EN

DIATERMO MB 200 D

ELECTROSURGICAL UNIT

USER MANUAL

GIMA

CE 0051

SUMMARY

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IMPORTANT

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

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

In case of necessity of technical assistance, contact LED SpA.

Produttore / *Manufacturer*

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

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INTRODUCTION

STANDARD AND OPTIONAL COMPOSITION

Code	Description	DIATERMO MB 200 D
-	Electrosurgical unit code	GMA10100.401
00100.01	Power supply cable 5m SIE-IEC	■/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
00401.10	Neutral electrode FLEX	■/1
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	○
00206.00	PENCIL - Handle without switch	○
00305.03	Double water-proof foot switch	○
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	○
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	○
00404.07	Cable for connection neutral electrode F7915/F7930	○
00411.00	CONNECTION - Bipolar cable 3mt EUR	○
00413.00	CONNECTION - Bipolar cable 3mt Artery Sealer EUR	○
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	○

Code	Description	DIATERMO MB 200 D
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	○
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	○
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	○
6429A	NEUTRAL - Steel Neutral Electrode 24x16cm	○
755VL	Disposable handle with finger switches (F4797)	○

Code	Description	DIATERMO MB 200 D
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	○

■/ Pcs = STANDARD ○= OPTIONAL

GENERAL DESCRIPTION

Electrosurgical equipment is capable of delivering currents suitable for cutting, coagulated cutting and monopolar coagulation or bipolar coagulation. Currents can be delivered for as long as the output circuit is activated.

Either single-plate neutral reference electrodes or the type with a conductive area divided into two zones can be used.

The units are controlled by means of buttons, knobs and indicators on the front panel; the power supply socket is located on the rear panel.

The units have automatic safety control systems that monitor the internal parameters and signal any faults/errors detected.

The operating parameters used are continuously memorised so that each time the equipment is switched on or changes operating mode, it re-proposes the last ones used.

The emission sound level can be varied, so that each operator can choose his own level according to the ambient working noise.

The equipment is capable of operating with handpieces with pushbuttons or with handpieces without pushbuttons with single or double foot control. In addition, using the special optional adapter, bipolar grippers can be connected to the equipment.

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 **DIATERMO MB 200 D** equipment is conceived for being used in the following sectors:

Description	DIATERMO MB 200 D
Electrosurgical unit code	GMA10100.401
Casualty Surgery	●
Dermatology	●
Dental	-
Endoscopy	●
Gastroenterology	●
General Surgery	●
Gynecology	●
First Aid	●
Neurosurgery	●
Orthopedics	●
Otorhinolaryngology	●
Pediatric Surgery	●
Plastic Surgery	●
Pneumology	●
Thorax Surgery	●
Trans Urethral Resection (TUR)	●
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 in the contraindications section.

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 ºC 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 ºC 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, you can 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 (you can 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). It is strongly allowed to assess the packaging integrity of sterile accessories before their initial use.

ATTENTION

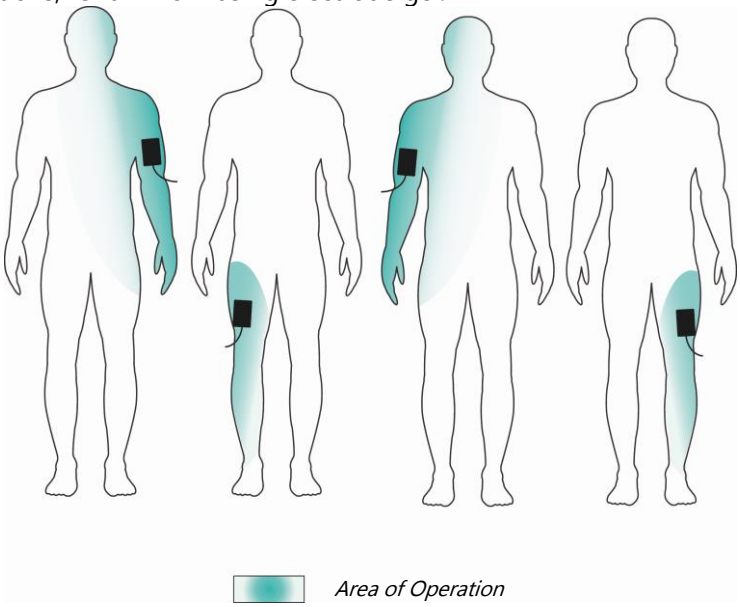
- **DO NOT USE** on patients with electronic implants such as cardiac pacemakers without consulting a qualified professional (e.g., a cardiologist). There is a potential risk of interference with the functioning of the electronic implant or damage to the implant itself.
- **DO NOT USE** in the presence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

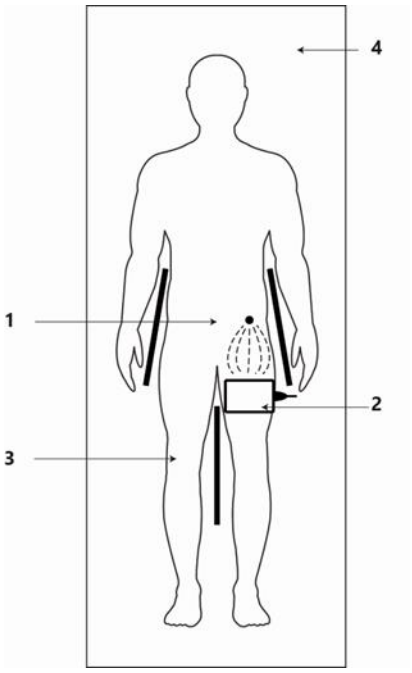
The following precautions are crucial for minimizing the risk of inadvertent burns:

- 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), it is allowed to 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), it's allowed to 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, you must place all monitoring electrodes as far away from the surgical electrodes as possible. Needle monitoring electrodes are discouraged. In any case, it is allowed to 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.
It is allowed to 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.

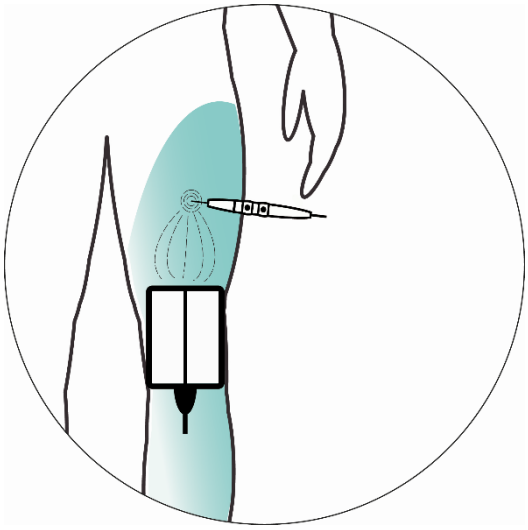
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

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.

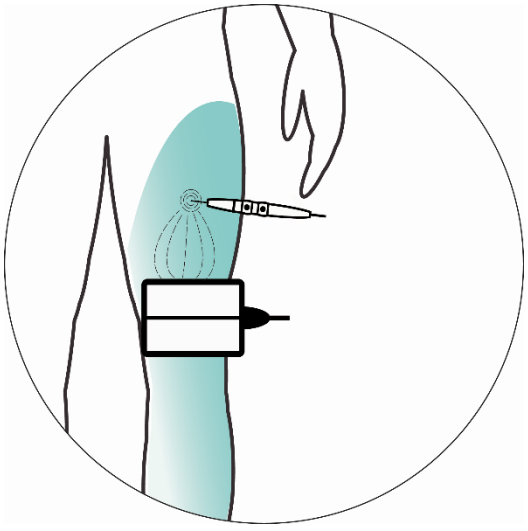
Ensuring the correct placement of the neutral electrode is of utmost importance to prevent burns and minimize patient risks. Below are some valuable tips to achieve this:

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 Shipping Damage:** Check the equipment for any damage caused during shipping. If you find any damage, please report it immediately to the carrier and document the damage found. You should also inform LED SpA or your seller. When returning the equipment, use the original packaging or packaging that ensures safe transport.
- **Unpack and Review the Documentation:** Carefully remove the appliance from its packaging and study the provided documentation and operating instructions. Ensure that the mains voltage, as indicated on the nameplate data, matches the local mains voltage (mains frequency: 50-60Hz). If necessary, replace the fuses with the values specified on the data plate.
- **Connect to a Grounded Power Socket:** Connect the power cord to a mains socket with a reliable earth connection.

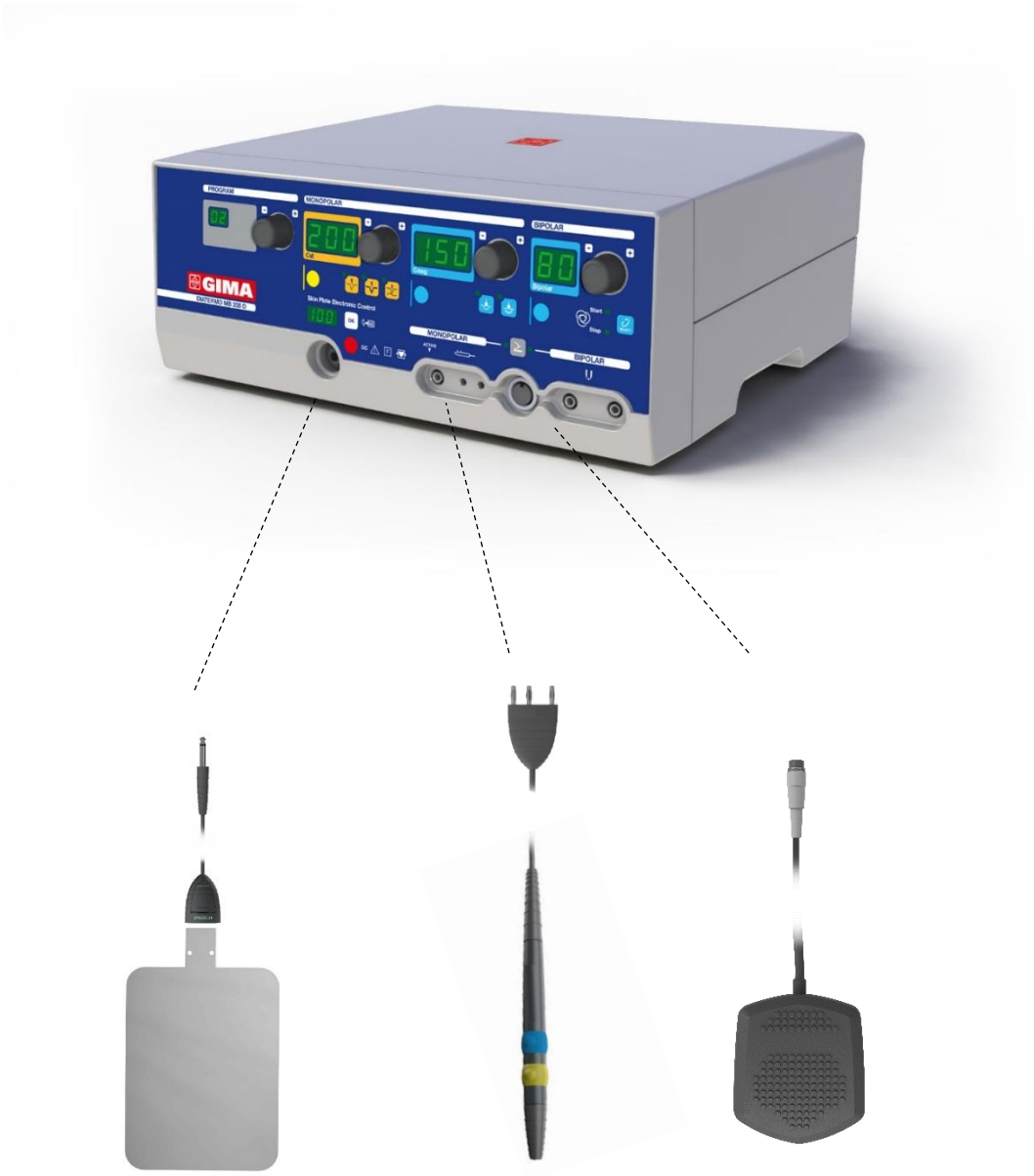
  USING THE EQUIPMENT WITHOUT PROPER GROUNDING IS STRICTLY PROHIBITED.
- **Ensure Proper Installation:** The equipment must be placed on a flat surface with dimensions at least corresponding to the base of the equipment. Leave a minimum of 25 cm of space around the equipment.
- **Connect Mains Cable:** Attach the mains cable to the power socket located on the rear panel of the unit.
- **Establish Equipotential Connection:** Connect the equipotential connection point on the rear left side of the unit to the equipotential socket of the system.
- **Connect Pedal or Footswitch (Optional):** If you have a pedal or double footswitch (optional), connect it to the corresponding connector on the front panel of the unit.
- **Connect Handpiece:** If you are using a handpiece with buttons, connect it to the appropriate connection points. If you are using a handpiece without buttons, it must be connected to the "active" socket.
- **Operate in a Suitable Environment:** Ensure that the equipment is used only in a dry environment. Any condensation that forms must be allowed to evaporate before operating the equipment. Adhere to the ambient temperature and humidity levels, and do not exceed the specified limits.
- **Environmental conditions**:

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

- **Upon Activation**: When turning on the equipment using the switch located on the rear panel, the device will start with the function and power levels used during the last activation.
- **Monopolar Mode:** In monopolar mode, it is essential to connect the neutral electrode cable to the corresponding neutral electrode. If a split neutral electrode is used, ensure that the circuit is properly closed (connected correctly to the patient). This action will cause the red indicator light on the neutral electrode connector to stop flashing if the impedance value is acceptable.
- **Before Using the Equipment:** Before attempting to use the equipment, it is necessary to connect the patient plate cable. When using split electrodes, close the circuit 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 you will receive an audible signal to indicate proper functionality.

CONNECTION AND USE OF ACCESSORIES

Use for **MONOPOLAR TECHNIQUE :**



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, ENHANCED 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 or SOFT COAG must be done pressing the correspondent pushbutton on the unit).

NOTE: to use foot-switch it's necessary to select Monopolar Foot-switch control.

Holder handle with two pushbuttons and a single foot switch: choose the cutting current CUT, ENHANCED or BLEND and the coagulation current FORCED COAG or SOFT COAG. 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. Select 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, ENHANCED 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 or SOFT COAG 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, ENHANCED or BLEND) or the coagulation (FORCED COAG or SOFT COAG), 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, ENHANCED 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 or SOFT COAG must be done pressing the correspondent pushbutton on the unit).

Use for **BIPOLAR TECHNIQUE：**

NOTE : TO USEBIPOLAR it's necessary to select Bipolar Foot-switch control.

Bipolar forceps (optional) and single foot switch: connect the optional cable and bipolar accessory. To deliver the current press the foot switch. To avoid the forceps' damage don't make short circuit with its tips.

Bipolar forceps (optional) and double foot switch (optional): connect the optional double foot switch, the bipolar cable and the bipolar accessory. 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 Cable for bipolar accessories connection

2 Bipolar accessory (ex: bipolar forceps)

CONNECTORS AND CONTROLS

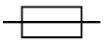
LABEL ON REAR PANEL

Safety requirements for high-frequency (HF) surgical equipment necessitate the clear printing of data and symbols on the cabinet, or at the very least, on one of the panels of the power unit. These data and symbols serve a crucial role in defining the equipment's characteristics and monitoring its operational conditions to guarantee safe and effective utilization of the device.

TECHNICAL DATA

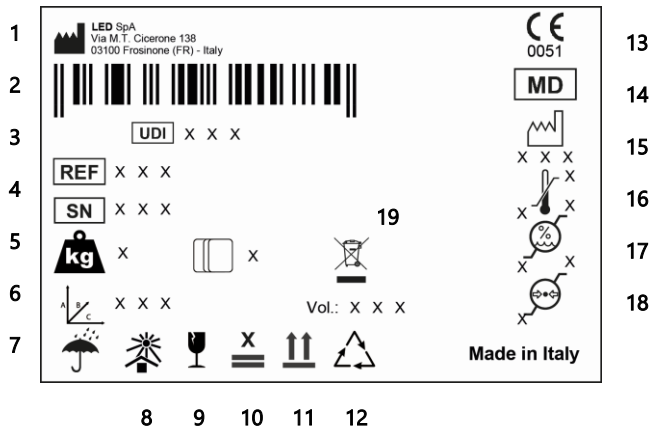
FREQUENCY	360kHz
CUT Output	200W - 300Ω
ENHANCED CUT Output	150W - 300Ω
BLEND Output	150W - 300Ω
FORCED Output	150W - 200Ω
SOFT Output	100W - 200Ω
FULGURATION Output	100W - 1000Ω
BIPOLAR PURE Output	120W - 50Ω
BIPOLAR TUR Output	200W - 50Ω
BIPOLAR COAG Output	120W - 50Ω
BIPOLAR SEALING Output	200W - 50Ω
POWER SUPPLY	100-240 Vac - 50/60 Hz selectable
ABSORPTION	750VA
FUSES	2xT 10AL, 250V
DUTY - CYCLE	intermittent 10 second emission / 30 second pause

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.
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. WEIGHT OF BOX
6. DIMENSIONS OF BOX
7. ISO15223-1 (5.3.4) KEEP DRY (Transport package shall not be kept from moisture)
8. ISO15223-1 (5.3.2) KEEP AWAY FROM SUNLIGHT (Transport package shall not be exposed to sunlight)
9. ISO15223-1 (5.3.1) FRAGILE (Contents of the package are fragile therefore it shall be handled with care)
10. STACKING LIMIT BY NUMBER (Indicates the maximum number of identical products that can be safely stacked on the bottom package)
11. ISO780 (3) THIS WAY UP (Indicates correct upright position of the transport package)
12. ISO 7001: 2007 RECYCLING (Indicates the location of a bin or container)
13. CE + Notified Body Number for MD Class (2017/745/UE)
14. ISO15223-1 (5.77) MD (Medical Device)
15. ISO15223-1 (5.1.3) DATE OF MANUFACTURER
16. ISO15223-1 (5.3.7) TEMPERATURE LIMITS (Indicates temperature limits within which the transport package shall be stored and handled)
17. ISO15223-1 (5.3.8) HUMIDITY LIMITS (Indicates humidity limits within which the transport package shall be stored and handled)
18. ISO15223-1 (5.3.9) ATMOSPHERIC PRESSURE LIMITS (Indicates atmospheric pressure limits within which the transport package shall be stored and handled)
19. WEEE PRODUCT (Directive 2012/19/EU)

FRONT PANEL

1. Program Display (point=busy / no point= free)
2. Program Knob (rotate=to view / short-push=to select / long- push=to store)
3. Display for indication MONOPOLAR cut level
4. Selection keys for cut mode (CUT-ENHANCED-BLEND)
5. Knob for cut level
6. Warning light for cut output MONOPOLAR
7. Display for indication MONOPOLAR coagulation level
8. Selection keys for coagulation mode (FORCED – SOFT)
9. Knob for MONOPOLAR coagulation level
10. Warning light for coagulation output MONOPOLAR
11. Display for indication BIPOLAR coagulation level
12. Knob for BIPOLAR coagulation level
13. Select key for bipolar automatic coagulation
14. Warning light for coagulation output BIPOLAR
15. Display for impedance reading
16. Key for acceptance impedance
17. Alarm indicator for excessive impedance in the neutral electrode circuit
18. Selection key for MONOPOLAR / BIPOLAR footswitch control
19. Bipolar output connector
20. Foot-switch connector
21. Handle connector for active electrode-holder for monopolar cut and coagulation
22. Connector for neutral electrode connection

OPERATING MODES

SWITCHING ON THE DEVICE

When switched on the electrosurgical unit reports performs automatically a test to establish the correct operation of itself and of the connected accessories as well. In case anomaly is found, 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, and activate the signal of alarm OC (open circuit).

NEUTRAL ELECTRODE'S CIRCUIT (SKIN PLATE ELECTRONIC CONTROL)

The neutral electrode's circuit is continually watched by a special circuit (Skin Plate Electronic Control) that prevents danger of burns to the patient due the loss of contact between the reference plate and the patient skin. The circuit is also watched to avoid that the variation of the characteristics of conductibility of the plate can provoke reduction of conductibility of the circuit, and therefore danger of burns to the patient.
The value of impedance found in the circuit of the neutral electrode is shown (by OC alarm lightening) to the operator that, if he considers it suitable to the job to develop, he accepts it by pressing the OK push button. If the value of impedance is excessive its acceptance it is not acknowledged by the microcontroller of the equipment (written 'UP' appears on the display), therefore the signal OC is not extinguished and the distribution of power has not allowed.

In order to reduce the acoustic pollution, the sound alarm is present only when pressed the foot-switch. If a single plate electrodes use watched only the connection of the neutral electrode plate to the unit.

If the impedance value is accepted, the impedance indication is recognized, and the display and OC indicator are extinguished.
If the shown impedance is accepted, but the impedance increases respect the accepted value, the unit avoid the distribution, shows the OC condition, without acoustic signal (only present during distribution) and shows the new impedance value.

PROGRAM

Using the section PROGRAM, it is possible to store 16 different operational conditions and levels of output power. To store the parameters, it is enough to perform the following procedure:

- Rotate the knob to find the number of the program that you want to use.

Note: A busy position program it's indicated with the digit point. A free position program it indicated with no digit point.

- Long press the knob to store data. (sound)
- To recall the stored data, it is enough to perform the following procedure.
- Rotate the knob to find the number of the program that you want to recall.

Note: A busy position program it's indicated with the digit point. A free position program it indicated with no digit point.

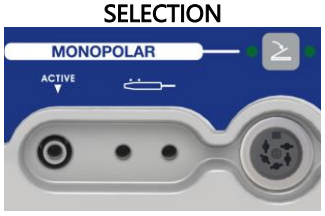
- Short press the knob to recall the parameters.

For modify a program it is enough to select the same program and to perform the procedure of storing once more.

MONOPOLAR

The supplying currents in the monopolar way for cut, coagulated cut and coagulation can be predisposed by the keys present in the MONOPOLAR section. The power level for every function can be predisposed by the knob level of CUT, and COAG sections. The set power levels remain in the memory.

MONOPOLAR 1

CUT	COAGULATION	HANDLE CONNECTOR AND MONOPOLAR FOOT SWITCH SELECTION
1 Cut	4 Forced Coag	
2 Enhanced Cut	5 Soft Coag	
3 Blend		

Note: For use foot-switch, press keys and view monopolar foot-switch light.

The description of the supplying currents is in the next paragraphs, according to the predisposition order of theselection keys, in the MONOPOLAR (see Fig. 1).

Current for Cut (CUT)

The best current for the cut is the pure sinusoidal wave without modulation that means with duty-cycle 100%. Such current, proper for cut without coagulation.

Current for Enhanced Cutting (ENHANCED CUT)

The ENAHNCED CUT current is a sinusoidal current characterized by modulation in amplitude and it is suitable to cut the tissues, in particular adipose tissues.

Mixed Current (BLEND)

The mixed current (BLEND) it is suited for coagulated cut when a deep coagulation together the cut is desired. This current is made by sine current suited or the cut associated to low voltage current suited for coagulation (deep coag). With this, a MIXING current suited for cut coagulated in absence of eschar and carbonization is obtained, particularly suitable for endoscopic surgery.

Current for Superficial Coagulation (FORCED COAG)

The modulated current (FORCED COAG) it is characterized by good property of surface coagulation behaving at the time it probable production of eschar and partial carbonization of the tissue. The advantage of this type of coagulation resides in the rapidity with which the effect is gotten.

SPEEDY Coag also said Fulgurate or Forced.

Current for Deep Coagulation (SOFT COAG)

The low voltage and low modulation current (SOFT COAG) is suited for coagulation of deep layers of the fabric in which the coagulation of the cellular albumin is gotten in absence of carbonization and without production of eschar. The process of coagulation is in this case more time expensive than that of the Speedy coagulation.

SOFT Coag also said Pin Point, Dessicate or Deep.

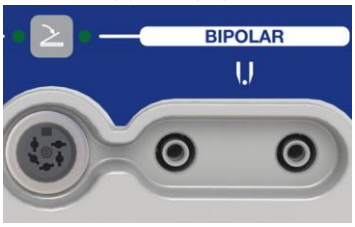
BIPOLAR

The distributable currents in the bipolar modality for coagulation can be selected by the keys of the BIPOLAR section. The power level for every function can be selected by the level Knob of Bipolar sections. The power levels selected remains in memory.

BIPOLAR

COAGULATION
Bipolar Coag

FORCEPS AND FOOT SWITCH CONNECTOR



Note: Use foot-switch, press keys and view bipolar foot-switch light.

Using COAG function it will need to connect the bipolar forceps to the connector for this function (BIPOLAR) and to use the foot-switch.

Bipolar Coagulation Current (BIPOLAR coag)

Type of coagulation practicable with bipolar forceps and that allows to supply, by handle or foot-switch, the RF output power on a impedance value of 100 ohm. This value is normally on the section of tissue between the forceps. This modality is practicable by SELECT key (see Autostart and Autostop paragraph).

AUTOSTART AND AUTOSTOP

In the 'BIPOLAR COAG' section there is the SELECT key, by this to enter to different four settings for the bipolar coagulation:

1. **No automatism for the distribution** (at the first use of the device). The distribution is realized by pressing the foot-switch and stops by leaving again the foot-switch;

2. START. The selection of this function is realized at a first pressure of the SELECT key and it's indicated by the lightening of the corresponding warning light. The distribution is started, by pressing the foot-switch, if there is contact between active electrode and tissue, and it stops by leaving again the foot-switch;

3. STOP. The selection of this function is realized at a second pressure of the SELECT key and it's indicated by the lightening of the corresponding warning light. The distribution is started, by pressing the foot-switch, (if also there isn't a contact between tissue and active electrode) and stops itself for the impedance value higher than 200 Ohm. So by pressing the foot-switch, if there is an impedance value higher than 200 Ohm, the distribution doesn't start.

4. AUTOSTART/AUTOSTOP. By this setting, practicable by three pressures of the SELECT key indicated by the lightening of the START and STOP warning lights, the bipolar coagulation can automatically be activated and disarmed. The distribution starts, by pressing the foot-switch, if there is a contact between tissue and active electrode and stops for the impedance values higher than 200 Ohm. So by pressing the foot-switch, if there is an impedance value higher than200 Ohm, the distribution doesn't start.

Another pressure of the SELECT key brings again to the no automatism function (1).

SIGNALING OF EXCESSIVE TIME OF DELIVERING

If the operator exceeds the maximum time of disbursement, allowed by the international norms, that is 10 seconds, after a time depending from the type of current, and from the level of the same one, the equipment could generate a signal of warning consisting in the text Hot flashing on the display and in impediment to the delivering of current. The interdiction lasting of the current delivery depends from the previous conditions of delivery.

SIGNALING OF EXCESSIVE IMPEDANCE IN THE NEUTRAL CIRCUIT (OC)

For the meaning of this warning signal please refer to the previous description of the neutral electrode circuit.
The warning light OC lightening if the circuit is open, it is extinguished by closing the plate and there is a respect for parameters selected and, in phase of distribution it's with an acoustic signal.

ADJUSTMENT OF THE ACOUSTIC SIGNAL LEVEL

To modify the emission acoustic signal it is necessary to follow those indications:

1. Switch on the unit through the mains switch while the CUT pushbutton is maintained pressed
2. When the unit has finished to check internal parameters, on the display CUT appears the message SOU., while on the COAG one, the value of the pre-set level. Now, the CUT pushbutton can be release.
3. Through the COAG knob it is possible varying the emission acoustic level. During the variation the sound emitted by the unit corresponds to the pre-set 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 unit has an automatic control system of some of the internal parameters. When switched on, the control is indicated on the display through the message SEL FCh. If there are not errors, the message PAS Sed appears; if there are errors, Err xxx appears. See Guide to the Problems' Solution for further information.

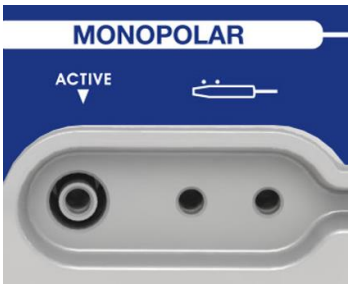
CONNECTOR

Neutral Electrode Connector

This is the connection point of the neutral electrode to be applied to the patient.
Single-use or multi-use, single-part or two-part neutral power lines can be used.

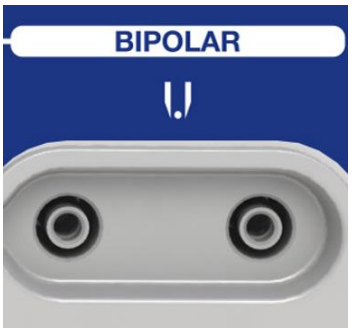
Handpiece connector for monopolar

This is the connection point of the handpiece. In case of use of handpieces without buttons (optional), they must be connected on the bushing indicated by the word ACTIVE.



Bipolar accessory connector

This is the connection point of the bipolar accessories.



BACK PANEL

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

UNIT POWER SUPPLY MODULE AND VOLTAGE SELECTOR

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

WARNING: before switch on the unit, operator must verify that requested mains voltage corresponds to the voltage available from the electrical net.

POWER ON-OFF MECHANICAL SWITCH

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

TECHNICAL CHARACTERISTICS

Tolerance	Description	DIATERMO MB 200 D
-	Electrosurgical unit code	GMA10100.401
-	Detection system of tissue impedance (Bipolar coagulation – auto start/autostop)	●
-	Bipolar coag with automatic activation/disactivation	●
-	Minimum preselectable power	0
-	Selection of the power through the monopole-encoder	●
± 20%	Maximum output power CUT (W)	200W→ 250Ω
± 20%	Maximum output power ENHANCED (W)	120W → 250Ω
± 20%	Maximum output power BLEND (W)	120W → 200Ω
± 20%	Maximum output power FORCED COAG (W)	150W → 150Ω
± 20%	Maximum output power SOFT COAG (W)	90W → 100Ω
± 20%	Maximum output power BIPOLAR COAG (W)	80W → 50Ω
± 5%	Modulation factor ENHANCED (Hz)	1.25
± 5%	Modulation factor BLEND (Hz)	50
± 5%	Modulation factor FORCED COAG (kHz)	10
-0.1 + 0.2	Crest Factor CUT	1.5
± 0.3	Crest Factor ENHANCED	2.0
± 0.3	Crest Factor BLEND	2.5
± 0.3	Crest Factor FORCED COAG	2.8
± 0.3	Crest Factor SOFT COAG	1.6
-0.1 + 0.2	Crest Factor BIPOLAR COAG	1.5
± 15%	Working frequency	600 kHz
± 15%	Maximum output voltage CUT (Vpp)	1500
± 15%	Maximum output voltage ENHANCED(Vpp)	1500
± 15%	Maximum output voltage BLEND (Vpp)	1800
± 15%	Maximum output voltage FORCED COAG (Vpp)	1500
± 15%	Maximum output voltage SOFT COAG (Vpp)	700
± 15%	Maximum output voltage BIPOLAR COAG (Vpp)	700
± 0.5	Size LxHxP mm	370x144x319
± 10	Weight (kg)	6
± 5%	Selectable mains power (Vac)	115 – 230
± 1%	Mains frequency (Hz)	50-60
± 0	Fuses 230Vac (5x20mm) TIMED	2xT 3.15AL 250V
± 0	Fuses 115Vac (5x20mm) TIMED	2xT 6.3AL 250V
± 10%	Electrical input power (VA)	350
± 10%	Electrical input current (230Vac) (A)	1.5
± 10%	Electrical input current (115Vac) (A)	3
-	Five steps adjustable sound level	●
-	Self-check	●
-	Power accuracy output warning	●
-	Skin Plate Electronic Control	●
-	Split or not split patient plate allowed	●
-	Working condition storing	16
-	Electrical Class (EN60601-1)	Class I Applicated Part CF
-	Protection Class (EN60529)	IP32
-	EN55011 (CISPR 11) Class (Class/Group)	2 / A
-	Patient circuit	F
-	Duty Cycle (action / pause) in seconds	10 / 30

Tolerance	Description	DIATERMO MB 200 D
-	MDR 2017/745/UE Classification	II b
-	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

There are no user-adjustable parts inside the equipment for calibration or service purposes. Opening the equipment casing voids the warranty. If repair or adjustment is necessary, the entire equipment should be sent to the LED SpA service center in APRILIA (LT), ITALY, along with a description of the issue. User maintenance primarily involves cleaning and sterilizing accessories and performing equipment checks before each use. Conducting functional and safety checks to verify parameters is the responsibility of specialized technical personnel.

CLEANING THE ENCLOSURE

Whenever possible, use only disposable accessories and dispose of them as special hospital waste. However, because some accessories may need to be reused, it is essential to thoroughly clean and sterilize them before each new use. Refer to the instructions for use (IFU) provided by the supplier of each reusable accessory for information on the maximum number of cycles and the type of sterilization required.

CLEANING AND STERILIZATION OF ACCESSORIES

If disposable non-sterile accessories are used, you must meticulously follow the Instructions for Use (IFU) provided by the manufacturer for the sterilization method and to dispose of them according to the currently applicable regulations.

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

GUIDE TO TROUBLESHOOTING

If an incident occurs, first it is advisable to check the network connection and the pre-established commands.

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.

REPLACE FUSE

Before replacing the fuse, disconnect the unit from the mains supply.

To replace the fuses use only the 5x20 fuse, operate as follows:

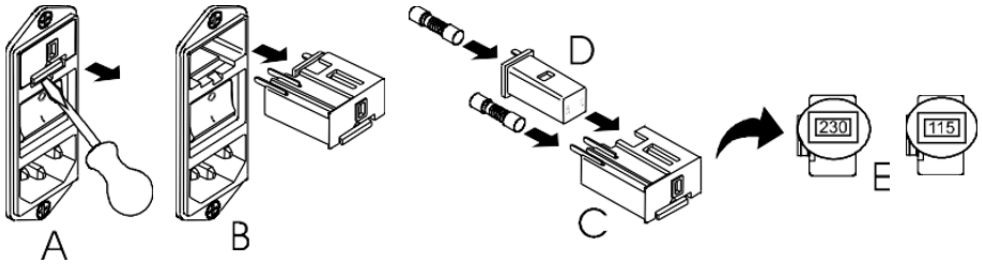
(A-B) Extract, with a small screwdriver, the fuse holder under the power socket.

(C) Insert the appropriate fuse in the module according to the following table:

Voltage 110-120 V Fuse Delayed 2x T6.3 AL, 250V / 5 x 20 mm

Voltage 220-240 V Fuse Delayed 2x T3.15A L, 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.



PRE-USE UNIT CHECK

Whenever the unit is scheduled for use, it is essential to perform a safety check, considering the following points:

- Inspect the integrity of cables, connections, wire breakage, etc.
- Ensure that all electrical equipment is properly grounded.
- Verify that all accessories to be used are available and sterilized.
- Check the operation of the OC light by disconnecting the reference electrode cable. Activate the unit and verify the OC light and audible alarm.
- Test the warning lights and audible signals by activating the CUT and COAG power switches.

SAFETY AND MEASUREMENT FUNCTION CHECKS

Periodically (at least once a year), safety checks and measurements should be scheduled by the Department of Biomedical Engineering or other specialists. These include:

- Inspection of power cables and connectors.
- Visual inspection of mechanical protections.
- Evaluation of protections against hazards from liquid leakage, penetration, drips, humidity, hygiene products, and disinfectants.
- Review of data on the device panel.
- Verification of the availability of the instruction manual.
- Examination of high-frequency output.
- Measurement of grounding conductivity resistance.
- Measurement of high-frequency leakage current.
- Assessment of neuromuscular stimulation.
- Verification of output power correction.

DIAGRAMS

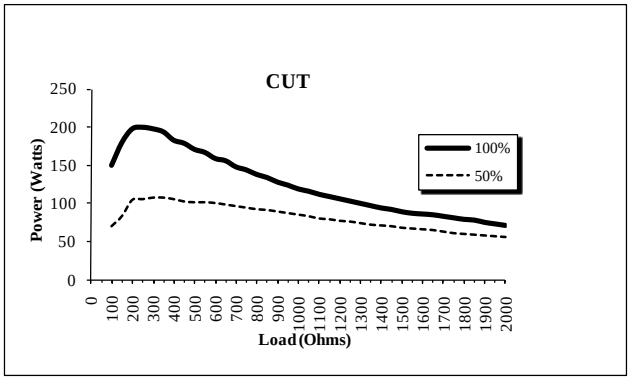


Diagram of maximum and average power on variable load 100-2000Ω CUT100%

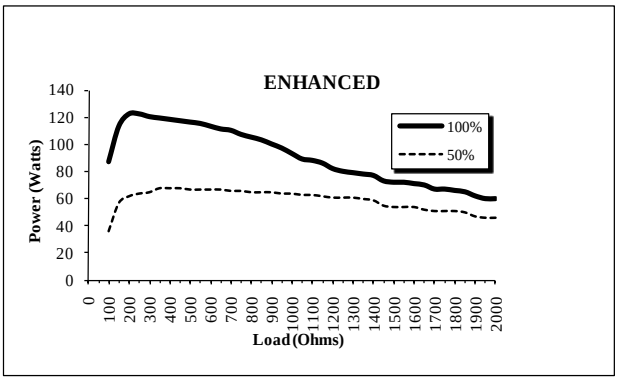


Diagram of maximum and average power on variable load 100-2000Ω ENHANCED

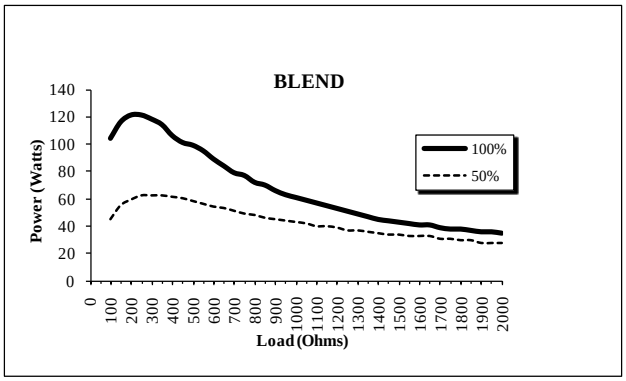


Diagram of maximum and average power on variable load 100-2000Ω BLEND

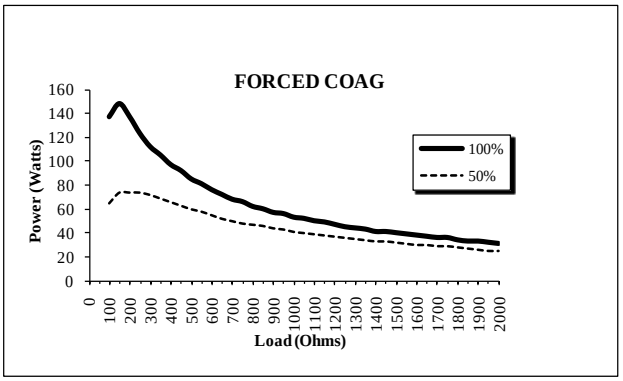


Diagram of maximum and average power on variable load 100-2000Ω FORCED COAG

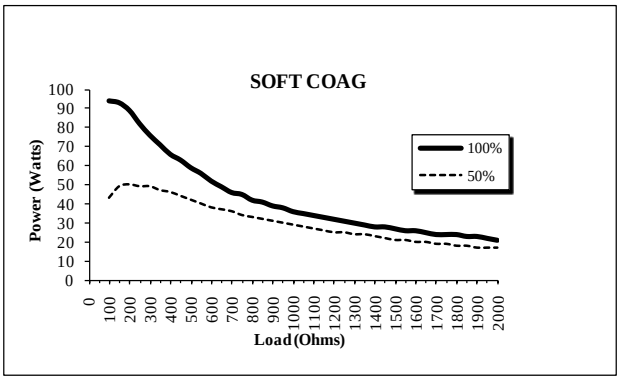


Diagram of maximum and average power on variable load 100-2000Ω SOFT COAG

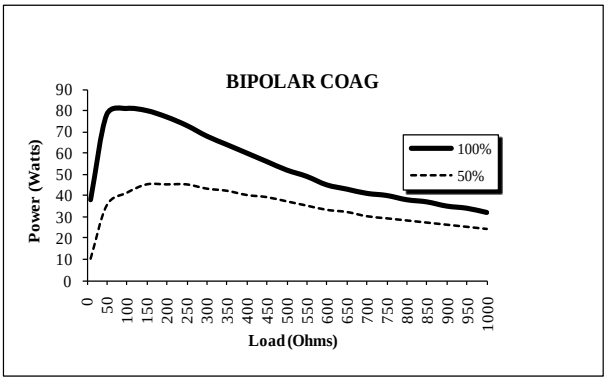


Diagram of maximum and average power on variable load 10-1000Ω BIPOLAR COAG

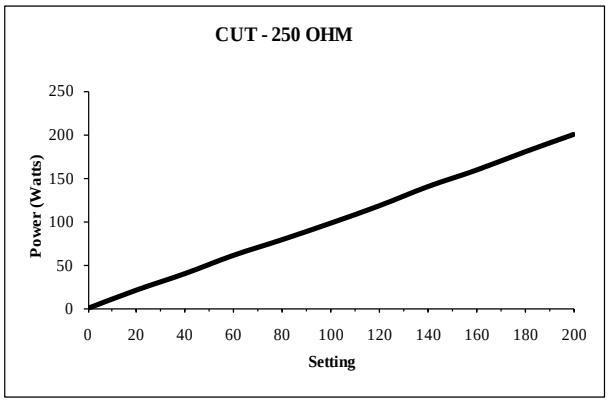


Diagram of Output Power on Rated Load CUT100%

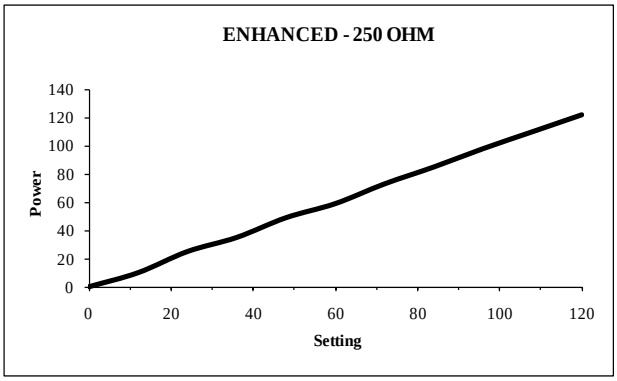


Diagram of Output Power on Rated Load ENHANCED

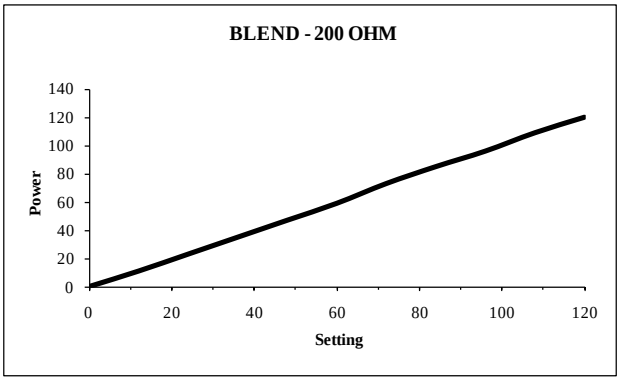


Diagram of Output Power on Rated Load
BLEND

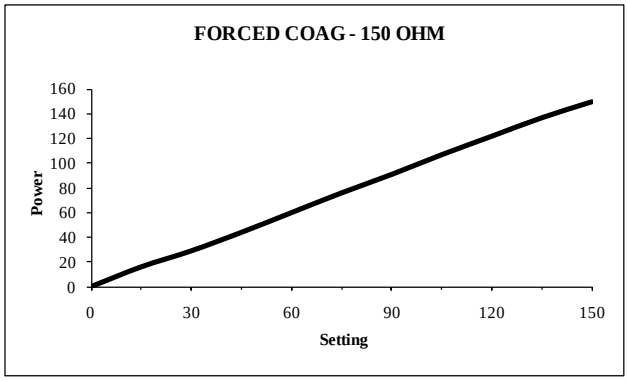


Diagram of Output Power on Rated Load
FORCED COAG

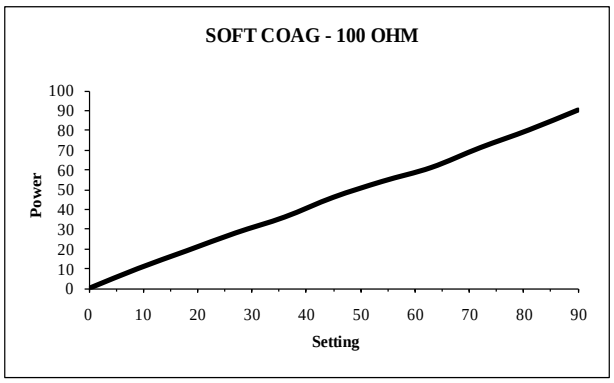


Diagram of Output Power on Rated Load
SOFT COAG

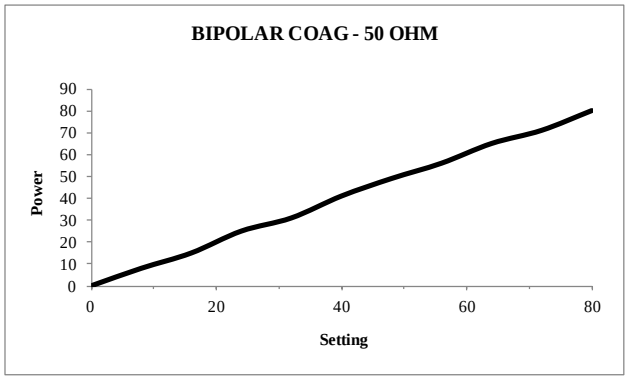
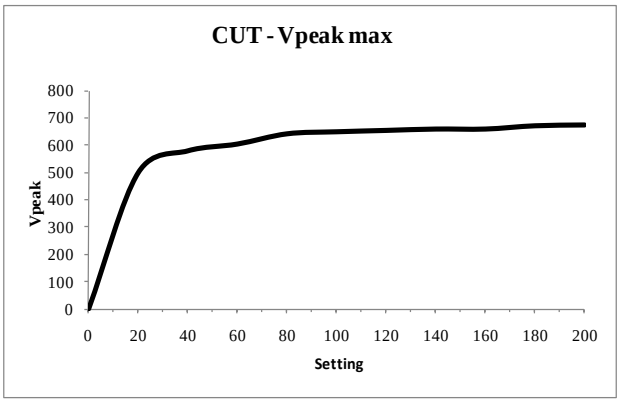
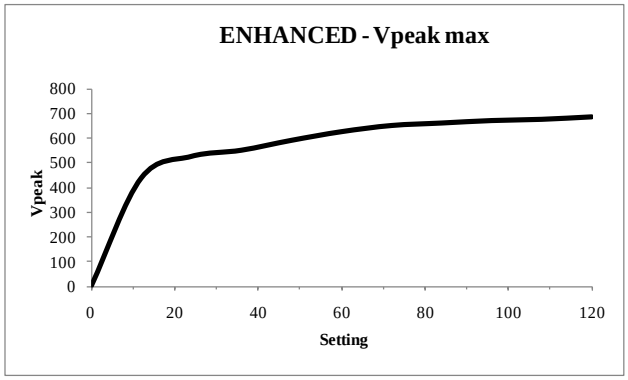


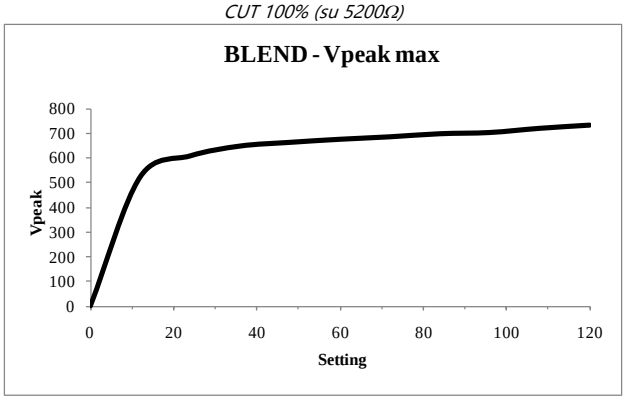
Diagram of Output Power on Rated Load
BIPOLAR COAG



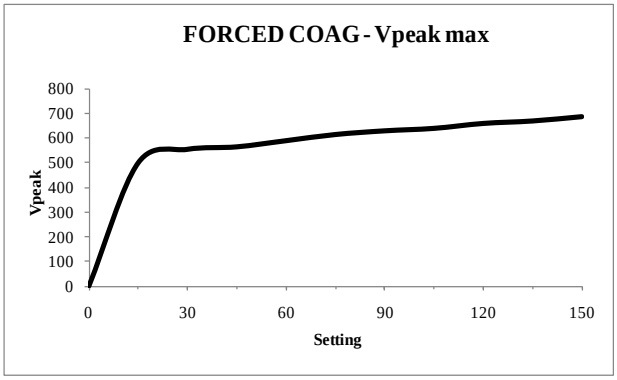
Maximum Output Voltage (Vp) Diagram for
CUT 100% (su 5200Ω)



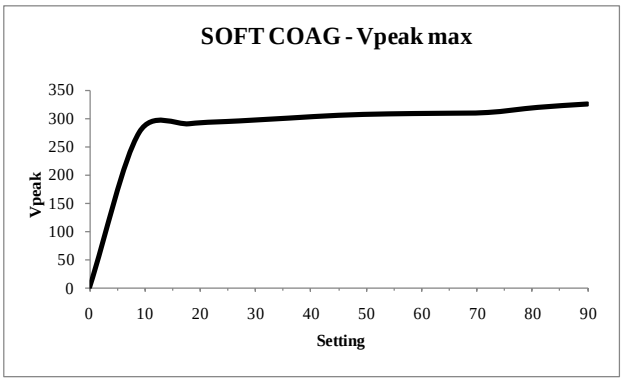
Maximum Output Voltage (Vp) Diagram for
ENHANCED (su 5200Ω)



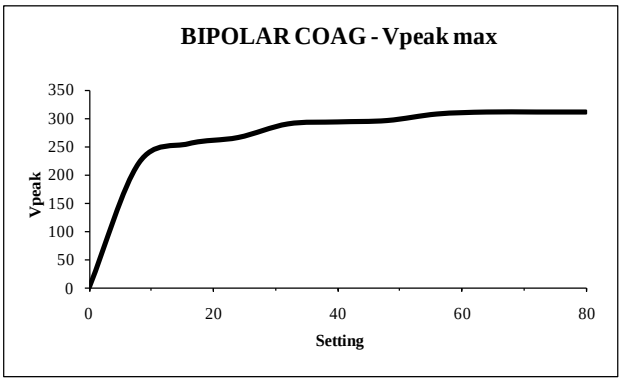
Maximum Output Voltage (Vp) Diagram for
BLEND (su 5200Ω)



Maximum Output Voltage (Vp) Diagram for
FORCED COAG (su 5200Ω)



Maximum Output Voltage (Vp) Diagram for SOFT COAG (su 5200Ω)



Maximum Output Voltage (Vp) Diagram for BIPOLAR COAG (su 5200Ω)

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

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MA395D_EN

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