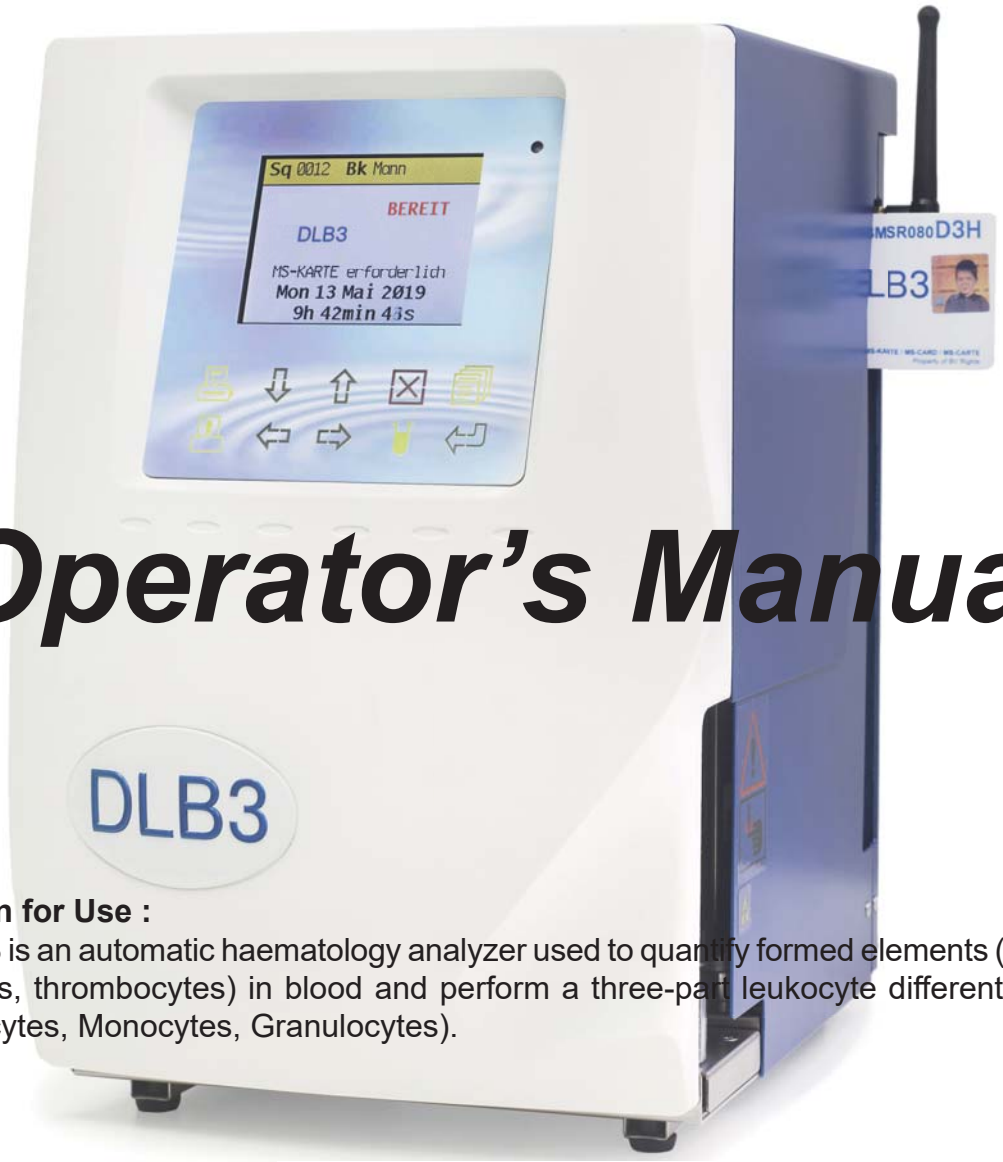
AUTOMATED
HAEMATOLOGY
CELL COUNTER

IVD



Operator's Manual

Indication for Use :
The DLB3 is an automatic haematology analyzer used to quantify formed elements (erythrocytes, leukocytes, thrombocytes) in blood and perform a three-part leukocyte differential cell count (Lymphocytes, Monocytes, Granulocytes).

DLB3

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This machine has the CE mark and is according to regulation (EU) 2017/746 concerning the in vitro diagnostic medical devices and repealing directive 98/79/EC and Commision Decison 2010/227/EU

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This machine, included the software and the computing keys, as well as the processes implemented, are the subject of intelectual propriety rights, in particular by certificates and royalties.

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INTRODUCTION

The DLB3 is an automatic haematology analyzer used to quantify formed elements (erythrocytes, leukocytes, thrombocytes) in blood and perform a three-part leukocyte differential cell count (Lymphocytes, Monocytes, Granulocytes).
Provided only for a professional use.

Use claimed :

The hematology analyzer, DLB3, is intended for professional in vitro diagnostic use only. Like any automatic counter-hematology analyzer it performs only approach to CBC (Complete Blood Count) requested by the attending physician.
A microscope slide reading remains the reference measurement for this type of analysis.
The use, as well as the claimed performance relate human blood and the control sample.
If installed in medical laboratories, only staff trained and authorized laboratory for the use of the device according to the law of the country can use.

The hematology analyzer DLB3 should be used only with dedicated reagents, following the recommendations in this guide.

Data generated by the DLB3 is not intended to replace professional judgement in the determination of a diagnosis or in monitoring patient therapy.

Before to use the DLB3 Analyzer, please read carefully this manual, taking care of all important recommendations.
This operator manual contains many warnings, remarks and notes aiming to draw your attention to these important security and service informations. In case of a no-respect of these informations, the correct use of the analizer is compromised.

PLEASE KEEP AVAILABLE THIS 'OPERATOR MANUAL' FOR ANY FUTURE NEEDS.

The screen shots represented on this manual can be different than the ones display on your instrument.

MELET SCHLOESING keeps the right to improve continually the product.
This could lead to a gap between the actual products characterics and those indicated on the manual.

Doctors and patients names used throughout the manual are purely fictitious and they are exclusively used for explanatories purpose.

DOCUMENTATION RULES

Information

Obligation

Warning / Important

Warning / Risk of hurt

Shock hazard

General danger

Biological risk

Direct current

Alternating current

This instrument is marked with a CE-mark and complies with the regulation IVDR (EU) 2017/746 concerning in vitro diagnostic medical devices

in vitro diagnostic medical device

Read instruction before use

Manufacturer

Fragile

Up

Preserve moisture

The electrical and electronic equipment complies with the Restriction of Hazardous Substances Directive and should be disposed of in a recovery and recycling appropriate structure.

1: WARNINGS AND CAUTIONS

See section 10.9 the LICENSE AGREEMENT before installing and using the instrument.

1.1. GENERAL INFORMATION

The haematology cell counter DLB3 is designed only for a professionnal use. Provided to be used on a medical analysis laboratory. Any other use is regarde as non-specified.

Please use this instrument following the operator's manual instructions.

The fiability of tests results can't be warranty if these instructions were not respected.

All operations must be disposed in accordance with local/national regulations. Always refer to labeling and operator's manual instructions to ovoid jeoparding the integrity of the system.

Any dysfunction resulting of a use no specified on this guide or the use of program no specified by MELET SCHLOESING Laboratoires can't be considered under warranty. If this device has been supplied to you other than through MELET SCHLOESING Laboratoires or one of its authorized distributors, MELET SCHLOESING Laboratoires can not guarantee this product in terms of specifi cations, latest version and latest documentation. Additional information should be obtained from your distributor.

The user is solely responsible for backing up the data contained in the devices. In addition, the modification of the device or the use of a modified device in violation of the rights of intellectual property would incur the responsibility of the author / user.

1.2. OPERATORS

Only properly trained perdonnal shall use instrument.

1.3. INSTALLATION AND UTILIZATION

Refer to section 2.3.2 about Warranty Restriction linked with an incorrect installation of the DLB3.

The analyzer must be installed on a flat rigid surface, in a clean, well ventiled and dust-free environnement.

Install the instrument in a place protected from humidity, liquid splashes, high temperature and direct sunlight.

Avoid shock and vibration

Be careful not to install the instrument near devices that emit electrical interference, such as radio, centrifuge, etc. Or nigh an environment which has electroconductive or flammable gases (As a place of storage of chemical products for example)

the socket is used as main disconnect device and must be aesily accessible.

The use of DLB3 in a dry environment, especially if synthetic materials are present (clothing, synthetic carpets, etc.) may cause harmful electrostatic discharge and lead to erroneous results.

DLB3 complies with emission and immunity requirements of EN 61326-2-6.
Do not use this device in close proximity to sources of strong electromagnetic radiation (eg RF sources intentionally unprotected), as these may interfere with proper operation. It is advisable to carry out an assessment of the electromagnetic environment before commissioning the automate.

While the tubing installation, keep the tubing without distortion and folding. All the tubing connectors must be installed manually. Don't use any sharp or blunt tool.

When running, never perform an analysis with open hood, or results will be inaccurate.

When an analysis is launch, do not move manually the carrier at the risk of needle damage, and injury.

- MELET SCHLOESING Laboratoires recommends the user to request the latest up-to-date version of the analyzer software from their distributor.

1.4. PRECAUTIONS

1.4.1. AGAINST ELECTRICAL HAZARD

To avoid all risk of fire or of electrical shock, this instrument must be installed to a power outlet with a proper voltage. Please not that the analyzer must be grounded (Refer to section 2.3.2)

It is advisable to carry out an assessment of the electromagnetic environment before commissioning the automate.

Avoid damage to the power cable : do not place any heavy object or pull on it.

The operator should not touch any electrical circuitry inside the cover. In particular, the risk of electrical shock is especially high when one's hands are wet.

Switch OFF the power supply before connecting any peripheral device. Connect IEC compliant peripherals only.

To ovoid, do not spill liquids, or get any metals inside the instrument.

In the unlikely event that the instrument emits an unusual odor or smoke, immediately turn OFF the main switch and unplug the power cable. Then contact MELET SCHLOESING Laboratoires service representative.

1.4.2 AGAINST BIOHAZARD

It's stronghly recommanded to wear protective garnments and gloves, while performing any tasks on the instrument.

Never touch waste, or parts that have come in contact with waste, with your bare hands.

Biological samples are potentially hazardous biological materials.
All samples, controls... must be considered potentially infectious.

Follow good laboratory practices when handling these products.
When performing any task on the instrument, wear protective garments, gloves and glasses and follow all others appropriate precautions.

If you inadvertently com in contact with potentially infectiuous materials or surfaces, immediately rinse the skin with large amounts of water, then follow your laboratory's prescribed cleaning and decontamination procedure.

The decontamination of the analyzer must be carried out in accordance with the legislation in force in the country of use, and the instructions issued by the laboratory.

1.5. REAGENTS HANDLING

Only the DIALAB brand Reagents must be used. If using other reagents, neither the characteristics nor the functioning of the MELET SCHLOESING Laboratoires hematology analyzers can be

Read REAGENTS INSTRUCTION before box opening (see Appendix 10.7)

All reagents are excluively for use with the Instruments marked DIALAB. Do not use them for any other purpose.

Please respect the expiry date and security instruction on the package.

For special safe practice, please refer to the reagents instruction

Make sure that reagents used with the instrument are stocked at level principal device unity. Do not place reagents at the top or under of the device.

When replacing the reagents do not fill and reuse the same bottle.

1.6. MAINTENANCE

For optimal performance, follow all cleaning and maintenance procedures described in this guide
Failure to observe this information compromises the perfect use of the device

When opening the front of the unit, securely engage the latch to prevent it from falling and causing injury.

ELECTRIC HAZARD
Switch the analyzer off and unplug the power cord from its socket before any maintenance is carried out inside the DLB3.

SHARP OR ANGULAR COMPONENTS HAZARD
Some components inside the DLB3 have sharp edges or angular corners. Operate with caution to avoid cuts to the hands.

BIOLOGICAL HAZARD
When you carry out DLB3 maintenance, take the same precautions as the one you take for handling biological samples.

1.7 DISPOSAL OF WASTES AND DEVICE

Waste fluids, reagents and infectious wastes must be disposed in accordance with local/national regulations.

According to local/national regulations, the device as well as electrical and electronic equipment wastes should be disposed of in a recovery and recycling appropriate structure.

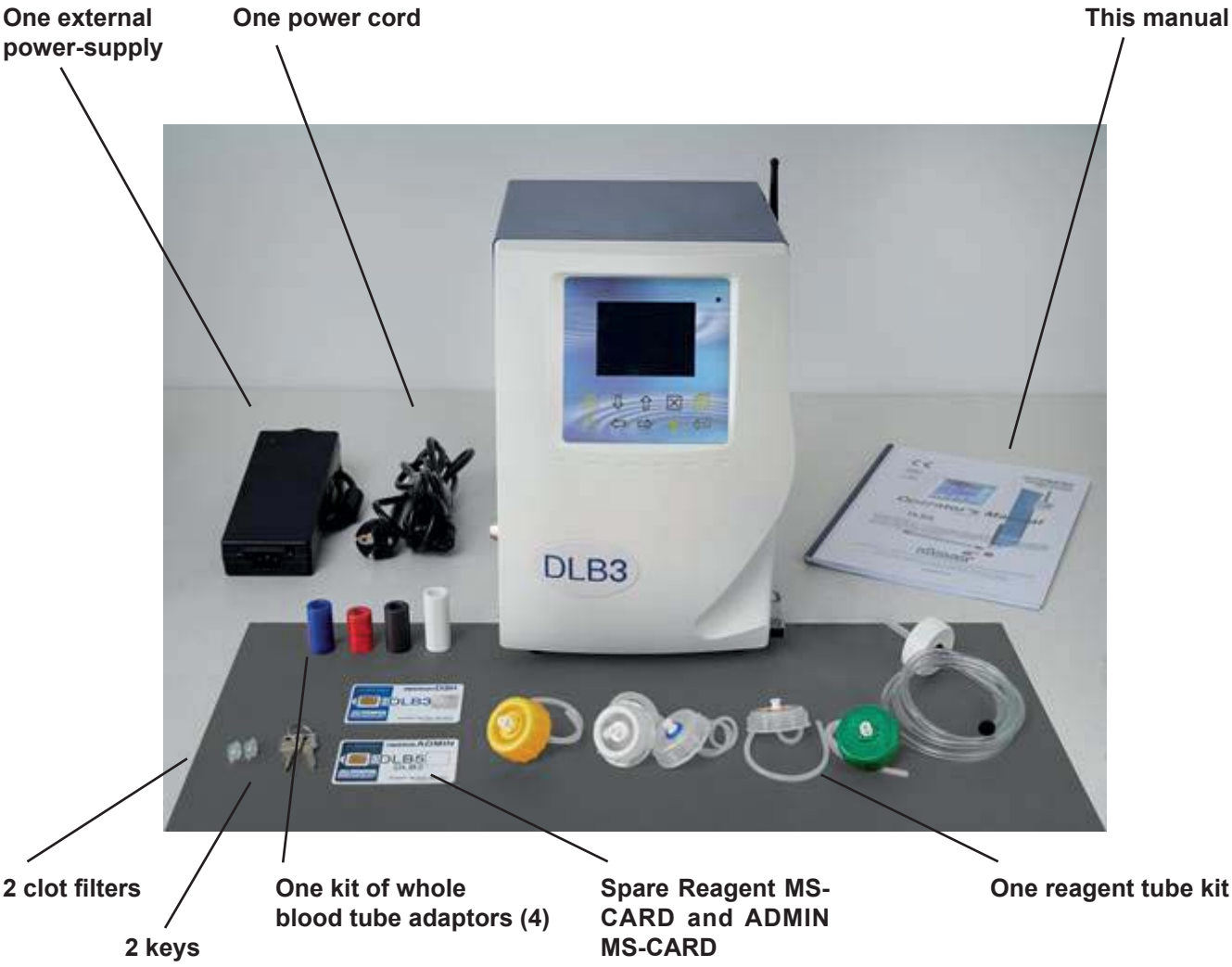
2: INSTALLATION PRESENTATION

2.1 INSTALLATION

The use of DLB3 in a dry environment, especially if synthetic materials are present (clothing, synthetic carpets, etc.) may cause harmful electrostatic discharge and lead to erroneous results.
Do not use the instrument in close proximity sources of strong electromagnetic radiation (eg RF sources intentionally unprotected), as these may interfere with proper operation.

2.1.1 Check equipment

When all the equipment out of the transport case as explained in the UNPACKING INSTRUCTION, check DLB3 accessories as follows:



If the instrument was ordered with optional accessories, check their presence (external alphanumeric keyboard, printer, cables to connect main computer, Wi-Fi antenna...).

A reagent Pack and a waste container (not included in the device box) are also required.

2.1.2 Instrument preparation

1) Take off the protective film which covers the instrument.
Do not use a knife.

2) Pull off the self-adhesive tape which blocks the carrier. Gently tilt the analyzer and take the inferior part off.

3) Access inside of DLB3.
- Unlock the machine by turning the key half-a-turn counterclockwise.

4) Open the DLB3.
- Pull the hood up by opening the front panel.

5) Steadying the hood.
- Move the latch a quarter turn.

6) Open position.
- Gently place the hood down onto the latch.

7) Pull off the self-adhesive tape dust protector from the upper part of the dilution chambers.

8) Close the machine.
- Lift the hood up slightly and move the latch back into place.
- Gently let the hood down to its closed position. (Do not drop !)
- Lock the machine by turning the key half-a-turn clockwise.

When running, never perform an analysis with open hood, or results will be inaccurate.

2.1.3 Reagent Pack installation

Verify DLB3 Reagent reference

Read REAGENTS INSTRUCTION before box opening (see Appendix).

1) Box opening

1) Open the boxes

2) In the Diadiff Box you will find the MS-Card for further use.

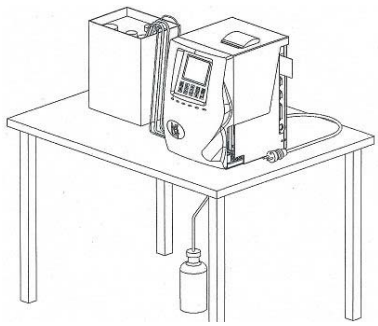
3) To open the bigger containers, push in the designated area.

2) Connection of tubes to Reagent Pack

ATTENTION

- Connect caps to bottles one at a time.
- Be careful to match the correct colours as indicated on the tube coupling and the reagent bottle (see the colour sticker on the bottle cap and the cardboard box).

- The reagents must be kept at the same level than the instrument. The waste container must be kept at lower level than the instrument, preferably on the floor.



1) Unscrew the cap and remove it.

2) Choose the correct tube from the tube kit.

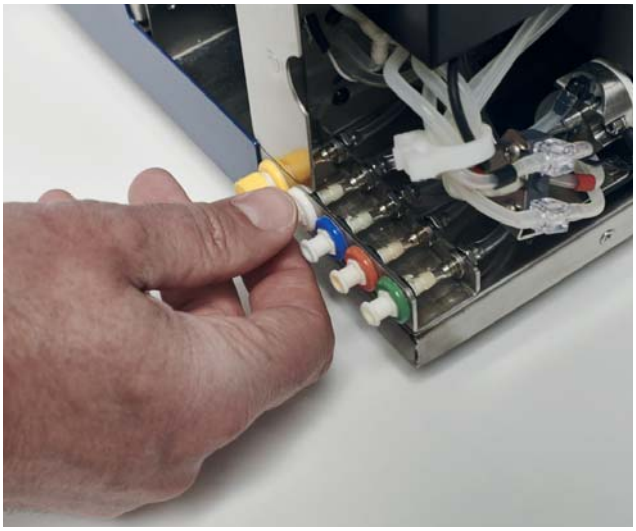
3) Insert the flexible tube into the bottle and screw the cap.

4) When all tubes are connected to the reagent bottles, put the pack at the left of the instrument.

5) Then connect the last tube (black coupling) to the waste container.

Connection of tubes to the intrument

On the lower left side of the instrument you will find a fluidic connector equipped with 5 plastic plugs (+ 1 plug located at the rear side).
These plugs are closed by protection caps to prevent dust and liquid leaks during transportation. Take off these caps by unscrewing and keep them in a safe place for future transportation.
Note that each plug has a colour band to differentiate them.
It is not necessary to open the instrument to carry out the operation described above. The photo was taken this way for a better interpretation.



Insert the reagent tubes contained in the plastic bag into the plugs. Lock them with a quarter turn without forcing.

The colours between the tubes and the plugs must correspond.

Black plug for the waste is positioned at the rear of the DLB3.

Remove the MS-CARD from its case and insert it into the card reader (see following page).

Matching colours

- Yellow : 3 Part LYSE (pale yellow liquid)
- White : DILUENT (colorless liquid)
- Blue : DETERGENT (blue liquid)
- Green : Rinse Solution
- Black : Waste

2.1.4 Electrical connections

The external connection ports are on the right side of the instrument. Their functions are described below.

Motherboard V1.3

Motherboard V1.4 or higher.

MS-CARD reader

- The reagent control card must be inserted into the card reader as shown on the right-hand photo, with the printed side facing forward.

Wi-Fi antenna (optional from mothervoard V1.5)

Ethernet*

Serial port communication #1

Ethernet (*optional), serial (computer) and USB B Ports

Serial port communication #2

Status of connexions See 10.4 section

USB B

- Serial port #2, USB B and Ethernet* are provided for computer connection.

Parallel and USB printer ports

- Provided for external printer connection. 25 pin female connector for parallel printer type ‘Centronics’ and USB A connector.

Keyboard connector

- Provided for external keyboard and/or barcode reader.
6 pin PS/2 connector.

CONNECT IEC 60950-1 AND IEC 61010-1 COMPLIANT PERIPHERALS ONLY

2.2 PRESENTATION

2.2.1 Front panel presentation

HOME SCREEN:

Indicator for next analysis
- Next sequence number
- Selected blood bank

Power Indicator
- Constant light if ready or blinking if system on standby

Status indicator
- Shows if system can work :
  Green : Ready
  Orange : Priming not ready
  Blue : Standby

MS-CARD check
- Message displayed if MS-CARD is not inserted into DLB3 card reader

Date/Time
- Real time on wait screen

Menu Key
- Displays Main Menu on the screen

Enter Key
- Validates current operation

Printout Key
- Manual printing

Vertical Cursor Keys
- Select item of the menu
- Changes parameter value in edit fields

Escape/Cancel Key
- Cancels current operation

Start Analysis
- Initiates a new analysis cycle

Paper feed key
- On built-in printer

Horizontal Cursor Keys
- Select sub-menu
- Select edit fields in parameter array

DLB3 keyboard use

Each sensitive key is located by a lighted icon: a key is lit when enabled.
A short beep acknowledges each key press.

The screen shown on the previous page is displayed when switching on the instrument, after the self-test phases. From now on it will be known as the 'home screen'.

2.2.2 External alphanumerical keyboard use

An external keyboard can be connected and used simultaneously (PS/2 type -see page 25 for connection). It provides additional functions such as the possibility of analysis identification. See other keys below.

Matching keys

DLB3 front panel	External keyboard
Escape Key	*Escape* key
Start Analysis	*F2* Function key
Menu key	*F1* Function key
Enter key	*Return* or *Enter* key
Cursor keys	Arrow keys
Print key	*Print screen* key
Paper feed key	*Insert* key

Other keys

- *F4* Function key allows analysis identification.
- *F5* Function key allows results transmission on serial port #2.
- *F8, F9* and *F10* Function keys allow a quick access to Male, Female and New born blood banks respectively to start an analysis.
- Numeric keys allow to enter values directly in editable numeric fields.
- *Tabulation* and *Shift+Tabulation* keys are used to switch from an editable field to another (same function with *right* and *left arrow* keys respectively).
- *Page up* and *Page down* keys allow to switch to previous or following data table.

Their use will be described in the next chapters.

2.3 SETTING UP ADVICE

2.3.1 Work environment

Choose a suitable place to install the instrument.
- Put it on a **flat rigid surface** and assure correct ventilation.
- Leave a clear space on the left side of the instrument for the reagent pack.
- Leave a minimum 10 cm space on the right side for the exit of the carrier.
- Choose a **dust-free environment**.
- Choose a cool environment.

A working environment between 20 °C...25 °C (68 °F...77 °F) is required to stay in the working temperature range of the reagents. Do not install the instrument or reagent pack behind a window exposed to sunlight. Analyses performed at a temperature outside this range could lead to incorrect results being reported.

DLB3 complies with emission and immunity requirements of EN 61326-2-6. Do not use this device in close proximity to sources of strong electromagnetic radiation (eg RF sources intentionally unprotected), as these may interfere with proper operation.
It is advisable to carry out an assessment of the electromagnetic environment before commissioning the DLB3.

2.3.2 Power connection

Use a ground connection plugged into the mains. A ground plug is essential for the instrument to work efficiently.
Perturbed mains or bad ground connection could lead to incorrect results.

- The absence of ground connection is DANGEROUS for user safety and for the intrument electronic parts. Any deterioration to parts of the DLB3 due to a non-compliant connection will invalidate the warranty on the instrument.
- The socket (see photo #1) is used as main disconnect device and must be easily accessible.

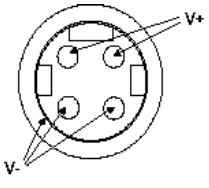
1- External power supply

Input: 100-240 V / 50-60 Hz 2 A
Automatic commutation voltage
Output: 24.0 V 6.25A

2- Internal power supply

Input: 24.0 V 6.25A
Fuse: F 7 A-125 V

Power switch (● ON)



3: FIRST UTILIZATION

CAUTION

**BEFORE SWITCHING ON THE DLB3,
CHECK THAT THE WASTE CONTAINER IS
CORRECTLY CONNECTED TO THE BLACK PLUG
LOCATED AT THE REAR OF THE DEVICE.**

The rest of reagents, detergents as well as all the waste must be eleminated in the respect of the legal instructions in effect in the country.

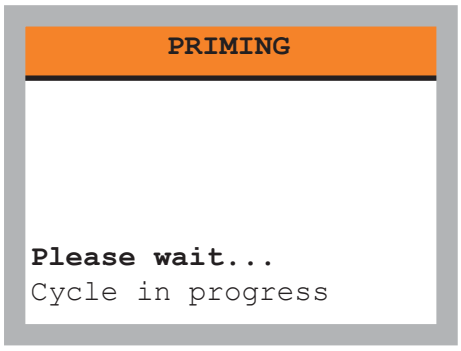
3.1 POWER UP

When all electrical and fluidic (reagents) connections are made according to the previous instructions, insert the MS-CARD into the card reader, with the printed side facing forward.
The instrument can be switched on by pressing the main power switch located at the rear of the instrument.

3.1.1 Self-tests

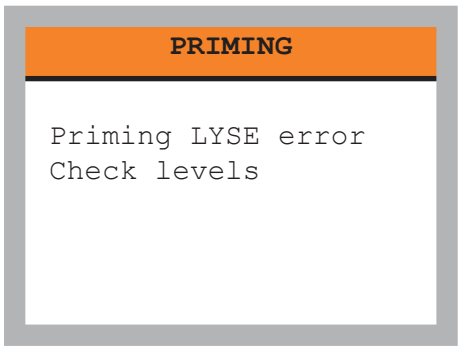
When power is on, the instrument starts several internal controls to test that the electrical and mechanical functions are correct.
This step is characterized by a succession of different sound frequency signals and a cyclic lighting of the LED on the front panel.
This step is followed by the setting of the diluent piston, sample needle and carrier.

3.1.2 Priming reagents



When the self-test step has been carried out successfully, the instrument knows that reagents are missing (this is the first installation). It will run then an automatic priming cycle. During this process a message as shown on the left is displayed.
This process can take several minutes to fill all tubes with reagent and purge all residual air bubbles.

- Abnormal priming of reagents



When installing the instrument for the first time or changing the reagent pack, the analyzer may not be fully primed.
A message displays to indicate which reagent has not been primed.
Let the instrument end the draining cycles until the home screen displays.
The priming will end automatically afterwards.

- Skipping priming step

If priming of reagents is not necessary at the power on (i.e. to consult previous analysis results), hold the Cancel key until the home screen is displayed.

3.2 PRINTOUT

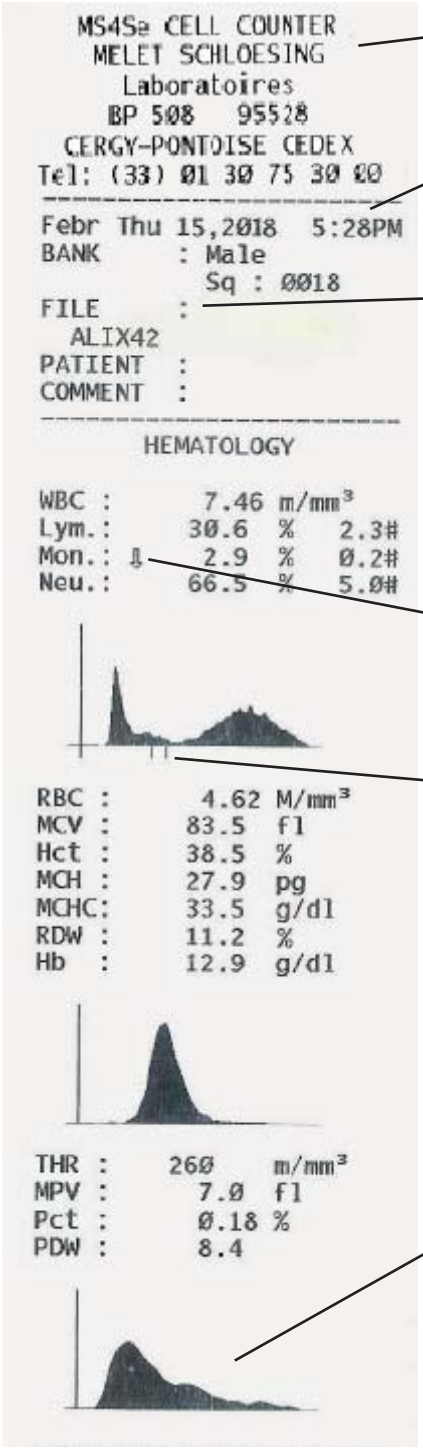
3.2.1 The printers

The internal thermal printer is OPTIONAL .

An external printer IS RECOMMENDED(parallel or USB) which can be connected for printing on personalized paper, pls see list of compatible printers.

3.2.3 Example of ticket

The ticket printed on built-in printer (OPTIONAL)can take different aspects according to the configuration setup (See *Printout Menu* chapter). The most common representation is reproduced



Personalized heading
- Configurable

Analysis information
- Date / Time
- Selected blood bank
- Sequence number

3 specific items
- Entered with DLB3 keyboard or an external alphanumeric keyboard (or code bar reader for PATIENT)

Haematology results

Min/max alarm
- Normal ranges can be enabled from Printout Menu and printed on the following line

Cursors
- Mono Start / End

Histograms
- Printout can be disabled from Printout Menu.

3.3 RUN AN ANALYSIS

3.3.1 General advice

Human bodily fluids are potentially hazardous biological materials.
This material should be handled as if capable of transmitting infectious disease as Hepatite B, Hepatite C and HIV.
Follow good laboratory practices when handling these products.
Take appropriate precautions when handling all laboratory samples to prevent skin contact (wearing coat, gloves, goggles, ...), ingestion, or inhalation.

IMPORTANT: Before running an analysis, read METHOD LIMITATION - INTERFERENCES chapter (Appendix 6).

IMPORTANT: Respect the pre-analytical phase in the preparation of samples and the quality procedures within the laboratory.

IMPORTANT: At each start of the analyzer and / or after priming of reagents, it is imperative to carry out two analyses, the first without putting tube and the second with a control blood or a tube of blood in the series to be analyzed.

IMPORTANT: Check perfectly the identification of the blood tube and its identification in the analyzer.

Blood sampling
The tested and recommended anticoagulant is K3 EDTA.
Other anticoagulants can generate inaccurate results.

Sampling tubes
Different sized blood sampling tubes can be used on the DLB3. Different adapters are available to adjust the right size of tube.

IMPORTANT: It is necessary to fill the tube with the correct blood quantity. If the amount of blood in the tube does not reach the necessary quantity, the analysis will not be stable and the platelet count will be disrupted. Fill the tube to the indicated line in order to have a correct proportion between the blood and the anticoagulant..

Homogenization
Before a blood analysis, the blood must be gently mixed. This step is very important and can sometimes require two minutes for a perfect homogenization.
Mix the whole blood by slowly inverting tube.
Thorough mixing is recommended when:
- Blood has just been taken sampled from the patient (less than 20 minutes).
- Blood is sedimented.

3.3.2 First analysis after installation

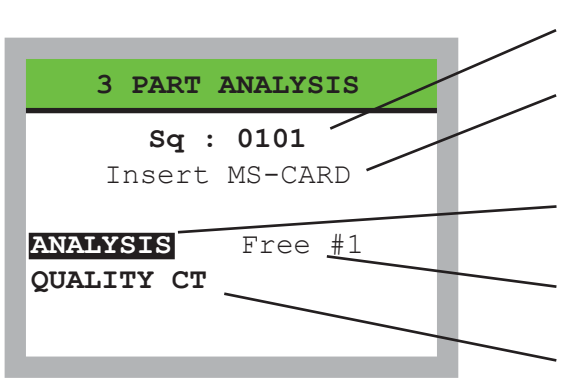
Function of the keys

The modifiable field is in inverse video (white characters on black background).

1- To change from one field to another	: **Right** and **Left** **arrows**
2- To change the value inside the selected field	: **High** and **Down** **arrows**
3- To abort the current action	: **Escape** key
4- To validate and quit the current function	: **Enter** key
5- To initiate an analysis cycle	: **Start analysis** Key

Press *Analysis* key on built-in keyboard
(or *F2* Function key on external keyboard)

The DLB3 screen displays as below to confirm the parameters of the analysis to run.



Sequence number
- For this analysis

Error message
- Displayed only if NO MS-CARD inserted into card reader

Selected line
- *Enter* Key runs analysis

Current blood bank
- Parameters used for this analysis

Run a quality control analysis
- Level of control blood is displayed when this item is selected

3.3.3 Start screen interpretation

If the DLB3 asks for a reagent control card, insert it into the card reader. The start test will be denied until a MS-CARD has been recognized.

- The sequence number
It is increased after each valid analysis is stored. There is an order number for the Blood Analysis and another for the Quality Control Analysis.

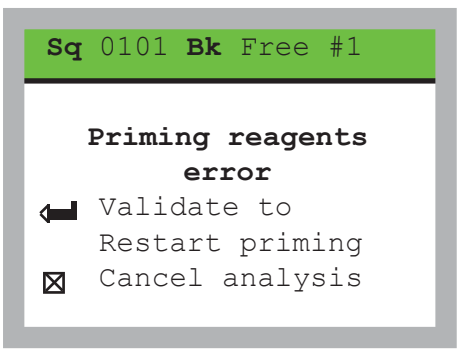
- Selected Menu line
A selected line appears highlighted in colour. This line will be activated when pressing *Enter* key.

- The Blood Bank
Determines the parameters run for the next analysis.
To change the bank, please follow these instructions:
- Press the *Right arrow* key: the blood bank name is highlighted to indicate that it is selected.
- Press the *Up arrow* or *Down arrow* key: names of the other available banks are sequentially displayed.
- Once the desired blood bank is displayed, press *Left arrow* or *Enter* key.
The ANALYSIS or BANK line of the menu is then re-selected.
- To run a test, the ANALYSIS line must be selected. If the BANK line is selected, press the *Up arrow* key to change the selection.

If an external keyboard is connected to the instrument, use *F8*, *F9* or *F10* function keys to skip this screen. The identification screen described on next page will be then displayed with the Male, Female or New-born blood banks respectively selected.

Cancel key (or *Escape* on external keyboard)
This key allows a return to the home screen, and generally cancels the current operation to return to the previous one.

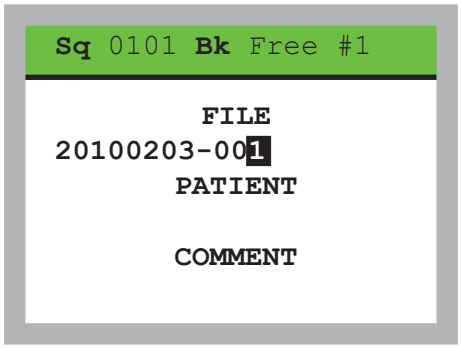
Enter key (or *Return/Enter* on external keyboard)
Press this key to confirm first analysis start.



Comment
If the reagent priming has not been completed correctly during the first power on, the opposite message is displayed.
Press *Enter* key to finish priming before the analysis.
This an intermediate step before the start of the counting described hereafter.
This message can also display if no analysis has been done for 6 hours.

3.3.4 Identification

The analysis validation activates two actions:
1) The carrier moves to the right side of the instrument. This allows the user to put the whole blood sample tube into the adapter.

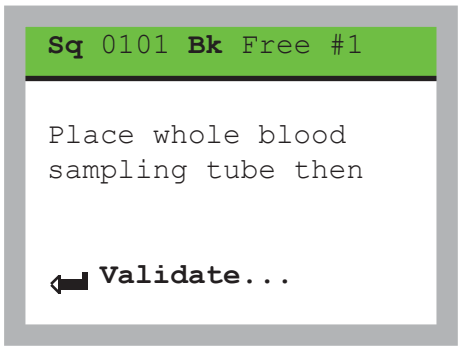


2) The screen opposite is displayed to identify the analysis. A file number is given by default, the cursor is then positioned on the last character. This number (1 by default when using the instrument for the first time) depends on the current date and number entered at the last analysis. The number starts with the current date (e.g. 20100203: YYYYMMDD) and ends with a number of 3 digits (e.g. 001) up to 999.

Modification with the built-in keyboard:
Up Arrow or *Down Arrow* keys allow scrolling of the letters up or down. *Right Arrow* or *Left Arrow* keys allow to shift from one letter to another along the line.

Modification with an external keyboard:
For an easier use. Just type the letters and correct with the correction key.

When the file number is correct, two procedures are possible:
1) Use the *Enter* key to move to the next line and enter data with a maximum of 20 characters per line.



With an external keyboard, the *Page up* key allows movement to the upper line.
If the cursor is on the last line the *Enter* key displays the following screen to confirm the blood sampling tube is present.

2) You can use the *Analysis* key (or F2 on the external keyboard) on the identification screen at any point in order to start the analysis cycle immediately.

WARNING

The blood sampling tube must be in the carrier before using this key. Never try to remove the sampling tube during the dilution cycle, this could generate a carrier translation error, or a risk of injury to the user.

Setting the sampling tube

Choose the correct sized tube adapter for the sampling tube.
Insert this adapter into the circular stand of the carrier.
Do not move the carrier during the handling and positioning of the adapter and tube.

WARNING NEEDLE : Risk of hurt. A pictogram indicates the danger. Rise and fall movments of the needle when the analysis begins.

When an analysis is launch, do not move manually the carrier at the risk of needle damage , and injury.

Take the cap off the sampling tube and insert it into the adapter.

When the message asking for the sampling tube is displayed, press *Enter* key or *Analysis* key (F2 key with an external keyboard).

Using a Barcode reader

When using a barcode reader while the instrument is on the wait screen, the identification screen is automatically displayed without using the *Analysis* key. Data is then automatically listed under the PATIENT item .
The barcode reader can also be used at any time: When the identification screen is displayed, during the analysis, or when the results are displayed.
Each of these 3 lines can admit 20 characters maximum.

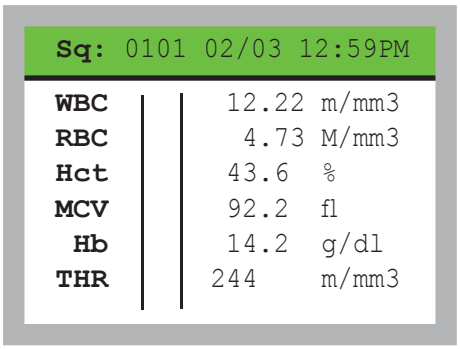
The identification screen will appear in the results screens described on the next page.
When this screen is displayed following the results screen, press *Up Arrow* key (or *F4* function key on external keyboard) to change into edit mode (display mode does not show the highlighted edit cursor).

The identification will be lost if the analysis is interrupted because of an anomaly (e.g. missing reagent).
When the analysis cycle starts, all the dilution and counting cycles are automatic.
The main steps of the cycle are displayed on the screen.

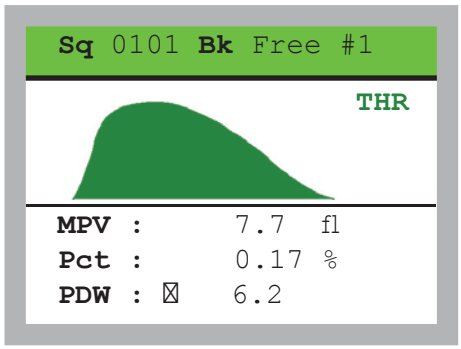
3.3.5 Results

Haematology results are displayed across 4 screens. To switch between screens, press *Right arrow* ⇨ or *Left arrow* ⇦ keys. The last screen (Identification) is also displayed to be modified if required.
Below, an example of the 4 results screens and identification screen:

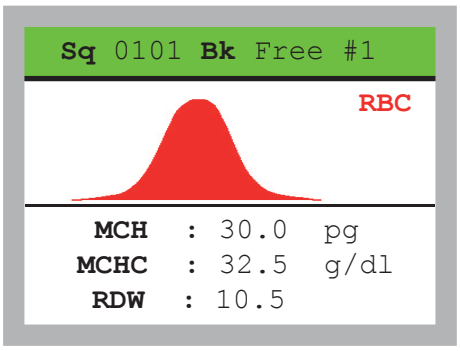
1st screen: Main results



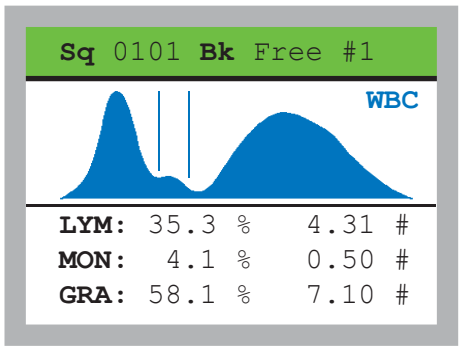
2nd screen: THR Results



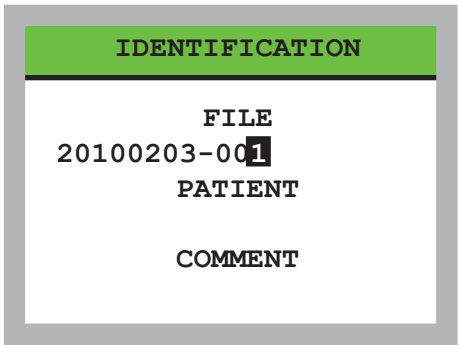
3rd screen: RBC Results



4th screen: WBC Results



Last screen: Patient ID



It is recommended to keep the scan impressions for archival purposes.

In addition to the quantitative results and histograms, other indications can appear on these screens:

3.3.5.1 Normal range alarm

If a test result is out of the normal range, an arrow is displayed to indicate if high or low (e.g. **PDW** result on the second screen above).

3.3.5.2 Counting Alarms

& Mark : A blockage has been detected during counting.
# Mark : A blockage has been detected just before counting.
@ Mark : homogeneity error has been detected during counting.
T Mark : Thalassemia possibility. (Only on Male, Female and New born banks).
? Mark : result is 0 due to impossibility of interpretation.
R Mark : result rejected caused by a bad counting parameter
- On lines RBC + MCV + Hct + Hb => MCHC too high
- On line WBC => 3 Part-diff error (Reminding of **L** or **I** alarm described below)

L Mark : On lines LYM + MON + GRA: WBC counting error => Lympho interferences
Caused by Platelet clumps or Nucleated RBC
M Mark : On lines LYM + MON + GRA: WBC counting error => monocytes too high
- Too high quantity of Blasts or haemolyzed blood (too old) or 3 part-diff not well calibrated

I Mark : On lines LYM + MON + GRA: WBC counting error => immature cells
Can be flagged also when 3 part-diff is not well calibrated or blood analyzed in an incorrect bank.
E Mark : error generally caused by hardware (e.g. photometer out of order).

A new analysis of the sample must be considered if a paramèter of the analysis are in counting alarm. an abnormal Leukocyte formula or any associated parameters outside the normal range (eg GB), a microscope blade must be made and be read if the formula required.

3.3.5.3 Update identification screen

The COMMENT line on the Identification screen can be changed when this screen is displayed by holding the *Up Arrow* ⇧ key (or *F4* Function key on an external keyboard).

3.3.5.4 Send results to a computer

Results can be transferred manually to a computer by pressing the *Up Arrow* ⇧ key (or *F5* Function key on an external keyboard) when the 1st screen is displayed. Refer to *Export Data* chapter for more details.

Only the analysis results available on the machine are valid (Screen and printer integrated).
In case of power failure during a transfer of results, renew the data export.

3.3.5.5 Results printout

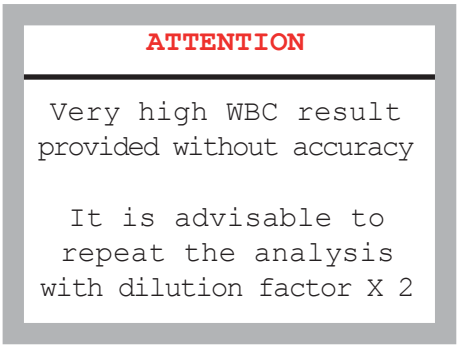
Press this key to print results (or *Print screen* on the external keyboard).

Results are printed on the external printer if this is on-line. If no external printer is available, a ticket is printed on built-in printer. Printing results can be more detailed than displayed about alarm marks.

On the external printer, the normal range alarms for the Leukocyte formula are done based on the results in % and are **AUTOMATICALLY REPORTED** on the results in absolute values (#).

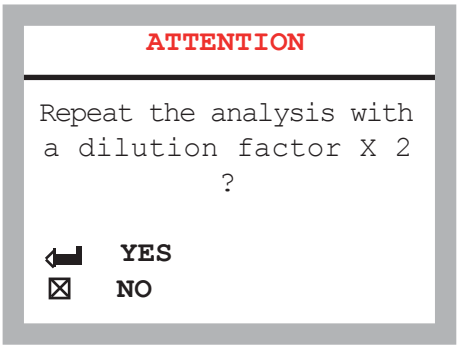
3.3.5.6 Dilution x 2

If the WBC result is very high (upper than 100 m/mm^3), the DLB3 displays the following warning message :



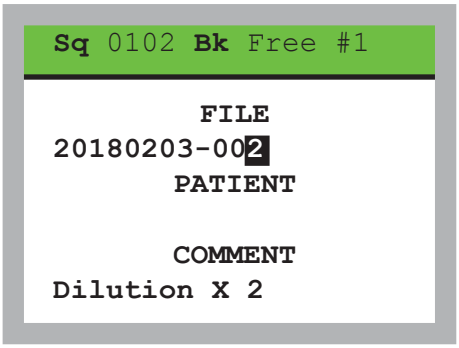
Then press any key to get the main results screen.

When you quit the result screens, with Escape/Cancel Key , the following screen is displayed :



If you answer NO , DLB3 goes back to the home screen.

If you answer YES , DLB3 goes back to the identification screen with the proposed **Dilution X 2** text in the comment field (see screen below).



At this step, if you continue to run the analysis, the predilution factor is automatically multiplied by 2.

The patient results will correspond to the original concentrations.

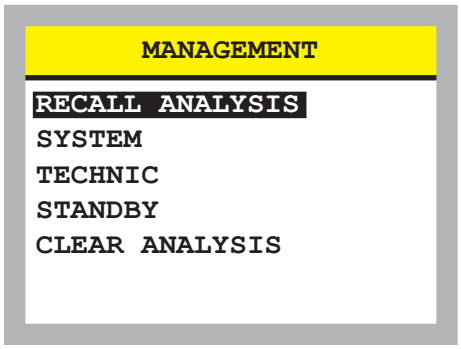
4: CONFIGURATION

System configuration is performed across different **Menus**.
Press *Menu* key when valid (LED on) or *F1* function key on an external keyboard.

4.1 MAIN MENU

The content of the menu depends on the current operator mode.
By default, the analyser works in user mode.
To change of mode, insert the ADMIN card (see section 6.4).

User mode :

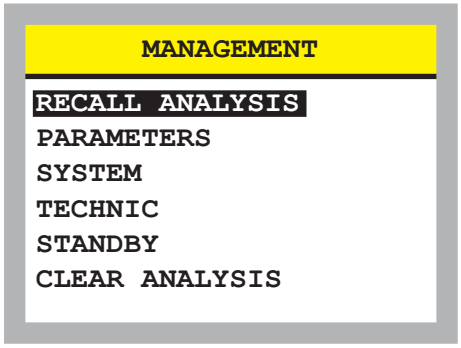


The main menu is displayed with the 1st line selected by default. The items order corresponds to the frequency of use.

To select another item, use keyboard *Up arrow* or *Down arrow* keys.
Example: to select the SYSTEM item, press *Down arrow* key twice.

When the SYSTEM line is selected, press *Enter* key to call the sub-menu.

Administrator mode :

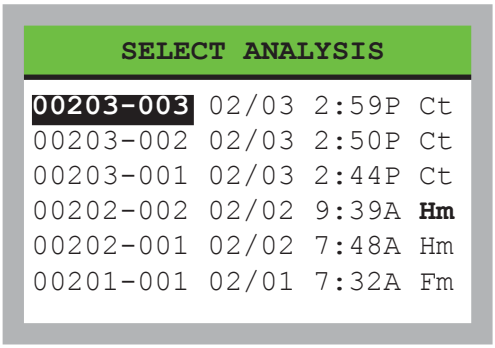


The main menu has an additional line :
PARAMETERS

4.2 RECALL ANALYSIS MENU

Allows the recall of an analysis from the last 250 analyses stored in the memory.

The 1st analysis displayed is the file number (only 9 ending characters of the File Name displayed) of the last analysis performed, followed by the date (Day/Month or Month/Day according to the language), time (24 h or 12h format according to the configuration) and 2 characters from the blood bank reference.



Up arrow ⇧ or *Down arrow* ⇩ keys allows the selection of the requested analysis. When the selected line reaches the end of an array, the next one is displayed. With an external keyboard, *Page up* or *Page down* keys allow a rapid change of screen.

The file number validation displays result screens of the selected analysis (see previous chapter).

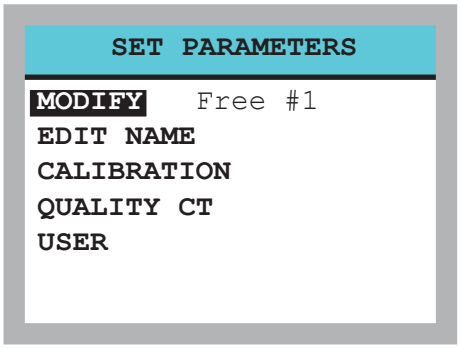
Blood bank abbreviations:
Refer to 6.1.1 section to know when these banks are available.

Hm	Male
Fm	Female
Nn	New born
Ct	Control
L1	Free # 1
L2	Free # 2

4.3 PARAMETERS MENU

The access of this menu required the insertion of an MS-CARD ADMIN on the DLB3 (see section 4.1 and 6.4).

This menu is called from the second line of the main menu (see section 4.1 and 6.4).



When the MODIFY or EDIT NAME lines are selected, the name of the current blood bank is displayed on the right. This is the bank affected if one of these lines is chosen.
To change the blood bank, select the name with the *Right arrow* key and choose among the available banks with the *Up arrow* or *Down arrow* keys.
Use then the *Left arrow* or *Enter* key to re-select MODIFY.

4.3.1 EDIT NAME BLOOD BANK

The name of a blood bank can be modified by this item.
It is only available for Free #1 and Free #2 banks (see reagent MS-CARD chapter).
For the editing name process, see the USER sub-menu chapter.
Comment: Each blood bank stocks its name in 3 languages. Calling the EDIT NAME menu will only change the name into the current language. Change the language temporarily and repeat the modification under other languages if needed.

4.3.2 MODIFY BLOOD BANK

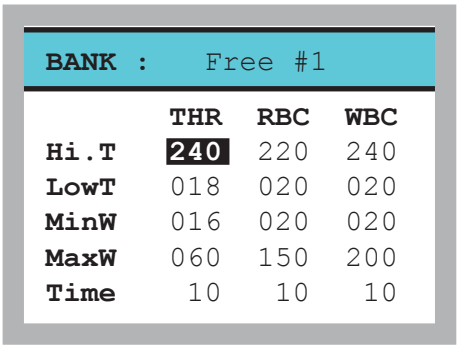
IMPORTANT

The first 4 screens, which include the counting and calibration parameters, must be changed with great care and if possible with the help of a MS Laboratoires technician. If incorrect data is entered then the analysis results will be inaccurate.

When validating the MODIFY line, a series of screens including all the parameters of the selected blood bank (e.g. Free #1) is displayed.
Each screen can be accessed with Page Up/Down keys on the external keyboard.
The content will be explained in detail in the event that a technician has to give modification instruction.

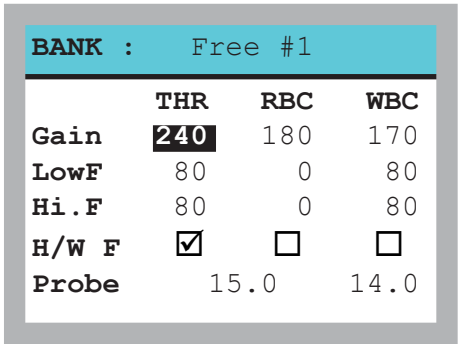
Note: It is necessary to quit a screen by the *Enter* key so that modified data can be recorded.

1st screen: Cell discriminator



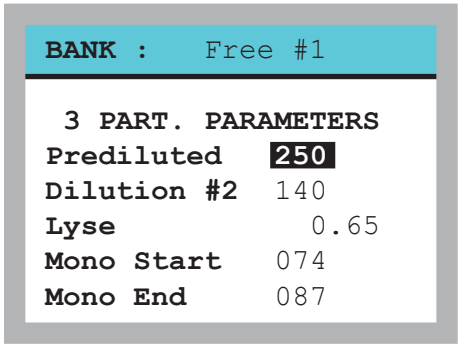
Hi.T: High dimensional threshold. Larger-sized cells are rejected.
LowT: Low dimensional threshold. Smaller-sized cells are rejected.
MinW: Minimal cell width. Smaller- width cells are rejected.
MaxW: Maximal cell width. Bigger- width cells are rejected.
Time: Counting time in seconds.

2nd screen: Cell discriminator



Gain: Amplifier coefficient
LowF: Low filter cell
Hi.F: High filter cell
H/W F: Height / Width filter cell
Probe: Probe voltage in volt

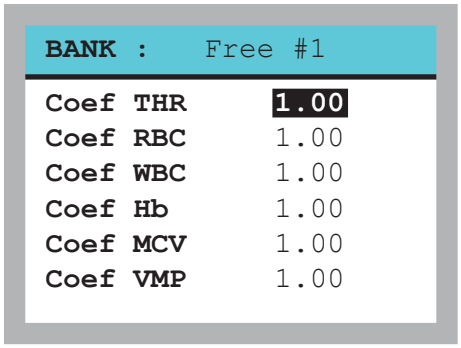
3rd screen: Dilution Parameters for 3-Part-Diff



Prediluted: 1st Dilution rate (WBC dilution)
Dilution #2: 2nd dilution rate (RBC / THR dilution)
Lyse: Lyse quantity in ml
Mono Start: Monocytes start cursor **
Mono End: Monocytes end cursor **

** See Appendix 3 '3 PART-DIFF. CALIBRATION'

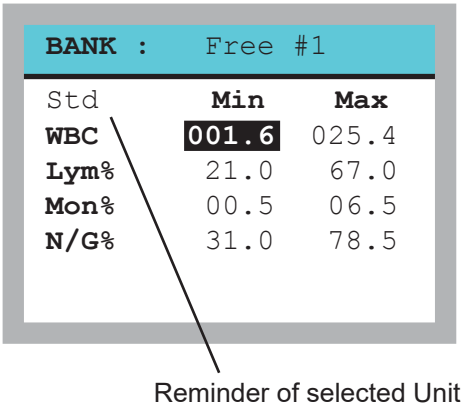
4th screen: Correction coefficients



Correction coefficients for the blood bank used for the calibration function.
Note: For the Control Blood bank, this screen does not appear. The calibration is done only by general calibration.

Values shown in this manual are only given as an example and may differ from the actual bank data in the device.

5 to 14th screen: Normal range



Normal range allows the flagging of threshold alarms in analysis results. We have:
3 haematology screens (units are listed in export data chapter according to the **Hb Unit** selected)
7 screens for reserved use

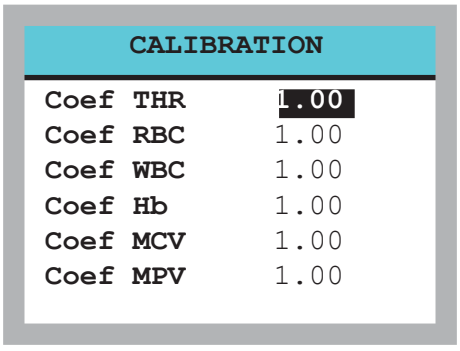
Note: alarms and normal range printouts are only taken into account if a non-zero value is entered into the parameter Max column.

Previously described coefficients can be printed on built-in printer in four groups:
1) Bank counting parameters and correction coefficients
2) Bank haematology normal range
3) Other bank normal range (reserved use)
4) Instrument calibration coefficients

Press the *Print* key (*Print screen* key on external keyboard) when one of these above group is displayed on the screen.

4.3.3 CALIBRATION

Instrument calibration coefficients

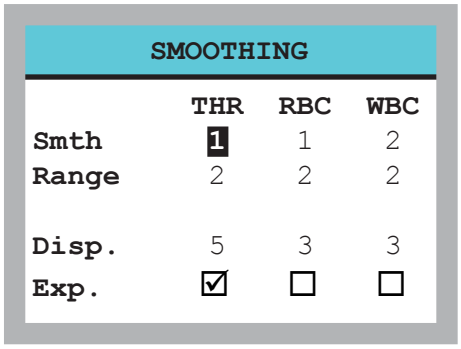


The selection of this line from the Parameters Menu displays first a coefficient correction screen. This screen is the same as the 4th parameters screen of the blood bank. The only difference is that it concerns the general calibration of the instrument.
It is not used to correct cell structure differences according to the different types of blood but only to adjust mechanical disparity between the different instruments (size of the counting aperture for example).
The instrument calibration must only be performed with control blood.
Refer to chapter 7.2 for automatic calibration.

When this screen is displayed, it can be printed (only on the built-in printer) by pressing the *Print* Key (*Print screen* key on external keyboard).

Smoothing coefficients

In order to improve the representation and calculations carried out on the distribution histograms, smoothing is performed, the characteristics of which are defined in the screen below. These parameters are the same for all blood banks and must not be changed.



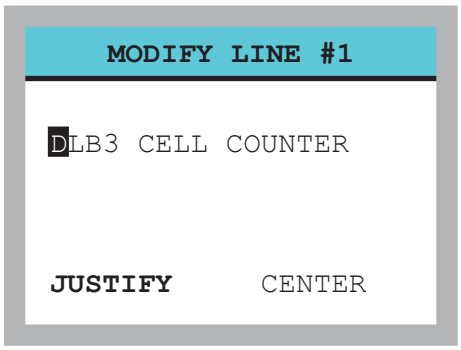
Smth.: Number of successive smoothings (0 to 3).
Range: Number of smoothed points (1, 2 or 3 respectively matching to 3, 5 or 7 points width).

Attention: Parameters above are used to calculate results. Changing one of this parameters could lead to de-calibration of some tests.

Disp.: Number of successive smoothings used to build displayed or printed histograms (0 : no smoothing to 3/5: maximum smoothing).
Exp.: Unchecked for a normal displayed or printed histogram, checked for a height-expanded histogram. The expansion will only be applied if it is necessary.

4.3.4 USER HEADING

Displays a succession of 4 screens which allow personalized headings to be entered and printed at the beginning of the analysis results.
Each screen edits a line of 40 characters maximum and allows the justification of the text on the report (left or center justified).
The heading is a maximum of 4 lines-long.
An empty line will not be printed.

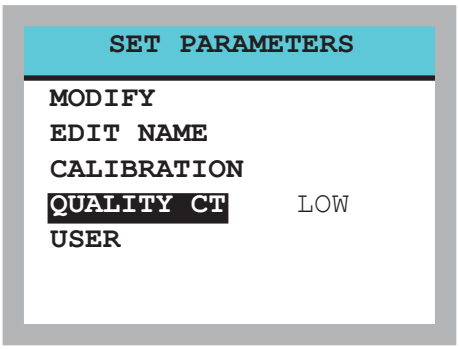


1) Edit with external alphanumeric keyboard:
Type the text with a maximum of 40 characters. The cursor will hold the last position if the end of the line is reached.
Use the *Enter* key to select JUSTIFY and eventually modify with the *Up arrow* or *Down arrow* keys.
Use the *Enter* key again to switch to the screen for the following line. (Line number appears in the title bar).

2) Edit with built-in keyboard:
Use *Up arrow* or *Down arrow* keys to change the selected character then jump to the next letter using the *Right arrow* key.
To cancel any character, select the space character.
When the line is finished, proceed by selecting the *Enter* key to choose JUSTIFY.

4.3.5 QUALITY CONTROL

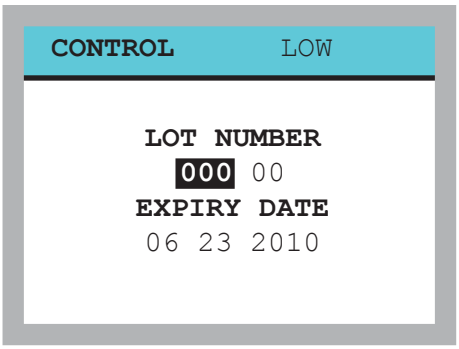
This menu permits the setting of control blood parameters on three levels to perform quality control tests.



When the menu item **QUALITY CT** is selected, the control blood level to be identified is displayed on the right. To change it, use the *Right arrow* key to select it and choose the desired level by means of the *Up arrow* or *Down arrow* keys, then validate.

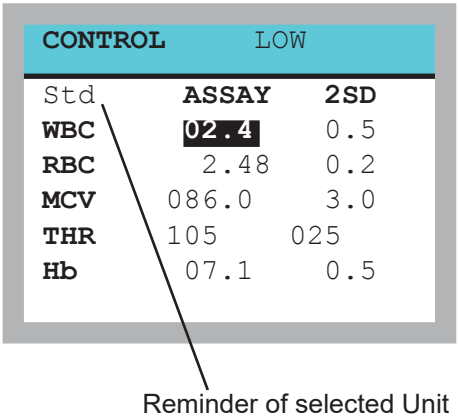
A blood control MS-Card is available to set automatically all the parameters as described below. See section 6.3.

Control blood identification



This first screen allows identification of the control blood at the required level.
If not defined previously, the date by default is displayed as the current date.
It is necessary to enter the information on this screen to perform a quality control analysis.
Note: LOT NUMBER is always numeric and cannot be alphanumeric.

Control blood values

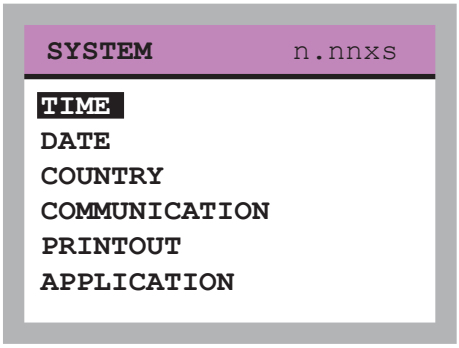


This second screen permits to enter the values for the control blood at this level.

Default values must be corrected in accordance with the used lot.
The first column consists of target values and the second the allowable tolerance for the 6 measured parameters.
For example:
WBC: 2.4 m/mm^3 ± 0.5 m/mm^3
RBC: 2.48 M/mm^3 ± 0.2 M/mm^3
...
Hb: 7.1 g/dl ± 0.5 g/dl

Hb value must be entered according to the unit selected from Hb Unit. A reminder of the selected unit is displayed above the tests name.

4.4 SYSTEM MENU

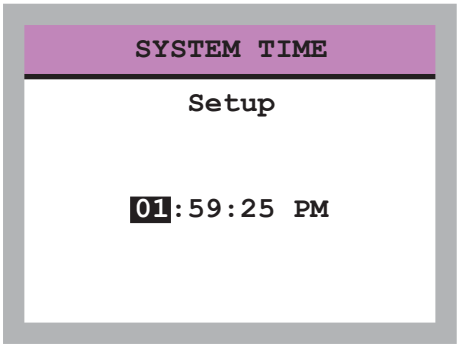


On the right of the title bar is the version number of the program.

To quit this sub-menu, press the *Cancel* key. Menus are called in a hierarchical way. Each time you quit a sub-menu, the previous menu is displayed until you reach the home screen.

4.4.1 TIME

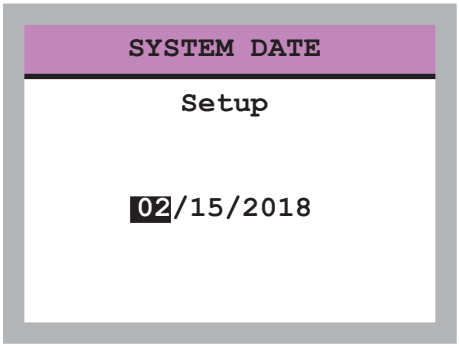
The current time is displayed, divided into 4 editable fields (Hour, Minute, Second, AM/PM). The changeable field is in inverted color. To move from one field to another, use *Right arrow* or *Left arrow* keys (and/or *Tab* or *Shift-Tab* keys on external keyboard).
To change a field value, use *Up arrow* or *Down arrow* keys (or directly enter the numeric value on an external keyboard).



This example is given for a 12h-mode configuration system. With a 24h-mode configuration system, the fourth field (AM or PM) disappears.
This last field can be modified with *Up arrow* or *Down arrow* keys (or by entering **A** or **P** characters on an external keyboard).
- To quit without validating the modifications use the *Cancel* key.
- To quit and save modifications, use the *Enter* key.

4.4.2 DATE

The current date is displayed, and divided into 3 editable fields (Month, Day, Year). To modify the date, proceed as explained above.

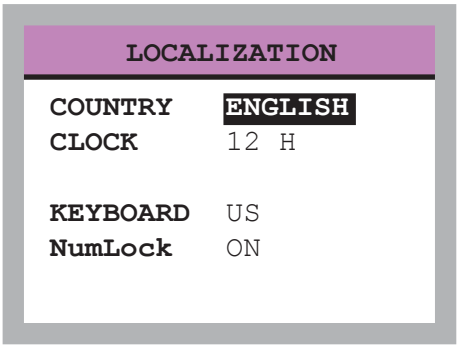


This example is given for a system configuration in the English language. For any other language, the display order Month and Day will be made according to the country (Day, Month, Year in French, for example).

4.4.3 COUNTRY

Select the active field by means of *Left arrow* or *Right arrow* keys (and/or *Tab* and *Shift+Tab* on an external keyboard).

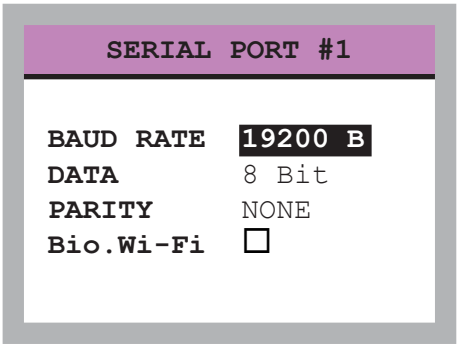
Modify the selected field content by means of *Up arrow* or *Down arrow* keys.



COUNTRY: Defines used language (French, English and a third customized language).
CLOCK: Choice between 12h or 24h format.
KEYBOARD: External keyboard type used. Choice between French (AZERTY), US (QWERTY) and third type.
NumLock: Defines external keyboard locking numeric keys, when power is turned on.

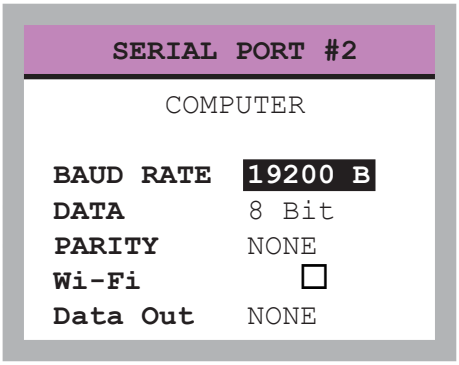
4.4.4 COMMUNICATION

1) Serial port #1: reserved use



BAUD RATE: Data flow on RS-232 port (1200 to 57,600 Baud).
DATA: Data frame (7 or 8 bit).
PARITY: None, Even or Odd.
Bio.Wi-Fi: Reserved use
Enter key validates data changes and provides a second identical array for computer connection.
With an external keyboard, *Page up* and *Page Down* keys allow running from one screen to another.

2) Serial port #2: Computer connection

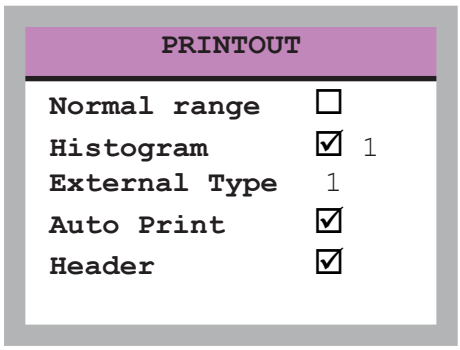


Wi-Fi: Reserved use
Data Out: This additional option gives the possibility to send results to a computer automatically at the end of the analysis.
3 options:
NONE: No automatic sending
Auto 1: Send results without histograms
Auto 2: Send results with histograms
See the 'Export data' chapter for more details on the sent data structure.

For use of this option, the computer must be permanently available to receive data.

4.4.5 PRINTOUT

This menu sets printout parameters.



Normal range: If checked, validates (⇩ ⇧) the normal range printing on the line following the test results line on built-in printer. Normalities are always printed on an external printer.
Note: They will only be printed if the Maximum value is not 0 in the Min/Max arrays.

Histogram: If selected, validates (⇩ ⇧) the printing of the histograms on printers.
Internal printer: ☑ 1 and ☑ 2 give the same result.
External printer: ☑ 1 prints fully black histograms, ☑ 2 just prints the histogram upper line in order to reduce ink consumption on some printers.

External Type: External printer type used. Use ⇩ or ⇧ to select printer type.
1 for a graphic printer with ESC/P compatibility (e.g. EPSON® type).
2 for draft printing in character mode.
3 for a graphic printer with PCL3 compatibility (e.g. Hewlett Packard® type).
(contact MS Laboratoires for the list of working printers or www.DIALABabos.com)

Auto Print: If checked, validates (⇩ ⇧) the automatic printing of analysis immediately after counting, simultaneously when results are displayed.

Header: ☑ to print the personalized heading. Otherwise a value (1-14) gives the number of skipped lines from the beginning of the printed page on an external printer. This value is ignored on the built-in printer as the personalized heading is not printed.

PRINTING COMMANDS

Reminder: Printing can only be selected when the LED from the Print key is on.

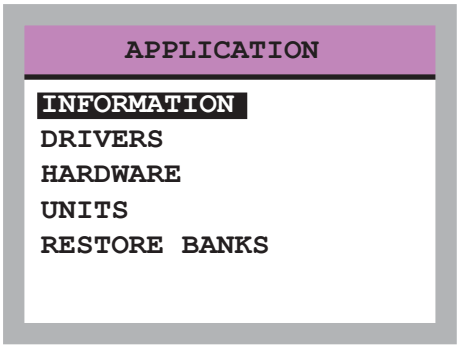
Results: Except for the case of automatic printing previously described, results can be printed when one of the result screens is displayed.

Reports: A set of analysis results can be printed when the instrument displays the home screen.

Calibration and Normalities: Calibration and normal range screens can be printed only on the built-in printer when they are displayed
(see previously 'CALIBRATION' / coefficients printout chapter).

4.4.6 APPLICATION SUB-MENU

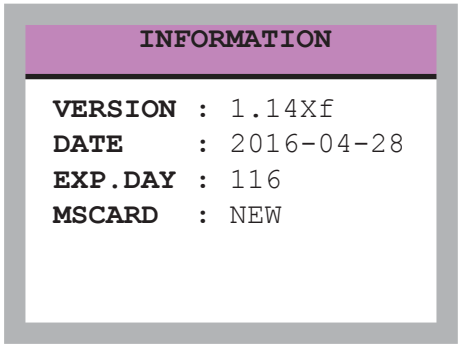
This command line calls a new sub-menu as shown below.



To quit this sub-menu, press the *Cancel* key. Menus are called in a hierarchical way. Each time you quit a sub-menu, the previous menu is displayed until you reach the waiting screen.

The HARDWARE and RESTORE BANKS lines appear only if the DLB3 is in administrator mode (see section 6.4).

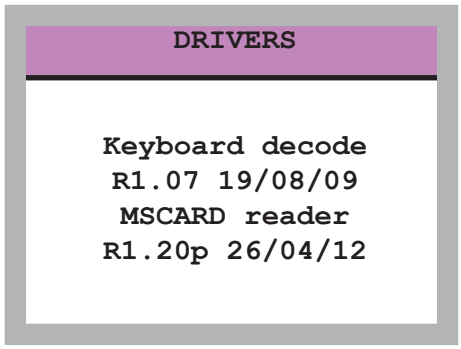
4.4.6.1 INFORMATION

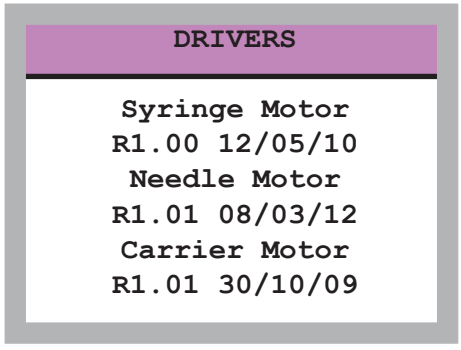


VERSION: Software version number.
DATE : Last software modification date.
(YYYY/MM/DD format)
EXP. DAY: Number of remaining days before the expiration date of the reagent pack.
MS-CARD : NEW: Appears only if a new MS-CARD is inserted into the card reader.

Printout key can be used to print the program version and the DLB3 serial number using the built-in printer.

4.4.6.2 DRIVERS





The first screen shows the external keyboard and MS-CARD reader driver version numbers. The revision number and the date of each driver could change according to the program version (a driver can be automatically updated, if needed, with a program update).

Quit this screen by the *Enter* key to see the second driver screen (*Cancel* key comes back to the previous menu).

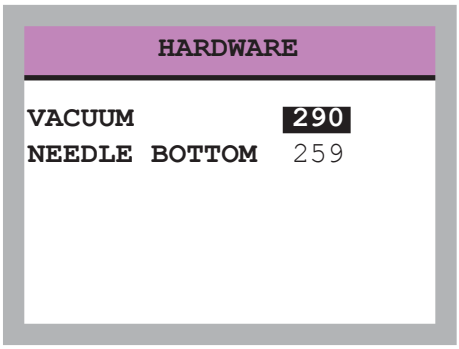
This last screen shows the motor driver version number.

Printout key can be used to print the drivers versions and the DLB3 serial number using the built-in printer.

4.4.6.3 HARDWARE

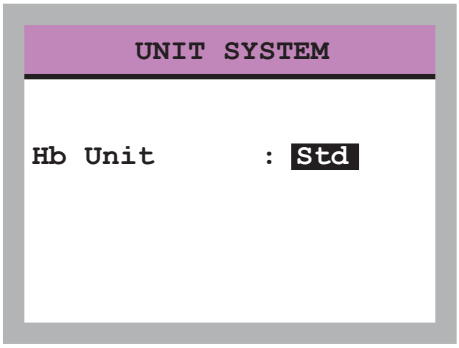
The HARDWARE sub-menu is accessible only if the DLB3 is in administrator mode (see 6.4 section).

The screen below, which includes the vacuum parameters, must be changed with great care and if possible with the help of a MS Laboratoires technician. If incorrect data is entered then the analysis results will be inaccurate.



VACUUM: Sets the counting vacuum of the RBC / THR and WBC canals in mBars.
NEEDLE BOTTOM: Indicates the sample needle bottom position value into the blood sample tube. Modify this value if the needle contacts the tube bottom assuming it is not of standard shape. 1 mm corresponds to approx. 4 units of this parameter.

4.4.6.4 UNITS



Hb Unit: Selects the unit in which Hb, MCHC and MCH or Hct results are given.
Std: Hb and MCHC in g/dl, MCH in pg
SI: Hb and MCHC in mmol/l, MCH in fmol
IU: Hb and MCHC in g/l, Hct 0. XX without unit

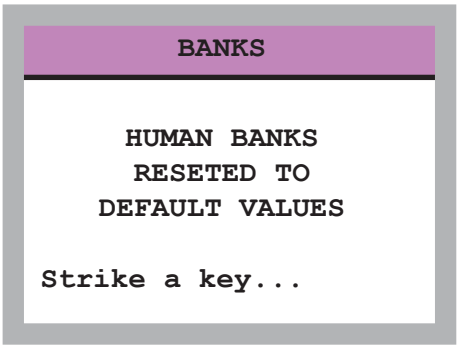
Note: Results AND Normal range for haematology are given in the selected units. Normal Range values from Parameters screen must also be entered according to this unit for these 3 parameters.

4.4.6.5 RESTORE BANKS

> The HARDWARE sub-menu is accessible only if the DLB3 is in administrator mode (see 6.4 section).

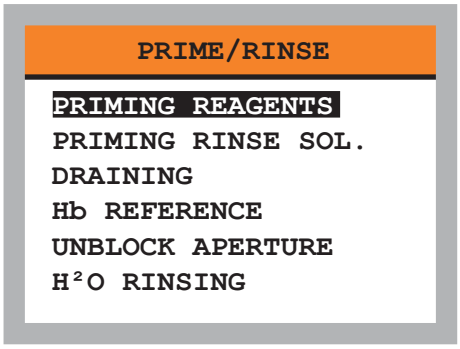
This screen allows the operator to restore bank parameters to their factory setup (reset parameters).

HUMAN BANKS: Male, Female and New-born banks restore.
VETERINARY BANKS: Not used.
FREE BANKS: Free #1 and Free #2 banks restore.
CONTROL BANK: Control bank restore.
Quit this screen by pressing the *Cancel* key to come back to the application sub-menu.



Press the *Return* key to reset the selected banks (e.g. HUMAN BANKS).
Then strike any key to go back to the factory setup screen.

4.5 PRIME/RINSE MENU



The technical menu allows specific intervention on the fluidic cycles of the instrument.
It must be used only in specific cases apart from the standard analysis cycles.

4.5.1 PRIMING REAGENTS

Primes all the reagents except the rinsing solution. This cycle must be carried out when the reagent pack is changed.

4.5.2 PRIMING RINSE SOL.

Primes only the rinsing solution. This cycle must be carried out when the reagent pack is changed.

4.5.3 DRAINING

Drains the measuring and dilution chambers. It must be used in case of failure of the standard liquid draining procedure caused by a functional anomaly.

4.5.4 Hb REFERENCE

Performs a cycle with a short simulated counting time.
This cycle is used to control the hemoglobin reference and eventually correct the photometer automatic calibration.
This cycle is automatically called after a startup or a standby and after priming reagents at power up.

NEVER RUN THIS CYCLE WITH THE INSTRUMENT FRONT COVER OPEN.

4.5.5 UNBLOCK APERTURE

To be carried out if several channels are simultaneously and frequently blocked while analysis. After this procedure, run an analysis without blood to rinse chambers.

4.5.6 H²O RINSING

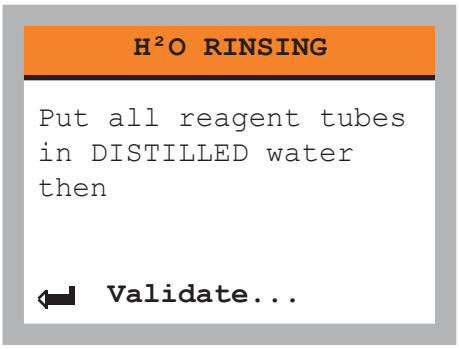
The aim of this procedure is to rinse all the fluidic circuits with distilled water to eliminate the reagents which could become crystallized in the tubes and valves.

This procedure must be carried out when the instrument will not be used for a long time (more than a week) or before transportation.

Selecting this menu item displays the screen below to inform the operator of the necessary handling required to implement this operation.

Operating mode

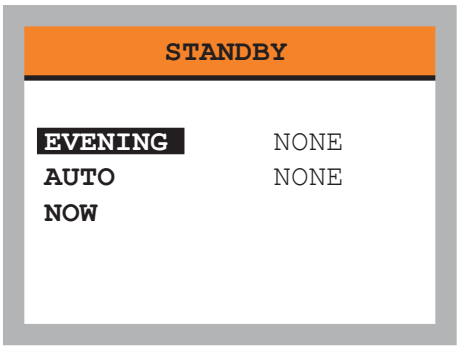
1) Use a container of distilled water (Rinsing solution can also be used).
2) Take the cap off the Rinse Solution and insert the tube into the distilled water container or unscrew the cap off the Rinse Solution container while leaving the tube inside.



3) Take off the cap of the DILUENT container, take the tube out and let it drain as much as possible. Insert the tube into the distilled water container.
4) Repeat the same procedure with the DETERGENT and LYSE tubes.
Note: Make sure that there is enough distilled water in the container so that all the tubes are correctly plunged into the water.
5) Select the RINSING H²O cycle to display the above screen and validate.
The instrument will carry out several rinsing cycles and reject all the reagents from the tubes into the waste container.
6) Unplug all tubes from the instrument and empty them as much as possible.
7) Put the protect caps back on the fluidic connector.

4.6 STANDBY MENU

A standby procedure can be performed on the instrument to guarantee that the fluidic circuits stay well-rinsed to reduce the crystallization risks due to reagent drying. This can occur if the instrument is not going to be used for a long time.
It is not an energy saving state.
However, there is no disadvantage in switching off the instrument when the standby cycle is finished. It is even recommended to turn off the analyzer regularly, once a week for example.
The STANDBY menu is displayed as below.
The instrument can be turned to standby mode automatically or manually.



EVENING: Automatic standby at a set hour.
Select NONE and, by *Up arrow* or *Down arrow* keys, choose the desired hour (modification by 15 mn steps).
AUTO: Automatic standby for a programmed period after an analysis.
Select NONE and, by *Up arrow* or *Down arrow* keys, choose the desired time (modification by 30 mn steps in a range of 30 mn to 7 h 30 mn). The instrument will be turned to standby mode according to the programmed time from this moment, the time will be reinstated after each new test.

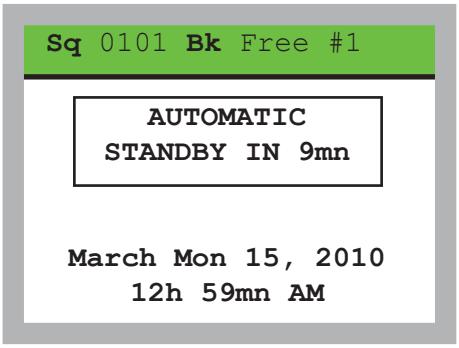
It is necessary to use the *Enter* key to save a modified data in both of the above cases. If you quit the program by using the *Left arrow* key, the modifications will not be saved.

If both configurations are programmed, the first time reached will start the standby mode.

NOW: The instrument starts immediately the rinsing cycle with the rinsing solution before turning to standby.
When the instrument is in standby mode, the display is off and the white LED (power indicator) blinks.

IMPORTANT

Never leave the instrument more than one day without performing an analysis or setting the standby mode. The correct method is to implement the standby procedure in the evening or before turning off the power after the last analysis of the day.



When the instrument displays the home screen, it beeps each minute to point out the remaining time before automatic standby.

Return to normal state

1) The appliance has been switched off after the standby procedure:
When the power is turned on, the device will do the following:

a) Rinsing liquid disposal.
b) Reagents priming.

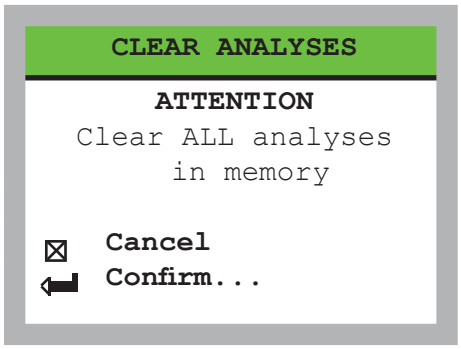
2) The appliance has not been switched off after a standby procedure:
Simply touch any key to reactivate the display. The word ***Ready*** written in green has been replaced by ***Standby*** written in blue.
All manipulations, such as setting parameters, recalling analysis, printing... can be carried out without quitting the standby mode.
The device turns back automatically to standby mode after a short time once it has returned to the home screen.

The only way to quit the standby mode is to run a new analysis. The appliance then carries out the rinsing cycles as described in 1) before asking for the sampling blood tube.

Standby cycles followed by wake-up cycles consume reagents. Do not switch the device to standby mode more than once a day: it is not necessary and would reduce the number of available analyses contained in the reagent pack.

4.7 CLEAR ANALYSES MENU

Selection of this item in the main menu displays the screen below.

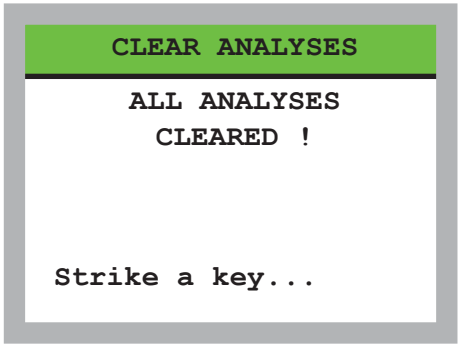


If selected by mistake, press the *Escape* Key to exit this screen.

If this option is validated ( ), the following occurs:
All 'Patient' results are cleared from memory.
All 'Quality Control' results are cleared from memory.
The file ID and the sequence numbers are reseted to **1**.

WARNING

When confirmed, the message below is displayed and results are irreversibly erased.



5: QUALITY CONTROL

5.0 USE OF BIOLOGICAL CONTROLS

Performing biological quality controls is a well established method of controlling performance hematology instruments. The use of stabilized blood cell preparations allows monitoring of stability, exactness and accuracy of measured values over a long period as well as early detection and prevention of problems.
It is advisable to carry out a quality control:

- before any start of operation,
- after maintenance,
- in case of doubt about the accuracy of the analysis results.

We recommend R&D CBC-3D® which is a tri level haematology control designed to document and monitor values obtained from haematology cell counters that use the impedance counting principle.

R&D CBC-3D® contains human erythrocytes, simulated leukocytes, and mammalian platelets in a plasma-like fluid. It is only for in vitro diagnostic use.

This preparation must be handled carefully as if it was a patient sample.

Human bodily fluids are potentially hazardous biological materials.
Human serum was used in the manufacture of this product.
This material should be handled as if capable of transmitting infectious disease.
Take appropriate precautions when handling all laboratory samples to prevent skin contact (gloves), ingestion, or inhalation.

Stability and storage
Do not freeze. Store between 2°... 8°C when not in use. Unopened tubes are stable until the expiration date on the label. Opened tubes are stable for 14 days after first use provided that they are handled properly .

Refer to the user's guide given with the kit (or with the tube) for more information.

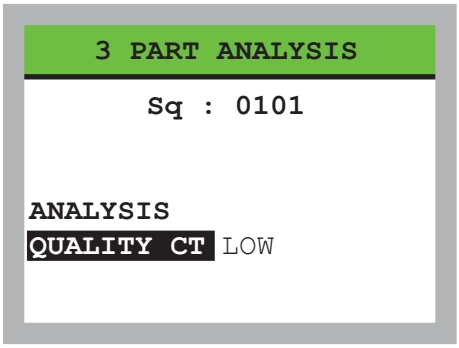
(*See next page for references*)

The control blood tubes or kits R&D CBC-3D® should be ordered from the local R&D distributor.

5.1 RUN QUALITY CONTROL ANALYSIS

RUN QUALITY CONTROL ANALYSIS

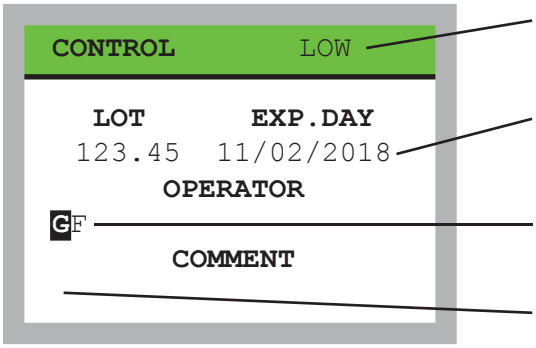
Quality control allows tests with control blood to check the correct calibration of the appliance at regular intervals.
It is performed as a standard blood analysis from the **QUALITY CT** menu item.



When this item is selected, the control blood level to analyze is displayed on the right. To change the level, see the parameters menu chapter.
The control blood must be identified to authorize the start of the test.

The control blood must be identified to authorize the start of the test.
(See section 4.3.5)

The screen which identifies the operator is displayed at the start of a Quality Control test.



Reminder of the control blood level

Reminder of the control blood identification

Operator identification
Initials only on two letters

Optional comments
Easier with an external alphanumeric keyboard

A first hit on the *Enter* key moves the cursor to the second line to edit comments and a second hit on this same key activates the test. With an external keyboard, the *Page up* key moves the edit cursor back to the previous line.

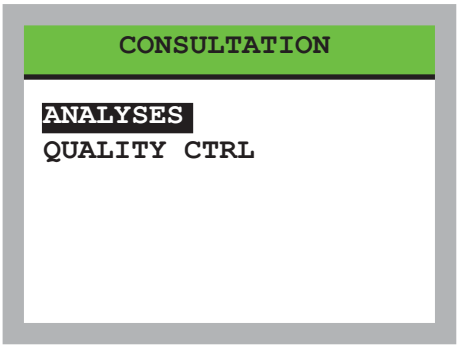
Differences between a standard analysis and a Quality Control analysis
When the test is finished, the results are displayed like as a standard blood analysis,
but the Min/max alarms are only controlled from the 5 parameters defined for the control blood.
From version 1.14, the alarm R is added to the ticket a QC analysis (quality control) in addition to up / down arrows if threshold alarm. Only 3 main parameters WBC, RBC and PLT are managed, the R appears on all results associated with the primary parameter subpopulations WBC, parameters associated with RBC (MCV, Hct, MCH, MCHC, RDW and Hgb) and / or PLT (MPV, Pct and IDP).

Only the 5 parameters normalities are printed.
The barcode reader is not accepted for quality control.

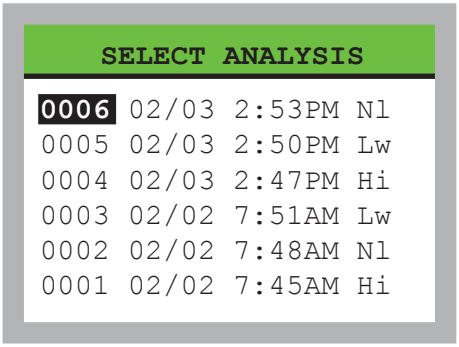
Recording

The results are saved in compact form in a separate array for blood analyses. Up to 125 quality control blood analyses can be saved.
These analyses have a different sequence number from the blood analysis.

5.2 RECALL ANALYSIS



Select the ANALYSES item in the main menu to recall analyses.
When quality control analyses have been saved, an intermediate menu allows the choice of analysis type to recall.



The 'SELECT ANALYSIS' menu for quality control is different from the blood analysis menu as follows:
The selected number is the sequence number and not the file number which does not exist in these tests.
Blood abbreviations are different:
Lw: Low level control blood
Nl: Normal level control blood
Hi: High level control blood

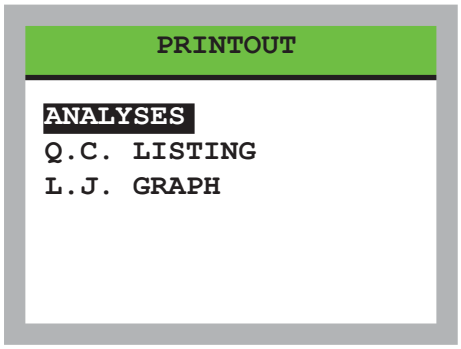
The recall of a quality control analysis is only displayed on two screens:
The first screen shows the 6 measured parameters results, the second shows the analysis identification which can be modified with an alphanumeric external keyboard, by pressing the *F4* function key or with the *Up Arrow* ⇧ key of the internal keyboard.
The other values and histograms are not saved in quality control mode.
The results will also be printed in reduced form. Full printing is only possible immediately after the test.

5.3 REPORTS

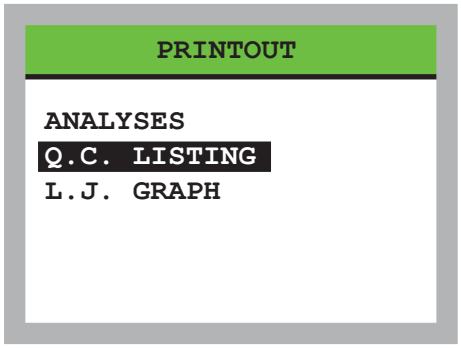
It is possible to print a set of analysis results in list or graphic type.

Operating mode

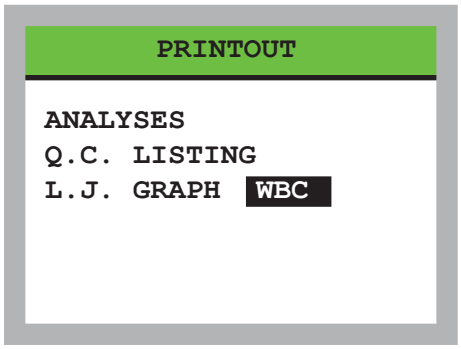
When the appliance is on home screen, press the *Print* key or *Print screen* key on an external keyboard (this will only be activated if at least ONE analysis exists in the device memory).
If both blood and quality control analysis exist, a first screen shown below is displayed, allowing to choose the analysis type to report :



Select ANALYSES to print out the analyses statistics report (C.V.) to internal or external printer.

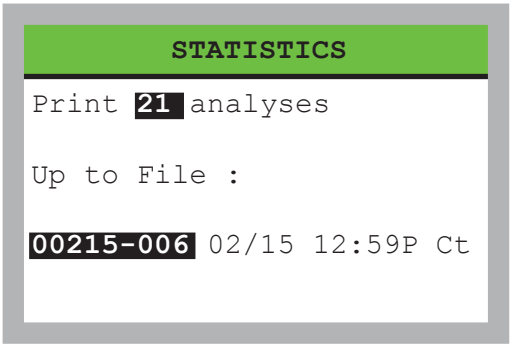


Select Q.C LISTING to print out a quality control report (listing type) to internal or external printer.



Select L.J. GRAPH to print out a quality control report (Levey-Jennings graph type) to internal printer (external printer is not managed). You must select the parameter which will be printed out: WBC, RBC, MCV, THR or Hb.

If only 1 analysis is stored in the device memory, the printing starts immediately. If not, a selection is proposed.



The screen on the left is displayed in two steps.

1) The first line defines the number of analyses to print.

If there are less than 21 analyses in memory, the number suggested by default will be the number of analyses in memory.
If there are more than 21 analyses in memory, the number suggested by default will be 21.

Change the value by the *Up arrow* or *Down arrow* keys. Validate ( ) when the displayed value is correct. No more than 32 tests can be printed at once.

2) If the number of analyses to print is equal to the quantity of analyses in memory, printing starts immediately.
If not, the second line is displayed to select the last analysis file number. The number suggested by default is the file number of the last analysis stored.
Change the file number by the *Up arrow* or *Down arrow* keys.
Start the printing with *Enter* key.

The list of the printed analyses will always begin with the most recent analysis.

5.3.1 Blood analysis report

All the results are printed in list format. After these results, a line gives the maximum gap between each test (exact value not approximate) and another line gives the variation coefficient of each test. Both lines will only be printed if at least 2 results are selected.
Both lines therefore really mean something if the list of printed results concerns the same blood.

On the built-in printer, only the main tests are printed because of the small width of the paper. Some values are rounded for the same reasons.

5.3.2 Quality control report

5.3.2.1 Q. C. Listing

Results are grouped together according to the control blood lot numbers.
- On the built-in printer (figure 5.3.2.1)
A first line shows the control blood target values and the percentage gap compared with the target value, for each analysis.
- On an external printer
The result value is followed by the percentage gap compared with the target value. If more than one analysis is printed for the same lot number, the gap between the two extreme values is printed on an extra line.
In both cases, if a gap is higher than 99%, it is shown by two stars.

Figure 5.3.2.1

```
QUALITY CONTROL
LOT NUMBER: ØØ1.ØØ
CONTROL    : NORMAL
   WBC  RBC MCV THR   Hb
Tg 7.5 4.5Ø  77 25Ø 13.4
Sq: Ø154   1Ø/28/2Ø1Ø
   - 1  + Ø + Ø + 7  - 1
Sq: Ø153   1Ø/28/2Ø1Ø
   + Ø  - 1 - Ø - 8  + Ø
Sq: Ø152   1Ø/28/2Ø1Ø
   + Ø  - 1 + Ø + 4  + 1
Sq: Ø151   1Ø/28/2Ø1Ø
   - 1  + Ø + Ø + 2  + 1
```

5.3.2.2 L.J. Graph

Levey-Jennings type graph.
Only five parameters are managed : WBC, RBC, THR, MCV and Hb.
The external printer is not managed.
Results are grouped together according to the control blood lot numbers and level, see following examples (Figures 5.3.2.2a to 5.3.2.2e).
If a result is out of range (lower than -2D or higher than +2D) it is marked R (Rejected).

Figure 5.3.2.2a

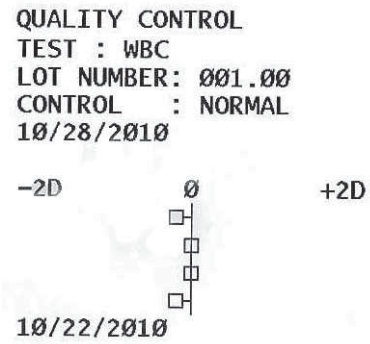


Figure 5.3.2.2b

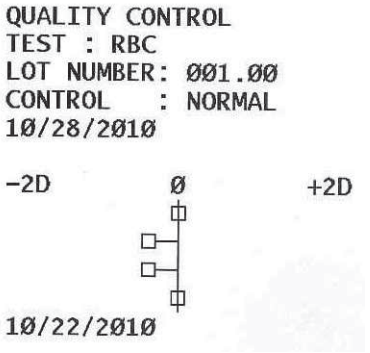


Figure 5.3.2.2c

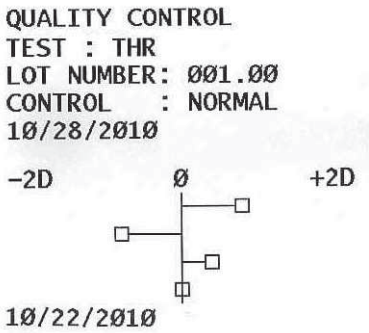


Figure 5.3.2.2d

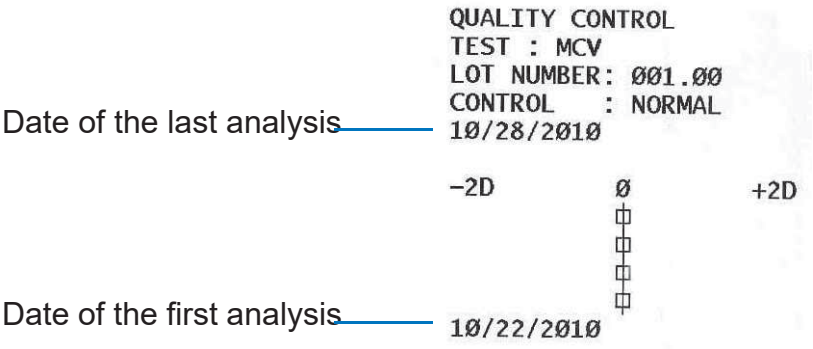
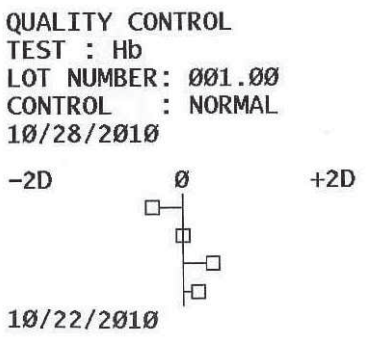


Figure 5.3.2.2e



6: MS-CARDS

6.1 REAGENT MS-CARD

The device can work without an MS-CARD for management access (configuration, analysis recall...) but a card is absolutely necessary to carry out an analysis. It enables to control the validity of the reagents and to manage their expiry date.

IMPORTANT
Check that the card outside appearance is conformed:
- That there is the genuine hologram.
- That there are all the written legal notices of property:
"Property of BV Rights - Vaduz - FL".
Please read the License agreement at the end of the manual.

A MS-CARD is provided with each reagent pack and a spare MS-CARD is provided with the device when it leaves the factory.

At each change of reagent pack, insert the new card enclosed with it.

Use-by-date of reagents

The date on the reagent pack gives the limit of validity of unopened products.
When the bottles are open, their use is limited to 4 months, controlled by the MS-CARD **which must be inserted into the instrument at each change of pack.** If used beyond, the analysis results will be inaccurate.
The number of days remaining before the expiry date can be controlled from the menu SYSTEM/ APPLICATION/INFORMATIONS.
When the expiry date is reached, a message is displayed at the power up of the instrument or when an analysis is run after a standby. The device authorizes analyses up until 10 days after the expiry date, beyond, a new MS-CARD is required.

Note: The device can display the expiry date deadline message even with a new card introduced into the card reader. It is necessary to run an analysis for recording the new expiry date in the memory.

Control of the analyses number

The MS-CARD also controls the maximum number of authorized analyses by reagent pack. At the end of an analysis, a message is displayed when there are 20, then 10 analyses left and when the last analysis has been done.
However, according to the frequency of use of the instrument, one reagent from the pack may be empty before you reach the maximum number of authorized analyses.

6.1.1 Blood banks

Below are the different blood banks and their abbreviations.

Blood Bank	Nb	Abv
Male	1	Hm
Female	2	Fm
New born	3	Nn
Control	4	Ct
Free #1	5	L1
Free #2	6	L2

Original parameters of banks Free #1 and Free #2 are not defined. They are intended for loading card parameters.

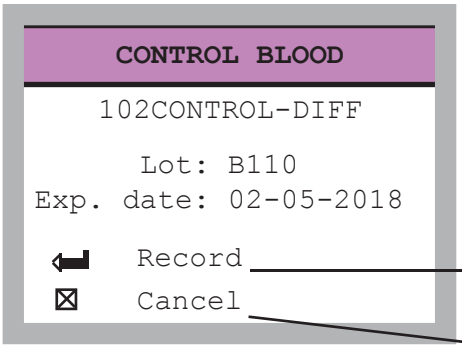
6.2 BLOOD BANK MS-CARD

NOT AVAILABLE.

6.3 CONTROL BLOOD MS-CARD

The control blood MS-Card permits to record all control blood parameters on three levels to perform quality control tests. See section 4.3.5 to get more information about these parameters.

Insert the card only when the device shows the home screen, then the screen below appears. The lot number and the expiry date are displayed.

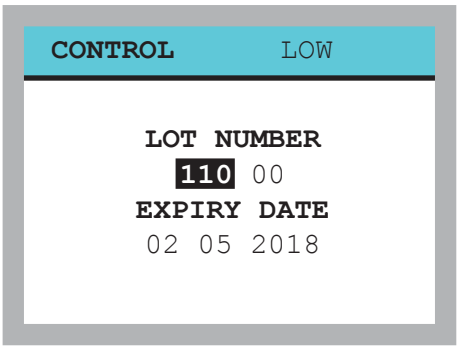


This choice copies the control blood data into the instrument.

This choice cancel the operation.

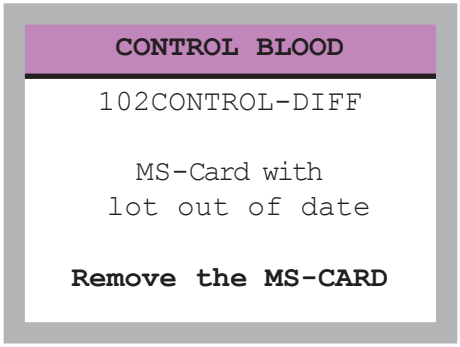
Operating mode

Verify the Lot number and the expiration date, then press the *Enter* key to record the new parameters into the instrument. Be careful, the old data are automatically replaced by the new one.
Attention: The letter in front of the lot number is never recorded.



To verify the new parameters, use PARAMETERS/ QUALITY CT and verify the lot number and the expiry date.

If the expiry date is out of date the screen below is displayed.



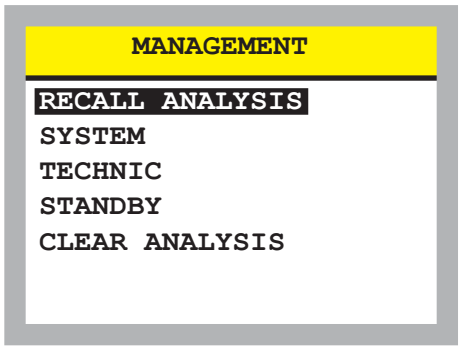
6.4 ADMIN MS-CARD

The DLB3 works by default in user mode.
In order to change to administrator mode, when the home screen is displayed, insert the ADMIN MS-Card.

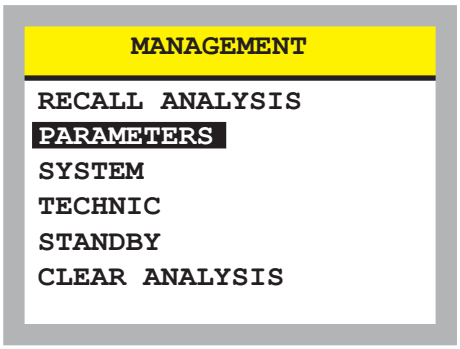
Only one ADMIN MS-Card is supplied with the analyser. It must be kept preciously during all the instrument life by the responsible of the laboratory.

In the administrator mode, the PARAMETERS menu is accessible (see section 4.3) as well as the HARDWARE sub-menu (see section 4.4.6.3). This card does not permit to launch an analysis.
Once the ADMIN card is inserted, the PARAMETERS line is added to the main menu ( ).

User Mode
Main menu

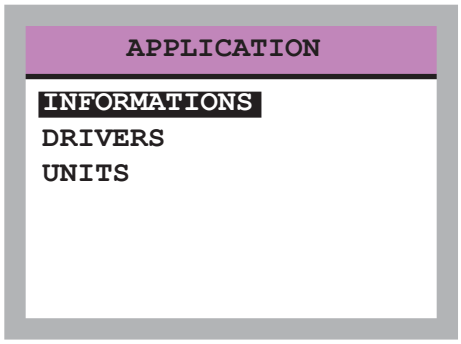


Administrator Mode
Main menu

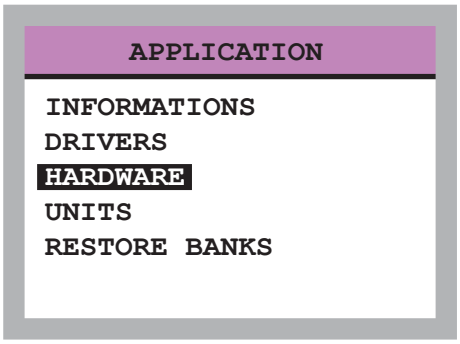


Also, when the ADMIN card is inserted, the HARDWARE and RESTORE BANKS lines are added to the application sub-menu.

User mode
Application menu



Administrator mode
Application menu



Finally, the ADMIN card is necessary with the AUTO CALIBRATION (see 7.2 section).

7: CALIBRATION

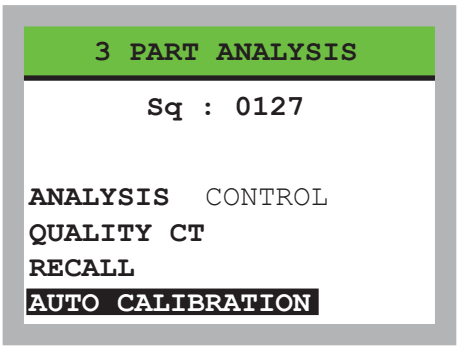
7.1 BANK CALIBRATION

NOT AVAILABLE.

7.2 AUTO CALIBRATION

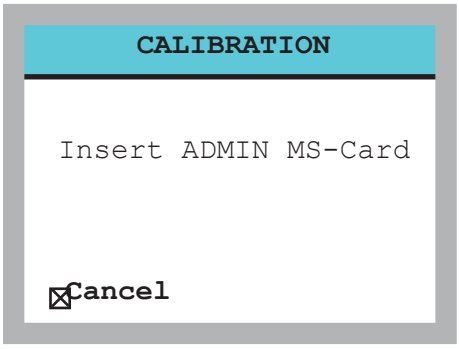
The operating mode described hereafter can be used to calculate automatically the DLB3 calibration coefficients for THR, RBC, WBC, Hb and MCV (MPV is not managed).
First, the target values for the level NORMAL of a control blood must be valid (see how to enter lot number and target values with section 4.3.5).

1) Run a NORMAL control blood analysis with bank CONTROL selected.
2) Quit the results screen to return to the home screen.
3) Press the *start analysis* key to run a new analysis.
If the analysis has no error and
If WBC result is inside the range 4,00 - 12,00 m/mm^3,
If THR result is inside the range 120 - 370 m/mm^3,
the analysis screen includes an additional line : AUTO CALIBRATION.

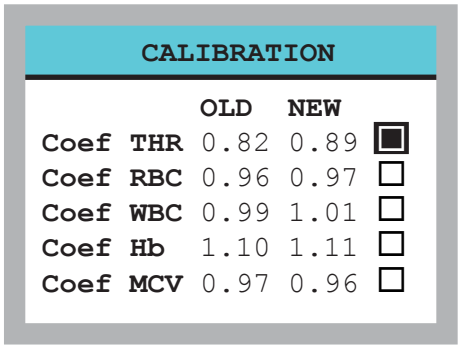


4a) Select the AUTO CALIBRATION line and validate with the *enter* key.
The below screen is displayed if ADMIN MS-Card is not inserted into instrument.
If not, the screen describes at the 4b) paragraph is directly displayed.

Insert an ADMIN MS-Card in order to go through the next stage (see 6.4 section).
It is possible to cancel the operation with the key and the DLB3 returns to the home page.



4b) The old and new coefficients are displayed. Check or uncheck the checkbox with the *start analysis* key (F2 or space bar with external keyboard) to accept or not the new coefficient.



Then press the *enter* key to save the new checked coefficient(s).
The DLB3 goes back to the home screen.
Then press again *start analysis* key to display the analysis menu and verify the corrected results with the item RECALL.

Note 1: Corrected results are not saved in the memory. The saved results must be discarded because they are invalid.
Note 2: **Do not recall the analysis by the RECALL ANALYSIS menu because, in this case, the results will be those of the original analysis.**

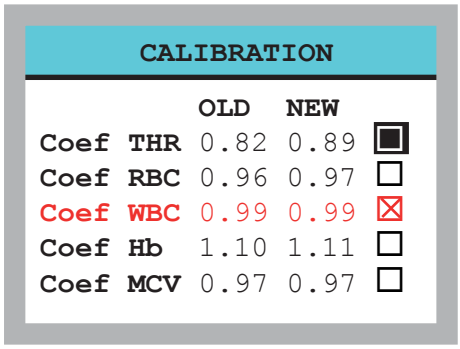
WARNING:

If the difference between the old and the new coefficient is higher than 50%, no correction is done and so New coef = Old coef.

The automatic calibration does not applied in three cases:

a- If the difference between the old and the new coefficient is higher than 50%.
b- If the new coefficient is higher or equal to 2.50.
c- If the new coefficient is lower than 0.10.

If one (or more) of those three cases is true,
the parameter line is written in red and the checkbox is replaced with a red-cross box,
and the coefficient will not be changed.



7.3 MANUAL CALIBRATION

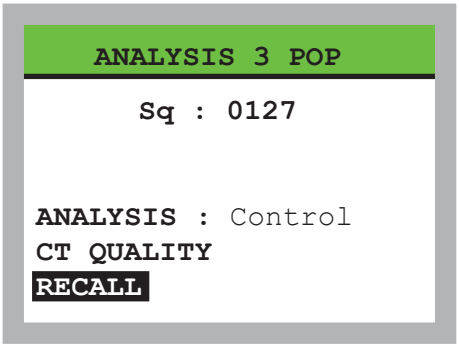
1) Run a sample of normal control blood on control bank and consult the results making sure that there are any clogged alarm and homogeneity error.
Note the tests which need a correction or print them.

2) Quit the result screen to come back to the home page.

3) Display the calibration parameters (MENU/PARAMETERS/CALIBRATION).

The access of this menu requires the insertion of an MS-CARD ADMIN on the DLB3 (see section 4.1 and 6.4).

Modify the correction coefficient according to the target valor. Validate passing through the next screen and go back to the home page.



4) Press the key to launch a new analysis. If the previous analysis is already in memory, the screen of end of analysis are has a supplementary RECALL line.
Displace the selection on the RECALL line and validate.
This allows to display the corrected results according to the new calibration parameters and control if the modifications are correct.
If not, repeat the operation since part 2).

Note 1 : the correct results will not be recorded, don't take the save results into account.

Note 2 : recall the analysis on this way to control the impact of the calibration correction.
Do not recall the analysis by RECALL ANALYSIS Menu because the results will be those recorded during the original analysis.

IMPORTANT

Modify the factory calibration coefficients (general coefficients) only for a recalibration with control bloods, on the *Control* bank.

8: MAINTENANCE

8.0 SAFETY

Personnel carrying out the DLB3 maintenance must be informed of the dangers linked to the analyzer.

- ELECTRICAL HAZARD.
- SHARP OR ANGULAR COMPONENTS HAZARD.
- BIOLOGICAL RISK

ELECTRICAL HAZARD

Switch the analyzer off and unplug the power cord from its socket before any maintenance is carried out inside the DLB3.

SHARP OR ANGULAR COMPONENTS HAZARD

Some components inside the DLB3 have sharp edges or angular corners.
Operate with caution to avoid cuts to the hands.

BIOLOGICAL RISK

When you carry out DLB3 maintenance, take the same precautions as the one you take for handling biological samples by wearing protective clothing such as overalls, gloves and goggles.
Waste disposal must be made according to local or national regulations.

8.1 INSTRUCTIONS FOR USE

Instrument power off

Always run a standby cycle before switching the power off if the instrument is not going to be used before the following day, particularly the evening.

This operation allows the fluidic circuits to be rinsed with the rinsing solution to reduce the risk caused by crystallization of the drying reagents.
Do not leave the instrument without working for more than 5 days. For good maintenance, just switch the appliance on and, when the rinsing cycles are finished, run a standby cycle again before switching off.
If the instrument is not going to be used for more than a week, run a full rinsing cycle with distilled water (MENU/PRIME/RINSE/H²O RINSING).

Periodic checkup

- Check (once a week) the cleanliness inside the instrument especially the dilutor chambers and the sample needle. If need be, clean them with distilled water and a soft cloth.
- Check if the two clots filters are dirty (red-colored due to considerable blood accumulation). If yes, do not clean them. Replace with new ones (see following page).

In case of an anomaly

When an operating incident happens during a dilution cycle, check the fluidic circuits before continuing, particularly the dilutor chambers to make sure no liquid remains at the bottom. If it were the case, run a draining cycle (MENU/PRIME/RINSE/DRAINING) before continuing.
If the error occurs just after the sampling step, run a blank cycle (run a test without blood tube) before running a new analysis.

Periodic cleaning

In order to clean the fluidic circuits thoroughly, it is recommended to perform the following cleaning operations:
- Put 1ml of cleaning solution (Ref 3MSR0213) into the dilutor chambers: RBC, PDL, Waste (See section 8.3, figure 8.3.1).
- Wait 15 - 30 min.
- Run three blank cycles (without blood).

The periodicity of this intervention depends on the use frequency of the device. The following rules may be respected:

- For 125 cycles pack: every 2 packs.
- For 1000 cycles batch: after each batch.

8.2 REAGENT PACK REPLACEMENT

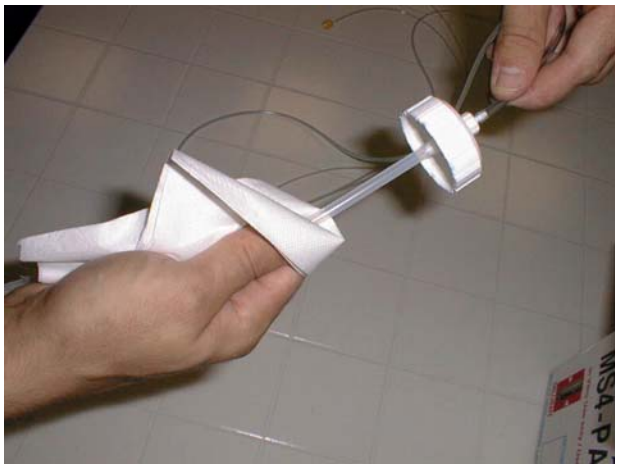
1) Open the new reagent pack box as previously described in *INSTALLATION* chapter.

2) Remove the MS-CARD from the new pack and replace the DLB3 one.

3) Unscrew all the caps of the old pack and remove all tubes as shown on the photo on the right.

Never transfer / mix reagents whether or not of the same nature or the same batch.

Never reuse an empty reagent container (batch, bag or bottle) or partially empty otherwise distort the results and / or damage the machine.



4) Take each dip-tube one at a time and clean it with distilled water and a non-fluffy cloth, then place into the new pack.
Match colours between tubes and bottles.

5) Screw the caps of the new pack onto the old bottles. Some bottles may not be empty.

6) Do not forget to empty the waste container. The rest of reagents, detergents as well as all the waste must be eleminated in the respect of the legal instructions in effect in the country.

7) Verify the clot filters and dilutor cleanliness. Change filters if necessary (see the following page).

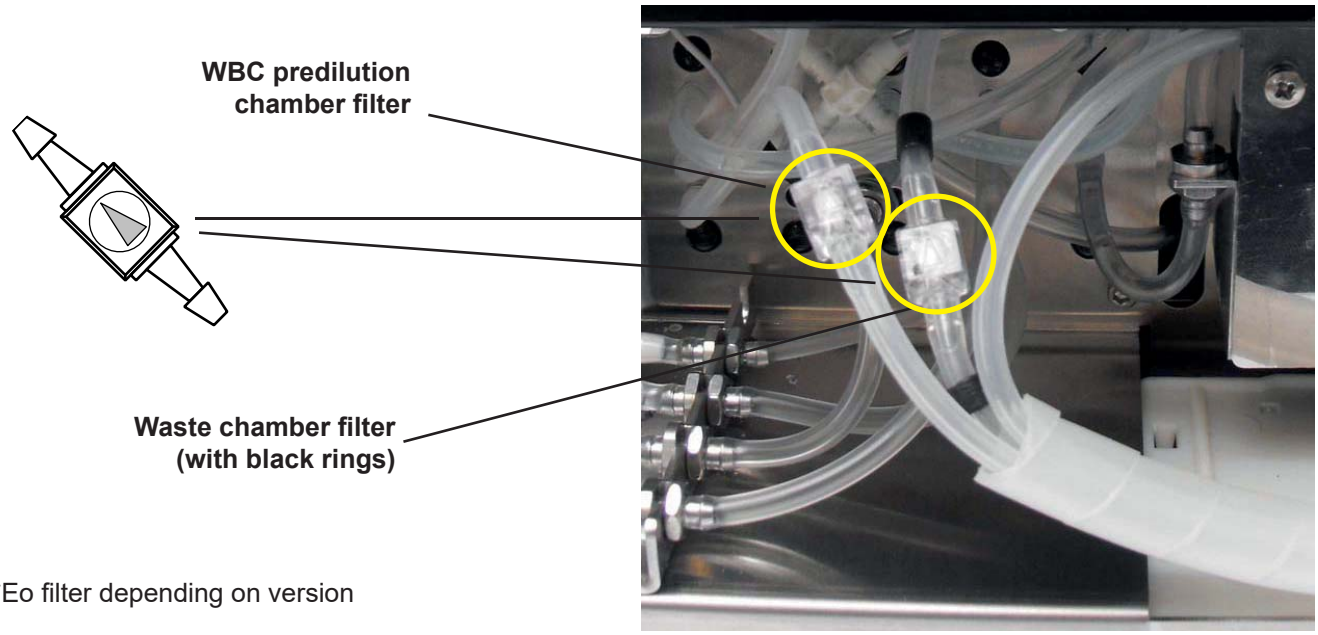
A new blood clot filter is provided with each reagent pack. It's highly recommended to change the filters when replacing pack. See section 8.3.

8) From the screen, select 'MENU/PRIME/RINSE/PRIMING REAGENTS' to prime reagents before running a new analysis.

8.3 BLOOD CLOT FILTERS

Filters are inserted on the two tubes connected to the dilutor chambers. They are used to stop blood clots in the fluidic circuit to avoid risks of blockages, mainly inside the counting aperture and valves.
See the picture below.
If they have to be replaced, take care to follow the direction indicated by the arrow on the filter body as depicted in the enlarged drawing. The arrow tip must always face towards the opposite side of the dilutor chambers.

Picture 8.3.1

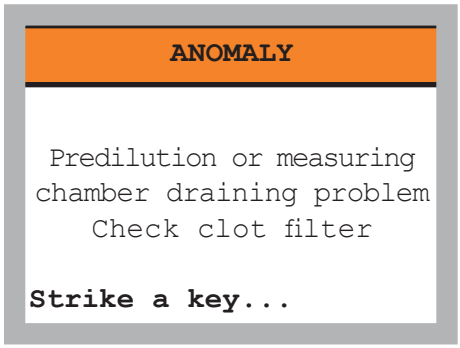


*Eo filter depending on version

To change a filter, pull the flexible tube tightly to take off the old filter then wet the new filter to make it easier to insert in the tube. The two black rings indicate the location of the waste circuit and no ring the location of the PDL circuit to avoid tube inversion during the waste or PDL filter change.

IMPORTANT

After changing a predilution chamber filter, it is necessary to perform a minimum of three blank counting cycles (run the analyses without the blood sampling tube) in order to decontaminate the fluidic circuits.



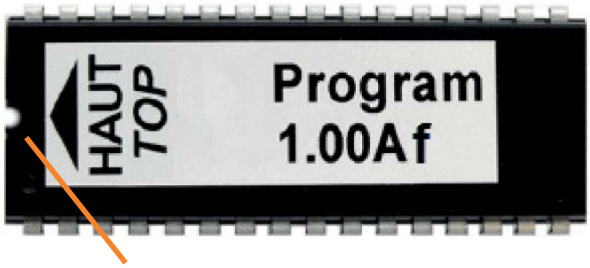
The message on the left indicates that a transfer anomaly which could be caused by a dirty filter has been detected.

Filter blockages may not be detected by the system but it can cause other types of anomalies: Repeated mixing errors during testing, too much residual liquid at the bottom of the dilution chambers...

8.4 UPDATING PROGRAM

It is highly recommended to ask your supplier for the newest version of the sofware.

BEFORE ANY REPLACEMENT ACTION,
TURN THE DLB3 POWER OFF
WITH POWER CABLE UNPLUGGED.



Locating position notch

An updating program requires the replacement of an electronic component (memory). See photo on the left. This component must be inserted into the correct position. Incorrect setting can cause the destruction of the component
Note the locating notch on the photo.

Printout calibration coefficients before updating program (MENU/PARAMETERS/CALIBRATION).

Program memory access

Unscrew the lower screw of the access hatch completely then slightly loosen the upper screw (about 1 turn).

Swivel the closing hatch around to set it in the above position.
Then, tighten the upper screw to maintain the hatch in this position.

Replacing the memory program

NOTE THE DIRECTION OF THE COMPONENT LOCATED BY ITS NOTCH

1) Pull up the memory socket lever.
2) Pull out the original component. It should come out easily.
3) Check that the pins of the new component are straight.
4) Insert the new component into the socket and check that:
- It is in the right way up (notch up)
- All the pins are correctly inserted into the socket.
5) While holding the component in place, fix it into the socket by pulling down the lever.

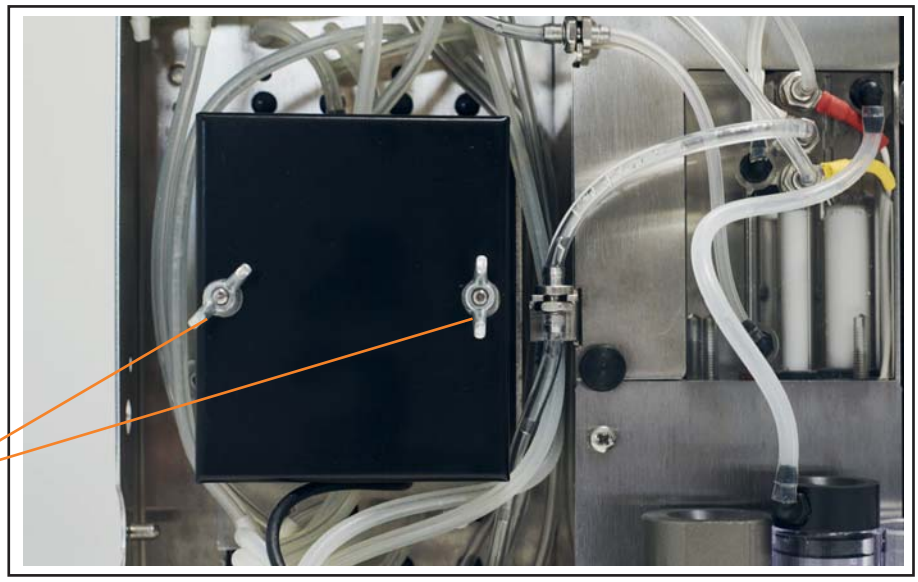
Once the replacement has been carried out, close the access hatch, plug the power cable and turn the power on.

Note: in some cases, when the power is on the self-test cycle can display a fixed screen for more than ten seconds.

IMPORTANT

There is a possibility that a change of program may cause the loss of analyses or calibration coefficients depending on the upgrading level. In case of such possibility, a special upgrade procedure will be provided to give the necessary instructions before the replacement of the memory program to avoid a complete recalibration of the analyser.

8.5 CHAMBERS ACCESS



Cover wing screws on WBC and RBC measuring chamber

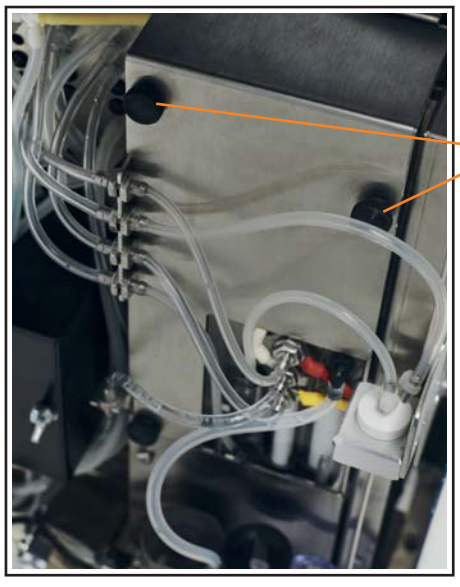
The measuring chambers are protected by a metallic cover fixed in place by wing screws.
If, for some reason, it is necessary to gain access (e.g. to change the counting aperture or photometer access), take off the screw and pull the cover forward.

IMPORTANT

Be very careful not to pinch a tube when putting cover back, as this could prevent the liquid flow.

Never run an analysis without the measuring chambers cover as this could alter the results.

8.6 AIR PUMP ACCESS



Cover screws on air and syringe pumps

Air pump

9: EXPORT DATA

9.1 COMPUTER CONNECTION

Computer connection allows DLB3 data transmission to the main computer in order to store analysis results, eventually add personal comments and store them in a medium with higher storage capacity than the DLB3 memory.

9.1.1 Hardware connection

To refer section 10.4 for the type available connection (RS232, USB, Ethernet, Wi-Fi).

9.1.2 Software connection

Set the parameters of the device communication port #2 in accordance with the required format of the main computer (MENU/SYSTEM/COMMUNICATION then screen #2 COMPUTER).

9.1.3 OPERATING MODE

Two possibilities: on computer request or automatically / by user from the DLB3.

Send on request

- The DLB3 is still in wait mode, ready to receive the orders from the main computer at any point of the cycle.
- The main computer sends a command order to the DLB3 and must wait for the answer (there is always an answer) to this order before sending another.
- If the texts sent by DLB3 are language-dependant (e.g. Blood Bank Name), they will be transmitted according to the language selected on the device.
- Each command sent by the main computer must begin with the **$$** double character (ASCII: 36 decimal, 24 hexadecimal) and end by a carriage return (CR) (ASCII: 13 decimal, 0D hexadecimal). If this basic rule is not respected, a communication failure can happen. The only way to solve the problem is to turn off the device.
- Each answer sent by the DLB3 begins with the **#** character (ASCII: 35 decimal, 23 hexadecimal) and ends by a carriage return (CR).
- #**E**(CR) answer indicates misunderstanding of the command (bad format order).
- Possible answer **#A**(CR) common to all requests asking for results indicates that no analysis is in memory.

It is advisable to check the answer to be sure that it is OK so the following information can be read.

- The ETX end of block answer has a value of 3.

Convention for formats used hereafter

c = Alphanumeric character (e.g. 10c = 10 characters)
n = Significant number, spaces stand in for the 0 on the left
N = Significant number always given
_ = Always a space

9.2 REQUESTS

9.2.1 Software revision number request

Command
$$SP(CR)
Answers
#P(CR) Request OK
cN.NNXs(CR) 'F' + Software revision on 6 digits + CR (e.g. F1.00Af)

c = F (Ascii: 70 decimal, 46 Hexadecimal) for DLB3.

It is advisable that this request be the first command sent by an application:
a) This confirms a good connection between the instrument and the computer.
b) This allows the correct management of the future upgrade of the requests. It is now very important to differentiate the formats between DLB 3 (DLB3), MS4 and MS4-5 for haematology results.

9.2.2 Set decimal separator for decimal results

Command
$$Vs(CR)
s: can take characters '.' (point -> ASCII: 46 decimal, 2E Hexadecimal) or
',' (comma -> ASCII 44: decimal, 2C Hexadecimal)
Answer
#V(CR) Request OK

By default, the decimal separator is the one from the selected language. To modify it, send this command before making requests to send out numeral results.

9.2.3 Set character string receiving format

Commands
$$CA(CR) All data is transmitted in character mode ASCII 0..127. (Default mode) DLB3 characters above 127 are approximate to match as well as possible
$$CB(CR) All characters >127 are transmitted in DOS format.
$$CC(CR) All characters >127 are transmitted in WINDOWS format
Answer
#C(CR) Request OK

The above two commands must be performed in the application before following other requests. These settings are lost when the device is turned off.

9.2.4 Stored analyses number request

Command
$$AM(CR)
Answers
#M(CR) Request OK
NNN(CR) Number of analyses in the DLB3 memory (Range 0..250)

9.2.5 Last analysis specification request

Command
$$AL(CR)
Answers
#A(CR) No analysis in memory on DLB3
#L(CR) Request OK
Follow specification as defined below
ETX

Sequence number	NNNN(CR)	
Reserved use	NN(CR)	
Blood bank number	NN(CR)	01 to 14
Blood bank name	10c(CR)	Left justified + spaces ***
Day	NN(CR)	
Month	NN(CR)	
Year	NNNN(CR)	
Hour	NN(CR)	Always 24 hours format
Minute	NN(CR)	
File	20c(CR)	
Patient	20c(CR)	
Comment	20c(CR)	

----> 102 characters by specification block

*** Transmitted in the language selected on the DLB3.

9.2.6 Specification of an analysis by its sequence number

Command

$$ASssss(CR) ssss = 4-digit sequence number (e.g.: 0081)

Answers

#A(CR) No analysis in memory on DLB3
#N(CR) No analysis in memory for this sequence number
#S(CR) Request OK
Follow Analysis specification described above
ETX

Comment

As the sequence numbers are classified in increasing order (except 9999 followed by 0001) the last analysis specification allows the last sequence number to be known and the previous ones to be deduced. This allows data to be sent out in small size blocks.

9.2.7 All stored analyses specification request

Command

$$AT(CR)

Answers

#A(CR) No analysis in memory on DLB3
#T(CR) Request OK
NNN(CR) Number of following analyses specification
Sending of the NNN specifications
ETX

CAUTION

Only the last 100 analyses are managed (even if 250 analyses are stored inside the memory). It is not recommended to use this request. 100 analyses in the device memory imply more than 10K characters to be sent. It is preferable to use the previously described method to read analysis one at a time.

9.2.8 Specification of all the analyses for a specific day

Command

$$ADdd/mm/yyyy(CR) (day / month / year)

Answers

#A(CR) No analysis in memory on DLB3
#N(CR) No analysis in memory for this day
#D(CR) Request OK
NNN(CR) Number of following analyses specification
Sending of the NNN specifications
ETX

9.2.9 Specification of all the analyses for a date beyond that specific day

Command
$$APdd/mm/yyyy(CR) (day / month / year)
Answers
#A(CR) No analysis in memory on DLB3
#N(CR) No analysis in memory beyond this day
#D(CR) Request OK
NNN(CR) Quantity of following analyses specification
Sending of the NNN specifications
ETX

Note: If several analyses specifications are sent out, they are in chronological order. The first sent out is the one of the last analysis done in the requested selection.

9.2.10 Histograms by a defined sequence number

A. THR/RBC/WBC histograms

Command
$$HGssss(CR)
Answers
#A(CR) No analysis in memory on DLB3
#N(CR) No analysis in memory for this sequence number
#G(CR) Request OK
Histograms sent out according to a right-justified 3 character fixed format.

Synchronization	THR(CR)
Quantity of THR for volume 1	NNN(CR)
.../...	
Quantity of THR for volume 256	NNN(CR)
Synchronization	RBC(CR)
Quantity of RBC for volume 1	NNN(CR)
.../...	
Quantity of RBC for volume 256	NNN(CR)
Synchronization	WBC(CR)
Quantity of WBC for volume 1	NNN(CR)
.../...	
Quantity of WBC for volume 256	NNN(CR)
Position of MonoStart cursor	NNN(CR)
Position of MonoEnd cursor	NNN(CR)
ETX	

9.2.11 Haematology results by a defined sequence number

A. Results alone

Command

$$HBssss(CR)

Answers

#A(CR) No analysis in memory on DLB3

#N(CR) No analysis in memory for this sequence number

#H(CR) Request OK

Sending of haematology results, 7-digit fixed format, centered on decimal point + CR

(20 lines of 8 characters / line)

ETX

B. Results and units

Command

$$HUssss(CR)

Answers

#A(CR) No analysis in memory on DLB3

#N(CR) No analysis in memory for this sequence number

#H(CR) Request OK

Sending of haematology results + units (7-digit fixed format: 1 space + left justified value +

right spaces) + CR

(20 lines of 15 characters / line)

ETX

C. Test name and results

Command

$$HCssss(CR)

Answers

#A(CR) No analysis in memory on DLB3

#N(CR) No analysis in memory for this sequence number

#H(CR) Request OK

Sending of haematology tests name (left-justified 4-digit fixed format:+ right spaces) + results

+ CR

(20 lines of 12 characters / line)

ETX

D. Test name, results and units

Command

$$HAssss(CR)

Answers

#A(CR) No analysis in memory on DLB3

#N(CR) No analysis in memory for this sequence number

#H(CR) Request OK

Sending of haematology tests name + results + units + CR

(20 lines of 19 characters / line)

ETX

E. Haematology results format

	Std Unit		SI Unit		IU Unit		
Test*	Result	Unit	Result	Unit	Result	Unit	
WBC_	_nnN.NN	_m/mm3_	_nnN,NN	_m/mm3_	_nnN,NN	_m/mm3_	(CR)
Lym.	__nN.N_	_%_____	__nN,N_	_%_____	__nN,N_	_%_____	(CR)
Mon.	__nN.N_	_%_____	__nN,N_	_%_____	__nN,N_	_%_____	(CR)
Gra.	__nN.N_	_%_____	__nN,N_	_%_____	__nN,N_	_%_____	(CR)
Eo._	__nN.N_	_%_____	__nN,N_	_%_____	__nN,N_	_%_____	(CR)
Ba._	__nN.N_	_%_____	__nN,N_	_%_____	__nN,N_	_%_____	(CR)
RBC_	__nN.NN	_M/mm3_	__nN,NN	_M/mm3_	__nN,NN	_M/mm3_	(CR)
Hct_	__nN.N_	_%_____	__nN,N_	_%_____	___0,NN	_____	(CR)
MCV_	_nnN.N_	_fl____	_nnN,N_	_fl____	_nnN,N_	_fl____	(CR)
MCH_	__nN.N_	_pg____	__nN,N_	_fmol__	__nN,N_	_pg____	(CR)
MCHC	__nN.N_	_g/dl__	__nN,N_	_mmol/l	_nnN___	_g/l___	(CR)
RDW_	__nN.N_	_____	__nN,N_	_____	__nN,N_	_____	(CR)
THR_	nnnN___	_m/mm3_	nnnN___	_m/mm3_	nnnN___	_m/mm3_	(CR)
Pct_	__nN.NN	_%_____	__nN,NN	_%_____	__nN,NN	_%_____	(CR)
MPV_	__nN.N_	_fl____	__nN,N_	_fl____	__nN,N_	_fl____	(CR)
PDW_	__nN.N_	_____	__nN,N_	_____	__nN,N_	_____	(CR)
Hb__	__nN.N_	_g/dl__	__nN,N_	_mmol/l	_nnN___	_g/l___	(CR)
Err1	iabcdef	_____	iabcdef	_____	iabcdef	_____	(CR)
Err2	rnmkghj	_____	rnmkghj	_____	rnmkghj	_____	(CR)
Err3	tuvsopq	_____	tuvsopq	_____	tuvsopq	_____	(CR)

*Test :

ATTENTION! Test name depends on localization/country setting (see section 4.4.3).
i.e. WBC_ is replaced by GB__ in french, by LEU_ in german, and so on...

Err 1-2,3: Each character can take '0' (No error) or '1' (Error with Alarm Mark reminder) value.

a: Small Blockage on THR channel (&)
b: Small Blockage on RBC channel (&)
c: Small Blockage on WBC channel (&)
d: Photometer or Hb Error (E)
e: WBC population Error (L/M/I)
f: Not Used, Always '0'
i: Thalassemia possibility (T)
s: EO Mixing/Homogenization (@)
o: Eosino Error (E)
p: Small Blockage on EO channel (&)
q: Big Blockage on EO channel (#)
g: THR Mixing/Homogenization (@)
h: RBC Mixing/Homogenization (@)
j: WBC Mixing/Homogenization (@)
k: Big Blockage on THR channel (#)
m: Big Blockage on RBC channel (#)
n: Big Blockage on WBC channel (#)
r: Analysis rejected (MCHC Pb) (R)
t: '0' if 5POP analysis, '1' if 3POP
u: Not Used, Always '0'
v: Baso rejected (R)

Note 1: The test names will be sent in the language selected on the DLB3, the value format and unit according to the **Hb Unit** selected in the APPLICATION menu (MENU/SYSTEM/APPLICATION/UNITS).
Note 2: DLB3 performed tests in 3 Part Mode, results are sent with the same above format with Eo. and Bas. = 0 and Err3 = 100 0000.

9.2.12 Haematology normal range by a blood bank number

Command

$$HSNN(CR)

NN represents the blood bank number (01 to 06)
(See section 6.1.1)

Answers

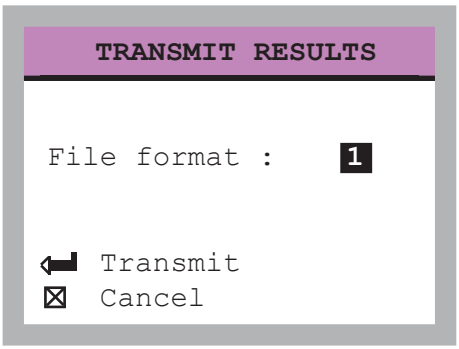
#A(CR) No blood bank for the specified number
#S(CR) Request OK
Sending of normal ranges, 7-digit fixed format centered on decimal point for Min values + '-' + 7-digits centered on decimal point for Max values + CR
(17 lines of 16 characters / line)
ETX

	Std / SI Unit	IU Unit	
WBC	_nnN.N_-_nnN.N_	_nnN.N_-_nnN.N_	(CR)
Lympho	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
Mono	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
Granulo	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
Eosino	_______-_______	_______-_______	(CR)
Baso	_______-_______	_______-_______	(CR)
RBC	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
Hct	__nN.N_-__nN.N_	___0.NN-___0,NN	(CR)
MCV	_nnN.N_-_nnN.N_	_nnN.N_-_nnN.N_	(CR)
MCH	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
MCHC	__nN.N_-__nN.N_	_nnN___-_nnN___	(CR)
RDW	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
THR	nnnN___-nnnN___	nnnN___-nnnN___	(CR)
Pct	_______-_______	_______-_______	(CR)
MVP	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
PDW	__nN.N_-__nN.N_	__nN.N_-__nN.N_	(CR)
Hb	__nN.N_-__nN.N_	_nnN___-_nnN___	(CR)

Normal ranges are sent in the same order as haematology results with the format and values corresponding to the **Hb Unit** selected in the APPLICATION menu (MENU/SYSTEM/APPLICATION/UNITS).

9.3 AUTO / MANUAL TRANSMISSION

Results can be sent from DLB3 either automatically at the end of a valid analysis (see MENU/ SYSTEM/COMMUNICATION), or manually when an analysis is displayed. In the latter case, press the *Up Arrow* ⇧ key when the main results screen is displayed (or *F5* Function key with an external keyboard from any analysis screen displayed) to make appear the following screen:



File format: (1 or 2) same as Auto 1, Auto 2 options in communication menu.

When a Quality Control analysis is performed, this line is not displayed because no histogram is sent in this mode.

Data format is identical to some options previously described in the communication mode on request.

A. Regular analysis data format

1) Decimal separator always a period (same as $$V**.** command).
2) Characters in ASCII < 128 (same as $$CA command).
3) Start character is the control character STX (2).
4) Sending of analysis specification (same as $$AL command): 102 characters.
5) Sending of analysis results with same format as $$HA command: 380 characters.
6) Sending of normal range of the displayed bank (same as $$HSnn command): 272 characters.
- If File format = 1 or selection = Auto 1: step 7 skipped).
7) Sending of histograms (same as $$HGssss command): 3092 characters.
8) Ends by the control character ETX (3) sending.

B. Control Quality analysis data format

1) Decimal separator always a period (same as $$V**.** command).
2) Characters in ASCII < 128 (same as $$CA command).
3) Start character is the control character STX (2).
4) Sending of analysis specification (same as $$AL command but with the fields content described at the following page): 102 characters.
5) Sending of analysis results with same format as $$HA command: 380 characters.
If the analysis is recalled from memory, only the 6 parameters recorded and some computed parameters will be sent with a significant value, the other parameters will be null.
6) Sending of normal range of the displayed bank (same as $$HSnn command): 272 characters.
Only the 6 normal ranges entered in the Control Blood level screen and recorded with the analysis will be sent with a significant value, others normal ranges parameters will be null.
7) Ends by the control character ETX (3) sending.

C. Control Quality analysis specification format

Sequence number	NNNN(CR)	
Number of lines of haematology results	NN(CR)	**a) - (17)
Blood bank number	NN(CR)	**b) - 15 to 17
Blood bank name	10c(CR)	**c) Left justified + spaces
Day	NN(CR)	
Month	NN(CR)	
Year	NNNN(CR)	
Hour	NN(CR)	Always 24 hour format
Minute	NN(CR)	
Lot number / Expiry Date	20c(CR)	**d)
Patient	20c(CR)	2 characters + 18 spaces
Comment	20c(CR)	

----> 102 characters by specification block

**a) The total number of lines sent with the results block contain 3 additional lines for error indicators
(See 'Haematology results format' previously)
**b) 15: Low level Control Blood
16: Normal level Control Blood
17: High level Control Blood
**c) Name of the level (this is the Control Blood bank)
Transmitted in the language selected on the DLB3
**d) - Lot Number: Format nnn.nn, Left-justified,
- 4 spaces,
- Expiry Date: mm/dd/yyyy or dd/mm/yyyy formats according to the selected language

IMPORTANT

Waste disposal of electrical and electronic equipment:
This device must be eliminated according to the current legislation of the country where it was used.

10: APPENDIX

10.1 DLB3 MAIN FEATURES

10.1.1. Main medical features

Measured parameters : WBC, RBC, THR, Hb, Hct
Calculated parameters: Lym%, Lym#, Mon%, Mon#, Gra%, Gra#
: MCV, MCH, MCHC, RDW
: MPV, Pct, PDW
Histograms : WBC, RBC, THR (Displayed and printed out)

Min/max range alarms : Programmable, displayed and printed out
Whole blood sample : 10 to 30 µl. Programmable dilution rate
Analysis time : Results in 50 s (Human)

10.1.2. Main software features

Language : French, English + 3rd customized language on request
Application : 6 Blood banks completely programmable
Storage : Up to 250 analyses in safeguard memory
: Up to 125 Quality Control results in safeguard memory
Q.C. : Q.C. graph (L. J. type) for WBC, RBC, THR, MCV and Hb

Display range	: WBC	0.00	to	655.35 m/mm^3			
	: Lym.	0.0	to	99.9	%	(0.00	to 655.35 m/mm^3)
	: Mon.	0.0	to	99.9	%	(0.00	to 655.35 m/mm^3)
	: Gra.	0.0	to	99.9	%	(0.00	to 655.35 m/mm^3)
	: RBC	0.00	to	99.99 M/mm^3			
	: RDW	0.0	to	99.9			
	: Hct	0.0	to	99.9	%	(0.0	to 0.99 with IU units)
	: MCH	0.0	to	999.9 pg		(0.0	to 99.9 fmol with SI units)
	: MCHC	0.0	to	99.9 g/dl		(0	to 999 mmol/l with SI units)
	: THR	0	to	9999 m/mm^3			
	: MPV	0.0	to	99.9 fl			
	: Pct	0.00	to	9.99 %			
	: PDW	0.0	to	99.9			
	: Hb	0.0	to	99.9 g/dl		(0.0	to 99.9 g/l with IU units)
	: Hb					(0	to 999 mmol/l with SI units)

10.1.3. Mechanical characteristics

General

Dimensions	: Width 210 mm, height 340 mm, depth 250 mm
Weight	: 13 Kg
External Power supply	: 100-240 Volt / 50-60 Hz 2.0 A (automatic commutation)
	: 24 VDC 6.25A
Environment	: Room temperature: 20 °C...25 °C (68 °F...77 °F) -> Reagents specification
	: Humidity: 90% maximum with no condensation
Display	: Graphic color TFT LCD 320 x 240 dots
Keyboard	: Built-in 11 sensitive keys
	: External PC type keyboard (optional)
	: Barcode reader for identification (optional)
Printer	: Optional : Built-in thermal printer 24 columns / 384 dots
	: External parallel or USB printer (optional)
Connections	: 1 serial RS-232 (1200 to 57600 bauds) for computer connection
	: 1 serial RS-232 (1200 to 57600 bauds) for biochemistry connection
	: 1 parallel for printer
	: 1 USB for printer
	: 1 USB for computer connection[1]
	: 1 Ethernet for computer connection (optional)
	: 1 Wi-Fi for computer connection (optional)
	: 1 PS/2 mini-DIN 6 pin for keyboard and/or barcode reader

Dilutor, counter

Dilutor	: Sequential dilution controlled step by step
Motors	: 3 stepping motors, 2 motors DC (pumps)
Valves	: 16 flip/flop valves warranty 50 million cycles
Sample needle	: Automatic internal and external cleaning
Counting type	: Electric field across
	- an 80 µm aperture for WBC
	- an 60 µm aperture for RBC and THR
Hb measurement	: Stabilized reduced Hb with photometry at 540 nm

Others

Acoustic level	: < 65 db
Functioning altitude	: < 2000 m (for altitude > 2000 m, consult us)

10.1.4 Performance characteristics

Limit of quantification

WBC 0,2 $10^3/mm^3$
PLT 15 $10^3/mm^3$

Linearity
(For high and low concentrations)

WBC 0,2 to 1,5 $10^3/mm^3$: +/- 0,2 $10^3/mm^3$
10 to 100 $10^3/mm^3$: +/- 10%
100 to 200* $10^3/mm^3$: +/- 15%

RBC 0,2 to 2 $10^6/mm^3$: +/- 0,2 $10^6/mm^3$
5 to 9 $10^6/mm^3$: +/- 5%

HGB 0,5 to 5 g/dl: +/- 0,5 g/dl
17 to 25 g/dl: +/- 5%

PLT 15 to 60 $10^3/mm^3$: +/- 15 $10^3/mm^3$
450 to 1000 $10^3/mm^3$: +/- 0,2 $10^3/mm^3$

Correlation-Linearity
(Correlation factors obtained by comparing the mesured values against a reference instrument)

LEU	R ≥ 0,98 within slope = 1 +/- 0,05
LYM	R ≥ 0,95 within slope = 1 +/- 0,15
Mono	R ≥ 0,60 within slope = 0,75 +/- 0,25
Gra	R ≥ 0,95 within slope = 1 +/- 0,15
RBC	R ≥ 0,98 within slope = 1 +/- 0,10
Hgb	R ≥ 0,98 within slope = 1 +/- 0,05
VGM	R ≥ 0,90 within slope = 1 +/- 0,10
Hct	R ≥ 0,98 within slope = 1 +/- 0,05
PLT	R ≥ 0,98 within slope = 1 +/- 0,10

Carry-over

WBC	≤1,0%
RBC	≤1,0%
PLT	≤ 1,0%
VGM	≤1,0%
Hct	≤ 1,0%
Hgb	≤ 1,0%

* With automatic dilution x2 if WBC result is higher than 100 $10^3/\mu l$.

Precision Repeatability	WBC	1,5 to 4 10^3/mm^3 : ≤ 4,0% up to 4 10^3/mm^3 : ≤ 3,0%
	RBC	2 to 4 10^6/mm^3 : ≤ 2,5% up to 4 10^6/mm^3 : ≤ 2,0%
	PLT	60 to 150 10^3/mm^3 : ≤10,0% 150 to 450 10^3/mm^3 : ≤ 5,1% up to 450 10^3/mm^3 : ≤ 5,0%
	VGM	60 to 70 fl : ≤1,0% 70 to 85 fl : ≤ 1,0% up to 85 fl : ≤ 1,0%
	Hct	15 to 30% : ≤ 2,5% up to 30% : ≤ 2,0%
	Hgb	5 to 10 g/dl : ≤ 2,5% up to 10 g/dl : ≤ 2,0%

Precision Reproductibility	WBC	1,5 to 4 10^3/mm^3 : ≤ 5,0% 4 to 10 10^3/mm^3 : ≤ 4,0% up to 10 10^3/mm^3 : ≤ 3,0%
	RBC	2 to 4 10^6/mm^3 : ≤ 3,5% 4 to 5 10^6/mm^3 : ≤ 2,1% up to 5 10^6/mm^3 : ≤ 2,0%
	PLT	60 to 150 10^3/mm^3 : ≤ 14,0% 150 to 450 10^3/mm^3 : ≤ 6,8% up to 450 10^3/mm^3 : ≤5,0%
	VGM	60 to 70 fl : ≤ 1,0% 70 to 85 fl : ≤ 1,0% up to 85 fl : ≤ 1,0%
	Hct	15 to 30% : ≤3,5% 30 to 40% : ≤ 2,4% up to 40% : ≤ 2,0%
	Hgb	5 to 10 g/dl : ≤ 3,5% 10 to 17 g/dl : ≤ 2,1% up to 17 g/dl : ≤ 2,0%

10.2 NORMAL RANGE

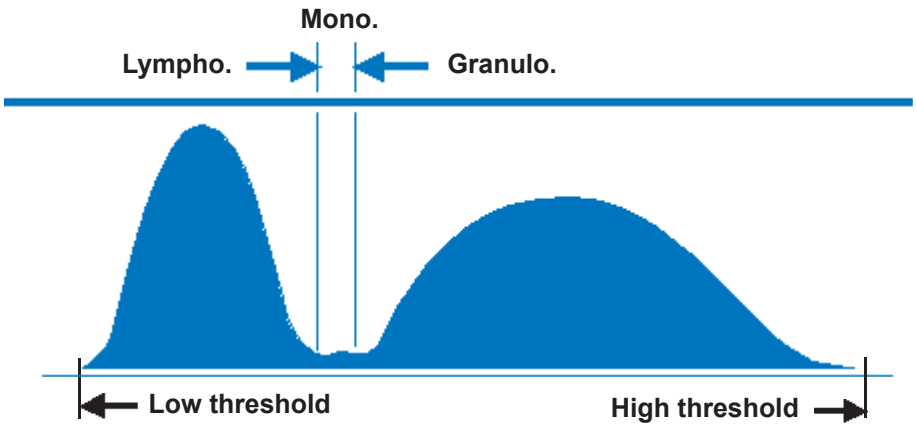
Normal range or reference range incorporated in the DLB3 analyser can be modified to match laboratory population met on a daily basis use (See section 4.3.2 : 6 to 15th screen : Normal range).
Expected normal range can indeed vary according to different factors such as gender, age, dietary pattern, hydric intake, geographical location and so on.

Human haematology reference range

PARAMETER	MALE	FEMALE	NEW BORN	UNITS
WBC	4,0-10,0	4,0-10,0	3,5-11,0	m/mm^3
Lym%	15,0-40,0	20,0-40,0	20,0-40,0	%
Mon%	1,0-10,0	1,0-10,0	1,0-10,0	%
Gra%	30,0-70,0	30,0-70,0	30,0-70,0	%
RBC	4,0- 5,9	3,8- 6,0	4,0- 5,5	M/mm^3
Hct	35,0-54,0	33,0-54,0	35,0-45,0	%
MCV	83,0-98,0	80,0-100,0	73,0-106,0	fl
MCH	25,0-33,0	25,0-32,0	35,0-45,0	pg
MCHC	28,0-36,0	28,0-36,0	28,0-36,0	g/dl
RDW	8,0-12,0	8,0-12,0	8,0-12,0	
THR	150 -450	100 -450	150 -450	m/mm^3
MPV	6,0-13,0	6,0-13,0	6,0-13,0	fl
PDW	6,0-10,0	6,0-10,0	6,0-10,0	
Hb	12,0-18,0	10,0-16,5	11,0-18,5	g/dl

10.3 3 PART-DIFF. CALIBRATION

The main WBC population cells are placed as follows:



The 'MONO' area is defined by both *Mono Start* and *Mono End* programmable pointers (MENU/PARAMETERS/MODIFY/3rd screen).
The Lympho counting is done in the area between the low threshold (*LowT*) and the left Mono pointer (*Mono Start*).
The Mono counting is done in the area between the left Mono pointer (*Mono Start*) and right Mono pointer (*Mono End*).
The Granulo counting is done in the area between the right Mono pointer (*Mono End*) and the high threshold (*Hi.T*).
Programming values are working on a full scale of 0 to 255.

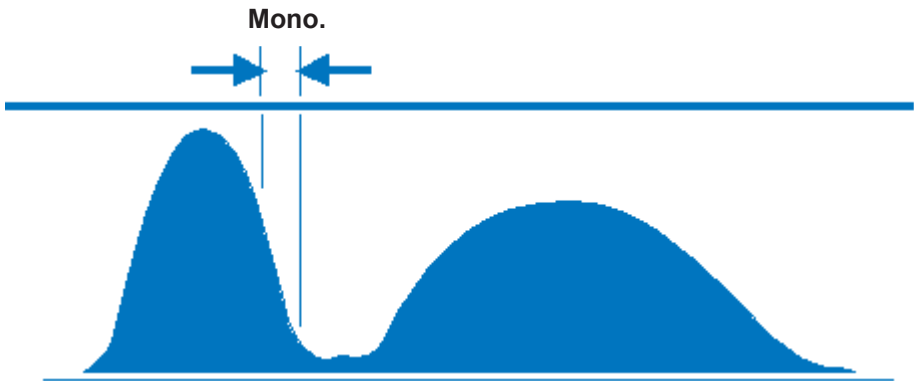
To calibrate the WBC 3 Part Differential, it is just necessary to place the 'Mono' (monocytes) pointers in the valley between the lymphocytes and granulocytes peaks. It is very important to respect, for the device 3 part-diff calibration, the following points:
- EDTA K^3 anticoagulant,
- Fill up the whole blood tube with defined blood quantity,
- Perfectly mix the whole blood for WBC stabilization and homogenization,
- Analyze the blood in the 4 hours following the patient sampling.

The monocytes quantity can be calibrated by increasing or decreasing the space between both cursors of the counting area.

WARNING

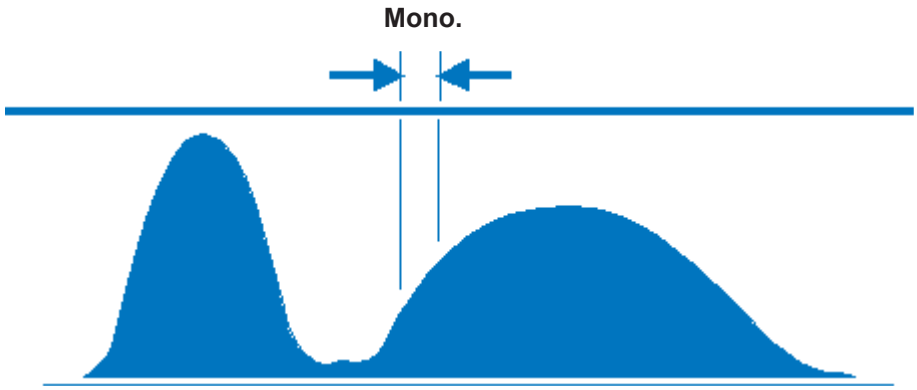
The leukocyte formula is usually not calibrated out of the ranges set by the manufacturer. Because Haematology is a subjective science, a different calibration of this formula is only useful to those whose results do not match with the ones proposed by default.

Incorrect calibration: 'Mono' area is shifted to the left



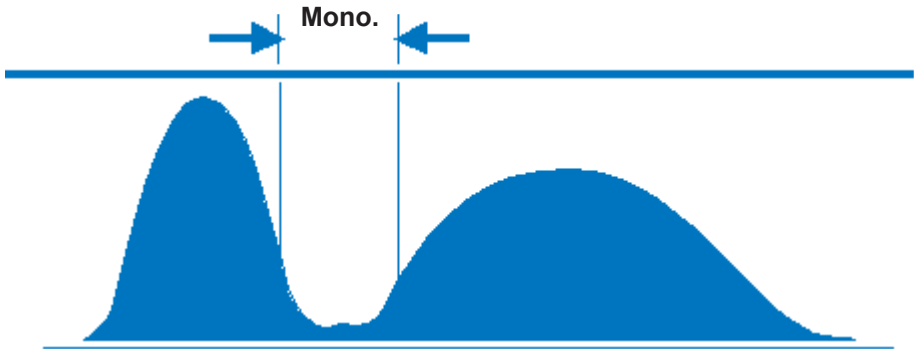
Consequence: Lympho results too low and Granulo results too high. Incorrect monocyte results.

Incorrect calibration: 'Mono' area is shifted to the right



Consequence: Lympho results too high and Granulo results too low. Incorrect monocyte results.

Incorrect calibration: 'Mono' area too large



Consequence: Lympho and Granulo results too low. Monocyte results too high.

10.4 CONNECTORS

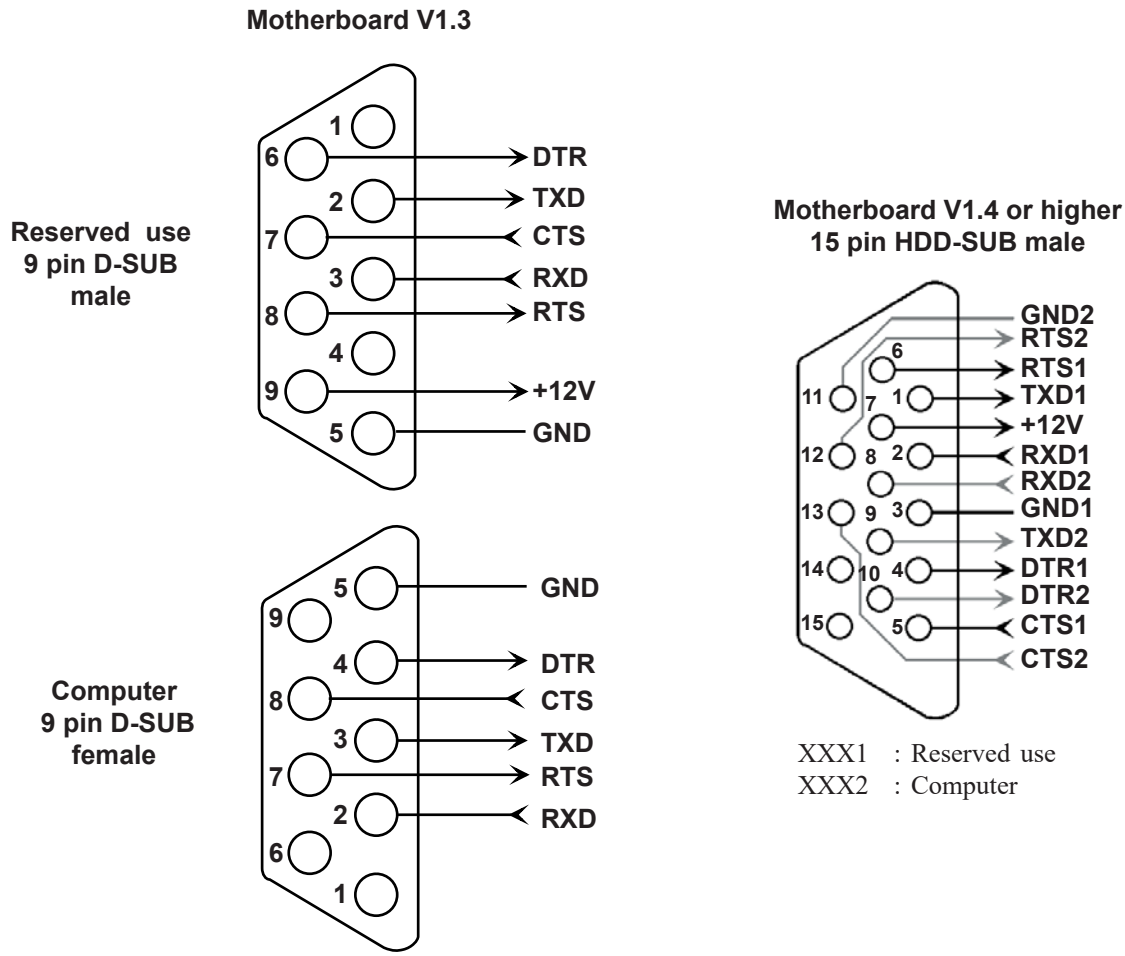
Pin Out

5 or 6 connectors are accessible on the right side of the device.

Parallel (//) printer / USB printer
The 25 pin female connector is provided for a parallel printer and use a standard PC parallel printer cord.
The USB connector is provided for and ONLY FOR a printer and use a standard PC USB printer cord. Do not try to use both connectors (// and USB) at the same time.
The standard pin out are not described here.

Keyboard
The 6 pin PS/2 connector is provided for an external PC type keyboard. The standard pin out is not described here.

Computer serial connectors
Provided by a D-Sub male/female connector with the pin out as below. The diagram represents the pin side of DLB3.
Note: The +12 V output is of a very low intensity and is provided for special external interface. Do not use it without the approval of MS-Laboratoires.



Computer USB connector (Motherboard V1.4 or higher)
Female USB B connector provided to connect DLB3 with a PC (Drivers required).

Computer Ethernet connector (Option) (Motherboard V1.4 or higher)
Ethernet connector provided to connect DLB3 on network.

Status LED of connections (Motherboard V1.4 or higher)
Status of active computer connections on DLB3.

Off :	Serial (RS232).
Green :	USB.
Red / Amber :	Ethernet (Wired or Wi-Fi, Wi-Fi in priority).

10.5 PC CONNECTION

PC Connection cable with 9 pins connector (Motherboard V1.3)

DLB3: Male DB9		PC: Female DB9
2		3
3		2
4		6
5	Shield Ground	5
7		8
8		7

PC Connection cable with 15 pins connector (Motherboard V1.4 or higher)

DLB3 : Female HDDB15		PC : Female DB9
8		3
9		2
10		6
11	Shield Ground	5
12		8
13		7

Cord dedicated for PC computer connection to DLB3

10.6 METHODE LIMITATION - INTERFERENCES

Specimen Requirements

The anticoagulant tested and recommanded is K3 EDTA plastic or glass tubes.
Other anticoagulants can generate inaccurate results.
Blood should be assayed within 4 hours if stored at room temperature (20 °C...25 °C) and 24 hours if stored between 2 °C...8 °C.

Sample tubes

Any size of sample tube can be used with an DLB3 if it has been correctly filled according to the manufacturer instructions. Various reducers are available to fit into the tube size.

Environmental Factors

The instrument should be operated at room temperature (20°C... 25°C) and reagents should be stored at temperatures between 15°C... 25°C. Reagents in use should be kept at room temperature.
Do not install the instrument or reagent pack behind a window exposed to sunlight.

Biological interferences

Sickled red blood cells may not be accurately recognized and produce erroneous results.

Samples with cold agglutinins may falsely decrease the red blood count[6]. The indices will indicate that the hemoglobin and hematocrit values do not agree. A manual evaluation of a blood smear is recommended. These samples should be incubated for 30 minutes at 37°C and reassayed.

Fragmented erythrocytes can not be detected and lead to error in results: the number of red blood cells is artificially low, that of platelets is artificially elevated and VGM and Hematocrit are falsely low. A manual evaluation of a blood smear can detect the source of errors[5].

Patient samples with nucleated red blood cells may falsely elevate the white blood count[5,7]. Additionally, the presence of these nucleated cells may interfere with the white cell differential. The instrument will give an «L» error code if the presence of NRBCs is suspected. A manual evaluation of a blood smear must be performed.

Platelet clumps and neonatal samples may interfere with the Drabkins method of hemoglobin determination. A manual evaluation of a blood smear can detect the source of errors[3].

Samples with extreme lipemia, chylomicrons or extremely high bilirubin concentrations might produce falsely elevated hemoglobin values[7]. Visual examination of the plasma after centrifugation can detect the source of errors.

Samples from patients with elevated chylomicrons and those receiving total parenteral nutrition

(TNP) including a high lipid concentration may falsely elevate the platelet count[5,7,8].

Circulating micromegakaryocytes may be counted as white blood cells. A manual evaluation of a blood smear can detect the source of errors[5].

Aggregated platelets may falsely elevate the white blood count and percentage of lymphocytes. The instrument will give an «L» error code if platelet aggregates are suspected[5,7].

The presence of immature white blood cells, including blasts, may affect the accuracy of the differential[5,7]. The instrument will give an «I» or «M» error code if blasts are suspected. A manual evaluation of blood smear is required.

Clinical studies have shown that the assay produces accurate results in the presence of malarial parasites, Howell-Jolly bodies, cryoglobulins and red cell fragments[5,7].

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10.7 REAGENTS INSTRUCTIONS

Please refer to the document «Instructions for use of reagents «delivered with the device. The reagent usage notice can also be downloaded from the website: www.dialab.at

1. REAGENTS USE

Reagents are intended for haematology cell counter use (MS-brand kind), meaning red and white cells, blood platelets, 3 part leukocyte differential counts.
For *in vitro* diagnostic use only.

2. REAGENTS CONTENT

Nature of reagents in Dialab pack:

DIALUENT

Buff ered isotonic solution - Diluent for kind MELET SCHLOESING Laboratoires cell counter.

Content: Sodium chloride
Sodium sulphate
Stabilizer
Ammonium IV

DIATERGENT

Isotonic detergent – transfer liquid for kind MELET SCHLOESING Laboratoires cell counter.

Content: Sodium chloride
Ethyl alcohol
Detergent
Colouring agent

DIA-DIFF

Lysing agent and haemoglobin assay – Intended for kind MELET SCHLOESING Laboratoires cell counter.

Content: Ammonium IV
Potassium cyanide
Stabilizer
Preservative

RINSE

Solution used to rinse the haematology cell counter – Used during standby.

Content: Distilled water
Preservative

3. PRINCIPLE AND REACTION DESCRIPTION

MELET SCHLOESING Laboratoires brand cell analysers count every blood population cell by cell (Red cells, White cells or blood Platelets).

MELET SCHLOESING Laboratoires brand analysers prepare the count and the analyse by insulating blood populations at first with a dilution.

A first dilution (with DIALUENT) enable the analyse of White cells present in small quantities. Then, a second dilution is made from the first one to count Red cells and blood Platelets (more significant quantities).

Automatic dilutions are completed from a programmable quantity of whole blood.

The quantity of blood collected can vary from about 9µl to 30 µl. This quantity varies according to the bank used.

MELET SCHLOESING Laboratoires brand cell counters are working with the measurement principle of a particle that modifies an electric current while passing through an orifice.

The cell is sucked up from the A tank up to the B tank by passing through a calibrated orifice. An electric current applies on both sides of this orifice. The cell does not have the same conductivity than its environment, then its passage through an orifice leads to a change of the current established between both electrodes. This current difference is registered and increment a counter at every cell passage.

A chemical agent is used to separate erythrocyte and leukocyte populations, because of size overlapping and quantities discrepancies. This chemical agent contained in lysis (DIA-DIFF) pops the cytoplasmic membrane of the Red Cells. Erythrocyte population disappears then to let leukocytes remaining.

A haemoglobin preservative is added in lysing agent to measure haemoglobin scaled down in a 540 nm photometric tank at the end of the counting.

The haemoglobin measurement is made from the first dilution. The lysing agent has a powerful haemoglobin reducer (potassium cyanide) and then the haemoglobin measurement follows DRABKIN method with a 540 nm reading.

The integration of luminous intensity transmitted is evaluated according to the BEER-LAMBERT formula.

A zero reference point is made after each analysis with specific liquid (DIALUENT).

An enzymatic liquid (DIATERGENT) ensures the system cleanliness between every analysis and allows avoiding contamination between two consecutive analysis.

4. PERFORMANCES

Specificity:

Several substances can interfere with total count results.

Interfering substances:

- Analgesic derivatives of procaine ester
- Medication with anticoagulant actions:
  Oral anticoagulant (K antivitamin), III and IV Antithrombin
- Patients treatment with Calcium heparinate derivatives from Choay laboratory, for concentration exceeding 4-6 mg/j
- High volume cortisone treatment

The case of lipemic serum is different, but can also affect results.

Method limits:

- Samples that can be used for a 3 part-diff :

Whole blood collected with anticoagulant K3 EDTA in plastic or glass tube.
It is necessary to collect blood on a radial vein, a jugular vein, or any other vein of sufficient diameter to allow a quick collection. Rough blood aspiration is to be avoided because of haemolysis phenomenon it can cause. Collection time also have to be limited to avoid micro coagulation problems.
A long and smooth homogenization of blood and anticoagulant mix is essential before every analysis.

- Sample preservation :

Whole blood samples are stabile during about 4 hours at room temperature and 24 hours between 2 °C...6 °C.

- Analysis :

During the analysis, other factors can interfere and modify results.
Room temperature and airing within the workspace are really important for samples as well as for reagents and can affect results. Then, it is recommended not to place the analysers behind a window, especially if it is sunny.
A closed and well ventilated room is advised.
Other factors such as electromagnetic radiation or electric network characteristic also have to be considered.
It is highly recommended not to place the analyser next to another electric device emitting high electromagnetic radiation that could interfere with analysis results.
Besides, it is recommended to test the earth electrode of the analyser plug, because a default could bring erroneous results.

5. RESULTS

Measured Parameters:

White blood cell	in thousands/mm^3
Red blood cell	in millions/mm^3
Platelet	in thousands/mm^3
Hematocrit	in %
Hemoglobin	in g/l

Calculated parameters:

MCV: Mean Corpuscular Volume (HCT/RBCx10)	in fl
MCH: Mean Corpuscular Haemoglobin (Hb/RBCx10)	in pg
MCHC: Mean Corpuscular Haemoglobin Concentration (Hb/HCTx100)	in g/dl
Lymphocytes in absolute value	in thousands/mm^3
Lymphocytes in %	in %
Monocytes in absolute value	in thousands/mm^3
Monocytes in %	in %
Granulocytes in absolute value	in thousands/mm^3
Granulocytes in %	in %

Supply parameters:

PCT: Plateletcrit	in %
MPV: Mean Platelet Volume	in fl
PDW: Platelet Distribution Width	without units
RDW: Red cells Distribution Width	without units

6. PRESERVATION NOTES:

Reagents must be stored at room temperature between 15°C... 25 °C (59°F... 77°F).
Significant temperature variation are to be avoided.

While closed, reagents have an 18 months-long expiry date or more for some (refer to expiry dates shown on the labeling).

When opened, reagents can be used within 16 weeks.

7. GUIDELINE:

See Reagents Pack Installation section 2.1.3 of this manual and Reagents Pack Replacement section 8.2 of this manual. .

8. SPECIAL SAFE PRACTICE:

Respect safety instructions and expiry dates.
For *in vitro* diagnostic use only.
Refer to the Instructions for use of reagents.

10.8 ERROR MESSAGES
(Sorted by type)

Press a key to acknowledge an error message

TYPE	MESSAGE	SIGNIFICATION	SOLUTION
POST	**Amplifier board not OK**	No answer from amplifier board	Check flat cable between amplifier board and mother board
POST	**Carrier not OK**	PB motor / End of stroke switch / flat cable / Tubes blocked / Mother board	Gear loose / Verify switches
POST	**Counting chip fault.**	PB PowerCell	Replace Mother board
POST	**Management system fault**	PB back up components group	Replace Mother board
POST	**Needle not OK**	PB motor / Mother board / Switch	Gear loose / Verify switches
POST	**Pressure sensor or Atmospheric pressure not OK**	Zero pressure uncalibrated / Air leak	Verify Air circuit / Replace Mother board
POST	**Pressure sensor unplugged or Air leakage**	Sensor broken / Air leak	Verify Air circuit / Replace Mother board
POST	**Photometer not OK**	PB LED / Photo transistor / cables / Mother board	Verify cables from amplifier board Replace Photometer / Mother board
POST	**Safeguard system fault**	PB (Management) Safeguard component	Replace Mother board
POST	**SAFEGUARD LOST ALL DATA**	PB RTC Battery / Main power surge / Upgrade program	(Replace RTC battery)
POST	**SafeKeeping lost all Analyses!**	PB RTC Battery / Main power surge	(Replace RTC battery)
POST	**SafeKeeping lost Quality control test**	PB RTC Battery / Main power surge	(Replace RTC battery)
POST	**SafeKeeping Err. System Setup lost.**	PB RTC Battery / Main power surge	(Replace RTC battery) Verify system configuration
POST	**SafeKeeping Err. Control Blood Parameters**	PB RTC Battery / Main power surge	(Replace RTC battery) Enter parameters
POST	**SafeKeeping Err. Blood Parameters**	PB RTC Battery / Main power surge	(Replace RTC battery) Enter parameters
POST	**Syringe not OK**	PB motor / Mother board / Switch	Move piston manually / Verify switch
POST	**Temperature probe not OK**	Temperature sensor malfunction	Replace Mother board temperature sensor
POST	**Power Fail +24V circuit**	External Power Supply malfunction (too low or too high)	Replace external power supply / Connection board
POST	**Power Fail +12V / -12V circuit**	Internal Power Supply malfunction or +/-12V short circuit	Replace internal power supply / Mother board

POST : POWER ON SELF TEST
PB : Problem

10.8 ERROR MESSAGES

(Sorted by type)

TYPE	MESSAGE	SIGNIFICATION	SOLUTION
CTRLQ	**ACTION DENIED Control blood not identified**		Identify from MENU - PARAMETER QUALITY CT
CTRLQ	**ACTION DENIED Control blood out of date.**		Replace Blood + Identification

HARD	**PHOTOMETER ERROR**	PB Calibration / Measuring Chamber w/o hood / Photo transistor	Close Chamber / Replace LED / Photo transistor

HARD	**ILLEGAL HARDWARE N**		Contact Distributor
SOFT	**Divide by 0**		Contact Distributor
SOFT	**Escape Code INT**		Contact Distributor
SOFT	**INT nn**		Contact Distributor
SOFT	**NMI Interrupt**		Contact Distributor
SOFT	**Overflow INT**		Contact Distributor
SOFT	**Unused OPCODE**		Contact Distributor

CTRLQ : QUALITY CONTROL
HARD : PB HARDWARE
SOFT : PB SOFTWARE
PB : Problem

10.8 ERROR MESSAGES
(Sorted by type)

TYPE	MESSAGE	SIGNIFICATION	SOLUTION
NORM	**ACTION DENIED Amplifier board in error**	Following POST Error	See POST Amplifier Error
NORM	**ACTION DENIED Motor error**	Following POST Error	See POST Motor Error
NORM	**ACTION DENIED Pressure sensor Out of order**	Following POST Error	See POST Pressure sensor Error
NORM	**ACTION DENIED System already in standby mode.**	You try to go in Standby mode but the instrument is already in Standby mode	
NORM	**ANALYSIS REJECT No interpretation possibility**	RBC quantity is too small (> 0.5 M)	Try Analysis again
NORM	**ANOMALY Air leakage Check tubes**	Air circuit leak	Verify tubes / Valve 1
NORM	**ANOMALY DETERGENT empty Check levels**	No Reagent / PB Sensor / Leak	Verify tubes / Valves / sensor
NORM	**ANOMALY DETERGENT empty or Air leakage**	Detergent missing or Air circuit leak	Verify tubes / Valves
NORM	**ANOMALY DILUENT empty Check levels**	No Reagent / PB Sensor / Leak	Verify tubes / Valves / sensor
NORM	**ANOMALY EO-DIFF reagent empty Check levels**	No Reagent (EO Lyse) / PB Sensor / Leak	Verify tubes / Valves / sensor
NORM	**ANOMALY Dilution transfer**	PB Transfer EO Dilution or Predilution -> measuring chamber	Tubes blocked / Clot filters blocked / Valves
NORM	**ANOMALY LYSE empty Check levels**	No Reagent (3PD Lyse) / PB Sensor / Leak	Verify tubes / Valves / sensor
NORM	**ANOMALY Vacuum mismatch: xxx**	PB Parameters Hardware Menu (Vacuum), PB Dilution qty, PB Air circuit leak, PB Transfer	Verify Parameters / Valve 1

NORM : Normal use
PB : Problem

10.8 ERROR MESSAGES
(Sorted by type)

TYPE	MESSAGE	SIGNIFICATION	SOLUTION
NORM	**ERROR Photometer Calibration**	PB Blank Reference for Hb	See photometer error
NORM	**ERROR Translation carrier**	PB End of stroke / location switch or tubes blocked	Verify switch / Unblock tubes
NORM	**ERROR Up/Down Needle**	PB End of stroke switch / Motor blocked	Verify switch / Unblock motor
NORM	**MS-CARD ERROR Illegal MS-CARD into the Card Reader**	PB SmartCard	Replace SmartCard
NORM	**MS-CARD ERROR MS-CARD EMPTY Insert new card before next analysis**	MS-CARD has not be replaced with new reagent Pack	Insert a new SmartCard
NORM	**MS-CARD ERROR Test fault while MS-CARD control. Insert new one**	PB SmartCard / PB card reader	Replace SmartCard / Mother board
NORM	**MS-CARD ERROR Unknown or bad inserted MS-CARD into the Card Reader**	Wrong side / PB Card / PB card reader	Replace SmartCard / Mother board
NORM	**NOT MODIFIABLE**	This parameter cannot be changed	
NORM	**Pos. Carrier ERR**	PB Location switch or tubes blocked	Verify switch / Unblock motor
NORM	**Priming DETERGENT error Check Levels**	PB Sensor / Leak / Detergent empty	Verify Detergent level /Tubes / Valves / sensor
NORM	**Priming DILUENT and LYSE error Check Levels**	PB Sensor / Leak / Diluent or Lyse empty	Verify Diluent and Lyse levels / Tubes / Valves / sensor
NORM	**Priming DILUENT error Check Levels**	PB Sensor / Leak / Diluent empty	Verify Diluent level /Tubes / Valves / sensor
NORM	**Priming LYSE error Check Levels**	PB Sensor / Leak / 3PD Lyse empty	Verify 3PD Lyse level /Tubes / Valves / sensor

NORM : Normal use
PB : Problem

10.8 ERROR MESSAGES
(Sorted by type)

TYPE	MESSAGE	SIGNIFICATION	SOLUTION
NORM	**Priming RINSE SOLUTION error Check Levels**	PB Leak / Rinse solution empty	Verify Rinse Solution level /Tubes / Valves
NORM	**PRINTING Ext. Printer not available. Printing on internal Printer**	External Printer power off / out of paper...	Verify external printer, validate to print on internal printer or cancel
NORM	**PRINTING Paper empty or cover open**	No paper in internal printer or cover bad closed	Verify paper, push the cover down if paper present
NORM	**TRANSMIT RESULTS SERIAL PORT #2 OFF LINE**	Occurs when trying to export results to computer	Verify cable between DLB 3® and computer. Computer must have a program RUNNING to open its Port
NORM	**Problem during rinsing**	Occurs during cleaning cycle after analysis	Verify carrier or reagents
NORM	**SAMPLING ERROR Cap on blood tube**	Cap on blood tube	Remove the cap on blood tube and try again
NORM	**MS-CARD BANK WRITE ERROR**	PB to save Blood Bank on a BLOOD BANK CARD	Replace SmartCard / Mother board
NORM	**MS-CARD The DLB 3 Bank does not match the MS-CARD Bank**	Blood Bank name different between DLB 3® memory and MS-CARD	If 'Continue' is selected, data will be lost

For any unsolved problem, please contact the SAV or your distributor.

MELET SCHLOESING Laboratoires recommends to request the latest up-to-date version of the analyzer software

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