TEKNO TOM 141DPS

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CE 0483

USER

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.

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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, the company will provide users with the relevant wiring diagrams and any other technical or practical information.

Content

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1 SELF-TEST WHEN SWITCHING ON

Each time it is turned on, the device will perform a full self-test, which will only stop if the device is working properly. When the self-test detects problems, it does not terminate, but aborts and reports the problem (certain error codes light up on the control panel displays).

The system checks the operation and the currents supplied during use, and in case of problems, blocks the power supply and reports the problem as described above. The complete explanation of the SELF-TEST SYSTEM can be found in the section AUTOMATIC SELF-MONITORING SYSTEM.

2 RADIOFREQUENCY SURGERY AND ASSOCIATED RISKS

Electrosurgery is based on the heating generated by a high-frequency electric current (> 300 kHz) in the biological tissues through which it flows. This warming can be:

- **Strong, fast** – the vapor pressure breaks down cell membranes and destroys them**: Pure Cut.**
- **Less and slower** – the cell fluids evaporate along with the tissue's coagulation components: **Coagulation** .

Between the previous two: **Blend Cut** (a first step from the Pure Cut to a slight coagulation behaviour)
This device allows two power uses: **MONOPOLAR** and **BIPOLAR.**

Monopolar operation - In this procedure, two electrodes are used (an active, small one, placed at the site of the procedure, and a neutral, large one, placed on another part of the patient's body). The current flows from the active electrode to the neutral one. Therefore, the thermal effect affects all tissues in between (it peaks where the active electrode touches the tissue).
Bipolar surgery – This procedure also uses two electrodes, but they are contained in a single instrument and are very close to each other. In this case, the thermal effect only affects the small amount of tissue between the tips of the instrument.

These currents are fundamental to solving many surgical problems, but they also entail specific risks. For example:

- **Burns to patient tissue** at the location where the neutral electrode is positioned due to excessive heat.
- **Burns to the patient or operator** due to the ignition of flammable substances or by the explosion of explosive gases caused by the normal sparks generated by the equipment when it is supplied with electricity.
- **malfunctions of other devices** (e.g. video systems, pacemakers) due to electromagnetic interference emanating from the device.
- A light **neuromuscular stimulation** caused mainly by coagulation currents that patients feel as "electric shocks" at the points where the electrodes touch the tissue.
- **Harm to the patient** due to the use of too strong or too weak currents.

3 INDICATIONS FOR USE

These units are suitable for monopolar (cutting, coagulation, cutting and coagulation) and bipolar (coagulation) application in all small/medium surgical procedures performed in clinics, operating theatres or similar environments (including coagulation and cutting in a liquid environment with small tools). These units can be used for: *gynaecology, dermatology, plastic surgery, ENT, maxillofacial surgery, gastroenterology.*

3.1 Important warnings

These devices have never caused adverse events and high-frequency surgical currents are vital in solving many problems, but they can cause unwanted side effects.
To reduce risks, international standards specify both the technical characteristics of the equipment and the warnings to be observed.

3.2 General warnings

- Do not make any modifications to the appliance and use it only if the electrical system complies with the regulations in force.
- Make sure that the device does not fall or be crushed. Place it on a firm and non-bulky surface, away from the patient and without accidental bumps. When not in use, turn it off with the power button.
- Place the appliance at least 30 cm away from walls or objects that could obstruct the cooling area.
- Do not use power extension cords and check with the technical department for compatibility when using different devices at the same time.
- Observe the recommended working hours and avoid unnecessary short circuits between the electrodes.
- The device does not allow the storage of personal patient data. The operating software does not exchange data outside the device.

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3.3 Initial

The initial installation of the device is risk-free, but must be carried out by qualified professionals who will turn on the device and check the condition of the supplied accessories.

3.4 Electrosurgical smoke extraction

The fumes produced during the use of electrosurgical devices are harmful to health. Therefore, special smoke vents must be used to reduce the risks to operators and patients.

3.5 Self-test of the company

The devices have self-test systems that detect equipment failures and possible usage errors both during operation and by a self-test every time they are switched on. In the event of malfunctions and abnormal power output, the systems block operation and inform operators by means of audible and/or visual signals (**ERROR CODES**).
Therefore, if the device does not provide power during operation, or normal performance seems less effective, but it has passed all self-tests and the systems do not report any problems, you should avoid increasing the power setting and perform further tests on the connected accessories.

The exams are as follows:

- Check that the neutral electrode is in proper contact (when using monopolar currents).
- Check the accessory cables and connectors by bending and pulling (the greatest risk of breakage is on the device side).
- Check the correct assembly of all monopolar or bipolar instruments and clean both the instrument tips and the joints of the bipolar instruments (if dirty, they can obstruct the flow of electricity to the tissue).
- Check the insulation of the blades of the bipolar scissors (if damaged, the current will not be able to reach the tissue).

3.6 Use of flammable substances or explosive gases

When emitting electricity, electrosurgical devices generate sparks that can ignite endogenous gases (e.g. in the intestine), explosive gases (e.g. oxygen, nitrogen dioxide) or materials soaked in these gases (cotton, gauze, cloths), as well as flammable products (disinfectants, solvents, cleaning agents) or materials soaked in these products (cotton, gauze, wipes). To mitigate these risks, do the following:

- Do not use the device in the presence of explosive/flammable gases and flammable substances. International standards require that flammable disinfectants must be completely evaporated before using a device. Carefully follow the instructions. Also, do not pour them indiscriminately into cavities (e.g. the navel).

3.7 Electromagnetic compatibility

The devices meet all applicable international EMC compatibility standards and are tested by expert panels, taking into account their operating environment (operating rooms and similar environments) with original accessories and 5 m cables.
The following should be observed:

- To avoid damage to the equipment or other equipment, use only original accessories.
- Bear in mind that electromagnetic interference from other devices can interfere even if the device meets all immunity requirements, and that it can interfere with the device's self-monitoring systems.
- Also, keep in mind that the device generates electromagnetic interference during power delivery, which can affect the operation of other devices used in the same location (such as patient monitors or video cameras). If possible, do not use the electrosurgical device on or near these devices (otherwise, check that they are working properly by activating the current delivery).

The tables on emissions and immunity can be found on S. 18

4 CONTRAINDICATIONS

The device is not suitable for patients with neuromuscular stimulators, pacemakers (these can lead to heart fibrillation, for example) or other implanted devices.
If the use of these devices is necessary for patients with such devices, contact the Cardiology Department and/or the Technical Department for qualified advice. The use of the bipolar procedure is the best solution in these cases.

4.1 Reporting product issues

According to 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.

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4.2 Patient population

All persons, whether adult or paediatric, who receive or are registered for surgical treatment. Patients who are not suitable for treatment with the HF surgical device are those with very severe heart problems or physically weak people, unless the doctor decides to do so regardless of the warnings and instructions. There are no contraindications to the use of electrosurgical devices in pregnant or breastfeeding women; although no events (e.g., thermal damage to the embryo) have been reported, the bipolar procedure is recommended in pregnant women and laparoscopic surgery is discouraged.

4.3 Intended user

The device is intended for use by qualified physicians who have already gained experience in the use of radiofrequency surgical devices and are adequately trained in the associated risks, problems and effects of this surgical technique.

4.4 Preparation of the patient

During longer surgeries, position the patient carefully to reduce the risk of pressure ulcers and burns.

A high current density can cause burns in the tissue through which it flows.
To reduce this risk, do the following:

- Remove all metal objects from the patient, including prostheses and catheters if possible.
- In laparoscopic surgery, check that the trocars and special instruments are well insulated.
- Isolate the patient from the metal parts of the operating table or heating mat with dry cloths or suitable materials, isolate the parts of the body with heavy secretion (sweat can also affect the insulation) and skin-to-skin contact (for example, between arms and body).
- During surgery, check that the insulation remains good, especially if the patient is moved or fluids are poured out.
- When preparing the surgical field, make sure that the wipes placed under or around the patient are not wetted with disinfectants. Dry all traces of these disinfectants, as well as their stagnation in body cavities (for example, in the navel).
- Position the monitoring electrodes that are not specially protected as far away from the power passage area as possible. Do not use needle or small monitoring electrodes.

4.5 Using the Neutral Electrode

When using monopolar currents, incorrect contact of the neutral electrode with the patient's tissue can pose two risks:

- Burns in the tissues where the neutral electrode is placed, if the contact is insufficient or uneven.
- The malfunction of the unit causes operators to increase power, increasing the previous risk even further.

To reduce these risks, use neutral electrodes as follows:

- When using a reusable NE, the following minimum contact surfaces must have: Electrode for powers up to 160W: at least 78 cm ^{2}
- Before each use, check that it has no damage (for example, from cuts or clearly damaged areas).
- Place the electrode on a part of the body near the surgical site (ideally, a soft spot without bony protrusions or superficial bumps that does not get wet during the preparation of the surgical field or during the operation).
- The best spots are thighs or calf. Placement under the buttocks and only if the area does not get wet could be suitable for arthroscopy, for example, but not for abdominal or urological surgery.
- The upper body is not suitable for this, as there may be other electrodes (e.g. for monitoring) there.
- Clean, shave, and massage the attachment site to improve circulation.
- Attach the electrode reliably, without an intermediate layer and with the widest possible contact. Avoid applying too much pressure so as not to create ischemic areas or abnormal contacts: for example, when positioning the patient on the operating table, isolate the hands or fingers from the neutral electrode.
- When disinfecting the surgical field, make sure that the NE and the positioning area do not get wet.
- During use, check that the contact is good, especially if the patient is moved or liquids are poured out.
- To select the most suitable NEs for your specific needs, contact the Technical Office.
- Use single-use NEs only once, follow the appropriate instructions, and ensure that they are of an appropriate size in relation to the patient (approx. 136 cm² for adults weighing more than 15 kg, approx. 84 cm² for children weighing 5 to 15 kg).
- When using disposable adhesive films, do not rely solely on their adhesive strength. Double section (SPLIT) films are best, as they allow the device's control circuit to automatically verify the correct contact with the fabric, thus ensuring maximum safety, but only if their dimensions correspond to those described above.
- Position the double-piece electrodes so that the two parts are about the same distance from the surgical site (for example, if you are working in the abdomen and the electrode is on the thigh, place it longitudinally to the leg).
- Avoid that the course of the current crosses the body or the heart area diagonally.

ATTENTION! THE USE OF SPLIT (DOUBLE) ELECTRODES IS HIGHLY RECOMMENDED AS IT REDUCES THE POSSIBILITY OF BURNS IN THE AREA OF APPLICATION OF THE NEUTRAL ELECTRODE.

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4.6 Use of currents and power

If the power delivered exceeds about 160 watts, all the monopolar currents of these devices cause a strong heating of the tissue in which the neutral electrode is placed, which entails a higher risk of burns. To reduce this, always use the lowest possible power and carefully follow the warnings below as well as all instructions for using neutral electrodes.

- Always test the functionality of a new appliance (e.g. with meat) and do not rely solely on experience with similar appliances.
- Always choose a low power at the beginning and gradually increase it until you achieve the desired result. However, keep in mind that even low power can be dangerous.
- Always use the lowest power that will give you the desired effect. When using monopolar currents, you must not exceed a power of 80/100 W for neutral electrodes in pediatrics, 30/50 W for newborns, and 40 W for manual electrodes in dental surgery.
- Use the bipolar technique for surgery on sensitive or highly innervated tissues, small areas of tissue and cavities, or when working on patients with pacemakers or similar devices if you are unsure of the correct positioning of the neutral electrode.

4.7 Precautions after using the device

Turn off the device immediately after the operation is complete to avoid accidental activation.
With the device turned off, remove the connected accessories by grasping them by the connectors and avoid pulling them out by pulling on the cables.
For maintenance, unplug the appliance by unplugging the power cord from the socket on the back of the appliance.

5 USE OF ACCESSORIES

The maximum length of the accessory cables that can be used with these devices is 5 m, the monopolar handles are suitable for the use of electrodes with a Ø 2.3 mm shaft and the cables for bipolar tweezers for connecting tweezers equipped with an international flat plug.

- Before use, always check the accessories, electrodes, device and associated cables, and never use non-original accessories that do not comply with all applicable regulations (technical, legal, biological compatibility), that do not work properly or are worn or dirty, as this does not ensure safety and its operation is unstable, resulting in a dangerous increase in performance.
- Never use accessories that are not suitable for the operating voltages of this device listed in the technical specifications of the manual, that have damaged insulation, that do not have the shaft parts that are insulated when the monopolar active electrodes are inserted into their handles, or that have their connectors that are not insulated when connected to the device.
- Check the correct electrical connection between the monopolar electrode and the electrode holder handpiece (the test can be performed by placing a small wet sponge on the neutral electrode before positioning it on the patient's body and checking the presence of the operating spark or light smoke according to the contact between the electrode and the sponge when the device is turned on, as confirmation of a sufficient connection; a setting of 30/40 is sufficient for the test. Do not use demineralized or low-salt water, as it has poor conductivity).
- When positioning the electrode cables for surgery, avoid them coming into contact with the patient or other conductors.
- When not in use, place live accessories on insulating material during operation.
- To avoid undesirable superficial carbonization of the tissue, activate the supply of monopolar currents only when the active electrode touches the tissue.

5.1 Additional Warnings for laparoscopic and endoscopic surgery in a conductive Liquid

Use the instruments under visual inspection and check that they are complete when you pull them out. Do not activate force delivery until the tips are close to the fabric and/or touching the tissue.
For laparoscopic procedures, make sure that the tips are far enough away from the tissues/trocars. Do not allow unused instruments to come into contact with tissue, and never use an instrument with a hot tip to move or position tissue.
In the case of endoscopic procedures in a line fluid, the amount of solution used (incoming and outgoing volume) should always be checked, especially in patients with cardiovascular problems or impaired kidney function.

5.2 Additional warnings about the use of bipolar scissors

Check the bipolar instruments before use and avoid tissue sticking to the tips
Mechanically cut the tissue with scissors by coagulating it with a coagulation stream (not a cutting stream).
To test the instruments, choose a coagulation current (power 20 W), moisten a gauze with a physiological solution and squeeze the gauze with the tips, without touching the wet part, and activate the current output. The smoke produced indicates proper operation; otherwise, check the cable, the proper connection of the instrument parts and the insulation of the tips.
To reduce tissue adhesion to the tips, use instruments with non-adhesive connectors, rinse the tissue, or moisten the tips of the instruments with saline.

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5.3 Specific problems with minor surgical procedures

If patients are not fully anesthetized, they may experience sensations similar to those of an electric shock. These are not real shocks (radio frequency currents can only cause burns), but mild neuromuscular stimulation, which are normal side effects of currents, especially when using monopolar coagulations.
To reduce these, proceed as follows:

- Use surgical gloves and, if possible, avoid contact with the floor (for example, through insulating clogs and chairs).

When using monopolar currents, the risk of burns, especially if the tissue touches conductive parts of the operating table or the place where the neutral electrode is placed, is quite high for all of the following reasons:

- Body hair prevents good contact of the neutral electrode with the tissue (careful shaving of the surgical site is necessary).
- Often, correct positioning of the neutral electrode is not possible and the patient is not well insulated from the conductive parts of the operating table (the insulating mat should always be used).
- The disinfectants and liquids used create abnormal contact areas between the tissue and the operating table or neutral electrode.
- Be very careful if you have to use disinfectants, solvents or other flammable materials, as it is normal for them to be ignited by sparking in the current.

To avoid or reduce these risks, do the following:

- Heed all the detailed warnings in this section!
- Use bipolar coagulation (tweezers or clamps with wide tips allow for very effective coagulation).

6 USE

- Place the device at least 30 cm away from walls or objects that could obstruct the ventilation area.
- Check whether the mains voltage corresponds to the technical data (see nameplate on the back).
- Plug in the device with the power button off (on the back) = 0.

6.1 Connection and operation of the double pedal control

- The pedal is waterproof and pneumatic (without the use of electric current).
- Plug it in as described in the SPECIFICATIONS, CONTROLS, AND ICONS section.
- Check that it is working correctly: the yellow pedal must activate the cutting and mixing cut modes; the blue pedal must activate the currents for the monopolar or bipolar coagulation modes.

6.2 Connection of the neutral electrode and function of the control circuit

In the case of bipolar coagulation, the electrode is not needed (**the** warning light only indicates that the electrode is not connected).
The international plug Ø 6.35 mm serves as a cable connection. 
Connect the cable to socket **6** (connect the electrode to the cable if necessary).

FUNCTION OF THE CONTROL CIRCUIT WITH A **SINGLE-SURFACE** NEUTRAL ELECTRODE
The circuit intervenes, triggers the alarms (interval tone, warning light **11** and the message **Err nP** on) and blocks the power supply if the cable is defective or not connected to the electrode and/or the device.
If necessary, check the cable, its connection to the electrode and the device.
FUNCTION OF THE CONTROL CIRCUIT WITH A NEUTRAL ELECTRODE WITH A **DOUBLE SURFACE** AREA
The circuit works as described above, both when the cable is broken or not connected to the electrode and device, and when the patient's electrode/tissue contact is insufficient/dangerous.
If necessary, check: the cable and its connection to the electrode and the device, the correct contact of the electrode.

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6.3 Connecting the accessory

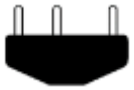
MONOPOLAR GRIP INSTRUMENT FOR USE WITH PEDAL CONTROL

The connection is a socket pin with Ø 6 and a bore with Ø 4 mm. 

Connect the accessory to socket **7B. (** To insert the electrode into the handle, unscrew the two parts.)

To connect non-standard monopole accessories, use the tk90302-21 adapter

MONOPOLAR HANDLE WITH MANUAL CONTROL

The international 3-pin plug serves as the connection. 

Connect the accessory to the **7A socket (** press to insert the electrode into the handle).

BIPOLAR INSTRUMENT

Connect the accessory to **socket 8**

The connector does not have a specific polarity.

6.4 Switching on the device (first automatic self-test)

Turn on the device with switch **1** (on the back), perform the first self-test and numbers and codes (including internal temperatures) will appear on the displays indicating the different phases: **THESE CODES DO NOT CONSTITUTE AN ALARM OR AN ERROR SITUATION.**

If the self-test system detects a problem, the use of the device is not permitted (see the "AUTOMATIC SELF-TEST" section).

If successful, the self-monitoring will end with an audible signal and the following indications on the displays:

- The software version
- When you turn it on for the first time, the number "1" is shown on the display
- Then, every time you restart, the streams and power automatically saved at the time of power off will be displayed on the displays.

6.5 Current selection and adjustment

FIRST SETTINGS OF THE CUTTING/MIXING CUTTING CURRENTS

- Press the 4A button and select the first desired current (for example: PURE – Pure Cut and use the 5A buttons to set the power shown on the respective display);
- By pressing the 4A button, an additional current can be selected from the available. The power adjustment is done with the same buttons, which are marked 5A.

By pressing the 4A button, all currents are selected as follows: *PURE* > *P PULSED* > *BLEND* > *B PULSED 1* > *B PULSED 2* > back to *PURE*

***PURE* -** Pure Cut	***P PULSED*** - Fast pulsed clean cut	***BLEND* -** Aperture Cut
***B PULSED 1* -** Fast Pulsed Mixed Cut	***B PULSED 2*** - Slow Pulsed Mixed Cut	

It is not possible to change the current type during activation.

6.6 Monopolar and bipolar coagulation currents

- Press button **4B** and select the first desired current (e.g.: *MICRO – micro-fine coagulation) and use buttons* **5B** to set the power shown on the corresponding display.
- By pressing the **4B** button, another amperage can be selected from the available ones. The power is adjusted using the same buttons, which **are marked 5B.**

As specified in the cut functions, all currents can be selected and adjusted.

By pressing the 5A button, all currents are selected as follows: *MICRO* > *M PULSED* > *FULG* > *F PULSED* > *BIPOLAR* > back to *MICRO*

MICRO - Gentle Coagulation	***M PULSED*** - Pulsed gentle coagulation
FULG – "Fulguration" Macrocoagulation	***F PULSED*** - Pulsed "Fulguration" *MACRO* COAGULATION
BIPOLAR - Bipolar Coagulation	

It is not possible to change the current type during activation.

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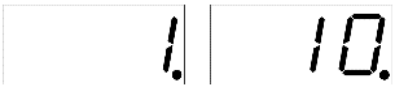
6.7 Performance change during use

The buttons of the two **5A** and **5B** sections, the services can be varied at any time, even during the submission.

6.8 Microcoagulation time (from 0.1 to 1 second)



- Press the **4B** button and select the current ***M PULSED***.
- Press the **4B** button again for 3 seconds. (The display shows the times: from 0.1 sec. to 1 sec.).
- Set the time using the **5B keys**.
- Press the **4B** button again (the display will show Power again) **.**

The set time is stored in the device and can then be changed in the same way.

6.9 Activating the currents with the pedal control

- To activate the monopolar cutting currents, press the YELLOW pedal
- (the device signals activation – yellow light on/low tone).
- To activate monopolar coagulation currents or bipolar coagulation, press the BLUE pedal.
- (the device signals activation – blue light on/high sound).

By selecting the P ***PULSED*** , ***B PULSED 1*** , ***B PULSED 2*** *and* ***F PULSED*** cutting functions: you press the pedal continuously, but the power output is interrupted.
If the M PULSED ***monopolar coagulation current is selected***, the current is delivered once and corresponds to the duration specified in the previous paragraph (from 0.1 to 1 second).
If you operate both pedals at the same time, the device will stop dispensing and display the corresponding error code (see section AUTOMATIC SELF-MONITORING SYSTEM).

6.10 Activation of monopolar currents with the handle with manual control

- Activate the monopolar currents by pressing the buttons on the handle (YELLOW = cutting) (BLUE = coagulation).
- The function of the device is carried out as described above via the double pedal.

6.11 Storage of settings and abnormal operation

The device always saves the settings and restores the state at the time of power off.
Any malfunctions are reported to the user by corresponding error codes on the display.
See the **item "AUTOMATIC SELF-TEST SYSTEM"** and the detailed information in the item **"IMPORTANT WARNINGS".**

7 CURRENTS

The services can also be found in the flow diagrams in the last chapter.

7.1 *PURE* (monopolar clean cut without coagulation effect).

It is suitable for biopsies, uterine conizations, endoscopic papillotomy and small hysteroscopies using electrodes with a very small cross-section:

- Needle or knife electrodes (basic setting 3-4).
- Tape/fine needle electrodes: SAD, SAD/1, SAD/2, SAD/3 with a diameter of 0.1 to 0.4 mm. (initial setting from 3-4).
- Ribbon electrodes type LLETZ/LEEP for conization in gynaecology (initial setting from 10)
- Flexible electrodes for papillotomy (initial setting from 20/30).

7.2 *P PULSED*

(Fast pulsed pure cut). The output power is about 50% that of pure electricity
It is identical to the PURE cut, it is used with the same electrodes and settings, but it is finer and suitable for very fine cuts, as it greatly reduces the thermal effect.

7.3 *BLEND* (monopolar blend)

It is suitable for achieving a good coagulating cut and is used with electrodes and a pure cut setting.
It is also indicated for polyp removal with an initial density of 20/30.

7.4 *B PULSED 1* - (fast pulsed aperture cut)

The power supplied is about 50% of the *BLEND* current.
It is identical to the *BLEND* cut, is used with the same electrodes and settings, but is pulsed and therefore much gentler.

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7.5 *B PULSED 2* - (slow pulsed aperture cut)

The power supplied is about 50% of the *BLEND* current.
It is identical to the *BLEND* incision, but is particularly suitable for polyp removal with an initial setting from 20/30.

7.6 *MICRO* (gentle coagulation with minimal sparking).

It is suitable for microcoagulation, coagulation of non-bleeding tissue and hair removal with the following electrodes:

- Very fine needle electrodes with initial setting of 1-2
- Non-insulated needles for telangiectasias and spider veins with an initial setting of 1-2.
- Ball electrodes with a diameter of 2-2.5 mm (initial setting of 15-20) and with a diameter of 3-4 mm (initial setting of 20-30).

7.7 *M PULSED* (gentle timed coagulation).

Microcurrent is identical, but much more suitable for performing all microcoagulations.

- Very fine needle electrodes with initial setting of 1-2 and initial pulse 0.3 sec.
- Non-insulated needles for telangiectasias and spider veins with initial setting of 1-2 and initial pulse 0.3 sec.
- Ball electrodes with diameters of 2, 2.5, 3 and 4 mm with initial setting of 15-30 and initial pulse 0.6 sec.

7.8 *FULG* ("fulguration" coagulation with strong sparking).

It is suitable for coagulation of all non-bleeding or bleeding tissues using the following electrodes:

- Needle or blade or tape electrodes, ball electrodes with a diameter of 3-4 mm and surgical tweezers (initial setting 20-30).
- Electrode's type LLETZ/LEEP for conization in gynaecology (initial setting from 20/30).
- Belts for flexible endoscopy (output setting from 20/30).
- It is also perfect for making very coagulating cuts.

7.9 *F PULSED* (pulsed "fulguration" coagulation)

The output power is about 50% of the *FULG* electricity.
It is identical to FULG coagulation, but gentler and is also ideal for strongly coagulating cuts.

7.10 *BIPOLAR* (Bipolar Coagulation)

It is intended for bipolar coagulation with the following accessories:

- Bipolar forceps (with 0.5-1 mm tips, initial setting 1-2) (with 1.5-2 mm tips, initial setting 4-5).
- Cannulas for nasal turbinates or similar applications (initial setting of 20-30) and forceps for laparoscopic surgery (initial setting of 20-40).

8 TECHNICAL FEATURES AND SERVICES

These devices do not provide monopolar currents with strong heating
S: Display Setting - **W:** Power (Watts) - **Ω:** Rated Load - **Vpp :** Peak/No-Load Peak Voltage -
CF: Crest Factor - **M:** Modulation - **DT:** Duty Cycle

PURE	**S** 160	160 **watts**	500**Ω**	**I max** 1 (@ 100 Ω) **– Vpp** 990 – **CF** 1.5 – **M** 0 % – **DT** 100 %
P PULSED	**S** 160	80 **watts**	„	**I max** 1 (@ 100 Ω) **- Vpp** 1380 - **CF** 3 - **M** 50 % - **DT** 100 %
BLEND	**S** 140	140 **watts**	„	**I max** 1 (@ 100 Ω) **– Vpp** 1410 – **CF** 2.3 – **M** 0%, **DT** 80%
B PULSED 1	**S** 140	70 **watts**	„	**I max** 1 (at 100 Ω) **– Vpp** 1600 – **CF** 3.5 – **M** 50%, **DT** 80%
B PULSED 2	**S** 140	38 **watts**	„	**I max** 1 (at 100 Ω) **– Vpp** 1630 – **CF** 3.6 – **M** 50 % – **DT** 80 %
MICRO	**S** 100	100 **watts**	„	**I max** 1 (@ 100 Ω) **- Vpp** 1530 - **CF** 3.4 – **M** 0 % - **DT** 50 %
M PULSED	**S** 100	100 **watts**	„	**I max** 1 (@ 100 Ω) **- Vpp** 1530 - **CF** 3.4 – **M** 0 % - **DT** 80 %
FULG	**S** 120	120 **watts**	750**Ω**	**I max** 0.7 (at 100 Ω) – **Vpp** 2280 – **CF** 3.5 – **M** 0% – **DT** 50%
F PULSED	**S** 120	60 **watts**	„	**I max** 0.7 (at 100 Ω) – **Vpp** 2270 – **CF** 5 – **M** 50 % – **DT** 50 %
BIPOLAR	**S** 100	100 **watts**	100**Ω**	**I max** 1.5 (at 50 Ω) – **Vpp** 500 – **CF** 2.8 – **M** 0 % – **DT** 100 %

The pulsed currents (**P PULSED** and **F PULSED**) provide an actual power equivalent to 50% of the setting on the display.
The *M PULSED* current generates a single pulse (adjustable from 0.1 to 1 second) and delivers the power shown on the display for the duration of the pulse. This results in a much stronger practical effect if the pulse is long and a gentler effect if the pulse is short. To achieve the desired result, both the power and the duration of the pulse must be adjusted.

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9 AUTOMATIC SELF-TEST SYSTEM

The self-test system (checks function, operating errors and device failures) works as follows:

- **When turned on** , it performs a full self-test that ends with a short beep.
- **During use** , function, operating errors and the output power are checked.

In both cases, the system blocks operations when it detects faults or malfunctions and informs operators by means of audible and/or visual signals, known as **ERROR CODES**.

9.1 Error code **Err OtA** with intermittent sound

No issues are reported, just that the continuous activation time is > 40 seconds.
Applicable countermeasures: None. Interrupt activation briefly and resume immediately.

9.2 Error code **Err ACt** with intermittent sound

Incorrect activation by the user: The simultaneous activation of two switches or a switch that cannot be used due to the selected types of use.
Possible countermeasures: Fix the error by activating the device in one of the allowed modes.

9.3 Error codes **Err Hnd** , **Err PEd** and **Err, but** with intermittent sound .

Indicates that during self-monitoring, when the device is turned on, there is an error or involuntary pressure of:
Err Hnd = handpiece button, **Err PEd** = pedal, **Err but** = button on the front.
Applicable countermeasures: Turn it off and on again to see if it confirms the problem. If the same error code occurs again, request technical support.

9.4 **t ° 2** + the detected temperature (continuous intermittent tone)

Indoor temperature too high
Possible countermeasures: Turn it off and on again, as this can be an error signal.

9.5 Other Error Codes

You report faults or technical problems
Applicable countermeasures: Turn it off and on again to see if it confirms the problem. If the same error code occurs again, request technical support.

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9.6 Problems not recognizable by the self-test system.

- The device is turned on and does not show any problems, but does not work properly when operating the manual or pedal control (it does not supply power and there is no power indicator – lights on or sound) or it works erratically: check if the pedal or manual activation control is faulty.
- To check if the pedal is broken, insert a rounded tip with a maximum diameter of 2 mm into the central hole of the pedal bushing. Press lightly to avoid piercing the inner diaphragm of the instrument. If the instrument does not activate when pressed, replace the pedal. Otherwise, contact technical support.
- If the handpiece does not activate the unit, replace it.
- The device is switched on, has passed the self-test when switched on and does not report any problems and it emits acoustic and visual activation signals but does not deliver power or the normal power seems lower/less effective: do not increase the power immediately, but carry out the tests described in the point "Self-monitoring of operation and delivery of anomalous power" of the IMPORTANT WARNINGS section.

The self-monitoring system is based on the ARM microcontroller in the device where the management software is stored. This software has been developed exclusively for the device in which it is inserted and cannot be operated "autonomously" (i.e. in "standalone" mode) or in devices other than the one for which it was developed. Attempting to use the software on devices or computers not intended for this purpose will have no effect.
The programmable system does not fall within the scope of the device and only stores data on functions and performance levels that will be useful to medical staff in subsequent surgeries.

No sensitive data is stored, exchanged or processed.

There is no interface in the device that allows exchange with the outside world, neither wireless (WLAN, Bluetooth, NFC modules) nor wired (RS232, Ethernet). The operating software, if available, is updated via a corresponding interface, the connection of which can only be carried out by appropriately trained specialists.

10 HANDLING

Use the device horizontally. If it is necessary to transport the device, use the original packaging.

11 STORAGE

When not in use, store the device in a dry and clean environment. Avoid spilling liquids over the device.

12 CLEANING AND STERILIZATION

- Clean the instrument and pedal with a neutral soap solution
- Do not use flammable liquids or detergents.
- After cleaning, dry the appliance carefully with a cloth.

Attention: The accessories are not sterile when sold. All reusable accessories (handles, monopolar active electrodes, bipolar cables) must be sterilized in an autoclave with a cycle of 121 °C/20 minutes or 134 °C/10 minutes. The maximum number of sterilizations allowed is indicated on the packaging of each individual accessory. At the end of sterilization, check the integrity of the insulation of the treated accessories.

NEVER STERILIZE WITH DRY HOT AIR STERILIZERS: PLASTIC MATERIALS AND INSULATION CAN BE DAMAGED!

When sterilizing, be careful not to bend the cables too much and dry all accessories well before use.

13 ROUTINE MAINTENANCE

The equipment must be subjected to an annual functional and safety test by qualified personnel who are familiar with the risks associated with the use of electrical equipment.
The tests must be carried out in accordance with the IEC 62353 standard and concern:

- Electrical safety tests (low-frequency leakage currents, resistance of the protective conductor)
- Checking the general function, the power fuses, the power cable.

In addition, in accordance with the specific IEC 60601-2-2 standards, the following must be carried out:

- Electrical safety tests (high-frequency leakage currents).
- General control (function, neutral electrode control circuit, power output, accessories).

It is also advisable to check the condition of the neutral conductive rubber electrodes and to check their nature and conductivity.

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14 DISPOSAL

Carry out the final disposal of the device and accessories in accordance with the various national laws (the device does not contain any hazardous substances).
Before disposal, sterilize all accessories that have come into contact with the patient.

15 SPECIFICATIONS

Controls and symbols, pedal control connection and performance diagrams

Technical features

Standards and classification: The equipment has been designed to meet the following standards:

- IEC 60601-1: Class I – Type CF
- IEC 60601-1-2 (EMC): Cat. A
- IEC 60601-2-2 standard
- Regulation (EU) 2017/745 on medical devices: IIB

Monopolar and bipolar operating frequency: 450 kHz +- 10 %
Output circuit: "floating", grounded at high and low frequencies and protected against the use of a defibrillator.
Power, Recording, and Backups : See data shield on the back of the device.
Intended use : Up = ≤2000m, in an environment with degree of pollution = grade 2 and with overvoltage of the power supply network = Cat. II
Housing: IP32 = Protected against the ingress of ∅solid foreign objects ≥ 2.5 mm and against dripping water at an inclination of up to 15°.
Pedal control: IP68 = Protected against dust and against the effects of immersion in water.
Cooling : By convection, without fan.
Activation signals : cutting (yellow light and low tone), coagulation (blue light and high tone)
Function Testing: By Microprocessor
Self-monitoring : Self-test (with **ERROR CODES**).
Neutral electrode control (single and double range) : Specific circuit with current lock and alarm signals.
Power cable : 2 m, cross-section 3x0.75 mm2 .
Dimensions and weight : (LxWxH) 25x24x12 cm – 4.5 kg

16 ENVIRONMENT; TRANSPORT AND STORAGE

Atmospheric operating conditions:
Temperature (°C): +10 ÷ +40. Humidity: 30% ÷ 75%. Pressure (hPA): 700 ÷ 1060
Climatic conditions for transport and storage:
Temperature (°C): -40 ÷ +70. Humidity: 10% ÷ 95%. Pressure (hPA): 500 ÷ 1060.

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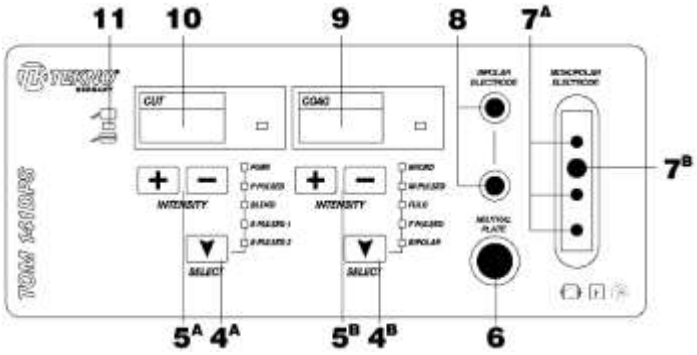
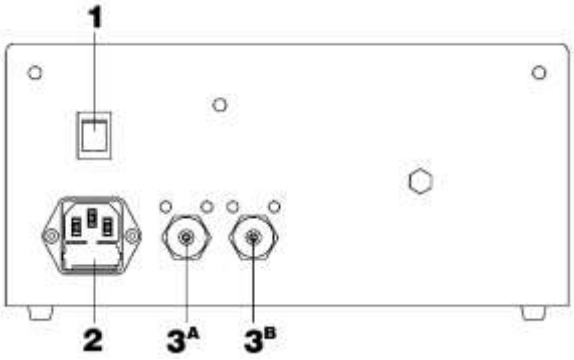
17 CONTROLS

17.1 Front



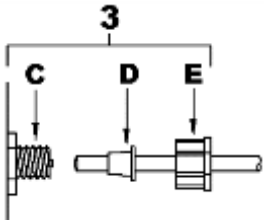
4) Current selection buttons
4A – Pure and blend cut (yellow)
4B - Monopolar and bipolar coagulation (blue)
5) Power Level Keys
5A – Pure and blend cut (yellow)
5B - Monopolar and bipolar coagulation (blue)
6) Socket for the neutral electrode
7) Socket for the monopolar instrument.
7A – For handle/instrument for use with manual control.
7B - For handle with pedal control
8) Bipolar Instrument Socket
9) Display and COAG (Coagulation) warning light
10) Display and CUT (Cut) warning light
11) Neutral electrode alarm (red light)

17.2 Back



1) Power switch
2) Entry module with fuse holder
3) Socket for pedal control
3A - Monopolar Cut (Yellow - Left)
3B – Monopolar or bipolar coagulation (blue – right).

17.3 Connection of the cables of the double pedal *tk 90019-00*



- From each bushing **C**, remove **the ring nut** E and remove the gasket **D** in the bushing.
- Insert these into the tubes of the pedal (**yellow = cutting, blue = coagulation**).
- **Without pressing the pedal** , insert pipes and seals into the sleeve.
- Screw the rings **E firmly** to the bushings **C** and press the pedals to ensure the correct Operation of the circuits.

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18 SYMBOLS

I - O	On Off
	Alternating voltage
	Class I - CF type device protected against the use of a defibrillator. This type ensures maximum safety against direct and indirect contacts as well as against low- and high-frequency leakage currents. Ground-insulated application part at high and low frequencies
	RF Isolated Patient Circuit
	Read the user manual
	Footswitch: CUT (yellow) = cutting - COAG (blue) = coagulation
	Serial number
	Article
IP32	Housing protected against solids larger than 2.5mm, against access with tools, against falling drops with an inclination of less than 15°.
	Separate disposal
	Manufacturer
	Medical
	Warning
	Follow the instructions for use
CE 0483	CE mark with Notified Body number: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart

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19 EMISSIONS

Notes and manufacturer's declaration – Electromagnetic emissions		
The device is designed for operation in areas with the following electromagnetic properties. The customer or operator of the equipment must ensure that the environment meets the specified specifications:		
Emission measurement	**Compliance**	**Environmental Electromagnetic Properties - Guidelines**
RF emissions CISPR 11	Group 2	In order to perform the intended function, the device must emit electromagnetic energy. This can affect the operation of adjacent instruments.
RF emissions CISPR 11	Class A	The device is suitable for use in all facilities, with the exception of private homes and facilities directly connected to the low-voltage public grid that supplies electricity to the buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2 standard	Incorrect	
Voltage fluctuations/flicker IEC 61000-3-3 standard	Incorrect	

NOTE: "Due to the EMISSION characteristics of this device, it is suitable for use in industrial areas and hospitals (CISPR 11 Class A). When used in residential areas (which normally require CISPR 11 Class B), this equipment may not provide sufficient protection for radio frequency communication services. The user may need to take corrective actions, such as relocating or realigning the device."

20 EMC

Instructions and Manufacturer's Declaration - Electromagnetic Immunity			
The device is suitable for use in the specified electromagnetic environment. The customer or user of this equipment must ensure that it is used in an electromagnetic environment as described below:			
Immunity measurement	**IEC 60601-1-2 Test Level**	**Conformity level**	**Electromagnetic environment**
Electrostatic Discharge (ESD) IEC 61000-4-2 standard	8 kV contact discharge 15 kV discharge into the air	Test stage IEC 60601-1-2 standard	Floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated electromagnetic field IEC 61000-4-3 standard	3 V/m from 80 MHz to 2.7 GHz	Test stage IEC 60601-1-2 standard	Portable and mobile RF communication devices should not be used near equipment, including cables. Minimum distance 30 cm
Rapid and transient eruptions IEC 61000-4-4 standard	2 kV for mains lines 1 kV for input/output lines > 3 m	Test stage IEC 60601-1-2 standard	The quality of the mains power supply should be equivalent to that of a typical business or hospital environment.
Spikes IEC 61000-4-5 standard	0.5/1 kV push-pull voltage 0.5/1/2 kV Phase Voltage	Test stage IEC 60601-1-2 standard	The quality of the mains power supply should be equivalent to that of a typical business or hospital environment.
Conductive interference caused by high-frequency fields IEC 61000-4-6 standard	3 V 150 kHz to 80 MHz 6 V ISM frequencies	Test stage IEC 60601-1-2 standard	Portable and mobile RF communication devices must not be used near the instrument, including near cables. Minimum distance 30 cm
Voltage dips, short-term interruptions and fluctuations in the supply voltage IEC 61000-4-11 standard	10 ms – 0% at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0 % at 0° 500 ms – 70% at 0° 5 s – 0 %	Test stage IEC 60601-1-2 standard	The quality of the mains power supply should be equivalent to that of a typical business or hospital environment. If the user of the device needs continuous operation during power outages, it is recommended to operate the device via an uninterruptible power supply or battery.
Magnetic field with mains frequency (50/60 Hz) IEC 61000-4-8 standard	30 A/m	Test stage IEC 60601-1-2 standard	The values of the magnetic fields at the mains frequency must correspond to those of a typical hospital or commercial environment.

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21 DIAGRAMS

Output Power Graphs (± 20%) – They include the following graphs

1 - The power variation of the monopolar currents (with resistances from 50 to 2000 Ω) by selecting 100% and 50% of the Maximum power **W (power) ▲ / Ω(resistance) ►**

- The power variation of the bipolar currents (with resistances from 100 to 1000 Ω) by selecting 100% and 50% of the Maximum power **W (power) ▲ / Ω(resistance) ►**

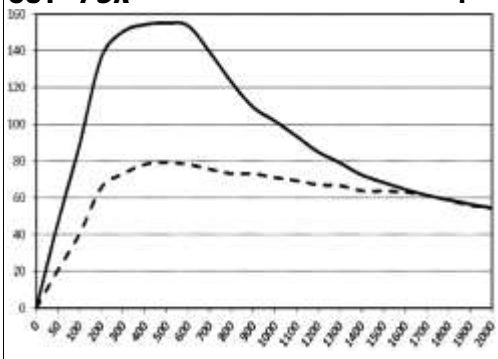
2 - The increase in the supplied power (at nominal resistance) by increasing the power. **W ▲ / Setting ►**

3 - The peak/peak voltage fluctuation when power increases. **Vpp ▲ / Setting ►**

The measurement is carried out in accordance with IEC 60601-2-2 (values are detected within 1 second, except for lower transients).

CUT - *PUR*

1



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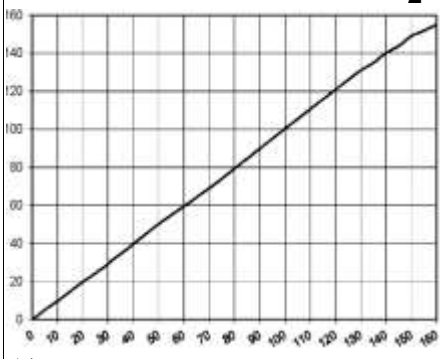
2



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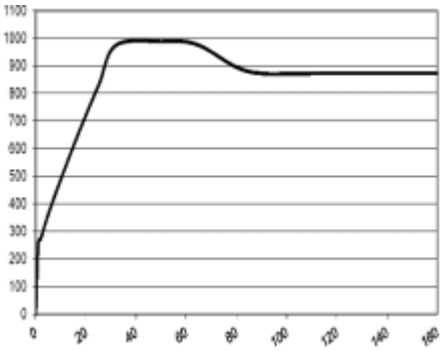
3



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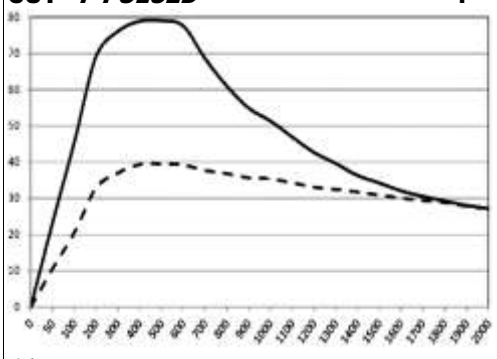
CUT - *P PULSED*

1



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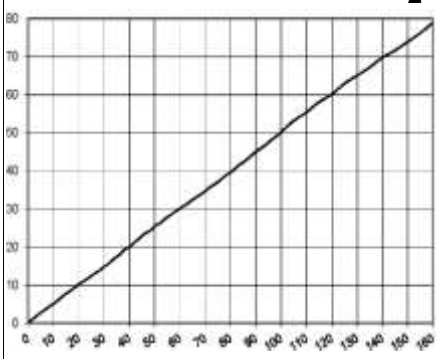

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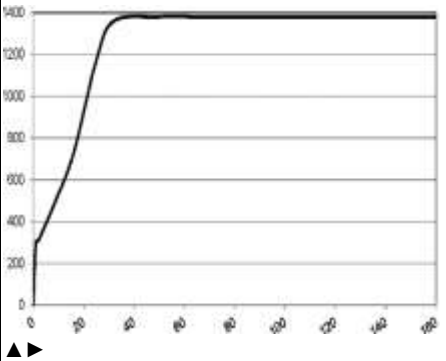

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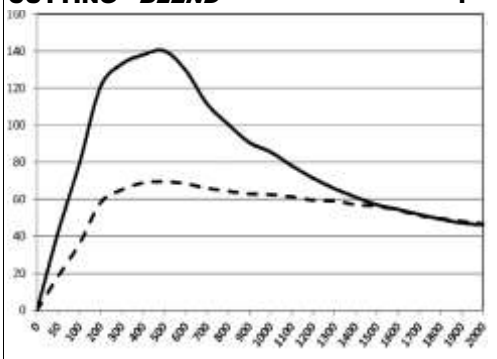
CUTTING - *BLEND*

1



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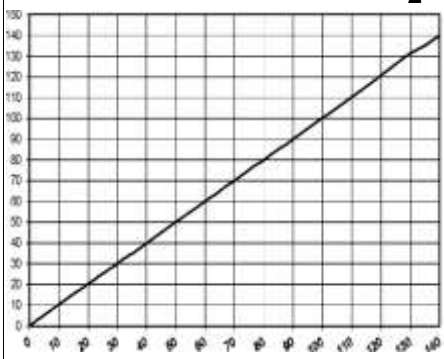
2



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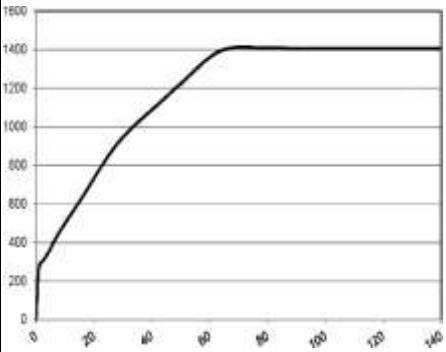
3



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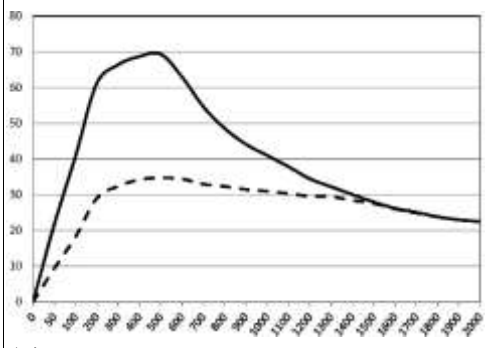
CUT - *B PULSED 1* (fast)

1



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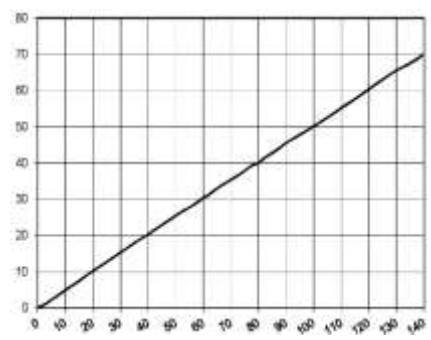

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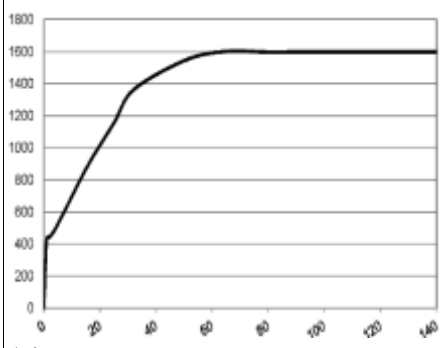
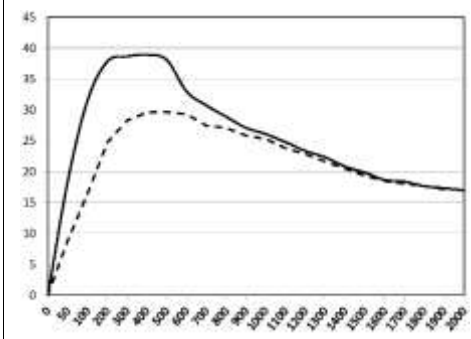


CUT - *B PULSED 2* (slow)

1



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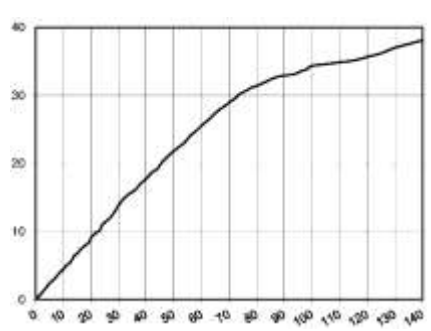

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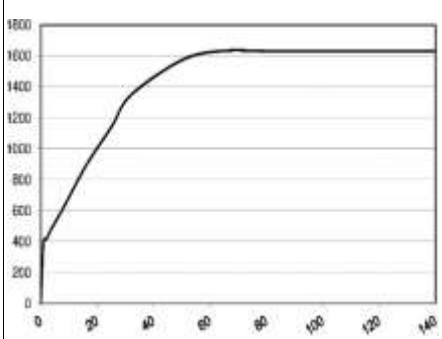
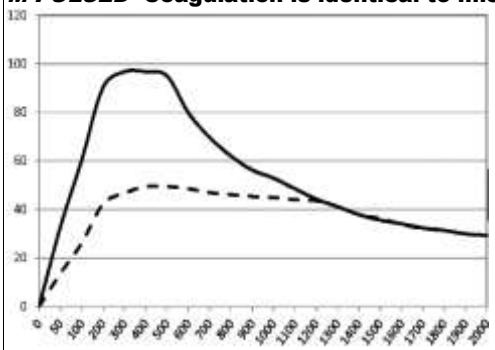


COAG - *MIKRO*

***M PULSED* Coagulation is identical to microcoagulation**

1



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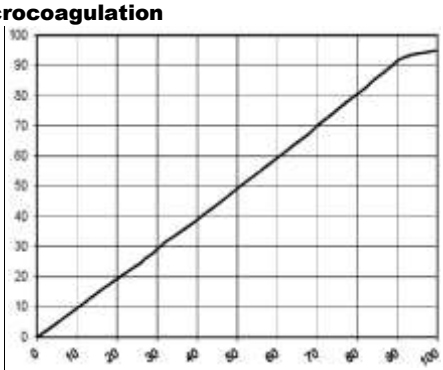

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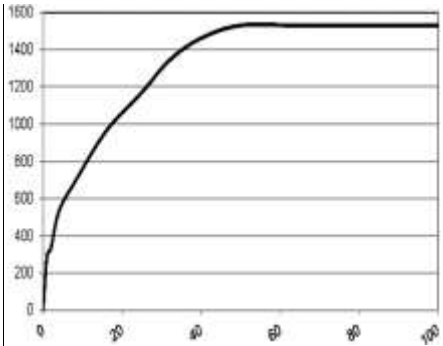
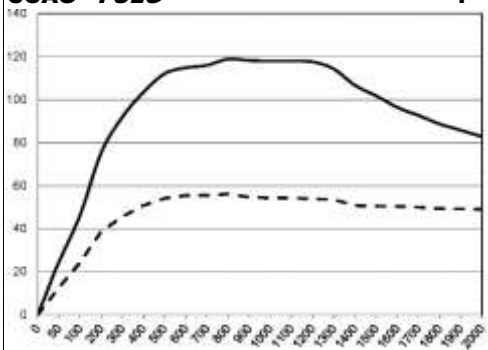


COAG - *FULG*

1



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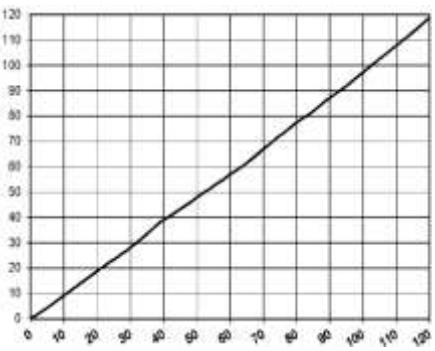

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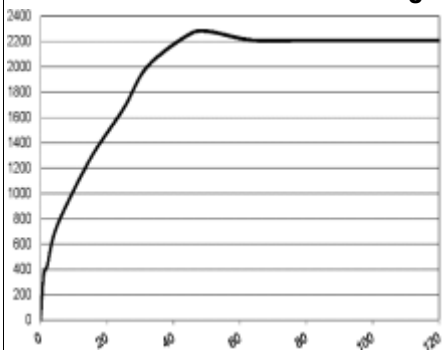

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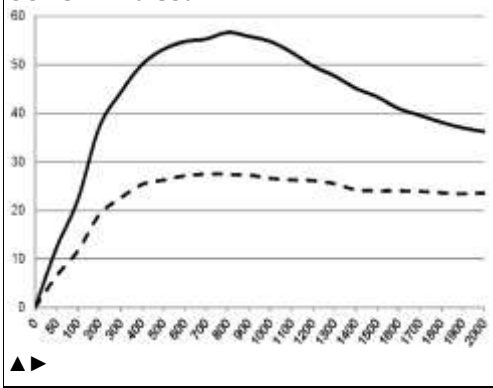
COAG - *F Pulsed* **1**



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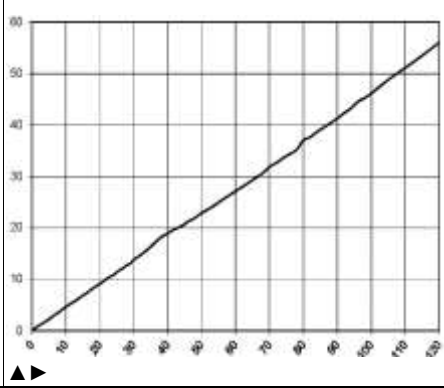

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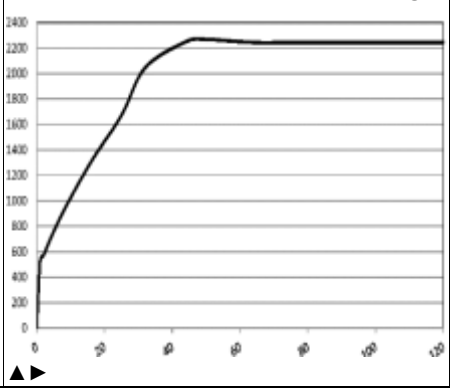

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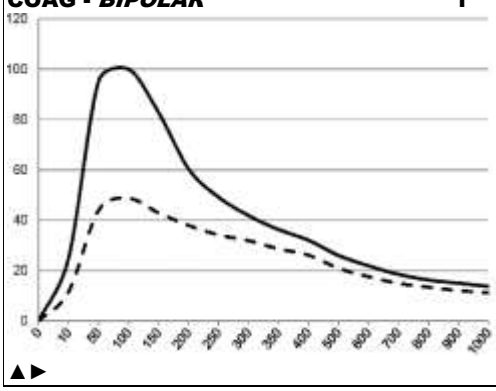
COAG - *BIPOLAR* **1**



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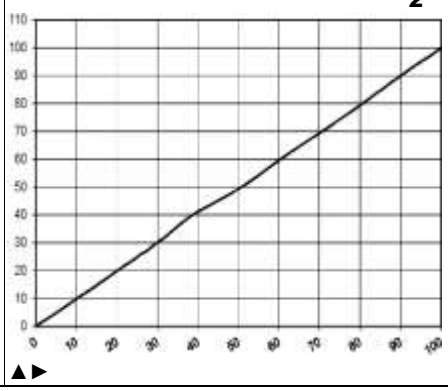

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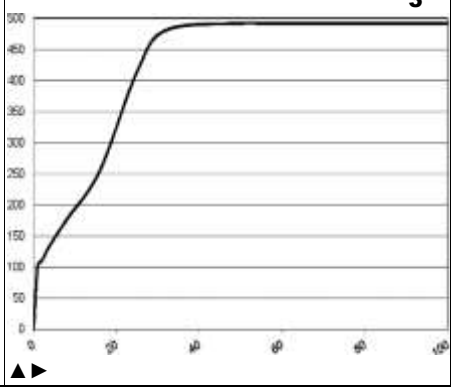

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