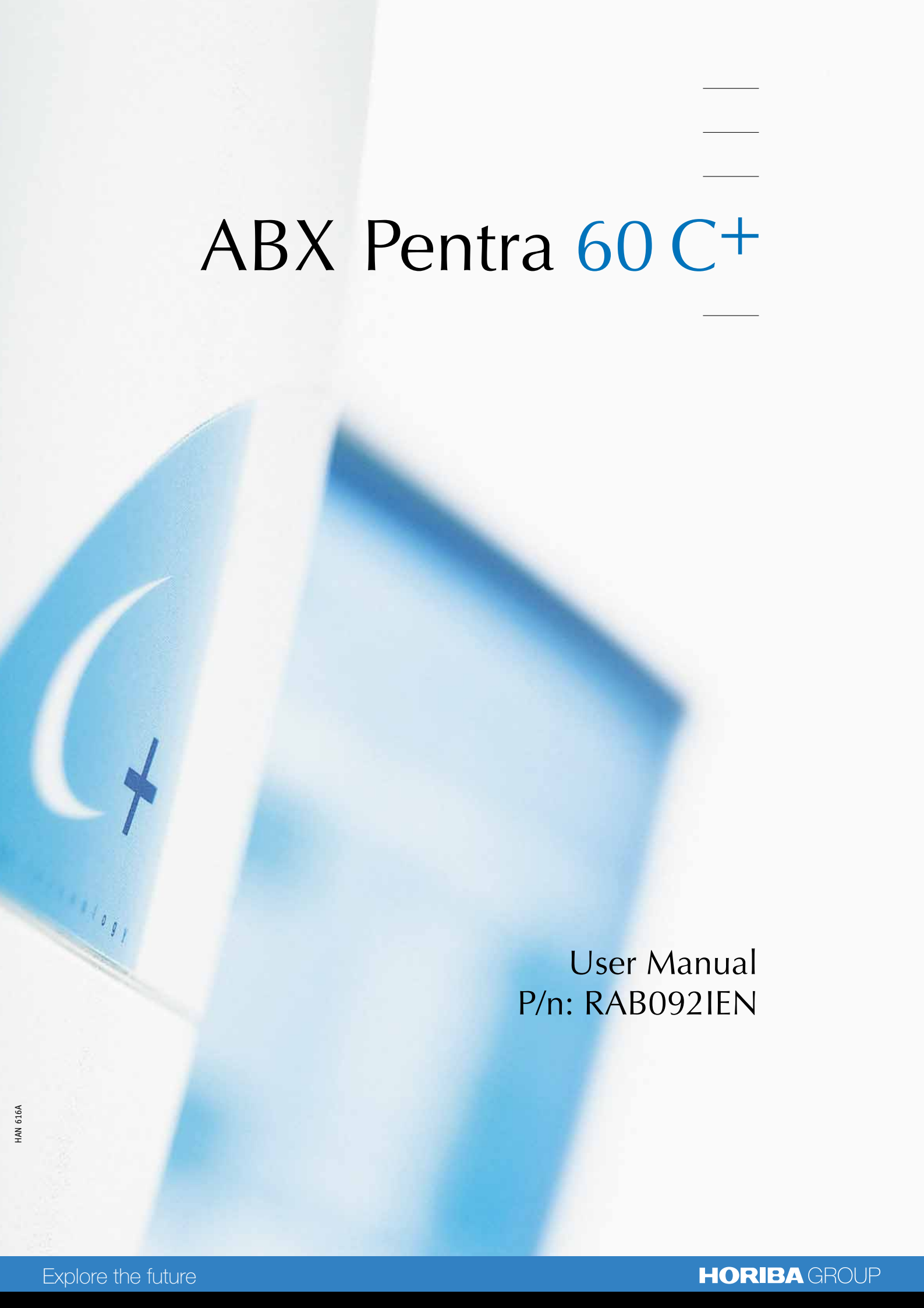




ABX Pentra 60 C+

User Manual
P/n: RAB092IEN

Instrument User Manual Update

RAM227AEN

ABX Pentra 60 C+

User Manual Update for Electrical Standard Certification



Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

Date: 28/7/08

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Update chart

Tab.1-1: Concerned sections of the Pentra 60 C+ user manual:

Section	Page	Paragraph	Item change
Front page	I	Manufacturer	Telephone and fax number addition. See "1. Manufacturer, page 4"
Front page	I	Manufacturer	Modification of Manufacturer logo. See "2. Logo modification, page 4"
Introduction	II	Copyright	Modification of Copyright. See "3. Copyright, page 4"
Introduction	III	Revisions	Modification of paper documents updates. See "4. Revisions, page 4"
Introduction	IV	1.1. Warnings	Peripheral devices compliance sentence modification. See "5. Warnings, page 4"
Introduction	VIII	1.6. Graphics and Symbols	Modification of Manufacturer logo and addition of new RoHS logos. See "6. Graphic and symbols, page 5"
Description & Technology	2.3	1.2. Pentra 60 C+ back side	New Serial Number Label. See "7. Pentra 60 C+ back side, page 5"
Specimen Run & Results	3-2	1.1. Waste levels	Addition of precautions about waste. See "8. Waste levels, page 6"
Specimen Run & Results	3-34	NE flag	Ne flag information. See "9. NE flag, page 6"
Maintenance & Troubleshooting	5.2	1.1. Reagent replacement	Addition of verification after reagent replacement. See "10. Verification after a reagent replacement, page 6"

Updates

1. Manufacturer

Telephone and fax numbers:

◆ Phone: + 33 (0)4.67.14.15.16

◆ Fax: + 33 (0)4.67.14.15.17

2. Logo modification



New Manufacturer logo.

3. Copyright

Copyright 2008 HORIBA ABX SAS

4. Revisions

Index	Technical note	Revision	Section	Date
A	RAH774AA	V1.50	All	26/06/2000
B	RAH792AA	V1.61	All	20/02/2001
C	RAH873AA	V2.2	ALL	14/01/2002
D	RAH986AA	V2.2.9	All	24/09/2003
E	RAN179A	V2.3.0 (RAM146AEN)	1, 3	16/11/2005
RAB092FEN	/	Instrument default settings (RAM200AEN) User manual update (RAM205AEN)	4 Intro, 1, 2, 3	10/10/2006
RAB092GEN	RAN321A	Platelet interferences (RAM210BEN) V2.4.0 (RAM215AEN)	2 3, 4, 5	08/06/2007
RAB092HEN	RAN321B	V2.4.X (RAM215BEN)	3, 4, 5	30/11/2007
RAB092IEN	/	Electrical standard certification (RAM227AEN)	Intro, 2, 3, 5	21/05/2008

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

When a subsequent software version changes the information in this document, a new electronic issue (CD-ROM and/or online help) will be released and supplied by HORIBA ABX.

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

5. Warnings

◆ All peripheral devices should comply with relevant standards.

6. Graphic and symbols



Manufacturer

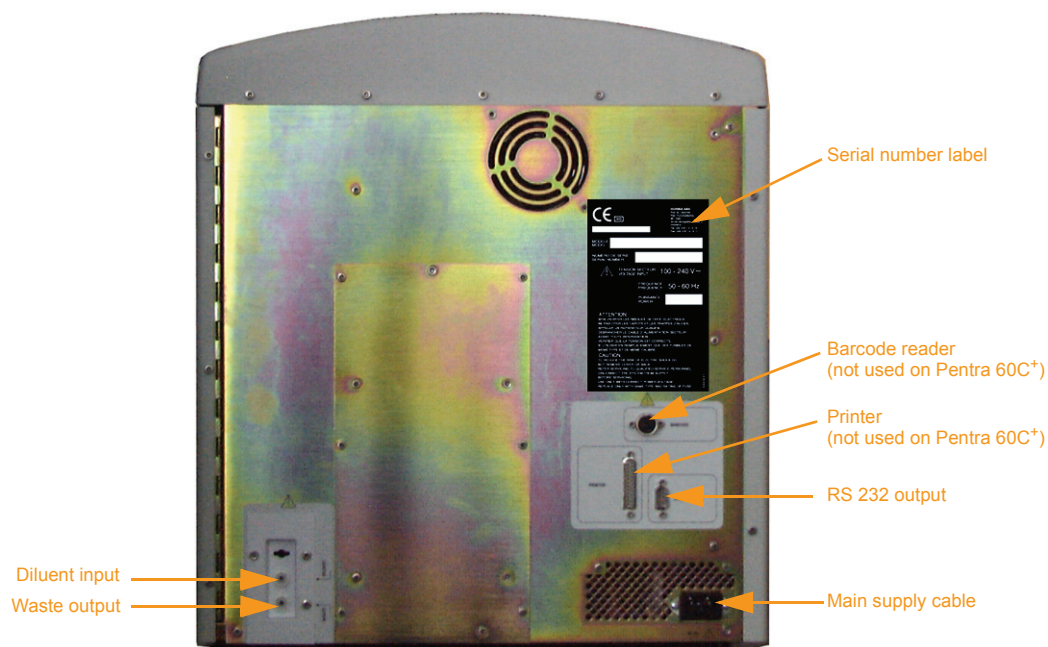


Packaging recycling mark



Notice of environment-friendly use period

7. Pentra 60 C+ back side



Serial number label



8. Waste levels



At the beginning of each day, before startup, check if the waste container needs to be emptied.

During the operation, do not remove the reagent tubes and the waste liquid tube under any condition.

9. NE flag

Meaning: **Neutro/Eosino**.

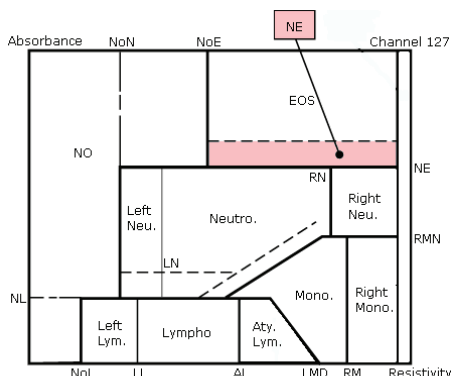
Presence of a significantly large population of cells located in the separation area between neutrophils and eosinophils because of a superimposition of the 2 populations. This flag occurs when the number of particles counted in this area is higher than the limit setup in **NE#** or when the number of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

Standard values for **NE**: % 1.1 / # 60

Suspected abnormalities:

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

This flag is associated with an (!) on LIC % and LIC # and replaces NEU %, NEU #, EOS %, EOS # by ----.



10. Verification after a reagent replacement



Make sure that a blank cycle and Control run will be carried out after the change of a reagent in the course of day.

Instrument User Manual Update

RAM215BEN

ABX Pentra 60 C+
Update for instrument version V2.4.X



Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

Date: 30/11/07

Update for instrument version V2.4.X

Tab.1-1: Concerned sections of the manual

Section	Page	Paragraph	Item change
Specimen run & Results	3-24	7.4. Flags	Addition of paragraph "Suspicion flags" See "1. Suspicion flag, page 2"
Specimen run & Results	3-45	7.5.3. Plt messages	Addition of message condition in "PLT Aggregate (1)" See "2. Plt messages, page 3"
Maintenance & Troubleshooting	5-2	1.1. Reagent replacement	Addition of ABX Diluent 10L See "3. ABX Diluent 10L, page 3"
Instrument configuration	4-2	1. Control	Addition of Export QC See "4. Export QC, page 3"

Index History:

From RAM215AEN to RAM215BEN: V2.4.0 replaced by V2.4.X and modification of conditions on platelets.

1. Suspicion flag

1.1. PLT

Conditions	Triggered flag	Consequences
If $PLT < 120 \times 10^3 / \text{mm}^3$ (in CBC mode only)	(!) on PLT and on PDW, MPV, PCT	PLT result needs to be confirmed according to Good Laboratory Working Practices
If $PLT < 120 \times 10^3 / \text{mm}^3 + PDW > 20$ (in CBC and DIFF mode)		

1.2. WBC

- ◆ If a flag LMNE+ or LMNE- or BASO+ is triggered, then a suspicion flag «!» on WBC parameter is generated too.
See "7.4.7. WBC balance".
- ◆ If a suspicion flag «!» on WBC occurs, then «!» is also generated on BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU%, ALY#, ALY%, LIC#, LIC% parameter results.
- ◆ A suspicion flag «!» is generated on the BAS#, BAS%, LYM#, LYM%, MON#, MON%, NEU#, NEU% and EOS#, EOS% parameter results if Hgb > 17,5 g/dl or invalid «---».

2. Plt messages

"H": high extreme limit

"L": low extreme limit

Message	Triggering conditions
Thrombocytosis	PLT > PLT H
Thrombocytopenia	PLT < PLT L
Microcytosis Schizocyte Small Cell	See triggering conditions for these flags in paragraph "7.4.5.Flags on RBC histogram".
PLT Aggregate (1)	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 < $150 \times 10^3 / \text{mm}^3$ PDW > 20 + PLT < $120 \times 10^3 / \text{mm}^3$ (in CBC mode only)*
Erythroblasts(2)	LL or WBC reject + L1 or WBC reject + LL1
Erythroblasts PLT Aggregate	If conditions 1 and 2 are not satisfied and if L1 or LL1 or WBC reject
Macroplatelets	MPV > 11

* New condition

3. ABX Diluent 10L

A 10 liters container of ABX Diluent is available under the part number: 0901010.

Software version v2.4.X introduces 10L or 20L volumes management (barcode identification, capacity, level, expiration date, etc.).

4. Export QC

Software version v2.4.X allows backup of QC results and statistics on floppy disk.

This backup file is registered on a «.csv» format in order to be reused on a spreadsheet type software.

4.1. Saved QC data

- ◆ Only one «.csv» file is generated for each control lot number.
- ◆ Each «.csv» file has a unique name and is generated in the current language and units. File name is saved on the following model : «xxx_AAAAMMJJ.csv» where xxx is the lot# and AAAAMMJJ the file creation date.

4.2. Limitations

RUO (for Research Use Only) parameters (PCT, PDW, ALY, LIC) are not saved on the Export QC file.

4.3. Export QC file content

Each file includes the following fields:

Header

Instrument name / Lab ID
Instrument serial number
Lot number
File creation date time
Start period for lot use
End period for lot use
Expiration date
Comment
User lot comment
Unit used

CBC data (Minotrol)

3 parts for Low, Normal and High levels
Results detailed by parameters
Statistics results
lot target values

DIFF data (Difftrol)

3 parts for Low, Normal and High levels
Results detailed by parameters
Statistics results
lot target values

See "Tab.1-1: DIF example" in the following page.

4.4. Procedure to export QC data

- ◆ Insert a Windows formatted Floppy disk into the drive.
- ◆ Open the «QC & Calibration» Tab (See "Fig.1-1: «QC & Calibration» tab, page 4").
- ◆ Select the lot to export (Fig.1-1-A).
- ◆ Click the «Export QC» button (Fig.1-1-B).

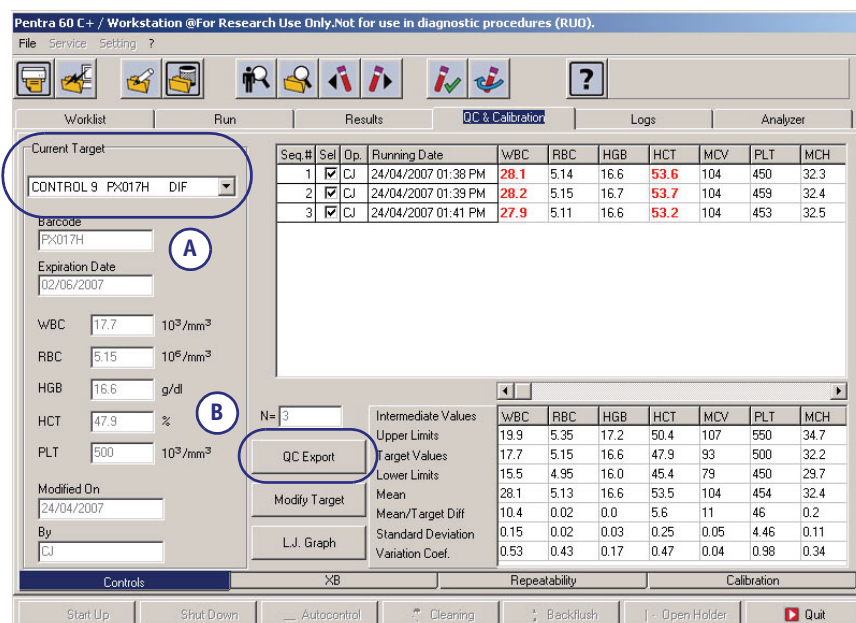


Fig.1-1: «QC & Calibration» tab

- ◆ Accept when the following message is displayed «Do you confirm QC export?»



- ◆ The use of Export QC function will copy all levels results of the **selected** lot on the floppy disk at the same time.
- ◆ Lot barcode identification must **not** be modified to allow QC exportation on floppy disk.
- ◆ **Statistical calculation** results displayed in .csv file on the floppy disc are based on the **raw values** determined by the instrument, and not by the rounded values of control runs displayed in this .csv file.

Instrument User Manual Update

RAM210BEN

ABX Pentra 60/60 C+ Platelet interferences



Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

Date: 6/4/07

Platelet interferences

1. ABX Pentra 60

Tab.1-1: Concerned sections of the manual

Section	Paragraph	Item change
Specifications	5.3. Known interfering substances	Modification of information about interference in the platelet results See "1.1. Plt (Platelets), page 2"

1.1. 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.

2. ABX Pentra 60 C+

Tab.1-2: Concerned sections of the manual

Section	Paragraph	Item change
Specifications	5.3. Known interfering substances	Modification of information about interference in the platelet results See "2.1. Plt (Platelets), page 2"

2.1. 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.

Instrument User Manual Update

RAM205AEN

ABX Pentra 60 C+ User manual update



Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

Date: 10/10/06

User manual update

Tab.1-1: Concerned sections of the manual

Section	Page	Paragraph	Item change
Introduction	II	Notice of liability	Paragraph correction See "1. Notice of liability, page 3"
Introduction	III	Revisions	Addition of internet link to Declaration of conformity See "2. Declaration of conformity, page 3"
Introduction	VI	1.4. Biological risks	Recommendations addition See "3. Biological risks, page 3"
Introduction	VIII	1.6. Graphics and symbols	WEEE Directive symbol addition See "4. Graphics and symbols, page 3"
Introduction	IX	2.1. Environment	"Safety requirements" Standard evolution See "5. Environment, page 3"
Introduction	X	2.6. Environment protection	WEEE Directive addition See "6. Environment protection, page 3"
Specifications	1-6	2.1. Power requirements	Heat output addition See "7. Power requirements, page 3"
Specifications	1-8	2. Physical specifications	Addition of "2.9. Compatible tube list" paragraph See "8. Compatible tube list, page 4"
Specifications	1-15	4.1. Reagent specifications	A.F.S.S.A.P.S reference deletion and Reagent leaflets update See "9. Reagent specifications, page 6"
Specifications	1-17	5.3. Known interfering substances	Modification of known interferences due to Chemotherapy See "10.1. White Blood Cells (Leukocytes), page 6"
Specifications	1-19	5.3. Known interfering substances	Modification of interference in the platelet result information See "10.2. Plt (Platelets), page 6"
Specifications	1-20	5.3. Known interfering substances	Addition of interferences in the basophil count information See "10.3. BAS# (Basophil cell count absolute), BAS% (Basophil percentage), page 6"
Description & Technology	2-11	2.3. Hgb measurement	Addition of measuring principle with Lysebio See "11. Hgb measurement, page 7"
Specimen run & Results	3-5	3. Calibration verification (control blood sampling)	Addition of calibration general information See "12. Calibration verification (control blood sampling), page 7"
Specimen run & Results	3-14	6. Running specimen	Addition of recommendations on the analysis mode selection See "13. Running specimen, page 8"
Specimen run & Results	3-39	7.4.4. Flags on WBC/BASO histogram	Addition of recommendations on CBC mode: L1 flag See "14. Flags on WBC/BASO histogram, page 8"
Specimen run & Results	3-43	7.4.7. WBC balance	Addition of CBC mode limitations See "15. WBC balance, page 8"

1. 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.

2. Declaration of conformity

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

3. Biological risks



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

4. Graphics and symbols



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

5. Environment

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

6. Environment protection

◆ European Legislation:



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

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

7. Power requirements

◆ Heat output..... Max 1440 Kjoules/h (1365 BTU/h)

8. Compatible tube list

8.1. 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 this lists, please contact your HORIBA ABX service representative.



On microsampling tubes, the 100µl volume can only be use 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:**

- **GBG214AS** Standard tube holder positions: Position 1, position 2, position 3, position 4
- **GBG215AS** Optional tube holder positions: Position 1, position 3, position 5, position 6

8.2. Tube holder position 1

Tab.1-2: Compatible tube position 1

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Pirecing 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
LDM Paris			EDTAKE	5ml	4,5ml	MAN+BC	With cap	Hemogard

8.3. Tube holder position 2

Tab.1-3: Compatible tube position 2

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Becton D	Vacutainer	6385	K3-EDTA	3ml		MAN	*Without cap	Rubber strongly not advisable
Terumo	Venohject	VT-03STK	K3-EDTA	3ml	3ml	MAN	With cap	Rubber strongly not advisable
Greiner	Minicollect**	450403	K3-EDTA	1ml			With cap	With valve

*Because of the cap thickness and the lack of space between the holder and the top of the tube, the tube holder may not open correctly.

****Requires an additional adjustment procedure:** in the Menu «Service\Mechanical Systems\Sampling needle Adjustment», adjust the «Level» on «Position 2» to «8.0» instead of «3.0» (See Section 5: Maintenance & Troubleshooting, 2.3.4. Sampling needle adjustment)

8.4. Tube holder position 3

Tab.1-4: Compatible tube position 3

Manufact	Model	Part number	Additive	Vol	Vacuum	Stickers	Piercing condition	Type of cap
Comar	R&D Systems	TX2B 18533IF		5ml	2,2ml		Without cap	With thread

8.5. Tube holder position 4

Tab.1-5: Compatible tube 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	ABX 3001001	0777008RED		0,5ml		*Out of format	With cap	Unlostable

*The tube accepts a small sticker (not supplied by the manufacturer).

8.6. Tube holder position 5

Tab.1-6: Compatible tube 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

*The tube accepts a small sticker (not supplied by the manufacturer).

**Cap fitted with an adaptor (require another probe adjustment).

8.7. Tube holder position 6

Tab.1-7: Compatible tube 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	

*The tube accepts a small sticker (not supplied by the manufacturer).

9. 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 provided Reagents, Controls and Calibrators leaflets/msds. Latest versions of these documents are available on www.horiba-abx.com/documentation.

10. Known interfering substances

10.1. White Blood Cells (Leukocytes)

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 3: Specimen run & Results, 7.4.7. WBC balance) is disabled. It is recommended to run these samples in DIFF mode.

10.2. Plt (Platelets)

Interference in the Platelet result may occur for samples from Patients undergoing parenteral treatment with injection of lipid emulsion.

10.3. BAS# (Basophil cell count absolute), BAS% (Basophil percentage)

◆ **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 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 leukomia, 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 cannot be distinguished.

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

11. Hgb measurement

◆ 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.

12. Calibration verification (control blood sampling)



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 results due for example to a clogging of the instrument.

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

- 1- Carry out a Concentrated cleaning procedure (refer to Section 5: Maintenance & Troubleshooting).
- 2- Perform two blank cycles to check the cleanliness of the instrument (if the blank measurement is not correct, please contact your HORIBA ABX representative).
- 3- Check the repeatability of the instrument by running 6 times a normal human blood without taking account of the first result (if the repeatability is not correct, please contact your HORIBA ABX representative).
- 4- Calculate the CV obtained out on the other 5 results. The values of CV must be 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 instrument is clean (blank cycles in conformity with the values given in the manual), the repeatability is correct (acceptable CV values) and the values of control are not within the acceptable limits, then it is possible to carry out the calibration:

- 6- Run at least 4 times Calibrator without taking the values of the first result into account.
- 7- Calibrate the instrument on the average of the last 3 results according to indications of the manual. Take care to respect the minimum and maximum calibration coefficient values given in the manual. Run 3 times again Calibrator to check the values.
- 8- Confirm the calibration while passing a control blood, the values have to be returned within acceptable limits.
- 9- After about thirty analyses of the day, check that values of MCV, MCH and MCHC are in conformity with the usual values of the laboratory.

13. Running specimen

◆ 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 1: Specifications, 5.3. Known interfering substances) and WBC balance (See Section 3: Specimen run & Results, 7.4.7. WBC balance).

14. Flags on WBC/BASO histogram

CBC and DIFF mode



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 and LL1 are available in DIFF mode and provide more reliability in anomaly detection. This mode should be recommended.

15. WBC balance



CBC mode Limitations

The WBC balance flag will indicate an instrument defect or it can also highlight a known interference (See Section 1: Specifications, 5.3. Known interfering substances).

In the case of pathology whose treatments weaken the leukocytic membranes, the agent of lysis of WBC channel can damage 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.

Instrument User Manual Update

RAM200AEN

ABX Pentra 60 C+ Instrument default settings



Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

Date: 10/10/06

Instrument default settings

Tab.1-1: Concerned sections of the manual

Section	Page	Paragraph	Item change
Instrument Configuration		Type parametering	Addition of Instrument Default parametering charts

1. General information

Type parametering:

- The following values are the software default values for pathological limits & thresholds (See "2.Pathological limits and thresholds, page 2"), Alarm levels ("3.Alarms levels, page 5"), Matrix thresholds (See "4.Matrix thresholds, page 8"), classified by types (standard, man, woman, Child 1,2,3).

Other modifications:

- Default values for XB limits (See "6.XB limits, page 11").
- Default values for Quality Control coefficients ("5.QC Variation Coefficients, page 11").

2. Pathological limits and thresholds

From the menu: Settings \ Type Parametering

Tab.1-2: STANDARD

	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
LYA%	0	0	2.5	2.5
CGI%	0	0	3.0	3.0
LYA#	0	0	0.25	0.25
GCI#	0	0	0.30	0.30

Tab.1-3: 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
LYA%	0	0	2.5	2.5
CGI%	0	0	3.0	3.0
LYA#	0	0	0.25	0.25
GCI#	0	0	0.30	0.30

Tab.1-4: 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
LYA%	0	0	2.5	2.5
CGI%	0	0	3.0	3.0
LYA#	0	0	0.25	0.25
GCI#	0	0	0.30	0.30

Tab.1-5: CHILD 1 (1 day old to 1 month old)

	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
LYA%	0	0	2.5	2.5
CGI%	0	0	3.0	3.0
LYA#	0	0	0.35	0.35
GCI#	0	0	0.35	0.35

Tab.1-6: CHILD 2 (1 month old to 2 year old)

	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
LYA%	0	0	2.5	2.5
CGI%	0	0	3.0	3.0
LYA#	0	0	0.35	0.35
GCI#	0	0	0.35	0.35

Tab.1-7: CHILD 3 (2 years old to 14 years old)

	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
LYA%	0	0	2.5	2.5
CGI%	0	0	3.0	3.0
LYA#	0	0	0.25	0.25
GCI#	0	0	0.30	0.30

3. Alarms levels

From the menu: Settings \ Type parametering

Tab.1-8: STANDARD

	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.1-9: MAN

	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.1-10: WOMAN

	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.1-11: CHILD 1 (1 day old to 1 month old)

	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.1-12: CHILD 2 (1 month old to 2 year old)

	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.1-13: CHILD 3 (2 years old to 14 years old)

	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

4. Matrix thresholds

From the menu: Setting\ Type Parametering

Tab.1-14: STANDARD

Matrix threshold	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Tab.1-15: MAN

Matrix threshold	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Tab.1-16: WOMAN

Matrix threshold	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Tab.1-17: CHILD 1

Matrix threshold	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Tab.1-18: CHILD 2

Matrix threshold	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Tab.1-19: CHILD 3

Matrix threshold	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

5. QC Variation Coefficients

From the menu: Settings \ QC & Calibration

Tab.1-20: Variation coefficients

	MAX CV
WBC	5
RBC	5
HGB	3
HCT	5
MCV	3
MCH	3
MCHC	3
RDW	10
PLT	10
MPV	10
NEU %	10
LYM %	10
MON %	35
EOS %	15
BAS %	10
NEU	10
LYM	10
MON	35
EOS	15
BAS	10

6. XB limits

From the menu: QC & Calibration\XB

Tab.1-21: XB Target value

	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

Customer Addendum

RAM146AEN

Pentra 60C+

User manual Pentra 60C+
Update for Instrument version V2.3.0

Date: 16/11/05

User manual Pentra 60C+



Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

Update for Instrument version V2.3.0

Section	Page	Paragraph	Item change
1. Specifications	11-14	3.3 New linearity limits	Modification of the linearity limits
3. Specimen run and results	2	1.3 Pentra 60C+ startup	Warning on instrument left on standby more than 36 hours added at the end of the paragraph.
	25	7.4.2. Flags giving an analysis default	Hgb < 0.7g/dL forced to 0 becomes: Hgb ≤ 0.1g/dL forced to 0
	47	8.2 End of the day rinsing	Warning on instrument left on standby more than 36 hours added at the end of the paragraph.

Table 1: Concerned sections Pentra 60C+

1. New linearity limits*

- 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:

Table 2: Linearities

Parameter	Linearity range	Linearity limits	Visible range	Error limit
WBC (10 ³ /μl)	0.40 to 130.80	0 to 120	120 to 150	±0.3 ±7.5%
RBC (10 ⁶ /μl)	0.23 to 9.76	0 to 8	8 to 18	±0.07 ±3%
HGB (g/dL)	0 to 31.06	0 to 24	24 to 30	±0.3 ±3%
HCT (%)	1.80 to 88.90	0 to 67	67 to 80	±2 ±3%
PLT (10 ³ /μl) (for Hgb ≥ 2g/dL)	3.30 to 2007	0 to 1900	1900 to 2800	±10 ±12.5%
PLT (10 ³ /μl) (for Hgb < 2g/dL & Plt > 15x10 ³ /mm ³)	7 to 2895	0 to 2800	2800 to 3200	±10 ±12.5%

* Source: 510K submission K030144

2. Flags giving an analysis default

Table 3: Results displayed

Parameter	Linearity limits	Visible range	> Visible range
WBC	«result»	«result» + «D»	DIL
RBC	«result»	«result» + «D»	DIL
HGB	«result»	«result» + «D»	DIL
HCT	«result»	«result» + «D»	DIL
PLT (for Hgb $\geq$ 2g/dL)	«result»	«result» + «D»	DIL
PLT (for Hgb<2g/dL & Plt>15x10 ³ /mm ³)	«result»	«result» + «D»	DIL

Table 4: Results transmitted or printout

Parameter	Linearity limits	Visible range	> Visible range
WBC	«result»	«result» + «D»	--.-- + D
RBC	«result»	«result» + «D»	--.-- + D
HGB	«result»	«result» + «D»	--.-- + D
HCT	«result»	«result» + «D»	--.-- + D
PLT (for Hgb $\geq$ 2g/dL)	«result»	«result» + «D»	--.-- + D
PLT (for Hgb<2g/dL & Plt>15x10 ³ /mm ³)	«result»	«result» + «D»	--.-- + D

Results displayed and printed out:

«PLT Concentrate» message indicates the triggering of the PLT extended linearity mode for an Hgb<2g/dL & Plt>15x10³/mm³ between 1900x10³/μL and 2800x10³/μL.

Results transmitted:

«C» message indicates the triggering of the PLT extended linearity mode for an Hgb<2g/dL & Plt>15x10³/mm³ between 1900x10³/μL and 2800x10³/μL.

3. Possible start up problems for Pentra 60C+ systems

The following warning is added section 3 “Specimen run & results” at the end of the paragraph 1.3 “Pentra 60C+ startup” and at the end of the paragraph 8.2 “End of the day rinsing”:



It is mandatory to power down the system if not used for more than a 36 hour period. This eliminates the possibility of the Dilution Chambers evaporating and causing startup problems.



Pentra 60 C+

User Manual



P/n: RAB092D

ABX DIAGNOSTICS

B.P. 7290

Rue du caducée

Parc Euromédecine

34184 MONTPELLIER Cedex 04 - FRANCE



Pentra 60 C+

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REVISIONS

INDEX	TECHNICAL NOTE	SOFTWARE REVISION	SECTION	DATE
A	RAH774AA	V1.50	ALL	23/06/2000
B	RAH792AA	V1.61	ALL	20/02/2001
C	RAH873AA	V2.2	ALL	14/01/2002
D	RAH986AA	V2.2.9	ALL	24/09/2003

- This document applies to the latest higher software version.
- When a subsequent software version changes the information in this document, a new issue will be released.

1. WARNINGS AND PRECAUTIONS

NOTE

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

IMPORTANT

IMPORTANT: Emphasizes an operating procedure that must be followed to avoid erroneous results.

CAUTION

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

WARNING

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

1.1. Warnings

- User manual must be entirely read and personnel trained by **ABX DIAGNOSTICS** 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 **ABX DIAGNOSTICS** instructions in order to avoid to compromise system integrity.
- The **ABX PENTRA 60 C+** responds to the Standards and directives named in the Declaration of Conformity added at the beginning of this manual.
- The reagents and accessoires stipulated by **ABX DIAGNOSTICS** have been validated in accordance with the European Directive for in-vitro medical devices (98/79/CE).
- The use of any other reagents and accessoires may place at risk the performance of the instrument, engaging the Users responsibility. In this case, **ABX DIAGNOSTICS** 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 should not be used in proximity.
- All peripheral devices should be IEC compatible.

1.2. Limited guarantee

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

- 1 - The system is operated under the instructions of this manual.
- 2 - Only software or hardware specified by **ABX DIAGNOSTICS** is installed on the instrument. This software must be the original copyrighted version.
- 3 - Services and repairs are provided by an **ABX DIAGNOSTICS** authorized technician, using only **ABX DIAGNOSTICS** 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.

CAUTION

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

1.3. Safety precautions, electronic and moving parts

- The following parts must not be handled or checked by the user:
 - Electrical power supply,
 - Electronic components.
- Operator injury may occur from an electric shock. Electronic components can shock and injure the user. Do not tamper with the instrument and do not remove any components (covers, doors, panels and so on) unless otherwise instructed within this document.
- Danger ! The battery may explode if it is not replaced correctly ! Replace only with the same or equivalent type recommended by the manufacturer. Dispose of used batteries according to the manufacturer's 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.

1.4. 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.
- **ABX DIAGNOSTICS** uses disinfectant product for instrument decontamination and highly recommends it to decontaminate your instrument.

1.5. Instrument cleaning

Instrument external cleaning

- The external surfaces of the instrument must be decontaminated considering the biological environment.

WARNING

***Never spill liquid on the instrument.
Never use Disinfectant product* that contains alcohol.***

- Computer 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 **ABX DIAGNOSTICS**:
ANIOS detergent disinfectant ; *WIP'ANIOS* ; ref: 1316.424

NOTE

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

Instrument internal cleaning

- Concentrated cleaning: Counting chambers and hydraulics parts are decontaminated by using the «Concentrated cleaning» function as described in **2.1.2. Concentrated cleaning**, page 5-11.

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.

NOTE

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

Pentra 60 C+

1.6. Graphics and symbols

	Switch off position		Switch on position
	Alternating current		Manufacturer
	In Vitro Diagnostics 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		

2. WORKING CONDITIONS

2.1. Environment

- The operation of the **ABX PENTRA 60 C+** 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 EN 61010-1). Please contact your local **ABX DIAGNOSTICS** representative for information regarding operation locations, when it does not comply with the recommended specifications.

2.2. Location

- The **ABX PENTRA 60 C+** should be placed on a clean and levelled table or workbench. Please note that the **ABX PENTRA 60 C+**, printer and reagents weigh approximately 40 kilograms (88 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.

2.3. Grounding

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

2.4. Humidity and temperature conditions

- **ABX PENTRA 60 C+** 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.

2.5. Electromagnetic environment check

- The **ABX PENTRA 60 C+** 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...).

2.6. Environment 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 **ABX PENTRA 60 C+** 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 **ABX DIAGNOSTICS** representative service department.

2.7. Transport 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.

2.8. Installation

- The **ABX PENTRA 60 C+** 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...).
- An **ABX DIAGNOSTICS** representative will install your instrument, computer, software and printer.

2.9. Package content

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

ABX PENTRA 60 C+	
1x RAXXXX	User manual
1x XBA453A	Barcode reader
1x XAA504A	Lexmark e210 printer
1x UC000002NUA2	Workstation
1x CCC006A	15" Screen
1x CBK045A (or CBK043A)	Keyboard Azerty (or Qwerty)
1x P60CP001	Pentra 60 C+
1x DACXXX	Supply cable 220V or 110V

3. PENTRA 60 C+ SOFTWARE

Menu bar

- Across the top of the window is the Menu bar, Menu bar displays the 4 available menus: **FILE, SERVICE, SETTING, ?** (help).



- You can access the menus by clicking directly on the mouse or using the keyboard: Press ALT + the first letter of the menu name. For example: ALT + F open FILE menu. Use UP and DOWN keys to select menu option or hit the underscored character in the option name.

Tool bar

- Below the Menu bar is the Tool bar, Tool bar displays common options:



Opens Print menu of selected tab



Move to Prior file



Sends selected area



Move to Next file



New entry



Validates result



Delete



Result rerun



Displays search screen



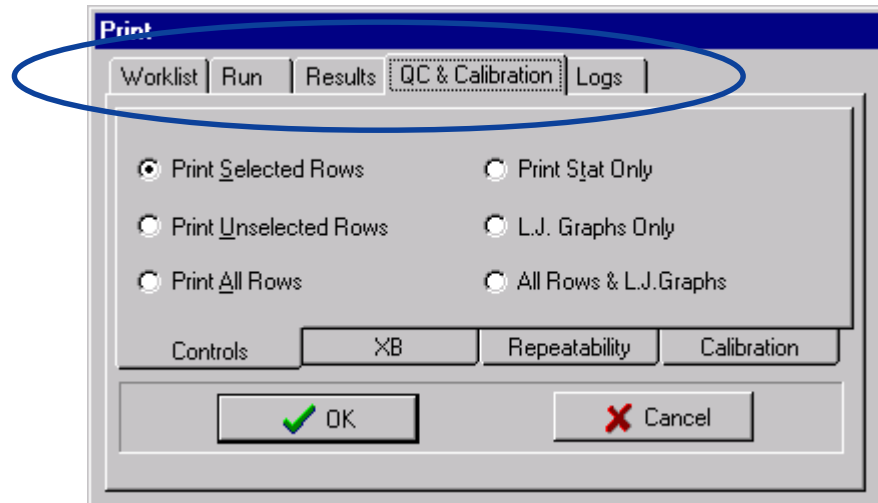
Access to help



Switch from grid to page menu

Tabs

- Tabs are used to group functions, the main tabs are: **WORKLIST**, **RUN**, **RESULTS**, **CALIBRATION & QC**, **ANALYZER**. Click on the tab to enter or hit CTRL + TAB to move to the next one.

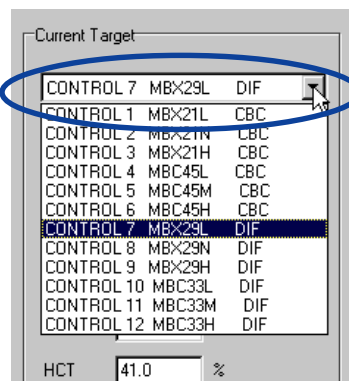


Buttons

- A button like  **Start Up**,  **Shut Down**, executes an action. If a button has a bold perimeter it can be activated by hitting ENTER key. When a button is rounded by a dotted line,  **OK**, it can be activated by hitting SPACE or ENTER key. TAB key allows movements from one button to the next one.

Scrolling list

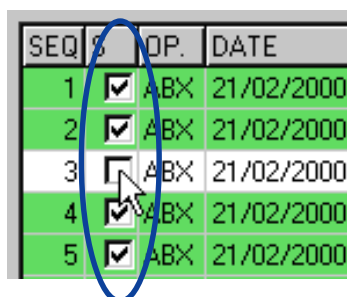
- A scrolling list is a little menu including a list of options and sometimes a field free to edit.



Pentra 60 C+

Checked box

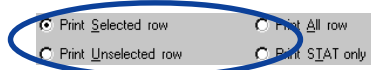
- A checked box activates ☒ or desactivates ☐ an option:



SEQ	S	OP	DATE
1	☒	ABX	21/02/2000
2	☒	ABX	21/02/2000
3	☐	ABX	21/02/2000
4	☒	ABX	21/02/2000
5	☒	ABX	21/02/2000

Radio button

- A radio button allows the user to choose between options excluding each other:



☒ Print Selected row	☐ Print All row
☐ Print Unselected row	☐ Print STAT only

Fields

- A field is a rectangle area used to input or display data such as Name, Date, ...

Some fields have predefined format: Date, Number, Text, ...

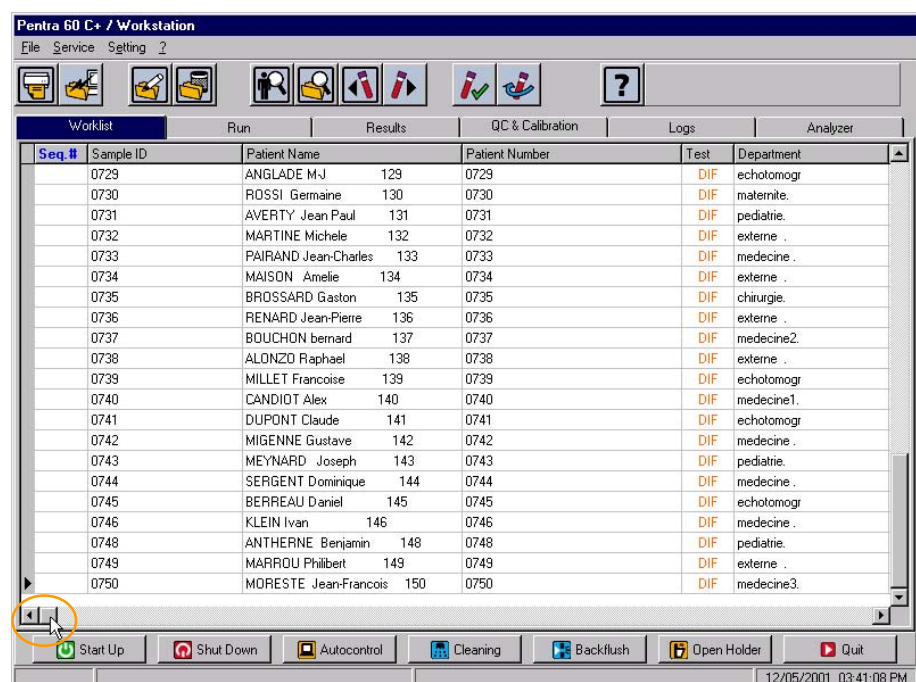
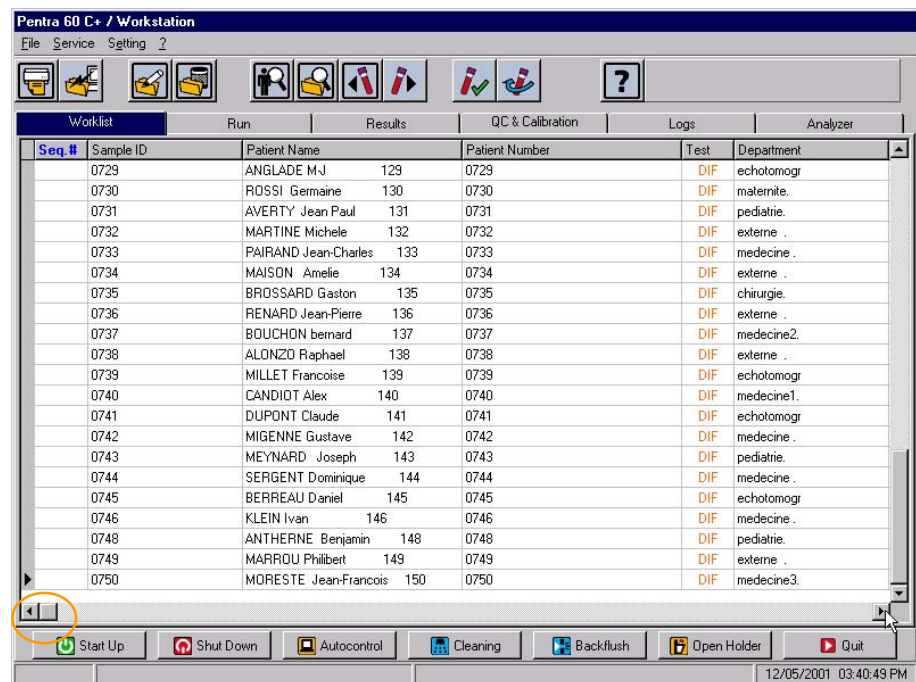
For example: TEST field in WORKLIST is the analysis mode (CBC or DIF) for the concerned specimen, click, or move into TEST field and press ENTER, to swap between CBC and DIF mode.

Lists

- Some information or fields are presented in a list format, use the mouse or direction keys to navigate inside the list, press ENTER to activate or change options.

Sliders

- When a window is too long or too high a vertical or horizontal slider appears. Use sliders to move from one part of the window to another. You can either drag the slider or click the arrows:



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Pentra 60 C+

1. TECHNICAL SPECIFICATIONS

- The **ABX Pentra 60 C+** is a fully automated hematology analyzer used for in vitro diagnostic testing of whole blood specimens. A control station (or workstation) is directly connected to the instrument.
- The **ABX Pentra 60 C+** is able to operate either in **CBC** mode (**C**ell **B**lood **C**ount: 12 parameters) or in **CBC + 5DIFF** mode (**5** population **D**ifferential count: 26 parameters).

1.1. Parameters

1.1.1. CBC Mode

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 *	Platelet Distribution Width
MPV	Mean Platelet Volume
Pct *	Plateletcrit

** PDW and PCT 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.*



Specifications

1.1.2. CBC + 5DIFF Mode

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 Lymphocyte % 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 *	Platelet Distribution Width
MPV	Mean Platelet Volume
Pct *	Plateletcrit

** 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.*

Pentra 60 C+

1.1.3. Units

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	#	%	#	%	#	%	#

- To select the set of units refers to Chapter 4. Instrument configuration



1.2. Throughput Analyses

- CBC Mode (**CBC**): 60/h
- CBC + 5DIFF Mode (**DIF**): .. 60/h

1.3. Tube Identification

- By means of the **ABX WORKSTATION**: Barcode labels or keyboard.

1.4. Reagents

- **ABX DILUENT** (20 litres)
- **ABX CLEANER** (1 litre, Integrated),
- **ABX EOSINOFIX** (1litre, Integrated),
- **ABX BASOLYSE II** (1 litre, Integrated),
- **ABX ALPHALYSE** or **BIOLYSE** (0.4 litre, Integrated)

1.5. Workstation Computer

- Processor frequency: * Pentium II 350 Mhz (min.)
- Memory capacity: * 128 Mb (min.)
- Hard drive: * 4 Gb (min.)
- Floppy + CD-ROM
- Keyboard: * 105 keys (Qwerty default or Option)
- Mouse: * Standard PS/2 compatible
- RS232 port: * x2 (Analyser/Local network)
- Screen: * 15" monitor (800x600 min.)
- Operating System: * Microsoft Windows NT 4.0 Service pack 4 GB or US

1.6. Measurements and computation

- Impedance for WBC, Plt, RBC, BASO.
- 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, PDW.

Pentra 60 C+

2. PHYSICAL SPECIFICATIONS

2.1. Power requirements

- Power supplies: * from 100Vac to 240Vac ($\pm 10\%$)
..... * 50 Hz to 60 Hz
- Power Consumption: * Analyzer and computer: 400 VA
..... * Printer (Depends on printer see Printer's manual)
..... * EPSON EPL5900: 900 VA

2.2. Operating temperature and humidity

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

2.3. Dimensions and Weight

- Analyzer dimensions: * Height: approximately 516 mm (20.3 in.)
..... * Width: approximately 444 mm (17.5 in.)
..... * Depth: approximately 481 mm (19 in.)
- Analyzer weight: * approximately 35Kgs (77lbs)
- Computer dimensions: * See computer's manual
- Computer weight: * See computer's manual

2.4. Minimum specimen volume

- CBC Mode (CBC): * 30 μ l
- CBC + 5DIFF Mode (DIF): .. * 53 μ l



2.5. Dilution ratios

- WBC/BASO * 1/200
- LMNE * 1/80
- RBC/Plt * 1/10 000
- Hgb * 1/250

2.6. Hgb measurement

- Hgb chamber, LED 555 nm.
- Modified Drabkin method (cyanmethemoglobin)
- Light source * Electroluminescent diode
- Wavelength * 550nm $\pm$ 10nm

2.7. Counting aperture diameters

- WBC/BASO * 80 μ m
- LMNE * 60 μ m
- RBC/Plt * 50 μ m

Pentra 60 C+

2.8. Reagent consumption (ml)

CYCLE	REAGENT					APPROXIMATE DURATION
	DILUENT	BASOLYSE II	CLEANER	EOSINOFIX	ALPHALYSE	
CBC (CBC)	22.6	2.1	0.9	X	0.4	60"
5DIFF (DIF)	28.5	2.1	0.9	1	0.4	60"
Startup*	65.4	2.1	3.7	1	1.4	4'50"
Shutdown	27	X	14	X	1	3'00"
Diluent Prime	44.9	X	X	X	X	3'10"
Cleaner Prime	X	X	24.8	X	X	1'20"
Eosinofix Prime	X	X	X	23.6	X	1'10"
Basolyse II Prime	X	23.6	1.1	X	X	2'20"
Lyse Prime	2.1	X	X	X	8.4	1'30"
All Reagents Prime	49	24	25.1	24	8.2	6'
Autoclean	13.4	1	1	1	0.3	1'35"
Autocontrol	25.4	X	1.4	X	1	1'50"

* for one background count only (maxi = 3)

3. SUMMARY OF PERFORMANCE DATA

3.1. Precision (Reproducibility)*

- The **ABX PENTRA 60 C+** was initially calibrated with Minocal Calibrator (Lot No. CX322, Expiry Date: 05-Aug-2002).
- Three levels of ABX MINOTROL material (Lot No: JX108) were run in duplicate once daily for a prolonged period (26th July 2002 to 30 August 2002) on all parameters. The results were used to quantify within run precision, and Total Precision in accordance with the NCCLS EP 5-A Guidelines.

PARAMETER	ABX MINOTROL CONTROL	WITHIN RUN SD	SD OF RUN MEANS	SD OF DAILY MEANS	TOTAL PRECISION (SD)
WBC	JX108 Low	0.001	N/A	N/A	0.001
	JX108 Normal	0.008	N/A	N/A	0.013
	JX108 High	0.031	N/A	N/A	0.045
RBC	JX108 Low	0.000	N/A	N/A	0.000
	JX108 Normal	0.001	N/A	N/A	0.001
	JX108 High	0.002	N/A	N/A	0.003
HGB	JX108 Low	0.001	N/A	N/A	0.001
	JX108 Normal	0.002	N/A	N/A	0.007
	JX108 High	0.005	N/A	N/A	0.012
HCT	JX108 Low	0.021	N/A	N/A	0.025
	JX108 Normal	0.064	N/A	N/A	0.122
	JX108 High	0.104	N/A	N/A	0.181
PLT	JX108 Low	6.271	N/A	N/A	20.646
	JX108 Normal	40.229	N/A	N/A	72.103
	JX108 High	154.146	N/A	N/A	381.388
PARAMETER	ABX MINOTROL CONTROL	WITHIN RUN CV%	CV% OF RUN MEANS	CV% OF DAILY MEANS	TOTAL PRECISION (CV%)
WBC	JX108 Low	1.8	N/A	N/A	1.93
	JX108 Normal	0.9	N/A	N/A	1.12
	JX108 High	0.9	N/A	N/A	1.05
RBC	JX108 Low	0.8	N/A	N/A	0.86
	JX108 Normal	0.6	N/A	N/A	0.79
	JX108 High	0.7	N/A	N/A	0.88
HGB	JX108 Low	0.4	N/A	N/A	0.57
	JX108 Normal	0.3	N/A	N/A	0.59
	JX108 High	0.4	N/A	N/A	0.60
HCT	JX108 Low	0.9	N/A	N/A	0.99
	JX108 Normal	0.7	N/A	N/A	0.97
	JX108 High	0.7	N/A	N/A	0.89
PLT	JX108 Low	3.1	N/A	N/A	5.69
	JX108 Normal	2.6	N/A	N/A	3.46
	JX108 High	2.5	N/A	N/A	4.01

*Source: 510K submission K030144

Pentra 60 C+

Precision claims*

PARAMETER	% CV	NOMINAL VALUES
WBC	< 2.0%	10.0 x 10 ³ /mm ³
RBC	< 2.0%	4.67 x 10 ⁶ /mm ³
HGB	< 1.0%	13.6 g/dl
HCT	< 2.0%	36.0 %
PLT	< 5.0%	243 x 10 ³ /mm ³

*Source: 510K submission K030144

3.2. Precision (Repeatability)

- Based on 10 consecutive samples of the same fresh whole blood sample without alarm:

PARAMETERS	%CV	TEST LEVEL
WBC	<2%	at 10x10 ³ /mm ³
RBC	<2%	at 5x10 ⁶ /mm ³
Plt	<5%	at 300x10 ³ /mm ³
Hgb	<1%	at 15 g/dL
Hct	<2%	at 45%

3.3. Linearity*

- **Linearity range:** The Manufacturer's tested linearity zone of the instrument using linearity kits and/or human blood.

- **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	DIFFERENCE (WHICH EVER IS GREATER)
WBC	0 to 120x10 ³ /mm ³	+/-0.2 or +/-3%
RBC	0 to 10x10 ⁶ /mm ³	+/-0.05 or +/-2%
Plt	0 to 2200x10 ³ /mm ³	+/-10 or +/-6%
Hgb	0.7 to 30 g/dL	+/-0.3 or +/-2%
Hct	0.7 to 80%	+/-2 or +/-3%

*Not validated for the U.S.A. Market.

3.4. Carryover

- The **ABX PENTRA 60 C+** 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).

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

Carry-over % is then:

	WBC	RBC	HGB	PLT
Mean low levels	1.06	1.58	5.28	31.33
Mean high levels	58.81	6.37	22.03	1106.67
Carry over %	-0.260	0.000	-0.179	-0.186

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.

Pentra 60 C+

- Carry-over Conclusion:

Results provided are extremely satisfactory. In order to provide for eventual possibilities within the laboratory environment the following claims shall be made :

	WBC	RBC	HGB	PLT
Claims	< 2.0%	< 2.0%	< 2.0%	< 2.0%

*Source: 510K submission K030144

3.5. Normal ranges*

PARAMETERS	MALE	FEMALE
WBC (10 ³ /μL)	4 - 10	4 - 10
RBC (10 ⁶ /μL)	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 /μL)	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

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!

*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)

3.6. Accuracy*

- The data shows good correlation between results achieved on the **ABX PENTRA 60 C+** versus the reference system, which can be resumed as follows:

PARAMETER	R ² (COMPARISON OF MEANS)	ACCURACY CLAIMS
WBC	0.997	>0.95
PLT	0.998	>0.95
RBC	N/A	N/A
HGB	N/A	N/A
HCT	N/A	N/A
LYM	N/A	N/A
NEU	N/A	N/A
MON	N/A	N/A
EOS	N/A	N/A
BAS	N/A	N/A

*Source: 510K submission K030144

3.7. Leukocyte differential count

- Not available at the time of publication.

3.8. Sample stability study

- Not available at the time of publication.

3.9. Flags giving an analysis default

Results exceeding instrument capacities

PARAMETER	DISPLAYED	PRINTED OUT	TRANSMITTED
0<WBC<120 (x10 ³ /mm ³)	«result»	«result»	«result»
WBC>120	---- + D	---- + D	--.-- + D
0<RBC<10 (x10 ⁶ /mm ³)	«result»	«result»	«result»
10<RBC<18	«result»+«D»	«result»+«D»	«result»+«D»
0<PLT<2200 (x10 ³ /mm ³)	«result»	«result»	«result»
PLT>2200	---- + D	---- + D	--.-- + D
0.7<HGB<30 (g/dL)	«result»	«result»	«result»
HGB>30	---- + D	---- + D	--.-- + D
0.7<HCT<80 (%)	«result»	«result»	«result»
HCT>80	---- + D	---- + D	--.-- + D

NOTE

Use the instrument diluent to dilute the sample if a «D» flag occurs on WBC or Hct.

4. REAGENTS SPECIFICATIONS

4.1. Reagent specifications

- In order for the instrument to operate correctly, high-quality reagents must be used. **ABX DIAGNOSTICS** provides all the necessary reagents.

NOTE

The ABX Diagnostics reagents specified for this instrument may have followed one or both of the approval methods below:

1 - have been registered by the A.F.S.S.A.P.S. «Agence Française de Sécurité Sanitaire des Produits de Santé» according to the procedure relative to laboratory reagents used for biological analyses.

2 - or approved in accordance with the European Directive 98/79/CE (Annex III) for in-vitro medical devices.

Please refer to the packaging of each reagent concerned to establish the approval method.

- Refer to Chapter **Annex** of this manual for all reagent specifications.

4.2. Waste handling precautions

WARNING

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

WARNING

Whilst every effort is taken by ABX Diagnostics 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 *Chapter 5. Maintenance & Troubleshooting*, specific maintenance procedures are listed. The maintenance procedures identified are mandatory for proper use and operation of the **ABX PENTRA 60 C+**. Failure to execute any of these recommended procedures may result in poor reliability of the system.

IMPORTANT

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

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. These white cell fragments will also interfere with the white cell partial differential parameters: LYM% + #, MON% + #, GRAN% + #. 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 leukocytes which may cause low WBC counts.

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.



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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)

Very small erythrocytes (microcytes), erythrocyte fragments (schizocytes) 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.

Elevated triglycerides and/or cholesterol: may interfere with correct platelet counting.

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 (Schizocytes) 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.

IMPORTANT

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.

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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.

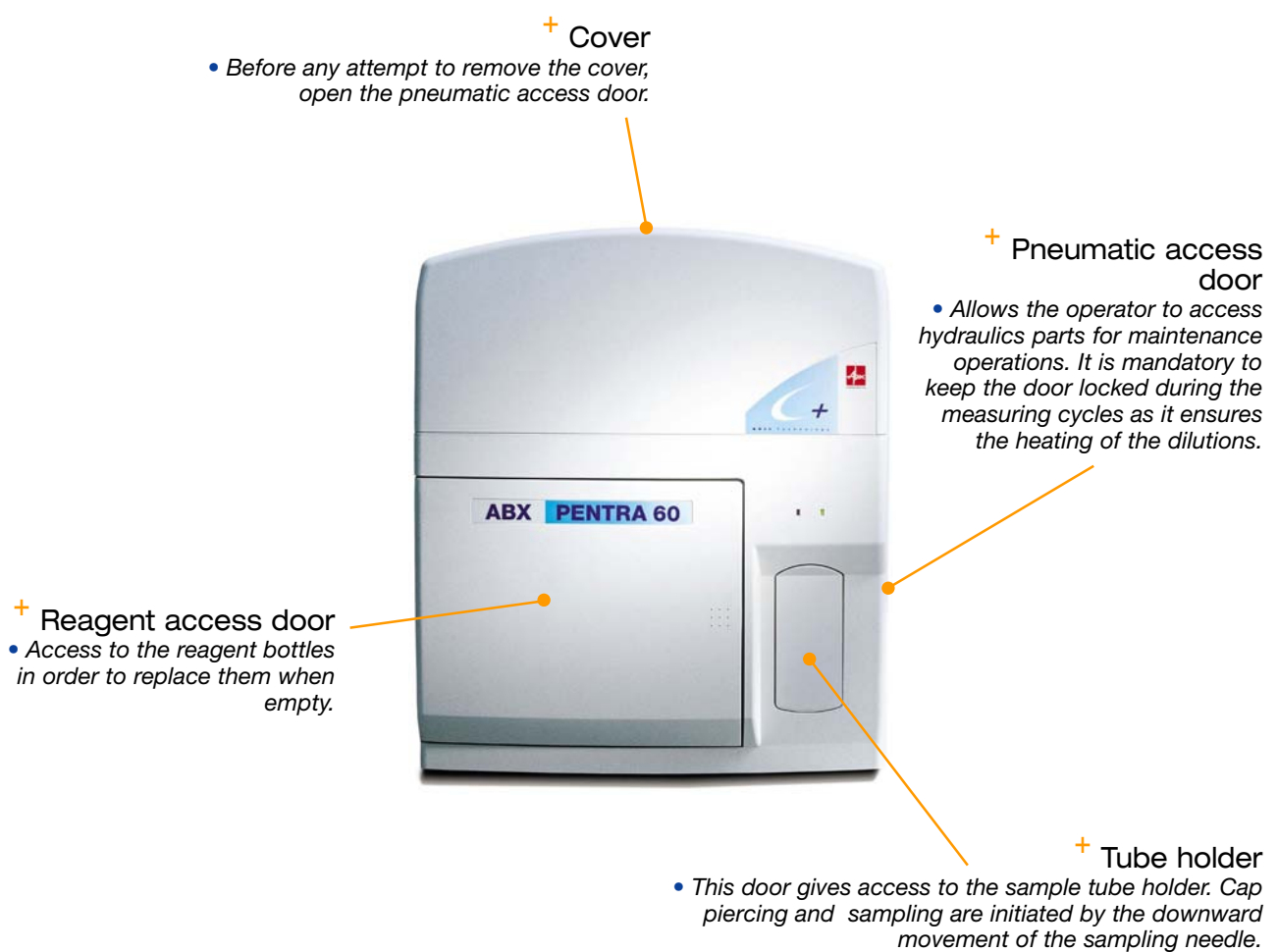
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Pentra 60 C+

1. PENTRA 60 C+ DESCRIPTION

1.1. Pentra 60 C+ front side





1.2. Pentra 60 C+ back side



Pentra 60 C+

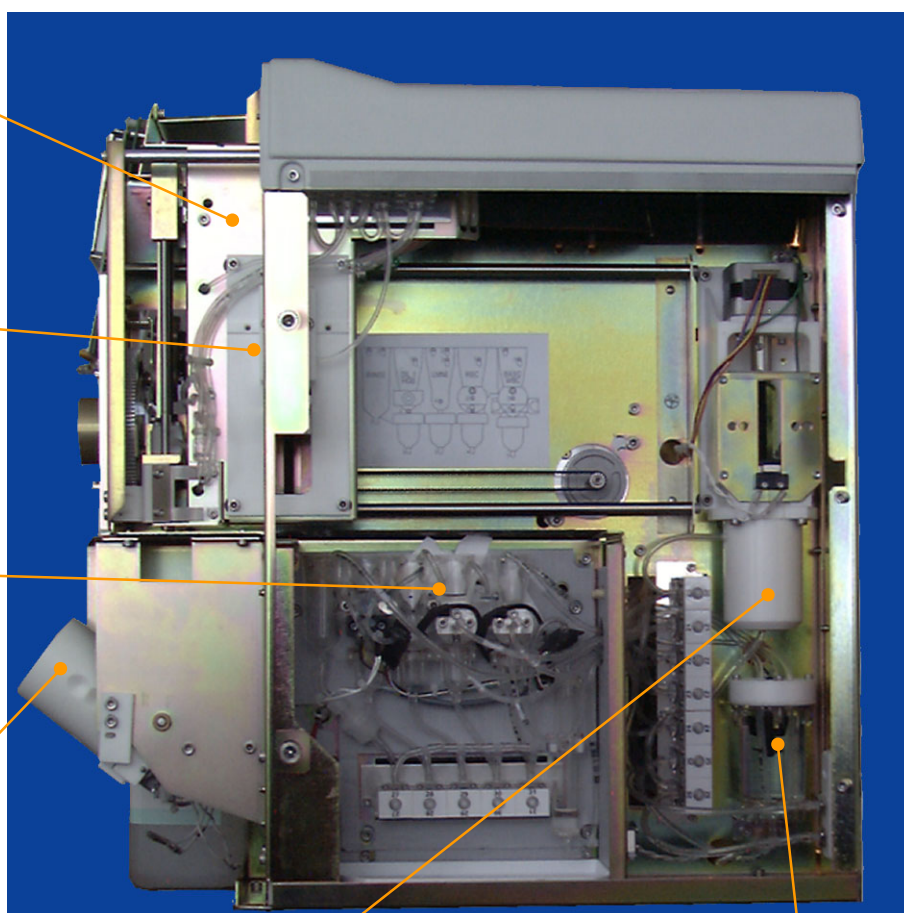
1.3. Mechanical and hydraulic modules

- + **Piercing carriage**
 - Ensures needle positioning for the different sampling stages and distribution,
 - Supports the sampling syringe and the blood distribution.

- + **Sampling syringe**
 - Distributes portions of the specimen into the dilution chambers,
 - Takes the sample from the first dilution and distributes it into the RBC/PLT chamber.

- + **Count assembly**
 - Receives the different rinsings and dilutions,
 - Regulates the temperature of dilutions,
 - Provides the dilutions for WBC/BASOS, RBC/Plt and Hgb.

- + **Tube holder**
 - 4 positions according to the sampling tube characteristics,
 - Selected position is the hole facing the inside of the instrument



- + **Draining syringe**
 - Drains the chambers,
 - Bubbles the mixtures,
 - Transfers, by vacuum, the LMNE specimen from the mixing chamber towards to the injector of the optical flowcell.

- + **Diluent tank**
 - Contains the necessary diluent for an analysis cycle,
 - Prevents Diluent degassing as it is being aspirated by the syringes,
 - Is vacuum filled by the counting syringe.

+ Optical bench

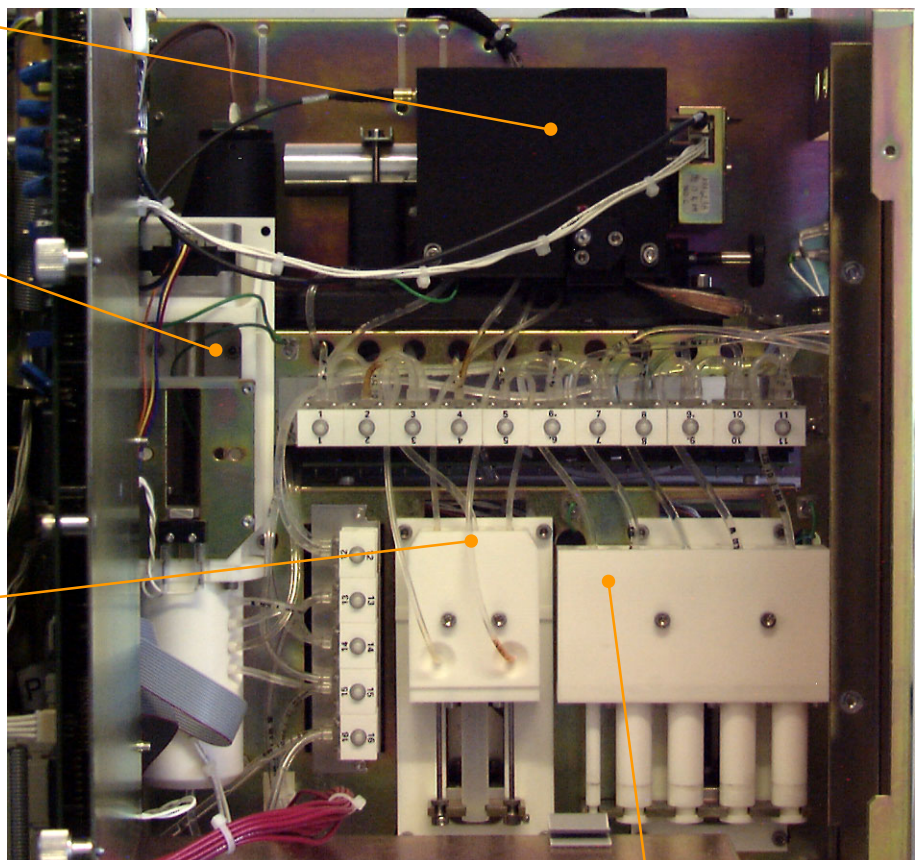
- Ensures the support and adjustment of the flowcell, lamp, and optical and electronic elements.

+ Counting syringe

- Ensures the vacuum for the WBC and BASOS counts,
- Ensures the vacuum for the RBC and the Plts counts,
- Ensures the vacuum for filling the diluent tank with diluent.

+ 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 into the flowcell.



+ Reagent Syringe assembly

- Ensures the correct proportioning of the reagents:
- Lysing reagent for hemoglobin (**ABX ALPHALYSE**),
 - 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/BASO (**ABX BASOLYSE II**).

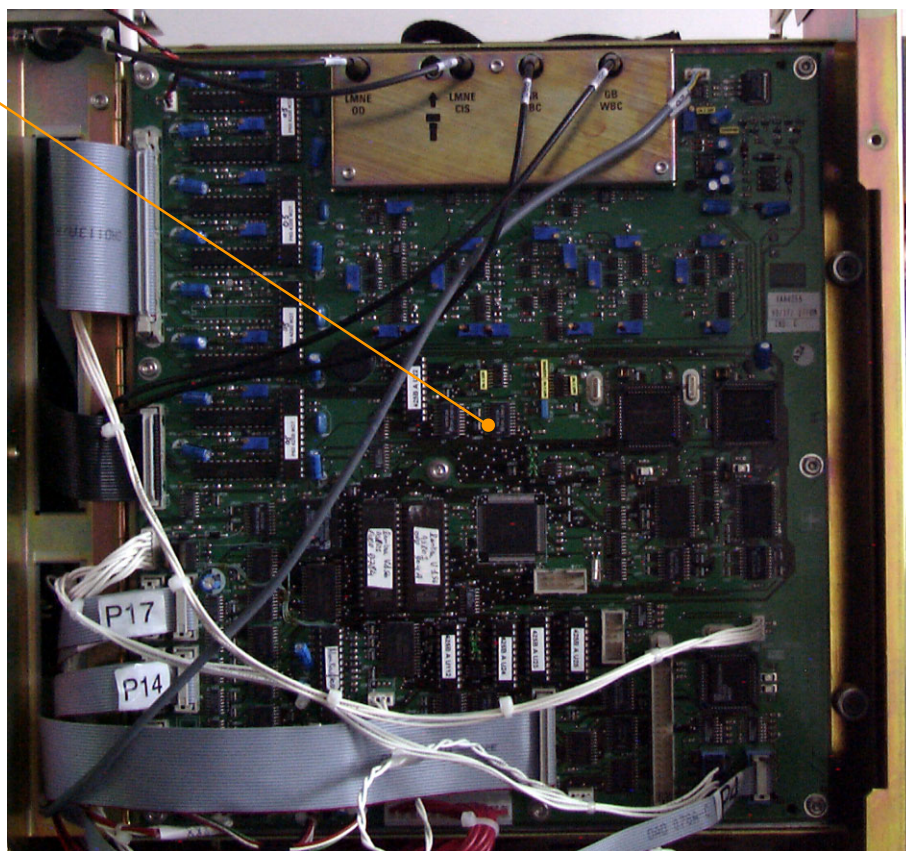
Pentra 60 C+

+ Main board

Located on the left side of the instrument. The board is fastened onto a door in order to allow access to the fluidic modules.

Main functions of the board

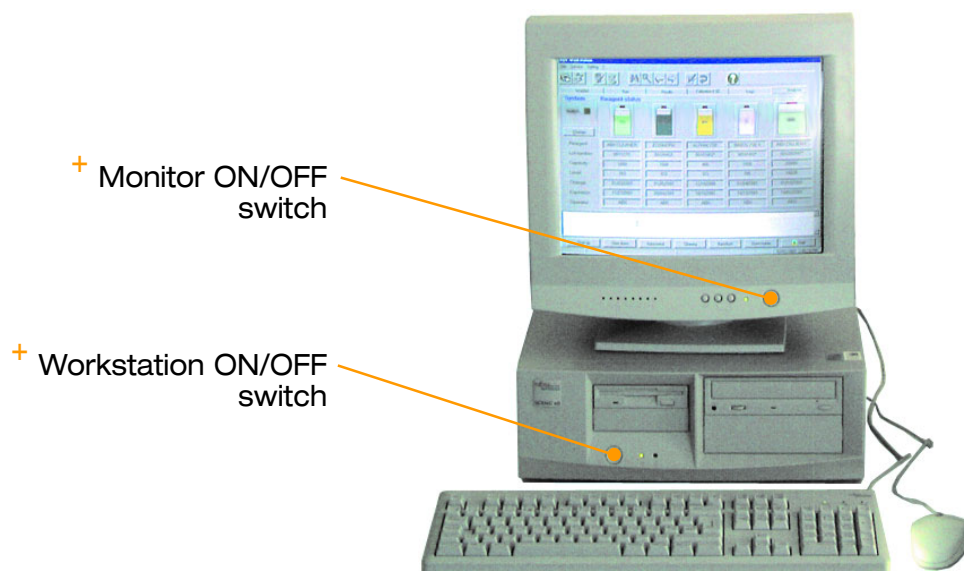
- Amplifies, processes and counts the following signals:
 - Resistive signals and LMNE optical signals,
 - RBC Signal,
 - Plt signal,
 - WBC/BASO signals.
- Measures hemoglobin,
- Pilots the motorised elements.



CAUTION

When opening the main board support panel, be careful not to disconnect or damage electric cables.

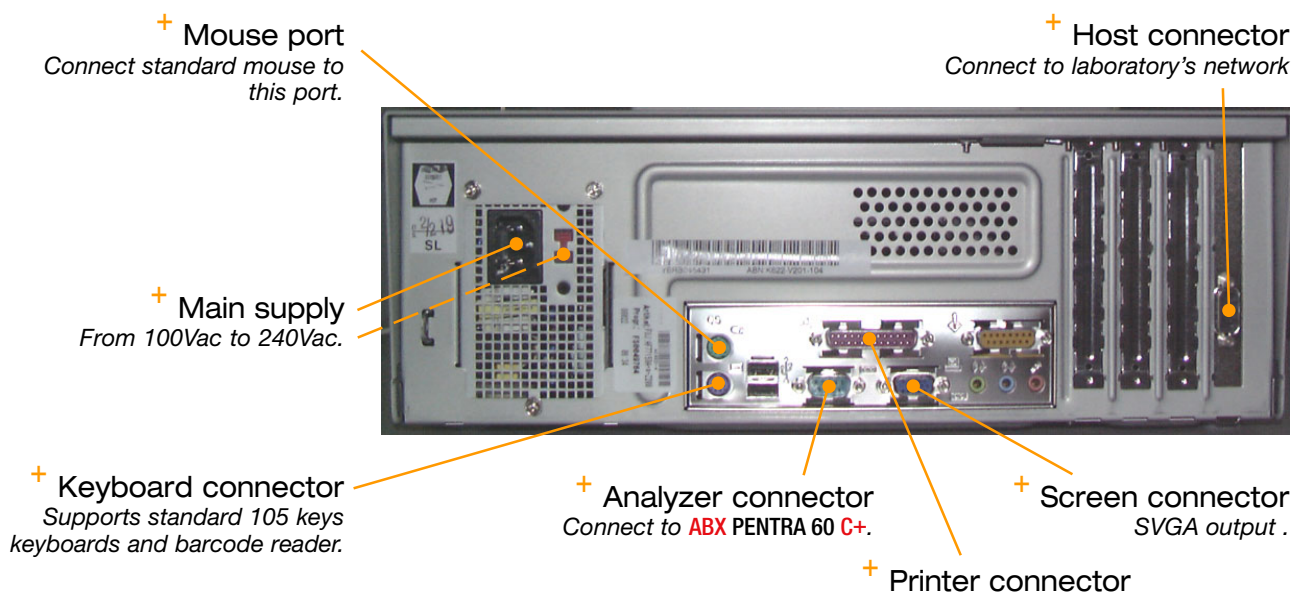
1.4. Computer's front side



NOTE

Diagrams on this page are given for information, computers from one country to another may be different.

1.5. Computer's back side



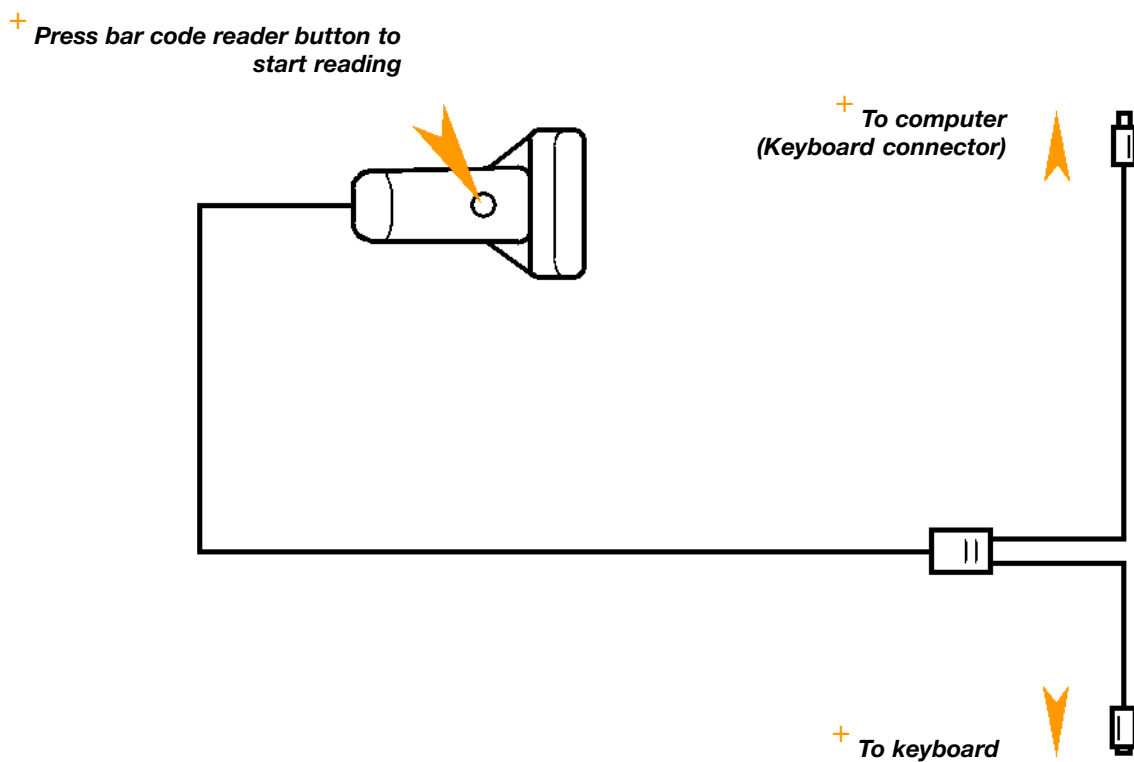
NOTE

Other connectors on the back of the computer are described in the computer's manual.

Pentra 60 C+

1.6. Barcode connection

- Connect barcode reader between computer and keyboard as shown below:



2. MEASURING PRINCIPLES

2.1. Multi Distribution Sampling System (MDSS)

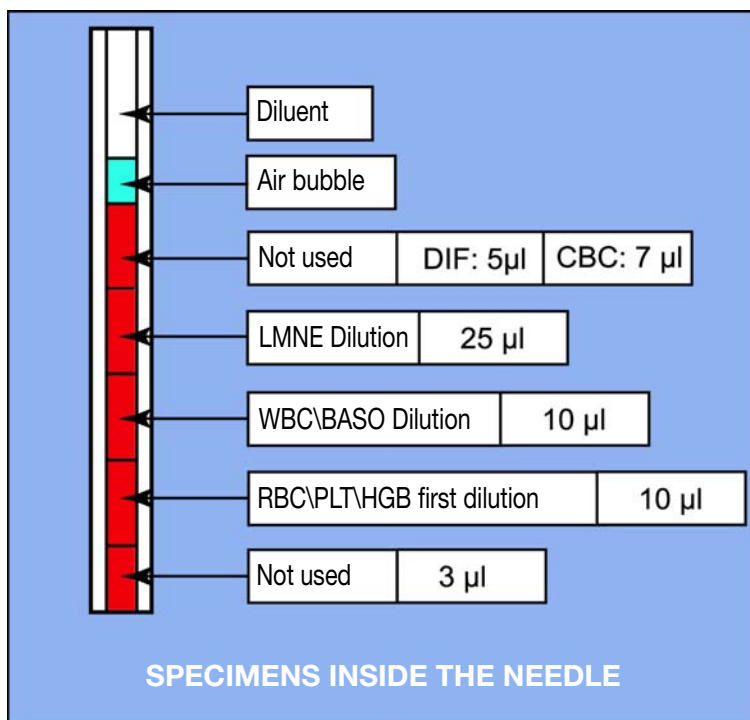
+ ABX PENTRA 60 C+ analysis

cycle needs
3 blood specimens distributed
as follows:

- one specimen for the first RBC/Plt dilution and the Hgb measurement.
- another specimen for the BASO/WBC count.
- the last specimen for the LMNE matrix.

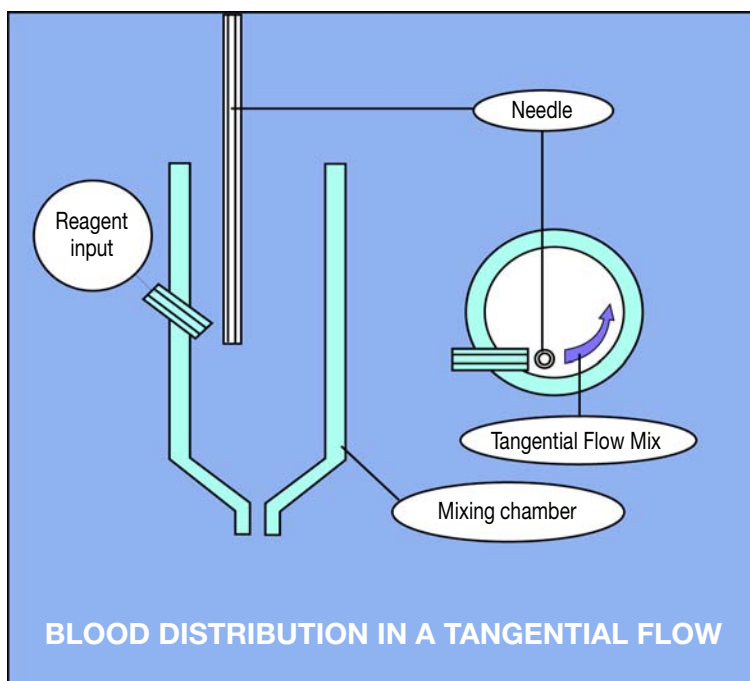
These 3 specimens are
provided by means
of a «multidistribution»
principle:

- 53 µl of blood are aspirated inside the needle (sufficient volume for all dilutions) then divided up and distributed to the chambers with reagents.
- Extremities of the specimen are not delivered to the dilutions.



+ Specimen distribution in

the chambers is carried out in a
tangential flow of reagent
which allows perfect mixing of
the dilution and avoids any
viscosity problems (this multi
distribution in a reagent flow is
an ABX DIAGNOSTICS patent).

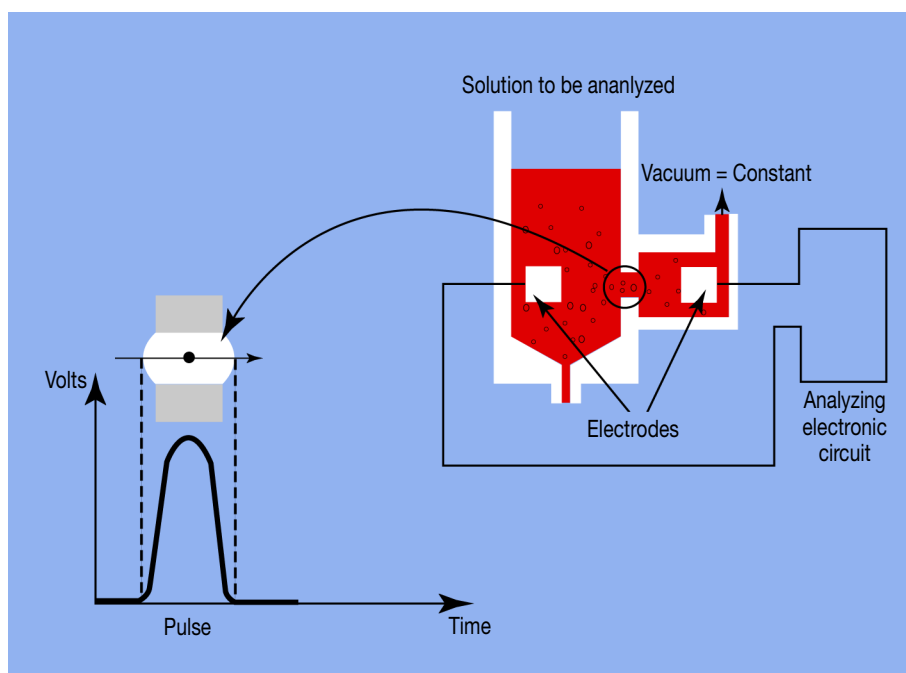


Pentra 60 C+

2.2. RBC / Plt detection principles

+ Measurement of impedance variation generated by the passage of cells through a calibrated micro aperture.

- The specimen is diluted in an electrolytic diluent (current conductor) and pulled through the calibrated micro-aperture. Two electrodes are placed on either side of the aperture. Electric current passes through the electrodes continuously.
- When the cell passes through the aperture, electric resistance between the two electrodes increases proportionately with the cell volume.
- The generated impulses have a very low voltage, which the amplification circuit increases, so that the electronic system can analyze them and eliminate the background noise.



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 5 seconds

**** : TWO SUCCESSIVE DILUTIONS ARE CARRIED OUT :**

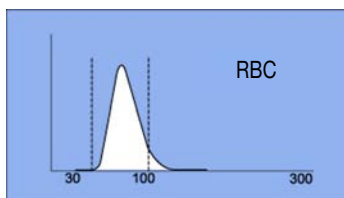
PRIMARY DILUTION FOR RBC AND PLT:

Blood (µl):	10		
ABX DILUENT (µL):	1700	dilution:	1/170

SECONDARY DILUTION RBC AND PLT (FROM THE PRIMARY DILUTION):

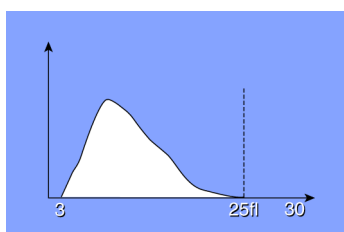
Dilution (µl):	42.5		
ABX DILUENT(µL):	2500	dilution:	1/58.8

FINAL DILUTION: 1/170 X 1/58.8 ≈ 1/10000



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 microcyte population present in the analysis area.

2.3. Hgb measurement

- The hemoglobin released by the lysis of the red blood cells combines with the potassium cyanide to form the chromogenous cyanmethemoglobin compound. This compound is then measured through the optical part of the first dilution chamber using a spectrophotometric technique at a wavelength of 550 nm.

TECHNICAL CHARACTERISTICS FOR THE MEASUREMENT OF THE HEMOGLOBIN:

Volume of blood	10 µl	Method	Photometry
Volume ABX DILUENT	1700 µl	Wavelength	550 nm
Volume ABX ALPHALYSE	400 µl		
Complement ABX DILUENT	400 µl		
Final dilution rate	1/250		
Temperature of reaction	35°C		

Result

- Final Hgb result represents: Absorbance value obtained x coefficient of calibration.

2.4. Hct measurement

- The height of the impulse generated by the passage of a cell through the micro-aperture is directly proportional to the volume of the analyzed RBC.
- The hematocrit is measured as a function of the numeric integration of the MCV.

2.5. RDW calculation

- The study of the RBC distribution detects erythrocyte anomalies linked to anisocytosis.
A Red Cell Distribution Width (RDW) will enable you to follow the evolution of the width of the curve in relation to the cell number and average volume.

$$RDW = \frac{K \cdot SD}{MCV}$$

With:

- K = system constant
- SD = Determined standard deviation according to statistical studies on cell distribution.
- MCV = Mean Corpuscular Volume of erythrocytes

2.6. MCV, MCH, MCHC calculation

- MCV (Mean Cell Volume) is calculated directly from the RBC histogram.
- MCH (Mean Cell Hemoglobin) is calculated from the Hgb value and the RBC number.
The mean hemoglobin weight in each RBC is given by the formula:

$$MCH \text{ (pg)} = \frac{\text{Hgb}}{\text{RBC}} \times 10$$

- 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:

$$MCHC \text{ (g/dL)} = \frac{\text{Hgb}}{\text{Hct}} \times 100$$

2.7. MPV Measurement

- The MPV (Mean Platelet Volume) is directly derived from the analysis of the platelet distribution curve.

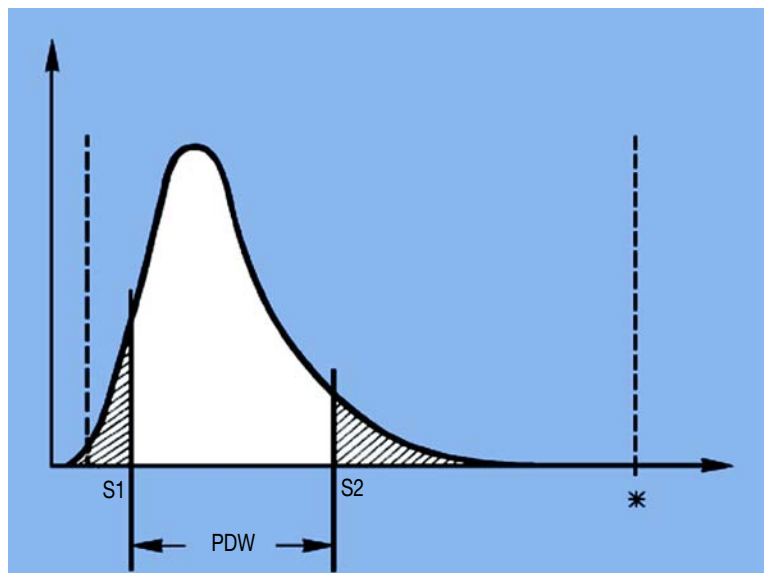
2.8. Pct calculation

- Thrombocrit is calculated according to the formula:

$$\text{Pct\%} = \frac{\text{Plt (10}^3/\mu\text{l)} \times \text{MPV (}\mu\text{m}^3\text{)}}{10\,000}$$

2.9. 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).



2.10. WBC and differential count

2.10.1. General principles

The WBC count is carried out twice by two different sensors:

- In the BASO count chamber at the same time as the BASOS count,
- In the optical chamber during the acquisition of the LMNE matrix.

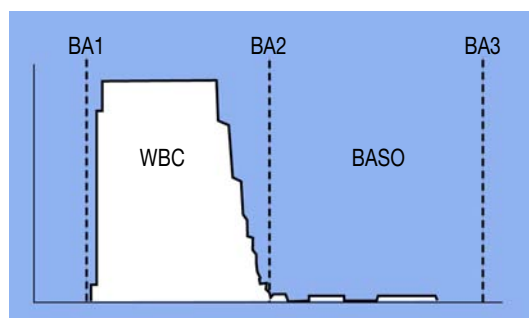
The reference count is the one obtained in the WBC and BASO count chamber.

2.10.2. BASO / WBC Count

- Detection principle is the same as for RBC.

Differentiation between BASOs and other leukocytes is obtained by means of the **BASOLYSE II** specific lysing action.

- All the WBCs are counted between the electrical threshold <0> threshold <BA3>.
- The basophils are located from threshold <BA2> to threshold <BA3>.



TECHNICAL CHARACTERISTICS OF THE WBC/BASO COUNT

Blood volume	10 µl	Method	Impedance
BASOLYSE II volume	2000 µl	Ruby diameter	80 µm
Dilution rate	1/200	Depression of count	200 mb
Reaction temperature	35 ° C	Duration of the count	2 X 6 seconds

Results

WBC: Number of cells per volume x coefficient of calibration.

BASO: Number of cells per volume x coefficient of calibration in percentage regarding the total number of leukocytes (BASO + WBC nuclei)

2.10.3. LMNE matrix

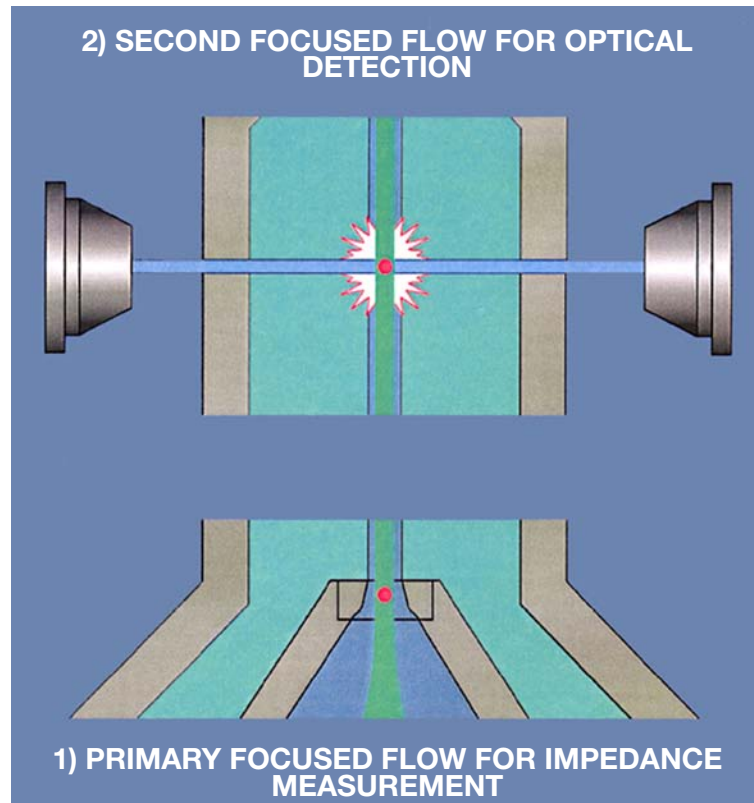
- The WBC and Differential count are based on 3 essential principles:

1- The double hydrodynamic sleeving «DHSS» (ABX DIAGNOSTICS patent)

2- The volume measurement impedance changes.

3- The measurement of transmitted light with 0° angle, which permits a response according to the internal structure of each element and its absorbance by means of incident light diffusion.

- 25µl of whole blood is delivered to the LMNE chamber in a flow of EOSINOFIX. This reagent lyses the RBC, stabilizes the WBC in their native forms and stains the eosinophil nuclei with a specific coloration.
- The solution is then stabilized with diluent and transferred to the measuring chamber. Each cell is measured both in absorbance (cytochemistry) and resistivity (volume).



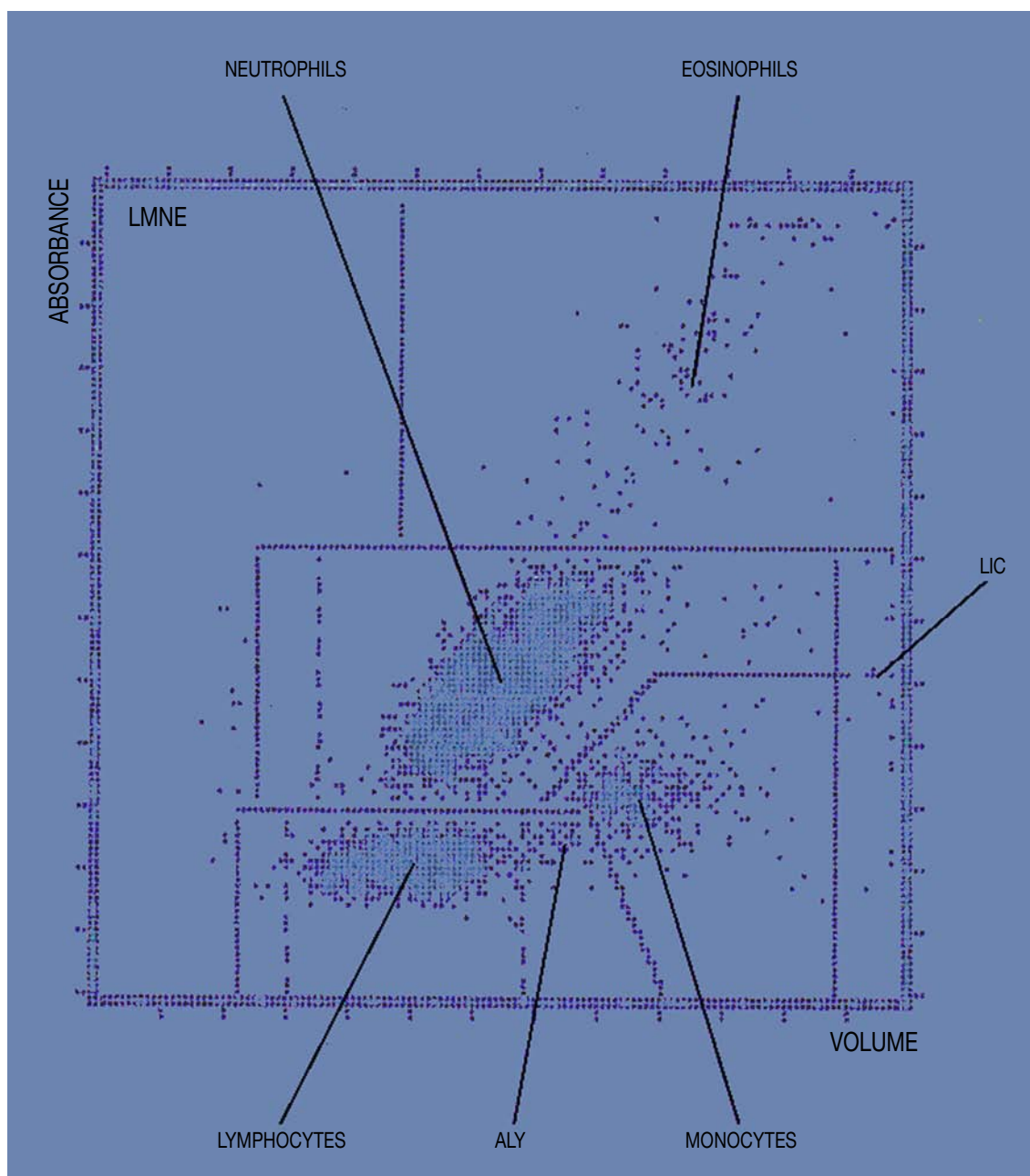
TECHNICAL CHARACTERISTICS OF THE WBC COUNT DURING THE ACQUISITION OF THE MATRIX

Blood volume	25 µl	Method	Impedance with hydrofocus
Eosinofix volume	1000 µl	Ruby diameter	60 µm
Diluent volume	1000 µl	Flow diameter	42 µm
Final dilution rate	1/80	Injection duration	12 seconds
Reaction temperature	35 ° C	Volume injected	72 µl
Incubation duration	12 s.		

Results

- From these measurements, a matrix is drawn up with volumes on the X-axis and optical transmission on the Y-axis. The study of the matrix image permits the clear differentiation of 4 out of 5 leukocyte populations. As a matter of fact, the basophil population is very small compared to the other 5 in a small blood sample.

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MONOCYTES: The monocytes, being cells with large kidney shaped nuclei and a large non-granular cytoplasm, will neither be scattered nor absorb a large amount of light. They will therefore be positioned in the lower part of the optical axis but clearly to the right of the volume axis. Certain large monocytes can be found on the right side of the matrix in the lower LIC (Large Immature Cells) zone. The immature granulocytic cells are detected by their larger volumes and by the presence of granules which increase the intensity of the scattered light. Therefore, cells such as metamyelocytes will be found clearly to the right of the neutrophils and nearly at the same level. Myelocytes and promyelocytes will be found in saturation position on the far right of the matrix. These last three populations will be counted as LIC (Large Immature Cells) and their given results are included in the neutrophil value. The blast cells will be found generally to the right of the monocytes, and, as such, will increase the LIC count. Small blasts will be found between the normal lymphocytes and monocytes. Platelets and debris from erythrocyte lysis represent the background noise population located in the lower left area of the matrix. Most of the population partition thresholds are fixed and give the limits of the morphological normality of leukocytes. Changes in the morphology of a population will be expressed on the matrix by a shifting of the corresponding population.

LYMPHOCYTES: The lymphocytes being small with regular shape, are positioned in the lower part of both the optical axis and volume axis. Normal lymphocyte populations are generally observed with a good volume homogeneity. Large lymphocytes are detected in the ALY (Atypical Lymphocytes) zone, where reactive lymphoid forms, stimulated lymphocytes and plasmocytes are also to be found. The far left side of the lymphocyte zone should normally be empty, but when small lymphocytes are present, population may exist in this area. The presence of platelet aggregates is detected by a distribution pattern that moves from the origin of the matrix (background zone) into the lymphocyte zone. The NRBCs with their cytoplasmic membranes lysed like the erythrocytes, will have their nuclei situated to the far left side of the lymphocyte zone.

EOSINOPHILS: With reagent action on cytoplasmic membranes, the leukocytes keep their native size and only eosinophils are colored for optical separation. Eosinophils will be situated in the upper part of the optical Y-axis due to their strong absorbance qualities and their size, which is nearly equivalent to large neutrophils.

NEUTROPHILS: The neutrophils, with their cytoplasmic granules and their generally segmented nuclei, will scatter light depending on their morphological complexity. A hypersegmented neutrophil will give an increased optical response with respect to a young neutrophil population which will be in the upper position of the optical axis depending on the presence of segmentation and/or granules.

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1. INSTRUMENT START UP

1.1. Waste levels

- At the beginning of each day check if the waste container needs to be emptied. Be careful! Wastes must be handled according to your local/national regulations.
- See *Chapter 5. Maintenance & Troubleshooting* to empty the waste container.

1.2. Printer start up

- Check the printer paper. If more printer paper is needed, replace the printer paper according to the *Printer user manual* supplied with the instrument.
- Press the ON/OFF switch. Check the control LEDs are ON.
- See *Chapter 4. Instrument configuration* to setup printing mode.

1.3. Pentra 60 C+ start up

- 1- Turn on the **ABX WORKSTATION** computer.
- 2- After computer boot press ALT+CTRL+DEL (or ALT+CTRL+SUPPR) to start a session & Start the Analyzer (On/Off switch located on the left side of the instrument)
- 3- Enter system password and wait until **ABX WORKSTATION** starts.

IMPORTANT

The instrument will not operate if the reagent temperature is under 35°C (69°F). If required a bargraph is displayed after start up to check and wait for temperature progression.



Specimen run & Results

- Analyzer indicator turns green if connection is successful and reagent levels are updated on the screen:

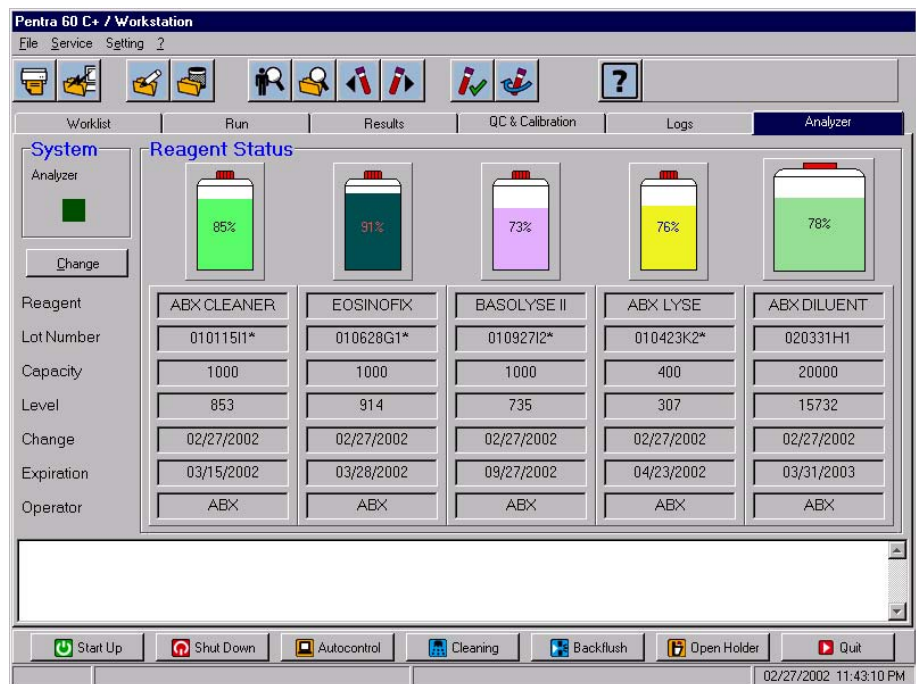
- Run a startup, click



Start Up

button.

- A rinse cycle is carried out,
- Then a background count (analysis cycle on reagent without blood specimen).



- If the background counts are not within acceptable limits the message «**STARTUP FAILED**» is displayed.

Background count limits:

$$WBC = 0.3 \times 10^3/mm^3$$

$$RBC = 0.03 \times 10^6/mm^3$$

$$Hgb = 0.3 g/dl$$

$$Plt = 7.0 \times 10^3/mm^3$$

2. SPECIMEN COLLECTION AND 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 biosafety procedures.

- When collecting blood specimens, Venous blood is recommended, but Arterial blood may also be used in extreme cases. Blood collection must be placed in 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.

2.1. 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.

2.2. 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 up to 48 hours.

2.3. Microsampling

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

2.4. Mixing

- The 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.

3. CALIBRATION VERIFICATION (CONTROL BLOOD SAMPLING)

- Before running specimens it is recommended that the operator runs a «Normal» control blood to verify that the system is within acceptable limits.
- The selection of the analysis mode (CBC/DIF) should be done according to the control used by the operator.
- For further informations please refer to *Chapter 4. Instrument configuration* to identify and enter new control blood lot.

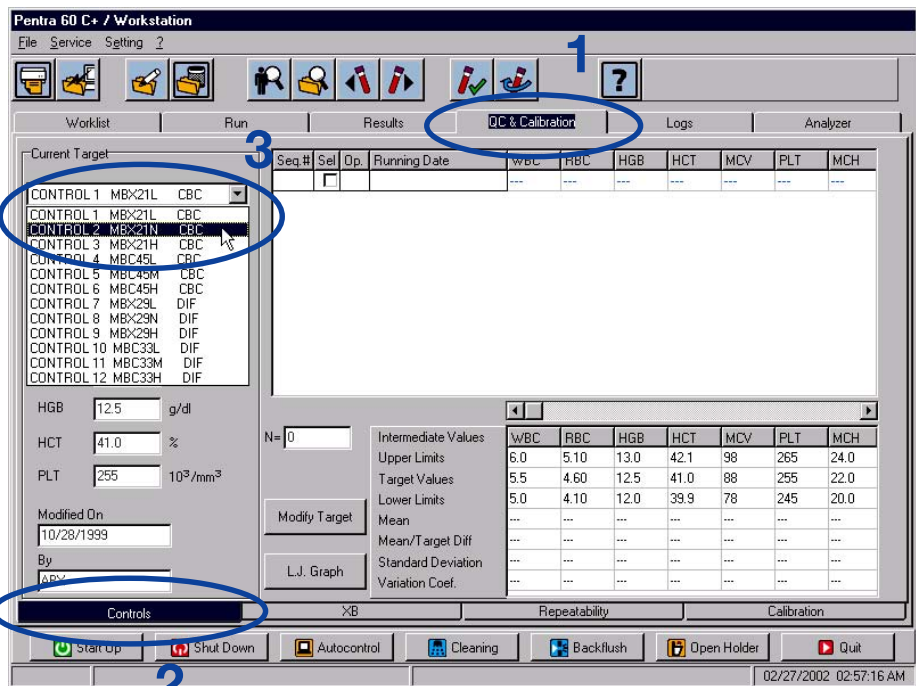
- Change the Lot number according to the Control blood you are going to use:

1- Enter «QC & Calibration» Tab.

2- Enter «Controls» Tab.

3- To select control blood lot:
Open «Current target» scrolling list and click on the control blood lot you are going to use.

+ If the control blood is not listed please refer to Chapter 4. *Instrument configuration*.



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+ **Previous** Controls ran with this lot are listed:

Seq.#	Sel	Op	Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH
1	✓	ABX	02/27/2002 02:58 AM	11.7	4.42	11.7	41.0	93	409	26.4
2	✓	ABX	02/27/2002 02:58 AM	11.5	4.50	11.8	42.1	94	408	26.1
3	✓	ABX	02/27/2002 02:58 AM	11.5	4.42	11.6	40.8	92	408	26.2
4	✓	ABX	02/27/2002 02:59 AM	11.4	4.43	11.6	41.1	93	398	26.3
5	✓	ABX	02/27/2002 02:59 AM	11.5	4.50	11.8	42.1	94	408	26.2
6	✓	ABX	02/27/2002 02:59 AM	11.5	4.42	11.5	40.8	92	408	26.2



- Prepare a «Normal» control blood according to the specific instructions detailed in the control blood package insert (temperature, mixing, etc...).
- Open the vial and locate it in the tube holder.
- In «**QC & Calibration\Controls**» Tab close the tube holder to start sampling.
- When the tube holder opens, remove and recap the vial.

IMPORTANT

Risk of erroneous results if the control blood is not continuously mixed between each analysis. Continue mixing the control blood between each analysis.

- When the analysis cycle ends, the result is displayed on the result chart table.
- Run the second calibrator sample when Green LED turns on.

Seq.#	Sel	Op	Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH
1	✓	ABX	02/27/2002 02:58 AM	11.7	4.42	11.7	41.0	93	409	26.4
2	✓	ABX	02/27/2002 02:58 AM	11.5	4.50	11.8	42.1	94	408	26.1
3	✓	ABX	02/27/2002 02:58 AM	11.5	4.42	11.6	40.8	92	408	26.2
4	✓	ABX	02/27/2002 02:59 AM	11.4	4.43	11.6	41.1	93	398	26.3
5	✓	ABX	02/27/2002 02:59 AM	11.5	4.50	11.8	42.1	94	408	26.2
6	✓	ABX	02/27/2002 02:59 AM	11.5	4.42	11.5	40.8	92	408	26.2

When control results are not within the acceptable ranges the parameter results are displayed in another color, perform the following:

- 1- Rerun the control,
- 2- Clean the system (see Chapter 5. **Maintenance & Troubleshooting**) and run the control again,
- 3- Open a new vial,
- 4- Recalibrate the system as in «**Recalibration**».

4. AUTO-CALIBRATION

NOTE

If calibration verification (control blood sampling) has failed, perform an Auto-calibration. Use a MINOCAL Calibrator to calibrate the instrument.

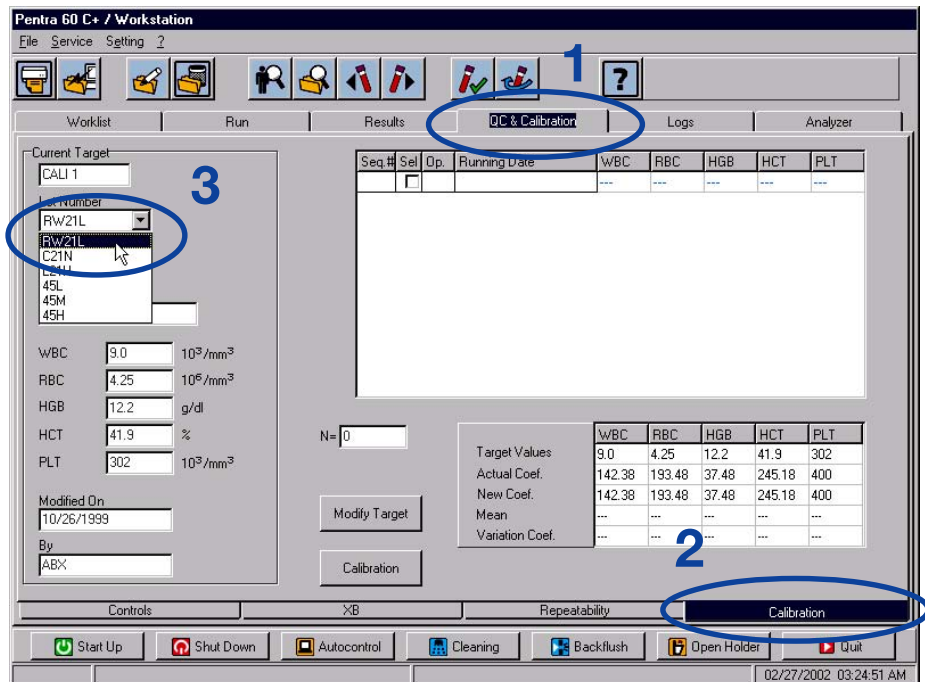
• Change Calibrator Lot number according to the Calibrator you are going to use:

1- Enter «QC & Calibration» Tab.

2- Enter «Calibrators» Tab.

3- Select calibrator: Open «Ident» scrolling list and click on the calibrator you are going to use.

+ If the calibrator is not listed please refer to Chapter 4. Instrument configuration.



- Prepare the calibrator according to the specific instructions detailed in the calibrator package insert (temperature, mixing, etc...).
- Open the vial and locate it in the tube holder.
- In «QC & Calibration\Calibrators» Tab close the tube holder.
- When the tube holder opens, remove and recap the vial.

IMPORTANT

Risk of erroneous results if the calibrator is not continuously mixed between each analysis. Continue mixing the calibrator between each analysis.

- When the analysis cycle ends, the first result is displayed on the result chart table.
- Run the second calibrator sample when Green LED turns on.

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IMPORTANT

In order to obtain the best possible calibration, it is recommended to run at least 5 calibrator samplings.

- The calibration of the **ABX** PENTRA 60 C+ can be performed on 3 to 11 analyses.

- The auto-calculation module performs statistics on these results in order to obtain the best calibration coefficients.

Pentra 60 C+ / Workstation

File Service Setting ?

Worklist Run Results **QC & Calibration** Logs Analyzer

Current Target

CALI 1

Lot Number: RW21L

Barcode: CAL21L

Expiration Date: 06/02/2002

WBC: 10.0 $10^3/\text{mm}^3$

RBC: 4.55 $10^6/\text{mm}^3$

HGB: 13.6 g/dl

HCT: 34.8 %

PLT: 260 $10^3/\text{mm}^3$

Modified On: 02/28/2002

By: ABX

Results Table:

Seq. #	Sel	Op.	Running Date	WBC	RBC	HGB	HCT	PLT
1	☒	ABX	02/28/2002 12:03 AM	10.1	4.55	13.6	34.5	261
2	☐	ABX	02/28/2002 12:05 AM	9.9	4.64	13.7	35.5	260
3	☒	ABX	02/28/2002 12:05 AM	9.9	4.55	13.5	34.4	260
4	☒	ABX	02/28/2002 12:06 AM	9.8	4.57	13.6	34.7	254
5	☒	ABX	02/28/2002 12:07 AM	10.1	4.55	13.6	34.5	261
6	☒	ABX	02/28/2002 12:07 AM	9.9	4.64	13.7	35.5	260

Statistics:

N=4

Target Values: WBC 10.0, RBC 4.55, HGB 13.6, HCT 34.8, PLT 260

Actual Coef.: WBC 122.39, RBC 199.43, HGB 43.47, HCT 206.66, PLT 257.9

New Coef.: WBC 122.56, RBC 198.36, HGB 43.5, HCT 206.97, PLT 257.25

Mean: WBC 10.0, RBC 4.57, HGB 13.6, HCT 34.7, PLT 261

Variation Coef.: WBC 1.01, RBC 0.92, HGB 0.66, HCT 1.51, PLT 0.17

Buttons: Start Up, Shut Down, Autocontrol, Cleaning, Backflush, Open Holder, Quit

02/28/2002 12:09:45 AM

1- Select results to be involved in the statistical calculation by clicking checked box in «Sel» column.

- To discard a result from the statistical calculation click again in checked box to remove the mark.

- The instrument calculates the statistical calibration factors for each parameter.

2- If the Coefficient of variation is within the limits setup as described *Chapter 4. Instrument configuration* and the percentage difference between the target and the mean value is less than 20, instrument will allow auto-calibration: Click on **Calibration** to update new calibration coefficients.

- Confirm the change by clicking **OK** in the following dialog box:

ABX WorkStation Information

Confirm Calibration

OK **Cancel**



5. WORKLIST

5.1. Worklist description

- The purpose of the worklist (*Worklist tab*) is to build the list of analyses to be performed and to view all the previous performed analyses.
- The worklist groups, list all the information (fields of the *Worklist tab*) relating to an analysis (patient) file.
- Description of the Worklist's fields:

Seq.#

Sequence number, automatically incremented by the software, is the chronologic number of specimen sampling and is unique.

Sample ID

After capture, the field is compared to the list of Reserved numbers corresponding to the analyses: Control, Calibration or Repeatability. If the number corresponds, the entry is completed automatically, changes to blue and becomes non-modifiable. The Identification field takes the name of the target corresponding to a Control, Calibration or Repeatability blood. If it does not correspond, it will be searched for among already performed analyses, a link is proposed on the existing patient. If it is not found, it is searched for among analyses to be performed. It is rejected if it already exists: this is the guarantee of unicity for analyses that have not been performed. Otherwise, this identification number is accepted (16 characters max.)

Patient Name

Name of the patient: A combo box detects and propose to duplicate an already listed Patient name or to separate it as an another Patient name (30 characters max.).

Patient Number

Number given to a patient, no detection of duplications (16 characters max.).

Test

Choose type of the analysis: Swap between **DIF** and **CBC** mode using SPACE or ENTER key, or use the combo box. Default type is **DIF** mode.

Department

Input patient blood sampling location, choose from one dynamic list or add a new name (10 characters max.).

Birth date

Patient date of birth (MM/DD/YYYY).

Age

Age is automatically updated with the patient date of birth.

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Gender

Choose from one predetermined combo box list: M, F or Blank.

Type

Allows to specify blood profile: Standard, Male, Female, Child... (Default is standard). Use the combo box to choose between types. See *Chapter 4. Instrument configuration* to define blood types.

Physician

Input physician name, choose from one dynamic list or add a new name (17 characters max.).

Collect date

Date and Time of blood collection in MM/DD/YYYY-HH:MM.

Op.

Operator field is automatically updated by the code of the operator who starts the instrument. (not operational at this time)

Comment

Use this field to enter comments (50 characters max.).

- Worklist color scheme:

A white line (free or not) shows a routine analysis to be run (create a new line with

Add new entry, , icon):

ABX			
-----	--	--	--

A red highlighted line shows the sample running at the time:

ABX	JHA49654	Kevin DUPONT
-----	----------	--------------

A green highlighted line shows a routine analysis completed:

ABX	3 12/24/1999 09:16 5656	Dupond
-----	-------------------------	--------

A blue highlighted line shows a cycle such as QC, Calibration or Repeatability, not performed:

ABX		BLANK
-----	--	-------

A pink highlighted line shows a performed service cycle:

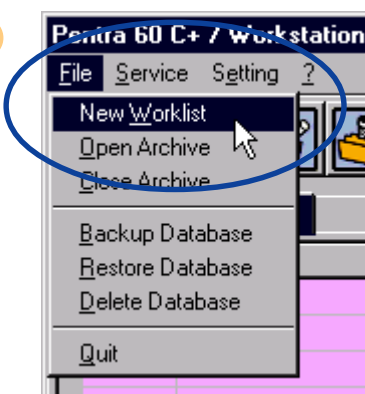
ABX	1 12/24/1999 08:44	BLANK
-----	--------------------	-------

5.2. Creating a new Worklist

- To create a new Worklist open File menu and select New Worklist option:

NOTE

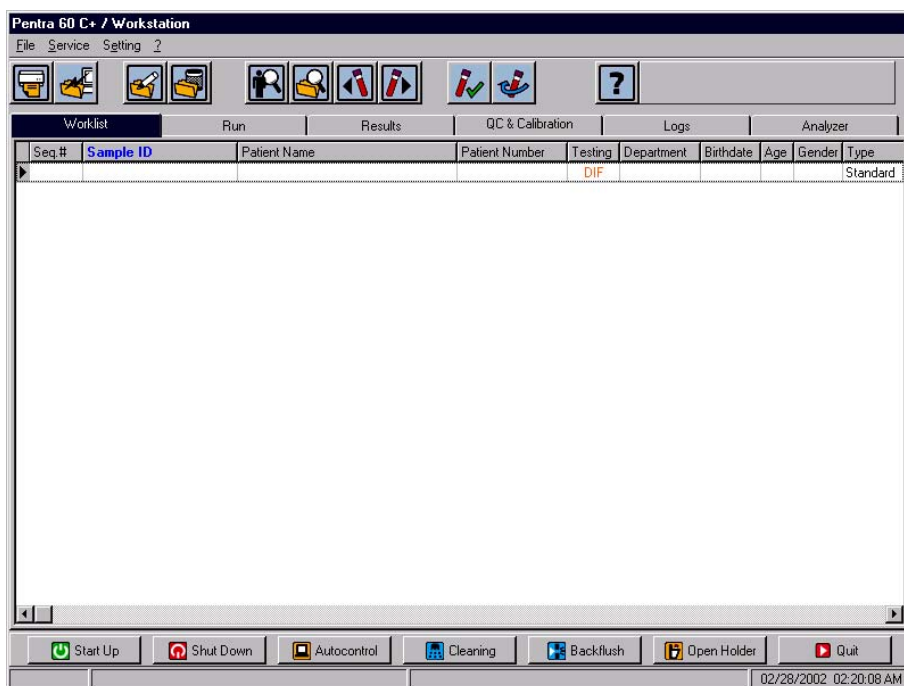
When a new Worklist is created the previous Worklist is automatically stored as an archive file.



NOTE

It is recommended to create a new Worklist everyday.

- An empty Worklist is opened:



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5.3. Worklist edition

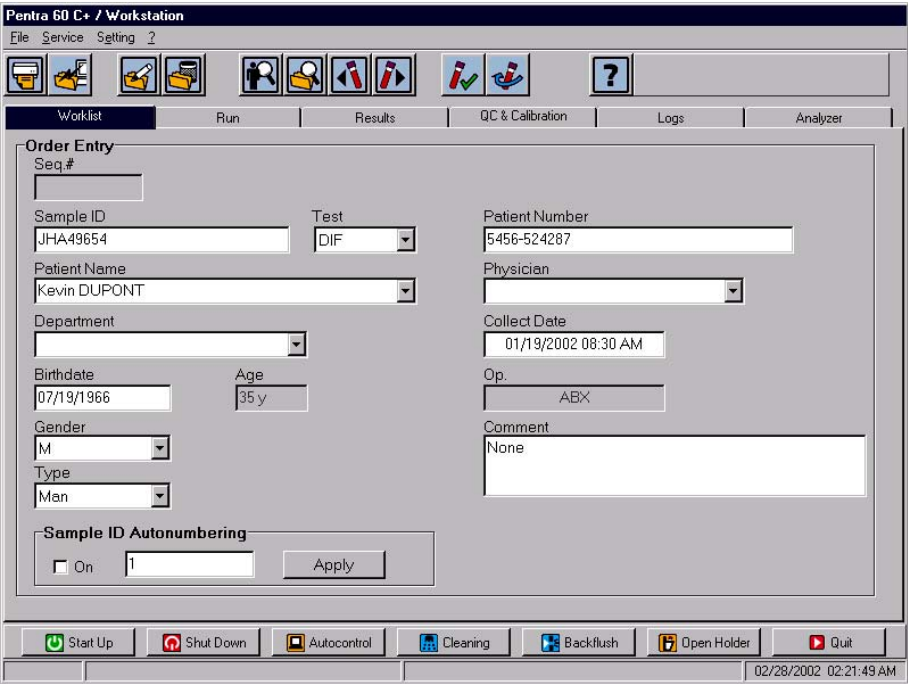
NOTE

If you run a sample without creating a patient file, a line will be automatically added at the end of the Worklist with default values and cannot be modified.

- To create a new patient file from the worklist, or from the «**Patient file**» window:
Click «**Add new entry**», , icon, a line is added at the end of the worklist, or a new patient file is opened (you can use  icon in tool bar to swap between «**Worklist**» and «**Patient file**» windows).

- From the «**Patient file**» window capture patient's datas:

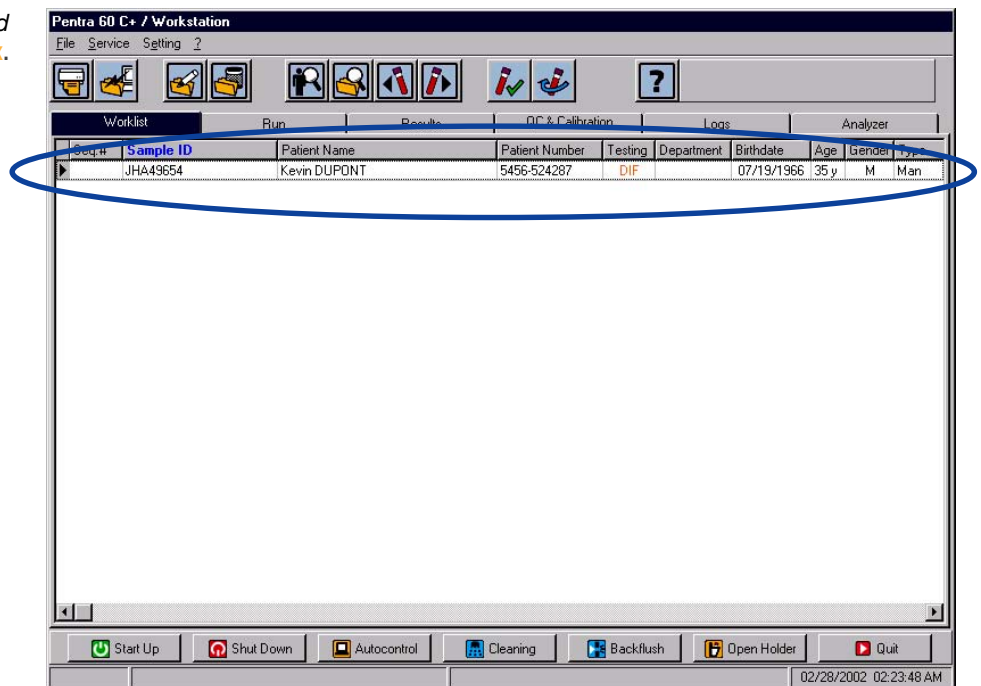
+ **Use TAB key to move from one field to another, SPACE or ENTER key to swap between positions.**



The screenshot displays the 'Pentra 60 C+ / Workstation' software interface. The 'Order Entry' window is active, showing a form for entering patient and sample data. The form includes fields for Sample ID (JHA49654), Test (DIF), Patient Number (5456-524287), Patient Name (Kevin DUPONT), Department, Birthdate (07/19/1966), Age (35 y), Gender (M), Type (Man), and Collect Date (01/19/2002 08:30 AM). There is also a section for 'Sample ID Autonumbering' with a checkbox 'On' and an 'Apply' button. The bottom of the window features a toolbar with icons for Start Up, Shut Down, Autocontrol, Cleaning, Backflush, Open Holder, and Quit. The status bar at the bottom right shows the date and time: 02/28/2002 02:21:49 AM.

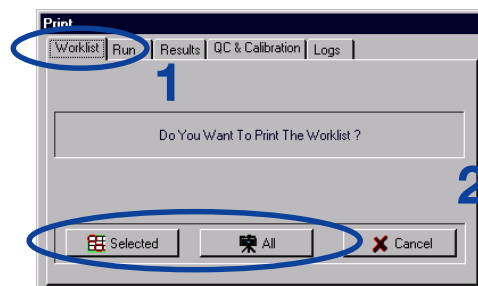
- In the worklist the new file is shown as follow:

+ See Worklist's keyboard shortcuts in the [Annex](#).



5.4. Worklist printout

- Click toolbar  icon, or «Menu\File\Printer», to open «Printer» dialog box:



1- Enter «**Worklist**» Tab.

2- Click  Selected button to print only selected worklist lines (patient line selection + CTRL key), or  All button to print all the worklist lines.

Pentra 60 C+

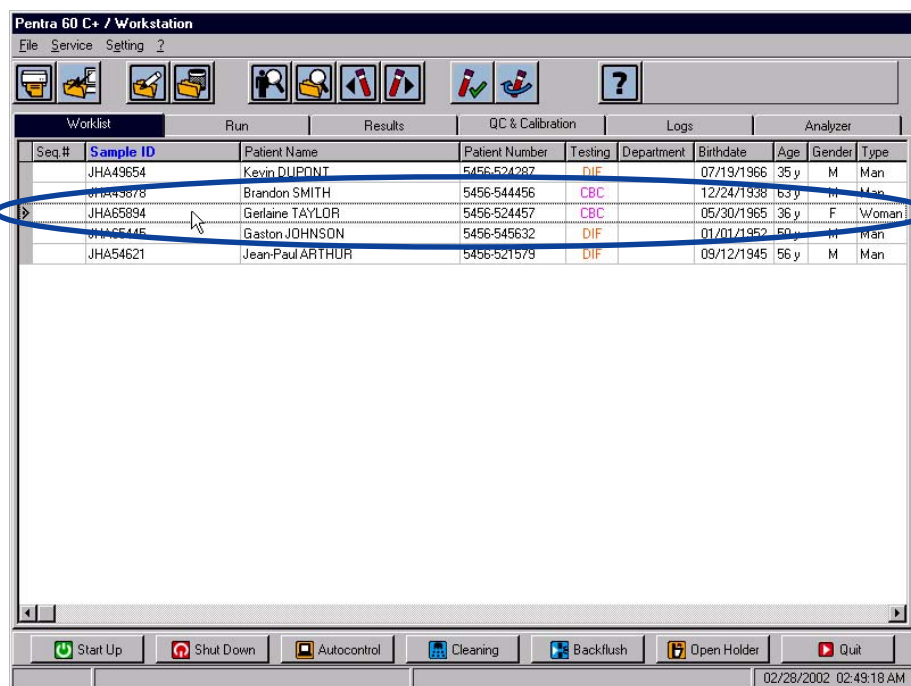
6. RUNNING SPECIMENS

- The specimen to be run is the first selected line in the Worklist or, if no line is selected, the line following last specimen ran or the first.

+ If you want to run a particular specimen, click the line holding CTRL key: the line is selected and the icon  appears in the lefthand column.

NOTE

This specimen will be the next to be run.



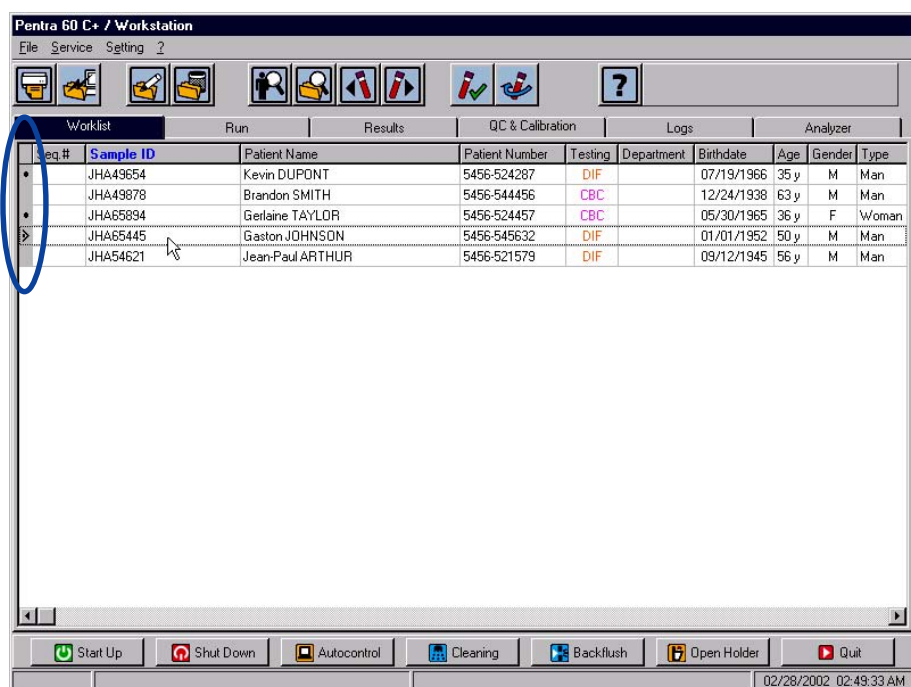
Pentra 60 C+ / Workstation									
File Service Setting ?									
									
Worklist		Run	Results	QC & Calibration	Logs	Analyzer			
Seq #	Sample ID	Patient Name	Patient Number	Testing	Department	Birthdate	Age	Gender	Type
▶	JHA49654	Kevin DUPONT	5456-524287	DIF		07/19/1966	35 y	M	Man
	JHA49878	Brandon SMITH	5456-544456	CBC		12/24/1938	63 y	M	Man
	JHA65894	Gerlaine TAYLOR	5456-524457	CBC		05/30/1965	36 y	F	Woman
	JHA65445	Gaston JOHNSON	5456-545632	DIF		01/01/1952	50 y	M	Man
	JHA54621	Jean-Paul ARTHUR	5456-521579	DIF		09/12/1945	56 y	M	Man

Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit 02/28/2002 02:49:18 AM

+ If you want to run several particular specimens, click all the different lines holding CTRL key, the lines are selected, the icon  appears in the lefthand column (except for the first).

NOTE

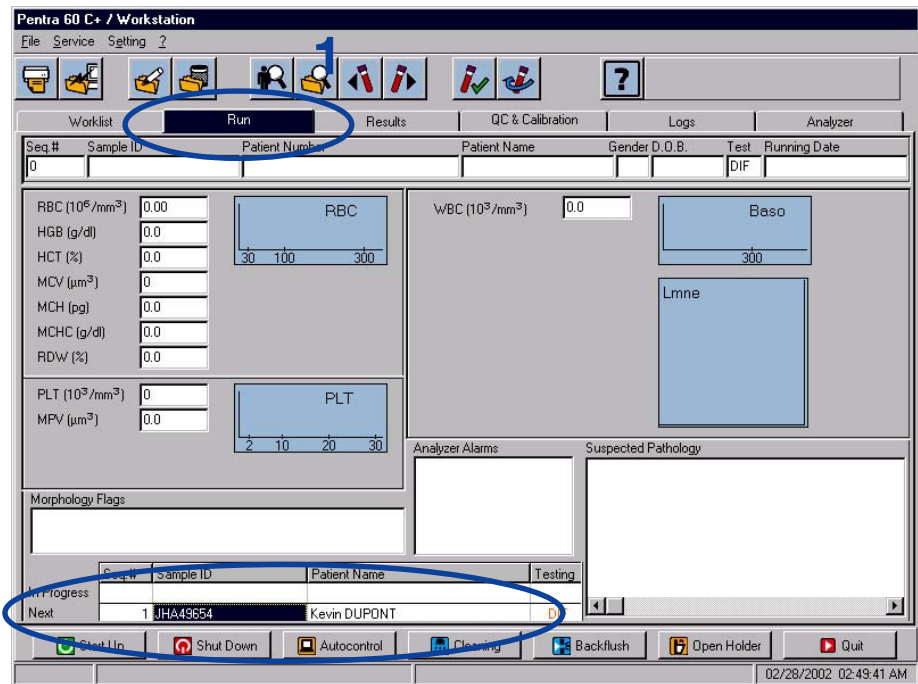
Worklist selected patient lines are the next specimens to be run (from the top to the end of the list).



Pentra 60 C+ / Workstation									
File Service Setting ?									
									
Worklist		Run	Results	QC & Calibration	Logs	Analyzer			
Seq #	Sample ID	Patient Name	Patient Number	Testing	Department	Birthdate	Age	Gender	Type
◀	JHA49654	Kevin DUPONT	5456-524287	DIF		07/19/1966	35 y	M	Man
◀	JHA49878	Brandon SMITH	5456-544456	CBC		12/24/1938	63 y	M	Man
◀	JHA65894	Gerlaine TAYLOR	5456-524457	CBC		05/30/1965	36 y	F	Woman
◀	JHA65445	Gaston JOHNSON	5456-545632	DIF		01/01/1952	50 y	M	Man
◀	JHA54621	Jean-Paul ARTHUR	5456-521579	DIF		09/12/1945	56 y	M	Man

Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit 02/28/2002 02:49:33 AM

1- Enter «Run» Tab.



- The next specimen to be run is shown in «Run» tab, field «Next»:

IMPORTANT

Blood specimen must be thoroughly and gently mixed (with a gentle up and down and rolling motion), before any measurement.

- Present the specimen as shown on the diagram to the right. When green LED is lit, close tube holder door to start sampling.
- When tube holder opens remove the tube. When the LED turns to green again the instrument is ready for the next analysis.

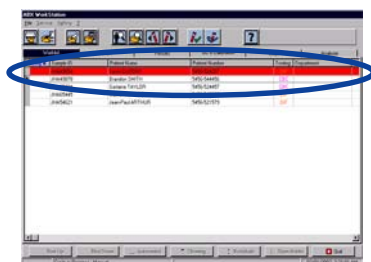


+ LEDs flash during specimen aspiration.

Pentra 60 C+

- «Run» tab shows during analysis of the specimen in progress («In progress» field) and the sample coming next («Next» field):

+ In Worklist the actual specimen running is highlighted in red:



Pentra 60 C+ / Workstation

File Service Setting ?

Worklist Run Results QC & Calibration Logs Analyzer

Seq.#	Sample ID	Patient Number	Patient Name	Gender	D.O.B.	Test	Running Date
0						DIF	

RBC ($10^6/\text{mm}^3$) 0.00 RBC WBC ($10^3/\text{mm}^3$) 0.0 Baso

HGB (g/dl) 0.0 HCT (%) 0.0 MCV (μm^3) 0 MCH (pg) 0.0 MCHC (g/dl) 0.0 RDW (%) 0.0

PLT ($10^3/\text{mm}^3$) 0 MPV (μm^3) 0.0

Morphology Flags

Analyzer Alarms Suspected Pathology

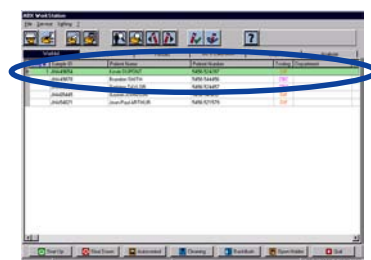
Seq.#	Sample ID	Patient Name	Testing
In Progress	1 JHA49654	Kevin DUPONT	CBC
Next	2 JHA49878	Brandon SMITH	CBC

Start Up Start Down Autocontrol Cleaning Backflush Open Holder Quit

Cycle in Progress : Manual 02/28/2002 02:49:41 AM

- At the end of the analysis, «Run» tab displays the results for the last specimen:

+ In Worklist, the line corresponding to the ran specimen has been highlighted in green:



ABX WorkStation

File Service Setting ?

Worklist Run Results QC & Calibration Logs Analyzer

Seq.#	Sample ID	Patient Number	Patient Name	Gender	D.O.B.	Test	Running Date
1	JHA49654	5456-524287	Kevin DUPONT	M	07/19/1966	CBC	03/01/2002 2:34:02 AM

RBC ($10^6/\text{mm}^3$) 4.61 RBC WBC ($10^3/\text{mm}^3$) 5.8 Baso

HGB (g/dl) 13.7 HCT (%) 39.5 MCV (μm^3) 86 MCH (pg) 29.7 MCHC (g/dl) 34.8 RDW (%) 15.3

PLT ($10^3/\text{mm}^3$) 203 MPV (μm^3) 9.9

Morphology Flags

Analyzer Alarms Suspected Pathology

Seq.#	Sample ID	Patient Name	Testing
In Progress	1 JHA49654	Kevin DUPONT	CBC
Next	2 JHA49878	Brandon SMITH	CBC

Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

03/01/2002 3:20:10 AM



Specimen run & Results

7. RESULTS

7.1. CBC Mode

7.1.1. Print output

Header ABX Parc Euromedecine Laboratoire d'hématologie Rue du Caducée - Montpellier
ABX Contact : Tel : 04-67-67-67-68 Fax : 04-67-67-67-68

Patient file **Patient Name :** Kevin DUPONT **Collect Date :** 01/19/2002 8:30 AM
Patient Number : 5456-524287 **Operator :** ABX **Department :**
Seq # : 4 **Sample ID :** JHA49654 **Physician :**
Birthdate : 07/19/1966 **Age :** 35 y **Gender :** M **Running Date :** 03/01/2002 2:34:02 AM **Blood Type :** Man
Comment : None

Results

	WBC	5.8	10 ⁶ /mm ³	Range 5.0 ... 12.0

	RBC	4.61	10 ¹² /mm ³	Range 4.00 ... 6.20
	HGB	13.7	g/dl	11.0 ... 18.8
	HCT	39.5	%	35.0 ... 55.0
	MCV	86	µm ³	80 ... 100
	MCH	29.7	pg	26.0 ... 34.0
	MCHC	34.8	g/dl	31.0 ... 35.0
	RDW	15.3	%	10.0 ... 20.0

Pathology flags **Suspected Pathology**

	PLT	203	10 ³ /mm ³	Range 150 ... 400
	MPV	9.9	µm ³	6.0 ... 10.0

Alarms **Morphology Flags** **Analyzer Alarms**

Microscopic Examination

Anisocytosis	☐	☐	☐	Neutrophils	_____	Metamyelocytes	_____
Hypochromia	☐	☐	☐	Band Cells	_____	Myelocytes	_____
Polychromasia	☐	☐	☐	Lymphocytes	_____	Promyelocytes	_____
Poikilocytosis	☐	☐	☐	Monocytes	_____	Blasts	_____
Microcytosis	☐	☐	☐	Eosinophils	_____	Atypical	_____
Macrocytosis	☐	☐	☐	Basophils	_____	NRBC's	_____
Plts Aggregates	☐	☐	☐	Comment :			

Legend > < HI, Limits **XXX** > < HI Limits **XXX** Reject **XXX** F: Female, M: Male, U: Unknown 03/01/2002 2:42:39 AM

Date time

Pentra 60 C+

7.1.2. Result tab

+ **The result is not validated**

+ **Patient file**

+ **CBC Results & Histograms**

+ **Morphology flags**

+ **Instrument alarms**

+ **Pathology flags**

Seq #	Sample ID	Patient Number	Patient Name	Gender	D.O.B	Test	Running Date
1	JHA49654	5456-524287	Kevin DUPONT	M	07/19/1966	CBC	03/01/2002 2:34:02 AM

Parameter	Value
RBC ($10^6/\text{mm}^3$)	4.61
HGB (g/dl)	13.7
HCT (%)	39.5
MCV (μm^3)	86
MCH (pg)	29.7
MCHC (g/dl)	34.8
RDW (%)	15.3
PLT ($10^3/\text{mm}^3$)	203
MPV (μm^3)	9.9

+ **The result is validated**

+ **The rerun option has been selected for this sample. The specimen line is duplicated in the worklist and will be the next sample to be run**

7.2. 5DIFF Mode

7.2.1 Print output

Header

ABX Parc Euromedecine
ABX Contact :

Laboratoire d'hématologie
Tel : 04-67-67-67-68

Rue du Caducée - Montpellier
Fax : 04-67-67-67-68

+

Patient file

Patient Name: Kevin DUPONT **Collect Date:** 01/19/2002 8:30 AM

Patient Number: 5456-524287 **Operator:** ABX **Department:**

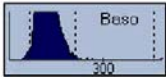
Seq #: 3 **Sample ID:** JHA49654 **Physician:**

Birthdate: 07/19/1966 **Age:** 35 y **Gender:** M **Running Date:** 03/01/2002 2:30:50 AM **Blood Type:** Man

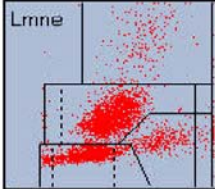
Comment: None

+

Results

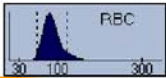


	WBC	5.8	10 ⁹ /mm ³	Range
%			5.0 ... 12.0	
NEU	51.1	!	2.94	!
LYM	35.1	!	2.02	!
MON	8.0	!	0.46	!
EOS	4.6	!	0.26	!
BAS	1.2		0.07	



+

Pathology flags



	RBC	4.58	10 ¹² /mm ³	Range
HGB	13.6			4.00 ... 6.20
HCT	39.0			11.0 ... 18.8
MCV	85			35.0 ... 55.0
MCH	29.8			80 ... 100
MCHC	35.0	h		26.0 ... 34.0
RDW	14.1			31.0 ... 35.0
PLT	198			10.0 ... 20.0
MPV	9.6			150 ... 400
				6.0 ... 10.0

Suspected Pathology

LEUKO : nrbc

+

Alarms

Morphology Flags

Leuko : LL, LL1

Analyzer Alarms

Microscopic Examination

+ ++ +++	Anisocytosis Hypochromia Polychromasia Poikilocytosis Microcytosis Macrocytosis Pits Aggregates	Neutrophils Band Cells Lymphocytes Monocytes Eosinophils Basophils Comment :
	Metamyelocytes Myelocytes Promyelocytes Blasts Atypical NRBC's	

Legend

> < H/L Limits XXX > < H/L Limits XXX Reject XXX

F: Female, M: Male, U: Unknown

03/01/2002 2:47:15 AM

+

Date time

Pentra 60 C+

7.2.2. Result tab

ABX WorkStation

File Service Setting ?

Worklist Run Results QC & Calibration Logs Analyzer

Seq.# Sample ID Patient Number Patient Name Gender D.O.B. Test Running Date

3 JHA49654 5456-524287 Kevin DUPONT M 07/19/1966 DIF 03/01/2002 2:30:50 AM

RBC ($10^6/\text{mm}^3$) 4.58 **HGB** (g/dl) 13.6 **HCT** (%) 39.0 **MCV** (μm^3) 85 **MCH** (pg) 29.8 **MCHC** (g/dl) 35.0 h **RDW** (%) 14.1

WBC ($10^3/\text{mm}^3$) 5.8 **NEU%** 51.1 ! **LYM%** 35.1 ! **MON%** 8.0 ! **EOS%** 4.6 ! **BAS%** 1.2

PLT ($10^3/\text{mm}^3$) 198 **MPV** (μm^3) 9.6

Morphology Flags
LL LL1

Analyzer Alarms

Suspected Pathology
NRBCs

Start Up **Shut Down** **Autocontrol** **Cleaning** **Backflush** **Open Holder** **Quit**

03/01/2002 3:16:00 AM

Annotations:

- Patient file**: Points to the Patient Number field.
- DIF Results & Histograms**: Points to the RBC histogram.
- Morphology flags**: Points to the Morphology Flags section.
- The result is not validated**: Points to the empty box in the Analyzer Alarms section.
- Instrument alarms**: Points to the Analyzer Alarms section.
- Pathology flags**: Points to the Suspected Pathology section.

The result is validated

Annotations:

- Points to the green box in the Analyzer Alarms section.

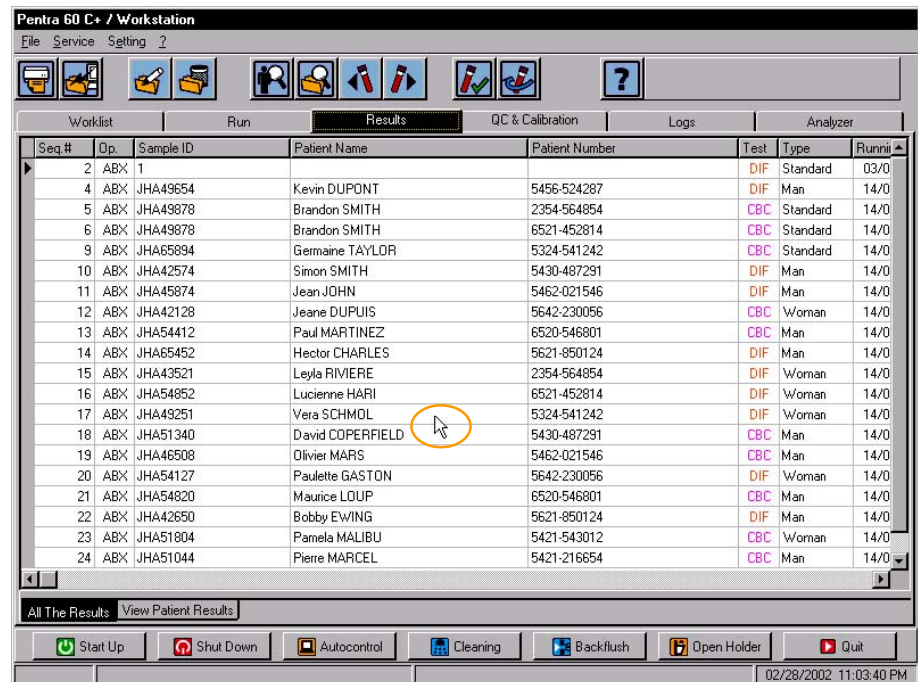
The rerun option has been selected for this sample. The specimen line is duplicated in the worklist and will be the next sample to be run

Annotations:

- Points to the red box in the Analyzer Alarms section.

7.3. «Results» tab in List mode

- To select and display one result from the list, double click over the **«Results»** tab to display the **«All The Results»** tab, then, double click over the result in the list to display it:



Pentra 60 C+ / Workstation
File Service Setting 2

Worklist Run Results QC & Calibration Logs Analyzer

Seq #	Op	Sample ID	Patient Name	Patient Number	Test	Type	Runni
2	ABX	1			DIF	Standard	03/0
4	ABX	JHA49654	Kevin DUPONT	5456-524287	DIF	Man	14/0
5	ABX	JHA49878	Brandon SMITH	2354-564854	CBC	Standard	14/0
6	ABX	JHA49878	Brandon SMITH	6521-452814	CBC	Standard	14/0
9	ABX	JHA65894	Germaine TAYLOR	5324-541242	CBC	Standard	14/0
10	ABX	JHA42574	Simon SMITH	5430-487291	DIF	Man	14/0
11	ABX	JHA45874	Jean JOHN	5462-021546	DIF	Man	14/0
12	ABX	JHA42128	Jeane DUPUIS	5642-230056	CBC	Woman	14/0
13	ABX	JHA54412	Paul MARTINEZ	6520-546801	CBC	Man	14/0
14	ABX	JHA65452	Hector CHARLES	5621-850124	DIF	Man	14/0
15	ABX	JHA43521	Leyla RIVIERE	2354-564854	DIF	Woman	14/0
16	ABX	JHA54852	Lucienne HARI	6521-452814	DIF	Woman	14/0
17	ABX	JHA49251	Vera SCHMOL	5324-541242	DIF	Woman	14/0
18	ABX	JHA51340	David COPERFIELD	5430-487291	CBC	Man	14/0
19	ABX	JHA48508	Olivier MARS	5462-021546	CBC	Man	14/0
20	ABX	JHA54127	Paulette GASTON	5642-230056	DIF	Woman	14/0
21	ABX	JHA54820	Maurice LOUP	6520-546801	CBC	Man	14/0
22	ABX	JHA42650	Bobby EWING	5621-850124	DIF	Man	14/0
23	ABX	JHA51804	Pamela MALIBU	5421-543012	CBC	Woman	14/0
24	ABX	JHA51044	Pierre MARCEL	5421-216654	CBC	Man	14/0

All The Results View Patient Results

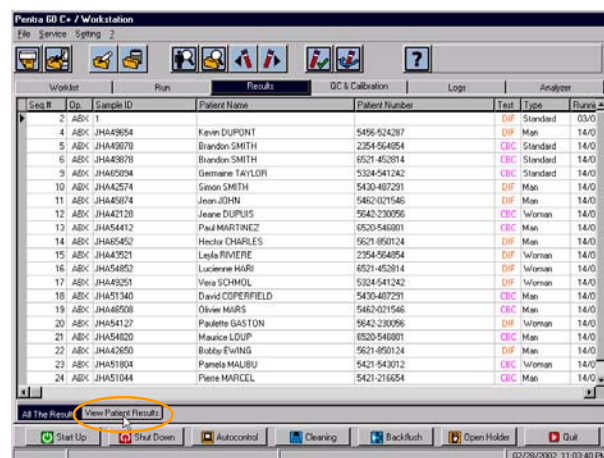
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

02/28/2002 11:03:40 PM

- To find one result in the worklist or in the archived lists, click over the **«View Patient Results»** tab:

NOTE

Research is done on results that have a «Patient Name» field unempty (Even if the criterions are Patient Number or Sample ID).



Pentra 60 C+ / Workstation
File Service Setting 2

Worklist Run Results QC & Calibration Logs Analyzer

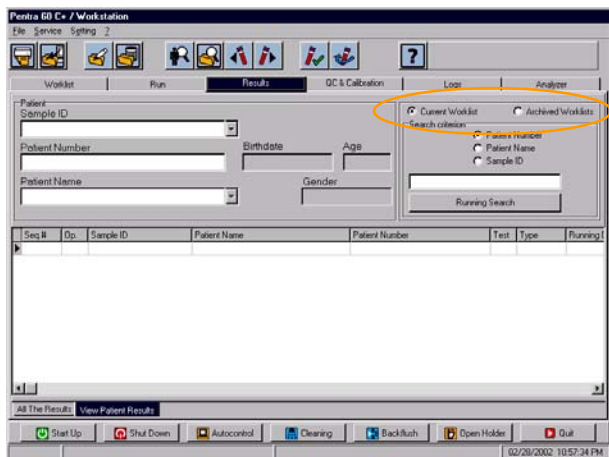
Seq #	Op	Sample ID	Patient Name	Patient Number	Test	Type	Runni
2	ABX	1			DIF	Standard	03/0
4	ABX	JHA49654	Kevin DUPONT	5456-524287	DIF	Man	14/0
5	ABX	JHA49878	Brandon SMITH	2354-564854	CBC	Standard	14/0
6	ABX	JHA49878	Brandon SMITH	6521-452814	CBC	Standard	14/0
9	ABX	JHA65894	Germaine TAYLOR	5324-541242	CBC	Standard	14/0
10	ABX	JHA42574	Simon SMITH	5430-487291	DIF	Man	14/0
11	ABX	JHA45874	Jean JOHN	5462-021546	DIF	Man	14/0
12	ABX	JHA42128	Jeane DUPUIS	5642-230056	CBC	Woman	14/0
13	ABX	JHA54412	Paul MARTINEZ	6520-546801	CBC	Man	14/0
14	ABX	JHA65452	Hector CHARLES	5621-850124	DIF	Man	14/0
15	ABX	JHA43521	Leyla RIVIERE	2354-564854	DIF	Woman	14/0
16	ABX	JHA54852	Lucienne HARI	6521-452814	DIF	Woman	14/0
17	ABX	JHA49251	Vera SCHMOL	5324-541242	DIF	Woman	14/0
18	ABX	JHA51340	David COPERFIELD	5430-487291	CBC	Man	14/0
19	ABX	JHA48508	Olivier MARS	5462-021546	CBC	Man	14/0
20	ABX	JHA54127	Paulette GASTON	5642-230056	DIF	Woman	14/0
21	ABX	JHA54820	Maurice LOUP	6520-546801	CBC	Man	14/0
22	ABX	JHA42650	Bobby EWING	5621-850124	DIF	Man	14/0
23	ABX	JHA51804	Pamela MALIBU	5421-543012	CBC	Woman	14/0
24	ABX	JHA51044	Pierre MARCEL	5421-216654	CBC	Man	14/0

All The Results View Patient Results

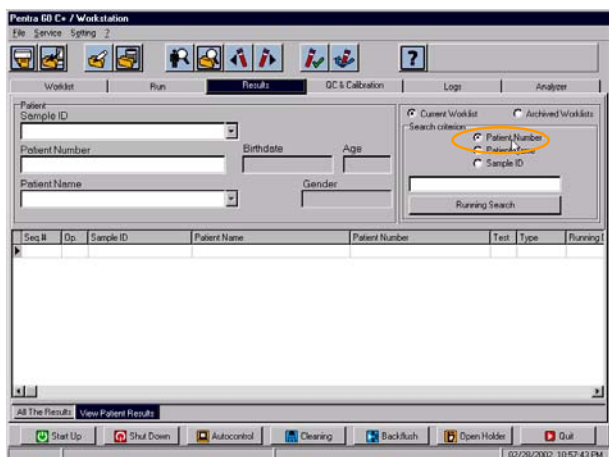
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

02/28/2002 11:03:40 PM

Pentra 60 C+

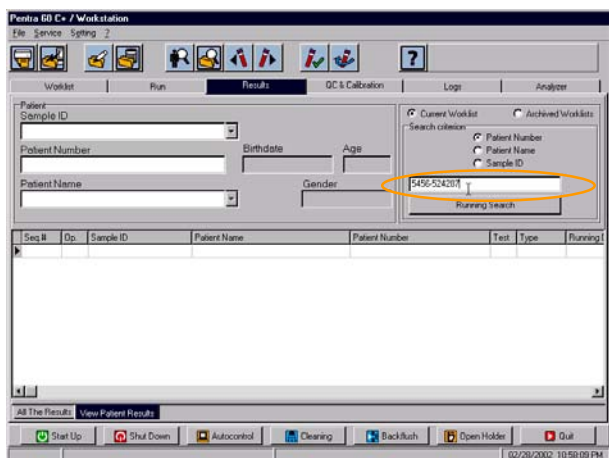


- Select the research over the Current worklist or over the Archived worklists.



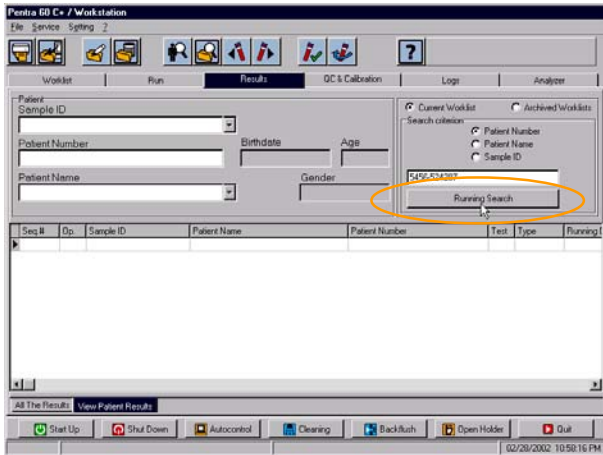
- Select the criterion used for the research:

Patient Number
Patient Name
Sample ID



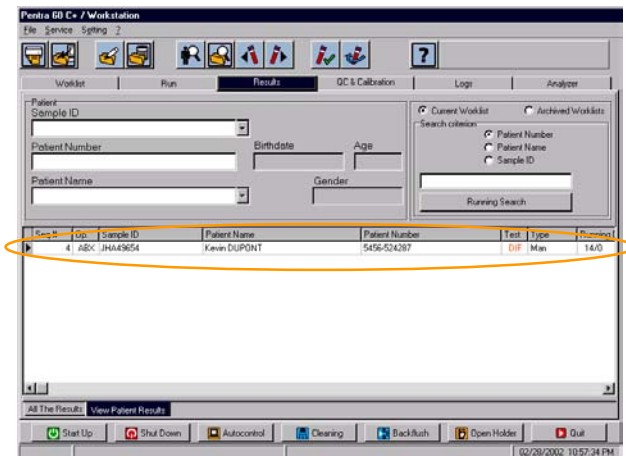
- Enter your research object.

(Exemple: Patient Number = 5456-524287)



- Start the research by clicking over the button

Running Search



- If the research is succeed, the result is displayed:

Pentra 60 C+

7.4. Flags

These flags can be divided up into 5 different groups:

- Flags linked to a result when it exceeds the normality limits.
- Flags linked to a problem in the morphology of blood cell population.
- Flags linked to a result or to instrument operation leading to a «default analysis».
- Flags linked to instrument in use.

NOTE

Each flag sensitivity can be adjusted by the operator (see Chapter 4. Instrument configuration)

7.4.1. Normal and panic ranges

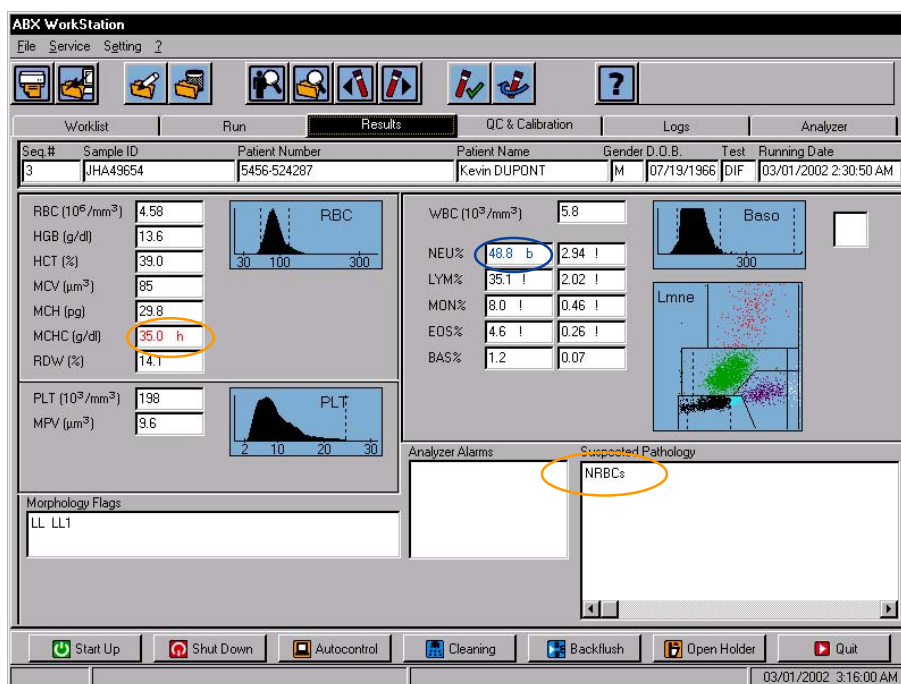
«h» indicates that the result is above the normal limit set by the user.

«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 may be criteria for the pathology messages.



7.4.2. Flags giving an analysis default

Different alarms can be activated if a parameter result exceeds instrument capacity:

- Result forced to 0,
- Replaced by ----,
- Result associated with an asterisk (*) or exclamation mark (!)

Results exceeding instrument capacity

PARAM.	CONDITIONS	CONSEQUENCES
WBC	$> 120 \times 10^3/\mu\text{L}$	WBC replaced by ---- D
	$> 150 \times 10^3/\mu\text{L}$	Diff # results replaced by ----
WBC and	$< 0 \times 10^3/\mu\text{L}$	Diff results replaced by ---- No WBC flag occurs No WBC/Baso histogram
RBC	$< 0.1 \times 10^6/\mu\text{L}$	No LMNE matrix
RBC	$\leq 0.01 \times 10^6/\mu\text{L}$	RDW, MCV, MCH, MCHC, RBC forced to 0 No RBC histogram
Hgb	$< 0.7 \text{ g/dL}$	Hgb forced to 0
	$< 2 \text{ g/dL}$	MCH, MCHC forced to 0
Hct	$< 0.7 \%$	Hct forced to 0
	$> 80 \%$	Hct replaced by ---- D
MCV	$< 10 \text{ fL}$	RDW replaced by ----
	$> 199 \text{ fL}$	MCV replaced by ----
Plt	$< 5.0 \times 10^3/\mu\text{L}$	MPV, Pct, PDW replaced by ---- No SCL flag occurs No Plt histogram
	MIC flag	PDW replaced by ----
	or SCL flag	
Pct	or $\text{Plt} < 5.0 \times 10^3/\mu\text{L}$	Pct replaced by ----
	SCL flag	
MPV	or $\text{Plt} < 5.0 \times 10^3/\mu\text{L}$	MPV replaced by ----
	SCL flag	

NOTE

Use the instrument diluent to dilute the sample if a ---- D flag occurs on WBC or Hct.

+ See Chapter 4. **Instrument configuration** to defined BHB# and MHB %.

Hgb blank

- At the end of the Startup cycle, the Hgb blank value is controlled. If this value is not within acceptable limits, a reject flag (shown by *) is triggered on the Hgb parameter.
- On each analysis cycle, the instrument performs a Hgb blank on diluent and checks this measured against the Hgb reference value. If this Hgb blank value is too different from the mean of the reference values of previous analyzes (higher than BHB# defined by the user) the instrument triggers a suspicion flag (shown by !) on the Hgb parameter.
- (!) is also associated with Hgb result if the difference between 3 successive measures on the same sample is higher than MHB % limit defined by the user.
- Sample has to be rerun.

NOTE

No result will be given on Hgb [----] instead] when 3 suspicion flags (!) associated with the Hgb reference value have been triggered off (MCHC and MCH are also not reported).

Reject (between two counts)

- A reject flag (shown by *) occurs when two counts on a parameter differ more than the pre-defined limits. It indicates that the result is not coherent and the sample has to be rerun.
- **RBC**
A reject on RBC gives a default analysis value, shown by a * on RBC, MCV, MCH, MCHC and RDW.
- **Plt**
A reject on Plt gives a default analysis value, shown by a * on Plt, Pct, MPV and PDW.
- **WBC**
A reject on WBC gives a default analysis value, shown by a * on WBC and Diff # results.

7.4.3. LMNE matrix flags

Suspicion

- When populations are detected in abnormal quantity in one or several boxes of the matrix, some flags may occur associated with (!).
If one result appears with one or several parameters associated with this (!), the result should be further investigated (pathology suspicion, clotted sample, plasma cells...).
- Twelve different flags may occur regarding the shifting of leukocyte populations on the matrix channel or the presence of abnormal populations.
These flags are: **Reject, NO, LL, LL1, NL, MN, RM, LN, RN, NE, ALY, GCI** (see flag signification further in this *Chapter*).

Reject (on LMNE matrix)

- 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 result is not reliable and specimen must be rerun.

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NO flag

Meaning: Background **NO**ise.

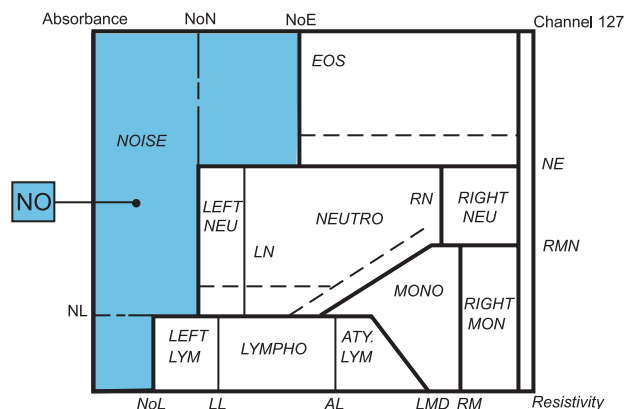
This flag occurs when the number of particles counted in the background noise area is higher than the limit set up in **NO#** or when the number of counted particles versus the total number of WBC, is above the **NO%** limit.

Suspected abnormalities:

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

+ **Standard values for NO:**
%100
#120

Adjustment:
see Chapter 4. **Instrument**
configuration



NOTE

This alarm is displayed in the «Analyzer Alarm» area on the result ticket.

LL flag

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:

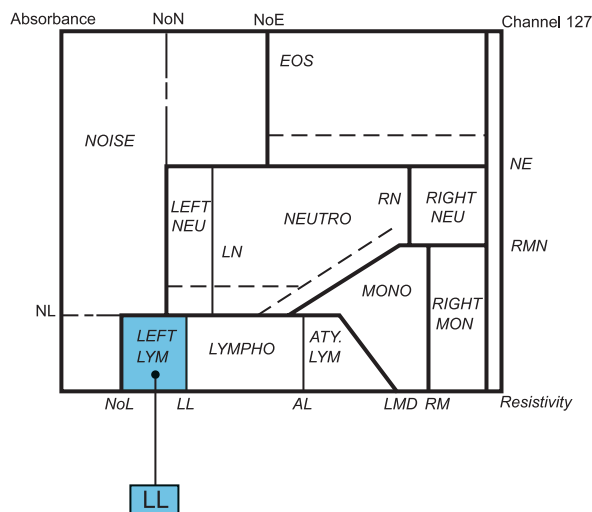
- Small lymphocytes,
- Platelets aggregates,
- NRBCs,
- Erythrocyte membrane resistant to lysis (stroma).

This flag occurs associated with an (!) on:

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

+ **Standard values for LL:**
% 100
50

Adjustment:
see Chapter 4. **Instrument
configuration**



Pentra 60 C+

LL1 flag

Meaning: Left Lymphocytes 1

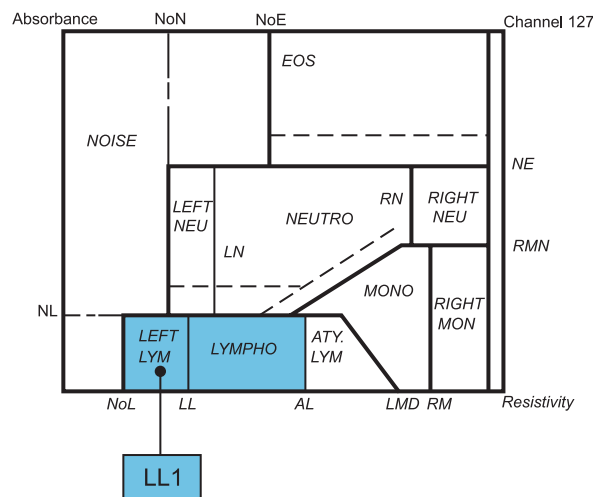
Presence of a significantly large population of cells on the left-hand side of the lymphocytes area. This flag occurs when the number of particles counted is higher than the limit set up in **LL1#** *and* when the number of particles counted in **LL** regarding to the total number of lymphocytes is above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

Suspected abnormalities:

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

+ **Standard values for LL1:**
 % 5
 # 45

Adjustment:
 see Chapter 4. **Instrument**
configuration



NL flag

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 to the total number of WBC is above **NL%** limit.

Suspected abnormalities:

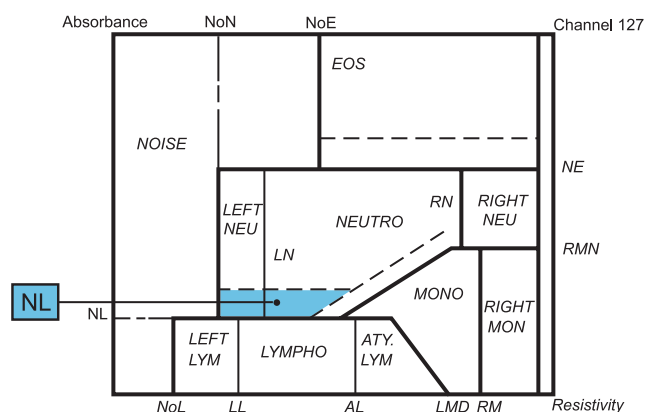
- Small neutrophils without granules and/or slightly segmented,
- Lymphocytes with a segmented nucleus or Activated Lymphocytes,
- Neutrophils with membrane weakness.

This flag occurs associated with an (!) on:

- LYM % LYM #
- NEU % NEU #

+ **Standard values for NL:**
% 3
120

Adjustment:
see Chapter 4. **Instrument
configuration**



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MN flag

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 occurs associated with an (!) on:

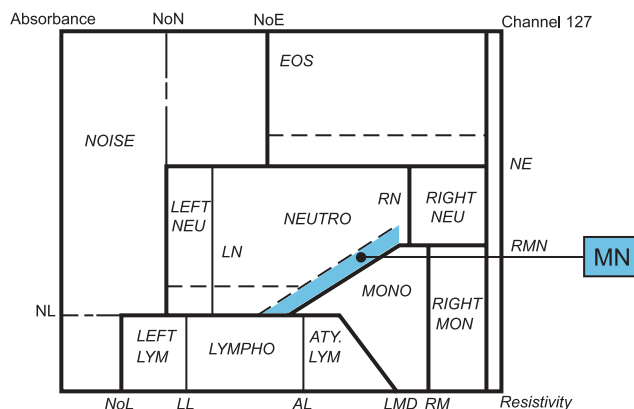
- ALY % ALY #
- LIC % LIC #

and replaces:

- NEU %, NEU #, MON %, MON # by ----

+ **Standard values for MN:**
% 100
120

Adjustment:
see Chapter 4. **Instrument**
configuration



LN flag

Meaning: **Left Neutro**

Presence of a significantly large population of cells located on the lefthand 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.

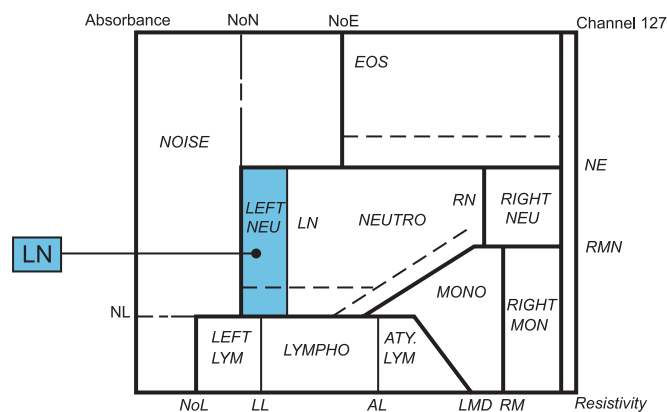
Suspected abnormalities:

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

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

+ **Standard values for LN:**
% 2.5
999

Adjustment:
see Chapter 4. **Instrument
configuration**



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NE flag

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:

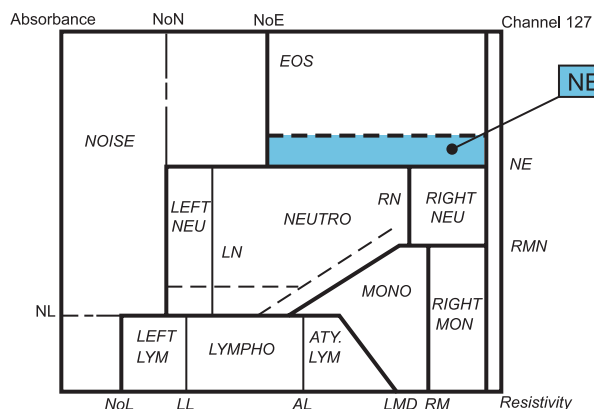
- LIC % LIC #

and replaces:

- NEU %, NEU #, EOS %, EOS # by ----

+ **Standard values for NE:**
% 1.1
60

Adjustment:
see Chapter 4. **Instrument configuration**



ALY flag

Meaning: Atypical Lymphocytes

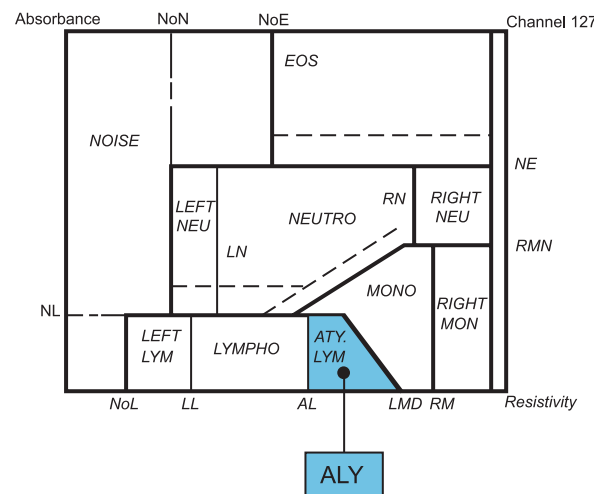
Presence of a significantly large population of cells located on the righthand side of the Lymphocytes area. This flag occurs when the number of particles counted in this area is higher than the limit setup in **ALY#** or when the number of particles counted regarding the total number of WBC is above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

Suspected abnormalities:

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

+ **Standard values for ALY:**
% 2
0.2

Adjustment:
see Chapter 4. **Instrument
configuration**



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RM flag

Meaning: **R**ight **M**ono

Presence of a significantly large population of cells located on the righthand 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:

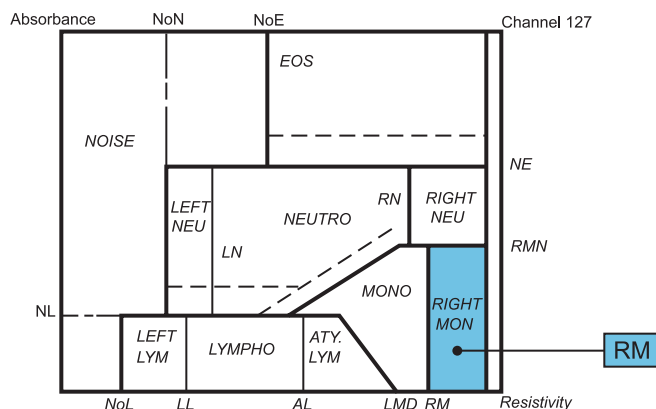
- Large monocytes,
- Hyperbasophilic monocytes,
- Myelocytes or promyelocytes,
- Large blasts.

This flag occurs associated with an (!) on:

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

+ **Standard values for RM:**
% 1.1
999

Adjustment:
see Chapter 4. **Instrument**
configuration



RN flag

Meaning: **Right Neutro**

Presence of a significantly large population of cells located on the righthand 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:

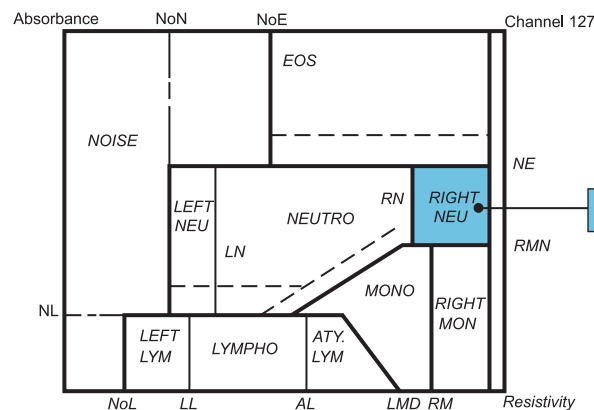
- Large neutrophils,
- Immature cells from granulocyte hemopoiesis (metamyelocytes, myelocytes, promyelocytes).

This flag is associated with an (!) on:

- NEU % NEU #
- LIC % LIC #

+ **Standard values for RN:**
% 1.1
999

Adjustment:
see Chapter 4. **Instrument
configuration**



Pentra 60 C+

LIC flag

Meaning: Large Immature Cells

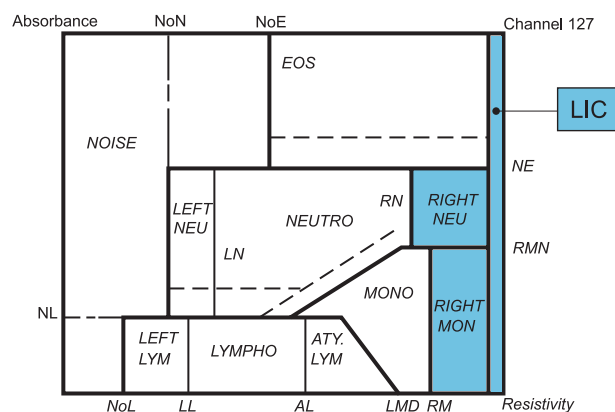
Presence of a significantly large population of cells located on **RN + RM + channel 127** areas. This flag occurs when the number of particles counted in this area is higher than the limit set up in **LIC#**, or when the number of counted particles regarding to the total number of WBC is above the **LIC%** limit.

Suspected abnormalities:

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

+ **Standard** values for **LIC**:
% 2
0.2

Adjustment:
see Chapter 4. **Instrument**
configuration



7.4.4. Flags on WBC/BASO histogram

CBC and DIFF Mode

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

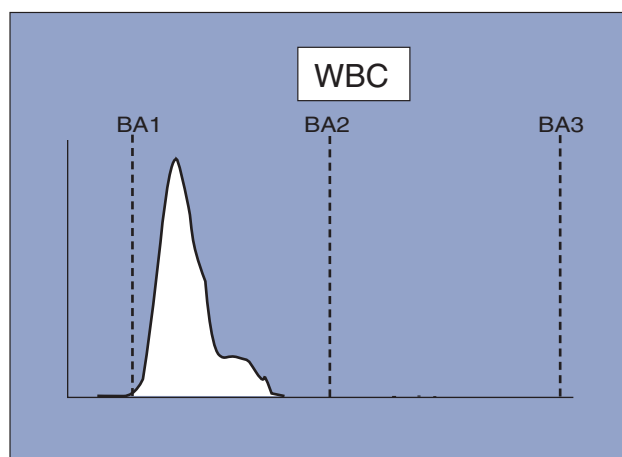
L1 indicates the presence of an abnormal number of cells in comparison with leukocytes.

Suspected abnormalities:

- Plt aggregates,
- NRBCs.

+ **Standard values for L1:**
% 3
200

Adjustment:
see Chapter 4. **Instrument
configuration**



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DIFF mode only

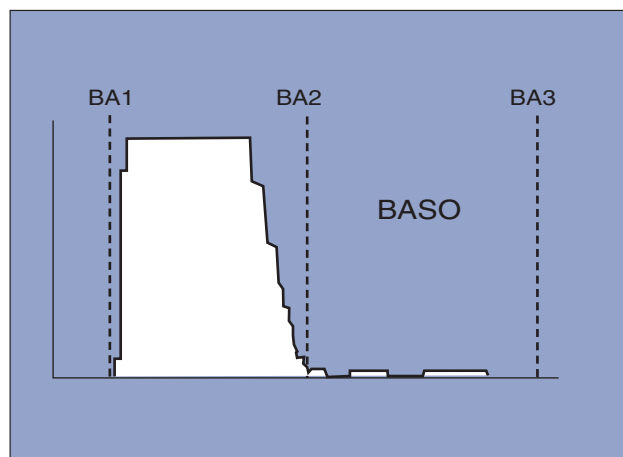
MB (Meaning: **M**ono **B**aso)

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

BASO+

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

The Basophils are not taken away from the matrix populations and ---- is displayed instead of the BAS % and BAS #.



NOTE

*The **BASO+** flag is displayed in the «Analyzer Alarm» area on the result ticket.*

7.4.5. Flags on RBC histogram

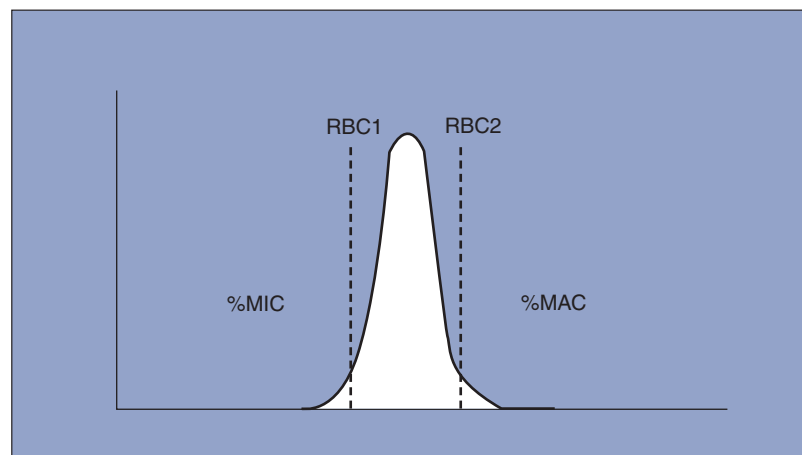
MIC & MAC flags

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 limits set up by user.

- RBC1 and RBC2 thresholds define the microcytic and macrocytic areas and are calculated according to the MCV and the RDW.

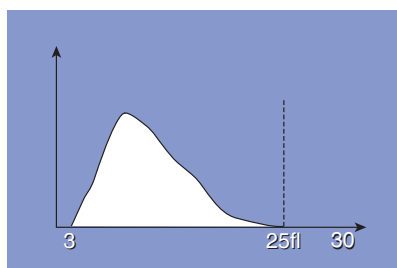
+ **Standard** values for **Mic**: %5
Mac: %45

Adjustment:
see Chapter 4. **Instrument
configuration**



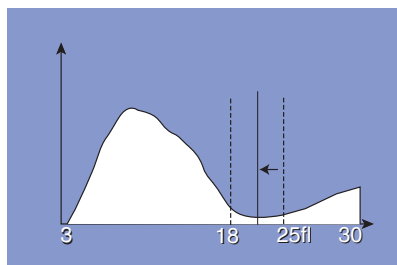
7.4.6. Flags on Plt histogram

- The Plt histogram has 256 channels between 2fL and 30fL. A mobile threshold (at 25 fL by default) moves according to the microcytic RBCs present in the platelet analysis area.

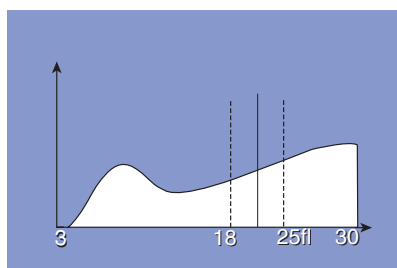


- The Plt flags are generated under the following conditions:

+ **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).



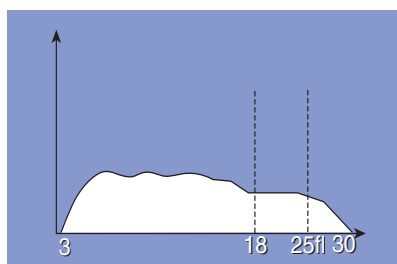
+ **When** the mobile threshold can not be positioned in the standard area (from 18fL to 25fL), a **Plt reject (*)** and a **MIC** flag are generated. The Plt result is not reliable. Verify the result using a Platelet Rich Plasma (PRP) or a manual count.



+ **If** the mobile threshold cannot be positioned (no valley between the Plt and RBC histograms) the **SCH (Schizocytes)** flag is generated.

Suspected abnormalities:

- Presence of schizocytes
- Presence of Platelet aggregates, check the result on a slide.



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

7.4.7. WBC balance

+ **WBC Balance** can be activated or deactivated: see Chapter 4. **Instrument configuration**

Control of the injected volume in the optical flowcell allows a second count of the WBC.

The two counts are compared, if the difference between both counts is higher than a defined threshold (depending of the quantity measured), a **LMNE+** or a **LMNE-** flag is generated.

- WBC count is within 0 and 2501:

If the WBC LMNE count is higher than 50% of the WBC BASO count, a **LMNE+** flag is generated.

If the WBC LMNE count is lower than 50% of the WBC BASO count, a **LMNE-** flag is generated.

- WBC count is within 2501 and 8000:

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

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

- WBC count is higher than 8000:

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

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

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

NOTE

The WBC balance flags (LMNE+ and LMNE-) shall not be triggered if and only if:

- *The test selected is «CBC».*
- *The WBC Balance option is not activated.*

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

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

7.5. Pathology messages

- Pathology suspicion messages may be displayed and printed out. Triggering conditions are linked to the laboratory limits entered by the user.

WARNING

These messages indicate a possible pathological disorder and should be used to assist with quick and efficient screening of abnormal samples and for diagnosis. It is recommended to use suitable reference methods to confirm diagnoses.

NOTE

There is no pathological message in the following cases:

- *On WBC: For a WBC < 0.1x10³/mm³ or WBC > 91.3x10³/mm³.
or for a counting reject
(Except if an Erythroblast flag is the NUCLEATED RBC).*
- *On RBC: For a counting reject or an RBC value < 0.1x10⁶/mm³.*
- *On Plt: For a counting reject or a Plt value < 5x10³/mm³.*

7.5.1. WBC messages

«H»: high extreme limit

«L»: low extreme limit

* means the pathology is detected, firstly, on the high and low absolute values of the corresponding parameter.

MESSAGE	TRIGGERING 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
NUCLEATED RBC	LL
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

7.5.2. RBC messages

«H»: high extreme limit

«L»: low extreme limit

MESSAGE	TRIGGERING CONDITIONS
ANEMIA	Hgb < Hgb L
ANISOCYTOSIS	RDW > RDW H
MICROCYTE	on MIC flag
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

7.5.3. Plt messages

«H»: high extreme limit

«L»: low extreme limit

MESSAGE	TRIGGERING CONDITIONS
THROMBOCYTOSIS	Plt > Plt H
THROMBOCYTOPENIA	Plt < Plt L
MICROCYTOSIS SCHIZOCYTE SMALL CELL	See Triggering conditions for these flags in paragraph Flags on RBC curve
Plt AGGREGATE (1)	Plt < 150x10 ³ /mm ³ + WBC Reject or NO + PDW > 20 or NO + MPV > 10 or NO + Plt < 150x10 ³ /mm ³ or NO + WBC Reject or L1 or LL1 + PDW > 20 or L1 or LL1 + MPV > 10 or L1 or LL1 + Plt < 250x10 ³ /mm ³
ERYTHROBLASTS (2)	LL or WBC reject + L1 or WBC reject + LL1
ERYTHROBLASTS Plt AGGREGATE	(1) and (2) are false + (L1 or LL1 or WBC reject)
MACROPLATELETS	MPV > 11

7.5.4. Miscellaneous

«**H**»: high extreme limit

«**L**»: low extreme limit

MESSAGE	TRIGGERING CONDITION
PANCYTOPENIA	WBC < WBC L and RBC < RBC L and Plt < Plt L

7.6. Analyzer alarms

Total rejection of the matrix

Meaning: poor correlation

The percentage of validated cells is abnormally low, appears when the correlation between the resistivity measurement of particles and their optical measurement is less than 50%.

Suspected abnormalities:

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

Others

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

8. CLEANING

8.1. Automatic cleaning

- When the instrument has run 75 specimens from the date changing, an automatic cleaning procedure is carried out.
- The automatic cleaning frequency can be adjusted by the user from 1 to 75 as described in Chapter 4. [Instrument configuration](#).

8.2. End of the day rinsing



- It is necessary to run a «**Shutdown**» cycle at the end of the day.
Press  **Shut Down** button, the instrument performs a complete cleaning with **ABX** cleaner, and puts the system in stand by mode.
- The instrument can be switched off if the working day is completed or left in standby mode overnight or until the next analysis.

NOTE

A startup cycle is required systematically after a shutdown cycle if the instrument has to be operated.

- After a Shutdown cycle a Startup cycle is required before running an analysis. Click  **Start Up** button before sampling otherwise the following message will be displayed:

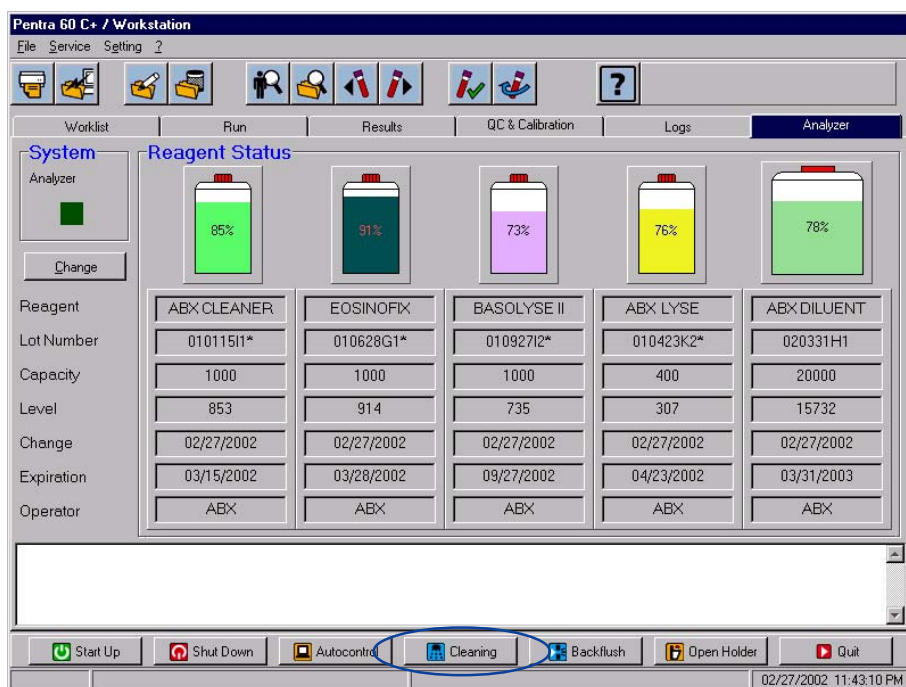


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8.3. After two or four hours of instrument inactivity

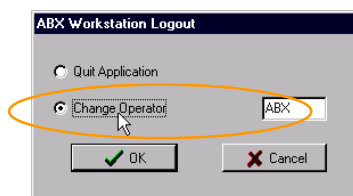
- If the instrument is not used for **two hours** a clean cycle will be necessary to run the next analysis. Click  **Cleaning** button before sampling.

- If the instrument is not used for **four hours** a startup and a clean cycle will be necessary to run the next analysis. Click  **Start Up** then  **Cleaning** buttons before sampling.

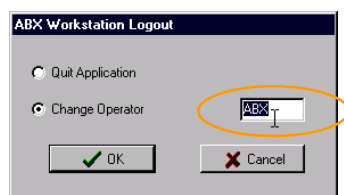


9. CHANGE OPERATOR NAME

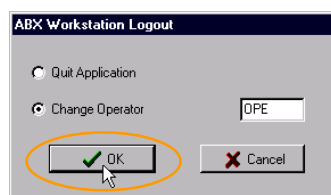
- To change the operator name, click button  Quit.
- In the following window select «**Change Operator**» option:



- Double click in the field «**Change Operator**» and enter the new operator name (3 letters max.):

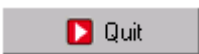
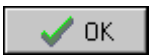


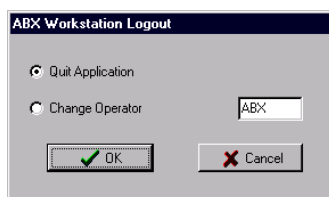
- Click button  OK to validate modification:



10. WORKSTATION SHUT DOWN

- At the end of the day press  button to perform a complete instrument cleaning with **ABX** cleaner.

- Click  button and confirm in the following window by clicking  button:



- Press ALT+CTRL+DEL (or ALT+CTRL+SUPPR) to open the «Logon window» and click «Shut down» button.
- The «Shutdown computer» window is opened, select «Shutdown» and click «OK».
- Wait until workstation shut down, then switch off the computer.

NOTE

It is advise to shut down the computer from time to time to compact database.

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1. CONTROL

- Quality control, for control bloods, allows for a set of analyses to be monitored based over a period of several months. Analyses are performed using known samples (also known as control blood or targets), the results are archived, and averaged, allowing statistical calculations to be extracted on the sample analysis system stability.
- For each control blood sample, up to 400 results can be archived in the database. 12 fields are reserved for Control blood lots and barcodes. To enter a new control blood you must modify one of these 12 fields.

1.1. New Control blood lot setup

For example: New control blood lot parameters:

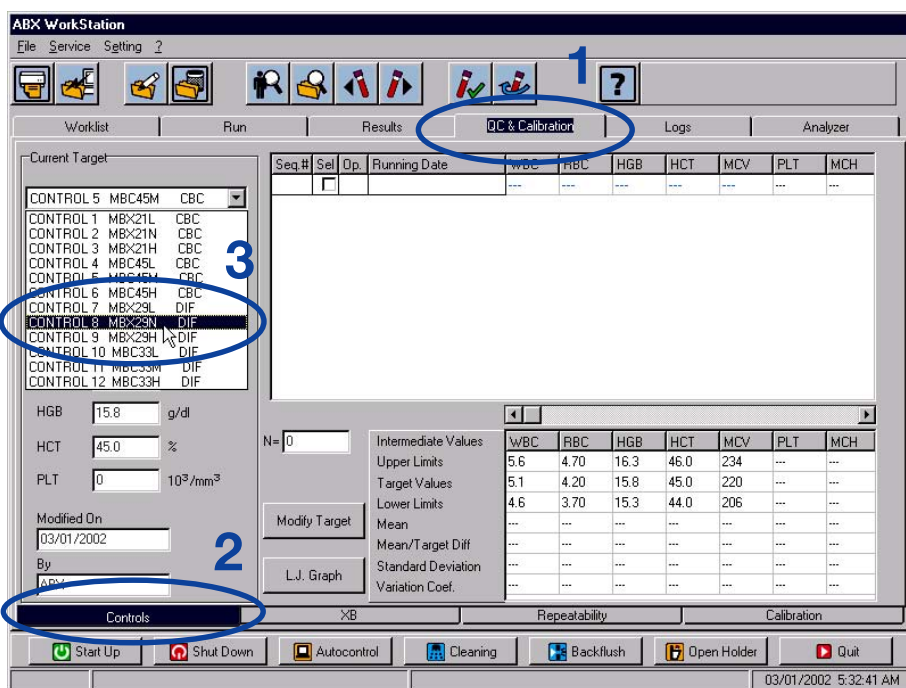
- Identification: JX99N
- Barcode: QC99N
- Expiration date: 07/19/2002

- Select Control blood Lot you are going to modify (MBX29N for example):

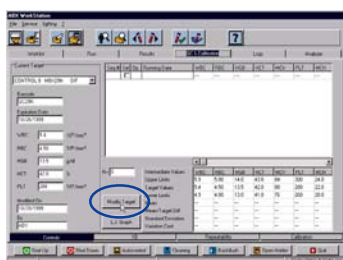
1- Enter «QC & Calibration» Tab.

2- Enter «Controls» Tab.

3- Select control: Open «Current target» scrolling list and click on the control blood lot you want to modify.

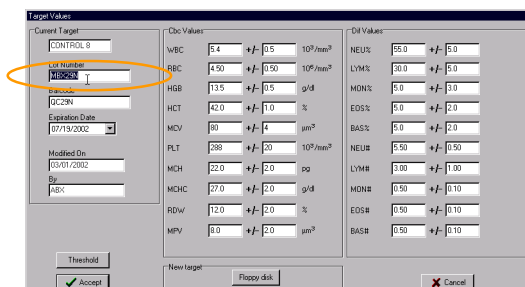


- Click on **Modify Target** button to open «Target modify» window:



ATTENTION

If you replace or modify a control blood lot and you save modifications, all previous performed analysis with this lot will be lost.



Target Values

Current Target: CONTROL 8

Lot Number: MBX29N

Barcode: JX99N

Expiration Date: 07/19/2002

Modified On: 03/01/2002

By: ABX

Threshold: []

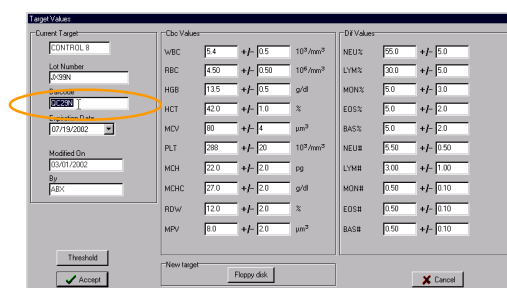
Accept [X] Cancel [X]

New target: [] Floppy disk []

Doc Values	Diff Values
WBC: 5.4 $\pm$ 0.5 $10^9/\text{mm}^3$	NEUT: 55.0 $\pm$ 5.0
RBC: 4.50 $\pm$ 0.50 $10^9/\text{mm}^3$	LYM%: 30.0 $\pm$ 5.0
HGB: 13.5 $\pm$ 0.5 g/dl	MON%: 5.0 $\pm$ 2.0
HCT: 42.0 $\pm$ 1.0 %	EOS%: 5.0 $\pm$ 2.0
MCV: 90 $\pm$ 4 μm^3	BAS%: 5.0 $\pm$ 2.0
PLT: 288 $\pm$ 20 $10^9/\text{mm}^3$	NEU%: 5.50 $\pm$ 0.50
MCH: 22.0 $\pm$ 2.0 pg	LYM%: 3.00 $\pm$ 1.00
MCHC: 27.0 $\pm$ 2.0 g/dl	MON%: 0.50 $\pm$ 0.10
RDW: 12.0 $\pm$ 2.0 %	EOS%: 0.50 $\pm$ 0.10
MPV: 8.0 $\pm$ 2.0 μm^3	BAS%: 0.50 $\pm$ 0.10

- Enter new control blood identification:
Click in «**Identification**» field in the «**Target modify**» window.
(For example: New control blood lot JX99N replaces MBX29N lot)

- Enter new calibrator Barcode:
Click in «**Barcode**» field in the «**Target modify**» window.
(For example: New barcode is QC99N and replaces QC29N)



Target Values

Current Target: CONTROL 8

Lot Number: JX99N

Barcode: QC99N

Expiration Date: 07/19/2002

Modified On: 03/01/2002

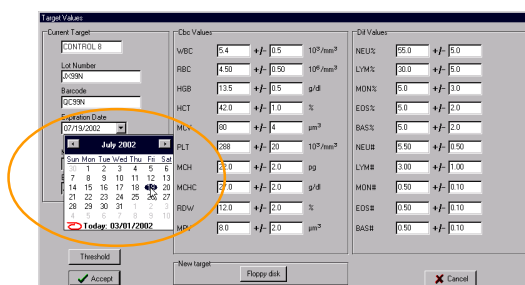
By: ABX

Threshold: []

Accept [X] Cancel [X]

New target: [] Floppy disk []

Doc Values	Diff Values
WBC: 5.4 $\pm$ 0.5 $10^9/\text{mm}^3$	NEUT: 55.0 $\pm$ 5.0
RBC: 4.50 $\pm$ 0.50 $10^9/\text{mm}^3$	LYM%: 30.0 $\pm$ 5.0
HGB: 13.5 $\pm$ 0.5 g/dl	MON%: 5.0 $\pm$ 2.0
HCT: 42.0 $\pm$ 1.0 %	EOS%: 5.0 $\pm$ 2.0
MCV: 90 $\pm$ 4 μm^3	BAS%: 5.0 $\pm$ 2.0
PLT: 288 $\pm$ 20 $10^9/\text{mm}^3$	NEU%: 5.50 $\pm$ 0.50
MCH: 22.0 $\pm$ 2.0 pg	LYM%: 3.00 $\pm$ 1.00
MCHC: 27.0 $\pm$ 2.0 g/dl	MON%: 0.50 $\pm$ 0.10
RDW: 12.0 $\pm$ 2.0 %	EOS%: 0.50 $\pm$ 0.10
MPV: 8.0 $\pm$ 2.0 μm^3	BAS%: 0.50 $\pm$ 0.10



Target Values

Current Target: CONTROL 8

Lot Number: JX99N

Barcode: QC99N

Expiration Date: 07/19/2002

Modified On: 03/01/2002

By: ABX

Threshold: []

Accept [X] Cancel [X]

New target: [] Floppy disk []

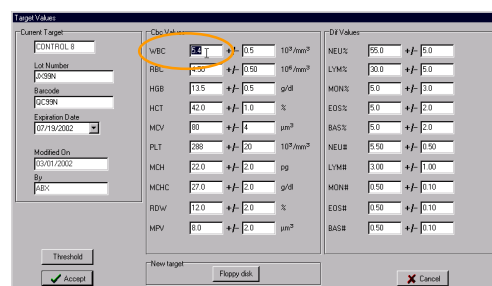
Doc Values	Diff Values
WBC: 5.4 $\pm$ 0.5 $10^9/\text{mm}^3$	NEUT: 55.0 $\pm$ 5.0
RBC: 4.50 $\pm$ 0.50 $10^9/\text{mm}^3$	LYM%: 30.0 $\pm$ 5.0
HGB: 13.5 $\pm$ 0.5 g/dl	MON%: 5.0 $\pm$ 2.0
HCT: 42.0 $\pm$ 1.0 %	EOS%: 5.0 $\pm$ 2.0
MCV: 90 $\pm$ 4 μm^3	BAS%: 5.0 $\pm$ 2.0
PLT: 288 $\pm$ 20 $10^9/\text{mm}^3$	NEU%: 5.50 $\pm$ 0.50
MCH: 22.0 $\pm$ 2.0 pg	LYM%: 3.00 $\pm$ 1.00
MCHC: 27.0 $\pm$ 2.0 g/dl	MON%: 0.50 $\pm$ 0.10
RDW: 12.0 $\pm$ 2.0 %	EOS%: 0.50 $\pm$ 0.10
MPV: 8.0 $\pm$ 2.0 μm^3	BAS%: 0.50 $\pm$ 0.10

- Enter new calibrator Expiration date:
Click in «**Expiration date**» field in the «**Target modify**» window. A calendar is opened, use LEFT and RIGHT arrows to scroll months, then years, and select the day with the pointer. (For example: new expiry date is the 07/19/2002)

- Check that target values are correct, if they are not enter new target values, click over the figure you want to replace:

NOTE

To update DIFFTROL control blood's alarm thresholds you must use the floppy disk.



Target Values

Current Target: CONTROL 8

Lot Number: JX99N

Barcode: QC99N

Expiration Date: 07/19/2002

Modified On: 03/01/2002

By: ABX

Threshold: []

Accept [X] Cancel [X]

New target: [] Floppy disk []

Doc Values	Diff Values
WBC: 5.4 $\pm$ 0.5 $10^9/\text{mm}^3$	NEUT: 55.0 $\pm$ 5.0
RBC: 4.50 $\pm$ 0.50 $10^9/\text{mm}^3$	LYM%: 30.0 $\pm$ 5.0
HGB: 13.5 $\pm$ 0.5 g/dl	MON%: 5.0 $\pm$ 2.0
HCT: 42.0 $\pm$ 1.0 %	EOS%: 5.0 $\pm$ 2.0
MCV: 90 $\pm$ 4 μm^3	BAS%: 5.0 $\pm$ 2.0
PLT: 288 $\pm$ 20 $10^9/\text{mm}^3$	NEU%: 5.50 $\pm$ 0.50
MCH: 22.0 $\pm$ 2.0 pg	LYM%: 3.00 $\pm$ 1.00
MCHC: 27.0 $\pm$ 2.0 g/dl	MON%: 0.50 $\pm$ 0.10
RDW: 12.0 $\pm$ 2.0 %	EOS%: 0.50 $\pm$ 0.10
MPV: 8.0 $\pm$ 2.0 μm^3	BAS%: 0.50 $\pm$ 0.10

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- You can use the floppy disk supplied by the Control blood lot to update automatically the target values, click button **Floppy disk** :

- Select the Control blood level (Low\Normal\High), then click **OK**.



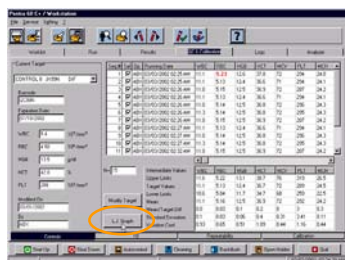
- Target values are updated, click button **Accept** to exit «Target Values» window and save modifications.

- «QC & Calibration\Controls» window is updated:

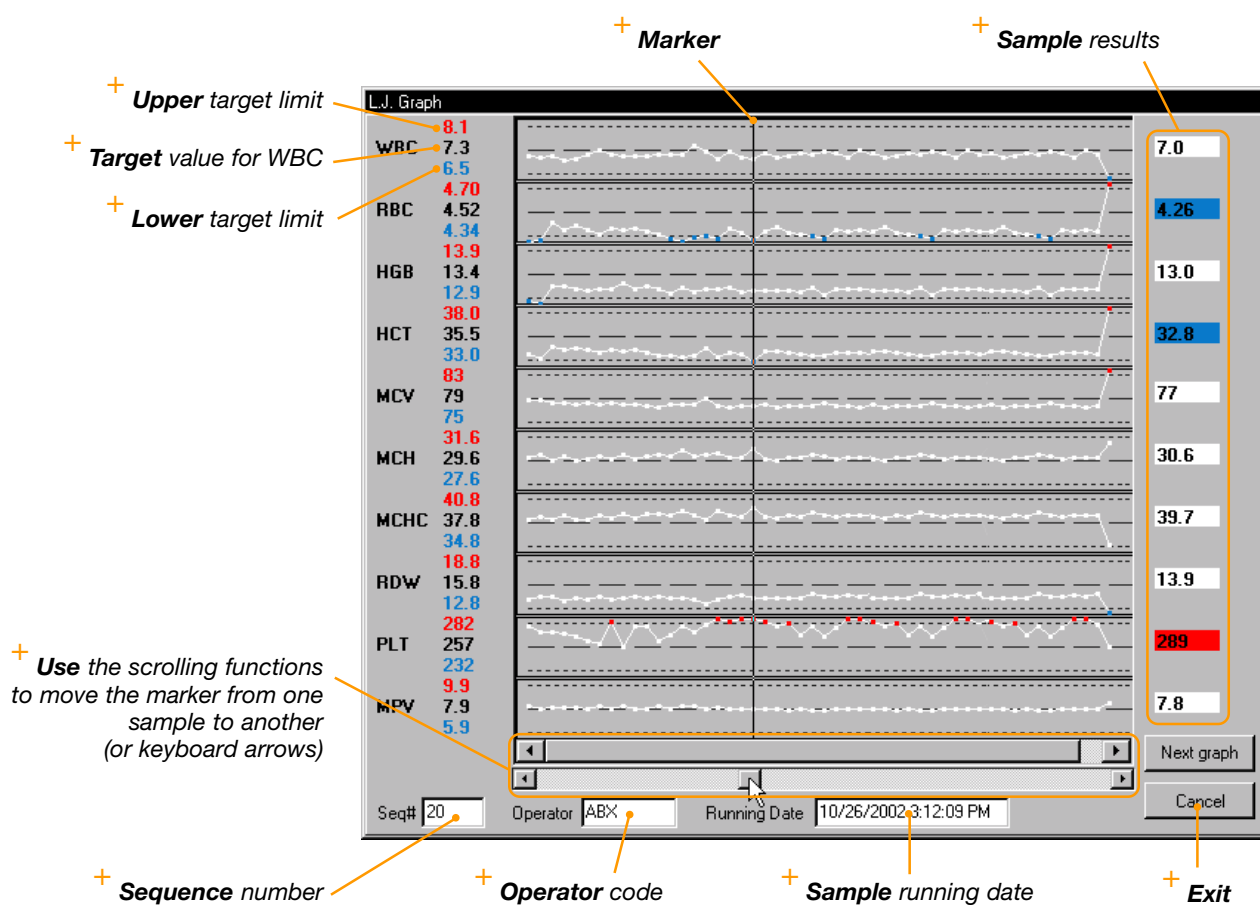
Seq.#	Sel	Op.	Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH
1	☐			---	---	---	---	---	---	---

	WBC	RBC	HGB	HCT	MCV	PLT	MCH
Intermediate Values	5.9	5.00	14.0	43.0	84	308	24.0
Upper Limits	5.4	4.50	13.5	42.0	80	288	22.0
Target Values	4.9	4.00	13.0	41.0	76	268	20.0
Lower Limits	---	---	---	---	---	---	---
Mean	---	---	---	---	---	---	---
Mean/Target Diff	---	---	---	---	---	---	---
Standard Deviation	---	---	---	---	---	---	---
Variation Coef.	---	---	---	---	---	---	---

1.2. L.J. Graphs



- This is the graphical representation of the time evolution of each parameter in relation to the target value. Graphs are given for each control blood lot, include all the results (selected or not) and contain up to 400 results.
- A marker is used to point at any result of the graph in order to obtain the values. The points of a graph are displayed **white**, in **red** if the corresponding results are higher than the upper target limit and in **blue** if the corresponding results are less than the lower target limit.



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2. CALIBRATION

- Calibration is a procedure to standardize the instrument by determining its deviation, if any, from calibration references and to apply any necessary correction factors.
- A minimum of three analyses cycles must be performed with a known sample (target) to calibrate the instrument. Results are averaged and new calibration coefficient values are calculated so as to generate results conforming to those supplied by the target.
- 6 fields (max. 11 results per fields) are reserved for Calibration blood lots and barcodes. To enter new parameters for a lot you must modify one of these 6 fields.

2.1. New Calibrator lot setup

For example: New calibrator vial parameters:

- Identification: CX294
- Barcode: N412H
- Expiration date: 08/05/2002

- Select Calibrator Lot number you are going to modify (C21N for example):

1- Enter «QC & Calibration» Tab.

2- Enter «Calibrators» Tab.

3- Select calibrator: Open «Ident» scrolling list and click on the calibrator you are going to modify.

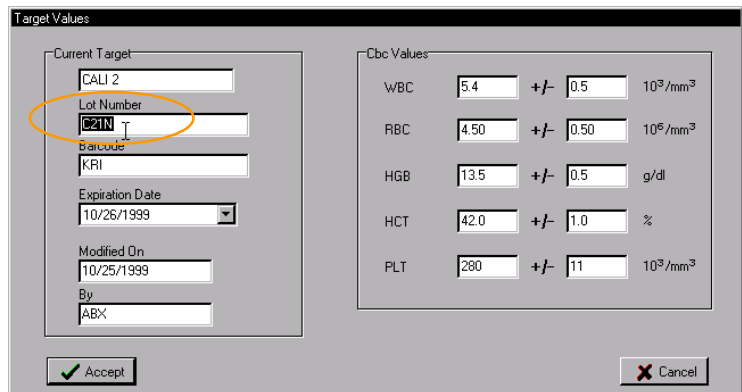
- Click on **Modify Target** button to open «Target modify» window:

ATTENTION

If you replace or modify a calibrator lot and you save modifications, all previous performed analysis with this lot will be lost.

- Enter new calibrator identification:
Click in «**Lot Number**» field in the «**Target Values**» window.

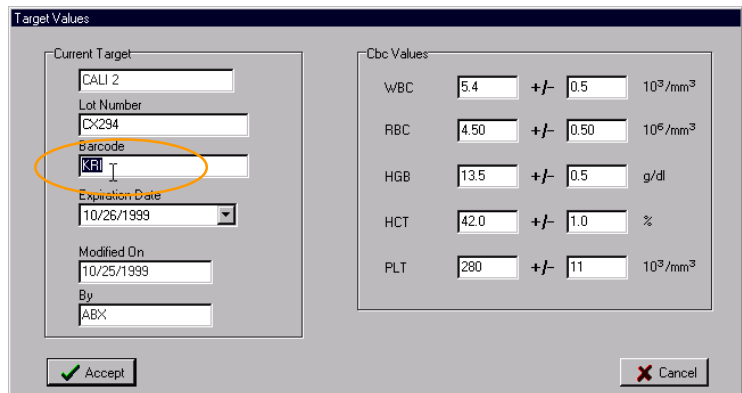
(For example: the calibrator C21N is replaced by CX294 calibrator)



The screenshot shows the 'Target Values' window. The 'Current Target' section has fields for 'CALI 2', 'Lot Number' (highlighted with an orange circle and containing 'C21N'), 'Barcode', 'KRI', 'Expiration Date' (10/26/1999), 'Modified On' (10/25/1999), and 'By' (ABX). The 'Cbc Values' section shows WBC (5.4 +/- 0.5 10³/mm³), RBC (4.50 +/- 0.50 10⁶/mm³), HGB (13.5 +/- 0.5 g/dl), HCT (42.0 +/- 1.0 %), and PLT (280 +/- 11 10³/mm³). 'Accept' and 'Cancel' buttons are at the bottom.

- Enter new calibrator Barcode:
Click in «**Barcode**» field in the «**Target Values**» window.

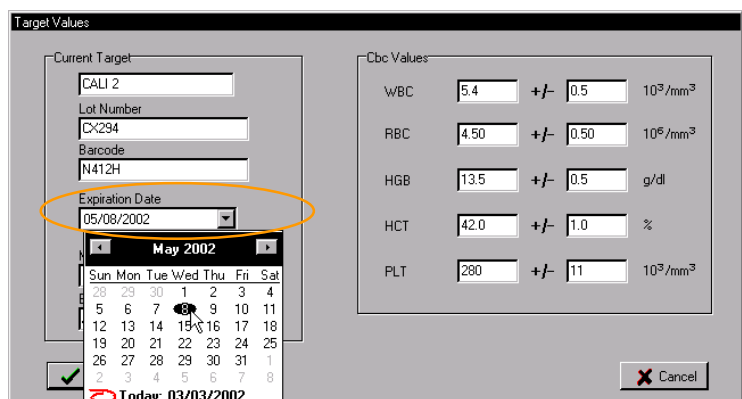
(For example: the barcode KRI is replaced by N412H)



The screenshot shows the 'Target Values' window. The 'Current Target' section has fields for 'CALI 2', 'Lot Number' (CX294), 'Barcode' (highlighted with an orange circle and containing 'KRI'), 'KRI', 'Expiration Date' (10/26/1999), 'Modified On' (10/25/1999), and 'By' (ABX). The 'Cbc Values' section is the same as the previous screenshot. 'Accept' and 'Cancel' buttons are at the bottom.

- Enter new calibrator Expiration date:
Click in «**Expiration Date**» field in the «**Target Values**» window.

(For example: new expiry date is the 08/05/2002)



The screenshot shows the 'Target Values' window. The 'Current Target' section has fields for 'CALI 2', 'Lot Number' (CX294), 'Barcode' (N412H), 'Expiration Date' (highlighted with an orange circle and containing '05/08/2002'), 'Modified On' (10/25/1999), and 'By' (ABX). A calendar for May 2002 is open, showing the date 08. The 'Cbc Values' section is the same as the previous screenshots. 'Accept' and 'Cancel' buttons are at the bottom. A status bar at the very bottom says 'Today: 03/03/2002'.

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- Check that target values are correct, if they are not enter new target values, click over the figure you want to replace:

Target Values

Current Target

CALI 2

Lot Number

CX294

Barcode

N412H

Expiration Date

05/08/2002

Modified On

10/25/1999

By

ABX

Cbc Values

WBC 5.4 +/- 0.5 $10^3/mm^3$

RBC 4.50 +/- 0.50 $10^6/mm^3$

HGB 13.5 +/- 0.5 g/dl

HCT 42.0 +/- 1.0 %

PLT 280 +/- 11 $10^3/mm^3$

Accept Cancel

- Click on  button to save changes.

Target Values

Current Target

CALI 2

Lot Number

CX294

Barcode

N412H

Expiration Date

05/08/2002

Modified On

10/25/1999

By

ABX

Cbc Values

WBC 5.4 +/- 0.5 $10^3/mm^3$

RBC 4.50 +/- 0.50 $10^6/mm^3$

HGB 13.5 +/- 0.5 g/dl

HCT 42.0 +/- 1.0 %

PLT 280 +/- 11 $10^3/mm^3$

Accept Cancel

- «QC & Calibration\Calibrators» window is updated:

Pentra 60 C+ / Workstation

File Service Setting ?

Worklist Run Results QC & Calibration Logs Analyzer

Current Target

CALI 2

Lot Number

CX294

Barcode

N412H

Expiration Date

05/08/2002

WBC 5.4 $10^3/mm^3$

RBC 4.50 $10^6/mm^3$

HGB 13.5 g/dl

HCT 42.0 %

PLT 280 $10^3/mm^3$

Modified On

03/03/2002

By

ABX

Modify Target

Calibration

N=0

Seq #	Sel	Op	Running Date	WBC	RBC	HGB	HCT	PLT
	☐			---	---	---	---	---

	WBC	RBC	HGB	HCT	PLT
Target Values	5.4	4.50	13.5	42.0	280
Actual Coef.	122.39	199.43	43.47	206.66	257.9
New Coef.	122.39	199.43	43.47	206.66	257.9
Mean	---	---	---	---	---
Variation Coef.	---	---	---	---	---

Controls XB Repeatability Calibration

Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

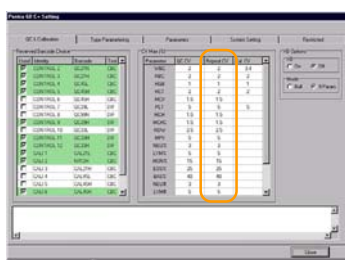
03/03/2002 03:13:10 AM

3. REPEATABILITY

- The measurement of repeatability is based on the set of results obtained from the consecutive analyses of the same human fresh normal blood sample.
- CBC** or **DIFF** type analyses can be invoked (combination is not supported) with a limit of 35 results per test. Beyond the 35th result, data generated from a new analysis will be disregarded.
- To remain undisturbed the CV calculation, the potential results containing defaults generated directly from the analyses channels are rejected. In that case, a dialogue box informs the user:



- Present the specimen as shown on the diagram below. When green LED is lit, close tube holder door to start sampling.



Pentra 60 C+ / Workstation

File Service Setting ?

Worklist Run Results **QC & Calibration** Logs Analyzer

Seq#	Set	Op.	Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW	MPV
5	☒	ABX	01/25/2002 04:45 PM	11.1	5.13	12.4	36.6	71	294	24.1	33.9	13.7	9.0
6	☒	ABX	01/25/2002 04:45 PM	11.0	5.14	12.5	36.8	72	296	24.3	34.0	13.5	8.8
7	☒	ABX	01/25/2002 04:46 PM	11.3	5.14	12.5	36.8	72	295	24.3	34.0	13.9	8.7
8	☒	ABX	01/25/2002 04:46 PM	11.0	5.15	12.5	36.9	72	287	24.2	33.7	13.8	8.7
9	☐	ABX	01/25/2002 04:46 PM	11.1	5.13	12.4	36.6	71	294	24.1	33.9	13.7	9.0
10	☐	ABX	01/25/2002 04:46 PM	11.0	5.14	12.5	36.8	72	296	24.3	34.0	13.5	8.8
11	☒	ABX	01/25/2002 04:46 PM	11.3	5.14	12.5	36.8	72	295	24.3	34.0	13.9	8.7
12	☒	ABX	01/25/2002 04:46 PM	11.0	5.15	12.5	36.9	72	287	24.2	33.7	13.8	8.7
13	☒	ABX	01/25/2002 04:47 PM	11.1	5.13	12.4	36.6	71	294	24.1	33.9	13.7	9.0
14	☒	ABX	01/25/2002 04:47 PM	11.0	5.14	12.5	36.8	72	296	24.3	34.0	13.5	8.8
15	☒	ABX	01/25/2002 04:47 PM	11.3	5.14	12.5	36.8	72	295	24.3	34.0	13.9	8.7
16	☒	ABX	01/25/2002 04:47 PM	11.0	5.15	12.5	36.9	72	287	24.2	33.7	13.8	8.7
17	☒	ABX	01/25/2002 04:47 PM	11.1	5.13	12.4	36.6	71	294	24.1	33.9	13.7	9.0
18	☒	ABX	01/25/2002 04:48 PM	11.0	5.14	12.5	36.8	72	296	24.3	34.0	13.5	8.8
19	☒	ABX	01/25/2002 04:48 PM	11.3	5.14	12.5	36.8	72	295	24.3	34.0	13.9	8.7

Test: CBC

N=15

Intermediate Values	WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW	MPV
Mean	11.1	5.14	12.5	36.8	71	293	24.2	33.9	13.8	8.8
Standard Deviation	0.12	0.01	0.05	0.11	0.12	3.32	0.09	0.11	0.17	0.11
Variation Coef.	1.05	0.14	0.39	0.29	0.17	1.13	0.37	0.33	1.24	1.25

Controls XB Repeatability Calibration

Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

03/03/2002 03:13:33 AM

- Consecutive results are archived and statistical calculations are performed. Select, ☒, or unselect, ☐, results to use for CV calculation.
- If a CV in % is upper than the limit set by the user, it is displayed against a **red** background. CVs are adjustable by the **«SystemQC & Cal.»** tab (see diagram beside).

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4. PATIENT OR XB QUALITY CONTROL

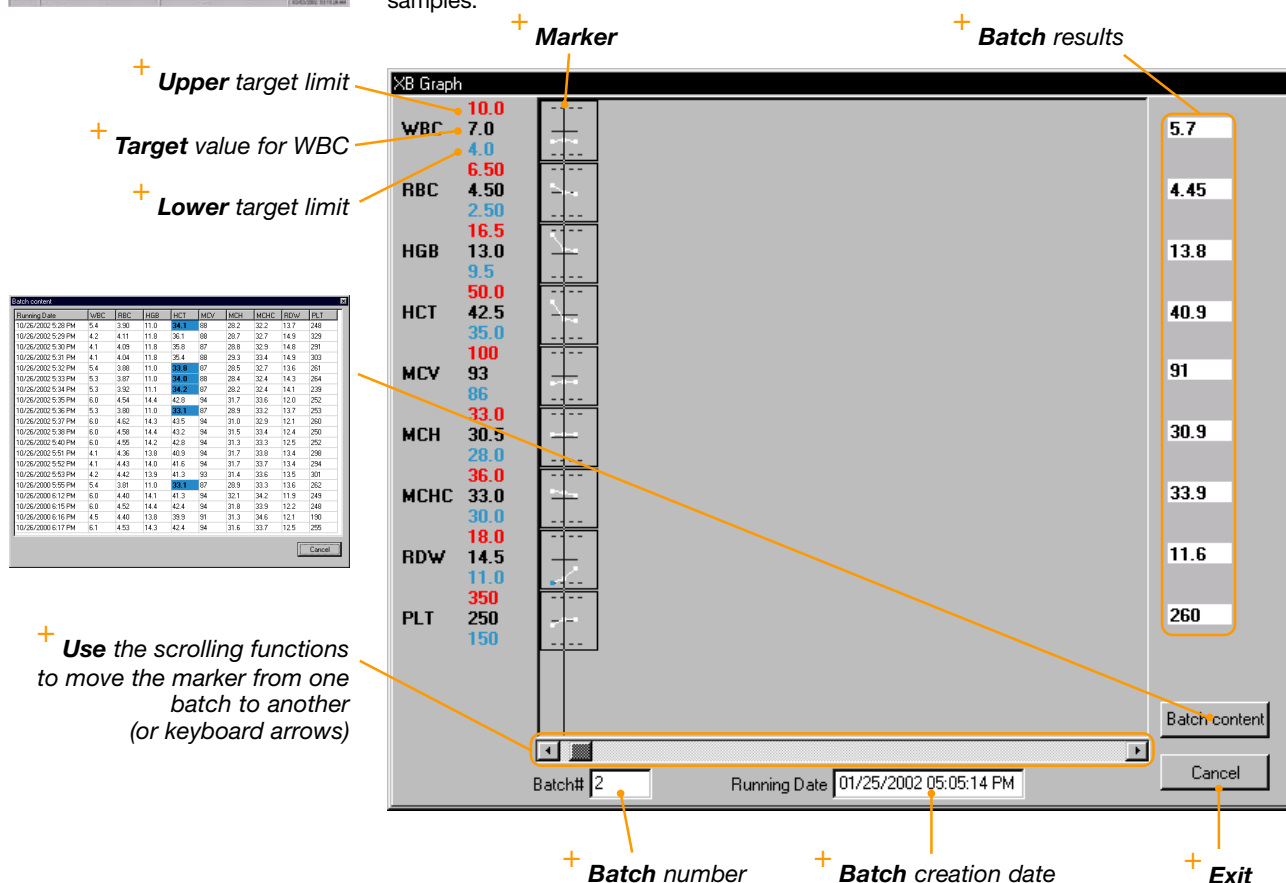
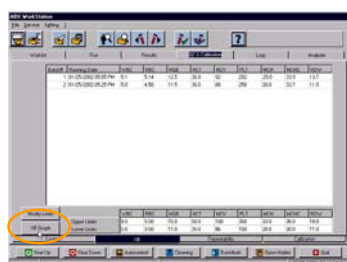
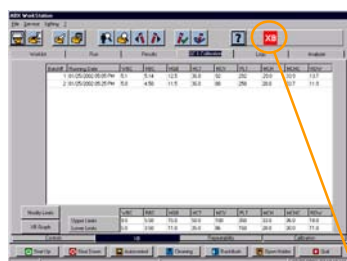
- The «XB» function, Quality Control, is based on a BULL method and includes a calculation on 3 parameters or on 9 parameters (see configuration in *QC & Calibration* further in this chapter). This method allows the operator to follow the evolution of the system on a long-term basis and to check any factor which may eventually affect the quality of the results. Gradual alteration to the quality of the calibration blood or the quality of the reagents can thus be brought to the fore more easily.

- The BULL calculation works automatically and progressively. It does not require any interventions from the operator, or the running of any specific controls. The statistical calculation includes all patient results that does not contain analysis default. When 20 results have been archived, a batch is calculated and archived also. A batch is a statistical point, each batch is included in the statistical calculation and gives a new point on the graph. Only the last 60 batches are archived, beyond 60 batches, the oldest batch will be overridden by the new one.

- A displayed alarm (XB) occurs if one parameter of this batch exceeds the XB limits, modifiable by the user (see configuration in *QC & Calibration* further in this chapter). This alarm is automatically deactivated following the inquiry of the XB tab.

- From the setting menu you can activate or deactivate the XB and the trigger of its alarm, or set the number of parameter from 3: MCV, MCG, MCHC to 9: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt.

- The statistical trend becomes more refined with time, according to the number of memorized samples.



5. SETTING MENU



«**Setting**» menu, in menubar, allows user to setup:

- **QC & Calibration** options:
 - Control blood & Calibrator barcode choice,
 - Quality control & Calibration coefficients of variation,
 - XB alarm's options.
- **Type parametring** options:
 - Name,
 - Pathological levels,
 - Pathological limits,
 - Alarm levels,
 - Curves and matrix threshold,
 - Age range,
 - Setup default type.
- **System setting** options:
 - Date\Time format,
 - RS Communication,
 - Printer description,
 - Floppy format,
 - Cycle option,
 - Unit format, language selection,
 - Analyzer ID,
 - Barcode reader setup,
 - Save\Restore configuration.
- **Restricted** options (Password required):
 - Internal instrument parameters,
 - Calibration coefficients.

Pentra 60 C+

5.1. QC & Calibration

- **Reserved Barcode Choice:** Displays and allows selection of the barcodes associated to the QC targets: In event of selection (☒) , any attempt to use this barcode (in Worklist or as a priority entry) will invoke the switching of the result (treatment and archiving) in the corresponding section: QC or Calibration. In the event of non-selection (☐) , the use of this barcode will have no effect on the passage of the cycle. The result is therefore switched to the routine environment.
- **CV & Vario max (%):** Adjustment of the QC, Repeatability and Calibration alarm limits. This box allows for the modification of the top CV limits or admissible variation expressed in % on the results of the Statistics & Calibration tab.
- **XB Options:** These options allow to setup the XB control number of parameters (3 or 9) and to set On/Off XB control system.

• Double click into the field where you want to modify the value and enter new value.

- Once modifications are completed click on

Close button to validate changes.

NOTE

Variation coefficients calculation for each parameter is done with unrounded values.

+ **Reserved** QC barcode selection.

The screenshot shows the 'Pentra 60 C+ Setting' window with the 'QC & Calibration' tab selected. The window is divided into several sections:

- Reserved Barcode Choice:** A table with columns 'Used', 'Identity', 'Barcode', and 'Test'. It lists various control and calibration targets with checkboxes for selection.
- CV Max (%):** A table with columns 'Parameter', 'QC CV', 'Repeat CV', and 'Cal CV'. It lists parameters like HCT, MCV, PLT, MCH, MCHC, RDW, MPV, NEU%, LYM%, MON%, EOS%, BAS%, NEU#, LYM#, MON#, EOS#, and BAS# with their respective CV limits.
- XB Options:** A section with radio buttons for 'XB On' and 'XB Off', and a 'Mode' section with radio buttons for 'Bull' and '9 Param'.

+ **CV** adjustment for QC, Repeatability and Calibration.

+ **XB Options:**
XB On/Off:

- Activates or deactivates XB function.
- XB Mode:**
 - 3 parameters MCV, MCH and MCHC.
 - 9 parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt.

5.2. Type parametering

20 different blood types are available, 16 can be edited according to your own specifications, for each type you can setup:

- Type name,
- Type pathological limits & thresholds,
- Type alarm levels,
- Type alarms & curve thresholds.

1- Enter «**Type parametering**» Tab.

2- Select the type to be displayed:

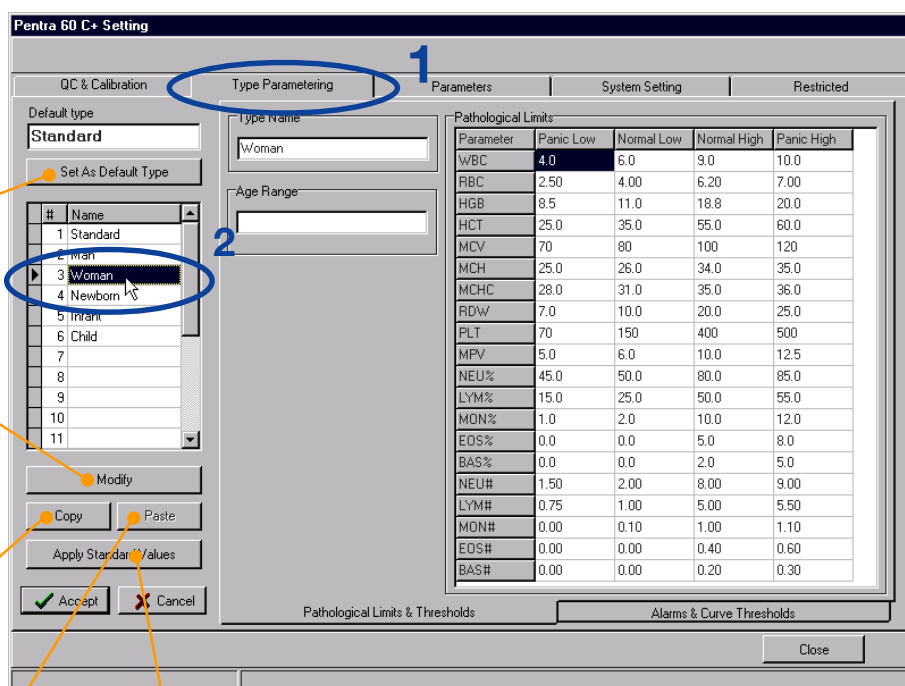
+ **Set as default type:**
use this button to set type as default type when a new Patient file is created.

+ **Modify:** use this button to modify type setup.

+ **Copy:** use this button to copy all the values from the selected type.

+ **Paste:** use this button to paste all the previous copied values in the selected type.

+ **Apply standard values:**
use this button to set type to default standard values.



Pentra 60 C+ Setting

QC & Calibration | **Type Parametering** | Parameters | System Setting | Restricted

Default type: Standard

Set As Default Type

Type Name: Woman

Age Range:

#	Name
1	Standard
2	Woman
3	Woman
4	Newborn
5	Infant
6	Child
7	
8	
9	
10	
11	

Modify

Copy Paste

Apply Standard Values

Accept Cancel

Pathological Limits & Thresholds

Alarms & Curve Thresholds

Close

Parameter	Panic Low	Normal Low	Normal High	Panic High
WBC	4.0	6.0	9.0	10.0
RBC	2.50	4.00	6.20	7.00
HGB	8.5	11.0	18.8	20.0
HCT	25.0	35.0	55.0	60.0
MCV	70	80	100	120
MCH	25.0	26.0	34.0	35.0
MCHC	28.0	31.0	35.0	36.0
RDW	7.0	10.0	20.0	25.0
PLT	70	150	400	500
MPV	5.0	6.0	10.0	12.5
NEU%	45.0	50.0	80.0	85.0
LYM%	15.0	25.0	50.0	55.0
MON%	1.0	2.0	10.0	12.0
EOS%	0.0	0.0	5.0	8.0
BAS%	0.0	0.0	2.0	5.0
NEU#	1.50	2.00	8.00	9.00
LYM#	0.75	1.00	5.00	5.50
MON#	0.00	0.10	1.00	1.10
EOS#	0.00	0.00	0.40	0.60
BAS#	0.00	0.00	0.20	0.30

Pentra 60 C+

5.2.1. Type Name

1- Select the type you want to modify the Name or create.

2- Click on **Modify** button to modify the selected type.

• Enter «User» password, then click **OK**.

User Password ?

Password

OK Cancel

3- Click in the «Type name» field and enter new type name:

Pentra 60 C+ Setting

QC & Calibration | Type Parametering | Parameters | System Setting | Restricted

Default type: Standard

Set As Default Type

Type Name: Man2

Age Range:

Name

1	Standard
2	Man
3	Woman
4	Newborn
5	Infant
6	Child
7	
8	
9	
10	
11	

Modify

Copy Paste

Apply Standard Values

Accept Cancel

Pathological Limits

Parameter	Panic Low	Normal Low	Normal High	Panic High
WBC	2.0	4.0	11.0	15.0
RBC	2.50	4.00	6.20	7.00
HGB	8.5	11.0	18.8	20.0
HCT	25.0	35.0	55.0	64.0
MCV	70	80	100	120
MCH	25.0	26.0	34.0	35.0
MCHC	28.0	31.0	35.0	36.0
RDW	7.0	10.0	20.0	25.0
PLT	70	150	400	500
MPV	5.0	6.0	10.0	12.5
NEU%	45.0	50.0	80.0	85.0
LYM%	15.0	25.0	50.0	55.0
MON%	1.0	2.0	10.0	12.0
EOS%	0.0	0.0	5.0	8.0
BAS%	0.0	0.0	2.0	5.0
NEU#	1.50	2.00	8.00	9.00
LYM#	0.75	1.00	5.00	5.50
MON#	0.00	0.10	1.00	1.10
EOS#	0.00	0.00	0.40	0.60
BAS#	0.00	0.00	0.20	0.30

Pathological Limits & Thresholds

Alarms & Curve Thresholds

Close

5.2.2. Type Pathological Limits & Threshold

Laboratory levels can be set by the operator according to its own specifications:

Normal ranges:

Results that exceed the «**Normal ranges**» limits are identified with a flag:

- «**h**» for results above the upper limit,
- «**l**» for results below the lower limit.

Panic ranges:

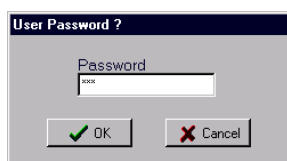
Results that exceed the «**Panic ranges**» limits are identified with a flag:

- «**H**» for results above the upper limit,
- «**L**» for results below the lower limit.

1- Select the type you want to modify the Pathological limits & thresholds.

2- Click on **Modify** button to modify the selected type.

- Enter «**User**» password, then click **OK**.



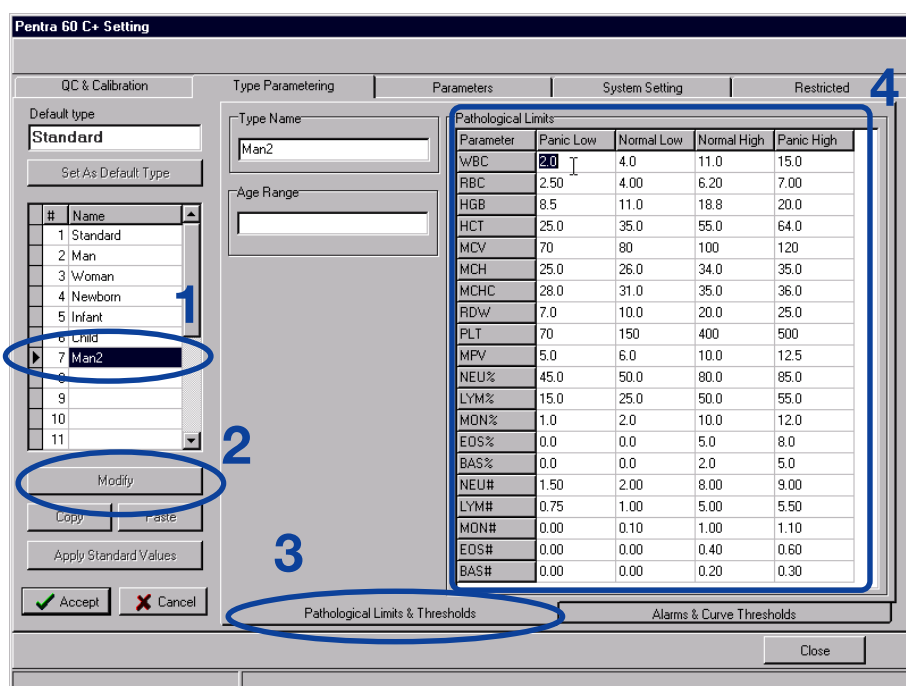
User Password ?

Password

OK Cancel

3- Enter «**Pathological Limits & Thresholds**» tab.

4- Click in the field you want to modify the value and enter new value for this type:



Pentra 60 C+ Setting

QC & Calibration Type Parametering Parameters System Setting Restricted

Default type: Standard

Set As Default Type

Type Name: Man2

Age Range:

Name

#	Name
1	Standard
2	Man
3	Woman
4	Newborn
5	Infant
6	Child
7	Man2
8	
9	
10	
11	

Modify

Copy Paste

Apply Standard Values

Accept Cancel

Pathological Limits

Parameter	Panic Low	Normal Low	Normal High	Panic High
WBC	20	4.0	11.0	15.0
RBC	2.50	4.00	6.20	7.00
HGB	8.5	11.0	18.8	20.0
HCT	25.0	35.0	55.0	64.0
MCV	70	80	100	120
MCH	25.0	26.0	34.0	35.0
MCHC	28.0	31.0	35.0	36.0
RDW	7.0	10.0	20.0	25.0
PLT	70	150	400	500
MPV	5.0	6.0	10.0	12.5
NEU%	45.0	50.0	80.0	85.0
LYM%	15.0	25.0	50.0	55.0
MON%	1.0	2.0	10.0	12.0
EOS%	0.0	0.0	5.0	8.0
BAS%	0.0	0.0	2.0	5.0
NEU#	1.50	2.00	8.00	9.00
LYM#	0.75	1.00	5.00	5.50
MON#	0.00	0.10	1.00	1.10
EOS#	0.00	0.00	0.40	0.60
BAS#	0.00	0.00	0.20	0.30

Pathological Limits & Thresholds

Alarms & Curve Thresholds

Close

Pentra 60 C+

5.2.3. Type Alarm & Curve Thresholds

- 1- Select the type you want to modify the Alarm & Curve thresholds.

- 2- Click on **Modify** button to modify the selected type.

- Enter «User» password, then click **OK**.

User Password ?

Password

Pentra 60 C+ Setting

QC & Calibration Type Parametering Parameters System Setting **restricted**

Default type: Standard

Set As Default Type

Name

1	Standard
2	Man
3	Woman
4	Newborn
5	Infant
6	Child
7	Man2
8	
9	
10	
11	

Modify

Copy Paste

Apply Standard Values

Accept **Cancel**

Alarm Levels

Alarm	Level %	Level #
NO	100	120
LL	100	50
LL1	5	45
NL	3	120
MN	100	120
RM	1.1	999
LN	2.5	999
RN	1.1	999
NE	1.1	60
L1	4	600

LMNE REJECT 50 HGBM% 3

MIC% 5 HGB# 60

MAC% 45

Curves And Matrix Thresholds

Parameter	Channel
NL	29
RMN	51
NE	82
FLN	2
FNE	2
FMN	2
NOL	22
NON	25
LL	30
LN	35
NOE	48
LMN	70
AL	68
LMU	78
LMD	90
MN	90
RM	118
RN	118

Pathological Limits & Thresholds **Alarms & Curve Thresholds**

Close

- 3- Enter «Alarms & Curve Thresholds» tab.

- 4- Click in the field you want to modify the value and enter new value for this type.

Alarms levels

- Each flag is adjustable according to a percentage and (or) an absolute value. Beyond these values the corresponding flag is triggered off.

- The meaning of each flag is described in *Chapter 3. Specimen run & Results*.

- Note:
HGB% indicates the reject level between the three HGB measures.
HGB# allows to reject an HGB reference value that is faulty.

FLAG SENSITIVITY STANDARDS					
FLAGS	%	#	FLAGS	%	#
LMNE REJ	50	0	RN	1.1	999
NO	100	120	NE	1.1	60
LL	100	50	L1	4	600
LL1	5	45	MIC	5	0
NL	3	120	MAC	45	0
MN	100	120	MACp	11	0
RM	1.1	999	HGB	3.0	60
LN	2.5	999			

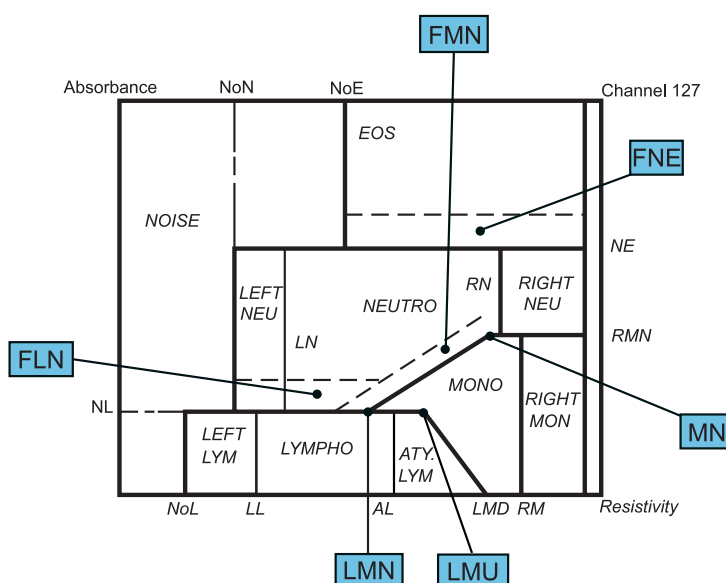
Curves and Matrix Thresholds

LMNE MATRIX THRESHOLDS

Each axis of the matrix (X and Y) is divided into 128 channels numbered from 0 to 127. 13 vertical indices (Y) and 13 horizontal indices (x) allow the user to locate these channels ten by ten. The first index of the matrix origin (at the bottom left) is the 0 channel, the fourth index of the matrix will be the channel 30 and so on. The threshold adjustment is expressed in channels.

+ **Threshold** levels may be re-adjusted:

- To improve the separation between different cell populations which may vary according to the anti-coagulant in use or instrument internal adjustment.
- To modify the flag areas in one way or another to improve their detection sensitivity. In this case, the numeric adjustment of the concerned flag must also be readjusted (see **Alarm levels**).
- To modify one or several matrix areas in order to define more precisely a specific population for research purposes.



- **AC** thresholds (Absorbance) horizontally shown on the matrix:

THRES.	PURPOSE	STD.	Low LIMIT	HIGH LIMIT
NL	Separation between Lymphocytes & Neutrophils	29	0	RMN
RMN	Separation between Right Mono & Right Neutrophils	51	NL	NE
NE	Separation between Neutrophils & Eosinophils	82	RMN	Channel 127

Pentra 60 C+

- The **FLN, FNE, FMN** thresholds indicate the width (in channel number) of the **LN, NE, MN** alarm areas:

THRES.	PURPOSE	STANDARD
FLN	Channel number for the NL alarm area	2
FNE	Channel number for the NE alarm area	2
FMN	Channel number for the MN alarm area	2

- **DC** thresholds (resistive) vertically shown on the matrix:

THRES.	PURPOSE	STD.	LOW LIMIT	HIGH LIMIT
NOL	Separation between Noise and Left Lymphocytes	22	0	LL
NON	Separation between noise and Left Neutro	25	NoL	NoE
LL	Separation between Left Lymphocytes and Lymphocytes	30	NoL	AL
LN	Separation between Neutro and Left Neutro	35	NoN	LMN
NOE	Separation between Noise and Eosino	48	NoN	Channel 127
LMN	Intersection dot between Lympho, Mono & Neutro thresholds	70	LN	LMU
AL	Separation between the Lympho and the Atypical Lympho	68	LL	LMU
LMU	Upper dot of the separation slope between Atypical lympho & Mono	78	AL	LMD
LMD	Lower dot of the separation slope between Atypical Lympho & Mono	90	LMU	RM
MN	Upper dot of the separation slope between Mono & Neutro	90	LMN	RM
RM	Separation between Monocytes and Right Monocytes	118	LMD	Channel 127
RN	Separation between Neutro and Right Neutrophils	118	MN	Channel 127



Instrument Configuration

• PLT CURVE THRESHOLD

The PL1 threshold is the number of the mobile channel that allows the calculation of the platelet population. It is automatically positioned.

+ See *PLT curve* in Chapter 3.
Specimen run & Results.

THRESHOLD	PURPOSE	STANDARD
PL1	Do not modify (No effect)	Mobile

• WBC CURVE THRESHOLDS

These thresholds are factory adjusted to the following values.

THRESHOLD	PURPOSE	CHANNEL
WBC1	Do not modify (No effect)	4
WBC2	Do not modify (No effect)	15
WBC3	Do not modify (No effect)	240

• RBC CURVE THRESHOLDS

These thresholds are factory adjusted to the following values.

+ See *RBC curve* in Chapter 3.
Specimen run & Results.

THRESHOLD	PURPOSE	CHANNEL
RBC1	Do not modify (No effect)	54
RBC2	Do not modify (No effect)	77

• BASO CURVE THRESHOLDS

All of the leukocytes are shown between the BA1 and BA3 thresholds.
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.

+ See *BASO curve* in Chapter 3.
Specimen run & Results.

THRESHOLD	PURPOSE	CHANNEL
BA1	Separation threshold between the L1# counting area and the WBC	35
BA2	Separation threshold between the WBC and basophils	110
BA3	End of the basophil counting area	240
BA4	Do not modify (No effect)	255

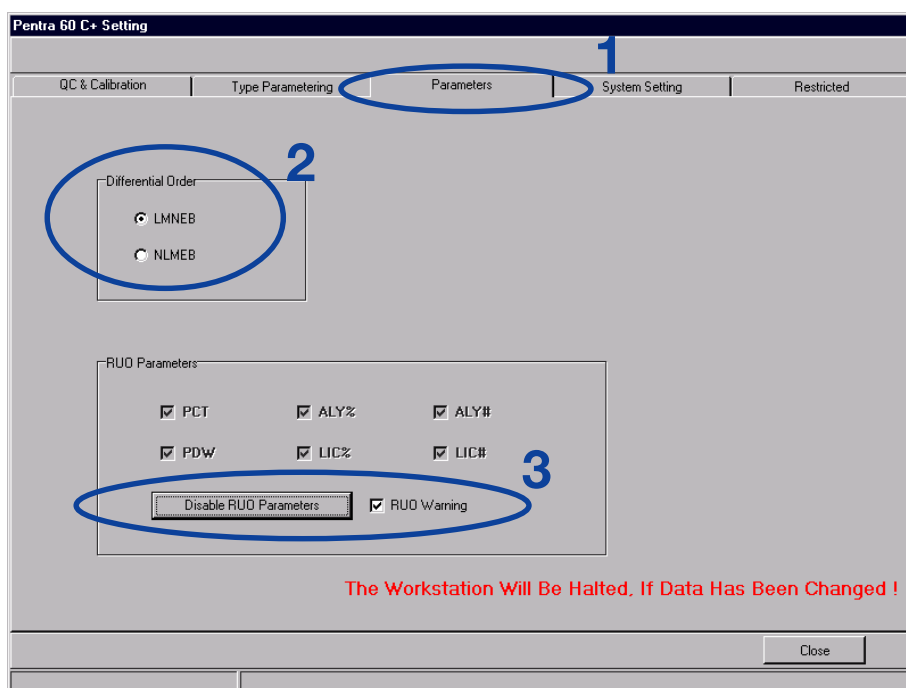
Pentra 60 C+

5.3. Parameters

1- Enter
«Setting\Parameters» tab:

2- Select the differential
presentation order:

3- Activate/Deactivate
RUO parameters (Pct,
PDW, ALY and LIC):



5.4. System Setting

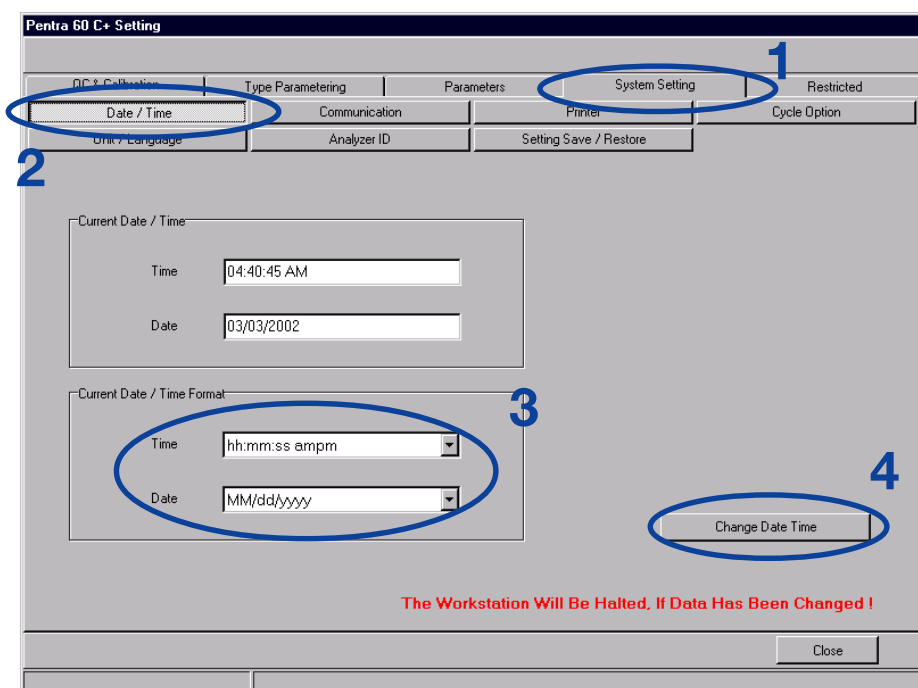
5.4.1. Date / Time

1- Enter «**Setting\System Setting**» tab:

2- Select «**Date\Time**» option:

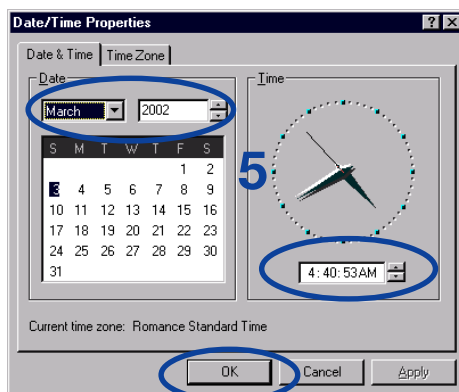
3- Select Date \ Time display format with the scrolling boxes:

4- Press **Change date time** button:



5- Enter new Date/Time:

6- Click **OK** button to save changes:



Pentra 60 C+

5.4.2. Communication

1- Enter «**Setting\System Setting**» tab:

2- Select «**Communication**» option:

3- RS232 Setting.

Pentra 60 C+ Setting

QC & Calibration | Type Parametering | Parameters | **System Setting** | Restricted

Date / Time | **Communication** | Printer | Cycle Option

Unit / Language | Analyzer ID | Setting Save / Restore

RS232 Configuration

Bauds: ☐ 4800 ☐ 9600 ☒ 38400 ☐ 57600 ☐ 115200

Stop Bit: ☒ 1 Stop ☐ 2 Stop

Length: ☒ 8 bits ☐ 7 bits

Parity: ☐ Odd ☐ Even ☒ None

Protocol: ☐ Xon/Xoff ☒ None

Analyzer Number:

Sending Configuration

Format: ☐ WORKS ☐ ARGOS ☒ ABX ☐ ASTM

Mode: ☒ UNIDIR ☐ SOH/EOT ☐ BIDIR

Time Out: Waiting Time: Works Separator: Time:

☐ Automatic disconnection

Sending Options

☒ Step-by-Step Transmission ☐ Send Control Results

☒ Unconditional Sending ☐ Conditional Sending

☐ Identified Results ☐ Without Default Analysis ☐ Without Alarms ☐ Within the Normal Range ☐ Within Extreme Values

RS232 Settings | ABX Format

Close

4- ABX format.

Pentra 60 C+ Setting

QC & Calibration | Type Parametering | Parameters | System Setting | Restricted

Date / Time | **Communication** | Printer | Cycle Option

Unit / Language | Analyzer ID | Setting Save / Restore

Numerical Results

☒ WBC ☒ LYM# ☒ MON# ☒ NEU# ☒ EOS# ☒ BAS# ☒ ALY# ☒ LIC#

☒ LYM% ☒ MON% ☒ NEU% ☒ EOS% ☒ BAS% ☒ ALY% ☒ LIC%

☒ RBC ☒ HGB ☒ HCT ☒ MCV ☒ MCH ☒ MCHC ☒ RDW

☒ PLT ☒ MPV ☒ Pct ☒ PDW

Flags And Pathologies

☒ WBC Flags ☒ LMNE Flags ☒ RBC Flags ☒ Plt Flags ☒ WBC Balance Flags ☒ General Flags ☒ WBC Pathology ☒ RBC Pathology ☒ Plt Pathology

Patient File

☒ Patient Number ☒ Patient Name ☒ Birthdate ☒ Age ☒ Gender ☒ Physician ☒ Department

☒ Sample ID ☒ Collect Date ☒ Date Of Analysis ☒ Test ☒ Analyzer Sequence Number ☒ Number of Runs ☒ Operator ☒ Comment ☒ Analyzer Number

Histograms and Thresholds

☒ WBC Histogram ☒ RBC Histogram ☒ Plt Histogram ☒ BASO Histogram ☒ LMNE Matrix

☒ WBC Threshold ☒ RBC Threshold ☒ Plt Threshold ☒ BASO Threshold ☒ LMNE Matrix Threshold

RS232 Settings | **ABX Format**

Close

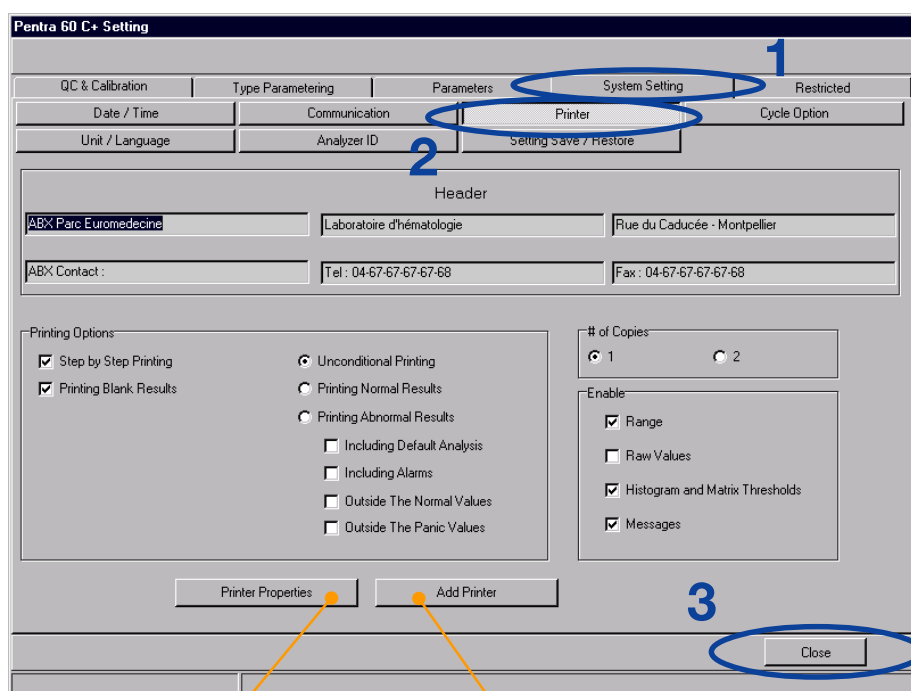
5.4.3. Printer

1&2- Enter «**Setting\System Setting**» tab and setup printer options:

NOTE

If window «**Add Printer**» or «**Printer Properties**» disappears, click another time on the button to make it appears again.

3- Exit by clicking **Close** button.



+ **Printer Properties:** Displays the printer properties window.

+ **Add Printer:** Open the dialog box to install new printer's driver.

Pentra 60 C+

5.4.4. Cycle Option

1- Enter «**Setting\System Setting**» tab:

2- Select «**Cycle Option**» option:

3- Enter Autoclean frequency (from 1 to 75):

4- Select «**Enable Automatic Startup**» option to run a startup cycle automatically when instrument is started:

The screenshot shows the 'Pentra 60 C+ Setting' window. At the top, there is a tabbed interface with the following tabs: 'QC & Calibration', 'Type Parametering', 'Parameters', 'System Setting', and 'Restricted'. The 'System Setting' tab is selected and circled with a blue oval and the number '1'. Below this, there is a sub-tabbed interface with the following sub-tabs: 'Date / Time', 'Communication', 'Printer', 'Cycle Option', 'Unit / Language', 'Analyzer ID', and 'Setting Save / Restore'. The 'Cycle Option' sub-tab is selected and circled with a blue oval and the number '2'. The main area of the window contains the following settings:

- Daily Workload:**
 - DIF Runs per Day: 40
 - CBC Runs per Day: 10
- Autoclean Frequency:** A text box containing the value '75', circled with a blue oval and the number '3'.
- Enable Automatic Startup:** A checkbox that is checked, circled with a blue oval and the number '4'.

At the bottom right of the window, there is a 'Close' button.

5.4.5. Unit / Language

1- Enter «**Setting\System Setting**» tab:

2- Select «**Unit / Language**» option:

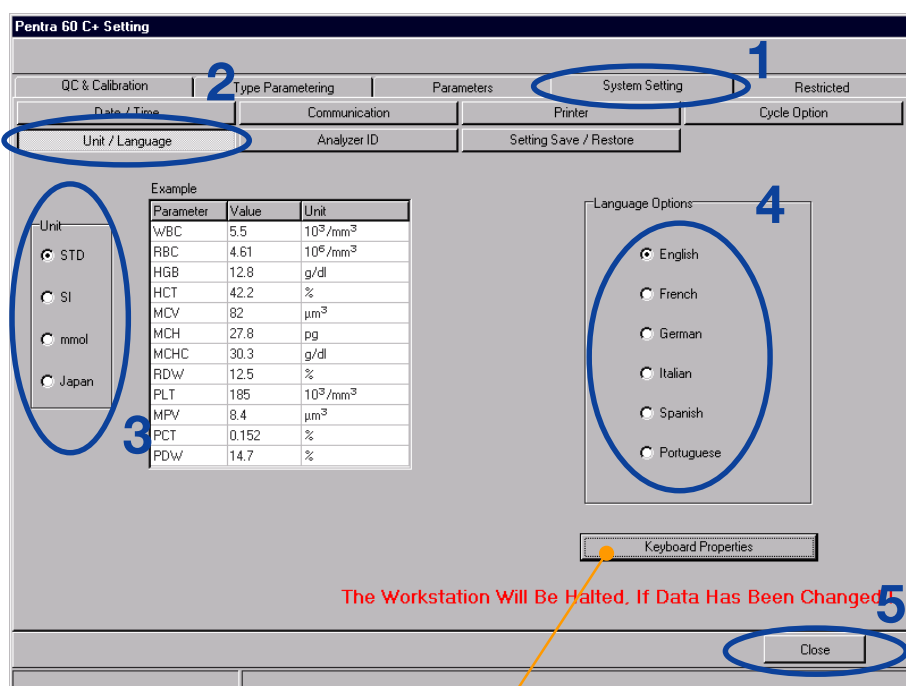
3- Select the unit system you want to use:

4- Select the language option:

5- Exit by clicking

Close

button:



+ **Change input locales:** Allows to select different keyboard layouts.
(Reserved for ABX Technician)

Pentra 60 C+

5.4.6. Analyzer ID

1- Enter «**Setting\System Setting**» tab:

2- Select «**Analyzer ID**» option:

3- Database setup:
«**Max Number of Records**» is the maximum number of records allowed to be stored in the database, before deletion of a number of records set by «**Number of Results to Delete**»:

4- Exit by clicking

Close

button:

The screenshot shows the 'Pentra 60 C+ Setting' window. The 'System Setting' tab is selected and circled with a blue circle and the number 1. Within this tab, the 'Analyzer ID' option is circled with a blue circle and the number 2. Below this, the 'Database setup' section is circled with a blue circle and the number 3. This section contains two input fields: 'Max Number of Records' with the value '10000' and 'Number of Results to Delete' with the value '500'. At the bottom right of the window, the 'Close' button is circled with a blue circle and the number 4. There is also a 'Close' button on the left side of the window, which is the one referred to in the text instructions.

5.4.7. Config Save / Restore

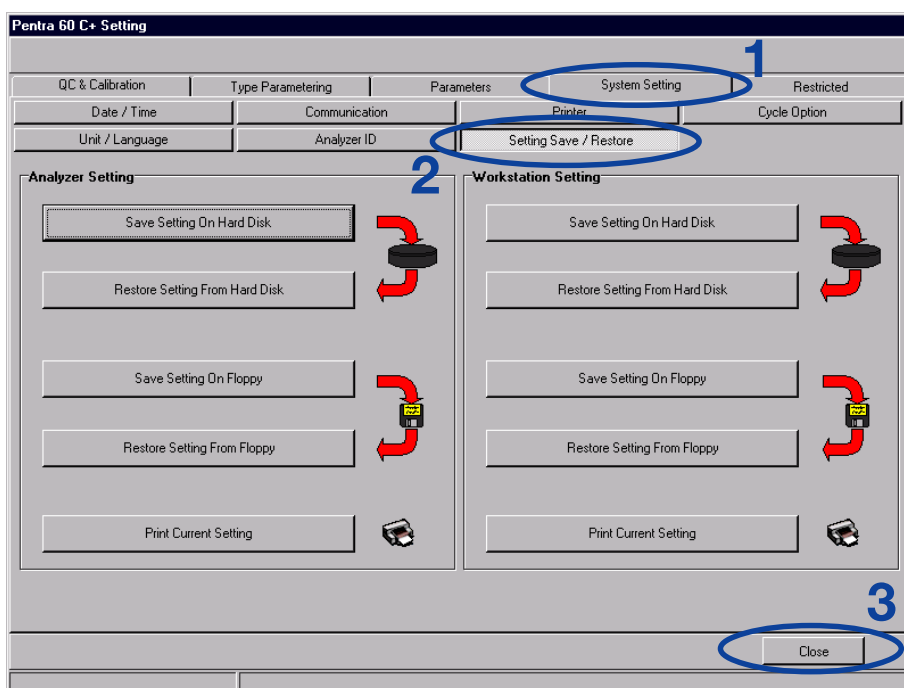
1- Enter «**Setting\System Setting**» tab:

2- Select «**Setting Save / Restore**» option and select the operation to be executed:

3- Exit by clicking

Close

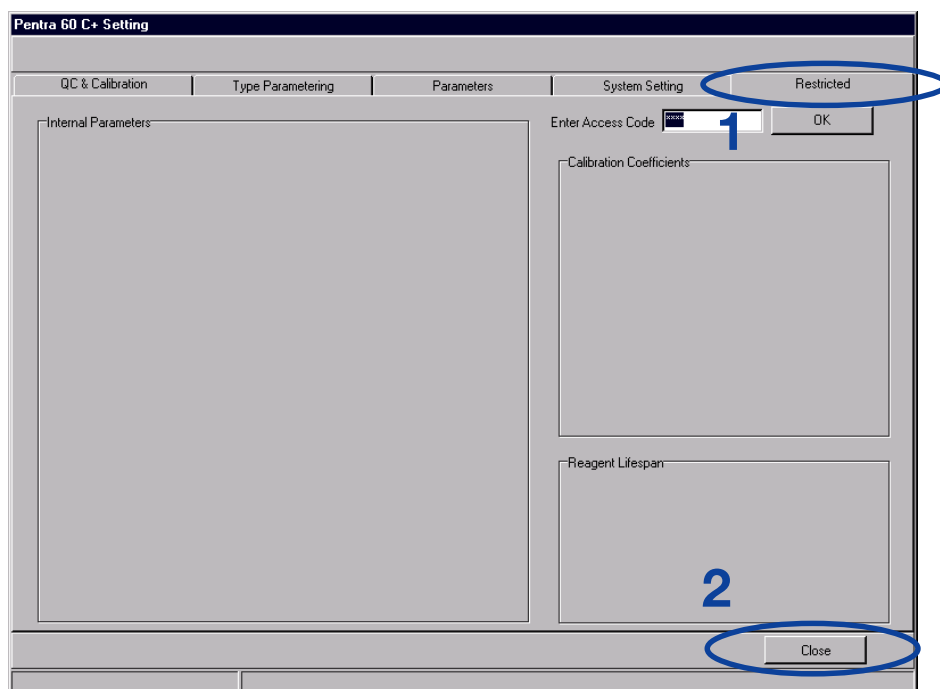
button:



Pentra 60 C+

5.5. Restricted (Reserved for Technicians)

1- Enter «**Setting\Restricted**»
tab:

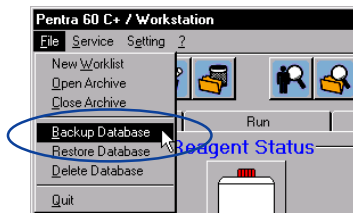


2- Exit by clicking
button:



6. BACKUP / RESTORE DATABASE

6.1. Backup database

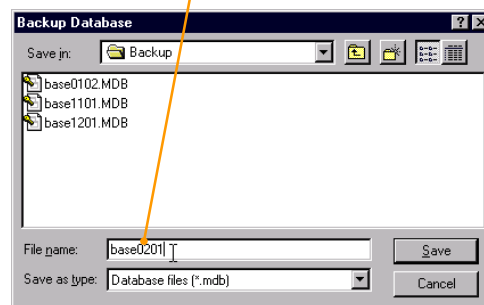


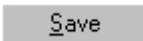
- Use command «**File\Backup Database**» to safeguard database: Current worklist as well as archived worklists, are compressed and stored on hard disk.
- It is recommended to safeguard database regularly to secure datas.
- From window «**Backup Database**» field «**File name**» enter the backup file name for the database (ex: «base0201»).

ATTENTION

In order not to exceed hard drive capacity it is recommended to use same database backup file name for every backup (Previous backup with this file name will be lost).

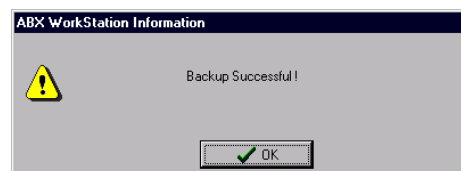
Call your ABX Diagnostics representative service department if hard drive capacity is exceeded.



- Click button  to start backup.
- When backup is finished the following window is displayed:

ATTENTION

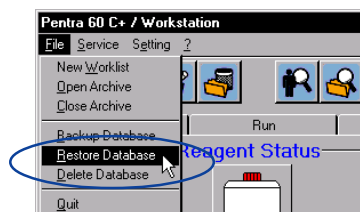
Backup duration (from 1 to 30 minutes) depends on the database length. To get a quick saving a weekly backup is recommended.



- Click button  to exit.

Pentra 60 C+

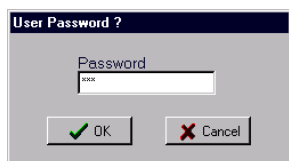
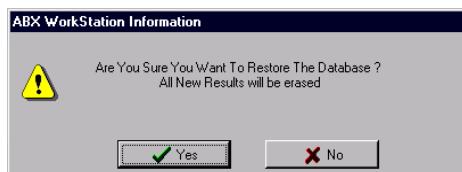
6.2. Restore database



- Previous work, not saved since the last database backup and current worklist will be lost if a database is restored.

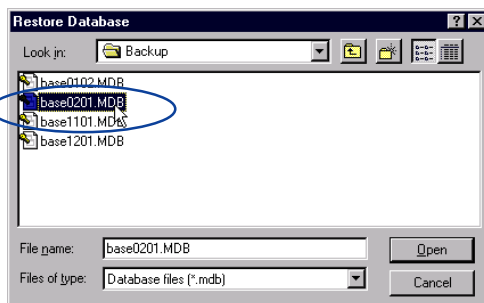
- Use command «**File\Restore Database**» to restore one of the database backup.

- The following window appears, confirm restoration by clicking .

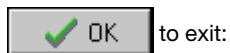


- Enter user password, then validate by clicking button .

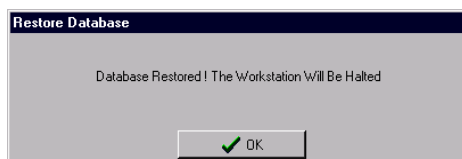
- Select the backup to be restored:



- When database restoration is ended the following message is displayed, click button

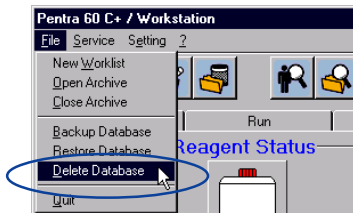


to exit:

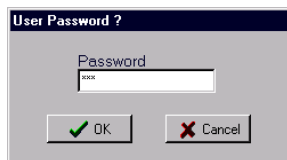


- Workstation is restarted.

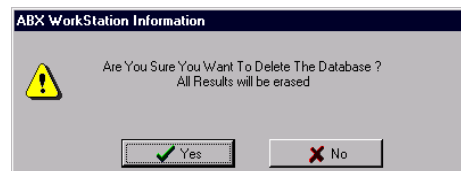
6.3 Delete Database

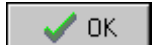


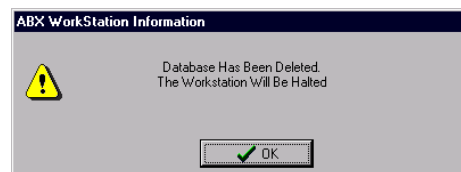
- «**File\Delete Database**» option erases all the results, and the worklist, from the current database.



- Enter user password, then validate by clicking button .
- Confirm deletion by clicking button .



- When deletion is finished the following message is displayed, click button  to exit:



- Workstation is restarted.

MAINTENANCE & TROUBLESHOOTING

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1. REPLACEMENT PROCEDURES

1.1. Reagent replacement

1.1.1. Reagent locations and connections

IMPORTANT

Risk of erroneous results if diluent container is installed further than 80cm (31.5 in.) below the instrument.

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

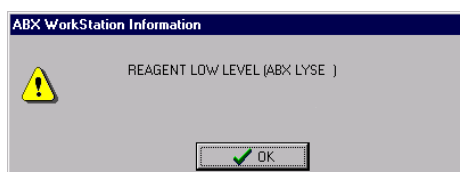


- 1- **ABX** Basolyse II
- 2- **ABX** Lyse
- 3- **ABX** Eosinofix
- 4- **ABX** Cleaner
- 5- **ABX** Diluent
- 6- Waste container

1.1.2. Bottle replacement

- At instrument startup the remaining quantity of each reagent is compared to the daily workload setup by user. If a reagent Low level is expected during working day, the following box is displayed:

+ You can click  and continue to run specimens until the message appears again, then concerned reagent must be changed.



IMPORTANT

Risk of erroneous results if one reagent is poured to another container. Never pour reagents from one container to another. Particles at the bottom of the old container can contaminate the new reagent and will cause unacceptable background results especially for Plts.



- Open the reagent front door,
- Remove the specified bottle from the reagent compartment and unscrew the bottle stopper assembly.

NOTE

Properly dispose of the empty reagent bottle.



- Uncap a new reagent bottle,
- Insert the stopper assembly tube into the new bottle and tighten to ensure an adequate seal.
- Put the new reagent bottle in the reagent compartment and close the door, properly dispose of the empty bottle.
- Confirm reagent bottle replacement in software (as described further).

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1.1.3. Diluent container replacement

IMPORTANT

Make sure diluent container is no more than 80cm (31.5 in.) below the instrument.

- Unscrew the diluent container stopper assembly,
- Uncap a new diluent container,
- Close the empty container with the cap,
- Insert the stopper assembly into the new diluent container and tighten it,
- Confirm diluent replacement in software (as described further).

1.1.4. After a Reagent replacement

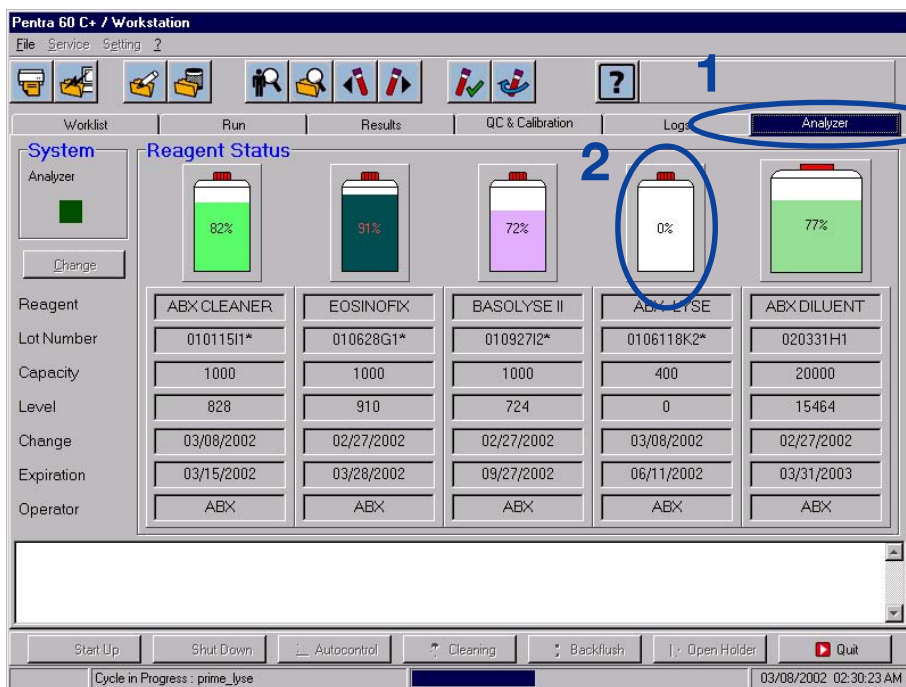
- When a reagent is replaced you need to confirm and update the **ABX WORKSTATION** software.

1- In «Analyzer» tab,

2- Double-click on the reagent bottle icon you want to replace (for example **ABX Lyse**):

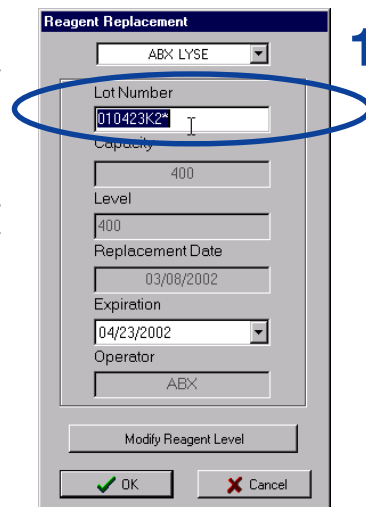
NOTE

You can either click **Change** button to open «Reagent replacement» dialog box.



- The «**Reagent replacement**» dialog box opens (**ABX Lyse** is selected in the reagent scrolling box):

1- Double-click in «**Lot number**» field, and enter new reagent lot number (this information is written on the reagent packaging):



Reagent Replacement

ABX LYSE

Lot Number: 010423K2*

Capacity: 400

Level: 400

Replacement Date: 03/08/2002

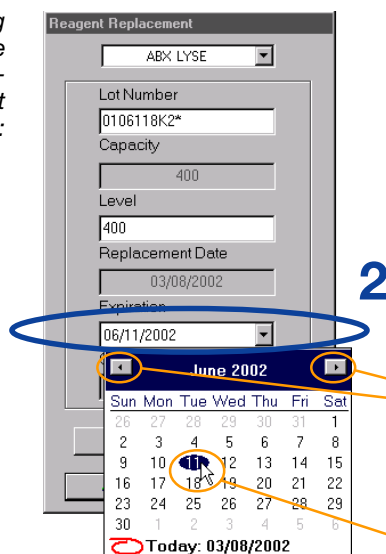
Expiration: 04/23/2002

Operator: ABX

Modify Reagent Level

OK Cancel

- 2- Open «**Expiration**» scrolling list to select expiration date with a calendar (this information is written on the reagent packaging):



Reagent Replacement

ABX LYSE

Lot Number: 0106118K2*

Capacity: 400

Level: 400

Replacement Date: 03/08/2002

Expiration: 06/11/2002

June 2002

Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

Today: 03/08/2002

Select Expiration date Month and Year with RIGHT and LEFT arrow buttons.

Select Expiration date Day by clicking on the calendar (the calendar will be closed automatically).

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- Click  button to close window
(or  Cancel to exit without saving modifications),

Reagent Replacement

ABX LYSE

Lot Number
0106118K2*

Capacity
400

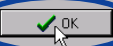
Level
400

Replacement Date
03/08/2002

Expiration
06/11/2002

Operator
ABX

Modify Reagent Level

 OK  Cancel

- Enter comments about the reagent change
(click  OK or press ENTER to validate):

Logs Comment

Please, Enter Your Comment For Updating The Log

Comment

 OK  Cancel



- A prime cycle is automatically started by the instrument.

- Change has been updated in the «Logs» tab:

Pentra 60 C+ / Workstation

File Service Setting ?

Worklist Run Results QC & Calibration **Logs** Analyzer

Logs

- ☒ Reagent
- ☐ Calibration
- ☐ Users
- ☐ Technicians
- ☐ Errors
- ☐ Startup

Add Entry

☒ Ask Logs Comment To User

Date	Operator	Reagent	Lot Number	Expiration Date	Comment
02/27/2002 12:26:27 AM	ABX	ABX CLEANER	01011511*	03/15/2002	blabla
02/27/2002 12:26:47 AM	ABX	EOSINOFIX	010628G1*	03/28/2002	blablabla
02/27/2002 12:27:03 AM	ABX	BASOLYSE II	01092712*	09/27/2002	bla blabla
02/27/2002 12:27:33 AM	ABX	ABX LYSE	010423K2*	04/23/2002	blabla blabla
02/27/2002 12:27:52 AM	ABX	ABX DILUENT	020331H1	03/31/2003	blablablabla
02/27/2002 02:55:06 AM	ABX	ABX CLEANER	01011511*	03/15/2002	blabla
03/08/2002 02:12:00 AM	ABX	ABX CLEANER	01011511*	03/15/2002	blablabla
03/08/2002 02:14:08 AM	ABX	ABX CLEANER	01011511*	03/15/2002	bla blabla
03/08/2002 02:26:23 AM	ABX	ABX LYSE	010423K2*	04/23/2002	blabla blabla
03/08/2002 02:30:17 AM	ABX	ABX LYSE	0106118K2*	06/11/2002	blablablabla

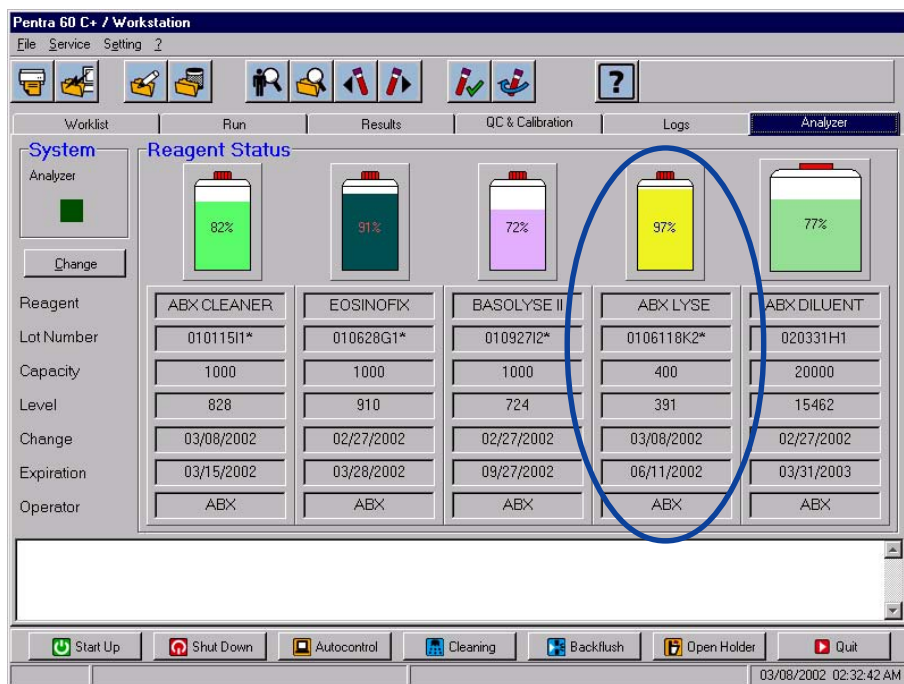
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

03/08/2002 02:53:10 AM



Maintenance & Troubleshooting

- Modifications are updated in «Analyzer» window:



1.1.5. Waste container replacement

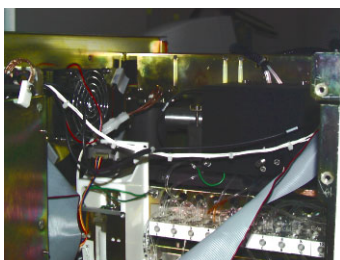
- Unscrew the waste container cap,
- Replace waste container according to your laboratory's protocol,
- Close the empty container with the cap and dispose of waste liquids according to your local/national organizations.

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1.2. Optical bench lamp replacement

Lamp replacement
(2 and 3mm hex keys
required)

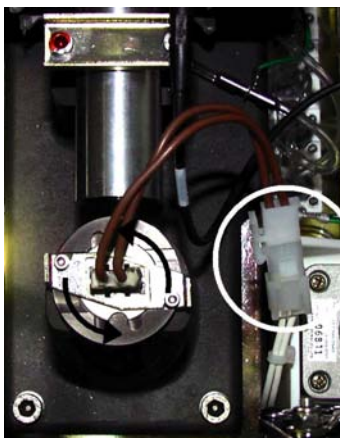
- Switch off the instrument and disconnect power supply cable,
- Remove the instrument cover:
 - Open the right door and unscrew cover screw in the upper front corner,
 - Unscrew the four screws of the left door,
 - In the left compartment unscrew the upper front corner screw,
 - Remove the six hex screws at the back of the instrument,
 - Remove instrument top cover carefully.
- Open mother board door (To keep the door open anchor it behind plastic catch).



CAUTION

Becareful when you open motherboard door not to disconnect or damage flat cable connected behind it.

- On the left top of the instrument locate the optical bench and the lamp (left side of the optical becnh).



WARNING

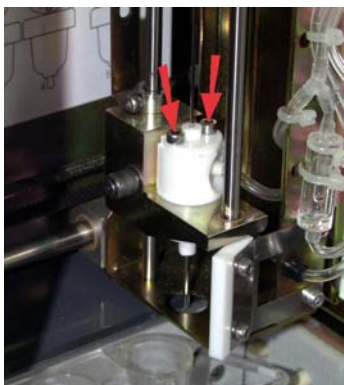
Wait for the lamp to cool down before handling it.

- Disconnect the lamp supply,
- Unscrew lamp fixation screws (few turns),
- Turn the lamp and remove it,
- Replace the lamp by a new one,
- Put back the fixation system and block the screws,
- Reconnect the lamp supply,
- Check that instrument operates normally:
 - Close the right door,
 - Connect power supply and start the instrument,
 - Check Lamp is lighted,
 - If it is wait until startup end, switch off the instrument and disconnect power supply cable, replace cover and close all doors, connect supply cable and turn the instrument on.
 - If not troubleshoot system to determine the problem.



1.3. Sampling probe replacement

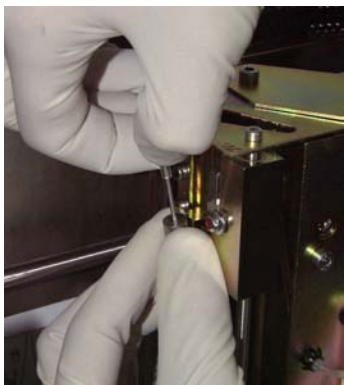
- Switch off the instrument and disconnect power supply cable,
- Open the pneumatic access door (on the right side of the instrument),
- Untight both rinsing block screws,



- Lift locker to free the probe,



- Disconnect gently the tube from the probe and replace the probe.



- Re-assemble in reverse order, tight the rinsing block screws.
- When start up is done check for no leak.

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2. MAINTENANCE

2.1. Hydraulic cycle maintenance chart table

- One of the principle factors contributing to accurate and reliable results is a well-maintained instrument. Several maintenance functions are available for the user to clean and check the instrument.

+ **Frequency** of maintenance cycles depends on the laboratory sample output, perform maintenance according to the chart table beside:

MAINTENANCE CYCLES (ANALYSES/DAY)	LABORATORY OUTPUT	
	≤100	>100
Shut Down	1 per day	1 per day
Autoconcentrated Cleaning	1 per month	2 per month

2.1.1. Shut down cycle

- At the end of each day do a Shut Down cycle to rinse the instrument (Fluidic tubing and apertures are cleaned to prevent instrument pollution).

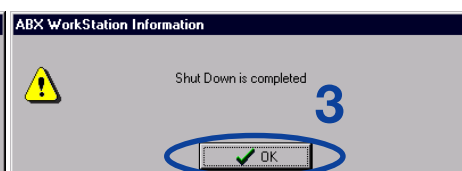
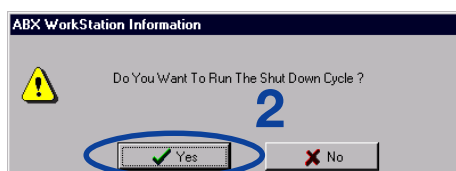
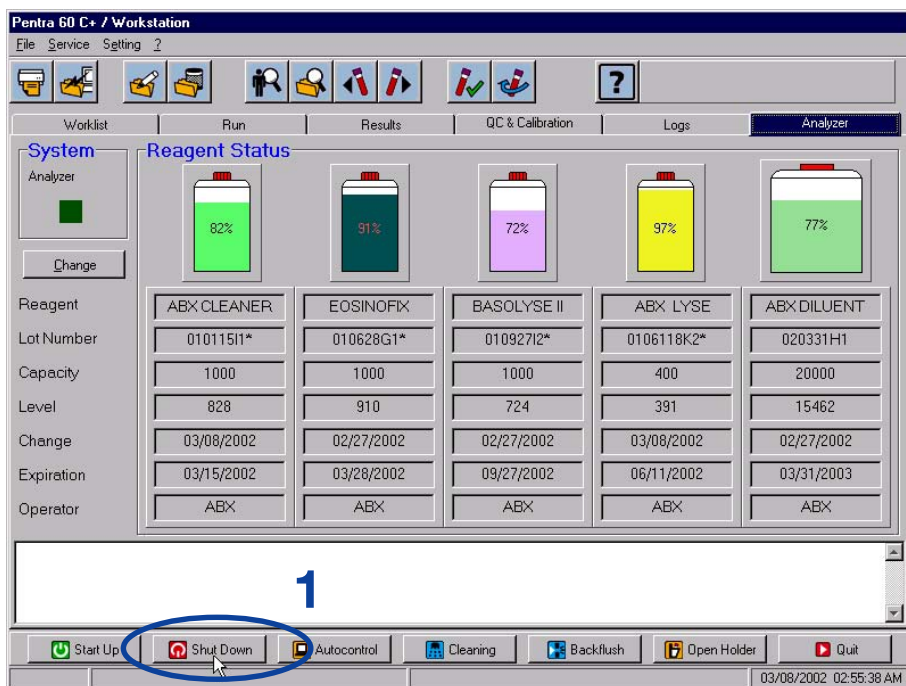
1- To run a Shut Down cycle

 **Shut Down** button:

2- Confirm Shut Down cycle:

3- Click button  **OK** when cycle is finished:

+ **During** cycle a progression a status bar is displayed:



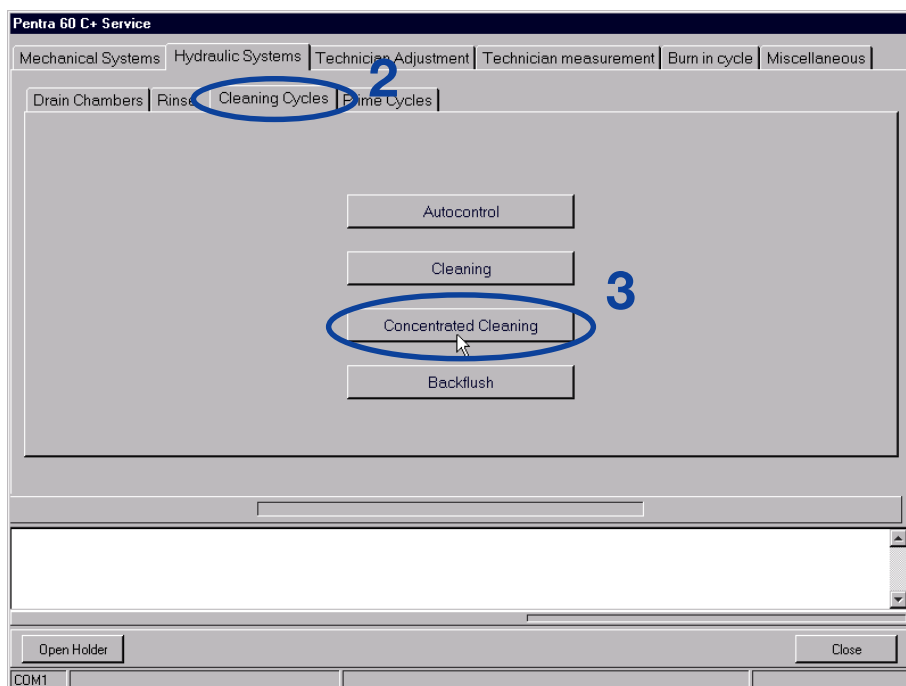
2.1.2. Concentrated cleaning

- Autconcentrated cleaning allows the chambers to be cleaned with bleach:

1- Open «Menu\Service\Hydraulic systems» window:

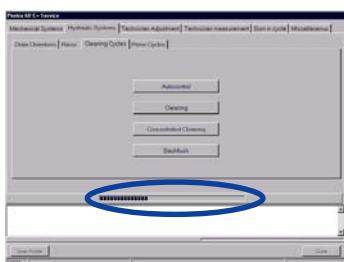


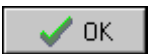
2- Open «Cleaning cycles» tab:

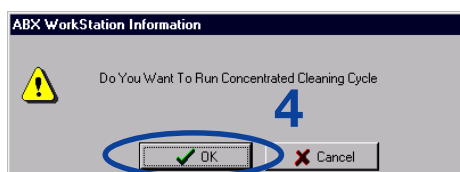


3- Click **Concentrated cleaning** button:

+ **During cycle a progression a status bar is displayed:**



4- Confirm start of concentrated cleaning by clicking button  :



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- A rinse cycle is started. Enter the comments to update «**Reagent**» log: Wait until the instrument displays the following message:

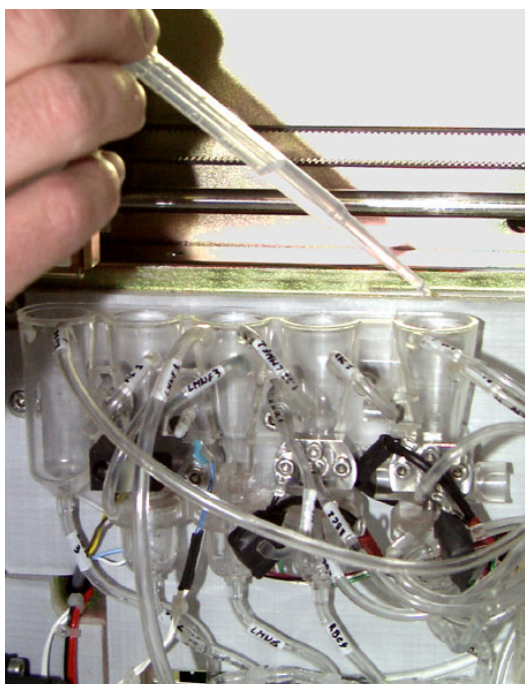
NOTE

Do not click «OK» before you pour minoclair.

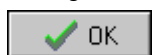
- Open the instrument pneumatic door.

- Use a 5ml syringe to pour 3ml of MINOCLAIR (or bleach diluted to 4° chloride) into each chamber and validate.

- Close the instrument door and wait for the instrument to complete the cleaning procedure (Concentrated cleaning duration is around 5 min.).



- 5- Exit Concentrated cleaning cycle by clicking button



- + During cycle a progression a status bar is displayed:

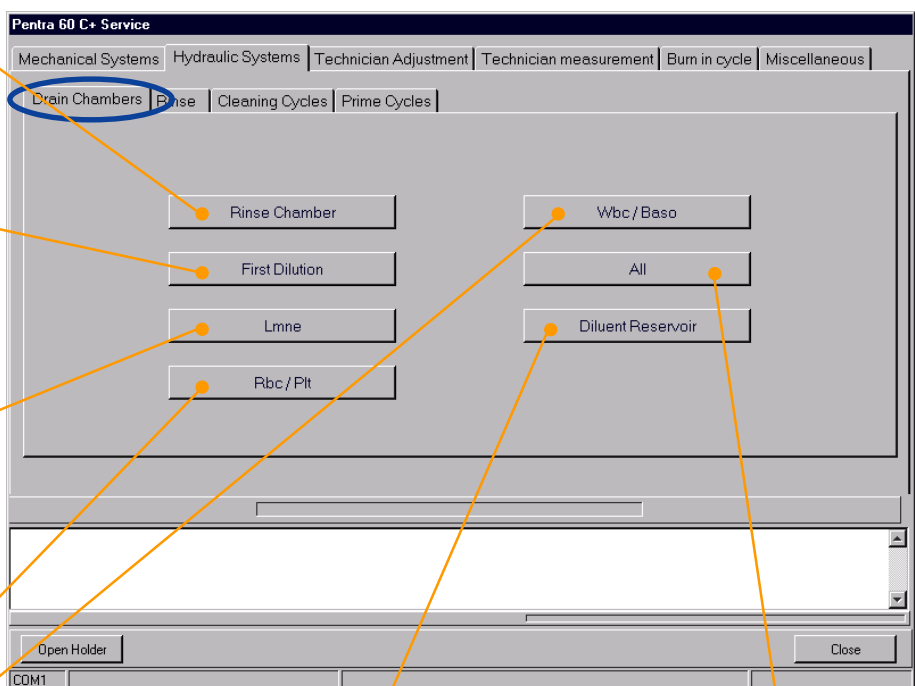
2.2. Hydraulics systems

1- Open
«Menu\Service\Hydraulic
Systems» window:



2.2.1. Drain chambers

- Run Drain chamber cycle if there is a problem with the chambers. From the «Menu\Service\Hydraulic systems\Drain chamber» select one of the following options:



+ Rinse

- Sampling probe rinsing chamber (1) drain,

+ First dilution

- First dilution chamber (2) drain,

+ LMNE

- LMNE chamber (3) drain,

+ RBC/Plt

- RBC/Plt chamber (4) drain,

+ WBC/BASO

- WBC/BASO chamber (5) drain,

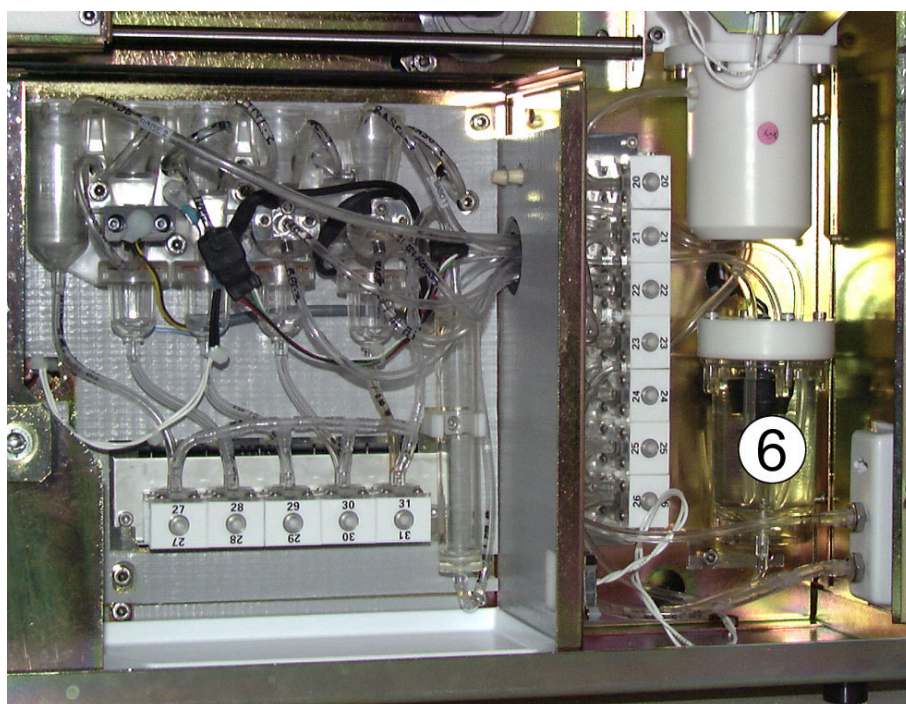
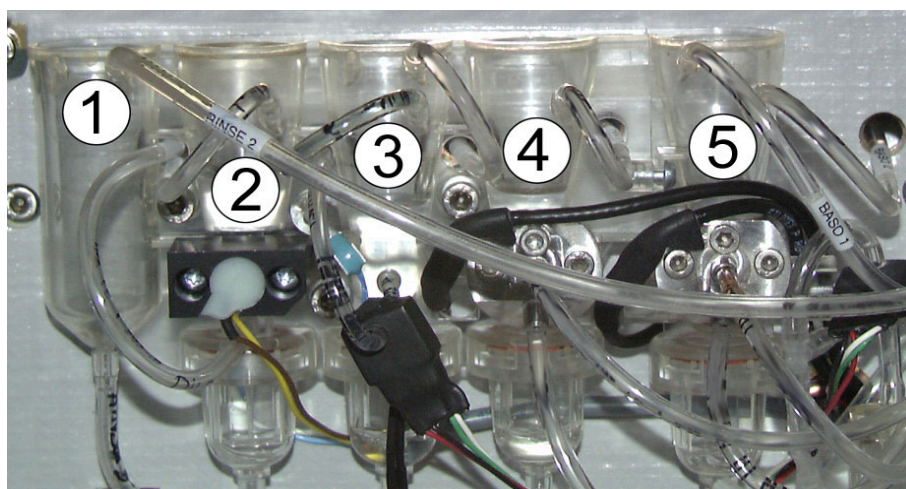
+ Diluent reservoir

- Diluent reservoir (6) drain.

+ All chambers

- General drain (1,2,3,4,5),

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2.2.2. Rinse

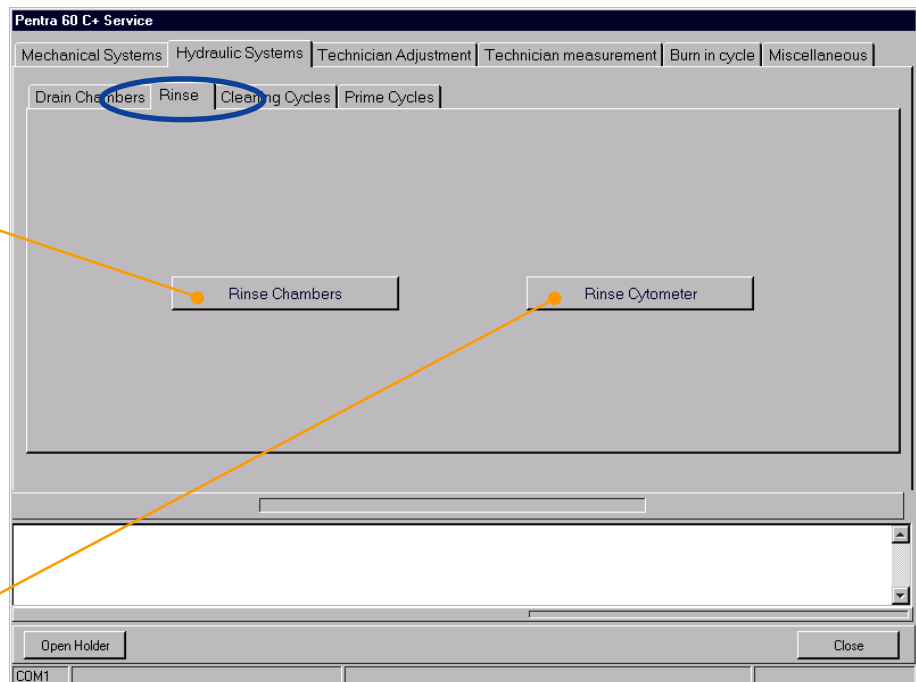
You can rinse instrument's chambers or cytometer with **ABX Diluent** from the «Menu\Service\Hydraulic systems\» select one of the following option:

- Rinse chamber if you have excessive flagging on **CBC** parameters.
- Rinse cytometer to remove bubbles from the flowcell if you have excessive flagging on **5DIFF** parameters.

• From the «Menu\Service\Hydraulic systems\Rinse» select one of the following options:

+ **ABX Diluent** is sent to chambers to rinse out these parts.

+ **ABX Diluent** is sent to Cytometer to rinse out this part.



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2.2.3. Cleaning cycles

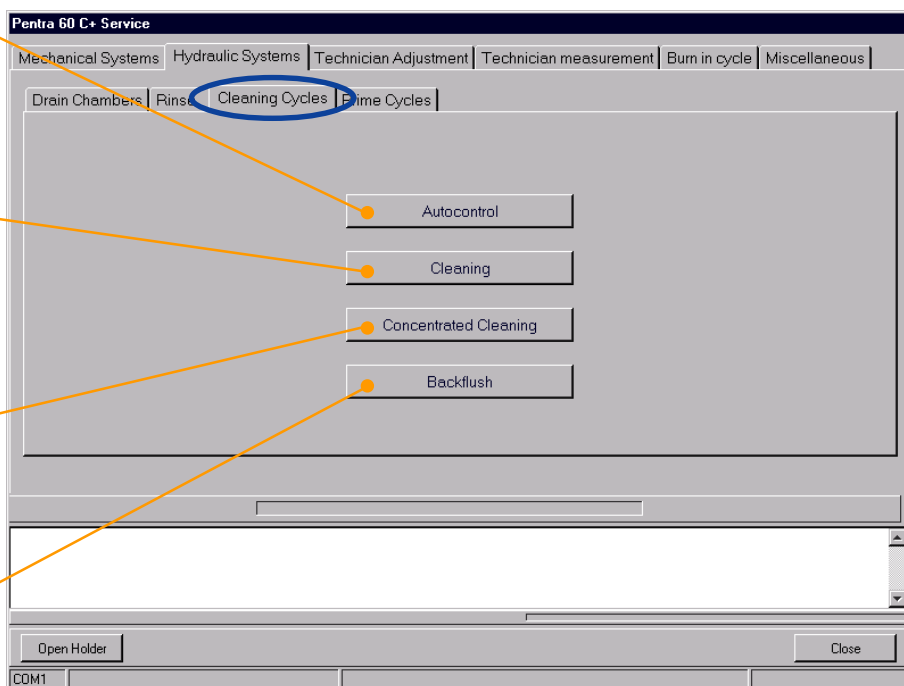
- Cleaning cycles are described further.
- From the «Menu\Service\Hydraulic systems\Cleaning Cycles» select one of the following options:

+ **Autocontrol** cycle:
Used principally following the emergency shut down of the instrument for re-initialization and cleaning (cycle evolution bargraph).

+ **Cleaning** cycle:
Cycle required by the instrument after two hours idle (cycle evolution bargraph).

+ **Concentrated** cleaning:
Cycle for cleaning chambers with bleach.

+ **Backflush** cycle: Cycle for cleaning counting chambers, by counter-pressure, in case of blockage.



2.2.3.1. Autocontrol cycle

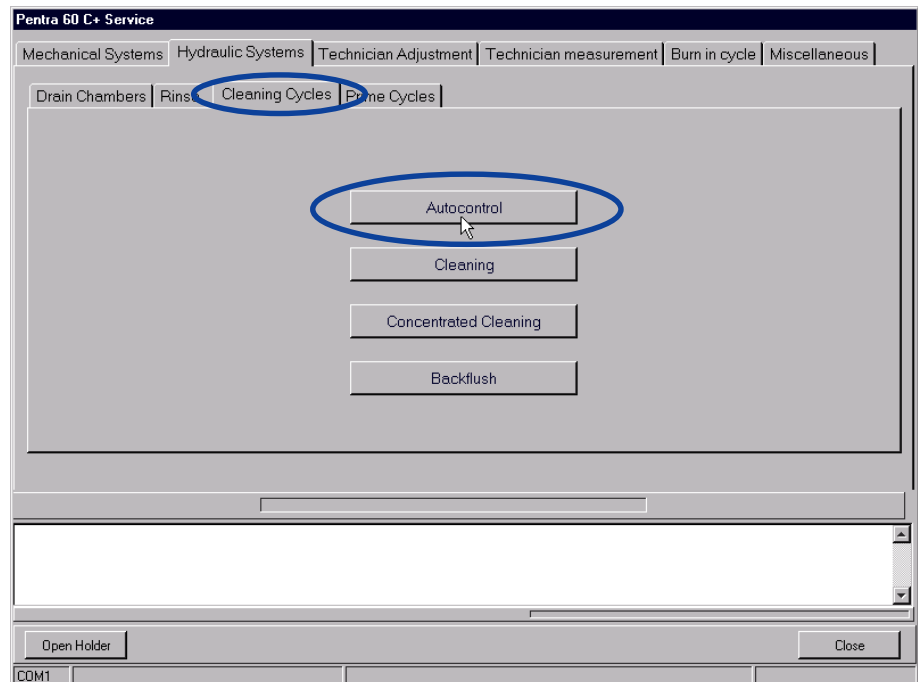
- This cycle is required after an emergency stop of the instrument, when a faulty operation has been detected or after a concentrated cleaning.

- Click  **Autocontrol** button:



+ A series of mechanical, hydraulic and electronic networks control is performed:

- General rinse,
- Control of the correct drains of the chambers,
- Initialization of the mechanical assemblies.



+ During cycle progression a status bar is displayed:



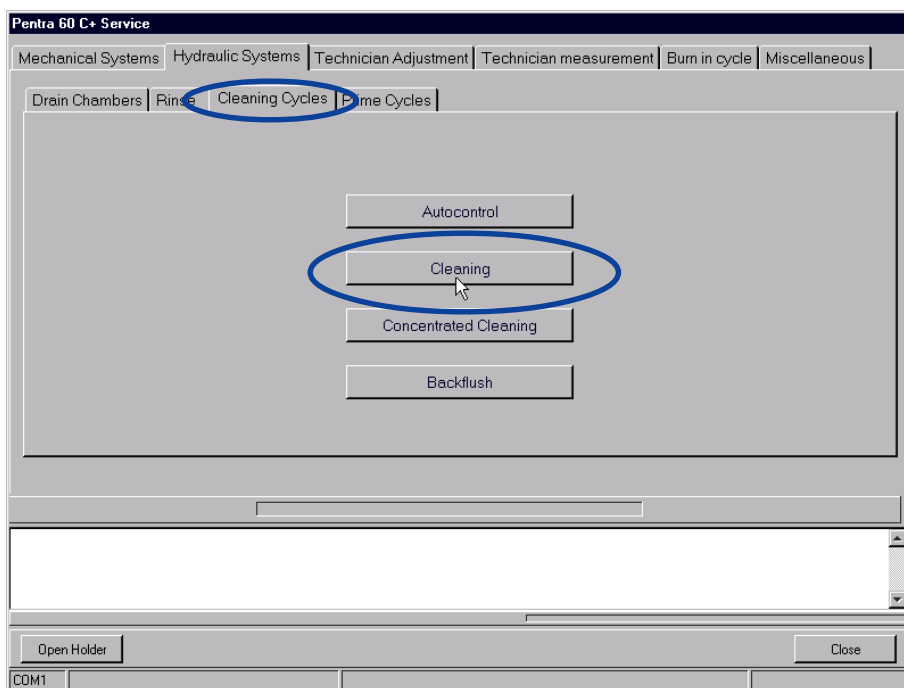
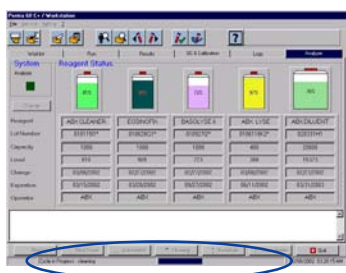
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2.2.3.2. Cleaning cycle

- This cycle is required by the instrument after two hours idle.
- Click  **Cleaning** button:



+ *During cycle a progression a status bar is displayed:*



2.2.3.3. Concentrated cleaning cycle

- This cycle is for cleaning chambers with bleach.
- Do this procedure if you suspect a clot or fibrin.
- See previous notes on how to perform a concentrated cleaning (paragraph «**Maintenance**»).

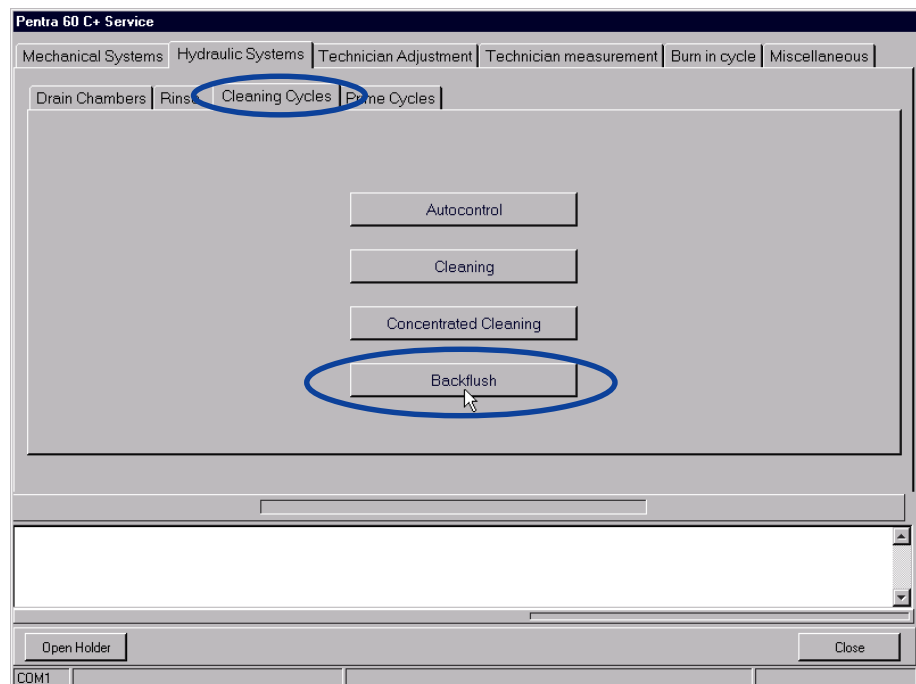
2.2.3.4. Backflush cycle

- The backflush cycle delivers pressure through the rear of the apertures to remove blockages.
- Do this procedure if you suspect the apertures are blocked.
- Click on  **Backflush** button:



+ **Delivers** pressure through the apertures of the counting chambers to clean them in case of blockages.

+ **During** cycle a progression status bar is displayed:



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2.2.4. Prime cycles

- This function primes reagents into the instrument.
- Do this procedure after service has been performed on the instrument.
- Click on one of these buttons to start the corresponding cleaning cycle:

+ Lyse
• Prime **ABX Lyse** reagent.

+ Diluent
• Prime **ABX Diluent** reagent.

+ Cleaner
• Prime **ABX Cleaner** reagent.

+ Eosinofix
• Prime **ABX Eosinofix** reagent.

+ Basolyse II
• Prime **ABX Basolyse II** reagent.

+ All reagents
• Prime all reagents.

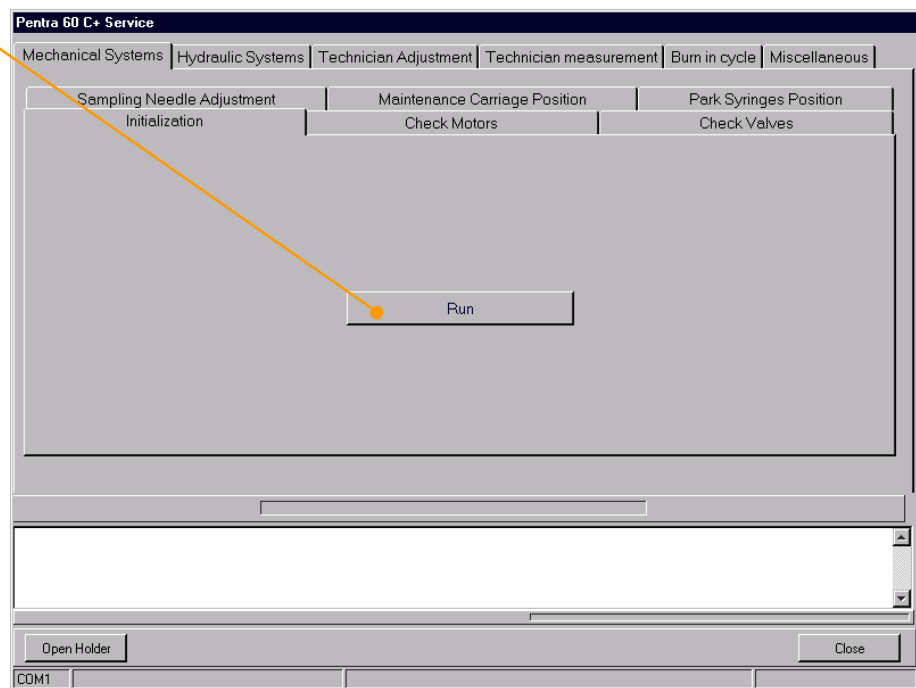
+ Unprime all
• Unprime all reagent.

The screenshot displays the 'Pentra 60 C+ Service' software window. The 'Prime Cycles' tab is selected and highlighted with a blue circle. The interface contains several buttons for reagent priming: 'Diluent', 'Cleaner', 'Eosinofix', 'Basolyse II', 'Lyse', 'All Reagents', and 'Unprime All'. Orange lines connect these buttons to their respective descriptions on the left. At the bottom of the window, there are 'Open Holder' and 'Close' buttons, and a 'COM1' status indicator.

2.3. Mechanical systems

2.3.1. Initialization

+ **All the mechanical assemblies (sampling probe, carriages, syringes....) return to their initial positions, i.e. the operating analysis positions.**



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2.3.2. Check motors

To control the correct operation of each motor:

- Switch off the instrument.

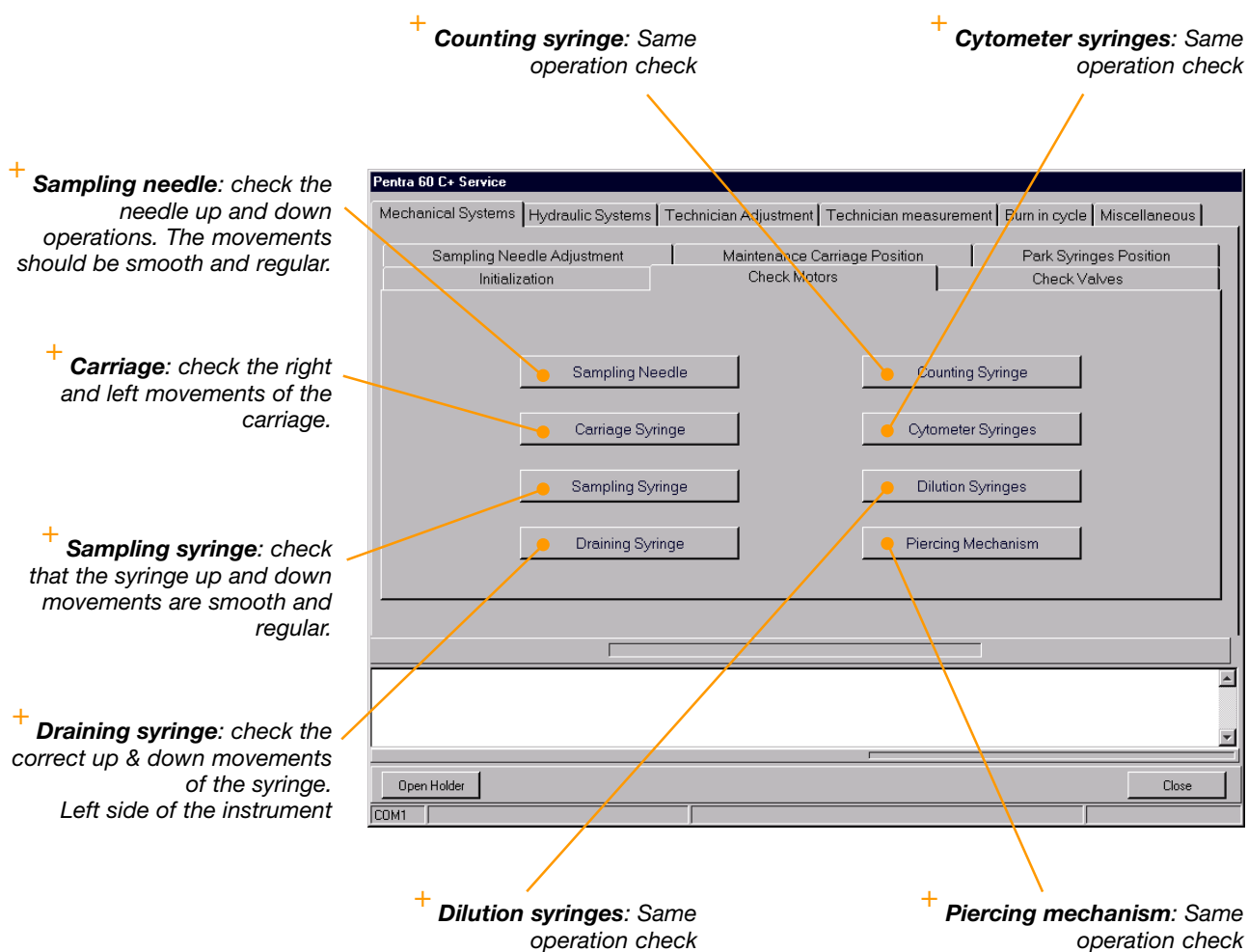
Open the door (see on previous page) and the left cover of the instrument:

- Loosen the 2 screws of the board support panel and open it.

Note: be careful of the flat cables while opening the door !

- Once both sides of the instrument are open, switch on the instrument.

Enter the check motors menu and control each motor pressing the corresponding number.
Right side of the instrument



2.3.3. Check valves

To control the correct operation of the valves:

- Open the door (see on previous pages) and the left cover of the instrument.
- The valves can be operated pressing the corresponding number of the assembly.
- Closely observe the valve operations; the movements have to be straight and regular.

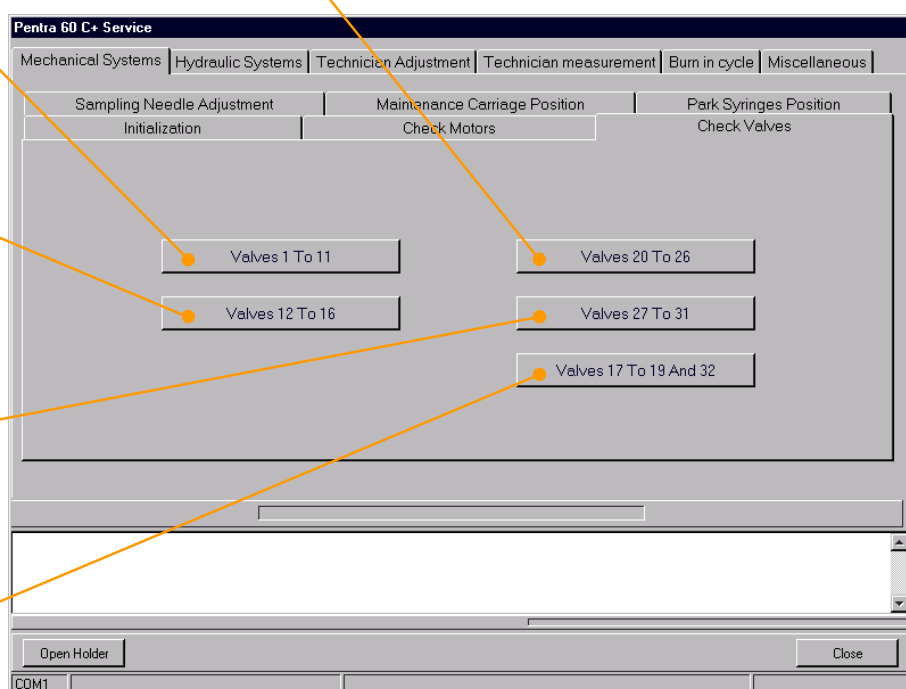
+ **Valves 20 to 26:** Check correct operation for these valves.

+ **Valves 1 to 11:** Check correct operation for these valves.

+ **Valves 12 to 16:** Check correct operation for these valves.

+ **Valves 27 to 31:** Check correct operation for these valves.

+ **Valves 17 to 19 & 32:** Check correct operation for these valves.



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2.3.4. Sampling needle adjustment

- Tube holder and sampling needle positions are factory adjusted, do not modify them.

+ **Hole depth, in millimeters, for each tube holder position Id.**

+ **Level of probe sampling in millimeters from the tube holder's bottom.**

Position Id	Depth	Level
1	56	3
2	44	3
3	12	3
4	17	3
5	22	3
6	29	3
7	42	3
8	12	3
9	12	3
10	12	3
11	12	3
12	12	3
13	12	3
14	12	3

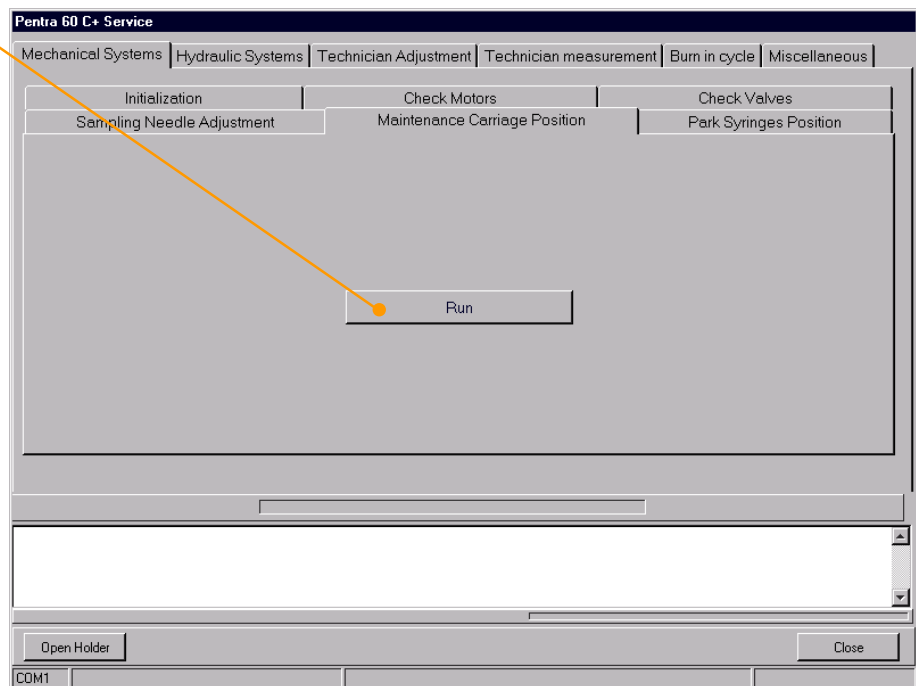
+ **Position Id** field returns the tube holder position after an «**Id holder position**» command.

+ **Id holder position** button returns the actual «**Position Id**» of the tube holder after you close it (Click Open tube holder button to open it again).

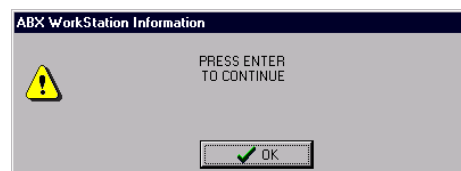
2.3.5. Maintenance carriage position

- Carriage shift cycle over the trays to simplify maintenance operations such as the replacement of a sampling needle for example.

+ **Run:** Moves sampling carriage to maintenance position.



+ **Press enter or click**  **OK** button to return to initial position.

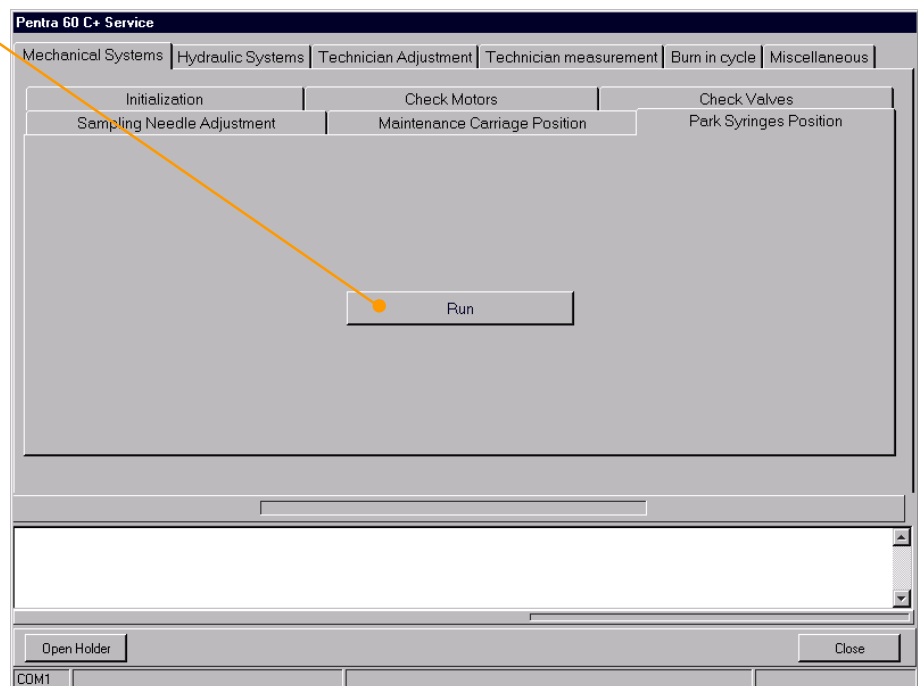


Pentra 60 C+

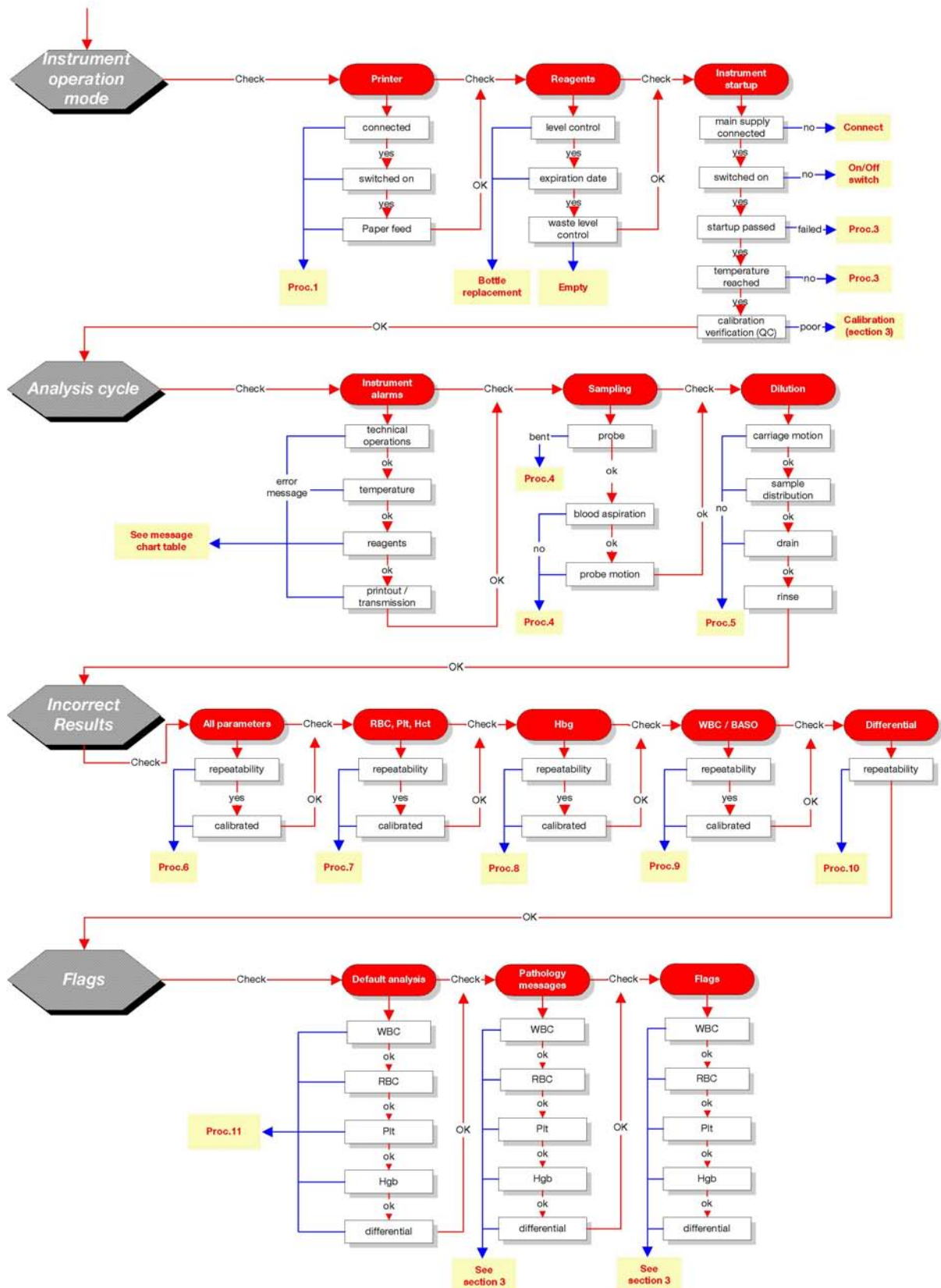
2.3.6. Park syringe position

- This function parks syringes when the instrument will not be used for a long period of time or for transportation:

+ **Run:** Moves syringes to park position.



3.TROUBLESHOOTING



3.1. Instrument operation mode

- ◆ Procedure 1
Printer
 - See printer user manual to connect, to switch on/off or to feed paper.

- ◆ Procedure 2
Workstation computer
 - See computer user manual to connect or to switch on/off workstation.

- ◆ Procedure 3
Reagents
 - Bottle replacement (see *Chapter 4. Instrument configuration*),
 - Waste container: empty and neutralize as recommended in *Chapter 1. Specifications*.

- ◆ Procedure 4
Instrument Startup

Startup failed:

- Check the reagent expiration dates: replace bottle if necessary,
- Re-run a startup,
- perform an auto-concentrated cleaning (*Chapter 5. Maintenance & Troubleshooting*).

Temperature not reached:

- Wait for 5 minutes to reach the operating temperature, if temperature is not reached call your **ABX DIAGNOSTICS Representative Service Department**.

Calibration verification out of the acceptable limits

- Clean the system see *Chapter 5. Maintenance & Troubleshooting* and rerun the control,
- Run a new vial,
- Calibrate the instrument (see *Chapter 4. Instrument configuration*).

◆ Procedure 5 Sampling Probe

Sampling probe

- Check the motion of the probe: «**Menu\Service\Mechanical systems\Check motors\Sampling needle**».
- Open the pneumatic access door.
- Run an analysis cycle on blood.
- Control the specimen aspiration (blood delivered in the chambers).
- Check the probe is not bent.

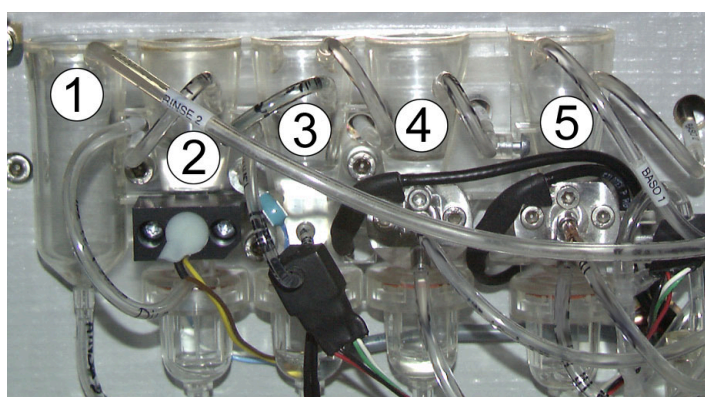
◆ Procedure 6 Dilution

Carriage motion

- Check that hydraulic operations appear to work properly (reagent level in each chamber, carriage motion).

Sample distribution:

- Run an analysis cycle and check that the specimen distribution is performed correctly into the chambers.
- A probe rinse is previously carried out in the rinse chamber (1) (blood appears in this chamber).
- 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).
- Check that bubbling is provided to these chambers once the specimen have been diluted.



Drain and rinse

- Check the chambers are drained and rinsed.
- If operations are faulty, identify the source of the malfunction and call your **ABX DIAGNOSTICS Representative Service Department**.

3.2. Results

◆ Procedure 7 All Parameters

Repeatability (according to the CV Specifications see Chapter 1. Specifications)

- 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:
 - Visually check that the sampling operation appears to be correct.
 - Control the sampling syringe operations (see Chapter 5. *Maintenance & Troubleshooting*)
 - Control the counting syringe operations (see Chapter 5. *Maintenance & Troubleshooting*)
 - Perform an autoconcentrated cleaning
- If all these operations appear to be correct, call your **ABX DIAGNOSTICS Representative Service Department**.

Calibration

- If the system appears to be operating properly, fresh uncontaminated reagents are being used and the precision is within the specifications, the **ABX PENTRA 60 C+** may need a calibration as described Chapter 4. *Instrument configuration*

◆ Procedure 8 RBC, Plt, Hct

Repeatability

- If RBC, Plt & Hct are not repeatable:
 - Check the second dilution is carried out correctly (sample from the chamber 2 to the chamber 4),
 - Check the Bubbling in the RBC/Plt chamber (4) once the dilution is carried out (the dilution remains transparent),
 - Perform an autoconcentrated cleaning.
- If all these operations appear to be correct, call your **ABX DIAGNOSTICS Representative Service Department**.

Calibration

- See procedure 7



Maintenance & Troubleshooting

◆ Procedure 9 Hgb

Repeatability

- Is the instrument non repeatable on Hgb ?
 - Run a analysis cycle,
 - Check the dilution colour in the chamber (2): «Milky» when the sample is first delivered to the chamber, then brown transparent when Lyse is injected,
 - Perform an autoconcentrated cleaning.
- If this does not correct the Hgb count, call your **ABX DIAGNOSTICS Representative Service Department.**

Calibration

- See procedure 7

◆ Procedure 10 WBC, BASO

Repeatability

- Is the instrument non repeatable on WBC/BASO ?
 - Perform an autoconcentrated cleaning.
- If this does not correct the Hgb count, call your **ABX DIAGNOSTICS Representative Service Department.**

Calibration

- See procedure 7

◆ Procedure 11 Differential

Repeatability

- Is the instrument non repeatable on differential ?
 - Perform an autoconcentrated cleaning.
- If this does not correct the WBC/BASO count, call your **ABX DIAGNOSTICS Representative Service Department.**

Pentra 60 C+

3.3. Flags

◆ Procedure 12 Default analysis

WBC

- Perform an autoconcentrated cleaning,
 - Rerun the specimen,
 - Check the operation of the liquid valve <23> and <14> (opening and closing during the cycle). If defective, replace the valve.
- If it does not correct WBC results, call your **ABX DIAGNOSTICS Representative Service Department**.

RBC, Plt

- Perform an autoconcentrated cleaning,
 - Rerun the specimen,
 - Observe the operation of the liquid valve <14> (opening and closing during the cycle). If not replace the valve.
- If it does not correct the RBC or Plt results, call your **ABX DIAGNOSTICS Representative Service Department**.



Hgb

- Is the Hgb LED illuminated when the system power is on ?
 - If not call your **ABX DIAGNOSTICS Representative Service Department**, if it is continue:
 - Perform an autoconcentrated cleaning,
 - Rerun the specimen.
- If it does not correct the Hgb results, call your **ABX DIAGNOSTICS Representative Service Department**.

Differential

- Confirm that the lamp is lit when the instrument is on. If not replace it as described below,
 - Run a cytometer rinse (see [Chapter 5. Maintenance & Troubleshooting](#)),
 - Re-run the specimen.
- If it does not correct the LMNE results, call your **ABX DIAGNOSTICS Representative Service Department**.

4. ERROR MESSAGES

4.1. Printer

MESSAGES	CAUSES	USER ACTIONS
The printer is disconnected, switched OFF or has not been selected	Printout operations disabled	Switch ON Press «ON LINE» See the printer user's manual

4.2. Calibration

MESSAGES	CAUSES	USER ACTIONS
Access denied	Incorrect password entered by operator	Enter correct password
Illegal date	Incoherent date entered by operator	Enter correct date
Minimum tagged CBC incorrect. X at least 3.	Selected results for calibration calculation	Select at least 3 results
Target file QC incorrect version	Bad file format or bad disk	Replace the disk
Target QC File Not Found	Bad file format or bad disk	Replace the disk
Target QC File Read Error	Bad file format or bad disk	Replace the disk
Target QC file unknown error	Bad file format or bad disk	Replace the disk
Calibration Failed : Coef. Out Of Range	Bad result	Restart calibration
Calibration Failed : Confirm To Force Calibration	Bad result	Restart calibration

4.3. Temperature

MESSAGES	CAUSES	USER ACTIONS
Temperature out of range	Thermic regulation problem	Call your ABX DIAGNOSTICS representative Service Department
Heating coil initialization	Operating temperature not reached	Wait for a few minutes

4.4. Reagents

MESSAGES	CAUSES	USER ACTIONS
No diluent, check level	Diluent reservoir empty	Replace the diluent container (see Chapter 5. <i>Maintenance & Troubleshooting</i>)
Reagent low level (reagent name)	none	Replace the reagent bottle (see Chapter 5. <i>Maintenance & Troubleshooting</i>)
Reagent low level	Message triggered at the end of the startup	Control the reagent levels / replace it
Drain time out	Draining problems	Call your ABX DIAGNOSTICS representative Service Department

4.5. Miscellaneous

MESSAGES	CAUSES	USER ACTIONS
Emergency stop, run an Autocontrol	Blocked motor Incorrect drains Thermal door opened	Control the motor operations Menu\Service\Mechanical systems\Check motors
..... not reaching home	Blocked motor	
Thermal door opened	Open during a cycle	Close the door and rerun sample
Illegal time	Incoherent time entered by operator	Enter correct time
Data not saved, value out of range	Incorrect value entered by operator	Enter correct value
User password	Password required to carry out an operation	Enter password
Bad reference position	Mechanical problem	Call your ABX DIAGNOSTICS representative Service Department
Language of Pentra changed, please restart the computer and instrument	Language has changed	Restart Instrument and Workstation

5. HAZARDS RELATING TO OPERATOR SAFETY & INSTRUMENT FUNCTION

- Hazards relating to operator safety / instrument function (injury or instrument damage which may occur during instrument operation or maintenance) are indicated by special conditions. Descriptions of these conditions are given in the first pages of the **ABX PENTRA 60 C+** manual.
- The normal operation of the **ABX PENTRA 60 C+** instrument must be done with the protection cover on in order to prevent injuries.
- During maintenance procedures or instrument checks, the instrument must be switched off and the power cable removed.
- The main hazards are given in the following 2 tables and are described as:

5.1. Hazards relating to instrument function

UNDESIRABLE EFFECTS	POSSIBLE CAUSES	INSTRUMENT RESPONSE	USER ACTION
Incorrect mechanical operation	Defective stepper motors	Motor alarms Current cycle stops	Autocontrol cycle
Incorrect hydraulic operation	Leaks or blockages	Reagent alarms Current cycle stops	Autocontrol cycle Startup cycle Prime reagent cycle
Incorrect optical operation	Defective optical parts Optical parts dirty	Specific flags Blank cycle measurements outside acceptable limits	Autocontrol cycle Cleaning cycle Autoconcentrated cleaning cycle
Incorrect electrical operation	Incorrect main supply voltage	No instrument initialization	Check main voltage

5.2. Hazards relating to operator safety

UNDESIRABLE EFFECTS	POSSIBLE CAUSES	INSTRUMENT RESPONSE	USER ACTION
Injury by sampling probe	Attempt to run sample during a non authorized period	Cycle start rejected	Refer to the manual sampling control LED indications Read the concerned documentation
Electrical hazards in general	Contacts with internal electrical parts of the instrument	No electrical contact possible during normal operation - Instrument grounded during installation	Read and follow the mentioned recommendation
Contact with reagents	Direct contact with reagents Leaks during operation checked during cycles	Integrated reagents Automatic aspiration and waste Liquid transfer	Follow the reagent handling recommendations given in Chapter 1
Contact with infectious samples	Direct contact with blood or with contaminated parts Contact with waste products	Automatic cleaning of the parts Automatic waste disposal	Read and follow the mentioned recommendation Follow the laboratory regulations

ANNEX

GLOSSARY	ANNEX-2
LIST OF ABBREVIATIONS	ANNEX-4
WORKLIST'S KEYBOARD SHORTCUTS	ANNEX-6
PNEUMATIC DIAGRAM	ANNEX-7

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
<i>agglutination</i>	<i>Clump</i>
background count	Measure of the amount of electrical or particle interference
<i>blank cycle</i>	<i>Runs diluent through the system to clean it out</i>
calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors
<i>calibration factors</i>	<i>These are correction factors that the system uses to fine-tune instrument accuracy</i>
calibrator	A substance traceable to a reference method for preparation or material used to calibrate, graduate, or adjust measurement
<i>carryover</i>	<i>The amount, in percent, of blood cells remaining in diluent following the cycling of a blood sample</i>
cell control	A preparation made of human blood with stabilized cells and surrogate material used for daily instrument quality control
<i>characteristics</i>	<i>See performance characteristics</i>
coefficient of variation	An expression in percent of data (SD) spread related to the mean $CV\% = (SD/mean) \times 100$
<i>control</i>	<i>A substance used for monitoring the performance of an analytical process or instrument</i>
CV	See Coefficient of variation
<i>default</i>	<i>An original factory setting</i>
expiration date	The last day that you can use that specific lot number of reagent, control or calibrator
<i>fL</i>	<i>Abbreviation for femtoliter</i>
femtoliter	One quadrillionth (10^{15}) of a liter
<i>field</i>	<i>An area on a screen for entering data</i>
flags	on printouts or screens, letters or symbols that appear next to parameter results to indicate specific conditions
<i>linearity</i>	<i>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</i>

lot number	A manufacturer's code that identifies products such as reagents, controls or calibrators
<i>mean</i>	<i>Arithmetic average of a group of data</i>
operating range	Range of results over which the instrument displays, prints and transmits data
<i>parameter</i>	<i>A component of blood that the instrument measures and reports</i>
performance	Actual performance of the instrument characteristics
<i>performance</i>	<i>Targeted performance of the instrument based on established ranges and parameters specifications</i>
quality control (QC)	A comprehensive set of procedures a laboratory establishes to ensure that the instrument is working accurately and precisely
<i>reproducibility</i>	<i>This procedure checks that the system gives similar results (within established limits) every time it measures the same sample</i>
SD	A measure of variation within a group samples or within a population (standard deviation)
<i>shutdown cycle</i>	<i>Cleans the instrument's fluidic lines and apertures to help prevent residue buildup</i>
specifications	see performance specifications
<i>startup cycle</i>	<i>Ensures that the instrument is ready to run; includes performing a background test</i>
verification	Procedure to analyze cell controls or whole blood with known values to determine if your results are within the acceptable range
<i>whole blood</i>	<i>Non-diluted blood; blood and anticoagulant only</i>

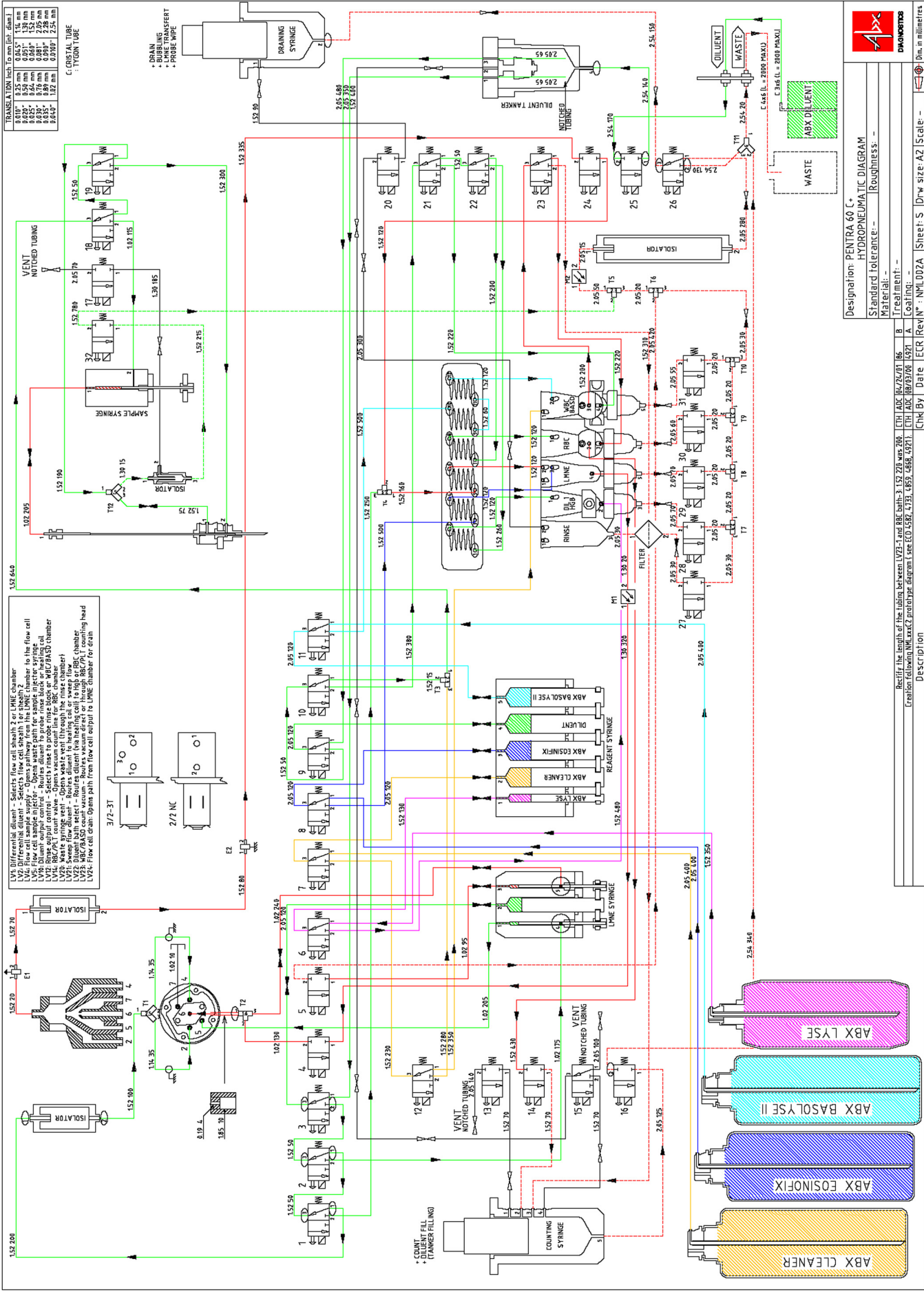
LIST OF ABBREVIATIONS

ABBREVIATION	MEANING
μL	microliter
μm	<i>micrometer</i>
ACD	acid-citrate-dextrose
ALY	<i>Atypical Lymphocyte</i>
BAS or BASO	basophil
bps	<i>bit per second</i>
CBC	cell blood count
Cl	<i>chlorine</i>
cm	centimeter
CV	<i>coefficient of variation</i>
DHSS	double hydrodynamic sleeving
diff	<i>differential</i>
dL	deciliter
EDTA	<i>ethylenediaminetetraacetic acid</i>
EOS	eosinophil
fL	<i>femtoliter</i>
ft	foot or feet
g	<i>gram</i>
Gb	gigabyte
Hct	<i>hematocrit</i>
Hgb	hemoglobin
Hz	<i>hertz</i>
L	liter
lb	<i>pound</i>
LED	light-emitting diode
LIC	<i>Large Immature Cell</i>
LYM	lymphocyte
m	<i>meter</i>
mb	millibar
Mb	<i>megabyte</i>
MCH	mean corpuscular hemoglobin
MCHC	<i>mean corpuscular hemoglobin concentration</i>
MCV	mean corpuscular volume
MDSS	<i>multi distribution sampling system</i>
MHz	megahertz
mL	<i>milliliter</i>
mm	millimeter

<i>MON</i>	<i>monocyte</i>
MPV	mean platelet volume
<i>MSDS</i>	<i>material safety data sheet</i>
n	number
<i>NEU</i>	<i>neutrophil</i>
nm	nanometer
<i>Pct</i>	<i>Plateletcrit</i>
PDW	Platelet Distribution Width
<i>Plt</i>	<i>platelet</i>
RBC	red blood cell
<i>RDW</i>	<i>red distribution width</i>
SD	standard deviation
<i>VA</i>	<i>voltampere</i>
Vac	volt alternatif current
<i>WBC</i>	<i>white blood cell</i>

WORKLIST'S KEYBOARD SHORTCUTS

KEYBOARD SHORTCUT	RESPONSE
Ctrl + click	Selection of a line or multiple lines.
Ctrl + Shift + click	Only active for performed analyses: Block selection by marking the beginning and then the end.
Alt + click	Only active for performed routine analyses: Displays the result.
Double click	Switching between list and sheet.
Arrow up	Goes to the previous line.
Ctrl + Arrow up	Goes to the first line of the grid.
Arrow down	Goes to the line following creation of a new entry of the worklist if on the last line.
Ctrl + Arrow down	Goes to the last line.
Page up	Goes up to number of lines displayed in the grid. Cancels the line selection.
Ctrl + Page up	Goes to the first line of the grid. Cancels the line selection.
Page down	Goes down to number of lines displayed in the grid. Cancels the line selection.
Arrow left	Moves one column to the left.
Ctrl + Arrow left	Goes to the first line of the column of the line in progress.
Arrow right	Moves one column to the right.
Ctrl + Arrow right	Goes to the last column of the line in progress.
Shift + Arrow down	Downward selection of several records.
Shift + Arrow up	Upward selection of several records.
Home	Goes to the first column of the line in progress.
Ctrl + Home	Goes to the first record of entire data set. Cancels the line selection.
End	Goes to the last column of the line in progress.
Ctrl + End	Goes to the last record of entire data set. Cancels the line selection.
Tab	Goes to the next cell in the grid.
Shift + Tab	Goes to the previous cell in the grid.
Ctrl + Delete	Deletes the selection in progress.
Insert	Inserts a new line below the line in progress and is positioned below. Cancels the line selection.
Escape	Cancels unsent modifications. Cancels the line selection.



Hematology ABX Devices (for in vitro diagnostic use)

ABX Diluent

Exclusive use:

Hematology ABX device	Exclusive
Micros 60	
ABC Vet	
Micros CRP	
Pentra 60	✓
Pentra 60 C+	✓
Pentra 80	✓
Pentra XL 80	✓
Pentra 120	✓
Pentra 120 Retic	✓
Pentra DX 120	✓
Slide Preparation System	

12/05/03
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REF 0901020 (20L)

REAGENT 20L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

Buffered isotonic solution for sheating and diluting leucocytes, and for the determination and differentiation of blood cells, and the measurement of hematocrit on ABX blood cell counters

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & expiration

Storage conditions: Stored at 18 to 25°C and away from the light.

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & handling precautions

Composition:

Sodium Chloride < 1 %
Natriumazid.. . . . < 0,1 %
Surfactant < 0,1 %

pH: 8,1 +/- 0,2 (T = 20°C)

Resistivity: 60,5 +/- 1 Ω (T = 20°C)

Description: Limpid and odourless aqueous solution.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

Specimen Collection and Mixing: see «Section: Workflow» in the instrument User Manual.

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

Hematology ABX Devices (for in vitro diagnostic use)

ABX Cleaner

Exclusive use:

Hematology ABX device	Exclusive
Micros 60	
ABC Vet	
Micros CRP	
Pentra 60	✓
Pentra 60 C+	✓
Pentra 80	✓
Pentra XL 80	✓
Pentra 120	✓
Pentra 120 Retic	✓
Pentra DX 120	✓
Slide Preparation System	

12/05/03
A95A00012-A

REF 0903010 (1L)

REAGENT 1L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

Enzymatic solution with proteolytic action for the cleaning of ABX blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & Expiration

Storage conditions: Stored at 18°C (65°F) to 25°C (77°F).

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting / Reagent Location and connexion» in the instrument User Manual.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & Handling precautions

Composition:

Organic Buffer < 0,2 %

Proteolytic Enzyme . . . < 0,2 %

pH: 9,6 +/- 0,4 (T = 20°C)

Resistivity: 72 +/- 2 Ω (T = 20°C)

Description: Transparent liquid.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

Specimen Collection and Mixing: see «Section: Workflow» in the instrument User Manual.

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual.

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

Hematology ABX Devices (for in vitro diagnostic use)

ABX Eosinofix

Exclusive use:

Hematology ABX device	Exclusive
Argos/Helios (5diff)	✓
Micros 60	
ABC Vet	
Micros CRP	
Pentra 60	✓
Pentra 60 C+	✓
Pentra 80	✓
Pentra XL 80	✓
Pentra 120	✓
Pentra 120 Retic	✓
Pentra DX 120	
Slide Preparation System	

12/05/03
A95A00003-A

REF 0206010 (1L)

REAGENT 1L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

Reagent for differentiation of leucocyte subpopulations on ABX blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & expiration

Storage conditions: Room temperature between 18°C (65°F) to 25°C (77°F).

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & handling precautions

Composition:

Propane 1,2 diol 3 %

Formic Dye 0,004 %

pH: 6,9 +/- 0,1 (T = 20°C)

Resistivity: 57 +/- 3 Ω (T = 20°C)

Description: Deep blue aqueous solution, smells of alcohol.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

Specimen Collection and Mixing: see «Section: Workflow» in the instrument User Manual.

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual.

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

Hematology ABX Devices (for in vitro diagnostic use)

ABX Basolyse II

Exclusive use:

Hematology ABX device	Exclusive
Micros 60	
ABC Vet	
Micros CRP	
Pentra 60	✓
Pentra 60 C+	✓
Pentra 80	✓
Pentra XL 80	✓
Pentra 120	
Pentra 120 Retic	
Pentra DX 120	
Slide Preparation System	

12/05/03
A95A00002-A

REF 0906003 (1L)

REAGENT 1L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

Erythrocyte lysing reagent for white blood cell counting and basophil differentiation on ABX blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & expiration

Storage conditions: Room temperature between 18°C (65°F) to 25°C (77°F).

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & handling precautions

Composition:

Hydrochloric Acid.....0,03 %

Detergent.....0,5 %

pH : 2,4 +/- 0,2 (T = 20°C)

Resistivity : 61 +/- 2 Ω (T = 20°C)

Description: Colorless aqueous solution.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

Specimen Collection and Mixing: see «Section: Workflow» in the instrument user manual.

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

Hematology ABX Devices (for in vitro diagnostic use)

ABX Alphalyse

12/05/03
A95A00009-A

Exclusive use:

● Hematology ABX device	Exclusive
Micros CRP	✓
Pentra 60	✓
Pentra 60 C+	✓
Pentra 80	✓
Pentra XL 80	✓
Pentra 120	✓
Pentra 120 Retic	✓
Pentra DX 120	✓
Slide Preparation System	

REF 0906004 (0,4L)
0902010 (1L)

REAGENT 0,4L or 1L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

Lysing agent for white blood cell counting, and hemoglobin determination on ABX blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & expiration

Storage conditions: stored at 18°C (65°F) to 25°C (77°F) away from light. Product will degrade if exposed to air, keep cap / probe assembly securely tightened.

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual. This reagent is for professional *in-vitro* diagnostic use only.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & handling precautions

Composition:

Potassium Cyanide.....0,03 %

Quaternary Amonium Salt.....< 3 %

pH: 10 +/- 0,5 (T=20°C)

Resistivity: 213 +/- 10 Ω (T=20°C)

Description: aqueous solution, limpid.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested. The product can be absorbed through an open wound, or inhalation. Please refer to the MSDS associated with the reagent.

Special precautions: Avoid contact with acid and aqueous acid environment: extremely toxic cyanide acid vapour can be formed. Please refer to the MSDS associated with the reagent.

Specimen Collection and Mixing: see «Section: Workflow» in the instrument User Manual

Limitations: see «Section: Specifications» in the instrument User Manual

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

Hematology ABX Devices (for in vitro diagnostic use)

ABX Lysebio

Exclusive use:

Hematology ABX device	Exclusive
Micros 60	✓
ABC Vet	
Micros CRP	
Pentra 60	✓
Pentra 60 C+	✓
Pentra 80	✓
Pentra XL 80	✓
Pentra 120	✓
Pentra 120 Retic	✓
Pentra DX 120	✓
Slide Preparation System	

23/04/03
A95A00011-A

REF 0906013 (0,4L)
0906012 (1L)

REAGENT 0,4L or 1L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

This reagent is used on ABX blood cell counters to lyse red blood cells and determine hemoglobin concentration.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & expiration

Storage conditions: Stored at 15°C (59°F) to 30°C (86°F) away from light.

Expiration date : refer to «expiration date» reagent packaging label

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & handling precautions

Composition :

Quarternary ammonium salt < 5%

Non ionic based surfactant < 3%

pH: 6,95 +/- 0,1 (T = 25°C)

Resistivity: 40 +/- 1 Ω

Description: Colorless, odourless.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent

Specimen Collection and Mixing: see «Section: Workflow» in the instrument User Manual

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

Hematology ABX Devices (for in vitro diagnostic use)

ABX Minoclair

Exclusive use:

Hematology ABX device	Exclusive	Concentrated cleaning use
Minos	✓	
ABC Vet		✓
Micros 60, Micros CRP		✓
Pentra 60		✓
Pentra 60 C+		✓
Pentra 80		✓
Pentra XL 80		✓
Pentra 120		
Pentra 120 Retic		
Pentra DX 120		
Slide Preparation System		

03/11/03
A95A00029-B

REF 0401005

REAGENT 0,5L

IVD 



ABX Diagnostics
BP 7290 - 34187 Montpellier
cedex 4 - France

1. Functions

Cleaning and bleaching solution for ABX blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics : see «Section: Specifications» in the instrument User Manual.

2. Conservation & Expiration

Storage conditions: Stored at 18°C (65°F) to 25°C (77°F).

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see «Section: Reagent Location and connection» in the instrument User Manual.

Measuring Principles : see «Section: Technology» in the instrument User Manual.

Results: Refer to the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

4. Composition & Handling precautions

Composition:

Sodium hypochlorite: 9 % v/v at 13% of active chloride.
Sodium hydroxide: 0,26%

pH: 12,4 +/- 0,5 (T = 20°C)

Resistivity: Not available

Description: Yellowish liquid.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

Specimen Collection and Mixing: see «Section: Specimen collection and Mixing» in the instrument User Manual.

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual.

Safe Waste Disposal: Follow your laboratory's protocol when neutralizing and disposing of waste. Please refer to the MSDS associated with the reagent.

6. Concentrated cleaning exclusive use

Minoclair may also be used as disinfectant and cleaning product on ABX Blood cell counters: see «Section: Concentrated cleaning» in the user manual, on the following instruments: ABC vet, Micros 60, Micros CRP, Pentra 60, Pentra 60C+, Pentra 80, Pentra XL80.

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