EN

DIATERMO
MB 122-MB 132-MB 160

HIGH FREQUENCY SURGICAL EQUIPMENT

USER MANUAL

GIMA

CE 0051

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IMPORTANT

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

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

If you need Technical Assistance, please contact LED SpA.

Produttore / *Manufacturer*

LED SpA

ELECTRONIC DESIGN AND PRODUCTION

Via Selciatella 40 – 04011 Aprilia (LT) - Italy

www.led.it

INTRODUCTION

INTENDED USE/ SECTORS OF APPLICATION

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

The **DIATERMO MB 122-MB 132-MB 160** equipment is designed to be used in the following sectors:

Description	**DIATERMO**		
	MB 122	**MB 132**	**MB 160**
Electrosurgical Unit Code	GMA10100.20	GMA10300.10	GMA10100.30 a.r
Outpatient Surgery	●	●	●
Dentistry	●	●	●
Dermatology	●	●	●
Endoscopy	-	-	-
First aid	●	●	●
Gastroenterology	-	-	-
General Surgery	-	-	-
Gynecology	-	-	-
Neurosurgery	-	-	-
Ophthalmology	-	-	-
Orthopedics	-	-	-
Otorhinolaryngology	-	-	-
Pediatric Surgery	-	-	-
Plastic Surgery	-	-	-
Pulmonology	-	-	-
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 GROUP

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

	DIATERMO MB 122	**DIATERMO MB 160**	**DIATERMO MB 132**
Electrosurgical Unit Code LED	GMA10100.20	GMA10100.30	GMA10300.10
Electrosurgical Unit Code GIMA	30540 / 30538 (value)	30541	30544

GIMA Code	**LED Code**	**Description**	**DIATERMO**		
			MB 122	**MB 160**	**MB 132**
-	00100.03	Power Cable 2MT SIEMENS-IEC	■ /1	■ /1	■ /1
30564	00401.00	120x160mm steel neutral electrode with 3 mt cable	■ /1 ○ (30538)	■ /1	○
-	00500.03	Assorted Electrode Kit (6Pcs) 5cm	■ /1	○	○
30551	755VL	Disposable handpiece with buttons	■ /1	■ /1	○
30577	00304.00	Single watertight foot pedal	■ /1 ○ (30538)	■ /1	■ /1
30644	00498.04	Adapter for bipolar operation	○	○	○
30560	500500.L11	Microsurgery/depilation needles (10Pcs)	○	○	■ /1
-	00100.01	Power Cord 5MT SIEMENS-IEC	○	○	○
-	00404.07	Neutral Electrode Connection Cable F7915/F7930	○	○	○

GIMA Code	LED Code	Description	DIATERMO		
			MB 122	MB 160	MB 132
-	00404.08_S	Disposable Neutral Electrode Connection Cable	○	○	■ /1
-	00402.02	M4-MP4 monopolar cable 3mt	○	○	○
-	00412.00	Silicon cable for Bipolar 3mt	○	○	○
30528	00500.L8/L	Loop electrode 10cm	○	○	○
30508	00500.L8	Loop electrode 5 cm	○	○	○
30527	00500.L7/L	Drop electrode 10 cm	○	○	○
30507	00500.L7	Drop electrode 5 cm	○	○	○
-	152-115	Blade electrode 16 cm	○	○	○
-	152-110	Blade electrode 7 cm	○	○	○
-	152-130	Ball electrode ⌀ 2mm 6 cm	○	○	○
-	152-145	Ball electrode ⌀ 3mm 14 cm	○	○	○
-	152-140	Ball electrode ⌀ 3mm 6 cm	○	○	○
-	152-150	Ball electrode ⌀ 4mm 6 cm	○	○	○
-	152-165	Ball electrode ⌀ 5mm 14 cm	○	○	○
-	152-160	Ball electrode ⌀ 5mm 6 cm	○	○	○
-	152-125	Needle electrode 13 cm	○	○	○
-	152-120	Needle electrode 7 cm	○	○	○
30523	00500.L3/L	Loop electrode ⌀ 4mm 10cm	○	○	○
30503	00500.L3	Loop electrode ⌀ 4mm 5cm	○	○	○
30524	00500.L4/L	Loop electrode ⌀ 8mm 10cm	○	○	○
30504	00500.L4	Loop electrode ⌀ 8mm 5cm	○	○	○
-	152-175-10	Loop electrode 5 cm	○	○	○
-	152-190-13	Drop electrode 10 cm	○	○	○
-	152-190-20	Drop electrode 5 cm	○	○	○
30522	00500.L2/L	Blade electrode 16 cm	○	○	○
30502	00500.L2	Blade electrode 7 cm	○	○	○
30526	00500.L6/L	Ball electrode ⌀ 2mm 6 cm	○	○	○
30506	00500.L6	Ball electrode ⌀ 3mm 14 cm	○	○	○
30529	00500.L10/L	Ball electrode ⌀ 3mm 6 cm	○	○	○
30509	00500.L10	Ball angled electrode ⌀ 3mm 5cm	○	○	○
30525	00500.L5/L	Angled hooked electrode 10cm	○	○	○
30505	00500.L5	Angled hooked electrode 5cm	○	○	○
-	310-550	Bipolar Electrode 20cm - angled	○	○	○
-	310-590	Bipolar Electrode 20cm - angled 2	○	○	○
-	310-510	Bipolar Electrode 20cm - straight	○	○	○
-	152-112	Curved blade electrode 7cm	○	○	○
-	152-132	Ball curved electrode ⌀ 2mm 6 cm	○	○	○
-	152-142	Ball curved electrode ⌀ 3mm 5 cm	○	○	○

GIMA Code	LED Code	Description	DIATERMO		
			MB 122	MB 160	MB 132
-	152-152	Ball curved electrode ⌀ 4mm 6 cm	○	○	○
-	152-162	Ball curved electrode ⌀ 5mm 6 cm	○	○	○
-	152-122	Curved needle electrode 7 cm	○	○	○
30521	00500.L1/L	Fine wire straight electrode 10cm	○	○	○
30501	00500.L1	Fine wire straight electrode 5cm	○	○	○
30530	00500.L9	Ball straight electrode ⌀ 3mm 5cm	○	○	○
30510	00500.L9/L	Ball straight electrode ⌀ 3mm 10cm	○	○	○
-	F7930	Bipartite conductive rubber neutral electrode w/cable	○	○	○
-	F7915	Single-part s/cable conductive rubber neutral electrode	○	○	○
-	00401.01	240x160mm steel neutral electrode with 3m cable	○	○	○
-	00401.02	Neutral steel electrode 120x160mm with 3 mt cable -autocl.	○	○	○
-	00401.03	240x160mm steel neutral electrode with 3 mt cable-autocl.	○	○	○
-	0350	Disposable neutral electrode	○	○	○
-	F7920	Bipartite disposable neutral electrode	○	○	○
-	152-195	Electrode for conization 13 cm	○	○	○
-	00400.00	Bunch reference electrode with cable	○	-	-
-	330-160	Monopolar Scissor 18cm	-	○	○
30500	00500.00	Assorted Electrode Kit (10Pcs) 5cm	○	■ /1	■ /1
30531	00500.00/L	Assorted electrodes kit (10Pcs) 10cm	○	○	○
30552	00201.02_S	Autoclavavle micro-needle handpiece	○	○	■ /1
-	00201.03	Micro-needle holder	○	○	■ /1
-	00205.00	Multi-use handpiece with buttons PENCIL S	○	○	○
-	00206.00	Multi-use handpiece without PENCIL buttons	○	○	○
-	00305.03	Double watertight footpad	○	○	○
-	310-110-05	Bipolar Forceps 11.5cm TIP 0.5mm	○	○	○
-	310-140-10	Bipolar Forceps 20cm TIP 1mm	○	○	○
-	310-140-20	Bipolar Forceps 20cm TIP 2mm	○	○	○
-	310-180-10	Bipolar Angled Pliers 20cm TIP 1mm	○	○	○
-	310-180-20	Double Angled Pliers 20cm TIP 2mm	○	○	○
-	310-182-10	Bipolar Crimping Pliers Angled 20cm TIP 1mm	○	○	○

GIMA Code	LED Code	Description	DIATERMO		
			MB 122	MB 160	MB 132
-	310-185-10	Bipolar Pliers Angled Curved 20cm TIP 1mm	○	○	○
-	310-112-05	Bipolar Curved Pliers 11.5cm TIP 0.5mm	○	○	○
-	310-142-10	Bipolar Curved Pliers 20cm TIP 1mm	○	○	○
-	310-142-20	Bipolar Curved Pliers 20cm TIP 2mm	○	○	○
-	330-134-20	Monopolar Pliers 20cm TIP 2mm	○	○	○
-	F7520	Electrode cleaning sponge 47x50mm	○	○	○
-	5365A	Neutral metal electrode	○	○	■ /1
305849	-	Multi-use handpiece	○	○	■ /1

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

DESCRIPTION

DIATERMO MB 122, MB 160 and MB 132 are electro-surgical equipment suited to deliver current for monopolar cut, soft coagulation, forced coagulation or bipolar coagulation. The current can be delivered for the whole time of activation of the output circuit or, with the model MB132, for an interval of time which can be preset. The preset time delivery can be repeated from 2 to 9 times.
It is possible to use either single plate neutral reference electrodes or electrodes with split conductive zone so to watch the plate to patient contact during the surgical intervention.

Control of the units is via front panel keys and display; mains inlet is located on the rear panel.
The units have automatic control systems that, monitoring the internal parameters, signal the possible damages/errors that are found.

The operational parameters that are used are constantly stored so that, every time the unit is switched on or the operative method is changed, the last utilized parameters are recalled.
The level of the emission sound can vary; every operator can choose his own level according to the noise of his working ambient.

Power output can be achieved either through holder-handles with pushbuttons or through single- or double-foot switch command. Moreover, applying a special optional adapter it is possible the unit connection to bipolar forceps.

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

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

- Mixed currents

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

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

2. *Faradic Effect*

Pulsed electric current causes neuro-muscular stimulation, originating from the stimulation of the physiological process of ion exchange, which is responsible for the transmission of stimuli that cause muscle spasms and cardiac phenomena of extrasystole and ventricular fibrillation. The effect of these stimuli is known as the faradic effect and is expressed by:

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

The physiological system of stimulus transmission follows a limiting curve in which pulsed or low-frequency currents generate a pacing pulse. With the high-frequency alternating current

(above 200 kHz), which is used in electrosurgery, there are no neuromuscular reactions (the change of polarity is so fast that it does not affect the patient at the level of neuro-muscular reactions), let alone electrolyte damage to the body.
For this reason, all high-frequency generating equipment for surgical use (electrosurgery) works on base frequencies above 300 kHz so as not to introduce electrical stimulation.

3. *Electrolytic Effect*

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

OPERATIVE TECHNICS

MONOPOLAR CUT

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

For precise cutting with minimal thermal impact and limited hemostasis, a pure sine wave current without modulation is preferred. This allows for precise control and safe use without harming adjacent bone. However, some level of modulation in the current is desirable to facilitate effective coagulation during the cutting process, making electrosurgery an advantageous technique.

The following rules help the operator achieve a good cut:

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

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

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

MONOPOLAR COAGULATION

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

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

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

Coagulation can be achieved through two different methods:

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

- Gently touch the bleeding vessel before activating the electrode.
- Cease electrode activation as soon as the tissue whitens to avoid damaging it.
- Keep the electrode tip clean (use optional electrode-cleaning sponges with code F7520).

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

BIPOLAR COAGULATION

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

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

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

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

CONTRAINDICATIONS

The use of electrosurgery is contraindicated in patients:

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

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

Some of the causes of burns are to be attributed to:

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

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

SAFETY

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

ATTENTION

- DO NOT USE on patients with electronic implants such as cardiac pacemakers without consulting a qualified professional (e.g., a cardiologist). There is a potential risk of interference with the functioning of the electronic implant or damage to the implant itself.
- DO NOT USE in the presence of flammable anaesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or near volatile solvents (such as ether or alcohol) as explosions may occur.
- DO NOT PLACE instruments near or in contact with flammable materials (such as gauze or surgical drapes). Activated or heated instruments can cause fires.
- When not in use, store instruments in a clean, dry, and highly visible area away from direct patient contact. Inadvertent contact with the patient can result in burns.
- INSPECT instruments and cables for damage before each use, especially the insulation of laparoscopic/endoscopic instruments. This inspection can be carried out visually under magnification or with a high-voltage insulation testing device. Insulation failures can lead to burns or other injuries to the patient or the operator.
- The surface of the active electrode may remain sufficiently hot to cause burns even after RF current is deactivated.
- Due to concerns about the potential carcinogenic and infectious properties of electrocautery byproducts (such as tissue smoke plumes and aerosols), protective eyewear,

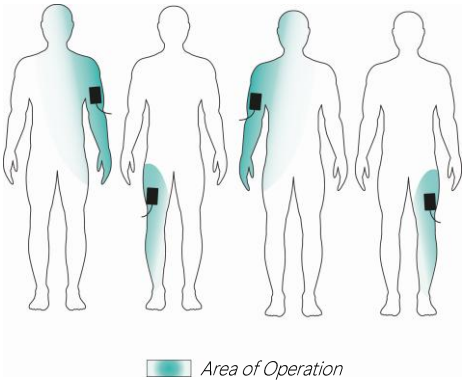
filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.

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

PRECAUTIONS

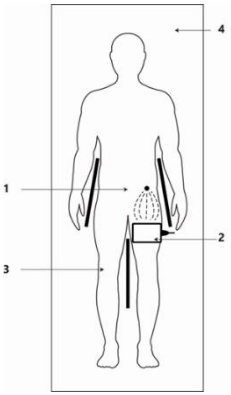
The following precautions are crucial for minimizing the risk of inadvertent burns:

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



- When using single-use neutral electrodes, always adhere to the provided expiry dates.
- For multi-use electrodes, ensure that the fixation systems in place guarantee stability during use.
- When applying the neutral electrode, avoid a transverse path and instead favour a vertical or diagonal path, especially when using a bipartite neutral electrode. This helps distribute current evenly across the surface of the neutral electrode and reduces the risk of patient burns.
- If you encounter difficulty in correctly applying the neutral electrode, consider using the bipolar technique instead of the monopolar approach, if feasible.
- To prevent the patient from coming into contact with earthed metallic parts or components with significant grounding capacity (such as an operating table or supports), use an antistatic drape for this purpose.

- To avoid skin-to-skin contact (e.g., between the arm and trunk, between the legs, or on the breasts, insert dry gauze. Additionally, ensure that body areas prone to profuse sweating are kept dry.



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

- When using both an electrosurgical scalpel and a physiological monitoring device on the same patient, place all monitoring electrodes as far away from the surgical electrodes as possible. Needle monitoring electrodes are discouraged. In any case, use monitoring systems that incorporate high-frequency current-limiting devices.
- Position surgical electrode cables in a manner that prevents contact with the patient or other conductive materials. Active electrodes that are not in use should be isolated from the patient.
- Consider utilizing bipolar techniques when operating on body parts with a relatively small cross-sectional area. This helps prevent unintended coagulation.
- Set the output power level to the lowest effective setting for the intended purpose, minimizing the risk of excessive tissue damage.
- If the electrosurgical unit exhibits an obvious low output level or operates incorrectly, even when set up for normal power delivery, this could indicate issues with the application of the neutral electrode or poor contact in the neutral electrode connections. Therefore, it is essential to verify the proper placement and connections of the neutral electrode before considering higher power settings.
- Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N2O) and oxygen, especially in chest or head operations, unless they can be safely aspirated.

Whenever possible, opt for non-flammable substances for cleaning and disinfection purposes. If flammable substances are used for cleaning, disinfection, or as solvents for adhesives, they should be allowed to completely evaporate before using the electrosurgical unit. There is a risk of flammable solutions accumulating under the patient or in cavities like the umbilicus and vagina. Any fluid in these areas should be removed before using the device. It's important to consider the presence of endogenous gases as well.

- Be aware that certain materials, such as cotton wool or gauze impregnated with oxygen, may ignite due to sparks produced by the appliance under normal conditions. Take necessary precautions to prevent such incidents.
- Patients with pacemakers or pacing electrodes are at risk of interference with their pacemaker's functionality or potential pacemaker damage when exposed to electrosurgical equipment. If any uncertainty arises, consult the cardiology department.
- Electrosurgical equipment emits high-frequency energy radiation that can affect other medical devices, unrelated electronics, telecommunications systems, and navigation systems. To prevent interference, you must maintain a minimum distance of at least 1.5 meters between the electrosurgical equipment and other devices.
- Regularly inspect accessories, with special attention to electrode cables and any endoscopy accessories, to ensure there is no damaged insulation or other defects that could compromise their safety or effectiveness.
- To connect accessories compatible with the equipment's characteristics, you must compare the insulation characteristics of the accessories (information provided by the manufacturers) with the specifications of the supplied unit (as outlined in the Technical Characteristics section). This step ensures proper compatibility and safe operation.
- Caution: Equipment failure could lead to an inadvertent increase in power output.

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

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

INSTALLATION

- The electric safety is insured only when the same are correctly connected to an efficient net linked to the earth in conformity with the actual safety requirements. It is necessary to verify this fundamental safety requisite and, in case of doubt, to require an accurate control of the plant from part of qualified personnel. The manufacturer cannot be considered responsible for possible damages caused from the lack of efficient connection to earth of the put in service. Operation without a protective earth connection is forbidden.
- Before connecting the equipment ascertain that the required voltage (showed on the rear panel) corresponds to the available mains.
- In case of incompatibility between the available wall socket and the feeding cable of the equipment, replace only with legally approved connectors and accessory items. The use of adapters, multiple connections or cable extensions is not advised. Should their use become necessary it is mandatory to use only simple or multiple adapter conforming to the actual safety requirements.
- Don't let the apparatus exposed to atmospheric agents. The unit must be protected from seepage of liquids.
- Don't obstruct openings or cracks of ventilation or heatsink
- Don't leave the equipment uselessly inserted. Switch off the equipment when not in use.
- The use of the unit is not suited in explosive rooms.
- DIATERMO MB 122-MB 160-MB 132 must be destined only to the use for that have been expressly designed. Any other use is to be considered improper and dangerous. The manufacturer cannot be considered responsible for possible damages due to improper, wrong and unreasonable uses.
- It is dangerous to modify or try modifying the characteristic of the equipment.
- Before effect any operation of cleaning or maintenance, disconnect the apparatus from the electric net, either unplugging it from the mains or switching off the mains switch of the plant.
- In case failure and/or bad operation of equipment switch off it. For the possible reparation address only to an authorized service centre and ask for the use of original spare parts. The lack to follow the above requirements could risk the safety of the equipment and can be dangerous for the user.

- Do not reduce or disable the audible signal warning the activation of the generator. A functioning activation signal can minimize or prevent patient or staff injury in the event of accidental activation.
- Avoid verifying the functioning of the unit by shorting the active electrode with the reference one or the active electrode with metallic parts.
- WARNING: When the electrosurgical unit is used in operating rooms it is necessary to just use waterproof footswitches (REF 00304.00 Water-proof pedal with single switch – REF 00305.03 Water-proof pedal with double switches)

PATIENT SAFETY

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

CORRECT PATIENT POSITIONING

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

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

- Adjust the anesthesia dosage to prevent excessive sweating.

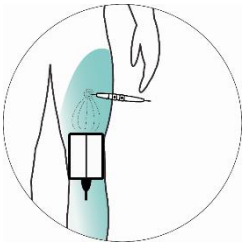
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

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

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

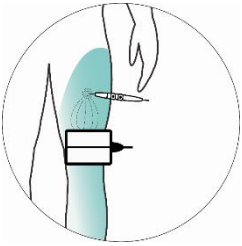
Ensuring the correct placement of the neutral electrode is of utmost importance to prevent burns and minimize patient risks. Below are some valuable tips to achieve this:

1. *Correct Positioning*



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

2. *Incorrect Positioning*



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

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

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

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

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

If the electrode were placed in an area subjected to pressure during the procedure, the compressive load would result in reduced skin perfusion. Consequently, the generated heat can only be partially dissipated, thereby increasing the risk of burns. Furthermore, there is an increased risk of pressure points (decubitus) formation due to the heating that occurs. This temperature rise leads to a higher demand for oxygen (O_2) and energy in the affected area, contributing to the potential development of pressure areas on the body.

PUTTING INTO SERVICE

- Inspect the unit for damages during transport. The claims for possible damages will be accepted only in case they are immediately communicated to the carrier; the damages that are found must be written down and presented to LED SpA or to your own retailer. If the unit is returned to the LED SpA or to your own retailer, it is necessary to use the original equipment's package or another equivalent one, to guarantee the safety during the transport.
- Unpack the equipment and carefully study the documentation and operating instruction supplied. Mains voltage, indicated above the inlet, must agree with the local mains voltage (mains voltage frequency: 50-60 Hz). The correct voltage setting is selected by turning the voltage selector when available. Insert the correct fuses in the module referring to the value written on the label.
- Connect mains cable to a mains outlet having good hearth connection.
  OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN.
- The unit must be installed on a level surface, with dimension, at least, correspondent to those of the base of the unit itself. Around the unit must be left a space of 25cm, at least.
- Connect the mains cable to the mains socket on the rear panel of the unit.
- Connect the equipotential binding post located at the left of the unit's back panel to equipotential socket of the plant.
- Connect the single foot switch or the double foot switch (optional) to the connector on the rear panel.
- Connect handle, in the case of use of handle without finger switch it shall be connected on the black buckle.
- In case of use of bipolar forceps (see BIPOLAR operation paragraph 4.4.5) it is necessary to use the special optional adapter (REF 00498.04).
- Let unit work in dry environment only. Any verified condensate must be let evaporate before putting in operation the unit. Don't exceed the temperature environment or the allowed moisture.
- Environmental conditions:
- Temperature: 10/40°C - Relative moisture: 30/75% - Pressure: 70/106k Pa
- When the unit is switched on, through the on/off switch on the frontal panel, after having checked the internal parameters, it will work with the function and the power level utilized during the last switching (when the unit is switched for the first time the level will be 00).

- Before using the unit, it is necessary connect the cable to the patient plate. Single plate electrodes and split plate electrodes can be. If the value of the impedance is acceptable, the OC indicator light will stop flashing and the alarm to sound.
- Having:
    - Holder-handle with two pushbuttons without foot switch: press the yellow pushbutton on the holder- handle to deliver the cutting current (the choice between CUT or BLEND must be done pressing the correspondent pushbutton on the unit); or the blue pushbutton on the holder handle to deliver coagulating current (the choice between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).
    - Holder handle with two pushbuttons and a single foot switch: choose the cutting current CUT or BLEND and the coagulation current FORCED COAG, SOFT COAG or BIPOLAR. Preset through the yellow pushbutton on the holder handle, the function for the cut that appears on the unit or, through the blue pushbutton on the holder handle, the function for the coagulation that appears on the unit. The current delivery takes place through the foot switch.
    - Holder handle with two pushbuttons and double foot switch: press the yellow foot switch or the yellow pushbutton of the holder handle to pre-set and deliver the cutting current (the choice between CUT or BLEND must be done pressing the correspondent pushbutton on the unit) or the blue foot switch or the blue pushbutton of the holder handle to pre-set and deliver the coagulating current (the choice between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).
    - Holder handle without pushbuttons and single foot switch: connect the holder handle to the black binding post and pre-set the current for the cut (CUT or BLEND) or the coagulation (FORCED COAG, SOFT COAG or BIPOLAR), press the foot switch to deliver the pre-set current.
    - Holder handle without pushbuttons and double foot switch: connect the holder handle to the black binding post and press the yellow footswitch to pre-set and deliver the cutting current (the choice between CUT or BLEND must be done pressing the correspondent pushbutton on the unit); press the blue foot switch to pre-set and deliver the coagulating current (the choice between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).
    - Bipolar forceps and single foot switch: connect the optional adapter (REF 00498.04). The equipment will select the BIPOLAR operative mode. To deliver

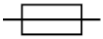
the current press the foot switch. To avoid the forcep's damage don't make short circuit with its tips.

- Bipolar forceps and double foot switch: connect the optional adapter (REF 00498.04). The equipment will select the BIPOLAR operative mode. To deliver the current press the foot switch for the coagulation (blue). To avoid the forcep's damage don't make short circuit with its tips.

DESCRIPTION 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.

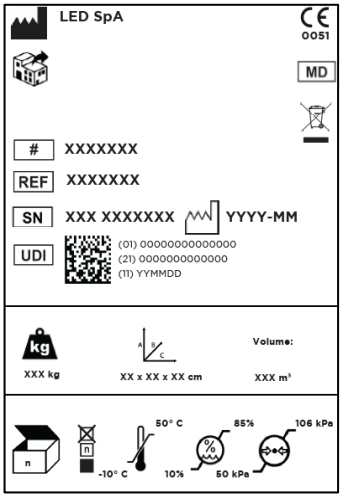
N°	SYMBOL	DESCRIPTION
1		Floating neutral electrode: not grounded at either high or low frequencies.
2		Class CF equipment protected against shock from the use of the defibrillator.
3		Non-ionizing radiation generating equipment.
4		Follow the instructions for use.
5	CE 0051	CE Mark (2017/745/EU) + Notified Body Number 0051 = IMQ Italy
6		The product should not be disposed of in municipal waste containers but should be disposed of with a separate collection.
7		Manufacturer.
8	SN	Serial number.
9		Date of manufacture.
10	UDI	Unique device identification.

N°	SYMBOL	DESCRIPTION
11		Medical device.
12		Distributor.
13		No maintenance by the user.
14		Catalog number (Code).
15		Temperature limits.
16		Humidity limits.
17		Atmospheric pressure limits.
18		High side.
19		FRAGILE – Handle with care.
20		Keep away from sunlight.
21		Protect from moisture.
22		Maximum number of stackable pieces.
23		Weight.
24		Dimensions.
25		Number of pieces.
26		Recycle.
27		Model/Trade Name.
28	IP	Degree of protection against the ingress of water and dust.
29		Fuse.

N°	SYMBOL	DESCRIPTION
30		Distribution packaging must not be knocked over or tipped over.

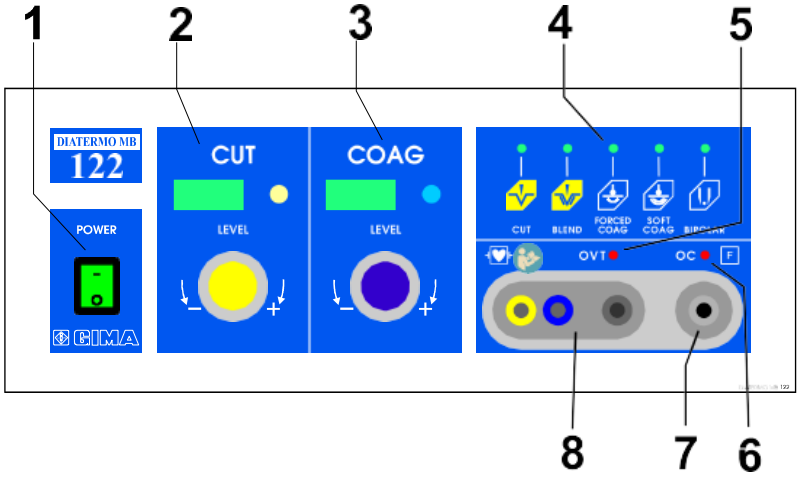
BOX LABEL

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:



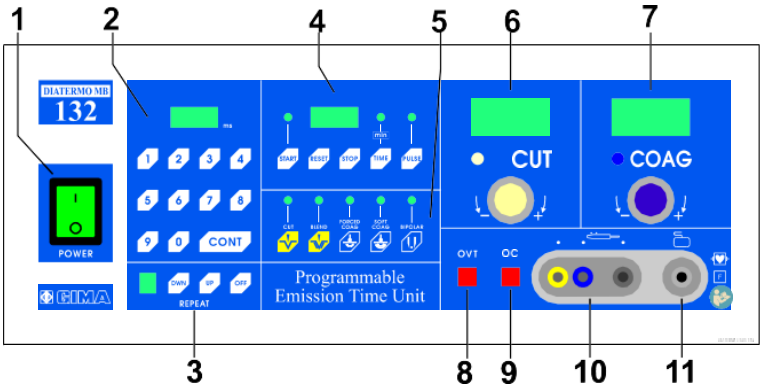
ISO 15223-1 (5.1.1) - **MANUFACTURER**
ISO 15223-1 (5.1.9) - **DISTRIBUTOR**
ISO 15223-1 (5.1.10) - **MODEL NUMBER**
ISO 15223-1 (5.7.10) - **UNIQUE DEVICE IDENTIFIER**
ISO 15223-1 (5.1.6) - **CATALOGUE NUMBER**
ISO 15223-1 (5.1.7) - **SERIAL NUMBER**
ISO 15223-1 (5.1.3) - **DATE OF MANUFACTURE**
BOX 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 DIATERMO MB 122-MB 160



1. Power switch
2. Section for cutting level control and indication
3. Section for control and indication of coagulation level
4. Keyboard for selecting how to use it.
5. Alarm indicator for excessive dispensing time.
6. Alarm indicator for excessive impedance in the neutral electrode circuit.
7. Connector for neutral electrode.
8. Handpiece connector with active electrode holder buttons.

FRONT PANEL DIATERMO MB 132



1. Power Switch
2. Timing Keypad
3. Pulse Repeat Keyboard
4. Time counter - Pulse counter
5. Keyboard Selection Mode
6. Section for Cutting Level Control and Indication
7. Section for Control and Indication of Coagulation Level
8. Alarm Indicator for Excessive Dispensing Time
9. Alarm Indicator for Excessive Resistance in the Neutral Electrode Circuit
10. Handpiece Connector with Active Electrode Holder Buttons
11. Neutral Electrode Connector

OPERATING MODES

Power On

When switched on, the electrosurgical unit automatically performs a correct operation test including the connected accessories. In the event of anomalies, an alphanumeric code message is shown according to the error code table reported in the MAINTENANCE chapter.

The test lasts about 10 seconds. At the end of the check, the equipment restores the last operating conditions used.

Neutral Electrode Circuit

If a bipartite electrode is used, the neutral electrode circuit is continuously monitored by a special circuit that prevents the danger of burns to the patient due to loss of contact between the patient plate and the skin.

When using single-part neutral electrodes, the circuit controls the connection of the plate with the unit.

If the impedance value is less than 200 Ohms, the OC alarm does not trip, in case of higher impedances the alarm trips and the power supply is interrupted.

Preparation of the Deliverable Currents

The currents that can be delivered for the various surgical operations can be set using the buttons to:

Current per Cut (CUT)

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

Coagulated-Cut Current (BLEND)

Blended current (BLEND) is suitable for coagulated cutting when deep coagulation associated with cutting is desired. This current consists of shear sinusoidal current associated with low voltage coagulation (SOFT COAG)

current. This provides a current suitable for coagulated shear in the absence of eschar and carbonization, which is particularly suitable for endoscopic interventions.

Superficial Coagulation Current (FORCED COAG)

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

Deep Coagulation Current (SOFT COAG)

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

Bipolar Coagulation Current (BIPOLAR)

The current delivered in this mode is pure sinusoidal at low voltage and suitable for coagulation without carbonization, both monopolar and bipolar. The use of the bipolar clamp is only permitted with this current. To allow the connection of the clamp cable, the use of an optional adapter (REF 00498.04) is required, which prevents any other type of current.

Particularly interesting is the automatic termination of bipolar coagulation by setting the delivery time (only for the MB132 model).

Over-dispense time (OVT) reporting

If the operator exceeds the maximum dispensing time of 10 seconds, the equipment generates a warning signal consisting of the intermittent OVT light signal. If, despite the warning signal, the operator insists on continuous dispensing, after a variable time, depending on the type of dispensing and its level, the warning signal turns into an impediment to dispensing which is signalled by the constantly illuminated OVT signal. The prohibition of disbursement lasts for a time dependent on the progressive conditions of disbursement.

Signaling Excessive Impedance in the Neutral Electrode (OC) Circuit

For the meaning of this signal, refer to the previous description of the neutral electrode circuit.

Adjusting the Beep Emission Level

To change the beep level, the following procedure must be performed: Turn on the equipment using the power switch while holding down the CUT button. After the equipment has checked the internal parameters, the word SOU appears on the CUT display. while on the COAG display the value of the set level. Now release the CUT button.

Using the COAG knob it is possible to vary the level of the emission sound, during the variation the equipment emits a sound corresponding to the selected level.

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

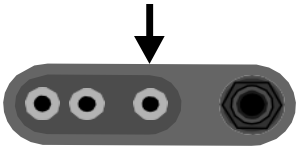
The equipment has a continuous automatic control system of some internal parameters. When it is switched on, it performs a check, indicated on the displays with the word SEL FCh, followed by the result of the same with PAS Sed if the system does not detect any irregularities or if not, by means of a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

CONNECTORS

Neutral electrode connector

This is the connection point of the neutral electrode or the optional adapter (REF 00498.04) when using the BIPOLAR function.

Handpiece connector



This is the connection point of the handpiece. If handpieces without buttons are used, they must be connected to the black bushing.

ADDITIONAL FUNCTIONS FOR MB132 MODELS

This check only applies to the Model MB132 electrosurgical unit which has the following additional features:

Dispensing Time	1/1000 sec to 999/1000 sec
Repeat Dispensing	2 to 9 times
Measurement of Sitting Time	Up to 999 minutes
Number of Power Outputs	Up to 999

PROGRAMMING THE BREWING TIME

If the MB132 is used, the actuation time for the power supply can be set with high precision.

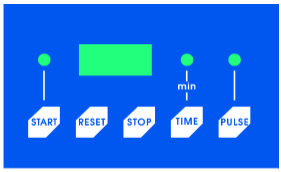
When timed output is required, the active time control is performed on the front panel by typing the value on the timing keyboard.

The emission of the high-frequency current will take place for the prearranged time each time a pedal or a button of the handpiece is pressed. If, after carrying out a timed job, it is necessary to return to the normal one, simply push the CONT button.

REPEATING BREW TIME

The timed emission of the high-frequency current can be repeated automatically from 2 to 9 times. The number of selected repetitions is indicated on the corresponding display. Press the UP and DOWN key to increase and decrease the number of repetitions. To cancel the repeat command and return to normal operation, you must push the OFF button: in this condition the display is not lit.

TREATMENT TIME COUNTER

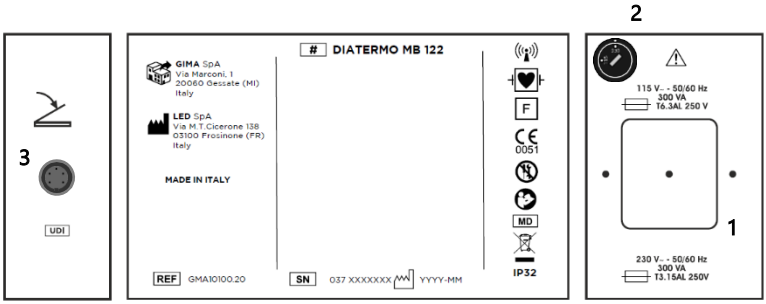


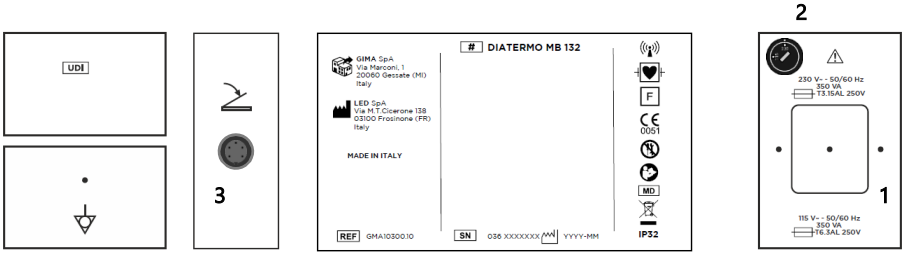
With the MB132 it is possible to automatically obtain the elapsed treatment time by setting the function using the TIME button and starting the count by means of the START button. To stop the counting, you must press the STOP button. Use the RESET button to reset the counter.

TIMED DISPENSE COUNTER

With the MB132 model, it is possible to automatically have the number of high-frequency current emissions by setting the function with the PULSE button and starting the count by pressing the START button. To stop the counting, you must press the STOP button. Use the RESET button to reset the counter.

REAR PANEL DIATERMO MB 122-MB 160 AND MB 132





1. Power Socket
2. Supply Voltage Selector
3. Pedal Connector

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. The aforementioned power module incorporates the power connector and line fuses.

WARNING: Before switching on the equipment, the operator should make sure that the mains voltage indicated corresponds to the available mains voltage.

PEDAL CONNECTOR

On the left side of the rear panel is the pedal socket.

ROTARY VOLTAGE CHANGER

Above the power supply module there is the 115/230Vac rotary voltage changer. Before powering the equipment, the correct supply voltage must be set by turning the voltage selector with the help of a blade screwdriver. The equipment is supplied set to 230Vac.

TECHNICAL CHARACTERISTICS

Tol.	Description	DIATERMO		
		MB 122	MB 160	MB 132
± 0%	Minimum power selectable	0	0	0
-	Power step	1	1	1
-	Digital power display	●	●	●
± 20%	Maximum power cutCUT (W)	120 → 250Ω	160 → 250Ω	120 → 250Ω
± 20%	Maximum cutting-coagulating power BLEND (W)	90 → 200Ω	120 → 200Ω	90 → 200Ω
± 20%	Maximum coagulation power COAG FORCED (W)	80 → 150Ω	100 → 150Ω	80 → 150Ω
± 20%	Maximum coagulation power COAG SOFT (W)	60 → 100Ω	80 → 100Ω	60 → 100Ω
± 20%	Maximum power bipolar BIPOLAR (W)	40 → 100Ω	60 → 100Ω	40 → 100Ω
± 5%	CUT modulation degree	Pure 100%	Pure 100%	Pure 100%
± 5%	BLEND modulation degree	Mod. 50%	Mod. 50%	Mod. 50%
± 5%	COAG FORCED modulation degree	Mod. 60%	Mod. 60%	Mod. 60%
± 5%	COAG SOFT degree of modulation	Mod. 90%	Mod. 90%	Mod. 90%
± 5%	BIPOLAR Degree of Modulation	Pure 100%	Pure 100%	Pure 100%

Tol.	Description	DIATERMO		
		MB 122	MB 160	MB 132
± 0.2	Crest Factor CUT	1.5	1.5	1.5
± 0.3	BLEND Crest Factor	2.1	2.1	2.1
± 0.3	COAG FORCED Crest Factor	2.0	2.0	2.0
± 0.3	COAG Crest Factor SOFT	1.7	1.7	1.7
± 0.2	BIPOLAR Crest Factor	1.5	1.5	1.5
± 10%	Working Frequency	600 kHz	600 kHz	600 kHz
± 15%	Maximum CUT voltage (Vpp on 5.2kΩ)	1050	1050	1050
± 15%	Maximum BLEND voltage (Vpp on 5.2kΩ)	1050	1050	1050
± 15%	Maximum COAG FORCED voltage (Vpp on 5.2kΩ)	1050	1050	1050
± 15%	COAG SOFT maximum voltage (Vpp on 5.2kΩ)	540	540	540
± 15%	BIPOLAR maximum voltage (Vpp on 5.2kΩ)	540	540	540
± 0.5	Weight Kg	7	7	8
± 10	Dimensions WxHxD mm	260x110x265	260x110x265	360x150x265
± 5%	Selectable power supply (Vac)	115 –230	115 –230	115 –230
± 1%	Mains frequency (Hz)	50-60	50-60	50-60
± 0	Fuses for 230Vac power supply (5x20) Delayed	2x 3.15A	2x 3.15A	2x 3.15A
± 0	Fuses for 115Vac power supply (5x20) Delayed	2x 6.3A	2x 6.3A	2x 6.3A
± 10%	Maximum power consumption (VA)	300	350	300
± 10%	Maximum absorbed current (A) at 230Vac	1.3	1.5	1.3
± 10%	Maximum absorbed current (A) at 115Vac	2.6	3	2.6
± 5	Sound emission adjustable in 5 steps (55- to 75dBA)	●	●	●
-	Fault self-diagnosis	●	●	●
-	Accurate control of emitted power	●	●	●
-	Possibility of connection of joined and bipartite electrodes	●	●	●
-	Pulse repetition	-	-	from 2 to 9
-	Timed emission	-	-	1 - 999 ms
-	Storage of last used settings	●	●	●
-	Electrical Classification (EN60601-1)	Class I Applied Part CF		
-	MDR Classification 2017/745/EU	II b	II b	II b
-	Protection Class (EN60529)	IP32	IP32	IP32
-	EN55011 Classification (CISPR 11)(Group/Class)	2 / A	2 / A	2 / A
-	Neutral Electrode	F	F	F
-	Duty Cycle (action / pause) in seconds	10 / 30	10 / 30	10 / 30
-	Pedal/manual activation type	●	●	●
-	Defibrillator protection	●	●	●
-	Emission time control > 10 seconds (OVT)	●	●	●

Tol.	Description	DIATERMO		
		MB 122	MB 160	MB 132
-	Equipotential socket	□	□	□
-	Metal housing painted RAL5028	●	●	●
-	Polycarbonate panels	●	●	●
-	Complies with EN60601-1 standard	●	●	●
-	Complies with EN60601-1-2 standard	●	●	●
-	Complies with IEC60601-2-2 standard	●	●	●

□ = OPTIONAL ● = 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. The equipment enclosure 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. User maintenance consists mainly of cleaning and sterilizing the accessories and checking the equipment before each use. The execution of functional and safety checks to verify 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; A light, non-abrasive detergent may be used.

CLEANING AND STERILIZATION OF ACCESSORIES

If non-sterile disposable accessories are used, the instructions for use (IFU) provided by the manufacturer of each sterilization method accessory should be strictly followed and disposed of according to current regulations.

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 the event of a problem, you must first check that you have correctly installed and prepared the accessories.

Problem	Probable cause	Solution
The equipment does not turn on	Interruption or absence of mains power	Check the power cord connection. Check the condition of the fuses and replace with suitable type if necessary.
OC alarm always Active	Interruption or poor contact on the Neutral electrode circuit	Check the cable connection to the neutral electrode. Replace the electrode connection cable.
The unit does not respond to the actuation command	Handpiece or foot pedal fault Incorrect handpiece or foot pedal connection Unit in OVT alarm	Replace the handpiece and/or foot pedal. Check the connection of the handpiece or foot pedal. Wait for the OVT light to turn off.
Error Code 001	Dispensing commands activated during The ignition	Unplug the handpiece and/or foot pedal and turn it back on unity.
Error Code 002	Error in the management module	Contact Technical Assistance
Error Code 003	Error in the management module	Contact Technical Assistance
Error Code 004	Error in the conversion circuit	Contact Technical Assistance
Error Code 005	Error in the reference voltage	Check the supply voltage Contact Technical Assistance
Error Code 009	Error in the control circuit of the Power	Contact Technical Assistance
Error Code 010	Error in the control circuit of the Power	Contact Technical Assistance

REPAIRS

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

Fuse Replacement

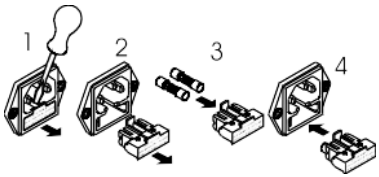
Before replacing the fuses, disconnect the equipment from the power supply.

To replace the fuses, use 5x20 type fuses of 3.15AT (time-delayed) (for 230Vac power supply) or 6.3A (for 115Vac power supply), proceed as follows:

1-2 Use a small slotted screwdriver to remove the drawer under the mains socket.

3 After removing the damaged fuses, insert two new fuses.

4 Reinsert the cassette.



CHECKING THE EQUIPMENT BEFORE USE

Whenever the use of the equipment is planned, a check of the main safety conditions must be implemented, considering at least the following:

- Check the integrity of the cables, connections, any damage to the insulation of the cables themselves.
- Make sure the equipment is properly grounded.
- Make sure that all accessories that are to be used are available and sterilized.
- By disconnecting the neutral electrode cable, carry out a visual and functional check of the OC alarm (acoustic/light).
- By dispensing the CUT and COAG function, check that the acoustic/light emission indications are working correctly.

CONTROL AND MEASUREMENT OF SAFETY FUNCTIONS

Checks and measurements should be carried out periodically (at least once a year) by the Bioengineering Service or other qualified personnel.

- Check the condition of cables and power connectors.
- Visual inspection of mechanical guards and protection against the hazards of spillage, dripping, moisture, liquid penetration, cleaning, sterilization and disinfection.
- Checking the data on the rating plate of the equipment.
- Checking the availability of the instruction booklet.
- Control of high-frequency output actuators.
- Measurement of conductivity resistance to earth.
- Measurement of high-frequency leakage current.
- Control of neuromuscular stimulation.
- Checking the accuracy of the output power.

DIAGRAMS

DIATERMO MB 122- MB 132

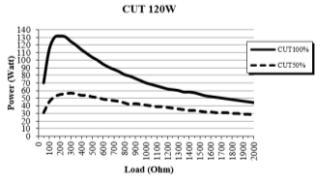


Diagram of maximum and medium power on variable load 100-2000Ω CUT

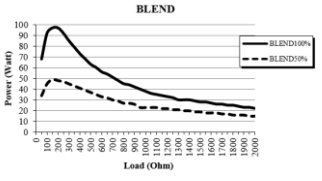


Diagram of maximum and medium power on variable load 100-2000Ω BLEND

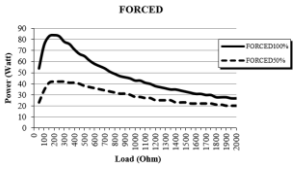


Diagram of maximum and medium power on variable load 100-2000Ω FORCED

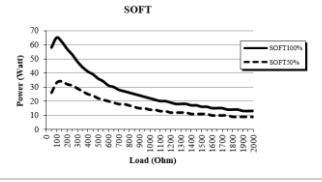


Diagram of maximum and medium power on variable load 100-2000Ω SOFT

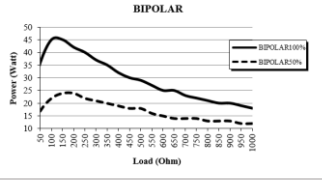
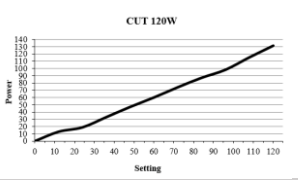
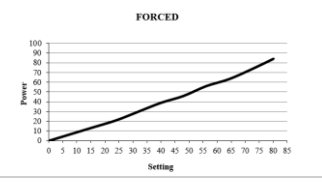


Diagram of maximum and medium power on variable load 10-1000Ω BIPOLAR

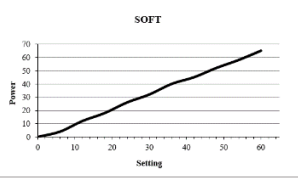


CUT Output Power Diagram on Rated Load

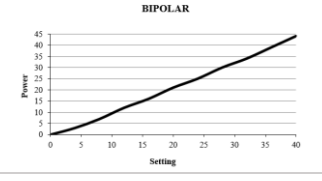
BLEND Output Power Diagram on Rated Load



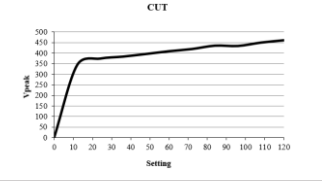
FORCED Output Power Diagram on Rated Load



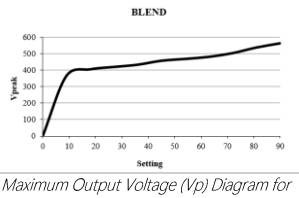
SOFT Output Power Diagram on Rated Load



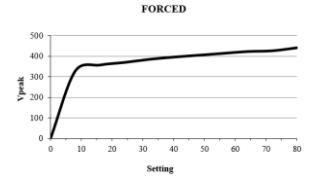
BIPOLAR Output Power Diagram on Rated Load



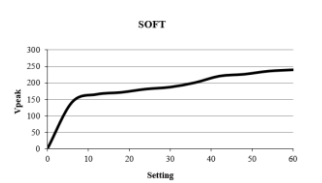
Maximum Output Voltage (Vp) Diagram for CUT



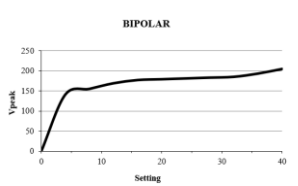
Maximum Output Voltage (Vp) Diagram for BLEND



Maximum Output Voltage (Vp) Diagram for FORCED



Maximum Output Voltage (Vp) Diagram for SOFT



Maximum Output Voltage (Vp) Diagram for BIPOLAR

DIATERMO MB 160

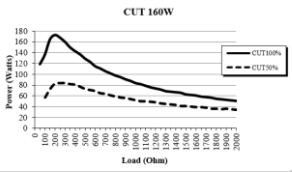


Diagram of maximum and medium power on variable load 100-2000Ω CUT

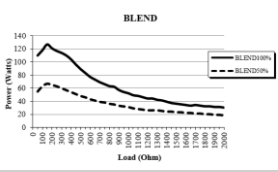


Diagram of maximum and medium power on variable load 100-2000Ω BLEND

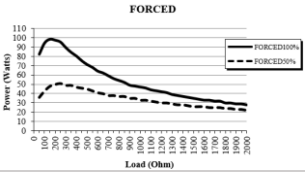


Diagram of maximum and medium power on variable load 100-2000Ω FORCED

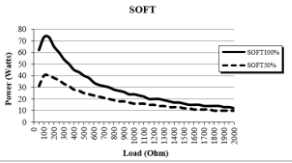


Diagram of maximum and medium power on variable load 100-2000Ω SOFT

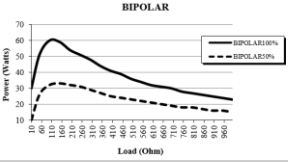
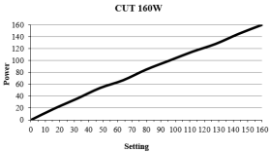
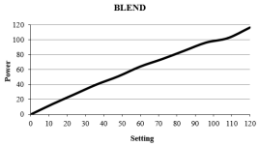


Diagram of maximum and medium power on variable load 10-1000Ω BIPOLAR

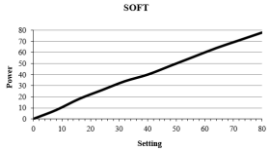


CUT Output Power Diagram on Rated Load

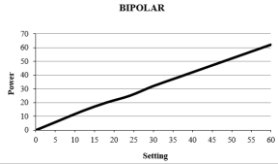


BLEND Output Power Diagram on Rated Load

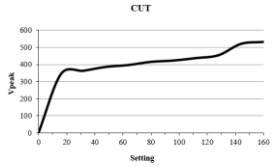
FORCED Output Power Diagram on Rated Load



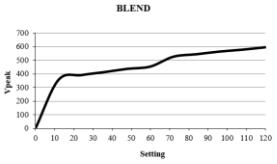
SOFT Output Power Diagram on Rated Load



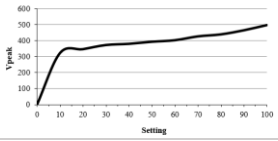
BIPOLAR Output Power Diagram on Rated Load



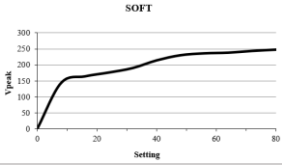
Maximum Output Voltage (Vp) Diagram for CUT



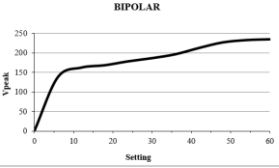
Maximum Output Voltage (Vp) Diagram for BLEND



Maximum Output Voltage (Vp) Diagram for FORCED



Maximum Output Voltage (Vp) Diagram for SOFT



Maximum Output Voltage (Vp) Diagram for BIPOLAR

Information on the reduction of hazardous substances in electrical and electronic equipment, as well as on waste disposal.	
	At the end of its life, this product must not be disposed of as municipal waste, it must be collected separately. If the waste is disposed of inappropriately, it is possible that some parts of the product (e.g. any accumulators) may have potentially negative effects on the environment and human health. The symbol on the side (crossed-out wheeled waste bin) indicates that the product should not be disposed of in municipal waste containers but should be disposed of separately. Penalties may apply for the illegal disposal of this product.

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MA036D_EN

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