CA·MI

Italian Medical Touch

NEW HOSPIVAC

IT Manuale d'uso

EN Instruction manual

FR Mode d'emploi

DE Handbuch

ES Manual de istrucciones

RU Инструкция по эксплуатации

PT Manual de instruções

TR Kullanim kilavuzu

CE 0123

30751/657 - Rev.8 del 15.04.2019

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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 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. Check the condition of the unit before each use. The surface of the unit should carefully inspected for visual damage. Check the mains cable and **do not connect to power** if damage is apparent**;**
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. Respect the safety regulations indicated for electrical appliances and particularly:
   - Use original components and accessories provided by the manufacturer 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;
   - Position the device on stable and flat surfaces in a way that the air inlets on the back aren't obstructed;
   - To avoid incidents, do not place the aspirator on unstable surfaces, which may cause it to accidentally fall and lead to a malfunction and/or breakage. Should there be signs of damage to the plastic parts, which may expose inner parts of the energised device, **do not connect the plug to the electrical socket.** Do not attempt to make the device work before it has been thoroughly checked by qualified personnel and/or the CA-MI technical service department.
   - Don't use in the presence of inflammable substances such as anaesthetic, oxygen or nitrous oxide;
   - Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;
   - 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;
   - Store and use the device in places protected against the weather and far from any sources of heat. After each use, it is recommended to store the device in its own box away from dust and sunlight.
   - In general, it is inadvisable to use single or multiple adapters and/or extensions. Should their use be necessary, you must use ones that are in compliance with safety regulations, however, taking care not to exceed the maximum power supply tolerated, which is indicated on the adapters and extensions.
4. For repairs, exclusively contact technical service and request the use of original spare parts.
   Failure to comply with the above can jeopardise the safety of the device;
5. **Use only for the purpose intended.** Don't use for anything other than the use defined by the manufacturer.
   The manufacturer will not be responsible for damage due to improper use or connection to an electrical system not complying with current regulation.
6. Instrument and accessory discharging must be done according to current regulations in the country of use.
7. **WARNING**: Do not change this equipment without the permission of the manufacturer CA-MI Srl. 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 technical assistance
8. 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;
9. The medical device is in contact with the patient by means of a disposable probe (not supplied with the device). If this device must be used with a specific suction probe, the end user is responsible for making sure it complies with the ISO 10993-1 rule;
10. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1;
11. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.
12. The medical device requires special precautions regarding electromagnetic compatibility and must be installed and used in accordance with the information provided with the accompanying documents: the NEW HOSPIVAC 350 / NEW HOSPIVAC 400 device must be installed and used away from mobile and portable RF communication devices (mobile phones, transceivers, etc.) that may interference with the said device.

Under certain failure conditions, the temperature of the casing (New Hospivac 400) may become hot and there may be a risk of burns if you touch those parts. In any case, the temperatures do not exceed the limit of 105°C (ref. Interpretation Sheet IEC 60601-1 / ISH May 2013)

The manufacturer 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

CONTRAINDICATIONS

- Before using the NEW HOSPIVAC 350 / NEW HOSPIVAC 400, consult the instructions for use: failure to read all the instructions in this manual can be harmful for the patient.
- The device cannot be used to drain chest fluids;
- The device must not be used for suction of explosive, corrosive or easily flammable liquids.
- NEW HOSPIVAC 350 / NEW HOSPIVAC 400 is not suitable for MRI. Do not introduce the device in MRI environments.

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	385 VA	230 VA
FUSE	F 1 x 4A L 250V	F 1 x 4A L 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	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 Atmospheric pressure: 800 ÷ 1060 hPa Altitude: 0 ÷ 2000m s.l.m.	
CONSERVATION CONDITION AND TRASPORT	Room temperature: -40÷ 70°C Room humidity percentage: 10 ÷ 100% RH Atmospheric pressure: 500 ÷ 1060 hPa	

WARRANTY CONDITIONS

This product is guaranteed for a period of 24 months from the date of purchase. The warranty includes the repair or replacement of defect spare parts free of charge, if the defect has been clearly described by the customer and determined by technical service. Inspections on the part of the seller, performed at the request of the customer and intended to determined wjether the device is fully functional, are not covered by the free-of-charge warranty service. This service will be charged to the customer depending on the effort required. The consumables components are not subject to warranty. Consumable components are silicon tubes, filters, seals, conical adaptor and suction catheter. Also exluded from warranty is all damage resulting from improper handling, wilful damage or improper care of the device. The warranty shall expire if repairs and servicing are not carried out by technical service.

RULES FOR RETURNING AND REPAIRING

UNDER NEW EUROPEAN RULES, CA-MI REQUIRES THE FOLLOWING PROCEDURES TO BE CARRIED OUT TO PROTECT THE INSTRUMENT AND THE SAFETY OF ALL WHO COME IN CONTACT WITH IT.

Before returning an instrument for repair, the external surfaces and all accessories **MUST** be carefully disinfected with a cloth soaked in methylated spirits or hypochlorite-based solution. The instrument and accessories should then be placed in a bag with a note outlining the disinfection undertaken.
Failure to follow this procedure will result in the instrument being returned to the purchaser unrepaired.
Instruments returned for repair **MUST** be accompanied by a description of the problem. CA-MI will not be responsible for damage caused through improper use. To avoid such damage, please read the instruction carefully.
Where CA-MI determines that an instrument is faulty, a replacement will be provided only if a SALES RECEIPT and STAMPED GUARANTEE are provided. CA-MI will not be responsible for damage accessories. These may be replaced at the customer's expence.

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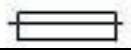
CLEANING THE MAIN UNIT

To clean the device external parts always use a cotton cloth dampened with detergent. Don't use abrasive or solvent detergents.
ATTENTION: During cleaning make sure that liquids do not come into contact with the membrane keyboard (only in versions with footswitch and flux deviator) and adjacent areas as this would damage the component, with possible infiltration of the liquid inside the device.
The symbol  positioned in the casing near the membrane keyboard requires the reading of the user instructions before each use.

PARTICULAR CARE SHOULD BE TAKEN TO ENSURE THAT THE INTERNAL PARTS OF THE EQUIPMENT DO NOT GET IN TOUCH WITH LIQUIDS. NEVER USE LIQUIDS (e.g. DETERGENTS AND/OR SANITISING SUBSTANCES) TO CLEAN THE MAIN UNIT (ESPECIALLY NEAR THE MEMBRANE KEYBOARD) AS THEY MAY PENETRATE INSIDE THE DEVICE

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).

SYMBOLS

	Class II isolation equipment
	CE marking in conformity with EC directive 93/42/EEC and subsequent changes
	CA-MI Srl - Via Ugo La Malfa nr.13 – Frazione Pilastro 43013 Langhirano (PR) Italy
	General warnings and/or specifications
	Consult the instruction manual before each use
	
	Atmospheric Pressure
	Humidity
	Operating limit temperature / Transport and storage limit temperature
	Applied Part type B (suction probe / conical fittings)
	Fuse
~	Alternate Current
Hz	Mains Frequency
	ON / OFF
(---)	Using the footswitch control (for intermittence suction)
(——)	Using the footswitch control (for continuous suction)
IPX1 (on the footswitch control label)	Degree of protection an electrical device provides in the case of accidental or intentional contact with the human body or with objects, and protection in the case of contact with water.
	1st DIGIT **PENETRATION OF SOLIDS** / **2nd DIGIT** **PENETRATION OF LIQUIDS**
	No protection / Protected against the vertical flow of drops of water

Please note technical specifications may vary upon the manufacturer's discretion!

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2012/19/UE-WEEE:
The symbol on the device indicates the separated collection of electric and electronic equipment. At the end of life of the device, don't dispose it as mixed solid municipal waste, but dispose it referring to a specific collection centre located in your area or returning it to the distributor, when buying a new device of the sample type to be used with the same functions. This procedure of separated collection of electric and electronic devices is carried out forecasting a European environmental policy aiming at safeguarding, protecting and improving environment quality, as well as avoiding potential effects on human health due to the presence of hazardous substances in such equipment or to an improper use of the same or of parts of the same **Caution:** The wrong disposal of electric and electronic equipment may involve sanctions.

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

This section contains information regarding the conformity of the compliance with the EN 60601-1-2 (2015) Standard.
CISPR group and category classification: group 1, category B.
The NEW HOSPIVAC 350 / NEW HOSPIVAC 400 surgical aspirator is an electro-medical device that requires particular precautions regarding electro-magnetic compatibility and which must be installed and commissioned according to the electro-magnetic compatibility information supplied. Portable and mobile radio communication devices (mobile phones, transceivers, etc.) may interfere with the medical device and should not be used in close proximity with, adjacent to or on top of the medical device.
If such use is necessary and unavoidable, special precautions should be taken so that the electro-medical device functions properly in its intended operating configuration (for example, constantly and visually checking for the absence of anomalies or malfunctions).
The use of accessories, transducers and cables different to those specified, with the exception of transducers and cables sold by the appliance and system manufacturer as spare parts, can lead to an increase in emissions or in a decrease of the immunity of the device or system. The following tables supply information regarding the EMC (Electromagnetic Compatibility) characteristics of the electro-medical device.

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The surgical aspirator NEW HOSPIVAC 350 / 400 is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator NEW HOSPIVAC 350 / 400 should assure that it's used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The surgical aspirator NEW HOSPIVAC 350 / 400 only used RF energy only for its internal functioning. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Irradiated / Conducted emissions CISPR11	Class [B]	The appliance is suitable fopr use in alla establishments included domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator NEW HOSPIVAC 350 / 400 is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator NEW HOSPIVAC 350 / 400 should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environments - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 8kV on contact ± 15kV in air	The device doesn't change its state	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 EN 61000-4-4	± 2kV power supply lines ± 1kV for input / output lines	The device doesn't change its state	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 0,5kV and ± 1,0kV differential mode	The device doesn't change its state	Mains power quality should be that of a typical commercial or hospital environment.
Volgate dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5%U_T (>95% dip U_T) for 0.5 cycle 40%U_T (>60% dip U_T) for 5 cycle 70%U_T (>30% dip U_T) for 25 cycle <5%U_T (>95% dip U_T) for 5 sec	-	Mains power quality should be that of a typical commercial or hospital environment. If the user of the surgical aspirator NEW HOSPIVAC 350 / 400 requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field EN 61000-4-8	30 A/m	The device doesn't change its state	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Note U_T is the value of the power supply voltage			

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Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator NEW HOSPIVAC 350 / 400 is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator NEW HOSPIVAC 350 / 400 should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance level**	**Electromagnetic environments - guidance**
Conducted Immunity EN 61000-4-6	3Vrms 150kHz to 80Mhz (for non life-supporting devices)	V_1 = 3 V rms	Portable and mobile RF communication equipment, including cables, should be used no closer to any part of the device, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5 / V_1] $\sqrt{P}$ rom 150kHz to 80MHz d = [12 / E_1] $\sqrt{P}$ from 80 MHz to 800MHz d = [23 / E_1] $\sqrt{P}$ from 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site study of the site, should be less that the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated Immunity EN 61000-4-3	3V/m 80MHz to 2.7GHz (for non life-supporting devices)	E_1 = 3 V / m	
Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by reflection from buildings, objects and people. a) The field intensity for fixed transmitters such as the base stations for radiotelephones (mobile and cordless) and terrestrial mobile radio, amateur radio devices, radio AM and FM transmitters and TV transmitters can not be theoretically and accurately foreseen. To establish an electro-magnetic environment generated by fixed RF transmitters, an electro-magnetic study of the site should be considered. If the field intensity measured in the place where the device will be used surpasses the above mentioned applicable level of conformity, the normal functioning of the device should be monitored. If abnormal performance arises, additional measures such as changing the device's direction or positioning may be necessary. b) The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 3 V/m.			

Recommended separation distance between portable and mobile radio-communication devices and the monitor			
The surgical aspirator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NEW HOSPIVAC 350 / 400 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the NEW HOSPIVAC 350 / 400 device, as recommended below, according to the maximum output power of the communications equipment.			
Maximum nominal output power of the Transmitter W	**Separation distance from the frequency transmitter (m)**		
	150 kHz to 80 MHz d = [3.5 / V_1] $\sqrt{P}$	80 MHz to 800 MHz d = [12/E_1] $\sqrt{P}$	800 MHz to 2.7 GHz d = [23/E_1] $\sqrt{P}$
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 a maximum nominal output power not shown above, the recommended separation distance in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the maximum nominal output power of the transmitter in Watt (W) depending on the transmitter's manufacturer. Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by the reflection from buildings, objects and people.			

ACCESSORIES SUPPLIED

ACCESSORIES SUPPLIED	CODE
N°2 COMPLETE ASPIRATION JAR 2000ml	RE 210351/01
CONICAL FITTING	RE 210420
SILICON SET TUBES 8 mm x 14 mm	51100/01
ANTIBACTERIAL AND HYDROFOBIC FILTER (for model New Hospivac 400)	SP 0047
ANTIBACTERIAL AND HYDROFOBIC FILTER (for model New Hospivac 350)	SP 0121
SAFETY TRAP	SP 0285
FOOTSWITCH CONTROL (for versions equipped with footswitch)	Cod. 52130
EUROPEAN POWER SUPPLY CORD (H05VV-F - 2x0.75mm^2 - 2mt)	SP 0021

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. 4000ml (REF RE 210006) or 5000ml (REF RE 210010) complete jar 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.

SAFETY TRAP with 220 ml capacity to collect the liquid that could leak from the overflow valve of the vessel. This ensures additional protection of the filter and pump. The trap is completely removable and autoclavable. Not available in versions equipped with FLOVAC disposable collection system

Aspiration jar: The mechanical resistance of the component is guaranteed up to 30 cycles of cleaning and sterilization. Beyond this limit, the physical-chemical characteristics of the plastic material may show signs of decay. Therefore, we recommend that you to change it.

Silicone tubes: the number of cycles of sterilization and/or cleaning is strictly linked to the employment of the said tube.
Therefore, after each cleaning cycle, it is up to the final user to verify whether the tube is suitable for reuse. The component must be replaced if there are visible signs of decay of the material constituting the said component.

Conical fitting: the number of cycles of sterilization and the number of cleaning cycles is strictly linked to the employment of the said component. Therefore, after each cleaning cycle, it is up to the final user to verify whether the fitting is suitable for reuse.
The component must be replaced if there are visible signs of decay in the material constituting the said component.

Service life of the device: More than 10000-12000 hours of operation (or 3 years) in accordance with the standard conditions of testing and operation. Shelf life: maximum 5 years from the date of manufacture.

WARNING: Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility. The medical device is provided without a specific suction probe. If this device must be used with a specific suction probe, the end user is responsible for making sure it complies with the EN 10079-1 regulation.

CLEANING ACCESSORIES AND INTERNAL PARTS

Before using the device, the manufacturer advises you to clean and/or sterilize the accessories.
Washing and / or cleaning the autoclavable jar as to be carried out as follows:

- Wear protection gloves and apron (glasses and face mask if necessary) to avoid contact with contaminating substances;
- Disconnect the tank from the device and remove the said container from the support of the device.
- Separate all the parts of the cover (overflow device, washer).
- Disconnect all tubes from the jar and the protection filter
- Wash each part of the container from secretions under cold running water and then clean every single part in hot water (temperature not exceeding 60°C)
- Once again, carefully wash each single part using, if necessary, a non-abrasive brush to remove any deposits. Rinse with hot running water and dry all parts with a soft cloth (non-abrasive). It is possible to wash with commercial disinfectants by carefully following the instructions and dilution values supplied by the manufacturer. After cleaning, leave the parts to dry in an open, clean environment.
- Dispose of the aspiration catheter according to that provided by local laws and regulations.

The silicone aspiration tubes and the conical fitting may be carefully washed in hot water (temperature must not exceed 60°C).
After cleaning, leave the parts to dry in an open, clean environment.
When cleaning is complete, reassemble the container for liquid aspirations according to the following procedure:

- 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 leackages or liquid exit

After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thouroughly.
Then soak in warm water (temperature shall not exceed 60°C). Wash thouroughly 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 – 15 min) making sure that the jar is positioned upsidedown. 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.
The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 121°C (1 bar relative pressure – 15 min).
The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C (1 bar relative pressure – 15 min).

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. 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 350 / NEW HOSPIVAC 400** suction equipment does not need maintenance or lubrication.
It is, however, necessary to inspect the unit before each use. With regard to training, given the information contained in the user manual and since it is easy to understand the said device, it doesn't appear to be necessary.
The device must be checked before each use in order to detect malfunctions and / or damage caused by transport and / or storage.
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 fuses **(F 1 x 4A L 250V)** reachable from exterior and situated in the plug protects the instrument.
For fuses replacing, always the type and the range. Before changing the fuse, disconnect the plug from the power supply socket.
Internally, the device (only for devices fitted with a circuit board) is protected by a fuse **(F 500mA L 250V)** that cannot be reached from the outside, so please contact a technician authorised by the manufacturer for its replacement.

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 proceede 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 MANUTACTURER DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

INSTRUCTIONS

- The working position must be such as to allow one to reach the control panel and to have a good view of the empty indicator, the jar and the antibacterial filter.
- If the device is to be transported from one place to another, to prevent the liquid collection jar from falling and consequently the liquid from spilling, removing the jar from the device is recommended.

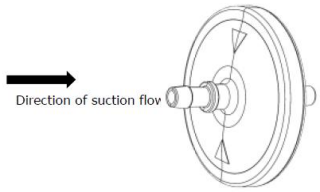
WARNING: For proper use, place the aspirator on a flat, stable surface in order to have the full volume of use of the jar and better efficiency of the overflow device. The vacuum jar, during use, must be used in vertical mode, to prevent the action of the backflow valve. If this protection is triggered, turn the device off and disconnect the pipe connected to the vacuum jar (indicated with the word VACUUM) on its cover.

- Connect the short silicone tube to the antibacterial filter connector (check the filter assembly photo) while the other end must be connected to the safety trap "IN" nozzle using a short silicone tube.

SAFETY TRAP: The two connections on the sides of the bar can be used to insert a safety trap in the BASIC and FS versions and two traps in the FULL version. The safety trap is an additional protection for the overflow valve of the vessel. In the event that the liquid goes beyond the overflow valve during the suction process, the trap collects the liquid thus protecting the antibacterial filter and the internal motor.

- Connect the remaining short silicone tube to the safety trap "OUT" nozzle, while the other end must be connected to the vessel cover nozzle bearing the word "VACUUM", which is fitted internally with the float (overflow device). When the 90% of the volume of the jar is reached there is the activation of the security float (the float close the aspiration connector on the jar) to avoid liquid penetration inside the device.

WARNING: Ensure that the filter is fitted with the Arrows at the patient side.



WARNING: The inside of the medical device must be regularly checked for the presence of liquids or other visible contamination (secretions). If liquids or other visible contamination are present, the medical device must be replaced immediately due to the risk of insufficient vacuum flow. These products have been designed, tested and manufactured exclusively for "single use" and for a period of use not exceeding 24 hours unless stated below.

- 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.

WARNING: The power supply cable plug is the element of separation from the electrical mains system: even if the units equipped with a special on / off switch button, the power supply plug must be kept accessible once the device is in use so as to allow a further method of disconnection from the mains supply system.

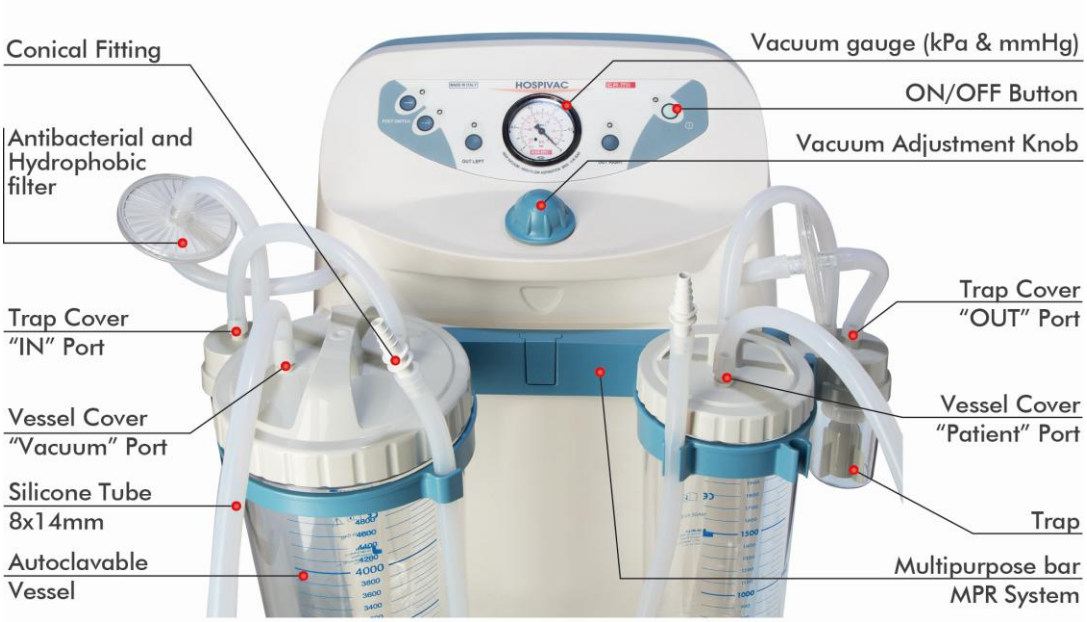
Multipurpose bar- MPR System

The device is equipped with a multipurpose bar to easily change accessories (such as rings of different diameters for different collection vessel capacities, safety traps, cannula holders or standard 30x10 mm stainless steel bar, on which any other accessory can be inserted using standard clamps)

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.



Using the footswitch control:
Connect the footswitch control feeding cable with the plug marked as ⚠FOOT SWITCH

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 ⚠FOOT SWITCH

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 blu ring fitted on the tank holder for a more comfortable insertion of the same container.

- After opening the package, fully stretch the bag and then flatten it concentrically to eliminate as much air as possible.
- Insert the bag and apply the cover to an appropriately sized reusable rigid container by pressing firmly around the entire perimeter. Make sure that the system is completely sealed.
- Close the connector marked as "TANDEM" with the lid provided.
- Connect the power source of the vacuum to the VACUUM port equipped with specific reusable conical fitting with "male" connection.
- Connect the patient tube to the PATIENT port of the cover
- Before use, check all closures and make sure there are no leaks, starting the aspiration source. If the bag expands to fully adhere to the walls of the rigid container and the cover bends towards the inside of the glass, the system is not leaking.
- Start the aspiration and periodically check the filling level of the container. The overflow valve will cause the interruption of aspiration if the aspirated fluids have reached the maximum filling level of the device.
- 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.**

Italian
Medical
Touch

Certificato di Garanzia / Warranty Certificate

Apparecchio tipo / Device model _____

Lotto di produzione / Lot _____ n° serie / serial number _____

Acquistato in data / Purchasing date _____

Rivenditore / Authorized Dealer _____

Via / Street _____ Località / Place _____

Venduto A / Purchased By _____

Via / Street _____ Località / Place _____

Descrizione del Difetto / Defect description _____

Timbro del Rivenditore / Retailer's stamp

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