Manuale d' Istruzioni / Instructions' Manual

DIATERMO
MB 240
MB 380

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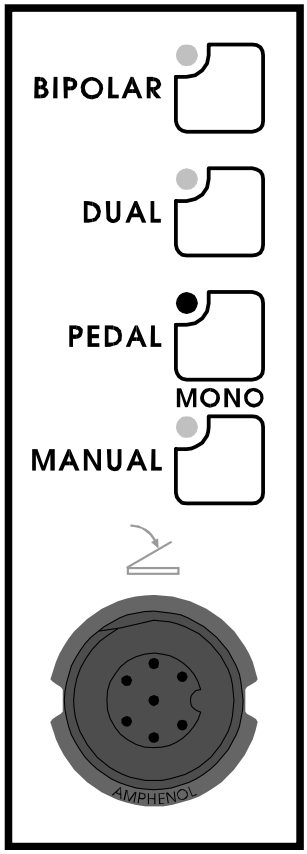
AVVERTENZA / *WARNING*

La funzione COAG3 (SPRAY) è attivabile solo utilizzando il pedale, quindi solo nel modo operativo PEDAL.

The function CAOG3 (Spray coagulation) is activable only by footswitch therefore only in PEDAL operation.



IMPORTANTE / IMPORTANT

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INDICE / INDEX

1. INTRODUCTION

1.1 INTENDED USE

The **DIATERMO MB380** and **DIATERMO MB240** electro-surgical units' use is exclusively reserved to specialized medical personnel.
The **DIATERMO MB380** and **DIATERMO MB240** equipments are intended for temporary use, during surgical treatments where monopolar or bipolar cut and / or coagulation are requested. The equipment is conceived for being used in the following sectors:

description	DIATERMO	
	MB 240	MB 380
Electrosurgical unit code	GMA10400.50A	GMA10400.60A
Causalty	●	○
Dermatology	●	○
Endoscopy	●	○
Gastroenterology	●	●
General surgery	●	●
Gynecology	●	○
Neurosurgery	●	●
Orthopedics	○	●
Otorhinolaryngology	●	○
Pediatric surgery	●	●
Plastic surgery	●	●
Pneumology	●	○
Thorax surgery	○	●
Urology	●	●
Vascular surgery	○	○
Veterinary	●	○

●= Recommended ○= Usable

1.2 CHECK LIST

Check that all the items and accessories which have been ordered have been delivered, according to the following list:

REF GMA10400.60A **DIATERMO MB380** Unit
OR
REF GMA10400.50A **DIATERMO MB240** Unit
REF 00100.01 Unit mains cable 5 meters long
REF F4243 Reusable handpiece with double switch
REF F4798 Disposable handpiece with double switch (5pcs)
REF 00404.06 Cable for connection of patient plate
REF F7905 Disposable patient plate (5pcs)
REF 00301.01 Waterproof double pedal switch
REF F4046 Sterile knife short electrode (3pcs)
REF F4050 Sterile knife long electrode (3pcs)
REF F4048 Sterile needle short electrode (3pcs)
REF F4044 Sterile ball short electrode (3pcs)
REF MA129 Instruction's Manual

1.3 GENERAL DESCRIPTION

The **DIATERMO MB380** and **DIATERMO MB240**, High Frequency Surgical Equipments, provide the facility to carry out monopolar and bipolar major surgery.
The equipments are 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. In this way most of the thermic problems, and the need for cooling fans, very dangerous for the batterium diffusion in the health care rooms, has been overcome.
Control of the unit is via the front panel keys, knobs and display; mains inlet and on/off switch are on the rear panel.
The type of surgical operation which can be carried out are those where monopolar and/or bipolar electrosurgical cutting or coagulation is requested.
Use of the **DIATERMO MB380** and **DIATERMO MB240** is restricted to trained medical personnel, and are to be used only for the purposes set down by the manufacturer.
DIATERMO MB380 and **DIATERMO MB240** consists of the following components:

- the generator, or unit
- the handpiece with two pushbuttons
- the electrodes
- the dispersive plate
- the pedal double

1.4 MONOPOLAR CUTTING

Monopolar cutting is the sectioning of the biological tissue caused by the passing of high density, high frequency current concentrated by the tip of the active electrode.
When the high frequency current, by the tip of the active electrode, is applied to the tissue, it creates intense molecular heat in the cell so that the cell explodes.
The cutting effect is achieved by moving the electrode through the tissue and destroying the cell one after the other. The movement of the electrode prevents the propagation of the heat laterally in the tissue, thus limiting the destruction to a single line of cells.
The best current for cutting is pure sine wave without any modulation which cuts very smoothly and provides the least thermal effect with poor hemostasis 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.
DIATERMO MB380 and **DIATERMO MB240** allows cutting with pure sine wave form as well as with two degrees of moderate modulation producing blend wave form with different crest-factors so more hemostatic effect than with pure sine wave form is achieved.
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
- Keep the electrode clean
- 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

1.5 MONOPOLAR COAGULATION

Monopolar coagulation is the hemostasis of small blood vessel of the bodily tissue through the passing of high frequency current in correspondence of the 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 from 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 hemostasis 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.
DIATERMO MB380 and **DIATERMO MB240** allows coagulation with three degrees of deep modulation producing blend wave form with different crest-factors so more thermal effect and consequently hemostatic effect than pure sine current has achieved. The available peak voltage and the high crest factor of the Spray Coagulation 3 allows the tayet surface area's carbonization without mechanical contact.
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.

1.6 BIPOLAR CUTTING

The bipolar cutting is the sectioning of the biological tissue caused by the passing of high density, high frequency current concentrated by the two tips of the forceps.
When the high frequency current is applied to the tissue between the two tips of the forceps, it creates intense molecular heat in the cell so that the cell explodes. Lower voltage than in the monopolar cutting is provided for bipolar cutting so that less sparking and damage of adjacent tissue sites is acheived.
DIATERMO MB380 and **DIATERMO MB240** allows cutting with pure sine wave without any modulation which cuts very smoothly and produces the least thermal effect.

1.7 BIPOLAR COAGULATION

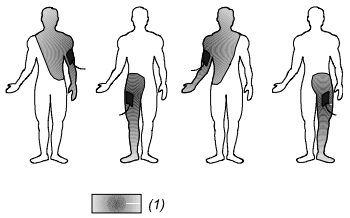
Bipolar coagulation is the hemostasis of small blood vessel of the bodily tissue between the two tips of the forceps.
When the current density is reduced the effect is to dry out the surface cells, without deep penetration, resulting in coagulation. These coagulate surface cells then serve as a layer of insulation, preventing heat from successive applications of current from penetrating too deeply.
DIATERMO MB380 and **DIATERMO MB240** allows coagulation with modulation producing blend wave form with sufficient crest-factors to obtain the thermal effect and consequent hemostatic effect that needs in the practice, with moderately low voltage to limit the lateral spread of thermal damage and the risk of interference with electronic circuits simultaneously connected to the patient.

2. SAFETY

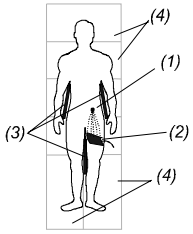
WARNING These operating instructions form an integral part of the equipments and must be available to the operating personnel at all times. All the safety instructions and advice notes are to be observed. Be sure that these operating instructions is furnished together the equipment when this is tranferred to other operating people. 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.

2.1 GENERAL

- Persons fitted with a heart pacemaker must not operate the equipment nor approach the same while it is in operation.
- Do not use the dispersive plate if the conductive adhesive has become dry.
- Do not reuse the disposable dispersive plate.
- Prior to place the dispersive plate clean, shave and dry the body's area.
- The whole surface of the dispersive plate must be placed on a well vascularized muscle as next as possible to the surgical area.
- 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 urgical gauze.



(1) Treatment area



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

- When high frequency electrosurgical unit and phisiological monitoring devices are used at a time in the same patient, all the monitoring electrodes, that has not resistive or inductive elements suitable to high frequency interferencies, 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 use of bipolar technique is recommended for surgical operation in regions of the body with relatively small section so to avoid unwanted coagulation.
- The power level should be the lowest useful to the work to do.
- Always check the dispersive plate when ever the electrosurgical unit fails to produce the desired effect.
- Reason for a low output power level, or for an uncorrect functioning of the electrosurgical unit when arranged for a normal output, may be lack of connection of the dispersive plate or its imperfect placement.
- The use of flammable anesthetics, of oxygen and of nitrogen protoxyde 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 which 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 pace-maker, or other stimulation electrode: an interference may occur with the stimulator signal or the stimulator itself can be damaged. Please refer to the cardiologic department when in doubt.
- The use of electrosurgery is not recommended in patients:
  - with serious unbalance of arterial pressure

- with serious illness of the nervous system
- with serious renal insufficiencies
- in state of pregnancy

- Inadvertent stimulation of a patient's muscle and nerves can be caused by low frequency currents originating in electric sparks between the electrode and the tissue of the patient. Should neuromuscular stimulation occur stop the surgery and check all the connections to the generator.
- If this does not solve the problem the generator must be inspected by qualified service personnel.
- Never lay the pen on the patient drape. Set it on the instrument tray when not in use. Accidental activation can cause patient burns beneath the blade of the active electrode.
- The electrosurgical equipment does emit unnoticed radiation of high frequency energy that may effect other medical equipments, unrelated electronics, telecommunications, navigational systems.

2.2 INSTALLATION

- The electric safety of **DIATERMO MB380** and **DIATERMO MB240** 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 neccessary 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 are not advised. Should their use become necessary it is mandatory to use only simple or multiple adapter conforming to the actual safety requirements.
- The use of any electric apparatus involves the observance of some fundamental rules. Particularly:
  - don't touch the apparatus with wet or damp feet or hands
  - don't use the apparatus with naked feet
  - don't let the apparatus exposed to atmospheric agents
- 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.
- **DIATERMO MB380** and **DIATERMO MB240** must be destined only to the use for the which 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 modify 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 a authorized service center and ask for the 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 injiury in the event of accidental activation.

2.3 APPLICABLE SAFETY STANDARDS

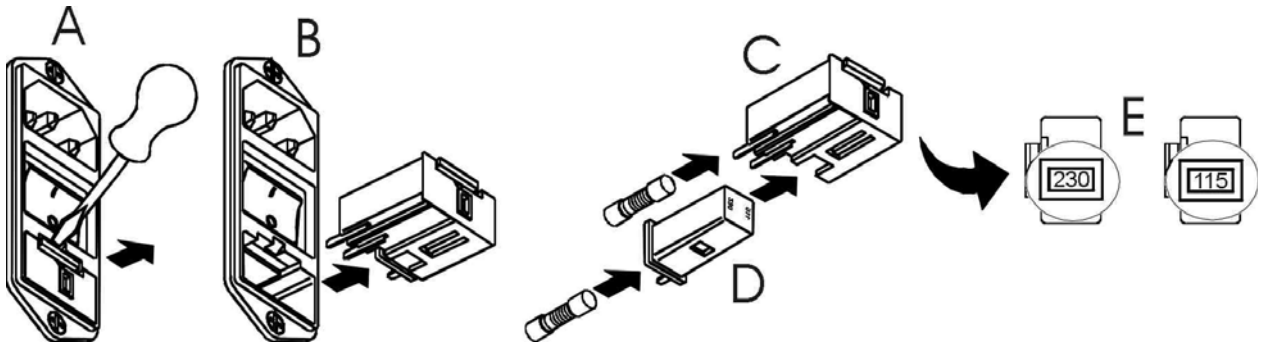
DIATERMO MB380 and **DIATERMO MB240** are conforms to the safety requirements of IEC 601-1/ EN60601-1 (Medical electrical equipment-General requirements for safety), and of IEC 601-2-2 / EN60601-2-2 (Medical electrical equipment - Particular requirements for the safety of high frequency surgical equipment).

3. INSTALLATION

- Inspect the equipment for damage during transit. Any damage should be reported to the carrier immediately.
- Unpack the equipment and carefully study the documentation and operating instruction supplied.
- The mains input voltage, indicated up the equipment mains input, must agree with the local mains voltage (mains frequency: 50-60 Hz).
-).
- 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:

Mains Voltage	110-120 V	Delayed fuse 10AT - 5 x 20 mm
Mains Voltage	220-240 V	Delayed fuse 5AT - 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 the mains cable to a mains outlet that has good earth connection.

OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN

- Position the equipment such that there is sufficient room at the ventilation slots at the rear of the unit. The ventilation slots in the rear of the equipment must be kept unobstructed. Air circulation must not be restricted in any way.
- Operate the equipment only in dry surroundings. Any condensation that occurs must be allowed to evaporate before putting the equipment into operation. Do not exceed the permissible ambient temperature or humidity.
- 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 4.3.5). In this way, if the value of the impedance is acceptable, the OC indicator light will stop flashing and the alarm to sound.
- Environmental conditions:

	Work	Transit/storage
▪ Temperature:	from 10 °C up to 40 °C	from -10 °C up to 50 °C
▪ Relative moisture:	from 30% up to 75%	from 10 % up to 100%
▪ Atmospheric pressure:	from 70 kPa up to 106 kPa	from 50 kPa up to 106 kPa

4. CONNECTORS AND CONTROLS

4.1 PLATE ON THE CABINET'S RIGHT SIDE

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

4.1.1 IDENTIFICATION DATA OF MANUFACTURER AND DEALER

The **DIATERMO MB380** and **DIATERMO MB240** H.F.Electrosurgical units are designed and manufactured by LED S.p.A. Via Secchia, 11 I-04011 APRILIA (LT) - ITALY.

The **DIATERMO MB380** and **DIATERMO MB240** H.F.Electrosurgical units are dealered by GIMA S.p.A. Via Trento, 10 I-20064 Gorgonzola (MI) - ITALY.

4.1.2 TECHNICAL DATA

DIATERMO MB380

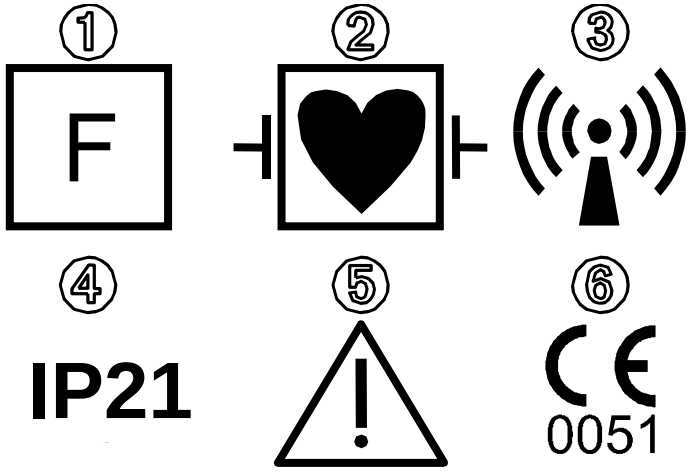
	MONOPOLAR OUTPUT COAG: 225 W - 300Ω	FREQUENCY:475 kHz
	MONOPOLAR OUTPUT CUT: 375 W - 300Ω	FREQUENCY:475 kHz
	BIPOLAR OUTPUT COAG: 80 W - 100Ω	FREQUENCY:525 kHz
	BIPOLAR OUTPUT CUT: 90 W - 100Ω	FREQUENCY:525 kHz
MAIN POWER:	115 Vac - 60 Hz FUSE: 2 x 10 AT (Antisurge) - 230 Vac - 50 Hz	FUSE: 2 x 5 AT (Antisurge)
DUTY-CYCLE:	intermittent 10 seconds emission / 10 seconds pause.	
CLASS:	I CF	

DIATERMO MB240

	MONOPOLAR OUTPUT COAG: 150 W - 300Ω	FREQUENCY:475 kHz
	MONOPOLAR OUTPUT CUT: 250 W - 300Ω	FREQUENCY:475 kHz
	BIPOLAR OUTPUT COAG: 80 W - 100Ω	FREQUENCY:525 kHz
	BIPOLAR OUTPUT CUT: 90 W - 100Ω	FREQUENCY:525 kHz
MAIN POWER:	115 Vac - 60 Hz FUSE: 2 x 10 AT (Antisurge) - 230 Vac - 50 Hz	FUSE: 2 x 5 AT (Antisurge)
DUTY-CYCLE:	intermittent 10 seconds emission / 10 seconds pause.	
CLASS:	I CF	

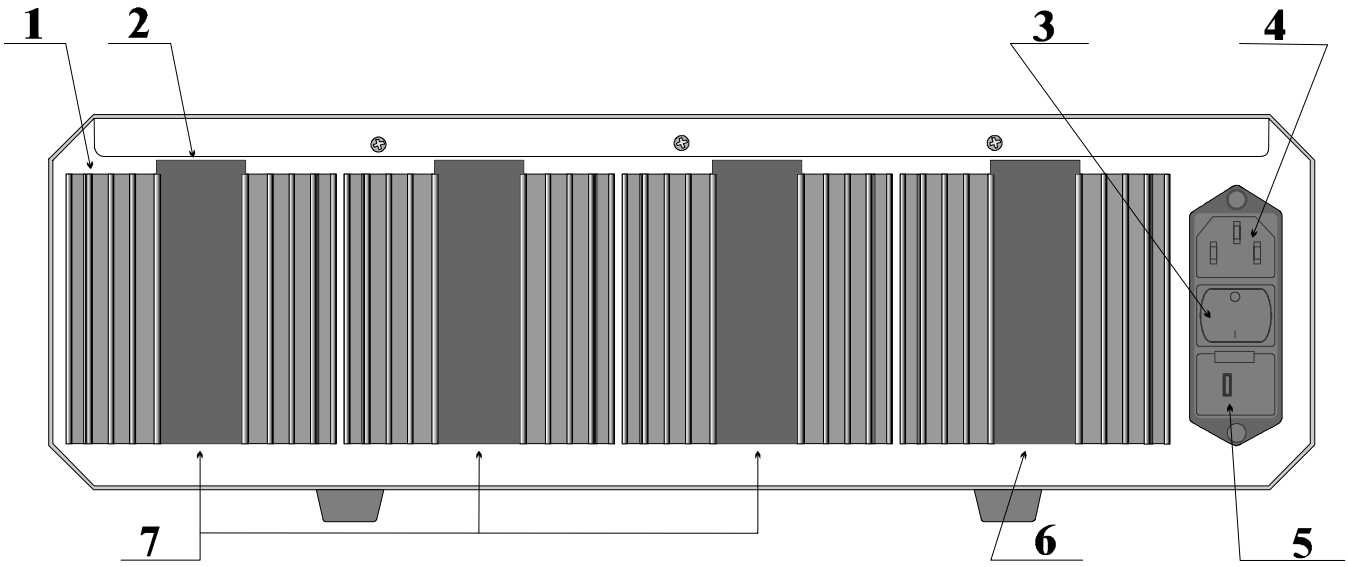
4.1.3 GRAPHIC SYMBOLS' MEANING

The requirements for the safety of H.F.
surgical equipment ask that some graphic symbols and technical data must be printed on the cabinet or on at least one of the panels of the generator unit to define its features and oversee its condition of work.
The meaning of the graphic symbols printed on the plate located on the right side of the cabinet is the following:
1- Floating Patient's Plate: not connected to the earth neither at low frequency nor at high frequency.
2- The equipment is protected against H.V. discharge due to the use of a Cardiac Defibrillator.
3- Not Ionizing Radiation emitted.
4- Equipment protected against dripping (IP21).
5- Read carefully the OPERATING INSTRUCTIONS before to attempt the use of the equipment.
6- Conforming the European Community Directive MDD93/42/ECC.



4.2 REAR PANEL

1 VENTILATION SLOT
2 PROTECTION AGAINST ESD
3 MAINS MECHANICAL SWITCH
4 MAINS INPUT CONNECTOR MODULE
5 FUSE HOLDER / VOLTAGE SELECTOR
6 BIPOLAR HIGH FREQUENCY AMPLIFIER MODULE
7 MONOPOLAR HIGH FREQUENCY AMPLIFIER MODULE



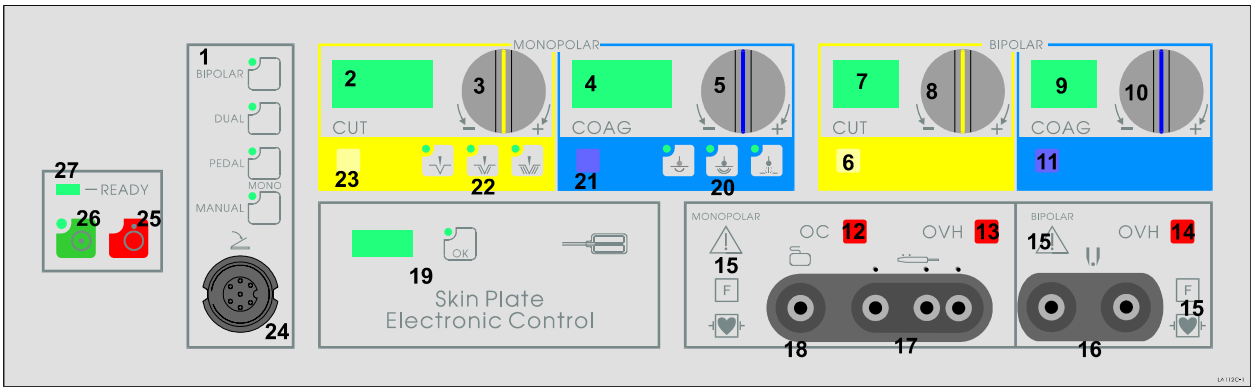
4.2.1 EQUIPMENT MAINS INPUT MODULE AND VOLTAGE SELECTOR.

The equipment mains input module provides the connection point for the power for the equipment's internal electronics. The mains input module incorporates the mains input socket, the main input voltage selector and in-line mains fuses.
WARNING: Before the unit is powered up the operator should check that the mains input voltage indicated on the power input module corresponds to the mains voltage supply to which it is to be connected, and that the correct mains fuse type for the selected mains voltage has been inserted.

4.2.2 POWER ON-OFF MECHANICAL 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 (i.e. left part). When the equipment is powered, the light inside the power on-off mechanical switch and the READY red Led on the right side of 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 a emergency stop switch, in the event of any fault. When the equipment is powered can be switched-on by the mains electronic switch located on the front panel.

4.3 FRONT PANEL



1 OPERATION SELECTION KEYS AND INDICATION LEDS
2 MONOPOLAR CUT POWER INDICATION
3 MONOPOLAR CUT POWER CONTROL
4 MONOPOLAR COAGULATION POWER INDICATION
5 MONOPOLAR COAGULATION POWER CONTROL
6 BIPOLAR CUT CURRENT OUTPUT WARNING LIGHT
7 BIPOLAR CUT POWER INDICATOR
8 BIPOLAR CUT POWER CONTROL
9 BIPOLAR COAGULATION POWER INDICATION
10 BIPOLAR COAGULATION POWER CONTROL
11 BIPOLAR COAGULATION CURRENT OUTPUT WARNING LIGHT
12 FAILURED PLATE CONNECTION WARNING LED'S ARRAY
13 MONOPOLAR HF AMPLIFIER MODULE'S OVER HEATING WARNING LED'S ARRAY
14 BIPOLAR HF AMPLIFIER MODULE'S OVER HEATING WARNING LED'S ARRAY
15 PRINTED WARNINGS SIGNALS
16 BIPOLAR FORCEPS CONNECTOR
17 MONOPOLAR HAND-PIECE CONNECTOR
18 PATIENT PLATE CONNECTOR
19 NEUTRAL ELECTRODE'S CIRCUIT SECTION
20 MONOPOLAR COAGULATION MODE SELECTION KEYS AND INDICATION LEDS
21 MONOPOLAR COAGULATION CURRENT OUTPUT WARNING LIGHT
22 MONOPOLAR CUT MODE SELECTION KEYS AND INDICATION LEDS
23 MONOPOLAR CUT CURRENT OUTPUT WARNING LIGHT
24 PEDAL INLET
25 SWITCH-OFF KEY
26 SWITCH-ON KEY
27 POWERED UNIT INDICATOR LED'S ARRAY

4.3.1 MAINS ELECTRONIC SWITCH

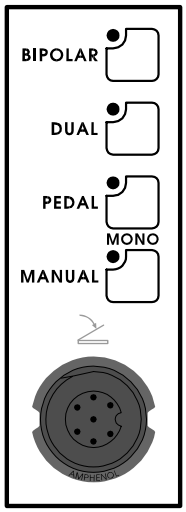
The mains electronic switch is used to control the switch-on of the equipment when the READY indicator is illuminated. To turn the equipment on, push the left key. When the equipment is switched-on the LED will illuminate.
To switch off the unit push the right key, this cut power to all the electronic circuits, thereby disabling all the equipment's functions.

4.3.2 USER KEYS

These keys are used by the user manual control the equipment by changing operative mode and output available current. The keys are split into two groups, the four operative keys, positioned at the right of the equipment, and the five current selector keys, positioned in the MONOPOLAR section.

4.3.3 OPERATIVE KEYS

The function of each of the operative keys is as follows:



BIPOLAR
Pressing the BIPOLAR key allow the unit only for bipolar operation excluding the monopolar section from the operative work. The operative condition is indicated by the BIPOLAR LED which will illuminate.

DUAL
Pressing the DUAL key allows the unit both for monopolar (except function COAG3 (SPRAY)) and bipolar operation. In this selected condition, monopolar current emission is controlled by-handpiece with double hand-switch while the bipolar current emission is controlled by double pedal. The double switch controls allow the independent selection of cut or coagulating emission current. The operative condition is indicated by the DUAL LED which will illuminate.
WARNING: When the DUAL operative mode is selected one of the monopolar current can be emitted together one of the bipolar current. In this case sum of the two current could exceed the maximum power value allowed by the international requirements which is limited to 400 Watts. The equipments automatically avoids the presetting not allowed output conditions.

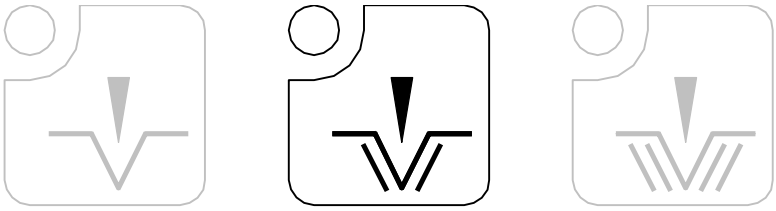
PEDAL
Pressing the PEDAL key allows the unit only for monopolar operation. In this selected condition, monoplar current emission is controlled by double pedal. The double pedal controls allow the independent selection of cut or coagulating emission current. The operative condition is indicated by the PEDAL LED which will illuminate.
ATTENTION: In this condition it is possible to select/to use function COAG3 (SPRAY).

MANUAL
Pressing the MANUAL key allows the unit only for monopolar operation. In this selected condition, monopolar current emission is controlled by handpiece with double hand switch. The double hand controls allow the independent selection of cut or coagulating emission current. The operative condition is indicated by the MANUAL LED which will illuminate.
ATTENTION: In this condition it is <u>not</u> possible to select/to use function COAG3 (SPRAY).

4.3.4 CURRENT'S SELECTION KEYS

The function of each of the current selector keys is as follows:
Pressing this key presets monopolar CUT current, i.e. pure current, to be delivered when a appropriated emission control is activated. Crest factor of the monopolar cut current is 1.4. Cut current preset condition is indicated by green LED which will illuminate.

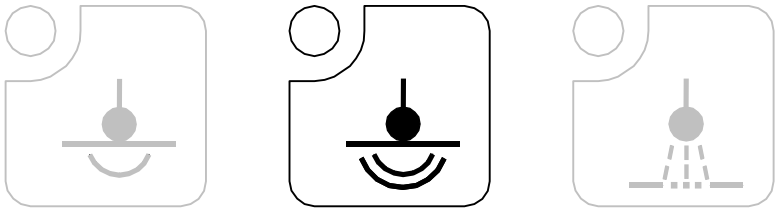
Pressing this key presets monopolar CUT/COAG 1 current, i.e. modulated current, to be delivered when a appropriated emission control is activated. Crest factor of the monopolar Cut/Coag 1 current is 1.5. Cut/Coag 1 current preset condition is indicated by green LED which will illuminate.



Pressing this key presets monopolar CUT/COAG 2 current, i.e. modulated current, to be delivered when a appropriated emission control is activated. Crest factor of the monopolar Cut/Coag 2 current is 1.7. Cut/COAG 2 current preset condition is indicated by green LED which will illuminate.

Pressing this key presets monopolar COAG 1 current, i.e. modulated current, to be delivered when the blu pedal (COAG) is activated. Crest factor of the monopolar Coag 1 current is 2.3. COAG 1 current preset condition is indicated by green LED which will illuminate.

Pressing this key presets monopolar COAG 2 current, i.e. modulated current, to be delivered when a appropriated emission-control is activated. Crest factor of the monopolar Coag 2 current is 3.5. COAG 2 current preset condition is indicated by green LED which will illuminate.



Pressing this key presets monopolar COAG 3 (SPRAY) current, i.e. modulated current, to be delivered when a appropriated emission control is activated. Crest factor of the monopolar Coag 3 (SPRAY) current is 7. COAG3 (SPRAY) preset condition is indicated by green LED which will illuminate.

4.3.5 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 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%

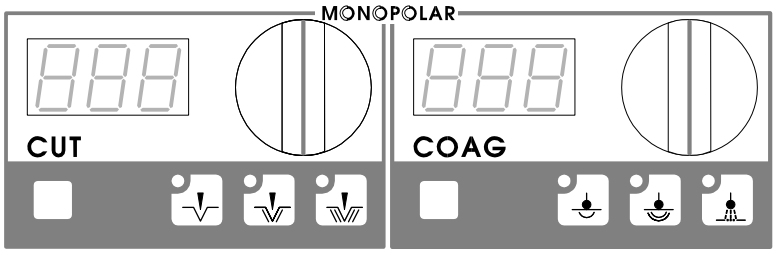
the equipment prevents the delivery of current, it indicates the OC condition and shows the new value of impedance.

4.3.6 CONTROL OF THE WARNINGS' ACOUSTIC LEVEL

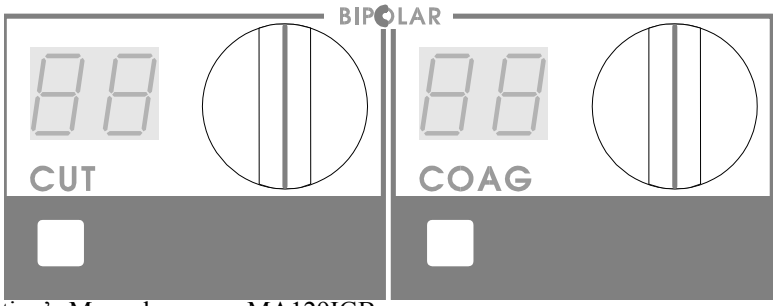
The sound level, of the warning signals those are present during the HF power delivery, is factory preset at about 70 dBA. It can be changed from about 40 dBA up to about 70 dBA in four steps.
To select the proper sound level please do as follows:
1 . Select Bipolar operative mode or be sure the Patient Plate is right connected, if one of the other operative modes is selected.
2 . Push the CUT/COAG 1 key and, maintaining this key pushed, push the CUT/COAG 2 key. All the four indication' LEDs in the operative mode section will light.
3 . Select the desired sound level by pushing one of the four keys: MANUAL for the lowest sound level, PEDAL and DUAL for intermediate levels or BIPOLAR for the highest sound levels.
When the sound level selection is finished, a short sound signal can be heard and the previously preset operative conditions are automatically restored.
The new preset sound level remains stored until a new selection is made.

4.3.7 DIGITAL DISPLAYS

The four Digital Displays are used for monitoring the preset output power, as follow:
MONOPOLAR CUT:
Displays the Monopolar Cut, or Monopolar Cut/Coagulation 1, or Monopolar Cut/Coagulation 2 preset output power level.
MONOPOLAR COAG:
Displays the Monopolar Coagulation 1, or the Monopolar Coagulation 2, or Monopolar Coagulation 3 Spray preset output-power level



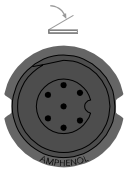
BIPOLAR CUT:
Displays the Bipolar Cut preset power level
BIPOLAR COAG:
Displays the Bipolar Coagulation preset power level.



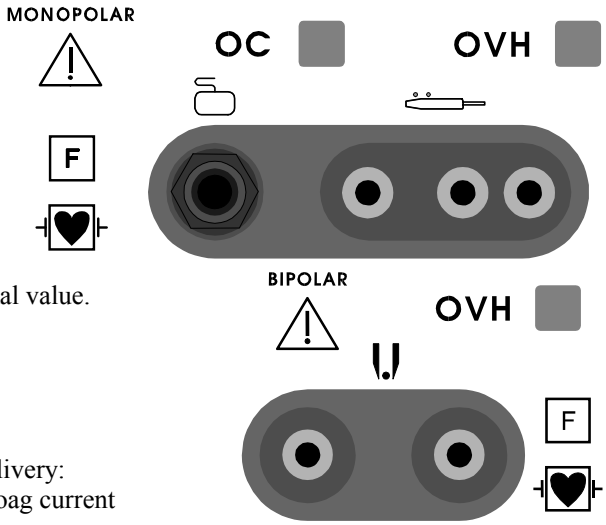
4.3.8 OUTPUT POWER CONTROL - INCREMENTAL ENCODER

When the unit is switched on by the electronic mains switch, all the power levels are automatically put at the minimum level. Whether the previous power levels are to be changed, four incremental encoders can be used to control the output power level and preset new values.
The four encoders provide fine control of the power, each for one of the available output current (MONOPOLAR CUT, MONOPOLAR COAG, BIPOLAR CUT, BIPOLAR COAG).
The use of the incremental encoder in the output level control allows to increase or decrease the output power level by steps as low as one single watt.

4.3.9 CONNECTORS



Pedal Connector
This is the connection point for the double pedal switch. The double pedal switch is allowed to control the emission either of the monopolar current or of the bipolar current depending by the operative condition. By the Cut (yellow) pedal switch the emission of the CUT current is controlled and by the Coag (blue) pedal switch the emission of the COAG current is controlled.
Monopolar Patient Plate Connector
This is the connection point for the Patient Plate.
The Patient Plate connection is continuously monitored, and should it fails, the current emission of the unit is immediately stopped.



Monopolar Handpiece Connector
This is the connection point for the handpiece with double hand-switch.-By the yellow key the emission of the monopolar CUT current is controlled and by the blue key the emission of the monopolar COAG current is controlled. The switch electric resistance is continuously monitored and the function of control of the emission stopped when the resistance value exceeds the normal value.
Bipolar Forceps
This is the connection point for the bipolar forceps.

4.3.10 SOUNDS SIGNAL

The following indicator sounds are emitted during the HF power delivery:
- A continuous sound at 2500 Hz frequency during Cut or Cut/coag current delivery.
- A continuous sound at 1250 Hz frequency during Coag current delivery.

The acoustic level of the two above said tones can be chosen by the operator . (Please refer to section 4.3.6)

4.3.11 INDICATOR LIGHTS

The four Indicator Lights are used for indicating various conditions of the unit's current emission, as follows:
MONOPOLAR CUT Illuminate when the unit emits Monopolar Cut current or Monopolar Cut/Coag current. The light's color is yellow.
MONOPOLAR COAG Illuminate when the unit emits Monopolar Coag current. The light's color is blue.
BIPOLAR CUT Illuminate when the unit emits Bipolar Cut current. The light's color is yellow.
BIPOLAR COAG Illuminate when the unit emits Bipolar Coag current.The light's color is blue.

4.3.12 WARNING SOUND

A modulated sound at 2500 Hz is emitted when the OC alarm is on. The sound level of this warning signal is fixed at about 70 dBA and it is not adjustable by the operator.

4.3.13 WARNING LEDS

Four red LEDs are provided for the unit's signal warning, as follows:
READY Illuminates when the unit is plugged to the mains, the mechanical mains-switch is on and the electronic mains switch is off. (The mechanical mains-switch is located in the rear panel of the unit).When this LED is illuminated the equipment is ready to be put in service by the mains electronic switch.
MONOPOLAR OC Illuminates when there is a failure in the connection of the monopolar patient plate (see 4.3.5). When this LED is illuminated the emission of the monopolar current is inhibited.
MONOPOLAR OVH Illuminates when the electronic power generator's temperature exceeds the normal range and the electronic circuit operation is no more safe. This can happen when the emission time exceeds the allowed duty cycle (10

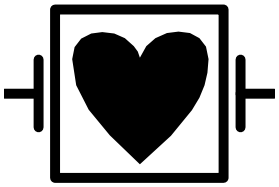
seconds emission / 30 seconds pause). When this LED illuminates the monopolar current emission has be immediately interrupt and stand-by condition has to be maintained for at least 25 seconds after the MONOPOLAR OVH LED ceases to be illuminated.
BIPOLAR OVH Illuminates when the electronic power generator's temperature exceeds the normal range and the electronic circuit operation is no more safe. This can happen when the emission time exceeds the allowed duty cycle 10 seconds emission / 30 seconds pause). When this LED illuminates the bipolar current emission has be immediately interrupt and stand-by condition has to be maintained for at least 25 seconds after the BIPOLAR OVH LED ceases to be illuminated.

4.3.14 PRINTED SYMBOLS

The symbols that are printed in the frontal panel are the meaning as follows:

Read carefully the OPERATING INSTRUCTIONS before to attempt the equipment's use.

Floating Patient Plate: not connected to the earth neither at low frequency nor at high frequency.



The equipment is protected against H.V.discharge due to the use of a Cardiac Defibrillator.

5. TECHNICAL SPECIFICATIONS

5.1 GENERAL

Equipment Description:
H.F. Electrosurgery Equipment for monopolar and bipolar major surgery. The units provides the facilities to fine preset the output power level and- choose the coagulating effect through the appropriate Crest Factor.
Cabinet:
Bench-top, metal housing, with the frontal panel covered by lexan sheet.

Height:	150 mm
Width:	470 mm
Depth:	370 mm
Weight:	15 Kg

Equipment Mains Input: Selectable 115 or 230 VAC, 50/60 Hz.
Maximum Current: 4 A (230V) or 8 A (115V)
IEC socket with in-line fuses and voltage selector.
In-line mechanical mains switch.
Displays:
Four Groups of LED Digital Displays provide the indication of the preset output level as follows:

DIATERMO MB380

MONOPOLAR CUT:	1 - 375
MONOPOLAR CUT/COAG 1:	1 - 340
MONOPOLAR CUT/COAG 2:	1 – 300
MONOPOLAR COAG 1:	1 - 225
MONOPOLAR COAG 2:	1 - 150
MONOPOLAR COAG 3 (SPRAY):	1 - 80
BIPOLAR CUT:	1 - 90
BIPOLAR COAG:	1 – 80

DIATERMO MB240

MONOPOLAR CUT:	1 - 250
MONOPOLAR CUT/COAG 1:	1 - 225
MONOPOLAR CUT/COAG 2:	1 - 200
MONOPOLAR COAG 1:	1 - 150
MONOPOLAR COAG 2:	1 - 100
MONOPOLAR COAG 3 (SPRAY):	1 - 80
BIPOLAR CUT:	1 - 90
BIPOLAR COAG:	1 - 80

Output Power Control By four incremental encoders one each for the control of the following kind of current:
MONOPOLAR CUT - MONOPOLAR COAG - BIPOLAR CUT - BIPOLAR COAG
The use of the incremental encoders allows the user to control very accurately the output power since it is possible to vary the preset output power in step as low as just 1 watt.
Max Output Power:

DIATERMO MB380

MONOPOLAR CUT:	375 W +/- 10%
MONOPOLAR CUT/COAG 1:	340 W +/- 10%
MONOPOLAR CUT/COAG 2:	300 W +/- 10%
MONOPOLAR COAG 1:	225 W +/- 10%
MONOPOLAR COAG 2:	150 W +/- 10%
MONOPOLAR COAG 3 (SPRAY):	80 W +/- 10%
BIPOLAR CUT:	90 W +/- 10%
BIPOLAR COAG:	80 W +/- 10%

DIATERMO MB240

MONOPOLAR CUT:	250 W +/- 10%
MONOPOLAR CUT/COAG 1:	225 W +/- 10%
MONOPOLAR CUT/COAG 2:	200 W +/- 10%
MONOPOLAR COAG 1:	150 W +/- 10%
MONOPOLAR COAG 2:	100 W +/- 10%

MONOPOLAR COAG 3 (SPRAY):	80 W +/- 10%
BIPOLAR CUT:	90 W +/- 10%
BIPOLAR COAG:	80 W +/- 10%

WARNING: WHEN THE DUAL OPERATIVE MODE IS SELECTED, THE SUM OF THE OUTPUT OF BOTH THE MONOPOLAR AND BIPOLAR CURRENT MUST NOT EXCEED 400 WATTS. If the output power presetting is made after DUAL operative mode is selected it will not be possible to increase the total power up the previously said value of 400 Watts. In the case the output power is preset before of the DUAL operative mode is selected, and the sum of the preset power exceeds the 400 Watts value, when the DUAL operative mode is selected, the digital displays showing the preset power, will blink and the output will be interdicted untill allowed preset condition had been restored.

Reference Load Resistance:

MONOPOLAR CUT:	300Ω
MONOPOLAR CUT/COAG 1:	300Ω
MONOPOLAR CUT/COAG 2:	300Ω
MONOPOLAR COAG 1:	300Ω
MONOPOLAR COAG 2:	300Ω
MONOPOLAR COAG 3 (SPRAY):	2 kΩ
BIPOLAR CUT:	100Ω
BIPOLAR COAG:	100Ω

No Load Max Voltage:

MONOPOLAR CUT:	1.4 kVpp +/-10%
MONOPOLAR CUT/COAG 1:	1.4 kVpp +/-10%
MONOPOLAR CUT/COAG 2:	1.4 kVpp +/-10%
MONOPOLAR COAG 1:	1.4 kVpp +/-10%
MONOPOLAR COAG 2:	1.4 kVpp +/-10%
MONOPOLAR COAG 3 (SPRAY):	4.2 kVpp +/-10%
BIPOLAR CUT:	0.5 kVpp +/-10%
BIPOLAR COAG:	0.5 kVpp +/-10%

Crest Factor:

MONOPOLAR CUT:	1.4
MONOPOLAR CUT/COAG 1:	1.5
MONOPOLAR CUT/COAG 2:	1.7
MONOPOLAR COAG 1:	2.3
MONOPOLAR COAG 2:	3.5
MONOPOLAR COAG 3 (SPRAY):	7
BIPOLAR CUT:	1.4
BIPOLAR COAG:	1.5

Output Frequency:

MONOPOLAR:	475 kHz +/- 10%
BIPOLAR:	525 kHz +/- 10%

Modulation Frequency:

MONOPOLAR CUT:	NONE
MONOPOLAR CUT/COAG 1:	10 kHz
MONOPOLAR CUT/COAG 2:	10 kHz
MONOPOLAR COAG 1:	10 kHz
MONOPOLAR COAG 2:	10 kHz
MONOPOLAR COAG 3 (SPRAY):	10 kHz
BIPOLAR CUT:	NONE
BIPOLAR COAG:	10 kHz

Allowed output time:

DUTY-CYCLE: 10 seconds output-25 seconds pause

Allowed maximum total output power: 400W.

5.2 OUTPUT POWER DIAGRAMS

See pages from 22 up to 25.

6. PREVENTIVE 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 04011 APRILIA (LT) - ITALY, or to a 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.

6.2 CLEANING OF THE CABINET

Switch the equipment off complitely 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 STERILIZATION OF THE ACCESSORY ITEMS

For what is possible it is recommended to use disposable accessories only and to eliminate them as special hospital refuse. Nevertheless, since some accessories must be used more than once it is mandatory to clean them with care and to sterilize them before the new use. The better way to clean and to sterilize the reusable accessories is to follow the instructions of the supplier of every element.
Don't clean H.F. cables, adapters or handles in an ultrasounds cleaner. Don't sterilize H.F. cables, adapters or handles with hot air sterilizers. After the use, clean the H.F. cables with a superficial alcoholic disinfectant. The H.F. cables or the handle can also be dipped in a cleaning and disinfectant solution, naturally, the life of service in this case can result reduced because of the oxidation of the contacts and cristalization of the electric thorns. Follow the instructions of the producer of the cleaning and disinfectants products and verify that the used active elements are compatible.
Then rinse completely all the parts with distilled water.
Steam sterilize at 134 °C (272 °F) H.F. cables, handles, adpters and electrodes.

6.4 REPAIRING

H.F. cable or handles cannot be repaired.
Replace always a defective item with a new one. All the accessories for HF electrosurgery, that are compatible with the electric characteristics of the unit and are conforming to the CE 93/42/EEC Directive, are applicable.

6.5 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, wire breakage, etc.
- Assure that all the electrical equipment is properly grounded
- Assure that all the accessories that should be used are available and sterilized.

6.6 FUNCTION AND SAFETY CHECKS AND TESTS

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

- 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 of the functioning of the patient plate monitoring circuit.
- Check of the functioning of the H.F. output controls
- Check of the uniformity of the resistance through the surface of the patient plate.

- Test of the earth conductivity resistance.
- Test of the earth leakage current.
- Test of H.F. leakage current.
- Control of the neuromuscular stimulation.
- Control of the accuracy of the output power.

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.