EN

hf Surg® Smart

HIGH FREQUENCY SURGICAL EQUIPMENT

USER MANUAL

HAGER WERKEN

CE 0051

SUMMARY

IMPORTANT

These instructions are a fundamental part of high-frequency surgery equipment, as they describe its operation and use; therefore, they must be read carefully before starting the installation and use of the equipment.

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

If you need Technical Assistance, contact LED SpA.

Produttore / *Manufacturer*

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

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INTRODUCTION

GENERAL DESCRIPTION

hf Surg Smart is an electro-surgical equipment suited to deliver current for monopolar cut, cut-coagulation and coagulation.
The types of surgical operation which can be carried out are that where monopolar minor electrosurgical cutting or coagulation is requested.
Power output can be active through single footswitch command.
The most advanced electronic components and circuitry including LSI microcontrollers are applied to provide all the prerequisite for safe and reliable operation.
Control of the unit is via the front panel knob, keys, and display; mains inlet and on/off switch are on the rear panel.
The units have automatic control systems that, monitoring the internal parameters, signal the possible damages/errors that are found.
The operational parameters that are used are constantly stored so that, every time the unit is switched on or the operative method is changed, the last utilized parameters are recalled.
With the device is possible to use single plate neutral reference electrodes.

INTENDED USE/ FIELDS OF APPLICATION

Medical device intended for temporary use for surgical operations in which cutting and/or coagulation of soft tissues is required, with a monopolar and/or bipolar technique, for survey minor and/or major in open and/or intra-operative percutaneous and/or endoscopic and/or laparoscopic.

The **hf Surg Smart** equipment is designed to be used in the following sectors:

Description	hf Surg Smart
Electrosurgery unit code	HAW10100.051
Casualty Surgery	●
Dermatology	●
Dental	●
Endoscopy	-
Gastroenterology	-
General Surgery	-
Gynaecology	-
First Aid	●
Neurosurgery	-
Orthopaedics	-
Otorhinolaryngology	-
Paediatric Surgery	-
Plastic Surgery	-
Pneumology	-
Thorax Surgery	-
Trans Urethral Resection (TUR)	-
Urology	-

● = Usable
- = Not Usable

INTENDED USER

Device for professional use. Use of the equipment is restricted to medical personnel with medical degrees specializing in high frequency electrosurgery.

INTENDED PATIENT POPULATION

The device is intended for use in adult patients — both male and female — aged 18 years and older, except for those listed under the *CONTRAINDICATIONS* section. Where appropriate, the device may also be used in paediatric patients. In such cases, its use must comply with the specific indications and instructions provided by qualified medical professionals specializing in high frequency electrosurgery. The decision to apply the device in the paediatric population shall remain at the discretion of the attending physician, based on clinical judgement and the nature of the planned surgical procedure.

STANDARD AND OPTIONAL COMPOSITION

Code	Description	Hf Surg Smart
-	Electrosurgical unit code	HAW10100.051
00100.03	Power supply cable 2m SIE-IEC	■/1
00202.00	Holter for Handle and Electrodes	■/1
00206.00	PENCIL - Handle without finger switches	■/1
00304.00	Waterproof footswitch	■/1
00404.02	CONNECTION - Cable for rod neutral electrode	■/1
00403.01	NEUTRAL - Rod neutral electrode	■/1
00500.00	ELECTRODE - Kit of assorted electrodes(10pcs) 5cm	■/1
00100.00	Power cable 2MT IT-IEC	○
00100.01	Power cable 5MT SIE-IEC	○
00100.04	Power cable 2MT USA-IEC	○
00100.05	Power cable 2MT GB-IEC	○
00100.07	Power cable 2MT BR-IEC	○
00100.09	Power cable 2MT AU-IEC	○
00100.10	Power cable 5MT JP-IEC	○
00201.02	PENCIL - Autoclavable micro-needle handpiece	○
00206.40	PENCIL – Monopolar handpiece ⌀ 4mm	○
00304.04_S	Waterproof footswitch	○
00304.PO	Protection for single footswitch	○

Code	Description	Hf Surg Smart
00400.00	Rod Neutral Electrode with Cable	○
00401.01	NEUTRAL - Neutral metal electrode 240x160mm with cable	○
00401.02	NEUTRAL - Neutral metal electrode 120x160mm autoclavable	○
00401.03	NEUTRAL - Neutral metal electrode 240x160mm autoclavable	○
00401.10	NEUTRAL – FLEX Neutral Electrode	○
00401.11	NEUTRAL – FLEX neutral electrode with cable	○
00401.12	NEUTRAL – FLEX neutral electrode with cable autoclavable	○
00403.02	NEUTRAL – Rod Neutral electrode ⌀ 20 mm	○
00402.00	CONNECTION – Monopolar cable M4-F4	○
00402.01	CONNECTION – Monopolar cable M4-F2,8	○
00402.02	CONNECTION – Monopolar cable M4-MP4	○
00402.03	CONNECTION – Monopolar cable M4-EU	○
00402.04	CONNECTION – Monopolar cable M4-F2÷2,8 mm	○
00404.08_S	CONNECTION - Cable for neutral electrode 5365/6429/FLEX	○
00404.09	Connection cable for neutral electrode 5365/6429/FLEX/FLEX S Autoclavable	○
00404.10	CONNECTION – cable for neutral plate US type	○
00404.11	CONNECTION – cable for neutral plate US type AUTOCLAVE	○
00498.06	Adapter for neutral electrode 6,3mm/Valley	○
00500.00/L	ELECTRODE - Assorted Electrode Kit (10Pcs) 10cm	○
152-110	ELECTRODE - Blade electrode 7 cm	○
152-112	ELECTRODE - Curved blade electrode 7 cm	○
152-115	ELECTRODE - Blade electrode 16 cm	○
152-120	ELECTRODE - Needle electrode 7 cm	○
152-122	ELECTRODE - Curved needle electrode 7 cm	○
152-125	ELECTRODE - Needle electrode 13 cm	○
152-130	ELECTRODE - Ball electrode ⌀ 2mm 6 cm	○
152-132	ELECTRODE - Curved ball electrode ⌀ 2mm 6 cm	○
152-140	ELECTRODE - Ball electrode ⌀ 3mm 6 cm	○
152-142	ELECTRODE - Curved ball electrode ⌀ 3mm 5 cm	○
152-145	ELECTRODE - Ball electrode ⌀ 3mm 14 cm	○
152-150	ELECTRODE - Ball electrode ⌀ 4mm 6 cm	○
152-175-10	ELECTRODE - Loop electrode 10x10 l.15 cm	○

Code	Description	Hf Surg Smart
152-190-13	ELECTRODE - Loop electrode 20x13 l.15 cm	○
152-190-20	ELECTRODE - Loop electrode 20x20 l.15 cm	○
152-195	ELECTRODE - Conization electrode 13 cm	○
500500.L1	ELECTRODE - Straight Fine Wire Electrode (5Pcs) 5cm	○
500500.L1/L	ELECTRODE - Straight Fine Wire Electrode (5Pcs) 10cm	○
500500.L10	ELECTRODE - Angled Ball Electrode ⌀ 3mm (5Pcs) 5cm	○
500500.L10/L	ELECTRODE - Angled Ball Electrode ⌀ 3mm (5Pcs) 10cm	○
500500.L11	Electrode for Microsurgery (10Pcs)	○
500500.L2	ELECTRODE - Fine Wire Angled Electrode (5Pcs) 5cm	○
500500.L2/L	ELECTRODE - Fine Wire Angled Electrode (5Pcs) 10cm	○
500500.L3	ELECTRODE - Loop electrode ⌀ 4mm (5Pcs) 5cm	○
500500.L3/L	ELECTRODE - Loop electrode ⌀ 4mm (5Pcs) 10cm	○
500500.L4	ELECTRODE - Loop electrode ⌀ 8mm (5Pcs) 5cm	○
500500.L4/L	ELECTRODE - Loop electrode ⌀ 8mm (5Pcs) 10cm	○
500500.L5	ELECTRODE - Angled Hook Electrode (5Pcs) 5cm	○
500500.L5/L	ELECTRODE - Angled Hook Electrode (5Pcs) 5cm	○
500500.L6	ELECTRODE - Angled Thick Wire Electrode (5Pcs) 5cm	○
500500.L6/L	ELECTRODE - Angled Thick Wire Electrode (5Pcs) 10cm	○
500500.L7	ELECTRODE - Drip electrode (5Pcs) 5 cm	○
500500.L7/L	ELECTRODE - Drip Electrode (5Pcs) 10cm	○
500500.L8	ELECTRODE - Loop electrode (5Pcs) 5 cm	○
500500.L8/L	ELECTRODE - Loop Electrode (5Pcs) 10cm	○
500500.L9	ELECTRODE - Straight ball electrode ⌀ 3mm(5Pcs) 5cm	○
500500.L9/L	ELECTRODE - Straight ball electrode ⌀3mm(5Pcs) 10cm	○
500500.L11	ELECTRODE – Microsurgery Electrode (10Pcs)	○
0350	Disposable Neutral Electrode (F7805)	○
5365A	NEUTRAL - Neutral electrode	○
6429A	NEUTRAL - Neutral metal electrode 240x160mm	○
F7520	Electrode cleaning sponge 47x50mm	○
TR003	Trolley 3 shelves	○
TR003W	Trolley 3 shelves wide	○
TR004	Trolley 4 shelves	○
TR005	Trolley 5 shelves	○
TR005W	Trolley 5 shelves wide	○
TRDRAWER01	Drawer for trolley type TR	○
TRDRAWER01W	Drawer for trolley type TR W	○

■/pcs = STANDARD ○ = OPTIONAL

ELECTROPHYSICAL PRINCIPLES

In electrosurgical interventions the traditional use of surgical blade is substituted by an electrosurgical needle that allows for fast and effective cut and coagulation of the targeted tissue.
The electrosurgical needle operates on the principle of converting electrical energy into heat and consists of the following components:

- A radiofrequency sinusoidal oscillator (0.4 - 4MHz).
- A wave packet generator with a packet repetition frequency of 15 – 30 kHz.
- A mixer for transferring the waveform to the power amplification block, either for cutting, coagulation, or a signal obtained from an appropriate combination of the two.
- A power amplifier block capable of supplying the required power in terms of current and transmitting the amplified signal to the electrodes through a transformer.
- A safety circuit for the return electrode, designed to detect any cable interruptions and deactivate the radiofrequency delivery.
- A specially shaped active electrode (handpiece).
- A return electrode (neutral) that completes the circuit through the patient.

Electric current flowing through biological tissue usually can cause:

1. *Joule Effect*
2. *Faradic Effect*
3. *Electrolytic Effect*

1. *Joule Effect*
   In biological tissue, when passed through by the electric current delivered by the electrosurgical scalpel, heating (Joule effect) is produced, which is dependent on tissue-specific electrical resistance, current density, and application time and can result in various cellular transformations.

$$Q = I^2 x\ R\ x\ T$$

The influence of the thermal effect (Joule effect) is realized by:

- **Current Intensity and output power**
- **Modulation level**
  Parameters that can be interpreted from the waveform of the high-frequency current produced by the generator.
- **Electrode shape**
  Pointed or rounded as required, it is very small in size; therefore, the current density on the tip surface [$A \cdot m^{-2}$] is very high. Thin-section electrodes create a 'high current density, and high temperature, promoting cutting action. Those with a large surface area create a lower current density, and lower temperature, realizing a coagulation effect.
- **State of active electrode**
  Thermal effects can be related to the resistance of the human body to which the contact resistance of the electrode must be added. It is essential to keep the active electrodes perfectly clean in order not to have a reduction in the effects.
- **Characteristics of the tissue**
  The resistive characteristics change according to the biological tissues.

Biological Tissue (range from 0,3 to 1 MHz)	Metals
Blood 0,16 x 10^3 Ω	Silver 0,16 x 10^{-5} Ω
Muscle, kidney, heart 0,2 x 10^3 Ω	Branch 0,17 x 10^{-5} Ω
Liver, spleen 0,3 x 10^3 Ω	Gold 0,22 x 10^{-5} Ω
Brain 0,7 x 10^3 Ω	Aluminium 0,29 x 10^{-5} Ω
Lung 1,0 x 10^3 Ω	
Fat 3,3 x 10^3 Ω	

(Example of specific resistances of organic and metallic materials)

Based on the temperature achieved and according to the pulse forms used, different techniques of using radiofrequency current on the human body are recognized as follows:

- Coagulation
  Temperatures of 60 to 70 °C in the area around the active electrode cause slow heating of the intracellular fluid, the water contained in the cell evaporates, and a clotting action is achieved that stops bleeding.
- Cut
  Temperatures above 100 °C in the area surrounding the active electrode result in the vaporization of the intracellular fluid and explosion of the cell. The vapor present around the electrode triggers an intercellular chain reaction in the direction in which the active electrode is handled, also transmitting the vaporization energy to the immediately surrounding tissues. Electrotomy is, therefore, not mechanical resection. If the temperature reaches 500 °C, tissue carbonization occurs with a cauterizing action.
- Mixed currents
  These are obtained by combining the effects of coagulation and electrotomy. A reduction in bleeding occurs during a cutting procedure, or as a cut that develops a substantial layer of eschar.
  The high frequencies used by the electrosurgical scalpel, however, do not allow the electromagnetic field to penetrate matter and cause the current to flow through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the centre of the conductor's cross-section. This effect, called the 'skin effect,' results in a decrease in the useful cross-sectional area for the passage of a current, and an increase in the electrical resistance of the material, and becomes a major problem in the neutral electrode. In fact, in this electrode the current density is very high (KA/m^2) at the edge, where excessive temperature rise due to the 'Joule effect' causes burns to the patient. Therefore, it is no accident that burns to the patient, which has occurred in surgical procedures, have the

shape of the edge of the neutral electrode. To reduce the risk of burns, it is necessary to dose the delivered power ($I^2 \cdot t$) appropriately and follow the rules for applying the neutral electrode to the patient (see *SAFETY* chapter).

2. *Faradic Effect*

Pulsed electric current causes neuro-muscular stimulation, originating from the stimulation of the physiological process of ion exchange, which is responsible for the transmission of stimuli that cause muscle spasms and cardiac phenomena of extrasystole and ventricular fibrillation.

The effect of these stimuli is known as the faradic effect and is expressed by:

$$R = I / \sqrt{F}$$

The physiological system of stimulus transmission follows a limiting curve in which pulsed or low-frequency currents generate a pacing pulse. With the high-frequency alternating current (above 200 kHz), which is used in electrosurgery, there are no neuromuscular reactions (the change of polarity is so fast that it does not affect the patient at the level of neuro-muscular reactions), let alone electrolyte damage to the body.

For this reason, all high-frequency generating equipment for surgical use (electrosurgery) works on base frequencies above 300 kHz so as not to introduce electrical stimulation.

3. *Electrolytic Effect*

The use of high-frequency currents reduces the electrolytic effect (ionic separation) in tissues due to the very short unidirectional conduction period of the current.

OPERATIVE TECHNIQUES

MONOPOLAR CUT

Monopolar cutting is the sectioning of biological tissue obtained from the passage of current, high frequency; high density concentrated by the tip of the active electrode. The high-frequency current applied to the tissue, through the tip of the active electrode, creates intense molecular heat in the cells that causes them to explode. The cutting effect is achieved by moving the electrode through the tissue destroying the cells one after another. The movement of the electrode prevents the propagation of lateral heat in the tissue, thus limiting destruction to a single cell line. The best current for cutting is the pure sinusoidal without any modulation, this, in fact, cuts with great precision producing the minimum thermal effect, with little haemostasis. Since its effect can be precisely controlled, it can be used safely without damage to the bone. Good coagulation during cutting is one of the main benefits of using electrosurgery, so a current with a certain degree of modulation is desirable.

The following rules help the operator to get a good cut:

- Keep the tissues moist but not wet.
- Survey the stroke before activating the electrode.
- Keep the electrode perpendicular to the tissue.
- Activate the electrode before contacting the tissue
- Maintain clean the electrode's tip (the optional sponges F7520 to clean the electrodes are usable).
- Wait at least five seconds before to repeat a stroke.

When the output power is properly set there should be:

- no resistance to the electrode movement through the tissue.
- no change in the cut surfaces colour.
- no fibres of tissue remained onto the electrode.

MONOPOLAR COAGULATION

Monopolar coagulation is the haemostasis of small blood vessels of body tissue through the passage of high-frequency current at the active electrode. When the current density is reduced and a large surface electrode is used, to dissipate energy over a larger area, the effect is to dry the surface of the cells, without deep penetration, resulting in coagulation. These coagulated cell surfaces act as an insulating layer, which prevents heat from subsequent current applications from penetrating too deep. The current normally used for coagulation is modulated. Depending on the percentage of modulation, there is precision of the cut, goodness of haemostasis and degree of tissue destruction. A greater modulation of the current leads to a more jagged cut, to a greater depth of destroyed tissue but to a more effective coagulation.

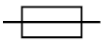
The following rules help the operator to achieve good coagulation:

- Select a ball or heavy wire electrode.
- Locate the bleeder, after having wiped the excess blood from the area, contact lightly the bleeder before activating the electrode.
- Stop the electrode activation as soon as the tissue blanches to avoid tissue damage.
- Maintain clean the electrode's tip (the optional sponges F7520 to clean the electrodes are usable).

MEANING OF GRAPHIC SYMBOLS

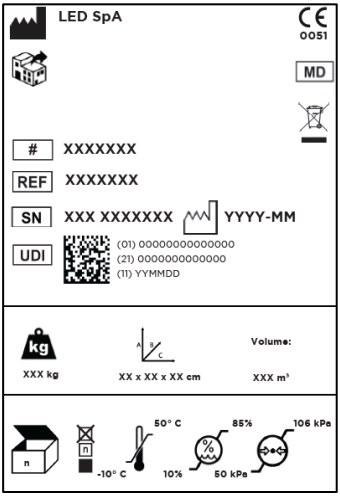
In accordance with international standards ISO 15223-1:2021 'Medical devices - Symbols to be used in information to be provided by the manufacturer' and ISO 780:2015 'Packaging - Packaging for distribution - Graphic symbols for handling and storage of packaging', all symbols on device labels and secondary packaging (cardboard box) must comply with the applicable regulatory requirements.

N°	SYMBOL	DESCRIPTION
1		Floating neutral electrode: not connected to ground at either high or low frequencies.
2		CF Class equipment protected against defibrillator-induced discharge.
3		Non-ionising radiation generator equipment.
4		Follow the instructions for use.
5		CE Mark (2017/745/EU) + Notified Body Number 0051 = IMQ Italy.
6		The product should not be disposed of in urban waste containers but must be disposed of through separate collection.
7		Manufacturer.
8	SN	Serial Number.
9		Production date.
10	UDI	Unique Device Identification.
11	MD	Medical Device.
12		Dealer.
13		No maintenance by the user.

N°	SYMBOL	DESCRIPTION
14		Catalogue number (Code).
15		Temperature Limits.
16		Humidity Limits.
17		Atmospheric Pressure Limits.
18		This Way Up.
19		FRAGILE – Handle With Care.
20		Keep away from sunlight.
21		Protect against moisture.
22		Number of maximum stackable packages.
23		Weight.
24		Dimensions.
25		Number of Pieces.
26		Recycle.
27		Model/Trade Name.
28	IP	Protection against harmful ingress of water or particulate matter.
29		Fuse.
30		Distribution packaging must not be overturned or tipped over.

BOX LABEL

With reference to ISO 15223-1:2021 "Medical devices - Symbols for use with medical devices, labels, labelling and information to be provided" and ISO 780:2015 "Packaging - Packaging for distribution - Graphical symbols for handling and storage of packages" on the unit packaging label on the package the following indications are given:



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) - **MANUFACTURING DATA**

BOX WEIGHT

BOX DIMENSIONS

BOX VOLUME

ISO 7000 (No. 2403) - **STACKING LIMITS BY NUMBER**

EU REGULATION 2017/745 (MDR) - **CE MARK WITH NOTIFIED BODY NUMBER**

ISO 15223-1 (5.7.7) - **MD (MEDICAL DEVICE)**

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**

CONTRAINDICATIONS

Electro surgery is contraindicated in the following subjects:

- having pacemaker.
- with stimulating electrodes.
- with metal prosthesis plant.
- with important arterial pressure unbalance.
- with important nervous disorders.
- with renal insufficiency.
- in state of pregnancy.

Burns are the most consequences of the HF electro surgery for the patient, even if these are not the only one. In fact, necrosis by compression, allergic reactions to the disinfectant, gas or inflammable liquids ignition.
Some important causes of burns are by:

- insufficient medical equipe training about all modalities to avoid or reduce the risks of burns by using HF electrosurgical units.
- use of disinfectants with high alcohol content.
- incorrect position of the patient during the electrosurgical operation.
- contact between active electrode and the skin.
- contact with liquid.
- long application of HF currents.
- incorrect application of the patient-plate.

To avoid or reduce the common HF electrosurgical risks it is very important to respect the rules and safety measurements exposed illustrate on the next chapter.

SAFETY

WARNING: Electro-surgery can be dangerous. Careless use of any element in the electrosurgical system may subject the patient to a serious burn. Read and understand all warnings, precautions, and directions for use before attempt to use any active electrode. 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 electrosurgical units; the user must check, before connecting other accessories to this unit, that they have characteristics of insulation compatible with those of this unit and utilized function (see Technical Characteristics).
You must inspect the integrity of the packaging of the sterile products.

ATTENTION

- **DO NOT USE** on patients with electronic implants such as cardiac pacemakers without consulting a qualified professional (e.g., a cardiologist). There is a potential risk of interference with the functioning of the electronic implant or damage to the implant itself.
- **DO NOT USE** in the presence of flammable anaesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or near volatile solvents (such as ether or alcohol) as explosions may occur.
- **DO NOT PLACE** instruments near or in contact with flammable materials (such as gauze or surgical drapes). Activated or heated instruments can cause fires.
- When not in use, store instruments in a clean, dry, and highly visible area away from direct patient contact. Inadvertent contact with the patient can result in burns.

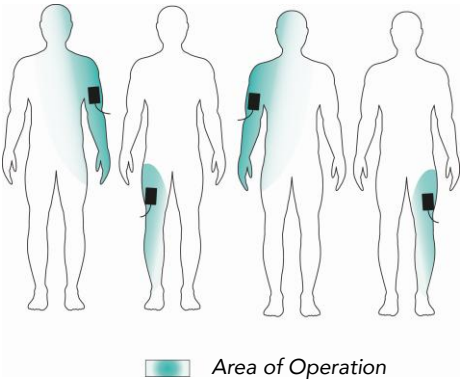
- INSPECT instruments and cables for damage before each use, especially the insulation of laparoscopic/endoscopic instruments. This inspection can be carried out visually under magnification or with a high-voltage insulation testing device. Insulation failures can lead to burns or other injuries to the patient or the operator.
- The surface of the active electrode may remain sufficiently hot to cause burns even after RF current is deactivated.
- Due to concerns about the potential carcinogenic and infectious properties of electrocautery byproducts (such as tissue smoke plumes and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Only connect adapters and accessories to the electrosurgical unit when the power is OFF. Failure to do so may result in patient or operating room personnel injury or electric shocks.
- If the device is powered with argon, warnings regarding gas embolisms must be included.
- If the instrument is reusable, a warning should be included that visual inspection alone may not be sufficient to ensure intact insulation.
- DO NOT ACTIVATE the instrument when it is not in contact with the target tissue, as this could cause injuries due to capacitive coupling with other surgical equipment.
- ASPIRATE fluids from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in proximity to an active electrode can carry electrical current or heat away from the target tissues, potentially causing unintended patient burns.
- DO NOT USE with hybrid systems, i.e., a combination of metal and plastic, when using monopolar active components. This can result in burns at alternative sites due to capacitive coupling. Use only all-metal or all-plastic systems.

- Before increasing the intensity, verify the adhesion of the neutral electrode and its connections. Apparent low power or device malfunction at normal operating settings may indicate improper neutral electrode application or poor contact in its connections.
- This unit has a CQM system; please note that the loss of secure contact between the neutral electrode and the patient will not trigger an alarm unless a compatible monitoring neutral electrode (split neutral electrode) is used.
- CAUTION: Set the intensity to the lowest level necessary to achieve the desired effect.
- CAUTION: Keep the active electrodes clean. Accumulated eschar may reduce the tool's effectiveness. Do not activate the instrument during cleaning. Operating room personnel may be injured.
- Any serious incidents related to the device must be reported to LED SpA, via Selciatella 40 04011 Aprilia (LT) Italy, and the competent authority:
  Ministero della salute – Direzione generale dei dispositivi medici e del servizio farmaceutico
  Viale Giorgio Ribotta, 5 – Roma
  E-mail: segr.dgfdm@sanita.it
  Tel.: +39 06 5994 3199 / +39 06 5994 3207

PRECAUTIONS

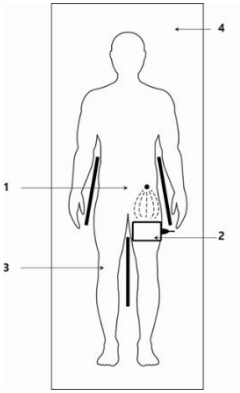
The following precautions are crucial for minimizing the risk of inadvertent burns:

- Ensure the secure and complete attachment of the neutral electrode to the patient's body, preferably at the extremities and as close to the surgical site as possible. Avoid connecting the neutral electrode to bony protrusions, prosthetic devices, areas with scar tissue, regions susceptible to fluid accumulation, or areas with a thick layer of subcutaneous fat. The application site should be free from hair, dry, and clean. Avoid using alcohol for skin cleaning. Except for veterinary medicine applications, refrain from using electrode gel.



- When using single-use neutral electrodes, always adhere to the provided expiry dates.
- For multi-use electrodes, ensure that the fixation systems in place guarantee stability during use.
- When applying the neutral electrode, avoid a transverse path and instead favour a vertical or diagonal path, especially when using a bipartite neutral electrode. This helps distribute current evenly across the surface of the neutral electrode and reduces the risk of patient burns.

- To prevent the patient from coming into contact with earthed metallic parts or components with significant grounding capacity (such as an operating table or supports), use an antistatic drape for this purpose.
- To avoid skin-to-skin contact (e.g., between the arm and trunk, between the legs, or on the breasts), insert dry gauze. Additionally, ensure that body areas prone to profuse sweating are kept dry.



1. *Active Electrode* – **2.** *Neutral Electrode*
3. *Dry Gauze* – **4.** *Antistatic Drape*

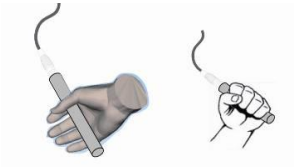
- When using both an electrosurgical scalpel and a physiological monitoring device on the same patient, place all monitoring electrodes as far away from the surgical electrodes as possible. Needle monitoring electrodes are discouraged. In any case, use monitoring systems that incorporate high-frequency current-limiting devices.
- Position surgical electrode cables in a manner that prevents contact with the patient or other conductive materials. Active electrodes that are not in use should be isolated from the patient.
- Set the output power level to the lowest effective setting for the intended purpose, minimizing the risk of excessive tissue damage.
- If the electrosurgical unit exhibits an obvious low output level or operates incorrectly, even when set up for normal power delivery, this could indicate

issues with the application of the neutral electrode or poor contact in the neutral electrode connections. Therefore, it is essential to verify the proper placement and connections of the neutral electrode before considering higher power settings.

- Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N_2O) and oxygen, especially in chest or head operations, unless they can be safely aspirated. Whenever possible, opt for non-flammable substances for cleaning and disinfection purposes. If flammable substances are used for cleaning, disinfection, or as solvents for adhesives, they should be allowed to completely evaporate before using the electrosurgical unit. There is a risk of flammable solutions accumulating under the patient or in cavities like the umbilicus and vagina. Any fluid in these areas should be removed before using the device. It's important to consider the presence of endogenous gases as well.
- Be aware that certain materials, such as cotton wool or gauze impregnated with oxygen, may ignite due to sparks produced by the appliance under normal conditions. Take necessary precautions to prevent such incidents.
- Patients with pacemakers or pacing electrodes are at risk of interference with their pacemaker's functionality or potential pacemaker damage when exposed to electrosurgical equipment. If any uncertainty arises, consult the cardiology department.
- Electrosurgical equipment emits high-frequency energy radiation that can affect other medical devices, unrelated electronics, telecommunications systems, and navigation systems. To prevent interference, you must maintain a minimum distance of at least 1.5 meters between the electrosurgical equipment and other devices.
- Regularly inspect accessories, with special attention to electrode cables and any endoscopy accessories, to ensure there is no damaged insulation or other defects that could compromise their safety or effectiveness.
- To connect accessories compatible with the equipment's characteristics, you must compare the insulation characteristics of the accessories (information

provided by the manufacturers) with the specifications of the supplied unit (as outlined in the *TECHNICAL CHARACTERISTICS* section). This step ensures proper compatibility and safe operation.

- **Caution**: Equipment failure could lead to an inadvertent increase in power output.
- Stimulation of the patient's muscles or nerves can be caused by low-frequency currents originating from electrical sparking between the electrodes and the patient's tissue. If neuromuscular stimulation occurs, stop surgery and check all connections to the generator. If the problem is not resolved in this way, the generator must be inspected by qualified personnel for maintenance.
- If a rod neutral electrode is used, it must be held solid in patient's hand.



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 connecting 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 allowed. Should their use become necessary it is mandatory to use only simple or multiple adapters 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 heatsink.
- 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.
- The device 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 cannot 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.
- 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 center 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.
- Do not reduce or disable the audible signal warning the activation of the generator. A functioning activation signal can minimize or prevent patient or staff injury in the event of accidental activation.
- Avoid verifying the functioning of the unit by shorting the active electrode with the reference one or the active electrode with metallic parts.
- If necessary, use a smoke-plume extraction system.

WARNING: When the electrosurgical unit is used in operating rooms it is necessary to just use waterproof footswitches (REF 00304.00 Waterproof pedal with single switch).

SAFETY FOR THE PATIENT

During the HF electrosurgical operations, the patient is a conductor of electrical voltage against earth potential. So, if there is a contact between patient and electrically conductive objects (metal, wet clothes, etc..), in the contact's point could be electrical current that causes thermal necrosis. So, you must inspect the equipment and its accessories before using and to respect all safety rules.

CORRECT POSITION OF THE PATIENT

It is important to avoid any intention or accidental contact between patient and grounded metallic parts and to make sure that:

- The patient is not in contact with metallic parts (operative table, supports).
- The flexible tube of the respirator does not touch the body of the patient.
- On the operative table with grounded connection there are always coatings that allow to discharge the electrostatic charges.
- The patient is on a thick basic tissue with insulating properties, covered by enough nets.
- The patient is not in contact with nets or wet mattress.
- The eventual organic secretions and the cleaning and other liquids do not wet the nets.
- There are not liquid under the patient.
- Urinary secretions are eliminated by the catheters.

- The body zones characterized by a higher sweating, the extremities in direct contact with trunk or the points of skin-skin contact are dried by the net's interposition (arm/trunk, leg/leg, breast, skin folds, etc.).
- All conductive and grounded supports, stirrups, are correctly insulated.
- Control the anaesthetics quantity to avoid a great sweat.

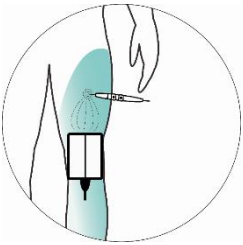
CORRECT POSITION OF THE NEUTRAL ELECTRODE

In monopolar electrosurgery, the use of a neutral electrode, also known as a current leakage plate, is essential. It facilitates the safe return of the cutting or coagulation current to the electrosurgical unit. There are two types of neutral electrodes:

1. **Neutral Electrode Monopartite** in which there is no control over the neutral-patient electrode contact.
2. **Bipartite Neutral Electrode** in which there is neutral-patient electrode control.

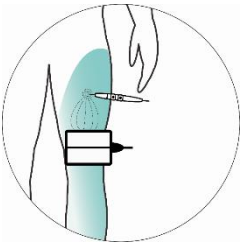
Ensuring the correct placement of the neutral electrode is of utmost importance to prevent burns and minimize patient risks. Below are some valuable tips to achieve this:

1. ***Correct positioning***



In the image alongside, the correct positioning of the split neutral electrode is illustrated. The patient-plate should be placed perpendicular to the surgical field. Avoid positioning it transversely and instead, prefer a vertical or diagonal orientation. This promotes a uniform distribution of the current over the surface of the neutral electrode, minimizing the risk of burns to the patient.

2. *Incorrect Positioning*



In the image alongside, the incorrect positioning of the split neutral electrode is illustrated. The parallel arrangement between the patient-plate and the surgical field causes a non-uniform distribution of current across the two surfaces of the neutral electrode, potentially leading to alarm notifications on the unit and preventing the correct activation of the device.

For both single-part and dual-part electrodes, before proceeding with the placement of the neutral electrode, clean and remove any residues of foreign substances from its surface.

Do not apply the neutral electrode on scars, bony prominences, or anatomical areas where prosthetic implants or monitoring electrodes are present. Instead, apply it on well-irrigated tissues, such as muscles and in proximity to the surgical site.

If a disposable neutral electrode is being used, adhere to the expiration dates. If a reusable neutral electrode is used, ensure that the fastening systems provide stability.

It is of paramount importance that the neutral electrode is firmly applied over its entire surface to prevent burns. When a neutral electrode partially detaches from the patient, the current density in the remaining electrode area increases. As the current density beneath the neutral electrode becomes uneven, non-uniform heating occurs, especially at the edges of the neutral electrode.

If the electrode were placed in an area subjected to pressure during the procedure, the compressive load would result in reduced skin perfusion.

Consequently, the generated heat can only be partially dissipated, thereby increasing the risk of burns. Furthermore, there is an increased risk of pressure points (decubitus) formation due to the heating that occurs. This temperature rise leads to a higher demand for oxygen (O_2) and energy in the affected area, contributing to the potential development of pressure areas on the body.

PUTTING INTO SERVICE

- 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 LED SpA or to your own retailer. If the unit is returned to the LED 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). Insert the correct fuses in the module referring to the value written on the label.
- 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 footswitch or the double footswitch (optional) to the connector on the rear panel.
- Connect handle, in the case of use of handle without finger switch it shall be connected on the buckle indicated “ACTIVE”.
- 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:
  Temperature: 10/40°C
  Relative Humidity: 30/75%
  Pressure: 70/106k Pa
- Before using the unit, it is necessary connect the cable to the patient plate, and these connected to unit. The neutral electrode must apply to patient (see Safety chapter). Single plate electrodes and split plate electrodes can be. When the unit is switched on if the value of the impedance is acceptable, the OC indicator light will stop flashing.
- When the unit is switched on, through the on/off switch on the rear panel, after having checked the internal parameters, it will work with the function and the power level utilized during the last switching (when the unit is switched for the first time the level will be 00).

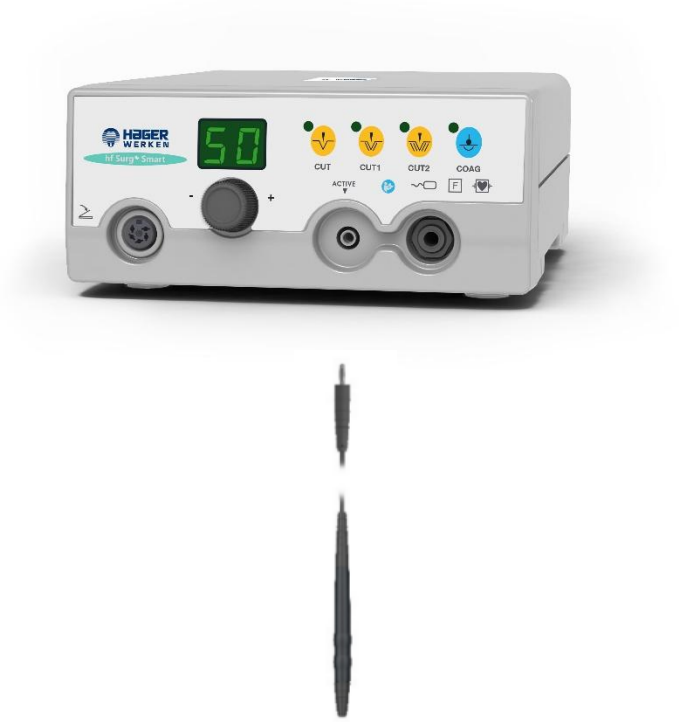
CONNECTION AND USE OF ACCESSORIES

For proper connection of accessories and components, refer to the images below.

1. **Footswitch connector:**

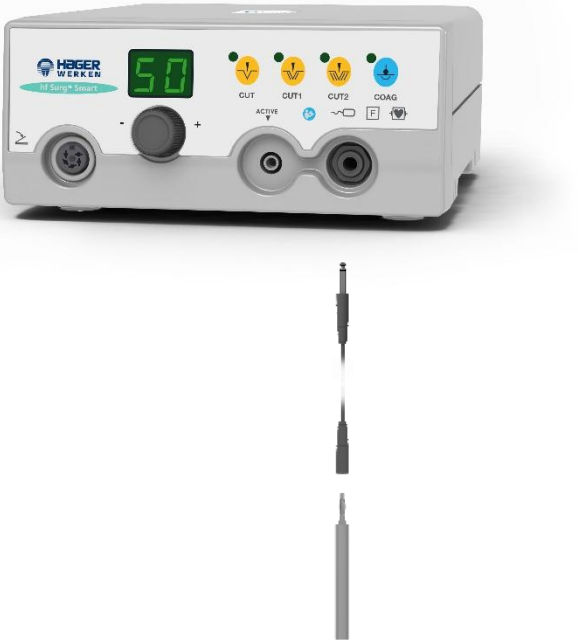
On the left side of the front panel is the socket for connecting the footswitch.

2. Handpiece connector:



On the front panel is the connection point of the handpiece.

3. Neutral electrode connector:



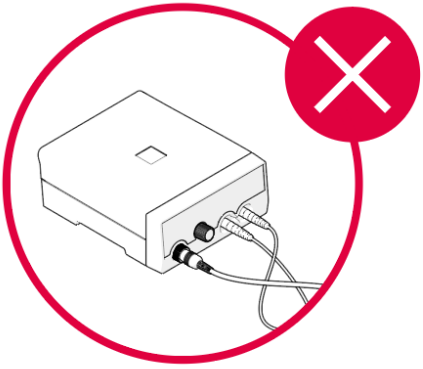
On the front panel is the neutral electrode connection point.

CORRECT CONNECTION OF ACCESSORIES AND/OR COMPONENTS

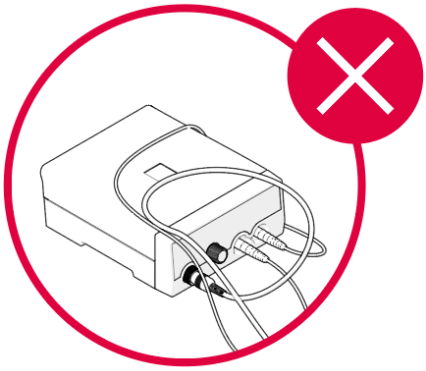
To ensure proper function, safety and durability of the medical device, it is essential to position accessories and/or components properly. Incorrect positioning may impair the efficiency of the device or damage the equipment. Useful information on this is explained below:

1. **Incorrect Positioning**

   The pictures below show two examples of cable misplacement: **cables twisted and/or coiled together,** and **cables twisted and/or coiled on top of the device**.

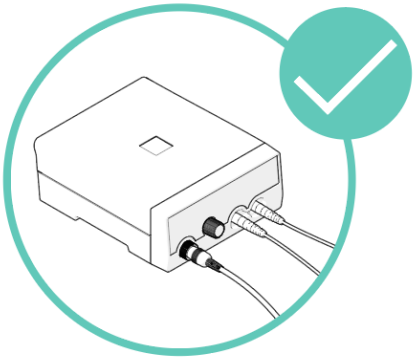


In the first case, cables that are twisted and/or coiled together tend to cause electromagnetic interference that can compromise signal quality, interfering with the accuracy and effectiveness of the device. In addition, the continuous friction and tension created by the braiding increase the wear and tear of the protective sheathing, with the risk of malfunctions.



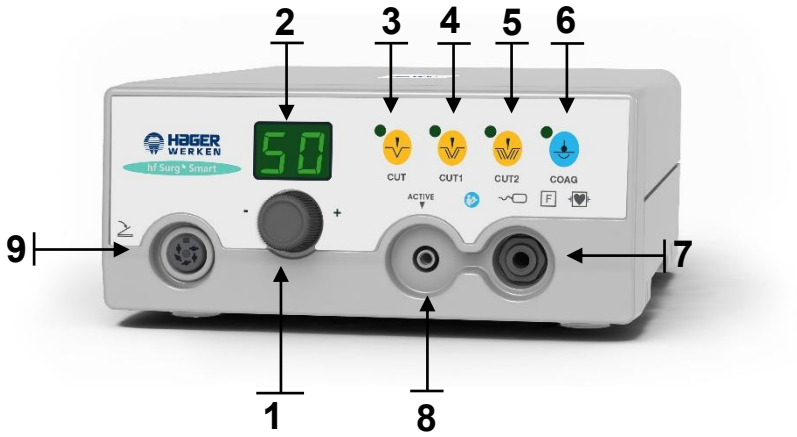
In the second case, twisted and/or coiled cables on top of the device suffer excessive mechanical pressure that can cause tension points and accelerate wear and tears, leading to structural damage. In addition, coiling tends to retain heat, reducing the efficiency and flexibility of cables, making them more vulnerable to long-term damage.

2. Correct Positioning



The illustration opposite shows the correct positioning of the cables. The correct arrangement of the cables requires that they be positioned parallel and well separated from each other. This configuration minimizes the risk of electromagnetic interference and prevents the cables from being damaged by friction or overlapping. Cables arranged in parallel allow for an orderly flow that facilitates maintenance and quick identification of any problems. In addition, an orderly arrangement helps keep the work area safer and free from possible obstacles.

FRONTAL PANEL



1. Knob for output level adjustment
2. 7-segments display output level indicator
3. CUT function selection button
4. CUT 1 function selection button
5. CUT 2 function selection button
6. COAG function selection button
7. Connector for neutral electrode connection
8. Connector for active electrode handle
9. Connector for footswitch

OPERATION MODE

SWITCH ON

When switched on the electrosurgical unit automatically performs a test to establish the correct operation of itself and of the connected accessories as well. In case anomaly is found an alphanumeric message it is shown coded according to the chart codes brought in the chapter *MAINTENANCE*.

This test lasts about 10 seconds. At the end of the control the equipment restores last use operational conditions.

PRESELECTION OF THE DELIVERABLE CURRENT

The deliverable current for the surgical operations can have preselected through push button for:

CUT CURRENT (CUT)

The optimal current for cutting is a pure sinusoidal wave without modulation, meaning it has a duty cycle of 100%. This type of current is suitable for cutting without coagulation.

COAGULATED-CUT CURRENT (CUT 1)

The coagulated-cut current (CUT1) is suitable for coagulated cutting when a moderate level of coagulation along with the cutting action is desired.

COAGULATED-CUT CURRENT (CUT 2)

The coagulated-cut current (CUT2) is suitable for coagulated cutting when a higher level of coagulation along with the cutting action is desired.

COAGULATION CURRENT (COAG)

The modulated COAG current is characterized by its ability to provide effective surface coagulation while also potentially producing eschar and partial carbonization of the tissue. The advantage of this type of coagulation lies in its quick onset and effectiveness.

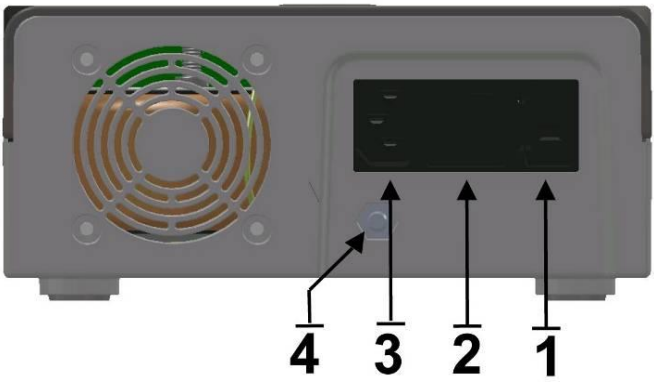
ADJUSTMENT OF THE ACOUSTIC SIGNAL LEVEL

To adjust the emission acoustic signal, follow these instructions:

1. Press and hold the CUT pushbutton while switching on the unit using the mains switch.
2. Once the unit has finished checking internal parameters, the display will show the message "S" followed by the value of the preset level (e.g., S3). You can now release the CUT pushbutton.
3. Use the knob to adjust the emission acoustic level. While adjusting, the sound emitted by the unit will correspond to the preset level.
4. Press the CUT pushbutton to confirm the level.

Level	Sound emission until 1m distance from the frontal panel
S1	55 dBA
S2	60 dBA
S3	65 dBA
S4	70 dBA
S5	75 dBA

BACK PANEL



1. Fuses holder/Voltage selector
2. Power On-Off switch
3. Mains voltage connector
4. Equipotential connector

POWER SUPPLY MODULE AND VOLTAGE SELECTOR

Power supply module is the connection point of mains voltage feeding to the unit. This module is provided with line fuses and the voltage selector.
WARNING: before switch on the unit, operator must 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. When the equipment is powered, the front panel will illuminate. Pressing the

switch in the 0 direction will cut power to the equipment, this operation allows it to be used as an emergency stop switch, in the event of any fault.

TECHNICAL CHARACTERISTICS

Tol.	Description	hf Surg Smart
-	Electrosurgical unit code	HAW10100.051
± 0%	Minimum power selectable	0
-	Power step	1
-	Digital power display	●
±20%	Maximum power CUT (W)	50 → 400Ω
±20%	Maximum power CUT 1 (W)	45 → 400Ω
±20%	Maximum power CUT 2 (W)	40 → 400Ω
±20%	Maximum power COAG (W)	40 → 400Ω
± 5%	Modulation degree CUT	Pure 100%
± 5%	Modulation grade CUT 1 (@10 kHz)	Mod. 90%
± 5%	Modulation grade CUT 2 (@10 kHz)	Mod. 80%
± 5%	Modulation grade COAG (@10 kHz)	Mod. 60%
-0.1 +0.2	Crest Factor CUT	1.5
± 0.3	Crest Factor CUT 1	1.8
± 0.3	Crest Factor CUT 2	2.1
± 0.3	Crest Factor COAG	2.3
± 10%	Working frequency	600 kHz
± 15%	Maximum CUT voltage (Vpp)	1000
± 15%	Maximum voltage CUT 1 (Vpp)	1000
± 15%	Maximum voltage CUT 2 (Vpp)	1000
± 15%	Maximum COAG voltage (Vpp)	1000
± 0.5	Weight (kg)	2.5
± 10	Dimensions LxHxD mm	190x85x239
± 5%	Selectable power supply (Vac)	115 –230
± 1%	Mains frequency (Hz)	50-60
-	Fuses for 230Vac power supply (5x20) Delayed	2x T1AL, 250V
-	Fuses for 115Vac power supply (5x20) Delayed	2x T2AL, 250V
± 10%	Maximum power consumption (VA)	280
-	Fault self-diagnosis	●

Tol.	Description	hf Surg Smart
-	Storage of last settings used	●
-	Electrical classification (EN60601-1)	Class I Applied Part CF
-	MDR Classification 2017/745/EU	II b
-	Protection Class (EN 60529)	IP32
-	Classification EN55011 (CISPR 11)	2 / A
-	(Group/Class)	F
-	Neutral electrode	10 / 30
-	Duty Cycle (action / pause) in seconds	Footswitch
-	Output activation type	●
-	Defibrillator protection	●
-	Equipotential socket	●

● = PRESENT

HARDWARE REQUIREMENTS

Microcontroller	ARM Cortex M4
Clock Frequency	100 MHz
Rom	256 KB
Ram	128 KB
Peripherals	UART, I2C, SPI, Watch-dog timer, USB2.0
Visual	Display 7-segments, mechanical buttons

MAINTENANCE

GENERAL

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, or to another 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 sterilization of the accessory items and checking of the equipment before each use. Carrying out function and safety check for verification of the parameters is demanded to specialize 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 nonabrasive cleanser may be used when necessary.

CLEANING AND STERILIZATION OF THE ACCESSORIES

If disposable non-sterile accessories are used, you must meticulously follow the Instructions for Use (IFU) provided by the manufacturer for the sterilization

method and to dispose of them according to the currently applicable regulations.
In the case of reusable accessories, you must adhere to the maximum number of cycles and the sterilization method specified in the manufacturer's Instructions for Use for each accessory.

GUIDE TO THE SOLUTION OF THE PROBLEMS

In case of problems before all you must 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.
The unit doesn't respond to the command of activation	Breakdown of the pedal. - Wrong connection of the pedal.	Replace the pedal. Verify the connection of the pedal.
Error Code 91	Current delivery control activated during switching on.	Disconnect the pedal and switch on the unit again.
Error Code 94	Error in the data conversion circuit.	Call for Service.
Error Code 95	Error of the reference voltage value.	Verify the main voltage. Call for Service.

REPAIRS

High frequency cables and electrode holder handle 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.

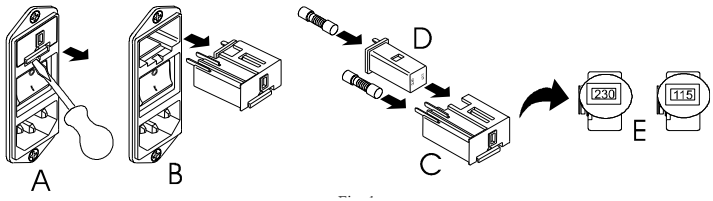
Only use fuse of the kind 5x20; they must have those characteristics: T3.15A (slow) (230Vac mains voltage), T6.3A (115Vac mains voltage), proceed as follows:

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

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

Mains Voltage	110-120 V	Delayed Fuse 2x T2AL, 250V / 5 x 20 mm
Mains Voltage	220-240 V	Delayed Fuse 2x T1AL, 250V / 5 x 20 mm

(D) Extract and rotate the detachable part in way to read the correct voltage in the **(E)** window – reinsert the fuse holder in the module.



CHECKING OF THE EQUIPMENT BEFORE EACH USE

Each time the use of the electrosurgical 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 and sterilized.

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 H.F. output controls.
- Check the uniformity of the resistance through the surface of the patient plate.
- Test the earth conductivity resistance.
- Test the earth leakage current.
- Test H.F. leakage current.
- Control of the neuromuscular stimulation.
- Control of the accuracy of the output power.

DIAGRAMS

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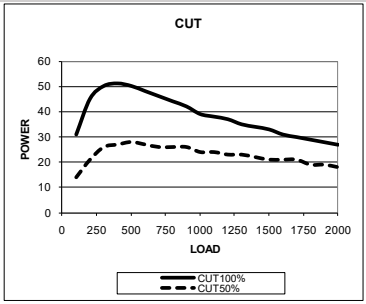
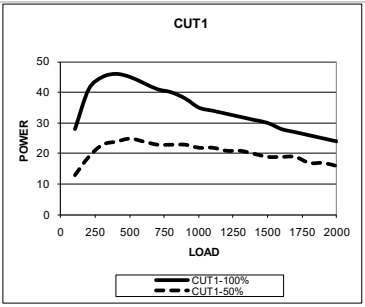
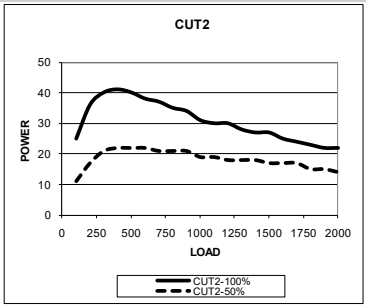


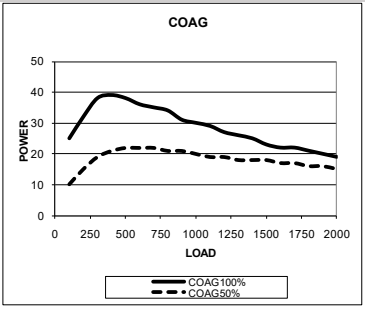
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT



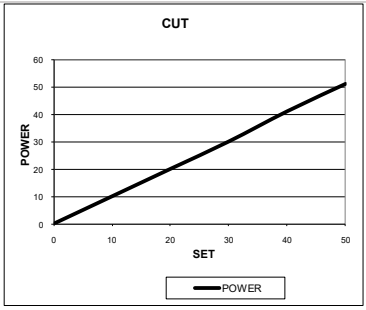
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT1



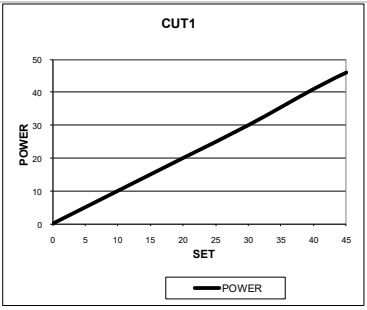
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT2



Diagrams of half and maximum output power versus impedance load 100-2000Ω COAG

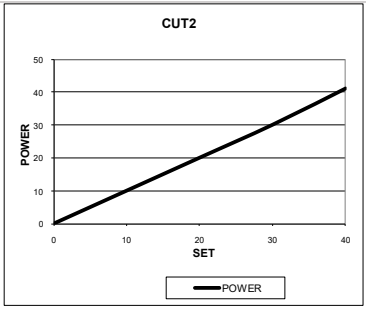


Diagrams of output power CUT versus nominal value

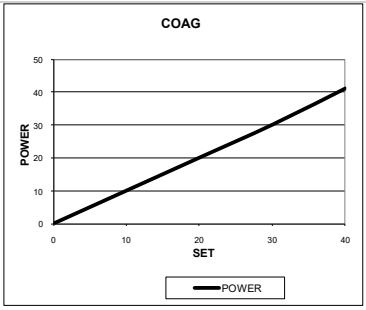


Diagrams of output power CUT1 versus nominal value

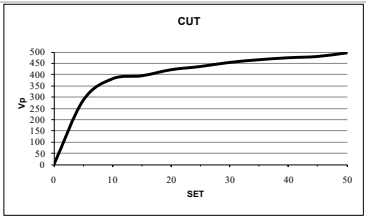
hf Surg Smart



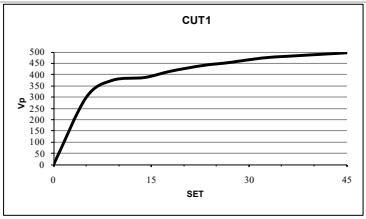
Diagrams of output power CUT2 versus nominal value



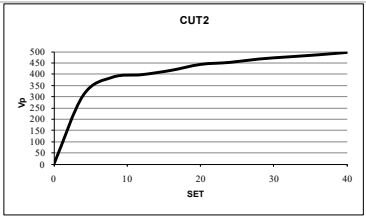
Diagrams of output power COAG versus nominal value



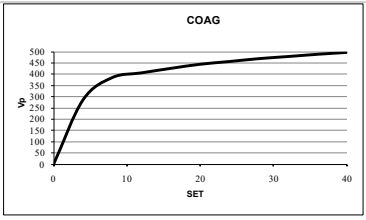
Diagrams of CUT maximum mains voltage output versus Vp



Diagrams of CUT1 maximum mains voltage output versus Vp



Diagrams of CUT2 maximum mains voltage output versus Vp



Diagrams of COAG maximum mains voltage output versus Vp

Information about elimination of this product (Applicable in the European Union and other European countries with separate collection systems).

On the end of the life, the present product mustn't be eliminated as urban refusal, but it must be eliminated in a separated collection.

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.

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.

In case of abusive elimination of this product, could be foreseen sanctions.

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