

ORPHEE 19, chemin du champ-des-filles CH-1228 Geneva / Plan-les-Ouates SWITZERLAND

Tel: +41 (0) 22 884 9090 Fax: +41 (0) 22 884 9099 http://www.orphee-medical.com



Mythic<sup>™</sup> 18 Vet Operator's Manual

## **REVISIONS**

Revision Nb	Date	Author	Software	Comments
01	01/02/2010	PhD	> V 1.0	Creation

### CONTACT ADDRESS

MANUFACTURER



Manufactured in France for ORPHEE SA
19, chemin du champ des filles
CH-1228 Geneva / Plan-les-Ouates
SWITZERLAND

Tel: +41 (0) 22 884 9090 Fax: +41 (0) 22 884 9099 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.

<u>NOTA</u>

Indicates important additional information

#### DANGER

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

- $\Rightarrow$  Check that the voltage setting matches the supply voltage.
- ⇒ Protective earthing is required; plug the MYTHIC 18 VET into a supply outlet which has an earth connection.
- ⇒ Preserve a good access to the supply outlet to be able to unplug the MYTHIC 18 VET 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 18 VET 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 18 VET
- $\Rightarrow$  Do not use the MYTHIC 18 VET where aerosol sprays are being used, or where oxygen is being administered.
- ⇒ Do not use the MYTHIC 18 VET out of doors
- ⇒ Always switch off the MYTHIC 18 VET and disconnect the power adaptor before dismantling any part.
- $\Rightarrow$  The MYTHIC 18 VET is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.
  - Only Veterinary 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 18 VET are potentially infective. Wearing rubber gloves is highly recommended and after completion of work, washes hands with disinfectant.
- ⇒ Always replace or use parts of the equipment by parts supplied by ORPHEE distributor.
- $\Rightarrow$  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.
- $\Rightarrow$  The treatment of waste and the elimination of a part or the complete instrument must be done in compliance with the local legislation.
- $\Rightarrow$  Any output or input connections (except the printer and the barcode reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.
- $\Rightarrow$  Do not open the door located on the right side of the instrument (see section 1.1.3) when a 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 EMC and needs to be installed and put into service according to the EMC information listed below.

### Guidance and manufacturer's declaration - Electromagnetic immunity

The MYTHIC 18 VET is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 18 VET should assure that it is used in such 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 18 VET, 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√P
Radiated RF IEC 61000-4-3	3 Vrms 80Mhz to 2,5 <i>G</i> hz	3 Vrms	d=1,25P 80MHz to 800MHz
120 01000-4-3	00MH2 10 2,50H2		d= 2,3√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:
			$((\bullet))$

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.

b Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.

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.

<sup>&</sup>lt;sup>a</sup> 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 18 VET is used exceeds the applicable RF compliance level above, the MYTHIC 18 VET 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 18 VET.



# 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 18 Vet

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 dispositivo / 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

Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati

autres documents normatifs appliqués

Applied common technical specifications, harmonised standards, national standards or other normative documents

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)

Ort, Datum / Lieu, date / Luogo, data / Place, date

Genève le 06 Juin 2009

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)

Annex III

N/A

Name und Funktion / Nom et fonction /Nome e funzione / Name and function

Philippe Daire RA & OA

## TABLE OF CONTENTS

1. INSTALLATION	10
1,1 Unpacking	10
1.1.1 Introduction	1C
1.1.2 Unpacking Procedure	10
1.1.3 Visual checking	11
1.2 Installation constraints	11
1.2.1 Installation place	
1.2.2 Installation environment	
1.3 Electrical connections	12
1.3.1 Power supply block	
1.4 Printer connection	
1.5 CONNECTION, CHANGE AND PRIMING REAGENTS	
1.5.1 Connection	
1.5.2 Priming	
1.6 Transportation and storage	
2. GENERAL OVERVIEW	17
2.1 GENERAL OVERVIEW  2.1 GENERALITIES	= *
2.2 OVERVIEW	
2.3 MAIN PART DESCRIPTION	
2.3.1 Display / Keyboard	
2.3.2 Dilution hydraulic part	
2.3.3 Mono electronic board	
2.3.4 Power Supply Block	
2.3.5 Reagent tray	
3. INSTRUMENT SET UP	24
3.1 User'S identification	
3.1.1 Start Up	
3.1.2 In process	
3.2 SYSTEM STATUS	
3.3 SET UP	
3.4 ADVANCED SET-UP	
3.4.1 Printer set up:	
3.4.2 Communication:	
3.4.3 Analysis options:	
3.4.4 Lab. parameters:	
3.4.5 Calibration factor:	
3.4.6 Other Setting:	
3.4.7 Storage options:	
3.4.8 Version release:	34 <b>35</b>
4. SPECIFICATIONS	
4.1 ANALYTICAL SPECIFICATIONS	
4.2 PHYSICAL SPECIFICATIONS	
4.3 REAGENTS SPECIFICATIONS	
4.3.1 Diluent	
4.3.2 Lysis reagent	
4.3.3 Cleaning solution	
4.4 ANALYTICAL LIMITATIONS	
4.3.1 Recommendations	
4.3.1 Interferences	
5. SAMPLE ANALYSIS	44
5.1 VERIFICATIONS BEFORE STARTING	
5,2 Start up	
5.3 REAGENT REPLACEMENT	
5.4 Start up rinsing	
5.5 Preparations before analysis	46
5.6 ANALYSIS	46
5.6.1 Introduction	
5.6.2 Sample Identification	
5.6.3 Sample run	49

	5.7 <b>R</b> ESULTS	49
	5.8 Printing	5
	5.8.1 Model report (A4) - external printer	
	5.8.2 Model report - Ticket printer	
	5.9 Logs	
	5.10 Archive	
	5.10.1 Results	
	5.10.2 View	
	5.11 STAND BY AND SHUT DOWN	
4	. QUALITY CONTROL	56
0.	<u>·</u>	
	6.1 Introduction	
	6.2 QC	
	6.2.1 Change	
	6.2.2 Run control blood	
	6.2.3 Levey-Jennings graph	
	6.2.4 Restore	
	6.3 REPEATABILITY	
7.	CALIBRATION	62
	7.1 RESULTS	
	7.1.1 Calibration blood analysis	
	7.1.2 Calibration	
	7.2 TARGET VALUE MODIFICATIONS	65
8.	. TECHNOLOGY	66
	8.1 DETECTION PRINCIPLE	66
	8.1.1 WBC, RBC, PLT Counting	
	8.1.2 Hemoglobin measurement	
	8.2 LEUCOCYTE ANALYSIS	
	8.3 Erythrocyte analysis	
	8.4 ANALYSIS OF PLATELETS	
	8.5 ALARMS	
	8.5.1 General Flags	
	8.5.2 Leukocytes Flags	
	8.5.4 Platelet Flags	
	8.5.5 Machine Flags	
	8.6 Hydraulic description	
	8.6.1 Sampling module	
	8.6.2 Counting bath module	
	8.6.3 Syringes module	
	, 3	
	8.7 SOFTWARE	
^	8.8.1 Windows	
9.	. SERVICE	73
	9.1 MAINTENANCE	
	9.1.1 Maintenance table	
	9.1.2 Concentrate cleaning	
	9.1.3 Piston greasing	
	9.2 Hydraulic cycles	
	9.3 MECHANICS	78
	9.4 Repairing	79
	9.4.1 Emergency stop	79
	9.4.2 Needle or o-ring replacement	
	9.4.3 Baths dismantling	
	9.4.4 Baths o-ring replacement	
	9.4.5 Aperture block replacement	
	9.5 TROUBLESHOOTING	
	9.5.1 Analytical problems	
	9.5.2 Other problems	
	9.6 Troubleshooting message	88
	9.7 Logs errors	9:
	9.8 Hydraulic diagram	

### 1. Installation

### 1.1 UNPACKING

#### 1.1.1 Introduction

The MYTHIC 18 VET is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.

- Only Veterinary 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 18 VET has been stored at a temperature less than  $10^{\circ}C$ , it must stay at room temperature during 24 hours before switching it on.

### 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.

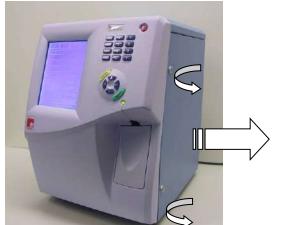
- Open the box on the top, remove the starter kit.
- Remove the MYTHIC 18 VET from the box.

#### Starter kit contents:

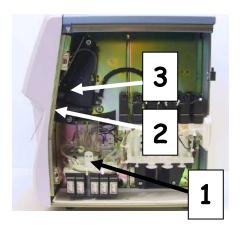
	INSTALLATION KIT			
QTY	Designation	Part Number		
1	M18 - WASTE	005-1001-90 24		
1	70W switching adapter	050-1001-01 70 24		
1	European Power line cord	150-2001-CEE C13 1000		
1	M18 Vet User manual	605-1201-02		
1	Screwdriver Slot 1/4"	700-7101-02		

	MAINTENANCE KIT				
QTY	Designation	Part Number			
1	Tygon tubing L=1000mm 1.52x3.2mm	005-1001-90 016 032			
1	Tygon tubing L=500mm 2.06x4mm	005-1001-90 020 040			
1	Tubing 9	005-1001-90 09			
1	Tubing 10	005-1001-90 10			
5	Cables Ties	153-0101-100 25			
2	O-ring Ø13.1x1.6 Fluocarbon 80SH	312-0505-1310 160			
1	O-ring Ø1.4x1.25 Fluocarbon 80SH	312-0505-140 125 010			
2	O-ring Ø5x1 Fluocarbon 80SH	312-0505-500 100			
1	Silicon grease (3gr)	410-0501-02 02			
1	Short Arm TORX T10 Tool	700-1101-10			
1	Short Arm TORX T20 Tool	700-1101-20			

### 1.1.3 Visual checking



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



#### To be checked:

- Counting chambers perfectly locked in their manifold locations.
- 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 18 VET 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.

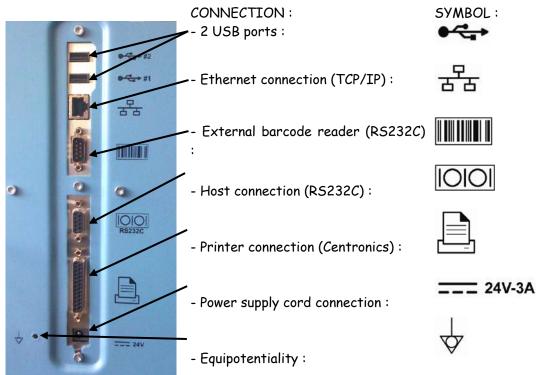
#### 1.2.2 Installation environment

- a) Indoor use;
- b) Altitude up to 2 000 m;
- c) Temperature 18 °C to 32 °C;
- d) Maximum relative humidity 80 % for temperatures up to 31  $^{\circ}C$  decreasing linearly to 50 % relative humidity at 40  $^{\circ}C$ ;
- 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 18 VET





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 18 VET 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 18 VET and, if possible in an upper position to avoid the contact with any liquid.

To disconnect electrically the MYTHIC 18 VET, remove the power supply plug from the main circuit.



- In the case of replacement of the main power wire supplied with the MYTHIC 18 VET the new one must comply with the local regulation ( $3\times1.5$ mm cable and 250V 10A plug).
- The MYTHIC 18 VET 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 18 VET ( ) or the USB plug ( ) to connect the printer cable. Select the printer driver (section 3.3).

### 1.5 CONNECTION, CHANGE AND PRIMING REAGENTS

MYTHIC 18 VET works with the reagents described in section  $\frac{4.3}{.}$ . Some commercial reagents can also be used. Please contact your Orphée's representative.

#### 1.5.1 Connection

#### Pack installation:

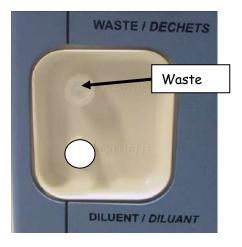




Before handling the reagents, read carefully their specifications described in section 4.3.

- Remove the door on the left side of the instrument.
- Put the M-Pack in the dedicated location.
- Remove the caps of the bottles
- Tighten the yellow caps on the Lysis bottle (yellow sticker), the blue one on the cleaning solution bottle (blue sticker), and the diluent cap on the bottle diluent.

#### Waste:



- 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.
- $\bullet$  The diluent must be placed at the same level as the MYTHIC 18 VET.
- Collect the waste in a container and treat it in compliance with your local legislation.

Example of neutralization procedure usually used in a laboratory:

For 20 liters of waste produced by the MYTHIC 18 VET, add 50 ml of a solution of sodium hydroxide (NaOH) at 200g/l, mix the container, add 100ml of bleach at 36° Cl, mix the container, wait one hour before empty it.



Only use this procedure if there is no specific local legislation for the treatment of the waste.

### 1.5.2 Priming

When first starting the MYTHIC 18 VET, it is necessary to perform a complete prime of the fluidic circuit.



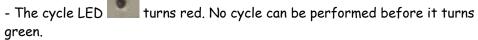
Before starting, be sure that all the reagent and waste tubes are properly connected.

### Priming procedure:

1 Switch on:

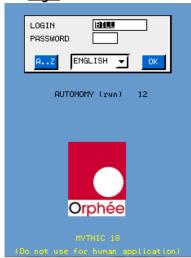


- Connect the power supply block.
- Press the ON/OFF button.



- The information window could stay up to 3 mn to enable the update of all files.

## ② Login:

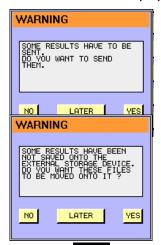


- The operator's identification display appears.
- Enter the user's identification, the password (see section 3.1) and press to validate.
- AUTONOMY (run) indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

## 3 System priming:



- The main menu is displayed.



- If this window appears, it means that several results in memory have not been sent before the MYTHIC 18 VET 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.



- Press on , then on REAGENTS to prime the pack.
- First, input LOT and Expiry date, press CHANGE RACK to validate.
- Second, press PRIME PACK to prime all the reagents.

#### - WASTE:



- Enter only the capacity of the container.
- After replacement of the waste container press

RESET

to reset to initialize the waste calculation.

MYTHIC 18 VET IS NOW READY TO WORK.

## 1.6 TRANSPORTATION AND STORAGE

Storage temperature:  $-10^{\circ}C$  to  $+50^{\circ}C$ .

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 18 VET is a fully automated analyzer performing hematological analysis on whole blood collected on EDTA tubes.

- Sample volume : 9,8 μl

- Throughput : 60 samples/hour

- 18 analysis parameters :

### Leukocyte parameters:

WB <i>C</i>	White Blood Cells
LYM%	Lymphocytes in percentage
LYM#	Lymphocytes
MON%	Monocytes in percentage

MON# Monocytes

GRA% Granulocytes in percentage

GRA# Granulocytes

### Erythrocyte parameters

RB <i>C</i>	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

<sup>\*</sup> For Investigation Use only in the United States of America.

### 2.2 OVERVIEW

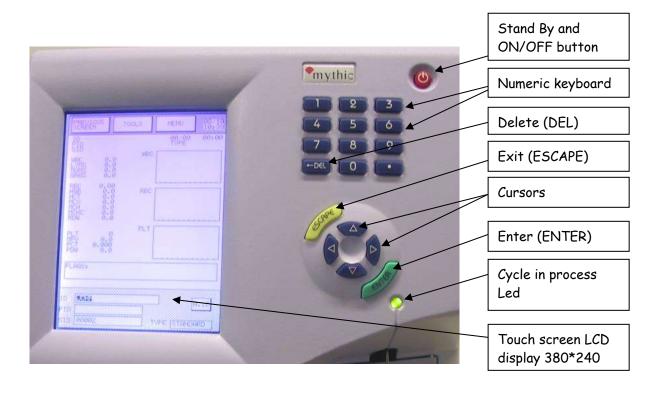


### MYTHIC 18 VET consist of 8 main parts:

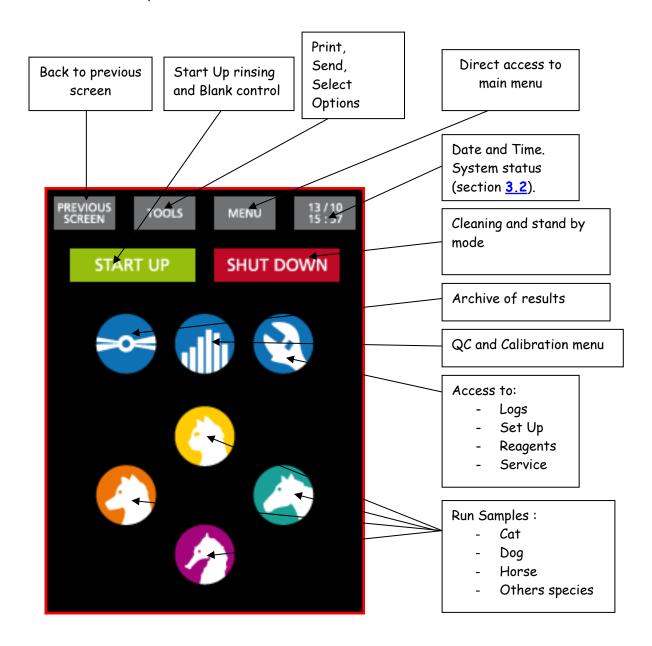
- 1. Display / Keyboard.
- 2. Dilution hydraulic part.
- 3. Mono electronic board.
- 4. Reagent tray.
- 5. Connection.
- 6. External power supply block.
- 7. Printer.
- 8. Barcode reader (option).

### 2.3 MAIN PART DESCRIPTION

## 2.3.1 Display / Keyboard



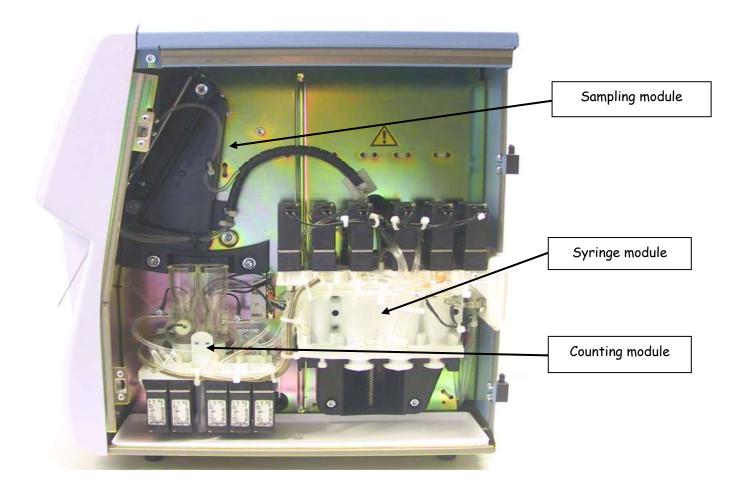
### Main Menu description



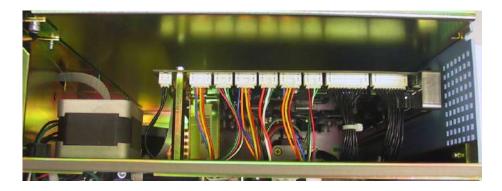
## 2.3.2 Dilution hydraulic part

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

- Sampling module:
  - o 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:
  - o WBC and RBC counting chambers and hemoglobin measurement.
  - Liquid valve manifold assembly and tubing.



### 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 18 VET is supplied with an external power supply block.



- In the case of replacement of the main power wire supplied with the MYTHIC 18 VET the new one must comply with the local regulation.
- The MYTHIC 18 VET 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

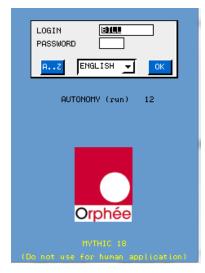


The reagent tray is dedicated for the pack of reagents.

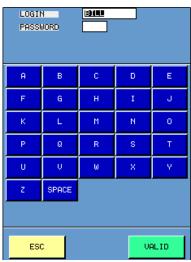
### 3. INSTRUMENT SET UP

#### 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... to enter your login.
- The window enables to change the language. Press to validate it.
- AUTONOMY (run) indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

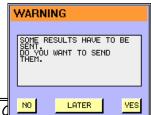


- Enter your identification name with the alphabetic keyboard.
- Place the cursor in the Password window.
- Enter your password for identification.
- For the first login, MYTHIC 18 VET propose 3 access levels:
  - User : No password
  - o Biologist: Password by default 1-2-3
  - Service people
- Biologist Password can be modified in section 3.4.6.

### 3.1.2 In process



- To change operator during the process, press to return to the main menu, and then press on
- To change identification, proceed as described above (section 3.1.1).



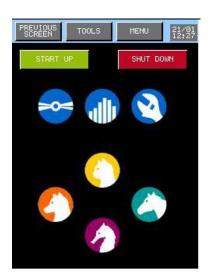
MYTHIC 18

- If this window appears, it means that several results in memory have not been sent before the MYTHIC 18 VET was switched off.
- Press YES to send them immediately, or press LATER to wait for 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



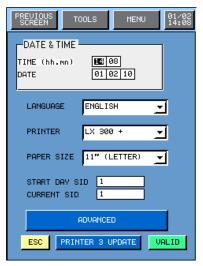
- Press on the date and hour to have access to the system status window.

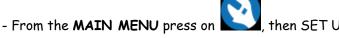


- Different system status information is displayed.

- To return to the MAIN MENU press

#### 3.3 SFT UP



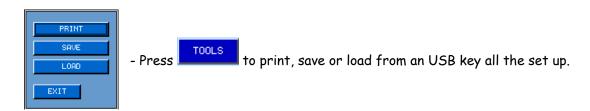


- This menu is available for all users.
- The DATE & TIME window enables to modify the time and the date
- To select the language of the Mythic menu, choose the right one in the Language combo box.

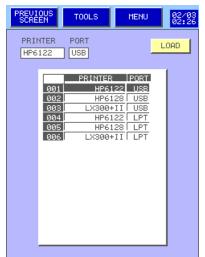
   PRINTER LX 300 + : Select the printer or no printing.
- PAPER SIZE 11" (LETTER) : Select the paper size depending on the number of results per page.
- START DAY SID 1 : Two SID are available; Start day SID enables to select the first SID for each new day.
- \_ CURRENT SID 1 : If you want to select a new SID number
- Biologist reserved for complete settings.

(See section 3.4).

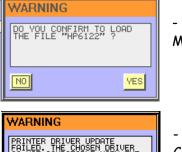
- Once modifications are done, press either VALID to valid or ESC to exit keeping the previous setting.



- 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  $\stackrel{\text{YES}}{\longrightarrow}$  then, the driver is loaded in the MYTHIC 22

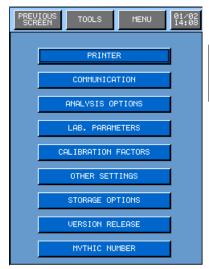


- This prompt appears if the release is failed. Check the USB connection or change the USB key or call your Orphée's representative.



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 modifications 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:



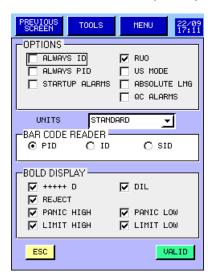
- Printer set up menu is intended to present the printing report
- To select an option on the report, press on the corresponding case.
- To enter a header, press A... key.
- To exit the menu, either press to keep the last setting, or to save the last modifications.

#### 3.4.2 Communication:



- Reserved for technical Service people.
- To set up the connection between  ${\it MYTHIC}$  and Host or between  ${\it MYTHIC}$  and  ${\it SVM}$  (Validation Station for  ${\it MYTHIC}$ ).

### 3.4.3 Analysis options:

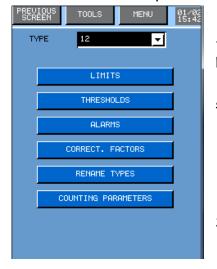


#### - OPTIONS box:

- ALWAYS ID and ALWAYS PID: To run a sample, user mandatory needs to enter a ID and/or a PID.
- $_{\odot}$  RUO: With tag the PCT and PDW parameters are displayed, printed and sent.
- US MODE: The Research Use Only message is printing below the printing report (only if RUO is tagged).
- ABSOLUTE LMG: With tag absolute values for sub-populations of leucocytes are displayed. In the other case, percentages are displayed.
- $\circ$  QC ALARMS: The message "QC failed" appear below the printing report when the QC result is out of tolerance or expired; The message "QC not done" appear below the printing report when it is not run.
- STANDARD : Gives a choice of three unit systems: Standard, International System, and mmol.
- CDB box: The bar code reader is dedicated to the PID, 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 to validate your choices or to exit keeping the previous setting.

### 3.4.4 Lab. parameters:



- Select the blood type in the combo box

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).

PLARMS

to adjust the flags level (see section 3.4.4.3).

CORRECT. FACTORS

to adjust the corrections factors (see section 3.4.4.3).

12

Then

then

then

then

press:

to adjust the parameters thresholds (see section 3.4.4.3).

Thresholds

to adjust the flags level (see section 3.4.4.3).

Thresholds

to adjust the flags level (see section 3.4.4.3).

Thresholds

to adjust the flags level (see section 3.4.4.3).

Thresholds

to adjust the flags level (see section 3.4.4.3).

- To enter a new blood type, press : to adjust the electronic gains for WBC, RBC and PLT as well as the lyse volume (from 250 to 500  $\mu$ l) and time of incubation (from 0 to 10 seconds).

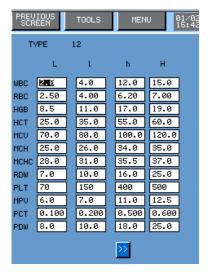
**NOTA**: The name of the first type STANDARD cannot be change.

- Press to print the blood type set up.

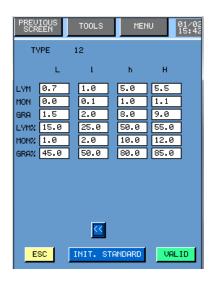


- PRINT ALL allow to print all the blood type set up (about 20 pages are printed) PRINT SELECTED
- only the blood type in the combo box is printed.

#### 3.4.4.1 Limits:

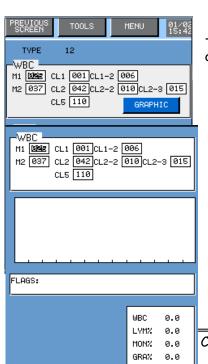


- This display enables to enter normal and panic limits for every 18 parameters given by the MYTHIC 18 VET (see section 8).
- To validate the new values, press VALID key in the next page (see below).



- Once modifications are done, press to validate or to exit without any modification.
- Press INIT. DEF. to return to the manufacturer parameter setting.

#### 3.4.4.2 Thresholds:



ESC TEST NIT. STANDARD

VALID

- The threshold display enables to modify the detection thresholds located on the WBC, RBC, PLT curves.

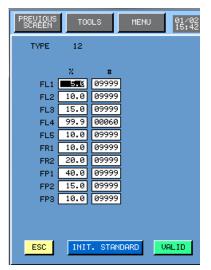


Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend modifying these values only after an Orphée's training.

- Once modifications are done, press to validate or to exit without any modification.
- Press INIT. STANDARD to return to the manufacturer parameter setting.

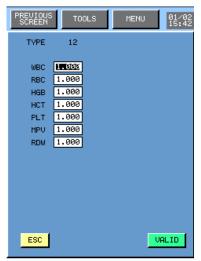
- This screen allows displaying the WBC thresholds position after a run.
- After modification press TEST to allow the recalculation and check the results and flags.
- Once modifications are done, press VALID to validate or ESC to exit without any modification.
- Press INIT. STANDARD to return to the manufacturer parameter setting.

#### 3.4.4.3 Alarms:



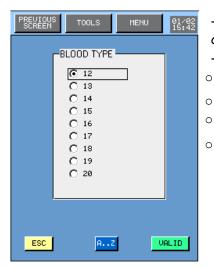
- In the Alarm menu, users can modify the sensitivity of the alarms for the different cells (WBC, RBC and PLT).
- Once modifications are done, press validate or to exit without any modification.
- Press INIT. STANDARD to return to the manufacturer parameter setting.

#### 3.4.4.5 Correction factors:



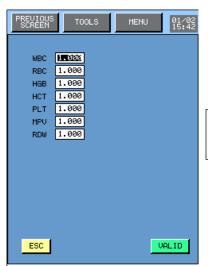
- This function can be reached only for any other type than the standard.
- In this menu, for each blood type, users can define a correction factor which is multiplied by the calibration factor given by a normal calibration (see section  $\overline{Z}$ ).
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

### 3.4.4.4 Rename Types:



- In the Blood type menu, users can define the limits, thresholds, alarms and calibration correction factors associated to each blood type.
- To modify the name of the blood type:
- Select the type
- Press A...Z
- Input the new name.
- Press VALID to validate or ESC to exit without any modification.

### 3.4.5 Calibration factor:

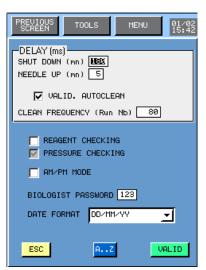


- In this menu, the user can modify the calibration factors without any calibration with calibration blood.



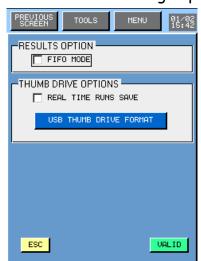
The modification of any of these factors without running a calibration blood could affect the quality of the result.

## 3.4.6 Other Setting:



- In **DELAY** box, the user can modify:
  - o Time in minutes to start the automatic shut down.
  - o Time in minutes to build up the needle.
- $_{\odot}\,$  The setting up of the automatic cleaning and its frequency in number of analysis.
- Reagent checking enables the reagent control (see section 1.5.2)
- Pressure checking enables the pressure control during a measurement cycle (see section 9.6).
- AM/PM mode enables to display the time of your choice.
- BIOLOGIST PASSWORD 123 enables to modify the biologist password.
- DATE FORMAT DD/MM/YY = enables to select the date format.
- Once modifications are done, press validate or to exit without any modification.

### 3.4.7 Storage options:



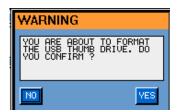
- Choose for a FIFO (first in /first out) mode or real time to store the results in the resident memory or in a USB key.
- REAL TIME RUNS SAVE enables to save the results in the USB key at the end of each measurement cycle.

- Press VALID to save the modification.

Press 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.

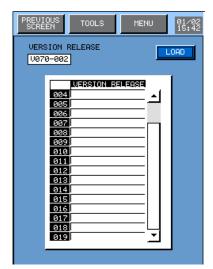


- Press yes if you agree to format the USB key. It is mandatory to format the USB key on the Mythic before to use it.



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

### 3.4.8 Version release:



- 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.

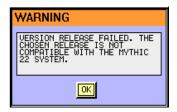




The current software version will be erased definitively.



- 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**: 60 samples/hour (approx.)

Sample Volume: 9,8  $\mu$ l (approx.)

Measurement Principle: WBC/RBC/PLT: Impedancemetry

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 <sup>3</sup> /mm <sup>3</sup> )	0 to 100	+/- 0,4 or +/- 4%
RBC (10 <sup>6</sup> /mm <sup>3</sup> )	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 <sup>3</sup> /mm <sup>3</sup> )	5 to 2 000	+/- 5 or +/- 5%

### Reportable range:

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

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

#### Repeatability:

Calculated with 20 runs of a fresh whole blood sample performed on a commercial MYTHIC 18 VET.

PARAMETERS	CV	RANGE
WB <i>C</i>	< 2,5%	> to 6,0×10³/mm³
LYM	< 5%	> to 15 %
MON	< 10%	> to 5 %
GRA	< 3%	> to 50 %
RBC	< 2%	> to 4,0×10 <sup>6</sup> /mm <sup>3</sup>
HGB	< 1,5%	> to 12,0 g/dL
HCT	< 2%	> to 35,0 %
MCV	< 1%	> to 85 fL
RDW	< 3%	> to 12
PLT	< 5%	> to 200×10³/mm³
PMV	< 3%	> to 7 fL

Calculated method:  $CV = \underline{S}$ 

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

$$N - 1$$

# Carry-Over:

For each parameter, we perform 3 runs from high concentration sample followed by 3 runs from empty cycles.

	WB <i>C</i>	RB <i>C</i>	HGB	PLT
High concentration value	18,0	5,33	17,9	466
Measured carry-over (%)	0	0,18	0	0,6
Maximum carry-over (%)	< 1,0	< 1,0	< 1,0	< 1,0

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

Carry-over = 
$$\frac{\text{(Result empty cycle 1) - (Result empty cycle 3)}}{\text{(Sample 3) - (Result empty cycle 3)}} \times 100$$

### Accuracy:

Parameter	Species	Coefficient of correlation	Intercept (Confidence interval)	Slope (Confidence interval)	Bias (95% Limits of agreement)
	Cat 0.94		0.26 (-0.14 to 0.61)	0.91 (0.88 to 0.95)	-0.074 (-6.959 to 6.815)
WBC	Dog	0.99	0.98 (0.68 to 1.36)	0.95 (0.92 to 0.98)	0.229 (-3.651 to 4.110)
	Horse	0.98	0.38 (0.17 to 0.56)	0.94 (0.92 to 0.97)	-0.126 (-1.496 to 1.243)
RBC	Cat	0.99	0.51 (0.37 to 0.66)	0.95 (0.93 to 0.97)	0.09 (0.400 to 0.581)
	Dog	0.99	0.26 (0.15 to 0.4)	1.0 (0.98 to 1.02)	0.241 (-0.096 to 0.578)
	Horse	0.98	0.38 (0.21 to 0.57)	0.93 (0.91 to 0.96)	-0.14 (-0.693 to 0.414)
HGB	Cat	0.99	0.38 (0.21 to 0.54)	0.92 (0.9 to 0.93)	-0.5 <b>11</b> (-1.256 to 0.234)
	Dog	1	1.02 (0.81 to 1.26)	0.93 (0.92 to 0.95)	0.1 (-0.57 to 0.76)
	Horse 0.98	0.48 (0.08 to 0.76)	0.94 (0.92 to 0.98)	-0.25 (-1.09 to 0.58)	

Parameter	Species	Coefficient of correlation	Intercept (Confidence interval)	Slope (Confidence interval)	Bias (95% Limits of agreement)
	Cat	0.99	2.05 (1.23 to 2.74)	0.94 (0.92 to 0.97)	0.16 (-2.15 to 2.48)
нст	Dog	0.99	1.2 (0.05 to 2.13)	0.95 (0.93 to 0.98)	-0.79 (-3.42 to 1.83)
	Horse	0.99	1.36 (0.43 to 2.13)	0.96 (0.93 to 0.98)	-0.17 (-1.95 to 1.61)
MCV	Cat	0.95	4.65 (2.5 to 7.12)	0.91 (0.85 to 0.96)	0.86 (-2.62 to 4.33)
	Dog	0.96	8.01 (4.54 to 11.37)	0.83 (0.78 to 0.88)	-3.16 (-6.03 to -0.28)
	Horse	0.94	3.62 (1.08 to 5.82)	0.9 (0.85 to 0.95)	-1.02 (-3.68 to 1.63)
PLT	Cat	0.8	-9.47 (-52.65 to 23.06)	0.88 (0.74 to 1.05)	-38.3 (-225.5 to 149)
	Dog	0.97	-8.06 (-27 to 7.22)	1.15 (1.1 to 1.22)	42.5 (-73.9 to 158.8)
	Horse	0.84	-18.08 (-37.57 to 4.82)	1.04 (0.93 to 1.16)	1.3 (-82.3 to 84.9)

### 4.2 PHYSICAL SPECIFICATIONS

### General:

Ambient temperature: from 18 to  $32^{\circ}C$ Relative Humidity: 80% maximum at  $32^{\circ}C$ 

Storage temperature: -10 to 50°C



If the MYTHIC 18 VET has been stored at a temperature less than  $10^{\circ}C$ , 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: 9kg (approx.)

Power supply Input: 24V - 3A DC

Electric consumption: In cycle: 30 VA (-30% +10%)

Stand By: 20 VA (-30% +10%) Maximum: 50 VA (-30% +10%)

Display: TFT Color LCD 240\*320

Mode portrait Retro-lighted

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

Memory capacity: > 1500 Files (Demographics, results and histograms)

QC: 6 levels (100 Files per level)

Connection: RS 232C

Ethernet (TCP/IP)

# Reagent Consumption (ml):

CYCLES		DILUENT	LYSE	CLEANER
Run Sample		12,80	0,34 **	0,42
Rinse All		6,00		
Back flush		6,00		0,20
Control		10,00		0,84
	All	28,00	4,00	9,00
Reagent Prime	Lyse	12,00	3,00	
	Diluent	30,00		
	Cleaner			8,60
Cleaning		6,00		2,10
Bleach		6,00		
Start Up *		32,80	0,34**	0,42
Shut Down				15,00

<sup>\*</sup> Consumption with one run sample, add one or two run sample consumption if needed.

### POWER SUPPLY BLOCK:

**Dimensions**: Height: 31 mm (approx.)

Width: 58,5 mm (approx.) Depth: 132 mm (approx.)

Weight: 0,35 kg (approx.)

Power supply Input: 100 to 240V AC - 1,5A

50-60Hz

REF: M18 Vet/UM-EN/001

<sup>\*\*</sup> The consumption of the lysis is given for the ORPHEE reagent with a standard adjustment and depends on the animal analyzed.

### 4.3 REAGENTS SPECIFICATIONS

All the reagents must be stored at room temperature (15°C to 25°C).

### 4.3.1 Diluent

Shelf life once opened: 60 days.

<u>Application</u>: The diluent is used to carry out the necessary dilutions for the measurement performed by the **MYTHIC 18 VET**. (see section 8)

Active components: 0,45% Sodium Chloride.

1,00% Sodium Sulfate.

Others components: Buffer.

Preservative.

<u>Description</u>: 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.

Eyes: Abundantly rinse during 15 mn.

Skin: Abundantly rinse.

Ingestion: Vomit.

If any doubt, call an emergency center.

### 4.3.2 Lysis reagent

Shelf life once opened: 60 days.

<u>Application</u>: Lytic reagent is used to lyse the red blood cells, the leukocyte differentiation and the cyanmethemoglobin complex formation used during the measurement performed on the **MYTHIC 18 VET** (see section 8)

Active components: 3,50% surfactant.

0,03% Potassium cyanide. Quaternary ammonium salt.

<u>Description</u>: Clear aqueous solution with a light almond odor.

### 4. SPECIFICATIONS

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

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

### First emergency care:

Inhalation: Breathe fresh air.

Eyes: Abundantly rinse during 15 mn.

Skin: Abundantly rinse. Ingestion: Vomit.

If any doubt, call an emergency center.

# 4.3.3 Cleaning solution

Shelf life once opened: 60 days.

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

Components: Enzyme

Potassium and Sodium salts. Surfactant and preservatives.

Coloring agent.

Description: Clear aqueous solution, blue color.

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

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

### First emergency care:

Inhalation: Breathe fresh air.

Eyes: To rinse abundantly during 15 mn.

Skin: To rinse abundantly.

Ingestion: Vomit.

If any doubt, call an emergency center.

REF: M18 Vet/UM-EN/001

### 4.4 ANALYTICAL LIMITATIONS

### 4.3.1 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.

### 4.3.1 Interferences

Parameter	Specimen		Possible Indication of Error
WB <i>C</i>	Cold Agglutinin	(+)	↑MCV, ↓HCT, red cell clumping on smear
	Nucleated RBC	(+)	NRBC on smear
	Cryoglobulins	(+)	
	Platelet aggregation	(+)	Platelet aggregates on smear
	Erythroblastosis	(+)	Erythroblasts on smear
RBC	Cold Agglutinin	(-)	↑MCV, ↓HCT, red cell clumping on smear
	Severe Microcytosis	(-)	
	Fragmented RBC	(-)	
	Leukocytosis (>100,000/μL)	(+)	Elevation of WBC
НGВ	Leukocytosis(>100,000/[L)	(+)	Elevation of WBC
	Lipemia	(+)	↑MCHC, "milky" appearance of plasma
	Abnormal Protein	(+)	↑MCHC, Lysed Hgb/WBC sample turns cloudy
HCT	Cold Agglutinin	(-)	↑MCV, ↓HCT, red cell clumping on smear
	Leukocytosis(>100,000/µL)	(+)	Elevation of WBC
	Abnormal Red Cell Fragility	(?)	
	Spherocytosis	(?)	↓MCV, spherocytes on smear
PLT	Pseudothrombocytopenia	(-)	Platelet Satellitism on smear
	Platelet Aggregation	(-)	Platelet Aggregates on smear
	Increased Microcytosis	(+)	↓MCV
	Megalocytic Platelets	(-)	

<sup>(+):</sup> Instrument count is affected by an increase in the result.

<sup>(-):</sup> Instrument count is affected by a decrease in the result.

<sup>(?):</sup> Instrument count is affected by either an increase or decrease in the result which is sample dependent.

### REF: M18 Vet/UM-EN/001

# 5. SAMPLE ANALYSIS

### 5.1 VERIFICATIONS BEFORE STARTING

Before starting MYTHIC 18 Vet, we recommend to check the reagent levels and the level of the waste container. Please also check the paper quantity in the printer.

### 5.2 START UP

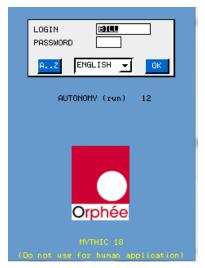
- Press ON/OFF button on the printer to start.
- Press ON/OFF button



on the Mythic.



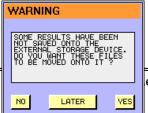
- The initialization menu is displayed and MYTHIC 18 VET performs a home position checking for the three motors.
- The cycle LED turns red. None cycle can be performed before it turns green.



- Enter your login and password as described in section 3.1.
- AUTONOMY (run) indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

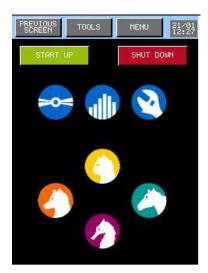


- If this window appears, it means that several results in memory have not been sent before the MYTHIC 18 VET was switched off.
- Press YES to send them immediately, or press LATER to wait at another time or NO if you do not want to send them.



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

### 5.3 REAGENT REPLACEMENT



- To check the level of reagents, press then REAGENT



- If the pack needs to be replaced, proceed as indicated in section  $\underline{\textbf{1.5.2}}$
- AUTONOMY (run) indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

### REF: M18 Vet/UM-EN/001

### 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: 0.5RBC: 0.1HGB: 0,5PLT: 10

If the level is higher, MYTHIC 18 VET proposes to perform a new start up or to escape. If the user chooses to escape, every result will be printed with "Start Up not done "message.

### 5.5 PREPARATIONS BEFORE ANALYSIS

The Veterinary blood venous sample must be collected in an EDTA K3 (Ethylene Diamine Tetracetic Acid, tri potassic) tube in sufficient quantity. The LMG results are available for six hours after the blood draw. The use of EDTA K2 leads to a poor quality level of the LMG results.

It must be correctly homogenized before analysis. It is recommended to use a rotary agitator turning between 20 to 30 turns/mn during 10 minutes.



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).

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 18 VET is delivered with a standard parameter setting described in section 3.

# 5.6.2 Sample Identification



- From the main menu, press one icon between the set of icons available:



: Dog



: Cat

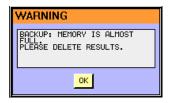


: Horse



: Others animals

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.

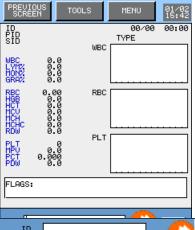


when the results memory is totally full.

section 5.10

- This prompt appears

- To delete results see



- 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.)
- o PID: Patient Identification (16 characters max.)
- o SID: Sample identification (16 characters max.)

NOTA: SID number is already done. (see section 3.2).



IDENTIFICATION PROCEDURE:

# 5. SAMPLE ANALYSIS

- REF: M18 Vet/UM-EN/001
- To enter or modify identification, place the cursor in the selected field with your finger or the arrow.

ESC

- To enter a figure, use the keyboard on the right of the screen, for a letter use the alphabetic keyboard by pressing  $\frac{\text{A..Z}}{\text{B..Z}}$ .
- To accede to another character page press  $\stackrel{\checkmark}{=}$  or  $\stackrel{>}{=}$
- To change the blood type, press the combo box  $\square$  and select the type
- To valid the entry and return to the previous screen, press
- To return to the previous screen without validation, press

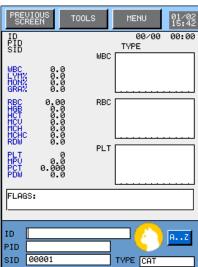
# 5.6.3 Sample run



- 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.

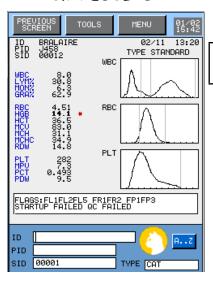


Wear rubber gloves and wash hands with a disinfectant after completion of work.



- As soon as the cycle is launched, the SID is incremented automatically and, thanks to its data processing multitasks, the MYTHIC 18 VET is available for the identification of the following sample (see section 5.6.2).

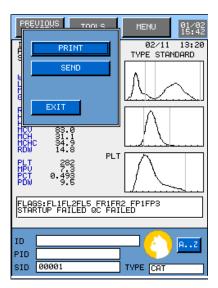
### 5.7 RESULTS



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

<u>NOTA</u>: 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 curves of distribution of each cellular population are located on the right screen.
- Under the results a zone (FLAGS) is reserved for analytical alarms.
- At the bottom of the screen, there are the three inlet fields for the identification of the following sample. (See section 5.6.2).
- Press to reprint or to resend the result.



- To print the result press

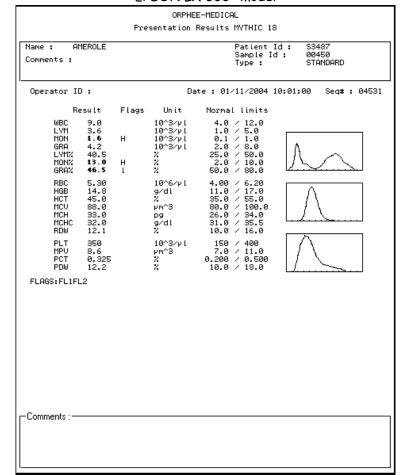
   To send the result, press
- To close the window, press

### 5.8 PRINTING

Once the analysis is finished, the MYTHIC 18 VET prints a result report. To modify the printing presentation or to disconnect the printer, see section 3.4.1.

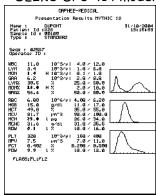
# 5.8.1 Model report (A4) - external printer

### EPSON LX 300+ model



# 5.8.2 Model report -Ticket printer

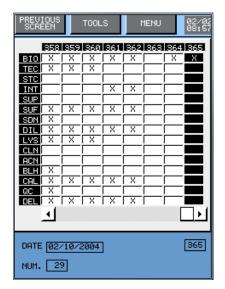
### SEIKO DPU 414 model



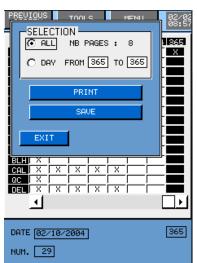
### **5.9 LOGS**

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

- MYTHIC 18 VET manages a simplified log allowing to save and display all the events done for the following actions:

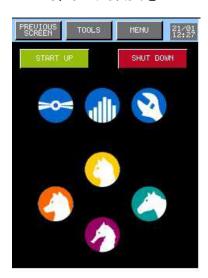


- BIO: Login with the Biologist code.
- **TEC**: Login with the service Technician code.
  - STC: Login with the "Super" service Technician code.
- INT: An intervention or maintenance has been performed.
- **SUP**: Start Up cycle has been performed.
- SUF: Start Up cycle has failed.
- SDN: Shut down cycle has been performed.
- DIL: Diluent replacement.
- LYS: Lysis replacement.
- CLN: Cleaner replacement.
- ACN: Auto cleaning cycle.
- **BLH:** Bleach cycle.
- CAL: Calibration.
- QC: Quality control.
- **DEL**: Results deleted in Archive.

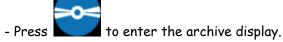


- Each column is identified by a number (recall at the right bottom of the screen 365). In the bottom of the screen is displayed the date DATE 02/10/2004 and under it the number of analysis NUM. 29 run during this day.
  - - To print the log report press
- Select oprint the logs of the number of pages indicated on the screen.
- To print the logs of one or more days select  $\Box$  DAY then enter the day reference number.
  - allows to save the log file in an USB key.

5.10 ARCHIVE

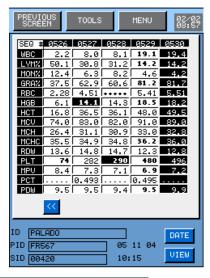


MYTHIC 18 VET can save more than the last 1000 patients with results, alarms, distribution curves.

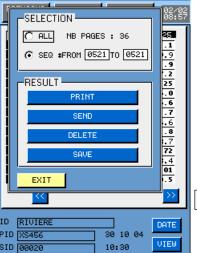


SEND

### 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 view an entire result, select the SEQ number wanted, press
- To print, send, delete or save (in an USB key) results press
- DATE allows to accede to the results date list.



- It is possible to print, send, delete or save (in a USB key):

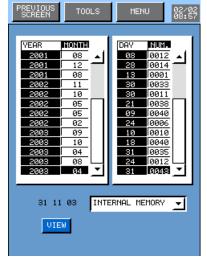
- . All results: Press 🔼 ALL
- . NB PAGES : 36 for printing.

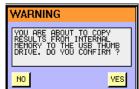
SEQ #FROM 0530 TO 0530

. Selected results: Select the first and the last results:



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

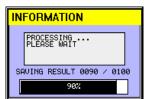




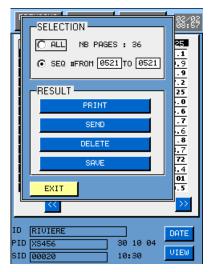
- This prompt appears to confirm the storage in the USB key.



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

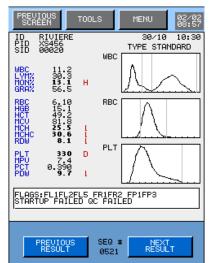


- This prompt allows to following the storage.

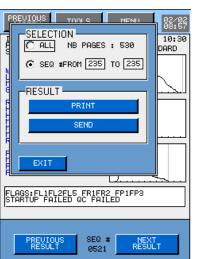


- To print, send, delete or save results per day press
- It is possible to print, send, delete or save:
  - . All results of the same month: Press 🌘 ALL
  - FROM 14 02 03
     Between two days of the same month: press TO 14 02 03
- The printed report is a list of all selected results between the two days.

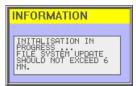
5.10.2 View



- Keys and allow displaying each result and its identification.
- To print, send or delete a result, press
- The printed report is full page with one or two results per page.
- To come back to the archive main page, press
- To come back to the Main Menu press

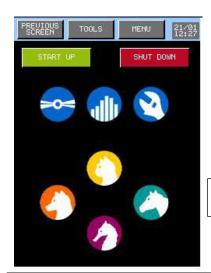


- To print or send a result, press
- It is possible to print or send:
  - . All results: Press 🌘 ALL
  - . Selected results: Select the first and the last results:
  - SEQ #FROM Ø526 TO Ø526
- To delete a result come back to the list display.



This message appears when you exit the result screens and it could stay up to 3' to enable the update of all the files.

### 5.11 STAND BY AND SHUT DOWN



- From the main menu, press automatically perform a shut down cycle.
- All the hydraulic circuits are rinsed, and then cleaned with the cleaning solution.
- At the end of the cycle, MYTHIC 18 VET 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 <u>5.2</u>)



MYTHIC 18 VET 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 18 VET 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.

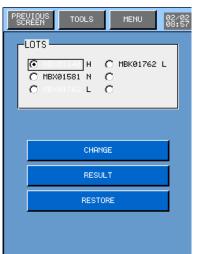
In case of exceeding the tolerances indicated on the blood control result sheet, it is recommended to perform a calibration (see section  $\overline{2}$ ).

### 6.2 QC

MYTHIC 18 VET 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.

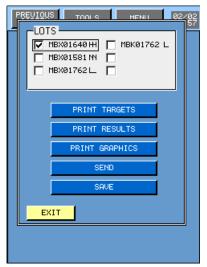


- Press then QUALITY CONTROL to have access to the quality control menu.



- 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 allows the modification of the identification and the target values.
- The key \_\_\_\_\_allows:
  - . To view the result table.
  - . To perform quality control analysis.
- The key RESTORE allows restoring the data from a USB key (results and targets) see section 6.2.4.
- To print or send the targets, results and graphics press

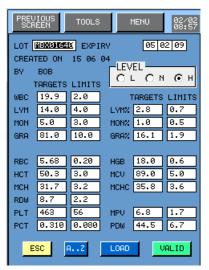
# 6. QUALITY CONTROL



- Tag the lot number to select then press the appropriate button.
- allows to save the targets, results and graphics in the USB key.

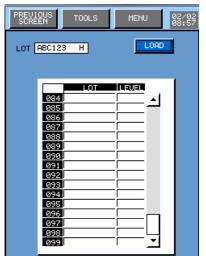
REF: M18 Vet/UM-EN/001

# 6.2.1 Change

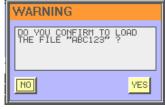


- In this display, the user can enter the:
  - o Lot number
  - o Expiry date
  - o Target values and tolerances
  - o Level
- Press to delete the modifications you made.
- Press to validate your modifications or the loading.
- Press to change the Lot number.
- To print the targets and limits come back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

<u>NOTA</u>: All the results in memory linked with the control lot number will be cleared as soon as the validation is confirmed.

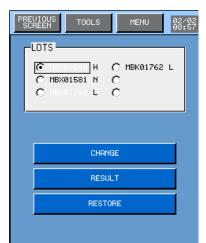


- Press to load from a USB key all the information about a new lot of calibrator.



- Press if you are sure to load the choice file.

### 6.2.2 Run control blood

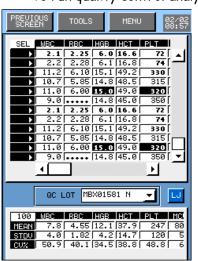


- Press to run the control blood.

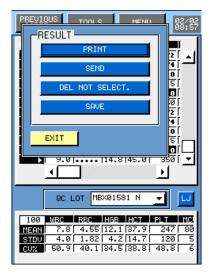


Before to run the control, check and clean the opening of the cover enabling the descent of the needle, to avoid any fall of dry blood particles inside the control tube

- To run quality control analysis:



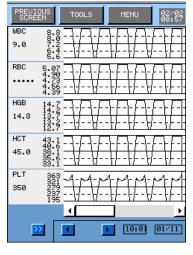
- o Press Results.
- Present the control blood under the sampling needle.
- o Press the start cycle trigger.
- The cycle LED located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- Repeat this operation as long as needed.
- The results are displayed in line run after run.
- The statistic calculations 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 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 a USB key) a result, press

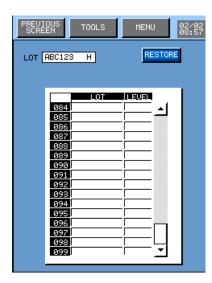
- Press 🔛 to open the Levey-Jennings graph screen.

# 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 1976 \to enable to move the cursor, the number is the number of the result
- give the date and the time of the displayed result.

### 6.2.4 Restore



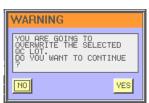
- This menu enables to restore all the information (results and targets) for the file selected from the USB key to the internal memory.



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



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



### 6.3 REPEATABILITY



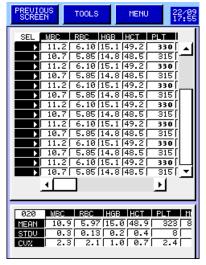
Page 60/93

- To run repeatability, press first then SERVIC



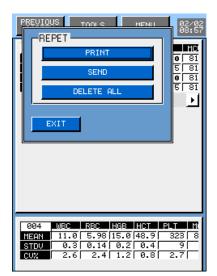
ts Reserved. MYTHIC 18

- 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 18 VET.

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

# 7. CALIBRATION



The calibration of the MYTHIC 18 VET 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).



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 then 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.



to print, send or save (in a USB key) all these information.

- To enter new values or to modify the values, press

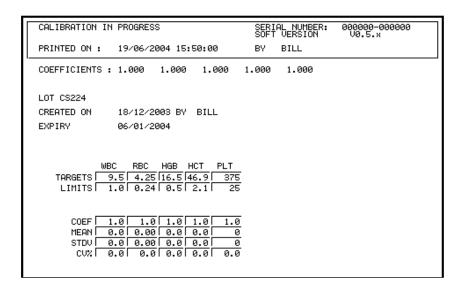
RESULT

CHANGE

- To calibrate, press

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)

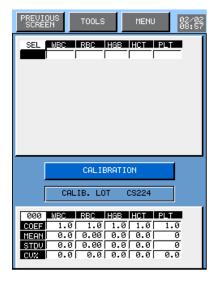
Model of print out calibration report:



### 7.1 RESULTS

### 7.1.1 Calibration blood analysis

This screen allows carrying out analysis on calibration blood to perform the MYTHIC 18 VET calibration. BEFORE TO CALIBRATE THE MYTHIC 18 VET, PLEASE CONTACT YOUR REPRESENTATIVE.



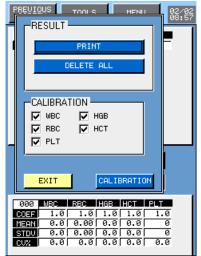
- Present the calibration tube under the sampling needle and press the trigger behind the needle.
- The cycle LED located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- The results are progressively sent on line in the table.
- Repeat the operation as many times as desired (maximum 10 runs).
- Statistical calculations are carried out automatically with each run.
- The window 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

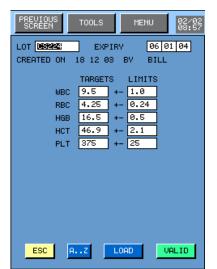




Before to start the calibration, unselect the results which you do not wish to use for the calculation of the calibration (see below section 7.1.1).

- The key CALIBRATION or TOOLS allows:
- To calibrate with the selected results.
- To delete the results, Press
   DELETE ALL
- To calibrate one or more parameters:
  - Select the parameter
- Press the key CALIBRATION

### 7.2 TARGET VALUE MODIFICATIONS



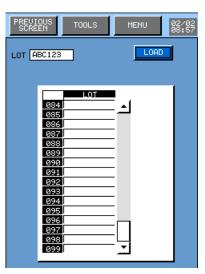
- To modify information relative to a batch or to create a new batch, please follow the following steps:
  - From Calibration Menu, press

    CHANGE

    CHANGE
  - Select the lot number LOT LOT
  - To modify the lot number press
- 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.
  - Press ESC to leave the menu without modification.

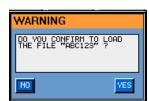


Any modification (lot number, date or target values) involves the deletion of all the associated results always in memory.





- Press LOAD to load from a USB key all the information about a new lot of calibrator.



- Press VES if you are sure to load the right file.

# 8. TECHNOLOGY

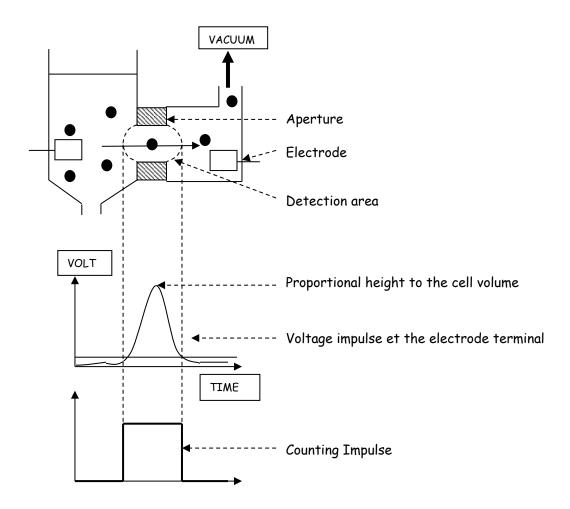
### 8.1 DETECTION PRINCIPLE

# 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 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 cyanmethemoglobin type, for lytic solution with cyanide and oxyhemoglobin for lytic solution without cyanide.

A measurement of the blank of hemoglobin is done for each analytic cycle and during the start up rinsing step.

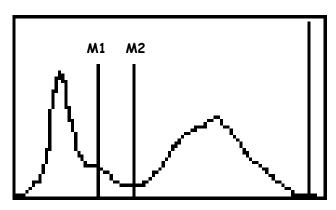
An automatic offset circuit for the LED 555 nm allows to maintain the blank level at the same range. It is not necessary to adjust this range with a potentiometer.

### 8.2 LEUCOCYTE ANALYSIS

The leukocyte analysis is done by impedancemetry in the WBC counting chamber, seven parameters are obtained:

	Parameters	Pathologies (adjustment section 3.4.4.1)
WBC	White Blood Cells	Leukocytosis : WBC>WBC h
		Leucopenia : WBC <wbc b<="" td=""></wbc>
LYM%	Lymphocytes in percentage	Lymphocytosis: LYM>LYM h (% &/or #)
LYM#	Lymphocytes in value	Lymphopenia : LYM <lym #)<="" (%&="" b="" or="" td=""></lym>
MON%	Monocytes in percentage	Monocytosis: MON>MON h (%&/or #)
MON#	Monocytes in value	
GRA%	Granulocytes in percentage	Granulocytosis : GRA > GRA h (%&/or #)
GRA#	Granulocytes in value	Ganulopenia : GRA < GRA b (%&/or #)

The formula approach is obtained by WBC distribution curve analysis after action of the lytic reagent. This reagent destroys the RBC and their stromas and acts on the white blood cell cytoplasmic walls.



In this case, lymphocytes are between the beginning of the curve and M1, monocytes between M1 and M2 and granulocytes higher than M2.

When the WBC result is lower than  $1.0\times10^3/\text{mm}^3$  the lymphocytes, monocytes and granulocytes results and the curve do not appear.

### 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:

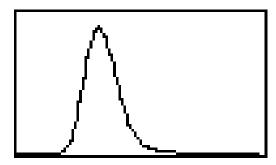
	Parameters	Pathologies (adjustment section 3.4.4.1)
RBC	Red Blood Cells	Erythrocytosis : RBC>RBC h
HGB	Hemoglobin	Anemia : HGB < HGB b
HCT	Hematocrit	
MCV	Mean Corpuscular Volume	Microcytosis : VMC <vmc b<="" th=""></vmc>
	·	Macrocytosis : VMC>VMC h
MCH	Mean Corpuscular Hemoglobin	
MCHC	Mean Corpuscular Hemoglobin Concentration	Hypochromia : MCHC <mchc b<="" th=""></mchc>
	-	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:

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

$$RDW = \underbrace{k \cdot SD}_{MCV}$$



### Wintrobe constant calculation:

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

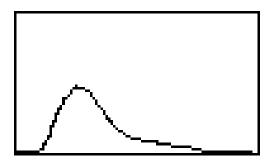
The Mean Corpuscular Hemoglobin Concentration (MCHC) is made from HGB and HCT by the formula below:

### 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<="" th=""></plt>
		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:

## 8.5 ALARMS

MYTHIC 18 VET manage 17 different alarms. These alarms allow the user to be alerted if there is a mistake which can affect the quality of the results. All of these alarms appear on the right of the result.



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

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

### 8.5.1 General Flags

The following alarms are common for all parameters.

\*: Counting or measure rejection. Can appear with WBC, RBC, PLT and HGB (see section 8.5.3 for HGB) 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.

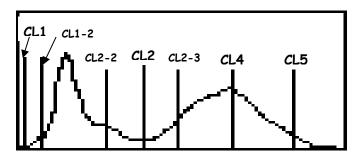
h: results higher than normal value.

**b**: results lower than normal value.

H: results higher than panic value.

B: results lower than panic value.

# 8.5.2 Leukocytes Flags



L1 = CL1 to CL1-2: Platelet aggregate or erythroblast

L2 = CL2 to CL2-2: Presence of Myelocytes, lymphoblast or basophiles.

L3 = CL2 to CL2-3: Presence of eosinophils, myelocytes.

L4 = CL4 Granulocyte volume too low

L5 = CL5 to the end: Presence of large size cells.

# 8.5.3 Erythrocyte and HGB Flags

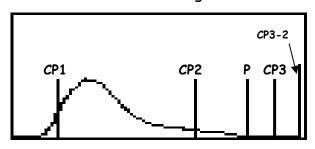


R1 = CR1: Abnormal quantity of microcytes at the left side.

R2 = CR2: Abnormal quantity of macrocytes at the right side.

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 Machine Flags

**INS\_T** = Means that the working temperature is lower than  $17^{\circ}C$  or higher than  $33^{\circ}C$  and the result could be affected.

INS\_P = Means that the vacuum counting is out of range, if the flag appears at each cycle, please contact your Orphée's representative.

### 8.6 HYDRAULIC DESCRIPTION

The hydraulic part of the MYTHIC 18 VET is very simple and made of only three modules:

- Sampling module.
- Counting bath module.
- Syringes module.

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 (patent pending) enables:

to draw the sample

to distribute the reagents

to drain the baths

to do the vacuum necessary for counting

and to push the waste to the waste container.

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.

# 8.7 SOFTWARE 8.8.1 Windows

### Common keys:

This three keys

PREVIOUS TOOLS MENU 92/92 are always present in all screen

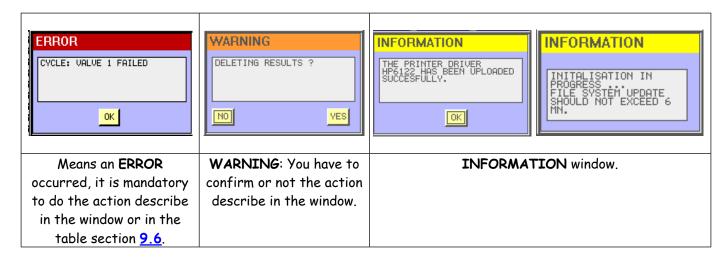
allows to come back to the previous display.

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:

MENU



## 9. SERVICE

The quality of the results and the reliability of the MYTHIC 18 VET 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		MONTHLY		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 5.1
- Start up: see section 5.2
- <u>Automatic Cleaning</u>: The cleaning is automatically performed by the **MYTHIC 18 VET** 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 18 VET in case of analyzes of pathological samples or if there are too many flags and too often.

- Concentrated cleaning: see section 9.1.1
- Shut down: see section 5.11
- <u>Cover cleaning</u>: 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

#### 9.1.2 Concentrate cleaning

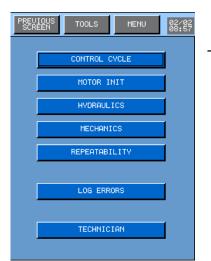
This cleaning is necessary when MYTHIC 18 VET Vet is in permanent rejection for one measured parameter.

Prepare a Sodium Hypochlorite solution at 12° in chloride (or 3.6%) (diluted 4 times with distilled water if sodium hypochlorite is concentrated at 48° in chloride or three times with 36°).

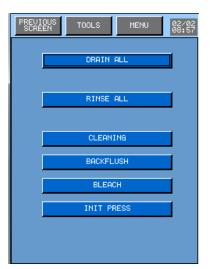


- Return to the main menu by pressing MENU.





- Press HYDRAULICS



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





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

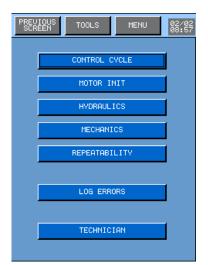
- Wait for the information window and then
- Open the door on the right side (see section 1.1.3).
- Put 2 ml of sodium hypochlorite solution (12° or 3.6%) in each counting chamber.
- Press the button in the window located in the screen center.
- MYTHIC 18 VET perform a maintenance cycle of the apertures follow with a standby mode during 2 min.
- After 2 min. MYTHIC 18 VET rinses all of the elements.



Perform a blank cycle before to run any analytic cycle

SERVICE

# 9.1.3 Piston greasing

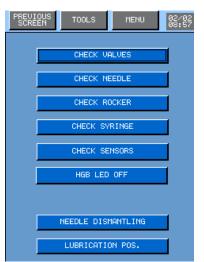


- To have access to the hydraulic cycle, press

• 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

from the MAIN MENU, then press

MECHANICS



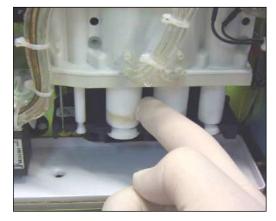
LUBRICATION POS. to put the piston of the syringe module in - Press the greasing position.





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

- Wait for the information window and then
- Open the door on the right side (see section 1.1.3).
- Put a small nut of grease on a finger.

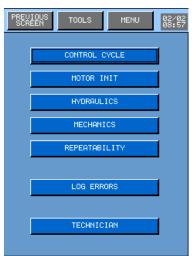


- Put a thin film of grease around each piston.



- 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.

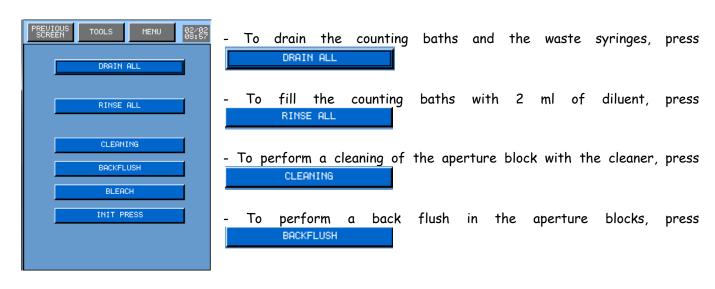
# 9.2 HYDRAULIC CYCLES



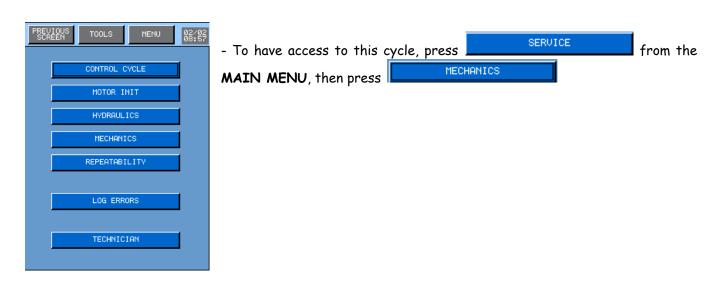
- To have access to the hydraulic cycle, press

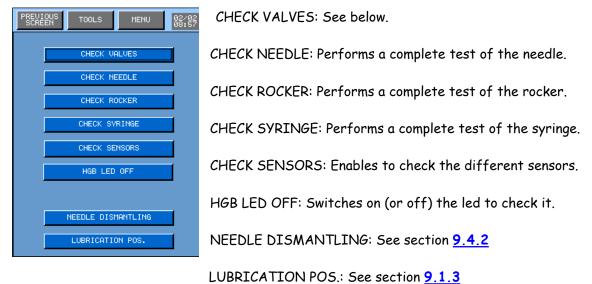
from the MAIN MENU, then press

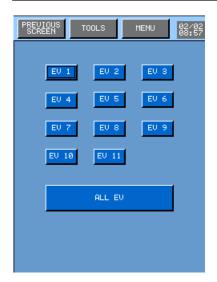
HYDRAULICS



#### 9.3 MECHANICS







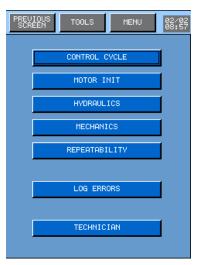
- To test each valve, press the dedicated button.

- To test all the valves press

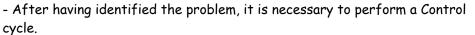


### 9.4 REPAIRING

# 9.4.1 Emergency stop



In case of mechanical or hydraulic problem, immediately press , the MYTHIC 18 VET will make an emergency stop.

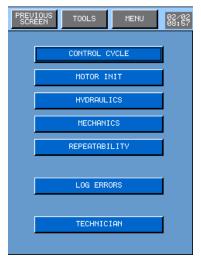


- To have access to this cycle, press SERVICE from the MAIN MENU, then press

# 9.4.2 Needle or o-ring replacement



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

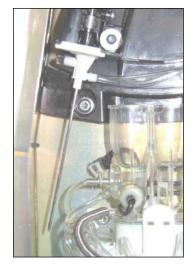


- From the main menu, press

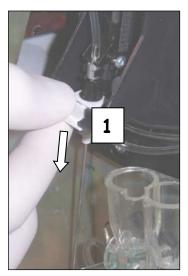
  to go to the display described on the left.

  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.

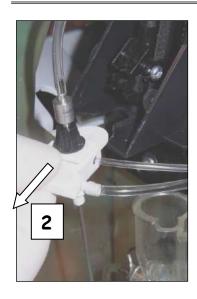
Wait for the information window and then open the door.



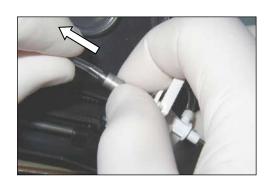
- The needle is in front of the counting chambers



- Remove the sampling module, while slightly lowering the clip  $oxed{1}$  to the bottom.



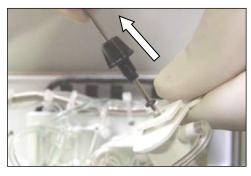
- Draw the system towards outside  ${f 2}$  .



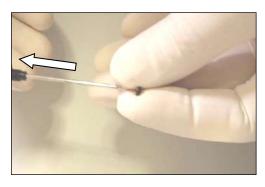
- Remove the tubing fixed at the end of the needle.



- 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:

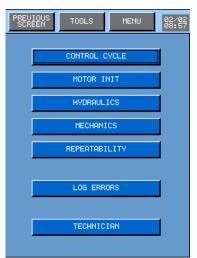
To reassemble the unit, carry out the various operations in the opposite direction. Place the seal on the needle gently not to wound it.

## 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.



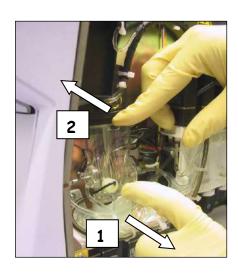
- From the MAIN MENU, press



then SERVICE and HYDRAULICS.



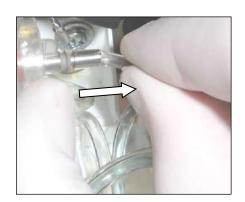
- Press DRAIN ALL to perform a draining of the counting baths.
- Open the door located on the right side of the instrument to have access to the hydraulic part.



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



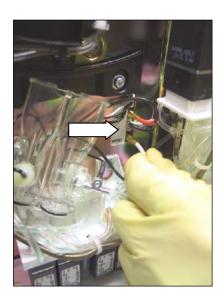
- Then, upwards, raise the counting module.



- 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.

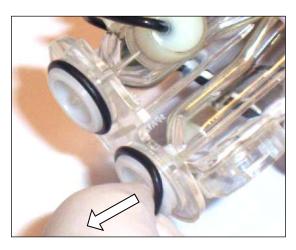
### REASSEMBLY PROCEDURE:

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:

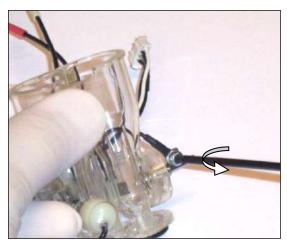
To reassemble the unit, carry out the various operations in the opposite direction.

Place the seal on the counting bath gently not to wound it.

# 9.4.5 Aperture block replacement

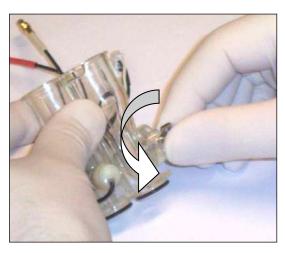


Wear rubber gloves and wash hands with a disinfectant after completion of work.

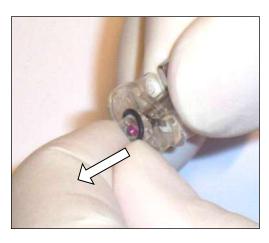


- Before performing the operation, drain the baths and dismantle the counting bath block (see section 9.4.3).
- Remove the tubing from the blocks to be replaced.
- With the help of the provided tool in the maintenance kit, unscrew the screw and remove the connection.

**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 results	No HGB	Check the bath wires.
			Check the lysis level.
			Check the right lysis tubing connection to the WBC bath.
		HGB OK	Check the bath wires.
			Perform a Cleaning Cycle and then a Bleach cycle 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.
RBC	No results	No HCT & PLT	Check the bath wires.
			Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful.
	Bad stability	HCT & PLT too	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 results		Check the led light on.
	Bad stability		Check if no bubble in the lysis tubing.
			Check the level bubble flow in the WBC bath during
			the run cycle.
	Rejection		Close the door.
		*	Perform a new Start Up cycle.

# 9.5.2 Other problems

ORIGIN	PROBLEMS	SOLUTIONS				
MYTHIC	Diluent leaks around the	Check the rinsing needle block (presence of clots) and clean				
	needle during the run cycle	it if necessary see section <u>9.4.2</u>				
	No starting	Check the power supply connection wires.				
	All results bad	Check the level diluent and if the supply tubing is pinched.				
		Check if the diluent is placed at the same level as the				
		MYTHIC 18 VET				
	No display	Check the flat cable.				
	ID and/or PID typing	ID and/or PID are mandatory (see section 3.4.3).				
	impossible					
	Message : cycle : pressure	Check the level of the reagents; check the tubing				
	default or Flag INS_P	connection of the fluidics.				
Printer	No printing	Check the paper.				
		Check the electrical connection.				
	Bad printing	Check the black ribbon.				

## 9.6 TROUBLESHOOTING MESSAGE

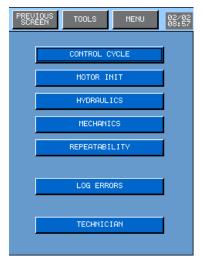
This section allows knowing what to do when a troubleshooting message appears on the screen. In any case, if a problem is not solved, call Orphée's representative.

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	Please connect USB thumb drive to the analyzer
MEMORY IS USED.	Thease connect COB manib arrive 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 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
	Try to send the file again If the problem still occurs, call an
COM: SIZE ERROR.	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.

MESSAGE	ACTION
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: 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.
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.

MESSAGE	ACTION
RS232: TIME OUT	Re-start the Mythic.
RUNNING AUTO CLEANING	Press OK.
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 cannot 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.
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.
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

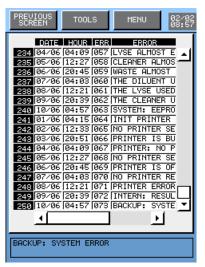




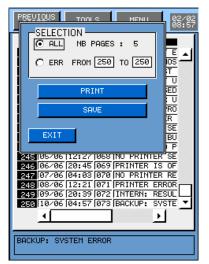


then SERVICE

- 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



- Select opint 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  $\Box$  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.

		tubing	tubing	tubing	tubing	tubing
	I	0,8×2,4mm	1,3×3mm	1,6x3,2mm	2×4mm	3×6mm
	Designation					
005-1001-90 01	Tubing 1			820+180mm		
005-1001-90 02	Tubing 2			250mm		
005-1001-90 03	Tubing 3				135+20mm	
005-1001-90 04	Tubing 4				175+15mm	
005-1001-90 05	Tubing 5				210mm	
005-1001-90 06	Tubing 6				170mm	
005-1001-90 07	Tubing 7			220mm		
005-1001-90 08	Tubing 8			80mm		
005-1001-90 09	Tubing 9		425mm			
005-1001-90 10	Tubing 10	370mm			8mm	
005-1001-90 11	Tubing 11				90mm	
005-1001-90 12	Tubing 12			60mm		
005-1001-90 13	Tubing 13			250mm		
005-1001-90 14	Tubing 14			250mm		
005-1001-90 15	Tubing 15			1000mm		
005-1001-90 16	Tubing 16			130mm		
005-1001-90 17	Tubing 17			80mm		
005-1001-90 18	Tubing 18			80mm		
005-1001-90 19	Tubing 19			80mm		
005-1001-90 20	Tubing 20			130mm		
005-1001-90 21	Tubing 21			600mm		
005-1001-90 22	Tubing 22		200mm			
	Tubing 23 - DILUENT					1500mm
005-1001-90 24	Tubing 24 - WASTE					1500mm

