

# VERGERY ELECTROSURGICAL UNIT

## USER MANUAL



Art. No. 323150

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## **IMPORTANT**

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

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

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

*Produttore / Manufacturer*

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*Edition 09.2017*

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## INTRODUCTION

### *General Description*

**VERGERY** is a electro-surgical equipment for veterinary use suited to deliver current for cut, coagulated-cut and coagulation (with different levels of coagulation) in monopolar modality and cut and coagulation in bipolar modality, with the bipolar coagulation modality can be activated a detection system of the tissues impedance with automatic activation and automatic stop when the coagulation is achieved (AUTOSTART – AUTOSTOP). Moreover using the specific function is possible to execute the synthesis and the vascular and venous coagulation through radiofrequency clamping (vessel sealing).

The current can be delivered for the whole time of activation of the output circuit or for an interval of time which can be preset.

The preset time delivery can be single, every time that the circuit of exit is activated, or repeated to in operation intervals of the performed planning.

A total of eighteen different modes of use and levels of power, can be recalled for the use simply (preset program). It's possible to modification of this ore memorize other more Custom programs (over 50).

It is possible to use either single plate neutral reference electrodes or electrodes with split conductive zone so to watch the stability of the plate to patient impedance during the surgical intervention.

Control of the units is via front panel touch keys and display; mains inlet is located on the rear panel.

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

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

The units can work either through holder-handles with or without pushbuttons with double foot switch command. It's possible to connect bipolar forceps to the unit for the bipolar functions.

## Standard and Optional Composition

Code	Description	VERGERY
-	Electrosurgical unit code	10100.V40A
00205.00	Reusable handle with finger switches	●/1
00500.00	Kit of assorted electrodes(10pcs) 5cm	●/1
152-110	Blade electrode 7 cm	●/3
152-120	Needle electrode 7 cm	●/3
152-150	Ball electrode Ø 4mm 6 cm	●/3
00401.00	Steel neutral electrode 120x160mm with cable	●/1
00304.00	Water-proof foot switch	●/1
00100.01	Power supply cable 5m 3x1.5mm SIEMENS-IEC	●/1
00202.00	Holder for Handle and Electrodes	●/1
152-132	Ball curved electrode Ø 2mm 6 cm	○
152-142	Ball curved electrode Ø 3mm 5 cm	○
152-152	Ball curved electrode Ø 4mm 6 cm	○
152-162	Ball curved electrode Ø 5mm 6 cm	○
152-130	Ball electrode Ø 2mm 6 cm	○
152-145	Ball electrode Ø 3mm 14 cm	○
152-140	Ball electrode Ø 3mm 6 cm	○
152-165	Ball electrode Ø 5mm 14 cm	○
152-160	Ball electrode Ø 5mm 6 cm	○
500500.L10/L	Bent ball electroØ 3mm (5pcs) 10cm	○
500500.L10	Bent ball electroØ 3mm (5pcs) 5cm	○
500500.L5/L	Bent hook electrode (5pcs) 10cm	○
500500.L5	Bent hook electrode (5pcs) 5cm	○
500500.L6/L	Bent thick wire electrode (5pcs) 10cm	○
500500.L6	Bent thick wire electrode (5pcs) 5cm	○
500500.L2/L	Bent thin wire electrode (5pcs) 10cm	○
500500.L2	Bent thin wire electrode (5pcs) 5cm	○
110-750NS	Bipolar Artery Sealer 27cm TIP 3mm	○
110-755NS	Bipolar Artery Sealer 25,5cm TIP 3mm	○
110-760NS	Bipolar Artery Sealer 17cm TIP 2mm	○
00411.00	Bipolar cable 3mt EUR	○
00413.00	Bipolar cable 3mt Artery Sealer	○
310-550	Bipolar electrode 20cm – curved	○
310-590	Bipolar electrode 20cm – curved 2	○
310-510	Bipolar electrode 20cm – direct	○
310-110-05	Bipolar Forceps 11,5cm TIP0.5mm	○
310-140-10	Bipolar Forceps 20cm TIP 1mm	○
310-140-20	Bipolar Forceps 20cm TIP 2mm	○
310-180-10	Bipolar Forceps Angled 20cm TIP 1mm	○
310-180-20	Bipolar Forceps Angled 20cm TIP 2mm	○
310-182-10	Bipolar Forceps Angled Curved 20cm TIP 1mm	○
310-185-10	Bipolar Forceps Angled Curved 20cm TIP 1mm	○
310-112-05	Bipolar Forceps Curved 11,5cm TIP0.5mm	○
310-142-10	Bipolar Forceps Curved 20cm TIP 1mm	○
310-142-20	Bipolar Forceps Curved 20cm TIP 2mm	○
152-112	Blade curved electrode 7 cm	○
152-115	Blade electrode 16 cm	○
00404.07	Cable for connection neutral electrode F7915/F7930	○
F7915	Conductive rubber neutral electrode without cable	○
F7930	Conductive rubber split neutral electrode without cable	○
152-195	Conization electrode 13 cm	○

Code	Description	VERGERY
755VL	Disposable handle with finger switches	○
0350	Disposable Neutral electrode	○
00305.03*	Double water-proof foot switch	○
500500.L7/L	Drop electrode (L7) (5pcs) 10cm	○
500500.L7	Drop electrode (L7) (5pcs) 5 cm	○
F7520	Electrode cleaning sponge 47x50mm	○
00201.01	Handle for microsurgical needle	○
00500.00/L	Kit of assorted electrode length 10cm (10pcs)	○
500500.L3/L	Loop electrode Ø 4mm (5pcs) 10cm	○
500500.L3	Loop electrode Ø 4mm (5pcs) 5cm	○
500500.L4/L	Loop electrode Ø 8mm (5pcs) 10cm	○
500500.L4	Loop electrode Ø 8mm (5pcs) 5cm	○
152-175-10	Loop electrode 10x10 l.15 cm	○
152-190-13	Loop electrode 20x13 l.15 cm	○
152-190-20	Loop electrode 20x20 l.15 cm	○
00402.02	Monopolar cable M4-MP4 3mt	○
330-134-20	Monopolar Forceps 20cm TIP2mm	○
330-160	Monopolar Surgical Scissors 18cm	○
152-122	Needle curved electrode 7 cm	○
152-125	Needle electrode 13 cm	○
500500.L11	Needles for micro-surgery (10Pcs)	○
500500.L8/L	Noose electrode (L8) (5pcs) 10cm	○
500500.L8	Noose electrode (L8) (5pcs) 5 cm	○
00100.03	Power supply cable 2m 3x1mm SIEMENS-IEC	○
00206.00	PENCIL - Reusable handle without finger switches	○
500500.L9/L	Straight ball electrode Ø 3mm (5pcs) 10cm	○
500500.L9	Straight ball electrode Ø 3mm (5pcs) 5cm	○
500500.L1/L	Straight thin wire electrode (5pcs) 10cm	○
500500.L1	Straight thin wire electrode (5pcs) 5cm	○
00401.01	Steel Neutral Electrode 24x16cm with cable	○
TR003W	Trolley 3 shelves wide	○
TR005W	Trolley 3 shelves wide	○
TR003	Trolley 3 shelves	○
TR004	Trolley 4 shelves	○
TR005	Trolley 5 shelves	○

●/ Pcs= STANDARD ○= OPTIONAL

*\*compatible only LOT 25016 or superior*



## ELECTROPHYSICAL PRINCIPLES

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

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

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

The current that crosses the biological tissue can cause:

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

### 1) Joule Effect

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

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

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

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

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

- **Electrode shape**

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

- **State of active electrode**

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

- **Characteristics of the tissue**

The resistive characteristics change according to the biological tissues.

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

*(Example of specific resistances of organic and metallic materials)*

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

#### **Coagulation**

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

#### **Cut**

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

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

#### **Mixed currents**

They are obtained by the mixing of coagulation and cut effects. There is a reduction of blood loss during the cut procedure, or like cut that develops a substantial eschar coat.

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

### **2) Faradic Effect**

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

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

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

The physiologic system of stimulus transmission follows a limit curve in which the pulsed currents or by low frequency produce an impulse of stimulation. By alternating current in high frequency (higher than 200 kHz), used in the electrosurgical needle, don't have neuro-muscular reactions (the change of polarity is so fast that the patient doesn't have consequences at a level of the neuro-muscular reactions), and there isn't an electrolytic damage of the organism. For this reason all the equipments generator of the high frequency for surgical use (electrosurgical needle) work on base frequencies higher than 300 kHz so that they don't produce electric stimulation.

### **3) Electrolytic Effect**

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

## OPERATIVE TECHNICS

### *Monopolar Cut*

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

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

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

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

When the output power is properly set there should be:

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

## ***Monopolar Coagulation***

When there is a temperature increment, for the heat produced for Joule effect in the tissue, it's realized the thermal coagulation and that is the partial solidification of the liquids and so the precipitation of colloidal substances. In particular fibrin forms in the blood and it, solidifying itself, obstructs the blood vessels.

To obtain the coagulation by the electrosurgical needle it needs to supply the active electrode with intermittent current so that the water goes out from the cell without destroying it. However also with the intermittent current, if the intensity of the current is too intense, the cut effect is realized.

Active electrodes particularly adapted for the coagulation are the electrodes with sphere shape, plate, or lanceolate used laterally.

The coagulation can be obtained by two different methods: by desiccation and fulguration.

### **Coagulation by desiccation**

It's obtained supplying the electrode by low voltages that not generate sparks (this guarantees that the action is pure coagulum and so every effects of the cut is absent). The electrode is placed in direct contact with the tissue and the quantity of heat developed desiccates it.

Generally the coagulated cellular surfaces act like an insulation layer, that prevents that the heat had to the successive applications of the current penetrates too much in depth.

The current normally used for the coagulation is the modulated type. In function of the percentage of the modulation is realized the precision of the cut, the goodness of the haemostasis and the level of the tissue destruction. A bigger modulation of the current gives a cut more irregular, and a bigger depth of tissue destroyed but a better coagulation.

The following rules help the operator to obtain a good coagulation:

- select a ball electrode or a large wire;
- localize the vessel bleeding after have been dried the exceeding blood from the area;
- touch lightly the vessel bleeding before to activate the electrode;
- stop the activation of the electrode when the tissue whiten to prevent to damage it;
- maintain clean the point of the electrode (for this scope it's advisable to use (for this scope it's advisable using the electrode cleaning sponges F7520).

### **Coagulation by fulguration or spray**

The electrode is supplied by high voltages so that, with the electrode separated from the tissue, can be one or more electrical arcs that die out in different places. The produced heat is so distributed on a surface of tissue bigger than it doesn't verify in the case of the single arc produced for the cut and that produces mostly coagulation. This method is ideal for the treatment of big surfaces with a diffuse blood loss and superficial one (for example hepatic resection) and/or to realize coagulation at open sternum in the cardiac-surgical.

### **Coagulation with anatomical forceps by the clamping**

The more used coagulation consists to stop the haematic flow by the clamping pressure between the ends of the forceps.

After have clamped the portion of the tissue or the blood vessel seat of the coagulation, the active electrode puts in contact with the proximal metal part of the forceps. The activation of the high frequency must be happen after this contact (forceps – active electrode) to prevent faradic effect (primer of an electric flat that exploits like conductor the air) that would cause electrical shock, burns to the operator, etc.

## ***Bipolar Cut and Coagulation***

In a different way from monopolar technical, with bipolar technique the portion of tissue interested by current passage in high frequency is very small. In this technique the bipolar forceps are used (with different dimensions and shapes) on which distal ends there are active and neutral electrodes. Clamping the interested tissue between the ends forceps, the current passage in high frequency will happen from an end to another one, exploiting the portion of tissue to treat like an electrical bridge.

- The bipolar cut consists in a dissection of the biological tissue by the passage of the high density current in high frequency concentrated by the two points of the bipolar forceps. Lately there is a great interest for this method, above all for the greater security offered and for the diffusion of the endoscopic and mininvasive surgical techniques.
- The bipolar coagulation is the haemostasis of small blood vessels of the body tissue between the two points of the forceps. When the current density is reduced the consequent effect is the desiccation of the cellular surface, without penetration in depth, with consequent coagulation.

The bipolar technique is extremely more safe because the current direction in high frequency is always determinate and not has unknown factors and probable erroneous directions, and the used powers are lower than those used in monopolar technique. For these reasons this technique is used above all in the more critical surgical operations, so it's important to maintain clean the distal ends of the forceps during the operation, because they are subject to accumulation of coagulated tissue, which limits the current passage and favors the sticking of the tissues.

The application of the neutral electrode (used obligatorily in the monopolar technique) isn't necessary, even if in a practical point of view it's always advisable the application on the patient during the initial preparatory phase.

## **CONTRAINDICATIONS AND COLLATERAL EFFECTS**

Electro surgery is not recommended in the following subjects:

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

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

Some important causes of burns are by:

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

To avoid or reduce the common HF electrosurgical risks it is very important to respect the rules and safety measurements exposed illustrate on the next chapter.

## SAFETY

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

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

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

### General

The following precautions reduce the risk of accidental burnings

- The whole surface of the patient plate must be placed on a well-vascularized muscle as next as possible to surgical area. Avoid connecting the patient plate to bony protrusions, prosthesis, cicatricial tissues, and parts of the body subjected to liquid accumulation or that present subcutaneous adipose tissue. The part of the body must be without hair, dry and clean. Do not use alcohol to clean the skin. With steel or conductive rubber neutral electrode, for veterinary use, the use of gelatinoids substances for the electrodes is advised.
- By using the disposable neutral electrodes respect the date of expire.
- By using the reusable electrodes (steel or rubber) ascertain that the fixing systems give warranty of stability.
- When you apply the neutral electrode avoid the transversal course and prefer the vertical or diagonal course, in particular if a split neutral electrode is used. That to allow a uniform distribution of the current on the surface of the neutral electrode and reduce the risk of burn to the patient.
- If it isn't possible to use correctly the neutral electrode, consider, if it's possible, the bipolar technique instead of the monopolar one.
- 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 paw and body of the patient). Insert an interface material like dry surgical gauze. Moreover, the parts of the body subjected to abundant perspiration must be maintained dry.
- When high frequency electrosurgical unit and physiological monitoring devices are used at a time in the same patient, all the monitoring electrodes, that have not resistive or inductive elements tested in high frequency interference environment, must be as far as possible from the electrodes of the electrosurgical unit. Avoid the use of monitoring needles.
- The connection to the electrodes should be located in such a way to avoid the contact both with the patient and with other cables.
- For surgical procedures where the HF current could flow through parts of the body having a relatively small cross-sectional area; the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.
- The power level should be the lowest useful to the work to do.
- Always check the return plate whenever electrosurgical unit fails to produce the desired effect. Reason for a low output power level, or for an incorrect functioning of the electrosurgical unit when arranged for a normal output, may be lack of connection of the return plate or its imperfect placement.
- The use of flammable anesthetics, of oxygen and of nitrogen protoxide should be avoided in the case of operation at the head or at chest level except the possibility of evacuating gas. Flammable materials used to clean, or to disinfect, should be let to evaporate before the use of the electrosurgical unit. There is risk of stagnation of flammable solutions under the patient or in body cavities as the umbilicus and the vagina. The fluid that deposits in these areas should be removed before the equipment use. The danger of endogenous gas ignition has to be considered. Some materials like cotton wool or gauze, when saturated with oxygen, may burst into flames because of the sparks produced by the equipment in the normal use.
- There is a risk for the patients fitted with heart pacemaker or other stimulation electrode: interference may occur with the stimulator signal or the stimulator itself can be damaged. Please refer to Cardiology Unit when in doubt.
- Electrosurgical equipment does emit unnoticed radiation of high frequency energy that may effect other medical equipment, unrelated electronics, telecommunications, and navigational systems.
- The accessory must be regularly checked, particularly the cables for the electrodes and the possible accessories for the endoscopy to verify that the insulation is not damaged.

- To avoid the connection of incompatible accessories to the unit, the insulation characteristics of the items to be replaced must be requested to the manufacturer and compared to those of the supplied unit (see Technical Characteristics)
- **Attention:** a damage of the electrosurgical unit could result in an unwanted increase of the output power.
- Inadvertent stimulation of a patient's muscle and nerves can be caused by low frequency currents originating in electric sparks between electrode and tissue of the patient. Should neuromuscular stimulation occur stop surgery and check all connections to generator. If this does not solve the problem, qualified service personnel must inspect generator.

## ***Installation***

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



## ***Safety for the Patient***

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

### ***Correct Position of the Patient***

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

- The animal is not in contact with metallic parts (operative table, supports..).
- The flexible tube of the respirator do not touch the body of the patient.
- On the operative table with grounded connection there are always coatings that allow to discharge the electrostatic charges.
- The animal is on a thick basic tissue with insulating properties, covered by a sufficient number of nets.
- The animal is not in contact with nets or wet mattress.
- The eventual organic secretions and the cleaning and other liquids do not wet the nets.
- There are not liquid under the patient.
- Urinary secretions are eliminating by the catheters.
- All conductive and grounded supports, stirrups, are correctly insulated.
- Control the anesthetics quantity to avoid a great sweating.

### ***Correct Position of Neutral Electrode***

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

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

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

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

## ***HF Electrosurgical in Laparoscopy***

Since its introduction minimally invasive surgery has revolutionized surgical operation offering any significant benefits to the patient of faster healing and less postoperative pain. In laparoscopy the monopolar HF electro surgery is the most used because it is highly versatile (pure cut, coagulation, blended cut that combines these two functions), but this modality can compromise patient safety by burns.

The constricted view of the surgical field, the poor maintenance of the laparoscopic instrumentation, interference on the video monitor, the insufficient training of the surgeon or his inattention, the smoke, the insulation failure, the capacitive currents, the contact of the tip of the active electrode with the surrounding tissue, these are all factors that increase the hazard of burns, intra-abdomen lesions, necrosis of the tissue, perforation of internal organs. The nature of the surgical environment – in which the active electrode is in close proximity to other conductive instruments and to tissue- may make the electrical currents transmission to unseen tissue off the laparoscope, causing unintentional tissue burns at non-targeted sites, by:

- direct coupling
- insulation failure
- capacitive coupling

Direct coupling occurs when the active electrode touches another metal instrument, transferring electrical current to it and possibly injuring tissue with which it comes in contact (for example bowel or other organs).

Insulation failure occurs when there is an excessive voltage, abuse, wear and tear, poor handling, or mechanical accident of the electrode shaft that happens during a single laparoscopic procedure or during disinfection and sterilization procedures. The breakdown along the unseen shaft of an activated electrode can allow electrical current to leak into surrounding non-targeted tissues, causing unobserved damage. Paradoxically, small cracks are more dangerous than large breaks because the current is more focused, and is therefore more likely to produce burns.

Capacitive coupling occurs when electrical current is induced from the active electrode to nearby conductive material, despite intact insulation. During HF electrosurgical operations the rapidly varying electrical field around the active electrode is only partially impeded by electrical insulation and creates stray electrical currents by alternately attracting and repelling ions in surrounding body tissue. Currents transferred in this way in nearby tissue can cause irreversible damage. The movement of electrically charged ions in capacitive coupled tissue can cause currents that can heat tissue sufficiently to produce burns.

Several measures are used during electrosurgical operations to limit and minimize the risks of patient injury:

- a better and more complete training for the medical staff;
- visual examination of the surgical instrumentation (active electrode, laparoscope);
- use of disposable electrodes (but the thinner insulation doesn't reduce the risk of breakdown or capacitive coupling);
- prohibiting the use of hybrid (plastic-metal) cannulas;
- adopting bipolar electro surgery (not-versatile, but safer, because the necrosis happen only if there is a long and continuous application of the current).

In the HF electro surgery burns are a real hazard that can be minimized by the knowledge of the causes and especially if the surgeon is prepared against these.

## INSTALLATION

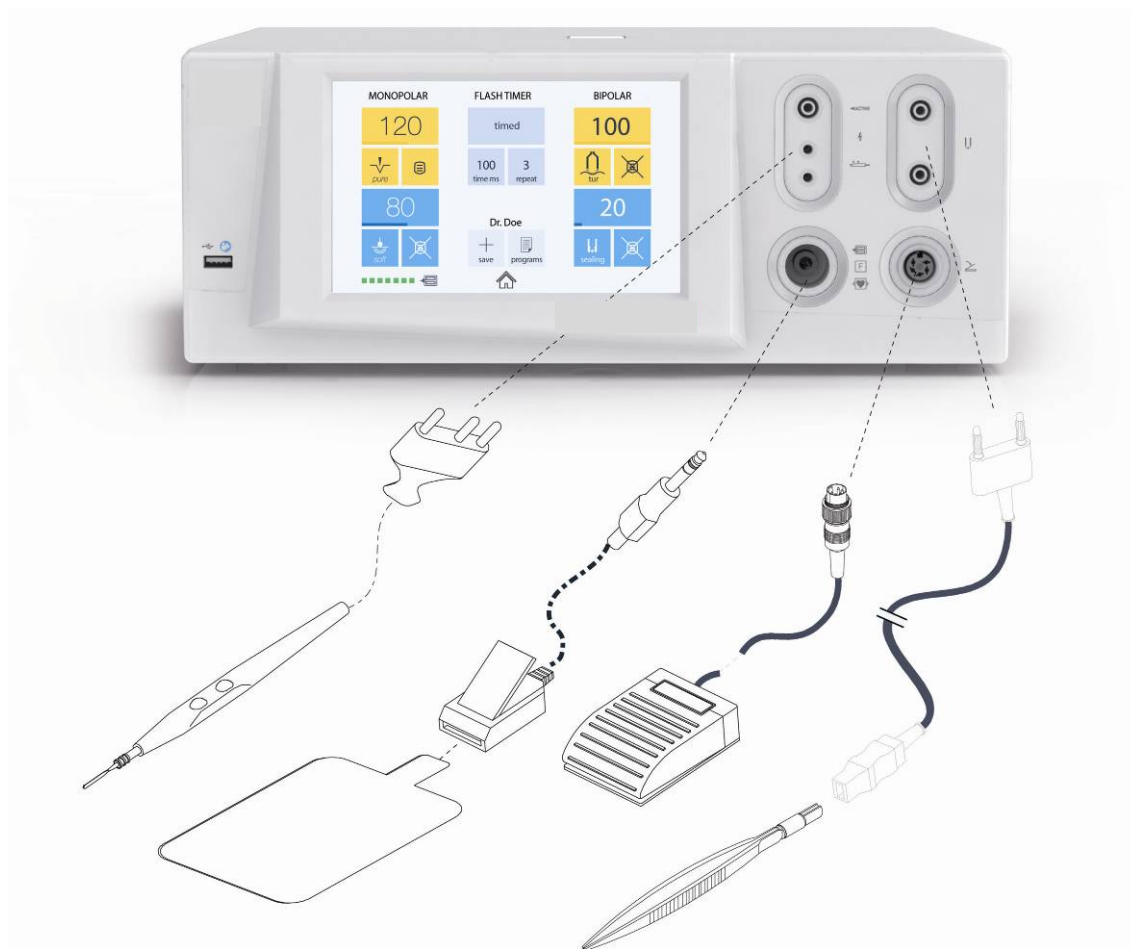
- Inspect the unit for damages during transport. The claims for possible damages will be accepted only in case they are immediately communicated to the carrier; the damages that are found must be written down and presented to LED SpA or to your own retailer. If the unit is returned to the LED SpA or to your own retailer, it is necessary to use the original equipment's package or another equivalent one, to guarantee the safety during the transport.
- Unpack the equipment and carefully study the documentation and operating instruction supplied. Mains voltage, indicated above the label data, must agree with the local mains voltage (mains voltage frequency: 50-60 Hz).
- Connect mains cable to a mains outlet having good hearth connection.

### OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN.

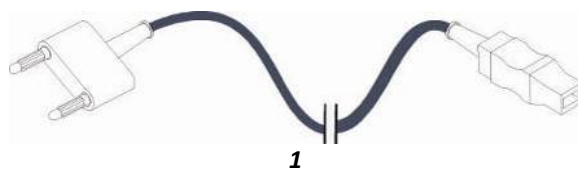
- The unit must be installed on a level surface, with dimension, at least, correspondent to those of the base of the unit itself. Around the unit must be left a space of 25cm, at least.
- Connect the mains cable to the mains socket on the rear panel of the unit.
- Connect, if request, the equipotential binding post located at the left of the unit's back panel to eventual equipotential socket of the plant.
- Connect the single foot switch or the double foot switch (optional)to the connector on the frontal panel of the unit.
- Connect handle to the corresponding connector and in the case of use of handle without push-buttons it shall be connected on the "ACTIVE" buckle.
- Let unit work in dry environment only. Any verified condensate must be let evaporate before putting in operation the unit. Don't exceed the temperature environment or the allowed moisture.
- Environments condition:

	<i>WORK</i>	<i>TRANSIT/STORAGE</i>
<i>Temperature:</i>	<i>10/40°C</i>	<i>-10/+50 °C</i>
<i>Relative moisture:</i>	<i>30/75%</i>	<i>10-100 %</i>
<i>Pressure:</i>	<i>70/106k Pa</i>	<i>50/106 kPa</i>

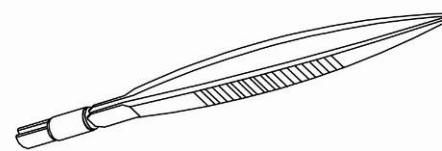
- When the unit is switched on, through the on/off switch on the rear panel, it will work with the function and the power level utilized during the last switching.
- In monopolar mode before using the unit, it is necessary connect the cable to the patient plate. When split plate electrodes are used it is necessary to close circuit. In this way, if the value of the impedance is acceptable, the indicator light on neutral connector will stop flashing.



**NOTE:** For BIPOLAR procedure you need other optional accessories:



1

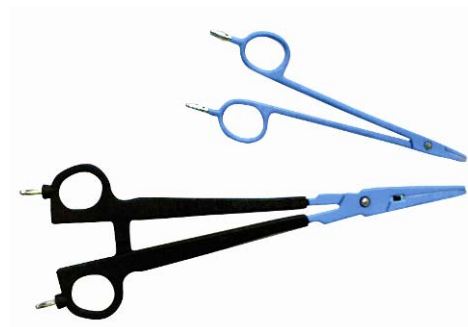
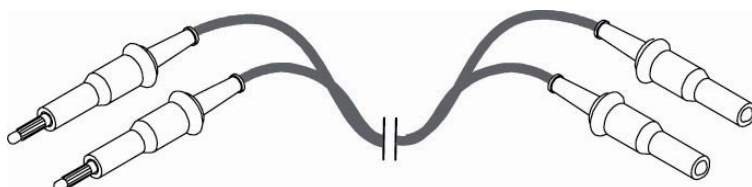


2

1 Cable for bipolar accessories connection  
2 Bipolar accessory (ex: bipolar forceps)

For the synthesis and the vascular and venous coagulation (Vessel Sealing):

3



4

3 Connection cable for Artesy Sealer forceps  
4 Artesy Sealer Forceps (various dimensions)

For optional accessories see page 5

## CONNECTOR AND CONTROLS

### Label on the Rear Panel

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

### Manufacturer's Identification Data

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

### Technical Data

FREQUENCY:	360kHz
Output CUT (CUT):	200W - 300Ω
Output ENHANCED CUT (CUT):	150W - 300Ω
Output BLEND (CUT /COAG):	150W - 300Ω
Output FORCED (COAG):	150W - 200Ω
Output SOFT (COAG):	100W - 200Ω
Output FULGURATION( COAG)	100W - 1000Ω
Output BIPOLAR PURE (CUT)	120W - 50Ω
Output BIPOLAR TUR (CUT)	120W - 50Ω
Output BIPOLAR COAG (COAG)	100W - 50Ω
Output BIPOLAR SEALING (COAG)	200W - 50Ω

MAIN POWER:	100-240 V - 50/60 Hz selecting
INLET POWER:	750VA
FUSE:	2xT 10AL, 250V
DUTY - CYCLE:	intermittent 10 seconds emission / 30 seconds of pause
CLASS:	I CF

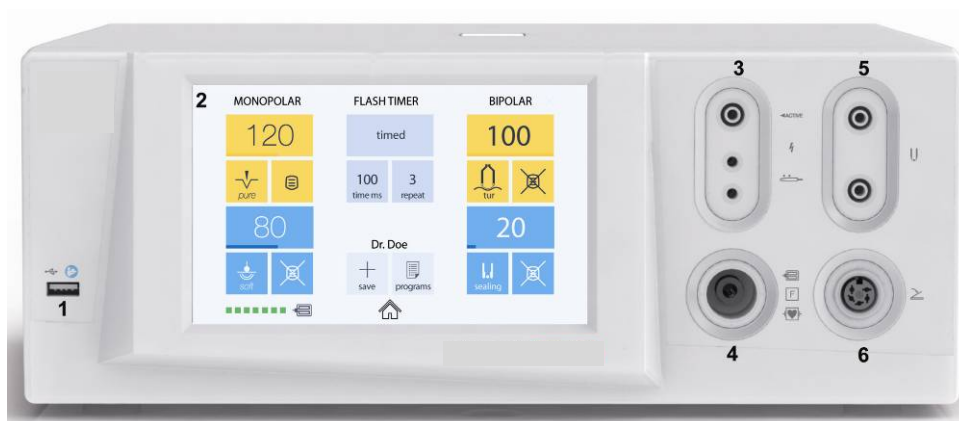
### Meaning of Graphics Symbols

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

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

								
1	2	3	4	5	6	7	8	9

## Frontal Panel



1. USB port
2. Display touchscreen (work screen)
3. Monopolar output connection
4. Connector for neutral electrode connection
5. Bipolar output connection
6. Foot-switch connection

### **1. USB PORT**

For software updating on the front unit is present one USB 2.0 port. See Update chapter.

### **2. DISPLAY TOUCHSCREEN**

Display LCD touchscreen permits the visualization and controls of all the built parameters in a determinate procedure.

### **3. MONOPOLAR OUTPUT CONNECTION**

This is the point of connection for the handle with double push-buttons to realize the functions of the cut CUT and coagulation COAG.

Remember that the handle without push-buttons must be connected to the 'active' connector.

### **4. NEUTRAL CONNECTION**

This is the point of connection for the neutral electrode to apply on the patient. Remember that the neutral electrode can be disposable and reusable.

### **5. BIPOLAR OUTPUT CONNECTION**

Point of connection for the bipolar forceps, by which the bipolar currents can be distributed to realize the bipolar coagulation.

### **6. FOOT-SWITCH CONNECTION**

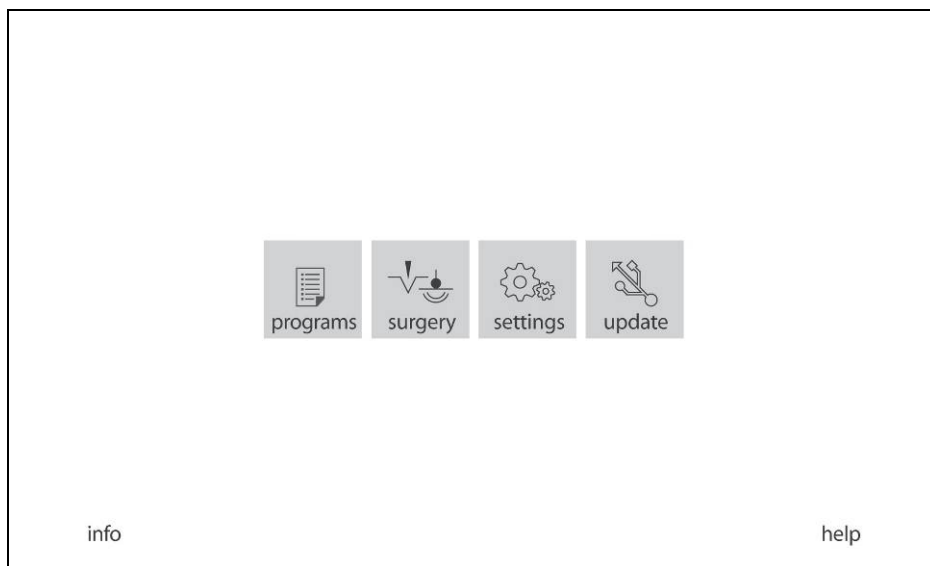
Point of connection for the foot-switch (single or optional double).

## Operation Mode

### Control and Switch On

The unit is directly controlled through the present icons on the display device touch screen. In order to confirm a selection to press the icon directly

When switched on the electrosurgical unit on the screen the initial shielded one appears that filler of the load of the installed software. After HOME screen appears:

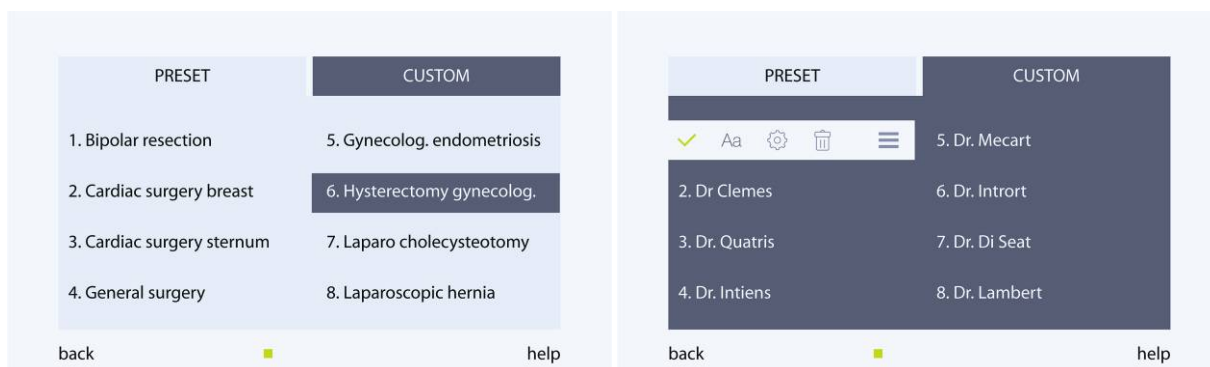


In this HOME screen it is possible to choose and work with: Programs, Surgery, change the Settings of work or Update software through USB port.

Through Info is possible see installed software versions.

The HELP key permits the visualization of the summarizing information, useful for the right interpretation of indications on the display

### Programs

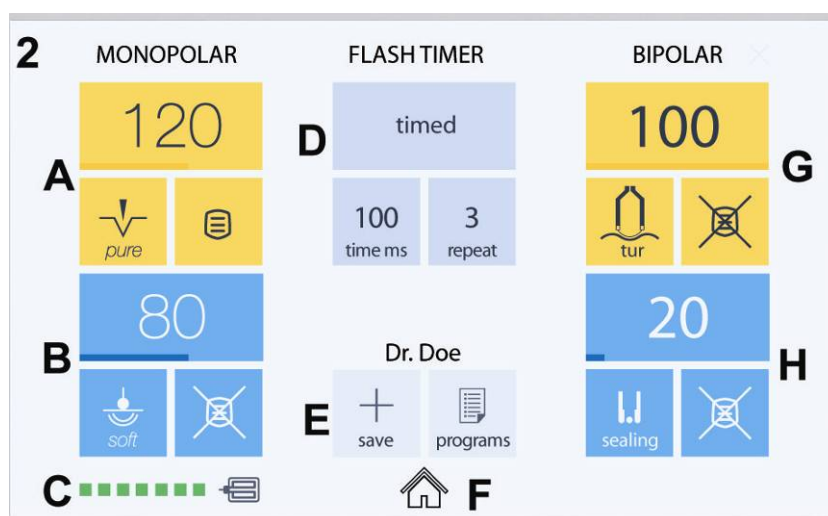


Chose **programs** in the screen appears preset or, through Custom page, personalized program. Through help is possible see characteristics of relative program. Touch back to return on Home page.

Through relative symbol (three line) Custom program can be: renominated (Aa) – modified (gear) – deleted (dumpster)

To create a Custom program see work screen (Surgery).

## Surgery



2. Display touchscreen (work screen)

A Monopolar Cut Section

B Monopolar Coagulation Section

C Monopolar indicator of impedance in the neutral electrode circuit

D Flash Timer Section

E Program Section

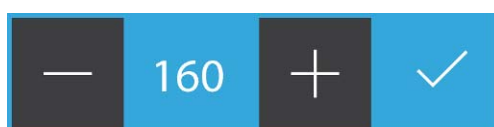
F Home Icon

G Bipolar Cut Section

H Bipolar Coagulation Section

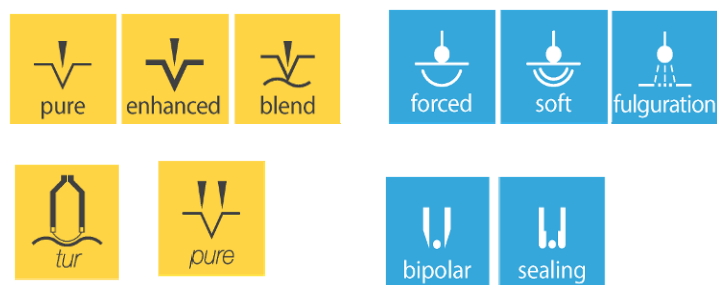
## MONOPOLAR and BIPOLAR SECTION

Touch icon with number for output regulation power, see example:



Regulate power through + and -, accept by V

Touch icon with function for choose it, see example:

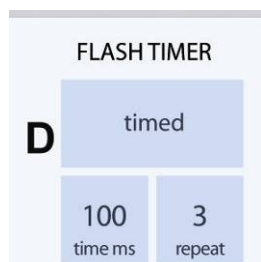




Touch icon with pedal for choose which is activated, see example:



## FLASH TIMER SECTION



In the section FLASH TIME, it is possible if select “timed” to set the number of repetition (repeat) of the impulses and their duration (time).

The **duration of the impulses** is indicated in the icon, for change it touch and regulate.

The equipment can be set to obtain the power supply during all the time of activation of the output circuit (indication continue) or for the power supply in a programmed time from 10 milliseconds to 30 seconds.

For the setting of the time follow the table below:

RF TIME		Supply Time		Step
		From	To	
10÷90	mSec	10 mSec	90 mSec	10 mSec
0.1÷0.9	Sec	0.1 Sec	0.9 Sec	0.1 Sec
1.0÷30	Sec	1 Sec	9.5 Sec	0.5 Sec

**NOTE:** To not use the temporized function (to obtain the supply during the activation time of the output circuit) set on RF TIME, the indication **continuous**.

The function RF time can be settled with all the functions, but do not interfere on the function AUTOSTART/AUTOSTOP in BIPOLAR modality.

The interval of the **repetition** of the impulses is indicated by the icon **repeat**:

The supply with the programmed duration of the impulses can be repeated, as long as the output circuit would be maintained active, for a presetting number of times (from continuous to 30 times). The interval from one repetition to another one is from value 1 equal to the double of the duration of the impulse.

**NOTE:** Setting the value 1 there will be only one impulse. Setting the value 00 there will be a cycle of repetition of the impulses during all the time of activation of the output circuit.

## PROGRAM SECTION



To memorize the parameters in Custom Program press Save, in the next screen is possible named it.

To recall a Custom or a Preset Program press programs, in the next screen is possible choose it (see Programs).

Name of Preset or Custom Program is visible in the screen.

## NEUTRAL PLATE CONTROL



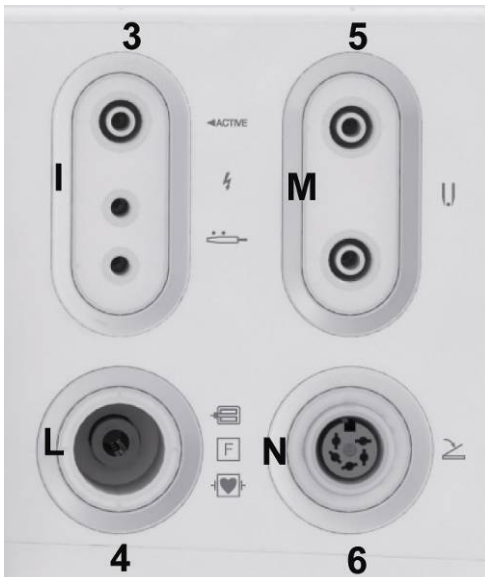
The neutral electrode's circuit is continually watched by a special circuit that prevents danger of burns to the patient due the loss of contact between the reference plate and the patient skin. The circuit is also watched to avoid that the variation of the characteristics of conductivity of the plate can provoke reduction of conductivity of the circuit, and therefore danger of burns to the patient.

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

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

If the impedance value is accepted, the impedance indication is recognized and the display allarm indicator on electrode neutral connector are extinguished.

## LIGHTS



### 3. Monopolar output connection

I Monopolar Indication Light

Off – Monopolar Function off (*touch on Monopolar text for on-off section*)

Yellow – Output Cut Current

Blue – Output Coag Current

### 4. Connector for neutral electrode connection

L Neutral Electrode Indication Light

Off – Monopolar Function off (*touch on Monopolar text for on-off section*)

Red - Allarm Open Circuit (See Neutral Plate Control)

### 5. Bipolar output connection

M Bipolar Indication Light

Off – Bipolar Function off (*touch on Bipolar text for on-off section*)

Yellow – Output Cut Current

Blue – Output Coag Current

### 6. Foot-switch connection

N Bipolar Indication Light

Off – Foot-switch not connected

Yellow – Output Cut Current

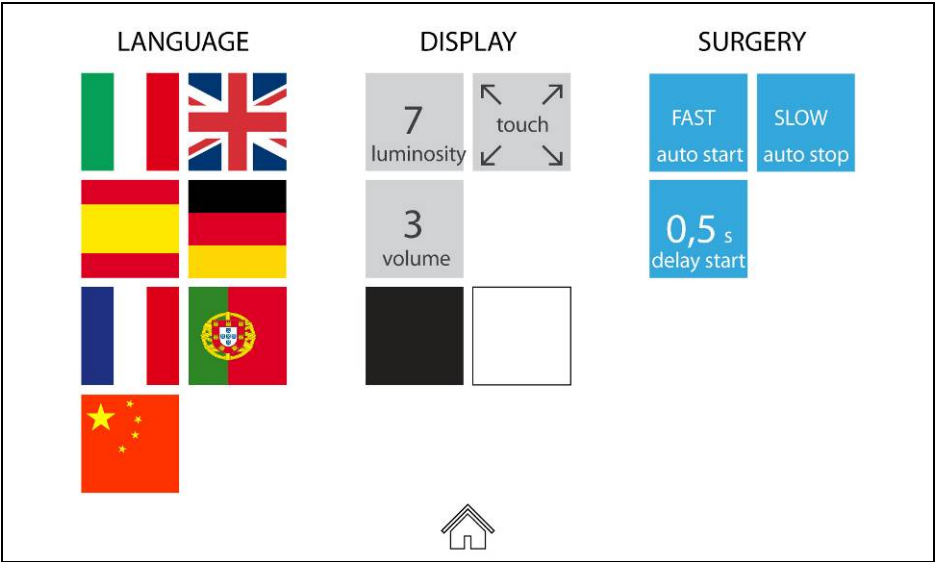
Blue – Output Coag Current

## DELIVERY WORK SCREEN



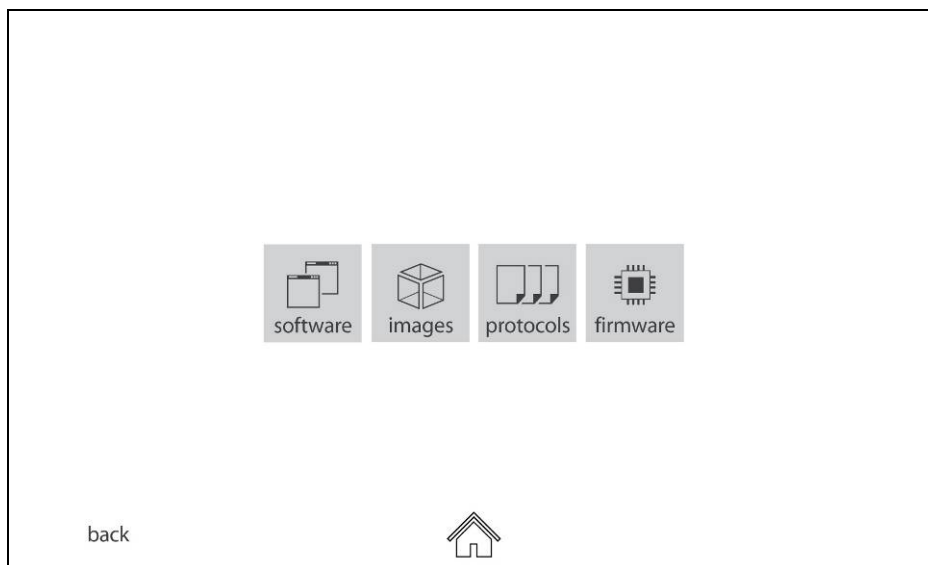
In delivery state on the screen appear the function with the relative level, this screen remain for few seconds, in this time you can adjust, by + and -, the output level, for close screen press X.

Settings



From HOME choosing the option “settings” and the successive screen it is possible change: Language, Display (luminosity and touch sensitivity), Volume, black or white display, setup of response of surgery delay start and Fast-medium-slow autostart-autostop. Touch icon to return on Home page.

## Update



From HOME choosing the option “update” and the successive screen it is possible to update: Software, Images, Protocols and firmware. Touch back to return on Home page.

To connect in the USB connector compatible device containing the compatible file of the software or images or protocols or firmware to update.

Select “Software” or “images” or “protocols” or “firmware” and the successive popup confirming this. Follow the instructions.

Select Home or back to exit from procedure.

## Monopolar

The supplying currents in the monopolar way for cut, coagulated cut and coagulation can be predisposed by the icon keys present in the MONOPOLAR section. The power level for every function can be predisposed by + and - level of CUT , and COAG sections. The set power levels remain in the memory.

CUT	COAGULATION
1 Cut	4 Forced Coag
2 Blend	5 Soft Coag
3 Enhanced Cut	6 Fulguration

**Note:** For use foot-switch, press relative key and view monopolar foot-switch symbol. See examples:



Foot-switch active



Foot-switch non active

The description of the supplying currents is in the next paragraphes, according to the predisposition order of the selection icon keys, in the MONOPOLAR section.

### Current for Cut (CUT)



The best current for the cut is the pure sinusoidal wave without modulation that means with duty-cycle 100%. Such current, proper for cut without coagulation.

### Mixed Current (BLEND)



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

### Current for Enhanced Cut (ENHANCED CUT)



The ENAHNCED CUT current is a sinusoidal current characterized by modulation in amplitude and it is suitable to cut the tissues, in particular adipose tissues.

### Current for Superficial Coagulation (FORCED COAG)



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

*FORCED Coag also said Speedy.*

### Current for Deep Coagulation (SOFT COAG)



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

*SOFT Coag also said Pin Point, Dessicate or Deep.*

## Current for Fulgurate Coagulation (FULGURATE)



The high-tension FULGURATE goes in the active electrode that isn't in contact with the portion of tissue to treat and mostly produces coagulation. This method is ideal to treat big surfaces with diffuse and surface blood loss (hepatic resection) and/or to realize coagulation at level of the open sternum in heart surgery.

## Bipolar

The distributable currents in the bipolar modality for coagulation can be selected by the icon keys of the BIPOLAR section. The power level for every function can be selected by + and - level of Bipolar sections. The power levels selected remains in memory.

CUT	COAGULATION
1 Bipolar Cut	3 Bipolar Coag
2 Bipolar TUR	4 Bipolar Vessel Sealing

**Note:** Use foot-switch, press relative key and view bipolar foot-switch symbol. See examples:



Foot-switch active



Foot-switch non active

Using BIPOLAR function it will need to connect the bipolar accessories to the connector for this function (BIPOLAR) and to use the foot-switch.

## Bipolar Current Cut (BIPOLAR CUT)



The current supplied by the bipolar forceps is high tension sinusoidal pure and adapted to the cut without coagulation.

## Trans Urethral Resection Current (BIPOLAR TUR)



The current TUR, supplied by the specific bipolar accessory is adapted to the cut and to the coagulated cut when a forced coagulation together the cut is desired. this current is made by sinusoidal current adapted to the cut associated to current for high-tension coagulation.

## Bipolar Coagulation Current (BIPOLAR COAG)



Type of coagulation practicable with bipolar forceps and that allows to supply, by handle or foot-switch, the RF output power on a impedance value of 100 ohm. This value is normally on the section of tissue between the forceps. This modality is practicable by SELECT key (see Autostart and Autostop paragraph).

## Vessel Sealing



Function type suitable for the synthesis and the coagulation vessel arterial and venous clamping by means of radio frequency.

The procedure is as follows: select a level suitable to the connected accessory and to the treatment to be performed; Gently clamp the vessel with slight pressure; no auto start hitchhiking or press the pedal and hold it down for the entire procedure; during coagulation, press lightly with pliers; clotting occurred in the pedal may be released.

## Autostart and Autostop

In the 'Bipolar' function can be choose four settings for bipolar coagulations:

**No automatism** for the distribution. The distribution is realized by pressing the foot-switch and stops by leaving again the foot-switch;



**START.** The distribution is started, by pressing the foot-switch, if there is contact between active electrode and tissue, and it stops by leaving again the foot-switch;



**STOP.** The distribution is started, by pressing the foot-switch, (if also there isn't a contact between tissue and active electrode) and stops itself when the tissue is coagulated . So by pressing the foot-switch, if there is an impedance value too higher, the distribution doesn't start.

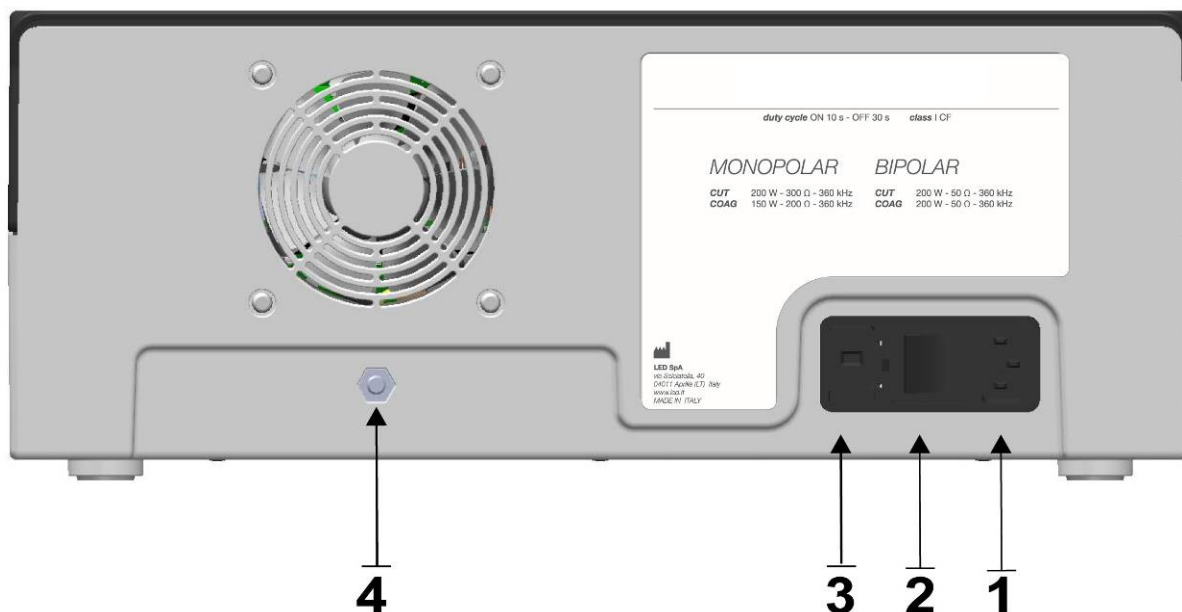


**AUTOSTART/AUTOSTOP.** The distribution starts, by pressing the foot-switch, if there is a contact between tissue and active electrode and stops when the tissue is coagulated. So by pressing the foot-switch, if there is an impedance value too higher, the distribution doesn't start





## Back Panel



- 1 Mains voltage connector
- 2 Power On-Off switch
- 3 Fuses holder
- 4 Equipotential connector

## Power Supply Module

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

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

## Power On-Off Switch

The POWER ON/OFF mechanical switch is used to control power to the equipment. To power the equipment, press the switch in the direction of the 1. 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.

## TECHNICAL CHARACTERISTICS

Tolerance	Description	SURGERY
—	Electrosurgical unit code	10100.V40
—	Detection system of tissue impedance (Bipolar coagulation – auto start/autostop)	●
—	Bipolar coag with automatic activation/disactivation	●
—	Minimum preselectable power	1
—	Selection of the power through touch screen	●
± 20%	Maximum output power CUT (W)	200W → 300Ω
± 20%	Maximum output power BLEND (W)	150W → 200Ω
± 20%	Maximum output power ENHANCED (W)	150W → 300Ω
± 20%	Maximum output power FORCED COAG (W)	150W → 200Ω
± 20%	Maximum output power SOFT COAG (W)	100W → 200Ω
± 20%	Maximum output power FULGURATION (W)	100W → 1000Ω
± 20%	Maximum output bipolar power BIPOLAR CUT (W)	120W → 50Ω
± 20%	Maximum output bipolar power BIPOLAR TUR (W)	200W → 50Ω
± 20%	Maximum output bipolar power BIPOLAR COAG (W)	120W → 50Ω
± 20%	Maximum output bipolar power BIPOLAR VESSEL SEALING (W)	200W → 50Ω
± 5%	Modulation factor BLEND (Hz)	50
± 5%	Modulation factor ENHANCED (Hz)	1.25
± 5%	Modulation factor FORCED COAG (kHz)	20
± 5%	Modulation factor FULGURATION (kHz)	20
± 5%	Modulation factor BIPOLAR TUR (Hz)	50
± 0.2	Crest Factor CUT	1.6
± 0.2	Crest Factor BLEND	2.0
± 0.2	Crest Factor ENHANCED CUT	2.5
± 0.2	Crest Factor FORCED COAG	3.0
± 0.2	Crest Factor SOFT COAG	1.6
± 0.2	Crest Factor FULGURATION	4.0
± 0.2	Crest Factor BIPOLAR CUT	1.6
± 0.2	Crest Factor BIPOLAR TUR	2.0
± 0.2	Crest Factor BIPOLAR COAG	1.6
± 0.2	Crest Factor BIPOLAR VESSEL SEALING	1.6
± 10%	Working frequency	360 kHz
± 15%	Maximum output voltage CUT (Vpp)	2000
± 15%	Maximum output voltage BLEND (Vpp)	1800
± 15%	Maximum output voltage ENHANCED CUT (Vpp)	1800
± 15%	Maximum output voltage FORCED COAG (Vpp)	2500
± 15%	Maximum output voltage SOFT COAG (Vpp)	1000
± 15%	Maximum output voltage FULGURATION (Vpp)	4000
± 15%	Maximum output voltage BIPOLAR CUT (Vpp)	650
± 15%	Maximum output voltage BIPOLAR TUR (Vpp)	1200
± 15%	Maximum output voltage BIPOLAR COAG (Vpp)	650
± 15%	Maximum output voltage BIPOLAR VESSEL SEALING (Vpp)	650
± 0.5	Size LxHxP mm	370x144x319
± 10	Weight (kg)	6
± 5%	Selectable mains power (Vac)	100 – 240
± 1%	Mains frequency (Hz)	50-60
± 0	Fuses (5x20) TIMED	2xT 10AL, 250V
± 10%	Electrical input power (VA)	750
± 10%	Electrical input current (240Vac) (A)	3,15
± 10%	Electrical input current (100Vac) (A)	7,5
—	Five steps adjustable sound level	●
—	Self-check	●
—	Power accuracy output warning	●
—	Skin Plate Electronic Control <sup>1</sup>	●

<sup>1</sup> Patient to plate contact monitoring system

Tolerance	Description	SURGERY
—	Split or not split patient plate allowed	●
—	Working (CUSTOM) condition storing <sup>2</sup>	Over 50
—	Electrical Class (EN60601-1)	I CF
—	MDD 93/42/EC Class	II b
—	EN55011 (CISPR 11) Class (Class/Group)	2 / B
—	Patient circuit	F
—	Duty Cycle (action / pause) in seconds	10 / 30
—	Output power control by foot-switch or finger-switch	●
—	Defibrillation-proof	●
—	Equipotential binding	●
—	ABS cabinet	●

● = PRESENT

<sup>2</sup> Continuous storing of the last settings

## MAINTENANCE

### *General*

No user adjustable parts are within the equipment, either for calibration or service purposes.

The equipment housing must not be opened: the warranty is invalidated by any unauthorized entry into the unit. In the event any repair or adjustment work being necessary, the whole equipment should be returned to the LED SpA. Service Centre 04011 APRILIA (LT) - ITALY, or to an other Authorized Centre, together with a description of the fault.

Maintenance work by the user is mainly the cleaning of the exterior of the cabinet, cleaning and sterilization of the accessory items and checking of the equipment before each use. Carrying out function and safety check for verification of the parameters is demanded to specialized technical people.

### *Cleaning of the Cabinet*

Switch the equipment off completely and disconnect the mains supply before any cleaning is undertaken. Clean the outside of the cabinet with a damp cloth. No chemical should be used; a mild non abrasive cleanser may be used when necessary.

### *Cleaning and Sterilization of the Accessories Items*

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

### *Guide to the Solution of the Problems*

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

Problems	Probable Cause	Solution
The equipment doesn't switch on.	Interruption or absence of the main feeding.	Verify the connection of the main cable. Verify the fuses and replace them, where necessary, with new ones of the proprie type.
Alarm Neutral Electrode always active	Interruption or lack of contact on the neutral electrode circuit.	Check the connection of the cable to the neutral electrode. Replace the cable of connection of the neutral electrode.
The unit doesn't respond to the command of activation	Breakdown of the handpiece or of the pedal. Wrong connection of the handpiece or of the pedal.	Replace the handpiece or the pedal. Verify the connection of the handpiece or of the pedal.

### *Repairs*

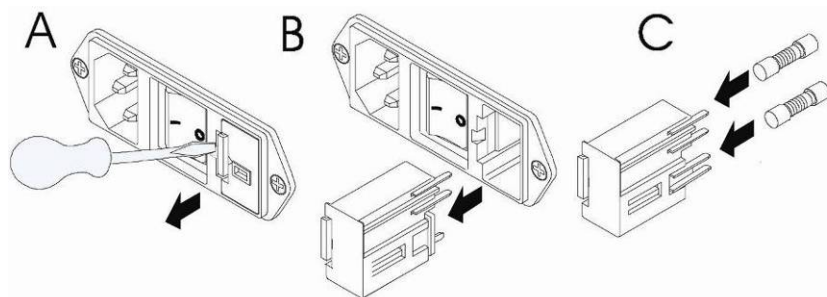
High frequency cables and electrode holder handle cannot be repaired. Always substitute a damaged part with a new one.

## Fuses Substitution

### **Before substituting the fuse, disconnect the unit from the mains system**

Only use fuse of the kind 5x20; they must have those characteristics: T10A (slow), proceed as follows:

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



## Checking of the Equipment Before Each Use

Each time the use of the electrosurgical equipment is planned a check of the most important safety aspects has to be implemented considering at least the following:

- Check the integrity of cords, connections, wires breakage, etc.
- Assure that all the electrical equipment is properly grounded
- Assure that all the accessories that should be used are available and sterilized.
- Check, by disconnecting the reference electrode cable, the functioning of the relative alarm light. Active unit and check alarm light and sound alarm warning.
- Check, by activating the CUT and COAG power switch, the functioning of the emission lights and sounds warnings.

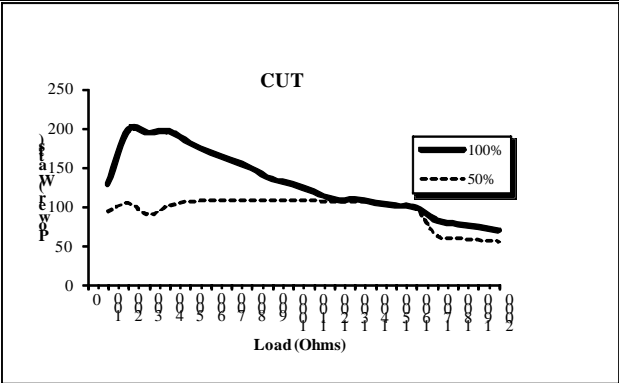
## Function and Safety Check and Test

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

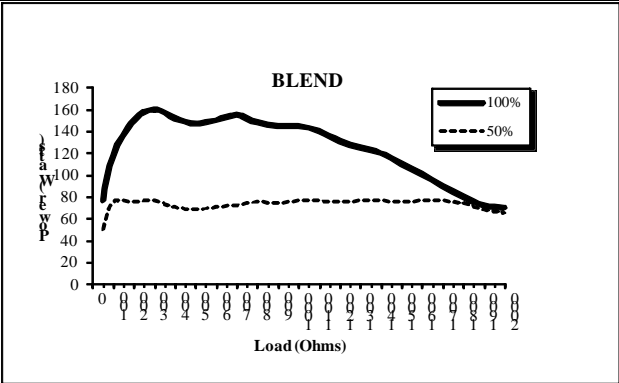
- Check of the connectors and mains supply cord conditions;
- Visual check of the mechanical protections;
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization and disinfection.
- Check of the Equipment's Data on the Label
- Check of the availability of the Instruction's Manual
- Check the functioning of the H.F. output controls
- Check the uniformity of the resistance through the surface of the patient plate.
- Test the earth conductivity resistance.
- Test the earth leakage current.
- Test H.F. leakage current.
- Control of the neuromuscular stimulation.
- Control of the accuracy of the output power.

DIAGRAMS

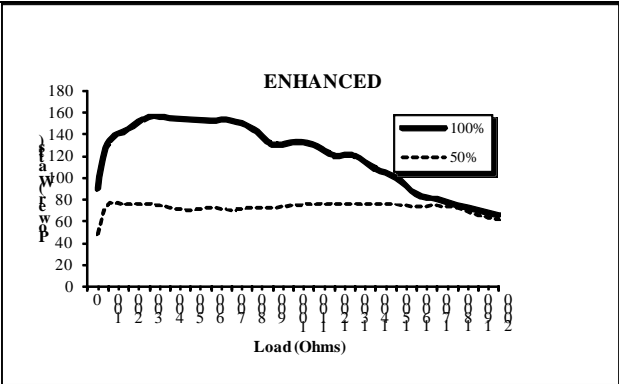
VERGERY



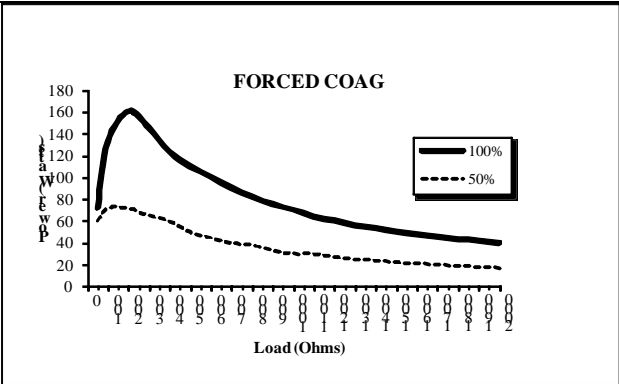
Diagrams of half and maximum output power versus impedance load  
100-2000Ω CUT100%



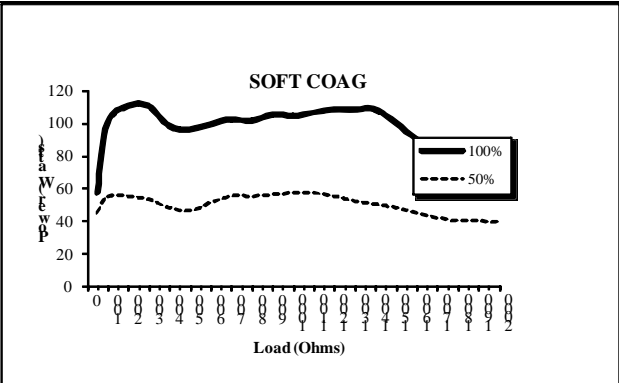
Diagrams of half and maximum output power versus impedance load  
100-2000Ω BLEND



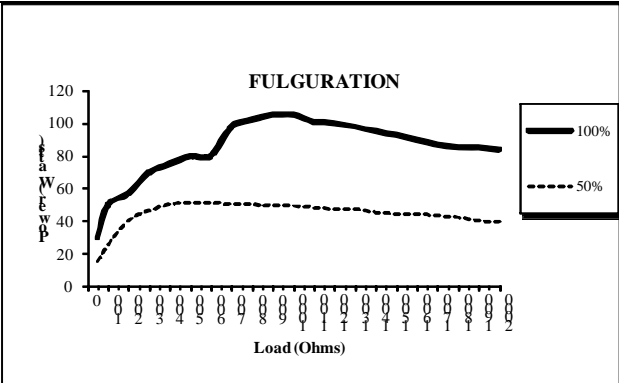
Diagrams of half and maximum output power versus impedance load  
100-2000Ω ENHANCED



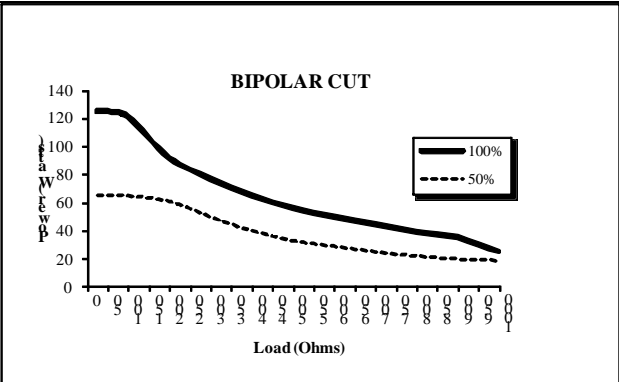
Diagrams of half and maximum output power versus impedance load  
100-2000Ω FORCED COAG



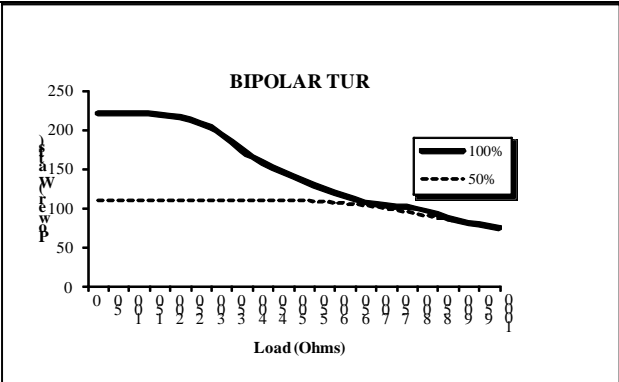
Diagrams of half and maximum output power versus impedance load  
100-2000Ω SOFT COAG



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

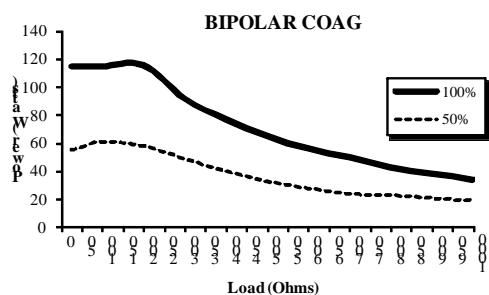


Diagrams of half and maximum output power versus impedance load  
10-1000Ω BIPOLAR CUT

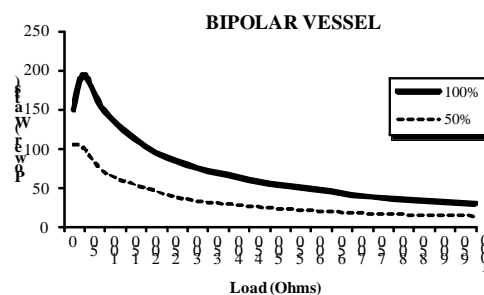


Diagrams of half and maximum output power versus impedance load  
10-1000Ω BIPOLAR TUR

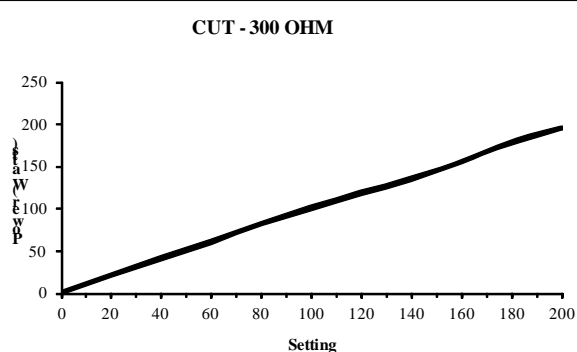
VERGERY



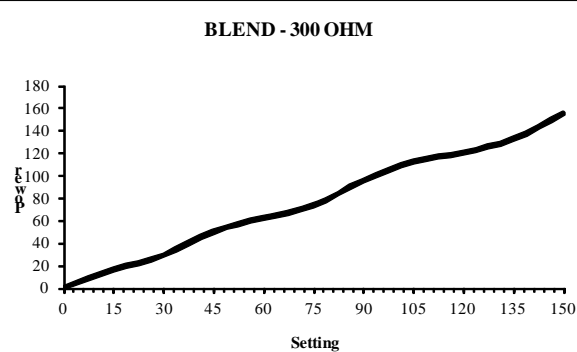
Diagrams of half and maximum output power versus impedance load  
10-1000 $\Omega$  BIPOLAR COAG



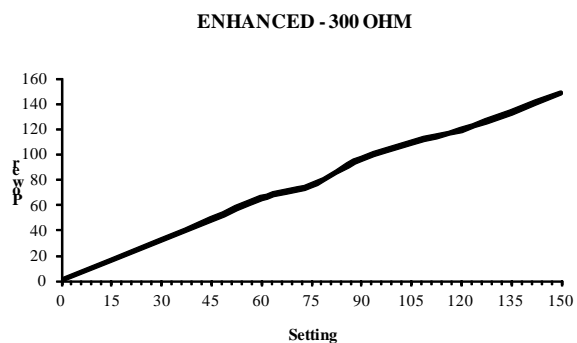
Diagrams of half and maximum output power versus impedance load  
10-1000 $\Omega$  BIPOLAR VESSEL



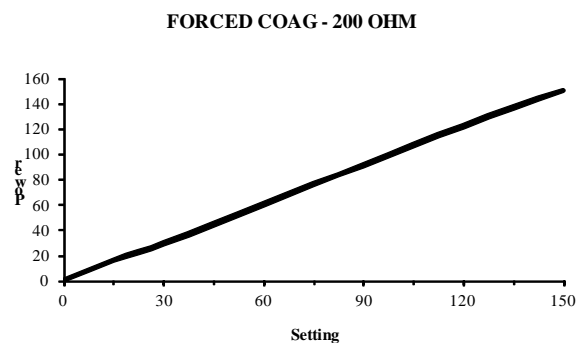
Diagrams of output power versus nominal value  
CUT100%



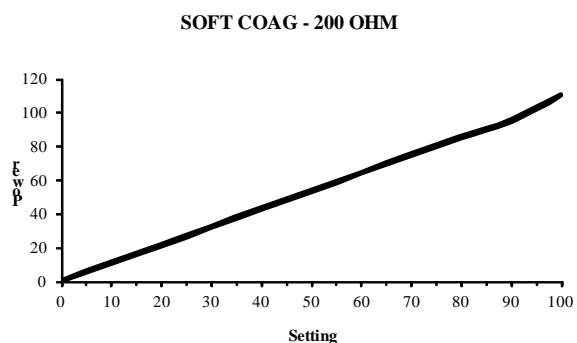
Diagrams of output power versus nominal value  
BLEND



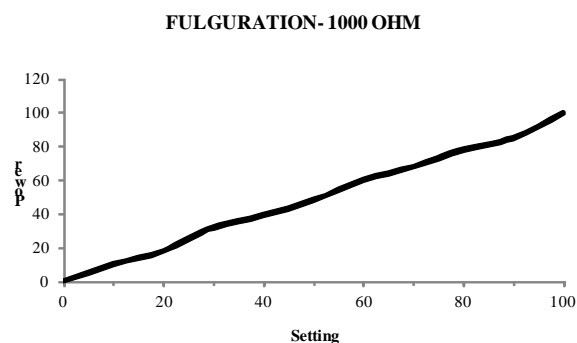
Diagrams of output power versus nominal value  
ENHANCED



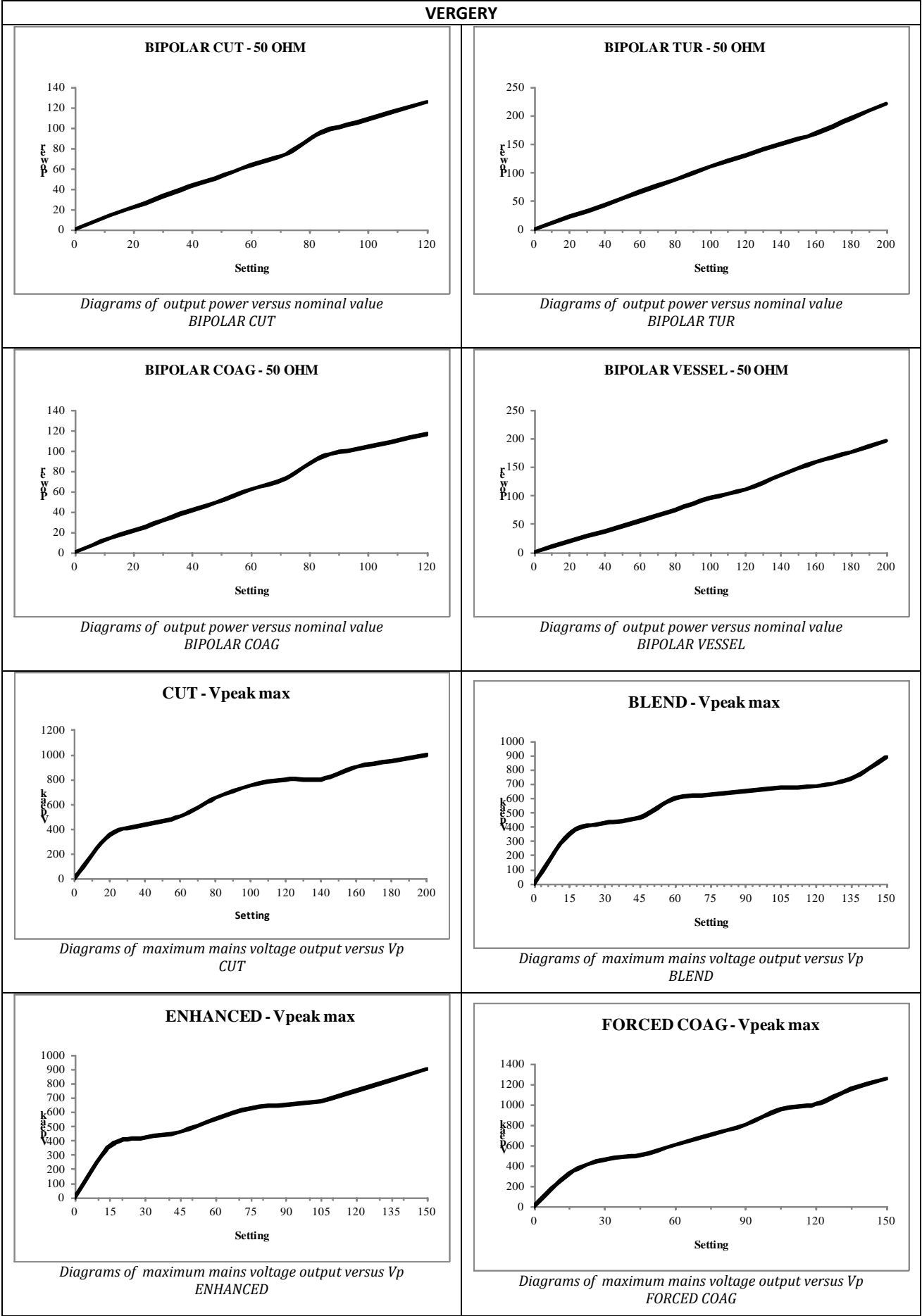
Diagrams of output power versus nominal value  
FORCED COAG



Diagrams of output power versus nominal value  
SOFT COAG



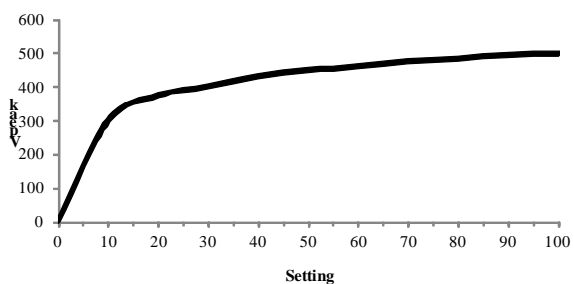
Diagrams of output power versus nominal value  
FULGURATION





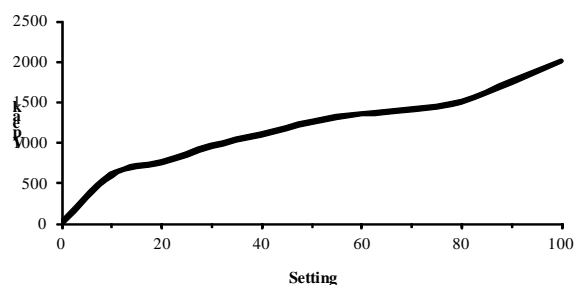
VERGERY

**SOFT COAG - Vpeak max**



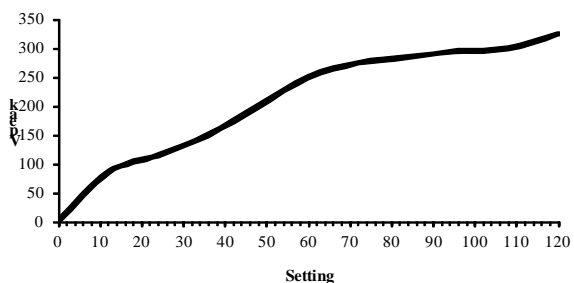
*Diagrams of maximum mains voltage output versus Vp  
SOFT COAG*

**FULGURATION - Vpeak max**



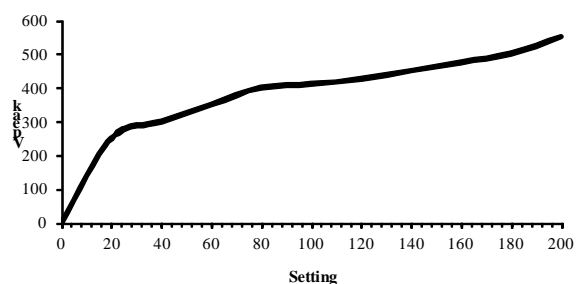
*Diagrams of maximum mains voltage output versus Vp  
FULGURATION*

**BIPOLAR CUT - Vpeak max**



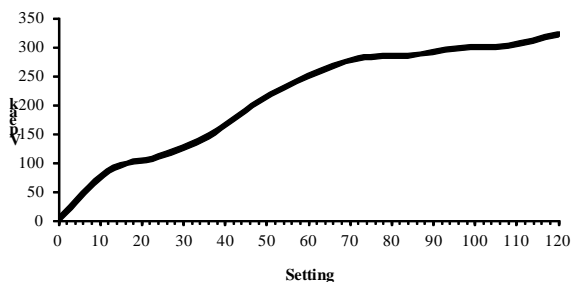
*Diagrams of maximum mains voltage output versus Vp  
BIPOLAR CUT*

**BIPOLAR TUR - Vpeak max**



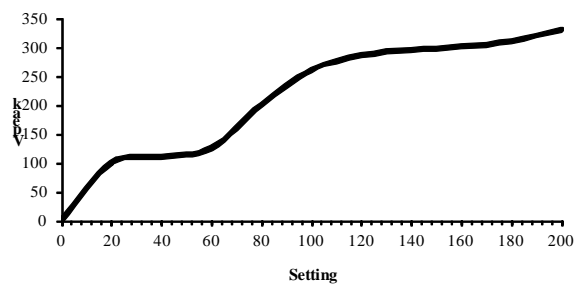
*Diagrams of maximum mains voltage output versus Vp  
BIPOLAR TUR*

**BIPOLAR COAG - Vpeak max**




*Diagrams of maximum mains voltage output versus Vp  
BIPOLARCOAG*

**BIPOLAR VESSEL - Vpeak max**



*Diagrams of maximum mains voltage output versus Vp  
BIPOLAR VESSEL*

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



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