

# SMOKE EVACUATOR

## ELECTROSURGICAL SMOKE EVACUATOR



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MA530\_EN



*Instruction's Manual*

**ENGLISH**



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## **IMPORTANT**

These operating instructions form an integral part of the equipment and must be available to the operating personnel at all times.

All the safety instructions and advice notes are to be observed. Be sure that these operating instructions are furnished together the equipment when this is transferred to other operating people.

In case of necessity of technical, or other type, assistance contact your own retailer.

*Produttore / Manufacturer*

**LED SpA**

*PROGETTAZIONI E PRODUZIONI ELETTRONICHE*  
Via Selciatella, 40 04011 APRILIA (LT) ITALIA



## General Description

**SMOKE EVACUATOR** is an aspiration and filtering system for the smokes produced during the surgical procedures.

The smokes, generated during the surgical procedures, have a bad, strong and long smell. These smokes consist of water vapour, organic gas, visible or invisible solid particles and viral parts. So a good aspiration and filtration eliminates bad smells, reduce the bacteriologist and/or viral risks, and solves, the particularly annoying problem of the optimal vision of the zone of the intervention, during the laparoscopic procedures.

In **SMOKE EVACUATOR** the activation of the aspiration can be:

- AUTOMATIC, through the remote electronic system of automatic survey of the activation of the high frequency electrosurgical unit;
- MANUAL, acting directly on the unit
- through a foot switch (optional)

The flux of the aspiration can be regulated to be suitable with the singular necessities. For Laparoscopic procedures there is a specific function L, quickly selectable.

**SMOKE EVACUATOR** has an electronic control of the aspiration with the indication of the usury status of the filters.

There are two different kind of filter, quickly substituable and constituted by a filtering ULPA type with a active carbons part dedicated to the elimination of the bad smells of the electrosurgical smokes and connector of 7/8".

The BLUE filter is the first filter and it is included with the unit for a initial time of use (5 hours).

The RED filter is an optional spare part, created for a long time of use (20 hours).

## Standard and Optional Composition

Code	Description	SMOKE
		EVACUATOR
-	Unit code (230Vac)	GMA10200.10
00100.03	Power supply cable 2m SIEMENS-IEC	●/1
00900.FST	First ULPA Filter (5h) - blu	●/1
00900.02	Aspiration kit	●/1
00900.01	Handle Aspiration kit	●/1
00900.FU01	ULPA Filter for SURTRON EVAC (20h) - red	○
00900.01/12	Handle Aspiration kit (12 pcs)	○
00900.02/06	Aspiration kit (6 pcs)	○
00900.04	Autoclavable tube D. 22 mm	○
00900.05	Autoclavable Aspiration Kit for SPECULUM D.7	○
00900.06/06	Filter D.22 (6 pcs)	○
00900.07	Autoclavable Handle Aspiration kit	○
00100.01	Power supply cable 5m 3x1.5mm SIEMENS-IEC	○
00304.00	Water-proof foot switch	○
TR003W	Trolley 3 shelves wide	○
TR003	Trolley 3 shelves	○
TR004	Trolley 4 shelves	○
TR005W	Trolley 5 shelves wide	○
TR005	Trolley 5 shelves	○

●/ Pcs= STANDARD ○= OPTIONAL

## SAFETY

Read and understand all warnings, precautions, and directions for use before attempt to use. Neither LED SpA, can be considered responsible for personal, material or consequential injury, loss or damage that results from improper use of the equipment and accessories.

The accessories supplied with the unit have characteristics compatible with this supplied unit, they could be incompatible with others units; the user must check, before connecting other accessories to this unit, that they have characteristics compatible with those of this unit.

It is recommended to inspect the integrity of the packaging of the sterile products.

The accessories (tubes and filter) must be treated as a special hospital waste.

### *Installation*

- The electric safety is insured only when the same are correctly connected to an efficient net linked to the earth in conformity with the actual safety requirements. It is necessary to verify this fundamental safety requisite and, in case of doubt, to require an accurate control of the plant from part of qualified personnel. The manufacturer cannot be considered responsible for possible damages caused from the lack of efficient connection to earth of the installation. Operation without a protective earth connection is forbidden.
- Before connect the equipment ascertain that the required voltage (showed on the rear panel) corresponds to the available mains.
- In case of incompatibility between the available wall socket and the feeding cable of the equipment, replace only with legally approved connectors and accessory items. The use of adapters, multiple connections or cable extensions is not advised. Should their use become necessary it is mandatory to use only simple or multiple adapter conforming to the actual safety requirements.
- Don't let the apparatus exposed to atmospheric agents. The unit must be protected from seepage of liquids. Don't obstruct openings or cracks of ventilation or heathsink
- Don't leave the equipment uselessly inserted. Switch off the equipment when not in use.
- The use of the unit is not suited in explosive rooms.
- **SMOKE EVACUATOR** must be destined only to the use for that have been expressly designed. Any other use is to be considered improper and dangerous. The manufacturer can not be considered responsible for possible damages due to improper, wrong and unreasonable uses.
- It is dangerous to modify or try modifying the characteristic of the equipment.
- **SMOKE EVACUATOR** and its compatible filters are not designed for the evacuation of liquids. If it is expected that the liquid is sucked from the device to evacuate the fumes, a liquid collection system must be installed along the vacuum tube. Failure to install a system for collecting fluids may cause the filter and electrical damage.
- Before effect any operation of cleaning or maintenance, disconnect the apparatus from the electric net, either unplugging it from the mains or switching off the mains switch of the plant.
- In case failure and/or bad operation of equipment switch off it. For the possible reparation address only to an authorized service centre and ask for the use of original spare parts. The lack to follow the above requirements could risk the safety of the equipment and can be dangerous for the user.

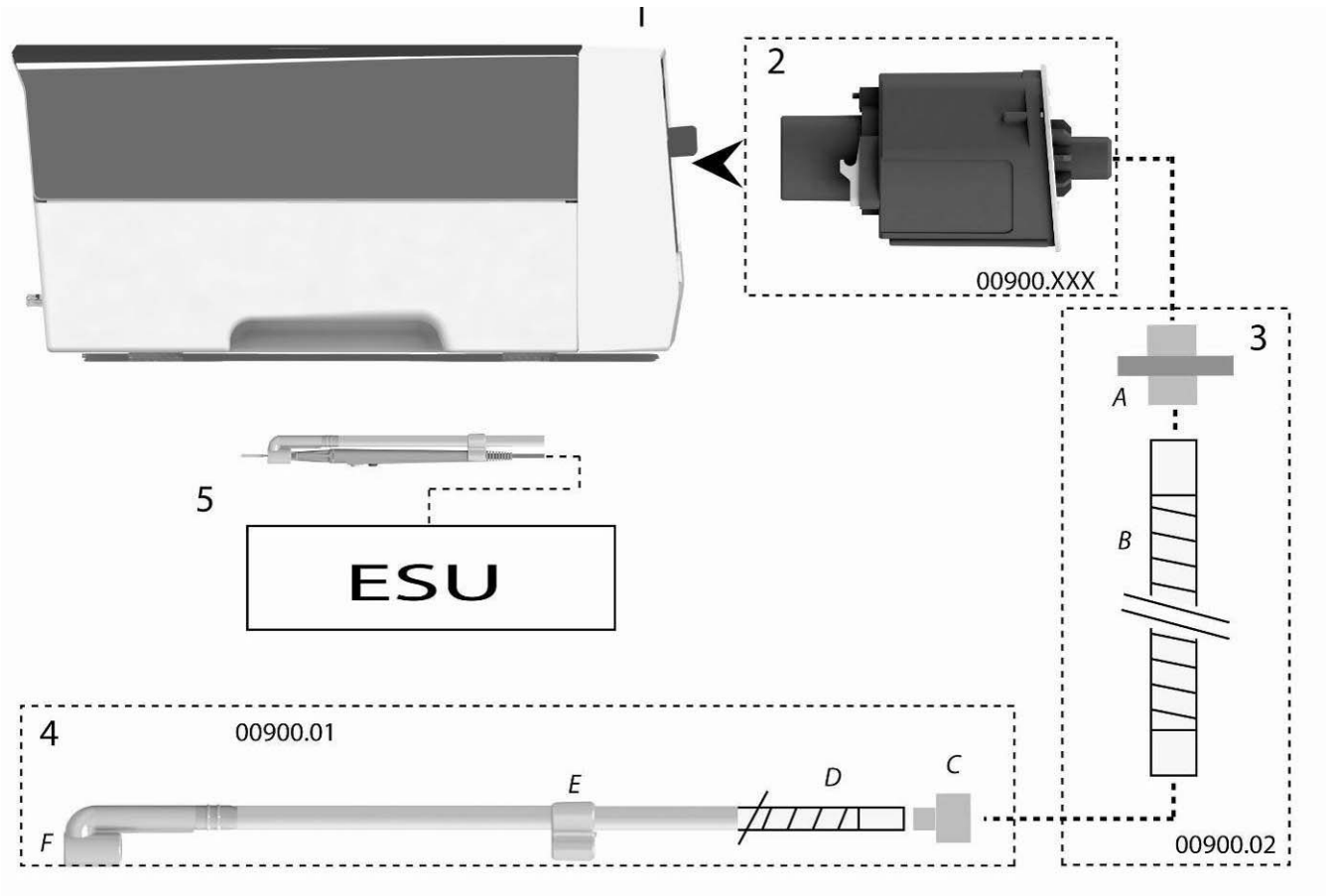
## INSTALLATION

- Inspect the unit for damages during transport. The claims for possible damages will be accepted only in case they are immediately communicated to the carrier; the damages that are found must be written down and presented to GIMA SpA or to your own retailer. If the unit is returned to the GIMA SpA or to your own retailer, it is necessary to use the original equipment's package or another equivalent one, to guarantee the safety during the transport.
- Unpack the equipment and carefully study the documentation and operating instruction supplied. Mains voltage, indicated above the inlet, must agree with the local mains voltage (mains voltage frequency: 50-60 Hz).
- **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- Connect mains cable to a mains outlet having good hearth connection.

### **OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN.**

- The unit must be installed on a level surface, with dimension, at least, correspondent to those of the base of the unit itself. Around the unit must be left a space of 25cm, at least.
- Connect the mains cable to the mains socket on the rear panel of the unit.
- Connect, if request, the equipotential binding post located at the left of the unit's back panel to eventual equipotential socket of the plant.
- Connect the single foot switch (optional) to the connector on the frontal panel of the unit.
- Insert a new filter on the unit.
- Connect output tubes on the filter (see figure).
- Let unit work in dry environment only. Any verified condensate must be let evaporate before putting in operation the unit. Don't exceed the temperature environment or the allowed moisture.
- Environments condition:

	<i>WORK</i>	<i>TRANSIT/STORAGE</i>
<i>Temperature:</i>	<i>10/40°C</i>	<i>-10/+50 °C</i>
<i>Relative moisture:</i>	<i>30/75%</i>	<i>10-85 %</i>
<i>Pressure:</i>	<i>70/106k Pa</i>	<i>50/106 kPa</i>



1 SMOKE EVACUATOR

2 FILTER

3 ASPIRATION KIT (00900.02) – A Filter B - Tube dia 22

4 HANDLE ASPIRATION KIT (00900.01) – C 10/22 – D Tube dia. 10 – E Clip – F – Handle Adpter

5 PARTICULAR OF HANDLE\* with 00900.01, the handle must be connect to your surgical unit (ESU\*).

\*not furnished



## CONNECTOR AND CONTROLS

### Label on the Rear Panel

The requirements for the safety of unit ask data and graphic symbols must be printed on the cabinet or on at least one of the panels of unit to define its features and oversee its condition of work.

### Manufacturer's Identification Data

SMOKE EVACUATOR are designed, manufactured and tested by the LED SpA in its own laboratories in Aprilia (LT) – Italy.

### Technical Data

Max vacuum flow rate:	1000 LPF (35 CFM)
Max static suction:	250 mbar (83 in H <sub>2</sub> O)
Filter Type	ULPA with active carbon
Filter efficiency	99,999X%
Particles diameter	0,12 micron
Size WxHxD mm	370x144x319
Weight	4
MAIN POWER:	230 Vac - 50/60 Hz
INLET POWER:	800VA
FUSE:	2xT 4AL, 250V (5x20mm)
CLASS:	I CF

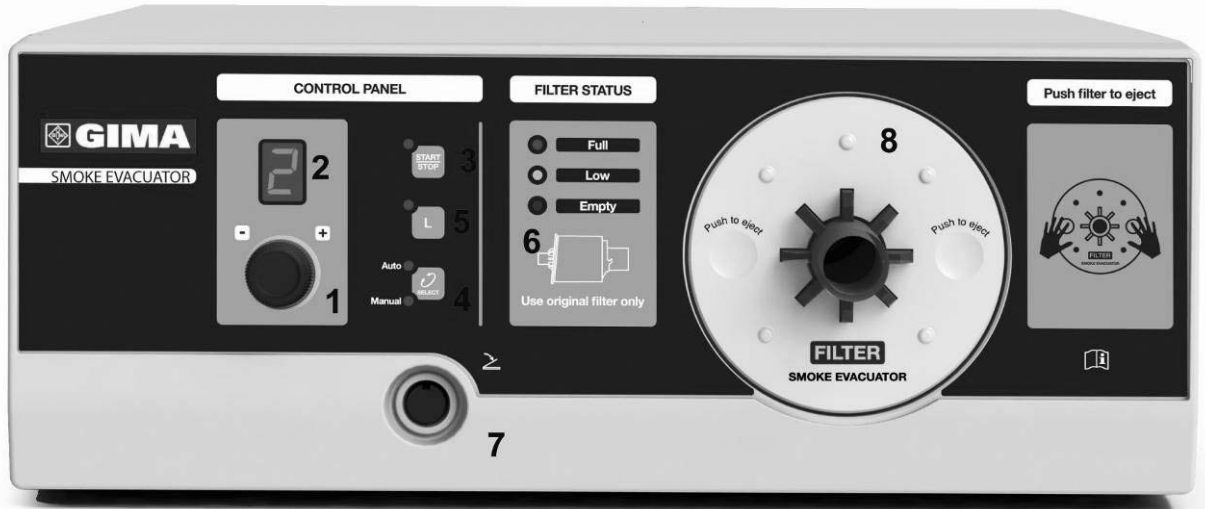
### Meaning of Graphics Symbols

The meaning of the graphic symbols printed on **SURTRON® EVAC**'s cabinet is the following:

- 1 – Consult instructions for use
- 2 - Corresponding to the European Directive 93/42/EC (2007/47/CE) – Class I
- 3 - The product mustn't be throw in the containers for urban wastes but it must be swallowed by a separate picking.
- 4 - Manufacturer
- 5 - Serial Number
- 6 - Date of manufacture

					
1	2	3	4	5	6

## Frontal Panel



1. Knob for aspiration level
2. Display for indication aspiration level
3. Key for start/stop aspiration (Manual)
4. Selection keys for work mode (AUTO or MANUAL)
5. Key for Laporoscopic procedure (L)
6. Filter Status (Green: Full / Yellow: Low / Red: Over)
7. Foot-switch connector
8. Filter

## Operation Mode

### Control Panel



To regulate the level of aspiration to rotate the handle. The level of aspiration planned is suitable on the display.

The device produces a smoke evacuation vacuum. Adjust the flow of air input and the position of the extremity of the rod or pipe to prevent patient injury and to prevent aspiration of surgical materials and surgical specimens. Before activating the aspiration to control the level of aspiration, a high aspiration level can create a strong and sudden suction action.

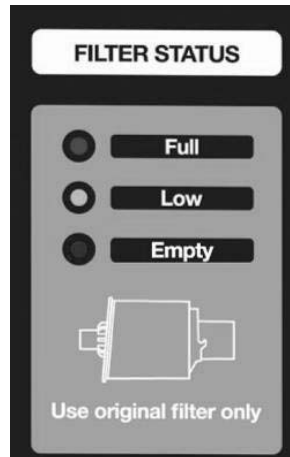
Through the key SELECT he plans the formality of job in:

- Auto (automatic detection system of electro-surgery emission). This mode may not work properly with non-production units LED or older. In the event of failure or erratic operation use the MANUAL.
- Manual, function.

In MANUAL mode, through the START / STOP button turns on and off the suction.

Press L button for laparoscopic procedure. In this modality level max is 3.

### **Filter Status**



This section presents the state of wear of the filter inserted.

The meaning of the lights is as follows:

Green	Fixed	from 20 to 5 h
Yellow *	Fixed	from 5 h to 1 h
Red	flashing	from > 1 to end of last intake
Red	Fixed	change filter

If no filter is inserted all three lights blink.

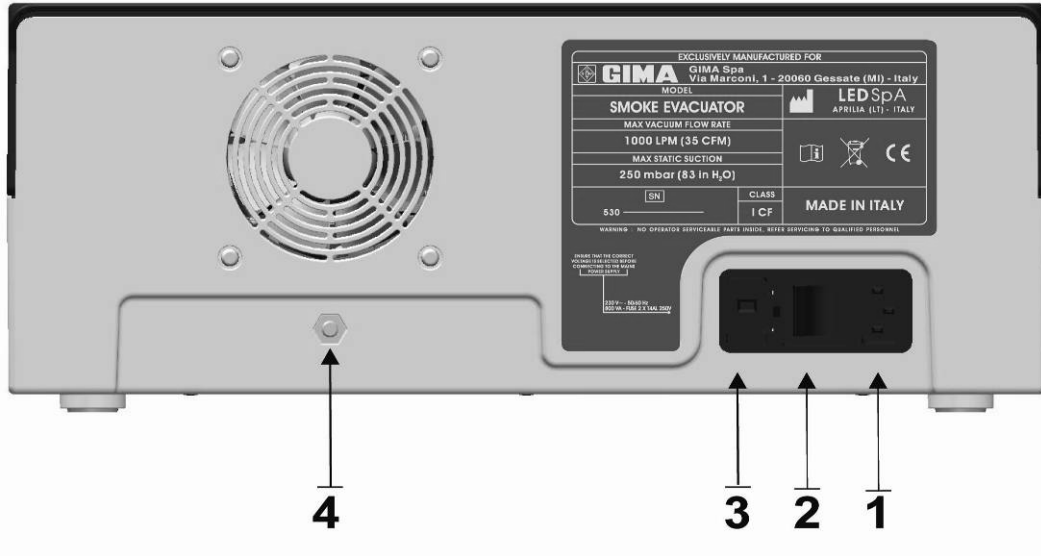
\*When yellow led it's on, for know how reserves time available, it's possible by pressing START/STOP + SELECT keys. The yellow led flashing and on display show number of hours yet available.

### **Foot-switch**



The unit can be activated through an optional footswitch. When using plug on the front of the pedal.

## Back Panel



- 1 Mains voltage connector
- 2 Power On-Off switch
- 3 Fuses holder
- 4 Equipotential connector

## Power Supply Module

Power supply module is the connection point of mains voltage feeding to the unit. This module is provided with line fuses.

**WARNING:** before switch on the unit, operator has to verify that requested mains voltage corresponds to the voltage available from the electrical net. (see chapter INSTALLATION).

## Power On-Off Switch

The POWER ON/OFF mechanical switch is used to control power to the equipment. To power the equipment, press the switch in the direction of the 1. Pressing the switch in the 0 direction will cut power to the equipment, this operation allows it to be used as a emergency stop switch, in the event of any fault.

## MAINTENANCE

### General

**WARNING:** Do not modify this equipment without authorization of the manufacturer

No user adjustable parts are within the equipment, either for calibration or service purposes.

The equipment housing must not be opened: the warranty is invalidated by any unauthorized entry into the unit. In the event any repair or adjustment work being necessary, the whole equipment should be returned to the LED SpA. Service Centre 04011 APRILIA (LT) - ITALY, or to an other Authorized Centre, together with a description of the fault.

Maintenance work by the user is mainly the cleaning of the exterior of the cabinet, cleaning and changing of the accessory items and checking of the equipment before each use. Carrying out function and safety check is demanded to specialized technical people.

### Cleaning of the Cabinet

Switch the equipment off completely and disconnect the mains supply before any cleaning is undertaken. Clean the outside of the cabinet with a damp cloth. No chemical should be used; a mild non abrasive cleanser may be used when necessary.

### Replacement of accessories

The accessories (tubes and filter) must be treated as a special hospital waste.

To replace the filter work this way:

- Turn off the unit
- Remove the filter outlet tube
- Push filter to eject.



### Guide to the Solution of the Problems

In case of problems before all it is advised to check for the correct installation of the unit and for the correct connection of the accessories.

Problems	Probable Cause	Solution
The equipment doesn't switch on.	Interruption or absence of the main feeding.	Verify the connection of the main cable. Verify the fuses and replace them, where necessary, with new ones of the proprie type.
Lighting of green, yellow and red light	Lack filter or incorrect connection.	Insert a new filter Repeat filter connection
Red light of filter status	Filter used	Change filter with new one.

### Repairs

Filter cannot be repaired. Always substitute a damaged part with a new one.

### Fuses Substitution

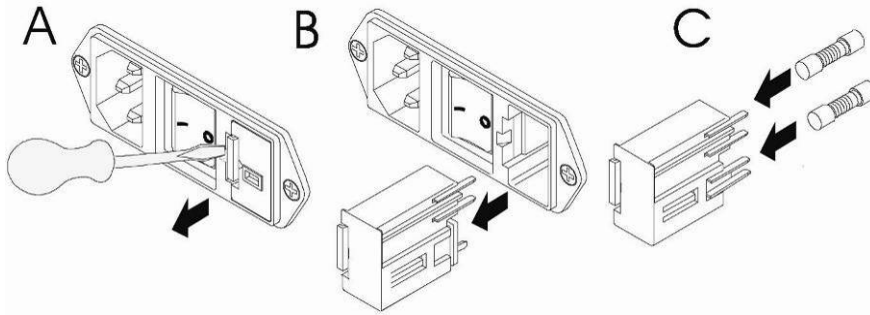
**Before substituting the fuse, disconnect the unit from the mains system**

Only use fuse of the kind 5x20, proceed as follows:

(A-B) Extract the fuse holder drawer from the power module.

(C) Insert the fuses making reference to the following chart:

Mains Voltage 220-240 V      Delayed Fuse 2x T4AL, 250V / 5 x 20 mm



### Checking of the Equipment Before Each Use

Each time the use of the equipment is planned a check of the most important safety aspects has to be implemented considering at least the following:

- Check the integrity of cords, connections, wires breakage, etc.
- Assure that all the electrical equipment is properly grounded
- Assure that all the accessories that should be used are available.
- Check, filter status.

### Function and Safety Check and Test

At least once a year, the biomedical engineering department or other qualified personnel should do the following check and test:

- Check of the connectors and mains supply cord conditions;
- Visual check of the mechanical protections;
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization and disinfection.
- Check of the Equipment's Data on the Label
- Check of the availability of the Instruction's Manual
- Check the functioning of the controls
- Test the earth conductivity resistance.
- Test the earth leakage current.

<b>Information about elimination of this product</b> <b>(Applicable in the European Union and other European countries with separate collection systems)</b>	
	<p>On the end of the life, the present product <u>mustn't</u> be eliminated as urban refusal, but it must be eliminated in a separated collection.</p> <p>If the product is eliminated in unsuitable way, it is possible that some parts of the product (for example some accumulators) could be negative for the environment and for the human health.</p> <p>The symbol on the side (barred dustbin on wheel) denotes that the products mustn't throw into urban refuses container but it must be eliminated with separate collection.</p> <p>In case of abusive elimination of this product, could be foreseen sanctions.</p>