



» TEKNO TOM 100 «





Tekno-Medical Optik-Chirurgie GmbH

Sattlerstr. 11
78532 Tuttlingen
Germany
SRN: DE-MF-000005822

Phone: +49 (0) 7461 / 17 01 0

Fax: +49 (0) 7461 / 17 01 50

E-mail: mail@tekno-medical.com

Homepage: www.tekno-medical.com



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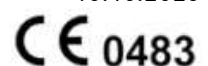
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Intended users, use of this manual

These devices must be used only for the purposes listed in this manual and only in OT / similar places by qualified operators who are experienced in electro-surgery and all related problems, risks and undesired side effects.

Users must do the following:

- Before starting the use of this device, they must read this manual carefully; in addition they must check the unit performance
- without considering only previous experiences with similar devices and contact the company if it is not clear for their specific needs.
- They must keep the manual where the device is used and replace it in case of loss.
- They must contact the company, either directly or through the local distributor, to obtain the needed information or replace the manual.

This unit is manufactured by TEKNO MEDICAL, Tuttlingen (Germany), which is responsible for its functioning, liability and safety only if:

- The device is used in an area that meets IEC Standards
- If both the installation and the use are performed according to the information of this manual.
- If checks or repairs are performed by authorized personnel who use original spare parts.

On request, TEKNO MEDICAL will provide the user with the related electric diagrams and/or any further technical or practical information.

In accordance with the requirements of the Medical Device Regulation EU MDR 2017/745 and our quality management system, even the smallest problems with this product should always be reported to TEKNO MEDICAL.

If you cannot reach us directly for reportable events, please send an e-mail to: safety@tekno-medical.com.

Serious incidents must also be reported to the competent authority in your country.



1 HIGH FREQUENCY SURGERY – PRINCIPLES, RISKS AND DIRECTIONS FOR USE

When electrical currents flow across biological tissues, they produce 3 effects: Electrolytic, Faradic and Thermal.

If the current has a frequency higher than 300kHz, the thermal effects remain above all and it is exploited to obtain the desired surgical result; in fact, when an electric current with such characteristics crosses with sufficient density the cellular liquid of tissues, it warms in different ways and generates what follows:

- A vapor pressure into liquids of cells very high which is able to provoke the explosion/destruction of their membranes: **Pure Cut**;
- A slower heating of liquids which permits their evaporation; in this way, tissues and vessels shrink and stop the bleeding: **Coagulation**;
- A process that is in the middle between phenomena above: **Coagulating Cut**.

HF SURGICAL CURRENTS ARE USABLE IN TWO MODES: MONOPOLAR AND BIPOLAR.

MONOPOLAR MODE. It requires the use of two electrodes (the active one, small and used by the operator; the neutral one, large and fixed on a different part of the patient's body) and the current flows from the first to the second electrode. Obviously, the thermal effect affects with different intensities all tissues included between electrodes.

BIPOLAR MODE. This mode requires the use of one instrument including both electrodes that are very close and the thermal effect affects only a very small quantity of tissues.

RISKS CAUSED BY THE USE OF HF-CURRENTS.

These currents are vital to solve many surgical needs, but they cause also some risks and unexpected side effects, mainly while using the monopolar mode. For example:

- **Burns on the patient's tissues** where operators place the neutral electrode caused by not sufficient/bad contact.
- **Burns on the surgeon's hand** when the insulation of the active electrodes/instruments is damaged;
- **Severe burns of patients /users** caused by the ignition/explosion of flammable/explosive gases or substances. Sparks generated during the delivery of power can ignite them.
- **Malfunction of other devices** (pace-maker, video systems) provoked by EMC interferences emitted during the power delivery;
- Unexpected damages of the patient's tissues caused by a delivery of too high powers.
- While using currents for coagulation, **neuromuscular stimulations** felt by patients or surgeons like "an electrical discharge".

To reduce these risks, International IEC standards establish both all the hardware/software measures to apply and all warnings to include in the User manual that users must comply carefully because their behaviour is vital to eliminate or, at least, to reduce these risks.

DIRECTIONS FOR USE

Intended use: Bipolar cut and coagulation during all operations of small/medium surgery in surgeries, OT and similar places.

Indications: Gynaecology, Dermatology, Plastic and Aesthetic Surgery, ORL, Maxillofacial Surgery, Other Surgeries, Gastroenterology, Veterinary.



2 IMPORTANT WARNINGS

Following warnings are vital to use these devices in the best and safest possible way.

We detail some warnings for information completeness even if they refer only to devices for major surgery.

2.1 General Information

- Never use the unit if the installations of the place of use do not comply with the current safety standards.
- Do not use extensions for the mains cord, when connecting many devices at the same time, ask the Technical Service about their compatibility.
- The smoke produced during the use of HF units is biologically noxious. In many countries, the Official Bodies who safeguard the health of patients and operators recommend the use of Smoke evacuators to evacuate and filter it.
- The use of a suitable smoke evacuator is very useful during the laparoscopy since it allows the best vision of the operating area without reducing the pressure inside the cavity.
- When using an HF unit for endoscopic procedures under liquid, monitor the quantity of irrigation fluids in the patient (input and output volumes), mainly if the patient has a limited renal function or cardiovascular insufficiency.

2.2 Flammable substances or explosive gases

All HF units produce during the power delivery sparks able to fire and explode endogenous gases (i.e., Inside the intestine), flammable gases (i.e., oxygen, nitrogen protoxide) or materials (cotton, gauze, sheets) saturated by these gases and fire flammable products (cleaning products, disinfectants or solvents) or materials (cotton, gauze, sheets) soaked by these products.

Standards require the complete evaporation of flammable products before starting the use of a HF unit.

Prudentially never use a HF unit in presence of all above gases/substances.

2.3 EMC- Electro-magnetic compatibility (Interferences, disturbances)

This HF devices complies with all international EMC standards and competent technical bodies have tested it by considering its use environment (OT, similar places). Nevertheless, and mainly during the power delivery, it can affect the functioning of following devices:

Planted pacemakers or neuromuscular stimulators/similar devices (i.e. they can cause fibrillations).

Ask for a qualified advice (i.e. From the Cardiology Division before operating a patient holder the pace-maker)

The bipolar mode is the best solution to operate a patient holder these devices.

Other medical equipment used together the HF device (i.e. monitoring devices, video cameras and so on).

- If possible, do not use the HF unit stacked with / adjacent to other equipment (Otherwise, check their proper functioning) and portable communication devices at a distance of less 1 meter from it.
- The use of not original accessories (i.e. cables with different lengths) can cause EMC problems...

Preparation of the patient for the operation and use of the monopolar neutral electrode

Always place the patient properly for the operation, mainly if it is long since the risk of burns and decubitus lesion rises in this case.

Even if the use of bipolar HF currents is the best way to avoid the worldwide known risk of the unexpected burns caused by monopolar currents, when using this device apply all following warnings prudentially:

- Take all the metallic objects off the patient (rings, etc.) and remember that the metallic parts (prosthesis, catheters, etc.) on the path of the current may cause increases of density of current.
- Check that the insulating parts of the operating table are good (Not able to cause a contact with a metallic part)
- With dry sheets or suitable materials, insulate the patient from any metallic part connected to earth or able to conduct electricity (table, supports). In the same way, insulate both the patient from the heating mattress and the strongly secreting parts of the body (Sweat can affect the insulation!) or the contacts skin-to-skin (i.e. between arms and body).
- During the operation, verify if the initial insulation remains good mainly when moving the patient or pouring liquids,
- When disinfecting the operating field, do not wet the sheets under or around the patient. Dry the traces of disinfectant on the skin also.



2.4 Use of all active instruments

Never use accessories not compliant with all applicable Standards, not well insulated, not suitable for the following working voltages: (About 400/450 Vpp “200/225 Vp” for the bipolar currents) and worn or damaged. Damaged accessories do not work properly and can lead users to increase the output power at dangerous levels.

- When starting the operation, check the status / the insulation of accessories and place all unused active accessories/cables on
- insulating materials during the operation. In addition, avoid their contact both with the patient and with other cables or conductive parts.
- To avoid not useful carbonizations of tissues, do not activate the power delivery if the electrode does not touch the tissues.

2.5 Use of bipolar scissors (For open and laparoscopic surgery)

Never cut tissues by a bipolar cut current. Cut tissues mechanically while coagulating them by the bipolar coagulation. The sticking of the bipolar instruments for coagulation and vessel sealing

The sticking of tissues on the tips of instruments is a normal and not avoidable problem. It is possible to reduce as follows: While using all instruments for coagulation or vessel sealing both clean their tips /jaws and wet or damp them as follows:

- If possible, use instruments with no-stick ends.
- Before and during use, clean the ends of all instruments and wet / damp them.
- Wet them in a bowl with physiological solution before the use and after 3/4 deliveries of power.
- Damp them by a gauze soaked in physiological solution before the use and after 3/4 deliveries of power.
- If possible, irrigate the tissue by physiological solution and deliver the power intermittently without pressing the ends too much.

2.6 The specific use of the bipolar instruments for laparoscopy

The use of these instruments requires a special care! Apply the following warnings in addition to those detailed in previous paragraphs.

- Always check the good insulation of trocar cannulas and never use currents with automatic start/stop system.
- Use instruments under visual control, check the distance of their ends from sensitive structures of the tissue and activate the current only if ends are in contact with tissues.
- Never use hot instruments (instrument with hot ends) as instrument for preparing and check if all parts are present after each withdrawal.
- When performing the vessel sealing, prudentially perform at least two coagulations / seals (to the left and to the right of the point to cut) and verify if vessels are well coagulated / sealed before performing the cut.

2.7 Use of currents and powers

- When start using a new HF unit, check its performance without considering previous experiences with similar devices.
- When start an operation with a new unit, set very low powers and then raise them progressively.
- Use the bipolar mode when operating on delicate or much innervated tissues, on small portions of tissue, on cavities and when Use the bipolar mode when operating on delicate or much innervated tissues, on small portions of tissue, on cavities and when operating
- on patients with pacemakers or similar implanted devices.
- Use the bipolar mode if the positioning of the neutral electrode for the monopolar mode is difficult.
- Use as much as possible the bipolar mode in veterinary. It avoids the worldwide known risk caused by the use of HF monopolar currents,
- that is the risk of unexpected burns either where the animal touches the operating table or where operators place the neutral electrode
- Remember that the use of too low powers can cause unexpected risks.
- Try to follow the suggested working times, and avoid useless short-circuits between active and neutral electrodes.

Regarding powers, the device is provided with an automatic self-test system with self-checks both at the switching ON and during the functioning, (See the point AUTOMATIC SELF-TEST SYSTEM AND PROBLEMS NOT DETECTABLE BY SELF-CHECKS.



The system blocks the functioning and informs users by ERROR CODES or acoustic/visual ALARMS in following cases:

- If it detects wrong activations (For example if the user pushes two activation switches simultaneously).
- In this case users can intervene by eliminating the mistake immediately.
- If it detects failures that cause: Absence of output power /Anomalous power delivery.
- In this case users can switch the device OFF and ON again (ask for technical assistance if the problem continues).

Therefore, if during use the device doesn't deliver the power (The normal powers appear less efficacious), but it has properly passed the self-check at the switching on and the systems do not signal problems by ERROR CODES or ALARMS, do not both increase too much the power and think that the problem depends on the unit. Do as follows:

- Check the good contact between the neutral electrode and patient's tissues while using monopolar currents.
- Check cables and connectors by bending and pulling them (They mainly break close to the instrument).
- Check the assembly and the internal connections of all instruments, mainly if for endoscopy or laparoscopy.
- Check the insulation of the blades of all bipolar scissors (If damaged by the sliding a short circuit occurs and the current to reach tissues).
- Clean the tips of all electrodes and instruments (If dirty, the current doesn't reach tissues).
- Clean the joints of the bipolar instruments for laparoscopy (If dirty the current doesn't reach tissues).

3 USE

- Place the unit on a shelf at not less than 30cm from the wall or other objects that can obstruct the ventilation areas.
- Check that the mains supply corresponds to technical data (See the data label on the back)
- Connect the device with the mains switch OFF = 0 (On the back).

3.1 Connection of the foot-switch

- The twin foot-switch is pneumatic without electrical current; it means water-proof and explosion-proof usable in OT.
- It is very useful to use the device in the same way of devices for operating theatres.
- Connect it as the paragraph Controls and Symbols details.
- Connection of accessories
- Connect the accessory to the socket 6

The connection does not require a specific polarity.

Switching **ON** and automatic starting self-test

Switch the device **ON** by the switch 1 (on the back) and the starting self-test runs immediately. On displays, numbers and codes (for example, internal temperatures) signalling each self-test phase appear. THEY ARE NOT ALARMS!

If the system detects failures it blocks the operation (See the paragraph AUTOMATIC SELF-TEST SYSTEM).

Otherwise, the self-check ends with an acoustic signal (on displays the software release appears for an instant).

After that, displays show the following:

- The first time users switch the device **ON**, displays show the number 1.
- At each new switching **ON**, displays show the power of currents used at the switching OFF.

3.2 Setting and adjustment of currents

SETTING OF THE CURRENTS FOR CUT / COAGULATING CUT

- Push the key **4A** and select the first current. For example, PURE = cut (the related led switches on).
- Adjust by keys **5A** the power (The display shows it). You can change the power always, even during the power delivery.
- If you like, push again the key **4A** to select a second current and adjust its power in the same way.
- In the same way you can set all currents



By pushing the key 4A, all currents can be selected progressively (PURE > PPULSED > BLEND > PURE >>)

PURE – Cut	P PULSED – Pulsed cut	BLEND – cut with strong coagulation
------------	-----------------------	-------------------------------------

- At the end push the key 4A and select the first current you prefer to start the operation.
- As above detailed, you can always change currents and/or powers during use.

3.3 SETTING OF THE CURRENTS FOR COAGULATION.

- Push the key 4B and select the first current. For example, MACRO –coagulation.
- Adjust by keys 5B the power (The display shows it). You can change the power always, even during the power delivery.
- If you like, push again the key 4B to select a second current and adjust its power in the same way.
- In the same way you can set all currents

By pushing the key 4B, all currents can be selected progressively (MACRO > MPULSED > MICRO >MACRO >>)

MACRO – Standard coagulation	MPULSED – Pulsed standard coagulation	MICRO – Delicate coagulation
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- At the end push the key 4B and select the first current you prefer to start the operation.

As above detailed, you can always change currents and/or powers during use.

Activation of currents by the twin foot-switch

- Push the yellow pedal to activate cut (pure and coagulating) currents.

The device signals the power delivery by a grave sound and the yellow light ON.

- Push the blue pedal to activate coagulation currents.

The device signals the power delivery by an acute sound and the blue light ON.

To use pulsed currents (PPULSED, MPULSED) push the pedal continuously. The delivery is automatically pulsed.

By pushing both pedals together, the self-test system blocks the device (See: AUTOMATIC SELF-TEST SYSTEM).

3.4 Memorization of settings and abnormal power delivery

The device memorizes all settings automatically and it resets at the switching ON those used at the switching OFF.

In case of abnormal power deliveries see paragraphs AUTOMATIC SELF-TEST SYSTEM and IMPORTANT WARNINGS (Specially the point Use of currents and powers).

3.5 Available currents, use and starting settings

To set powers, see both the data of related tables and currents diagrams (The diagrams of the column 2 show the power change versus the setting adjustment).

PURE (bipolar cut with low coagulating effect).

- It is suitable to cut tissues by nipping them with bipolar forceps having tips 0,5/1mm, (starting setting 40-50)
- It is suitable to cut tissues by using instruments with two needles (starting setting 40-50)
- It is suitable to cut tissues in hysteroscopy in saline by using bipolar instruments -5Fr(starting setting 90-100)

PPULSED (pulsed cut).

- It is identical to the PURE cut and it usable in the same way, but it is more suitable to obtain fine cuts.

BLEND (coagulating cut).

- It is suitable to obtain a stronger coagulating cut and it is usable in the same way of the PURE cut.
- It is not suitable for the use in hysteroscopy in saline.

MACRO (standard bipolar coagulation).

- It is suitable to perform bipolar coagulations with following instruments:
- Bipolar forceps (with tips 0,5/1mm, starting setting 1-2W) (with tips 1,5/2mm, starting setting 4-5)
- Needles for turbinals or similar uses (starting setting from 20 – 30).
- Forceps or scissors for laparoscopy (starting setting from 30 – 40).

MPULSED (pulsed standard bipolar coagulation).

- It is identical to the MACRO and it usable in the same way, but it is more suitable to obtain results that are more delicate.
- MICRO (delicate bipolar coagulation).

It is similar to the MACRO current and it is usable in the same way, mainly with instruments with thin tips.



4 AUTOMATIC SELF-CHECK SYSTEM

The device is provided with a self-test system that checks its operation, its failures and wrong usages by users. It operates as follows:

At the switching ON. It performs a complete self-check that ends, if the device has properly passed it, with a short sound (on displays, the code of the software release appears for a brief moment).

During use. It goes on checking the device operation, any wrong usages and output powers.

In both cases in the system detects both wrong usages and failures, it blocks the power delivery by informing users with acoustic and/or visual signals named ERROR CODES.

Short list of ERROR CODES with possible countermeasures by users.

4.1 Error code Err OtA with intermittent sound.

It does not signal problems or failures, but it is only an information for users about the continuous power activation for a time < 40 sec.

Applicable countermeasures: Stop the power activation for a brief moment and start it again immediately.

4.2 Error code Err ACt with intermittent sound.

It signals that users are pushing either two activation switches simultaneously or an activation switch not usable with that use mode.

Applicable countermeasures: Stop the wrong use.

4.3 Error codes 12 and 14 with intermittent sound.

**It signals during the starting self-check a failure or an inadvertent pressure of the following:
12 = Pedals of the foot-switch, 14 = Keys of the front panel.**

Applicable countermeasures: Switch the device OFF and ON again to verify the signaling (If confirmed, ask for the technical assistance).

4.4 Error code to2 + the detected temperature with intermittent sound

It signals that the device internal temperature is too high and could signal a failure.

Applicable countermeasures: Switch the device OFF and ON again to verify the signaling (eventually after 20/30 seconds).

4.5 Other Error Codes

They signal failures or technical problems

Applicable countermeasures: Switch the device OFF and ON again to verify the signaling (If confirmed, ask for the technical assistance).

4.6 Problems not detectable by the self-test system.

The unit is ON and it does not signal problems, but by pushing foot-switches it either does not deliver the power (None acoustic and visual signal) or it operates in a not constant way.

Verify if the foot-switch (related tubing) is broken by inserting and pushing into the central hole of the socket a rounded tip
The unit is ON, it does not signal problems and emits all activation signals, but it does not deliver the power or the normal power appears less efficacious.

Verify accessories, cables as detailed in the paragraph IMPORTANT WARNINGS



5 HANDLING, STORAGE, CLEANING AND STERILIZATION

- When not used, kept the device in a dry and not dusty place. Be careful that no liquid is poured on it.
- Always store with care the device and all accessories in order to avoid damages. To ship it, use the original packaging.
- Clean the unit with a simple soap solution, by taking care that no liquid goes inside and then wipe it with a dry cloth.
- Clean the foot-switches in the same way or by using a cold disinfecting solution. Not use flammable products!

At the moment of the sale accessories are not sterile.

Sterilize monopolar and bipolar active accessories with related cables by steam autoclave at 121 °C or with suitable cold solutions, the neutral ones by suitable cold solutions.

The packaging of each accessory includes a label with the instructions for use and the sterilization mode (allowable number of cycles and time of each cycle).

DO NOT STERILIZE BY DRY HOT AIR DEVICES, THEY BREAK PLASTICS AND INSULATIONS!

- During the sterilization, do not bend connection cables too much and wipe, before use, all the parts of the accessories very well in order to eliminate all the humidity. The best thing to do is to centrifuge them.

6 CONSUMABLES, TECHNICAL CHECKS AND FINAL DISPOSAL

- The device does not include consumables or materials with limited service life.
- IEC standards require the performing by qualified personnel, even better by the Manufacturer, of a regular check of these devices (Theoretically once per year) including the following:

In accordance with general standards IEC 60601-1.

- The check of the electrical safety (Low Frequency Leakage currents, Resistance of the protective earth conductor and so on).
- The check of the general operation, of the mains fuses, of the supply cord and so on.

In accordance with specific standards IEC 60601-2-2 for HF surgical equipment.

- The check of electrical safety (High Frequency Leakage currents and so on).
- The check of the operation of the control circuit of the neutral electrode.
- The check of powers by considering the values specified in the diagrams included in this manual (the tolerance is 20% about the powers higher than 10% of the maximum power of each current,
- Perform the final disposal according to the specific National Laws, but remember that the unit does not include dangerous substances or materials.

Sterilize before the disposal all accessories used on patients



7 TECHNICAL DATA

7.1 Technical features

Generator: Electronic type, compliant with IEC 601-2-2 standards and suitable for bipolar uses (Generator PER: 97%).
Working frequency: Monopolar/bipolar working frequency 450kHz +/- 10%.
Classification: (CE2007/47= IIB) (IEC= Class I - Type CF) (EMC= Cat. A).
Output circuit: "floating" insulated from earth at high/low frequencies and protected against the use of the defibrillator.
Supply, absorption and fuses: See the data label on the back.
Intended use: Up to ≤2000mt, in environment with pollution degree = Cat II, with a supply network with overvoltage = Cat 2.
Enclosure IPN₃N₂, = Protected against the ingress of solid objects $\geq 2,5$ mm and against water drops when tilted up to 15°.
Foot-switch IPN₆N₇ = Protected against both the dust and effects of a momentary immersion in water.
Cooling: By convection without fan.
Activation signals Cut (yellow light and grave sound), Coagulation (blue light and acute sound)
Operation control: By microprocessor with self-checks and ERROR CODES
Supply cord: 2meters, section 3x0, 75 mm².
Dimensions and weight: cm (WxDxH) 22x24x12 – about Kg 4.5

Environmental and atmospheric conditions for use, transport and storage

For the use: Temperature (°C) +10 ÷ +40. **Humidity** 30% ÷ 75%. **Pressure** (hPa): 700 ÷ 1060.

For the transport and storage: Temperature (°C) -40 ÷ +70. **Humidity** 10% ÷ 95%. **Pressure** (hPa): 500 ÷ 1060.

7.2 Currents and Powers

S: Setting - **W:** Power (Watts) - Ω : Rated load -

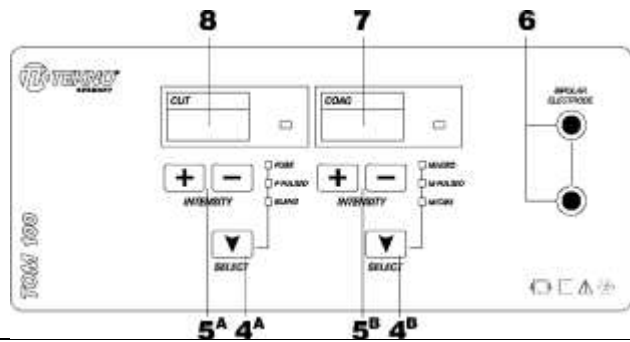
V_{pp}: Open circuit peak to peak voltage - **CF:** Crest factor - **M:** Modulation - **DT:** Duty Cycle -

Pure	S 120	120	400	V_{pp} 975 - CF 2.75 - M 0% - DT 100%
P_{PULSED}	S 120	60 W	"	V_{pp} 990 - CF 3,98 - M 50% - DT 100%
Blend	S 100	100	"	V_{pp} 975 - CF 2.8 - M 0%, DT 80%
Macro	S 100	100	100	V_{pp} 640 - CF 3,6 - M 0%, DT 80%
M_{PULSED}	S 100	50 W	"	V_{pp} 640 - CF 5 - M 0% - DT 50%
Micro	S 100	100	"	V_{pp} 600 - CF 3.4 - M 0% - DT 50%



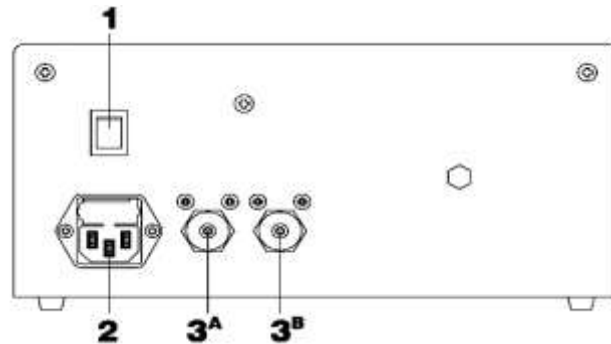
8 CONTROLS AND SYMBOLS

- 4) Key of currents selection (4A- Cut / 4B- Coagulation)
 5) Key of power adjustment (5A- Cut / 5B- Coagulation) .
 6) Socket for the instrument
 7) Display and light COAG (coagulation)
 8) Display and light CUT (cut)



BACK

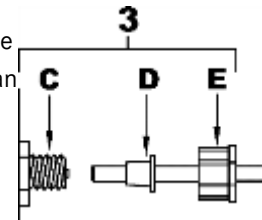
- 1) Main switch.
 2) Mains cord appliance inlet with fuses.
 3) Socket for the foot-switch (3A- Cut -Yellow (3B- Coagulation - Blue - right)



Connection of the foot-switch

Unscrew from each socket C the nut E and take away the conic gasket D inside the

- Insert tubings of the pedal (**Yellow = cut Blue = coagulation**) into nuts and
- **Without pushing pedals** insert tubings and gaskets into sockets.
- Screw nuts E to sockets C tightly.



I - O ON - OFF



Alternated current



Separate waste



Be careful Read the User manual

Device of Class I - Type CF protected against the use of the defibrillator. This type grants the highest level of safety against direct and not direct contacts, for leakage currents specially.

A floating applied part is insulated from earth at high and low frequencies.



CONFORMITY EMC/DIRECTIVE 89/336/CEE: CATEGORY A (Distances to be kept from not vital devices)

Source of the Current RF	Typical Power (W)	Distance (m)	For broadcasting stations which use frequencies less than 800MHz, the distance can be established by using the equation: A: $d = 4\sqrt{P}$
Microcellular telephones CT1,CT2,CT3	0.01	0.4	For broadcasting stations which use frequencies between 800MHz and 2.5GHz, the distance can be established by using the equation: B: $d = 2.3\sqrt{P}$ P = Nominal power of the transmitter in watt (W), established by the manufacturer.
Mobile telephones DECT, Wireless devices (modems, LANs)	0.25	2	
Mobile telephones (USA)	0.6	3	
Hand mobile telephones (GSM, NMT, Europe) (DECS 1800)	2 8	6 11	
Walkie-talkie (police, firemen, protection, maintenance)	5	9	
Bag mobile telephones	16	16	
Mobile radio (police, firemen, protection)	100	40	



Currents diagrams (tolerance $\pm 20\%$)- They include following diagrams:
 1- The change of output powers (with loads from 10 to 1000 Ω) by setting the 100% and the 50% of the maximum power Maximum power W (power) \blacktriangle / Ω (loads) \blacktriangleright
 2- The increase of the output power (with the rated load) versus the power setting increases W \blacktriangle / Setting \blacktriangleright
 3- The change of the peak-to-peak voltage versus the power setting increase Vpp \blacktriangle / Setting \blacktriangleright
 The measurement is performed in accordance with IEC 60601-2-2 (Values detected within 3 seconds by excluding transients < 1 sec).

