PROFESSIONAL MEDICAL PRODUCTS

ASPIRATORE CHIRURGICO TOBI CLINIC
TOBI CLINIC SUCTION ASPIRATOR
ASPIRATEUR TOBI CLINIC
CHIRURGISCHER ABSAUGER TOBI CLINIC
ASPIRADOR QUIRÚRGICO TOBI CLINIC

REF **28214 - 28215 - 28216 - 28231**

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TOBI CLINIC 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. Available under request with differents versions for applications and use (version with remote control, version with 4 litre jars, version with flow direction regulator).

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

IMPORTANT SAFETY RULES:

1. Check the condition of the unit before each use. The surface of the unit should carefully 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. None of elec-

tric 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 TOBI CLINIC device must be installed and used away from mobile

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 Directive and its normatives.

CONTRAINDICATIONS:

- Before using the TOBI CLINIC, 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.
- TOBI CLINIC 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	**TOBI CLINIC**
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	600 x 460 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.

PARTICULAR CARE SHOULD BE TAKEN TO ENSURE THAT THE INTERNAL PARTS OF THE EQUIPMENT DO NOT GET IN TOUCH WITH LIQUIDS.
NEVER CLEAN THE EQUIPMENT WITH WATER.

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

ACCESSORIES SUPPLIED

- N°2 COMPLETE ASPIRATION JAR 2000ml
- CONICAL FITTING
- TUBES SET 8 mm x 14 mm
- ANTIBACTERIAL AND HYDROFOBIC FILTER
- FOOTSWITCH CONTROL (for versions equipped with footswitch control)
- EUROPEAN POWER SUPPLY CORD

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 complete tank versions are available on request.

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.

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

After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thouroughly. Then soak in warm water (temperature shall not exceed 60°C). Wash thouroughly and if necessary use a non-abrasive brush to remove incrustations. Rinse in running warm water and dry all parts with a soft cloth (non-abrasive).
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

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. Turn the butterfly connector to OFF. 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 TOBI CLINIC 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 1.6 A 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 **(T 50mA L 250V)** that cannot be reached from the outside, so please contact a technician authorised by the manufacturer for its replacement.

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 on the 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 and unblock the shut-off valve. The unit twill only work in the upright 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
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 Srl 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.

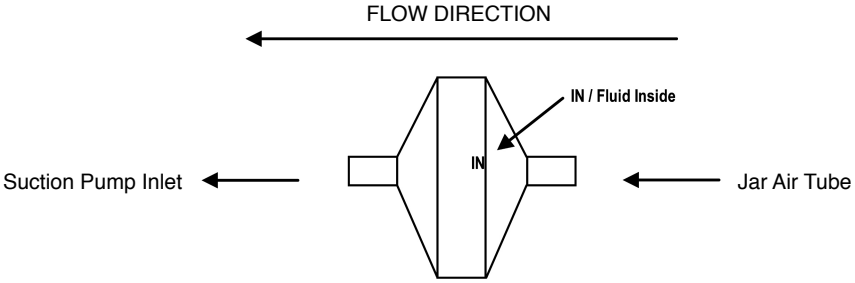
INSTRUCTIONS

- 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 the liquid from spilling, removing the jar from the device is recommended.

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

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.

WARNING: Ensure that the IN marker on the filter is on the side facing the collection jar lid and fitted into the “VACUUM”.
A wrong connection causes immediate destruction in case of contact with sucked liquids.



- Connect the short silicon tube 1, with antibacterial filter 2, to the suction connector 3. The other tube, with one end connected to the filter must be connected with the other end to the jar's connector 4 where has been fixed the red float (security float).
- When the 90% of the volume of the jar is reached there is the activation of the security float (the float close the aspiration connector on the jar) to avoid liquid penetration inside the device. The device must be used on a plan of horizontal operation.
- Connect the long silicon tube 5 to the other jar's lid connector 6
- Connect the other end of the long silicon tube 5 to the probe plastic connector 7
- Connect the power cord to the device than connect the plug to the electrical mains supply.
- Unscrew the jar's lid and fill the jar 1/3 full or ordinary water (this for an easy cleaning operations and an rapid reaching of the functionality vacuum) then rescrew the lid on the jar correctly.
- Push switch 8 on position I to start suction
- Once finished push switch on O position and unplug
- To extract the accessories and start with cleaning it.

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.

Footswitch control device:

The equipment, on request, is provided with a footswich control device. It allows the continuous use of the surgical aspirator. In this case, the plug of the footswitch device shall be inserted into the appropriate socket outlet placed on the back side of the equipment.

Near the ON/OFF Switch, there is a commutator that operates the device directly using the mains or by using the footswitch control.
When the switch is turned on (green light) and the commutator is in position I, the device works directly using the mains.
When the switch is turned on (green light) and the commutator is in position II, the device works via remote control (footswitch control).
When the switch is turned on (green light) and the commutator is in position 0, the device is powered but not in operation.

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.

Warning: The accidental inversion of connections may cause contamination for the operator and/ or for the vacuum generation equipment.

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.
The TOBI CLINIC 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 surgical aspirator TOBI CLINIC is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator TOBI CLINIC should assure that it's used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The surgical aspirator TOBI CLINIC 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 surgical aspirator TOBI CLINIC 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 surgical aspirator TOBI CLINIC is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator TOBI CLINIC should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environments - 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, conceret 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	± 0.5kV ± 1kV differential 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 UT) 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 surgical aspirator TOBI CLINIC request that the appliance operates continuosly, the use of a continuity unit is recommended.
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 surgical aspirator TOBI CLINIC is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator TOBI CLINIC 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	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 TOBI CLINIC device, than the separation distance calculated by the equation applicable to the transmitter frequency. **Recommended separation distance** $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated Immunity EN 61000-4-3	3V/m 80MHz to 2.7GHz (for non life-supporting devices)	E1 = 3 V / m	$d=\left[\frac{12}{E_1}\right]\sqrt{P}$ from 80MHz to 800MHz $d=\left[\frac{23}{E_1}\right]\sqrt{P}$ from 800MHz to 2,5GHz 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: 

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

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

b) The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 3 V/m.

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

The surgical aspirator is intended to operate in an electro-magnetic environment where RF irradiated interferences are under control. The client or operator of the TOBI CLINIC device can help prevent electro-magnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and the TOBI CLINIC device, as recommended below, in relation to the radio-communication maximum output power.

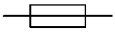
Maximum nominal output power of the Transmitter W	**Separation distance from the frequency transmitter (m)**		
	150KHz a 80MHz $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80MHz a 800MHz $d=\left[\frac{12}{E_1}\right]\sqrt{P}$	800MHz a 2,5GHz $d=\left[\frac{23}{E_1}\right]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters with a maximum nominal output power not shown above, the recommended separation distance in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the maximum nominal output power of the transmitter in Watt (W) depending on the transmitter's manufacturer.

Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied.

Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by the reflection from buildings, objects and people.

SYMBOLS

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

0/I/II	Remote Control	Hz	Mains frequency
IPX1	Covering Protection rate		Humidity limit

The technical specifications may change without notice

Disposal: *The product must not be disposed of along with other domestic waste. The users must dis- pose 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.