generated in the software rather than the raster when, for example:
 - An order is pending a ReRun
 - The rack on which the tube is found is in progress of an analysis

5.9. Blank cycle logs

For every Startup analysis performed, a notification is done.

- ◆ A Startup has passed if the cycle is launched and the WBC, RBC, HGB and PLT parameters are within acceptable limits. the notification line is displayed in green.
- ◆ A Startup has failed if the cycle is launched and if the three consecutive analyses done gave wrong results on the WBC or RBC or HGB or PLT parameters, the notification line is red.
- ◆ A Startup has failed if HGB blank value is not within acceptable limits. The notification line is red.
- ◆ The default limit values are:
 - $WBC \leq 0.3 \cdot 10^3 / \text{mm}^3$
 - $RBC \leq 0.03 \cdot 10^6 / \text{mm}^3$
 - $HGB \leq 0.3 \text{ g/dl}$
 - $PLT \leq 7 \cdot 10^3 / \text{mm}^3$
 - $LMNE < 0.30\%$

5.10. Patient logs

- ◆ For every modification to a patient file (by the WorkList or by the HOST), a notification is done.
- ◆ When exception is generated because of the mismatch of the rack/position of the sample and the order Section 4: Workflow, **1.7. Exception management**, page 4-11, a notification is done.
- ◆ When the user matches an order and a result in the association screen, a notification is done. If a recomputing of the result is done, the notification shall contain this information.

5.11. Logs by Date

This function groups the Calibration logs, Maintenance logs and Reagents logs together on the same screen and displayed by date.

Two scrolling lists «From» and «To» allow the user to display log events in a chosen interval.

These events (when they exist) are displayed in a grid mode and detailed in the right part of the screen.

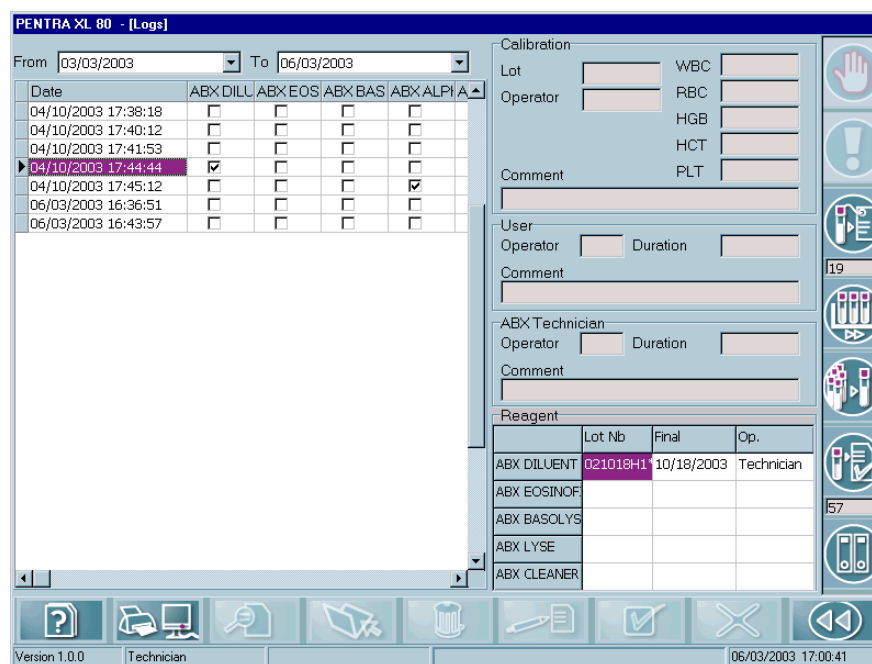


Fig. 3-31 Logs per Day

Select one line of the grid to display events of the day (see Fig. 3-31, page 3-36).

All the events of the current date (selected line) can be printed out by selecting «Print/Send» key.



- ◆ The grid can be sorted by decreasing date if the date displayed in the «From» field is anterior to the date displayed in the «To» field.
- ◆ LMNE channel calibrations are not visible in this screen.

Contents

1. Workflow	4-3
1.1. Sample tube management.....	4-3
1.2. Workflow	4-3
1.3. Worklist.....	4-4
1.4. Sample identification.....	4-5
1.5. Barcode Identification	4-5
1.6. Sample identification on Rack/position	4-8
1.7. Exception management.....	4-11
1.8. Sample runs and order association.....	4-13
1.9. Rerun conditions	4-13
1.10. Patient file management	4-14
1.11. Loading Worklist from the LIS.....	4-14
2. Worklist description	4-15
2.1. Overview	4-15
2.2. Accessing the Worklist function.....	4-15
2.3. Worklist grid.....	4-16
2.4. Rack view.....	4-22
3. Sample collection & mixing.....	4-25
3.1. Recommended anticoagulant	4-25
3.2. Blood sample stability	4-25
3.3. Microsampling	4-25
3.4. Mixing.....	4-25
4. Running specimen.....	4-26
5. Run results and associated Flags.....	4-27
5.1. Printer output format	4-27
5.2. Run Result screen	4-28
5.3. Flags.....	4-30
6. Report	4-51
6.1. Reviewing Report	4-51
6.2. Construction of a Report.....	4-57

6.3. Validation or rejection of a Report	4-63
6.4. Rerunning sample manually.....	4-64
6.5. Run /order association	4-68
7. Archives	4-70
7.1. Accessing the Archives	4-70
7.2. Daily Report Description	4-71
7.3. Patient Report	4-73
7.4. Reviewing a Report in full screen mode.....	4-75
7.5. Reviewing exported reports.....	4-75
8. Status	4-77
8.1. Accessing the Status screen.....	4-77
8.2. Status screen description.....	4-78
8.3. Rack status.....	4-79

Workflow chapter includes the following

1. **Workflow**, page 4-3
2. **Worklist description**, page 4-15
3. **Sample collection & mixing**, page 4-25
4. **Running specimen**, page 4-26
5. **Run results and associated Flags**, page 4-27
6. **Report**, page 4-51
7. **Archives**, page 4-70

1. Workflow

This chapter describes the overall operation of Patient sample management through the system, which include: creating orders, matching orders (automatic and manual), patient file management, sample exceptions, and many other features which identify the sample all the way to final reports. The chapter section description is as indicated in the following order:

- 1.1. **Sample tube management**, page 4-3
- 1.2. **Workflow**, page 4-3
- 1.3. **Worklist**, page 4-4
- 1.4. **Sample identification**, page 4-5
- 1.5. **Barcode Identification**, page 4-5
- 1.6. **Sample identification on Rack/position**, page 4-8
- 1.7. **Exception management**, page 4-11
- 1.8. **Sample runs and order association**, page 4-13
- 1.10. **Patient file management**, page 4-14
- 1.11. **Loading Worklist from the LIS**, page 4-14

1.1. Sample tube management

Pentra XL 80 can automatically load racks once the sample tubes have been positioned.

The STAT mode can be utilized to analyze one to several specimens manually while in the rack mode. The rack will stop at the introduction of the STAT mode and continue with the remaining samples on the rack once the STAT mode is complete.

1.2. Workflow

Once the Pentra XL 80 has started the analysis process on a sample tube, an order is generated to search the worklist for 2 of the following criteria:

- ◆ The Rack position number where the tube has been placed:
- ◆ The barcode Sample ID



The order-searching mode is generated based on specific settings that were selected by the operator (See Section 5: Settings, **2.2. General tab**, page 5-6).

When the associated order is found, the instrument will automatically perform the required analysis that was generated from the information in the worklist, such as defined blood type and the patient demographics that are associated with each sample.

1.3. Worklist

Worklist orders allow the following criteria:

- ◆ A single identification of a sample tube
- ◆ Selection of the test to be performed (CBC or DIFF).
- ◆ Selection parameter ranges according to the specific blood types, (i. e. Male, Female, Child, etc...)
- ◆ The creation of a patient file and patient demographics
- ◆ Matching orders to specific patient files

When creating orders, there are only 2 modes available:

1- A graphics screen (see **2.4. Rack view**, page 4-22) that simulates a rack view with sample tube positions. This mode must be used with the following Setting : «*Rack / Position*» (See Section 5: Settings, **2.2.5. Identification option**, page 5-7).

2- A grid that is intended to identify the sample tube by means of Barcode labeling. Entering the sample tube position in the rack is not available while in this mode. This mode must only be used with the following setting, «*Barcode*» (See Section 5: Settings, **2.2.5. Identification option**, page 5-7).



The worklist sample management depends on laboratory organization. This must be defined when the instrument is installed (barcode or rack/position).

1.4. Sample identification

A Single sample number identifies orders that are generated from the worklist. If the operator does not enter a number, the instrument will automatically assign a number as followed: «AUTO_SID_xxxxx»

Sample ID	Rack	Pos.	Patient ID
0070			
123658		1	1
36597		1	2
AUTO_SID4		1	3
AUTO_SID5		1	6
AUTO_SID6		1	8
AUTO_SID7		1	9
AUTO_SID8		1	10

Fig. 4-1 Automatic sample numbering

If the operator enters an order with a Sample ID that already exist in worklist, the previous order will be updated! Modifications cannot be performed during the sample analysis process. Orders are deleted once the sample analysis is complete.

3 modes of sample identification are available:

- ◆ Barcode identification (see [1.5. Barcode Identification](#), page 4-5)
- ◆ Rack/Position identification (see [1.6. Sample identification on Rack/position](#), page 4-8)
- ◆ Automatic numbering by the instrument.

1.5. Barcode Identification

The Barcode Identification mode is the most recommended mode on the Pentra XL 80 because it ensures the best security and flexibility. Easy association between Sample orders and the sample tube can be identified by the barcode.

The «Sample ID» field must match that of the barcode label. Entering the sample tube position in the rack is not available while in this mode.

1.5.1. Setting: Barcode / Manual match = OFF

The «Sample ID» field corresponds to the barcode of the label. In this mode it is impossible to allocate a position for the tube in the worklist.

The Pentra XL 80 tab: «Settings/Soft parameters/General tab/barcode option» is set as shown:
(See Section 5: Settings, **2.2.5. Identification option**, page 5-7)

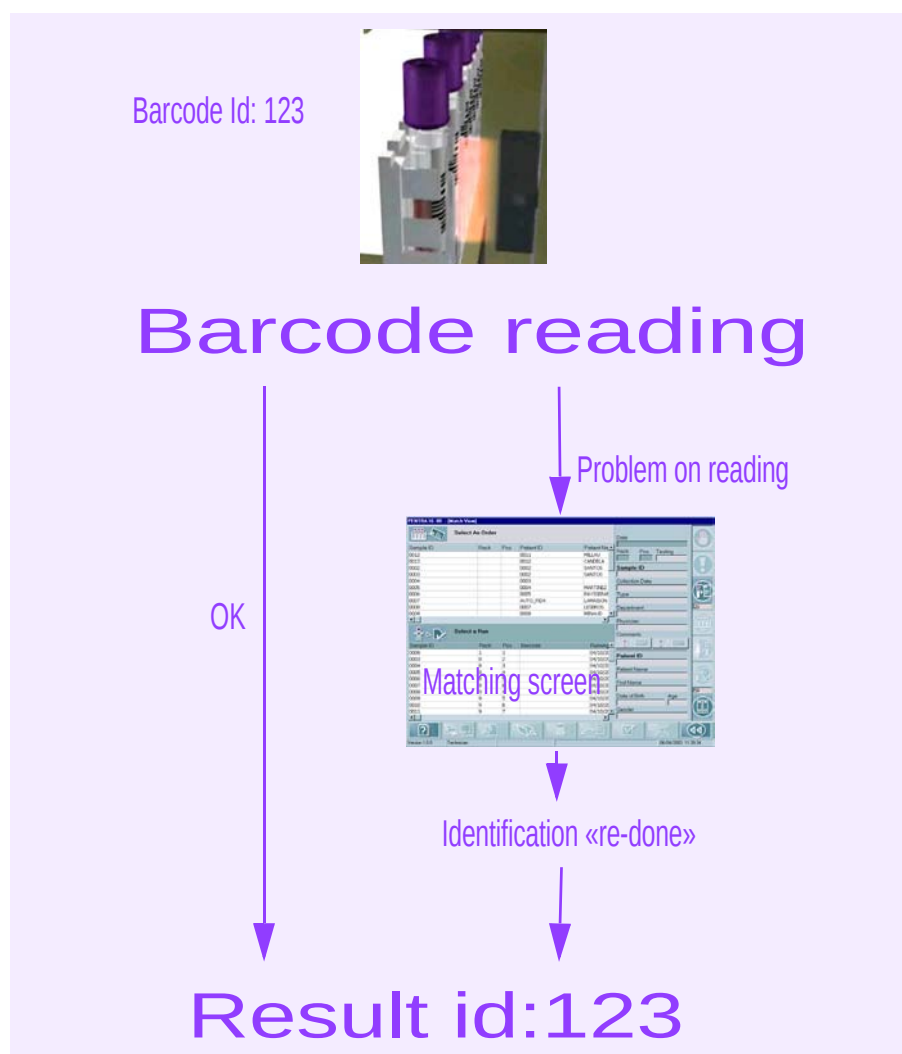
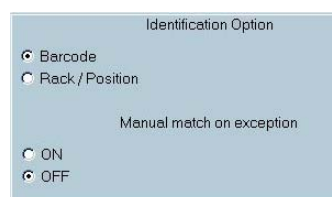


Fig. 4-2 Barcode / Manual match OFF

1.5.2. Setting: Barcode / Manual match = ON

The Pentra XL 80 tab: «Settings/Soft parameters/General tab/barcode option» is set as shown:
(See Section 5: Settings, **2.2.5. Identification option**, page 5-7)

Identification Option

☒ Barcode
☐ Rack / Position

Manual match on exception

☒ ON
☐ OFF

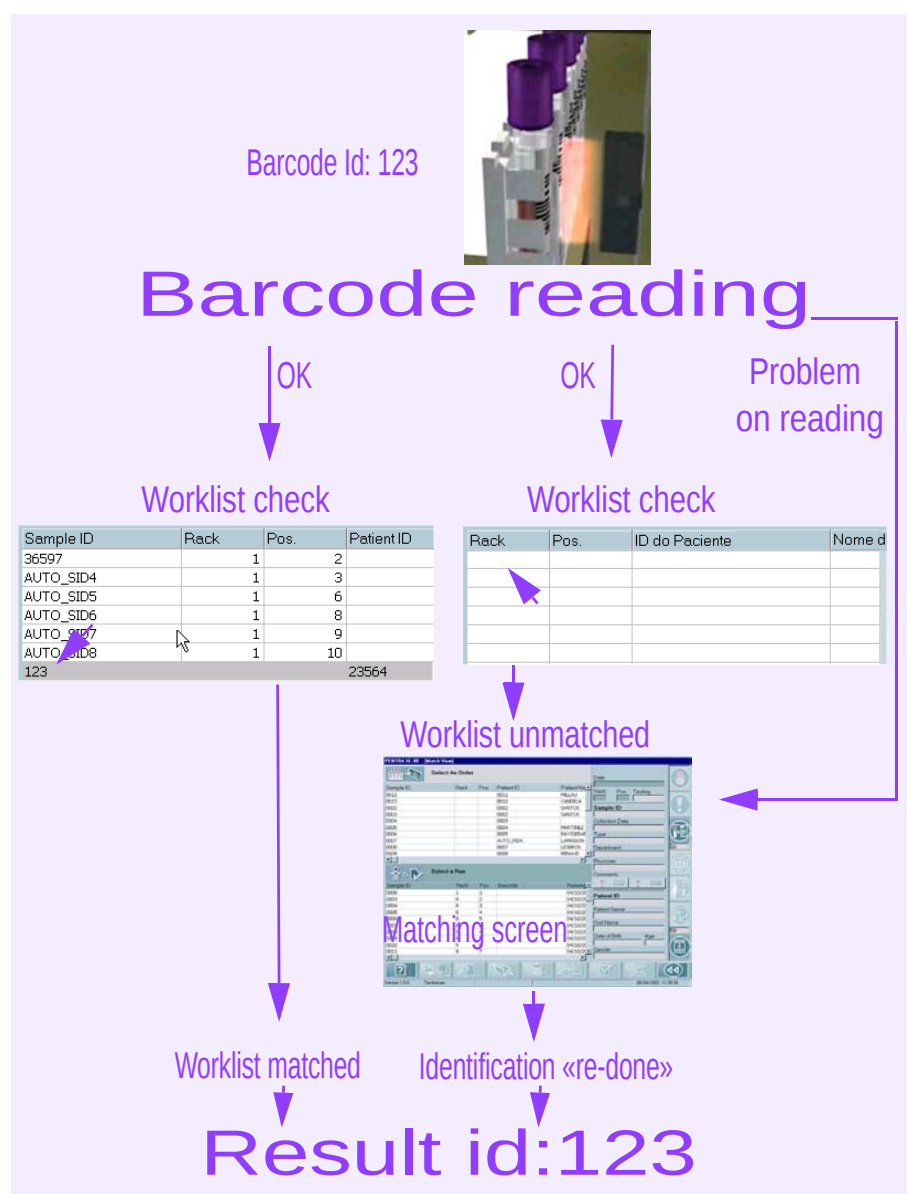


Fig. 4-3 Barcode / Manual match ON

1.6. Sample identification on Rack/position

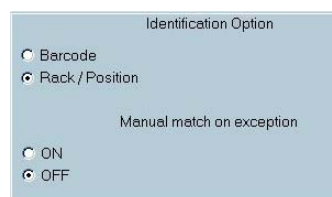
Setting: «*Rack / Position*» (See Section 5: Settings, **2.2.5. Identification option**, page 5-7), i.e. that the identifier is given by the sample position on the rack.

When a Barcode label is not used on a sample tube, the order must contain the sample tube position in the rack. The «Sample ID» field is now available for manual entry, but it is not mandatory to do so.

- ◆ If the sample tube position in the rack was indicated, the Run results will contain sample identification.
- ◆ If not, the instrument assigns an auto numbering («AUTO_SID_xxx») to ensure that the final Run results for this sample contains a single identification.

1.6.1. Setting: Rack/position / Manual match = OFF

The Pentra XL 80 tab: «*Settings/Soft parameters/General tab/barcode option*» is set as shown:
(See Section 5: Settings, **2.2.5. Identification option**, page 5-7)



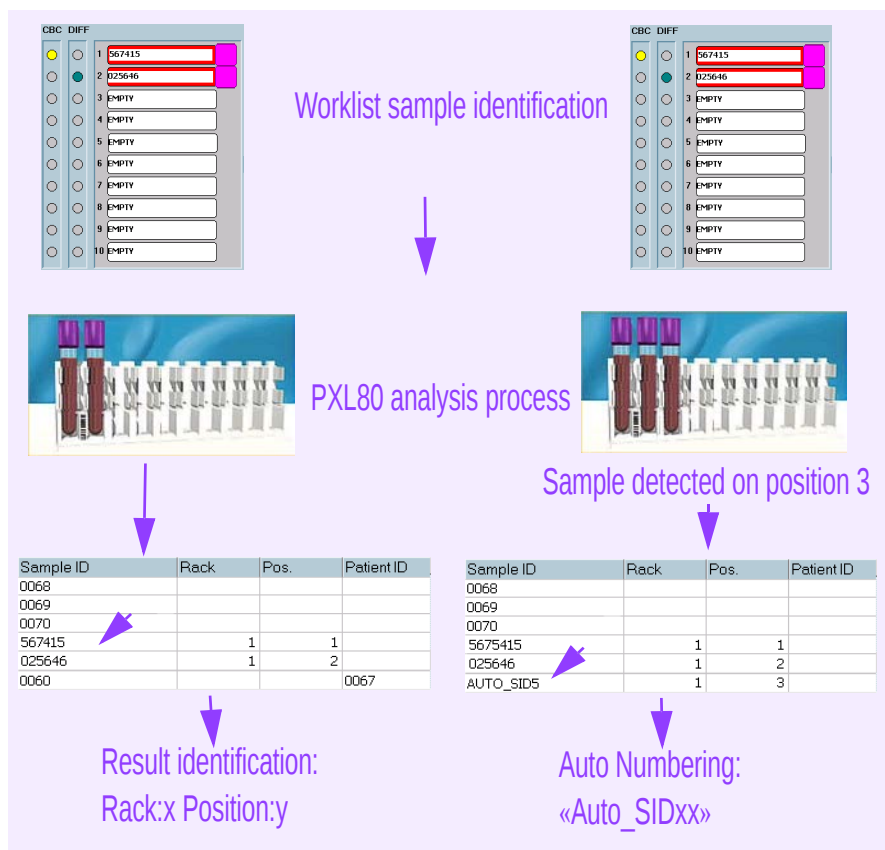


Fig. 4-4 Rack position / Manual match OFF

1.6.2. Setting: Rack/position / Manual match = ON

The Pentra XL 80 tab: «Settings/Soft parameters/General tab/barcode option» is set as shown:
(See Section 5: Settings, **2.2.5. Identification option**, page 5-7)

Identification Option

☐ Barcode

☒ Rack / Position

Manual match on exception

☒ ON

☐ OFF

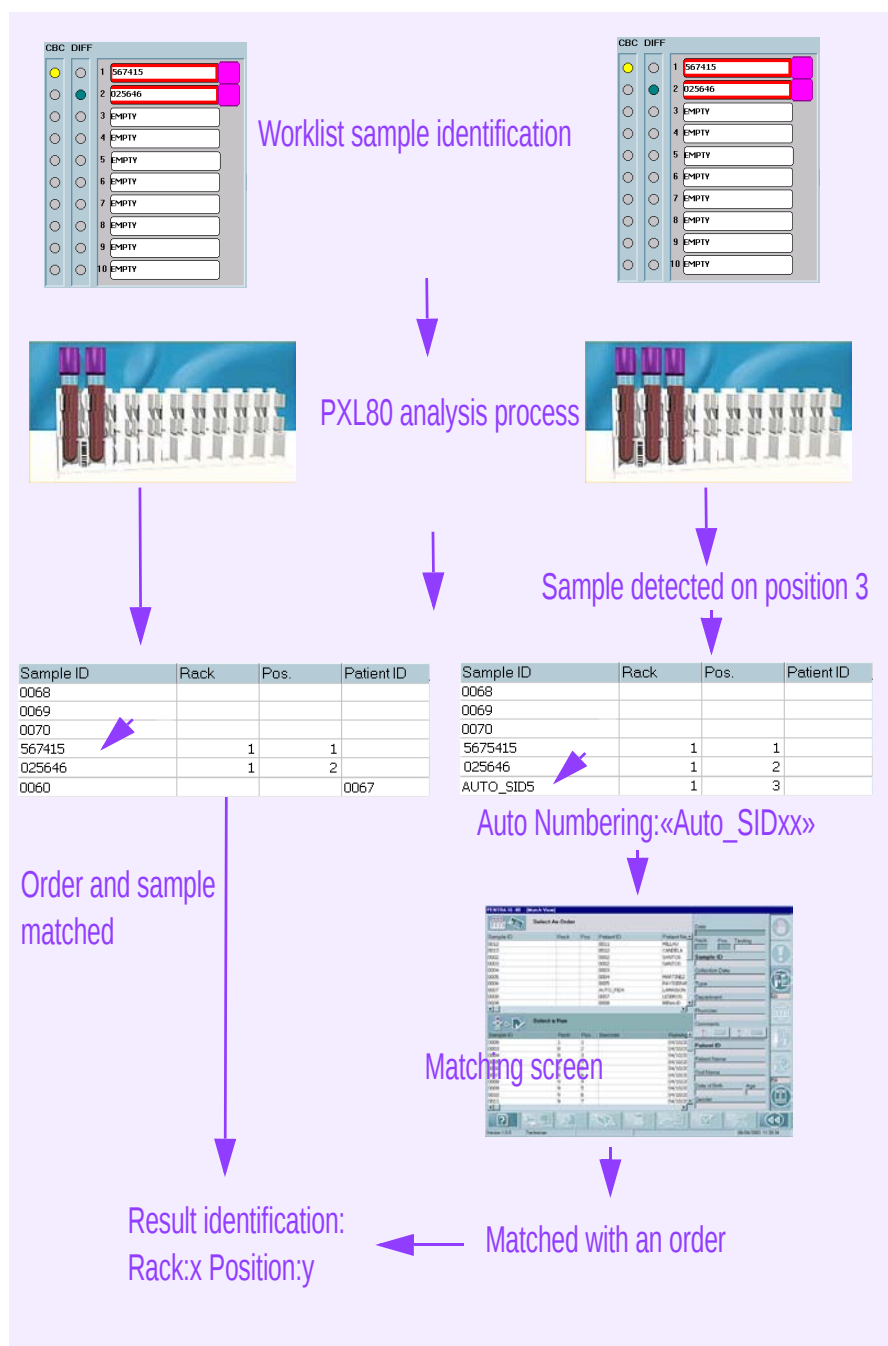


Fig. 4-5 Rack position / Manual match ON

1.7. Exception management

The usual sample identification management is the automatic and secure matching of orders with the corresponding sample tubes.

Exceptions will occur when automatic matching is impossible. For instances, when a sample tube is found in a non-defined position in the worklist, or when a barcode label cannot be read

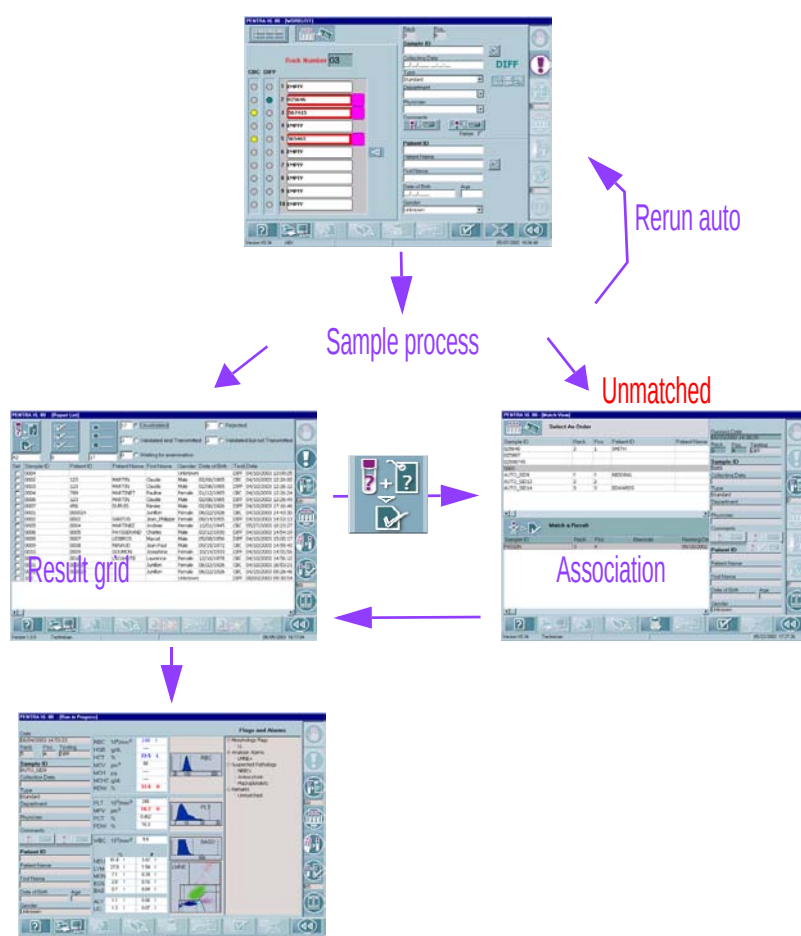


Fig. 4-6 Order/result workflow

Setting the exceptions criteria must be performed in the configuration of the Setting function. «Manual match on Exception» (See Section 5: Settings, **2.2.5. Identification option**, page 5-7) defines a specific treatment of expectations. Run Results obtained for each specific expectation condition are saved in a specific screen, which allows the matching of identified orders to non-identified runs (see **6.5.1. Association grid description**, page 4-68).

1.7.1. Sample identification on both barcode and Rack/Position

If a sample tube is identified by a barcode, although the setting is «Rack / Position» (See Section 5: Settings, **2.2.5. Identification option**, page 5-7), the instrument checks that the worklist Sample ID corresponds to the tube barcode identification, and that the rack/position of the tube corresponds to the one entered in the Worklist. If not, the instrument generates an exception.

Example:

RACK

Rack: 1

Position: 1

Barcode: 123

WORKLIST

Rack:1

Position: 1

Sample ID: 124



Sample ID	Rack	Pos.	Patient ID
0068			
0069			
0070			
124	1	1	
36597	1	2	
0060			0067

The tube, identified «123» position 1/1, does not correspond to the order position 1/1 which is identified «124».

- ◆ This tube is analyzed in the instrument default test.
- ◆ The result and the order must be manually matched.

1.7.2. Identification with barcode, without order

However Pentra XL 80 does not generate an exception in this case, provided that the rack/position of this tube, has not been reserved for an order in the worklist.

Example:

RACK

Rack: 1

Position: 1

Barcode: 123

WORKLIST

Rack:

Position:

Sample ID:



Rack	Pos.	ID do Paciente	Nome d

- ◆ This tube is analyzed in the instrument default test.
- ◆ If the setting is «Manual match on Exception = ON» (See Section 5: Settings, **2.2.5. Identification option**, page 5-7), the Sample ID provided with the result is the barcode.

It is important to define the specific working method for sample identification in your laboratory:

- ◆ Systematic use of barcodes must be defined as: «Barcode».
- ◆ If barcode are not used, select «Rack / Position».
- ◆ If both Barcode and Rack/position are used, select the «Rack / Position».

1.8. Sample runs and order association

This screen allows manual matching between sample runs and worklist orders that have been classified as «exceptions».

This screen will show 2 lists:

- ◆ Sample Runs, found by the instrument and defined as «Non-matched».
- ◆ Sample Runs that are «Non-matched» to Orders

To match the Runs of non identified tubes with orders see [6.5. Run /order association](#), page 4-68.



Matching non identified Runs with order, never modifies orders.

1.9. Rerun conditions

Automatic Rerun is performed according to the rules defined in the «Settings» function (See Section 5: Settings, [4.3. Rerun conditions](#), page 5-17), if an order has been created in the Worklist and if the sample run is matched with the order.



If none order has been created in the Worklist, the run is identified with an auto numbering, then no Rerun will occur.

▼ Scenario #1 allowing automatic Rerun

The Setting is : «Rack / Position» and «Manual match on Exception = OFF»,

The order has been created by «Rack position»

The order is identified by an AutoSID or a SID

The run has been matched with the order

▼ Scenario #2 allowing automatic Rerun

The Setting is : «Barcode» and «Manual match on Exception = OFF»,

A barcode has been read

The order has not been created

▼ Scenario #3 allowing automatic Rerun

The Setting is : «Barcode» and «Manual match on Exception = ON»,

The order has been created

The order is identified by a SID

The run has been matched with the order.

1.10. Patient file management

The Pentra XL 80 Patient file management enables the filling of orders if the patient demographic data is known.

- ◆ If no data is placed into the «Patient ID» field, an automatic identification number is created as followed: «AUTO_PID_xxx». This mode will create limitations for sample processing!
- ◆ It is highly recommended that you use the «Patient ID» field to create a single Patient ID for each patient sample. This field is highly necessary to create patient files that can be archived and easily associated with (searching on «Patient ID» criteria) in order. Patient demographical data can only be modified when it is «Manually» created on the instrument. The Host computer can only modify patient demographical data that has been transmitted to the instrument by a LIS. When a patient file is modified (by the LIS or manually by the user), all previous reports attached to that file are flagged!

1.11. Loading Worklist from the LIS

The Pentra XL 80 contains communication connections for Bi-directional transmission to and from a Host computer.

A single Patient ID always identifies Worklist orders generated from the Host computer.

When loading from the Host, if identification number of the tube already exists in the worklist, previous order will be updated to include the last modifications of the new order.

Remember, it is impossible to update the order on the instrument when it has been transmitted to the instrument from the Host computer.

2. Worklist description

2.1. Overview

A worklist is a list of orders generated on a daily basis. These orders can include:

- ◆ Orders for samples that have not been analyzed
- ◆ Orders for samples that have been analyzed, but a «Rerun» status has been requested. Reruns can be automatic according to the settings in «System Rules» (See Section 5: Settings, [4.3. Rerun conditions](#), page 5-17) or Manual reruns from the «Report» screen (see [6.4. Rerunning sample manually](#), page 4-64).

Once the sample order has been analyzed and automatically matched to an order, the orders are removed from the worklist.

The orders are also removed from the worklist when the operator manually matches them to a result (see [6.5.3. Runs/orders matching](#), page 4-69).

Orders can be entered into the Worklist as followed:

- ◆ Manually from the Worklist (see [2.3.1. Creating an order](#), page 4-17) or from the «Reports» screen, if you are requesting a «Rerun» (see [6.4. Rerunning sample manually](#), page 4-64).
- ◆ Automatically from a host computer (non modifiable)

Worklist functions are described in the following chapter sections:

- [2.2. Accessing the Worklist function](#), page 4-15
- [2.3. Worklist grid](#), page 4-16
- [2.4. Rack view](#), page 4-22

2.2. Accessing the Worklist function

Select the «Worklist» key on the generic toolbar.

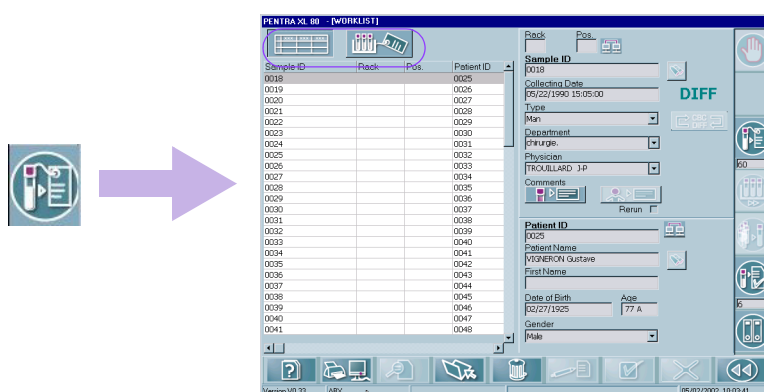
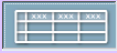


Fig. 4–7 Worklist access

The worklist is available in two screens with use of the following buttons:

▼ Worklist view selection keys

Heading / Key	Name	Function
	Grid view key	Displays the worklist grid view (see 2.3. Worklist grid , page 4-16)
	Rack view key	Displays the Rack view (see 2.4. Rack view , page 4-22). Enabled if the barcode option is on Rack/Position (see 1.3. Worklist , page 4-4)

Tab. 4-1: Worklist selection keys

The order «Capture/Modification» is available on the right-hand side of these screens from both worklist views.

2.3. Worklist grid

[2.3.1. Creating an order](#), page 4-17

[2.3.2. Contextual toolbar keys](#), page 4-18

[2.3.3. Grid functions](#), page 4-18

[2.3.4. Order information fields](#), page 4-19

[2.3.5. Searching by sample ID](#), page 4-20

[2.3.6. Searching by patient name](#), page 4-20

[2.3.7. Printing out the worklist](#), page 4-21

The left part of the screen shows the list of orders (the left/right slider allows the display of hidden information on the orders). The right part allows the creation/modification of the orders in the «Edit» mode.



The Worklist patient file management depends on the specific working method for sample identification in your laboratory. (see [1. Workflow](#), page 4-3).

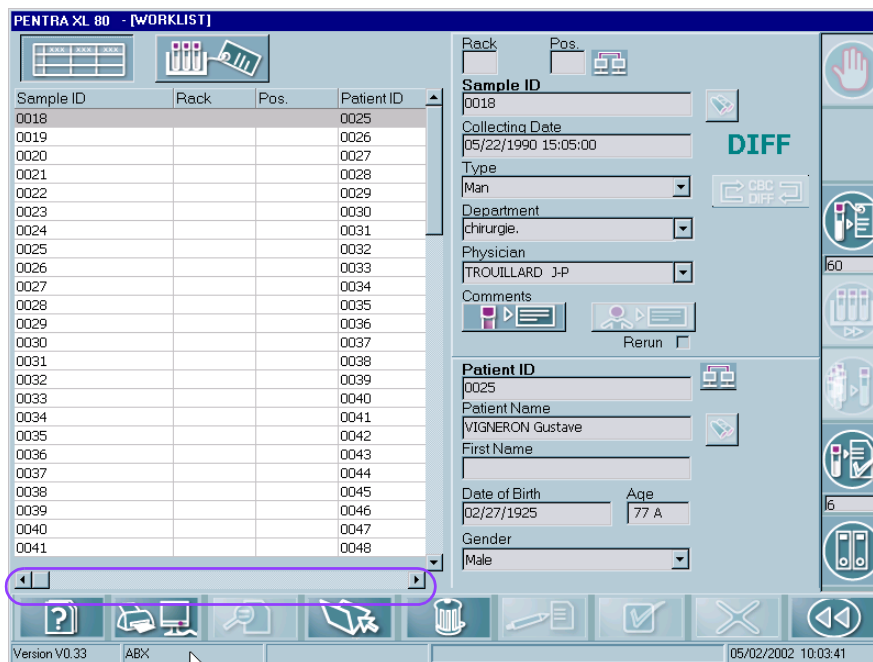


Fig. 4-8 Worklist grid

2.3.1. Creating an order

From the «Worklist grid», select the «Insert» key (see [Tab. 4-2: Function Keys](#), page 4-18) to create a new order.

Fill in the order information using the right part of grid screen (see [Tab. 4-3: Order fields](#), page 4-19).

Select the test to be performed by clicking the «CBC/DIFF» key

(Refer to [1.4. Sample identification](#), page 4-5)

Then select the «OK» once all entries have been made.

2.3.2. Contextual toolbar keys

Heading / Key	Name	Function
	Edit	Modification of an order: - Rack and position fields, Sample ID are not modifiable. - Orders transmitted from the host can not be modified too.
	Insert	Entry of a new order (Rack and Position fields are not available for data entry)
	Delete	Deletes orders (except if the rack is in the process of being analyzed)
	Print	Prints worklist (see 2.3.7. Printing out the worklist , page 4-21)

Tab. 4-2: Function Keys

2.3.3. Grid functions

- ◆ When the user selects a «line» of information, the order details are displayed on the right hand side of the screen.

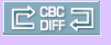
Sample ID ++	Rack	Pos.	Patient ID
025646	3	2	SMITH
025987			
02598745			
565465	3	5	JONES
AUTO_SID1	3	1	REDDING
AUTO_SID4			ELEONOR

Rack	Pos.	Patient ID --	Patient Name
3	2	SMITH	
3	1	REDDING	
3	5	JONES	Marleen
		ELEONOR	MIKA

Fig. 4-9 Sorting out by title clicked

- ◆ Select a column description (or title) to sort out the items within:
 - One click for ascending order (++)
 - Two clicks for descending order (--)
 - Three clicks to restore the initial order.
- ◆ Multiple selections are not allow at this time. Only one selection at a time.

2.3.4. Order information fields

	Heading / Button	Function	Format
Sample Information	Rack	Number of rack in which the tube is placed	2 characters
	Pos. 	Tube position in the rack. Button displayed, if the Rack position has been received from the host	from 1 to 10
	Sample ID 	Entry of Sample ID Search sample key: (see 2.3.5. Searching by sample ID , page 4-20)	16 characters
	Type	Type associated to the blood characteristics (See Section 5: Settings, 8. Sample Types , page 5-43)	Selection list (20 characters max)
	Test Button 	Selection of CBC or DIFF mode Enabled if the software is in «EDIT» or «INSERT» mode.	Default test is displayed
	Sample comment 	Opens a «Sample comments» window	50 characters
	Rerun	Indicates that order is a Rerun	checked box
Clinical information	Department	Department requesting the order (See Section 5: Settings, 2.3. Department/Physicians tab , page 5-8)	Selection list or capture enabled (20 characters max)
	Physician	Physician requesting the order (See Section 5: Settings, 2.3. Department/Physicians tab , page 5-8)	Selection list or capture enabled (20 characters max)
	Collecting date	Date and time of the specimen collection	Date/time
Patient Information	Patient comment 	Opens a «Patient comments» window	50 characters
	Patient ID 	Entry of Patient ID Search Patient key: (see 2.3.6. Searching by patient name , page 4-20)	25 characters
	Patient name	Entry of patient name	20 characters
	First name	Entry of patient first name	5 characters
	Date of birth	Entry of patient date of birth	edit box
	Age	Patient age	5 characters
	Gender	Male, Female or Unknown	drop down list
	Patient data 	If displayed, indicates that patient data has been received from the Host	

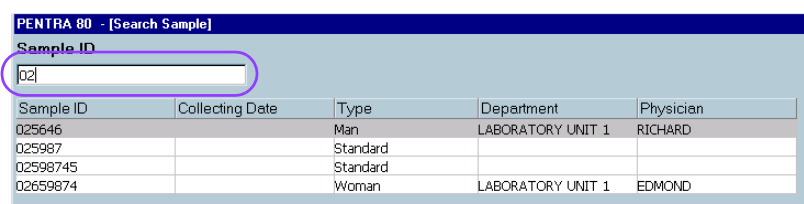
Tab. 4-3: Order fields

2.3.5. Searching by sample ID

The operator has the ability to select a specific sample record from the Sample ID field. Just select the «Search Sample» key. (see **Tab. 4-3: Order fields**, page 4-19).

The «Search Sample» key is accessible if the «Edit» or «Insert» mode has been selected.

Once the «Search Sample» key has been selected, the following screen will be displayed:



Sample ID	Collecting Date	Type	Department	Physician
025646		Man	LABORATORY UNIT 1	RICHARD
025987		Standard		
02598745		Standard		
02659874		Woman	LABORATORY UNIT 1	EDMOND

Fig. 4-10 Search by sample ID screen



Only the samples recorded in the Worklist are displayed in the «Search Sample» window! «Samples in progress» will not be displayed!

The «Sample ID» field enables the user to type in the first characters of the sample ID desired. As each letter is typed, the grid is refreshed to display the Sample list corresponding to the characters entered.

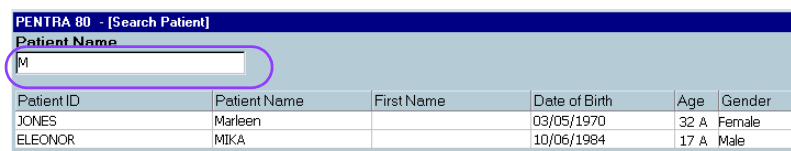
The «Sample ID» field enables the operator to view the Alpha or Numeric character sequencing as it is being typed. As each character is being typed, the Grid refreshes and displays the Sample list that corresponds to the characters entered.

When a specific «Sample ID» is located, select the «OK» key to exit the screen and return to the Worklist.

2.3.6. Searching by patient name

The operator has the ability to select a specific Patient file from the Patient Name field. Just select the «Search Patient» key (see **Tab. 4-3: Order fields**, page 4-19).

Once the «Search Patient» key has been selected, the following screen will be displayed:



Patient ID	Patient Name	First Name	Date of Birth	Age	Gender
JONES	Marleen		03/05/1970	32 A	Female
ELEONOR	MIKA		10/06/1984	17 A	Male

Fig. 4-11 Search patient window

The «Patient Name» field enables the operator to view the Alpha or Numeric character sequencing as it is being typed. As each character is being typed, the Grid refreshes and displays the Patient list that corresponds to the characters entered.

When a specific «Patient Name» is located, select the «OK» key to exit the screen and return to the Worklist.

2.3.7. Printing out the worklist

Selecting the «Print» key from the Contextual toolbar will print out the «Worklist Grid».

The following window appears (see **Fig. 4-12**, page 4-21):

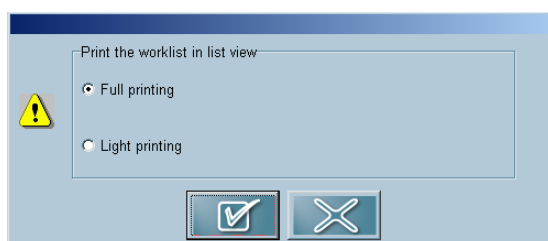


Fig. 4-12 Worklist printout window

A «Full printing» and «Light printing» mode are available:

▼ Full printing

Order informations are printed out in the grid mode: Patient, clinical, sample....(see [Fig. 4-13](#), page 4-21)

Worklist							
List							
•Rack	•Pos.	•Testing	•Sample ID	•Collecting Date	•Type	•Department	•Rerun
•Physician	•Patient ID		•Patient Name		•Gender	•Operator	
•Sample Comments	•Patient Comments				•First Name	•Date of Birth	•Age
•3	•2	•DIFF	•AUTO_SID13		•Standard	•	
•			•		•Unknown	•Technician	•False
•					•	•	•
•							
•							
•3	•3	•DIFF	•AUTO_SID14		•Standard	•	
•			•		•Unknown	•Technician	•False
•					•	•	•
•							
•							
•							

Fig. 4-13 Worklist grid printout

▼ Light printing

A light printout of the Worklist (one order by line) is also available:

Select the «Light printing» option and press the «OK» button (see [Fig. 4-14](#), page 4-21).

Worklist									
List									
Rack	Pos.	Sample ID	Patient ID	Patient Name	First Name	Testing	Type	Age	Refu
		54453	AUTO_PID4	t1		DIFF	Man		No
		24543	test1			DIFF	Standard		No
		ethikidsrvkhl	AI (T1) PID5	t2		DIFF	Man		No

Fig. 4-14 Worklist light printout

2.4. Rack view

When no barcode are used, the order must contain the sample tube position in the rack (see **1.6. Sample identification on Rack/position**, page 4-8).

From the «Worklist grid» select the «Rack view» key

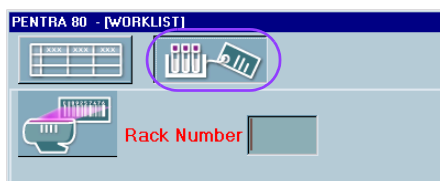


Fig. 4-15 Capture of the rack number

Read the «Rack Number» with the External Barcode reader to display the Rack graphics screen.

This «Rack View» will display the order information and test type requested for each position on the rack.

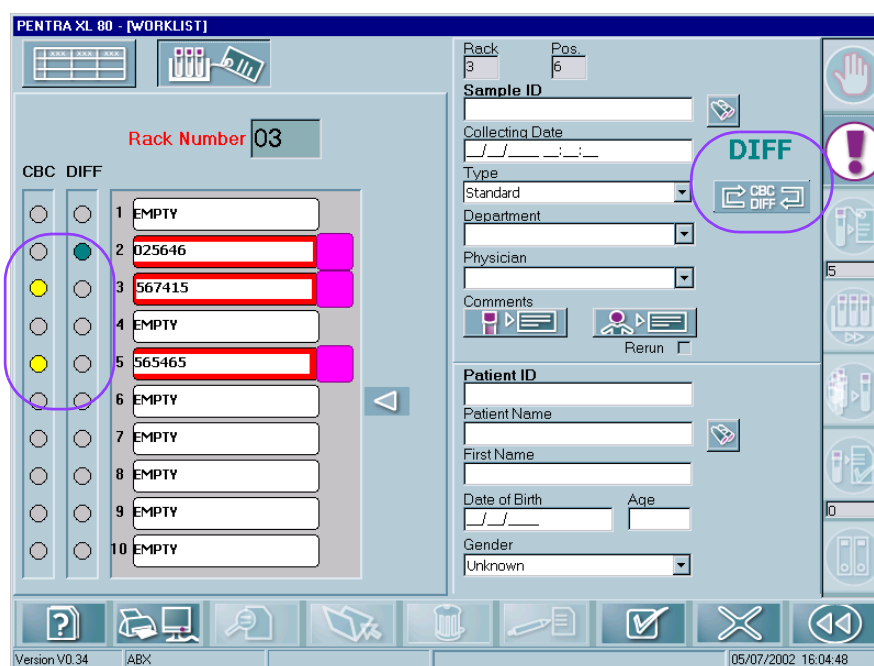


Fig. 4-16 Rack view screen

Select one empty position to enter a new sample tube.

Fill in the order field information (see **Tab. 4-3: Order fields**, page 4-19):

- Sample Information,
- Clinical information
- Patient Information

Select the test type to be performed on the sample. Note the color of the indicators:

- ◆ DIFF in Green
- ◆ CBC in yellow

If a test type is not selected, an instrument Default test is performed (DIFF).

The cursor automatically moves to the next rack position. (If no positions are available, the cursor then moves to the next rack number)

2.4.1. Auto-Numbering

If a «Sample ID» is not entered into a sample tube position, an Auto-number is given to the order as indicated:

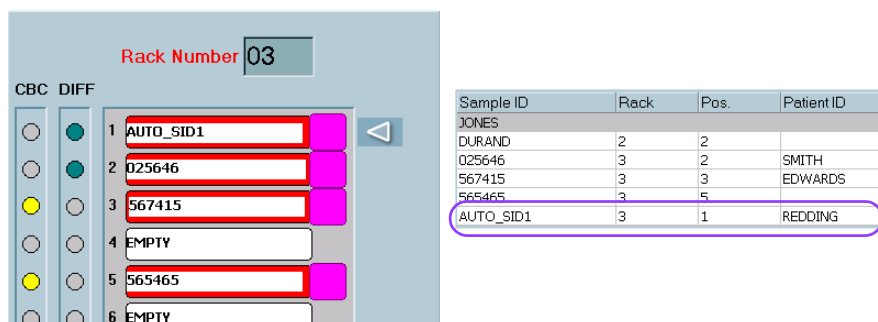


Fig. 4-17 Rack auto_numbering

Select the «Worklist Grid view» key (see [Tab. 4-1: Worklist selection keys](#), page 4-16) to display orders associated with the captured rack.



For more details about sample identification , refer to [1. Workflow](#), page 4-3.

2.4.2. Rack view contextual toolbar keys

Heading / Key	Name	Function
	Edit	- Modification of an order for a position already filled (except if the rack is in the process of being analyzed): - Rack and position fields, Sample ID are not modifiable.
	Delete	- Deletes orders for a position already filled (except if the rack is in the process of being analyzed) Two choices: - Emptying the rack and position fields - Deleting the order
	Print	(see 2.4.4. Printing the rack view , page 4-24)

Tab. 4-4: Function Keys

2.4.3. Rack view functions

- ◆ The operator is able to select an «Empty» tube to directly enter a new order specifically to this position (If a rack is currently being processed, order entry is not allowed).
- ◆ If the tube position is not empty, sample and patient information are displayed.

2.4.4. Printing the rack view

From the «rack view» screen, Select the «Print/send» key.

Worklist							
Rack Nb3							
•Pos.	•Physician •Patient ID •Sample Comments •Patient Comments	•Testing	•Sample ID •Patient Name	•Collecting Date	•Type •Gender •First Name	•Department •Operator •Date of Birth	•Rerun •Age
•1	•RICHARD •SMITH • •	•DIFF	•025646 •	•	•Man •Unknown •	•LABORATORY UNIT 1 •ABX •	•False •
•2	• • • •	•DIFF	•AUTO_SID13 •	•	•Standard •Unknown •	• •Technician •	•False •
•3	• •EDWARDS • •	•DIFF	•AUTO_SID14 •	•	•Man •Male •	• •Technician •	•False •

Fig. 4–18 Rack view print out

The rack view printout ticket shows:

- the patient informations
- the sample informations
- the clinical informations

3. Sample collection & mixing

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 and/or Face shields, and follow other bio-safety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent bio-safety procedures.

When collecting blood specimens, Venous blood is recommended, but Arterial blood may also be used in extreme cases. Blood collection must be placed in a Vacuum or atmospheric collection tubes.

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

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.

3.1. Recommended anticoagulant

The recommended anticoagulant is K3EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer.

K2EDTA is an acceptable alternative, as long as the sample collection is made in normal conditions. Otherwise, blood clots may be possible.

3.2. Blood sample stability

Specimens may be used between 15/20 minutes after collection. The results on all parameters depend on the mode of conservation of the sample.

Depending on the parameter to be measured, the sample stability may be upto 48 hours.

Refer to Section 2: Specifications, **3. Summary of performance data**, page 2-7.

3.3. Microsampling

The «Open tube» sampling mode enables the user to work with 100µl microsamples (for pediatrics and geriatrics).

3.4. Mixing

The cap piercing mode performs an automatic pre-mixing cycle by rotation which lasts approximately 1 minute.

For the open tube mode, blood samples must be gently and thoroughly mixed just before placing them into the tube holder and closing the tube holder door. This will ensure a homogeneous mixture for measurement.

4. Running specimen

See Daily Guide: RAB156

▼ Recommendations on the analysis mode selection (CBC or DIFF)

When selecting CBC analysis, there is no control mode on WBC erroneous countings that may be caused by specific treatments on patients (See Section 2: Specifications, [5. Limitations](#), page 2-16) and WBC balance description (See Section 4: Workflow, [5.3.9. WBC balance](#), page 4-44).

5. Run results and associated Flags

«Runs results and associated flags» chapter includes:

- ◆ 5.1. Printer output format, page 4-27
- ◆ 5.2. Run Result screen, page 4-28
- ◆ 5.3. Flags, page 4-30

A «Report» function allows the operator to review the «Run Results» of the day (see 6. Report, page 4-51).

A «Run In Progress» function displays, Run results of the current analysis.

5.1. Printer output format

Report Printout Unvalidated

Print report date 05/04/2008 15:12:09		Sample ID 0042	Collection Date
Type Standard	Department	Physician	
Comments			
Patient ID	Patient Name	First Name	
Date of Birth	Age	Gender	Unknown
Operator			
Technician	Startup Status	Startup not done	

	Range	Flags and Alarms
RBC 	RBC 4.72 $10^9/\text{mm}^3$ HGB 11.21 g/dL HCT 40.0 % MCV 86 μm^3 MCH 23.7% pg MCHC 28.0% g/dL RDW 12.8 %	Flags Analyzer Alarms LMNE+ Suspected Pathology Hypochromia
PLT 	PLT 225 $10^9/\text{mm}^3$ MPV 10.2 h μm^3 PCT 0.231 % PDW 19.0 h %	
WBC & DIFF 	WBC 5.6 $10^9/\text{mm}^3$ % NEU 49.1% 2.59% LYM 36.3% 1.99% MON 10.1% 0.56% EOS 4.0% 0.22% BAS 0.6% 0.03% ALY 1.5% 0.08% LIC 0.8% 0.04%	LMNE

Microscopic Examination			
	+	++	+++
Anisocytosis	☐	☐	☐
Hypochromia	☐	☐	☐
Polychromasia	☐	☐	☐
Poikilocytosis	☐	☐	☐
Microcytosis	☐	☐	☐
Macrocytosis	☐	☐	☐
PLT Clumps	☐	☐	☐
Neutrophils	☐	☐	☐
Bands	☐	☐	☐
Lymphocytes	☐	☐	☐
Monocytes	☐	☐	☐
Eosinophils	☐	☐	☐
Basophils	☐	☐	☐
Metamyelocytes	☐	☐	☐
Myelocytes	☐	☐	☐
Promyelocytes	☐	☐	☐
Blasts	☐	☐	☐
ATV LYM	☐	☐	☐
Other	☐	☐	☐
Total (100%)	☐	☐	☐
NRBC's	☐	☐	☐

Out of Panic Range XXX Out of Normal Range XXX XXX

- ◆ The operator can modify the Printer output format by selecting the «Settings» function key (See Section 5: Settings, 5.4. Printer, page 5-31).

5.2. Run Result screen

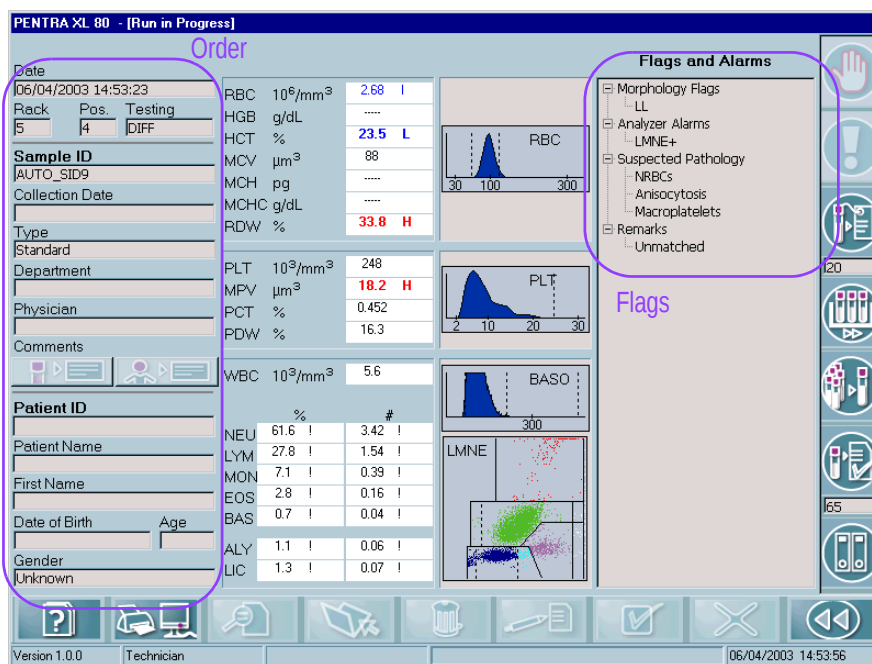


Fig. 4–19 Reports display screen

Runs of current analysis are automatically displayed as shown.

Flags appear on a «tree view» mode based on five categories:

- Morphology Flags
- Analyzer Alarms
- Suspected Pathologies
- Quality Assurance Flags
- Remarks

These flags are listed in **5.3. Flags**, page 4-30

▼ Zoom in feature

A zoom feature is available for each parameter graphic (RBC, PLT, BAS, LMNE), by selecting the histogram or matrix representation (see **Fig. 4–20**, page 4-29)

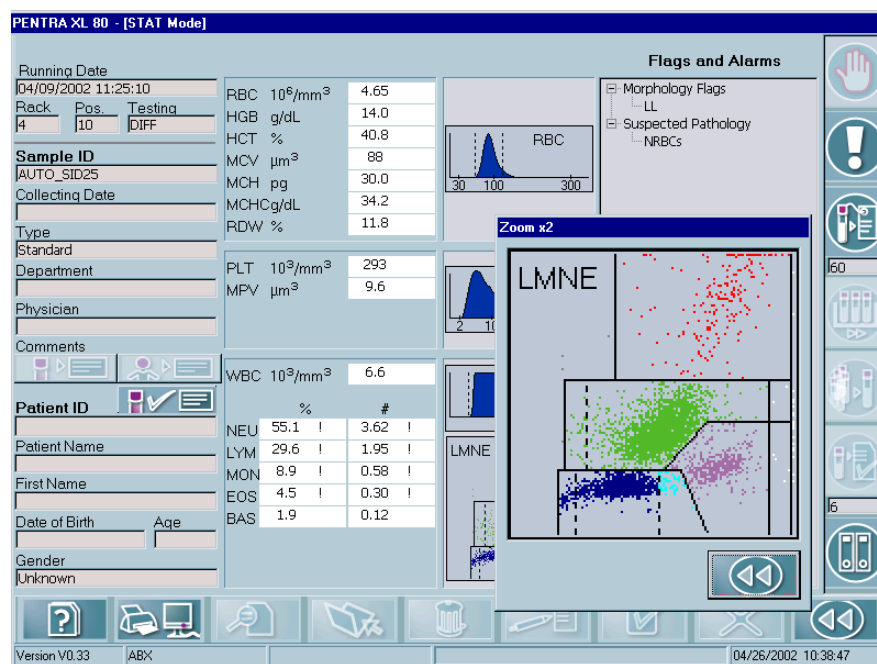


Fig. 4–20 Result display zoom

Select the «Return» key to return the display to normal.

5.3. Flags

Flags are divided up into 5 different groups:

- ◆ Flags linked to Run results that exceed the normal parameter limits:
 - **5.3.1. Normal and panic ranges**, page 4-30
- ◆ Flags linked to Run results that exceed the linear range of the instrument that leads to «Rejected Analysis»:
 - **5.3.2. Results exceeding Linear ranges of the instrument**, page 4-31;
 - **5.3.3. Analysis reject**, page 4-33
- ◆ Flags linked to an abnormal morphology in the blood cell populations, or to an anomaly during counts.
 - **5.3.4. Suspicion flags**, page 4-33
 - **5.3.5. LMNE matrix flags**, page 4-35;
 - **5.3.6. Flags on WBC/BAS histogram**, page 4-41;
 - **5.3.7. Flags on RBC histogram**, page 4-42
 - **5.3.8. Flags on PLT histograms**, page 4-42;
 - **5.3.12. Pathology messages**, page 4-47.
- ◆ Analyzer alarms:
 - **5.3.11. Analyzer alarms**, page 4-46
 - **5.3.9. WBC balance**, page 4-44
- ◆ Flags linked to statistical function:
 - **5.3.13. Statistical function flags**, page 4-50.
- ◆ Flags linked to patient history:
 - **5.3.10. Delta Check**, page 4-45



The operator can adjust the Sensitivity of each flag (See Section 5: Settings, 8. Sample Types, page 5-43)

5.3.1. Normal and panic ranges

«h» indicates that the result is above the normal limit set by the user.

«l» indicates that the result is below the normal limit set by the user.

«H» indicates that the result is above the panic limit set by the user.

«L» indicates that the result is below the panic limit set by the user.

These flags can also be criteria for the pathology messages.

5.3.2. Results exceeding Linear ranges of the instrument

(See Section 2: Specifications, **3.3. Linearity**, page 2-9)

Parameter	Linearity limits	Visible range	> Visible range
WBC	«result»	«WBC result+D» displayed and printed «WBC result+O» transmitted to the LIS*	«--- D» displayed and printed «--- O» transmitted to the LIS*
		«LYM, MON, NEU, EOS, BASO, ALY , LIC» reported to «-----»	
RBC	«result»	«RBC result+D» displayed and printed «RBC result+O» transmitted to the LIS*	«--- D» displayed and printed «--- O» transmitted to the LIS*
		«MCV, MCH, MCHC and RDW» reported to «-----»	
HGB	«result»	«HGB result+D» displayed and printed «HGB result+O» transmitted to the LIS*	«--- D» displayed and printed «--- O» transmitted to the LIS*
		«MCH and MCHC» reported to «-----»	
HCT	«result»	«HCT result+D» displayed and printed «HCT result+O» transmitted to the LIS*	«--- D» displayed and printed «--- O» transmitted to the LIS*
		«MCH and MCHC» reported to «-----»	
PLT (for HGB>2g/dL)	«result»	«PLT result+D» displayed and printed «PLT result+O» transmitted to the LIS*	«--- D» displayed and printed «--- O» transmitted to the LIS*
		«MPV, PCT and PDW» reported to «-----»	
PLT (for HGB<2g/dL, PLT>15x10 ³ /mm ³)	«result»**	«PLT result+D» displayed and printed** «PLT result+O» transmitted to the LIS*	«--- D» displayed and printed** «--- O» transmitted to the LIS*
		«MPV, PCT and PDW» reported to «-----»	

Tab. 4-5: Results exceeding Linear ranges of the instrument

* ABX format.

** A «Platelet Concentrate Mode» message will be displayed and printed for an HGB<2g/dL and PLT>15x10³/mm³.

▼ CDR Mode

(See Section 2: Specifications, **3.9. CDR Mode specifications**, page 2-13)

Parameters	> Dilution ratio value	> Dilution ratio value visible ranges
WBC CDR mode	RBC Value between brackets + D «(value)D» printed and displayed «(value)0» transmitted to the LIS*	WBC replaced with «(---) D» «(---) D» printed and displayed «(---)0» transmitted to the LIS*
RBC CDR mode	RBC Value between brackets + D «(value)D» printed and displayed «(value)0» transmitted to the LIS*	RBC replaced with «(---) D» «(---) D» printed and displayed «(---)0» transmitted to the LIS*
HGB CDR mode	HGB Value between brackets + D «(value)D» printed and displayed «(value)0» transmitted to the LIS*	HGB replaced with «(---) D» «(---) D» printed and displayed «(---)0» transmitted to the LIS*
HCT CDR mode	HCT Value between brackets + D «(value)D» printed and displayed «(value)0» transmitted to the LIS*	HCT replaced with «(---) D» «(---) D» printed and displayed «(---)0» transmitted to the LIS*
PLT CDR mode (for HGB>2g/dL)	PLT Value between brackets + D «(value)D» printed and displayed «(value)0» transmitted to the LIS*	PLT replaced with «(---) D» «(---) D» printed and displayed «(---)0» transmitted to the LIS*
PLT CDR mode (for HGB<2g/dL, PLT>15X10 ³ /mm ³)	PLT value between brackets + D «(value)D» printed and displayed «(value)0» transmitted to the LIS*	PLT replaced with «(---) D» «(---) D» printed and displayed «(---)0» transmitted to the LIS*

Tab. 4-6: Results exceeding Linear ranges of the instrument in the CDR Mode

* ABX format.

5.3.3. Analysis reject

A reject flag (shown by *) occurs when two counts on a parameter differ more than the pre-defined limits. It indicates that the parameter result is inconclusive and should be investigated for (Manual) rerun status and/or instrument malfunction if consistent on every sample.

▼ RBC

If the RBC parameter is rejected, the MCV, MCH, MCHC, and RDW parameter results are replaced by «---» and/or have the «*» indicator.

▼ WBC

If the WBC parameter is rejected, the diff. parameter results are replaced by «---» and/or have the «*» indicator.

▼ PLT

If the PLT parameter is rejected, the PCT, MPV, and PDW parameter results shall be replaced by «---» and/or have the «*» indicator.

▼ LMNE

- ◆ A reject on the LMNE channel indicates a poor correlation between the resistive and the optical measurements on the matrix. It is shown by a «*» on all the differential parameters in % and #. The results are not reliable and specimen must be re-analyzed.
- ◆ NO flag: (see **NO flag**, page 4-35)

5.3.4. Suspicion flags

▼ Plt

A suspicion flag (!) on PLT parameter indicates the detection of a possible anomaly during platelet count.

Conditions	Triggered flag	Consequences
If PLT message «Platelets Aggregates» occurs and if PLT < PLT L (PLT low Normal limit defined by the user as described in 5.3.1. Normal and panic ranges, page 4-30)	(!) on PLT and on PDW, MPV, PCT	Plt result needs to be confirmed according to Good Laboratory Working Practices
If MCHC or MCH parameters are outside Panic limits (defined by the user as described in 5.3.1. Normal and panic ranges, page 4-30)		
If PLT < $120 \times 10^3 / \text{mm}^3$ (in CBC mode only)		
If PLT < $120 \times 10^3 / \text{mm}^3$ + PDW > 20 (in DIFF mode only)		



No automatic validation can occur when PLT parameter has been suspected (!).

▼ Hemoglobin

- ◆ A «!» suspect flag is generated if two consecutive Hemoglobin blank measurements are different from the pre-defined value in «Settings / Type Parametering / Alarms and Curves Threshold Tab / Alarm Level Grid / HGB parameter absolute value» (See Section 5: Settings, **8.3.1. Alarm levels**, page 5-47).
- ◆ A «!» suspect flag is generated if the three Hemoglobin measurements are different from the pre-defined value in «Settings, Type Parameterising, Alarms and Curves Threshold Tab, Alarm Level Grid, HGB parameter percent value» (See Section 5: Settings, **8.3.1. Alarm levels**, page 5-47).
- ◆ If 3 consecutive «!» suspect flags are noted on Hemoglobin during «Sample Analysis», the Hemoglobin value will be rejected and replaced with «---».
- ◆ During instrument «STARTUP», the HGB Blank measurement value is pre-defined from fresh Diluent. If the Blank value is not within the measured limits, the message «Startup Failed: HGB Blank» will be displayed.

▼ LMNE

- ◆ When WBC populations are detected in abnormal quantities in one or more areas of the LMNE matrix, a «!» suspect flag will be displayed next to the parameter(s) in question. If one result appears with one or several parameters that display a «!» suspect flag, the result should be further investigated. (Pathology suspicion, clotted sample, plasma cells, etc...).
- ◆ A suspicion flag «!» is generated on the BAS#, BAS%, LYM#, LYM%, MON#, MON%, NEU# and NEU% parameter results if Hgb > 17,5 g/dl or invalid «---».
- ◆ If a suspicion flag «!» on WBC occurs, then «!» is also generated on BAS#, BAS%, LYM#, LYM%, MON#, MON%, NEU#, NEU% , ALY#, ALY%, LIC#, LIC% parameter results.
- ◆ If a flag LMNE+ or LMNE- or BASO+ (see **5.3.9. WBC balance**, page 4-44) is triggered, then a suspicion flag «!» on WBC parameter is generated too.

▼ RBC

Conditions	Triggered flag	Consequences
If MCHC or MCH parameters are outside Panic limits (defined by the user as described in 5.3.1. Normal and panic ranges , page 4-30)	(!) on RBC	(!) on HCT, MCV

5.3.5. LMNE matrix flags

▼ NO flag

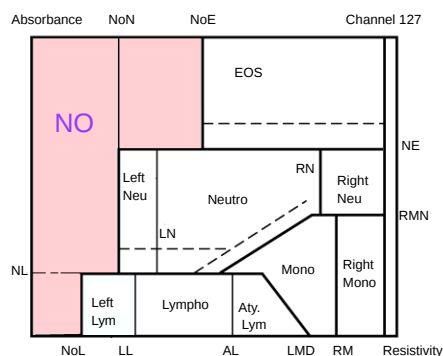


Fig. 4–21 No flag

Standard value for NO:

– %100 #120

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Background **NO**ise.

This flag occurs when the number of particles counted in the background noise area is higher than the limit set up in **NO#** or when the number of counted particles versus the total number of WBC, is above the **NO%** limit.

Suspected abnormalities:

- Platelet aggregates,
- Large number of platelets,
- Erythrocyte membrane resistant to lysis (stroma),
- NRBCs,
- Pollution.



This alarm appears in the «Analyzer Alarms» area on the screen and the printout.

▼ LL flag

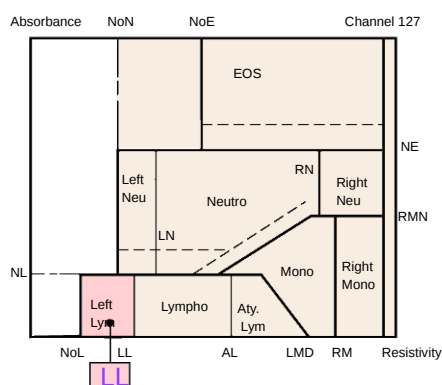


Fig. 4-22 LL flag

Standard value for LL:

– %100 #50

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Left Lymphocytes

Presence of a significantly large population on the left-hand side of the lymphocyte area. This flag appears when the number of particles counted is higher than the limit set up in **LL#** or when the number of counted particles versus the total number of WBC exceeds the **LL%** limit.

Suspected abnormalities:

- Small lymphocytes,
- Platelets aggregates,
- NRBCs,
- Erythrocyte membrane resistant to lysis (stroma).

This flag is associated with an (!) on:

- LYM% LYM#
- NEU% NEU#
- MON% MON#
- EOS% EOS#
- ALY% ALY#
- LIC% LIC#

▼ LL1 flag

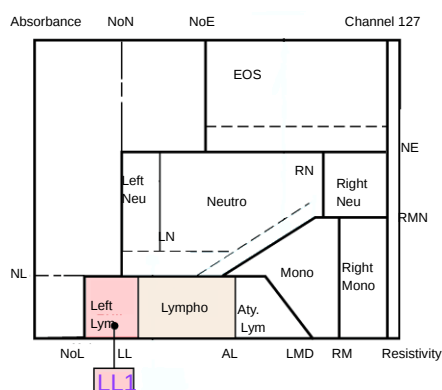


Fig. 4-23 LL1 flag

Standard value for LL1:

– %5 #45

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Left Lymphocytes 1

Presence of a significantly large population of cells on the left-hand side of the lymphocytes area. This flag occurs when the number of particles counted is higher than the limit set up in **LL1#** and when the number of particles counted in **LL** regarding the total number of lymphocytes is above the **LL1%** limit.

Suspected abnormalities:

- Platelet aggregates,
- NRBCs,
- Erythrocyte membrane resistant to lysis (stroma),
- Stroma,
- Small abnormal lymphocytes.

▼ NL flag

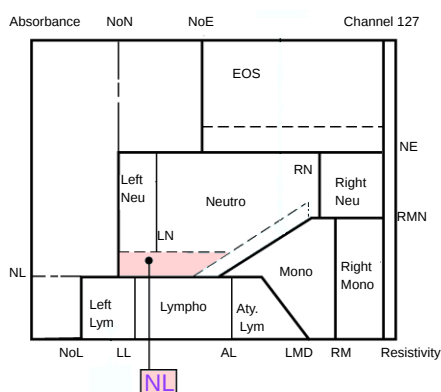


Fig. 4-24 NL flag

Standard value for NL:

– %3 #120

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Neutro/Lympho

Presence of a significantly large population of cells located in the separation threshold area between lymphocytes and neutrophils. This flag occurs when the number of particles counted in this area is higher than the limit set up in **NL#**, or when the number of counted particles regarding the total number of WBC is above **NL%** limit.

Suspected abnormalities:

- Small neutrophils without granules and/or slightly segmented,
- Lymphocytes with a segmented nucleus or Activated Lymphocytes,
- Neutrophils with membrane weakness.

This flag is associated with an (!) on:

– LYM% LYM#

– NEU% NEU#

▼ MN flag

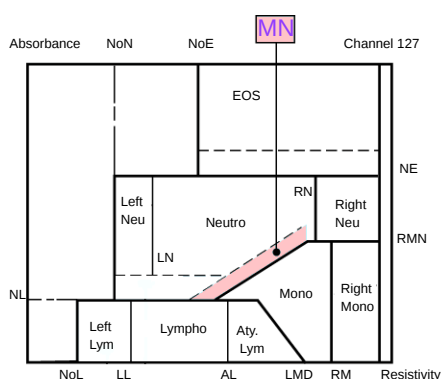


Fig. 4-25 MN flag

Standard value for MN:

– %100 #120

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Mono/Neutro

Presence of a significantly large population of cells located in the separation threshold area between monocytes and neutrophils. This flag occurs when the number of particles counted in this area is higher than the limit set up in **MN#** or the number of particles counted in MN versus the total number of WBC is above the **MN%** limit.

Suspected abnormalities:

- Monocytes having granules in their cytoplasm or hyperbasophilic monocytes,
- Young neutrophils with non-segmented nuclei (bandcells).

This flag is associated with an (!) on:

– ALY % ALY #

– LIC % LIC #

and replaces:

– NEU% NEU#,

– MON% MON#

by «---»

▼ LN flag

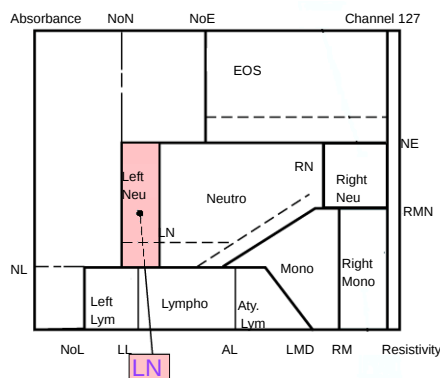


Fig. 4-26 LN flag

Standard values for LN:

– %2,5 #999

Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47

Meaning: Left Neutro

Presence of a significantly large population of cells located on the left-hand side of the neutrophil area. This flag occurs when the number of particles counted in this area is higher than the limit setup in **LN#** or when the number of particles counted regarding the total number of WBC is above **LN%** limit.

Suspected abnormalities:

- Neutrophil destruction due to incorrect storage of the sample or an old sample,
- Contamination, stroma or platelet aggregates.

This flag is associated with an (!) on all WBC differential parameters.

▼ NE flag

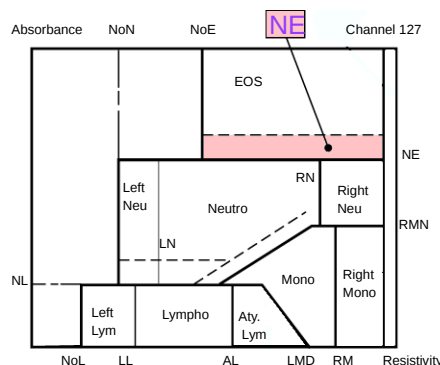


Fig. 4-27 NE flag

Standard value for NE:

– %1,1 #60

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Neutro/Eosino.

Presence of a significantly large population of cells located in the separation area between neutrophils and eosinophils because of a superimposition of the 2 populations. This flag occurs when the number of particles counted in this area is higher than the limit setup in **NE#** or when the number of particles counted regarding the total number of WBC is above the **NE%** limit.

Suspected abnormalities:

- Young eosinophils,
- Giant hypersegmented neutrophils,
- Eosinophils with low intracytoplasmic material,
- Immature cells.

This flag is associated with an (!) on:

– LIC % LIC #

and replaces:

– NEU %, NEU #,

– EOS %, EOS #

by «----»

▼ RM flag

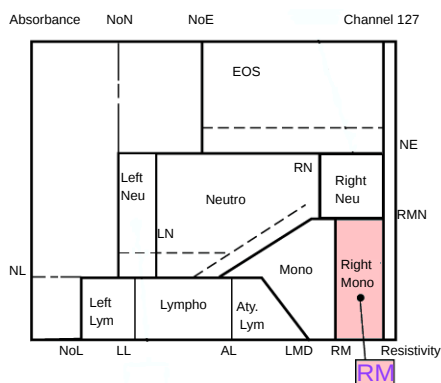


Fig. 4-28 RM flag

Standard value for RM:

– %1,1 #999

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Right Mono

Presence of a significantly large population of cells located on the right-hand side of the monocyte area (low LIC). This flag occurs when the number of particles counted in this area is higher than the limit setup in **RM#** or when the counted particles regarding the total of WBC is above **RM%** limit

Suspected abnormalities:

- Large monocytes,
- Hyperbasophilic monocytes,
- Myelocytes or promyelocytes,
- Large blasts.

This flag is associated with an (!) on:

- NEU% NEU #
- MON% MON #
- LIC% LIC #

▼ RN flag

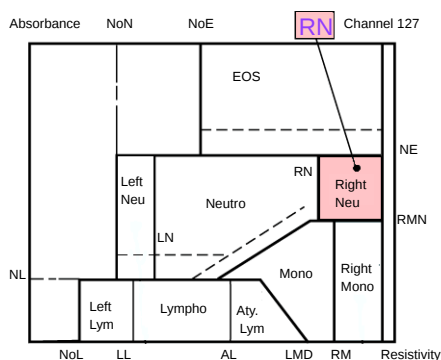


Fig. 4-29 RN flag

Standard value for RN:

– %1,1 #999

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

Meaning: Right Neutro

Presence of a significantly large population of cells located on the right-hand side of the neutrophil area (high LIC). This flag occurs when the number of particles counted in this area is higher than the limit setup in **RN#** or when the number of particles counted regarding the total number of WBC is above the **RN%** limit.

Suspected abnormalities:

- Large neutrophils,
- Immature cells from granulocyte hemopoiesis (metamyelocytes, myelocytes, promyelocytes).

This flag is associated with an (!) on:

- NEU% NEU #
- LIC% LIC #

▼ LIC flag

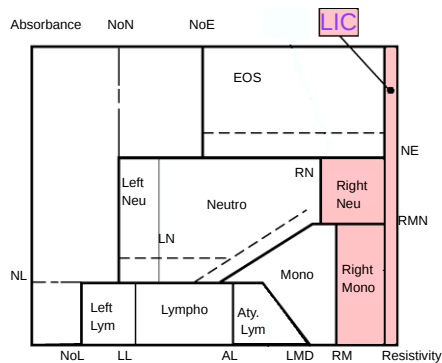


Fig. 4-30 LIC flag

Standard value for LIC: %3 #0,3

(See Section 5: Settings, **8.5. Defaults settings of the Pentra XL 80 types**, page 5-51)

Meaning: Large Immature Cells

Presence of a significantly large population of cells located on RN + RM + channel 127 areas. This flag occurs when the number of particles counted in this area is higher than the limit set up in **LIC#**, or when the number of counted particles regarding the total number of WBC is above the **LIC%** limit (See Section 5: Settings, **8.2. Pathological limits**, page 5-46).

Suspected abnormalities:

- Large monocytes,
- Hyper basophilic monocytes,
- Myelocytes, Metamyelocytes, Promyelocytes,
- Large Blasts,
- Large Neutrophils.

▼ ALY flag

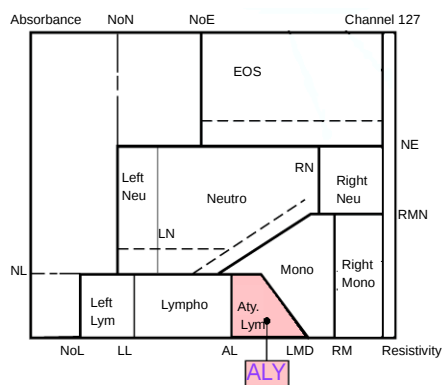


Fig. 4-31 ALY flag

Standard value for ALY: %2,5 #0,25

(See Section 5: Settings, **8.5. Defaults settings of the Pentra XL 80 types**, page 5-51)

Meaning: Atypical Lymphocytes

Presence of a significantly large population of cells located on the right-hand side of the Lymphocytes area. This flag occurs when the number of particles counted in this area is higher than the limit setup in **ALY#** or when the number of particles counted regarding the total number of WBC is above the **ALY%** limit (See Section 5: Settings, **8.2. Pathological limits**, page 5-46).

Suspected abnormalities:

- Large Lymphocytes,
- Reactive Lymphoid forms,
- Stimulated lymphocytes,
- Plasmocytes.

5.3.6. Flags on WBC/BAS histogram

▼ L1 flag (CBC and DIFF mode)



Fig. 4-32 WBC histogram

Standard value for L1: %3 #200

(See Section 5: Settings, **8.3. Alarms & Curve thresholds**, page 5-47)

L1 flag is established according to the ratio of the cells counted between the 0 channel and BA1.

L1 indicates the presence of an abnormal number of cells in comparison with leukocytes.

Suspected abnormalities:

- PLT aggregates,
- NRBCs.

L1 flag is associated with an (!) on WBC value and on absolute values of the differential parameters.



In certain cases, the L1 flag will not be triggered off because of the poor sensitivity of this flag (large platelet aggregates and/or erythroblasts) that are beyond the electronic threshold. This happens in CBC mode only. Two additional flags LL (see **LL flag**, page 4-36) and LL1 (see **LL1 flag**, page 4-36) are available in DIFF mode and provide more reliability in anomaly detection. This mode should be recommended.

▼ MB flag (DIFF mode only)

Meaning: Mono BAS

This flag occurs when the percentage of basophils found in the BAS channel is above the percentage of Lympho/Mono/Neutro raw counts, found in the LMNE matrix channel.

▼ BASO+ (DIFF mode only)

If the BAS % exceeds 50 %, a BASO+ flag is generated.

The Basophils will not be removed from the LMNE Matrix populations and a «---» will be displayed instead of the BAS % and BAS #.



This alarm appears in the «Analyzer Alarms» area on the screen and on the print-out.

5.3.7. Flags on RBC histogram

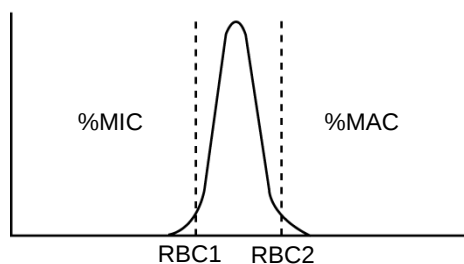


Fig. 4-33 RBC histogram

Standard values for MIC: %5

Standard values for MAC: %45

(See Section 5: Settings, [8.3. Alarms & Curve thresholds](#), page 5-47)

MIC and **MAC** flags are generated when the percentage of cells counted in the microcytic area (MIC) and macrocytic area (MAC) compared to the total number of RBCs are above the set limits for both MIC and MAC percentages set up by the user.

RBC1 and **RBC2** thresholds define the microcytic and macrocytic areas and are calculated according to the MCV and the RDW from the RBC histogram.

5.3.8. Flags on PLT histograms

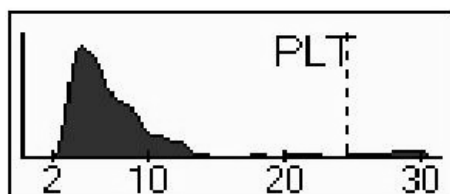
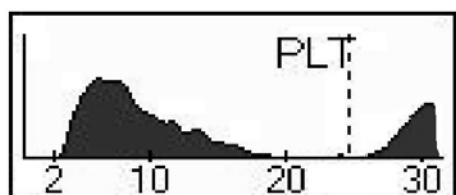


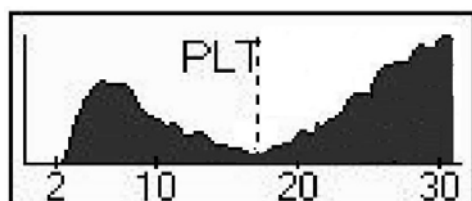
Fig. 4-34 PLT histogram

The PLT histogram contains 256 channels between 2fL and 30fL. A mobile threshold (at 25 fL by default) moves according to the microcytic RBC's that are present in the platelet analysis area.

The PLT flags are generated under the following conditions:



An excessive presence of particles on the right side of the threshold area (after 25 fL) will generate the MIC (Microcytes) flag (shown in the platelet alarm area). In this case the mobile threshold looks for a valley between 18fL and 25fL (standard area).



If the mobile threshold can not position itself in the standard area (between 18fL to 25fL), a PLT reject (*) and a MIC flag will be generated. The PLT results are not reliable. Verify the result using a Platelet Rich Plasma (PRP) or a manual platelet count.

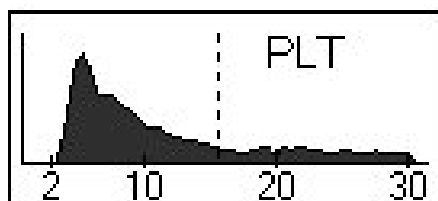


Fig. 4-35 PLT Flags

If the mobile threshold cannot be positioned (no valley between the PLT and RBC histograms) the **SCH (schistocytes)** flag will be generated.

Suspected abnormalities:

- Presence of schistocytes
 - Presence of PLT aggregates,
- Verify this abnormality by viewing the peripheral blood smear to confirm your results.

The **SCL (Small Cell)** flag will indicate the presence of small cells in the 2fL and 3fL zone. A second analysis should be carried out and the results verified.

5.3.9. WBC balance

During the initial count of the WBC's in the WBC/BASO chamber, a second WBC count is performed from the injected volume through the LMNE optical flowcell.

The two counts are compared. If the difference between the LMNE and WBC/BASO counts are higher than the defined threshold, depending on the quantity of cells measured, a **LMNE+** or a **LMNE-** flag will be generated based upon the following conditions:

◆ The WBC count is within 0 and 2501:

If the WBC LMNE count is **50%** higher than the WBC BAS count, a **LMNE+** flag will be generated.

If the WBC LMNE count is **50%** lower than the WBC BAS count, a **LMNE-** flag will be generated.

◆ WBC count is within 2501 and 8000:

If the WBC LMNE count is **20%** higher than the WBC BASO count, a **LMNE+** flag will be generated.

If the WBC LMNE count is **20%** lower than the WBC BASO count, a **LMNE-** flag will be generated.

◆ WBC count is higher than 8000:

If the WBC LMNE count is **15%** higher than the WBC BASO count, a **LMNE+** flag will be generated.

If the WBC LMNE count is **15%** lower than the WBC BASO count, a **LMNE-** flag will be generated.

The WBC BAS channel is considered as a reference and is used to calibrate the WBC LMNE channel. The calculated ratio between the two channel calibration coefficients is stable (except during technical intervention). In any case it is the WBC BAS result that is reported.



The WBC balance flags will appear in the «Analyzer alarm» area.

The WBC balance flags (LMNE+ and LMNE-) are activated only if the test selected is «DIFF» and if this flag has been activated. The WBC Balance can be enabled or disabled by an approved ABX Service Technician. Contact your local ABX Technical Service Representative for selection of this option.

These flags are associated with an (!) on all differential parameters (% and #).

CBC mode Limitations

The WBC balance flag will indicate an instrument defect or it can also highlight a known interference (See Section 2: Specifications, **5. Limitations**, page 2-16).

In the case of pathology whose treatments weaken the leucocytic membranes, the agent of lysis of WBC channel can damaged the cells and give a lower leukocytes counting.

The LMNE+ flag will then be triggered off and a suspicion will be integrated to the WBC results. We thus recommend not to disable WBC balance flag and to work in DIFF mode for all the samples which can present this possible interference. Selecting the CBC mode will disable this control mode. It is thus recommended to use this mode for patient not presenting this type of interference.

5.3.10. Delta Check

Current analysis is compared to history (when it does exist) parameter by parameter.

This comparison is applied on hematologic parameters and when the difference between history and current results are not within operator defined limits (See Section 5: Settings, [4.5. Setting Delta check](#), page 5-22), following flags should appear:

- ◆ Delta Check D+
- ◆ Delta Check D-

▼ Delta Check triggering conditions

1- Absolute Delta check

$D = \text{Current value} - \text{history value}$

If Absolute value $D >$ absolute value set by the operator (See Section 5: Settings, [4.5. Setting Delta check](#), page 5-22)

- Then Dabs+ is generated if $D > 0$
- or Dabs- is generated if $D < 0$

2- Relative Delta Check

D% is calculated with the below formula :

$$D\% = \frac{(\text{current value} - \text{history})}{(\text{current value} + \text{history}) / 2} \times 100$$

If absolute value $D\% >$ relative value set by the operator (See Section 5: Settings, [4.5. Setting Delta check](#), page 5-22)

- Then D%+ is generated if $D\% > 0$
- or D%- is generated if $D\% < 0$

3- Delta check status



Delta check + is triggering off if Dabs+ and D%+ have been generated



Delta check - is triggering off if Dabs- and D%- have been generated

This alarm can be reviewed in the «Report Details» screen (see [6. Report](#), page 4-51 to access to this screen)



Fig. 4-36 Delta check in the «Report Details» screen

5.3.11. Analyzer alarms

▼ CO flag

Meaning: poor correlation.

Correlation is noted as the percentage of validated cells measured between the Resistive measurement and the Optical measurement as they pass through the LMNE flowcell. If the cell measurements between the resistive and optical are less than 50%, a **CO** flag will be indicated.

Suspected abnormalities:

- Stroma interfering with the measurement,
- Strong pollution,
- Incorrect adjustment of the optical bench.

▼ Others

- From LMNE Matrix: **NO** flag
- From WBC Balance: **LMNE+**; **LMNE-**
- From WBC/BAS Histogram: **BASO+**

5.3.12. Pathology messages

Pathological suspicion messages will be displayed and/or printed out. The triggering conditions are linked to the laboratory limits that were entered by the user.



These messages will indicate a possible pathological condition and should be used to assist with quick and efficient screening of abnormal samples along with detection of certain conditions that lead to specific diagnosis. It is recommended to use known reference methods to confirm diagnoses.

▼ WBC Messages

Message	Condition
Leukocytosis	WBC > WBC H
Leukopenia	WBC < WBC L
Lymphocytosis	LYM # > LYM # H or if LYM % > LYM % H *
Lymphopenia	LYM # < LYM # L or if LYM % < LYM % L *
Neutrophilia	NEU # > NEU # H or if NEU % > NEU % H *
Neutropenia	NEU # < NEU # L or if NEU % < NEU % L *
Eosinophilia	EOS # > EOS # H or if EOS % > EOS % H *
Myelemia	NEU % > NEU % H and LIC # > LIC # H
Large Immature Cell	LIC # > LIC # H or LIC % > LIC % H
Atypic Lymphocyte	ALY # > ALY # H or ALY % > ALY % H
Left Shift	(MN or NL) and RN
Monocytosis	MON # > MON # H or if MON % > MON % H *
Basophilia	BAS # > BAS # H or if BAS % > BAS % H *
Blasts	BAS # > BAS # H and LIC # > LIC # H and RM
Interpretation Not possible	WBC < $0,1 \times 10^3 / \text{mm}^3$ or WBC > $85,0 \times 10^3 / \text{mm}^3$ or CO alarm

Tab. 4–7: WBC pathology messages

«H»: extreme high limit

«L»: extreme low limit

*: indicates that the pathology is detected on the high and low absolute values of the parameter in question.

▼ RBC messages

Message	Condition
Anemia	HGB < HGB L
Anisocytosis	RDW > RDW H
Microcyte	MIC
Microcyte +	% MIC > 10%
Microcyte ++	% MIC > 15 %
Macrocyte	on Mac Flag
Hypochromia	MCHC < MCHC L
Cold Agglutinin	MCHC > MCHC H and WBC < 91.3x10 ³ /mm ³
Microcytosis	MCV < MCV L
Macrocytosis	MCV > MCV H
Erythrocytosis	RBC > RBC H
Interpretation Not possible	RBC < 0,01x10 ⁶ /mm ³ or RBC reject (or RBC>0.03 during Startup)

Tab. 4–8: RBC pathology messages

«H»: extreme high limit

«L»: extreme low limit

▼ PLT messages

Message	Condition
Thrombocytosis	PLT > PLT H
Thrombocytopenia	PLT < PLT L
Microcytosis	MIC
schistocytes	No threshold between RBC and PLT on the curves.
Small Cell	Small cells at the beginning of the Platelet curve.
Platelets Aggregate	<u>condition 1</u> PLT < $150 \times 10^3 / \text{mm}^3$ + WBC reject or NO + PDW > 20 or NO + MPV > 10 or NO + PLT < $150 \times 10^3 / \text{mm}^3$ or NO + WBC reject or (L1 or LL1) + PDW > 20 or (L1 or LL1) + MPV > 10 or (L1 or LL1) + PLT < $150 \times 10^3 / \text{mm}^3$ or PDW > 20 + PLT < $120 \times 10^3 / \text{mm}^3$ (in CBC mode only, a suspicion flag «!» is triggered on PLT)
NRBCs	<u>Condition 2</u> LL or WBC reject + L1 or WBC reject + LL1
Platelets Aggregate Erythroblasts	<u>If conditions 1 and 2 are not satisfied</u> and if L1 or LL1 or WBC reject
Macroplatelets	MPV > 11
Interpretation Not possible	PLT < $5,0 \times 10^3 / \text{mm}^3$ or PLT reject (or PEC alarm during Startup)

Tab. 4–9: PLT pathology messages

«H»: extreme high limit

«L»: extreme low limit

▼ Miscellaneous

Message	Condition
Pancytopenia	RBC < L and WBC < L and PLT < L

Tab. 4–10: Miscellaneous pathology messages

«H»: extreme high limit

«L»: extreme low limit

5.3.13. Statistical function flags

▼ XB flag

This alarm is a specific alarm that is associated with patient quality control. This particular flag is noted when batch results are outside the XB limits established by the user.

- ◆ If one of the mean values from 1 batch of 20 samples is outside of the established limits, an XB alarm will be activated (See Section 3: Quality Assurance and Logs, [2.5. XB limits](#), page 3-19).
- ◆ Selecting and Deselecting an analysis can activate the XB alarm.
- ◆ The user has the option of enabling or disabling the XB alarm in the «Instrument Settings» functions (See Section 5: Settings, [3.2. XB options](#), page 5-12).
- ◆ The XB alarm can stop the instrument operations if the user has selected the XB alarm conditions in the «Instrument Settings» functions (See Section 5: Settings, [2.2. General tab](#), page 5-6)

▼ QC failed

This flag will appear when the quality control does not meet the criteria that were selected in the «Instrument Settings» functions. The user has the option of selecting or de-selecting these criteria (See Section 5: Settings, [2.2. General tab](#), page 5-6).

6. Report

This section describes how to:

- 1- Review Reports of the day (see [6.1. Reviewing Report](#), page 4-51),
- 2- Construct a «Report» (see [6.2. Construction of a Report](#), page 4-57)
- 3- Validate or reject Reports (see [6.3. Validation or rejection of a Report](#), page 4-63)
- 4- Request Manual Reruns (see [6.4. Rerunning sample manually](#), page 4-64)
- 5- Associate unmatched Run results with Worklist orders (see [6.5. Run /order association](#), page 4-68),

6.1. Reviewing Report

6.1.1. Accessing the Report list

Select the «Reports» key on the generic toolbar.

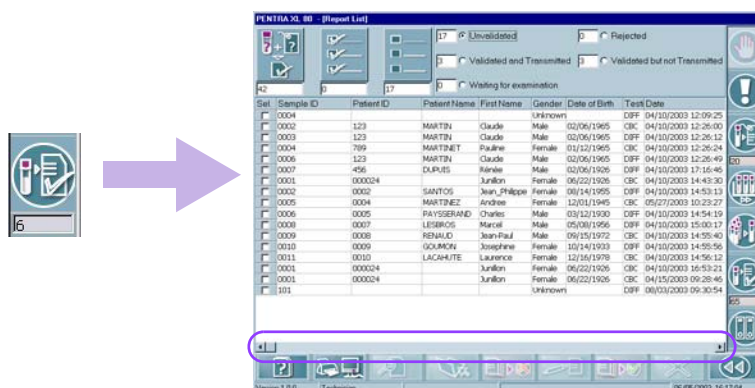


Fig. 4-37 Report list

6.1.2. Report Function sequence

4 screens allows the operator to «manually» validate the reports:

- ◆ Report List: List of all the reports of the day
- ◆ Report View: Review of reports in a full page mode
- ◆ Report Details: Construction of the report with Run results. Review of history.
- ◆ Report Edit: Creation or review of a manual entry.

The sequence from one screen to the other is the following:

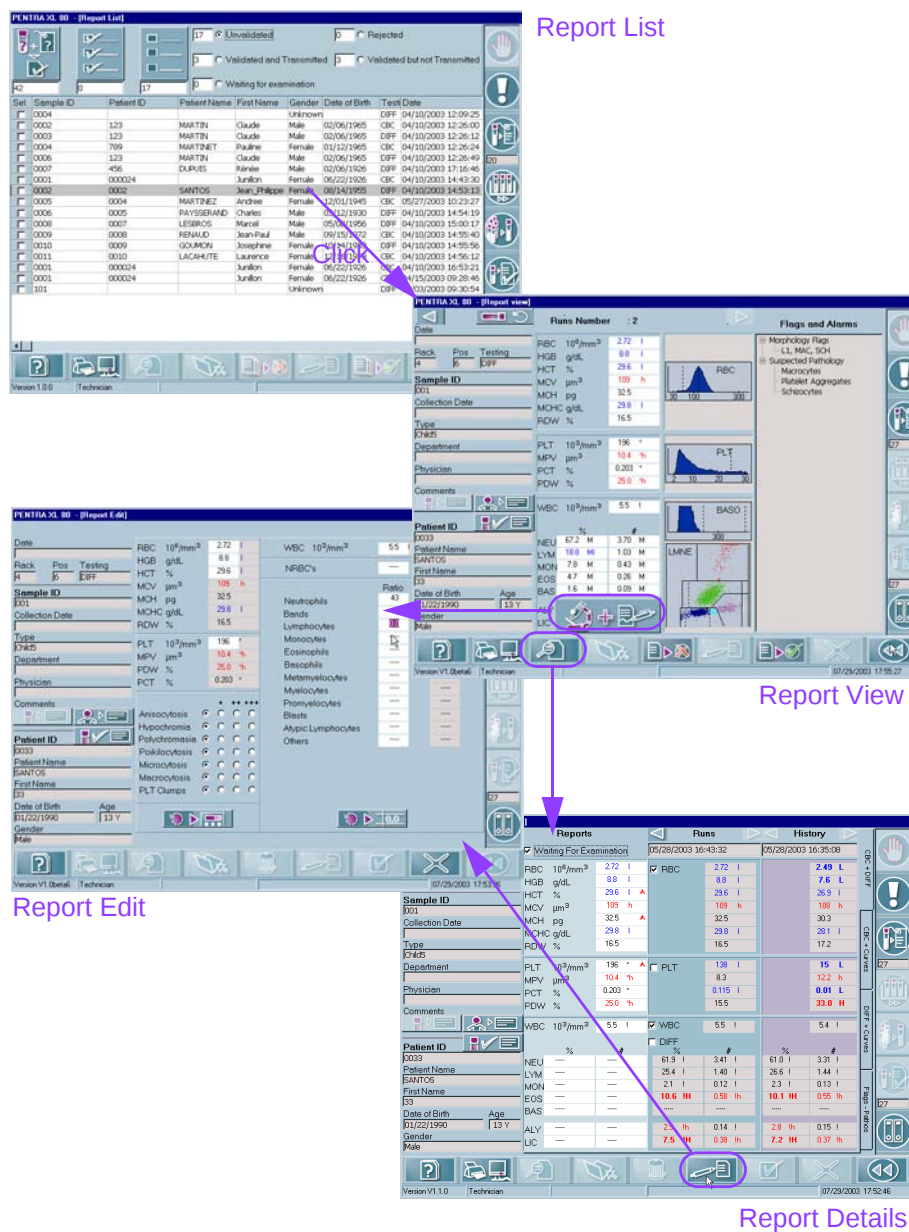


Fig. 4-38 Report function sequence

6.1.3. Report list

3 States are possible for report:

- ◆ Validated: The report succeeds to operator defined criteria and has been automatically validated (See Section 5: Settings, **4.2. Biological validation conditions**, page 5-15), or manually (see **6.1.2. Report Function sequence**, page 4-51).
- ◆ Unvalidated: Default state of the report
- ◆ Rejected: The Report failed to be validated. It has been manually rejected.



Validated or rejected Reports are non modifiable.

▼ function keys

Heading / Key	Name/Action	Function
	Association key	- Launches the Run results Association View (see 6.5. Run /order association, page 4-68) - Disabled if a cycle is in progress or if there is no unmatched result This key is associated with a counter which indicates the number of Run Results saved in the «Matching» chart.
	Select all	Checks all the Run lines in the list (column «Selected») A counter displays the number of selected Runs.
	Unselect all	Unchecks all the Run lines in the list (column «Selected») A counter displays the number of unselected Runs.
	Print/Send	Print or send options (see 6.4.1. Printout or Transmit Report list , page 4-65)
	Reject reports	This key will reject the <u>Selected</u> Reports of the «Report List» screen (see 6.3. Validation or rejection of a Report , page 4-63)
	Validate reports	This key will validate the <u>Selected</u> Reports of the «Report List» screen (see 6.3. Validation or rejection of a Report , page 4-63)
Click a line	Click a line	Displays the corresponding Report in full page (see 6.1.4. Report display , page 4-55)

Tab. 4-11: Report list Function Keys

▼ Report list information

Use the slider (see Fig. 4-37, page 4-51) to display all the items in the Report list as indicated below:

- Sample ID Number,
- Patient information: Patient ID, Patient name, First Name, Gender, Date of birth
- Test performed
- Analysis date
- Following filters :

1- **«Unvalidated»**: when checked, the «Report list» shows the «Unvalidated» Reports only. A counter indicates their current number in the list.

2- **«Validated and transmitted»**: exclusive display of the Reports that have been transmitted and validated. A counter indicates their current number in the list.

3- **«Waiting for examination»**: exclusive display of the Reports that are «Waiting for examination». A counter indicates their current number in the list.

4- **«Rejected»**: exclusive display of the Reports that are «Rejected». A counter indicates their current number in the list.

5- **«Validated but not Transmitted»**: exclusive display of the Reports that are «Validated but not Transmitted». A counter indicates their current number in the list.

- The current report line is displayed in grey.
- The selected report lines are displayed in green.

▼ Sorting out

Sorting Reports is available in the following columns:

- Date time
- Sample ID
- Patient ID

Sel.	Sample ID ++	Patient ID	Patient Name	First Name	Gender	Date of Birth	Test
☐	0001	000024		Junillon	Female	06/22/1926	CBC
☐	0001	000024		Junillon	Female	06/22/1926	CBC
☐	0001	000024		Junillon	Female	06/22/1926	CBC
☐	0002	0002	SANTOS	Jean_Philippe	Female	08/14/1955	DIF
☐	0002	0002	SANTOS	Jean_Philippe	Female	08/14/1955	DIF
☐	0002	123	MARTIN	Claude	Male	02/06/1965	CBC
☐	0003	123	MARTIN	Claude	Male	02/06/1965	DIF

Sel.	Patient ID	Patient Name	First Name	Gender	Date of Birth	Test	Date --
☐	000024		Junillon	Female	06/22/1926	CBC	04/10/2003 09:28:00
☐	456	DUPUIS	Rénée	Male	02/06/1926	DIFF	04/10/2003 17:16:00
☐	0002	SANTOS	Jean_Philippe	Female	08/14/1955	DIFF	04/10/2003 16:53:00
☐	000024		Junillon	Female	06/22/1926	CBC	04/10/2003 16:53:00
☐	0007	LESBROS	Marcel	Male	05/09/1956	DIFF	04/10/2003 15:00:00
☐	0010	LACAHUTE	Laurence	Female	12/16/1978	CBC	04/10/2003 14:56:00

Fig. 4-39 Report grid information

Click a column title for sorting the Report data (see Fig. 4-39, page 4-54):

- Click once for ascending order (++)
- Click twice for descending order (--)
- Click three times to return to the original order.

6.1.4. Report display

From the «Report list» screen, click a line of the grid to display the Report in a full screen mode as indicated below:

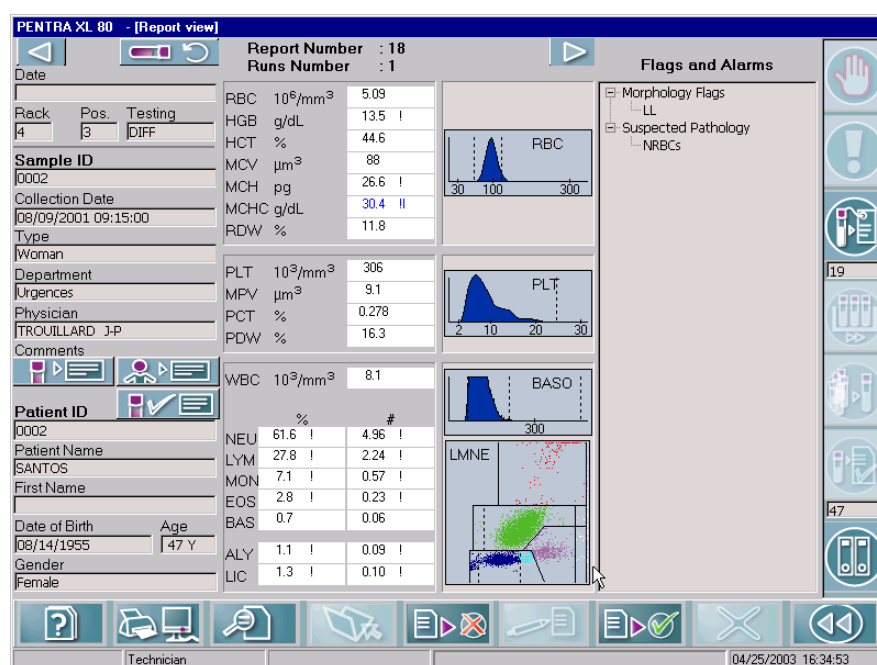


Fig. 4-40 Report display



The «Date» field remains blank as long as the Report is «Unvalidated».

If not, the displayed date is the date of the Report validation or rejection.

▼ Report display keys

Heading / Key	Name	Function
	Left arrow	Displays the previous Report in a full screen mode
	Right arrow	Displays the next report in a full screen mode
	Rerun	Rerun request: generates a new entry in the worklist having the same order (see 6.4. Rerunning sample manually , page 4-64)
	Report comment	Allows the operator to add a comment to Report
Number of Runs	Number of Runs	n: number of Runs associated with the current Report.
	Reject report	This key will reject the current Report. A confirmation message is displayed to perform the rejection (see 6.3. Validation or rejection of a Report , page 4-63)
	Validate report	This key will validate the current Report (see 6.3. Validation or rejection of a Report , page 4-63)
	Detail	Opens the «Report Details» screen view in order to access to all Runs and histories (see 6.2.1. Report Details , page 4-57)
Optional:		
	Expanded DIFF	If the Differential has been manually entered, this key is displayed. It allows the access to the «Report Edit» screen (see 6.2.2. Report Edit , page 4-60)
	Report Comment	This key allows the operator to modify the Report Comment. The comment can not be modified if the Report is already rejected or validated.

Tab. 4-12: Report display Function Keys

6.2. Construction of a Report

Run results includes 4 hematological parameter groups: RBC, PLT, WBC, Differential.

Sample «Reports» are determined from runs, automatic reruns and manual entries required for an order (See Section1: Introduction, [5. Workflow overview](#), page 1-22).

◆ See [6.2.1. Report Details](#), page 4-57, to construct the report with Run results and to review histories.

◆ See [6.2.2. Report Edit](#), page 4-60 to create or review a manual entry.

6.2.1. Report Details

From the «Report Display» view (see [6.1.4. Report display](#), page 4-55), select «Details»:

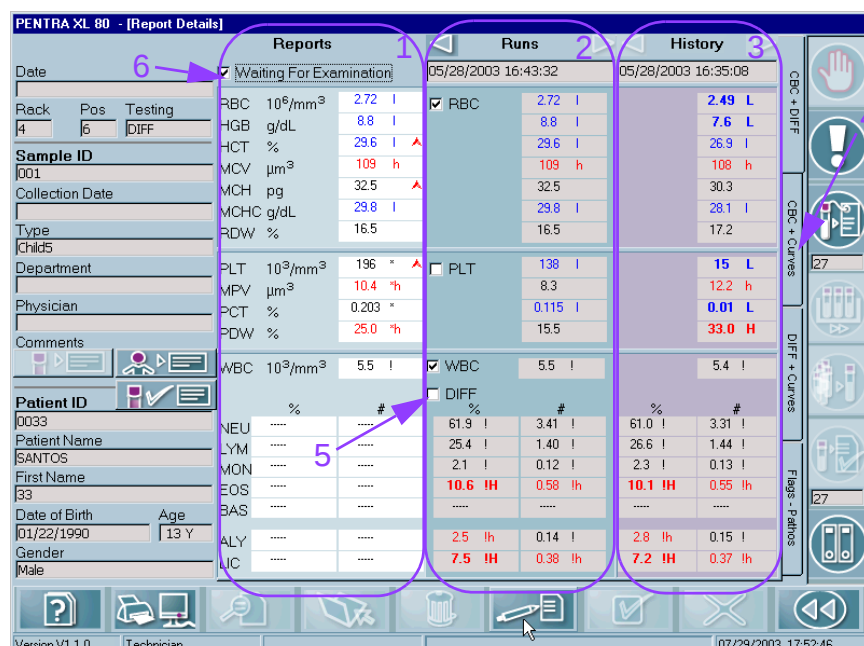


Fig. 4-41 Report Details screen

- 1- Current Report (see [Current Report panel](#), page 4-58)
- 2- Run results associated to this report (see [Run Results panel](#), page 4-59)
- 3- histories of the Patient (see [«history» panel](#), page 4-60)
- 4- Four tabs to review parameters, curves and alarms:
 - CBC + DIFF parameters values
 - CBC values + PLT, RBC, WBC histograms
 - DIFF values + LMNE matrix + BAS histogram
 - Flags + Pathology messages
- 5- Selection/deselection of the Parameter blocks
- 6- «Waiting for examination» indicator

▼ Current Report panel

The displayed Report is composed of selected parameter groups from the Run Results and/or Manual entry.

- 1- If a parameter group has been unselected (see Fig. 4-42, page 4-58), parameters are unvalidated and replaced by (---)
- 2- When a manual entry has been performed, a «M» is displayed next to the parameters (see Fig. 4-42, page 4-58). The «Expanded DIFF» key is displayed when a manual entry has been performed.
- 3- The «Waiting for examination» checked box can be modified, only if the report is «Unvalidated».

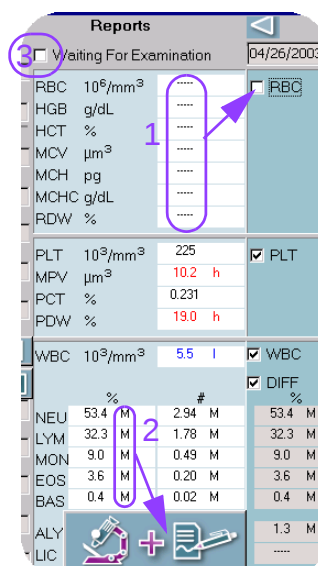


Fig. 4-42 Manual entry indicator and unvalid parameters

- 4- When a report is rejected, parameters are crossed out (see Fig. 4-43, page 4-58).

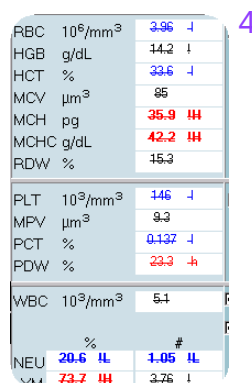


Fig. 4-43 Rejected report

▼ Run Results panel

Selection of parameter groups is possible only if the report is «Unvalidated».

Use the «Runs arrows» (left and right) to review all runs and select the parameter groups to construct the report (see Fig. 4-44, page 4-59). Selecting one parameter group of a Run will uncheck the same parameter groups of all the other Runs.

The «Report panel» is automatically refreshed when a selection is performed.

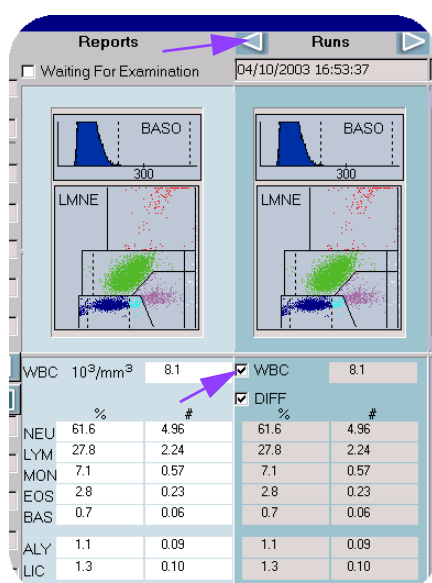


Fig. 4-44 Selection of parameter group

When a parameter group including alarms, is selected, these alarms will be associated with the report (see Fig. 4-45, page 4-59)

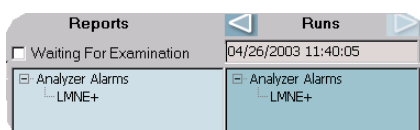


Fig. 4-45 Run results panel

When a «Manual entry» has been performed, a «M» is displayed next to the parameters (see Fig. 4-46, page 4-59)

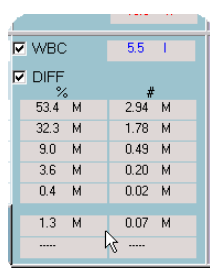


Fig. 4-46 Manual entry indicator

▼ «history» panel

history is the most recent Validated Report, which is used for the «Delta Check» survey (See Section 5: Settings, [4.5. Setting Delta check](#), page 5-22).

The older reports (historic) can be reviewed in the «history» panel but will not interfere in the «Delta Check» calculation.

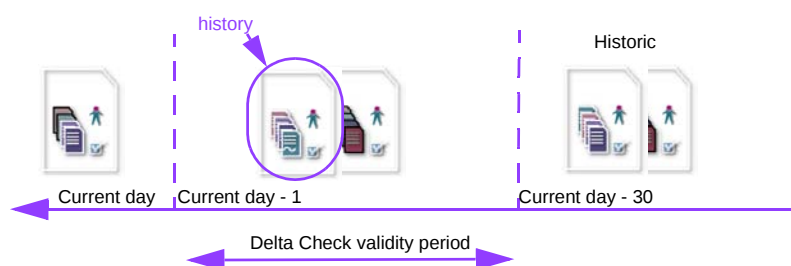


Fig. 4-47 history scheme

When there is no history, the «history» panel remains blank.

If a Report is DIFF, and the history is CBC, missing parameters are ignored and replaced by «---».

Report Type	Value	Unit
CBC + DIFF	4.38	!
CBC + DIFF	11.4	!
CBC + DIFF	39.1	!
CBC + DIFF	89	!
CBC + DIFF	26.1	!
CBC + DIFF	29.3	II
CBC + DIFF	11.7	!
CBC + Curves	211	!
CBC + Curves	8.7	!
CBC + Curves	0.183	!
CBC + Curves	14.3	!
DIFF + Curves	6.4	!

Fig. 4-48 Review of the history

Reviewing the previous validated reports can be done using Left/Right arrows (see [Fig. 4-48](#), page 4-60).

6.2.2. Report Edit

▼ Accessing the Report Edit screen (see [6.1.2. Report Function sequence](#), page 4-51)

1- From the «Report Display» or «Report Details» screen, selecting the «Expanded Diff» key will open the «Report Edit» screen view in a read Only mode, in order to consult the «Manual entry».

2- From the «Report Details» screen, selecting the «Edit» key will open the «Report Edit» screen view in an edition mode



«Manual entry» can only be performed on «Unvalidated» reports, by using the «Report Edit» function screen.

Parameter	Value	Unit	Flag
RBC	2.72	$10^6/\text{mm}^3$	
HGB	8.8	g/dL	
HCT	29.6	%	
MCV	105	μm^3	h
MCH	32.5	pg	
MCHC	29.8	g/dL	l
RDW	16.5	%	
PLT	196	$10^3/\text{mm}^3$	h
MPV	10.4	μm^3	h
PDW	25.0	%	h
PCT	0.203	%	*
WBC	5.5	$10^3/\text{mm}^3$	
NRBC's	-----	% / WBC	
Neutrophils	43.0	%	2.37
Bands	0.0	%	0.00
Lymphocytes	12.0	%	0.66
Monocytes	5.0	%	0.28
Eosinophils	3.0	%	0.17
Basophils	1.0	%	0.05
Metamyelocytes	0.0	%	0.00
Myelocytes	0.0	%	0.00
Promyelocytes	0.0	%	0.00
Blasts	0.0	%	0.00
Atypical Lymphocytes	0.0	%	0.00
Others	0.0	%	0.00

Fig. 4-49 Report Edit screen

▼ Manual entry procedure

Select the «Edit» key to make the following fields editable:

- ◆ RBC, HGB, HCT, PLT, WBC, Differential %, NRBC's (see 1, Fig. 4-49 Report Edit screen, page 4-61)
- ◆ Comments (see 2, Fig. 4-49 Report Edit screen, page 4-61)

Enter values in the standard units in the editable fields

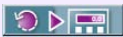
Select the «Recalculation» key.

Select the «OK» key.

The Report now includes the new values of the manual entry.

- ◆ A «M» flag is displayed next to the parameters on Report screens.
- ◆ Analyzer Alarms, Pathology messages, histograms and curves remain the same.
- ◆ Hematology flags are recalculated.

▼ Report Edit function keys

Heading / Key	Name/Action	Function
	Clear	Reset to «0» the differential parameters
	Recalculation	Calculation of the parameters of the different groups (RBC, PLT, WBC, DIFF) according to the manual entries.
	Validate	Once Recalculation has been performed, this key will force the differential to 100%. Then the Report includes these new differential, instead of the previous one.
	Cancel	Does not modify the Report. Displays the previous values.
	Edit	Allows to Edit the Manual entry fields.
	NRBC's	Percentage of NRBC's on the slide. Range: 0 to 100.

Tab. 4-13: Report list Function Keys

6.3. Validation or rejection of a Report



Validated or rejected reports are non modifiable.

The «Report list» provides the status of a report:

- ◆ **Validated:** The report succeeds to operator defined criteria and has been automatically validated (See Section 5: Settings, **4.2. Biological validation conditions**, page 5-15), or manually.
- ◆ **Unvalidated:** Default state of the report
- ◆ **Rejected:** The Report failed to be validated. It has been manually rejected.

The «Unvalidated» Reports can be Manually rejected or validated from the Report List (see **6.1.3. Report list**, page 4-53) or the Report Display (see **6.1.4. Report display**, page 4-55) screens.

6.3.1. Validation of several Reports

- 1- Open the «Report List» screen by selecting the «Report» key (see **6.1.1. Accessing the Report list**, page 4-51)

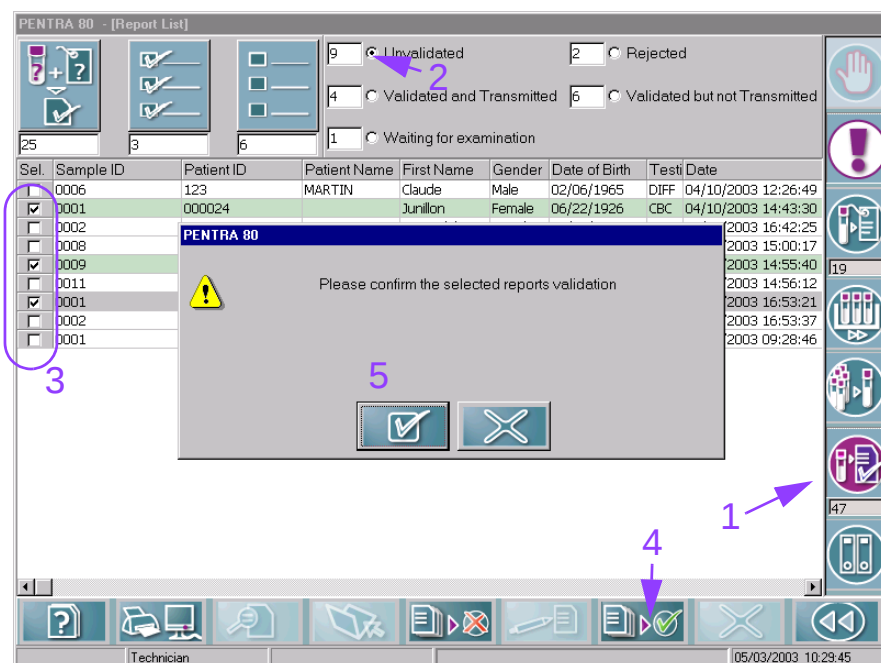


Fig. 4-50 Report validation

- 2- Select the «Unvalidated» view of the screen.
- 3- Then select the Reports to validate
- 4- select the «Validate Report» key

5- A confirmation message is displayed. Select the «OK» key.

Reports are automatically transferred to the «Validated» view of the «Report List»



According to the settings of the «Transmit» conditions, these Reports are transferred either to «Validated and transmitted» or «Validated but not transmitted» view (See Section 5: Settings, 4.4. Print and transmit conditions, page 5-21).

6.3.2. Rejection of several Reports

Proceed the same than described in 6.3.1. Validation of several Reports, page 4-63, but Select the «Reject Report» key instead of «Validate Report».

A confirmation of the Rejection is displayed. Select the «OK» key.

Reports are automatically transferred to the «Rejected» view of the «Report List»

6.3.3. Validation or Rejection of a single Report

Open the «Report List» screen by selecting the «Report» Key (see 6.1.1. Accessing the Report list, page 4-51).

Select the «Unvalidated» view of the screen.

Click the Report to validate to open it in the «Report Display» screen (see 6.1.4. Report display, page 4-55).

Select «Validate» or «Reject» key.

If the Report includes defects, the following window is open

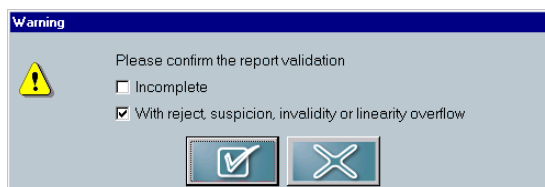


Fig. 4-51 Report validation warning

This window can not be modified by the operator and means:

«Incomplete»: all parameter groups have not been included in the Report.

«With reject, suspicion, invalidity or linearity overflow»: Some of the parameter groups of the Report includes reject, and/or suspicions, and/or invalidities, and/or are outside linearity limits of the instrument.

Select «OK» to confirm the Report Validation or Rejection.



A notification is done in the «Remarks» heading of the alarm Tree view to identify the parameter groups of the Report.

6.4. Rerunning sample manually

The user has the ability to manually select a «Rerun» from the Report being reviewed in the

«Full Screen» Mode.

From the «Report display» screen (see Fig. 4–40, page 4-55), select the «Rerun» key.

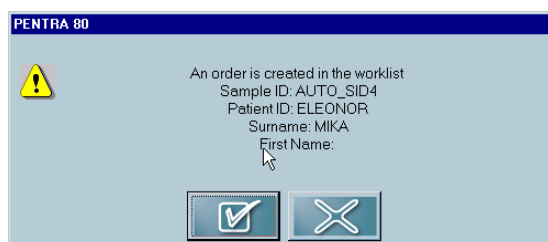


Fig. 4–52 Rerun request

When the Rerun key has been selected, a message will be displayed asking for confirmation on the Sample ID, Patient ID, Patient Name, and the Patient First name.

A new entry is then generated into the «Worklist». Proceed as described in Daily Guide: RAB156C to run the analysis on this new order.



The «Rerun» key is disabled if the Run Results are unmatched (see **6.5. Run /order association**, page 4-68) or if a Rerun for this order is already in the Worklist.

An automatic Rerun is triggered on a sample:

IF a mishap occurs during Rerun analysis (for instance: Emergency stop of the instrument), the first Run results are stored in the «Unvalidated» list of the «Report list» function.

Validation or Rejection operations on these Run results might be impossible.

If this happens, proceed as follows to «unlock» these Run Results:

Open the Worklist selecting the «Worklist» key

Locate the order that has been automatically generated for the Rerun analysis.

Select this order and use the «Delete» key to erase it.

Now the Results of the first run should be accessible for «Validation» or «Rejection».

6.4.1. Printout or Transmit Report list

Several printing and report transmission options are available from the «Report List».

Press the «Print/Send» key, then choose one of the following options:

▼ Printing options

Print/Send

Print

Send

☐ Print report list for selected rows
☐ Print compact report list for selected rows
☐ Print report list for all rows
☒ Print compact list for all rows
☐ Print report in full page for selected rows
☐ Print report in full page for all rows
☐ Print the last report in full page
☐ Print the run + rows in full page for selected rows

Fig. 4-53 Printing options screen

- Print selected Reports in a grid mode (see Fig. 4-54, page 4-66)
- Print selected Reports in a light grid mode (see Fig. 4-55, page 4-66)
- Print all Reports in a grid mode
- Print all Reports in a light grid mode
- Print selected Reports in a full screen mode
- Print all Reports in a full screen mode
- Print the most recent Report in a full screen mode
- Print Run Results and Raw counts of the selected Reports in a full screen mode.

Report List																						
Patient ID PID0001				Sample ID 0003				Testing DIFF				Unvalidated										
Patient Name Alemmand				Final report date 06/04/2003 17:49:31				Physician				Department										
First Name Alain				Type Man				Gender Male				Date of Birth 01/01/1950				Age 43 Y						
RBC	3.15	HGB	8.9	HCT	32.6	MCV	103 h	MCH	28.3	MCHC	27.4 L	RDW	17.4	PLT	137	MPV	8.3	PCT	0.114	PDW	15.5	
WBC	5.9	NEU%	61.9	LYM%	26.4	MON%	2.1	EOS%	10.6H	BAS%	---	NEU	3.66	LYM	1.50	MON	0.12	EOS	0.63H	BAS	---	
ALY%	2.5H	UC%	7.5H	ALY	0.16	LIC	0.41h															
Patient ID 0002				Sample ID 0002				Testing DIFF				Unvalidated										
Patient Name				Final report date 06/06/2003 10:57:53				Physician				Department										
First Name				Type Standard				Gender Unknown				Date of Birth				Age						
RBC	5.03	HGB	15.1	HCT	41.5	MCV	82	MCH	30.1	MCHC	36.5 H	RDW	13.9	PLT	147	MPV	7.9	PCT	0.117	PDW	14.2	
WBC	3.6	NEU%	25.4L	LYM%	60.5H	MON%	0.6L	EOS%	4.9	BAS%	8.6H	NEU	0.92L	LYM	2.18	MON	0.02	EOS	0.18	BAS	0.31H	
ALY%	0.3	UC%	5.6H	ALY	0.01	LIC	0.19															
Out of Panic Range				Out of Normal Range																		

Fig. 4-54 Selected rows printout

Compact Reports List																			
RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	PDW	PCT	WBC	NEU%	LYM%	MON%	EOS%	BAS%	ALY%	LIC%	NEU
LYM	MON	EOS	BAS	ALY	LIC	BND%	MET%	MYE%	PRO%	BLA%	OTHERS%	BND	MET	MYE	PRO	BLA	OTHERS	NRBC%	
*SID: AUTO_SID4				*PID: 2001				*Final report date 01/06/2004 17:45:37				* Name: Unvalidated							
3.91	9.5 L	30.9 L	79 I	24.2 L	30.7 L	16.0 h	484	8.4	13.5	0.408	5.9	69.1	18.2	10.5	1.1	1.1	1.8	4.0 H	4.10
1.08	0.62	0.07	0.07	0.11	0.23														
Comments				Flags: LIC				Unvalidated											
*SID: AUTO_SID5				*PID: 2001				*Final report date 01/06/2004 17:45:49				* Name: Unvalidated							
5.13	12.2	37.7	73 I	23.7 L	32.3	13.0	180	10.9	21.5 H	0.196	5.1	27.2	61.2	7.0	3.8	0.8	2.0	7.1 H	1.37 IL
3.09	0.35	0.19	0.04	0.10	0.33 IH														
Comments				Flags: L1 LL RM LL1 LIC NO LMNE-				Unvalidated											
*SID: AUTO_SID6				*PID: 2001				*Final report date 01/06/2004 17:46:03				* Name: Unvalidated							
3.91	9.5 L	30.9 L	79 I	24.2 L	30.7 L	16.0 h	484	8.4	13.5	0.408	5.9	69.1	18.2	10.5	1.1	1.1	1.8	4.0 H	4.10
1.08	0.62	0.07	0.07	0.11	0.23														
Comments				Flags: LIC				Unvalidated											
*SID: 2001				*PID: 2001				*Final report date 01/06/2004 17:47:03				* Name: Unvalidated							
5.13	12.2	37.7	73 I	23.7 L	32.3	13.0	180	10.9	21.5 H	0.196	5.1	27.2	61.2	7.0	3.8	0.8	2.0	7.1 H	1.37 IL
3.09	0.35	0.19	0.04	0.10	0.33 IH														
Comments				Flags: L1 LL RM LL1 LIC NO LMNE-				Unvalidated											
Printed on 01/06/2004 17:56:39 Operator : Technician Page 1																			

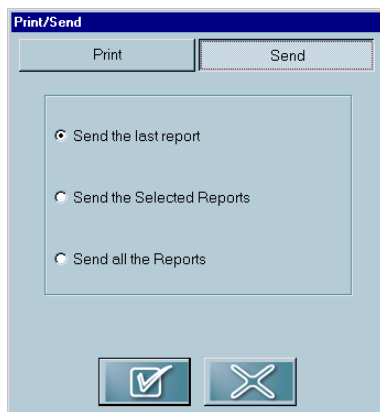
Fig. 4-55 Compact report list



Printing the «raw counts» will be possible only if:

- ◆ «Print the run + raw counts in full page for selected rows» option is selected as shown in **Fig. 4-53 Printing options screen, page 4-66** and
- ◆ «System\Printer\raw» option (See Section 5: Settings, **5.4. Printer**, page 5-31) has been checked too.

▼ Sending options



- Send the most recent Report to the LIS
- Send the selected Reports to the LIS
- Send all the Reports to the LIS

Fig. 4-56 Sending options screen

6.5. Run /order association

An Unmatched Report (see 1.7. **Exception management**, page 4-11) needs to be manually associated with an order to be validated, printed or transmitted.

A notification of the «Manual match» will be systematically attached to this Report.

6.5.1. Association grid description

From the «Report list» screen (see 6.1.1. **Accessing the Report list**, page 4-51), select the «Association» key (This function will be disabled if all the results are already matched with orders!)

Sample ID	Rack	Pos	Patient ID	Patient Name
0012			0011	MILLAU
0013			0012	CANDELA
0002			0002	SANTOS
0003			0002	SANTOS
0004			0003	
0005			0004	MARTINEZ
0006			0005	PAYSSERA
0007			AUTO_PID4	LAMAISON
0008			0007	LESBROS
0009			0008	RENAUD

Sample ID	Rack	Pos	Barcode	Running
0006	1	1		04/10/20
0003	8	2		04/10/20
0004	8	3		04/10/20
0005	8	4		04/10/20
0006	8	5		04/10/20
0007	8	6		04/10/20
0008	9	4		04/10/20
0009	9	5		04/10/20
0010	9	6		04/10/20
0011	9	7		04/10/20

Fig. 4-57 Association grid

This screen will show 2 lists:

- ◆ Worklist orders (not matched to runs) as it has been defined in the Worklist (sample ID, patient ID, etc...).
- ◆ Runs with Rack/Position of the tubes or/and Barcode Identification of the sample as the instrument has read it.

On the right-hand side of the screen:

- ◆ Running date, Rack#, Position fields associated to the selected Runs
- ◆ Other fields of the order (in grey) defined in the Worklist.



Orders in progress are not displayed in this screen.

6.5.2. Association grid keys

Heading / Key	Name	Function
	Delete	Deletes selected order of the Worklist: a confirmation message is displayed «Do you want to delete the order which sample ID is XXX»
	OK	Associates the selected order with the selected runs (see 6.5.3. Runs/orders matching , page 4-69). A notification is done in the logs.
Click a line	Click a line	On the run list: - Displays the Rack and position of the tube; displays the running date too. - Allows to match the tube with its default order (if no order is selected)

Tab. 4–14: Association function Keys

6.5.3. Runs/orders matching

This screen will allow the user to manually match Sample tubes and Worklist Orders that have been classified as «Exceptions» (see **1.7. Exception management**, page 4-11).

Select a run (*in the lower half of the association grid*) that you want to associate an order with.

Now select the order (*in the upper half of the association grid*) to associate to the selected run.

Then select the «OK» key. A confirmation message will be displayed (see **Fig. 4–58**, page 4-69)

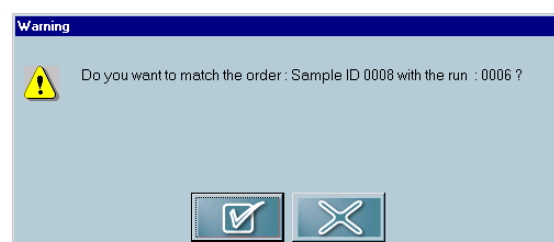


Fig. 4–58 Matching confirmation

Once the matching has been performed, the selected lines will disappear. The matched run will be added to the «Report list» screen (see **Report list information**, page 4-54)

A notification is added to the instrument logs.



- ◆ If the order type is different from the Run one, the Run results will be recomputed (with the new type settings: thresholds, limits....). The recomputed Run results will be flagged in the «Remarks» flags (see **5.2. Run Result screen**, page 4-28).
- ◆ If the order test differs from the Run test, then the test of the matched Run = CBC
- ◆ When the user validates the association and no order is selected, the following message will be displayed: «Do you still want to match the tube with its default order?».

7. Archives

At the end of the day on the 24:00 clock, all Reports from the previous day are automatically archived into the system memory (if Begin of day screen has been configured as described in Daily Guide: RAB156C).

Reviewing the «Archives» is accessible by three modes:

- 1- By date: Daily Reports (see **7.2. Daily Report Description**, page 4-71)
- 2- By patient: Patient Reports (see **7.3. Patient Report**, page 4-73)
- 3- Reviewing Reports exported to an external media (see **7.5. Reviewing exported reports**, page 4-75)

7.1. Accessing the Archives

Select the «Archives» key from the generic toolbar.

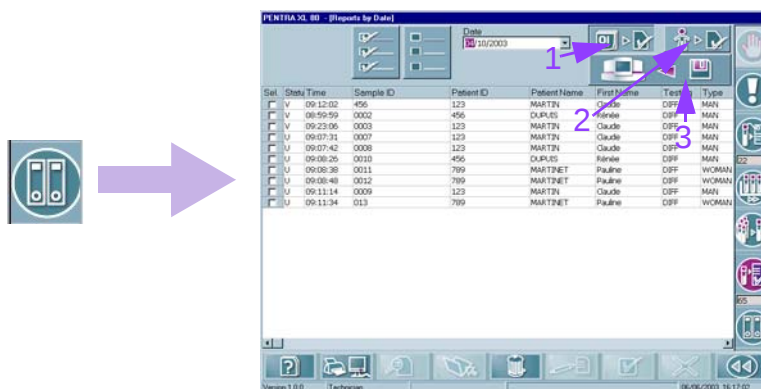


Fig. 4-59 Archives access

When the «Archives» function is opened, the «Daily Reports» screen is displayed.

7.2. Daily Report Description

PENTRA XL 80 - [Reports by Date]

Date: 04/07/2003

Sel.	Statu	Time	Sample ID ++	Patient ID	Patient Name	First Name	Testing	Type
☐	U	13:59:32	0001	123	MARTIN	Claude	DIFF	MAN
☐	U	13:59:42	0002	456	DUPUIS	Rénée	DIFF	MAN
☐	U	14:08:55	0002	123	MARTIN	Claude	DIFF	MAN
☐	U	13:59:54	0003	123	MARTIN	Claude	DIFF	MAN
☐	U	14:09:07	0003	123	MARTIN	Claude	DIFF	MAN
☐	U	14:00:04	0004	456	DUPUIS	Rénée	DIFF	MAN
☐	U	14:09:19	0004	123	MARTIN	Claude	DIFF	MAN
☐	U	14:09:31	0005	123	MARTIN	Claude	DIFF	MAN
☐	U	14:00:15	0005	123	MARTIN	Claude	DIFF	MAN
☐	?	14:01:56	0006				DIFF	STANDAI
☐	U	14:00:24	0006	123	MARTIN	Claude	DIFF	MAN
☐	U	14:10:00	0006	456	DUPUIS	Rénée	DIFF	MAN
☐	?	14:01:01	0007				DIFF	STANDAI
☐	?	14:02:06	0007				DIFF	STANDAI
☐	?	13:54:34	AUTO_SID1				DIFF	STANDAI
☐	?	13:54:45	AUTO_SID2				DIFF	STANDAI
☐	?	13:54:56	AUTO_SID3				DIFF	STANDAI
☐	?	13:55:07	AUTO_SID4				DIFF	STANDAI
☐	?	13:55:28	AUTO_SID5				DIFF	STANDAI
☐	?	13:55:38	AUTO_SID6				DIFF	STANDAI
☐	?	13:55:48	AUTO_SID7				DIFF	STANDAI

Version 1.0.0 Technician 06/06/2003 16:35:39

Fig. 4-60 Daily result grid

The «Daily Report» grid contains all the Reports (**Validated, Rejected, Unmatched, Unvalidated**) from a single day of work which include, the Status (see [Report Status](#), page 4-71), the time, the Sample ID, the Patient ID and name, first name, the Test CBC/DIFF and the sample type given to the sample.

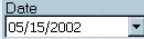
Select a date that you want to review by using the scrolling icon to move through the list.

▼ Report Status

Each Report shown in the «Archives» function, includes an indicator which provides its status as indicated:

- «V»: Validated Report
- «U»: Unvalidated Report
- «R»: Rejected Report
- «?»: Unmatched Report
- «W»: Report Waiting for Examination
- «T»: Validated and Transmitted Report

▼ Daily results function keys

Heading / Key	Name	Function
	Patient Report	Displays the search by patient screen (see 7.3. Patient Report , page 4-73)
	Daily Report	Displays the search by date screen (see 7.2. Daily Report Description , page 4-71)
	Media	Opens Exported Report Media selection window (Floppy disk or network) (see 7.5. Reviewing exported reports , page 4-75)
	Date	Opens a calendar in order to select the Report validation date. The date can also be manually typed in
	Delete	Enables the deletion of all, unselected or selected analyses
	Select all	Checks all the Report lines of the list. (column «Selected»)
	Unselect all	Unchecks all the Report lines in the list (column «Selected»)
	Print/Send	Printing or sending options: all the lines or selected lines only (see Fig. 4-61 , page 4-72)
Click a line	Click a line	Displays the Report in full screen mode. (see 7.4. Reviewing a Report in full screen mode , page 4-75)
Click «Sample ID», «Patient ID» or «Time» headings	Sorting out	One click for ascending order (++ beside heading) Another click for descending order (-- beside heading) A third click restores initial order (see Fig. 4-60 , page 4-71).

Tab. 4-15: Daily Report function Keys

▼ Printing options

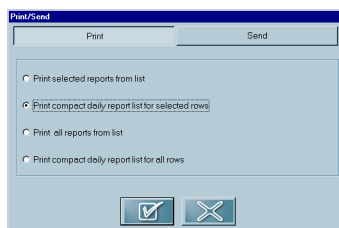


Fig. 4-61 Printing options

7.3. Patient Report

The Archives function allows the user to review demographics of the patient.

If the «Patient ID» is known, follow the steps as indicated:

From the Daily Report grid, select the «Patient Report» key (see **Tab. 4–16: Patient Archives function Keys**, page 4-74)

PENTRA XL 80 - [Reports by Patient]

Patient ID: 123
Patient Name: MARTIN
First Name: Claude
Gender: Male
Date of Birth: 02/06/1965
Age: 38 Y

Date	04/10/2003 09:11	04/10/2003 09:07	04/10/2003 09:07	
RBC	10 ⁶ /mm ³	5.5	5.1	5.5
HGB	g/dL			
HCT	%	44.2 IL	41.0 L	49.1 I
MCV	μm ³	37.2 I	45.6	36.3
MCH	pg	8.5 I	8.1	10.1 h
MCHC	g/dL	9.5 IH	4.7	4.0
RDW	%	0.6 I	0.6	0.5
PLT	10 ³ /mm ³	1.8 I	1.3	1.5
MPV	μm ³	1.0 I	0.6	0.8
PCT	%	2.43 I	2.09	2.69
PDW	%	2.05 I	2.32	1.99
WBC	10 ³ /mm ³	0.47 I	0.41	0.55
NRBCs	%	0.52 IH	0.24	0.22
NEU	%	0.03 I	0.03	0.03
LYM	%	0.10 I	0.07	0.08
MON	%	0.05 I	0.03	0.04
EOS	%			
BAS	%			
ALY	%			
LIC	%			
NEU	#			
LYM	#			
MON	#			
EOS	#			
BAS	#			
ALY	#			
LIC	#			
BND	%			

Version 1.0.0 Technician 06/06/2003 16:20:54

Fig. 4–62 Patient Archives screen

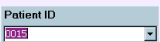
The Slider icon 1 can be used to display all the Reports that are associated with this patient.

The Slider icon 2 can be used to display all the parameters that are associated with this patient: the differential including NEU, LYM, MON, EOS, BAS, ALY (Atypical Lymphocytes), LIC (Large Immature Cells), but also, if a Manual entry has been performed: Bands, Metamyelocytes, Myelocytes, Promyelocytes, Blasts, Others, percentages and absolute values. And CBC parameters: RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, PDW, PCT, NRBC



- ◆ When a Manual entry has been performed a «M» is displayed next to parameters.
- ◆ Bands, Metamyelocytes, Myelocytes, Promyelocytes, Blasts, Others, NRBC are reported to (---) when the Report differential has been determined from an instrument analysis run.
- ◆ Rejected reports show crossed parameters (see **Fig. 4–43**, page 4-58)

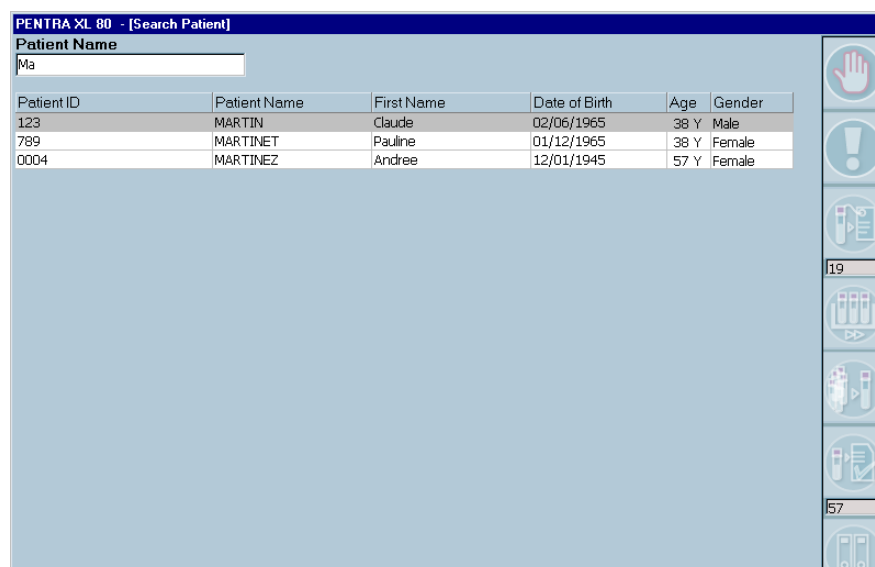
7.3.1. Patient Archives function keys

Heading / Key	Name	Function
	Daily Reports	Displays the search by date screen (see 7.2. Daily Report Description , page 4-71)
	Patient ID	When a patient is selected, Reports are displayed on the right hand side
	Search patient Button	Launches the search patient Screen (see 7.3.2. Search patient , page 4-74)
	Print/Send	Printing of the last 4 files with patient data, Running data, matrix and histograms
Click a Report	Click a report band	Displays the Report in full screen mode Section 4: Workflow, 7.4. Reviewing a Report in full screen mode , page 4-75

Tab. 4-16: Patient Archives function Keys

7.3.2. Search patient

In order to review the reports associated to a known patient, select the «Search patient» key (see [Tab. 4-16: Patient Archives function Keys](#), page 4-74)



Patient ID	Patient Name	First Name	Date of Birth	Age	Gender
123	MARTIN	Claude	02/06/1965	38 Y	Male
789	MARTINET	Pauline	01/12/1965	38 Y	Female
0004	MARTINEZ	Andree	12/01/1945	57 Y	Female

Fig. 4-63 Search patient screen

Type the Patient name (or the First characters) into the «Patient Name» field located in the upper left-hand portion of the screen. If this patient exists in the «Archives» function, it will be displayed on a single line along with the rest of patient information (Patient ID, First name, Birthday, Gender, etc...).

Now select the «OK» key to display the patient Reports.

7.4. Reviewing a Report in full screen mode

7.4.1. Patient Archives screen

From the «Patient Archives» screen (see **Fig. 4-62**, page 4-73), select the Report that you want to display in full screen.

From the Report display, the «Report Details» and «Report Edit» screens can be displayed (Read only) as described in **6.1. Reviewing Report**, page 4-51

Other Reports that are associated with the same patient, can be displayed by using the right and left arrows.

To return to the «Patient Reports» screen, select the «Return» key in the full screen mode.

7.4.2. Daily Reports screen

From the «Daily Report» screen (see **Fig. 4-60**, page 4-71), select the line of the result that you want to display in full screen.

From the Report display, the «Report Details» and «Report Edit» screens can be displayed (Read only) as described in **6.1. Reviewing Report**, page 4-51

Other Reports that are associated with the same patient, can be displayed by using the right and left arrows.

To return to the «Daily Reports» screen, select the «Return» key in the full screen mode

Printing out and/or transmitting this result to a host computer is enabled from this screen by selecting the «Print/Send» key.

7.5. Reviewing exported reports

The «Media» key allows to review Exported Reports that have been deleted from the «Archives» Function.

Selecting the «Media» key will open a «choice box» to define the exported data location (Floppy disk or Network, refer to Section 5: Settings, **6.4. Report exportation**, page 5-38).

Whatever the Media, this one is read if data are accessible, a browser ie5 is launched to display data in a chart. Sorting out is available in the following fields:

- ◆ Sample ID,
- ◆ Patient ID,
- ◆ Patient Name,
- ◆ Validation Date

PENTRA XL 80 - [Archives Media]

Date of Birth	Age	Validation date	Report status	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	HCT %
1960-01-01T00:00:00	43 Y	2003-06-04T17:06:54	1	3.6 H	5.03	15.2	41.5
1960-01-01T00:00:00	43 Y	2003-06-04T17:15:13	1	4.3 H	2.88 L	7.6 L	29.5 L
1960-01-01T00:00:00	43 Y	2003-06-04T17:48:31	0	5.9 I	3.15 L	8.9 L	32.6 L
1926-06-22T00:00:00	76 Y	2003-06-12T09:02:36	0	3.5 IL	4.88	15.1	41.7
		2003-06-12T09:10:13	0	3.6 H	4.85	15.1	41.5
		2003-06-12T09:10:52	0	3.5 H	4.88	15.1	41.7
1987-11-12T00:00:00	15 Y	2003-06-12T09:25:33	1	5.9 I	3.04 L	8.9 L	32.6 L

Version 1.0.0 Technician 06/12/2003 16:02:24

Fig. 4-64 Exported Reports table

8. Status

This function screen provides instrument real time information about the following:

- 1- All Reagent levels with CBC and DIFF analyses capacity
- 2- Counters for racks waiting for analysis, racks running and racks that have been analyzed for the current day.
- 3- Statistics on the current day (analyses, maintenance cycles...)
- 4- Statistics since the installation of the Pentra XL 80.

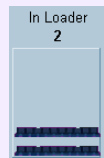
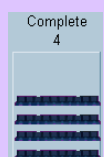
8.1. Accessing the Status screen

Select the «Status» key of the main menu



Fig. 4–65 Status screen

▼ Status screen selection keys

Heading / Key	Name	Function
	Print/send	Prints the Status screen with additional information for reagents. Can not be transmitted.
	In loader	Click the «In loader» view to open the Worklist.
	Complete	Click the «Complete» view to open the «Rack view» screen
	Reagent	Click the Reagent bottle to perform a reagent replacement procedure (See Section 7: Maintenance & Troubleshooting, 2.1. Reagent replacement , page 7-9)

Tab. 4–17: Status selection keys

8.2. Status screen description

8.2.1. Reagent level view

Each reagent bottle has its graphic representation with the reagent level left, in percentage of the total volume of the bottle (container for diluent).

When a reagent level is too low, an alarm is displayed to warn the operator. Proceed as described in Section 7: Maintenance & Troubleshooting, [2.1. Reagent replacement](#), page 7-9.

Analysis capacity: provides the number of CBC and DIFF analyses that can be carried out with the current reagent left in all bottles.

8.2.2. Statistics of the day

- ◆ The «Pie chart» displays statistics on patient runs only:
 - 1- in blue: run results within normal ranges
 - 2- in black: run results out of Normal limits (see [5.3.1. Normal and panic ranges](#), page 4-30)
 - 3- in red: run results out of Panic limits (see [5.3.1. Normal and panic ranges](#), page 4-30)
- ◆ A bar graph with the DIFF and CBC analyses in percentage of the total analyses of the day.
- ◆ A bar graph with the percentage of Rerun performed in the day.

- ◆ Counters for Maintenance cycles performed in the day (Startup, ShutDown, Autoclean).

8.2.3. Statistic summary

Statistics since the first startup of the instrument are the same than for Daily Statistics (see **8.2.2. Statistics of the day**, page 4-78).

8.3. Rack status

8.3.1. In loader

Selecting the «In loader» view will open the «Worklist» function (see **2.4. Rack view**, page 4-22).

To return to «Status» screen, select the «Return» key.

8.3.2. Complete

Selecting the «Complete» view will open the «Rack view» function (see **Fig. 4-66**, page 4-80)

This is a graphic view of the rack ejection tray. It shows the racks that have been run since the «Begin of Day», the most recent one is the bottom one.

Rack numbers are displayed on the left side of each rack view.

DIFF tubes are shown in green, CBC tubes in yellow.

The position of the tube in the rack is given at the bottom of the «Rack view» screen.

▼ Rack view screen selection keys

Heading / Key	Name	Function
	Detail	When a tube have been previously selected, the «Details» key will open the «Report Details» screen. (see Fig. 4-41 , page 4-57)
	Tube selection	One click on a tube is shown by a red circle (see Fig. 4-66 , page 4-80). This will display the demographics of this tube in the right part of the screen (Sample and Patient data).
	Sample ID search	Opens the «Search by Sample ID» screen (see 2.3.5. Searching by sample ID , page 4-20): The result of the search is shown by red tubes (see Fig. 4-67 , page 4-81)
	Patient search	Opens the «Search by Patient ID» screen (see 2.3.6. Searching by patient name , page 4-20) The result of the search is shown by red tubes (see Fig. 4-67 , page 4-81)

Tab. 4-18: Rack view selection keys

▼ Selection of a tube in the Rack view screen

The selection of a tube is shown by a red circle (1) around the tube position (see Fig. 4–66, page 4-80). The Demographics of the tube is displayed on the right part of the screen.

From this selection, the «Report details» view is accessible, by selecting the «Details» key (2).

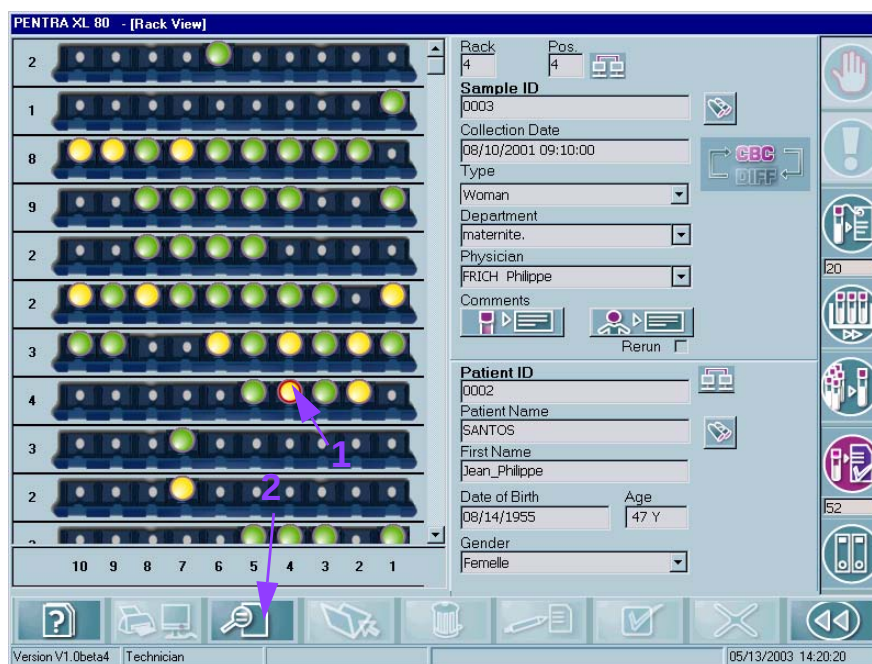


Fig. 4–66 Selection of a tube

▼ Search sample screen

When a sample ID or Patient name has been searched by using «Sample ID search» key or «Patient Name search» key, the positions of the found results are shown in red (see Fig. 4–67, page 4-81)

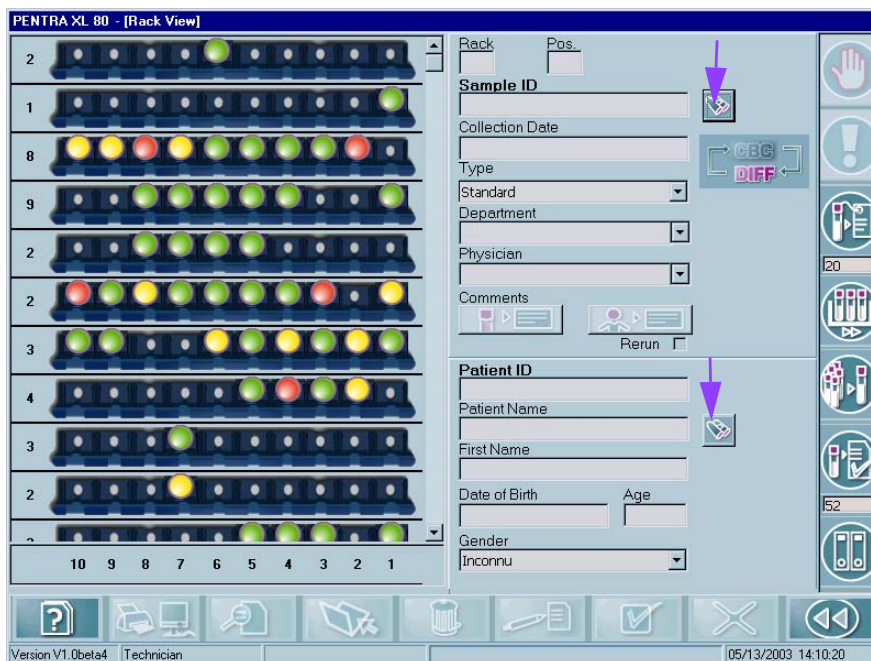


Fig. 4–67 Search sample screen

ABX Pentra **XL** 80

Contents

1. Menu «Settings» overview	5-3
1.1. Accessing the «Settings» menu	5-3
1.2. Menu Settings functions.....	5-4
2. Soft parameters.....	5-5
2.1. Accessing the Soft Parameters menu	5-5
2.2. General tab	5-6
2.3. Department/Physicians tab	5-8
2.4. Units tab.....	5-10
3. Quality assurance settings	5-12
3.1. Accessing the QA settings.....	5-12
3.2. XB options	5-12
3.3. Number of calibration runs.....	5-13
3.4. Coefficients of variation ranges.....	5-13
4. Rules	5-15
4.1. Accessing the «Rules» screen.....	5-15
4.2. Biological validation conditions	5-15
4.3. Rerun conditions	5-17
4.4. Print and transmit conditions	5-21
4.5. Setting Delta check.....	5-22
5. System.....	5-23
5.1. Accessing the «System» screen	5-23
5.2. Local settings	5-23
5.3. Communication.....	5-25
5.4. Printer	5-31
5.5. Cycle option.....	5-35
6. Save and restore	5-36
6.1. Access to «Save/Restore» screen.....	5-36
6.2. Configuration	5-36
6.3. Dump database	5-38
6.4. Report exportation.....	5-38

7. User profiles.....	5-40
7.1. Accessing the User screen.....	5-40
7.2. User menu function keys	5-40
7.3. Creating a new «User» profile.....	5-41
8. Sample Types.....	5-43
8.1. Accessing the «Types» parameters menu	5-43
8.2. Pathological limits	5-46
8.3. Alarms & Curve thresholds.....	5-47
8.4. Age range	5-51
8.5. Defaults settings of the Pentra XL 80 types	5-51

The following section is the Pentra XL 80 «Settings» menu description, including

1. **Menu «Settings» overview**, page 5-3
2. **Soft parameters**, page 5-5
3. **Quality assurance settings**, page 5-12
4. **Rules**, page 5-15
5. **System**, page 5-23
6. **Save and restore**, page 5-36
7. **User profiles**, page 5-40
8. **Sample Types**, page 5-43

1. Menu «Settings» overview

1.1. Accessing the «Settings» menu

Select the «SETTINGS» key on the Main screen.

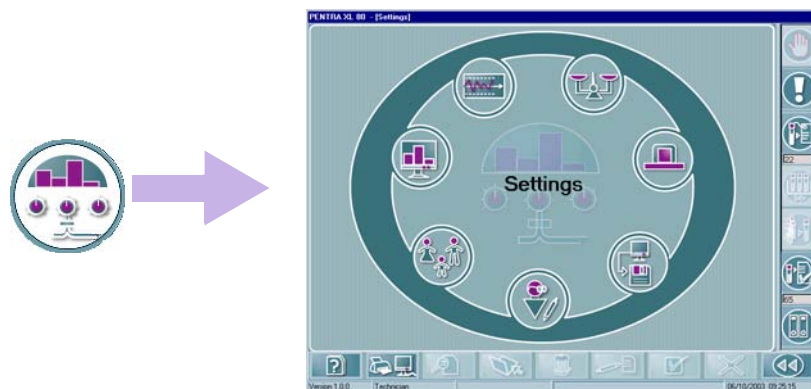


Fig. 5-1 Settings menu access key

1.2. Menu Settings functions

Key	Name	Function
	Soft Parameters	Opens the management screens for software options (see 2.1. Accessing the Soft Parameters menu , page 5-5)
	Quality Assurance	Allows to define CV for calibration, QC and Within Run (see 3. Quality assurance settings , page 5-12). The XB mode must also be set here.
	Rules	Opens management screens to define criteria for printing, sending to Host and rerun conditions. (see 4. Rules , page 5-15)
	System	Opens management screens for specific system options (date and time, RS 232, printer) (see 5. System , page 5-23)
	Save/Restore Configuration	Opens management screen for saving, restoring the software configuration (see 6. Save and restore , page 5-36)
	Users	Opens management screen to define operator profiles (see 7. User profiles , page 5-40)
	Type Parametering	Allows configuration of instrument according to the types of blood run (see 8. Sample Types , page 5-43)

Tab. 5-1: Menu settings function Keys

2. Soft parameters

2.1. Accessing the Soft Parameters menu

From the «Settings» window, select the «Soft parameters» key. This will bring up the Soft parameters general menu

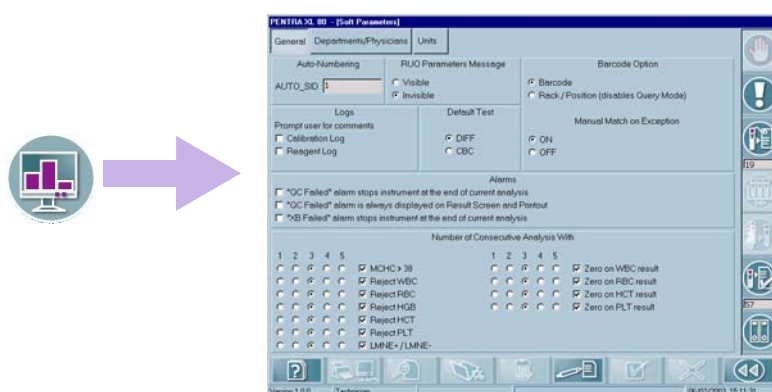


Fig. 5-2 Soft parameters - General menu

There are three tabs available from this menu:

- ◆ General (see [2.2. General tab](#), page 5-6)
- ◆ Department/Physicians (see [2.3. Department/Physicians tab](#), page 5-8)
- ◆ Units (see [2.4. Units tab](#), page 5-10)

2.2. General tab

2.2.1. General tab functionalities

Key/Heading	Name	Function
Auto Numbering	Auto Numbering	Defines the initial value of the autonumbered Sample ID (see 2.2.2. Automatic numbering , page 5-6)
RUO parameters	RUO parameters	Enables/disables RUO parameters for printing and sending operations (see 2.2.3. RUO parameters , page 5-6)
Logs	Logs	Enables/disables automatic prompts for logs (see 2.2.4. Instrument Logs , page 5-7)
Default test	Default test	Test performed when no order is associated to a sample tube.
Barcode Option	Barcode Option	Depends on laboratory operation mode (all sample identified with barcode or not; see 2.2.5. Identification option , page 5-7)
Alarms	Alarms	QC or XB alarms options Section 4: Workflow, 5.3.13. Statistical function flags , page 4-50: Are the «QC failed» and «XB» blocking alarms ?
Number of consecutive analyses with	Stopping conditions	Defines the number of consecutive instrument mishaps or alarms for stopping analysis operations (from 1 to 5 times). Operator can choose the number of consecutive triggers of each alarm. These are selected by default. They can be disabled.

Tab. 5-2: General tab function Keys

2.2.2. Automatic numbering

When the instrument has not received an order, the instrument then associates an automatic Sample ID number that is incremented for each new cycle. This automatic Sample ID number is identified in the ID field as «AUTO_SIDn» where «n» is the incremented number that is entered in this box.

Select the «Edit» key and then select the «AUTO_SID» box figure (see **Fig. 5-2**, page 5-5).

Now type in a beginning number to start the daily sequencing then select the «OK» key to confirm your entry.



In order to enter the initial daily auto-numbering start sequence, the Worklist from the previous day must be erased (See Daily Guide: RAB156C)

2.2.3. RUO parameters

The RUO parameters (Research Use Only) are as indicated: PCT, PDW, ALY, LIC.

If the «Visible» box on the soft parameter screen has a Check mark (see **Fig. 5-2**, page 5-5), the instrument software will trigger the following message when results are displayed on the screen: «PCT, PDW, ALY and LIC are for research use only». This message will also be printed out and/or transmitted to the LIS.

Select the «Edit» key, and then place a Check mark in the «Visible» or «Invisible» box.

Now select the «OK» key to confirm your choice.

2.2.4. Instrument Logs

When a reagent is replaced, an instrument calibration is performed, and/or a maintenance operation is carried out, a report of these interventions is automatically created in the appropriate instrument log (Reagents, Calibration, or Maintenance).

When these boxes are checked (see Fig. 5-2, page 5-5), a prompt requiring comments, is automatically displayed (see Fig. 5-3, page 5-7).

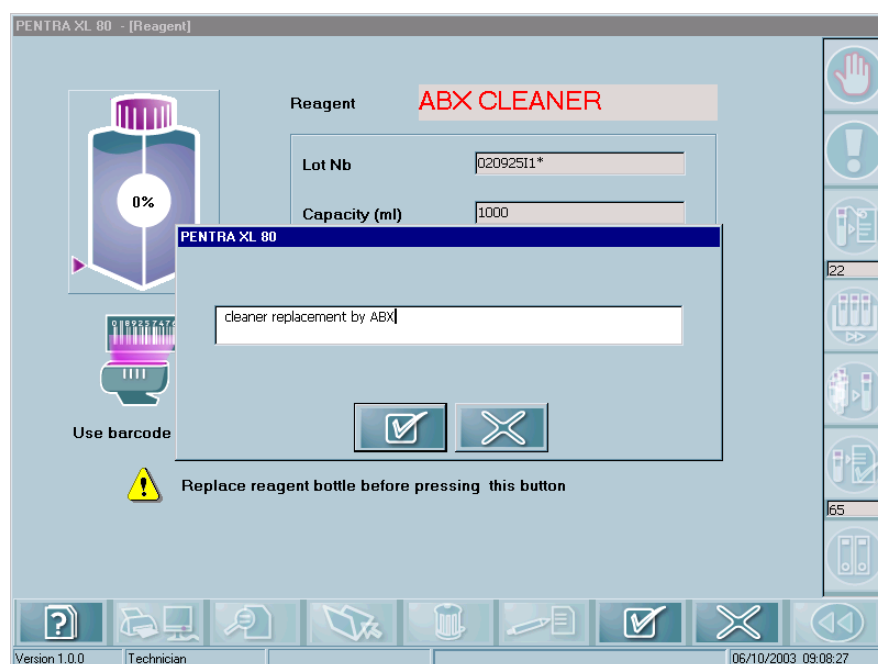


Fig. 5-3 Comments dialog box

From the Soft parameters screen, select the «Edit» key, then select the appropriate boxes for your applications.

Once your selections have been made, select the «OK» key to confirm your selections.

2.2.5. Identification option

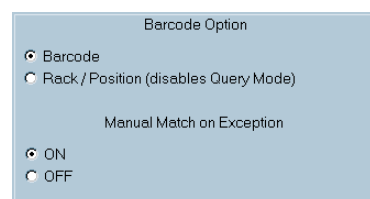


Fig. 5-4 Identification option

This option must be setup according to the specific working order of the laboratory operations (See Section 4: Workflow, 1. Workflow, page 4-3).

▼ Identification Option:

- ◆ Barcode: check this option if all tubes are going to be identified by barcode labels.
- ◆ Rack/position: Check this option if samples With and Without barcode labels are going to be analyzed on the instrument.

▼ Manual match on Exception

Must be «ON» to allow a manual match between orders and results (See Section 4: Workflow, **1.7. Exception management**, page 4-11).

2.3. Department/Physicians tab

To prevent manual entering of clinical information for each order, this tab provides fields to enter Department names and Physician names that are requesting the analysis of the samples (See Section 4: Workflow, **2. Worklist description**, page 4-15).

From the “Soft Parameters” menu, select the “Department/Physicians” tab.

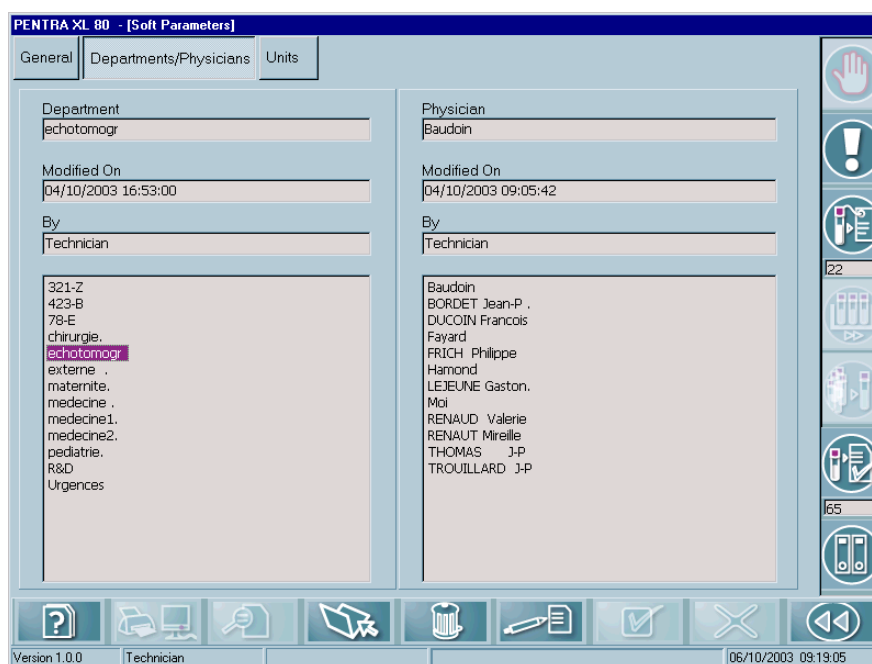


Fig. 5-5 Department/Physicians tab

Use the following function keys to insert, delete or modify a department/Physician.

▼ Functions keys

Key	Name	Function
	Edit	Modification of the selected line (if the focus is on the department list, the software allows the modification of a department; 20 characters maximum)
	Insert	Addition of new department/Physician (if the focus is on the department list, the software allows the addition of a department; 20 characters maximum)
	Delete	Deletion of department or Physician (if the focus is on the department list, the software allows the deletion of a department)

Tab. 5-3: Function Keys

2.4. Units tab

Selection of a set of units among the following:

UNITS							
	WBC	RBC	HGB	HCT	PLT	MCV	
STD	10 ³ /mm ³	10 ⁶ /mm ³	g/dl	%	10 ³ /mm ³	μm ³	
SI	10 ⁹ /l	10 ¹² /l	g/l	l/l	10 ⁹ /l	fl	
mmol/l	10 ⁹ /l	10 ¹² /l	mmol/l	l/l	10 ⁹ /l	fl	
JAPAN	10 ² /mm ³	10 ⁴ /mm ³	g/dl	%	10 ⁴ /mm ³	μm ³	
	MCH	MCHC	RDW	MPV	PCT	PDW	
STD	pg	g/dl	%	μm ³	%	%	
SI	pg	g/l	%	fl	10 ⁻² /l	%	
mmol/l	fmol	mmol/l	%	fl	10 ⁻² /l	%	
JAPAN	pg	g/dl	%	μm ³	%	%	
	LYC	LYC	MON	MON	NEU	NEU	EOS
STD	%	#	%	#	%	#	%
SI	%	#	%	#	%	#	%
mmol/l	%	#	%	#	%	#	%
JAPAN	%	#	%	#	%	#	%
	EOS	BAS	BAS	ALY	ALY	LIC	LIC
STD	#	%	#	%	#	%	#
SI	#	%	#	%	#	%	#
mmol/l	#	%	#	%	#	%	#
JAPAN	#	%	#	%	#	%	#

Tab. 5-4: Units

Open the «Units» tab

Now select the «Edit» key and scroll through the «Unit Selection» list (see Fig. 5-6, page 5-11)

Select the units of choice and then select the «OK» key to confirm your selection.

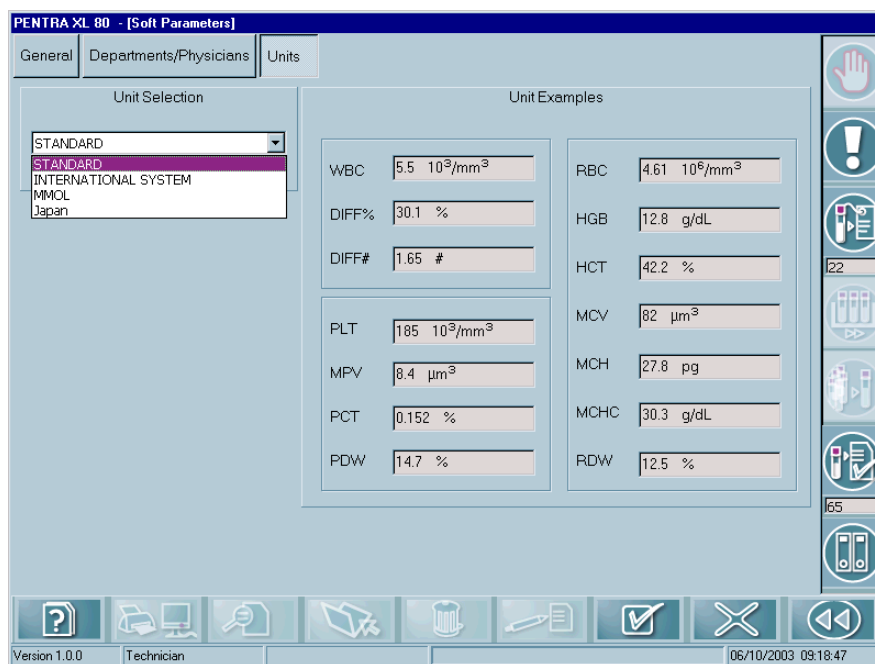


Fig. 5-6 Units tab

3. Quality assurance settings

3.1. Accessing the QA settings

From the «Settings» window, select the «Quality Assurance» key

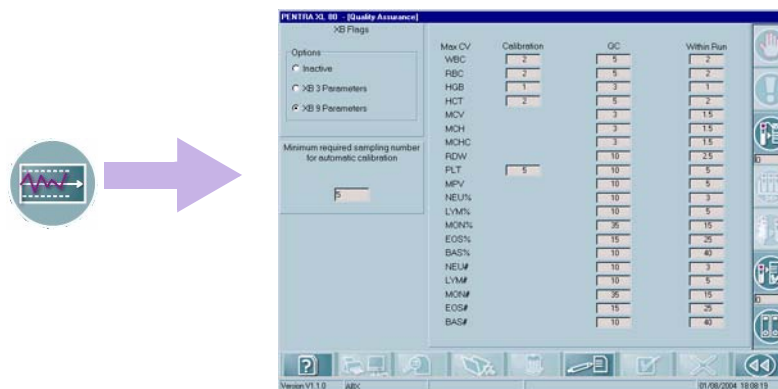


Fig. 5-7 Quality Assurance settings

There are three configurations available in this menu:

- ◆ XB options (see 3.2. XB options, page 5-12)
- ◆ Number of calibration runs (see 3.3. Number of calibration runs, page 5-13)
- ◆ Calibration, QC and XB coefficient values (see 3.4. Coefficients of variation ranges, page 5-13)

3.2. XB options

The «XB» function (See Section 3: Quality Assurance and Logs, 2. Patient Quality Control (XB), page 3-14) is based on a BULL method and includes a calculation on 3 or on 9 (extended) parameters.

The 3 parameters include: MCV, MCH, MCHC.

The 9 parameters include: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT.

This function allows the operator to select the XB mode: 3, 9 parameters or «XB» calculation disabled (Menu XB inaccessible).

- ◆ Select the «EDIT» key and check the chosen radio key.
- ◆ Select the «OK» key to confirm your selection.

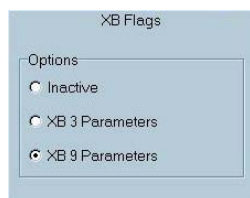


Fig. 5–8 XB options

3.3. Number of calibration runs

The number of calibration runs that can be entered by the user is from (1 to 99) runs if requested. The Minimum number of runs for good statistical calculations during calibration is (5).

From the «Quality Assurance» window, select the «Edit» key (see [Fig. 5–7](#), page 5-12).

Now select the titled field «*Minimum required sampling number for automatic calibration*», and highlight the number in the field.

Modify the number to the number of runs requested for calibration (Remember, the Minimum is 5).

Now select the «OK» key to confirm your entry.

3.4. Coefficients of variation ranges

Coefficients of variation (CV) applied on statistical calculations, as calibration (See Section 3: Quality Assurance and Logs, [4.4.1. Calibration passed, page 3-29](#)), QC (See Section 3: Quality Assurance and Logs, [1.3. QC data screen grid, page 3-7](#)) and within run grids (See Section 3: Quality Assurance and Logs, [3.1. Accessing the Within Run Data Grid, page 3-21](#)) are modifiable within this window.

Max CV	Calibration	QC	Within Run
WBC	2	5	2
RBC	2	5	2
HGB	1	3	1
HCT	2	5	2
MCV		3	1.5
MCH		3	1.5
MCHC		3	1.5
RDW		10	2.5
PLT	5	10	5
MPV		10	5
NEU%		10	3
LYM%		10	5
MON%		35	15
EOS%		15	25
BAS%		10	40
NEU#		10	3
LYM#		10	5
MON#		35	15
EOS#		15	25
BAS#		10	40

Fig. 5–9 CV default values

Select the «EDIT» key and highlight the figure you want to modify.

Enter the new value and select the «OK» key.

4. Rules

4.1. Accessing the «Rules» screen

From the «Settings» window, select the «Rules» key

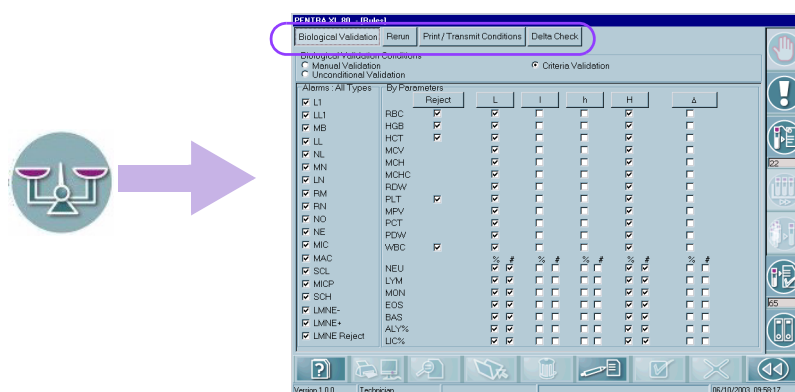


Fig. 5–10 Accessing the Rules screen

The «Rules» screen includes four tabs which will enable the operator to configure the following conditions:

- ◆ Biological validation conditions (see [4.2. Biological validation conditions](#), page 5-15)
- ◆ Rerun conditions (see [4.3. Rerun conditions](#), page 5-17)
- ◆ Print conditions (see [4.4. Print and transmit conditions](#), page 5-21)
- ◆ Transmit conditions (see [4.4. Print and transmit conditions](#), page 5-21)

and to adjust the sensitivity of the «Delta Check» flags (see [4.5. Setting Delta check](#), page 5-22)

4.2. Biological validation conditions

In this tab (see [Fig. 5–11](#), page 5-16), the user has the option to enable or disable the automatic biological validation.

One among three criteria must be chosen:

- ◆ **Manual validation:** This is to disable the automatic validation. The reports remain «unvalidated» and can be manually validated or rejected.
- ◆ **Unconditional validation:** All the reports are automatically validated, apart from **unmatched** reports.
- ◆ **Validation criteria:** the operator must choose the criteria, that if triggered, will «unvalid» the report. Only one criteria present in a report is enough to «unvalid» it. When these criteria are selected, a report will be unvalidated if:
 - hematological results trigger alarm (L1, LL1, MB...) or

– hematological results are beyond their parameter limits, which are defined by the user (see **8.2. Pathological limits**, page 5-46) or trigger Delta check alarms or samples that are rejected.

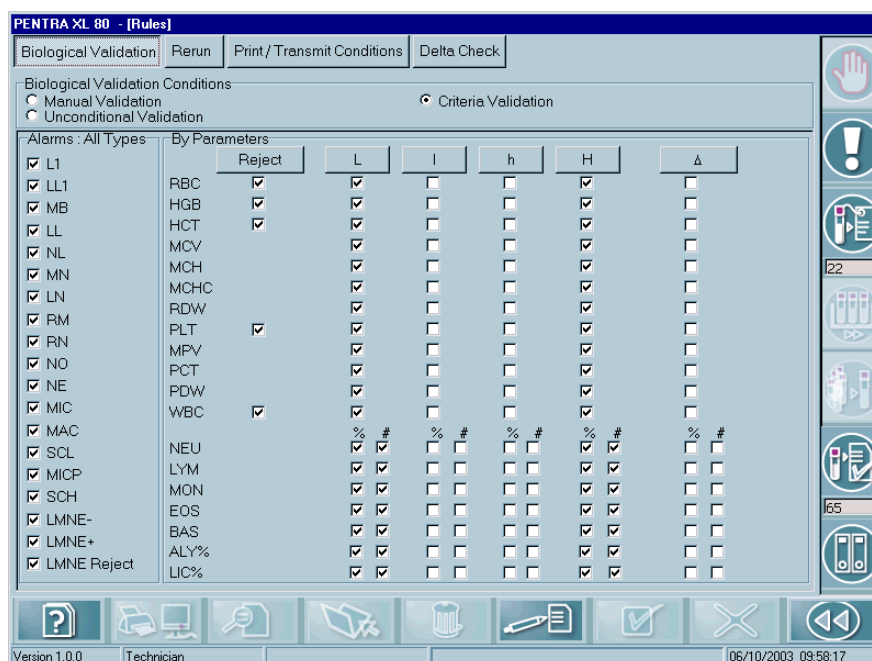


Fig. 5-11 Biological validation tab

For modification of the «Biological Validation Conditions», proceed as followed:

- ◆ Select the «Edit» key.
- ◆ Select the Criteria.
- ◆ If «Validation criteria» has been selected (1), then check the criteria parameter by parameter, or row by row selecting the corresponding key (2, one click will check all parameters of the row, a second click will uncheck all).
- ◆ Select the «OK» key to confirm your choice.



- ◆ Only one set of criteria is available for all sample types.
- ◆ Automatic «biological validation» will work, when Delta check has not been computed for the following reasons: history is missing, or delta check is disabled (see **4.5. Setting Delta check**, page 5-22), or one parameter of the history has been unvalidated or was outside linearity limits
- ◆ Automatic «biological validation» will not work (Reports remain «unvalidated») when Delta check has not been computed for the following reasons: one parameter of the report was unvalidated or outside the linearity limits.
- ◆ Factory adjustment is: all criteria selected
- ◆ No automatic validation can occur when PLT parameter has been suspected (!) (See Section 4: Workflow, **5.3.4. Suspicion flags**, page 4-33).

4.3. Rerun conditions

In these 3 tabs, the user has the option of establishing the criteria for sample rerun conditions. The re-sampling of sample tubes will be based on these criteria

Re-sampling will be required if:

- a – hematological results trigger alarm conditions (L1, LL1, MB...). These criteria are defined for all types of blood (see [4.3.1. Rerun on alarms](#), page 5-17).
- b – hematological results are beyond their parameter limits, which are defined by the user, or samples that are rejected. These criteria are specific to each sample Type (see [4.3.2. Rerun by parameters](#), page 5-18).
- c – hematological results are beyond the linearity limits (see [4.3.3. Rerun on «Dilution»](#), page 5-18).
- d – hematological results trigger Delta check alarms (See Section 4: Workflow, [5.3.10. Delta Check](#), page 4-45)
- e – Sample have been correctly identified in the Worklist and Runs have been matched with orders (See Section 4: Workflow, [1.9. Rerun conditions](#), page 4-13).

4.3.1. Rerun on alarms

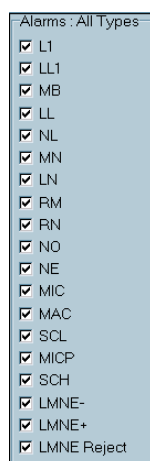


Fig. 5–12 Rerun on alarm

Refer to Section 4: Workflow, [5.3. Flags](#), page 4-30, for Hematological alarms interpretation prior to selection in this screen.

For modification of the Rerun conditions in Alarms:

- ◆ From the «Rerun» screen, select the «General» tab.
- ◆ Scroll the «Types» list, and select a type to configure.
- ◆ Select the «Edit» key.
- ◆ Select the alarm box that you want to trigger the re-sampling.
- ◆ if you want to apply these modifications on all sample types, select the «Apply on all Types» check box.
- ◆ Select the «OK» key to confirm your choice of re-sampling conditions

4.3.2. Rerun by parameters

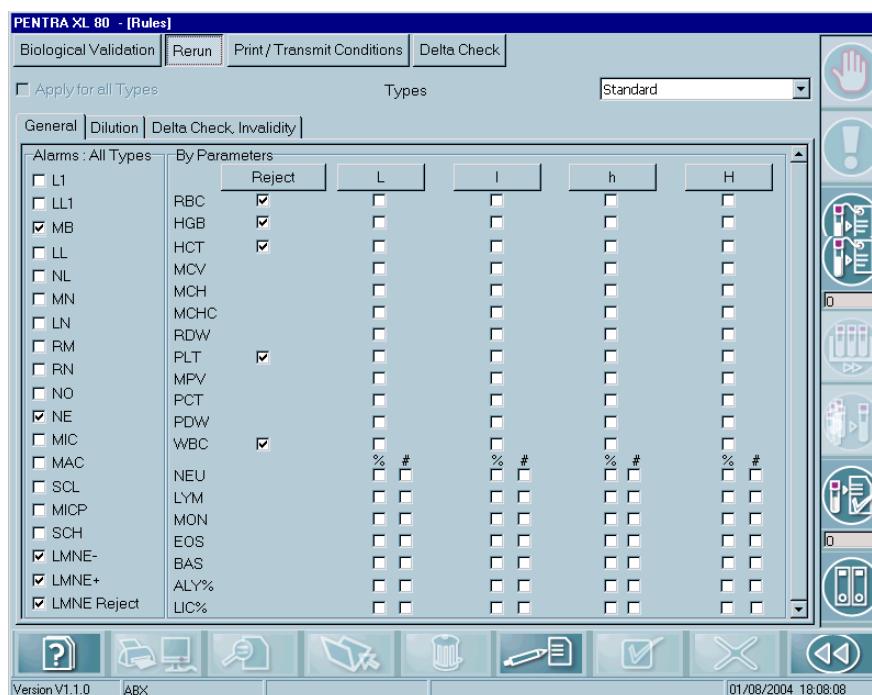


Fig. 5–13 Rerun by parameters default settings

From the «Rerun» screen, select the «General» tab.

Scroll the «Types» list, and select a type to configure.

Select the «EDIT» key.

Choose the limits (Panic, Normal set by the user) or rejected parameters that will trigger a rerun.

Select or De-select the boxes to trigger or not trigger a rerun on parameter limits.

If you want a rerun for any parameter that is out of the normal low limits, select the «Normal l» key and select any of the parameters that you would like to have a rerun on low limits.

If you want to apply these modifications on all sample types, select the «Apply on all Types» check box.

Now select the «OK» key to confirm your selections

4.3.3. Rerun on «Dilution»



HORIBA ABX Validated dilution ratios are:

- ◆ 1/3 for WBC/LMNE
- ◆ 1/2 for RBC/HGB/PLT

Other dilutions ratio may not allow any results to be shown "value replaced by (--) D" according to local registrations.



Dilution tab settings are applied on all Sample types.
Please refer to Section 8: Annex, **1. CDR mode**, page 8-2 for details about CDR mode.

When hematological results trigger dilution flag (See Section 4: Workflow, **5.3.2. Results exceeding Linear ranges of the instrument**, page 4-31), an automatic re-sampling can be required, by configuring this menu.

From the «Rerun» screen, select the «Dilution» tab

Select the «EDIT» key.

Choose the parameter that will trigger a rerun in case of a «D» flag.

Now select the Dilution ratio (1, 1/2, 1/3, 1/5) in comparison with the initial dilution. The instrument will perform automatically this new dilution into both dilution chambers:

- ◆ WBC, LMNE chamber (See Section 6: Description & Technology, **3.3. WBC and differential count**, page 6-17) and
- ◆ RBC, PLT, HGB chamber (See Section 6: Description & Technology, **3.2. CBC detection principles**, page 6-13).

Now select the «OK» key to confirm your selections

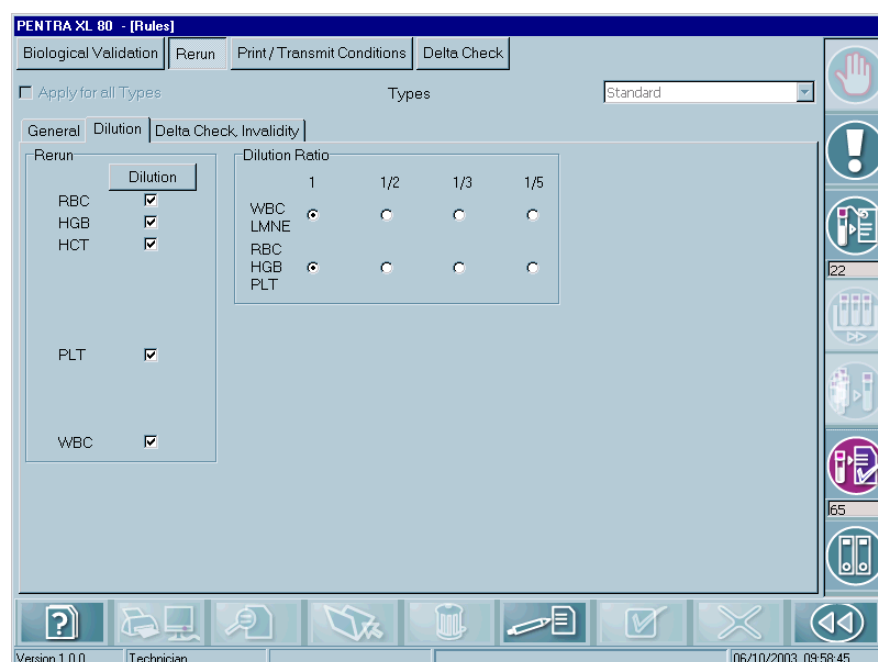


Fig. 5-14 Dilution tab

4.3.4. Rerun on Delta Check and invalidity



These tab settings are applied on all Sample types.

When hematological results trigger Delta check flag (See Section 4: Workflow, [5.3.10. Delta Check](#), page 4-45) or if parameters are «invalid» (results are replaced with «---», refer to Section 4: Workflow, [5.3. Flags](#), page 4-30), an automatic re-sampling can be required:

From the «Rerun» screen, select the «Delta Check, Invalidity» tab

Select the «EDIT» key.

Choose the parameter that will trigger a rerun on a «Delta check» flag or «invalidity».

Now select the «OK» key to confirm your selections.

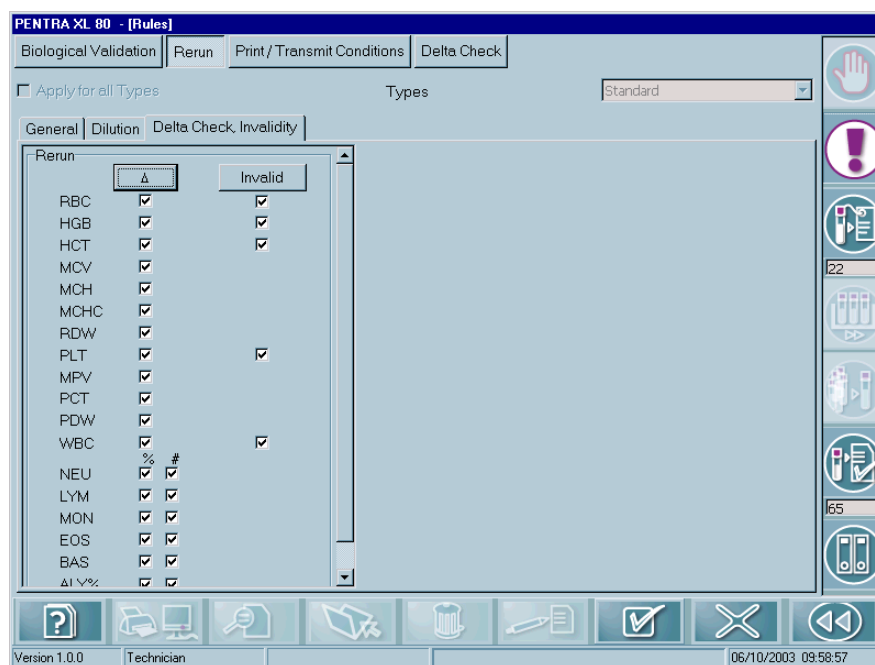


Fig. 5-15 Delta Check, Invalidity tab

4.4. Print and transmit conditions

From the «Rules» screen, select the «Print and Transmit conditions» tab.

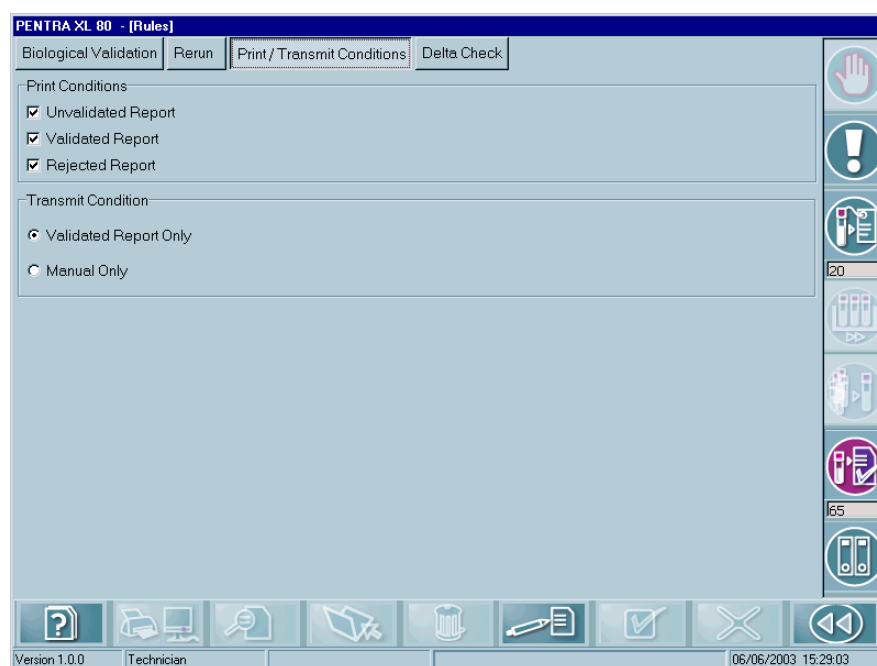


Fig. 5–16 Print/Transmit conditions

▼ Conditions for printing.

The operator can define the Reports that need to be automatically printed. All conditions can be selected simultaneously.

Default adjustment is:

- ◆ *Unvalidated report and Rejected report* (selected)
- ◆ *Validated report* (unselected)

▼ Transmit Conditions

The operator can define the Reports that are automatically transmitted to the LIS. This condition is exclusive.

Default adjustment is: «Validated Report Only» (selected)



- ◆ «Manual only» option will disable any automatic transmission.
- ◆ Whatever the «Transmit conditions» that have been set, manual transmissions are always possible.

4.5. Setting Delta check

This function enables the operator to configure the Delta Check flag sensitivity (See Section 4: Workflow, [5.3.10. Delta Check](#), page 4-45).

From the Rules screen, select the «Delta check» tab (see [Fig. 5-17](#), page 5-22)

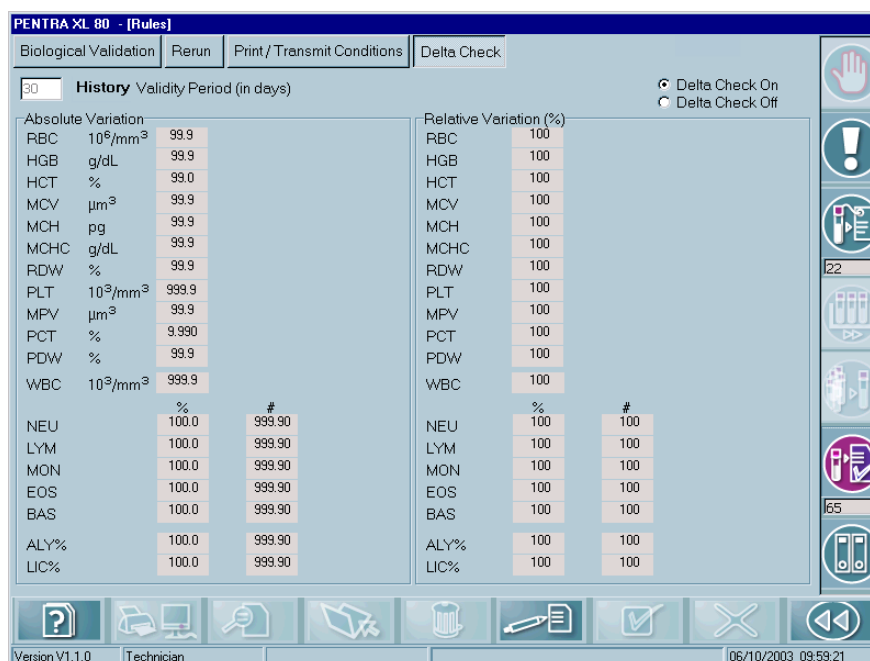


Fig. 5-17 Delta Check tab

The **Absolute variation** gives the Maximum difference (in absolute value) between the current parameter and its history (See Section 4: Workflow, [6.2.1. Report Details](#), page 4-57). This value is used for the «Delta check» flag triggering.

The **Relative variation** gives the Maximum difference in percentage between the current parameter and its history. This value is used for the «Delta check» flag triggering.

The **History validity period** gives the maximum period in days taken into account in the «Delta Check» survey. The factory adjustment value is 30 (min 0, max 999).

Delta check on/off: if «off», no «Delta Check» alarm will occur.

In order to modify the Absolute or Relative Variation values:

- ◆ Select the «EDIT» key
- ◆ Choose «Delta check On»
- ◆ Highlight the figure you want to modify and type in the new value.
- ◆ Confirm by selecting the «OK» key.

5. System

5.1. Accessing the «System» screen

From the «Settings» window, select the «System» key

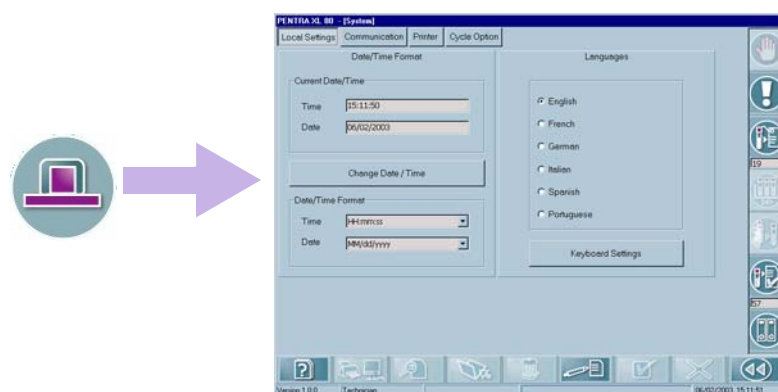


Fig. 5–18 System screen

The «System» screen includes four tabs for the configuration of:

- ◆ Local settings (see [5.2. Local settings](#), page 5-23)
- ◆ Communication (see [5.3. Communication](#), page 5-25)
- ◆ Printer (see [5.4. Printer](#), page 5-31)
- ◆ Cycle option (see [5.5. Cycle option](#), page 5-35)

5.2. Local settings

This tab allows the date/time format modification (see [5.2.1. Date and time format](#), page 5-23) and language modification (see [5.2.2. Languages options](#), page 5-24):

5.2.1. Date and time format

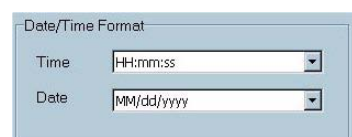


Fig. 5–19 date/time format

Select the «Edit» key, then scroll through the «Date» or «Time» lists.

- ◆ The date formats are as followed:
 - MM/dd/yyyy,
 - dd/MM/yyyy,
 - yyyy/MM/dd.

◆ The time format options in the drop down list are as followed:

- hh:mm:ss (am or pm)
- HH:mm:ss.

5.2.2. Languages options

The software language options are:

- English
- French
- German
- Italian
- Spanish
- Portuguese.

From the «Local Settings» screen, select the «Edit» key then select language that is appropriate for your operations.

Now select the «OK» key to confirm your selection.

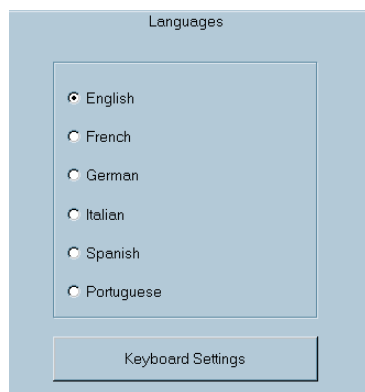


Fig. 5–20 Language format

5.2.3. Change date and time

From the «Local settings» tab (see [Fig. 5–18](#), page 5-23), select the «Edit» key.

Then select «Change Date/Time» key. Change the date and time so that the computer can become updated with the current date and time.

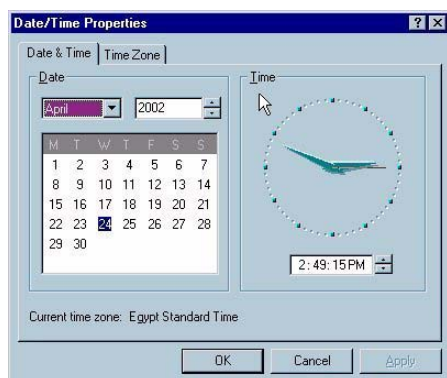


Fig. 5-21 Date and time window

5.3. Communication

This function allows to configure the Pentra XL 80 connexion mode:

5.3.1. General tab, page 5-25

5.3.2. ABX format tab, page 5-27

5.3.3. RS232 settings tab, page 5-28

5.3.4. ASTM format, page 5-28

5.3.5. Network settings, page 5-28



The «System/Communication» menu settings affects what information is sent to and received from the LIS. This information has been configured in your system by a qualified technician using the LIS Output Format documentation (P/N: RAA024B).

5.3.1. General tab

The format, the mode and the link of the LIS connexion are defined in this tab. According to the format (ABX or ASTM) and mode chosen, several options are possible:

Format	ABX	ASTM
UNIDIR mode: Communication from the PXL80 to the LIS	editable	disabled
SOH/EOT	editable if UNIDIR	disabled
BIDIR mode: Communication in both directions	editable	checked, Read Only
RS232 settings: Baud rate, Parity, Stop Bit, Flow control and Data bits (see 5.3.3. RS232 settings tab , page 5-28)	checked, Read Only	editable
Network settings: Configuration of the Ethernet link	disabled	editable
Soh/Soh conflict: Time Out before new Soh when there is a Soh/Soh conflict	editable	disabled
Response time: Time Out (in seconds) for the reception	editable	disabled
Max time: Time Out (in seconds) before automatic disconnection	editable	disabled
Automatic disconnect: Automatic disconnection	editable	checked, Read Only
Query mode: The query connection mode allows the P80XL to require the order to the LIS	editable	editable

Tab. 5-5: Communication General tab

Sending options	Function	Default value
Send Quality Control Reports	Do the Qc analysis send to the LIS?	Unchecked
Send Within Run Reports	Do the Within Run results send to the LIS?	Unchecked
Send Startup Reports	Do the Startup results send to the LIS?	Unchecked
Send Unmatched Reports	Do the Unmatched Reports send to the LIS?	Unchecked

Tab. 5-6: Sending options

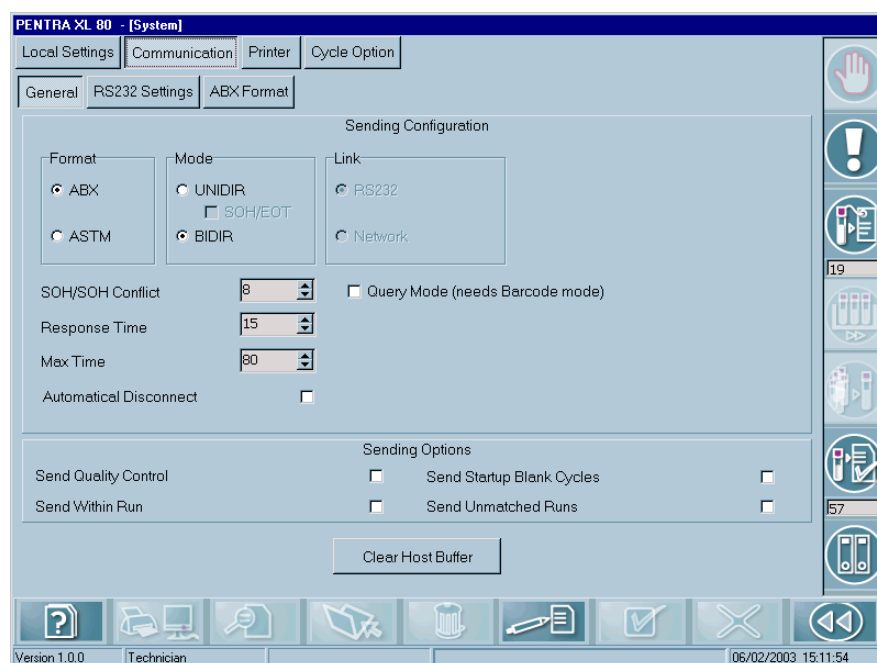


Fig. 5–22 System Communication tab

5.3.2. ABX format tab

According to the Format chosen on the «General» tab (see [5.3.1. General tab](#), page 5-25), an «ABX format» tab is available.

The ABX Format allows the transmitted data batches to be variable in size. This variable size allows the transmission of Histograms, Thresholds, and 5-DIFF matrixes as shown on the system.

The RS232 settings tab can be modified according to the selections chosen by the operator (see [5.3.3. RS232 settings tab](#), page 5-28).

Heading/key	Function
Numerical results	Selected hematology parameters sent to the LIS
Flags and Pathologies	Flags and Pathologies (See Section 4: Workflow, 5.3. Flags , page 4-30) associated to the <u>selected</u> parameters sent to the LIS
Patient File	Selected fields sent to the LIS (See Section 4: Workflow, 2. Worklist description , page 4-15)
Histograms and thresholds	Selected data sent to the LIS

Tab. 5–7: ABX Format settings

5.3.3. RS232 settings tab

According to the format chosen (ABX or ASTM, **5.3.1. General tab**, page 5-25), the «RS232 Settings» tab will be available to set the following:

Heading/key	Function	Default value
Baud Rate	speed selection	9600
Parity	parity selection	None
Flow control	protocol selection	Xon/Xoff
Stop bits	Stop bit selection	1 or 2
Data bits	length selection	8 bits (Read Only)

Tab. 5–8: RS 232 settings

5.3.4. ASTM format

According to the configuration of the «General» tab (see **5.3.1. General tab**, page 5-25), the «ASTM format» tab is available.



This format has been configured in your system by a qualified technician using the LIS Output Format documentation. Call your HORIBA ABX representative for any modification of this information.

Heading/key	Function
Numerical results	Selected hematology parameters sent to the LIS
Flags and Pathologies	Flags and Pathologies (See Section 4: Workflow, 5.3. Flags , page 4-30) associated to the <u>selected</u> parameters sent to the LIS
Patient File	Selected fields sent to the LIS (See Section 4: Workflow, 2. Worklist description , page 4-15)

Tab. 5–9: ASTM Format settings

5.3.5. Network settings

This tab is available only if your instrument has been configured to have a «Network» Link (See Section 5: Settings, **5.3.1. General tab**, page 5-25).

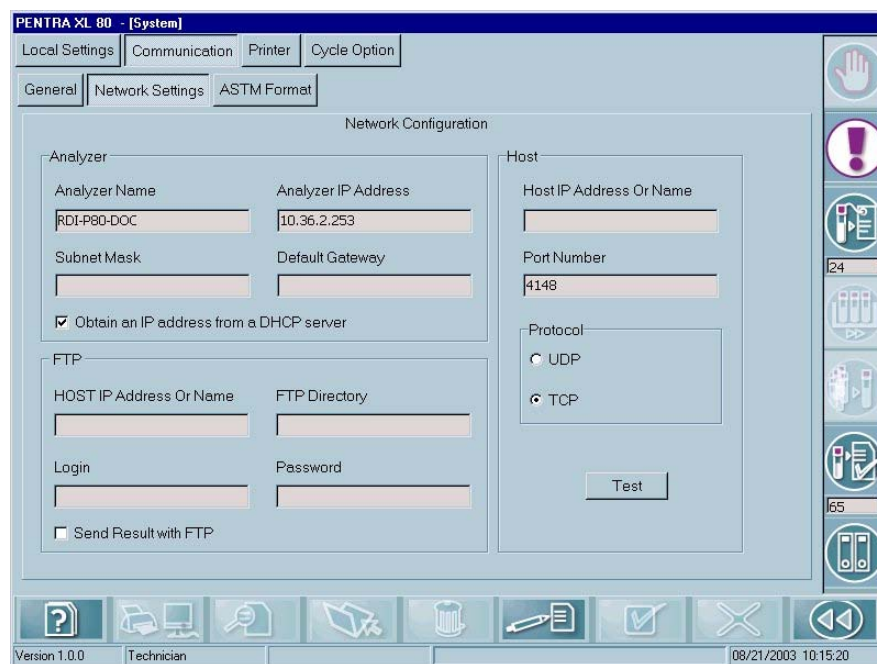


Fig. 5-23 System Network settings

Two methods are available for the Pentra XL 80 Ethernet connexion:

- ◆ By using «Sockets» process
- ◆ By using a FTP file transfert protocol

Heading/key	Function	Default value
Analyser Name	DNS (Domain Name System) of the instrument	empty
Analyser IP address	Instrument IP address	empty
Subnet Mask	Subnet Mask	empty
Default Gateway	Default Gateway	empty
Obtain an IP address from a DHCP server	Ask IP to server (DHCP)	checked
Port Number	Port Number used by TCP/IP sockets	4148
Host IP address or Name	Host IP address or DNS name	empty
FTP directory	Directory name of the FTP server	empty
Login	Login allocated by the FTP server	empty
password	password for the FTP login	empty
Send result with FTP	Selection of the FTP transfert (disable the Socket Transfert)	unchecked
Test	Runs a short network Test	
Protocol	selection between TCP or UDP socket	TCP

Tab. 5–10: Network settings

5.4. Printer

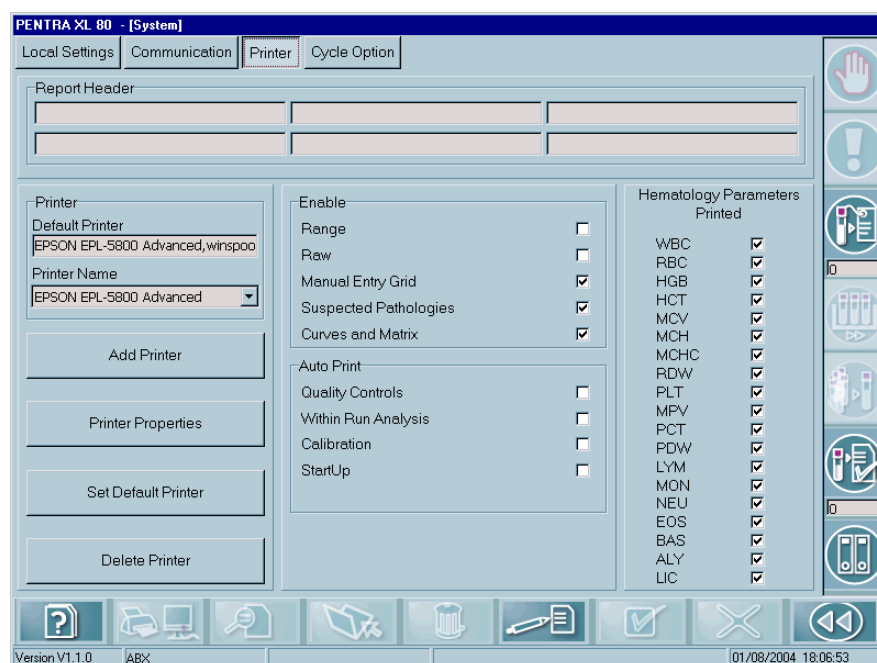


Fig. 5–24 System Printer tab

Default settings for the checked boxes are as shown [Fig. 5–24](#), page 5-31.

To modify printer properties, select the «Edit» key and use one the following functions:

Heading	key/List	Function
Report header	Report header	Six fields of 20 characters maximum each (see Fig. 5-25 , page 5-33))
Printer	Printer Name	List of installed printers
	Default printer	Printer used by the software
	Add printer	Calls «Windows NT» window for adding a local printer
	Printer properties	Calls the printers properties screen (see 5.4.2. Printer properties , page 5-34)
	Set Default Printer	The printer displayed into the printer list is the default printer
Enable	Delete Printer	The printer displayed into the printer list is removed
	Range	Normal limits are printed out when checked (see Fig. 5-25 , page 5-33)
	Raw	Raw counts are printed out when checked (see Fig. 5-25 , page 5-33)
	Manual entry grid	Manual formula are printed out when checked (see Fig. 5-25 , page 5-33)
	Suspected pathologies	Pathologies are printed out if checked (see Fig. 5-25 , page 5-33)
Auto Print	Curves and matrix	Printed out when checked
	Quality control Within Run analysis Calibration Startup	Quality control, Within Run, Calibrator, Startup, Unmatched results are automatically printed out when checked
	Hematology parameters	Selected parameters are not printed out

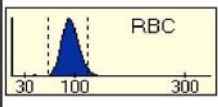
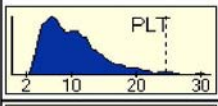
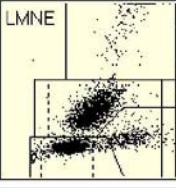
Tab. 5-11: Printer settings



Printing the «raw counts» will be possible only if:

- ◆ «System\Printer\Raw» option (See **Fig. 5-24**“System Printer tab”, page 31) has been checked in this screen
- ◆ «Print the run + raw counts in full page for selected rows» option is selected (See Section 4: Workflow, **6.4.1. Printout or Transmit Report list**, page 4-65).

5.4.1. Printout example

Report Printout				Unvalidated																																																																																													
Final report date 06/04/2003 15:16:18		Sample ID 0061		Collection Date																																																																																													
Type Standard		Department		Physician																																																																																													
Comments																																																																																																	
Patient ID		Patient Name		First Name																																																																																													
Date of Birth		Age		Gender																																																																																													
Comments																																																																																																	
Operator Technician		Startup Status		Startup not done																																																																																													
		<table border="1"> <tr><td>RBC</td><td>4.72</td><td>10⁶/mm³</td><td><</td><td>Range</td><td>></td></tr> <tr><td>HGB</td><td>—</td><td>g/dL</td><td>4.00</td><td>6.20</td><td></td></tr> <tr><td>HCT</td><td>40.0</td><td>%</td><td>11.0</td><td>18.8</td><td></td></tr> <tr><td>MCV</td><td>85</td><td>μm³</td><td>35.0</td><td>65.0</td><td></td></tr> <tr><td>MCH</td><td>—</td><td>pg</td><td>80</td><td>100</td><td></td></tr> <tr><td>MCHC</td><td>—</td><td>g/dL</td><td>26.0</td><td>34.0</td><td></td></tr> <tr><td>RDW</td><td>12.8</td><td>%</td><td>31.0</td><td>35.0</td><td></td></tr> <tr><td>PLT</td><td>225</td><td>10³/mm³</td><td>10.0</td><td>20.0</td><td></td></tr> <tr><td>MPV</td><td>10.2 fL</td><td>μm³</td><td>6.0</td><td>10.0</td><td></td></tr> <tr><td>PCT</td><td>0.231</td><td>%</td><td>0.200</td><td>0.500</td><td></td></tr> <tr><td>PDW</td><td>19.0 fL</td><td>%</td><td>8.0</td><td>18.0</td><td></td></tr> </table>		RBC	4.72	10 ⁶ /mm ³	<	Range	>	HGB	—	g/dL	4.00	6.20		HCT	40.0	%	11.0	18.8		MCV	85	μm ³	35.0	65.0		MCH	—	pg	80	100		MCHC	—	g/dL	26.0	34.0		RDW	12.8	%	31.0	35.0		PLT	225	10 ³ /mm ³	10.0	20.0		MPV	10.2 fL	μm ³	6.0	10.0		PCT	0.231	%	0.200	0.500		PDW	19.0 fL	%	8.0	18.0		<table border="1"> <tr><th colspan="2">Flags and Alarms</th></tr> <tr><td>Analyzer Alarms</td><td>LMNE+</td></tr> </table>		Flags and Alarms		Analyzer Alarms	LMNE+																						
RBC	4.72	10 ⁶ /mm ³	<	Range	>																																																																																												
HGB	—	g/dL	4.00	6.20																																																																																													
HCT	40.0	%	11.0	18.8																																																																																													
MCV	85	μm ³	35.0	65.0																																																																																													
MCH	—	pg	80	100																																																																																													
MCHC	—	g/dL	26.0	34.0																																																																																													
RDW	12.8	%	31.0	35.0																																																																																													
PLT	225	10 ³ /mm ³	10.0	20.0																																																																																													
MPV	10.2 fL	μm ³	6.0	10.0																																																																																													
PCT	0.231	%	0.200	0.500																																																																																													
PDW	19.0 fL	%	8.0	18.0																																																																																													
Flags and Alarms																																																																																																	
Analyzer Alarms	LMNE+																																																																																																
		<table border="1"> <tr><td>WBC</td><td>5.5</td><td>10³/mm³</td><td><</td><td>Range</td><td>></td></tr> <tr><td>NEU</td><td>49.1%</td><td>%</td><td>4.0</td><td>11.0</td><td></td></tr> <tr><td>LYM</td><td>36.3%</td><td>%</td><td>50.0</td><td>80.0</td><td>2.00 8.00</td></tr> <tr><td>MON</td><td>10.1%</td><td>%</td><td>25.0</td><td>50.0</td><td>1.00 5.00</td></tr> <tr><td>EOS</td><td>4.0%</td><td>%</td><td>2.0</td><td>10.0</td><td>0.10 1.00</td></tr> <tr><td>BAS</td><td>0.5%</td><td>%</td><td>0.0</td><td>5.0</td><td>0.00 0.40</td></tr> <tr><td>ALY</td><td>1.5%</td><td>%</td><td>0.0</td><td>2.0</td><td>0.00 0.20</td></tr> <tr><td>UC</td><td>0.8%</td><td>%</td><td>0.0</td><td>2.0</td><td>0.00 0.20</td></tr> </table>		WBC	5.5	10 ³ /mm ³	<	Range	>	NEU	49.1%	%	4.0	11.0		LYM	36.3%	%	50.0	80.0	2.00 8.00	MON	10.1%	%	25.0	50.0	1.00 5.00	EOS	4.0%	%	2.0	10.0	0.10 1.00	BAS	0.5%	%	0.0	5.0	0.00 0.40	ALY	1.5%	%	0.0	2.0	0.00 0.20	UC	0.8%	%	0.0	2.0	0.00 0.20																																														
WBC	5.5	10 ³ /mm ³	<	Range	>																																																																																												
NEU	49.1%	%	4.0	11.0																																																																																													
LYM	36.3%	%	50.0	80.0	2.00 8.00																																																																																												
MON	10.1%	%	25.0	50.0	1.00 5.00																																																																																												
EOS	4.0%	%	2.0	10.0	0.10 1.00																																																																																												
BAS	0.5%	%	0.0	5.0	0.00 0.40																																																																																												
ALY	1.5%	%	0.0	2.0	0.00 0.20																																																																																												
UC	0.8%	%	0.0	2.0	0.00 0.20																																																																																												
<table border="1"> <tr><th colspan="4">Microscopic Examination</th></tr> <tr><th></th><th>+</th><th>++</th><th>+++</th></tr> <tr><td>Anisocytosis</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>Hypochromia</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>Polychromasia</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>Poikilocytosis</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>Microcytosis</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>Macrocytosis</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>PLT Clumps</td><td>☐</td><td>☐</td><td>☐</td></tr> <tr><td>Neutrophils</td><td colspan="3"> </td></tr> <tr><td>Bands</td><td colspan="3"> </td></tr> <tr><td>Lymphocytes</td><td colspan="3"> </td></tr> <tr><td>Monocytes</td><td colspan="3"> </td></tr> <tr><td>Eosinophils</td><td colspan="3"> </td></tr> <tr><td>Basophils</td><td colspan="3"> </td></tr> <tr><td>Metamyelocytes</td><td colspan="3"> </td></tr> <tr><td>Myelocytes</td><td colspan="3"> </td></tr> <tr><td>Promyelocytes</td><td colspan="3"> </td></tr> <tr><td>Blast</td><td colspan="3"> </td></tr> <tr><td>ATY LYM</td><td colspan="3"> </td></tr> <tr><td>Other</td><td colspan="3"> </td></tr> <tr><td>Total(100%)</td><td colspan="3"> </td></tr> <tr><td>NRBC's</td><td colspan="3"> </td></tr> </table>						Microscopic Examination					+	++	+++	Anisocytosis	☐	☐	☐	Hypochromia	☐	☐	☐	Polychromasia	☐	☐	☐	Poikilocytosis	☐	☐	☐	Microcytosis	☐	☐	☐	Macrocytosis	☐	☐	☐	PLT Clumps	☐	☐	☐	Neutrophils				Bands				Lymphocytes				Monocytes				Eosinophils				Basophils				Metamyelocytes				Myelocytes				Promyelocytes				Blast				ATY LYM				Other				Total(100%)				NRBC's			
Microscopic Examination																																																																																																	
	+	++	+++																																																																																														
Anisocytosis	☐	☐	☐																																																																																														
Hypochromia	☐	☐	☐																																																																																														
Polychromasia	☐	☐	☐																																																																																														
Poikilocytosis	☐	☐	☐																																																																																														
Microcytosis	☐	☐	☐																																																																																														
Macrocytosis	☐	☐	☐																																																																																														
PLT Clumps	☐	☐	☐																																																																																														
Neutrophils																																																																																																	
Bands																																																																																																	
Lymphocytes																																																																																																	
Monocytes																																																																																																	
Eosinophils																																																																																																	
Basophils																																																																																																	
Metamyelocytes																																																																																																	
Myelocytes																																																																																																	
Promyelocytes																																																																																																	
Blast																																																																																																	
ATY LYM																																																																																																	
Other																																																																																																	
Total(100%)																																																																																																	
NRBC's																																																																																																	

Out of Panic Range xxx Out of Normal Range xxx

Fig. 5-25 Result printout

5.4.2. Printer properties

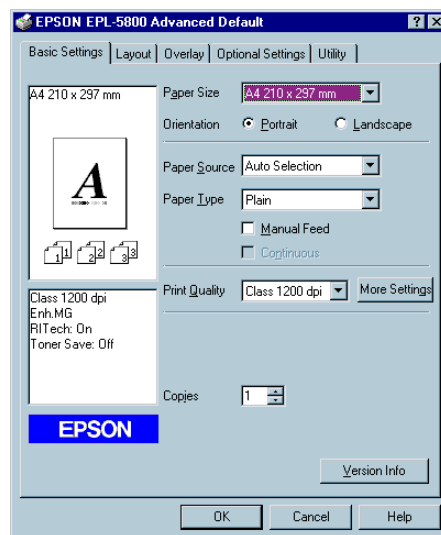


Fig. 5-26 Printer properties example

5.5. Cycle option

To modify one of the cycle option, select the «Edit» key and use the following functions:

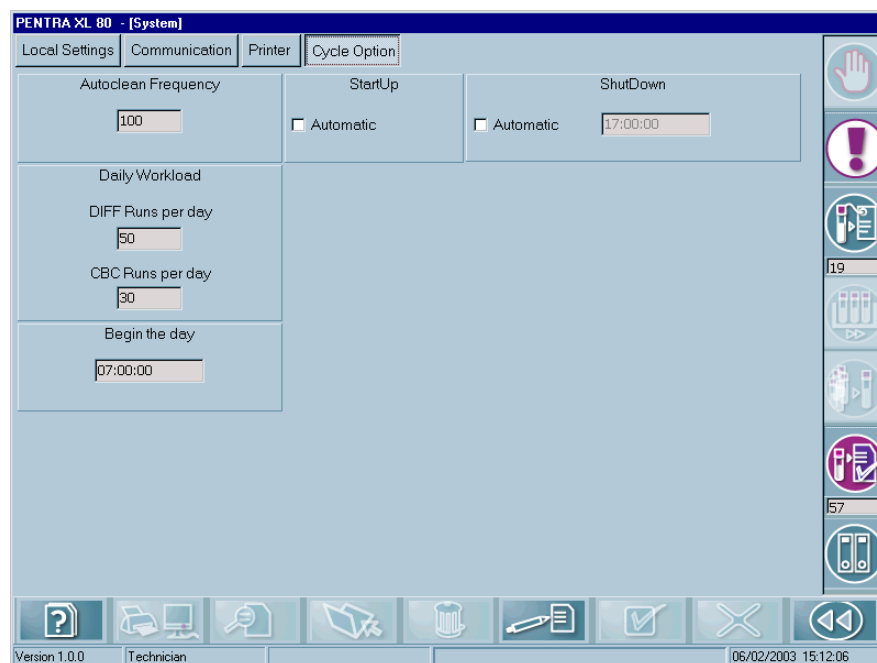


Fig. 5–27 System Cycle option tab

Heading/key	Function	Default value
Autoclean Frequency	Number of analyses performed to trigger the autoclean cycles	100
Startup	Startup cycle is automatic at begin of day (if checked)	Checked
Shutdown	Shutdown cycle is automatic at the programmed time (if checked)	Checked
Daily workload	Workflow notion (approximate number of DIF & CBC analyses per day). Used to warn the operator if reagent level is too short for the working day.	
Begin the Day	Options (described in Daily Guide: RAB156C) when the Begin of Day occurs, are available if: 1. the instrument is started on a new working day (date changed) 2. the Begin of day time is over (see Fig. 5–27, page 5-35)	

Tab. 5–12: Cycle option

6. Save and restore

6.1. Access to «Save/Restore» screen

From the «Settings» window, press the «System» key

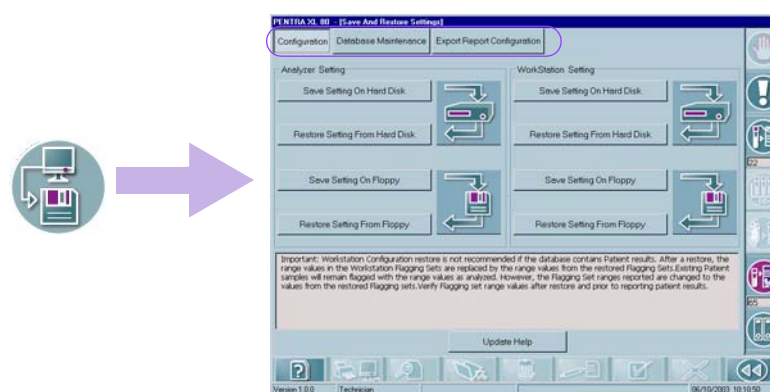


Fig. 5–28 Save and restore configuration

The «Save and restore» screen provides the operator with three tab choices as indicated:

- ◆ 6.2. Configuration, page 5-36
- ◆ 6.3. Dump database, page 5-38
- ◆ 6.4. Report exportation, page 5-38

6.2. Configuration

6.2.1. Analyzer setting functions

Heading/key	Function
Save settings on hard disk	Opens a dialogue window in order to save the current configuration
Restore setting from hard disk	Opens a dialogue window in order to select one of the save settings
Save setting on floppy	Opens a dialogue window in order to save the current configuration on a disk.
Restore settings from floppy	Opens a dialogue window in order to select one of the save settings on the disk

Tab. 5–13: Analyzer save/restore

6.2.2. Workstation setting functions

Heading/key	Function
Save settings on hard disk	Opens a dialogue window in order to select the save path of the current configuration
Restore setting from hard disk	Opens a dialogue window in order to select one of the save settings
Save setting on floppy	Opens a dialogue window in order to select the save path of the current configuration on a disk. If the floppy is unformatted, the software then invites the user to format it.
Restore settings from floppy	Opens a dialogue window in order to select one of the save settings on the disk

Tab. 5–14: Workstation save/restore

6.2.3. Update of the online help

The User Manual CDROM includes the user manuals in all languages (English, Italian, Spanish, Portuguese, German, Danish, Swedish, Greek and French).

This one contains the User manuals in a PDF format for printing and reviewing operations.

It also includes last update of the online help file. This one can be easily installed on your Pentra XL 80, using the «Help Update» key, as follows:

- ◆ Insert the CDROM into the instrument CD drive.
- ◆ Open the «Settings/Save and Restore settings» screen
- ◆ Press the «Update help» key to access to User manual screen. The contents of this CDROM can be reviewed on all PC having an Acrobat reader software installed (version 5.0 or higher).
- ◆ Choose your language

The «Print pdf» key opens the user manual in «Acrobat reader» software in order to be read or printed.

The «View HTML» key opens the online help recorded on the CDROM.

The «Install Help» key will install the new online help (from the CDROM) on your instrument and erase the previous one.

6.3. Dump database

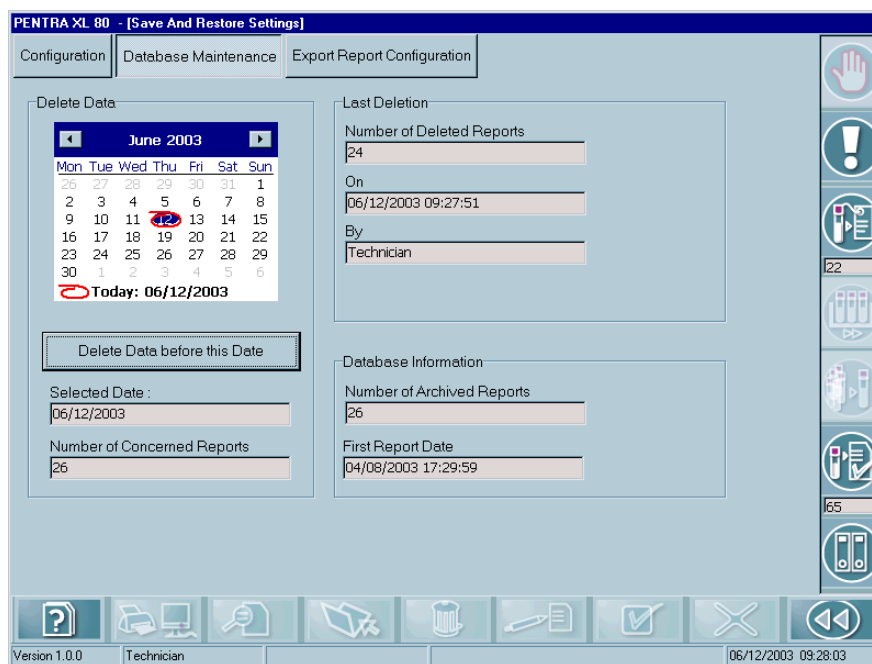


Fig. 5–29 Database maintenance tab

Heading/key	Function
Delete data before this date	Upon confirmation, deletes all orders, runs and results and associated patients prior to the selected date. A notification is made in the logs.

Tab. 5–15: Database maintenance key

6.4. Report exportation

6.4.1. Monthly exportation

Once a month, it is possible to save the reports (that have been deleted by the operator) on an external media (floppy disks or network hard disk) in another format than the one used by the Pentra XL 80.

The format used to export the reports, is «compressed XML». This one can be easily exploited by a standard browser (*Internet Explorer™ 5 for example*), but can not be re-imported on the Pentra XL 80.

All the reports that are deleted in the current month, are stored to be exported at the beginning of each month (if required by the operator). This exportation is performed during the «Begin of day» sequence of the new month (See Daily Guide: RAB156C).

To configure Report exportation and destination, proceed as followed:

- ◆ From the «Save and restore» menu screen, select the «Export Report Configuration» tab

- ◆ Select the «EDIT» key
- ◆ Select the check box to authorize the exportation of deleted results at the beginning of each new month
- ◆ Now choose the media: floppy disk or network by FTP
- ◆ In case Network by FTP has been chosen, now enter:
 - Host name or IP address of the FTP server
 - The share folder of the FTP server
 - The login and password of your FTP account
- ◆ Select the «OK» key to confirm.

6.4.2. Day by day exportation

It is also possible to require the exportation of the deleted files of the last working day, at the startup of the instrument.

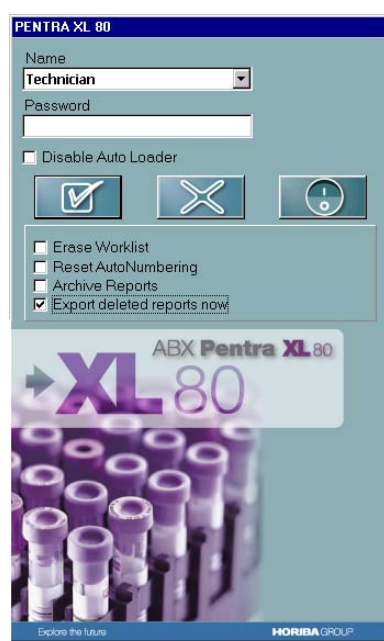


Fig. 5–30 Begin of day exportation option

Export deleted reports now: when checked, the instrument will proceed to an immediate exportation of the last day deleted files. If unchecked, the deleted files will be exported at the beginning of each new month if the instrument is configured as described in [6.4.1. Monthly exportation](#), page 5-38.

7. User profiles

In the Pentra XL 80 software, there are 3 groups of user profiles.

- ◆ The ABX «*technicians*» profile which gives access to specific technical functions which is accessed only by an HORIBA ABX certified technician.
- ◆ The «*TrainedUsers*» software profile which allows access to Service menus useful for instrument maintenance operations. It also allows access to Instrument settings and Calibration functions.
- ◆ The «*Users*» profile wich allows access to daily working operations.

▼ **User profiles sections:**

- ◆ **7.1. Accessing the User screen**, page 5-40
- ◆ **7.2. User menu function keys**, page 5-40
- ◆ **7.3. Creating a new «User» profile**, page 5-41

7.1. Accessing the User screen

From the «Settings» window, select the «User» key

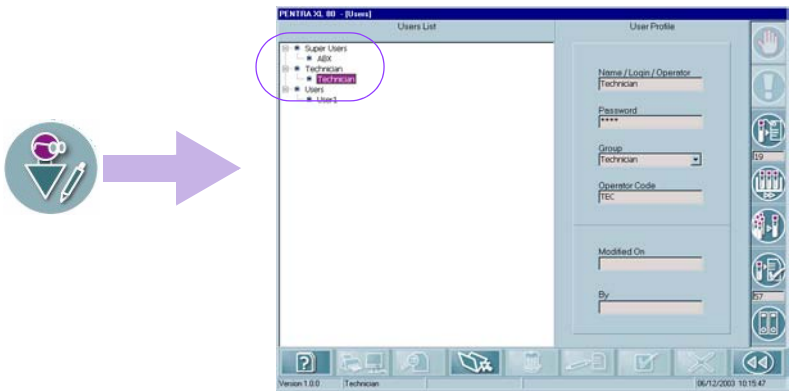


Fig. 5-31 Setting User profiles

7.2. User menu function keys

Key	Name	Function
	Insert	Allows a new user to be added
	Edit	Modifies a user profile
	Delete	Deletes a user profile. A confirmation profile is displayed.

Tab. 5-16: User menu function keys

7.3. Creating a new «User» profile

To create a New Profile, follow the steps as indicated:

- ◆ From the «Settings» window, select the «User» key
- ◆ Select the «Insert» key.
- ◆ In the «Name/login/operator» field, type in your operator name (10 characters maxi)
- ◆ Enter your password (10 characters maximum, Default password is «ABX»)
- ◆ Select the «Group» field and scroll through the list to select a «User» or «Trained User» profile.
- ◆ Now select the «Operator Code» field and enter your code.
- ◆ Once all information requested has been completely filled in, on the «User» screen, select the «OK» key to confirm your entries. Your profile will now be added to one of the profile lists



A user can edit, insert, delete a login of the same level or a lower level but not at a higher level.

Entering the name of the user is done in the login windows (See Daily Guide: RAB156C).

▼ User login while Pentra XL 80 software running

A new user can login, without reinitializing the instrument:

- Double-click the second box (A) of the Footer (see **Fig. 5-32 User list**, page 5-41).

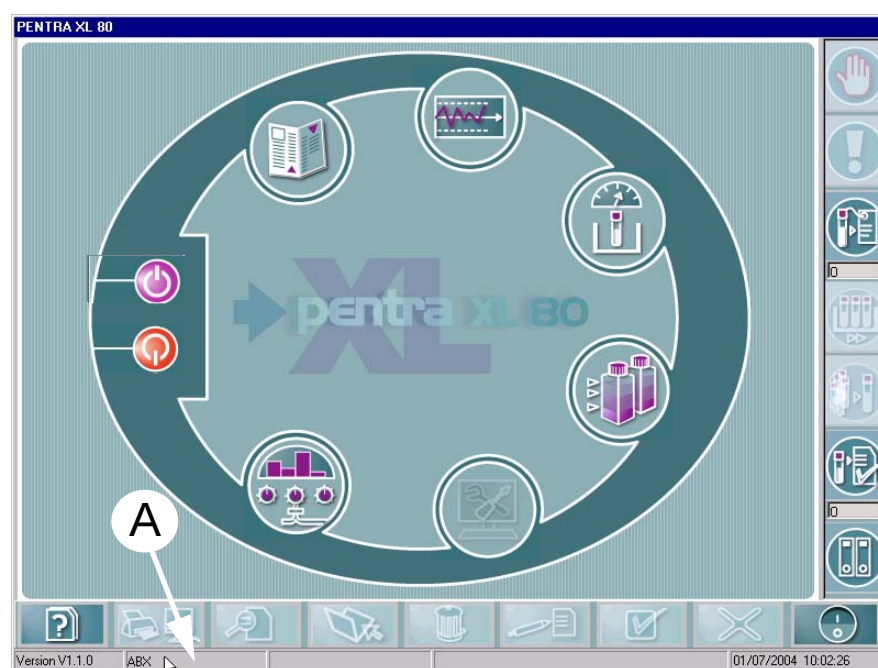


Fig. 5-32 User list

- When the «Login» window appears, select the user in the list.

- Enter the password, then press the «Validate button» (see [Fig. 5-33 User password](#), page 5-42).

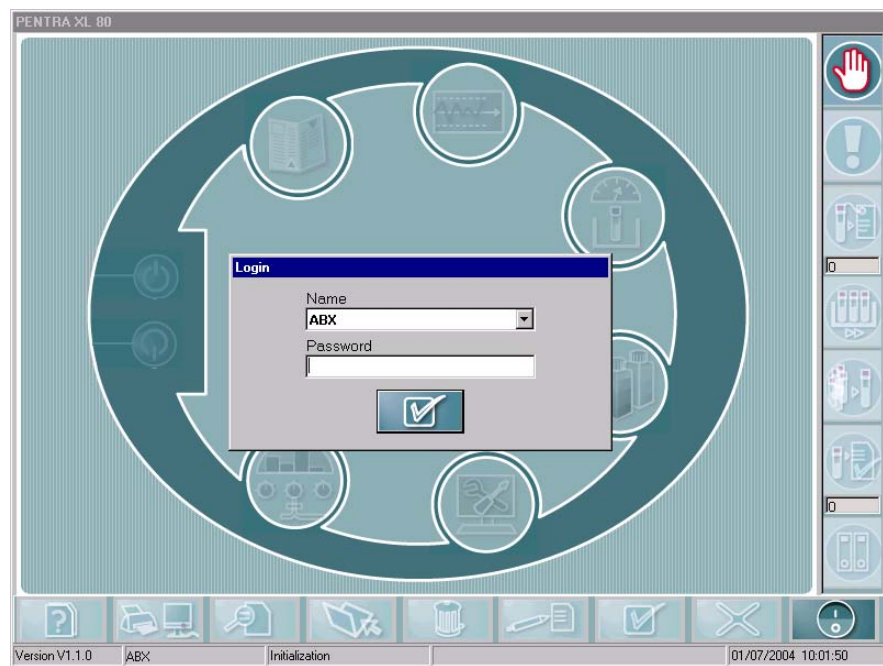


Fig. 5-33 User password



This functionality is not available in the «Settings» and «Calibration» menus and also while a cycle is running on the instrument.

8. Sample Types

20 different blood sample types are available. 8 of these sample types have already been incremented (Standard, Man, Woman, Child1, Child2, Child3, Child4 and Child5). The «Types» screen will allow the operator to create the following changes:

- ◆ A new type (see [8.1. Accessing the «Types» parameters menu](#), page 5-43)
- ◆ Pathological limits (see [8.2. Pathological limits](#), page 5-46)
- ◆ Alarm levels & curve thresholds (see [8.3. Alarms & Curve thresholds](#), page 5-47)

8.1. Accessing the «Types» parameters menu

From the «Settings» window, select the «Type» key

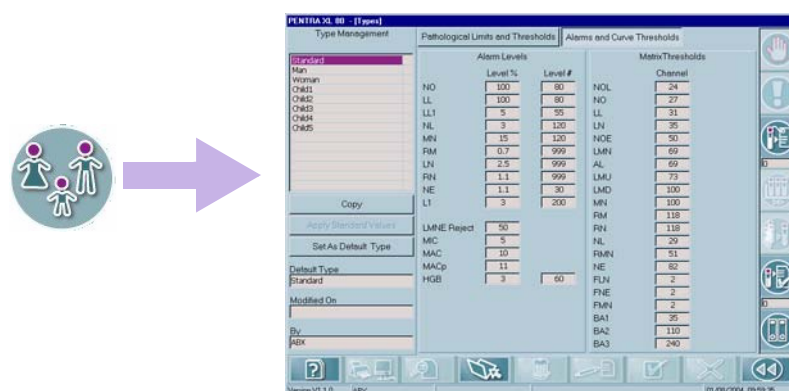


Fig. 5-34 Type parameters - Alarms & curves thresholdsTab

From this menu, the operator will have the ability to:

- ◆ Create a new blood type (see [8.1.2. Creating a new blood sample type](#), page 5-44)
- ◆ Modify Pathological limits (see [8.1.3. Modifying limit/Alarm values](#), page 5-44)
- ◆ Modify Alarms & Curve thresholds (see [8.1.3. Modifying limit/Alarm values](#), page 5-44)



When one of the «Child» types is selected, a third tab will appear indicating «Age Range» (see [8.4. Age range](#), page 5-51).

8.1.1. Functions keys

Key/Heading	Name	Function
	Insert	Allows to define a new blood type (see 8.1.2. Creating a new blood sample type , page 5-44)
	Edit	Allows to modify the selected type (except the «Standard» type which is always in read only)(see 8.1.3. Modifying limit/Alarm values , page 5-44)
Type management	Copy	Copies values from one type to another (see 8.1.4. Sample Type copying , page 5-45)
	Apply standard values	In «Edit» mode, the selected type takes values of the «standard» type
	Set as default type	The type selected in the list becomes the default type

Tab. 5-17: Types function Keys

8.1.2. Creating a new blood sample type

Select the «Insert» key

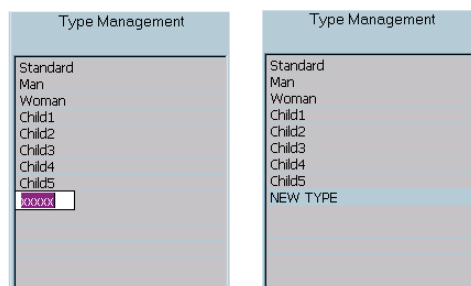


Fig. 5-35 Creating a new type

Type in the name of the type (20 characters maximum).

From here you may:

- ◆ Select the «OK» key to confirm the new type created.
- ◆ Select the «Apply standard values» to paste the values from the «standard type» to the new created type, and then select the «OK» key to confirm the pasted values.
- ◆ Copy values from one type to the new created type (see [8.1.4. Sample Type copying](#), page 5-45).
- ◆ Modify limits or modify alarms levels & curves thresholds (see [8.1.3. Modifying limit/Alarm values](#), page 5-44).

8.1.3. Modifying limit/Alarm values

From the «Pathological limits» tab (or «Alarms & curves Thresholds» tab), select the «Edit» key.

Click the figure you want to modify and enter a new value.

Once all entries have been made, select the «OK» key to confirm your modifications.

8.1.4. Sample Type copying

From the «Type management» field, select a sample type that you would like to copy from (in the below example: «Woman»),

Then select the «Copy» key.

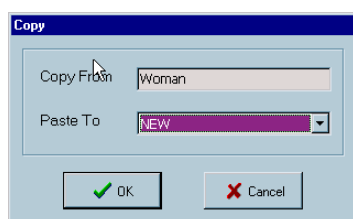


Fig. 5–36 Type copying

In the «Copy» window, scroll the list to choose the type where the values must be pasted.

Now select the «OK» key.

8.1.5. Type automatic association

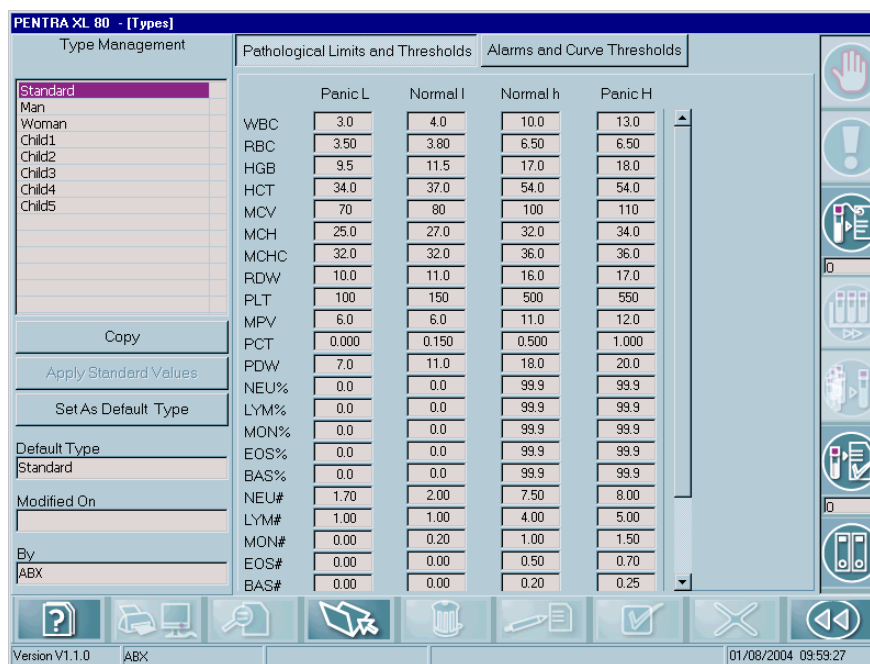
▼ Sample with known types (except «Standard»)

If the type is known (when the order is created) or captured in the worklist, this one is used to provide results.

▼ Sample with no type

- ◆ The «default type» (see [Tab. 5–17: Types function Keys](#), page 5-44) is automatically associated to provide results.
- ◆ When the «Standard» type is captured in the order or defined as «default type», an automatic search on «Department», «Date of birth» or «Gender» field is performed:
 - 1- if a type name has been entered in the «department» field, this one is used to provide results.
 - 2- if the «date of birth» corresponds to one of the child «age ranges» (see [8.4. Age range](#), page 5-51), this one is used to provide results.
 - 3- if the «Gender» is known, the «Male» or «Female» type is used to provide results

8.2. Pathological limits



	Panic L	Normal L	Normal h	Panic H
WBC	3.0	4.0	10.0	13.0
RBC	3.50	3.80	6.50	6.50
HGB	9.5	11.5	17.0	18.0
HCT	34.0	37.0	54.0	54.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6.0	6.0	11.0	12.0
PCT	0.000	0.150	0.500	1.000
PDW	7.0	11.0	18.0	20.0
NEU%	0.0	0.0	99.9	99.9
LYM%	0.0	0.0	99.9	99.9
MON%	0.0	0.0	99.9	99.9
EOS%	0.0	0.0	99.9	99.9
BAS%	0.0	0.0	99.9	99.9
NEU#	1.70	2.00	7.50	8.00
LYM#	1.00	1.00	4.00	5.00
MON#	0.00	0.20	1.00	1.50
EOS#	0.00	0.00	0.50	0.70
BAS#	0.00	0.00	0.20	0.25

Fig. 5-37 Pathological limits tab

A set of limits is available for each sample type. The operator, according to the laboratory specifications, can modify these limits. The limits that have been entered into the 8 different types (Standard, Man, Woman, Child1, Child2, Child3, Child4, and Child5) are Factory Default values (see [8.5.1. Pathological limits and thresholds](#), page 5-51).

The «Standard Type» values are set values and cannot be modified by the user.

Man, Woman, Child1, Child2, Child3, Child4, and Child5 Factory Default values can be modified by the user.

- ◆ Results exceeding the «Normal Ranges» limits are marked with the following flags:
 - «h» for results above the normal upper limit,
 - «l» for results below the normal lower limit.
- ◆ Results exceeding the «Panic Ranges» limits are marked with the following flags:
 - «H» for results above the extreme upper limit,
 - «L» for results below the extreme lower limit.

8.3. Alarms & Curve thresholds

8.3.1. Alarm levels

Each flag is adjustable according to the numbers entered in the percentage and(or) an absolute value field of the parameter. The flags are triggered by values exceeding these set numbers.

Alarm Levels		
	Level %	Level #
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Fig. 5-38 Standard alarm levels

(See Section 4: Workflow, [5.3. Flags](#), page 4-30)

Default values have been incremented for the 8 types (Standard, man, woman, child1, child2, child3, child4 and child5).

(see [8.1.3. Modifying limit/Alarm values](#), page 5-44)

(see [8.5.2. Alarms levels](#), page 5-60)

8.3.2. 5DIFF Matrix thresholds

Each axis of the matrix (X and Y) is divided into 128 channels numbered from 0 to 127.

13 (Y) vertical indices and 13 (X) horizontal indices will allow the user to locate these channels by multiples of 10. The first index channel of the 5-Diff matrix is the origin (at the bottom left corner). This is the «0» channel. The second channel will be 10, the third channel will be 20, the fourth channel will be 30, and so on. The threshold adjustments are expressed in channels.

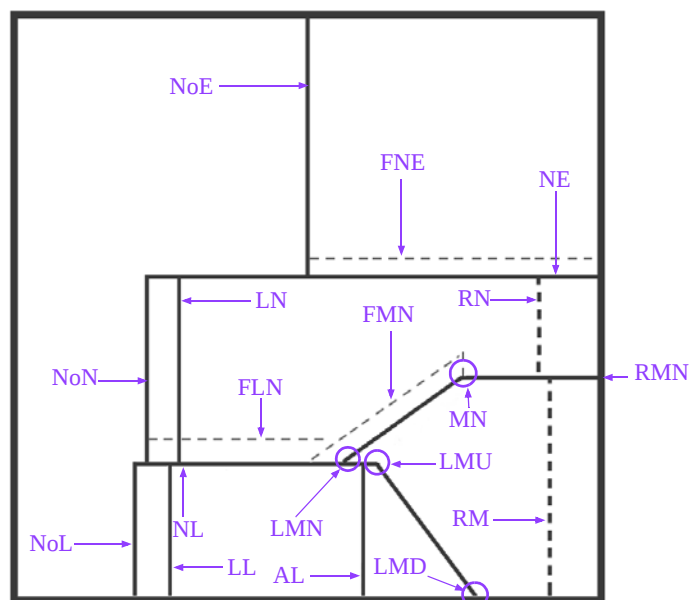


Fig. 5-39 Matrix thresholds

There are only 3 basic reasons to adjust the matrix thresholds. (see **8.1.3. Modifying limit/Alarm values**, page 5-44):

- To improve the separation between different cell populations which may vary according to the selection of anti-coagulant for blood sample collection or minor internal instrument adjustments.
- To modify the alarm areas of these cell populations for improvement in detection sensitivity.
- To modify one or more matrix areas in order to define a more precise measurement of a specific cell population for research purposes.

(see **8.5.3. Matrix thresholds**, page 5-64)

Thresh.	Purpose	Low limit	High limit
NOL	Separation between Noise & Left Lympho	0	LL
NON	Separation between Noise & Left Neutro	NOL	NOE
LL	Separation between Left Lympho & Lympho.	NOL	AL
LN	Separation between Neutro & Left Neutro	NON	LMN
NOE	Separation between Noise & Eosino	NON	Cha. 127
LMN	Intersec. dot between Lympho/Mono/Neutro area.	LN	LMU
AL	Separation between Lympho & Left Lympho	LL	LMU
LMU	Upper dot of the separation slope ALY/Mono	AL	LMD
LMD	Lower dot of the separation slope ALY/Mono	LMU	RM
MN	Upper dot of the separation slope Mono/Neutro	LMN	RM
RM	Separation between Mono & Right Mono	LMD	Cha. 127
RN	Separation between Neutro & Right Neutro	MN	Cha. 127

Tab. 5–18: Matrix DC thresholds (resistive)

Threshold	Purpose	Low limit	High limit
NL	Separation between Lympho & Neutro	0	RMN
RMN	Separation between Right Mono & Right Neutro	NL	NE
NE	Separation between Neutro & Eosino	RMN	Channel 127

Tab. 5–19: AC Thresholds (Absorbance)

Threshold	Purpose
FLN	Channel number for the NL alarm area
FNE	Channel number for the NE alarm area
FMN	Channel number for the MN alarm area

Tab. 5–20: Channel Width

8.3.3. BAS curve threshold

All of the leukocytes are shown between 0 and BA3 thresholds (See Section 6: Description & Technology, **3.3. WBC and differential count**, page 6-17).

L1 absolute value is calculated between the channel 0 and the BA1 threshold. The percentage of basophils is calculated according to the number of particles from the BA2 threshold to the BA3 threshold.

These thresholds are factory adjusted to the following values.

Threshold	Purpose
BA1	Separation between L1# counting area and WBC
BA2	Separation between WBC & BAS
BA3	End of the BAS Counting area

Tab. 5-21: BAS thresholds

8.4. Age range

This tab is accessible if and only if one of the «child» types has been selected from the «Type management» list (see Fig. 5-35, page 5-44).

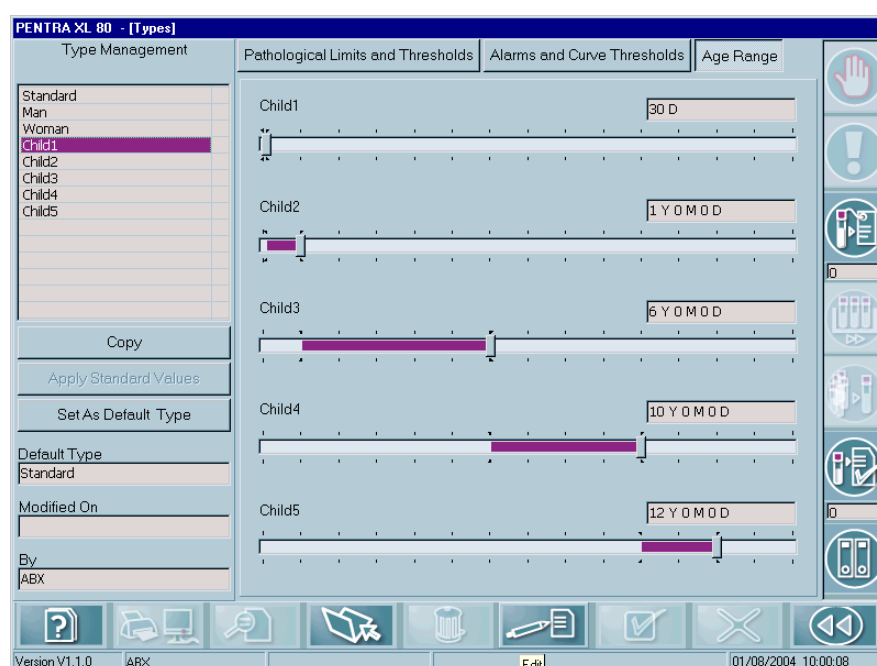


Fig. 5-40 Types - Age Range

This tab will allow the user to define limits between pediatric areas. The child type range is displayed in purple. The low range of a child (n+1) begins at the high range of child (n) + 1 day.

The date format of the range is as followed: «xx year xx month xx day»

To modify the range of one child, select the «Edit» key.

Move left/right the cursor of the child type to display the wished high range.

Select the «OK» key to confirm your range selection.

8.5. Defaults settings of the Pentra XL 80 types

The following values are the software default values for pathological limits & thresholds (Section 5: Settings, **8.5.1. Pathological limits and thresholds**, page 5-51,) Alarm levels (Section 5: Settings, **8.5.2. Alarms levels**, page 5-60), Matrix thresholds, classified by types (standard, man, woman, Child 1,2,3,4 and 5).

8.5.1. Pathological limits and thresholds

From the menu: Settings \ Types \ Pathological limits and Thresholds (Section 5: Settings, **8.1.3. Modifying limit/Alarm values**, page 5-44)

Standard type	Panic L	Normal l	Normal h	Panic H
WBC	3.00	4.00	10.00	13.00
RBC	3.50	3.80	6.50	6.50
HGB	9.50	11.5	17.0	18.0
HCT	34.0	37.0	54.0	54.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	1.70	2.00	7.50	8.0
LYM	1.00	1.00	4.00	5.00
MON	0.00	0.20	1.00	1.50
EOS	0.00	0.00	0.50	0.70
BAS	0.00	0.00	0.20	0.25
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Tab. 5–22: Standard default settings

Man	Panic L	Normal l	Normal h	Panic H
WBC	3.00	4.00	10.00	13.00
RBC	3.50	4.50	6.50	6.50
HGB	11.0	13.0	17.0	18.0
HCT	37.0	40.0	54.0	54.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	1.70	2.00	7.50	8.0
LYM	1.00	1.00	4.00	5.00
MON	0.00	0.20	1.00	1.50
EOS	0.00	0.00	0.50	0.70
BAS	0.00	0.00	0.20	0.25
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Tab. 5-23: Man default settings

Woman	Panic L	Normal l	Normal h	Panic H
WBC	3.00	4.00	10.00	13.00
RBC	3.50	3.80	5.80	6.00
HGB	9.50	11.5	16.0	17.0
HCT	34.0	37.0	47.0	50.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	1.70	2.00	7.50	8.0
LYM	1.00	1.00	4.00	5.00
MON	0.00	0.20	1.00	1.50
EOS	0.00	0.00	0.50	0.70
BAS	0.00	0.00	0.20	0.25
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Tab. 5–24: Woman default settings

Child 1	Panic L	Normal l	Normal h	Panic H
WBC	10.0	10.0	26.0	30.0
RBC	4.00	4.00	6.00	6.00
HGB	13.5	13.5	19.5	19.5
HCT	44.0	44.0	64.0	64.0
MCV	98	100	112	114
MCH	30.0	30.0	38.0	38.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	6.00	6.00	26.0	26.0
LYM	2.00	2.00	11.0	11.0
MON	0.40	0.40	3.10	3.10
EOS	0.00	0.00	0.85	0.85
BAS	0.00	0.00	0.65	0.65
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.35	0.35
LIC#	0	0	0.35	0.35

Tab. 5–25: Child 1 default settings

Child 2	Panic L	Normal l	Normal h	Panic H
WBC	10.0	10.0	26.0	30.0
RBC	4.00	4.00	6.00	6.00
HGB	13.5	13.5	19.5	19.5
HCT	44.0	44.0	64.0	64.0
MCV	98	100	112	114
MCH	30.0	30.0	38.0	38.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	6.00	6.00	26.0	26.0
LYM	2.00	2.00	11.0	11.0
MON	0.40	0.40	3.10	3.10
EOS	0.00	0.00	0.85	0.85
BAS	0.00	0.00	0.65	0.65
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.35	0.35
LIC#	0	0	0.35	0.35

Tab. 5–26: Child 2 default settings

Child 3	Panic L	Normal l	Normal h	Panic H
WBC	5.00	5.00	15.0	17.0
RBC	4.10	4.10	5.50	5.50
HGB	11.5	12.0	14.0	14.5
HCT	36.0	36.0	44.0	44.0
MCV	71	73	89	91
MCH	24.0	24.0	30.0	30.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	1.50	1.50	8.50	8.50
LYM	2.00	2.00	8.00	8.00
MON	0.00	0.00	0.8	0.8
EOS	0.00	0.00	0.65	0.65
BAS	0.00	0.00	0.20	0.30
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.35	0.35
LIC#	0	0	0.35	0.35

Tab. 5-27: Child 3 default settings

Child 4	Panic L	Normal l	Normal h	Panic H
WBC	4.50	4.50	13.5	15.0
RBC	4.00	4.00	5.40	5.40
HGB	11.0	11.5	14.5	15.0
HCT	37.0	37.0	45.0	45.0
MCV	75	77	91	93
MCH	24.0	24.0	30.0	30.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	1.80	1.80	8.00	8.00
LYM	1.50	1.50	6.50	6.50
MON	0.00	0.00	0.8	0.8
EOS	0.00	0.00	0.60	0.60
BAS	0.00	0.00	0.20	0.30
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Tab. 5–28: Child 4 default settings

Child 5	Panic L	Normal l	Normal h	Panic H
WBC	4.50	4.50	13.5	15.0
RBC	4.00	4.00	5.40	5.40
HGB	11.0	11.5	14.5	15.0
HCT	37.0	37.0	45.0	45.0
MCV	75	77	91	93
MCH	24.0	24.0	30.0	30.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0.00	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU	1.80	1.80	8.00	8.00
LYM	1.50	1.50	6.50	6.50
MON	0.00	0.00	0.8	0.8
EOS	0.00	0.00	0.60	0.60
BAS	0.00	0.00	0.20	0.30
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Tab. 5–29: Child 5 default settings

8.5.2. Alarms levels

From the menu: Settings \ Types \ Alarms and Curves Thresholds (see Section 5: Settings, **8.1.3. Modifying limit/Alarm values**, page 5-44)

Standard	Level %	Level #
N0	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5-30: Standard type alarm levels

Man	Level %	Level #
N0	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5–31: Man alarm levels

Woman	Level %	Level #
N0	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5–32: Woman alarm levels

Child 1	Level %	Level #
N0	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5-33: Child 1 alarm levels

Child 2	Level %	Level #
N0	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5-34: Child 2 alarm levels

Child 3	Level %	Level #
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5-35: Child 3 alarm levels

Child 4	Level %	Level #
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5-36: Child 4 alarm levels

Child 5	Level %	Level #
N0	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE Reject	50	
MIC	5	
MAC	45	
MACp	11	
HGB	3	60

Tab. 5–37: child 5 alarm levels

8.5.3. Matrix thresholds

From the menu: Settings \ Types \ Alarms and Curves Thresholds

Standard	Channel	Standard	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5–38: Matrix Threshold values of the Standard type

Man	Channel	Man	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5–39: Matrix Threshold values of the Man type

Woman	Channel	Woman	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5–40: Matrix Threshold values of the Woman type

Child 1	Channel	Child 1	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5-41: Matrix Threshold values of the Child 1 type

Child 2	Channel	Child 2	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5-42: Matrix Threshold values of the Child 2 type

Child 3	Channel	Child 3	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5-43: Matrix Threshold values of the Child 3 type

Child 4	Channel	Child 4	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5-44: Matrix Threshold values of the Child 4 type

Child 5	Channel	Child 5	Channel
NOL	24	RN	118
NON	27	NL	29
LL	31	RMN	51
LN	35	NE	82
NOE	50	FLN	2
LMN	69	FNE	2
AL	69	FMN	2
LMU	73	BA1	35
LMD	100	BA2	110
MN	100	BA3	240
RM	118		

Tab. 5–45: Matrix Threshold values of the Child 5 type

Description & Technology

Contents

1. Pentra XL 80 description	6-2
1.1. Front View	6-2
1.2. Left side view	6-3
1.3. Right side view	6-4
1.4. Stat tube holder	6-5
1.5. Rear view	6-6
2. Automatic mode principles.....	6-7
3. Measuring principles	6-11
3.1. Multi distribution sampling sytem (MDSS)	6-11
3.2. CBC detection principles	6-13
3.3. WBC and differential count	6-17

The following section is the **Pentra XL 80** technology description, including

- 1. **Pentra XL 80 description**, page 6-2
- 2. **Automatic mode principles**, page 6-7
- 3. **Measuring principles**, page 6-11

1. Pentra XL 80 description

1.1. Front View



Fig. 6-1 Pentra XL 80 front view

- 1- **Reagent cover**: Access to bottles
- 2- **Rack loading tray**: Capacity of 10 racks of 10 tubes
- 3- **Rack ejection tray**: Capacity of 10 racks
- 4- **Left front cover** : Access to the rack mechanical loading system
- 5- **Tube holder door** : opens when performing manual analysis
- 6- **Right Front cover**: Access to the rack ejection mechanical system

1.2. Left side view



Fig. 6-2 Pentra XL 80 left side view

1- **Reagent Access** : Open this cover to replace empty bottles

2- **Optical bench**: Ensures the support and adjustment of the flowcell, lamp, and optical and electronic elements.

3- **LMNE Syringe assembly**:

- Ensures the correct proportioning of the stop diluent in the LMNE chamber,
- Injects the specimen into the flowcell,
- Injects the interior and exterior sheath flow into the flowcell.

4- **Reagent Syringe assembly**:

- Ensures the correct proportioning of the reagents:
- Lysing reagent for hemoglobin (ABX Lyse),
- Cleaning reagent (ABX Cleaner),
- Lysing reagent for DIFF count (ABX Eosinofix),
- Diluent used for the dilutions (ABX Diluent) except the LMNE stop diluent,
- Lysing reagent for WBC/BAS (ABX Basolyse II).

5- **Floppy and CD drivers**

1.3. Right side view



Fig. 6-3 Pentra XL 80 right side view

1- Sampling syringe : Whole blood sample take and distribution of portions of the specimen into the dilution chambers.

2- Count Assembly :

- Receives the different rinsings and dilutions,
- Regulates the temperature of dilutions,
- Provides the dilutions for WBC/BAS, RBC/PLT and HGB

3- Mother board : Amplifies, processes and counts the following signals:

- Resistive signals and LMNE optical signals,
- RBC Signal, PLT signal,
- WBC/BAS signals,
- Measures hemoglobin.

1.4. Stat tube holder

There are 3 Positions for the Stat tube holder door :

- ◆ Open (as shown)
- ◆ Rack mode (intermediate position)
- ◆ Sampling position (rear)



Fig. 6-4 Stat tube holder

1- Sampling position 1: For 5ml tubes

2- Sampling position 2: For 3ml tubes

3- Sampling position 3: For Controls/Calibrators & Latex material.

4- Sampling position 4: For microtainer

5- LEDs

- When the Green LED is lit, the instrument is ready to sample,
- When both LEDs are blinking alternately, instrument is busy sampling,
- When the Red LED is lit instrument is in operation.



Refer to Section 8: Annex, **3. Compatible tube list**, page 8-6.

1.5. Rear view



Fig. 6-5 **Rear View**

- 1- Serial number label
- 2- Main power supply inlet
- 3- Diluent and waste connections
- 4- Host computer connection
- 5- Printer connection

2. Automatic mode principles

▼ Rack loading

The Pentra XL 80 will allow continuous loading of sample tube racks during all phases of operation. Racks are placed and then drawn onto a mechanism, which allows the mixing and sampling of each tube within the rack. Micro-switches allow detection of the racks when placed in the loading tray.

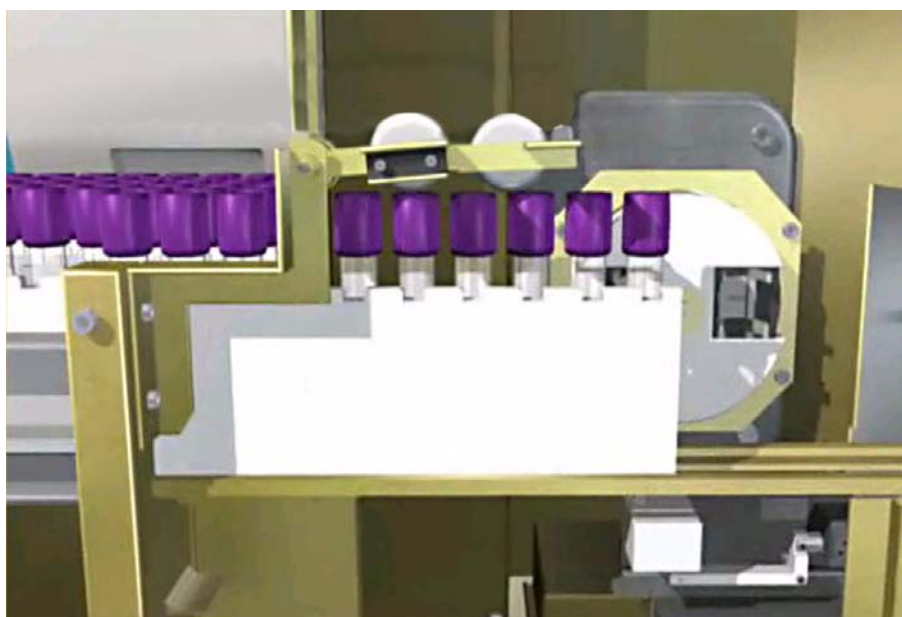


Fig. 6-6 Tube height detection and correction

The Sample tube is detected and the tube height is adjusted by the presence of 2 rolling detectors within the mechanism (see [Fig. 6-6](#), page 6-7). Sensors are also present within the mechanism to index the rack position at any time during its presence through the loader.

▼ Sample mixing

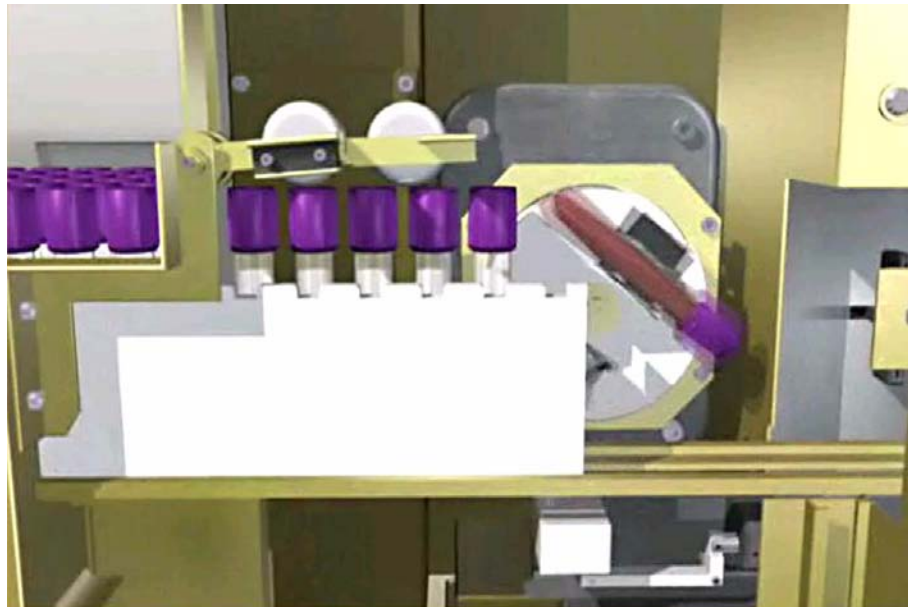


Fig. 6-7 Sample mixing

360° end-over-end rotations for approximately 1 minute, ensures optimum mixing of the samples.

The «Tube Grabber» contains 2 grabbers, which work in conjunction with the tube sampling. The first tube grabber grabs the number 1 tube and mixes it for 30 seconds. The tube is then placed back into the rack. The same process applies for the second tube in the rack. Then both tubes numbered 1 and 3 are grabbed and mixed at the same time for another 30 seconds more. The tubes are placed back into the rack and then tubes numbered 2 and 4 are taken and mixed and so on...

▼ Sample tube identification

An internal Barcode reader identifies both racks and sample tubes to ensure true identification and security of results.



Fig. 6–8 Sample tube identification

▼ Sample Cap Piercing

In order to keep the sample volume at a very small amount, approximately (60µl), **HORIBA ABX** utilizes a «Double needle sample probe». This probe consists of an external piercing needle with narrow internal sampling probe that aspirates the sample while the cap is being pierced.

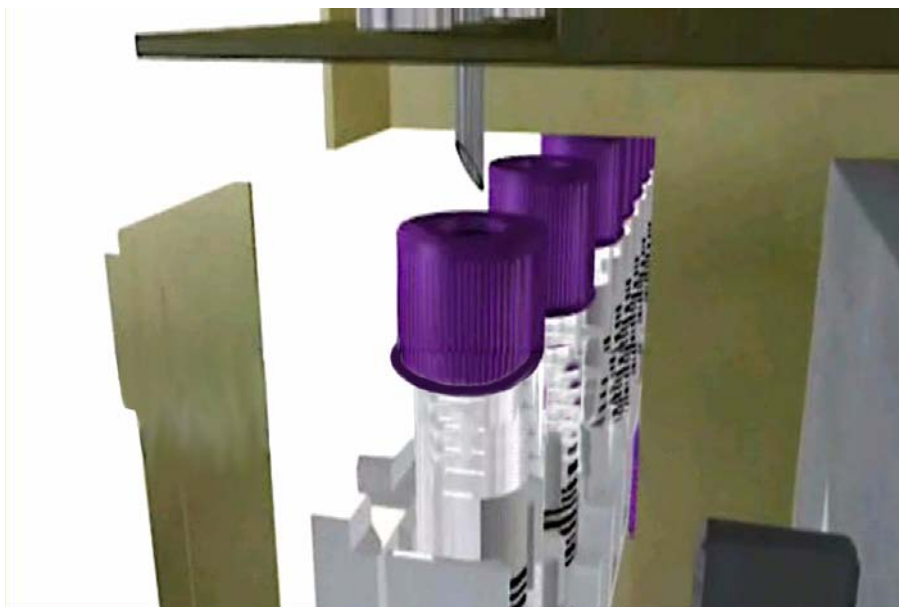


Fig. 6-9 Sample Cap piercing

3. Measuring principles

3.1. Multi distribution sampling sytem (MDSS)

3.1.1. CBC mode

While in the CBC Mode, 30µl of whole blood is aspirated then delivered into the following chambers as indicated:
One segment of sample for the Dilution chamber which is used for the RBC/PLT dilution and the Hemoglobin measurement.
The other segment of sample is used for the WBC/BASO count.

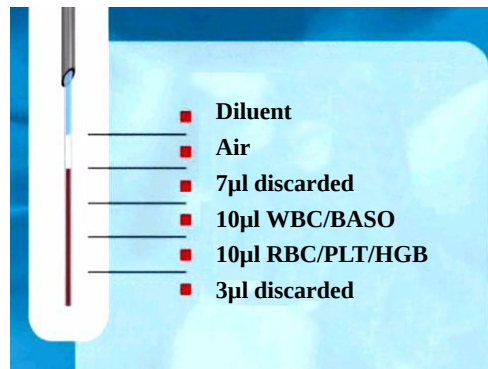


Fig. 6–10 Segment distribution in CBC mode

3.1.2. Diff Mode

While in the DIFF Mode, 53µl of whole blood is aspirated then delivered with into the following chambers as indicated:
One segment of sample for the Dilution chamber which is used for the RBC/PLT dilution and the Hemoglobin measurement.
The second segment of sample is used for the WBC/BASO count.
The last segment of sample is used for the LMNE chamber from which the sample is taken into the flowcell for the LMNE count.

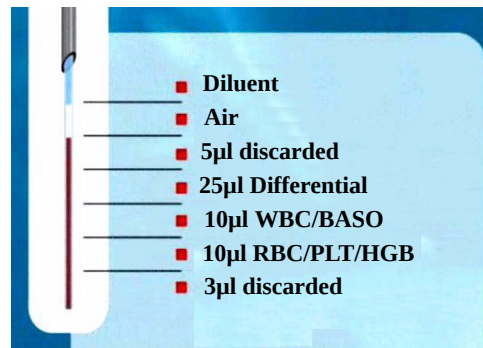


Fig. 6–11 Segment distribution in DIFF mode

3.1.3. Sample distribution

Each segment of sample is distributed into the chambers by means of a (Tangential flow) of reagent. This flow allows for perfect mixing of each dilution and avoids any viscosity problems. This tangential flow process is patented by **HORIBA ABX**.

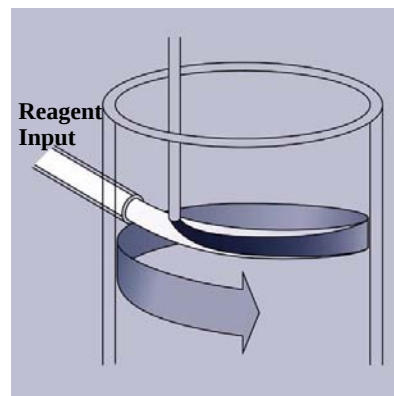


Fig. 6-12 Sample distribution in a tangential flow

3.2. CBC detection principles

3.2.1. RBC/PLT

The RBC's and PLT's are measured by an electronic impedance variation principle. This means that an electronic field is generated around the micro-aperture within the chamber in which the blood cells are pulled through.

The sample is diluted with an electrolytic Diluent (electronic current conducting fluid), mixed then pulled through a calibrated micro-aperture. Two electrodes are placed on either side of the aperture and electric current continuously passes between the two electrodes.

As the blood cells pass through the aperture, they create resistance (Impedance) in the electronic field between the two electrodes. The voltage, which measures the cells, is proportional to the size of the cell. 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.

These electronic voltages vary in pulse size as the cells pass through the aperture. The pulses are amplified, channeled according to size and threshold, grouped and then mathematically calculated along with the calibration coefficients to give a final numerical value for both RBC's and PLT's.

▼ Results

Number of cells counted per volume unit
x calibration coefficient

▼ Histograms

RBC: Distribution curves on 256 counting channels from 30fl to 300fl.

PLT: Distribution curves on 256 channels from 2fl to a mobile threshold. This threshold moves according to the micro-cyte population present in the analysis area.

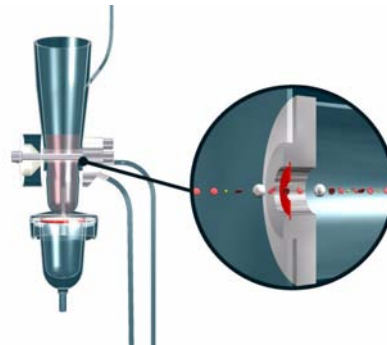


Fig. 6–13 Impedance Principles

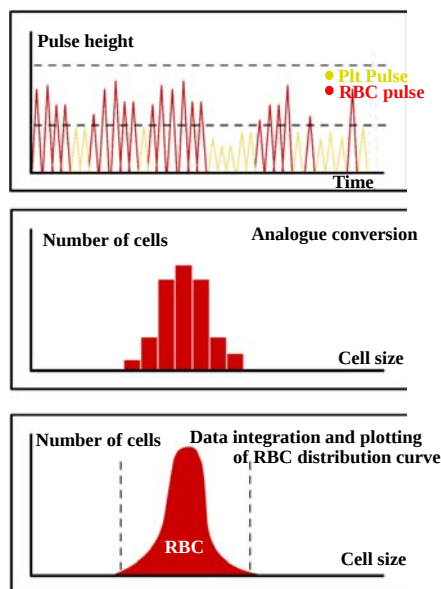


Fig. 6–14 RBC distribution curve

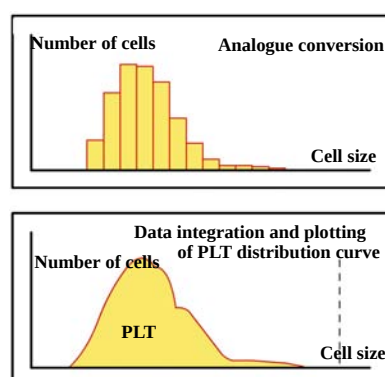


Fig. 6–15 PLT Distribution curve

▼ dilutions

Technical characteristics of the RED BLOOD CELL and PLATELET counts			
Initial blood volume	10 µl	Method	Impedance
Vol. ABX DILUENT	2500 µl	Aperture diameter	50 µm
Final dilution rate**	1/10000	Count vacuum	200 mb
Temperature of reaction	35°C	Count period	2 X 6 seconds

** : Two successive dilutions are carried out : Primary Dilution for RBC and PLT:

Blood (µl)	10 µl		
Vol. ABX DILUENT	1700	dilution	1/170

Secondary Dilution RBC and PLT (from the primary dilution)

Dilution (µl)	42,5 µl		
Vol. ABX DILUENT	2500	dilution	1/58,8

Final dilution: $1/170 \times 1/58,8 = 1/10000$

Tab. 6-1: RBC/PLT dilutions

3.2.2. HGB Measurement

During the analysis cycle, lysing reagent is released into the Dilution chamber.

▼ Alphalyse

This reagent breaks down the RBC cell membrane and releases the Hemoglobin within the cell. The hemoglobin, released by the lysing reagent, combines with the Potassium cyanide from the lysing reagent to form a chromogenous cyanmethemoglobin compound. This compound is then measured through the optical part of the first dilution chamber by way of spectrophotometry at a wavelength of 550nm.

▼ Lysebio

Reagent for erythrocyte lysis and cyanide-free determination of hemoglobin.

By addition of agent of lysis, hemoglobin is released. All the heme iron is oxidized and stabilized. Oxidation resulting complexes are quantified by spectrophotometry at a wavelength of 550nm

Technical characteristics for the HGB MEASUREMENT			
Blood volume	10 µl	Method	Photometry
Vol. ABX DILUENT	1700 µl	Wavelength	550 nm
Vol. LYSE	400 µl		
complement ABX DILUENT	400 µl		
Final dilution rate	1/250		
Temperature of reaction	35°C		

Tab. 6-2: HGB measurement

▼ Results

Hemoglobin results are given as such: Absorbance value obtained from the sample x coefficient of calibration.

3.2.3. HCT Measurement

All the RBC pulses are grouped into various sizes. Each group pulse height is then averaged. All the pulse height averages are then averaged one final time for a mean average of all the RBC pulse heights. This function is a numeric integration of the MCV.

The HCT results are given as a percentage of this integration.

3.2.4. RDW calculation

The RDW (*Red cell Distribution Width*) is used to determine erythrocyte abnormalities linked to Anisocytosis. The RDW will enable the user to follow the evolution of the width of the RBC histogram in relation to the number of cells and their average volume.

The RDW is also a calculation from the RBC histogram.

Calculations are as followed:

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

With:

- ◆ K = system constant
- ◆ SD = Standard Deviation according to statistical studies on cell distribution within the RBC histogram.
- ◆ MCV = Mean Corpuscular Volume of erythrocytes

3.2.5. MCV, MCH, MCHC calculation

- ◆ MCV (Mean Cell Volume) is calculated directly from the entire RBC histogram.
- ◆ MCH (Mean Cell Hemoglobin) is calculated from the HGB value and the RBC count.
- ◆ The mean hemoglobin weight in each RBC is given by the formula:

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

- ◆ MCHC (Mean Corpuscular Hemoglobin Contained) is calculated according to the HGB and HCT values. Mean HGB concentration in the total volume of RBC is given by the formula:

$$\text{MCHC (g/dL)} = \text{HGB/HCT} \times 100$$

3.2.6. MPV Measurement

The MPV (Mean Platelet Volume) is directly derived from the analysis of the platelet distribution curve.

3.2.7. Pct Calculation

Thrombocrit is calculated according to the formula:

$$\text{Pct\%} = \text{PLT (10}^3/\text{mm}^3) \times \text{MPV (}\mu\text{m}^3) / 10\,000$$

3.2.8. PDW calculation

PDW (Platelet Distribution Width) is calculated from the PLT histogram.

The PDW is represented by the width of the curve between 15% of the number of platelets starting from 2 fl (S1), and 15% of the number of platelets beginning with the variable top threshold (S2).

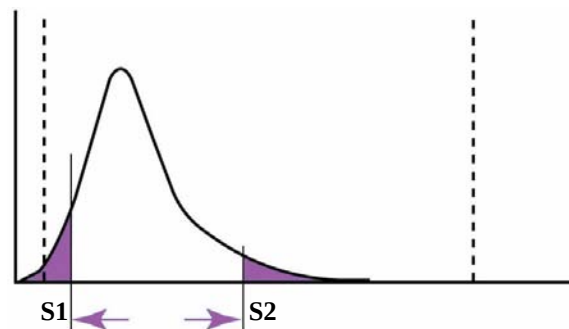


Fig. 6-16 PDW calculation

3.3. WBC and differential count

3.3.1. General counting principles

The WBC count is carried out twice by two different analysis methods which utilize the total WBC count in both areas:

- ◆ Once in the BAS count chamber during the same time as the BAS count,
- ◆ Once in the optical chamber during the same time as the LMNE count.

The WBC reference count is the count which is obtained from the WBC/BAS count chamber.

3.3.2. BAS/WBC Count

The measurement principle is exactly the same as the RBC/PLT measurement. The Differentiation between the BASO's and the other leukocytes is obtained by the use of the **ABX BASOLYSE II** reagent with its specific lysing action. All the WBCs are counted between the electronic thresholds from **<BA1>** to **<BA3>**.

The basophils are counted between thresholds **<BA2>** and **<BA3>**.

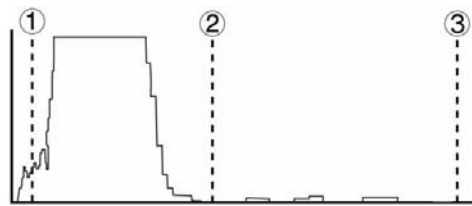


Fig. 6-17 WBC/BAS histogram

Technical characteristics of the WBC/BAS counts			
Initial blood volume	10 µl (CBC or CBC/DIFF)	Method	Impedance
Vol. ABX BASOLYSE II	2000 µl	Aperture diameter	80 µm
Final dilution rate	1/200	Count vacuum	200 mb
Temperature of reaction	35°C	Count period	2 X 6 seconds

Tab. 6-3: WBC/BAS count

▼ Results

WBC: The number of cells counted within a specified amount of time per volume x WBC coefficient of calibration.

BAS: The number of cells counted within a specified amount of time per volume x the WBC calibration coefficient in a percentage as to the total number of leukocytes (Basophils and WBC nuclei)

3.3.3. LMNE Matrix count

The WBC and 5-part Differential count in the flowcell are based on 3 essential principles:

- The double hydrodynamic sleeving «DHSS» which allows a linear flow of the cells through the light path (**HORIBA ABX** patent)
- The cell volume, which is measured by electrical current (*impedance changes*).
- The measurement of Transmitted light at a 0° angle, which allows a measured response according to the internal structure of each cell and its absorbance, as unabsorbed light passes through the spaces in the nuclear material of each cell. This is known as diffused light. 25µl of whole blood is delivered into the LMNE chamber in a tangential flow of EOSINOFIX. This reagent lyses the RBC's, stabilizes WBC's in their native forms, and stains the Eosinophil nuclei with a specific coloration for their measurement in the matrix. The solution is then stabilized with Diluent and transferred into the LMNE flowcell. Each cell is measured in absorbance (cytochemistry) and resistive (volume) impedance changes

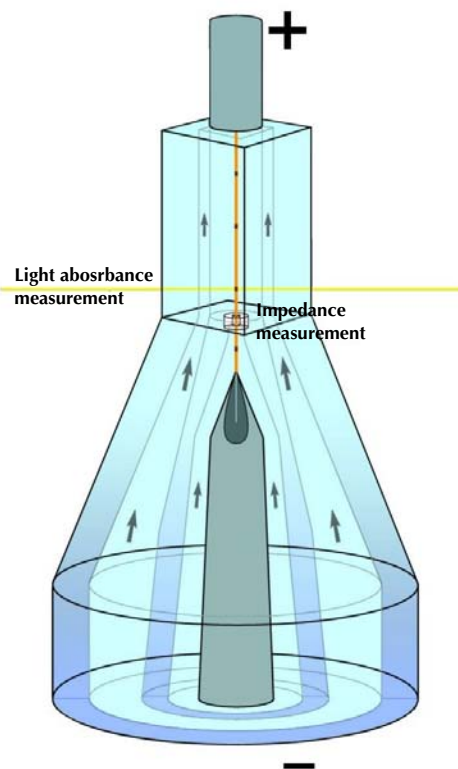


Fig. 6-18 DHSS principles

Technical characteristics of the WBC counts during the acquisition of the matrix

Initial blood volume	25 µl	Method	Impedance with hydrofocus
Vol. ABX Eosinofix	1000 µl	Aperture diameter	60 µm
Diluent Volume	1000 µl	Flow diameter	42 µm
Final dilution rate	1/80	Injection duration	12 s
Temperature of reaction	35°C	Volume injected	72µl
Incubation duration	12s		

Tab. 6-4: WBC counts

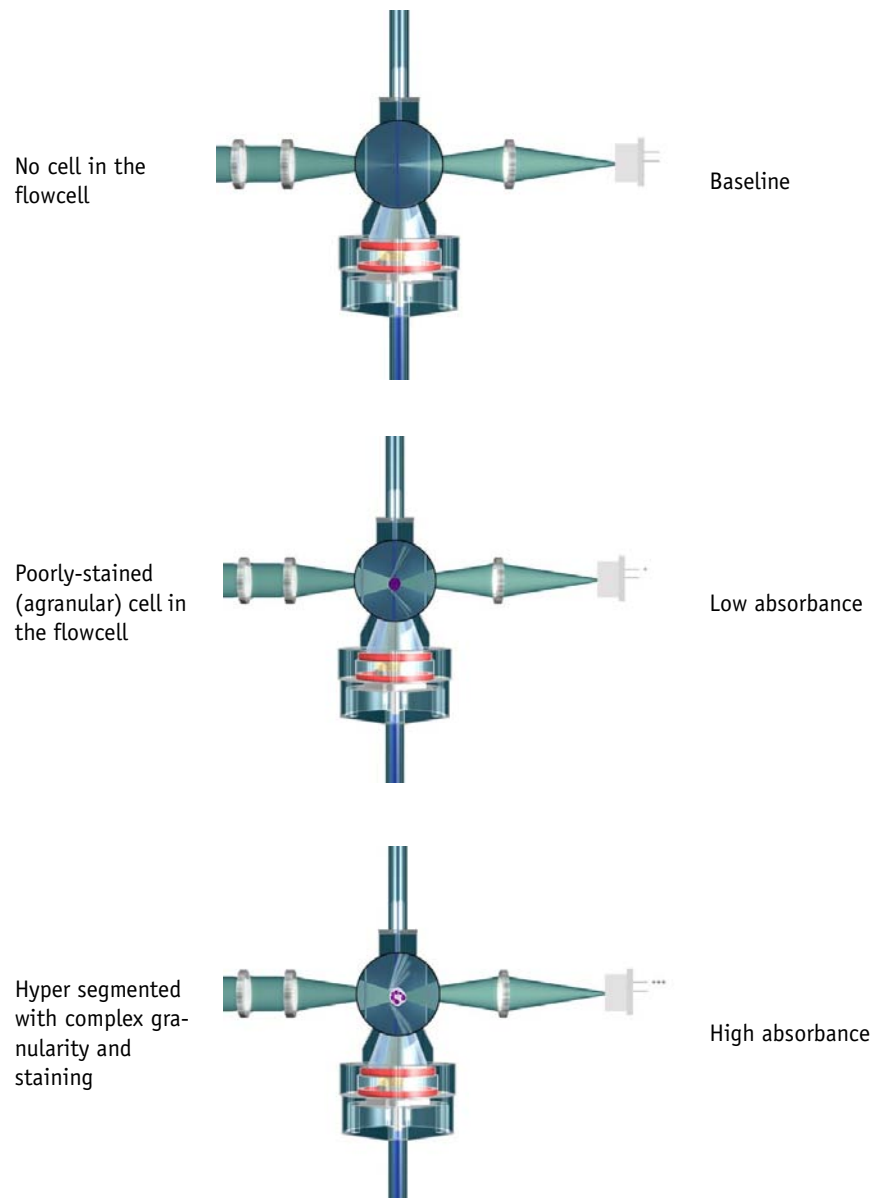


Fig. 6-19 Absorbance measurement

▼ Results

From the Absorbance and Resistive measurement of the leukocytes, a matrix is developed with cell volumes on the X-axis and optical transmission on the Y-axis. Study of the matrix image allows a clear differentiation of 4 of the 5 leukocyte populations. Due to the low percentage of Basophils in comparison to the rest of the leukocytes, they have a separate measurement of their own instead of being present in the matrix.

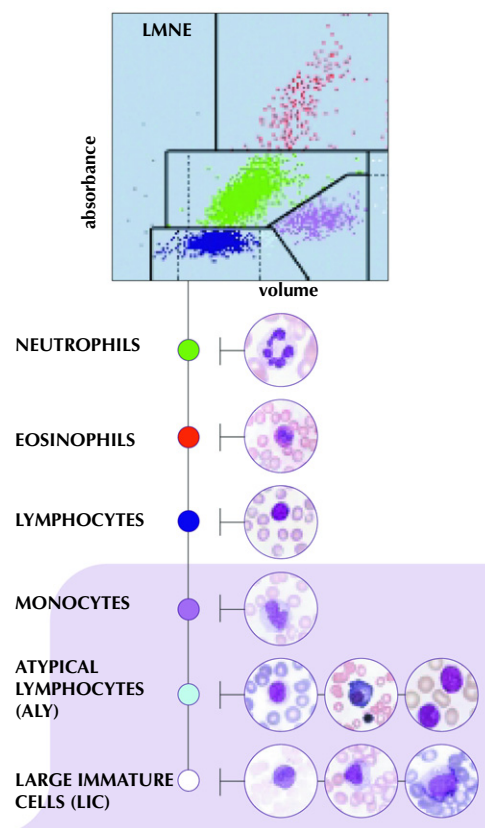


Fig. 6–20 LMNE matrix results

LYMPHOCYTES: The Lymphocytes are a very small round shaped cell with condensed cytoplasm and large nucleus. These cells are normally positioned in the lower part of the optical Y-axis as well as the lower part of the volume X-axis because of their small size. The far left side of the lymphocyte zone (LL) should normally be empty. Any detection of cells in the (LL) zone will indicate Small lymphocytes, Platelet aggregates, NRBC's (*Nucleated Red Blood Cells*), and improperly adjusted flowcell alignment. Background noise may also be detected in this zone if the interference is great.

MONOCYTES: The Monocytes are a very large irregular shaped cell with large convoluted nuclei. The nucleus contains folds and sometimes vacuoles. The cytoplasm is also large with non-granular intra-cellular material. These cells will not scatter or absorb a large amount of light when passing through the flowcell. They will therefore be positioned in the lower part of the optical Y-axis. Because the monocytes are a large cell, they will be placed to the right of the volume X-axis.

NEUTROPHILS: The Neutrophils are larger in size than the lymphocytes. The neutrophils contain granular material in their cytoplasm along with a segmented nucleus. Due to these cellular features, more light will show through these cells as they pass through the flowcell. This affect will place the neutrophils higher on the optical Y-axis and spread them along the volume X-axis according to their maturity. Hyper-segmentation and increased granules will place these cells even higher on the optical Y-axis.

EOSINOPHILS: The Eosinophils are somewhat like the neutrophils. They contain granular material and segmented nuclei within the cytoplasm. The granular material is colorized with the ABX EOSINOFIX before they are passed through the light path in the flowcell. Due to the colorization action of the reagent, the eosinophils will be place in the highest part of the optical Y-axis. Hyper-segmentation and increased granules will spread this population across the right top of the matrix.

Additional parameters: LIC (Large Immature Cells) and ALY (Atypical Lymphocytes) complete the matrix spectrum of cellular placement.

Immature granulocytic cells are detected by their larger volumes and by the increased granules, which allow more light to pass through the cells and increase the intensity of scattered light. Therefore, cells such as metamyelocytes will be found to the right of the neutrophils and almost at the same level. Myelocytes and promyelocytes will be found on the far right of the matrix in the saturation position. The metamyelocytes, myelocytes, and promyelocytes will all be classed as (LIC) and there given results will be included in the neutrophil value. The Blast cells will be generally located to the right of the monocyte population and, as such, will increase the (LIC) count. Small blast cells will be found between the normal lymphocyte and monocyte populations (ALY).

Platelet aggregates and debris from RBC cell fragments are found in the background noise area, at the lower left corner of the matrix. Most of the cell population thresholds are fixed and give the normal limits for the normal leukocyte morphologies. Changes in the morphology of a specific population will be indicated on the matrix by a shift in the corresponding population.

A Blast alarm is generated from increased counts within the (LIC) area; this is correlated with the Blast detection on the Basophil histogram.

Large lymphocytes are usually detected in the (ALY) (*Atypical Lymphocytes*) zone, where reactive lymphoid forms, stimulated lymphocytes, and plasmocytes are also found as well..

ABX Pentra **XL** 80

Maintenance & Troubleshooting

Contents

1. Maintenance & Troubleshooting procedures	7-3
1.1. Hydraulic cycles maintenance chart table	7-3
1.2. Maintenance procedures	7-3
1.3. Instrument general cleaning.....	7-4
1.4. Instrument Rinse	7-6
2. Replacement procedures	7-9
2.1. Reagent replacement	7-9
2.2. Optical bench lamp replacement.....	7-15
2.3. Sampling probe replacement	7-17
3. Instrument panels & cover Removals	7-19
3.1. Left front door removal	7-19
3.2. Right front door removal.....	7-20
3.3. Right-hand side panel removal	7-20
3.4. Left-hand side panel removal.....	7-21
4. Service menu description	7-22
4.1. Super User menu	7-22
4.2. Mechanical menu	7-24
4.3. Hydraulic menu	7-31
4.4. Others	7-36
5. Troubleshooting	7-37
5.1. Instrument operation mode.....	7-38
5.2. Results	7-39
5.3. Flags	7-41
6. Hydraulic diagram.....	7-43
7. Error messages.....	7-44
7.1. Analyzer error types and help messages.....	7-45
7.2. Transfer error types and help messages	7-46
7.3. STAT mode error type and help message	7-47
7.4. Environment Error Types and Help Messages.....	7-47

7.5. User Error Types and Help Messages	7-49
7.6. Expiration Date Error Types and Help Messages.....	7-49
7.7. Analyzer Internal Error Types and Help Messages	7-49

The following section provides Pentra XL 80 maintenance and troubleshooting information, including:

1. **Maintenance & Troubleshooting procedures**, page 7-3
2. **Replacement procedures**, page 7-9
3. **Instrument panels & cover Removals**, page 7-19
4. **Service menu description**, page 7-22
5. **Troubleshooting**, page 7-37
6. **Hydraulic diagram**, page 7-43
7. **Error messages**, page 7-44

1. Maintenance & Troubleshooting procedures

1.1. Hydraulic cycles maintenance chart table

One of the main contributing factors to accurate and reliable results is an instrument that is maintained on a constant basis and correctly performed by the operator. Several maintenance functions are available on the system for the user to clean and check the instrument.

The frequency of maintenance cycles depends upon the number of analysis cycles per day. Perform the instrument maintenance according to the chart table.

Maintenance	Sample output (Analyses per Day)	
Cycles	≤ 100	> 100
Startup	1 per day	1 per day
Shut down	1 per day	1 per day
Concentrated cleaning	1 per month	2 per month

1.2. Maintenance procedures

Operations	Frequency
Reagent replacement	Each time a low level reagent occurs (see 2.1. Reagent replacement , page 7-9)
Optical bench lamp replacement	On request (see 2.2. Optical bench lamp replacement , page 7-15)
Sampling probe replacement	On request (see 2.3. Sampling probe replacement , page 7-17)
Rinse chamber filter cleaning	Once a month (see 1.3.3. Rinse chamber filter cleaning , page 7-5)
Instrument decontamination	before any intervention on your instrument (See Instrument general cleaning , page 7-4)
Instrument Rinse	(See Instrument Rinse , page 7-6)

1.3. Instrument general cleaning

1.3.1. Instrument external cleaning

The external surfaces of the instrument must be decontaminated considering the biological environment.



- 1 - Never spill liquid on the instrument.
- 2 - Never use Disinfectant product* that contains alcohol

▼ Touch screen

Use a soft cloth, slightly wet with disinfectant product*. Wipe gently the screen and dry to remove any trace of moisture.

▼ All contaminated surfaces (covers, counting assembly area...)

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

▼ Stainless steel parts

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.

1.3.2. Instrument internal cleaning

▼ Concentrated cleaning

Counting chambers and hydraulics parts are decontaminated by using the «Concentrated cleaning» function as described in **4.3.5. Concentrated cleaning**, page 7-34.

▼ Sampling probe

Sampling probe 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 analysis on bleach, using the «Stat» mode as described in Daily Guide: RAB156C.



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

1.3.3. Rinse chamber filter cleaning

- 1- This filter has to be cleaned once a month as follows:
- 2- Dismantle the Right hand side panel as described in **3. Instrument panels & cover Removals**, page 7-19, in order to access to dilution chambers.

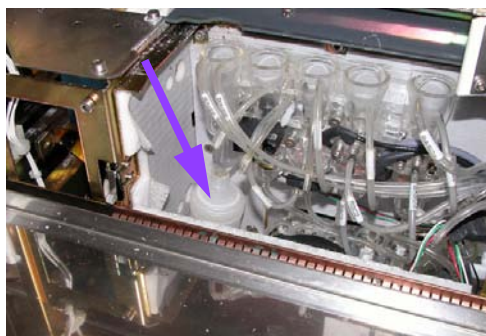


Fig. 7-1 Rinse chamber filter location

- 3- Locate the filter below the rinse chamber.
- 4- Remove the filter, disconnecting tubings, and open it unscrewing both parts.



Fig. 7-2 Dismantling the filter

- 5- Rinse both parts of the filter under tap water.
- 6- Leave the filter dry, and re-install reverse order.

1.4. Instrument Rinse

Run this procedure before the transport of the instrument, after a demonstration or before a long period without functioning.

1.4.1. Instrument rinse

- 1- Run an Instrument general cleaning (See [Instrument general cleaning](#), page 7-4).
- 2- Remove straws from Reagent bottles and plunge them into an empty bottle.
- 3- Remove straw from Diluent cubitainer and plunge it into the empty bottle.
- 4- Enter: **Service \ Super User Menu \ Hydraulic \ Unprime Cycle** then click the «All» button (See [Unprime cycle screen](#), page 7-6).

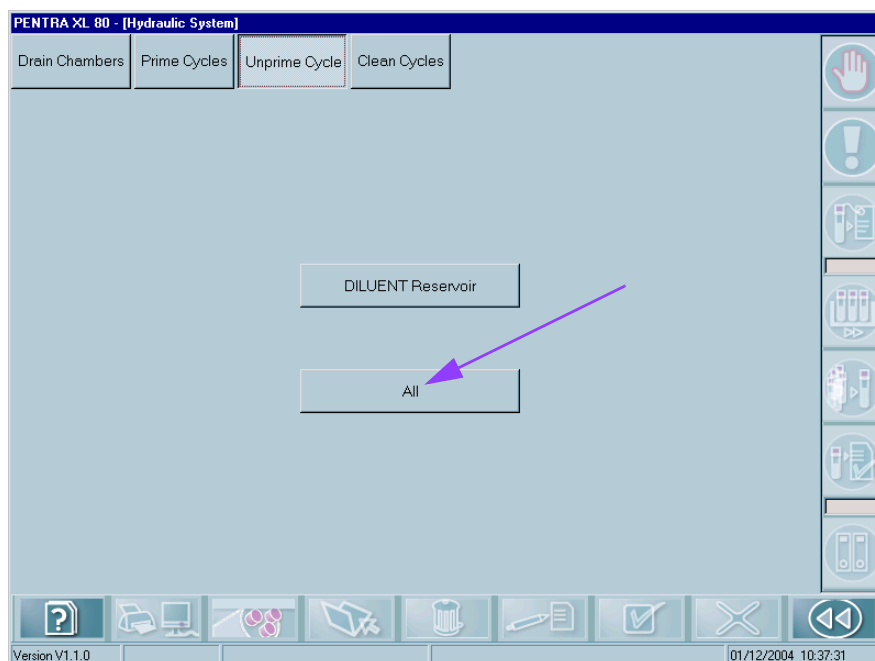


Fig. 7-3 Unprime cycle screen

- 5- Press the «Validate» button then repeat this cycle a second time.
- 6- Dry the straws using absorbant paper.
- 7- Plunge the straws in a bottle full of distilled water.
- 8- Enter: **Service \ Super User Menu \ Hydraulic \ Prime Cycles** then click the «ALL REAGENTS» button (See [Prime cycles screen](#), page 7-7).

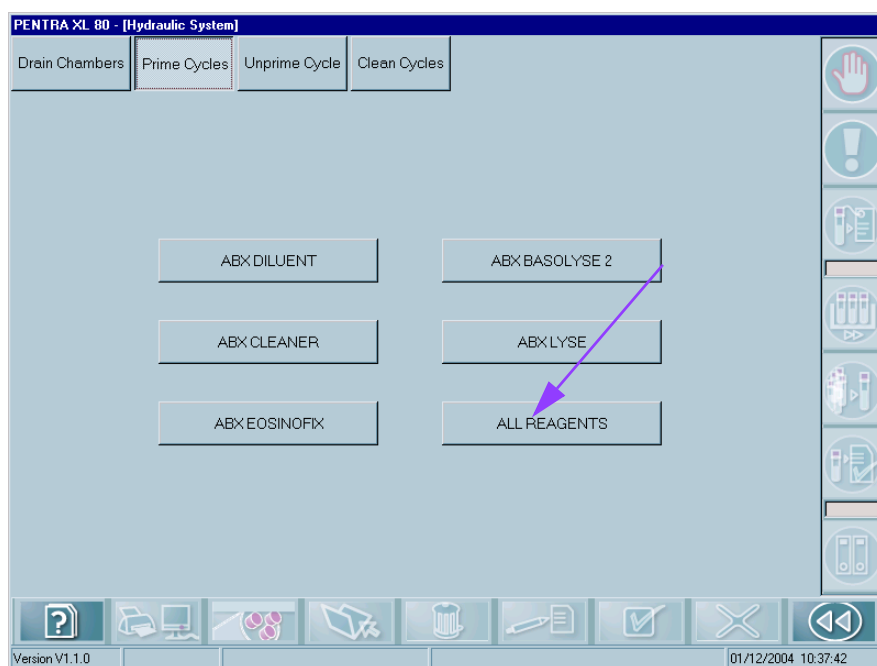


Fig. 7-4 Prime cycles screen

- 9- Press the «Validate» button then repeat this cycle a second time.
- 10- Run several manual cycles.
- 11- Remove the straws from the distilled water bottle then plunge them into an empty bottle.
- 12- Run several «ALL» Unprime cycles (See [Unprime cycle screen](#), page 7-6) to drain the instrument.

1.4.2. Syringes and carriage park

Move the syringes and the carriage in a safe position:

- 1- Enter: **Service \ Super User Menu \ Others** and press the «Run park syringe position» button (See [Park screen](#), page 7-8).

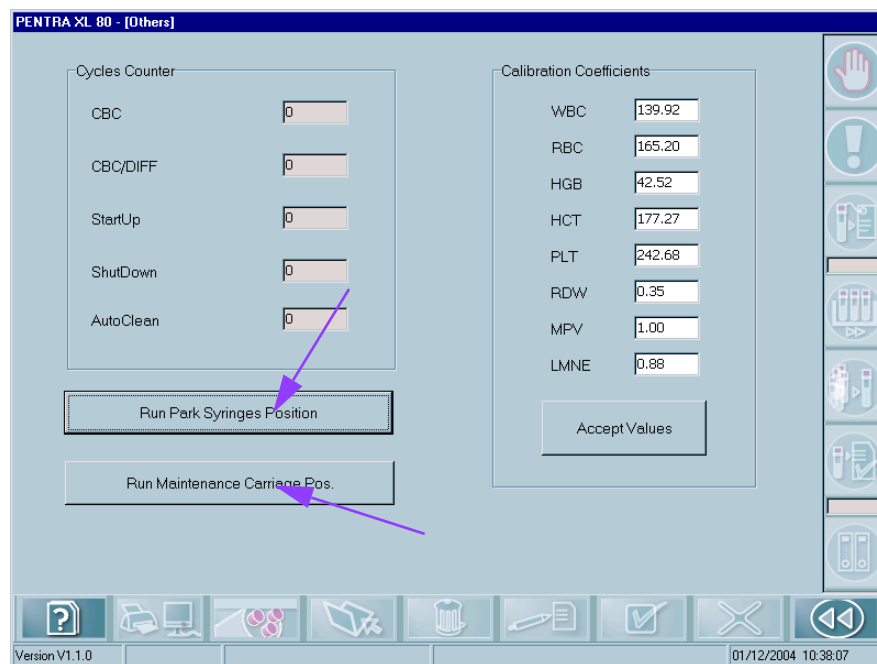


Fig. 7-5 Park screen

- 2- Before the transport of the instrument press the «Run maintenance carriage position» button.
- 3- Block the carriage using the «Plastic rails» (See **Plastic rails**, page 7-8).

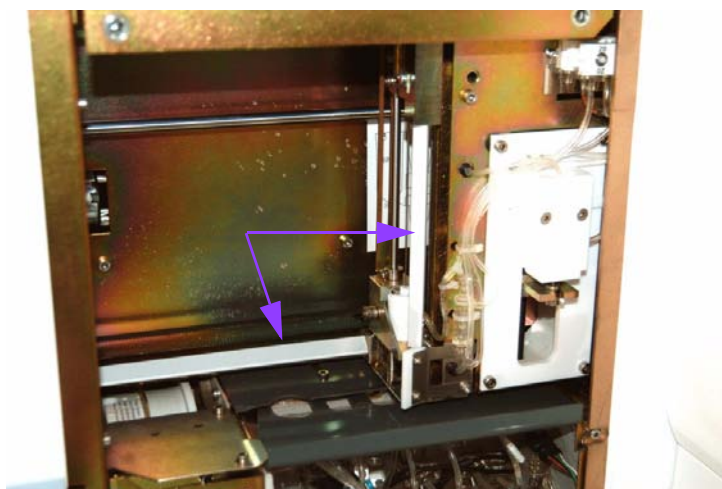


Fig. 7-6 Plastic rails

- 4- Close the door and turn off the instrument.

2. Replacement procedures

This section describes how to replace:

- ◆ a low level reagent (see **2.1. Reagent replacement**, page 7-9)
- ◆ an optical bench lamp (see **2.2. Optical bench lamp replacement**, page 7-15)
- ◆ the sampling probe (see **2.3. Sampling probe replacement**, page 7-17)

2.1. Reagent replacement

2.1.1. Reagent locations and connections



When installing the Diluent on the system, it is most important to maintain the depth of the container no lower than 80 cm (31.5 in.) below the instrument. If the depth limit is exceeded, erroneous results will occur.

Diluent and Waste tubing lengths are critical upon installation. Follow the recommended lengths for best results:

DILUENT input tubing: Cristal 3x6/ 2 meters (80 in.) maximum.

WASTE output tubing: Cristal 4x6/ 2 meters (80 in.) maximum.



Make sure that a blank cycle and Control run will be carried out after the change of a reagent in the course of day.

Bottles and container locations (see **Fig. 7-7**, page 7-10):

- 1- ABX lyse
- 2- ABX Basolyse II
- 3- ABX Eosinofix
- 4- ABX Cleaner
- 5- ABX Diluent
- 6- Waste container



Fig. 7-7 Reagent location

2.1.2. Integrated reagents & Diluent container replacement

During instrument startup, the instrument software compares the remaining quantity of each reagent to the daily workload setup. If one or more reagents reach a «Low Level» during the working day, an alarm occurs and the following alarm window will appear indicating the following message (see Fig. 7-8, page 7-11):

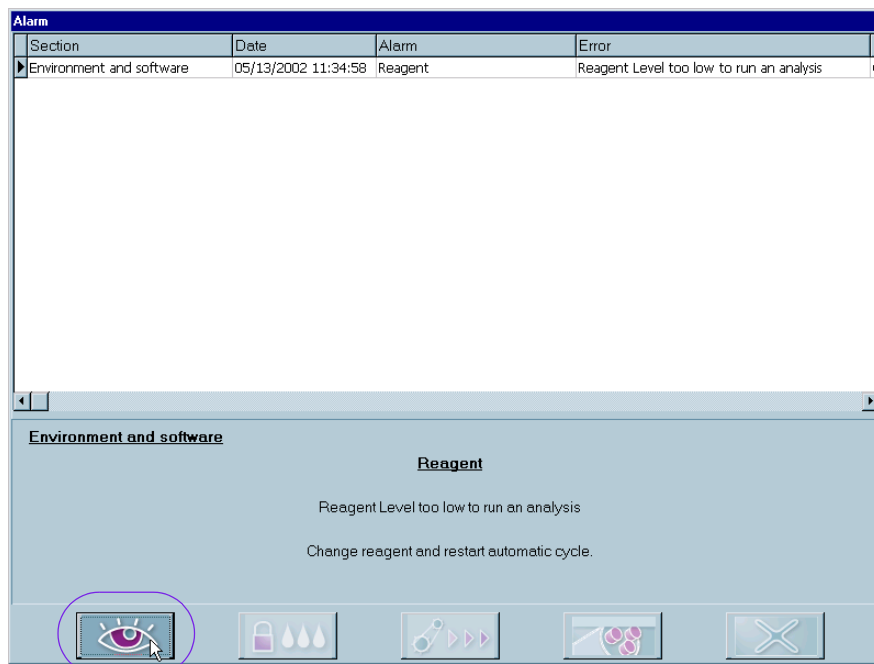


Fig. 7-8 Reagent low level alarm

When a Reagent «Low Level» alarm appears on the screen, select the «Check» key (see Fig. 7-8, page 7-11) to display the «Reagent Status» window (see Fig. 7-9, page 7-11).

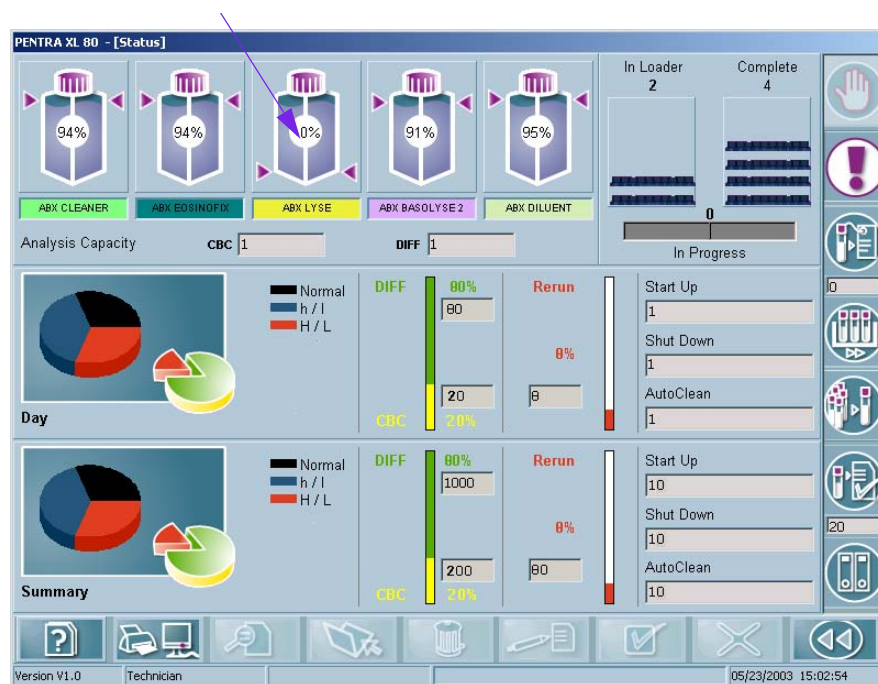


Fig. 7-9 Reagent status window

From the reagent status window, select the reagent you want to replace. Once you select the reagent, the following screen will be displayed (see Fig. 7-9, page 7-11).

Now select the «Edit» key to modify any reagent specifications (see Fig. 7-10, page 7-12).

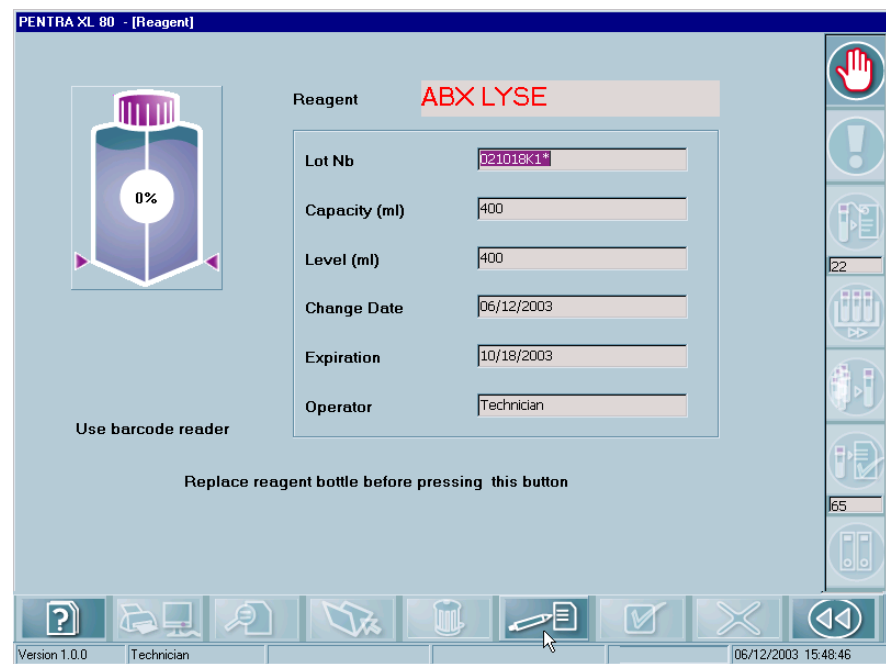


Fig. 7-10 Reagent edit

The screenshot displays the 'PENTRA XL 80 - [Reagent]' window. On the left, there is a graphic of a reagent bottle with a '0%' label. Below it, the text 'Use barcode reader' is visible. In the center, the reagent is identified as 'ABX LYSE'. To the right of this, there is a form with the following fields: 'Lot Nb' (containing '021018K1*'), 'Capacity (ml)' (containing '400'), 'Level (ml)' (containing '0'), 'Change Date' (containing '06/12/2003'), 'Expiration' (containing '10/18/2003'), and 'Operator' (containing 'Technician'). Below these fields, a message reads 'Replace reagent bottle before pressing this button'. On the right side of the window, there is a vertical toolbar with several icons, including a hand, an exclamation mark, and various test icons. At the bottom of the window, there is a status bar with icons for help, printer, search, and other functions. The status bar also shows 'Version 1.0.0', 'Technician', and the date/time '06/12/2003 15:48:46'.

Fig. 7-11 Reagent replacement

Select the «Lot Nb» field and then use the Barcode reader to update some of the reagent specifications: Lot number, Expiration date (see [Fig. 7-11](#), page 7-13).

The reagent level is set to an automatic default level. Verify this level and/or change it to the correct level in milliliters if necessary. Select the «Level» field and edit if necessary. (see [Fig. 7-12](#), page 7-14).

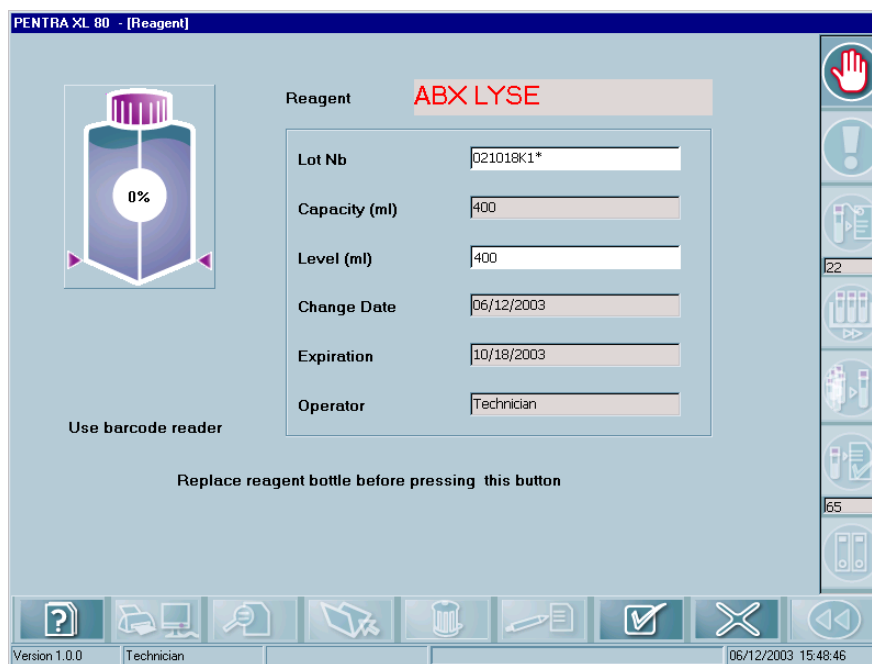


Fig. 7-12 Reagent Level

Select the «OK» key to accept the changes (see [Fig. 7-13](#), page 7-14).

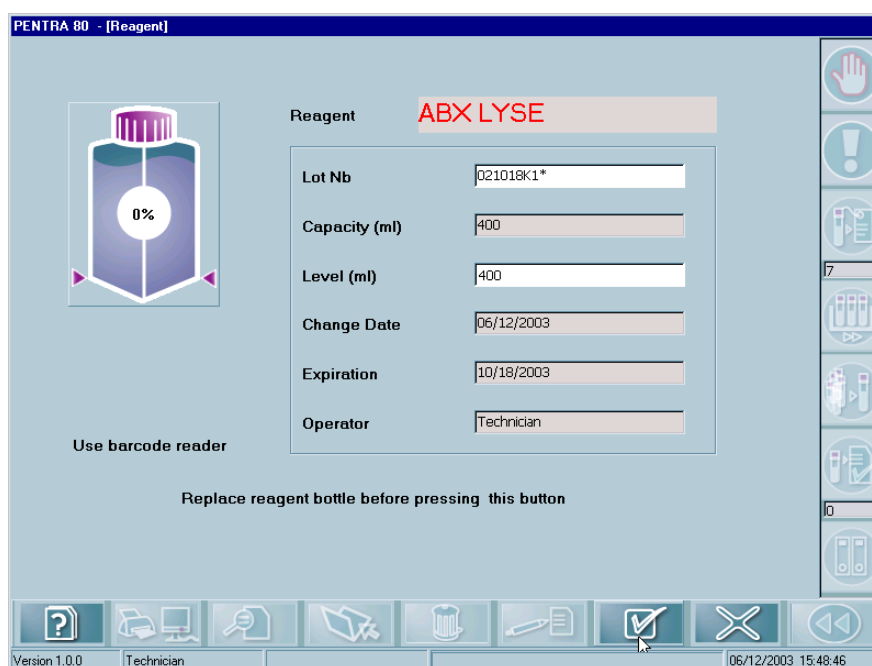


Fig. 7-13 Reagent replacement validation

Once the «OK» key has been selected, the instrument automatically primes the reagent (see **Fig. 7-14**, page 7-15).

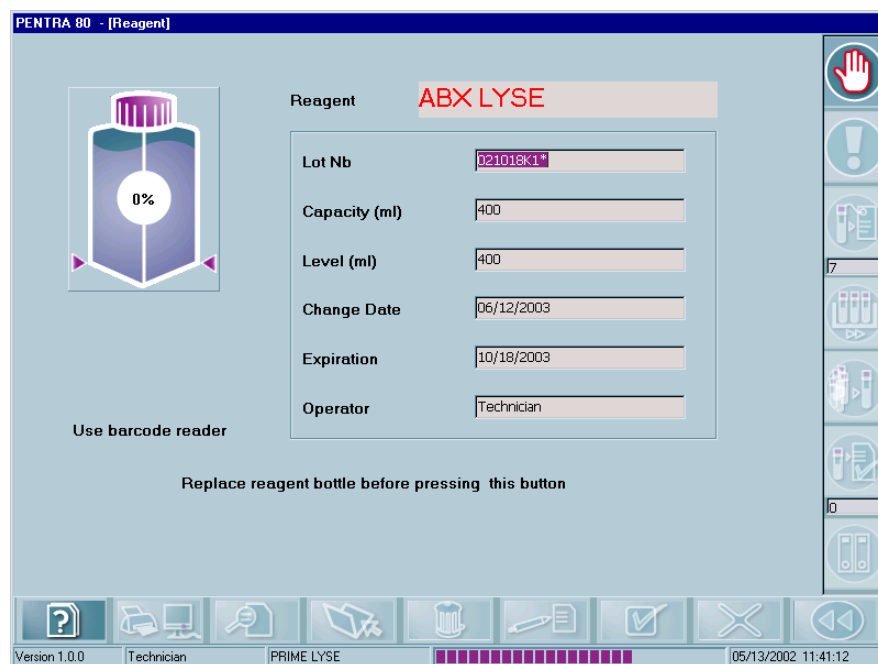


Fig. 7-14 Reagent priming

2.1.3. Waste container replacement

Unscrew the waste container cap.

Replace waste container according to your laboratory's protocol.

Close the empty container with the cap and dispose of waste liquids according to your local/national organizations.

2.2. Optical bench lamp replacement

2.2.1. Lamp replacement



Wait for the lamp to cool down before handling it.

Power off the instrument.

Open the instrument left-hand and right-hand side panels, lift the top cover of the instrument as well (see **3. Instrument panels & cover Removals**, page 7-19).

Locate the Optical bench at the top left of the instrument (see **Fig. 7-15**, page 7-16)

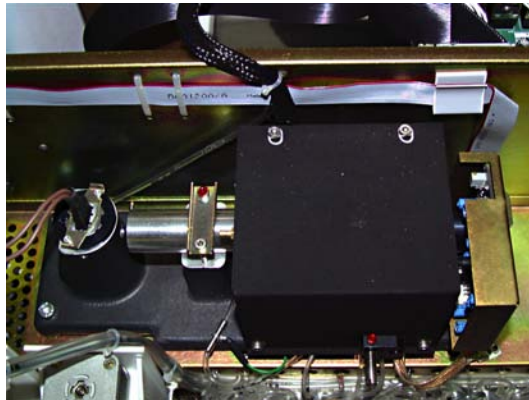


Fig. 7-15 Optical bench location

Disconnect the lamp connector (see [Fig. 7-16](#), page 7-16).

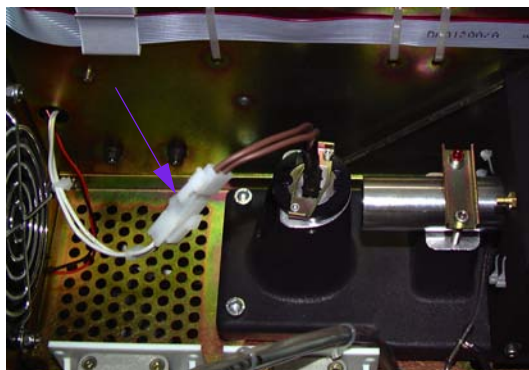


Fig. 7-16 Optical bench lamp disconnection

Loosen the lamp holding bracket screws a few turns (see [Fig. 7-17](#), page 7-16).



Fig. 7-17 Lamp fixation screws

Turn the lamp bracket from the loosened screws and remove the lamp (see [Fig. 7-18](#), page 7-17).



Fig. 7-18 Lamp dismantling

Once the old lamp has been removed, replace it with a new lamp.

Use a lint free wipe to clean any residue or fingerprints from the new lamp before placing it into the optical bench. This will ensure that the new lamp will perform at its optimum peak.

Tighten the lamp fixation screws.

Connect the lamp to its power supply.

2.2.2. Lamp test

Once the lamp replacement is complete, verify that the instrument operates correctly. Power on the instrument and verify that the Optical Bench lamp is lit.

If the lamp is illuminated, wait until the instrument startup is complete then power off the instrument and re-install the covers and panels.

- 1- If the lamp is not illuminated,
- 2- Verify that the lamp connection is connected properly.
- 3- Remove the lamp and verify that the lamp filament is not damaged.
- 4- Try another lamp if available.
- 5- If all these simple remedies do not work, contact your local HORIBA ABX representative.

2.3. Sampling probe replacement

Power off the instrument.

Remove the right-hand side panel from the instrument (see **3. Instrument panels & cover Removals**, page 7-19).

Run a «Maintenance syringe position» sequence («Super user\Others» menu ; **4.4. Others**, page 7-36)

Lift the locker (top-retaining bracket) to free the sample probe (see [Fig. 7-19, page 7-18](#)).



Fig. 7-19 Probe locker

Gently disconnect the tubing connected to the top of the sample probe and remove the probe (see [Fig. 7-20, page 7-18](#)).



Fig. 7-20 Probe replacement

Place the sample tubing back onto the top of the sample probe.

Re-insert the top retaining part of the sample probe back into its retaining slot.

Lower the locking arm to secure the probe.

Tighten the Rinse block retaining screws for a good seal on the sample probe.

Power on the instrument and verify that there are no fluid leaks during startup. Re-install the right-hand side panel.

3. Instrument panels & cover Removals

Chapters in this section:

- ◆ **3.1. Left front door removal**, page 7-19
- ◆ **3.2. Right front door removal**, page 7-20
- ◆ **3.3. Right-hand side panel removal**, page 7-20
- ◆ **3.4. Left-hand side panel removal**, page 7-21

Power off the instrument.

Disconnect the power supply cable.

3.1. Left front door removal

Pull the Left Front cover down, as indicated in (1), and then pull out to remove it, as indicated in (2) (see **Fig. 7-21**, page 7-19).

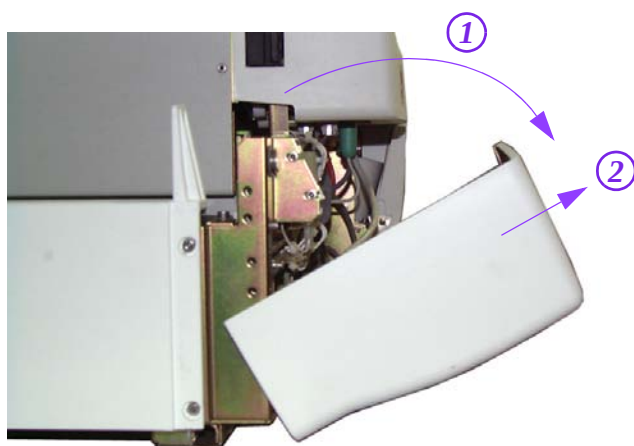


Fig. 7-21 Left Front cover

3.2. Right front door removal

Pull the Right Front cover down, as indicated in (1), and then pull out to remove it, as indicated in (2) (see [Fig. 7-22](#), page 7-20).

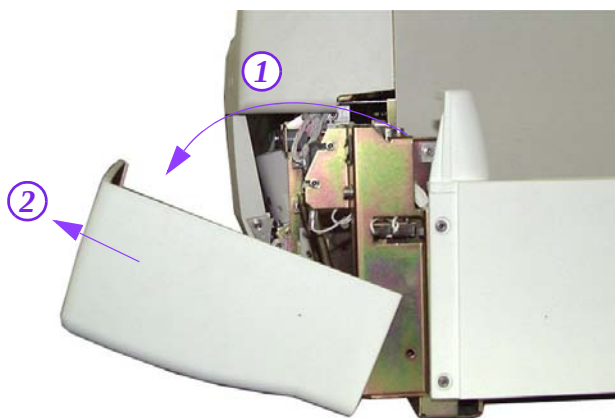


Fig. 7-22 Right front cover

3.3. Right-hand side panel removal

Locate the 2 locking screws at the top of the right side panel. Place a flat-tipped screwdriver into the screw slots and turn counter-clockwise to unlock the screws (see [Fig. 7-23](#), page 7-20).

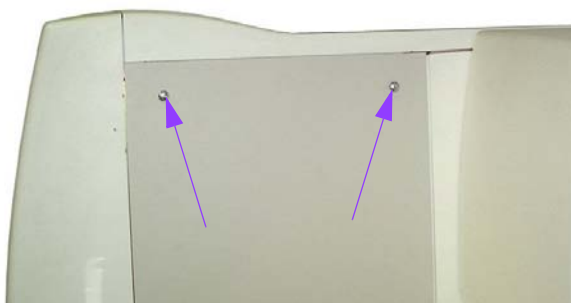


Fig. 7-23 Righthand side panel

Lift the panel up and out of its placement slot.

3.4. Left-hand side panel removal

Lift the reagent compartment cover to expose the 2 retaining screws on the rear of the left side panel.

Remove **Left Panel** by unscrewing 2x CHC M4X6 at the front and loosening 2x CHC M4X6 at the rear (see [Fig. 7-24](#), page 7-21).

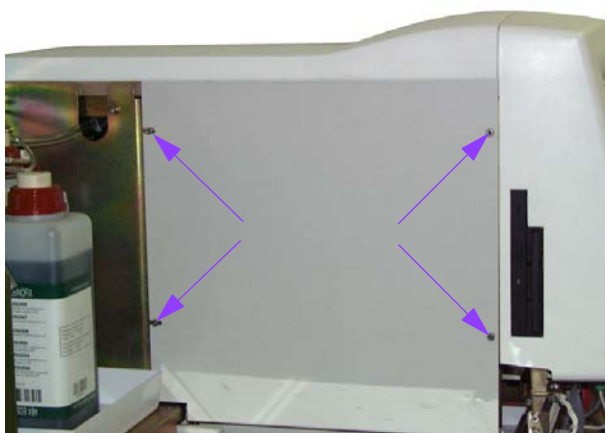


Fig. 7-24 Lefthand side panel

Now slide the left side panel forward and lift it out of the instrument.

4. Service menu description

When the user enters the «Service Menu» screen, the following menus will be available to the user.

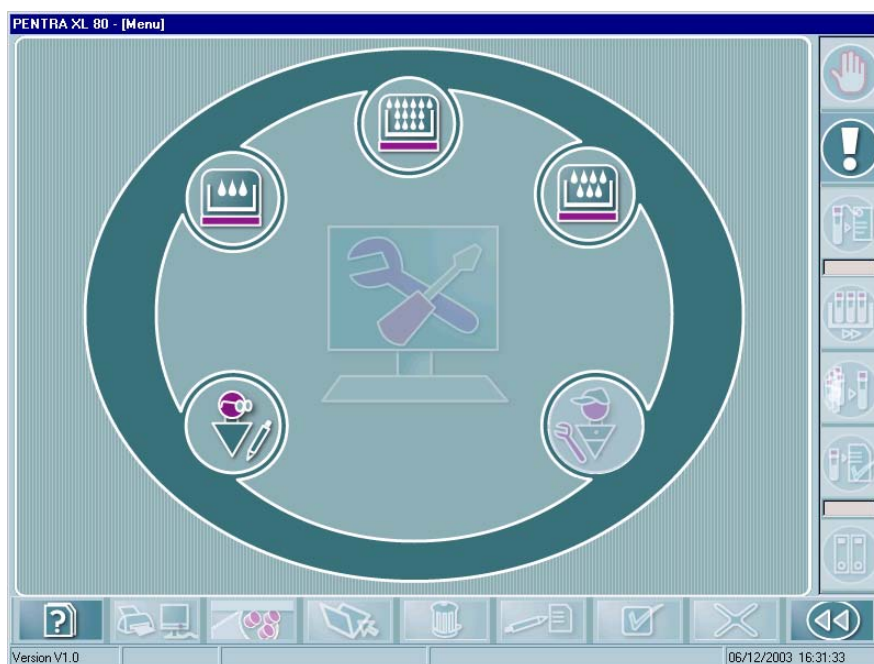


Fig. 7-25 Service Menu screen

3 Maintenance Hydraulical cycles are available on this menu:

- ◆ **Miniclean:** short rinsing sequence of the counting chambers
- ◆ **Concentrated Cleaning:** Thorough cleaning of the chambers with a bleach solution (see [Concentrated cleaning](#), page 7-34)
- ◆ **Autoclean:** Automatic Cleaning cycle. This can be automatically run every «n» analysis cycles (See Section 5, [5.5. Cycle option](#), page 5-35).

as well as a «Super User» sub menu (see [4.1. Super User menu](#), page 7-22)

4.1. Super User menu

3 menus are available to the user for maintenance intervention on the instrument:

- ◆ [4.2. Mechanical menu](#), page 7-24
- ◆ [4.3. Hydraulical menu](#), page 7-31
- ◆ [4.4. Others](#), page 7-36

Maintenance & Troubleshooting

Service menu description

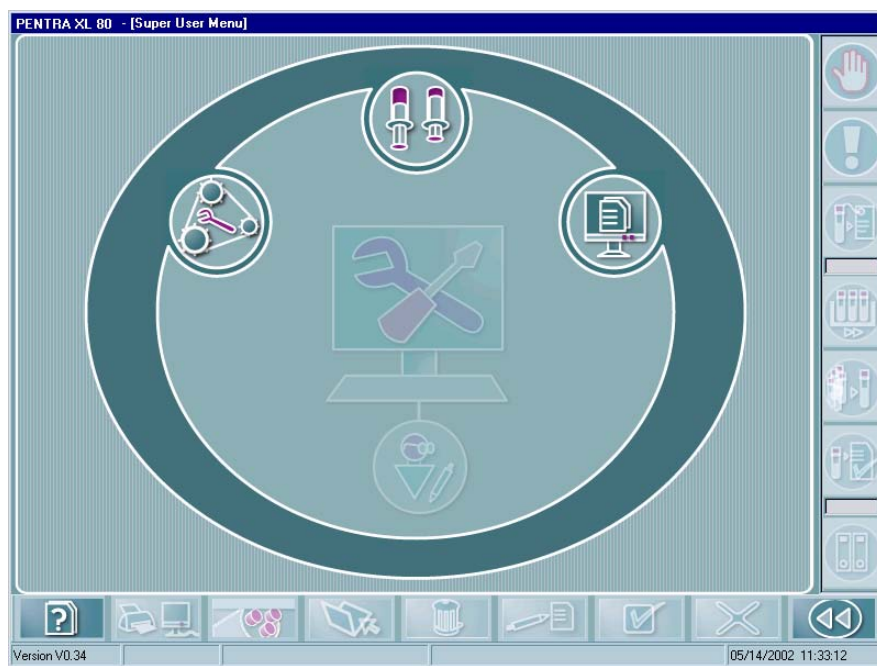


Fig. 7-26 Super User menu

4.2. Mechanical menu

4.2.1. Instrument Initialization

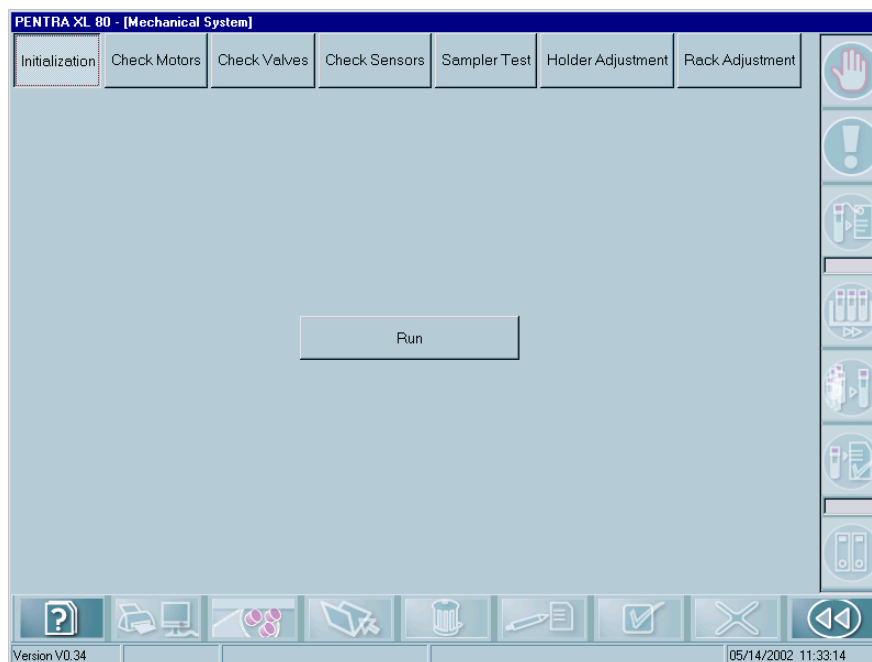


Fig. 7-27 Super User\Mechanical\Initialization

Select the «Initialization» key, and then select the «Run» key to start the initialization cycle. This cycle will place all mechanical assemblies in a «ready for analysis position». This will be a starting state for the Auto-sampler, Sampling probe, sample Carriage, Syringes, etc.... This is also termed as a mechanical homing for all assemblies to their ready position.

4.2.2. Check motors

This menu will allow the user to check the operation of all the motor driven assemblies independently:

Power off the instrument.

Open the instrument right and left front doors and remove the right-hand and left-hand side panels (see **3. Instrument panels & cover Removals**, page 7-19).

Once the side panels have been removed, power on the instrument.

From the Main screen, select the «Super User Menu» and then **/Mechanical /Check Motors**.

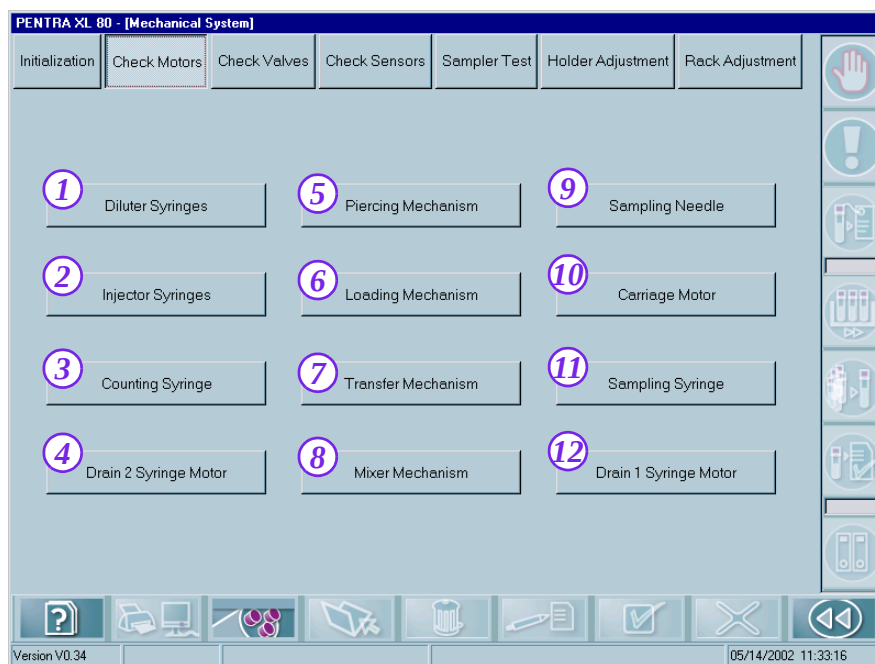


Fig. 7-28 Super User\Mechanical\Check Motors

- 1- Diluter Syringes:** Left-hand side of the instrument, check for smooth and complete movement of the syringe.
- 2- Injector Syringes:** Lefthand side of the instrument, check for smooth and complete movement of the syringe.
- 3- Counting Syringe:** Lefthand side of the instrument, check for smooth and complete movement of the syringe.
- 4- Drain 2 Syringe Motor:** Lefthand side of the instrument, check for smooth and complete movement of the syringe.
- 5- Piercing Mechanism:** Close the Tube Holder Door and verify smooth and complete piercing movement.
- 6- Loading Mechanism:** Check for smooth and complete movement of Rack Loader.
- 7- Transfer Mechanism:** Check for smooth and complete movement of the rack transfer mechanism.
- 8- Mixer Mechanism:** Check for smooth and complete rotational movement of the sample tube mixer.
- 9- Sampling Needle:** Check for smooth and complete movement of the sample probe
- 10- Carriage Motor:** Right-hand side of the instrument, Check for smooth and complete movement of the sampling carriage.
- 11- Sampling Syringe:** Right-hand side of the instrument on the carriage, check for smooth and complete movement of the Sampling syringe.
- 12- Drain 1 Syringe Motor:** Right-hand side of the instrument, check for smooth and complete movement of the Waste/Drain syringe.

4.2.3. Check valves

This menu will allow the user to check the operation of all electrical valves on the instrument:

Power off the instrument.

Open the instrument right and left front doors and remove the right-hand and left-hand side panels (see **3. Instrument panels & cover Removals**, page 7-19).

Once the side panels have been removed, power on the instrument. From the Main screen, select the «Super User Menu» and then **/Mechanical /Check Valves**.

Closely observe the valve operations; movements have to be straight and regular.

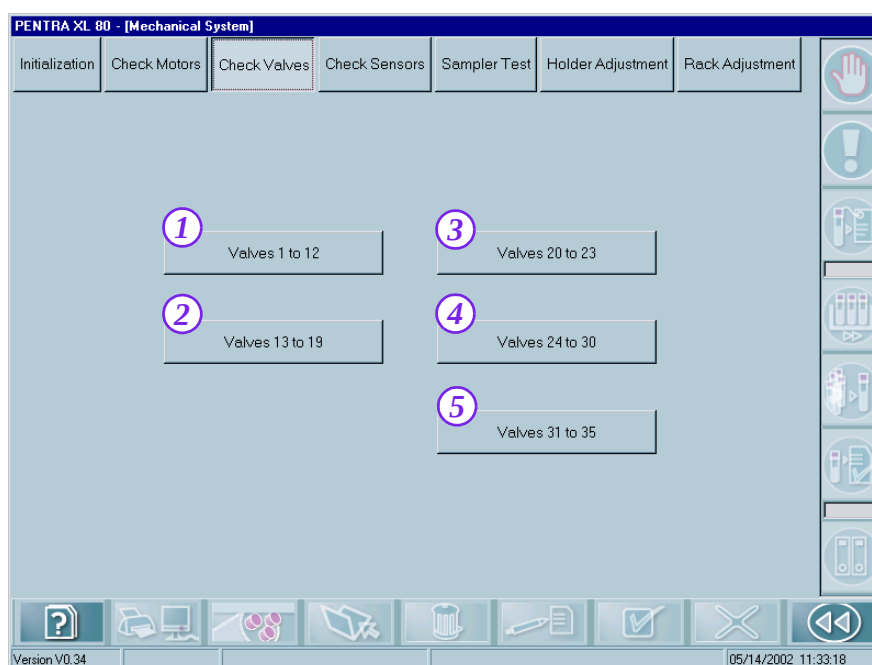


Fig. 7-29 Super User\Mechanical\Check Valves

- 1- **Valves 1 to 12:** Verify the correct operation of these valves
- 2- **Valves 13 to 19:** Verify the correct operation of these valves
- 3- **Valves 20 to 23:** Verify the correct operation of these valves
- 4- **Valves 24 to 30:** Verify the correct operation of these valves
- 5- **Valves 31 to 35:** Verify the correct operation of these valves

4.2.4. Check Sensors

Verify the activity of all of the mechanical sensors (mainly switches) on the instrument. If all switches are working properly, they will be indicated in «Green».

From the Main screen, select the «Super User Menu» and then **/Mechanical /Check Sensors**.

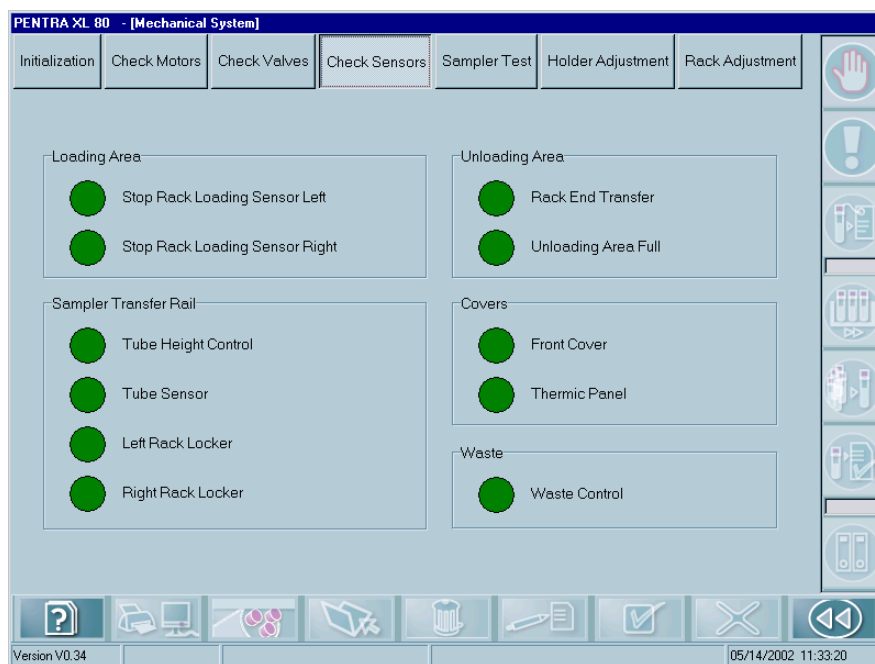


Fig. 7-30 Super User\Mechanical\Check Sensors

Verify that all sensors are indicated in «Green». If any sensor(s) are indicated in «Red», contact your local HORIBA ABX Technical Support Representative for further instructions.

4.2.5. Sampler test

Obtain a Sample tube rack and place some tubes in position and leave 2 or 3 empty spaces.

From the Main screen, select the «Super User Menu» and then **/Mechanical /Sampler Test**.

Now select the «Start Rack» key and verify that the rack identification and all the tubes in the rack have been detected:

- ◆ Rack number
- ◆ Type of rack (CBC or DIFF)
- ◆ Barcode numbers

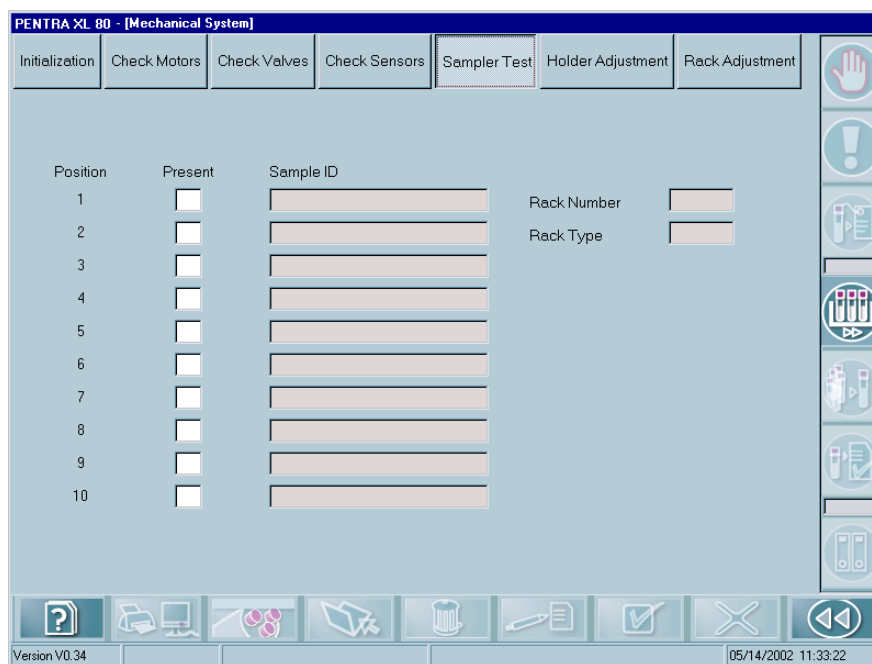


Fig. 7-31 Super User\Mechanical\Sampler Test

4.2.6. Sample tube Holder adjustment

The Sample tube holder and sampling needle positions has been factory adjusted. Do not attempt to modify them unless instructed to do so by an HORIBA ABX Representative!

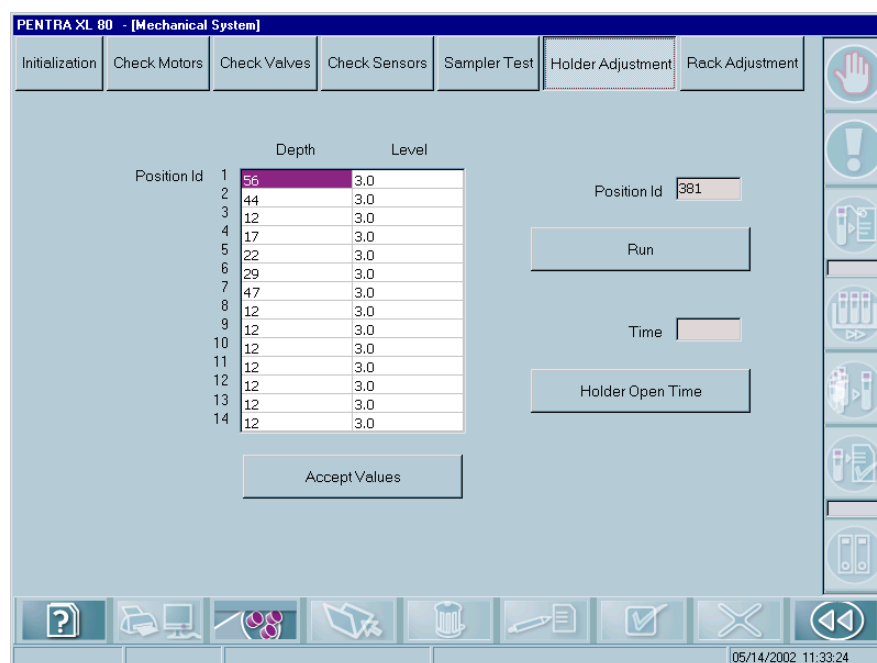


Fig. 7-32 Super User\Mechanical\Holder Adjustment

- ◆ **Depth:** For each hole position Id, the depth is measured in millimeters.
- ◆ **Level:** This measurement is subtracted from the total depth of each hole position Id, so that the sample probe will not touch the bottom of any sample tube placed in these positions.
- ◆ **Position id:** This measurement is taken from the Sample probe «Home» position to the top flat surface of the tube holder.
- ◆ **Accept Values** key: This key is used to accept any changes made to the Depth and Level fields.
- ◆ **Run** key: This key allows the acceptance of the number of steps from the Sample probe «Home» position to the top flat surface of the tube holder. The obtained value is returned into **Position id** field.
- ◆ **Holder Open Time** key: This key allows the instrument to calculate the amount of time it takes for the tube holder to completely open. This value will be entered into the «Time» field.

4.2.7. Rack adjustment

The **Rack Adjustment** menu allows to define for each type of rack the depth and level of sampling inside the tube.

- ◆ **Depth:** This measurement is the actual depth of the rack in millimeters corresponding to the rack «Type».
- ◆ **Level:** This measurement is subtracted from the depth of sampling in millimeters in, relationship to the rack «Type».
- ◆ **Accept Values** key: This key is used to accept any changes made to the Depth and Level fields.

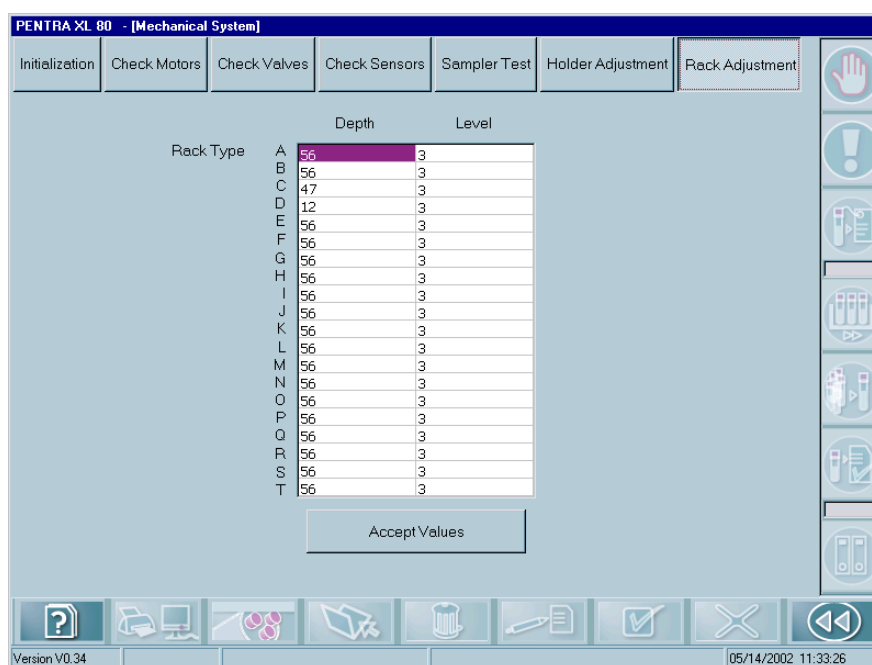


Fig. 7-33 Super User\Mechanical\Rack Adjustment

4.3. Hydraulical menu

4.3.1. Drain chambers

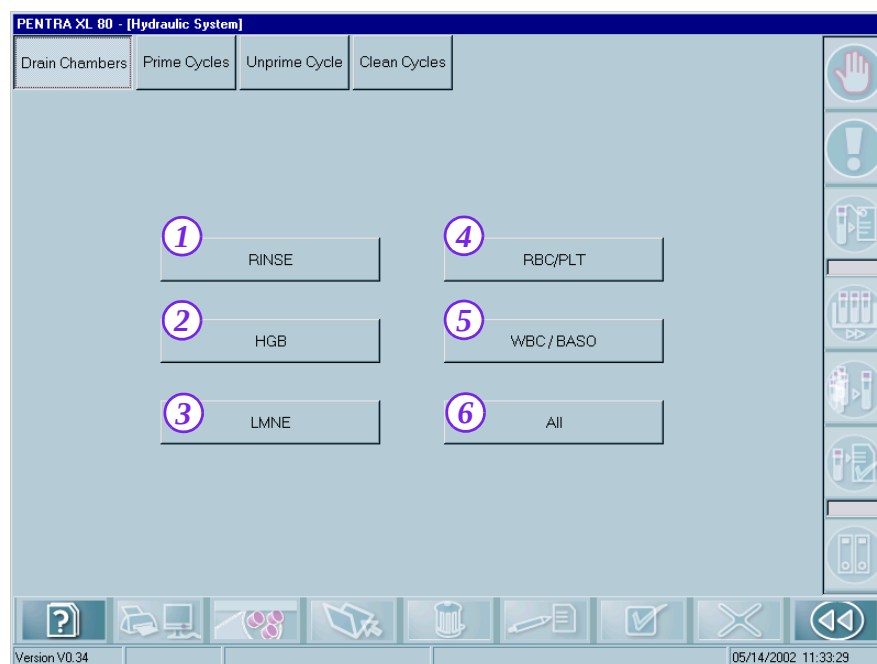


Fig. 7-34 Super User\Hydraulical\Drain Chambers

- 1- **Rinse:** Drains the rinse chamber
- 2- **HGB:** Drains the HGB chamber
- 3- **LMNE:** Drains the LMNE chamber
- 4- **RBC/PLT:** Drains the RBC/PLT chamber
- 5- **WBC/BASO:** Drains the WBC/BASO chamber
- 6- **All:** Drains all the chambers.

4.3.2. Prime cycles

This menu will allow the user to prime reagents into the instrument.

Run this procedure after service has been performed on the instrument.



This function allows only the priming of reagents into the instrument. It does not set the reagent quantities to 100%

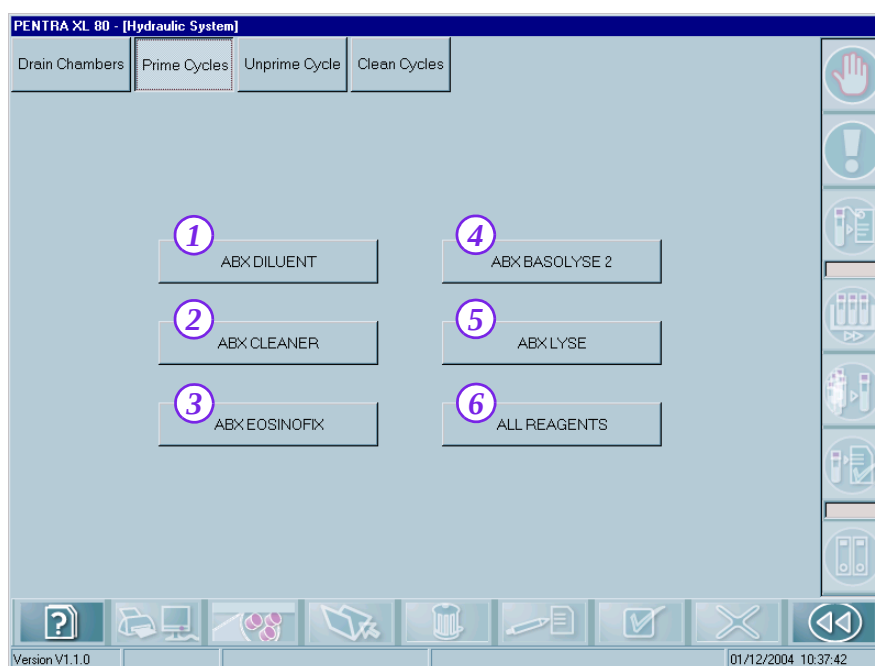


Fig. 7-35 Super User\Hydraulical\Prime Cycles

- 1- **ABX Diluent:** Primes ABX Diluent reagent
- 2- **ABX Cleaner:** Primes ABX Cleaner reagent
- 3- **ABX Eosinofix:** Primes ABX Eosinofix reagent
- 4- **ABX Basolyse 2:** Primes ABX Basolyse 2 reagent
- 5- **ABX Lyse:** Primes ABX Lyse reagent
- 6- **All reagents:** Primes all reagents at the same time

4.3.3. Unprime cycle

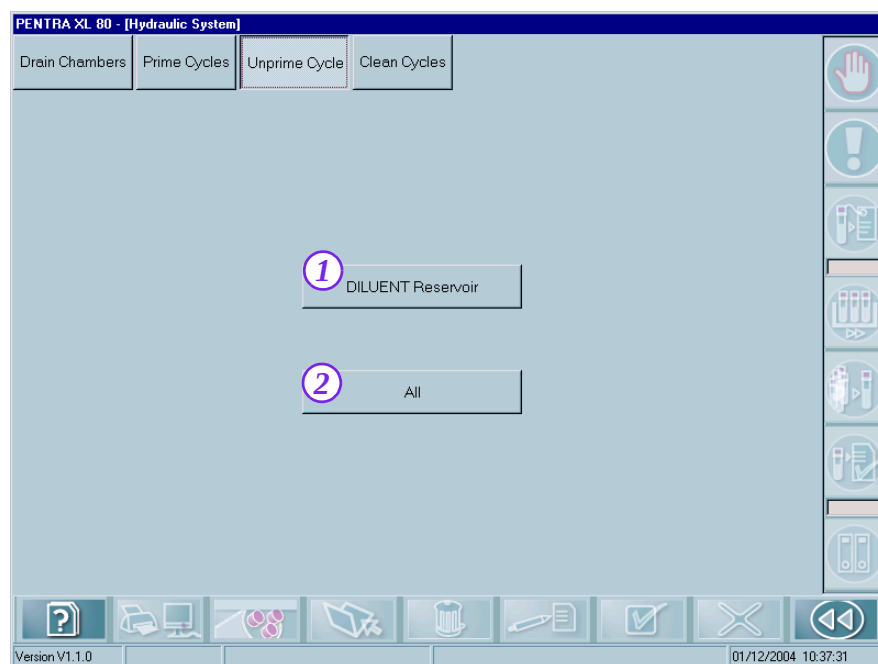


Fig. 7–36 Super User\Hydraulical\Unprime Cycle

- 1- **Diluent reservoir:** Drains the diluent reservoir
- 2- **All:** Unprimes all the reagents from the instrument

4.3.4. Clean Cycles

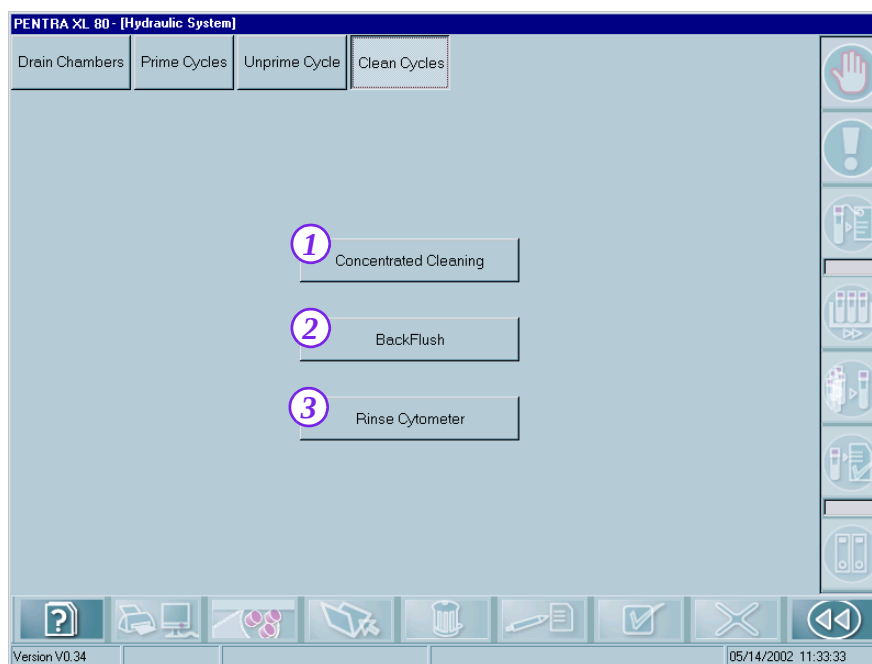


Fig. 7-37 Super User\Hydraulical\Clean Cycle

- 1- **Concentrated Cleaning:** Allows to clean chambers with a bleach solution.
- 2- **BackFlush:** This cycle allows the user to clear the counting chambers with counter-pressure in case of aperture blockage.
- 3- **Rinse Cytometer:** This cycle allows the user to backflush the LMNE flowcell with ABX Diluent to rid the counting area of air bubbles and/or blockage.

4.3.5. Concentrated cleaning

remove the right-hand side panel (see [3. Instrument panels & cover Removals](#), page 7-19) to access to the chambers.

Select **Concentrated Cleaning** key then press **Validate** key in the following window to confirm the cycle (see [Fig. 7-38](#), page 7-34).

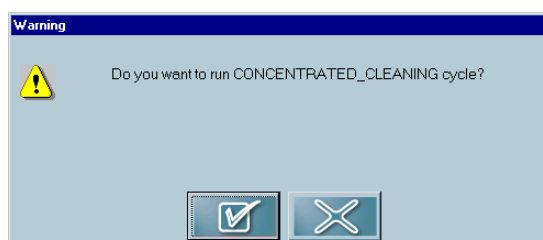


Fig. 7-38 Concentrated cleaning confirmation

The cycle starts, when the following window is displayed (see [Fig. 7-39](#), page 7-35) and be-

fore pressing **Validate** key, pour into each chamber 3ml of Minoclair or bleach diluted to 4° chloride (see [Fig. 7-40](#), page 7-35).

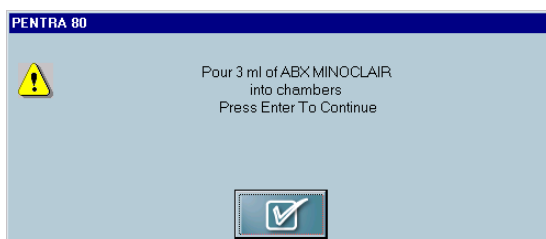


Fig. 7-39 Concentrated cleaning pour Minoclair

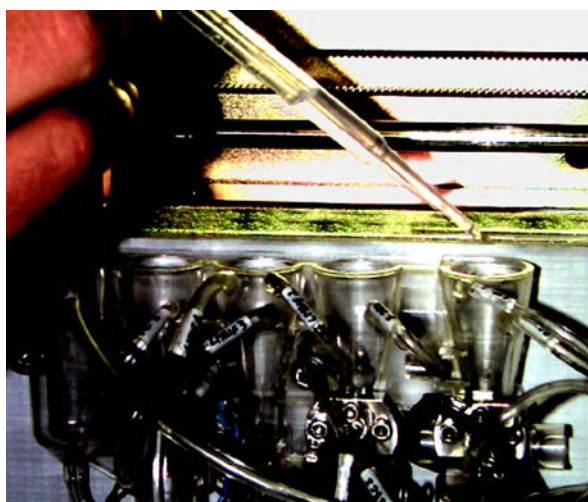


Fig. 7-40 Pour Minoclair

Select **Validate** key once Minoclair has been distributed into all the chambers. Then the following message is displayed.

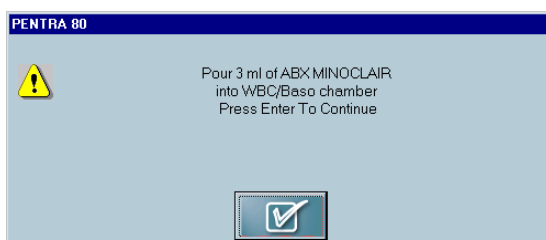


Fig. 7-41 Concentrated cleaning pour Minoclair into WBC/Baso chamber

Pour 3ml of Minoclair or bleach diluted to 4° chloride into WBC/BASO chamber (last chamber on the right side, [Fig. 7-40](#), page 7-35).

Select **Validate** key.

Wait for the instrument to complete the cleaning.

4.4. Others

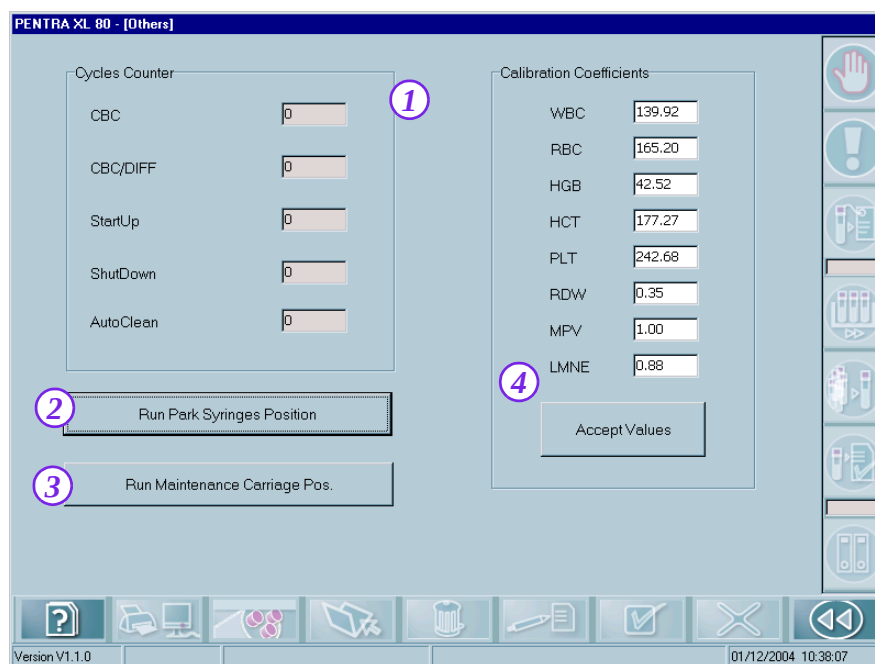


Fig. 7-42 Super User\Others

1- Cycles Counter: shows the number of specified cycles performed by the instrument.

2- Run Park Syringe Position: This key allows the user to place the syringe pistons in a safe position for long-term non-usage or storage and when the instrument will be in transport from one location to another.

3- Run Maintenance Carriage Pos.: This key allows the user to automatically move the Sample Carriage over the chamber area for sample probe replacement and/or other maintenance procedures that may require the movement of the sample carriage.

4- Each calibration coefficient can be forced to a value: Enter the value you want to modify in the «Calibration coefficients» grid. Confirm the modifications by pressing the «Accept values». A notification is automatically done in the «calibration» logs (see [Fig. 7-11](#), page 7-13)



Any modification of the coefficients will affect the results and shall be the responsibility of the user.

5. Troubleshooting

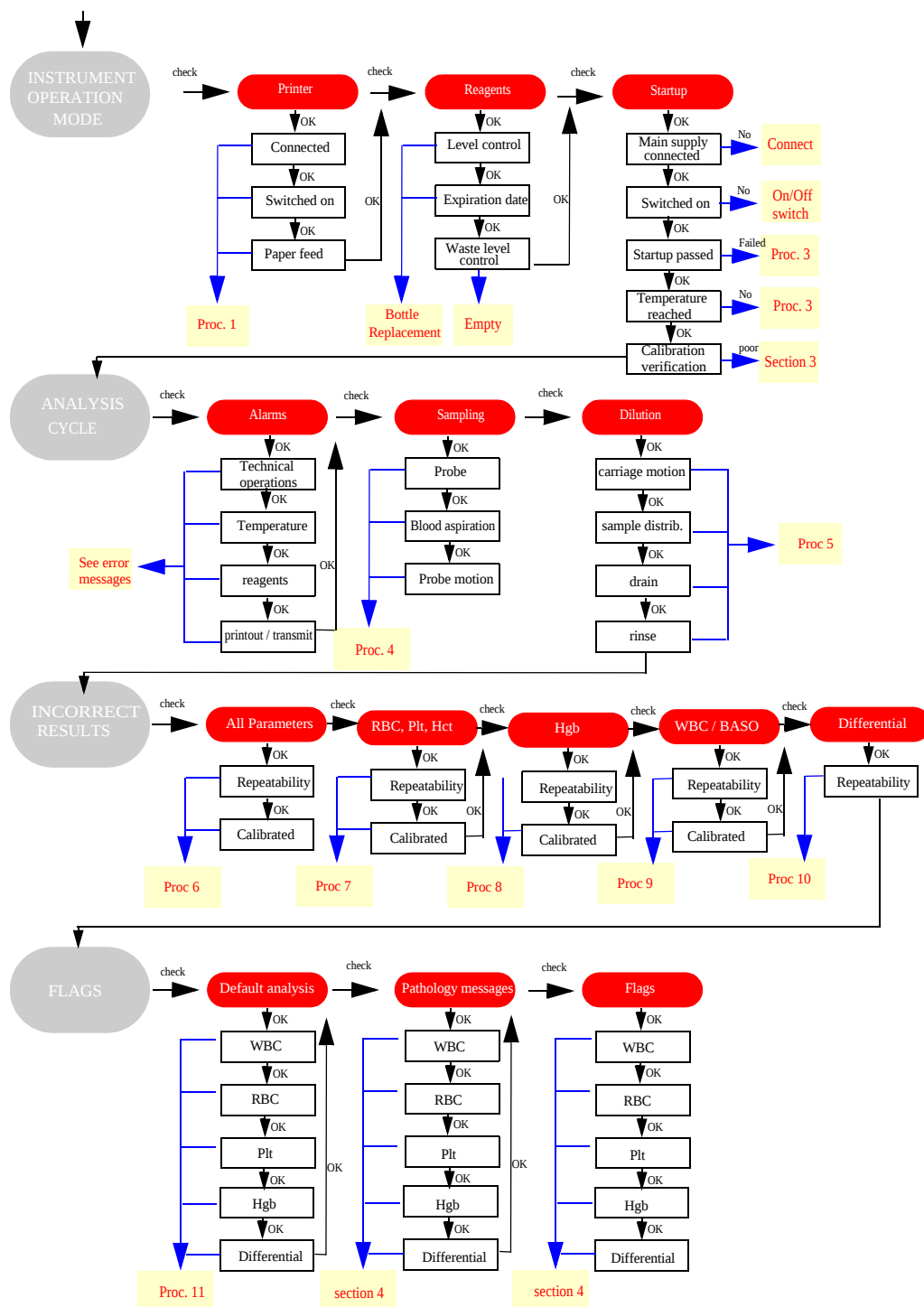


Fig. 7-43 Troubleshooting guide

5.1. Instrument operation mode

▼ Procedure 1: Printer

See printer's user manual to connect, to switch on/off or to feed paper.

▼ Procedure 2: Reagents

Bottle replacement (see [2.1.2. Integrated reagents & Diluent container replacement](#), page 7-10).

Waste container (see [2.1.3. Waste container replacement](#), page 7-15).

▼ Procedure 3: Instrument startup

Startup failed:

- a – Check all reagent's expiration dates: Replace bottle if necessary.
- b – Re-run a Startup cycle.
- c – Perform a concentrated cleaning (see [4.3.4. Clean Cycles](#), page 7-34).

Temperature not reached:

- a – Wait for five minutes to reach the operating temperature
- b – If temperature is not reached call your HORIBA ABX representative service department

Calibration verification out of acceptable limits:

- a – Clean the system (see [4.3.4. Clean Cycles](#), page 7-34) and re-run the control.
- b – Run a new vial.
- c – Calibrate the instrument Section 3, [4. Calibration](#), page 3-25

▼ Procedure 4: Sampling probe

Sampling probe:

- a – Check probe motion (see [4.2.2. Check motors](#), page 7-24).
- b – Open the righthand side panel to access to the chambers Section 7, [3.3. Right-hand side panel removal](#), page 7-20.
- c – Run an analysis cycle on blood.
- d – Control the specimen aspiration (Blood delivering in the chambers).
- e – Check the probe is not bent.

▼ Procedure 5: Dilution

Carriage motion:

- a – Check that hydraulic operations appear to work properly (Reagent level in each chamber and carriage motion).

Sample distribution:

- a – Run an analysis cycle and check that specimen distribution is performed correctly into chambers.
- b – A probe rinse is previously carried out in the rinse chamber (1) (Blood appears in this chamber).
- c – The first specimen is delivered to the first dilution chamber (2) (Brown colour), the second to the WBC\Baso chamber (5) (Clearer) and the third one to the LMNE chamber (3) (The darkest).
- d – Check that bubbling is provided to these chambers once the specimen have been diluted.

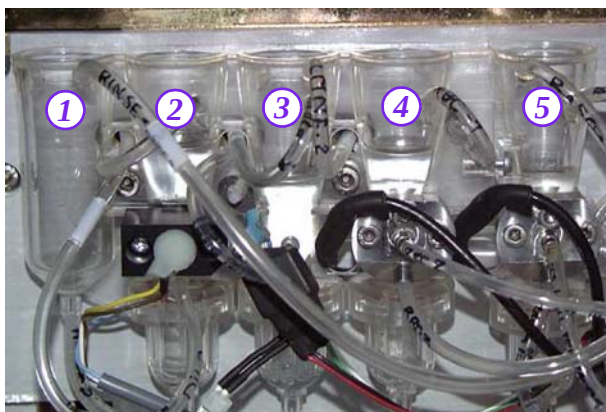


Fig. 7-44 Chambers

Drain and rinse:

- a – Check chambers are drained and rinsed.
- b – If operations are faulty, identify the source of the malfunction when possible and call your HORIBA ABX representative department.

5.2. Results

▼ Procedure 6: All parameters

Repeatability: According to the CV specifications (See Section 2, [3. Summary of performance data](#), page 2-7)

Is the instrument non repeatable on all parameters ? If not perform directly the procedure corresponding to the non repeatable parameter. If all parameters are not repeatable continue this procedure.

- c – Visually check that the sampling operation appears to be correct.
- d – Control the sampling syringe operations (see [4.2.2. Check motors](#), page 7-24).
- e – Control the counting syringe operations (see [4.2.2. Check motors](#), page 7-24).
- f – Perform a concentrated cleaning (see [4.3.4. Clean Cycles](#), page 7-34).

- g – If all these operations appear to be correct, call your **HORIBA ABX** representative department.

Calibration

- a – If the system appears to be operating properly, if fresh uncontaminated reagents are being used and the precision is within the specifications, Pentra XL 80 may need a calibration Section 3, **4. Calibration**, page 3-25.

▼ Procedure 7: RBC, PLT, HCT

Repeatability (If RBC, PLT & HCT are non repeatable):

- a – Check the second dilution is carried out correctly (42,5µl of this dilution are aspirated from chamber 2 into hydraulical circuit and injected with diluent into chamber 4).
- b – Check bubbling in the RBC\PLT chamber (**4**) once the dilution is carried out (Dilution remains transparent).
- c – Perform a concentrated cleaning (see **4.3.4. Clean Cycles**, page 7-34).
- d – If all these operations appear to be correct, call your **HORIBA ABX** representative department.

Calibration:

- a – Perform a calibration of the instrument (see **Calibration**, page 7-40).

▼ Procedure 8: HGB

Repeatability (If HGB is non repeatable):

- a – Run an analysis cycle.
- b – Check dilution colour in the chamber (**2**): «Milky» when sample is first delivered to the chamber then brown transparent when lyse is injected.
- c – Perform a concentrated cleaning (see **4.3.4. Clean Cycles**, page 7-34).
- d – If this does not correct the HGB count, call your **HORIBA ABX** representative department.

Calibration:

- a – Perform a calibration of the instrument (see **Calibration**, page 7-40).

▼ Procedure 9: WBC, Baso

Repeatability (If WBC\Baso are non repeatable)

- a – Perform a concentrated cleaning (see **4.3.4. Clean Cycles**, page 7-34).
- b – If this does not correct the WBC\Baso count, call your **HORIBA ABX** representative department.

Calibration:

- a – Perform a calibration of the instrument (see **Calibration**, page 7-40).

▼ Procedure 10: Differential (LMNE)

Repeatability (If Differential results are non repeatable)

- a – Perform a concentrated cleaning (see [4.3.4. Clean Cycles](#), page 7-34).
- b – If this does not correct the Differential count, call your **HORIBA ABX** representative department.

5.3. Flags

▼ Procedure 11: Default analysis

WBC:

- a – Perform a concentrated cleaning (see [4.3.4. Clean Cycles](#), page 7-34).
- b – Re-run the specimen.
- c – Check the operation of liquid valve <23> and <14> (Opening and closing during cycle). If defective replace the valve.
- d – If this does not correct the WBC results, call your **HORIBA ABX** representative department.

RBC, PLT:

- a – Perform a concentrated cleaning (see [4.3.4. Clean Cycles](#), page 7-34).
- b – Re-run the specimen.
- c – Check the operation of liquid valve <14> (Opening and closing during cycle). If defective replace the valve.
- d – If this does not correct the RBC\PLT results, call your **HORIBA ABX** representative department.

HGB:

- a – Check the HGB LED is illuminated when system is on:



Fig. 7-45 HGB LED

- b – Perform a concentrated cleaning (see [4.3.4. Clean Cycles](#), page 7-34).
- c – Re-run the specimen.
- d – Check the operation of liquid valve <14> (Opening and closing during cycle). If defective

tive replace the valve.

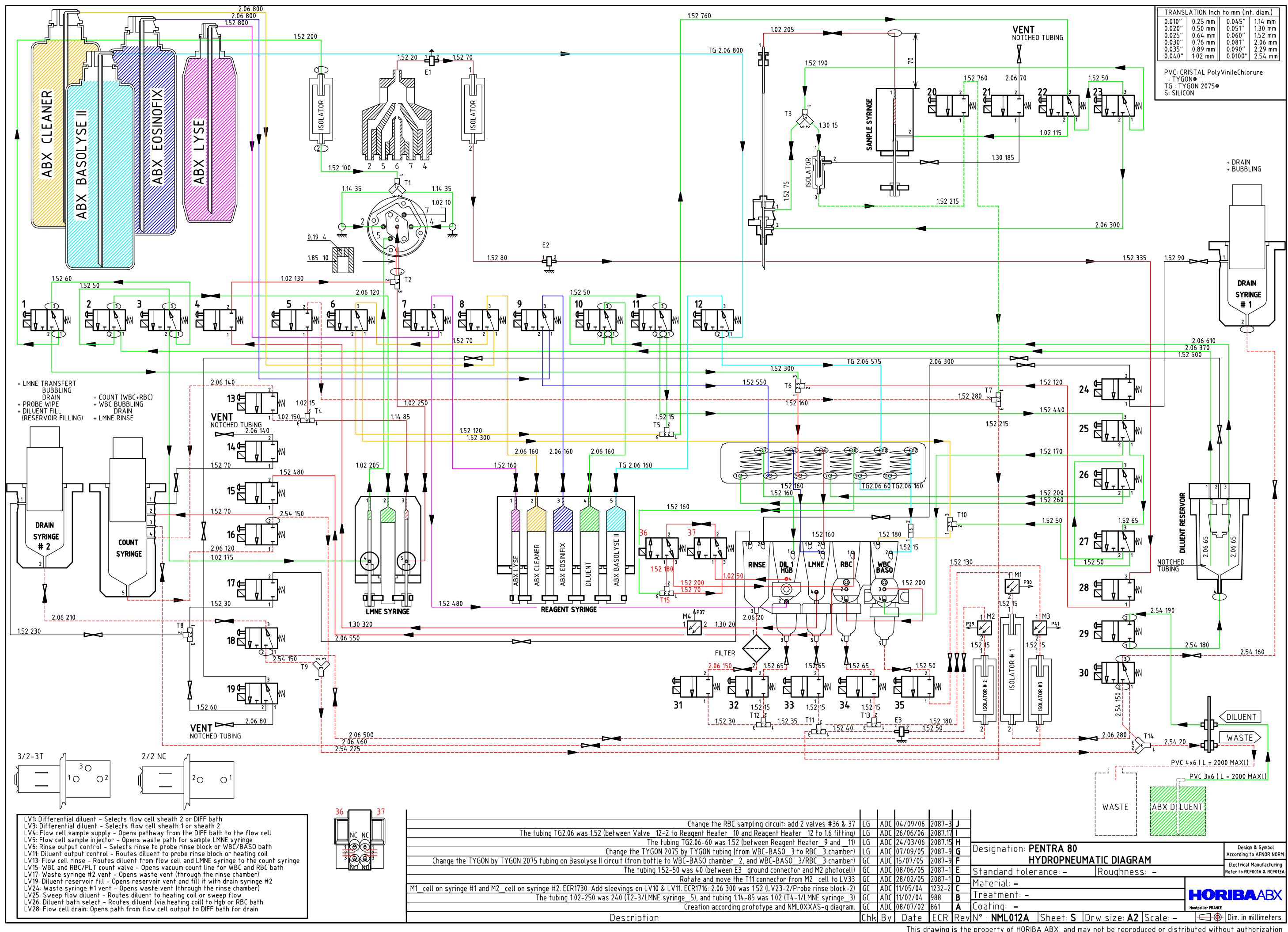
- e – If this does not correct the HGB results, call your **HORIBA ABX** representative department.

Differential (LMNE):

- a – Check optical bench lamp is lit when instrument is on. If not replace the lamp (see **2.2. Optical bench lamp replacement**, page 7-15).
- b – Run a Cytometer rinse (see **4.3.4. Clean Cycles**, page 7-34).
- c – Re-run the specimen.
- d – If this does not correct the WBC results, call your **HORIBA ABX** representative department.

6. Hydraulic diagram

see on next page



This drawing is the property of HORIBA ABX, and may not be reproduced or distributed without authorization

7. Error messages

When an error or an alarm is detected by the instrument, it is reported into the Alarm screen. The **Alarm** key is activated and blinks (see [Fig. 7-46 Alarm key](#), page 7-44), press **Alarm** key to access to the Alarm screen (see [Fig. 7-47 Alarm screen](#), page 7-44). Check the type of error and follow the instruction from the Alarm screen.



Fig. 7-46 Alarm key

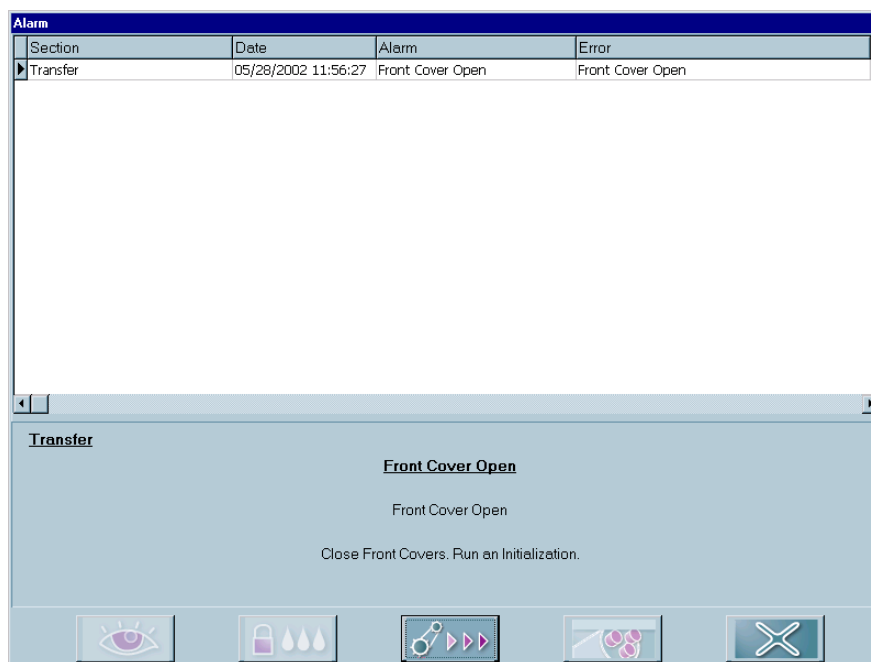


Fig. 7-47 Alarm screen

Error messages in this section:

- ◆ [7.1. Analyzer error types and help messages](#), page 7-45
- ◆ [7.2. Transfer error types and help messages](#), page 7-46
- ◆ [7.3. STAT mode error type and help message](#), page 7-47
- ◆ [7.4. Environment Error Types and Help Messages](#), page 7-47
- ◆ [7.5. User Error Types and Help Messages](#), page 7-49
- ◆ [7.6. Expiration Date Error Types and Help Messages](#), page 7-49
- ◆ [7.7. Analyzer Internal Error Types and Help Messages](#), page 7-49

7.1. Analyzer error types and help messages

Alarm	Error type	Help Message
Carriage motor failure	Carriage Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
Carriage mechanism not reaching home	Carriage Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
Counting syringe motor failure	Counting Syringe Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
Counting syringe mechanism not reaching home	Counting Syringe Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
Diluter syringe motor failure	Diluter Syringe Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
Diluter syringe mechanism not reaching home	Diluter Syringe Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
DRAIN 1 syringe motor failure	DRAIN 1 Syringe Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
DRAIN 1 syringe mechanism not reaching home	DRAIN 1 Syringe Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
DRAIN 2 syringe motor failure	DRAIN 2 Syringe Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
DRAIN 2 syringe mechanism not reaching home	DRAIN 2 Syringe Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
Drain sensor [sensor number (1, 2 or 3)] time out	Drain Sensor	Run an Auto Clean
Injection syringe motor failure	Injection Syringe Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
Injection syringe mechanism not reaching home	Injection Syringe Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
LMNE transfer sensor time out	LMNE transfer sensor	Run an Auto Clean
Needle motor failure	Needle Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu
Needle mechanism not reaching home	Needle Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
Piercing UP or DOWN bad position	Piercing Syringe Motor	Run an Auto Clean Check Motor in Service Menu
Reagent temperature out of range. Value Min. & Max.	Reagent Temperature	Run an initialization
Reagent Temperature sensor not connected	Reagent Temperature sensor	Run an initialization
Reagent Temperature sensor failure	Reagent Temperature sensor	Run an initialization
Sampling syringe motor failure	Sampling Syringe Motor home switch always detected	Run an Auto Clean Check Motor in Service Menu

Alarm	Error type	Help Message
Sampling syringe mechanism not reaching home	Sampling Syringe Motor Mechanism initialization failed	Run an Auto Clean Check Motor in Service Menu
Thermostated Compartment Temperature sensor not connected	Thermostated Compartment Temperature	Run an initialization
Thermostated Compartment Temperature sensor failure	Thermostated Compartment Temperature	Run an initialization
Thermostated Compartment temperature out of range. Value Min. & Max.	Thermostated Compartment Temperature	Run an initialization
Thermostated Compartment Panel open	Thermostatic Compartment Door	Run an Auto Clean
Lamp voltage is out of order	The LMNE optical bench lamp is out of order	Replace the lamp (see 2.2. Optical bench lamp replacement , page 7-15)

7.2. Transfer error types and help messages

Alarm	Error Type	Help Message
Loading motor mechanism not reaching home	Sampler Loading Motor Mechanism initialization failed	Run an initialization Check motor in Service Menu
Loading motor failure	Sampler Loading Motor home switch always detected	Run an initialization Check motor in Service Menu
Stop rack loading switch not detected	Sampler Loading Motor	Run an initialization Check motor in Service Menu
Stop rack loading switch detected	Sampler Loading Motor	Run an initialization Check motor in Service Menu
Sampler Transfer mechanism not reaching home	Sampler Transfer Motor Mechanism initialization failed	Run an initialization Check motor in Service Menu
Sampler Transfer motor failure	Sampler Transfer Motor home sensor always detected	Run an initialization Check motor in Service Menu
Stop rack Transfer switch not detected	Sampler Transfer Motor End transfer rack switch not detected	Run an initialization Check switch in Service Menu
Stop rack Transfer switch detected	Sampler Transfer Motor End transfer rack switch always detected	Run an initialization Check switch in Service Menu
Mixer mechanism not reaching home	Mixer Motor Mechanism initialization failed	Run an initialization Check motor in Service Menu
Mixer motor failure	Mixer Motor home sensor always detected	Run an initialization Check motor in Service Menu
Mixer Bad grabber position	Mixer Motor Grabbers sensor position not detected	Run an initialization Check motor in Service Menu
Rack in wrong side position	Rack in the wrong side in loading area	Set rack in the right side position and restart automatic cycle

Alarm	Error Type	Help Message
No rack	No Rack in loading area	No message
Unloading area full	Unloading area full	Unload racks and restart automatic cycle
Tube too high in rack	Tube too high. tube may not be correctly inserted in rack	Run an initialization. Open left front cover and remove rack from loading area. Close left front cover and restart automatic cycle
Bad rack transfer movement (left)	Movement control	Run an initialization
Bad rack transfer movement (right)	Movement control	Run an initialization
Undesirable Rack Movement Detected	Movement control	Run an initialization
Front cover open	Front cover open	Close front covers Run an initialization

7.3. STAT mode error type and help message

Alarm	Error Type	Help Message
Tube holder mechanism failure	Door not open	No message

7.4. Environment Error Types and Help Messages

Alarm	Error Type	Help Message
%d Incoherent(s) Result(s) for %s	Incoherent Results	Run an initialization
Communication With Analyzer Cut Off	System	Run an initialization
Communication With Analyzer Failed	System	Run an initialization
End Sampler Transfer Sensor Error	Sensor state	Run an initialization
Error on raw results sending	Result failed	Run an initialization
Holder Sensor 1 in Wrong Position	Sensor state	Run an initialization
Holder Sensor 2 in Wrong Position	Sensor state	Run an initialization
Holder Sensor 3 in Wrong Position	Sensor state	Run an initialization
Holder Sensor 4 in Wrong Position	Sensor state	Run an initialization

Alarm	Error Type	Help Message
Loader Left Sensor Error	Sensor state	Run an initialization
Loader Right Sensor Error	Sensor state	Run an initialization
Lower Piercing Sensor in Wrong Position	Sensor state	Run an initialization
Mismatch Between the First and Second Barcode Tube Read on Rack %d Pos. %d	Barcode	Run an initialization
No diluent in analyzer reservoir	Incorrect level of diluent into reservoir	Check diluent level and run a prime diluent cycle
Printer alarm	Printer problem	Check printer
Printer module closed	Software	No message
QC Failed	QC Failed	Check Quality Control data in QC screen
Rack Moving Left Sensor Error	Sensor state	Run an initialization
Rack Moving Right Sensor Error	Sensor state	Run an initialization
Rack not identified	No read of Rack Barcode Label	Check barcode label
Reagent level too low for daily workload	Out of Reagent	Check reagent
Reagent level too low to run a analysis	Out of Reagent	Check reagent and restart automatic cycle
Reagent level too low to run a rack	Out of Reagent	Check reagent and restart automatic cycle
Result not stored	Software	Run an autoclean
RS232 alarm	RS232 external problem	Check host connection
Sample ID %d already in progress	Software	No message
LIS communication module closed	Software	No message
Tube Detection Sensor in Wrong Position	Sensor state	Run an initialization
Tube Level Detection Sensor in Wrong Position	Sensor state	Run an initialization
Two racks with same ID %d in transfer rail	Barcode	No message
Unable to launch print module	Software	No message
Unable to launch SIL communication module	Software	No message
Unloader Sensor in Wrong Position	Sensor state	Run an initialization
Upper Piercing Sensor in Wrong Position	Sensor state	Run an initialization

Alarm	Error Type	Help Message
Waste container full	Waste Container Full	Empty waste container and restart automatic cycle
XB failed	XB failed	Check XB in XB screen

7.5. User Error Types and Help Messages

Alarm	Error Type	Help Message
Instrument stopped by user		Run an AutoClean
Instrument stopped by user at the end of analysis		Run an Initialization
Instrument stopped by user at the end of rack		

7.6. Expiration Date Error Types and Help Messages

Alarm	Error Type	Help Message
Reagent(s) %s expired		Change reagent and restart automatic cycle
QC Lot Nb\Barcode %s expired		Check QC expiration date and use another QC Lot

7.7. Analyzer Internal Error Types and Help Messages

Alarm	Error Type	Help Message
Com error on slave %d	Communication error with slave	Run an Initialization
Error management failed	Unknown cycle	Run an Initialization
Error on cycle %d		Run an Initialization
Error on start internal chrono.		Run an Initialization
HGB Blank Error Management	HGB blank cycle incorrect	Run an Autoclean
Home Motor %d error		Run an Initialization
Incorrect pos.motor carriage (%d) Min : %d Max : %d	Carriage motor bad position	Run an Initialization
Incorrect pos.motor counting (%d) Min : %d Max : %d (Incorrect pos.motor PRESSURE (%d) Min : %d Max : %d)	Pressure motor bad position	Run an Initialization
Incorrect pos.motor diluter (%d) Min : %d Max : %d	Diluter motor bad position	Run an Initialization

Alarm	Error Type	Help Message
Incorrect pos.motor drain 1 (%d) Min : %d Max : %d (Incorrect pos.motor FLUSH (%d) Min : %d Max : %d)	Flush motor bad position	Run an Initialization
Incorrect pos.motor drain 2 (%d) Min : %d Max : %d	DRAINING_2 motor bad position	Run an Initialization
Incorrect pos.motor injector (%d) Min : %d Max : %d	Injector motor bad position	Run an Initialization
Incorrect pos.motor loading (%d) Min : %d Max : %d	Loader motor bad position	Run an Initialization
Incorrect pos.motor mixer (%d) Min : %d Max : %d	Mixer motor bad position	Run an Initialization
Incorrect pos.motor needle (%d) Min : %d Max : %d	Needle motor bad position	Run an Initialization
Incorrect pos.motor sampling (%d) Min : %d Max : %d	Sampling motor bad position	Run an Initialization
Incorrect pos.motor tranfer (%d) Min : %d Max : %d	Translation motor bad position	Run an Initialization
Internal Barcode Error	Barcode internal connection problem	Run an Initialization
Internal synchronization failed	System stop due to synchronization problem	Run an Autoclean
Motor %d is busy		Run an Initialization
Run a new cycle while analyzer is busy	Analyzer already in cycle	Run an Autoclean
Valve already activated		Run an Initialization

Contents

1. CDR mode	8-2
2. Reagent Leaflets	8-5
3. Compatible tube list	8-6
3.1. Compatible tube list for Tube holder	8-6
3.2. Compatible tube list for rack.....	8-8

This section includes the following:

1. **CDR mode**, page 8-2
2. **Reagent Leaflets**, page 8-5
3. **Compatible tube list**, page 8-6

1. CDR mode

The CDR (Customized Dilution Ratio) mode allows the user to obtain a result from samples with a very high cell concentration. The instrument may perform automatic dilution to 1/2, 1/3 or 1/5, based upon operator dilution ratio selection.

If the dilution ratio selected is one that has been validated by HORIBA ABX (refer to Section 2: Specifications, **3.9. CDR Mode specifications**, page 2-13) these results are reportable. All other dilution ratios may be considered for information use only. Non-validated dilution ratio may not allow any results to be shown «value replaced by (---) D» according to local regulations.

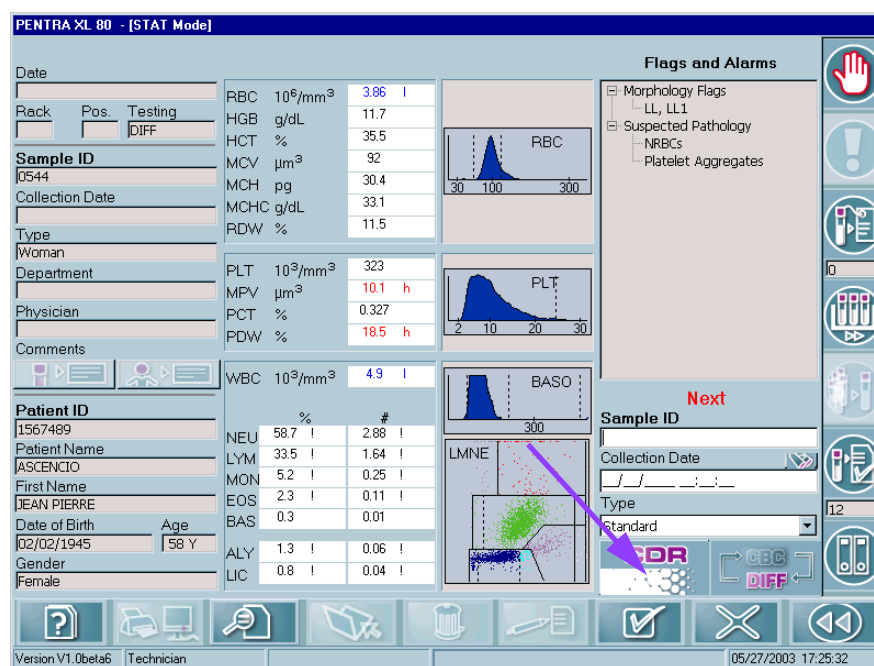
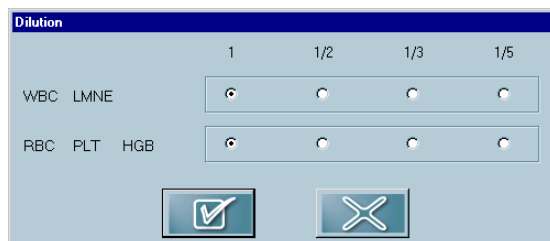


Fig. 8-1 CDR access key

From the «Stat mode» screen, select the «CDR» key (see **Fig. 8-1**, page 8-2), in order to open the «Dilution» screen.



Two parameter groups (WBC, LMNE or RBC, PLT, HGB) can be independently diluted with 3 predefined dilution ratios (1, 1/2, 1/3, 1/5). The dilution ratios validated by HORIBA ABX are the WBC and LMNE of 1/3 and the RBC, HGB and PLT of 1/2.



If the test is DIFF, the dilution ratio for WBC is applied on the LMNE values.

Select a dilution ratio, and confirm with the «OK» key. This ratio will be applied to the next order only.

Run your analysis as described in Daily Guide: RAB156C.



An automatic dilution can be programmed on Pentra XL 80, when hematological results trigger dilution flag as described in Section 5: Settings, **4.3.3. Rerun on «Dilution»**, page 5-18

When the CDR mode is used (dilution not equal to 1), the dilution ratio selected will be indicated in the Run Results Tree view as shown:

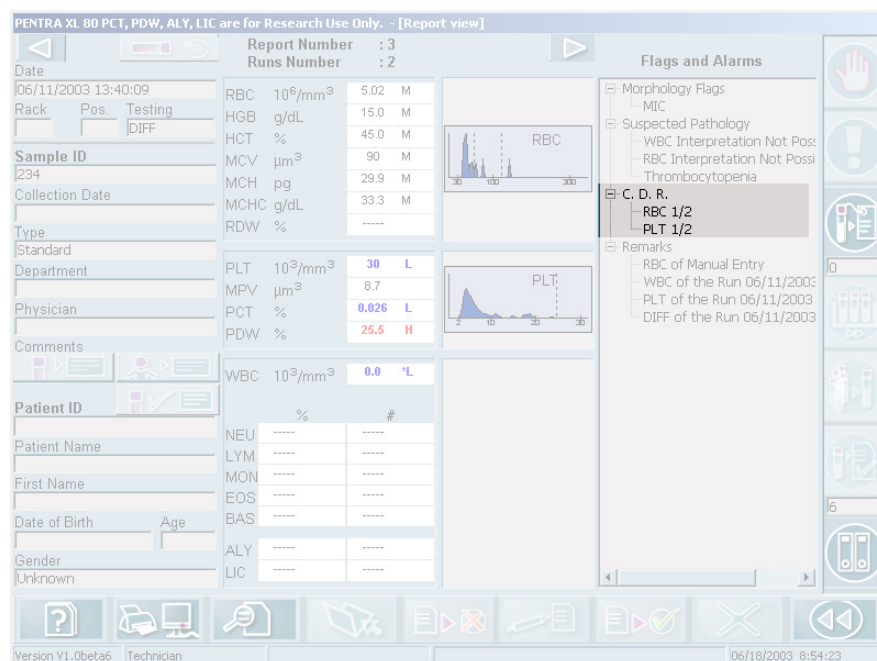


Fig. 8-2 CDR Tree View

- ◆ The results issued of the CDR mode are shown within brackets (xx.xx) into the Run display screen. When these Run Results are selected in the Report, the CDR parameters are also indicated with brackets (xx.xx).
- ◆ RDW parameter is reported to "---"



Refer to Section 2: Specifications, **3.9. CDR Mode specifications**, page 2-13

2. Reagent Leaflets



The CD ROM RAX055 delivered with your instrument provides Reagents, Controls and Calibrators leaflets/msds.

Latest versions of these documents are available on «www.horiba-abx.com/documentation».

3. Compatible tube list

3.1. Compatible tube list for Tube holder



Tube lists given in the tables below are not exhaustive. If the tubes in use in your laboratory does not match with these lists, please contact your Horiba ABX service representative.

Warning on microsampling tubes:

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

- The tube must be held always in vertical position
- Blood mixing must be obtained by slight tapping on the tube

Do not rotate the tube for mixing, otherwise the blood will be spread on the tube side, and the minimum required level will be lost.

▼ Legend:

- **MAN:** Manufacturer
- **BC:** Barcode

▼ Tube holder position:

- **GBL0183S** Standard tube holder: Position 1, position 2, position 3, position 4
- **GBL0372S** Optional tube holder: Position 1, position 5, position 6, position 7

3.1.1. Tube holder position 1

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Becton D	Vacutainer	368452	K3-EDTA	5ml		MAN+BC	With cap	Rubber with groove
Becton D	Vacutainer	367651	K3-EDTA	5ml	2ml	MAN+BC	With cap	Hemogard
Becton D	Vacutainer	367856	K3-EDTA	5ml	3ml	MAN+BC	With cap	Hemogard
Becton D	Vacutainer	367652	K3-EDTA	5ml	3ml	MAN+BC	With cap	Hemogard
Becton D	Vacutainer	367654	K3-EDTA	5ml	4.5ml	MAN+BC	With cap	Hemogard
Terumo	Venoject II	VP-053SDK	K3-EDTA	5ml	3ml	MAN	With cap	Ultraseal
Terumo	Venoject	VT-050STK	K3-EDTA	5ml	5ml	MAN	With cap	Rubber with groove
Terumo	Venoject	VT-053STK	K3-EDTA	5ml	3ml	MAN	With cap	Rubber with groove
CML	ABX 3004002	TH5C0C	K3-EDTA	5ml	4ml	MAN+BC	With cap	Rubber strongly not advisable
Greiner	Vacurette	454087	K3-EDTA	5ml	2ml	MAN+BC	With cap	Hemogard
Greiner	Vacurette	454086	K3-EDTA	5ml	3ml	MAN+BC	With cap	Hemogard
Greiner	Vacurette	454036	K3-EDTA	5ml	4ml	MAN+BC	With cap	Hemogard
Greiner	Vacurette	454223	K3-EDTA	5ml	4,5ml	MAN+BC	With cap	Hemogard
Sarstedt		04-1901		2.6ml				Locking mechanism

Tab. 8-1: compatible tube position 1

3.1.2. Tube holder position 2

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Becton D	Vacutainer	6385	K3-EDTA	5ml		MAN	*Without cap	Rubber strongly not advisable
Terumo	Venoject	VT-030STK	K3-EDTA	3ml	3ml	MAN	With cap	Rubber strongly not advisable
Greiner	Minicollect**	450403	K3-EDTA	1ml			With cap	with valve

Tab. 8-2: Compatible tube position 2

*Because of the cap thickness and the lack of space between the holder and the top of the tube, the holder may not open correctly

** **Requires an additional adjustment procedure:** in the Menu «Service\Super User Menu\Mechanical System\Holder Adjustment», adjust The «Level» on «Position 2» to «8.0» instead of «3.0» (See Section 7: Maintenance & Troubleshooting, [4.2.6. Sample tube Holder adjustment](#), page 7-28).

3.1.3. Tube holder position 3

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Comar	R&D system	TX2B 18533IF		5ml	2,2ml		Without cap	with thread

Tab. 8-3: Compatible tube position 3

3.1.4. Tube holder position 4

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Sarstedt		901091		0,5ml		*Out of format	Without cap	Unlostable
Kabe	ABX3001001	0777008RED		0,5ml		*Out of format	Without cap	Unlostable

Tab. 8-4: Compatible tube position 4

*The tube accepts a small sticker (not supplied by the manufacturer)

3.1.5. Tube holder position 5

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Becton D	Microtainer	365975		0,5ml		*Out of format	Without cap	**Microgard

Tab. 8-5: Compatible tube position 5

*The tube accepts a small sticker (not supplied by the manufacturer)

Cap fitted with an adaptator: **Requires an additional adjustment procedure: in the Menu «Service\Super User Menu\Mechanical System\Holder Adjustment», adjust the «Level» on «Position 5» to «10.0» instead of «3.0» (See Section 7: Maintenance & Troubleshooting, [4.2.6. Sample tube Holder adjustment](#), page 7-28)

3.1.6. Tube holder position 6

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Becton D	Microtainer	365973		0,5ml		*Out of format	Without cap	

Tab. 8-6: Compatible tube position 6

*The tube accepts a small sticker (not supplied by the manufacturer)

3.1.7. Tube holder position 7

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Sarstedt	Monovette	05.1167.100		2.7ml				Locking mechanism

Tab. 8-7: Compatible tube position 7

3.2. Compatible tube list for rack

3.2.1. Rack GBL0280 (type A or B)

Manufact	Model	Part number	Additive	Vol.	Vacuum	Stickers	Piercing condition
Becton D	Vacutainer	367651	K3-EDTA	5ml	2ml	With cap	Hemogard
Becton D	Vacutainer	367652	K3-EDTA	5ml	3ml	With cap	Hemogard
Becton D	Vacutainer	367654	K3-EDTA	5ml	4.5ml	With cap	Hemogard
Becton D	Vacutainer	368452	K3-EDTA	5ml		With cap	Hemogard
Sarstedt		04-1901		2.6ml			Locking mechanism
Terumo	Venohject	VT-050STK	K3-EDTA	5ml	5ml	With cap	Rubber with groove
Terumo	Venohject	VT-053STK	K3-EDTA	5ml	3ml	With cap	Rubber with groove
Greiner	Vacurette	454036	K3-EDTA	5ml	4ml	With cap	Hemogard
Greiner	Vacurette	454223	K3-EDTA	5ml	4.5ml	With cap	Hemogard

Tab. 8-8: compatible tube list Rack A or B

3.2.2. Rack GBL0327 (Type C)

Manufact	Model	Part number	Additive	Vol.	Vacuum	Stickers	Piercing condition
Sarstedt	Monovette	05.1167.100		2.7ml			Locking mechanism

Tab. 8-9: compatible tube list Rack C

ABX Pentra **XL** 80

Contents

1. Glossary	9-2
2. Index	9-4

This section includes the following:

1. Glossary, page 9-2

2. Index, page 9-4

1. Glossary

Definition	
accuracy	Ability of the instrument to agree with a predetermined reference value at any «point within the operating range; closeness of a result to the true (accepted) value»
agglutination	Clump
background count	Measure of the amount of electrical or particle interference
blank cycle	Runs an analysis on diluent in order to verify the counting aperture cleanliness.
calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors
calibration factors	These are correction factors that the system uses to fine-tune instrument accuracy
calibrator	A substance traceable to a reference method for preparation or material, used to calibrate, graduate, or adjust measurement
carryover	The amount, in percent, of blood cells remaining in diluent following the cycling of a blood sample
cell control	A preparation made of human blood with stabilized cells and surrogate material used for daily instrument quality control
characteristics	See performance characteristics
coefficient of variation	An expression in percent of data (SD) spread related to the mean $CV\% = (SD / \text{mean}) \times 100$
control	A substance used for monitoring the performance of an analytical process or instrument
CV	See Coefficient of variation
default	An original factory setting
expiration date	The last day that you can use that specific lot number of reagent, control, or calibrator
fL	Abbreviation for femtoliter
femtoliter	One quadrillionth (10 ¹⁵) of a liter
field	An area on a screen for entering data
flags	on printouts or screens, letters or symbols that appear next to parameter results to indicate specific conditions
linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb and Plt, at varying levels of concentration of these parameters within specified limits

Definition	
LIS	Abbreviation for Laboratory Information System
lot number	A manufacturer's code that identifies products such as reagents, controls or calibrators
mean	Arithmetic average of a group of data
order	Set of data used for the request of the analytical process
operating range	Range of results over which the instrument displays, prints and transmits data
parameter	A component of blood that the instrument measures and reports
performance	targeted performance of the instrument based on established ranges and parameters specifications
Platelet concentrate	Labile blood product, composed of platelets, produced by blood bank centers and intended for transfusion
PRP	Cellular suspension in the plasma, high platelet concentration obtained by sedimentation from a whole blood sample to determine on the hematology analyzer the platelet count in the presence of a contaminating microcytic RBC population.
Quality control (QC)	A comprehensive set of of procedures a laboratory establishes to ensure that the instrument is working accurately and precisely
reproducibility	This procedure checks that the system gives similar results (within established limits every time it measures the same sample
SD	A measure of variation within a group samples or within a population (standard deviation)
Shutdown cycle	Cleans the instrument's fluidic lines and apertures to help prevent residue buildup
Specifications	See performance specifications Section 2: Specifications, 3. Summary of performance data , page 2-7
Startup cycle	Ensures that the instrument is ready to run; includes performing a background test
Verification	Procedure to analyze cell controls or whole blood with known values to determine if your results are within the acceptable range
Whole blood	Non-diluted blood; blood and anticoagulant only

2. Index

A

Age range Chap 5-51
Alarm level Chap 5-47
Archives Chap 4-70
 Access Chap 4-70
 Daily Report Chap 4-71
 Patient Report Chap 4-73
 Search patient Chap 4-74
Association grid Chap 4-68
Automatic numbering Chap 4-23, Chap 5-6

B

BASO/WBC Count Chap 6-17
Batch Chap 3-18

C

Calibration
 General recommendations Chap 3-25
Carryover Chap 2-10
CDR mode Chap 8-2
 Specifications Chap 2-13
Clean Cycles Chap 7-34
Consumption
 power consumption Chap 2-5
 Reagent Chap 2-6
Contextual toolbar Chap 1-14
Cycle
 option Chap 5-35

D

Date and time Chap 5-23
Default settings of instrument types Chap 5-51
Delta check
 Setting Chap 5-22
Drain chambers Chap 7-31
Dump database Chap 5-38

E

Environmental protection Chap 1-10

Error messages Chap 7-44

F

Flags Chap 4-27
 Alarm levels Chap 5-47
 ALY flag Chap 4-37
 BASO+ Chap 4-41
 CO flag Chap 4-46
 L1 flag Chap 4-41
 LIC flag Chap 4-40
 LL flag Chap 4-36
 LL1 flag Chap 4-36
 LMNE- Chap 4-44
 LMNE+ Chap 4-44
 LN flag Chap 4-38
 MAC Chap 4-42
 MIC Chap 4-42
 MN flag Chap 4-37
 NE flag Chap 4-40
 NL flag Chap 4-37
 NO flag Chap 4-35
 Normal and panic ranges Chap 4-30
 Pathology messages Chap 4-47
 QC failed Chap 4-50
 reject Chap 4-33
 Results exceeding Linear ranges of the instrument
 Chap 4-31
 RM flag Chap 4-39
 RN flag Chap 4-39
 SCH Chap 4-43
 SCL Chap 4-43
 Suspicion Chap 4-34
 XB flag Chap 4-50
Front View Chap 6-2

H

History Chap 4-60

I

Identification option Chap 5-7

L

L.J. Graphs Chap 3-6

Languages Chap 5-24
Limitations Chap 2-16
Linearity Chap 2-9
Logs Chap 1-17, Chap 3-32, Chap 5-7

M

Main functions Chap 1-17
Maintenance Chap 7-3
 chart table Chap 7-3
Manual match on Exception Chap 5-8
Manual Rerun Chap 4-64
MCV, MCH, MCHC calculation Chap 6-16
MDSS Chap 6-11
Measuring principles Chap 6-11
 CBC detection principles Chap 6-13
 LMNE Matrix Chap 6-18
 WBC and differential Chap 6-17
Mixing Chap 4-25
MPV Measurement Chap 6-16

N

Normal and panic ranges Chap 4-30
Normal Ranges Chap 2-11

O

Optical bench lamp replacement Chap 7-15
Order
 overview Chap 1-22
Order & runs association Chap 4-51

P

Panels & cover dismantling Chap 7-19
Pathological limits Chap 5-46
Pathology messages Chap 4-47
Pct Calculation Chap 6-16
PDW calculation Chap 6-16
Performance data Chap 2-7
Precision Chap 2-7
Precision (Repeatability) Chap 2-8
Prime cycles Chap 7-32
Print conditions Chap 5-21
Printer Chap 1-26, Chap 5-31

Printout Chap 5-33
 properties Chap 5-31

Printout Chap 4-27

Q

Quality Assurance Chap 1-17
 access Chap 3-3
 Coefficients of variation ranges Chap 5-13
 Number of calibration runs Chap 5-13
 settings Chap 5-12
 XB options Chap 5-12
Quality control Chap 3-4
 access Chap 3-4
 Delete results Chap 3-9
 Graphics Chap 3-8
 keys Chap 3-5
 L.J. Graphs Chap 3-6
 Print results Chap 3-9
 Run Chap 3-13
 screen grid Chap 3-7
 Send results Chap 3-9
 Targets Chap 3-10

R

Rack Chap 1-13
 Identification Number Chap 1-13
RDW calculation Chap 6-15
Reagent Chap 2-4, Chap 6-2
 consumption Chap 2-6
 cover Chap 6-2
 Diluent and waste connections Chap 6-6
 replacement Chap 7-9
Repeatability Chap 2-7
Report Chap 4-51
 Access Chap 4-51
 Anteriority Chap 4-60
 Construction Chap 4-57
 Details Chap 4-57
 Display Chap 4-55
 Edit Chap 4-60
 List Chap 4-53
 Manual entry Chap 4-58, Chap 4-61

Rejected Chap 4-58, Chap 4-63

Validation Chap 4-63

Rerun

Conditions Chap 5-17

Delta Check Chap 5-19

On «Dilution» Chap 5-18

On alarms Chap 5-17

Run in Progress Chap 1-17

Run Result screen Chap 4-28

Runs & Report overview Chap 1-23

Runs/orders matching Chap 4-69

RUO parameters Chap 5-6

S

Sample

Compatible tube list Chap 2-6, Chap 8-6

Sampling probe replacement Chap 7-17

Save/Restore Chap 5-36

Search patient Chap 4-20

Services Chap 1-17

Settings Chap 1-17, Chap 5-3

Access Chap 5-3

General tab Chap 5-6

Identification option Chap 5-7

Save/Restore Chap 5-36

Soft parameters Chap 5-5

system Chap 5-23

thresholds Chap 5-48

User profiles Chap 5-40

Shutdown Chap 1-17

Soft parameters Chap 5-5

Software Chap 1-14

arborescence and Hints Chap 1-18

overview Chap 1-14

Specifications Chap 2-2

Parameters Chap 2-2

Physical Chap 2-5

Reagent Chap 2-15

Stability study Chap 2-12

Startup Chap 1-17

Status Chap 1-17

Super User menu Chap 7-22

Check motors Chap 7-24

Check Sensors Chap 7-26

Check valves Chap 7-26

Holder adjustment Chap 7-28

Hydraulical Chap 7-31

Mechanical Chap 7-24

Rack adjustment Chap 7-30

Sampler test Chap 7-27

System

Local settings Chap 5-23

Printer Chap 5-28, Chap 5-31

RS232 settings Chap 5-28

T

Temperature conditions Chap 1-10

Thresholds Chap 5-48

Troubleshooting Chap 7-37

Tube

List for rack Chap 8-9

List for tube holder Chap 8-6

Tube holder door Chap 6-2

Types Chap 5-43

Defaults settings Chap 5-51

U

Units Chap 5-10

User profiles Chap 5-40

W

Warning and precautions Chap 1-2

Waste container Chap 7-15

Waste handling Chap 2-15

Within Run Chap 3-21

access Chap 3-21

Key Chap 3-21

Run Chap 3-22

Workflow Chap 4-3

association Chap 4-13

Barcode Identification Chap 4-5

Exception management Chap 4-11

Rack/position Chap 4-8

Sample ID Chap 4-3, Chap 4-5

Worklist Chap 4-4

Worklist Chap 4-15

access key Chap 4-15

Auto-Numbering Chap 4-23

grid Chap 4-16

order Chap 4-17

Rack view Chap 4-22

search patient Chap 4-20

search sample Chap 4-20

X

XB Chap 3-14

access Chap 3-15

Batch Chap 3-18

Graphs Chap 3-16

Grid screen Chap 3-17

Key Chap 3-15

limits Chap 3-19

Z

Zoom Chap 4-28

ABX Pentra **XL** 80
