EN

DIATERMO 50-80

ELECTROSURGICAL UNIT USER MANUAL





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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

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

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INTRODUCTION

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 50** and **DIATERMO 80** equipment are designed to be used in the following sectors:

Description	DIATERMO		
	50	80	
Electrosurgical unit code	GMA10100.051	GMA10100.081	
Casualty Surgery	•	•	
Dental	•	•	
Dermatology	•	•	
Endoscopy	-	-	
First Aid	•	•	
Gastroenterology	-	-	
General Surgery	-	-	
Gynecology	-	-	
Neurosurgery	-	-	
Oftalmology	-	-	
Orthopedics	-	-	
Otorhinolaryngology	-	-	
Pediatric Surgery	-	-	
Plastic Surgery	-	-	
Pneumology	-	-	
Urology	-	-	
Vascular Surgery	-	-	

- = Usable
- = Not Usable

INTENDED USER

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

INTENDED USER

Adults - Men and Women (≥18 years), excluding patients present in the section "Contraindications".

STANDARD AND OPTIONAL COMPOSITION

	DIATERMO 50	DIATERMO 80
Electrocuraical Unit Code	GMA10100.051	GMA10100.081
	(30625)	(30626)

Codo	Description	DIATERMO	
Code	Description	50	80
30518	Monopolar disposable handpiece	∎/1	∎/1
00500.03	Assorted electrode kit (6Pcs) 5cm	∎/1	∎/1
00401.00 (30564)	Neutral metal electrode 120x160mm with 3 m cable	∎/1	∎/1
00304.00	Single tin pedal	∎/1	∎/1
00100.03	Power cable 2MT 3x1mm SIE-IEC	∎/1	∎/1
500500.L11	Microsurgery/depilation needles (10Pcs)	0	0
TR003	Trolley 3 shelves	0	0
TR003W	3 deck trolley	0	0
TR004	4 deck trolley o		0
TR005	5 shelves trolley o		0
00100.01	Power cable 5MT 3x1.5mm SIE-IEC o		0
00404.02	Neutral electrode connection cable	0	-
00404.07	Neutral electrode connection cable F7915/F7930	0	0
00404.08	Disposable neutral electrode connection cable	0	0
500500.L8/L	Loop electrode (5Pcs) 10cm o o		0
500500.L8	Electrode loop (5Pcs) 5 cm o		0
500500.L7/L	Drop electrode (5Pcs) 10cm o		0

Cada	Description	DIATERMO	
Code	Lode Description		80
500500.L7	Drop electrode (5Pcs) 5 cm	0	0
152-115	Blade electrode 16 cm	0	0
152-110	Blade electrode 7 cm	0	0
152-130	Ball electrode ø 2mm 6 cm	0	0
152-145	Ball electrode ø 3mm 14 cm	0	0
152-140	Ball electrode ø 3mm 6 cm	0	0
152-150	Ball electrode ø 4mm 6 cm	-	0
152-125	Needle electrode 13 cm	0	0
152-120	Needle electrode 7 cm	0	0
500500.L3/L	4 mm (5pcs.) 10 cm loop electrode	0	0
500500.L3	Loop electrode ø 4mm (5Pcs) 5cm	0	0
500500.L4/L	Loop electrode ø 8mm (5Pcs) 10cm	0	0
500500.L4	Loop electrode ø 8mm (5Pcs) 5cm	0	0
152-175-10	Loop electrode 10x10 l.15 cm	0	0
152-190-13	Loop electrode 20x13 l.15 cm o o		0
152-190-20	Bend electrode 20x20 l.15 cm o		0
500500.L2/L	Fine wire angled electrode (5pcs.) 10cmo		0
500500.L2	Fine wire angled electrode (5Pcs) 5cm o		0
500500.L6/L	Thick wire angled electrode (5Pcs) 10cm \circ		0
500500.L6	Thick wire angled electrode (5pcs.) 5cm o		0
500500.L10/L	Ball angled electrode ø 3mm (5Pcs) 10cm	0	0
500500.L10	Ball angled electrode ø 3mm (5Pcs) 5cm	0	0
500500.L5/L	Hook angled electrode (5Pcs) 5cm	0	0
500500.L5	Hook angled electrode (5pcs.) 5cm	0	0
152-112	Curved blade electrode 7 cm	0	0
152-132	Ball bent electrode ø 2mm 6 cm	0	0
152-142	Ball bent electrode ø 3mm 5 cm	0	0
152-152	Ball bent electrode ø 4mm 6 cm - o		0
152-122	Curved needle electrode 7 cm o o		0
500500.L1/L	Straight fine wire electrode (5Pcs) 10 cm	0	0
500500.L1	Fine wire straight electrode (5Pcs) 5cm	0	0
500500.L9	Ball straight electrode ø 3mm(5Pcs) 5cm	0	0
500500.L9/L	Ball straight electrode ø 3mm(5Pcs) 10cm	0	0
00403.01	Neutral bunch electrode	0	-

Cada	Description	DIATERMO	
Code	Code Description		80
F7930	Bipolar conductive rubber neutral electrode w/cable	-	0
F7915	Single-ended conductive rubber neutral o o		0
0350	Disposable neutral electrode	0	0
F7920	Disposable two-part neutral electrode	-	0
152-195	Electrode for conization 13 cm	0	0
00400.00	Bunch reference electrode with cable	0	0
00500.00	Assorted electrode kit (10 pcs) 5 cm	0	0
00500.00/L	Assorted electrode kit (10Pcs) 10cm	0	0
00201.01	Micro-needle handpiece	0	0
00206.00	Handpiece without buttons	0	0
F7520	Electrode cleaning sponge 47x50mm	0	0

■/pz = STANDARD

• = OPTIONAL

- = NOT COMPATIBLE

DESCRIPTION

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

DIATERMO 80 is an electrosurgical device capable of delivering currents suitable for cutting, coagulated cutting, coagulation and monopolar microcoagulation. The type of surgical operations that can be performed are those in which minor monopolar cutting or coagulation is required.

The types of surgical operation which can be carried out are those where monopolar minor electrosurgical cutting or coagulation is requested.

Power output can be active through single foot switch command.

The equipment is designed for desk-top use.

The most advanced electronic components and circuitry including LSI microcontrollers are applied to provide all the prerequisite for safe and reliable operation.

Control of the unit is via the front panel knob, keys and display; mains inlet and on/off switch are 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.

With the device is possible to use single plate neutral reference electrodes.

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	Motols
(range from 0,3 to 1 MHz)	Wetas
Blood 0,16 x 10 ³ Ω	Silver 0,16 x 10 ⁻⁵ Ω
Muscle, kidney, heart 0,2 x $10^3 \Omega$	Branch 0,17 x 10 ⁻⁵ Ω
Liver, spleen 0,3 x $10^3 \Omega$	Gold 0,22 x 10 ⁻⁵ Ω
Brain 0,7 x 10 ³ Ω	Aluminium 0,29 x 10⁻⁵ Ω
Lung 1,0 x 10 ³ Ω	
Fat 3,3 x 10 ³ Ω	

(Example of specific resistances of organic and metallic materials)

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

Coagulation

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

• Cut

Temperatures above 100 °C in the area surrounding the active electrode result in the vaporization of the intracellular fluid and explosion of the cell. The vapor present around the electrode triggers an intercellular chain reaction in the direction in which the active electrode is handled, also transmitting the vaporization energy to the immediately surrounding tissues.

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

Mixed currents

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

The high frequencies used by the electrosurgical scalpel, however, do not allow the electromagnetic field to penetrate matter and cause the current to flow through the conductor more on the outermost surface, decreasing exponentially and becoming negligible in the center of the conductor's cross-section. This effect, called the 'skin effect,' results in a decrease in the useful cross-sectional area for the passage of a current, and an increase in the electrical resistance of the material, and becomes a major problem in the neutral electrode. In fact, in this electrode the current density is very high (KA/m²) 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 no 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:

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 neuromuscular 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 TECHNIQUES

MONOPOLAR CUT

Monopolar cutting is the sectioning of biological tissue obtained from the passage of current, high frequency; high density concentrated by 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 another. 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 haemostasis. 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 get a good cut:

- Keep the tissues moist but not wet;
- Survey the stroke before activate the electrode;
- Keep the electrode perpendicular to the tissue;
- Activate the electrode before making contact with the tissue
- Maintain clean the electrode's tip (the optional sponges F7520 to clean the electrodes are usable);
- Wait at least five seconds before to repeat a stroke.

When the output power is properly set there should be:

- no resistance to the electrode movement through the tissue;
- no change in the cut surfaces color;
- no fibers of tissue remained onto the electrode.

MONOPOLAR COAGULATION

Monopolar coagulation is the haemostasis of small blood vessels of body tissue through the passage of high-frequency current at the active electrode. When the current density is reduced and a large surface electrode is used, to dissipate 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 deep. The current normally used for coagulation is modulated. Depending on the percentage of modulation, there is precision of the cut, goodness of haemostasis and degree of tissue destruction. A greater modulation of the current leads to a more jagged cut, to 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 or heavy wire electrode;
- Locate the bleeder, after having wiped the excess blood from the area, contact lightly the bleeder before activating the electrode;
- Stop the electrode activation as soon as the tissue blanches to avoid tissue damage;
- Maintain clean the electrode's tip (the optional sponges F7520 to clean the electrodes are usable).

MEANING OF GRAPHIC SYMBOLS

N°	SYMBOL	DESCRIPTION
1	F	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	E	Follow the instructions for use.
5	C E 0051	CE Mark (2017/745/EU) + Notified Body Number 0051 = IMQ Italy.
6	X	The product should not be disposed of in urban waste containers but must be disposed of through separate collection.
7	^	Manufacturer.
8	SN	Serial Number.
9	~~~	Production date.
10	UDI	Unique Device Identification.
11	MD	Medical Device.
12		Dealer.
13		No maintenance by the user.
14	REF	Catalogue number (Code).
15	ł	Temperature Limits.
16	<u>_</u>	Humidity Limits.
17	<u>_</u>	Atmospheric Pressure Limits.
18	<u>11</u>	This Way Up.

N°	SYMBOL	DESCRIPTION
19	Ĭ	FRAGILE – Handle With Care.
20	类	Keep away from sunlight.
21	Ť	Protect against moisture.
22	×	Number of maximum stackable packages.
23	o kg	Weight.
24	A B	Dimensions.
25		Number of Pieces.
26	\triangle	Recycle.
27	#	Model/Trade Name.
28	IP	Protection against harmful ingress of water or particulate matter.
29		Fuse.

BOX LABEL

With reference ISO15223-1 "Medical Devices-Symbols to be used with medical device, labels, labelling and information to be supplied" and ISO780 "Packaging – Pictorial marking for handling of goods" on box label of UNIT's carton box are present these indications:



9 10 11 12

1. ISO15223-1 (5.1.1) MANUFACTURER

8

- 2. ISO15223-1 (5.7.10) UDI code = EAN code
- 3. ISO15223-1 (5.1.6) CATALOGUE NUMBER
- 4. ISO15223-1 (5.1.7) SERIAL NUMBER
- 5. WEIGHT OF BOX
- 6. DIMENSIONS OF BOX
- ISO15223-1 (5.3.4) KEEP DRY (Transport package shall not be kept from moisture)
- ISO15223-1 (5.3.2) KEEP AWAY FROM SUNLIGHT (Transport package shall not be exposed to sunlight)
- **9.** ISO15223-1 (5.3.1) FRAGILE (Contents of the package are fragile therefore it shall be handled with care)
- **10.** STACKING LIMIT BY NUMBER (Indicates the maximum number of identical products that can be safely stacked on the bottom package)
- **11.** ISO780 (3) THIS WAY UP (Indicates correct upright position of the transport package)

- **12.** ISO 7001: 2007 RECYCLING (Indicates the location of a bin or container)
- **13.** CE + Notified Body Number for MD Class (2017/745/UE)
- **14.** ISO15223-1 (5.77) MD (Medical Device)
- **15.** ISO15223-1 (5.1.3) DATE OF MANUFACTURER
- **16.** ISO15223-1 (5.3.7) TEMPERATURE LIMITS (Indicates temperature limits within which the transport package shall be stored and handled)
- **17.** ISO15223-1 (5.3.8) HUMIDITY LIMITS (Indicates humidity limits within which the transport package shall be stored and handled)
- ISO15223-1 (5.3.9) ATMOSPHERIC PRESSURE LIMITS (Indicates atmospheric pressure limits within which the transport package shall be stored and handled)
- **19.** WEEE PRODUCT (Directive 2012/19/EU)

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.

COLLATERAL EFFECTS

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

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

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

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

SAFETY

WARNING: Electrosurgery carries inherent risks, and improper usage of any component within the electrosurgical system can result in severe burns to the patient. It is absolutely crucial that you meticulously read and comprehensively understand all instructions before attempting to utilize an active electrode. Neither the manufacturer nor any retailers can be held liable for any harm or damage, whether direct or indirect, caused to individuals or equipment due to the incorrect use of the device and its accompanying accessories.

The accessories provided with this unit are designed to be compatible specifically with this unit and may not work with other electrosurgical units. Prior to connecting any additional accessories to this unit, the user must confirm that these accessories possess insulation characteristics that align with those of this unit (please refer to the "TECHNICAL CHARACTERISTICS" section for details). The user 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 (N₂O) 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, it is allow to 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), you must use an antistatic drape for this purpose.
- To avoid skin-to-skin contact (e.g., between the arm and trunk, between the legs, or on the breasts), it's allowed to insert dry gauze. Additionally, ensure that body areas prone to profuse sweating are kept dry.



Active Electrode – 2. Neutral Electrode
 Dry Gauze – 4. Antistatic Drape

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

placement and connections of the neutral electrode before considering higher power settings.

- Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N2O) and oxygen, especially in chest or head operations, unless they can be safely aspirated. Whenever possible, opt for non-flammable substances for cleaning and disinfection purposes. If flammable substances are used for cleaning, disinfection, or as solvents for adhesives, they should be allowed to completely evaporate before using the electrosurgical unit. There is a risk of flammable solutions accumulating under the patient or in cavities like the umbilicus and vagina. Any fluid in these areas should be removed before using the device. It's important to consider the presence of endogenous gases as well.
- Be aware that certain materials, such as cotton wool or gauze impregnated with oxygen, may ignite due to sparks produced by the appliance under normal conditions. Take necessary precautions to prevent such incidents.
- Patients with pacemakers or pacing electrodes are at risk of interference with their pacemaker's functionality or potential pacemaker damage when exposed to electrosurgical equipment. If any uncertainty arises, it is allowed to consult the cardiology department.
- Electrosurgical equipment emits high-frequency energy radiation that can affect other medical devices, unrelated electronics, telecommunications systems, and navigation systems. To prevent interference, you must maintain a minimum distance of at least 1.5 meters between the electrosurgical equipment and other devices.
- Regularly inspect accessories, with special attention to electrode cables and any endoscopy accessories, to ensure there is no damaged insulation or other defects that could compromise their safety or effectiveness.
- To connect accessories compatible with the equipment's characteristics, you
 must compare the insulation characteristics of the accessories (information
 provided by the manufacturers) with the specifications of the supplied unit (as

outlined in the Technical Characteristics section). This step ensures proper compatibility and safe operation.

• **Caution**: Equipment failure could lead to an inadvertent increase in power output.

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

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

INSTALLATION

- Electrical safety is guaranteed only when the equipment is correctly connected to a reliable power supply network with proper grounding, in compliance with current safety standards. It is essential to ensure this fundamental safety requirement, and if there are any doubts, seek a comprehensive inspection of the system by qualified personnel. The manufacturer cannot be held responsible for potential damage caused by the absence of an efficient earth connection in the installation. Operating the equipment without a protective earth connection is strictly prohibited.
- Before connecting the equipment, verify that the provided voltage, as indicated on the rear panel, matches the voltage available in your mains power supply.

- In the event of any incompatibility between the power socket and the equipment's power cable, only replace it with a suitable type. It is not allowed to use adapters, multiple connections, or extension cables. If their use becomes necessary, it is mandatory to employ single or multiple adapters that comply with current safety standards.
- Protect the equipment from exposure to outdoor elements such as rain and direct sunlight. The apparatus must be shielded to prevent the infiltration of liquids.
- Do not keep the equipment plugged in unnecessarily. Turn it off when it is not in use to conserve energy and ensure safe operation.
- This equipment is not designed for use in explosive environments. Avoid using it in such environments where there may be a risk of ignition or explosion.
- The equipment should be used only for its intended purpose. Any other use should be considered improper and potentially dangerous. The manufacturer cannot be held responsible for any damage resulting from improper, incorrect, or unreasonable use.
- Modifying or attempting to modify the equipment is dangerous and should not be done. Altering the characteristics of the equipment can lead to unsafe operation and potential hazards.
- Before performing any cleaning or maintenance procedure, disconnect the appliance from the electrical supply by either unplugging it from the mains or turning off the main switch of the system.
- In the event of equipment breakage or malfunction, power it off immediately. For any necessary repairs, seek assistance only from an authorized service center and request the use of original spare parts. Failure to adhere to these regulations may jeopardize equipment safety and pose risks to the user.
- Do not reduce or disable the acoustic signal indicating generator activation.
 A functioning activation signal can help minimize or prevent injuries to patients or personnel in the event of accidental activation.

- Do not test the equipment's operation by generating power between the active and neutral electrode or between the active electrode and metal parts. Testing in this manner can be unsafe.
- If required, use appropriate fume extraction methods in the surgical field to manage the release of smoke or fumes generated during procedures.

ATTENTION: When using the equipment in an operating room, it is essential to utilize only immersion-tight foot switches (such as code 00304.00 for a single watertight pedal or code 00305.03 for a double watertight pedal). This ensures safety during surgical procedures.

PATIENT SAFETY

During high-frequency electrosurgery procedures, it's crucial to understand that the patient becomes a conductor of electrical voltage relative to the earth potential. Consequently, if there is contact between the patient and electrically conductive objects (such as metal objects, damp or wet sheets, cloths, etc.), it can result in the generation of electric current at the point of contact.

The user 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 (see above) setting is selected as shown in fig. E. Insert the correct fuses in the module referring to the value written on the label.
- The predisposition of the correct mains voltage is performed in the following way:
 - (A-B) Extract the fuse holder drawer from the power module.
 - (C) Insert the fuses referring to the following chart:

DIATERMO 50

Mains Voltage	110-120 V	Delayed Fuse 2x T2AL, 250V / 5 x 20 mm
Mains Voltage	220-240 V	Delayed Fuse 2x T1AL, 250V / 5 x 20 mm
DIATERMO 80		
Mains Voltage	110-120 V	Delayed Fuse 2x T4AL, 250V / 5 x 20 mm
Mains Voltage	220-240 V	Delayed Fuse 2x T2AL, 250V / 5 x 20 mm

(D) Extract and rotate the detachable part in way to read the correct voltage in the (E) window – reinsert the fuse holder in the module.



- 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, if request, the equipotential binding post located at the left of the unit's back panel to eventual 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 buckle indicated "ACTIVE".
- 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.

Environments condition:

Temperature: 10/40°C Relative Humidity: 30/75% Pressure: 70/106k Pa

- Before using the unit, it is necessary connect the cable to the patient plate, and these connected to unit. The neutral electrode must apply to patient (see Safety chapter). Single plate electrodes and split plate electrodes can be. When the unit is switched on if the value of the impedance is acceptable, the OC indicator light will stop flashing.
- When the unit is switched on, through the on/off switch on the rear 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).

DIATERMO 50FRONTAL PANEL



- 1. Level control
- 2. Level indications
- **3.** Selection key and light for CUT function
- Selection key and light for CUT 1 function
- Selection key and light for CUT 2 function
- **6.** Selection key and light for COAG function
- 7. Connector for neutral electrode connection
- 8. Handle connector for active electrode-holder
- 9. Foot-switch connector

DIATERMO 80 FRONTAL PANEL



- 1. Level control
- 2. Level indications
- **3.** Selection key and light for CUT function
- **4.** Selection key and light for BLEND function
- 5. Selection key and light for COAG function

- **6.** Selection key and light for MICRO function
- 7. OC Alarm indicator for excessive impedance in the neutral electrode circuit
- **8.** Connector for neutral electrode connection
- **9.** Handle connector for active electrode-holder
- 10. Foot-switch connector

DIATERMO 50 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.

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.

Coagulated-Cut Current (CUT 1)



The coagulated-cut current (CUT1) it is suited for coagulated cut when a medium coagulation together the cut is desired.

Coagulated-Cut Current (CUT 2)



The coagulated-cut current (CUT2) it is suited for coagulated cut when a more coagulation together the cut is desired.

Coagulation Current (COAG)



The modulated current 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.

DIATERMO 80 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.

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.

Coagulated-Cut Current (BLEND)



The coagulated-cut current (BLEND) it is suited for coagulated cut when a deep coagulation together the cut is desired. With this blending, a current suited for cut coagulated in absence of eschar and carbonization

is obtained.

Coagulation Current (COAG)



The modulated current 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.

Micro-Coagulation Current (MICRO)

<u>.</u>

Modulated current MICRO is suitable for little blood-vessel coagulation. The coagulation process is more checked and exact in this case.

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

For the meaning of this warning signal please 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.
- When the unit has finished to check internal parameters, on the display appears the message S + value of the preset level (example S3). Now, the CUT pushbutton can be released.
- **3.** Through the 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
S1	55 dBA
S2	60 dBA
S3	65 dBA
S4	70 dBA
S5	75 dBA

CONNECTORS NEUTRAL ELECTRODE CONNECTOR

This is the point of connection of the neutral electrode.

This is the point of connection of electrode handle.



HANDPIECE CONNECTOR

ACTIVE

FOOT-SWITCH CONNECTOR



On the left part of the front panel, it is foot-switch connector.

BACK PANEL



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

Power Supply Module and Voltage Selector

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

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

Power On-Off Switch

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

TECHNICAL CHARACTERISTICS

	DIATERMO 50	DIATERMO 80
Electrocurgical Unit Code	GMA10100.051	GMA10100.081
	(30625)	(30626)

T 1		DIATI	DIATERMO	
101.	Description	50	80	
± 0%	Minimum presectable power	0	0	
-	Level step	1	1	
-	Digital level display	•	•	
±20%	Maximum output power CUT (W)	$50 \rightarrow 400 \Omega$	$80 \rightarrow 400 \Omega$	
±20%	Maximum output power CUT 1 (W)	$45 \rightarrow 400 \Omega$	-	
±20%	Maximum output power CUT 2 (W)	$40 \rightarrow 400 \Omega$	-	
± 20%	Maximum output power BLEND (W)	-	$60 \rightarrow 400 \Omega$	
±20%	Maximum output power COAG (W)	$40 \rightarrow 400 \Omega$	$50 \rightarrow 400 \Omega$	
±20%	Maximum output power MICRO (W)	-	$20 \rightarrow 600 \Omega$	
± 5%	Modulation factor CUT	Pure 100%	Pure 100%	
± 5%	Modulation factor CUT 1 (@10 kHz)	Mod. 90%	-	
± 5%	Modulation factor CUT 2 (@10 kHz)	Mod. 80%	-	
± 5%	Modulation factor BLEND (@10 kHz)	-	Mod. 70%	
± 5%	Modulation factor COAG (@10 kHz)	Mod. 60%	Mod. 50%	
± 5%	Modulation factor MICRO (@10 kHz)	-	Mod. 50%	
-0.1 +0.2	Crest Factor CUT	1.5	1.5	
± 0.3	Crest Factor CUT 1	1.8	-	
± 0.3	Crest Factor CUT 2	2.1	-	
± 0.3	Crest Factor BLEND	-	1.9	
± 0.3	Crest Factor COAG	2.3	2.2	
± 0.3	Crest Factor MICRO	-	2.2	
± 10%	Working frequency	600 kHz	700 kHz	
± 15%	Maximum output voltage CUT (Vpp)	1000	1000	
± 15%	Maximum output voltage CUT 1 (Vpp)	1000	-	
± 15%	Maximum output voltage CUT 2 (Vpp)	1000	-	
± 15%	Maximum output voltage BLEND (Vpp)	-	1000	
± 15%	Maximum output voltage COAG (Vpp)	1000	1000	
± 15%	Maximum output voltage MICRO (Vpp)	-	900	
± 0.5	Weight Kg	2.5	2.5	
± 10	Size WxHxD mm	190x85x239	190x85x239	
± 5%	Selectable power (Vac)	115 –230	115 –230	

Tal	Description	DIATERMO	
I OI.	Description	50	80
± 1%	Mains frequency (Hz)	50-60	50-60
-	Fuses (230Vac) 5x20 type TIMED	2x T1AL, 250V	2x T2AL, 250V
-	Fuses (115Vac) 5x20 type TIMED	2x T2AL, 250V	2x T4AL, 250V
± 10%	Electrical input power (VA)	280	280
-	Self-check	•	•
-	Split or not split patient plate allowed	-	•
-	Last working condition storing	•	•
-	Electrical Class (EN60601-1)	CLASS I APPLICATED PART CF	CLASS I APPLICATED PART CF
-	MDR 2017/745/UE Class	ll b	ll b
-	IP Protection Class (EN 60529)	IP32	IP32
-	EN55011 (CISPR 11) Class (Group / Class)	2/A	2 / A
-	Patient circuit	F	F
-	Duty Cycle (action / pause) in seconds	10 / 30	10 / 30
-	Output power control	Foot-switch	Foot-switch
-	Defibrillation-proof	•	•
-	Equipotential binding	•	•
-	ABS cabinet	•	•

• = PRESENT - = NOT PRESENT

HARDWARE REQUIREMENTS

Microcontroller	ARM Cortex M4	
Clock Frequency	100 MHz	
Rom	256 KB	
Ram	128 KB	
Peripherals	UART, I2C, SPI, Watch-dog timer, USB2.0	
Visual	Display 7-segments, mechanical buttons	

MAINTENANCE

GENERAL

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.
The unit doesn't respond to the command of activation	Breakdown of the pedal Wrong connection of the	Replace the pedal. Verify the connection of the pedal.
Error Code 91	Current delivery control activated during switching on.	Disconnect the pedal and switch on the unit again.
Error Code 92	Error in the management board.	Call for Service.
Error Code 93	Error in the management board.	Call for Service.
Error Code 94	Error in the data conversion circuit.	Call for Service.
Error Code 95	Error of the reference voltage value.	Verify the main voltage. Call for Service.
Error Code 99	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: T3.15A (slow) (230Vac mains voltage), T6.3A (115Vac mains voltage), proceed as follows:

(A-B) Extract the fuse holder drawer from the power module.

(C) Insert the fuses referring to the following chart:

DIATERMO 50

Mains Voltage	110-120 V	Delayed Fuse 2x T2AL, 250V / 5 x 20 mm
Mains Voltage	220-240 V	Delayed Fuse 2x T1AL, 250V $$ / 5 x 20 mm $$

DIATERMO 80

Mains Voltage	110-120 V	Delayed Fuse 2x T4AL, 250V / 5 x 20 m	ım
Mains Voltage	220-240 V	Delayed Fuse 2x T2AL, 250V / 5 x 20 m	ım

(D) Extract and rotate the detachable part in way to read the correct voltage in the (E) window – reinsert the fuse holder in the module.



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 activating the 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











impedance load 100-2000Ω COAG

Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND







Diagrams of CUT maximum mains voltage output versus Vp versus Vp



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

Official Dealer

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