User and Service Manual
KALOS

Heater for haemofiltration, CRRT and hemoperfusion

CE
0476

Device manufactured by:

MEDICA S.p.A.
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1. INTRODUCTION

This manual addresses qualified operators and all persons who by their role, competence or appointment are to perform and manage treatments using KALOS.

This manual contains all the information necessary for appropriate and proper installation and use of KALOS. Do not interact with KALOS before having carefully read this manual and understood these instructions in order to operate correctly and safely.

Do not operate using procedures not indicated and contemplated in this manual. If you have any doubts or need clarification, please do not hesitate to contact the After Sales Service of:

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Via Degli Artigiani, 7
41036 MEDOLLA
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Do not attempt to make any repairs or perform operations of any technical nature on KALOS if you do not have the necessary skills or training and failing specific authorisation from MEDICA or its authorised dealers.

MEDICA is not responsible in any case and in any way for damages or accidents to the patient or the user deriving from incorrect application of the instructions contained in this manual.

1.1. Intended use

KALOS is an active medical device with the function of heating or keeping constant the temperature of the dialysis fluid or replacement fluid in haemofiltration and CRRT treatments, and to heat or keep constant the temperature of blood in hemoperfusion treatments.
It is used in conjunction with a treatment device that regulates the fluid's circulation.
it is independent from the above-mentioned device for what concerns the regulation of the temperature and of the safety management.

1.2. Description

KALOS is easy to use and can be programmed by way of an operator panel equipped with:

- keyboard for setting the control set point to the desired temperature by simply pressing the arrow keys: increase, decrease to change the value and Enter to confirm.
- large backlit graphic display, allowing the simultaneous display of the outlet temperature, the set point value and information on the heater's functional status.
- acoustic alarms in the form of a buzzer and the display of explicit messages on the display.

KALOS is produced in a small container (L270, H150, W85 mm), suitable for installation on a rod of diameter 15 to 35 mm. It consists of the following main elements:

1. **OPERATOR panel:** with backlit LCD graphic display, standby LED signalling, 4 function keys. The panel allows the user to simultaneously visualise the temperature values (set and detected), the functional status, the alarms and the control set point programming.
2. **Temperature measurement** by way of Pt500 platinum sensors: 2 sensors on the outgoing tube and 4 sensors on the heating plate. The sensors are arranged in 2 different circuits, one for control and the other for monitoring.

3. **Temperature regulation:** 2 PID controllers in a double ring. The controlled value is the temperature of the outlet tube, with limited control of the maximum temperature on the plate.
4. **Temperature alarms**: 2 alarms for high tube temperature and 2 alarms for high plate temperature
5. **Heating resistance command:** triac proportional control
6. **Power:** 230Vac or 115Vac with the setting installed at the time of the device's manufacture.
7. **Alarm diagnostics** on 2 levels: Warn and Alarm with an indication of the code and type of malfunction
8. **Program memory:** 256Kb Flash EPROM suitable for reconfiguration within the core program

1.3. Diagnostics and warnings:

Checks are carried out and a warning signal sent for the following events:
- no flow
- door open
- plate temperature > 40 °C
- warning for temperature detected >, <, = the set point
- alarm for high tube and plate temperature
- failure of one or more sensors

1.4. Kalos versions

CODE	Description
M90117	KALOS with 230 VAC power
M90153	KALOS with 115 VAC power

1.5. Identifying features of the software

When switching **KALOS** on, the display will, for a few seconds, show the identification code of the software installed:

Display when switched on

where:
yyyyy.xxx = software version of the program
UTIV4 = software identifier of the application

Subsequently, another screen will appear where the software customization code (recipe) is indicated:

SW CUSTOMIZATION CODE (RECIPE)

KALOS can be used with other medical devices, manufactured by Medica S.p.A., based on the sw customization loaded on it according to the table below:

SW customization code (recipe)	Filename*	Note	Medical Device	Device code
B01 VETSMART	A401_B01_VETSMART.L.txt	For Kalos rev. V2-802X0002	VETSMART	M03993
	A803_B01_VETSMART.L.txt	For Kalos rev. V2-802X0003, V2-802X0004		M90080
B02 BLOODH	A404_B02_BLOODH.L.txt	For Kalos rev. V2-802X0002	LIPIDSMART	M90162
				M90194
B02 BLOODH65	A803_B02_BLOODH65.L.txt	For Kalos rev. V2-802X0003, V2-802X0004	LIPIDSMART	M90162
				M90194
			ESTORFLOW	M03789
C01 PLASMA	A803_C01_PLASMA.L.txt	For Kalos rev. V2-802X0003, V2-802X0004	AFERSMART	M90022
				M90095
				M90414

*Where "L" in the filename indicates the language.

Warning: make sure Kalos is connected to the medical device foreseen by the SW customization code (recipe) loaded on it.

1.6. Contraindications

Do not use KALOS if the patient's treatment requires performance outside the operating and accuracy range as well as the safety limits specified in this manual.
The medical device in question may not be used in environments where there is the possibility of inflammable anaesthetic gas mixtures forming.

1.7. Safety philosophy

KALOS is accurate and safe.
The accuracy and safety of the temperature measurement are entrusted to the redundant platinum sensors on two different acquisition circuits.
The safety of operation and diagnostics of any malfunctions are determined by the heater's management structure, which consists of two microcontrollers, one responsible for managing control, the other for monitoring.
Thanks to this type of structure, KALOS reverts to a safe state in the event of a single fault on the electronics so that the operator is unable to use the machine.

1.8. Manufacturer liability

MEDICA S.p.A. is responsible for the safety, reliability and service of the machine if and only if it is used in accordance with the instructions contained in this manual and if the electrical connections are in compliance with the regulations in force.

MEDICA has been certified and operates in compliance with the standards set by the ISO 9001 and ISO 13485 norms.

1.9. Storage

After use, KALOS must be stored in a suitable place away from adverse atmospheric agents. If the machine needs to be cleaned, use a soft cloth and detergents that do not contain aggressive chemicals. Do not use sprays or liquids directly on KALOS as it is not waterproof. It is advisable to cover KALOS to protect it against dust and dirt and to store it in a safe place where it cannot be damaged.

1.10. Warranty

The warranty period is valid for 24 months from the date of installation of the medical device

Good functioning of the medical device is guaranteed for this period, both for the quality of the materials used and the care taken in its construction, provided that the user observes the instructions contained in this manual, especially regarding the maintenance operations which must be performed by technical staff authorised by Medica.

As MEDICA cannot control the maintenance operations carried out on the medical device by unauthorised personnel, it declines all responsibility for the effects such operations may have on persons and/or things during the use of the medical device.
Any unauthorised operation performed during the period of warranty will immediately invalidate the warranty.

Any component parts of the medical device which, on MEDICA's final judgement, prove to have material or manufacturing defects will be repaired or replaced free of charge at MEDICA's facility.

The expenses to ship the machine to the service centre are to be borne by the purchaser.

Not covered by this warranty are all the parts and components that should result defective due to negligence or carelessness in use, improper installation or maintenance, transport and handling carried out without the due caution, or circumstances which cannot in any way be directly attributed to manufacturing defects.

Should the machine prove to have manufacturing defects, the warranty covers the repair of these defects; therefore, compensation for direct or indirect damages of any nature to persons or things resulting from the period of inefficiency of the machine are excluded.

MEDICA, moreover, declines all responsibility for any direct or indirect damages to persons or things as a consequence of failure to observe the instructions for use, in particular the warnings relating to installation, use and maintenance of the medical device.

Any parts replaced under warranty shall remain the property of MEDICA.

The life span of the device is 10 years (as a minimum period of availability of spare parts for the AMD); within this time Medica guarantees assistance in / out of warranty.

For any disputes that may arise, MEDICA designates the Court of Modena as the sole competent court, unless otherwise specified by provisions of the law.

Purchasing the machine accompanied by this user manual constitutes full acceptance of the above warranty conditions and moreover cancels any other implicit or explicit warranty previously formulated.

For further information or clarifications on use, maintenance and technical service, contact your local distributor or the Medica staff at the following address:

MEDICA S.p.A.

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1.11. Safety warnings

This manual contains the information necessary for the device's correct use.
For the safety of patients, operators and the equipment, this manual must be carefully read before using the machine.
Any warning concerning the safety of patients, operators or the equipment in this manual is marked with the following symbol:

Warning: make sure all personnel involved in the installation, operation and maintenance of this equipment have read and fully understood these instructions before attempting to install, operate, or maintain this equipment.

- **The device should not be used in an OXYGEN- RICH ENVIRONMENT.**
- **The device should not be used in conjunction with a FLAMMABLE ANAESTHETIC MIXTURE or with EXPLOSIVE AGENTS.**

"WARNING: To avoid the risk of electric shock, this device must only be connected to a mains supply with earthing protection."

Check that the infusion equipment, connected to the heater, has a pressure control system that stops the infusion and sends an alarm message in case of reduced or excessive pressure in the hydraulic circuit of the heating bag and infusion kit.

Warnings included in IEC 60601-2-16 (2012) point 201.7.9.2.2.

1. In order to prevent cross-contamination between patients it is necessary to:
   - Only use the medical device with the intended single-use devices; the use of different medical devices other than those intended relieves Medica of any liability related to damage to patients, users and/or things.
   - The kit is supplied sterile and pyrogen-free; check the integrity of the protective wrapping and do not use if it is torn or damaged.
   - Handle the disposable kit with the utmost care and remove it at the end of treatment wearing disposable gloves for safety and adopting all the precautions necessary to reduce the risk of exposure to or transmission of potentially contaminating infectious agents, such as HIV or hepatitis viruses.

2. In order to correctly connect and disconnect the patient it is necessary to:
   - The patient must be connected or disconnected only by adequately trained medical or paramedical staff paying attention that the Luer-lock connectors, once the protective caps have been removed, do not come into contact with different materials or surfaces and are immediately inserted in the dedicated catheter or needle connectors.
   - Firmly anchor the patient's arterial and venous access points, using the appropriate plasters.

3. In order to reduce the risks arising from an incorrect connection of the disposable device (extracorporeal circuit) the operator needs to carefully read and follow the instructions in the chapters on the assembly of single treatment lines. In addition to the monitor, images are displayed that assist the operator in the correct assembly of the disposable lines.

4. The medical device does not manage concentrated dialysis fluids

5. It is recommended that the operator and responsible organisation avoid using electro-medical equipment with leakage currents on the patient in applied parts above a type CF in the vicinity of the patient in combination with central venous cannulation using atrial localisation.

This manual must be read and understood before initiating any operation with the medical device. MEDICA is not in any way responsible for accidents to persons or things following failed or incorrect application of the instructions contained in this manual.

Keep this manual in an easily accessible place within reach of the operators and in such a way as to ensure its integrity over time. Should this manual be lost, immediately request a copy from the manufacturer or its authorised distributors.

OPERATIONAL FRAMEWORK FOR USING THE DEVICE

The active medical device is used in a hospital setting, in connection with a suitable circuit for heating and extracorporeal blood or other fluids circulation.
It is not permitted to use the device at home, as well as the use by the patient without adequate supervision by health professionals.

For the patient's safety, the medical device's use requires the supervision of trained and qualified staff, with in-depth knowledge of the treatment methods allowed.
Medical and paramedical staff should be present during the whole treatment.

Before operating on the medical device, make sure that all the operations required for complete and safe installation have been carried out and that the system is adequately stable and the control unit correctly secured to the trolley.

When moving the medical device, it should be pushed from the rear using the appropriate handles on the rear panel.

It is forbidden to lift the apparatus secured to the trolley using the handles on the trolley's rear panel. To lift the apparatus, grip the bottom of the trolley.

The machine is compliant with the Directive on Electromagnetic Compatibility. It is in any case advisable to take the precaution not to use the machine in the immediate vicinity of high-power equipment or devices which by their nature emit strong electromagnetic fields. (SEE CHAPTER ON THE WARNINGS ON ELECTROMAGNETIC COMPATIBILITY)

For the use of Disposable Device accessories, refer to the information supplied by the manufacturer

on the device itself.

The power cord may only be replaced with an equivalent cord, of the same length and section characteristics. Contact the manufacturer's customer service for a replacement.

1.12. Operating environment

Kalos is designed for use in all environments including residential ones that are directly fed to the low voltage public grid.
Connection to the electrical network should be done with an L, N, EP (earth) 3-wire cable using the power cord provided, plugged into an outlet that holds the earthing conductor.

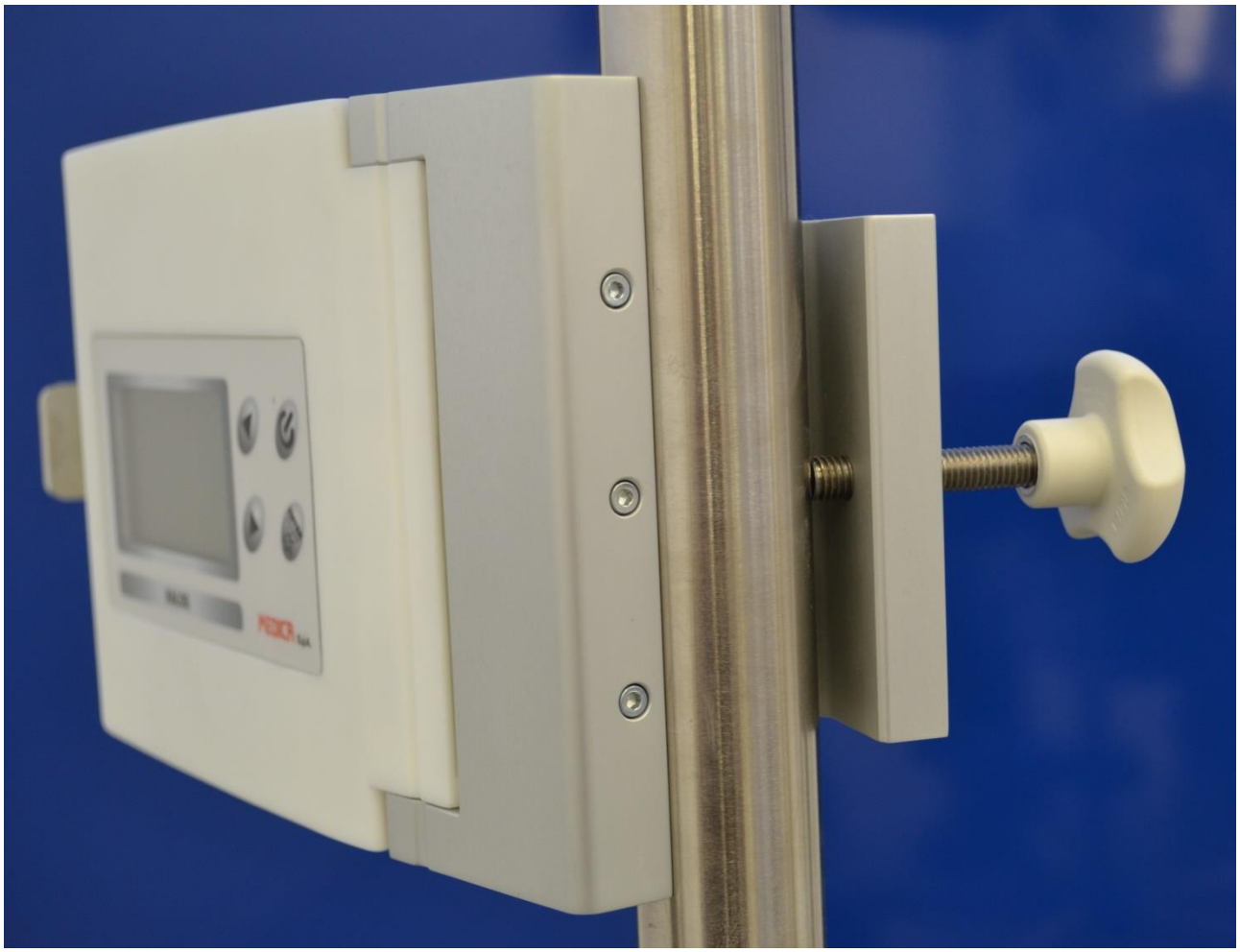
1.12.1. Hazards

The use of Kalos in the presence of inflammable substances, eg. anaesthetics, can cause explosions.
Do not open the controller casing to perform maintenance when plugged in.
There are hazardous voltages inside that expose the user to the danger of electric shock. It is advisable to have qualified personnel carry out any technical work.

2. Installing the device

Follow the instructions below to install KALOS:

- Secure KALOS with its dedicated support to a vertical rod, which guarantees the device's mechanical stability, and tighten the knob.
- Position the device vertically as shown in the photo, with the power plug underneath.
- Do not position the device in such a way as to complicate the power plug's disconnection.



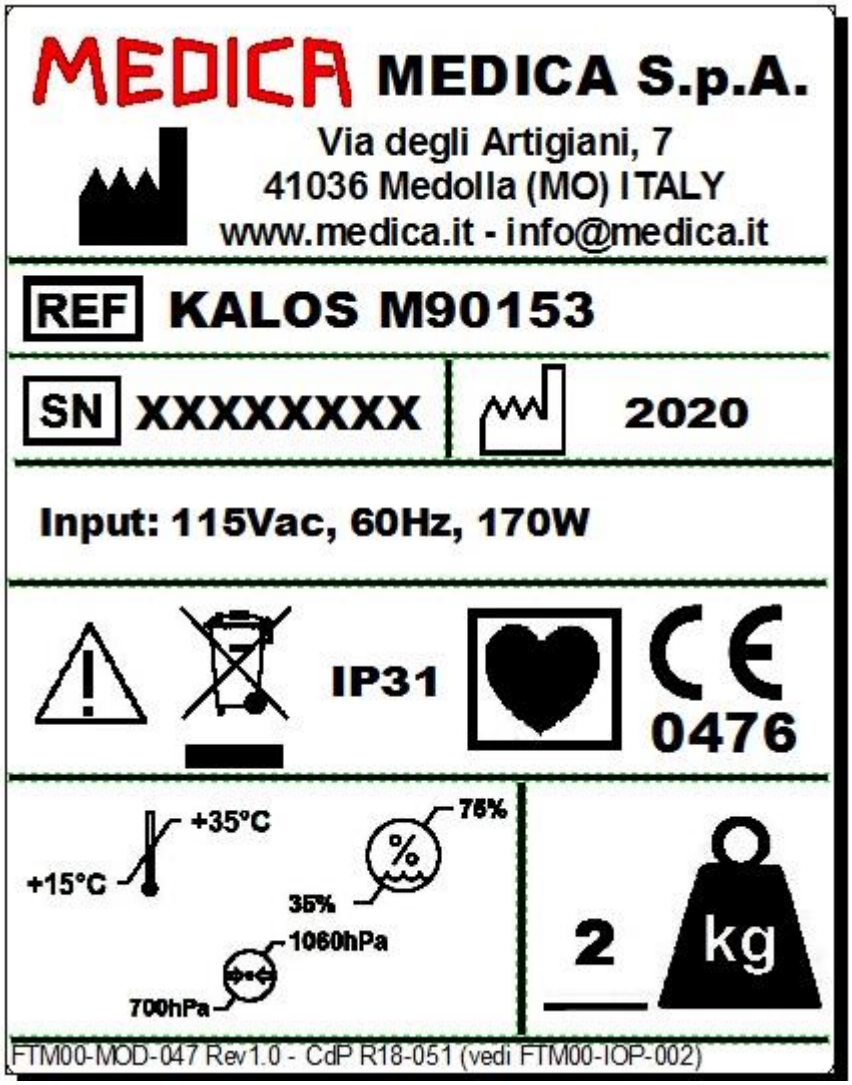
KALOS Support

3. LABELS AND MEANING OF SYMBOLS

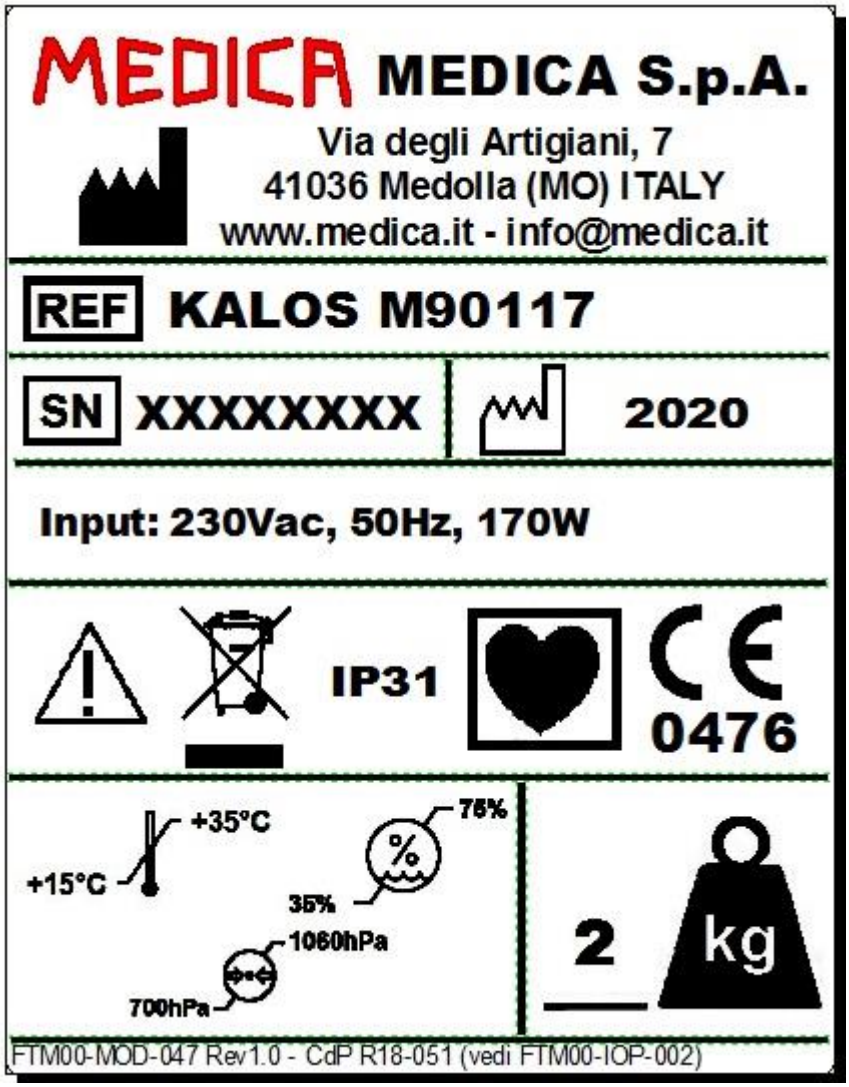
The symbols on the control panel and in the software are explained in the chapter DEVICE'S OPERATION AS A HEATER.

3.1. Rating label

On the rear panel of the device is the following rating label.

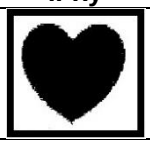
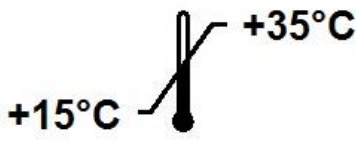


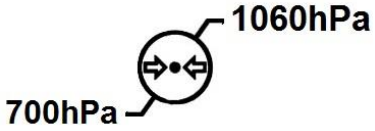
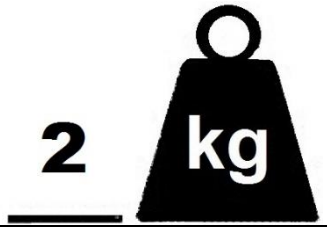
Rating label for KALOS with 115 Vac power



Rating label for KALOS with 230 Vac power

3.1.1. Meaning of symbols on the rating label.

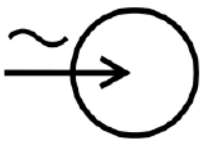
Information and symbols	*Description*
MEDICA	*Logo of the manufacturer*
	Symbol indicating the manufacturer of the device
MEDICA S.p.A.	Manufacturer name
Via Degli Artigiani, 7 41036 MEDOLLA MODENA – ITALY	Address of the manufacturer
REF ...	Device model
SN ...	Serial number of device
	Year of production
Ingresso/Input	It indicates the following input parameters: • supply voltage • Frequency of the supply voltage • Maximum power consumed by the device
	It indicates the user of dangers to the patient or operator in the use of the device, if the operator does not read the manual before use.
	*Separate disposal of the electrical and electronic devices.*
IPxy	*Protection grade of enclosure.*
	Indicates the degree of protection against electrical hazards applied part: CF type in accordance with the standard on the safety of medical devices IEC 60601-1.
CE 0476	It indicates that the device complies with the requirements of the Council Directive of the European Communities concerning medical devices 93/42 / EEC.
	It indicates the ambient temperature limits at which the medical device can be safely exposed during use.

Information and symbols	*Description*
	It indicates the relative humidity limits in which the medical device can be safely exposed during use.
	It indicates the atmospheric pressure limits that the medical device can be safely exposed during use.
	It indicates the weight of the device.

3.2. Connections Label

In the bottom side of the Kalos, there is a completion label with indication functions.

3.2.1. Meaning of symbols on the connections label.

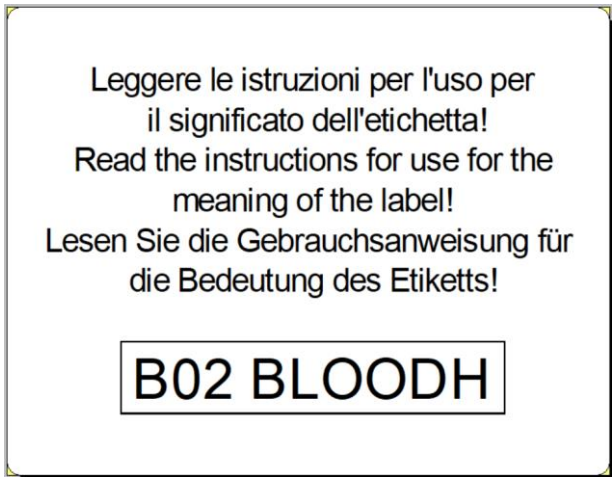
Information and symbols	*Description*
COM	Serial service communication connection
	Rated power input, a.c.

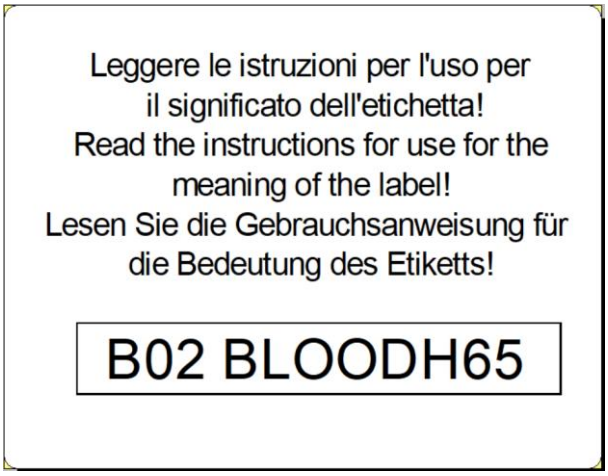
3.3. Information label

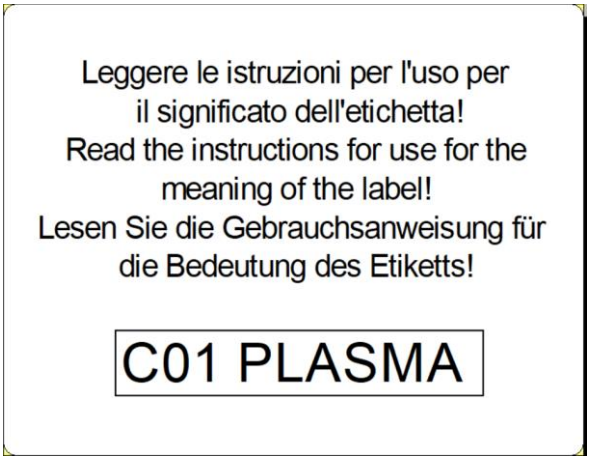
Near the main label there is also the following coloured label on a blue background that specifies the user must read the manual before using the device:

3.4. SW customization code (recipe) labels

The labels inform the users to read manual for the meaning of the reported SW customization code (recipe).

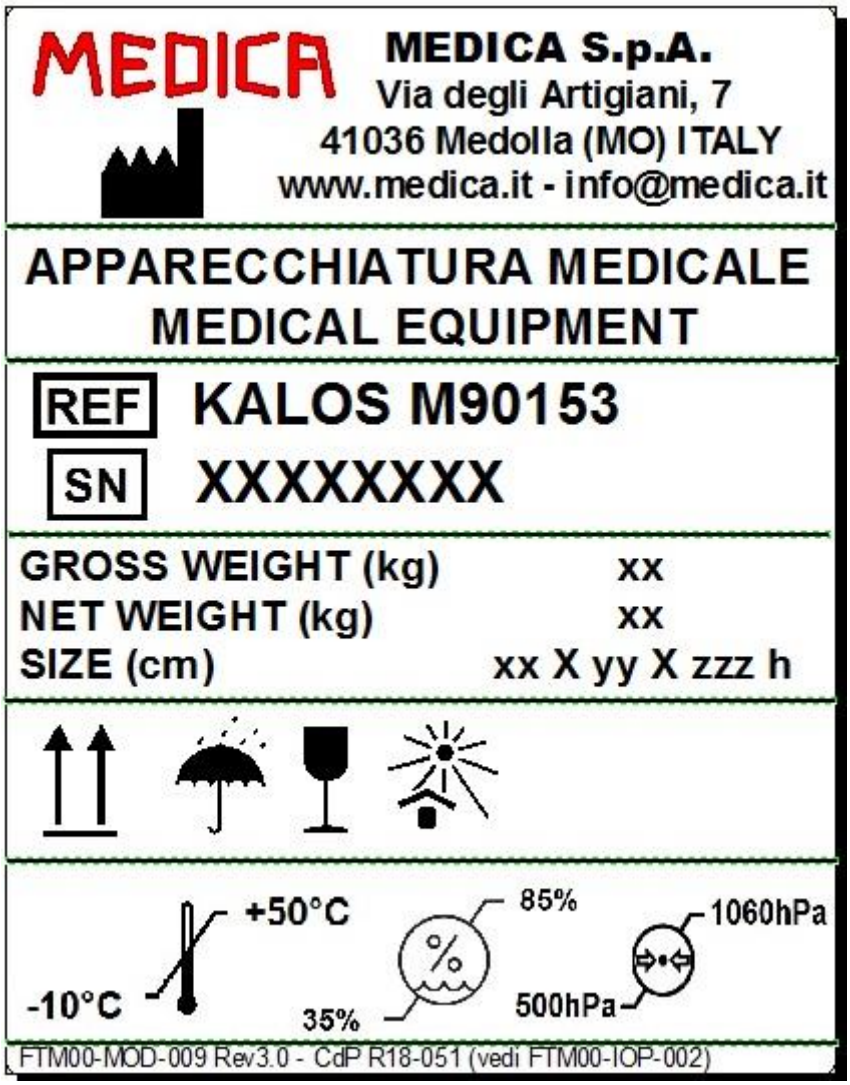

Leggere le istruzioni per l'uso per
il significato dell'etichetta!
Read the instructions for use for the
meaning of the label!
Lesen Sie die Gebrauchsanweisung für
die Bedeutung des Etiketts!
B02 BLOODH


Leggere le istruzioni per l'uso per
il significato dell'etichetta!
Read the instructions for use for the
meaning of the label!
Lesen Sie die Gebrauchsanweisung für
die Bedeutung des Etiketts!
B02 BLOODH65

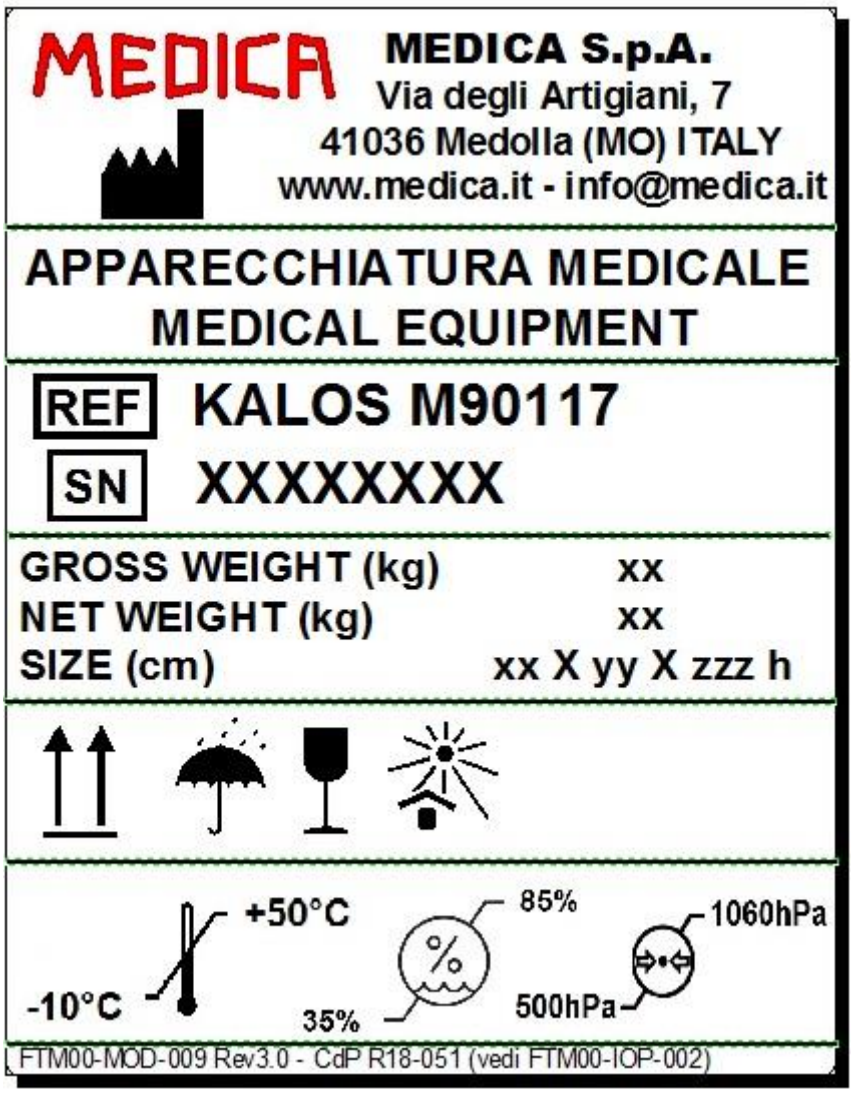

Leggere le istruzioni per l'uso per
il significato dell'etichetta!
Read the instructions for use for the
meaning of the label!
Lesen Sie die Gebrauchsanweisung für
die Bedeutung des Etiketts!
C01 PLASMA

3.5. Medical device packaging label

This label is found on the packaging of the device:

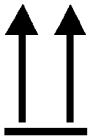
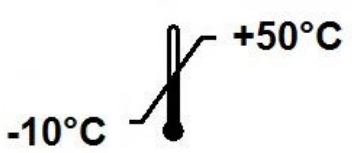
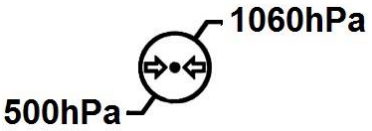


Packaging label for KALOS M90153



Packaging label for KALOS M90117

The following table shows the meaning of the symbols on the packaging label:

Symbol	Meaning
	Keep dry the packed device.
	It indicates that at the time of storage, packaging must be placed in the direction indicated by the arrows.
	Fragile, handle with care the packaged medical device.
	It indicates that the packed medical device should not be exposed to direct sunlight or bright light.
	Indica i limiti di temperatura a cui il dispositivo medico imballato può essere esposto in sicurezza durante il trasporto e l'immagazzinamento. It indicates the temperature limits at which the packed medical device can be exposed safely during transport and storage.
	Indica i limiti di umidità relativa a cui il dispositivo medico imballato può essere esposto in sicurezza durante il trasporto e l'immagazzinamento. It indicates the relative humidity limits to which the packed medical device may be exposed in safety during transport and storage.
	Indica i limiti di pressione atmosferica a cui il dispositivo medico imballato può essere esposto in sicurezza durante il trasporto e l'immagazzinamento. It indicates the atmospheric pressure limits which the packed medical device can be exposed safely during transport and storage.

3.6. Meaning of symbols on the packaging label of sterile accessories

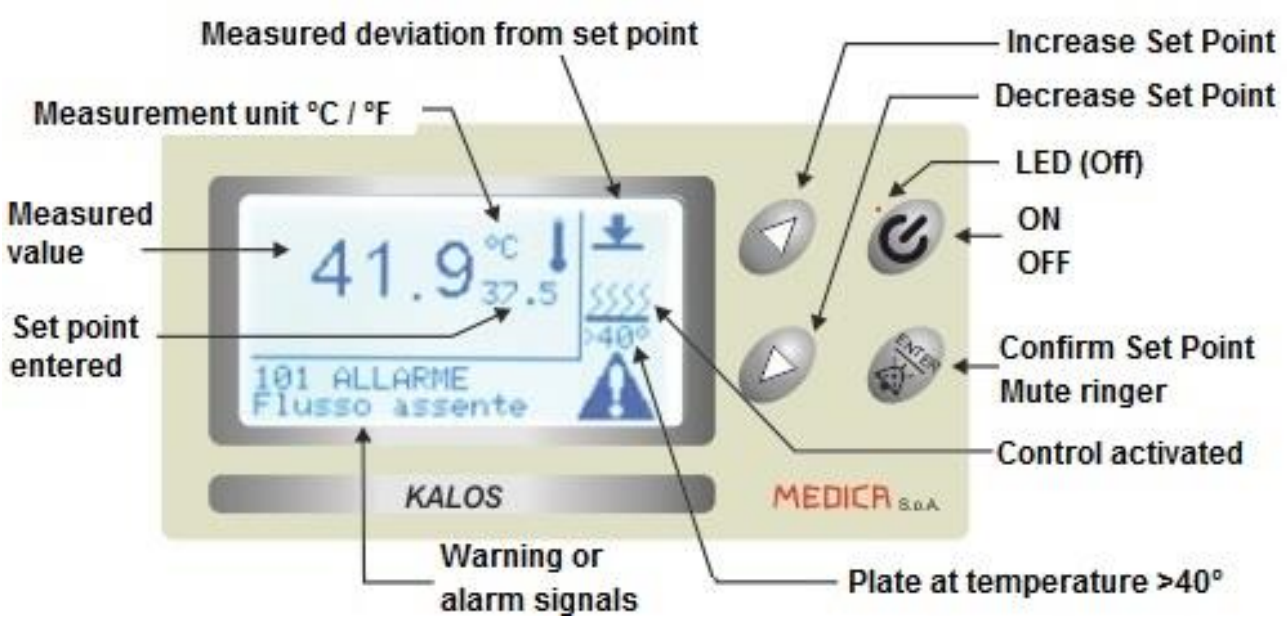
The following table shows the symbols on the packaging of sterile accessories.

Symbols	Meaning
	Sterile device. The sterile device should only be used if the packaging is undamaged and the expiration date has not passed.
	Ethylene oxide sterilised device
	Radiation sterilised device
	Do not resterilise or reuse this device. The device is a disposable device and is intended for single use only. Its reuse, reprocessing, or resterilisation may compromise the structural integrity of the device and / or lead to failure of the device which, in turn, may result in patient injury, illness or death
	This symbol indicates the sterilisation expiration date. Do not use the device beyond the expiration date

4. OPERATION OF THE DEVICE

4.1. Operator panel

From the front panel, the operator can easily check the functional status of the heating process and, using the keys, set the new temperature required for treatment, confirming this with ENTER.



The operator panel consists of:

Backlit LCD graphic display screen on which is displayed the device's operating status and interactive programming

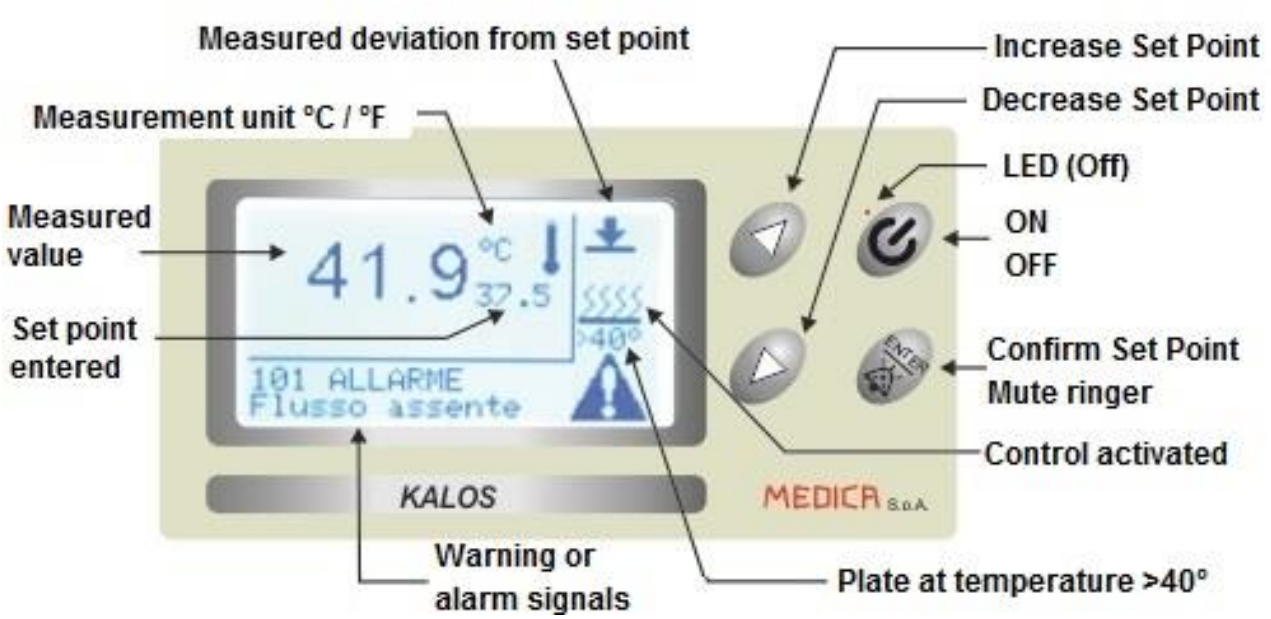
Led which indicates the standby state: control off and power voltage present

Programming keys: to change the temperature set point value, the ENTER key confirms the new value.

The ENTER key mutes the ringer

The ON/OFF button for switching the controller on or putting it in standby

4.2. Description of the display fields



When KALOS is on, the display shows the following information fields:

Measured value

Temperature value in °C /°F detected by the sensor in contact with the tube leaving the bag

Set point

Value in °C /°F of the temperature set for regulation

Unit of measurement

°C/°F for the detected and set temperature values

Measured deviation from set point

Indicates whether the measured value relative to the set point is:

- higher, up arrow (as in the figure)
- within the limits, up and down arrows
- lower, down arrow

Heating on

This symbol, as in the figure, indicates that the control function is on

Absence of the symbol indicates that the control function has been turned off due to an alarm

The symbol *door open* indicates that the door is open. With the door open, the control function is off

Plate at a temperature > 40°

Indicates that the temperature of the heating plate is > 40 °C

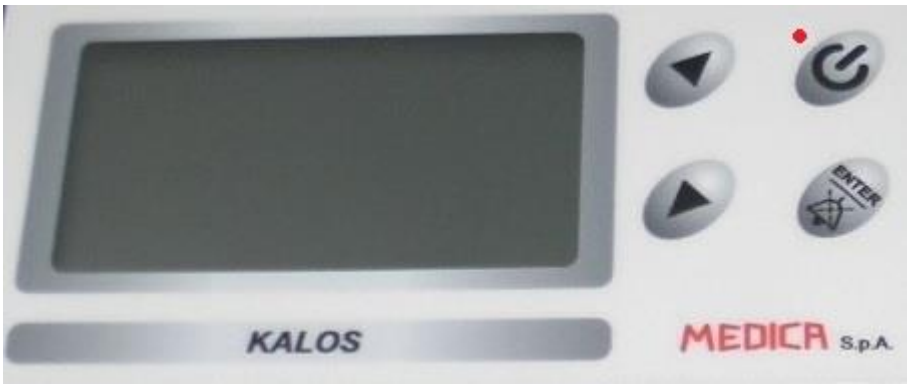
Warning or Alarm signals

This field allows the simultaneous viewing of multiple items of information:

Number	Signal's unique number
Type	Alarm or Warning
Description	Description of the event
Icon	Symbol that indicates severity

4.3. Switching on the device

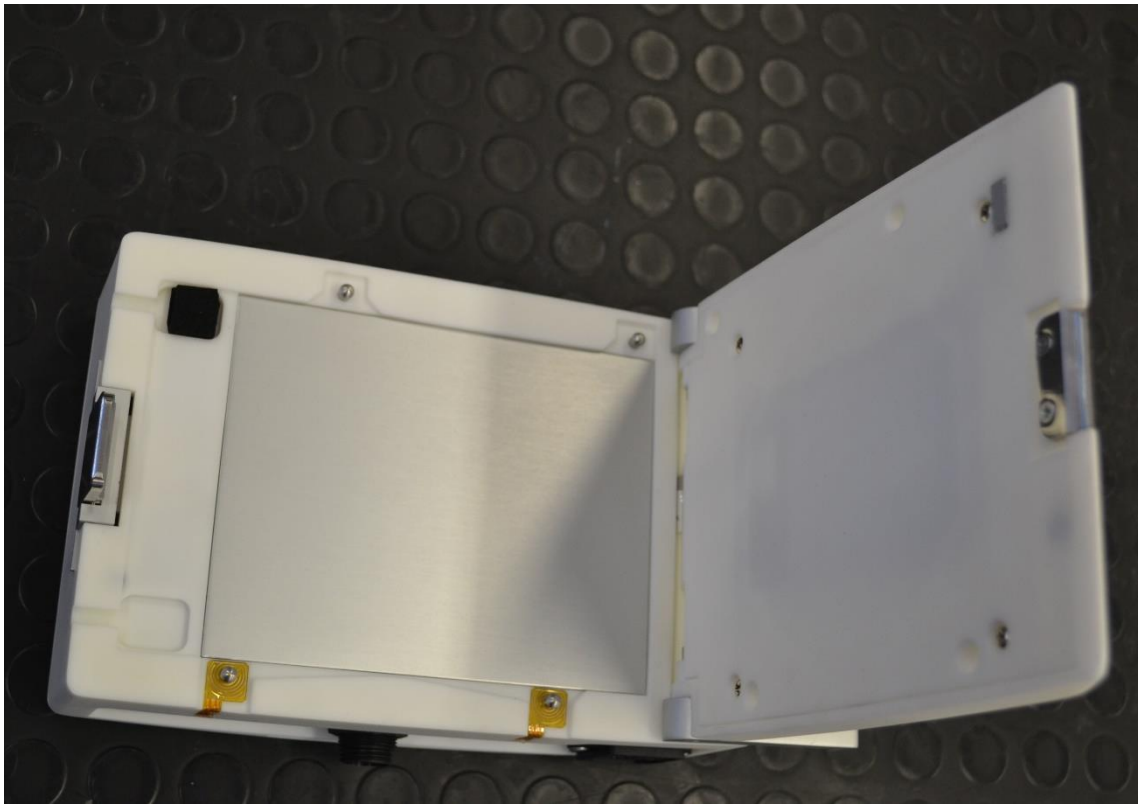
Connect the power cord to the power supply and the socket located under the device. In this situation, the Kalos is in standby with the display off, the standby LED on and heating inhibited.



Device in standby

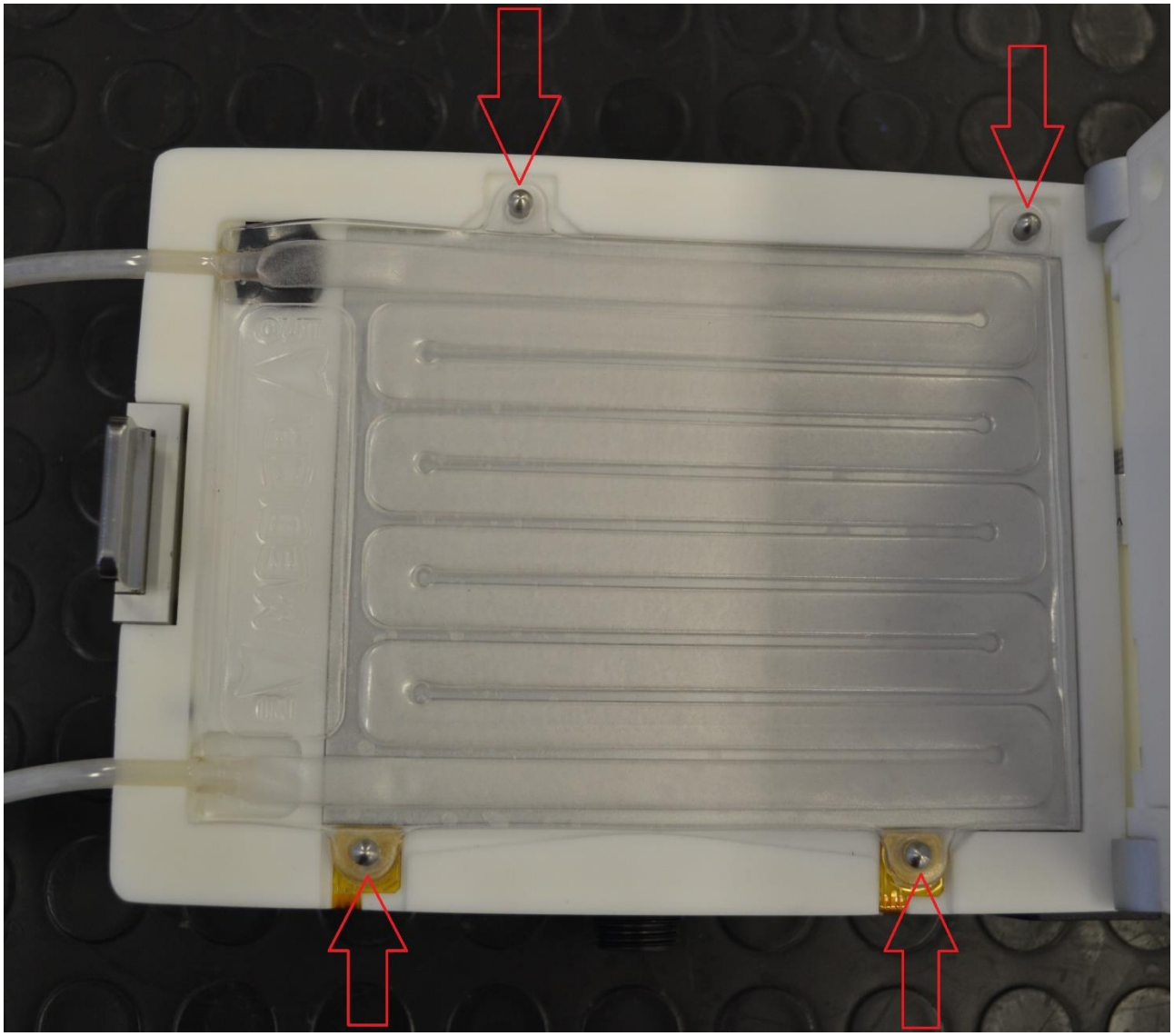
4.4. Inserting the heating bag

Before turning on the heater the following operations to insert the heating bag must be performed.
Open the lid of the bag compartment, sliding the lock lever sideways while lifting the lid of the bag compartment.



With the bag compartment door open, place the heating bag in the appropriate position following the guidelines below:

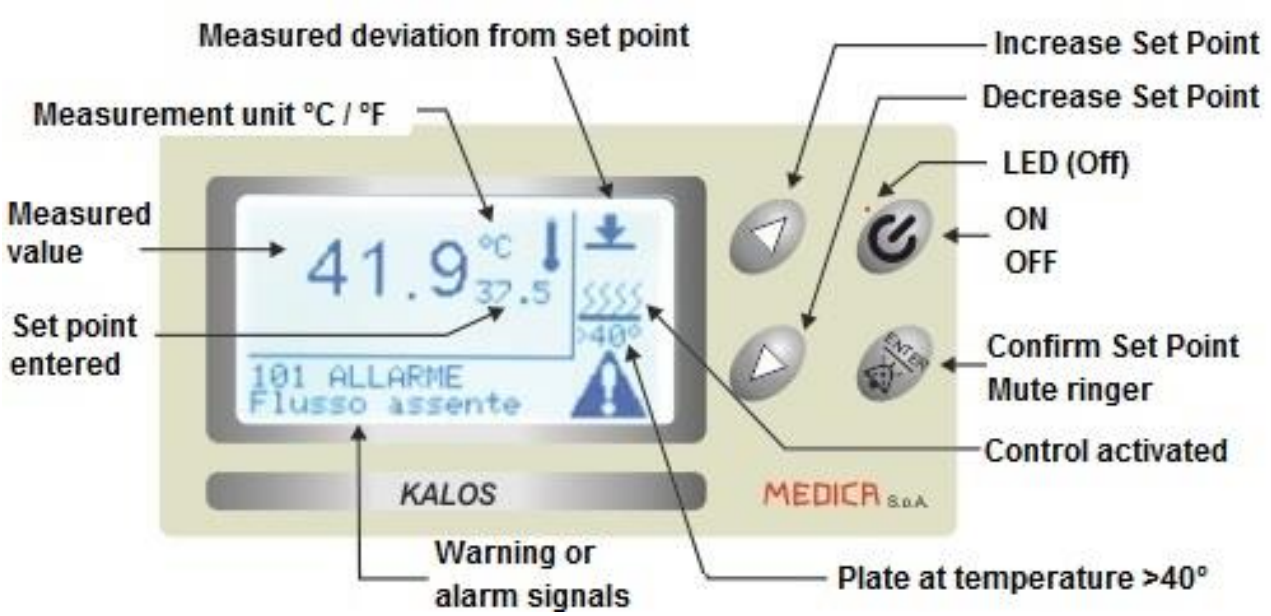
- Position each of the bag holes over its dedicated pin (see arrows in the picture below);
- Insert the inlet and outlet tubes into the dedicated slots.
- Verify that there are no obstructions to the flow of fluid along the path from the pump to the user.



To replace the bag switch off the heater (OFF) and, once the device has returned to room temperature, proceed as described previously.

4.5. Activation of heating and temperature control

Once the bag to be heated has been inserted, press the ON-OFF button for at least 5 seconds to turn on the heater and temperature control.
The display screen lights up: the control function turns on with the control set point indicated on the display.
If one wishes to change the set point value, proceed as follows.



4.6. Changing the temperature control set point

a) By pressing the ▲ ▼ keys, set the desired value in the "Set point" field.
Note that pressing the key once will change the value by 0.1°, keeping the key permanently pressed will change it more quickly.
b) Once the desired value has been reached, confirm the value, which will be flashing, with **ENTER**.
Note that the new value must be confirmed within 10 seconds of the flashing, to be accepted as the new control value.

4.7. Functional description of the keys

Key	Prime function	Secondary function	Notes
	**STANDBY ON/OFF** If pressed for at least 5 seconds: - Turns on the heater and temperature control, LED off (standby OFF) - Turns off the heater and temperature control, LED on (standby ON)		
	**INCREASE** Increases the set point value. Pressure that is: - *momentary* increases the set point value by 0.1° - *persistent* increases the value quickly.		1)
	**DECREASE** Decreases the set point value. Pressure that is: - *momentary* decreases the set point value by 0.1° - *persistent* decreases the value quickly.		1)
	**ENTER** Confirms the set point value that is flashing.	Mutes ringer	2)

Notes:
1) After releasing the key, the set point value will flash for 10 seconds while waiting to be confirmed or not confirmed.
2) To confirm the new set point value, press ENTER within 10 seconds of the flashing; otherwise, by not confirming the change made, the previous figure will remain as the control value.

4.8. Switching off the device

To switch Kalos off the following operations must be performed:

- Press the ON/OFF key for at least 5 seconds. This interrupts the heating and temperature control, the display switches off and the standby LED lights up.
- Unplug the power cord from the socket situated underneath Kalos: the standby LED turns off.

4.9. Summary of steps in the device's use

For clarity, the following table shows the steps for using Kalos.

Step in the use of Kalos	**Action in order to proceed to the next step**	**Standby LED**	**Display**	**Temperature control**	**Heating element**
Kalos not connected to the power supply.		Off Standby OFF	Off	Disabled	Off
	Connect the power supply lead.				
Kalos connected to the power supply with display screen off and heating element off (standby position)		On Standby ON	Off	Disabled	Off
	Insert the heating bag.				
	Press the ON/OFF button for at least 5 seconds to turn the heater on.				
Kalos connected to the power supply with display screen on, heating element on and temperature control activated.		Off Standby OFF	On	Activated 	On 
Kalos connected to the power supply with display screen on, heating element on and temperature control activated.	Change the set temperature using the ▲ ▼ keys and press ENTER to confirm.	Off Standby OFF	On	Activated 	On 
	Event that generates a warning or alarm, resulting in the interruption of heating and temperature control.				
Kalos connected to the power supply with display screen on and heating element off due to a warning or activated alarm (for example: maximum temperature exceeded).		On Standby ON	On (Display indicates a warning or alarm)	Disabled	Off

When the following symbol appears on the display screen it indicates that the heating element is turned on and temperature control is active:

If the symbol is not visible on the display screen, this indicates that the heating element is turned off and temperature control is disabled.

5. ALARMS

5.1. Description of the alarm system

The device's alarm system consists of the following elements:

- Buzzer alarm system (buzzer complies with IEC 60601-1-8 standards).
- Visual alarm signalling system with display of the alarm code and a brief description of the type of alarm on the device's display screen.
- When the device is switched on, it performs a self-check of the buzzer, generating an acoustic alarm and displaying the alarm symbols

All of the Kalos device's alarms are to be considered 'low priority', as defined in IEC 60601-1-8 par. 6.1.2.

5.1.1. Malfunction alarms with interruption of control function

Error code	message	Description of cause	Buzzer
ALRM_199	Master RAM FAIL	Hardware problem (RAM) in primary processor	Yes
ALRM_198	Master FLASH FAIL	Hardware problem (Flash) in primary processor	Yes
ALRM_197	Master CRC PROG	Data programmed by primary processor are incongruent	No
ALRM_195	Saf RAM FAIL	Hardware problem (RAM) in safety processor	Yes
ALRM_194	Saf FLASH FAIL	Hardware problem (Flash) in safety processor	Yes
ALRM_193	Saf CRC PROG	Data programmed by safety processor are incongruent	No
ALRM_126	Probe tT-StT KO"	Hardware problem in both tube probes (primary and safety processor)	Yes
ALRM_125	Probe ts2-Sts2 KO	Hardware problem in both plate probes (primary and safety processor) of fluid outlet	Yes
ALRM_124	Probe ts3-Sts3 KO	Hardware problem in both plate probes (primary and safety processor) of fluid inlet	Yes
ALRM_113	High tube T	High tube temperature generated by the primary processor (>42°)	Yes
ALRM_112	Saf: High tube T	High tube temperature generated by the safety processor(>43°)	Yes

5.1.2. Alarms that *unless otherwise specified* DO NOT interrupt the control function

Error code	message	Description of cause	Buzzer
ALRM_102	Water present	Presence of water	Yes
ALRM_101	Safety KO	Lack of communication with safety processor	No
ALRM_100	No flow	Failure to detect an adequate difference between inlet and outlet temperature: probably no flow	Yes
WARN_099	Flow measure KO	Hardware problem in the probes that detect the presence/absence of flow	Yes
WARN_098	High plate T	Alarm for high plate temperature detected by the primary processor *(disables the triac and stops heat generation)(>57°)*	Yes
WARN_097	PRE tube T	Pre-alarm for high tube temperature detected by the primary processor(>40°)	Yes
WARN_096	PRE plate T	Pre-alarm for high plate temperature detected by the primary processor(>56°)	Yes
WARN_095	Low tube T	Alarm for low tube temperature detected by the primary processor(<30°)	No
WARN_094	Low plate T	Alarm for low plate temperature detected by the primary processor(<25°)	No
WARN_088	Saf:High plate T	Alarm for high plate temperature detected by the primary processor (*disables the triac and stops heat generation*) (>60°)	Yes
WARN_087	Saf:PRE tube T	Pre-alarm for high tube temperature detected by the safety processor(>41°)	Yes
WARN_086	Saf:PRE plate T	Pre-alarm for high plate temperature detected by the safety processor(>59°)	Yes
WARN_085	Saf:Low tube T	Alarm for low tube temperature detected by the safety processor(<28°)	No
WARN_084	Saf:Low plate T	Alarm for low plate temperature detected by the safety processor(<23°)	No
WARN_030	Door Open	Open door alarm interrupts the control function (*disables the triac and stops heat generation*)	No
WARN_027	Low M-Vdd	low voltage alarm	Yes

5.1.3. Hardware malfunction alarms that do NOT interrupt the control function

Error code	Message	Description of cause	Buzzer
WARN_026	Probe StT KO	StT probe anomaly	No
WARN_025	Probe Sts3 KO	Sts3 probe anomaly	No
WARN_024	Probe Sts2 KO	Sts2 probe anomaly	No
WARN_023	Probe tT KO	tT probe anomaly	No
WARN_022	Probe ts3 KO	ts3 probe anomaly	No
WARN_021	Probe ts2 KO	ts2 probe anomaly	No
WARN_012	Master CRC CALIB	anomaly in the integrity of probe calibration data in the primary processor	No
WARN_011	Saf CRC CALIB	anomaly in the integrity of probe calibration data in the safety processor	No

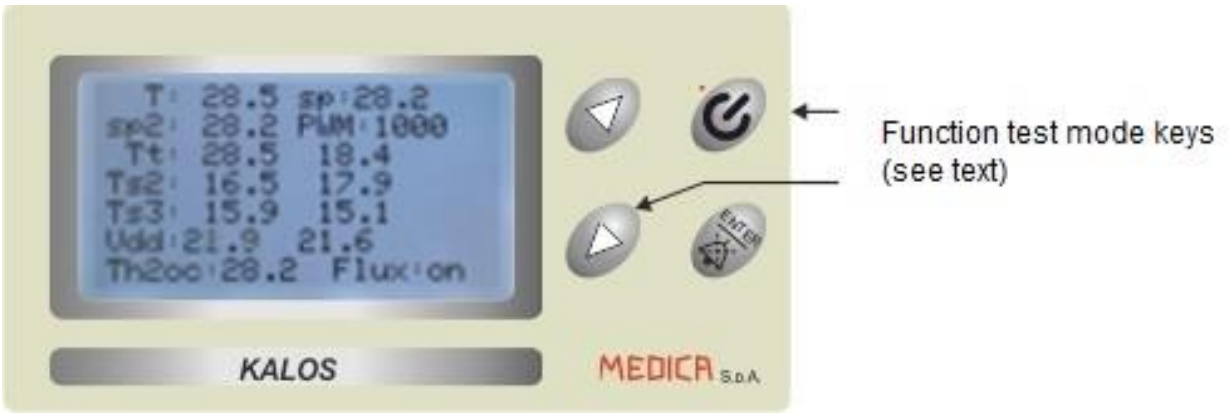
6. Maintenance of the device

6.1. Function tests and diagnosis of malfunctions

6.1.1. Function tests

The diagnostic mode in Kalos is helpful in determining the cause of any anomalies.

To enter this mode proceed as follows:
a) set Kalos to standby using the ON/OFF button
b) disconnect the power cord.
c) press and hold down the ▼ and ON/OFF keys.
d) connect the power cord.
e) release the keys.



To exit the mode, set Kalos to standby by pressing the ON/OFF button.
In diagnostic mode, the control function is active, the set point may be changed using the previously described mode and the display screen shows all the values measured as described below.

With reference to the values in the previous figure:

Initials	Value	Description		Initials	Value	Description
T	28.5	Value detected by tube sensor		sp	28.2	Tube control set point
sp2	28.2	Plate control set point		PWM	1000	100.0% heater command

Values in °C detected by the probes in the Master and control circuits

Initials	Description	Master value		Control value
Tt	Tube temperature value	28.5		18.4
Ts2	S2 plate temperature value	16.5		17.9
Ts3	S3 plate temperature value	15.9		15.1
Vdd	DC supply voltage value	21.9		21.6

Processed values

Initials	Value / Description		Initials	Value / Description
Th2oo	28.2; Calculated value of liquid temperature at outlet		Flux	On; flow present diagnostic

6.1.2. Malfunction Diagnosis

6.1.2.1. Faulty probe

If the temperature probe is defective or the detected temperature is > 80 °C the value of the field appears as "----".
Turn off the control function; wait for cooling and then check the value again.
If it remains "----", then the controller needs to be repaired.

6.1.2.2. Abnormal supply voltage

The mains voltage determines the VDD value. This value must be between 17.5 and 25 Vdc.
Check that the supply voltage value is within +10% /-15% of the rated value.
If the mains voltage is correct and the VDD value is < 17.5 Vdc the instrument must be repaired.

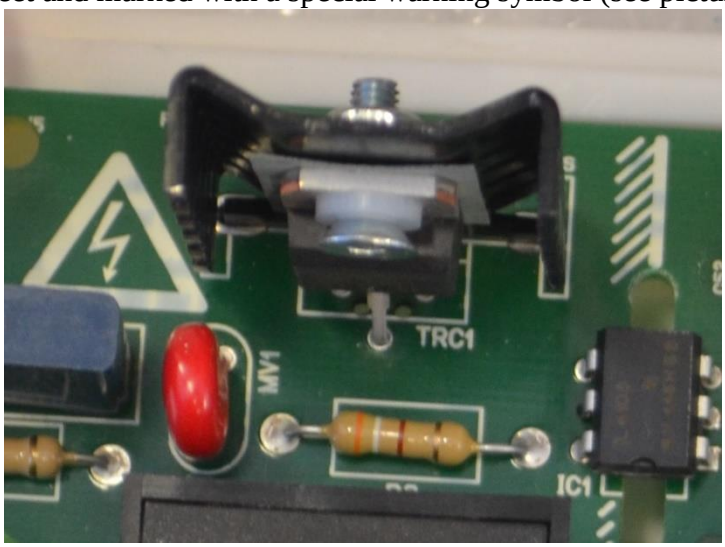
6.1.2.3. KALOS doesn't turn on

If when connecting the mains voltage Kalos doesn't turn on: both the LED and the display screen are blank, check that both fuses on the power connector are intact and, if necessary, replace them after disconnecting the power cord.

6.2. Safety precautions for technical assistance operators

The technical assistance operators must observe the following safety guidelines:

- Before opening the device to perform maintenance they must unplug the power cord and wait until the heating plate has returned to room temperature.
- Attention must be paid to the high voltage components (115VAC or 230VAC) included in the device data sheet and marked with a special warning symbol (see picture below).



6.3. Replacing the power cable

The power cable must be replaced with a new cord having the same technical characteristics. If in doubt, contact the manufacturer's technical service.

6.4. Replacing the fuses

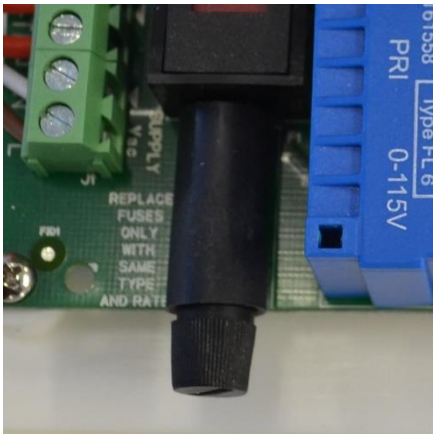
If when connecting the mains voltage Kalos doesn't turn on: both the LED and the display screen are blank, check that both externally accessible fuses in the power socket are intact and, if necessary, replace them after disconnecting the power cord.

Technical characteristics of the 2 externally accessible fuses on the power outlet group:

- for KALOS 230VAC: dimensions 5x20 mm, 1A-T, 250VAC.
- for KALOS 115VAC: dimensions 5x20 mm, 2A-T, 250VAC.

The Kalos also has an internal fuse to protect the circuit board that may only be replaced by technical support staff with the following characteristics:

- for KALOS 230VAC: dimensions 5x20 mm, 200mA-T, 250VAC.
- for KALOS 115VAC: dimensions 5x20 mm, 400mA-T, 250VAC.



6.5. Electrical circuit diagrams and other technical information

The MANUFACTURER will provide on request the circuit diagrams, the list of components, descriptions, calibration instructions, or other information to assist the TECHNICAL SUPPORT STAFF in repairing those parts of the device that the MANUFACTURER has agreed should be repaired by the TECHNICAL SUPPORT STAFF.

7. Routine maintenance and cleaning of the device

Before cleaning the heater disconnect the mains plug.
Thoroughly clean all external surfaces and the heating plate with non-aggressive detergents (see list of non-recommended detergents).
Check the rubber tube tip periodically for signs of wear and replace if necessary.

7.1. Non-recommended detergents

Do not use the following detergents for cleaning:

- Sulphuric acid (Foamy Q&A)
- Aromatic solvents (petroleum, paint solvents, etc.)
- Chlorinated solvents (trichloroethane, MEK, toluene, etc.)
- Ammonia, acetone, benzene, xylene

8. TECHNICAL SPECIFICATIONS

8.1. General technical specifications

- Dimensions: 270 x 150 x 85 mm
- Weight: 2 Kg
- Mains power supply: 115-230VAC selectable at the time of manufacture
- Life span (time during which technical support and spare parts are guaranteed): 10 years from date of sale
- Liquid crystal display
- 4 key membrane keyboard:
    - On/Standby
    - Heating On/Off
    - Increase temperature
    - Decrease temperature
- Heating element: 200W.
- The heating of the fluid takes place via conduction, the safest heating method, through the direct contact of the metal heating plate with the bag in which the blood circulates.
- Temperature of incoming liquid: [15-30]°C
- Flow of incoming liquid: [10-200]ml/min
- The temperature of the outlet fluid:
    - may be controlled in the range: from 36 °C to 39 °C
    - accuracy: +/- 2 °C;
    - sensitivity: 0.5 °C.
- The desired exit temperature is set using two dedicated keys, in steps of 0.5°C
- A measurement channel, independent from the main one, opens a safety relay should the heating plate temperature exceed 65°C
- A sensor on the cover allows one to check if the cover is open. Should the cover be open, the heater is turned off; should the temperature of the plate exceed 45° with the cover open, an alarm alerts the user.
- Information on the display screen:
    - Temperature control on
    - Temperature control off
    - Target Temperature
    - Possible alarm
- When the device is turned on it sets to a default temperature of 37°, with the heating plate off.
- Power button: when connected to the mains, the device immediately enters standby mode: microcontroller active, heating element unpowered. A button on the membrane keypad turns the device on and resets it to standby mode.
- Detachable power cord with VDE plug on the device equipped with a retention mechanism.

8.2. Compliance with standards

The KALOS active medical device complies with the following standards:

- IEC 60601-1
- IEC 60601-2-16
- IEC 60601-1-2
- IEC 60601-1-8

8.3. Classification of the device

Classification of the device according to the European Directive MDD 93/42 and subsequent amendments	II b
Product classification according to IEC 60601-1	Class I Type CF Operating mode: continuous (operating in NORMAL USE conditions for an unlimited time, provided that the specified prescribed temperature limits are not exceeded)
IP classification according to IEC 60529	IP 31

8.4. Features of the device's electrical insulation from the mains

The device is electrically isolated from the mains in the following way:

- The metal heating plate, which is placed between the heating element and the disposable bag through which the patient's infusion liquid flows, is connected to the protective earth.
- The system's electrical circuit is electrically isolated from the mains by means of components isolated at a safe voltage.

8.5. Technical specifications of the environment

Technical specifications of the installation and operational environment :

- Ambient temperature: 15 to 35 °C
- Relative humidity: 35 to 75 % (non-condensing)
- Atmospheric pressure: 70 to 106 kPa
- Avoid direct exposure to sunlight

Technical specifications of the transport environment:

- Ambient temperature: -10 to 50 °C
- Relative humidity: 35 to 85 % (non-condensing)
- Atmospheric pressure: 50 to 106 kPa

Technical specifications of the storage environment:

- Ambient temperature: -10 to 50 °C
- Relative humidity: 35 to 85 % (non-condensing)
- Atmospheric pressure: 50 to 106 kPa

8.6. Electrical specifications

Power	230Vac for the 230Vac version 115vac for the 115Vac version
Tolerance:	+/-10% of the rated value (IEC 60038)
Frequency	50 ÷ 60 Hz [47Hz ÷ 63Hz]
Absorption:	5 Va (in standby); 170Va with heating at 100%
Sinusoidal VIBRATIONS	10÷58 Hz with +/- 0.35mm deviation 58-150 Hz with 5 g, reference IEC68 part 2-6
Shock	30 g, 11 ms, 3 shocks/axis, reference IEC68 part 2-27
2 externally accessible fuses on the power outlet group	for KALOS 230VAC: dimensions 5x20 mm, 1A-T, 250VAC. for KALOS 115VAC: dimensions 5x20 mm, 2A-T, 250VAC.
an internal fuse to protect the circuit board that may only be replaced by technical support staff	for KALOS 230VAC: dimensions 5x20 mm, 200mA-T, 250VAC. for KALOS 115VAC: dimensions 5x20 mm, 400mA-T, 250VAC.
Buzzer noise level	Average measured value 62.0 dBA

8.7. Measurement and other specifications

ANALOGUE INPUTS

Impedance sensor input:	For detection of leakage from the bag
Temperature sensor inputs:	3 + 3 for PT500 sensors, range -10÷100°C
Resolution:	0.1°C from 0÷80°C
Accuracy:	0.2°C from 0÷80°C ± 1 digit at 25°C
Inputs for measuring VDD:	1 +1, range 10÷ 30Vdc
Resolution:	0.1°V from 10÷30Vdc
Accuracy:	0.3Vdc from 10÷30Vdc ± 1 digit at 25°C
Conversion type:	Sigma delta A/D
Conversion frequency:	1 probe every 0.1 seconds
Temperature drift:	< 100 ppm/°C

Digital inputs

Number	1 self-powered for open door sensor
Voltage supplied	5Vdc
Input activation current	1 mA
Filter	50 ms

Heater command

Number	1 triac with zero crossing
Type of control	PID double ring
Resolution command	1/1024 for 0÷100,0%
Accuracy	>1% on the output range

Heating safety

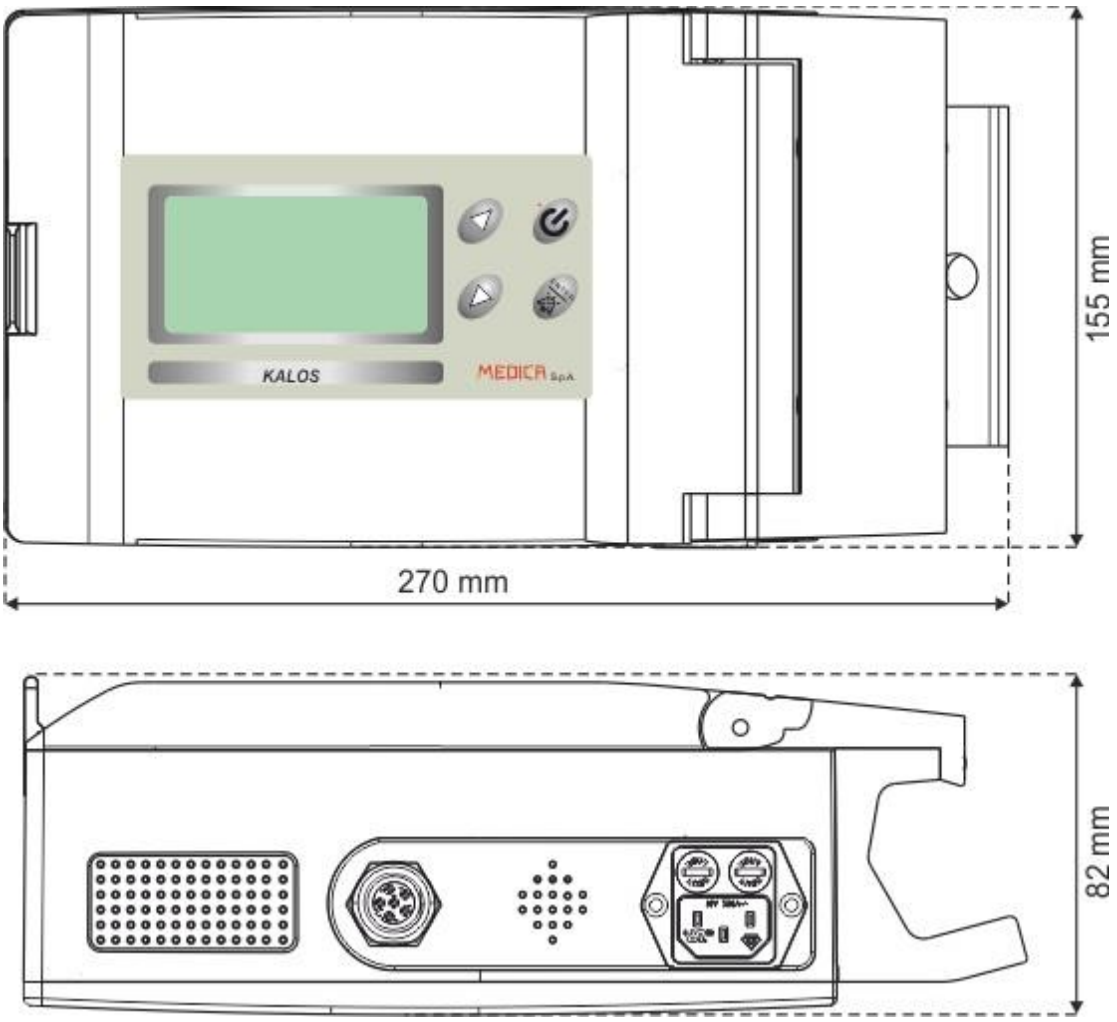
Number	1 NA relay in series with the heating plate
Contact rating	5A at 230Vac resistive load
Insulation	5kV between container and outputs 2.5kV between outputs and other circuits

Other specifications

RETENTION OF PROGRAMMED DATA	minimum 4 years in the absence of power
COMMUNICATION INTERFACE with supervisor	N° 1 RS-232 isolated on a circular connector with Modbus slave protocol
Insulation	2kV Vac between communication inputs and other circuits

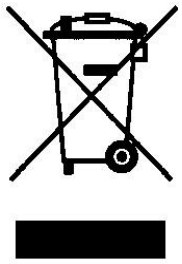
8.8. Mechanical specifications

ASSEMBLY	On instrument mounting rod
DIMENSIONS	standard L270xH150,W85 (mm)
CONTAINER	Self-extinguishing ABS
FRONT	scratch-resistant polycarbonate
PROTECTION GRADE of front panel and heating plate	- IP 31 standard: CEI EN 60529 (DIN 40 050) VDE 0470 part 1
PROTECTION GRADE of other accessible parts	- IP 31 standard: CEI EN 60529 (DIN 40 050) VDE 0470 part 1
WEIGHT	2 kg



Mechanical design of KALOS casing

9. Disposal of the device



The device must be disposed of according to the local directives.

Inside the European Union it must be disposed in compliance with the European Community Council Directive 2012/19/UE concerning the Electrical and Electronic Equipment.

The device complies to European Community Council Directive 2012/19/UE.

WARNING: For a correct disposal, please take care the relevant state laws and clinic procedures, related to contaminated products handling and discarding.
The packaging has to be discarded according to the rules in force.

The following symbol stating separate collection for electric and electronic devices:

WARNING: For proper disposal of the medical device, also adhere to the current laws and hospital procedures regarding contaminated devices.

The medical device packaging material must be disposed of in accordance with the regulations in force in the individual destination countries.

10. Accessories

The KALOS equipment uses the following accessories:

Code	Description
	Disposable heating kit for KALOS

11. Warnings relating to electromagnetic compatibility

KALOS is designed and built to comply with the **IEC 60601-1-2** standard on compliance with the Electromagnetic Compatibility (EMC) requirements in electro-medical devices.

Manufacturer's guide and statement - Electromagnetic emissions		
EMISSIONS TEST	**TEST LEVEL IEC 60601-1-2**	**INDICATIONS ON THE ELECTROMAGNETIC ENVIRONMENT**
RF Emissions CISPR 11	Group 1	*KALOS* uses RF energy only for its internal function. Thus, its emissions are very low and are not likely to cause interference with nearby electronic devices.
RF Emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliant	

Despite this, the KALOS device can interfere with other nearby devices.
The device should not be used near or stacked with other equipment.
Install the device away from other equipment that radiate high frequencies (short wave, microwave, electrosurgical units, mobile phones).

The apparatus is designed to operate in an electromagnetic environment in which RF irradiated disturbances are controlled. The customer or operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communications devices (transmitters) and the medical device, as recommended below, in relation to the maximum output power of radiocommunication devices.

Maximum emission power of the transmitter (W)	**Separation distance (m) based on transmitter frequency**		
	from 150 kHz to 80 MHz d = 1.2 √P	**from 80 MHz to 800 MHz d = 1.2 √P**	**from 800 MHz to 2.5 GHz d = 2.3 √P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with maximum rated output power not shown above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the transmitter frequency, where *P* is the maximum rated output power of the transmitter in Watts (W) according to the transmitter manufacturer.

Note:

(1) At 80 MHz and 800 MHz the highest frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.

WARNING

If the electro-medical device is used near other devices, the operator should check that it works correctly: if the device is subjected to **nearby electromagnetic fields emitted from wireless communication devices in Radio Frequency (see table below)**, its functionality is not guaranteed. The system for measuring biological values can be affected, resulting in unwanted alarms that limit the use of the device, while still maintaining its safety. The feedback systems implemented detect unexpected changes in the parameters and block the treatment to avoid risks to the patient. In this context there are no risks for the operator, apart from those already addressed.

Immunity to nearby EM fields related to wireless RF communication devices (EN 61000-4-3):			
Service	**Field strength (V/m)**	**Frequency**	**Signal modulation**
TETRA 400	27	380MHz÷390MHz	18Hz PM 50%
GMRS 460 FRS 460	28	430MHz÷470MHz	18Hz PM 50%
LTE Band 13, 17	9	704MHz÷787MHz	217Hz PM 50%
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	28	800MHz÷960MHz	18Hz PM 50%
GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3, 4, 25 UMTS	28	1700MHz÷1990MHz	217Hz PM 50%
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	28	2400MHz÷2570MHz	217Hz PM 50%
WLAN 802.11 a/n	9	5100MHz÷5800MHz	217Hz PM 50%

For reasons of electromagnetic compatibility, the electro-medical device must be used only with the following power cable:

- Power supply cable: SHURTER code 6051.2003 - length: 2 meters
- In addition to the above cable, a power strip of AS-MEDICAL, models MEDI PROTECT and MEDI PROTECT-FIX can be used.

WARNING: the use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of ME EQUIPMENT or ME SYSTEM as replacement of parts for internal components may result in increased emissions or decreased IMMUNITY immunity of the ME EQUIPMENT or ME SYSTEM

Table 4 - Manufacturer's guide and statement - Radiofrequency			
The KALOS equipment is designed to operate in the electromagnetic conditions specified below. The customer or user of KALOS must ensure that it is used in these conditions.			
Immunity test	**Standard level IEC 60601-1-2**	**Level of compliance**	**Electromagnetic environment**
RF Conduct	3 Veff	3 Veff	$d = 1.17 \sqrt{P}$. Where P is the maximum rated output power of the transmitter in Watts (W) according to the manufacturer of the transmitter and where d is the recommended operating distance expressed in m (m).
RF Irradiated	10 V/m (26 MHz -1GHz) …….. 3 V/m (1GHz –2.5GHz)	10 V/m 3 V/m	$d = 0.35 \sqrt{P}$ from 80 MHz to 800 MHz $d = 0.70 \sqrt{P}$ from 800 MHz to 1 GHz $d = 2.33 \sqrt{P}$ from 1GHz to 2.5 GHz Where P is the maximum rated output power of the transmitter in Watts (W) according to the manufacturer of the transmitter and where d is the recommended operating distance expressed in m (m).

Manufacturer's guide and statement - Electromagnetic Immunity			
The KALOS equipment is designed to operate in the electromagnetic conditions specified below. The customer or user of KALOS must ensure that it is used in these conditions.			
Immunity test	**Standard level IEC 60601-1-2**	**Level of compliance**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±15 kV air - ±8 kV contact	±15 kV air, level 3 - ±8 kV contact, level 2	Floors should be made of wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV common mode - ±1 kV differential mode	±2 kV common mode - ±1 kV differential mode	The quality of the mains voltage must be that of a typical commercial or hospital setting.
Surge IEC 61000-4-5	±1 kV differential mode - ±2 kV common mode	±1 kV differential mode - ±2 kV common mode	The quality of the mains voltage must be that of a typical commercial or hospital setting.
Voltage dips, short interruptions and voltage changes on the power input lines IEC 61000-4-11	<5%U_T (>95% drop in U_T) for 0.5 cycles. 40%U_T (60% drop in U_T) for 5 cycles – 70%U_T (30% drop in U_T) for 25 cycles – < 5%U_T (95% drop in U_T) for 5 s	< 5%U_T (>95% drop in U_T) for 0.5 cycles - 40%U_T (60% drop in U_T) for 5 cycles – 70%U_T (30% drop in U_T) for 25 cycles – < 5%U_T (95% drop in U_T) for 5 s	The quality of the mains voltage must be that of a typical commercial or hospital setting. If the user requires normal performance even in the event of power failure, it is recommended to use a backup power source
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Network frequency magnetic fields must have characteristic levels of a typical room in a commercial or hospital setting.
Remarks:	UT is the AC mains voltage before the test level is applied		