PROFESSIONAL MEDICAL PRODUCTS

# *ASPIRATORE CHIRURGICO TOBI MANUALE*
# *TOBI MANUALE SUCTION ASPIRATOR*
# *ASPIRATEUR TOBI MANUEL*
# *CHIRURGISCHER ABSAUGER “TOBI MANUALE”*
# *ASPIRADOR QUIRÚRGICO “TOBI MANUALE”*
# *APARELHO DE SUCÇÃO CIRÚRGICO “TOBI MANUALE”*

**REF** **28220**

CE 0476

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**TOBI MANUALE SUCTION ASPIRATOR** it's a manual device to be used for the emergency field to be used for the aspiration of the body liquids (mucus or catarrh or blood). Easily movable and designed for a manual use. Thanks to this characteristics and to the rating that it has product is particularly suitable for a emergency use, on the thacheotomized patients, minor surgical applications and post - operative therapy at home. Made of highly heat resistant, in conformity with the latest European safety standard, the product is supplied with a polycarbonate 0.4 litre autoclavable jar with overflow valve.

### *GENERAL WARNING*

Read instruction manual carefully before use.
Only highly qualified staff use reserved the instrument must not disassembled.
For technical service always contact Gima S.p.A.

## *IMPORTANT SAFETY RULES*

1. Check the condition of the unit before each use.
2. 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;
   - Place instrument on stable and flat surfaces;
   - Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;
   - Keep off the reach of children or not capable people without supervision;
   - Preserve and use the medical device in environments protected from atmospheric factors and at distance from heat sources;
   - Don't use the device thoracic drainage.
3. 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.
4. **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.
5. Instrument and accessory discharging must be done according to current regulations in the country of use.
6. None of mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the mechanical parts. Always contact technical assistance.
7. 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.

The manufactured cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse. Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance with the technical requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives.

## *TECHNICAL CHARACTERISTICS*

| | |
|---|---|
| Model | TOBI MANUALE SUCTION ASPIRATOR |
| TIPOLOGY (MDD 93/42/EEC) | Medical Device Class IIa |
| Classification UNI EN ISO 10079-2 | MEDIUM VACUUM / 22l/min |
| Maximum suction aspiration (without jar) | -40kPa (- 0.40 bar) |
| Weight | 1.150 Kg |
| Dimension | 225 x 165 (h) x 85 mm |
| Working condition | Room temperature: 5 ÷ 35°C<br>Room humidity percentage: 30 ÷ 75% RH<br>Altitude: 0 ÷ 2000m s.l.m |
| Conservation condition | Room temperature: - 40 ÷ 70°C<br>Room humidity percentage: 10 ÷ 100% RH |

The technical specifications may change without notice
Shelf life: maximum 5 years from the date of manufacture

## ACCESSORIES SUPPLIES

- Complete aspiration jar 4000ml
- Conical fitting
- Transparent tubes set 6 mm x 10mm
- Hydrophobic and antibacterial filter

The filter is made of hydrophobic material and blocks the passage of liquids that come into contact with it.
Replace it whenever you suspect that it may be contaminated and/or it becomes wet or discoloured.
Replace the filter every time it is used if the suction pump is used on patients in unknown pathological situations and where an assessment of indirect contamination is not possible.
If, however, the patient's pathology is known and/or there is no risk of indirect contamination, the filter should be replaced after every work shift or once a month 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.**

**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 10079-2 regulation.

## CLEANING OF ACCESSORIES

To clean the plastic housing of the device wear disposable latex gloves and clean with denaturated alcohol or hypoclorite solutions.

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 jar from the device
- Disconnect all tubes from the jar and the protection filter
- Empty and dispose of the Jar according to the laws in force in your country;
- Separate all parts of the cover (overflow valve, o-ring);

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) making sure that the jar is positioned upsidedown.

After sterilization and cooling at environment temperature of the parts make sure that these are not damaged. Assemble the jar as follows:

- 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 aspiration tubes can be sterilized on autoclave using a sterilization cycle at 120°C. The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C.

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

**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.

## *PERIODICAL MAINTENANCE CHECKS*

The TOBI MANUALE SUCTION ASPIRATOR does not need maintenance or lubrication. It is necessary to check functioning and instrument before every use. Unpack the instrument and always check integrity of plastic parts, they might have been damaged during previous use. Close the aspirator outlet with your finger. Press the foot and check vacuum functionally.

| Type of fault | Cause | Remedy |
|---|---|---|
| 1. No aspiration | Jar Cap badly screwed down | Unscrewed the cap, then rescrew it correctly |
| 2. No aspiration | Lid seal not in its seat | Unscrew the cap and insert the seal properly in its seat |
| 3. The float doesn't close | The float it's covered by dirty material | Unscrewed the cap, leave the and put in on autoclave |
| 4. The float doesn't close | If the cap has been washed, ensure that the float is not partially detached | Fit the float into it's place |
| 5. Low suction | Foam inside the jar | Fill the jar to 1/3 full of ordinary water |
| 6. No aspiration due to flow leakage of mucus | Filter blocked | Replace filter |
| 7. The Vacuum power on the patient side is either very low or absent | • Protection filter blocked or damaged<br>• Connection tubes blocked, kinked or disconnected<br>• Shut-off valve blocked or damaged<br>• Pump motor damaged | • Replace the filter<br>• Replace or reconnect the tubes, check the jar connections<br>• 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<br>• Refer to authorised service personnel |
| Faults 1 - 2 - 3 - 4 - 5 - 6 - 7 | 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.

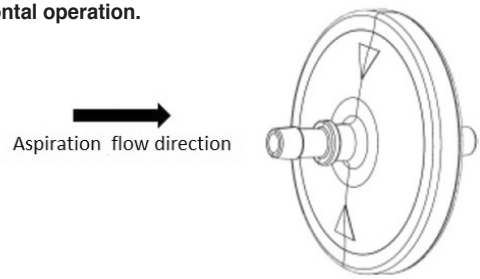
BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT GIMA TECHNICAL SERVICE. GIMA DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

## *INSTRUCTION FOR USE*

Connect the short silicon tube, with antibacterial filter, to the suction connector. The other tube, with one end connected to the filter must be connected with the other end to the jar's lid connector where has been fixed the red 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.**

**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.**

- Connect the long silicon tube to the other jar's lid connector
- Connect the other end of the long silicon tube to the probe plastic connector then connect the suction probe to it.
- 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) the rescrew the lid on the jar correctly.
- Push foot to start suction.
- To extract the accessories and start with cleaning as write in the clean chapter

**NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER**
**MAKE SURE THAT CHILDREN AND/OR MENTALLY ILL PEOPLE DO NOT USE THE DEVICE WITHOUT ADULT SURVEILLANCE**

## *SYMBOLS*

| | | | |
|---|---|---|---|
| | Caution: read instructions (warnings) carefully | | Consult 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 | SN | Serial number |
| | Temperature limit | | Humidity limit |

**GIMA WARRANTY TERMS**
The Gima 12-month standard B2B warranty applies.