

**Anexa nr.32 Aspirator Urgenta, Supervega Battery/ 28190, Gima, Italia****Nr. de inregistrare AMDM: DM000149362**

<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferita, Standarde de referință</i>
<p>Aspirator urgențe Cod 130320 Descriere Aspiratoarele portabile de urgență alimentate cu baterii care sînt utilizate în situații de urgență în afecțiuni ale căilor respiratorii în spitale și în teritoriu. Aspiratoarele portabile de urgență sunt utilizate pentru a elimina secreții, sînge, vomă care obstrucționează căile respiratorii ale pacientului și păstrează căile deschise către plămîni pentru a permite ventilarea spontană sau mecanică.</p> <p>Parametru Specificația Vas colector Capacitatea <math>\geq 1,000</math> (1 L) Protecție la umplere obligatoriu Vasul să fie bine fixat de dispozitiv și montat ergonomic pentru posibilitatea manipularilor rapide asupra pacientului obligatoriu Reutilizabil obligatoriu Suport/diviziune pentru atașare a tubului de aspirare de dispozitiv obligatoriu Vacuum Rata, mm Hg 0 la <math>\geq 600</math> Timpul pînă cînd ajunge la 300 mm Hg, sec. <math>\leq 6</math> Rata de flux la vacuum maxim, l/min. <math>\geq 36</math> Reglator aspirație da Baterie internă reutilizabilă obligatoriu Timp de lucru la vacuum maxim <math>\geq 60</math> min Semnal baterie descărcată acustic, vizual Greutatea totală inclusiv accesoriile <math>&lt; 6</math> kg Tensiunea de alimentare 220 V, 50 Hz Accesorii Filtru antibacterian "15 buc., să se indice codul sau modelul produsului oferit" Vas colector Reutilizabil "1 buc., să se indice codul sau modelul produsului oferit"</p>	<p>Aspirator urgențe Cod 130320 Descriere Aspiratoarele portabile de urgență alimentate cu baterii care sînt utilizate în situații de urgență în afecțiuni ale căilor respiratorii în spitale și în teritoriu. Data sheet; Aspiratoarele portabile de urgență sunt utilizate pentru a elimina secreții, sînge, vomă care obstrucționează căile respiratorii ale pacientului și păstrează căile deschise către plămîni pentru a permite ventilarea spontană sau mecanică. Data sheet;</p> <p>Parametru Specificația Vas colector Capacitatea <math>\geq 1,000</math> (1 L)- Data sheet; Protecție la umplere obligatoriu - Data sheet; Vasul este bine fixat de dispozitiv și montat ergonomic pentru posibilitatea manipularilor rapide asupra pacientului - Data sheet, poza Reutilizabil - Data sheet; Diviziune pentru atașare a tubului de aspirare de dispozitiv, Data sheet, poza Vacuum Rata, mm Hg 0 la <math>\geq 600</math> Timpul pînă cînd ajunge la 300 mm Hg, sec. = 6 Rata de flux la vacuum maxim, l/min. <math>\geq 36</math> Data sheet Reglator aspirație da- Data sheet Baterie internă reutilizabilă Data sheet Timp de lucru la vacuum maxim - 60 min, Data sheet Semnal baterie descărcată acustic, vizual- Data sheet Greutatea totală inclusiv accesoriile -4,05 kg, Data sheet Tensiunea de alimentare 100-240 V, 50/60 Hz Data sheet Accesorii Filtru antibacterian 15 buc.-28229 Vas colector Reutilizabil 1 buc., -28226</p>



# GIMA

## "SUPER VEGA" 36 BATTERY ASPIRATOR

**Code:** 28190  
**Category:** Battery aspirators  
**Unit of sale:** 1 pc.  
**Minimum order:** 1  
**Type:** Medical device  
**Class:** II A  
**NSIS:** 1968723  
**CND:** Z120105  
**EAN13:** 8023279281903



**Description:** SUPER VEGA BATTERY - plastic case - 36 l/min.

Professional, portable suction units for body, oral, nasal or tracheal liquids aspiration in adults or children. Supplied with three different operation options: AC/DC adapter, internal lead rechargeable battery and 12 V make it a versatile unit approved for NON-STOP operation without overheating. Visual and acoustic alarm indicating low battery level. Ergonomic handle ensures a comfortable and secure grip. Bottle with safety float control valve to prevent overflow.

Made in Italy.

**Technical Specifications:** Suction power: 36 air l/min  
Max suction: -0.80 bar (600 mm/Hg)  
Operating Voltage: 100-240 V - 50/60 Hz  
Battery autonomy: approx 60 min  
Recharging time: 240 minutes  
Noise level: 65.5 dBA  
Size - Weight: 350x210x180 mm - 4.05 kg  
Norms: Class II Type BF, EN 60601-1-1, EN 60601-1-2, EN 60601-1-11, 93/42 EEC

**Standard accessories:** Bottle 1 l - autoclavable at 121°C  
AC/DC universal adapter (100-240V - 50-60Hz)  
Silicone tubing set  
Anti-bacterial filter  
Suction catheter  
Cigarette lighter adaptor (12V 4A)  
User manual (GB, IT, FR, DE, ES, GR, PL, RO, PT)



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

**ASPIRATORE SUPER VEGA BATTERY PLUS**  
**SUPER VEGA BATTERY PLUS SUCTION UNIT**  
**ASPIRATEUR SUPER VEGA BATTERY PLUS**  
**SAUGER SUPER VEGA BATTERY PLUS**  
**ASPIRADOR SUPER VEGA BATTERY PLUS**  
**ASPIRADOR SUPER VEGA BATTERY PLUS**  
**SSAK AKUMULATOROWY SUPER VEGA BATTERY PLUS**  
**ASPIRATOR SUPER VEGA BATTERY PLUS**  
**ΣΥΣΚΕΥΗ ΑΝΑΡΡΟΦΗΣΗΣ SUPER VEGA BATTERY PLUS**

**REF** 28190



**Gima S.p.A.**  
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Made in Italy



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**SUPER VEGA BATTERY PLUS SUCTION UNIT** is a suction pump particularly suited for use in hospital wards, in patients with tracheotomy, in small surgical applications and post-operative treatments at home. A device that can be used for nasal, oral and tracheal aspirations in adults or for body liquids in children (for example mucus, phlegm and blood). 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 complete with sterilizable polycarbonate jug with overflow valve. Features a suction regulator and vacuum gauge located on the front panel.



### **GENERAL WARNING**

Read instruction manual carefully before use. 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 be disassembled. For technical service always contact Gima S.p.A.

### **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 immerse the appliance into water;
  - Do not place or store the aspirator in places where it may fall or be pulled into the bathtub or washbasin. In the event it is accidentally dropped, do not attempt to remove the device from the water whilst the plug is still connected: disconnect the mains switch, remove the plug from the power supply and contact the GIMA technical service department. Do not attempt to make the device work before it has been thoroughly checked by qualified personnel and/or the GIMA technical service department.
  - 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;
  - 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 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 BATTERY PLUS SUCTION UNIT device must be installed and used away from mobile and portable RF communication devices (mobile phones, transceivers, etc.) that may interfere 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 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
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 (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.
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.
13. 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.
14. 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.
15. 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.**

## CONTRAINDICATIONS

- Before using the SUPER VEGA BATTERY PLUS 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.
- SUPER VEGA BATTERY PLUS SUCTION UNIT is not suitable for MRI. Do not introduce the device in MRI environments.

## TECHNICAL CHARACTERISTICS

Model	SUPER VEGA BATTERY PLUS 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) or with cigarette lighter adapter (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
Insulation Class (when used with a car cigarette lighter cable)	Class II
Weight	4.06Kg
Size	350 x 210 x 180 mm
Battery Holding Time	60 minutes
Battery Time Charge	240 minutes
Accuracy of Vacuum Indicator	± 5%
Working Condition	Room temperature: 5 ÷ 35°C Room humidity percentage: 10 ÷ 93% RH Atmospheric pressure: 800 ÷ 1060 hPa
Conservation condition and Transport	Room temperature: - 25 ÷ 70°C Room humidity percentage: 0 ÷ 93% 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**

- Complete aspiration jar 1000ml
- Conical fitting
- Tubes set 8 mm x 14 mm
- Hydrophobic and antibacterial filter
- AC/DC adapter
- Power supply cord for AC/DC adapter
- Cigarette lighter cable

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

**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.

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 is 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.
- Empty and dispose of the contents of the suction vessel (also comply with regional regulations);
- 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).
- Dispose of the aspiration catheter according to the provisions of local laws and regulations.

The jug and lid can be further disinfected using a common disinfectant, strictly following the instructions and dilution values provided by the manufacturer. At the end of cleaning operations, leave to air dry in a clean environment.

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

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 SUPER VEGA BATTERY PLUS 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. The device is protected by a safety fuse (**F 10A L 250V**) situated in the cigarette lighter cable. When replacing, always check the type and value as indicated.

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 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
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	<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>• Contact the technical service</li> </ul>
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 overflow security system is activated, don't proceed with the liquid aspiration. If the overflow security system doesn't work there are two cases:

1st case – If the overflow security system doesn't work the aspiration will be stopped by the bacteriological filter who avoids the liquid penetration inside the device.

2nd case – If both the security system and the bacteriological filter do not work, there is the possibility that liquid has leaked 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**

- The device must be checked before each use in order to identify any operating faults and/or damage due to transport and/or storage.
- The work surface must be flat and stable in order that the control panel can be reached and so that the vacuum gauge, vase and antibacterial filter are clearly visible.
- It is recommended not to hold the device in your hand and/or avoid prolonged contact with the body of the device.

**WARNING: For correct use, position the suction unit on a flat and stable surface**, thus maximising the available volume of the vase and improving the efficiency of the overflow device.

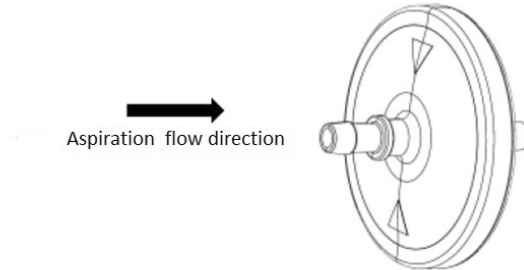
### **Operation with AC/DC power pack:**

- 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 using cigarette lighter DC 12V

- Connect the device's external plug 12V to the lighter 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 lighter cables (view the chapter "Important Safety Rules")

### 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.



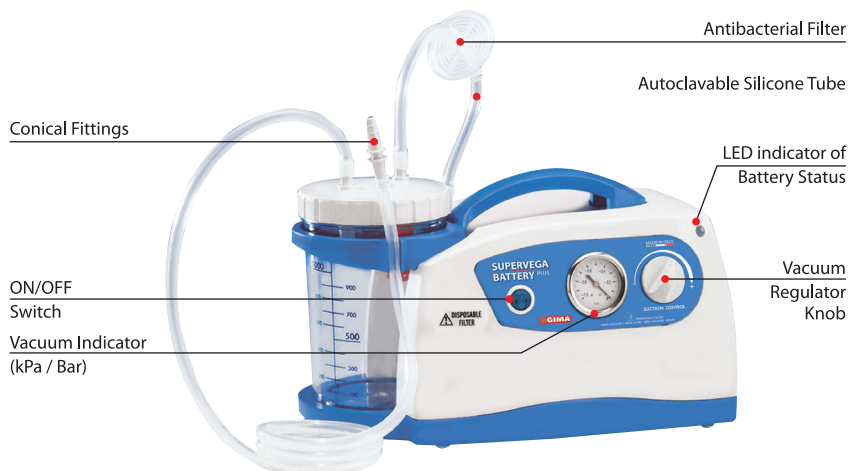
**WARNING:** Before using the device, check the battery power status. Before each use proceed with charging the battery. To maintain the device in good conditions, recharge the battery every 3 months (when not in use).

**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 is connected (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 recharge	Battery recharge running	Wait
Steady Green Led	During recharge	Recharging cycle complete	Remove power supply
Steady Red Led	During battery operation	Flat battery	Start recharging cycle <b>WARNING:</b> 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**

**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 SUPER VEGA BATTERY PLUS 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.

<b>Guidance and manufacturer's declaration – electromagnetic Emissions</b>		
The SUPER VEGA BATTERY PLUS SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPER VEGA BATTERY PLUS SUCTION UNIT should make sure that it's used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
Irradiated / Conducted emissions CISPR11	Group 1	The SUPER VEGA BATTERY PLUS 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 SUPER VEGA BATTERY PLUS 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	

<b>Guidance and manufacturer's declaration – Immunity Emissions</b>			
The SUPER VEGA BATTERY PLUS SUCTION UNIT is intended for use in the electromagnetic environment specified below. The customers or the user of the SUPER VEGA BATTERY PLUS SUCTION UNIT should make sure that it's used in such an environment.			
<b>Immunity Test</b>	<b>Level indicated by the EN 60601-1-2</b>	<b>Compliance Level</b>	<b>Electromagnetic environment - guidance</b>
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 SUPER VEGA BATTERY PLUS 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			
<p>The SUPER VEGA BATTERY PLUS SUCTION UNIT is intended for use in the electromagnetic environment specified below.                      The customers or the user of the SUPER VEGA BATTERY PLUS SUCTION UNIT should make sure that it's used in such an environment.</p>			
Immunity Test	Level indicated by the EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
<p>Conducted Immunity EN 61000-4-6</p>	<p>3Vrms 150kHz to 80MHz (for non life-supporting devices)</p>	<p>V1 = 3 V rms</p>	<p>The portable and mobile RF communication devices, including cables, must not be used closer to the SUPER VEGA BATTERY PLUS SUCTION UNIT device, than the separation distance calculated by the equation applicable to the transmitter frequency.  <b>Recommended separation distance</b></p>
<p>Radiated Immunity EN 61000-4-3</p>	<p>10V/m 80MHz to 2.7GHz (for non life-supporting devices)</p>	<p>E1 = 10 V / m</p>	$d = \left[ \frac{3,5}{V^1} \right] \sqrt{P}$ $d = \left[ \frac{12}{E^1} \right] \sqrt{P} \quad \text{from 80 MHz to 800MHz}$ $d = \left[ \frac{23}{E^1} \right] \sqrt{P} \quad \text{from 800 MHz to 2.7 GHz}$ <p>Where <math>P</math> 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>9)</sup>, could be lower than the level of conformity of each frequency interval<sup>10)</sup>.                      It is possible to check for interference in proximity to devices identified by the following symbol: </p>
<p><b>Note 1:</b> At 80 MHz and 800 MHz the interval with the highest frequency is applied  <b>Note 2:</b> 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.</p>			
<p>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 10 V/m.</p>			

**Recommended separation distance between portable and mobile radio-communication devices and the monitor**

The SUPER VEGA BATTERY PLUS 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 SUPER VEGA BATTERY PLUS 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 SUPER VEGA BATTERY PLUS 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
	Product code		Lot number
	Medical Device complies with Directive 93/42/EEC		Type BF applied part
	WEEE disposal		Class II applied
	Serial number		Temperature limit
	Battery		Atmospheric Pressure limit
	Direct current		Alternating current
	Covering Protection rate		Mains frequency
	ON / OFF		Humidity limit



**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.