SURTRON TOUCH *HP*

ELECTROSURGICAL UNIT

User Manual

ELECTROSURGERY

EN

Summary

IMPORTANT

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

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

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

Produttore / *Manufacturer*

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INTRODUCTION

Destination of Use / Sectors of Application

The use of HF electro surgical equipment **SURTRON® TOUCH HP 300** and **SURTRON® TOUCH HP 400** has reserved to specialized medical personnel. The equipment has destined to a temporary use, for surgical operations in emergency room or hospital. It has foreseen its use in the monopolar cut, cut coagulated or coagulation mode or in bipolar cut or coagulation mode. The equipment is conceived for being used in the following sectors:

Description	**SURTRON ® TOUCH**	
	HP 300	**HP 400**
Electrosurgical unit code	10400.T802	10400.T902
Dermatology	●	○
Endoscopy	●	○
Gastroenterology	●	●
General Surgery	●	●
Gynecology	●	○
Neurosurgery	●	●
Orthopaedics	○	●
Otorhinolaryngology	●	○
Paediatric Surgery	●	●
Plastic Surgery	●	●
Pneumology	●	○
Thorax Surgery	○	●
Trans Urethral Resection (TUR)	○	●
Urology	●	●
Vascular Surgery	○	○
Veterinary	●	○

●= Recommended
○= Usable

Standard and Optional Composition

Code	Description	SURTRON® TOUCH	
		HP 300	HP 400
-	Electrosurgical unit code	10400.T802A	10400.T902A
00100.01	Power supply cable 5m SIE-IEC	●/1	●/1
00205.00	PENCILS S – Handle with switch	●/1	●/1
00305.06	Double water-proof foot switch TOUCH / TOUCH HP	●/1	●/1
00306.06[1]	Double water-proof foot switch TOUCH HP with selector	●/1	●/1
00404.08	CONNECTION - Cable for neutral electrode disposable type 5365/6429/FLEX	●/1	●/1
152-110	ELECTRODE - Blade electrode 7 cm	●/3	●/3
152-115	ELECTRODE - Blade electrode 16 cm	●/3	●/3
152-120	ELECTRODE - Needle electrode 7 cm	●/3	●/3
152-150	ELECTRODE - Ball electrode ∅ 4mm 6 cm	●/3	●/3
755VL	Disposable handle with finger switches (F4797)	●/5	●/5
F7520	Electrode cleaning sponge 47x50mm	●/1	●/1
F7920	Disposable Split Neutral electrode (F7820)	●/5	●/5
00100.00	Power supply cable 2m IT-IEC	○	○
00100.03	Power supply cable 2m SIE-IEC	○	○
00100.04	Power supply cable 2m USA-IEC	○	○
00100.05	Power supply cable 2m GB-IEC	○	○
00100.07	Power supply cable 2m BR-IEC	○	○
00100.09	Power supply cable 2m AU-IEC	○	○
00100.10	Power supply cable 5m JP-IEC	○	○
00205.40	PENCILS S – Handle with switch (for electrode 4mm)	○	○
00206.00	PENCIL - Handle without switch	○	○
00206.40	PENCIL - Handle without switch (for electrode 4mm)	○	○
00306.06[1]	Double water-proof foot switch TOUCH HP with selector	○	○
00401.01	NEUTRAL - Steel Neutral Electrode 24x16 cm with cable	○	○
00401.03	NEUTRAL - Steel Neutral Electrode 24x16 cm with cable autoclavable	○	○
00401.10	NEUTRAL - Steel Neutral Electrode FLEX 120x210mm	○	○
00401.11	NEUTRAL - Steel Neutral Electrode FLEX 120x210mm with cable	○	○
00401.12	NEUTRAL - Steel Neutral Electrode FLEX 120x210mm with cable autoclavable	○	○
00401.20	NEUTRAL - Steel Neutral Split Electrode FLEX S 120x210mm	○	○
00401.21	NEUTRAL - Steel Neutral Split Electrode FLEX S 120x210mm with cable	○	○
00401.22	NEUTRAL - Steel Neutral Split Electrode FLEX S 120x210mm with cable autoclavable	○	○
00402.00	CONNECTION - Monopolar cable M4-F4 3mt	○	○
00402.01	CONNECTION - Monopolar cable M4-F2.8 3mt	○	○
00402.02	CONNECTION - Monopolar cable M4-MP4 3mt	○	○
00402.03	CONNECTION - Monopolar cable M4-EU 3mt	○	○
00402.04	CONNECTION - Monopolar cable M4-F2.M 3mt	○	○
00404.07	Cable for connection neutral electrode F7915/F7930	○	○
00404.09	CONNECTION - Cable for neutral electrode disposable type 5365/6429/FLEX autocl.	○	○
00411.00	CONNECTION - Bipolar cable EUR	○	○
00413.00	CONNECTION - Bipolar cable 3mt Artery Sealer EUR	○	○
00414.00	CONNECTION - Bipolar cable 3mt US	○	○
00415.00	CONNECTION - Bipolar cable 3mt ENDO1 (F4-F2)	○	○
00416.00	CONNECTION - Bipolar cable 3mt ENDO2 (MP2-F2)	○	○
00417.00	CONNECTION - Bipolar cable 3mt ENDO3 (MP2-F4)	○	○
00418.00	CONNECTION - Bipolar cable 3mt SCISS (F2.4-F2.4)	○	○
00420.00	Reusable handle with finger switch for Argon	○*	○*
00420.12	Argon coagulation electrode 150mm	○*	○*
00420.10	Argon coagulation electrode 75mm	○*	○*
00420.14	Argon coagulation electrode 370mm	○*	○*
00430.00	Connection cable for flexible Argon probes, 2.5mt	○*	○*
00430.10	Monopolar flexible Argon probe 1.5mm, 1.5mt	○*	○*
00430.12	Monopolar flexible Argon probe 1.5mm, 3mt	○*	○*
00430.20	Monopolar flexible Argon probe 2.3mm, 1mt	○*	○*
00430.22	Monopolar flexible Argon probe 2.3mm, 2.2mt	○*	○*
00430.24	Monopolar flexible Argon probe 2.3mm, 3mt	○*	○*

Code	Description	SURTRON® TOUCH	
		HP 300	HP 400
00430.30	Monopolar flexible Argon probe 3.2mm, 2.2mt	○*	○*
0350	Disposable Neutral electrode (F7805)	○	○
10500.30	SURTRON ABC Pressure reducer UNI11144 Gruppo VIII	○*	○*
110-750NS	BIPOLAR - Bipolar Artery Sealer 27cm TIP 3mm	○	○
110-755NS	BIPOLAR - Bipolar Artery Sealer 25,5cm TIP 3mm	○	○
110-760NS	BIPOLAR - Bipolar Artery Sealer 17cm TIP 2mm	○	○
152-112	ELECTRODE - Blade curved electrode 7 cm	○	○
152-122	ELECTRODE - Needle curved electrode 7 cm	○	○
152-125	ELECTRODE - Needle electrode 13 cm	○	○
152-130	ELECTRODE - Ball electrode ∅ 2mm 6 cm	○	○
152-132	ELECTRODE - Ball curved electrode ∅ 2mm 6 cm	○	○
152-140	ELECTRODE - Ball electrode ∅ 3mm 6 cm	○	○
152-142	ELECTRODE - Ball curved electrode ∅ 3mm 5 cm	○	○
152-145	ELECTRODE - Ball electrode ∅ 3mm 14 cm	○	○
152-152	ELECTRODE - Ball curved electrode ∅ 4mm 6 cm	○	○
152-160	ELECTRODE - Ball electrode ∅ 5mm 6 cm	○	○
152-162	ELECTRODE - Ball curved electrode ∅ 5mm 6 cm	○	○
152-165	ELECTRODE - Ball electrode ∅ 5mm 14 cm	○	○
152-175-10	ELECTRODE - Loop electrode 10x10 l.15 cm	○	○
152-190-13	ELECTRODE - Loop electrode 20x13 l.15 cm	○	○
152-190-20	ELECTRODE - Loop electrode 20x20 l.15 cm	○	○
152-195	ELECTRODE - Conization electrode 13 cm	○	○
310-110-05	BIPOLAR - Bipolar Forceps 11,5cm TIP0.5mm	○	○
310-112-05	BIPOLAR - Bipolar Forceps Curved 11,5cm TIP0.5mm	○	○
310-140-10	BIPOLAR - Bipolar Forceps 20cm TIP 1mm	○	○
310-140-20	BIPOLAR - Bipolar Forceps 20cm TIP 2mm	○	○
310-142-10	BIPOLAR - Bipolar Forceps Curved 20cm TIP 1mm	○	○
310-142-20	BIPOLAR - Bipolar Forceps Curved 20cm TIP 2mm	○	○
310-180-10	BIPOLAR - Bipolar Forceps Angled 20cm TIP 1mm	○	○
310-180-20	BIPOLAR - Bipolar Forceps Angled 20cm TIP 2mm	○	○
310-182-10	BIPOLAR - Bipolar Forceps Angled Curved 20cm TIP 1mm	○	○
310-185-10	BIPOLAR - Bipolar Forceps Angled Curved 20cm TIP 1mm	○	○
310-510	BIPOLAR - Bipolar electrode 20cm – direct	○	○
310-550	BIPOLAR - Bipolar electrode 20cm – curved 1	○	○
310-590	BIPOLAR - Bipolar electrode 20cm – curved 2	○	○
330-134-20	MONOPOLAR - Monopolar Forceps 20cm TIP2mm	○	○
330-160	MONOPOLAR - Monopolar Surgical Scissors 18cm	○	○
410-100-15	BIPOLAR – Bipolar Forceps Clamp Scissors 15cm	○	○
410-100-19	BIPOLAR – Bipolar Forceps Clamp Scissors 19cm	○	○
410-200-18	BIPOLAR – Bipolar Forceps Scissors 18cm	○	○
410-200-21	BIPOLAR – Bipolar Forceps Scissors 21cm	○	○
410-200-23	BIPOLAR – Bipolar Forceps Scissors 23cm	○	○
6429A	NEUTRAL - Steel Neutral Electrode 24x16 cm	○	○
F7915	Conductive rubber neutral electrode without cable	○	○
F7930	Conductive rubber split neutral electrode without cable	○	○
TRST001	Trolley for SURTRON TOUCH HP	○	○
TRCYLSUP01	Support for Cylinder	○*	○*

●/ Pcs= STANDARD ○= OPTIONAL

* not compatible with versions without integrated Argon module (10400.T802 / 10 - 10400.T902 / 10)
[1] from number 0239949

General Description

SURTRON® TOUCH HP 300 and **SURTRON TOUCH HP 400** are high frequency electro-surgical equipment suited to deliver current for monopolar cut, coagulated cut, in monopolar modality and cut and coagulation in bipolar modality. In 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).

A total of eighteen different modes of use and levels of power, can be stored and recalled for the use simply. (Pre-set Programs). It is possible to modify them, and it is possible to create over 50 programs.

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.

Some versions (10400.T902 / 10400.T802) are equipped with the Argon integrated module to perform no-contact coagulation, through optional compatible applicators, such as rigid electrodes or flexible probes, therefore specific electrosurgical procedures for coagulation with Argon gas are possible for both surgery in the open air than in endoscopy. Argon is an inert gas that used in conjunction with specific currents for high frequency coagulation generated by the unit, allows to obtain a non-contact surface coagulation thanks to the ionization of the gas through the high frequency current.

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 blocks 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

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

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, favouring 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 $0,7 \times 10^3$	Aluminium $0,29 \times 10^{-5}$
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 ºC 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 ºC 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 verified 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^2) on the edge, where the excessive increase of temperature by Joule effect causes burns for the patient. So, it isn't accidental that the burns for the patient, during the electrosurgical interventions, have the shape of the edge neutral electrode. To reduce the burns risk, must 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 equipment 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 his professional judgment as he does every time in his practice.

- Keep the tissues moist but not wet
- Survey the stroke before activating the electrode
- Keep the electrode perpendicular to the tissue
- Activate the electrode before contacting 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 colour
- no fibres of tissue remained onto the electrode.

Transurethral resection
A particular use of the cut is represented by the immersion of the active electrode (for this scope it's used a metal loop) in a liquid, for re-move tissue from the bladder and prostate. In this circumstance it's realized a high dispersion of the energy through the liquids and so it's important to use cut current that compensate these energetical dispersions.
By using coagulation currents and/or mixed cut currents the blood loss is reduced.

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. 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 do 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 having 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 whitens 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 hematic flow by the clamping pressure between the ends of the forceps.
After having 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 happening 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 end's 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 non-invasive 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 safer 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 favours 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 equipped training about all modalities to avoid or reduce the risks of burns by using HF electrosurgical units;
- use of disinfectants with high alcohol content;
- incorrect position of the patient during the electrosurgical operation;
- contact between active electrode and the skin;
- contact with liquid;
- long application of HF currents;
- incorrect application of the patient-plate.

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

SAFETY

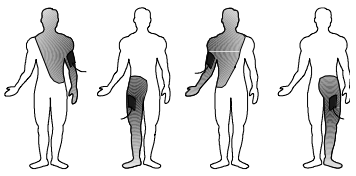
WARNING: Electro-surgery can be dangerous. Careless use of any element in the electrosurgical system may subject the patient to a serious burn. Read and understand all warnings, precautions, and directions for use before attempt to use any active electrode. Neither LED SpA, can be considered responsible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

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

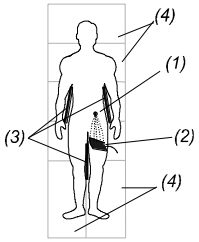
General

The following precautions reduce the risk of accidental burnings

- The whole surface of the patient plate must be placed on a well-vascularized muscle as next as possible to surgical area. Avoid connecting the patient plate to bony protrusions, prosthesis, cicatricial tissues, and parts of the body subjected to liquid accumulation or that present subcutaneous adipose tissue. The part of the body must be without hair, dry and clean. Do not use alcohol to clean the skin. Unless for veterinary use, the use of gelatinoids substances for the electrodes is not advised.
- By using the disposable neutral electrodes respect the date of expire.
- By using the reusable electrodes ascertain that the fixing systems give warranty of stability.
- When you apply the neutral electrode avoid the transversal course and prefer the vertical or diagonal course, 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 arm and body of the patient). Insert an interface material like dry surgical gauze. Moreover, the parts of the body subjected to abundant perspiration must be maintained dry.



(1) Treatment area



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

- When high frequency electrosurgical unit and physiological monitoring devices are used at a time in the same patient, all the monitoring electrodes, that have not resistive or inductive elements tested in high frequency interference environment, must be as far as possible from the electrodes of the electrosurgical unit. Avoid the use of monitoring needles.
- The connection to the electrodes should be 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 anaesthetics, 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 left 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 must 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 affect 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 connecting 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 heatsink
- 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 cannot 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.

Caution when handling argon cylinders

- Argon cylinders may only be transported with valve protection (cylinder cap) in vertical position and secured in place. No force of any kind should be exerted on cylinders, cylinder connections or pressure reducers. Protect the argon cylinder by means of chains, straps, or safety belts from tipping over or falling during transport, storage and use.
- Argon cylinders may only be connected to the SURTRON with the pressure reducers and hoses provided by LED SpA.
- Close the safety valves of the argon cylinders after use.
- Danger of gas emphysema: never put the gas outlet jet of the rigid Argon electrodes directly on the tissue during gas activation.
- Danger of embolism: Never blow Argon into the vascular system. The gas outlet jet must not be guided and activated vertically over the tissue. An angle of approximately 45° to the tissue has been proven to be best.
- Danger by increase intra-abdominal pressure: With laparoscopic applications the Argon gas flow increases the intra-abdominal pressure. It is recommended that electronic pressure discharge CO2 insufflators be used. During activation, monitor the intra-abdominal pressure and if necessary, discharge pressure via the trocar.
- Unintentional activation of the Argon handle directly in front of the endoscope optics can destroy this. The Argon plasma beam must not be directed onto the camera chip during endoscopic applications with video endoscopes.
- Wrong or bad Argon quality gas can cause injury to the patient. Argon having 4.8 quality is germ-free in the gas bottle (manufacturing condition). In order to guarantee the germ-free condition, the valve on the bottle and the gas outlet on the gas supply device must be disinfected before connection.

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 electrically conductive objects (metal, wet clothes, etc.), in the contact's point could be electrical current that causes thermal necrosis. So, it is recommended to inspect the equipment and its accessories before using and to respect all safety rules.

Correct Position of the Patient

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

- The patient is not in contact with metallic parts (operative table, supports.).
- The flexible tube of the respirator does 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 patient is on a thick basic tissue with insulating properties, covered by an enough net.
- The patient is not in contact with nets or wet mattress.
- The eventual organic secretions and the cleaning and other liquids do not wet the nets.
- There are not liquid under the patient.
- Urinary secretions are eliminating by the catheters.
- The body zones characterized by a higher sweating, the extremities in direct contact with trunk or the points of skin-skin contact are dried by the net's interposition (arm/trunk, leg/leg, breast, skin folds, etc.).
- All conductive and grounded supports, stirrups, are correctly insulated.
- Control the anaesthetics quantity to avoid a great sweating.

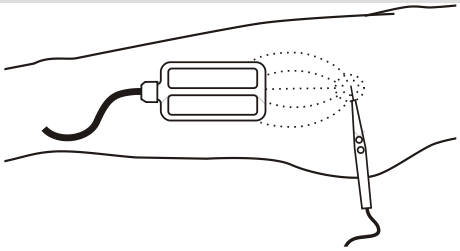
Correct Position of Neutral Electrode

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

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

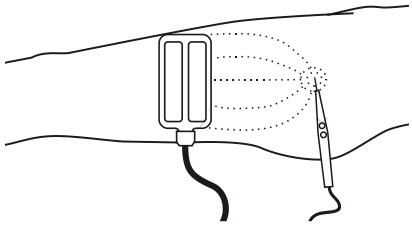
neutral electrode by two surfaces (with divided cables) where there is a check on the contact between neutral electrode and patient.

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



(CORRECT application)

In this picture it is shown the correct position of the neutral electrode by the two surfaces. The patient-plate must be placed perpendicularly to the operative field. It is important to avoid the transversal way and prefer the vertical or diagonal one, thereby it is allowed a uniform distribution of the current on all two surfaces and reduces the risk of burns for the patient.



(WRONG application)

Neutral electrode is often applied in an incorrect way, in parallel to the operative field. So, the current distribution is not uniform on the two surfaces. If possible that the OC acoustic signal is started and the unit starting is not allowed.

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 near 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 happens 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 inlet, must agree with the local mains voltage (mains voltage frequency: 50-60 Hz). If necessary, replace the fuses with the value indicated on the rating plate.
- Connect mains cable to a mains outlet having good hearth connection.

OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN.

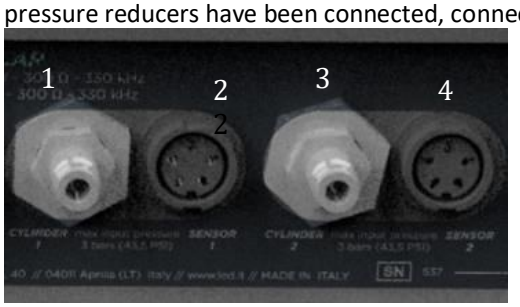
- The unit must be installed on a level surface, with dimension, at least, correspondent to those of the base of the unit itself. Around the unit must be left a space of 25cm, at least.
- Connect the mains cable to the mains socket on the rear panel of the unit.
- Connect, if request, the equipotential binding post located at the left of the unit's back panel to eventual equipotential socket of the plant.
- Connect the double pedals to the connectors on the rear panel of the unit.
- Connect handle to the corresponding connectors and in the case of use of handle without pushbuttons 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:

	WORK	*TRANSIT/STORAGE*
Temperature:	*10/40°C*	*-10/+50 °C*
Relative moisture:	*30/75%*	*10-85 %*
Pressure:	*70/106k Pa*	*50/106 kPa*

- When the unit is switched on, through the on/off switch on the frontal panel, after having checked the internal parameters, it will work with the function and the power level utilized during the last switching.

<u>Only for versions with integrated Argon module</u>

- The unit can only operate with Argon gas. Before connecting make sure that you are about to connect Argon gas and no other dangerous gases. In case of missing indications or in case of doubt do not connect to the unit. Operate only in non-humid environments. Do not exceed the permitted environmental conditions. Use Argon gas cylinders that comply with current regulations.
- On the back of the unit, connect two Argon gas cylinders (1/3), where previously the optional REF10500.30 pressure reducers have been connected, connect the cable for the gas sensor (2/4).



1 – Gas Argon gas cylinder inlet 1
2 – Cylinder gas sensor connector 1
3 – Gas Argon gas cylinder inlet 2
4 – Cylinder gas sensor connector 2

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

1

2

1 Cable for bipolar accessories connection
2 Bipolar accessories (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

SURTRON® TOUCH HP 300-400 HF electrosurgical unit are designed, manufactured and tested by the LED SpA in its own laboratories in Aprilia (LT) – Italy.

Technical Data

SURTRON® TOUCH HP 300

MONOPOLAR APPLICATION		*BIPOLAR APPLICATION*	
FREQUENCY:	360kHz	FREQUENCY:	360kHz
Output CUT (CUT):	300W - 300Ω	Output BIPOLAR CUT (CUT):	150W - 100Ω
Output ENHANCED (CUT):	200W - 300Ω	Output BIPOLAR MICRO CUT (CUT):	50W - 100Ω
Output BLEND (CUT /COAG):	200W - 300Ω	Output BIPOLAR TUR CUT (CUT):	300W - 300Ω
Output DUO CUT (CUT):	150W - 300Ω	Output BIPOLAR COAG (COAG):	150W - 50Ω
Output TUR CUT (CUT):	250W - 300Ω	Output MICRO COAG (COAG):	50W – 50Ω
Output FORCED (COAG):	120W - 150Ω	Output BIPOLAR TUR COAG (COAG):	250W - 50Ω
Output SOFT (COAG):	120W - 150Ω	Output VESSEL SEALING	250W - 50Ω
Output FULGURATION (COAG):	80W - 500Ω		
Output DUO COAG (COAG):	80W - 500Ω		
Output SPRAY (COAG):	100W - 1000Ω		
Output SPRAY ARGON(COAG)*:	100W - 1000Ω		

SURTRON® TOUCH HP 400

MONOPOLAR APPLICATION		*BIPOLAR APPLICATION*	
FREQUENCY:	360kHz	FREQUENCY:	360kHz
Output CUT (CUT):	400W - 300Ω	Output BIPOLAR CUT (CUT):	150W - 100Ω
Output ENHANCED (CUT):	250W - 300Ω	Output BIPOLAR MICRO CUT (CUT):	50W - 100Ω
Output BLEND (CUT /COAG):	250W - 300Ω	Output BIPOLAR TUR CUT (CUT):	300W - 300Ω
Output DUO CUT (CUT):	200W - 300Ω	Output BIPOLAR COAG (COAG):	150W - 50Ω
Output TUR CUT (CUT):	300W - 300Ω	Output MICRO COAG (COAG):	50W – 50Ω
Output FORCED (COAG):	150W - 150Ω	Output BIPOLAR TUR COAG (COAG):	250W - 50Ω
Output SOFT (COAG):	150W - 150Ω	Output VESSEL SEALING	250W - 50Ω
Output FULGURATION (COAG):	100W - 500Ω		
Output DUO COAG (COAG):	100W - 500Ω		
Output SPRAY (COAG):	120W - 1000Ω		
Output SPRAY ARGON(COAG)*:	120W - 1000Ω		

MAIN POWER:	100-240 Vac - 50/60 Hz
INLET POWER:	1000VA
FUSE:	2xT 10AL, 250V
DUTY - CYCLE:	intermittent10 seconds emission / 30 seconds of di pause
CLASS:	I CF

**Argon Functions*

Only models with integrated Argon (codes 10400.902 / 10400.802)

Max output flow:	10 LPM
Max output pressure:	2.0 bar (29 psi)

Meaning of Graphics Symbols

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

1- Floating Neutral Electrode: patient circuit is isolated from earth at both high and low frequencies.
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 Directive Medical Device 93/42/EC (2007/47/EC)
6- The product mustn't be throwing in the containers for urban wastes, but it must be swallowed by a separate picking.
7- Manufacturer
8- Serial Number
9- Date of manufacturer

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

Frontal Panel

1. Touch switch
2. Touchscreen display (work screen)
3. Monopolar output connectors
4. Connector for neutral electrode connection
5. Bipolar output connectors
6. Neutral Electrode Check Light
7. Argon gas outlet connector (only versions with integrated module)

1. ON / OFF BUTTON

With the unit powered (switch on the rear panel on I), identified by the red colour of the light band near the key, it is possible to press the key to turn on the unit, the light turns green and the unit is on.

2. DISPLAY TOUCHSCREEN

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

3. CONNECTORS FOR MONOPOLAR OUTPUTS

These are the connection points of the handpieces with double buttons to deliver the CUT and COAG coagulation cutting functions. When using handpieces without buttons or monopolar cables (optional) they must be connected to the upper bushings.

4. NEUTRAL CONNECTION

This is the connection point of the neutral electrode to be applied to the patient.
Single-use or multi-use, single-card or bipartite neutral electrodes can be used.

5. CONNECTORS FOR BIPOLAR OUTPUTS

These are the connection points of the bipolar accessories.

6. NEUTRAL ELECTRODE CHECK LIGHT

Indicator of impedance in the neutral electrode circuit.

7. ARGON GAS OUTPUT CONNECTOR

For versions with integrated Argon module there is a LUER LOCK connector to be connected to the optional Argon coagulation handpiece.

Operation Mode

Control and Switch On

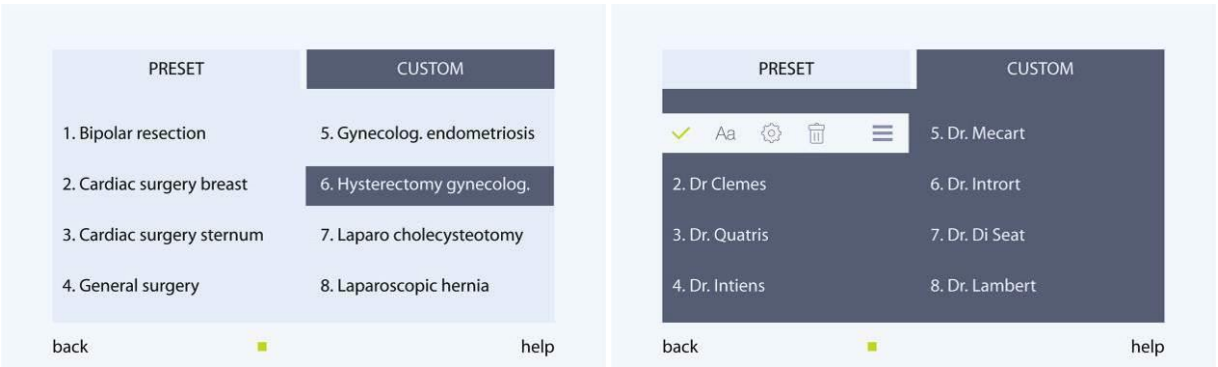
The unit is directly controlled through the present icons on the display device touch screen. In order to confirm a selection to press the icon directly

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.

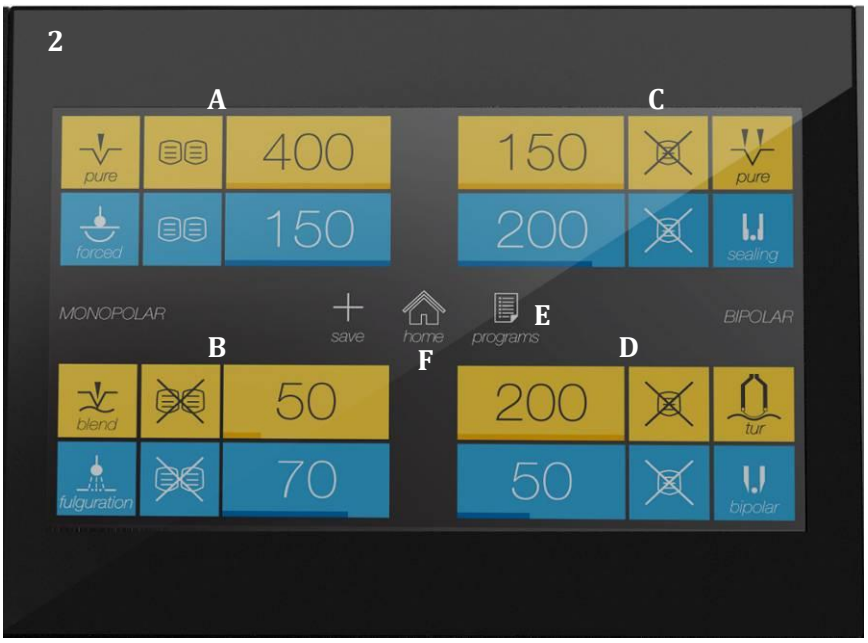
Through Info is possible see installed software versions.
The HELP key permits the visualization of the summarizing information, useful for the right interpretation of indications on the display

Programs



Chose **programs** in the screen appears pre-set 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: denominated (Aa) – modified (gear) – deleted (dumpster)
To create a Custom program, see work screen (Surgery).

Surgery



2. Display touchscreen (work screen)
A Monopolar 1 section
B Monopolar 2 section
C Bipolar 1 section
D Bipolar 2 section
E Program section
F Home Icon

MONOPOLAR and BIPOLAR SECTION

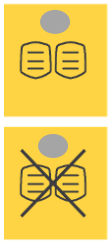
Touch icon with number for output regulation power, see example:

Regulate power through + and -, accept by ✓

Touch icon with function for choose it, see example:

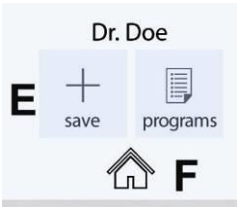
Touch icon with pedal for choose which is activated, see example:

standard foot-switch



foot-switch with selector

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 Pre-set Program press programs, in the next screen is possible choose it (see Programs).
Name of Pre-set 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 conductibility of the plate can provoke reduction of conductibility 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 electrode 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 alarm indicator on electrode neutral connector are extinguished.

LIGHTS

I Monopolar Indication Light 1
Yellow – Output Cut Current
Blue – Output Coag Current
L Monopolar Indication Light 2
Yellow – Output Cut Current
Blue – Output Coag Current
M Bipolar Indication Light 1
Yellow – Output Cut Current
Blue – Output Coag Current
N Bipolar Indication Light 2
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 remains for few seconds, in this time you can adjust, by + and -, the output level, for close screen press X.

ARGON FUNCTIONS

Only for the prepared models, using the ARGON monopolar coagulation function, it is possible to access the additional ARGON functions.

PURGE

Each time a new instrument is used, it must be saturated with Argon gas, for this purpose use the PURGE button.

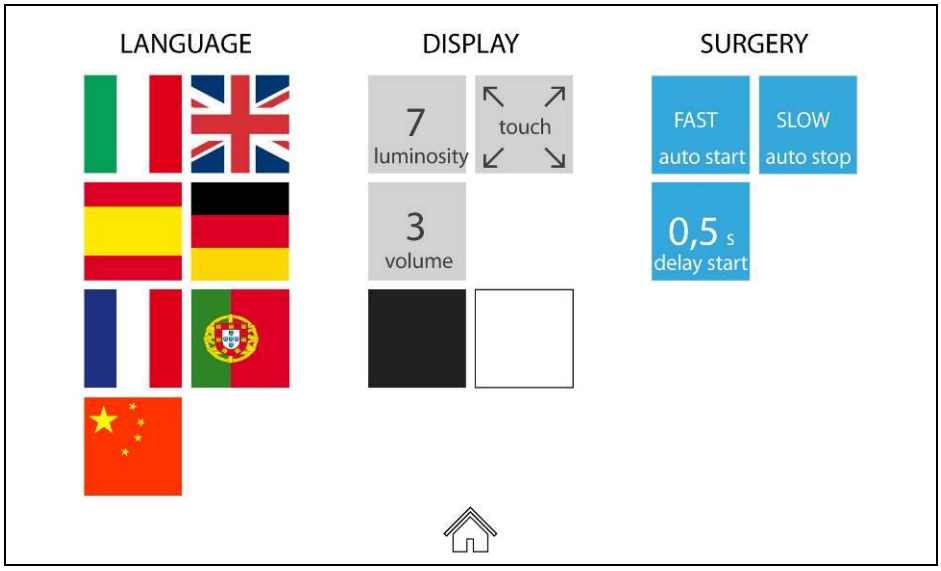
Over Pressure This light indicates excessive pressure in the circuit. Check the pressure reducer (max. Input 3.5 Bar)

No Gas This light indicates the lack of gas or a low level of pressure in the circuit. Check the level of the cylinders and the pressure reducer.

ADJUSTMENT

It is possible to adjust the Argon gas flow from 0.2 to 5 (for Laparoscopic mode) or from 0.5 to 10 (for open mode).

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 and (from SW1.1.1 HW1.1.0) Auto-start with or without foot-switch activation. Touch icon to return on Home page.

Update

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

To connect in the USB connector, in the back part of unit, 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 show 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	6 Forced Coag
2 Enhanced	7 Soft Coag
3 Blend	8 Fulguration
4 Duo CUT	9 Duo COAG
5 TUR CUT	10 Spray
	11 Argon

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

Foot-switch active

Foot-switch non active

With the pedal with optional selector code 00306.06 connected to the monopolar connector (7) it is possible, by pressing the present selector, to select the MONOPOLAR 1 or BIPOLAR 1 output. By pressing the selector again, the pedal operates in a traditional way.

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

Current for Cut (CUT - Pure)

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.

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, adipose tissues. From SW1.1.4 and HW1.1.4 there are six different effects (from 5 to 50%).

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. From SW1.1.3 and HW1.4.0 there are six different effects (from 20 to 70%).

Duplicate Cutting Current (DUO CUT)

Duplicate Cutting function set on both connected handpieces. It is possible to deliver the same function simultaneously on the two handpieces.

Trans Urethral Resection Current (TUR CUT)

The TUR current, with a specific bipolar accessory, is suitable for cutting and coagulated cutting when forced coagulation is desired together with the cut. This current is made by the sinusoidal current adapted to the shear associated with the current for high voltage coagulation.

Current for Superficial Coagulation (FORCED COAG)

The modulated current (FORCED COAG) it is characterized by good property of surface coagulation behaving at the time its 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 (FULGURATION)

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.

Duplicate Coagulation Current (DUO COAG)

Duplication Coagulation function set on both connected handpieces. It is possible to deliver the same function simultaneously on the two handpieces.

Spray Coagulation Current (SPRAY COAG)

The high-voltage current SPRAY COAG flows into the active electrode which is not placed in contact with the portion of tissue to be treated and produces mainly coagulation. This method is ideal for treating large surfaces with diffuse and superficial bleeding (e.g. liver resection) and / or to achieve coagulation at the level of the sternum open in the field of cardiac surgery

Argon Spray Coagulation Current (SPRAY ARGON)

For the versions with the integrated Argon module using this function, the controls for the gas supply (gas level control, flow etc) are activated. In versions that do not include the integrated module (10400.902 / 10 - 10400.802 / 10) it is necessary to connect an external Argon compatible unit (SURTRON ABC).
Argon is an inert gas that is used to achieve a coagulating effect on patient tissue. The gas contained in the cylinder is dispensed at low pressure in the direction of the tissue, while a function with output voltage is activated, apt to trigger the Argon spark and, therefore, to start the coagulation process (without contact between active electrode and fabric), which is extremely effective and useful not only in traditional open surgery such as liver resections, but also in laparoscopic and endoscopic resections

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 TUR Coag
	5 Bipolar Vessel Sealing

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

Foot-switch activate

Foot-switch not active

With the pedal with optional selector code 00306.06 connected to the bipolar connector (5) it is possible, by pressing the present selector, to select the BIPOLAR 1 or BIPOLAR 2 output. By pressing the selector again, the pedal operates in a traditional way.

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. From SW1.1.3 and HW1.1.0 there is bipolar MICRO CUT function with max power 50W.

Trans Urethral Resection Current (BIPOLAR TUR Cut)

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 an 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).
From SW1.1.3 and HW1.1.0 there is bipolar MICRO COAG function with max power 50W.

Trans Urethral Resection Current Coag (BIPOLAR TUR Coag)

The TUR COAG current, with a specific bipolar accessory, is suitable for cutting and coagulated cutting when forced coagulation is desired together with the cut. This current is made by the sinusoidal current adapted to the shear associated with the current for high voltage coagulation.

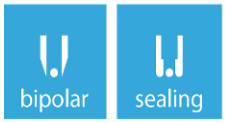
Vessel Sealing

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.

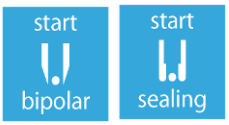
Autostart and Autostop

In the Bipolar functions it is possible to access four different operating settings:

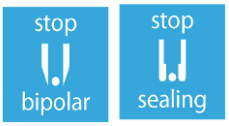
No automatism for the distribution. The distribution is realized by pressing the foot-switch and stops by leaving again the foot-switch;



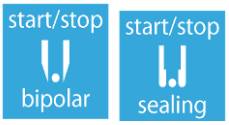
START. The distribution is started, by pressing the foot-switch, if there is contact between active electrode and tissue, and it stops by leaving again the foot-switch;



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.



(Fig. 2)

Back Panel

1 Mains voltage connector
2 Power On-Off switch
3 Fuses holder
4 Equipotential connector
5 BIPOLAR pedal connector
6 Prese USB sockets
7 MONOPOLAR pedal connector
8 Cylinder inlet connector 1 Argon*
9 Cylinder sensor connector 1 Argon*
10 Cylinder inlet connector 2 Argon*
11 Cylinder sensor connector 2 Argon*
12 External signal connector
** only models with Integrated Argon Module*

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 must verify that requested mains voltage corresponds to the voltage available from the electrical net.

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 an emergency stop switch, in the event of any fault.

TECHNICAL CHARACTERISTICS

Toll.	Description	SURTRON TOUCH	
		HP 300 10400.T802	HP 400 10400.T902
± 20%	Maximum output power CUT (W)	300W on 300Ω	400W on 300Ω
± 20%	Maximum output power ENHANCED (W)	200W on 300Ω	250W on 300Ω
± 20%	Maximum output power BLEND (W)	200W on 300Ω	250W on 300Ω
± 20%	Maximum output power DUO CUT (W)	150W on 300Ω	200W on 300Ω
± 20%	Maximum output power TUR CUT (W)	250W on 300Ω	300W on 300Ω
± 20%	Maximum output power FORCED COAG (W)	120W on 150Ω	150W on 150Ω
± 20%	Maximum output power SOFT COAG (W)	120W on 150Ω	150W on 150Ω
± 20%	Maximum output power FULGURATION (W)	80W on 500Ω	100W on 500Ω
± 20%	Maximum output power DUO COAG (W)	80W on 500Ω	100W on 500Ω
± 20%	Maximum output power SPRAY COAG (W)	100W on 1000Ω	120W on 1000Ω
± 20%	Maximum output power SPRAY COAG ARGON (W)	100W on 1000Ω	120W on 1000Ω
± 20%	Maximum output power BIPOLAR CUT (W)	150W on 100Ω	150W on 100Ω
± 20%	Maximum output power BIPOLAR MICRO CUT (W)	50W on 100Ω	50W on 100Ω
± 20%	Maximum output power BIPOLAR TUR (W)	300W on 300Ω	300W on 300Ω
± 20%	Maximum output power BIPOLAR COAG (W)	150W on 50Ω	150W on 50Ω
± 20%	Maximum output power BIPOLAR MICRO COAG (W)	50W on 50Ω	50W on 50Ω
± 20%	Maximum output power BIPOLAR TUR COAG (W)	250W on 50Ω	250W on 50Ω
± 20%	Maximum output power VESSEL SEALING (W)	250W on 50Ω	250W on 50Ω
± 10%	Working frequency MONOPOLAR	360 kHz	360 kHz
± 15%	Working frequency BIPOLAR	360 kHz	360 kHz
± 5%	Modulation factor ENHANCED (Hz)	1.5/1.5/2.5/2.5/3.5/3.5	1.5/1.5/2.5/2.5/3.5/3.5
± 5%	Modulation factor BLEND (Hz)	50	50
± 5%	Modulation factor FULGURATION (kHz)	30	30
± 5%	Modulation factor TUR CUT (kHz)	50	50
± 5%	Modulation factor FORCED COAG (kHz)	30	30
± 5%	Modulation factor DUO COAG (kHz)	30	30
± 5%	Modulation factor SPRAY COAG (kHz)	30	30
± 5%	Modulation factor SPRAY COAG ARGON (kHz)	30	30
± 5%	Modulation factor BIPOLAR TUR CUT (Hz)	200	200
± 0.2	Crest Factor CUT	1.6	1.6
± 0.3	Crest Factor ENHANCED CUT	3.3/3.2/3.1/3.0/2.8/2.6	3.3/3.2/3.1/3.0/2.8/2.6
± 0.3	Crest Factor BLEND	2.4/2.8/2.7/2.6/2.5/2.4	2.4/2.8/2.7/2.6/2.5/2.4
± 0.3	Crest Factor FULGURATION	3.8	3.8
± 0.3	Crest Factor DUO CUT	1.6	1.6
± 0.3	Crest Factor TUR CUT	2.4	2.4
± 0.3	Crest Factor FORCED COAG	3.4	3.4
± 0.3	Crest Factor SOFT COAG	1.6	1.6
± 0.3	Crest Factor COAG	3.8	3.8
± 0.3	Crest Factor SPRAY COAG	4.3	4.3
± 0.3	Crest Factor SPRAY COAG ARGON	4.3	4.3
± 0.2	Crest Factor BIPOLAR CUT / MICRO CUT	1.6	1.6
± 0.2	Crest Factor BIPOLAR COAG / MICRO COAG	1.6	1.6
± 0.2	Crest Factor BIPOLAR TUR CUT	1.6	1.6
± 0.2	Crest Factor BIPOLAR TUR COAG	1.6	1.6
± 0.2	Crest Factor VESSEL SEALING	1.6	1.6
± 15%	Maximum output voltage CUT (Vpp)	2800	2800
± 15%	Maximum output voltage ENHANCED CUT (Vpp)	2500	2500
± 15%	Maximum output voltage BLEND (Vpp)	2400	2400
± 15%	Maximum output voltage DUO CUT (Vpp)	1900	1900
± 15%	Maximum output voltage TUR CUT (Vpp)	2500	2500
± 15%	Maximum output voltage FORCED COAG (Vpp)	2800	2800
± 15%	Maximum output voltage SOFT COAG (Vpp)	1200	1200

Toll.	Description	SURTRON TOUCH	
		HP 300 10400.T802	**HP 400** 10400.T902
± 15%	Maximum output voltage FULGURATION (Vpp)	3500	3500
± 15%	Maximum output voltage DUO COAG (Vpp)	3500	3500
± 15%	Maximum output voltage SPRAY COAG (Vpp)	5000	5000
± 15%	Maximum output voltage SPRAY COAG ARGON (Vpp)	5000	5000
± 15%	Maximum output voltage BIPOLAR CUT (Vpp)	1100	1100
± 15%	Maximum output voltage BIPOLAR COAG (Vpp)	1100	1100
± 15%	Maximum output voltage BIPOLAR TUR CUT (Vpp)	1900	1900
± 15%	Maximum output voltage BIPOLAR TUR COAG (Vpp)	1000	1000
± 15%	Maximum output voltage VESSEL SEALING (Vpp)	1000	1000
–	Touch Screen (Size (inch) “)	● (9“)	● (9“)
–	Applicable split neutral electrode[1]	●	●
–	Bipolar with the possibility of AUTOSTART / AUTOSTOP	●	●
–	Automatic impedance control	●	●
–	Integrated Argon Module	● opt	● opt
–	Connectable Argon cylinders *	2	2
–	Minimum Level selectable	1	1
–	Work condition memorization	●	●
–	Step power unitary for powers from 0W to 50W	●	●
–	Step power 10 for powers higher than 50W	●	●
± 0.5	Size LxAxP mm	450x170x400	450x170x400
± 10	Weight (kg)	16	16
± 5%	supply voltage (Vac)	100-240	100-240
± 1%	Main frequency (Hz)	50-60	50-60
–	Fuses 5x20 type TIMED	2 x T10AL, 250V	2 x T10AL, 250V
± 10%	Electrical input power (VA)	1000	1000
± 10%	Electrical input current (240Vac) (A)	5	5
± 10%	Electrical input current (100Vac) (A)	10	10
–	Adjustable sound level	●	●
–	Power accuracy output warning	●	●
–	Last setting storing	●	●
–	Working (CUSTOM) condition storing	50	50
–	Self-check	●	●
–	Electric Class (EN60601-1)	I CF	I CF
–	MDD 93/42/EC Class	II b	II b
–	EN55011 (CISPR 11) Class (Class/Group)	2 / A	2 / A
–	Patient circuit	F	F
–	Duty Cycle (action / pause) in seconds	10 / 30	10 / 30
–	Monopolar output can be activated (pedal or handpiece buttons)	Foot/Finger	Foot/Finger
–	Bipolar output can be activated	Pedal or automatism	Pedal or automatism
–	Defibrillation-proof	●	●
–	Equipotential binding	●	●
–	ABS and metallic cabinet	●	●
–	Maximum Input Pressure Argon *	3,5 Bar	3,5 Bar
–	Pressure Input Argon *	3,0 Bar	3,0 Bar
–	Maximum output pressure Argon *	2.0 Bar	2.0 Bar
–	Argon exit flow *	0,5 – 10 LPM	0,5 – 10 LPM

●= PRESENT * only versions with integrated Argon module

[1] Patient to plate contact monitoring system

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 another 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 specialize 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 no abrasive cleanser may be used when necessary.

Cleaning and Sterilization of the Accessories Items

The best thing to do is to use only onetime 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. The error code generated and the description is shown on the display

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 proper type.
Alarm OC always active	Interruption or lack of contact on the neutral electrode circuit	Check the connection of the cable to the neutral electrode. Replace the cable of connection of the neutral electrode
The unit doesn't respond to the command of activation	Breakdown of the handpiece or of the pedal - Wrong connection of the handpiece or of the pedal - Alarm OVT activated	Replace the handpiece or the pedal. Verify the connection of the handpiece or of the pedal. Wait for the OVT warning signal getting out.
Error Code 001	Current delivery control activated during switching on	Disconnect the handpiece or the pedal and switch on the unit again.
Error Code 010	Error in the output power activation circuit	Call for Service
Error Code 022	Comunication Error	Call for Service

Repairs

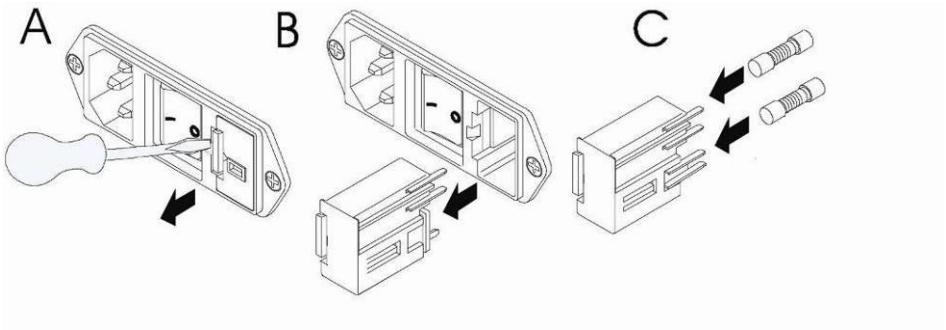
High frequency cables and electrode holder handle cannot be repaired. Always substitute a damaged part with a new one.

Fuses Substitution

Before substituting the fuse, disconnect the unit from the mains system
Only use fuse of the kind 5x20; 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 must 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.

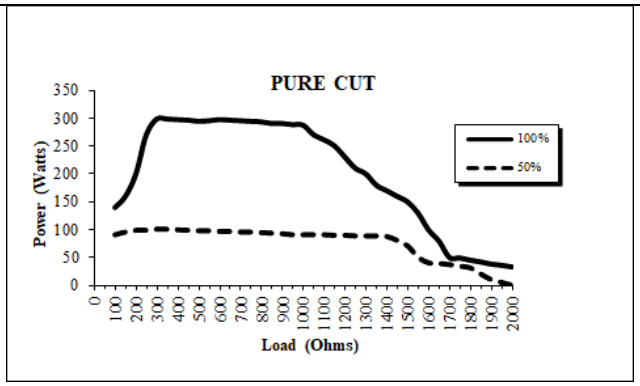
Function and Safety Check and Test

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

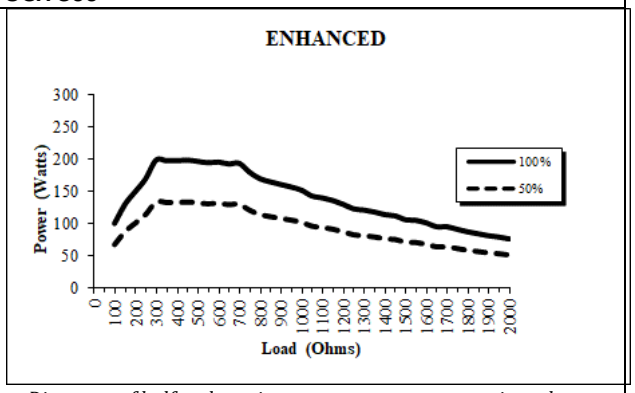
- Check of the connectors and mains supply cord conditions.
- Visual check of the mechanical protections.
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization and disinfection.
- Check of the Equipment's Data on the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

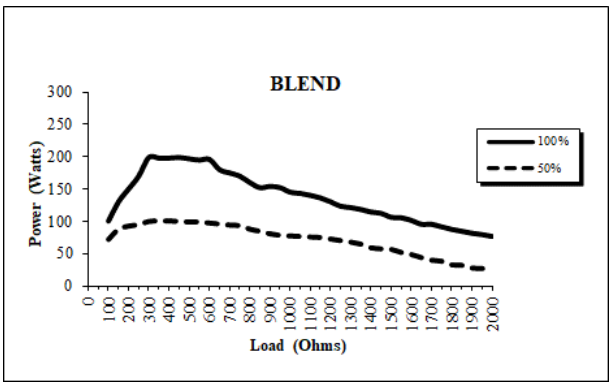
SURTRON® TOUCH 300



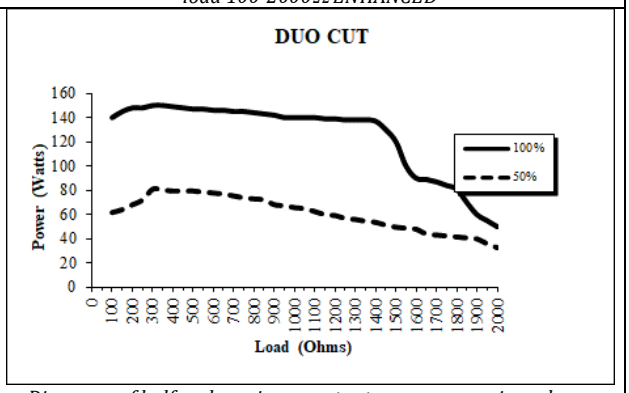
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT



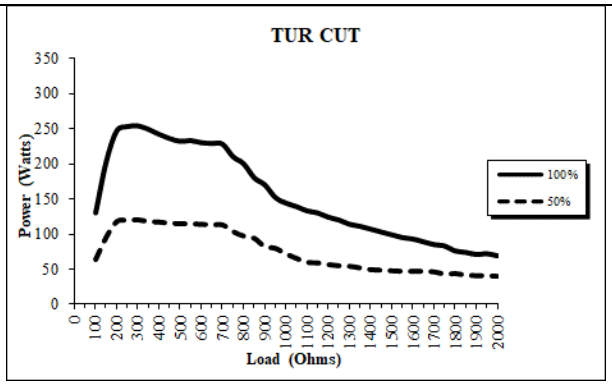
Diagrams of half and maximum output power versus impedance load 100-2000Ω ENHANCED



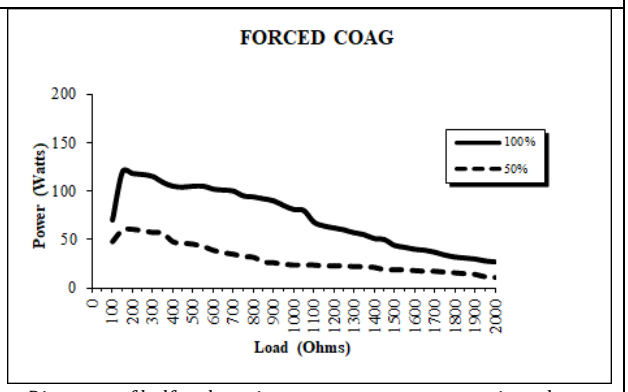
Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND



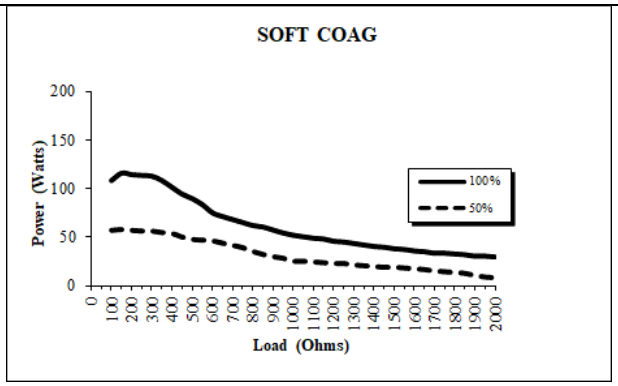
Diagrams of half and maximum output power versus impedance load 100-2000Ω DUO



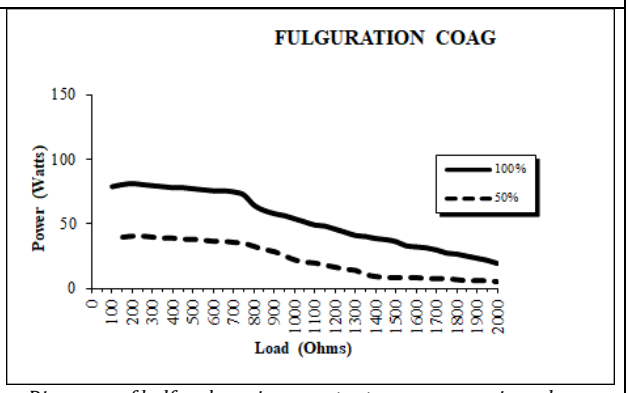
Diagrams of half and maximum output power versus impedance load 100-2000Ω TUR CUT



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

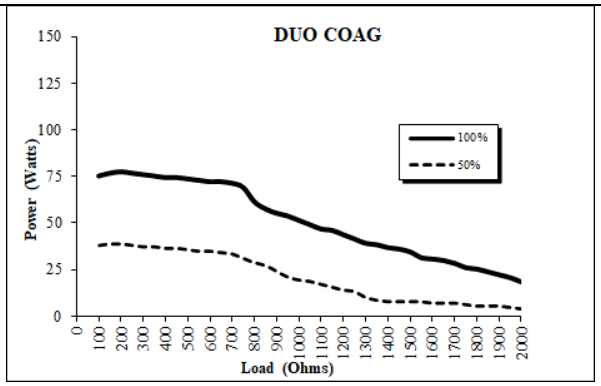


Diagrams of half and maximum output power versus impedance load 100-2000Ω SOFT COAG

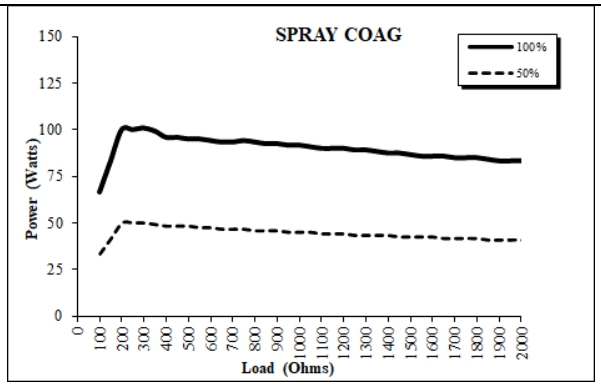


Diagrams of half and maximum output power versus impedance load 10-2000Ω FULGURATION

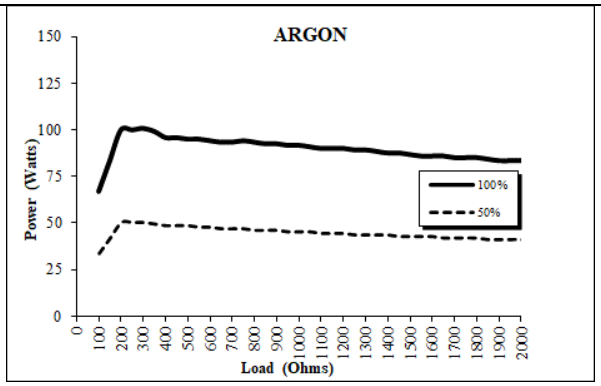
SURTRON® TOUCH 300



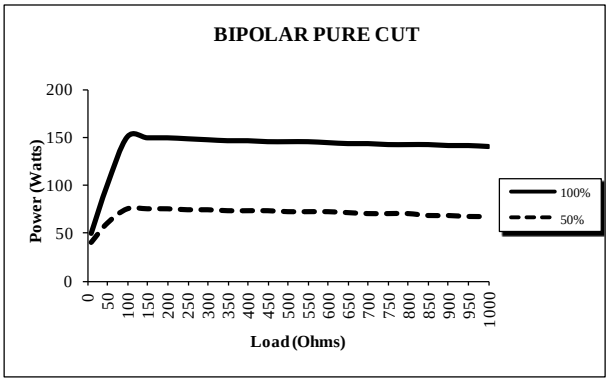
Diagrams of half and maximum output power versus impedance load 10-2000Ω DUO COAG



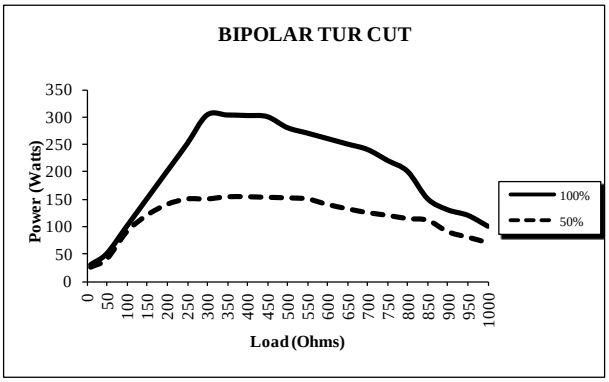
Diagrams of half and maximum output power versus impedance load 100-2000Ω SPRAY COAG



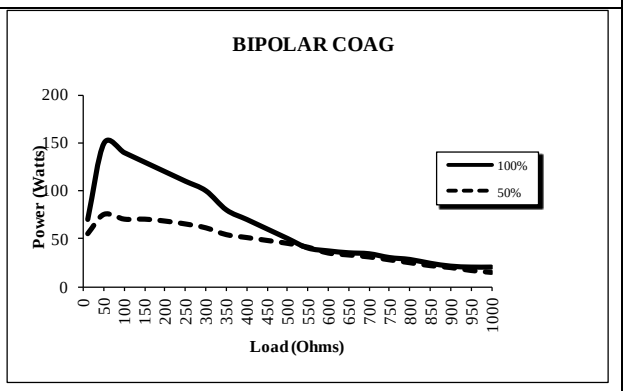
Diagrams of half and maximum output power versus impedance load 100-2000Ω ARGON



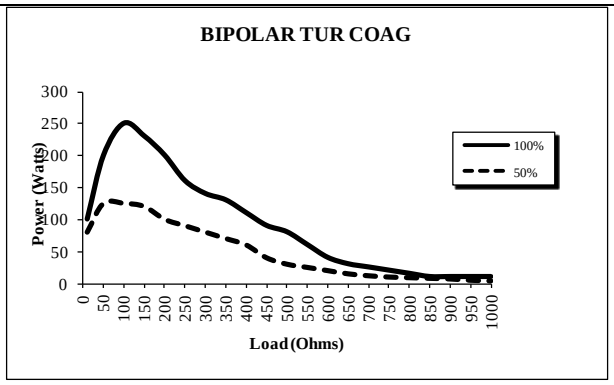
Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR CUT



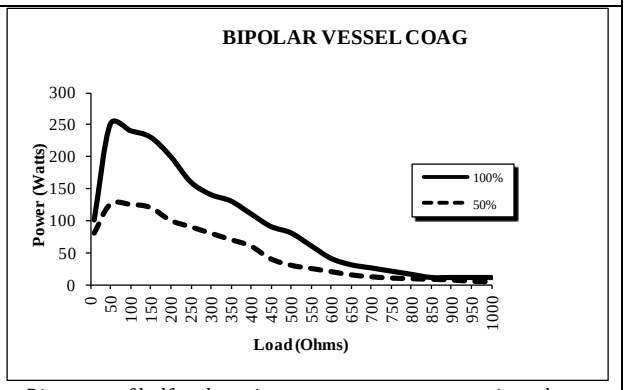
Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR TURCUT



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

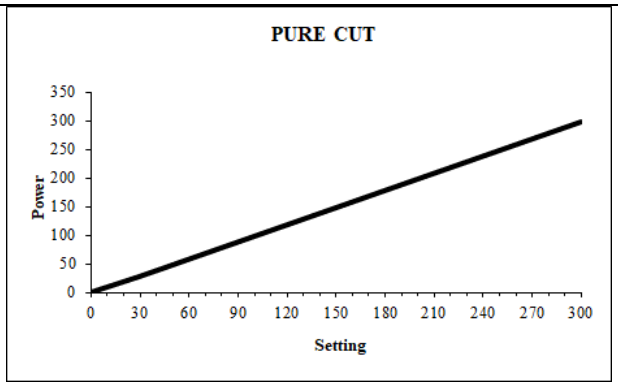


Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR TUR COAG

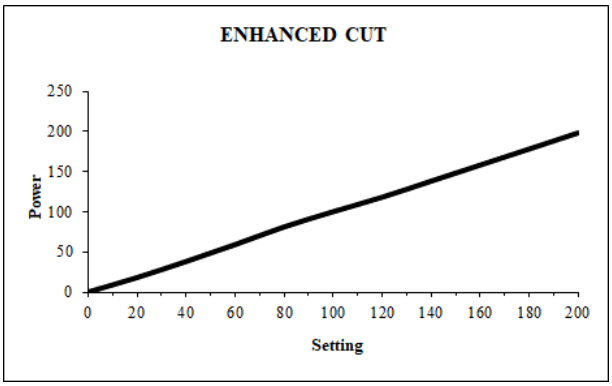


Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR VESSEL

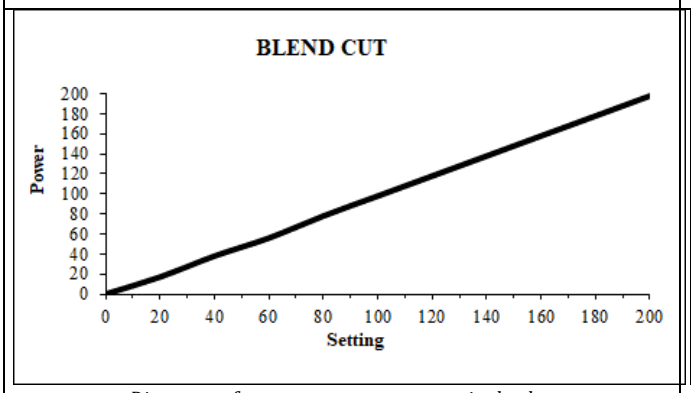
SURTRON® TOUCH 300



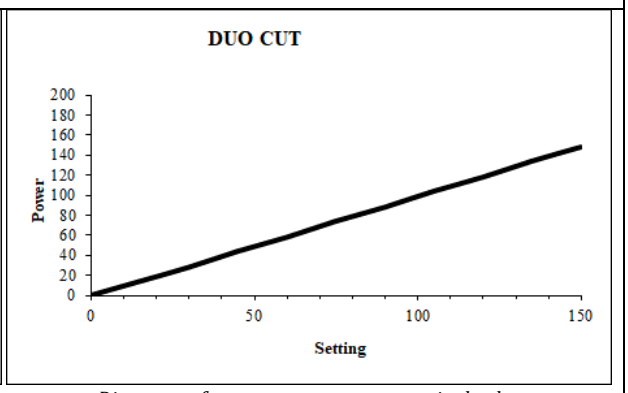
Diagrams of output power versus nominal value
CUT100%



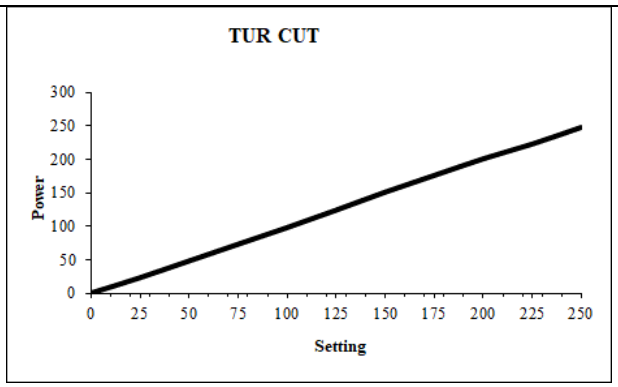
Diagrams of output power versus nominal value
ENHANCED



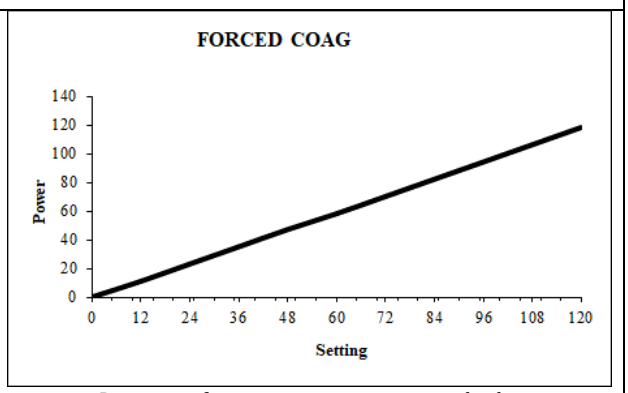
Diagrams of output power versus nominal value
BLEND



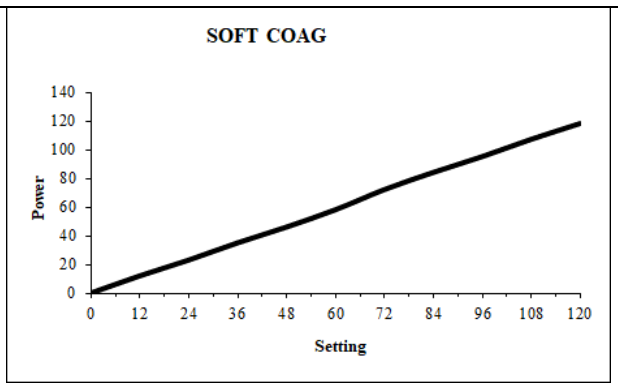
Diagrams of output power versus nominal value
DUO CUT



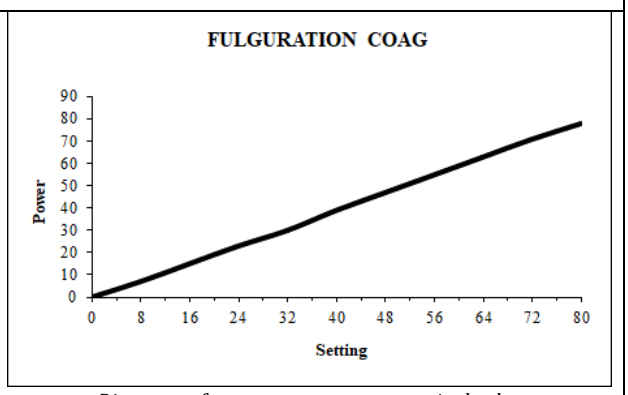
Diagrams of output power versus nominal value
TUR CUT



Diagrams of output power versus nominal value
FORCED COAG



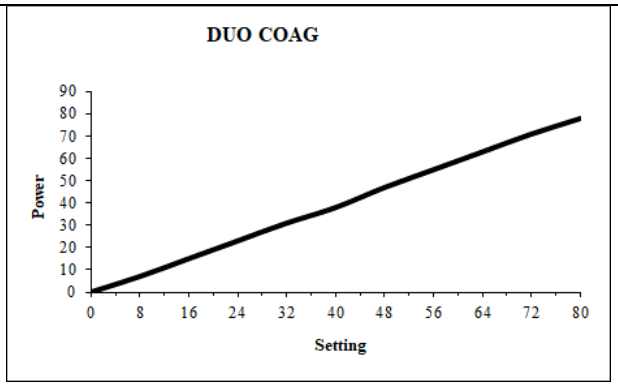
Diagrams of output power versus nominal value
SOFT COAG



Diagrams of output power versus nominal value
FULGURATION

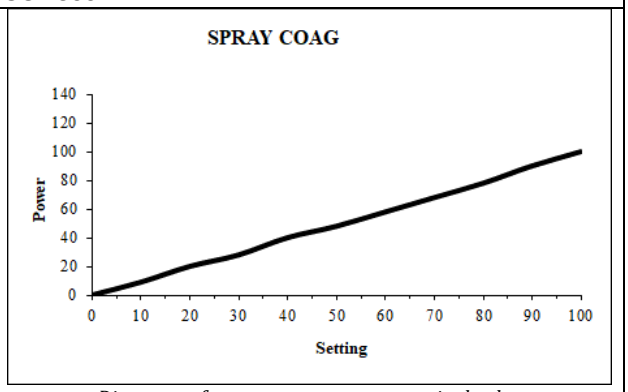
SURTRON® TOUCH 300

DUO COAG



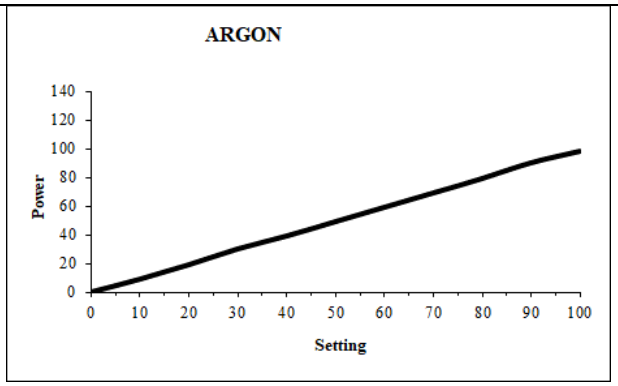
Diagrams of output power versus nominal value
DUO COAG

SPRAY COAG



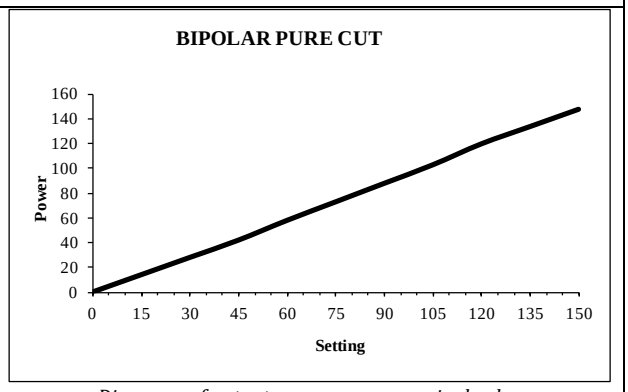
Diagrams of output power versus nominal value
SPRAY

ARGON



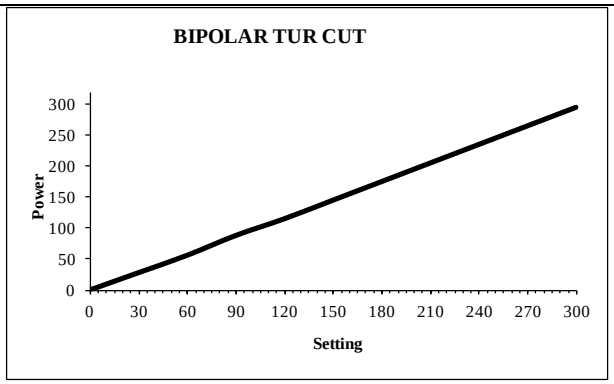
Diagrams of output power versus nominal value
ARGON

BIPOLAR PURE CUT



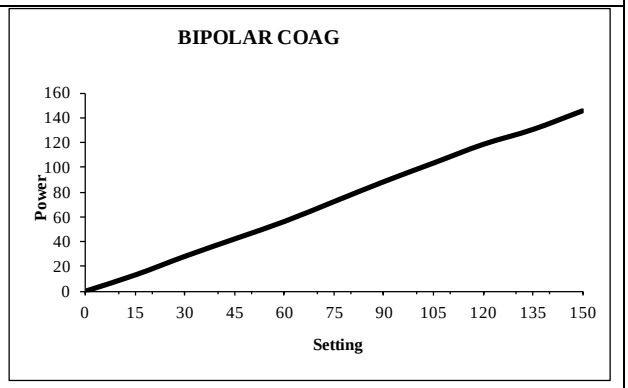
Diagrams of output power versus nominal value
BIPOLAR CUT

BIPOLAR TUR CUT



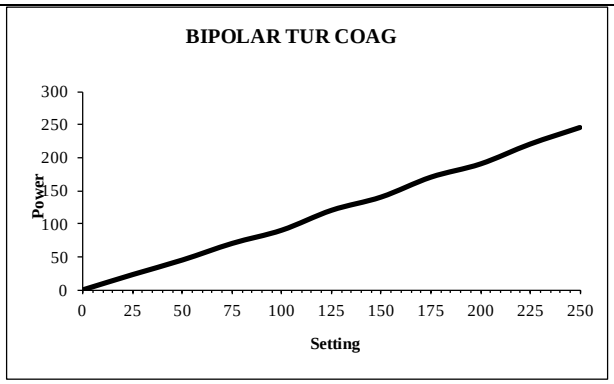
Diagrams of output power versus nominal value
BIPOLAR TURCUT

BIPOLAR COAG



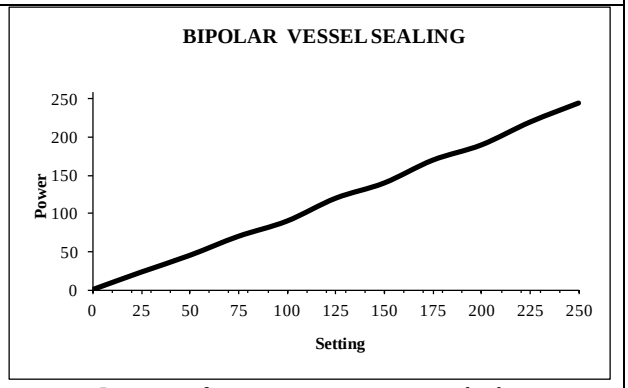
Diagrams of output power versus nominal value
BIPOLAR COAG

BIPOLAR TUR COAG



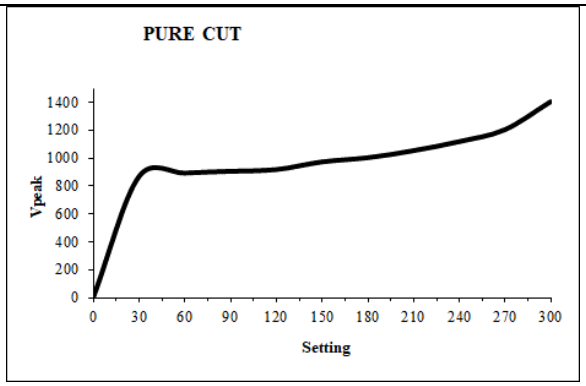
Diagrams of output power versus nominal value
BIPOLAR TUR COAG

BIPOLAR VESSEL SEALING

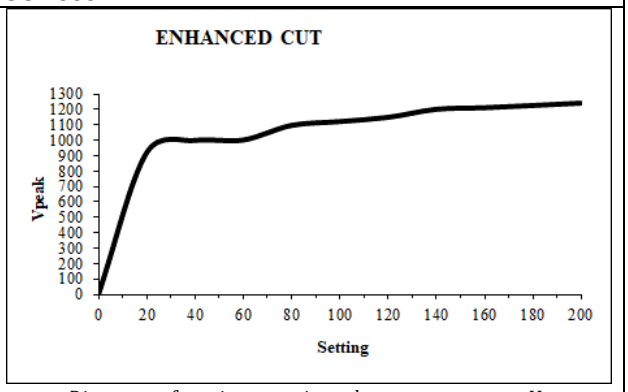


Diagrams of output power versus nominal value
BIPOLAR VESSEL

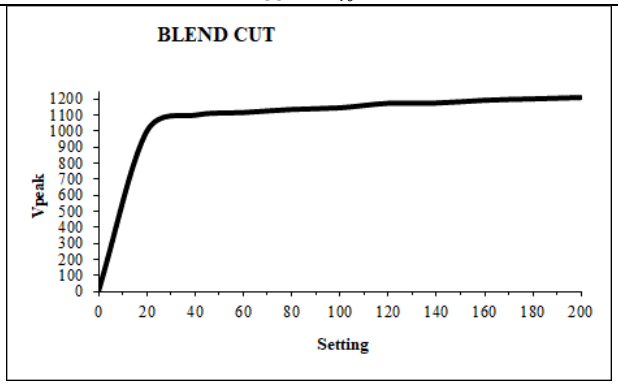
SURTRON® TOUCH 300



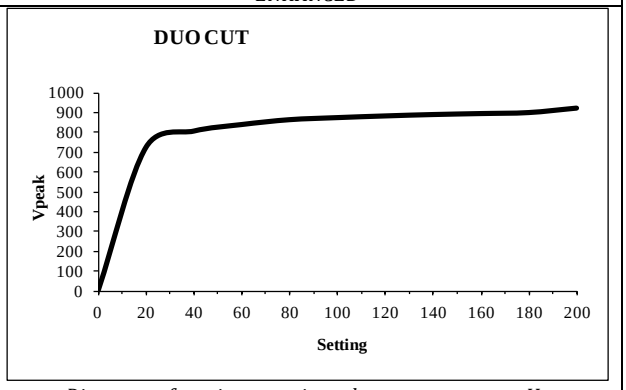
Diagrams of maximum mains voltage output versus Vp
CUT 100%



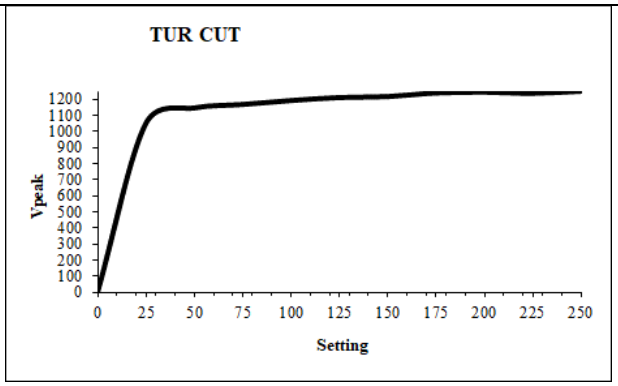
Diagrams of maximum mains voltage output versus Vp
ENHANCED



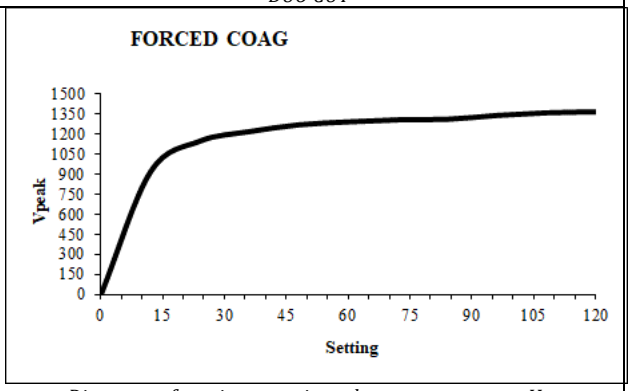
Diagrams of maximum mains voltage output versus Vp
BLEND



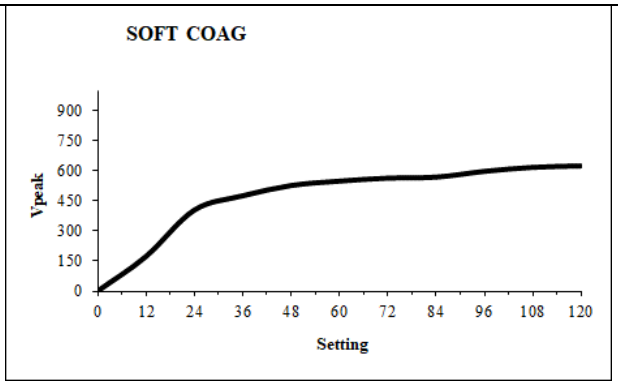
Diagrams of maximum mains voltage output versus Vp
DUO CUT



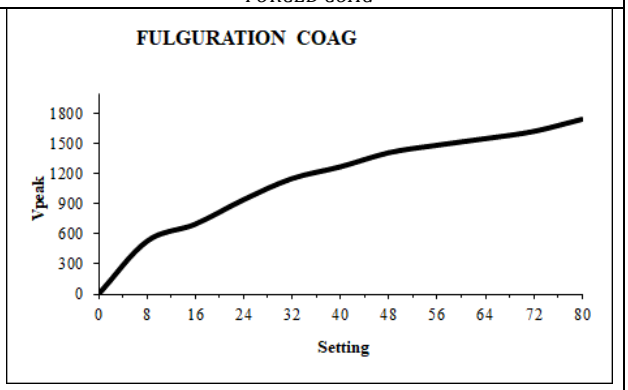
Diagrams of maximum mains voltage output versus Vp
TUR CUT



Diagrams of maximum mains voltage output versus Vp
FORCED COAG

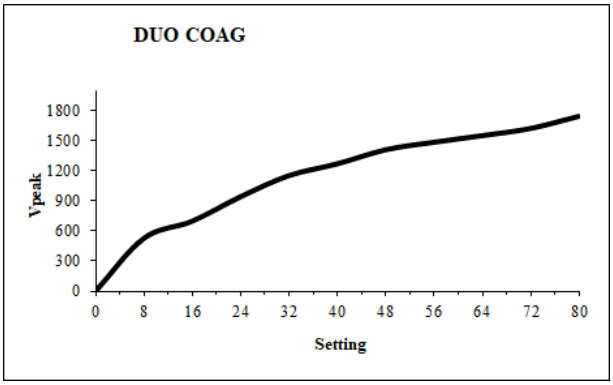


Diagrams of maximum mains voltage output versus Vp
SOFT COAG

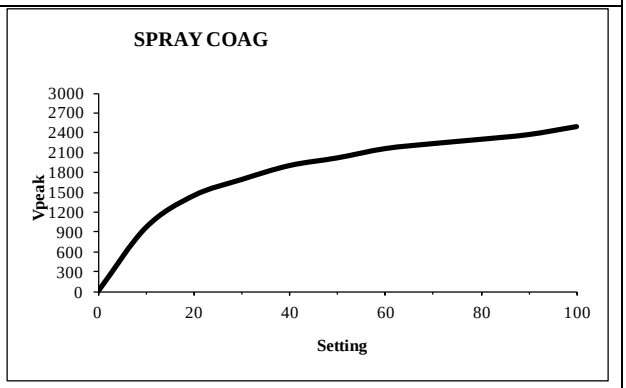


Diagrams of maximum mains voltage output versus Vp
FULGURATION

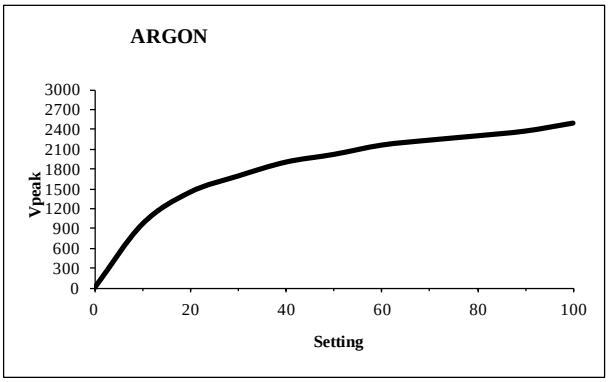
SURTRON® TOUCH 300



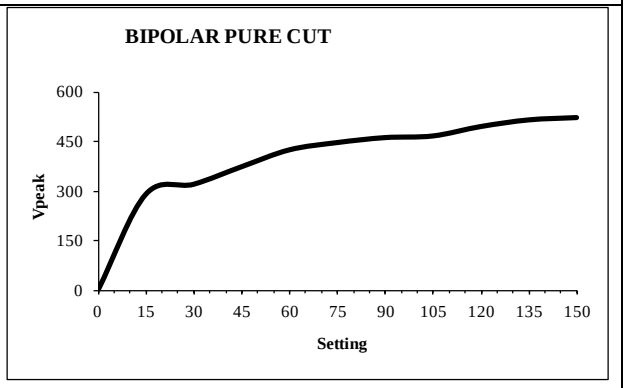
Diagrams of maximum mains voltage output versus Vp
DUO COAG



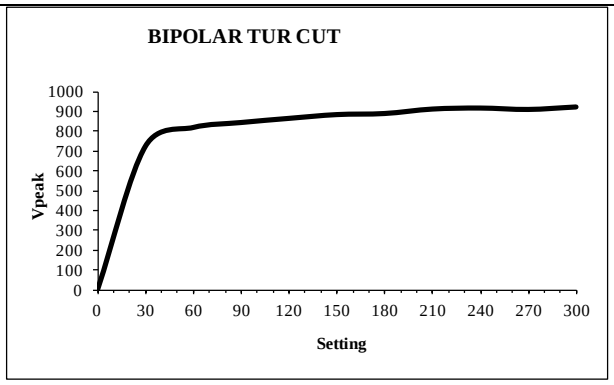
Diagrams of maximum mains voltage output versus Vp
SPRAY



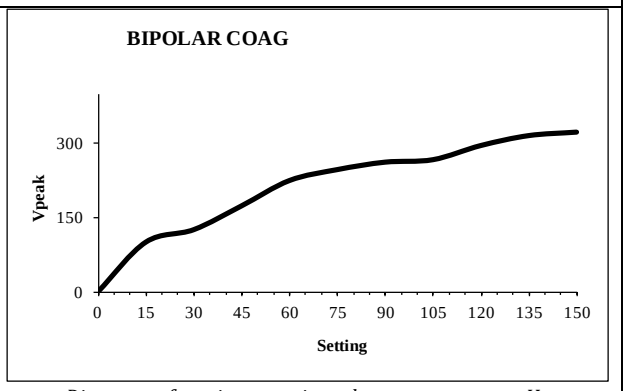
Diagrams of maximum mains voltage output versus Vp
ARGON



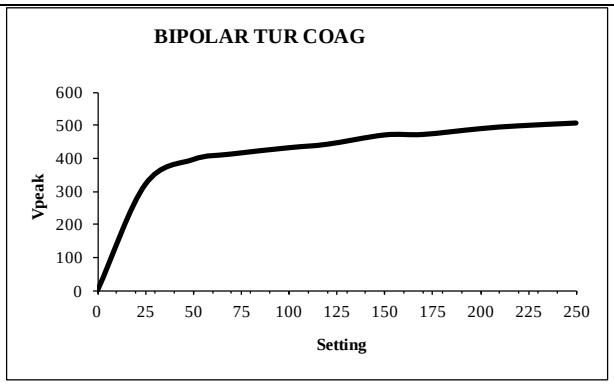
Diagrams of maximum mains voltage output versus Vp
BIPOLAR CUT



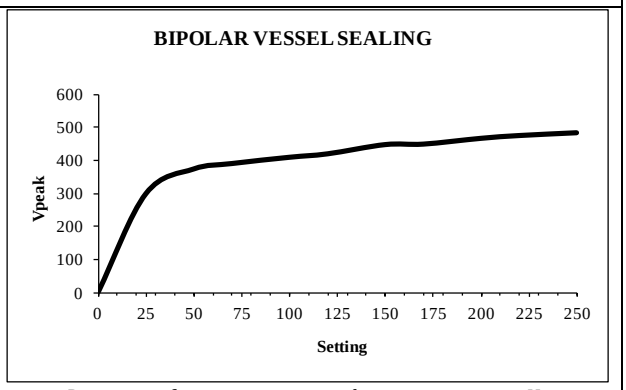
Diagrams of maximum mains voltage output versus Vp
BIPOLAR TUR



Diagrams of maximum mains voltage output versus Vp
BIPOLAR COAG

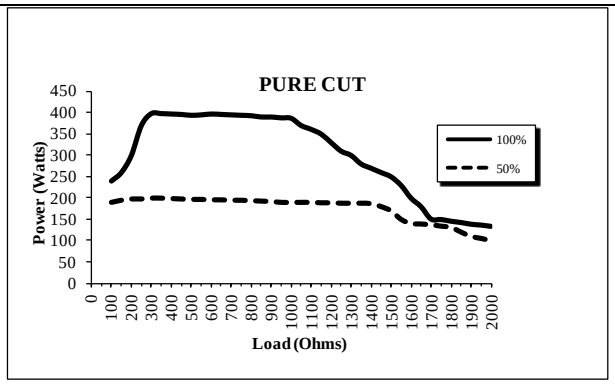


Diagrams of maximum mains voltage output versus Vp
BIPOLAR TUR COAG

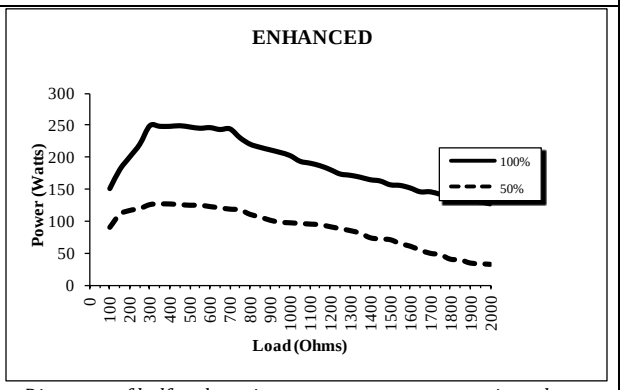


Diagrams of maximum mains voltage output versus Vp
BIPOLAR VESSEL

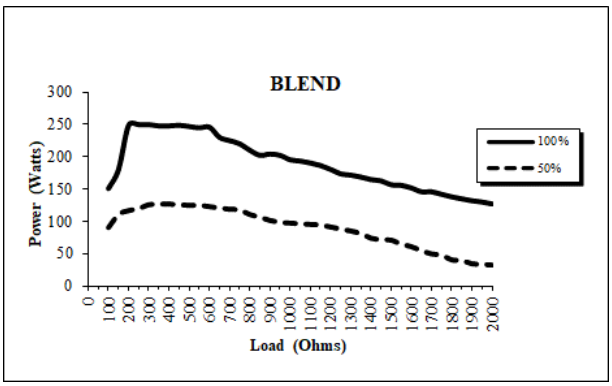
SURTRON® TOUCH 400



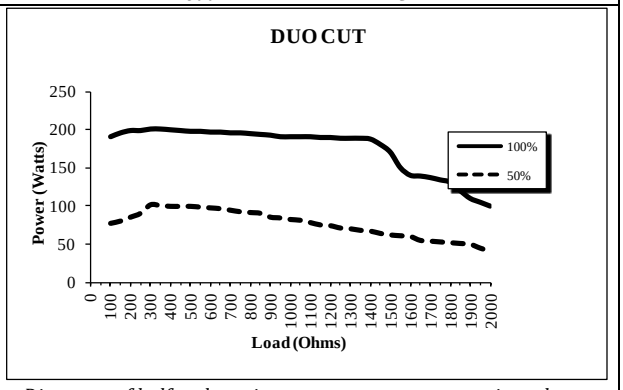
Diagrams of half and maximum output power versus impedance load 100-2000Ω CUT



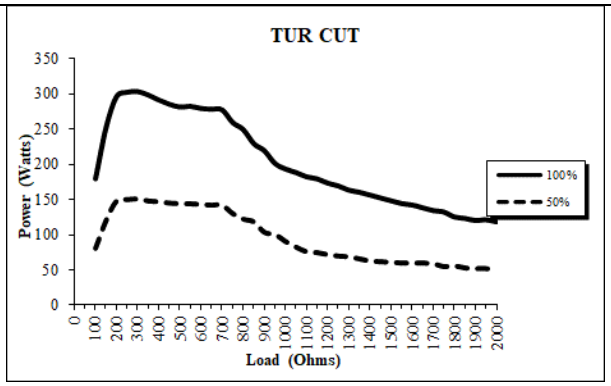
Diagrams of half and maximum output power versus impedance load 100-2000Ω ENHANCED



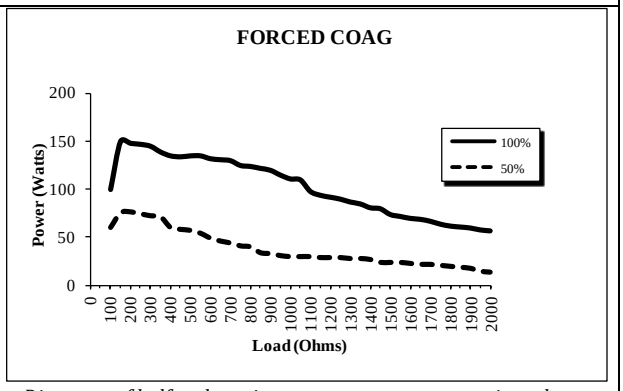
Diagrams of half and maximum output power versus impedance load 100-2000Ω BLEND



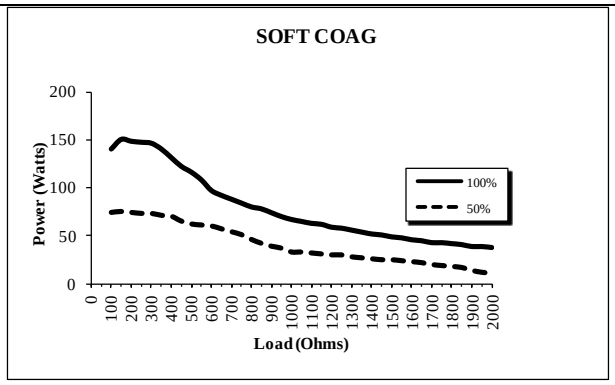
Diagrams of half and maximum output power versus impedance load 100-2000Ω DUO



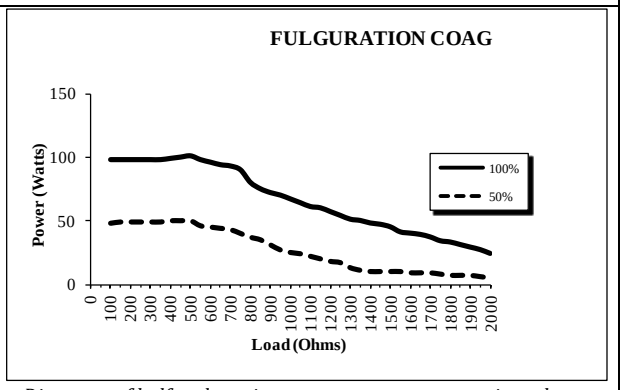
Diagrams of half and maximum output power versus impedance load 100-2000Ω TUR CUT



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

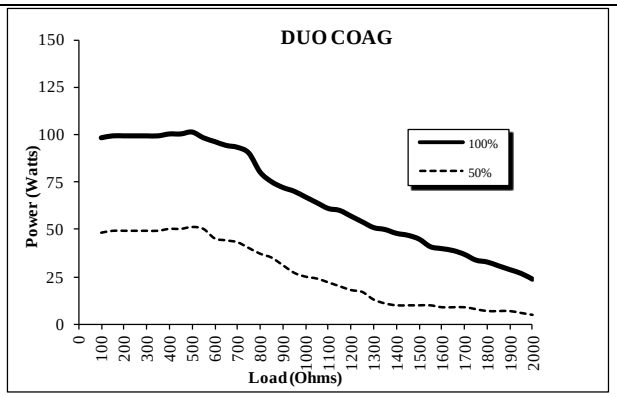


Diagrams of half and maximum output power versus impedance load 100-2000Ω SOFT COAG

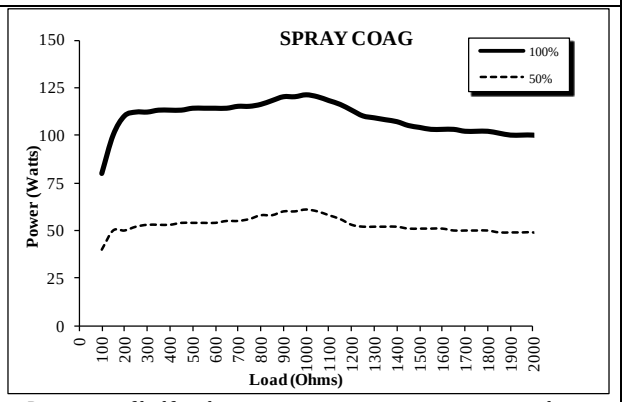


Diagrams of half and maximum output power versus impedance load 10-2000Ω FULGURATION

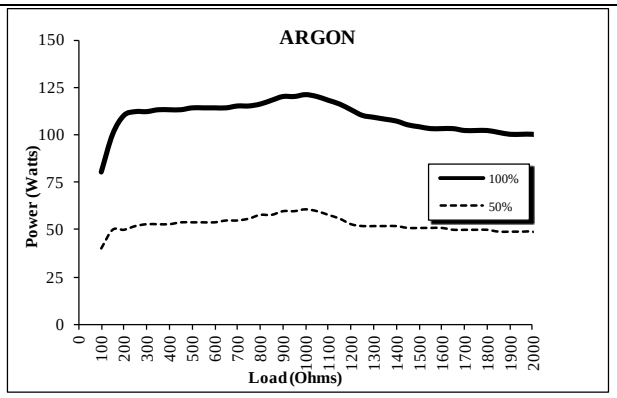
SURTRON® TOUCH 400



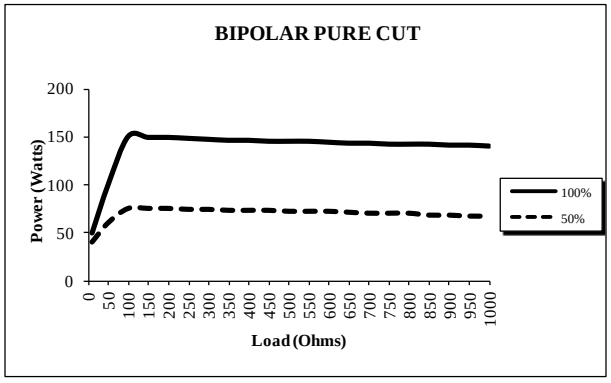
Diagrams of half and maximum output power versus impedance load 10-2000Ω DUO COAG



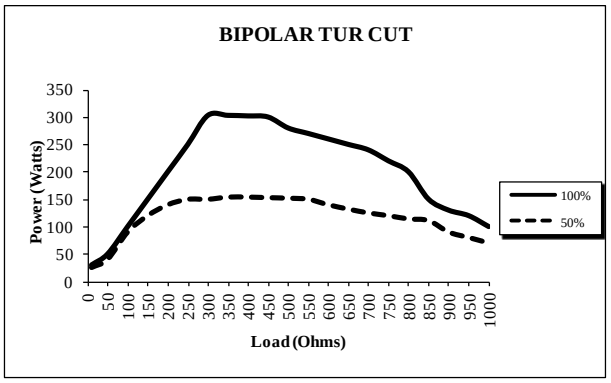
Diagrams of half and maximum output power versus impedance load 100-2000Ω SPRAY COAG



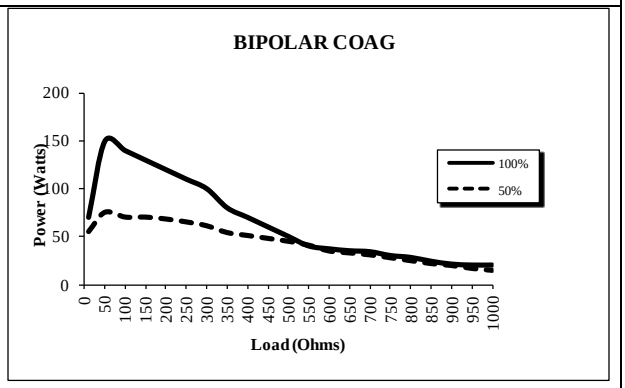
Diagrams of half and maximum output power versus impedance load 100-2000Ω ARGON



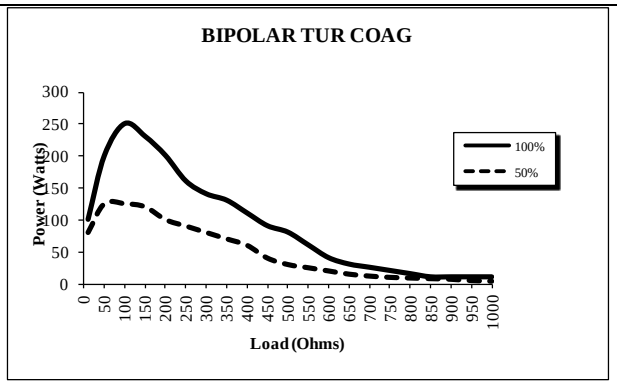
Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR CUT



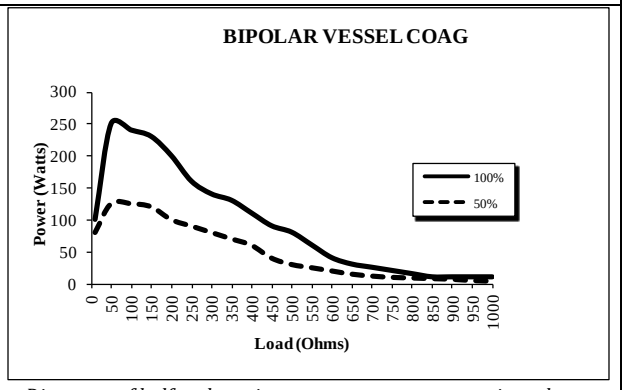
Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR TURCUT



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

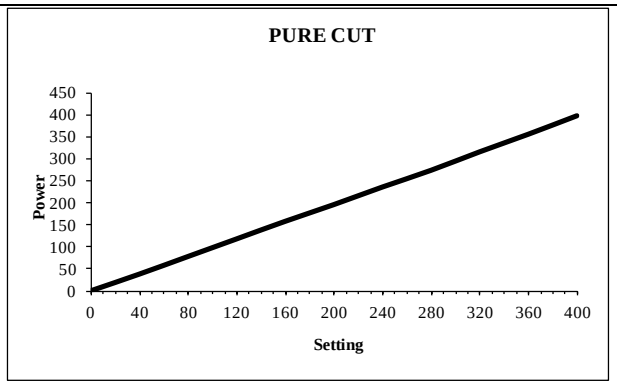


Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR TUR COAG

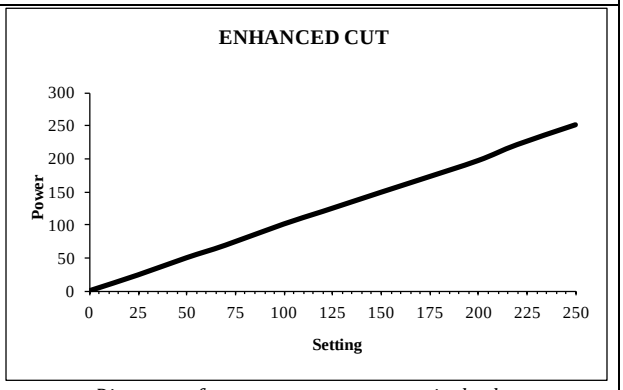


Diagrams of half and maximum output power versus impedance load 10-1000Ω BIPOLAR VESSEL

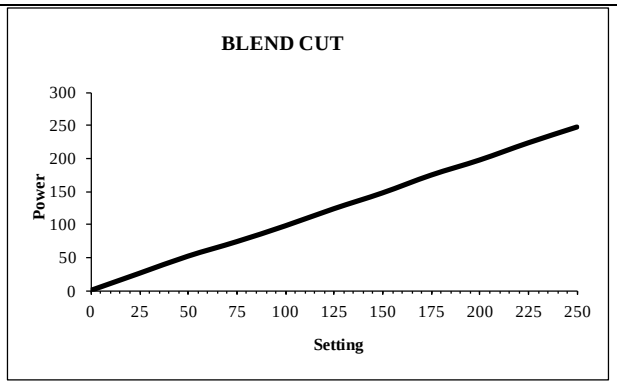
SURTRON® TOUCH 400



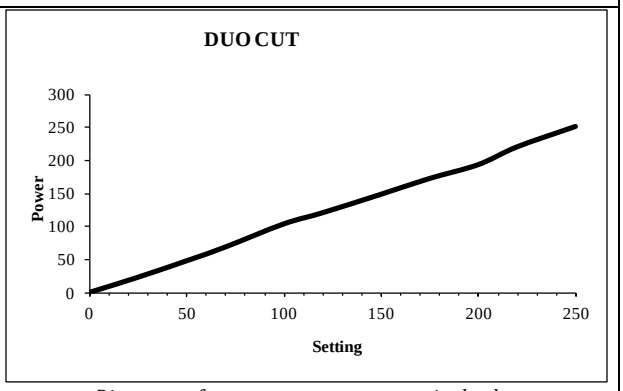
Diagrams of output power versus nominal value
CUT100%



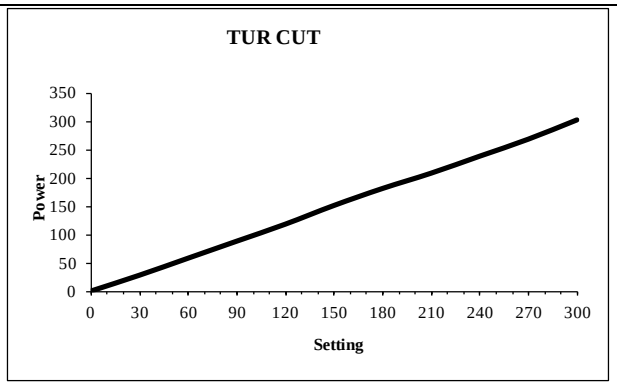
Diagrams of output power versus nominal value
ENHANCED



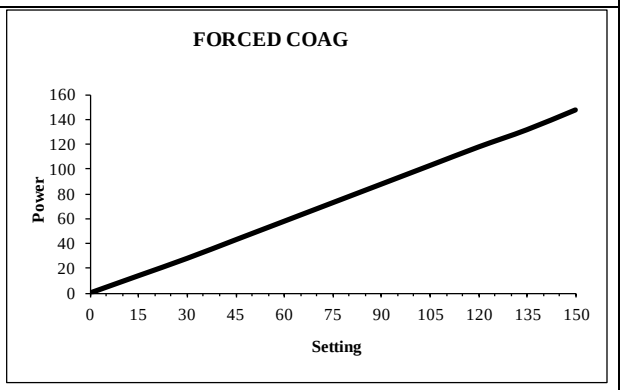
Diagrams of output power versus nominal value
BLEND



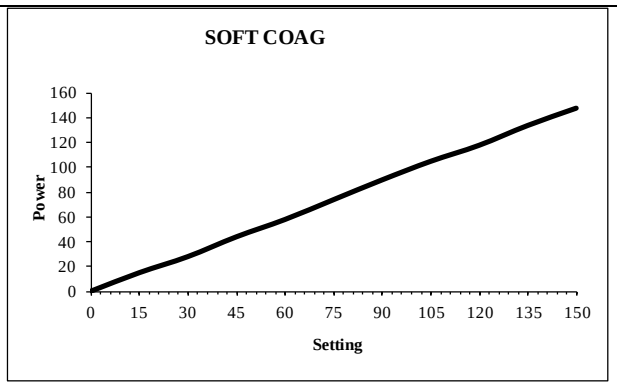
Diagrams of output power versus nominal value
DUO CUT



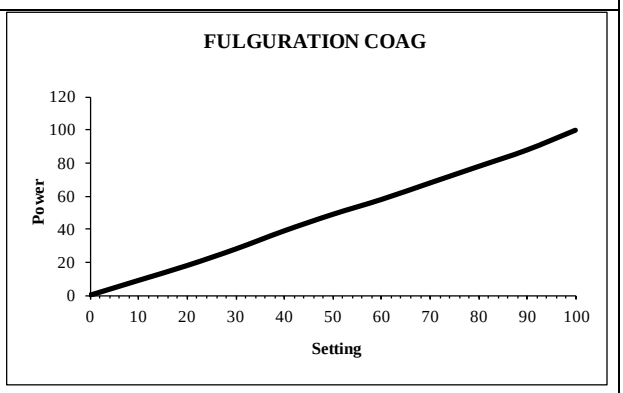
Diagrams of output power versus nominal value
TUR CUT



Diagrams of output power versus nominal value
FORCED COAG



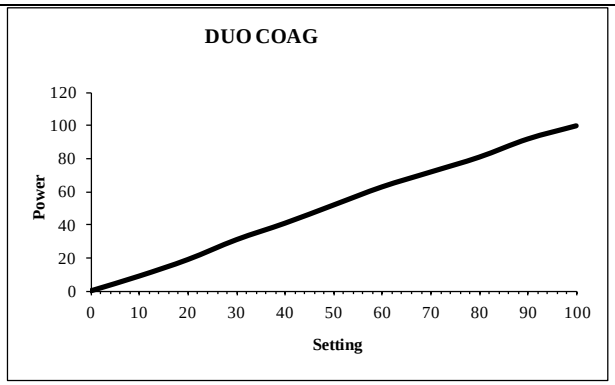
Diagrams of output power versus nominal value
SOFT COAG



Diagrams of output power versus nominal value
FULGURATION

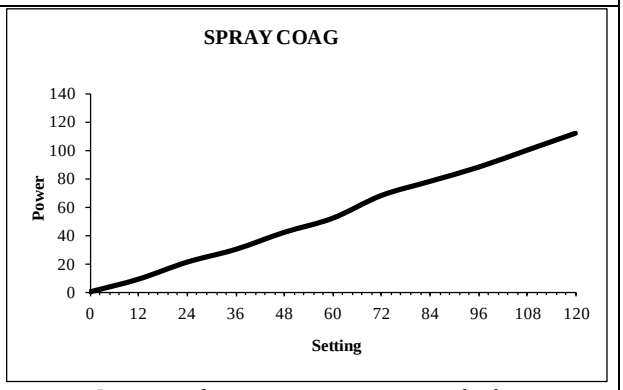
SURTRON® TOUCH 400

DUO COAG



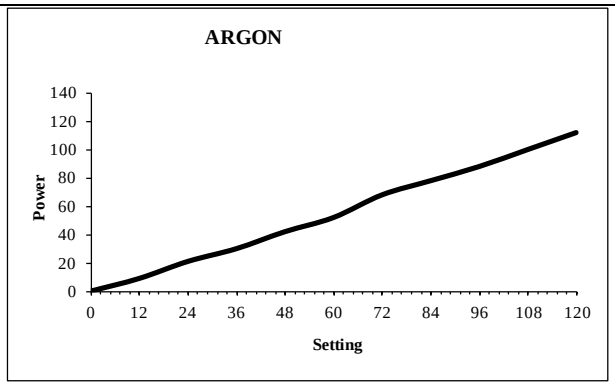
Diagrams of output power versus nominal value
DUO COAG

SPRAY COAG



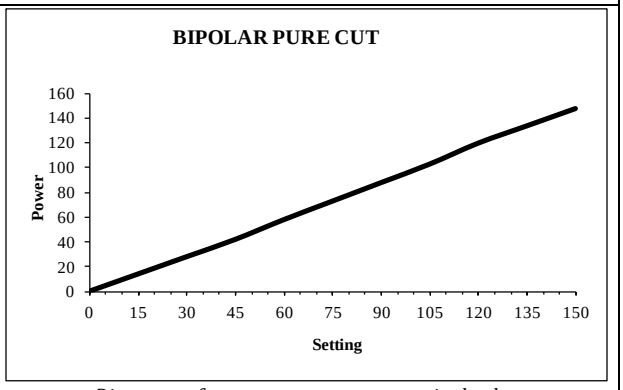
Diagrams of output power versus nominal value
SPRAY

ARGON



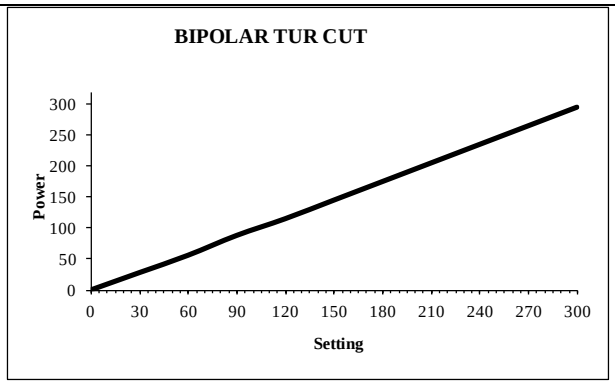
Diagrams of output power versus nominal value
ARGON

BIPOLAR PURE CUT



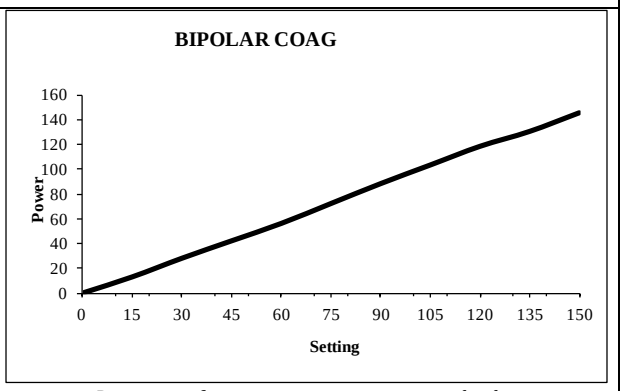
Diagrams of output power versus nominal value
BIPOLAR CUT

BIPOLAR TUR CUT



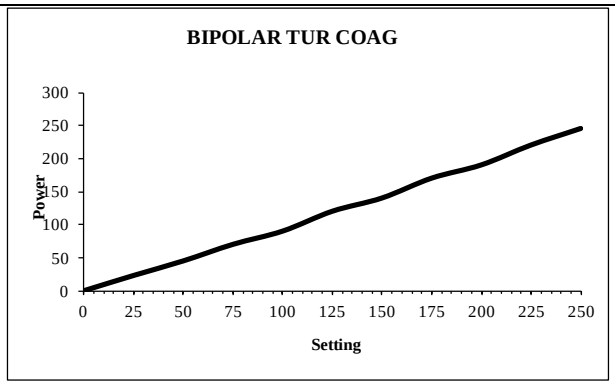
Diagrams of output power versus nominal value
BIPOLAR TURCUT

BIPOLAR COAG



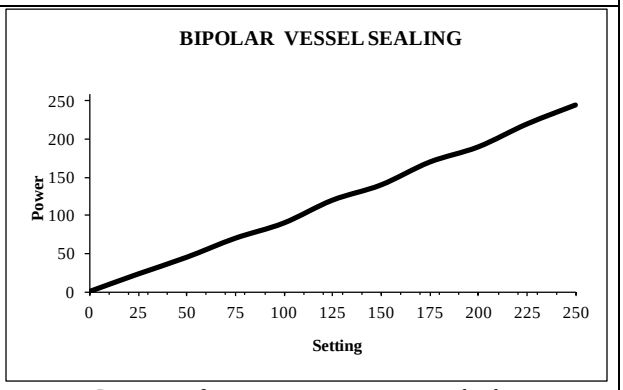
Diagrams of output power versus nominal value
BIPOLAR COAG

BIPOLAR TUR COAG



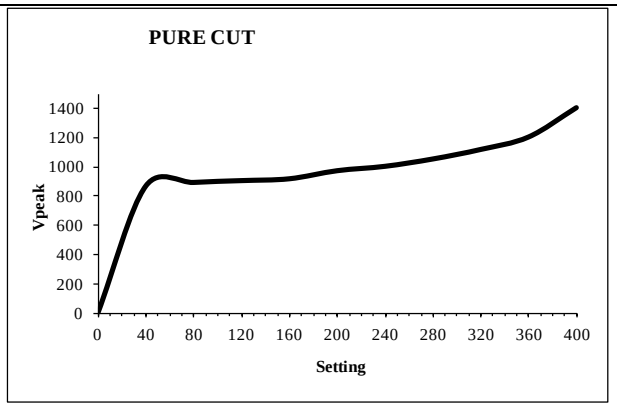
Diagrams of output power versus nominal value
BIPOLAR TUR COAG

BIPOLAR VESSEL SEALING

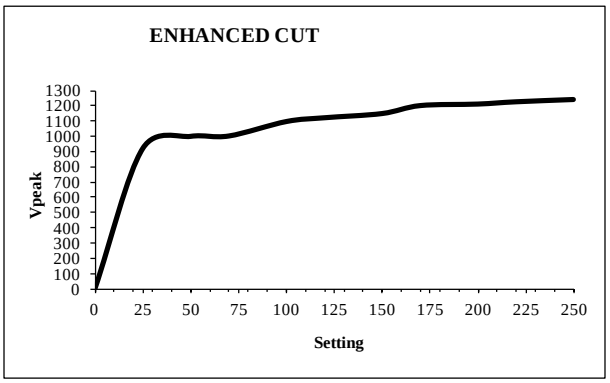


Diagrams of output power versus nominal value
BIPOLAR VESSEL

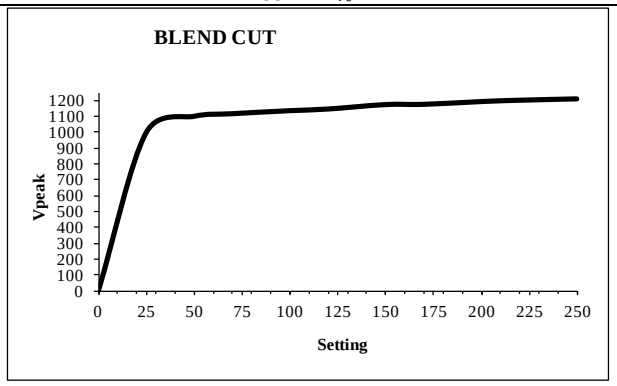
SURTRON® TOUCH 400



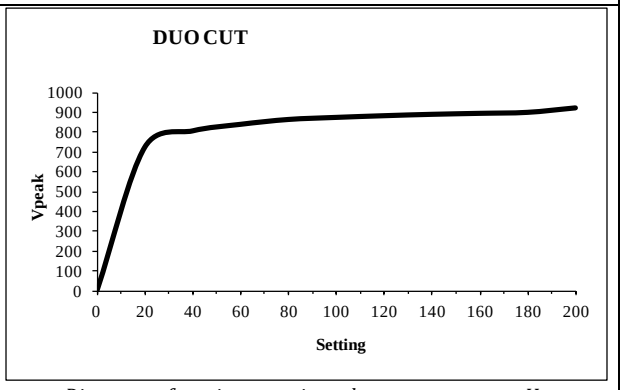
Diagrams of maximum mains voltage output versus Vp
CUT 100%



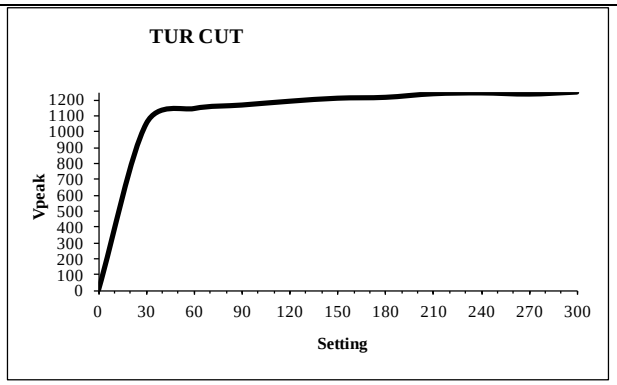
Diagrams of maximum mains voltage output versus Vp
ENHANCED



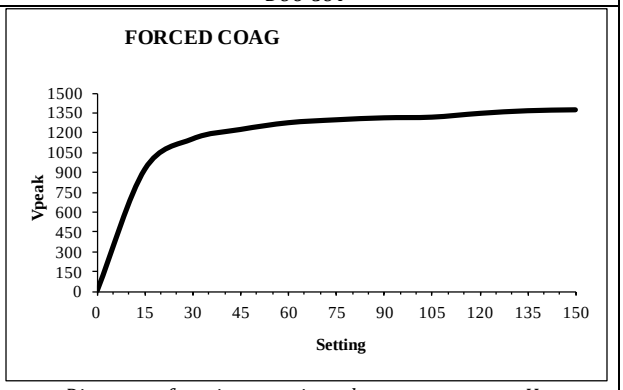
Diagrams of maximum mains voltage output versus Vp
BLEND



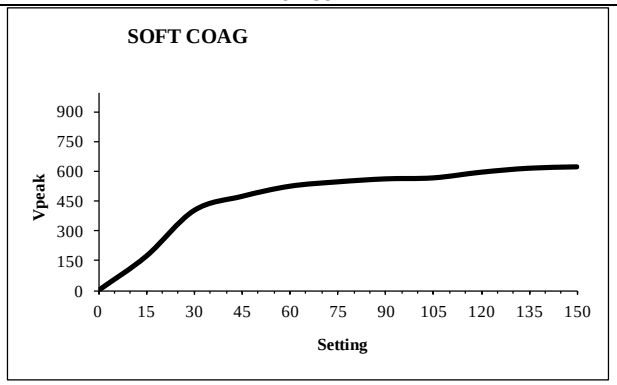
Diagrams of maximum mains voltage output versus Vp
DUO CUT



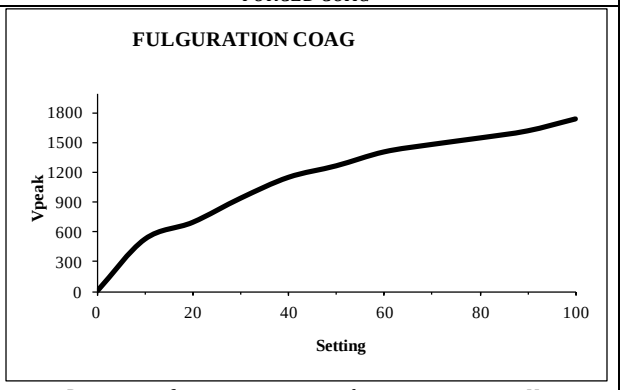
Diagrams of maximum mains voltage output versus Vp
TUR CUT



Diagrams of maximum mains voltage output versus Vp
FORCED COAG

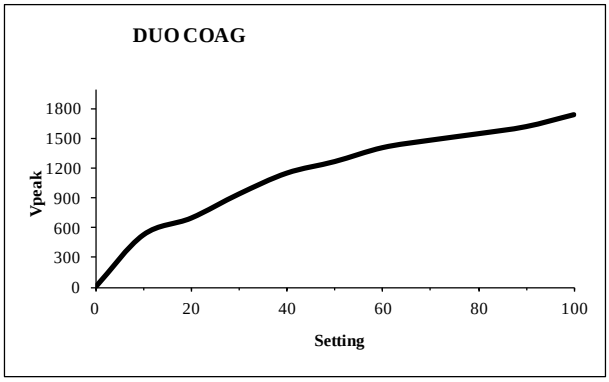


Diagrams of maximum mains voltage output versus Vp
SOFT COAG

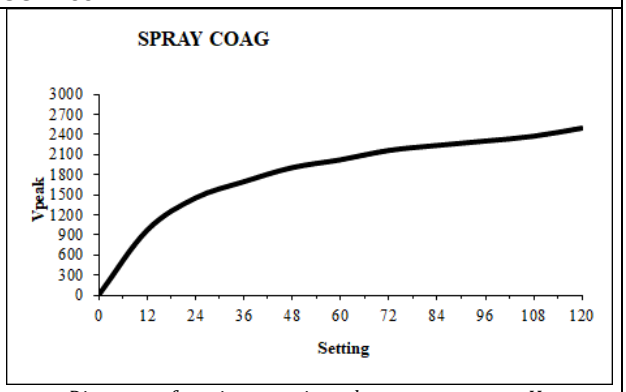


Diagrams of maximum mains voltage output versus Vp
FULGURATION

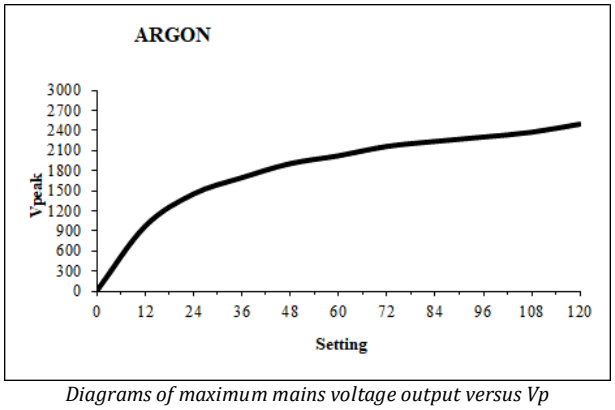
SURTRON® TOUCH 400



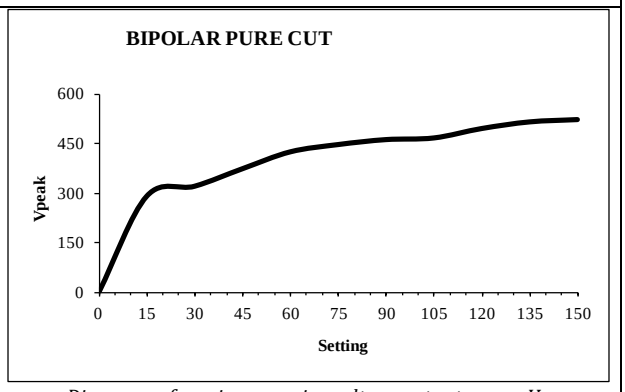
Diagrams of maximum mains voltage output versus Vp
DUO COAG



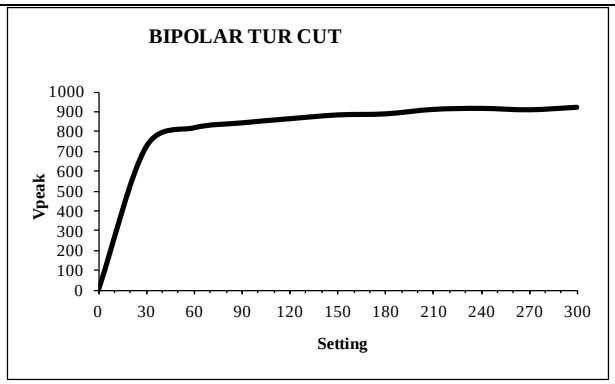
Diagrams of maximum mains voltage output versus Vp
SPRAY



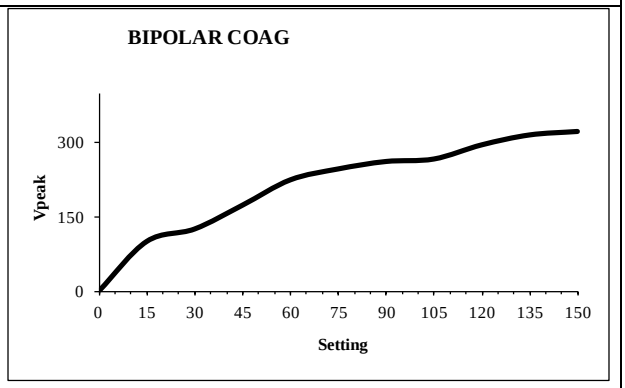
Diagrams of maximum mains voltage output versus Vp
ARGON



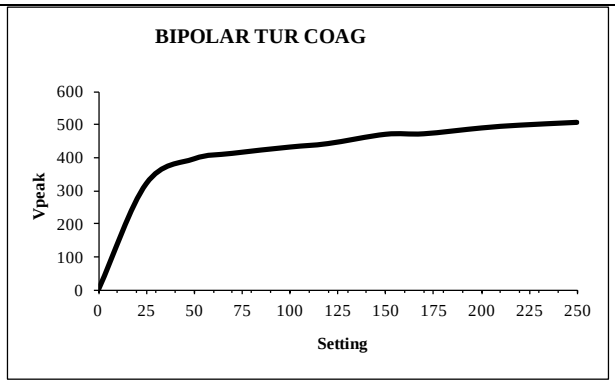
Diagrams of maximum mains voltage output versus Vp
BIPOLAR CUT



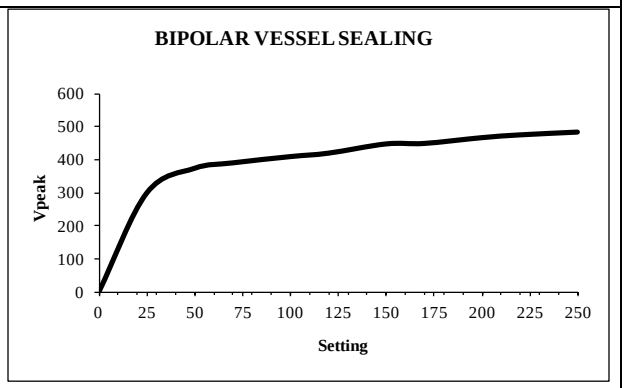
Diagrams of maximum mains voltage output versus Vp
BIPOLAR TUR



Diagrams of maximum mains voltage output versus Vp
BIPOLAR COAG



Diagrams of maximum mains voltage output versus Vp
BIPOLAR TUR COAG



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)	
	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.

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ELECTROSURGERY

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SURTRON TOUCH *HP*

ELECTROSURGERY

ONE TOUCH,
MANY SURGERIES.

ELECTROSURGERY

100% *MADE IN ITALY*

WE FOLLOW THE PRODUCTION PROCESS, FROM INITIAL CONCEPT TO THE FINAL PRODUCT, ENTERELY IN OUR FACTORY.

LED SpA is a company that specialises in design and manufacture of medical equipments.

LED brand achieved wide prestige in the electrosurgery field worldwide. The company grew by using innovative manufacturing methods and by investing in reasearch and development of new technologies.

The design and the production effected inside its own factory guarantee an elevated quality and safety of the products.

LED SpA's mission is to continuously research and develop new electrosurgical products, in the aim to improve the quality of the surgeons work.

LED® ELECTROSURGERY

PERFORMANCE
USABILITY
DESIGN
RELIABILITY

SURTRON® TOUCH *HP, the new generation of the electrosurgery.*

Performance, usability, design and reliability: these are the strengths of the new **SURTRON TOUCH** *HP*. A radiofrequency generator suitable for microsurgery and precise surgery in monopolar and bipolar modality.

The initial setup of **SURTRON TOUCH** *HP* and the adjustment of settings during a surgery are easily selectable through the large touchscreen.

The simplicity of the **SURTRON TOUCH** *HP* allows you to use it without any learning time, resulting in time savings.

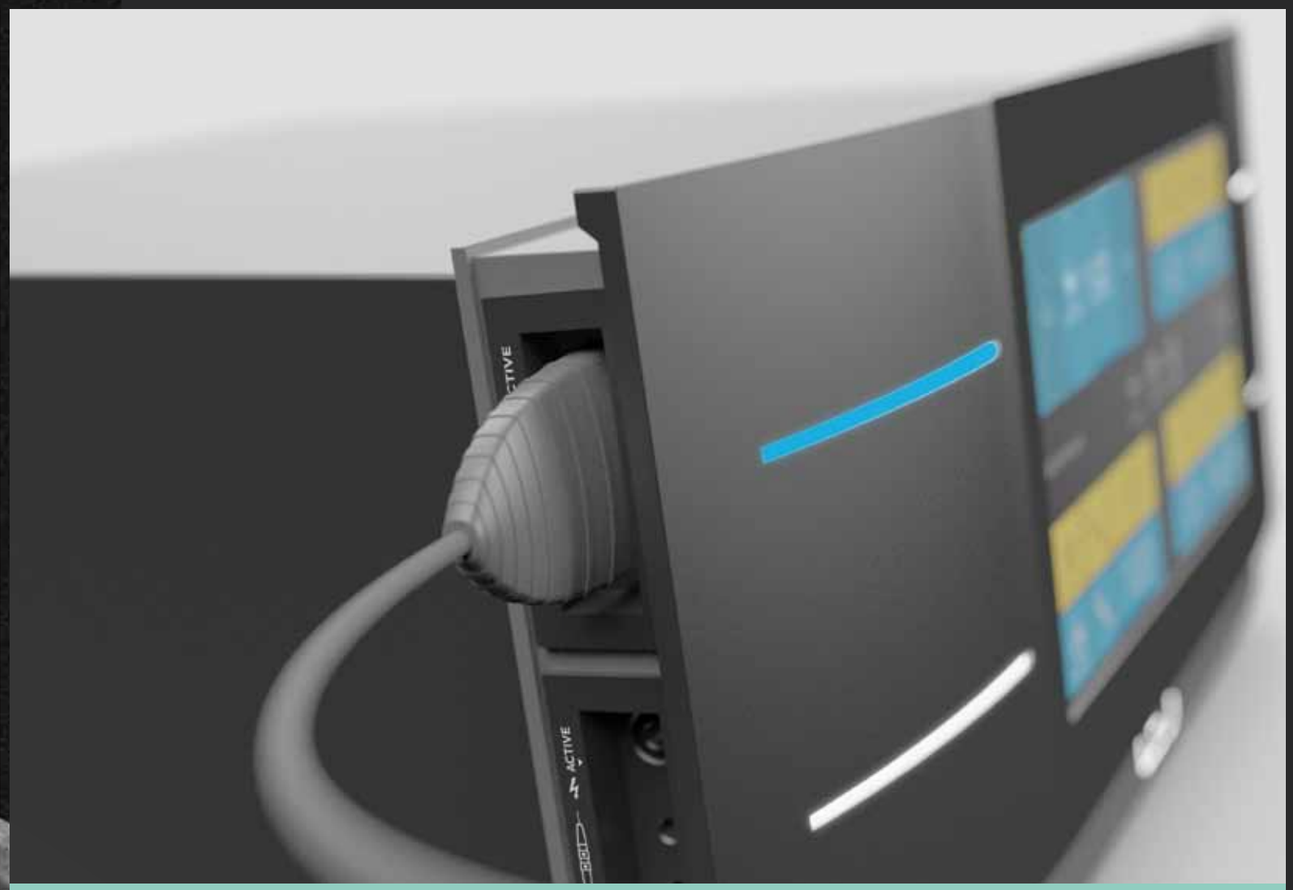
WHAT'S NEW

Two surgeons can work simultaneously and integrated Argon unit.

Over 35 years of experience in electrosurgery field and the continuous technical research have led to the design of **SURTRON TOUCH** *HP*. A new generation of technologically and functional features

_ Simultaneous activation of Monopolar and Bipolar
_ Contemporary dual monopolar
_ Contemporary dual bipolar
_ Integrated ARGON unit
_ Power control depending on impedance
_ Activating power with pedal and / or handpiece
_ Neutral-patient electrode contact control
_ Cutting function under saline solution TUR
_ Modular cut in wet conditions BLEND
_ VESSEL SEALING to clamp vessels up to 7 mm
_ Possibility of use for minimally invasive surgery
_ Monopolar / Bipolar functions
_ Autostart / Autostop in Bipolar modality
_ Adjusting the intensity of the sound

NEW LAYOUT



An intuitive and logic work enviroment

SURTRON TOUCH *HP* has a particularly basic and intuitive work environment.

Horizontal matching between monitors, RGB light indications and connectors provides a clear and easy-to-read overview.

The accessories sockets are laterally placed, allowing you to control important information without disturbances such as connectors and attached accessories cables.

The large 9 “touchscreen touchscreen gives rise to a sleek flat front design and ensures faster and more efficient cleaning in the operating room.

25% LIGHTER

SURTRON TOUCH *HP* has a total weight of 13.5 kgs, 25% less than the previous generation.

STATE OF THE ART DEVICE

SURTRON TOUCH *HP* has a 9 “capacitive touchscreen display with an intuitive user interface.

SURTRON TOUCH *HP* enables highly professional surgery with ergonomic and safety solutions. The connection of the neutral electrode is continuosly monitorated, if a split neutral plate is used, the device will monitor the contact between the patient and the electrode. The possibility to switch the functions and to set the supply of the power from the handpiece allows the execution of interventions without distracting attention from the operating range.

CUT

MONOPOLAR

400 W-300 Ω

250 W-300 Ω

250 W-300 Ω

200 W+200 W
300 Ω

BIPOLAR

150 W-50 Ω

200 W-50 Ω

SURTRON TOUCH *HP* has several **monopolar** cutting modes. In addition to the standard *PURE* function, there is a cut for high impedance called *ENHANCED*. A modular cut to avoid escaping and having a better result in wet conditions called *BLEND*. The new *DUO* function, particularly important, allows the use of a standard cut with two handpieces simultaneously.
In the **bipolar** section in addition to the *PURE* standard cut, the device offers cutting function without escaping under saline *TUR* solution.

COAG

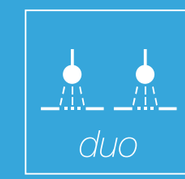
MONOPOLAR

150 W-300 Ω

150 W-200 Ω

100 W-500 Ω

100 W-1000 Ω



50 W+50 W
500 Ω

BIPOLAR

120 W-50 Ω

200 W-50 Ω

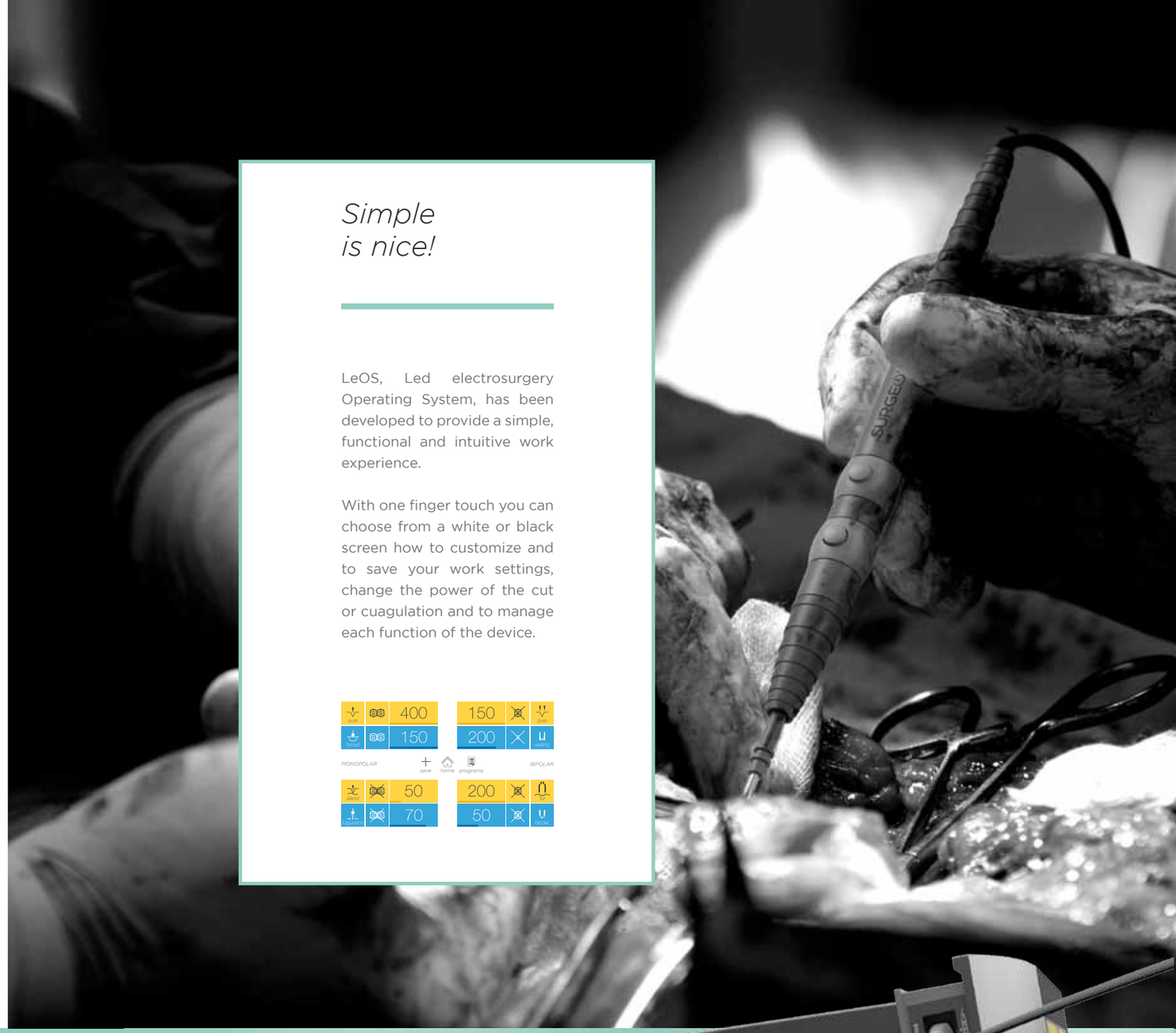
Monopolar coagulation modality allows superficial coagulation called *FORCED* or deep coagulation called *SOFT*, generated by the low voltage emitted.
The *FULGURATION* and *SPRAY* functions allow a fast coagulation without contact thanks to the high voltage supplied. The new *DUO* mode also allows a superficial coagulation with two handles at the same time. In the **bipolar** section, the standard *BIPOLAR* and *SEALING* function to clamp vessels in a fast and safe way up to 7 mm finish the wide range of functions of the **SURTRON TOUCH** *HP*.

Surgeon and device: they are one and the same thanks to **SURTRON TOUCH** *HP*. The software is divided into four sections corresponding to the four sockets on the sides. Each socket corresponds to bright LEDs indicating the yellow, blue clotting cutout. The light remains white while waiting for delivery.

SIMPLE FUNCTIONAL INTUITIVE

Simplicity, this is the goal we set for ourselves to achieve.

The simplified set up is designed to give priority to surgery, not to the search and the comprehension of functions.



Simple is nice!

LeOS, Led electrosurgery Operating System, has been developed to provide a simple, functional and intuitive work experience.

With one finger touch you can choose from a white or black screen how to customize and to save your work settings, change the power of the cut or cuagulation and to manage each function of the device.

Features

Codice prodotto	**10400.T902**
Maximum output power monopolar PURE	**400 W 300 Ω**
Maximum output power monopolar ENHANCED	**250 W 300 Ω**
Maximum output power monopolar cut-coag BLEND	**250 W 300 Ω**
Maximum output power monopolar coag FORCED	**150 W 300 Ω**
Maximum output power monopolar coag SOFT	**150 W 200 Ω**
Maximum output power monopolar coag FULGURATION	**100 W 500 Ω**
Maximum output power monopolar coag SPRAY	**100 W 1000 Ω**
Maximum output power monopolar coag SPRAY ARGON	**100 W 1000 Ω**
Maximum output power bipolar cut PURE	**120 W 50 Ω**
Maximum output power bipolar cut-coag TUR	**200 W 50 Ω**
Maximum output power bipolar coag BIPOLAR	**120 W 50 Ω**
Maximum output power bipolar coag SEALING	**200 W 50 Ω**
Working frequency Monopolar / Bipolar	**360 kHz**
Patient circuit	**F**
ARGON flow regulation	**0.2 - 10 LPM**
ARGON maximum inlet pressure	**3.0 bar (43,5psi)**
Selectable input voltage	**100 - 240 Vac**
Mains frequency	**50 / 60 Hz**
Electrical input power	**1000 VA**
Size WxHxD	**470x220x460 mm**
Weight	**13,5 Kgs**

Controls

Patient/Plate circuit monitoring
Output power monitoring
Self check control
HF leakage currents control
Compensation of mains fluctuation

Safety

EN60601-1
EN60601-1-2
EN60601-2-2
Electrical Class: I CF
MDD 93/42/EC Class: II b

Standard accessories

Disposable handle with switches (5pcs)
Reusable handle with switches
Blade electrode 7 cm (3 pcs)
Blade electrode 16 cm (3 pcs)
Needle electrode 7 cm (3 pcs)
Ball electrode 6 cm (3 pcs)
Cable for neutral electrode
Disposable split neutral electrode (5pcs)
Electrode cleaning sponge
Double water-proof foot-switch (2 pcs)
Power supply cable 5 mt

Note

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CERTIFICATO CE

Certificato n. 116/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

LED SPA

03100 FROSINONE (FR) - VIA MARCO TULLIO CICERONE 134 (ITA) - Italy

mantiene negli stabilimenti di:

04011 APRILIA (LT) - VIA SELCIATELLA 40 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Apparecchi per diatermia

Apparecchi per elettrochirurgia ad alta frequenza

Apparecchiature per l'erogazione di gas ARGON con flusso controllato

Apparecchiature per l'erogazione di gas CO2 con flusso controllato

Apparecchi per laserterapia

Apparecchi per magnetoterapia

Apparecchi per pressoterapia

Apparecchi per terapia a microonde

Apparecchio per terapia combinata

Apparecchi per ultrasuonoterapia

Elettrodo coagulatore

Accessori per elettrochirurgia

Apparecchi per elettroterapia ed elettrostimolatori

Apparecchi per terapia ad onda d'urto

Accessori per aspirazione fumi

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Emesso il:	1998-10-15
Data di Aggiornamento:	2018-01-22
Sostituisce:	2017-10-12
Data Scadenza:	2022-04-12

IMQ cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

MOD. 1475A / 2

CERTIFICATO CE

Certificato n. 116/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Riferimento pratiche IMQ:
DM17-0014421-01; DM17-0018027-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	1998-10-15
Data di Aggiornamento:	2018-01-22
Sostituisce:	2017-10-12
Data Scadenza:	2022-04-12

IMQ

cosign

IMQ ESQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

CERTIFICATO CE

Certificato n. 116/MDD

MOD. 1475A / 2

Allegato

Apparecchi per diatermia

Apparecchi per elettrochirurgia ad alta frequenza

Apparecchiature per l'erogazione di gas ARGON con flusso controllato

Apparecchiature per l'erogazione di gas CO2 con flusso controllato

Apparecchi per laserterapia

Apparecchi per magnetoterapia

Apparecchi per pressoterapia

Apparecchi per terapia a microonde

Apparecchio per terapia combinata

Apparecchi per ultrasuonoterapia

Elettrodo coagulatore

Accessori per elettrochirurgia

Apparecchi per elettroterapia ed elettrostimolatori

Apparecchi per terapia ad onda d'urto

Accessori per aspirazione fumi

Modd. Come da documento allegato "ELENCO PRODOTTI - PRODUCT LIST" rev. 2 del 15/12/2017; valido solo se provvisto del timbro IMQ.

Emesso il:	1998-10-15
Data di Aggiornamento:	2018-01-22
Sostituisce:	2017-10-12
Data Scadenza:	2022-04-12

IMQ cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

MOD. 1475A / 2

EC CERTIFICATE

Certificate No 116/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

LED SPA

03100 FROSINONE (FR) - VIA MARCO TULLIO CICERONE 134 (ITA) - Italy

manages in the factories of:

04011 APRILIA (LT) - VIA SELCIATELLA 40 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Equipment for diathermic therapy

High frequency surgical equipment

Equipment for ARGON gas supply

Equipment for CO2 gas supply

Therapeutic laser equipments

Magnetotherapy equipments

Pressure therapy equipment

Microwave therapy equipments

System therapy equipment

Ultrasound therapy equipment

Coagulator needle

Electrosurgical accessories

Electrotherapy equipments and electrostimulators

Shockwave therapy equipments

Accessories for smoke evacuator

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Date:	1998-10-15
Updated:	2018-01-22
Substitution Date:	2017-10-12
Expiry Date:	2022-04-12

IMQ cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

MOD. 1475A / 2

EC CERTIFICATE

Certificate No 116/MDD

Full Quality Assurance System Approval Certificate

Reference to IMQ files Nos:
DM17-0014421-01; DM17-0018027-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date:	1998-10-15
Updated:	2018-01-22
Substitution Date:	2017-10-12
Expiry Date:	2022-04-12

IMQ cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
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This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 116/MDD

Annex

Equipment for diathermic therapy

High frequency surgical equipment

Equipment for ARGON gas supply

Equipment for CO2 gas supply

Therapeutic laser equipments

Magnetotherapy equipments

Pressure therapy equipment

Microwave therapy equipments

System therapy equipment

Ultrasound therapy equipment

Coagulator needle

Electrosurgical accessories

Electrotherapy equipments and electrostimulators

Shockwave therapy equipments

Accessories for smoke evacuator

Type ref. As to annex document "ELENCO PRODOTTI - PRODUCT LIST" rev. 2 dated 15/12/2017; valid only if provided with IMQ stamp.

Date:	1998-10-15
Updated:	2018-01-22
Substitution Date:	2017-10-12
Expiry Date:	2022-04-12

IMQ cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This is a translation of the Italian text, which prevails in case of doubts

ALLEGATO ELENCO PRODOTTI / *ANNEX PRODUCT LIST:* 01
MARCA / *TRADE MARK* LED
Apparecchi per diatermia / *Equipment for diathermic therapy* Modd. RF ABLATOR; THERMA
Apparecchi per elettrochirurgia ad alta frequenza / *High frequency surgical equipment* Modd. CUTTER VET; SURTRON 50D; SURTRON 80D; SURTRON 80; SURTRON 120; SURTRON 160; SURTRON 200; SURTRON FLASH 80; SURTRON FLASH 120; SURTRON FLASH 160 HF; SURTRON FLASH 200; SURTRON 240 HP; SURTRON 250 HP; SURTRON 300 HP; SURTRON 380 HP; SURTRON 400 HP; SURTRON SB; SURTRON TOUCH 200
Apparecchiature per l'erogazione di gas ARGON con flusso controllato / *Equipment for ARGON gas supply* Mod. SURTRON ABC
Apparecchiature per l'erogazione di gas CO2 con flusso controllato / *Equipment for CO2 gas supply* Modd. CARBOMED; CARBOMED CO2
Apparecchi per laserterapia / *Therapeutic laser equipments* Modd. GIOTTO CLASSIC 1; GIOTTO CLASSIC 2; GIOTTO STUDIO; LAMBDA; LAMBDA 2; LAMBDA YAG
Apparecchi per magnetoterapia / *Magnetotherapy equipments* Modd. BIO FIELD PROFESIONAL; BIO MAGNETIC; BIO MEDICAL ; BIOMEDICAL; BIOSALUS; EASY MED; MAGNETICA; MAGNETO BASE +; MAGNETOSAN; MICHELANGELO BASIC; MICHELANGELO CLASSIC; MICHELANGELO STUDIO; PRO MAGNETIC; TESLA; TESLA 2; TESLA PULSE; THERAFIELD; T-KURO SENSOR; VITAL MAGNETIC
Apparecchi per pressoterapia / *Pressure therapy equipment* Modd. HP PRESSO; PRESSA; PRESSOMED; TINTORETTO CLASSIC 5 SECT; TINTORETTO SPECIAL 8 SECT; TINTORETTO STUDIO
Apparecchi per terapia a microonde / *Microwave therapy equipments* Mod. BERNINI STUDIO
Apparecchio per terapia combinata / *System therapy equipment* Modd. ERACLES; COMBISAN; SONORA COMBI
Apparecchi per ultrasuonoterapia / *Ultrasound therapy equipment* Modd. DONATELLO BASIC 1; DONATELLO BASIC 3; DONATELLO CLASSIC; SONAR AUTO; SONORA; US SONIC
Elettrodo coagulatore / *Coagulador needle* Modd. SB COMB ARRAY; SURTRON breENT
Accessori per elettrochirurgia / *Electrosurgical accessories* Modd. PENCIL; PENCIL S; CONNECTION; NEUTRAL; ELECTRODE; BIPOLAR; MONOPOLAR
Apparecchi per elettroterapia ed elettrostimolatori / *Electrotherapy equipments and electrostimulators* Modd. ELECTRA 2; ELECTRA 4; LEONARDO BASIC 1; LEONARDO BASIC 2; LEONARDO BASIC 4; LEONARDO CLASSIC 1; LEONARDO CLASSIC 2; LEONARDO CLASSIC 4; LEONARDO SPECIAL 2; LEONARDO SPECIAL 4; IONO BASE +; STIM BASE +
Apparecchi per terapia ad onda d'urto / *Shockwave therapy equipments* Mod. ONDA
Accessori per aspirazione fumi / *Accessories for smoke evacuator* Modd. Tubi aspirazione fumi EVAC */ EVAC smoke evacuation tubes*

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and its partner
CISQ/IMQ-CSQ
hereby certify that the organization

LED SPA

VIA SELCIATELLA 40 - 04011 APRILIA (LT)

for the following field of activities

Design, manufacturing and after sale services of active medical devices for electro surgery and physiotherapy and related accessories sterile and not, and of equipment for aesthetic use

Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: 2016 - 07 - 04 Expiry date: 2019 - 07 - 19

Registration Number: IT - 1307

The status of validity of the certificate can be verified at http://www.cisq.com or by e-mail to fedcisq@cisq.com

Michael Drechsel
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR Spain AFNOR Certification France AIB-Vinçotte International Belgium APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico Inspecta Certification Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland Quality Austria Austria RR Russia SIGE Mexico SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 9120.LED2

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

LED SPA

VIA MARCO TULLIO CICERONE 138 - 03100 FROSINONE (FR)

UNITA' OPERATIVE
OPERATIVE UNITS
VIA SELCIATELLA 40 - 04011 APRILIA (LT)

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

ISO 9001:2008

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione ed assistenza tecnica di dispositivi medici attivi per elettrochirurgia e terapia fisica e relativi accessori sterili e non, e di apparecchi per estetica
Design, manufacturing and after sale services of active medical devices for electro surgery and physiotherapy and related accessories sterile and not, and of equipment for aesthetic use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2008 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-06-12	2016-07-04	2019-07-19

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14; in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14; otherwise the validity of this certificate will expire

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ
www.cisq.com

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 19

SGQ N°005A, SGA N°006D,SCR N°005F
SSI N°003G, FSM N°007I, SGE N°006M
EMAS N°003P, PRD N°005B,PRS N°080C,
ISP N°063E, LAB N°0121, LAT N°021
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

CSQ
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www.imq.it

CISQ is a member of
IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 9124.LED3

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

LED SPA

VIA MARCO TULLIO CICERONE 138 - 03100 FROSINONE (FR)

UNITA' OPERATIVE
OPERATIVE UNITS
VIA SELCIATELLA 40 - 04011 APRILIA (LT)

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione ed assistenza tecnica di dispositivi medici attivi per elettrochirurgia e terapia fisica e relativi accessori sterili e non, e di apparecchi per estetica
Design, manufacturing and after sale services of active medical devices for electro surgery and physiotherapy and related accessories also sterile and not, and of equipment for aesthetic use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-06-12	2016-07-04	2019-07-19

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28; in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28; otherwise the validity of this certificate will expire

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ
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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N°005A, SGA N°006D,SCR N°005F
SSI N°003G, FSM N°007I, SGE N°006M
EMAS N°003P, PRD N°005B,PRS N°080C,
ISP N°063E, LAB N°0121, LAT N°021
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years