Anexa 16 Negatoscop, Cod 210700

Specificatia tehnica solicitata	Specificatia tehnica ofertata, Model 27366 (Gima, Italia)
Negatoscop, Cod 210700 Descriere Dispozitiv destinat pentru vizualizarea filmelor radiografice sau tomografice Parametru Specificație Nr. de cadre ≥2 Nr. de lampe ≥2 Reglare luminozitate da Fixarea filmelor da Fixare masă/perete Ecran anti-glare da Alimentare 220V, 50Hz	Negatoscop, Cod 210700 Descriere Dispozitiv destinat pentru vizualizarea filmelor radiografice sau tomografice Parametru Specificație Nr. de cadre -2 Nr. de lampe -2 Reglare luminozitate da Fixarea filmelor da Fixare masă/perete- da Ecran anti-glare da Alimentare 220V, 50Hz

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Date: 2021.07.12 11:28:44 EEST
Reason: MoldSign Signature
Location: Moldova

BIEFFE ITALIA s.r.l. weiko®
Sede legale: Viale Lincoln, 178 - 81100 Caserta (Italy)
Stabilimento: Consorzio Siné
Zona ASI Aversa Nord 81032 Carinaro (CE)
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C.C.I.A.A. 147379
Trib. S. Maria C.V. 16412
P. IVA 02220390617

Bank:
CARIPARMA c/c 000056503302
ABI 06230 CAB 14910 CIN E
IBAN IT75 E 06230 14 910 000056503302
BIC Swift CRP PIT 2P

DECLARATION OF CONFORMITY

CE

BIEFFE ITALIA s.r.l.

Annex VII Directive 93/42/CEE and further modifications and integrations

Declares under its responsibility that the products:

Standard VIEWER

codes

BFAL 43.43 OR; BFL 43.70 OR/VE/OV; BFAL 43.90 OR/VE/OV;
BFAL 43.120 OR/VE/OV; BFAL 43.150 OR/VE/OV;
BFAL 86.120 OR; BFAL 86.150 OR

Luminous OPTOTYPE

Codes

BFAL 27.67 AL; BFAL 27.67 BL; BFAL 27.67 CL; BFAL
27.67 DL; BFAL 27.67 EL; BFAL 27.67FBL

Non luminous OPTOTYPE

Codes

BFAL 27.67 A; BFAL 27.67 B; BFAL 27.67 C; BFAL 27.67 D;
BFAL 27.67 E; BFAL 27.67 F

are in conformity with:

- the essential requirements of the EEC Directive 93/42/CEE and further modifications and integrations as Class I medical device

Carinaro, June 2018

BIEFFE ITALIA s.r.l
Dr. Flavio Ferrazzano
CEO

Rev.02

DICHIARAZIONE DI CONFORMITA'

CE

BIEFFE ITALIA s.r.l.

Allegato VII della Direttiva 93/42 /CEE e ulteriori modifiche e integrazioni

Dichiara, sotto la propria responsabilità, che i prodotti:

NEGATIVOSCOPIO standard

Codici

BFAL 43.43 OR; BFL 43.70 OR/VE/OV; BFAL 43.90 OR/VE/OV;
BFAL 43.120 OR/VE/OV; BFAL 43.150 OR/VE/OV;
BFAL 86.120 OR; BFAL 86.150 OR

OTTOTIPO luminoso

Codici

BFAL 27.67 AL; BFAL 27.67 BL; BFAL 27.67 CL; BFAL 27.67 DL;
BFAL 27.67 EL; BFAL 27.67FBL

OTTOTIPO non luminoso

Codici

BFAL 27.67 A; BFAL 27.67 B; BFAL 27.67 C; BFAL 27.67 D;
BFAL 27.67 E; BFAL 27.67 F

sono conformi:

ai requisiti previsti dalla **Direttiva 93/42/CEE** e successive modifiche ed integrazioni relativi ai dispositivi medici in qualità di Dispositivo Medico Classe I

Carinaro, Giugno 2018

BIEFFE ITALIA s.r.l
Dr. Flavio Ferrazzano
Amministratore Unico

Rev.02

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Coordinate Bancarie:
CARIPARMA c/c 000056503302
ABI 06230 CAB 14910 CIN E
IBAN IT75 E 062 30 14 910 000056503302
BIC Swift CRP PIT 2P

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.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
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E-mail: info@kiwacermet.it
www.kiwa.it

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

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

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
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SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C

LIGHT BOX 38x 92 cm - double

Code:	**27366**
Category:	**Standard light boxes**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**102557**
CND:	**Z110702**
EAN13:	**8023279273663**

Description:

GIMA light boxes are designed according to clinical standards for an extra white light for an accurate and precise reading of any detail.

• External dimensions
- Lenght: 97 cm
- Height: 43 cm
- Depth: 12 cm
• Weight: 11 kg
• 2 panels

Incorporates a 3 mm acrylic screen compliant with safety norms (fuses, Schuko plug, green light On/Off, ...).

Can be used on the table placed horizontally, vertically, depending on model or wall mounted.

Body made of oven-fired epoxy powder coated aluminium and injected ABS (colour RAL 7035).

Technical Specifications:

Color temperature: cold white 6,500 ° K
Power supply: 230 V - 50 Hz (60 Hz available with surcharge)
Protection fuse: 2x1A
Bipolar switch
Plug: Schuko with 2 meters cable
UL, DVE, IMQ approved components
Made in Italy

Lot 5 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 "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

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**

Gima S.p.A.
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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.

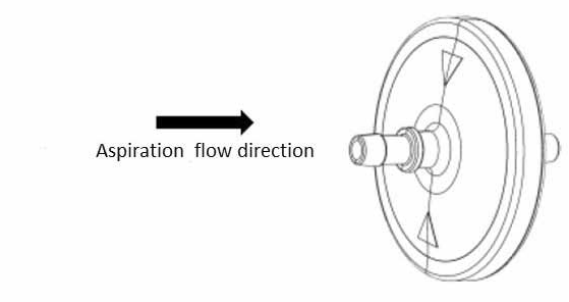
WARNING: For proper use, place the aspirator on a flat, stable surface in order to have the full volume of use of the jar and better efficiency of the overflow device. The vacuum jar, during use, must be used in vertical mode, to prevent the action of the backflow valve. If this protection is triggered, 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.

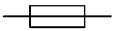
Recommended separation distance between portable and mobile radio-communication devices and the monitor

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.