EN

DIATERMO MB 120F-200F

HIGH FREQUENCY SURGICAL EQUIPMENT

USER MANUAL

GIMA

CE 0051

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IMPORTANT

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

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

If you need technical assistance, please contact LED SpA.

Produttori / *Manufacturer*

LED SpA

ELECTRONIC DESIGN AND PRODUCTION

Via Selciatella 40 04011 Aprilia (LT) Italia

www.led.it

INTRODUCTION

GENERAL DESCRIPTION

The high-frequency electrosurgical equipment, DIATERMO MB 120F and DIATERMO MB 200F, are designed to deliver currents suitable for cutting, coagulated cuts, coagulation in monopolar mode and coagulation in bipolar mode.

In the bipolar coagulation mode, the tissue impedance detection system allows automatic activation and deactivation when optimal coagulation is achieved (AUTOSTART – AUTOSTOP).

Currents can be supplied either for the entire duration of the output circuit activation, or for a predetermined time interval. The timed dispensing can be single, activated every time the output circuit is activated, or repeated at regular intervals, according to the set programming.

The equipment allows for the storage and quick recall of up to five different operating modes and power levels. Neutral single-plate or dual-conductive area electrodes can be used to monitor the stability of plate-to-patient contact impedance during surgery.

Control of the units is managed via buttons and indicators located on the front panel, while the power socket is located on the rear panel. The equipment has automated safety systems that continuously monitor internal parameters, reporting any faults or errors detected. Operating parameters are stored continuously, ensuring that each time the equipment is switched on or the operating mode is changed, it reverts to the last selected settings.

The level of the acoustic signal can be adjusted, allowing operators to choose the most suitable sound intensity for the working environment. The equipment is compatible with push-button handpieces and buttonless handpieces that can be used with a dual pedal set. In addition, bipolar accessories can be attached to perform specific functions in bipolar mode.

In summary, the DIATERMO MB 120F and DIATERMO MB 200F medical devices offer high versatility and safety for a wide range of electrosurgical applications, ensuring precise and reliable control.

INTENDED USE

Medical device intended for temporary use for surgical procedures in which soft tissue cutting and/or coagulation is required, with monopolar and/or bipolar technique, for minor and/or major investigations in open and/or intraoperative percutaneous and/or endoscopic and/or laparoscopic surgery.

The DIATERMO MB 120F and DIATERMO MB 200F equipment are designed to be used in the following sectors:

Description	DIATERMO MB 120F	DIATERMO MB 200F
Electrosurgical Unit Code	GMA10300.101	GMA10300.401
Ambulatory Surgery	●	●
Chest Surgery	-	●
General Surgery	-	●
Pediatric Surgery	-	●
Plastic surgery	-	●
Transurethral Surgery (TUR)	-	●
Vascular Surgery	-	●
Dermatology	●	●
Endoscopy	-	●
Gastroenterology	-	●
Gynaecology	-	●
Neurosurgery	-	●
Dentistry	●	-
Ophthalmology	-	●
Orthopaedics	-	●
ENT	-	●
Pneumology	-	●
First aid	●	-
Urology	-	●

● = Usable
- = Not usable

INTENDED USER

Device for professional use. The use of the equipment is reserved for medical personnel with a degree in medicine who specialize in high-frequency electrosurgery.

INTENDED PATIENT POPULATION

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

STANDARD AND OPTIONAL COMPOSITION

Code	Description	DIATERMO	
		MB 120F	MB 200F
-	Electrosurgical Unit Code	GMA10300.101	GMA10300,401
00100.01	SIE-IEC power cable (5m)	■/1	■/1
00201.02	PENCIL - Autoclavable micro-needle handpiece	■/1	■/1
00202.00	Support for Handpiece and Electrodes	■/1	■/1
00205.00	PENCIL S - Handpiece with buttons	■/1	■/1
00304.00	Waterproof single pedal	■/1	■/1
00404.08_S	CONNECTION - Neutral electrode connection cable for disposable/5365 type	■/1	■/1
00500.00	ELECTRODE - Assorted Electrode Kit (10Pcs) 5cm	■/1	■/1
0350	Disposable Neutral Electrode (F7805)	■/2	■/2
152-110	ELECTRODE - Blade electrode 7 cm	■/3	■/3
152-120	ELECTRODE - Needle electrode 7 cm	■/3	■/3
152-150	ELECTRODE - Ball electrode ⌀ 4mm 6 cm	■/3	■/3
500500.L11	Microsurgery/Hair Removal Needles (10Pcs)	■/1	■/1
5365A	Neutral metal electrode 120x160mm	■/1	■/1
F7920	Bipartite Disposable Neutral Electrode (F7820)	■/2	■/2
00100.00	Power cable 2MT IT-IEC	○	○
00100.03	Power cable 2MT SIE-IEC	○	○
00100.04	Power cable 2MT USA-IEC	○	○
00100.05	2MT GB-IEC power cable	○	○
00100.07	Power cable 2MT BR-IEC	○	○
00100.09	Power cable 2MT AU-IEC	○	○
00100.10	Power cable 5MT JP-IEC	○	○
00206.00	PENCIL - Handpiece without buttons	○	○
00305.03	Double waterproof pedal set	○	○
00400.00	Fan Deck Reference Electrode with Cable	○	-
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 c. c. Autoclav	○	○
00401.03	NEUTRAL - Neutral metal electrode 240x160mm c. c. Autoclav.	○	○
00402.00	CONNECTION - M4-F4 monocore cable 3mt	○	○
00402.01	CONNECTION - M4-F2.8 3mt monocore cable	○	○
00402.02	CONNECTION - Monopolar cable M4-MP4 3mt	○	○
00404.07	Connection cable Neutral electrode F7915/F7930	○	○
00411.00	CONNECTION - Two-core cable EUR 3mt	○	○
00500.00/L	ELECTRODE - Assorted Electrode Kit (10Pcs) 10cm	○	○
152-112	ELECTRODE - Curved blade electrode 7 cm	○	○
152-115	ELECTRODE - Blade electrode 16 cm	○	○
152-122	ELECTRODE - Curved needle electrode 7 cm	○	○
152-125	ELECTRODE - Needle electrode 13 cm	○	○
152-130	ELECTRODE - Ball electrode ⌀ 2mm 6 cm	○	○
152-132	ELECTRODE - Curved ball electrode ⌀ 2mm 6 cm	○	○
152-140	ELECTRODE - Ball electrode ⌀ 3mm 6 cm	○	○
152-142	ELECTRODE - Curved ball electrode ⌀ 3mm 5 cm	○	○
152-145	ELECTRODE - Ball electrode ⌀ 3mm 14 cm	○	○

Code	Description	DIATERMO	
		MB 120F	MB 200F
152-152	ELECTRODE - Curved ball electrode ⌀ 4mm 6 cm	○	○
152-160	ELECTRODE - Ball electrode ⌀ 5mm 6 cm	○	○
152-162	ELECTRODE - Curved ball 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 Curved Forceps 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 - Curved Bipolar Forceps 20cm TIP 1mm	○	○
310-142-20	BIPOLAR - Curved Bipolar Forceps 20cm TIP 2mm	○	○
310-180-10	BIPOLAR - Angled Bipolar Forceps 20cm TIP 1mm	○	○
310-180-20	BIPOLAR - Angled Bipolar Forceps 20cm TIP 2mm	○	○
310-182-10	BIPOLAR - Curved Angled Bipolar Forceps 20cm TIP 1mm	○	○
310-185-10	BIPOLAR - Curved Angled Bipolar Forceps 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 - Straight Fine Wire Electrode (5Pcs) 5cm	○	○
500500.L1/L	ELECTRODE - Straight Fine Wire Electrode (5Pcs) 10cm	○	○
500500.L10	ELECTRODE - Angled Ball Electrode ⌀ 3mm (5Pcs) 5cm	○	○
500500.L10/L	ELECTRODE - Angled Ball Electrode ⌀ 3mm (5Pcs) 10cm	○	○
500500.L2	ELECTRODE - Fine Wire Angled Electrode (5Pcs) 5cm	○	○
500500.L2/L	ELECTRODE - Fine Wire Angled Electrode (5Pcs) 10cm	○	○
500500.L3	ELECTRODE - Loop electrode ⌀ 4mm (5Pcs) 5cm	○	○
500500.L3/L	ELECTRODE - Loop electrode ⌀ 4mm (5Pcs) 10cm	○	○
500500.L4	ELECTRODE - Loop electrode ⌀ 8mm (5Pcs) 5cm	○	○
500500.L4/L	ELECTRODE - Loop electrode ⌀ 8mm (5Pcs) 10cm	○	○
500500.L5	ELECTRODE - Angled Hook Electrode (5Pcs) 5cm	○	○
500500.L5/L	ELECTRODE - Angled Hook Electrode (5Pcs) 10cm	○	○
500500.L6	ELECTRODE - Angled Thick Wire Electrode (5Pcs) 5cm	○	○
500500.L6/L	ELECTRODE - Angled Thick Wire Electrode (5Pcs) 10cm	○	○
500500.L7	ELECTRODE - Drip electrode (5Pcs) 5 cm	○	○
500500.L7/L	ELECTRODE - Drip Electrode (5Pcs) 10cm	○	○
500500.L8	E ELECTRODE - Loop electrode (5Pcs) 5 cm	○	○
500500.L8/L	ELECTRODE - Loop Electrode (5Pcs) 10cm	○	○
500500.L9	ELECTRODE - Straight ball electrode ⌀ 3mm(5Pcs) 5cm	○	○
500500.L9/L	ELECTRODE - Straight ball electrode ⌀ 3mm(5Pcs) 10cm	○	○
6429A	NEUTRAL - Neutral metal electrode 240x160mm	○	○
755VL	Disposable Handpiece with Buttons (F4797)	○	○
F7520	Electrode cleaning sponge 47x50mm	○	○
F7915	Neutral electrode made of single-part conductive rubber s/cable	○	○

Code	Description	DIATERMO	
		MB 120F	MB 200F
F7930	Neutral electrode made of bipartite conductive rubber s/cable	○	○
TR003	Trolley 3 floors	○	○
TR003W	Trolley 3 shelves wide	○	○
TR004	Trolley 4 floors	○	○
TR005	Trolley 5 floors	○	○
TR005W	5-tier trolley wide	○	○

■/ Pcs = STANDARD ○= OPTIONAL

ELECTROPHYSICAL PRINCIPLES

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

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

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

Electric current flowing through biological tissue usually can cause:

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

1. ***Joule Effect***

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

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

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

- **Current Intensity and output power**

- **Modulation level**

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

- **Electrode shape**

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

- **State of active electrode**

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

- **Characteristics of the tissue**

  The resistive characteristics change according to the biological tissues.

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

(Example of specific resistances of organic and metallic materials)

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

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

- **Cut**

  Temperatures above 100 °C in the area surrounding the active electrode result in the vaporization of the intracellular fluid and explosion of the cell. The vapor present around the electrode triggers an intercellular chain reaction in the direction in which the active electrode is handled, also transmitting the vaporization energy to the immediately surrounding tissues.
  Electrotomy is, therefore, not mechanical resection. If the temperature reaches 500 °C, tissue carbonization occurs with a cauterizing action.

- **Mixed currents**

  These are obtained by combining the effects of coagulation and electrotomy. A reduction in bleeding occurs during a cutting procedure, or as a cut that develops a substantial layer of eschar. The high frequencies used by the electrosurgical scalpel, however, do not allow the electromagnetic field to penetrate matter and cause the current to flow through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the 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.

OPERATING TECHNIQUES

MONOPOLAR CUTTING

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

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

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

When the output power level is adequate, it is expected to achieve:

- no resistance to electrode movement through the tissue;
- no variation in the color of the cut surfaces;
- No residual tissue fibers on the electrode.

MONOPOLAR COAGULATION

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

Coagulation can be achieved by two different procedures:

- Coagulation by drying
  It is obtained by feeding the electrode with low voltages so that no sparks are generated (this ensures that the action obtained is pure coagulation and therefore there is no shear effect). The electrode is placed in direct contact with the tissue and the amount of heat developed on contact dries it.
  Typically, coagulated cell surfaces act as an insulating layer, which prevents heat from subsequent applications of current from penetrating too deeply.
  The current normally used for coagulation is modulated. Depending on the percentage of modulation, there is precision of the cut, goodness of hemostasis and degree of tissue destruction. Greater modulation of the current leads to a more jagged cut, a greater depth of destroyed tissue, but more effective coagulation.
  The following rules help the operator to achieve good coagulation:
  - select a ball electrode or thick wire;
  - locate the bleeding vessel after wiping excess blood from the area;
  - lightly touch the bleeding vessel before activating the electrode;
  - Stop activating the electrode as soon as the tissue turns white to avoid damaging it.
  - keep the tip of the electrode clean (for this purpose, the optional electrode cleaning sponges with code F7520 are used).

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

BIPOLAR COAGULATION

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

distal ends of the forceps clean during surgery, because they are subject to the accumulation of coagulated tissue, which limits the passage of current and favors bonding to the tissues.
The application of the neutral electrode (which is mandatory in the monopolar technique) is not necessary, although from a practical point of view it is always allowed to be applied to the patient during the initial preparation phase.

CONTRAINDICATIONS

The use of electrosurgery is contraindicated in patients:

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

In the field of electrosurgery, high-frequency burns are the main injuries caused to the patient, although they are not the only ones. In fact, compression necrosis, allergic reactions to disinfectants, ignition of flammable gases or liquids are detected.
Some of the primary causes of burns can be attributed to:

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

In order to avoid or reduce the risks associated with the use of high-frequency electrosurgery, it is necessary to comply with the rules and safety measures described in the next chapter.

SAFETY

WARNING: Electrosurgery can be dangerous: Improper use of each of the elements of the electrosurgical system can cause severe burns to the patient. It is imperative that you carefully read and fully understand all instructions before attempting to use an active electrode. Neither the manufacturer nor any of the dealers can be held responsible for loss or damage caused to persons and equipment, directly or indirectly, due to improper use of the device and its accessories.
The accessories supplied with the unit have features that are compatible with this unit, they may be incompatible with other electrosurgical units. The user must check, before attaching other accessories

to this unit, that they have insulation characteristics compatible with those of this unit (refer to the "TECHNICAL SPECIFICATIONS" chapter). The integrity of the packaging of any sterile accessories should be checked before first use.

WARNINGS

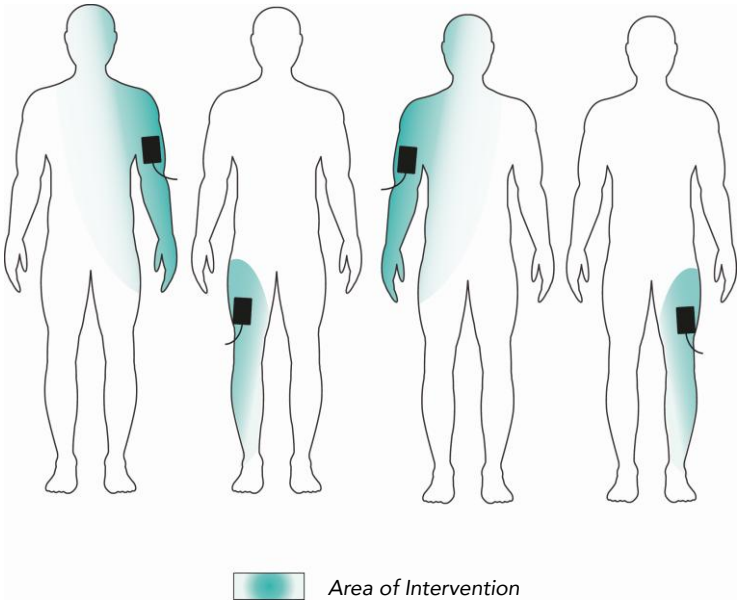
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). There is a possible hazard because interference with the action of the electronic system may occur or the system may be damaged.
- DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or near volatile solvents (such as ether or alcohol), as explosion may occur.
- DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Tools that are activated or hot from use may cause a fire.
- When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Unintentional contact with the patient may cause burns.
- Inspect instruments and cords for damage before each use, especially the insulation of laparoscopic/endoscopic instruments. This can be done visually under magnification or with a high-voltage insulation test fixture. Insulation failures can cause burns or other injury to the patient or operator.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is turned off.
- Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue and aerosol smoke plume), protective goggles, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Connect adapters and accessories to the electrosurgical unit only when the power is off. Failure to do so may result in injury or electric shock to the patient or operating room personnel.
- If the device is enhanced with argon, warnings regarding gas embolisms should be included.
- If the instrument is reusable, a warning should also be included that visual inspection alone may not be sufficient to ensure that the insulation is intact.
- DO NOT activate the instrument when it is not in contact with the target tissue, as this may cause injury due to capacitive coupling with other surgical equipment.
- DRAW fluid from the area before activating the tool. Conductive fluids (e.g., blood or saline) in direct contact with or near an active electrode can carry electrical current or heat away from the target tissues, which can cause unwanted burns to the patient.
- DO NOT USE with hybrid systems, i.e. a combination of metal and plastic, when using monopolar active components. This can cause alternate site burns due to capacitive coupling. Use only all-metal or all-plastic systems.
- Before increasing the intensity, check the adherence of the neutral electrode and its connections. An apparent low power or failure of the device to operate at normal operating settings may indicate incorrect application of the neutral electrode or poor contact in its connections.
- This unit has a CQM system, please note that loss of secure contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode (split neutral electrode) is used.
- Caution: The intensity should be set to the lowest level necessary to achieve the desired effect.
- Caution: Keep the active electrodes clean. Accumulation of eschar can reduce the effectiveness of the tool. Do not activate the tool during cleaning. Injuries to operating room personnel may occur.

- Any serious incident occurring in relation to the device must be reported to LED SpA (via Selciatella n.40, 04011 Aprilia (LT) ITALY) and to the competent authority:
  Ministry of Health – General Directorate of Medical Devices and Pharmaceutical Service
  Viale Giorgio Ribotta, 5 – Rome
  E-mail: segr.dgfdm@sanita.it
  Tel.: +39 06 5994 3199 / +39 06 5994 3207

PRECAUTIONS

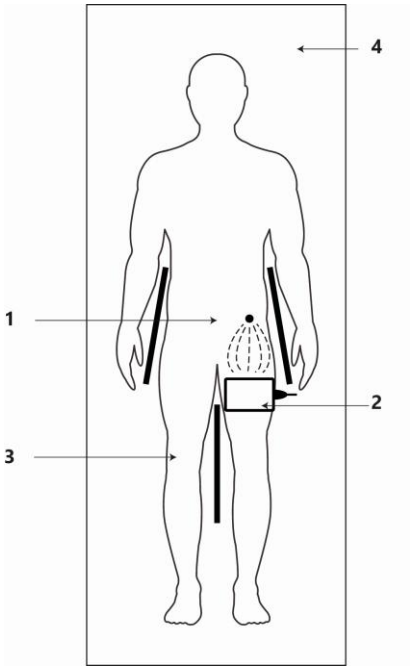
The following precautions are intended to reduce the risk of accidental burns:

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



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

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



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

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

materials such as cotton wool or gauze, when impregnated with oxygen, can ignite due to sparks produced by the appliance under normal conditions.

- There is a danger to patients with pacemakers (pacemakers) or pacing electrodes as interference with the action of the stimulator may occur or the stimulator itself may be damaged. If in doubt, you should contact the Cardiology Department.
- Electrosurgical equipment emits high-frequency energy radiation without warning which may affect other medical equipment, unrelated electronics, telecommunications, navigation systems. To avoid interference, a distance of at least 1.5 meters must be placed between the electrosurgical equipment and other devices.
- The user should check the accessories regularly. In particular, electrode wires and any endoscopy accessories should be checked for damage.
- In order to connect accessories compatible with the characteristics of the equipment, the insulation characteristics of the accessories (to be requested from the manufacturers) must be compared with the characteristics of the unit supplied (see Technical Characteristics).
- Caution: A failure of the surgical equipment could result in an unintended increase in output power.
- Stimulation of the patient's muscles or nerves can be caused by low-frequency currents originating from electrical sparking between the electrodes and the patient's tissue. If neuromuscular stimulation occurs, stop surgery and check all connections to the generator. If the problem is not resolved in this manner, the generator should be inspected by qualified service personnel.

INSTALLATION

- Electrical safety is ensured only when it is correctly connected to an efficient power supply network connected to the ground in accordance with current safety standards. It is necessary to verify this basic safety requirement and, if in doubt, to request a thorough inspection of the system by qualified personnel. The manufacturer cannot be held responsible for possible damage caused by the lack of an efficient ground connection of the installation. Operation without protective ground connection is prohibited.
- Before connecting the equipment, make sure that the required voltage (indicated on the rear panel) matches the available mains.
- In the event of an incompatibility between the available power outlet and the power cord of the equipment, replace only with a suitable type. The use of adapters, multiple connections, or extension cables is not permitted. If their use is necessary, it is mandatory to use only single or multiple adapters that comply with current safety standards.
- Do not leave the apparatus exposed to atmospheric agents (rain, sun, etc.). The apparatus must be protected from liquid ingress.
- Do not leave the equipment plugged in unnecessarily. Turn it off when not in use.
- The equipment is not suitable for use in explosive environments.
- The equipment should only be intended for the use for which it was specially designed. Any other use must be considered improper and dangerous. The manufacturer cannot be held responsible for possible damage due to improper, incorrect or unreasonable use.
- It is dangerous to modify or attempt to modify the characteristics of the equipment.

- Before carrying out any cleaning or maintenance operation, disconnect the appliance from the mains by removing the plug from the mains or by switching off the main switch of the system.
- In the event of breakage or malfunction of the equipment, switch it off. For possible repairs, refer only to an authorized service center and request the use of original spare parts. Failure to comply with the above rules may risk the safety of the equipment and may be dangerous for the user.
- Do not reduce or eliminate the generator activation beep. A working activation signal can minimize or prevent injury to the patient or staff in the event of accidental activation.
- The operation of the equipment should not be verified by emitting the power between the active and neutral electrode or between the active electrode and metal parts.
- If necessary, use fume extraction means in the field of intervention.

WARNING: When using in the operating room, only immersion-resistant foot switches must be used (code 00304.00 single watertight pedal – code 00305.03 double watertight foot pedal).

PATIENT SAFETY

During high-frequency electrosurgery, the patient behaves like an electrical conductor. A non-zero potential difference is established between the patient and the ground and therefore, if contact were made between the patient and electrically conductive objects (made of metal, damp or wet drapes and cloths, etc.), an electric current would be generated at the point of contact that could cause thermal necrosis. The appliance and its accessories must therefore be checked before use and all relevant safety regulations must be observed.

CORRECT PATIENT POSITIONING

Avoid any intentional or accidental contact between the patient and grounded metal parts and ensure that:

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

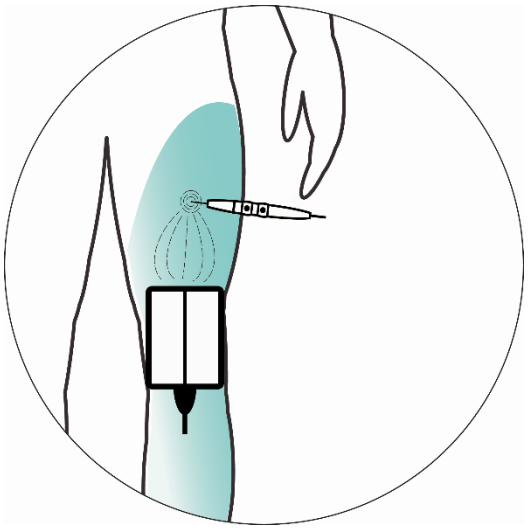
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

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

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

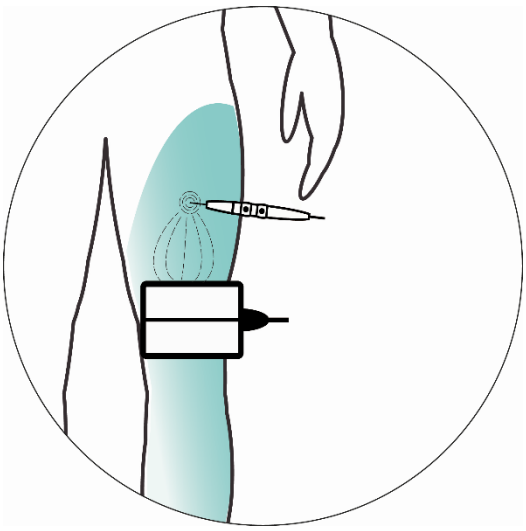
It is vitally important to pay attention to the accurate placement of the neutral electrode in order to prevent burns and minimize risks to the patient. The following is useful information in this regard:

1. *Correct Positioning*



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

2. *Incorrect Positioning*



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

For both single-part and two-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 to scars, bony protrusions, or anatomical parts where there are prosthetic implants or monitoring electrodes. Instead, apply it to well-supplied tissues, such as muscles and near the surgical site.

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

It is of paramount importance that the neutral electrode is firmly applied over its entire surface to avoid burns. When a neutral electrode partially detaches from the patient, the density of the current flow in the part of the electrode that is still applied increases. Because the density of the current flow below the neutral electrode is uneven, uneven heating occurs, especially at the edges of the neutral electrode.
If the electrode were placed in a region under pressure during surgery, the compressive load would result in a reduction in skin perfusion. In this way, only part of the heat can be removed, which increases the risk of burns. In addition, there is an increased risk of pressure points (decubitus) forming due to the heating that occurs. This increase in temperature causes an increased need for oxygen (O2) and energy in the affected area, contributing to the possible development of areas of pressure on the body.

LAPAROSCOPIC HF ELECTROSURGERY

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

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

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

- **Direct coupling**, which occurs when the active electrode comes into contact with another metal instrument, causing electrical current to be transmitted and increasing the risk of burns to surrounding tissue, such as intestines or other organs;
- **Failure to insulate**, in this case the insulation of the electrode can be compromised by the use of excessive voltage, improper use, or mechanical breakage of the electrode rod. This can happen during a surgical procedure or during the cleaning and sterilization phases of

instruments. A break in the insulation that is not visible, when the electrode is activated, represents a danger of unpredictable burns, therefore more insidious. Curiously, a small insulation break is more dangerous than a large one, as the current is more concentrated and therefore more likely to cause burns;

- **Capacitive coupling**, which occurs when electric current is induced by the active electrode on conductive materials, even if the insulation is intact. During high-frequency electrosurgery procedures, the rapid change in the electric field around the active electrode is only partially hindered by the insulation, generating ionic currents that, when in contact with the tissue, cause sufficient heating to cause burns.

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

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

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

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

PUTTING INTO SERVICE

- Inspect the equipment for any damage caused by transportation. Claims for any damage will be accepted only if notified immediately to the carrier, drawing up a note of the damage found, to be presented to LED SpA or to its seller. In case of return of the equipment to LED SpA or to the seller, it is necessary to use the original packaging of the product or a packaging that guarantees equivalent safety for transport.
- Remove the appliance from its packaging and carefully study the documentation and operating instructions provided. The mains voltage, indicated on the nameplate, must be equal to the local mains voltage (mains frequency: 50-60Hz). If necessary, replace the fuses with the value indicated in the nameplate data.
- Connect the power cord to a mains socket with a good earth connection.
  OPERATION OF THE EQUIPMENT WITHOUT AN EARTH CONNECTION IS PROHIBITED.
- The equipment should be installed on a flat surface that is at least as large as the base of the equipment. At least 25cm of space must be left around the equipment.
- Connect the mains cable to the power outlet located on the rear panel of the unit.
- Connect the equipotential bonding point on the rear left of the unit to the equipotential bonding receptacle of the implant.
- Connect the foot pedal or dual pedal set (optional) to the connector on the front panel of the unit.
- Connect a handpiece with buttons to the corresponding connection points and in the case of use of a handpiece without buttons, the same must be connected on the "active" bushing.
- Only operate the equipment in a dry environment. Any condensation that occurs must be evaporated before operating the equipment. Do not exceed the ambient temperature or permissible humidity.
- Environmental conditions:

	TRANSPORT	STORAGE/OPERATION
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 A 106 kPa	from 50 to 106 kPa

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

CONNECTING & USING ACCESSORIES

Using the MONOPOLAR TECHNIQUE :

A handpiece with two buttons without foot pedal: press the yellow button on the handpiece to deliver the cutting current (the choice between CUT and BLEND must be made by pressing the corresponding button on the tool) or the blue button on the handpiece to deliver the coagulation current (the choice between FORCED COAG, SOFT COAG and BIPOLAR must be made by pressing the corresponding button on the tool).

NOTE: FOR PEDAL USE you must select the pedal control for monopolar.

A handpiece with two buttons and a single foot pedal: use the selection buttons on the apparatus to set between CUT or BLEND cutting and FORCED COAG, SOFT COAG or BIPOLAR coagulation, preselect, using the yellow button on the handpiece, the cutting function selected on the apparatus or preselect, using the blue button on the handpiece, the coagulation function selected on the apparatus. The emission is made by means of a foot pedal.

A handpiece with two buttons and the double pedal (optional): press the yellow pedal or the yellow button on the handpiece to select and deliver the cutting current (the choice between CUT and BLEND must be made by pressing the corresponding button on the tool) or the blue foot pedal or the blue button on the handpiece to select and deliver the coagulation current (the choice between FORCED COAG, SOFT COAG and BIPOLAR must be carried out by pressing the corresponding button on the device).

A buttonless handpiece (optional) and single foot pedal: Connect the handpiece to the bushing indicated ACTIVE and select the CUT or BLEND cutting current or the FORCED COAG, SOFT COAG or BIPOLAR coagulation current and to deliver the desired current press the foot pedal.

A buttonless handpiece (optional) and double foot pedal (optional): connect the handpiece to the bushing indicated ACTIVE and press the yellow pedal to select and deliver the cutting current (the choice between CUT and BLEND must be made by pressing the corresponding button on the tool) or the blue pedal to select and deliver the coagulation current (the choice between FORCED COAG, SOFT COAG and BIPOLAR must be carried out by pressing the corresponding button on the device).

Using the BIPOLAR TECHNIQUE :

A bipolar clamp (optional) and single foot pedal: Connect the cable and bipolar accessory (optional). Deliver the current by pressing the foot pedal. To avoid damaging the pliers, do not short-circuit the tips.

A bipolar clamp (optional) and dual foot pedal (optional): Connect the bipolar cable and accessory (optional). Deliver the current by pressing the coagulation pedal (blue). To avoid damaging the pliers, do not short-circuit the tips.

NOTE: To operate the unit in bipolar technology, you need a number of optional accessories, in particular:

1. Connection cable for bipolar forceps

2. Bipolar Accessory (e.g. pliers)

MEANING OF GRAPHIC SYMBOLS

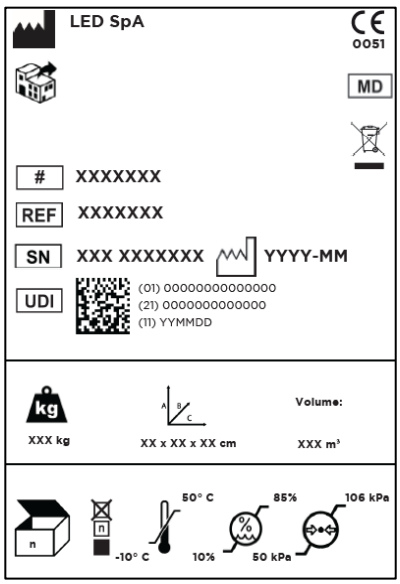
In accordance with the international standards ISO 15223-1:2021 "Medical devices - Symbols to be used in the information to be provided by the manufacturer" and ISO 780:2015 "Packaging - Packaging for distribution - Graphic symbols for handling and storage of packaging", all symbols on device labels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

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

SYMBOL	DESCRIPTION
	Protect from moisture.
	Maximum number of stackable pieces.
	Weight.
	Dimensions.
	Number of pieces.
	Recycle.
	Model/Trade Name.
IP	Degree of protection against the ingress of water and dust.
	Fuse.

BOX LABEL

With reference to ISO 15223-1:2021 "Medical devices — Symbols for use with medical devices, labels, labeling and information to be provided" and ISO 780:2015 "Packaging — Packaging for distribution — Graphic symbols for handling and storage of packages" the following information is shown on the packaging label of the unit on the packaging:



ISO 15223-1 (5.1.1) - **MANUFACTURER**
ISO 15223-1 (5.1.9) - **DISTRIBUTOR**
ISO 15223-1 (5.1.10) - **MODEL NUMBER**
ISO 15223-1 (5.7.10) - **UNIQUE DEVICE IDENTIFIER**
ISO 15223-1 (5.1.6) - **CATALOGUE NUMBER**
ISO 15223-1 (5.1.7) - **SERIAL NUMBER**
ISO 15223-1 (5.1.3) - **DATE OF MANUFACTURE**
BOX WEIGHT
BOX DIMENSIONS
BOX VOLUME
ISO 7000 (No. 2403) - **STACKING LIMIT BY NUMBER**
EU REGULATION 2017/745 (MDR) - **CE MARK WITH NOTIFIED BODY NUMBER**
ISO 15223-1 (5.7.7) - **MD (MEDICAL DEVICE)**
DIRECTIVE 2012/19/EU - **WEEE PRODUCT**
ISO 15223-1 (5.3.7) - **TEMPERATURE LIMIT**
ISO 15223-1 (5.3.8) - **HUMIDITY LIMIT**
ISO 15223-1 (5.3.9) - **ATMOSPHERIC PRESSURE LIMITATION**

FRONT PANEL

1. Pulse Repetition Interval Display
2. Timed dispensing time display
3. FLASH TIME section settings knob/encoder
4. MONOPOLAR CUT level display
5. Function selection keys MONOPOLAR CUT
6. MONOPOLAR CUT level knob
7. Output indicator light MONOPOLAR CUT
8. Display of MONOPOLAR COAGULATION levels
9. Function selection keys MONOPOLAR COAGULATION
10. MONOPOLAR COAGULATION level knob
11. Exit indicator light MONOPOLAR COAGULATION
12. Display of BIPOLAR COAGULATION levels
13. BIPOLAR COAGULATION level knob
14. Select button for automatic bipolar coagulation
15. Exit indicator light BIPOLAR COAGULATION
16. Neutral electrode impedance reading display
17. Neutral electrode impedance acceptance button
18. Alarm for excessive impedance of the neutral electrode
19. MONOPOLAR/BIPOLAR foot control selection button
20. BIPOLAR output connector
21. Dispensing pedal connector
22. Connector for active handpiece MONOPOLAR
23. Connector for neutral electrode connection
24. Buttons for memorizing how to use

OPERATING MODES

IGNITION

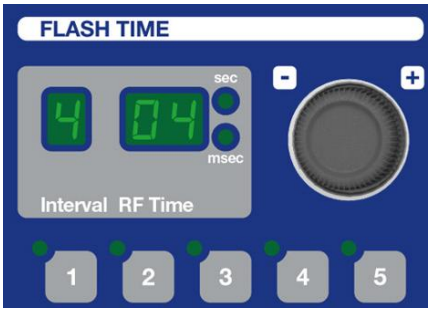
When switched on, the electrosurgical unit automatically performs a test of correct operation, including the connected accessories. In the event of anomalies, an alphanumeric coded message appears on the seven-segment display, according to the error code table in the *MAINTENANCE* chapter. The test lasts about 10 seconds. At the end of the check, the equipment restores the last operating conditions used and indicates the flashing OC (open circuit) alarm signal.

NEUTRAL ELECTRODE CIRCUIT (SKIN PLATE ELECTRONIC CONTROL)

The neutral electrode circuit is continuously monitored by a special circuit (SKIN PLATE ELECTRONIC CONTROL) which prevents the loss of contact between the patient reference plate or the change in the conductivity characteristics of the plate from causing a reduction in the conductivity of the circuit and therefore a risk of burns to the patient.

The impedance value found in the neutral electrode circuit is shown (with the OC alarm flashing) to the operator who, if he considers it suitable for the work to be done, accepts it by pressing the OK button ('YES' appears on the display). If the impedance value is excessive, the acceptance is not received by the device ('UP' appears on the display) and consequently the OC signal does not go out and power delivery is not permitted.
In order to reduce noise pollution, the audible alarm is only triggered if the dispensing pedal is kept pressed.
If single-part neutral electrodes are used, the circuit controls only the connection of the neutral electrode with the unit.
If the impedance value is accepted, the impedance indication is received and the display and OC indicator are permanently switched off.
If, after accepting the shown impedance, the value of the impedance increases relative to the accepted value, the equipment prevents dispensing, indicates the OC condition, which has no beep (present only during dispensing), and shows the new impedance value. To accept this new value, press the OK button.

PULSE REPETITION INTERVAL AND DISPENSING TIME PROGRAMMING



In the FLASH TIME section, you can select the selection of the pulse repetition number (INTERVAL) and the pulse duration (RF TIME).

The adjustable value is indicated by the dot on the display. To move the point from Interval to RF Time, press the knob/encoder. To adjust the selected value (the one indicated with the dot), turn the encoder knob.

The duration of the pulses is indicated by the dual display (RF TIME).
The equipment can be set up to obtain dispensing for the entire time of activation of the output circuit (CO indication) or for dispensing at a programmed time from 10 thousandths of a second to 30 seconds. For setting the time, follow the following table:

RF TIME	Spy	Dispensing time		Pitch Adjustment
		From	*to*	
10÷90 AM	ms	10 ms	90 ms	10 ms
0.1÷0.9	s	0.1 s	0.9 s	0.1 s
1.0÷9.5	s	1 s	9.5 s	0.5 s
10÷30 AM	s	10 s	30 s	1 s
CO	ms	Throughout the time the output circuit is activated (handpiece button or foot pedal)		

NOTE: To not use the timed function (to achieve dispensing for the entire time the output circuit is on) set to RF TIME, the CO.

The RF TIME function can be set with all functions but does not interfere with the AUTOSTART/AUTOSTOP function in the BIPOLAR output.

The pulse repetition interval is indicated by the individual display (INTERVAL).

The programmed pulse duration dispensing can be repeated, if the output circuit is kept on, for a pre-selected number of times (2 to 9 times). The interval between repetitions is twice the duration of the pulse.

NOTE**:** Setting the value to 1 gives you a single pulse. Setting the value to 0 results in a pulse repeat cycle for the entire time the output circuit is activated.

The INTERVAL function is not active if the pulse duration (RF TIME) is CO.

MEMORIZATION OF HOW TO USE

Using the five keys you can store 5 different operating modes and power levels.

Whereas:

- An empty position is characterized by the corresponding green LED off. By briefly pressing the button, you will hear a sound and the LED is off.
- A position used is characterized by the corresponding green LED being lit. By briefly pressing the button, you hear a sound and the LED is on.

To store the parameters, simply perform the following procedure:

1. Long press and hold the button to which you want to associate the settings (functions/levels/pulse duration/pulse interval) to be stored.
2. Once the message has been memorized, a double sound is heard.

NOTE: If a key is pressed to which the settings have been previously stored (green LED on), changing any of the settings, the LED will turn off. To memorize these variations, repeat the memorization procedure (long press the button until the double sound). To recall the old settings, press the button briefly.

MONOPOLAR

The currents that can be delivered in monopolar mode for cutting, coagulated cutting and coagulation can be set by means of the buttons in the MONOPOLAR section. The power level for each function can be set using the level knobs of the CUT and COAG sections. The set power levels remain stored.

(Fig. 1)

MONOPOLAR

CUT	COAGULATION	HANDPIECE CONNECTOR AND MONOPOLAR PEDAL CONTROL
1 Cut 2 Blends 3 Enhanced Cut	4 Forced Coag 5 Soft Coag	

NOTE: FOR PEDAL USE you must select the pedal control for monopolar. Corresponding indicator light on.

Below is a description of the currents that can be delivered, based on the order of arrangement of the selection buttons, in the MONOPOLAR section.

CUT CURRENT (CUT)

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

ENHANCED CUT CURRENT (ENAHNCED)

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

BLENDED CURRENT (BLEND)

The mixed stream (BLEND) is suitable for coagulated cutting when deep coagulation associated with cutting is desired. Its waveform with a modulation percentage lower than pure coagulation This current consists of shear-friendly sinusoidal current associated with current suitable for low-voltage coagulation (soft coag). This results in a current suitable for coagulated cutting in the absence of eschar and carbonization, which is particularly suitable for endoscopy operations.

SURFACE COAGULATION CURRENT (FORCED COAG)

The modulated current FORCED COAG is characterized by good surface coagulation properties leading at the same time to probable eschar production and partial tissue carbonization. The advantage of this type of coagulation lies in the speed with which the effect is obtained.

FORCED Coag is also called Fulgurate or Speedy.

DEEP COAGULATION CURRENT (SOFT COAG)

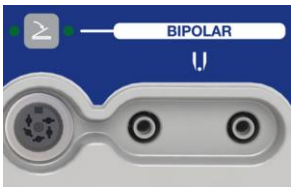
The low-voltage, low-modulation current SOFT COAG is suitable for coagulation of deep tissue layers in which cellular albumin coagulation is achieved in the absence of

carbonization and without eschar production. The coagulation process is slower in this case than in FORCED COAG coagulation.
SOFT Coag is also referred to as Pin Point, Dessicate or Deep.

BIPOLAR

The currents that can be delivered in the bipolar mode for cutting, coagulated cutting and coagulation can be set by means of the buttons in the BIPOLAR section. The power level for each function can be set using the level knob in the COAG section. The set power levels remain stored.

BIPOLAR

COAGULATION	BIPOLAR ACCESSORY CONNECTOR AND BIPOLAR PEDAL CONTROL SELECTION
1 Bipolar Coag	

Note: For BIPOLAR you must use the foot pedal and select the pedal control for bipolar. Corresponding indicator light on.

When using the COAG functions, it will be necessary to connect the bipolar accessories to the connector responsible for this function (BIPOLAR).

BIPOLAR COAG CURRENT

A type of coagulation that can be carried out with bipolar forceps and which allows the radiofrequency output power to be delivered via a handpiece or pedal on an impedance of about 100 ohms. This value is approximately the same as the section of fabric that can normally be between the tips of the pliers. Interesting is the possibility of entering the auto-start and self-stop of the dispensing through the SELECT button (refer to the paragraph "AUTOSTART AND AUTOSTOP").

AUTOSTART AND AUTOSTOP

In the 'BIPOLAR COAG' section there is the SELECT button, through which you can access four different settings valid for bipolar coagulation:

1. No automatic dispensing system is set (when the device is used for the first time). Dispensing is done by pressing the pedal and ceases when the pedal is released;

2. Auto START. This function is selected when the SELECT button is pressed for the first time and is indicated by the corresponding indicator light. The dispensing is activated, by pressing the pedal, if there is contact between the active electrode and the tissue, and stops by releasing the pedal;

3. Auto STOP. This function is selected by pressing the SELECT button twice and is indicated by the corresponding indicator light. The output is activated by pressing the pedal (even if there is no contact between the tissue and the active electrode) and stops for impedance values greater than 200 Ohms. Therefore, when the pedal is pressed, if there is an impedance value higher than 200 Ohms, the delivery is not activated.

4. Auto START/Auto STOP. Through this setting, accessible by three presses of the SELECT button and signaled by the illumination of both the START and STOP lights, bipolar coagulation can be activated and deactivated automatically. Dispensing is activated by pressing the pedal if there is contact between the tissue and the electrode active and ceases for impedance values greater than a certain value. Therefore, when the pedal is pressed, if there is an impedance value higher than a certain value, the delivery is not activated.

Pressing the SELECT button again returns you to function (1) with no automatic settings set.

REPORTING EXCESSIVE TIME

If the operator exceeds the maximum dispensing time of 10 seconds, the equipment may, after a variable time, depending on the type of dispensing and the level of the same, generate a warning signal consisting of the word Hot flashing on the displays and the obstruction of the possibility of dispensing. The prohibition of disbursement lasts for a period of time depending on the progressive conditions of disbursement.

EXCESSIVE IMPEDANCE SIGNALING IN THE NEUTRAL ELECTRODE (OC) CIRCUIT

For the meaning of this message, refer to the previous description of the neutral electrode circuit. The OC light flashes if the circuit is open, it goes out by closing the plate and if the set parameters are within the set parameters and, during the dispensing phase, it is accompanied by an acoustic signal.

ADJUSTING THE LEVEL OF THE BEEP

To change the level of the emission beep, you need to perform the following procedure:

1. Turn on the equipment at the power switch while holding down the CUT button.
2. After the appliance has checked the internal parameters, the word SOU appears on the CUT display , while the value of the set level appears on the COAG display. Now release the CUT button.
3. By means of the COAG knob it is possible to vary the emission sound level, during the variation the equipment emits a sound corresponding to the selected level.
4. To confirm the data, press the CUT button.

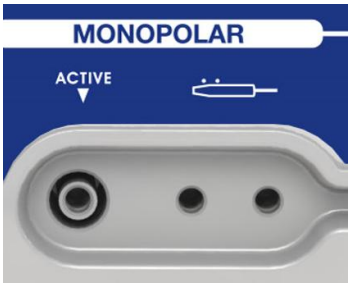
Level	Sound emission at 1m from the front panel
1	55 dBA
2	60 dBA
3	65 dBA
4	70 dBA
5	75 dBA

AUTOMATIC CONTROL OF INTERNAL PARAMETERS

The equipment has a continuous system of automatic control of some internal parameters. When switched on, it performs a check, indicated on the displays with the word **SEL FCh**, followed by the result of the same with **PAS Sed** if the system does not detect any irregularities or if not, by means of a coded error signal in the form **Err xxx**.
For more details, see Troubleshooting Guide.

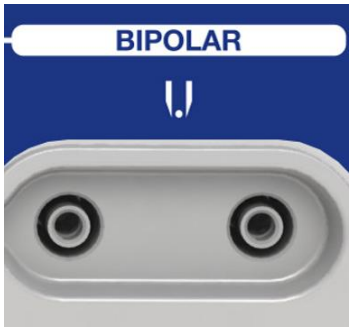
CONNECTORS

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.



REAR PANEL

1. Power socket
2. Power switch
3. Fuse holder / Voltage selector switch
4. Equipotential bonding

EQUIPMENT POWER SUPPLY MODULE AND VOLTAGE SELECTOR SWITCH

The equipment power supply module is the power supply connection point for the internal electronics of the equipment. This power module incorporates the power connector and line fuses. The voltage selector switch is located inside the power supply module.
WARNING: Before switching on the equipment, the operator should ensure that the mains voltage indicated in the voltage selector corresponds to the voltage to which it is connected and that fuses appropriate to the selected voltage have been inserted.

POWER SWITCH

The mechanical power switch is used to turn on the power supply to the equipment. To turn on the power supply to the equipment, press the switch in direction 1. When the power is on, the front panel is illuminated. By pressing the switch in direction 0 the power supply will be switched off, this operation allows the mechanical switch to be used as an emergency switch in the event of any fault.

SPECIFICATIONS

Tolerance	Description	DIATERMO MB 120F	DIATERMO MB 200F
-	Electrosurgical Unit Code	GMA10300.101	GMA10300,401
-	Bipolar coagulation with automatic activation/deactivation	●	●
-	Tissue impedance detection system (bipolar coag. – autostart/autostop)	●	●
-	Pulse interval repetition	●	●
-	Timed output (10msec - 30sec)	●	●
-	Selectable minimum power	0	0
-	Power control via monopole-encoder	●	●
± 20%	Maximum cutting power CUT (W)	120W→ 250Ω	200W→ 250Ω
± 20%	Maximum power cut-coagulated BLEND (W)	90W → 200Ω	120W → 200Ω
± 20%	Maximum Cutting Power ENHANCED (W)	90W → 250Ω	120W → 250Ω
± 20%	Maximum coagulation power FORCED COAG (W)	80W → 150Ω	150W → 150Ω
± 20%	Maximum coagulation power SOFT COAG (W)	60W → 100Ω	90W → 100Ω
± 20%	Maximum Bipolar Coagulation Power BIPOLAR COAG (W)	60W → 50Ω	80W → 50Ω
± 5%	BLEND Modulation Frequency (Hz)	50	50
± 5%	ENHANCED Modulation Frequency (Hz)	1.25	1.25
± 5%	FORCED COAG modulation frequency (kHz)	10	10
-0.1 + 0.2	Crest-Factor CUT	1.5	1.5
± 0.3	BLEND Ridge Factor	2.5	2.5
± 0.3	ENHANCED CUT Crestal Factor	2.0	2.0
± 0.2	Ridge Factor FORCED COAG	2.8	2.8
± 0.3	Crest-Factor SOFT COAG	1.6	1.6
-0.1 + 0.2	Crest-Factor BIPOLAR COAG	1.5	1.5
± 20%	Working Frequency	600 kHz	600 kHz
± 15%	Max no-load voltage CUT (Vpp)	1500	1500
± 15%	Max no-load voltage BLEND (Vpp)	1800	1800
± 15%	Max no-load voltage ENHANCED CUT (Vpp)	1500	1500
± 15%	Max no-load voltage FORCED COAG (Vpp)	1500	1500
± 15%	Max no-load voltage SOFT COAG (Vpp)	700	700
± 15%	Max no-load voltage BIPOLAR COAG (Vpp)	700	700
± 0.5	Dimensions WxHxD mm	370x144x319	370x144x319
± 10	Weight (kg)	6	6
± 5%	Selectable power supply (Vac)	115 – 230	115 – 230
± 1%	Network Frequency (Hz)	50-60	50-60
± 0	Fuses for 230Vac (5x20) power supply Time delay	2xT 3.15A	2xT 3.15A
± 0	Fuses for 115Vac (5x20) power supply Time Delay	2xT 6.3A	2xT 6.3A
± 10%	Maximum power consumption (VA)	350	350
± 10%	Maximum current consumption (230Vac) (A)	1.3	1.5
± 10%	Maximum current consumption (115Vac) (A)	2.6	3
-	Adjustable sound emission	●	●
-	Self-diagnosis of faults	●	●
-	Control of the power output	●	●
-	Sistema System Plate Electronic Control[1]	●	●
-	Possibility of connecting joint and bipartite electrodes	●	●
-	Storable settings[2]	5	5
-	Electrical Rating (EN60601-1)	Class I Applied Part CF	Class I Applied Part CF
-	Protection class (EN60529)	IP32	IP32

[1] Neutral electrode contact control - patient

[2] Continuous storage of the last settings

Tolerance	Description	DIATERMO MB 120F	DIATERMO MB 200F
-	MDR Classification 2017/745/EU	II b	II b
-	EN55011 Classification (CISPR 11) (Class/Group)	2 / A	2 / A
-	Duty Cycle (Action/Pause) in seconds	10 / 30	10 / 30
-	Pedal Activation Type / Manual	●	●
-	Defibrillator protection	●	●
-	Equipotential bonding	●	●
-	ABS enclosure	●	●

● = 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	7-segment display, mechanical buttons

MAINTENANCE

GENERALITY

There are no user-adjustable parts inside the equipment for calibration or service.
The enclosure of the equipment must not be opened – the warranty is voided by any unauthorized tampering with the unit. In the event of a need for repair or adjustment, the entire equipment should be sent to the LED SpA - APRILIA (LT) - ITALY service center, together with a description of the fault.
Maintenance by the user consists mainly of cleaning and sterilizing the accessories and checking the equipment before each use. The execution of functional and safety checks for the verification of the parameters is entrusted to specialized technical personnel.

CLEANING THE CONTAINER

Turn off the equipment completely and disconnect the mains before any cleaning. Wipe the outside of the container with a damp cloth. Do not use any solvent or chemical components; Lightweight, non-abrasive detergent can be used.

CLEANING AND STERILIZING ACCESSORIES

If non-sterile disposable accessories are used, the instructions for use (IFU) provided by the manufacturer of each accessory for the sterilization method must be strictly followed and disposed of in accordance with the regulations currently in force.
When using reusable accessories, the maximum number of cycles and the sterilization method indicated in the instructions for use provided by the manufacturer of each accessory must be observed.

TROUBLESHOOTING GUIDE

In case of problems, you must first check that you have correctly installed and prepared the accessories. The generated error code is shown on the seven-segment display, and the description is shown on the LCD.

Problem	Probable Cause	Solution
The equipment does not turn on.	Interruption or absence of mains power.	Check the power cord connection. Check the condition of the fuses and replace with a suitable type if necessary.
Always-on OC alarm.	Interruption or poor contact on the neutral electrode circuit	Check the cable connection to the neutral electrode. Replace the electrode connection cable.
The unit does not respond to the actuation command.	Handpiece or pedal failure Incorrect connection of the handpiece or pedal. Unit in OVT alarm .	Replace the handpiece and/or foot pedal. Check the connection of the handpiece or foot pedal. Wait for the OVT indication to turn off.
Error code 001	Dispensing controls activated during power-up.	Unplug the handpiece and/or foot pedal and turn the unit back on.
Error code 002	Error in the engine engine.	Contact the Technical Assistance Service.
Error Code 003	Error in the engine engine.	Contact the Technical Assistance Service.
Error Code 004	An error occurred in the conversion circuit.	Contact the Technical Assistance Service.
Error Code 005	Error in the reference voltage.	Check the supply voltage. Contact the Technical Assistance Service.
Error Code 009	Error in the power control circuit.	Contact the Technical Assistance Service.
Error Code 010	Error in the power control circuit.	Contact the Technical Assistance Service.

REPAIRS

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

REPLACING THE FUSES

BEFORE REPLACING THE FUSES, DISCONNECT THE EQUIPMENT FROM THE POWER SUPPLY.

To replace the fuses, use 5x20 type fuses of T3.15A (time delay) (for 230Vac power supply) or T6.3A (for 115Vac power supply), proceed as follows:

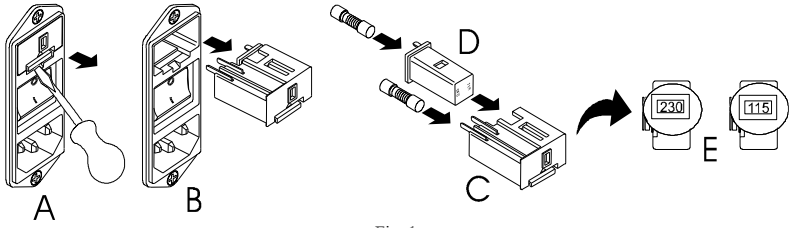
(A-B) Use a small screwdriver to remove the fuse boxes from the power supply module.

(C) Insert the fuses by referring to this table:

Tension 110-120 V Time-Delay Fuses T6.3 A / 5 x 20 mm

Tension 220-240 V Time-Delay Fuses T3.15 A / 5 x 20 mm

(D) From the fuse drawer, pull out and rotate until you read in the window (E), the selected voltage - reinsert the fuse holder into the module.



CHECKING THE UNIT BEFORE USE

Whenever the use of the unit is scheduled, it is necessary to establish a control of the main safety conditions considering the following points:

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

CONTROL AND MEASUREMENT OF SAFETY FUNCTIONS

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

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

DIAGRAMS

DIATERMO MB 120F

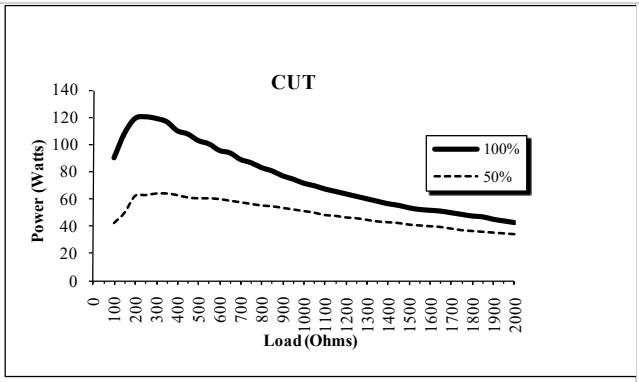


Diagram of maximum and average power on variable load 100-2000Ω CUT100%

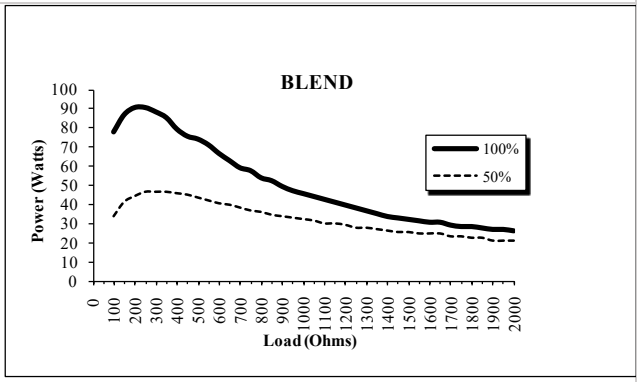


Diagram of maximum and average power on variable load 100-2000Ω BLEND

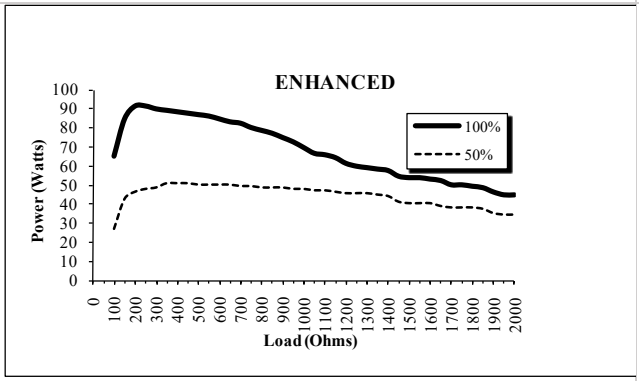


Diagram of maximum and average power on variable load 100-2000Ω ENHANCED

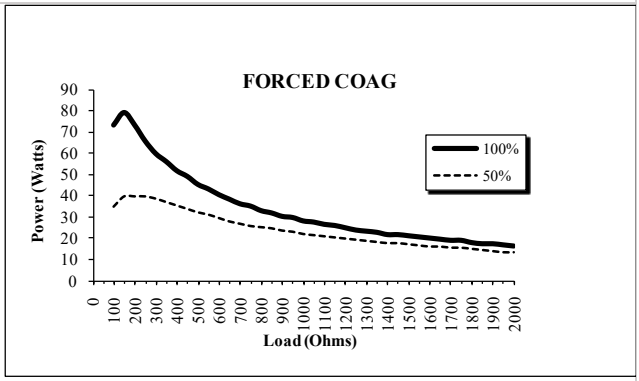


Diagram of maximum and average power on variable load 100-2000Ω FORCED COAG

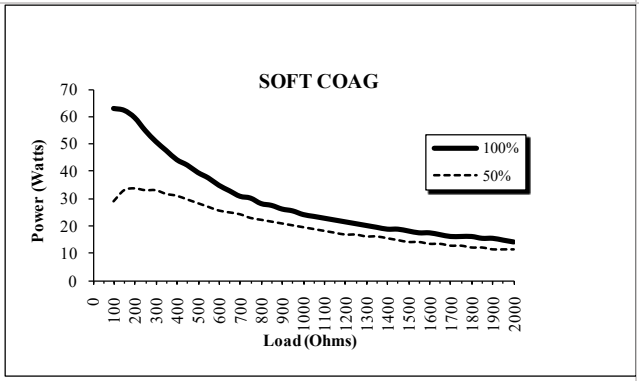


Diagram of maximum and average power on variable load 100-2000Ω SOFT COAG

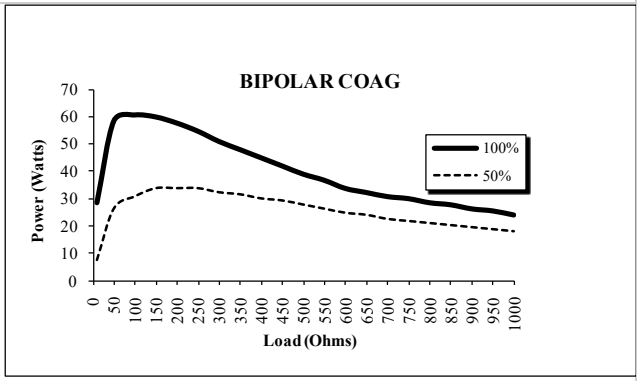


Diagram of maximum and average power on variable load 10-1000Ω BIPOLAR COAG

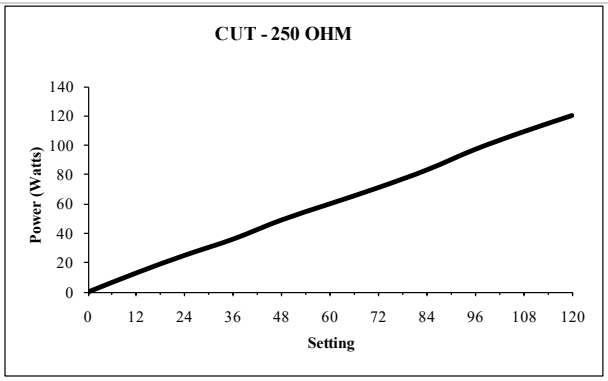


Diagram of Output Power on Rated Load CUT100%

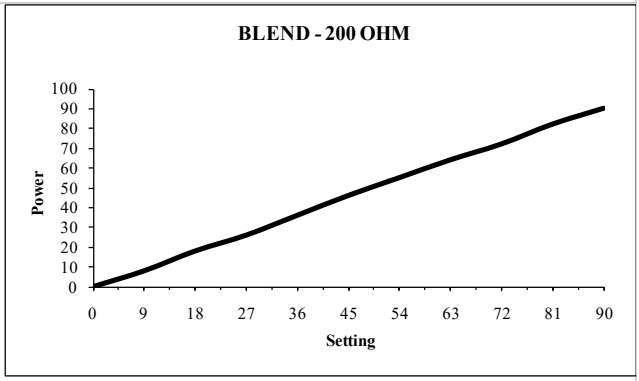


Diagram of Output Power on Rated Load BLEND

DIATERMO MB 120F

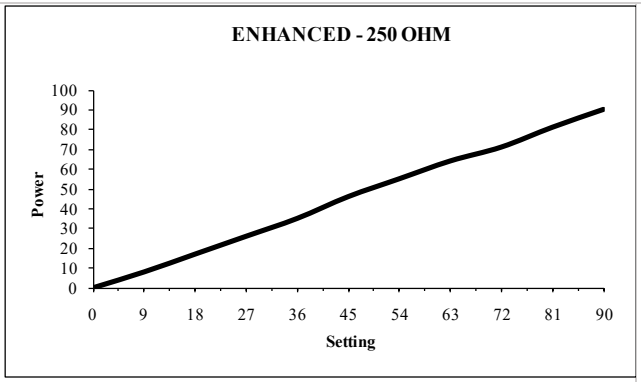


Diagram of Output Power on Rated Load
ENHANCED

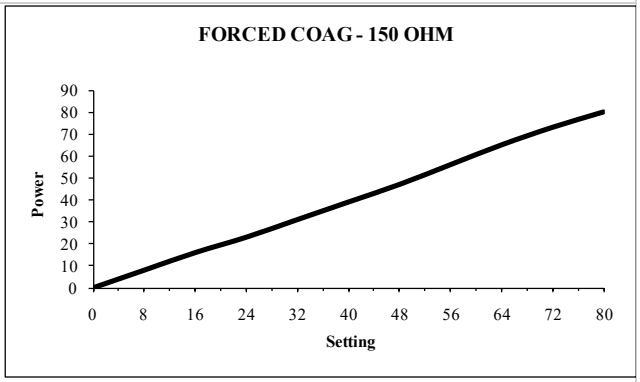


Diagram of Output Power on Rated Load
FORCED COAG

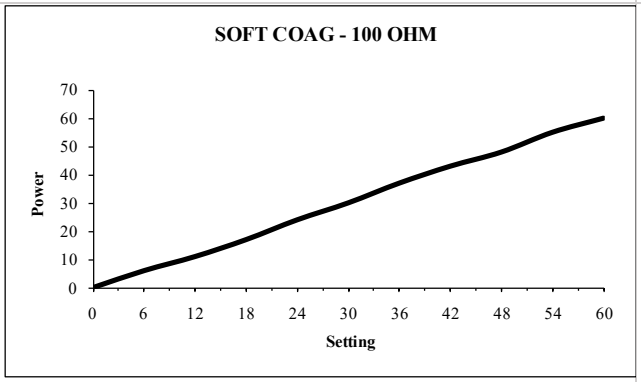


Diagram of Output Power on Rated Load
SOFT COAG

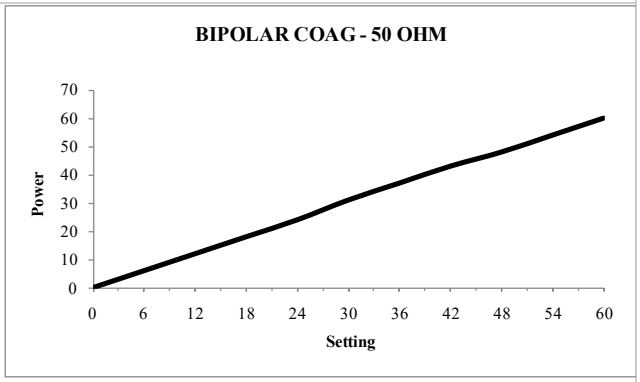
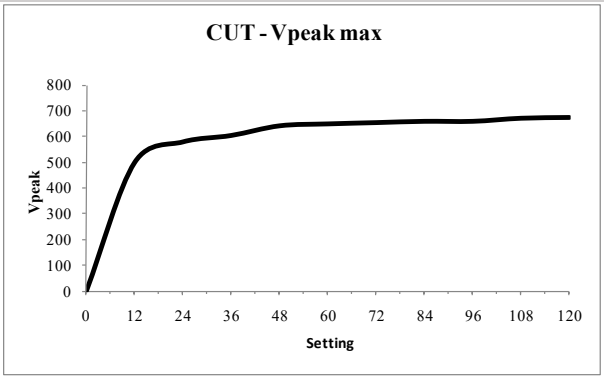
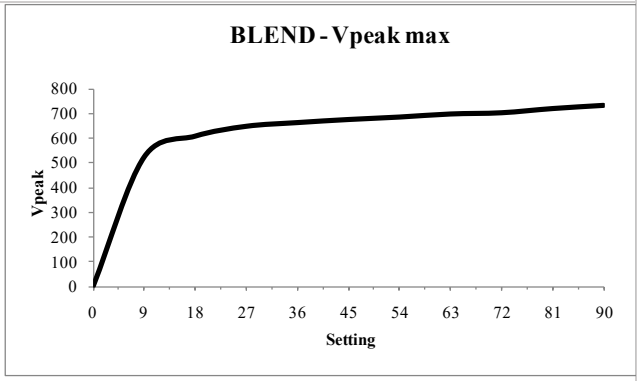


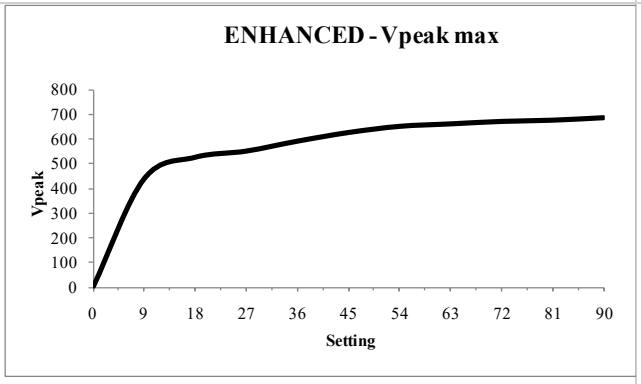
Diagram of Output Power on Rated Load
BIPOLAR COAG



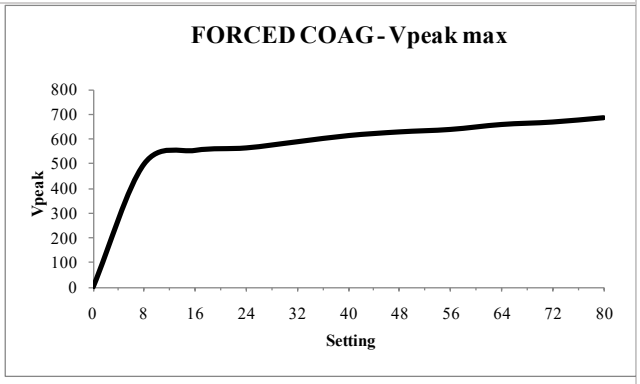
Maximum Output Voltage (Vp) Diagram for
CUT100%



Maximum Output Voltage (Vp) Diagram for
BLEND

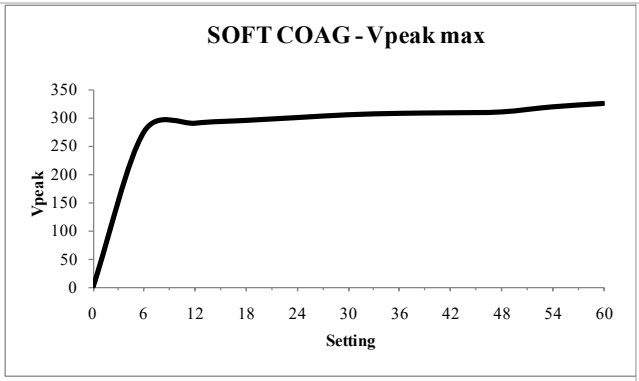


Maximum Output Voltage (Vp) Diagram for
ENHANCED

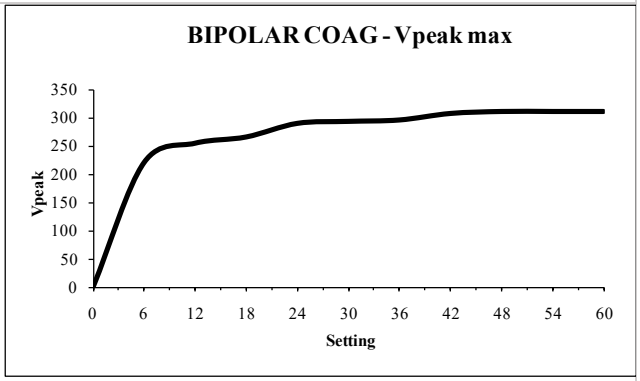


Maximum Output Voltage (Vp) Diagram for
FORCED COAG

DIATERMO MB 120F



Maximum Output Voltage (Vp) Diagram for SOFT COAG



Maximum Output Voltage (Vp) Diagram for BIPOLAR COAG

DIATERMO MB 200F

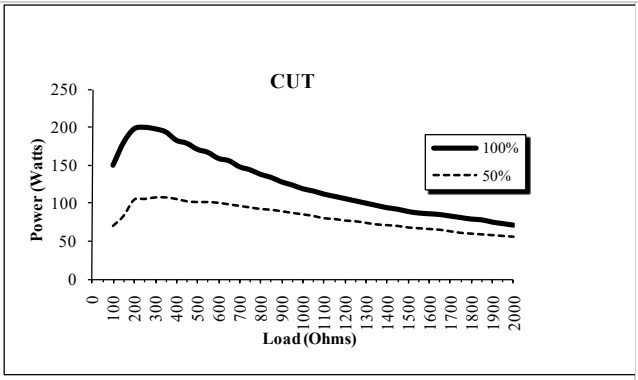


Diagram of maximum and average power on variable load 100-2000Ω CUT100%

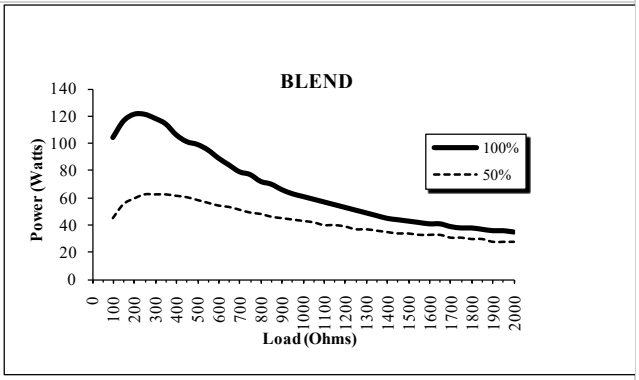


Diagram of maximum and average power on variable load 100-2000Ω BLEND

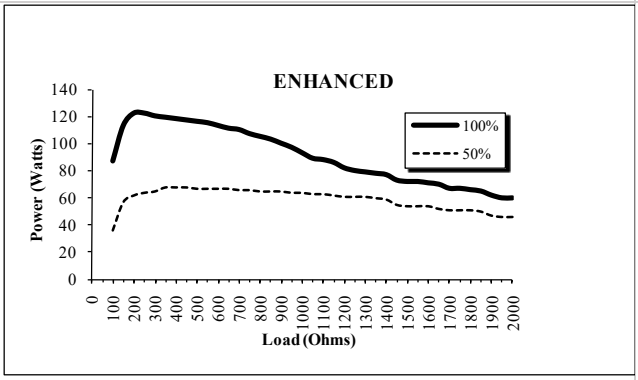


Diagram of maximum and average power on variable load 100-2000Ω ENHANCED

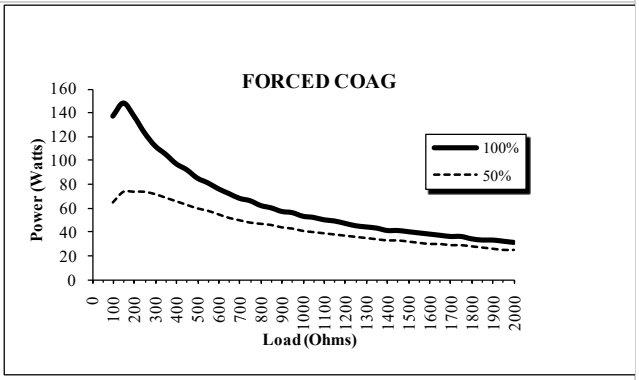


Diagram of maximum and average power on variable load 100-2000Ω FORCED COAG

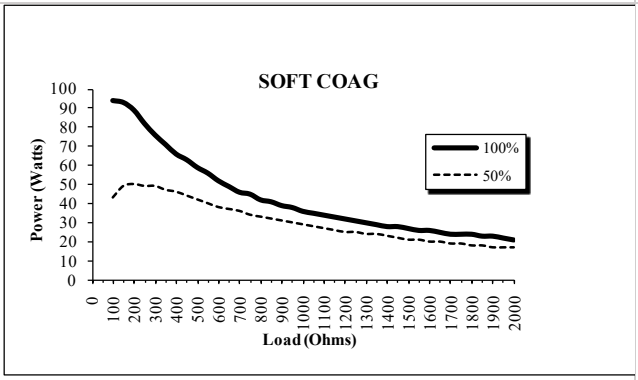


Diagram of maximum and average power on variable load 100-2000Ω SOFT COAG

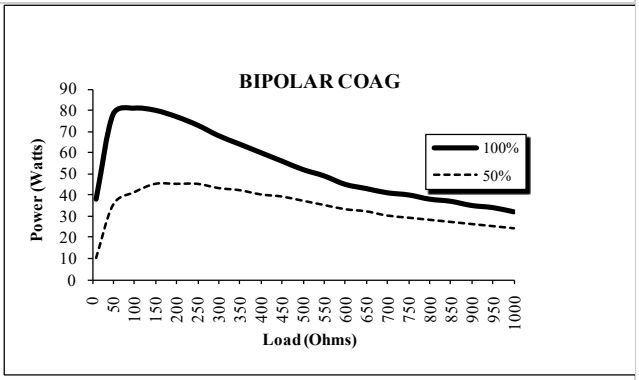


Diagram of maximum and average power on variable load 10-1000Ω BIPOLAR COAG

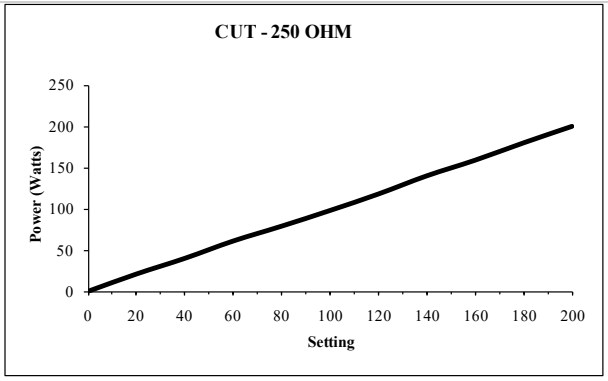


Diagram of Output Power on Rated Load CUT100%

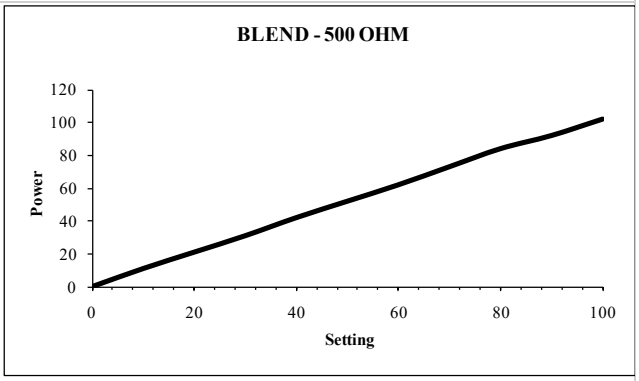


Diagram of Output Power on Rated Load BLEND

DIATERMO MB 200F

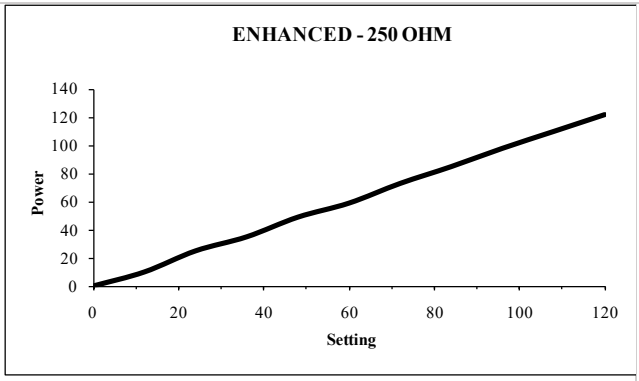


Diagram of Output Power on Rated Load
ENHANCED

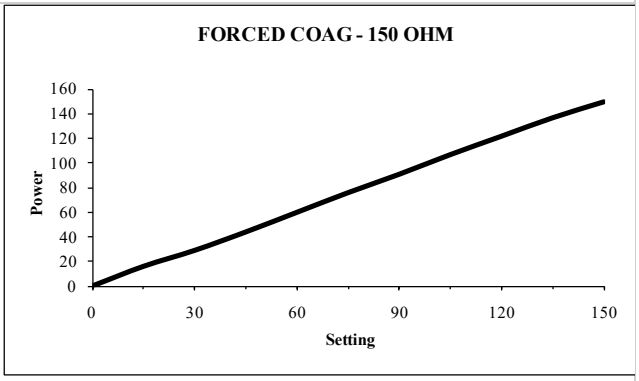


Diagram of Output Power on Rated Load
FORCED COAG

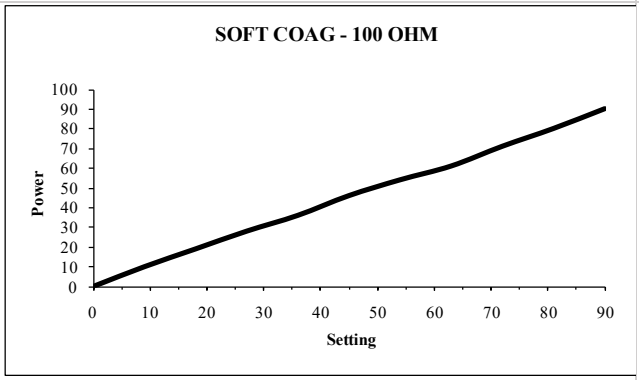


Diagram of Output Power on Rated Load
SOFT COAG

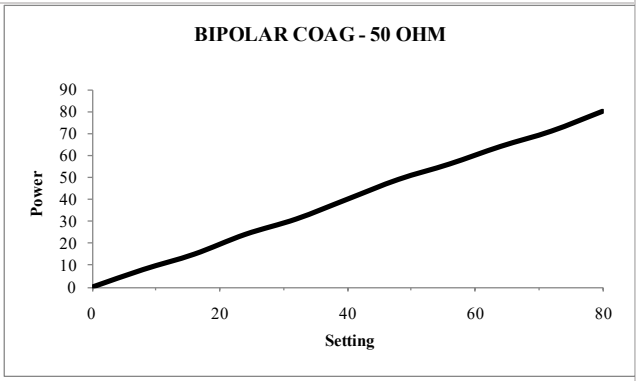
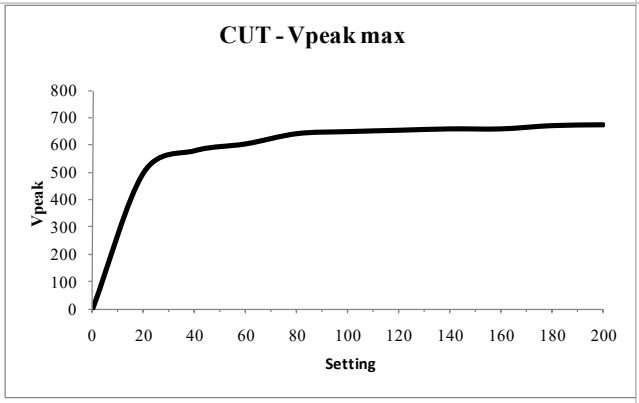
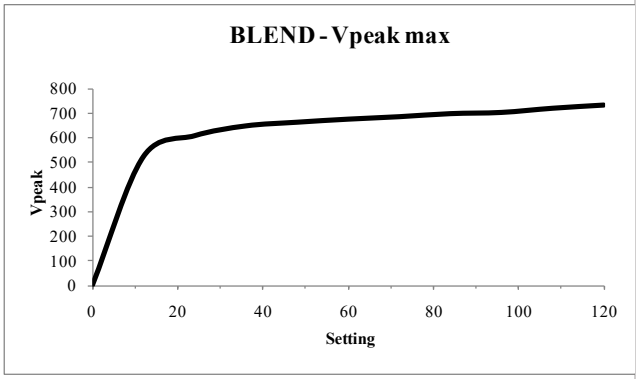


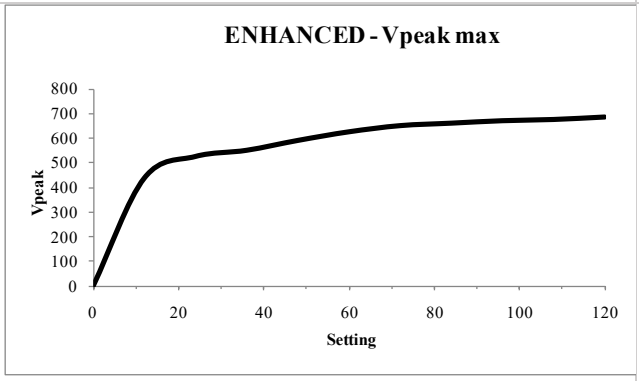
Diagram of Output Power on Rated Load
BIPOLAR COAG



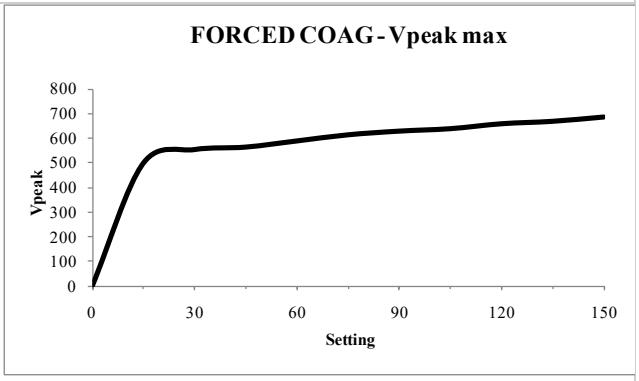
Maximum Output Voltage (Vp) Diagram for
CUT100%



Maximum Output Voltage (Vp) Diagram for
BLEND

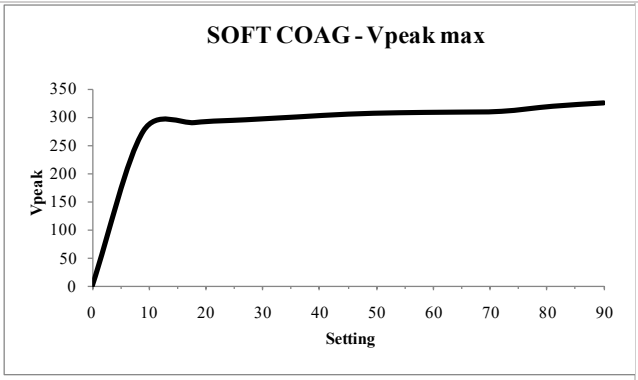


Maximum Output Voltage (Vp) Diagram for
ENHANCED

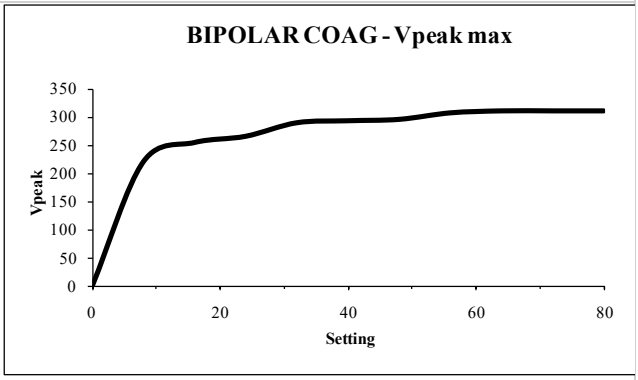


Maximum Output Voltage (Vp) Diagram for
FORCED COAG

DIATERMO MB 200F



Maximum Output Voltage (Vp) Diagram for SOFT COAG



Maximum Output Voltage (Vp) Diagram for BIPOLAR COAG

Information on the disposal of this product (applicable in countries with separate collection systems)	
	At the end of its life cycle, the product present does not have to be disposed of as municipal waste, but must be disposed of in a separate collection. If the product is disposed of inappropriately, it is possible that some parts of the product (e.g. some batteries) may be harmful to the environment and human health. The symbol on the side (crossed-out wheeled dustbin) indicates that the products must not be disposed of in the municipal waste container but must be disposed of separately. In case of unauthorized disposal of this product, penalties may be foreseen.

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MA396D_EN

Official Dealer

GIMA SPA

via Marconi, 1
20060 Gessate (MI) - Italy
gima@gimaitaly.com – export@gimaitaly.com
Phone +39 02 9538541
Fax +39 02 95381167
www.gimaitaly.com

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