MANUALE D'ISTRUZUIONI/ INSTRUCTION'S MANUAL

DIATERMO
MB 200

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MA182IGBc

IMPORTANTE / IMPORTANT

Queste istruzioni operative costituiscono una parte fondamentale dell'apparecchiatura per chirurgia ad alta frequenza, in quanto ne descrivono il funzionamento e l'uso, pertanto devono essere lette attentamente prima di iniziare l'installazione e l'uso dell'apparecchiatura.

Tutte le istruzioni di sicurezza o note di avvertimento devono essere osservate. Siate certi che queste istruzioni operative siano fornite insieme all'apparecchiatura quando è trasferita ad altro personale operativo.

Nessuna parte di questo documento può essere fotocopiata, riprodotta o tradotta in un'altra lingua senza il consenso scritto.

In caso di necessità di Assistenza Tecnica, contattare il proprio rivenditore.

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 is furnished together the equipment when this is transferred to other operating people.

No part of this document could be photocopied, reproduced or translated in other language without the written consent.

In case of necessity of technical assistance contact your own retailer.

Produttore / *Manufacturer*

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CE
0051

INDICE / INDEX

1. INTRODUCTION

1.1 DESTINATION OF USE / SECTORS OF APPLICATION

The use of HF electro surgical equipment **DIATERMO MB200** has reserved to specialized medical personnel. The equipment has destined to a temporary use, for surgical operations in emergency room or hospital. It has foreseen its use in the monopolar cut, cut coagulated or coagulation mode or in bipolar cut and coagulation mode.
The equipment is proper for endoscopic operations.
The equipment is conceived for being used in the following sectors:

Causalty	*Recommended*
Endoscopy	*Recommended*
First Aid	*Recommended*
Gastroenterology	*Recommended*
General surgery	*Usable*
Gynecology	*Recommended*
Neurosurgery	*Recommended*
Orthopedics	*Usable*
Otorhinolaryngology	*Recommended*
Pediatric surgery	*Usable*
Plastic surgery	*Usable*
Pneumology	*Recommended*
Urology	*Recommended*
Vascular surgery	*Recommended*
Vetenary	*Recommended*

1.2 STANDARD COMPOSITION

●/pcs= STANDARD

code	description	DIATERMO MB200
GMA10100.40A	Electrosurgical unit code	●/1
00498.04	Bipolar adpter	●/1
00404.08	Cable for connection disposable/5365 neutral plate	●/1
0210	Blade electrode 7 cm	●/3
0230	Ball electrode 7 cm	●/3
0220	Needle electrode 7 cm	●/3
5365A	Steel neutral electrode	●/1
00500.00	Kit of assorted electrodes(10pcs)	●/1
F4148	Reusable handle with finger switches	●/1
MA182	Manual of instructions	●/1
00302.00	Waterproof foot switch	●/1

1.3 GENERAL DESCRIPTION

DIATERMO MB200 is an electro-surgical equipment suited to deliver current for monopolar cut, cut coagulated, with different degrees of coagulation and coagulation or bipolar cut and coagulation.
A total of ten different modes of use and levels of power, can be stored and recalled for the use simply. It is possible to use either single plate neutral reference electrodes or electrodes with split conductive zone so to watch the stability of the plate to patient impedance during the surgical intervention.

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

The operational parameters that are used are constantly stored so that, every time the unit is switched on or the operative method is changed, the last utilized parameters are recalled.

The level of the emission sound can vary; every operator can choose his own level according to the environmental conditions of working.

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

1.4 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 electrosurgery 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 judgement 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 adviced).
- 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 colour
- no fibers of tissue remained onto the electrode

1.5 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 judgement 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 adviced).

1.6 BIPOLAR CUT AND COAGULATION

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

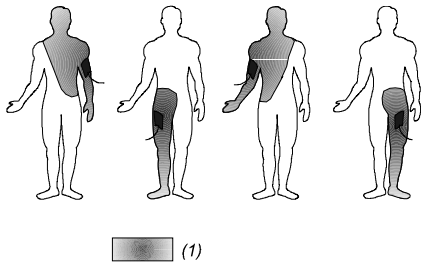
2. SAFETY

WARNING: Electrosurgery 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 S.p.A., Frosinone, Italy nor any of the subsidiary sales organisations 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 (see Technical Characteristics).

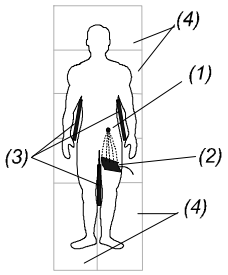
2.1 GENERAL

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. The use of gelatinoid substances for the electrodes is not adviced.
- 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) Reference 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 has not resistive or inductive elements tested 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.
- For surgical procedures where the h.f. current could flow through parts of the body having a relatively small cross-sectional area; the use of bipolar techniques may be desiderable in order to avoid unwanted coagulation.
- 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 anaesthetics, of oxygen and of nitrogen protoxide should be avoid 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.

2.2 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 MB200** 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 authorised 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 minimise or prevent patient or staff injury in the event of accidental activation.
- Avoid verifying the functioning of the unit by shorting the active electrode with the reference one or the active electrode with metallic parts.

WARNING: When the electrosurgical unit is used in operating rooms it is necessary to just use waterproof foot-switches
(**REF** 00302.00 Water-proof pedal with single switch – **REF** 00301.03 Water-proof pedal with double switches)

3. 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 setting is selected by turning the voltage selector when available. Insert the correct fuses in the module referring to the value written on the label.
- Connect mains cable to a mains outlet having good hearth connection
  OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN
- The unit must be installed on a level surface, with dimension, at least, correspondent to those of the base of the unit itself. Around the unit must be left a space of 25cm, at least.
- Connect the mains cable to the mains socket on the rear panel of the unit.
- Connect the equipotential binding post located at the left of the unit's back panel to equipotential socket of the plant.
- Connect the single foot switch or the double foot switch (optional) to the connector on the rear panel.
- Connect handle, in the case of use of handle without finger switch it shall be connected on the black buckle.
- In case of use of bipolar forceps (see figure paragraph 4.4.6) it is necessary to use the special adapter (REF 00498.04).
- Let unit work in dry environment only. Any verified condenses must be let evaporate before putting in operation the unit. Don't exceed the temperature environment or the allowed moisture. Environmental conditions: Temperature: 10/40°C - Relative moisture: 30/75% - Pressure: *70/106k Pa*
- When the unit is switched on, through the on/off switch on the frontal panel, after having checked the internal parameters, it will work with the function and the power level utilized during the last switching (when the unit is switched for the first time the level will be 00).
- Before using the unit, it is necessary connect the cable to the patient plate. Both when single plate electrodes and when split plate electrodes are used it is necessary to confirm the impedance acceptance by pressing the key OK (see paragraph 4.3.2). In this way, if the value of the impedance is acceptable, the OC indicator light will stop flashing and the alarm to sound.
- Having:

Holder-handle with two pushbuttons without foot switch: press the yellow pushbutton on the holder-handle to deliver the cutting current (the choice between CUT, BLEND and BIPOLAR CUT must be done pressing the correspondent pushbutton on the unit); or the blue pushbutton on the holder handle to deliver coagulating current (the choice between FORCED COAG, SOFT COAG and BIPOLAR COAG must be done pressing the correspondent pushbutton on the unit).
Holder handle with two pushbuttons and a single foot switch: choose the cutting current CUT, BLEND or BIPOLAR CUT and the coagulation current FORCED COAG, SOFT COAG or BIPOLAR COAG. Preset through the yellow pushbutton on the holder handle, the function for the cut that appears on the unit or, through the blue pushbutton on the holder handle, the function for the coagulation that appears on the unit. The current delivery takes place through the foot switch.
Holder handle with two pushbuttons and double foot switch: press the yellow foot switch or the yellow pushbutton of the holder handle to pre-set and deliver the cutting current (the choice between CUT, BLEND and BIPOLAR CUT must be done pressing the correspondent pushbutton on the unit) or the blue foot switch or the blue pushbutton of the holder handle to pre-set and deliver the coagulating current (the choice between FORCED COAG, SOFT COAG and BIPOLAR COAG must be done pressing the correspondent pushbutton on the unit).
Holder handle without pushbuttons and single foot switch: connect the holder handle to the black binding post and pre-set the current for the cut (CUT, BLEND or BIPOLAR CUT) or the coagulation (FORCED COAG, SOFT COAG or BIPOLAR COAG), press the foot switch to deliver the pre-set current.
Holder handle without pushbuttons and double foot switch: connect the holder handle to the black binding post and press the yellow footswitch to pre-set and deliver the cutting current (the choice between CUT, BLEND and BIPOLAR CUT must be done pressing the correspondent pushbutton on the unit); press the blue foot switch to pre-set and deliver the coagulating current (the choice between FORCED COAG, SOFT COAG and BIPOLAR COAG must be done pressing the correspondent pushbutton on the unit).
Bipolar forceps and single foot switch: connect the furnished adapter (see paragraph 4.4.6). The equipment will select the BIPOLAR operative mode (BIPOLAR CUT or BIPOLAR COAG), choose the desired function pressing the corresponding button. To deliver the current press the foot switch. To avoid the forcep's damage don't make short circuit with its tips.
Bipolar forceps and double foot switch: connect the furnished adapter (see paragraph 4.4.6). The equipment will select the BIPOLAR operative mode (BIPOLAR CUT or BIPOLAR COAG), choose the desired function pressing the corresponding button. To deliver the current press the foot switch for the coagulation (blue). To avoid the forcep's damage don't make short circuit with its tips.

4. CONNECTORS AND CONTROLS

4.1 LABEL ON THE REAR PANEL

The requirements for the safety of H.F. surgical equipment ask technical 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.

4.1.1 MANUFACTURER'S IDENTIFICATION DATA

DIATERMO MB200 HF electrosurgical unit is designed, manufactured and tested by the LED SpA in its own laboratories in Aprilia (LT) - Italy.

4.1.2 TECHNICAL DATA

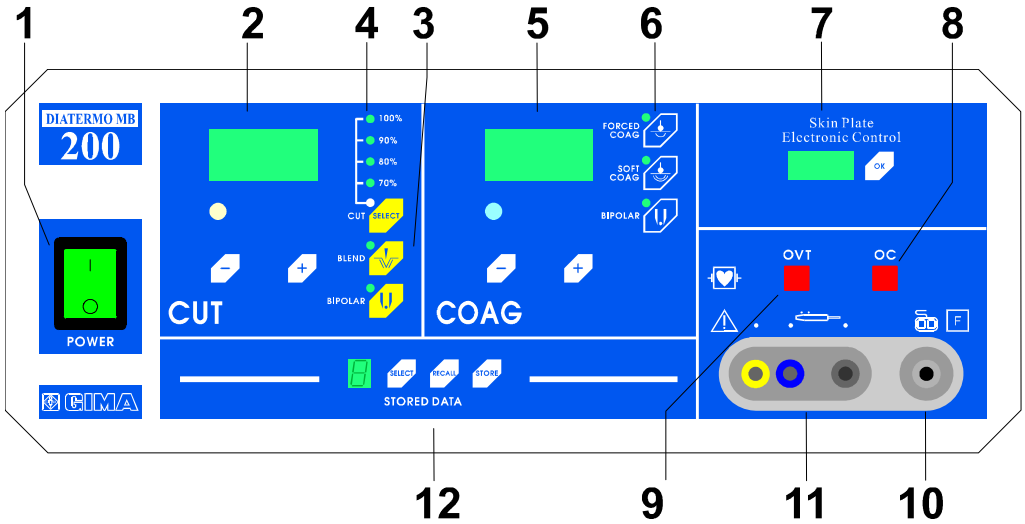
Output CUT(Cut):	200 W - 250 Ω	FREQUENCY:	600 kHz
Output BLEND(Cut coagulated):	120 W - 200 Ω	FREQUENCY:	600 kHz
Output FORCED(Coagulation):	150 W - 150 Ω	FREQUENCY:	600 kHz
Output SOFT(Coagulation):	90 W - 100 Ω	FREQUENCY:	600 kHz
Output BIPOLAR COAG (Coagulation):	100 W - 100 Ω	FREQUENCY:	600 kHz
Output BIPOLAR CUT (Cut):	120 W - 250 Ω	FREQUENCY:	600 kHz
MAIN POWER :	115/230 V - 50/60 Hz selectable		
INLET POWER:	350VA		
FUSE:	(230V~) 2xT3.15 A (type 5x20) / (115V~) 2xT6.3 A (type 5x20)		
DUTY - CYCLE:	10 seconds active /30 seconds pause		
CLASS:	I CF		

4.1.3 MEANING OF GRAPHIC SYMBOLS

The meaning of the graphic symbols printed on **DIATERMO MB200** 's cabinet is the following:
1. Floating Patient's plate: neither at low-frequency nor at high frequency earth connected
2. The equipment is protected against Cardiac Defibrillator discharge.
3. Not Ionising Radiation emitted
4. Read carefully INSTRUCTION MANUAL before to attempt the use of the equipment.

1 2 3 4

4.2 FRONTAL PANEL



1 Mains switch
2 Section of control and indication level of cut current
3 Cut - function keyboard
4 Luminous indications pure cut 100%, cut 90%, cut 80% cut 70%
5 Section of control and indication level of coagulation current
6 Coagulation - function keyboard
7 Reading section and impedance-acceptance
8 OC (open circuit) alarm
9 Alarm warning for current delivery over time
10 Return plate connection
11 Handle connection
12 Keyboard for program selection, recording and data recall

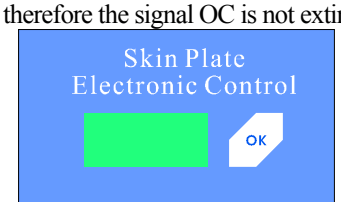
4.3 OPERATION MODE

4.3.1 SWITCHING ON

When switched on the electrosurgical unit performs automatically 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, and activate the signal of alarm OC (open circuit).

4.3.2 NEUTRAL ELECTRODE'S CIRCUIT (SKIN PLATE ELECTRONIC CONTROL)

The neutral electrode's circuit is continually watched by a special circuit (Skin Plate Electronic Control) that prevents danger of burns to the patient due the loss of contact between the reference plate and the patient skin. The circuit is also watched to avoid that the variation of the characteristics of conductibility of the plate can provoke reduction of conductibility of the circuit, and therefore danger of burns to the patient.
The value of impedance found in the circuit of the neutral electrode is shown to the operator that, if he considers it suitable to the job to develop, he accepts it by pressing the OK push button. The signal OC is extinguished. If the value of impedance is superior to 300 ohms its acceptance it is not acknowledged by the microcontrollor of the equipment, therefore the signal OC is not extinguished and the disbursement of power has not allowed.



If the value of impedance accepted is acknowledged, the indication of the impedance stops.
If when the unit has switched on, the adapter for using the bipolar forceps is had been inserted, after the test of correct operation, the equipment selects automatically the bipolar operational mode without performing the cycle related to the control of the neutral electrode circuit.
If after having acknowledged the shown impedance the value of this it increases relatively to the acknowledged value according to the followings increases:

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

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

4.3.3 STORING OF CONDITION OF USE

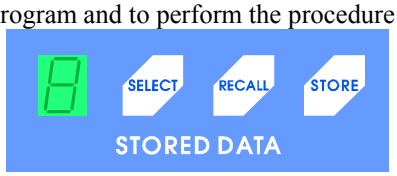
Using the section STORED DATA it is possible to store 9 different operational conditions and levels of output power (program 0 is the default one).
To store the parameters it is enough to perform the following procedure:

Press the key SELECT to find the number of the program that you want to use.
Press the key STORE to store the parameters.

To recall the stored data it is enough to perform the following procedure:

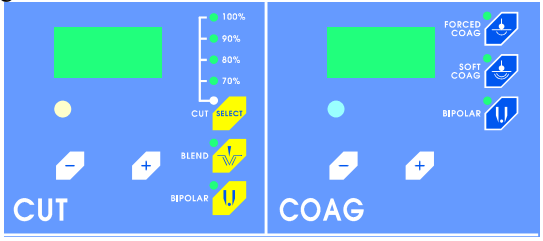
Press the key SELECT to find the number of program that you want to recall. Press the key RECALL to recall the parameters.

For modify a program it is enough to select the same program and to perform the procedure of storing once more.

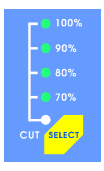


4.4 PRESELECTION OF THE DELIVERABLE CURRENT

The deliverable current for the surgical operations can have pre-selected through push button at the side of sections CUT and COAG. The power of the level for any functions can be pre-selected through the buttons + e – of the sections CUT e COAG. The selected power's levels remain memorized.



4.4.1 CUT AND COAGULATED CUT (CUT)



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

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

4.4.2 MIXED CURRENT (BLEND)

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

4.4.3 BIPOLAR CUT CURRENT (BIPOLAR CUT)

This current is high voltage pure sine current and suited for cut without coagulation either monopolar or bipolar. The use of bipolar forceps it is allowed only with this current. To allow the connection of the cable bipolar forceps it is necessary the use of an adapter that prevents any other type of current from delivering. (see figure page 31)

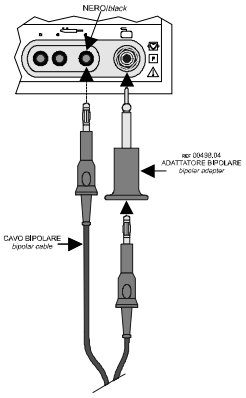
4.4.4 CURRENT FOR SUPERFICIAL COAGULATION (FORCED COAG)

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

4.4.5 CURRENT FOR DEEP COAGULATION (SOFT COAG)

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

4.4.6 BIPOLAR COAGULATION CURRENT (BIPOLAR COAG)



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

4.6 SIGNALING OF EXCESSIVE TIME OF DELIVERY (OVT)

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

4.7 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.

4.8 PRESETTABLE SETTING BY USER

User is allowed to preset the following settings: Acoustic signals level; power level steps.
To modify the acoustic signals level do as for the following instructions::
Switch on the unit while the CUT pushbutton is maintained pressed.
When the unit has finished the internal parameters check, on the CUT display will appear the message **SOU.** and on the COAG display will appear the preset value.
Release the CUT pushbutton. Set the new acoustic level by the COAG pushbuttons. While the level adjustment the corresponding sound level can be heard.

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

Press the CUT pushbutton to confirm the level. After the sound level confirmation, on the CUT display the message **Sbd** appears while on the COAG display is shown the actual amplitude of the steps for power higher the 20. If the step amplitude output has wished to be changed (from 1 to 5 or viceversa) press the + and – COAG pushbutton.
Press the CUT pushbutton to confirm the chosen data.

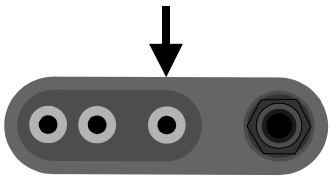
4.9 AUTOMATIC CONTROL OF THE INTERNAL PARAMETERS

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

4.10 CONNECTORS

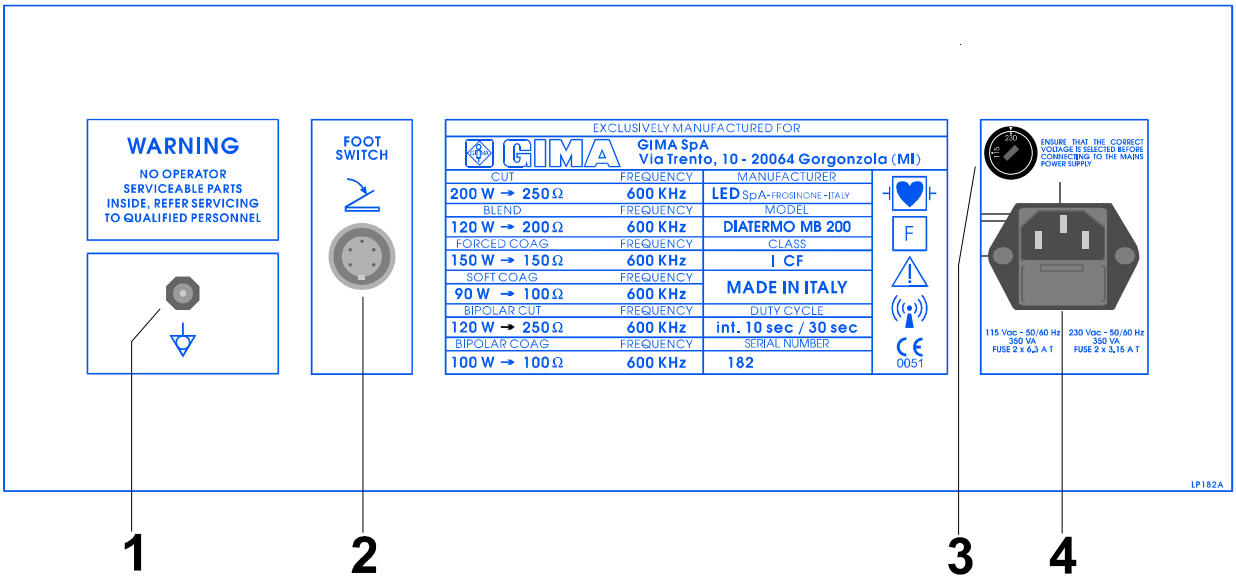
Connector for return plate
This is the point of connection of the return plate or of the bipolar adapter for BIPOLAR function.

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



4.11 BACK PANEL

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



4.11.1 POWER SUPPLY MODULE

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

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

4.11.2 PEDAL CONNECTOR

On the left part of the back panel it is pedal connector.

4.11.3 TURNABLE VOLTAGE SELECTOR

On the power supply block can be present a voltage selector suitable for the selection of 115V~ or 230V~ mains voltage. Before powering the unit, it is necessary to preset the correct mains voltage by properly set the voltage selector. The unit is factory preset to 230V~.

5. TECHNICAL CHARACTERISTICS

Tollerance	Description	DIATERMO MB 200
–	Electrosurgical unit code	GMA10100.40A
–	Minimum preselectable power	0
–	Step power unitary or 5[5]	●
–	Digital level display	●
–	Selection of the power through the buttons	●
⌖ 20%	Maximum output power CUT (W)	200 → 250⌖
⌖ 20%	Maximum output power CUT 90% (W)	200 → 250⌖
⌖ 20%	Maximum output power CUT 80% (W)	200 → 250⌖
⌖ 20%	Maximum output power CUT 70% (W)	200 → 250⌖
⌖ 20%	Maximum output power BLEND (W)	120 → 200⌖
⌖ 20%	Maximum output power COAG FORCED (W)	150 → 150⌖
⌖ 20%	Maximum output power COAG SOFT (W)	90 → 100⌖
⌖ 20%	Maximum output power BIPOLAR CUT(W)	120 → 250⌖
⌖ 20%	Maximum output power BIPOLAR COAG (W)	100 → 100⌖
⌖ 5%	Modulation factor CUT	Pure 100%
⌖ 5%	Modulation factor CUT 90%	Mod. 90%[6]
⌖ 5%	Modulation factor CUT 80%	Mod. 80%[2]
⌖ 5%	Modulation factor CUT 70%	Mod. 70%[2]
⌖ 5%	Modulation factor BLEND	Pure 100%
⌖ 5%	Modulation factor COAG FORCED	Mod. 60%[2]
⌖ 5%	Modulation factor COAG SOFT	Pure 100%
⌖ 5%	Modulation factor BIPOLAR CUT	Pure 100%
⌖ 5%	Modulation factor BIPOLAR COAG	Pure 100%
⌖ 0.2	Crest Factor CUT	1.5
⌖ 0.3	Crest Factor CUT 90%	1.6
⌖ 0.3	Crest Factor CUT 80%	1.7
⌖ 0.3	Crest Factor CUT 70%	1.8
⌖ 0.3	Crest Factor BLEND	2.1
⌖ 0.3	Crest Factor COAG FORCED	2.0
⌖ 0.3	Crest Factor COAG SOFT	1.5
⌖ 0.2	Crest Factor BIPOLAR CUT	1.5
⌖ 0.2	Crest Factor BIPOLAR COAG	1.5
⌖ 10%	Working frequency	600 kHz
⌖ 15%	Maximum output voltage CUT (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage CUT90% (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage CUT80% (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage CUT70% (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage BLEND (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage COAG FORCED (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage COAG SOFT (Vpp on 5.2k⌖)	540
⌖ 15%	Maximum output voltage BIPOLAR CUT (Vpp on 5.2k⌖)	1050
⌖ 15%	Maximum output voltage BIPOLAR COAG (Vpp on 5.2k⌖)	540
⌖ 0.5	Weight Kg	8
⌖ 10	Size HxLxDmm	360x150x265
⌖ 5%	Selectable mains power(V~)	115 –230
⌖ 1%	Mains frequency (Hz)	50-60
⌖ 0	Fuses 230V~ (5x20) TIMED	2x 3.15A
⌖ 0	Fuses 115V~ (5x20) TIMED	2x 6.3A
⌖ 10%	Electrical input power (VA)	350
⌖ 10%	Electrical input current (230V~) (A)	1.5
⌖ 10%	Electrical input current (115V~) (A)	3
⌖ 5	Five steps adjustable sound level (from 55- to 75dBA)	●
–	Self-check	●
–	Power accuracy output warning	●
–	Skin Plate Electronic Control[7]	●
–	Split or not split patient plate allowed	●
–	Repetition of timed delivery for second	●[8]
–	Timed delivery	1 – 999 ms
–	Working condition storing	9 +[9]

[5] Pre-selectable
[6] Frequency of modulation 10kHz
[7] Patient to plate contact monitoring system
[8] Dipendent from the timing
[9] Continous-memorization of the last settings

Tollerance	Description	DIATERMO MB 200
–	Electrical Class (EN60601-1)	I CF
–	MDD 93/42/EEC Class	II b
–	EN55011 (CISPR 11) Class (Class/Group)	2 / B
–	Patient circuit	F
–	Duty Cycle (action / pause) in seconds	10 / 30
–	Output power control by foot-switch or finger-switch	●
–	Defibrillation-proof	●
–	Ten seconds delivery warning (OVT)	●
–	Equipotential binding	●
–	Metallic cabinet RAL5028 painted	●
–	Polycarbonate covered panels	●
–	Conform to EN60601-1 (1997)	●
–	Conform to EN60601-1-2 (1995)	●
–	Conform to IEC60601-2-2 (1998)	●
–	Conform to EN60601-1-4 (1998)	●

●= STANDARD

6. MAINTENANCE

6.1 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 S.p.A. Service Centre 04010 APRILIA (LT) - ITALY, or to a other Authorised 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 sterilisation 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 specialised technical people.

6.2 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.

6.3 CLEANING AND STERILISATION OF THE ACCESSORY ITEMS

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 sterilise those accessories before the new use. The best way to clean and sterilise the reusable items is to follow the direction of the supplier of each item. When original reusable accessories supplied by LED S.p.A. are applied, the cleaning by using soft cleanser and sterilisation through steam sterilisation at 121 °C is recommended.

6.4 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.

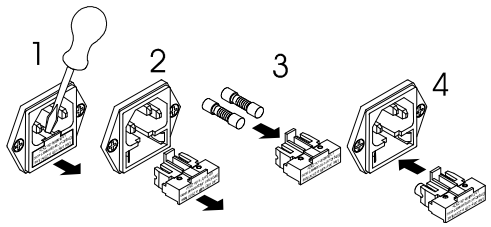
Problems	**Probable Cause**	**Solution**
The equipment doesn't switch on.	Interruption or absence of the main feeding	Verify the connection of the main cable. Verify the fuses and replace them, where necessary, with new ones of the propre type.
Alarm OC always active.	Interruption or lack of contact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

6.5 REPAIRS

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

6.5.1 FUSE SUBSTITUTION

Before substituting the fuse, disconnect the unit from the mains system.
Only use fuse of the kind 5x20; they must have those characteristics: 3.15AT (slow) (230V~ mains voltage), 6.3A (115V~ mains voltage), proceed as follows:
1-2 Extract, with a small screwdriver, the drawer under the mains socket
3 Extract the damaged fuse and insert two new ones
4 Reinsert the drawer



6.6 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 sterilised.
- Check, by disconnecting the reference electrode cable, the functioning of the OC light and sound alarm warning.
- Check, by activating the CUT and COAG power switch, the functioning of the emission lights and sounds warnings.

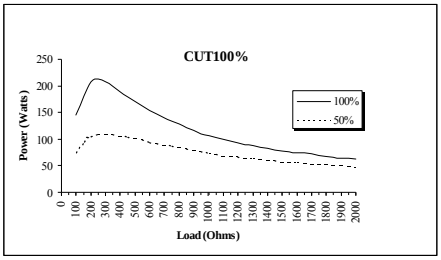
6.7 FUNCTION AND SAFETY CHECK AND TEST

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

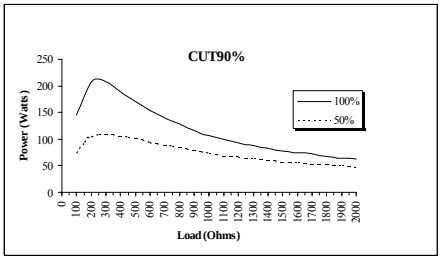
- Check of the connectors and mains supply cord conditions;
- Visual check of the mechanical protections;
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization and disinfection.
- Check of the Equipment's Datas on the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

GRAFICI / DIAGRAMS

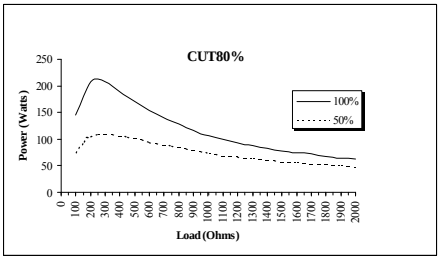
DIATERMO MB200



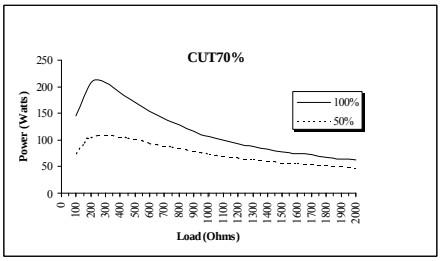
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT100%



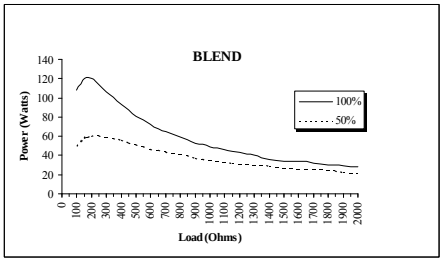
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT90%



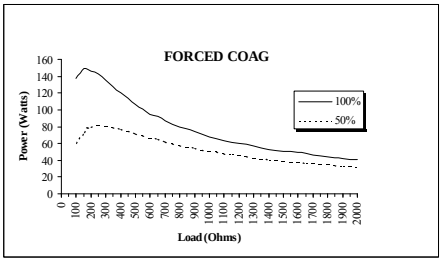
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT80%



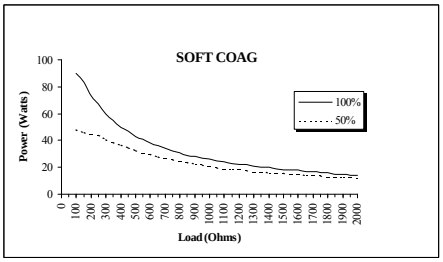
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT70%



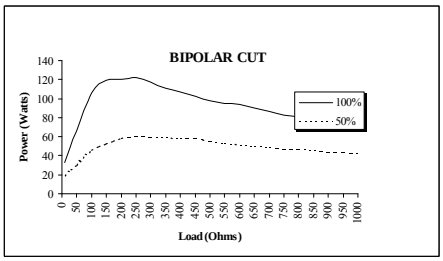
Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND



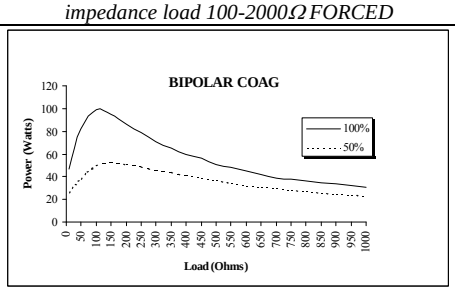
Diagrams of half and maximum output power versus impedance load 100-2000Ω FORCED



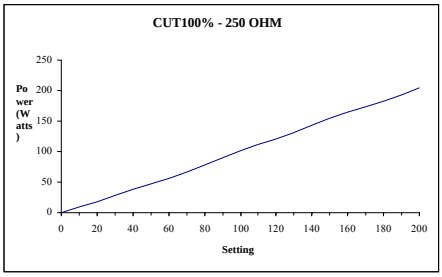
Diagrams of half and maximum output power versus impedance load 100-2000Ω SOFT



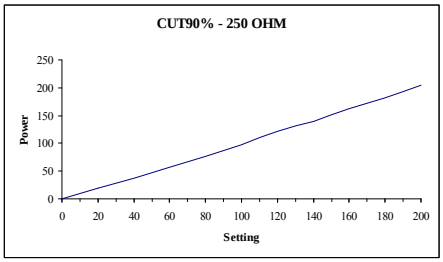
Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR CUT



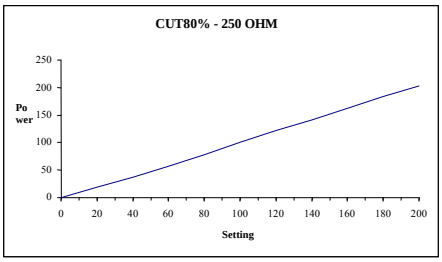
Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR COAG



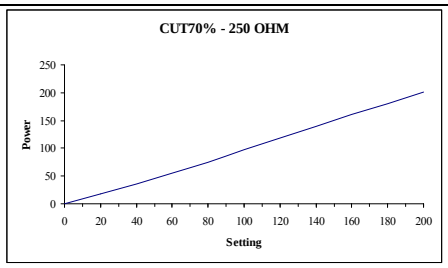
Diagrams of output power CUT100% versus nominal value



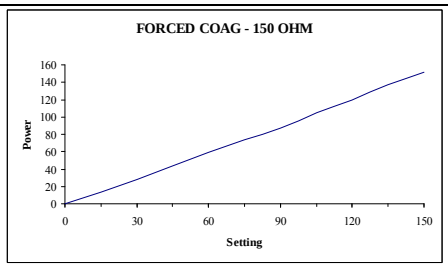
Diagrams of output power CUT 90%versus nominal value



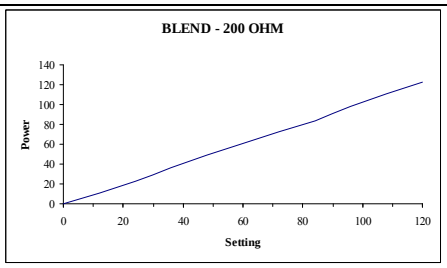
Diagrams of output power CUT80%versus nominal value



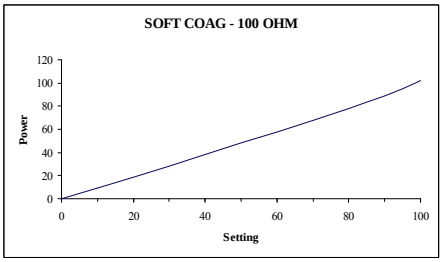
Diagrams of output power CUT70% versus nominal value

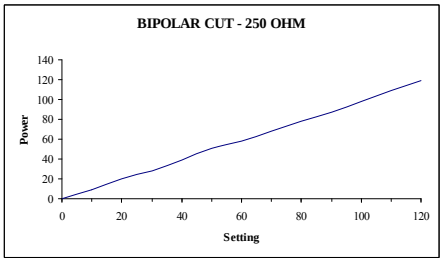


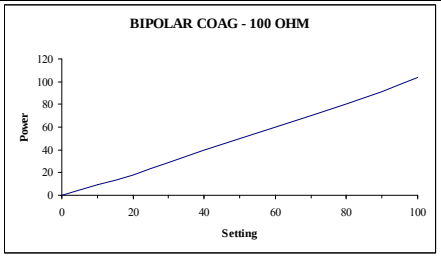
Diagrams of output power FORCED versus nominal value



Diagrams of output power BLEND versus nominal value

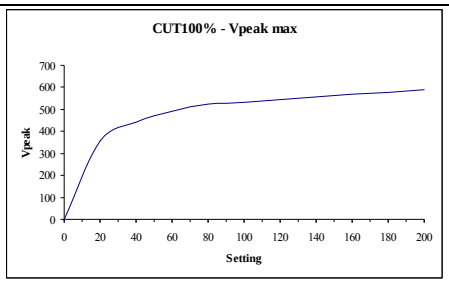
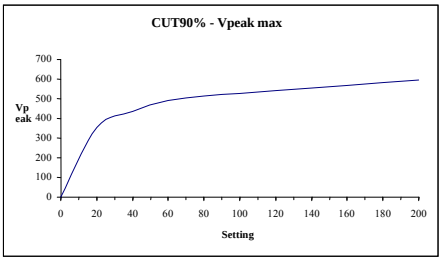
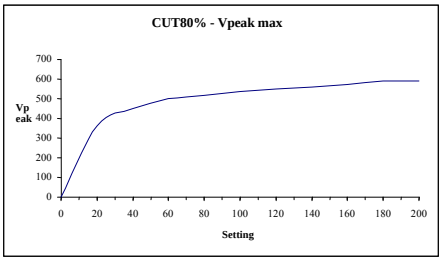
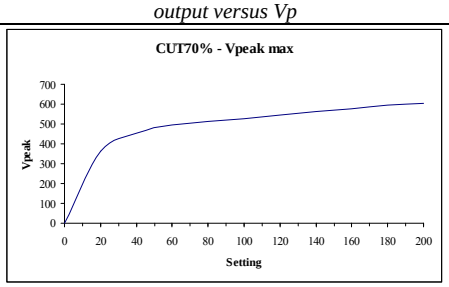
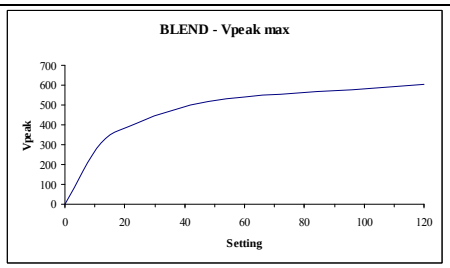
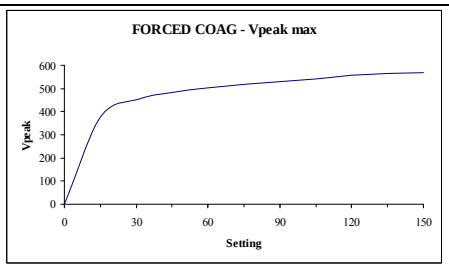
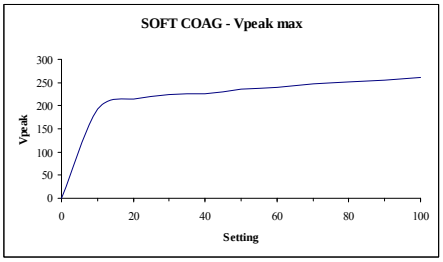
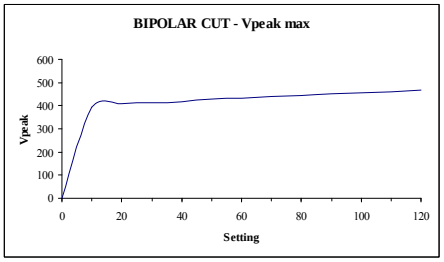
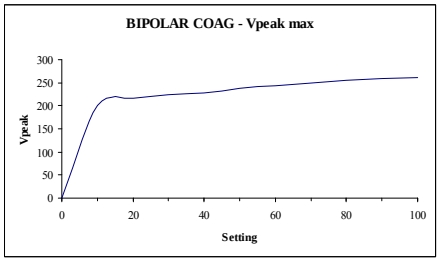






Diagrams of output power BIPOLAR COAG versus

DIATERMO MB200

Diagrams of output power SOFT versus nominal value	*Diagrams of output power BIPOLAR CUT versus nominal value*	*nominal value*
 *Diagrams of CUT 100% maximum mains voltage output versus Vp*	 *Diagrams of CUT90% maximum mains voltage output versus Vp*	 *Diagrams of CUT80% maximum mains voltage output versus Vp*
 *Diagrams of CUT70% maximum mains voltage output versus Vp*	 *Diagrams of BLEND maximum mains voltage output versus Vp*	 *Diagrams of FORCED maximum mains voltage output versus Vp*
 *Diagrams of SOFT maximum mains voltage output versus Vp*	 *Diagrams of BIPOLAR CUT maximum mains voltage output versus Vp*	 *Diagrams of BIPOLAR COAG maximum mains voltage output versus Vp*

Informazioni in base all'Art. 13 del D.Lgs. 151/05 del 25/07/2005 "Attuazione delle Direttive 2002/95/CE e 2003/108/CE, relative alla riduzione di sostanze pericolose nelle apparecchiature elettriche ed elettroniche, nonché allo smaltimento dei rifiuti.

A fine vita il presente prodotto non deve essere smaltito come rifiuto urbano, lo stesso deve essere oggetto di una raccolta separata.

Se il rifiuto viene smaltito in modo non idoneo è possibile che alcune parti del prodotto (ad esempio eventuali accumulatori) possono avere effetti potenzialmente negativi per l'ambiente e sulla salute umana.

Il simbolo a lato (contenitore di spazzatura su ruote barrato) indica che il prodotto non deve essere gettato nei contenitori per i rifiuti urbani ma deve essere smaltito con una raccolta separata.

In caso di smaltimento abusivo di questo prodotto sono previste delle sanzioni.

Information about elimination of this product (Applicable in the European Union and other European countries with separate collection systems)

On the end of the life, the present product mustn't be eliminated as urban refusal, but it must be eliminated in a separated collection.

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.