

DIATERMO

50 / 80

MONOPOLAR ELECTROSURGICAL UNIT



DIATERMO 80



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Instruction's Manual

ENGLISH

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IMPORTANT

These operating instructions form an integral part of the equipment and must be available to the operating personnel at all times.

All the safety instructions and advice notes are to be observed. Be sure that these operating instructions are furnished together the equipment when this is transferred to other operating people.

In case of necessity of technical, or other type, assistance contact your own retailer.

Produttore / Manufacturer

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INTRODUCTION

Destinazione d'Uso / Settori di Applicazione

The use of HF electro surgical equipment **DIATERMO 50** and **DIATERMO 80** has reserved to specialized medical personnel. The equipment has destined to a temporary use, for monopolar minor surgery operations. It has foreseen its use in the monopolar cut, cut coagulated and coagulation mode.

The equipment is conceived for being used in the following sectors:

Description	DIATERMO	
	50	80
Electrosurgical unit code	GMA10100.051	GMA10100.081
Casualty Surgery	●	●
Dental	—	○
Dermatology	●	●
First Aid	●	●
Vascular Surgery	○	●
Veterinary ¹	—	○

● = Recommended ○ = Usable — = Not Recommended / Not Usable

Standard and Optional Composition

REF (GIMA code)	Description	DIATERMO	
		50	80
-	Electrosurgical unit code	GMA10100.051 (30625)	GMA10100.081 (30626)
(30518)	Disposable handle without finger switches	●/1	●/1
00500.03	Kit of assorted electrodes(6pcs) 5cm	●/1	●/1
00401.00 (30564)	Steel neutral electrode 120x160mm with cable 3 mt	●/1	●/1
00304.00	Waterproof foot switch	●/1	●/1
00100.03	Power supply cable 2m 3x1mm SIEMENS-IEC	●/1	●/1
152-132	Ball curved electrode Ø2mm 6 cm	○	○
152-142	Ball curved electrode Ø3mm 5 cm	○	○
152-152	Ball curved electrode Ø4mm 6 cm	—	○
152-130	Ball electrode Ø2mm 6 cm	○	○
152-145	Ball electrode Ø3mm 14 cm	○	○
152-140	Ball electrode Ø3mm 6 cm	○	○
152-150	Ball electrode Ø4mm 6 cm	—	○
500500.L10/L	Bent ball electroØ3mm (5Pz) 10cm	○	○
500500.L10	Bent ball electroØ3mm (5Pz) 5cm	○	○
500500.L5/L	Bent hook electrode (5Pz) 10cm	○	○
500500.L5	Bent hook electrode (5Pz) 5cm	○	○
500500.L6/L	Bent thick wire electrode (5Pz) 10cm	○	○
500500.L6	Bent thick wire electrode (5Pz) 5cm	○	○
500500.L2/L	Bent thin wire electrode (5Pz) 10cm	○	○

¹ For small pet

REF (GIMA code)	Description	DIATERMO	
		50	80
500500.L2	Bent thin wire electrode (5Pz) 5cm	○	○
152-112	Blade curved electrode 7 cm	○	○
152-115	Blade electrode 16 cm	○	○
152-110	Blade electrode 7 cm	○	○
00404.07	Cable for connection neutral electrode F7915/F7930	○	○
00404.08	Cable for connect.neutral electrode disposa.type	○	○
00404.02	Cable for rod neutral electrode	○	—
F7915	Conductive rubber neutral electrode without cable	○	○
F7930	Conductive rubber split neutral electrode without cable	—	○
152-195	Conization electrode 13 cm	○	○
0350	Disposable Neutral electrode	○	○
F7920	Disposable Split Neutral electrode	—	○
500500.L7/L	Drop electrode (L7) (5pcs)10cm	○	○
500500.L7	Drop electrode (L7) (5pcs)5 cm	○	○
F7520	Electrode cleaning sponge 47x50mm	○	○
00201.01	Handle for microsurgical needle	○	○
00500.00/L	Kit of assorted electrodes(10pcs) 10cm	○	○
00500.00	Kit of assorted electrodes(10pcs) 5cm	○	○
500500.L3/L	Loop electrode ∅ 4mm (5Pz) 10cm	○	○
500500.L3	Loop electrode ∅ 4mm (5Pz) 5cm	○	○
500500.L4/L	Loop electrode ∅ 8mm (5Pz) 10cm	○	○
500500.L4	Loop electrode ∅ 8mm (5Pz) 5cm	○	○
152-175-10	Loop electrode 10x10 l.15 cm	○	○
152-190-13	Loop electrode 20x13 l.15 cm	○	○
152-190-20	Loop electrode 20x20 l.15 cm	○	○
152-122	Needle curved electrode 7 cm	○	○
152-125	Needle electrode 13 cm	○	○
152-120	Needle electrode 7 cm	○	○
500500.L11	Needles for micro-surgery (10Pcs)	○	○
500500.L8/L	Noose electrode (L8) (5pcs) 10cm	○	○
500500.L8	Noose electrode (L8) (5pcs) 5 cm	○	○
00100.01	Power supply cable 5m 3x1.5mm SIEMENS-IEC	○	○
F4814	Reusable handle without finger switches	○	○
00403.01	Rod neutral electrode	○	—
00400.00	Rod neutral electrode with cable	○	○
500500.L9/L	Straight ball electrode ∅ 3mm (5pcs) 10cm	○	○
500500.L9	Straight ball electrode ∅ 3mm (5pcs) 5cm	○	○
500500.L1/L	Straight thin wire electrode (5pcs) 10cm	○	○
500500.L1	Straight thin wire electrode (5pcs) 5cm	○	○
TR003	Trolley 3 shelves	○	○
TR003W	Trolley 3 shelves	○	○
TR004	Trolley 4 shelves	○	○
TR005	Trolley 5 shelves	○	○

●/ Pcs= STANDARD

○= OPTIONAL

— = NOT COMPATIBLE

General Description

DIATERMO 80 is an electro-surgical equipment suited to deliver current for monopolar cut, cut-coagulation, coagulation and micro-coagulation.

DIATERMO 50 is an electro-surgical equipment suited to deliver current for monopolar cut, cut-coagulation and coagulation.

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 **DIATERMO 80** is possible to use either single plate neutral reference electrodes or electrodes with split conductive zone.

With **DIATERMO 50** is possible to use either single plate neutral reference electrodes.

ELECTROPHYSICAL PRINCIPLES

In the electrosurgical interventions the traditional use of blade surgical is substituted by electrosurgical needle that allows making in a fast, simple and effective way the cut and coagulation.

The electrosurgical needle is made on the principle of electrical energy conversion in heat and it's constituted by:

- a sinusoidal oscillator in radiofrequency;
- a generator of wave packets, with repetition frequency of packets equal to 15 – 30 kHz;
- a mixer for the transfer, to the power amplification block, of the only wave form adapt to the cut, or the only wave form for the coagulum, or a signal obtained by an opportune mixing of the two;
- a power amplification block able to supply the necessary power in terms of current and to transmit to the electrodes, by transformer, the amplified signal;
- a security circuit for the return electrode (for over 50W), to take possible cable interruptions and disarm the radiofrequency supply;
- by an active electrode opportunely shaped (handle);
- by a return electrode (neutral) that close the circuit by the patient.

The current that crosses the biological tissue can cause:

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

1) Joule Effect

In the biological tissue, crossed by electrical current, it's produced a heating (thermal effect), dependent by the electrical resistance of the tissue, by the current density, by the application time and that can determine many cellular transformations.

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

The thermal effect influence (Joule Effect) is made by:

- **Current Intensity and output power**
- **Modulation level**

Parameters interpretable by the wave form of the high frequency current produced by the generator.

- **Electrode shape**

The electrode shape can be needle or rounded according to the necessity, it has reduced dimension; for this the current density on the point surface [$A \cdot m^{-2}$] is highest. The electrodes with a thin section create a high current density, and high temperature, favoring the cut action. Those with a big surface create a smaller current density, a smaller temperature, realizing a coagulation effect.

- **State of active electrode**

The thermal effects can be reported to the human body resistance, to which must be added the electrode contact resistance. It's indispensable to maintain the active electrodes perfectly clean to not have a reduction of it.

- **Characteristics of the tissue**

The resistive characteristics change according to the biological tissues.

Biological tissue (range from 0,3 to 1 MHz)	Metals
Blood $0,16 \times 10^3$	Silver $0,16 \times 10^{-5}$
Muscle, kidney, heart $0,2 \times 10^3$	Branch $0,17 \times 10^{-5}$
Liver $0,3 \times 10^3$	Gold $0,22 \times 10^{-5}$
Brain $0,7 \times 10^3$	Aluminum $0,29 \times 10^{-5}$
Lung $1,0 \times 10^3$	
Fat $3,3 \times 10^3$	

(Example of specific resistances of organic and metallic materials)

According to the come temperature and in function of used pulse form, it's possible to recognize many types of effects produced by the current in radiofrequency on the human body:

Coagulation

Temperatures from 60 to 70 °C in the area around the active electrode cause a slow heating of intra-cellular liquid, the water contained in the cell evaporates and an action of coagulum is obtained, so the blood flow is stopped.

Cut

Temperature over 100 °C in the area around the active electrode determines the evaporation of the intracellular liquid and the cell explosion. The vapor around the electrode baits a chain reaction in the direction where the active electrode is worked, transmitting the evaporation energy to the tissues around it.

The cut isn't, for this, a mechanical resection. If the temperature comes to 500 °C it's verify the tissue with an action of cauterization.

Mixed currents

They are obtained by the mixing of coagulation and cut effects. There is a reduction of blood loss during the cut procedure, or like cut that develops a substantial eschar coat. The high frequency used by electro-surgical needle, don't allow to the electromagnetic field to penetrate deeply in the matter and so the current crosses the conductor mostly in the external surface, reduces in an exponential way and becomes negligible in the centre of the conductor section. This effect, called 'skin-effect' cause a reduction of the useful section for the current passage, an increase of the electrical resistance and becomes an important problem in the neutral electrode. In fact in this electrode the current density is very high (KA/m^2) on the edge, where the excessive increase of temperature by Joule effect causes burns for the patient. So it isn't accidental that the burns for the patient, during the electro-surgical interventions, have the shape of the edge neutral electrode. To reduce the burns risk have to dose opportunely the supply power ($I^2 \cdot t$) and to follow the rules for the application of the neutral electrode on the patient (see cap. SAFETY).

2) Faradic Effect

The pulsed current causes the neuro-muscular stimulation, originated by stimulation of physiologic process of ionic exchange, responsible of the transmission of stimulus that cause muscular spasms and cardiac symptoms of extra systole and ventricular fibrillation.

The effect of this stimulus is known like faradic effect and it is expressed by:

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

The physiologic system of stimulus transmission follows a limit curve in which the pulsed currents or by low frequency produce an impulse of stimulation. By alternating current in high frequency (higher than 200 kHz), used in the electro-surgical needle, don't have neuro-muscular reactions (the change of polarity is so fast that the patient doesn't have consequences at a level of the neuro-muscular reactions), and there isn't an electrolytic damage of the organism.

For this reason all the equipments generator of the high frequency for surgical use (electro-surgical needle) work on base frequencies higher than 300 kHz so that they don't produce electric stimulation.

3) Electrolytic Effect

The use of high frequency currents reduces the electrolytic effect (ionic division) in the tissues, caused by the shortest period of unidirectional conduction of the current.

OPERATIVE TECHNICS

Monopolar Cut

Monopolar cut is the sectioning of the biological tissue achieved by the high-density passage of HF current, which is concentrated at point of the active electrode. The HF current, when it is applied to the tissue, through the point of the active electrode, it creates intense molecular heat in the cells so high that explosion of it is caused. The cut effect is achieved by moving the electrode through the tissue and destroying the cells one after the other. The movement of the electrode prevents the propagation of the side heat in the tissue, thus limiting to a single line the cells' destruction.

The best HF current for cutting is pure sine wave without any modulation that cuts very smoothly and provides the least thermal effect with poor haemostasis while cutting. Because its effects can be precisely controlled, it can be used safely without damage to the bone, but since good coagulation while cutting is one of principal benefits of using electro surgery a current with a certain amount of modulation is desirable.

The following rules help the operator to obtain good cutting, however every user must follow first of all his professional judgment as he does every time in his practice.

- 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 advised);
- 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 vessel of the bodily tissue through passing of high frequency current in correspondence of active electrode. When the current density is reduced and a broad-surfaced electrode is used, to dissipate the energy over a larger area, the effect is to dry out the surface cells, without deep penetration, resulting in coagulation. These coagulate surface cells then serve as a layer of insulation, preventing heat derived by successive applications of current from penetrating too deeply. The current normally used for coagulation is modulated and depending from the modulation percentage is the smoothness of cutting, goodness of haemostasis and likelihood of tissue destruction. Deeper current modulation brings to somewhat roughly cutting and the chance of some slight depth of tissue destruction but more efficient coagulation.

The following rules help the operator to obtain good coagulation: however every user must follow first of all his professional judgment as he does every time in his practice:

- Select a ball or heavy wire electrode;
- Locate the bleeder, after have 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 advised).

CONTRAINDICATIONS AND COLLATERAL EFFECTS

Electro surgery is not recommended in the following subjects:

- having pacemaker;
- with stimulating electrodes;
- with metal prosthesis plant;
- with important arterial pressure unbalance;
- with important nervous disorders;
- with renal insufficiency;
- in state of pregnancy.

Burns are the most consequences of the HF electro surgery for the patient, even if these are not the only one. In fact necrosis by compression, allergic reactions to the disinfectant, gas or inflammable liquids ignition.

Some important causes of burns are by:

- insufficient medical equipe training about all modalities to avoid or reduce the risks of burns by using HF electrosurgical units;
- use of disinfectants with high alcol 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 common HF electrosurgical risks it is very important to respect the rules and safety measurements exposed illustrate on the next chapter.

SAFETY

WARNING: Electro-surgery can be dangerous. Careless use of any element in the electrosurgical system may subject the patient to a serious burn. Read and understand all warnings, precautions, and directions for use before attempt to use any active electrode. Neither LED SpA, can be considered responsible for personal, material or consequential injury, loss or damage that results from improper use of the equipment and accessories.

The accessories supplied with the unit have characteristics compatible with this supplied unit, they could be incompatible with others electrosurgical units; the user must check, before connecting other accessories to this unit, that they have characteristics of insulation compatible with those of this unit and utilized function (see Technical Characteristics).

It is recommended to inspect the integrity of the packaging of the sterile products.

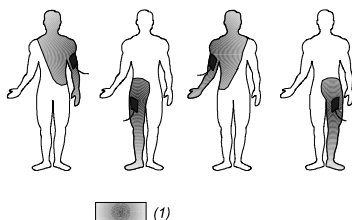
General

The following precautions reduce the risk of accidental burnings

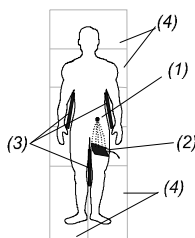
- The whole surface of the patient plate must be placed on a well-vascularized muscle as next as possible to surgical area. Avoid connecting the patient plate to bony protrusions, prosthesis, cicatricial tissues, and parts of the body subjected to liquid accumulation or that present subcutaneous adipose tissue. The part of the body must be without hair, dry and clean. Do not use alcohol to clean the skin.

Unless for veterinary use, the use of gelatinoids substances for the electrodes is not advised.

- By using the disposable neutral electrodes respect the date of expire.
- By using the reusable electrodes ascertain that the fixing systems give warranty of stability.
- When you apply the neutral electrode avoid the transversal course and prefer the vertical or diagonal course, in particular if a split neutral electrode is used. That to allow a uniform distribution of the current on the surface of the neutral electrode and reduce the risk of burn to the patient.
- The patient does not must be in contact with metal parts that are connected to the earth or have a large electrical coupling capacity to the earth (for example: operating-table or metallic support). The use of antistatic sheets is advised.
- Avoid the skin to skin contact (for example between arm and body of the patient). Insert an interface material like dry surgical gauze. Moreover, the parts of the body subjected to abundant perspiration must be maintained dry.



(1) Treatment area



(1) Active electrode - (2) Neutral Electrode (3) Dry gauze - (4) Antistatic cloth

- When high frequency electrosurgical unit and physiological monitoring devices are used at a time in the same patient, all the monitoring electrodes, that have not resistive or inductive elements tested in high frequency interference environment, must be as far as possible from the electrodes of the electrosurgical unit. Avoid the use of monitoring needles.
- The connection to the electrodes should be located in such a way to avoid the contact both with the patient and with other cables.
- The power level should be the lowest useful to the work to do.
- Always check the return plate whenever electrosurgical unit fails to produce the desired effect. Reason for a low output power level, or for an incorrect functioning of the electrosurgical unit when arranged for a normal output, may be lack of connection of the return plate or its imperfect placement.
- The use of flammable anesthetics, of oxygen and of nitrogen protoxide should be avoided in the case of operation at the head or at chest level except the possibility of evacuating gas. Flammable materials used to clean, or to disinfect, should be let to evaporate before the use of the electrosurgical unit. There is risk of stagnation of flammable solutions under the patient or in body cavities as the umbilicus and the vagina. The fluid that deposits in these areas should be removed before the equipment use. The danger of endogenous gas ignition has to be considered. Some materials like cotton wool or gauze, when saturated with oxygen, may burst into flames because of the sparks produced by the equipment in the normal use.
- There is a risk for the patients fitted with heart pacemaker or other stimulation electrode: interference may occur with the stimulator signal or the stimulator itself can be damaged. Please refer to Cardiology Unit when in doubt.

- Electrosurgical equipment does emit unnoticed radiation of high frequency energy that may effect other medical equipment, unrelated electronics, telecommunications, and navigational systems.
- The accessory must be regularly checked, particularly the cables for the electrodes and the possible accessories for the endoscopy to verify that the insulation is not damaged.
- To avoid the connection of incompatible accessories to the unit, the insulation characteristics of the items to be replaced must be requested to the manufacturer and compared to those of the supplied unit (see Technical Characteristics).
- **Attention:** a damage of the electrosurgical unit could result in an unwanted increase of the output power.
- Inadvertent stimulation of a patient's muscle and nerves can be caused by low frequency currents originating in electric sparks between electrode and tissue of the patient. Should neuromuscular stimulation occur stop surgery and check all connections to generator. If this does not solve the problem, qualified service personnel must inspect generator.

Installation

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

- Do not reduce or disable the audible signal warning the activation of the generator. A functioning activation signal can minimize or prevent patient or staff injury in the event of accidental activation.
- Avoid verifying the functioning of the unit by shorting the active electrode with the reference one or the active electrode with metallic parts.
- If necessary use a smoke-plume extraction system.

WARNING: When the electrosurgical unit is used in operating rooms it is necessary to just use waterproof foot-switches (REF 00302.00 Water-proof pedal)

Safety for the Patient

During the HF electrosurgical operations the patient is a conductor of electrical voltage against earth potential. So if there is a contact between patient and electrical conductive objects (metal, wet clothes, etc.), in the contact's point could be electrical current that causes thermal necrosis. So it is recommended to inspect the equipment and its accessories before using and to respect all safety rules.

Correct Position of the Patient

It is important to avoid any intention or accidental contact between patient and grounded metallic parts and to make sure that:

- The patient is not in contact with metallic parts (operative table, supports..).
- The flexible tubes of the respirator do not touch the body of the patient.
- On the operative table with grounded connection there are always coatings that allow discharging the electrostatic charges.
- The patient is on a thick basic tissue with insulating properties, covered by a sufficient number of nets.
- The patient is not in contact with nets or wet mattress.
- The eventual organic secretions and the cleaning and other liquids do not wet the nets.
- There are not liquid under the patient.
- Urinary secretions are eliminating by the catheters.
- The body zones characterized by a higher sweating, the extremities in direct contact with trunk or the points of skin-skin contact are dried by the nets interposition (arm/trunk, leg/leg, breast, skin folds, etc.).
- All conductive and grounded supports, stirrups, are correctly insulated.
- Control the anesthetics quantity to avoid a great sweating.

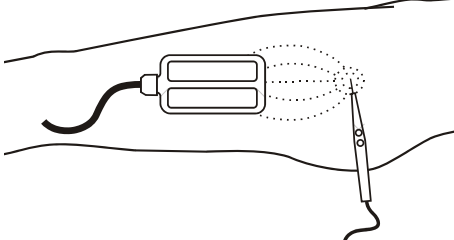
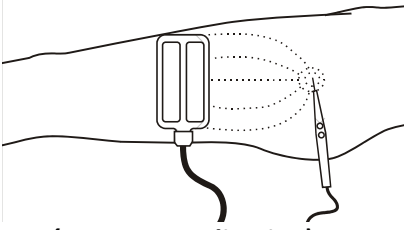
Correct Position of Neutral Electrode

The use of the neutral electrode (or patient-plate for the leakage of current) is necessary in the monopolar technique, because it allows the "return" of the cutting or coagulation current to the scalpel. The types of the neutral electrode are two:

neutral electrode by single surface (with joint cables) where there is not a check on the contact between neutral electrode and patient.

neutral electrode by two surfaces (with divided cables) where there is a check on the contact between neutral electrode and patient. *Only for DIATERMO 80.*

Keep attention on the correct position of the patient-plate to avoid burns and other risks for the patient, we recommended regard to this by the following information.

 <p>(CORRECT application)</p>	<p>In this picture it is shown the CORRECT position of the neutral electrode by the two surfaces. The patient-plate must be placed perpendicularly to the operative field. It is important to avoid the transversal way and prefer the vertical or diagonal one, thereby it is allowed a uniform distribution of the current on all two surfaces and reduces the risk of burns for the patient.</p>
 <p>(WRONG application)</p>	<p>Neutral electrode is often applied in an INCORRECT way, in parallel to the operative field. So the current distribution is not uniform on the two surfaces.</p>

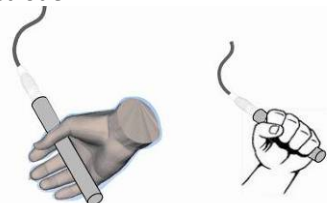
Before to apply the neutral electrode, clean and eliminate any external substances from its surface.

Do not apply the neutral electrode on cicatrix, bony protrusion or near prosthesis or monitoring electrodes. But apply it on sprinkled tissues, such as muscles and near the operative site. If you use a disposable neutral electrode respect the date of use, if you use a not disposable neutral electrode make sure that the fixing systems guarantee stability.

It is very important that the neutral electrode is firmly applied on its entire surface to avoid burns. When the neutral electrode is partially taken off from the patient, the current density on the remaining applied part is higher. Because the density of the current flow under the neutral electrode is not uniform, it verifies a not uniform heating, especially near the borders of the neutral electrode.

Rod Neutral Electrode

Optional Rod neutral electrode must be held solid in patient's hand.



INSTALLATION

- 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 making reference to the following chart:

DIATERMO 50

Mains Voltage 110-120 V Delayed Fuse 2x T2 A / 5 x 20 mm

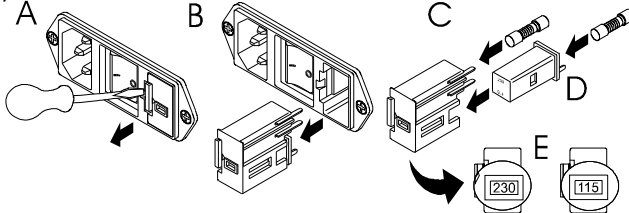
Mains Voltage 220-240 V Delayed Fuse 2x T1 A / 5 x 20 mm

DIATERMO 80

Mains Voltage 110-120 V Delayed Fuse 2x T4 A / 5 x 20 mm

Mains Voltage 220-240 V Delayed Fuse 2x T2 A / 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.

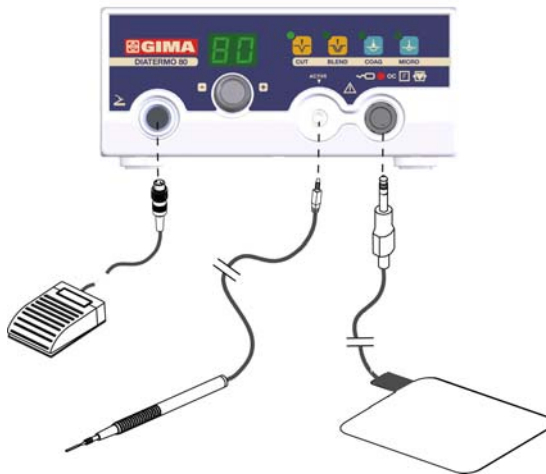


- Connect mains cable to a mains outlet having good hearth connection.
OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN.
- The unit must be installed on a level surface, with dimension, at least, correspondent to those of the base of the unit itself. Around the unit must be left a space 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 to the connector on the front panel.
- Connect handle 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.
- Condition environments:
Temperature: 10/40°C
Relative moisture: 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).

Per il **DIATERMO 80** Elettrodi neutri monopartiti e bipartiti possono essere utilizzati. Con l'unità accesa, se il valore dell'impedenza letto dall'apparecchiatura è accettabile, l'indicatore luminoso OC cesserà di lampeggiare.

- All'accensione, effettuata attraverso l'interruttore posto sul retro nel modulo di alimentazione, l'apparecchiatura dopo aver eseguito un controllo dei parametri interni sarà impostata con la funzione e i livelli di potenza utilizzati all'ultima accensione (alla prima accensione i livelli saranno 00).



DIATERMO 50 - 80 *typical configuration*

CONNECTOR AND CONTROLS

Label on the bottom of unit

The requirements for the safety of H.F. surgical equipment ask data and graphic symbols must be printed on the cabinet or on at least one of the panels of generator unit to define its features and oversee its condition of work.









Manufacturer's Identification Data

DIATERMO 50 and **DIATERMO 80** HF electrosurgical unit are designed, manufactured and tested by the LED SpA in its own laboratories in Apria (LT) – Italy.

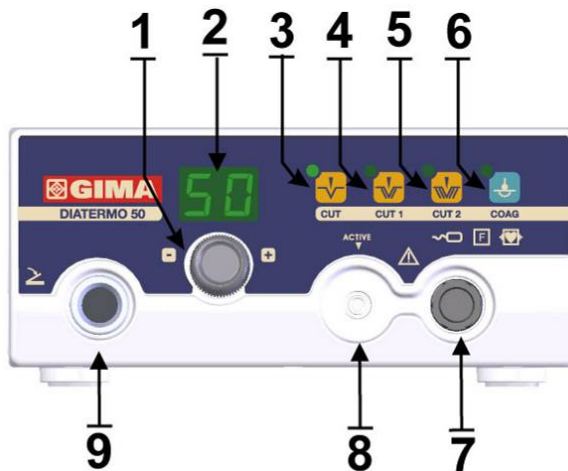
Meaning of Graphics Symbols

The meaning of the graphic symbols printed on **DIATERMO**'s cabinet is the following:

- 1- Floating Patient's plate: neither at low-frequency nor at high frequency earth connected.
- 2- The equipment is CF class, protected against Cardiac Defibrillator discharge.
- 3- Not Ionizing Radiation emitted.
- 4- Corresponding to the Directive Medical Device 93/42/EC (2007/47/EC).
- 5- The product mustn't be thrown in the containers for urban wastes but it must be swallowed by a separate picking
- 6- Manufacturer
- 7- Serial Number
- 8- Follow instructions for use

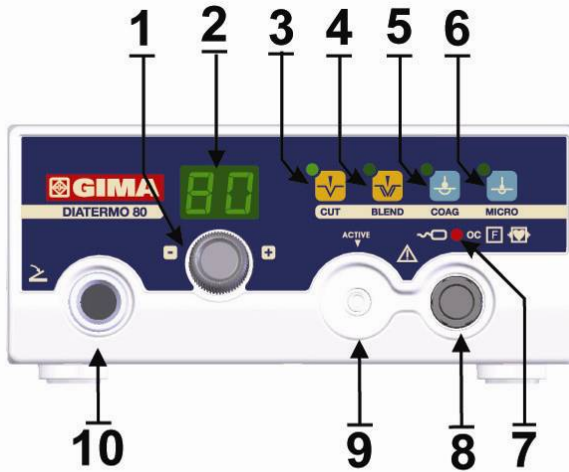
							
1	2	3	4	5	6	7	8

Frontal Panel DIATERMO 50



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

Frontal Panel DIATERMO 80



- 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

Operation Mode

Switch On

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

DIATERMO 80 Neutral Electrode's Circuit

Only for the **DIATERMO 80**, the neutral electrode is continually watched by a special circuit that prevents danger of burns to the patient due the loss of contact between the neutral electrode and the patient skin, if split electrode is used. If the impedance value of the patient circuit is more than 200 ohm the value is not accepted, in this case the OC indicator light flashing and if the output circuit is activated no power out and there is a sound alarm.

In order to reduce the acoustic pollution, the sound alarm is present only when pressed the foot-switch.

If a single plate electrodes use watched only the connection of the neutral electrode plate to the unit.

Preselecting of the Deliverable Current

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

DIATERMO 50



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 1 (CUT 1)



The coagulated-cut current (CUT1) it is suited for coagulated cut when a medium coagulation together the cut is desired.
(Only for **DIATERMO 50**)

Coagulated-Cut Current 2 (CUT 2)



The coagulated-cut current (CUT2) it is suited for coagulated cut when a more coagulation together the cut is desired.
(Only for **DIATERMO 50**)

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



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.

(Only for DIATERMO 80)

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)



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

(Only for DIATERMO 80)

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

Only for DIATERMO 80. 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.
2. 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.



Handle Connector

This is the point of connection of electrode handle.

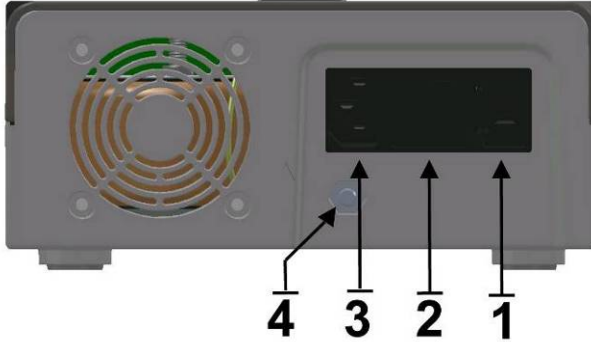


Foot-switch Connector

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 has to 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

Toll.	Descrizione	DIATERMO	
		50	80
-	Electrosurgical unit code	GMA10100.051	GMA10100.081
± 0%	Minimum preselectable power	0	0
-	Level step	1	1
-	Digital level display	●	●
±20%	Maximum output power CUT (W)	50 → 400Ω	80 → 400Ω
±20%	Maximum output power CUT 1 (W)	45 → 400Ω	-
±20%	Maximum output power CUT 2 (W)	40 → 400Ω	-
± 20%	Maximum output power BLEND (W)	-	60 → 400Ω
±20%	Maximum output power COAG (W)	40 → 400Ω	50 → 400Ω
±20%	Maximum output power MICRO (W)	-	20 → 600Ω
± 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
± 1%	Mains frequency (Hz)	50-60	50-60
-	Fuses (230Vac) 5x20 type TIMED	2x T1A	2x T2A
-	Fuses (115Vac) 5x20 type TIMED	2x T2A	2x T4A
± 10%	Electrical input power (VA)	200	230
± 10%	Electrical input current (A) 230Vac	0.9	1
± 10%	Electrical input current (A) 115Vac	1.8	2
-	Self-check	●	●
-	Split or not split patient plate allowed	-	●
-	Last working condition storing	●	●
-	Electrical Class (EN60601-1)	I CF	I CF
-	MDD 93/42/EC Class	II b	II b
-	EN55011 (CISPR 11) Class (Class/Group)	2 / B	2 / B

Toll.	Descrizione	DIATERMO	
		50	80
-	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

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 an other 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 specialized 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 non abrasive cleanser may be used when necessary.

Cleaning and Sterilization of the Accessories Item

The best thing to do is to use only one time use accessories and discard them after use. Since some of the accessory items are to be used more than once it is mandatory to clean carefully and sterilize those accessories before the new use. The best way to clean and sterilize the reusable items is to follow the direction of the supplier of each item. When original reusable accessories supplied by LED SpA are applied, the cleaning by using deep cleanser and sterilization through steam sterilization at 121 °C / 134 °C is recommended.

Guide to the Solution of the Problems

In case of problems before all it is advised to check for the correct installation of the unit and for the correct connection of the accessories.

Problems	Probable Cause	Solution
The equipment doesn't switch on.	Interruption or absence of the main feeding.	Verify the connection of the main cable. Verify the fuses and replace them, where necessary, with new ones of the proprie type.
Alarm OC always active (<i>only for DIATERMO 80</i>)	Interruption or lack of contact on the neutral electrode circuit.	Check the connection of the cable to the neutral electrode. Replace the cable of connection of the neutral electrode.
The unit doesn't respond to the command of activation	Breakdown of the pedal. - Wrong connection of the pedal.	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.

Problems	Probable Cause	Solution
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, proceed as follows:

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

(C) Insert the fuses making reference to the following chart:

DIATERMO 50

Mains Voltage 110-120 V Delayed Fuse 2x T2 A / 5 x 20 mm

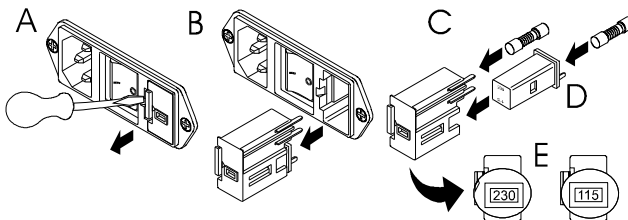
Mains Voltage 220-240 V Delayed Fuse 2x T1 A / 5 x 20 mm

DIATERMO 80

Mains Voltage 110-120 V Delayed Fuse 2x T4 A / 5 x 20 mm

Mains Voltage 220-240 V Delayed Fuse 2x T2 A / 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.



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.
- Only for **DIATERMO 80** check, by disconnecting the neutral electrode cable, the functioning of the OC light. Active unit and check OC light and sound alarm warning.
- Check, by activating the power switch, the functioning of the emission sounds warnings.

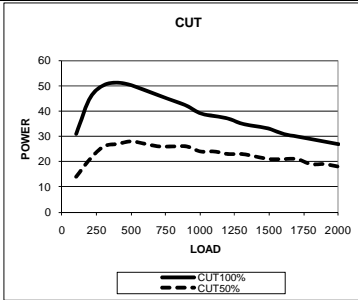
Function and Safety Check and Test

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

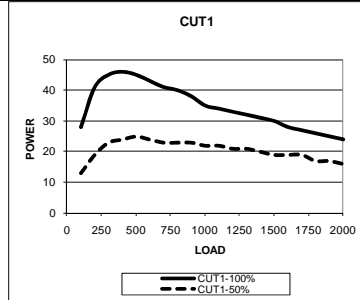
- Check of the connectors and mains supply cord conditions.
- Visual check of the mechanical protections.
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization and disinfection.
- Check of the Equipment's Data on the 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

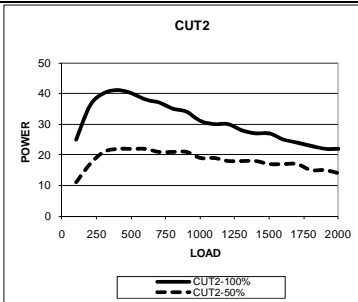
DIATERMO 50



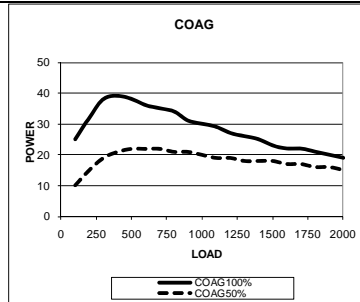
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT



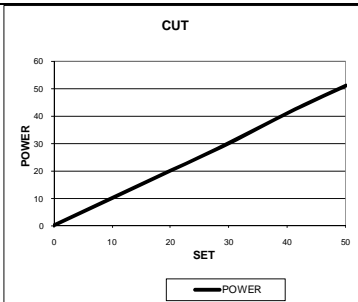
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT1



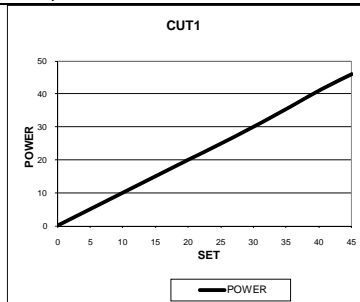
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT2



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

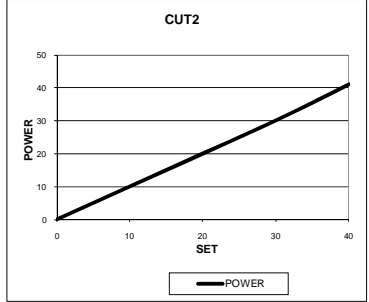


Diagrams of output power CUT versus nominal value

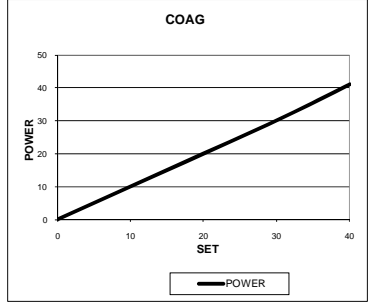


Diagrams of output power CUT1 versus nominal value

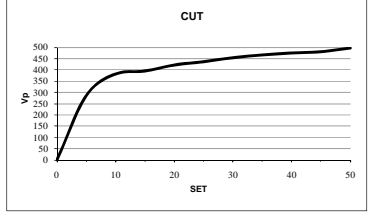
DIATERMO 50



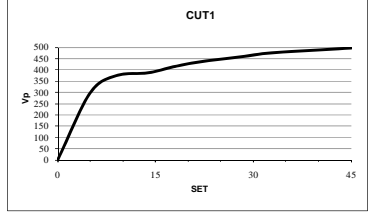
Diagrams of output power CUT2 versus nominal value



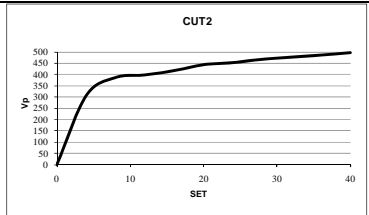
Diagrams of output power COAG versus nominal value



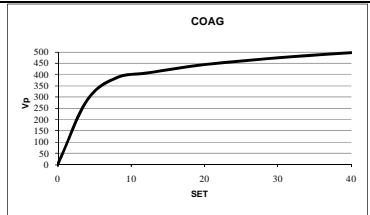
Diagrams of CUT maximum mains voltage output versus Vp



Diagrams of CUT1 maximum mains voltage output versus Vp

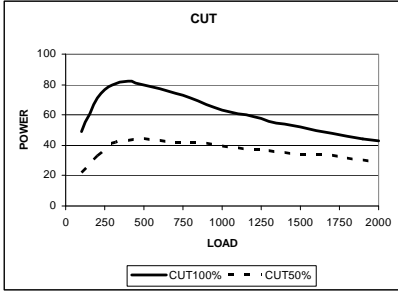


Diagrams of CUT2 maximum mains voltage output versus Vp

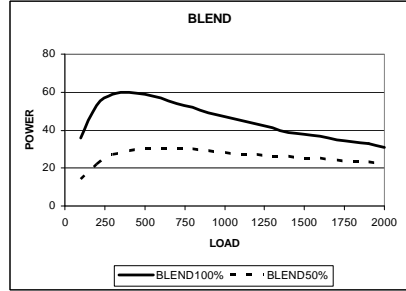


Diagrams of COAG maximum mains voltage output versus Vp

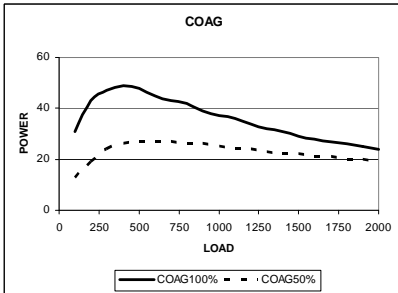
DIATERMO 80



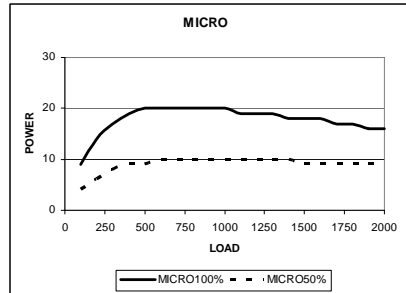
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT



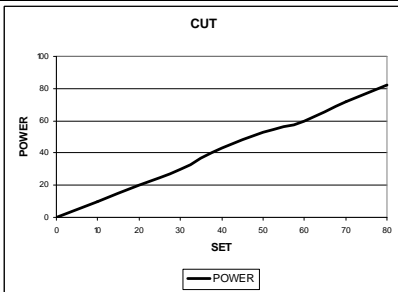
Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND



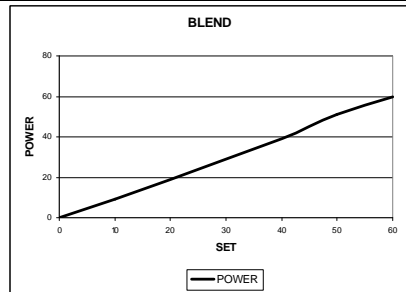
Diagrams of half and maximum output power versus impedance load 100-2000Ω COAG



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

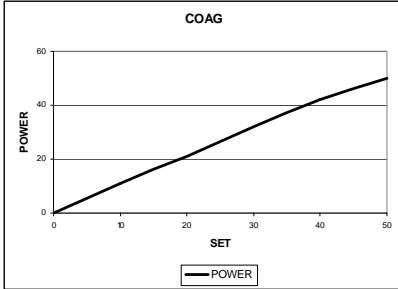


Diagrams of output power CUT versus nominal value

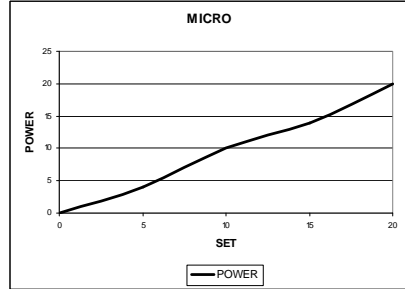


Diagrams of output power BLEND versus nominal value

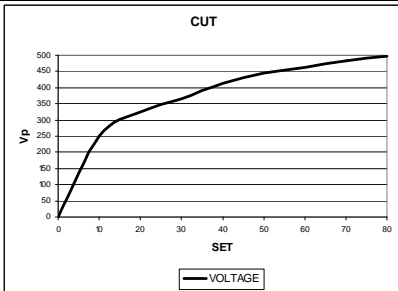
DIATERMO 80



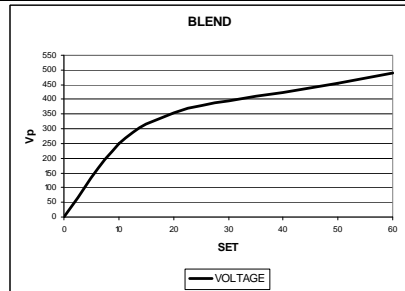
Diagrams of output power COAG versus nominal value



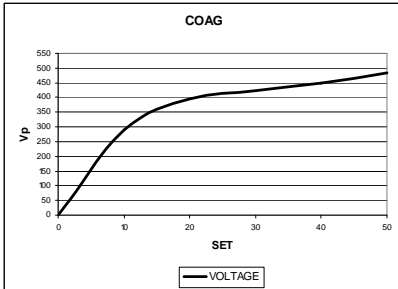
Diagrams of output power MICRO versus nominal value



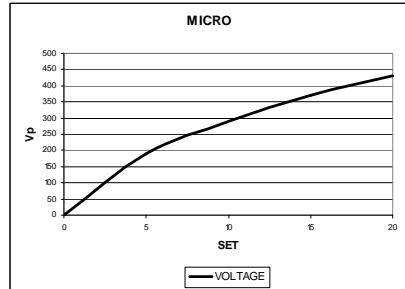
Diagrams of CUT maximum mains voltage output versus Vp



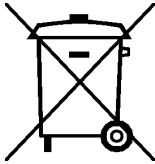
Diagrams of BLEND maximum mains voltage output versus Vp



Diagrams of COAG maximum mains voltage output versus Vp



Diagrams of MICRO maximum mains voltage output versus Vp

Information about elimination of this product (Applicable in the European Union and other European countries with separate collection systems)	
	<p>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.</p> <p>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.</p> <p>The symbol on the side (barred dustbin on wheel) denotes that the products <u>mustn't</u> throw into urban refuses container but it must be eliminated with separate collection.</p> <p>In case of abusive elimination of this product, could be foreseen sanctions.</p>

