STEMA MASTER ELECTROSURGICAL UNIT INSTRUCTIONS FOR USE

Version: 1.0

Read these Operation Manual before using
the device and keep it for further reference

SYMBOLS USED IN THIS MANUAL:

Important information

What to do

What not to do

Warning

Contents

The attachments to this Operating Manual contain the Safety Manual and the Catalogue of Accessories. Please contact the manufacturer if there are no attachments.

1. Areas of use for the STEMA MASTER system

The STEMA MASTER system can be used for cutting and coagulation in all surgical procedures. It is intended for both open and laparoscopic surgery, as well as endoscopic procedures.

STEMA MASTER enables work in a fluid environment, for instance in mono- and bipolar TUR electroresection. The device is equipped with a CF output (floating), so that it can be used on the central nervous system and the heart. Depending on the purchased version of the STEMA MASTER device, it can be equipped with an argon module, allowing to perform argon-enhanced cutting and coagulation treatments during open surgery, laparoscopic procedures, and using flexible electrodes in endoscopic surgery.

It can also have the integrated ThermoStapler® mode for sealing large blood vessels and for preparing tissues using special instruments.

1.1 STEMA MASTER operating modes

STEMA MASTER system may be equipped with the following operating modes:

- MONO CUT (standard monopolar cutting)
- PRECISE CUT (precise monopolar cutting)
- MIXED CUT (drying monopolar cutting)
- MUCO CUT (monopolar cutting for mucosectomy procedures)
- POLIPO CUT (endoscopic monopolar cutting – polypectomy)
- PAPILLO CUT (endoscopic monopolar cutting – papillotomy)
- ARTRO CUT (arthroscopic monopolar cutting in fluid environment)
- URO CUT (urological monopolar cutting in fluid environment)
- HYSTERO CUT (gynaecological monopolar cutting in fluid environment)
- ARGON CUT (argon-enhanced monopolar cutting)
- SOFT COAG (soft monopolar coagulation)
- FORCED COAG (forced monopolar coagulation)
- HYBRID COAG (forced monopolar coagulation with non-contact work function)
- SPRAY COAG (monopolar non-contact coagulation,)
- ENDO SPRAY (endoscopic monopolar non-contact coagulation)
- STANDARD ARGON (argon-enhanced monopolar coagulation)
- ENDO ARGON (argon-enhanced endoscopic monopolar coagulation)
- PULSE ARGON (argon-enhanced pulse endoscopic monopolar coagulation)
- URO COAG (urological monopolar coagulation in fluid environment)
- ARTRO COAG (arthroscopic monopolar coagulation in fluid environment)

- HYSTERO COAG (gynaecological monopolar coagulation in fluid environment)
- BI-CUT (bipolar cutting)
- URO BI-CUT (urological bipolar cutting in fluid environment)
- ARTRO BI-CUT (arthroscopic bipolar cutting in fluid environment)
- SOFT BI-COAG (soft bipolar coagulation)
- FORCED BI-COAG (forced bipolar coagulation)
- URO BI-COAG (urological bipolar coagulation in fluid environment)
- ARTRO BI-COAG (artroscopic bipolar coagulation in fluid environment)
- SCISS BI-COAG (soft bipolar coagulation for cutting with bipolar scissors)
- ThermoStapler® (bipolar system for sealing large blood vessels)

The availability of particular modes depends on the configuration of the unit.

The electrosurgery system can **only be used by persons trained in the field of safety** principles in electrosurgery.

2. Electrosurgery basics

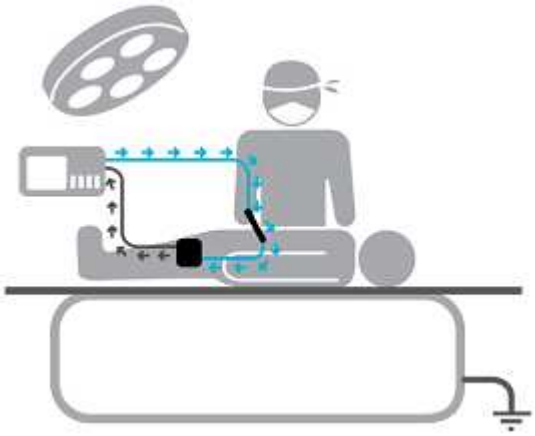
Currently, electrosurgery is a technique used in nearly all kinds of surgical procedures. In order to use electrosurgery effectively, it is necessary to learn and understand it, and to apply the safety rules designed for maximum protection of both the surgeon and the patient.

An electrosurgical unit is a device that uses electricity to generate high-frequency (HF) alternating current. The thermal effect caused by the HF current flowing through the tissue is used for tissue cutting or coagulation. An electrosurgical unit generates alternating current of frequency higher than 300 [kHz], so there is no risk of unintended effect of muscle and nerve electrolysis/stimulation.

When working with an electrosurgical unit generating high-frequency current, always remember the two fundamental rules:

- the current flows along all the available paths
- HF leakage current flows between two adjacent conductors even if they are separated from each other

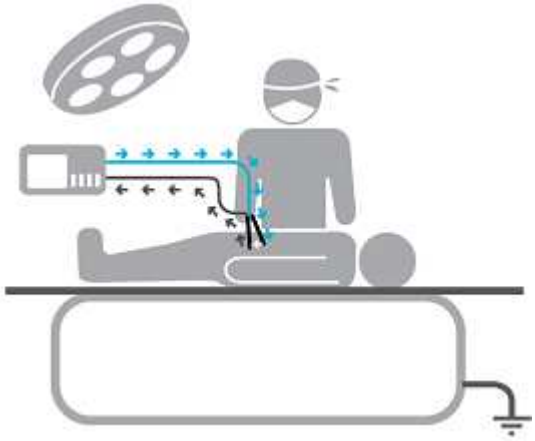
2.1 Monopolar operation



In the monopolar mode, the HF current is delivered to the tissue by the active electrode. The cutting or coagulation effect results from the concentration of the high density HF current on the small surface of the active electrode. This causes the increase of temperature and evaporation of water from the tissue in the direct vicinity of the active electrode and eventually results in haemostasis and arrest of bleeding, or cutting of tissue.

Subsequently, the HF current flows to the neutral electrode where it is dispersed. In this way, the density of the HF current decreases and no unintended thermal effect occurs at the site of the neutral electrode application. From the neutral electrode the HF current returns to the unit.

2.2 Bipolar operation



When the device operates in the bipolar mode, HF current flows between two jaws of a bipolar instrument and concentrates exclusively on the small area located between them. In the bipolar mode the dangerous flow of current through the patient's body to the neutral electrode does not occur, so the risk of burns occurring outside the immediate surgical area is minimised. Thus, the bipolar coagulation modes are safer than the monopolar modes and they are particularly recommended for procedures involving patients with cardiac pacemakers or for procedures performed on organs of small cross-section area. In the bipolar mode, the neutral electrode is not required.

3. Symbol

resistance to defibrillation impulse for type CF devices

floating-type patient circuit

general symbol for precaution

STEMA electrosurgical devices are manufactured in protection class I CF. It is the highest class of patient protection against electric shock from electromedical devices. Type CF applied parts can be used in contact with any part of the patient body including the heart.

4. Device appearance and construction

The generator casing is made of metal without ventilation holes. The front panel is made of plastic. One can easily keep the device clean; generally available disinfection agents may be used for cleaning.

4.1 Front panel

The STEMA MASTER system has two universal SDS outputs with instrument detection **(Fig. 1 items 1 and 3)**, one monopolar output **(item 2)** and one bipolar output **(item 4)**.

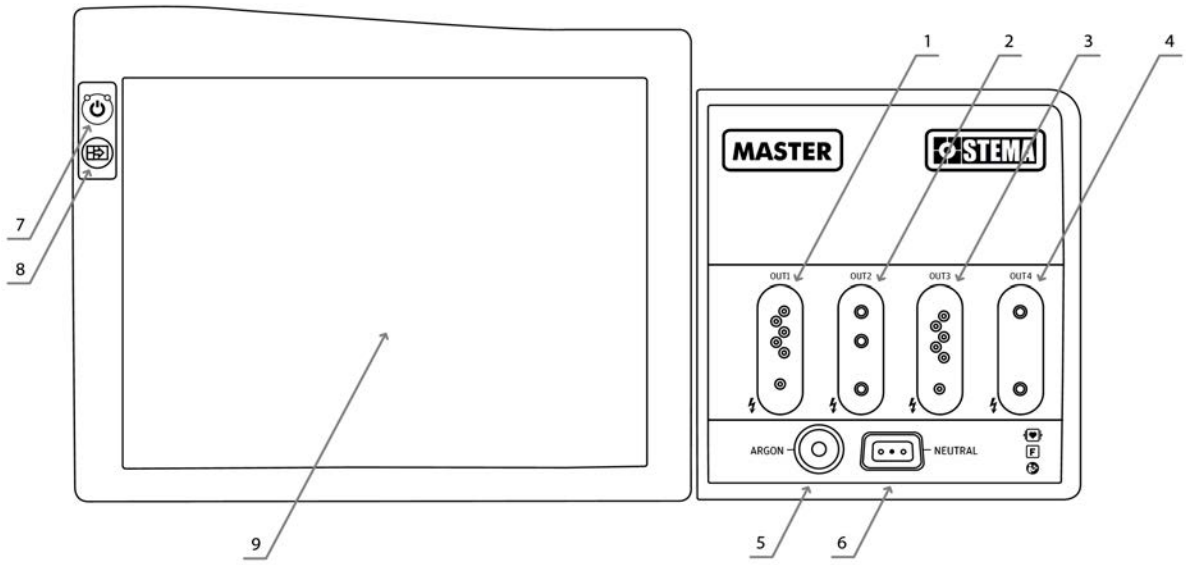


Figure 1. STEMA MASTER frontside view.

The front panel of the STEMA MASTER system contains the following items **(Fig. 1)**:

- universal SDS output with instrument detection – socket one **(1)**
- monopolar output– socket two **(2)** 2.1.17 Galimybė vienu metu prijungti monopolinį ir bipoliarinį instrumentus
- universal SDS output with instrument detection – socket three **(3)**
- bipolar output – socket four **(4)** 2.1.17 Galimybė vienu metu prijungti monopolinį ir bipoliarinį instrumentus
- argon output **(5)** 2.1.1 Suderinamas su argono plazmos prietaisu
- neutral electrode socket **(6)**
- stand-by button **(7)**
- main view button **(8)**
- touch panel screen **(9)** 2.1.2 Lietimui jautrus ekranas

4.2 Back panel

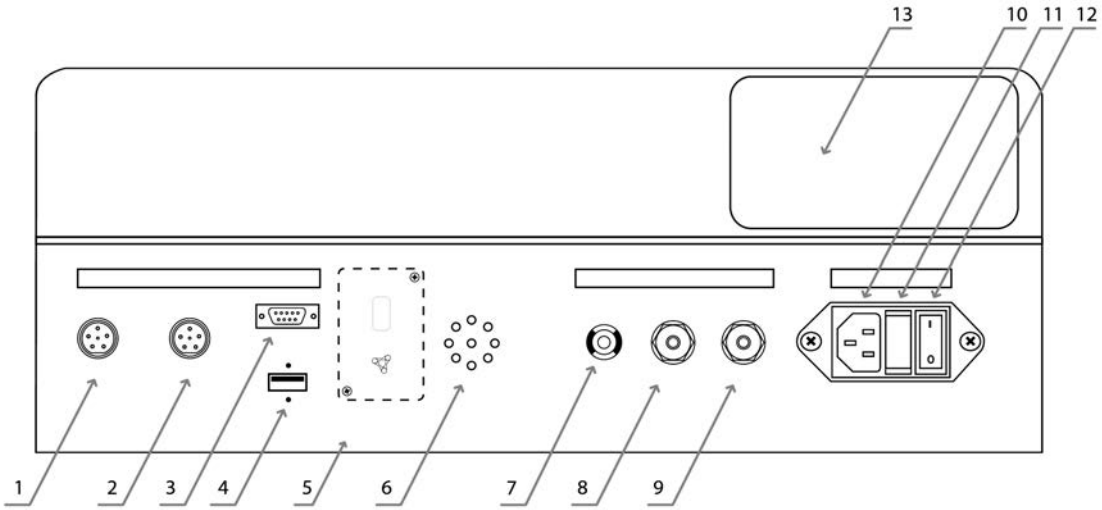


Figure 2. STEMA MASTER backside view.

The back panel of the casing, as shown in **Fig. 2**, contains the following items:

- universal footswitch socket for all outputs **(1)** 2.1.3 Rankinis ir kojinis prietaiso valdymas
- footswitch socket for one of the inputs – by default it is assigned to the third SDS output **(2)**
- RS service port **(3)**
- USB port **(4)**
- wireless footswitch receiver module **(5)**
- speaker **(6)**
- additional grounding pin **(7)**
- argon supply input I **(8)**
- argon supply input II **(9)**
- power cable input **(10)**
- fuse socket **(11)**
- main power switch **(12)**
- manufacturer’s rating plate **(13)**

4.3 Main panel

The STEMA MASTER system has a mobile display, which can be tilted to adjust to the user's needs. Owing to this feature, the system can be placed at different heights. To increase or decrease the screen angle, just move it in the right direction.

The system is equipped with four sockets **(Fig. 1 items 1, 2, 3, 4).** Each socket has an assigned control panel **(Fig. 5, items 1, 2, 3, 4).**

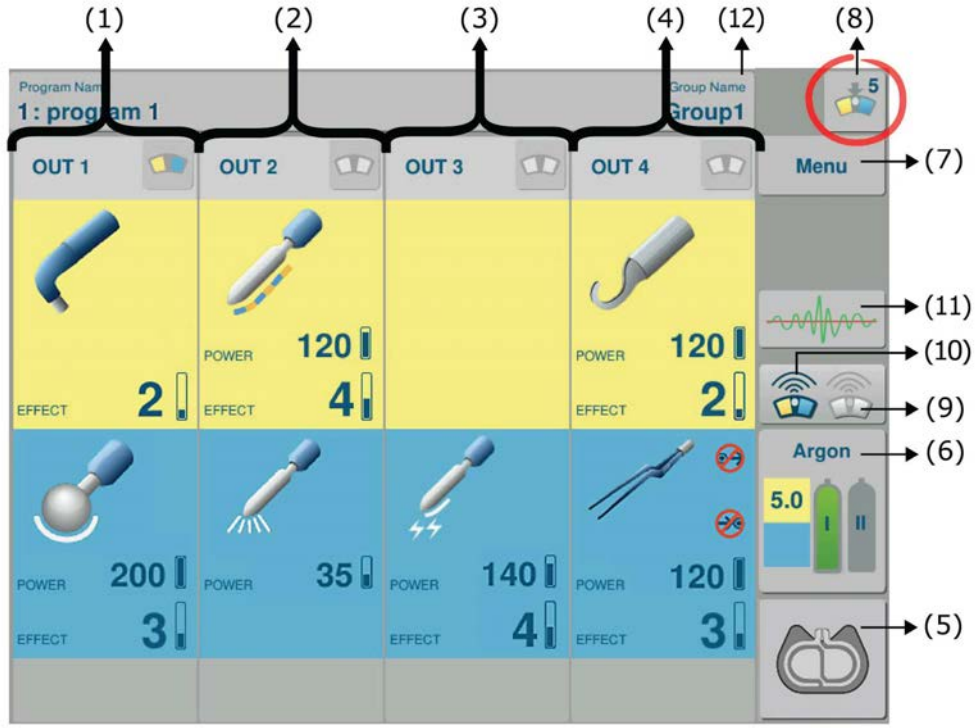


Figure 3. The main panel.

The main panel in the basic configuration of the STEMA MASTER system (Fig. 3):

- output I control panel **(1)**
- output II control panel **(2)**
- output III control panel **(3)**
- output IV control panel **(4)**
- neutral electrode indicator NEM **(5)**
- argon indicators and argon flow settings panel **(6)**
- Menu button **(7)**
- MultiSwitch indicator **(8)**
- icon of wireless footswitch assigned to the universal socket "Footswitch" **(9)**
- icon of wireless footswitch assigned to the SDS socket III **(10)**
- power monitor **(11)**
- program selection button **(12)**

Each of the four panels, corresponding to four outputs, is active. To change the settings (operating mode, effects, power limit, additional settings), touch the selected element. The figure below describes a selected panel:

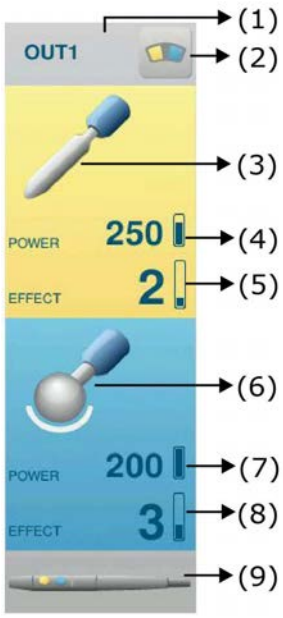


Figure 4. Control panel for output 1.

Fig. 4 shows the control panel for output 1, where:

- output 1 window **(1)**
- footswitch control selection button **(2)**
- cutting mode icon **(3)**
- power limit for the selected cutting mode **(4)**
- effect level for the selected cutting mode **(5)**
- coagulation mode icon **(6)**
- power limit for the selected coagulation mode **(7)**
- effect level for the selected coagulation mode **(8)**
- detection status of the SDS instrument connected to output 1 **(9)**

4.4 Active panel – detailed view for a given output

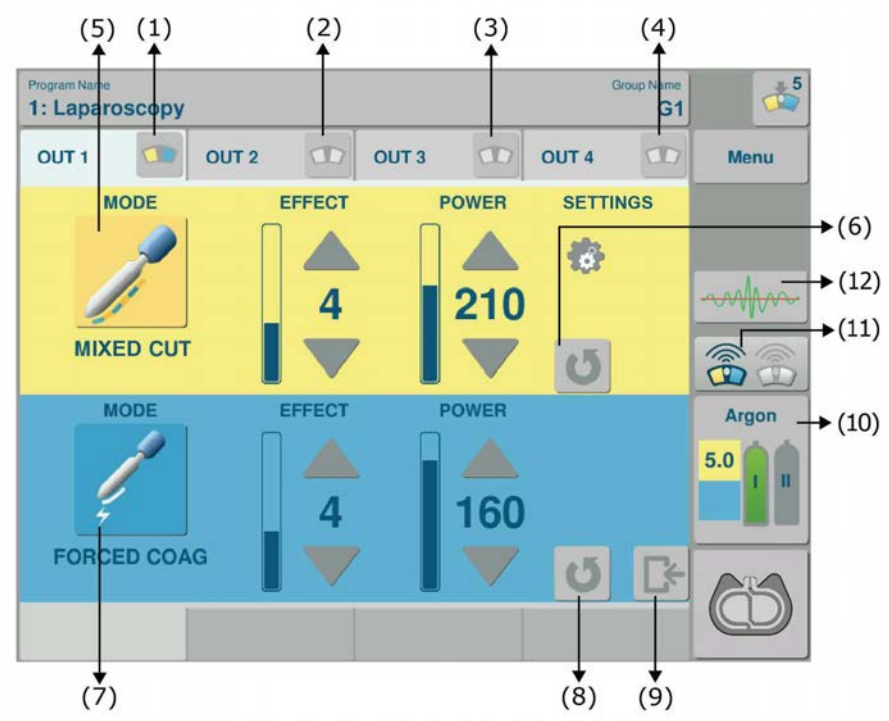


Figure 5. Panel view with two modes – cutting and coagulation.

The detailed view of the control panel for a given output **(Fig. 5)** contains:

- output selection button for footswitch control **(1, 2, 3, 4)**
- cutting mode icon **(5)**
- restoring the suggested settings for a selected cutting mode **(6)**
- coagulation mode icon **(7)**
- restoring the suggested settings for a selected coagulation mode **(8)**
- exit from the detailed view for a given output **(9)**
- argon flow settings button **(10)**
- wireless footswitch icon **(11)**
- power monitor **(12)**

5. STEMA MASTER technical specifications

(the list of available modes can differ depending on device version)

POWER SUPPLY		
Power supply voltage	2.1.25 Elektros tinklas 230 V, 50Hz	230 [V]±10% 50 [Hz] or optionally 110, 220 [V]±10% 60 [Hz]
Nominal power consumption		770 [VA]
SAFETY CONDITIONS		
Electric shock protection:		
Class		I
Degree		CF
Degree of protection		IP2X
Low frequency leakage currents		according to EN 60601-1
High-frequency leakage currents		according to EN 60601-2-2
Generator operation frequency		333 [kHz]
Defibrillation impulse resistance		according to EN 60601-1
NEUTRAL ELECTRODE APPLICATION CONTROL SYSTEM	2.1.13 Neutralaus elektrodo elektrinės grandinės kontrolės sistema	
Optical indication		7 levels
POWER OUTPUT IN THE MONOPOLAR CIRCUIT	2.1.16 Pjovimo efektyvumo nustatymas ≥ 9 pakopos	
MONO CUT Monopolar cutting with adjustable degree of haemostasis The mode is available in monopolar and SDS outputs.	2.1.4 Standartinio monopolinio pjovimo režimo galia ≥ 350 W	9 effects Up to 350 [W]
PRECISE CUT Precise cutting with adjustable degree of haemostasis The mode is available in monopolar and SDS outputs.		9 effects Up to 50 [W]
MIXED CUT Drying cutting with adjustable degree of haemostasis in the cutting phase, with adjustable cutting time and coagulation time (0.05–0.25 [s]) The mode is available in monopolar and SDS outputs.	2.1.5 Monopolinio sauso pjovimo režimo galia ≥ 200 W	9 effects Up to 200 [W]
MUCO CUT Monopolar cutting for mucosectomy procedures. The mode is available in SDS outputs with tool connected.		9 levels
POLIPO CUT Polypectomy with adjustable duration of a single cycle (0.05–0.25 [s]) and cutting time in the cycle (5%–20%) The mode is available in SDS outputs with EE-010-031 tool connected.		9 levels
PAPILLO CUT Papillotomy with adjustable duration of cutting and coag time in the cycle. The mode is available in SDS outputs with EE-010-031 tool connected.		9 levels
ARTRO CUT Cutting in non-conductive liquids with adjustable degree of haemostasis The mode is available in SDS outputs with EK-021-100, EK-021-110 tools connected.		9 effects

URO CUT Urological cutting in non-conductive liquids with adjustable degree of haemostasis The mode is available in SDS outputs with AD-010-021, AD-010-022 tools connected.	9 effects	
HYSTERO CUT Gynaecological cutting in non-conductive liquids with adjustable degree of haemostasis The mode is available in SDS outputs with AD-010-021, AD-010-022 tools connected.	9 effects	
ARGON CUT Argon-enhanced cutting with adjustable degree of haemostasis The mode is available in monopolar and SDS outputs with EK-021-200 tool connected.	9 effects Up to 350 [W]	2.1.10 Argono pjovimo režimo galia ≥ 350 W
SOFT COAG Soft coagulation with adjustable coagulation intensity The mode is available in monopolar and SDS outputs.	9 effects Up to 200 [W]	2.1.6 Monopolinės vidutinės intensyvumo koaguliacijos režimo galia ≥200W
FORCED COAG Forced coagulation with adjustable coagulation intensity The mode is available in monopolar and SDS outputs.	9 effects Up to 200 [W]	2.1.7Monopolinės forsuotos koaguliacijos režimo galia ≥ 200 W
HYBRID COAG Universal coagulation with adjustable coagulation intensity The mode is available in monopolar and SDS outputs.	9 effects Up to 200 [W]	2.1.8 Monopolinės forsuotos koaguliacijos su pjovimu režimo galia ≥ 200W
SPRAY COAG Spray non-contact coagulation The mode is available in monopolar and SDS outputs.	Up to 80 [W]	2.1.9 Monopolinės kibirkštinės koaguliacijos režimo galia ≥ 80W
ENDO SPRAY Endoscopic monopolar non-contact coagulation. The mode is available in SDS outputs with EE-010-031 tool connected.	Up to 30 [W]	
STANDARD ARGON Argon-enhanced coagulation for open and laparoscopic procedures The mode is available in monopolar and SDS outputs with EK-021-200 tool connected.	Up to 80 [W]	
ENDO ARGON Endoscopic argon-enhanced coagulation The mode is available in SDS outputs with EK-021-210 tools connected.	Up to 40 [W]	
PULSE ARGON Argon-enhanced pulse coagulation with adjustable cycle duration (0.05 [s]–0.25 [s]) The mode is available in SDS outputs with EK-021-210 tools connected.	Up to 40 [W]	
URO COAG Urological monopolar coagulation in non-conductive liquids The mode is available in SDS outputs with AD-010-021, AD-010-022 tools connected.	9 effects	
ARTRO COAG Arthroscopic monopolar coagulation in non-conductive liquids The mode is available in SDS outputs with EK-021-100, EK-021-110 tools connected.	9 effects	
HYSTERO COAG Gynaecological monopolar coagulation in non-conductive liquids The mode is available in SDS outputs with AD-010-021, AD-010-022 tools connected.	9 effects	

OUTPUT POWER IN THE BIPOLAR CIRCUIT	
BI-CUT Bipolar cutting with adjustable degree of haemostasis The mode is available in bipolar and SDS outputs with EK-010-100, EK-010-101, EK-010-102, EK-010-103 tools connected.	9 effects Up to 120 [W]
URO BI-CUT Urological cutting in conductive liquids The mode is available in SDS outputs with AD-010-030, AD-010-031, AD-010-032, tools connected.	9 levels
ARTRO BI-CUT Arthroscopic cutting in conductive liquids The mode is available in SDS outputs with BD-xxx-xx, EK-010-100, EK-010-101, EK-010-102, EK-010-103 tools connected.	9 levels
SOFT BI-COAG Bipolar coagulation The mode is available in bipolar and SDS outputs.	9 effects Up to 120 [W]
FORCED BI-COAG Forced bipolar coagulation The mode is available in bipolar and SDS outputs.	9 effects Up to 120 [W]
URO BI-COAG Bipolar coagulation in fluid environment for bipolar resection The mode is available in SDS outputs with AD-010-030, AD-010-031, AD-010-032, tools connected.	9 effects
ARTRO BI-COAG Arthroscopic bipolar coagulation in conductive liquids The mode is available in SDS outputs with BD-xxx-xx, EK-010-100, EK-010-101, EK-010-102, EK-010-103 tools connected.	9 effects
SCISS BI-COAG soft bipolar coagulation for cutting with bipolar scissors The mode is available in SDS outputs with EK-010-058 tool connected.	9 effects
ThermoStapler® with adjustable procedure intensity The mode is available in SDS outputs with EK-010-117, EK-010-118, EK-003-030, EK-030-600, EK-030-601, EK-030-602, EK-030-603, EK-030-604, EK-030-605, EK-030-606, EK-030-607 tools connected.	Up to 300 [W], 9 effects
ARGON	
Argon – type	4.8 (99,998%) or higher
Gas input pressure	3-5 [Bar]
Gas outflow	0.1–10.0 [l/min]
Adjustment	0.1 l/min throughout the range
Pressure measurement	Reducer (with manometer) (0.4 [MPa]) on argon cylinder
OTHER	
Device dimensions	495 x 415 x 225 [mm] with display
Weight	12,2 [kg]
WORKING LIFE	10 YEARS

2.1.11Bipoliarinės vidutinės intensyvumo koaguliacijos režimo galia ≥ 120 W

2.1.12 Bipoliarinės forsuotos intensyvumo koaguliacijos režimo galia ≥ 120 W

table 1 STEMA MASTER technical specifications

The technical specifications listed in the table may change as our products develop.

6. STEMA MASTER accessories list

No.	ITEM DESCRIPTION	QUANTITY
1	Power cable 4 [m]	1
2	Instructions for use	1
3	Electrosurgical equipment safety guidelines	1

table 2 Standard equipment of the STEMA MASTER system

7. Preparing the system for work

Getting the system ready to work involves the connection of the power cable and accessories.

Operation Manual and Electrosurgical equipment safety guidelines are complete documentation for the device, which should be read before handling the device.

7.1 Connecting power cables

The power cable can only be plugged or unplugged when the system is off. The unit conforms to class I electric shock protection, and requires one phase power supply with outlets equipped with a grounding pin. The power supply socket is located on the back panel of the casing **(Fig. 4, item 10)**.

The system does not require connecting any additional grounding cable. It is used for grounding if power supply without grounding is used or in places where the electric shock protection system requires it.

The footswitch is connected to the universal socket ("Main footswitch") in the back panel of the device casing; it allows to control all outputs of the system **(Fig. 4, item 1)**. The alternative footswitch for controlling only one output is connected to the "Alternative footswitch" socket **(Fig. 4, item 2)**. As a default "Alternative footswitch" controls output III.

The method of connecting the footswitches and the power cable is presented in **Fig. 8** where:

- Main footswitch controlling all outputs **(1)**
- Alternative footswitch **(2)**
- power cable **(3)**

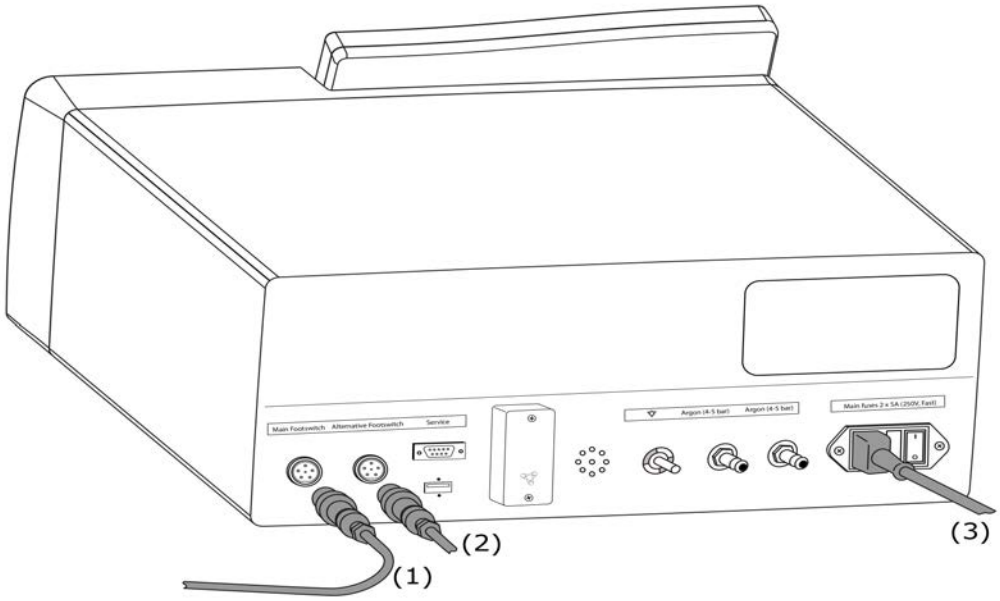


Figure 6. Method of connecting the footswitches and the power cable.

The STEMA MASTER system allows to connect the following footswitches:

- wired 1-button footswitch for cutting,
- wired 1-button footswitch for coagulation,
- wired 2-button footswitch,
- wired 2-button footswitch, MultiSwitch,
- wireless 2-button footswitch, MultiSwitch.

For more information about the connection of a wireless footswitch, see **section 7.5**.

The method of connecting **accessories** to the universal outputs **(Fig. 1 items 1, 3)** with the Smart Device instrument detection system is explained in **Fig. 7**.

The method of connecting **accessories** to the monopolar output **(Fig. 1 item 2)** and the bipolar output **(Fig. 1 item 4)** is explained in **Fig. 8**.

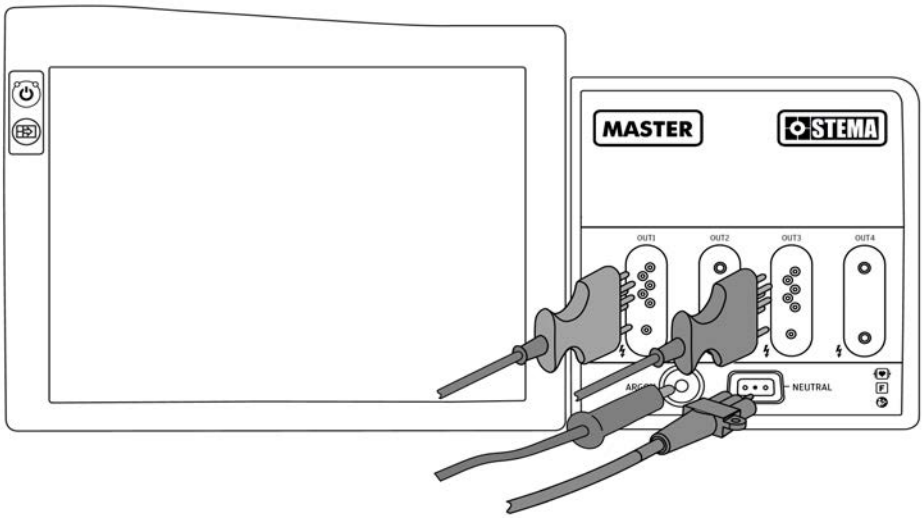


Figure 7. Method of connecting accessories to outputs 1 and 3 (SDS) in the STEMA MASTER systeem

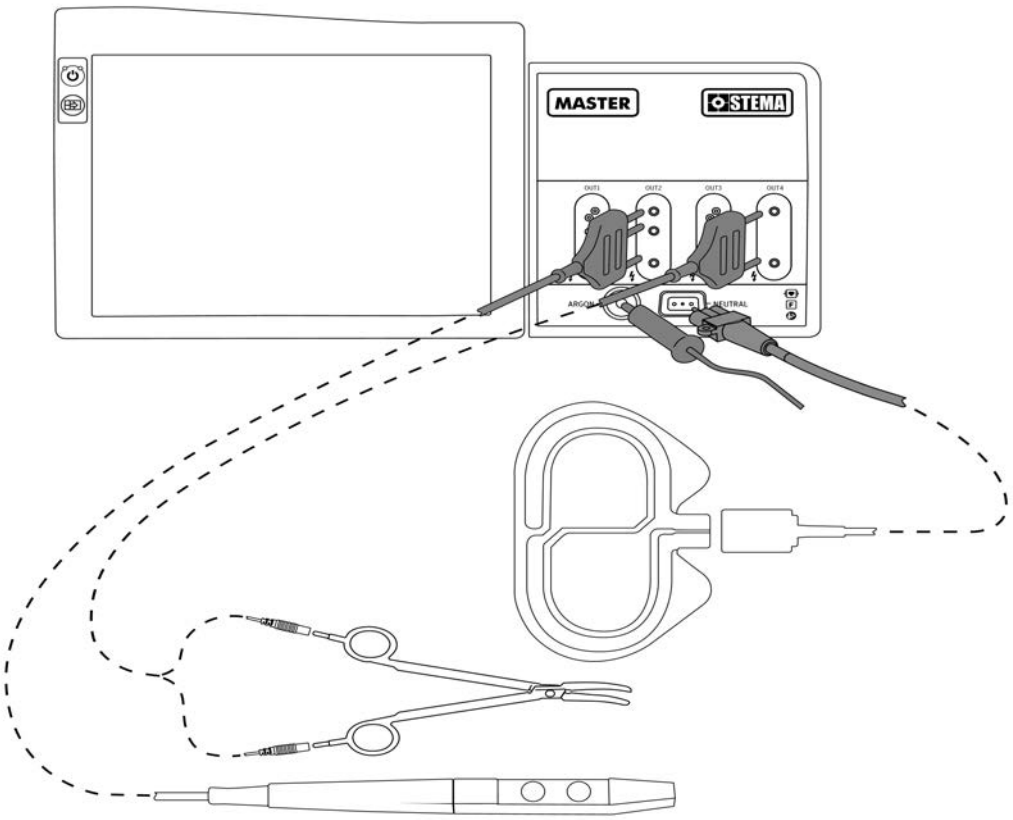


Figure 8. Method of connecting accessories to outputs 2 (monopolar) and 4 (bipolar) in the STEMA MASTER system

7.2 Pneumatic ducts connection

The gas (argon) under reduced pressure **(3-5 Bar)** is connected to the output extensions **(Fig. 2, items 8, 9)** on the back panel of the unit. The system allows to connect two bottles. The gas is drawn from the inlet where an argon cylinder under pressure is connected. The gas is drawn from the inlet where an argon cylinder is connected, or from inlet 1, if two cylinders are connected. If the regulator is equipped with cylinder pressure measurement, the gas will first be drawn from the lower pressure cylinder. If two argon cylinders are connected, when the gas is depleted in one cylinder, the device will automatically switch to the other cylinder.

Connect gas only under a reduced pressure (3-5 Bar).

Argon class 4.8 (99.998%) or 5.0 (99.999%) is used for argon coagulation.
The method of connecting argon and argon ducts is presented in **Fig. 9 and 10.**

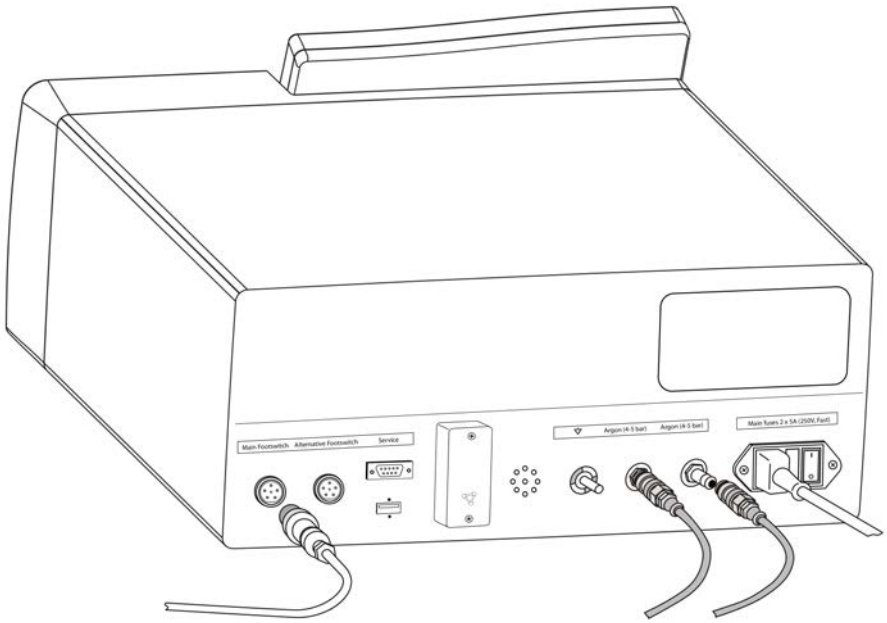


Figure 9. Method of connecting the argon ducts to the STEMA MASTER system.

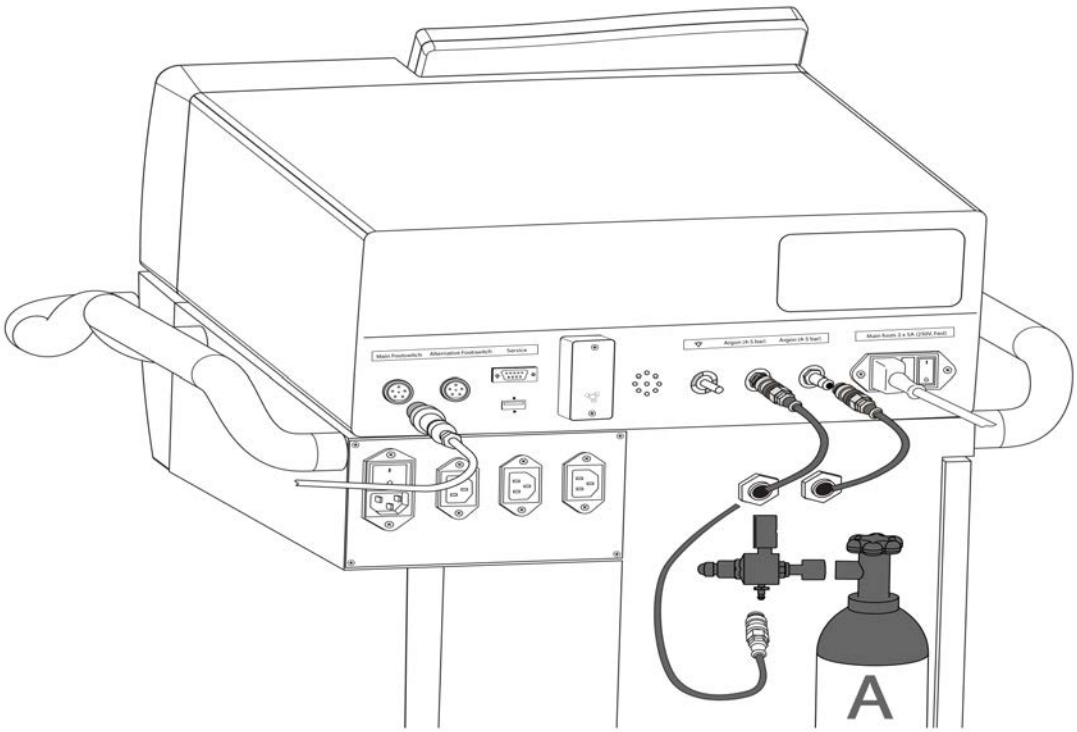


Figure 10. Method of connecting argon to the STEMA MASTER system.

For more information about argon ducts, see section 7.6.3.

7.3 Connecting accessories for electrosurgical procedures

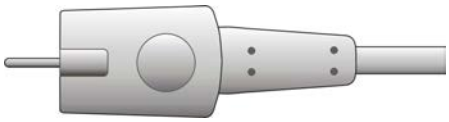
The units manufacturer allows to use of STEMA accessories only for accessories available in STEMA catalogue.

The STEMA MASTER system is equipped with high-quality electrosurgical accessories, which allow performing various procedures in the fields of general and vascular surgery, gynaecology, oncology, and many others.

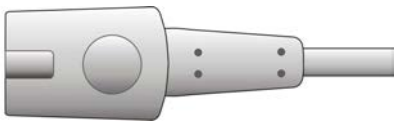
The following accessories can be connected to the sockets on the front panel of the system:

7.3.1 Neutral electrode cable

The connection output of the **neutral electrode output** is made in compliance with the USA standard **(Fig. 1, item 6)**:



Disposable Neutral electrode plug

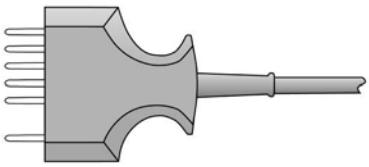


Reusable Neutral electrode plug

For more information on the neutral electrode, see section 8.2 "Neutral electrode monitoring".

7.3.2 Instrument cable for universal SDS sockets

The **universal output with instrument detection** made according to the Smart Device System standard **(Fig. 1, items 1 and 3)**.



Universal SDS socket

7.3.3 Monopolar electrode cable with 3-pin plug

The **active monopolar electrode** handle socket is made in compliance with the so-called 3-pin standard **(Fig. 1, item 2)**.

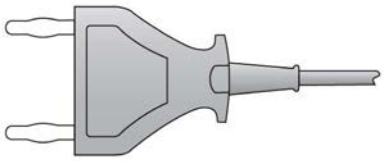
Active monopolar electrode handle plug

The active electrode plug handle is compatible with standard monopolar cables and electrode handles with the following diameters:

- 4 [mm] – with handles of 4 mm in diameter
- 2.4 [mm] – with handles of 2.4 [mm] and 4 [mm] in diameter (with an adapter for 2.4 [mm] electrodes)

7.3.4 Bipolar instrument cable for 2-pin sockets

The socket of the **bipolar output** is made in compliance with the 29 [mm] standard **(Fig. 1, item 4)**. The system is compatible with bipolar tools of various types, for both open and laparoscopic surgery.



Bipolar 2-pin plug

7.3.5 Argon duct

The connection socket for **argon output** is made in compliance with the Luer Lock standard **(Fig. 1, item 5)**.

Argon plug

When in doubt as to which accessories may be connected and how to connect them, please contact either the manufacturer or the distributor.

7.4 Instrument detection

The universal sockets in the STEMA MASTER systems are equipped with an **instrument detection system – the SDS system**. It can detect and identify the connected instrument.

Instrument detection applies only in the case of instruments with SDS plug.

The instrument detection system identifies the connected accessories and automatically adjusts the operating mode and settings. It also remembers the last used settings for each instrument, and remembers the last settings when using the instrument again. After connecting a newly purchased instrument, the device recognises its type and recalls the last used power/effect settings.

An additional advantage of the instrument detection system is the limitation of the available operating modes to those intended for the selected instrument only.

The figures below present the list of modes before connecting an instrument to a SDS socket **(table 1. STEMA MASTER technical specifications)**, and a limited list of modes after connecting an instrument to a socket with the SDS system **(Fig. 11)**.

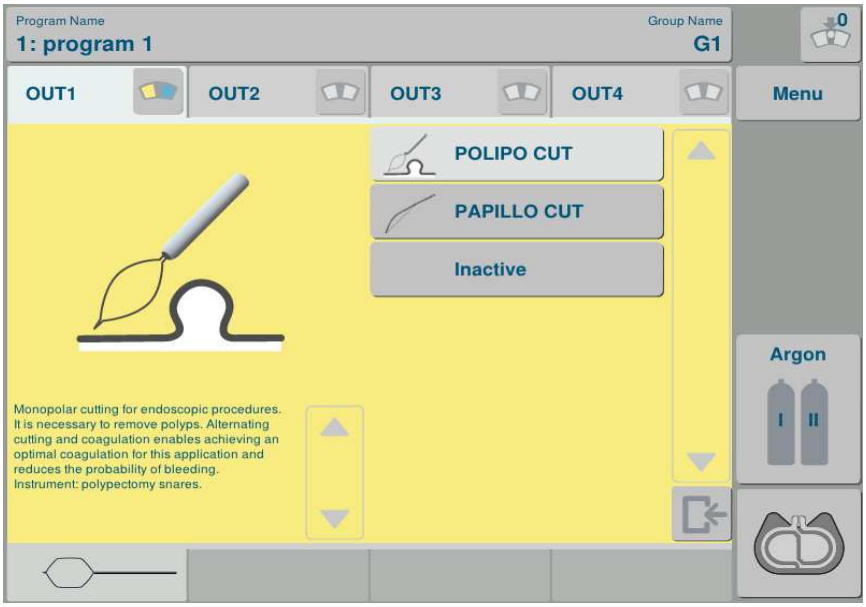


Figure 11. Complete list of cutting modes available before connecting the endoscopic cable..

In addition, the SDS instrument detection system allows to limit the maximum usable power for those instruments that need it. It is impossible to exceed the upper limit of the assigned power. This increases the safety of work, and reduces the risk of damaging an instrument by using too high power settings.

Fig. 12 shows data on the instrument connected to the system. To display these data, touch the instrument detection status window panel **(Fig. 3, item 9)**.

They contain:

- instrument name and icon,
- manufacturing LOT number,
- maximum cutting power (if applicable for a connected instrument),
- maximum coagulation power (if applicable for a connected instrument),
- manufacturer's name,
- instrument manufacture date,
- device index

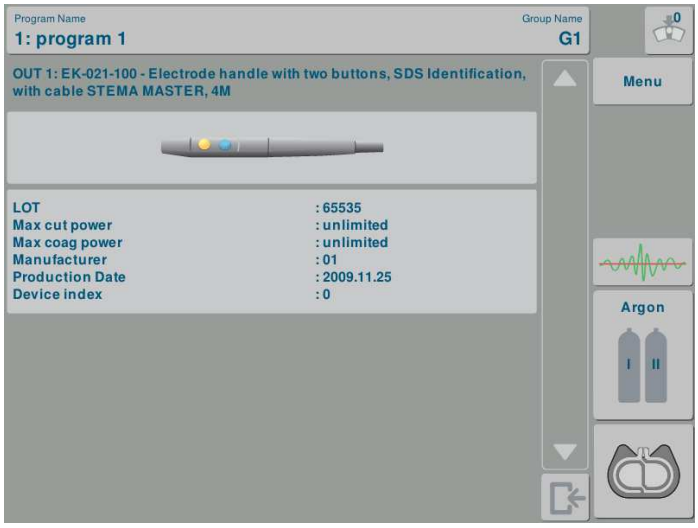


Figure 12. Data of an instrument connected to a socket with the SDS system.

7.5 Wireless footswitch receiver

The STEMA MASTER system is compatible with both wired and wireless footswitches. The wireless footswitch uses wireless transmission, sending data with radio waves, which allows to increase the flexibility of the control system. In this way, the amount of cabling in the operating room is reduced.

Two footswitches can be connected simultaneously to the STEMA MASTER system. It is possible to freely configure the wired and wireless footswitches.

The wireless footswitch for the STEMA MASTER system is adapted with a dongle. The dongle should be connected to the footswitch socked in the back panel of the system **(Fig. 2, item 1 or 2)**. It is connected in the same way as the plug of a standard wired footswitch.

For additional information about the wireless footswitch, see the footswitch instructions for use.

7.6 Settings

The settings are made independently for each output and for each program.

The types of available settings assigned to each mode are presented in the table 3.

It is possible to change the settings using the footswitch **(Section 8.11.2 The MultiSwitch function)**.

The list of available modes of the STEMA MASTER system depends on its version and may differ from the table below.

Mode type	Types of available settings			
MONO CUT	Effect	Power [W]		
PRECISE CUT	Effect	Power [W]		
MIXED CUT	Effect	Power [W]	Cutting time [s]	Coagulation time [s]
MUCO CUT	Level	-	Cutting time [s]	
POLIPO CUT	Level	-	Cutting [%], Cycle time [s]	Endo-Detect System
PAPILLO CUT	Level	-	Cutting time [ms]	Coagulation time [ms]
ARTRO CUT	Effect	-		
URO CUT	Effect	-		
HYSTERO CUT	Effect	-		
ARGON CUT	Effect	Power [W]		Argon flow [l/min]
BI-CUT	Effect	Power [W]		
URO-BI-CUT	Effect			
ARTRO BI-CUT	Effect			
SOFT COAG	Effect	Power [W]		
FORCED COAG	Effect	Power [W]		
HYBRID COAG	Effect	Power [W]		
SPRAY COAG	–	Power [W]		
ENDO SPRAY	-	Power [W]		
URO COAG	Effect	-		
ARTRO COAG	Effect	-		
HYSTERO COAG	Effect	-		
STANDARD ARGON	–	Power [W]		Argon flow [l/min]
ENDO ARGON	–	Power [W]		Argon flow [l/min]
PULSE ARGON	–	Power [W]	Pulse time [s]	Argon flow [l/min]
SOFT BI-COAG	Effect	Power [W]	AutoStart time [s]	AutoStop time [s]
FORCED BI-COAG	Effect	Power [W]		AutoStop time [s]
URO BI-COAG	Effect	-		
ARTRO BI-COAG	Effect	-		
SCISS BI-COAG	Effect	-		
THERMOSTAPLER®	Effect	Power [W]		

table 3 types of available setting for each mode

7.6.1 Working parameter adjustment

The STEMA MASTER system is equipped with the SDS instrument detection system. When a SDS instrument is connected, the system identifies it and automatically lists the suggested operating modes and effects, as well as power limit.

If a SDS instrument was used previously with the STEMA MASTER system, then the last settings used for this instrument type will be loaded.

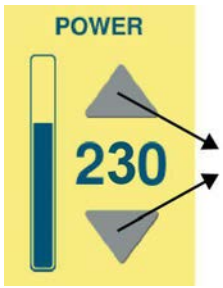
When using standard mono- or bipolar instruments, before starting the procedure, set the effect which is appropriate for a given procedure, and, if necessary, a power limit for the selected mode.

The STEMA MASTER system has a system of automatic adjustment of the output power depending on the operating conditions – the STEMA MASTERResult System. A processor measures all operating parameters in real time and adjusts the output power on an ongoing basis so as to obtain the selected effect. The power level set by the user and visible on the screen in the upper power limit for a given mode.

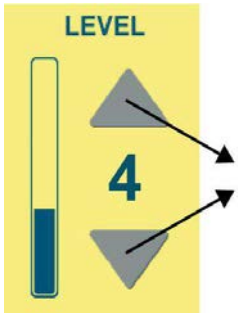
The power limit and the effect are set independently for cutting and coagulation modes. They are set independently for each output, for each mode and program.

The power level and effect are displayed on the touch panel. To change them, click the number indicating a setting or level. Then change the setting using the arrow icons.

The STEMA MASTER system is equipped with a set of suggested settings for each operating mode.



power adjustment



level adjustment

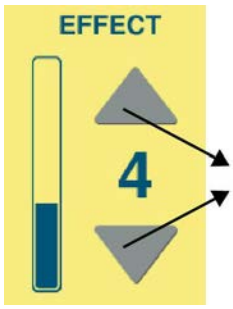
Before the first use of the system, it is recommended to become familiar with the effects of various settings, performing trials on fresh beef meat.

7.6.2 Effect adjustment

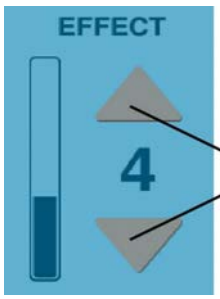
In the cutting, forced coagulation and hybrid coagulation modes, increasing an effect setting results in obtaining a higher degree of haemostasis.

In the soft coagulation mode, increasing an effect results in a shorter coagulation time, and stronger drying of the tissue surface.

The settings are changed on the touch panel using the arrow icons.



haemostasis degree adjustment



haemostasis degree adjustment for forced or hybrid coagulation, or soft coagulation intensity

Effect (power) adjustment is possible also by handle and by MultiSwitch button on the footswitch.

a) adjustment by the handle

To activate this function, simultaneously press buttons yellow and blue on the handle. Window with adjusted parameter will appear on the screen. Yellow button increases the effect (power), blue button decreases the effect. To exit the adjustment mode wait for a moment without pressing any buttons.

b) adjustment by the footswitch

To activate this function, press for 2 seconds the black MultiSwitch button on the footswitch. Window with adjusted parameter will appear on the screen. Yellow button increases the effect (power), blue button decreases the effect. To exit the adjustment mode, press again the MultiSwitch button or wait for a moment without pressing any buttons.

Figure 13. Effect adjustment by the footswitch.

7.6.3 Argon flow settings

In order to change the **argon flow setting** and to **prime the ducts with argon**, after selecting the appropriate mode, click the icon labelled Argon **(Fig. 5, item 10)**. The argon flow adjustment option for a given mode, and the argon duct priming icon will appear on the screen. To change the argon flow settings, touch the appropriate arrows on the argon flow scale.

Before starting work, fill-up the argon ducts with the gas by pressing the PURGE icon.

In argon-enhanced endoscopic coagulation modes, the argon flow can be adjusted in a limited range to 2.5 [l/min].

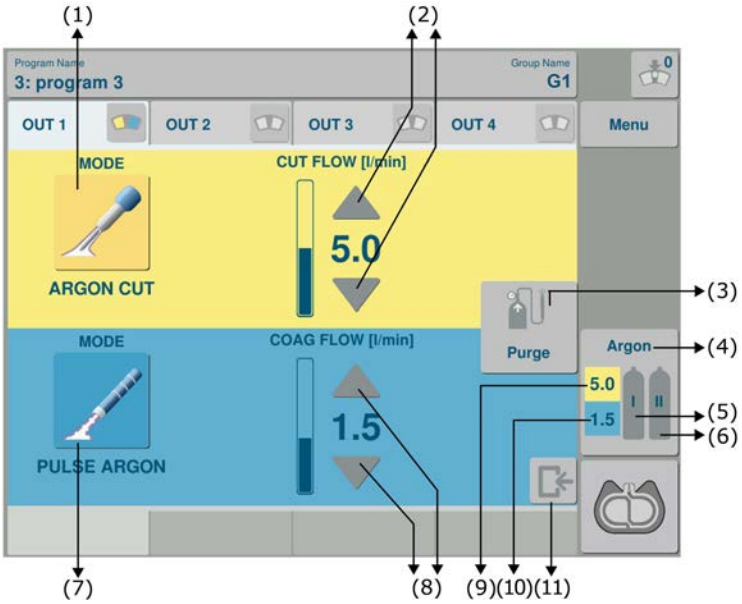


Figure 14. Argon flow adjustment for argon-enhanced modes.

Fig. 14 presents:

- example mode of argon-enhanced cutting **(1)**
- argon flow adjustment for cutting **(2)**
- argon duct filling **(3)**
- argon panel **(4)**
- cylinder no. 1 status **(5)**
- cylinder no. 2 status **(6)**
- example mode of argon-enhanced coagulation **(7)**
- argon flow adjustment for coagulation **(8)**
- argon flow setting value for cutting **(9)**
- argon flow setting value for coagulation **(10)**
- exit **(11)**

The argon-enhanced modes are only available for outputs 1 and 2 (Fig. 1, items 1, 2).

When two argon cylinders are connected, they are switched automatically. When the gas in cylinder no. 1 is depleted, the system switches itself to argon supply from cylinder no. 2. **Fig. 10** shows how to connect two cylinders.

7.6.3.1 Cautions for using argon-enhanced coagulation

Fill the instruments with argon before each procedure. To do this, press the argon duct filling button.

When using non-primed argon instruments, air can be introduced into the tissues.

The flexible argon electrode should not be placed directly on the tissue.

Do not blow argon into the vascular system.

During laparoscopic surgeries, argon flow causes an increase in insufflation pressure.

PERFORMING ARGON-ENHANCED LAPAROSCOPIC PROCEDURES IS ONLY ALLOWED WITH INSUFFLATORS HAVING A PRESSURE NIVELATION FUNCTION. In case of doubt, consult the insufflator supplier to confirm that the insufflator has such function.

To prevent sudden increase in insufflation pressure during argon application, the trocar valve should be open. If the pressure reaches the critical level, stop argon application and wait until the pressure decreases below this level.

Independently of monitoring the pneumoperitoneum pressure using the insufflator, a separate, continuous pressure control by the operating team is required.

Always consult the instructions for use of argon accessories.

7.6.3.2 Suggested settings

The output power should be effecting to reach the intended purpose. Please remember that electrosurgery involves a risk of burns in the patient, when the output power is too low – cutting and coagulation require more time, which may cause an excessive thermal invasion in the surrounding tissue. Therefore, the setting should be selected according to the operator's experience, by referring to the appropriate clinical recommendations or results of an appropriate practice.

Below are given the suggested settings for each procedure. The settings can differ, depending on the needs. STEMA made every effort to determine the optimum suggested settings.

Open surgery:

Argon-enhanced coagulation (STANDARD ARGON mode):

- gas flow: 5.0 l/min
- coagulation power: 35 W

Argon-enhanced cutting (ARGON CUT mode):

- gas flow: 5.0 l/min
- cutting power: 250 W
- effect: 3

Laparoscopy and endoscopy:

SUGGESTED SETTINGS:

- gas flow: 1.5 l/min
- coagulation power: 20 W
- pulse time 0.1 [s] – (only for the PULSE ARGON mode)

In laparoscopy, due to the enclosed space of the operating field, the flow settings should be low.

The enclosed volume of the operating field creates the risk of blowing an excessive amount of gas into the abdomen. For more information about the risks, see section 10 "Protection measures and warnings".

7.6.4 Power monitoring

STEMA MASTER uses sophisticated measurement system, that constantly checks parameters on output in real-time and immediately changes the output power to varying conditions in the operation area.

Most of the modes have two key parameters: Effect and Power. Effect adjusts the desired result on the tissue. Power is adjusted automatically to achieve the chosen effect, and the value shown on screen is the upper limit of power generated by ESU.

The device has a power monitoring tool, that shows the actual generated power on the output.

Power Monitor

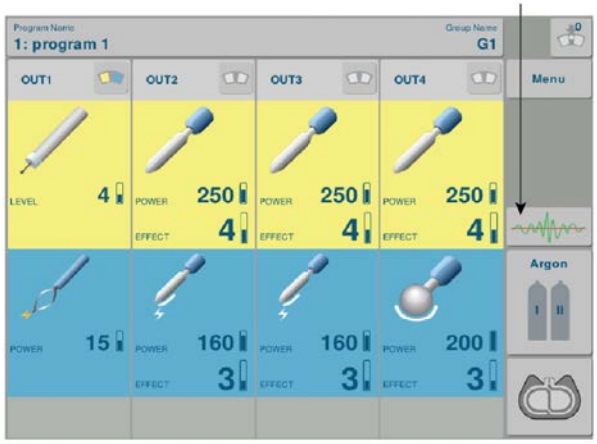
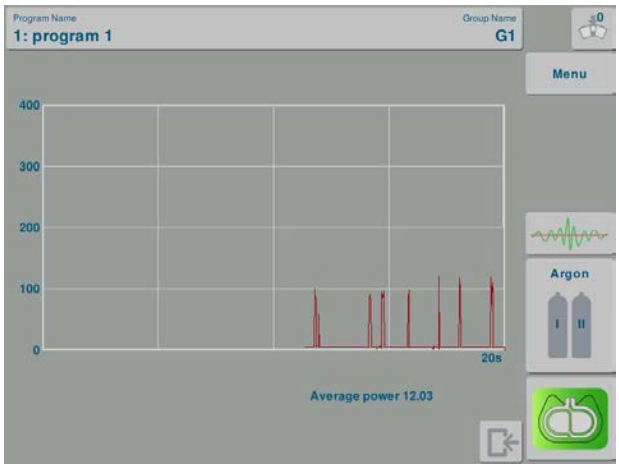


Figure 15. Power Monitor

The illustration below shows the power measurement graph. Last 60 seconds of activation is displayed, including pauses.\



Rysunek 16. Power monitoring graph.

The graph shows the current power output. Under the graph there is also average value in Watts [W].

Power monitoring feature is not available for the following spray coagulation modes: SPRAY COAG, STANDARD ARGON, ENDO ARGON, PULSE ARGON.

Power monitoring feature is not available during the time of activation.

8. System operation and surgical procedures

8.1 Turning the system on

To switch the system on, use the main power switch located on the back panel **(Fig. 2, item 12)**, then the stand-by button on the front panel **(Fig. 1, item 7)**. Pressing the stand-by button turns the system on.

The start-up process takes a few seconds. During this time, an internal test of the system and the connected accessories is run. Then the main screen is displayed on the touch panel. The main screen in divided into four panels which correspond to the respective connection sockets of the system.

Following safety rules, accessories may also be connected while the system is on. In this case, pay attention to prevent the possible activation of the system by accidental pressing of the handle button or the footswitch.

8.2 Neutral electrode monitoring – the NEM SYSTEM

8.2.1 Monitoring of application of split disposable neutral electrodes

In the monopolar operation mode, the system requires a neutral electrode to be connected.

STEMA devices are equipped with a neutral electrode application monitoring system, referred to as NEM (Neutral Electrode Monitor). NEM System installed in STEMA devices is designed for use with TWIN SAFE disposable split neutral hydrogel electrodes: large and small.

Only these neutral electrodes are compatible with NEM (Neutral Electrode Monitor) System.

Only the use of disposable split neutral hydrogel electrodes with an TWIN SAFE belt, allowing for equal distribution of high-frequency current on the entire electrode surface, in combination with the NEM system, guarantees continuous monitoring of neutral electrode adhesion and ensures maximum patient safety during the procedure.

The only disposable neutral electrodes approved by the manufacturer for use with NEM safety system are electrodes for adult patients and children (large) and electrodes for children weighing less than 5 kg (small). The use of small electrode limits the list of available modes of operation as well as the power – down to max. 150W.

Neutral electrodes other than those mentioned above may not ensure proper cooperation with NEM neutral electrode safety system.

The manufacturer is not responsible for the use of STEMA electrosurgical devices with neutral electrodes other than those mentioned above, or for any incidents resulting from such use.

Before starting the procedure, you should select the type of the neutral electrode used. In order to do that, click the electrode icon and select the type.

After each system start-up, the electrode for adults (large) is selected by default.

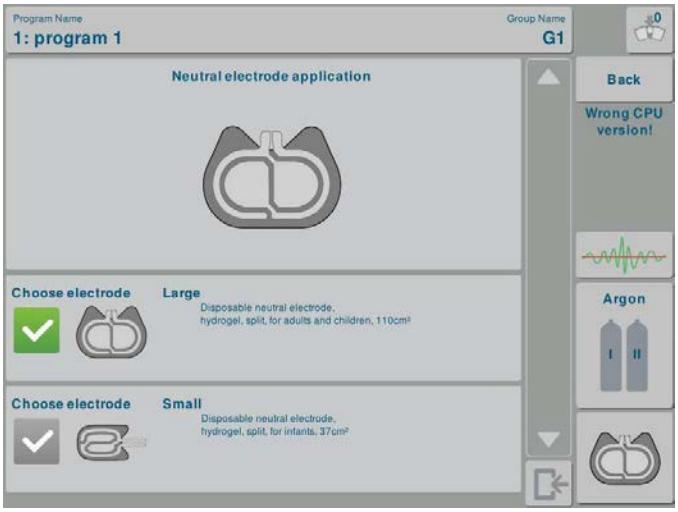
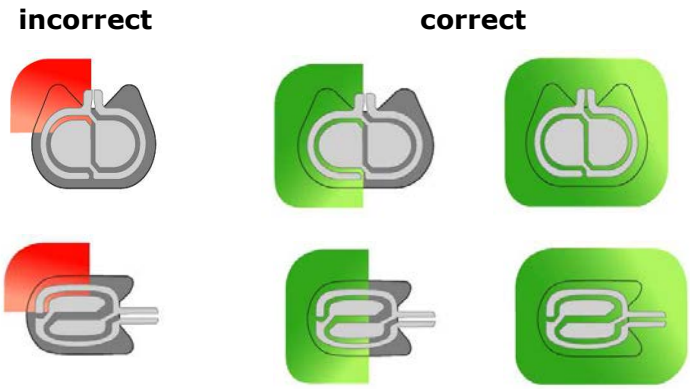


Figure 17. Neutral electrode selection.

The display will show information on the proper application of the neutral electrode. This will be indicated by green colour surrounding the electrode symbol on the screen.

Indication of neutral electrode application status:



An important advantage of the split neutral electrode monitoring system is that the monitoring is performed on a continuous basis, also during the operation of the generator.

If system activation is attempted in case of inadequate application of the divided neutral electrode, an error message will be displayed on the screen. Then neutral electrode connection should be checked.

The figure below informs about neutral electrode error.

Figure 18. Incorrectly connected neutral electrode.

The neutral electrode monitoring system does not affect operation in bipolar mode.

8.2.2 Split disposable electrodes

The neutral electrode cannot be modified in any way.

Once applied, the electrode should not be transferred to another place.

Never use electrodes after their expiry date.

Do not use force to remove the electrode. It should be unstuck carefully.

Before applying a disposable neutral electrode, dry the application site very carefully. When using alcohol-based disinfectants, wait for the alcohol to evaporate.

When using disposable electrodes, always check their expiry date.

A disposable electrode can only be used once.

The neutral electrodes are supplied in closed sachets. After package opening, an electrode must be used within 15 days. After that time, the conductive substance dries out and does not ensure sufficient conduction.

Disposable electrodes should be applied carefully.

When applying the neutral electrode make sure that it faces the operative field with its longer side. This requirement does not apply to TwinSafe electrodes which have a special construction and can be applied in any position.

If it is necessary to apply the electrode in a different place, use a new electrode.

Check the neutral electrode application and the connected cables every time the patient's position has been changed.

Protect the neutral electrodes against wetting during the procedure.

8.2.3 Non-split reusable electrodes

When performing surgical procedures:

- requiring high power settings (e.g. TURP);

- posing a risk of flooding the neutral electrode with liquids;

- where the staff is not able to control the neutral electrode application;

IT IS NOT RECOMMENDED TO USE REUSABLE NEUTRAL ELECTRODES.

When using one-piece silicone electrodes, the surgical team is fully responsible for their correct application. Therefore, pay special attention to correctly place the neutral electrode to avoid burns at its application site during the procedure. The application of a one-piece neutral electrode should be monitored throughout the entire procedure.
Before applying a neutral electrode, read the instructions supplied by its manufacturer.

One-part, reusable neutral (silicone) electrode **does not enable** application monitoring by the system, that is, control of adhesion to the patient's body. Only correct electrode connection to the system is monitored.

The neutral electrode should never be wet or wrapped with anything.

Do not spread additional conductive gels on the surface of the neutral electrode.

When disconnecting the neutral electrode, never do it by pulling the cable.

Under no circumstances try to repair the neutral electrode by yourself.

Examine the condition of the electrode and the connection cable before use. Do not use electrodes with visible surface defects or damaged insulation.

The reusable silicone electrode should be attached with a special tape for neutral electrode fixing to prevent it from moving.

Prevent fluid intrusion between the electrode and the patient's body.

When performing procedures on small children, electrodes of appropriate paediatric size should be used.

Reusable neutral electrodes should be disinfected before use (see section 12 "System and accessories maintenance").

Remember that a silicone electrode loses its conductive properties as active substances are rinsed out from the rubber. Such an electrode increases the risk of burns. Therefore, not only the systems but also the reusable electrodes should be subject to regular inspections.

Always read the manufacturer's instructions before applying a neutral electrode.

ALWAYS observe the manufacturer's instructions on the package of the neutral electrode.

8.2.4 Neutral electrode application principles

Do not apply the electrode on scar tissue, cuts or scratches.

Do not apply the electrode in areas that are concave, bony or include protrusions.

Do not apply the electrode on excessively hairy skin – shave the application area, if necessary.

Do not use at sites with excessive fatty tissue, e.g. the abdomen or buttocks.

Do not apply the neutral electrode over implants.

When disconnecting the neutral electrode, never do it by pulling the cable.

The neutral electrode cannot touch any conductive elements, e.g. metal parts of the table.

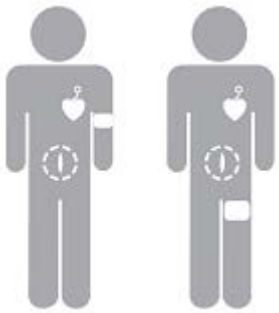
The neutral electrode should be applied to adhere to the patient's body with its entire surface.

The neutral electrode should be applied on clean and dry skin. The neutral electrode should be applied on smooth, well vascularised areas, without skin folds, for instance on the upper arm or thigh.

The electrode should be placed in the vicinity of the operative field but no closer than 20 [cm] from it.

When applying the neutral electrode make sure that it faces the operative field with its longer side.

DISPOSABLE NEUTRAL HYDROGEL ELECTRODE APPLICATION SITES



incorrectly correctly

Correct sites of neutral electrode application in patients with a cardiac pacemaker.

Correct sites of neutral electrode application in adult patients.

Correct sites of neutral electrode application in a child.

8.3 Operating mode selection

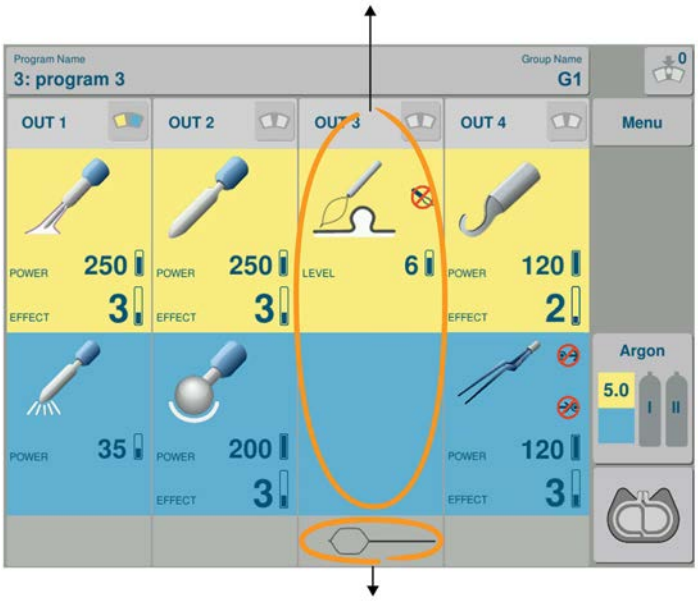
To select the operating mode and set its parameters, please perform the following procedures:

STEP 1

Touch the panel corresponding to the output to which a given accessory is connected.

The entire panel area is active.

control panel of the socket to which the instrument is connected



detection bar indicating the instrument connected to output 3

Figure 19. Operating mode selection – step 1.

If an SDS instrument is connected to an output with the instrument detection system (**Fig. 1 items 1 and 3**), the device will automatically limit the list of available modes (see section 7.4), and will set the suggested mode for the connected instrument.

STEP 2

Expand the list of available modes by touching any cutting mode icon (in order to set the desired cutting mode in the next step), or any coagulation mode icon (in order to set the desired coagulation mode).

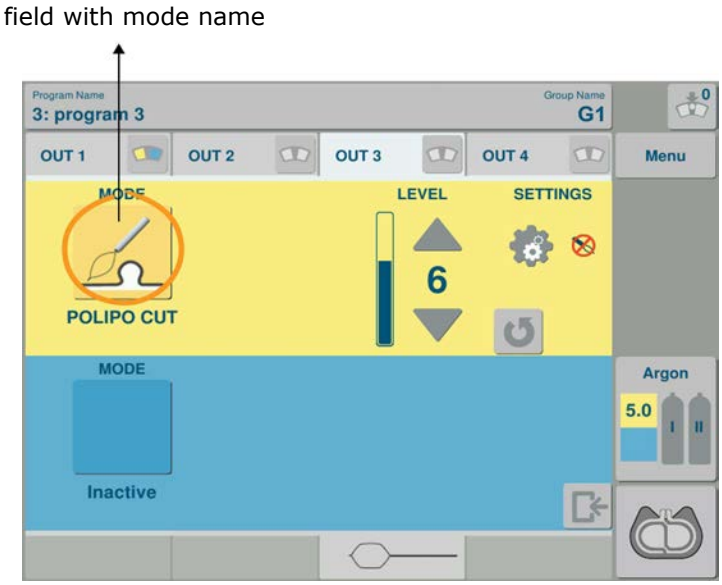


Figure 20. Operating mode selection – step 2.

STEP 3

Select the operating mode which is appropriate for the procedure by clicking on the bar with the selected mode name. To confirm the selected mode, double-click the bar with the mode name, or click the exit window or the exit button.

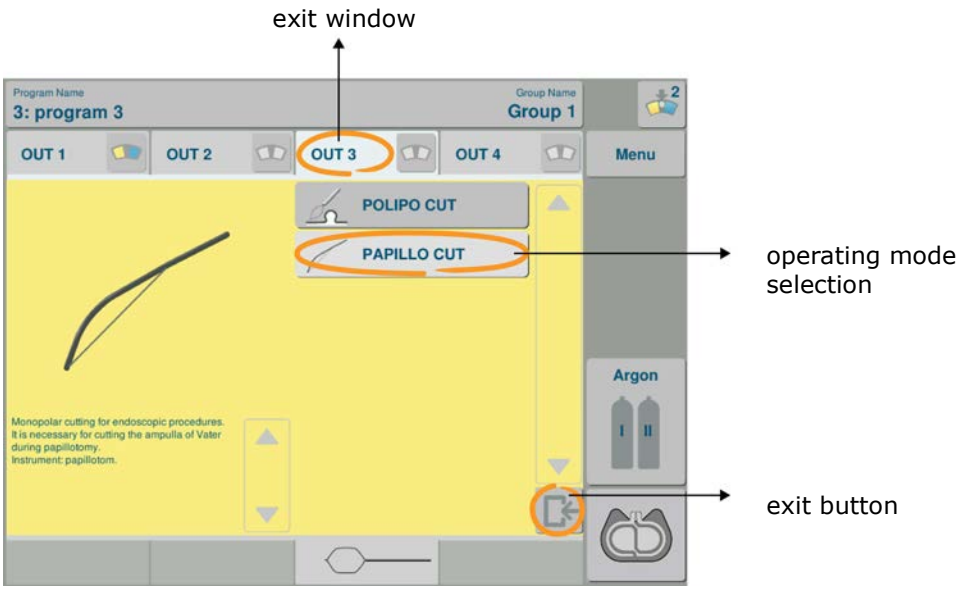


Figure 21. Operating mode selection – step 3.

STEP 4

Set the parameters for the procedure using the arrows for adjustment of settings, and the advanced settings button, if available for a given mode.

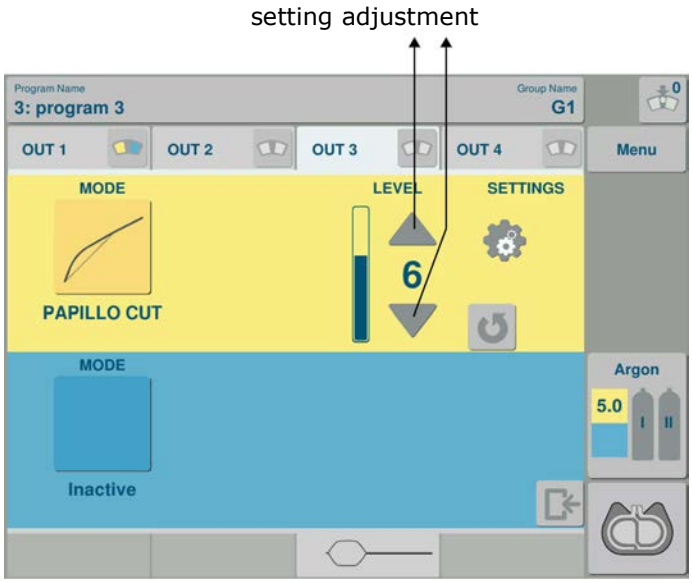
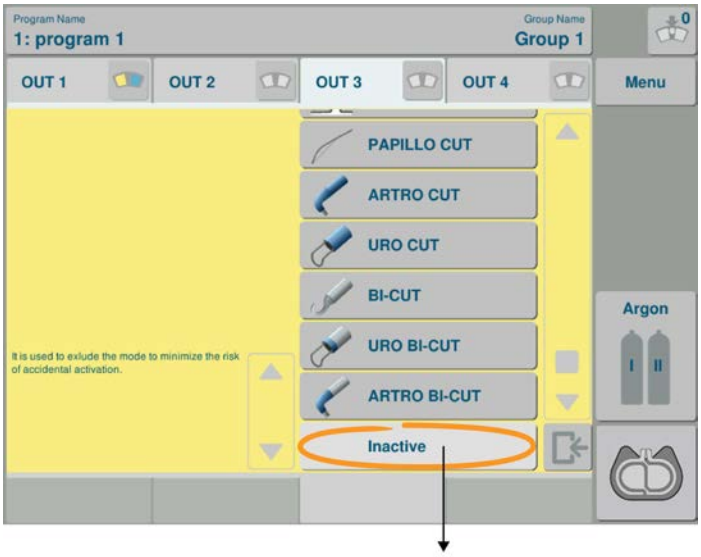


Figure 22. Operating mode selection – step 4.

There are always two active modes on the panel: one cutting mode and one coagulation mode. If the user intends to use only one operating mode (cutting or coagulation), it is recommended to set the inactive status for the other mode for safety reasons. The inactive status mode prevents from accidental use.

To set the inactive status to a mode, select the "**inactive**" window from the mode list.



inactive modeFigure f modes

Figure 23. List o with an inactive mode.

Panel appearance with an inactive mode:

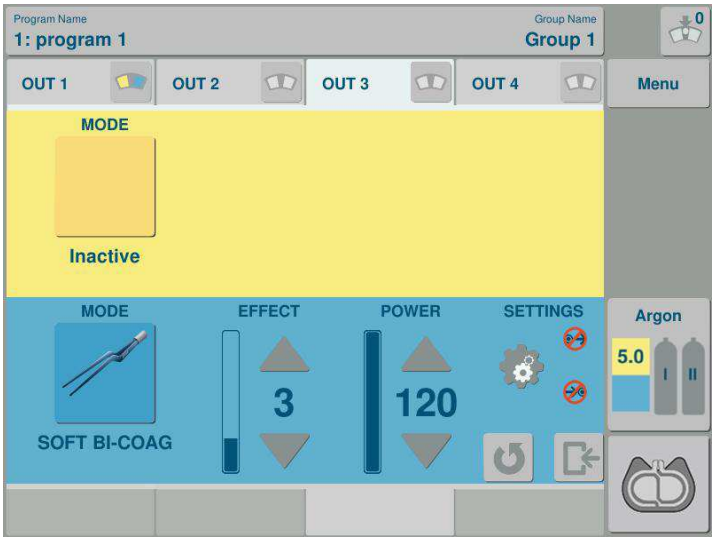


Figure 24. Panel with an inactive mode.

8.4 STEMA MASTER system activation methods

The STEMA MASTER system can be activated:

- using the handle,
- using the footswitch,
- using the AutoStart function (in bipolar coagulation mode).

8.4.1 Activation from handle

To activate the system using the handle, connect a handle with two buttons (cutting and coagulation).

The output, to which the instrument is plugged, is activated.

The activation parameters correspond to those set on the panel corresponding to the activated output.

The yellow button is used to activate cutting, and the blue button is used to activate coagulation.

8.4.2 Activation from footswitch:

a) universal socket for footswitch which is supporting all outputs **(Fig. 2, item 1)**; when using the switch connected to this socket, it is possible to activate the cutting and coagulation modes in all four outputs of the system. The output indicated using the footswitch-controlled output selection button is activated **(Fig. 4, items 1, 2, 3, 4).**

b) socket for footswitch which is supporting one of output - assigned by default to the third SDS output **(Fig. 4. item 2)**; it is possible to activate output 3 using the second footswitch socket. The second footswitch socket allows to activate cutting and coagulation always in the third output.

 – footswitch active

 – footswitch inactive

For example, **Fig. 25** contains the screen in which the third output is activated using the footswitch.

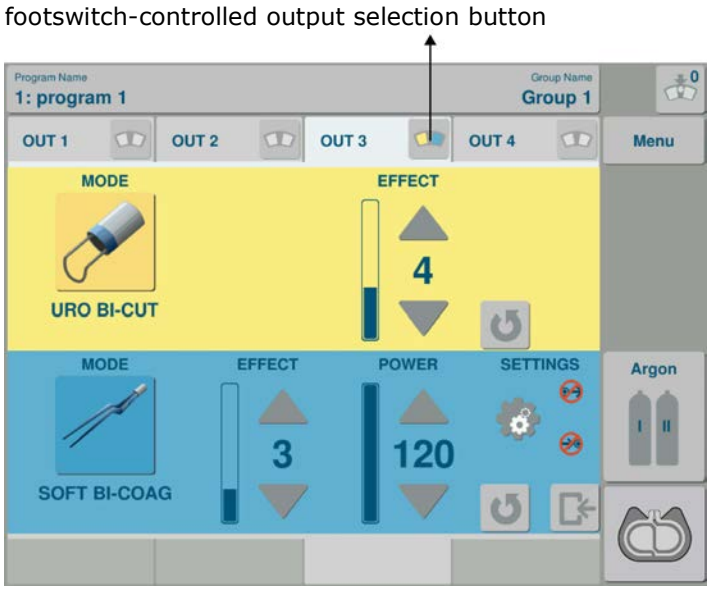


Figure 25. Activation of the third output using the footswitch.

8.4.3 System activation using the AutoStart function

If the AutoStart function is available in the bipolar coagulation mode, automatic activation after grasping the tissue is possible.

After grasping the tissue and the set delay, the generator is turned on. It is stopped when the forceps are opened, or after a specified time when using the AutoStop function.

For more details see 8.8.1 The AutoStart and AutoStop functions in bipolar coagulation.

8.5 Monopolar cutting

Depending on software version, the STEMA MASTER system is equipped with the following monopolar cutting modes:

MONO CUT Monopolar cutting with various haemostasis effects.

Effect 1 is mainly used to cut the tissues, when no additional bleeding control is necessary. This cutting mode is the most tissue-sparing. Subsequent levels increase the degree of haemostasis. They are used when more intensive bleeding control is necessary already at the cutting stage. A greater degree of haemostasis enables better bleeding control but has a stronger thermal effect on the tissue.

Instrument: monopolar electrodes, e.g. knife, loop, needle.

PRECISE CUT Precise monopolar cutting.

Used when cutting small and precise structures. A more gentle current allows to increase cutting precision.

Instrument: monopolar electrodes, e.g. knife, loop, needle.

MIXED CUT Monopolar drying cutting.

Alternating cutting and soft coagulation allow to cut tissues with severe bleeding, while minimising blood loss.

Instrument: monopolar electrodes, e.g. knife, loop, needle.

This mode is described in detail in section 8.5.1.

MUCO CUT Monopolar cutting for mucosectomy procedures.

Discontinuous cutting current enables safe and effective dissection of tissues.

Instrument: endoscopic mucosectomy knife.

POLIPO CUT Monopolar cutting for endoscopic procedures.

Necessary for polyp removal. Alternating cutting and coagulation allow to obtain optimum coagulation and reduce the risk of bleeding.

This mode is described in detail in section 8.5.2.

Instrument: loops for polypectomy.

PAPILLO CUT Monopolar cutting for endoscopic procedures.

Used for cutting Vater’s papilla during a papillotomy procedure.

This mode is described in detail in section 8.5.2.

Instrument: papillotome.

ARTRO CUT Monopolar cutting for arthroscopic procedures.

This mode is used in wet environment. It requires the use of non-conductive fluids, e.g. distilled water, glycine.

Instrument: monopolar arthroscopic electrodes.

HYSTERO CUT Monopolar cutting for gynaecological procedures (hysteroscopy) in non-conductive liquids, e.g. purisol or glucose.

Instrument: loop electrode.

URO CUT Monopolar cutting for urological procedures.

This mode is used in difficult (wet) environment. It is necessary for TURP and TURB procedures.

Instrument: monopolar urological resectoscope.

ARGON CUT Argon-enhanced monopolar cutting.

The argon cover reduces the amount of formed smoke and smell. The thermal damage of tissues is reduced, and bleeding control is improved. This function is particularly desirable during procedures that require intensive use of device.

Instrument: needle- or lancet-type argon electrodes.

For additional information, see section 7.6.3

Argon modes are available only from output I and output II.

Cutting is usual performed using a knife or loop electrode, which is connected to a monopolar handle, then to the monopolar or universal sockets **(Fig. 1 items 1 and 3)**, with the corresponding panels controlling the respective outputs.

Before starting cutting, select the power or level, and the type of the desired effect (see section 7.6).

In the case of polypectomy and papillotomy, select Cutting% and level (see section 8.5.2).

The type and parameters of monopolar cutting are set in the yellow part of the panel, corresponding to the currently used output.

In cutting mode, the system is activated using the yellow button in the electrode handle, or the yellow button of the footswitch.

8.5.1 Drying cutting – MIXED CUT

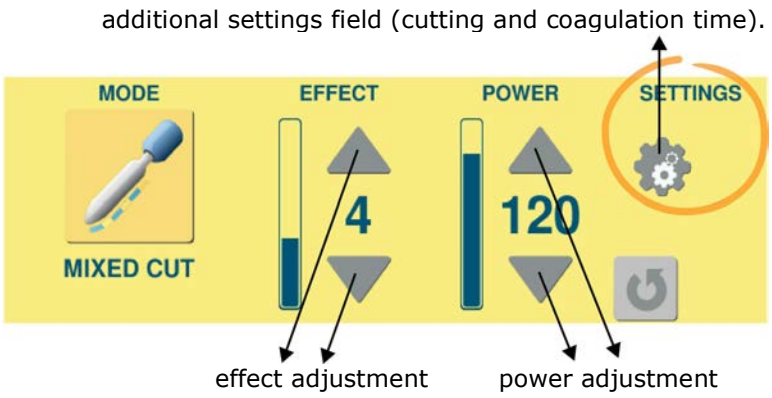
Intended use

The MIXED CUT mode is alternating cutting and soft coagulation.

It is used for very strong coagulation during procedures involving severe bleeding, where tissue "drying" is necessary. To enable this mode, select the appropriate cutting type button.

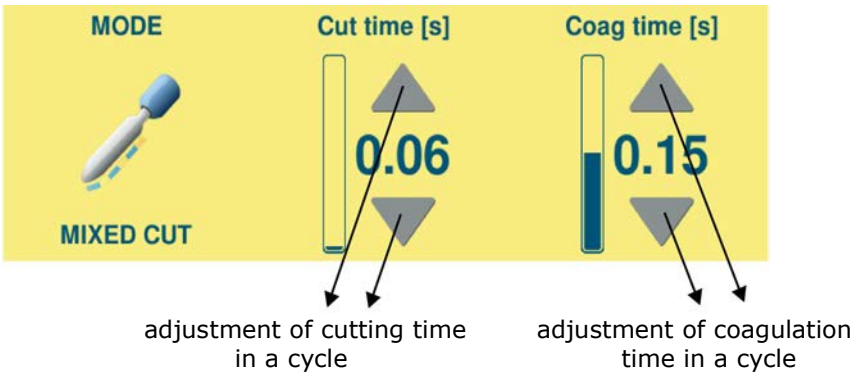
Power and effect settings

For this mode, cutting power and effect can be adjusted. The settings are made on the panels corresponding to cutting for the selected output:



Time settings

To adjust time settings, click on the additional settings field. By changing these settings, the time of each mode (cutting and coagulation) is adjusted during a cycle:



Suggested settings for the MIXED CUT mode:

Effects: 4

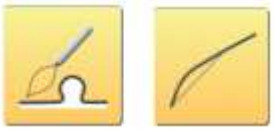
Power: 120 W

Cutting time: 0.06 s

Coagulation time: 0.15 s

8.5.2 Polypectomy and Papillotomy

Intended use:

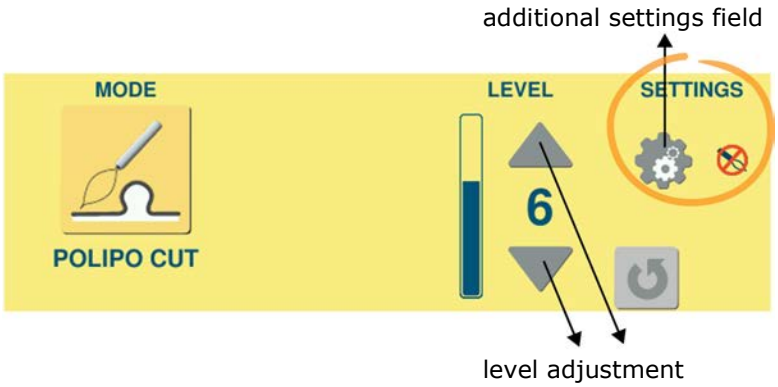


Special cutting modes for endoscopic procedures. In this mode, the coagulation and cutting are performed alternately, enabling tissue coagulation and cutting with an endoscopic instrument. The typical applications include polypectomy and papillotomy.

To enable this mode, select the appropriate cutting type button.

Cutting level and percentage setting

After connecting a SDS endoscopic cable, the system will recall the suggested settings for this mode automatically.



Level – indicates the degree of cutting and coagulation in the polypectomy and papillotomy modes.

Level 1 indicates the lowest effective cutting and coagulation level in endoscopic procedures. Level 9 indicates the highest safe cutting and coagulation level in endoscopic procedures.

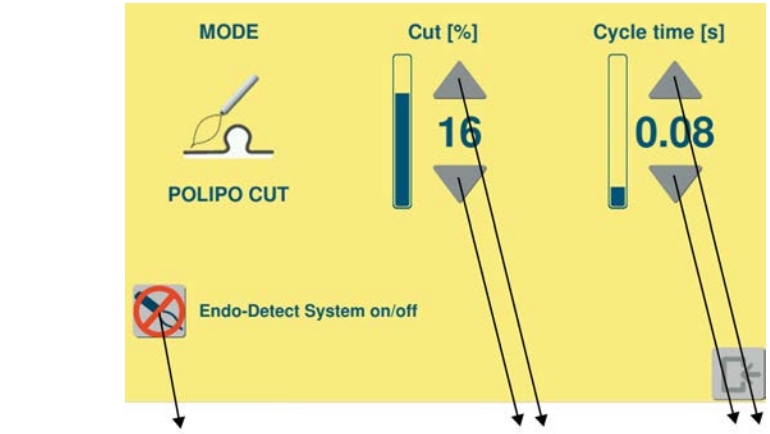
The power settings in this mode are selected automatically for each level, to obtain a repeatable endoscopic cutting effect, regardless of tissue parameters.

Percentage settings

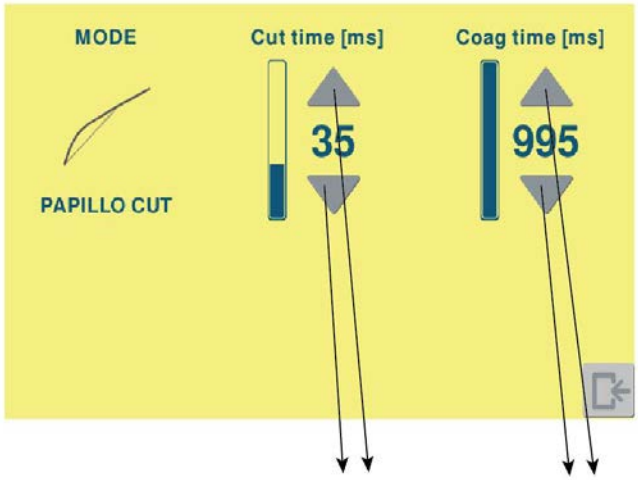
Before starting the procedure, set the correct cutting level and percentage (CUTTING %) on the panel corresponding to cutting for the selected output. This option enables to adjust the percentage share of cutting in a cycle. The remaining time is coagulation. To change the settings, touch the keys on the scale (indicated by arrows).

Time settings

To adjust the duration of one cycle, click the additional settings icon. To change the cycle time settings, touch the keys on the scale (indicated by arrows).



loop closing detection — adjustment of cutting percentage — adjustment of cutting in a cycle



adjustment of cutting time — adjustment of coagulation time

Endo-Detect System – loop closing detection


In the Polypectomy mode, the Endo-Detect system is an additional option. It is loop detection. When the Endo-Detect system is active, the system makes it impossible to activate current flow in a loop which is not applied on the tissue. It increases the safety of endoscopic procedures by limiting the risk of accidental activation of current in a loop which is not applied on the tissue. When the system detects a non-closed loop, a sound will be emitted and a message will appear on the screen.

This function is disabled by default. You can turn it on by touching the Endo-Detect button. To disable the detection, touch this button again.

Enabling this function reduces the risk of operator's error. It prevents accidental activation of a loop which is not closed on the tissue, thus reducing the risk of perforation.

NOTE: do not use the Endo Detect function when removing polyps smaller than 2 [mm].

Suggested settings for Polypectomy

Cutting percentage:	16%
Level:	6
Time:	0.08 [s]

Please remember that the effect of cutting and the selected settings depend on:

- **size and a type of the polyp**
- **loop movements by the operator – too fast and too strong closing of the loop can cause mechanic cut of non-coagulated polyp tissue which can lead to bleeding.**

Suggested settings for Papillotomy

Cutting time:	35 [ms]
Level:	6
Coagulation time:	995 [ms]

8.6 Monopolar coagulation

Depending on software version, the STEMA MASTER system is equipped with the following monopolar coagulation modes:

SOFT COAG Low-voltage monopolar contact coagulation.

This mode allows for deep coagulation, reaching deeper than the other types.

Instrument: monopolar electrodes, e.g. ball, spatula, lancet.

FORCED COAG Monopolar contact coagulation.

The traditional type of coagulation which allows for quick and efficient coagulation of local bleeding.

Instrument: monopolar electrodes, e.g. ball, spatula, lancet.

HYBRID COAG Monopolar coagulation for contact and non-contact applications with high voltage.

Instrument: monopolar electrodes, e.g. ball, spatula, lancet.

SPRAY COAG Non-contact monopolar coagulation with high voltage.

It allows to coagulate larger areas rapidly and effectively. It eliminates tissue adherence to the instrument.

Instrument: monopolar electrodes, e.g. ball, spatula, lancet.

NOTE: Do not use needle electrodes.

ENDO SPRAY Monopolar endoscopic coagulation .

It is used for rapid haemostasis of local haemorrhages.

Instrument: polypectomy snare.

ARTRO COAG Arthroscopic monopolar coagulation in non-conductive liquids, e.g. purisol or glucose.

Instrument: monopolar arthroscopic electrodes.

HYSTERO COAG Gynaecological monopolar coagulation in non-conductive liquids, e.g. purisol or glucose.

Instrument: monopoloar histeroscope - loop or ball electrodes.

URO COAG Urological monopolar coagulation coagulation (TURP, TURBT) in non-conductive liquids, e.g. purisol or glucose.

Instrument: monopolar resectoscope - loop or ball electrodes.

8.6.1 Argon coagulation

STANDARD ARGON Argon-enhanced monopolar coagulation.

This mode is used for non-contact coagulation of bleeding tissue surfaces. It eliminates smoke and smell. It ensures a very shallow and gentle coagulation.

Instrument: rigid argon electrodes for coagulation (see section 7.6.3).

NOTE: Argon modes are available only from output I (SDS) and output II (monopolar or SDS, depending on the configuration).

ENDO ARGON Argon-enhanced monopolar coagulation for endoscopic procedures.

It ensures a very shallow and gentle coagulation. It is necessary when there is a risk of perforation. The elimination of smoke ensures a perfect visibility of the operating field (see section 7.6.3).

Instrument: flexible argon probes.

NOTE: Argon modes are available only from output I (SDS) and output II (monopolar or SDS, depending on the configuration).

PULSE ARGON Argon-enhanced pulse monopolar coagulation.

It is used in gastroenterology for bleeding control. It enables precise dosing exactly at the bleeding site.

Instrument: flexible argon probes (see section 7.6.3).

NOTE: Argon modes are available only from output I (SDS) and output II (monopolar or SDS, depending on the configuration).

Before starting monopolar spray coagulation, select the power, and with the other monopolar coagulation modes, select the power and the type of the desired effect (see section 7.6).

The type and parameters of monopolar coagulation are set in the blue part of the panel, corresponding to the currently used output.

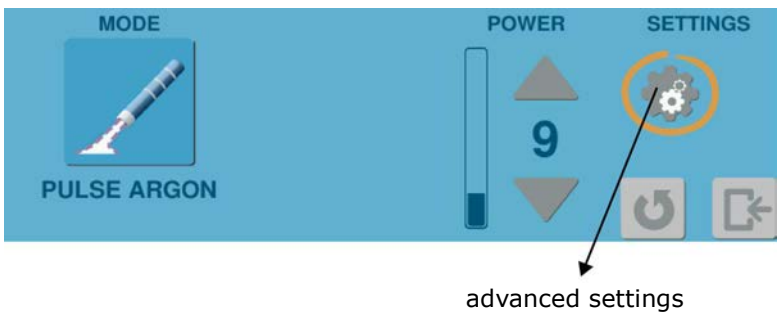
In monopolar coagulation mode, the system is activated using the blue button in the electrode handle, or the blue button of the footswitch.

8.6.2 Argon-enhanced pulse coagulation

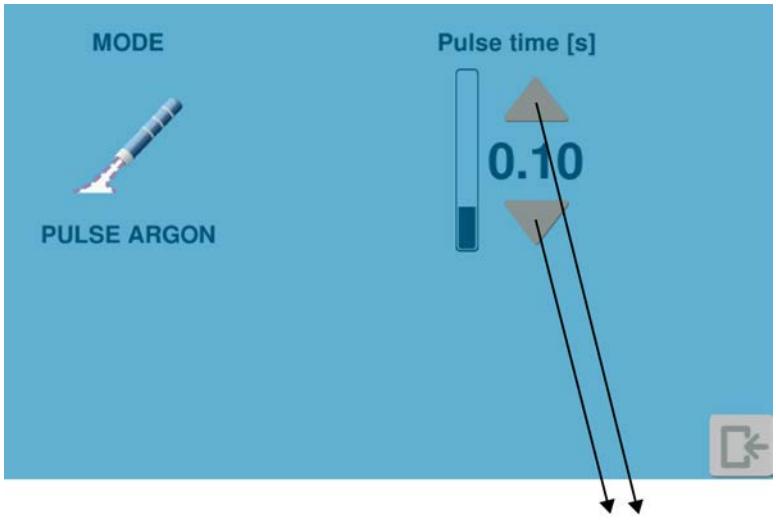
Monopolar pulse coagulation is a modified argon-enhanced coagulation. It is used whenever there is a risk of perforation and a very gentle coagulation and precise dosage is required, for instance in gastroenterology.

For this mode, set the power. The settings are made on the panels corresponding to coagulation for the selected output: To adjust argon flow settings, touch the Argon icon (see section 7.6.3).

When working in this mode, pulse time can be adjusted. To adjust the pulse time, select the advanced settings icon.



To adjust the pulse time, use the arrows on the touch panel.



pulse time adjustment

This time can be adjusted from 0.05 [s] to 0.25 [s].

Suggested settings for the PULSE ARGON mode:

Power:	20
Pulse time:	0.1 [s]
Argon flow:	1.5 [l/min]

8.7 Bipolar cutting

Depending on software version, the STEMA MASTER system is equipped with the following bipolar cutting modes:

BI-CUT Bipolar cutting with different effects of haemostasis. Special bipolar instruments are used for this mode. This mode is particularly useful for procedures performed in neonates and patients with heart pacemaker.

URO BI-CUT Bipolar cutting for urological procedures. This mode is used in wet environment. It requires the use of conductive fluids, e.g. normal saline. It is intended for TURP and TURB procedures.

Instrument: bipolar urological resectoscope.

ARTRO BI-CUT Bipolar cutting for arthroscopic procedures. This mode is used in wet environment. It requires the use of conductive fluids, e.g. normal saline.

Instrument: bipolar arthroscopic electrodes.

Bipolar cutting parameters, its type, effects and power or level are set in the yellow part of the panel for a universal or bipolar output.

Bipolar cutting can be activated using both footswitch sockets.

Bipolar cutting is activated using the yellow button of the footswitch.

8.8 Bipolar coagulation

Depending on software version, the STEMA MASTER system is equipped with the following bipolar coagulation modes:

SOFT BI-COAG Low-voltage bipolar contact coagulation. In this mode, the current flows between the electrode tips, and no passive electrode is required. The typical use is for closing individual medium-sized blood vessels.

Instruments: bipolar forceps, bipolar needle electrodes, bipolar laparoscopic instruments.

FORCED BI-COAG High-voltage bipolar coagulation. In this mode, the current flows between the electrode tips, and no passive electrode is required. The typical use is for closing medium-sized blood vessels.

Instruments: bipolar forceps, bipolar needle electrodes, bipolar laparoscopic instruments.

ARTRO BI-COAG Arthroscopic bipolar coagulation in conductive liquids, e.g. saline solution.

Instruments: bipolar arthroscopic electrodes

SCISS BI-COAG Universal soft bipolar coagulation for cutting with bipolar scissors.

Instruments: bipolar SDS scissors.

URO BI-COAG Bipolar coagulation used for urological procedures TURP and TURB. This mode is used in fluid environment.

Instrument: bipolar urological resectoscope, loop electrode or ball.

The type and parameters of bipolar coagulation are set in the blue part of the panel.

Bipolar cutting can be activated using both footswitch sockets.

In the bipolar coagulation mode, the system can be activated in two ways: automatically when the tissue is grasped (if the AutoStart function is available) or using the footswitch.

Footswitch operation:

In this mode, the surgeon starts and stops system activation using a footswitch. The blue button of a footswitch is used for activation of bipolar coagulation.

Automatic operation:

If the AutoStart function is available in the bipolar coagulation mode, automatic activation after grasping the tissue is possible.

After grasping the tissue and the set delay, the generator is turned on. It is stopped when the forceps are opened, or after a specified time when using the AutoStop function.

8.8.1 The AutoStart and AutoStop functions in bipolar coagulation

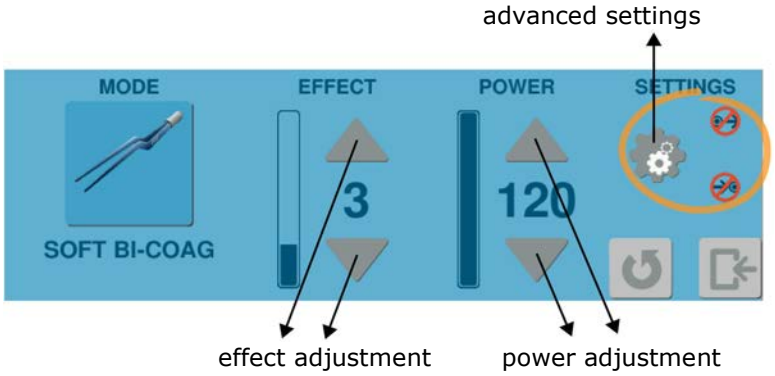
The AutoStart and AutoStop functions are available for low-voltage bipolar coagulation (SOFT BI-COAG mode only). High-voltage bipolar coagulation (FORCED BI-COAG) allows to set the AutoStop time.

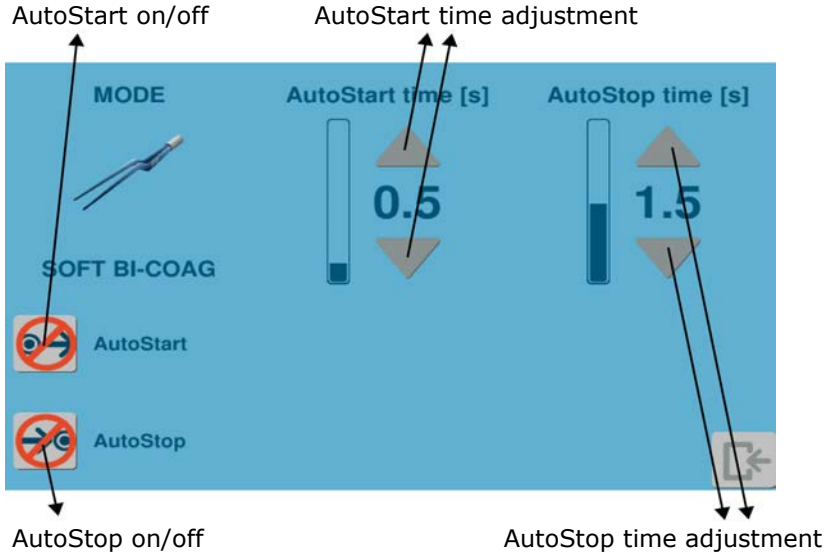
Power and effect settings

The effect and power limit are set for the low-voltage bipolar coagulation mode. The settings are made on the panels corresponding to bipolar coagulation for the selected output.

To enable the AutoStart and AutoStop function, touch the advanced settings icon on the panel.

The AutoStart and AutoStop functions are disabled by default.





AutoStart function. In bipolar operation mode, it is possible to automatically activate the bipolar forceps when tissue is grasped. This function can be enabled in the bipolar coagulation settings. It allows for bipolar work without using a footswitch. The delay between tissue grasping and generator activation can be set in the range from 0.05 to 3 [s] (default 0.5 [s]) using the time adjustment buttons.

The AutoStart function is turned off by default after each system start-up.

The AutoStop function limits the time of bipolar coagulation. This time can be adjusted from 0.1 [s] to 3 [s] (default 1.5 [s]) using the time adjustment buttons.

8.9 ThermoStapler®

Depending on software version, the STEMA MASTER device can also offer a mode for sealing large blood vessels.

ThermoStapler® is a special bipolar current allowing to seal large blood vessels and to prepare tissue bundles before cutting. It eliminates the need for traditional staplers and ligation. This mode is especially helpful for the resection of organs and tumours. The instrument used in this mode is bipolar clamp.

This mode is used for closing blood vessels with diameter of up to 7 [mm], and for preparation of tissues, e.g. before mechanical cutting. The use of special instruments which combine the mechanical and thermal effects is required. In this mode, a pulsating current, which enables deep tissue coagulation, appears on the instrument.

Suggested settings:

Effect: 3

Power: 80 [W] (for laparoscopic procedures)

Power: 150–200 [W] (for open surgery)

In the ThermoStapler® mode, the set power means the maximum power. However, when using laparoscopic instruments, we suggest to limit the power to 80 [W].

Nevertheless, please take into account the fact that, despite common opinion, setting too low power causes excessive heating of the adjacent tissues in most modes. It is because low power increases the time of activation and increases heat migration.

Correctness of performed work using the ThermoStapler®

In the ThermoStapler® mode, after complete tissue sealing, the system automatically turns the generator off. The system measures the parameters of the closed tissue and automatically cuts the current when the optimum effect is obtained.

The correctness of the performed work is signalled by an acoustic signal and a message on the screen:

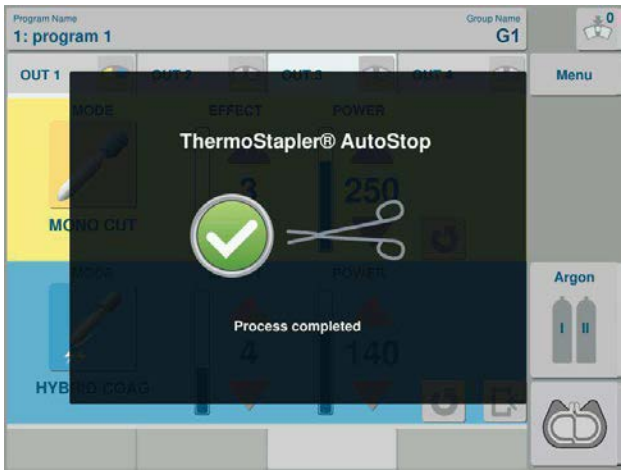


Figure 26. Message: ThermoStapler® AutoStop – cycle completed.

Exceeding the allowed ThermoStapler® time

This mode has an additional function informing the used about exceeding the allowed time of ThermoStapler® operation. If a message and an acoustic signal appear during a procedure, check the clamp application and verify the settings – if possible, increase the settings to obtain a stronger coagulation effect.

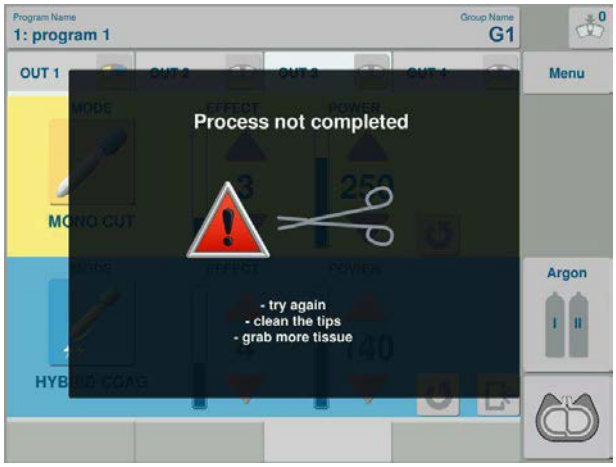


Figure 27. Message: The allowed ThermoStapler® time has been exceeded.

It is recommended to check if the power and effect settings are close to those suggested.

If the clamp is applied incorrectly, the following message will appear on the screen:

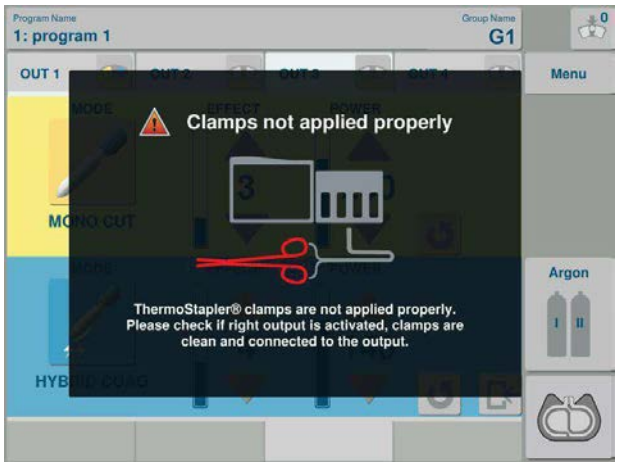


Figure 28. Message: The allowed ThermoStapler® time has been exceeded.

The above message means that the coagulation process has not been completed correctly. Act according to the instruction, re-apply the clamp and activate the current flow.

8.10 System overload control

The system has work time restrictions, which protect it from overloading (OVERLOAD). The restrictions depend on the power settings and the type of procedure. In extreme conditions, overload control allows to at least 10 seconds of work after 30 seconds of rest.

System overload is signalled by an acoustic signal and a message "System cooling". The system forces an interruption in the procedure until the indicator turns off (about 30 seconds).

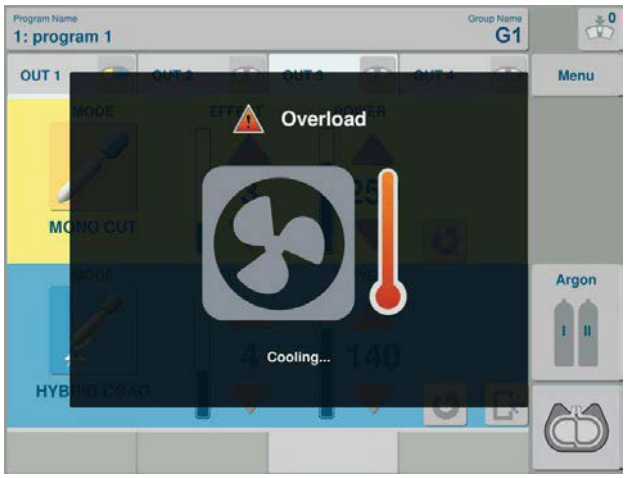


Figure29. Message: System cooling.

Do not restrict system cooling during operation. It means that the system cannot be covered with anything during operation. If the system rests on a shelf, ensure that there is at least 2 [cm] of clearance above the device.

A failure to ensure the appropriate cooling conditions will cause the overheating to occur earlier and to last longer.

Do not put any objects on the device. Due to the risk of flooding, the system should be installed above and at a distance from fluids and irrigation conduits.

8.11 Program setting

All settings stored in the system memory by its users are saved independently for each program. The saved programs remain in the system memory even when power is switched off, and they can be recalled by pressing the bar with the program name on the touch panel, then selecting an appropriate program from the list.

Program recording method:

To define your own programs, select the program management bar on the touch panel.

Figure 30. Program management bar.

A window for program management will appear on the screen.

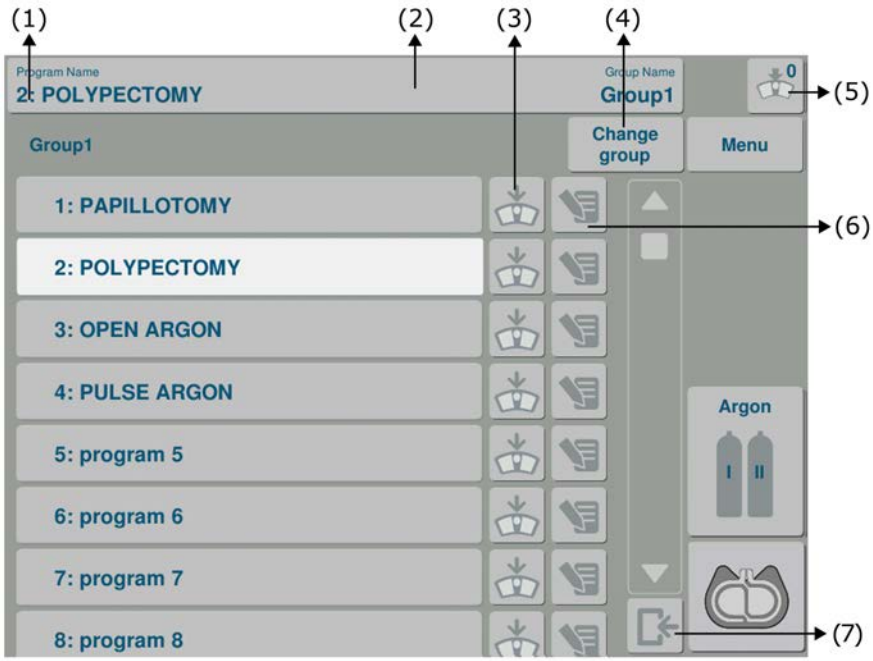


Figure 31. Program management window.

The program management windows contains **(Fig. 31)**:

- program number **(1)**
- program management bar **(2)**
- program add/remove to/from the MultiSwitch function list **(3)**
- group change mode button **(4)**
- button with a number indicating the number of programs in the MultiSwitch function **(5)**
- name edit button **(6)**
- exit button **(7)**

To save a program, select a program to save from the list. To change the program name, select the name edit button, enter the new name, and confirm with the enter button.

Double-click on the Shift button enables the CapsLock function.

To exit program management, select the exit button.

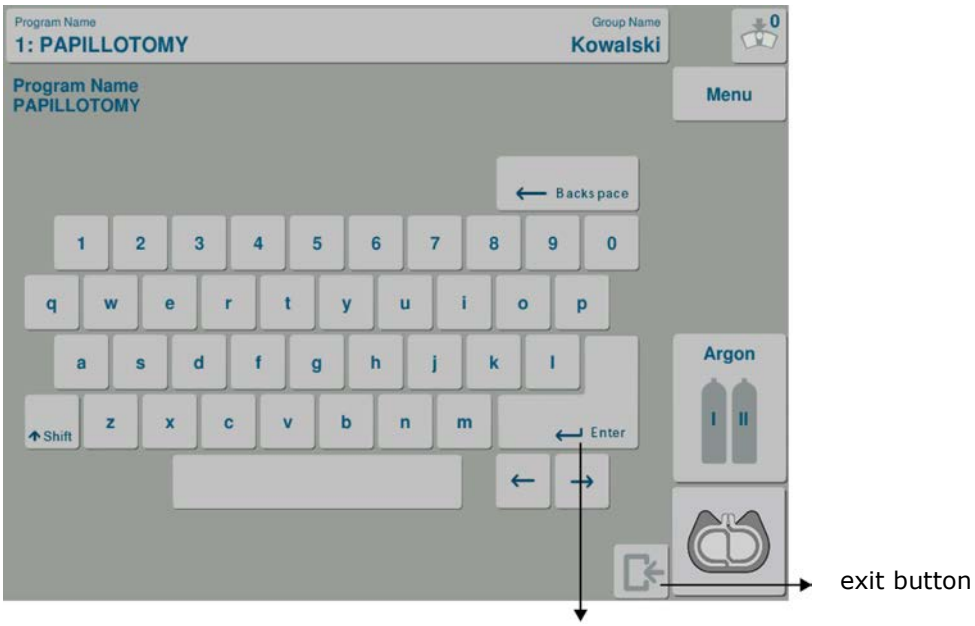


Figure 32. Giving names to programs and groups.

The MultiSwitch button at the program name **(Fig. 31, item 3)** is used to add/remove the MultiSwitch function to/from the list of programs for the currently selected program.

It is possible to save a program in a different group by using the "Group change" button **(Fig. 31, item 4)**. A group can be changed similarly to program change.

The programs are divided into 7 groups, each containing 15 programs. 2.1.14

Programų skaičius prietaise (darbinių parametrų nustatymų skirtingiems panaudojimo atvejams) ≥ 30

8.11.1 Copying of programs

To copy the program click on the touch panel the program management bar **(Fig. 30).** Then choose a program from the list to copy it, click the edit name button and the Copy icon **(Fig. 32).**
Then choose the program, where you would like to copy all the parameters. Click the Paste icon – the copied parameters will be saved in the chosen program **(Fig. 33)**. The copied program can be saved under a new name.

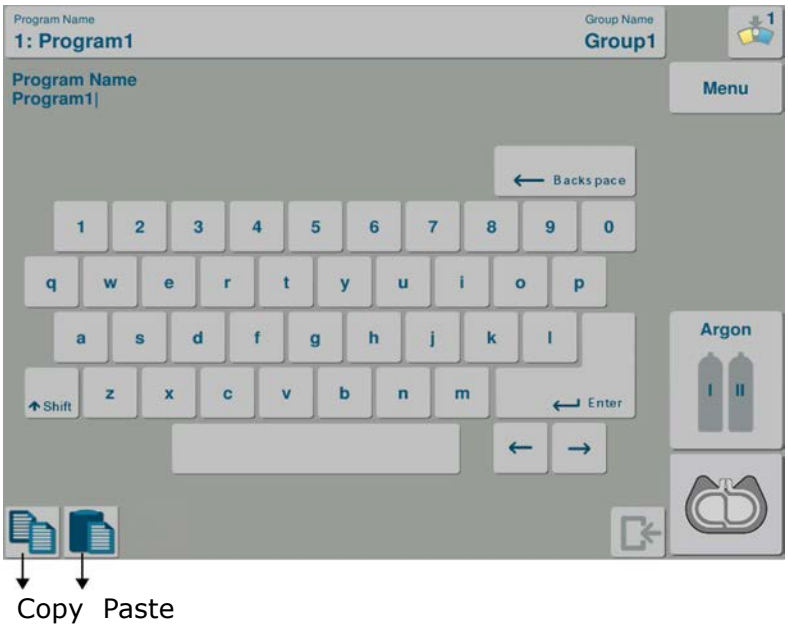


Figure 33. Save the copied program.

You can copy programs also between groups.

8.11.2 The MultiSwitch function

The MultiSwitch function allows to switch the programs rapidly using a three-button footswitch. To switch the programs currently added to the MultiSwitch list, press the middle button of the footswitch.

The number of programs in the list is indicated on the button **(Fig. 31 item 5)**. The number of the currently selected program is next to the program name **(Fig. 31, item 1)**.

The MultiSwitch function allows to switch the programs in the selected group.

Using the MultiSwitch button in the footswitch it is possible to adjust the effect or power. Press the button and hold for more than 2 seconds in order to switch to the view where the effect may be decreased using the cut button or increased using the coagulation button.

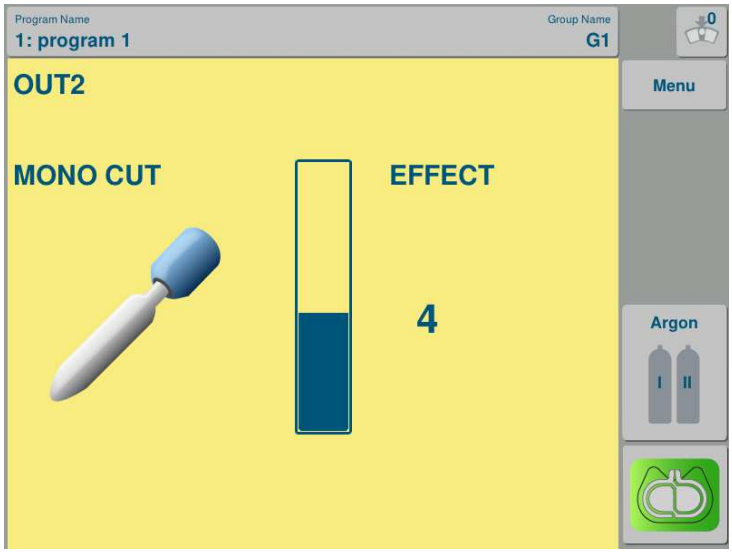


Figure 34. Effect adjustment using the footswitch.

The MultiSwitch button may also be used to change the program. Press the button shortly to make the change, which is indicated on the screen.

Figure 35. Program change using the MultiSwitch button.

8.12 Menu content

Selecting the Menu button on the main panel allows to use the following tools:

- Catalogue
- Language
- Style
- Volume
- Screen brightness
- Recommended settings
- Service
- Contact
- Inspection due date
- Maximum activation time

To enter a tool, click one of the following icons:

Figure 36. Menu content.

8.12.1 Catalogue

To review the catalogue of accessories, click the Catalogue icon.

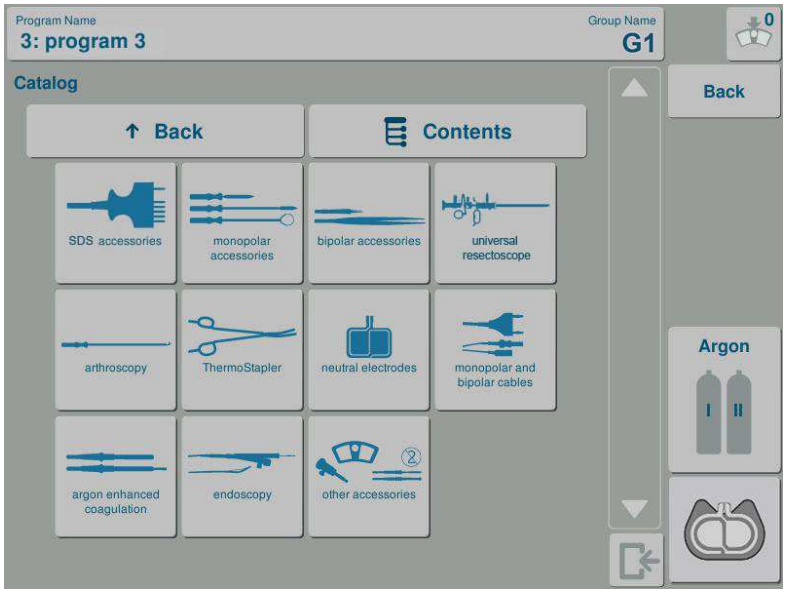


Figure 37. Catalogue of accessories.

Catalogue updates are free of charge. The medical representative can update the catalogue during a commercial visit.

8.12.2 Change of text and message language

The STEMA MASTER system offers an option of selecting the language for texts and messages that appear on the touch panel of the system. To change the language, click the field with the selected language version. Depending on system version, the language versions may differ. However, there are always two basic versions, i.e. Polish and English.

Figure 38. Language selection for texts and messages.

8.12.3 Style change

The system offers an option to change graphics, so that it is possible to work in both bright (Sunset) and dark (Night) operating room. It also allows to change icons (Sunset 3D), which graphically indicate the nature of work in a given mode.

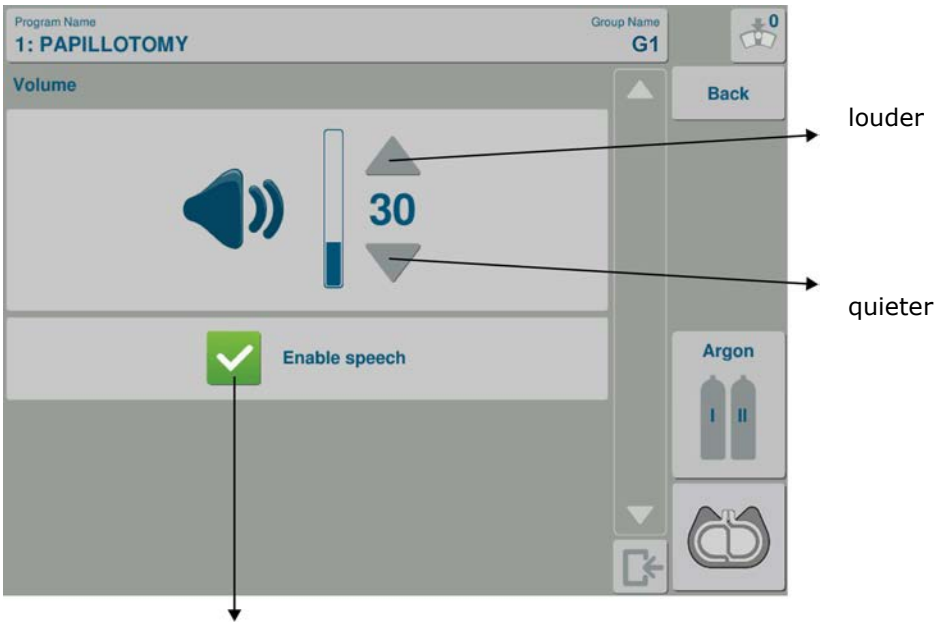
To change graphics, select the Appearance icon, then indicate the style which is the most appropriate for the user's current needs. Sunset 3D, Night, Sunset.

Figure 39. Style change.

8.12.4 Volume adjustment

The volume of the acoustic signals of the interface can be adjusted by the user. To reduce/increase the volume, touch the respective button on the volume scale.

It is possible to enable or disable voice messages by touching the checkbox.



checkbox for enabling/disabling voice messages

Figure 40. Volume adjustment.

For safety reasons, when working with electrosurgical unit, it is not possible to completely mute the acoustic signals. The alarm sounds always remain at the same volume level, regardless of volume adjustments

8.12.5 Screen brightness change

The STEMA MASTER system offers an option to adjust screen brightness. To adjust brightness, touch the Screen brightness icon and increase or decrease screen brightness as required using the arrows.

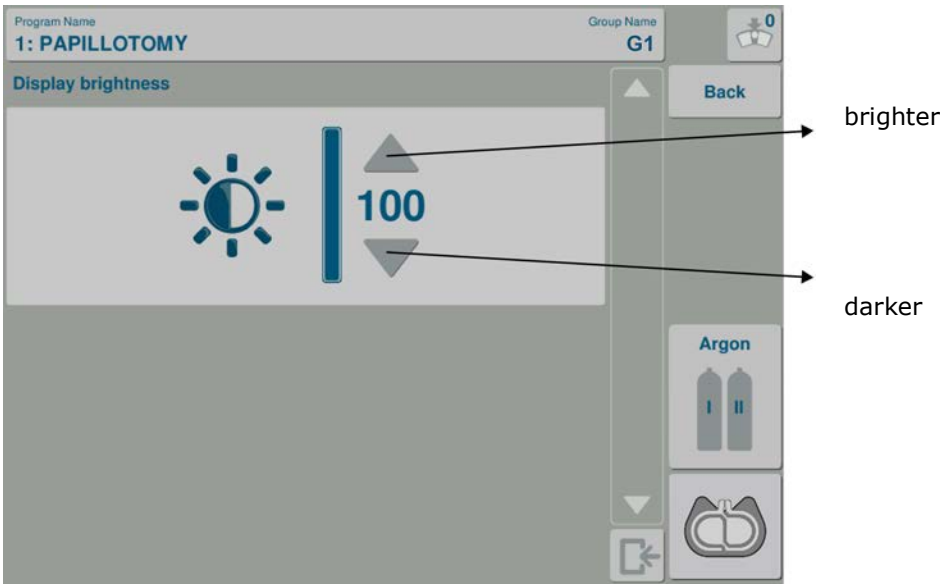


Figure 41. Screen brightness adjustment.

8.12.6 Service

The Service icon enables access to service settings. This option is available for authorised service; a password is required.

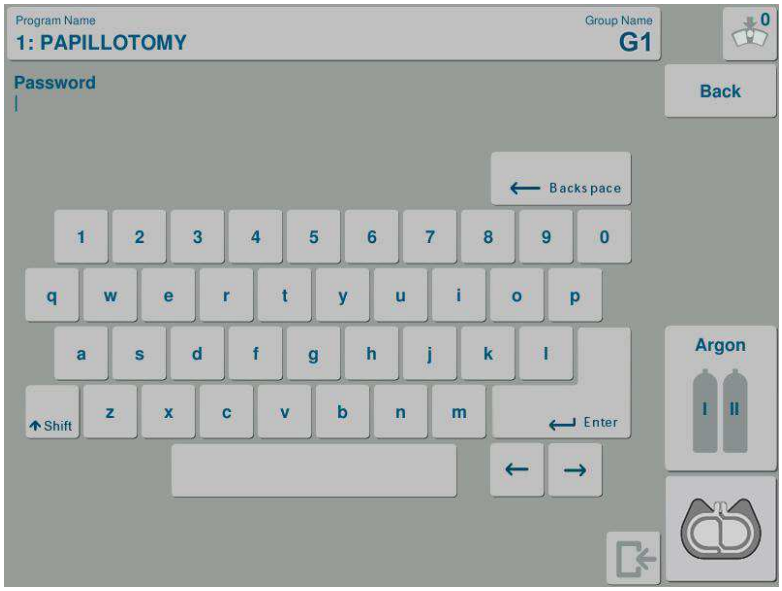
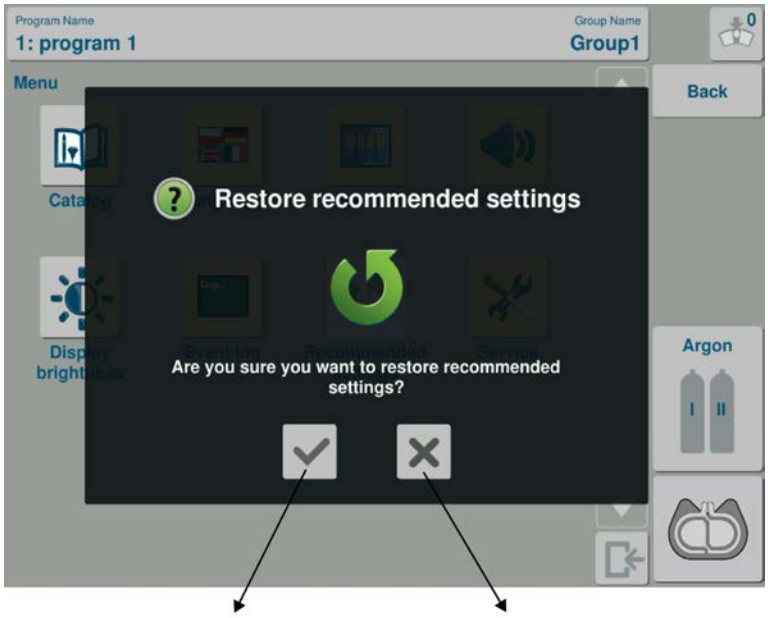


Figure 42. Access to service settings.

8.12.7 Restoring the suggested settings

The Suggested settings icon allows to return to the factory suggested settings. All settings of the programs and groups in the system are deleted.



restoring the suggested settings function

cancelling the suggested settings restore

Figure 43. Restoring the suggested settings.

8.12.8 Inspection due date

The Inspection due date icon allows to check inspection validity. There you can find informations about earlier inspections.

Figure 44. Inspection due date.

8.12.9 Contact

This icon contains contact details for the manufacturer's or authorized distributor's place of business.

Figure 45. Contact.

8.12.10 Maximum activation time

The STEMA MASTER System comes with an option of limiting activation time within the range of 30–180 seconds. This function is by default programmed at 90 seconds, and 0 seconds means that the function is off.

Figure 46. Maximum activation time

8.13 Turning the system off

When the procedure is completed, turn the system off using the stand-by button (press and hold it for about 1 second) **(Fig. 1, item 7)**, then using the power switch **(Fig. 2, item 12)**, and disconnect the power cord from the power outlet. After switching the system off, disconnect the electrodes and forceps from the cables, then disconnect the electrode cables from the system.

When performing argon-enhanced procedures, close the argon cylinder after switching the device off.

9. Errors and messages

2.1.15 Klaidos atveju aparatas turi indikuoti klaidos kodą arba kita forma pateikiamą pranešimą apie klaidos pobūdį

9.1 The most common errors during system operation

No.	Error type	Signalling	Troubleshooting
1	The touchscreen remains dark after turning the system on	Sound, visual signalling using a LED near the output, LED next to the start button is on, type not selected yet.	Wait about 30 seconds when the system performs the internal test and accessories test.
2	An error message is displayed when the system is turned on.	example message: 	Act according to instructions on the screen.
3	I cannot find the operating mode of interest.	The instrument detection status window signals a connected instrument. The mode is not listed.	Use a different instrument compatible with the desired operating mode.
4	Why can’t I set higher power?	The connected instrument limits the maximum allowed power. Small ectrode was selected.	Use a tool which allows the use of a higher power.

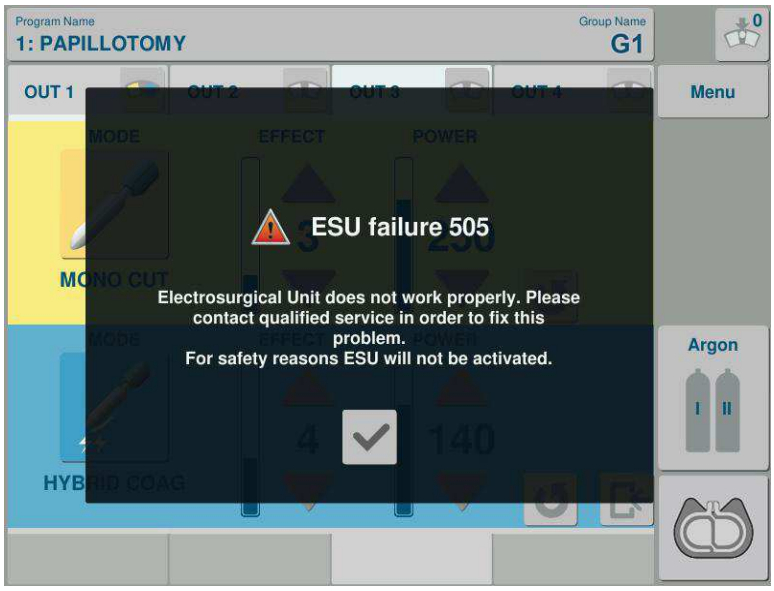
table 4 Possible errors during system operation

9.2 List of errors and messages

Below there is a list of errors and messages that may appear on the system panel.

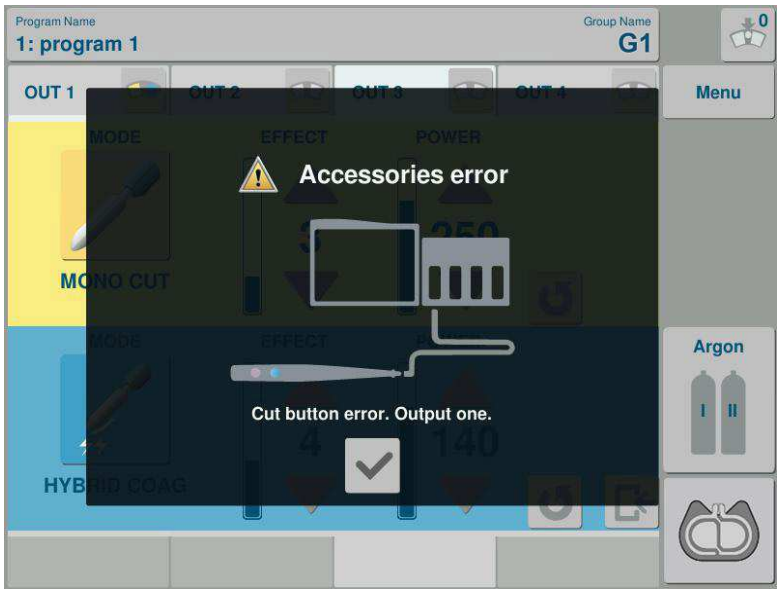
Some messages must be acknowledged by selecting the checkbox: 

UNIT ERROR 505



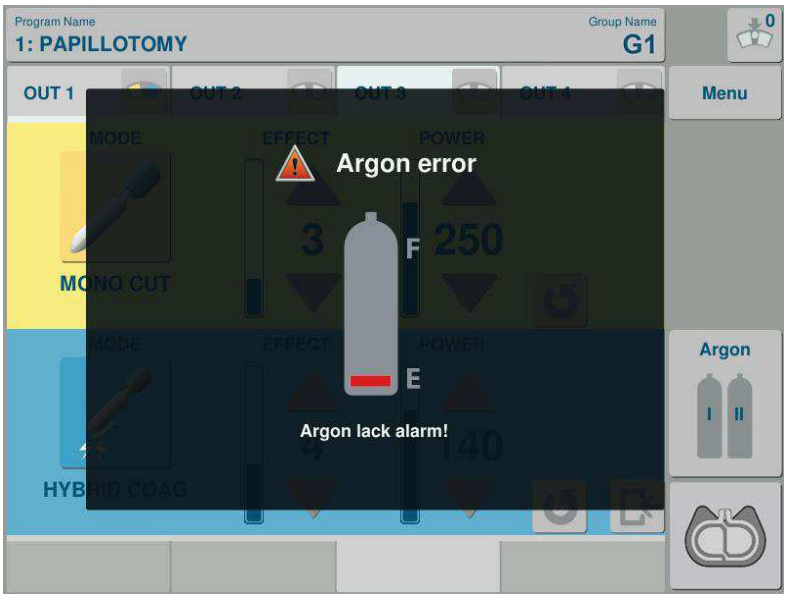
The system has locked for safety reasons.
Contact the service.

ACCESSORY ERROR



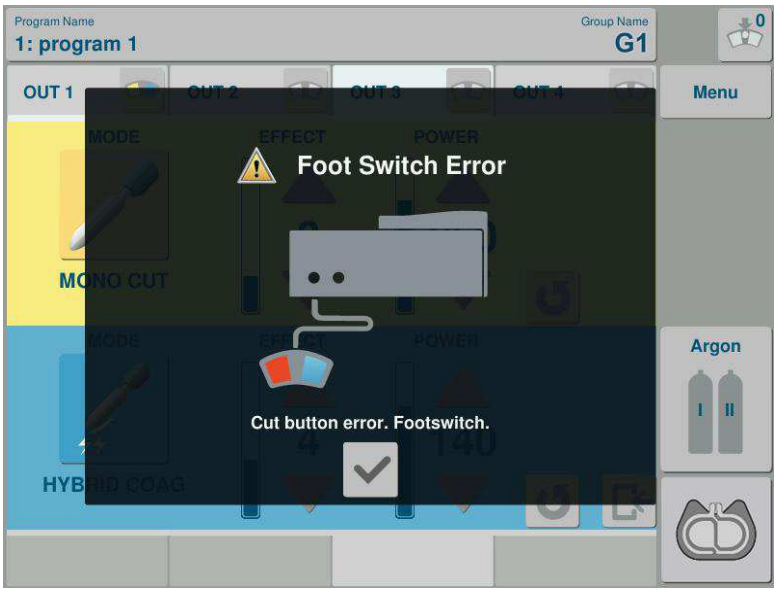
Shorted switch on the handle. Please release the handle button. If the button is released and the system continues to display the message, the accessory is damaged. Connect a functioning accessory.

ARGON ERROR



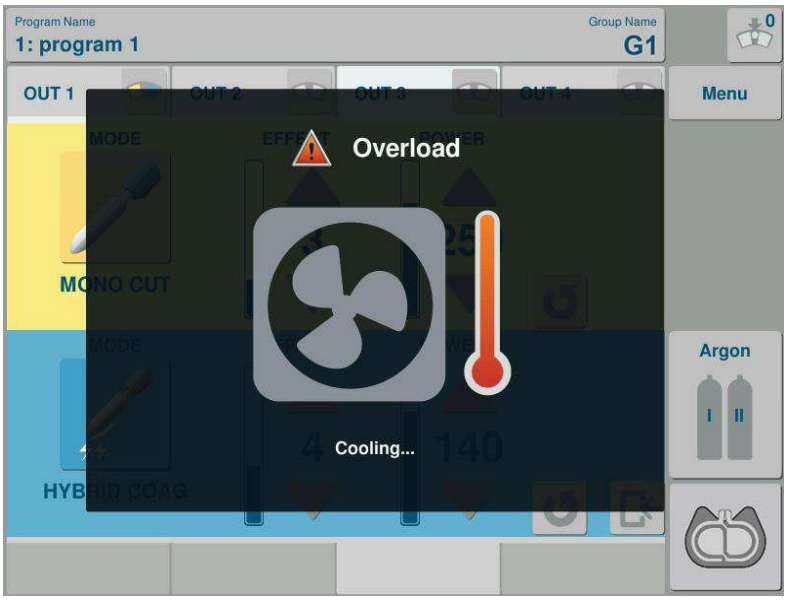
A message informing about the lack of argon. Refill the argon.

FOOTSWITCH ERROR



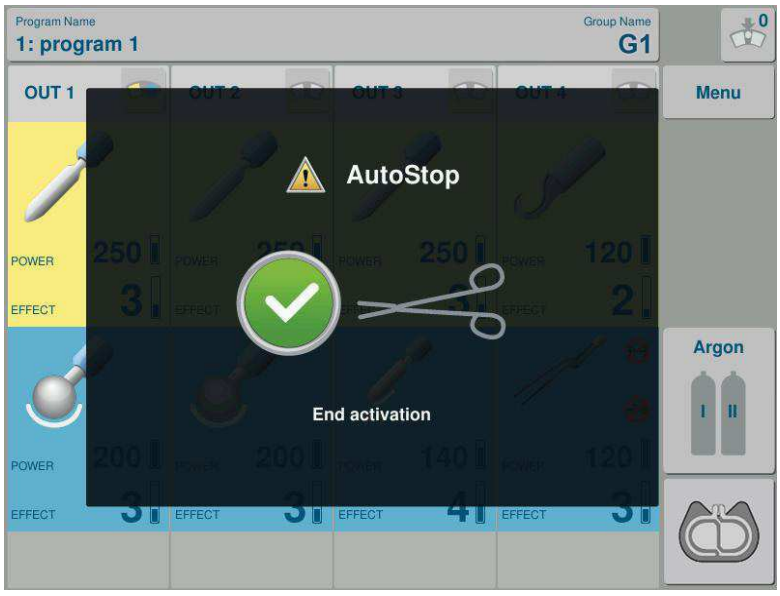
Shorted button on the footswitch. Please release the footswitch button. If the message is still displayed, the cutting button on the footswitch is damaged. Connect a functioning footswitch.

SYSTEM COOLING



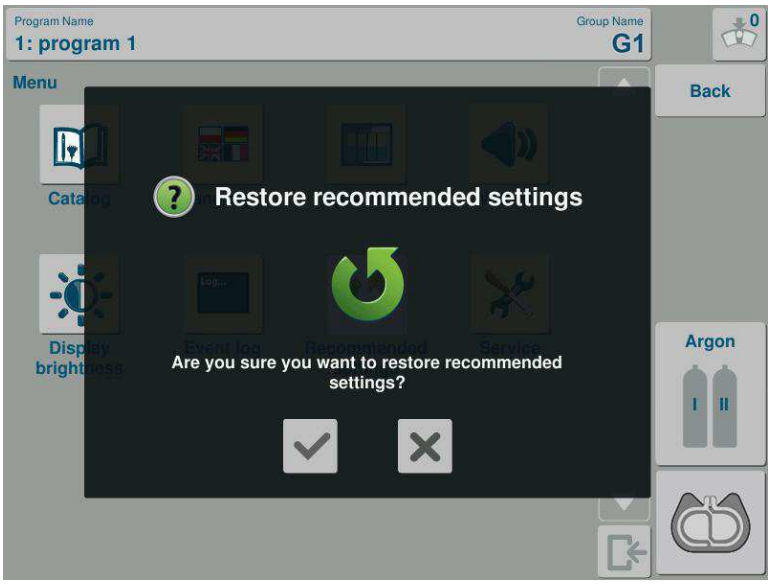
The system is cooled to protect it from overheating (see section 8.9). The system forces an interruption in the procedure until the indicator turns off (about 30 seconds).

AUTOSTOP



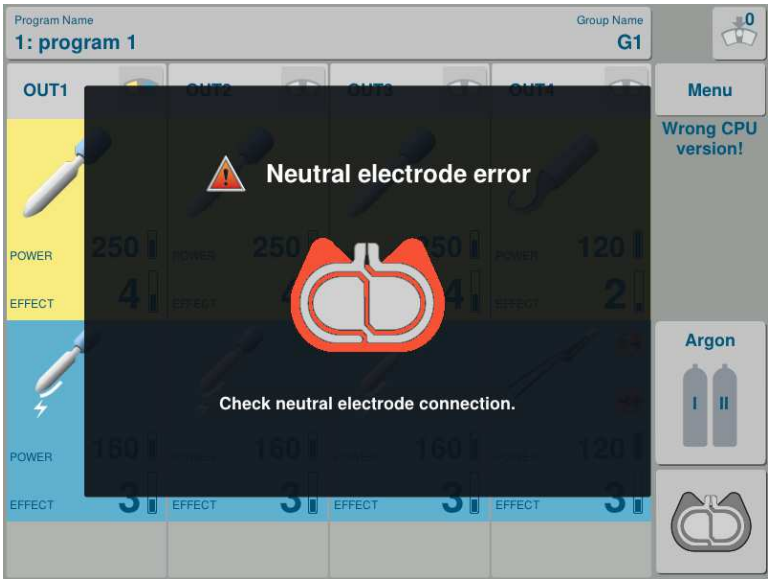
The message informs that AutoStop has stopped working.

RESTORING THE SUGGESTED SETTINGS



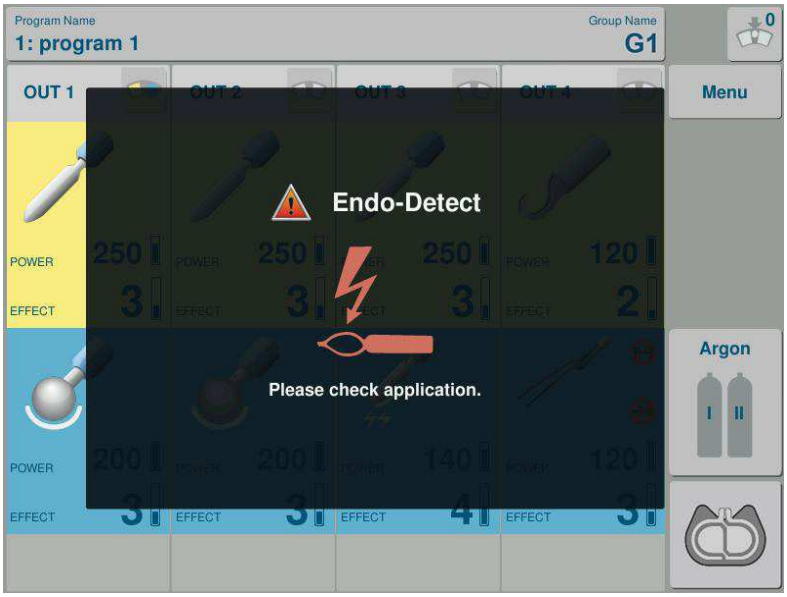
Selecting the appropriate checkbox on the touch panel cancels the set modes in the programs and groups and returns to the factory settings in the entire system.

NEUTRAL ELECTRODE APPLICATION



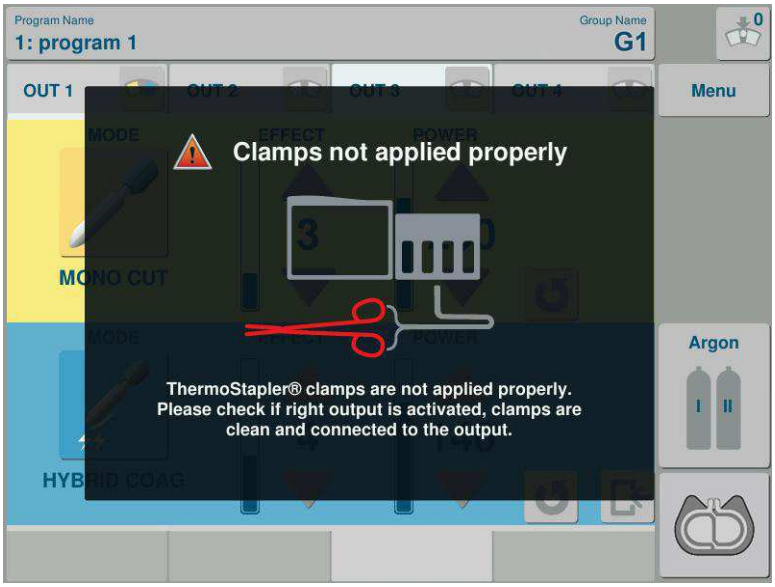
Check the neutral electrode connection. For additional information, see sections 8.2.1

ENDO-DETECT



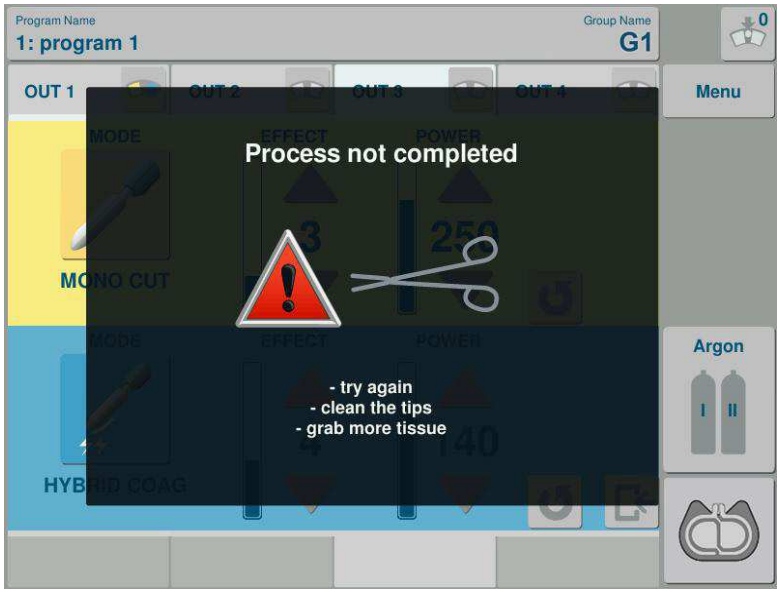
Closed loop detection message, informing that a non-closed loop has been detected. Please check loop application.

CLAMP APPLIED INCORRECT



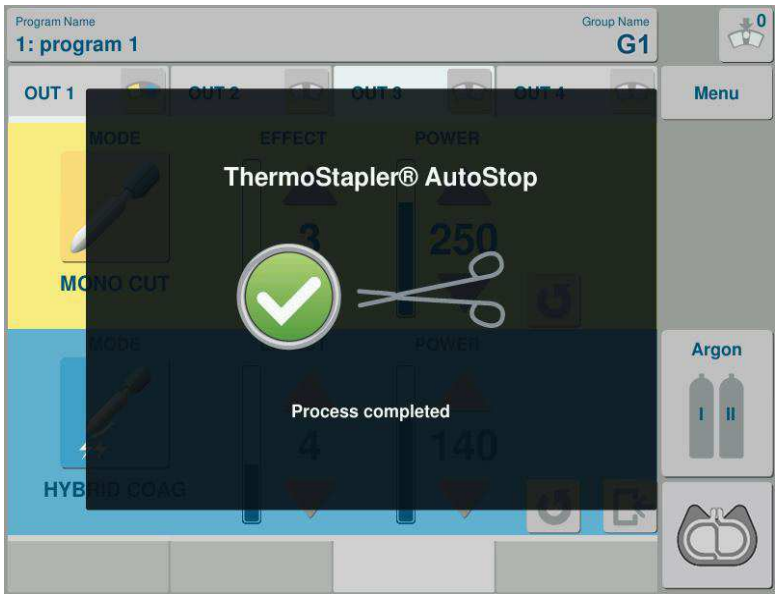
The ThermoStapler® clamp has not been applied correctly. Please check if the correct output is activated, if the forceps are clean and if they are assigned to the correct output.

EXCEEDING THE ALLOWED THERMOSTAPLER® TIME



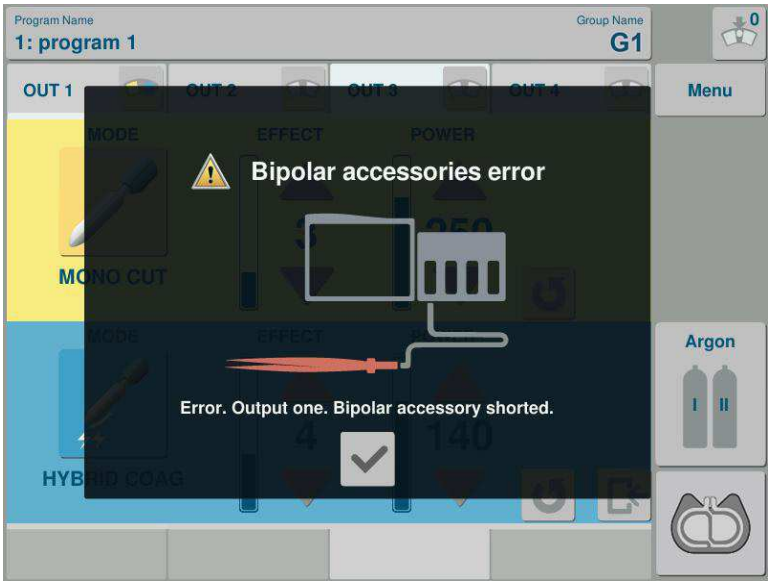
The vessel has not been closed. Please re-apply the clamp.

THERMOSTAPLER® AUTOSTOP



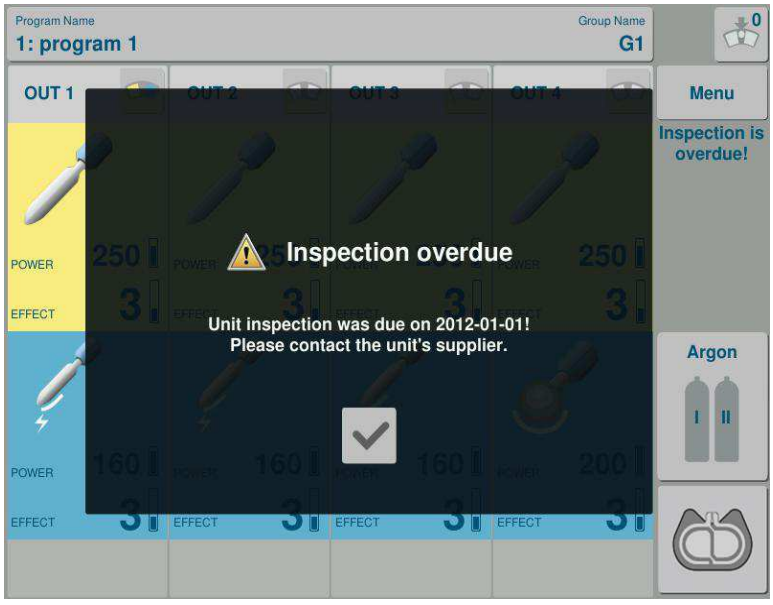
A message informing about the correct termination of the ThermoStapler® work.

BIPOLAR ACCESSORY ERROR



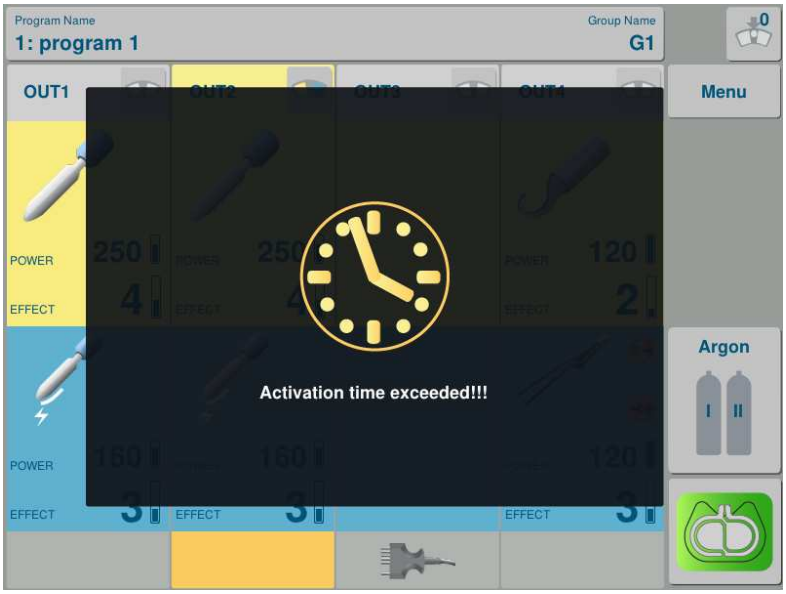
The bipolar instrument is shorted. Please open the instrument branches.

INSPECTION OVERDUE



Inspection overdue. Please contact with an authorized service.

MAXIMUM ACTIVATION TIME



Limitation of activation time was selected.
The system forces activation to stop. After reactivation the time is calculated from the start.

10. Protection measures and warnings

10.1 When performing electrosurgical procedures, minimize the risk of burns by:

a) using only the recommended accessories,
b) constantly checking the cables for connecting the application electrodes, and in particular their insulation condition,
c) correct application of the neutral electrode (see Section "Neutral Electrode Monitoring"),
d) not allowing any fluids to enter between the silicone neutral electrode and the patient's body,
e) securing the patient from coming into contact with metal and grounding elements; in particular, the patient should be efficiently insulated from a grounded operation table. For this purpose, a plastic film should be placed between the operating table and the surgical drapes on which the patient is positioned,
f) avoiding touching the patient's skin; in case it is necessary, dry gauze should be used as an insulator
g) not allowing the parts of the patient's body to come into contact with each other (for instance the hand touching the thigh)
h) the neutral electrode should be applied as close as possible to the procedure site, but not closer than 20 [cm] from the operating field.

10.2 When planning surgeries that cannot be safely completed in the case of basic electrosurgical system failure, one should prepare a complete and ready-to-use substitute electrosurgical system.

10.3 When performing procedures on patients connected to monitoring devices (ECG), remember to place the monitoring electrodes as far as possible from the electrosurgical electrode application site. Furthermore, it is recommended to use monitoring devices equipped with protective systems against high-frequency currents. Do not use needle electrodes for monitoring devices.

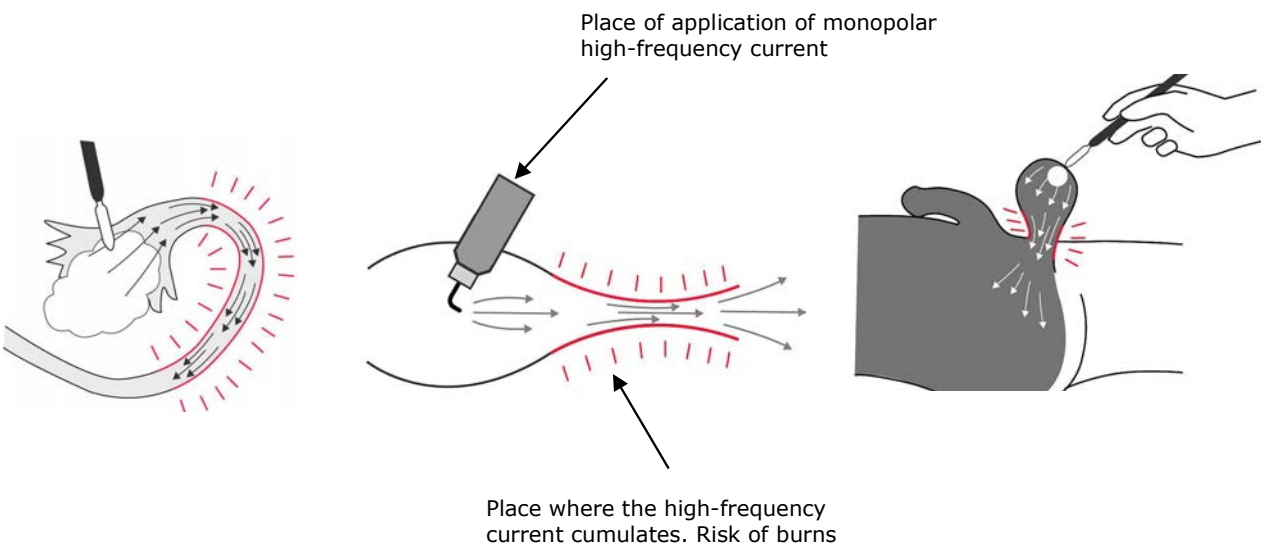
10.4 The application electrode cables should be connected so that:
- they do not touch the patient
- they are not intertwined with other cables

10.5 The active electrode handle, active mono- and bipolar electrodes cannot be put on the patient's body due to the risk of accidental activation and other risks. Moreover, the active electrodes become hot during operation. Take special precautions because accidental touching of tissues with a hot instrument can cause burns and perforation.

10.6 CHANNELLING EFFECT

In procedures where high-frequency current might flow through body parts with a small transverse diameter or through other pedicles (e.g. ovary-Fallopian tube, testes, gallbladder) there is a risk that the high-frequency current will cumulate in the narrowest place. This may lead to unwanted heat generation (burns) and tissue necrosis in a spot that is distant from the operating field. This phenomenon is known as the channelling effect. The bipolar mode should be employed in such cases, since it minimizes the risk of coagulation in unwanted locations.

Examples of locations where the channelling effect may occur:



10.7 The output power setting should not be greater than necessary for performing a given procedure.

10.8 An error of an electrosurgical device may result in undesirable increase of output power and inadvertent damaging of patient's tissues. A yearly technical inspection of the device in an authorized manufacturer's service centre shall minimize the risk of failure.

10.9. An evident drop in the output power, when settings are normal, can mean:

- incorrect application of the neutral (silicone) electrode,
- damaged cables,
- residues of coagulated tissue on the instrument.

Check for the above situations before increasing the power.

10.10 Unclean electrodes can cause a reduction in unit quality. This especially applies to soft and bipolar coagulation. The active electrodes should be cleaned of residual tissues during the procedures.

10.11 During the operations performed in the region of the thorax or the head it is recommended to avoid using the flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen, unless those agents are sucked away.

10.12 In order to remove gases and increase the visibility during the operation, it is recommended to use smoke-plume extraction, when it is not possible to remove it in any other way.

10.13 Use non-flammable disinfectants. Otherwise, they should be left to evaporate before the procedure. There is also a risk of pouring those agents under the body or into a body cavity. Should this happen, such flooded areas should be dried. A flammable agent can be set on fire by a spark occurring during normal system operation.

10.14 Sparks at the active electrode pose the risk of setting bandages and metabolic gases on fire.

10.15 During a procedure, there is also a risk that a heart pacemaker can be damaged or its function can be interfered during a procedure. In these cases, the bipolar technique should be used. If monopolar modes are necessary, the neutral electrode should be placed at a possibly greatest distance from the pacemaker. The active electrode should not be used near the stimulator. It is recommended to apply the current for a short time at short time intervals. Before using electrosurgery, consult an authorised representative of the heart pacemaker and a cardiac surgeon. Check the pacemaker thoroughly after the procedure. It is not permitted to use electrosurgery systems on patients with heart pacemakers under outpatient clinic conditions.

10.16 High-frequency leakage currents can cause burns at a distance from the electrode application site, if they are in contact with conductive elements.

10.17 The often-used "through-the-instrument" coagulation technique should only be applied when using properly insulated forceps. There are special forceps with insulated handles. **Surgical gloves do not sufficiently protect the operator from burns.** Never use spray coagulation when applying this technique.

10.18 When using spray coagulation, keep an appropriate distance from the fingers, metal parts of endoscope optics, fiberscopes.

10.19 When performing endoscopic procedures:

- maintain the active part of the electrode in the operator's field of vision to avoid accidental burn or coagulation at a random site
- avoid contact with the metal parts of the endoscope
- use a non-conductive cap on the endoscope eyepiece

10.20 While designing electrosurgical generators, STEMA paid special attention to the increasingly restrictive requirements regarding electromagnetic emissions. As a result, solutions that ensure minimal emission levels were selected to fulfil current and future requirements.

On-site measurements have confirmed a high level of electromagnetic safety in the STEMA generators. Under typical work conditions, an 8-hour daily exposure field occurs at a distance of 5 to 15 [cm] away from the working cables. Beyond 20–40 cm, the field falls below the maximum value without a time limit. Electromagnetic fields occur mainly around the cables, and the device itself is not a significantly emitting element.

When not activated, generators do not emit high-frequency power. As field distribution depends on the specific workplace, system placement and wiring, the measurements must be performed individually. Your local OSH authority can determine the detailed distribution of the emission zones for you.

11. Technical inspection, warranty and service

After each procedure, inspect the state of power cables, electrodes, and the footswitch.

After connecting the system to a power supply, an autotest of the device and the connected accessories is performed. If an error pops up on the display, an appropriate error message is displayed (see section 9) with an alarm sound.

MECHANICAL FAILURES

In the case of damage to the sockets, switches, casing, or film keyboard, or if the device is dropped, the contact an authorised service before further use.

The manufacturer's authorised service can perform a more detailed technical inspection.

SERVICE

Electrosurgical unit is a device classified in the highest used risk class of a medical device, i.e. class IIb.

It means that all companies performing installation, inspection, calibration or repair of these devices must have the required competence confirmed by authorisation of the manufacturer of the medical device.

A periodical inspection is required once a year. The manufacturer only admits the use of systems which have an up-to-date inspection performed by an authorised service.

The Declaration of Conformity supplied by the manufacturer does no inludes devices whose maintenance, services or repairs are carried out by unauthorized services.

The STEMA MASTER unit is equipped with a system, that signalises the term of the technical inspection of the electrosurgical unit. The message is shown at the screen for 30 days before the term expires. Within this time you have to contact the authorised service to arrange the technical inspection.

Figure 47. Inspection due soon.

The manufacturer <u>does not anticipate</u> any calibrations or repairs of the electrosurgical system to be performed by the user, with the exception of power and mode settings.

The user is obliged to perform technical inspections recommended by the manufacturer, which should be performed by a service authorised by the manufacturer. If this condition is fulfilled, the manufacturer remain responsible for device safety. If the user does not adhere to the manufacturer's instructions and the required inspections are not performed, then, according to the laws, the responsibility is transferred to the user.

In order to ensure the correct operation of the device, the installation and staff training should be performed by an authorised representative of STEMA. Each participant of such training receives a certificate which entitles him/her to use STEMA electrosurgical unit. These procedures are obligatory.

More information on the authorised services may be obtained from the manufacturer.

Service:

STEMA Medizintechnik GmbH
Hermann-Erich-Busse Str. 4, 78333 Stockach, Germany
Tel. 0049 7771 8753 51, Fax 0049 7771 8753 50,
email: info@stema-medizintechnik.de

In case of failure, please contact with service to get the return material authorization number. Once done, the device can be delivered to service centre.

SYSTEM TRANSPORT

Please adhere to standard safety measures when transporting the system. During transport, the system must be protected against mechanical damage and moisture.

If the system was transported for a long time, it should be allowed to reach room

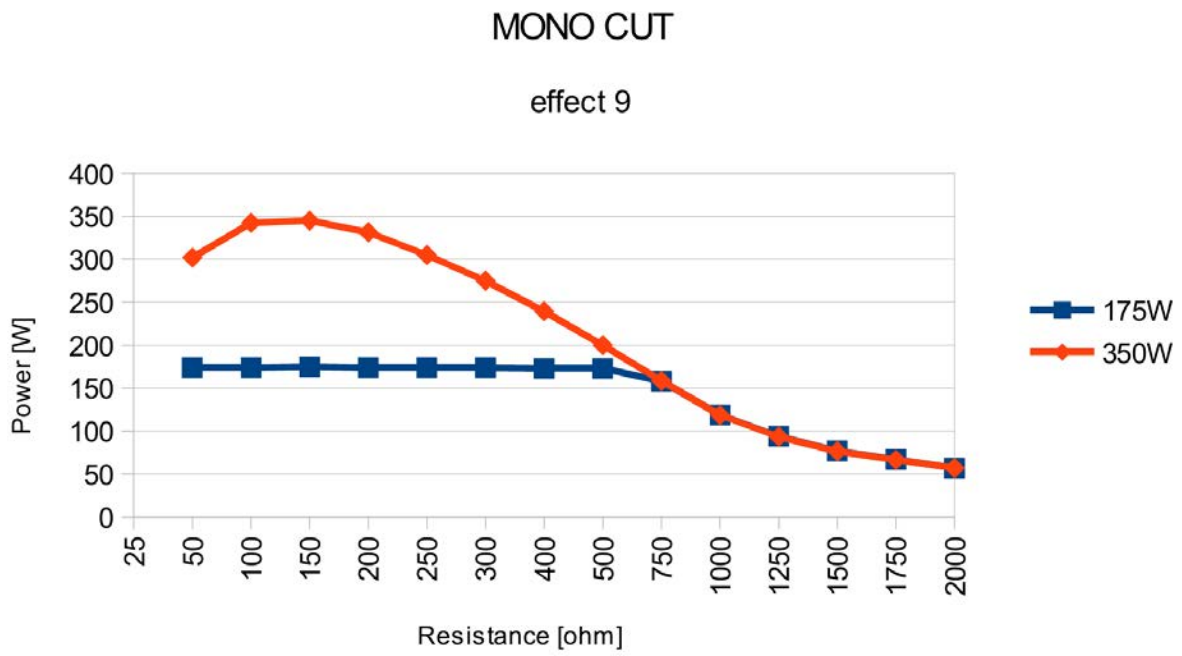
temperature before it is started.

VOLTAGE FOR MODES

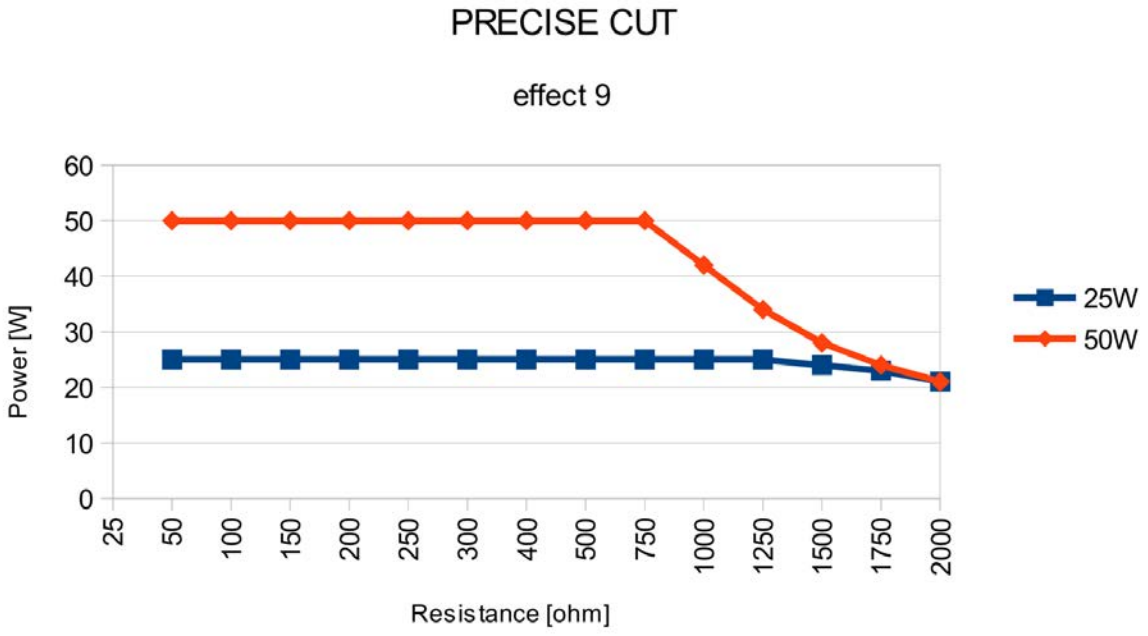
MODE	VOLTAGE
MONO CUT	1200Vp
PRECISE CUT	800Vp
MIXED CUT	400Vp
MUCO CUT	760Vp
POLIPO CUT	500Vp
PAPILLO CUT	1,2kVp
ARTRO CUT	700Vp
URO CUT	700Vp
HYSTERO CUT	700Vp
ARGON CUT	1200Vp
BI-CUT	1000Vp
URO BI-CUT	500Vp
ARTRO BI-CUT	450Vp
SOFT COAG	225Vp
FORCED COAG	1,5kVp
HYBRID COAG	1,7kVp
SPRAY COAG	5,7kVp
ENDO SPRAY	2,6Vkp
URO COAG	1,5kVp
ARTRO COAG	1,5kVp
HYSTERO COAG	1,5kVp
STANDARD ARGON	5,7kVp
ENDO ARGON	5,7kVp
PULSE ARGON	5,7kVp
SOFT BI-COAG	225Vp
FORCED BI-COAG	1kVp
URO BI-COAG	175Vp
ARTRO BI-COAG	175Vp
SCISS BI-COAG	175Vp
THERMOSTAPLER®	225Vp

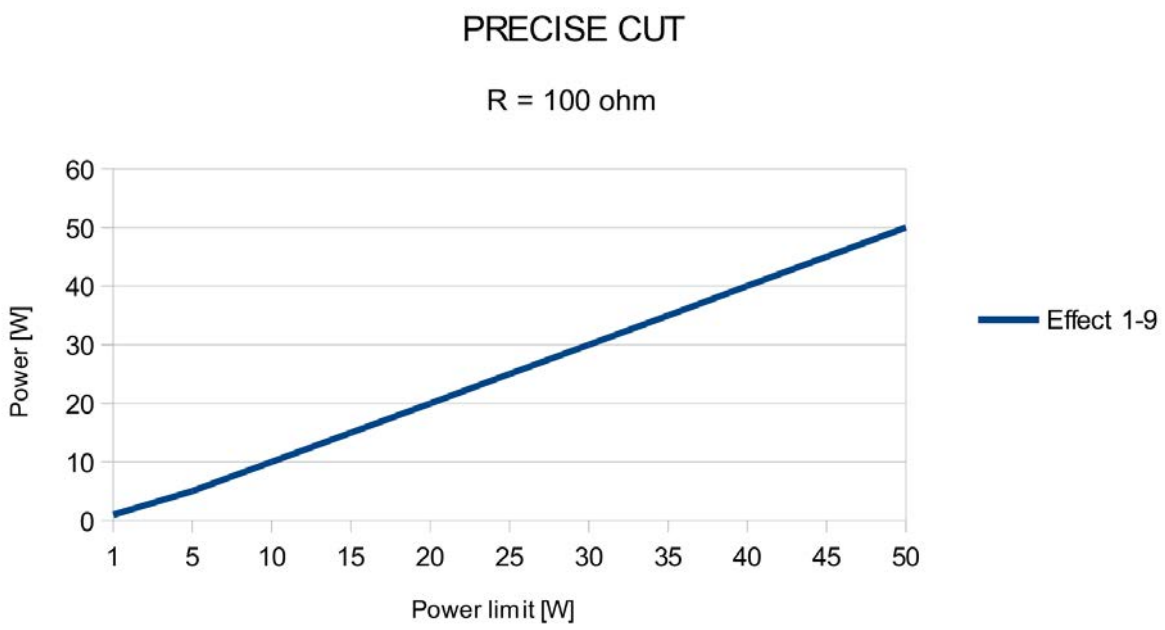
OUTPUT GRAPHS

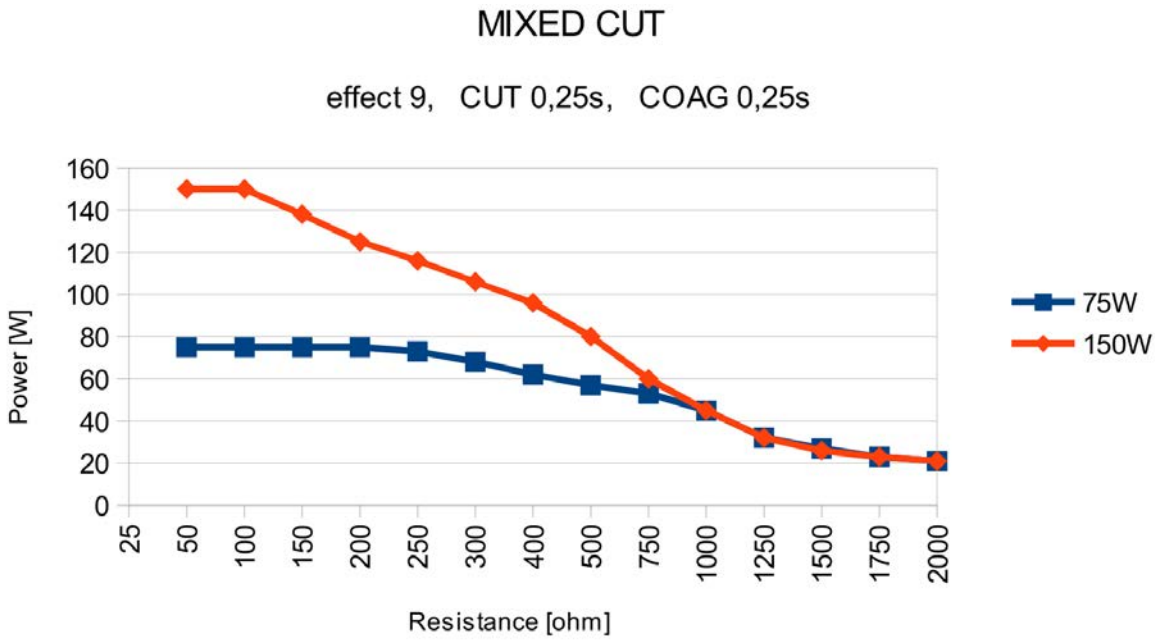
The presented graphs could change with the development of our products

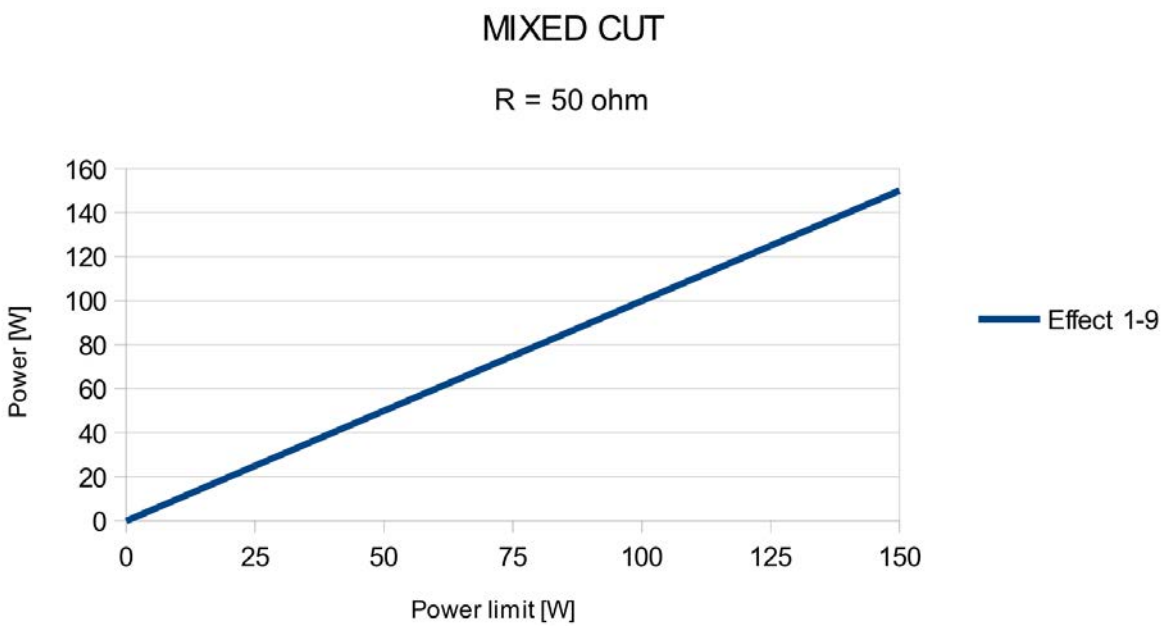


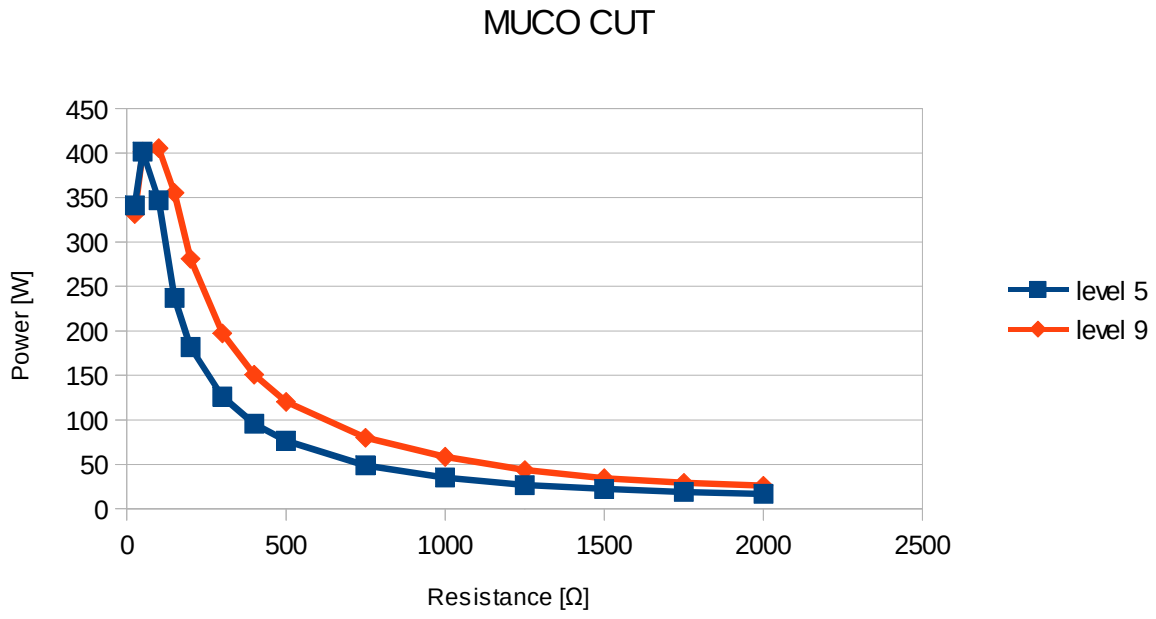

MONO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
0
50
100
150
200
250
300
350
Power limit [W]
Effect 1-9


PRECISE CUT
effect 9
Power [W]
60
50
40
30
20
10
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
25W
50W


PRECISE CUT
R = 100 ohm
Power [W]
60
50
40
30
20
10
0
1
5
10
15
20
25
30
35
40
45
50
Power limit [W]
Effect 1-9

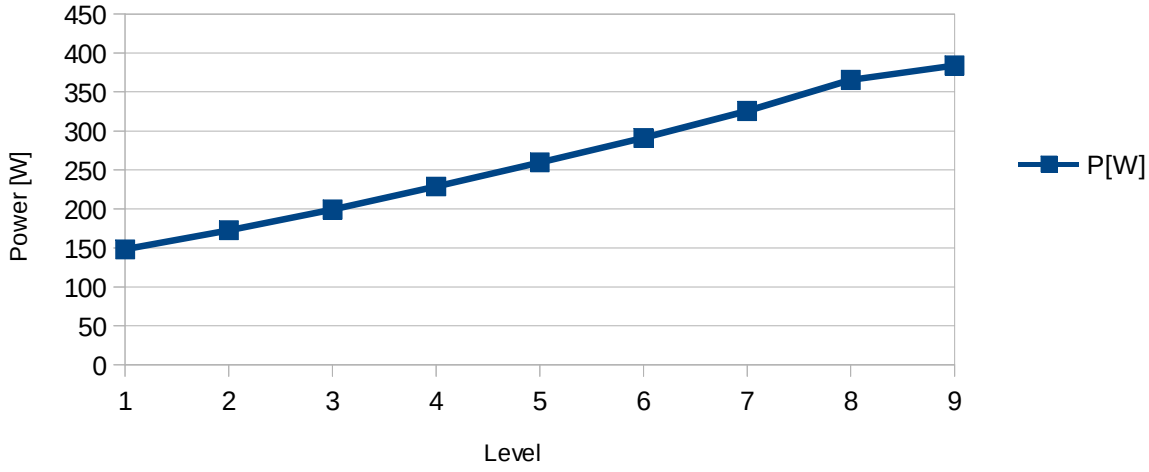

MIXED CUT
effect 9, CUT 0,25s, COAG 0,25s
Power [W]
160
140
120
100
80
60
40
20
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
75W
150W


MIXED CUT
R = 50 ohm
Power [W]
160
140
120
100
80
60
40
20
0
0
25
50
75
100
125
150
Power limit [W]
Effect 1-9

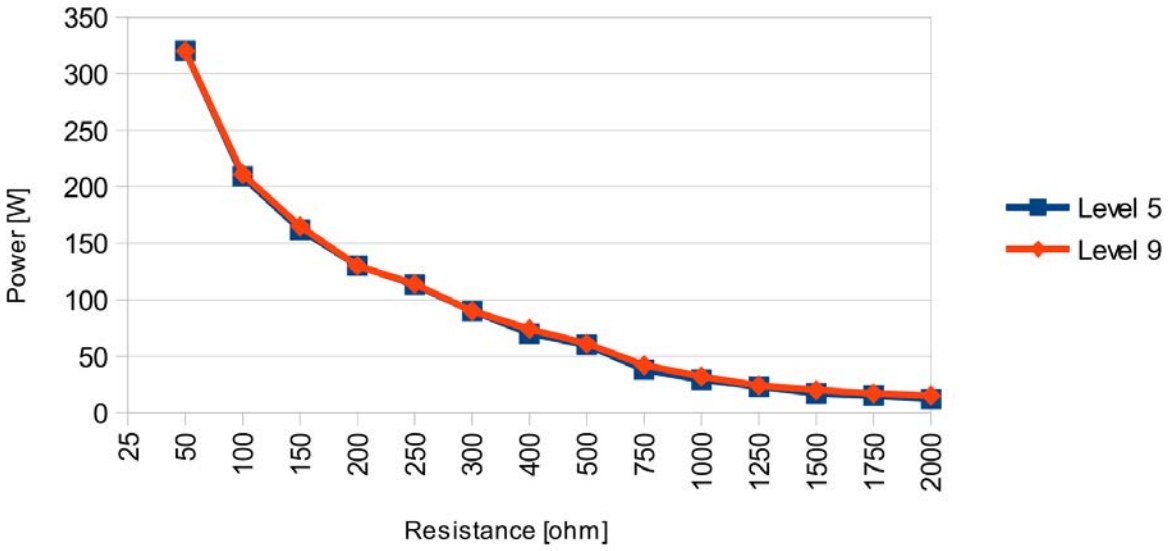

MUCO CUT
Power [W]
450
400
350
300
250
200
150
100
50
0
0
500
1000
1500
2000
2500
Resistance [Ω]
level 5
level 9

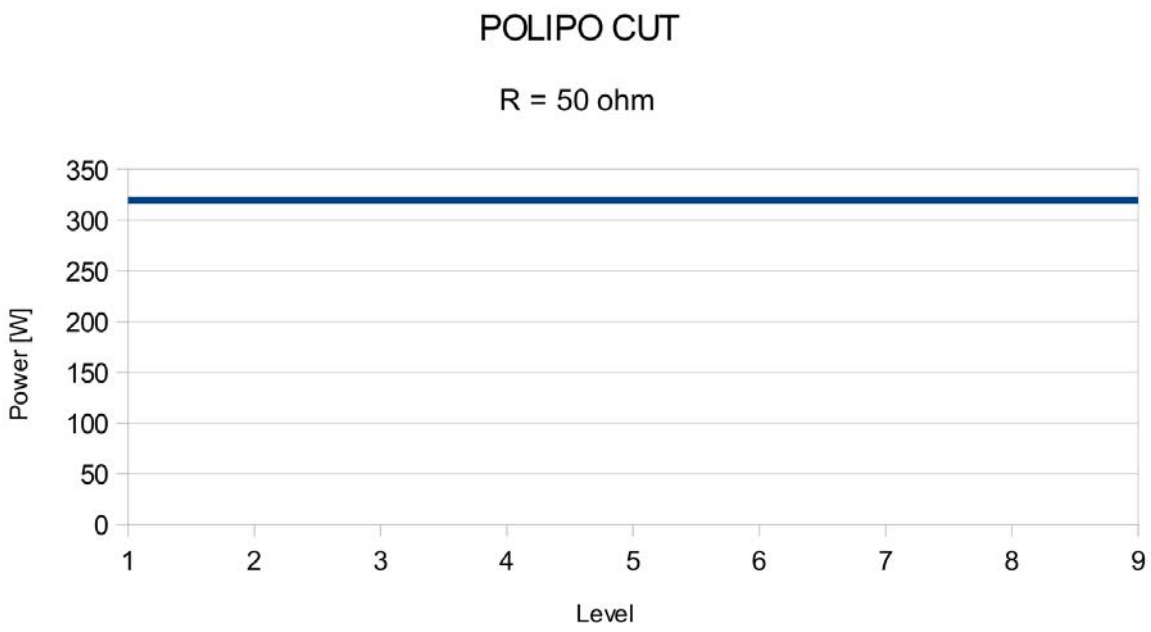
MUCO CUT

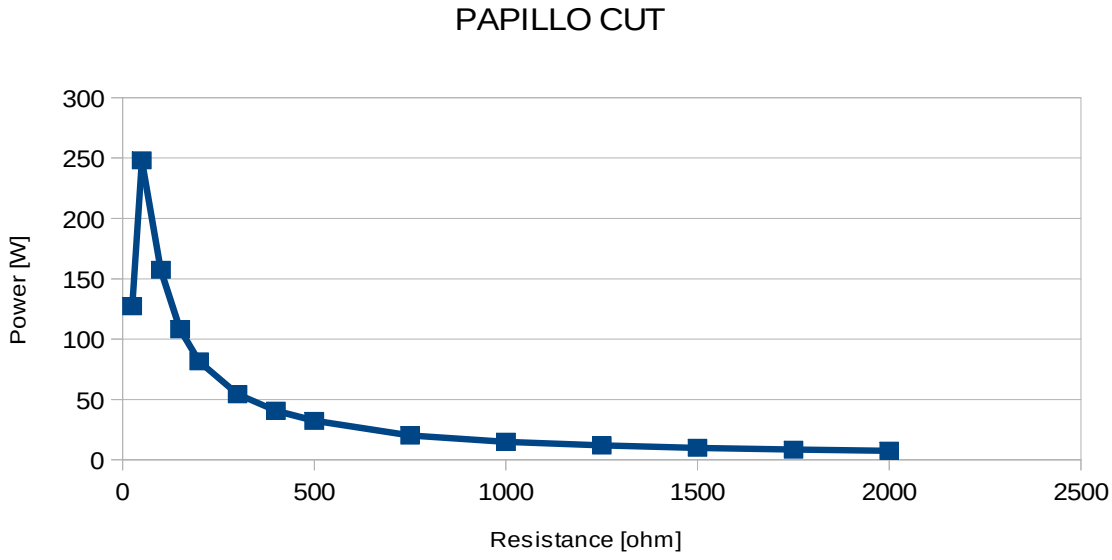
R = 135 ohm



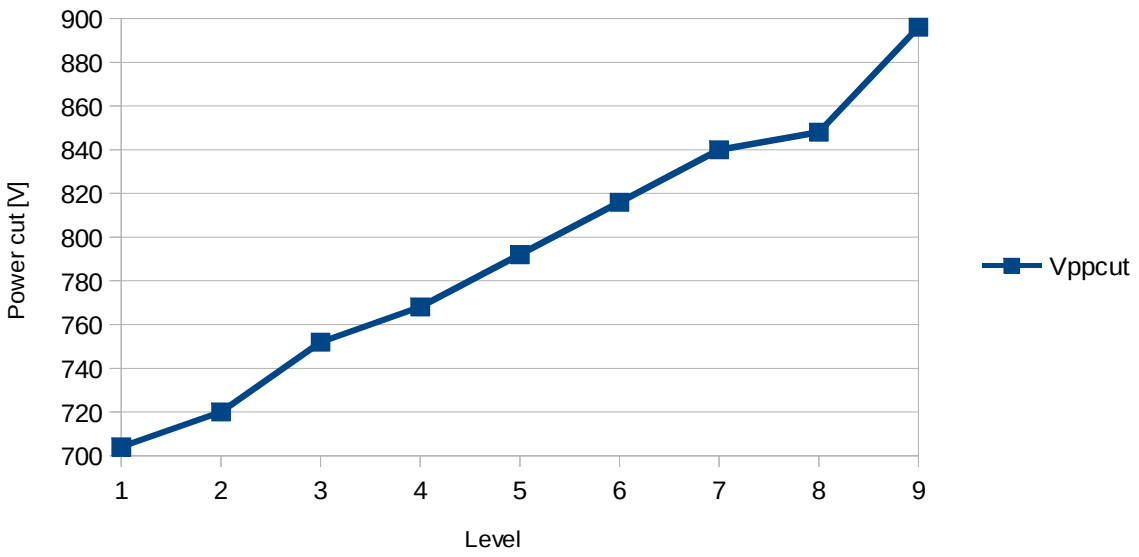
POLIPO CUT



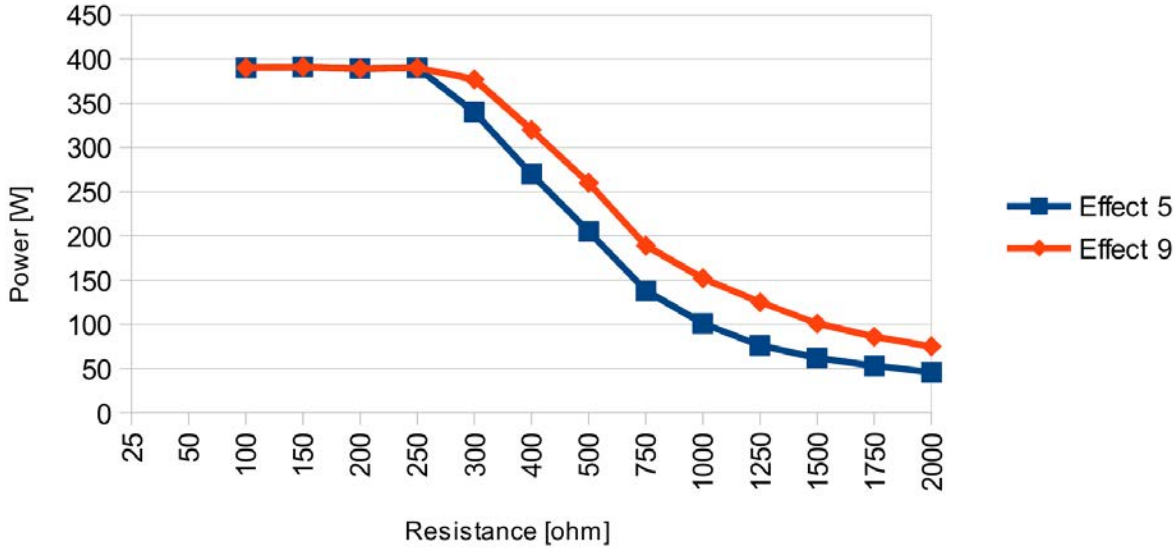

POLIPO CUT
R = 50 ohm
Power [W]
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Level

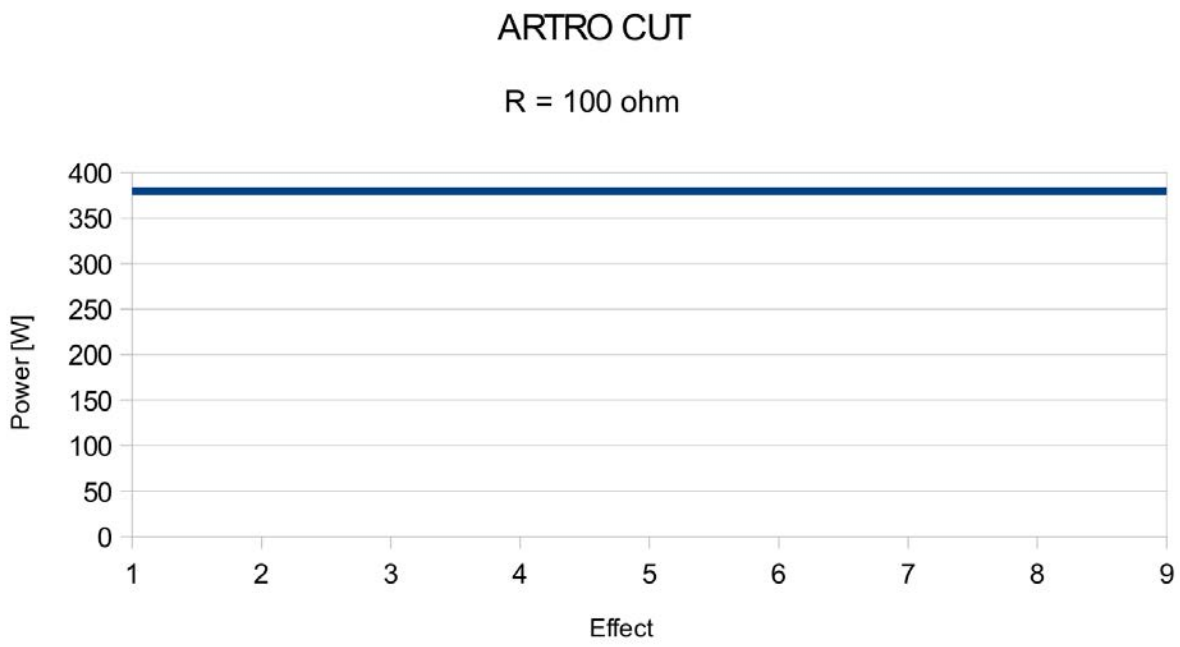

PAPILLO CUT
Power [W]
300
250
200
150
100
50
0
0
500
1000
1500
2000
2500
Resistance [ohm]

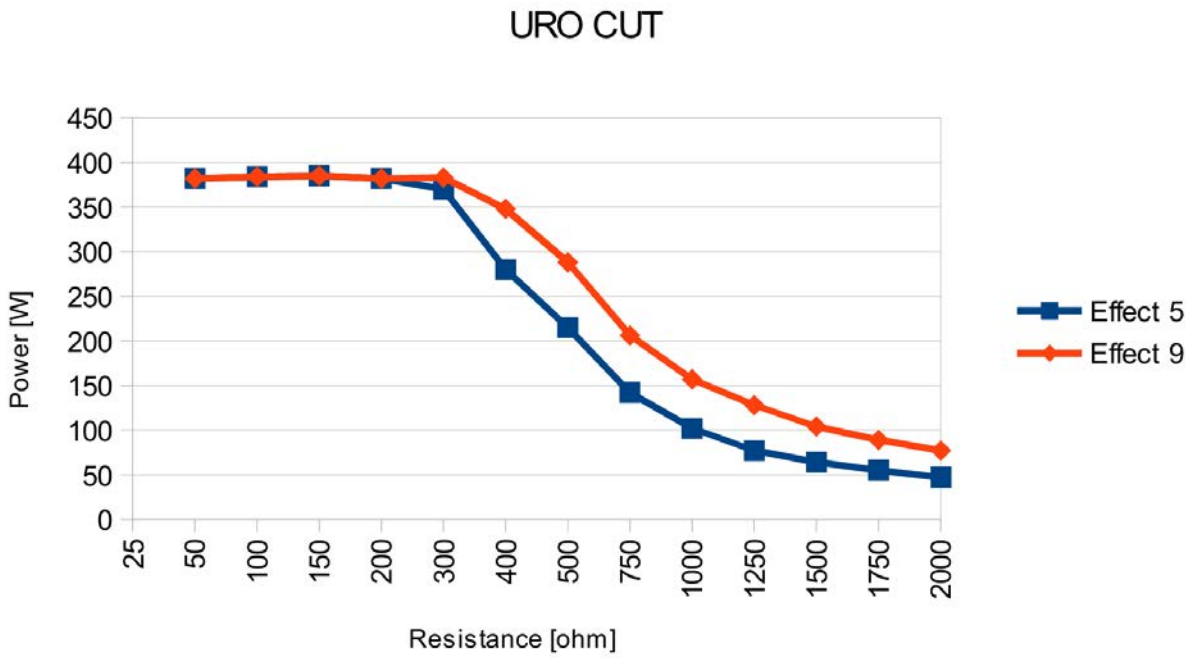
PAPILLO CUT

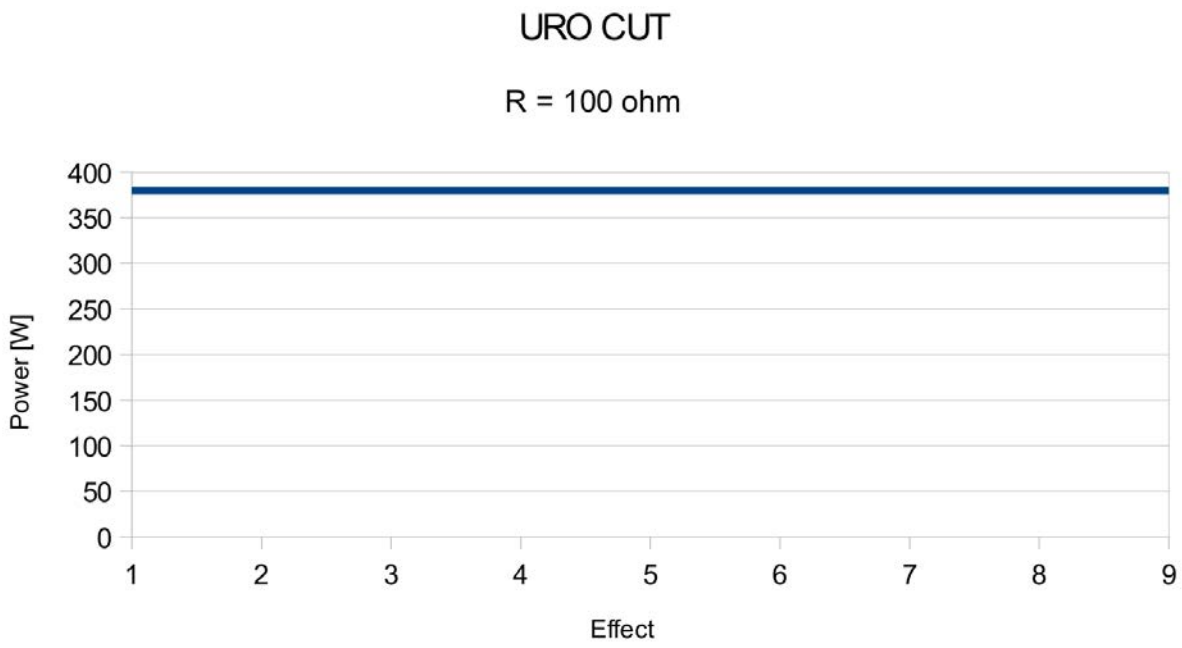


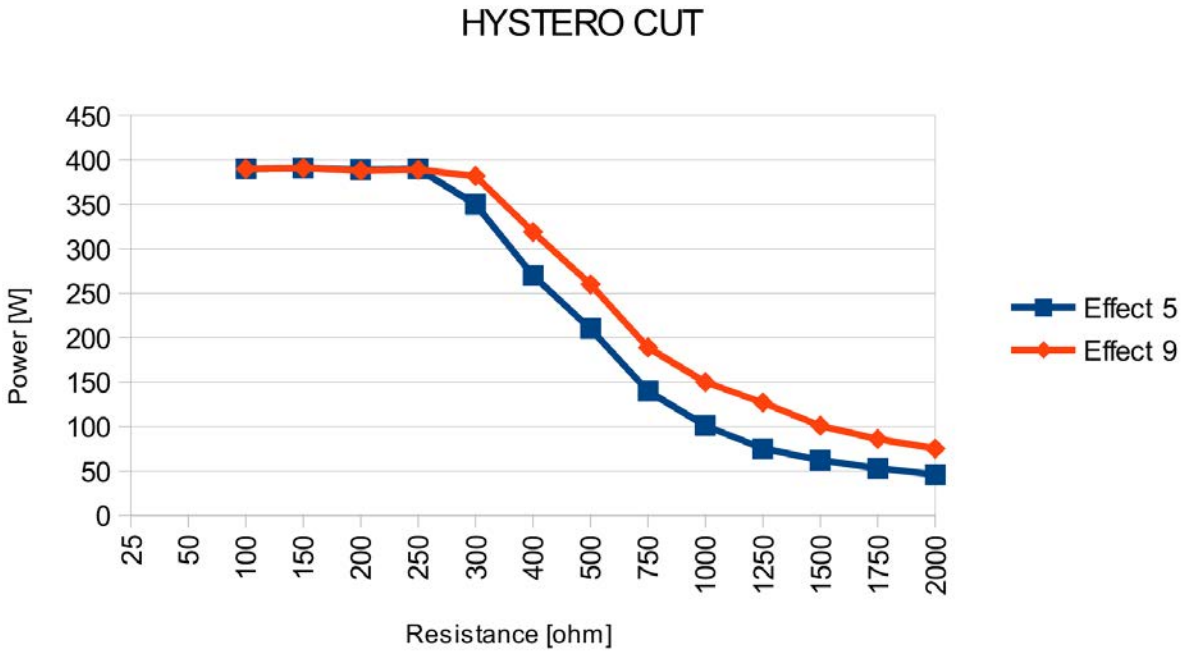
ARTRO CUT

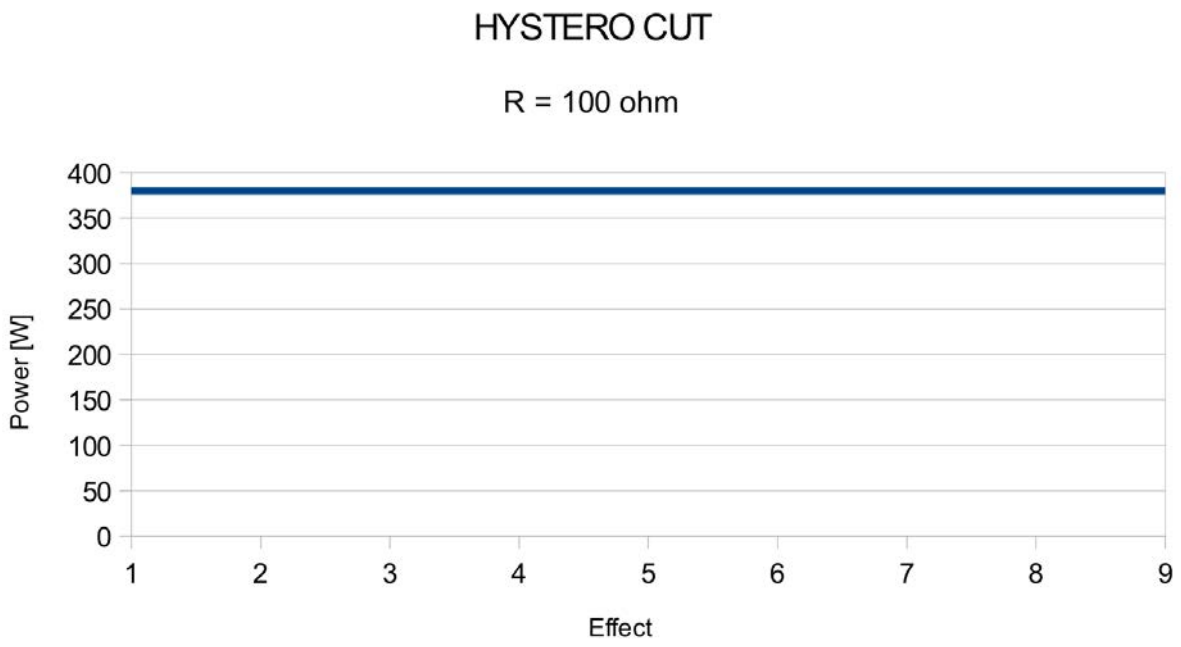


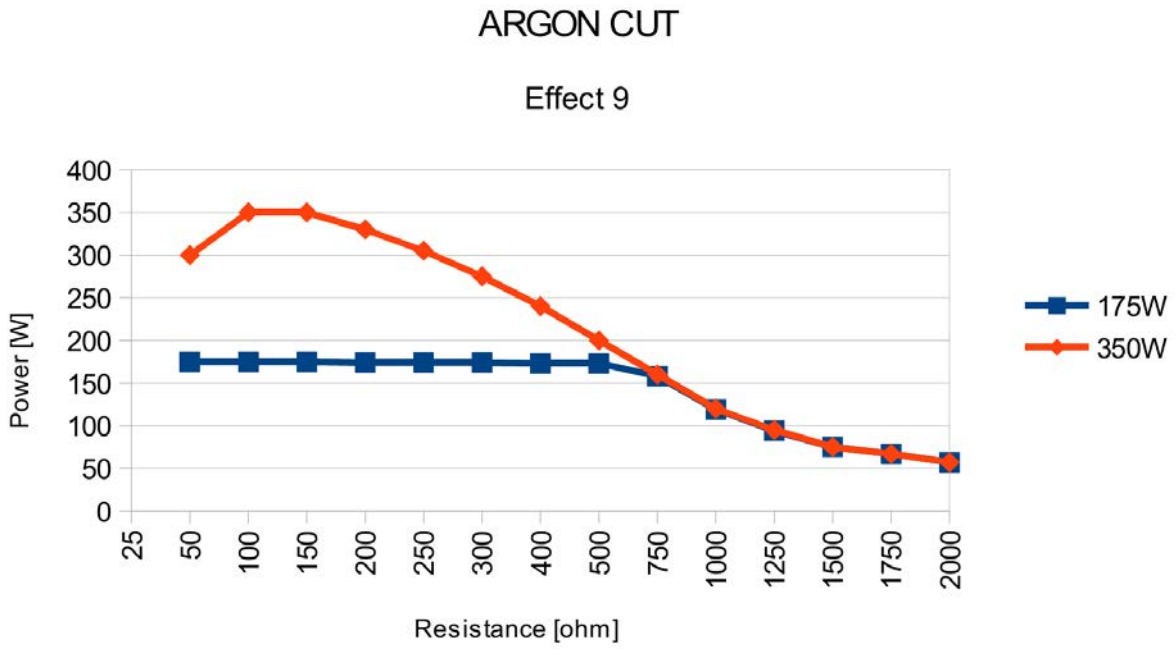

ARTRO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect


URO CUT
Power [W]
450
400
350
300
250
200
150
100
50
0
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

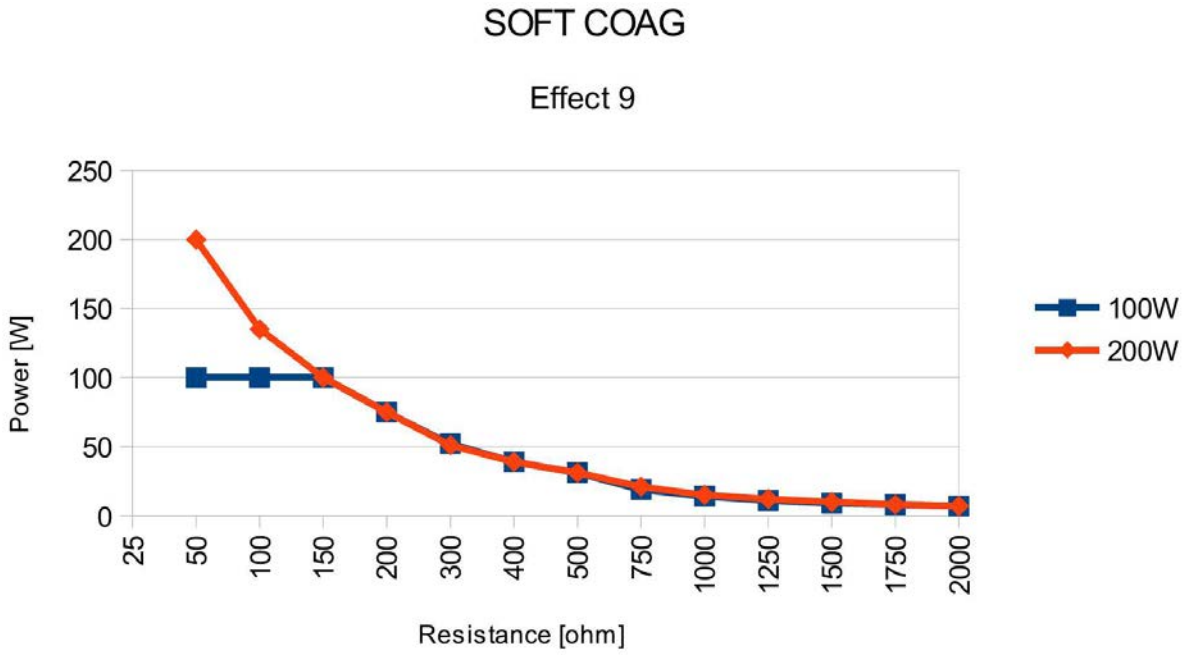

URO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

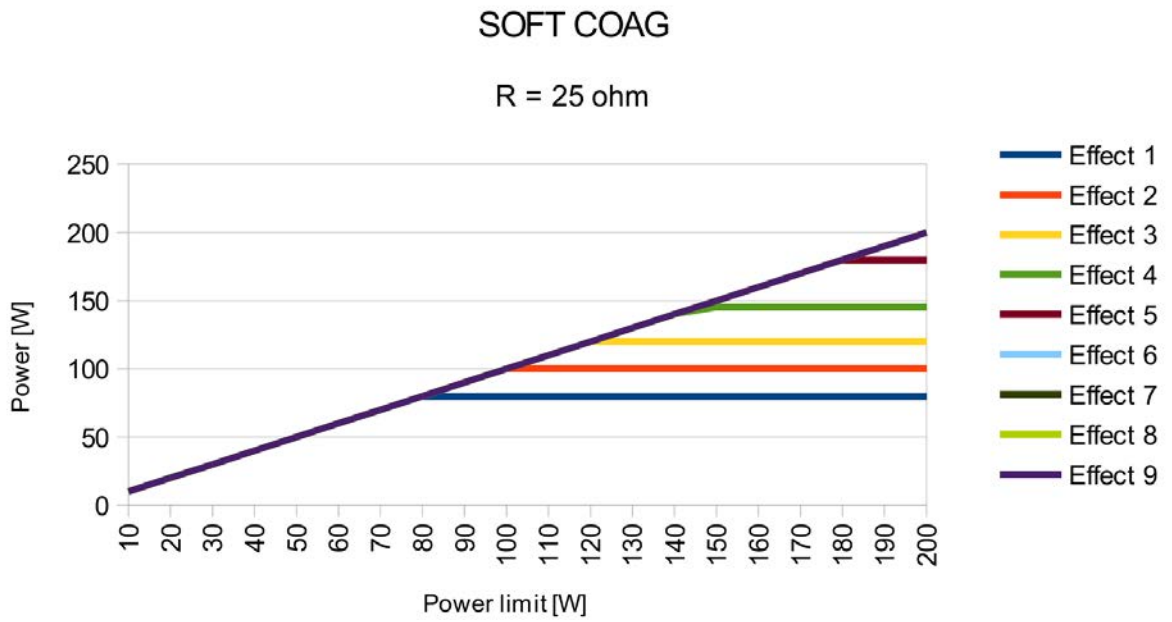

HYSTERO CUT
Power [W]
450
400
350
300
250
200
150
100
50
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

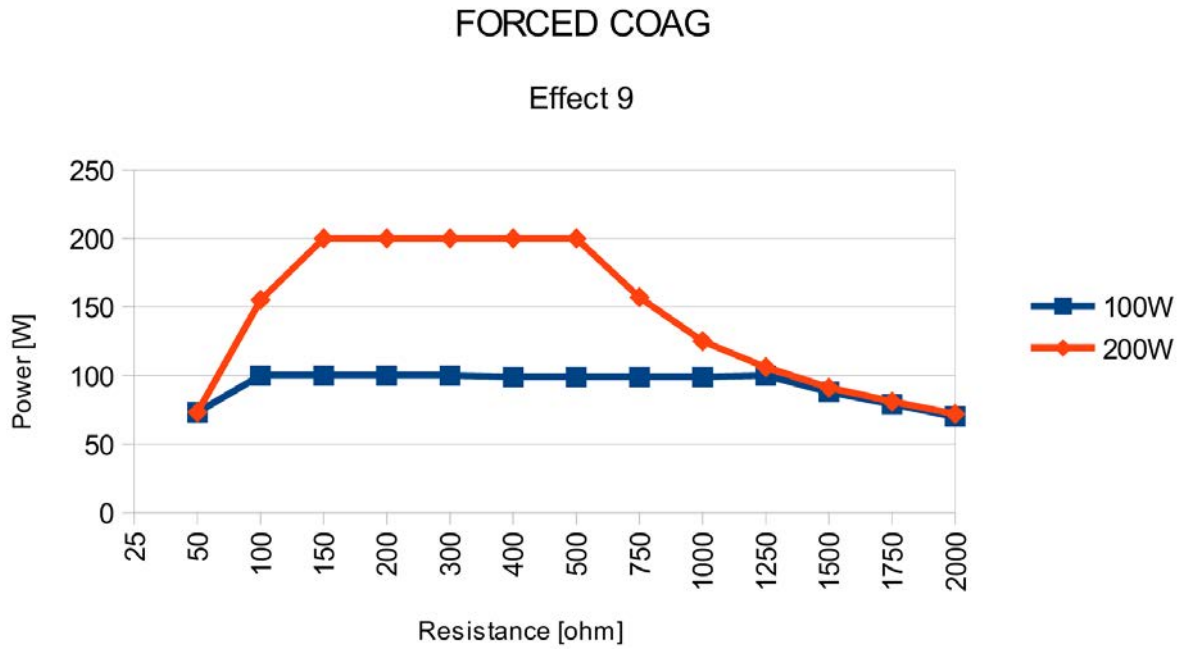

HYSTERO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

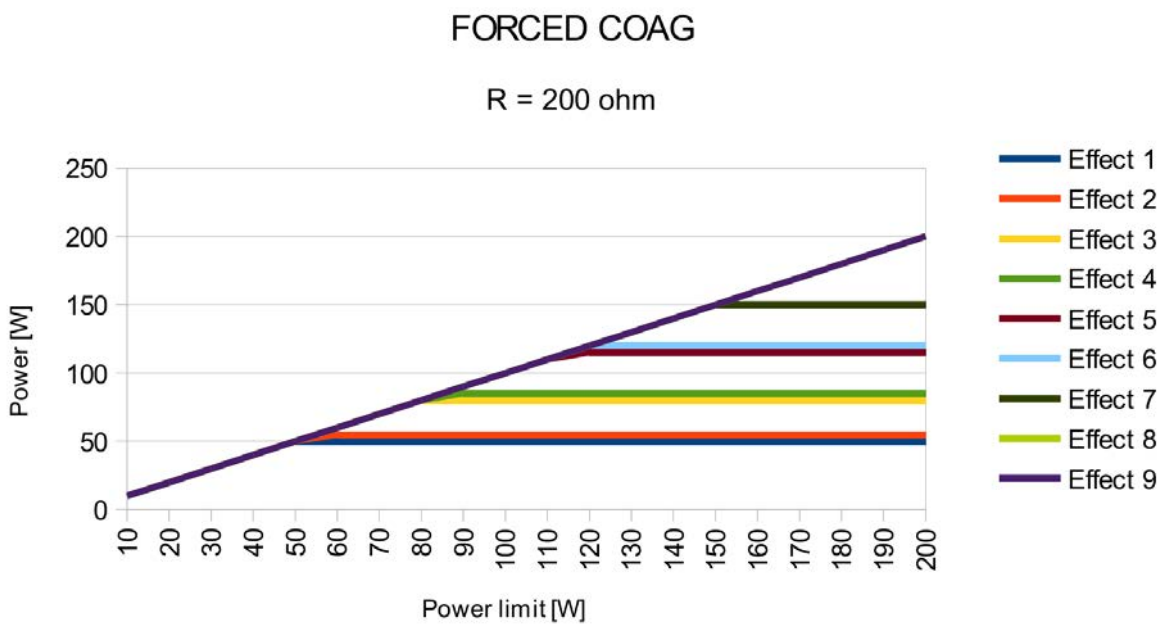

ARGON CUT
Effect 9
Power [W]
400
350
300
250
200
150
100
50
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
175W
350W

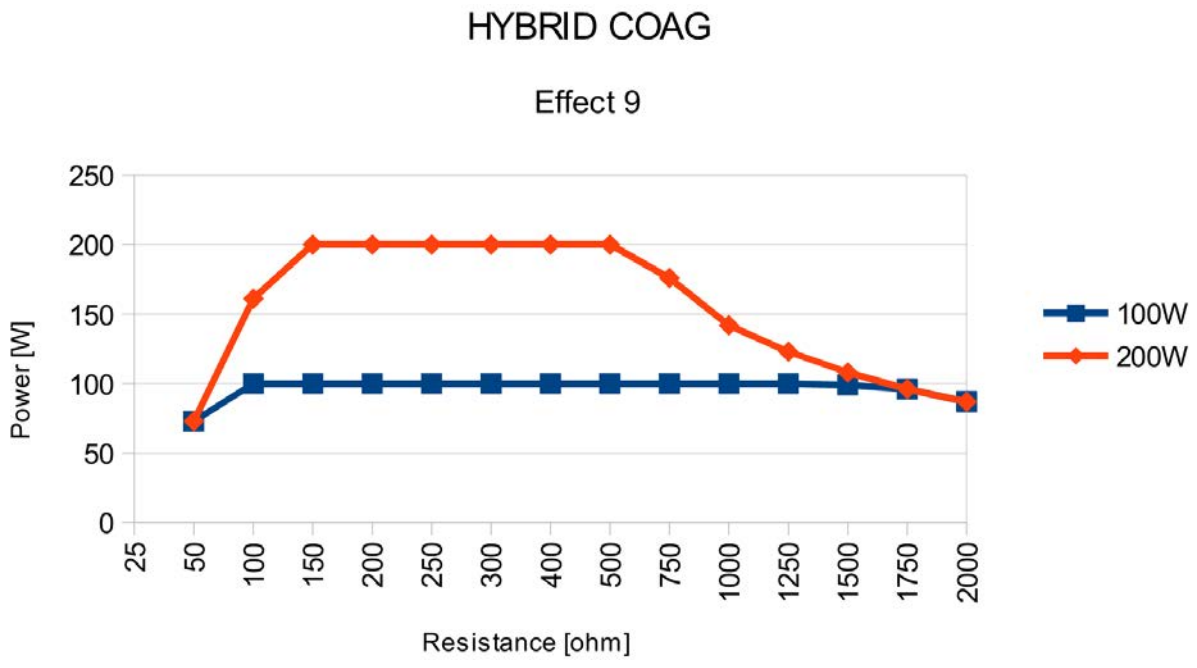

ARGON CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
50
100
150
200
250
300
350
Power limit [W]
Effect 1-9

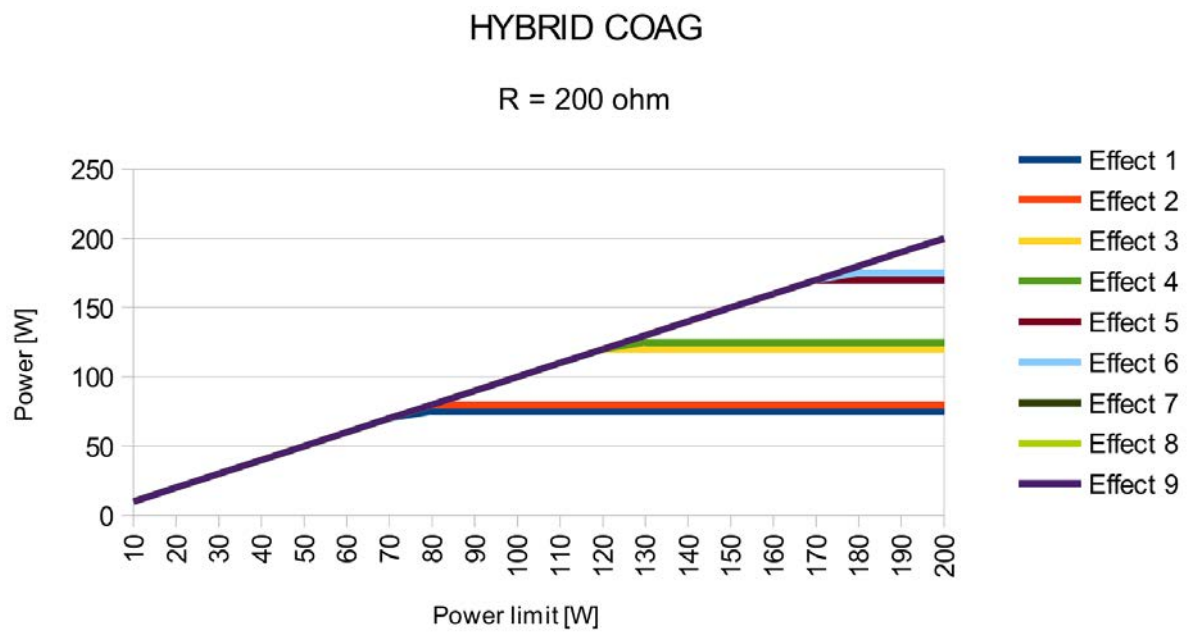

SOFT COAG
Effect 9
Power [W]
250
200
150
100
50
0
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
100W
200W

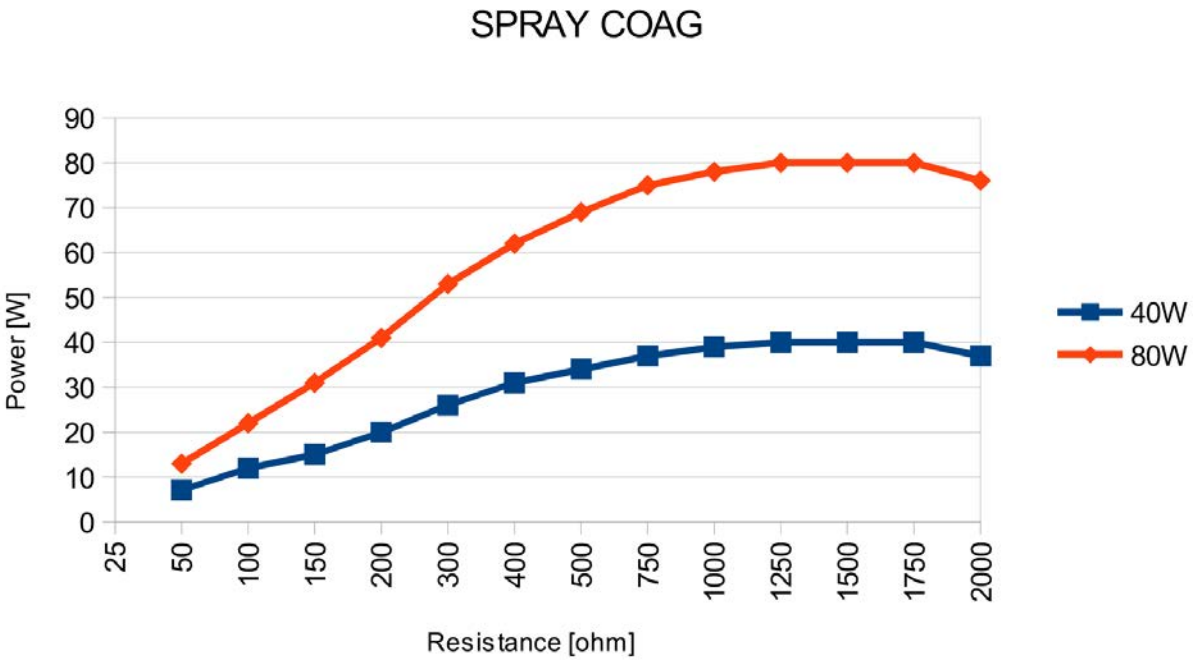

SOFT COAG
R = 25 ohm
Power [W]
250
200
150
100
50
0
10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200
Power limit [W]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9

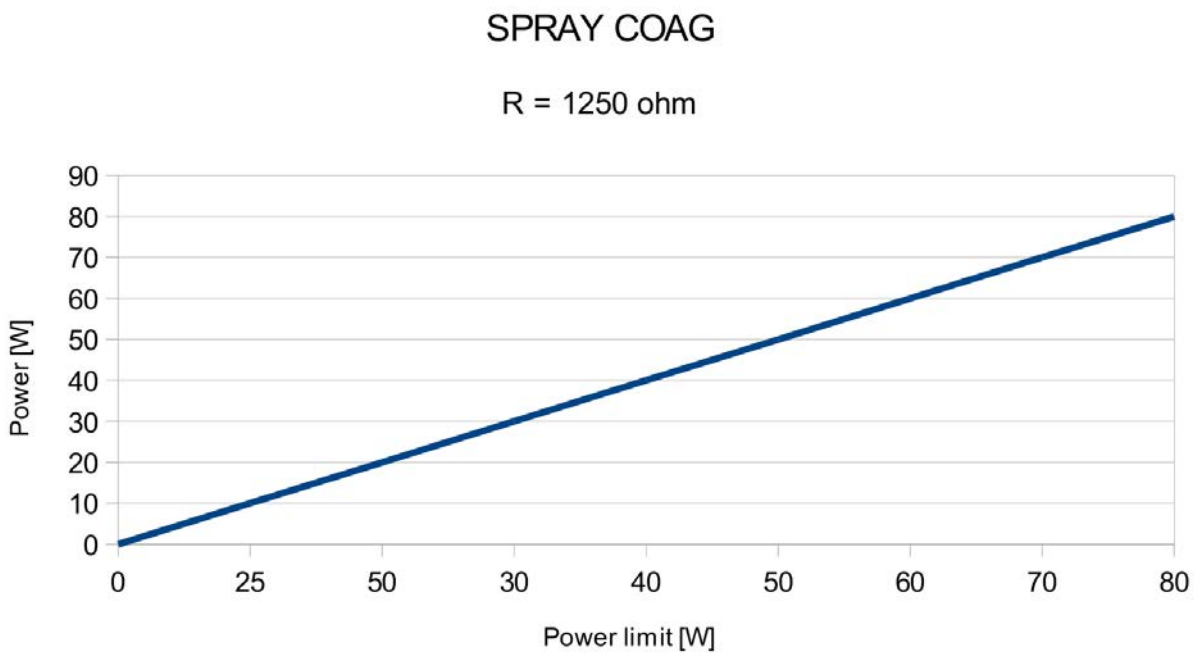

FORCED COAG
Effect 9
Power [W]
250
200
150
100
50
0
25 50 100 150 200 300 400 500 750 1000 1250 1500 1750 2000
Resistance [ohm]
100W
200W

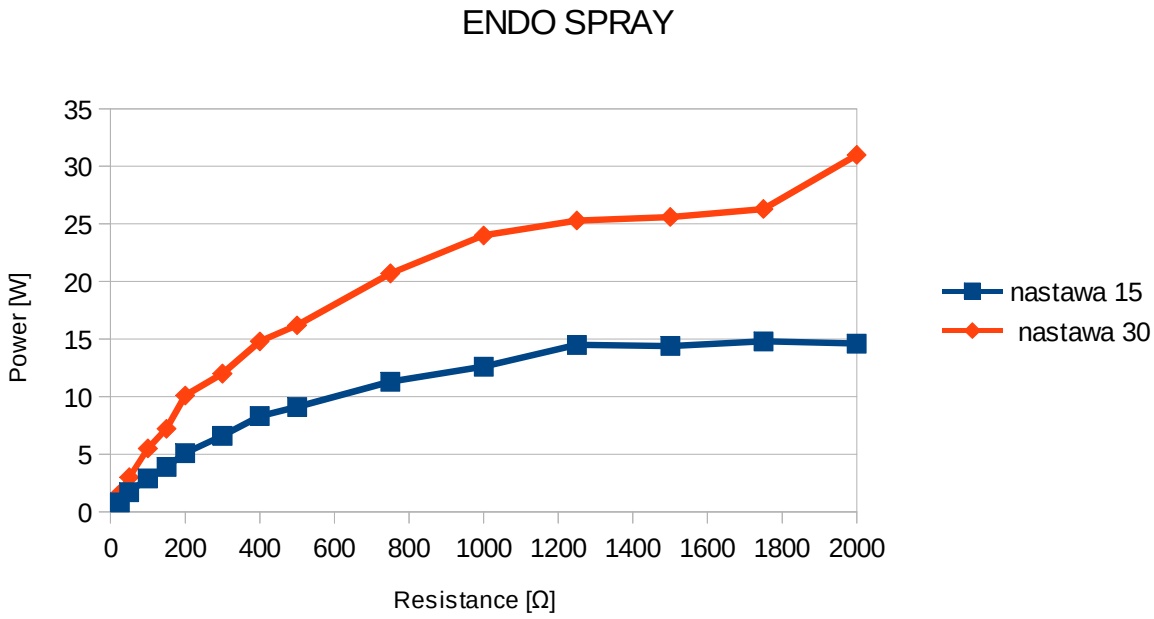

FORCED COAG
R = 200 ohm
Power [W]
250
200
150
100
50
0
10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200
Power limit [W]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9


HYBRID COAG
Effect 9
Power [W]
250
200
150
100
50
0
25 50 100 150 200 250 300 400 500 750 1000 1250 1500 1750 2000
Resistance [ohm]
100W
200W


HYBRID COAG
R = 200 ohm
Power [W]
250
200
150
100
50
0
10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200
Power limit [W]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9

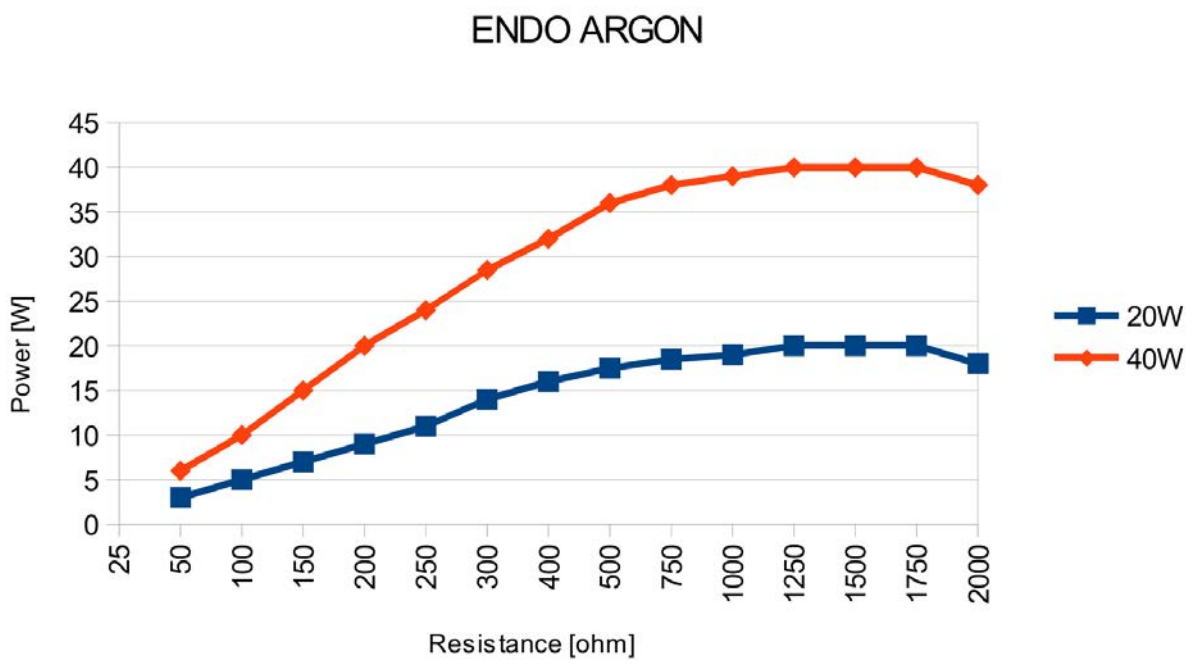

SPRAY COAG
Power [W]
90
80
70
60
50
40
30
20
10
0
25 50 100 150 200 300 400 500 750 1000 1250 1500 1750 2000
Resistance [ohm]
40W
80W


SPRAY COAG
R = 1250 ohm
Power [W]
90
80
70
60
50
40
30
20
10
0
0
25
50
30
40
50
60
70
80
Power limit [W]

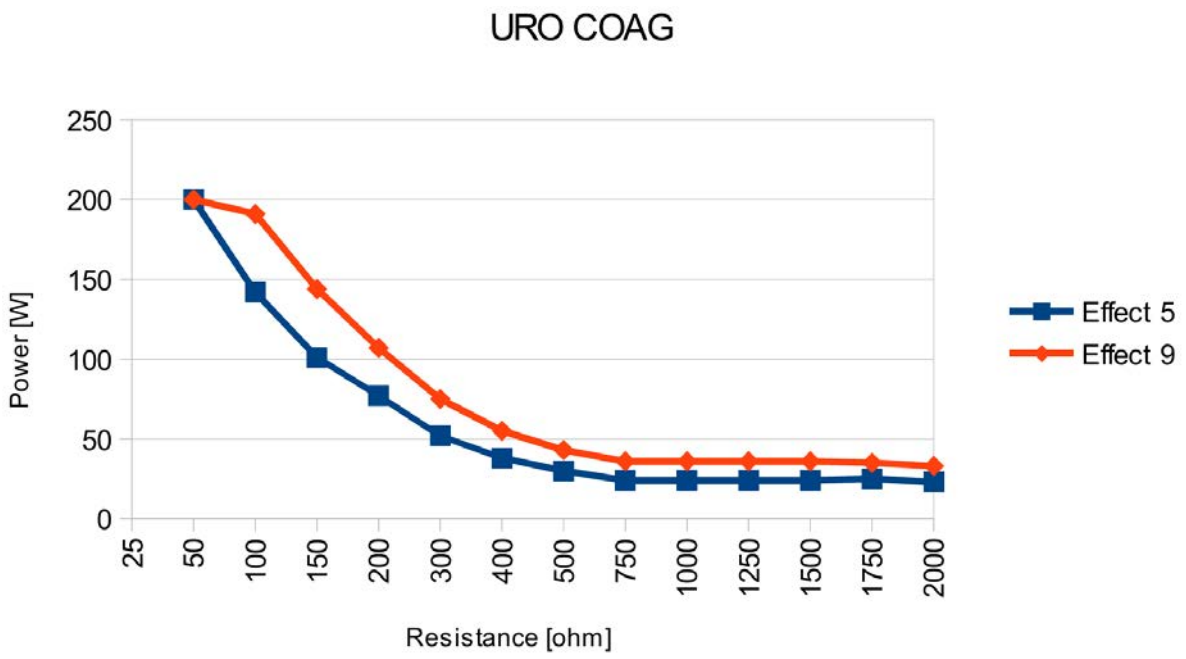

ENDO SPRAY
Power [W]
35
30
25
20
15
10
5
0
0
200
400
600
800
1000
1200
1400
1600
1800
2000
Resistance [Ω]
nastawa 15
nastawa 30

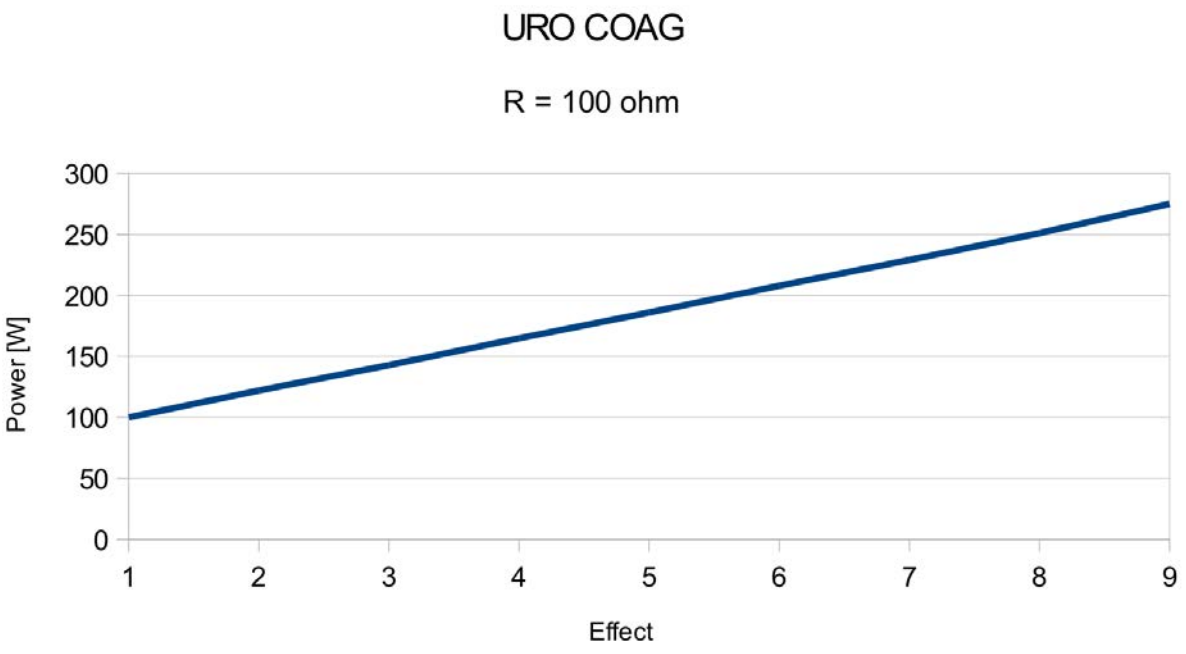

STANDARD ARGON
Power [W]
90
80
70
60
50
40
30
20
10
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
40W
80W

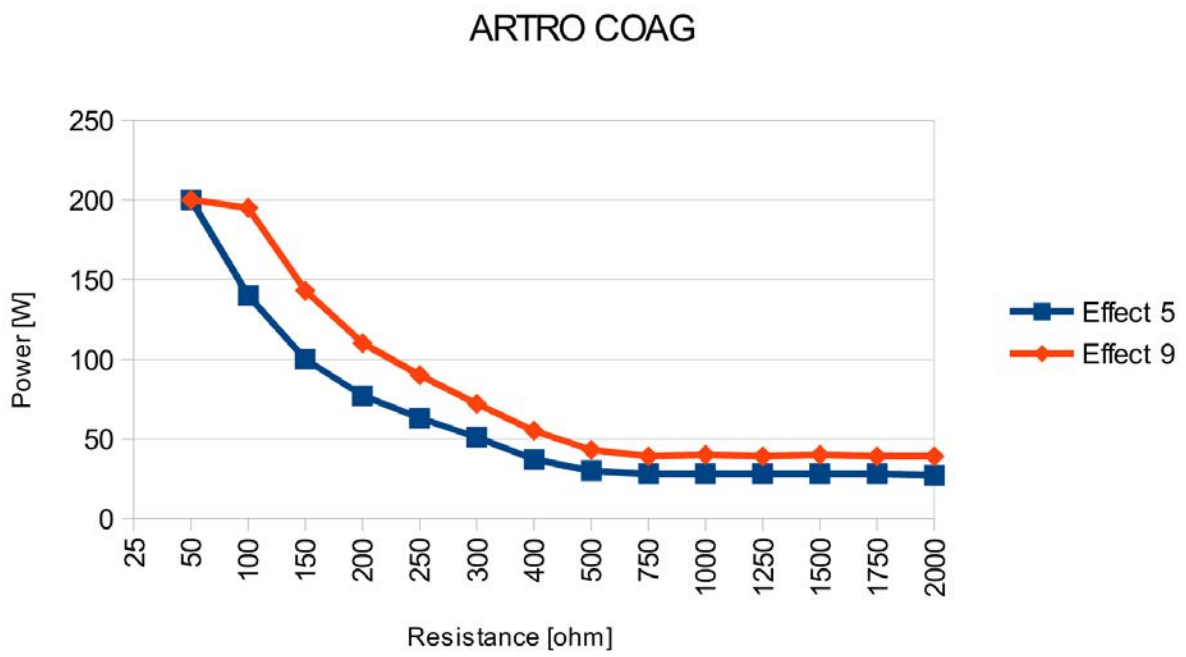

STANDARD ARGON
R = 1250 ohm
Power [W]
90
80
70
60
50
40
30
20
10
0
0
10
20
30
40
50
60
70
80
Power limit [W]

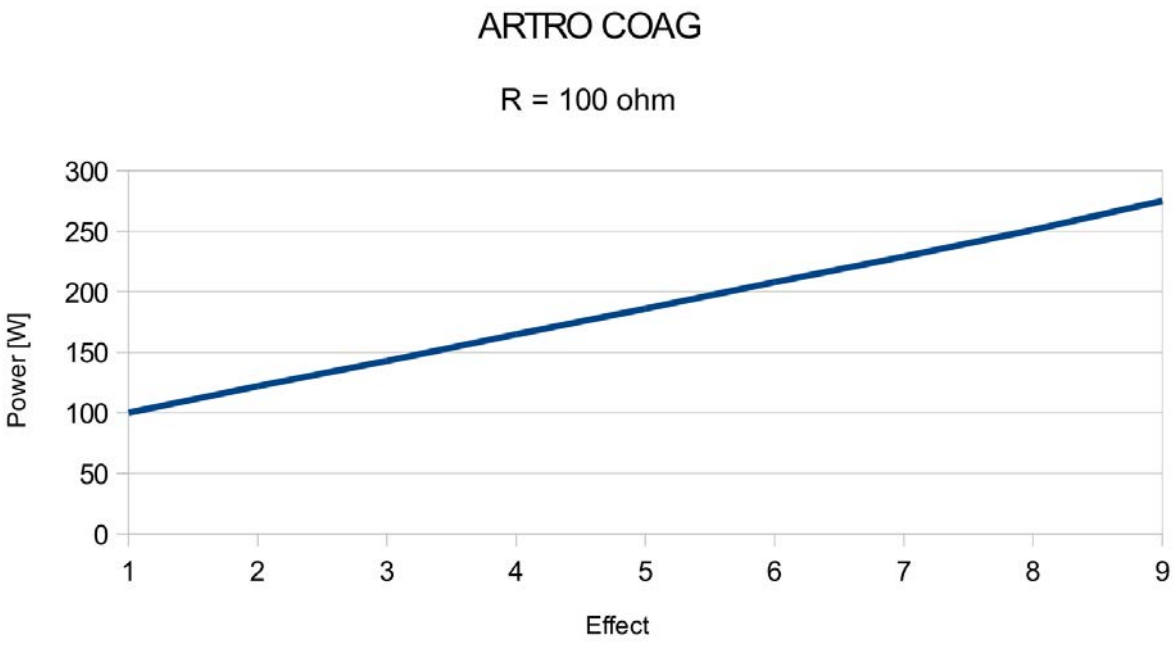

ENDO ARGON
Power [W]
45
40
35
30
25
20
15
10
5
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
20W
40W

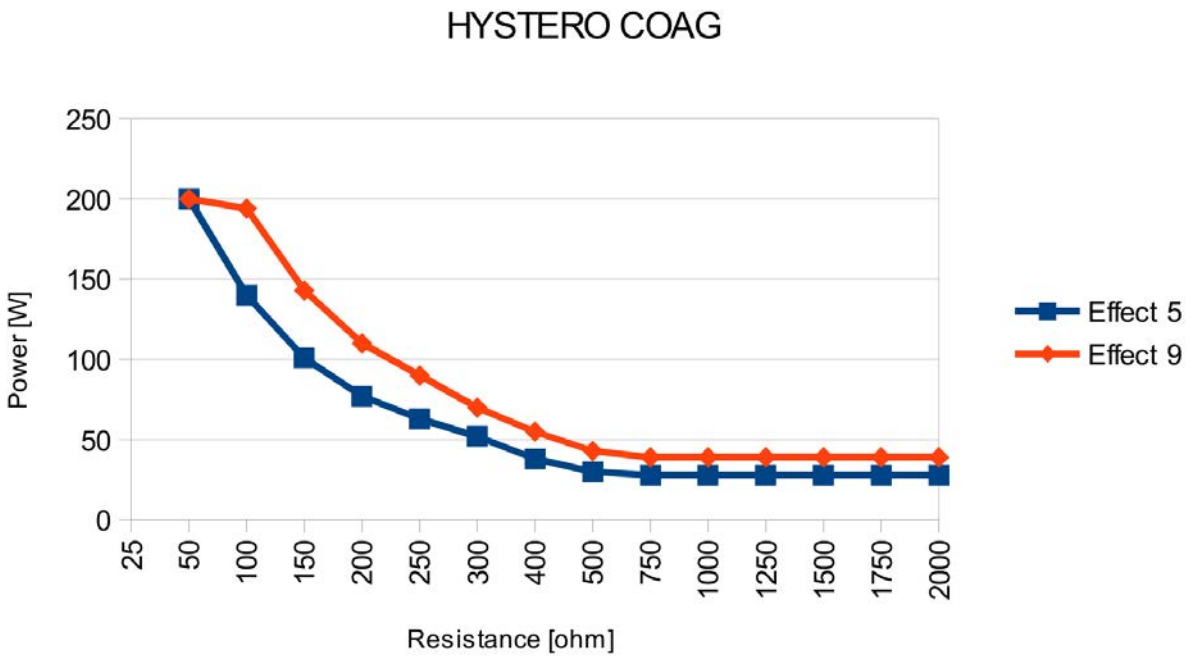

ENDO ARGON
R = 1250 ohm
Power [W]
45
40
35
30
25
20
15
10
5
0
0
5
10
15
20
25
30
35
40
Power limit [W]

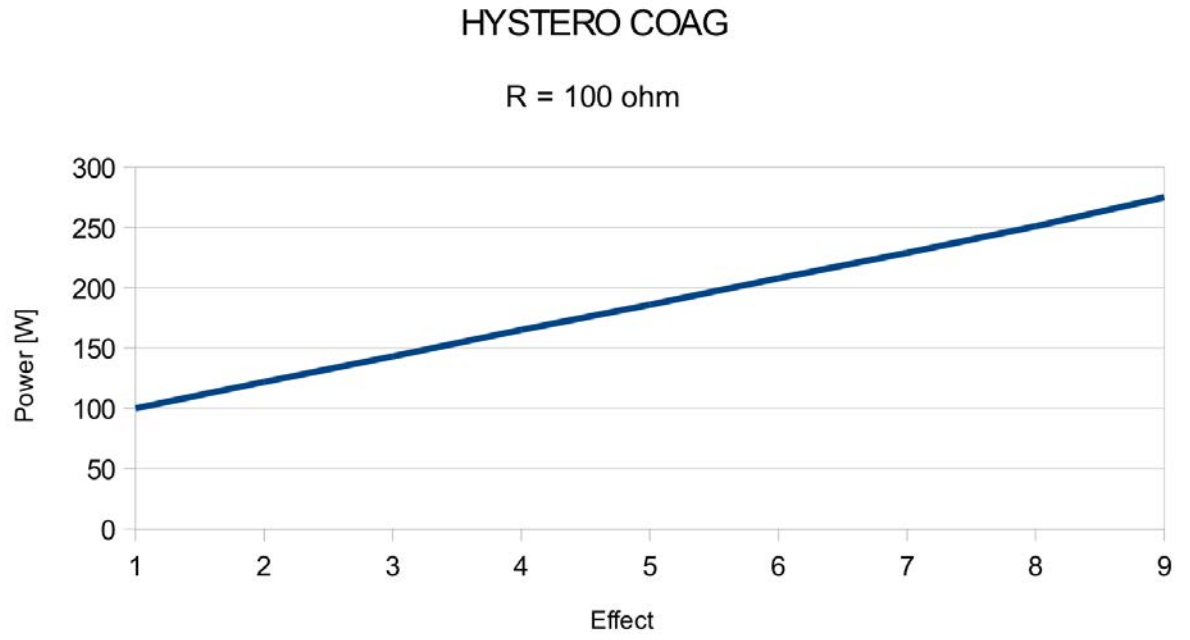

URO COAG
250
200
150
100
50
0
Power [W]
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

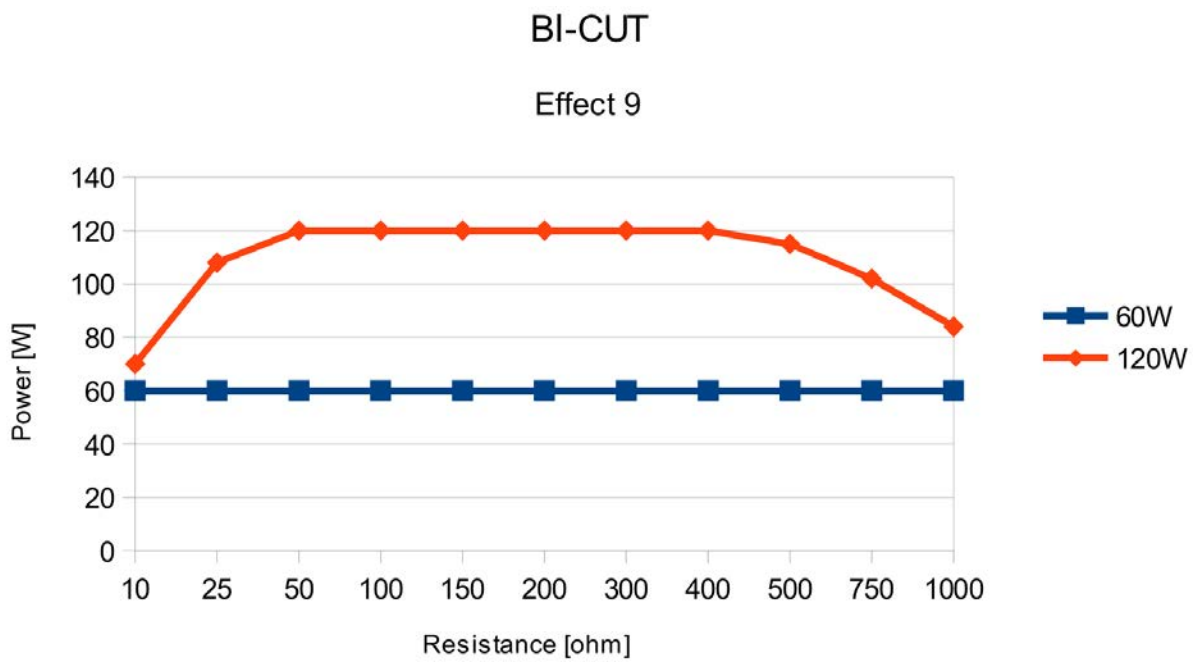

URO COAG
R = 100 ohm
300
250
200
150
100
50
0
Power [W]
1
2
3
4
5
6
7
8
9
Effect

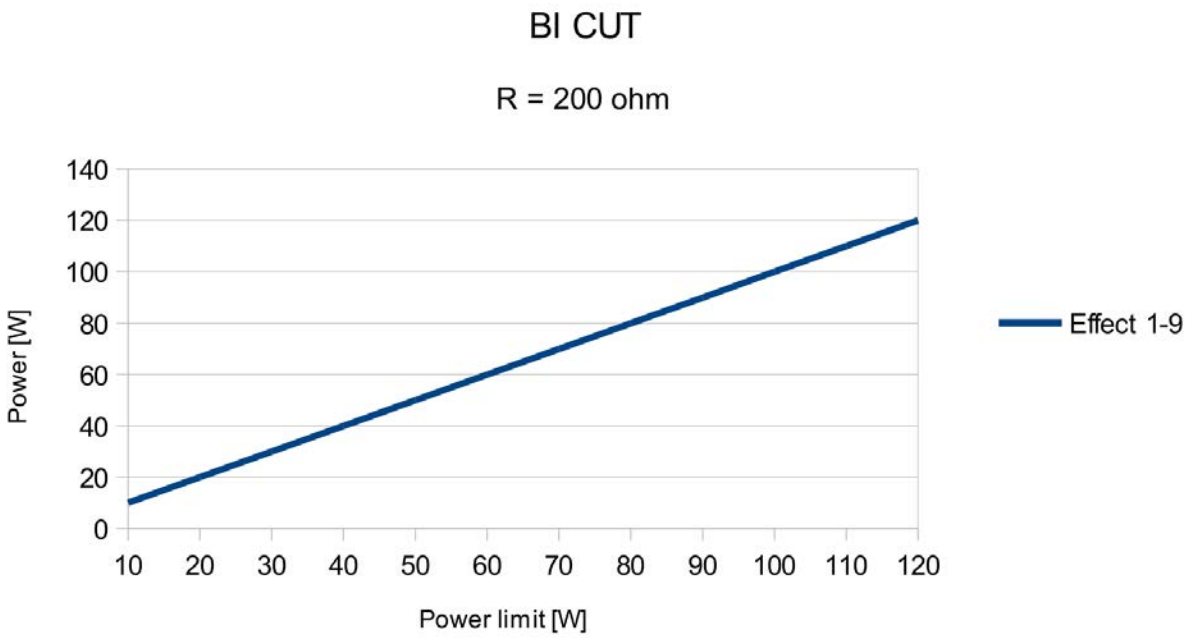

ARTRO COAG
Power [W]
250
200
150
100
50
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

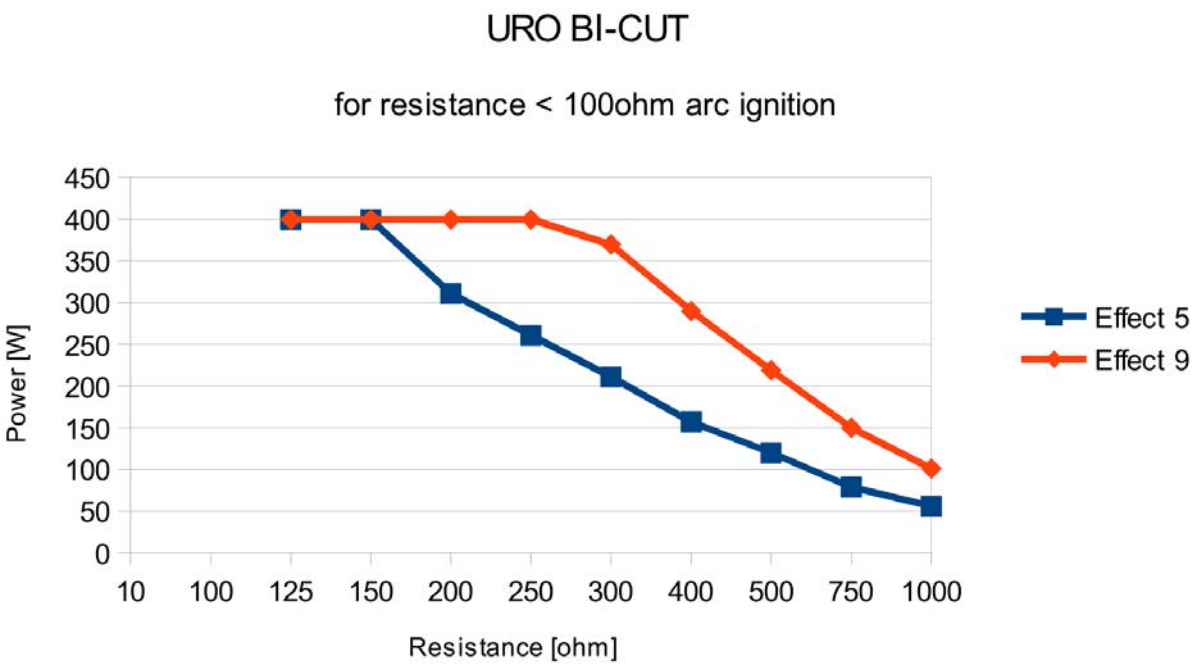

ARTRO COAG
R = 100 ohm
Power [W]
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

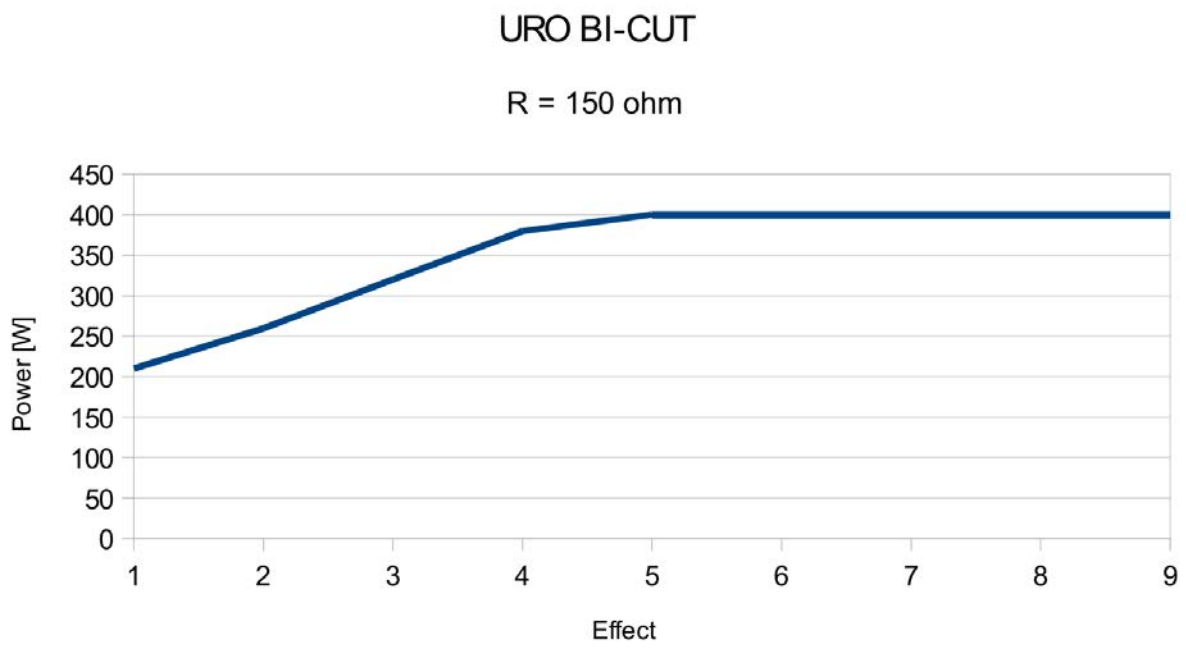

HYSTERO COAG
250
200
150
100
50
0
Power [W]
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

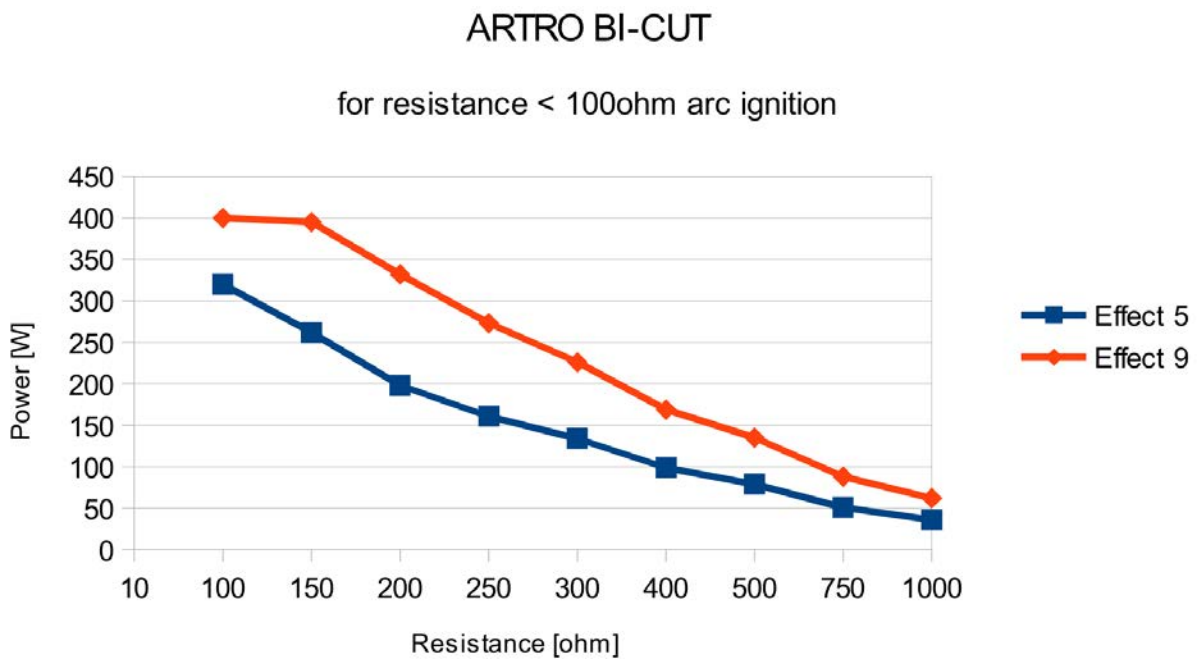

HYSTERO COAG
R = 100 ohm
300
250
200
150
100
50
0
Power [W]
1
2
3
4
5
6
7
8
9
Effect

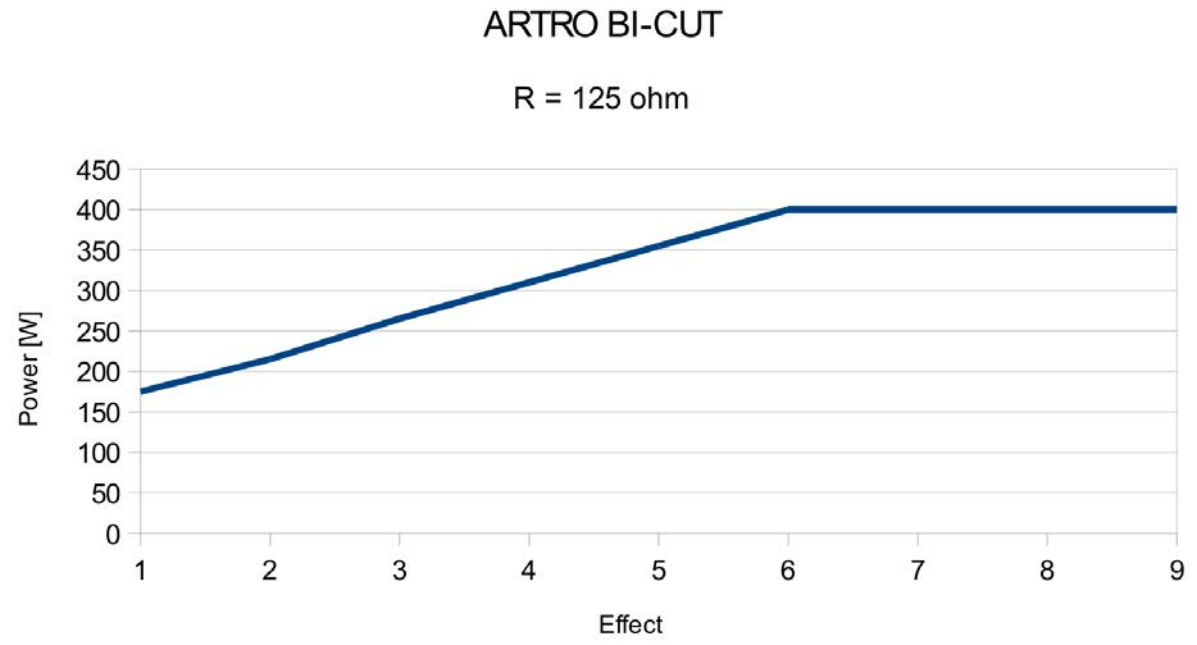

BI-CUT
Effect 9
Power [W]
140
120
100
80
60
40
20
0
10
25
50
100
150
200
300
400
500
750
1000
Resistance [ohm]
60W
120W

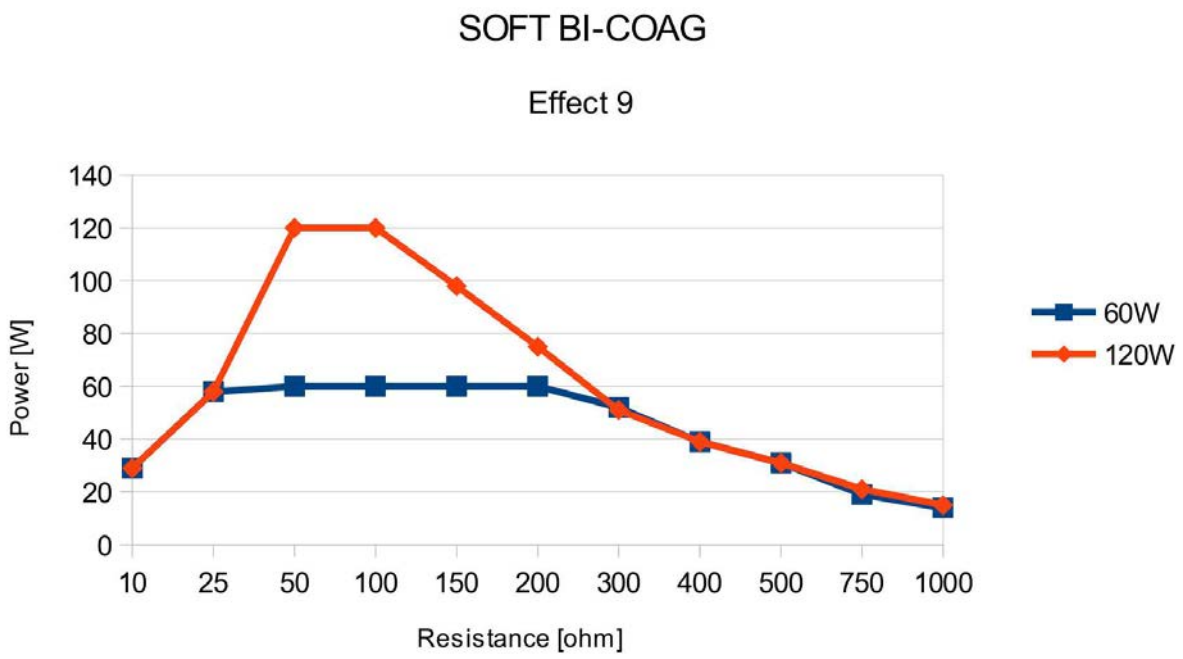

BI CUT
R = 200 ohm
Power [W]
140
120
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
110
120
Power limit [W]
Effect 1-9

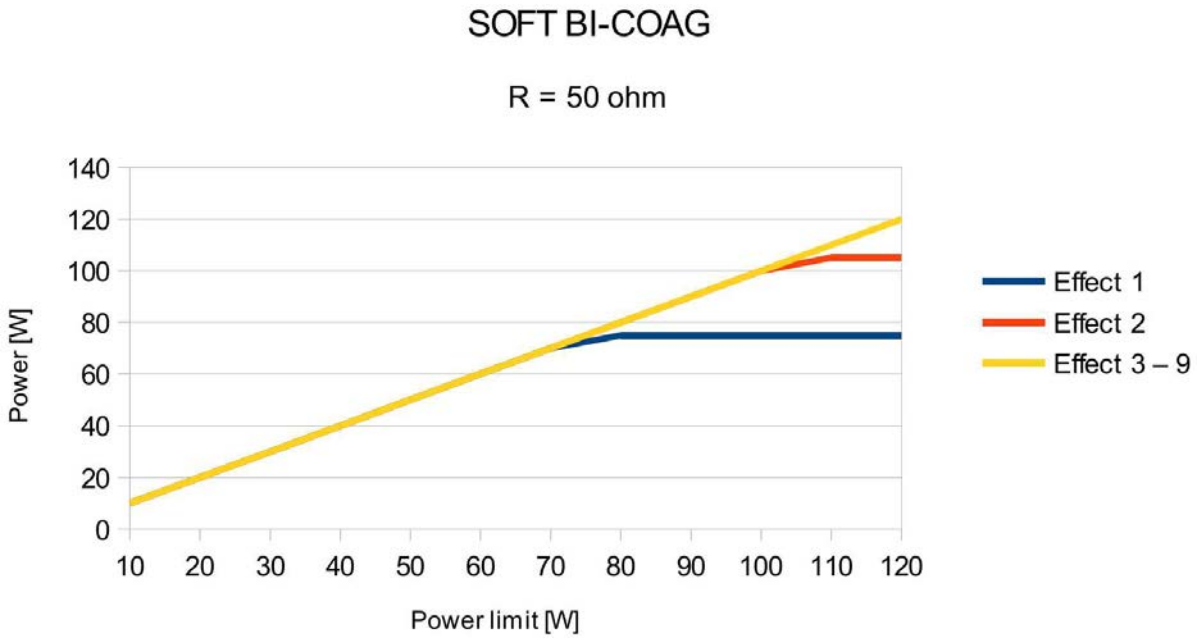

URO BI-CUT
for resistance < 100ohm arc ignition
Power [W]
450
400
350
300
250
200
150
100
50
0
10
100
125
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9

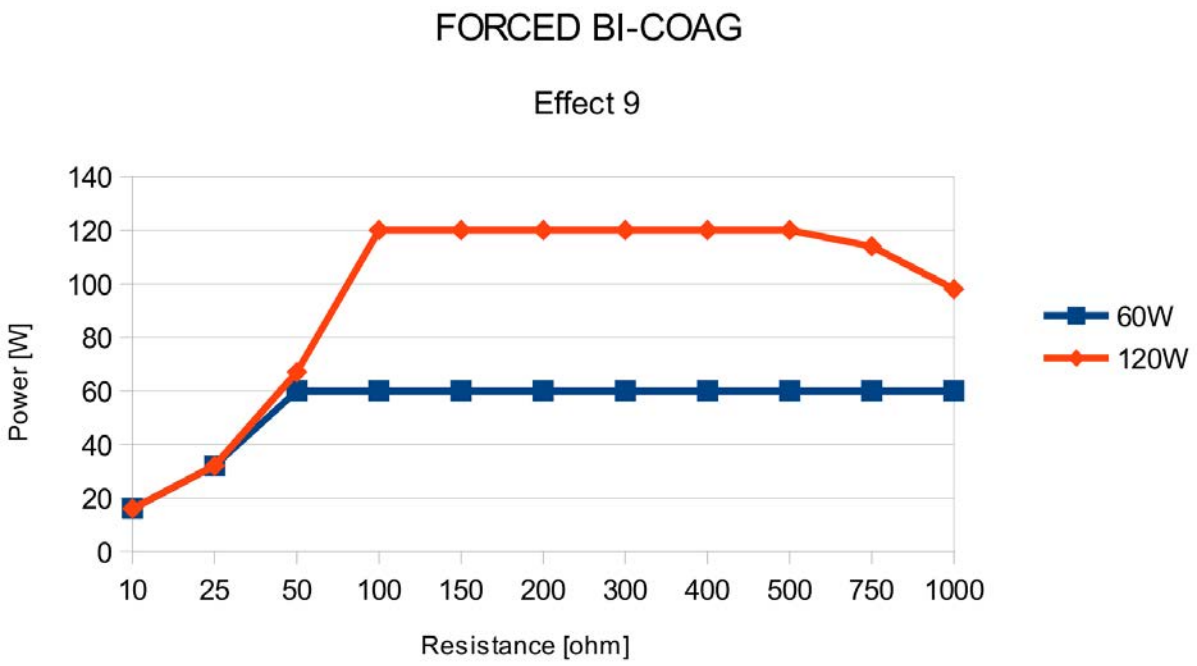

URO BI-CUT
R = 150 ohm
Power [W]
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

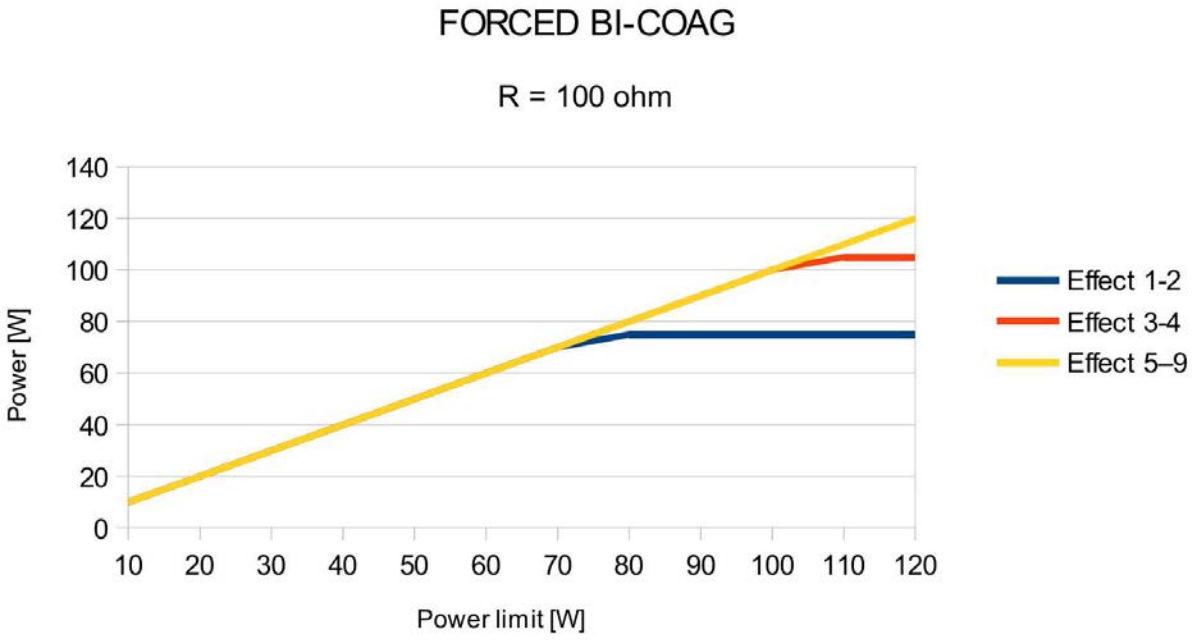

ARTRO BI-CUT
for resistance < 100ohm arc ignition
Power [W]
450
400
350
300
250
200
150
100
50
0
10
100
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9

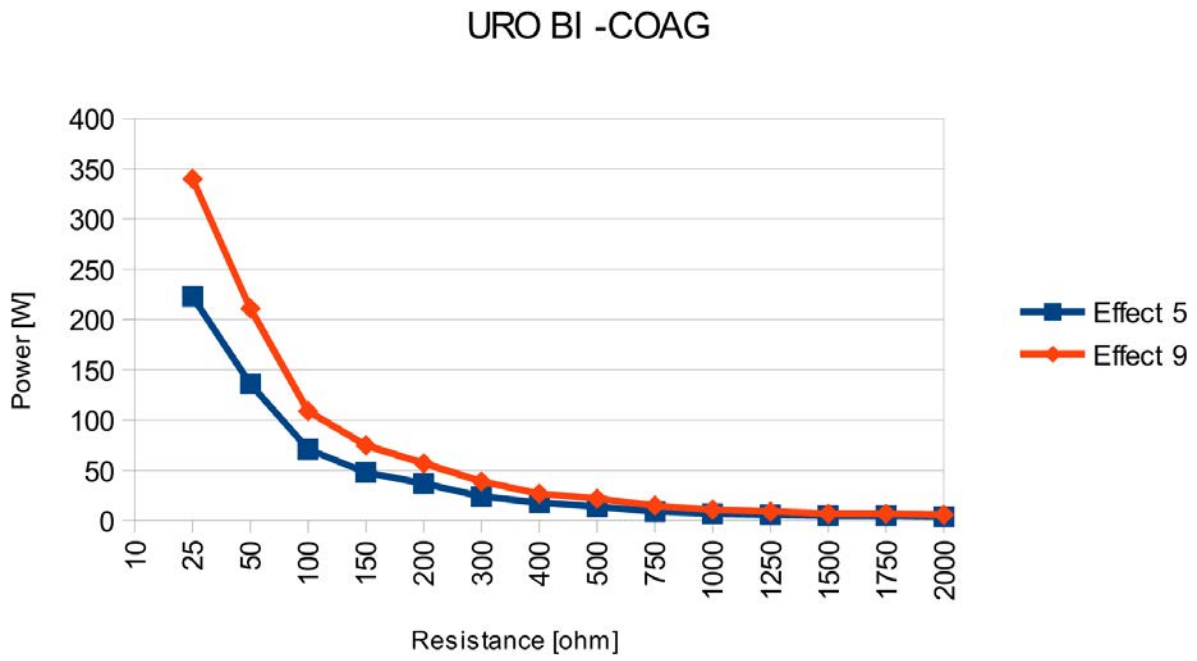

ARTRO BI-CUT
R = 125 ohm
Power [W]
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

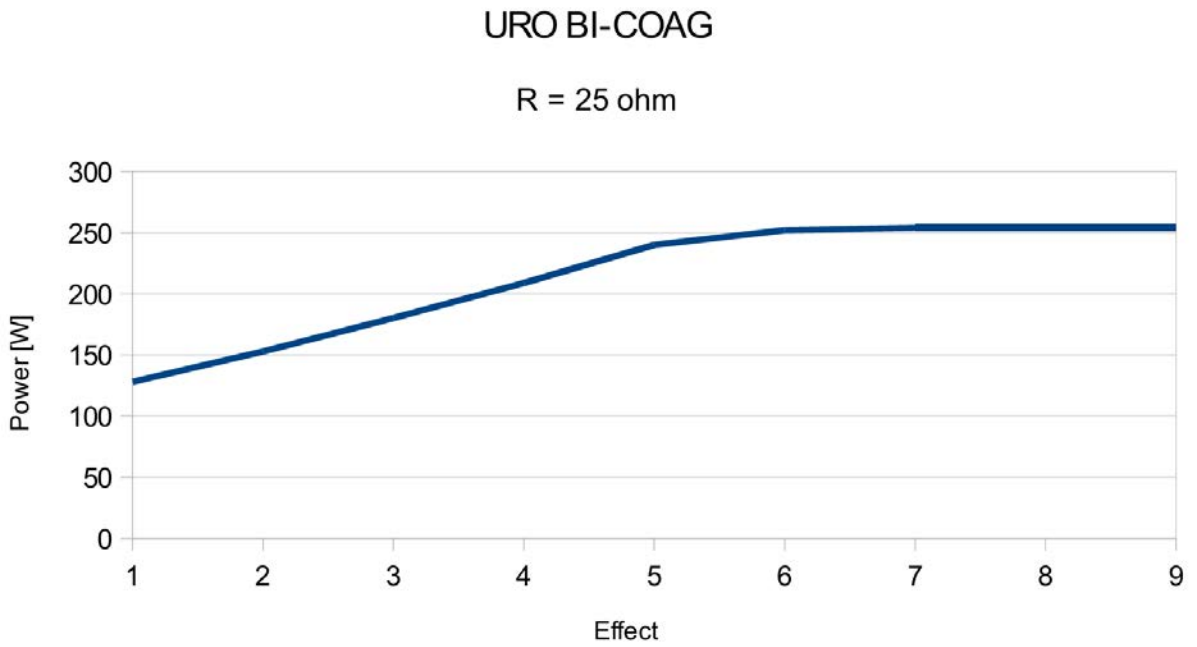

SOFT BI-COAG
Effect 9
Power [W]
140
120
100
80
60
40
20
0
10
25
50
100
150
200
300
400
500
750
1000
Resistance [ohm]
60W
120W

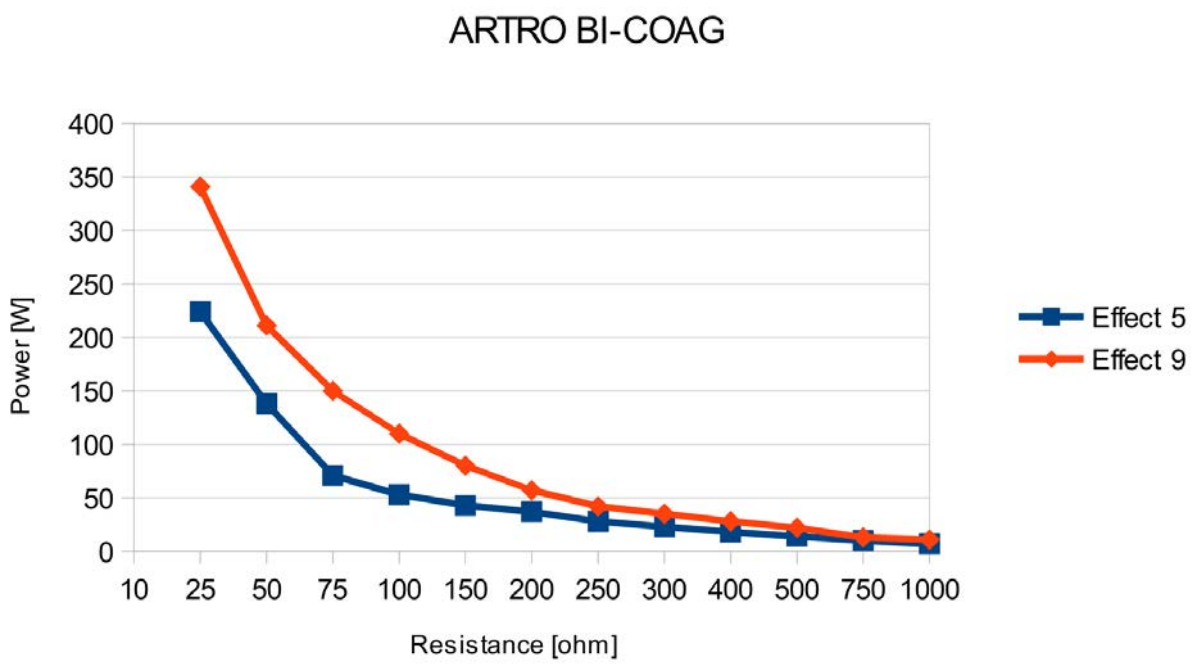

SOFT BI-COAG
R = 50 ohm
Power [W]
140
120
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
110
120
Power limit [W]
Effect 1
Effect 2
Effect 3 – 9

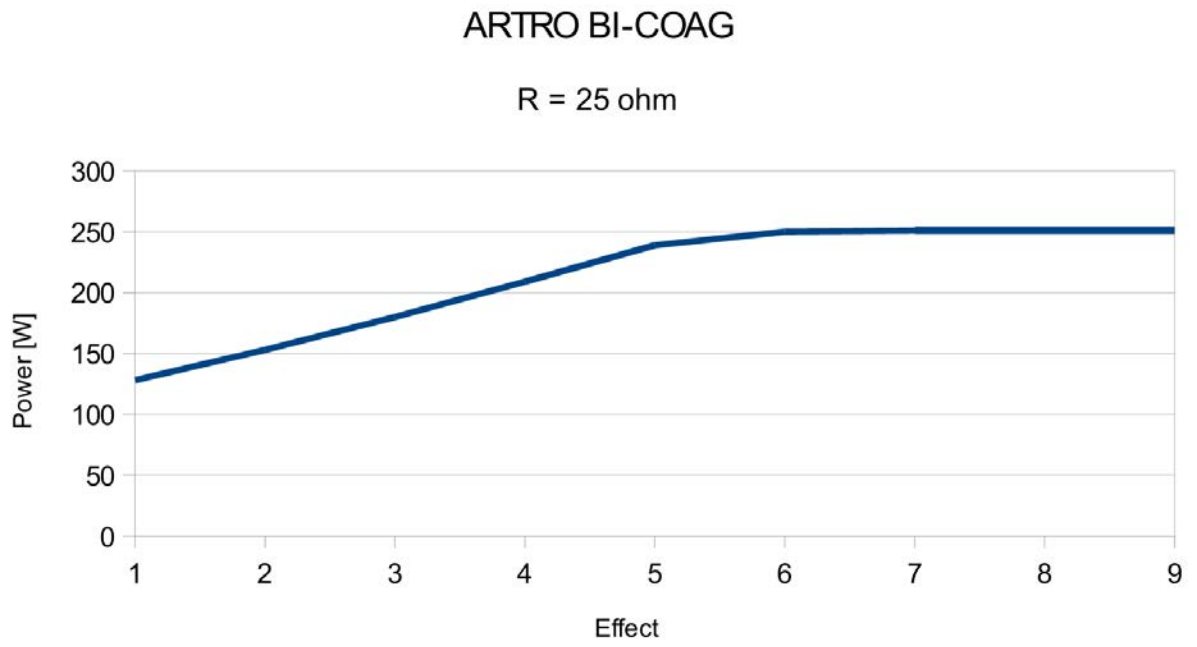

FORCED BI-COAG
Effect 9
Power [W]
140
120
100
80
60
40
20
0
10
25
50
100
150
200
300
400
500
750
1000
Resistance [ohm]
60W
120W

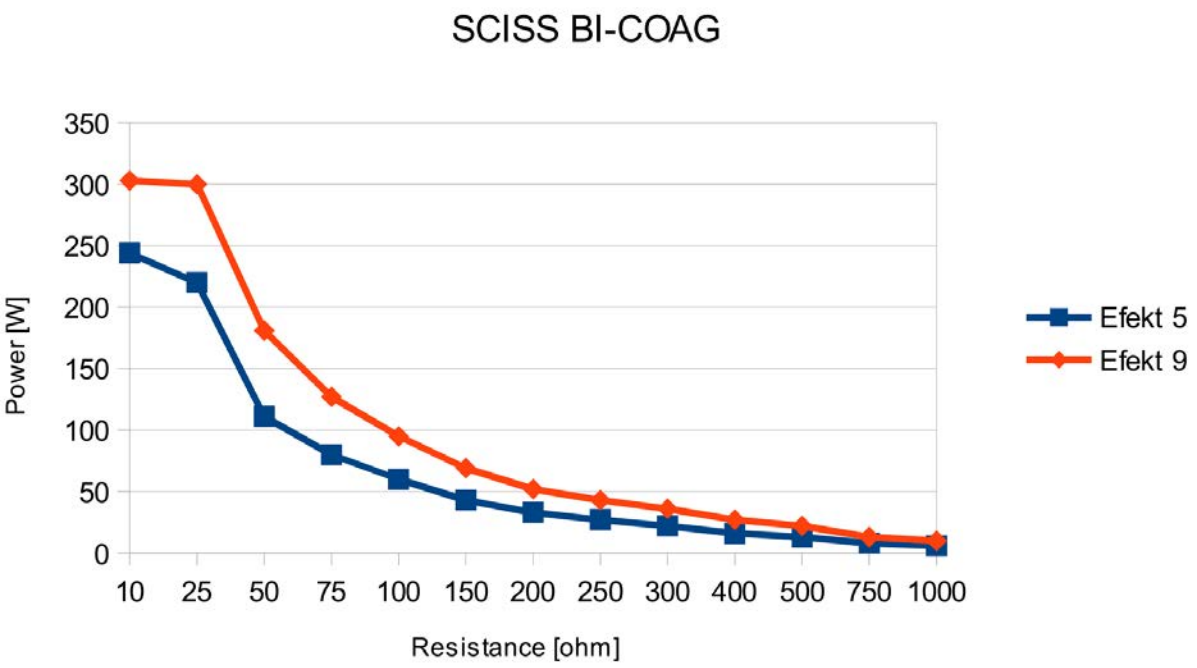

FORCED BI-COAG
R = 100 ohm
Power [W]
140
120
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
110
120
Power limit [W]
Effect 1-2
Effect 3-4
Effect 5–9

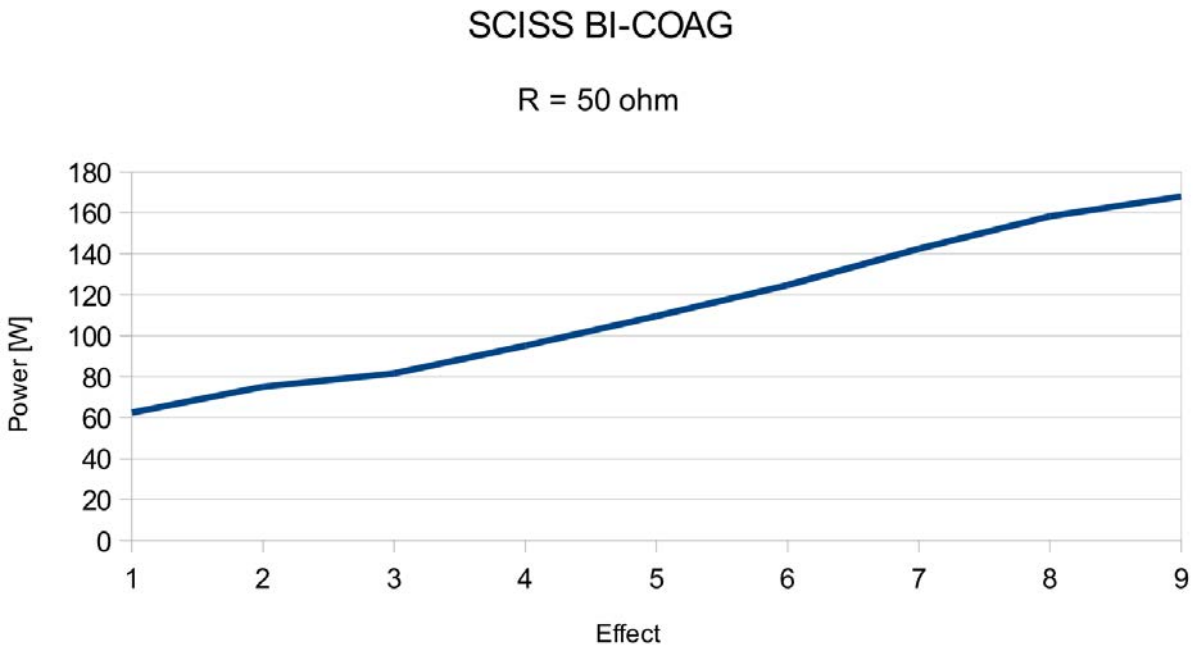

URO BI -COAG
Power [W]
400
350
300
250
200
150
100
50
0
10
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

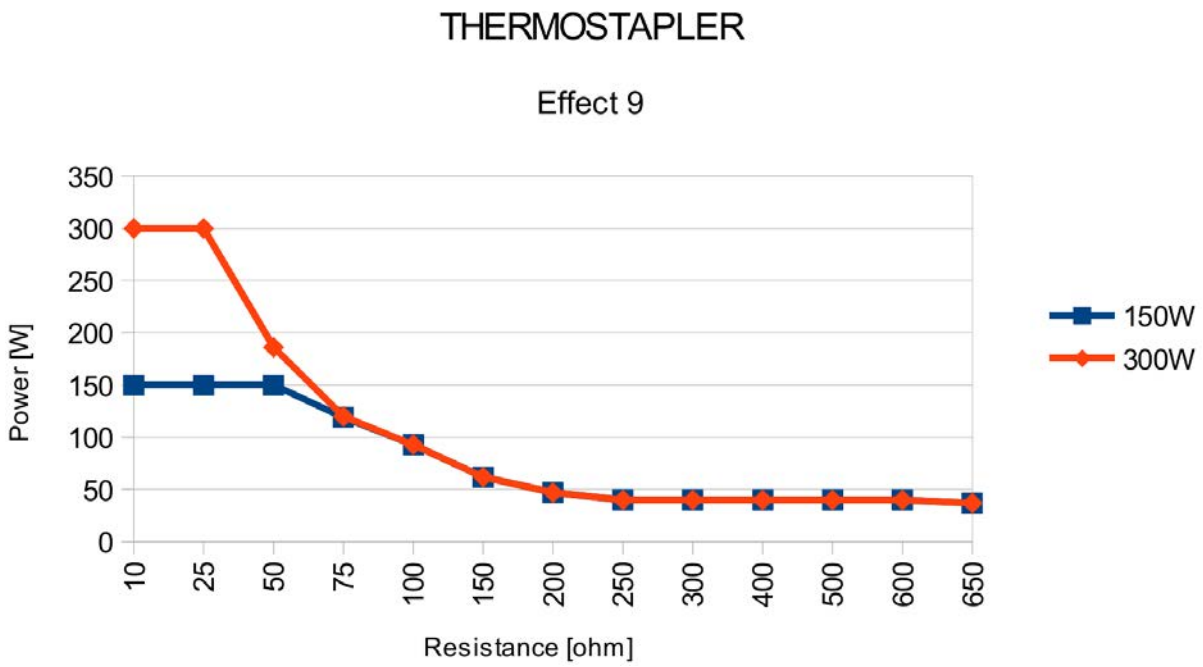

URO BI-COAG
R = 25 ohm
Power [W]
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

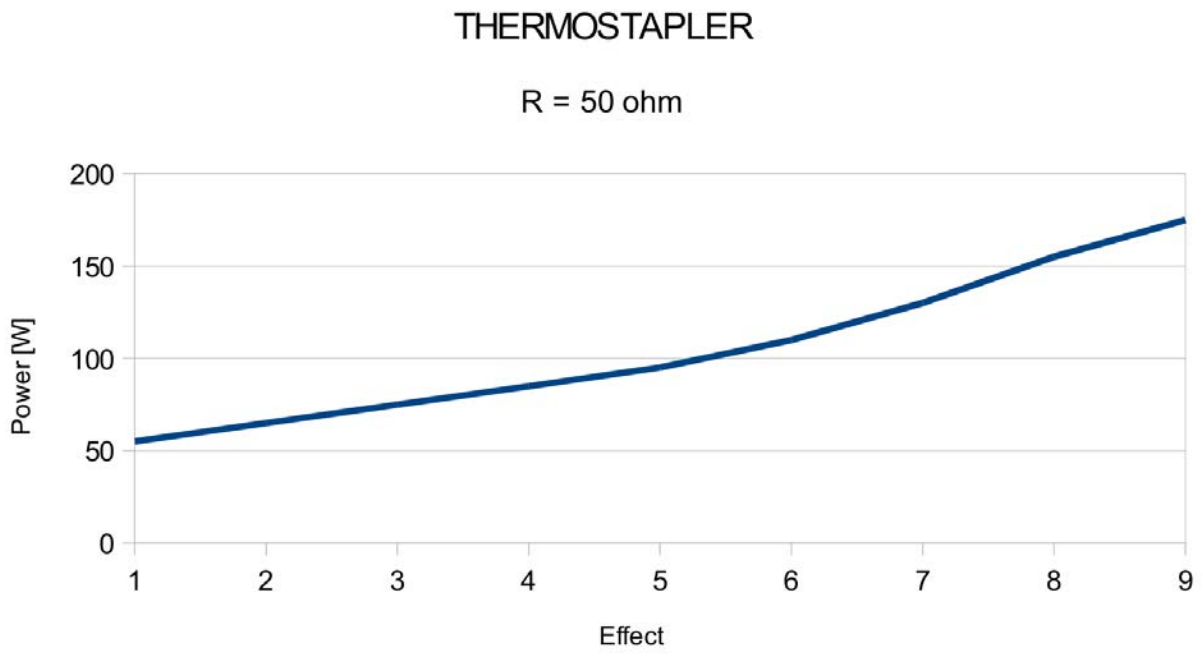

ARTRO BI-COAG
Power [W]
400
350
300
250
200
150
100
50
0
10
25
50
75
100
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9


ARTRO BI-COAG
R = 25 ohm
Power [W]
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect


SCISS BI-COAG
Power [W]
350
300
250
200
150
100
50
0
10
25
50
75
100
150
200
250
300
400
500
750
1000
Resistance [ohm]
Efekt 5
Efekt 9


SCISS BI-COAG
R = 50 ohm
Power [W]
180
160
140
120
100
80
60
40
20
0
1
2
3
4
5
6
7
8
9
Effect


THERMOSTAPLER
Effect 9
Power [W]
350
300
250
200
150
100
50
0
10
25
50
75
100
150
200
250
300
400
500
600
650
Resistance [ohm]
150W
300W


THERMOSTAPLER
R = 50 ohm
Power [W]
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

12. System and accessories maintenance

CLEANING

STEMA MASTER has been designed to ensure easier-than-ever operation and maintaining the system clean, in combination with its versatile applications in electrosurgical procedures.

As the system case is made of metal without any ventilation holes, it can be cleaned using disinfectants, and the touch panel can be cleaned using alcohol-based disinfectants.

Clean the system without allowing any fluid to enter inside the device.

STERILISATION OF ACCESSORIES

Sterilization should be adapted to the supplier's recommendations for a specific accessory. The supplied accessories, unless otherwise noted, are **not sterile and require sterilisation before they can be used**.

Unless otherwise marked, the offered electrosurgical accessories may be steam sterilized at up to 134°C and a pressure of 2 Bar. When using different accessories, please observe the manufacturer's recommendations.

12.1 Recommended cleaning and sterilising agents for non-disposable electrosurgical accessories

Consult the manufacturer's sterilisation instructions before cleaning and sterilisation of non-disposable accessories.

12.1.1 Manual washing

Non-disposable elements, heavily soiled with tissue remains, should be pre-cleaned with a plastic cleaning plate or plastic brush. Then use one of the following recommended agents for accessory cleaning and sterilisation:

Manufacturer	Product
Braun Melsungen	Stabimed
	Helipur H plus N
	Prontocid N
Henkel Hygiene	Sekucid konz.
	Sekusept forte / forte S
Johnson & Johnson	CIDEX
Schuelke & Mayr	Gigasept FF
	Lysetol FF
Anios	Aniosyme PLA
	Salvanios PH10

The following agents are recommended for disinfecting neutral (silicone) electrodes:

Manufacturer	Product
Henkel Hygiene	Incidin perfekt
	Minutil
	Incidur F

12.1.2 Mechanical washing

Manufacturer	Product
Henkel Hygiene	Sekumatic FR / Washing
	Sekumatic FRE / Washing
	Sekumatic FD / Disinfection
Schuelke & Mayr	Thermosept RKF / Washing
	Thermosept DK / Disinfection
Dr Weigert	Neodisher FE / Washing
	Neodisher Septo DN / Disinfection

In order to avoid mechanical damage, do not dry electrode handles in compressed air under a pressure higher than 3 [bar].

12.1.3 Autoclave sterilization

Unless specified otherwise, non-disposable products should be sterilised in an autoclave (in accordance with DIN 58946):

temperature 134°C
max time up to 20 minutes
pressure 2 bar

12.1.4 Formaldehyde sterilisation

DO NOT STERILISE IN FORMALDEHYDE

13. Environmental requirements

	Transport and storage	Operation
Temperature	−20°C to +50°C	+10°C to +40°C
Relative humidity	10 – 90%	10 – 90%
Pressure	700 – 1060 hPa	700 – 1060 hPa

13.1 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
STEMA MASTER is intended for use in the electromagnetic environment specified below. The customer or the user of STEMA MASTER should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	STEMA MASTER must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment nay be affected. When STEMA MASTER is not activated, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	STEMA MASTER is suitable for use in all establishments other than domestic 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/	Complies	

flicker emissions IEC 61000-3-3		

Guidance and manufacturer's declaration – electromagnetic immunity			
STEMA MASTER is intended for use in the electromagnetic environment specified below. The customer or the user of STEMA MASTER should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tie. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations an 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 s	< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If it is necessary to continue the operation during power mains interruptions, it is recommended that STEMA MASTER is powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) 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 1: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
STEMA MASTER is intended for use the electromagnetic environment specified below. The customer or the user of STEMA MASTER should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the STEMA MASTER, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	$3V_{RMS}$ 150 kHz to 80 MHz	$3V_{RMS}$	d = 1,2 $\sqrt{P}$

Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3V/m	d = 1,2 $\sqrt{P}$ 80MHz to 800MHz d = 2,3 $\sqrt{P}$ 800MHz to 2,5GHz
			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.

[a] Fields 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 witch STEMA MASTER is used exceeds the applicable RF compliance level above, STEMA MASTER should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating STEMA MASTER.

[b] Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and STEMA MASTER

STEMA MASTER is intended for use in an electromagnetic environment in witch radiated RF disturbances are controlled. The customer or the user of STEMA MASTER can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and STEMA MASTER 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 = 1,2 $\sqrt{P}$	80 MHz to 800 MHz d = 1,2 $\sqrt{P}$	800 MHz to 2,5 GHz d = 2,3 $\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at 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.

14. Environmental protection guidelines

Since the transposition of the 2002/96/EU directive into the national law, the following rules are binding:

- Electric and electronic equipment must not be disposed of together with household waste.
- The user is obliged to dispose of a broken or redundant electrical or electronic device at a dedicated collection point, put it in a special container, or possibly return it to the seller.

The details are set forth in the relevant national laws. This obligation is indicated on the product packaging or in the manual in the form of a crossed-out waste bin. By sorting waste for recycling, you help to protect the natural environment.