SUCTION UNIT NEW HOSPIVAC350
SUCTION UNIT NEW HOSPIVAC400

USER MANUAL

CE 0123

NEW HOSPIVAC 400 / NEW HOSPIVAC 350 is a surgical aspirator power-fed at 230V ~ / 50Hz, to be used for suctioning body liquids (such as mucus, phlegm and blood) provided with 4 antistatic wheels, two of which with braking device, and a pulling handle.
This equipment is designed for easy transport and continuous utilization.
Thanks to these characteristics and to its functions, this device is particularly suitable for utilization in hospital wards and operation theatres both for suctioning body liquids and for gynaecological and dermatological (liposuction) applications.
It's provided with a plastic body, with thermal and electrical isolation in compliance with European safety standards, two complete suction tanks in polycarbonate suitable for sterilization, and a float valve, besides being fitted with a suction regulator and a vacuum gauge on the front panel.
Versions fitted with footswitch control and flux deviator are available on request. The electronic management system fitted on the front panel allows to perform suction by means of the footswitch control as well as to suction liquids in both tanks provided without having to switch the equipment off to reconnect the second tank.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE

ONLY HIGHLY QUALIFIED STAFF USE RESERVED

THE INSTRUMENT MUST NOT BE DISASSEMBLED
FOR A TECHNICAL SERVICE ALWAYS CONTACT CA-MI

KEEP OFF THE REACH OF CHILDREN OR NOT CAPABLE PEOPLE WITHOUT SUPERVISION
FULL CONTAINERS MUST BE HANDLED WITH GREAT CARE DURING TRANSFER TO THE DISPOSAL AREAS, FOLLOWING THE LOCAL PROCEDURES AND REGULATIONS

IMPORTANT SAFETY RULES

1. On opening the packaging, check the integrity of the appliance, paying particular attention to the presence of damage to the plastic parts, which may make access possible to internal live parts and also to breakage and / or peeling of the power supply cable. **In these cases don't connect the plug to the electric socket. Carry out these controls before each use.**
2. before connecting the appliance always check that the electric data indicated on the data label and the type of plug used, correspond to those of the mains electricity to witch it's to be connected.
3. If the plug supplied with the appliance is incompatible with the mains electricity socket, contact qualified staff for replacement of the plug with a suitable type. The use of simple or multiple and / or extension adapters is not generally recommended. Whenever their use is indispensable, use those in compliance with safety regulations, however paying attention not to exceed the maximum power supply limits, which are indicated on the adapters and extensions.
4. Respect the safety regulations indicated for electrical appliances and particularly:
   - Use original components and accessories provided by the manufacturer CA-MI Srl to guarantee the highest efficiency and safety of the device;
   - The device can be used only with the bacteriological filter;
   - Never immerge the appliance into water;
   - Avoid touching the aspirator with wet hands and always prevent the equipment from getting in touch with liquids. Never leave the equipment near water or immerse it into a liquid. Should the equipment fall into water, detach its power cable from the socket before touching it;
   - None of the electrical and/or mechanical parts of the machine is designed to be repaired by the client and/or by its user. Do not open the aspirator or disassembly its electrical and/or mechanical parts. Always report to CA.MI. technical support;
   - Using the equipment in environmental conditions other than those indicated in this manual may seriously endanger its safety and technical parameters;
   - Position the appliance on flat stable surfaces;
   - Position the device in a way that the air inlets on the back aren't obstructed;
   - Never use the device in environments which have anaesthetic mixtures inflammable with air, oxygen or nitric oxide;
   - Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;

- Keep off the reach of children or not capable people without supervision;
- Don't leave the appliance connected to the power supply socket when not in use;
- Don't pull the power supply cable to disconnect the plug remove the plug from the mains socket correctly;
- Preserve and use the medical device in environments protected from atmospheric factors and at a distance from heat sources;
- Don't use the device thoracic drainage.

5. For repairs, exclusively contact CA-MI technical service and request the use of original spare parts. Failure to comply with the above can jeopardise the safety of the device.

6. **This medical device must be destined exclusively for the use for witch it has been designed ad described in this manual.** Any different use must be considered incorrect and therefore dangerous; the manufacturer cannot be considered liable for damage caused by improper, incorrect and / or unreasonable use or if the appliance is used in electrical plants that are not in compliance with the regulations in force.
7. Particular precautions must be made concerning electromagnetic compatibility. The medical device must be installed and used according to information supplied with the accompanying documents.
8. Instrument and accessories discharging must be done following current law regulations in every country of use.
9. None of electric or mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the electric / mechanical parts. Always contact CA-MI technical assistance.
10. Using the device in environmental conditions different than those indicated in this manual may harm seriously the safety and the technical characteristics of the same.

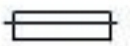
IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 002/96/EC:

I n respect of art. 13 Decreto Legislativo 25 Luglio 2005, n.151 "Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal". The symbol as over applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste. At the end of device useful, the user will must deliver it to the able collecting centres for electric and electronic garbage, or give back to the retailer in the moment of equivalent new device purchasing, one against one. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of witch it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the ambient and health. In case of abusive disposal of device by user, will be applied administrative endorsements in compliance with current standard.

TECHNICAL CHARACTERISTICS

TYPOLOGY (MDD 93/42/EEC)	Class IIa Medical Decice	
MODEL	**NEW HOSPIVAC 400**	**NEW HOSPIVAC 350**
UNI EN ISO 10079-1	HIGH VACUUM / HIGH FLOW	HIGH VACUUM / HIGH FLOW
POWER FEEDING	230V~ / 50Hz	230V~ / 50Hz
POWER CONSUMPTION	300 VA	230 VA
FUSE	F 1 x 4A 250V	F 1 x 4A 250V
MAXIMUM SUCTION PRESSURE (without jar)	-90kPa / -0.90 Bar / -675mmHg	-90kPa / -0.90 Bar / -675mmHg
MAXIMUM SUCTION FLOW (without jar)	90 l/min	60 l/min
WEIGHT	20 Kg	13 Kg
SIZE	460 x 850 (h) x 420 mm	
DUTY CYCLE (to 35°C and 110% operating voltage)	Non – Stop Operated	
SICILICONE TUBE SIZE	Ø 8 x 14 mm	
ACCURANCY OF VACUUM INDICATOR	± 5%	
WORKING CONDITION	Room temperature: 5 ÷ 35°C Room humidity percentage: 30 ÷ 75% RH Altitude: 0 ÷ 2000m s.l.m.	
CONSERVATION CONDITION AND TRASPORT	Room temperature: -40÷ 70°C Room humidity percentage: 10 ÷ 100% RH	

SYMBOLS

	Class II isolation equipment
CE 0123	CE marking in conformity with EC directive 93/42/EEC and subsequent changes Manufactured by: CA-MI Srl Via Ugo La Malfa nr.31 – 43010 Pilastro (PR) Italia
	Warning, consult the instruction manual
	To Preserve in place coolness and dry land
	Conservation temperature: -40 ÷ 70°C
	Type B equipment
	Fuse
~	Alternate Current
Hz	Mains Frequency
	ON / OFF
(---)	Using the footswitch control (for intermittence suction)
(——)	Using the footswitch control (for continuous suction)

CLEANING THE MAIN UNIT

To clean the device external parts always use a cotton cloth dampened with detergent. Don't use abrasive or solvent detergents.

PARTICULAR CARE SHOULD BE TAKEN TO ENSURE THAT THE INTERNAL PARTS OF THE EQUIPMENT DO NOT GET IN TOUCH WITH LIQUIDS. NEVER CLEAN THE EQUIPMENT WITH WATER.

During all clearing operations use protection gloves and apron (if need be, also wear a face mask and glasses) to avoid getting in contact with contaminating substances (after each utilization cycle of the machine).

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The surgical aspirator **NEW HOSPIVAC 400 / NEW HOSPIVAC 350** is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator **NEW HOSPIVAC 400 / NEW HOSPIVAC 350** should assure that it's used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Power disturbance CISPR11	Group 1	The surgical aspirator NEW HOSPIVAC 400 / NEW HOSPIVAC 350 only used RF energy only for its internal functioning. Therefore its RF emissions are very low and are not cause interference in proximity of any Electronic appliances.
Irradiated / Conducted emissions CISPR11	Class [B]	The surgical aspirator NEW HOSPIVAC 400 / NEW HOSPIVAC 350 can be used in all environments, including domestic and those connected directly to the public mains distribution that supplies power to environments used for domestic scopes.
Harmonic emissions IEC/EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic Immunity		
The surgical aspirator **NEW HOSPIVAC 400 / NEW HOSPIVAC 350** is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator **NEW HOSPIVAC 400 / NEW HOSPIVAC 350** should assure that it's used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic environments - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6kV on contact ± 8kV in air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC/EN 61000-4-4	± 2kV power supply	Mains power quality should be that of a typical commercial environment or hospital
Surge IEC/EN 61000-4-5	± 1kV differential mode	Mains power quality should be that of a typical commercial environment or hospital
Loss of voltage, brief voltage interruptions and variations IEC/EN 61000-4-11	5%U_T for 0.5 cycle 40%U_T for 05 cycle 70%U_T for 25 cycle <5%U_T for 5 sec	Mains power quality should be that of a typical commercial environment or hospital If the user of the surgical aspirator NEW HOSPIVAC 400 / NEW HOSPIVAC 350 request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field IEC/EN 61000-4-8	3A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Conducted Immunity IEC/EN 61000-4-6	3Vrms 150kHz to 80MHz (for appliances that aren't life - supporting)	-
Irradiated Conducted IEC/EN 61000-4-3	3V/m 80MHz to 2.5 GHz (for appliances that aren't life - equipment)	-
Note U_T is the value of the power supply voltage		

ACCESSORIES SUPPLIED

DESCRIPTION
N°2 COMPLETE ASPIRATION JAR 2000cc
CONICAL FITTING
TUBES SET 8 mm x 14 mm
ANTIBACTERIAL AND HYDROFOBIC FILTER
FOOTSWITCH CONTROL cod. 52130 (for versions equipped with footswitch control)

Replacing the antibacterial filter:
The filter is made of hydrophobic material that stops the passage of liquids into the same filter.
If you suspect the filter may have been contaminated and/or got wet or discoloured, always remove and replace the filter.
If the equipment is to be used on patients with unknown pathological conditions or should you evaluate the possibility of indirect contamination, remove and **replace the filter after each utilization**. The filter is not designed for decontamination, disassembly and/or sterilization. If you suspect the filter may have been contaminated and/or got wet or discoloured, always remove and replace the filter. If the equipment is to be used on patients whose pathologies are known and not implying any indirect contamination risks, we recommend to remove and replace the filter at the end of each work shift or else every month, even if the equipment has not been used. 4000cc complete tank versions are available on request.
Versions fitted with FLOVAC® 2000ml or 3000ml disposable collection systems (including a re-usable rigid polycarbonate container and a disposable Liner) are also available on request.

<u>WARNING:</u> Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.

CLEANING ACCESSORIES AND INTERNAL PARTS

At the end of the application switch the equipment off and clean all its accessories as follows:
- Wear protection gloves and apron (if need be, also wear a face mask and glasses) to avoid getting in contact with contaminating substances;
- Disconnect the tank from the equipment removing any tubes connected to the container and paying particular attention to avoiding accidental contaminations;
- Empty and dispose of the flacon content complying with hospital regulations as well as with any provisions in force, including local regulations;
- Separate all the parts of the lid (float device and rings).

After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thoroughly.
Then soak in warm water (temperature shall not exceed 60°C). Wash thoroughly and if necessary use a non-abrasive brush to remove incrustations. Rinse in running warm water and dry all parts with a soft cloth (non-abrasive).
The jar and the cover can be autoclaved by placing the parts into the autoclave and running one sterilization stem cycle at 121°C (1 bar relative pressure) making sure that the jar is positioned upside down. Mechanical resistance of the jar is guaranteed up to 30 cycles of sterilization and cleaning at the indicated conditions (EN ISO 10079-1). Beyond this limit the physical-mechanical characteristics of the plastic may decrease and replacement of the part is therefore recommended. After sterilization and cooling at environment temperature of the parts make sure that these are not damaged. Assemble the jar as follows:
- Place the overflow valve into its seat in the cover (under VACUUM connector);
- Insert floating valve keeping the o-ring towards the opening of the cage;
- Place the o-ring into its seat around the cover;
- After completing assembling operations always make sue that cover seals perfectly to avoid vacuum leakages or liquid exit.

The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 120°C.
The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C.
The device is ready for a new employment now.

DO NOT WASH, STERILIZE OR PUT IN AUTOCLAVE THE ANTIBACTERIAL FILTER

Instruction for disposal Liner Flovac®:

If the device is equipped with disposable collection systems FLOVAC ® carry out the disposal of the bag as follows:

Turn off the Vacuum and remove all the tubes connected to the Liner, giving particular attention to avoid accidental contamination.

Fit the appropriate plugs to the "PATIENT" and "TANDEM" ports, pressing the home firmly, taking care to avoid accidental contamination.

Turn the butterfly connector to OFF. Remove the liner bag from the rigid container and transfer it to the waste disposal area, ensuring that all the openings are sealed, keeping in mind the product is potentially infectious. This product must be disposed of in accordance with the current hospital regulations.

MAINTENANCE

The **NEW HOSPIVAC 400 / NEW HOSPIVAC 350** suction equipment does not need maintenance or lubrication.

It is necessary to check functioning and instrument before every use. Unpack the instrument and **always check** integrity of plastic parts and feeding cable, they might have been damaged during previous use.

Always check the integrity of the footswitch power cord. Connect cable to electrical network and turn switch on.

Close the aspiration outlet with your finger and with suction regulator in maximum vacuum position check that the vacuum indicators reaches

-90 kPa (-0.90 bar) maximum. Rotate the knob from right to left and check the aspiration regulating control. The vacuum indicator should go down -40 kPa (-0.40 bar). Verify that loud noises are not present, these can indicate wrong functioning.

A protection fuse (**F 1 x 4A 250V**) reachable from exterior and it situated in the plug protects the instrument. For use replacing, always check the type and the range indicated.

Fault type	Cause	Solution
1. The suction unit doesn't work	Cable is damaged External power source failure	Replace the cable Check the external power source
2. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
3. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
4. The Vacuum power on the patient side is either very low or absent	a) Vacuum regulator set to minimum b) Protection filter blocked or damaged c) Connection tubes blocked, kinked or disconnected d) Shut-off valve blocked or damaged e) Pump motor damaged	a) Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge b) Replace the filter c) Replace or reconnect the tubes, check the jar connections d) Empty the jar, or disconnect the tube from the jar and unblock the shut-off valve. The unit twill only work in the upright position e) Refer to authorised service personnel
5. The float doesn't close	If the cap has been washed, ensure that the float is not partially detached	Insert the float into it's place
6. The float doesn't close	The float it's covered by dirty material	Unscrewed the cap, leave the and put in on autoclave
7. Low suction	Foam inside the jar	Fill the jar to 1/3 full of ordinary water
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7	**None of the remedies has achieved the desired results**	**Contact the seller or CA-MI After-sales Assistance Service**

If the overfill security system it's activated, don't proceed with the liquid aspiration.

If the overfill security system doesn't work there are two cases:

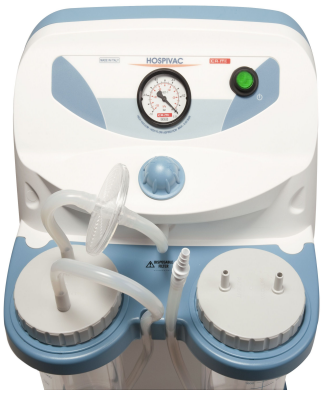
1° case – If the overfill security system doesn't work the aspiration will be stopped by the bacteriological filter who avoid the liquid penetration inside the device. 2° case – If both the security system doesn't work, there is the possibility that liquid comes inside the device, in this case return the device to CA-MI technical service.

CA-MI Srl will provide upon request electric diagrams, components list, descriptions, setting instructions and any other information that can help the technical assistance staff for product repair.

BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT CA-MI TECHNICAL SERVICE. THE MANUFACTURER DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

INSTRUCTIONS

- Connect the short silicon tube fitted with the antibacterial fi with the
  Device suction union (you may choose either the right or th left union).
- The other tube, by one end connected with the filter, shoul instead
  be connected with the union on the tank lid marked as "VACUUM" in
  which the float (signalling when the device is too full) is fitte The float signals when the maximum level of volume is rea (i.e. 90% of the tank volume has already been used) to pre liquid from entering the machine (the float closes the lid junction).
  <u>This equipment should only be utilised on an horizontal working surface.</u>



<u>WARNING</u>: Ensure that the IN marker on the filter is on the side facing the collection jar lid and fitted into the "VACUUM".
A wrong connection causes immediate destruction in case of contact with sucked liquids.

- Connect the long silicon tube with the lid union still free and marked as "PATIENT".
- Connect the conical junction for probe insertion with the free end of the long silicon tube.
- Insert the plug of the equipment feeding cable into a power socket.
- Press the ON/OFF button to start the medical equipment.
- To deal with foam formation within the tank, unscrew the tank lid and fill 1/3 of the tank with water (to make cleaning easier and speed up depression while operating the equipment), place the lid on the jar.
- While using the equipment, the suction tank should always be used vertically to avoid the intervention of the antireflux valve. In case of intervention of this protection, switch the device off and disconnect the tube connected with the suction tank (the one marked as "VACUUM") on the same lid.
- You can then detach all accessories and perform cleaning operations as described under "Cleaning accessories and internal parts" below.

<u>Using the footswitch control:</u> Connect the footswitch control feeding cable with the plug marked as "FOOTSWITCH CONTROL".
After the device has been connected, all Leds are still off. When the ON/OFF button is pressed, all Leds are activated at once for 1 second (autotest).
At the end of the autotest cycle, the ON/OFF button led will flash.
Press the button marked as (---) to perform suction using the footswitch control and execute intermittence work cycles.
Press the button marked as (-) to perform remote suction using the footswitch control (continuous suction).
To stop suction just push on the footswitch control with strength.

Using the footswitch control and the flow deviator: If using equipment fitted with a flow deviator, users may direct suctioned liquids in any of the two collection tanks provided. Flow deviator comes with two complete suction kits (2 sets of tubes, 2 antibacterial and hydrophobic filters and two conical junctions).
After the device has been connected, all Leds are still off. When the ON/OFF button is pressed, all Leds are activated at once for 1 second (autotest). At the end of the autotest cycle, the ON/OFF button led will flash.
To decide which side to perform the suction from, press OUT LEFT or OUT RIGHT and the selected button led will show a blue light.
Press the ON/OFF button again to start the suction cycle.
If the device is set up for using the flow deviator, ensure the antibacterial filter has been positioned on both sides.
Connect the footswitch control feeding cable with the plug marked as “FOOTSWITCH CONTROL”.
Press the button marked as (---) to perform suction using the footswitch control and execute intermittence work cycles.
Press the button marked as (-) to perform remote suction using the footswitch control (continuous suction).
To stop suction just push on the footswitch control with strength. Press the ON/OFF button to stop the medical equipment. Before removing the feeding plug, ensure autotest has been performed on the panel.

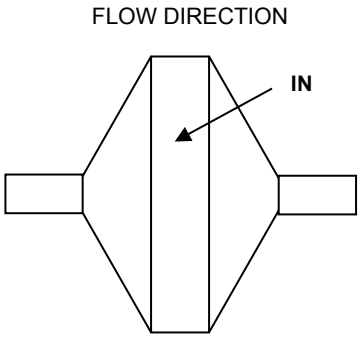
Using FLOVAC® disposable collection system: Before connecting the disposable collection system, remove the white ring fitted on the tank holder for a more comfortable insertion of the same container.
Connect the short tube with the throttle connector marked as “VACUUM” fitted on the lid of the disposable pocket. The container should be positioned on ON. The long silicon tube should be connected with the connector marked as “PATIENT”.
In order to perform suction, close the connector marked as “TANDEM” with the lid provided.
If using the equipment with FLOVAC® disposable collection system antibacterial filters are not required since each disposable pocket is already provided with an inside filter. The hydrophobic antireflux and antibacterial filter provided will protect the equipment, while also acting as float valve deactivating vacuum generation when the maximum volume level is reached.
When the float valve intervenes signalling the device is too full, the suction source must be disconnected within no more than 5 minutes.
Warning: The accidental inversion of connections may cause contamination for the operator and/or for the vacuum generation equipment.

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER

⚠ **MAKE SURE THAT CHILDREN AND/OR MENTALLY ILL PEOPLE DO NOT USE THE DEVICE WITHOUT ADULT SURVEILLANCE**

ALWAYS PLACE THE DEVICE IN POSITIONS FOR EASY DISCONNECTION.

Filter Assembling
Mod: NEW HOSPIVAC 400 / NEW HOSPIVAC 350



Suction pump Inlet

Jar Air Tube

RULES FOR RETURNING AND REPAIRING

COMPLYING WITH THE NEW EUROPEAN RULES, CA-MI INDICATES THE IMPORTANT POINTS TO PROTECT INSTRUMENT AND OPERATORS HYGIENE. THESE RULES MUST BE RESPECTED IN ORDER TO GUARANTEE HYGIENE AND SAFETY TO ALL THE PEOPLE OPERATING WITH THE INSTRUMENT TO OBTAIN QUALITY AND WELL BEING.

CA-MI warrants it's products for **24 months** after purchasing date.
In front of this warranty, CA-MI will be obliged only to repair or substitute free of charge the products or parts of them that, after verification effected on our factory, or our authorized Service Center, by the Technical Service, results defective.
The product must be accompanied by a description of the defect.
The warranty, with exclusion of responsibility for direct and indirect damages, it is thought limited to the solos defects of material or workmanship and it stops having effect when the device results however gotten off, tampered or sheltered out of the Factory or from the Authorized Service center.
The commodity always travels to risk and danger of the buyer, without any responsibility of CA-MI for damages caused by the transport or dismay from the vector.Every returned instrument will be hygienically checked before repairing.
If CA-MI finds instrument not suitable for repairing due to clear signs of internal or external contamination, the same will be returned to customer with specification of NOT REPAIRED INSTRUMENT, accompanied by an explanation letter.
CA-MI will decide if contamination is due to bad functioning or misuse. If contamination is due to bad functioning, CA-MI will substitute the instrument, only if a SALE RECEIPT and STAMPED GUARANTEE accompany the same.
CA-MI is not responsible for contaminated accessories, they will be substitute at customer's expenses.
For this reason it is **COMPULSORY** to carefully disinfect the external part of the instrument and accessories with a cloth soaked in methylated spirits or hypochlorite-based solutions. Put the instrument and accessories in a bag with indication of disinfecting. We also request to specify the kind of fault, in order to speed up repairing procedures.
To this end, please read the instructions carefully in order to avoid damaging the equipment through improper use.
Always specify the fault encountered so that CA-MI can establish whether it falls into the category of the faults covered by the guarantee.

CA-MI Srl cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse.
Any minimal modification/repair on the device voids the warranty and does not guarantee the compliance with the technical requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives.