



# GIMA

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PROFESSIONAL MEDICAL PRODUCTS

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## SUPER VEGA SUCTION ASPIRATOR - 2 x 2 L - on trolley with footswitch



Instruction manual

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**REF**

**28192**



Gima S.p.A.

Via Marconi, 1 – 20060 Gessate (MI) Italy

Made in Italy

**CE** 0476



**SUPER VEGA SUCTION ASPIRATOR** it's an electrical powered surgical aspirator used for the nasal, oral and tracheal suction in man and child of body liquids (mucus, catarrh or blood). The equipment is intended for continuous operation. . The equipment is equipped with a trolley provided with 5 wheels (three of them are provided with locking system in order to avoid the equipment can overbalance) and an external plastic enclosure. Thanks to this characteristics and to the rating that it has, this product is particularly suitable for hospital use, on the tracheotomized patients, minor surgical applications and post-operative therapy at home. Made of highly heat resistant, electrically insulated plastic material in conformity with the latest European safety standard, the product is supplied with a complete polycarbonate autoclavable jar with overflow valve and it is equipped with aspiration regulator and vacuum indicator located on the front panel. Available under request with different version for application and use (version with remote control, ecc.)

## 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 GIMA**

**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 which 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 GIMA 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.
  - Don't use the device thoracic drainage.
  - 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. 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 SUPER VEGA SUCTION ASPIRATOR 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.
7. Instrument and accessory discharging must be done according to current regulations in the country of use.
8. **WARNING:** Do not change this equipment without the permission of the manufacturer Gima S.p.A. 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
9. 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.
10. The medical device is in contact with the patient by means of a disposable probe (supplied with the device) furnished with the relative CE compliance certification according to the requirements of regulation ISO 10993-1: thus, no allergic reactions and skin irritations may occur.
11. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1.

12. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.

**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.**

### TECHNICAL CHARACTERISTICS

Model	SUPER VEGA SUCTION ASPIRATOR	
Typology (MDD 93/42/EEC)	Medical Device Class IIa	
Classification UNI EN ISO 10079-1	HIGH VACUUM / HIGH FLOW	
Main Voltage	230 V ~ / 50 Hz	
Power consumption	110 VA	
Fuse	F 1 x 1.6A L 250 V	
Maximum suction aspiration (without jar)	-80kPa (- 0.80bar)	
Minimum suction aspiration (without jar)	Less than -40kPa (-0.40 bar)	
Maximum flow (without jar)	40 l/min	
Weight	6.2 Kg	
Dimension	380 x 920 (h) x 360mm	
Functioning	NON-STOP OPERATED	
Working condition	Room temperature:	5 ÷ 35 °C
	Room humidity percentage:	30 ÷ 75 % RH
	Atmospheric pressure:	800 ÷ 1060 hPa
Conservation and transport condition	Room temperature:	- 40 ÷ 70 °C
	Room humidity percentage:	10 ÷ 100% RH
	Atmospheric pressure:	500 ÷ 1060 hPa








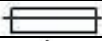












#### IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2012/19/UE-WEEE:

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 same 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.

## SYMBOLS

	Class 2 isolation equipment	
	CE marking in conformity with EC directive 93/42/CEE and subsequent changes	
	General warnings and/or specifications	
	Consult the instruction manual	
	Manufacturer: Gima S.p.A. Via Marconi, 1 - 20060 Gessate (MI) Italy	
	Applied Part type BF (suction probe)	
	Keep in a cool, dry place	
	Fuse	
	Conservation temperature: - 25 ÷ 70° C	
	Atmospheric Pressure	
	Alternate current	
	Mains frequency	
	ON / OFF	
	Remote Control	
	Batch production	
	Serial number	
	Model / Ref number	
 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.	
	<b>1st DIGIT PENETRATION OF SOLIDS</b>	<b>2nd DIGIT PENETRATION OF LIQUIDS</b>
	No protection	Protected against the vertical flow of drops of water

## CLEANING DEVICE

Use a soft dry cloth with not – abrasive and not – solvent detergents. 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).

## ACCESSORIES SUPPLIES

DESCRIPTION	CODE
N°2 COMPLETE ASPIRATION JAR 2000cc	RE 210351/01
CONICAL FITTING	RE 210420
TUBES SET 8 mm x 14 mm	RE 210355/03
ANTIBACTERIAL AND HYDROPHOBIC FILTER	SP 0121
FOOTSWITCH CONTROL (for versions equipped with footswitch control)	Cod. 52130
EUROPEAN POWER SUPPLY CORD	SP 0020

The filter is produced with (PTFE) hydrophobic material to prevent fluids entering the pneumatic circuit. It should be changed immediately if it becomes wet or if there is any sign of contamination or discolouration. It should also be changed if the unit is used with a patient whose risk of contamination is unknown. **Don't use the suction unit without the protection filter.** If the suction unit is used in an emergency or in a patient where the risk of contamination is not known the filter must be changed after each use. On request, are available versions with disposable collection system (FLOVAC® 2000ml) composed by a reusable polycarbonate vessel and polyethylene disposable bag (collection liner for fluids suction canisters).

**Suction catheter:** Single-use device to be used on a single patient. Do not wash or re-sterilize after use. Reuse may cause cross-infections. Don't use after lapse of the sell-by date



Check the expiry date on the original packaging of the suction catheter and check the integrity of the sterile packaging. GIMA declines any liability for injury to the patient correlated to the deterioration of the above-mentioned sterile packaging due to handling of the original packaging by third parties.

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

**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 850 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.

## CLEANING OF ACCESSORIES

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 sure that cover seals perfectly to avoid vacuum leakages or liquid exit

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 – 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. 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.

### PERIODICAL MAINTENANCE CHECKS

The **SUPER VEGA SUCTION ASPIRATOR** 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.

Unpack the instrument and **always check** integrity of plastic parts and feeding cable, they might have been damaged during previous use. Connect the cable to electrical network and turn the switch on.

Close the aspirator outlet with your finger and with suction regulator at maximum check that the vacuum indicators reaches at least -80kPa (-0.80 bar). Rotate the knob from right to left. The vacuum indicator should go down -40kPa (-0.40 bar).

Check that no loud noises are present. A protection fuses (**F 1 x 1.6 A 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 (**T 50mA L 250V**) that cannot be reached from the outside, so please contact a technician authorised by the manufacturer for its replacement.

Type of fault	Cause	Remedy
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 not screwed on correctly	Unscrew the cap, and re-screw it
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	<ul style="list-style-type: none"> <li>• Vacuum regulator set to minimum</li> <li>• Protection filter blocked or damaged</li> <li>• Connection tubes blocked, kinked or disconnected</li> <li>• Shut-off valve blocked or damaged</li> <li>• Pump motor damaged</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge</li> <li>• Replace the filter</li> <li>• Replace or reconnect the tubes, check the jar connections</li> <li>• Empty the jar, or disconnect the tube from the jar and unblock the shut-off valve. The unit will only work in the upright position</li> <li>• Refer to authorised service personnel</li> </ul>
5. The float doesn't close	If the cap has been washed, ensure that the float is not partially detached	Fit the float into its 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
<b>Faults 1 - 2 - 3 - 4 - 5 - 6 - 7</b>	<b>None of the procedures have achieved the desired results</b>	<b>Contact GIMA customer service</b>

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

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

1° case - If the overflow 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 GIMA technical service.

*Gima S.p.a. 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 GIMA TECHNICAL SERVICE. GIMA DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.**

## INSTRUCTION FOR USE

### Assembly of the device SUPER VEGA SUCTION ASPIRATOR:

Take the 5 arm base and set up the 5 wheels that come with the above device. The wheels provided with braking device must be placed one next to the order. Take the support bar that comes with the device SUPER VEGA SUCTION ASPIRATOR and place it in the hole on the 5-arm base. From under the base, lock the two parts by means of the supplied screw.

Eventually, place the device on the trolley.

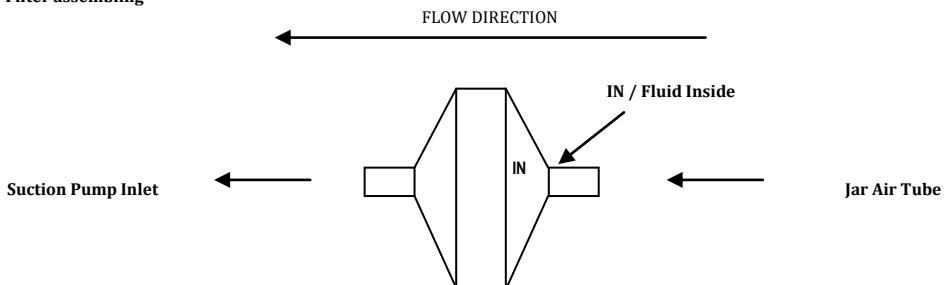
- The device must be checked before each use in order to detect malfunctions and / or damage caused by transport and / or storage.
- The working position must be such as to allow one to reach the control panel and to have a good view of the empty indicator, the jar and the antibacterial filter.
- If 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.

- Place the unit on a flat, horizontal surface
- Connect one end of the short silicon tube, with antibacterial filter, to the suction connector on the lid of the jar.
- The other tube already connected to the filter has to be connected to the "VACUUM" jar outlet, where has been fixed the red float (security float). 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 FLUID SIDE or 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.

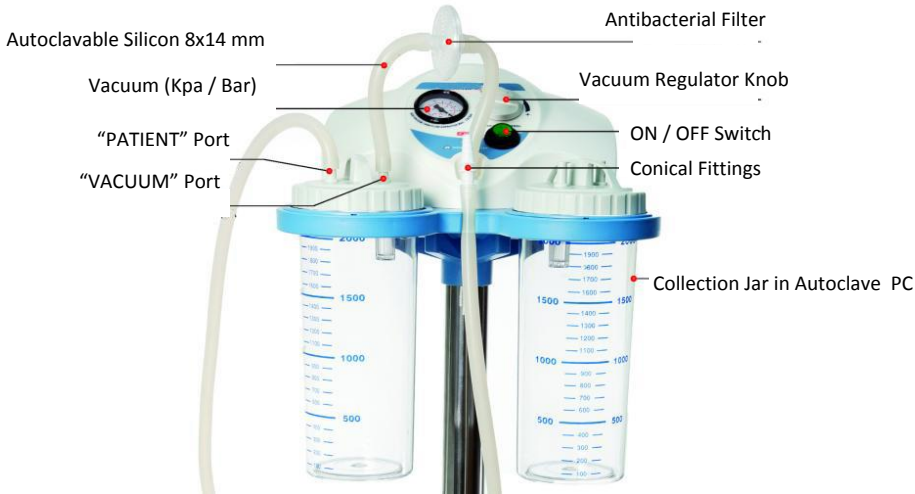
### Filter assembling



- Connect the long silicone tube to the "PATIENT" jar outlet
- Connect the other end of the long silicon tube to the probe plastic connector, then connect the suction probe to it.
- Connect the power cord to the device then connect the plug to the electrical mains supply.
- Push switch on position I to start suction.
- Unscrew the lid of the jar and fill the jar 1/3 full of ordinary water (this assists the unit to reach peak vacuum performance and makes clean-up easier) then re-screw the lid on the jar correctly.
- During operation the jar has to be in vertical position to avoid overflow valve to cut off aspiration. Should this happen, switch off the device and disconnect the tube from the jar cover (from "VACUUM" outlet).

- Once finished push switch on **0** position and unplug.
- Remove the accessories and clean.
- At the end of each use, place the device in its box away from dust.

**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.



**WARNING: NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER**

**Footswitch control device:** The equipment, on request, is provided with a footswitch control device. It allows the continuous use of the surgical aspirator. In this case, the plug of the footswitch device shall be inserted into the appropriate socket outlet placed on the back side of the equipment.



Near the footswitch control plug, there is a commutator that operates the device directly using the mains or by using the footswitch control.

When the switch is turned on (green light) and the commutator is in position I, the device works directly using the mains.

When the switch is turned on (green light) and the commutator is in position II, the device works via remote control (footswitch control)

When the switch is turned on (green light) and the commutator is in position 0, the device is powered but not in operation

**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).

**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.**

## RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

This section contains information regarding the conformity of the compliance with the EN 60601-1-2 Standard. The SUPER VEGA SUCTION 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 SUPER VEGA SUCTION ASPIRATOR is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPER VEGA SUCTION ASPIRATOR should assure that it's used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
Irradiated / Conducted emissions CISPR11	Group 1	The SUPER VEGA SUCTION ASPIRATOR 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 SUPER VEGA SUCTION ASPIRATOR 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 EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

### Guidance and manufacturer's declaration – Immunity Emissions

The SUPER VEGA SUCTION ASPIRATOR is intended for use in the electromagnetic environment specified below. The customers or the user of the sSUPER VEGA SUCTION ASPIRATOR should assure that it's used in such an environment.			
Immunity Test	Level indicated by the EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6kV on contact ± 8kV in air	The device doesn't change its state	Floors should be wood, concret 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 environment or hospital.
Surge EN 61000-4-5	± 1kV differential mode	The device doesn't change its state	Mains power quality should be that of a typical commercial environment or hospital.
Loss of voltage, brief voltage interruptions and variations EN 61000-4-11	5%U <sub>T</sub> (>95% dip U <sub>T</sub> ) for 0.5 cycle 40%U <sub>T</sub> (>60% dip U <sub>T</sub> ) for 5 cycle 70%U <sub>T</sub> (>30% dip U <sub>T</sub> ) for 25 cycle <5%U <sub>T</sub> (>95% dip U <sub>T</sub> ) for 5 sec	-	Mains power quality should be that of a typical commercial environment or hospital. If the user of the SUPER VEGA SUCTION ASPIRATOR request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field EN 61000-4-8	3A/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.
Nota U <sub>T</sub> is the value of the power supply voltage			

**Guidance and manufacturer's declaration – Immunity Emissions**

The SUPER VEGA SUCTION ASPIRATOR is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPER VEGA SUCTION ASPIRATOR should assure that it's used in such an environment.

Immunity Test	Level indicated by the EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
Conducted Immunity EN 61000-4-6	3Vrms 150kHz to 80MHz (for non life-supporting devices)	$V_1 = 3 \text{ V rms}$	The portable and mobile RF communication devices, including cables, must not be used closer to the ASKIR C30 device, than the separation distance calculated by the equation applicable to the transmitter frequency. Recommended separation distance $d = [3.5 / V_1] \sqrt{P}$ $d = [12 / E_1] \sqrt{P}$ from 80 MHz to 800MHz $d = [23 / E_1] \sqrt{P}$ from 800 MHz to 2.5 GHz  Where P is the maximum nominal output voltage of the transmitter in Watt (W) depending on the manufacturer of the transmitter and the recommended separation distance in metres (m). The intensity of the field from the fixed RF transmitters, as determined by an electro-magnetic study of the site <sup>a)</sup> , could be lower than the level of conformity of each frequency interval <sup>b)</sup> . It is possible to check for interference in proximity to devices identified by the following symbol: 
Radiated Immunity EN 61000-4-3	3V/m 80MHz to 2.5GHz (for non life-supporting devices)	$E_1 = 3 \text{ V / m}$	

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 SUPER VEGA SUCTION ASPIRATOR is intended to operate in an electro-magnetic environment where RF irradiated interferences are under control. The client or operator of the SUPER VEGA SUCTION ASPIRATOR device can help prevent electro-magnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and the SUPER VEGA SUCTION ASPIRATOR device, as recommended below, in relation to the radio-communication maximum output power.

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 2.5 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.

**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 determine whether 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 excluded 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, GIMA 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 unrepared.

Instruments returned for repair **MUST** be accompanied by a description of the problem. Gima will not be responsible for damage caused through improper use. To avoid such damage, please read the instruction carefully.

Where Gima determines that an instrument is faulty, a replacement will be provided only if a SALES RECEIPT and STAMPED GUARANTEE are provided. Gima will not be responsible for damage accessories. These may be replaced at the customer's expense.



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PROFESSIONAL MEDICAL PRODUCTS

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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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MADE IN ITALY