Contact
medical innovations

ELECTROSURGICAL GENERATOR

ECONT-0201.3

User's Manual

Digitally signed by Jighili Tatiana
Date: 2021.06.25 17:29:34 EEST
Reason: MoldSign Signature
Location: Moldova

Revision: 5.3
20.11.2019, Kyiv

CE 2409

Contact Co., ltd.,
21 S. Bandery ave., 04655 Kyiv, Ukraine
Ph: +380 44 4909356, fax: +380 44 4909357
export@contact-endoscopy.com
www.contact-endoscopy.com

EC REP

EMBITRON s.r.o.
č.p. 290, 330 23 Vochov, Czech Republic
Ph: +420 371 511 600
embitron@embitron.cz
www.embitron.cz

Read this manual before operating and save this book for future reference

This manual describes the recommended procedures for inspecting and preparing the ECONT-0201.3 Electrosurgical Generator prior to its use and the care and maintenance after its use.

Failure to follow the instructions in this manual may result in damage to and/or malfunction of the equipment.

Do not use this device for any other purpose than that for which it has been designed.

CONTENT

1 INTRODUCTION

This User's Manual will help you to install ECONT-0201.3 Electrosurgical Generator (hereinafter – the unit) and optimally adjust its working parameters for use. This document will also instruct you how to operate the unit, how to keep it clean, sterilize it, will give you maintenance and service guidelines and recommendations, for best performance results.

CONVENTIONS

The following conventions have been established for the text of this manual to aid in the identification of potential hazards of operation:

WARNING! Could result in death or serious injury.

CAUTION! May result in minor or moderate injury or property-damage.

NOTE. May result in property-damage. Also, advises owner/operator about important information on the use of this equipment.

SYMBOLS ON MARKING

	Alternating current
	Defibrillation-proof type CF applied part
	"OFF" (power)
	"ON" (power)
	Stand-by
	General warning sign
	Equipotentiality
	Keep dry
	Top-Bottom
	Fragile, handle with care
	Maximum number of packages per stack
	Manufacturer
	Date of manufacture
	WEEE wheeled bin

SYMBOLS ON MARKING

SN	Serial number
IP31	Degrees of protection provided by enclo-sures (IP-Code)
REF	Catalogue number
EC REP	Authorized representative in the European Community
CE	Mark of conformity with European Community Directive 93/42/EEC
	National mark of conformity with technical regulations

WARNING! To prevent usage problems please carefully study this User's Manual.

CAUTION! In case of non-fulfillment of the User's Manual's require-ments warranty will be void.

2 PRODUCT DESIGNATION

The Electrosurgical Generator ECONT-0201.3 is the high-efficient expert class electrosurgical system. The unit is designed for use in electrosurgical treatment.

The main modes and features of the unit are:

- two monopolar and one bipolar outputs;
- adaptive algorithm with output power maintaining for wide range of tissue resistances (100...1000 Ohms);
- neutral electrode continuity and LF/HF current leakage monitoring;
- self-test of generator and accessories after switching the power on;
- monopolar modes activation: by footswitch or handle;
- fully automatic vessel sealing system;
- special mono- and bipolar modes for arthroscopy, urology and gynaecology;
- Autostart/Autostop for mono- and bipolar modes;
- up to 100 personal user presets (programs);
- flat front panel, easy to clean, with pushbuttons for modes and power regulation;
- colour TFT monitor displays effective output power levels in all operating modes.

Operation conditions for the unit are:

- ambient temperature – from +10 to +35 °C
- relative humidity - not more 80 % at +25 °C.

NOTE. This unit is not a product of life-support.

NOTE. The producer reserves the right to introduce constructional changes not deteriorating the quality of the product. Owing to the constant improvement of the unit the present User's Manual may not explain partial constructional changes that do not affect the operation rules of the unit.

3 GENERAL SAFETY PRECAUTIONS

The following precautions should always be exercised with the use of all electro-medical equipment to ensure safety to all involved parties – user(s), patient(s), etc.

3.1 Training

This equipment should only be used under the supervision of a trained physician in a medical facility. Do not use in other locations or for any other purposes than the intended application.

3.2 Installation

1. This equipment should NEVER be installed or used in areas where the unit could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment.

2. This equipment should NEVER be installed or used in the presence of flammable or explosive gases or chemicals.

3. This equipment should NEVER be installed, used or transported in an inclined position nor should it be subjected to impact or vibration.

4. For safety reasons, this equipment must be properly grounded. (This equipment should be connected to a three (3)-prong hospital grade receptacle in U.S.A. or Canada).

5. Ensure that all power requirements are met and comfort to those specified on the rating place located on the rear panel.

6. Do not allow the power cord to became twisted, crushed or pulled taut.

7. When using an isolation transformer for any ancillary equipment, ensure the power requirements of the units do not exceed the output power of the isolation transformer. For further information, contact your local distributor.

WARNING! Never drop this equipment or subject it to severe impact as it could compromise the functionality and/or safety of the unit. Should this equipment be mishandled or dropped, do not use it. Return it to an authorized service facility for inspection and repair.

CAUTION! All units connecting to the unit must be Classified Medical Equipment. Additional information processing equipment connected to the unit form a Medical System and the operator must determine that all equipment comply with the appropriate end-product standard (such as IEC 60950 or IEC 60065) and the Standard for Medical System, IEC 60601-1-1.

3.3 Prior to Use

1. Confirm that this equipment functions properly and check the operation of all switches, indicators, etc.

2. Do not allow it to be grounded to other electrical units being used on the patient. Rubber gloves should always be worn to prevent grounding through user(s).

3. Confirm that other units used in conjunction with equipment function properly and that these other units will not adversely affect the operation or safety of this equipment.

4. Check and confirm that all cords or cables are connected correctly and securely.

3.4 During Use

1. Make sure that contact is made between the patient and this equipment.

2. To avoid damage to the front panel do not press any keys with any sharp or pointed objects.

3. During clinical procedures, avoid unnecessary prolonged use, which could compromise patient/user safety.

4. Continually monitor this equipment and the patient for any signs of irregularities.

5. In the event that some type of irregularity is noted to the patient or this equipment, take the appropriate action to ensure patient safety.

6. This equipment should only be used according to the instruction and operating conditions described in this manual. Failure to do so could result in compromised safety, equipment malfunction or instrument damage.

7. To prevent fire or electric shock, do not open or expose the unit to rain or moisture. Refer to all servicing to qualified personnel only.

WARNING! In case of using a defibrillator it is necessary to disconnect the unit from a mains supply and remove all instruments from an operating area.

3.5 After Use

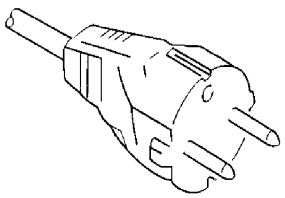
1. Refer to to the operating instructions supplied with all the components of the endoscopic set to establish the right order in which components should be turned off. Some peripheral units may have been turned off first to avoid compromising their operation.

2. Wipe all surfaces clean with gauze slightly dampened with alcohol.

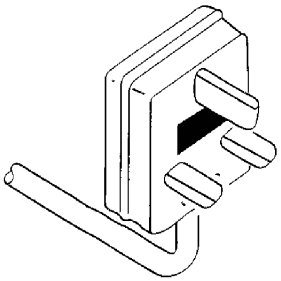
3. Be sure connector interfaces and ventilation ports are not allowed wet or splashed with liquids.

POWER REQUIREMENT

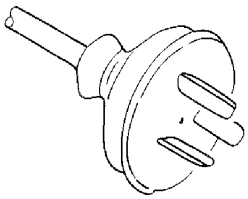
Check the standard power plug configurations that are used in your country. If the appropriate power cord is not included in your product, notify your local distributor.



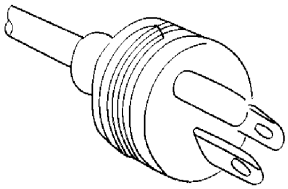
Continental Europe
(Use a SEV approved plug for Switzerland)



U.K.



Australia
and
New Zealand



U.S.A. and
Canada
(Hospital Grade)

3.6 Medical Precautions

3.6.1 General Warnings

This equipment is not intended for use in areas subjected to explosion hazards because may arise ignition of flammable media.

The unit can interfere with operation of surrounding electronic equipment.

Please always clean and disinfect the unit with incombustible substances, otherwise let vaporize the applied flammable substances before operation.

Never use needle electrodes for monitoring and if you are obliged to use them, separate their cable from monitor when the unit is on.

Monitoring equipment, stimulating or taking photography probes may leak HF current and cause accidental burn so isolate them from neutral electrode or surgical electrode as far as possible.

Observe 15-centimeter between active electrode and ECG electrode when they are in use with HF unit simultaneously.

If electrosurgical method used on patient having cardiac pacemaker or any other electronic units, may lead to irreparable damage or electromagnetic interference with their operation so consult a cardiologist and take sufficient care before operation. Use monitoring system and keep on hand defibrillator.

The flammable liquid may accumulate under patient or body cavities such as navel, vagina or bowel so before the operation remove liquid from these areas.

Put connecting cable of electrode in such a manner to avoid any contact with patient or any conductor In order to reduce the accidental burn hazards.

Place the outputs, patient plate, monopolar electrode and bipolar forceps in such a manner do not come into contact with the patient and each others inadvertently. Isolate the active electrode are not in use now from patient's body.

If you operate on the head and chest area, don't utilize flammable anesthetic substances or oxidizing agents (such as Nitrous Oxide N_2O or Oxygen) unless be sucked them out of the body.

The patient's body must not be allowed to come into contact with nearby electrically conductive objects (e.g. operating table, metal objects and wet towel). Since contact areas will generally be small in such cases, burn could arise from excessive current densities.

It is recommended to utilize antistatic sheet (covering).

Since elastic surface on operating table has a little electrical conduction are not suitable for isolation of patient from metal objects, thick dry electrically insulating pad thus be inserted between patient and the operating table and under any objects in use. Use absorbent towel to prevent the accumulation of liquid under patient.

Use monitoring system is equipped with HF current limit objects.

Some material like cotton string and gauze when they are saturated with Oxygen may ignite from the sparking of the unit in ordinary use.

In case you think that the output power rate is less than general situation, you may consider following items before increasing the output power of the unit.

- Utilize merely accessories which are compatible with unit and never use damaged or defective accessories. Always check them and get confident of the accuracy of their insulation.
- Notice that at the time of activating output of the unit, it can electronically interfere with operation of surrounding electronic equipments.
- Never connect simultaneously two surgery pens to one output connector because two pens will be activate and inactivate simultaneously.
- Do not place connecting cables of monopolar pen and patient plate on the front panel as far as possible because it may causes Electromagnetic interference in the electric circuits of the unit.

Take whole specific precaution of electromagnetic compatibility and those which have been mentioned in section 3.6.4 of this manual.

Portable and RF telecommunication equipment may interfere with the operation of the unit electromagnetically.

If any damage occurs in the unit, the output power rate may increases (in contrast with the selected level).

Some factors, except increase of current density, may cause Necrosis. For instance during long lasting surgery operation such as cardiac surgery or neurosurgery, some tissue which are under pressure (such as buttocks and back of the head) will get necrosis. Even the patient's skin will get necrosis due to the pressure of fastening tightly plastic parts or bands to fix the patient plate. Sometimes long lasting contact of the tissue with chemical and allergen materials (such as disinfectants) will cause necrosis. In the case of observing early symptoms of necrosis (like unusual skin pale) take necessary measures to remedy injured parts.

If you think output power no longer is optimal, check to be certain everything is in proper working order before increasing the power level:

- is power level on panel properly set?
- are desired conditions on the front panel properly set?
- is neutral electrode in monopolar mode properly connected?
- are cables and plugs firmly connected?
- are active and neutral electrode cleaned?

The unit should be operated with the compatible accessories (refer to chapter 6) and never apply defective and damaged accessories.

All thermal instruments used in surgery produce smoke which potentially contains infective agents that may be hazardous to staff.

Dedicated smoke evacuators must be used and the filters recommendations.

High filtration face masks should be worn in all procedures that produce surgical plume to minimize the inhalation of carbonaceous particles.

WARNING! Patient can also suffer burns due to inadvertent activation of the HF generators due to occurring any direct or indirect contact between electrode and patient through dampened cloth or any conductive objects.

In fact unintended activation of the generators can occur as follows:

- if the footswitch or finger switch inadvertently depressed
- if there is a fault in one of the accessories cables
- if the unit is defective
- if the connection of footswitch or electrode to the unit causes an inadvertent activation, the defect arises from accessories.
- if the generators are activated without any connection of accessories to the unit, the unit will be defective.

To prevent the accidental burn, never leave active electrodes in manners that could result in direct or indirect contact through the mediation of electrically conductive objects or damp cloth.

If active electrode remains in constant contact when the generator will not be triggered, Endoscopy or TUR, pay more attention to the audible and optical signals due to activation of generators.

In status do not need any generator activation for example, when you withdraw the electrode from the patient's body, certainly put output power displays in minimum level or switch off the unit.

The active electrode can become very hot during cut and coagulation procedures, toughing or electrical sparking which could result in accidental burn when they come in contact with the other tissue.

In the Bipolar technique, the HF current area is limited to the tips of instrument, and then burn hazards are reduced in comparison with monopolar technique because the output power is very low.

3.6.2 Neutral Electrode Control

WARNING!Always use the lowest output setting necessary in order to lessen the possibility of unintended burn injury.

Accidental burns due to malfunction of neutral electrode can be reliably prevented if the safety instructions are observed:

- Put Neutral electrode in such a manner producing sufficient contact surface with the patient skin (refer to Figure 1). It may cause burning If contact surface is small because the current densities enter the contact sites are very high.
- Clean, massage and shave the patient's skin at contact areas to increase the conduction of skin where the neutral electrode is positioned.
- The entire conductive neutral electrode surface should be firmly fastened to proper areas, upper arms or thighs positioned much nearer to the operational site to reduce the current's path between active monopolar electrode and neutral electrode. The current must never run across heart or lungs.

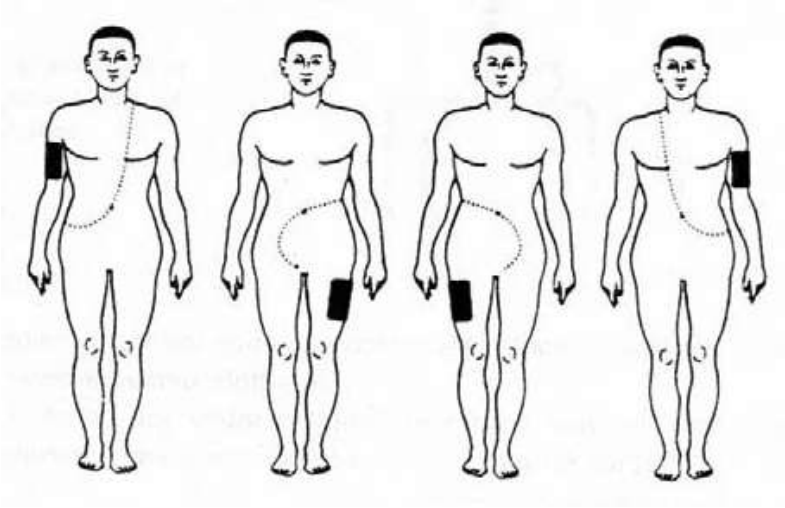


Figure 1 - The proper areas for fastening the neutral electrode

- Do not position neutral electrode on hypodermic large blood vessel.
- Securely fasten neutral electrode by using band in order to maintain contact over the full surface of the internal electrode. Check slippage of the neutral electrode if the patient is repositioned.
- A dry towel or gauze should be placed between skins to prevent skin areas touching each other for example, between arms and patient's body and between thighs.
- Always wipe the area in which sweats profusely and the parts may be in contact with the other parts.
- A dry patient plate or pad must only be used without gel if there is absolute certainty that the contact area between patient and plate electrode cannot become wet at any time during the entire operation (as a result of perspiration, rinsing fluid, disinfectants, blood, etc.)
- Never use water or saline solution as a contact fluid for attaching patient plate.
- If Electrosurgery is performed on patient with a metal implant, place the patient plate in such a way that the currents do not pass through the implant.

3.6.3 To Minimize Adherence Effect in Bipolar Technique

The bipolar technique offers the following benefits compared to the monopolar technique:

1. The applied HF current is smaller.
2. No electrode is used.
3. HF current flows between both identical tips electrode.
4. Hazards of unintentionally burning patient are negligibly small.
5. Prevents form unpredictable and unwanted coagulation.
6. Possibility of the electromagnetic interference with other electronic is drastically low.

Therefore, the bipolar operative technique should be preferred whenever it can be used.

In bipolar technique, one or more of the following complications could arise:

- Sticking tissues and clots to the tips of forceps sometimes caused to reopen the blood vessel when the forceps are withdrawn so the instrument should be kept clean at all times.
- Setting the output power more than you need or remaining the forceps on tissues at long time could be result in carbonizing the tissues and lead to adhesion of the tissue.
- On the other hand, if the unit is activated before keeping electrode in contact with tissue, the initial sparking between electrode and tissue will cause either to carbonize the tissue or to adhere the tissue to the electrode.

As far as possible, keep electrode in contact with tissue before activating of bipolar generator.

Switch off the HF-current as soon as sufficient coagulation has been formed.

Do not continue coagulation does not have any intended surgical effect.

Always keep electrode clean and completely remove the tissue residues from electrode.

Moisten the dry tissue to be coagulated with sterile water or with corporeal salt solution.

If the tissue is adhered to the electrode during bipolar operation, switch off the HF current and withdraw the electrode then wait a minute to reduce the adherence through capillaries and adjacent tissues secretion.

To coagulate the tissue keep electrode in contact with the tissue for a brief period after the HF current is switched off. In fact, fluid flows from capillaries and adjacent tissues will soften and dissolve adhering matter at the contact surface. Use sterile water or corporeal salt solution in such intensive cases.

Always clean the electrode after every use because the tissues fluids cover the electrode surface. Remaining such fluids on electrode conduct the current slightly so the surgeon thinks that output power is low.

3.6.4 Electromagnetic Interference

WARNING! Interference produced by the HF surgical equipment may adversely influence the operation of adjacent electronic instruments.

If you see abnormal situation in the adjacent equipment, note that it can be because of the action of the HF surgical equipment.

If you realize that the interference only occurs when the generator is active, use following guidelines to reduce interference:

- Use the lowest appropriate power setting

- Use low-voltage modes such as CUT or SOFT COAG instead of high-voltage modes like BLEND.

- Use bipolar technique instead of monopolar.

- Keep the electrosurgical equipment and active accessories away from the susceptible equipment. But if the non-activated electrosurgical equipment causes interference, provide more distance between the electrosurgical equipment and other susceptible equipment and when not using HF surgical equipment, you can turn it off.

For patients with cardiac pacemakers or other active implants, interference may occur, and even they can be damaged.

When use of electrosurgical equipment is urgent in patients with cardiac pacemakers, use following guidelines to reduce the risk :

- Use only Bipolar technique, if possible.

- Check carefully the electrosurgical cables, instrument connections and patient return electrode contact to prevent possible sparking from a poor contact.

- Place the patient return electrode close to the surgical site in such a way that the currents in the body do not pass through the heart area or pacemaker.

- Ensure that there is good continuous ECG monitoring during the electrosurgical procedure.

- Ensure that a defibrillator is in hand at all times.

4 SPECIFICATIONS

Item	Specification
Supply voltage	230 / 110 (switchable) V AC, 50 Hz
Rated power consumption	750 W max
Nominal frequency	440 kHz
Display / Controls	TFT / pushbuttons
Monopolar cutting:	
Forced cutting (Hemostasis 0...7)	400W for 400 Ohm
Universal cutting (Hemostasis 0...7)	300W for 400 Ohm
TUR cutting (Hemostasis 0...7)	300W for 400 Ohm
Pure cutting	75W for 200 Ohm
Monopolar coagulation:	
Soft coagulation	120W for 100 Ohm
Universal coagulation (1...3)	150...200W for 500 Ohm
Spray coagulation	120W for 2000 Ohm
Fulguration	150W for 2000 Ohm
Bipolar cutting:	
Cutting (Hemostasis 0...7)	100W for 100 Ohm
Bi-TUR cutting	300W for 200 Ohm
Cutting in isotonic medium	300W for 100 Ohm
Bipolar coagulation:	
Micro coagulation	60W for 50 Ohm
Standard coagulation	100W for 100 Ohm
Forced coagulation	150W for 200 Ohm
Vessel sealing:	
Vessel sealing (1...5)	75...175W for 300 Ohm
Safety features	in accordance with IEC 60601-1, IEC 60601-2-2
HF leakage currents	in accordance with IEC 60601-2-2
Equipment Class, Type	Class I, CF-type
Potential Risk Class	IIb
Mode of Operation	Continuous with short-time loading
Water protection degree	IP31
Operating Environment	
Temperature	+10 to +35 °C
Relative Humidity	not more 80 % at +25 °C
Air Pressure	700 to 1060 hPa
Storage Environment	
Temperature	+5 to +40 °C

Item	Specification
Relative Humidity	not more 80 % at +25 °C
Air Pressure	700 to 1060 hPa
Dimensions	355 (W) x 150 (H) x 360 (D) mm
Weight	8,0 kg

IMPORTANT SPECIFICATIONS

Maximal output power in monopolar Forced cutting mode - 400 W at 400 Ohm.

5 OPERATION MODES AND FEATURES

5.1 Monopolar cosmetic cutting

General description:

- Special mode, power control is not available.

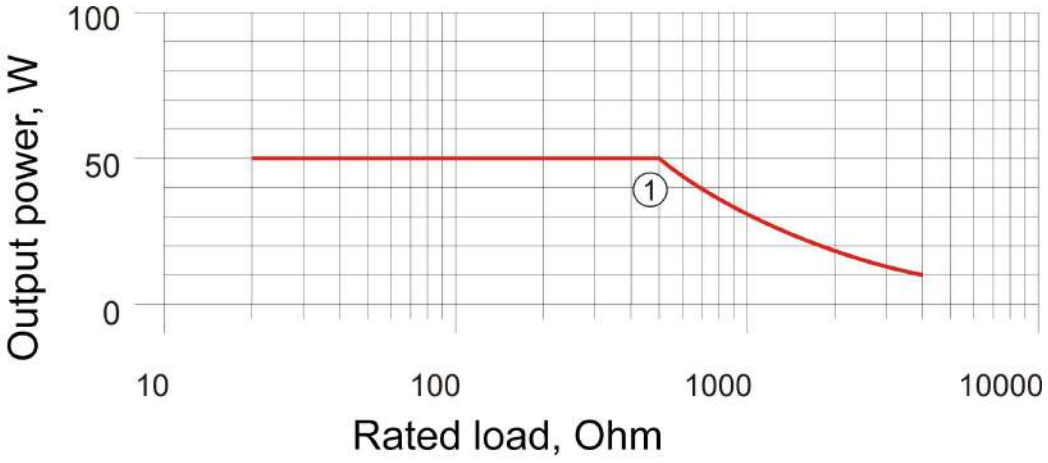
Features and recommended usage:

- Cutting of cover tissues with minimal effect of visible scars after healing by primary intention.

Recommended electrodes:

- Extremely thin needle electrodes with a diameter of not more than 0.2 mm.

Load characteristic:



5.2 Monopolar clear cutting

(with suppression of spark formation)

General description:

- Special mode, power control is available; gas support is only available for M2 channel when connecting the Gas Supply Unit.

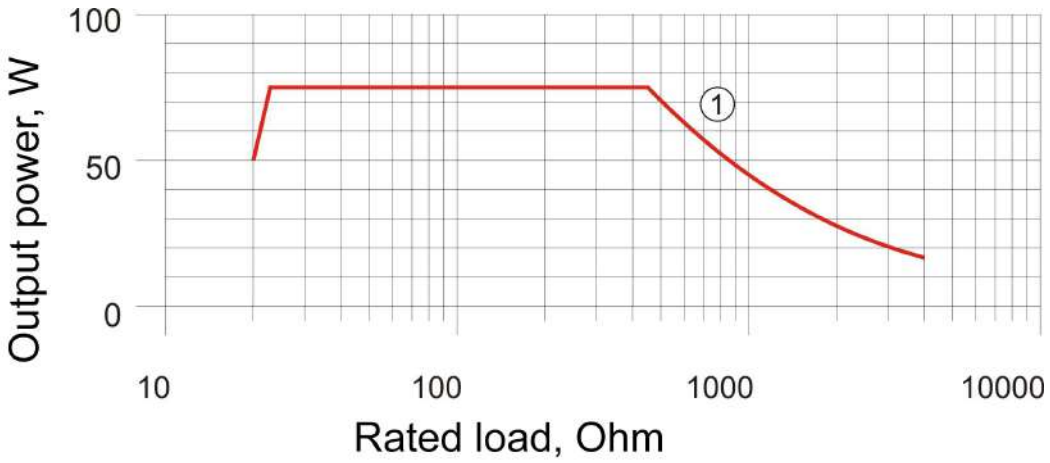
Features and recommended usage:

- Cutting of any tissue with good electrical conductivity (such as muscle or vascular tissues) at minimum carbonizing and minimal possible level of hemostatic effect.

Recommended electrodes:

- Needle electrodes, hook-shaped electrodes.
- Gas support - special electrodes for gas plasma electrosurgery.

Load characteristic:



5.3 Monopolar cutting with electrode-hooks

General description:

- Universal mode, power control is available, hemostatic effect settings available (7 steps).
- Modes «Autostop» are available.

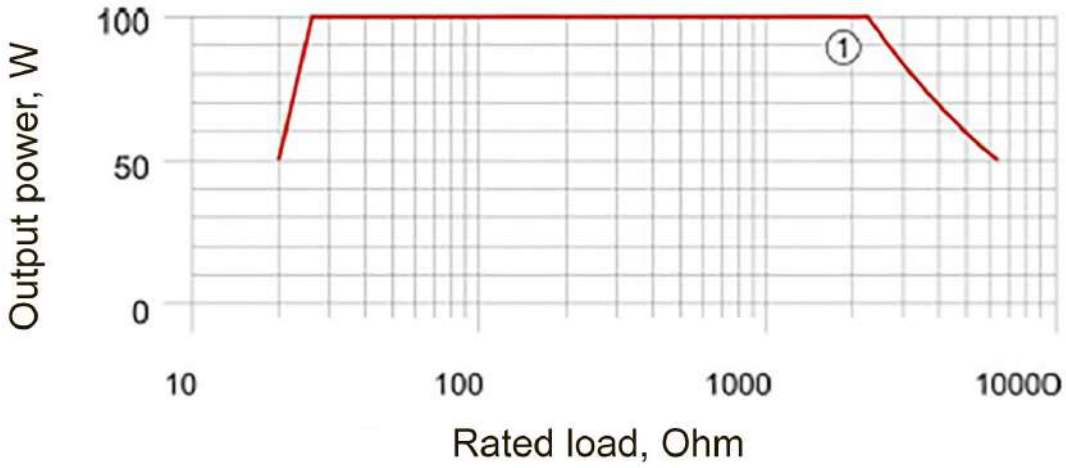
Features and recommended usage:

- Incision of tissues with different electrical conductivity and with adjustable level of hemostatic effect for use in laparoscopy.

Recommended electrodes:

- Electrodes-hooks for laparoscopy.

Load characteristic:



5.4 Monopolar universal cutting

General description:

♦ Universal mode, power control is available, hemostatic effect settings available (7 steps), gas support is only available for M2 channel when connecting the Gas Supply Unit.

Features and recommended usage:

♦ Cutting tissue with varying conductivity with adjustable level of hemostatic effect:

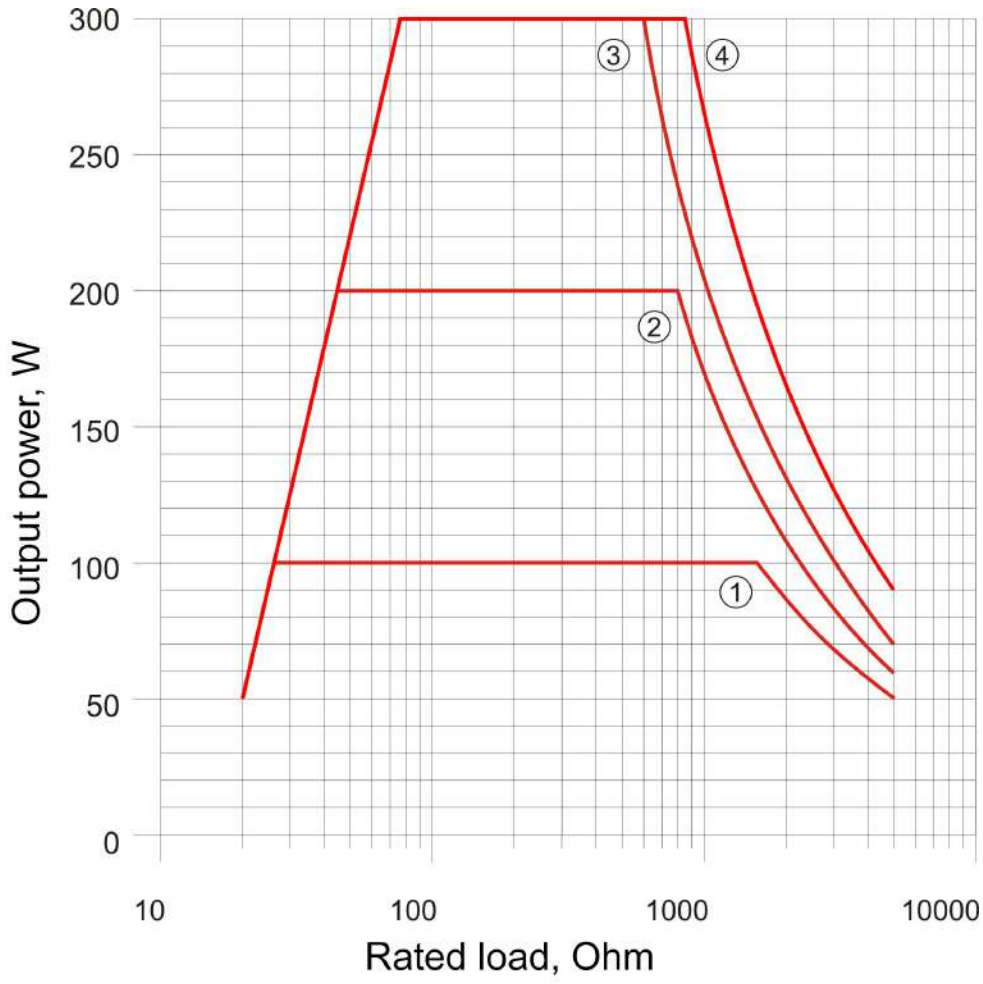
- CUTTING 1 – tissue with high blood supply;
- CUTTING 2 – tissue with an average blood supply;
- CUTTING 3 – tissue with low blood supply;
- CUTTING 4 –dry tissue.

Recommended electrodes:

♦ Electrodes-knives, electrode- spatulas, electrodes-hooks.

♦ Gas support – special electrodes for gas-plasma electrosurgery.

Load characteristic:



5.5 Monopolar forced cutting

General description:

- Universal mode, power control is available, hemostatic effect settings available (7 steps), gas support is only available for M2 channel when connecting the Gas Supply Unit.

Features and recommended usage:

- Cutting tissue with low electrical conductivity with an adjustable level of hemostatic effect. The tissue cutting during transurethral resection (TUR) and hysteroresectoscopy.

Recommended electrodes:

- Electrodes-knives, electrode- spatulas, electrodes-hooks.
- Gas support – special electrodes for gas-plasma electrosurgery.

Load characteristic:

5.6 Pulsed cut

General description:

- Universal mode, power control is available indirectly.

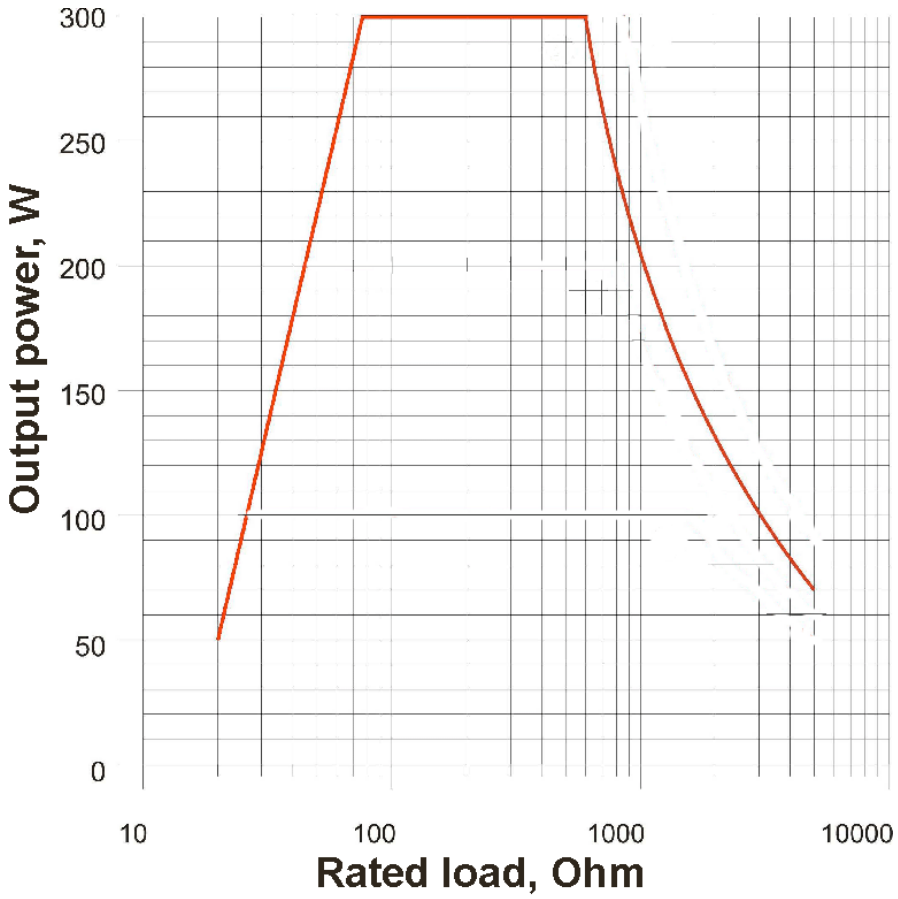
Features and recommended usage:

- Tissue cutting with the lowest possible hemostasis in cases where a highly effective control of the incision is required consists of cutting pulses that are applied at a frequency of once per second. The maximum power of the cutting pulse is not adjustable, the duration of the cutting pulse is adjustable from 1 to 20 (from 7 to 140 milliseconds in increments of 7 milliseconds, while the average cutting power varies from 2 to 40 W in increments of 2 W).
- It is recommended to use in endoscopic interventions for papillotomy / sphincterotomy.

Recommended electrodes:

- Special flexible monopolar loop electrodes for polypectomy.

Load characteristic:



5.7 Pulsed cut with coagulation

General description:

- Universal mode, power control is available indirectly, hemostatic effect settings available (7 steps).

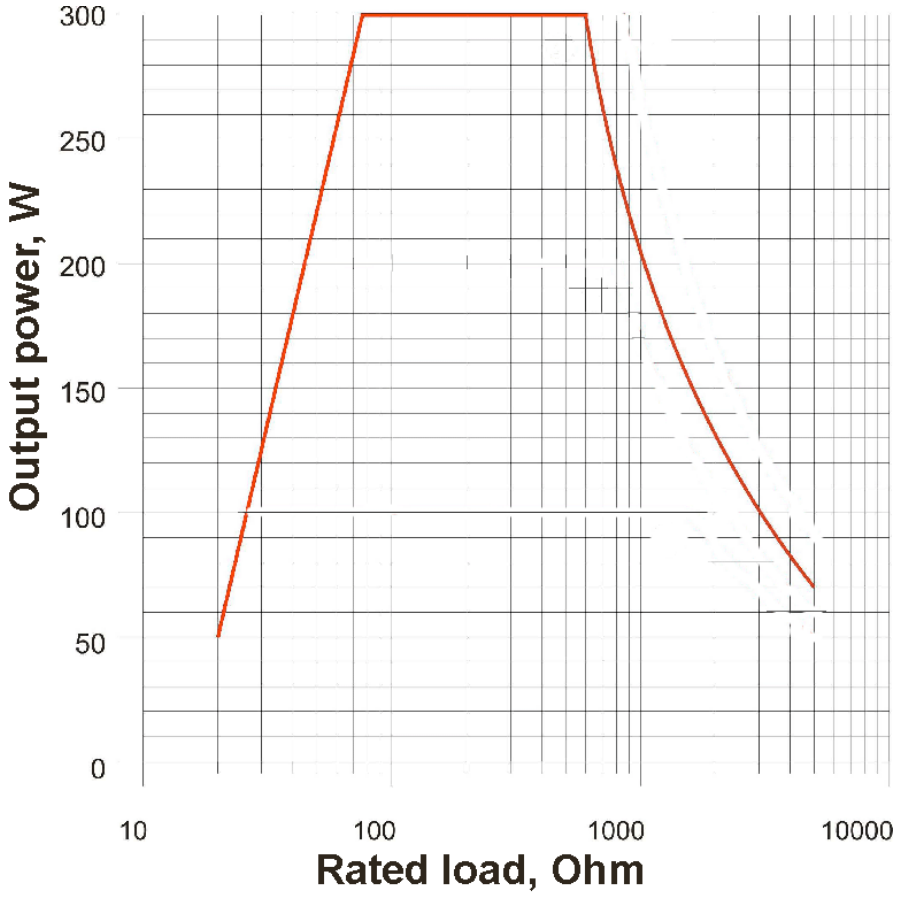
Features and recommended usage:

- Tissue cutting with well reproducible controlled hemostasis in cases where a highly effective incision control is required consists of cutting pulses and coagulation pulses, which are applied once per second. The maximum power of the cutting pulse is not adjustable, the duration of the cutting pulse is adjustable from 1 to 20 (from 7 to 140 milliseconds in increments of 7 milliseconds, while the average cutting power varies from 2 to 40 W in increments of 2 W).
- It is recommended to use in endoscopic interventions for papillotomy.

Recommended electrodes:

- Special flexible monopolar loop electrodes for polypectomy.

Load characteristic:



Additional capability:

- Capture control (disconnected), autostop (disconnected).

- Capture control (disconnectable) - ensures the impossibility of power supply in the absence of contact of the electrode with the tissue.
- Autostop (disconnectable) - provides a power cut when the electrode is disconnected from the tissue.

5.8 Monopolar mild coagulation

General description:

- Universal mode, power control is available.

Features and recommended usage:

- Coagulation without tissue carbonization and minimal probability of electrode adhesion to the tissue. Compared with other coagulation modes the coagulation depth is increased. To increase the depth of coagulation, select a lower power and coagulate for a longer period of time. If you need to perform coagulation over a shorter period of time, set a higher power level.
- It is recommended in all cases, which require reliable performance of coagulation with a fairly high penetration depth effect, as well as in cases where the adhesion of the electrodes to the tissue prevents effective coagulation.

Recommended electrodes:

- Electrodes with large contact area: electrode-buttons, ball electrodes for deep coagulation.

Load characteristic:

5.9 Monopolar twin coagulation

General description:

- Universal mode, power control is available.

Features and recommended usage:

- Universal coagulation enables the simultaneous independent activation of two monopolar electrodes. The mutual influence of the two monopolar channels is minimal.

Recommended electrodes:

- Electrodes with relatively large contact area: ball electrodes, electrodes-knives, electrode-spatulas.

Load characteristic:

5.10 Monopolar universal coagulation

General description:

♦ Universal mode, power control is available.

Features and recommended usage:

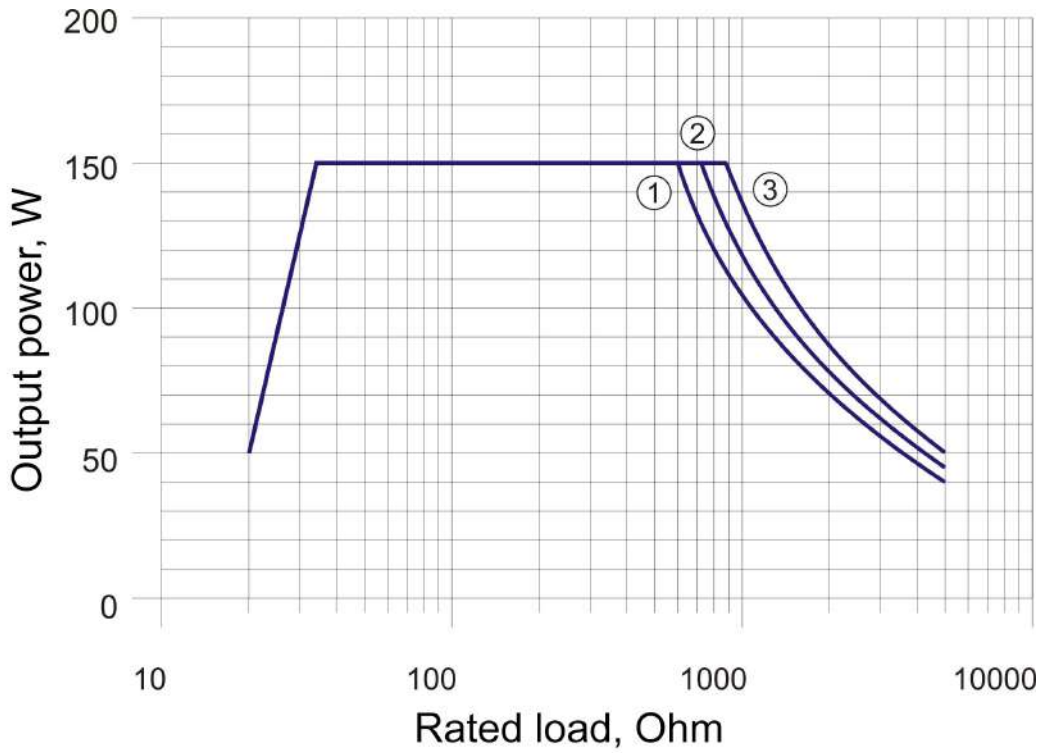
♦ Rapid coagulation of tissue with moderate tissue carbonization. It is recommended in all cases requiring a rapid coagulation:

- COAGULATION 1 – coagulation with minimal tissue carbonization;
- COAGULATION 2 – standard coagulation with moderate tissue carbonization;
- COAGULATION 3 – enhanced rapid coagulation with slightly higher tissue carbonization..

Recommended electrodes:

♦ Electrodes with relatively large contact area: ball electrodes, electrodes-knives, electrode- spatulas.

Load characteristic:



5.11 Monopolar non-contact coagulation

General description:

- Special mode, power control is available.

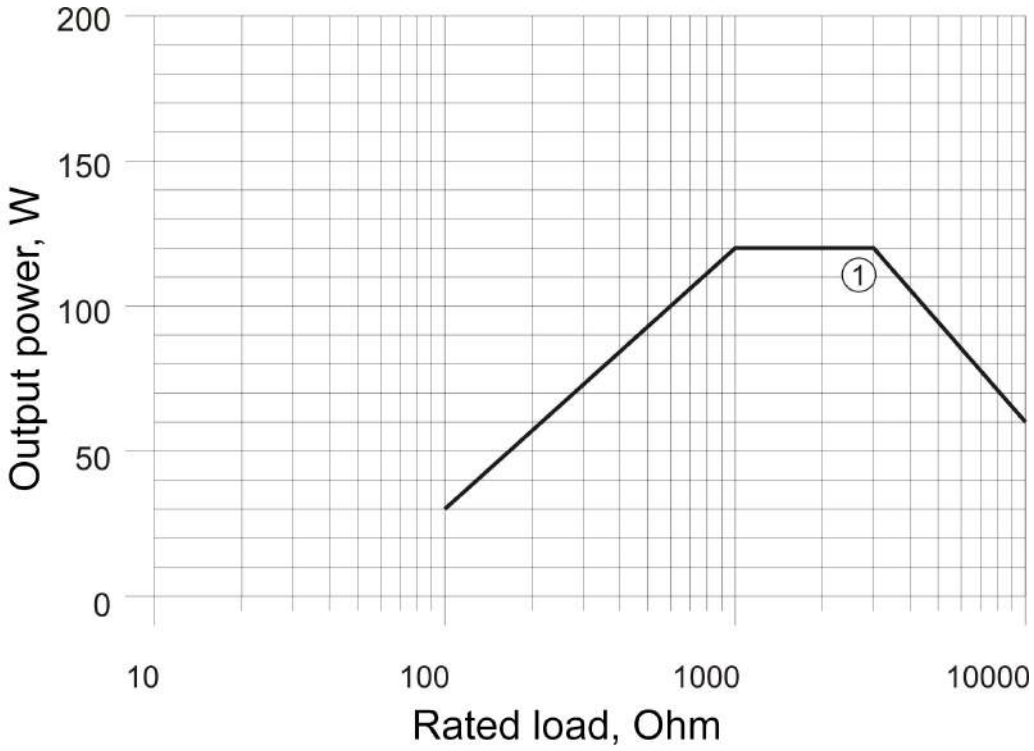
Features and recommended usage:

- Non-contact coagulation of large surfaces with diffuse bleeding and a small depth of penetration of the effect.

Recommended electrodes:

- Ball electrodes, electrodes-knives, electrode- spatulas.

Load characteristic:



5.12 Monopolar coagulation contactless agonoplasma

General description:

- Special mode, power control is available.
- The mode cannot be activated in the gas absence (argon).

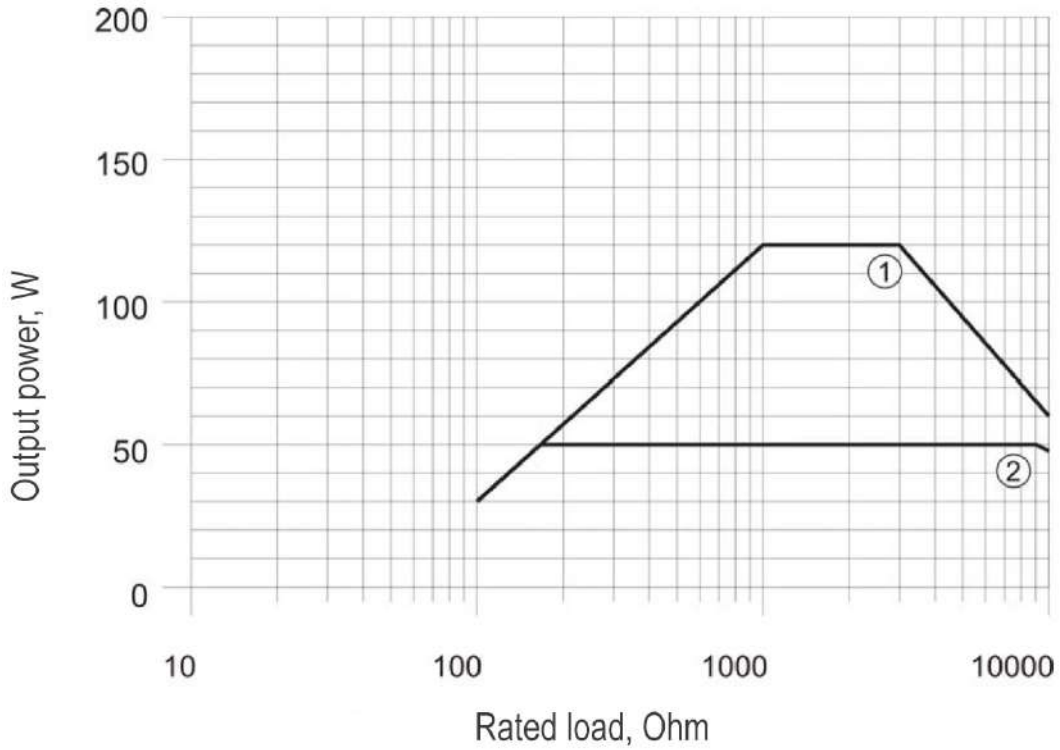
Features and recommended usage:

- Effective non-contact coagulation of large surfaces with diffuse bleeding with a small depth of penetration of the effect under conditions of gas support (argon - argon plasma coagulation, or APC) when the Gas Supply Unit is connected.
- It is recommended when performing coagulation, for example, tissues of the liver parenchyma or spleen, mucous tissues.

Recommended electrodes:

- LAPARO (1) - special argon plasma coagulation electrodes for laparoscopy or open surgery.
- ENDO (2) - special flexible electrodes of argon plasma coagulation (APC probes) for flexible endoscopy.

Load characteristic:



5.13 Monopolar modes for arthroscopy

General description:

- Special mode, power control is available.

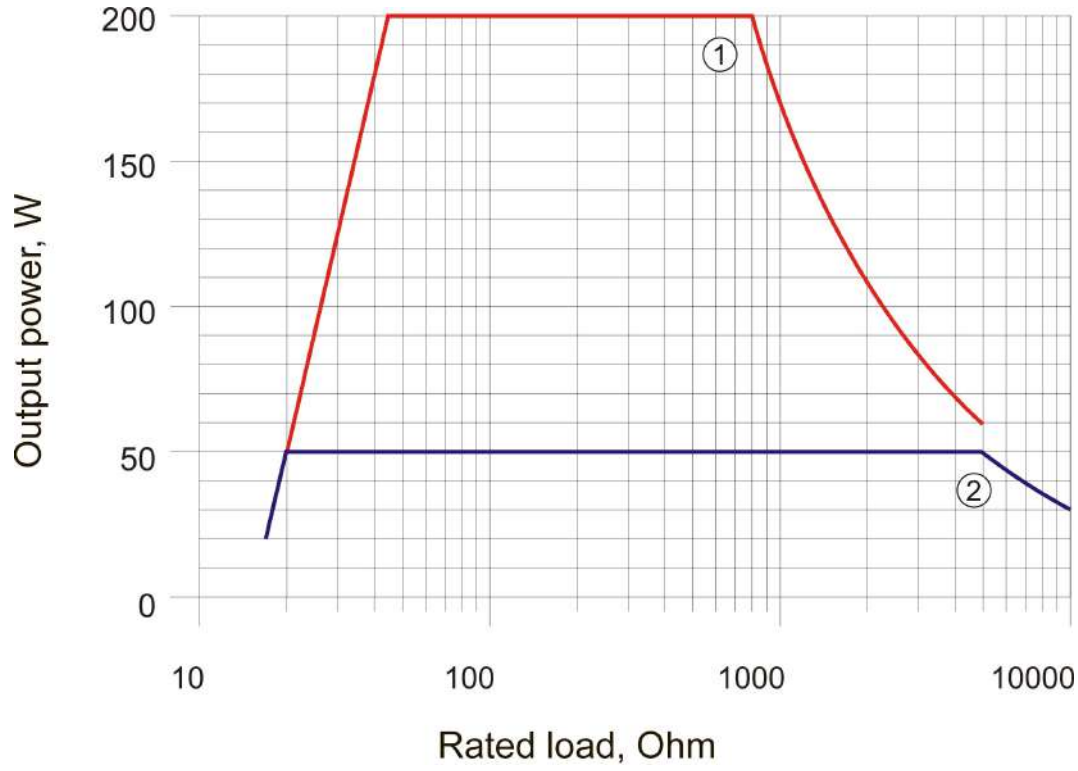
Features and recommended usage:

- Monopolar cutting modes ARTRO CUT (1) and monopolar coagulation ARTRO COAG (2) are recommended for use in arthroscopy.

Recommended electrodes:

- Special monopolar electrodes for arthroscopy.

Load characteristic:



5.14 Monopolar modes for urology and gynecology

General description:

- Special modes, power control is available.

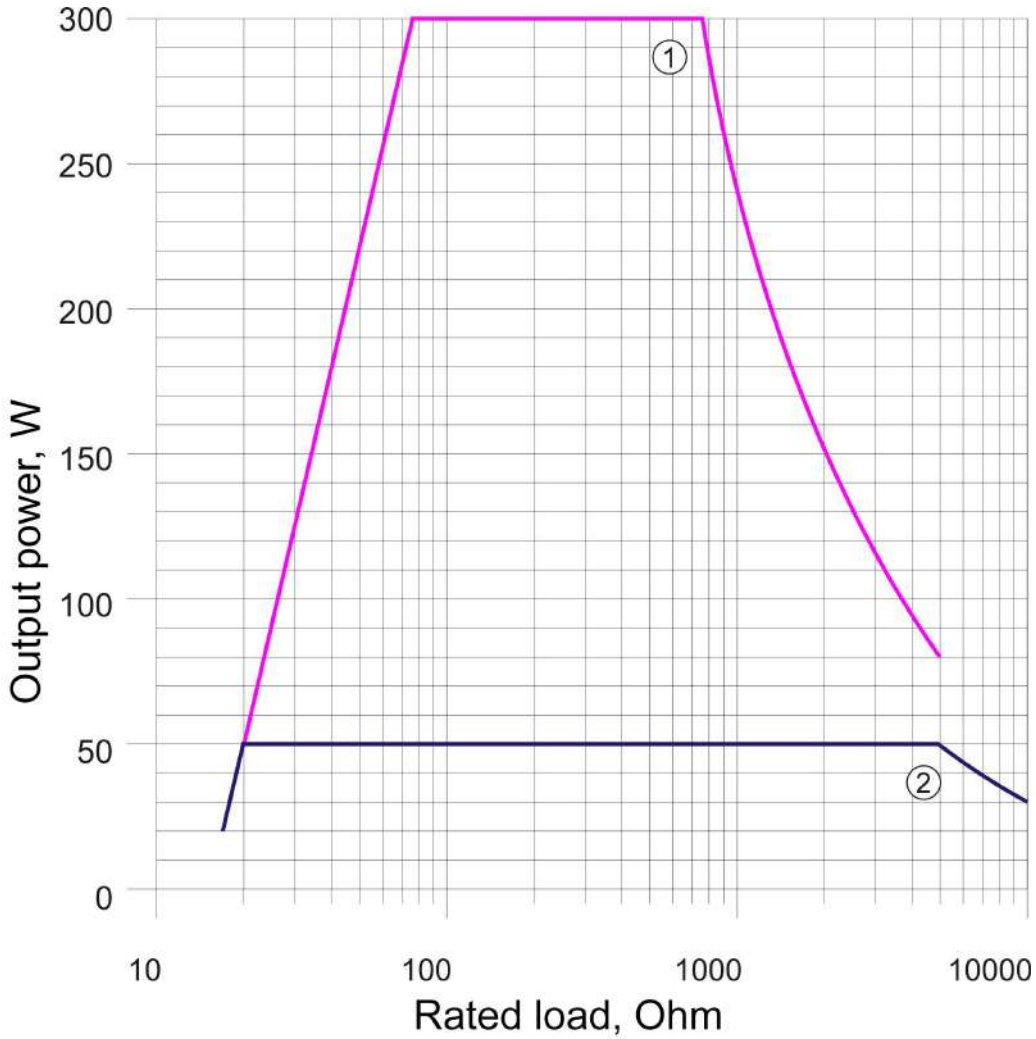
Features and recommended usage:

The modes of monopolar cutting of TUR (1) and monopolar coagulation of TUR (2) are optimized for operation in non-isotonic liquid environment and are recommended for use in urology and gynecology when performing cystoresectoscopy and hysteroresectoscopy.

Recommended electrodes:

- Special monopolar electrodes for cysto- resectoscopy and hysteroresectoscopy.

Load characteristic:



5.15 Bipolar cutting

General description:

- Universal mode, power control is available, hemostatic effect settings available (7 steps), autostop available, autostart available (includes autostop).

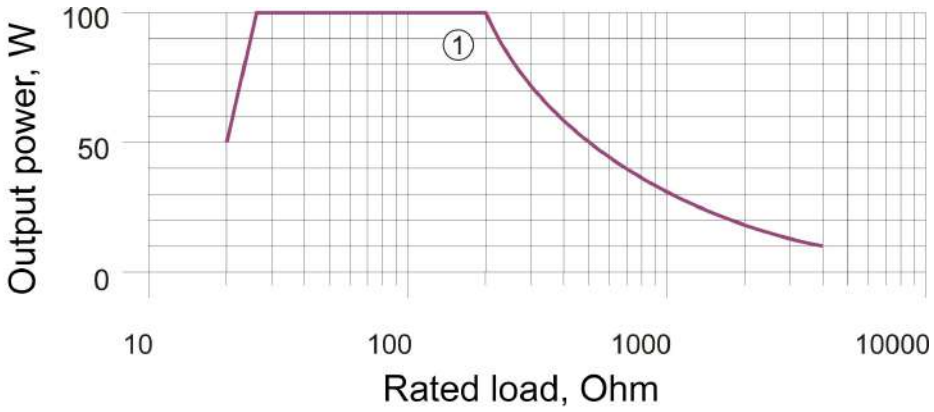
Features and recommended usage:

- Tissue cutting with different conductivity and with an adjustable level of hemostatic effect.

Recommended electrodes:

- Bipolar scissors.

Load characteristic:



5.16 Bipolar coagulation

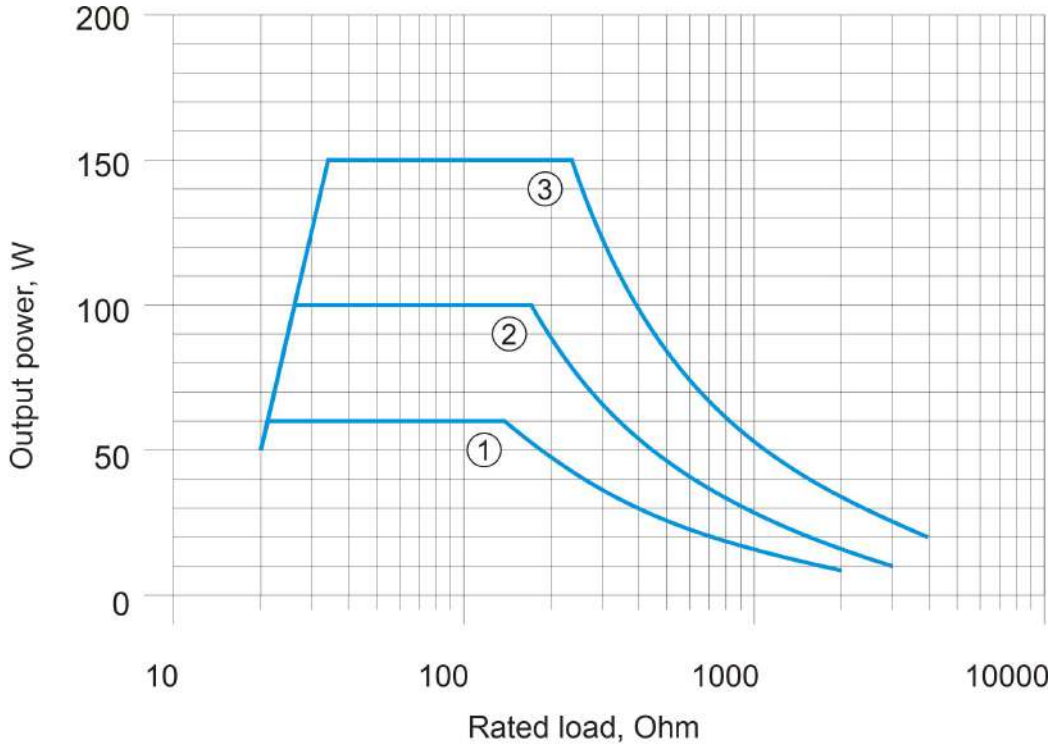
General description:

- Universal modes, power control is available, autostop available, autostart available (includes autostop).

Features and recommended usage (recommended electrodes):

- MICRO (1) - bipolar coagulation without carbonization (bipolar tweezers electrodes for microsurgery);
- STANDARD (2) - bipolar coagulation with minimal carbonization (bipolar tweezers, forceps, clamp electrodes);
- FORCED (3) - fast bipolar coagulation with moderate carbonization (bipolar tweezers, forceps, clamp electrodes).

Load characteristic:



5.17 Bipolar modes for urology and gynecology

General description:

- Special modes, power control is available.

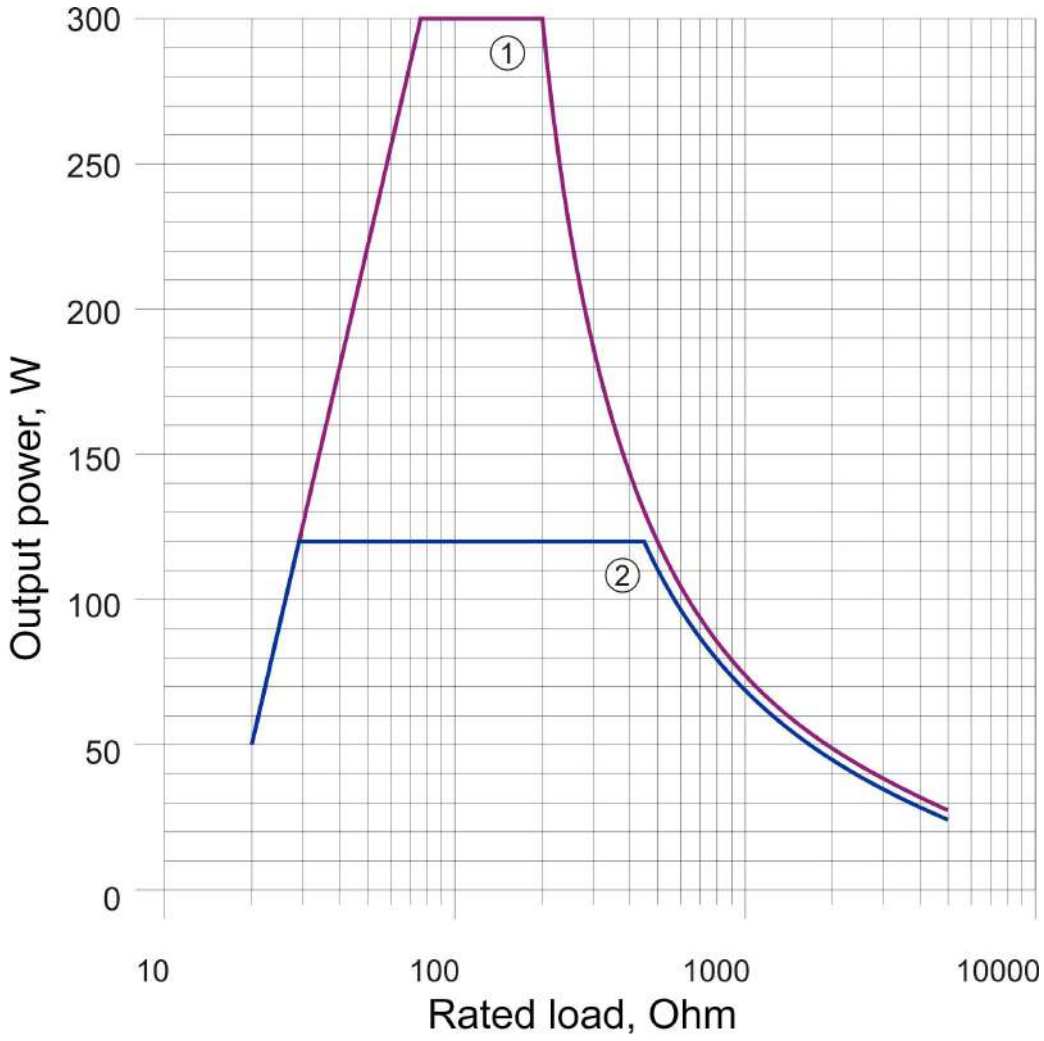
Features and recommended usage:

- The modes of bipolar cutting BI-TUR (1) and bipolar coagulation BI-TUR (2) are optimized for operation in isotonic liquid environment and are recommended for use in urology and gynecology when performing cystoresectoscopy and hysteroresectoscopy.

Recommended electrodes:

- Special bipolar electrode for cystoresectoscopes and hysteroresectoscopes.

Load characteristic:



5.18 Bipolar modes for arthroscopy

General description:

♦ Special modes, power control is available.

Features and recommended usage:

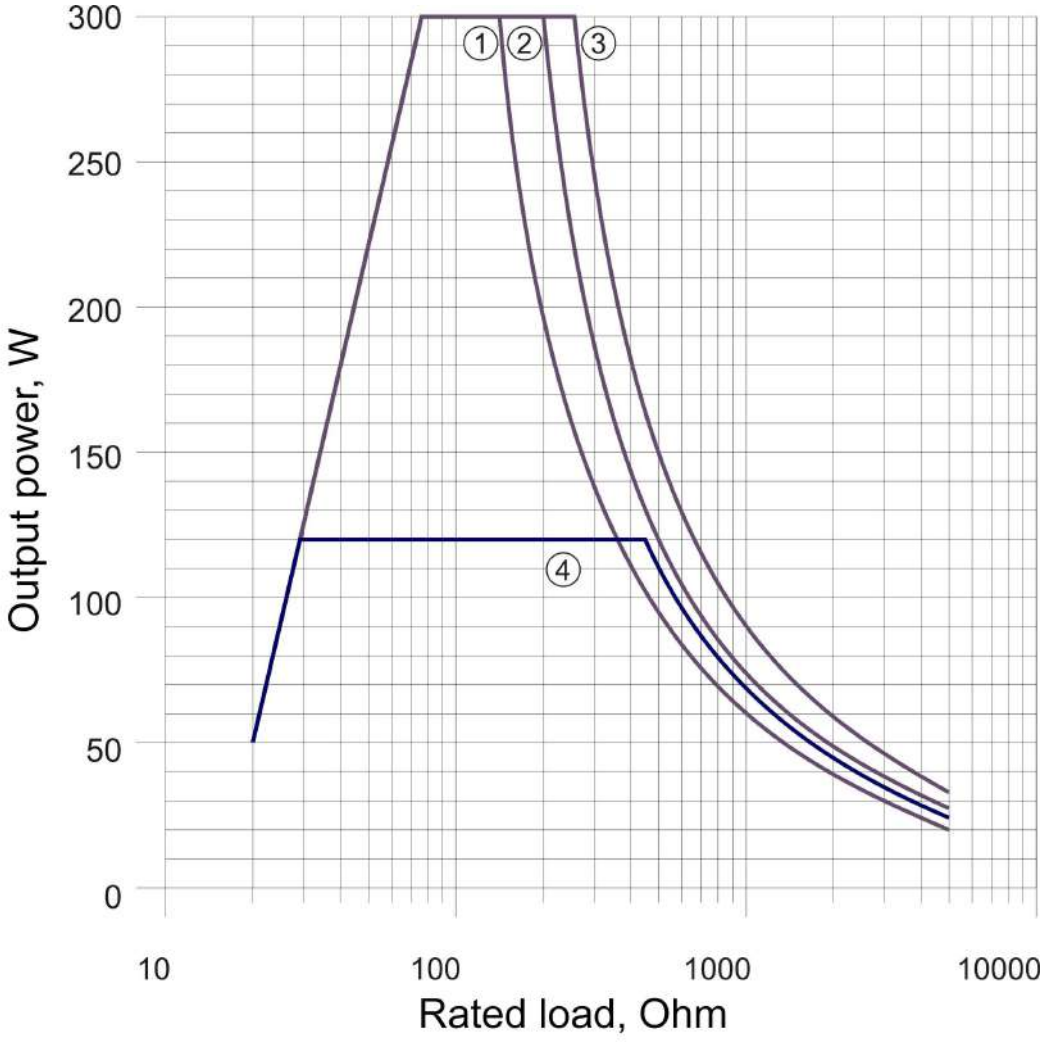
♦ Modes of bipolar cutting ARTHROCUTTING (1, 2, 3) and bipolar coagulation ARTHROCOAGULATION (4) are recommended for use in arthroscopy.

Recommended electrodes:

♦ Special bipolar electrodes for arthroscopy:

- ARTHROCUTTING 1 – for instruments with a small electrode area;
- ARTHROCUTTING 2 – for instruments with a medium electrode area;
- ARTHROCUTTING 3 – for instruments with a large electrode area.

Load characteristic:



5.19 Bipolar modes. Thermoelectroligation of vessels

General description:

♦ Special modes, power control is available but limited.

Features and recommended usage:

♦ Modes are designed to replace mechanical ligation of vessels with a diameter of up to 7 mm.

♦ During the thermoelectroligation procedure (TEL) between the jaws of the instrument the hardware-controlled evaporation occurs of liquid and denaturation of the protein components of the processed tissue of the vessel which leads to the formation of a homogeneous collagen structure, securely closing the lumen.

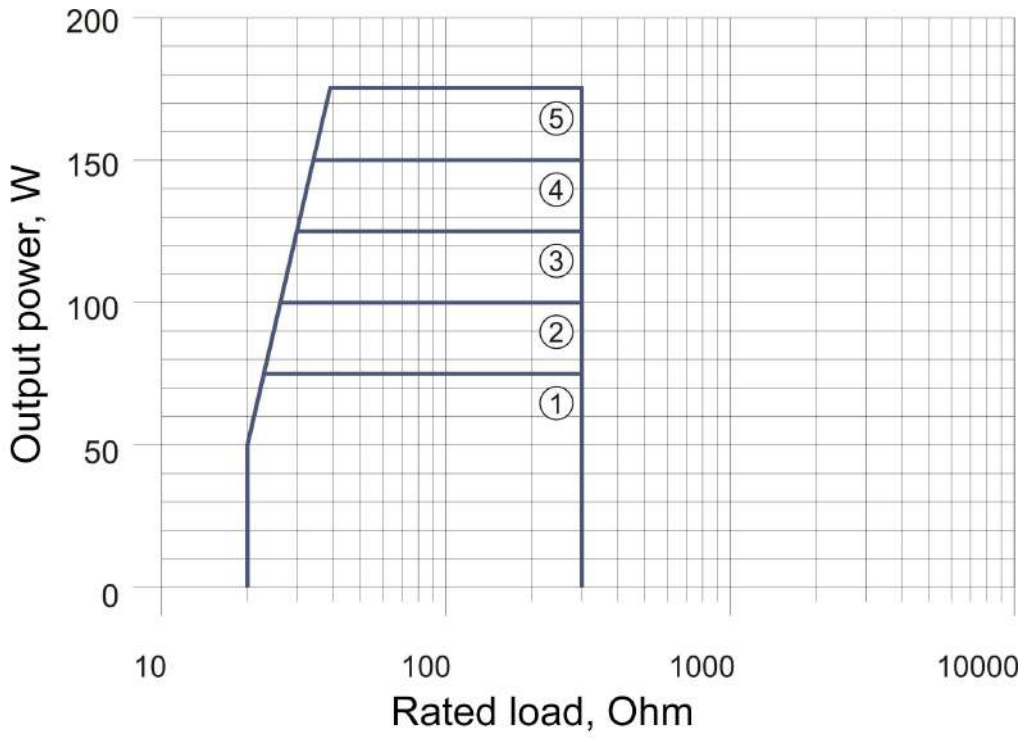
NOTE. When the Medtronic electrode (Covidien, Valleylab) is connected, the mode will be automatically selected. While the electrode is connected the mode change is impossible.

Recommended electrodes:

♦ Special bipolar electrodes for arthroscopy:

- TEL 5 mm (1, 2, 3) – for instruments with a small electrode area (laparoscopic instrument with a diameter of 5 mm);
- TEL 10 mm (2, 3, 4) – for instruments with an average electrode area (laparoscopic instrument with a diameter of 10 mm);
- TEL gen surgey (3, 4, 5) – for instruments with a large electrode area (an instrument for gen surgery).

Load characteristic:



WARNING! Modes are designed to replacing the mechanical ligation of vessels with a diameter of 7 mm.

Use of modes is permitted only for specialists properly trained in thermo-electroligation procedure. Otherwise, a serious damage to the patient's health may occur.

Use of modes is permitted only with the application of specialized instruments.

Possible build-up of tissue of treated vessels on the instrument jaws may interfere with the correct TEL procedure and therefore the cleanliness of the instrument jaws should be monitored.

Power limit adjustment is allowed in case of emergency need to increase or decrease the procedure time.

When reducing the procedure time (increasing power) there is a risk of non-homogeneous collagen while preserving the vessel lumen.

With an increase of the procedure time (decreasing power) there is a risk of tissue adhesion of ligating vessel to the instrument electrode, as well as the risk of increased tissue necrosis outside the scope between the instrument jaws.

Prior to the procedure check up the following:

- Fixation of instrument jaws with rack.

- No tension of ligating vessel.

- No contact of non-insulated parts of the instrument with surrounding tissues or metal objects.

- No immersion of ligating vessel into fluid, including blood.

Activation of the mode by foot switch or control buttons on the instrument is carried out prior the appearance of the transmission-type indicator (green) and audio signal (double short) of the successful ligation completion, or an error occurred.

Possible errors and actions when they occur:

1. Red transmission-type indicator, a long signal - short circuit of instrument jaws. In this case:

- Check the absence of metal objects in the capture zone (e.g., a titanium clip).

- Check the position of the instrument jaws (some instruments may allow contacting of jaws in case of capturing an insufficient amount of tissue), if necessary, grab more sufficient amount of tissue or perform the capture at a different site.

- Possible instrument failure, replace the instrument if necessary.

2. Yellow transmission-type indicator, quad signal – high tissue resistance in the area of capture or improper instrument connection to the unit . In this case:

- Check for the tissue availability between the instrument jaws and conformity of the captured tissue type to design mode.

- Check the instrument connection to the unit and integrity of the instrument cable.

- Possible instrument failure, replace the instrument if necessary.

3. Change of the continuous procedure signal to intermittent one without transmission-type indicator and with the continuation of the procedure occurs if ligation procedure is performed for a longer time. In this case:

- Check that the ligating vessel site is not immersed into fluid.

- Check that nonisolated parts of the instrument do not contact with the surrounding tissues.

- Check that the selected mode corresponds to the instrument.

The unit automatically performs a ligation procedure; it requires a continuous procedure visual control on the part of the operating specialist. In case of necessity, releasing the foot switch or control button on the instrument leads to an interruption of the procedure.

Locking the instrument jaws with a rack continues until the appearance of transmission-type indicator and sound of the successful ligation completion, or an error occurred.

A visual inspection is required of steam exiting the ligating vessel area in order to prevent burns of surrounding tissue.

It is forbidden to activate the instrument cutting element prior successful completion of the ligation procedure.

Before dissection of the ligated vessel it is required to check visually the quality of ligation.

Dissection of the ligated vessel is performed only with the instrument jaws locked with a rack on the center of the ligated area.

6 COMPLETE SET

Complete set is described in Table 1.

Table 1 - Complete set

No.	Item	Quantity
1	Unit	1
2	Power cord	1
3	Neutral electrode with cable, L=4 m	1*
4	Foot switch with cable, L=4 m	1*
5	Monopolar laparoscopy cable, L=3 m	1*
6	User's Manual	1

* - per customer's request

7 OPERATION CONTROLS

Before turning on, please study carefully the operation controls and indicators on the front and rear panels (Figures 2 and 3 accordingly).

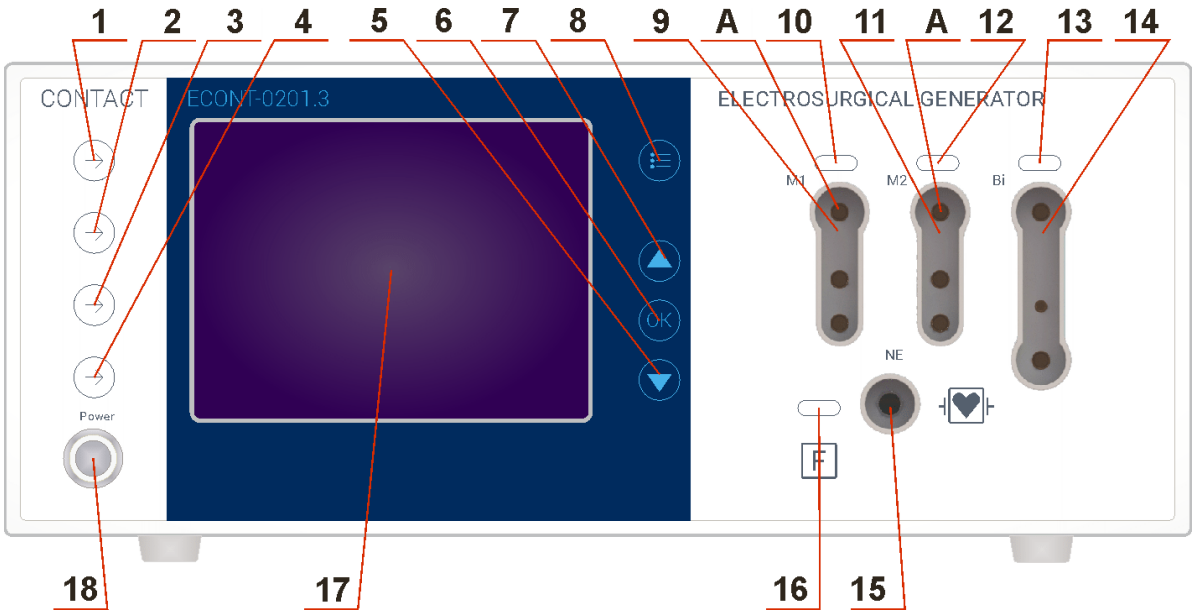


Figure 2 - Operation controls, front panel

No	Description
1	Multi-function button 1 (MFB1)
2	Multi-function button 2 (MFB2)
3	Multi-function button 3 (MFB3)
4	Multi-function button 4 (MFB4)
5	Button «DOWN»
6	Button «OK»
7	Button «UP»
8	Button «MENU»
9	Monopolar output connector M1 (no gas support)
10	Indicator of RF power output M1
11	Monopolar output connector M2 (with gas support)
12	Indicator of RF power output M2
A	Power RF sockets RF of monopolar outputs connectors M1 and M2
13	The indicator of RF power at Bi channel output
14	Bipolar output connector of general-purpose Bi
15	Neutral electrode (NE) connector
16	NE status indicator
17	LCD screen
18	Power on/Stand by button

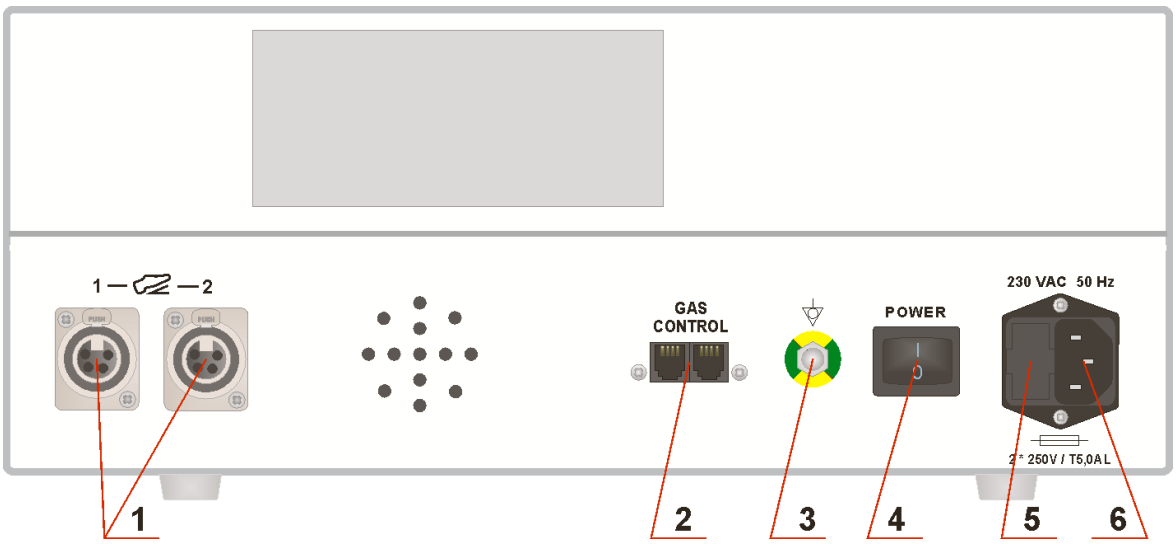


Figure 3 - Operation controls, rear panel

No	Description
1	Footswitch 1 and 2 connector
2	Gas Supply Unit control cable connectors
3	Connector for potential equalization
4	Main power switch
5	Fuses
6	Power Cord Socket

NOTE. Safety fuses type 5*20 250V/T5,0AL are used in the unit.

NOTE. M1 connector is designed to connect cables and instruments for operation without gas support. M2 connector is designed to connect cables and instruments for operation with gas support only.

8 INTENDED USE

8.1 Accessories for Electrosurgical Operations

The unit is equipped with high-quality electrosurgical accessories, and it allows various procedures in general and vascular surgery, gynecology, oncology, and many others.

The neutral electrode connection socket 15 (refer to Figure 2) is made according to the 6.3 mm standard.

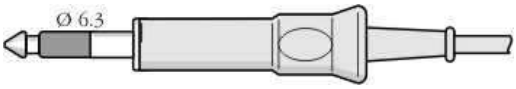


Figure 4 - Neutral electrode plug

More information on the neutral electrode can be found in section 3.6.2 of the User's Manual.

The sockets A of the active monopolar outputs M1 and M2 (refer to Figure 2) is also made according to the so-called 3-pin standard. In the case of laparoscopy procedures, one can use a cable with a single 4-mm banana plug.

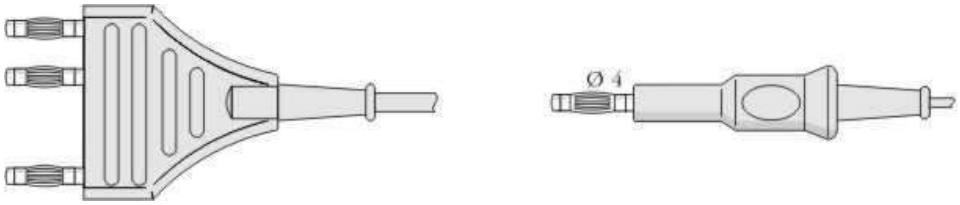


Figure 5 - Active electrode plug and Endoscope monopolar plug

The unit can be connected to with standard monopolar electrodes, with a diameter of:

- 4 mm, with handles 4 mm in diameter,

- 2.4 mm, with handles 2.4 mm in diameter and handles 4 mm in diameter (using an adapter for 2.4 mm electrodes).

The bipolar output socket 14 (refer to Figure 2) is made according to the 2 x 4 mm standard.

One can use cables with two separate 4-mm banana plugs. The unit can operate with bipolar tools of various types, both for open surgery and laparoscopy.

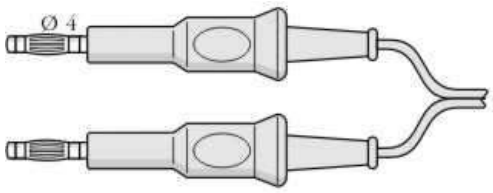


Figure 6 - 2-part bipolar plug

In case of doubt as to the permissibility and manner in which accessories may be connected, one should contact either the manufacturer or the distributor.

Accessories sterilization - see the end of this section.

8.2 Potential equalization

Basically the unit (CF-type) is earthed with the 3-wire power supply cord. However, in a combination with other medical equipment, the potential equalization should be made if the medical equipment is connected via a multiple socket-outlet in patient environment.

For more information, please refer to IEC60601-1 standard.

8.3 Setting-up

Remove the unit and its accessories from the shipping package.

NOTE. After transportation or storage in cold season before unpacking it is recommended to maintain the unit in a heated room for 6-10 hours.

Place the unit on a stable, level surface (desk, stand etc).

NOTE. Do not use the unit in any environment with explosive and flammable gases.

Position the power switch button on the rear panel to "0" (Off) position.

Using the supplied network cable connect the unit to AC 220 V, 50 Hz. Ensure unit quality grounding via a network cable.

The connection mode of the accessories is explained in Figures 7.

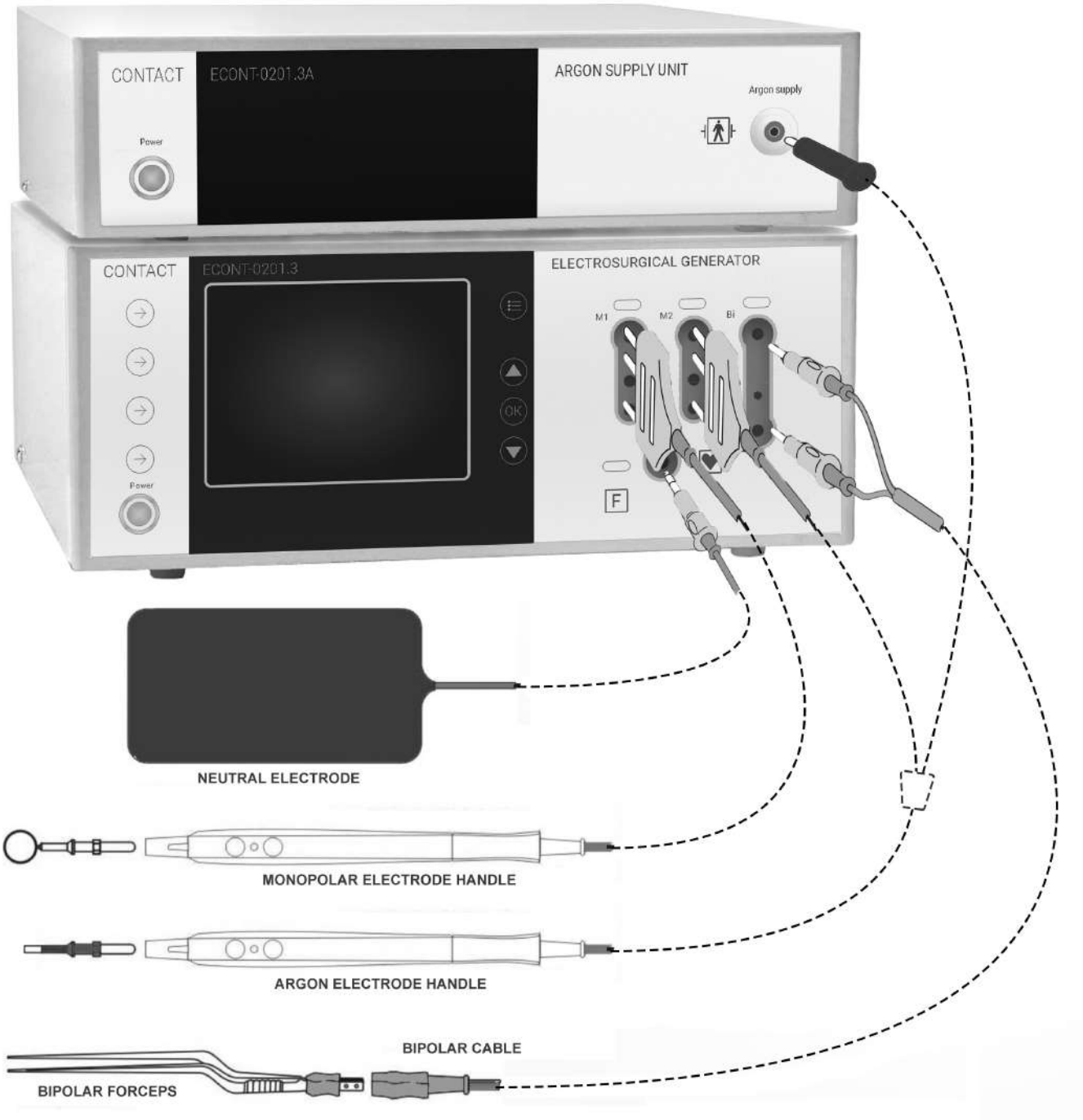


Figure 7 - Accessories connection

WARNING! Use the cables supplied with the unit.

- Connect the cable of main two-key foot switch to the connector located on the rear panel of unit and lock the connector. Connect the cable of additional one- or two-key foot switch (if it is included into supply package) to the rear panel connector on the unit, lock the connector.
- Connect the neutral electrode cable to the unit and connect the neutral electrode to the cable.

- Turn on the power using power switch on the rear panel. The Power on/Stand by button 18 (Fig. 2) on the front panel should blink, thereby indicating that the unit is in a standby mode. Press the button 18 (Fig. 2) on the front panel to put the unit into operation mode. The Power on/Stand by Button has to light up continuously.
- When turning on the unit the screen during the software download will display the logo and service information.
- During the boot unit performs a self-test. In case of errors or events that require user intervention, a message appears at the top of the screen above the logos.
- Critical errors are displayed in red, further operation is impossible. In the event of a critical error, contact the customer service department.
- Non-critical errors are displayed in yellow, to continue operation, follow the prompts on the screen.
- Events are displayed in white, to continue operation, follow the prompts on the screen.
- In case of successful completion of downloading the unit will go to the operation mode; LCD display shows the main screen.
- Set the type of neutral electrode «Solid» (see. «Using OSD menu»).
- Connect NE cable to NE connector (pos. 15 Fig. 2) and a reusable solid NE. Check the status of the neutral electrode: NE indicator (pos. 16 Fig. 2) should be lit in green. If the LED lights red, check the integrity of the neutral electrode cable and detach connections.
- Check the condition of the footswitches, and, if necessary, make the adjustment of footswitches application (see «Selection of the footswitches application settings»).
- Briefly activate the unit using each of the footswitch keys. When activating the unit, check the Indicators 10, 12 and 13 (Fig. 2) of the respective monopolar M1 and M2 and bipolar Bi output connectors and unit operation modes.

After checking, turn off the device and unplug its power cable.

8.4 Using OSD

SCREEN SAVER

When you turn the unit on the screen during the software download will display a logo. The system information is displayed under the logo.

During the boot time unit also performs an internal self-test. In case of errors or events that require user intervention, the corresponding text appears above the logo.

Critical errors are displayed in red, the operation is impossible.

Non-critical errors are displayed in yellow, to continue the operation press «OK» button (pos. 6 Fig.2).

NOTE. In the menu "OK" button is displayed with a symbol .

Events are displayed in green, to continue follow the prompts on the screen. Actions of buttons are signed on the screen next to them.

MAIN SCREEN – MAIN SCREEN LAYOUT (PANELS)

Figure 8-A

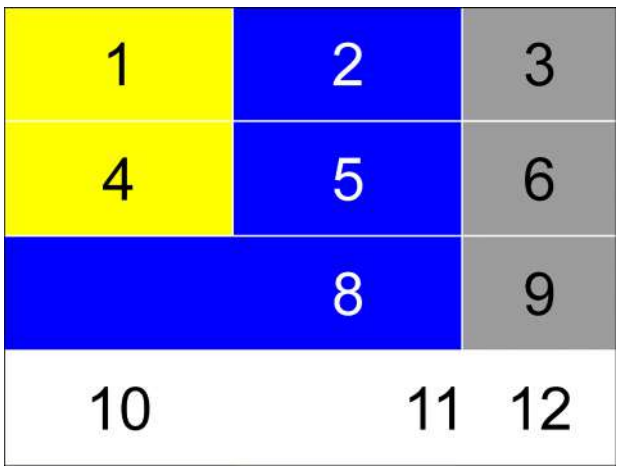


Figure 8-B

In operating mode the main screen is divided into panels:

1 - indicates the current setting of cutting mode of the M1 monopolar channel;

2 - indicates the current settings of coagulation mode of the M1 monopolar channel;

3 - indicates the application of M1 channel footswitches;

4 - indicates the current setting of cutting mode of the M2 monopolar channel;

5 - indicates the current setting of coagulation mode of the M2 monopolar channel;

6 - indicates the application of M2 channel footswitches;

7 - indicates the current setting of cutting mode of bipolar Bi channel;

8 - indicates the current setting or coagulation mode (Fig. 8-A), or ligation of vessels mode (Fig. 8-B) of bipolar Bi channel – depending on the selected mode of bipolar Bi channel;

9 - indicates application of bipolar Bi channel footswitches;

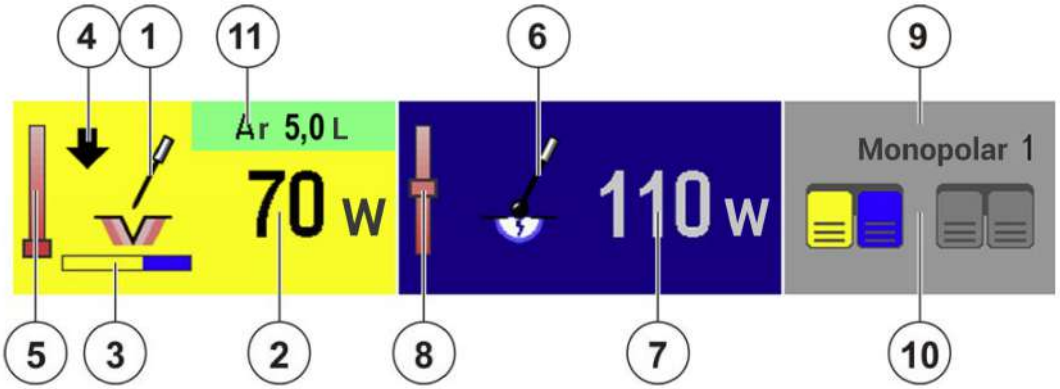
10 - displays the name of the current Application;

11 - indicates the status of the neutral electrode and availability of gas in the tank;

12 - displays the time and date.

SELECTING SETTINGS AND PARAMETER SETTINGS FOR MONOPOLAR M1, M2 and BIPOLAR BI CHANNELS

Standard line view of monopolar channel M2 mode settings on the main screen (for M1 and Bi channels - the same, except for indicator 10):



1. Icon of Cutting Mode
2. Set power of Cutting Mode
3. Hemostatic effect Cutting Mode
4. Indicator of additional functions of the current mode
5. Tissue type indicator of Cutting Mode
6. Icon of Coagulation Mode
7. Set power of Coagulation Mode
8. Tissue type indicator of Coagulation Mode
9. Channel name
10. Icon of footswitches application
11. Indicator of argon support and volumetric gas flow

NOTE. Tissue type indicator is not a parameter; it should be set by a specialist. The position of this indicator marker changes in accordance with the selected mode and its effect and displays a designed resistance of tissue depending on its blood supply, for this mode and its effect. The lower the indicator marker, for more blood supply (more conductive) tissues (e.g., muscle tissue) the mode is optimized, and conversely, the higher the indicator marker, for the less blood supply of tissues (e.g., omentum) it is optimized.

To change the settings for M1 channel, press MFB1 (pos. 1 Fig. 2):

When pressed once, it changes the colour of the panel 1 of configuration parameters for Monopolar cutting mode of M1 channel, next to the value of mode set power the arrow icons appear, at that:

- «UP» and «DOWN» buttons allow changing the set power for M1 channel cutting mode.
- «OK» button transfers the settings screen of M1 channel cutting mode.

Repeated pressing of MFB1 changes colour of panel 2 of configuration parameters for Monopolar coagulation mode of M1 channel, next to the value of mode set power the arrow icons appear, at that:

- UP» and «DOWN» buttons allow changing the set power for M1 channel coagulation mode.

- If the minimum or automatic power is set the long press with of «DOWN» button allows disabling the channel. Channel enabling is performed with a long press of «UP» button.
- «OK» button transfers the settings screen of M1 channel coagulation mode.

NOTE. Changing the selection of setting panels 1 and 2 is possible, when you press MFB1 in a loop.

Similarly to actions with channel M1, to change the M2 channel settings, use MFB2, and to change Bi channel settings – MFB3.

Standard screen view of Cutting mode settings for M2 channel (for cutting mode and coagulation mode of M1 and Bi channels – similarly, except for gas flow):

MFB1–MFB4 buttons used for changing settings the appropriate line 1-4 of the Mode Setting Screen, line changes color, at that:

- «UP» and «DOWN» buttons allow changing the selected Mode parameter.
- «OK» button transfers to the Main screen saving the selected parameters.

NOTE. Lines application of the Mode Settings Screen:

1 – Mode selection.

2 – selection of maximum power and, if available, gas flow (selectable setting is switched in a loop).

3 – Hemostatic effect selection.

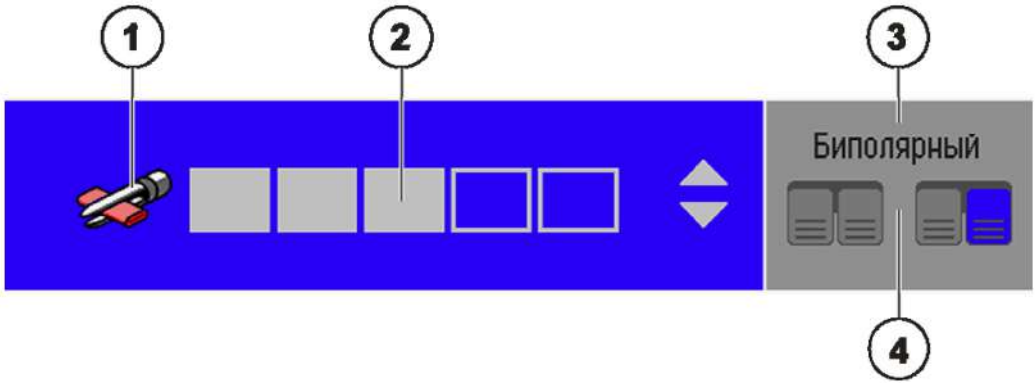
4 – Mode smart settings selection.

NOTE. Lines 1, 2, 3 of the Mode Settings Screen have color corresponding to the Mode (yellow — cutting, blue — coagulation).

Line 4 is white.

Settings unavailable for adjusting are in the line of dark gray color.

Typical view of the settings line for the modes of the bipolar Bi channel in the Main screen (for vessel ligation modes):



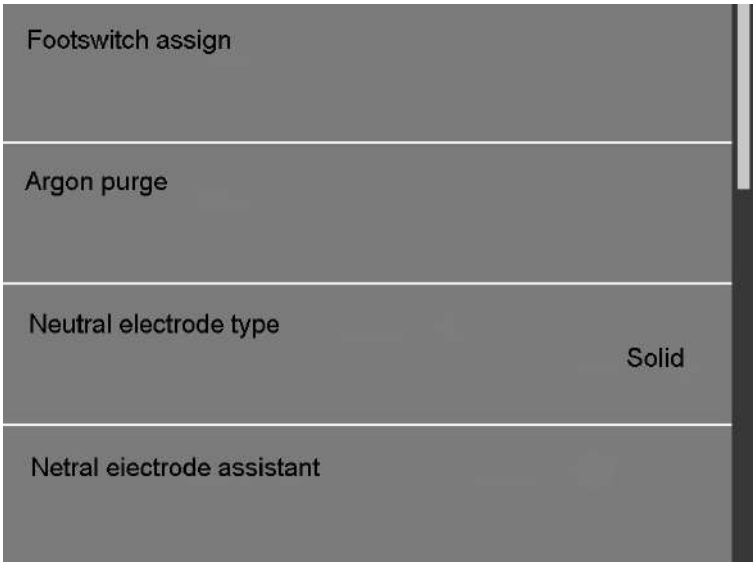
1. Icon of vessel ligation modes
2. Power limit indicator
3. Channel name
4. Icon of footswitches application

To change the parameters of the Bi channel in the case of the selected one of the vessel ligation modes, press MFB 3 (pos. 3 Fig. 1):

- With a single press, the area 8 (Fig. 2-B) of the settings of the parameters of the vessel ligation modes of the Bi channel changes color. Next to the value of the installed power of the mode, arrow icons appear, while:
- The «UP» and «DOWN» buttons allow you to change the installed power for the Bi channel ligation mode.
- The «OK» button brings you to the settings screen for the ligation mode of channel Bi.

UNIT SETTING

To switch to the unit settings screen, press «MENU» button (pos. 8 Fig. 2).



Unit settings screen includes the following options:

1. Footswitches assign

2. Argon purge (gas path before applying APC)
3. Selecting the type of neutral electrode
4. Assistant overlay of neutral electrode
5. Additional status indicator of separate neutral electrode on the main screen
6. Adjusting volume of the unit beeps
7. Enable/Disable start ringtone
8. Choosing a popup window display mode
9. Power indicator type selection
10. Selecting delay of unused settings screen closing
11. Deleting programs
12. Adjusting the screen brightness
13. Date and Time Settings
14. Selection of the menu language unit
15. Unit information

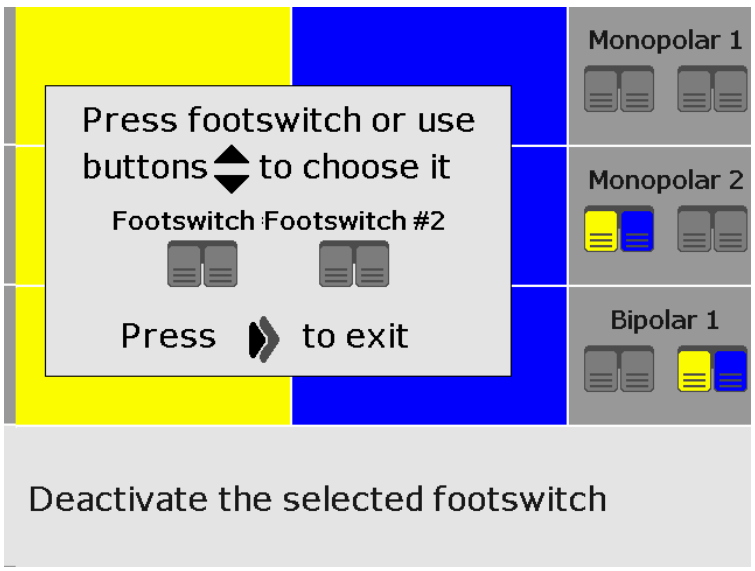
Switching between the pages of the list of settings is carried out by the buttons «UP» and «DOWN».

Changing the settings is carried out in the appropriate line with MFB1– MFB4 buttons.

If any line is greyed out, then in these settings the parameter is not available for adjustment. For example, when selected solid type of neutral electrode the neutral electrode Assistant is not available because it is designed for Devided neutral electrode.

SETTINGS SELECTION FOR FOOTSWITCHES APPLICATION

With the active screen of unit settings pressing MFB will display the footswitches application screen:



When you open the footswitches application settings screen in the panels of applied footswitches, the footswitches keys previously assigned to control the activation of any M1, M2 and Bi channels Modes will be highlighted with the appropriate Mode colos. Footswitches icon in the center of the pop-up screen will be in gray.

To assign or reassign any footswitches keys, briefly press this button, or use the UP and DOWN buttons to select footswitches keys manually. The selected key icon in the center of the pop-up screen will be highlighted with the appropriate color. To assign the selected footswitch key for control of:

– M1 channel enabling — press MFB1;

– M2 channel enabling — press MFB2;

– Bi channel enabling — press MFB3;

– pressing MFB4 will disable the selected footswitch key.

NOTE. The number of displayed footswitches corresponds to the number of connected footswitches. If two footswitches are connected, the left icon corresponds to Footswitch 1, right – Footswitch 2.

NOTE. When assigning the yellow footswitch key for Bi channel enabling and selected ligation modes the footswitch will be disabled and not highlighted in the Main Screen (this channel has no cutting mode).

Pressing OK button will put the unit to the Unit Settings Screen, repeated pressing – Main Screen saving the settings.

PURGE

With the device settings window active, pressing the MFB corresponding to the Purge line initiates purging and filling the instrument's gas path with working gas.

NOTE. Be sure to purge after each connection of the gas channel of the cable of the electrode holder to the device and after each replacement of the active electrode of the APC.

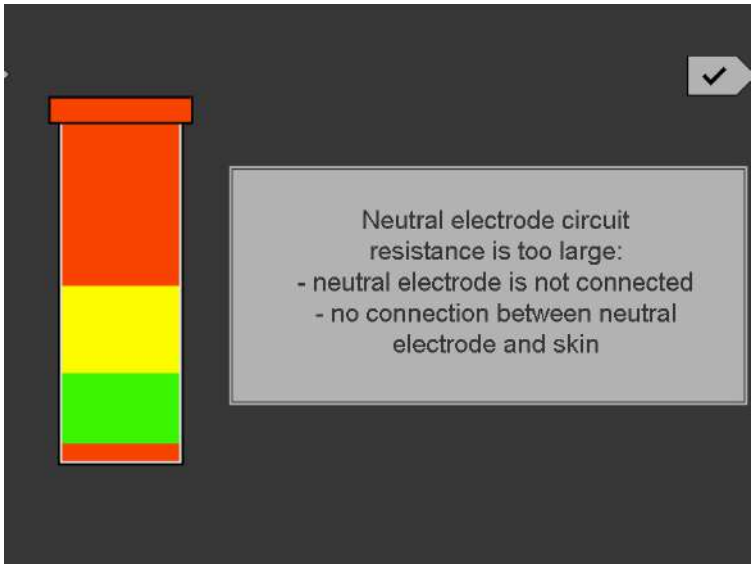
SELECTION OF NEUTRAL ELECTRODE TYPE

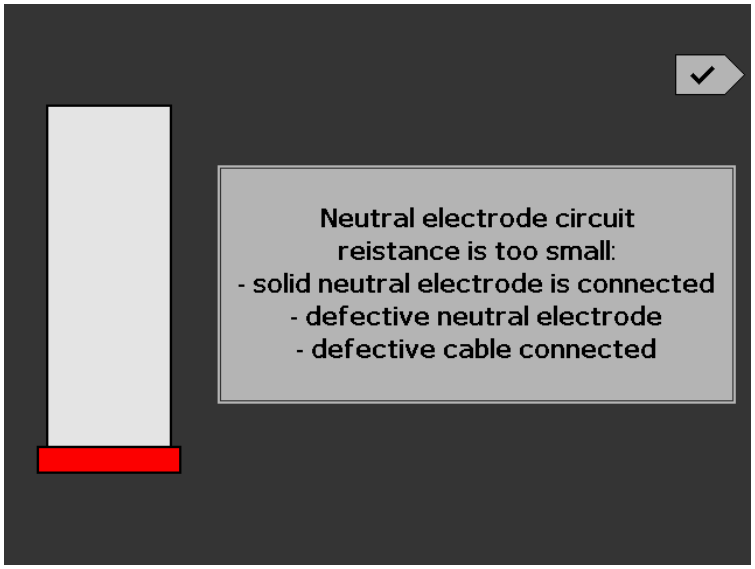
If the unit setting screen is enabled, by pressing MFB select the neutral electrode type - solid or divided (switching takes place in a loop).

OVERLAPPING THE NEUTRAL ELECTRODE USING NEUTRAL ELECTRODE ASSISTANT

NOTE. Neutral Electrode Assistant is not available if you select the "Solid" type of neutral electrode.

With unit setting screen enabled open by pressing MFB the neutral electrode assistant for overlaping a divided neutral electrode:





The resistance of the divided neutral electrode circuit is shown on the screen in a vertical color chart. The right side of the screen displays prompt text. After completion of overlapping the neutral electrode, press OK or MENU.

ENABLING ADDITIONAL INDICATOR FOR NEUTRAL ELECTRODE OVERLAPPING IN MAIN SCREEN

NOTE. Additional indicator of neutral electrode is not available if you select the "Solid" type of neutral electrode».

With unit setting screen enabled enable by pressing MFB the additional indicator of neutral electrode overlapping which will be displayed in the Main screen below the neutral electrod icon. Repeated pressing of MFB disables this feature.

SETTING SOUND VOLUME (EXCEPT FOR EMERGENCY)

With unit setting screen enabled pressing MFB button will an increase the audio signals volume. Upon reaching the maximum volume the repeated pressing will set a minimum volume value –volume adjustment occur in a loop.

DISABLING THE UNIT START RINGTONE

With unit setting screen enabled pressing MFB button will enable or disable the unit start ringtone.

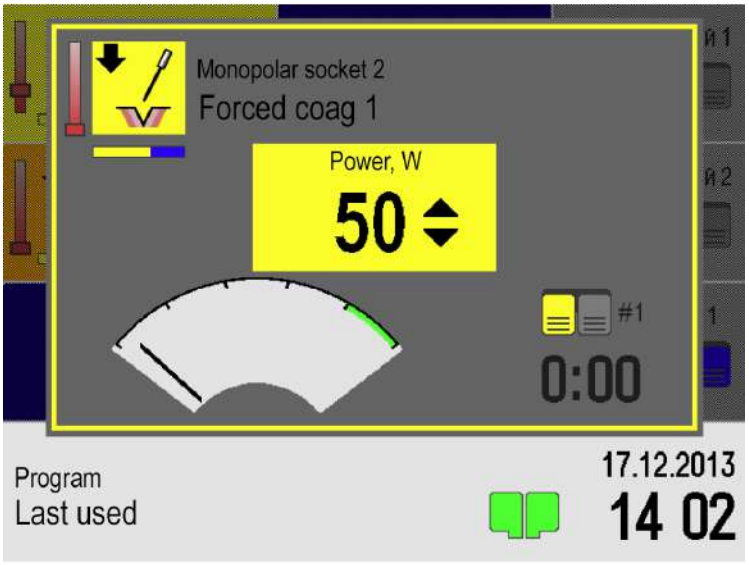
SELECTING POP-UPS DISPLAY MODE

With unit setting screen enabled pressing MFB button provides mode selection of the pop-ups display mode – «ON», «Only enabled», «OFF» - with switching in a loop.

When set parameter is «Off», popups do not appear.

When set parameter is «Only enabled» the pop-up displaying active mode settings appear when you enable this mode using footswitch or control buttons of the electrode holder.

When set parameter is «On» pop-ups appear in the same way as with the set parameter «Only enabled», as well as when increasing or decreasing power using «UP» and «DOWN» buttons for the selected with MFB1–MFB3 buttons Mode parameter in the Unit Main Screen.



REAL HF POWER INDICATOR TYPE

NOTE. Selection of the power indicator type is available when the pop-up screens mode is enabled.

When the device's settings window is active, pressing the MFB corresponding to the Power indicator type line selects the type of indicator in the pop-up window - «Off», «Real power arrow», «Digital real power» or «Digital real tissue resistance» – with switching in a loop.

When the parameter «real power arrow» is set, the indication of real power during the activation process is performed by a dial indicator as a percentage of the set.

When the «Digital Real Power» parameter is set, the indication of real power during activation is performed by a digital indicator in Watts.

When the «Digital real tissue resistance» parameter is set, the indication of tissue resistance during activation is performed by a digital indicator in Ohms.

SELECTING A DELAY OF A NON-USE SETTINGS WINDOW

With unit setting screen enabled pressing MFB button selects the time adjustment line, after which any opened settings screen will be closed with the transition to the Main Screen in the absence of actions by the user.

Once the line has been selected, its color will change and by pressing «UP» and «DOWN» buttons you can adjust the delay time.

Pressing «OK» button will switch the unit t the Unit Settings Screen deselecting the line highlighting.

Repeated pressing of «OK» button will switch the unit to the Main Screen and save the settings.

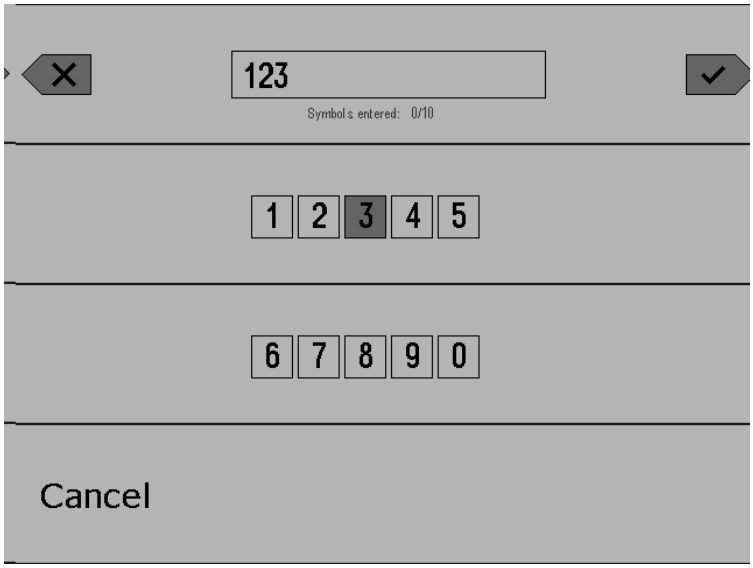
DELETING PROGRAMS

With unit setting screen enabled pressing MFB button opens the program list screen available in the unit memory.

Switching between the pages of the program list is carried out using «UP» and «DOWN» buttons.

Pressing MFB1–MFB4, if the program is not protected with a password, without requiring confirmation removes the program in the same button line. Clicking the «OK» button will switch the unit back to the Unit Settings Screen.

If the program is password-protected, the password entry screen appears:



In the password entry screen:

- Pressing MFB1 button deletes the entered character or, if no character entered, cancels the removal of the program and returns the program list screen in memory.
- Pressing MFB2–MFB3 buttons selects the next character to be entered. Switching the selected character takes place in a loop.
- Pressing MFB4 button cancels the removal of the program and returns the program list screen in memory.
- Pressing «UP» and «DOWN» buttons allows moving the highlighting of the entered character by the line above or below, respectively.

- Pressing «OK» button enters the selected character.
- Pressing «MENU» button checks the entered password, and if it is correct removes the program and returns the program list screen in memory.

SCREEN BRIGHTNESS SETUP

With unit setting screen enabled pressing MFB button selects adjustment line of the screen brightness. Once the line has been selected, its color will changes by pressing «UP» and «DOWN» buttons and you can adjust the brightness. Clicking the «OK» button will switch the unit to the Unit Settings Screen deselecting the highlighting of the line; repeated pressing of «OK» button will switch the unit to the Unit Settings Screen and save the settings.

TIME AND DATE SETUP

With unit setting screen enabled pressing MFB button opens Time and Date Setup screen.

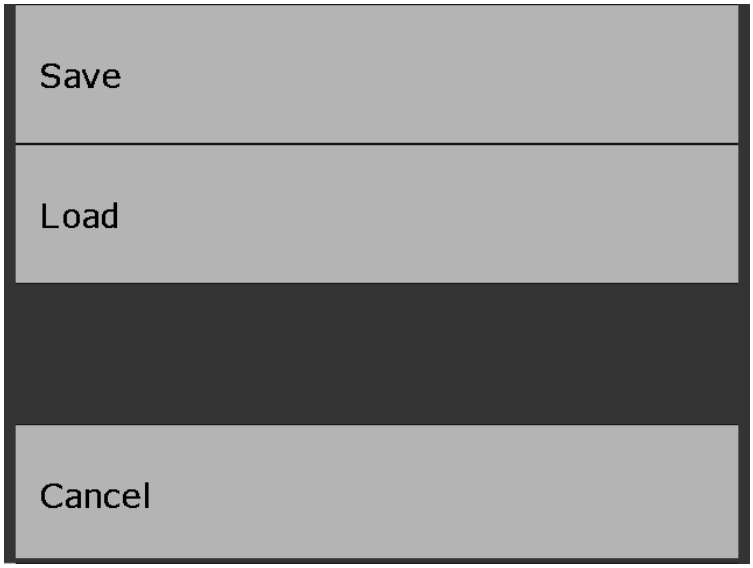
Using MFB2 and MFB3 buttons select the parameter to change. Pressing MFB2 button select the hour or minute to adjust. Pressing MFB3 button select the day, month or year. Selecting of parameters is taking place in a loop. Icons appear above and below the selected parameter of the up and down arrows. Once one of the parameters has been selected, using «UP» and «DOWN» buttons it is possible to adjust. Pressing «OK» button will return the unit to the Unit Settings Screen and save the configured time and date values. Pressing the «MENU» button will return the Unit Settings Screen without saving the set values of time and date.

SAVING PROGRAMS

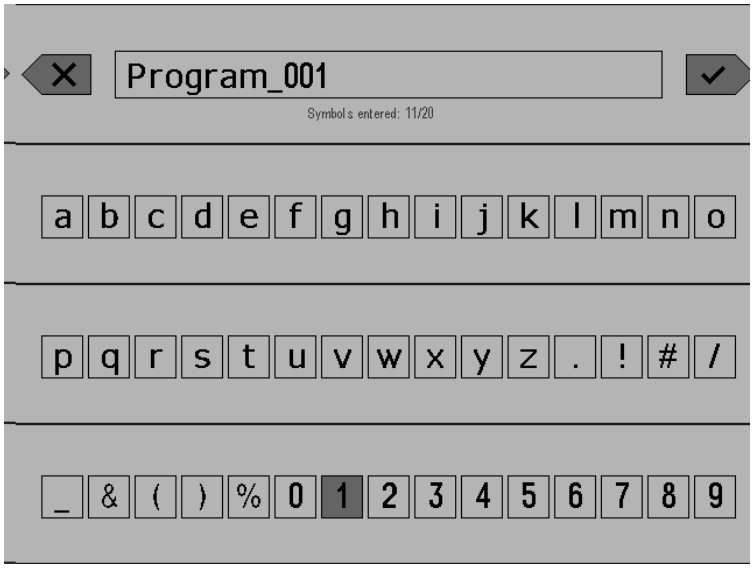
Term PROGRAM in this User's Manual represents a specific set of parameters and settings of the unit current modes, setting of NE type, application of footswitches, volume adjustment, settings the pop-up screens and auto-closing of settings.

The unit memory can store up to 100 sets of registered user (program) settings.

If you installed a set of these parameters according to your preferences, you can save them in the unit memory, as follows: after unit setup according to your preferences in the main screen click MFB4 – Programs screen will be displayed.



To save the Program, click MFB1 – Save Program screen appears.



To form the name of the Program, select using MFB2–MFB4 buttons the desired character (lines 2-4) and press «OK» button, enter it into the name of the Program (Line 1).

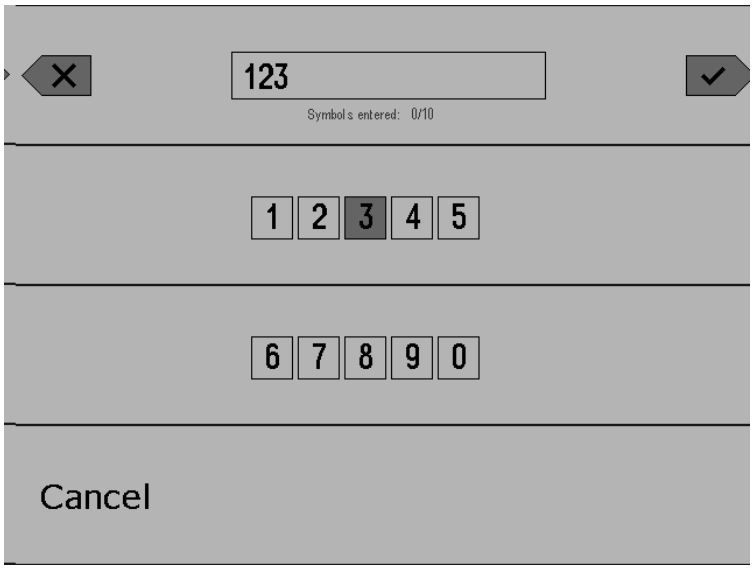
Pressing «UP» and «DOWN» buttons will move the character highlight on the line up or down, respectively.

Similarly, enter the names of all the characters of the Program.

Pressing MFB1 button deletes the last character. If no character entered pressing MFB1 button cancels Program saving.

After entering the name, press «MENU» button to save the program. A pop up screen appears, in which it is possible to assign a password to the program or continue saving without assigning a password.

Press «MENU» button to save the program without a password and press «OK» to set the password for a program. In the first case, the program will be saved and the main screen appears. In the second case, a new password screen appears.

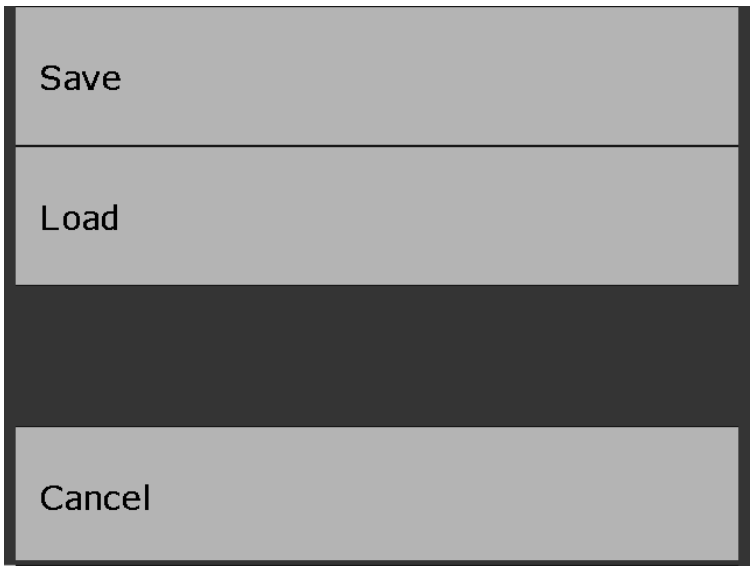


In the password entry screen:

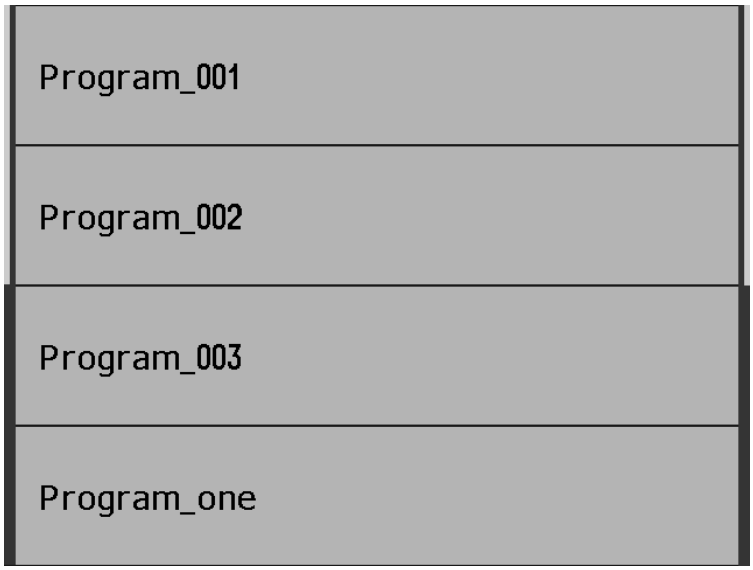
- Pressing MFB1 button deletes the entered character or, if no character entered, cancels the removal of the program and returns the program list screen in memory.
- Pressing MFB2–MFB3 buttons selects the next character to be entered. Switching the selected character takes place in a loop.
- Pressing MFB4 button cancels the removal of the program and returns the program list screen in memory.
- Pressing «UP» and «DOWN» buttons allows moving the highlighting of the entered character by the line above or below, respectively.
- Pressing «OK» button enters the selected character.
- Pressing «MENU» button saves the program and password.

DOWNLOADING PROGRAMS

To download a previously saved Program in the Main screen click MFB4 – Program screen will appear.



Next, in the Program screen press MFB2 – Program selection screen will appear.



In the Program selection screen using «UP» and «DOWN» buttons select the Program List Page containing the program you want to download, and then by pressing the corresponding MFB button select the Program.

Unit will switch to the Main screen with the settings of the downloaded Program.

8.5 Shared operation with argon supply unit

In order to stop the diffuse capillary bleeding within a large area using monopolar contactless argon-plasma coagulation (APC) method, the argon supply unit can be connected to the unit.

When operating the unit with argon support plug and prepare argon supply unit in accordance with its instruction manual.

In the unit settings screen enable purge function of gas supply unit. Verify the availability of gas flow at the outlet of the gas supply unit («ARGON» connector). Purging is carried out for 9 seconds and turned off automatically.

8.6 Preoperative preparation

Isolate the patient from any conductive objects and, in the first place, from the operating table. 2-3 layers of hospital sheeting may serve as isolation, which should exceed the size of the operating table by 20-30 cm.

Connect the neutral electrode cable to the corresponding connector located on the unit front panel and attach the neutral electrode o the cable.

Place the neutral electrode under the patient's buttocks. Apply the electrode without additional pads. Remember that improperly installed electrode may cause patient's burns.

WARNING! Be careful when connecting instruments and units to the patient, which are not adapted to share operation with the electrosurgical equipment.

Depending on the intended type of exposure, connect the corresponding cables to the monopolar and bipolar channels output connectors.

WARNING! M1 channel operates without gas support only.

M2 channel operates with gas support only. Cables and instruments for operation with gas support should be connected only to M2 channel.

WARNING! Cables of the electrosurgical electrodes should be positioned in such a way as to prevent them from contacting patient or other connecting cables. Temporarily unused active electrodes should be stored separately from the patient.

NOTE. When using monopolar cables without manual control connect them only to A sockets of M1 and M2 connectors. Connecting this cable to other sockets may cause damage to the unit.

Depending on the intended type of exposure, connect the corresponding active electrodes or instruments to the cables.

8.7 Operation

Turn on the unit. The unit will perform booting and self-test.

NOTE. The unit will automatically remember the operating mode and settings you used last before turning it off and load them at start-up. In the name field of the Program «Last used».

Set (in accordance with the previous description):

1. Neutral electrode type tah you plan to use;
2. Footswitch application;
3. modes and mode parameters for planned outputs.

When neutral electrode cable is connected to the neutral electrode the NE status indicator (pos. 16 Fig. 2) should light in green. If NE status indicator is red, check the integrity of neutral electrode cable, plug connections, and in the case of the divided NE the quality of NE application on the patient.

The cutting mode is enabled by pressing the left (yellow) footswitch or yellow control button on the instrument. The unit will enable "CUTTING" indicator in yellow, located above the corresponding connector, and special sound signal throughout the entire process of cutting. Mode activation using the footswitch is performed in accordance with a previously applied footswitch assignment.

The coagulation mode is enabled by pressing the right (blue) footswitch or blue control button on the instrument. The unit will enable "COAGULATION" indicator in blue, located above the corresponding connector, and special sound signal throughout the entire process of cutting. Mode activation using the footswitch is performed in accordance with a previously applied footswitch assignment.

8.8 Cleaning

NOTE. Always disconnect the power cable before cleaning the unit

The unit can be cleaned with any cleaning agents, which is used for external cleaning of electric medical equipment, according to the instructions given by the manufacturer of the cleaning solution.

Follow the instructions provided by the manufacturer of cleaning agents.

Do not allow excessive moisture or liquids to reach direct contact with the unit.

Do not use cleaning agents that are not permitted for use with plastics, such as: Ammonia, Acetone, salty acids (HCl), etc.

Do not allow cleaning agents or liquids to enter the unit outlets.

8.9 Disinfecting

NOTE. Always disconnect the power cable before disinfecting the unit

Use any disinfecting agents which is commonly applied while disinfecting surfaces of electric medical equipment. Such disinfecting agents usually arrive in the form of sprays or damp cloths.

Follow the instructions given by the manufacturer of the disinfecting solution.

Do not allow disinfecting agents or liquids to enter the unit outlets.

8.10 Accessories Sterilization

Sterilisation should be performed according to the recommendations of a specific accessory supplier. The accessories supplied by the manufacturer, unless specified otherwise, are non-sterile and require sterilisation before use.

The offered electrosurgery accessories, unless specified otherwise, may be steam sterilised at up to 134 °C at 2.3 Bar. If other accessories are used, the manufacturer's instructions should be observed.

NOTE. Temperatures over 138° C may damage the parts!

9 MAINTENANCE, SERVICING AND REPAIR

Performance of preventive maintenance is not essential. Regular maintenance can, however, contribute to identifying potential problems before they become serious, thus enhancing the equipment's reliability and extending its useful operating life. Maintenance services can be obtained from your local representative or from the manufacturer.

Defective items of equipment are to be serviced and repaired exclusively by persons authorized by the manufacturer. All repair work shall employ original manufacturer's parts only.

9.1 Fuses Replacement

CAUTION! Always disconnect the power cable before fuses replacement.

Fuses can be replaced, when necessary, by the user. Replace only with identical type of fuses (type 5*20 250V/T5,0AL).

Turn main switch off and connect the power cable. After that turn main switch on.

10 TROUBLESHOOTING

Table 2 describes possible troubles and recommended solutions.

Table 2 – List of problems

Possible problem	Possible reason(s)	Solution(s)
The Power on/Stand by Button (pos.18 fig. 2) of the unit is not lit after unit switched on.	No mains voltage. AC power cable is not properly connected. Unit fuse(s) is(are) damaged.	Check the voltage in the mains supply. Check that the AC power cable is properly connected. Check the unit fuses. If necessary, replace with new ones.

All other faults, not specified in Table 2, can be repaired only by the qualified specialist of the service centre or at the manufacturer's site.

11 TRANSPORTATION AND STORAGE

The unit should NEVER be stored in areas where it could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment.

The unit should NEVER be stored in the presence of flammable or explosive gases or chemicals.

The unit should NEVER be stored or transported in an inclined position, nor should it be subjected to impact or vibration.

Cords, accessories, etc., should be cleaned and neatly stored.

The unit should be maintained in a clean condition during storage and be ready for subsequent use.

Transportation of the packed unit should be performed at ambient temperature from minus 40 °C up to plus 70 °C and relative humidity not more than 80 % at the temperature plus 25 °C.

If the transportation was performed in winter or under humid conditions, leave the unit in the heated space for 6-10 hours.

All the requirements of the manipulation signs and warning notices should be strictly followed during packing, transporting and unloading to prevent mechanical damage, dust and humidity penetration.

The unit has to be stored in the covered premise at ambient temperature from plus 5 °C to plus 40 °C and relative humidity not more than 80 % at the temperature plus 25 °C.

The air in the premise where the unit is stored should be free from the contaminants causing corrosion.

Practical storage life without additional preservation is 3 years.

12 RECOVERY

Unit which cannot be used no more have to be recovered.

Recovering measures have to be made by authorized organizations.

13 POST-SALES SUPPORT AND WARRANTY

Manufacturer supports all post-sales services perfectly.

The unit provides a full 24 months warranty against defect due to defective parts, workmanship or Manufacturer's fault. If the product should become defective within the warranty period it will be repaired or replaced free of charge at Manufacturer's discretion.

- Receive the warranty registration card that should be filled correctly and completely.
- The warranty provisions do not cover failure due to shipment and misuse.
- The warranty provisions do not apply where the unit has been serviced by a person not authorized by Manufacturer or serviced with nonapproved parts.
- The warranty provisions do not cover the accessory failure, so replace defective part with a new one.

14 APPENDIX. EMC

CAUTION

Use only the recommended accessories. Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of the unit.

CAUTION

Measurements can be affected by mobile and RF communications equipment. It should be assured that the unit is used in the electromagnetic environment specified.

CAUTION

To prevent EMC effect on the unit, one should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

CAUTION

Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such units may result in strong interference with the unit performance.

Guidance and manufacturer's declaration – electromagnetic emissions		
ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators are intended for use in the electromagnetic environment specified below. The customer or the user of the ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators are intended for use in the electromagnetic environment specified below. The customer or the user of ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators should assure that they are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (>60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (>60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators requires continued operation, it is recommended that ECONT-0201.1, ECONT-0201.2 , ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T - is the a.c. mains voltage prior to application of test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators are intended for use in the electromagnetic environment specified below. The customer or the user of ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators should assure that they are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.16$\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.16$\sqrt{P}$ 80 MHz to 800 MHz d = 2.33 $\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators are used exceeds the applicable RF compliance level above, ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators should be observed to verify normal operation. If abnormal performance is observed, additional measures may necessary, such as reorienting or relocating ECONT-0201.1, ECONT-0201.2 , ECONT-0201.3 (with ECONT-0201.3A) Electrosurgical Generators.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 Electrosurgical Generators

ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 Electrosurgical Generators are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 Electrosurgical Generators can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ECONT-0201.1, ECONT-0201.2, ECONT-0201.3 Electrosurgical Generators as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.16\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.16\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,16	1,16	2,33
10	3,67	3,67	7,37
100	11,6	11,6	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.