PROFESSIONAL MEDICAL PRODUCTS

ASPIRATORE SUPERVEGA EVO
SUPERVEGA EVO SUCTION UNIT
ASPIRATEUR SUPERVEGA EVO
ABSAUGER SUPERVEGA EVO
ASPIRADOR SUPERVEGA EVO

REF **28183**

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SUPERVEGA EVO is a desk-type electric suction unit for the aspiration of body liquids (such as mucus , phlegm and blood), oral, nasal and tracheal aspiration in adults or children. Its shape, elegantly narrow, is motly designed for fitting into ambulance care and emergency use.
This device has been designed to offer ease of transport and continuous use, thanks to an electronic system that manages the power supply. The large LCD display facilitates the use of the device and increases suction by adjusting the control buttons.
The signal on the LCD screen, placed on the front panel, allows you to monitor the charge status of the Lithium battery. The lithium battery and the innovative Feedback system, which guarantees a smart use by automatically controlling and adjusting the suction power, allow the battery to increase its autonomy and decrease the noise produced.
The “PROXIMITY” function allows the device to be activated/deactivated via an infra-red proximity sensor (detecting the presence of the hand from a distance of tenths of centimetres without touching the suction unit) and it prevents and avoids possible crosscontamination between patients as they are treated in turns.
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.

GENERAL WARNING

Read instruction manual carefully before use.
A careful and correct use ensures optimal operation of the device.
The device is for use by qualified personnel (surgeon / professional nurse / assistant). The use of the device at home is restricted to an adult in full possession of mental faculties and / or home carers.
The instrument must not disassembled. For technical service always contact Gima S.p.A.

BASIC SAFETY RULES

1. When opening the packaging, check the integrity of the device, paying particular attention should there be any damage to the plastic parts, which could make accessible the internal parts of the device under voltage, and to breakage and/or peeling of the power cable. **In case of any damage, do not connect the plug to the electrical socket. To replace it, contact Gima technical service.**
2. Before connecting the device, always check that the electrical details indicated on the data label and the type of plug used correspond to those of the electrical network to which you intend to connect it.
3. Comply with the safety rules indicated for electrical equipment and in particular:
   - Use only original accessories and components, supplied by the manufacturer Gima in order to ensure maximum efficiency and safety of the device.
   - Always use the medical device with the antibacterial filter supplied by the manufacturer Gima in order to ensure maximum efficiency and safety of the device.
   - Never immerse the device in water or other liquids.
   - Do not use the device in environments where there are flammable anaesthetic mixtures with air, oxygen or nitrous oxide which could cause explosions and/or fires.
   - Do not place the aspirator on unstable operating surfaces whose accidental fall could cause malfunctions and/or breakages. Should there be any damage to the plastic parts, which could make accessible the internal parts of the device under voltage, **do not connect the plug to the electrical socket**. Do not try to operate the device before it has undergone a thorough check by qualified personnel and/or by the Gima technical service.
   - Do not use the device in environments where there are flammable anaesthetic mixtures with air, oxygen or nitrous oxide which could cause explosions and/or fires.
   - Avoid touching the device with wet hands and in any case always ensure that the device does not come into contact with liquids.
   - Prevent children and/or incapacitated users from using the device without due supervision.
   - 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 weatherproof environments and away from any heat sources.
   - The device cannot be used to drain chest fluids.
   - 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.
   - Never leave the appliance near water, do not immerse it in any liquid. If the device has fallen into water, unplug it before you hold it. Do not use the appliance if the plug or AC / DC power supply is damaged or

wet (send it immediately to an authorized service center or technical service).

4. For repairs, exclusively contact Gima technical service or a technical assistance centre authorised by the manufacturer and only original spare parts may be used. Failure to comply with the above may compromise the safety of the device.
5. **This device must only be used for its intended use and as described in this manual.** Any use other than that for which the device is intended must be considered improper and therefore dangerous; the manufacturer cannot be held liable for damages caused by improper, erroneous and/or unreasonable use or if the device is used in electrical systems which do not comply with current safety standards.
6. The medical device requires special precautions regarding electromagnetic compatibility and must be installed and used according to the information provided with the accompanying documents: the device must be installed and used away from mobile and portable RF communication devices (cell phones, transceivers, etc.) that could affect the device itself.
7. WARNING: Do not modify this device without the manufacturer's authorisation. No electrical and/or mechanical part contained in the device has been designed to be repaired by the user. Failure to comply with the above may compromise the safety of the device.
8. The use of the device in environmental conditions other than those indicated in this manual can seriously affect its safety and technical parameters.
9. The medical device comes into contact with the patient through the single-use probe. Any suction cannulas that enter the human body, purchased separately from the machine, must comply with the requirements of ISO 10993-1.
10. The product and its parts are biocompatible in accordance with the requirements of the EN 60601-1 standard.
11. The operation of the device is very simple and therefore no further measures are required other than those indicated in the following user manual.
12. The lithium-ion battery contained within the medical device should not be considered normal household waste. Dispose of this component at a suitable collection point for its recycling.
13. Use in Home-Care: Keep all accessories of the device out of reach of children under 36 months of age since they contain small parts that may be swallowed.
14. Do not leave the device unattended in places accessible to children and/or persons not in full possession of mental faculties as they may strangle themselves with the patient's tube and/or the power cable.

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

Modell	SUPERVEGA EVO
Typology (MDD 93/42/EEC)	Class IIa Medical device
UNI EN ISO 10079-1 CLASSIFICATION	High vacuum / High flow
Power Feeding	14V ⎓ 4A with AC/DC adapter (input: 100-240V~ - 50/60Hz - 100VA) or Internally powered equipment (Li-Ion battery 14.8V ⎓ 5.2A) or with cigarette lighter adapter (12V ⎓ 4A)
Maximum Suction Pressure (adjustable)	-75kPa (-0.75 Bar)
Minimum Suction Pressure (adjustable)	-15kPa (-0.15 bar)
Maximum Suction Flow	26 l/min
Insulation Class (when used with the SUPPORT BRACKET)	Class II
Insulation Class (when used with an Internal battery)	Internally Powered Equipment
Weight	2.70 Kg
Size	350 x 210 x 180mm
Battery Holding Time	70 minuti
Battery Time Charge	360 minutes

Working Condition	Room temperature: 0 ÷ 40°C Room humidity percentage: 0 ÷ 85% RH Atmospheric pressure: 800 ÷ 1060 hPa
Conservation condition and transport	Room temperature (≤ 1 mounth): : - 20°C ÷ 45°C Room temperature (≤ 3 mounth): - 20°C ÷ 35°C Room temperature (≤ 1 year): 0°C ÷ 25°C Room humidity percentage: 0 ÷ 85% RH Atmospheric pressure: 500 ÷ 1060 hPa

The technical specifications may change without notice.

Please note that if the device is used at an altitude higher than 2.500 m asl, the yield intended as suction flow may vary sensitively due to the decrease in atmospheric pressure.

MAIN UNIT CLEANING OPERATIONS

To clean the outside of the device, use a cotton cloth moistened with a detergent.
Do not use abrasive cleaning substances and solvents. Before carrying out any cleaning and/or maintenance operation, disconnect the device from the power supply, by unplugging or turning off the device switch.

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

- Complete aspiration jar 1000ml
- Conical fitting
- Tubes set 8x14 mm
- Hydrophobic and antibacterial filter
- AC/DC adapter
- Power supply cord for AC/DC adapter
- Cigarette ligther cable

Available under request with different versions with complete jar 2000ml.

Anti-bacterial and hydrophobic filter: designed for the individual patient to protect patient and machine from cross-infections. Prevents the liquids, that come into contact with it, from passing through it. Replace it whenever you suspect that it may be contaminated and/or it becomes wet or discoloured. Replace the filter every time it is used if the suction pump is used on patients in unknown pathological situations and where an assessment of indirect contamination is not possible. The filter is not manufactured to be decontaminated, dismantled and/or sterilised. If, however, the patient's pathology is known and/or there is no risk of indirect contamination, the filter should be replaced after every work shift or once a month even if the device is not used.

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 30000 hours of operation in accordance with the standard conditions of testing and operation. Shelf life: maximum 5 years from the date of manufacture.

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.

Lithium-ion battery charge cycles: The lithium-ion battery included in the device is guaranteed for over 300 charging cycles. When you near the 300 charging cycles, you can ask the manufacturer to check the operating status or ask for the battery pack to be replaced to ensure that the component is always in perfect condition

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

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 sue that cover seals perfectly to avoid vacuum leackages or liquid exit

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

PERIODICAL MAINTENANCE CHECKS

The SUPERVEGA EVO suction equipment does not need maintenance or lubrication.
It is, however 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. Remove the appliance from the box and always check that the plastic parts and AC/DC adaptor are intact which may have been damaged during previous use. Connect the universal transformer to the device using the relevant connector and insert the power cable plug of the adaptor in the power socket. After starting the device, block off the suction nozzles with your finger and check for suction.
Make sure you do not hear excessively annoying noises that may highlight a malfunction.
The device is protected by a protective fuse **(F 10A L 250V)** located in the cigarette lighter cable. Always check the type and amperage indicated when replacing it. Internally, the device (see electrical sheet) is protected by two fuses F1 and F2 **(F 15A L 125V)**, which cannot be reached from the outside; refer to technical personnel authorised by the manufacturer to replace them.
The device is equipped with a Lithium-Ion Battery, which cannot be reached from the outside. Only refer to GIMA technical service personnel to replace it.

Only use batteries recommended by Gima. Use of batteries other than those recommended will make the warranty void and null.
Only qualified personnel are authorised to replace the internal battery. Any operation Performed by non-trained personnel may cause danger (e.g. Excessive temperature)

The device should be checked at least once every 12 months by technical service. Every 24 months it is compulsory to have a safety inspection and technical maintenance performed on the device.

Typical defect	Cause	Remedy
1. Steady Red Back-Light	Low battery	If equipped with an AC/DC power supply, connect the power cable to the mains, with the switch not pressed and leave it to charge until a Steady White Back-Light is shown (ref. TAB.I)
2. No Led On and Back-Light failure	Device locked	Internal technical problem. Contact technical assistance.
3. No aspiration	Vessel lid screwed incorrectly	Unscrew and tighten the lid of the vessel
4. No aspiration	Cover gasket not in place	Unscrew the cover and reposition the gasket in its cover housing.
5. Blocked float	Fouling on the float	Unscrew the cover, remove the float and proceed with cleaning.
6. Failure to close the float	If the cap has been washed, check that the float is not partially detached	Wedge float
7. Slow aspiration	Foam formation inside the collecting vessel	Fill the vessel 1/3 full of normal water
8. No aspiration caused by mucus leakage	Clogged filter	Replace the filter
9. Low and/or no vacuum power	• Unsuitable aspiration level • Protection filter blocked • Connection pipes to the filter and the device blocked, kinked or disconnected • Overflow valve closed or blocked • Damaged pump	• Proceed to set the correct aspiration value • Filter replacement • Connect the pipes to the filter and/or vessel or replace them if clogged • Unblock the overflow valve, hold the device upright • Contact the Gima technical service
Defects 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9	None of the remedies was effective	Contact your Gima dealer or service centre

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 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. The medical device contains firmware. This information is made available in order to assist the technical assistance personnel in the eventual repair of the appliance.

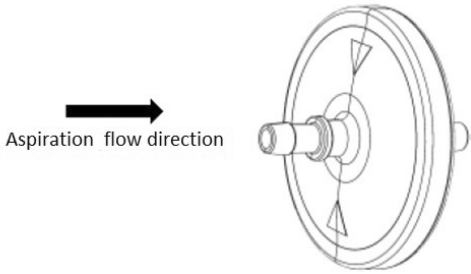
BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT GIMA TECHNICAL SERVICE. GIMA DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

INSTRUCTION FOR USE

- 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 LCD screen, the suction tank and the antibacterial filter.

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.

Filter assembling



Make sure the filter is assembled with the arrows on the side of the patient.

WARNING: The inside of the medical device must be regularly checked for the presence of liquids or other visible contamination (secretions). In the presence of liquids or other visible contamination, immediately replace the medical device due to the risk of an insufficient vacuum flow rate.
These products have been designed, tested and manufactured exclusively for single patient use and for a period no longer than 24 hours.

Operation using with AC/DC switching adapter

Connect the short silicon tube, with antibacterial filter, to the suction connector (VACUUM). The other tube, with one end connected to the antibacterial filter with the other end to jar's lid connector where has been fixed the red 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 the avoid liquid penetration inside the device.

- Connect the long silicon tube to the other jar's lid connector (PATIENT PORT).
- To start the treatment press the ON/OFF button and check its green back-light. When the device is switched on the LCD screen activates displaying a bar-graph, graduated scale, and negative pressure value, which must be set by the operator.

- The negative pressure is set with keys - and +, which are found below the LCD screen: Press one of the two keys with the motor on. The level of the negative pressure will flash at the centre of the display. Release the key and, after 3 seconds, the value will be operating (fixed digit on the display) and saved. The desired value remains fixed until the operator varies the negative pressure, whilst the bar-graph moves along the semi-circumference stopping in correspondence (graph) of the value set.

The maximum negative pressure value that can be set is: -75kPa (-0.75 bar)
The minimum negative pressure value that can be set is: -15kPa (-0.15 bar)

- To suspend and / or terminate the treatment press the ON / OFF button and and pull the plug out from the power socket.
- Unscrew the jar's lid and fill the jar 1/3 full or ordinary water (this for an easy cleaning operations and an rapid reaching of the functionally vacuum) then rescrew the lid on the jar correctly.
- To extract the accessories and start with cleaning.
- At the end of each use place the device back in the box, protected against dust.

WARNING: The power cord plug is the element of separation from the electrical mains, even if the device is equipped with an on/off button. Once the device is in use, the power plug must remain accessible to allow another method of disconnection from the electrical mains.

The device features an energy saving function which allows the device to increase its autonomy and decrease the number of revs of the motor. In order to do so, it controls the negative pressure which is generated only when the operator suctions body fluids.
If the operator does not carry out the suction process the device lowers the number of revs of the motor, thus protecting the duration of the internal battery.

Operation with internal battery

- Connect the device accessories according to the information outlined in the chapter "Operation with AC/DC power adapter";
- Press the switch to position I to turn the device on (the external power pack does not need to be connected)
- The fully charged battery life is about 70 minutes with continuous operation.

WARNING: Before using the device, check the charge level of the lithium-ion battery. Charge the battery before each use. To keep the device in good working order, charge the battery every 3 months (if not used).

Charging operations (through the supplied AC/DC adapter): To charge the internal battery, connect the universal adaptor (supplied) to the mains electricity supply for about 6 hours (360 minutes) with the device switched off (not operating).

The symbol  positioned near the 12V jack on the casing requires the user to read the instructions before each use, identifying the model and type of power supply which can be connected through the information provided in the instructions for use.

LIGHT INDICATORS

The device is provided with a light indicator (directly on the LCD screen) which allows you to view the operation of the device, autonomy of the battery, and the charge phase in progress.
The light indications, which appear during operation, are indicated in table I.
The charge cycle starts automatically by placing the device on the specific support bracket (ref. Support Bracket and Charge Chapter). The charge occurs only when the motor of the suction unit is off.
DISPLAY IN CHARGE: this is on with white back-light and it remains on for the entire time. It switches off if there is no external voltage. The charge phase lasts until the device is powered and the battery is kept at its maximum charge. The large digits display “CHA” .

TAB. I – INDICATOR LIGHTS DURING OPERATIONS

Back-light signals	Phase	Problem / Cause	Solution
Fixed white back-light and progressive activation of the bar-graph	During the Charge phase	Battery charge in progress	Wait
Fixed white back-light and fixed activation of the bargraph	During the Charge phase	Charging cycle complete	Remove the device from the support plate of the ambulance
Fixed green back-light	During battery operation	Primary status / Battery fully charged	Battery operation guaranteed
Fixed yellow back-light	During battery operation	Intermediate status / Battery not fully charged	Battery operation guaranteed / start the charge cycle upon activation of the red back-light
Fixed red back-light	During battery operation	Low battery	Start charge phase ATTENTION: A long and continuous beep is produced during this signal to warn the operator about the low charge level of the battery.
Flashing red back-light	Automatic switch-off of the device due to discharged battery	Battery fully discharged	The flashing back-light switches on upon reactivation of the device. Immediately start the battery charge cycle.

TAB. II – WRITTEN SIGNALS / BUTTON LED SIGNAL

Button LED signal / written signal	Function	Colour	Position
ON/OFF button	Power on	Green	Near the front panel key
Proximity Button	Switch the ON/OFF key	Blue	LED located above the “Proximity” key
CHA	Displays the battery charge status	Fixed white back-light and progressive activation of the bargraph	Central in digits of large dimensions
Small three-digit number (000)	Displays the voltage of the device if in charge phase or it displays the full scale of the bar-graph.	Fixed white or green back-light depending on whether external power supply or battery and progressive activation of the bar-graph are used.	Sideways in small digits
Bar-graph (arc bar-graph)	It displays the trend of the negative pressure or of the charge status	Progressive activation of the bar-graph (black)	Arc-shaped in the middle of the screen

Large three-digit number (000)	It displays the negative pressure set by keys “up” and “dw”	Fixed white or green back-light depending on whether external power supply or battery is used.	Central in digits of large dimensions

Operation using cigarette lighter DC 12V

- Connect the device’s external plug 12V to the ligther plug with the cigarette lighter cable. Check the battery power status of the vehicle before the cigarette lighter cable. Press the switch to start suction
- Press the switch to the I position to turn it on.
  WARNING: Only use the originally supplied or recommended replacement cigarette ligther cables (view the chapter “Important Safety Rules”).

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER

Proximity functions

- Pressing the “Proximity” (Lights BLUE LED) is activated on / off the motor by an infrared proximity sensor that detects the presence of the operator’s hand from a few inches away. This allows the operator to use the device without touching or focus on pressing the button.
- The on / off button is also active with the function of proximity inserted and can be used as an alternative.
- To remove the “Proximity” you have to re-press the button.

The “Proximity” is retained, or if it was active before power off, then on again to return to this, but if it was not active will remain disabled. The function set to power down the card after 20 minutes after turning off the engine if it is not then on again.

The unwanted approach of the hand to the Proximity sensors causes the device to switch off.
To reactivate the function, place the hand close to the sensors.
NOTE: It is up to the end user to activate or deactivate the Proximity sensor. With the Function off, the device is activated/deactivated by pressing the ON/OFF key.

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

This section contains information regarding the conformity of the compliance with the EN 60601-1-2 Standard (2015).
The SUPERVEGA EVO SUCTION UNIT 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 differing from 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 SUPERVEGA EVO SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPERVEGA EVO SUCTION UNIT should make sure that it's used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The SUPERVEGA EVO SUCTION UNIT 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 SUPERVEGA EVO SUCTION UNIT 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 SUPERVEGA EVO SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPERVEGA EVO SUCTION UNIT should make sure 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) 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 environment or hospital.
Surge EN 61000-4-5	± 1kV differential mode +/-2 kV ordinary 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_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 environment or hospital If the user of the SUPERVEGA EVO SUCTION UNIT request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field with network frequency (50/60 HZ) EN 61000-4-8	30A/m	The device doesn't change its state	The power frequency magnetic field should be measured in the intended installation location to make sure that it's sufficiently low.
Note U_T is the value of the power supply voltage			

Guidance and manufacturer's declaration – Immunity Emissions

The SUPERVEGA EVO SUCTION UNIT is intended for use in the electromagnetic environment specified below.
The customers or the user of the SUPERVEGA EVO SUCTION UNIT should make sure 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)	V1 = 3 V rms	The portable and mobile RF communication devices, including cables, must not be used closer to the SUPERVEGA EVO SUCTION UNIT device, than the separation distance calculated by the equation applicable to the transmitter frequency. **Recommended separation distance**
Radiated Immunity EN 61000-4-3	10V/m 80MHz to 2.7GHz (for non life-supporting devices)	E1 = 10 V / m	$d=\left[\frac{3,5}{V^1}\right]\sqrt{P}$ $d=\left[\frac{12}{E^1}\right]\sqrt{P}$ from 80 MHz to 800MHz $d=\left[\frac{23}{E^1}\right]\sqrt{P}$ from 800 MHz to 2.7 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[a)], could be lower than the level of conformity of each frequency interval [b)]. It is possible to check for interference in proximity to devices identified by the following symbol: 

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 SUPERVEGA EVO SUCTION UNIT surgical aspirator is intended to operate in an electro-magnetic environment where RF irradiated interferences are under control. The client or operator of the SUPERVEGA EVO SUCTION UNIT device can help prevent electro-magnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and the SUPERVEGA EVO SUCTION UNIT 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)**		
	150KHz to 80MHz $d=\left[\frac{3,5}{V^1}\right]\sqrt{P}$	80MHz to 800MHz $d=\left[\frac{12}{E^1}\right]\sqrt{P}$	800MHz to 2,7GHz $d=\left[\frac{23}{E^1}\right]\sqrt{P}$
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			

SYMBOLS

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Date of manufacture
REF	Product code	LOT	Lot number
CE	Medical Device complies with Directive 93/42/EEC		Type BF applied part
	WEEE disposal		Class II applied
SN	Serial number		Temperature limit
	Battery		Atmospheric Pressure limit
	Direct current		Humidity limit
IP21	Covering Protection rate		ON / OFF

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

DISPOSAL OF WASTE BATTERIES - (Directive 2006/66/EC) This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste. By ensuring these batteries are disposed of correctly, you will help prevent potentially negative consequences for the environment and human health which could otherwise be caused by inappropriate waste handling of the battery. The recycling of the materials will help to conserve natural resources. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, your household waste disposal service or the shop where you purchased the product.

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.