EN

DIATERMO 50 T

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

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INTRODUCTION

DESCRIPTION

DIATERMO 50 T is an electrosurgical device capable of delivering currents suitable for cutting, coagulated cutting and coagulation.

The type of surgical operations that can be performed are those in which minor monopolar cutting or coagulation is required.

Currents can be delivered using foot control.

The most advanced circuits and electronic components, including LSI microcontrollers, are applied to ensure all the necessary requirements for reliable and safe operations.

The unit is controlled via a touchscreen interface and graphic indicators located on the front panel; The mains socket is located on the rear panel.

The equipment has automatic safety control systems which, by monitoring internal parameters, report any faults or errors detected.

The operating parameters used are continuously stored so that, each time the equipment is switched on or changed operating mode, it automatically repeats the last set values.

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 50 T** equipment is designed to be used in the following sectors:

Description	DIATERMO 50 T
Electrosurgical Unit Code	GMA10100. T05
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. The use of the equipment is reserved for medical personnel with a degree in medicine specialized in high frequency electrosurgery.

INTENDED PATIENT POPULATION

The device is intended for use in adult patients – both male and female – 18 years of age and older, except those listed in the *Contraindications* section. If necessary, the device can also be used in paediatric 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

Description	DIATERMO 50 T
Electrosurgical Unit Code	GMA10100.T05

DIATERMO 50 T		
Code	**Description**	**Quantity**
00100.03	Power cable 2m SIE-IEC	■/1
30518	Monopolar Handpiece	■/1
00304.00	Waterproof pedal	■/1
00401.00	NEUTRAL - Neutral steel electrode 120x160mm with cable	■/1
00500.03	ELECTRODE - Assorted Electrode Kit 5 cm (6 pcs)	■/1
00100.00	Power cable 2m IT-IEC	○
00100.01	Power cable 5m SIE-IEC	○
00100.04	2m US-IEC Power Cord	○
00100.05	2m GB-IEC power cable	○

DIATERMO 50 T		
Code	**Description**	**Quantity**
00100.07	Power cable 2m BR-IEC	○
00100.09	Power cable 2m AU-IEC	○
00100.10	Power cable 5m JP-IEC	○
00201.02_S	PENCIL - Microsurgical needle handpiece AUTOCLAVABLE	○
00206.00	PENCIL – Autoclavable handpiece without buttons	○
00206.40	PENCIL – Autoclavable handpiece without buttons	○
00304.04_S	Single Waterproof Pedal (3 m)	○
00400.00	Magnetic hammer electrode with cable	○
00401.01	NEUTRAL - Neutral steel electrode 240x160mm with cable	○
00401.02	NEUTRAL - 120x160mm steel neutral electrode with autoclavable cable	○
00401.03	NEUTRAL - Neutral steel electrode 240x160mm with autoclavable cable	○
00401.10	NEUTRAL – FLEX 210 x 120 mm metal neutral electrode autoclavable without cable	○
00401.11	NEUTRAL – FLEX 210 x 120 mm metal neutral electrode with cable	○
00401.12	NEUTRAL – FLEX 210 x 120 mm autoclavable metal neutral electrode with cable	○
00401.20	NEUTRAL – FLEX S 210 x 120 mm metal neutral electrode autoclavable without cable	○
00401.21	NEUTRAL – Neutral metal electrode FLEX S 210 x 120 mm with cable	○
00401.22	NEUTRAL – FLEX S 210 x 120 mm autoclavable metal neutral electrode with cable	○
0350	Disposable Neutral Electrode (F7805)	○
00403.01	NEUTRAL - Neutral hammer electrode ⌀ 1.2 cm	○
00403.02	NEUTRAL - Neutral hammer electrode ⌀ 2 cm	○
00402.00	CONNECTION – Cable for M4-F4 neutral electrode connection	○
00402.01	CONNECTION – M4–F2.8 single-core cable 3 m	○
00402.02	CONNECTION – M4–MP4 single-core cable 3 m	○
00402.03	CONNECTION – M4–EU single-core cable	○
00402.04	CONNECTION – M4–F2÷2.8 mm single-core cable	○
00404.02	CONNECTION – Single-core cable J6.3 – F4 mm	○

DIATERMO 50 T		
Code	**Description**	**Quantity**
00404.08_S	CONNECTION - Disposable neutral electrode connection cable /5365	○
00404.09	CONNECTION – Autoclavable Cable for Connection of Disposable Neutral Electrode 5365-6429/FLEX	○
00404.10	CONNECTION – US Type Neutral Plate Cable	○
00404.11	CONNECTION – Autoclavable cable for US type neutral plate	○
00500.00/L	ELECTRODE - Assorted electrode kit 10 cm long (10 pcs)	○
152-110	ELECTRODE - Blade electrode 7 cm	○
152-112	ELECTRODE - Curved blade electrode 7 cm	○
152-115	ELECTRODE - Blade electrode 16 cm	○
152-120	ELECTRODE - Needle electrode 7 cm	○
152-122	ELECTRODE - Curved needle electrode 7 cm	○
152-125	ELECTRODE - Needle electrode 13 cm	○
152-130	ELECTRODE - Ball electrode ⌀ 2 mm 6 cm	○
152-132	ELECTRODE - Curved ball electrode ⌀ 2 mm 6 cm	○
152-140	ELECTRODE - Ball electrode ⌀ 3 mm 6 cm	○
152-142	ELECTRODE - Curved ball electrode ⌀ 3 mm 5 cm	○
152-145	ELECTRODE - Ball electrode ⌀ 3 mm 14 cm	○
152-150	ELECTRODE - Ball electrode ⌀ 4 mm 6 cm	-
152-175-10	ELECTRODE - Loop electrode 10x10 length. 15 cm	○
152-190-13	ELECTRODE - Loop electrode 20x13 length. 15 cm	○
152-190-20	ELECTRODE - Loop electrode 20x20 length. 15 cm	○
152-195	ELECTRODE - Coning electrode 13 cm	○
500500.L1	ELECTRODE - Straight Thin Wire Electrode (5 pcs) 5 cm	○
500500.L1/L	ELECTRODE - Straight Thin Wire Electrode (5 pcs) 10 cm	○
500500.L10	ELECTRODE - Bent ball electrode ⌀ 3 mm (5 pcs) 5 cm	○
500500.L10/L	ELECTRODE - Bent ball electrode ⌀ 3 mm (5 pcs) 10 cm	○
500500.L11	Microsurgery needles (10 pcs)	○
500500.L2	ELECTRODE - Fine wire bent electrode (5 pcs) 5 cm	○
500500.L2/L	ELECTRODE - Fine wire bent electrode (5 pcs) 10 cm	○
500500.L3	ELECTRODE - Loop electrode ⌀ 4 mm (5 pcs) 5 cm	○
500500.L3/L	ELECTRODE - Loop electrode ⌀ 4 mm (5 pcs) 10 cm	○
500500.L4	ELECTRODE - Loop electrode ⌀ 8 mm (5 pcs) 5 cm	○
500500.L4/L	ELECTRODE - Loop electrode ⌀ 8 mm (5 pcs) 10 cm	○
500500.L5	ELECTRODE - Bent Hook Electrode (5 pcs) 5 cm	○
500500.L5/L	ELECTRODE - Bent hook electrode (5 pcs) 10 cm	○

DIATERMO 50 T		
Code	**Description**	**Quantity**
500500.L6	ELECTRODE - Thick Wire Bent Electrode (5 pcs) 5 cm	○
500500.L6/L	ELECTRODE - Thick Wire Bent Electrode (5 pcs) 10 cm	○
500500.L7	ELECTRODE - Teardrop electrode (L7) (5 pcs) 5 cm	○
500500.L7/L	ELECTRODE - Teardrop electrode (L7) (5 pcs) 10 cm	○
500500.L8	ELECTRODE - Loop electrode (L8) (5 pcs) 5 cm	○
500500.L8/L	ELECTRODE - Loop electrode (L8) (5 pcs) 10 cm	○
500500.L9	ELECTRODE - Straight ball electrode ⌀ 3 mm (5 pcs) 5 cm	○
500500.L9/L	ELECTRODE - Straight ball electrode ⌀ 3 mm (5 pcs) 10 cm	○
5365A	NEUTRAL - Neutral steel electrode 120x160 mm	○
6429A	NEUTRAL - Steel neutral electrode 240x160 mm	○
F7520	Electrode cleaning sponge 47x50 mm	○
F7915	Conductive rubber neutral electrode without cable	○
F7920	Two-Piece Disposable Neutral Electrode (F7820)	○
F7930	Two-part conductive rubber neutral electrode without cable	○
00498.06	Neutral Electrode Adapter 6.3 mm/ Valley	○
00498.08	Bipolar Adapter EUR/2xM 2.5	○
00498.10	Bipolar Adapter EUR/3xM 4	○
330-134-20	Monopolar surgical forceps	○
TR003	Trolley 3 shelves	○
TR003W	Wide 3-shelf trolley	○
TR004	Trolley 4 shelves	○
TR005	Trolley 5 shelves	○
TR005W	Wide 5-shelf trolley	○

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

ELECTROPHYSICAL PRINCIPLES

In surgical procedures, the traditional use of the cold-blade scalpel has been largely replaced by the electrosurgical unit, which offers the possibility of performing tissue cutting and coagulation procedures quickly, easily and effectively.

The electrosurgical unit is built on the basis of the principle of conversion of electrical energy into heat (Joule's principle) and consists of:

- a radio frequency sinusoidal oscillator (0.4 - 4MHz);
- a wave packet generator, with a packet repetition rate of 15 – 30 kHz;
- a mixer for transferring to the power amplifier block either the only waveform suitable for cutting, or the waveform only for the clot, or a signal obtained by a suitable mixing of the two;
- a power amplifier block capable of supplying the necessary power in terms of current and transmitting the amplified signal to the electrodes, by means of a transformer;
- a safety circuit for the return electrode, to detect any cable breaks and deactivate the radio frequency delivery;
- a suitably shaped active electrode (handpiece);
- a return (neutral) electrode that closes the circuit through the patient.

The electric current that passes through biological tissue can usually cause:

1. ***Joule effect***
2. ***Faradic Effect***
3. ***Electrolyte effect***

1. *Joule Effect*

In the biological tissue, crossed by the electric current delivered by the electrosurgical unit, a heating (Joule effect) is produced, depending on the specific electrical resistance of the tissue, the current density, the time of application and which can lead to various cellular transformations.

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

The influence of the thermal effect (Joule effect) is achieved through:

- Current intensity and output power

- Degree of modulation
  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 surface of the tip [$A \cdot m^{-2}$] is very high. The thin-section electrodes create a high current density, a high temperature, favouring the cutting action. Those with a large surface area create a lower current density, a lower temperature, realizing a coagulation effect.

- Active electrode status
  The thermal effects are 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 so as not to have a reduction in effects.

- **Fabric characteristics**
  Resistive characteristics vary in relation to biological tissues.

Biological tissue (in the range of 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 material and metals)

Based on the temperature reached and depending on the pulse forms used, different techniques for the use of radio frequency current on the human body can be recognized:

- **Coagulation**
  Temperatures of 60 to 70 °C in the area around the active electrode cause the intra-cellular fluid to slowly heat up, the water contained in the cell evaporates, and a clot action is obtained that stops bleeding.

- **Electrotomy (Cutting)**
  Temperatures above 100 °C in the area surrounding the active electrode result in the vaporization of the intra-cellular fluid and the 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 not, therefore, a mechanical resection. If the temperature reaches 500 °C, tissue charring occurs with a cauterizing action.

- **Mixed currents**

  They 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 consistent layer of eschar.

  The high frequencies used by the electrosurgical unit, however, do not allow the electromagnetic field to penetrate the matter and cause the current to pass through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the center of the conductor section. This effect, called the "skin effect", leads to a decrease in the cross-section useful for the passage of current, an increase in the electrical resistance of the material and becomes a significant problem in the neutral electrode. In fact, in this electrode the current density is very high (KA/m^2) at the edge, where the excessive increase in temperature due to the 'Joule effect' causes burns to the patient. It is therefore no coincidence that the burns to the patient, which occurred in surgery, have the shape of the edge of the neutral electrode. To reduce the risk of burns, the power output ($I^2 \cdot t$) must be appropriately dosed and the rules for applying the neutral electrode to the patient must be followed (see *chapter SAFETY).*

2. *Faradic Effect*

The pulsed electric current causes neuro-muscular stimulation, originating from the stimulation of the physiological process of ion exchange, 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 pharadic effect and is expressed by:

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

The physiological stimulus transmission system follows a boundary curve in which pulsed or low-frequency currents generate a stimulation pulse. With the high-frequency alternating current (above 200 kHz), used in the electrosurgical unit, there are no neuromuscular reactions (the change of polarity is so fast that it does not affect the patient in terms of neuro-muscular reactions), nor electrolyte damage to the body.

For this reason, all high frequency generating equipment for surgical use (electrosurgical units) work on basic frequencies above 300 kHz so as not to introduce electrical stimulation.

3. *Electrolyte effect*

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

OPERATING TECHNIQUES

MONOPOLAR CUT

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

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

- keep the fabric moist but not wet;
- keep the electrode perpendicular to the tissue;
- activate the output circuit before making contact with the fabric;
- keep the electrode tip clean (use the optional F7520 electrode cleaning pads for this purpose);
- allow the fabric to cool before cutting again.

When the power output level is right, you should get:

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

MONOPOLAR COAGULATION

Monopolar coagulation is the hemostasis of small blood vessels in body tissue through the passage of high-frequency current at the active electrode. When the current density is reduced and a large surface area electrode is used to dissipate the energy over a larger area, the effect is to dry the surface of the cells, without deep penetration, resulting in coagulation. These coagulated cell surfaces act as an insulating layer, which prevents heat from subsequent current applications from penetrating too deeply. The current normally used for coagulation is modulated. Depending on the percentage of modulation, there is precision of the cut, goodness of the hemostasis and degree of destruction of the tissue. A greater modulation of the current leads to a more jagged cut, a greater depth of destroyed tissue but to a more effective coagulation.

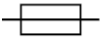
The following rules help the operator to achieve good coagulation:

- select a ball electrode or a thick wire;
- locate the bleeding vessel after wiping excess blood from the area;
- lightly touch the bleeding vessel before activating the electrode;
- stop activating the electrode as soon as the tissue whitens to avoid damaging it;
- keep the electrode tip clean (use the optional F7520 electrode cleaning pads for this purpose).

DESCRIPTION OF SYMBOLS

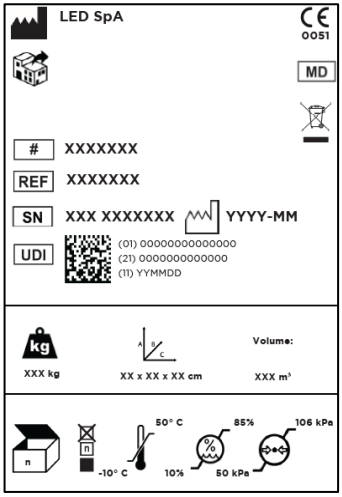
In accordance with the international standards ISO 15223-1:2021 "Medical devices - Symbols to be used in the information to be provided by the manufacturer" and ISO 780:2015 "Packaging - Packaging for distribution - Graphic symbols for handling and storage of packaging", all symbols on device labels 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 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		Serial number.
9		Date of manufacture.
10		Unique device identification.
11		Medical device.
12		Distributor.
13		No maintenance by the user.

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

PACKAGING 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**

CONTRAINDICATIONS

The use of electrosurgery is contraindicated in patients:

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

In the field of electrosurgery, high-frequency burns are the main injuries caused to the patient, although they are not the only ones. In fact, compression necrosis, allergic reactions to disinfectants, ignition of flammable gases or liquids are found.

Some of the primary causes of burns are attributable to:

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

In order to avoid or reduce the risks associated with the use of high-frequency electrosurgery, the rules and safety measures described in the next chapter must be observed.

SAFETY

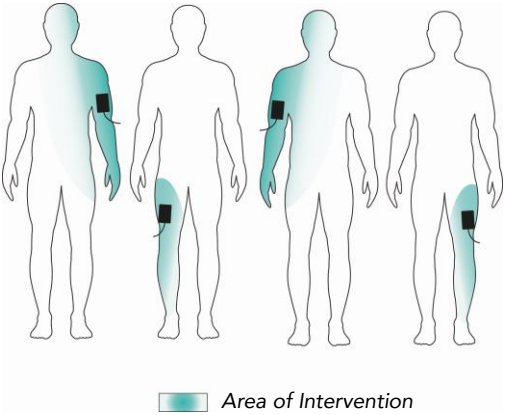
WARNING: Electrosurgery can be dangerous. Careless use of every element of the electrosurgical system can expose the patient to serious burns. Read all warnings, cautions, and directions for use before attempting to operate the equipment. LED SpA cannot be held responsible for direct or consequential damage or loss, to persons or property, resulting from improper use of the equipment and/or accessories.

The accessories, supplied or optional (refer to *STANDARD AND OPTIONAL COMPOSITION),* have characteristics compatible with the unit supplied, the same accessories may not be suitable for use with other electrosurgical equipment, the user should check before connecting other accessories to the unit that they have insulation characteristics compatible with the unit and the function used from time to time (make sure that they are compatible with the unit and the function used from time to time (make reference to the *chapter TECHNICAL CHARACTERISTICS).*
The integrity of the packaging of any sterile accessories must be checked before use.

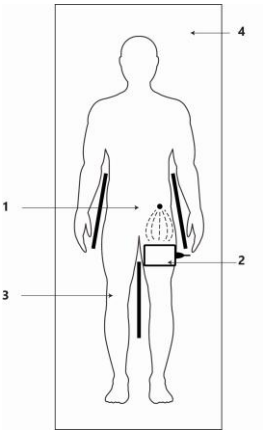
PRECAUTIONS

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

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



- Using single-use neutral electrodes, respect the expiration dates.
- When using multi-purpose electrodes, make sure that the fastening systems guarantee stability.
- When applying the neutral electrode, avoid the transverse path and prefer the vertical or diagonal path, especially if using a bipartite neutral electrode. This is to allow an even distribution of current on the surface of the neutral electrode and reduce the risk of burns to the patient.
- If it is not possible to apply the neutral electrode correctly, consider the bipolar technique instead of the monopolar technique if possible.
- The patient should not come into contact with metal parts that are grounded or have an appreciable grounding capacity (e.g. an operating table, supports, etc.). The use of an antistatic sheet is permitted for this purpose.
- Skin-to-skin contact (e.g. arm-to-trunk, leg-to-leg, breasts, etc.) should be avoided by inserting dry gauze. In addition, areas of the body subject to profuse sweating should be kept dry.



1. *Active Electrode* – **2.** *Neutral Electrode*
3. *Dry gauze* – **4.** *Antistatic Fabric*

- When the electrosurgical unit and a physiological monitoring device are used simultaneously on the same patient, all monitoring electrodes should be placed as far away from the surgical electrodes as possible. Needle monitoring electrodes are not allowed. In any case, monitoring systems incorporating high-frequency current-limiting devices are permitted.
- Surgical electrode cables should be positioned in such a way as to avoid contact with the patient or other conductors. Active electrodes, which are temporarily unused, must remain isolated from the patient.
- The use of bipolar techniques is allowed in the case of surgery on parts of the body with a relatively small cross-section, to avoid unwanted clotting.
- The set output power level should be as low as possible for the intended purposes.
- An evident low output level or incorrect operation of the electrosurgical unit, when it is set up for normal power delivery, may indicate a defective application of the neutral electrode or a bad contact in the connections of the

same. Therefore, the application of the neutral electrode and its connections should be checked before selecting a higher power.

- The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided in the case of chest or head surgery, unless it is possible to aspirate them. Non-flammable substances should be used for cleaning and disinfection wherever possible. Flammable substances used for cleaning, disinfection or as adhesive solvents should be allowed to evaporate before using the electrosurgical unit. There is a risk of stagnation of flammable solutions under the patient or in cavities such as the navel and vagina. Any fluid that settles in these areas should be removed before using the appliance. The danger of endogenous gases must be considered. Some materials such as cotton wool or gauze, when impregnated with oxygen, may ignite due to sparks produced by the appliance under normal conditions.
- There is a danger to patients with pacemakers (pacemakers) or pacing electrodes as interference with the action of the stimulator may occur or the stimulator itself may be damaged. In case of doubt, you should contact the Cardiology Department.
- Electrosurgical equipment emits high-frequency energy radiation without warning which may affect other medical equipment, unrelated electronics, telecommunications, navigation systems. To avoid interference, a distance of at least 1.5 meters must be placed between the electrosurgical equipment and other devices.
- The user should check the accessories regularly. In particular, electrode cables and any endoscopy accessories should be checked for damage.
- In order to connect accessories compatible with the characteristics of the equipment, the insulation characteristics of the accessories (to be requested from the manufacturers) must be compared with the characteristics of the unit supplied (refer to the *TECHNICAL CHARACTERISTICS* chapter).

- **Caution**: Failure of surgical equipment could result in an unintended increase in output power.

  Note: Stimulation of the patient's muscles or nerves can be caused by low-frequency currents originating from an electrical sparkle between the electrodes and the patient's tissue. If neuromuscular stimulation occurs during surgery, take the following measures:

  1. Suspend the intervention immediately.
  2. Thoroughly inspect all connections to the generator to identify any problems or loose connections.
  3. If the problem persists and cannot be resolved by checking the connections, the generator should be inspected by qualified personnel for necessary maintenance and troubleshooting.

INSTALLATION

- Electrical safety is ensured only when it is correctly connected to an efficient earthed power supply in accordance with current safety standards. This basic safety requirement should be checked and, if in doubt, the system should be thoroughly checked by qualified personnel. The manufacturer cannot be held responsible for possible damage caused by the lack of an efficient ground connection of the installation. Operation without protective ground connection is prohibited.
- Before connecting the equipment, make sure that the required voltage (indicated on the rear panel) corresponds to the available mains.
- In the event of incompatibility between the available power outlet and the power cord of the equipment, replace only with a suitable type. The use of adapters, multiple connections, or extension cables is not permitted. If their use is necessary, it is mandatory to use only single or multiple adapters that comply with current safety standards.

- Do not leave the appliance exposed to atmospheric agents (rain, sun, etc.). The device must be protected from the ingress of liquids.
- Do not leave the appliance inserted unnecessarily. Turn it off when not in use.
- The equipment is not suitable for use in explosive environments.
- The equipment must be intended only for the use for which it was specially designed. Any other use must be considered improper and dangerous. The manufacturer cannot be held responsible for possible damage due to improper, incorrect or unreasonable use.
- It is dangerous to modify or attempt to modify the characteristics of the equipment.
- Before carrying out any cleaning or maintenance operation, disconnect the appliance from the mains by removing the plug from the mains or turning off the main switch of the system.
- If the equipment breaks or malfunctions, switch it off. For repairs, refer only to an authorized service center and ask for the use of original spare parts. Failure to comply with the above regulations may risk the safety of the equipment and may be dangerous for the user.
- Do not reduce or eliminate the generator activation beep. A working activation signal can minimize or prevent injury to the patient or personnel in the event of accidental activation.
- The operation of the equipment must not be verified by emitting power between the active and neutral electrode or between the active electrode and metal parts.
- If necessary, use fume extraction means in the field of intervention.

WARNING: In operating room use, only dive-tight foot switches should be used (code 00304.00 watertight single foot pedal – code 00305.03 watertight double foot pedal board).

PATIENT SAFETY

During high-frequency electrosurgery the patient behaves like an electrical conductor. A potential difference different from zero is established between the patient and the earth and therefore, if contact were made between the patient and electrically conductive objects (metal, damp or wet cloths and cloths, etc.), an electric current would be generated at the point of contact which could give rise to thermal necrosis. It is therefore permitted to carry out appropriate checks of the appliance and its accessories before use and to comply with all the necessary safety regulations.

CORRECT PATIENT POSITIONING

Avoid any intentional or accidental contact between the patient and earthed metal parts and make sure that:

- The patient is not in contact with metal parts (operating table, supports).
- Any tubes of respirators do not rest on the patient's body.
- On the operating table with ground connection, there are always coatings capable of discharging electrostatic charges.
- The patient is placed on a thick base fabric with insulating properties, which in turn is covered with a sufficient number of intermediate layers of covering sheets.
- The patient is not in contact with damp sheets or mattresses.
- Any secretions from the body and liquids applied for cleaning purposes or other types of liquids do not wet the dry sheets.
- There are no fluid residues below the patient.
- Any urinary excretions are eliminated through the use of catheters.
- Regions of the body characterized by more intense sweating, extremities in direct contact with the trunk of the body or skin-to-skin contact points are

kept dry through the interposition of drapes (arm/trunk of the body, leg/leg, breasts, skin folds, etc.).
- All conductive and grounding brackets are properly insulated.
- Adjust the amount of anesthetics so that excessive sweating is avoided.

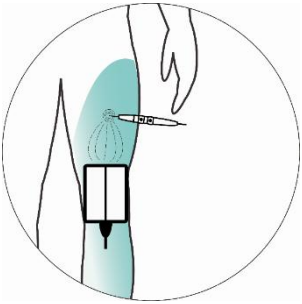
CORRECT APPLICATION OF THE NEUTRAL ELECTRODE

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

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

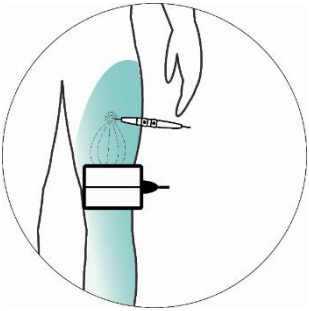
It is vitally important to pay special attention to the accurate positioning of the neutral electrode in order to prevent burns and minimize risk to the patient. Useful information is provided below:

1. *Correct positioning*



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

2. *Incorrect positioning*



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

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

Do not apply the neutral electrode to scars, bony protrusions, or anatomical parts where prosthetic implants or monitoring electrodes are present. Instead, apply it to well-supplied tissues, such as muscles and near the operative site.

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

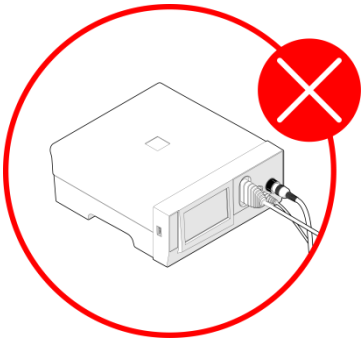
It is of paramount importance that the neutral electrode is firmly applied over its entire surface to avoid burns. When a neutral electrode partially detaches from the patient, the density of the current flow in the part of the electrode that is still applied is increased. Because the density of the current flow below the neutral electrode is inhomogeneous, uneven heating occurs, especially at the edges of the neutral electrode.

If the electrode were placed at a region under pressure during surgery, the compressive load would result in a reduction in skin perfusion. In this way, the heat developed can only be partially removed, so that the risk of burns increases. In addition, there is an increased risk of pressure point formation (decubitus) due to the heating that occurs. This increase in temperature causes a greater need for oxygen (O_2) and energy in the affected area, contributing to the possible development of areas of pressure on the body.

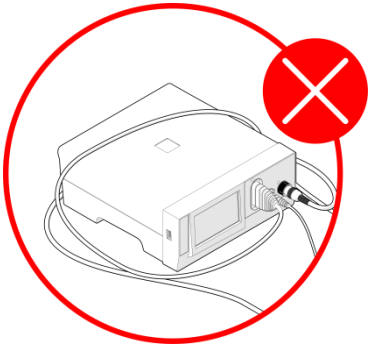
CORRECT CONNECTION OF ACCESSORIES AND/OR COMPONENTS

To ensure the proper functioning, safety, and durability of the medical device, it is crucial to position the accessories and/or components appropriately. Incorrect placement may impair the efficiency of the device or damage the equipment. Here is useful information about this:

1. **Incorrect positioning**
   The images below show two examples of incorrect cable placement: **braided and/or coiled cables** and **braided and/or coiled cables on top of the device**

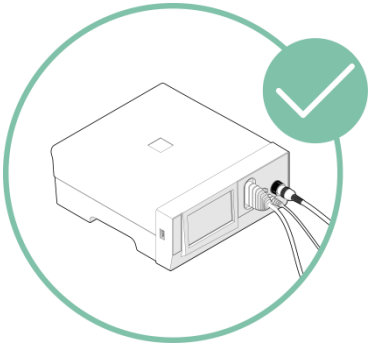


In the first case, cables that are twisted and/or coiled together tend to cause electromagnetic interference that can compromise the quality of the signal, interfering with the accuracy and effectiveness of the device. In addition, the continuous friction and tension created by the braid increase the wear and tear of the protective sheath, with the risk of malfunction.



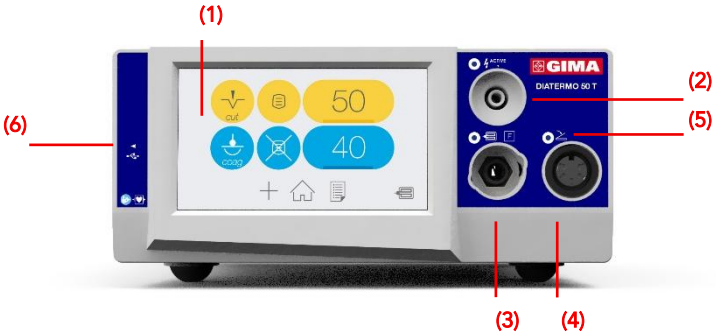
In the second case, the braided and/or coiled cables on top of the device experience excessive mechanical pressure that can cause tension points and accelerate wear, resulting in structural damage. In addition, coiling tends to retain heat, reducing the efficiency and flexibility of cables, making them more vulnerable to damage in the long term.

2. Correct positioning



The image on the side shows the correct positioning of the cables. The correct arrangement of the same requires that they are positioned in parallel and well separated from each other. This configuration minimizes the risk of electromagnetic interference and prevents cables from being damaged due to friction or overlapping. Cables arranged in parallel allow for an orderly flow that facilitates maintenance and quick identification of any problems. In addition, a tidy layout helps to keep the work area safer and free from possible obstacles.

FRONT PANEL



(1) Display Touchscreen
(2) Handpiece connector
(3) Neutral electrode connector
(4) Pedal connector
(5) Indicator lights (coagulation blue – cut yellow – stand-by mode)
(6) USB port

OPERATING MODES

CONTROL AND IGNITION

The unit is operated directly via the icons displayed on the device's touchscreen. To confirm a choice, simply tap the icon directly.

Once the electrosurgical unit is turned on, the specific software begins to load on the screen. The progress of the software application process is shown via the filling of the bar at the bottom of the screen.

When this process is complete, you will see the Home screen:

On the Home screen, you can select and interact with the following options:

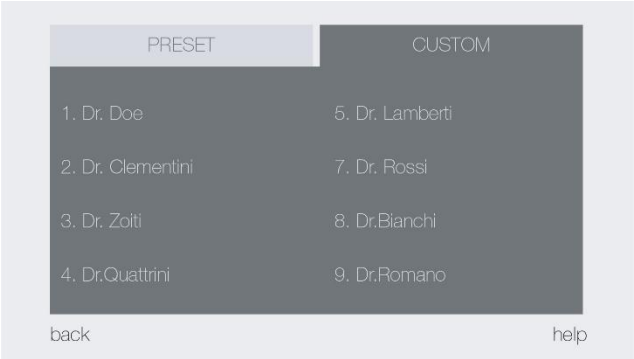
- Programs
- Surgery
- Settings
- Update (Updating the software via the USB port).

The "*Info*" option allows you to view the software versions that are currently installed. By pressing the "*Help*" button, you can access an informative summary that is useful for correctly interpreting the indications on the display.

PROGRAMS

Selecting the "*Programs* " option on the home screen will open two distinct pages:

1. **Presets**: This section will show the default programs that have already been configured and stored in the system. They represent standard settings for a variety of common surgical procedures.



Simply click "*Start Program*" to activate the preset program and make it ready to use.

2. **Custom:** This page will display programs that have been created and customized by you or your surgeon. These programs reflect the specific settings that the user has configured to address particular needs or unique procedures.

At first, the screen will appear blank. For instructions on how to create a custom program, please refer to the next paragraph ("*Programs Section* ").

Distinguishing between these two pages allows caregivers to easily access a range of predefined or customized settings, based on the specific needs of the surgery. This gives you flexibility in selecting settings depending on the context.

In addition, by using the "*Help*" button, you can get information about the features of the selected program. To return to the home page, simply select the "*Back* " option.

SURGERY

By selecting the "Surgery" option on the home page, the following screen will be displayed:

Through which it is possible to distinguish different sections:

(A) Cutting Section
(B) Coagulation Section
(C) Section for Adding New Programs
(D) Home icon
(E) Programs Section
(F) Neutral electrode circuit impedance indicator

Each of these options allows you to adjust various parameters, which will have the option to be saved as a new custom program.

PREPARATION OF THE CURRENTS THAT CAN BE SUPPLIED

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

CUT CURRENT

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

CURRENT FOR CUT-COAGULATED 1 (CUT 1)

The CUT1 current is suitable for coagulated shear when medium coagulation associated with shear is desired.

CURRENT FOR CUT-COAGULATED 2 (CUT 2)

The CUT2 current is suitable for coagulated shear when more clotting associated with shear is desired.

COAGULATION CURRENT (COAG)

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.

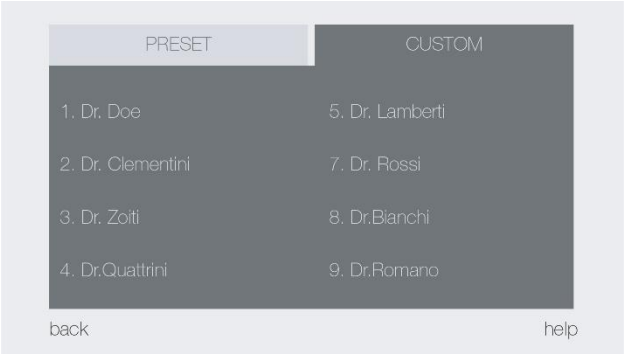
PROGRAMS SECTION

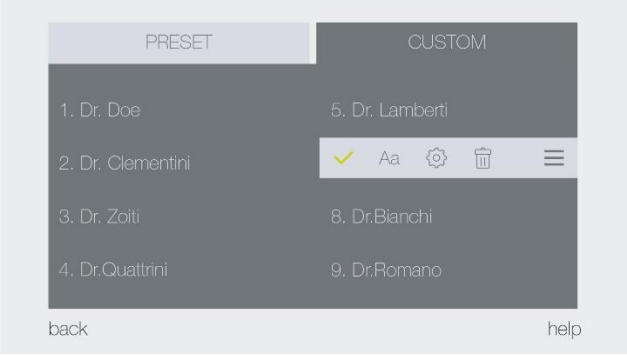
On the "*Surgery*" screen, you can add a custom program or view the programs present.

To create a new program, follow these steps:

- Set the desired values on the "*Surgery* " screen;
- Press on "+" and choose the name to be assigned, ending the process by clicking on "*enter* ";

The new custom programs can be viewed in the "*Programs* " section.





Through the icon representing three lines, you can perform different actions on the custom program:

Rename it.

Edit it

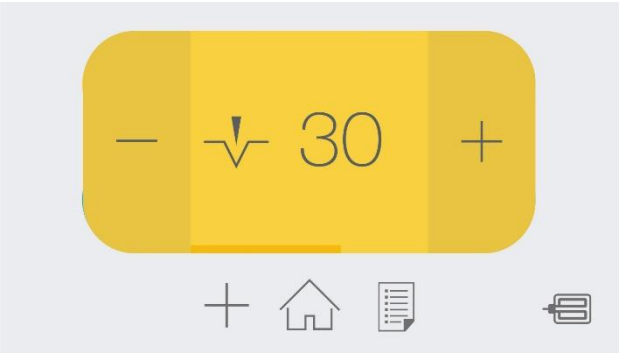
Delete it.

NEUTRAL ELECTRODE CONTROL

The neutral electrode circuit is continuously monitored by a special circuit that checks, only when bipartite neutral electrodes are used, that the loss of contact between the patient's reference plate or the variation in the conductivity characteristics of the neutral electrode may cause a reduction in the conductivity of the circuit and therefore an increased risk of burns for the patient.

In order to reduce noise pollution, the audible alarm only occurs if the discharge pedal is held down.
It is important to note that when using single-section neutral electrodes (single part) the circuit only controls the connection of the neutral electrode with the unit; Therefore, it is critical to ensure that the entire surface of the neutral electrode is applied correctly and securely to the patient.

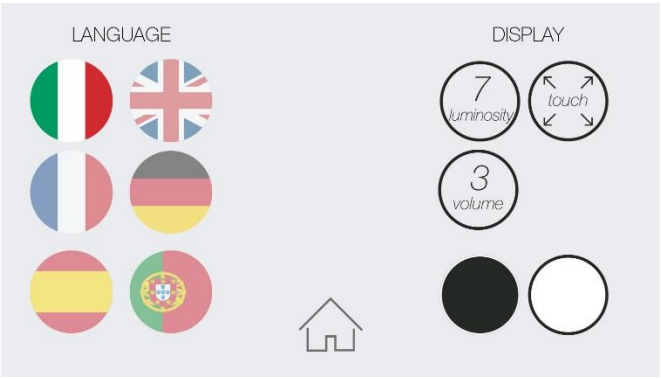
DISPENSING SCREEN



In the dispensing state, the function with its level will appear on the screen. This screen remains for a few seconds, during which you can adjust, with + and -, the output level.

SETTINGS

Starting from the home page and choosing the "*Settings*" option, the following screen will appear:



Through which it will be possible to view two sections:

- Language;
- Display, through which you can change the brightness, touch sensitivity, volume and black or white display.

UPDATES

Starting from the home page and choosing the "*Update*" option, it will be possible to update:

- Software,
- Images,
- Protocols.

To perform updates, you must connect a device that can be paired with the USB connector and contains the compatible file of the software, images, protocols, or firmware to be updated.

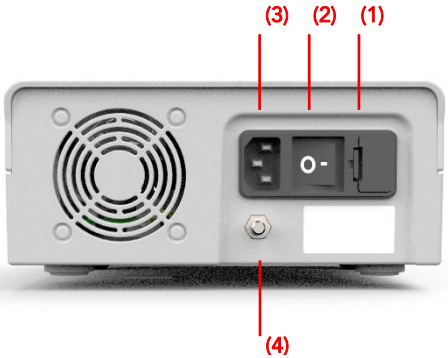
Follow these steps:

1. Insert the compatible device into the USB connector of the equipment.
2. On the screen, select the corresponding option from "Software," "Images," or "Protocols."
3. Afterward, confirm your selection via the popup that will appear.
4. Follow the on-screen instructions to complete the update process.

5. Once the update is complete, you can select the "Home" or "Back" option to exit the procedure and return to the home screen.

It is crucial to follow the on-screen instructions carefully throughout the entire process to ensure a successful and secure update.

REAR PANEL



(1) Fuse holder / Voltage selector switch
(2) Power switch
(3) Power socket
(4) Equipotential Bonding

EQUIPMENT POWER 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. The voltage selector switch is located inside the power supply module.

WARNING: Before switching on the equipment, the operator should ensure that the mains voltage indicated in the voltage selector corresponds to the voltage to

which it is connected and that fuses appropriate for the selected voltage have been inserted.

POWER SWITCH

The mechanical power switch is used to switch on the power supply to the equipment. To turn on the power to the equipment, press the switch in direction 1. When the power is on, the front panel is illuminated. Pressing the switch in direction 0 will disconnect the power supply, which allows the mechanical switch to be used as an emergency switch in the event of a fault.

TECHNICAL CHARACTERISTICS

Tol.	Description	DIATERMO 50 T
-	Electrosurgical Unit Code	GMA10100.T05
± 0%	Selectable minimum power	0
-	Power step	1
-	Digital power display	●
±20%	Maximum Power CUT (W)	50 → 400Ω
±20%	Maximum Power CUT 1 (W)	45 → 400Ω
±20%	Maximum power CUT 2 (W)	40 → 400Ω
±20%	Maximum Power COAG (W)	40 → 400Ω
± 5%	Modulation degree CUT	Pure 100%
± 5%	Modulation degree CUT 1 (@10 kHz)	Mod. 90%
± 5%	Modulation degree CUT 2 (@10 kHz)	Mod. 80%
± 5%	Modulation degree COAG (@10 kHz)	Mod. 60%
± 0.3	Crest Factor CUT	1.5
± 0.3	Crest Factor CUT 1	1.8
± 0.3	Crest Factor CUT 2	2.1
± 0.3	Crest Factor COAG	2.3
± 10%	Working frequency	600 kHz
± 15%	Maximum CUT voltage (Vpp)	1000
± 15%	Maximum voltage CUT 1 (Vpp)	1000
± 15%	Maximum voltage CUT 2 (Vpp)	1000
± 15%	Maximum COAG voltage (Vpp)	1000

Tol.	Description	DIATERMO 50 T
± 0.5	Weight	1.5 kg
± 10	Dimensions	94x194x233 mm
± 5%	Selectable Power Supply (Vac)	100-240
± 1%	Network frequency (Hz)	50-60
-	Power supply fuses (5x20) Time Delay	2x T2AL, 250V
± 10%	Maximum power consumption (VA)	200
-	Fault self-diagnosis	●
-	Connection of joined and bipartite electrodes possible	●
-	Storing Last Used Settings	●
-	Electrical Rating (EN60601-1)	Class I CF Applied Part
-	MDR 2017/745/EU classification	II b
-	Protection class (EN 60529)	IP32
-	EN55011 classification (CISPR 11) (Group/Class)	2 / A
-	Neutral electrode	F
-	Duty Cycle (Action/Pause) in seconds	10 / 30
-	Output Activation Type	Pedal
-	Defibrillator protection	●
-	Equipotential Bonding	●
-	ABS housing	●

● = PRESENT - = NOT PRESENT

HARDWARE REQUIREMENTS

Microcontroller	ARM Cortex M4
Clock Frequency	200 MHz
Flash	2048 KB
Ram	512 KB
SDRAM DDR2	512 MB
Nand Flash	1 Gb
Peripherals	UART, I2C, SPI, Watch-dog timer, USB2.0
Visual	4.3'' touchscreen display

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 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.
The unit does not respond to the actuation command.	Pedal failure. Incorrect connection of the pedal	Replace the foot pedal. Check the connection of the foot pedal.
Error Code 001	Dispensing commands activated during The ignition	Unplug the foot pedal and turn the unit back on.
Error Code 004	DAC not verified	Contact Technical Assistance.
Error Code 005	Error in the reference voltage	Check the supply voltage. Contact Technical Assistance.

REPAIRS

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

REPLACING THE FUSES

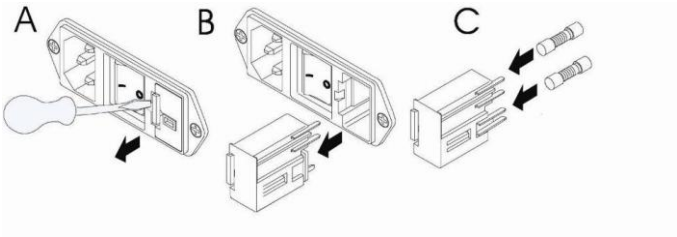
Before replacing the fuses, disconnect the equipment from the power supply.

To replace the fuses, use type 5x20 fuses from T2AL (time-delayed) and proceed as follows:

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

(C) Insert the fuses following this reference:

Voltage 100-240 V Time Delay Fuses 2xT2AL, 250V / 5 x 20 mm



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.

- With the neutral electrode control circuit closed, check the correct functioning of the acoustic/light emission indications by providing the CUT and COAG function.

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 50 T

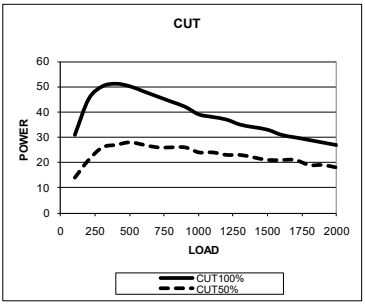


Diagram of maximum and medium power on variable load 100-2000Ω CUT

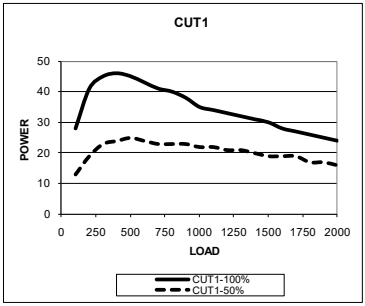


Diagram of maximum and medium power on variable load 100-2000Ω CUT1

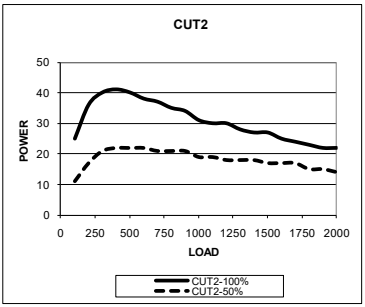


Diagram of maximum and medium power on variable load 100-2000Ω CUT2

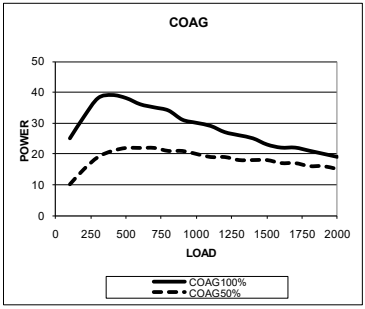
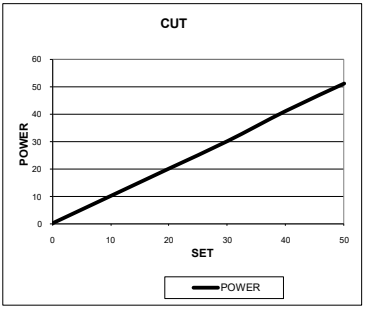
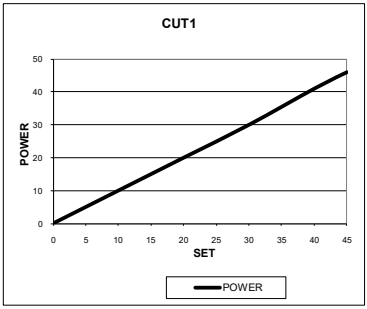


Diagram of maximum and medium power on variable load 100-2000Ω COAG

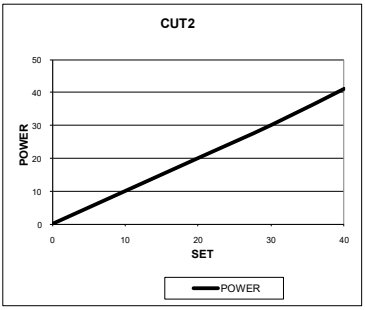


CUT Output Power Diagram on Rated Load

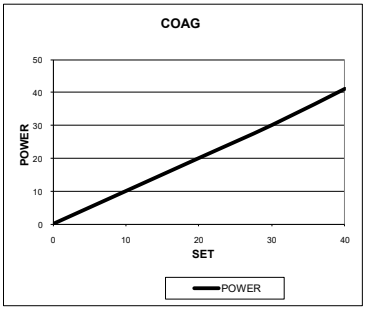


CUT1 Output Power Diagram on Rated Load

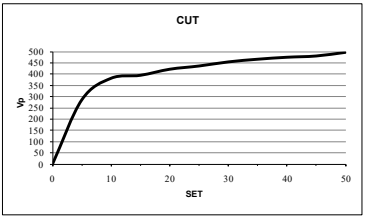
DIATERMO 50 T



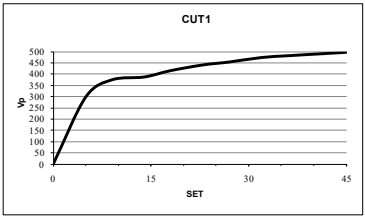
CUT2 Output Power Diagram on Rated Load



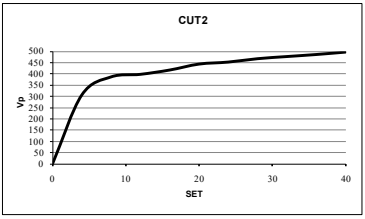
COAG Output Power Diagram on Rated Load



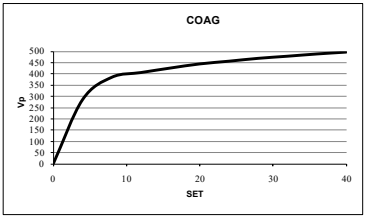
Maximum Output Voltage (Vp) Diagram for CUT



Maximum Output Voltage (Vp) Diagram for CUT1



Maximum Output Voltage (Vp) Diagram for CUT2



Maximum Output Voltage (Vp) Diagram for COAG

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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MA756B_EN

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