

# MINISAT

## USER MANUAL

Software Version 2.xx

*distributed by:*



CE

**Cod. ManMST03f**  
Last revision: 20180404  
Ver: 1.2



**INDEX**

<b>1. GENERAL DESCRIPTION .....</b>	<b>6</b>
1.1. Foreword.....	6
1.2. Technical characteristics.....	6
1.3. Precautions and limitations .....	10
1.3.1. Intended use .....	10
1.3.2. Performance .....	10
1.3.3. Protection .....	10
<b>2. INSTALLATION AND PRELIMINARY OPERATIONS .....</b>	<b>11</b>
2.1. Transportation, storage and unpacking.....	11
2.1.1. Composition of the supply .....	12
2.2. Installation .....	12
2.3. Disinstallation .....	12
<b>3. USE.....</b>	<b>14</b>
3.1. Introduction switch on of the instrument .....	14
3.2. Start up of the instrument, autodiagnosis and printing of the messages.....	14
3.3. Warming phase .....	14
3.4. Main manu .....	15
3.5. Checking the calibration system .....	16
3.6. Precaution during the use of the instrument .....	16
3.7. SAT (Soluble antioxidant ) .....	17
<b>4. MAINTENANCE .....</b>	<b>19</b>

**FIGURE INDEX**

<i>Figure 1.1 - Front view .....</i>	<i>8</i>
<i>Figure 1.2 - Front panel with indication of the parts .....</i>	<i>8</i>
<i>Figure 1.3 Back panel with indication of the parts .....</i>	<i>9</i>

## **I. RESPONSIBILITY DECLARATION**

H&D declines all responsibility for damage due to any type of modifications made on the Hardware and Software due to connection to other instruments not carried out by our personnel or not previously authorized by our firm. In case the apparatus is damaged do not switch it on until it has been repaired by a technician from our company's Service Department.

Any type of electric operation required to install or repair the instrument must be carried out by our staff; do not install in any other way.

The instrument should be used under the environment conditions and according to safety norms given in points II and III of the following chapter, in order to guarantee that the results obtained by the instrument are equivalent to those given in the technical specifications.



**WARNING**

***Use this instrument only after reading this manual***

## **II. SAFETY PRECAUTIONS**

The photometer **MINISAT** guarantees the maximum safety to the operator during its operation. However, as there is dangerous internal voltage, the operator must follow the general safety rules:

- \* Make sure that the Power Supply has the required voltage before switching on the instrument.
- \* Do not use the commands or adjustments inside the instrument and notify the service staff as soon as any anomaly occurs during functioning.
- \* In case of overabsorption (due to short circuit or other failure or sudden changes in the instrument of voltage) intervene to ensure that the internal protection interrupts the power. In this case, if you look at it instrument has an intermittent functioning characterized by phases of spontaneous and off, unplug the cable from the power supply and notify the staff of the Technical Assistance Service.
- \* Do not open the instrument. Inside the instrument there are not parts serviceable or replaceable by the user.
- \* Do not put foreign objects (screwdrivers, drills, etc..) into openings in the body of the instrument.
- \* Do not try to unscrew the screws on the bottom cover of the instrument
- \* Any repair of the instrument must be carried out by the Technical Assistance Service.
- \* Any electric operation that is necessary to the installation must be carried out by qualified staff.
- \* If the instrument is damaged do not switch it on until it has been repaired by a technician of the Technical Assistance Service.
- \* Take care to prevent penetration of liquids into the instrument. If it occurs accidentally, unplug the instrument from the mains and do not reconnect it until the instrument has been checked by the Technical Assistance Service.
- \* Disconnect the instrument if it is left inactive for a long period.
- \* Note on the use of biological samples:



***Handling clinical samples presents a significant biological safety hazard and should be carried out with extreme caution.***

**III. ELECTRICAL FEATURES AND LINE DISTURBANCE**










Disturbances on the power line may be caused by several factors such as:

- Starting and stopping of electric motors.
- Atmospheric phenomena.
- Connection and disconnection of high line loads.

Serious power supply line disturbances have negative effects on the system.

<b>Distribution</b>	:	1 phase and neutral
<b>Power supply</b>	:	100 ÷ 240 VAC 50 - 60 Hz
<b>Consumption</b>	:	25 W

**TABLE OF SYMBOLS**

Number	Symbol	Description
1		Alternating current
2		Ground terminal
3		On (power)
4		Off (power)
5		Caution: risk of electric shock
6		Caution: see attached documentation
7		Caution: biological risk
8		CE mark
9		Instrument with double insulation

## CHAPTER 1

### GENERAL DESCRIPTION

#### 1.1 FOREWORD

**MINISAT** is a POCT (Point of Care Testing) photometer that measures antioxidant potential on saliva sample. The principle adopted is the absorbance measurement of a sample solution in a cuvette through a monochromatic light beam; once reading the absorbance value the instrument provides automatically with the conversion into the appropriate units.

The aluminum block containing the photometric unit are thermostated at 37°C.

Even if every effort has been done in order to improve the friendliness of use of the equipment, it is important to have a very good understanding of the user manual including the labeling and any information describing the reagents adopted.

This allows to take the maximum advantage of the characteristics of **MINISAT** avoiding problems and obtaining accurate analytical results.

The manufacturer has the rights to introduce any modification to any information contained in the present user manual without prior notification.

#### 1.2 TECHNICAL CHARACTERISTICS

Photometric system	
Light source	: High efficiency led.
Spectral range	: 505 nm interferential filter with 8 nm bandwidth
Photo detector	: High sensitivity solid state.
Measuring principle	: Lambert Beer's law
Temperature	: 37 °C
Interface	
Display	: backlit graphic touchscreen
Connection	: USB2.0

<b>General Characteristics</b>	
Power supply	: 100 ÷ 240 VAC 50 - 60 Hz
Consumption	: 25 VA
<b>Operating conditions</b>	
Temperature	: 15 ÷ 32 °C (operating) ÷ 50 °C (non operating)
Relative humidity	: 20 ÷ 80 % (operating) 0 ÷ 90 % (non operating)
Altitude	: < 2000 m (operating)
Environmental coefficient	; 2
Acoustic Pressure	: <50dBA
Protection class IP	IP30
Safety	: EEC 73/23 and EEC 93/68 DIRECTIVE
Electromagnetic compatibility	: EEC 89/336 DIRECTIVE
In vitro diagnostics	: EC 98/79 DIRECTIVE
Dimensions	: 275 x 200 x 78(h) mm
Weight	: 1,4 Kg

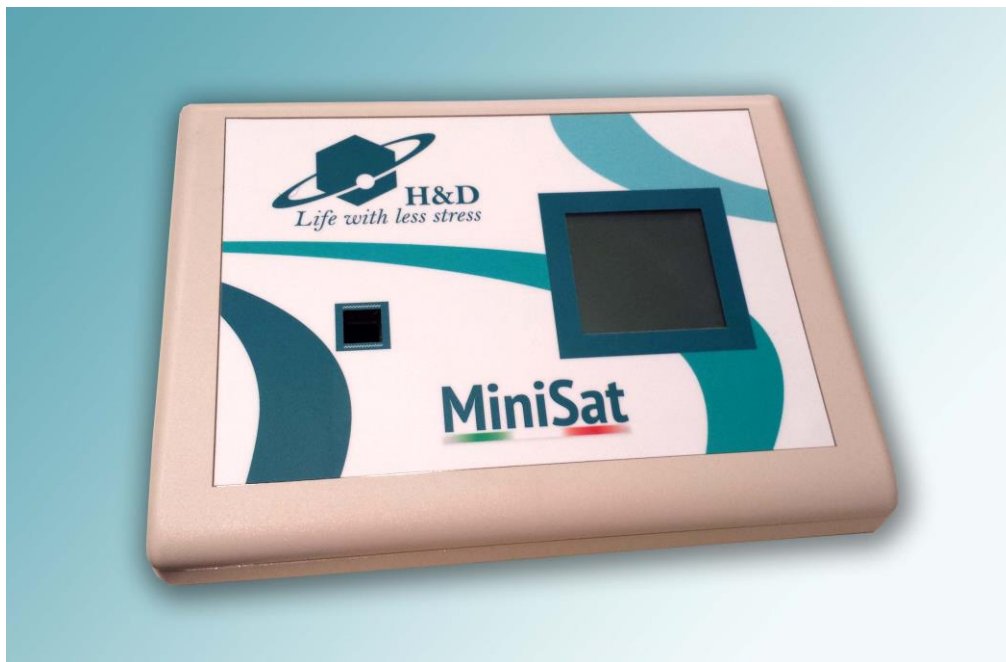


Figure 1.1 - Front view

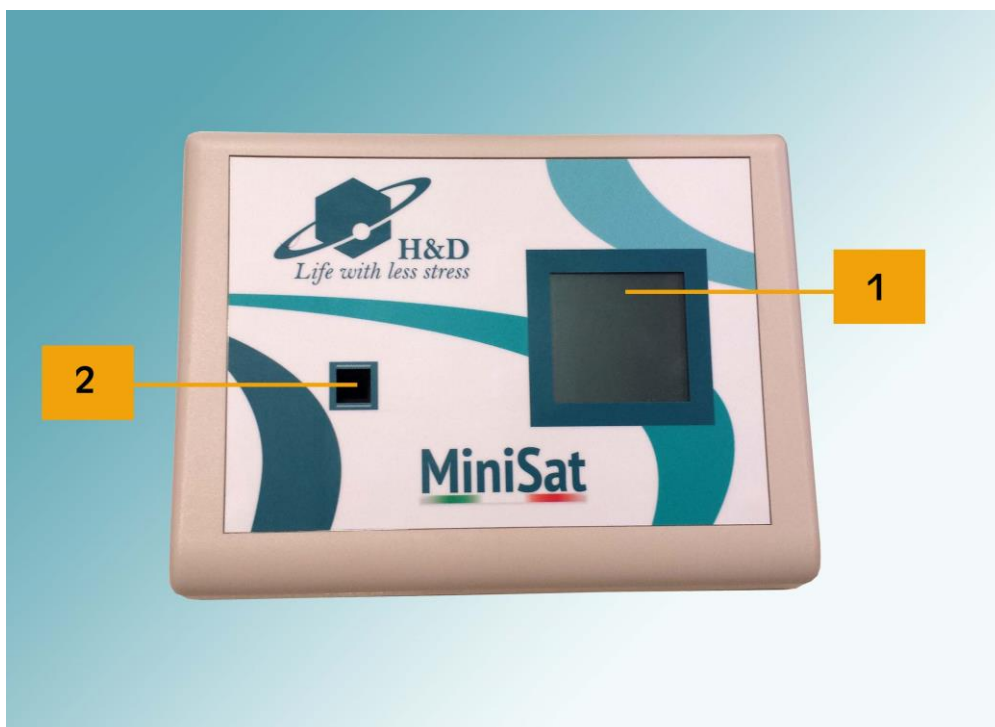


Figure 1.2 - Front panel with indications of the parts

Nr. Rif.	Name	Description
1	Display	The display shows help messages for the operator
2	Reading Cell	Temperature is stabilized at 37°C



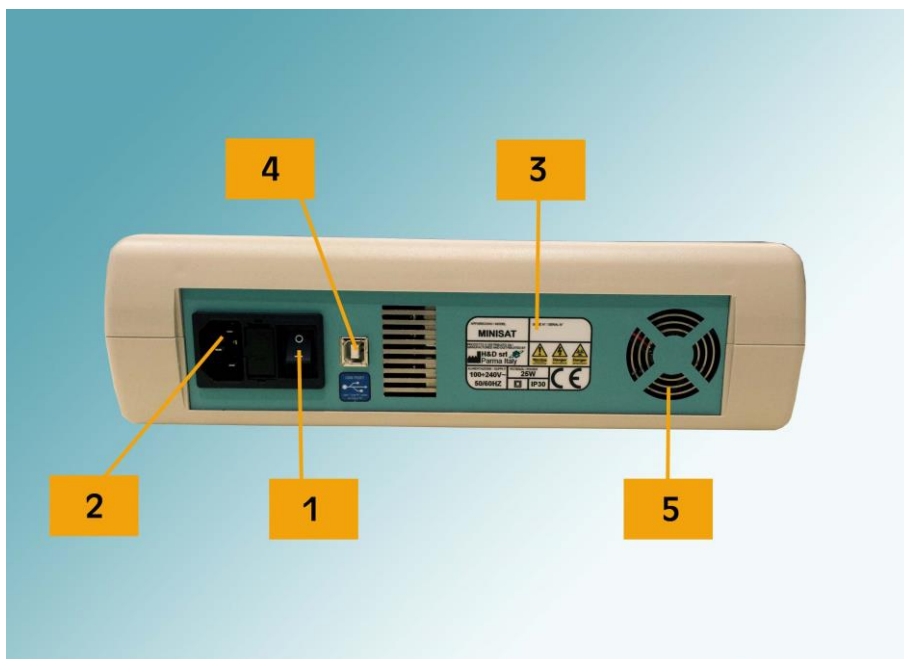


Figure 1.3 - Back panel with indications of the parts

Nr. Rif.	Name	Description
1	Switch	For turning on the instrument. To turn on, move the switch to “I” position, to turn off move to “O” position
2	Mains outlet	For connecting to mains (cable included in the package).
3	Technical and Safety Labelling	There are some technical information, the serial number and manufacturing information. They draw attention to some issues concerning the safe use of the instrument.
4	Interface USB	Type B USB outlet for connecting to PC (the cable is an accessory)
5	Fan	To avoid excessive internal heat

### 1.3 PRECAUTIONS AND LIMITATIONS

#### 1.3.1 INTENDED USE

The device MINISAT is intended for in Vitro Diagnostic use and performing oxidative stress tests.

The instrument must be used together with in Vitro Diagnostic kits. It is the responsibility of the user to ensure that the kits are approved for the use on the instrument.




Refer to the kit use instruction for information about material disposal.

#### 1.3.2 PERFORMANCE

The MINISAT instrument is programmed to be used performing oxidative stress tests.

***It is the responsibility of the user to ensure compliance with the requirements of each individual test manufacturer.***

#### 1.3.3. PROTECTION

	<p>Electronic components may cause electric shock and injury. Do not remove covers or doors if not specifically recommended in this manual.</p>
	<p>The use of clinical samples involves an important biological risk and must therefore be carried out with the utmost caution.</p>
	<p>The instrument is designed to ensure maximum protection of the user during normal operation.</p>

## CHAPTER 2

### INSTALLATION AND PRELIMINARY OPERATIONS

---

---



***Check the integrity of the box before opening it.***

---

---

#### 2.1 TRANSPORTATION, STORAGE AND UNPACKING

There are certain precautions to keep in mind during transportation, storage and unpacking of the instrument in order to avoid damages also due to storage in an improper environment.

##### TRANSPORTING

In its packaging the instrument weighs about 1.88 Kg and about 0.6 Kg without packaging. The dimensions are 385 x 270 x 135 (h) mm with packaging, and 140 x 270 x 385 mm without packaging.

No special equipment is required for transporting, loading or unloading the instrument in its box.

When handling the equipment the warning on the outside of the packaging (TOP-BOTTOM) must be respected.

##### STORAGE

The equipment should be stored in its original packing consisting of one box, and stored in respect of the warnings applied to the outside (TOP-BOTTOM).

If during storage or shipment the packing is damaged it is necessary to check it at least to make sure that the instrument has not undergone evident damage; the packing should then be repaired before storage.

In case of damage, notify the Supplier.

The type of packing ensures reliable protection and insulation if the crate is deposited in a suitable place; it is necessary to store it in a dry place free of dust.

##### UNPACKING

Unpacking is a simple operation. Unpack carefully. Keep the packing in case the instrument should be shipped back. Lift the instrument at the sides, placing your hands near the edges of the base plate. Keep the instrument vertical at all times.

### 2.1.1 COMPOSITION OF THE SUPPLY

Proceed to unpack the instrument. The following accessories are supplied with it:

<b>Q.ty</b>	<b>Description</b>	<b>Code</b>
1	MiniSAT	MSAT
1	User Manual	ManMST02d
1	White Pipette	Minipip10
1	Green Pipette	Minipip40
1	Power Cable Supply	
1	USB Cable	
1	nib for display	
1	Plastic blue tweezer	

### 2.2 INSTALLATION

The photometer overall dimensions are 225 X 165 X 70(h) mm. In order to ease the maintenance procedures, it would be better to leave some space around it. It's also preferable to place the instrument far from other instruments in order to avoid mutual interactions.

The primary activities for installing the instrument are:

- Identify a person in charge of the activities necessary for installation, who will contact the Supplier for any explanations that may be necessary.
- Select the place of installation.
- Purchase any accessories other than those supplied with the instrument.

Although the photometer has been designed with components capable of operating in a hostile environment, it is a good idea to check the environmental conditions in order to ensure more reliable performance.

- High temperatures can age the parts and produce temporary or even permanent alterations.
- A particular dusty environment may cause an abrasive action on the components and therefore reduce their life.
- Vibrations can cause errors in the measurements made by the instrument.
- High frequency and high intensity pulses generated by electronic devices or induced by surroundings may cause errors in the system.
- Do not place the instrument near any heat source like radiators, hot air tubes or in places directly exposed to sun rays.

- Avoid storage in places subject to sudden temperature change.
- Install the instrument on a flat and not inflammable surface; the surface must have at least the same dimension of the instrument.
- The instrument must be placed on its own feet.

A power outlet should be available in the place of installation. It should have the following characteristics:

<b>Distribution</b>	: 1 phase, neutral and ground
<b>Power supply</b>	: 100 - 240 VAC 50 - 60 Hz
<b>Consumption</b>	: 15 W

A cable with two wires and a plug with two contacts are supplied with each instrument, for connection to the power mains. Since the instrument belongs to the class 2 (having double insulation) it must not be connected to the ground; however only connect to an installation in accordance with earth and differential switch.

Environmental features of the place of installation:

<b>Temperature</b>	: 15 ÷ 32 °C (operating) 0 ÷ 50 °C (non operating)
<b>Relative Humidity</b>	: 20 ÷ 80 % (operating) 0 ÷ 90 % (non operating)
<b>Altitude</b>	: < 2000 m (operating)

### **2.3 DISINSTALLATION**

Disconnect the electric connection on the rear panel (serial port and power cable).

## CHAPTER 3

### USE

#### 3.1 .INTRODUCTION – SWITCH ON OF THE INSTRUMENT

In each phase, the instrument indicates the operations to perform by specific messages appearing on the display. In particular the procedures for the tests are supported by running messages written on the second line of the display. If the operator is experienced, he/she can skip such messages and go to the next phase by pressing the specific key.

To turn on the instrument you have to use the switch located on the right side of the back of the instrument. After switching on the instrument, the phases described in the following paragraphs will be executed.

#### 3.2 START UP OF THE INSTRUMENT, DISPLAY OF THE PRESENTATION MESSAGE, AUTO-DIAGNOSIS

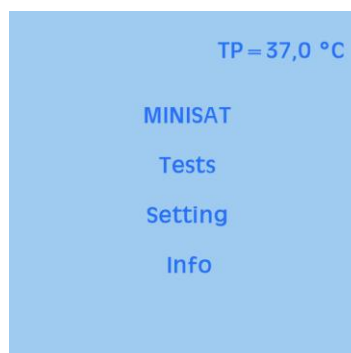
The display shows for some moments the following message:



The auto-diagnosis starts immediately and, if some problems are detected, a warning message will be shown in the display referring to the defects detected

#### 3.3 WARMING PHASE

If the warming phase of the reading cell (it starts at the switching on of the instrument) is not finished yet, the display will show the following message:



The actual reading cell temperature is shown in the top-right side of the display:

In the upper part of the display you will see the actual temperatures of the reading cell.

If no keys are pressed, the instrument stays in these conditions till the temperature of the reading cell have reached 37°C. Such temperature will be later maintained in a constant manner during the whole functioning of the instrument.

By pressing any key it is possible to exit this waiting phase before the 37°C are reached (such operation has to be done only in case of a modification of the **Setup**).

Once the Warming up phase is terminated, the **Main Menu** will be available.

### 3.4 MAIN MENU

**Tests:** allows to perform all available tests present in the instrument;

- **Settings:** main settings menu;

- **Info:** shows all the available informations about the installed system, the serial number and other useful elements to be communicated to the assistance service in case of issues;

#### TESTS MENU

Here is possible to start all the procedures of the tests installed in the instrument.

Follow all the indications on display e those present in the procedures attached to the bought tests.

#### SETTINGS MENU

**Correction Factor:** This function allows you to set the K-factor for each test executable from the machine, ie the correction factors necessary to compensate for small differences in sensitivity that occur between different batches of reagents. These values are clearly stated on the packaging of the purchased kits;

**Note:**

The k-factor variables have values in the range 0 to 20; the value 10 represents the neutral value (without correction); values in the range 11 to 20 produce a correction in a 5% increase for each unit; values in the range 0 to 9 produce a fix in 5% decrease for each unit;

- **LCD Contrast:** setting the light of the display;

- **Date and Time:** setting of the internal clock. The set time will also be printed on receipts;

- **Language:** Allows you to choose the language used in the system;

- **Calibration of cuvette:** It allows the calibration of the sensor that control the insertion of the cuvette in the reading room. Follow the indications to display.

- **Service:** Service menu available for technical assistance. Normally the password that is protected is NOT provided, unless by decision of the Service, for remote diagnosis in cases of severe damage.

#### INFO MENU

In this section you can find the information related to:

SN: serial number of the instrument

FW: the firewall version

HW: the hardware version

### 3.5 CHECKING THE CALIBRATION SYSTEM

The **MINISAT** system should be checked periodically with **Controls Serum** in order to assure that its results are correct.

### 3.6 PRECAUTIONS DURING THE USE OF THE INSTRUMENT



WARNING

---

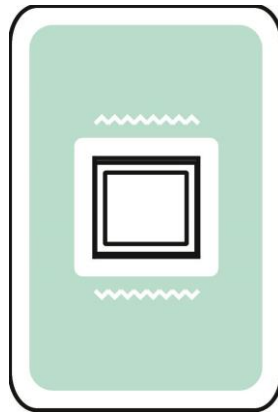
---

*The correct use of the centrifuge requires to follow the recommendations described here below:*

---

---

- Insert the cuvette pressing it down to the bottom of the housing. A spring helps correctly positioning the cuvette and holds it still during the reading.
- The cuvette must be inserted in the reading slot with the ribbed sides positioned according to the instruction reported on the label.





### 3.7 SAT TEST (SOLUBLE ANTIOXIDANT TEST)

#### Part 1^ - Taking saliva sample and test preparation

Give the piece of cotton (folded into 4 parts) to the patient and invite him to roll it in the mouth for 1 minute (for about 60 bites without chewing the cotton) in order to induce the production of saliva. Saliva should be conveyed on the cotton

At the end of the minute, squeeze the cotton with the plastic blue tweezer or manually, in order to collect the saliva into the disposable plastic container, then discard the used cotton.,

#### Part 2^ - test procedure



- To start the SAT test click on “ **Tests** ”.  
The display will show the follow message: “ **SAT** ”, click on the arrow at the bottom right to continue-  
Then the message displayed will be: “ **Please draw the saliva sample with the cotton square** ” → “ **Verify and eventually change the Kf** ”.
- It is necessary to verify that the Kf displayed on the first line of the display is the same as shown on the reagent package. If not, change the K-factor.



- Take the cuvette containing the SAT R1 reagent and add 40  $\mu$ L of R2 solution using the **green light** pipette equipped with the instrument and the relative disposable tip.
- Mix by inversion for about 10 seconds- following the countdown of the instrument



- Insert the cuvette into the reading cell, making sure that the ribbed sides are oriented according to the instruction reported and in accordance with the label and also make sure that the cuvette is pushed until the bottom of the reading cell. The instrument carry out the first reading in about 2 seconds.
- Remove the cuvette from the reading cell following the instructions that appear on the display.



- Take a sample of 10  $\mu$ L of saliva and add it into the cuvette containing the R1+R2 SAT solution which you just removed from the reading cell of the instrument. The saliva must be taken using the white pipette equipped with the instrument and the relative disposable tip.



- Close the cuvette with the lid and mix by inversion for about 10 seconds.
- Insert the cuvette into the reading cell, as above, making sure that the ribbed sides are oriented according to the instruction reported and in accordance with the label and also make sure that the cuvette is pushed until the bottom of the reading cell. The instrument carry out the second reading.



- Wait 1 minutes for the result that appears on the display.

## CHAPTER 4

### MAINTENANCE

MINISAT does not require special maintenance procedures. The following devices are sufficient, in general, to preserve the integrity of the instrument:

- Keep the instrument in a dry and dust-free place; humidity content must be within the range specified under operating conditions and condensed humidity should be avoided.
- Avoid rapid changes of temperature both during the use and the storage.
- Clean periodically, or when it is necessary, the body of the instrument with a soft, dry cloth, avoid rubbing vigorously to prevent damage to the display.
- If necessary (visible presence of deposits of liquid) clean gently with a cotton gauze the inside of the reading cell or of the centrifuge.
- In case of long inactivity disconnect the instrument from the mains and cover the instrument with a cover lid.