EN

SURTRON® TOUCH 200

HIGH FREQUENCY SURGICAL EQUIPMENT

USER MANUAL

CE 0051

SUMMARY

IMPORTANT

This instruction manual is an essential part of the HF electrosurgery unit and should be kept available to the user in all circumstances. It is critically important that you carefully read and fully understand all instructions and directions before attempting any use of an active electrode.

It is imperative that you strictly follow all safety warnings and instructions. Please ensure that this documentation is included with the device in case it is transferred to another team.

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

SURTRON® TOUCH 200 is an electrosurgical device suitable for delivering a current for cutting, coagulated cutting and coagulation (with different coagulation levels) in monopolar and bipolar modes. The unit can operate either via active pens, which have buttons for easy activation, or with pens without buttons using a foot control. You can connect bipolar pliers to the unit for bipolar functions.

In addition to the traditional use of the foot pedal, bipolar coagulation can also be achieved via a detection mode called "AUTOSTART" and "AUTOSTOP" in certain devices, using the foot pedal to start the mode. Activation and final coagulation are regulated by the level of impedance in the tissue over time, allowing for automatic activation until the tissue is ideally coagulated, signaling the device to stop clotting. The use of this specific function allows the possibility of performing vascular and venous coagulation through radiofrequency blocking (vessel/artery sealing).

The FLASH TIME mode allows the current to be supplied for the entire activation period or for a time interval that can be preset. The dispensing can be single or continuous and you can adjust the time (seconds or milliseconds) through which to complete the intervals.
There are a total of eighteen different preset operating programs, and each can be easily selected. To do this, just press the program icon. You can create and store your own custom programs (over 50).

Neutral electrodes with a split conductive zone can be used to monitor the stability of the plate-patient impedance during surgery.

The units are controlled via touch keys and display on the front panel; The main entrance is located on the rear panel.

The operating parameters used are constantly stored so that every time the unit is switched on or the operating method is changed, the parameters selected last time are recalled.

During activation and use of the device, the level of the emission sound (beep) may vary; Each operator can choose their level according to the working conditions. The initial activation sound of the device when it is turned on cannot be changed due to safety regulations.

STANDARD AND OPTIONAL COMPOSITION

Code	Description	SURTRON® TOUCH 200
-	Electrosurgical unit code	10100.T40
00100.01	Power supply cable 5m SIE-IEC	■/1
00202.00	Holder for Handle and Electrodes	■/1
00205.00	PENCIL S - Handle with Switch	■/1
00304.00	Water-proof foot switch	■/1
00404.08_S	Cable for connected neutral electrode disposable type / 5365A	■/1
00500.00	ELECTRODE - Kit of assorted electrodes(10pcs) 5cm	■/1
152-110	ELECTRODE - Blade electrode 7 cm	■/3
152-120	ELECTRODE - Needle electrode 7 cm	■/3
152-150	ELECTRODE - Ball electrode ⌀ 4mm 6 cm	■/3
5365A	NEUTRAL - Steel neutral electrode 120x160mm	■/1
F7920	Disposable Split Neutral electrode (F7820)	■/2
00100.00	Power supply cable 2m IT-IEC	○
00100.03	Power supply cable 2m SIE-IEC	○
00100.04	Power supply cable 2m USA-IEC	○
00100.05	Power supply cable 2m GB-IEC	○
00100.07	Power supply cable 2m BR-IEC	○
00100.09	Power supply cable 2m AU-IEC	○
00100.10	Power supply cable 5m JP-IEC	○
00201.02	PENCIL - Handle for microsurgical needle autoclavable	○
00205.40	PENCIL – Handle with switches ⌀ 4 mm	○
00206.00	PENCIL - Handle without switch ⌀ 2,4 mm	○
00206.40	PENCIL – Handle without switch ⌀ 4 mm	○
00304.04_S	Water-proof foot switch	○
00304.PO	Protection for single foot switch	○
00305.03_S	Double water-proof foot switch	○
00306.03_S	Water-proof double foot switch with selector	○
00401.00	NEUTRAL - Steel neutral electrode 120x160mm with cable	○
00401.01	NEUTRAL - Steel neutral electrode 240x160mm with cable	○
00401.02	NEUTRAL - Steel neutral electrode 120x160mm with cable autoclavable	○
00401.03	NEUTRAL - Steel neutral electrode 240x160mm with cable autoclavable	○
00401.10	NEUTRAL – Steel neutral electrode FLEX 210x120 mm autoclavable	○
00401.11	NEUTRAL – Steel neutral electrode FLEX 210x120 mm with cable	○
00401.12	NEUTRAL – Steel neutral electrode FLEX 210x120 mm with cable autoclavable	○
00401.20	NEUTRAL – Steel neutral electrode FLEX S 210x120 mm	○
00401.21	NEUTRAL – Steel neutral electrode 210x120 mm with cable	○
00401.22	NEUTRAL – Steel neutral electrode 210x120 mm with cable autoclavable	○
00402.00	CONNECTION - Monopolar cable M4-F4 3mt	○
00402.01	CONNECTION - Monopolar cable M4-F2.8 3mt	○
00402.02	CONNECTION - Monopolar cable M4-MP4 3mt	○
00402.03	CONNECTION – Monopolar cable M4_EU 3 mt	○

Code	Description	SURTRON® TOUCH 200
00402.04	CONNECTION – Monopolar cable M4-F2÷2,8 mm 3 mt	○
00404.07	Cable for connection neutral electrode F7915/F7930	○
00404.09	Cable for connection neutral disposable 5365-6429	○
00404.10	Cable for neutral plate US type	○
00404.11	Cable for neutral plate US type AUTOCLAVE	○
00411.00	CONNECTION - Bipolar cable 3mt EUR	○
00412.00	CONNECTION – Bipolar cable 3mt TWIN	○
00413.00	CONNECTION - Bipolar cable 3mt Artery Sealer EUR	○
00414.00	CONNECTION – Bipolar cable US 3mt	○
00415.00	CONNECTION – Bipolar cable ENDO (MP3-F3) 3 mt	○
00416.00	CONNECTION – Bipolar cable ENDO (MP2 – F2,4) 3mt	○
00417.00	CONNECTION – Bipolar cable ENDO3 (MP2-F4) 3 mt	○
00418.00	CONNECTION – Bipolar cable ENDO3 (2xM4 2xF2.4) 3 mt	○
00498.06	Adapter for neutral electrode 6,3mm/Valley	○
00498.08	Bipolar adapter EUR/2xM2,5	○
00498.10	Bipolar adapter EUR/3xM4	○
00500.00/L	ELECTRODE - Kit of assorted electrode length 10cm (10pcs)	○
0350	Disposable Neutral electrode (F7805)	○
110-750NS	BIPOLAR - Bipolar Artery Sealer 27cm TIP 3mm	○
110-755NS	BIPOLAR - Bipolar Artery Sealer 25,5cm TIP 3mm	○
110-760NS	BIPOLAR - Bipolar Artery Sealer 17cm TIP 2mm	○
152-112	ELECTRODE - Blade curved electrode 7 cm	○
152-115	ELECTRODE - Blade electrode 16 cm	○
152-122	ELECTRODE - Needle curved electrode 7 cm	○
152-125	ELECTRODE - Needle electrode 13 cm	○
152-130	ELECTRODE - Ball electrode ⌀ 2mm 6 cm	○
152-132	ELECTRODE - Ball curved electrode ⌀ 2mm 6 cm	○
152-140	ELECTRODE - Ball electrode ⌀ 3mm 6 cm	○
152-142	ELECTRODE - Ball curved electrode ⌀ 3mm 5 cm	○
152-145	ELECTRODE - Ball electrode ⌀ 3mm 14 cm	○
152-152	ELECTRODE - Ball curved electrode ⌀ 4mm 6 cm	○
152-160	ELECTRODE - Ball electrode ⌀ 5mm 6 cm	○
152-162	ELECTRODE - Ball curved electrode ⌀ 5mm 6 cm	○
152-165	ELECTRODE - Ball electrode ⌀ 5mm 14 cm	○
152-175-10	ELECTRODE - Loop electrode 10x10 l.15 cm	○
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	○
310-110-05	BIPOLAR - Bipolar Forceps 11,5cm TIP0.5mm	○
310-112-05	BIPOLAR - Bipolar Forceps Curved 11,5cm TIP0.5mm	○
310-140-10	BIPOLAR - Bipolar Forceps 20cm TIP 1mm	○
310-140-20	BIPOLAR - Bipolar Forceps 20cm TIP 2mm	○
310-142-10	BIPOLAR - Bipolar Forceps Curved 20cm TIP 1mm	○
310-142-20	BIPOLAR - Bipolar Forceps Curved 20cm TIP 2mm	○
310-180-10	BIPOLAR - Bipolar Forceps Angled 20cm TIP 1mm	○

Code	Description	SURTRON® TOUCH 200
310-180-20	BIPOLAR - Bipolar Forceps Angled 20cm TIP 2mm	○
310-182-10	BIPOLAR - Bipolar Forceps Angled Curved 20cm TIP 1mm	○
310-185-10	BIPOLAR - Bipolar Forceps Angled Curved 20cm TIP 1mm	○
310-510	BIPOLAR - Bipolar electrode 20cm – direct	○
310-550	BIPOLAR - Bipolar electrode 20cm – curved	○
310-590	BIPOLAR - Bipolar electrode 20cm – curved 2	○
330-134-20	MONOPOLAR - Monopolar Forceps 20cm TIP2mm	○
410-100-15	BIPOLAR – Bipolar Clamp Scissors 15 cm TIP 0,5 mm	○
410-100-19	BIPOLAR – Bipolar Clamp Scissors 19 cm TIP 0,5 mm	○
410-200-18	BIPOLAR – Bipolar Scissors 18 cm TIP 2 mm	○
410-200-21	BIOPOLAR – Bipolar Scissors 21 cm TIP 2 mm	○
410-200-23	BIPOLAR – Bipolar Scissors 23 cm TIP 2 mm	○
330-160	MONOPOLAR - Monopolar Surgical Scissors 18cm	○
500500.L1	ELECTRODE - Straight thin wire electrode (5pcs) 5cm	○
500500.L1/L	ELECTRODE - Straight thin wire electrode (5pcs) 10cm	○
500500.L10	ELECTRODE - Bent ball electro⌀ 3mm (5pcs) 5cm	○
500500.L10/L	ELECTRODE - Bent ball electro⌀ 3mm (5pcs) 10cm	○
500500.L11	Needles for micro-surgery (10Pcs)	○
500500.L2	ELECTRODE - Bent thin wire electrode (5pcs) 5cm	○
500500.L2/L	ELECTRODE - Bent thin wire 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 - Bent hook electrode (5pcs) 5cm	○
500500.L5/L	ELECTRODE - Bent hook electrode (5pcs) 10cm	○
500500.L6	ELECTRODE - Bent thick wire electrode (5pcs) 5cm	○
500500.L6/L	ELECTRODE - Bent thick wire electrode (5pcs) 10cm	○
500500.L7	ELECTRODE - Drop electrode (L7) (5pcs) 5 cm	○
500500.L7/L	ELECTRODE - Drop electrode (L7) (5pcs) 10cm	○
500500.L8	ELECTRODE - Noose electrode (L8) (5pcs) 5 cm	○
500500.L8/L	ELECTRODE - Noose electrode (L8) (5pcs) 10cm	○
500500.L9	ELECTRODE - Straight ball electrode ⌀ 3mm (5pcs) 5cm	○
500500.L9/L	ELECTRODE - Straight ball electrode ⌀ 3mm (5pcs) 10cm	○
00202.00-9005	Electrodes and handle support	○
6429A	NEUTRAL - Steel Neutral Electrode 24x16cm	○
755VL	Disposable handle with finger switches (F4797)	○
F7520	Electrode cleaning sponge 47x50mm	○
F7915	Conductive rubber neutral electrode without cable	○
F7930	Conductive rubber split neutral electrode without cable	○
TR003	Trolley 3 Shelves	○
TR003W	Trolley 3 Shelves wide	○
TR004	Trolley 4 Shelves	○
TR005	Trolley 5 Shelves	○
TR005W	Trolley 5 Shelves wide	○

Code	Description	SURTRON® TOUCH 200
TRDRAWER01	Drawer for trolley type TR	○
TRDRAWER01W	Drawer for trolley type TR W	○

■/ Pcs = STANDARD ○= OPTIONAL

INTENDED USE

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 equipment is designed to be used in the following sectors:

Description	SURTRON® TOUCH 200
Electrosurgical Unit Code	10100.T40
Outpatient Surgery	●
Dermatology	●
Dentistry	-
Endoscopy	●
Gastroenterology	●
General Surgery	●
Gynaecology	●
First aid	●
Neurosurgery	●
Orthopaedics	●
ENT	●
Pediatric Surgery	●
Plastic surgery	●
Pneumology	●
Chest surgery	●
Transurethral resection (TUR)	●
Urology	●
Vascular Surgery	●

● = Usable
- = Not usable

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

The device is intended for use in adult patients – both male and female – 18 years of age and older, except those listed in the *Contraindications* section. If necessary, the device can also be used in pediatric patients. In these cases, its use must comply with the specific indications and instructions provided by qualified medical professionals specialized in high-frequency electrosurgery. The decision to apply the device in the paediatric population remains at the discretion of the treating physician, based on clinical judgement and the nature of the intended surgical procedure.

ELECTROPHYSICAL PRINCIPLES

In surgical procedures, the traditional use of the knife scalpel has been largely replaced by the electrosurgical unit, which offers the possibility of performing tissue cutting and coagulation procedures quickly, easily and effectively.

The electrosurgical unit is built on the basis of the principle of conversion of electrical energy into heat (Joule's principle) and consists of:

- a radio frequency sinusoidal oscillator (0.4 - 4MHz);
- a wave packet generator, with a packet repetition rate of 15 – 30 kHz;
- a mixer for transferring to the power amplifier block either the only waveform suitable for cutting, or the waveform only for the clot, or a signal obtained by a suitable mixing of the two;
- a power amplifier block capable of supplying the necessary power in terms of current and transmitting the amplified signal to the electrodes, by means of a transformer;
- a safety circuit for the return electrode, to detect any cable breaks and deactivate the radio frequency delivery;
- a suitably shaped active electrode (handpiece);
- a return (neutral) electrode that closes the circuit through the patient.

The electric current that passes through biological tissue can usually cause:

1. ***Joule effect***
2. ***Pharadic Effect***
3. ***Electrolyte effect***

1. *Joule Effect*

In the biological tissue, crossed by the electric current delivered by the electrosurgical unit, a heating (Joule effect) is produced, depending on the specific electrical resistance of the tissue, the current density, the time of application and which can lead to various cellular transformations.

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

The influence of the thermal effect (Joule effect) is achieved through:

- **Current intensity and output power**

- **Degree of modulation**
  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 surface of the tip [$A \cdot m^{-2}$] is very high. The thin-section electrodes create a high current density, a high temperature, favoring the cutting action. Those with a large surface area create a lower current density, a lower temperature, realizing a coagulation effect.

- **Active electrode status**
  The thermal effects are 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 so as not to have a reduction in effects.

- **Fabric characteristics**
  Resistive characteristics vary in relation to biological tissues.

Biological tissue (in the range of 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 material and metals)

Based on the temperature reached and depending on the pulse forms used, different techniques for the use of radio frequency current on the human body can be recognized:

- **Coagulation**
  Temperatures of 60 to 70 °C in the area around the active electrode cause the intra-cellular fluid to slowly heat up, the water contained in the cell evaporates, and a clot action is obtained that stops bleeding.

- **Electrotomy (Cutting)**
  Temperatures above 100 °C in the area surrounding the active electrode result in the vaporization of the intra-cellular fluid and the 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 not, therefore, a mechanical resection. If the temperature reaches 500 °C, tissue charring occurs with a cauterizing action.

- Mixed currents

They 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 consistent layer of eschar.

The high frequencies used by the electrosurgical unit, however, do not allow the electromagnetic field to penetrate the matter and cause the current to pass through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the center of the conductor section. This effect, called the "skin effect", leads to a decrease in the cross-section useful for the passage of current, an increase in the electrical resistance of the material and becomes a significant problem in the neutral electrode. In fact, in this electrode the current density is very high (KA/m^2) at the edge, where the excessive increase in temperature due to the 'Joule effect' causes burns to the patient. It is therefore no coincidence that the burns to the patient, which occurred in surgery, have the shape of the edge of the neutral electrode. To reduce the risk of burns, the power output ($I2 \cdot t$) must be appropriately dosed and the rules for applying the neutral electrode to the patient must be followed (see *chapter SAFETY).*

2. *Pharadic Effect*

The pulsed electric current causes neuro-muscular stimulation, originating from the stimulation of the physiological process of ion exchange, 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 pharadic effect and is expressed by:

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

The physiological stimulus transmission system follows a boundary curve in which pulsed or low-frequency currents generate a stimulation pulse. With the high-frequency alternating current (above 200 kHz), used in the electrosurgical unit, there are no neuromuscular reactions (the change of polarity is so fast that it does not affect the patient in terms of neuro-muscular reactions), nor electrolyte damage to the body.

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

3. *Electrolyte effect*

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

OPERATING TECHNIQUES

MONOPOLAR CUT

Monopolar cutting is the sectioning of biological tissue obtained by the passage of current, at high frequency, high density concentrated from 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 the other. 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 hemostasis. 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 achieve a good cut:

- keep the fabric moist but not wet;
- keep the electrode perpendicular to the tissue;
- activate the output circuit before making contact with the fabric;
- keep the electrode tip clean (the optional electrode cleaning sponges with code F7520 are used for this purpose);
- allow the fabric to cool before cutting again.

When the power output level is adequate, you expect to achieve:

- no resistance to electrode movement through the fabric;
- no variation in the colour of the cut surfaces;
- No residual tissue fibre on the electrode.

MONOPOLAR COAGULATION

When there is an increase in temperature, due to the heat generated by the Joule effect in the tissue, thermal coagulation takes place, i.e. the partial solidification of organic liquids and therefore the precipitation of colloidal substances. In particular, fibrin is formed in the blood which, as it solidifies, obstructs the blood vessel.
To obtain coagulation with the electrosurgical unit, it is necessary to supply the active electrode with an intermittent current so that the amount of heat developed does not produce the explosion of the cells and therefore the cutting of the tissue, but only their heating so that the water contained escapes from the cell without destroying it. However, even with intermittent current, if the current intensity is too intense, the cutting effect occurs.
Active electrodes that are particularly suitable for coagulation are sphere-shaped electrodes, plates, or lanceolate electrodes used laterally.

Coagulation can be achieved by two different procedures:

- Coagulation by drying
  It is obtained by powering the electrode with low voltages so that no sparks are generated (this ensures that the action obtained is of a pure clot and therefore any cutting effect is absent). The electrode is placed in direct contact with the tissue and the amount of heat developed on contact dries it out.
  Typically, coagulated cell surfaces act as an insulating layer, which prevents heat from subsequent current applications from penetrating too deeply.
  The current normally used for coagulation is modulated. Depending on the percentage of modulation, there is precision of the cut, goodness of the hemostasis 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 electrode or a thick wire;
  - locate the bleeding vessel after wiping excess blood from the area;
  - lightly touch the bleeding vessel before activating the electrode;
  - Stop activating the electrode as soon as the tissue whitens to avoid damaging it.
  - keep the electrode tip clean (the optional electrode cleaning sponges with code F7520 are used for this purpose).

- Coagulation with anatomical forceps by clamping
  The most frequently used coagulation technique is to block blood flow by clamping pressure between the end of the forceps.
  After clamping the portion of tissue or blood vessel where the coagulation is located, the active electrode is placed in contact with the proximal metal part of the forceps. The activation of the high frequency must take place after this contact (clamp – active electrode) in order to avoid the pharadic effect (triggering of an electric discharge that uses air as a conductor) which would cause electric shock, burns to the operator, etc.

BIPOLAR COAGULATION

Unlike the monopolar technique, with the bipolar technique the portion of tissue affected by the passage of high-frequency current is very small. In this technique, bipolar clamps (of different sizes and shapes) are used, on the distal ends of which there are the active and neutral electrode. By tightening the tissue to be operated on between the ends of the clamp, the passage of high-frequency current will take place from one end to the other, using the part of the fabric to be treated as an electrical bridge.
Bipolar coagulation is the haemostasis of small blood vessels in body tissue between the two tips of the forceps. When the current density is reduced the effect is to dry the cell surface, without penetrating deeply, resulting in coagulation.
The bipolar technique is extremely safer because the direction of the high-frequency current is always determined and predictable and does not reserve unknowns and potential erroneous directions, and the powers used are much lower than those used in the monopolar technique. For

these reasons, this technique is used especially in the most delicate surgeries, and it is therefore essential to keep the distal ends of the forceps clean during surgery, because they are subject to the accumulation of coagulated tissue, which limits the passage of current and favors gluing to the tissues.
The application of the neutral electrode (used compulsorily in the monopolar technique) is not necessary, although from a practical point of view it is always allowed to be applied to the patient during the initial preparation phase.

CONTRAINDICATIONS

The use of electrosurgery is contraindicated in patients:

- pacemaker wearers;
- with stimulation electrodes;
- with metal prosthetic implants;
- with serious blood pressure imbalances;
- with serious diseases of the nervous system;
- with serious renal insufficiency;
- pregnant.

In the field of electrosurgery, high-frequency burns are the main injuries caused to the patient, although they are not the only ones. In fact, compression necrosis, allergic reactions to disinfectants, ignition of flammable gases or liquids are found.

Some of the primary causes of burns are attributable to:

- insufficient training of medical personnel on the methods necessary to avoid or reduce the risk of burns by using high-frequency electrosurgical devices;
- use of disinfectants with a high alcohol content;
- incorrect positioning of the patient during electrosurgery;
- contact of the active electrode with the patient's skin;
- contact with liquids;
- prolonged application of high-frequency currents;
- Incorrect application of the neutral electrode.

In order to avoid or reduce the risks associated with the use of high-frequency electrosurgery, the rules and safety measures described in the next chapter must be observed.

SAFETY

WARNING: Electrosurgery can be dangerous: Improper use of each of the elements of the electrosurgical system can cause serious burns to the patient. It is imperative that you carefully read and fully understand all instructions before attempting to use an active electrode. Neither the manufacturer nor any of the dealers can be held responsible for loss or damage caused to persons and equipment, directly or indirectly, due to improper use of the device and its accessories.
The accessories supplied with the unit have features compatible with this unit, may be incompatible with other electrosurgical units. The user must check, before connecting other accessories to this unit, that they have insulation characteristics compatible with those of this unit (see *chapter TECHNICAL SPECIFICATIONS).* The packaging of any sterile accessories should be checked for integrity before first use.

WARNINGS

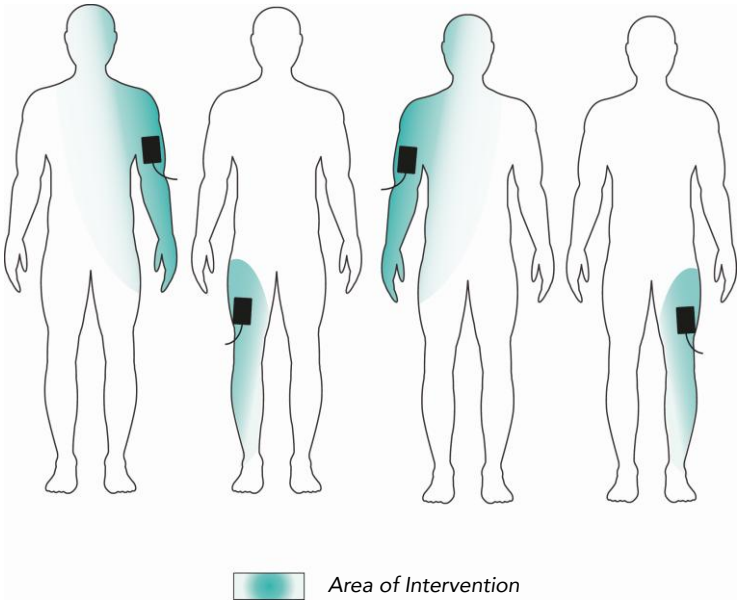
- **DO NOT USE** in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). There is a possible hazard because interference with the action of the electronic system may occur, or the system may be damaged.
- **DO NOT USE** in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) 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). Tools that are activated or hot from use may cause a fire.
- When not using instruments, place them in a clean, dry, and highly visible area that is not in contact with the patient. Unintentional contact with the patient may cause burns.
- Inspect instruments and cables for damage before each use, especially the insulation of laparoscopic/endoscopic instruments. This can be done visually under magnification or with a high-voltage insulation test device. Insulation failures can cause burns or other injury to the patient or operator.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is turned off.
- Because of concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective goggles, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Connect adapters and accessories to the electrosurgical unit only when the power is off. Failure to do so may result in injury or electric shock to the patient or operating room personnel.
- If the device is enhanced with argon, warnings regarding gas embolisms should be included.
- If the instrument is reusable, a warning should also be included that visual inspection alone may not be sufficient to ensure that the insulation is intact.
- **DO NOT ACTIVATE** the instrument when it is not in contact with the target tissue, as this may cause injury from capacitive coupling with other surgical equipment.
- **DRAW** fluid out of the area before operating the tool. Conductive fluids (e.g., blood or saline) in direct contact with or near an active electrode can carry electrical current or heat away from the target tissues, which can cause unwanted burns to the patient.

- **DO NOT USE** with hybrid systems, i.e., a combination of metal and plastic, when using monopolar active components. This can cause alternate site burns due to capacitive coupling. Use only all-metal or all-plastic systems.
- Before increasing the intensity, check the adhesion of the neutral electrode and its connections. Apparent low power or failure of the device to operate at normal operating settings may indicate incorrect application of the neutral electrode or poor contact in its connections.
- This unit has a CQM system, please note that loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode (split neutral electrode) is used.
- **Caution**: The intensity must be set to the lowest level necessary to achieve the desired effect.
- **Caution**: Keep the active electrodes clean. Eschar buildup can reduce the effectiveness of the tool. Do not activate the tool while cleaning. Injury to operating room personnel may occur.
- 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

PRECAUTIONS

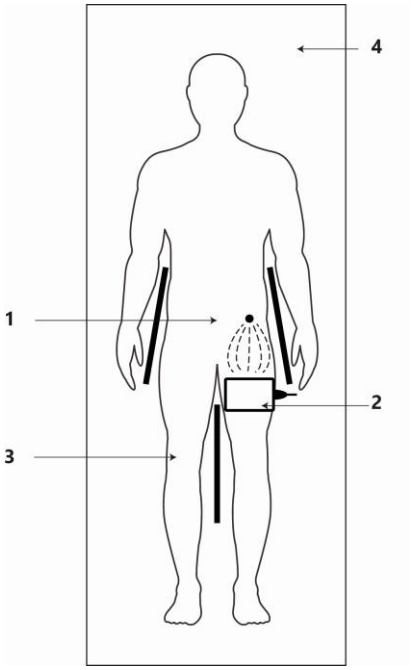
The following precautions are intended to reduce the risk of accidental burns:

- The neutral electrode should be reliably connected over the entire area to the patient's body, preferably at the extremities, as close as possible to the point of intervention. Avoid attaching the neutral electrode to bony protrusions, prostheses, scar tissues, areas prone to fluid accumulation or that have a thick state of subcutaneous adipose tissue. The application area must be hair-free, dry and clean. Do not use alcohol to cleanse the skin. Except for use in veterinary medicine, the use of electrode gels is not permitted.



- Using single-use neutral electrodes, respect the expiration dates.
- When using multi-purpose electrodes, make sure that the fastening systems guarantee stability.
- When applying the neutral electrode, avoid the transverse path and prefer the vertical or diagonal path, especially if using a bipartite neutral electrode. This is to allow an even distribution of current on the surface of the neutral electrode and reduce the risk of burns to the patient.
- If it is not possible to apply the neutral electrode correctly, consider the bipolar technique instead of the monopolar technique if possible.
- The patient should not come into contact with metal parts that are grounded or have an appreciable grounding capacity (e.g. an operating table, supports, etc.). For this purpose, the use of an antistatic sheet is permitted.

- Skin-to-skin contact (e.g. arm-to-trunk, leg-to-leg, breasts, etc.) should be avoided by inserting dry gauze. In addition, areas of the body subject to profuse sweating should be kept dry.



1. *Active Electrode* – **2.** *Neutral Electrode*
3. *Dry gauze* – **4.** *Antistatic Fabric*

- When the electrosurgical unit and a physiological monitoring device are used simultaneously on the same patient, all monitoring electrodes should be placed as far away from the surgical electrodes as possible. Needle monitoring electrodes are not allowed. In any case, monitoring systems incorporating high-frequency current-limiting devices are permitted.
- Surgical electrode cables should be positioned in such a way as to avoid contact with the patient or other conductors. Active electrodes, which are temporarily unused, must remain isolated from the patient.
- Bipolar techniques are allowed in the case of surgery on parts of the body with a relatively small cross-section, to avoid unwanted clotting.
- The set output power level should be as low as possible for the intended purposes.
- An evident low output level or incorrect operation of the electrosurgical unit, when it is set up for normal power delivery, may indicate a defective application of the neutral electrode or a bad contact in the connections of the same. Therefore, the application of the neutral electrode and its connections should be checked before selecting a higher power.
- The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided in the case of chest or head surgery, unless it is possible to aspirate them. Non-flammable substances should be used for cleaning and disinfection wherever possible. Flammable substances used for cleaning, disinfection or as adhesive solvents should be allowed to evaporate before using the electrosurgical unit. There is a risk of stagnation of flammable solutions under the patient or in cavities such as the navel and vagina. Any fluid that settles in these areas should be removed before using the appliance. The danger of endogenous gases must be considered. Some materials such as cotton wool or gauze, when impregnated with oxygen, may ignite due to sparks produced by the appliance under normal conditions.

- There is a danger to patients with pacemakers (pacemakers) or pacing electrodes as interference with the action of the stimulator may occur or the stimulator itself may be damaged. In case of doubt, you should contact the Cardiology Department.
- Electrosurgical equipment emits high-frequency energy radiation without warning which may affect other medical equipment, unrelated electronics, telecommunications, navigation systems. To avoid interference, a distance of at least 1.5 meters must be placed between the electrosurgical equipment and other devices.
- The user should check the accessories regularly. In particular, electrode cables and any endoscopy accessories should be checked for damage.
- In order to connect accessories compatible with the characteristics of the equipment, the insulation characteristics of the accessories (to be requested from the manufacturers) must be compared with the characteristics of the unit supplied (see Technical Specifications).
- Caution: Failure of surgical equipment could result in an unintended increase in output power.
- Stimulation of the patient's muscles or nerves can be caused by low-frequency currents originating from an electric sparkle 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 should be inspected by qualified service personnel.

INSTALLATION

- Electrical safety is ensured only when it is correctly connected to an efficient earthed power supply in accordance with current safety standards. This basic safety requirement should be checked and, if in doubt, the system should be thoroughly checked by qualified personnel. The manufacturer cannot be held responsible for possible damage caused by the lack of an efficient ground connection of the installation. Operation without protective ground connection is prohibited.
- Before connecting the equipment, make sure that the required voltage (indicated on the rear panel) corresponds to the available mains.
- In the event of incompatibility between the available power outlet and the power cord of the equipment, replace only with a suitable type. The use of adapters, multiple connections, or extension cables is not permitted. If their use is necessary, it is mandatory to use only single or multiple adapters that comply with current safety standards.
- Do not leave the appliance exposed to atmospheric agents (rain, sun, etc.). The device must be protected from the ingress of liquids.
- Do not leave the appliance inserted unnecessarily. Turn it off when not in use.
- The equipment is not suitable for use in explosive environments.
- The equipment must be intended only for the use for which it was specially designed. Any other use must be considered improper and dangerous. The manufacturer cannot be held responsible for possible damage due to improper, incorrect or unreasonable use.
- It is dangerous to modify or attempt to modify the characteristics of the equipment.
- Before carrying out any cleaning or maintenance operation, disconnect the appliance from the mains by removing the plug from the mains or turning off the main switch of the system.
- If the equipment breaks or malfunctions, switch it off. For repairs, refer only to an authorized service center and ask for the use of original spare parts. Failure to comply with the above regulations may risk the safety of the equipment and may be dangerous for the user.
- Do not reduce or eliminate the generator activation beep. A working activation signal can minimize or prevent injury to the patient or personnel in the event of accidental activation.
- The operation of the equipment must not be verified by emitting power between the active and neutral electrode or between the active electrode and metal parts.
- If necessary, use fume extraction means in the field of intervention.

WARNING: When using the equipment in the operating room, it is essential to use only watertight foot switches (such as code 00304.00 for a single watertight foot pedal or code 00305.03 for a double watertight foot pedal). This ensures safety during surgical procedures.

PATIENT SAFETY

During high-frequency electrosurgery the patient behaves like an electrical conductor. A potential difference different from zero is established between the patient and the earth and therefore, if contact were made between the patient and electrically conductive objects (metal, damp or wet cloths and cloths, etc.), an electric current would be generated at the point of contact which could give rise to thermal necrosis. You must therefore carry out appropriate checks of the appliance and its accessories before use and comply with all the relevant safety regulations.

CORRECT PATIENT POSITIONING

Avoid any intentional or accidental contact between the patient and earthed metal parts and make sure that:

- The patient is not in contact with metal parts (operating table, supports).
- Any tubes of respirators do not rest on the patient's body.
- On the operating table with ground connection, there are always coatings capable of discharging electrostatic charges.
- The patient is placed on a thick base fabric with insulating properties, which in turn is covered with a sufficient number of intermediate layers of covering sheets.
- The patient is not in contact with damp sheets or mattresses.
- Any secretions from the body and liquids applied for cleaning purposes or other types of liquids do not wet the dry sheets.
- There are no fluid residues below the patient.
- Any urinary excretions are eliminated through the use of catheters.
- Regions of the body characterized by more intense sweating, extremities in direct contact with the trunk of the body or skin-to-skin contact points are kept dry through the interposition of drapes (arm/trunk of the body, leg/leg, breasts, skin folds, etc.).
- All conductive and grounding brackets are properly insulated.
- Adjust the amount of anaesthetics so that excessive sweating is avoided.

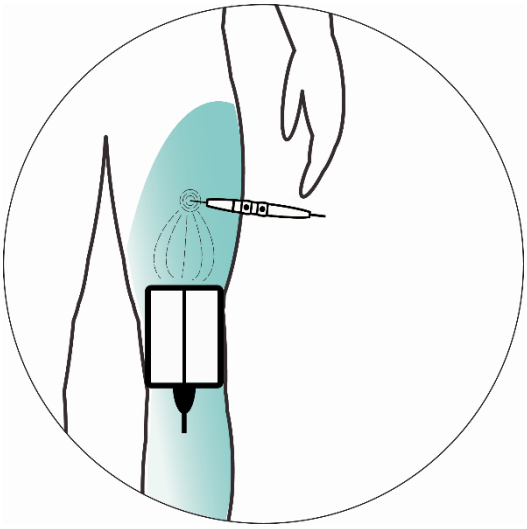
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

The use of the neutral electrode (or current leakage plate) is indispensable in the monopolar technique, as it allows the "return" of the cutting or clot current to the electrosurgical unit. There are two types of neutral electrode:

1. **Single-part neutral electrode:** In which there is no control over the neutral electrode-patient contact.
2. **Bipartite Neutral Electrode:** In which the neutral-patient electrode is controlled.

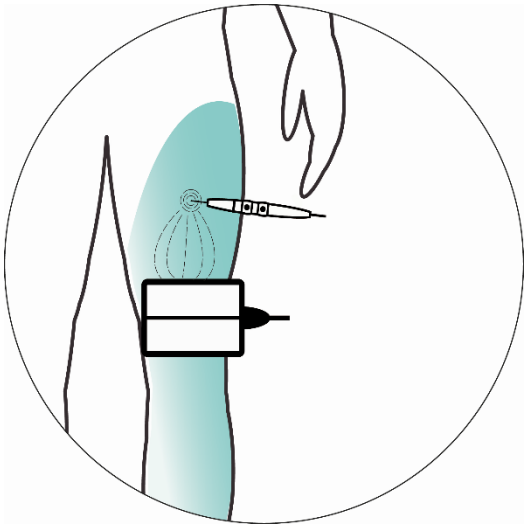
It is vitally important to pay special attention to the accurate positioning of the neutral electrode in order to prevent burns and minimize risk to the patient. Useful information is provided below:

1. *Correct Placement*



The image on the side shows the correct positioning of the bipartite neutral electrode. The patient plate must be placed in a perpendicular position with respect to the operating field. Avoid placing it in a transverse direction and, instead, favor a vertical or diagonal orientation. This promotes an even distribution of current on the surface of the neutral electrode, minimizing the risk of burns to the patient.

2. *Incorrect positioning*



The image on the side illustrates the incorrect positioning of the bipartite neutral electrode. The parallel arrangement between the patient plate and the operating field causes an uneven distribution of current on the two surfaces of the neutral electrode, leading to possible alarm signals on the unit and preventing the device from being activated correctly.

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

Do not apply the neutral electrode to scars, bony protrusions, or anatomical parts where prosthetic implants or monitoring electrodes are present. Instead, apply it to well-supplied tissues, such as muscles and near the operative site.

If you are using a disposable neutral electrode, respect the expiry dates, if you are using a disposable neutral electrode, make sure that the fastening systems guarantee stability.

It is of paramount importance that the neutral electrode is firmly applied over its entire surface to avoid burns. When a neutral electrode partially detaches from the patient, the density of the current flow in the part of the electrode that is still applied is increased. Because the density of the current flow below the neutral electrode is inhomogeneous, uneven heating occurs, especially at the edges of the neutral electrode.
If the electrode were placed at a region under pressure during surgery, the compressive load would result in a reduction in skin perfusion. In this way, the heat developed can only be partially removed, so that the risk of burns increases. In addition, there is an increased risk of pressure point formation (decubitus) due to the heating that occurs. This increase in temperature causes a greater need for oxygen (O_2) and energy in the affected area, contributing to the possible development of areas of pressure on the body.

ELECTROSURGERY AD HF IN LAPAROSCOPY

Laparoscopic, or minimally invasive, surgery has revolutionized the landscape of surgical interventions, bringing significant benefits in terms of recovery and healing times for the patient. In this context, the use of high-frequency (HF) monopolar surgery is widely used due to its flexibility in performing mixed cuts, coagulations and cuts that combine both functions. However, this mode of operation carries risks for the patient, especially the risk of burns.

Burn risks can be heightened by various factors, including limited field of view, inadequate maintenance of laparoscopic equipment, interference on the monitor, insufficient surgeon preparation or distractions, excessive smoke development, inadequate insulation, capacitive currents, and accidental contact of the active electrode tip with surrounding tissue. These factors can contribute to the increased risk of burns, internal injuries, tissue necrosis and organ perforation.

In addition, the very environment of the surgery, in which the active electrode is in close proximity to conductive instruments and body tissue, can facilitate the transmission of electrical currents to areas not visible through:

- **Direct coupling**, which occurs when the active electrode comes into contact with another metal instrument, causing electrical current to be transmitted and increasing the risk of burns to surrounding tissue, such as the intestines or other organs;
- **Lack of insulation**, in this case the insulation of the electrode can be compromised by the use of excessive voltage, improper use or mechanical breakage of the electrode rod. This can happen during a surgical procedure or during the cleaning and sterilization phases of the instruments. A non-visible insulation breakdown, when the electrode is activated, represents a danger of unpredictable, therefore more insidious, burns. Curiously, a small break in insulation is more dangerous than a large one, since the current is more concentrated and therefore more susceptible to causing burns;
- **Capacitive coupling**, which occurs when electrical current is induced by the active electrode on conductive materials, even if the insulation is intact. During high-frequency electrosurgery procedures, the rapid change in the electric field around the active electrode is only partially

hindered by the insulation, generating ionic currents that, when in contact with the tissue, cause enough heating to cause burns.

It is crucial to address these risks with the utmost care and to take preventive measures to ensure patient safety when using high-frequency surgery in a laparoscopic setting.

To minimize the risks of burns during laparoscopic high-frequency electrosurgery procedures, the following preventive measures are proposed:

- **Comprehensive staff training**: Ensure thorough and thorough training for medical and healthcare personnel participating in electrosurgery procedures. A comprehensive knowledge of procedures, risks, and preventive measures is essential.
- **Accurate inspection of surgical instruments**: Perform a detailed visual examination of surgical instrumentation, including the active electrode and laparoscope. This can help identify any defects or wear that could increase the risk of burns.
- **Use of disposable electrodes**: Although disposable electrodes may have thinner insulation that does not reduce the occurrence of a breakage or capacitive coupling, their use is wear-free.
- **Ban on hybrid material cannulas**: Avoid using cannulas made of hybrid materials, such as plastic and metal, as they can increase the risk of direct coupling and capacitive coupling.
- **Adoption of the bipolar technique**: The bipolar technique is less versatile than the monopolar technique, but it is considered safer as heat injuries are localized and occur only with prolonged current application.

Ultimately, it is evident that burns are a real concern in high-frequency electrosurgery procedures. However, with a thorough understanding of the possible causes and thorough preparation of the medical team, it is possible to limit their incidence and effectively manage potentially risky situations.

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.

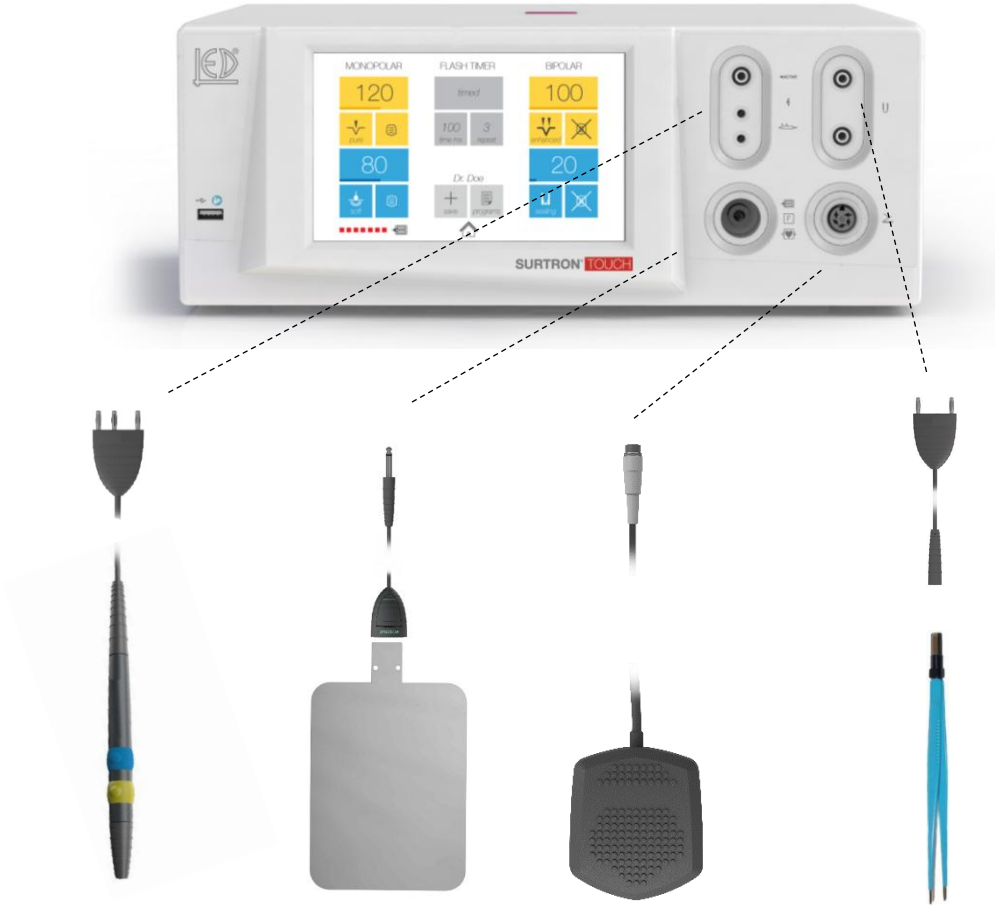
  OPERATION OF THE EQUIPMENT WITHOUT AN EARTH CONNECTION IS PROHIBITED.
- The equipment must be installed on a flat surface that is at least the same size as the base of the equipment. At least 25cm of space must be left around the equipment.
- Connect the mains cable to the power outlet located on the 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 foot pedal or dual pedal set (optional) to the connector on the front panel of the unit.
- Connect a handpiece with buttons to the corresponding connection points and in the case of use of a handpiece without buttons, the same must be connected on the "active" bushing.
- Operate the equipment only in a dry environment. Any condensation that occurs must be evaporated before the equipment is operated. Do not exceed room temperature or permitted humidity.
- Environmental conditions:

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

- When switched on, made through the switch on the rear panel, the equipment will be set with the function and power levels used at the last power on.
- In the monopolar mode, you need to connect the neutral electrode cable with the connected neutral electrode. If a bipartite neutral electrode is used, the circuit (properly connected to the patient) must be closed. This way, if the impedance value is acceptable, the red light on the neutral electrode connector stops flashing.
- Before attempting to use the equipment, the patient plate cable must be connected. With bipartite electrodes, the circuit must be closed by connecting the electrode to the patient. If the impedance value read by the equipment is acceptable, the OC indicator light will stop flashing and the delivery will be signaled by an acoustic signal.

CONNECTING AND USING ACCESSORIES AND/OR COMPONENTS



Depending on the specific needs of each procedure, optional accessories may be required. These accessories can be designed to meet particular requirements, improve accuracy, or optimize surgery outcomes. Examples of optional accessories may include:

- ***For the bipolar procedure*** **:**

1 : *Cable for connecting two-core accessories*

2 : *Bipolar accessory (e.g. bipolar clamps)*

- ***For vessel synthesis and coagulation (Vessel Sealing):***

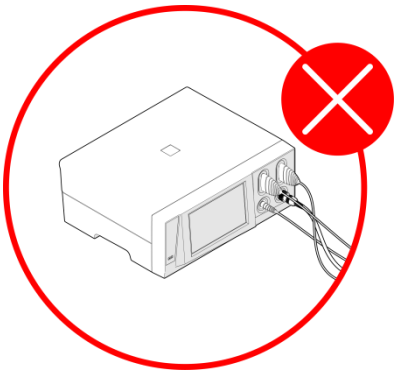
3 : *Connection cable for Artery Sealer pliers*

4 : *Pliers for Artery Sealer*

CORRECT CONNECTION OF ACCESSORIES AND/OR COMPONENTS

To ensure the proper functioning, safety, and durability of the medical device, it is crucial to position the accessories and/or components appropriately. Incorrect placement may impair the efficiency of the device or damage the equipment. Here is useful information about this:

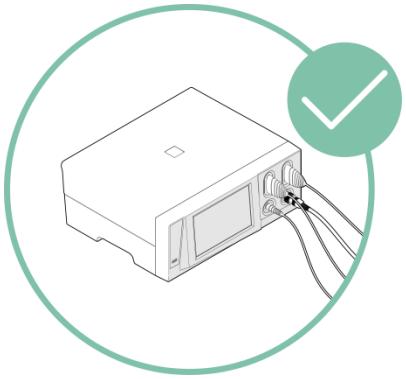
1. **Incorrect positioning**
   The images below show two examples of incorrect cable placement: **braided and/or coiled cables** and **braided and/or coiled cables on top of the device.**



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

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

2. **Correct Placement**

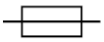


The image on the side shows the correct positioning of the cables. The correct arrangement of the same requires that they are positioned in parallel and well separated from each other. This configuration minimizes the risk of electromagnetic interference and prevents cables from being damaged due to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

MEANING OF GRAPHIC SYMBOLS

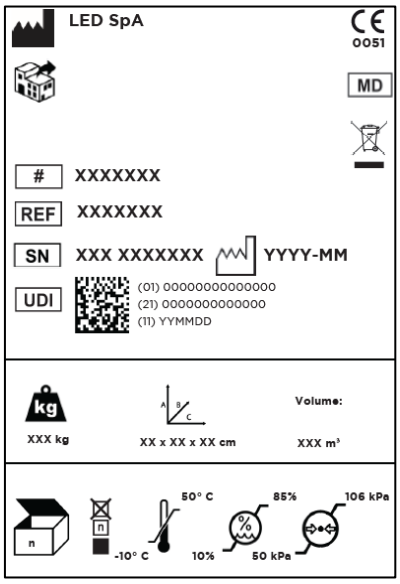
In accordance with the international standards ISO 15223-1:2021 "Medical devices - Symbols to be used in the information to be provided by the manufacturer" and ISO 780:2015 "Packaging - Packaging for distribution - Graphic symbols for handling and storage of packaging", all symbols on device labels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

SYMBOL	DESCRIPTION
	Floating neutral electrode: not grounded at either high or low frequencies.
	Class CF equipment protected against shock from the use of the defibrillator.
	Non-ionizing radiation generating equipment.
	Follow the instructions for use.
	CE Mark (2017/745/EU) + Notified Body Number 0051 = IMQ Italy
	The product should not be disposed of in municipal waste containers but should be disposed of with a separate collection.
	Producer.
	Serial number.
	Date of manufacture.
	Unique device identification.
	Medical device.
	Distributor.
	No maintenance by the user.
	Catalog number (Code).
	Temperature limits.
	Humidity limits.
	Atmospheric pressure limits.
	High side.
	FRAGILE – Handle with care.
	Keep away from sunlight.
	Protect from moisture.
	Maximum number of stackable pieces.
	Weight.
	Dimensions.
	Number of pieces.

SYMBOL	DESCRIPTION
	Recycle.
	Model/Trade Name.
IP	Degree of protection against the ingress of water and dust.
	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 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**

FRONT PANEL

1. USB PORT

For software update, use the USB 2.0 port on the front of the unit.

2. TOUCHSCREEN DISPLAY

The backlit LCD touchscreen display allows the display and selection of all the parameters set and settable in a given procedure.

3. CONNECTOR FOR SINGLE-POLE OUTPUT

This is the handpiece connection point with dual buttons to activate the cutting (CUT) and coagulation (COAG) functions. If handpieces without buttons or single-core cables (optional) are used, they must be connected to the socket marked "ACTIVE".

4. NEUTRAL ELECTRODE CONNECTOR

This is the connection point of the neutral electrode to be applied to the patient.
Disposable or multi-use, single-partite, or bipartite neutral electrodes can be used.

5. CONNECTOR FOR BIPOLAR OUTPUT

This is the connection point of the bipolar accessories.

6. PEDAL CONNECTOR

On the front panel there is a socket for connecting the pedal or the double pedal set (optional).

OPERATING MODES

CONTROL AND IGNITION

The unit is operated directly via the icons displayed on the device's touchscreen. To confirm a choice, simply tap the icon directly.

Once the electrosurgical unit is turned on, the specific software begins to load on the screen. The progress of the software application process is shown via the filling of the bar at the bottom of the screen.
When this process is complete, you will see the Home screen:

On the Home screen, you can select and interact with the following options:

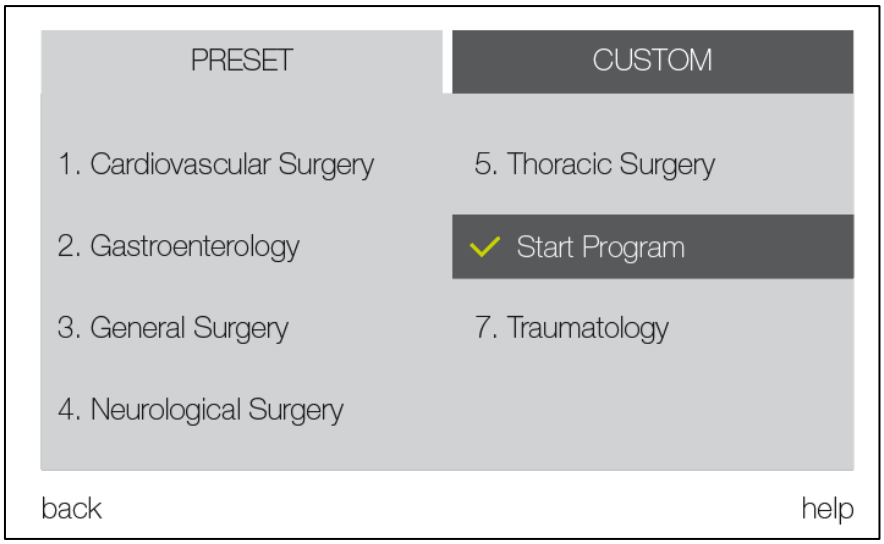
- Programs
- Surgery
- Settings
- Update (Updating the software via the USB port).

The "*Info*" option allows you to view the software versions that are currently installed. By pressing the "*Help*" button, you can access an informative summary that is useful for correctly interpreting the indications on the display.

PROGRAMS

Selecting the "*Programs* " option on the home screen will open two distinct pages:

1. **Presets**: This section will show the default programs that have already been configured and stored in the system. They represent standard settings for a variety of common surgical procedures.



Simply click "*Start Program*" to activate the preset program and make it ready to use.

2. **Custom:** This page will display programs that have been created and customized by you or your surgeon. These programs reflect the specific settings that the user has configured to address particular needs or unique procedures.

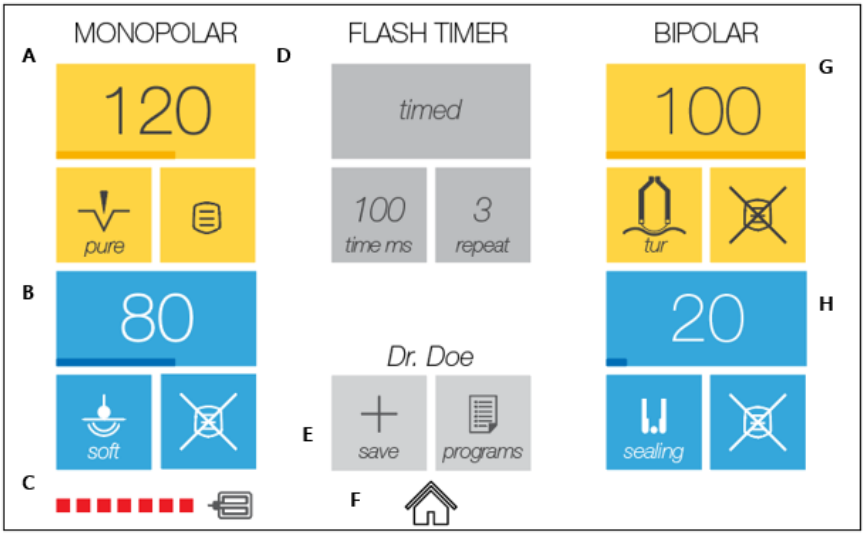
At first, the screen will appear blank. For instructions on how to create a custom program, please refer to the next paragraph ("*Programs Section* ").

Distinguishing between these two pages allows caregivers to easily access a range of predefined or customized settings, based on the specific needs of the surgery. This gives you flexibility in selecting settings depending on the context.

In addition, by using the "*Help* " button, you can get information about the features of the selected program. To return to the home page, simply select the "*Back* " option.

SURGERY

By selecting the "*Surgery* " option on the home page, the following screen will be displayed:



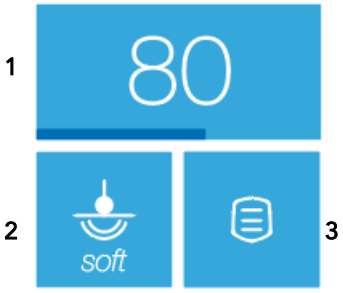
Through which it is possible to distinguish different sections:

A. Monopolar section cutting
B. Monopolar Coagulation Section
C. Neutral electrode circuit impedance indication
D. Timing Section
E. Programs Section
F. Home icon
G. Bipolar Section Cutting
H. Bipolar Section Coagulation

Each of these options allows you to adjust various parameters, which will have the option to be saved as a new custom program.

MONOPOLAR SECTION

In the sections intended for the adjustment of cutting or coagulation, both in monopolar and bipolar modes, there are three icons:



1. *Icon to adjust the output power*
   By tapping the number icon, you can adjust the output power. Here's an example to illustrate the process:

   Pressing "+" and "–" adjusts the power, while pressing the "✓" button confirms the selected value.

2. *Icon to select the current that can be delivered*
   By tapping on the icon with the function, you can select the one you want.

CUT CURRENT

The best current for cutting is the pure sine wave without modulation, i.e. with 100% duty-cycle.

BLEND CURRENT

Mixed current (BLEND) is suitable for coagulated cutting when deep coagulation combined with cutting is desired. Its waveform has a lower modulation percentage than pure coagulation. This current is composed of a sinusoidal current component suitable for cutting, combined with a current component suitable for low-voltage coagulation (SOFT COAG). This creates a current that is suitable for coagulated cutting without eschar formation or charring and is particularly suitable for endoscopic procedures.

ENHANCED CUT CURRENT

The ENAHNCED CUT is a sinusoidal current characterized by amplitude modulation and is suitable for cutting tissues, in particular adipose tissues.

SURFACE COAGULATION CURRENT (FORCED COAG)

Modulated current (FORCED COAG) exhibits good surface coagulation properties but may also result in the probable formation of eschar and slight charring of the tissue. The advantage of this type of coagulation lies in the speed with which the desired effect is achieved.

FORCED COAG is also called Speedy.

DEEP COAGULATION CURRENT (SOFT COAG)

The low voltage and low modulation current (SOFT COAG) is suitable for coagulation of deep layers of the tissue in which coagulation of cellular albumin is obtained in the absence of carbonization and without the production of eschar. The coagulation process is slower in this case than in FORCED COAG coagulation.

SOFT Coag is also called Pin Point, Dessicate or Deep.

CURRENT FOR FULGURANT COAGULATION (FULGURATE)

The current for high-voltage fulgurating coagulation (FULGURATE) goes into the active electrode which is not in contact with the part of the tissue to be treated and produces coagulation for the most part. This method is ideal for treating large surfaces with diffuse and superficial blood loss (liver resection) and/or for achieving coagulation at the level of the open sternum in cardiac surgery.

3. *Pedal activation icon*

By tapping on the icon with the pedal you can choose which one to activate, for example:

Pedal Activated

Pedal not activated

BIPOLAR SECTION

In the bipolar section, as well as in the monopole section, it is possible to adjust the output power, select the current that can be delivered and activate the pedal. The difference lies in the selectable functions specific to each mode.
You will need to connect the bipolar accessories to the connectors for this function and use the foot switch.

BIPOLAR CUT-OFF CURRENT (BIPOLAR CUT)

The current supplied by bipolar pliers is a pure sinusoidal high voltage suitable for cutting without coagulation.

TRANS URETHRAL CURRENT BIPOLAR RESECTION (BIPOLAR TUR)

The TUR current, using a specific bipolar accessory, is suitable for both cutting and coagulated cutting when forced coagulation is sought together with cutting. This current is composed of a sinusoidal current component suitable for cutting, along with a high-voltage current component for coagulation.

BIPOLAR COAGULATION CURRENT (BIPOLAR COAG)

This type of coagulation can be carried out with bipolar forceps and allows the radiofrequency output power to be delivered on low impedances, such as those presented by the section of tissue that can normally be included between the tips of the forceps.

VESSEL SEALING

This type of function is suitable for arterial and venous vessel synthesis and coagulation by radiofrequency clamping.
The vessel is gently blocked with light pressure, radiofrequency is started and the pressure is continued with forceps until coagulation has taken place.

For the operation of the bipolar modes, refer to the paragraph "AUTOSTART AND AUTOSTOP".

AUTOSTART AND AUTOSTOP

In the Bipolar functions it is possible to access four different operating settings:

- **No dispensing automation set**

The delivery takes place only by pressing the pedal and stops by releasing it.

- **START**

To activate the "*start bipolar* " or "*start sealing* " function, press the pedal; make contact between the active electrode and the tissue, and in this way the delivery is activated. If you want to stop, release the pedal.

- **STOP**

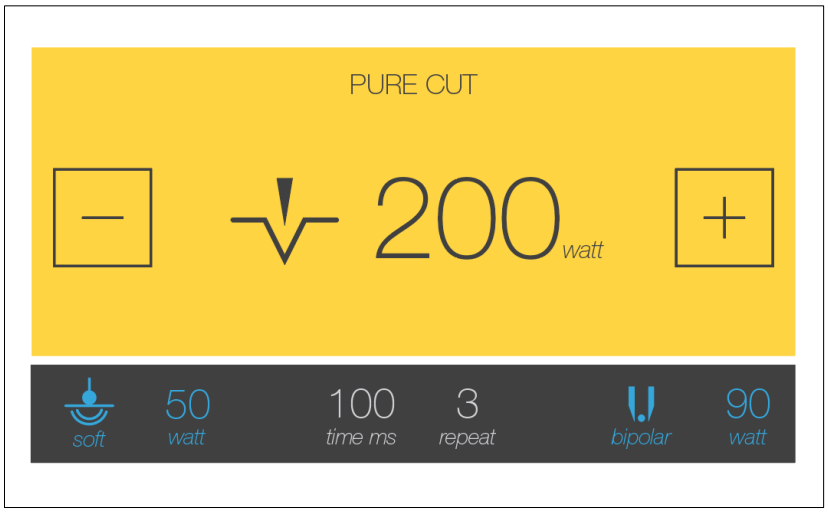
To activate the "*stop bipolar* " or "*stop sealing* " function, press the pedal; The delivery is activated (even if there is no contact between the tissue and the active electrode) and stops when the tissue is coagulated or if the pedal is released.

- **AUTOSTART/AUTOSTOP**

To activate the "*bipolar start/stop*" or "*start/stop sealing*" function, press the pedal; make contact between the active electrode and the tissue, and in this way the delivery is activated. The latter ceases when the tissue is coagulated or if the pedal is released.

DISPENSING SCREEN

In the dispensing state, the function with its level will appear on the screen. This screen remains for a few seconds, during which you can adjust, with + and -, the output level.



TIMER SECTION

Through the "TIMING" section it is possible to select the "*continuous*" option, to have a continuous delivery, or "*timed*", through which to set the parameters of the pulses.

For the programming of the timing of the pulses, the following are considered:

- The "*time* " section, through which the duration of the pulses is set (from 10 milliseconds to 30 seconds);
- The "*repeat* " section, to choose the number of pulse repetitions (from 1 to infinity).

It is crucial that the foot pedal is pressed for as long as you want to use the timed function.

TIME		Dispensing time		Step
		From	*At*	
10÷90 AM	Msec	10 msec	90 msec	10 msec
100÷900 mm	Msec	0.1 sec	0.9 sec	100 msec
1.0÷30	Sec	1 sec	9.5 sec	0.5 sec

The "*timed*" function can be adjusted with all functions but does not interfere with the AUTOSTART/AUTOSTOP function in BIPOLAR mode.

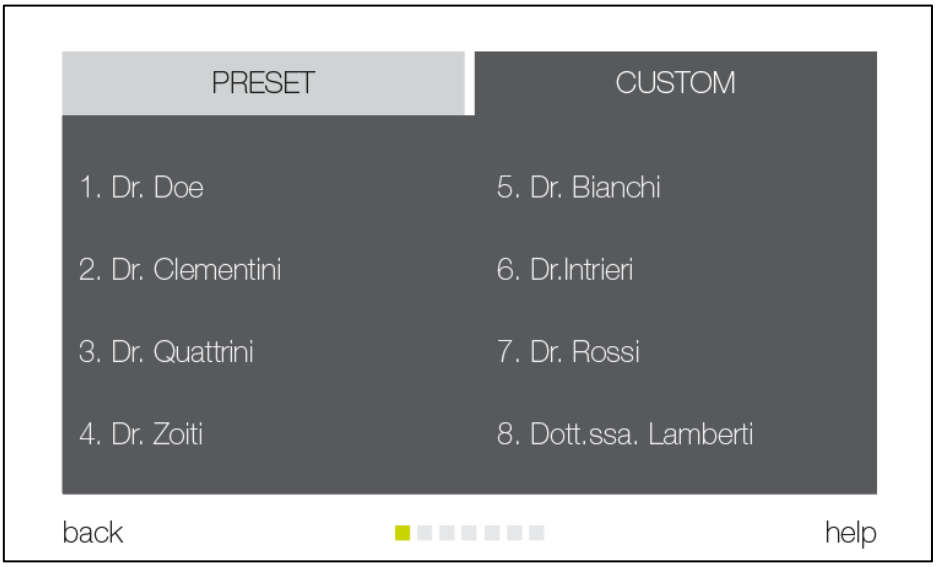
PROGRAMS SECTION

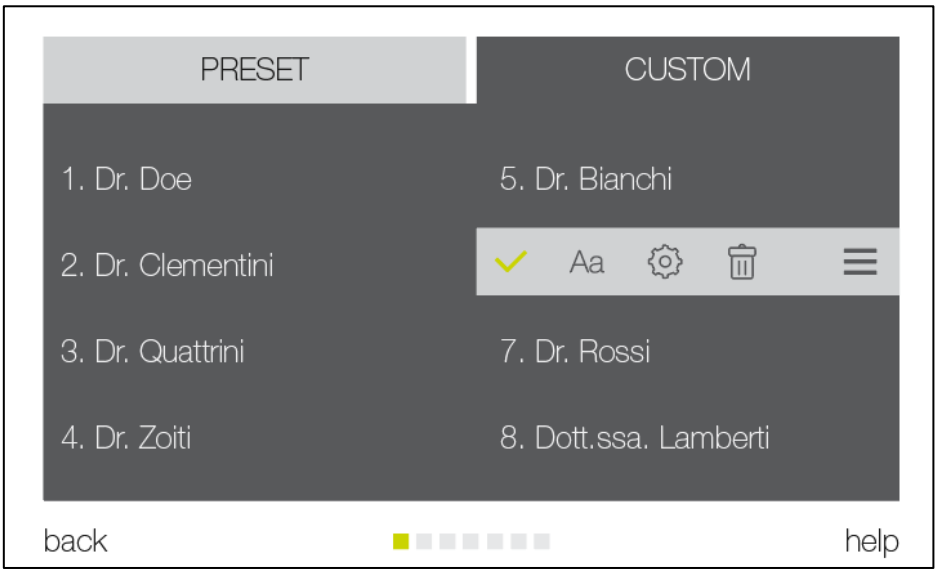
On the "*Surgery*" screen, you can add a custom program or view the programs present.

To create a new program, follow these steps:

- Set the desired values on the "*Surgery* " screen;
- Press on "+ *save* " and choose the name to be assigned, ending the process by clicking on "*enter* ";

The new custom programs can be viewed in the "*Programs* " section.





Through the icon representing three lines, you can perform different actions on the custom program:

Aa Rename.

Change

Delete.

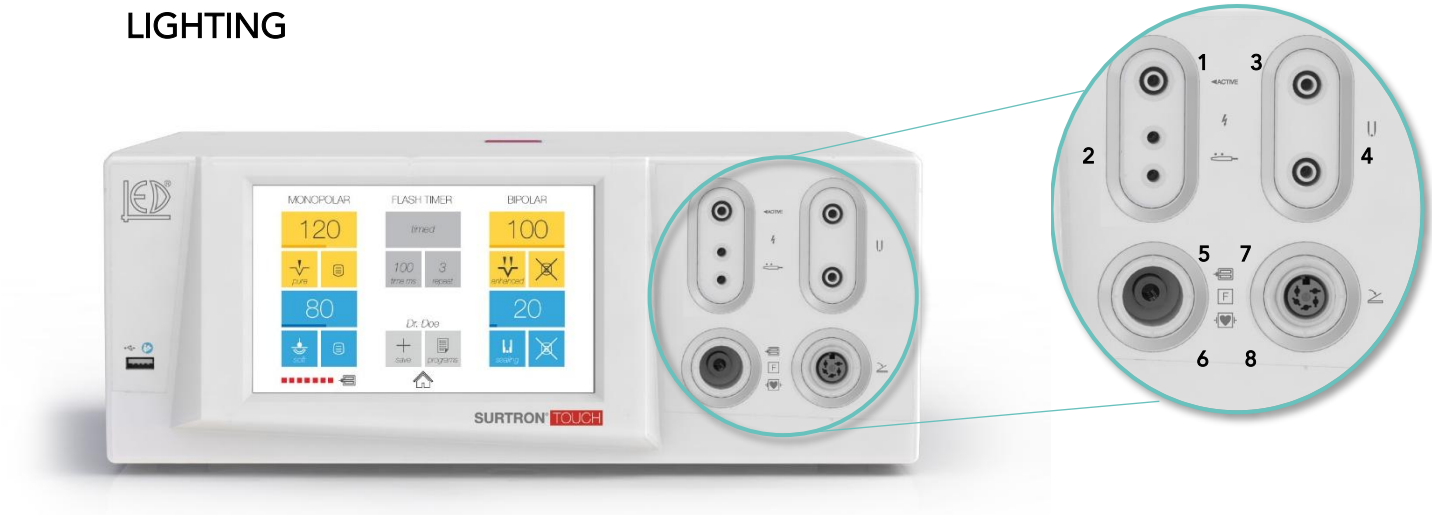
NEUTRAL ELECTRODE CONTROL

The neutral electrode circuit is continuously monitored by a special circuit that checks, only when bipartite neutral electrodes are used, that the loss of contact between the patient's reference plate or the variation in the conductivity characteristics of the neutral electrode may cause a reduction in the conductivity of the circuit and therefore an increased risk of burns for the patient.

In order to reduce noise pollution, the audible alarm only occurs if the discharge pedal is held down.

It is important to note that when using single-section neutral electrodes (single part) the circuit only controls the connection of the neutral electrode with the unit; Therefore, it is critical to ensure that the entire surface of the neutral electrode is applied correctly and securely to the patient.

LIGHTING



1. **Single-pole output connector**

2. **Monopolar Output Light**, which has three modes:
   - Indicator Light Off – Monopolar Functions Off *(tap on the display "MONOPOLAR" to turn the section on and off)*
   - Yellow Light – Cutoff Current Output
   - Blue Light – Coagulation Current Output

3. **Bipolar output connector**

4. **Bipolar Output Light**, which has three modes:
   - Indicator Light Off – Bipolar function not active (touch on the display "*BIPOLAR*" to activate or deactivate function)
   - Yellow Light – Cutoff Current Output
   - Blue Light – Coagulation Current Output

5. **Connector for neutral electrode connection**

6. **Neutral electrode connection light**, which has two modes:

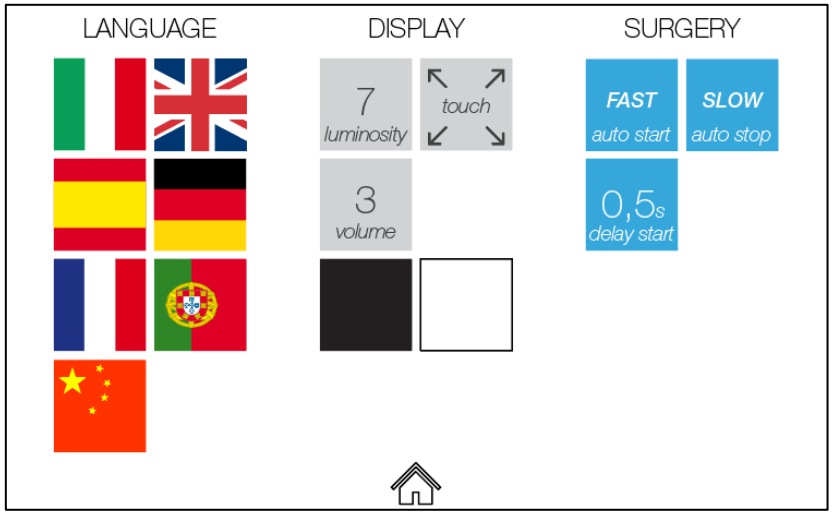
- White Indicator Light – Correct Neutral Electrode Placement
- Red Indicator Light – Incorrect or missing neutral electrode placement

7. **Connector for pedal connection**

8. **Pedal light**, if off indicates the pedal is not connected

SETTINGS

Starting from the home page and choosing the "*Settings*" option, the following screen will appear:



Through which it will be possible to view three sections:

- Language;
- Display, through which you can change the brightness, touch sensitivity, volume and black or white display;
- Surgery, which involves the selection of the response of the delay of surgery and fast and medium-slow autostart/hitchhiking.

With the start and autostart functions (see paragraph "AUTOSTART AND AUTOSTOP") it is possible to select the delay time between the contact between the active electrode and the fabric and the activation of the dispensing (from 0.1 s to 2.0 s).

While the start sensitivities of the autostart and autostop functions can be set to SLOW, MEDIUM and FAST.

Pressing on the "*home*" icon will go back.

UPDATES

Starting from the home page and choosing the "*Update*" option, it will be possible to update:

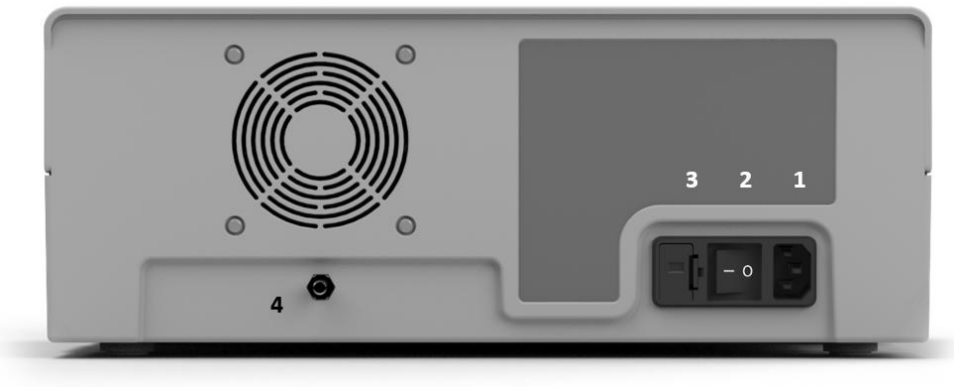
- Software
- Images
- Protocols
- Firmware.

To perform updates, you must connect a device that can be paired with the USB connector and contains the compatible file of the software, images, protocols, or firmware to be updated.
Follow these steps:

1. Insert the compatible device into the USB connector of the equipment.
2. On the screen, select the corresponding option from "Software," "Images," "Protocols," or "Firmware."
3. Afterward, confirm your selection via the popup that will appear.
4. Follow the on-screen instructions to complete the update process.
5. Once the update is complete, you can select the "*Home*" or "*Back*" option to exit the procedure and return to the home screen.

It is crucial to follow the on-screen instructions carefully throughout the entire process to ensure a successful and secure update.

REAR PANEL



1. Power Socket
2. Power Switch
3. Fuse Holder / Voltage Selector Switch
4. Equipotential Bonding

EQUIPMENT POWER MODULE AND VOLTAGE SELECTOR SWITCH

The equipment power module is the power connection point for the equipment's internal electronics. The aforementioned power module incorporates the power connector and line fuses. The voltage selector switch is located inside the power supply module.

WARNING: Before switching on the equipment, the operator should ensure that the mains voltage indicated in the voltage selector corresponds to the voltage to which it is connected and that fuses appropriate for the selected voltage have been inserted.

POWER SWITCH

To turn on the power to the equipment, press the switch in direction 1. When the power is on, the front panel is illuminated. Pressing the switch in direction 0 will disconnect the power supply, which allows the mechanical switch to be used as an emergency switch in the event of a fault.

TECHNICAL SPECIFICATIONS

Tolerance	Description	SURTRON® TOUCH 200
-	Electrosurgical Unit Code	10100.T40
-	Tissue impedance monitoring system (bipolar coagulation – autostart/autostop)	•
-	Bipolar coagulation with automatic activation/deactivation	•
-	Selectable minimum power	1
-	Unit control via touch screen	•
± 20%	Maximum CUT power (W)	200W→ 300Ω
± 20%	Maximum BLEND power (W)	150W → 200Ω
± 20%	Maximum ENHANCED power (W)	150W → 300Ω
± 20%	Maximum FORCED COAG power (W)	150W → 200Ω
± 20%	Maximum SOFT COAG power (W)	100W → 200Ω
± 20%	Maximum FULGURATION power (W)	100W → 1000Ω
± 20%	Maximum BIPOLAR CUT power (W)	120W → 50Ω
± 20%	Maximum BIPOLAR TUR power (W)	200W → 200Ω
± 20%	Maximum BIPOLAR COAG power (W)	120W → 50Ω
± 20%	Maximum BIPOLAR VESSEL SEALING power (W)	200W → 50Ω
± 5%	BLEND modulation frequency (Hz)	50
± 5%	ENHANCED modulation frequency (Hz)	1.25
± 5%	FORCED COAG modulation frequency (kHz)	20
± 5%	FULGURATION modulation frequency (kHz)	20
± 5%	BIPOLAR TUR modulation frequency (Hz)	50
± 0.3	CUT crest factor	1.9
± 0.3	BLEND crest factor	3.0
± 0.3	ENHANCED CUT crest factor	3.0
± 0.3	FORCED COAG crest factor	3.0
± 0.3	SOFT COAG crest factor	1.9
± 0.3	FULGURATION crest factor	3.2
± 0.3	BIPOLAR CUT crest factor	2.4
± 0.3	BIPOLAR TUR crest factor	2.4
± 0.3	BIPOLAR COAG crest factor	2.4
± 0.3	BIPOLAR VESSEL SEALING crest factor	2.4
± 10%	Operating frequency	360 kHz
± 15%	Maximum open-circuit voltage CUT (Vpp)	2200
± 15%	Maximum open-circuit voltage BLEND (Vpp)	2000
± 15%	Maximum open-circuit voltage ENHANCED CUT (Vpp)	2500
± 15%	Maximum open-circuit voltage FORCED COAG (Vpp)	3500
± 15%	Maximum open-circuit voltage SOFT COAG (Vpp)	1500
± 15%	Maximum open-circuit voltage FULGURATION (Vpp)	4500
± 15%	Maximum open-circuit voltage BIPOLAR CUT (Vpp)	1000
± 15%	Maximum open-circuit voltage BIPOLAR TUR (Vpp)	1200
± 15%	Maximum open-circuit voltage BIPOLAR COAG (Vpp)	1000
± 15%	Maximum open-circuit voltage BIPOLAR VESSEL SEALING (Vpp)	1300
± 0.5	Dimensions L×H×D (mm)	370x144x319
± 10	Weight (kg)	6
± 5%	Power supply (Vac)	100 – 240
± 1%	Mains frequency (Hz)	50-60
± 0	Supply fuses 5×20 mm, delayed	2xT 10AL 250V
± 10%	Maximum power consumption (VA)	750
± 10%	Maximum current consumption 240 Vac (A)	3,15
± 10%	Maximum current consumption 100 Vac (A)	7,5
-	Adjustable sound emission	•
-	Self-diagnostic system	•

Tolerance	Description	SURTRON® TOUCH 200
-	Output power control	●
-	System Plate Electronic Control	●
-	Capability to connect united and bipartite electrodes	●
-	Storable settings	Over 50
-	Electrical classification (EN 60601-1)	Class I Applied Part CF
-	MDR 2017/745/EU classification	II b
-	Protection class (EN 60529)	IP32
-	EN 55011 (CISPR 11) classification – Class/Group	2 / A
-	Neutral electrode	F
-	Duty cycle (action/pause) in seconds	10 / 30
-	Activation type pedal/manual	●
-	Defibrillator protection	●
-	Equipotential socket	●
-	ABS housing	●

● = PRESENT - = NOT PRESENT

HARDWARE REQUIREMENTS

Microcontroller	ARM Cortex M4
Clock Frequency	200 MHz
Flash	2048 KB
RAM	512 KB
SDRAM DDR2	512 MB
Nand Flash	1 Gb
Peripherals	UART, I2C, SPI, Watch-dog timer, USB2.0
Visual	Touchscreen display 7'' 800x480 px

MAINTENANCE

GENERALITY

There are no user-adjustable parts inside the equipment for calibration or servicing.
The equipment housing must not be opened: the warranty is voided by any unauthorized tampering with the unit. In case of repair or adjustment needs, the entire equipment should be sent to the LED SpA service centre in APRILIA (LT), ITALY, along with a description of the fault.
User maintenance mainly consists of cleaning and sterilizing the accessories and checking the equipment before each use. Functional and safety checks to verify parameters must be performed by qualified technical personnel.

CLEANING THE HOUSING

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

CLEANING AND STERILIZATION OF ACCESSORIES

If non-sterile disposable accessories are used, carefully follow the Instructions for Use (IFU) provided by the manufacturer of each accessory for the sterilization method and dispose of them according to current regulations.
When using reusable accessories, the maximum number of cycles and the sterilization method specified in the Instructions for Use provided by the manufacturer of each accessory must be strictly followed.

TROUBLESHOOTING GUIDE

In the event of a problem, you must first check that you have correctly installed and prepared the accessories. The error code generated is shown on the display.

Problem	Probable Cause	Solution
The equipment does not turn on	Interruption or absence of mains power	Check the power cord connection. Check the condition of the fuses and replace with suitable type if necessary.
Neutral Electrode alarm always on	Interruption or poor contact on the neutral electrode circuit	Check the cable connection to the neutral electrode. Replace the electrode connection cable.
The unit does not respond to the actuation command	Handpiece or foot pedal fault Incorrect handpiece or foot pedal connection Unit in OVT alarm	Replace the handpiece and/or foot pedal. Check the connection of the handpiece or foot pedal. Wait for the OVT light to turn off.
Error Code 001	Dispensing controls activated during power-up	Unplug the handpiece and/or foot pedal and turn the unit back on.
Error Code 004	Error in the conversion circuit	Contact Technical Assistance
Error Code 010	Error in the output power activation circuit	Contact Technical Assistance
Error Code 022	Communication Error	Contact Technical Assistance

REPAIRS

High-frequency cables or electrode handpieces cannot be repaired. Always replace a defective part with a new one.

REPLACING THE FUSES

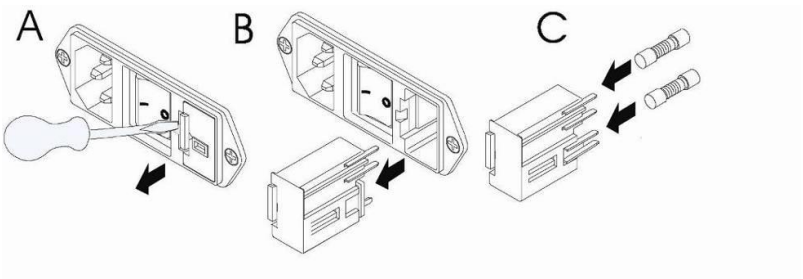
Before replacing the fuses, disconnect the equipment from the power supply.

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 with reference to these data:

Tension 100-240V Time-Delay Fuses T10 AL, 250V / 5 x 20 mm



CHECKING THE UNIT BEFORE USE

Whenever the unit is programmed to be used, a check of the main safety conditions must be established by considering the following points:

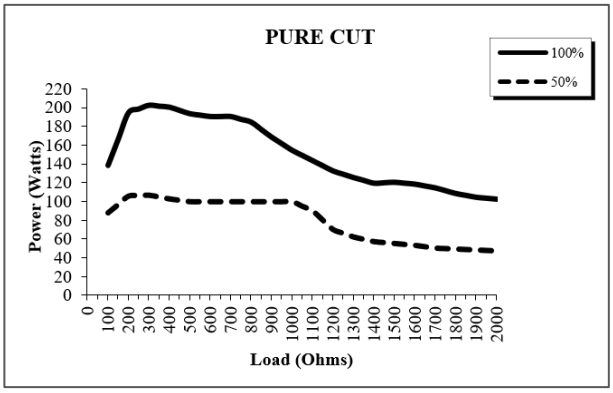
- Check the integrity of cables, connections, broken wires, etc.;
- Make sure all electrical equipment is properly grounded;
- Ensure that all accessories that should be used are available and sterilized;
- Check the operation of the OC light by disconnecting the reference electrode cable. Active unit and control OC light and audible alarm alert;
- By activating the CUT and COAG power switch, check the operation of the emission light and acoustic warnings.

CONTROL AND MEASUREMENT OF SAFETY FUNCTIONS

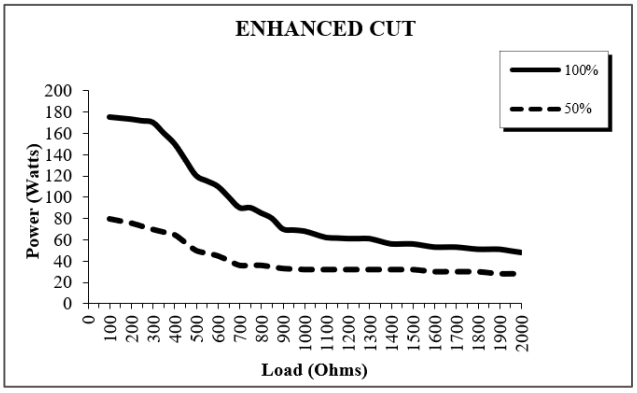
Periodically (at least once a year) checks and measurements should be scheduled by the Department of Bioengineering or other specialists.

- Check the condition of cables and power connectors.
- Visual inspection of mechanical guards.
- Control of protections against the dangers deriving from the spillage and penetration of liquids, drips, moisture, hygiene products and disinfectants.
- Checking the data on the device plate.
- Check the availability of the instruction manual.
- High-frequency output control.
- Measurement of conductivity resistance to ground.
- High-frequency leakage current measurement.
- Control of neuromuscular stimulation.
- Output power correction control.

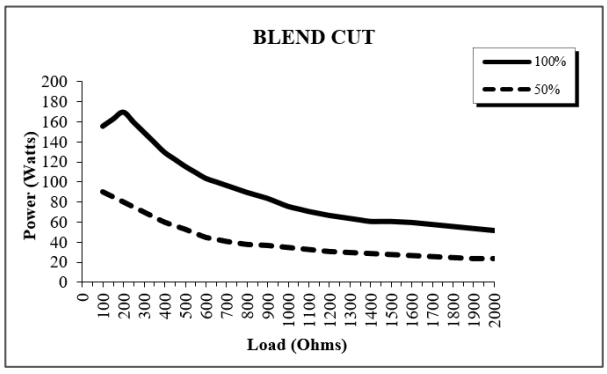
GRAPHS



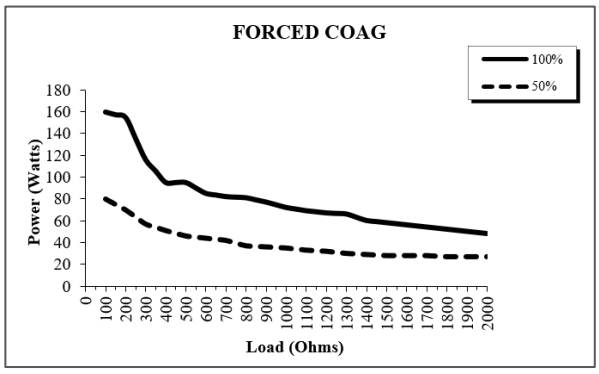
Maximum and average power diagram on variable load 100-2000Ω for PURE CUT



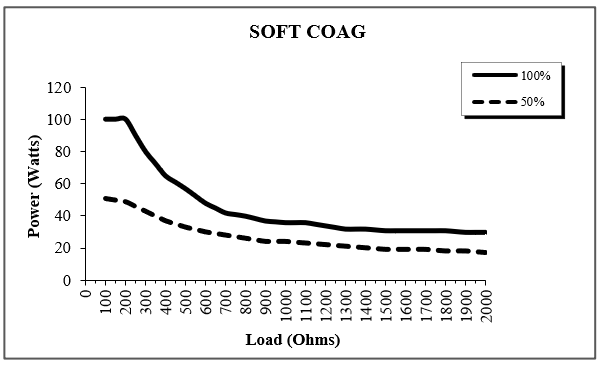
Maximum and average power diagram on variable load 100-2000Ω for ENHANCED CUT



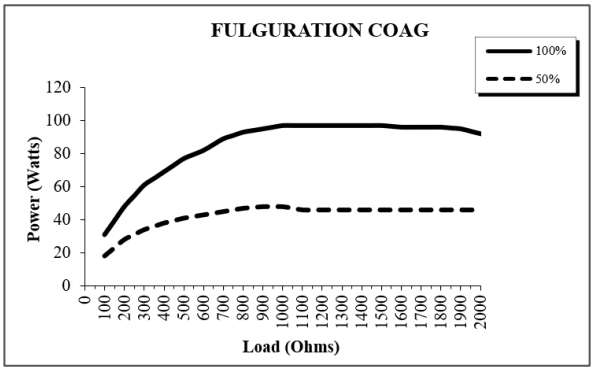
Maximum and average power diagram on variable load 100-2000Ω for BLEND CUT



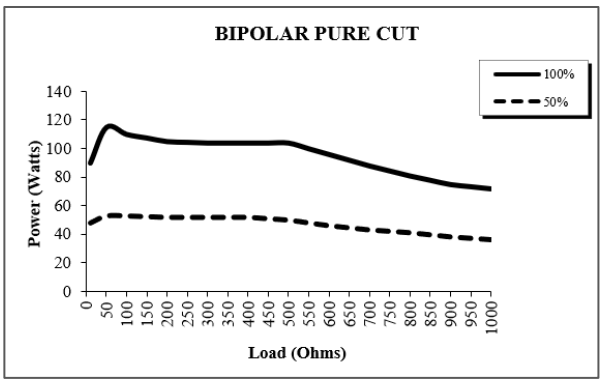
Maximum and average power diagram on variable load 100-2000Ω for FORCED COAG



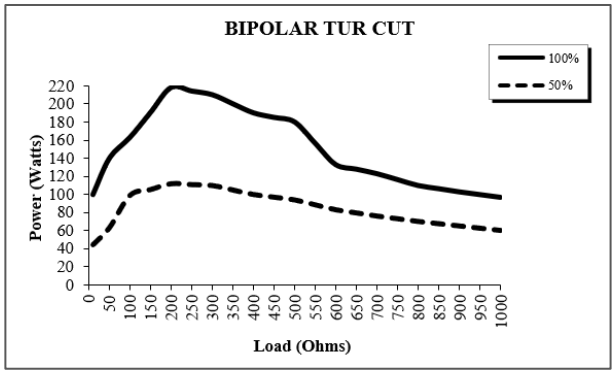
Maximum and average power diagram on variable load 100-2000Ω for SOFT COAG



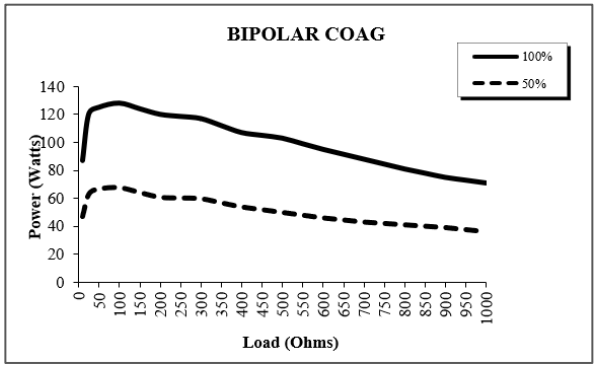
Maximum and average power diagram on variable load 100-2000Ω for FULGURATION COAG



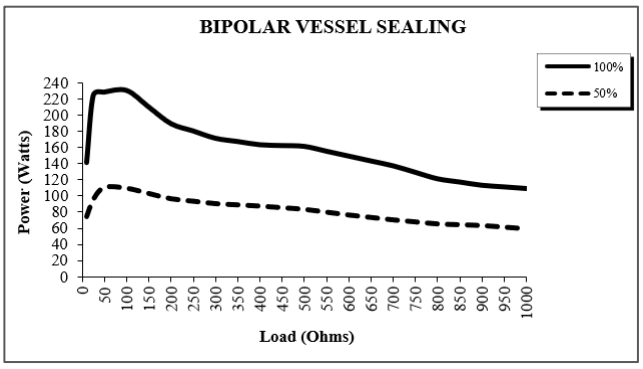
Maximum and average power diagram on variable load 10-1000Ω for BIPOLAR PURE CUT



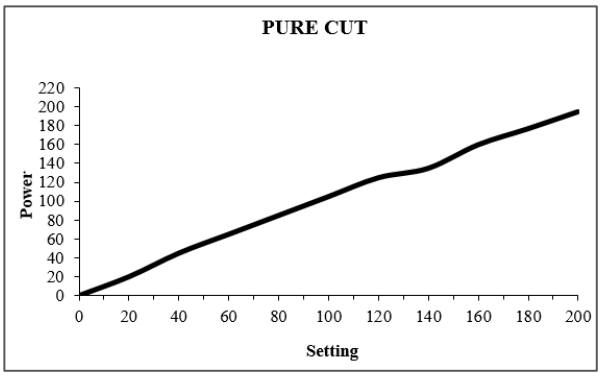
Maximum and average power diagram on variable load 10-1000Ω for BIPOLAR TUR CUT



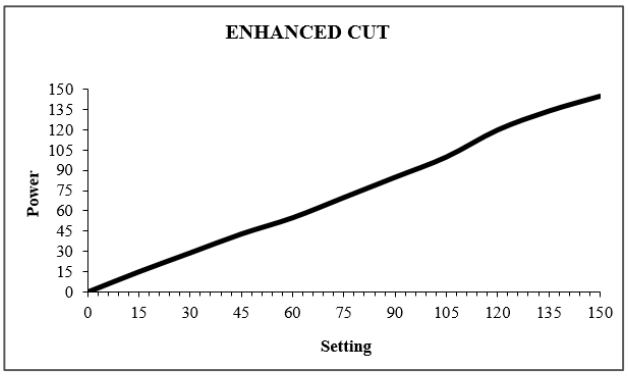
Maximum and average power diagram on variable load 10-1000Ω for BIPOLAR COAG



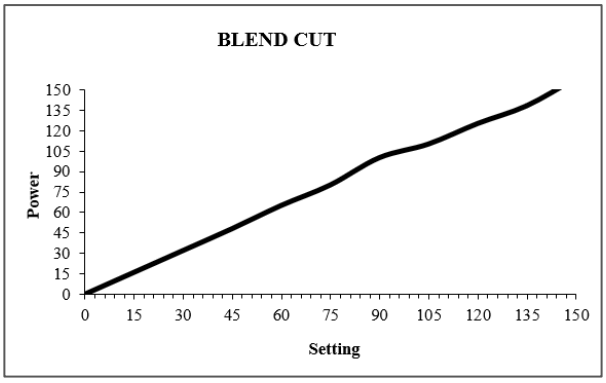
Maximum and average power diagram on variable load 10-1000Ω for BIPOLAR VESSEL SEALING



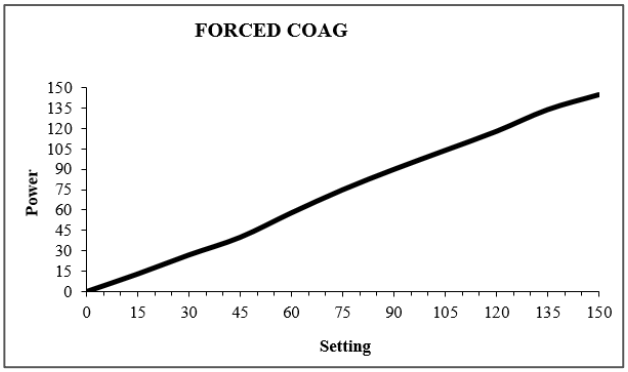
Output Power Diagram on Rated Load for PURE CUT



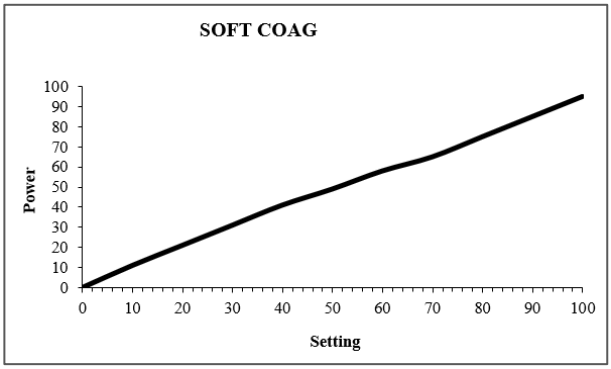
Output Power Diagram on Rated Load for ENHANCED CUT



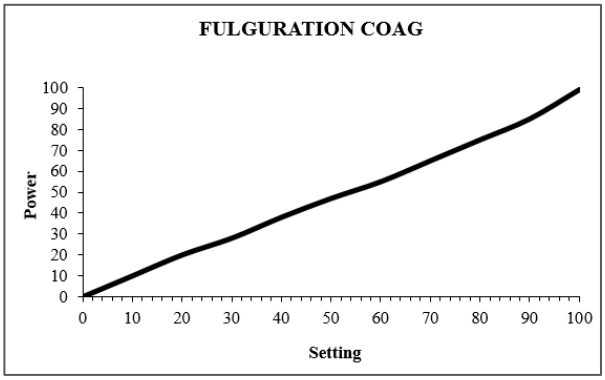
Output Power Diagram on Rated Load for BLEND CUT



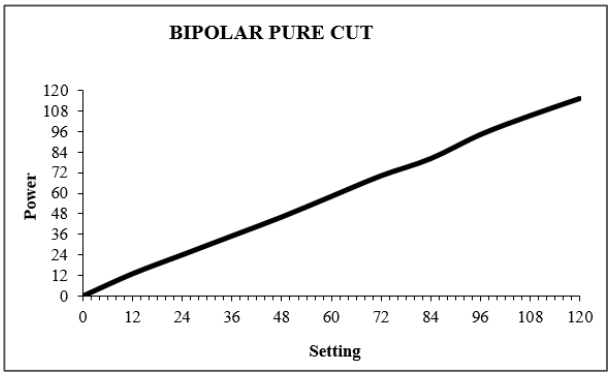
Output Power Diagram on Rated Load for FORCED COAG



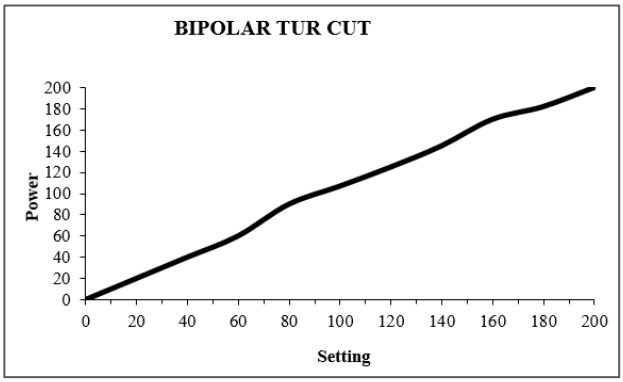
Output Power Diagram on Rated Load for SOFT COAG



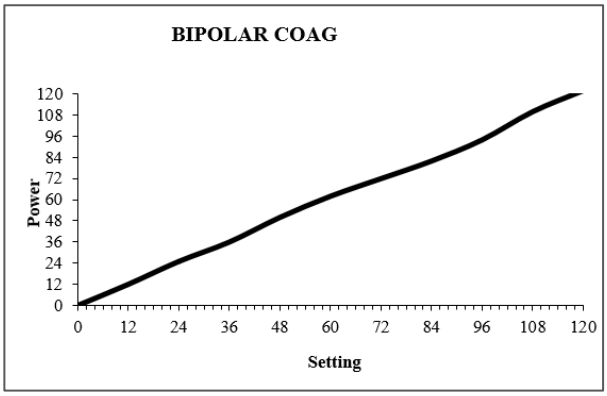
Output Power Diagram on Rated Load for FULGURATION COAG



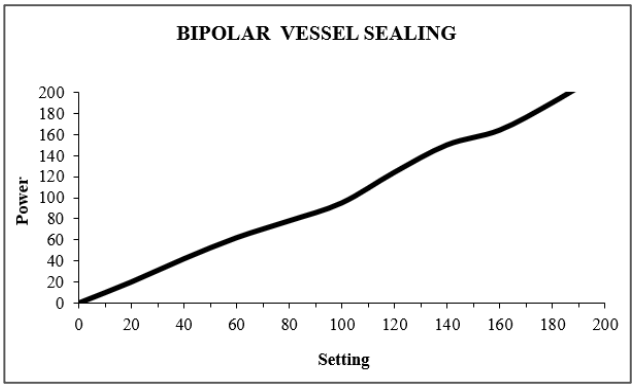
Output Power Diagram on Rated Load for BIPOLAR PURE CUT



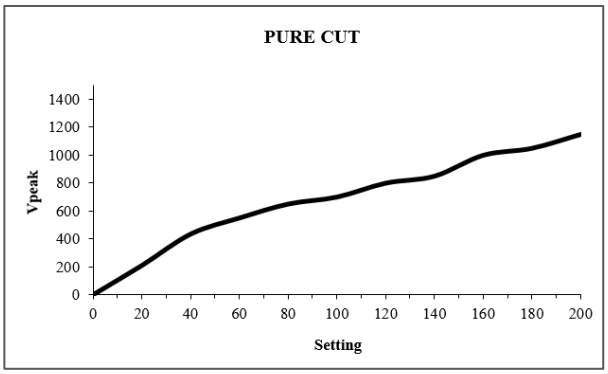
Output Power Diagram on Rated Load for BIPOLAR TUR CUT



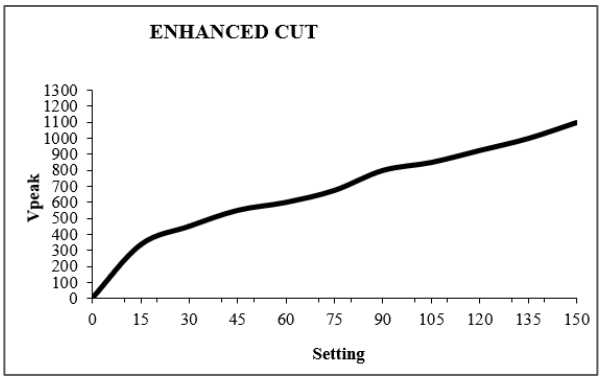
Output Power Diagram on Rated Load for BIPOLAR COAG



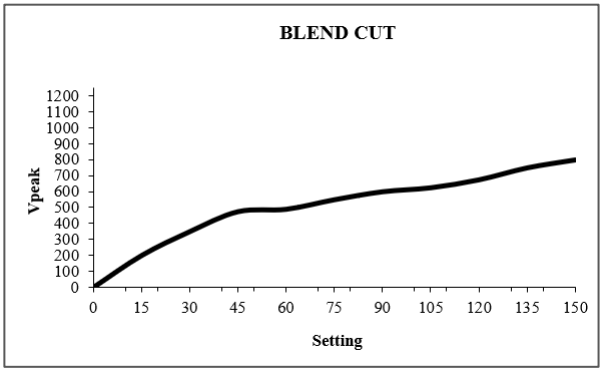
Output Power Diagram on Rated Load for BIPOLAR VESSEL SEALING



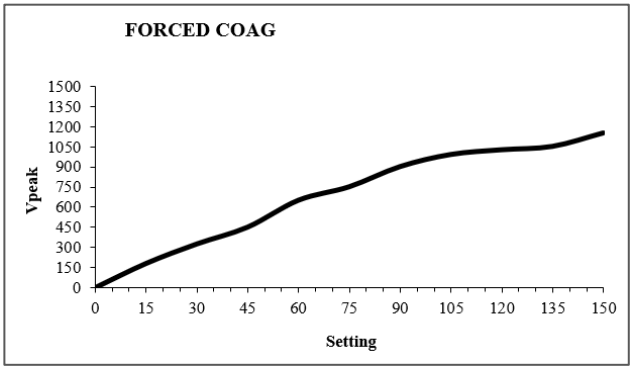
Maximum Output Voltage Diagram (Vpeak) for PURE CUT



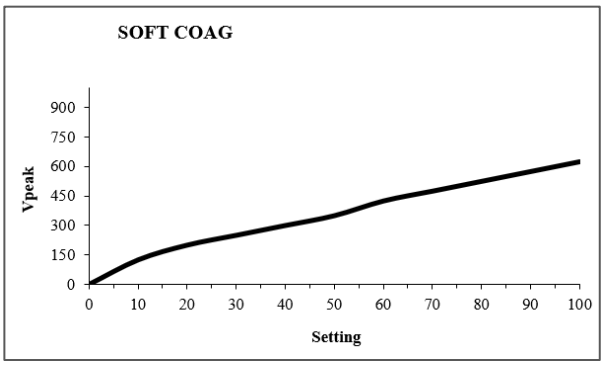
Maximum Output Voltage Diagram (Vpeak) for ENHANCED CUT



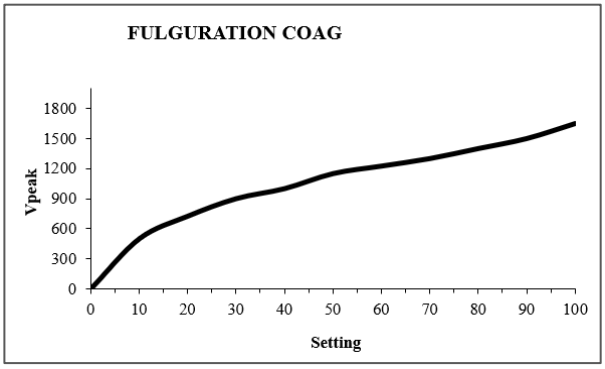
Maximum Output Voltage Diagram (Vpeak) for BLEND CUT



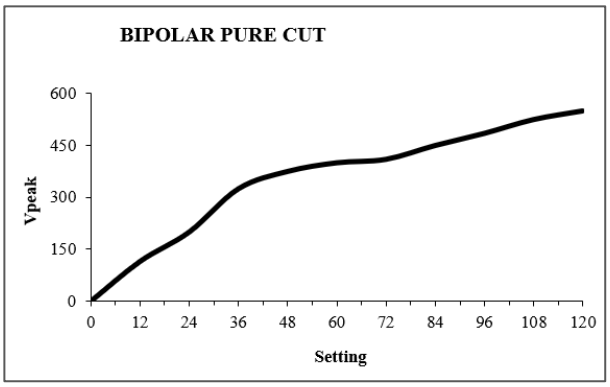
Maximum Output Voltage Diagram (Vpeak) for FORCED COAG



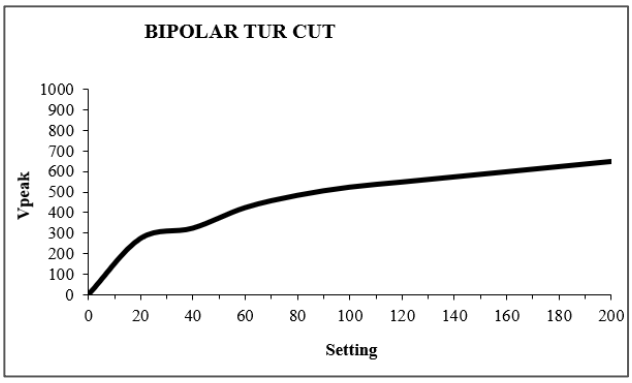
Maximum Output Voltage Diagram (Vpeak) for SOFT COAG



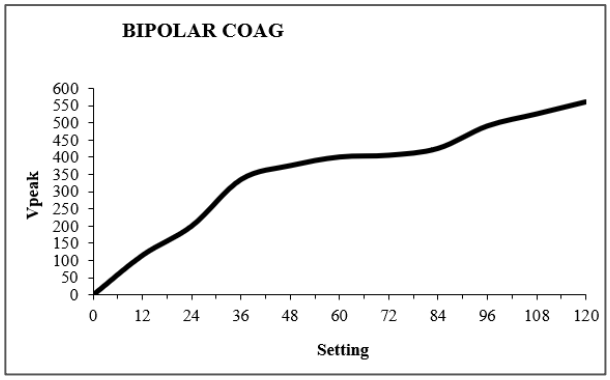
Maximum Output Voltage Diagram (Vpeak) for FULGURATION COAG



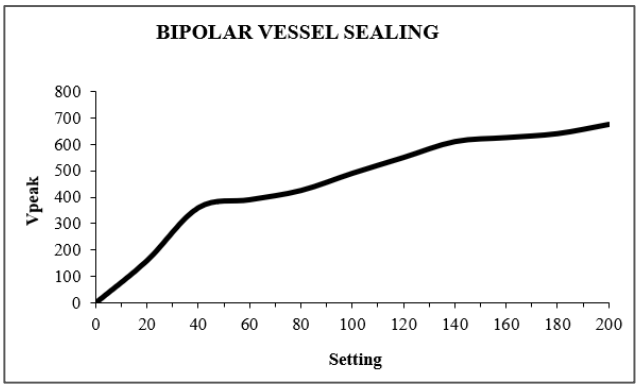
Maximum Output Voltage Diagram (Vpeak) for BIPOLAR PURE CUT



Maximum Output Voltage Diagram (Vpeak) for BIPOLAR TUR CUT



Maximum Output Voltage Diagram (Vpeak) for BIPOLAR COAG



Maximum Output Voltage Diagram (Vpeak) for BIPOLAR VESSEL SEALING

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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LED SpA

via Selciatella 40
04011 Aprilia (LT) Italy
info@led.it
Phone +39 06 92870045
Fax +39 06 92870046

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