TEKNO TOM 80

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CE 0483

INTENDED USERS

These devices are to be used only for the purposes described in this guide and only in operating rooms or suitable clinics. from qualified users who are familiar with electrosurgery and its risks and side effects, and who observe all the information and warnings listed in this manual.

HOW TO USE THE MANUAL

Read the manual carefully before use and check the performance before using the device on patients. Don't rely solely on experience with similar devices. Keep the manual at the place of use of the device and replace it if lost. If the manual is not sufficient for your specific requirements, contact TEKNO-MEDICAL or your local dealer directly for the necessary information or to replace the manual in case of loss.

The manufacturer is responsible for its function, reliability, and safety only if the equipment is used in an area that complies with all applicable IEC standards, if the installation and use is carried out in accordance with the information contained in this manual using original accessories, and if repairs or periodic checks are carried out by authorized personnel using genuine spare parts. Upon request, TEKNO-MEDICAL will provide users with the relevant wiring diagrams and any other technical or practical information.

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Content

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1 INTRODUCTION AND DIRECTIONS OF USE

(Physical and electrical principles of the HF currents – Related risks)

When electrical currents flow across biological tissues, they produce 3 effects: Electrolytic, Faradic and Thermal.
By applying a current, with frequency higher than 300kHz (named HF current), the electrolytic / faradic phenomena disappear or are very limited and the thermal one remains. This effect 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 the tissues, it warms it and generates what follows:
A heating so rapid that the vapor pressure into the internal and external liquids of cells breaks their membranes and provokes their division: **Pure Cut;**
A heating, slower, which permits to the liquid to evaporate very slowly; in this way, the coagulating parts of the tissues can coagulate: **Coagulation;**
A process which is in the middle between the two phenomena described above: **Coagulating Cut.**

⚠ This device allows the use of the HF currents in 2 ways: **MONOPOLAR** and **BIPOLAR** MODE

MONOPOLAR MODE
This mode requires the use of two electrodes (the active one, small and used on the point of operation; the neutral one, large and fixed on a different part of the patient's body) and the current flows from the active to the neutral electrode. The thermal effect affects all tissues included between electrodes.

BIPOLAR MODE
Also this mode requires two electrodes, but they are included in the same instrument and are very closed.
In this case the thermal effect produced by the current affects only a very small quantity of tissues.

1.1 Risks caused by the use of HF-currents

The HF surgical devices are basic to solve surgical needs, but the use of HF currents, mainly when the monopolar mode is used, presents also some risks. Here under some examples are detailed:

Burns, on the patient's tissues where the neutral electrode is placed, caused by not sufficient 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. In fact, the normal sparks generated during the delivery of power can ignite them.
Bad functioning of other devices (pace-maker, video systems) provoked by EMC interferences emitted during the delivery of the HF currents;
Damages of the patient's tissues caused by a delivery of too high powers.
Slight neuromuscular stimulation, notably while using currents for coagulation, where the active electrode and neutral electrode are used. This stimulation can be felt by patients or surgeons like "an electrical discharge".

1.2 Directions for use

These devices are usable for following uses: Monopolar cut / coagulating cut, Monopolar coagulation, Monopolar cut or coagulation under liquid by using small instruments and Bipolar coagulation during all operations of small/medium surgery in surgeries, OT and similar places. These devices are usable for following fields: Gynaecology, Dermatology, Plastic and Aesthetic Surgery, ORL, Maxillofacial Surgery, Other Surgeries, Gastroenterology, Veterinary.

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2 IMPORTANT WARNINGS

Following warnings are vital to use these devices in the best and safest possible way.
Some warnings are inserted 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 it has a poor renal function or cardiovascular insufficiency.

2.2 Flammable substances or explosive gases

All HF units produce during the power delivery small 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 Electro-magnetic interferences

The unit complies with all EMC standards, but it can, mainly during the monopolar use, damage the functioning of:

- **Other devices used in O.T.** (i.e. monitoring devices, video-cameras, and so on).
  To reduce this problem, connect the ESU to a mains socket different from that used to supply these devices and, if necessary, ask for qualified technical assistance.
- **Pace-Makers, neuromuscular stimulators or other implanted devices**
  When operating on patients with these devices, ask for qualified advice from the Cardiology Division.

Remember that the bipolar mode is the best solution to operate these patients.

2.4 Preparation and positionig of the patient

Operators, when using a HF unit, must avoid all causes which can badly affect the path of the current and the related thermal effect inside tissues because they cause the following risk:

Burns of the patient's tissues where the density of current is too high. For example:

- An implanted metallic prosthesis concentrates the passage of the current in the surrounding tissues.
- Damp/wet sheets placed under or around the patient and the metallic trocars for laparoscopy can
- cause an anomalous passage of the current.

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To reduce this risk users must do the following:

- Take all the metallic objects off the patient (rings, etc.), remember also that the metallic elements (prosthesis, catheters, etc.) on the path of the current may cause increases of density of current;
- When performing a laparoscopic procedure, check the insulation of trocars and instruments;
- With dry sheets or other suitable materials insulate the patient from any metallic part connected to earth or which may conduct electricity (operating table, supports). In the same way insulate the patient from the heating mattress and the secreting parts of the body or the contacts skin-to-skin (i.e. between arms and body).
- Remember that also the sweat can affect the insulation.
- During the operation, mainly if the patient is moved or liquids are poured, verify if the insulation remains good.
- When preparing the operating field, don't use flammable disinfectants and take care that the used disinfectants do not wet the sheets positioned under or around the patient. Also dry the traces of disinfectant on the skin.
- Place all the not specifically protected monitoring electrodes as far away as possible from the electrodes of the HF unit. Avoid, if possible, the use of needle type or very small monitoring electrodes;

2.5 Use of the neutral electrode

When using monopolar currents, the bad contact of the neutral electrode causes two specific risks:
Burns on the tissues where the neutral electrode is fixed because the passage of the current is not homogeneous (it flows through areas with better contact and worse contact) and it produces, in the areas with better contact, a thermal effect so high to cause burns.
The bad functioning of the HF unit which leads users to raise the delivered powers and increases, in this way, the risk of burns where the neutral electrode is positioned (higher power = higher risk).
In order to obtain the best and homogeneous contact, choose, use and place the neutral electrode (NE) as follows:

- Check that the NE, if it is a reusable type, is not either worn or damaged.
- Place it on an area of the body as close as possible to the intervention point (the ideal is a soft part without hairs, protuberant bones or superficial differences), but which not get wet both when preparing or disinfecting the operating field and during use. Clean this area, shave it and massage it in order to improve the circulation.
- Normally, the better points are calf and thigh, but obviously if the operation does not affect these areas.
- Fix the NE properly with the best possible contact, without placing anything in between, but do not press
- it too much, in order to avoid ischemic zones. Avoid anomalous contacts (i.e. When positioning the patient's arm on the operating table, insulate the hand/ the fingers from the neutral electrode).
- When preparing and disinfecting the operating field, avoid wetting the NE or the related area.
- During use, mainly if the patient is moved or liquids are poured, verify if the intended contact remains constant.
- For the choice, according to specific needs) of the best "disposable" NE; contact the Technical Service.
- Use a disposable NE only once and follow its instructions. The right dimensions are approx. 136cm2 for patients with body weight higher than 15 Kg; approx. 84cm2 for children with body weight from 5 to 15 Kg.
- When using adhesive NE, do not rely on their characteristics only. The use of a supplementary fixing grants a more reliable contact (i.e. an elastic bandage, able to cover the entire NE, but without pressing it too much).
- Remember that, mainly when high powers are used, if a "Split" NE is not used, the control circuit of the unit can't verify the contact between the NE and patient's tissues; that is, it does not guarantee the intended safety.
- When fixing a "Split" NE, set it to obtain the same distance between both the parts of the NE and the operation area (i.e. when intervening on the abdominal area, if the NE is on the thigh, place it lengthwise on the leg).
- As the space between the NE and the operating area represents a sort of "path" for the HF current, be sure that it does not across diagonally the body or it crosses the heart.

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2.6 Use of all the active accessories

- The standard monopolar pencils of the company are suitable to connect active electrodes with stems having a diameter of 2, 3 mm.
- Never use accessories not compliant with all applicable standards, not well insulated, not suitable for the following working voltages: (About 4500/5000 Vpp. “2250/2500 Vp” for the monopolar currents) (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 and 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.

2.7 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.

2.8 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.

2.9 Specific use of the monopolar and bipolar instruments for laparoscopy

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

- Always check the good insulation of trocar cannulas.
- Use the instrument under visual control and, after each withdrawl; check that all parts are present.
- Maintain a correct distance between the ends of the instrument and sensitive structures of the tissue.
- Activate the current only if the ends of the instrument are in contact with tissues.
- Never use, during the operation, a hot instrument (An instrument with hot ends) as instrument for preparing.
- Never use currents for coagulation with automatic start/stop system.

When using bipolar instruments for coagulation and vessel sealing, do also the following:

- 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.

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2.10 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.
- Always use the lowest possible power and never use a monopolar power higher than 100W when using neutral electrodes for
- Pediatrics and 50/70W using electrodes for new-born.
- 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.
- 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 use, (See 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).

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2.11 Specific problems (Minor surgery, Veterinary)

During the use in minor surgery and the patient is not fully anesthetized, a phenomenon felt like “electrical discharge” can occur.
It is not a dangerous electrical discharge since HF currents can only cause burns, but it is a slight neuromuscular stimulation that is a normal side effect of the HF current (mainly while delivering monopolar coagulations). To avoid / reduce it, do the following:

- Use surgical gloves to insulate the hand.
- If possible, avoid the contact with the ground (For example by using clogs, insulating chairs and so on).
- While using HF monopolar currents in veterinary, the risk of unexpected burns either where the animal touches the operating table or where operators place the neutral electrode is quite high because of that follows:
- The fur does not allow operators to obtain the good contact of the neutral electrode (Operators have to cut it).
- Sometimes animal dimensions do not allow the good positioning of the neutral electrode.
- Many times operators cannot insulate the animal from the conductive parts of the operating table.
- The disinfectants / liquids that come down through the fur produce anomalous paths of current that can cause burns.

To avoid or reduce this risk, do the following:

- Apply very carefully all the warnings of this paragraph about the use of the neutral electrode.
- If possible, use the bipolar coagulation (Forceps with large tips allow the obtaining of a very efficacious coagulation).

3 USE

3.1 General

- 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).

3.2 Connection of the foot-switch

- The foot-switch is pneumatic without electrical current; it means water-proof and explosion-proof usable in OT.
- Connect it as the paragraph Controls and Symbols details.

3.3 Connection of the neutral electrode and operation of its control circuit

The electrode is not needed to use the bipolar coagulation (The light 11 ON signals only that the electrode is not connected).
The cable connector is the international plug Ø 6, 35 mm.

- Connect the cable to the socket 6 (If needed, connect the cable to the electrode).

3.3.1 Operation of the control circuit (single area neutral electrode)

The circuit intervenes, activates alarms (Intermittent sound, light 11 and signal Err n-P ON) and blocks the power delivery if the cable is broken or not connected to the electrode and/or to the device.
In this case check the cable and its connection to the electrode or to the device.

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3.3.2 Operation of the control circuit (split neutral electrode)

The circuit intervenes as above if the cable is broken, if it is not connected to the electrode and/or to the device and if the contact between the electrode and patient tissues is poor and dangerous.
In this case check the cable, its connection to the electrode or to the device and the contact between electrode and patient tissues.

3.4 Connection of accessories

3.4.1 Monopolar handle / instrument

The cable connector is a plug Ø 6 with a hole Ø 4 mm.
Connect the accessory to the socket 7 (To insert the electrode into the pencil unscrew the two parts of the handle).

3.4.2 Bipolar handle / instrument

Connect the accessory to the socket 8
The connection does not require a specific polarity.

3.5 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) signaling 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 poker of currents used at the switching OFF.

3.6 Setting and adjustment of currents -

3.6.1 Setting of the currents for cut / coagulating cut

- Select the area 10 - CUT of currents by pushing the keys 4A or 5A (The display of the deactivated area blinks).
- Push the key 4A and select the first current you like. For example, PURE = 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 > BPULSED 1 > BPULSED 2 > PURE >>)

PURE – Pure cut	**PPULSED** – Pulsed pure cut	**BLEND** – Coagulating cut
BPULSED 1 – Pulsed coagulating cut	**BPULSED 2** – Slowly pulsed coagulating cut	

- 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.

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3.6.2 Setting of the currents for monopolar or bipolar coagulation

- Select the area **9 - COAG** of currents by pushing the keys **4B** or **5B** (The display of the deactivated area blinks).
- Push the key **4B** and select the first current you like. For example, **MICRO** – micro coagulation (the related led switches on).
- 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

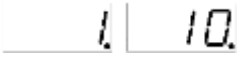
By pushing the key 4B, all currents can be selected progressively (**MICRO** > **MPULSED** > **FULG** > **FPULSED** > **BIPOLAR** > **MICRO** >>)

MICRO – Delicate coagulation	**MPULSED –** Pulsed delicate coagulation
FULG - Macro coagulation "fulguration"	**FPULSED –** Pulsed macro coagulation "fulguration"
BIPOLAR – Bipolar coagulation	

- 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.

3.6.3 Temporization of the Micro coagulation (from 0.1 to 1 sec)



- Push the key 4B and select the **MPULSED** current.
- Push again the key **4B** for 3-4 seconds
- The display changes and shows times: from one tenth of second (1.) to one second (10).
- Adjust the time by keys **5B** and push again the key **4B** (The display shows again the power level).
- The device memorizes the set time that can be always changed in the same way to set the best value in order to obtain the proper result.

3.7 Activation of all currents by the foot-switch

- To activate a cut current select the area **10-CUT** by pushing keys **4A** or **5A** (The display of the deactivated area blinks).
- If you want to use a current different from the already memorized one, select it by the key **4A**
- Push the foot-switch (the unit signals the activation by the yellow light ON and a grave sound).
- To activate a coagulation current select the area **10-COAG** by pushing keys **4B** or **5B** (The display of the deactivated area blinks).
- If you want to use a current different from the already memorized one, select it by the key **4B**
- Push the foot-switch (the unit signals the activation by the blue light ON and an acute sound).
- To use pulsed currents (**PPULSED**, **BPULSED1**, **BPULSED2** and **FPULSED**) push the pedal continuously.

The delivery is automatically pulsed.

- To use the temporized monopolar coagulation MPULSED push the pedal.

Each time you push the pedal the delivery is very short (from 0,1 to 1 second) automatically.

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

3.8 Activation of monopolar currents by the hand-switch

Activate the power delivery directly by pushing the buttons of the pencil (yellow = **cut**) (blue = **coagulation**).
The device operates as above detailed for the single foot-switch.

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3.9 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)

3.10 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 adjustement).

3.10.1 PURE (monopolar pure cut without coagulating effect).

It is suitable to obtain each pure cut: uterine conization in gynaecology, papillotomy in flexible endoscopy, cut under liquid for minor isteroscopy and so on. It gives better results by using thin electrodes:

- Needle, knife electrodes (Starting settings from 3-4).
- Thin loop electrodes or very thin needle electrodes: tk90081-10*, tk90081-15*, tk90081-20*, tk90081-40* from 0.1 to 0.4 mm. (Starting setting from 3-4).
- LLETZ/LEEP electrodes for conization (Starting setting from 10).
- Electrodes for papillotomy (Starting setting from 20/30).

3.10.2 PPULSED (monopolar pulsed pure cut- fast).

It is identical to the **PURE** cut and is usable with same electrodes and powers, but it is more suitable to obtain very fine cuts.

3.10.3 BLEND (monopolar coagulating cut).

It is suitable to obtain a properly coagulating cut and it is usable with the identical electrodes and settings of the **PURE** cut.
It is also suitable to perform polipectomies (starting setting from 20/30).

3.10.4 BPULSED1 (pulsed monopolar coagulating cut - fast)

It is identical to the **BLEND** cut and is usable with same electrodes and powers, but it is more delicate.

3.10.5 BPULSED2 (pulsed monopolar coagulating cut - slow)

It is identical to the **BLEND** cut, but it is especially suitable to perform polypectomies (starting setting from 20/30).

3.10.6 MICRO (delicate coagulation with minimum sparking).

It is suitable to perform all micro coagulations (i.e. the epilation) and the coagulation of not bleeding tissues by using following electrodes:

- insulated thin needle for epilation (starting setting from 1-2).
- very thin not insulated needles from 0.1 to 0.4 mm. (starting setting from 3-4).
- ball electrodes 2-2,5mm (starting setting from 15-20).
- ball electrodes 3-4mm (starting setting from 20-30).

3.10.7 MPULSED (coagulation with delivery time from 0,1 to 1,0 sec)

It is identical to the **MICRO** coagulation, but grants to its very short delivery time is the best to perform all micro-coagulations.

- insulated thin needle for epilation (starting setting from 1-2 and starting pulse 0,3 sec.).
- very thin not insulated needles from 0.1 to 0.4 mm. (starting setting from 3-4 and starting pulse 0,3 sec).
- ball electrodes 2-2,5mm (starting setting from 15-20 and starting pulse 0,6 sec).
- ball electrodes 3-4mm (starting setting from 20-30 and starting pulse 0,6 sec).

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3.10.8 FULG (macro coagulation "fulguration" with high sparking)

It is suitable to coagulate all both bleeding and not bleeding tissues by using following electrodes:

- needle, knife or loop electrodes, ball electrodes and surgical forceps (starting setting from 20-30).
- LLETZ/LEEP electrodes for conization (starting setting from 20-30).
- loops for flexible endoscopy (starting setting from 20-30).
- It is perfect to perform a cut with strong coagulating effect by using needle or knife electrodes (starting setting 20-30).

3.10.9 FULG PULSED (Pulsed macro coagulation "fulguration)

It is identical to the **FULG** coagulation, but it is more suitable for same uses if users like a more delicate result.

3.10.10 BIPOLAR (bipolar coagulation).

It is suitable to perform bipolar coagulations with following instruments:

- bipolar forceps (If provided with tips 0,5/1mm, starting setting 1-2) (If provided with tips 1,5/2mm, starting setting 4-5)
- needles for turbinals or similar uses (starting setting from 20 – 30).
- forceps for laparoscopy (starting setting from 20 – 40).

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 bloks the power delivery by informing users with acoustic and/or visual signals named **ERROR CODES**.

4.1 Error codes

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.
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.
Error codes 12, 13 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, **13** = Buttons of the hand-switch pencil , **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).
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).
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).

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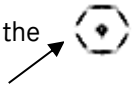
Problems not detectable by the self-test system.

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 and the proper connection of the monopolar neutral electrode as detailed in the paragraph IMPORTANT WARNINGS (Mainly points: Use of currents and powers and Specific problems (Minor surgery, Veterinary)

5 POSITIONING AND MOVEMENT, STORAGE, CLEANING AND STERILIZATION

When not used, keep 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.
- **Do 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.

6 CONSUMABLES, TECHNICAL CHECKS AND DISPOSAL

6.1 Consumables

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:

6.2 In accordance with general standards IEC 60601-1.

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

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

- Check of electrical safety (High Frequency Leakage currents and so on).
- Check of the operation of the control circuit of the neutral electrode.
- 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,

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6.4 Disposal

According to the article no. 13 of the Legislative Decree no. 151 dated 25th July 2005 "Fulfilment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, for the reduction in the use of dangerous substances in electric and electronic devices, as well as for the waste disposal": The symbol on the left is present either on the unit or on its packaging and it indicates that the product must be separately disposed of.
The separate waste collection of this kind of unit is arranged and managed by the manufacturer. Therefore, the user, to dispose of an old unit, must contact the producer and follow the procedure which it established. The correct separate collection for the recycling process, for the treatment and the eco-friendly disposal of the old unit, contributes to avoid any possible negative effects on the environment or on human health and it helps the recycling of the materials that compose the unit. The illegal disposal of the product by the user implies the imposition of the fines established in the Legislative Decree no. 22/1997 (art. 50 and following).

7 TECHNICAL DATA

7.1 Technical features

Generator: Electronic type, compliant with IEC 601-2-2 standards and suitable for monopolar and bipolar usesl
Working frequency: Monopolar/bipolar working frequency 450kHz +- 10%.
Generator PER: 97%.
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 I IPN$_3$N$_2$ = Protected against the ingress of solid objects ∅ ≥ 2,5 mm and against water drops when tilted up to 15°.
Foot-switch IPN$_3$N$_2$, = 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
Self-test system: By microprocessor with self-checks and ERROR CODES
Neutral electrode (single area and double area) control: Specific circuit with power delivery block and alarm signals.
Supply cord: 2meters, section 3x0,75 mm2.
Dimensions and weight: cm (WxDxH) 22x24x12 – about Kg 4.5

7.2 Environmental and atmospheric conditions for use, transport and storage

For use: Temperature (°C) +10 ÷ +40. Humidity 30% ÷ 75%. Pressure (hPa): 700 ÷ 1060.
FOR TRANSPORT AND STORAGE: TEMPERATURE (°C) -40 ÷ +70. HUMIDITY 10% ÷ 95%. PRESSURE (HPA): 500 ÷ 1060.

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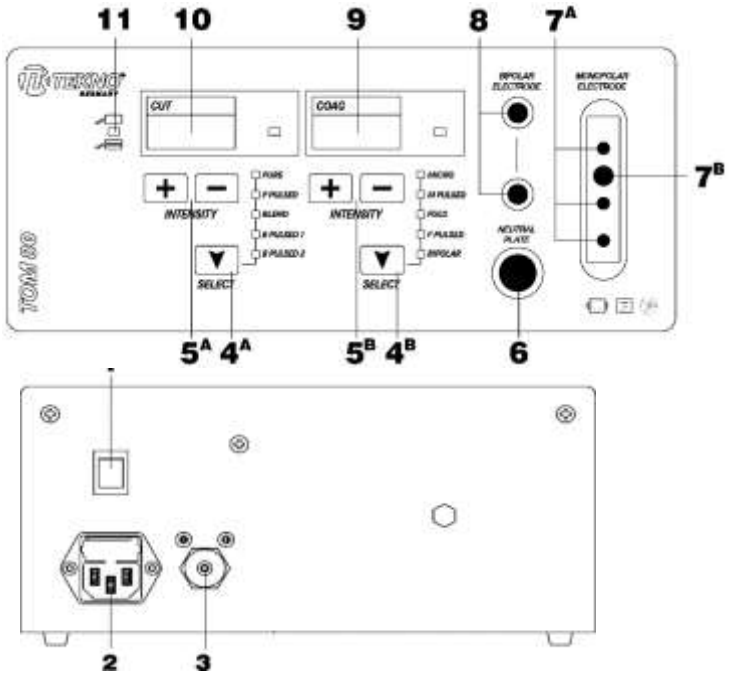
7.3 Currents and Powers

S: Setting - **W**: Power (Watts) - Ω: Rated load – **Vpp**: Open circuit peak to peak voltage - **CF**: Crest factor – **M**: Modulation - **DT**: Duty Cycle –

Current	S	W	Rated load	VPP / CF / M / DT
PURE	140	140	500 Ω	**Vpp** 1000 – **CF** 1.5 – **M** 0% - **DT** 100%
PPULSED	140	70	500 Ω	**Vpp** 1380 – **CF** 3 – **M** 50% - **DT** 100%
BLEND	120	120	500 Ω	**Vpp** 1400 – **CF** 2.3 – **M** 0%, **DT** 80%
BPULSED1	120	60	500 Ω	**Vpp** 1550 – **CF** 3.5 – **M** 50%, **DT** 80%
BPULSED2	120	38	500 Ω	**Vpp** 1580 – **CF** 3.6 – **M** 50% - **DT** 80%
MICRO	80	80	500 Ω	**Vpp** 1530 – **CF** 3.4 – **M** 0% - **DT** 50%
MPULSED	80	80	500 Ω	**Vpp** 1530 – **CF** 3.4 – **M** 0% - **DT** 50%
FULG	120	120	750 Ω	**Vpp** 2300 - **CF** 3.5 - **M** 0% - **DT** 50%
FPULSED	120	60	750 Ω	**Vpp** 2300 - **CF** 5 - **M** 50% - **DT** 50%
BIPOLAR	100	100	100 Ω	**Vpp** 500 - **CF** 2.8 - **M** 0% - **DT** 100%

The **MPULSED** current delivers single pulses that are long from 0,1 to 1 second and, by setting the same power, it produces a stronger practical effect when the pulse is long and a lower practical effect when the pulse is short.
To obtain the intended effect, users must adjust both the power and the pulse lengt

8 CONTROLS AND SYSTEMS



1) Mains switch.
2) Mains cord socket with fuses inlet.
3) Socket for the foot-switch
4) Key of currents selection
- **4A**- Pure cut / coagulating cut (yellow).
- **4B**- Monopolar and bipolar coagulation (blue).

5) Keys of power adjustment
- **5A**- Pure cut / coagulating cut (yellow).
- **5B**- Monopolar and bipolar coagulation (blue).

6) Socket for the neutral electrode
7) Socket for the monopolar instrument.
- **7A** Connection of the monopolar hand switched instrument
- **7B** Connection of the monopolar foot switched instrument.

8) Socket for the bipolar instrument
9) Display and light COAG (coagulation)
10) Display and light CUT (cut)
11) Alarm light of the neutral electrode (red).

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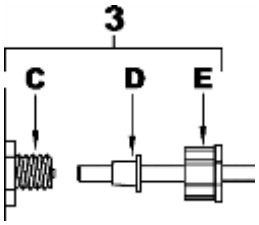
Connection of the foot-switch (tk 90018-00)

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

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



I = ON 0 = OFF	Alternate 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)
Microcellular telephones CT1,CT2,CT3	0.01	0.4
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
Mobile telephones	16	16
Mobile radio (police, firemen, protection)	100	40

For broadcasting stations which use frequencies less than 800MHz, the distance can be established by using the equation: A: $d = 4\sqrt{P}$
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)

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9 CURRENTS

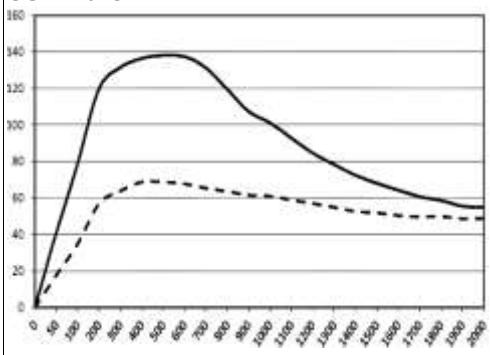
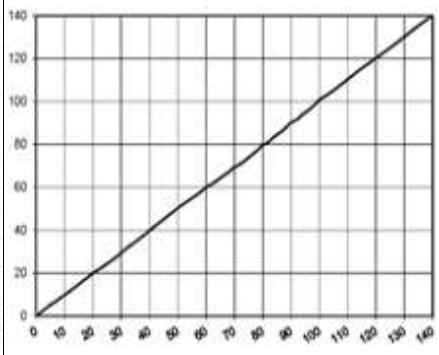
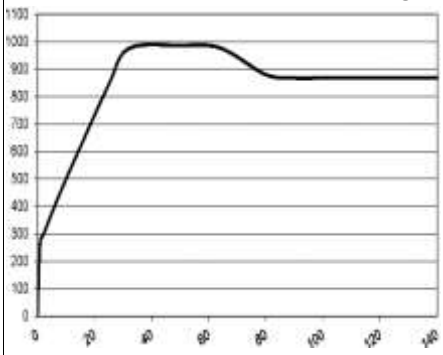
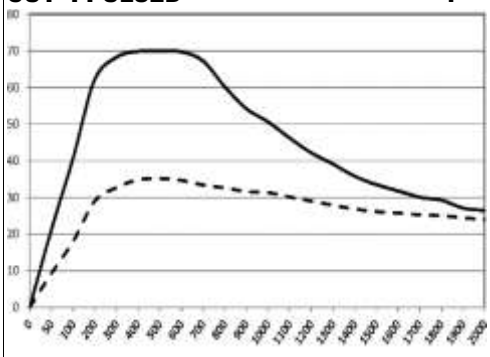
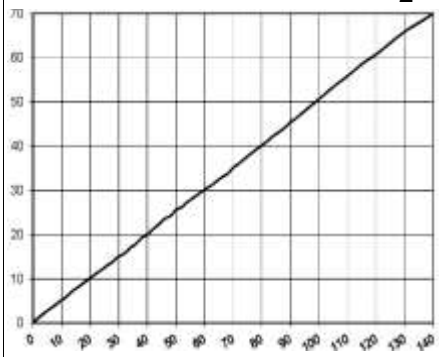
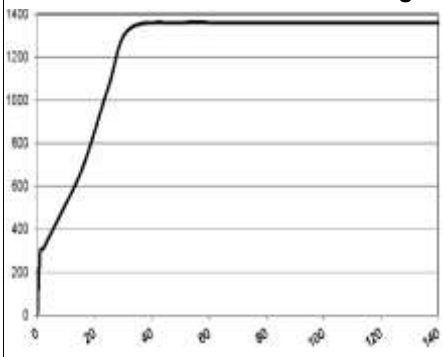
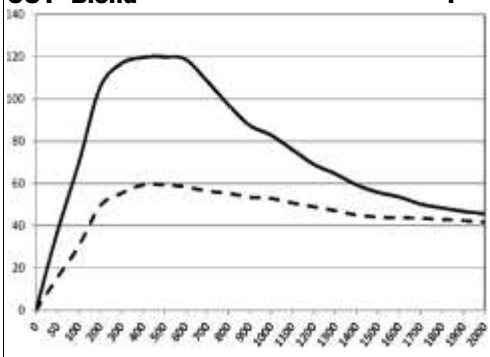
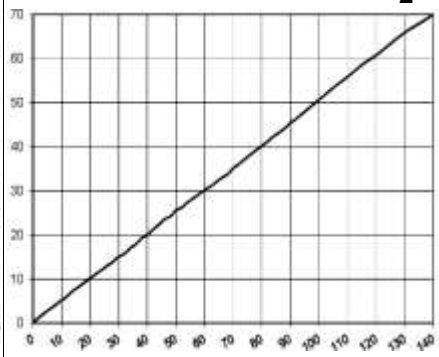
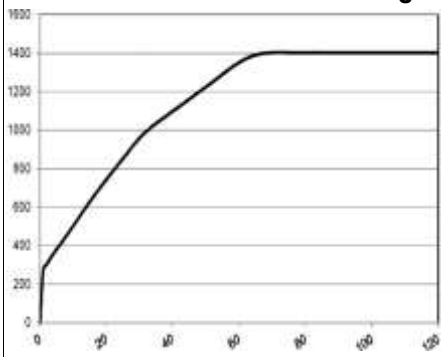
Currents diagrams (tolerance ± 20%)- They include following diagrams:

1- The change of the monopolar output power (with loads from 50 to 2000 Ω) by setting the 100% and the 50% of the maximum power
Maximum power **W (power) ▲ / Ω (loads) ►**
The change of the bipolar output power (with loads from 10 to 1000 Ω) by setting the 100% and the 50% of the maximum power
Maximum power **W (power) ▲ / Ω (loads) ►**

2- The increase of the output power (with the rated load) versus the power setting increase **W ▲ / Setting ►**

3- The change of the peak to peak voltage versus the power setting increase **Vpp ▲ / Setting ►**

The measurement is performed in accordance with IEC 60601-2-2 (Values detected within 3 seconds by excluding transients < 1 second).

CUT- Pure **1**  ▲ ►	**2**  ▲ ►	**3**  ▲ ►
CUT- PPULSED **1**  ▲ ►	**2**  ▲ ►	**3**  ▲ ►
CUT- Blend **1**  ▲ ►	**2**  ▲ ►	**3**  ▲ ►

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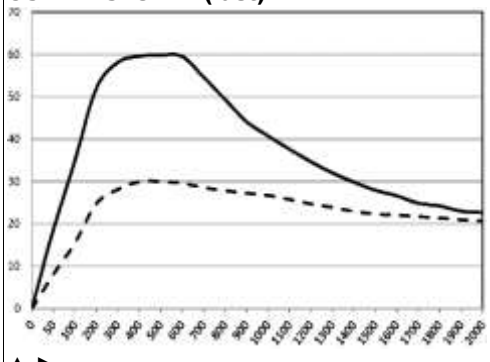
CE 0483

CUT- BPULSED1 (fast)

1



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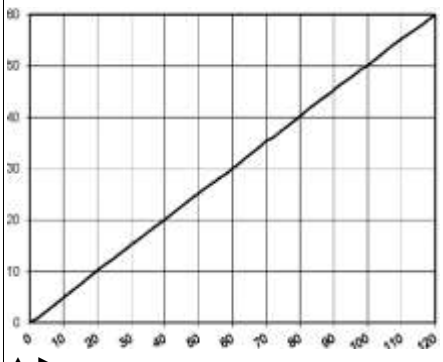

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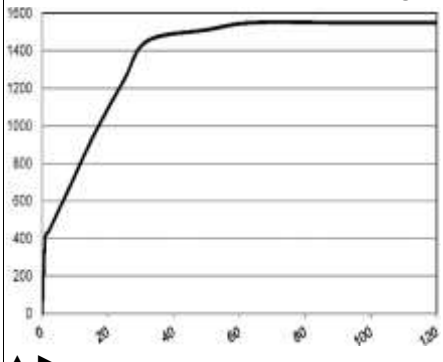
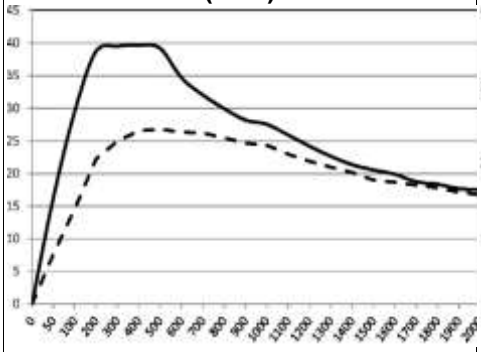


CUT- BPULSED2 (slow)

1



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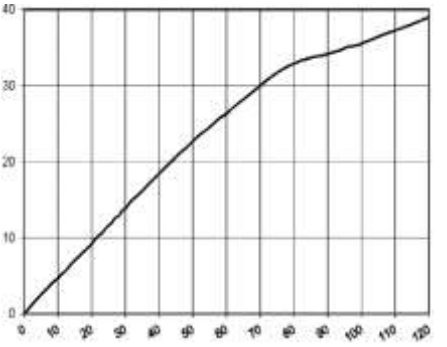

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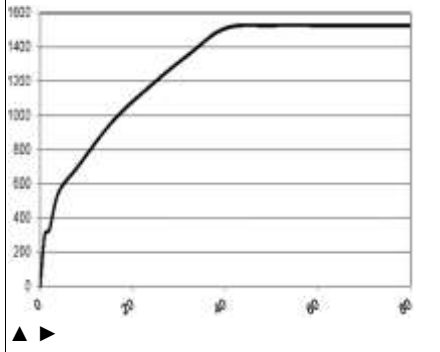
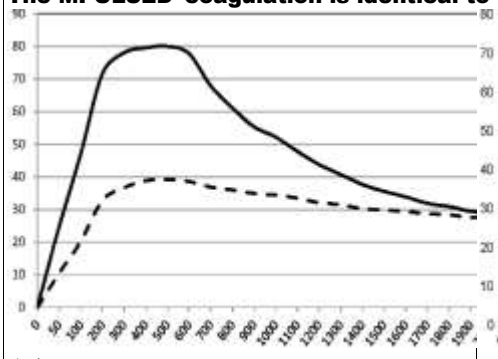


COAG- Micro

1

The MPULSED coagulation is identical to the Micro



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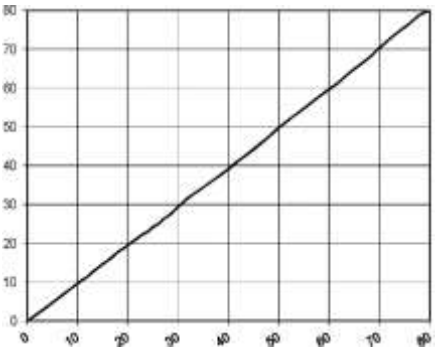

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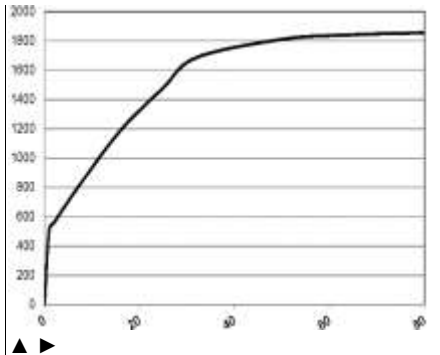
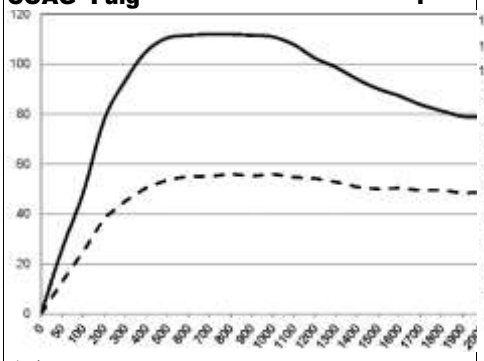


COAG- Fulg

1



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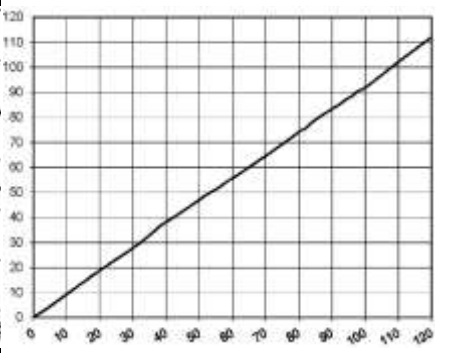

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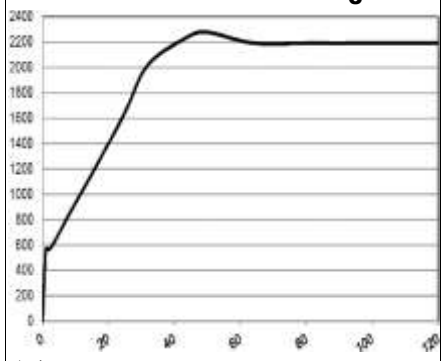

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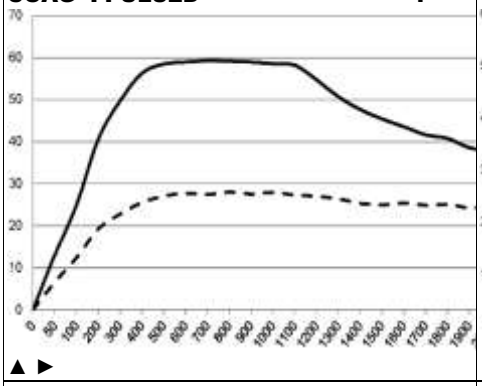
COAG- FPULSED 1



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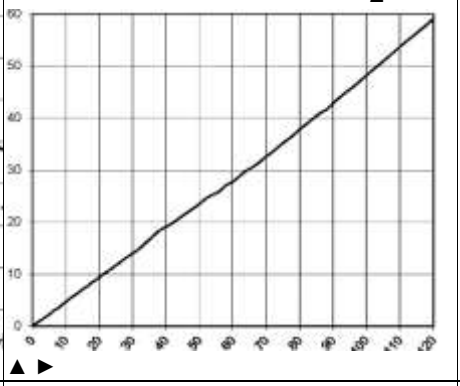

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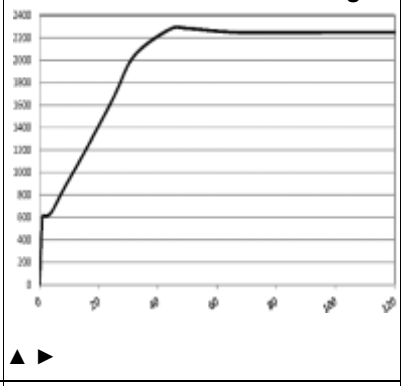

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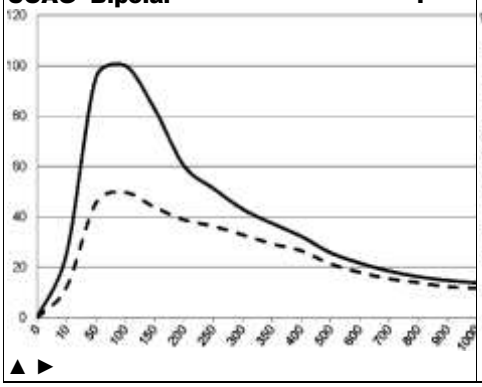
COAG- Bipolar 1



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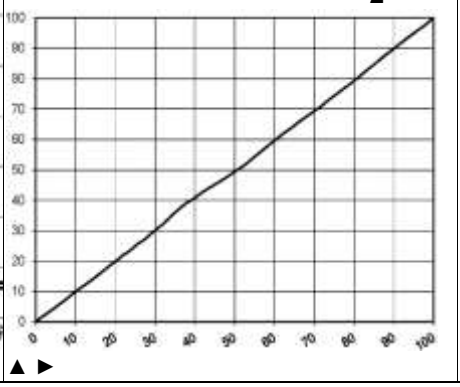

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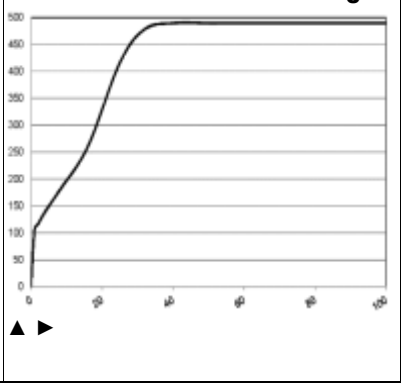

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