PROFESSIONAL MEDICAL PRODUCTS

ASPIRATORE SUPERVEGA BATTERY - SU CARRELLO
SUPERVEGA BATTERY SUCTION ASPIRATOR - ON TROLLEY
ASPIRATEUR SUPERVEGA BATTERY - SUR CHARIOT
ABSAUGER SUPERVEGA BATTERY - AUF TROLLEY
ASPIRADOR SUPERVEGA BATTERY - SOBRE CARRO

REF **28193**

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M28193-M-Rev.1-01.21

SUPERVEGA BATTERY SUCTION UNIT is a surgical suction pump with the following electrical characteristics: 14V ⎓ 4A with AC/DC (input: 100-240V~ - 50-60Hz – 1.5A) to be used for nasal, oral and tracheal aspirations in adults or for body liquids in children (for example mucus, phlegm and blood) equipped with 5 wheels with braking device. Thanks to these characteristics and its high performance levels, this device is particularly suitable for use in hospital wards, in small surgical applications and post-operative treatments. A device designed to offer ease-of-transport and almost continuous use thanks to the adoption of an electronic system to manage the power supply. Supplied with an audible alarm and visual tell-tale (luminous LED) to indicate the battery status. Featuring a body in plastic with high thermal and electrical insulation in compliance with recently introduced European safety regulations. Supplied with no. 2 complete sterilisable polycarbonate jugs with overflow valve. Features a suction regulator and vacuum gauge located on the front panel.

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 be 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.
   - 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.
   - Prevent children from using the device without proper supervision;
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 SUPERVEGA BATTERY SUCTION UNIT 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. **WARNING:** Do not change this equipment without the permission of the manufacturer GIMA S.p.A. None of electric or mechanical parts has 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). Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.
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 lead battery integrated in the device is not to be considered as an ordinary domestic waste. Such a component must be disposed of in a specific collection centre in order to be recycled.

CONTRAINDICATIONS

- Before using the SUPERVEGA BATTERY SUCTION UNIT, 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.
- SUPERVEGA BATTERY SUCTION UNIT is not suitable for MRI. Do not introduce the device in MRI environments.

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	SUPERVEGA BATTERY SUCTION UNIT
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 (Pb Battery 12V ⎓ 4A)
Current Consumption	4.0A
Maximum Suction Pressure (without jar)	-80kPa (-0.80 Bar)
Minimum Suction Pressure (without jar)	Less -40kPa (-0.40 bar)
Maximum Suction Flow (without jar)	36 l/min
Insulation Class (when used with the AC/DC adapter)	Class II
Insulation Class (when used with an Internal battery)	Internally Powered Equipment
Weight	7.98 Kg
Size	320 x 990 (h) x 300 mm
Battery Holding Time	60 minutes
Battery Time Charge	240 minutes
Dimension of silicon aspiration tube	Ø 8x14 mm
Accuracy 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 Transport	Room Temperature: - 40°C ÷ 70°C Room Humidity Percentage: 10 ÷ 100% RH Atmospheric pressure: 500 ÷ 1060 hPa

The technical specifications may change without notice.

CLEANING OF THE 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. Before carrying out any cleaning and / or maintenance operation, disconnect the appliance from the power supply, unplugging it or turning off the switch on the device.

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 under 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

- N°2 complete aspiration jar 2000ml
- Conical fitting
- Tubes set 8 mm x 14 mm
- Hydrophobic and antibacterial filter
- AC/DC adapter
- European power supply cord for AC/DC adapter

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. If 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.
The filter is not designed to be decontaminated, disassembled and/or sterilised. If the patient's pathology is known and/or no risk of indirect contamination exists, it is advisable to replace the filter after each work shift or at any rate on a monthly basis even if the device is not used.

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 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 1000 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: 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 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

Disposing of disposable bags:

If the device is fitted with FLOVAC® disposable collection systems (consisting of a rigid, reusable polycarbonate container and a single-use polyethylene collection bag), proceed with the disposal of the bag as follows: Deactivate the suction source and remove all tubes connected to the container, paying particular attention to avoid accidental contamination. Attach the plugs to the “PATIENT” and “TANDEM” connectors by inserting them firmly, paying particular attention to avoid accidental contamination. Take the device to the waste collection area with all the openings correctly sealed, taking into consideration that the product may potentially be infected. Discard the product in compliance with the regulations in force at the hospital.

PERIODICAL MAINTENANCE CHECKS

The SUPERVEGA BATTERY SUCTION UNIT 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. Unpack the instrument and always check integrity of plastic parts and AC/DC switching adapter , feeding cable, they might have been damaged during previous use. Connect cable to electrical network and turn switch on. Close the aspirator outlet with your finger and with suction regulator in maximum vacuum position check that the vacuum indicators reaches -80kPa (-0.80 bar) minimum (internal battery). Rotate the knob from right to left and check the aspiration regulating control. The vacuum indicator should go down -40kPa (-0.40 bar). Verify that loud noises are not present, these can indicate wrong functioning.
Internally, the device is protected (see electrical specifications) by two fuses F1, F2 **(T 15A L 125V)** that cannot be reached from the outside. Therefore, contact the manufacturer to request the assistance of an authorized and qualified technician when they need to be replaced. If it's replaced make sure that its replacement is always the same type and value, as indicated.
The device is made up of a lead battery which cannot be accessed from the outside. In order to replace it, consult the technical staff authorised by the manufacturer.

USE ONLY THE RECOMMENDED BATTERIES FROM GIMA. THE USE OF OTHER BATTERIES IS NOT RECOMMENDED AND INVOLVES THE CANCELLATION OF WARRANTY

In the event that the service personnel has to replace the internal battery, pay special attention to the polarity of the same component. The + / - polarities are indicated directly on the battery.

Fault type	Cause	Solution
1. Red light on	Battery run down	Hook up the power cord to the electricity mains, positioning the equipment power switch on 0.
2. No light	Defective AC/DC adapter or technical internal problem	Contact the technical service.
3. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
4. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
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
8. No aspiration due to flow leakage of mucus	Filter blocked	Replace filter
9. The Vacuum power on the patient side is either very low or absent	• Vacuum regulator set to minimum • Protection filter blocked or damaged • Connection tubes blocked, kinked or disconnected • Shut-off valve blocked or damaged • Pump motor damaged	• Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge • Replace the filter • Replace or reconnect the tubes, check the jar connections • 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 • Contact the technical service
10. Noisy	Technical internal problem	Contact the technical service
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10	None of the remedies has achieved the desired results	Contact the seller or GIMA 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 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 SUPERVEGA BATTERY 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 SUPERVEGA BATTERY 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.

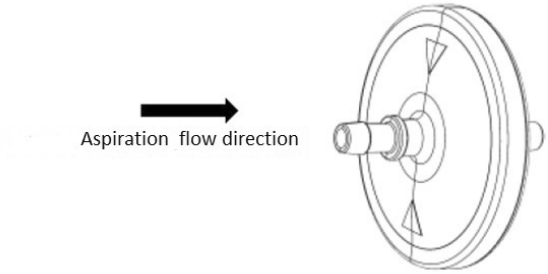
WARNING: For proper use, place the aspirator on a flat, stable surface, in order to have the full volume of use of the jar and better efficiency of the overflow device. The vacuum jar, during use, must be used in vertical mode, to prevent the action of the backflow valve. If this protection is triggered,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

Operation with AC/DC power pack:

- Connect the short silicone tube with the antibacterial filter to the suction port. The other tube, connected to the filter on one end, must be connected to the spout on the vase lid with the float assembled inside (overflow device). The overflow device is triggered (the float closes off the internal lid fitting) when the maximum volume (90% of the effective vase volume) is reached, thus preventing the liquid from penetrating the inside of the machine. The device must be used on a flat, horizontal surface.
- Connect the long silicone tube to the free spout on the lid; the free end of the tube must be connected to the conical fitting for the probe coupling, to which the suction probe must then be connected.
- Connect the universal power pack to the device using the dedicated connector and insert the power cord plug into the socket. To start the treatment, press the switch into position I to turn the device on
- Set the desired vacuum level (Bar / kPa) through the vacuum regulator. Turn the knob in a clockwise direction to increase the vacuum level: these values can be read on the "vacuum gauge".
- To suspend and/or end the treatment, press the switch again and pull the plug out of the socket
- To mitigate the formation of foam inside the vase, unscrew and remove the lid from the vase, and fill the latter with 1/3 water (to facilitate cleaning operations and speed up depressurisation during operation), then screw the lid back onto the vase.
- Remove the accessories and proceed with cleaning operations.
- 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.

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 with Internal Battery

- Press the switch in position I to turn the device on (the external power pack doesn't need to be connected)
- The fully charged battery life is about 60 minutes with continuous operation.

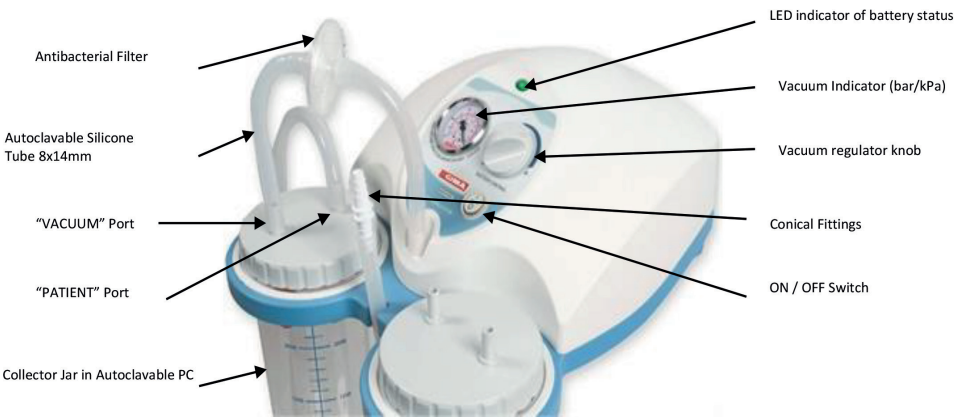
WARNING: Before using the device, check the battery power status. Before each use proceed with charging the battery. To maintain the device in good conditions, recharge the battery every 3 months (when not in use).

Recharging operations: to be able to charge the internal battery it is necessary to connect the universal switching adapter to the electric network for approx. 240 minutes with the main switch to position 0.

TAB. I – INDICATOR LIGHTS DURING OPERATIONS
When an external power supply (regardless of the state of the battery charger) and when the device is working (after having turned it on), the LED stays in a FIXED GREEN position.

LED Signal	Phase	Problem / Cause	Solution
Flashing Green Led	During rechanrge	Battery recharge running	Wait
Steady Greed Led	During rechanrge	Recharging cycle complete	Remove power supply
Steady Red Led	During battery operation	Flat battery	Start recharging cycle WARNING: During this signal, you will hear a long, continuous beep (duration of sound 0.8 sec / sound frequency: every 8.5 sec), which notifies the user regarding the battery discharge.
Flashing Red Led	Device automatically turns off when the battery is flat	Battery completely flat	When the device is restarted the LED will flash red: begin the battery recharge cycle immediately
Steady Orange Led	During battery operation	Intermediate status	Guaranteed battery function / Recharge when the red LED signal comes on.

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER



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 adhereto 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 5minutes.

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 BATTERY 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 BATTERY SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPERVEGA BATTERY 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 BATTERY 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 BATTERY 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 BATTERY SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPERVEGA BATTERY 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 BATTERY 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 BATTERY SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPERVEGA BATTERY 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 BATTERY 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	3V/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 BATTERY 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 BATTERY 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 BATTERY 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 B applied part
	WEEE disposal		Class II applied
SN	Serial number		Temperature limit
	Battery		Atmospheric Pressure limit
	Direct current		Humidity limit
~	Alternating current	Hz	Mains frequency
	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.