IT-EN

SMOKE EVACUATOR

ASPIRATORE DI FUMI PER ELETTROCHIRURGIA/ SMOKE EVACUATOR FOR ELECTROSURGERY

MANUALE D'USO/USER MANUAL



GIMA

CE

SUMMARY

IMPORTANT....19
INTRODUCTION....20
GENERAL DESCRIPTION....20
INTENDED USE....20
INTENDED USER....20
INTENDED PATIENT POPULATION....21
STANDARD AND OPTIONAL COMPOSITION....21
SAFETY....22
PUTTING INTO SERVICE....23
CONNECTORS AND CONTROLS....25
LABEL ON THE BACK PANEL....25
MEANING OF GRAPHIC SYMBOLS....25
BOX LABEL....26
CONNECTING ACCESSORIES....27
FRONT PANEL....28
OPERATING MODES....29
CONTROL PANEL....29
FILTER STATUS....29
FOOTSWITCH....30
REAR PANEL....30
EQUIPMENT POWER MODULE....30
MECHANICAL POWER SWITCH....31
SPECIFICATIONS....31
MAINTENANCE....31
GENERALITY....31
CLEANING THE HOUSING....31
REPLACING ACCESSORIES....32
TROUBLESHOOTING GUIDE....32
REPAIRS....32
REPLACING THE FUSES....32
CONTROL AND MEASUREMENT OF SAFETY MEASURES....33

IMPORTANT

These instructions are a key part of the equipment, as they describe its operation and use; therefore, they must be read carefully before beginning the installation and use of the equipment.

All safety instructions or warning notes must be observed. Be assured that these operating instructions are provided with the equipment when it is transferred to other operating personnel.

If you need Technical Assistance, please contact LED SpA.

Produttore / *Manufacturer*

LED SpA

ELECTRONIC DESIGN AND PRODUCTION

Via Selciatella 40 – 04011 Aprilia (LT) - Italy

www.led.it

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INTRODUCTION

GENERAL DESCRIPTION

SMOKE EVACUATOR is an advanced system for extracting and filtering fumes generated during electrosurgical procedures.
The fumes produced during these procedures have a strong, persistent odour and contain water vapor, organic gases, visible and invisible solid particles, as well as potential viral agents. Effective suction and adequate filtration help eliminate unpleasant odours, reduce the risk of bacteriological and viral contamination and improve visibility of the operating area, a particularly critical aspect in laparoscopic procedures.

The activation of the suction in the SMOKE EVACUATOR can take place in three ways:

- Automatic: thanks to a remote electronic system that detects the activation of a high-frequency electrosurgical unit (available only for compatible generators).
- Manual: by direct control over the unit.
- Via footswitch (optional), for easier handling.

The suction flow is adjustable to suit different operating needs. In addition, there is a dedicated function for laparoscopic procedures, which can be easily activated.

SMOKE EVACUATOR is equipped with an advanced electronic control that monitors the state of wear of the filters, ensuring optimal operation at all times.

Two types of filters are available, which are easily replaceable and feature ULPA filtration technology with an activated carbon stage to neutralize unpleasant odours. Both filters are compatible with a 7/8" (22 mm) connection:

- BLUE filter: supplied as standard, ideal for standard use up to 5 hours.
- RED filter: available as an option, designed for extended use of up to 20 hours.

INTENDED USE

Medical device for the removal and filtering of fumes and aerosols from the surgical site produced during electrosurgical and laser procedures.

INTENDED USER

Device for professional use. The use of the equipment is reserved for medical personnel with a degree in medicine specialized in high-frequency electrosurgery.

INTENDED PATIENT POPULATION

Adults - Men and women (≥18 years old).

STANDARD AND OPTIONAL COMPOSITION

Code	Description	SMOKE EVACUATOR
-	Equipment Code	GMA10200.10
00100.03	SIE-IEC power cable (2m)	■/1
00900.01	Kit with handpiece holder for surgical smoke evacuator (ø22 mm)	■/1
00900.02	Surgical Smoke Evacuator Kit (ø22 mm)	■/1
00900.FST/10	ULPA filter for first supply (5h) - BLUE	■/1
00100.00	IT-IEC power cable (2m)	○
00100.01	SIE-IEC power cable (5m)	○
00100.04	US-IEC power cable (2m)	○
00100.05	GB-IEC power cable (2m)	○
00100.07	BR-IEC power cable (2m)	○
00100.09	AU-IEC power cable (2m)	○
00100.10	JP-IEC power cable (5m)	○
00304.00	Waterproof single footswitch	○
00900.01/12	Kit with handpiece holder for surgical smoke evacuator (ø22 mm)	○
00900.02/06	Surgical Smoke Evacuator Kit (ø22 mm)	○
00900.04	Autoclavable evacuation tube (ø22 mm)	○
00900.05	Autoclavable evacuation tube (ø7 mm with ø 7/22 adapter)	○
00900.06/06	Hydrophobic filters (ø22 mm)	○
00900.07	Kit with handpiece holder for autoclavable surgical smoke evacuator (ø22 mm)	○
00900.08/12	Evacuation kit for TROCAR Luer Lock (ø22 mm)	○
00900.FU01/10	ULPA filter (20h) - RED	○
TR003	Trolley 3 shelves	○
TR003W	Trolley 3 wide shelves	○
TR004	Trolley 4 shelves	○
TR005	Trolley 5 shelves	○
TR005W	Trolley 5 wide shelves	○

■/ Pcs= STANDARD ○= OPTIONAL

SAFETY

It is recommended that you read all warnings, cautions, and operating instructions carefully before using the equipment. Improper use of the unit or its accessories may result in damage to persons or property.
LED SpA declines all responsibility for direct or indirect damage resulting from incorrect use of the device.
The accessories provided are compatible with the unit but may not be suitable for use with other devices. Any use of accessories and/or components not supplied by LED SpA remains solely and exclusively the responsibility of the end user, who must verify their adequacy and compatibility in terms of safety, essential performance and electromagnetic compatibility with respect to the equipment supplied.
Disposable accessories, such as tubes and filters, must be disposed of in accordance with current regulations for the management of hospital waste.

WARNINGS

- Connection to the mains supply: Electrical safety is only guaranteed if the unit is properly connected to an earthed power supply, which complies with current safety regulations. If you are unsure, contact a qualified technician. Ungrounded use is strictly prohibited.

- Power supply voltage: Before plugging in the appliance, check that the voltage indicated on the rear panel corresponds to that of the available mains supply.

- Adapters and extension cords: If the available power outlet is not compatible with the power cord, use only adapters that are certified and comply with safety regulations.

- Weather Protection: Do not expose the equipment to rain, direct sun, or excessive moisture. Protect it from liquid ingress and do not block the ventilation slots.

- Switching off: The appliance should be switched off when not in use to avoid unnecessary consumption and wear and tear.

- Hazardous Environments: Do not use the equipment in environments that are at risk of explosion or saturated with flammable gases.

- Intended use: The unit should only be used for the purpose for which it was designed. Any other use is considered improper and potentially dangerous. LED SpA is not responsible for damage resulting from improper or unauthorized use.

- Unauthorized modifications: It is forbidden to modify or attempt to alter the characteristics of the appliance, as this may compromise its safety and functionality.

- Liquid Suction: The SMOKE EVACUATOR and its filters are not designed for liquid suction. If there is a risk of accidental vacuuming, a liquid collection system should be installed along the suction circuit. Vacuuming liquids may damage the unit and filters.

- Cleaning and maintenance: Before any cleaning or maintenance, disconnect the appliance from the mains power supply by removing the plug or turning off the main switch.

- Repairs: In the event of a malfunction, switch off the appliance immediately and contact an authorised service centre only. The use of non-genuine replacement parts may compromise the safety and compliance of the unit.

- Failure to follow these instructions could compromise the safety of the equipment and pose a risk to the operator.

- Any serious accident that has occurred in relation to the device must be reported to LED SpA (via Selciatella n.40, 04011 Aprilia (LT) ITALY) and to the competent authority:
  Ministry of Health – Directorate-General of Medical Devices and Pharmaceutical Service
  Viale Giorgio Ribotta, 5 – Rome
  E-mail: segr.dgfdm@sanita.it
  Tel.: +39 06 5994 3199 / +39 06 5994 3207

PUTTING INTO SERVICE

- Inspect the equipment for any damage caused by transportation. Claims for any damage will be accepted only if notified immediately to the carrier, drawing up a note of the damage found, to be presented to LED SpA or its seller. In the event of returning the equipment to LED SpA or to the seller, it is necessary to use the original packaging of the product or packaging that guarantees equivalent transport safety.

- Remove the appliance from its packaging and carefully study the documentation and operating instructions provided. The mains voltage, indicated on the rating plate, must be equal to the local mains voltage (mains frequency: 50-60Hz). If necessary, replace the fuses with the rating indicated in the rating plate.

- Connect the power cord to a mains outlet with a good earth connection.

OPERATION OF THE EQUIPMENT WITHOUT AN EARTH CONNECTION IS PROHIBITED.

- The equipment must be installed on a flat surface that is at least the same size as the base of the equipment. At least 25cm of space must be left around the equipment.

- Connect the mains cable to the power outlet located on the rear panel of the unit.

- Connect the bonding point on the rear left of the unit to the bonding socket on the system.

- Connect the footswitch (optional) to the connector on the front panel of the unit.

- Insert a new filter into the unit making sure it is properly seated.

- Connect the outlet tubes to the filter, following the instructions in the reference figures.

- Use the equipment only in dry environments. If condensation occurs, allow it to evaporate completely before operating the unit.

- Avoid extreme environmental conditions that may affect the proper operation of the device.

- Environmental conditions:

	OPERATION	TRANSPORT / STORAGE
Temperature:	from 10 to 40 °C	from -10 to 50 °C
Relative humidity:	from 30% to 75%	from 10 to 100%
Atmospheric pressure:	from 70 to 106 kPa	from 50 to 106 kPa

CONNECTORS AND CONTROLS

LABEL ON THE BACK PANEL

Equipment safety requirements require that data and graphic symbols must be printed on the cabinet or on at least one of the panels of the generator set to define its characteristics and monitor its working conditions.

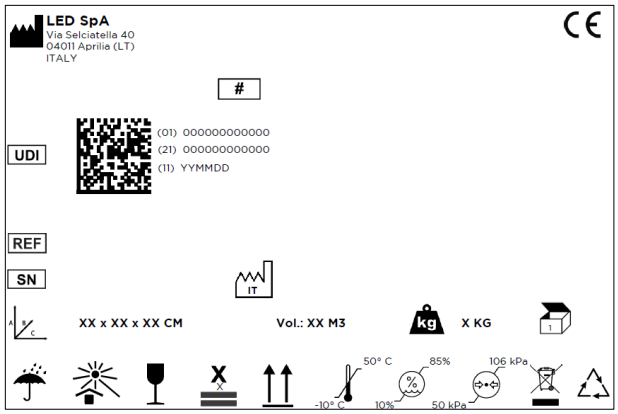
MEANING OF GRAPHIC SYMBOLS

N°	SYMBOL	DESCRIPTION
1.		Class CF equipment protected against shock from defibrillator use
2.		Follow the instructions for use
3.	CE	CE mark (2017/745/EU)
4.		The product should not be disposed of in municipal waste containers but should be disposed of with a separate collection
5.		Manufacturer
6.	SN	Serial Number
7.		Date of production
8.	UDI	Unique Device Identification
9.		Distributor
10.		No maintenance by the user
11.	REF	Catalog Number (Code)
12.		Temperature limits
13.		Humidity limits
14.		Atmospheric pressure limits
15.		High Side
16.		FRAGILE – Handle with care
17.		Keep away from sunlight
18.		Protect from moisture
19.	X	Maximum number of stackable packages
20.	kg	Weight
21.		Dimensions
22.		Number of pieces

N°	SYMBOL	DESCRIPTION
23.		Recycle
24.	#	Model/Trade Name
25.		Fuse

BOX LABEL

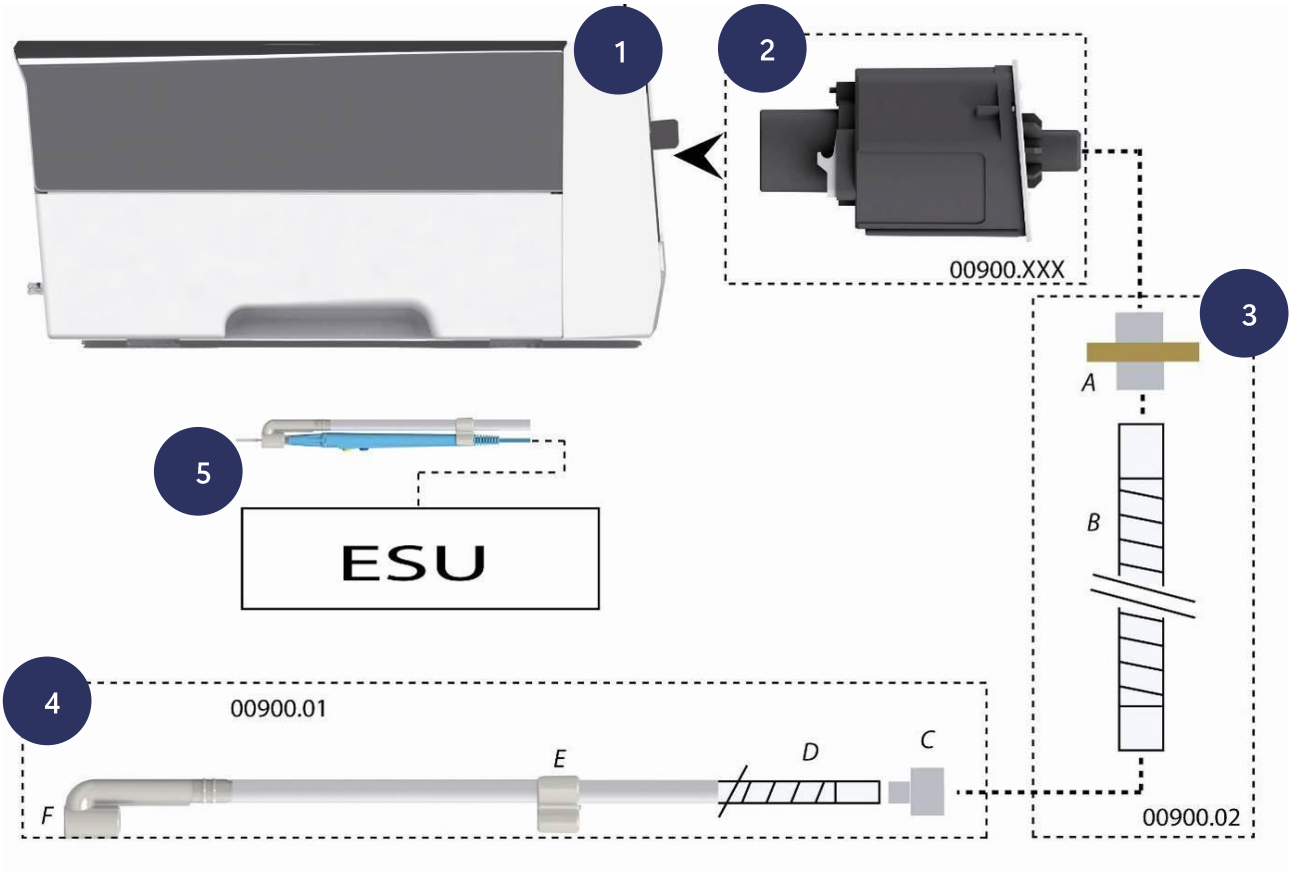
With reference to ISO 15223-1:2021 "Medical devices — Symbols for use with medical devices, labels, labeling and information to be provided" and ISO 780:2015 "Packaging — Packaging for distribution — Graphic symbols for handling and storage of packages" the following information is shown on the packaging label of the unit on the packaging:



ISO 15223-1 (5.1.1) - MANUFACTURER
ISO 15223-1 (5.1.9) - DISTRIBUTOR
ISO 15223-1 (5.1.10) - MODEL NUMBER
ISO 15223-1 (5.7.10) - UNIQUE DEVICE IDENTIFIER
ISO 15223-1 (5.1.6) - CATALOGUE NUMBER
ISO 15223-1 (5.1.7) - SERIAL NUMBER
ISO 15223-1 (5.1.3) - DATE OF MANUFACTURE
BOX WEIGHT
BOX DIMENSIONS
BOX VOLUME
ISO 7000 (No. 2403) - STACKING LIMIT BY NUMBER
EU REGULATION 2017/745 (MDR) - CE MARK
DIRECTIVE 2012/19/EU - WEEE PRODUCT
ISO 15223-1 (5.3.7) - TEMPERATURE LIMIT
ISO 15223-1 (5.3.8) - HUMIDITY LIMIT
ISO 15223-1 (5.3.9) - ATMOSPHERIC PRESSURE LIMITATION

CONNECTING ACCESSORIES

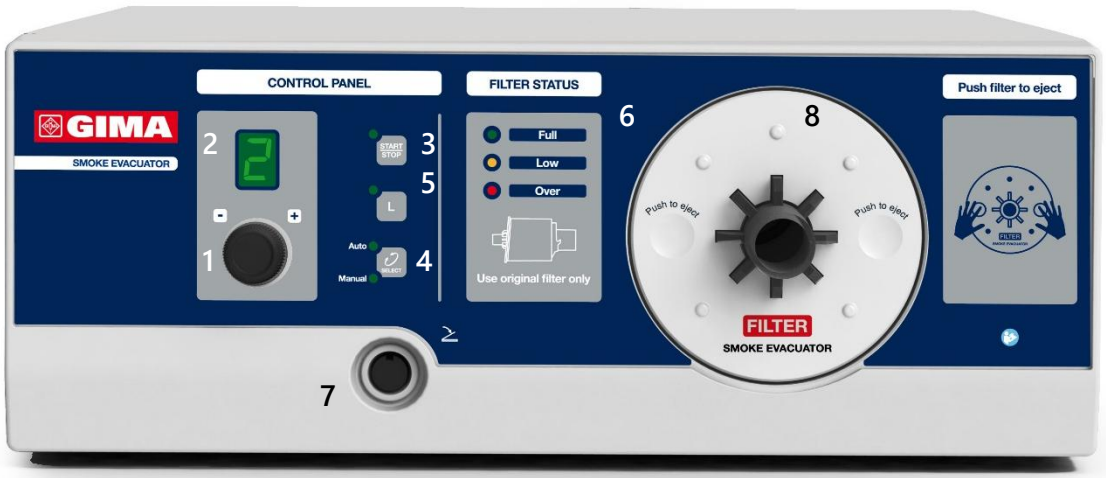
For the correct connection of the accessories, please refer to the image below.



6. SMOKE EVACUATOR – Smoke extraction unit.
7. FILTER – Filter component for air purification.
8. SUCTION HOSE KIT (00900.02)
    - A – Filter
    - B – Ø22 mm tube
9. HANDPIECE SUCTION KIT (00900.01)
    - C – 10/22mm Adapter
    - D – Tube Ø10 mm
    - E – Fixing clip
    - F – Handpiece Adapter
10. Connecting the handpiece with the 00900.01 kit. The handpiece must be connected to the electrosurgical unit (ESU*).

* The handpiece is not supplied.

FRONT PANEL



1. Suction level adjustment knob
2. Display with suction level indication
3. START/STOP button for vacuuming in manual mode
4. Mode selection button (AUTO/MANUAL)
5. Dedicated button for laparoscopic procedures (L)
6. Filter Status LED
   Green: full filter
   Yellow: filter in reserve
   Red: filter out of stock
7. Footswitch connector
8. Suction filter

OPERATING MODES

CONTROL PANEL



To adjust the suction level, turn the knob. The set level is shown on the display.
The unit generates a high vacuum, so it is essential to regulate the suction flow and position the tubing end correctly to prevent patient injury or accidental aspiration of surgical material or specimens.
Before activating suction, always check that the selected level is safe for the patient and does not result in unintentional aspiration of tissues or specimens.

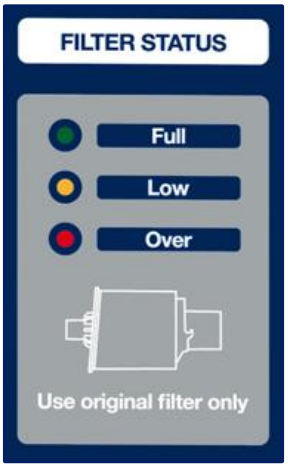
Using the SELECT button, you can choose between two operating modes:

- AUTO (Auto Activation)
  The unit starts automatically when it detects the activation of the electrosurgical unit and stops with a preset delay when the dispensing is complete.
- MANUAL (Manual Activation)
  Suction is manually activated or deactivated by pressing the START/STOP button.

Pressing the L button activates the specific mode for laparoscopic procedures, with a maximum level that can be set to 3.

FILTER STATUS

The filter status is indicated by indicator lights with the following meaning:



Indicator	State	Remaining autonomy
Solid green	Normal	20 to 5 hours
Solid yellow	Reserve	5 to 1 hour
Flashing red	Almost sold out	< 1 hour (until the end of the last activation)
Solid red	Filter Out of Stock	Replace the filter

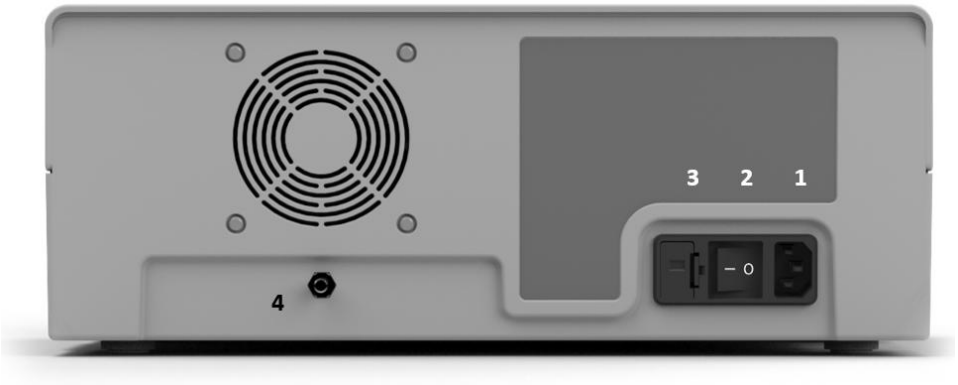
- If **no filter** is inserted, **all indicator lights flash at the same time.**
- In **reserve condition** (yellow light on) and with suction deactivated, it is possible to know the number of **hours remaining** by pressing and holding the **START/STOP + SELECT buttons at the same time.** The yellow light will start flashing and the **display will show the available hours.**

FOOTSWITCH



The unit can be activated via an optional foot pedal, which can be connected to the appropriate connector on the front panel.

REAR PANEL



1. Power Socket
2. Power Switch
3. Fuse holder
4. Equipotential Socket

EQUIPMENT POWER MODULE

The equipment power supply module is the connection point for powering the internal electronics. Includes power connector, circuit breaker and line fuses.

WARNING: Before switching on the equipment, the operator should make sure that the mains voltage indicated in the data plate corresponds to the voltage to which it is connected.

MECHANICAL POWER SWITCH

The mechanical power switch is used to turn the power to the equipment on or off. To turn on the power, press the switch to position 1 (upward). When the power is on, the front panel is illuminated. Pressing the switch to position 0 will turn off the power. This operation can also be used as an emergency switch in the event of a fault.

SPECIFICATIONS

Description	**SMOKE EVACUATOR**
Equipment Code	GMA10200.10
Maximum suction flow	1000 LPM (35 CFM)
Maximum suction pressure	250 mbar (83 in H_2O)
Filter type	ULPA with activated carbons
Filter efficiency	99,999X%
Diameter of filtered particles	0,12 µm
Dimensions (W × H × D)	370 × 144 × 319 mm
Weight	4 kg
Supply voltage	230 VAC– 50/60 Hz
Input	300 VA
Fuses	2 × T 2AL, 250 V (5 × 20 mm)
Electric class	I CF

MAINTENANCE

GENERALITY

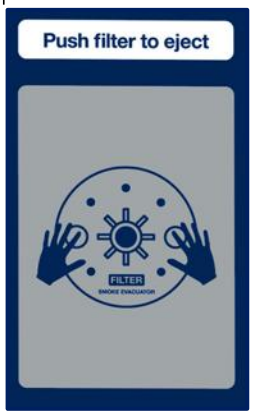
There are no user adjustable parts inside the equipment for calibration or service.
The equipment enclosure must not be opened – the warranty is voided by any unauthorized tampering with the unit. In the event of a need for repair or adjustment, the entire equipment should be sent to the LED SpA - APRILIA (LT) - ITALY service center, together with a description of the fault.
User maintenance consists mainly of cleaning and sterilizing the accessories and checking the equipment before each use. The execution of functional and safety checks to verify the parameters is entrusted to specialized technical personnel.

CLEANING THE HOUSING

Turn off the equipment completely and disconnect the mains before any cleaning. Wipe the outside of the housing with a damp cloth. Do not use any solvent or chemical components. A light, non-abrasive detergent may be used.

REPLACING ACCESSORIES

Accessories, such as tubing and filters, should be disposed of in accordance with hospital waste control procedures.



To replace filters:

- Turn off the unit.
- Remove any outlet tubes connected to the filter.
- Press down on the sides of the filter to remove it.

TROUBLESHOOTING GUIDE

In the event of a problem, you must first check that you have correctly installed and prepared the accessories.

Problem	Probable Cause	Solution
The equipment does not turn on	No or interruption of mains power	- Check that the power cord is properly connected. - Check the condition of the fuses and replace them, if necessary, with the correct type.
All LEDs (green, yellow, and red) lit	Filter not inserted correctly	- Insert a new filter. - If already inserted, remove it and repeat the operation.
Red filter status LED on	Filter Out of Stock	Replace the filter with a new one.

REPAIRS

Filters and tubes cannot be repaired. Always replace a defective part with a new one.

REPLACING THE FUSES

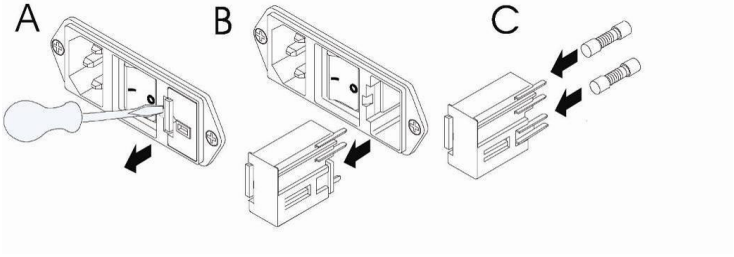
BEFORE REPLACING THE FUSES, DISCONNECT THE EQUIPMENT FROM THE POWER SUPPLY.

To replace the fuses, use type 5x20 fuses and proceed as follows:

(A-B) Use a small screwdriver to remove the fuse boxes from the power supply module.

(C) Insert the fuses by referring to the following:

Tension 220-240 V Time-Delay Fuses 2x T2AL, 250V / 5 x 20 mm



CHECKING THE UNIT BEFORE USE

Each time the unit is programmed, a check of the main safety conditions must be carried out, considering the following points:

- Check the integrity of the cables, connections and check for broken wires.
- Make sure all electrical equipment is properly grounded.
- Check that all necessary accessories are available and sterilized.
- Check the state of charge of the filter, to evaluate that it lasts long enough for the operation to be performed.

CONTROL AND MEASUREMENT OF SAFETY MEASURES

The Department of Bioengineering or other specialists must schedule checks and measurements of the equipment at least once a year, including the following points:

1. **Condition of cables and power connectors**
   Check the integrity of cables and connectors for visible damage, and proper function.
2. **Visual inspection of mechanical guards**
   Check that all mechanical guards are intact and in working order.
3. **Protections against the dangers arising from the spillage and penetration of liquids**
   Inspect the equipment for protection against liquids, drips, moisture, hygiene products, and disinfectants.
4. **Instruction Manual**
   Make sure the instruction manual is available and up to date.
5. **Measurement of the resistance of the earth connection**
   Carry out the measurement of the resistance of the earth connection to ensure proper operation of the grounding system and electrical safety.

Information on deleting this product (applicable in countries with separate collection systems)	
	At the end of its life cycle, the present product must not be disposed of as municipal waste but must be disposed of in a separate collection. If the product is disposed of inappropriately, it is possible that some parts of the product (e.g. some accumulators) may be negative for the environment and human health. The symbol on the side (crossed-out dustbin on wheel) indicates that products should not be thrown into the municipal waste container but should be disposed of separately. Penalties may apply for the improper disposal of this product.

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