Coag&Cut M120

ELECTRIC SURGERY FOR MONOPOLAR AND BIPOLAR SURGERY

Mano Médical

Medical equipment for veterinarians

CE

SUMMARY

IMPORTANT

This instruction manual is an integral part of the HF electrosurgery unit and must be kept at the disposal of user personnel at all times. It is imperative that you carefully read and fully understand all instructions and directions before attempting to use an active electrode.

All safety warnings and instructions must be strictly observed. Ensure that this documentation is provided with the device when it is transferred to another team.

If technical assistance is required, contact the manufacturer or the retailer.

Report any serious incident related to the device to the manufacturer and to the competent authority of the Member State in which the user is established.

Fabricant / *Manufacturer*

LED SpA

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INTRODUCTION

Intended Use

Medical devices, reserved for the use of specialized medical personnel, intended for temporary use for surgical operations in which the cutting and/or coagulation of soft tissues is necessary, with a monopolar or bipolar technique, for minor open surgery and endoscopic.
The units are intended for the following sectors:

Description	**Coag&Cut M120**
Unit Code	MME10100.V201
Ambulatory Surgery	●
Pediatric Surgery	-
Plastic Surgery	-
Vascular Surgery	●
Dermatology	●
Endoscopy	-
Gastroenterology	-
Gynecology	○
Neurosurgery	-
Odontology	○
Orthopedics	-
Otorhinolaryngology	○
Pulmonology	-
First Aid	●
Urology	-

● = Recommended
○ = Usable
- = Not usable / Not recommended / Not advised

Standard Composition

Code	Description	Coag&Cut M120
-	Electrosurgical unit code	MME10100.V201
00100.03	Power supply cable 2m SIE-IEC	●/1
00202.00	Holter for handle and electrodes	●/1
00205.00	PENCIL S - Handle with switch	●/1
00304.00	Waterproof foot switch	●/1
00404.08_S	Cable for connect.neutral electrode disposa.type /5365	●/1
00500.00	ELECTRODE - Kit of assorted electrodes(10pcs) 5cm	●/1
5365A	NEUTRAL - Steel neutral electrode 120x160mm	●/1

●/ Pz = STANDARD

General Description

Coag&Cut M120 is an electrosurgical device that outputs currents for coagulated cutting/cutting, monopolar coagulation or bipolar coagulation. The currents can be emitted during the activation time of the output circuit.
It is possible to use neutral electrodes with a single plate or those with conductive surfaces divided into two zones.
The device is controlled by means of buttons and indicators placed on the front panel; the mains power input is on the rear panel.
The units have automatic control systems of the internal parameters and signal the possible damages / errors detected.
The operating parameters that are used are constantly saved so that each time the unit is powered up or the method of operation is changed, the last used parameters are recalled.
The transmission warning level (beep) may vary; each operator can choose his own level according to the ambient noise in the exercise of his activity.
Units can be operated with PMs with or without push buttons or by single or dual foot pedal control. On the other hand, it is possible to adapt a bipolar plug for coagulation (optional).

ELECTROPHYSICAL PRINCIPLES

In surgical interventions, the traditional use of the cold blade scalpel has been replaced by the electro scalpel, which allows tissue cutting and coagulation operations to be carried out quickly, simply and efficiently.
The electrocautery is built on the basis of the conversion of electrical energy into heat (Joule's principle) and it is made up of:

- a sinusoidal oscillator in radio frequency (0.4 - 4MHz);
- a wave packet generator, with a packet repetition frequency of 15-30 kHz;
- a mixer for the transfer to the power amplification block of the only waveform suitable for cutting or the only waveform suitable for coagulation, or a signal obtained by appropriate mixing of the two forms of waves;
- a power amplifier block capable of supplying the necessary power in terms of current and transmitting an amplified signal to the electrodes via a transformer;
- a safety circuit for the return electrode, to control a possible interruption of the cable and to suspend the emission of the radio frequency;
- an active electrode attached to a PM;
- a neutral return electrode, which closes the circuit through the patient.

The effects of electric current passing through biological tissue can cause:

1. Joule effect
2. Faraday effect
3. Electrolytic Effect

1) Joule Effect

In the biological tissue crossed by the electric current of the electro scalpel, there is a heating, Joule effect, depending on the specific electrical resistance of the tissue, the power of the current, the time of application which can determine different transformations cellular.

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

The influence of the thermal effect, Joule effect is realized by:

• Current intensity and output power

• By degrees of modulation

Interpretable parameters of the waveform of the high frequency current produced by the generator.

• Shape of the electrode

Pointed or rounded according to the requirement, it is of reduced dimensions, however the current density on the surface of the point [$A \cdot m^{-2}$] is very high. Thin section electrodes create high current density, high temperature, promoting cutting action. Those with a large surface create a lower current density, a lower temperature, favoring a coagulation effect.

• Resistance of the active electrode

The thermal effects are related to the resistance of the body to which must be added the contact resistance of the electrode. It is essential to keep the active electrodes perfectly clean so as not to have a reduction in the cutting effect.

• Characteristics of fabrics

The differences in resistivity change according to the biological tissues.

Biological tissue (In the range of 0.3 to 1 MHz)	**Metals**
Blood 0,16 x 10^3 Muscle, kidney, heart 0,2 x 10^3 Liver, spleen 0,3 x 10^3 Brain 0,7 x 10^3 Lung 1,0 x 10^3 Fat 3,3 x 10^3	Silver 0,16 x 10^{-5} Copper 0,17 x 10^{-5} Gold 0,22 x 10^{-5} Aluminium 0,29 x 10^{-5}

(Example of specific resistances of fabrics and metals)

Based on the temperature reached and according to the speeds of movement used, it is possible to use different radio frequency current techniques on the body.

Coagulation

A temperature of 60 to 70 ºC in the area around the active electrode causes a slow rise in the temperature of the intracellular fluid, the water contained in the cells vaporizes and a clot action is obtained which blocks bleeding.

Cut

A temperature of approximately 100 ºC in the proximal zone of the active electrode causes the vaporization of the intracellular liquid and the explosion of the cells. The vapor present around the electrode initiates an intercellular chain reaction depending on the direction in which the active electrode is used, immediately transmitting the energy of vaporization to the surrounding tissues.
The cut is therefore not a mechanical resection. If the temperature reaches 500°C, tissue carbonization occurs with a cauterizing action.

Mixed currents

Mixed currents are obtained by combining the effects of coagulation and electrotomy. It is verified a reduction of the bleeding during a cutting procedure, or according to the manipulation a consistent layer of necrosis.

The high frequencies used by the electro scalpel, however, do not allow the electromagnetic field to penetrate the material and they cause the current through the conductor and more specifically on the outermost surface, decreasing exponentially to become negligible at the center. of the conductor section. This effect, known as the

'skin effect', involves a reduction in the section necessary for the passage of the current, an increase in the electrical resistance of the material and it becomes a considerable problem for the neutral electrode. Indeed, in this electrode the current density is very high (KA/m^2) on the edges, and where the excessive increase in temperature by 'Joule effect' causes burns to the patient. It is not uncommon for a patient to have been burned during an operation, which is confirmed by the burn having the shape of the edge of the neutral electrode. To reduce the risk of burns, it is necessary to dose the output power with caution ($I^2 \cdot t$) and to comply with the rules for the application of the neutral electrode on the patient, (see SAFETY chapter).

2) Faraday Effect

The pulsed electric current causes neuromuscular stimulation, which initiates the process of stimulating the physiological process of ion exchange, responsible for the transmission of stimuli that cause muscle spasms and cardiac phenomena of extrasystole and ventricular fibrillation.

The effect of these stimuli is known as the faraday effect and is expressed as:

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

The physiological stimulation transmission system follows a limiting curve in which the pulsed or low frequency currents generate a stimulation surge. With the high frequency alternating current, higher than 200 kHz, used in the electro scalpel, there are no neuromuscular reactions, the exchange of polarity being fast enough not to influence the patient at the level of neuromuscular reactions, or cause electrolyte damage to the body.
For this reason, all high frequency generating equipment for surgical use, electro scalpel, operate with base frequencies above 300 kHz, so as not to cause electrical stimulation.

3) Electrolytic Effect

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

OPERATIVE TECHNIQUES

Monopolar Cut

The monopolar cut is the sectioning of the biological tissue obtained by the passage of high frequency and high density current concentrated by the tip of the active electrode. When the high-frequency current is applied to the tissue through the tip of the active electrode, it generates molecular heat in the cells so intense that it causes them to burst. The cutting effect is achieved by moving the electrode through the tissue and destroying cells one after another. The movement of the electrode avoids the lateral propagation of heat in the tissue, thus limiting the destruction to a single line of cells.
The best current for cutting is pure sinusoidal current, without any modulation, as it gives a clean incision with minimal thermal and therefore haemostatic effect. This effect can be adjusted with great precision, it can be used safely without damaging the bones, but good coagulation during the cut being one of the main advantages of electro surgery, it is preferable to use a current with some modulation.
Here are some guidelines that will help the surgeon get a good incision:

- keep the fabric moist but not wet;
- try the cut before activating the electrode;
- hold the electrode perpendicular to the tissue;
- activate the electrode before putting the instrument in contact with the tissue;
- keep the electrode very clean (for this purpose it is advisable to use the “optional” electrode cleaning sponges F7520);
- wait at least five seconds before repeating a cutting pass.

If the power output is correct, there should be:

- no resistance to movement of the electrode in the tissue;
- no change in color of incised surfaces;
- no fabric fibers on the electrode.

Monopolar Coagulation

Monopolar coagulation is the hemostasis of small blood vessels in body tissue by passing high frequency current through the active electrode.
When, to dissipate the energy over a larger surface, a current with reduced density and a large surface electrode are used, the superficial cells are dried without penetrating in depth, thus obtaining a coagulation effect. The superficial coagulated cells serve as an insulating layer and prevent the heat deriving from subsequent applications of current from penetrating too deeply into the tissues.
The current generally used for coagulation is modulated: the sharpness of the incision, the quality of hemostasis and the degree of tissue destruction depend on the percentage of modulation. A more marked modulation of the current gives a less clean incision and a deeper destruction of the tissues, but a better coagulation.

Here are some indications that will help the surgeon to obtain a good coagulation:

- Select a ball or thick wire electrode.
- Locate the bleeding vessel.
- After staunching the blood, lightly touch the vessel before activating the electrode.
- Stop activating the electrode as soon as the tissue has bleached, so as not to damage it;
- Keep the electrode very clean (for this purpose it is advisable to use the “optional” electrode cleaning sponge F7520).

Bipolar Coagulation

Bipolar coagulation is the hemostasis of small blood vessels in the tissue between the two ends of a special tweezer. When the current density is reduced the effect is that of drying the cell surface, without deep penetration, and without consequent coagulation. These superficially coagulated cells act as an insulating layer, which prevents the heat from successive applications from penetrating too deeply.

CONTRAINDICATIONS AND SIDE EFFECTS

The use of electrosurgery is contraindicated in patients:

- pacemaker carriers;
- with stimulation electrodes;
- with metallic prostheses;
- with serious blood pressure imbalances;
- with serious diseases of the nervous system;
- with serious kidney failure;
- in a state of pregnancy.

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

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

- insufficient training of surgeons or health personnel on the modalities necessary to avoid or reduce the risk of burns with the use of high-frequency electro-scalpel equipment;
- use of highly alcoholic disinfectants;
- erroneous positioning of the patient during the procedure;
- contact of the active electrode with the patient's skin;
- contact with liquids;
- abnormally prolonged application of high frequency currents;
- incorrect application of the neutral electrode.

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

SECURITY

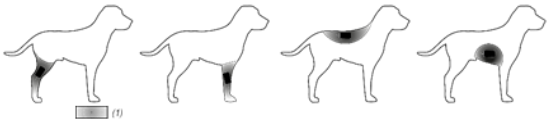
WARNING: Electrosurgery can be dangerous: improper use of each of the elements of the electrosurgical system can cause serious burns to the patient. It is imperative that you carefully read and fully understand all instructions before attempting to use an active electrode. Neither the manufacturer LED SpA nor any of the retailers can be held liable for loss or damage caused to persons and equipment, directly or indirectly, because of improper use of the device and its accessories.
The accessories supplied with the unit have characteristics compatible with this unit, they could be incompatible with other electrosurgical units; the user must check, before connecting other accessories to this unit, that they have insulation characteristics compatible with those of this unit (see technical characteristics). It is recommended to check the integrity of the packaging of any sterile accessories before the first use.

Generality

The following precautions reduce the risk of accidental burns:

- The neutral electrode should be placed over the entire available surface of the patient's body, preferably at the extremities, as close as possible to the intervention area. Avoid connecting the neutral electrode to protruding bony parts of the patient, prostheses, scar tissue, parts of the body subject to the accumulation of fluids or subcutaneous fatty tissue. The body part should be hairless, dry, and clean. Do not use alcohol to clean the skin. Except for veterinary use, the use of gel is not recommended for electrodes.
- If you use a single-use neutral electrode, respect the use-by dates.
- If you are using a reusable electrode, make sure that the attachment is in good condition and guarantees continuity.
- Apply the neutral electrode in such a way as to avoid the transverse path of the current (prefer the vertical or diagonal path) if a neutral electrode divided in two is used. This is to allow an even distribution of current over the surface of the neutral electrode and reduce the risk of burns to the patient.
- If it is not possible to apply the neutral electrode correctly, prefer, if possible, the bipolar technique instead of monopolar.
- The patient must never be in contact with metal parts connected to earth or having a high coupling capacity towards earth (for example the operating table or supports). We recommend the use of antistatic fabrics.

- Avoid skin to skin contact (e.g., paw to trunk, paw to paw, udder, etc.) by applying dry surgical gauze. Also, areas where sweat accumulates should be dry.



(1) Application areas

- If electrosurgical generators for physiological monitoring are used at the same time and on the same patient, all the electrodes must be as far as possible from the electrodes of the electrosurgical generator. Avoid using monitoring needles. We recommend monitoring systems that incorporate devices with high frequency current limitation.
- The connection to the electrodes should be positioned to avoid contact with both the patient and other cables. Active electrodes must remain isolated from the patient.
- The use of the bipolar technique is recommended for surgical operations on parts of the body of relatively small section in order to avoid any undesirable coagulation.
- The output power level must be as low as possible for the result to be achieved.
- A power level that is too low or the unit malfunctions when it is prepared for normal power may indicate improper application of the neutral electrode or poor contact in the connections. For this reason the neutral electrode application and connections should be checked before selecting a higher wattage.
- In the event of head or thorax surgery, avoid the use of a flammable anesthetic of oxygen and nitrous oxide (N2O), unless it is possible to aspirate these gases. For disinfection, flammable substances must not be used. Before using the electrosurgical unit, allow all the gases that have been used to clean or disinfect to evaporate. Flammable solutions may collect under the patient or in hollow parts of the body such as the navel or vagina. Any fluids that deposit in these areas must be removed before using the unit. The danger of endogenous gases must also be considered. When impregnated with oxygen, certain materials such as cotton wool or gauze can catch fire on contact with the sparks normally produced by the device.
- There is a risk for patients fitted with pacemakers or other stimulation electrodes, because if there is interference with the signal from the pacemaker, the signal may be damaged. If in doubt, it is best to seek advice from the cardiology department.
- The electrosurgical device emits, without warning, electrical radiation on the telecommunications and navigation systems.
- The user is advised to examine the accessories. In particular the cables to ensure that the electrodes and possible accessories, such as endoscopy, to ensure that the insulation is not damaged.

- To connect accessories compatible with the characteristics of the unit, it is advisable to compare the insulation characteristics of the accessories (ask the dealers) with those of the unit supplied (see the technical characteristics).
- **Caution**: Damage to the unit may cause an unwanted increase in output power.
- Stimulation of the patient's muscles or nerves may be caused by low frequency currents caused by an electric spark between the electrodes and the patient's tissue. If this occurs, stop surgery immediately and check all generator connections. If none are defective, have the unit examined by a service technician.

Putting into service

- Electrical safety is guaranteed only if the appliance is correctly connected to a power supply network connected to earth in accordance with current safety standards. It is imperative to verify this fundamental condition. If in doubt, ask qualified personnel to carry out a meticulous check of the entire electrical circuit. The manufacturer cannot be held responsible for damage caused by the lack of an effective commissioning ground. It is also forbidden to carry out an operation with a device that is not effectively earthed. (If in doubt have electrical commissioning checked)
- Before connecting the device, make sure that the voltage (indicated on the rear panel) corresponds to that of the mains.
- In the event of incompatibility between the current socket and the power cable, replace them with connectors and accessories that are legally authorized. It is not recommended to use adapters, multiple sockets or extension cords. If you cannot do otherwise, at least ensure that they comply with the safety standards in force.
- Do not leave the device exposed to atmospheric agents (rain, sun, etc.).
- Do not leave the appliance plugged in unnecessarily. Turn it off when you're done using it.
- The use of the unit is not allowed in an environment with risk of explosion.
- The unit must be intended exclusively for the use for which it was specially designed. Any other use is improper and dangerous. The manufacturer cannot be held liable for damage caused by improper, erroneous or incorrect use.
- It is dangerous to modify, or attempt to modify, the characteristics of the device.
- Before any cleaning or maintenance operation, disconnect the appliance either by removing the plug from the socket or by turning on the main switch.
- In case of damage or malfunction turn off the unit. For all repairs, call an assistance center and ask for original spare parts. Any other solution risks compromising the security of the device and especially that of its user. (The safest thing is to return the device to the manufacturer)

- Do not deactivate or reduce the level of the acoustic signal signaling the activation of the generator. An activation signal can minimize or at least avoid harm to the patient or personnel in the event of accidental activation.
- Operation of the unit must not radiate power between the active and neutral electrode or between the active electrode and surrounding metal parts.
- If necessary, use a smoke extractor on the operating field.

WARNING : Use in the operating room requires the use of a waterproof pedal (option: Waterproof single pedal REF 00304.00 – Waterproof double pedal REF 00305.03)

Patient safety

During high frequency procedures, the patient is a live conductor of grounded electrical current. If, therefore, there is an electrical contact between the patient and conductive objects, metal, fabrics and wet or soaked fabrics, etc.), at the point of contact an electric arc will form which could cause thermal necrosis. It is recommended to carry out the appropriate checks of the workstation and its accessories before use and to respect all the safety rules provided for the use of electrosurgery devices.

Proper Patient Positioning

Avoid intentional or accidental patient contact with grounded metal parts and ensure that:

- The patient is not in contact with metal parts, operating table, supports. That ventilator tubes do not accidentally press on the patient's body.
- On the operating table with ground connection, there should always be coverings capable of discharging electrostatic currents.
- The patient is positioned on a base fabric with insulating properties, itself placed on intermediate layers of insulation.
- The patient is not in contact with wet fabrics or mattresses.
- Possible body secretions and liquids applied for hygiene or other types of liquids do not wet the dry tissues.
- That there are no liquid residues under the patient.
- Any urinary excretions are eliminated using catheters.
- The areas of the body most characterized by intense perspiration, the extremities in direct contact with the trunk of the body or the points of skin-to-skin contact are kept dry by interposing fabrics (leg/trunk, leg/leg, breasts, skin folds, etc.).
- All conductive and earthed supports, stirrups, are suitably insulated.
- The quantity of anesthetics is well regulated to avoid excessive perspiration.

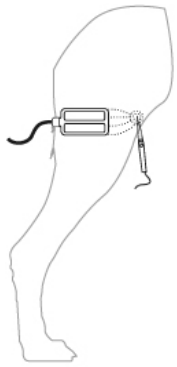
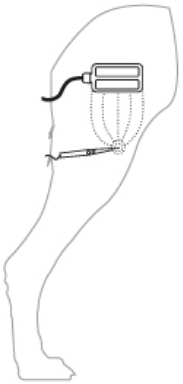
Position correcte de l'Électrode Neutre

The use of the neutral electrode (or current dispersion plate) is essential in the monopolar technique, to avoid any "return" of the cutting or coagulation current to the electrocautery.

Two types of neutral electrodes:

- **Neutral electrode**, with single connection cables, with which there is no control over the contact between the neutral electrode-patient.
- **Neutral electrode divided into two parts**, with separate connection cables with which there is a neutral electrode-patient control.

Attention must be paid to the correct positioning of the neutral electrode to avoid burns and risks for the patient, (see information on this subject below).

(CORRECT APPLICATION) 	In the illustration on the left, you can see the CORRECT positioning of the neutral electrode divided in two. The patient plate should be positioned perpendicular to the operating field. Avoid the transverse path and prefer the vertical or diagonal path to allow a uniform distribution of the current on the surface of the neutral electrode.	***(WRONG APPLICATION)*** 	Example of the neutral electrode split in two and applied incorrectly, parallel to the operating field. In this way the current distribution is not uniform on the two surfaces of the neutral electrode.

Whether for single part or split electrodes, before positioning the neutral electrode, clean and remove any remaining foreign substances from its surface. Do not apply the neutral electrode on scars, bony prominences or on anatomical parts in which there are metal prostheses or remote monitoring electrodes. Apply it, on the other hand, on the well bathed tissues such as the muscles and near the operative site. If a disposable neutral electrode is used, respect the expiry dates, if on the other hand a non-disposable neutral electrode is used, ensure that the fixing systems guarantee good conductivity. It is of paramount importance that the neutral electrode is fully applied over its entire surface to avoid burns. When a neutral electrode partially loses contact with the patient, the current flow density in the portion of the electrode still applied experiences a current rise. The density of the current flow under the neutral electrode is no longer homogeneous, and there is an ill-distributed heating on the surface which is especially true on the edges of the neutral electrode.

Electrosurgical HF Laparoscopy

Laparoscopy is now a reality that has revolutionized surgical procedures by guaranteeing improvements for the patient in terms of recovery and healing time. Undoubtedly in laparoscopy monopolar HF surgery is the most used for its eclecticism, pure cut, coagulation, mixed cut which combines both functions, however this operational modality can involve some risks for the patient: burns.

Reduced visual field, insufficient maintenance of laparoscopic instrumentation, interference on the screen, insufficient preparation of the surgeon or his distraction, significant development of smoke, inadequate insulation, capacitive currents, contact of the tip of the active electrode with the surrounding tissue, are all factors that contribute to increasing the danger of burns, intra-abdominal lesions, tissue necrosis, perforation of internal organs. The natural surgical environment in which the active electrode is close to other conductive instruments and body tissue can favor the transmission of electric currents outside the visible field of laparoscopy, causing accidental burns, through:

- direct coupling
- lack of insulation
- capacitive coupling.

The direct coupling takes place while the active electrode is in contact with another metal instrument, transmitting an electric current to it and then increasing the risk of burns to the surrounding tissue, for example to the intestine, or to other organs. The insulation can be compromised using an excessive tension with an improper use or the mechanical rupture of the rod of the electrode which can occur during an operational procedure or in the phases of cleaning and sterilization of the instrumentation. Poor invisible insulation of the electrode, when it is activated without foreseeing the risk of danger of burns, therefore more insidious. A small break in the insulation is paradoxically more dangerous than a large one, because the more the current is concentrated the more it is likely to cause burns.

The capacitive coupling is verified when the electric current is induced by the active electrode on conductive material, although the insulation is perfect. During HF electrosurgery interventions, the rapid variation of the electric field around the active electrode is only partially thwarted by the insulation and creates ionic currents which, on contact with the tissue, cause a rise in temperature which can reach up the burn.

To limit the risk of burns during HF electrosurgery procedures in laparoscopy, the following measures are recommended:

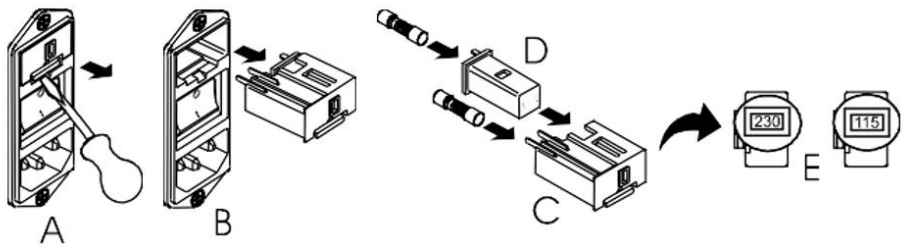
- More complete and scrupulous training of the medical staff.
- Thorough visual examination of the surgical instrumentation (laparoscopic active electrode, etc.).
- Use of disposable electrodes – Please note that the finer insulation that characterizes them requires more careful verification of possible breakage or current output generator coupling.
- Prohibition of the use of cannulas made of composite materials, plastic-metal).

- Adoption of the bipolar technique for coagulation, less versatile, but safer, because the necroses due to the dispersed heat are only local in the event of prolonged application of the current.

From all that has been exposed, it follows with certainty that burns are a real problem of electro surgery interventions in HF, however they can be contained and limited if the possible causes are well known and especially if the medical team is prepared to face them.

PUTTING INTO SERVICE

- Inspect the device for any damage that occurred during transport. Claims for damages will be accepted only if they are immediately communicated to the deliverer and indicated on the delivery note in return to LED SpA or to your own retailer. If the unit is returned to LED SpA or your retailer, it is necessary to use the original packaging of the product or packaging that guarantees the safety and integrity of the material during transport.
- Remove the device from its packaging and scrupulously study the documentation and instructions for use supplied. The voltage indicated above the power supply input must be the same as the local mains voltage (frequency: 50-60 Hz). The units designed for the 115/230Vac supply voltage are delivered with a connection for the 230Vac supply voltage. The modulus relating to the value written on the label.
- For the provision of the correct power supply voltage refer to the following indications:
  (A-B) Extract the fuse holder from the power module.
  (C) Insert the appropriate fuse into the module according to the following table:
  Voltage 110-120 V Fuse Delayed 2x T6.3 A / 5 x 20 mm
  Voltage 220-240 V Fuse Delayed 2x T3.15 A / 5 x 20 mm
  (D) Fuse holder cassettes, extract and turn until reading in the window.
  (E) Designated voltage - reinsert the fuse holder into the holder.



- Connect the power cable to a mains socket with good earthing.

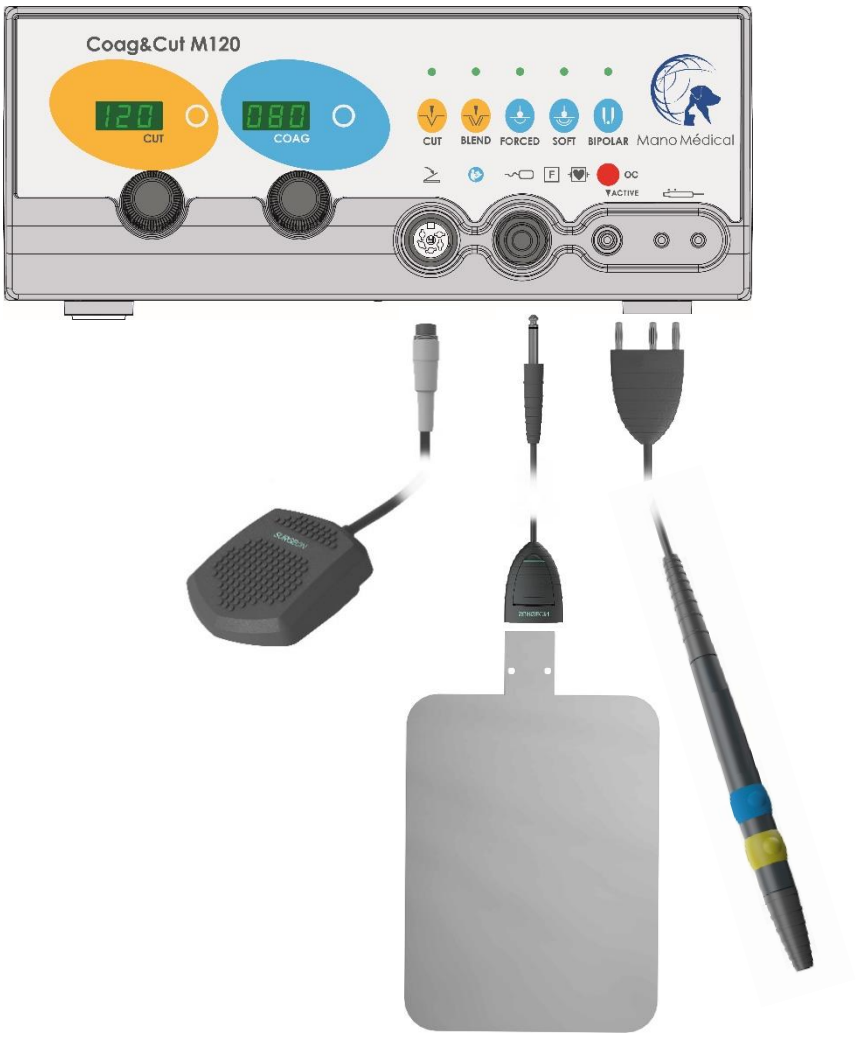
IT IS FORBIDDEN TO OPERATE THE APPLIANCE IF IT IS NOT CORRECTLY EARTHED.

- The unit must be installed on a flat surface, the dimensions of which correspond at least to the base of the appliance. Around the unit a space of at least 25 cm must be left.
- Connect the mains power cord to the socket located at the back of the device.
- Connect, if applicable, the point for the equipotential bonding present on the rear part of the unit to the commissioning equipotential connection, if any.
- Position and fix the single or double pedal (optional) on the connector on the front of the device.
- Connect the PM with two push-buttons, (If using a PM without a push-button, the plug must be placed in the connector marked "ACTIVE".
- If bipolar forceps are used, it is necessary to use the special optional adapter (REF 00498.00).
- The appliance must be used in a very dry room. Let all condensation evaporate before turning the unit on. Do not raise the ambient temperature or humidity above the usually accepted standards.
- Ambient conditions:

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

- Before starting to use the device, it is essential to assemble the neutral electrode and the connection cable and to connect the neutral electrode to the device. The neutral electrode must be positioned correctly on the patient (see Safety chapter). With the neutral electrodes divided into two parts when the device is switched on, if the impedance value read by the device is acceptable, the OC indicator light will stop flashing.

- When the unit is powered up and turned on by the switch located at the rear, when the self-test is complete, the operating setting levels will be displayed with the power values of the last use (when the unit is switched for the first time the level will be 00).



Monopolar Standard Configuration

- Use in **MONOPOLAR TECHNIQUE**:

Treatment with two-push-button PM without foot pedal:
Press the yellow push button on the PM to obtain a cutting current (the choice between CUT and BLEND is executed by pressing the corresponding push button on the unit) press the blue button on the PM to obtain a current coagulation (choices between FORCED COAG, SOFT COAG, and BIPOLAR must be selected by pressing the corresponding buttons on the unit).

Treatment with a PM with two push buttons and a simple footswitch:
Select using the keys on the unit a function between the CUT or BLEND cut and the FORCED COAG, SOFT COAG or BIPOLAR coagulation, then PRESS the PM contact - yellow key for the pre-selected cut, blue key for the pre-selected coagulation. To activate the electrode, press the pedal while keeping the PM button pressed.

Treatment with PM with two push buttons and double footswitch contact (optional):
Press the yellow switch on the pedal or the yellow push button on the PM to select and output the cutting current (the choice between CUT and BLEND must be established beforehand by pressing the corresponding push buttons on the unit) or the blue switch on the pedal or the blue push button on the PM to emit the coagulation current (the choice between FORCED COAG, SOFT COAG and BIPOLAR must be established beforehand by pressing the corresponding push button on the unit).

Treatment with PM without push button (option) and a single contact pedal:
Connect the PM to the "ACTIVE" socket and select the current for the CUT or BLEND cut or the FORCED COAG, SOFT COAG or BIPOLAR coagulation current on the device. To obtain the selected current press the pedal.

Treatment with PM with two push buttons and double footswitch contact (optional):
Connect the PM to the "ACTIVE" socket and press the YELLOW side of the pedal to obtain the cutting current (the choice between CUT and BLEND must be established by pressing the corresponding button on the unit) or press the side BLUE of the pedal to establish the coagulation current (the choice between FORCED COAG, SOFT COAG and BIPOLAR must be established by pressing the pusher on the unit).

- Use in **BIPOLAR TECHNIQUE**:

Bipolar forceps (optional) and simple pedal:
Connect the optional adapter (REF 00498.00). The device works only in BIPOLAR mode. The pedal makes contact possible and deactivates the manual function; Press the pedal to coagulate. To avoid damaging the clamp, do not make a short circuit.

Bipolar forceps (option) and double pedal (option):
Connect the special adapter (REF 00498.00). The device works only in BIPOLAR mode. The pedal makes contact possible and deactivates the manual function. Press the side of the pedal corresponding to BLUE (Coagulation). To avoid damaging the clamp, do not make short circuits.

NOTE: *To obtain the bipolar function it is necessary to have a series of optional accessories, in particular:*

1. Adapter for bipolar operation	*2. Cable for bipolar forceps*	*3. Accessory for bipolar (Exe: Bipolar forceps)*
		

CONNECTORS AND CONTROLS

Number plate on the lower part

Safety requirements for H.F. surgical equipment require graphical data and symbols that must be printed on the module or on at least one of the panels of the generator unit to define its features and to monitor its operating status.

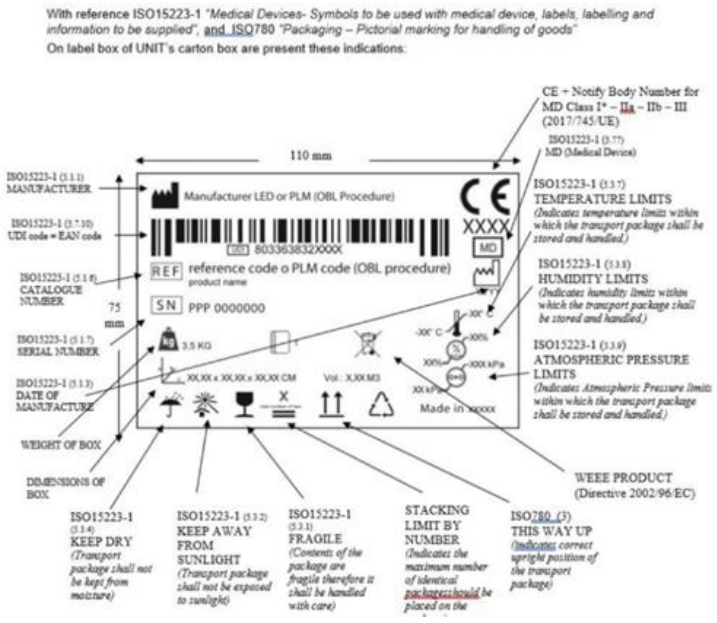
Identity of Manufacturer

Coag&Cut M120 high frequency electrosurgical unit is designed, built and tested in the facilities of LED SpA Aprilia (Lt) – Italy.

Meanings of the Graphic Symbols

								
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*

The meaning of the graphic symbols printed on the plate placed on the rear panel of the device and on the packaging is as follows:
1- Floating patient plate: it is not connected to earth, nor to high or low frequencies.
2- The class CF device is protected against discharge caused by the use of a defibrillator.
3- Unit that does not generate ionizing radiation.
4- Follow the instructions.
5- CE marking
6-At the end of life, the current product should not be eliminated as an urban refuse, but it should be eliminated in a separate collection.
7- Manufacturer.
8- Serial number.
9- Manufacturing data.



Frontal Panel

1-CUT function selection key 2-BLEND function selection key (cutting/coagulation) 3-FORCED COAG function selection key (superficial coagulation) 4-SOFT COAG function selection key (deep coagulation) 5-BIPOLAR function selection key 6-Alarm indicator for excessive impedance in the neutral electrode circuit	7-Socket for active PM connection (electrode holder) 8-Socket for neutral electrode connection 9-Pedal socket 10-Button for coagulation level regulation 11-Button for cutting level regulation 12-Indicative cutting level 13-Cutting output indicator 14-Indicative coagulation level 15-Coagulation Output Indicator

Operating Modality

Switching on the device

As soon as it is switched on, the unit automatically performs a functional test of all the parameters and of the connected accessories. In the event of an anomaly, an alphanumeric message in code appears. The test lasts at least 10 seconds. At the end of the check, the unit restores the last operating conditions used.

Neutral Electrode Circuit

If a double electrode is used, the neutral electrode circuit is monitored by a special circuit which warns of the danger of burning the patient by loss of contact between the neutral plate and the skin. If single electrodes are used the circuit controls the connection of the plate to the unit.
If the Impedance value is greater than 200 ohms the OC alarm is not triggered, if the impedance is higher the alarm is triggered and the power transmission is blocked.

In order to reduce noise pollution, the audible alarm produces a sound only during the emission and the activation of the current.

If the single neutral electrode is used, the circuit only controls the connection of the neutral electrode to the unit.

Emission Current Selections

Emission currents for surgical operations can be selected by the front panel push-buttons for:

Current for Cutting (CUT)

The best current for cutting (sinusoidal without modulation, with duty cycle 100%). This current is indicated for cutting without coagulation.

Current for Coagulation Cut (BLEND)

The current (BLEND) is indicated for the coagulated cut when a deep coagulation associated with the cut is desired. This current consists of the sinusoidal current for the cut associated with low voltage coagulation (soft coag). With this we obtain a current indicated coagulated cut (for endoscopy).

Current for Superficial Coagulation (FORCED)

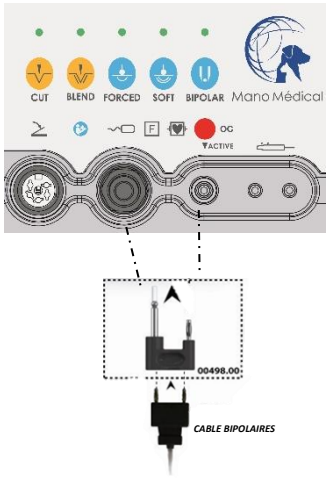
The FORCED COAG modulated current is characterized by good coagulation properties with the formation of superficial eschars and carbonization of the tissue. The advantage of this type of coagulation lies in the speed with which an effect is obtained.

Current for Deep Coagulation (SOFT)

The SOFT low voltage and low modulation current is indicated for the coagulation of the deep layers of the tissue in which the coagulation of the cellular albumin is obtained in the absence of carbonization and without the production of eschar. The coagulation process in this case is slower than in FORCED type coagulation.

Bipolar Coagulation Current (BIPOLAR)

The current emitted in this modality is pure sinusoidal at low voltage and indicated for monopolar and bipolar coagulation without carbonization. The use of the bipolar forceps is authorized only with this current. To allow connection of the cable for bipolar clamp it is necessary to use the optional adapter (REF 00498.00) which blocks all other currents.



Signaling of Excessive Transmission Time

If the operator exceeds the maximum transmission time of 10 seconds, the device could, after a variable time, depending on the type of current and the level of use, generate a warning signal consisting of the inscription Hot flashing on the display and blocking the transmission. Blocking transmission depends on the conditions that triggered the alarm.

Signaling of Excessive Impedance in the Neutral Circuit (OC)

For the meaning of this indication see the previous description of the neutral electrode circuit.

Transmit Signal Acoustic Level adjustment

To modify the emission acoustic signal, it is necessary to follow these instructions:

1. Turn on the device and hold down the CUT button.
2. When the unit has finished checking the internal parameters, the CUT display will show the message SOU., while on the COAG display the value of the previous settings will appear. You can release the CUT button.
3. Through the COAG potentiometer it is possible to change the acoustic emission level. During the adjustment the variation of the noise emitted by the unit corresponds to the pre-set level.
4. To confirm the level, press the CUT button.

Level	Acoustic signal at 1mm from front panel
1	55 dBA
2	60 dBA
3	65 dBA
4	70 dBA
5	75 dBA

Control of Internal Parameters

The unit has an automatic control system for some of the internal parameters. Once powered, the control is indicated on the display by the message SEL FCh, or with PAS SeD if there are no errors or, on the contrary, signaling by an error code in the form Err xxx.

See the troubleshooting guide for more information.

Connector

Connector for neutral electrode

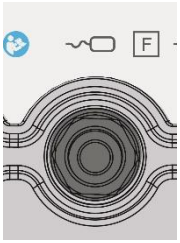


Illustration of the connection point for the neutral electrode or the optional adapter (REF 00498.00) when using the BIPOLAR function.

PM electrode holder connector

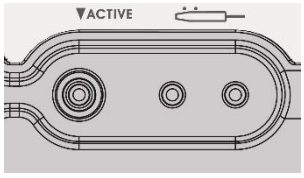


Illustration of the electrode holder PM connection point. If PM electrode holders without pushers are used, the plug must be connected to the ACTIVE socket.

Pedal connector

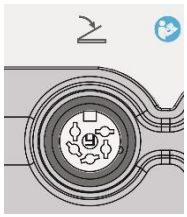
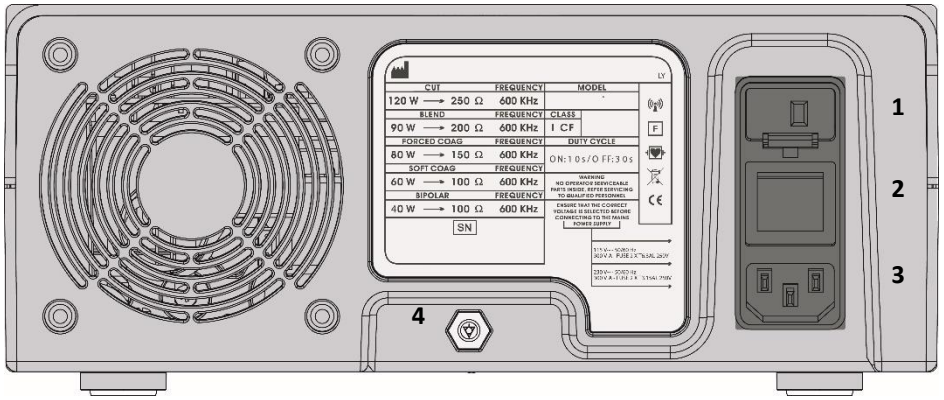


Illustration of the pedal connector. On the left side of the front panel the connector for the pedal connection.

Back Panel

1. Fuse holder / Voltage selector
2. Power switch
3. Power socket
4. Equipotential connection



Unit Power Supply Module and Voltage Selector

The unit's power supply module is the power connection point for the unit's internal electronics. The power module incorporates the power connector and safety fuses. The voltage selector is inside the power supply bracket.

WARNING: before starting the unit, the operator must check that the voltage required for operation corresponds to the voltage supplied by the mains.

Power Switch

The mechanical power switch is used to enable power to the scalpel. To activate the power supply of the device, press the switch in direction, 1. When the circuit is open, the front panel is illuminated. By pressing the switch in direction 0 the power supply will be interrupted. This operation allows the mechanical switch to be used as an emergency switch in the event of any breakdown.

TECHNICAL CHARACTERISTICS

Toll.	Description	Coag&Cut M120
-	Electrosurgical unit code	MME10100.V201
± 0%	Minimum presectable power	0
-	Level step	1
-	Digital level display	•
±20%	Maximum output power CUT (W)	120→250Ω
± 20%	Maximum output power BLEND (W)	90→200Ω
± 20%	Maximum output power COAG FORCED (W)	80→150Ω
± 20%	Maximum output power COAG SOFT (W)	60→100Ω
± 20%	Maximum output power BIPOLAR (W)	40→100Ω
± 5%	Modulation factor CUT	Pure100%
± 5%	Modulation factor BLEND	Pure100%
± 5%	Modulation factor COAG FORCED	Mod. 60%
± 5%	Modulation factor COAG SOFT	Mod. 90%
± 5%	Modulation factor BIPOLAR	Pure100%
-0.1+0.2	Crest Factor CUT	1.5
± 0.3	Crest Factor BLEND	2.1
± 0.3	Crest Factor COAG FORCED	2.0
± 0.3	Crest Factor COAG SOFT	1.7
-0.1+0.2	Crest Factor BIPOLAR	1.5
± 10%	Working frequency	600 kHz
± 15%	Maximum output voltage CUT (Vpp on 5.2kΩ)	1050
± 15%	Maximum output voltage BLEND (Vpp on 5.2kΩ)	1050
±15%	Maximum output voltage FORCED (Vpp on5.2kΩ)	1050
± 15%	Maximum output voltage SOFT (Vpp on5.2kΩ)	540
± 15%	Maximum output voltage BIPOLAR (Vpp on 5.2kΩ)	540
± 0.5	Weight Kg	5
± 10	Size WxHxD mm	254 x 104 x 288
± 5%	Selectable power (Vac)	115–230
± 1%	Mains frequency (Hz)	50-60
-	Fuses (230Vac) 5x20 type TIMED	2xT3.15A
-	Fuses (115Vac) 5x20 type TIMED	2xT6.3A
± 10%	Electrical input power (VA)	300
± 10%	Electrical input current (A) 230Vac	1.3

± 10%	Electrical input current (A) 115Vac	2.6
± 5	Five steps adjustable sound level (from 55- to 75dBA)	●
-	Self-check	●
-	Power accuracy output warning	●
-	Split or not split patient plate allowed	●
-	Last working condition storing	●
-	Electrical Class (EN60601-1)	I CF
-	EN55011 (CISPR 11) Class (Group/Class)	2/A
-	Patient circuit	F
-	Duty Cycle (action / pause) in seconds	10/30
-	Output power control by footswitch or finger-switch	●
-	Defibrillation-proof	●
-	Equipotential binding	●
-	ABS cabinet	●

● = PRESENT - = NOT PRESENT

MAINTENANCE

The device does not contain any parts or parts to be adjusted for use and calibration. The case must not be opened: the warranty is void if the device is repaired without authorisation. If repair or adjustment is required, it must be returned to the technical assistance centre of LED SpA APRILIA (LT), ITALY, together with a description of the inconvenience found. The maintenance to be provided by the user consists mainly of cleaning and sterilizing the accessories and checking the device before use. Functional and safety checks as well as verification of parameters must be entrusted to specialized technicians.

Case Cleaning

Switch off the appliance and unplug it before cleaning. Run a damp cloth over the outside of the case. Chemical solvents should not be used; you can use a non-abrasive washing up liquid.

Cleaning and Sterilization of Accessories

It is advisable to use only single-use accessories and to treat them as special hospital waste. When certain accessories must be used several times, it is imperative to clean them carefully and sterilize them before using them again. The best way to clean and sterilize accessories is to follow the instructions provided by the manufacturer of each item. Do not clean high frequency cables, adapters or electrode holders in an ultrasonic bath. Do not sterilize high frequency cables, adapters or electrode holders in a hot air sterilizer. After use, clean the high frequency cables with a superficial alcoholic disinfectant. The high frequency cable or the PM may be immersed in a disinfectant solution, of course, the service life in this case may be short due to oxidation of the contacts and crystallization in the sockets. Follow the manufacturer's instructions for cleaning products and check that the elements used are compatible. Steam sterilize the high frequency cables, adapters and autoclaving electrodes at 134°C.

Guide and Problem Solving

If an incident occurs, first it is advisable to check the network connection and the pre-established commands.

Problems	**Probable Cause**	**Solution**
The equipment doesn't switch on.	Interruption or absence ofthe main feeding.	Verify the connection of themain cable. Verify the fuses and replace them, where necessary, withnew ones of the proprie 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 neutralelectrode.
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 thepedal. Verify the connection of thehandpiece or of the pedal. Wait for the OVT warning signal getting out.
Error Code 001	Current delivery controlactivated during switching on.	Disconnect the handpiece orthe pedal and switch on the unit again.
Error Code 002	Error in the managementboard.	Call for Service.
Error Code 003	Error in the managementboard.	Call for Service.
Error Code 004	Error in the data conversioncircuit.	Call for Service.
Error Code 005	Error of the reference voltage value.	Verify the main voltage.Call for Service.
Error Code 009	Error in the output poweractivation circuit.	Call for Service.
Error Code 010	Error in the output poweractivation circuit.	Call for Service.

Réparations Repairs

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

Replace Fuse

Before replacing the fuse, disconnect the unit from the mains supply.
To replace the fuses use only the 5x20 fuse, operate as follows:

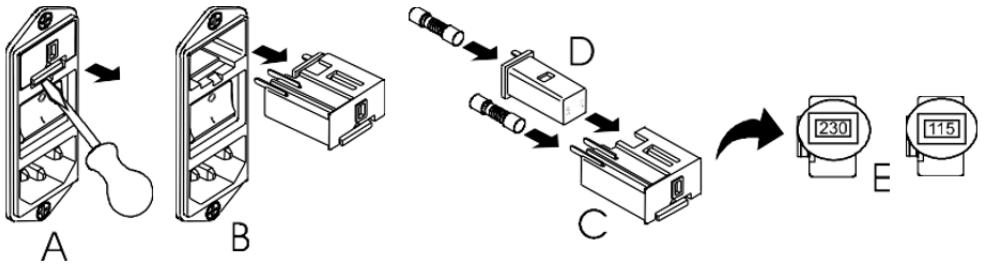
(A-B) Extract, with a small screwdriver, the fuse holder under the power socket.

(C) Insert the appropriate fuse in the module according to the following table:

Voltage 110-120 V Fuse Delayed T6.3 A / 5 x 20 mm
Voltage 220-240 V Fuse Delayed T3.15 A / 5 x 20 mm

(D) Extract the fuse holder cassette, turn until you read in the window.

(E) The designated voltage - reinsert the fuse holder in its location.



Checking the Unit Before Use

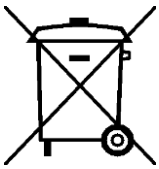
Whenever the use of the unit is programmed, it is necessary to establish a control of the main safety conditions considering the following points:

- Check the condition of the cables, connections, and any damage to the insulation of the cables.
- Make sure the unit is properly grounded.
- Ensure that all accessories to be used are available and sterilized.
- Carry out, by separating the cable from the neutral electrode, a visual and functional check of the OC alarm (light). Put in a cutting or coagulation situation and check the correct operation of the OC alarm (acoustic/light).
- With the neutral electrode control circuit closed (check that OC is off). Perform, by activating the CUT and COAG function, a check of the correct operation of the acoustic transmission indications.

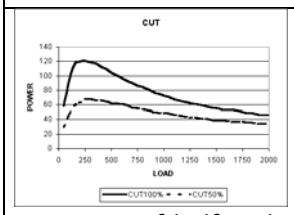
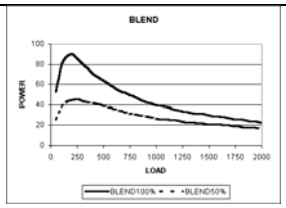
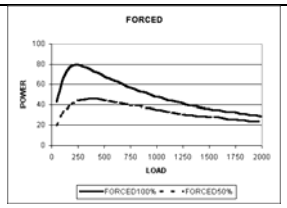
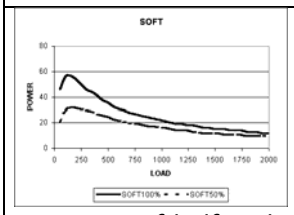
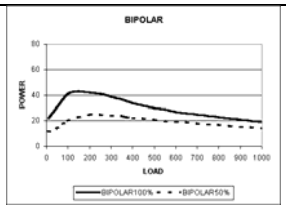
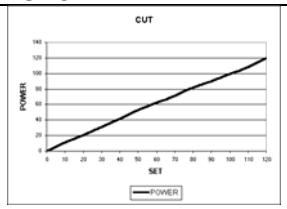
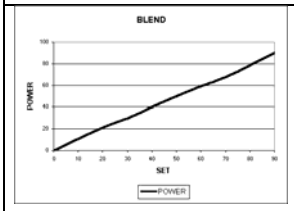
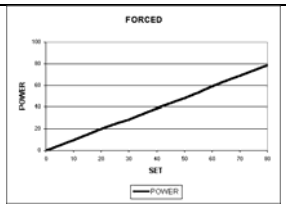
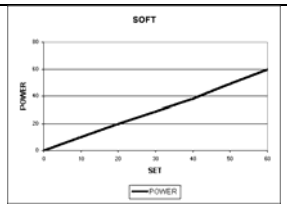
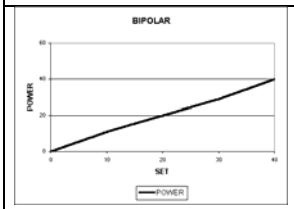
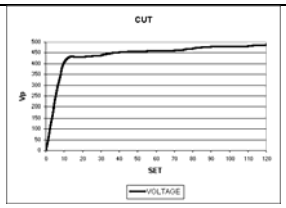
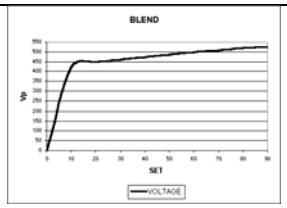
Control and Measurement of Safety Functions

Periodically (at least once a year) checks and measurements should be scheduled by the Bioengineering Department or other specialists.

- Checking the condition of cables and power connectors.
- Visual inspection of mechanical protections.
- Control of protections against the dangers arising from the spillage and penetration of liquids, drippings, humidity, hygiene products and disinfectants.
- Control of data on the plate of the device.
- Checking the availability of the instruction manual.
- High frequency output control.
- Measurement of conductivity resistance to earth.
- Measurement of high frequency leakage current.
- Control of neuromuscular stimulation.
- Output power correction control.

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.

DIAGRAMS

Coag&Cut M120		
		
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT	*Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND*	*Diagrams of half and maximum output power versus impedance load 100-2000Ω 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*	*Diagrams of output power CUT versus nominal value*
		
Diagrams of output power BLEND versus nominal value	*Diagrams of output power FORCED versus nominal value*	*Diagrams of output power SOFT versus nominal value*
		
Diagrams of output power BIPOLAR versus nominal value	*Diagrams of CUT maximum mains voltage output versus Vp*	*Diagrams of BLEND maximum mains voltage output versus Vp*

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