EN

DIATERMO MB 200

HIGH FREQUENCY SURGICAL EQUIPMENT

USER MANUAL

GIMA

CE 0051

SUMMARY

IMPORTANT

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

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

If you need Technical Assistance, contact LED SpA.

Produttore / *Manufacturer*

LED SpA

ELECTRONIC DESIGN AND PRODUCTION

Via Selciatella 40 04011 Aprilia (LT) Italia

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INTRODUCTION

GENERAL DESCRIPTION

DIATERMO MB 200 is an electro-surgical equipment suited to deliver current for monopolar cut, cut coagulated, with different degrees of coagulation and coagulation or bipolar cut and coagulation.
A total of ten different modes of use and levels of power, can be stored and recalled for the use simply. It is possible to use either single plate neutral reference electrodes or electrodes with split conductive zone so to watch the stability of the plate to patient impedance 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 environmental conditions of working.

The units can work either through holder-handles with or without pushbuttons or through single- or double-foot switch command. Moreover, applying a special adapter it is possible the unit connection to bipolar forceps.

INTENDED USE/ FIELDS OF APPLICATION

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

The DIATERMO MB 200 equipment is designed to be used in the following sectors:

Description	DIATERMO MB 200
Electrosurgical Unit Code	GMA10100.40
Casualty Surgery	●
Dermatology	●
Endoscopy	●
Gastroenterology	●
General Surgery	●
Gynecology	●
Neurosurgery	●
Oftalmology	●
Orthopedics	●
Otorhinolaryngology	●
Pediatric Surgery	●
Plastic Surgery	●
Pneumology	●
Urology	●
Vascular Surgery	●
Thorax Surgery	●
Trans Urethral Resection (TUR)	●

● = Usable

INTENDED USER

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

INTENDED PATIENT POPULATION

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

STANDARD COMPOSITION

Code	Description	DIATERMO
		MB 200
-	Code Electrosurgical Unit	GMA10100.40
00498.04	Bipolar adpter	■ /1
152-110	Blade electrode 7 cm	■ /3
152-150	Ball electrode 7 cm	■ /3
152-120	Needle electrode 7 cm	■ /3
00401.00	Steel neutral electrode with cable	■ /1
00500.00	Kit of assorted electrodes(10pcs)	■ /1
00205.00	Reusable handle with finger switches	■ /1
00304.00	Waterproof foot switch	■ /1

■/pcs = STANDARD

ELECTROPHYSICAL PRINCIPLES

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

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

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

Electric current flowing through biological tissue usually can cause:

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

1. *Joule Effect*

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

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

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

- Current Intensity and output power

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

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

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

- Characteristics of the tissue
  The resistive characteristics change according to the biological tissues.

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

(Example of specific resistances of organic and metallic materials)

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

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

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

- Mixed currents
  These are obtained by combining the effects of coagulation and electrotomy. A reduction in bleeding occurs during a cutting procedure, or as a cut that develops a substantial layer of eschar.
  The high frequencies used by the electrosurgical scalpel, however, do not allow the electromagnetic field to penetrate matter and cause the current to flow through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the center of the conductor's cross-section. This effect, called the 'skin effect,' results in a decrease in the useful cross-sectional area for the passage of a current, and an increase in the electrical resistance of the material, and becomes a major problem in the neutral electrode. In fact, in this electrode the current density is very high (KA/m^2) at the edge, where excessive temperature rise due to the 'Joule

effect' causes burns to the patient. Therefore, it is no accident that burns to the patient, which has occurred in surgical procedures, have the shape of the edge of the neutral electrode. To reduce the risk of burns, it is necessary to dose the delivered power ($I^2 \cdot t$) appropriately and follow the rules for applying the neutral electrode to the patient (see *SAFETY* chapter).

2. *Faradic Effect*

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

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

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

3. *Electrolytic Effect*

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

OPERATIVE TECHNICS

MONOPOLAR CUT

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

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

The following rules help the operator achieve a good cut:

- Keep the tissue moist but not wet.
- Maintain the electrode perpendicular to the tissue.
- Activate the output circuit before making contact with the tissue.
- Keep the electrode tip clean (for this purpose, 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 CUT AND COAGULATION

Bipolar cut consists in the sectioning of the biological tissue due to the passage of HF current concentrated on the tips of the bipolar forceps.
When the HF current is applied to the tissue, between the two tips of the forceps, an intense molecular heat in the cell is created, so that the cell explodes.
Bipolar coagulation consists in the haemostasis of small blood vessels of the body tissue between the two tips of the forceps.
When the current density is reduced, the drying of the cellular surface is obtained, without deep penetration and its consequent coagulation. These superficially coagulated cells act as a layer of insulation that prevent the heat, due to successive current applications, to penetrate too deeply.

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 medicals 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.

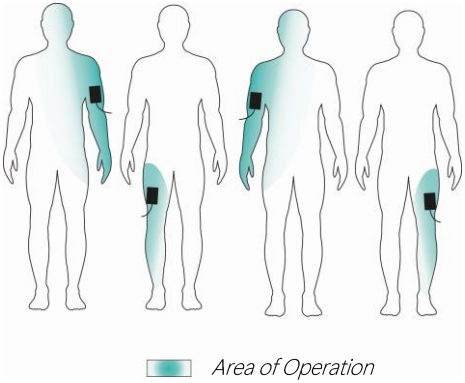
- The surface of the active electrode may remain sufficiently hot to cause burns even after RF current is deactivated.
- Due to concerns about the potential carcinogenic and infectious properties of electrocautery byproducts (such as tissue smoke plumes and aerosols), protective eyewear, filtration masks, 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

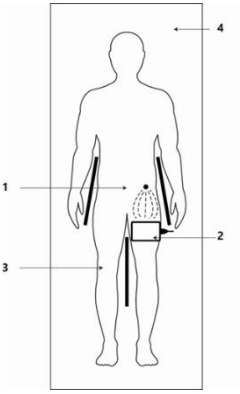
PRECAUTIONS

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 (N_2O) 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 adapters 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 200 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.

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.

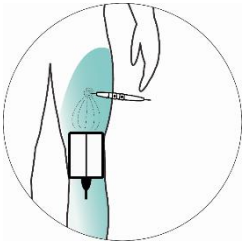
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

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.

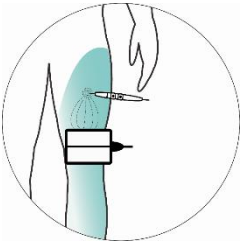
Ensuring the correct placement of the neutral electrode is of utmost importance to prevent burns and minimize patient risks. Below are some valuable tips to achieve this:

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 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

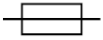
between FORCED COAG, SOFT COAG or BIPOLAR must be done pressing the correspondent pushbutton on the unit).

- 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 forceps' 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.

MEANING OF GRAPHIC SYMBOLS

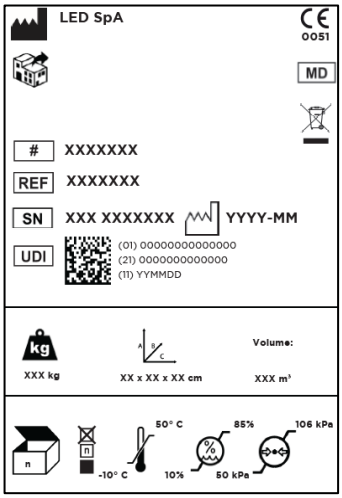
In accordance with the international standards ISO 15223-1:2021 "Medical devices – Symbols to be used in information to be provided by the manufacturer" and ISO 780:2015 "Packaging — Distribution packaging — Graphic symbols for the handling and storage of packaging", all symbols shown on the device labels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

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

N°	SYMBOL	DESCRIPTION
15		Temperature Limits.
16		Humidity Limits.
17		Atmospheric Pressure Limits.
18		This Way Up.
19		FRAGILE – Handle With Care.
20		Keep away from sunlight.
21		Protect against moisture.
22		Number of maximum stackable packages.
23		Weight.
24		Dimensions.
25		Number of Pieces.
26		Recycle.
27		Model/Trade Name.
28	IP	Protection against harmful ingress of water or particulate matter.
29		Fuse.
30		Packaging intended for distribution must not be knocked over or tipped over.

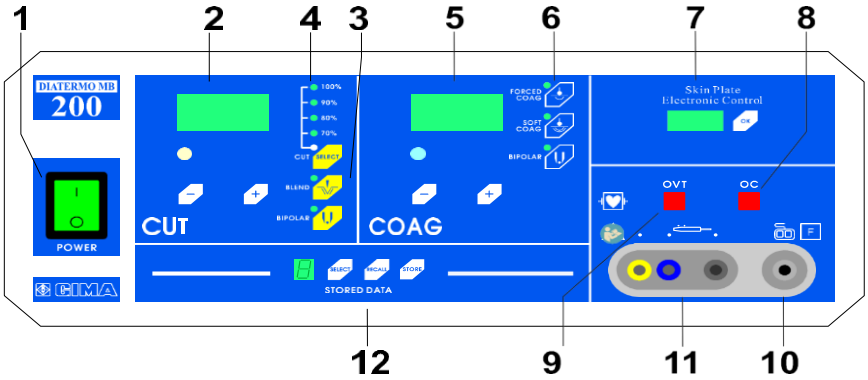
BOX LABEL

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



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 PER UNIT
EU REGULATION 2017/745 (MDR) - CE MARKING 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 LIMIT

FRONTAL PANEL



1. Power switch
2. Section for cutting level control and indication
3. Cutting function mode selection keypad
4. Indicator lights 100% pure cut, 90% cut, 80% cut, 70% cut
5. Section for control and indication of coagulation level
6. Coagulation function mode selection keypad
7. Neutral electrode impedance reading and acceptance section
8. Alarm indicator for excessive impedance in neutral electrode circuit
9. Alarm indicator for excessive delivery time
10. Connector for neutral electrode connection
11. Connector for handpiece with active electrode holder buttons
12. Section for recording and recall of stored setting data

OPERATION MODE

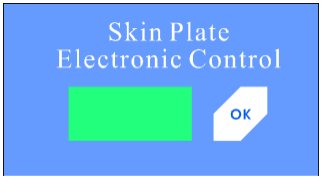
Switch On

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

Neutral Electrode's Circuit

The neutral electrode's circuit is continually watched by a special circuit (Skin Plate Electronic Control) that prevents danger of burns to the patient due the loss of contact between the reference plate and the patient skin. The circuit is also watched to avoid that the variation of the characteristics of conductibility of the plate can provoke reduction of conductibility of the circuit, and therefore danger of burns to the patient.

The value of impedance found in the circuit of the neutral electrode is shown to the operator that, if he considers it suitable to the job to develop, he accepts it by pressing the OK push button. The signal OC is extinguished. If the value of impedance is superior to 300 ohms its acceptance it is not acknowledged by the microcontroller of the equipment, therefore the signal OC is not extinguished, and the disbursement of power has not allowed.



If the value of impedance accepted is acknowledged, the indication of the impedance stops.

If when the unit has switched on, the adapter for using the bipolar forceps is had been inserted, after the test of correct operation, the equipment selects automatically the bipolar operational mode without performing the cycle related to the control of the neutral electrode circuit.

If after having acknowledged the shown impedance the value of this, it increases relatively to the acknowledged value according to the followings increases:

- for acknowledged impedance <20 Ω → value + 30 Ω
- for acknowledged impedance between 20 Ω and 100 Ω → value + 60 Ω
- for acknowledged impedance > 100 Ω→ value + 50%

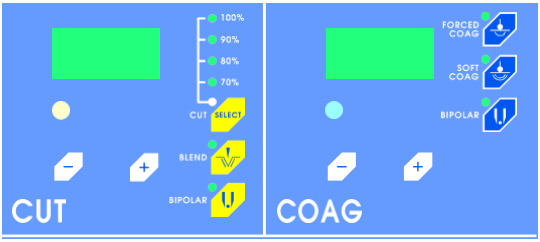
The equipment prevents the delivery of current, it indicates the OC condition and shows the new value of impedance.

STORING OF CONDITION OF USE

Using the section STORED DATA it is possible to store 9 different operational conditions and levels of output power (program 0 is the default one).
To store the parameters, it is enough to perform the following procedure:
Press the key SELECT to find the number of the program that you want to use. Press the key STORE to store the parameters.
To recall the stored data, it is enough to perform the following procedure:
Press the key SELECT to find the number of programs that you want to recall. Press the key RECALL to recall the parameters.
For modify a program it is enough to select the same program and to perform the procedure of storing once more.

PRESELECTION OF THE DELIVERABLE CURRENT

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



Cut Current (CUT)

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

Such current, proper for cut without coagulation, it can be moderately modulated for getting cut with different degrees of coagulation. The degree of modulation can be varied, among the values 100% and 70% of duty cycle in four steps, by choosing the duty- cycle of the delivered current, through the push button SELECT and checking the value gotten through the up led tip.

Naturally the degree of coagulation increases when the duty cycle value decreases.

Mixed Current (BLEND)

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

Bipolar Cut Current (BIPOLAR CUT)

This current is high voltage pure sine current and suited for cut without coagulation either monopolar or bipolar. The use of bipolar forceps it is allowed only with this current.

To allow the connection of the cable bipolar forceps it is necessary the use of an adapter that prevents any other type of current from delivering.

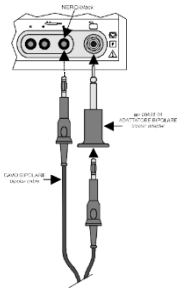
Current For Superficial Coagulation (FORCED COAG)

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

Current For Deep Coagulation (SOFT COAG)

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

Bipolar Coagulation Current (BIPOLAR COAG)



This current is low voltage pure sine current and suited for coagulation without carbonization either monopolar or bipolar. The use of bipolar forceps it is allowed only with this current. To allow the connection of the cable bipolar forceps it is necessary the use of an adapter that prevents any other type of current from delivering.

Signalling of Excessive Time of Delivery (OVT)

If the operator exceeds the maximum time of disbursement, recommended by the international norms, that is 10 seconds, the equipment produces a signal of warning consisting of bright intermittent signal OVT. If despite the signal of warning the operator insists in the continuous delivering, after a time depending on the type of current, and from the level of the same one, the signal of warning is transformed in impediment to the delivering of current that is signalled through the signal OVT constantly illuminated.

The interdiction lasting of the current delivery depends from the previous conditions of delivery.

Signalling of Excessive Impedance in the Circuit of Neutral Electrode (OC)

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

Adjustment of the Acoustic Signal Level

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

1. Switch on the unit through the mains switch while the CUT pushbutton is maintained pressed.
2. When the unit has finished to check internal parameters, on the display CUT appears the message SOU., while on the COAG one, the value of the preset level. Now, the CUT pushbutton can be released.
3. Through the COAG knob it is possible varying the emission acoustic level. During the variation the sound emitted by the unit corresponds to the preset level.
4. Press the CUT pushbutton to confirm the level.

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

Automatic Control of the Internal Parameters

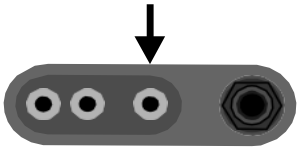
The unit has an automatic control system of some of the internal parameters. When switched on, the control is indicated on the display through the message SEL FCh. If there are not errors, the message PAS Sed appears; if there are errors, Err 001 appears. See Guide to the Problems' Solution for further information.

CONNECTORS

Connector for return plate

This is the point of connection of the return plate or of the bipolar optional adapter for BIPOLAR function.

Connector for handle



This is the point of connection of electrode handle. In the case of use of handle without finger switch it shall be connected to the black buckle.

BACK PANEL

1 Equipotential binding
2 Connector for pedal
3 Voltage selector
4 Mains voltage connector

POWER SUPPLY MODULE

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

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

PEDAL CONNECTOR

On the left part of the back panel, there is the footswitch connector.

TURNABLE VOLTAGE SELECTOR

On the power supply block can be present a voltage selector suitable for the selection of 115Vac or 230Vac mains voltage. Before powering the unit, it is necessary to preset the correct

mains voltage by properly set the voltage selector. The unit is factory preset to 230Vac.

TECHNICAL CHARACTERISTICS

Tol.	Description	DIATERMO MB 200
-	Electrosurgical Unit Code	GMA10100.40
-	Minimum preselectable power	0
-	Step power unitary or 5	●
-	Digital level display	●
-	Selection of the power through the buttons	●
± 20%	Maximum output power CUT (W)	200 → 250Ω
± 20%	Maximum output power CUT 90% (W)	200 → 250Ω
± 20%	Maximum output power CUT 80% (W)	200 → 250Ω
± 20%	Maximum output power CUT 70% (W)	200 → 250Ω
± 20%	Maximum output power BLEND (W)	120 → 200Ω
± 20%	Maximum output power COAG FORCED (W)	150 → 150Ω
± 20%	Maximum output power COAG SOFT (W)	90 → 100Ω
± 20%	Maximum output power BIPOLAR CUT(W)	120 → 250Ω
± 20%	Maximum output power BIPOLAR COAG (W)	100 → 100Ω
± 5%	Modulation factor CUT	Pure 100%
± 5%	Modulation factor CUT 90%	Mod. 90%
± 5%	Modulation factor CUT 80%	Mod. 80%
± 5%	Modulation factor CUT 70%	Mod. 70%
± 5%	Modulation factor BLEND	Pure 100%
± 5%	Modulation factor COAG FORCED	Mod. 60%
± 5%	Modulation factor COAG SOFT	Pure 100%
± 5%	Modulation factor BIPOLAR CUT	Pure 100%
± 5%	Modulation factor BIPOLAR COAG	Pure 100%
± 0.2	Crest Factor CUT	1.5
± 0.3	Crest Factor CUT 90%	1.6
± 0.3	Crest Factor CUT 80%	1.7
± 0.3	Crest Factor CUT 70%	1.8
± 0.3	Crest Factor BLEND	2.1
± 0.3	Crest Factor COAG FORCED	2.0
± 0.3	Crest Factor COAG SOFT	1.5

Tol.	Description	DIATERMO MB 200
-	Electrosurgical Unit Code	GMA10100.40
± 0.2	Crest Factor BIPOLAR CUT	1.5
± 0.2	Crest Factor BIPOLAR COAG	1.5
± 10%	Working frequency	600 kHz
± 15%	Maximum output voltage CUT (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage CUT90% (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage CUT80% (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage CUT70% (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage BLEND (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage COAG FORCED (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage COAG SOFT (Vpp on 5.2kΩ)	540
± 15%	Maximum output voltage BIPOLAR CUT (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage BIPOLAR COAG (Vpp on 5.2kΩ)	540
± 0.5	Weight Kg	8
± 10	Size HxLxDmm	360x150x265
± 5%	Selectable mains power(V~)	115 –230
± 1%	Mains frequency (Hz)	50-60
± 0	Fuses 230V~ (5x20) TIMED	2x 3.15A
± 0	Fuses 115V~ (5x20) TIMED	2x 6.3A
± 10%	Electrical input power (VA)	350
± 10%	Electrical input current (230V~) (A)	1.5
± 10%	Electrical input current (115V~) (A)	3
± 5	Five steps adjustable sound level (from 55- to 75dBA)	●
—	Self-check	●
—	Power accuracy output warning	●
—	Skin Plate Electronic Control[7]	●
—	Split or not split patient plate allowed	●
—	Repetition of timed delivery for second	●
—	Electrical classification (EN60601-1)	Class I Applicated Part CF
-	MDR Classification 2017/745/EU	II b
-	Protection Class (EN60529)	IP32
-	Classification EN55011 (CISPR 11)(Group/Class)	2 / A
-	Neutral electrode	F

Tol.	Description	DIATERMO MB 200
-	Electrosurgical Unit Code	GMA10100.40
-	Duty Cycle (action / pause) in seconds	10 / 30
-	Pedal/manual activation type	●
-	Defibrillator protection	●
-	Emission time control > 10 seconds (OVT)	●
-	Equipotential socket	●
-	RAL5028 metal housing	●
-	Polycarbonate panels	●

● = 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

No user adjustable parts are within the equipment, either for calibration or service purposes.
The equipment housing must not be opened: the warranty is invalidated by any unauthorized entry into the unit. In the event any repair or adjustment work being necessary, the whole equipment should be returned to the LED SpA. Service Centre 04011 APRILIA (LT) - ITALY, or to another Authorized Centre, together with a description of the fault.

Maintenance work by the user is mainly the cleaning of the exterior of the cabinet, cleaning and sterilization of the accessory items and checking of the equipment before each use. Carrying out function and safety check for verification of the parameters is demanded to specialize technical people.

CLEANING OF THE CABINET

Switch the equipment off completely and disconnect the mains supply before any cleaning is undertaken. Clean the outside of the cabinet with a damp cloth. No chemical should be used; a mild nonabrasive cleanser may be used when necessary.

CLEANING AND STERILIZATION OF THE ACCESSORIES ITEMS

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

GUIDE TO THE SOLUTION OF THE PROBLEMS

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

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

REPAIRS

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

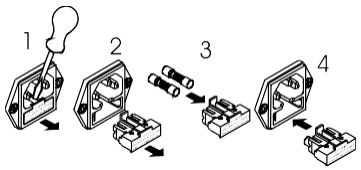
FUSES SUBSTITUTION

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

Only use fuse of the kind 5x20; they must have those characteristics: 3.15AT (slow) (230Vac mainsvoltage), 6.3A (115Vac mains voltage), proceed as follows:

1-2 Extract, with a small screwdriver, the drawer under the mains socket3 Extract the damaged fuse and insert two new ones

4 Reinsert the drawer



CHECKING OF THE EQUIPMENT BEFORE EACH USE

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

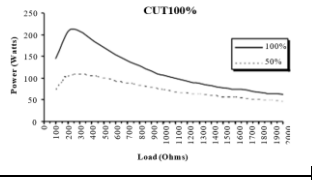
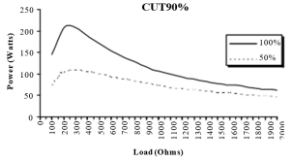
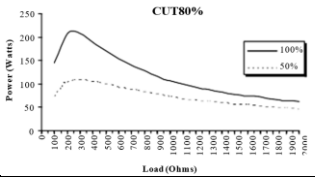
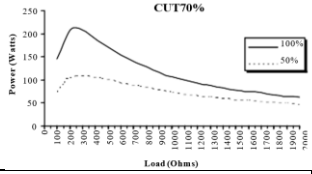
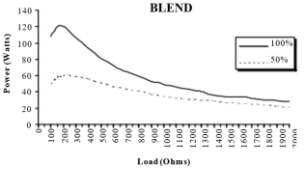
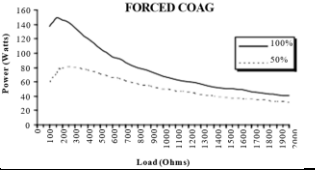
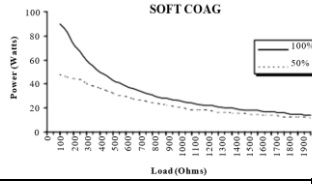
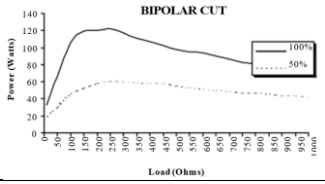
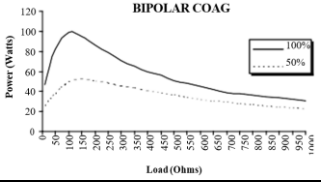
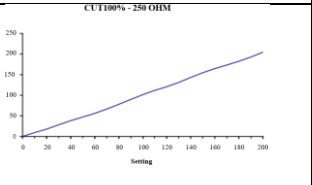
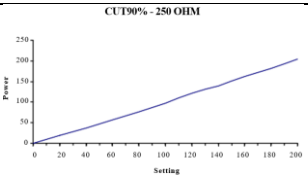
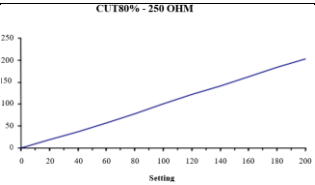
- Check the integrity of cords, connections, wires breakage, etc.
- Assure that all the electrical equipment is properly grounded.
- Assure that all the accessories that should be used are available and sterilized.
- Check, by disconnecting the reference electrode cable, the functioning of the OC light.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

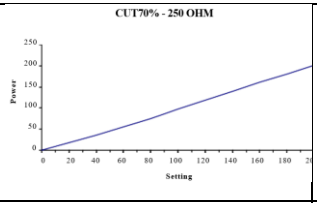
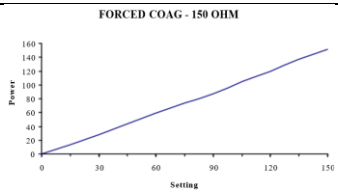
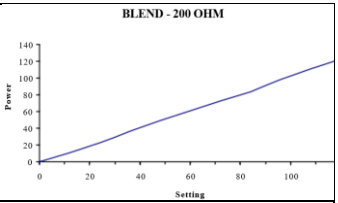
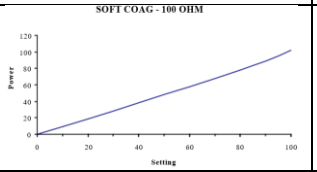
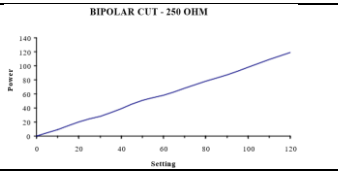
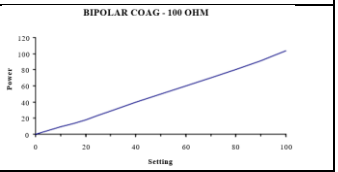
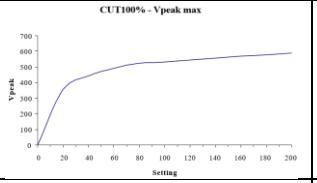
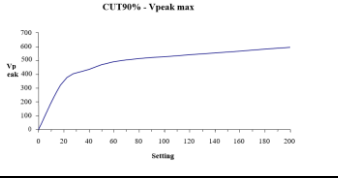
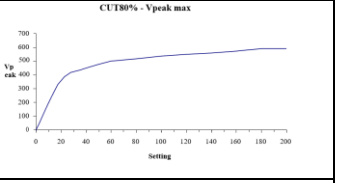
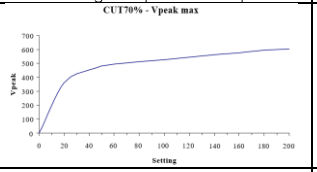
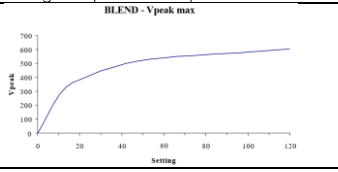
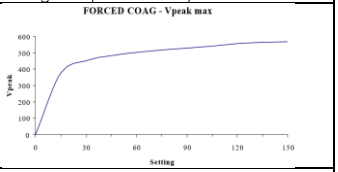
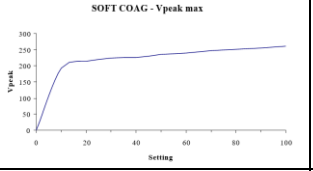
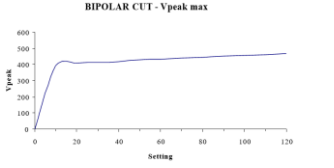
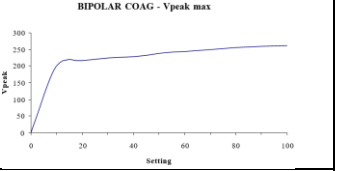
FUNCTION AND SAFETY CHECK AND TEST

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

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

DIAGRAMS

		
Diagrams of half and maximum output power versus impedance load 100-2000 Ω CUT100%	Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT90%	Diagrams of half and maximum output power versus impedance load 100-2000 Ω CUT80%
		
Diagrams of half and maximum output power versus impedance load 100-2000 Ω CUT70%	Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND	Diagrams of half and maximum output power versus impedance load 100-2000Ω FORCED COAG
		
Diagrams of half and maximum output power versus impedance load 100-2000Ω SOFT COAG	Diagrams of half and maximum output power versus impedance load 100-2000Ω BIPOLAR CUT	Diagrams of half and maximum output power versus impedance load 100-2000Ω BIPOLAR COAG
		
Diagrams of output power CUT100% versus nominal value	Diagrams of output power CUT90% versus value	Diagrams of output power CUT80% versus value

		
Diagrams of output power CUT70% versus nominal value	Diagrams of output power FORCED COAG versus nominal value	Diagrams of output power BLEND versus nominal value
		
Diagrams of output power SOFT versus nominal value	Diagrams of output power BIPOLAR CUT versus nominal value	Diagrams of output power BIPOLAR COAG versus nominal value
		
Diagrams of CUT 100% maximum mains voltage output versus Vp	Diagrams of CUT 90% maximum mains voltage output versus Vp	Diagrams of CUT 80% maximum mains voltage output versus Vp
		
Diagrams of CUT 70% maximum mains voltage output versus Vp	Diagrams of BLEND maximum mains voltage output versus Vp	Diagrams of FORCED COAG maximum mains voltage output versus Vp
		
Diagrams of SOFT COAG maximum mains voltage output versus Vp	Diagrams of BIPOLAR CUT maximum mains voltage output versus Vp	Diagrams of BIPOLAR COAG maximum mains voltage output versus Vp

Information regarding the reduction of hazardous substances in electrical and electronic equipment, as well as waste disposal.

At the end of its life, this product must not be disposed of as household waste; it must be collected separately.
If the waste is disposed of incorrectly, certain parts of the product (such as any batteries) may have potentially harmful effects on the environment and human health.
The symbol shown here (a crossed-out wheeled bin) indicates that the product must not be disposed of in household waste bins but must be disposed of via separate collection.
Penalties apply for the unauthorised disposal of this product.

MA182D_EN Edition 2025-09

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