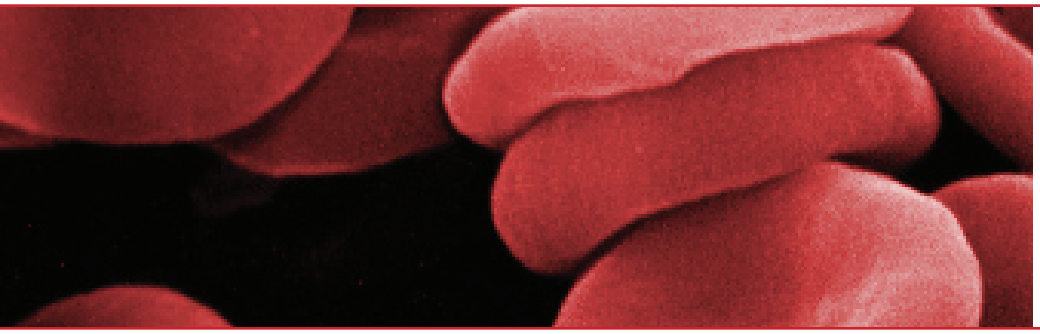
mythic 22



Orphée

User's Manual

Orphée SA

19, chemin du Champ des Filles - 1228 CH-Plan Les Ouates / SWITZERLAND
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Cod. M22/UM-EN/006

REVISIONS

Revision Nb	Date	Author	Software	Comments
01	16/11/05	HC	> V1.0	Creation
02	27/03/06	OM/HC	> V1.0.0-008	Sections 3.4.6 / 4.2 / 5.6.3 / 9.8 modified
03	25/10/06	HC/SH	> V.1.1.0	Sections 3.4.4 / 5.7 / 8.5 / 9.6 / 9.1.1 modified
04	03/05/07	HC	> V 2.0.0	Management of USB key (sections 3.3/5.10/6.2/7.2)
05		HC/CM	> V2.2.0	Add flags information. (section 8.5.5 / 8.5.6) Modify (QC & CALIBRATION) Update Hydraulic diagram and tubing list Update of Installation Kit
06	07/12/09	OM		Update of Maintenance Kit Update Hydraulic diagram and tubing list

CONTACT ADDRESS

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SWITZERLAND

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Fax : +41 (0) 22 794 4391
http://www.orphee-medical.com

LOCAL AGENT

READ THIS BEFORE USING THE EQUIPMENT

	**WARNING! RISK OF DANGER! Indicates a procedure to be strictly respected in order to avoid any risks for the operator (user) or damages on the instrument or on the quality of results.**
	**Indicates that wearing gloves is mandatory before performing the described operation due to risk of contact with materials that may be infectious.**
	**Indicates hot temperatures surfaces and risk of burns**
NOTA	**Indicates important additional information**

DANGER

Misuse of electrical equipment may cause electrocution, burns, fire and other hazards.

⇨ Check that the voltage setting matches the supply voltage.
⇨ Protective earthing is required, plug the **MYTHIC 22** into a supply outlet which has an earth connection.
⇨ Preserve a good access to the supply outlet to be able to unplug the MYTHIC 22 in emergency case.
⇨ Do not place the power supply adapter in liquid, nor put it where it could fall into liquid. If the power supply adapter becomes wet, unplug it before touching it.
⇨ Do not use the **MYTHIC 22** if it is not working properly, or if it has suffered any damage (damage to the supply cord or its plug; damaged caused by dropping the power supply adapter).
⇨ Do not let the power supply adapter or its flexible cord come into contact with surfaces which are too hot to touch.
⇨ Do not place anything on top of the **MYTHIC 22**
⇨ Do not use the **MYTHIC 22** where aerosol sprays are being used, or where oxygen is being administred.
⇨ Do not use the **MYTHIC 22** out of doors
⇨ Always switch off the **MYTHIC 22** and disconnect the power adaptor before dismantling any part.

⇨ The **MYTHIC 22** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.

- Only human blood or artificial control blood should be run.
- Only the reagents mentioned in this manual are permitted to use.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.

⇨ Due to the use of this equipment, all parts and surfaces of the **MYTHIC 22** are potentially infective. Wearing rubber gloves is highly recommended and after completion of work, wash hands with disinfectant.
⇨ Always replace or use parts of the equipment by parts supplied by ORPHEE distributor.
⇨ Basic safety precautions should always be taken. If the equipment is not used according to the manufacturer's instructions, the protective by the equipment may be impaired.
⇨ The treatment of waste and the elimination of a part or the complete instrument must be done in compliance with the local legislation.
⇨ Any output or input connections (except the printer and the barcode reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.
⇨ Do not open the door located on the right side of the instrument (see section 1.1.3) when an hydraulic cycle is in progress for it would lead to an immediate stop. To re-start, shut the door and run a Control cycle (see section 9.3.1)

KEEP THESE INSTRUCTIONS

This equipment needs special precautions regarding general requirements for safety.

Guidance and manufacturer's declaration – Electromagnetic emmissions		
The MYTHIC 22 is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 should assure that it is used in such an environment.		
Emmissions test	**Compliance level**	**Electromagnetic environment - guidance**
Harmonic emissions IEC 61000-3-2	Class A	The MYTHIC 22 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The MYTHIC 22 is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MYTHIC 22 requires continued operation during power mains interruptions, it is recommended that the MYTHIC 22 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic immunity			
The MYTHIC 22 is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MYTHIC 22, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150Khz to 80Mhz	3 Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80Mhz to 2,5Ghz	3 Vrms	$d = 1,2\sqrt{P}$ 80MHz to 800MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80Mhz and 800MHz, the higher frequency range applies. NOTE 2 Theses guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM an FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should considered. If the measured field strength in the location in which the MYTHIC 22 is used exceeds the applicable RF compliance level above, the MYTHIC 22 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MYTHIC 22. [b] Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.			

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The user may find the following booklet, prepared by the Federal Communications Commission, helpful:
How to identify and Resolve Radio/TV Interference Problems. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.
Pursuant to Part 15.21 of the FCC Rules, any changes or modifications to this equipment not expressly approved by C2

The symbol  on the product indicates that this product may not be treated as household waste. Instead it shall be handed over the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling of this product, please contact your local city office or your distributor of this product.

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

Orphée S.A.
19 Chemin du Champ des Filles
1228 Plan Les Ouates

Wir erklären in alleiniger Verantwortung, dass
Nous déclarons sous notre propre responsabilité que
Dichiariamo sotto nostra responsabilità che
We declare under our sole responsibility that

das Medizinprodukt für die In-vitro-Diagnostik
le dispositif médical de diagnostic in vitro
il dispositivo medico-diagnostico in vitro
the in vitro diagnostic medical device

Mythic 22
Ref. M22OT

mit folgender Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG
avec la classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE
con la classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

☐Produkt der Liste A, Anhang II / Dispositif de la liste A, annexe II /
Dispositivo dell'elenco A, allegato II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Dispositif de la liste B, annexe II /
Dispositivo dell'elenco B, allegato II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist /
Dispositif destiné à l'autodiagnostic non listé dans l'annexe II /
Dispositivo per test autodiagnostico non elencato nell'allegato II /
Device for self-testing not listed in Annex II
☒ Sonstiges Produkt / Autre dispositif / Altro dispostivo / Other device

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

remplit toutes les exigences de la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.

soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.

meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

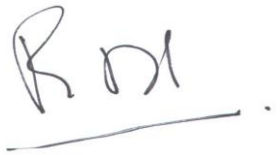
Angewandte Gemeinsame Technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati Applied common technical specifications, harmonised standards, national standards or other normative documents	IEC 60601-1-2 (2001) EN 61000-3-2 EN 61000-3-3 EN 61000-4-2 (95) A1 (98) A2 (01) EN 61000-4-3 (02) EN 61000-4-4 (95) A1(01) EN 61000-4-5 A1 (01) EN 61000-4-6 (96) A1 (01) EN 61000-4-11 (94) A1 (01) EN 55011 Class B EN 55022 Class B IEC 61010-1 (2001) IEC 61010-2-081 (2001) IEC 61010-2-101 (2002)
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimentodi valutazionedellaconformità Conformity assessment procedure	
Konformitätsbewertungsstelle (falls beigezogen) Organe respons. de l'évaluat.de la conformité(si consulté) Organo incaric. della valutaz. della conform. (se consultato) Notified Body (if consulted)	N/A
Ort, Datum / Lieu, date / Luogo, data / Place, date	Name und Funktion / Nom et fonction /Nome e funzione / Name and function
Genève le 06 Juin 2008	 Philippe Daire RA & QA

TABLE OF CONTENTS

1. INSTALLATION

1.1 UNPACKING

1.1.1 Introduction

The **MYTHIC 22** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.

- Only human blood or artificial control blood should be run.
- Only the reagents mentioned in this manual are permitted to use.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.

If the MYTHIC 22 has been stored at a temperature less than 10°C it must be left at room temperature during 24 hours.
It must be calibrated at each displacement and installation (See section 7).

1.1.2 Unpacking Procedure

Before unpacking the instrument, we recommend to check the box of the instrument and notify any damage to the carrier.

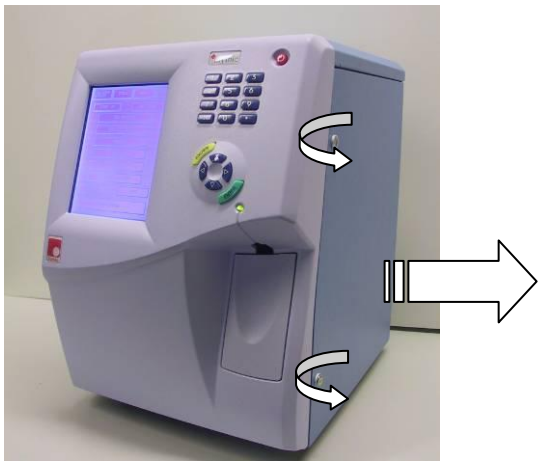
- Open the box on the top, remove the starter kit.
- Remove the **MYTHIC 22** from the box.

Starter kit contents:

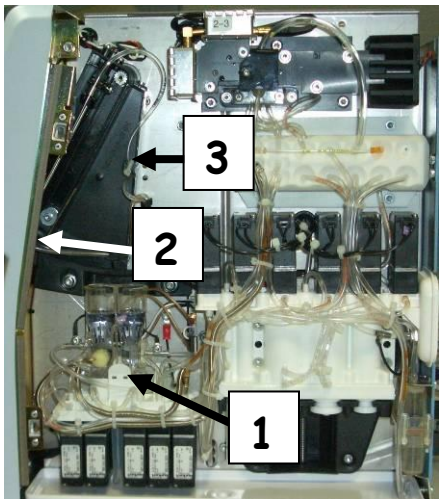
INSTALLATION KIT	
QTY	**Designation**
1	Tubing DILUENT
1	Tubing WASTE
1	150W switching adapter
1	European Power line cord
1	MYTHIC 22 User manual
1	MYTHIC 22 Installation Report
1	MYTHIC 22 Quality Control Certificate
1	Screwdriver Slot 1/4"

MAINTENANCE KIT	
QTY	**Designation**
1	Tygon tubing L=500mm 1.02mm
1	Tygon tubing L=500mm 1.3mm
1	Tygon tubing L=1000mm 1.52x3.2mm
1	Tygon tubing L=500mm 2.06x4mm
1	Tubing 10
1	Tubing 50
5	Cables Ties
1	Rinsing Head O-ring
1	Silicon grease (3gr)
1	Short Arm TORX T10 Tool
1	Short Arm TORX T20 Tool

1.1.3 Visual checking



- Open the door on the right side with the key provided in the kit.



To be checked :

1- Counting chambers perfectly locked in their manifold locations.
2- Needle's dismountable system located in the rocker.
3- Rocker in front position at the maximum course.

HAZARDOUS MOVING PARTS, BEWARE TO STAY AWAY FROM THESE PARTS WHEN THE MACHINE IS SWITCH ON.

1.2 INSTALLATION CONSTRAINTS

1.2.1 Installation place

To ensure that the **MYTHIC 22** fulfills its function, place the instrument on a table which supports the weight of the instrument, printer and reagents (around 40 Kg). Leave a space of 10 cm in the rear of the instrument to ensure a well-ventilated place. Avoid a place that can be exposed to direct sunlight.

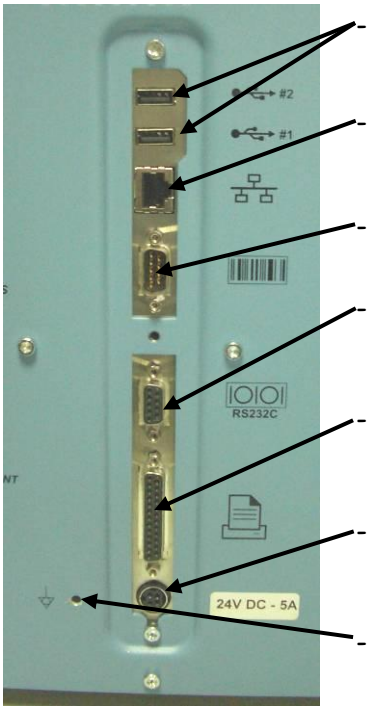
1.2.2 Installation environment

a) Indoor use;
b) Altitude up to 2 000 m;
c) Temperature 18 °C to 34 °C;
d) Maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C;
e) MAINS supply voltage fluctuations up to ±10 % of the nominal voltage;
f) Transient over voltages typically present on the MAINS supply.
g) Rated pollution degree II.

Please contact Orphée's representative if you want to use the instrument in special conditions (height higher than 2000 m or special power supply conditions).

1.3 ELECTRICAL CONNECTIONS

All the connectors are in the rear of the **MYTHIC 22**



CONNECTION : SYMBOL :

- 2 USB ports (section 3.4.7) :
- Ethernet connection (TCP/IP) :
- External barcode reader (RS232C) :
- Host connection (RS232C) :
- Printer connection (Centronics) :
- Power supply cord connection : 24V
- Equipotentiality :

⚠	**Any output or input connections (except the printer and the bar code reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.**

1.3.1 Power supply block

MYTHIC 22 must be connected to the power with the power supply block provided with the starter kit. Choose a well-ventilated place for the block and be sure to connect this power supply in a socket-outlet with a correct earth connection.

The power supply block must be placed at the rear of the **MYTHIC 22** and, if possible in an upper position to avoid the contact with any liquid.

To disconnect electrically the **MYTHIC 22,** remove the power supply plug from the main circuit.

⚠	**- In the case of replacement of the main power wire supplied with the MYTHIC 22 the new one must comply with the local regulation (3×1.5mm cable and 250V 10A plug).** **- The MYTHIC 22 has been certified with the power supply box provided with the machine. The use of another external power supply box is not guaranteed. Please contact your Orphée's representative.**

1.4 PRINTER CONNECTION

Connect the printer cable in conformity with the printer user's manual.

Use the parallel rear plug of the **MYTHIC 22 (**) or the USB plug ( ) to connect the printer cable. Select the printer driver (section 3.3).

1.5 CONNECTION, CHANGE AND PRIMING REAGENTS

MYTHIC 22 works with the reagents described in section 4.3. Some commercial reagents can also be used. Please contact your Orphée's representative.

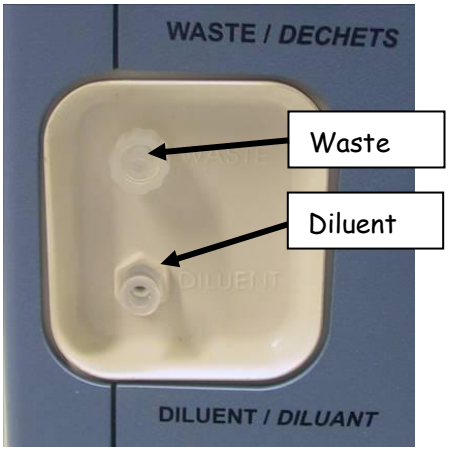
1.5.1 Connection

Lysis reagent and cleaning solution:

Before handling the reagents, read carefully their specifications described in section 4.3.

- Remove the door on the left side of the instrument.
- Put the reagent bottles in the dedicated location.
- Remove the caps of the bottles
- Tighten the red caps on the Lyse bottle (red sticker) and the blue one on the cleaning solution bottle (blue sticker).

Diluent and waste:



- Connect the diluent tube (male connector) on the outlet on the bottom and tighten the cap on the diluent container.
- To use a 20 liter diluent container adds the tubing straw adaptor supplied with the installation kit.
- Connect the waste tube (female connector) on the outlet on the top and tighten the cap on an empty container.

- **Do not modify the type and the length of the diluent and waste tubes.**
- **The diluent must be placed at the same level as the MYTHIC 22.**

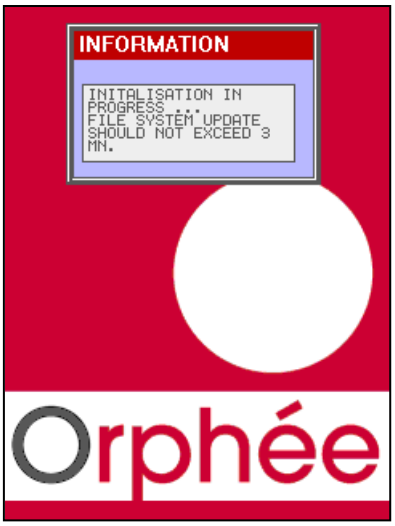
It is mandatory to collect the waste in a container and treat it in compliance with your local legislation.

1.5.2 Priming

When first starting the **MYTHIC 22**, it is necessary to perform a complete prime of the fluidic circuit.

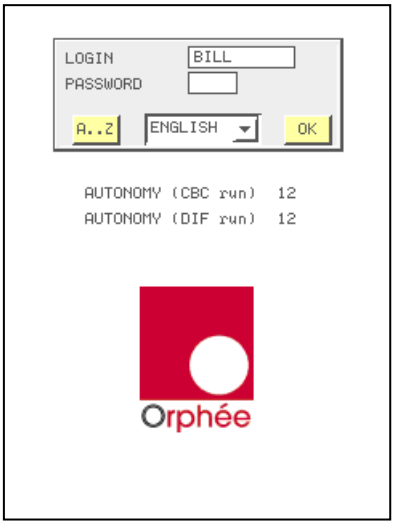
	**Before starting, be sure that all the reagent and waste tubes are properly connected.** **The reagents must be stored 24 hours minimum at room temperature before use.**

Priming procedure :



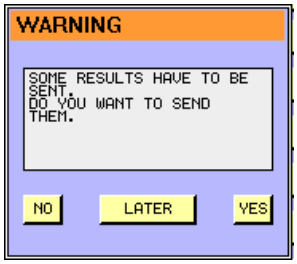
① Switch on:

- Connect the power supply block.
- Press the ON/OFF button. 
- The cycle LED  turns red. No cycle can be performed before it turns green.
- The information window could stay up to 3 mn to enable the update of all the files.

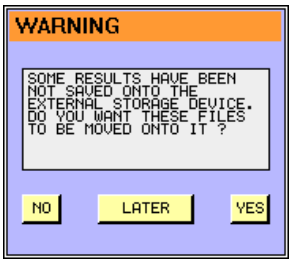


② Login:

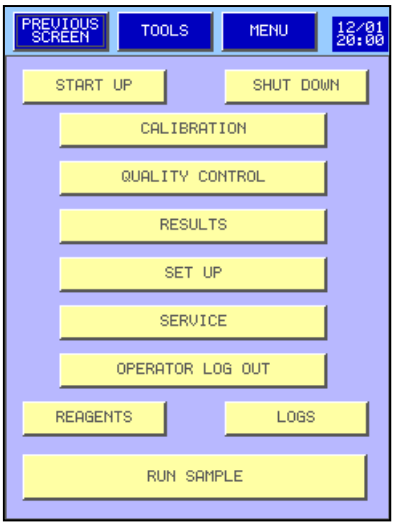
- The operator's identification display appears.
- Enter the user's identification, the password (see section 3.1) and press OK to validate.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).



- If this window appears, it means that several results in memory have not been sent before the MYTHIC 22 was switched off.
- Press YES to send them immediately, or press LATER to wait at another time or NO if you do not want to send them.



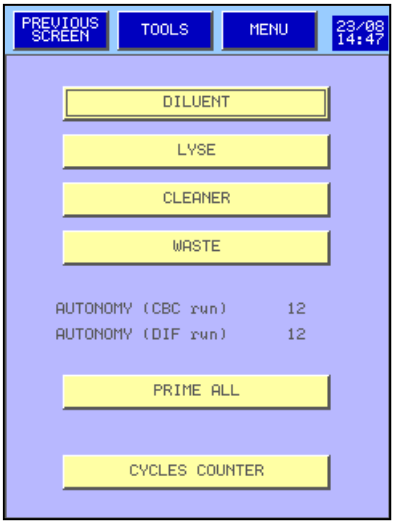
- No USB key is available, connect an USB key then press YES or see section 3.4.7 to change the archive mode.



③ <u>System priming</u>:

- The main menu is displayed.
- Press on REAGENTS.

NOTA	To do an emergency stop push shortly on the switch on/off button 

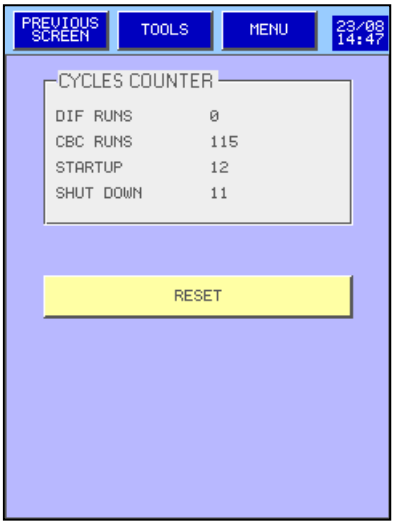


- Press PRIME ALL : The **MYTHIC 22** performs a complete priming cycle.

- The cycle LED  turns red. No cycle can be performed before it turns green.

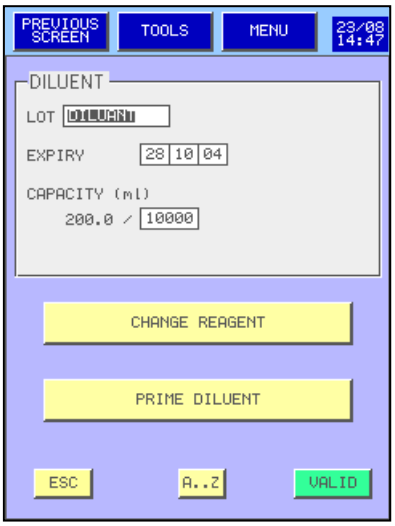
- **AUTONOMY (run)** indicates the number of samples (runs.
- To prime or to know the quantity of reagent press the dedicated button.

- Press CYCLES COUNTER to visualize the cycle counters.



- To reset the counter with the button RESET, please contact your Orphée's representative.

DILUENT PRIME:



- From the **MAIN MENU** press REAGENTS then DILUENT to have access to this screen.

- Enter lot number, the expiry date and the container capacity.

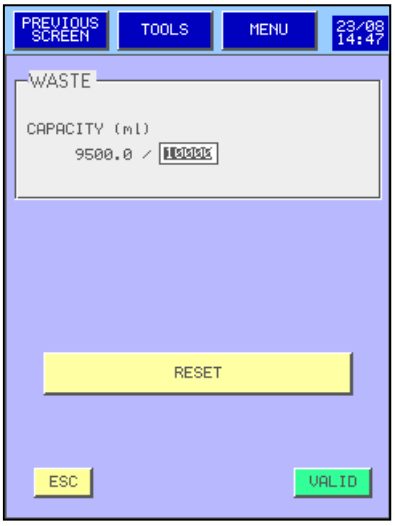
- Press CHANGE REAGENT to validate the new entry or after changing a new container with the same information.

- After the replacement a new container or to prime the diluent, press PRIME DILUENT

- A new entry is automatically done in the logs (see section 5.9)

LYSE AND CLEANER PRIME:
Proceed as described above for the diluent.

WASTE:



- Enter only the capacity of the container.

- After replacement of the waste container press RESET to reset to initialize the waste calculation.

MYTHIC 22 IS NOW READY TO WORK.

1.6 TRANSPORTATION AND STORAGE

Storage temperature: -10°C to +50°C.
If the **MYTHIC 22** has been stored at a temperature less than 10°C it must be left at room temperature during **24** hours.
Before transportation outside the laboratory, perform a complete cleaning with a disinfectant in compliance with the local legislation.

2. GENERAL OVERVIEW

2.1 GENERALITIES

MYTHIC 22 is a fully automated analyzer performing hematological analysis on whole blood collected on EDTA K2 or K3 tubes.

- Sample volume: 15,7 µl (inside the needle, the total volume could be upper in function of the blood remaining outside of the needle).
- Throughput: > 45 samples/hour
- 22 analysis parameters in DIF mode and 12 parameters in CBC mode:

Leukocyte parameters:

WBC	White Blood Cells
LYM	Lymphocytes in % & # (DIF mode only)
MON	Monocytes in % & # (DIF mode only)
NEU	Neutrophils in % & # (DIF mode only)
EOS	Eosinophils in % & # (DIF mode only)
BAS	Basophiles in % & # (DIF mode only)

Erythrocyte parameters:

RBC	Red Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Blood cells Distribution Width

Thrombocyte parameters:

PLT	Platelet
MPV	Mean Platelet Volume
PDW*	Platelet Distribution Width
PCT*	Thrombocrit

***** For Investigation Use only in the United States of America

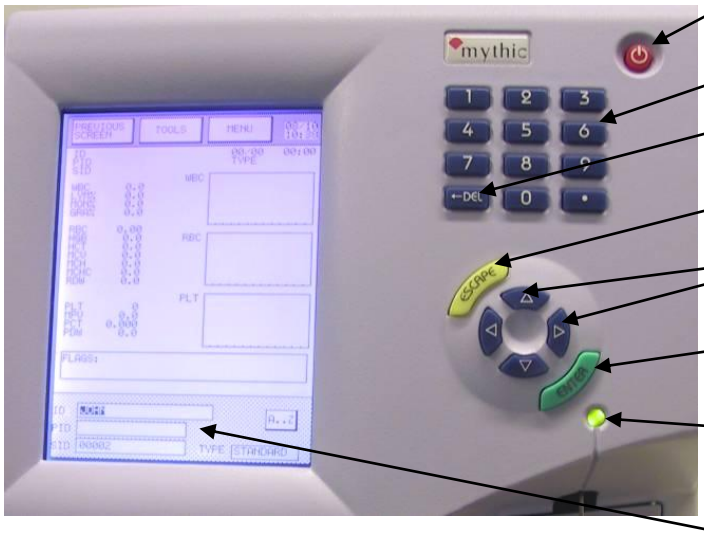
2.2 OVERVIEW

MYTHIC 22 consists of 8 main parts:

1. Display / Keyboard.
2. Dilution hydraulic part.
3. Mono electronic board.
4. Reagent tray.
5. Connection.
6. External power supply block.
7. Printer.
8. Barcode reader (option).

2.3 MAIN PART DESCRIPTION

2.3.1 Display / Keyboard



Stand By and ON/OFF button

Numeric keyboard

Delete (DEL)

Exit (ESCAPE)

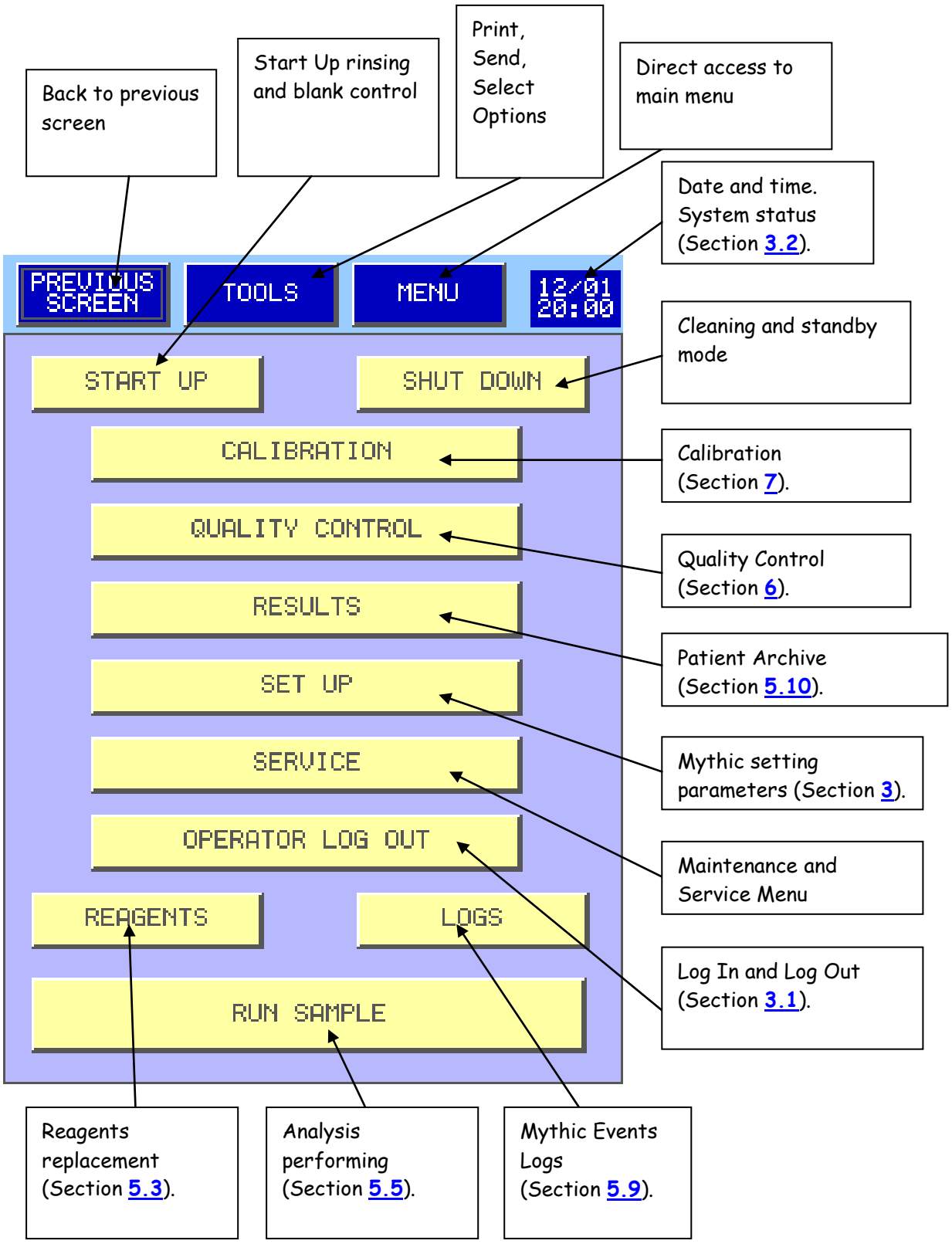
Cursors

Enter (ENTER)

Cycle in process Led

Touch screen LCD display 380*240

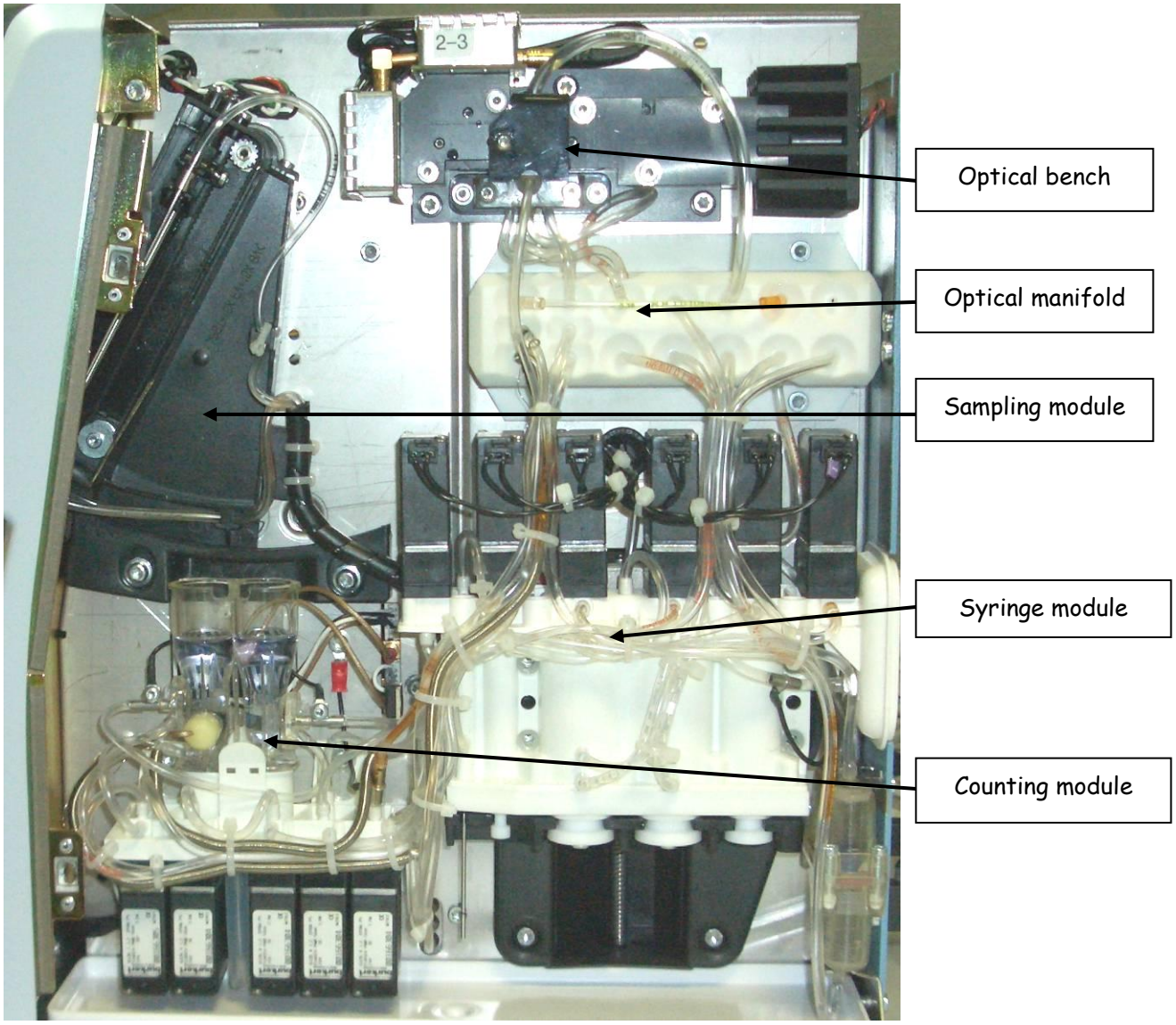
Main Menu description



2.3.2 Dilution hydraulic part

All the fluidic part is on the right side of the instrument and consists of only five modules:

- Sampling module :
  - Rocker (patent pending): Manages the rise and descent of the needle.
- Syringe module (patent pending) consists of one block :
  - Reagent syringes (Diluent, lysis), sampling and air syringes.
  - Liquid valve manifold assembly and tubing.
- Counting chambers :
  - WBC and RBC counting chambers and hemoglobin measurement.
  - Liquid valve manifold assembly and tubing.
- Optical Manifold :
  - Liquid valve manifold assembly and tubing.
- Optical bench :
  - Optical bench (patented) with his flow cell (patented).



2.3.3 Mono electronic board

The mono electronic board is located between the hydraulic part and the reagent tray.
The board, driven by a 32-bit processor, manages the following parts:

- Sample needle, rocker, syringe block motors.
- Display and keyboard.
- Connexion mode (RS232, Ethernet, …).
- Printer.
- Measurement (Counting, hemoglobin measurement).
- Data processing.
- External barcode reader.

⚠	**To avoid all deterioration risks, only the service people can touch this electronic board.**

2.3.4 Power Supply Block

MYTHIC 22 is supplied with an external power supply block.

⚠	**- In the case of replacement of the main power wire supplied with the MYTHIC 22 the new one must comply with the local regulation.** **- The MYTHIC 22 has been certified with the power supply box provided with the machine.** **- The use of another external power supply box is not guaranteed. Please contact your Orphée's representative.**

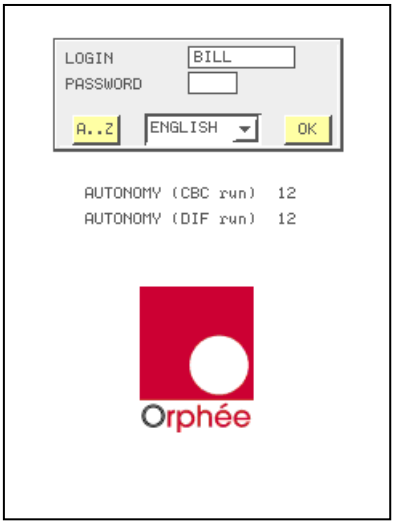
2.3.5 Reagent tray

The reagent tray is dedicated to the OnlyOne lysing reagent and cleaning solution bottles.

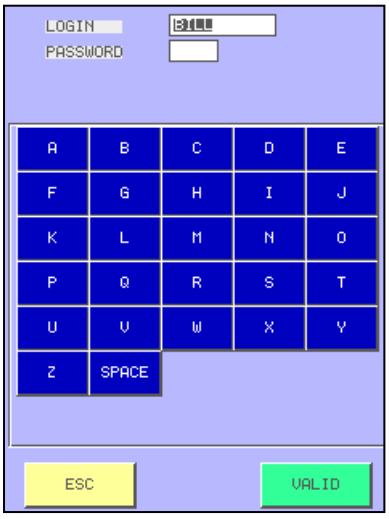
3. INSTRUMENT SET UP

3.1 USER'S IDENTIFICATION

3.1.1 Start Up

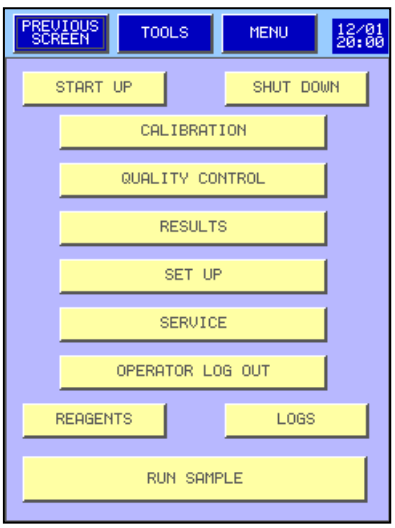


- After the instrument's initialization, the identification window is displayed.
- In the window LOGIN BILL, the last operator's identification appears.
- Either the identification is yours, press PASSWORD and enter your password or the identification is not, press A..Z to enter your login.
- The window ENGLISH enables to change the language. Press OK to validate it.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).



- Enter your identification name with the alphabetic keyboard.
- Place the cursor in the Password window.
- Enter your password for identification.
- For the first login, **MYTHIC 22** proposes 3 access levels :
  - **User** : No password
  - **Biologist** : Password by default **1- 2- 3**
  - **Service people**
- Biologist Password can be modified in section 3.3.6.

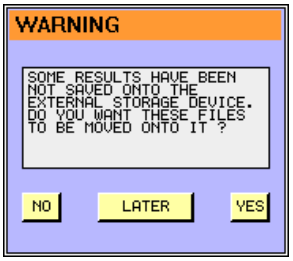
3.1.2 In process



- To change operator during the process, press MENU to return to the main menu, and then press on OPERATOR LOG OUT

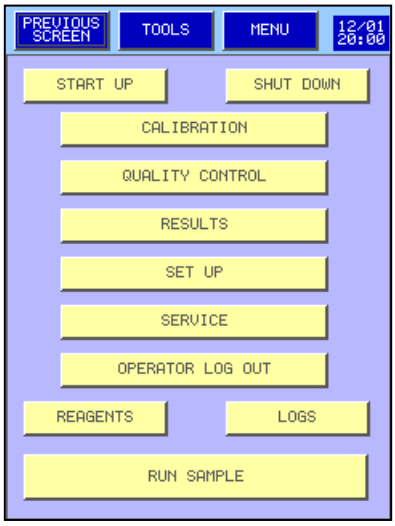
- To change identification, proceed as described above (section 3.1.1).

- If this window appears, it means that several results in memory have not been sent before the MYTHIC 22 was switched off.
- Press YES to send them immediately, or press LATER to wait at another time or NO if you do not want to send them.

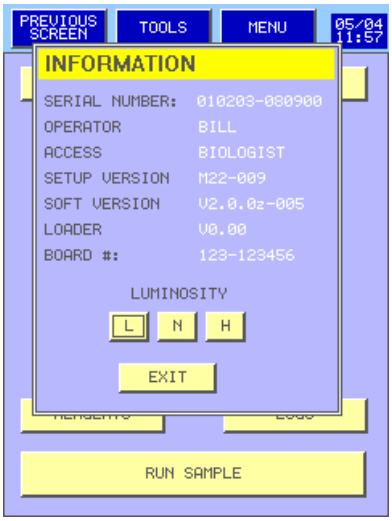


- No USB key is available, connect an USB key then press YES or see section 3.4.7 to change the archive mode.

3.2 SYSTEM STATUS



- Press on the date and hour 23/08 14:47 to have access to the system status window.

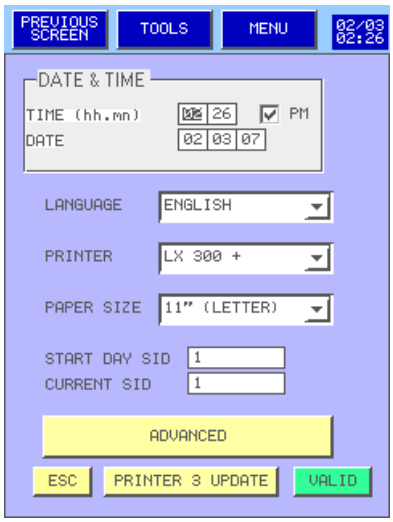


- Different system status information is displayed.

- To change the screen luminosity press **L**, **N** or **H**

- To return to the **MAIN MENU** press EXIT

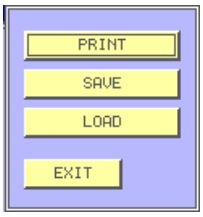
3.3 SET UP



- From the **MAIN MENU** press on SET UP
- This menu is available for all users.
- The **DATE & TIME** window enables to modify the time and the date
- To select the language of the Mythic menu, choose the right one in the Language combo box. LANGUAGE ENGLISH
- PRINTER LX 300 + : Select the printer or no printing.
- PAPER SIZE 11" (LETTER) : Select the paper size depending on the number of results per page.
- START DAY SID 1 : Two SID are available; Start day SID enables to select the first SID for each new day.
- CURRENT SID 1 : If you want to select a new SID number
- ADVANCED : Biologist reserved for complete settings.

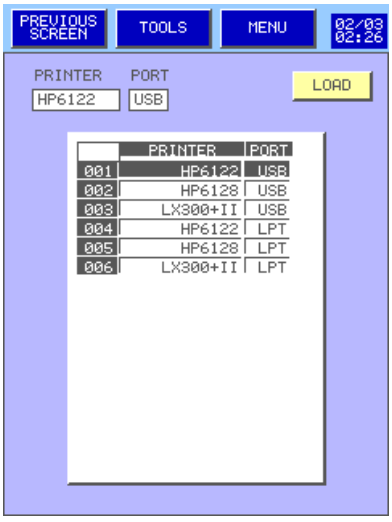
(See section 3.4).

- Once modifications are done, press either VALID to valid or ESC to exit keeping the previous setting.

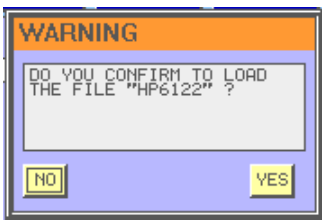


- Press TOOLS to print, save or load from an USB key all the set up.

- To load new printer drivers plug the USB key then press on PRINTER 3 UPDATE in the previous screen.



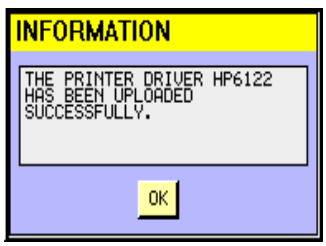
- Select the printer and its connection mode.
- Then press LOAD



- Press YES then, the driver is loaded in the MYTHIC 22

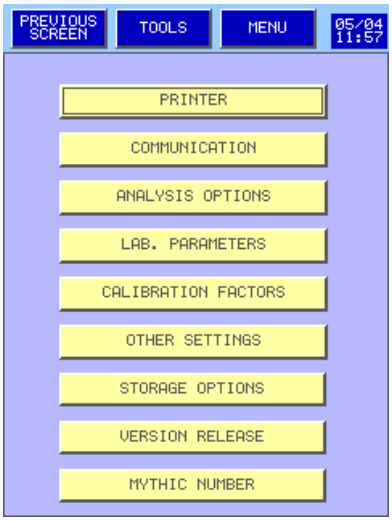
- This prompt appears if the release is failed. Check the USB connection or change the USB key or call your Orphée's representative.

This prompt appears if the



release is done successfully.

3.4 ADVANCED SET-UP

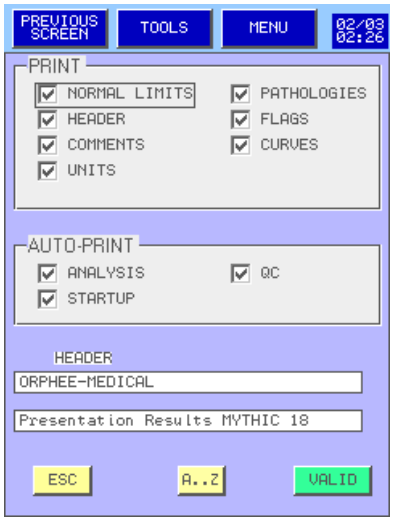


- **This menu is reserved to biologist** (see section 3.1).

	**Any modification can affect the quality of the results. We recommend modifying these values only after an Orphée's training.**

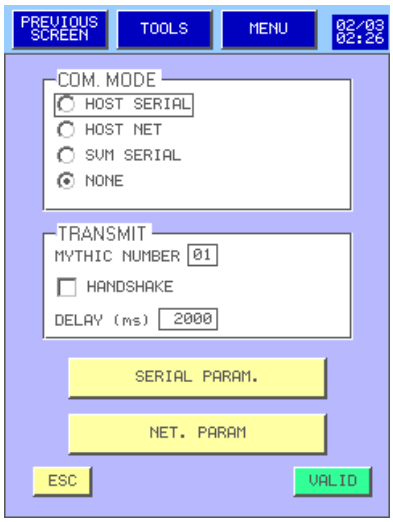
- Please refer below for the description of each key.

3.4.1 Printer set up:



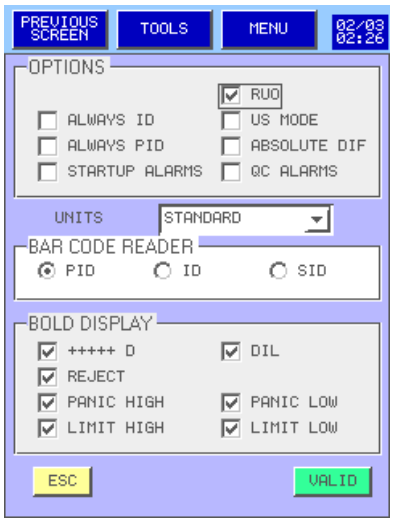
- Printer set up menu is intended to present the printing report
- To select an option on the report, press on the corresponding case.
- To enter a header, press A..Z key.
- To exit the menu, either press ESC to keep the last setting, or VALID to save the last modifications.

3.4.2 Communication:



- Reserved for technical Service people.
- To set up the connection between **MYTHIC** and Host.

3.4.3 Analysis options:



- **OPTIONS** box:
  - **ALWAYS ID** and **ALWAYS PID**: To run a sample, user mandatory needs to enter a ID and/or a PID.
  - **RUO**: With tag the PCT and PDW parameters are displayed, printed and send.
  - **US MODE**: The Research Use Only message is printing below the printing report.
  - **ABSOLUTE DIF**: With tag absolute values for sub-populations of leucocytes are displayed. In the other case, percentages are displayed.
  - **QC ALARMS**: The message QC_F "QC failed" appear below the printing report when the QC result is out of tolerance or expired (see section 8.5.5); The message QC_ND "QC not done" appear below the printing report when it is not run (see section 8.5.5).

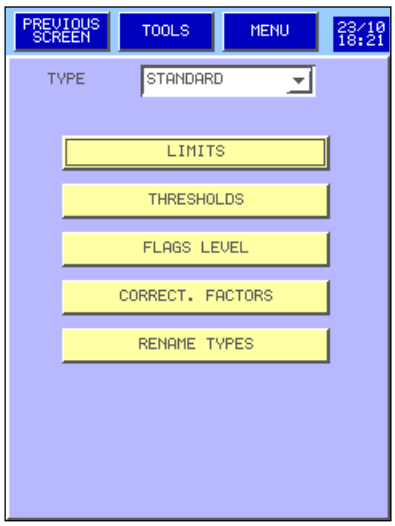
- UNITS STANDARD : Gives a choice of three unit systems: Standard, International System, and mmol.

- **Barcode Reader** box: The reading of the bar code is dedicated to the PID or ID or SID.

- **BOLD DISPLAY** box: display and print in bold-faced type the different choices in this box.

Once modifications are done, press either VALID to validate your choices or ESC to exit keeping the previous setting.

3.4.4 Lab. parameters:



- Select the blood type in the combo box TYPE STANDARD then press:

LIMITS to adjust the normal and panic limits (see section **3.4.4.1**).

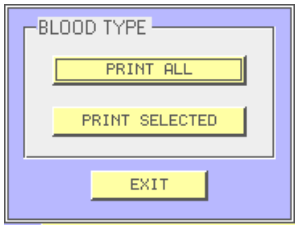
THRESHOLDS to adjust the parameters thresholds (see section **3.4.4.2**).

FLAGS LEVEL to adjust the flags level (see section **3.4.4.3**).

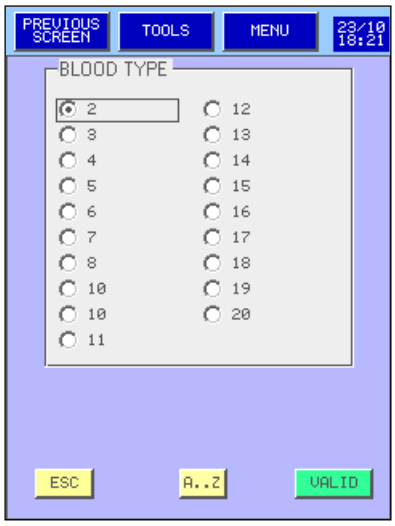
CORRECT. FACTORS to adjust the corrections factors (see section **3.4.4.4**).**NOTA**: No correction factors with type STANDARD.

- To enter a new blood type, press RENAME TYPES

NOTA: The name of the first type STANDARD cannot be change.

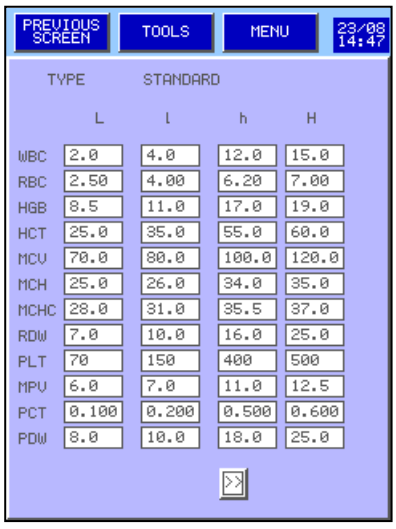


- Press TOOLS to print the blood type set up.
- PRINT ALL allow to print all the blood type set up (about **20** pages are printed)
- PRINT SELECTED only the blood type in the combo box is printed.



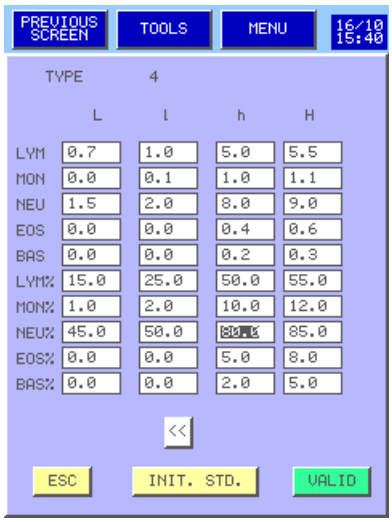
To rename a blood type press RENAME TYPES then select it then press A..Z to accede at the alphabetic keyboard then press VALID to validate or ESC to exit without any modification.

3.4.4.1 Limits:



- This display enables to enter normal and panic limits for every 22 parameters given by the **MYTHIC 22** (see section 8).

- To validate the new values, press VALID key in the next page (see below).



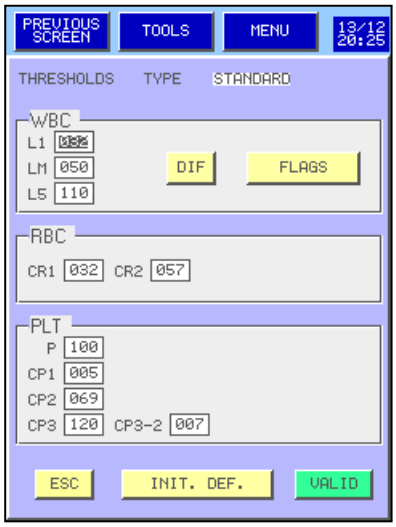
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. STD. to return to the parameter setting of the standard type.

Example of reference values from **LABORATOIRE D'HEMATOLOGIE DU C.H.U. D'ANGERS (FRANCE)**

	First week	8 days to 3 months	3 months to 3 years	3 to 6 years	6 to 15 years	Adult
WBC $10^3/\mu L$ ($10^9/L$)	10,0 to 30,0	6,0 to 18,0	6,0 to 15,0	5,0 to 13,0	5,0 to 11,0	4,0 to 10,0
Neutrophils ($10^3/\mu L$)	6,0 to 26,0	1,5 to 8,5	1,5 to 8,5	1,5 to 8,5	1,8 to 8,0	1,8 to 7,5
Eosinophils ($10^3/\mu L$)	0,2 to 0,85	0,2 to 1,2	0,05 to 0,7	0,02 to 0,65	0 to 0,6	0,04 to 0,8
Basophils ($10^3/\mu L$)	0 to 0,64	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2
Lymphocytes ($10^3/\mu L$)	2,0 to 11,0	2,0 to 11,0	4,0 to 10,5	2,0 to 8,0	1,5 to 6,5	1,0 to 4,5
Monocytes ($10^3/\mu L$)	0,4 to 3,1	0,05 to 1,1	0 to 0,8	0 to 0,8	0 to 0,8	0,2 to 1,0
RBC $10^6/\mu L$ ($10^{12}/L$)	5,0 to 6,0	3,8 to 4,8	3,6 to 5,2	4,1 to 5,3	4,0 to 5,4	M : 4,5 to 5,8 F : 3,8 to 5,4
HGB g/dL	14,5 to 22,5	10 to 16	10,5 to 13,5	10,5 to 13,5	11,5 to 14,5	H : 13,5 to 17,5 F : 12,5 to 15,5
HCT %	44 to 58	38 to 44	36 to 44	36 to 44	37 to 45	M : 40 to 50 F : 37 to 47
MCV fl	100 to 120	85 to 96	70 to 86	73 to 89	77 to 91	82 to 98
MCH pg	34 to 38	24 to 34	23 to 31	24 to 30	24 to 30	> or = 27
MCHC g/dL	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36
PLT $10^3/\mu L$ ($10^9/L$)	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400

3.4.4.2 Thresholds:



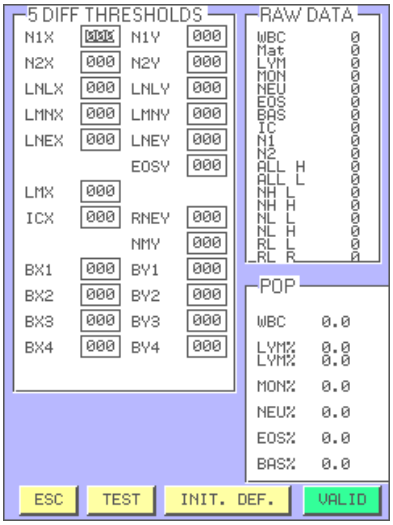
- The threshold display enables to modify the detection thresholds located on the WBC scattergram and RBC, PLT curves (see section 8).

Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend modifying these values only after an Orphée's training.

- To accede for modification to the scatter gram threshold press DIF and to the flags threshold press FLAGS.

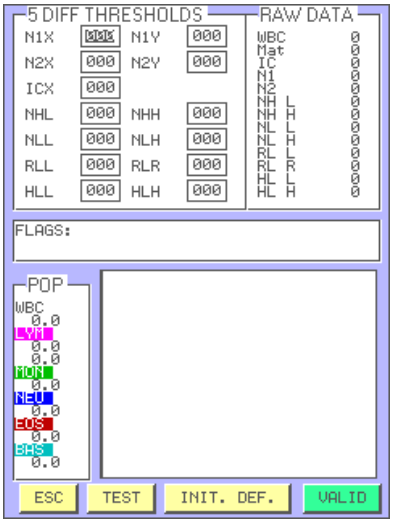
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. DEF. to return to the manufacturer parameter setting.



Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend to modify these values only after an Orphée's training.

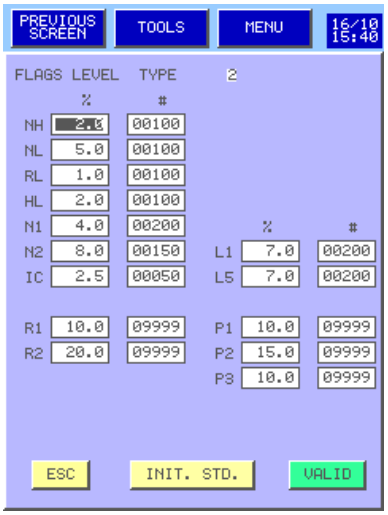
- Press INIT. DEF. to return to the manufacturer parameter setting.



	Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend to modify these values only after an Orphée's training.

- Press INIT. DEF. to return to the manufacturer parameter setting.

3.4.4.3 Flags level :

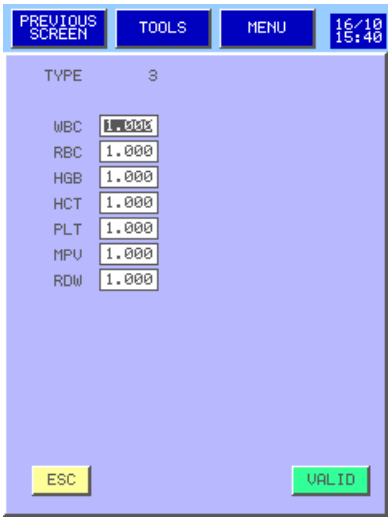


- In the Alarm menu, users can modify the sensitivity of the alarms for the different cells: WBC, RBC, PLT and differential (See section 8.5).

- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. STD. to return to the parameter setting of the standard type.

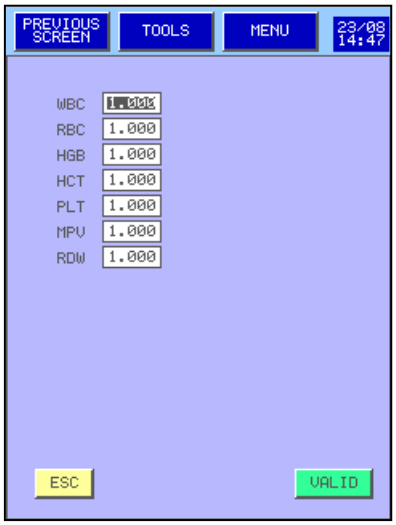
3.4.4.5 Correction factors:



- In this menu, for each blood type, users can define a correction factor which is multiplied by the calibration factor given by a normal calibration (see section 7).

- Once modifications are done, press VALID to validate or ESC to exit without any modification.

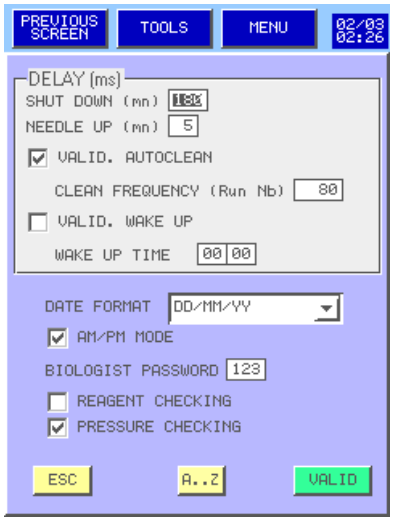
3.4.5 Calibration factor:



- To accede at this menu press CALIBRATION FACTORS in the ADVANCED SET UP MENU (see section 3.4)
- In this menu, the user can modify the calibration factors without any calibration with calibration blood.
- A **M** letter appears on the right of the date of calibration in case of modification.

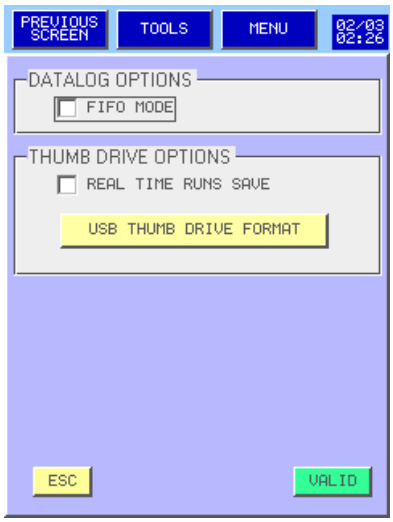
⚠	**The modification of any of these factors without running a calibration blood could affect the quality of the result.**

3.4.6 Other Setting:



- In **DELAY** box, the user can modify:
  - Time in minutes to start the automatic shut down.
  - Time in minutes to buildup the needle.
  - The setting up of the automatic cleaning VALID. AUTOCLEAN and its frequency in number of analysis CLEAN FREQUENCY (Run Nb) 80 .
  - The setting up of the automatic wake up VALID. WAKE UP and its daily time WAKE UP TIME 14 00
  - Reagent checking enables the reagent control (see section 1.5.2)
  - Pressure Checking is accessible for technician only.
- BIOLOGIST PASSWORD 123 enables to modify the biologist password.
- DATE FORMAT DD/MM/YY enables to select the date format.
- AM/PM mode enables to display the format of time of your choice.
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

3.4.7 Storage options:

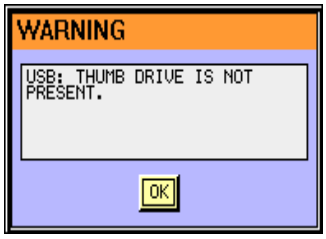


MYTHIC 22 can save more than the last 1000 patients with results, alarms, distribution curves in the internal memory and until a maximum of 60 000 results in a memory stick (USB key) of 512 Mbit or more.
All the capacity until 2 Gbit maximum can be used.
Because the technology of the USB key is very different from one to the other, some of them could not work. For more information contact your Orphée's representative.

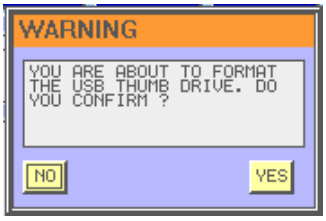
- Choose for a FIFO (first in /first out) mode or real time to store the results in the resident memory or in a USB key.

- Choose REAL TIME RUNS SAVE to directly save sample run onto USB key.
If USB key is available, result will be store at the end of the sample run.

Press USB THUMB DRIVE FORMAT to format USB key. The system will format the USB Key and build specific directories for Mythic management.



- This prompt appears if none USB key is available.

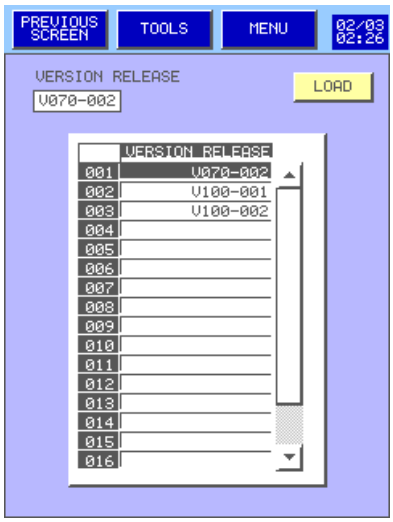


- Press yes if you agree to format the USB key. It is mandatory to format the USB key on the Mythic before to use it.

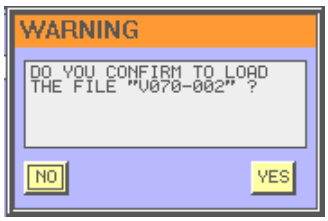
⚠	**All the information includes in the USB key will be erased.**

3.4.8 Version release:

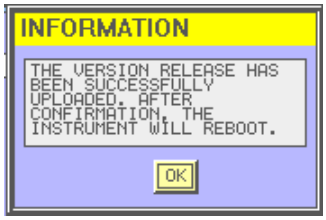
⚠	**Load a new software version only with the agreement of an Orphée's representative**



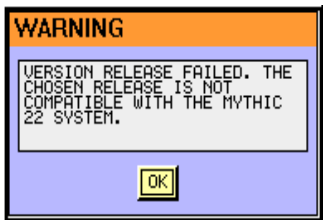
- Press LOAD to load a new software version from a USB key.
- Choose the right version then,
- Press yes only if you are sure to load new version software.



⚠	**The current software version will be erased definitively.**



- This prompt appears to confirm the version loading.



- This prompt appears when the release of the software is failed.

- Choose another version or call your Orphée's representative.

4. SPECIFICATIONS

4.1 ANALYTICAL SPECIFICATIONS

Throughput: > 45 samples/hour

Sample Volume: 15,7 µl (inside the needle, the total volume could be upper in function of the blood remaining outside of the needle).

Measurement Principle: WBC/RBC/PLT: Impedancemetry
Five part diff: Optical flow cytometry
Hemoglobin: Spectrophotometry at 555 nm
Hematocrit: Volume integration

Linearity:
Linearity is measured with linearity sample performed four times for each level.

PARAMETERS	RANGE	LIMITS (the larger)
WBC ($10^3/mm^3$)	0 to 100	+/- 0,4 or +/- 4%
RBC ($10^6/mm^3$)	0,1 to 8	+/- 0,07 or +/- 3%
HGB (g/dL)	0,5 to 24	+/- 0,3 or +/- 2%
HCT (%)	5 to 70	+/- 2 or +/- 3%
PLT ($10^3/mm^3$)	5 to 2 000	+/- 10 or +/- 5%

Reportable range:
Within the reportable range, the results are flagged with a **D** to indicate that it is necessary to re-dilute and re-run the sample.

PARAMETERS	REPORTABLE RANGE
WBC ($10^3/mm^3$)	100 to 150
RBC ($10^6/mm^3$)	8 to 15
HCT (%)	70 to 80
PLT ($10^3/mm^3$)	2000 to 4 000

Repeatability:
Calculated with 20 runs of a fresh whole blood sample performed on a commercial **MYTHIC 22**.

PARAMETERS	CV	RANGE
WBC	< 2,5%	> to $6,0\times10^3/mm^3$
LYM	< 5%	> to 15 %
MON	< 10%	> to 7 %
NEU	< 4%	> to 50 %
EOS	< 10%	> to 5%
BAS	< 40%	> to 2%
RBC	< 2%	> to $4,0\times10^6/mm^3$
HGB	< 1,5%	> to 12,0 g/dL
HCT	< 2%	> to 40,0 %
MCV	< 1%	> to 85 fL
RDW	< 4%	> to 14
PLT	< 5%	> to $250\times10^3/mm^3$
PMV	< 3%	> to 8 fL

Calculated method: $CV = \frac{SD}{\bar{X}}$

$$SD = \sqrt{\frac{\Sigma x^2 - \frac{(\Sigma x)^2}{N}}{N - 1}}$$

Carry-Over:
For each parameter, we perform 3 runs from a high concentration sample followed by 3 runs without sample.

	WBC	RBC	HGB	PLT
High concentration value	$145\times10^3/mm^3$	$8.40\times10^6/mm^3$	20 g/dL	$2300\times10^3/mm^3$
Measured carry-over (%)	0.68	0	0	0.04
Maximum carry-over (%)	< 1,0	< 1,0	< 1,0	< 1,0

The percentages of carry-over inter samples is calculated with the following formula:

$$\text{Carry-over} = \frac{\text{(Low value cycle 1) - (Low value cycle 3)}}{\text{(High value cycle 3) - (Low value cycle 3)}} \times 100$$

Accuracy:
Correlation was done with one commercial instrument (HORIBA ABX PENTRA 120 ®) and with about 100 normal blood samples (without alarm).

PARAMETERS	N	R (%)
WBC ($10^3/mm^3$)	127	0,997
LYM (%)	113	0,989
MON (%)	113	0,935
NEU (%)	113	0,988
EOS (%)	113	0,950
BAS (%)	113	0,187
RBC ($10^6/mm^3$)	127	0,991
HGB (g/dL)	127	0,997
HCT (%)	127	0,984
MCV (fL)	127	0,947
RDW (%)	127	0,746
MCH (pg)	127	0,963
MCHC (g/dL)	127	0,151
PLT ($10^3/mm^3$)	127	0,990
MPV (fL)	127	0,890

Calculated method: $$\mathbf{r} = \frac{n.\Sigma xy - \Sigma x.\ \Sigma y}{\sqrt{(n.\ \Sigma x^2 - (\Sigma x^2))(n.\ \Sigma y^2 - (\Sigma y^2))}}$$

PENTRA 120 ® is a registered trademark of HORIBA ABX.

4.2 PHYSICAL SPECIFICATIONS

General:
Ambient temperature: from 18 to 34°C
Relative Humidity: 80% maximum at 32°C
Storage temperature: -10 to 50°C

If the MYTHIC 22 has been stored at a temperature less than 10°C, it must stay at room temperature during 24 hours before switching it on.

INSTRUMENT:

Dimensions: Height: 350 mm (approx.)
Width: 250 mm (approx.)
Depth: 340 mm (approx.)

Weight: 12kg (approx.)

Power supply Input: 24V –5A DC

Electric consumption: During cycle: 75 VA (-30% +10%)
Stand By: 20 VA (-30% +10%)
Maximum: 110 VA (-30% +10%)

Display: TFT Color LCD 240*320
Mode portrait
Retro-lighted

Barcode (option): Barcode reader: C39/ Barcode / 2 interleaved 5

Memory capacity: > 500 Files (Demographics, results and histograms) in the internal memory
> 60 000 files in a 512 Kbit USB key
QC: 6 levels (100 Files per level)

Connection: RS 232C
Ethernet (TCP/IP)

Reagent Consumption (ml): Software Version **> V2.2.0-005**

CYCLES		DILUENT	LYSE	CLEANER
Run Sample	DIF	21,0	0,96	0,45
	CBC	13,10	0,73	0,45
Rinse All		11,0	--	--
Back flush		11,0	--	0,30
Control		14.7	--	0,50
Reagent Prime	All	39,20	5,6	5,60
	Lysis OnlyOne	5,7	6,5	--
	Diluent	31.0	--	--
	Cleaner	--	--	5,6
Cleaning		12,7	0,2	5.6
Bleach		46,0	1.1	0.45
Start Up *		49.6	3,2	0,45
Shut Down		--	0,5	23.0
Latex WBC		14.5	1.10	0.45
Latex RBC		7.10	--	--
Latex OPT (1)		13.00	0.9	--
Latex OPT (2)		13.00	0.9	--
Latex OPT (3)		13.00	0.9	--
Optical Led		1.00	0.10	--

***** Consumption with one run sample, add one or two run sample consumption if needed.

POWER SUPPLY BLOCK:

Dimensions:	Height:	55 mm
	Width:	127 mm
	Depth:	230 mm
Weight:		1,32Kg
Power supply Input:		100 to 240VAC (2A/230VAC at maximum load – 4A/115VAC at maximum load) 50-60Hz

PRINTER (LX-300+):

Dimensions:	Height:	164 mm (approx.)	
	Width:	366 mm (approx.)	
	Depth:	275 mm (approx.)	
Weight:		4,4 kg (approx.)	
Power supply:		Model 120V	Model 220-240V
		99 to 132Vac	198 to 264Vac
		50 to 60 Hz	
Electric consumption:		23W (approx.)	
Paper size:		Depends on the format chosen in the set up.	
Printer:		Impact (9 needles)	
Speed:		Up to 300 cps (character per second)	

4.3 REAGENTS SPECIFICATIONS

All the reagents must be stored at room temperature (18°C to 25°C).

4.3.1 Diluent

ORPHEE code number: **HM22-003-10**
Opening shelf life: 60 days.

Application: The diluent is used to carry out the necessary dilutions for the measurement performed by the **MYTHIC 22**.(see section **8**)

Active components: Solid content: 0,9%.

Others components: Buffer.
Preservative.

Description: Clear and odorless aqueous solution.

Storage: At room temperature until the expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 minutes.
Skin: not skin irritating.
Ingestion: rinse out mouth; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measure :

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, Universal binders saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

4.3.2 Lytic reagent "OnlyOne"

ORPHEE code number: **HM22-002-1**
Opening shelf life: 60 days.

Application: OnlyOne Lytic reagent is used as unique leukocyte and hemoglobin reagent to lyse red blood cells, enable cells subpopulations differentiation and counting and quantitatively determine hemoglobin content of blood samples on **MYTHIC 22**, (see section 8)

Active components:
- alkaline salts and buffering means
- ionic and non-ionic surfactants mix
- Leuko-protective agents
- non toxic Hemoglobin chelate
- Preservatives

Description: A clear pale yellow aqueous solution (with slight characteristic smell) composed of alkaline salts, inorganic buffers, leukoprotective agents, detergents, a non toxic haemoglobin stabilizing chelate, and preservatives

NOTA: This reagent does not contains any cyanide, neither formaldehyde, nor azide.

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 minutes.
Skin: Abundantly rinse during 15 minutes; seek for medical advice in case of persisting symptoms
Ingestion: give large amount of water; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measure :

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, Universal binders saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

4.3.3 Cleaning solution

ORPHEE code number: **HM22-001-1**
Opening shelf life: 60 days.

Application: The cleaning solution is used to carry out the cleaning of the measurement system and hydraulic circuit (see section **8**).

Components: Enzyme
Propylene glycol 2,5-10%:
Dangerous component with critical values that require monitoring at the workplace
(CAS 55-57-6; EINECS 200-338-0)
OES long term value: 474mg/m^3 150ppm total
10mg/m^3 particulates
Violet dye.

Description: Clear aqueous solution, violet color, with characteristic smell

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear on a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 minutes.
Skin: Abundantly rinse during 15 minutes ; seek for medical advice in case of persisting symptoms
Ingestion: give large amount of water; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measures:

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

4.4 ANALYTICAL LIMITATIONS

4.4.1 Recommendations

MAINTENANCE:
Please respect the maintenance procedure and the quality control procedure. Otherwise, results can be affected.

GENERALITIES:
Some abnormal samples may give incorrect results by automated cell counting methods. The following table shows examples of specific specimens that could cause errors.

Each result for a new patient out of lab linearity limits or with an alarm must be checked with a conventional method or checked with blood smear.

4.4.2 Interferences

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22	action
WBC	Cold Agglutinin	(+)	*Cause* : high IgM level may lower RBC and increase MCV *Indication* : ↑MCV, ↓HCT, N1 &/or N2 &/or L1 &/or HL flags	Seek for red cell clumping on Smear
	Nucleated RBC Erythroblastosis	(+)	*Indication* : NRBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for NRBC on smear.
	Unlysed RBC	(+)	*Cause:* in some rare instance few erythrocytes may not be completely lysed. *Indication* : lyse-resistant RBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags	
	Cryoglobulins	(+)	*Cause:* In association with various pathologies cryoglobulins cause the WBC, RBC, Plt and Hgb to increase *Indication*: high level of all above mentioned items in case of myeloma, carcinoma, leukemia and other proliferative disorders, pregnancy…	Warm the specimen up to 37°C(99°F) for 30min and re-assay immediately after.
	Platelet aggregation	(+)	*Indication* : aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for Platelet aggregates on smear

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22	action
LYM (# & %)	Nucleated RBC Erythroblastosis	(+)	*Indication:* NRBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags	Seek for NRBC on smear.
	Platelet aggregation	(+)	*Indication:* aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for Platelet aggregates on smear
MON (# & %)	Large or atypical lymphocytes	(+)	*Cause:* These lymphocytes are larger than normal lymphocytes and tend to overlap the MON clump on the scattergram *Indication:* reduced LYM/MON gap with LYM band RL flags	Seek for Erythroblasts on smear
	Small Neutrophils	(+)	*Cause :* These few segmented and granulations-lacking Neutrophils tend to overlap the MON clump on the scattergram *Indication:* reduced NEU/MON gap with NL flags	
	Lymphoid & myeloid Blasts	(+)	*Cause :* Blasts are large and polymorphic immature cells that may overlap all normal cells clumps *Indication*: reduced/absent LYM/MON even MON/NEU/LYM gap with overlapping population RL &/or NL &/or HL flags	Seek for blasts on smear
	Excessive number of basophils	(+)	*Cause:* in case of basophilia the basophils clump may overlap the MON clump on the scattergram *Indication:* reduced LYM/MON gap RL &/or HL &/or NL flags	Seek for basophils on smear
	Immature monocytes	(+)	*Cause:* Immature monocytic line cells proliferate in certain pathologies (multiple myeloma, monocytic leukemia…) and generate a band at the right of normal MON clump that causes an inaccurate high level of monocytes. *Indication*: : diffuse MON clump with right-end flame population IC &/or L5 &/or NL flags	Seek for immature monocytes on smear
NEU (# & %)	Excessive number of eosinophils	(+)	*Cause:* The excessive presence of eosinophils (eosinophilia) may interfere with NEU counting *Indication:* EOS clump is overlapping NEU clump NH flag	check the eosinophils clump on the scattergram to eliminate eosinophilia
	Immature granulocytes	(+)	*Cause :* metamyelocytes, myelocytes, promyelocytes, blasts or plasma cells are large and polymorphous cells that may overlap NEU clump *Indication:* diffuse spreading out NEU clump NL &/or RL &/or IC &/or L5 flags	Seek for immature cells on smear

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22	action
EOS (# & %)	Granulations modifications	(-)	*Cause:* Toxic or abnormal granules, as much as degranulated areas may alter optical properties of eosinophils and cause an erroneous EOS counting *Indication:* diffuse downwards spreading EOS clump overlapping NEU clump, NH Flag	Seek for Granulations modifications on smear
	Atypical Neutrophils	(+)	*Cause:* hyper-segmented or giant Neutrophils may overlap EOS clump *Indication:* upwards spreading NEU clump overlapping EOS clump, NH &/or IC &/or L5 Flags	Seek atypical Neutrophils on smear
BAS (# & %)	Blasts, immature, atypical cells	(+)	*Cause:* abnormal cells may overlap the basophils clump and interfere with the basophil counting *Indication:* absence of LYM/MON(NEU) gap with RL &/or NL &/or HL flags	Seek for blasts on smear
RBC	Cold Agglutinin	(-)	*Cause:* high IgM level may lower RBC and increase MCV *Indication:* ↑MCV, ↓HCT	Seek for red cell clumping on Smear
	Severe Microcytosis	(-)	*Cause:* in very rare case of severe microcytosis, size of microcytes may fall below the minimum RBC threshold. *Indication:* ↓RBC, ↑Plt R1 &/or P3 flags	Seek for microcytes on Smear
	Macrocytosis	(-)	*Cause:* in case of macrocytosis, size of macrocytes may overcome the maximum RBC counting zone. *Indication :* ↓RBC, ↑MCV, R2 flag	
	RBC agglutination	(?)	*Cause:* agglutinated RBC may cause a low inaccurate RBC count. *Indication*: abnormal MCH and MCHC values	Seek for clumped RBC on Smear
	Fragmented RBC	(-)	*Cause:* RBC fragments (schizocytes) may agglutinate and interfere with RBC counting. *Indication:* ↓RBC, ↑Plt, ↑MPV, P2 flag	Seek for schizocytes on Smear
	Leukocytosis	(+)	*Cause:* high level of WBC may cause an erroneous RBC count. *Indication:* very high WBC (>100,000/µL), ↑RBC , ↑MCHC	Centrifuge the sample and re-assay the re-diluted RBC part.

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22	action
HGB	Leukocytosis	(+)	*Cause:* high level of WBC causes excessive light scatter that interferes with Hgb measurement. *Indication:* very high WBC (>100,000/µL), ↑MCHC	Centrifuge the sample remove WBC and re-assay the re-diluted RBC part. Or use reference spectrophotometric method
	hyperlipidemia	(+)	*Cause:* in case of high level of lipids in blood will give the plasma a "milky" appearance that causes inaccurate Hgb measurement. *Indication:* plasma appearance ↑MCHC,	Use reference manual methods and a plasma blank to determine Hgb
	Abnormal Protein hyperproteinemia, hyperbilirubinemia	(+)	*Cause:* in case of high level (or abnormal) of proteins in blood will give the lysed sample a "cloudy" appearance that causes inaccurate Hgb measurement. *Indication:* lysed sample appearance ↑MCHC	Use reference manual methods and a plasma blank to determine Hgb
HCT	Cold Agglutinin	(-)	*Cause:* high IgM level may lower RBC and increase MCV *Indication:* ↑MCV, ↓HCT,	Seek for red cell clumping on Smear
	Leukocytosis	(+)	Elevation of WBC	
	Abnormal Red Cell Fragility	(-)	*Cause*: in case of chemotherapy cytotoxic and immunosuppressive drugs may increase RBC as well as WBC fragility leading to a low HCT *Indication:* P1 flag	
	Spherocytosis	(?)	*Cause:* in case of Spherocytosis, sphered RBC are smaller than normal RBC leading to a low HCT *Indication:* ↓MCV, P2 &/or P3&/or R1 flags	Seek for spherocytes on Smear
MCV	RBC agglutination	(?)	*Cause:* agglutinated RBC may cause an inaccurate MCV value. *Indication*: abnormal MCH and MCHC values	Seek for clumped RBC on Smear Use reference manual methods to determine the accurate MCV value.
	Megalocytic Platelets	(-)	*Cause:* may cause a low inaccurate MCV value because of an excessive size *Indication:* ↓Plt ↑MPV , P2 flag	Seek for megalocytic platelets on Smear
	Leukocytosis	(+)	*Cause:* high level of WBC interferes with MCV determination. *Indication:* very high WBC (>100,000/µL) , ↑MCHC	Use reference manual methods to determine the accurate MCV value.

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22	action
MCH	See Hgb value and RBC count interferences		*The MCH is determined according to Hgb value and RBC count. The limitations listed for Hgb and RBC may cause indirect interferences.*	
MCHC	See Hgb and HCT values interferences		*The MCMH is determined according to Hgb and HCT values. The limitations listed for Hgb and HCT may cause indirect interferences.*	
RDW	See RBC count interferences	(?)	*The RDW is determined according to RBC count. The limitations listed for RBC may cause indirect interferences.*	
PLT	Platelet Aggregation	(-)	*Cause:* Clumped platelets may cause a decreased platelet count *Indication:* aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags, ↓Plt ↑MPV	Seek for Platelet aggregates on Smear The specimen should be recollected in sodium citrate anticoagulant and re-assayed
	Severe Microcytosis	(+)	*Cause:* in case of severe microcytosis, microcytes and schizocytes are below the RBC inferior threshold and may be counted with Platelets and cause an erroneously high Plt count *Indication:* ↓RBC, ↑Plt R1 &/or P3 &/or P2 flags	Seek for microcytes on Smear
	Megalocytic Platelets	(-)	*Cause :* may cause a low inaccurate platelet count as these platelets exceed the upper threshold for the platelet parameter and are not counted *Indication :* ↓Plt ↑MPV P2 flag	Seek for megalocytic platelets on Smear
	RBC agglutination	(?)	*Cause:* agglutinated RBC may trap platelets and cause a low inaccurate Plt count. *Indication:* abnormal MCH and MCHC values	Seek for clumped RBC on Smear
	Hemolysis	(+)	*Cause:* hemolysed samples contain RBC stromas that cause a high inaccurate Plt count. *Indication:* abnormal MCH and MCHC values ↓RBC	

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

5. SAMPLE ANALYSIS

5.1 VERIFICATIONS BEFORE STARTING

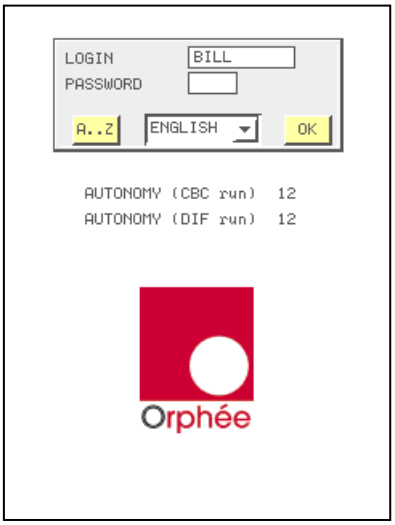
Before starting **MYTHIC 22**, we recommend to check the reagent levels in each bottle, and the level of the waste container. Please also check the paper quantity in the printer.

5.2 START UP

- Press ON/OFF button on the printer to start.
- Switch on the power supply (the power supply can stay on).
- Press ON/OFF button  on the Mythic.

- The initialization menu is displayed and **MYTHIC 22** performs a home position checking for the three motors.

- The cycle LED  turns red. None cycle can be performed before it turns green.

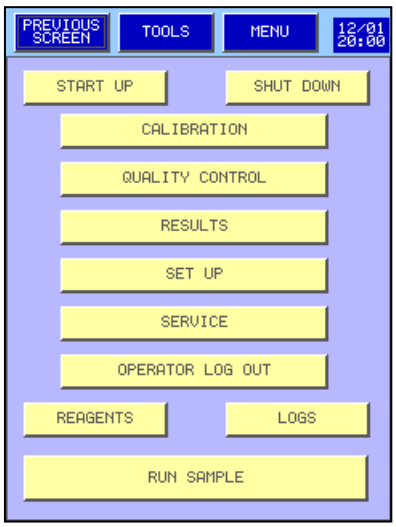


- Enter your login and password as described in section 3.1.

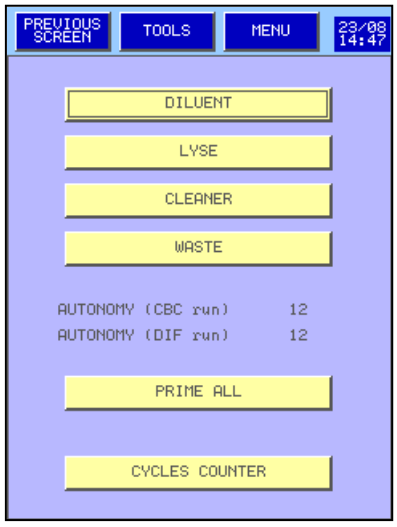
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform in CBC or DIF mode (calculated with the smaller quantity of reagents).

5.3 REAGENT REPLACEMENT

	**The reagents must be stored 24 hours minimum at room temperature before use.**



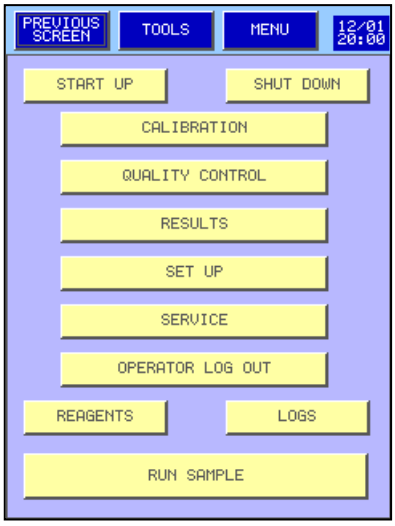
- To check the level of each reagent, press 



- If one or more reagent needs to be replaced, proceed as indicated in section 1.5.2

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform in CBC or DIF mode (calculated with the smaller quantity of reagents).

5.4 START UP RINSING



- To rinse the system before analysis, press START UP

- The cycle LED  turns red. None cycle can be performed before it turns green.

- Mythic will perform 1 to 3 empty cycles to check the carry over level. This level should not to exceed the following ratios:
  - WBC : 0.5
  - RBC : 0.1
  - HGB : 0,5
  - PLT : 10

If the level is higher, **MYTHIC 22** displays a window "START UP FAILED" press OK and perform a new start up. If the user chooses to run samples, every result will be printed with **"Start Up not done"** message.

5.5 PREPARATIONS BEFORE ANALYSIS

The human blood venous sample must be collected in an EDTA **K2** or **K3** (Ethylene Diamine Tetracetic Acid, two or tri potassic) tube in sufficient quantity. The 5 part diff results are available (with more flags) up to **48 hours** after the blood draw and only if the sample is stored at **4 to 8°C**.
It must be correctly homogenized before analysis. It is recommended to use a rotary agitator turning between 20 to 30 turns/ minutes during **10 minutes**.
The results and the flags could be affected in case of too much sampling (more than 10 times).

	**A volume of insufficient blood for the quantity of anticoagulant or a bad mixing may involve an erroneous result.**

5.6 ANALYSIS

5.6.1 Introduction

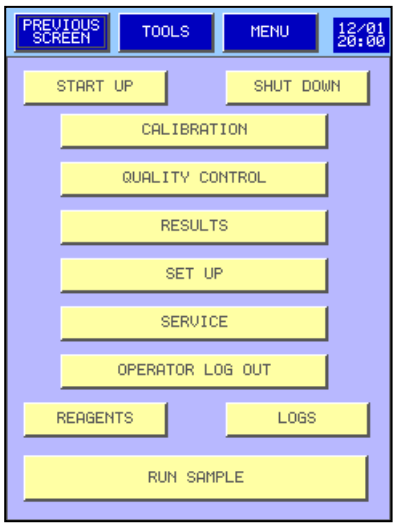
	**It is recommended (or mandatory according to the legislation) to carry out a Quality Control (QC) and possibly a calibration before any analysis (see section 6 & 7).** **Read the analytical limitations (see section 4.4) before run the sample.**

	**The working temperature of the fluidic part must be reached before starting the analysis.** **The average time to reach it is around 15' at a room temperature > 23 °C (see 5.6.3).**

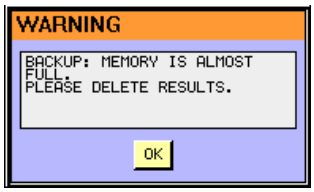
If the quality control is not carried out, it is recommended to perform two analyses on a normal sample of the day before, before beginning the series.

NOTA: The **MYTHIC 22 CT** is delivered with a standard parameter setting described in section 3.

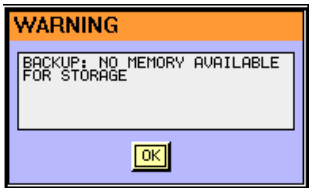
5.6.2 Sample Identification



- From the main menu, press RUN SAMPLE to reach the analysis display.

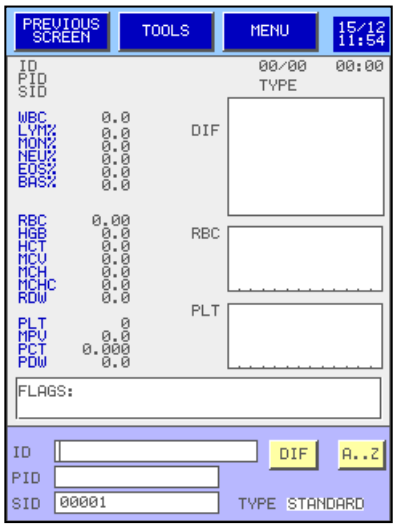


- This prompt appears when the results memory is almost full. To avoid this message, select the option FIFO mode in the set up.



- This prompt appears when the results memory is totally full.

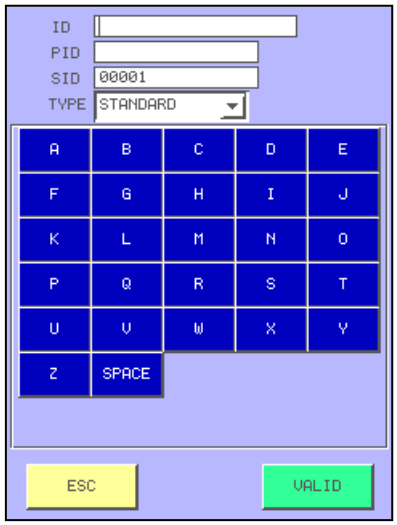
- To delete results see section 5.10



- The display bottom is reserved for the entry of the next sample identification to run.
- Three fields allow the entry of the identification:
  - ID: Patient Name (**20** characters max.)
  - PID: Patient Identification (**16** characters max.)
  - SID: Sample identification (**16** characters max.)

NOTA: SID number is already done. (See section 3.3)

- Press A..Z to accede to the blood type and alphabetic characters.
- Press DIF or CBC to change the measurement mode.



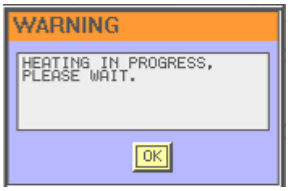
IDENTIFICATION PROCEDURE:

- To enter or modify identification, place the cursor in the selected field with your finger or the arrow.
- To enter a figure, use the keyboard on the right of the screen, for a letter use the alphabetic keyboard by pressing A..Z.
- To accede to another character page press << or >>.
- To change the blood type, press the combo box TYPE STANDARD and select the type
- To valid the entry and return to the previous screen, press VALID.
- To return to the previous screen without validation, press ESC.

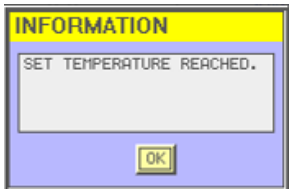
5.6.3 Sample run

	**Wear rubber gloves and wash hands with a disinfectant after completion of work.**

NOTA: The needle will be available as soon as the working temperature is reached (about 15 minutes at 23°C of room temperature).



This prompt means that the temperature setting of the enclosure and/or the reagent is not reached yet.



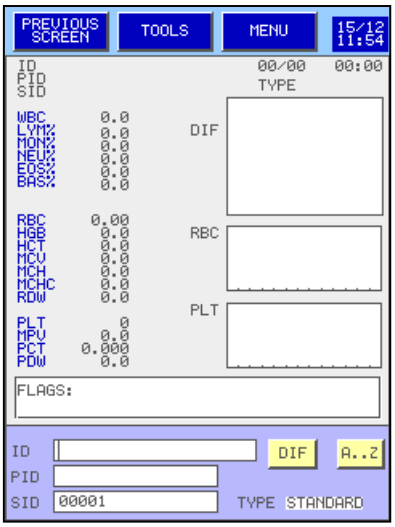
This prompt means that the temperature setting of the enclosure and/or the reagent is reached and that a cycle can be run.

As soon as the temperature is reached, a measurement cycle can be run :

- If the needle is not visible, first presses the start cycle trigger and wait for the descent.

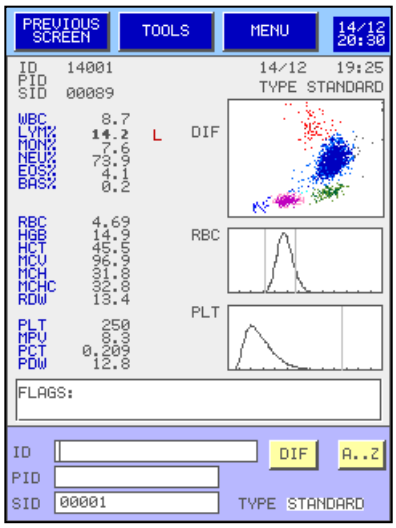
- Present the tube of the blood sample under the needle and press the start cycle trigger.

- The cycle LED  located at the top of the needle becomes red the tube can be removed only when the needle up.
- A new cycle can be started again when it turns by again green.



- As soon as the cycle is launched, the SID is incremented automatically and, thanks to its data processing multitasks, the **MYTHIC 22** is available for the identification of the following sample (See section 5.6.2).

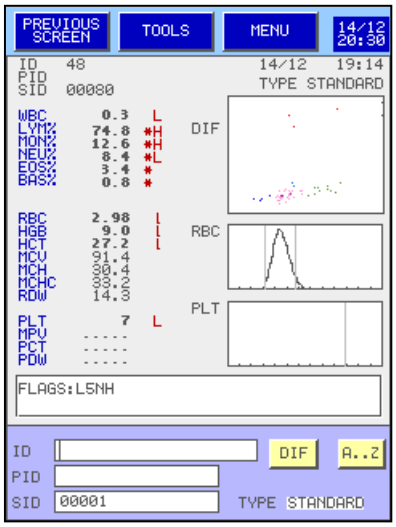
5.7 RESULTS



- The results of the analysis are sent before the cycle is finished (to be checked) at the same time as the printer starts.

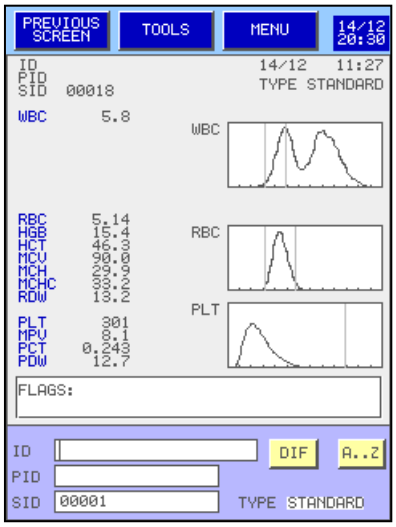
NOTA: It is not necessary to wait for the end of the result printing to launch a new analysis.

- The results are sent to the selected unit (See section 3).
- The information located on the right of each parameter corresponds to the indicators for out of range limits and for the rejections (see section 3).
- The scattergram and curves of distribution of each cellular population are located on the right screen.
- Under the results a zone (FLAGS) is reserved for analytical alarms (see section 8.5).
- At the bottom of the screen, there are the three inlet fields for the identification of the next sample. (See section 5.6.2).

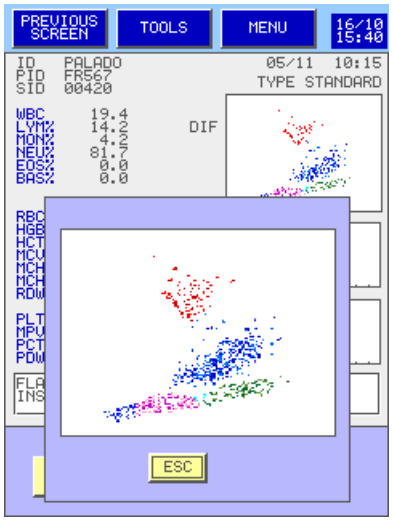


- Example of an abnormal result analysis in **DIF** mode with flags located at the right of the results and in the flag box under the result.

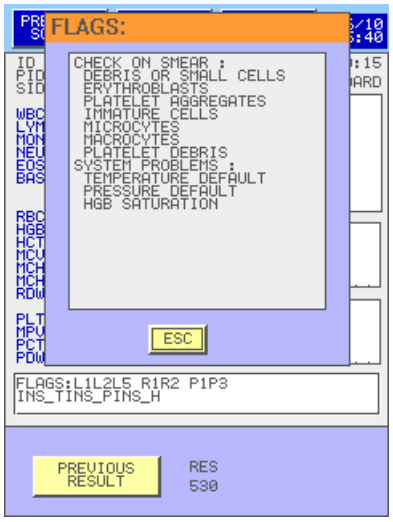
	**It is mandatory to read the section 8.5 to understand the flags meaning.**



- Example of a normal result analysis in **CBC** mode.



- Press on the matrix to access to a zoomed view.

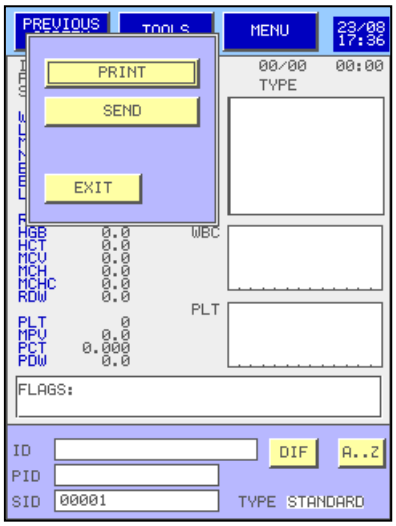


- Press on the flags zone to open the flags window.

- In regard of the different flags found by the MYTHIC 22 the upper part propose list of the cells to check on the smear.

	**In any case this proposal is a commitment, it is mandatory to read the section 8.5 to understand the flags meaning.**

Press on flag region to access detailed flags window.
- The lower part describes the machine problem (see section 8.5.2).



- Press TOOLS to reprint or to resend the result.

- To print the result press PRINT.
- To send the result, press SEND.
- To close the window, press EXIT.

5.8 PRINTING

Once the analysis is finished, the **MYTHIC 22** prints a result report. To modify the printing presentation or to disconnect the printer, see section **3.4.1**.
To load a new printer driver, see section **3.3**.

5.8.1 Model report (A4) – external printer

One result per page

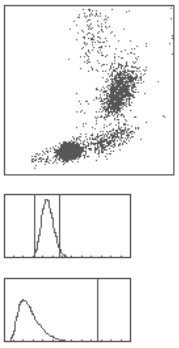
DIF mode

ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00017
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:25:56 Seq# : 00032

	Result	Flags	Unit	Normal limits
WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	**11.3**	h	%	2.0 / 10.0
NEU%	**42.8**	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
LYM	2.3		10^3/l	1.0 / 5.0
MON	0.6		10^3/l	0.1 / 1.0
NEU	2.4		10^3/l	2.0 / 8.0
EOS	0.3		10^6/l	0.0 / 0.4
BAS	0.0		10^6/l	0.0 / 0.2
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0



FLAGS:

MONOCYTOSIS NEUTROPENIA

Comments :

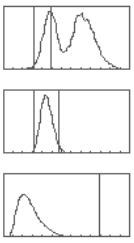
CBC mode

ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00018
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:27:30 Seq# : 00033

	Result	Flags	Unit	Normal limits
WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0

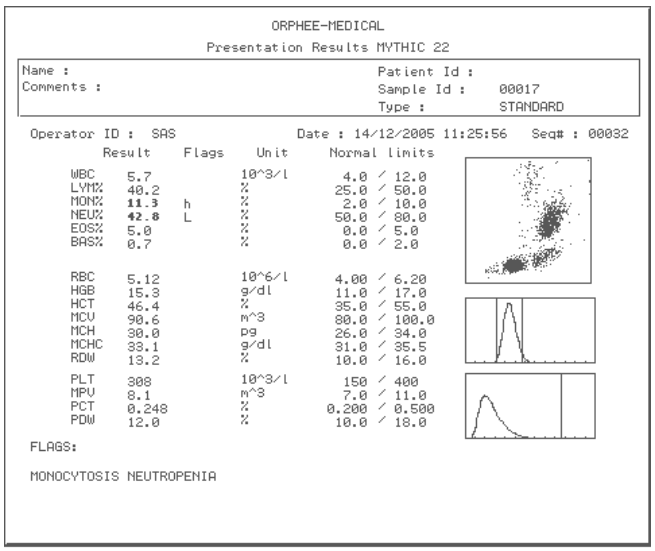


FLAGS:

Comments :

Two results per page

DIF mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00017
Type : STANDARD

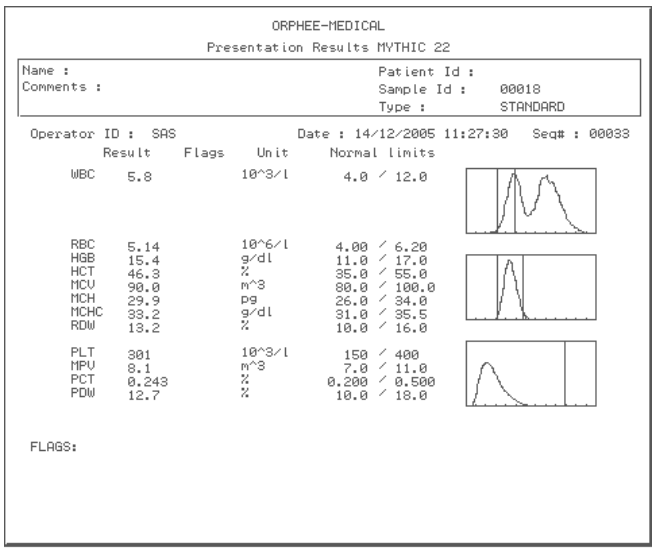
Operator ID : SAS Date : 14/12/2005 11:25:56 Seq# : 00032

	Result	Flags	Unit	Normal limits
WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	**11.3**	h	%	2.0 / 10.0
NEU%	**42.8**	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0

FLAGS:

MONOCYTOSIS NEUTROPENIA

CBC mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00018
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:27:30 Seq# : 00033

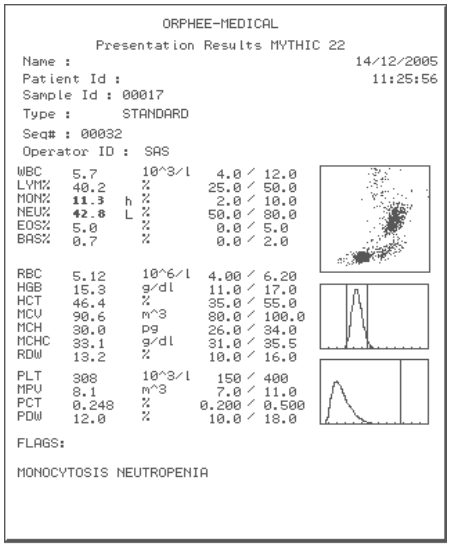
	Result	Flags	Unit	Normal limits
WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0

FLAGS:

5.8.2 Model report – Thermal printer

SEIKO DPU 414 model

DIF mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

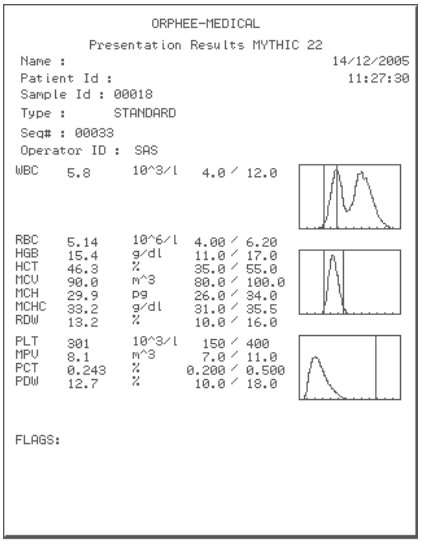
Name :
Patient Id :
14/12/2005
11:25:56
Sample Id : 00017
Type : STANDARD
Seq# : 00032
Operator ID : SAS

WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	**11.3**	h	%	2.0 / 10.0
NEU%	**42.8**	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0

FLAGS:

MONOCYTOSIS NEUTROPENIA

CBC mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

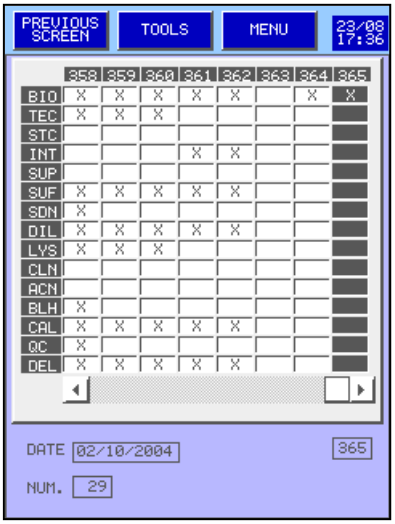
Name :
Patient Id :
14/12/2005
11:27:30
Sample Id : 00018
Type : STANDARD
Seq# : 00033
Operator ID : SAS

WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0

FLAGS:

5.9 LOGS

From the main menu, press LOGS to reach the logs display



- **MYTHIC 22** manage a simplified log allowing saving and displaying all the events done for the following actions:
  - **BIO**: Login with the Biologist code.
  - **TEC**: Login with the service Technician code.
  - **STC**: Login with the "Super" service Technician code.
  - **INT**: An intervention or maintenance has been performed.
  - **SUP**: Start Up cycle has been performed.
  - **SUF**: Start Up cycle has failed.
  - **SDN**: Shut down cycle has been performed.
  - **DIL**: Diluent replacement.
  - **LYS**: Lysis replacement.
  - **CLN**: Cleaner replacement.
  - **ACN**: Autocleanning cycle.
  - **BLH**: Bleach cycle.
  - **CAL**: Calibration.
  - **QC**: Quality control.
  - **DEL**: Results deleted in Archive.

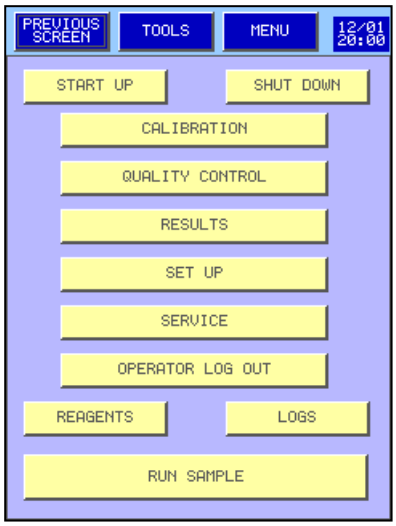
Each column is identified by a number (recall at the right bottom of the screen 365). In the bottom of the screen is displayed the date DATE 02/10/2004 and under it the number of analysis NUM. 29 run during this day.

- To print the log report press TOOLS
- Select ALL to print the logs of the number of pages indicated on the screen.
- To print the logs of one or more days select DAY then enter the day reference number.

SAVE allows to save the log file in an USB key.

The recommended maintenances are described in a table section 9.1.1.

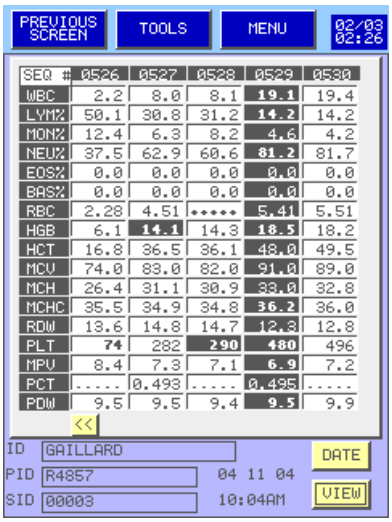
5.10 ARCHIVE



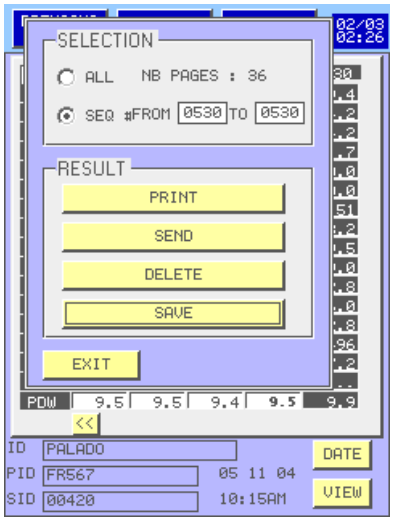
MYTHIC 22 CT can save more than the last 500 patients with results, alarms, distribution curves in the internal memory and until a maximum of 60000 results in a memory stick (USB key) of 512 Mbit or more (see section 3.4.7).

- Press RESULTS to enter the archive display.

5.10.1 Results



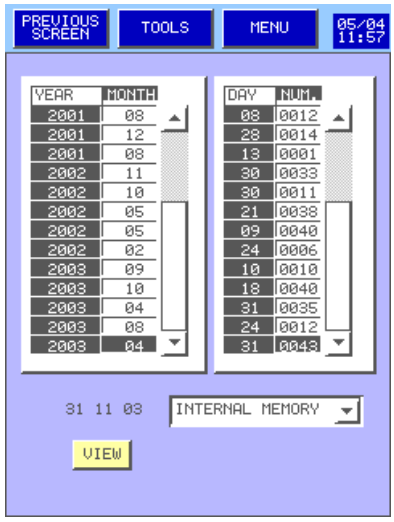
- The Archive display allows viewing the results of the analysis.
- The first column presents the name of the different parameters, the first line the result number.
- The results of the patients are presented in column.
- At the bottom of the display, under the table, the **ID**, **PID**, **SID**, **SEQ** number, date and time of the selected patient (dark background) are presented for each result selected.
- The button << >> , located under the table, allows changing pages.
- To find a result in the list, select the **SEQ** number wanted, press RES
- To view an entire result, select the **SEQ** number wanted, press VIEW
- To print, send, delete or save (in an USB key) results press TOOLS
- DATE allows to accede to the results date list.

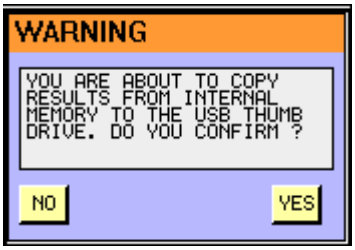


- It is possible to print, send, delete or save (in a USB key) :
  . All results: Press ALL
  . NB PAGES : 36 for printing.
  . Selected results: Select the first and the last results:
  SEQ #FROM 0530 TO 0530

- Then press on PRINT SEND DELETE or SAVE

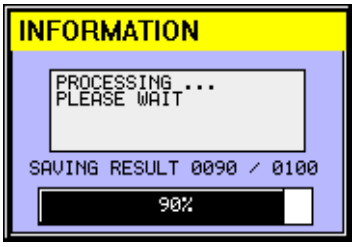
NOTA : the printed report is a **list** of all selected patients.





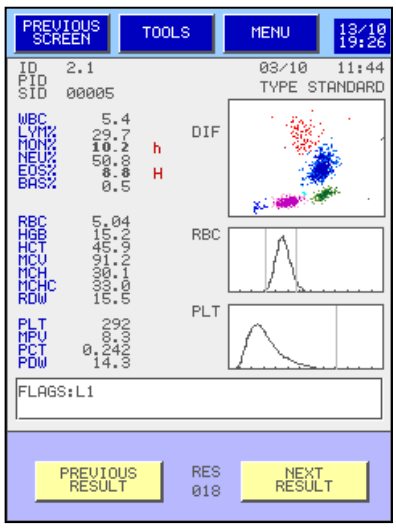
- This prompt appears to confirm the storage in the USB key.

	**If you press YES the selected results will be deleted from the internal memory and stored in the USB key.**



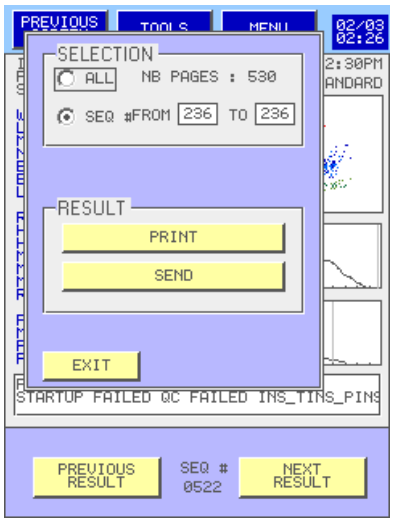
- This prompt allows following the storage.

5.10.2 View



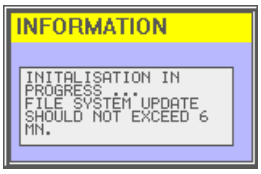
- Keys PREVIOUS RESULT and NEXT RESULT allow displaying each result and its identification.
- To print, send or delete a result, press TOOLS
- The effects of the **TOOLS** key are as described in section 5.10.1.
- The printed report is full page with one or two results per page.

- To come back to the archive main page, press PREVIOUS SCREEN.
- To come back to the Main Menu press MENU.



- It is possible to print or send:
  . All results: Press ALL
  . NB PAGES : 36 for printing.
  . Selected results: Select the first and the last results:
  SEQ #FROM 0530 TO 0530

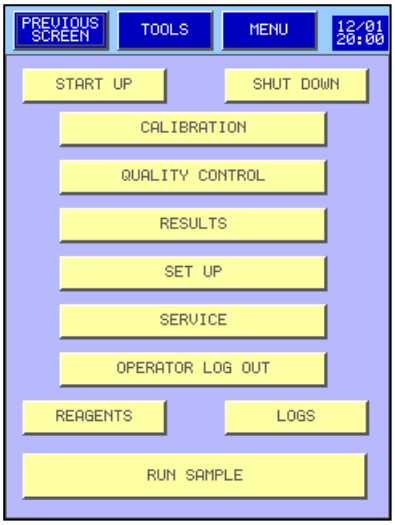
- Then press on PRINT or SEND



This message appears when you exit the result screens and it could stay up to 6 mn to enable the update of all the files.

5.11 STAND BY AND SHUT DOWN

NOTA: It is recommended to switch off the MYTHIC 22 if it is not use for several hours consecutives.



- From the main menu, press SHUT DOWN. **MYTHIC 22** automatically performs a shut down cycle.
- All the hydraulic circuits are rinsed, and then cleaned with the cleaning solution.
- At the end of the cycle, **MYTHIC 22** automatically stop.
- Shut Down can be automatically performed after a setting time (see section 3.4.6)

NOTA: After a shut down, it is impossible to perform an analytical cycle without launching a start up cycle. (See section 5.2)

MYTHIC 22 must stay at rest with cleaning solution during three hours every 24 hours.

6. QUALITY CONTROL

6.1 INTRODUCTION

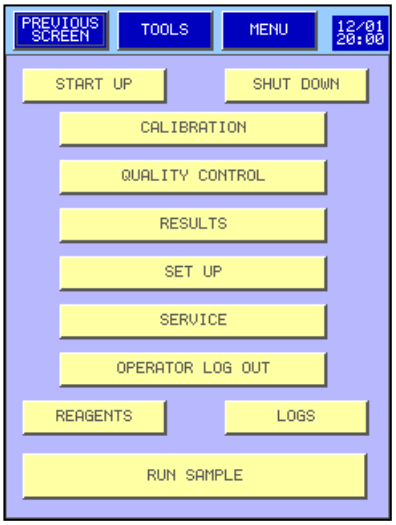
Quality control allows checking the stability of the **MYTHIC 22** analytical performances when operating.

	**The control blood must be used before its expiry date and stored according to the manufacturer instructions for use. It must be well-mixed before use.**

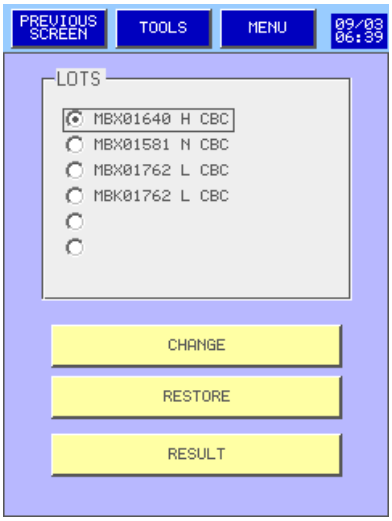
In case of no local regulation, it is recommended to run a control blood at the beginning of each working day before running sample.
In case of exceeding the tolerances indicated on the blood control result sheet, it is recommended to perform a Cleaning cycle (see section 9.1.2) followed by a STARTUP cycle.
If result still exceeding the tolerances indicated on the blood control result sheet, it is recommended to perform a calibration (see section 7).

6.2 QC

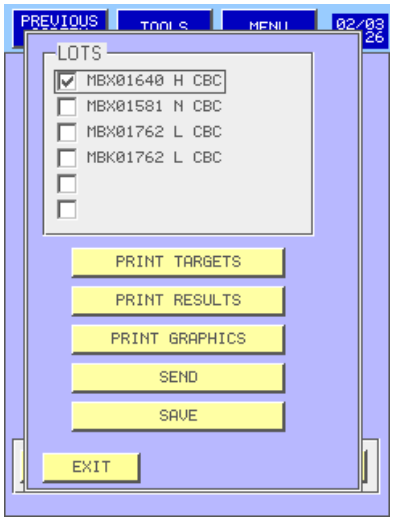
MYTHIC 22 stores in memory up to 100 results per lot, for 6 different lots. Results of each lot can be viewed in tables and Levey-Jennings graph.



- Press QUALITY CONTROL to have access to the quality control menu.



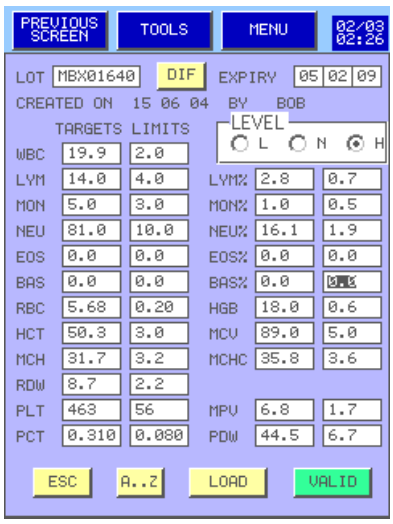
- Quality control display presents the identification of the lots.
- The last active lot is labeled with a dark dot on the left lot.
- To choose another lot, press on the wished lot.
- The key CHANGE allows the modification of the identification and the target values.
- The key RESTORE allows restoring the data from a USB key.
- The key RESULT allows:
  . To view the result table.
  . To perform quality control analysis.
- To print, send or save the targets, results and graphics press TOOLS.



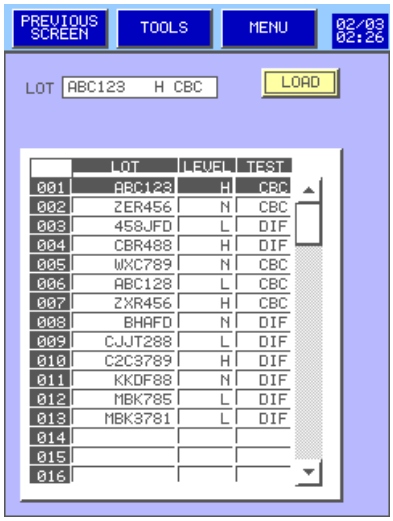
- Tag the lot number to select then press the appropriate button.

- SAVE allows to save the targets, results and graphics in the USB key.

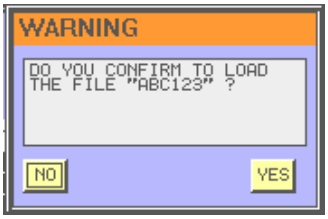
6.2.1 Change



- In this display, the user can enter the:
  - Lot number
  - Expiry date
  - Target values and tolerances
  - Level
- Press DIF to change the analysis mode.
- Press ESC to delete the modifications you made.
- Press VALID to validate your modifications or the loading.
- Press A..Z to change the Lot number.
- To print the targets and limits come back to the previous display.
- Press LOAD to load the target and tolerances values, the lot number and expiry date from a USB key.

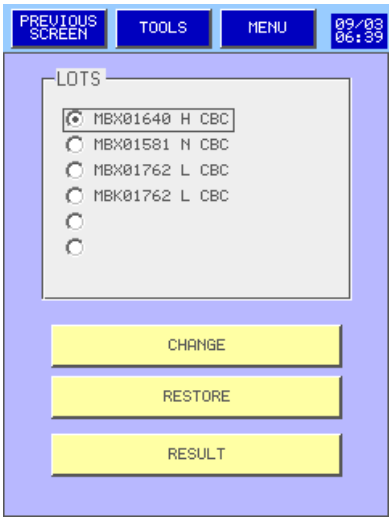


- Select the right lot then press LOAD



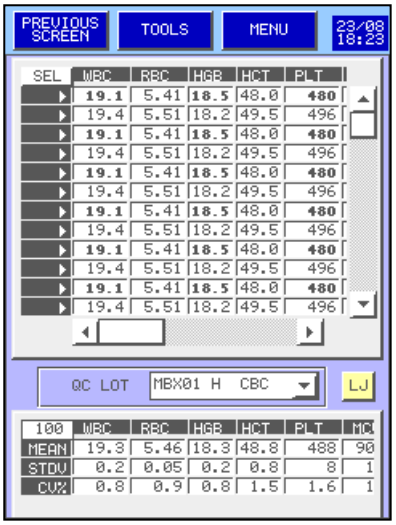
- Press YES to confirm.

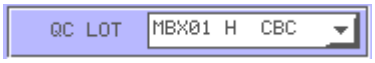
6.2.2 Run control blood

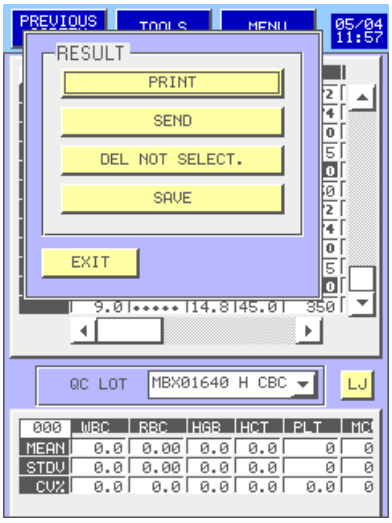


- Press RESULT to run the control blood.

	**Before to run the control, check and clean the opening of the cover dedicated to the down of the needle to avoid any fall of dry blood particles inside the control tube**



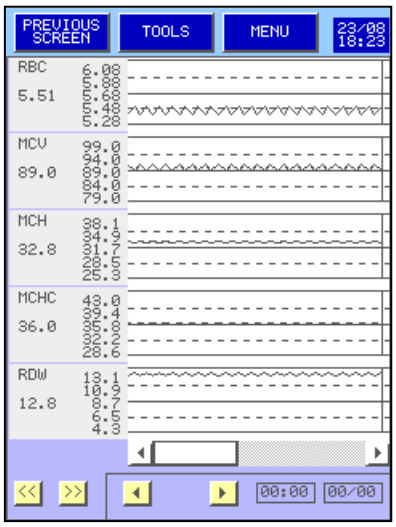
- To run quality control analysis:
  - Present the control blood under the sampling needle.
  - Press the start cycle trigger.
- The cycle LED  located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- Repeat this operation as long as needed.
- The results are displayed in line run after run.
- The statistic calculation are shown at the bottom of the display and are automatically done after each run.
- The cursor  allows displaying results for the other parameters
- The window  allows access to the results in memory for another blood control lot.
- The column SEL allows to validate or to unselect a result.



- To print, send, delete or save (in an USB key) a result, press TOOLS

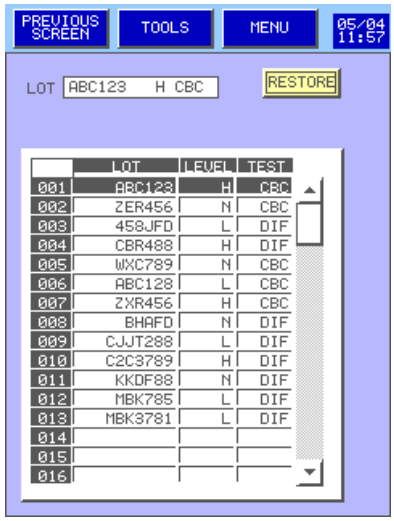
- Press LJ to open the Levey-Jennings graph screen.

6.2.3 Levey-Jennings graph

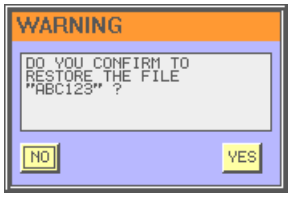


- This menu enables to display the Levey-Jennings graph for each quality control run.
- The column on the left shows each parameter with the target values and the limits. The value under the name of the parameter is the value where the cursor is located on the graph.
- The keys << and >> enable to display the other results.
- The cursor located under the graph enables to display all the registered results.
- The keys 076 enable to move the cursor; the number is the number of the result
- 00:00 00/00 give the date and the time of the displayed result.

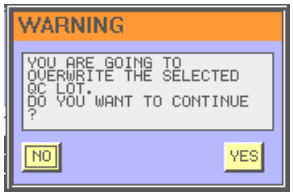
6.2.4 Restore



- This menu enables to restore all the information (results and targets) for the file selected from the USB key to the internal memory.

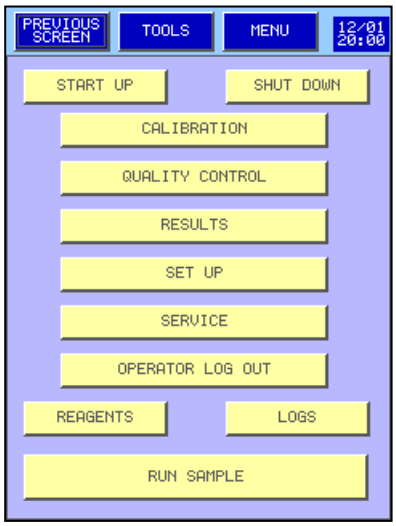


- Press YES if you are sure to load the selected file.

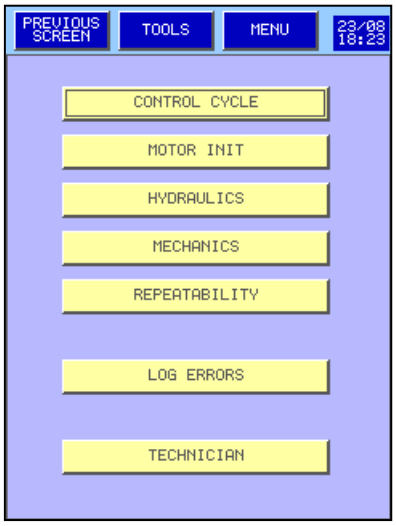


All the information of the selected file will be overwrite by the one from the USB key.

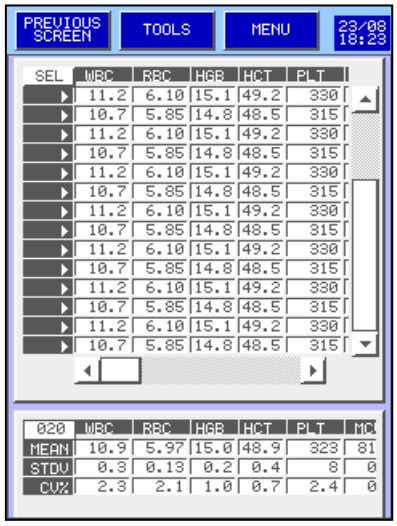
6.3 REPEATABILITY



- To run repeatability, press first SERVICE

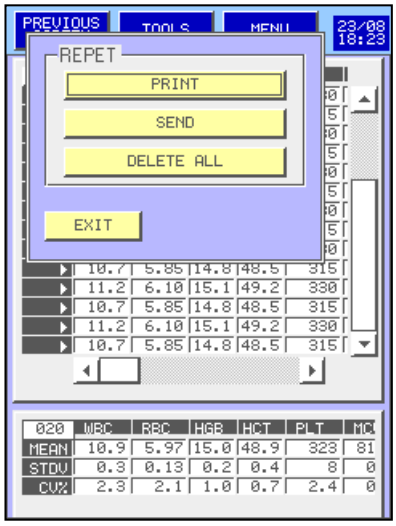


- The key REPEATABILITY allows having access to the repeatability display.



This screen allows carrying out a test of repeatability on all the parameters measured by the **MYTHIC 22**.

- Present the sample under the sampling needle and press in the trigger located behind the needle.
- The cycle LED  located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- Repeat the operation as many times as desired (maximum **20** runs).
- The results are progressively sent on line in the table.
- Statistical calculations are automatically carried out with each run.
- The cursor located between the two tables enables to send the other results (the results of statistical calculations move at the same time).
- The column SEL allows to validate or to unselect a result.



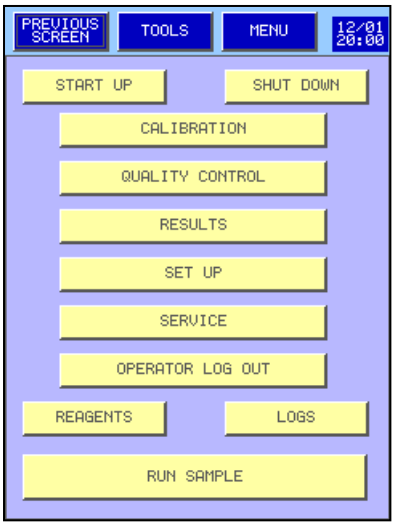
- The key TOOLS allows carrying out the following actions:
  - o Print the table.
  - o Send the results.
  - o Delete the results.

7. CALIBRATION

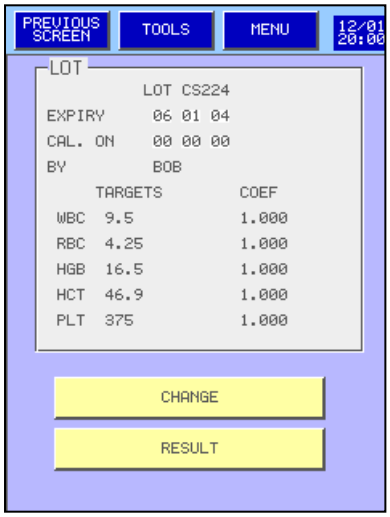
	**The calibration of the MYTHIC 22 should be carried out only if the QC carried out on a blood control used under the recommended conditions, is out of the limits to a significant degree (see section 6).**

	**Before the launch of a calibration, make sure that the analyzer is ready for use. Do not hesitate to run a cleaning cycle followed by a STARTUP cycle.**

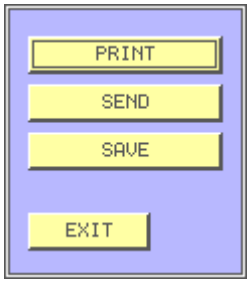
	**The calibration blood must be used before its expiry date, be mixed and stored in accordance with the instructions of use recommended by the manufacturer.**



- To reach the screen Calibration, press the key CALIBRATION from the main menu.



- This menu sends the following information:
  - Lot number of the last used calibrator.
  - The expiry date of the current lot.
  - The last date of calibration.
  - The operator name.
  - The target values.
  - The current coefficients of calibration.
- Press CHANGE to enter new values or to modify the values
- Press RESULT to calibrate
- Press TOOLS then



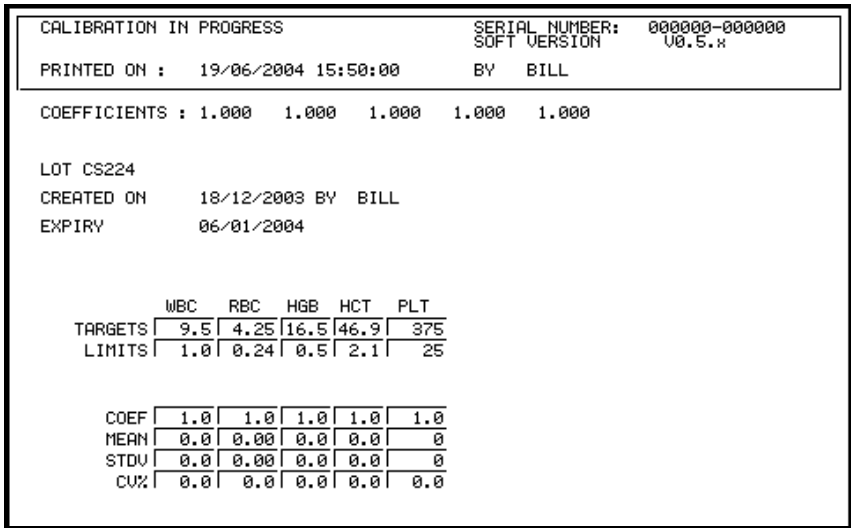
PRINT, to print these information (see the print out report above).

SEND, to send these information.

SAVE to store these information in the USB key.

NOTA: If the **M** letter appears on the right of the date of calibration, that means that the last calibration was done by modification of the calibration factor (see section 3.4.5)

Model of print out calibration report:



CALIBRATION IN PROGRESS — SERIAL NUMBER: 000000-000000 — SOFT VERSION V0.5.x

PRINTED ON : 19/06/2004 15:50:00 BY BILL

COEFFICIENTS : 1.000 1.000 1.000 1.000 1.000

LOT CS224

CREATED ON 18/12/2003 BY BILL

EXPIRY 06/01/2004

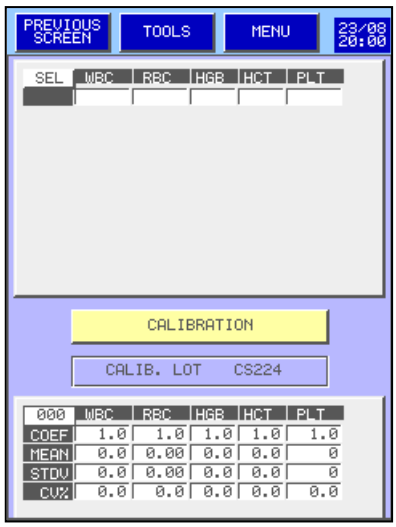
	WBC	RBC	HGB	HCT	PLT
TARGETS	9.5	4.25	16.5	46.9	375
LIMITS	1.0	0.24	0.5	2.1	25

COEF	1.0	1.0	1.0	1.0	1.0
MEAN	0.0	0.00	0.0	0.0	0
STDV	0.0	0.00	0.0	0.0	0
CV%	0.0	0.0	0.0	0.0	0.0

7.1 RESULTS

7.1.1 Calibration blood analysis

This screen allows carrying out analysis on calibration blood to perform the **MYTHIC 22** calibration.



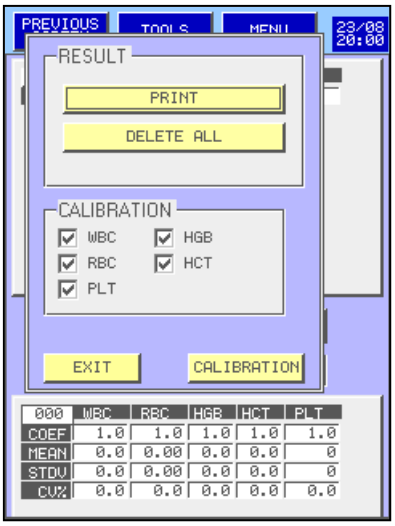
- Present the calibration tube under the sampling needle and press the trigger behind the needle.
- The cycle LED  located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- The results are progressively sent on line in the table.
- Repeat the operation as many times as desired (maximum **10** runs).
- Statistical calculations are carried out automatically with each run.
- The window CALIB. LOT CS224 located between the results and the statistical calculation reminds the lot number of the calibrator.
- The column SEL allows to validate or to unselect a result.
- To calibrate press CALIBRATION or TOOLS.

Before to run the calibrator, check and clean the opening of the cover dedicated to the down of the needle to avoid any fall of dry blood particles inside the calibrator tube

NOTA: The results of the analyses carried out on one calibrator during the same day remain with the screen and are used in calculations if they are selected.

7.1.2 Calibration

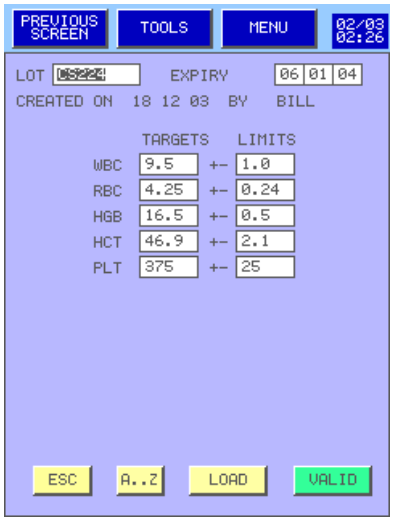
	**Before to start the calibration, unselect the results which you do not wish to use for the calculation of the calibration (See below section 7.1.1).**



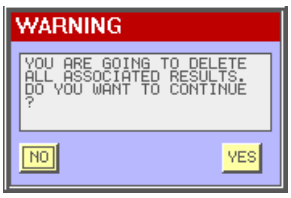
- The key CALIBRATION or TOOLS allows:
  - To calibrate with the selected results.
  - To delete the results. Press DELETE ALL
  - To print the results. Press PRINT (see below the print report)

- To calibrate one or more parameters:
  - Select the parameter
  - Press the key CALIBRATION

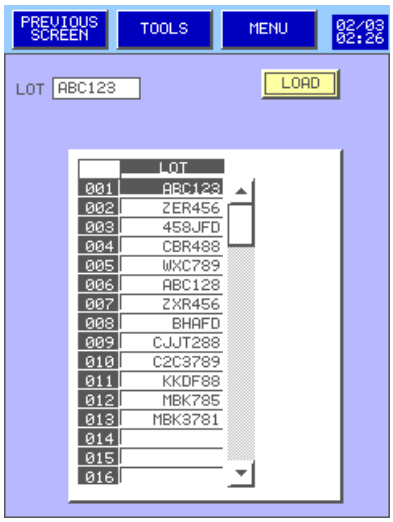
7.2 TARGET VALUE MODIFICATIONS



- To modify information relative to a batch or to create a new batch, please follow the following steps:
  - From **Calibration Menu**, press CHANGE.
  - Select the lot number LOT CS224
  - To modify the lot number press A..Z
  - Select the field to be modified.
  - Enter your new value with the numerical keyboard or with the alphabetical keyboard.
  - Press VALID to validate your modifications or the loading.
  - Press ESC to leave the menu without modification.
  - Press LOAD to load the target and tolerances values and expiry date and lot number from a USB key.

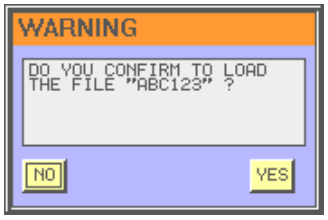


	**Any modification (lot number, date or target values) involves the deletion of all the associated results always in memory.**



- Plug the USB key then

- Select the right lot then press LOAD.



Press YES to confirm the loading of the target and tolerances values and expiry date and lot number.

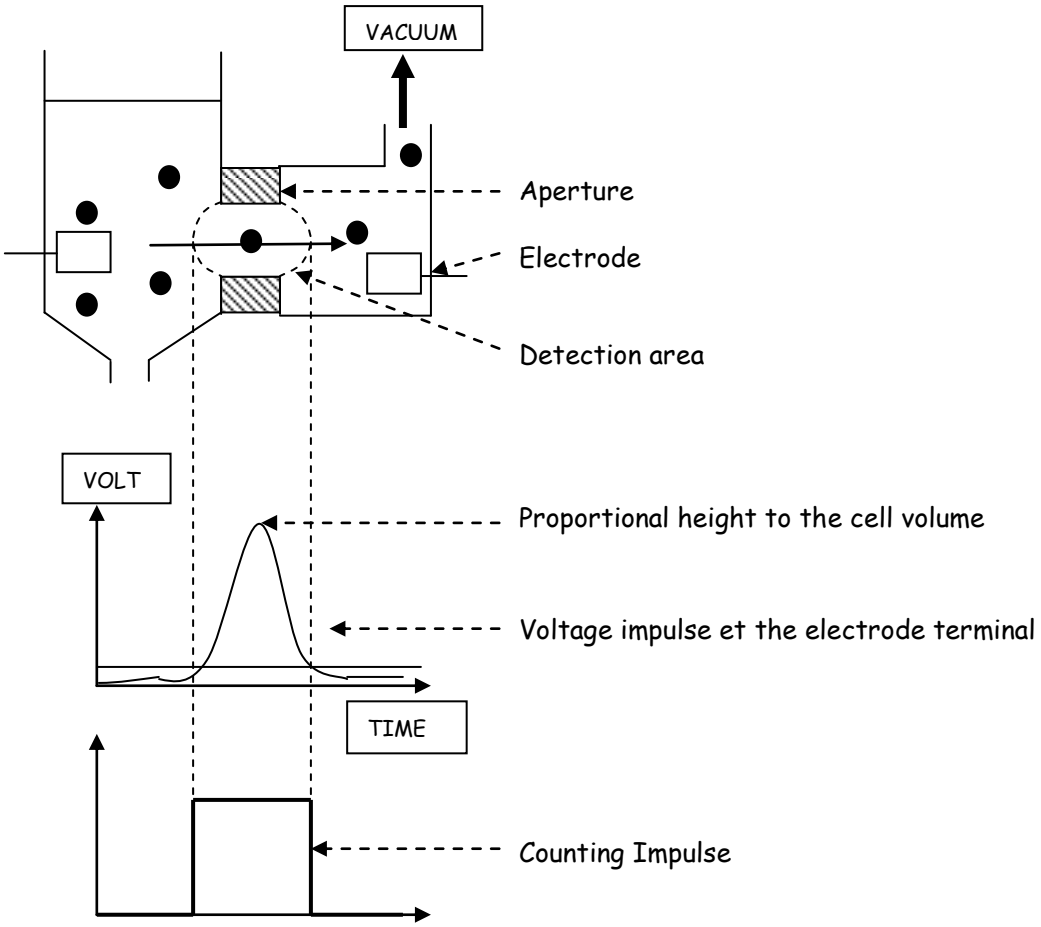
8. TECHNOLOGY

The innovative technology of the **MYTHIC 22** is covered by **six** pending patents. A new innovative concept of optical measurement system and an unique lysing reagent were developed to obtain a so small and powerful analyzer.

8.1 DETECTION PRINCIPLE

8.1.1 WBC, RBC, PLT Counting

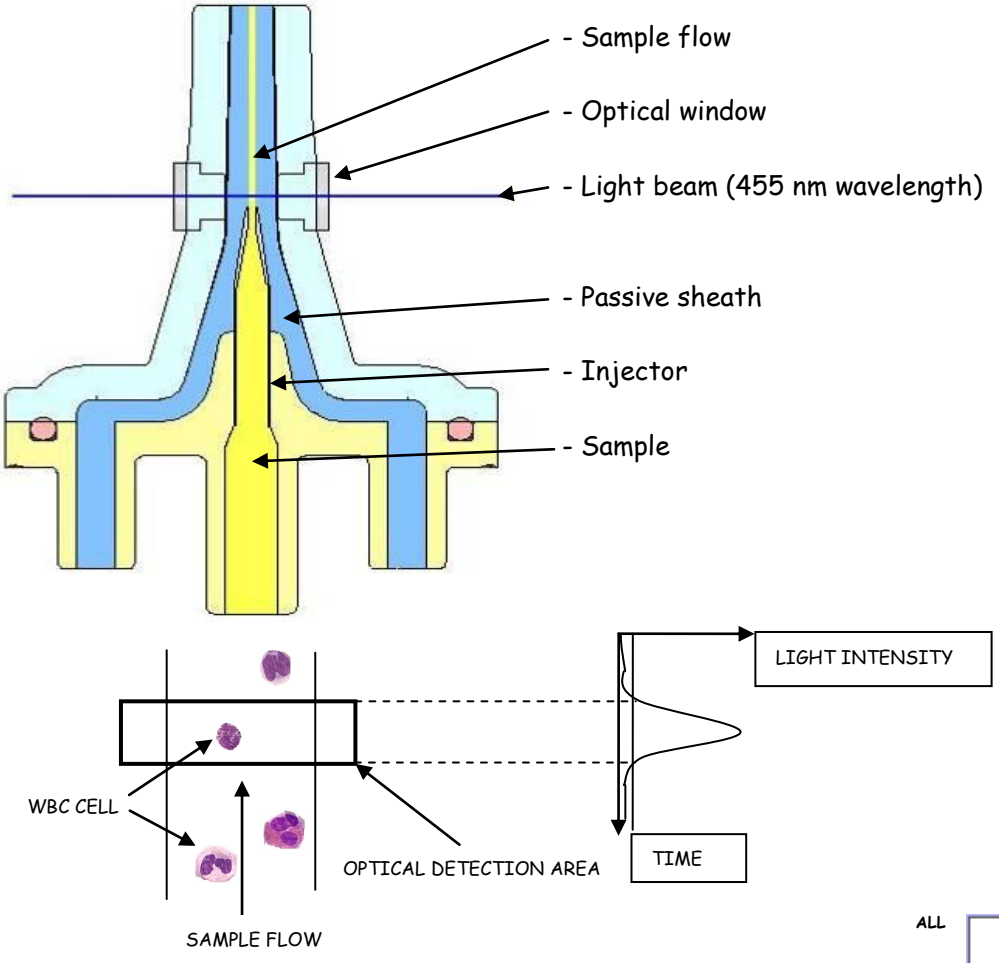
The counting of the cellular elements in a blood sample is done with the impedancemetry technique.
This technique is based on the modification of the impedance of a calibrated aperture soaking in an electrolyte and going through a constant course delivered by two electrodes located on both sides of the aperture.
A vacuum applied on a side of the aperture allows the cells passage. They oppose their physical volume to the course passage. A voltage impulse is registered at the electrodes terminal. The height of this impulse is proportional to the cell volume.



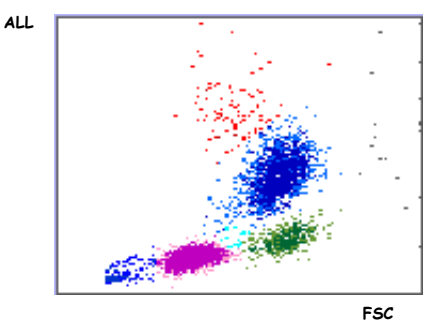
8.1.2 Five part diff measurement

The innovative optical detection system is covered by two patents pending. This technology (called **OCHF** for **O**ptical **C**ytometer **H**ydrofocus **F**ree) is based on an unique and innovative concept of an active sample flow and a passive sheath.
The sample flow is introduced in the flow cell under pressure and the sheath is only dedicated to maintain it. This principle enables to introduce a large quantity of sample and to use a great dilution rate (which allows doing the Hemoglobin measurement with the same dilution).
The main advantages are:

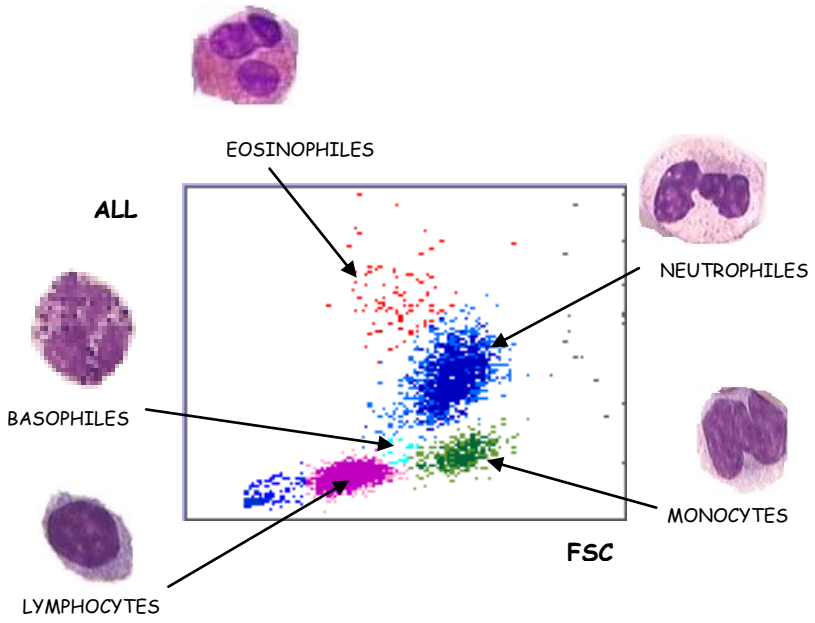
- High level of reliability of the optical adjustment.
- Only two measurement axes for five parameters.
- High resolution matrix.
- Only one passive sheath with low reagent consumption.
- No hydro focusing system.
- Low level of contamination between two measurements.
- Very low cost flow cell (injected plastic).



For each cell throwing the optical detection area, two pulses are generated, one for the Axis Loss Light (ALL) measurement and one for the Forward Side SCatter (FSC) measurement.
The result of those two axes of measurement is the high definition matrix that enables to identify five WBC populations.



The five part diff is obtained by the optical matrix analysis after action of the lytic reagent (pending patent). This reagent destroys the RBC and their stromas, composes the oxy hemoglobin chromogen and protects the white blood cell membrane to keep it in closed native state.



8.1.3 Hemoglobin measurement

The hemoglobin measurement is directly done in the WBC chamber, by spectrophotometry at 555 nm. Hemoglobin is detected by formation of a chromogen oxy hemoglobin type (cyanide free technique).
A measurement of the blank of hemoglobin is done for each analytic cycle and during the start up rinsing step.
An automatic offset circuit for the LED 555 nm allows maintaining the blank level at the same range. It is not necessary to adjust this range with a potentiometer.

8.2 LEUCOCYTE ANALYSIS

The leukocyte number analysis is done by impedancemetry in the WBC counting chamber, the other ten parameters are obtained by flow cytometry measurement (see section **8.1.2**) :
All the thresholds of the differential are adjustable in the 20 blood types (see section **3.4.4.2**)

Parameters		Pathologies (adjustment section **3.4.4.1**)
WBC	White Blood Cells	Leucocytosis : WBC>WBC h Leucopenia : WBC<WBC b
LYM%	Lymphocytes in percentage	Lymphocytosis : LYM>LYM h (% &/or #) Lymphopenia : LYM<LYM b (%&/or #)
LYM#	Lymphocytes in value	
MON%	Monocytes in percentage	Monocytosis : MON>MON h (%&/or #)
MON#	Monocytes in value	
NEU%	Neutrophils in percentage	Neutrophilis : NEU > NEU h (%&/or #) Neutropenia : NEU < NEU b (%&/or #)
NEU#	Neutrophils in value	
EOS%	Eosinophils in percentage	Eosinophilis : EOS > EOS h (%&/or #)
EOS#	Eosinophils in value	
BAS%	Basophils in percentage	Basophilis : BAS > BAS h (%&/or #)
BAS#	Basophils in value	

8.3 ERYTHROCYTE ANALYSIS

The erythrocyte analysis is done by impedancemetry in the RBC counting chamber and by analysis of the hemoglobin inside WBC chamber as previously described. Seven parameters are obtained:

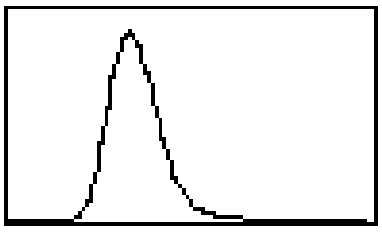
Parameters		Pathologies (adjustment section 3.4.4.1)
RBC	Red Blood Cells	Erythrocytosis : RBC>RBC h
HGB	Hemoglobin	Anemia : HGB < HGB b
HCT	Hematocrit	
MCV	Mean Corpuscular Volume	Microcytosis : VMC<VMC b Macrocytosis : VMC>VMC h
MCH	Mean Corpuscular Hemoglobin	
MCHC	Mean Corpuscular Hemoglobin Concentration	Hypochromia : MCHC<MCHC b Cold Agglutinin : MCHC>MCHC h
RDW	Red blood cells Distribution Width	Anisocytosis 1 : RDW>RDW h1

Hematocrit (**HCT**) is measured by integration volume of all of the red blood cells which flow in the RBC counting chamber aperture.
MCV is obtained by calculation, following the formula:

$$\mathbf{MCV} = \frac{HCT \bullet 10}{RBC}$$

The RBC distribution curve analysis allows the measurement of **RDW**. RDW is an expression of the standard deviation divided by MCV. This parameter evaluates the RBC anisocytosis.

$$\mathbf{RDW} = \frac{k \bullet SD}{MCV}$$



Wintrobe constant calculation:
The Mean Corpuscular Hemoglobin (MCH) calculation is made from HGB and RBC by the formula below :

$$\mathbf{MCH} = \frac{HGB \bullet 10}{RBC}$$

The Mean Corpuscular Hemoglobin Concentration (MCHC) is made from HGB and HCT by the formula below :

$$\mathbf{MCHC} = \frac{HGB \bullet 100}{HCT}$$

8.4 ANALYSIS OF PLATELETS

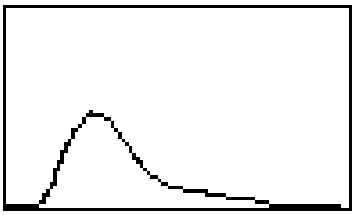
Platelet analysis is made by impedancemetry in the RBC counting chamber at the same time with red blood cells. Four parameters are obtained:

Parameters		Pathologies (adjustment section 3.4.4.1)
PLT	Platelets	Thrombopenia : PLT<PLT b Thrombocytosis : PLT>PLT h
MPV	Mean Platelet Volume	Giant platelets : MPV> MPV h
PDW	Platelet Distribution Width	
PCT	Thrombocrit	

The analysis of the platelet distribution curve allows measuring the Mean Platelet Volume (**MPV**) and the Platelet Distribution Width (**PDW**).

Thrombocrit (**PCT**) is made from PLT and MPV by formula below:

$$\mathbf{PCT} = \frac{PLT \bullet MPV}{10000}$$



8.5 FLAGS

MYTHIC 22 CT manages 25 different flags. These flags allow the user to be alerted if there is a problem which can affect the quality of the results. All of these flags appear on the right of the result.

In presence of one or more flags, it is recommended to check the result by a conventional measure or on blood smear.

NOTA: Most of these flags can be modified by the user (see section 3).

8.5.1 General Flags

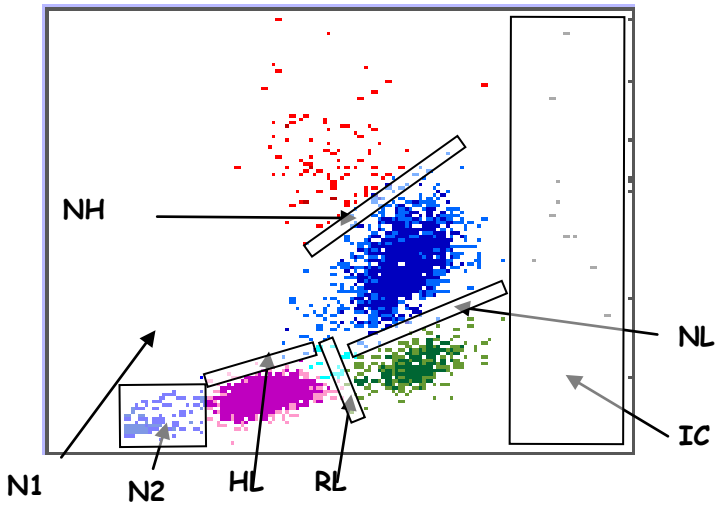
The following alarms are common for all parameters.
XXX *****: Counting or measure rejection. It can appear with WBC, RBC, PLT and HGB (see section 8.5.3 for HGB and section 8.5.2 for DIF parameters).
XXX**D**: Higher than linearity limits but lower than the reportable limits. WBC, RBC, PLT, HCT, HGB.
+++D: Higher than the reportable limits. WBC, RBC, PLT, HCT, HGB.
----: Rejected value.
h: results higher than normal value.
b: results lower than normal value.
H: results higher than panic value.
B: results lower than panic value.

8.5.2 Instrument Flags

W_CL: Suspicion of WBC aperture clog, if it persists runs a concentrated cleaning (see section 9.1.2).
R_CL: Suspicion of RBC aperture clog, if it persists runs a concentrated cleaning (see section 9.1.2).
O_CL: Suspicion of Optical injector clog, if it persists runs a concentrated cleaning (see section 9.1.2).
OPT- : Counting gap between resistive and optical WBC count, if it persists run a concentrated cleaning (see section 9.1.2).
INS-H: HGB channel saturation, run a START UP cycle.
INS-T: A temperature (enclosure, reagents or ambient) is out of range (see section 9.5.2)
INS-P: Pressure default (see section 9.5.2).

8.5.3 Leucocytes Flags

SCATTERGRAM FLAGS:



All the followings flags levels are adjustable in the 20 types of blood (see section 3.4.4).

Number of cells in a zone:

N1 (**N**oise **1**): Presence of platelet aggregate, debris or resistant RBC

N2 (**N**oise **2**): Presence of platelet aggregate, erythroblast or small lymphocytes.

IC: Presence of **I**mmature **C**ells (from the mono or polynucleated cells line)

Number of cells located of each side of the threshold:

RL (**R**ight **L**ymphocytes: Presence of atypical lymphocytes or basophiles.

HL (**H**igh **L**ymphocytes): Presence of basophiles, small Neutrophils (without granulations or few segmented), band cells.

NL (**N**eutrophils **L**ow): Presence of small Neutrophils (without granulations or few segmented), band cells or hyper basophil Monocytes.

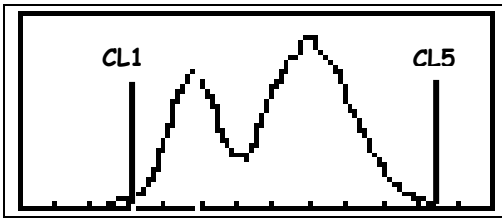
NH (**N**eutrophils **H**igh): Presence of giant Neutrophils, hyper segmented Neutrophils, eosinophils with few granulations or damaged eosinophils.

	**These flags may appear if the blood was not store in good conditions or if it was sampled too much (more than 10 times).**

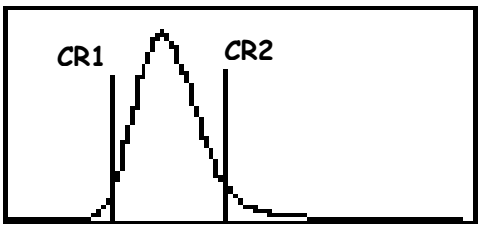
DIF parameters display rules:

- If one or more DIF parameters (LYC, MON, NEU, EOS or BAS) are following with a star (XXX *) the sample must be checked on smear.
- Basophile result must be checked on smear if it is following by a star (XXX *).

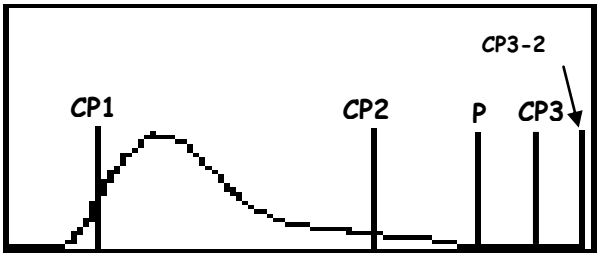
WBC CURVE FLAGS:
This curve is done by the WBC channel measurement and does not appear on the normal results screen. The flags L1 and L5 complete the flags N2 and IC.

	**L1** = Presence of platelet aggregate, erythroblast or small lymphocytes at the left of **CL1**. **L5** = Presence of immature cells at the right of **CL5**.

8.5.3 Erythrocyte and HGB Flags

	**R1** = Abnormal quantity of microcytes at the left side of **CR1**. **R2** = Abnormal quantity of macrocytes at the right side of **CR2**. **HGB: *** means bad measure of the HGB blank.

8.5.4 Platelet Flags

	**P1** = **0** to **CP1**: Presence of abnormal quantity of debris or small cells. **P2** = **P** to **CP2**: Presence of schizocytes. **P3** = **CP3** to **CP3-2**: Presence of microcytes.

8.5.5 QC Flags

QC_F: QC Failed means that the results are outside the limits entered for one or several parameters (see section 6.2.1).
QC_ND: QC Not Done means that the Quality Control has not been done or that the analysis are done with QC results outside the limits (see section 6.2.1).

8.5.6 STARTUP Flags

SU_F: STARTUP Failed means that the results are outside the limits for one or several parameters (see section 5.4).
SU_ND: STARTUP not done means that the Start Up has not been done or that the analysis are done with results of the Start Up outside the limits (see section 5.4).

8.6 HYDRAULIC DESCRIPTION

The hydraulic part of the **MYTHIC 22** is very simple and made of these modules:

- Sampling module.
- Counting bath module.
- Syringes module.
- Optical manifold.
- Optical bench.

The modules are connected together by semi rigid tubing.

8.6.1 Sampling module

This module (patent pending) enables to draw the sample and to perform the WBC and RBC/PLT dilutions.
It is assembled with a rotating rocker moving around a support which maintains the system to move up and down the sampling needle.
A very reliable system of rack-gear moves the rocker.
The cleaning system of the sampling needle can be removed without tool (see section **9.3.2**).
The o-ring of the needle included in the cleaning system can also be removed without tool (see section **9.3.2**).
The maintenance of these parts is very easy to perform.

8.6.2 Counting bath module

This module allows to count the WBC and RBC/PLA and to measure the HGB.
It is made with a manifold maintaining the reagent commutation valves and the counting bath block with their measurement block including the apertures.
The counting bath block assembly and these apertures can be removed without tool (see section **9.3.3**/**4**/**5**).

8.6.3 Syringes module

This module (two patents pending) enables:

- to draw the sample
- to distribute the reagents
- to drain the baths
- to do the vacuum necessary for counting
- to push the waste to the waste container
- to push the WBC sample and the diluent sheath in the flow cell .

It is made with a manifold maintaining the fluid commutation valves and with the syringes bloc including five syringes :

- The sampling syringe
- The lysis syringe
- The two waste and vacuum/pressure syringes
- And the diluent syringe.

Only one motor drives the five syringes.
The diluent input and the waste output are also included in this manifold.

8.6.4 Optical manifold

This manifold allows driving the different reagent toward the counting bath module or toward the optical bench. It maintain seven commutation valves

8.6.5 Optical bench

This very important part (two pending patents) allows to measure the leucocytes sub population.
It is made of three parts:
- An illumination module: which contain the semi conductor light source, a beam adjustment glass smear, and lens.
- A flow cell: made in injected plastic in which the sample and the passive sheath flow away.
- And the detection module: which contains lens, a beam separation glass smear, photodiodes and the amplifier boards for the two measurement axes.

8.8 SOFTWARE

8.8.1 Windows

Common keys:

These three keys 

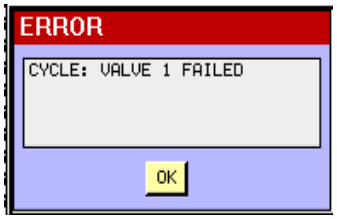
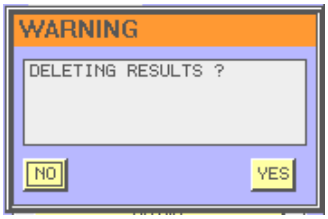
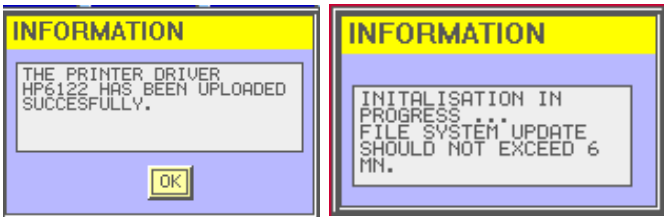
are always present in all screen

allows to come back to the previous display.

allows to come back to the MENU display where ever you are in the arborescence.

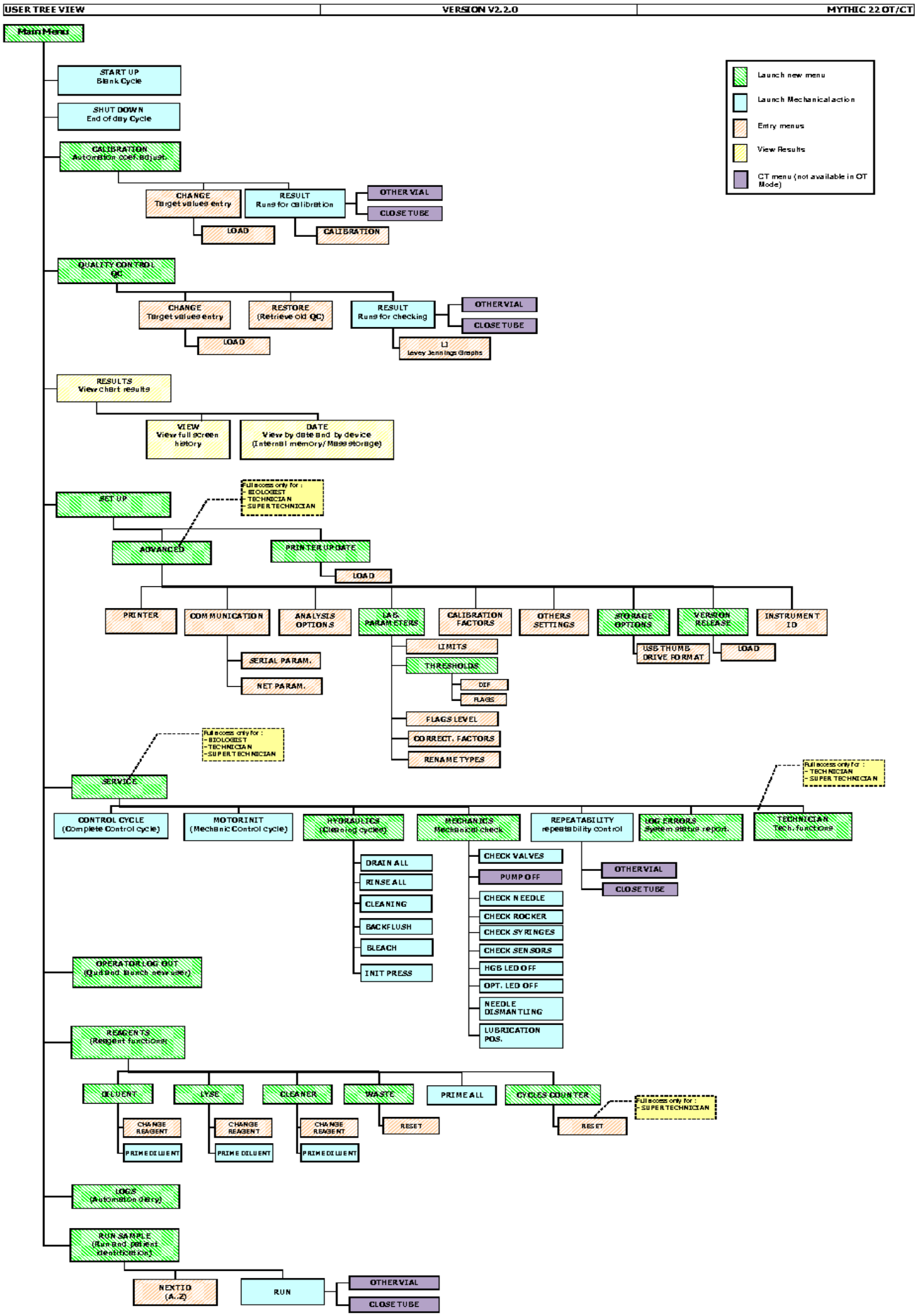
depends on the screen it allows to open a window dedicated to perform an action, for example to select information, to print, send or delete it.

Windows:

		
Means an **ERROR** occurred, it is mandatory to do the action describe in the window or in the table section 9.6.	**WARNING**: You have to confirm or not the action describe in the window.	**INFORMATION** window.

8.8.2 Menu tree

See next page.



9. SERVICE

The quality of the results and the reliability of the **MYTHIC 22** are directly linked to the strict respect of the maintenance hereafter described.

To perform the maintenance and the repair described in this section, it is mandatory to have received adequate training, to wear rubber gloves and wash hands with a disinfectant after completion of work.

9.1 MAINTENANCE

9.1.1 Maintenance table

NOTA: This table is made for an average number of **50** samples per day. **For more, please increase proportionally the number of maintenances**.

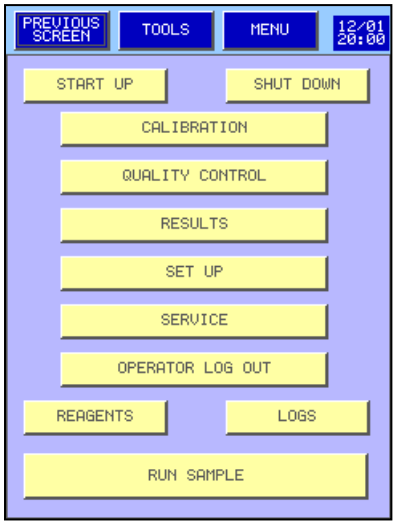
MAINTENANCE	DAILY		WEEKLY		QUARTERNALY		HALF A YEAR		ANNUALLY	
	User	Tech	User	Tech	User	Tech	User	Tech	User	Tech
Reagents level	X									
Start Up	X									
Automatic cleaning	X									
Concentrate cleaning			X							
Shut down	X									
Cover cleaning	X									
Piston greasing					X					X
Needle greasing					X					
Needle o-ring replacement										X
Syringes o-ring replacement										X
Motor screw greasing										X

- Reagents level control: see section 5.3
- Start up: see section 5.2
- Automatic Cleaning: The cleaning is automatically performed by the **MYTHIC 22** following the set up defined by the user (see section 3.3.6). (The standard value is 80).
Increase the frequency of the cleaning of the **MYTHIC 22** in case of analyzes of pathological samples or if there are too many flags and too often.
- Concentrated cleaning: see the following section 9.1.2
- Shut down: see section 5.11
- Cover cleaning: Clean the cover above and around the sampling needle with a wet paper with a disinfectant to eliminate the blood trace.
- Piston greasing: see section 9.1.3

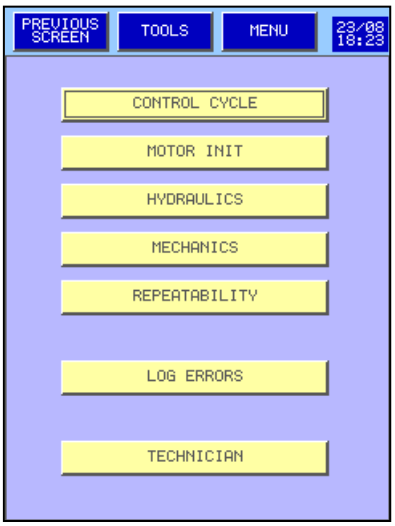
NOTA: Maintenance information's are registered in a log (see section 5.9).

9.1.2 Concentrate cleaning

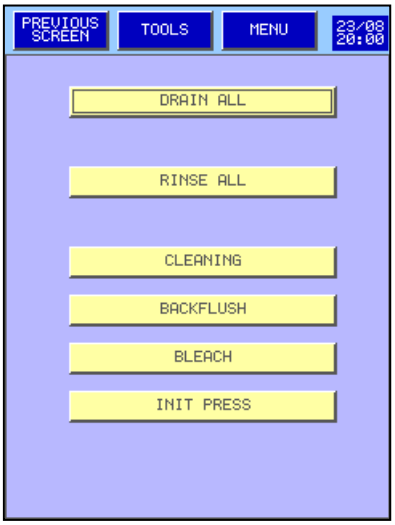
This cleaning is necessary once a week to clean the WBC and RBC baths or when **MYTHIC 22** is in permanent rejection for one measured parameter or if it give too much clog flags (see section 8.5.1).
Prepare a Sodium Hypochlorite solution at 12° in chloride (diluted 4 times with distilled water if sodium hypochlorite is concentrated at 48° in chloride or three times with 36°).



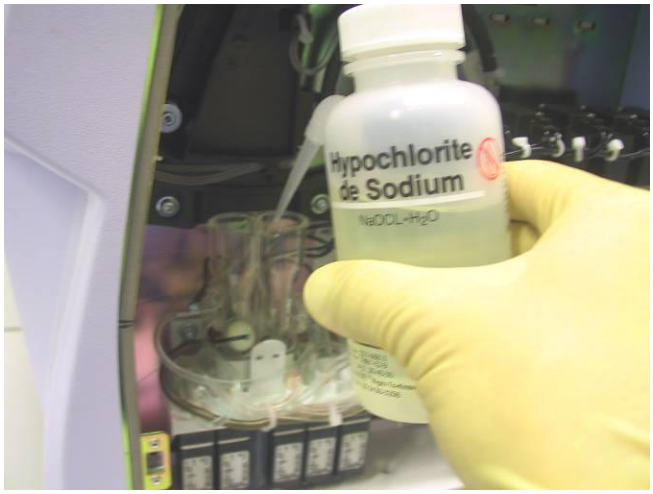
- Return to the main menu by pressing MENU.
- Then press SERVICE.



- Press HYDRAULICS.



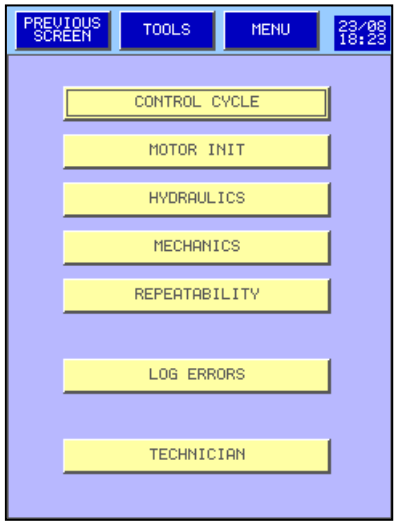
- Press BLEACH to start the cycle (drain the counting chamber).



- Open the door on the right side (see section 1.1.3).
- Put **3** ml of sodium hypochlorite solution in each counting chamber.
- Press the button in the window located in the screen center.
- **MYTHIC 22** performs a maintenance cycle of the apertures and the flow cell follow with a standby mode during 2 min.
- After 2 min. **MYTHIC 22** rinses all of the elements. Operator can perform an analytic cycle.

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

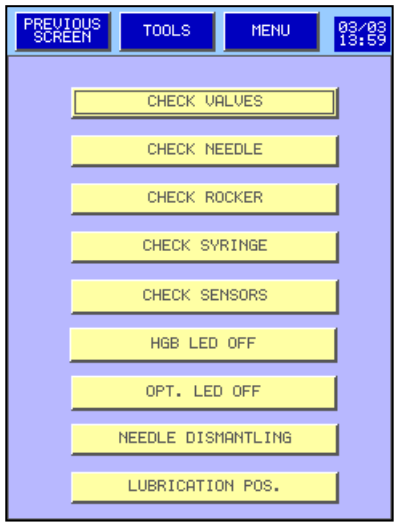
9.1.3 Piston greasing



- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, then press MECHANICS

NOTA: The greasing frequency must be increase proportionally to the number of samples per day (See maintenance table 9.1.1).

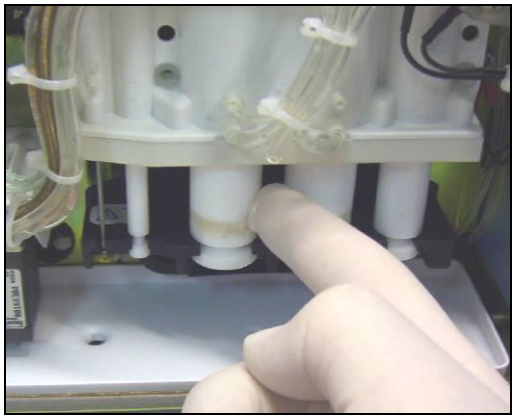
	Operators must be trained and to know that due to moving parts there is a risk to pinch their fingers between pistons and the syringe body.



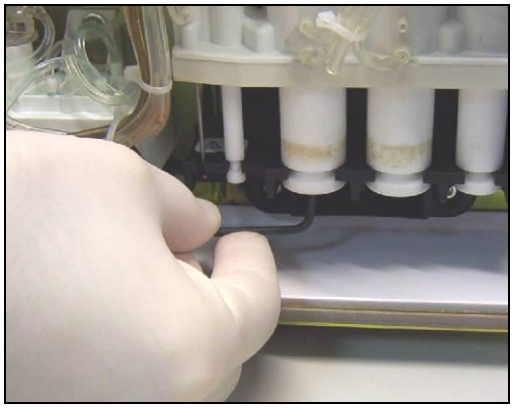
- Press LUBRICATION POS. to put the piston of the syringe module in the greasing position.

Wear rubber gloves and wash hands with a disinfectant after completion of work.

- Open the door on the right side (see section 1.1.3).
- Put a small nut of grease on a finger.

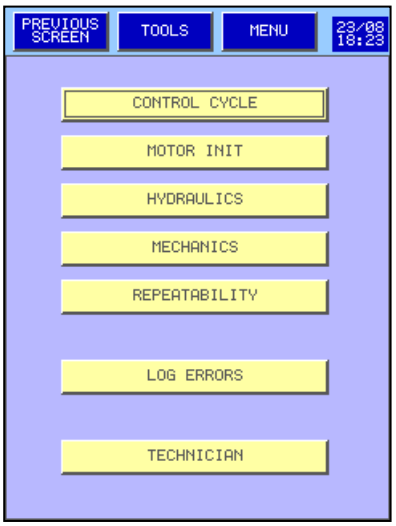


- Put a **THIN FILM** of grease around each piston.

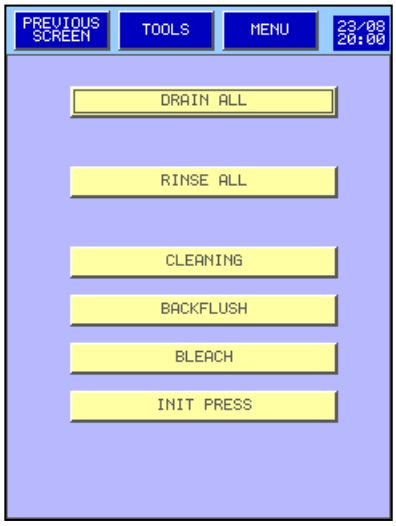


- Turn the two big pistons (waste pistons) with the help of the key supplied in the installation kit.
- Continue to put a thin film of grease around each piston.
- The other pistons can be turned with fingers.

9.2 HYDRAULIC CYCLES



- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, then press HYDRAULICS



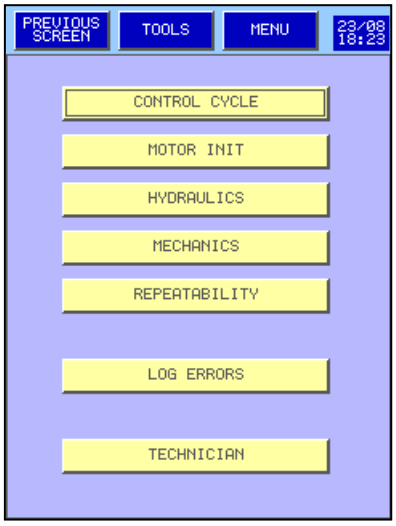
- To drain the counting baths the flow cell and the waste syringes, press DRAIN ALL

- To fill the counting baths and the flow cell with diluent, press RINSE ALL

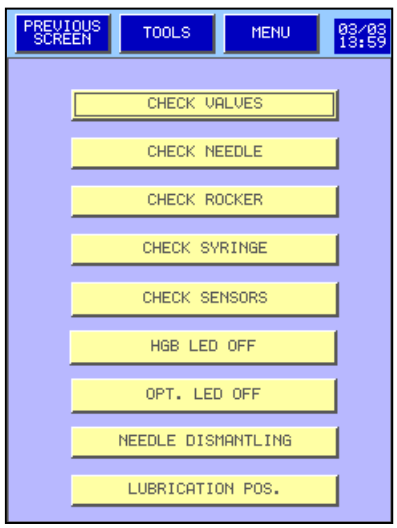
- To perform a cleaning of the aperture blocks and the flow cell with the cleaner, press CLEANING

- To perform a back flush in the aperture blocks and the flow cell, press BACKFLUSH

9.3 MECHANICS



- To have access to this cycle, press SERVICE from the **MAIN MENU**, then press MECHANICS



CHECK VALVES see below.

CHECK NEEDLE performs a complete test of the needle.

CHECK ROCKER performs a complete test of the rocker.

CHECK SYRINGE performs a complete test of the syringe.

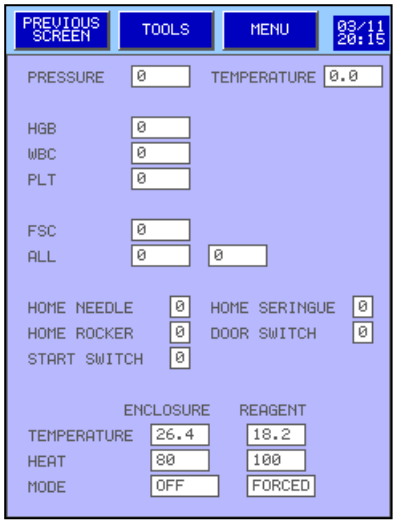
CHECK SENSORS see below.

HGB LED OFF switches on (or off) the HGB led to check it.

OPT. LED OFF switches on (or off) the optical led to check it.

NEEDLE DISMANTLING see section 9.4.2

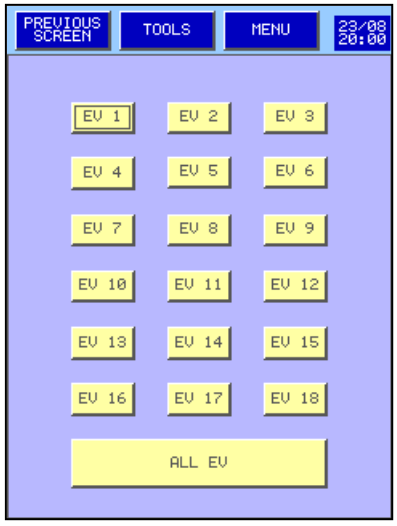
LUBRICATION POS. see section 9.1.3



- This screen allows checking if the different sensors are available in case of problem.

NOTA: To understand the function of each sensor we recommend to do an Orphée's training.

- Range of standard temperature measured by the sensors:
  Ambient: 17°C <--> 37°C
  Enclosure: 33°C <--> 40°C
  Reagents: 34°C <--> 45°C

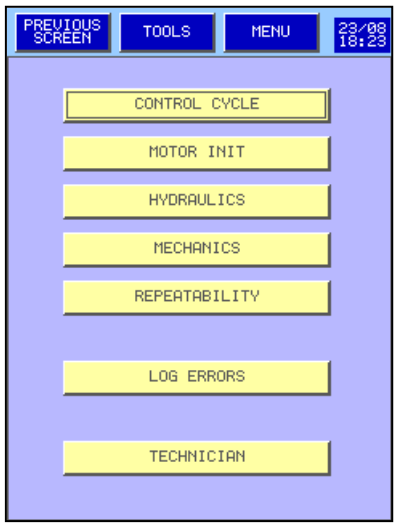


- To test each valve, press the dedicated button.

- To test all the valves press 

9.4 REPAIRING

9.4.1 Emergency stop



In case of mechanical or hydraulic problem, immediately press  , the **MYTHIC 22** will make an emergency stop.

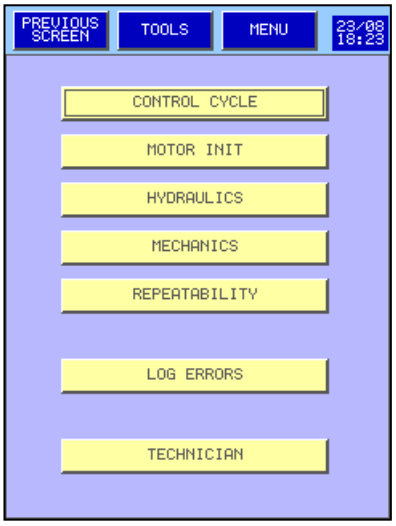
- After having identified the problem, it is necessary to perform a Control cycle.

- To have access to this cycle, press 

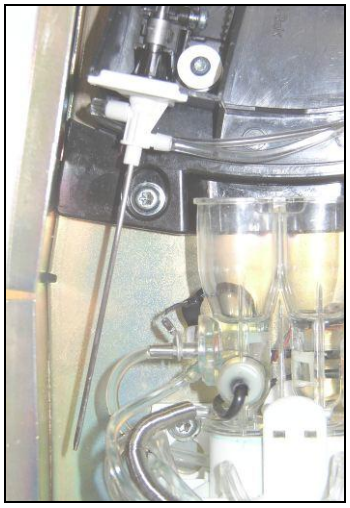
from the **MAIN MENU**, then press 

9.4.2 Needle or o-ring replacement

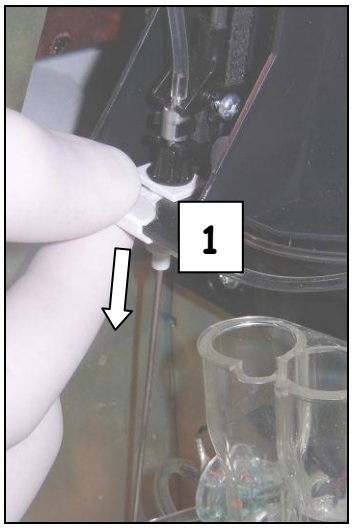
	**Wear rubber gloves and wash hands with a disinfectant after completion of work.**



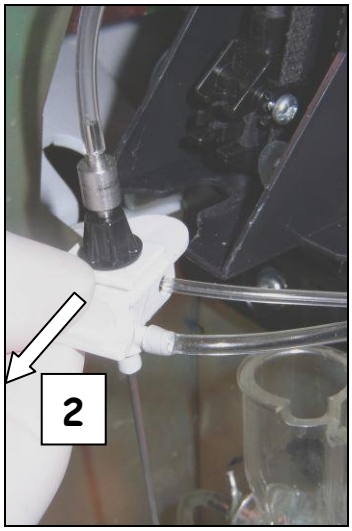
- From the main menu, press SERVICE then MECHANICS to go to the display described on the left.
- Press on NEEDLE DISMANTLING
- The rocker places the sampling needle in the disassembling position.
- Open the door located on the right side to have access to the hydraulic part.



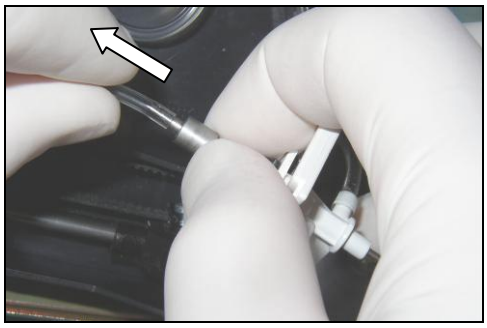
- The needle is in front of the counting chambers



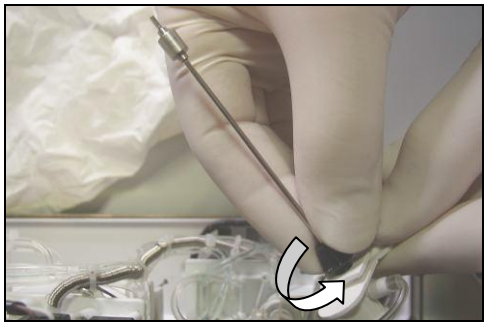
- Remove the sampling module, while slightly lowering the clip 1 to the bottom.



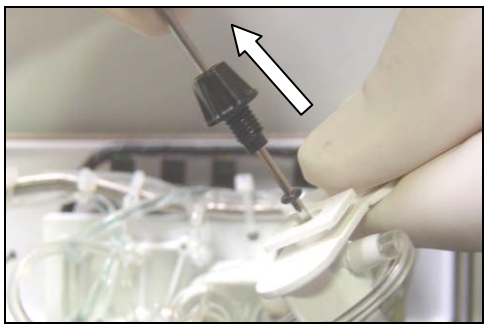
- Draw the system towards outside **2** .



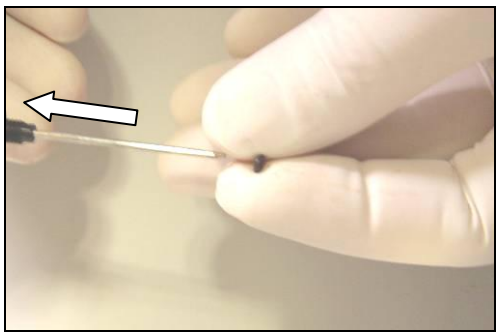
- Remove the tubing fixed at the end of the needle.



- Unscrew the serrated roller which maintains the seal and the needle.



- Leave the serrated roller, the needle and the o-ring from the rinsing head.



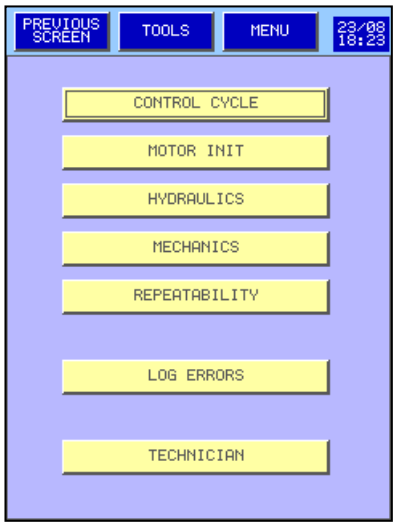
- Remove the o-ring.
- Replace the needle with or the o-ring.

REASSEMBLY PROCEDURE:
To reassemble the unit, carry out the various operations in the opposite direction. Place the seal on the needle gently not to wound it.

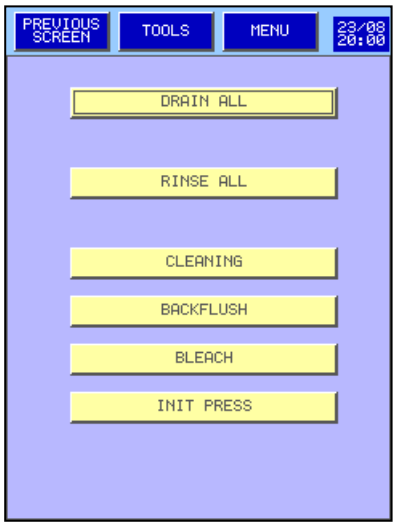
9.4.3 Baths dismantling

This procedure must be carried out to replace the bath seals on the manifold or the aperture seals.

	**Wear rubber gloves and wash hands with a disinfectant after completion of work.**

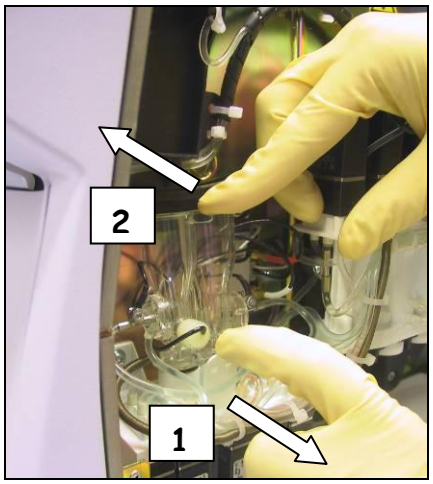


- From the **MAIN MENU**, press SERVICE then press HYDRAULICS.

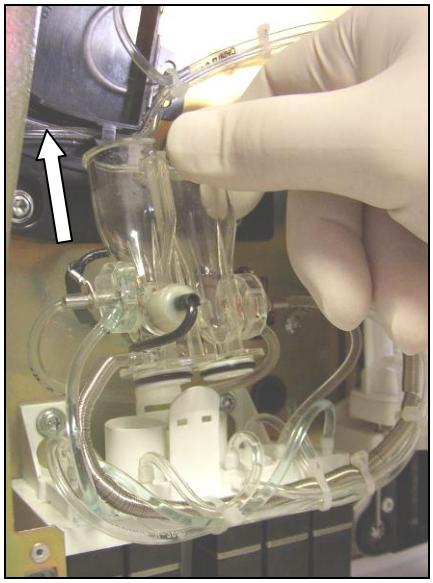


- Press DRAIN ALL to perform a draining of the counting baths.

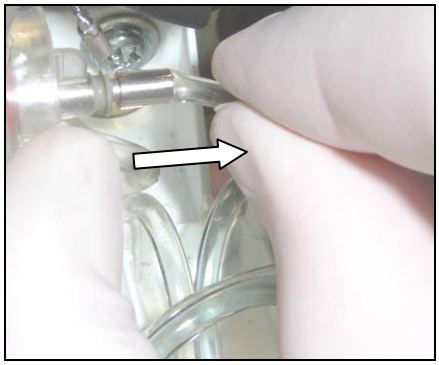
- Open the door located on the right side of the instrument to have access to the hydraulic part.



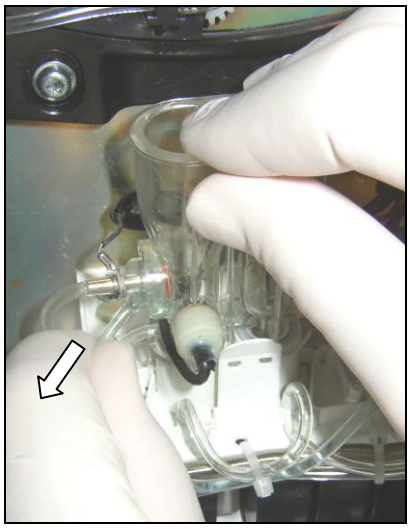
- To remove the counting bath module, draw on the clip **1** while pushing the top from the counting bath towards the inside of the machine **2**.



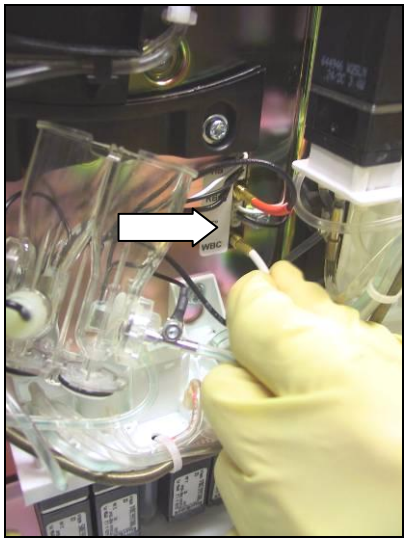
- Then, upwards, raise the counting module.



- Next, remove the tubing fixed on the RBC counting head, located on the right side of the counting module.



- Remove the tubing fixed on the plastic fitting located under the stainless tube from WBC counting block.



- Remove all connectors.

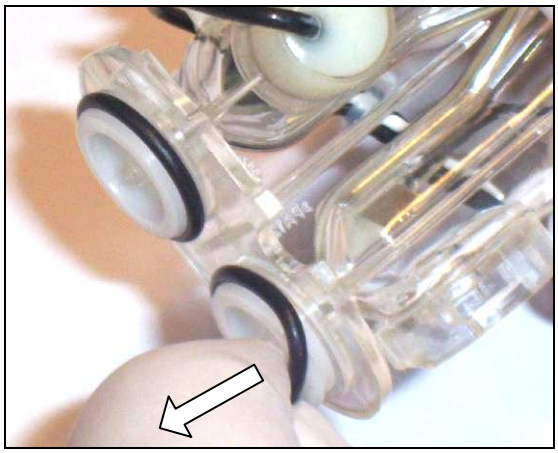
- The counting bath module can now be handled to carry out the desired operations of replacement.

REASSEMBLY PROCEDURE:

To reassemble the unit, carry out the various operations in the opposite direction.

9.4.4 Baths o-ring replacement

	**Wear rubber gloves and wash hands with a disinfectant after completion of work.**



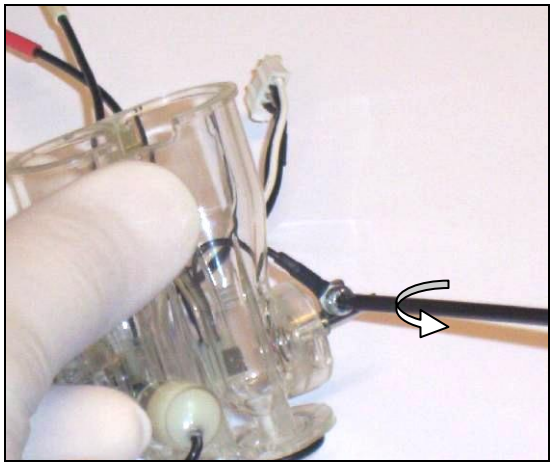
- Before performing the operation, drain the baths and dismantle the counting bath block (see section **9.4.3**).

- Replace the o-ring and/or the complete bath block.

REASSEMBLY PROCEDURE:
To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the counting bath gently not to wound it.

9.4.5 Aperture block replacement

	**Wear rubber gloves and wash hands with a disinfectant after completion of work.**

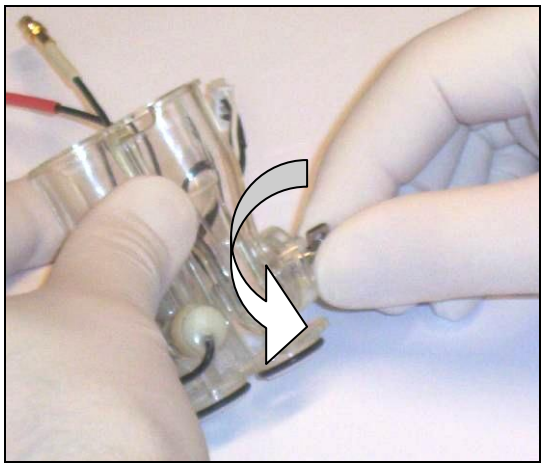


- Before performing the operation, drain the baths and dismantle the counting bath block (see section **9.4.3**).

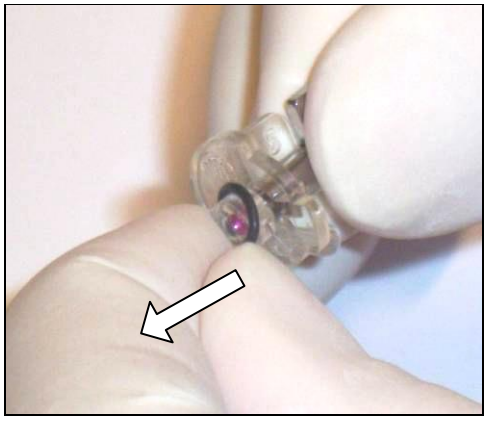
- Remove the tubing from the blocks to be replaced.

- With the help of the provided tool in the maintenance kit, unscrew the screw and remove the connection.

NOTA: This operation can be performed without dismantling the complete bath block.



- Unscrew the aperture block of a quarter of turn.



- Remove the o-ring and replace by a new one or replace the whole part.

NOTA: The WBC aperture block is marked with a figure **8** on the ear and with a figure **5** for the RBC.

REASSEMBLY PROCEDURE :

To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the aperture block gently not to wound it.

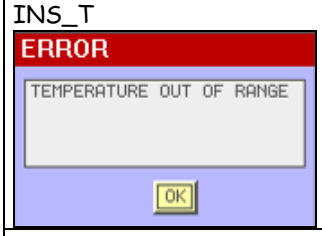
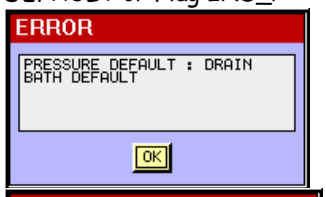
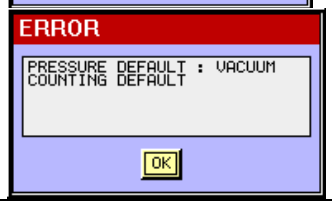
9.5 TROUBLESHOOTING

In any case, if a problem is not solved, call Orphée's representative.

9.5.1 Analytical problems

PARAMETERS	PROBLEMS	CONDITIONS	SOLUTIONS
WBC	No result	No HGB	Check the lysis level. Check the right lysis tubing connection to the WBC bath. Check the valve Nb 9.
		HGB OK	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful. Change the aperture block if unsuccessful.
	Bad stability		Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the WBC bath during the run cycle. Check the reagent and enclosure temperature.
5 DIFF	No result or bad stability	No HGB & WBC	Check the lysis level. Check the right lysis tubing connection to the WBC bath. Check the valve Nb 9.
		HGB & WBC OK	Perform a Back flush Cycle and then a Bleach cycle if unsuccessful. Check the valves Nb 12, 13, 16 & 17. Check the reagent and enclosure temperature. Check the preamp connection wires.
	Rejection	*	Check the results on blood smear.
RBC	No result	No HCT & PLT	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful.
	Bad stability	HCT & PLT	Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the RBC bath during the run cycle. Check the level bubble flow in the WBC bath during the first dilution.
HGB	No result		Check the led light on
	Bad stability		Check if no bubble in the lysis tubing. Check the reagent and enclosure temperature. Check the level bubble flow in the WBC bath during the run cycle.
	Rejection Flag INS_H	--- * 	Close the door. Perform a new Start Up cycle. Perform a new Start Up cycle.

9.5.2 Other problems

ORIGIN	PROBLEMS	SOLUTIONS
MYTHIC	Diluent leaks around the needle during the run cycle	Check the rinsing needle block (presence of clots) and clean it if necessary see section **9.4.2**
	No starting	Check the power supply connection wires Check the switch on button located on the power supply block.
	All results bad	Check the level diluent and if the tubing is pinched. Check if the diluent is at the same level than the analyzer.
	No display	Check the flat cable.
	ID and/or PID typing impossible	ID and/or PID are mandatory (see section **3.4.3**).
	Message : TEMPERATURE OUT OF RANGE or flag INS_T 	Check the origin of the problem of temperature in section **9.3**. Trigger temperature values: Ambient: 17°C <--> 37°C Enclosure: 33°C <--> 40°C Reagents: 34°C <--> 45°C
	Message: CYCLE: PRESSURE DEFAULT or Flag INS_P  	Cases of occurrence: - drain chamber default: check the tubing connection of the fluidics - counting vacuum default: perform a piston greasing (see section **9.1.3**) and check the tubing connection of the fluidics For all occurrences check also the level of the reagents.
Printer	No printing	Check the paper. Check the electrical connection.
	Bad printing	Check the black ribbon.

9.6 TROUBLESHOOTING MESSAGE

This section allows knowing what to do when a troubleshooting message appears on the screen.
If the problem go on contact your Orphee representative.

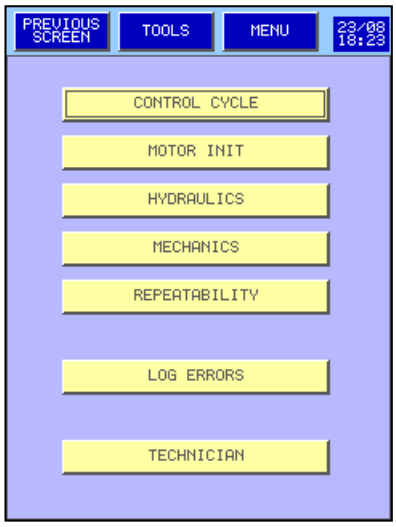
MESSAGE	ACTION
BACKUP : FOLDER NOT FOUND	Re-start the Mythic.
BACKUP: BAD FOLDER DUPLICATION	Re-start the Mythic
BACKUP: CALIBRATION HISTORY IS FULL	Delete the calibration results.
BACKUP: FAIL TO SAVE RESULT ONTO THE EXTERNAL STORAGE DEVICE. THE INTERNAL MEMORY IS USED.	Please connect USB thumb drive to the analyzer
BACKUP: FILE SYSTEM FAILED.	Re-start the Mythic.
BACKUP: LAST RESULT SAVED.	Memory full, next result will not be saved. You have to delete

MESSAGE	ACTION
	results.
BACKUP: MEMORY IS ALMOST FULL. PLEASE DELETE RESULTS.	Delete results
BACKUP: NO MEMORY AVAILABLE FOR STORAGE	Delete the stored results.
BACKUP: QC HISTORY IS FULL	Delete the Q.C. results of the ongoing lot.
BACKUP: REPEATABILITY HISTORY IS FULL	Delete the repeatability results.
BACKUP: SECTOR FAILED.	hardware failure on memory
BACKUP: SYSTEM ERROR	Re-start the Mythic.
CLEAN NOT DONE	Perform a rinse cycle.
CLEANER ALMOST EMPTY	Replace the bottle and perform a prime Cleaner
COM: BAD CYCLE MODULE	Rebuild cycles with good options
COM: CRC CONTROL ERROR	Communication error retry
COM: SIZE ERROR.	Try to send the file again If the problem still occurs, call an Orphée representative.
CONTROL CYCLE NOT DONE	Perform a control cycle.
CYCLE STOPPED BY USER	Emergency stop, please perform a control cycle.
CYCLE: BUSY	Wait before performing a cycle.
CYCLE: CMD VALVE FAILED	Change the valve
CYCLE: EMERGENCY STOP	Perform a control cycle.
CYCLE: FLUIDIC DOOR OPENED	Close the door, in case of emergency stop run a control cycle
CYCLE: HGB CHANNEL SATURATION. PLEASE RUN STARTUP.	Run Startup Cycle. If the problem still occurs, call an Orphée representative.
CYCLE: INIT NOT DONE	Perform an initialization or a control cycle.
CYCLE: PRESSURE DEFAULT	May occurred by leak of reagent, check tubing in the fluidics
CYCLE: VALVE XX FAILED	Change the valve
DILUENT ALMOST EMPTY	Replace the container and perform a prime Diluent
HARDWARE: A.L.L BOARD ID FAILED.	check the hardware connection on ALL Board
HARDWARE: F.S.C BOARD ID FAILED.	check the hardware connection on FSC Board
HARDWARE: FAN FAILED.	check if your temperature fan is running
HARDWARE: HEAT ENCLOSURE FAILED.	Call an Orphée representative.
HARDWARE: HEAT ENCLOSURE STOPPED.	check your enclosure sensor
HARDWARE: HEAT REAGENT FAILED.	Call an Orphée representative.
HARDWARE: HEAT REAGENT STOPPED.	check your reagent sensor
HARDWARE: SYSTEM ERROR	Re-start the Mythic.
HEATING IN PROGRESS, PLEASE WAIT.	Wait for the system to reach its temperature
ID AND/OR PID MANDATORY (CHECK SETUP). SID ALWAYS MANDATORY.	Enter an ID and/or PID and SID
INIT PRINTER	Switch on the printer or invalidate the printings.
INTERN: COUNT ERROR	Re-start the Mythic.
INTERN: MEMORY CORRUPTED	Re-start the Mythic.
INTERN: NO MEMORY AVAILABLE	Re-start the Mythic.
INTERN: RESULT AREA IS LOCKED	Wait before performing a cycle. If persisting, re-start the Mythic.
INVALID DATA FORMAT.	The files format are not available for the Mythic
LOT ALREADY EXISTS. ACTION CANCELLED.	Select other lot
LYSE ALMOST EMPTY	Replace the bottle and perform a prime Lysis
MECA: HOME NEEDLE NOT FOUND	Perform an initialization or a control cycle.
MECA: HOME ROCKER NOT FOUND	Perform an initialization or a control cycle.

MESSAGE	ACTION
MECA: HOME SYRINGE NOT FOUND	Perform an initialization or a control cycle.
MECA: MOTOR NEEDLE BUSY	Re-start the Mythic.
MECA: MOTOR ROCKER BUSY	Re-start the Mythic.
MECA: MOTOR SYRINGE BUSY	Re-start the Mythic.
MECA: MOTOR SYRINGE GAP	Perform a pistons greasing
MECA: NEEDLE NOT IN TOP POSITION	Perform a control cycle.
NETWARE: SERVER INIT. FAILED	Call an Orphée representative.
NETWARE: CLIENT INIT. FAILED.	Call an Orphée representative.
NO PRINTER RESPONSE	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NUMBER MAX. OF FILES REACHED. PLEASE DELETE FILES.	Delete some files
OUT OF RANGE	Modify the value
PRINTER DRIVER UPDATE FAILED. THE CHOSEN DRIVER IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the correct version
PRINTER ERROR	Switch on the printer or invalidate the printings.
PRINTER IS BUSY	Switch on the printer or invalidate the printings.
PRINTER IS OFF	Switch on the printer or invalidate the printings.
PRINTER: NO PAPER	Add some paper.
RINSE NOT DONE	Perform a clean cycle.
RS232: ACK ERROR	Re-start the Mythic.
RS232: INTERNAL ERROR	Re-start the Mythic.
RS232: SYNCHRO ERROR	Re-start the Mythic.
RS232: TIME OUT	Re-start the Mythic.
RUNNING AUTO CLEANING	Press OK.
SET TEMPERATURE REACHED.	The samples can be run
SETUP: MODIFICATION NOT ALLOWED.	You have to be Logged with the good access code
START UP CYCLE NOT DONE	Perform a start up cycle.
STARTUP CYCLE FAILED	Perform a new start up cycle
SVM: BAD VERSION	Update the SVM software
SVM: COM. TIME OUT	Re-start the SVM.
SVM: ILLEGAL SERIAL NUMBER.	This MYTHIC can not be connected to the SVM
SVM: UNMATCH	Re-enter the file or confirm it (manual connection on the SVM).
SVM: WG	Westgard alarm.
SVM: XB	XB alarm.
SYSTEM LOCKED HEATING FAILED	Call an Orphée representative.
SYSTEM: DOWNLOADING NEW VERSION. PLEASE WAIT	System is resetting after version release
SYSTEM: EEPROM COM ERROR	Re-start the Mythic.
SYSTEM: FATAL ERROR	Re-start the Mythic.
SYSTEM: INTERNAL TIME OUT	Re-start the Mythic.
TEMPERATURE OUT OF RANGE	Room temperature out of the limits (<18 or >34°C).
THE CLEANER USED IS OUT OF DATE.	Replace the bottle and perform a prime Cleaner
THE DILUENT USED IS OUT OF DATE.	Replace the container and perform a prime Diluent
THE LYSE USED IS OUT OF DATE.	Replace the bottle and perform a prime Lysis
USB: DIRECTORY DOES NOT EXIST.	Try again or change for another USB Thumb.

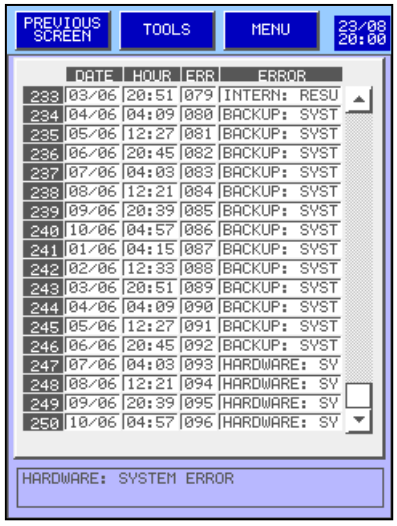
MESSAGE	ACTION
USB: DIRECTORY IS NOT EMPTY.	Try again or change for another USB Thumb.
USB: EMPTY FILE	Try again or change for another USB Thumb.
USB: THUMB DRIVE I/O ERROR	Try again or change for another USB Thumb.
USB: THUMB DRIVE IS FULL.	Delete some files
USB: THUMB DRIVE IS NOT PRESENT.	Please connect USB thumb drive to the analyzer
USB: TOO MANY FILES OPENED.	Delete some files
USB: UNABLE TO CREATE DIRECTORY.	Try again or change for another USB Thumb.
USB: UNABLE TO OPEN DIRECTORY.	Try again or change for another USB Thumb.
USB: UNABLE TO OPEN FILE	Try again or change for another USB Thumb.
USB: WRITE PROTECTED FILE.	Try again or change for another USB Thumb.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the correct version
WASTE ALMOST FULL	Replace the waste container

9.7 LOGS ERRORS



- From the MAIN MENU press SERVICE .

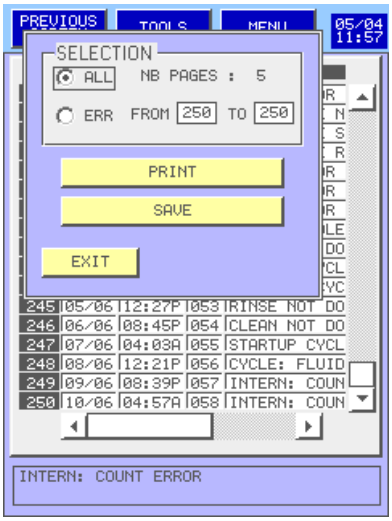
- Then press LOG ERRORS



- This screen allows visualizing the date and timing when an error has occurred, as well as the code and the origin of this error.

- To see the origin of the error, press on the figure located on the left of the date, the complete error appears at the bottom.

- To print it press TOOLS .



- Select ALL to print the errors of the number of pages indicated on the screen.
- To print or save (in an USB key) the error of one or more days select ERR FROM 250 TO 250 then enter the error reference number.

9.8 HYDRAULIC DIAGRAM

The length and inner diameters of the tubing shown on the diagram below the tubing table must be strictly respected when replaced, otherwise there is a significant risk in the quality of results given.

	ID 0.38 mm	ID 0.89 mm	ID 1x2.7mm	ID 1x3mm PU	ID 1,3x3mm	ID 1,55x3,4mm	ID 2,1x4mm	ID 2,79 mm	ID 3x6mm	ID 5x8mm	ID 2,4x4mm
Designation											
Tubing 5							210mm				
Tubing 6							130mm				
Tubing 8						80mm					
Tubing 12						60mm					
Tubing 13						250mm					
Tubing 14						250mm					
Tubing 17						80mm					
Tubing 18						80mm					
Tubing 22					200mm						
Tubing 23 - DILUENT									1500mm		
Tubing 24 - WASTE									1500mm		
Tubing 25										55mm (45°)	
Tubing 26										5mm	
Tubing 3							135 + 20 mm				
Tubing 9					40mm						
Tubing 10		500mm					2 X 10mm				
Tubing 30					130mm						5mm
Tubing 31					80mm						5mm
Tubing 32						510mm					
Tubing 33				240mm							
Tubing 34						270mm					
Tubing 35							130mm				
Tubing 36							230mm				
Tubing 37						190mm					
Tubing 38							180mm				
Tubing 39							180mm				
Tubing 40						960mm					
Tubing 41						200mm					
Tubing 42						180mm					2x5mm
Tubing 43			250mm				3 x 15mm				2x5mm
Tubing 44							270mm				
Tubing 45							100mm				
Tubing 46						400mm					
Tubing 47			240mm				3 x 15 mm				2x5mm
Tubing 48						150mm					5mm
Tubing 49						70mm					
Tubing 50	100mm						2 x 20 mm				5mm
Tubing 51								180mm			
Tubing 52						50mm					
Tubing 53						60mm					
Tubing 54			365mm								
Tubing 55			140mm				15mm				
Tubing 56						10mm					
Tubing 57							80mm				
Tubing 58						1000mm					
Tubing 59							8mm