Lot 20 Aspirator urgențe SuperVega Battery, cod 28190, fabricant Gima, Italia	
Parametri solicitați	*Parametri oferiți*
Aspirator urgențe Cod 130320 Descriere Aspiratoarele portabile de urgenţă alimentate cu baterii care sînt utilizate în situaţii de urgenţă în afecţiuni ale căilor respiratorii în spitale şi în teritoriu. Aspiratoarele portabile de urgenţă sunt utilizate pentru a elimina secreţii, sînge, vomă care obstrucţionează căile respiratorii ale pacientului şi păstrează căile deschise către plămîni pentru a permite ventilarea spontană sau mecanică. **Parametru Specificaţia** Vas colector Capacitatea ≥ 1,000 (1 L) Protecție la umplere da Vasul să fie bine fixat de dispozitiv și montat ergonomic pentru posibilitatea manipularilor rapide asupra pacientului da Reutilizabil da Suport/diviziune pentru atașare a tubului de aspirare de dispozitiv da Vacuum Rata, mm Hg 0 la ≥ 500 Timpul pînă cînd ajunge la 300 mm Hg, sec. ≤ 4 Rata de flux la vacuum maxim, l/min. ≥ 25 Reglator aspirație da Indicator vacuum da, eroarea ≥±10% Baterie internă reutilizabilă da Timp de lucru la vacuum maxim ≥ 60 min Semnal baterie descărcată acustic vizual Greutatea totală inclusiv accesoriile < 6 kg Tensiunea de alimentare 220 V, 50 Hz Filtru antibacterial, unică utilizare ≥ 15 buc.	Aspirator urgențe Cod 130320 Descriere Aspiratoarele portabile de urgenţă alimentate cu baterii care sînt utilizate în situaţii de urgenţă în afecţiuni ale căilor respiratorii în spitale şi în teritoriu. Aspiratoarele portabile de urgenţă sunt utilizate pentru a elimina secreţii, sînge, vomă care obstrucţionează căile respiratorii ale pacientului şi păstrează căile deschise către plămîni pentru a permite ventilarea spontană sau mecanică. **Parametru Specificaţia** Vas colector Capacitatea - 1,000 (1 L) Protecție la umplere da Vasul este bine fixat de dispozitiv și montat ergonomic pentru posibilitatea manipularilor rapide asupra pacientului da Reutilizabil da Suport/diviziune pentru atașare a tubului de aspirare de dispozitiv da Vacuum Rata, mm Hg 0 la -600 Timpul pînă cînd ajunge la 300 mm Hg, sec. ≤ 4 Rata de flux la vacuum maxim, l/min. ≥ 25 Reglator aspirație da Indicator vacuum da, eroarea ≥±10% Baterie internă reutilizabilă da Timp de lucru la vacuum maxim ≥ 60 min, da Semnal baterie descărcată acustic si vizual Greutatea totală inclusiv accesoriile -4.9 kg Tensiunea de alimentare 220 V, 50 Hz Filtru antibacterial, unică utilizare - 15 buc.

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Reason: MoldSign Signature
Location: Moldova

Lot 22 Aspirator chirurgical (performanță medie) CLINIC PLUS SUCTION/28198, fabricant Gima S.p.A., Italia	
Parametri solicitați	*Parametri oferiți*
Aspirator chirurgical (performanță medie) Cod 130340 Descriere Aspiratoarele chirurgicale sunt capabile să creeze o presiune de vid > 600 mmHg. Cele mai multe proceduri chirurgicale necesită aspirare pentru a elimina sângele şi lichidele care se acumulează în zona operatorie şi obstrucționează vizibilitatea chirurgului. Parametru Specificația Vacuum Limita maximă ≥ 650 mmHg Rata de flux, l/min. ≥ 50 l/min Indicator vacuum da, eroarea ≥ ±10% Reglator aspirație da Nivelul de zgomot, dBA ≤ 60 dBA Vas colector "În timpul aspirării se utilizează doar un vas colector" da Selector mecanic de vas da Numărul 2 buc. Capacitatea, L ≥ 4 L Protecție la umplere pentru fiecare vas da Vas tip reutilizabil da Suport mobil "Container pentru amplasarea tubului de aspirare sau alt mecaniz de fixare a tubului de aspirarea" da Suport cu rotile ≥ 4 roti Roti cu frina da, ≥ 2 buc. Mîner pentru transportare da Accesorii Pedală de pornire/oprire a aspirației da Filtru de unică utilizare 15 buc. Tensiunea de alimentare 220 V, 50 Hz	Aspirator chirurgical (performanță medie) Cod 130340 Descriere Aspiratoarele chirurgicale sunt capabile să creeze o presiune de vid > 600 mmHg. Cele mai multe proceduri chirurgicale necesită aspirare pentru a elimina sângele şi lichidele care se acumulează în zona operatorie şi obstrucționează vizibilitatea chirurgului. Parametru Specificația Vacuum Limita maximă 0,90 bar - 675 mmHg Rata de flux, l/min. 60 l/min Indicator vacuum da, eroarea ≥ ±10% Reglator aspirație da Nivelul de zgomot, dBA 51,7 dBA Vas colector "În timpul aspirării se utilizează doar un vas colector" da Selector mecanic de vas da Numărul 2 buc. Capacitatea, L - 4 L Protecție la umplere pentru fiecare vas da Vas tip reutilizabil da Mecanic de fixare a tubului de aspirarea" da Suport cu rotile 4 roti Roti cu frâna da, 2 buc. Mâner pentru transportare da Accesorii Pedală de pornire/oprire a aspirației da Filtru de unică utilizare 15 buc. Tensiunea de alimentare 230 V, 50/60 Hz

Lot 23 Aspirator chirurgical (performanță avanată) CLINIC PLUS SUCTION, 28198, fabricant Gima, Italia	
Parametri solicitați	*Parametri oferiți*
Aspirator chirurgical (performanță avansată) Cod 130350 Descriere Aspiratoarele chirurgicale sunt capabile să creeze o presiune de vid > 600 mmHg. Cele mai multe proceduri chirurgicale necesită aspirare pentru a elimina sîngele şi lichidele care se acumulează în zona operatorie şi obstrucţionează vizibilitatea chirurgului. Parametru Specificația Vacuum Limita maximă ≥ 670 mmHg Rata de flux, l/min. ≥ 60 l/min Indicator vacuum da, eroarea ≥±10% Reglator aspirație da Nivelul de zgomot, dBA ≤ 50 dBA Vas colector "În timpul aspirării se utilizează doar un vas colector" da Selector mecanic de vas da Numărul vaselor 2 buc. Capacitatea, L ≥ 4 L Protecție la umplere pentru fiecare vas da Vas tip reutilizabil da Suport "Container pentru amplasarea tubului de aspirare sau alt mecaniz de fixare a tubului de aspirarea" da Suport cu rotile ≥ 4 roti Roti cu frina da, ≥ 2 buc. Mîner pentru transportare da Accesorii Pedală de pornire/oprire a aspirației da "Suport/diviziune pentru fixarea/păstrarea cablului de alimentare 220 V, 50 Hz" da Filtru de unică utilizare 15 buc. Tensiunea de alimentare 220 V, 50 Hz	Aspirator chirurgical (performanță avansată) Cod 130350 Descriere Aspiratoarele chirurgicale sunt capabile să creeze o presiune de vid > 600 mmHg. Cele mai multe proceduri chirurgicale necesită aspirare pentru a elimina sîngele şi lichidele care se acumulează în zona operatorie şi obstrucţionează vizibilitatea chirurgului. Parametru Specificația Vacuum Limita maximă 0,90 bar - 675 mmHg Rata de flux, l/min. 60 l/min Indicator vacuum da, eroarea ≥ ±10% Reglator aspirație da Nivelul de zgomot, dBA 51,7 dBA Vas colector "În timpul aspirării se utilizează doar un vas colector" da Selector mecanic de vas da Numărul 2 buc. Capacitatea, L - 4 L Protecție la umplere pentru fiecare vas da Vas tip reutilizabil da Suport / mecaniz de fixare a tubului de aspirarea" da Suport cu rotile 4 roti Roti cu frâna da, 2 buc. Mâner pentru transportare da Accesorii Pedală de pornire/oprire a aspirației da Filtru de unică utilizare 15 buc. Tensiunea de alimentare 230 V, 50/60 Hz

Lot 47 Pulsoximetru de buzunar OXY-4 cod 35091 fabricant Gima, Italia	
Parametri solicitați	*Parametri oferiți*
Pulsoximetru de buzunar Cod 260440 Descrierea Pulsoximetru de buzunar pentru medic, dispozitiv cu alimentare pe baza baterii, care măsoară pulsul, Indicele de perfuzie (PI) si saturația de oxigen (SpO2) Parametru Specificație Interval de măsurare SPO2 70-100% Pulsul 30-250 bpm Acuratețe SPO2 ±2% intre 70-100% Pulsul ±3% intre 30-250 bpm Rezoluția SPO2 ±1% Pulsul ±1 bpm Afișaj SPO2 da Indicele de perfuzie (PI) da Valoare pulsului da Indicator baterie descărcată da Display LED sau LCD Alarme Auditiv da Vizual da Alimentare Baterie tip AAA Alkaline "Stingerea automată în caz de neutilizare" da "Durata de funcționare în continuu" ≥ 10 ore Set de baterii inclus 1 set	Pulsoximetru de buzunar Cod 260440 Descrierea Pulsoximetru de buzunar pentru medic, dispozitiv cu alimentare pe baza baterii, care măsoară pulsul, Indicele de perfuzie (PI) si saturația de oxigen (SpO2) Parametru Specificație Interval de măsurare SPO2 35 - 100% Pulsul 30 - 240 bpm Acuratețe SPO2 ≤3% intre 70-100% Pulsul ±2% intre 30-240 bpm Rezoluția SPO2 ±1% Pulsul ±2 bpm Afișaj SPO2 da Indicele de perfuzie (PI) da Valoare pulsului da Indicator baterie descărcată da Display OLED Alarme: Auditiv da Vizual da Alimentare Baterie tip AAA Alkaline "Stingerea automată în caz de neutilizare" da (în 8 sec) "Durata de funcționare în continuu" ≥ 30 ore Set de baterii inclus 1 set

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**

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CE 0476

M28190-M-Rev.4-09.20

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 immerge 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 interference with the said device.
7. **Instrument and accessory discharging must be done according to current regulations in the country of use**.
8. **WARNING:** Do not change this equipment without the permission of the manufacturer GIMA S.p.A. None of electric or mechanical parts 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 facultiesas 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 ligther 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. 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 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 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 is activated, don't proceede with the liquid aspiration. If the overfill security system doesn't work there are two cases:

1st case – If the overfill 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 filtrer 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.

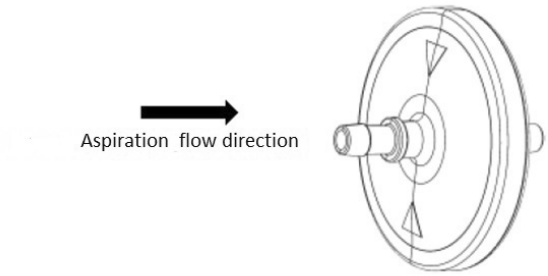
Operation with AC/DC power pack:

- 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 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")

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 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

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.

Guidance and manufacturer's declaration – electromagnetic Emissions		
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.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
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	

Guidance and manufacturer's declaration – Immunity Emissions			
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.			
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 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

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.

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 SUPER VEGA BATTERY PLUS 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 10 V/m.

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
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	~	Alternating current
IP21	Covering Protection rate	Hz	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.

"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.

With incorporated rechargeable batteries. It can operate at 12 V power supply at rechargeable batteries and, thanks to an electronic system, at 230 V while recharging batteries.

Autonomy: approx 60 min
Recharging time: 120-150 minutes.
Max suction: -0.80 bar
Suction power: 36 air litres/min
It has unbreakable 1,000 ml standard bottle autoclavable at 120°C with safety float control valve to prevent overflow.

Technical Specifications:

- **Operating Voltage: 100-240 V - 50/60 Hz**
- **Size: 350 x 210 x 180 mm**
- **Weight: 4.9 kg**
- **Max suction -0.80 bar**
- **Suction power: 36 air litres/min**
- **Norms: IEC 601-1 - Class II Type B**
- **Made in Italy**

Standard accessories:

- **Bottle 1 litre - autoclavable at 120° C**
- **Silicone tubing set**
- **Suction catheter**
- **Anti-bacteria filter**
- **Cable to recharge batteries from power supply**
- **Cable to recharge batteries from car**
- **Multi-language user manual (GB, IT, FR, DE, ES)**

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www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DICHIARAZIONE DI CONFORMITÀ

DECLARATION OF CONFORMITY

La Società GIMA S.P.A., con sede a GESSATE (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/*Ref. #***
PULSOXIMETRO OXY-4 - blu / *OXY-4 FINGER OXIMETER - blue*	35091

appartenente alla classe di rischio IIa in accordo alla regola 10 dell'Allegato IX, della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class IIa, according to rule 10 of the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità, che soddisfa i requisiti di cui all'Allegato V del sopra citato decreto legislativo, come risulta dal Certificato n. MED 26036 rilasciato in data 25/10/06 dal KIWA CERMET ITALIA S.p.A., Via Cadriano 23, 40057 Cadriano di Granarolo (BO), Organismo Notificato 0476;
  are manufactured according to the Quality System which satisfies requirements of the Annex V of the above mentioned directive, as stated in the Certificate No. MED 26036 issued on 25/10/06 by KIWA CERMET ITALIA S.p.A., Via Cadriano 23, 40057 Cadriano di Granarolo (BO), Notified Body 0476;
- sono conformi alla direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011, sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.
  comply with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of certain hazardous substances in electrical and electronic equipment.

Gessate, 17/12/2019

GIMA S.p.A.
Il legale Rappresentante
(Nicola Manzoni)

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	22
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2020-04-24

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

Sede Operativa / *Operational Headquarter:*
Via Marconi, 1
20060 Gessate, MI - Italia

Sede Legale / *Registered Headquarter*
Via Tommaso Grossi, 2
20121 Milano, MI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*
Dispositivi per aerosolterapia / *Aerosol therapy devices*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Kiwa Cermet Italia S.p.A.
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Rif. rapporto di audit/ *Ref. audit report:* del/dated 08-14/11/2019

Chief Operating Officer
Giampiero Belcredi
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Data:27/04/2020 08:18:48

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1104

Marca / *Brandname:*
VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici e vasi di ricambio / Surgical aspirators and jars

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Modello / Model:

Kit pap test / Pap smear kit

Modello / Model:

Spatula cervicale monouso sterile in plastica o legno / Disposable sterile plastic or wooden cervical spatula

Modello / Model:

Speculum vaginale monouso sterile perno centrale - mix / Disposable sterile vaginal speculum central pin – mix

Modello / Model:

Speculum vaginale monouso sterile perno centrale - piccolo, medio, grande / Disposable sterile vaginal speculum central pin - small, medium, large

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2020-04-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Speculum vaginale monouso sterile tache - mix / Disposable sterile vaginal speculum tache - mix

Modello / Model:

Speculum vaginale monouso sterile vite centrale - mix / Disposable sterile vaginal speculum middle screw - mix

Modello / Model:

Speculum vaginale monouso sterile vite laterale - mix / Disposable sterile vaginal speculum side screw - mix

Modello / Model:

Speculum vaginale monouso sterile vite laterale (piccolo, medio, grande) / Disposable sterile vaginal speculum side screw - small, medium, large

Modello / Model:

Tampone di trasport in plastica sterile / Sterile plastic transport swab

Marca / *Brandname:*
Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Proctoscopio adulti / Adult proctoscope

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CERTIFICATE

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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per aerosolterapia / *Aerosol therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Modello / Model:

Aerosol a pistone adulti e bambini / Adult and Kids compressor nebulizers

Marca / *Brandname:*
EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Marca / *Brandname:*
MISTRAL

Modello / Model:

Aerosol professionale a pistone per uso domiciliare / Professional compressor nebulizers for home healthcare environment

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104

Marca / *Brandname:*
BOSTON / BOSTON OLPRESS / BOSTON LOBIVON / BOSTON COMBISARTAN / BOSTON VALPRESSION / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TOKIO ZANTIPRESS / DAYTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

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Organismo Notificato n. 0476
Notified Body nr. 0476

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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Marca / *Brandname:*
SIRIO

Modello / Model:
Manometro Aneroide / Aneroid manometer

Marca / *Brandname:*
YTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Modello / Model:
Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital SphygmomanometersWRIST / ARM

Modello / Model:
Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Marca / *Brandname:*
DA POLSO/WRIST - DA BRACCIO/ARM / 24 H ABPM

Modello / Model:
Sfigmomanometri Digitali Automatici / Digital Automatic Sphygmomanometers

Marca / *Brandname:*
YTON / DOMINO

Modello / Model:
Sfigmomanometri Digitali / Digital Sphygmomanometers

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di Kiwa Italia Holding S.r.l.
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Chief Operating Officer
Giampiero Belcredi

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Data:27/04/2020 08:20:55

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Marca / *Brandname:*
DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Marca / *Brandname:*
FARMAMED / LINEA F / CARREFOUR / GS /PBpharma / 36.2 T&B / SUCCHIOTTO °C / BASALE / GIMA

Modello / Model:

Termometri clinici digitali classici e flessibili / Digital clinical thermometers classic and flexible

Marca / *Brandname:*
FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Marca / *Brandname:*
PBpharma /GIMA

Modello / Model:

Termometri clinici digitali auricolari e frontali multifunzione / Digital clinical ear and ahaed multifunction thermometers

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CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	22
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2020-04-24

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 1301, MD 0104

Modello / Model:

Altimetro - Plicometro - Metro per neonati / Height meter - Skinfold caliper - Baby measuring meter

Codice NANDO / *NANDO codes:*
MD 1301, MD 0104, MDS 7010

Modello / Model:

Bilancia pesapersona / Scales - ASTRA - FAMILY - PEGASO

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0101

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Modello / Model:

Maschera per rianimazione CPR / CPR resuscitator mask

Modello / Model:

Maschere in silicone autoclavabili / Maschere autoclavabili in silicone GIMA PLUS / Silicone autoclavable face masks / Silicone autoclavable face masks GIMA PLUS

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit

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CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2020-04-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Modello / Model:

Reservoir monouso (sacche ossigeno) e valvola / Oxygen reservoir and valve

Modello / Model:

Valvola PEEP e adattatore / Valvola antireflusso e posteriore / Peep valve and adapter / Non-rebreathing valve and intake valve

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack

Tipologia / *Medical Devices:*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit per sutura standard / Kit per rimozione sutura / kit procedurale sutura / kit standard per parto / Standard suture pack / Suture removal pack / Suture procedure pack / Standard delivery pack

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Organismo Notificato n. 0476
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Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2020-04-24

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Forbici per bende di Lister / Forbici chirurgiche standard / Lister bandage scissors / Standard surgical scissors

Modello / Model:

Pinza di Magill / Pinza di Hartmann per orecchio / Magill forceps / Hartmann ear forceps

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Forbici di Mayo / Forbici di Metzenbaum / Forbici Iris / Forbice ombelicale / Forbice per chirurgia orecchio di Bellucci / Pinze per medicazione standard / Pinze di Hunter-Splinter / Pinze emostatiche di Adson / Pinze emostatiche Halstead-Mosquito / Pinza per dissezione McIndoe / Pinze di Pean / Pinza di Spencer-Wells / Pinza portatamponi di Foerster / Portaghi di Hegar- Mayo / Portaghi di Crile-Wood / Mayo scissors / Metzenbaum scissors / Iris scissors / Umbilical scissors / Bellucci ear scissors / Standard dressing forceps / Hunter-Splinter forceps/ Adson haemostatic forceps/ Halstead-Mosquito dissection forceps / McIndoe dissection forceps/ Pean forceps / Spencer-Wells forceps/ Foerster polypus forceps/ Hegar-Mayo needle holder / Crile-Wood needle holder

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

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CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		
Previous expiry date			

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

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GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A

CERTIFICATE

Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer
Giampiero Belcredi

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SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C

PROFESSIONAL MEDICAL PRODUCTS

ASPIRATORE CHIRURGICO CLINIC PLUS
CLINIC PLUS SUCTION ASPIRATOR
ASPIRATEUR CLINIC PLUS
CHIRURGISCHER ABSAUGER CLINIC PLUS
ASPIRADOR QUIRÚRGICO CLINIC PLUS
ASPIRATOR CHIRURGICZNY CLINIC PLUS
ASPIRATORUL CHIRURGICAL CLINIC PLUS
ΧΕΙΡΟΥΡΓΙΚΟΣ ΑΝΑΡΡΟΦΗΤΗΡΑΣ CLINIC PLUS

REF **28194 - 28196 - 28198**

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www.gimaitaly.com
Made in Italy

0476

M28194-M-Rev.1-11.20

CLINIC PLUS SUCTION ASPIRATOR is a surgical aspirator power-fed at 230V ~ / 50Hz, to be used for suctioning body liquids (such as mucus, phlegm and blood) provided with 4 antistatic wheels, two of which with braking device, and a pulling handle. This equipment is designed for easy transport and continuous utilization. Thanks to these characteristics and to its functions, this device is particularly suitable for utilization in hospital wards and operation theatres both for suctioning body liquids and for gynaecological and dermatological (liposuction) applications. It's provided with a plastic body, with thermal and electrical isolation in compliance with European safety standards, two complete suction tanks in polycarbonate suitable for sterilization, and a float valve, besides being fitted with a suction regulator and a vacuum gauge on the front panel. Versions fitted with footswitch control and flux deviator are available on request. The electronic management system fitted on the front panel allows to perform suction by means of the footswitch control as well as to suction liquids in both tanks provided without having to switch the equipment off to reconnect the second tank.

GENERAL WARNING

Read instruction manual carefully before use
Only Higly qualified staff use reserved
The instrument must not be disassembled. For a technical service always contact GIMA
Keep off the reach of children or not capable people without supervision
Full containers must be handled with great care during transfer to the disposal areas, following the local procedures and regulations

IMPORTANT SAFETY RULES

1. Check the condition of the unit before each use. The surface of the unit should carefully inspected for visual damage. Check the mains cable and do not connect to power if damage is apparent;
2. Before connecting the appliance always check that the electric data indicated on the data label and the type of plug used, correspond to those of the mains electricity to witch it's to be connected;
3. Respect the safety regulations indicated for electrical appliances and particularly:
   - Use original components and accessories provided by the manufacturer to guarantee the highest efficiency and safety of the device.
   - The device can be used only with the bacteriological filter.
   - Never immerge the appliance into water.
   - Position the device on stable and flat surfaces in a way that the air inlets on the back aren't obstructed.
   - To avoid incidents, do not place the aspirator on unstable surfaces, which may cause it to accidentally fall and lead to a malfunction and/or breakage. Should there be signs of damage to the plastic parts, which may expose inner parts of the energised device, **do not connect the plug to the electrical socket**. Do not attempt to make the device work before it has been thoroughly checked by qualified personnel and/or the 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.
4. For repairs, exclusively contact technical service and request the use of original spare parts. Failure to comply with the above can jeopardise the safety of the device.
5. **Use only for the purpose intended.** Don't use for anything other than the use defined by the manufacturer. The manufacturer will not be responsible for damage due to improper use or connection to an electrical system not complying with current regulation.
6. Instrument and accessory discharging must be done according to current regulations in the country of use.
7. **WARNING:** Do not change this equipment without the permission of the manufacturer Gima S.p.A. None of electric or mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the electric / mechanical parts. Always contact technical assistance.

8. Using the device in environmental conditions different than those indicated in this manual may harm seriously the safety and the technical characteristics of the same;
9. The medical device is in contact with the patient by means of a disposable probe (not supplied with the device). If this device must be used with a specific suction probe, the end user is responsible for making sure it complies with the ISO 10993-1 rule;
10. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1;
11. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.
12. The medical device requires special precautions regarding electromagnetic compatibility and must be installed and used in accordance with the information provided with the accompanying documents: the CLINIC PLUS SUCTION ASPIRATOR device must be installed and used away from mobile and portable RF communication devices (mobile phones, transceivers, etc.) that may interference with the said device.


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 CLINIC PLUS SUCTION ASPIRATOR, 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.
- CLINIC PLUS SUCTION ASPIRATOR is not suitable for MRI. Do not introduce the device in MRI environments.

TECHNICAL CHARACTERISTICS

TYPOLOGY (MDD 93/42/EEC)	Class IIa Medical Decice
MODEL	**CLINIC PLUS SUCTION ASPIRATOR**
UNI EN ISO 10079-1	HIGH VACUUM / HIGH FLOW
POWER FEEDING	230V ~ / 50Hz
POWER CONSUMPTION	230 VA
FUSE	F 1 x 4A L 250V
MAXIMUM SUCTION PRESSURE (without jar)	-90kPa / -0.90 Bar / -675mmHg
MAXIMUM SUCTION FLOW (without jar)	60 l/min
WEIGHT	13 Kg
SIZE	460 x 850 (h) x 420 mm
DUTY CYCLE	Non – Stop Operated
SICILICONE TUBE SIZE	Ø 8x14 mm
ACCURANCY OF VACUUM INDICATOR	± 5%
WORKING CONDITION	Room temperature: 5 ÷ 35°C Room humidity percentage: 30 ÷ 75% RH Atmospheric pressure: 800 ÷ 1060 hPa Altitude: 0 ÷ 2000m s.l.m.
CONSERVATION CONDITION AND TRASPORT	Room temperature: - 40°C ÷ 70°C Room humidity percentage: 10 ÷ 100% RH Atmospheric pressure: 500 ÷ 1060 hPa

CLEANING THE MAIN UNIT

To clean the device external parts always use a cotton cloth dampened with detergent. Don't use abrasive or solvent detergents.

ATTENTION: During cleaning make sure that liquids do not come into contact with the membrane keyboard (only in versions with footswitch and flux deviator) and adjacent areas as this would damage the component, with possible infiltration of the liquid inside the device..

The symbol  positioned in the casing near the membrane keyboard requires the reading of the user instructions before each use.

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

During all clearing operations use protection gloves and apron (if need be, also wear a face mask and glasses) to avoid getting in contact with contaminating substances (after each utilization cycle of the machine).

ACCESSORIES SUPPLIED

- N°2 COMPLETE ASPIRATION JAR
- CONICAL FITTING
- SILICON SET TUBES 8 mm x 14 mm
- ANTIBACTERIAL AND HYDROFOBIC FILTER
- SAFETY TRAP
- FOOTSWITCH CONTROL (for versions equipped with footswitch)
- EUROPEAN POWER SUPPLY CORD (H05VV-F - 2x0.75mm² - 2mt)

REPLACING THE ANTIBACTERIAL FILTER: The filter is made of hydrophobic material that stops the passage of liquids into the same filter. If you suspect the filter may have been contaminated and/or got wet or discoloured, always remove and replace the filter. If the equipment is to be used on patients with unknown pathological conditions or should you evaluate the possibility of indirect contamination, remove and replace the filter after each utilization. The filter is not designed for decontamination, disassembly and/or sterilization. If you suspect the filter may have been contaminated and/or got wet or discoloured, always remove and replace the filter. If the equipment is to be used on patients whose pathologies are known and not implying any indirect contamination risks, we recommend to remove and replace the filter at the end of each work shift or else every month, even if the equipment has not been used. 4000ml or 5000ml complete jar versions are available on request. Versions fitted with FLOVAC® 2000ml or 3000ml disposable collection systems (including a re-usable rigid polycarbonate container and a disposable Liner) are also available on request.
SAFETY TRAP with 220 ml capacity to collect the liquid that could leak from the overflow valve of the vessel. This ensures additional protection of the filter and pump. The trap is completely removable and autoclavable. Not available in versions equipped with FLOVAC disposable collection system.

WARNING: Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO10993-1 standards on material biocompatibility.

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.

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

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

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

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

CLEANING ACCESSORIES AND INTERNAL PARTS

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

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

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

- Place the overflow valve into its seat in the cover (under VACUUM connector)
- Insert floating valve keeping the o-ring towards the opening of the cage
- Place the o-ring into its seat around the cover
- After completing assembling operations always make sue that cover seals perfectly to avoid vacuum leackages or liquid exit

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 and assemble the container for the aspirated liquids. The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 121°C (1 bar relative pressure – 15 min). The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C (1 bar relative pressure – 15 min).

DO NOT WASH, STERILIZE OR PUT IN AUTOCLAVE THE ANTIBACTERIAL FILTER

Instruction for disposal Liner Flovac®:
If the device is equipped with disposable collection systems FLOVAC ® carry out the disposal of the bag as follows: Turn off the Vacuum and remove all the tubes connected to the Liner, giving particular attention to avoid accidental contamination. Fit the appropriate plugs to the “PATIENT” and “TANDEM” ports, pressing the home firmly, taking care to avoid accidental contamination. Remove the liner bag from the rigid container and transfer it to the waste disposal area, ensuring that all the openings are sealed, keeping in mind the product is potentially infectious. This product must be disposed of in accordance with the current hospital regulations.

MAINTENANCE

The CLINIC PLUS SUCTION ASPIRATOR suction equipment does not need maintenance or lubrication. It is, however, necessary to inspect the unit before each use. With regard to training, given the information contained in the user manual and since it is easy to understand the said device, it doesn't appear to be necessary. The device must be checked before each use in order to detect malfunctions and / or damage caused by transport and / or storage. Always check the integrity of the footswitch power cord. Connect cable to electrical network and turn switch on. Close the aspiration outlet with your finger and with suction regulator in maximum vacuum position check that the vacuum indicators reaches -90 kPa (-0.90 bar) maximum. Rotate the knob from right to left and check the aspiration regulating control. The vacuum indicator should go down -40 kPa (-0.40 bar). Verify that loud noises are not present, these can indicate wrong functioning. A protection fuses (F 1 x 4A L 250V) reachable from exterior and situated in the plug protects the instrument. For fuses replacing, always the type and the range. Before changing the fuse, disconnect the plug from the power supply socket. Internally, the device (only for devices fitted with a circuit board) is protected by a fuse (F 500mA L 250V)

Fault type	**Cause**	**Solution**
1. The suction unit doesn't work	Cable is damaged External power source failure	Replace the cable Check the external power source
2. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
3. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
4. The Vacuum power onthe patient side is either very low or absent	a) Vacuum regulator set to minimum b) Protection filter blocked or damaged c) Connection tubes blocked, kinked or disconnected d) Shut-off valve blocked or damaged e) Pump motor damaged	a) Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge b) Replace the filter c) Replace or reconnect the tubes, check the jar connections d) Empty the jar, or disconnect the tube from the jar andunblock the shut-off valve. The unit twill only work in theupright position e) Refer to authorised service personnel
5. The float doesn't close	If the cap has been washed, ensure that the float is not partially detached	Insert the float into it's place
6. The float doesn't close	The float it's covered by dirty material	Unscrewed the cap, leave the and put in on autoclave
7. Low suction	Foam inside the jar	Fill the jar to 1/3 full of ordinary water
8. No aspiration due to flow leakage of material and fluid	Filter blocked	Replace filter
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8	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. THE MANUTACTURER DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

INSTRUCTIONS

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

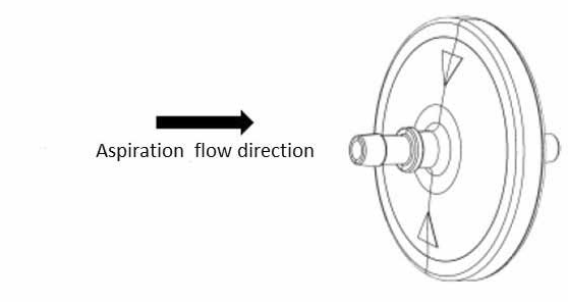
WARNING: For proper use, place the aspirator on a flat, stable surface in order to have the full volume of use of the jar and better efficiency of the overflow device. The vacuum jar, during use, must be used in vertical mode, to prevent the action of the backflow valve. If this protection is triggered,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

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

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

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

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

- Connect the long silicon tube with the lid union still free and marked as "PATIENT".
- Connect the conical junction for probe insertion with the free end of the long silicon tube.
- Insert the plug of the equipment feeding cable into a power socket.
- Press the ON/OFF button to start the medical equipment.
- To deal with foam formation within the tank, unscrew the tank lid and fill 1/3 of the tank with water (to make cleaning easier and speed up depression while operating the equipment), place the lid on the jar.
- While using the equipment, the suction tank should always be used vertically to avoid the intervention of the antireflux valve. In case of intervention of this protection, switch the device off and disconnect the tube connected with the suction tank (the one marked as "VACUUM") on the same lid.
- You can then detach all accessories and perform cleaning operations as described under "Cleaning accessories and internal parts" below.

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

MULTIPURPOSE BAR- MPR SYSTEM

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

USING THE FOOTSWITCH CONTROL:

Connect the footswitch control feeding cable with the plug marked as

After the device has been connected,all Leds are still off. When the ON/OFF button is pressed, all Leds are activated at once for 1 second (autotest). At the end of the autotest cycle, the ON/OFF button led will flash. Press the button marked as (---) to perform suction using the footswitch control and execute intermittence work cycles. Press the button marked as (-) to perform remote suction using the footswitch control (continuous suction). To stop suction just push on the footswitch control with strength.

USING THE FOOTSWITCH CONTROL AND THE FLOW DEVIATOR:

If using equipment fitted with a flow deviator, users may direct suctioned liquids in any of the two collection tanks provided. Flow deviator comes with two complete suction kits (2 sets of tubes, 2 antibacterial and hydrophobic filters and two conical junctions). After the device has been connected, all Leds are still off. When the ON/OFF button is pressed, all Leds are activated at once for 1 second (autotest). At the end of the autotest cycle, the ON/OFF button led will flash. To decide which side to perform the suction from, press OUT LEFT or OUT RIGHT and the selected button led will show a blue light.

Press the ON/OFF button again to start the suction cycle. If the device is set up for using the flow deviator, ensure the antibacterial filter has been positioned on both sides. Connect the footswitch control feeding cable with the plug marked as

Press the button marked as (---) to perform suction using the footswitch control and execute intermittence work cycles. Press the button marked as (-) to perform remote suction using the footswitch control (continuous suction). To stop suction just push on the footswitch control with strength. Press the ON/OFF button to stop the medical equipment. Before removing the feeding plug, ensure autotest has been performed on the panel.

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 adhere to the walls of the rigid container and the cover bends towards the inside of the glass, the system is not leaking.
- Start the aspiration and periodically check the filling level of the container. The overflow valve will cause the interruption of aspiration if the aspirated fluids have reached the maximum filling level of the device.
- When the float valve intervenes signalling the device is too full, the suction source must be disconnected within no more than 5 minutes.

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

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

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

Guidance and manufacturer's declaration – Immunity Emissions			
The CLINIC PLUS SUCTION ASPIRATOR is intended for use in the electromagnetic environment specified below. The customers or the user of the CLINIC PLUS SUCTION ASPIRATOR should assure that it's used in such an envitonment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environments - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	+/-8kV contact +/-15kV in air	The device doesn't change its state	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4	+/-2kV power supply lines +/-1kV for input / output lines	The device doesn't change its state	Mains power quality should be that of a typical commercial or hospital enviro ment.
Surge EN 61000-4-5	± 0,5kV ± 1,0kV differential mode	The device doesn't change its state	Mains power quality should be that of a typical commercial or hospital environ-ment.
Volgate dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% U_T (>95% dip U_T) for 0,5 cycle 40 % U_T (60% dip U_T) for 5 cycle 70 % U_T (30% dip UT) for 25 cycle <5 % U_T (>95% dip U_T) for 5 sec	- -	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CLINIC PLUS SUCTION ASPIRATOR requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field (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 assure that it's sufficiently low.
Note UT is the value of the power supply voltage.			

Guidance and manufacturer's declaration – Immunity Emissions

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

Immunity Test	**Level indicated by the EN 60601-1-2**	**Livello di conformità**	**Electromagnetic environments - guidance**
Conducted Immunity EN 61000-4-6	da 3Vrms 150kHz a 80MHz (for non life-supporting devices)	V1 = 3 V rms	Portable and mobile RF communication equipment, including cables, should be used no closer to any part of the device, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{12}{E_1}\right]\sqrt{P}$ from 80MHz to 800MHz $d=\left[\frac{23}{E_1}\right]\sqrt{P}$ from 800MHz to 2,7GHz Where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site study of the site, should be less that the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated Immunity EN 61000-4-3	da 3V/m 80MHz a 2.7GHz (for non life-supporting devices)	E1 = 10 V / m	

Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied.
Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by reflection from buildings, objects and people.

a) The field intensity for fixed transmitters such as the base stations for radiotelephones (mobile and cordless) and terrestrial mobile radio, amateur radio devices, radio AM and FM transmitters and TV transmitters can not be theoretically and accurately foreseen. To establish an electro-magnetic environment generated by fixed RF transmitters, an electromagnetic study of the site should be considered. If the field intensity measured in the place where the device will be used surpasses the above mentioned applicable level of conformity, the normal functioning of the device should be monitored. If abnormal performance arises, additional measures such as changing the device's direction or positioning may be necessary.
b) The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 3 V/m.

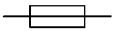
Recommended separation distance between portable and mobile radio-communication devices and the monitor

The surgical aspirator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CLINIC PLUS SUCTION ASPIRATOR device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the CLINIC PLUS SUCTION ASPIRATOR device, as recommended below, according to the maximum output power of the communications equipment.

Maximum nominal output power of the Transmitter W	**Separation distance from the frequency transmitter (m)**		
	150KHz a 80MHz $d=\left[\frac{3,5}{V^1}\right]\sqrt{P}$	80MHz a 800MHz $d=\left[\frac{12}{E^1}\right]\sqrt{P}$	800MHz a 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.

SYMBOLOGIE

	Class II applied		Medical Device compliant with Directive 93/42/CEE
	General warnings and/or specifications		Type B applied part
	Keep away from sunlight		Keep in a cool, dry place
	Atmospheric pressure limit		Humidity limit
	Temperature limit		WEEE disposal
	Manufacturer		Date of manufacture
~	Alternating current	Hz	Mains Frequency
	On / Off		Fuse
(—)	Using the footswitch control (for continuous suction)	(---)	Using the footswitch control (for intermittence suction)

REF	Product code	LOT	Lot number
SN	Serial number		Follow instructions for use

IPX1 (on the footswitch control label)	Covering Protection rate

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

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.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

PROFESSIONAL MEDICAL PRODUCTS

PULSOXIMETRO OXY-4
OXY-4 PULSE OXIMETER
OXYMÈTRE OXY-4
PULOXIMETER OXY-4
OXÍMETRO OXY-4
OXÍMETRO DE PULSO OXY-4
ΚΟΡΕΣΤΟΜΕΤΡΟ OXY-4
OKSYMETR OXY-4

MANUALE D'USO E MANUTENZIONE
USE AND MAINTENANCE BOOK
INSTRUCTIONS DE FONCIONNEMENT ET ENTRETIEN
BETRIEBS UND WARTUNGS ANWEISUNGEN
MANUAL DE USO Y MANTENIMIENTO
MANUAL DE USO E MANUTENÇÃO
ΕΓΧΕΙΡΙΔΙΟ ΧΡΗΣΗΣ ΚΑΙ ΣΥΝΤΗΡΗΣΗΣ
PODRĘCZNIK EKSPLOATACJI I KONSERWACJI

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ACHTUNG: *Diese Anleitung muss vor dem Einsatz des Produkts aufmerksam gelesen und vollständig verstanden werden.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*
ATENÇÃO: *Os operadores devem ler e entender completamente este manual antes de usar o produto.*
ΠΡΟΣΟΧΗ: *Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.*
UWAGA: *Użytkownik powinien uważnie zapoznać się z tym podręcznikiem przed jego użyciem.*

REF **35091 - 35092 - 35093**

Gima S.p.A
Via Marconi, 1
20060 Gessate (MI) - Italy
Made in China

CE 0476

M35091-M-Rev.3-07.19

Instructions to User

Read these instructions carefully before using this equipment. These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

- The contents contained in this manual are subject to change without notice.
- The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours- If any abnormal condition is found, please change the position of Pulse Oximeter.
- For the individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, can not stare at the light.- The Pulse Oximeter is not a treatment device.
- Testee can not use enamel or other makeup on the finge.
- Testee's fingernail can not be too long- Please peruse the relative content about the clinical restrictions and caution.

1. SAFETY

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affectpatient's safety and monitoring performance with regard to sensors and clips. It is recommended that the device should be inspected minimally before each use. When there is obvious damage, stop using the oximeter.
- Necessary maintenance must be performed by qualifid service technicians ONLY. Users are not permitted to maintain it by themselves.

- The oximeter cannot be used together with the devices and accessories not specified in Use's Manual.
- Special attention should be paid while the Pulse Oximeter is used constantly when the ambient temperature over 37°C, burning hurt may occur because of over-heating of the sensor at this situation.

1.2 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.

– The device should be kept out of the reach of children.
- If the oximeter gets wet, please stop using it and do not resume operation until it is dry and checked for correct operation. When it is carried from cold environment to warm and humid environment, please do not use it immediately. Allow at least 15 minutes for Pulse Oximeter to reach ambient temperature.
- DO NOT press the keys on front panel with sharp materials or sharp points.
- High temperature or high pressure steam disinfection to the oximeter is not permitted. Refer to User's Manual for instructions of cleaning and disinfection.
- The finger should be put in properly and correctly.
- Do not shake the finger. Keep at ease during measurement.
- Do not put wet finger directly into sensor.
- Do not let anything block the emitting light from the device.
- Ensure that there is artery vessel within measuring site where the light transmits through.
- Vigorous exercise and the interference from the electrosurgical device may affect the measuring accuracy.
- If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

2. OVERVIEW

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemo-

globin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$SpO_2 = HbO_2/ (HbO_2 + Hb) \times 100\%$

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2.1 Features

- Large true color OLED display of SpO_2 , PR Pulse Bar, PI & Plethysmogram.
- Innovative 4 directions display.
- Automatic power on/off.
- Audible & visible over-limit indication.
- Shift parameter display between PR and PI.
  2AAA alkaline batteries with low power consumption.
- Low battery voltage indication.

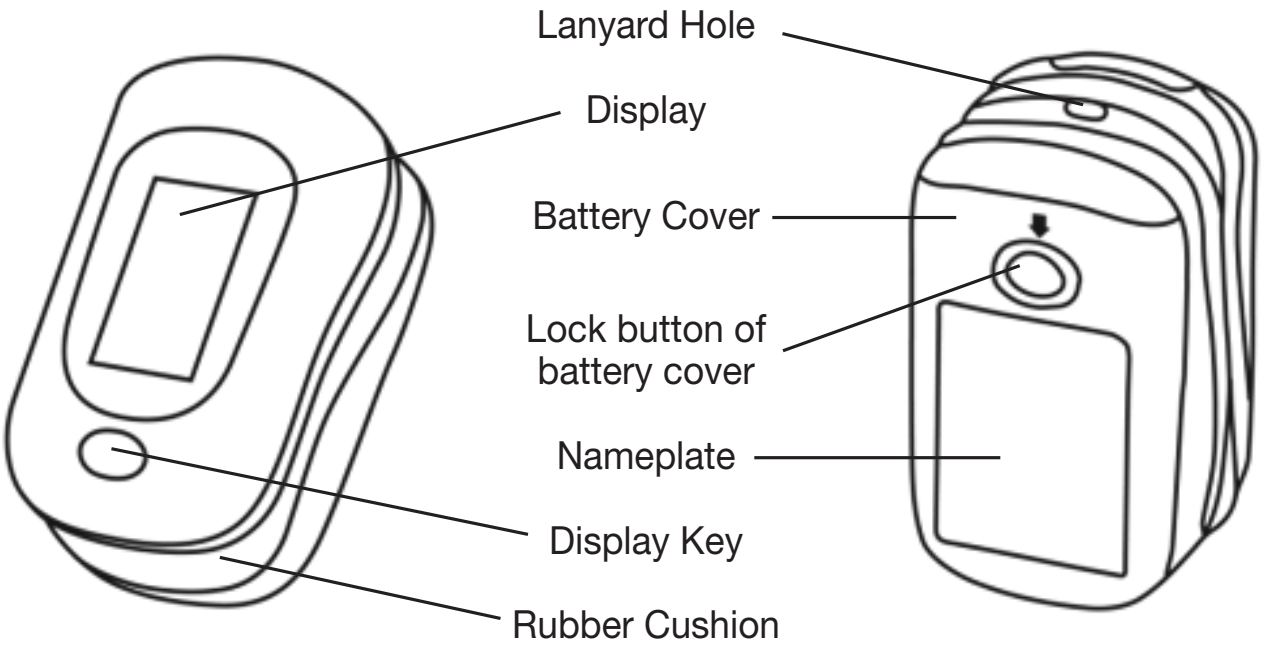


Figure 1

2.2 Major Applications and Scope

The Fingertip Oximeter is compact, convenient to use and carry and with low power consumption. You just need to put the fingertip into the sensor of the device, the SpO_2 value will appear on the screen immediately.

The Fingertip Oximeter can detect SpO_2 and pulse rate through patient's finger.

This device is applicable to home, hospital (including internal medicine, surgery, anesthesia, pediatrics, emergency room etc.), oxygen bar, the community medical center, alpine area and it also can be used before or after sports, and the like.

This device is not appropriate to be used for continuous monitoring.

2.3 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this Pulse Oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 monitoring used in treatment has become more popular. (For example, such as monitoring patients with serious respiratory disease, patients under anesthesia during operation and premature and neonatal infants) The status of SpO_2 can be determined in timely manner

by measurement and will allow finding the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

Factors affecting SpO_2 measuring accuracy (interference reason)
- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- Vascular dyes or external used color-up product such as nail enamel or color skin care.
- Excessive patient movement.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Exposure to the chamber with High pressure oxygen.
- There is an arterial occlusion proximal to the sensor.
- Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing.

Factors causing low SpO_2 Measuring value (pathology reason)
- Hypoxemia disease, functional lack of HbO_2.
- Pigmentation or abnormal oxyhemoglobin level.
- Abnormal oxyhemoglobin variation.
- Methemoglobin disease.
- Sulfhemoglobinemia or arterial occlusion exists near sensor.
- Obvious venous pulsations.
- Peripheral arterial pulsation becomes weak.
- Peripheral blood supply is not enough.

2.4 Caution
A. The finger should be placed properly (see the figure 3 of this manual), or else it may cause inaccurate measurement.
B. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
C. The SpO_2 sensor should not be used at a location or limb tied with

arterial canal or blood pressure cuff or receiving intravenous injection.

D. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO_2.
E. Make sure the optical path is free from any optical obstacles like rubberized fabric.
F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

3. BATTERY INSTALLATION

1. Press the lock button of the battery cover, meanwhile, pull the cover back and take it out.
2. Refer to Figure 2, insert two AAA size batteries into the battery compartment properly.
3. Replace the cover. Please make sure that the batteries are correctly installed since the incorrect installation may cause the device inoperable.

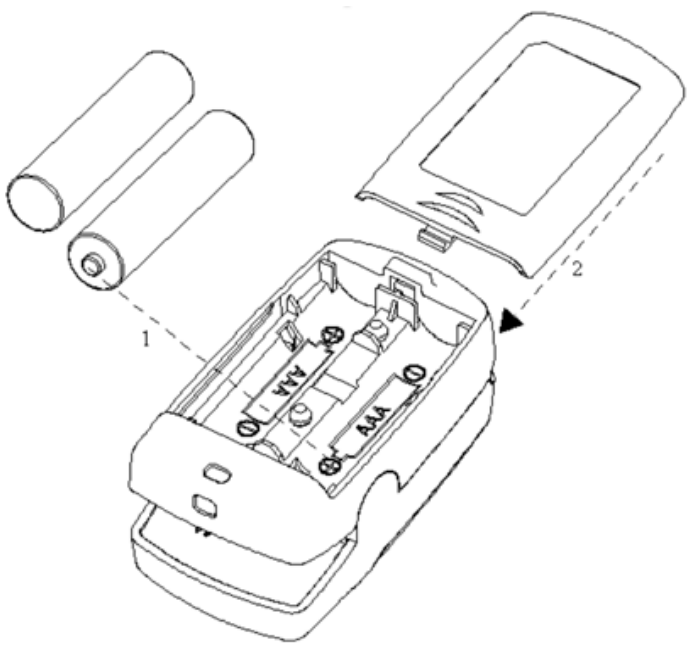


Figure 2
Battery Installation

4. OPERATION

4.1 Start Measurement

1. Open the clip as shown in Figure 3.
2. Put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.
3. The device will power on automatically in 2 seconds, and start to display software version number.
4. Next enter into data display screen (as shown in Figure 4). The user can read the values and view the waveform from display screen.

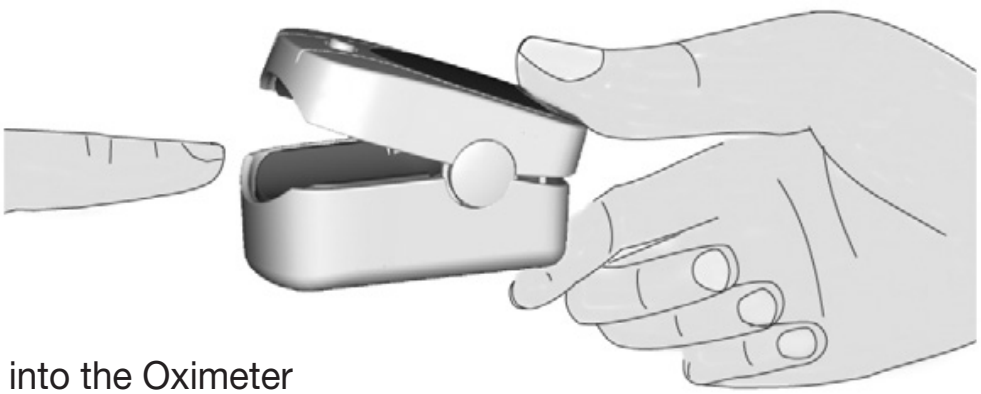


Figure 3 Put finger into the Oximeter

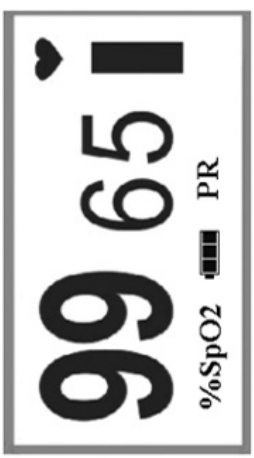


Figure 4 A1

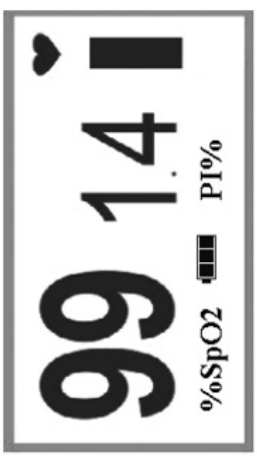


Figure 4 A2

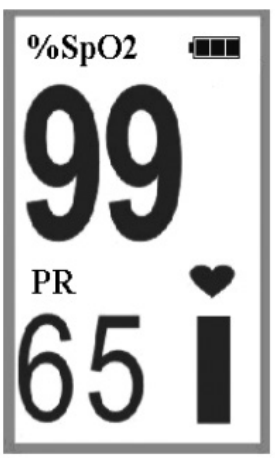


Figure 4 B1

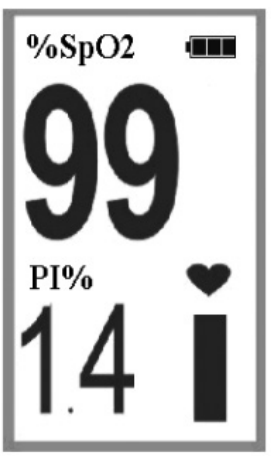


Figure 4 B2

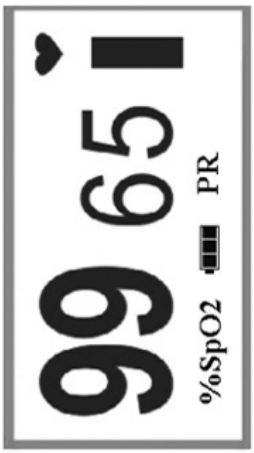


Figure 4 C1

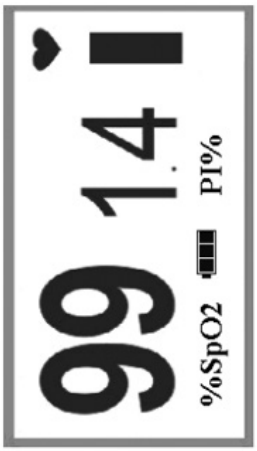


Figure 4 C2

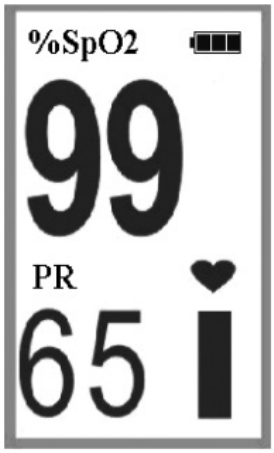


Figure 4 D1

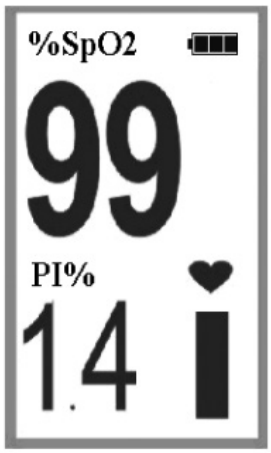


Figure 4 D2

Screen Description:

"**%SpO$_2$**": The title of SpO$_2$; "**99**": SpO$_2$ value, unit:%;

"**PR**": The title of Pulse Rate; "65": Pulse Rate value, unit: bpm (beat per minute);

"♥": Pulse beat icon;

"▌": Pulse bar-graph;

"**PI%**": The title of Perfusion Index; "1.4": Perfusion Index value, unit: %;;

" ▮▮▮ ": Battery power indicator.

5. Change display direction
   Four directions display alternately. Short time press "Display Key" to flip the screen 90° each time in a cyclical manner as shown in Figure 4. When the screen displays towards the left side, the plethysmogram will be viewed.
6. Shift parameter display between PR and PI during measurement Long time press the "Display Key", shift the parameter display between PR and PI. But when the PR is shifted to PI display and no button operation is performed after 20 seconds, the PI will change to PR display automatically.

4.2 Over-limit indication and Beep Silence

When measuring, if SpO_2 value or pulse rate value exceeds the limit, the device will beep automatically and the value which exceeds its limit will flash on the screen (Refer to chapter 4 for the detailed information). When the beep sound is activated by over-limit, it will become silent or d-active at the following situations:

1. The SpO_2 and PR value return to normal range.
2. Press Display Key to mute. If this over-limit event persists, the Pulse Oximeter will resume beeping automatically later in 2 minutes.
3. Remove the finger from the Pulse Oximeter or SpO_2 probe.

5. TECHNICAL SPECIFICATIONS

A. SpO_2 measurement:

dual-wavelength LED sensor with wavelength:
Red light: 663 nm, Infrared light: 890 nm.
Maximal average optical output power: ≤1.5mW
Measuring range: 35%~100%
Measuring accuracy:
≤ 3% for SpO_2 range from 70% to 100%
SpO_2 low over-limit: 90%

B. Pulse Rate measurement:

Measuring range: 30bpm~240bpm
Measuring accuracy: ±2bpm or ±2% (whichever is greater)
Pulse Rate over-limit: high over-limit: 120bpm; low over-limit: 50bpm

C. Perfusion Index (PI) Display

Range: 0.2%~20%

D. Audible & visual over-limit indication

When measuring, if SpO_2 value or pulse rate value exceeds the limit, the device will beep automatically and the value which exceeds its limit will flash on the screen. The Oximeter will shut down automatically in 8 seconds with no signal.

E. Display: Color OLED Display

F. Power supply requirement:

2 x LR03 (AAA) alkaline batteries
Working voltage: 2.2V~3.3VDC
Operating current: ≤40mA

G. Environment requirement

Operating Temperature: 5 ~40°C
Operating Humidity: 30~80%
Atmospheric pressure: 70~106kPa

H. The performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meets the specification described above when the pulse modulation amplitude is as low as 0.6%.

I. Resistance to ambient light interference:

The accuracy of SpO_2 and PR measurement still meets the specification described above when the device is tested by SpO_2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50Hz/60Hz fluorescent light.

J. Dimensions: 60 mm (L) × 33 mm (W) × 30 mm (H)
Net Weight: 35g (including battery)

K. Classification:

The type of protection against electric shock: Internally powered equipment.
The degree of protection against electric shock: Type BF applied parts.
The degree of protection against harmful ingress of liquids: Ordinary equipment without protection against ingress of water.
Electro-Magnetic Compatibility: Group I, Class B.

6. ACCESSORIES

A. A lanyard
B. Two batteries
C. A carrying pouch
D. A User Manual

Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

7. REPAIR AND MAINTENANCE

The expected service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the use of maintenance.

A. Please change the batteries when the low-voltage indicator lightens.
B. Please clean the surface of the device before using. Wipe the device with 75% alcohol wipes, and then let it dry in air or wipe it dry. Do not allow liquid to enter the device.
C. Please take out the batteries if the oximeter will not be used for for any more than 7 days.
D. The recommended storage environment of the device is -20ºC to 60ºC ambient temperature and 10% to 95% relative humidity with atmospheric pressure: 50kPa~107.4kPa.
E. The Pulse Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. However, if it is necessary to verify its precision routinely, the user can do the verification by means of SpO_2 simulator, or it can be done by the local third party testing house.

7.1 Cleaning and Disinfecting Instruction

Surface-clean sensor with a soft cloth damped with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a mild bleach solution.

Then surface-clean by soft cloth damped ONLY with clean water and let air dry or wipe it dry.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the Pulse Oximeter if it is damaged visually

High-pressure sterilization cannot be used on the device.
Do not immerse the device in liquid.
It is recommended that the device should be kept in a dry environment

8. TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate display instable	1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving.	1. Place the finger correctly inside and try again. 2. Let the patient keep calm.
Cannot turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3 . The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
No display	1. The device will power off automatically when it gets no signal for 8 s. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Declaration of Conformity:
The manufacturer hereby declares that this device complies with the following standards:
IEC 60601-1
IEC60601-1-2
IEC60601-1-11, ISO 80601-2-61 and follows the provisions of the council directive MDD93/42/EEC.

9. KEY OF SYMBOLS

Symbol	Description	Symbol	Description
	Type BF applied part		WEEE disposal
	Caution: read instructions (warnings) carefully		Keep away from sunlight
	Follow instructions for use		Keep in a cool, dry place
%SpO_2	Oxygen saturation (percentage)	CE	Medical Device complies with Directive 93/42/EEC
PR	Pulse rate (beats per minute)	REF	Product code
	Pulse beat icon	LOT	Lot number
	Low battery voltage		Manufacturer
SN	Serial number		Date of manufacture

***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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1: Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The user of this device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments. It uses internal power supply and has no connection with power supply network.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Table 2: Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of this device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level1	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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 IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	N/A

Surge IEC 61000-4-5	±1 kV line (s) to line(s) ±2 kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	N/A	N/A
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Table 3: Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of this device should assure that it is used in such an environment.

NOTA 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTA 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.
b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment**
Conducted RF IEC 61000-4-6	3 Vrms da 150 kHz 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter..
Radiated RF IEC 61000-4-3	3 V/m da 80 MHz 2,5 GHz	3 V/m	**Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0.01	N/A	0,12	0,23
0.1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.