EN

SURTRON® *80-120-160*

ELECTROSURGICAL UNIT

USER MANUAL

CE
0051

SUMMARY

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IMPORTANT

These instructions are integral to the high-frequency surgery equipment, detailing its operation and use. Therefore, it is crucial to read them carefully before initiating the installation and use of the equipment.

Please adhere to all safety instructions and warning notes. Ensure that these operating instructions accompany the equipment when transferred to other operating personnel.

For Technical Assistance, please contact LED SpA.

Produttore / *Manufacturer*

LED SpA

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INTRODUCTION

INTENDED USE/ FIELDS OF APPLICATION

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

The **SURTRON® 80-120-160** equipment are designed to be used in the following sectors:

Description	**SURTRON®**		
	80	**120**	**160**
Electrosurgical unit code	10100.101	10100.201	10100.301
Casualty Surgery	●	●	●
Dental	●	●	●
Dermatology	●	●	●
Endoscopy	-	-	-
First Aid	●	●	●
Gastroenterology	-	-	-
General Surgery	-	-	-
Gynecology	-	-	-
Neurosurgery	-	-	-
Oftalmology	-	-	-
Orthopedics	-	-	-
Otorhinolaryngology	-	-	-
Pediatric Surgery	-	-	-
Plastic Surgery	-	-	-
Pneumology	-	-	-
Urology	-	-	-
Vascular Surgery	-	-	-

● = Usable
- = Not Usable

INTENDED USER

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

INTENDED PATIENT POPULATION

Adults - Men and Women (≥18 years), excluding patients present in the section "Contraindications".

STANDARD AND OPTIONAL COMPOSITION

Description	SURTRON®		
	80	120	160
Electrosurgical unit code	10100.101	10100.201	10100.301

Code	Description	SURTRON®		
		80	120	160
00100.03	Power cable 2MT SIE-IEC	■/1	■/1	■/1
00202.00	Holder for handpiece and electrodes	■/1	■/1	■/1
00205.00	PENCIL S - Handpiece with buttons	■/1	■/1	■/1
00304.00	Single watertight foot pedal	■/1	■/1	■/1
00404.08_S	Connecting cable Neutral electrode type mono/5365	■/1	■/1	■/1
00500.00	ELECTRODE - Assorted electrode kit (10 pcs.) 5cm	■/1	■/1	■/1
5365A	NEUTRAL - Neutral metal electrode 120x160mm	■/1	■/1	■/1
00100.00	Power cable 2MT IT-IEC	○	○	○
00100.01	Power cord 5MT SIE-IEC	○	○	○
00100.04	Power cord 2MT USA-IEC	○	○	○
00100.05	Power cord 2MT GB-IEC	○	○	○
00100.07	Power cord 2MT BR-IEC	○	○	○
00100.09	Power cord 2MT AU-IEC	○	○	○
00100.10	Power cord 5MT JP-IEC	○	○	○
00201.02	PENCIL - Autoclavable Micro-Needle Handpiece	○	○	○
00205.40	PENCIL - Handpiece with autoclavable buttons	○	○	○
00206.00	PENCIL - Handpiece without buttons	○	○	○
00206.40	PENCIL - Handpiece without buttons	○	○	○
00304.04_S	Waterproof single foot pedal (3 m)	○	○	○
00305.03_S	Double watertight foot control	○	○	○
00400.00	Cluster reference electrode with cable	○	○	-

Code	Description	SURTRON®		
		80	120	160
00401.00	NEUTRAL - Neutral metal electrode 120x160mm with cable	○	○	○
00401.01	NEUTRAL - Neutral metal electrode 240x160mm with cable	○	○	○
00401.02	NEUTRAL - Neutral metal electrode 120x160mm with autoclavable cable	○	○	○
00401.03	NEUTRAL - Neutral metal electrode 240x160mm with autoclavable cable	○	○	○
00401.10	NEUTRAL - Neutral electrode steel FLEX 120x210mm	○	○	○
00401.11	NEUTRAL - Neutral electrode steel FLEX 120x210mm with cable	○	○	○
00401.12	NEUTRAL - FLEX 120x210mm Stainless Steel Neutral Electrode with autoclavable cable	○	○	○
00401.20	NEUTRAL - FLEX S 120x210mm Stainless Steel Neutral Electrode with cable	○	○	○
00401.21	NEUTRAL - FLEX S 120x210mm Stainless Steel Neutral Electrode with autoclavable cable	○	○	○
00401.22	NEUTRAL - FLEX S 120x210mm steel neutral electrode with cable	○	○	○
00402.00	CONNECTION - M4-F4 3m monopolar cable	○	○	○
00402.01	CONNECTION - M4-F2.8 3m monopolar cable	○	○	○
00402.02	CONNECTION - Monopolar cable M4-MP4 3m	○	○	○
00402.03	CONNECTION - M4-EU Monopolar cable 3m	○	○	○
00402.04	CONNECTION - M4-F2-2.8 3m Monopolar cable	○	○	○
00404.07	CONNECTION - Neutral electrode cable F7915/F7930	○	○	○
00404.09	CONNECTION - Neutral electrode cable 5365-6429/FLEX-FLEX S autoclavable	○	○	○
00404.10	CONNECTION - Neutral electrode cable US	○	○	○
00411.00	CONNECTION - Bipolar cable 3m EUR	○	○	○
00412.00	CONNECTION - Bipolar Cable 3mt TWIN	○	○	○
00413.00	CONNECTION - Bipolar cable Artery Selar	○	○	○
00414.00	CONNECTION - Bipolar cable 3mt US	○	○	○
00415.00	CONNECTION - Bipolar cable 3mt ENDO1 (F4-F2)	○	○	○
00416.00	CONNECTION - Bipolar cable 3mt ENDO2 (MP2-F2)	○	○	○
00417.00	CONNECTION - Bipolar cable 3mt ENDO3 (MP2-F4)	○	○	○
00418.00	CONNECTION - Bipolar cable 3mt SCISS (F2.4-F2.4)	○	○	○
00498.00	Bipolar operation adapter	○	○	○
00498.06	Adapter for neutral electrode 6.3mm/Valley	○	○	○
00498.08	Adapter for bipolar operation EUR/2xM2,5	○	○	○
00498.10	Bipolar operating adaptor EUR/3xM4	○	○	○
00500.00/L	ELECTRODE - Assorted Electrode Kit (10Pcs) 10cm	○	○	○
0350	Disposable Neutral Electrode (F7805)	○	○	○

Code	Description	SURTRON®		
		80	120	160
152-110	ELECTRODE - 7cm Blade Electrode	○	○	○
152-112	ELECTRODE - 7cm Curved blade electrode	○	○	○
152-115	ELECTRODE - Blade electrode 16 cm	○	○	○
152-120	ELECTRODE - Needle electrode 7 cm	○	○	○
152-122	ELECTRODE - Curved needle electrode 7 cm	○	○	○
152-125	ELECTRODE - Needle electrode 13 cm	○	○	○
152-130	ELECTRODE - Ball electrode ⌀ 2mm 6 cm	○	○	○
152-132	ELECTRODE - Ball bent electrode ⌀ 2mm 6 cm	○	○	○
152-140	ELECTRODE - Ball electrode ⌀ 3mm 6 cm	○	○	○
152-142	ELECTRODE - Ball bent electrode ⌀ 3mm 5 cm	○	○	○
152-145	ELECTRODE - Ball electrode ⌀ 3mm 14 cm	○	○	○
152-150	ELECTRODE - Ball electrode ⌀ 4mm 6 cm	○	○	○
152-152	ELECTRODE - Curved ball electrode ⌀ 4mm 6 cm	○	○	○
152-160	ELECTRODE - Ball electrode ⌀ 5mm 6 cm	-	○	○
152-162	ELECTRODE - Ball bent electrode ⌀ 5mm 6 cm	-	○	○
152-165	ELECTRODE - Ball electrode ⌀ 5mm 14 cm	-	○	○
152-175-10	ELECTRODE - Bend electrode 10x10 l.15 cm	○	○	○
152-190-13	ELECTRODE - Bend electrode 20x13 l.15 cm	○	○	○
152-190-20	ELECTRODE - Bend electrode 20x20 l.15 cm	○	○	○
152-195	ELECTRODE - Electrode for conization 13 cm	○	○	○
310-110-05	BIPOLAR - Bipolar Pliers 11.5cm TIP0.5mm	○	○	○
310-112-05	BIPOLAR - Bipolar Curved Pliers 11.5cm TIP0.5mm	○	○	○
310-140-10	BIPOLAR - Bipolar Pliers 20cm TIP 1mm	○	○	○
310-140-20	BIPOLAR - Bipolar Pliers 20cm TIP 2mm	○	○	○
310-142-10	BIPOLAR - Bipolar Crimping Pliers 20cm TIP 1mm	○	○	○
310-142-20	BIPOLAR - Bipolar Curved Pliers 20cm TIP 2mm	○	○	○
310-180-10	BIPOLAR - Bipolar Angled Pliers 20cm TIP 1mm	○	○	○
310-180-20	BIPOLAR - Bipolar Angled Pliers 20cm TIP 2mm	○	○	○
310-182-10	BIPOLAR - Bipolar Angled Pliers 20cm TIP 1mm	○	○	○
310-185-10	BIPOLAR - Bipolar Angled Pliers 20cm TIP 1mm	○	○	○
310-510	BIPOLAR - Bipolar Electrode 20cm - straight	○	○	○
310-550	BIPOLAR - Bipolar electrode 20cm - angled	○	○	○
310-590	BIPOLAR - Bipolar Electrode 20cm - angled 2	○	○	○
330-134-20	MONOPOLAR - Monopolar Pliers 20cm TIP2mm	-	○	○
330-160	MONOPOLAR - Monopolar Scissors 18cm	-	○	○
500500.L1	ELECTRODE - Fine wire straight electrode (5Pcs) 5cm	○	○	○
500500.L1/L	ELECTRODE - Fine Wire Straight Electrode (5Pcs) 10cm	○	○	○
500500.L10	ELECTRODE - Spherical angled electrode ⌀ 3mm (5Pcs) 5cm	○	○	○

Code	Description	SURTRON®		
		80	120	160
500500.L10/L	ELECTRODE - Spherical angled electrode ⌀ 3mm (5Pcs) 10cm	○	○	○
500500.L11	Microsurgery needles (10Pcs)	○	○	○
500500.L2	ELECTRODE - Fine wire angled electrode (5Pcs) 5cm	○	○	○
500500.L2/L	ELECTRODE - Fine wire angled electrode (5Pcs) 10cm	○	○	○
500500.L3	ELECTRODE - 4mm loop electrode ⌀ 4mm (5Pcs) 5cm	○	○	○
500500.L3/L	ELECTRODE - Loop electrode ⌀ 4mm (5Pcs) 10cm	○	○	○
500500.L4	ELECTRODE - Loop electrode ⌀ 8mm (5Pcs) 5cm	○	○	○
500500.L4/L	ELECTRODE - Loop electrode ⌀ 8mm (5Pcs) 10cm	○	○	○
500500.L5	ELECTRODE - Angled Hook Electrode (5Pcs) 5cm	○	○	○
500500.L5/L	ELECTRODE - Hook Angled Electrode (5Pcs) 10cm	○	○	○
500500.L6	ELECTRODE - Thick wire angled electrode (5Pcs) 5cm	○	○	○
500500.L6/L	ELECTRODE - Thick wire angled electrode (5Pcs) 10cm	○	○	○
500500.L7	ELECTRODE - Thick wire angled electrode (5Pcs) 5cm	○	○	○
500500.L7/L	ELECTRODE - Droplet Electrode (5Pcs) 10cm	○	○	○
500500.L8	ELECTRODE - Loop Electrode (5Pcs) 5cm	○	○	○
500500.L8/L	ELECTRODE - Noose Electrode (5Pcs) 10cm	○	○	○
500500.L9	ELECTRODE - Straight ball electrode ⌀ 3mm(5Pcs) 5cm	○	○	○
500500.L9/L	ELECTRODE - Ball straight electrode ⌀ 3mm(5Pcs) 10cm	○	○	○
6429A	NEUTRAL - Neutral metal electrode 240x160mm	○	○	○
755VL	Disposable handpiece with buttons (F4797)	○	○	○
F7520	Electrode cleaning sponge 47x50mm	○	○	○
F7920	Disposable bipartite neutral electrode (F7820)	○	○	○
F7930	Conductive rubber bipartite neutral electrode w/cable	○	○	○
TR003	Trolley 3 shelves	○	○	○
TR003W	Trolley 3 shelves wide	○	○	○
TR004	Trolley 4 shelves	○	○	○
TR005	Trolley 5 shelves	○	○	○
TR005W	Trolley 5 shelves wide	○	○	○

■/pcs = STANDARD ○ = OPTIONAL - = NOT COMPATIBLE

DESCRIPTION

The **SURTRON® 80-120-160** electrosurgical devices can deliver currents suitable for cutting, coagulated cutting, and coagulation, both in monopolar and bipolar modes. These currents can be delivered for the entire duration of the output circuit activation.

Single-plate or split-conductive area reference neutral electrodes can be used. Unit control is achieved through buttons, knobs, and indicators located on the front panel, while the power outlet is positioned on the rear of the equipment.

These devices are equipped with automatic safety control systems, which, by monitoring internal parameters, signal any detected faults or errors. The utilized operational parameters are continuously stored, allowing the equipment to recall the last settings used each time it is turned on or changes operational mode.

The emitted sound level can be adjusted based on the operator's preferences and working environmental conditions. The equipment can be operated using handpieces with or without buttons, with a single foot pedal or a double pedal system. Additionally, by using a special optional adapter, bipolar forceps can be connected to the equipment.

ELECTROPHYSICAL PRINCIPLES

In electrosurgical interventions the traditional use of surgical blade is substituted by an electrosurgical needle that allows for fast and effective cut and coagulation of the targeted tissue.

The electrosurgical needle operates on the principle of converting electrical energy into heat and consists of the following components:

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

Electric current flowing through biological tissue usually can cause:

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

1. *Joule Effect*

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

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

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

- Current Intensity and output power

- Modulation level

  Parameters that can be interpreted from the waveform of the high-frequency current produced by the generator.

- Electrode shape

  Pointed or rounded as required, it is very small in size; therefore, the current density on the tip surface [$A{\cdot}m^{-2}$] is very high. Thin-section electrodes create a 'high current density, and high temperature, promoting cutting action. Those with a large surface area create a lower current density, and lower temperature, realizing a coagulation effect.

- State of active electrode

  Thermal effects can be related to the resistance of the human body to which the contact resistance of the electrode must be added. It is essential to keep the active electrodes perfectly clean in order not to have a reduction in the effects.

- **Characteristics of the tissue**

  The resistive characteristics change according to the biological tissues.

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

(Example of specific resistances of organic and metallic materials)

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

- **Coagulation**

  Temperatures of 60 to 70 °C in the area around the active electrode cause slow heating of the intracellular fluid, the water contained in the cell evaporates, and a clotting action is achieved that stops bleeding.

- **Cut**

  Temperatures above 100 °C in the area surrounding the active electrode result in the vaporization of the intracellular fluid and explosion of the cell. The vapor present around the electrode triggers an intercellular chain reaction in the direction in which the active electrode is handled, also transmitting the vaporization energy to the immediately surrounding tissues.

  Electrotomy is, therefore, not mechanical resection. If the temperature reaches 500 °C, tissue carbonization occurs with a cauterizing action.

- **Mixed currents**

  These are obtained by combining the effects of coagulation and electrotomy. A reduction in bleeding occurs during a cutting procedure, or as a cut that develops a substantial layer of eschar.

  The high frequencies used by the electrosurgical scalpel, however, do not allow the electromagnetic field to penetrate matter and cause the current to flow through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the center of the conductor's cross-section. This effect, called the 'skin effect,' results in a decrease in the useful cross-sectional area for the passage of a current, and an increase in the electrical resistance of the material, and becomes a major problem in the neutral electrode. In fact, in this electrode the current density is very high (KA/m^2) at the edge, where excessive temperature rise due to the 'Joule effect' causes burns to the patient. Therefore, it is no accident that burns to the patient, which has occurred in surgical procedures, have the shape of the edge of the neutral electrode. To reduce the risk of burns, it is necessary to dose the delivered power ($I^2 \cdot t$) appropriately and follow the rules for applying the neutral electrode to the patient (see SAFETY chapter).

2. *Faradic Effect*

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

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

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

The physiological system of stimulus transmission follows a limiting curve in which pulsed or low-frequency currents generate a pacing pulse. With the high-frequency alternating current (above 200 kHz), which is used in electrosurgery, there are no neuromuscular reactions (the change of polarity is so fast that it does not affect the patient at the level of neuro-muscular reactions), let alone electrolyte damage to the body.
For this reason, all high-frequency generating equipment for surgical use (electrosurgery) works on base frequencies above 300 kHz so as not to introduce electrical stimulation.

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

OPERATIVE TECHNICS

MONOPOLAR CUT

Monopolar cutting is a technique used to dissect biological tissue by directing a high-frequency, high-density electrical current from the active electrode's tip. This current generates intense molecular heat within the cells, causing them to rupture. As the electrode moves through the tissue, it shears and destroys cells sequentially. This movement prevents the lateral spread of heat within the tissue, confining the destruction to a single line of cells.

For precise cutting with minimal thermal impact and limited hemostasis, a pure sine wave current without modulation is preferred. This allows for precise control and safe use without harming adjacent bone. However, some level of modulation in the

current is desirable to facilitate effective coagulation during the cutting process, making electrosurgery an advantageous technique.
The following rules help the operator achieve a good cut:

- Keep the tissue moist but not wet.
- Maintain the electrode perpendicular to the tissue.
- Activate the output circuit before making contact with the tissue.
- Keep the electrode tip clean (for this purpose, use optional electrode-cleaning sponges with code F7520).
- Allow the tissue to cool before making a new cut.

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

- No resistance when moving the electrode through the tissue.
- No change in the color of the cut surfaces.
- No residual tissue fibers on the electrode.

MONOPOLAR COAGULATION

When an increase in temperature occurs, caused by the heat generated through the Joule effect in the tissue, thermal coagulation takes place. This process involves the partial solidification of organic liquids and the precipitation of colloidal substances. Specifically, within the blood, fibrin forms, which, as it solidifies, can obstruct blood vessels.

To achieve coagulation using an electrosurgical scalpel, it's essential to provide the active electrode with an intermittent current. This prevents excessive heat generation, which could lead to cell explosion and tissue cutting, allowing for controlled heating instead. This controlled heating causes the water within the cells to escape without destroying them. However, even with intermittent current, if the current intensity is too high, it can still result in a cutting effect.

Active electrodes well-suited for coagulation purposes include those with ball, plate, or lance shapes, used laterally.

Coagulation can be achieved through two different methods:

- Coagulation by desiccation
  This is achieved by supplying the electrode with low voltages to prevent the generation of sparks (ensuring that the action obtained is pure coagulation without any cutting effect). The electrode is placed in direct contact with the tissue, and the amount of heat generated on contact dries it out. Typically, coagulated cellular surfaces act as an insulating layer, preventing heat from subsequent current applications from penetrating too deeply. The current normally used for coagulation is modulated. Depending on the modulation percentage, you get a balance between precision in cutting, effectiveness in hemostasis, and tissue destruction. Greater modulation of the current leads to a more jagged cut, greater depth of tissue destruction, but more effective coagulation.
  The following rules help the operator achieve good coagulation:
  - Select a ball electrode or a thick wire electrode.
  - Locate the bleeding vessel after excess blood has been dried from the area.
  - Gently touch the bleeding vessel before activating the electrode.
  - Cease electrode activation as soon as the tissue whitens to avoid damaging it.
  - Keep the electrode tip clean (use optional electrode-cleaning sponges with code F7520).

- Coagulation with anatomical forceps by clamping
  The most commonly used coagulation technique involves blocking the blood flow by applying clamping pressure at the end of the forceps. After clamping the tissue portion or the blood vessel where coagulation is needed, the active electrode is brought into contact with the proximal metal part of the forceps. The high-frequency activation must occur after this contact (forceps - active electrode) to avoid the Faradic effect (initiation of an electrical discharge that uses air as a conductor), which could cause electrical shock, burns to the operator, etc.

BIPOLAR COAGULATION

In contrast to the monopolar technique, the bipolar technique focuses the high-frequency current on a very small portion of tissue. This method employs bipolar forceps with various sizes and shapes on their distal ends, serving as both the active and neutral electrodes. By clamping the tissue to be operated on between these forceps, the high-frequency current flows from one end to the other, using the tissue itself as an electrical bridge.

Bipolar coagulation, achieved using this technique, effectively controls bleeding in small blood vessels within body tissues situated between the two clamp tips. When the current density is reduced, it primarily dries the cell surface without deep penetration, resulting in coagulation.

The bipolar technique is considered safer due to the predictable and consistent direction of the high-frequency current. It eliminates the uncertainties and potential errors associated with unknown current paths, and it requires much lower power levels compared to the monopolar technique. Consequently, it is commonly used in delicate surgical procedures.

It is crucial to maintain the cleanliness of the distal ends of the forceps during surgery as they tend to accumulate coagulated tissue, which can impede current flow and cause tissue adhesion. While the use of a neutral electrode, mandatory in the monopolar technique, is not necessary in bipolar procedures, it is often allowed for practical reasons during the initial preparation phase

CONTRAINDICATIONS

The use of electrosurgery is contraindicated in patients:

- pacemaker carriers
- with stimulation electrodes
- with metallic prostheses
- with serious blood pressure imbalances
- with serious diseases of the nervous system
- with serious kidney failure
- in state of pregnancy.

In the context of electrical surgery, burns due to high frequency are the main causes of burns caused to the patient, but they are not the only ones involved. One can also get necroses by compression, allergic reactions to disinfectants, gas sparks or flammable liquids.
Some of the causes of burns are to be attributed to:

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

To avoid or reduce the risks associated with the use of high frequency electrosurgery, it is necessary to respect the rules and safety measures illustrated in the following chapter.

SAFETY

WARNING: Electrosurgery carries inherent risks, and improper usage of any component within the electrosurgical system can result in severe burns to the patient. It is absolutely crucial that you meticulously read and comprehensively understand all instructions before attempting to utilize an active electrode. Neither the manufacturer nor any retailers can be held liable for any harm or damage, whether direct or indirect, caused to individuals or equipment due to the incorrect use of the device and its accompanying accessories.
The accessories provided with this unit are designed to be compatible specifically with this unit and may not work with other electrosurgical units. Prior to connecting any additional accessories to this unit, the user must confirm that these accessories possess insulation characteristics that align with those of this unit (please refer to the "TECHNICAL CHARACTERISTICS" section for details). You must assess the packaging integrity of sterile accessories before their initial use.

ATTENTION

- **DO NOT USE** on patients with electronic implants such as cardiac pacemakers without consulting a qualified professional (e.g., a cardiologist). There is a potential risk of interference with the functioning of the electronic implant or damage to the implant itself.

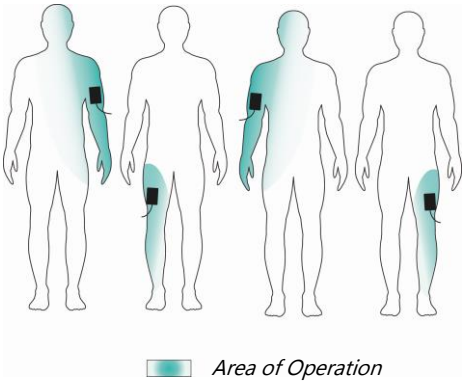
- **DO NOT USE** in the presence of flammable anaesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or near volatile solvents (such as ether or alcohol) as explosions may occur.
- **DO NOT PLACE** instruments near or in contact with flammable materials (such as gauze or surgical drapes). Activated or heated instruments can cause fires.
- When not in use, store instruments in a clean, dry, and highly visible area away from direct patient contact. Inadvertent contact with the patient can result in burns.
- **INSPECT** instruments and cables for damage before each use, especially the insulation of laparoscopic/endoscopic instruments. This inspection can be carried out visually under magnification or with a high-voltage insulation testing device. Insulation failures can lead to burns or other injuries to the patient or the operator.
- The surface of the active electrode may remain sufficiently hot to cause burns even after RF current is deactivated.
- Due to concerns about the potential carcinogenic and infectious properties of electrocautery byproducts (such as tissue smoke plumes and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Only connect adapters and accessories to the electrosurgical unit when the power is **OFF**. Failure to do so may result in patient or operating room personnel injury or electric shocks.
- If the device is powered with argon, warnings regarding gas embolisms must be included.
- If the instrument is reusable, a warning should be included that visual inspection alone may not be sufficient to ensure intact insulation.
- **DO NOT ACTIVATE** the instrument when it is not in contact with the target tissue, as this could cause injuries due to capacitive coupling with other surgical equipment.

- **ASPIRATE** fluids from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in proximity to an active electrode can carry electrical current or heat away from the target tissues, potentially causing unintended patient burns.
- **DO NOT USE** with hybrid systems, i.e., a combination of metal and plastic, when using monopolar active components. This can result in burns at alternative sites due to capacitive coupling. Use only all-metal or all-plastic systems.
- Before increasing the intensity, verify the adhesion of the neutral electrode and its connections. Apparent low power or device malfunction at normal operating settings may indicate improper neutral electrode application or poor contact in its connections.
- This unit has a CQM system; please note that the loss of secure contact between the neutral electrode and the patient will not trigger an alarm unless a compatible monitoring neutral electrode (split neutral electrode) is used.
- **CAUTION**: Set the intensity to the lowest level necessary to achieve the desired effect.
- **CAUTION**: Keep the active electrodes clean. Accumulated eschar may reduce the tool's effectiveness. Do not activate the instrument during cleaning. Operating room personnel may be injured.
- Any serious incidents related to the device must be reported to LED SpA, via Selciatella n.40, 04011 Aprilia (LT) - ITALY, and the competent authority:
  Ministero della salute – Direzione generale dei dispositivi medici e del servizio farmaceutico
  Viale Giorgio Ribotta, 5 – Roma
  E-mail: segr.dgfdm@sanita.it
  Tel.: +39 06 5994 3199 / +39 06 5994 3207

PRECAUTIONS

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

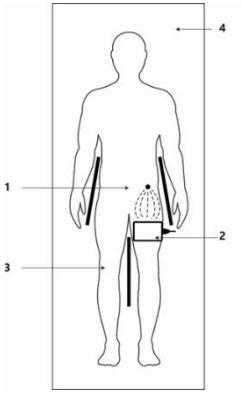
- Ensure the secure and complete attachment of the neutral electrode to the patient's body, preferably at the extremities and as close to the surgical site as possible. Avoid connecting the neutral electrode to bony protrusions, prosthetic devices, areas with scar tissue, regions susceptible to fluid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



- When using single-use neutral electrodes, always adhere to the provided expiry dates.
- For multi-use electrodes, ensure that the fixation systems in place guarantee stability during use.
- When applying the neutral electrode, avoid a transverse path and instead favour a vertical or diagonal path, especially when using a bipartite neutral

electrode. This helps distribute current evenly across the surface of the neutral electrode and reduces the risk of patient burns.

- If you encounter difficulty in correctly applying the neutral electrode, consider using the bipolar technique instead of the monopolar approach, if feasible.
- To prevent the patient from coming into contact with earthed metallic parts or components with significant grounding capacity (such as an operating table or supports), use an antistatic drape for this purpose.
- To avoid skin-to-skin contact (e.g., between the arm and trunk, between the legs, or on the breasts) insert dry gauze. Additionally, ensure that body areas prone to profuse sweating are kept dry.



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

- When using both an electrosurgical scalpel and a physiological monitoring device on the same patient, place all monitoring electrodes as far away from the surgical electrodes as possible. Needle monitoring electrodes are discouraged. In any case, use monitoring systems that incorporate high-frequency current-limiting devices.

- Position surgical electrode cables in a manner that prevents contact with the patient or other conductive materials. Active electrodes that are not in use should be isolated from the patient.
- Consider utilizing bipolar techniques when operating on body parts with a relatively small cross-sectional area. This helps prevent unintended coagulation.
- Set the output power level to the lowest effective setting for the intended purpose, minimizing the risk of excessive tissue damage.
- If the electrosurgical unit exhibits an obvious low output level or operates incorrectly, even when set up for normal power delivery, this could indicate issues with the application of the neutral electrode or poor contact in the neutral electrode connections. Therefore, it is essential to verify the proper placement and connections of the neutral electrode before considering higher power settings.
- Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N2O) and oxygen, especially in chest or head operations, unless they can be safely aspirated. Whenever possible, opt for non-flammable substances for cleaning and disinfection purposes. If flammable substances are used for cleaning, disinfection, or as solvents for adhesives, they should be allowed to completely evaporate before using the electrosurgical unit. There is a risk of flammable solutions accumulating under the patient or in cavities like the umbilicus and vagina. Any fluid in these areas should be removed before using the device. It's important to consider the presence of endogenous gases as well.
- Be aware that certain materials, such as cotton wool or gauze impregnated with oxygen, may ignite due to sparks produced by the appliance under normal conditions. Take necessary precautions to prevent such incidents.
- Patients with pacemakers or pacing electrodes are at risk of interference with their pacemaker's functionality or potential pacemaker damage when exposed

to electrosurgical equipment. If any uncertainty arises, consult the cardiology department.

- Electrosurgical equipment emits high-frequency energy radiation that can affect other medical devices, unrelated electronics, telecommunications systems, and navigation systems. To prevent interference, you must maintain a minimum distance of at least 1.5 meters between the electrosurgical equipment and other devices.
- Regularly inspect accessories, with special attention to electrode cables and any endoscopy accessories, to ensure there is no damaged insulation or other defects that could compromise their safety or effectiveness.
- To connect accessories compatible with the equipment's characteristics, you must compare the insulation characteristics of the accessories (information provided by the manufacturers) with the specifications of the supplied unit (as outlined in the Technical Characteristics section). This step ensures proper compatibility and safe operation.
- **Caution**: Equipment failure could lead to an inadvertent increase in power output.

  Note: Stimulation of the patient's muscles or nerves may be caused by low-frequency currents resulting from electrical sparking between the electrodes and the patient's tissue. If neuromuscular stimulation occurs during surgery, take the following steps:

  1. Pause the surgery immediately.
  2. Thoroughly inspect all connections to the generator to identify any potential issues or loose connections.
  3. If the problem persists and cannot be resolved through connection checks, it is imperative to have the generator inspected by qualified personnel for necessary maintenance and troubleshooting.

INSTALLATION

- Electrical safety is guaranteed only when the equipment is correctly connected to a reliable power supply network with proper grounding, in compliance with current safety standards. It is essential to ensure this fundamental safety requirement, and if there are any doubts, seek a comprehensive inspection of the system by qualified personnel. The manufacturer cannot be held responsible for potential damage caused by the absence of an efficient earth connection in the installation. Operating the equipment without a protective earth connection is strictly prohibited.
- Before connecting the equipment, verify that the provided voltage, as indicated on the rear panel, matches the voltage available in your mains power supply.
- In the event of any incompatibility between the power socket and the equipment's power cable, only replace it with a suitable type. It is not allowed to use adapters, multiple connections, or extension cables. If their use becomes necessary, it is mandatory to employ single or multiple adapters that comply with current safety standards.
- Protect the equipment from exposure to outdoor elements such as rain and direct sunlight. The apparatus must be shielded to prevent the infiltration of liquids.
- Do not keep the equipment plugged in unnecessarily. Turn it off when it is not in use to conserve energy and ensure safe operation.
- This equipment is not designed for use in explosive environments. Avoid using it in such environments where there may be a risk of ignition or explosion.
- The equipment should be used only for its intended purpose. Any other use should be considered improper and potentially dangerous. The manufacturer cannot be held responsible for any damage resulting from improper, incorrect, or unreasonable use.

- Modifying or attempting to modify the equipment is dangerous and should not be done. Altering the characteristics of the equipment can lead to unsafe operation and potential hazards.
- Before performing any cleaning or maintenance procedure, disconnect the appliance from the electrical supply by either unplugging it from the mains or turning off the main switch of the system.
- In the event of equipment breakage or malfunction, power it off immediately. For any necessary repairs, seek assistance only from an authorized service center and request the use of original spare parts. Failure to adhere to these regulations may jeopardize equipment safety and pose risks to the user.
- Do not reduce or disable the acoustic signal indicating generator activation. A functioning activation signal can help minimize or prevent injuries to patients or personnel in the event of accidental activation.
- Do not test the equipment's operation by generating power between the active and neutral electrode or between the active electrode and metal parts. Testing in this manner can be unsafe.
- If required, use appropriate fume extraction methods in the surgical field to manage the release of smoke or fumes generated during procedures.

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

PATIENT SAFETY

During high-frequency electrosurgery procedures, it's crucial to understand that the patient becomes a conductor of electrical voltage relative to the earth potential. Consequently, if there is contact between the patient and electrically conductive objects (such as metal objects, damp or wet sheets, cloths, etc.), it can result in the generation of electric current at the point of contact.
You must conduct thorough inspections of the device and its accessories before use, and to strictly adhere to all pertinent safety regulations.

CORRECT PATIENT POSITIONING

Prevent any deliberate or accidental contact between the patient and grounded metal components by ensuring the following:

- The patient does not come into contact with metal parts such as the operating table or supports.
- Ensure that respirator hoses do not rest on the patient's body.
- Always maintain coatings on the grounded operating table to dissipate electrostatic charges.
- Place the patient on a thick fabric with insulating properties, covered with an adequate number of layers.
- Ensure the patient does not touch damp sheets or mattresses.
- Prevent body secretions, cleaning fluids, or other liquids from soaking dry sheets.
- Keep the area beneath the patient free of liquid residue.
- Employ catheters to manage urinary excretions.
- Keep areas of the body prone to increased sweating or areas with skin-to-skin contact points dry using drapes (e.g., arm/body trunk, leg/leg, breasts, skin folds).
- Properly insulate all conductive and grounding supports and brackets.
- Adjust the anesthesia dosage to prevent excessive sweating.

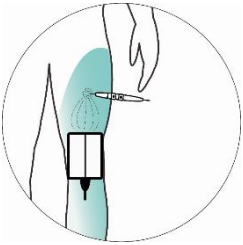
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

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

1. **Monopolar Neutral Electrode**: In this type, there is no control over the contact between the neutral electrode and the patient.
2. **Bipartite Neutral Electrode**: This type offers control over the contact between the neutral electrode and the patient.

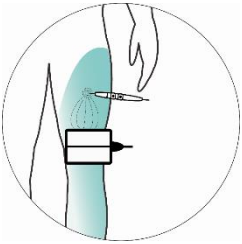
Ensuring the correct placement of the neutral electrode is of utmost importance to prevent burns and minimize patient risks. Below are some valuable tips to achieve this:

1. Correct positioning



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

2. Incorrect Positioning



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

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

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

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

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

If the electrode were placed in an area subjected to pressure during the procedure, the compressive load would result in reduced skin perfusion. Consequently, the generated heat can only be partially dissipated, thereby increasing the risk of burns. Furthermore, there is an increased risk of pressure points (decubitus) formation due to the heating that occurs. This temperature rise leads to a higher demand for

oxygen (O_2) and energy in the affected area, contributing to the potential development of pressure areas on the body.

HIGH-FREQUENCY ELECTROSURGERY IN LAPAROSCOPY

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

The risks of burns can be exacerbated by various factors, including limited visual field, 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 an increased risk of burns, internal injuries, tissue necrosis, and organ perforation.

Furthermore, within the surgical environment, where the active electrode closely interacts with conductive instruments and bodily tissue, there are factors that can promote the transfer of electrical currents to concealed areas. These factors include:

1. **Direct Coupling:** This occurs when the active electrode makes contact with another metal instrument, leading to the transmission of electrical current and an increased risk of burns to nearby tissue, such as the intestines or other organs.
2. **Insulation Failure:** In this case, the insulation surrounding the electrode can become compromised due to excessive voltage, improper use, or damage to the electrode shaft. This can happen during surgery or during the cleaning and sterilization of instruments. An invisible insulation breakdown, when the

electrode is activated, poses a risk of unpredictable and potentially more insidious burns. Surprisingly, a minor insulation breakdown can be more hazardous than a major one, as it concentrates the current, making burns more likely.

3. **Capacitive Coupling:** This occurs when the active electrode induces electrical current in conductive materials, even if the insulation remains intact. During high frequency electrosurgery, the rapid changes in the electric field around the active electrode are only partially hindered by insulation, generating ionic currents that, upon contact with tissue, can cause sufficient heating to induce burns.

   Addressing these risks with great care and implementing preventive measures is crucial to ensuring patient safety during high-frequency surgery in a laparoscopic setting.

   To minimize the risk of burns during high frequency electrosurgery procedures in laparoscopy, consider the following preventive measures:

   - **Comprehensive Staff Training:** Provide thorough and meticulous training for medical and healthcare personnel involved in electrosurgery procedures. It is essential to ensure they have a complete understanding of the procedures, associated risks, and preventive measures.
   - **Detailed Inspection of Surgical Instruments:** Conduct a meticulous visual examination of surgical instruments, 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 necessarily reduce the risk of insulation breakdown or capacitive coupling, they are free from wear and tear.
   - **Avoidance of Hybrid Material Cannulas:** Steer clear of using cannulas made of hybrid materials, such as plastic and metal, as they can heighten the risk of direct coupling and capacitive coupling.

- **Adoption of Bipolar Technique:** While the bipolar technique may be less versatile than the monopolar one, it is considered safer because heat injuries are localized and occur only with prolonged current application.

In conclusion, burns are a genuine concern in high frequency electrosurgery procedures. However, with a deep understanding of potential causes and thorough preparation of the medical team, it is possible to limit their occurrence and effectively manage potentially risky situations.

PUTTING INTO SERVICE

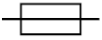
- Inspect the equipment for any damages caused during transportation. Claims for damages will only be accepted if immediately notified to the carrier, with a note detailing the observed damages to be submitted to LED SpA or the respective seller. In case of returning the equipment to LED SpA or the seller, it is necessary to use the original product packaging or packaging that ensures equivalent transport safety.
- Remove the device from the packaging and carefully study the provided documentation and operating instructions. The mains voltage, indicated at the power input, must be equal to the local mains voltage (mains frequency: 50-60Hz). Equipment designed for 115/230Vac power supply is supplied for 230Vac power supply; in case of 115Vac power supply, besides preparing the power supply voltage, replace the fuses with the value indicated on the nameplate data.
- Connect the power cable to a mains outlet with a good grounding connection.

OPERATION OF THE EQUIPMENT WITHOUT GROUND CONNECTION IS PROHIBITED.

- The equipment must be installed on a flat surface with dimensions at least corresponding to the base of the equipment itself. Leave at least 25cm of space around the equipment.
- Connect the power cable to the power outlet located on the rear panel of the unit.
- Connect, if necessary, the equipotential bonding point on the back of the unit to the potential bonding socket in the system.
- Connect the single pedal or optional double footswitch to the connector on the front of the equipment.
- Connect the handpiece with two buttons; in the case of using a buttonless handpiece, it must be connected to the "ACTIVE" section of the connector.
- When using a bipolar forceps, use the special optional adapter (REF 00498.00).
- Operate the equipment only in a dry environment. Any condensation that occurs must evaporate before operating the equipment. Do not exceed the ambient temperature or allowed humidity.
- Environmental conditions:
    - Temperature: from 10°C to 40°C
    - Relative humidity: from 30% to 75%
    - Atmospheric pressure: from 70 kPa to 106 kPa
- Before attempting to use the equipment, connect the neutral electrode connection cable and attach the neutral electrode. The neutral electrode must be properly fixed to the patient (see Safety chapter). Both single-piece and two-piece neutral electrodes can be used. With the unit turned on, if the impedance value read by the equipment is acceptable, the OC indicator light will stop flashing.
- At startup, done through the switch on the rear power module, the equipment, after checking internal parameters, will be set with the function and power levels used at the last startup (the levels will be 00 at the first startup).

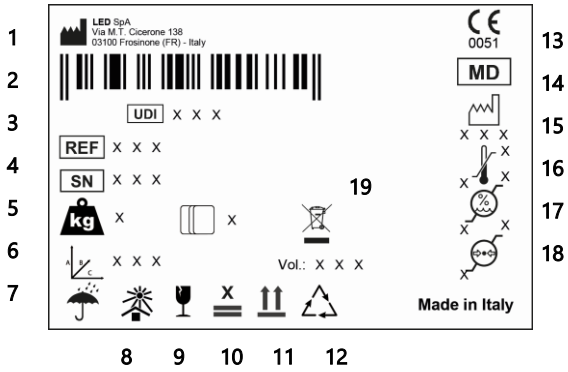
MEANING OF GRAPHIC SYMBOLS

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

N°	SYMBOL	DESCRIPTION
19		FRAGILE – Handle With Care.
20		Keep away from sunlight.
21		Protect against moisture.
22		Number of maximum stackable packages.
23		Weight.
24		Dimensions.
25		Number of Pieces.
26		Recycle.
27		Model/Trade Name.
28	IP	Protection against harmful ingress of water or particulate matter.
29		Fuse.

BOX LABEL

With reference ISO15223-1 “Medical Devices-Symbols to be used with medical device, labels, labelling and information to be supplied” and ISO780 “Packaging – Pictorial marking for handling of goods” on box label of UNIT’s carton box are present these indications:



1. ISO15223-1 (5.1.1) MANUFACTURER
2. ISO15223-1 (5.7.10) UDI code = EAN code
3. ISO15223-1 (5.1.6) CATALOGUE NUMBER
4. ISO15223-1 (5.1.7) SERIAL NUMBER
5. BOX WEIGHT
6. BOX DIMENSIONS
7. ISO15223-1 (5.3.4) KEEP DRY (The transport package must be kept dry)
8. ISO15223-1 (5.3.2) KEEP OUT OF SUNLIGHT (The transport package must not be exposed to sunlight)
9. ISO15223-1 (5.3.1) FRAGILE (The contents of the package are fragile; therefore, they must be handled with care)
10. STACKING LIMIT BY NUMBER (Indicates the maximum number of identical products that can safely be stacked on the bottom package)
11. ISO780 (3) HIGH SIDE (Indicates the correct vertical position of the transport pack)
12. ISO 7001: 2007 RECYCLING (Indicates the location of a container)
13. CE + Notified Body number for class MD (2017/745/EU)
14. ISO15223-1 (5.77) MD (Medical device)
15. ISO15223-1 (5.1.3) DATE OF MANUFACTURE
16. ISO15223-1 (5.3.7) TEMPERATURE LIMITS (Indicates temperature limits within which the transport package must be stored and handled)
17. ISO15223-1 (5.3.8) HUMIDITY LIMITS (Specifies the humidity limits within which the transport package must be stored and handled)
18. ISO15223-1 (5.3.9) ATMOSPHERIC PRESSURE LIMITS (Indicates the atmospheric pressure limits within which the transport package must be stored and handled)
19. WEEE PRODUCT (Directive 2012/19/EU)

CONNECTION OF ACCESSORIES

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

1. **Footswitch connector**:

On the left side of the front panel, there is the socket for connecting the footswitch or optional double footswitch.

2. Connector for neutral electrode:

On the front panel is the connection point for the neutral electrode or the optional adapter (REF 00498.00) in case of using the BIPOLAR function.

3. Handpiece connector:

On the front panel is the connection point for the handpiece. In case of using buttonless handpieces (optional), they must be connected to the 'ACTIVE' section of the connector.

USE OF ACCESSORIES

Use for **MONOPOLAR**:

Holder-handle with two pushbuttons without foot switch: press the yellow pushbutton on the holder-handle to deliver the cutting current (the choice between CUT or BLEND must be done pressing the correspondent pushbutton on the unit); or the blue pushbutton on the holder handle to deliver coagulating current (the choice between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).

Holder handle with two pushbuttons and a single foot switch: choose the cutting current CUT or BLEND and the coagulation current FORCED COAG, SOFT COAG or BIPOLAR. Preset through the yellow pushbutton on the holder handle, the function for the cut that appears on the unit or, through the blue pushbutton on the holder handle, the function for the coagulation that appears on the unit. The current delivery takes place through the foot switch.

Holder handle with two pushbuttons and optional double foot switch: press the yellow foot switch or the yellow pushbutton of the holder handle to pre-set and deliver the cutting current (the choice between CUT or BLEND must be done pressing the correspondent pushbutton on the unit) or the blue foot switch or the blue pushbutton of the holder handle to pre-set and deliver the coagulating current (the choice between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).

Holder handle without pushbuttons (optional) and single foot switch: connect the holder handle to the buckle indicated "ACTIVE" and pre-set the current for the cut (CUT or BLEND) or the coagulation (FORCED COAG, SOFT COAG or BIPOLAR), press the foot switch to deliver the pre-set current.

Holder handle without pushbuttons (optional) and double foot switch (optional): connect the holder handle to the buckle indicated "ACTIVE" and press the yellow footswitch to pre-set and deliver the cutting current (the choice between CUT or BLEND must be done pressing the correspondent pushbutton on the unit); press the blue foot switch to pre-set and deliver the coagulating current (the choice between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).

Use for **BIPOLAR**:

Bipolar forceps (optional) and single foot switch: connect the optional adapter (**REF** 00498.00). The equipment will select the BIPOLAR operative mode. To deliver the current press the foot switch. To avoid the forceps' damage don't make short circuit with its tips.

Bipolar forceps and double foot switch: connect the optional adapter (**REF** 00498.00). The equipment will select the BIPOLAR operative mode. To deliver the current press the foot switch for the coagulation (blue). To avoid the forceps' damage don't make short circuit with its tips.

NOTE: For BIPOLAR procedure you need other optional accessories:

1. Bipolar adapter

2.Cable for bipolar accessories connection

3.Bipolar accessory (ex: bipolar forceps)

FRONT PANEL

1. Knob for adjusting the output power level of the CUT function
2. Indicator for adjusting the output power level of the CUT function
3. CUT function output indicator
4. Knob for adjusting the output power level of the COAG function
5. Power output level adjustment indicator of the COAG function
6. COAG function output indicator
7. Selection button and corresponding indicator for CUT function
8. Selection button and indicator light for BLEND cut function
9. Selection key and relative indicator light for FORCED COAG surface function
10. Selection key and relative LED for deep coagulation function SOFT COAG
11. Selection key and relative indicator for BIPOLAR function
12. Alarm indicator for excessive impedance in the neutral electrode circuit
13. Connector for handpiece with active electrode holder buttons
14. Connector for neutral electrode
15. Connector for foot pedal

OPERATION MODE

SWITCH ON

When switched on the electrosurgical unit automatically performs a test to establish the correct operation of itself and of the connected accessories as well. In case anomaly is found an alphanumeric message it is shown coded according to the chart codes brought in the chapter MAINTENANCE. This test lasts about 10 seconds. At the end of the control the equipment restores last use operational conditions.

NEUTRAL ELECTRODE'S CIRCUIT

The neutral electrode is continually watched by a special circuit that prevents, danger of burns to the patient due the loss of contact between the neutral electrode and the patient skin, if split electrode is used. If the impedance value of the patient circuit is more than 200 ohm the value is not accepted, in this case the OC indicator light flashing, and if the output circuit is activated no power out and there is a sound alarm.

To reduce the acoustic pollution, the sound alarm is present only when pressed the footswitch.

If a single plate electrode use watched only the connection of the neutral electrode plate to the unit.

PRESELECTION OF THE DELIVERABLE CURRENT

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

Cut Current (CUT)

The optimal current for cutting is a pure sinusoidal wave without modulation, indicating a duty cycle of 100%. This type of current is suitable for cut-only procedures without coagulation.

Coagulated-Cut Current (BLEND)

The coagulated-cut current (BLEND) is designed for coagulated cuts when a deep coagulation along with the cut is desired. This current combines a sine current for the cut with a low-voltage current suitable for coagulation (SOFT COAG). The resulting blend creates a current suitable for coagulated cuts without eschar and carbonization, making it particularly well-suited for endoscopic surgery.

Superficial Coagulation Current (FORCED COAG)

The modulated current (FORCED COAG) is known for its effective surface coagulation properties, although it may lead to the probable production of eschar and partial carbonization of the tissue. The advantage of this coagulation type lies in the speed with which the desired effect is achieved.

Deep Coagulation Current (SOFT COAG)

The low voltage and low modulation current (SOFT COAG) is designed for coagulation of deep tissue layers, achieving coagulation of cellular albumin without carbonization and without producing eschar. The coagulation process in this case takes more time compared to forced coagulation.

Bipolar Coagulation Current (BIPOLAR)

The low voltage pure sine current (SOFT COAG) is specifically designed for coagulation without carbonization, suitable for both monopolar and bipolar applications. The use of bipolar forceps is permitted only with this current. To enable the connection of the cable for bipolar forceps, it is necessary to use an optional adapter (REF 00498.04), which ensures that no other type of current is delivered.

SIGNALING OF EXCESSIVE TIME OF DELIVERY (OVT)

If the operator exceeds the maximum delivery time of 10 seconds, the equipment might, after a variable period depending on the type and level of delivery, generate a warning signal indicated by a flashing "Hot" on the displays, and it will prevent further delivery. The restriction on delivery continues for a duration that depends on the evolving delivery conditions.

SIGNALLING OF EXCESSIVE IMPEDANCE IN THE CIRCUIT OF NEUTRAL ELECTRODE (OC)

For the meaning of this indication, refer to the previous description of the neutral electrode circuit. If the single-part neutral electrode is not properly connected or if a two-part neutral electrode is used and the measured impedance exceeds approximately 200 ohms, the visual signal is activated through the flashing of the OC indicator.

Moreover, in the event of attempting to activate the delivery under these conditions, the procedure is automatically interrupted, and the OC indicator flashes again, accompanied by an audible alarm that alerts the operator to the encountered problem.

ADJUSTMENT OF THE ACOUSTIC SIGNAL LEVEL

To modify the emission acoustic signal, follow these instructions:

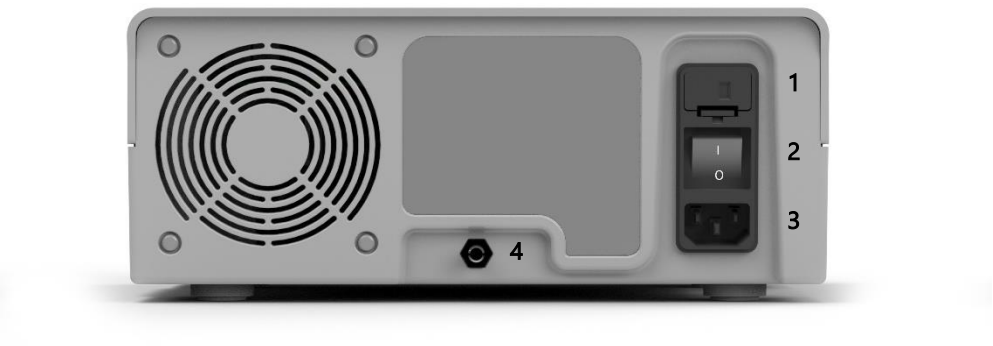
1. Turn on the unit using the mains switch while keeping the CUT pushbutton pressed.
2. When the unit completes the internal parameter check, the message "SOU." appears on the CUT display, and the COAG display shows the value of the preset level. The CUT pushbutton can now be released.
3. Use the COAG knob to adjust the emission acoustic level. During the adjustment, the sound emitted by the unit corresponds to the preset level.
4. Press the CUT pushbutton to confirm the level.

Level	Sound emission until 1m distance from the frontal panel
1	55 dBA
2	60 dBA
3	65 dBA
4	70 dBA
5	75 dBA

AUTOMATIC CONTROL OF THE INTERNAL PARAMETERS

The equipment is equipped with a continuous automatic control system for certain internal parameters. Upon startup, it performs a check, indicated on the displays with the message **'SEL FCh**' followed by the result, which appears as **'PAS Sed'** if the system detects no irregularities or, alternatively, through an error code notification in the form **'Err xxx'**. For further details, refer to the 'Troubleshooting Guide'.

BACK PANEL



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

POWER SUPPLY MODULE AND VOLTAGE SELECTOR

The power module of the equipment represents the connection point for the internal electronics power. This module includes the power connector and line fuses, with the voltage selector located inside.

CAUTION: Before turning on the equipment, the operator should ensure that the mains voltage indicated on the voltage selector matches the connected voltage, and appropriate fuses for the selected voltage are inserted.

POWER ON-OFF SWITCH

The mechanical power switch is used to turn on the equipment. To power on 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 turn off the power. This operation also allows using the mechanical switch as an emergency switch in the event of any malfunction.

TECHNICAL CHARACTERISTICS

Tol.	Description	SURTRON®		
		80	120	160
-	Electrosurgical unit code	10100.101	10100.201	10100.301
± 0%	Minimum presectable power	0	0	0
-	Level step	1	1	1
-	Digital level display	●	●	●
±20%	Maximum output power CUT (W)	80 → 250Ω	120→250Ω	160→250Ω
± 20%	Maximum output power BLEND (W)	60 → 200Ω	90 → 200Ω	120→200Ω
± 20%	Maximum output power COAG FORCED (W)	50 → 150Ω	80 → 150Ω	100→150Ω
± 20%	Maximum output power COAG SOFT (W)	40 → 100Ω	60 → 100Ω	80 → 100Ω
± 20%	Maximum output power BIPOLAR (W)	30 → 100Ω	40 → 100Ω	60 → 100Ω
± 5%	Modulation factor CUT	Pure 100%	Pure 100%	Pure 100%
± 5%	Modulation factor BLEND	Pure 50%	Pure 50%	Pure 50%
± 5%	Modulation factor COAG FORCED	Mod. 60%	Mod. 60%	Mod. 60%
± 5%	Modulation factor COAG SOFT	Mod. 90%	Mod. 90%	Mod. 90%
± 5%	Modulation factor BIPOLAR	Pure 100%	Pure 100%	Pure 100%
-0.1 +0.2	Crest Factor CUT	1.5	1.5	1.5
± 0.3	Crest Factor BLEND	2.1	2.1	2.1
± 0.3	Crest Factor COAG FORCED	2.0	2.0	2.0
± 0.3	Crest Factor COAG SOFT	1.7	1.7	1.7
-0.1 +0.2	Crest Factor BIPOLAR	1.5	1.5	1.5
± 10%	Working frequency	600 kHz	600 kHz	600 kHz
± 15%	Maximum output voltage CUT (Vpp on 5.2kΩ)	1050	1050	1050
± 15%	Maximum output voltage BLEND (Vpp on 5.2kΩ)	1050	1050	1050
±15%	Maximum output voltage FORCED (Vpp on5.2kΩ)	1050	1050	1050
± 15%	Maximum output voltage SOFT (Vpp on5.2kΩ)	540	540	540
± 15%	Maximum output voltage BIPOLAR (Vpp on 5.2kΩ)	540	540	540
± 0.5	Weight Kg	5	5	5
± 10	Size WxHxD mm	254 x 104 x 288	254 x 104 x 288	254 x 104 x 288
± 5%	Selectable power (Vac)	115 –230	115 –230	115 –230
± 1%	Mains frequency (Hz)	50-60	50-60	50-60
-	Fuses (230Vac) 5x20 type TIMED	2x T3.15A	2x T3.15A	2x T3.15A
-	Fuses (115Vac) 5x20 type TIMED	2x T6.3A	2x T6.3A	2x T6.3A
± 10%	Electrical input power (VA)	230	300	350
± 10%	Electrical input current (A) 230Vac	1	1.3	1.5
± 10%	Electrical input current (A) 115Vac	2	2.6	3

Tol.	Description	SURTRON®		
		80	120	160
± 5	Five steps adjustable sound level (from 55- to 75dBA)	●	●	●
-	Self-check	●	●	●
-	Power accuracy output warning	●	●	●
-	Split or not split patient plate allowed	●	●	●
-	Last working condition storing	●	●	●
-	Electrical Class (EN60601-1)	Class I Applicated Part CF		
-	MDR 2017/745/UE Class	II b	II b	II b
-	IP Protection Class (EN 60529)	IP32	IP32	IP32
-	EN55011 (CISPR 11) Class (Group/Class)	2 / A	2 / A	2 / A
-	Patient circuit	F	F	F
-	Duty Cycle (action / pause) in seconds	10 / 30	10 / 30	10 / 30
-	Output power control by foot-switch or finger-switch	●	●	●
-	Defibrillation-proof	●	●	●
-	Equipotential binding	●	●	●
-	ABS cabinet	●	●	●

● = PRESENT - = NOT PRESENT

HARDWARE REQUIREMENTS

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

MAINTENANCE

GENERAL

Inside the equipment, there are no user-adjustable parts for calibration or maintenance. The equipment housing should not be opened, as any unauthorized tampering with the unit invalidates the warranty. In case of repair or adjustment needs, the entire apparatus should be sent to the LED SpA service center in APRILIA (LT) - ITALY, along with a description of the malfunction. User maintenance primarily involves cleaning and sterilizing accessories and checking the equipment before each use. Performing functional and safety checks to verify parameters is the responsibility of specialized technical personnel.

CLEANING OF THE CABINET

Switch off the equipment completely and disconnect the mains supply before initiating any cleaning. Clean the exterior of the cabinet with a damp cloth. Avoid using chemicals; a mild, non-abrasive cleanser may be used when necessary.

CLEANING AND STERILIZATION OF THE ACCESSORIES ITEMS

If disposable non-sterile accessories are used, you must meticulously follow the Instructions for Use (IFU) provided by the manufacturer for the sterilization method and to dispose of them according to the currently applicable regulations.
In the case of reusable accessories, you must adhere to the maximum number of cycles and the sterilization method specified in the manufacturer's Instructions for Use for each accessory.

TROUBLESHOOTING GUIDE

In case of problems before all you must check for the correct installation of the unit and for the correct connection of the accessories.

Problems	Probable Cause	Solution
The equipment doesn't switch on.	Interruption or absence of the main feeding.	Verify the connection of the main cable. Verify the fuses and replace them, where necessary, with new ones of the proprie type.
Alarm OC always active	Interruption or lack of contact on the neutral electrode circuit.	Check the connection of the cable to the neutral electrode. Replace the cable of connection of the neutral electrode.
The unit doesn't respond to the command of activation	Breakdown of the handpiece or of the pedal. Wrong connection of the handpiece or of the pedal. Alarm OVT activated.	Replace the handpiece or the pedal. Verify the connection of the handpiece or of the pedal. Wait for the OVT warning signal getting out.
Error Code 001	Current delivery control activated during switching on.	Disconnect the handpiece or the pedal and switch on the unit again.
Error Code 002	Error in the management board.	Call for Service.
Error Code 003	Error in the management board.	Call for Service.
Error Code 004	Error in the data conversion circuit.	Call for Service.
Error Code 005	Error of the reference voltage value.	Verify the main voltage. Call for Service.
Error Code 009	Error in the output power activation circuit.	Call for Service.
Error Code 010	Error in the output power activation circuit.	Call for Service.

REPAIRS

High frequency cables and electrode holder handle cannot be repaired. Always substitute a damaged part with a new one.

FUSES SUBSTITUTION

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

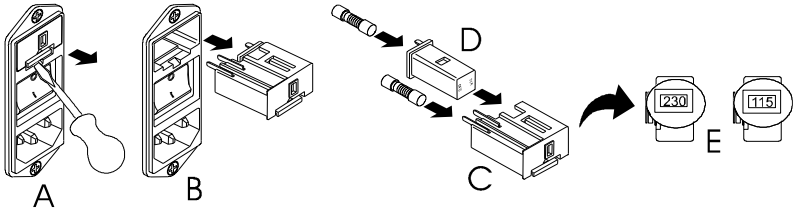
Only use fuse of the kind 5x20; they must have those characteristics: T3.15A (slow) (230Vac mains voltage), T6.3A (115Vac mains voltage), proceed as follows:

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

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

Mains Voltage	110-120 V	Delayed Fuse 2xT6,3AL, 250V / 5 x 20 mm
Mains Voltage	220-240 V	Delayed Fuse 2xT3,15AL, 250V / 5 x 20 mm

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



CHECKING OF THE EQUIPMENT BEFORE EACH USE

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

- Check the integrity of cords, connections, wires breakage, etc.
- Assure that all the electrical equipment is properly grounded.
- Assure that all the accessories that should be used are available and sterilized.
- Check, by disconnecting the reference electrode cable, the functioning of the OC light. Active unit and check OC light and sound alarm warning.
- Check, by activating the CUT and COAG power switch, the functioning of the emission lights and sounds warnings.

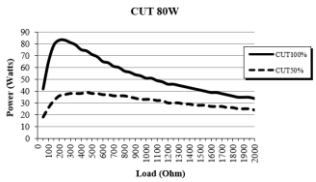
FUNCTION AND SAFETY CHECK AND TEST

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

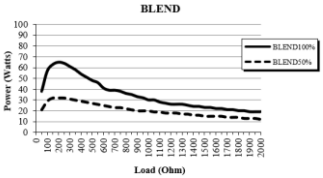
- Check of the connectors and mains supply cord conditions.
- Visual check of the mechanical protections.
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization, and disinfection.
- Check of the Equipment's Data on the Label.
- Check of the availability of the Instruction's Manual.
- Check the functioning of the H.F. output controls.
- Check the uniformity of the resistance through the surface of the patient plate.
- Test the earth conductivity resistance.
- Test the earth leakage current.
- Test H.F. leakage current.
- Control of the neuromuscular stimulation.
- Control of the accuracy of the output power.

DIAGRAMS

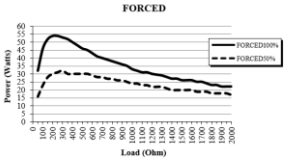
SURTRON® 80



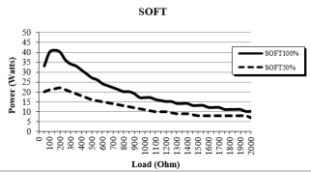
Maximum and average power diagram on variable load 100-2000Ω CUT



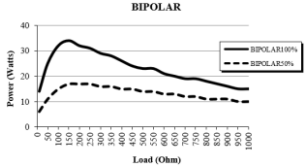
Maximum and average power diagram on variable load 100-2000Ω BLEND



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

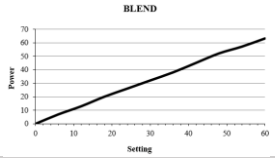


Maximum and average power diagram on variable load 100-2000Ω SOFT



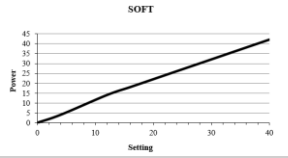
Maximum and average power diagram on variable load 10-1000Ω BIPOLAR

CUT output power diagram on nominal load

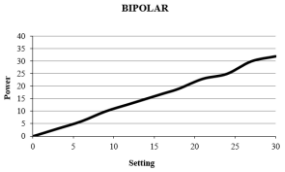


BLEND output power diagram on nominal load

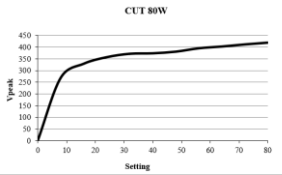
FORCED output power diagram on nominal load



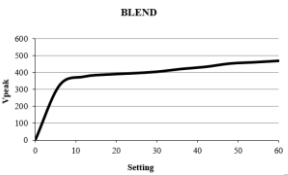
SOFT output power diagram on nominal load



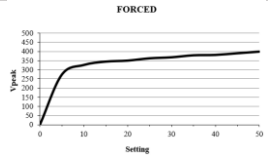
BIPOLAR output power diagram on nominal load



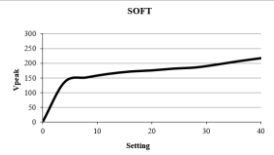
Maximum output voltage diagram (Vp) for CUT



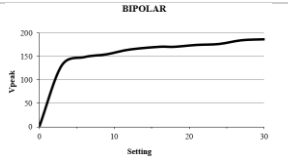
Maximum output voltage diagram (Vp) for BLEND



Maximum output voltage diagram (Vp) for FORCED

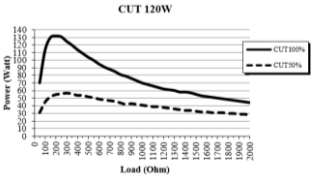


Maximum output voltage diagram (Vp) for SOFT

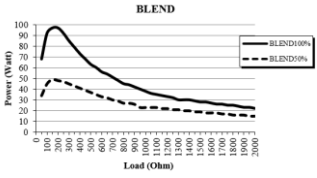


Maximum output voltage diagram (Vp) for BIPOLAR

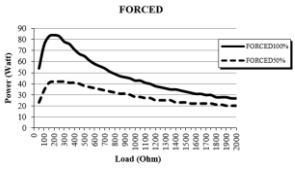
SURTRON® 120



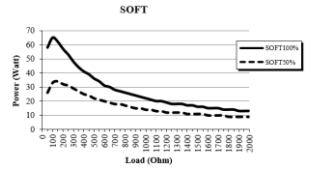
Maximum and average power diagram on variable load 100-2000Ω CUT



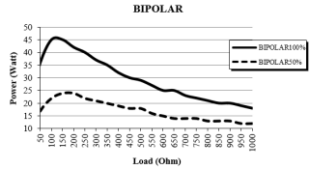
Maximum and average power diagram on variable load 100-2000Ω BLEND



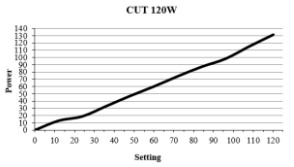
Maximum and average power diagram on variable load 100-2000Ω FORCED



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



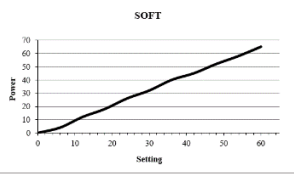
Maximum and average power diagram on variable load 10-1000Ω BIPOLAR



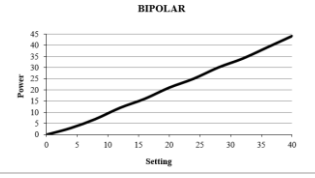
CUT output power diagram on nominal load

BLEND output power diagram on nominal load

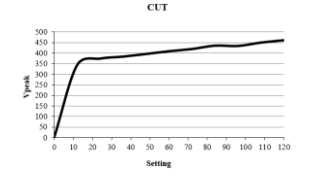
FORCED output power diagram on nominal load



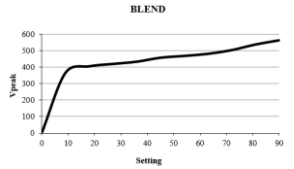
SOFT output power diagram on nominal load



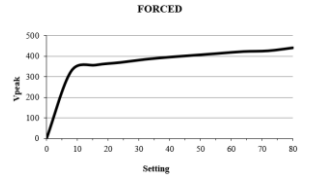
BIPOLAR output power diagram on nominal load



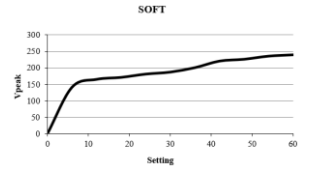
Maximum output voltage diagram (Vp) for CUT



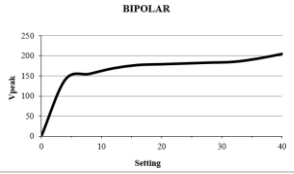
Maximum output voltage diagram (Vp) for BLEND



Maximum output voltage diagram (Vp) for FORCED

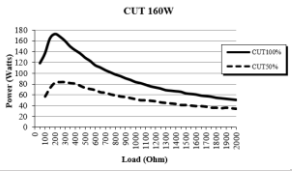


Maximum output voltage diagram (Vp) for SOFT

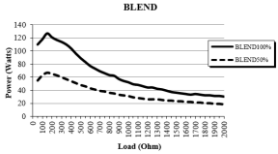


Maximum output voltage diagram (Vp) for BIPOLAR

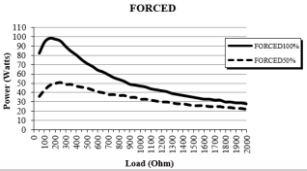
SURTRON® 160



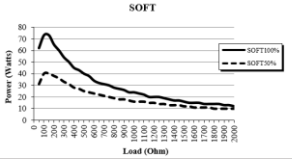
Maximum and average power diagram on variable load 100-2000Ω CUT



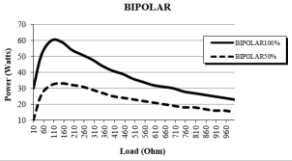
Maximum and average power diagram on variable load 100-2000Ω BLEND



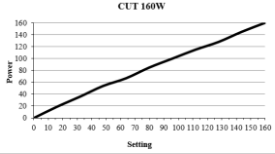
Maximum and average power diagram on variable load 100-2000Ω FORCED



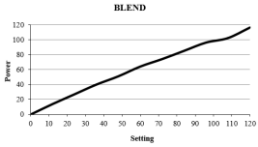
Maximum and average power diagram on variable load 100-2000Ω SOFT



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

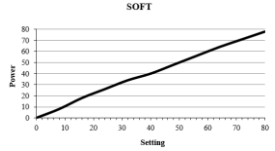


CUT output power diagram on nominal load

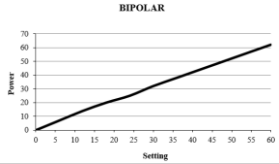


BLEND output power diagram on nominal load

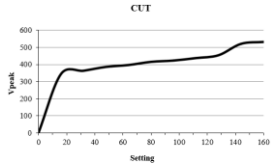
FORCED output power diagram on nominal load



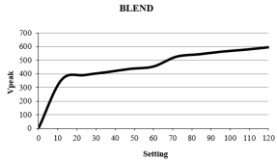
SOFT output power diagram on nominal load



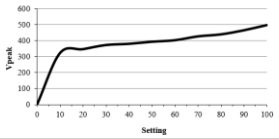
BIPOLAR output power diagram on nominal load



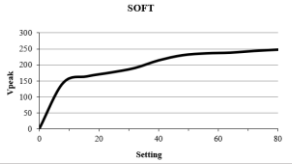
Maximum output voltage diagram (Vp) for CUT



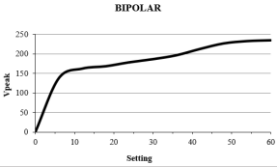
Maximum output voltage diagram (Vp) for BLEND



Maximum output voltage diagram (Vp) for FORCED



Maximum output voltage diagram (Vp) for SOFT



Maximum output voltage diagram (Vp) for BIPOLAR

Information related to the reduction of hazardous substances in electrical and electronic equipment, as well as waste disposal.	
	At the end of its life, this product must not be disposed of as municipal waste; it should be subject to separate collection. Inappropriate disposal may have potentially adverse effects on the environment and human health, especially for certain parts of the product (such as any batteries). The symbol shown (a trash bin on wheels crossed out) indicates that the product should not be thrown into municipal waste containers but must be disposed of through separate collection. Sanctions are applicable in case of improper disposal of this product.

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MA362D_EN

Manufacturing site

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