HF-Unit, 700-Series

High-End with Touchscreen (ARG/VS/DIA)

- **Automatic power adjustment**
- **Real-time monitoring of output parameters**
- **10" high-resolution color touch screen**
- **Up to 100 user presets**

- Integrated brightness adjustment of the screen
- Different languages incorperated
- Power monitor
- Overload protection
- Specialist modes for specific applications in urology, arthroscopy and laparoscopy
- Communication with the user in different languages, voice Communication commands inform about the diathermy operating status
- Once switched on, the unit performs a comprehensive internal autotest, with detailed results displayed
- The neutral electrode monitoring controls the quality of the application
- Monopolar cutting: pure, with haemostasis, cutting with desiccation, and for procedures in liquid environment (urology, arthroscopy)
- Monopolar coagulation: soft, forced, spray, hybryd, standard argon, endoscopic and pulse argon
- Bipolar cutting: standard and for procedures in liquids environment (urology, arthroscopy)
- Bipolar coagulation: soft, forced and for procedures in liquid environment (urology, arthroscopy) endoscopic cutting and coagulation modes
- Argon coagulation and cutting

Recommended Accessories

	Item no.	
Double footswitch, multiswitch, 6-pin, 5 m	16-2002-1217	
Equipment trolley for HF-unit	16-2000-1500	

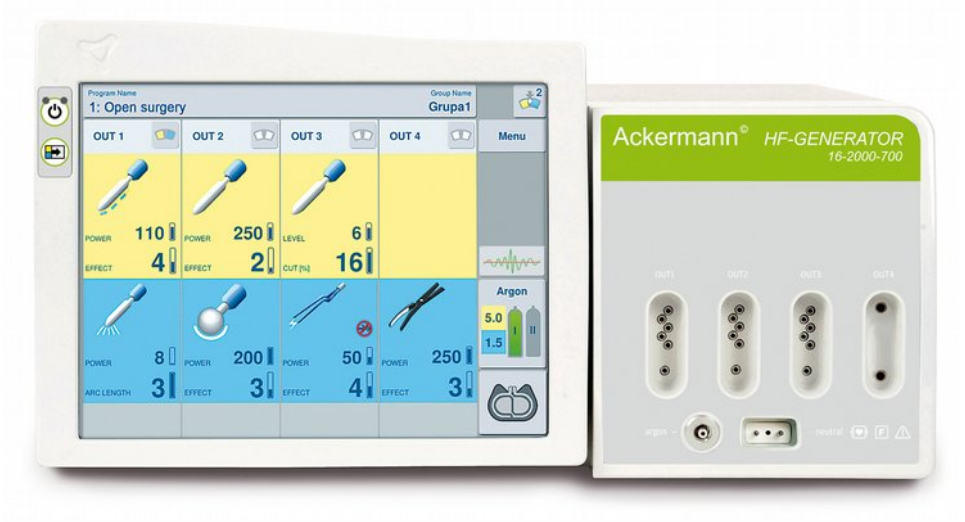
Technical Specifications

Item # **16-2000-700** / High-End High-Frequency Surgical Unit with Touchscreen, ARG/ VS/ DIA, 400 W (220 V)

Monopolar cutting		**Monopolar coagulation**	
Pure monopolar cutting	400 W for 200 Ω	Soft monopolar coagulation	180 W for 50 Ω
Blend monopolar cutting I	180 W for 200 Ω	Forced monopolar coagulation	180 W for 300 Ω
Blend monopolar cutting II	150 W for 200 Ω	Spray monopolar coagulation	80 W for 1250 Ω
Blend monopolar cutting III	150 W for 200 Ω	Hybrid monopolar coagulation	180 W for 200 Ω
Urological monopolar cutting	400 W for 200 Ω	Argon monopolar coagulation	80 W for 1250 Ω
Endoscopic monopolar cutting	400 W for 200 Ω	Argon pulse coagulation	80 W for 1250 Ω
Argon monopolar cutting	350 W for 200 Ω		
Bipolar cutting		**Bipolar coagulation**	
Bipolar cutting (4 levels)	150 W for 200 Ω	Bipolar coagulation	120 W for 50 Ω
Urological bipolar cutting	400 W for 50 Ω	AutoStart / Autostop	Automatic start / stop of bi. coa.
Argon		**VesSeal**	
Gas type	Pure argon ≥ 4.8 /99.998%	Urological	300 W for 50 Ω
Inlet gas pressure	0.3-0.5 MPa	Autostop	Automatic stop of sealing process, when achieving the opticmal effect
Gas outflow	0.1-9.9 l/min, reg. 0.1 l/min		
Pressure gauge	Reducer on argon cylinder		
Safety features			
Protection against electric shock	CF		
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 60601-1		
NEM System	Neutral electrode control		
Autotest	Self-test of generator and accessories after switching the power on, service codes display		
Overload	Generator overload protection		
Weight and dimensions		**Power supply**	
Dimensions	495 x 415 x 225 mm	Supply voltage	220-240 V +/- 10% 50/60 Hz
Weight	12.2 kg	Rated power input	1080 VA

16-2000-700/701/702/703 ELECTROSURGICAL UNIT

INSTRUCTIONS FOR USE



Rev. 05/2018

SERVICE ADDRESS:
Ackermann Instrumente GmbH
Eisenbahnstrase 65-67
78604 Rietheim-Weilheim
Germany

SYMBOLS USED IN THIS MANUAL:

Important notice

Recommendation

Caution

Warning

CE

Contents

IMPORTANT NOTICE

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 HF 16-2000-700 system

The HF 16-2000-700 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.

HF 16-2000-700 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 HF 16-2000-700 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 VesSeal mode for sealing large blood vessels and for preparing tissues using special instruments.

1.1 HF 16-2000-700 operating modes

HF 16-2000-700 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)
- DUAL CUT (monopolar cutting in simultaneous work mode)
- 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)
- DUAL COAG (forced monopolar coagulation in simultaneous work mode)
- BI-CUT (bipolar cutting)
- URO BI-CUT (urological bipolar cutting in fluid environment)
- HYSTERO BI-CUT (gynaecological 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)
- HYSTERO BI-COAG (gynaecological 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)
- VesSeal (bipolar system for sealing large blood vessels)

IMPORTANT NOTICE

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

2. Electrosurgery basics

Currently, electrosurgery is a technique used in virtually 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.

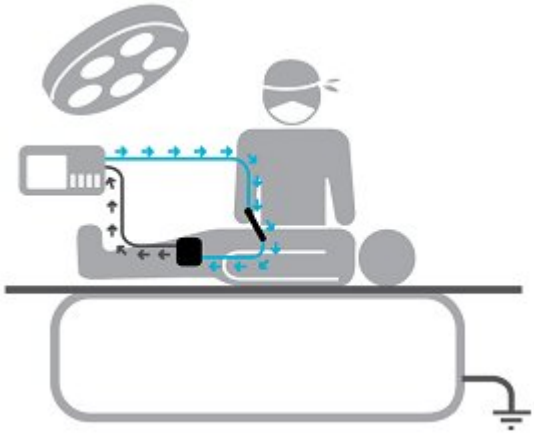
An electrosurgical unit is a device that uses electricity to generate high-frequency (HF) alternating current. The thermal effect caused by the HF current flowing through the tissue is used for tissue cutting or coagulation. An electrosurgical unit generates alternating current at frequencies higher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

WARNING

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

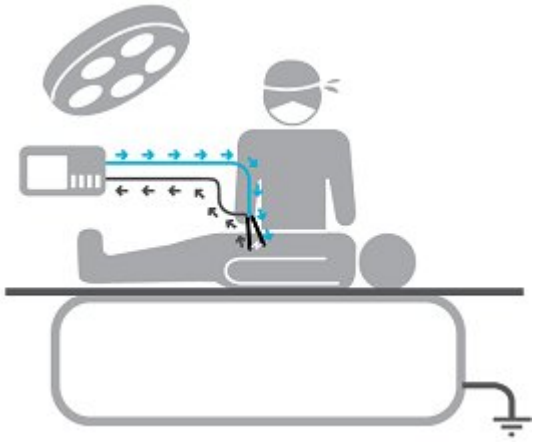
2.1 Monopolar operation



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 in 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, 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 with a small cross-sectional area. In the bipolar mode, the neutral electrode is not required.

3. Symbol

	Defibrillation-proof type CF applied part		Non-Ionizing Radiation
	The generator output is floating (isolated) with respect to ground		Serial number
	Caution		Catalogue number
	Dangerous voltage		Equipotentiality
	Manufacturer		Conforms to Directive 93/42/EEC
	Consult instructions for use		The product may not be disposed of as normal domestic waste
	Follow the Instructions for Use		Batch code
	Date of manufacture		"Fragile, handle with care"
	Do not use if package is damaged		

Ackermann 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. The device can easily be kept clean; generally available disinfection agents may be used for cleaning.

4.1 Front panel

In the basic configuration (Version I), the HF 16-2000-700 system has three universal ASD outputs with instrument detection **(Fig. 1, items 1, 3 and 4)** and one monopolar output **(item 2)**.

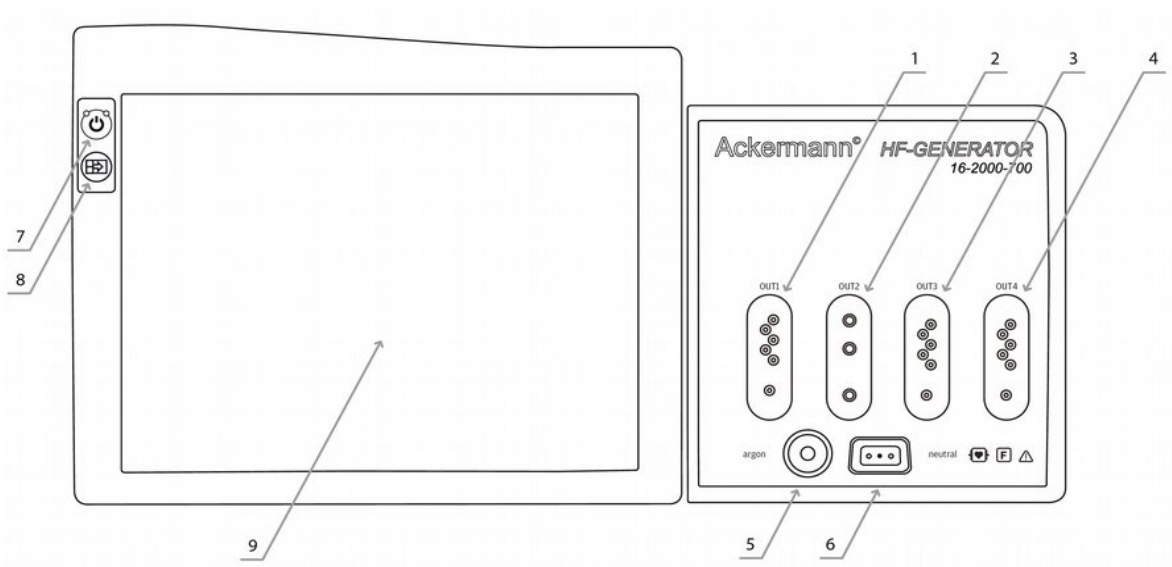


Fig. 1. HF 16-2000-700 frontside view (Version I)

The front panel of the HF 16-2000-700 system (Version I) contains the following items **(Fig. 1)**:

- stand-by button **(7)**
- main view button **(8)**
- touch panel screen **(9)**
- universal ASD output with instrument detection – socket one **(1)**
- monopolar output – socket two **(2)**
- universal ASD output with instrument detection – socket three **(3)**
- universal ASD output with instrument detection – socket four **(4)**
- argon output **(5)**
- neutral electrode socket **(6)**

In Version II, the HF 16-2000-700 system has four universal ASD outputs with instrument detection **(Fig. 2 items 1, 2, 3, 4)**.

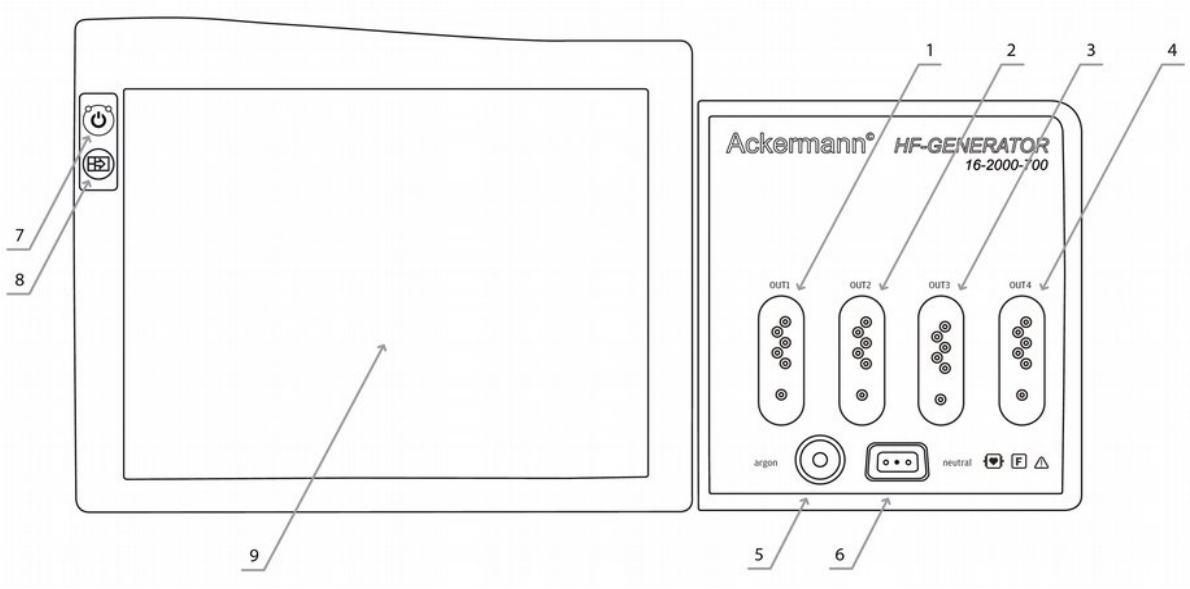


Fig. 2. HF 16-2000-700 frontside view (Version II).

The front panel of the HF 16-2000-700 system (Version II) contains the following items **(Fig. 2)**:

- universal ASD output with instrument detection – socket one **(1)**
- universal ASD output with instrument detection – socket two **(2)**
- universal ASD output with instrument detection – socket three **(3)**
- universal ASD output with instrument detection – socket four **(4)**
- argon output **(5)**
- neutral electrode socket **(6)**
- stand-by button **(7)**
- main view button **(8)**

Version III of the HF 16-2000-700 system is also available with the following configuration of outputs:
ASD – MONOPOLAR – ASD – BIPOLAR **(Fig. 3).**

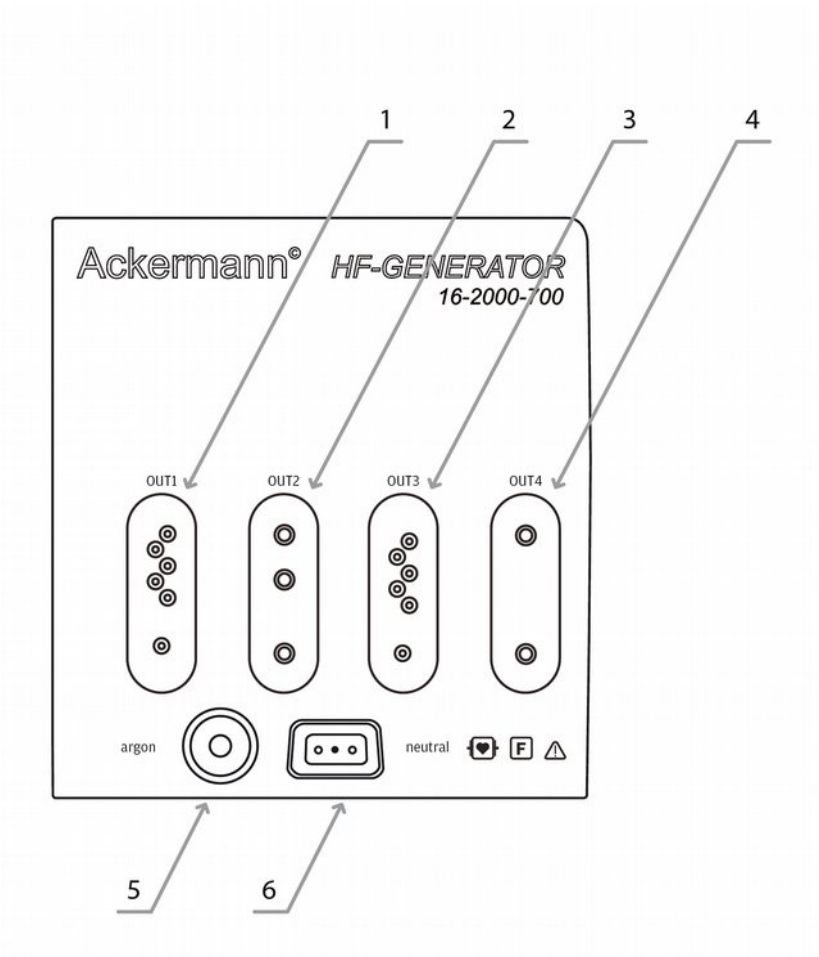


Fig. 3. Equipment connection sockets.

- universal ASD output with instrument detection **(1)**
- monopolar output **(2)**
- universal ASD output with instrument detection **(3)**
- bipolar output **(4)**
- argon output, gas outflow **(5)**
- neutral electrode socket **(6)**

4.2 Back panel

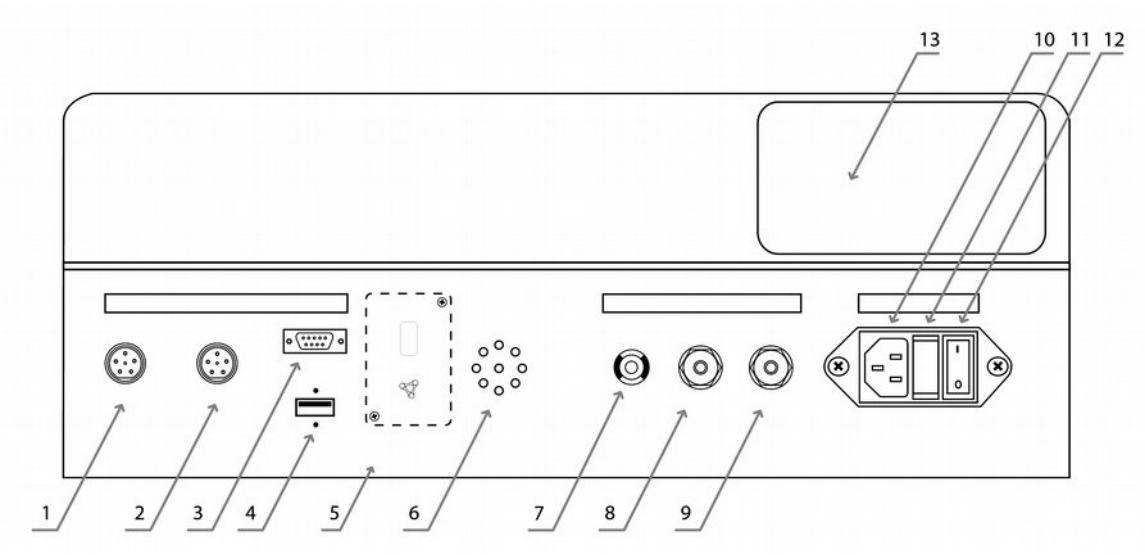


Fig. 4. HF 16-2000-700 backside view.

The back panel of the casing, as shown in **Fig. 4**, contains the following items:

- universal footswitch socket for all outputs **(1)**
- footswitch socket for one of the inputs – by default it is assigned to the third ASD 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 HF 16-2000-700 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).**

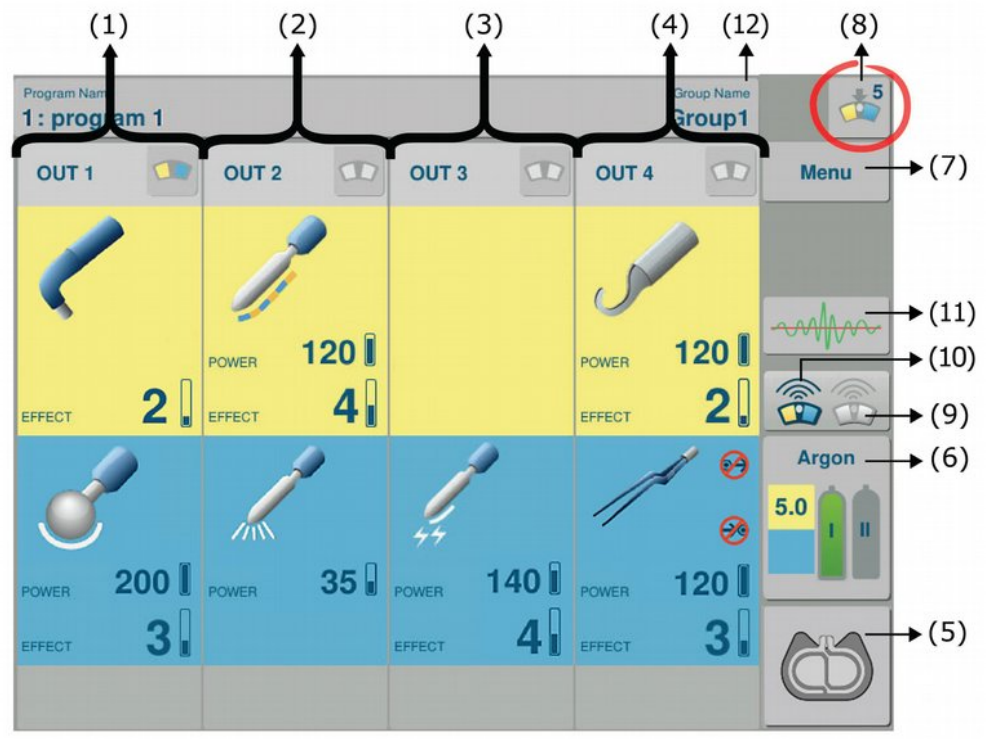


Fig. 5. The main panel.

The main panel in the basic configuration of the HF 16-2000-700 system (Fig. 5):

- 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 ASD 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:

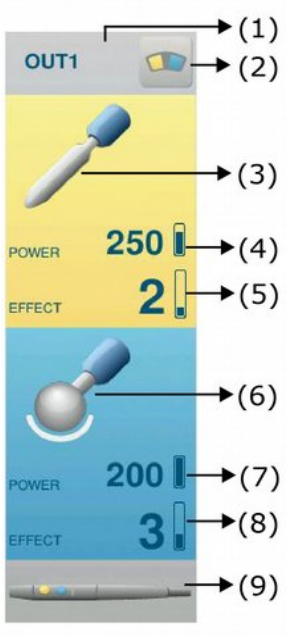


Fig. 6. Control panel for output 1.

Fig. 6 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 ASD instrument connected to output 1 **(9)**

4.4 Active panel – detailed view for a given output

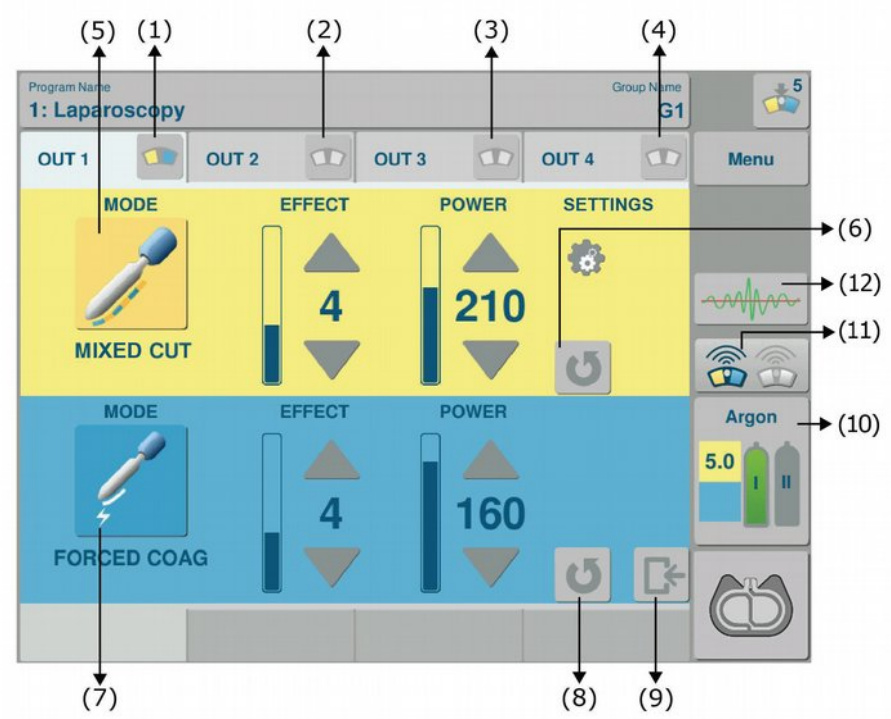


Fig. 7. Panel view with two modes – cutting and coagulation.

The detailed view of the control panel for a given output **(Fig. 7)** 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. HF 16-2000-700 technical specifications

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

Table 1. HF 16-2000-700 technical specifications

POWER SUPPLY	
Power supply voltage	220-240 V ±10% 50/60 Hz or optionally 110-120 V ±10% 50/60 Hz
Nominal power consumption	1350 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	
Optical indication	7 levels
POWER OUTPUT IN THE MONOPOLAR CIRCUIT	
MONO CUT Monopolar cutting with adjustable degree of haemostasis The mode is available in monopolar and ASD outputs.	9 effects Up to 350 W
PRECISE CUT Precise cutting with adjustable degree of haemostasis The mode is available in monopolar and ASD 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 ASD outputs.	9 effects Up to 150 W
MUCO CUT Monopolar cutting for mucosectomy procedures. The mode is available in ASD outputs with 281-03S 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 ASD outputs with 281-03S tool connected.	9 levels
PAPILLO CUT Papillotomy with adjustable duration of cutting and coag time in the cycle. The mode is available in ASD outputs with 281-03S tool connected.	9 levels

ARTRO CUT Cutting in non-conductive liquids with adjustable degree of haemostasis The mode is available in ASD outputs with 322-14S, 327-14S tools connected.	9 effects
URO CUT Urological cutting in non-conductive liquids with adjustable degree of haemostasis The mode is available in ASD outputs with 405-04S, 408-14S tools connected.	9 effects
HYSTERO CUT Gynaecological cutting in non-conductive liquids with adjustable degree of haemostasis The mode is available in ASD outputs with 405-04S, 408-14S tools connected.	9 effects
ARGON CUT Argon-enhanced cutting with adjustable degree of haemostasis The mode is available in monopolar and ASD outputs with 932-14S tool connected.	9 effects Up to 350 W
DUAL CUT Monopolar cutting with adjustable degree of haemostasis in simultaneous work mode. The mode is available on first two outputs OUT1 (ASD) and OUT2 (ASD or 3-pin monopolar) with 322-14S, 327-14S, 215-23S, 218-23S tools connected.	9 effects Up to 350 W
SOFT COAG Soft coagulation with adjustable coagulation intensity The mode is available in monopolar and ASD outputs.	9 effects Up to 200 W
FORCED COAG Forced coagulation with adjustable coagulation intensity The mode is available in monopolar and ASD outputs.	9 effects Up to 200 W
HYBRID COAG Universal coagulation with adjustable coagulation intensity The mode is available in monopolar and ASD outputs.	9 effects Up to 200 W
SPRAY COAG Spray non-contact coagulation The mode is available in monopolar and ASD outputs.	Up to 80 W
ENDO SPRAY Endoscopic monopolar non-contact coagulation. The mode is available in ASD outputs with 281-03S tool connected.	Up to 30 W
STANDARD ARGON Argon-enhanced coagulation for open and laparoscopic procedures The mode is available in monopolar and ASD outputs with 932-14S tool connected.	Up to 80 W
ENDO ARGON Endoscopic argon-enhanced coagulation The mode is available in ASD outputs with 432-46S,432-45S 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 ASD outputs with 432-46S, 432-45S tools connected.	Up to 40 W
URO COAG Urological monopolar coagulation in non-conductive liquids The mode is available in ASD outputs with 405-04S, 408-14S tools connected.	9 effects

ARTRO COAG Arthroscopic monopolar coagulation in non-conductive liquids The mode is available in ASD outputs with 322-14S, 327-14S tools connected.	9 effects
HYSTERO COAG Gynaecological monopolar coagulation in non-conductive liquids The mode is available in ASD outputs with 405-04S, 408-14S tools connected.	9 effects
DUAL COAG Forced coagulation with adjustable coagulation intensity in simultaneous work mode. The mode is available on first two outputs OUT1 (ASD) and OUT2 (ASD or 3-pin monopolar) with 322-14S, 327-14S, 215-23S, 218-23S tools connected.	9 effects Up to 200 W
OUTPUT POWER IN THE BIPOLAR CIRCUIT	
BI-CUT Bipolar cutting with adjustable degree of haemostasis The mode is available in bipolar and ASD outputs with 351-03S, 351-05S, 351-13S, 351-15S tools connected.	9 effects Up to 120 W
URO BI-CUT Urological cutting in conductive liquids The mode is available in ASD outputs with 348-04S, 354-04S, 349-04S, tools connected.	9 levels
HYSTERO BI-CUT Gynaecological cutting in conductive liquids. The mode is available in ASD outputs with 348-04S, 354-04S, 349-04S, tools connected.	9 levels
ARTRO BI-CUT Arthroscopic cutting in conductive liquids The mode is available in ASD outputs with 58S-xxx, 351-05S, 351-13S, 351-15S tools connected.	9 levels
SOFT BI-COAG Bipolar coagulation The mode is available in bipolar and ASD outputs.	9 effects Up to 120 W
FORCED BI-COAG Forced bipolar coagulation The mode is available in bipolar and ASD outputs.	9 effects Up to 120 W
URO BI-COAG Bipolar coagulation in fluid environment for bipolar resection The mode is available in ASD outputs with 348-04S, 354-04S, 349-04S, tools connected.	9 effects
HYSTERO BI-COAG Bipolar coagulation in fluid environment for gynaecological procedures. The mode is available in ASD outputs with 348-04S, 354-04S, 349-04S, tools connected.	9 effects
ARTRO BI-COAG Arthroscopic bipolar coagulation in conductive liquids The mode is available in ASD outputs with 58S-xxx, 351-03S, 351-13S, 351-15S tools connected.	9 effects
SCISS BI-COAG soft bipolar coagulation for cutting with bipolar scissors The mode is available in ASD outputs with 358-03S tool connected.	9 effects
VesSeal with adjustable procedure intensity The mode is available in ASD outputs with 401-03S, 401-05S, 824-13S, 801-16S, 801-18S, 801-23S, 801-28S, 801-66S, 801-68S, 801-73S, 801-78S tools connected.	Up to 300 W, 9 effects

ARGON	
Argon – type	4.8 (99.998%) or higher
Gas input pressure	0.3 – 0.5 MPa (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

IMPORTANT NOTICE

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

6. HF 16-2000-700 accessories list

Table 2. Standard equipment of the HF 16-2000-700 system

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

7. Preparing the system for work

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

IMPORTANT NOTICE

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 in 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.

How to connect the footswitches and the power cable is presented in **Fig. 8** where:

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

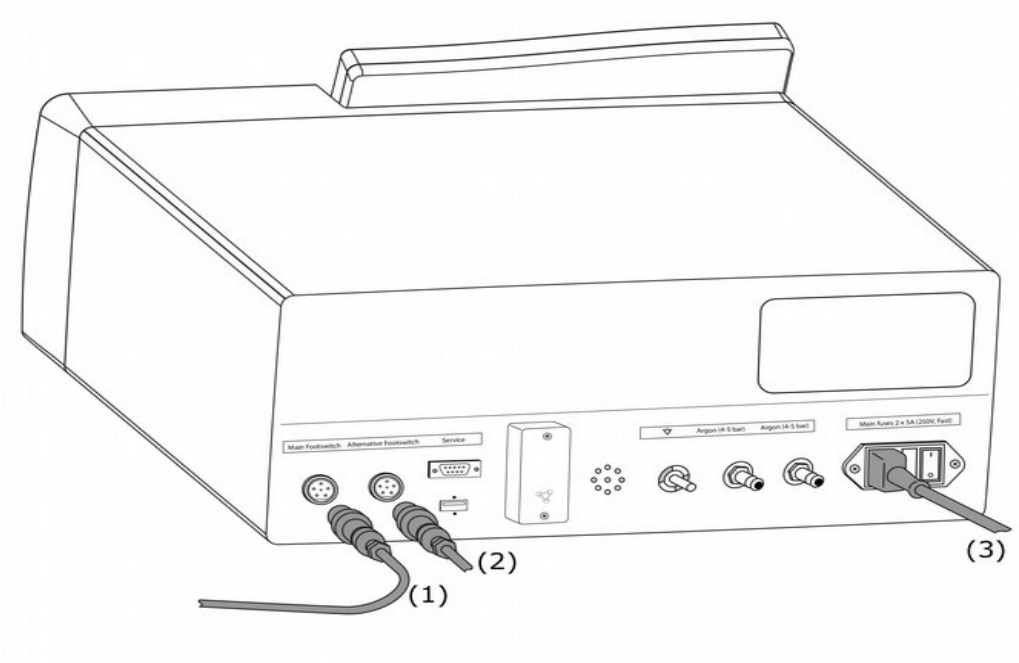


Fig. 8. How to connect the footswitches and the power cable.

The HF 16-2000-700 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,
- wired 2-button footswitch,
- wireless 3-button footswitch, MultiSwitch,

For information about connecting a wireless footswitch, see **section 7.5**.

How to connect **accessories** to the universal outputs **(Fig. 1 items 1, 3)** with the Smart Device instrument detection system is explained in **Fig. 9**.

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. 10**.

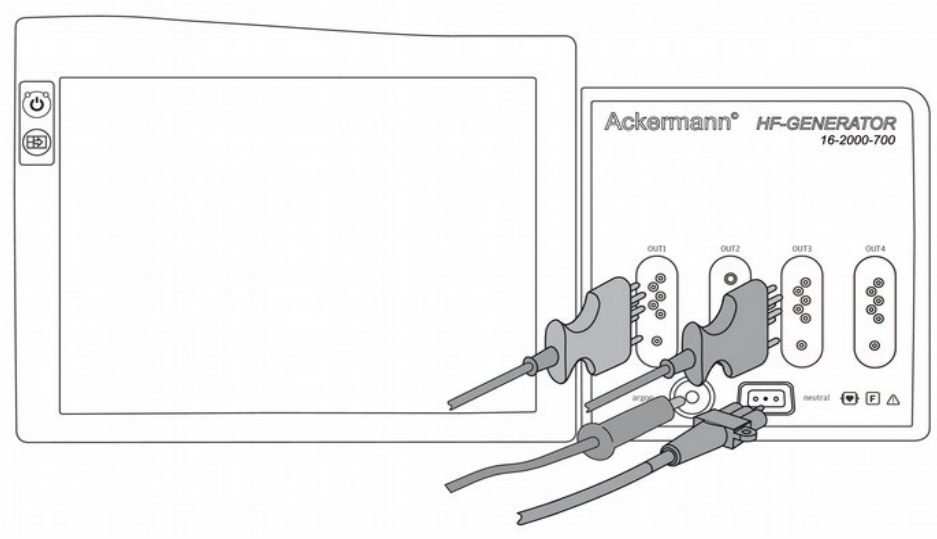


Fig. 9. How to connect accessories to outputs 1 and 3 (ASD) in the HF 16-2000-700 system, Version I

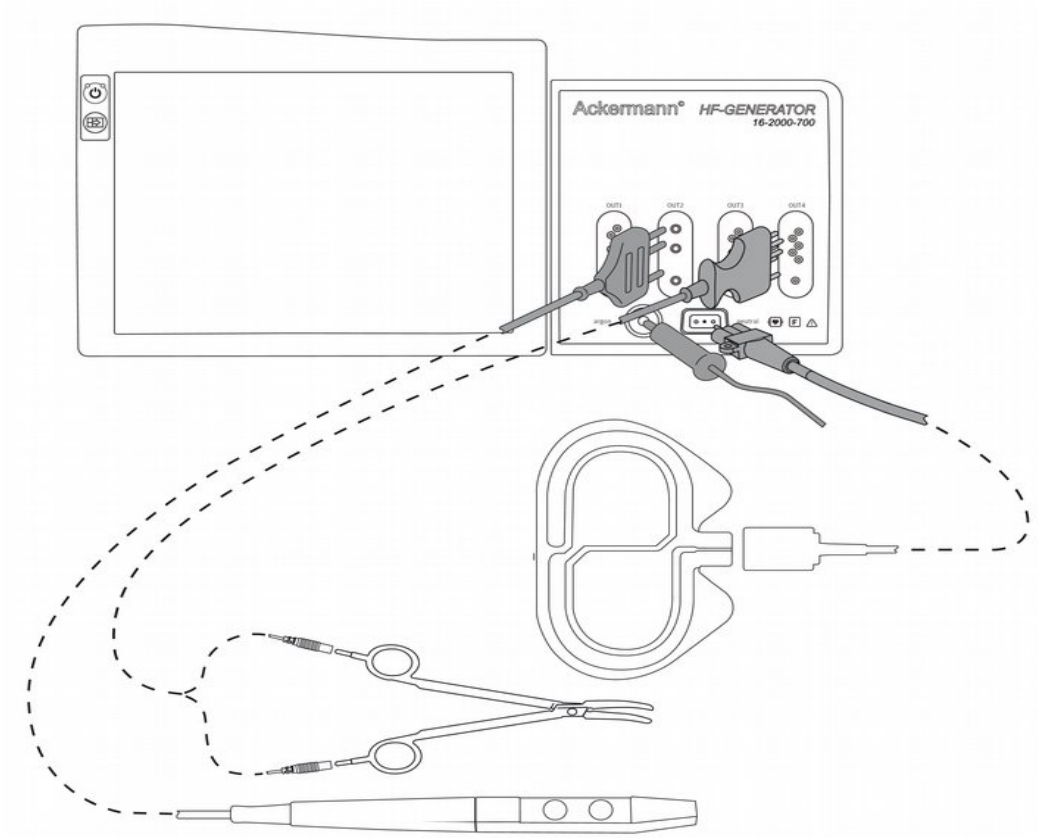


Fig. 10. How to connect accessories to outputs 2 (monopolar) and 4 (bipolar) in the HF 16-2000-700 system, Version II

7.2 Pneumatic ducts connection

The gas (argon) under reduced pressure **(0.3 – 0.5 MPa** (3-5 Bar)**)** is connected to the output extensions **(Fig. 4, 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.

WARNING

Connect gas only under a reduced pressure (0.3 – 0.5 MPa (3-5 Bar)**).**

Argon class 4.8 (99.998%) or 5.0 (99.999%) is used for argon coagulation.

How to connect the argon and argon ducts is presented in **Fig. 11 and 12.**

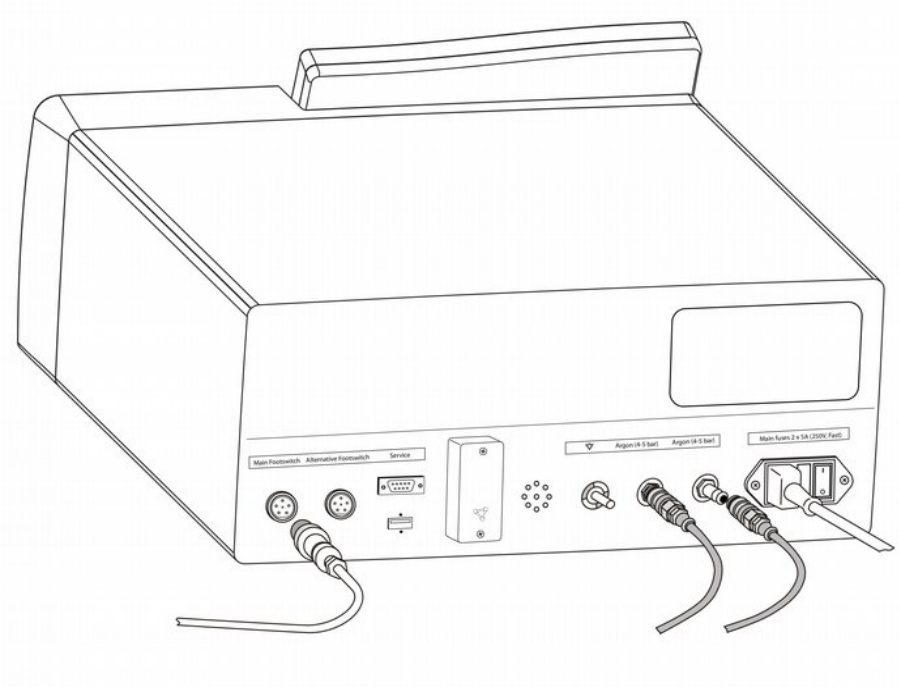


Fig. 11. How to connect the argon ducts to the HF 16-2000-700 system.

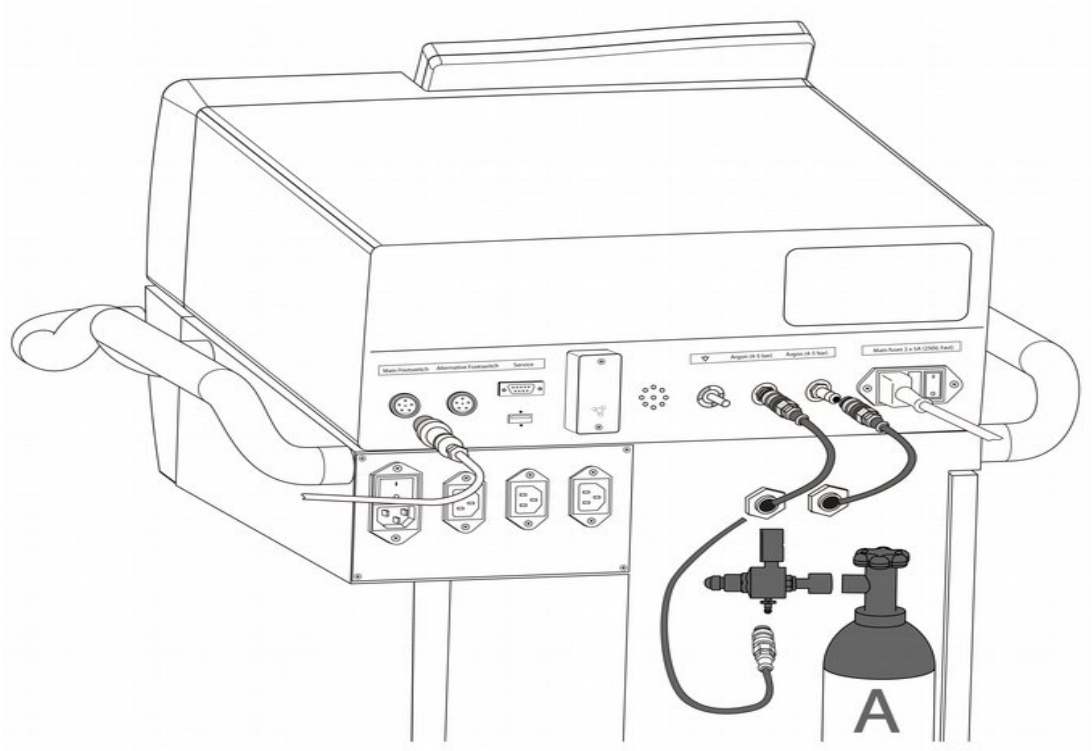


Fig. 12. How to connect argon to the HF 16-2000-700 system.

For more information about argon ducts, see section 7.6.3.

7.3 Connecting accessories for electrosurgical procedures

IMPORTANT NOTICE

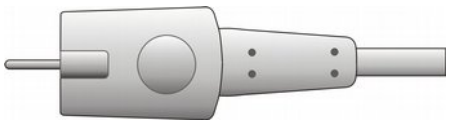
The units manufacturer allows to use of Ackermann accessories only for accessories available in Ackermann catalogue.

The HF 16-2000-700 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.

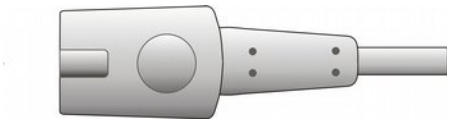
The following accessories can be connected to the sockets on the front panel of the system:

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

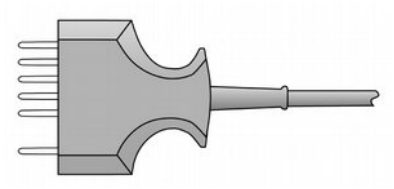


Reusable Neutral electrode plug

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

7.3.2 Instrument cable for universal ASD sockets

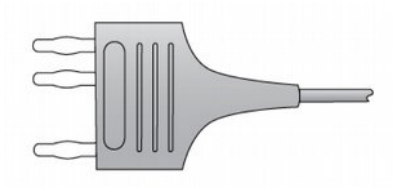
The **universal output with instrument detection** made according to the Smart Device System standard **(Fig. 1, items 1,3,4)**.



Universal ASD 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)**.



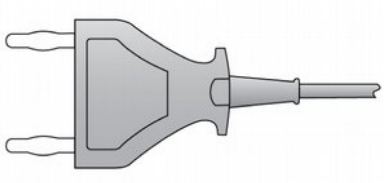
Active monopolar electrode handle plug

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

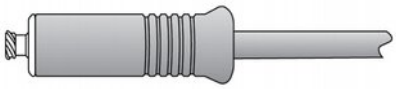
The socket of the **bipolar output** is made in compliance with the 29 mm standard **(Fig. 3, item 4)**. The system is compatible with bipolar tools of various types, for both open and laparoscopic surgery.



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

IMPORTANT NOTICE

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 HF 16-2000-700 systems are equipped with an **instrument detection system – the ASD system**. This can detect and identify the connected instrument.

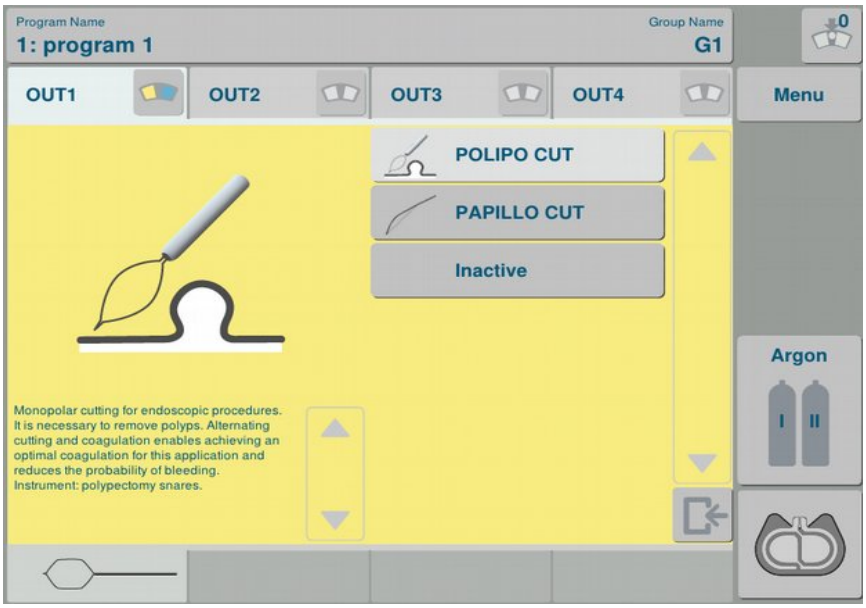
IMPORTANT NOTICE

Instrument detection applies only in the case of instruments with ASD 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



ASD socket **(Table 1. HF 16-2000-700 technical specifications)**, and a limited list of modes after connecting an instrument to a socket with the ASD system **(Fig. 13)**.

Fig. 13. Complete list of cutting modes available before connecting the endoscopic cable.

In addition, the ASD 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. 14 shows data on the instrument connected to the system. To display these data, touch the instrument detection status window panel **(Fig. 5, 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

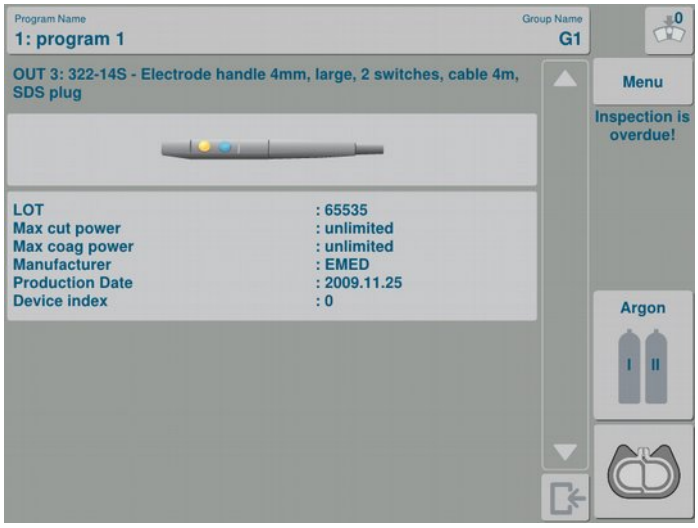


Fig. 14. Data of an instrument connected to a socket with the ASD system.

7.5 Wireless footswitch receiver

The HF 16-2000-700 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.

IMPORTANT NOTICE

Two footswitches can be connected simultaneously to the HF 16-2000-700 system. It is possible to freely configure the wired and wireless footswitches.

The wireless footswitch for the HF 16-2000-700 system is adapted with a dongle. The dongle should be connected to the footswitch socked in the back panel of the system **(Fig. 4, item 1 or 2)**. It is connected in the same way as the plug of a standard wired footswitch.

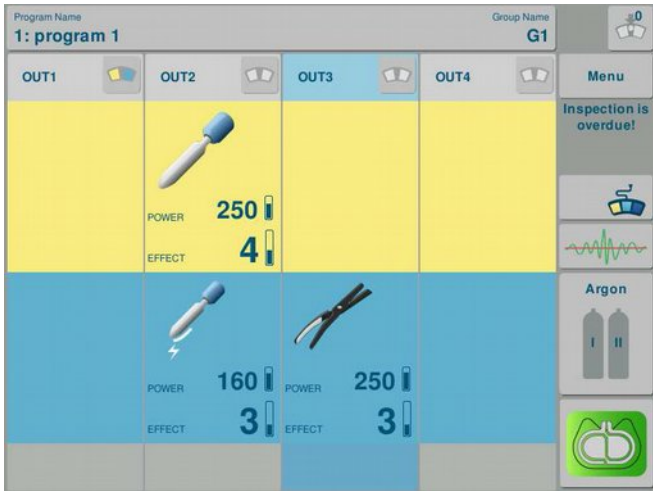
IMPORTANT NOTICE

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

7.5.1 Operation with 3-button footswitch

Footswitch should be connected to „MAIN FOOTSWITCH" socket located in the rear side of the unit.
Yellow and blue switches are used for activation of cutting and coagulation modes. The dark blue switch activates mode on coagulation panel output OUT 3.

MultiSwitch button can be used to remote change of either the program or effect /power (Section 7.6.2)



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 HF 16-2000-700 system depends on its version and may differ from the table below.

Table 3. Types of available setting for each mode

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
DUAL CUT	Effect	Power W		
BI-CUT	Effect	Power W		
URO-BI-CUT	Effect	-		
HYSTERO 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	-		
DUAL COAG	Effect	Power W		
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	-		
HYSTERO BI-COAG	Effect	-		
ARTRO BI-COAG	Effect	-		
SCISS BI-COAG	Effect	-		
VesSeal	Effect	Power W		

7.6.1 Working parameter adjustment

The HF 16-2000-700 system is equipped with the ASD instrument detection system. When a ASD instrument is connected, the system identifies it and automatically lists the suggested operating modes and effects, as well as power limit.

If a ASD instrument was used previously with the HF 16-2000-700 system, then the last settings used for this instrument type will be loaded.

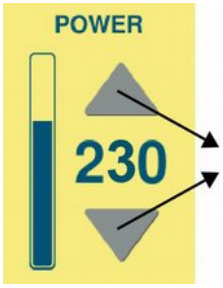
When using standard mono- or bipolar instruments, before starting the procedure, set the effect which is appropriate for a given procedure, and, if necessary, a power limit for the selected mode.

The HF 16-2000-700 system has a system of automatic adjustment of the output power depending on the operating conditions. 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.

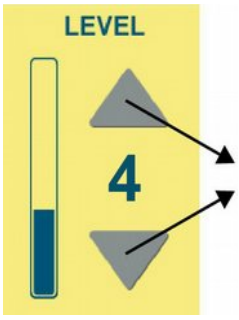
The power limit and the effect are set independently for cutting and coagulation modes. They are set independently for each output, for each mode and program.

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 HF 16-2000-700 system is equipped with a set of suggested settings for each operating mode.



power adjustment



level adjustment

IMPORTANT NOTICE

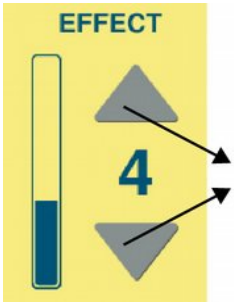
Before the first use of the system, it is recommended to become familiar with the effects of various settings, performing trials on fresh beef meat.

7.6.2 Effect adjustment

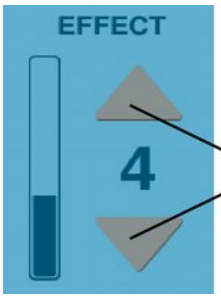
In the cutting, forced coagulation and hybrid coagulation modes, increasing an effect setting results in obtaining a higher degree of haemostasis.

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.

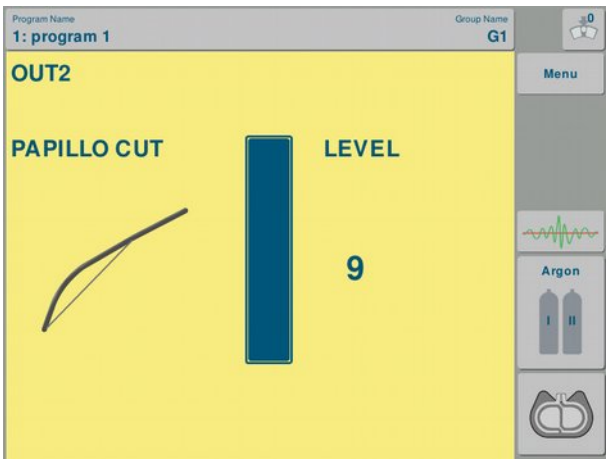


Fig. 15. Effect adjustment by the footswitch.

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. 7, 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.

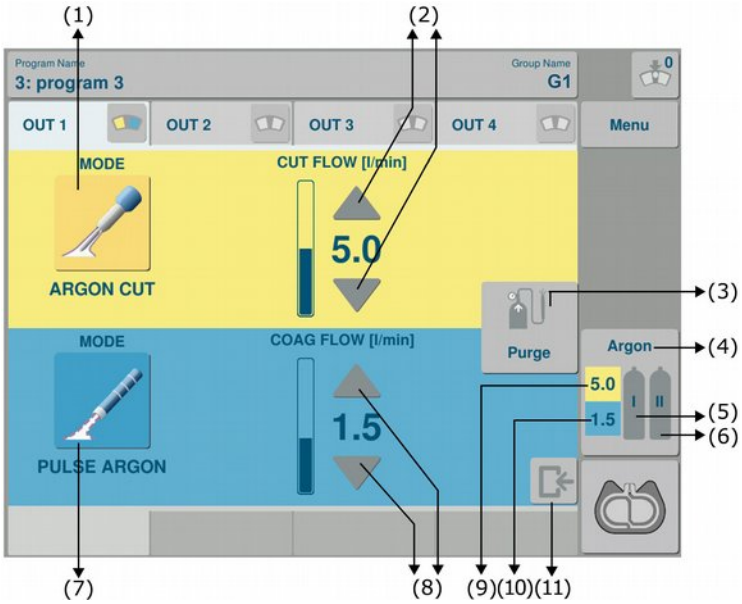


Fig. 16. Argon flow adjustment for argon-enhanced modes.

Fig. 16 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)**

IMPORTANT NOTICE

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. 12 shows how to connect two cylinders.

7.6.3.1 Cautions for using argon-enhanced coagulation

WARNING

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.

CAUTION

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.

WARNING

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.

IMPORTANT NOTICE

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 for 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. Ackermann 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)

WARNING

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

HF 16-2000-700 uses sophisticated monitoring 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 the HF unit.

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

Power Monitor

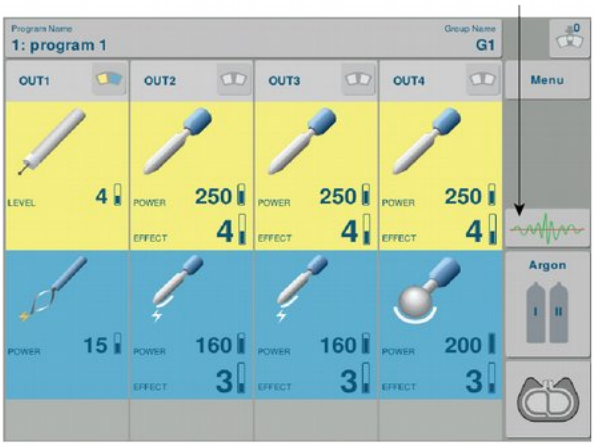


Fig. 17. Power Monitor

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

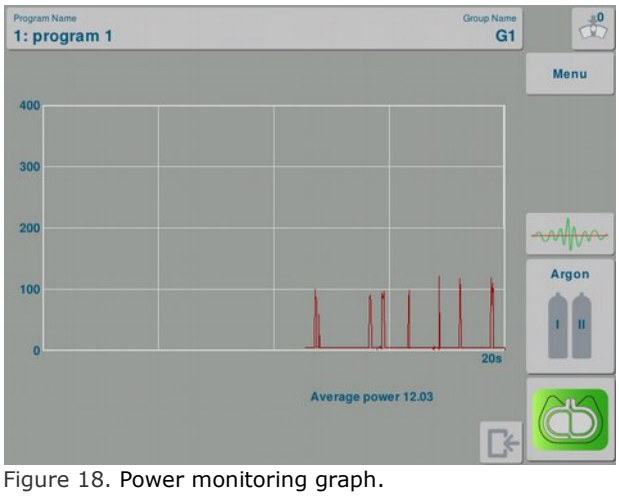


Figure 18. Power monitoring graph.

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

WARNING

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. 4, 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 is run of the system and the connected accessories. 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.

Ackermann devices are equipped with a neutral electrode application monitoring system, referred to as NEM (Neutral Electrode Monitor). NEM System installed in Ackermann devices is designed for use with ACK neutral electrodes with catalogue numbers 16-2000-1212DFL and 16-2000-1212SMFL.

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

Only the use of disposable neutral electrodes with an ACK SAFE belt, allowing for equal distribution of high-frequency current over 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.

IMPORTANT NOTICE

The only disposable neutral electrodes approved by the manufacturer for use with NEM safety system are electrodes with catalogue number 16-2000-1212DFL for adult patients and electrodes 16-2000-1212SMFL for infants below 5kg weight. It is necessary to limit the power to max. 150W while using 16-2000-1212SMFL electrode.

Neutral electrodes other than those mentioned above may not function properly with the NEM neutral electrode safety system.

The manufacturer is not responsible for the use of Ackermann 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 16-2000-1212DFL for adults is selected by default.

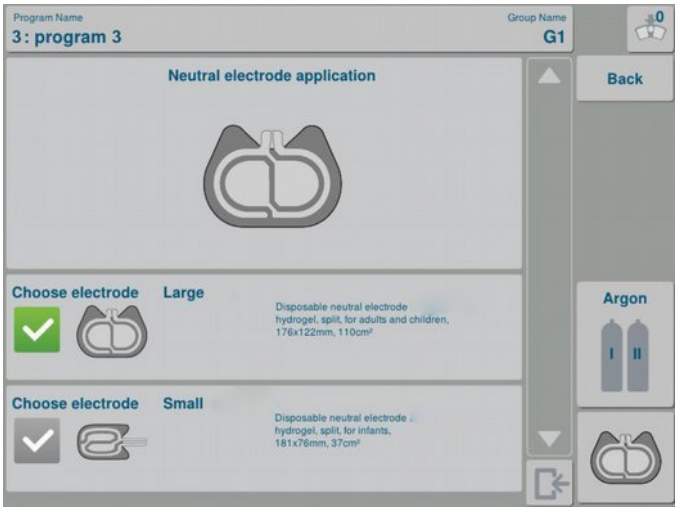
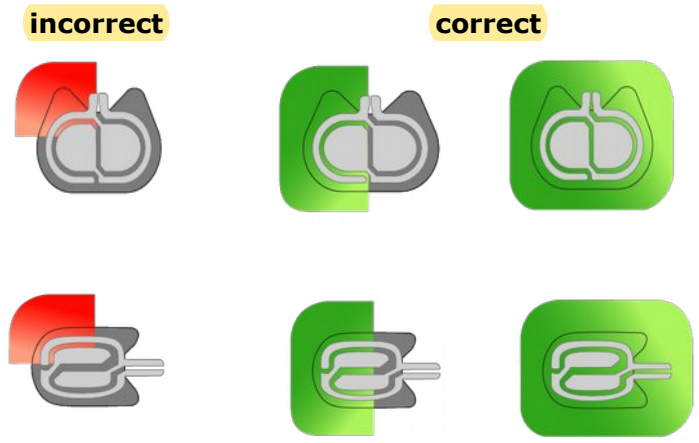


Fig. 19. Neutral electrode selection.

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 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.

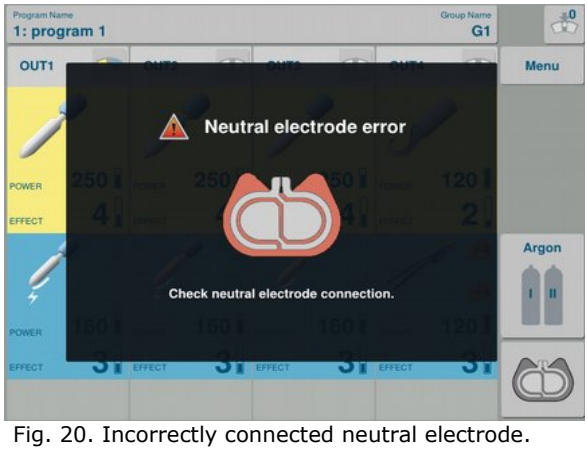


Fig. 20. Incorrectly connected neutral electrode.

IMPORTANT NOTICE

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

8.2.2 Split disposable electrodes

CAUTION

The neutral electrode cannot be modified in any way.

Once attached, the electrode should not be transferred to another location.

Never use electrodes after their expiry date.

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

RECOMMENDATION

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 its longer side faces the operative field. This requirement does not apply to ACK Safe electrodes which have a special construction and can be applied in any position.

If it is necessary to attach the electrode at a different location, 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

CAUTION

When performing surgical procedures:

- which require high power settings (e.g. TURP);

- which present a risk of flooding the neutral electrode with liquids;

- where the staff are not able to monitor the neutral electrode application;

USE OF REUSABLE NEUTRAL ELECTRODES IS NOT RECOMMENDED.

IMPORTANT NOTICE

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. 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.

WARNING

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

CAUTION

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 so by pulling the cable.

Do not, under any circumstances try to repair the neutral electrode yourself.

RECOMMENDATION

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").

WARNING

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

CAUTION

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 so by pulling the cable.

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

RECOMMENDATION

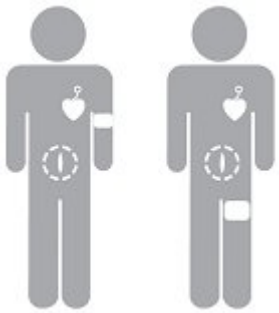
The neutral electrode should be applied so as to adhere to the patient's body with its entire surface.

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 its longer side faces the operative field.

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.

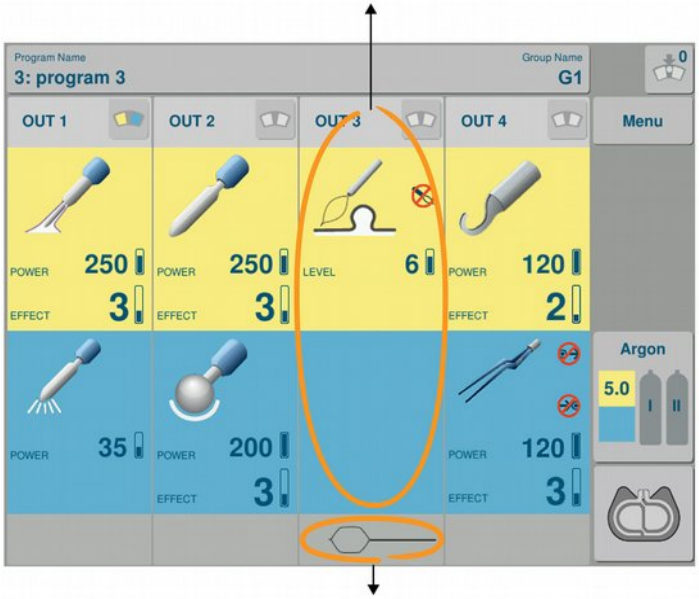


Fig. 21. Operating mode selection – step 1.

If an ASD instrument is connected to an output with the instrument detection system (**Fig. 1 items 1, 3, 4**), 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).

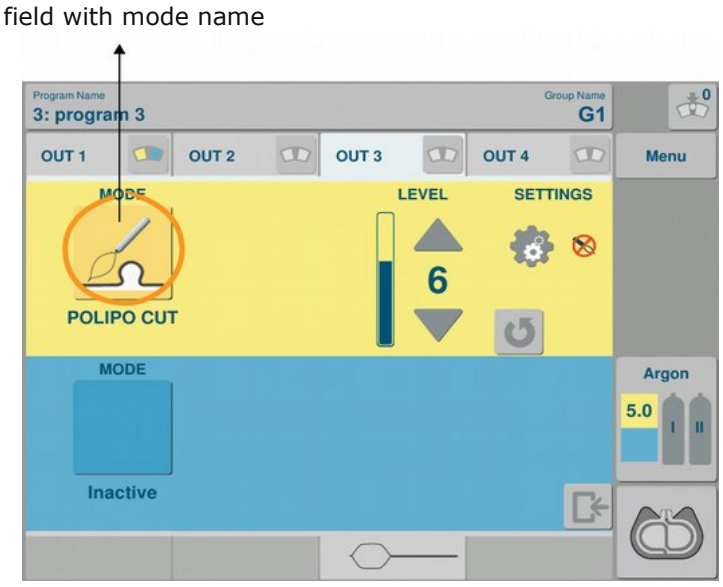


Fig. 22. Operating mode selection – step 2.

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.

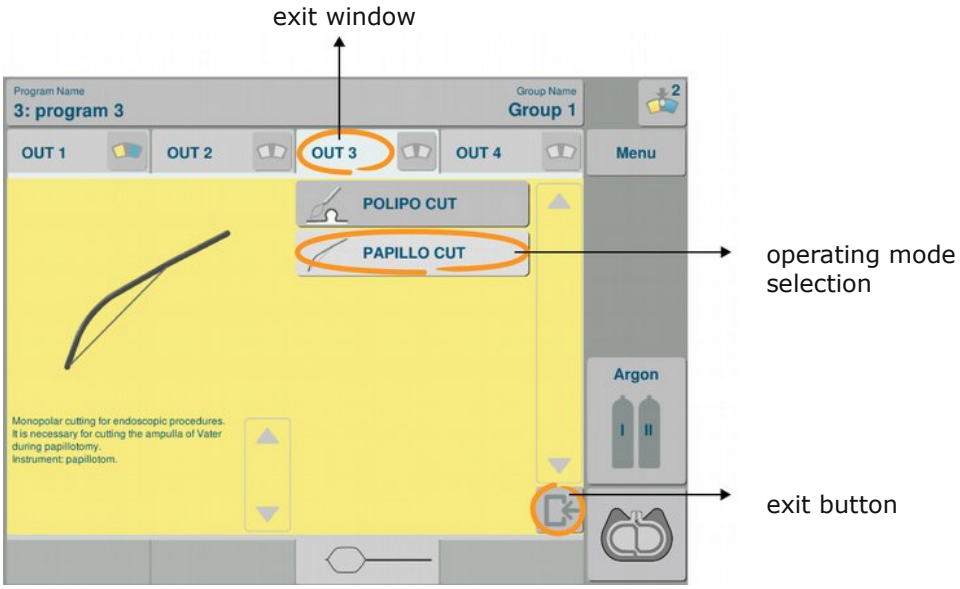


Fig. 23. Operating mode selection – step 3.

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.

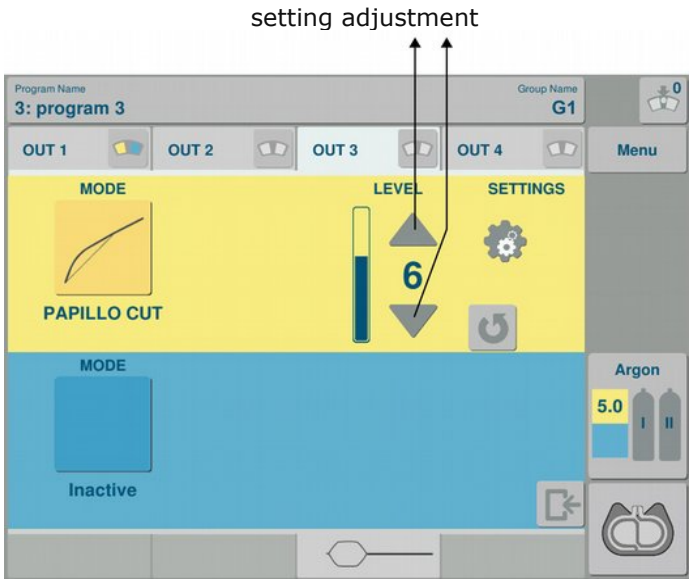
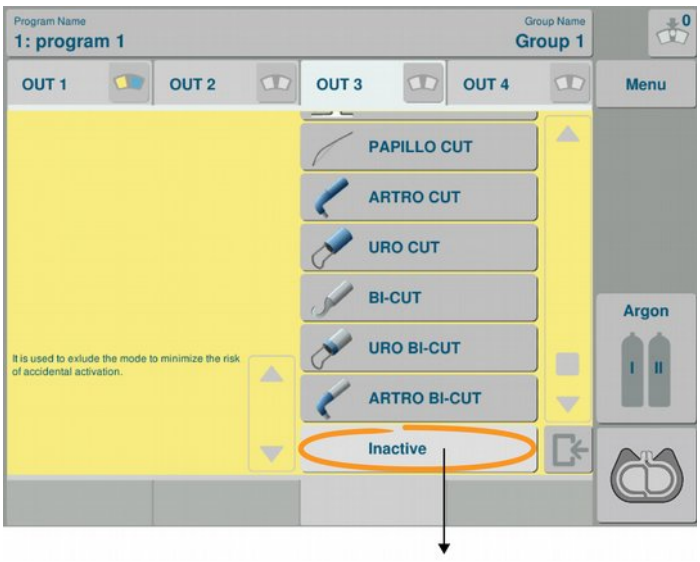


Fig 24. Operating mode selection – step 4.

IMPORTANT NOTICE

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

Fig. 25. List o with an inactive mode.

Panel appearance with an inactive mode:

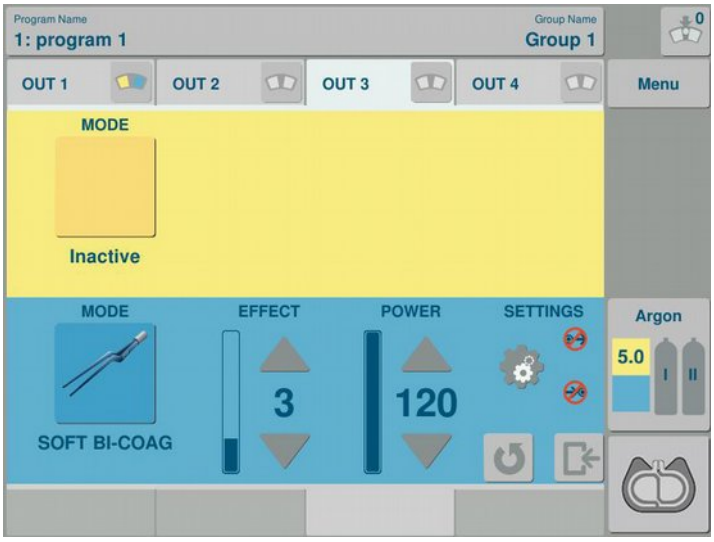


Fig. 26. Panel with an inactive mode.

8.4 HF 16-2000-700 system activation methods

The HF 16-2000-700 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. 4, 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. 6, items 1, 2, 3, 4).**

b) socket for footswitch which is supporting one of output - assigned by default to the third ASD 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. 27** contains the screen in which the third output is activated using the footswitch.

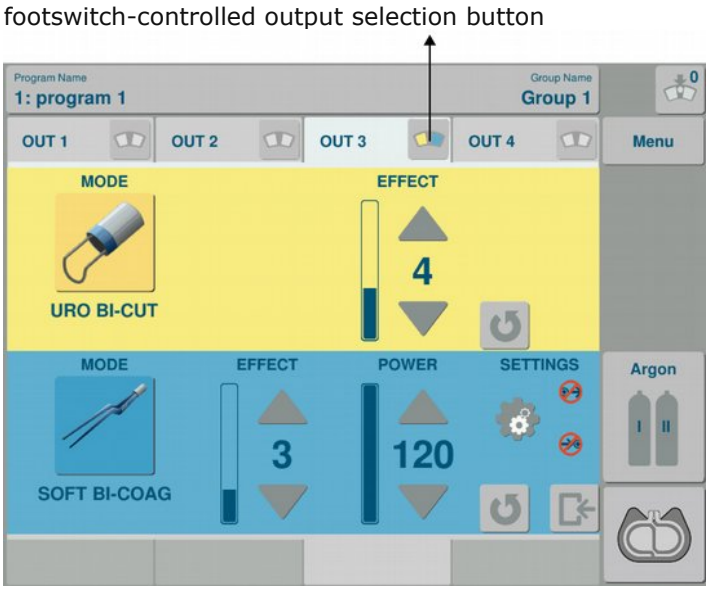


Fig 27. Activation of the third output using the footswitch.

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 HF 16-2000-700 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.

DUAL CUT Monopolar cut in simultaneous mode.

Cutting with 9 different effects of haemostasis. Enables the activation of two monopolar handles simultaneously, therefore two operators can perform action at the same time.
Specialistic mode, applied i.e. in cardiac surgery.

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

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, 2, 3, 4** – for HF 16-2000-700 system Version I), 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 for monopolar cutting are set in the yellow part of the panel, corresponding to the currently used output.

IMPORTANT NOTICE

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

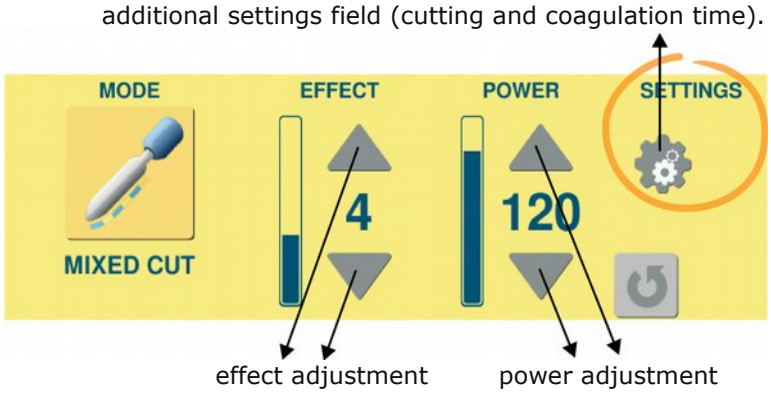
Intended use

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.

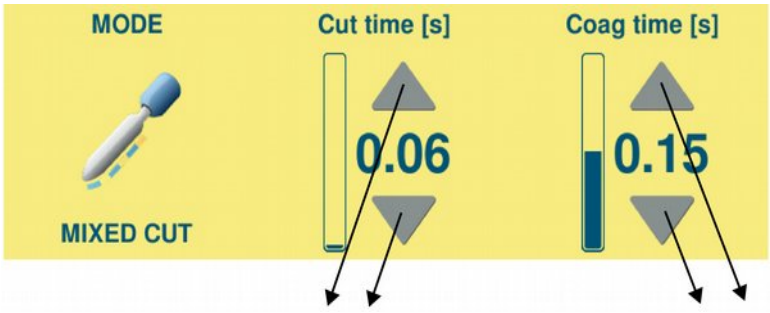
Power and effect settings

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:



adjustment of cutting time in a cycle

adjustment of coagulation time in a cycle

Suggested settings for the MIXED CUT mode:

Effects: 4

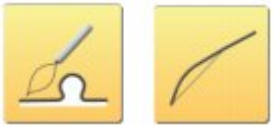
Power: 120 W

Cutting time: 0.06 s

Coagulation time: 0.15 s

8.5.2 Polypectomy and Papillotomy

Intended use:

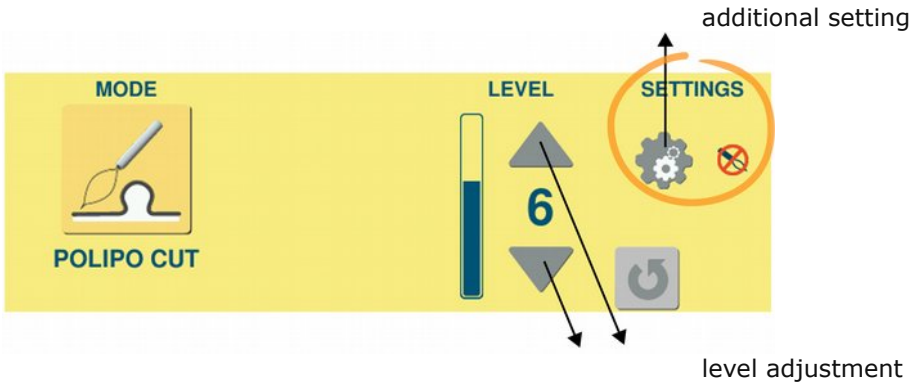


Special cutting modes for endoscopic procedures. In this mode, the coagulation and cutting are performed alternately, enabling tissue coagulation and cutting with an endoscopic instrument. The typical applications include polypectomy and papillotomy.

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

Cutting level and percentage setting

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



IMPORTANT NOTICE

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.

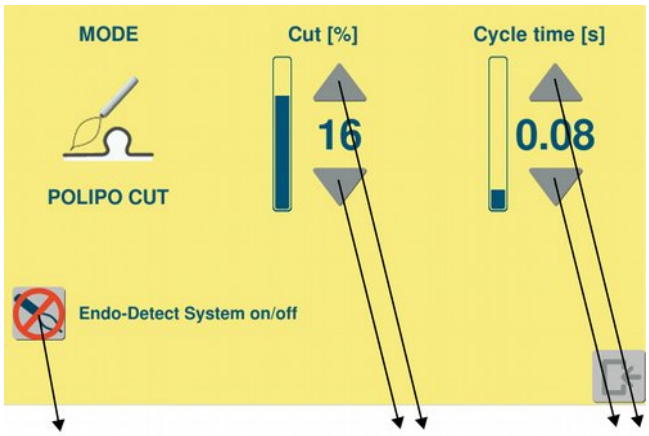
The power settings in this mode are selected automatically for each level, to obtain a repeatable endoscopic cutting effect, regardless of tissue parameters.

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

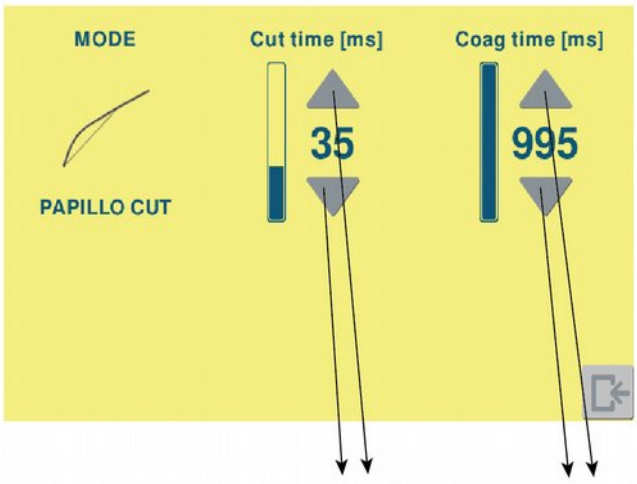
To adjust the duration of one cycle, click the additional settings icon. To change the cycle time settings, touch the keys on the scale (indicated by arrows).



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.

WARNING

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.

CAUTION

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

WARNING

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 HF 16-2000-700 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.

DUAL COAG Monopolar coagulation in simultaneous mode

Monopolar contact coagulation with 9 different effects, enables fast and effective coagulation of bleeding area. Enables the activation of two monopolar handles simultaneously therefore two operators can perform action at the same time.

Specialistic mode, applied i.e. in cardiac surgery.

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

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 (ASD) and output II (monopolar or ASD, 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 (ASD) and output II (monopolar or ASD, 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 (ASD) and output II (monopolar or ASD, 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 for monopolar coagulation are set in the blue part of the panel, corresponding to the currently used output.

IMPORTANT NOTICE

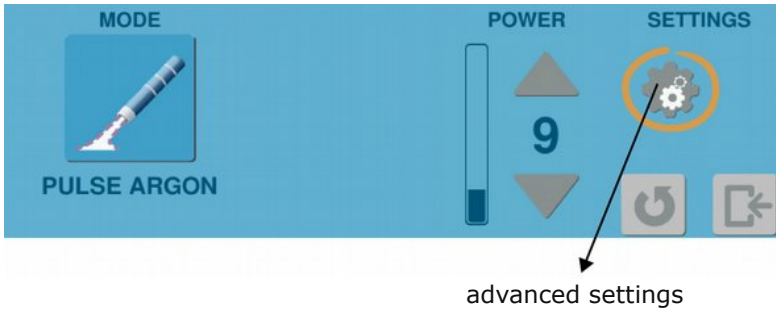
In monopolar coagulation mode, the system is activated using the blue button in the electrode handle, or the blue button of the footswitch.

8.6.2 Argon-enhanced pulse coagulation

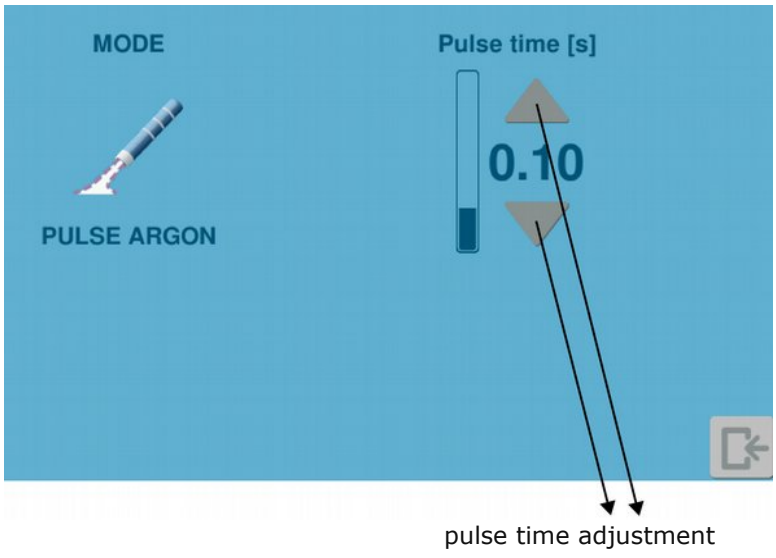
Monopolar pulse coagulation is a modified argon-enhanced coagulation. It is used whenever there is a risk of perforation and a very gentle coagulation and precise dosage is required, for instance in gastroenterology.

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.



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

Suggested settings for the PULSE ARGON mode:

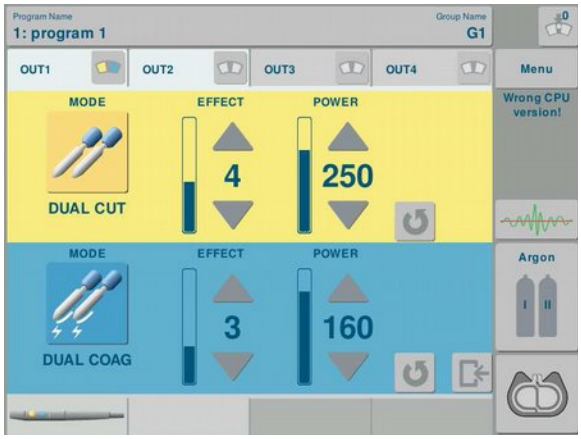
Power:	20
Pulse time:	0.1 s
Argon flow:	1.5 l/min

8.7 SIMULTANEOUS WORK (optional)

Simultaneous work means that two monopolar handles can be activated simultaneously. This option allows two operators to perform CUTTING or COAGULATION at the same time.

In HF 16-2000-700 unit this function is available in two modes:

DUAL CUT and DUAL COAG.



DUAL CUT = MONO CUT - 9 effects, max output power 350 W.

DUAL COAG = FORCED COAG - 9 effects, max output power 200 W.

DUAL CUT and DUAL COAG modes are available on 1st and 2nd socket of unit, i.e. OUT1 (ASD) and OUT2 (ASD or 3-pin monopolar).

To make the simultaneous work modes appear in the menu, it is neccessary to activate the OUT1. ASD socket must be connected with monopolar handle 322-14S, 327-14S, 215-23S/25S, 218-23S/25S.

In simultaneous work mode two instruments can be used to perform the same electrosurgical procedure i.e. cutting or coagulation. Both instruments are using the same output settings so the two operators are able to perform cutting or coagulation. The parametrs for both instruments are set automatically.

If the second operator would choose a different mode than the first operator, the HF 16-2000-700 informs user that desired mode is unavailable at the moment. This action doesn't affect or disturb the work of first operator.

AUTOMATIC POWER LEVEL ADJUSTMENT

When using simultaneous modes the power level is set automatically for both instruments to obtain the desired effect. The power output parameter shown on the screen is the upper limit that can be provided by HF 16-2000-700 unit. The actual and average level provided by unit can be displayed on power screen when the performed action is finished.

8.8 Bipolar cutting

Depending on software version, the HF 16-2000-700 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.

HYSTERO BI-CUT Bipolar cut for gynaecological procedures (hysteroscopy) in conductive liquids: saline solution or Ringer's solution..
Instrument: bipolar histeroscope/resectoscope - loop electrode.

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.

IMPORTANT NOTICE

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

8.9 Bipolar coagulation

Depending on software version, the HF 16-2000-700 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 ASD 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.

HYSTERO BI-COAG Bipolar coagulation for gynaecological procedures (hysteroscopy) in conductive liquids: saline solution or Ringer's solution.

Instrument: bipolar histeroscope/resectoscope - loop electrode or ball.

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

Bipolar cutting can be activated using both footswitch sockets.

IMPORTANT NOTICE

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.

8.9.1 The AutoStart and AutoStop functions in bipolar coagulation

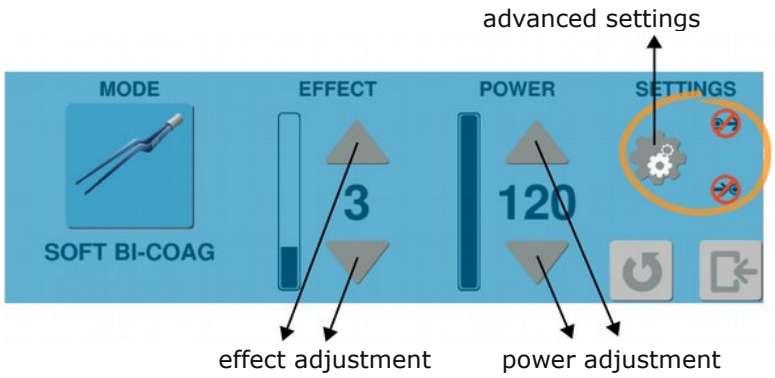
The AutoStart and AutoStop functions are available for low-voltage bipolar coagulation (SOFT BI-COAG mode only). High-voltage bipolar coagulation (FORCED BI-COAG) allows to set the AutoStop time.

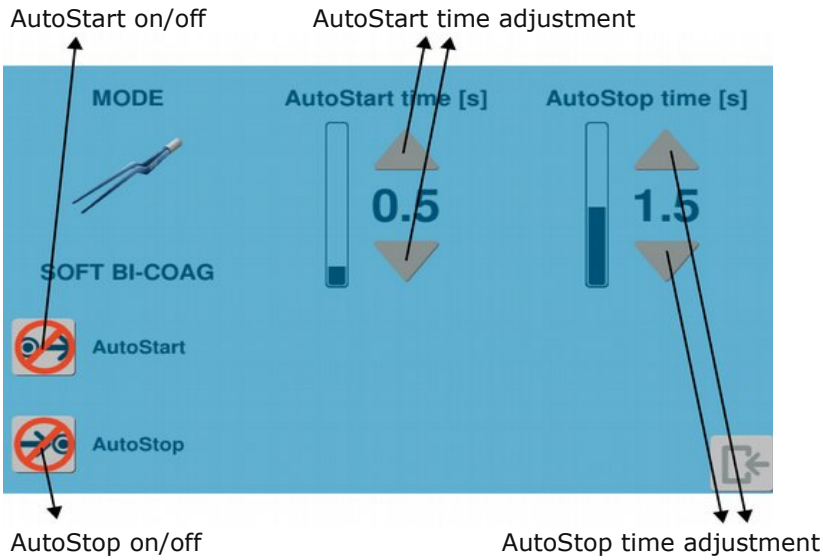
Power and effect settings

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.

8.10 VesSeal

Depending on software version, the HF 16-2000-700 device can also offer a mode for sealing large blood vessels.

VesSeal 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 VesSeal 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 VesSeal

In the VesSeal 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:

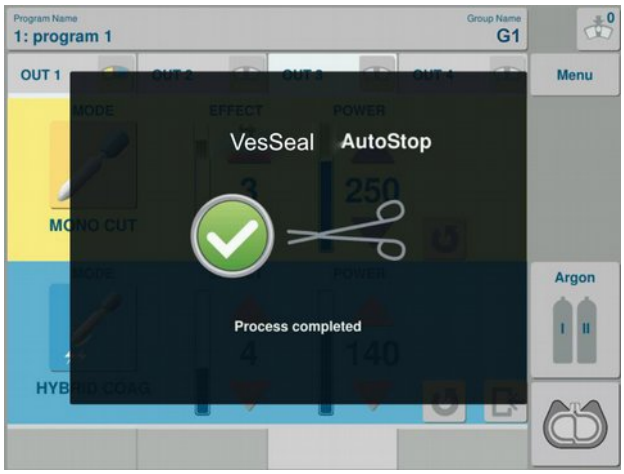


Figure 28. Message: AutoStop – cycle completed.

Exceeding the allowed VesSeal time

This mode has an additional function informing the used about exceeding the allowed time of VesSeal 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.

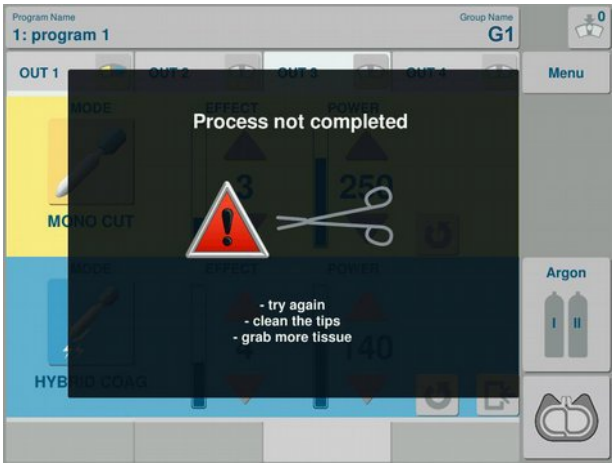


Figure 29. Message: The allowed VesSeal time has been exceeded.

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:

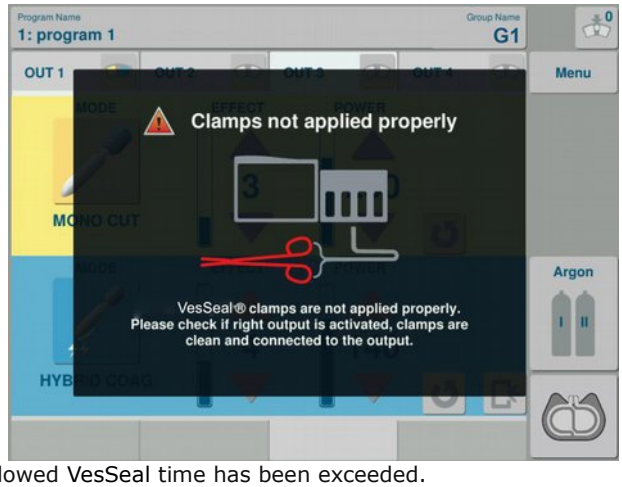


Figure 30. Message: The allowed VesSeal time has been exceeded.

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.

8.11 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).

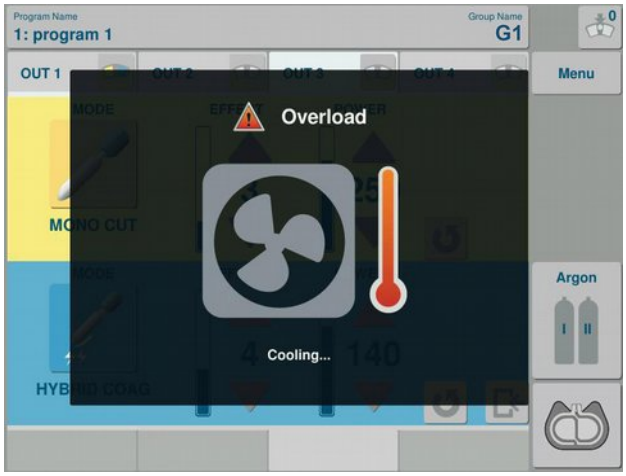


Figure 31. Message: System cooling.

WARNING

Do not restrict system cooling during operation. This means 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 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.

8.12 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 32. Program management bar.

A window for program management will appear on the screen.

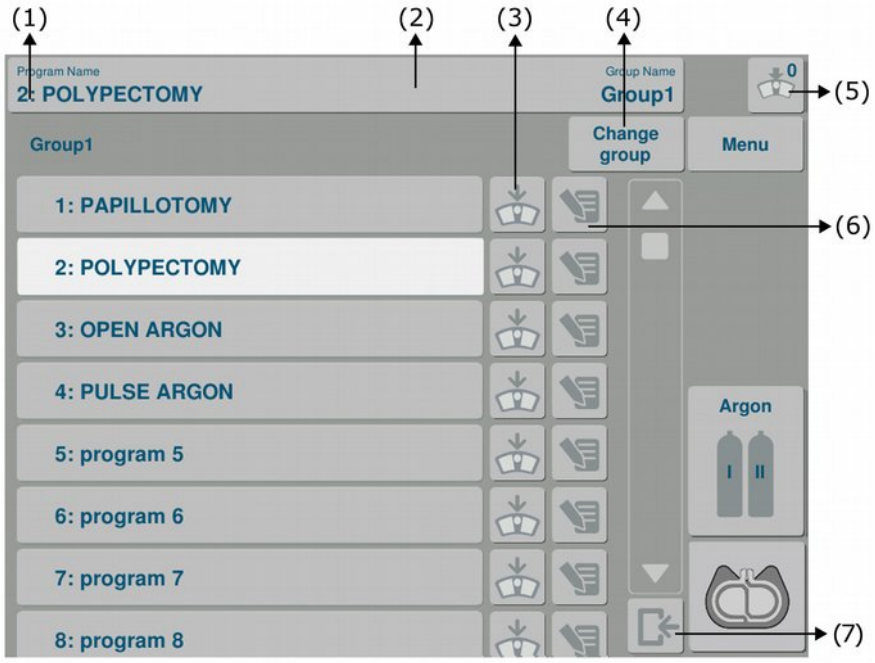


Figure 33. Program management window.

The program management windows contains **(Fig. 33)**:

- 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.

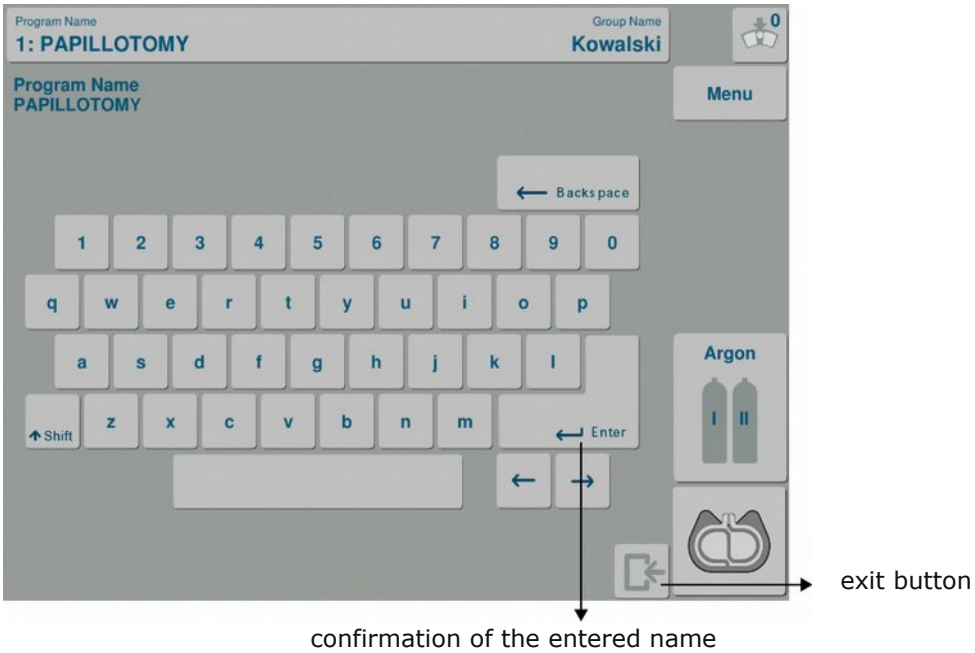


Figure 34. Giving names to programs and groups.

The MultiSwitch button at the program name **(Fig. 33, 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. 33, item 4)**. A group can be changed similarly to program change.

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

8.12.1 Copying of programs

To copy the program click on the touch panel the program management bar **(Fig. 32).** Then choose a program from the list to copy it, click the edit name button and the Copy icon **(Fig. 34).**
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. 35)**. The copied program can be saved under a new name.

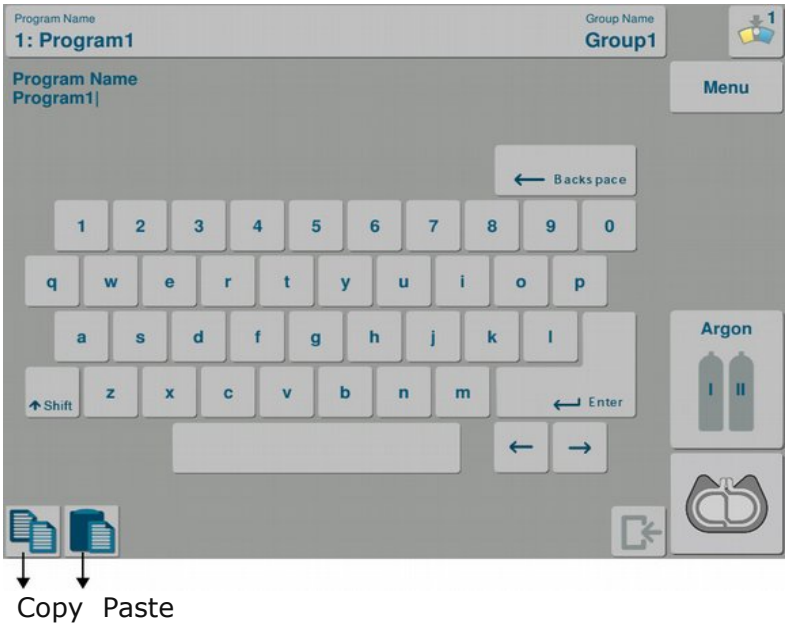


Figure 35. Save the copied program.

You can copy programs also between groups.

8.12.2 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. 33 item 5)**. The number of the currently selected program is next to the program name **(Fig. 33, 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.

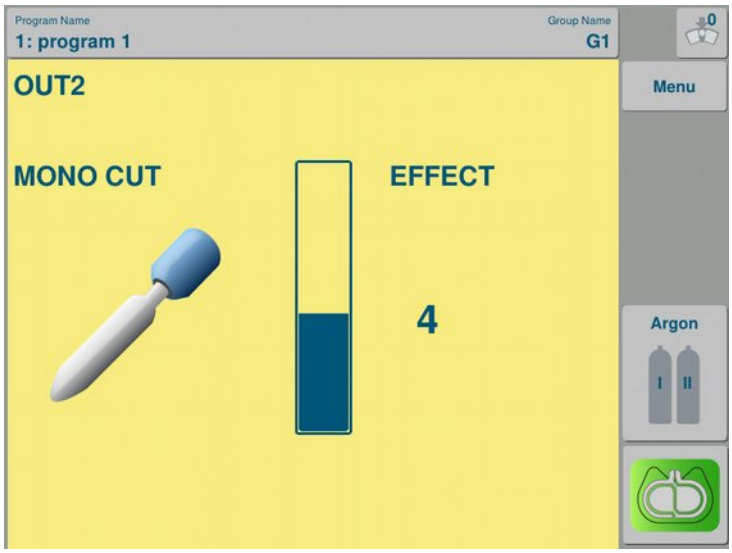


Figure 36. Effect adjustment using the footswitch.

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 37. Program change using the MultiSwitch button.

8.13 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:

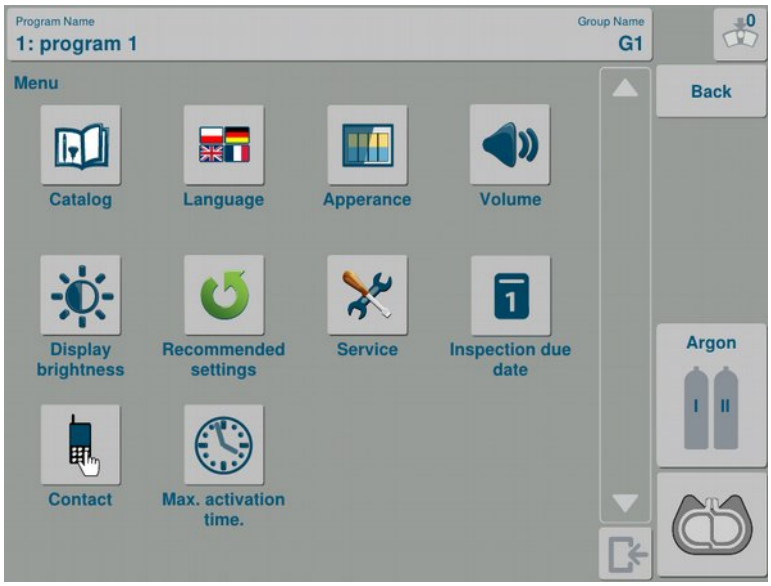


Figure 38. Menu content.

8.13.1 Catalogue

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

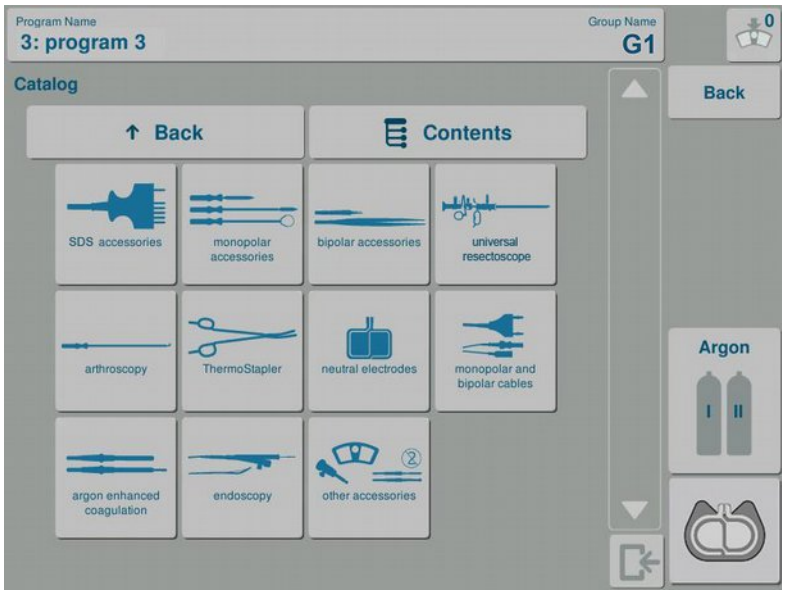


Figure 39. Catalogue of accessories.

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

8.13.2 Change of text and message language

The HF 16-2000-700 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 40. Language selection for texts and messages.

8.13.3 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 41. Style change.

8.13.4 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.

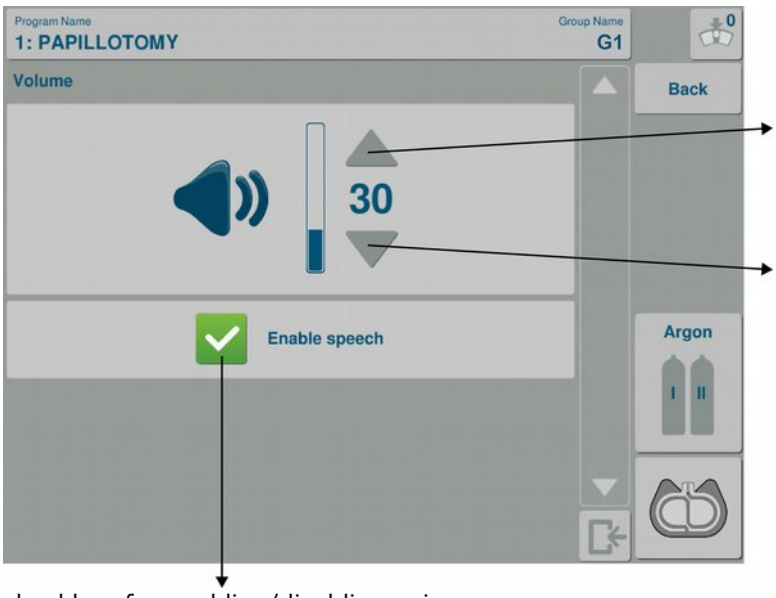


Figure 42. Volume adjustment.

IMPORTANT NOTICE

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.

8.13.5 Screen brightness change

The HF 16-2000-700 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.

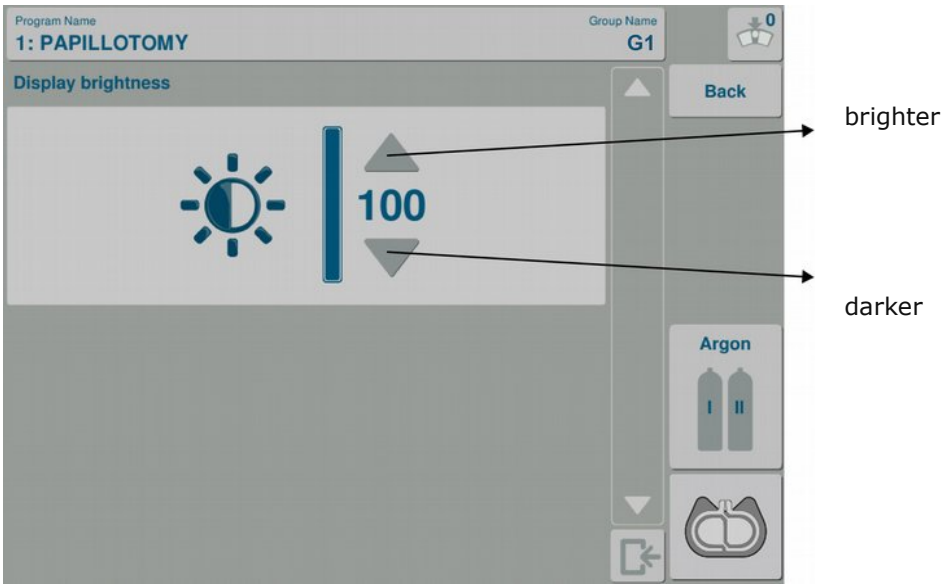


Figure 43. Screen brightness adjustment.

8.13.6 Service

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

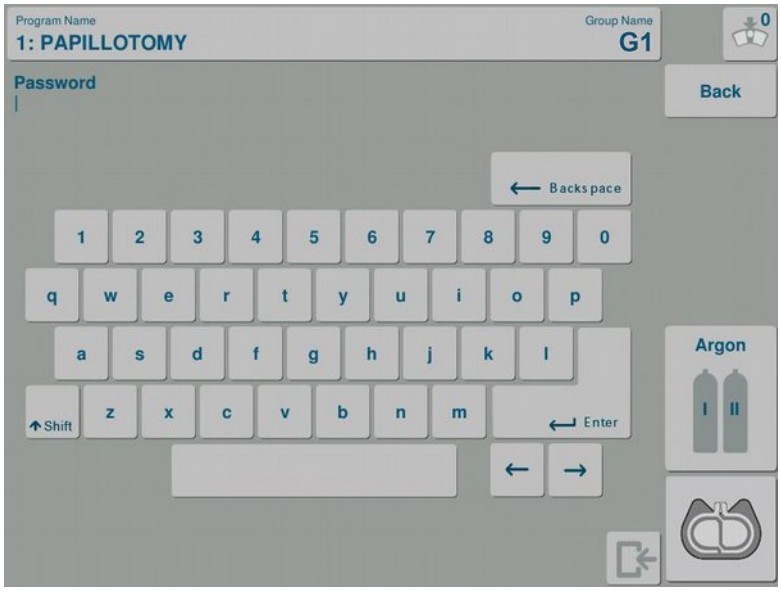
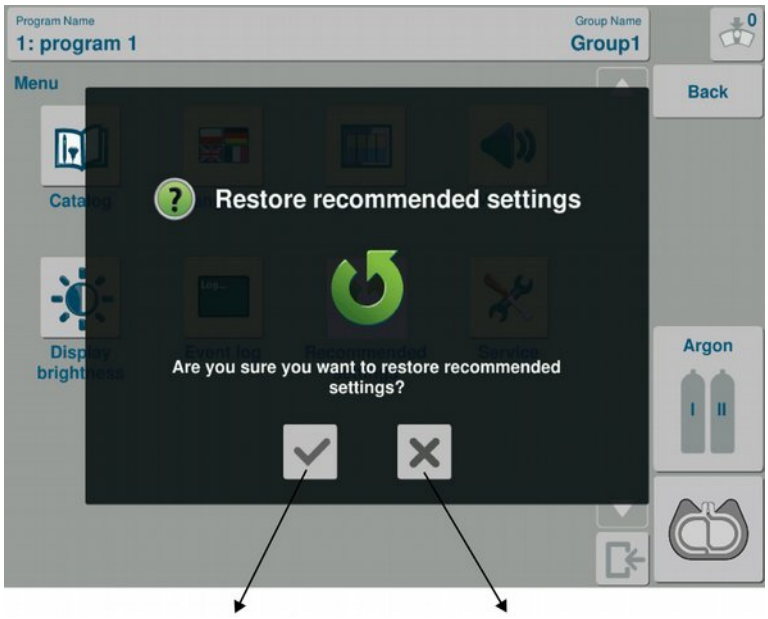


Figure 44. Access to service settings.

8.13.7 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 45. Restoring the suggested settings.

8.13.8 Inspection due date

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

Figure 46. Inspection due date.

8.13.9 Contact

This icon contains contact details for the manufacturer's address.

Figure 47. Contact.

8.13.10 Maximum activation time

The HF 16-2000-700 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 48. Maximum activation time

8.14 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. 4, 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

9.1 The most common errors during system operation

Table 4. Possible errors during system operation

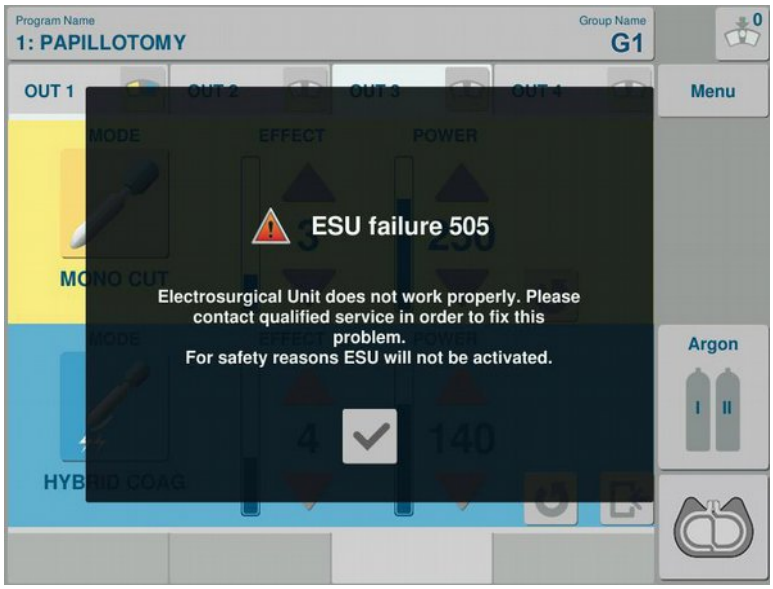
No.	Error type	Signalling	Troubleshooting
1	The touchscreen remains dark after turning the system on	Sound, visual signalling using a LED near the output, LED next to the start button is on, type not selected yet.	Wait about 30 seconds when the system performs the internal test and accessories test.
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. Electrode 812-83H was selected.	Use a tool which allows the use of a higher power.

9.2 List of errors and messages

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

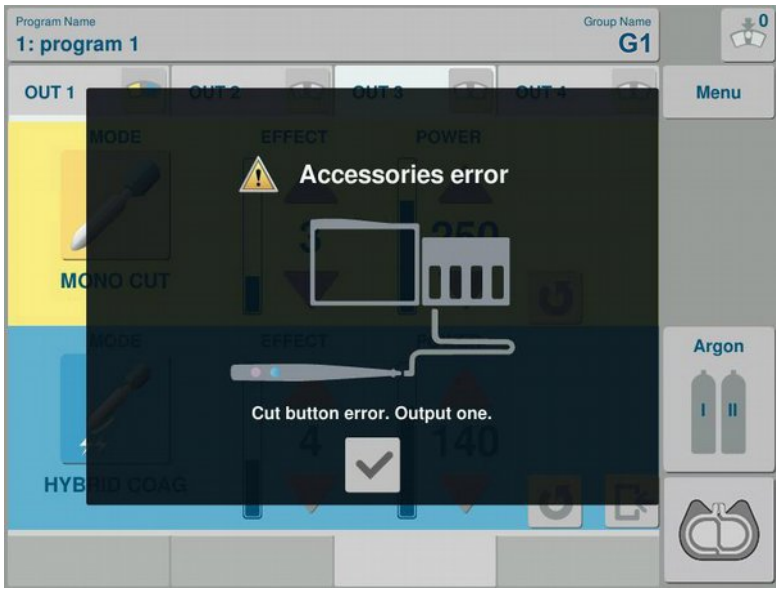
Some messages must be acknowledged by selecting the checkbox: 

UNIT ERROR 505



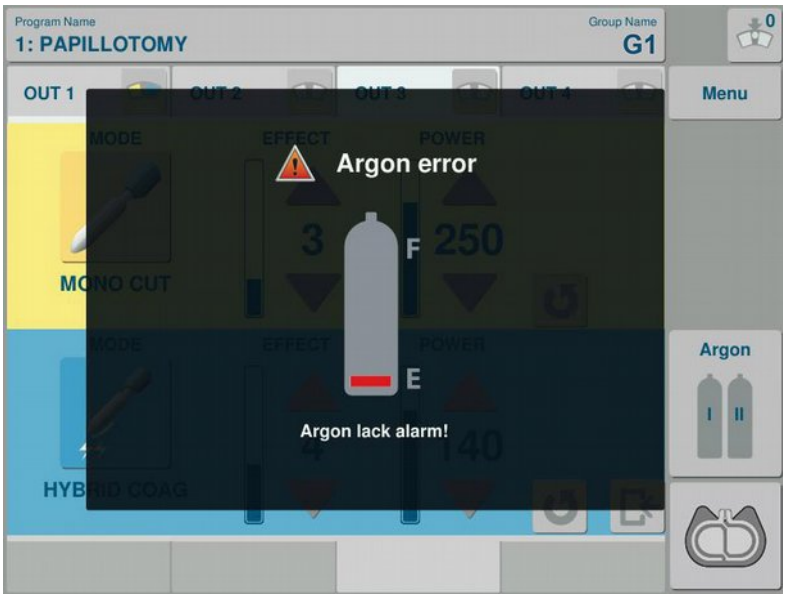
The system has locked for safety reasons.
Contact the service.

ACCESSORY ERROR



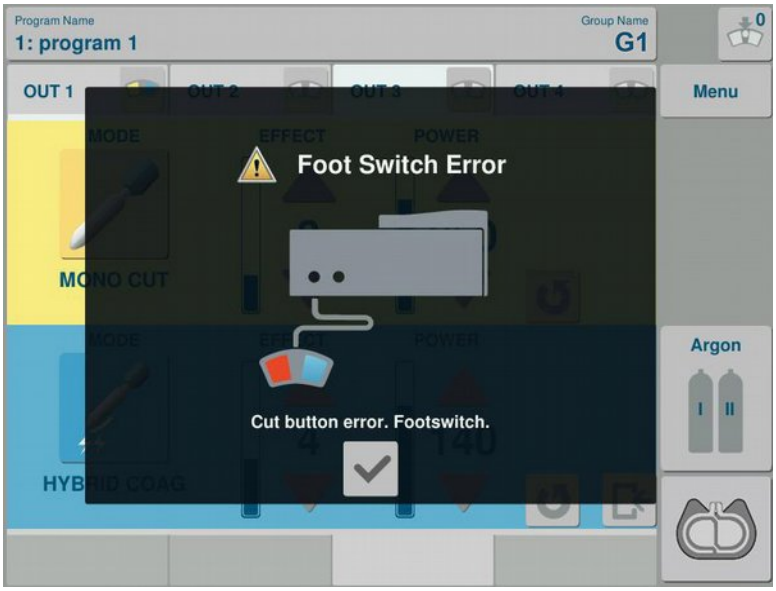
Shorted switch on the handle. Please release the handle button. If the button is released and the system continues to display the message, the accessory is damaged. Connect a functioning accessory.

ARGON ERROR



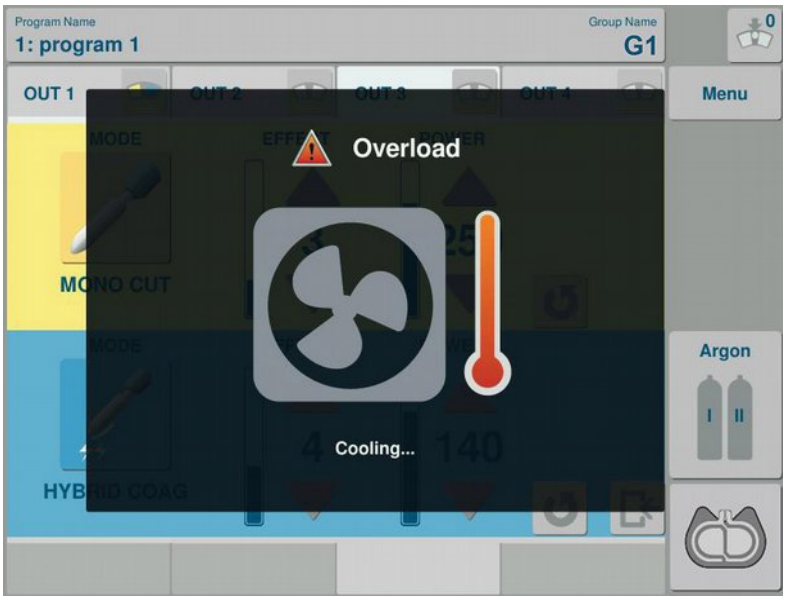
A message informing about the lack of argon. Refill the argon.

FOOTSWITCH ERROR



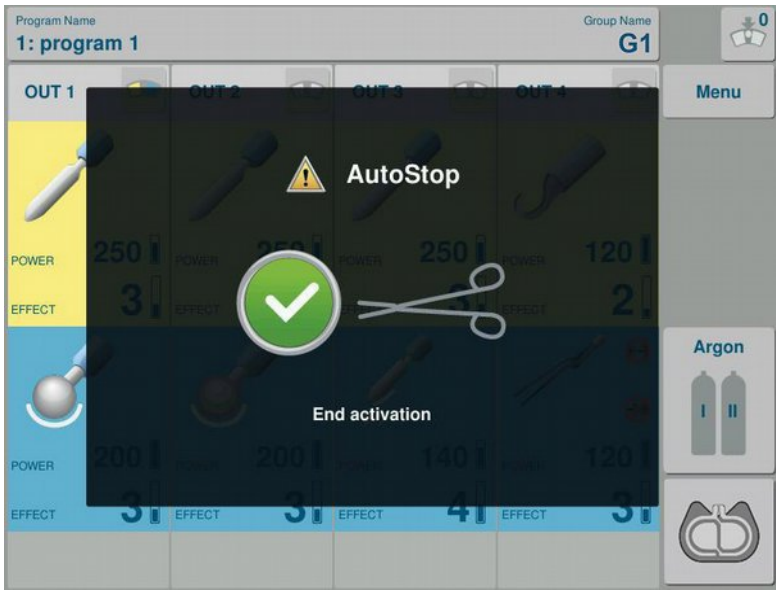
Shorted button on the footswitch. Please release the footswitch button. If the message is still displayed, the cutting button on the footswitch is damaged. Connect a functioning footswitch.

SYSTEM COOLING



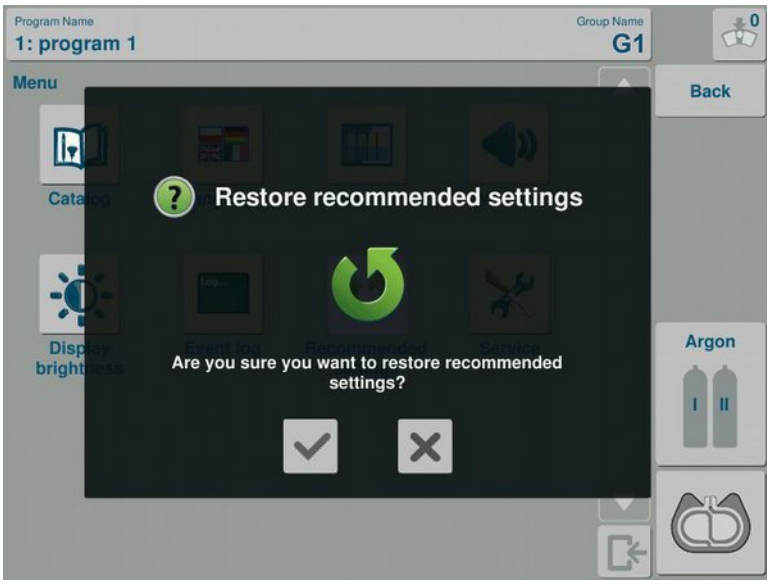
The system is cooled to protect it from overheating (see section 8.9). The system forces an interruption in the procedure until the indicator turns off (about 30 seconds).

AUTOSTOP



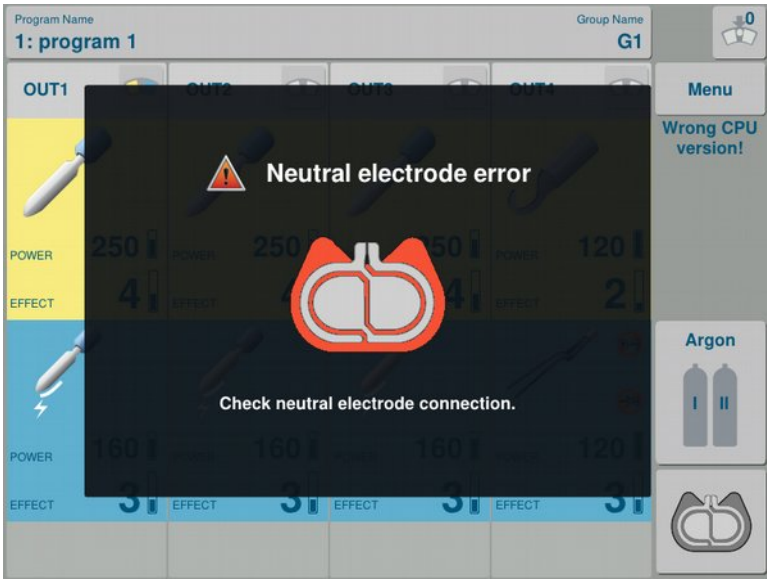
The message informs that AutoStop has stopped working.

RESTORING THE SUGGESTED SETTINGS



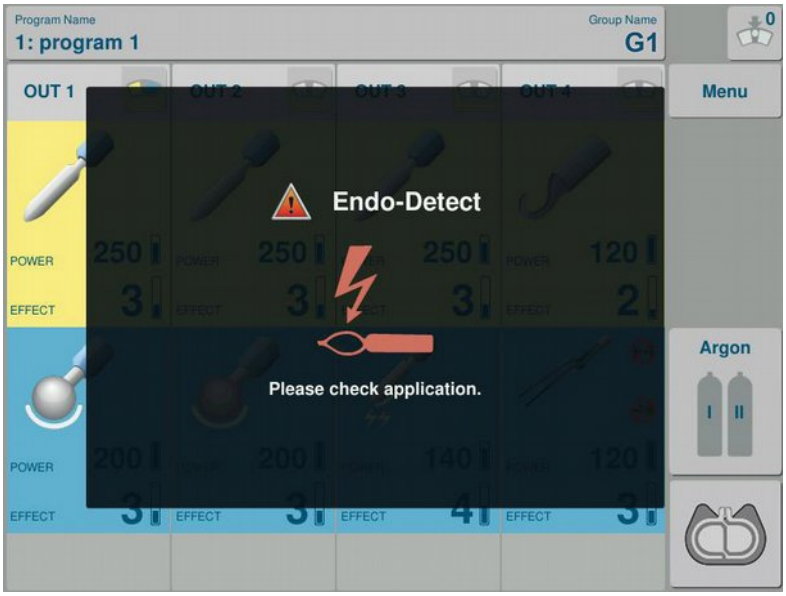
Selecting the appropriate checkbox on the touch panel cancels the set modes in the programs and groups and returns to the factory settings in the entire system.

NEUTRAL ELECTRODE APPLICATION



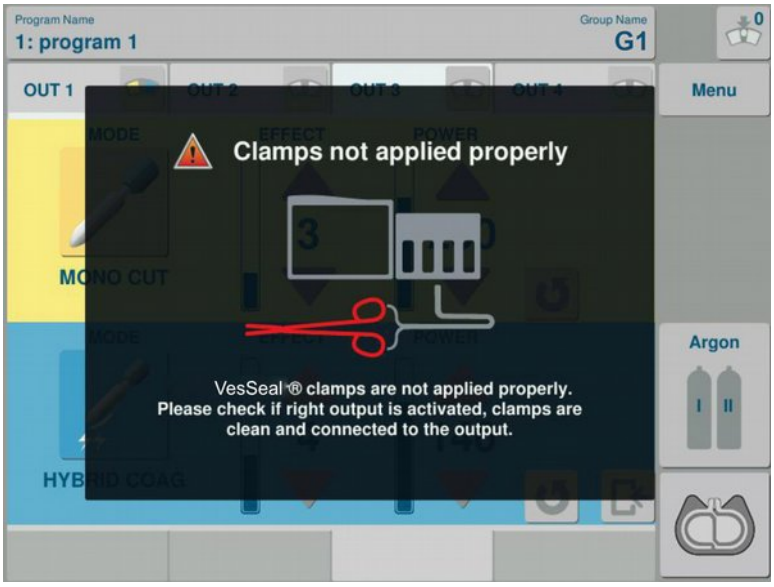
Check the neutral electrode connection. For additional information, see sections 8.2.1

ENDO-DETECT



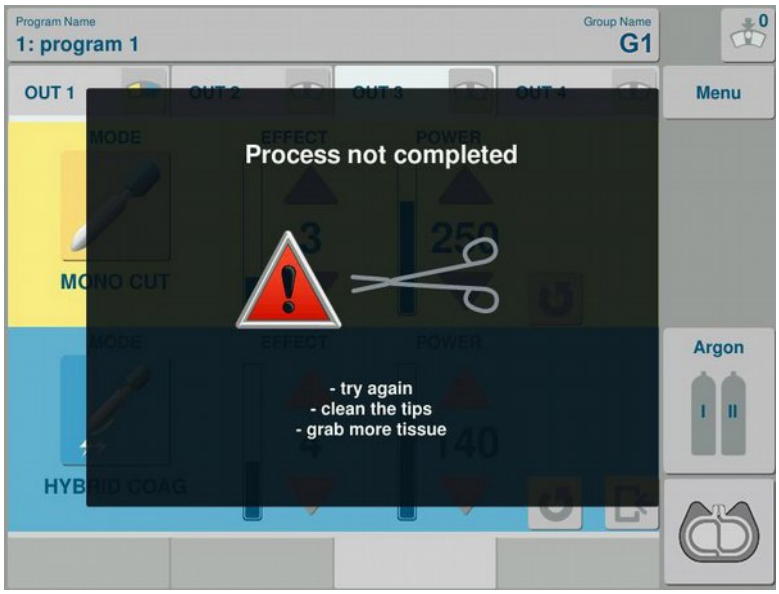
Closed loop detection message, informing that a non-closed loop has been detected. Please check loop application.

CLAMP APPLIED INCORRECT



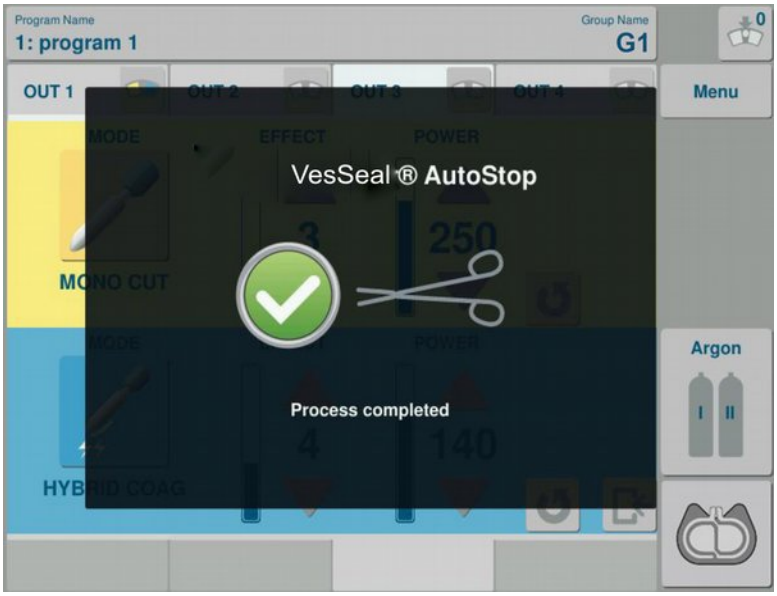
The VesSeal clamp has not been applied correctly. Please check if the correct output is activated, if the forceps are clean and if they are assigned to the correct output.

EXCEEDING THE ALLOWED VesSeal TIME



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

VesSeal AUTOSTOP

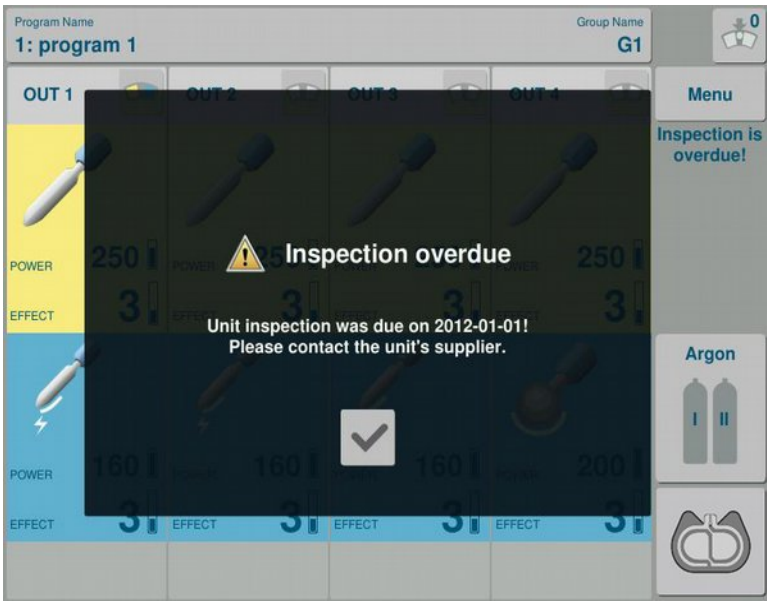


A message informing about the correct termination of the VesSeal work.

BIPOLAR ACCESSORY ERROR

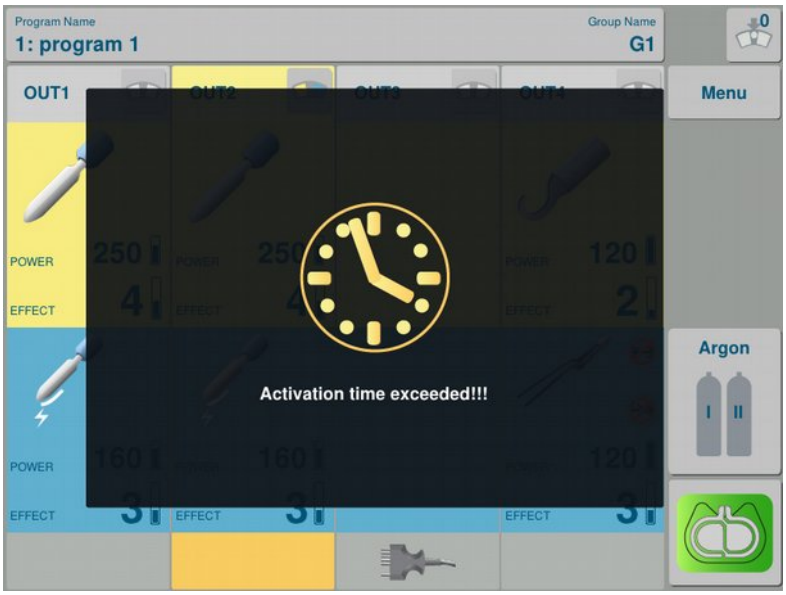
The bipolar instrument is shorted. Please open the instrument branches.

INSPECTION OVERDUE



Inspection overdue. Please contact our 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.

SIMULTANEOUS WORK

When second of two operators choose a different mode than the mode already activated by the first operator, the **HF 16-2000-700** will inform user that desired mode is unavailable at the moment. This action doesn't affect or disturb the work of first operator.

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) correctly applying 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, a complete and ready-to-use substitute electrosurgical system should be prepared.

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:

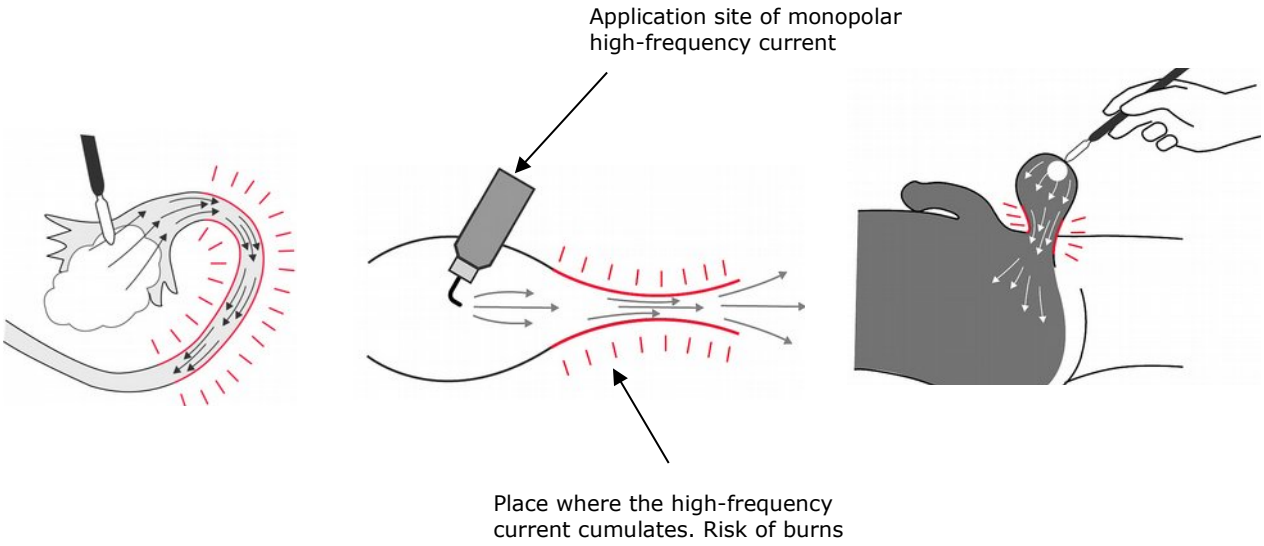
- they do not touch the patient
- they are not intertwined with other cables

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 accidentally touching 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 in 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 anaesthetics or oxidising gases such as nitrous oxide (N_2O) and oxygen, unless those agents are aspirated away.

10.12 In order to remove gases and increase the visibility during the operation, use of smoke-plume extraction is recommended, where removal is not possible 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 present 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 for the heart pacemaker and a cardiac surgeon. Check the pacemaker thoroughly after the procedure. Use of electrosurgery systems on patients with heart pacemakers is not permitted 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 commonly-used "through-the-instrument" coagulation technique should only be applied when using properly insulated forceps. These 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 at an appropriate distance from the fingers, metal parts of endoscope optics, fiberscopes.

10.19 When performing endoscopic procedures:

IMPORTANT NOTICE

- maintain the active part of the electrode in the operator's field of vision to avoid accidental burns 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 In designing electrosurgical generators, Ackermann 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 Ackermann 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 emission from the device itself is not significant.

When not activated, generators do not emit high-frequency power. As field distribution depends on the specific workplace, system placement and wiring, 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 event 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.

IMPORTANT NOTICE

A periodic inspection is required once a year. The manufacturer only admits the use of systems where 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, servicing or repair by unauthorized services.

The HF 16-2000-700 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 49. Inspection due soon.

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

The user is obliged to ensure that technical inspections recommended by the manufacturer are performed, which should be undertaken 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, in accordance with the applicable legislation, the responsibility is transferred to the user.
In order to ensure correct operation of the device, installation and staff training should be performed by an authorised representative of Ackermann. Each participant of such training receives a certificate which entitles him/her to use Ackermann electrosurgical unit. These procedures are mandatory.

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

Service:

Ackermann Instrumente GmbH

Eisenbahnstr. 65-67, 78604 Rietheim-Weilheim, Germany

Tel. +49 7461 966 17-0, Fax. +49 7461 966 1770

E-Mail: info@ackermanninstrumente.de

IMPORTANT NOTICE

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 period of time, it should be allowed to reach room temperature before it is started.

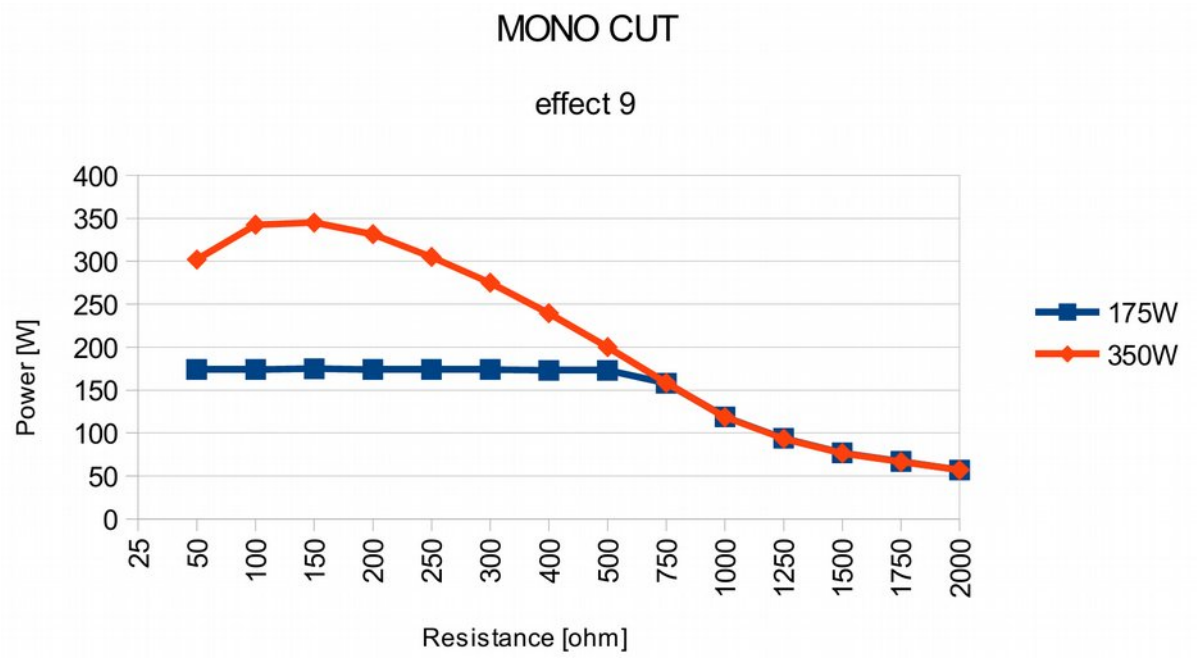
VOLTAGE FOR MODES

MODE	VOLTAGE
MONO CUT	1200 Vp
PRECISE CUT	800 Vp
MIXED CUT	400 Vp
MUCO CUT	760 Vp
POLIPO CUT	500 Vp
PAPILLO CUT	1.2 kVp
ARTRO CUT	700 Vp
URO CUT	700 Vp
HYSTERO CUT	700 Vp
ARGON CUT	1200 Vp
DUAL CUT	1200 Vp
BI-CUT	1000 Vp
URO BI-CUT	500 Vp
HYSTERO BI-CUT	500 Vp
ARTRO BI-CUT	450 Vp
SOFT COAG	225 Vp
FORCED COAG	1.5 kVp
HYBRID COAG	1.7 kVp
SPRAY COAG	5.7 kVp
ENDO SPRAY	2.6 Vkp
URO COAG	1.5 kVp
ARTRO COAG	1.5 kVp
HYSTERO COAG	1.5 kVp
DUAL COAG	1.5 kVp
STANDARD ARGON	5.7 kVp
ENDO ARGON	5.7 kVp
PULSE ARGON	5.7 kVp
SOFT BI-COAG	225 Vp
FORCED BI-COAG	1 kVp
URO BI-COAG	175 Vp
HYSTERO BI-COAG	175 Vp
ARTRO BI-COAG	175 Vp
SCISS BI-COAG	175 Vp
VesSeal	225 Vp

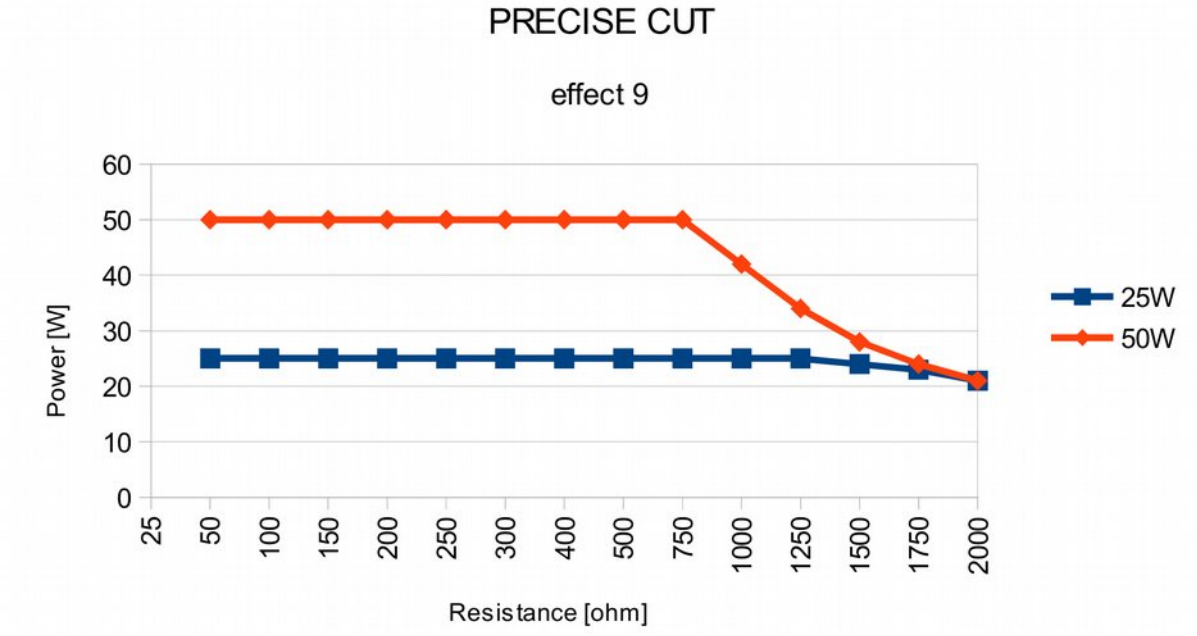
OUTPUT GRAPHS

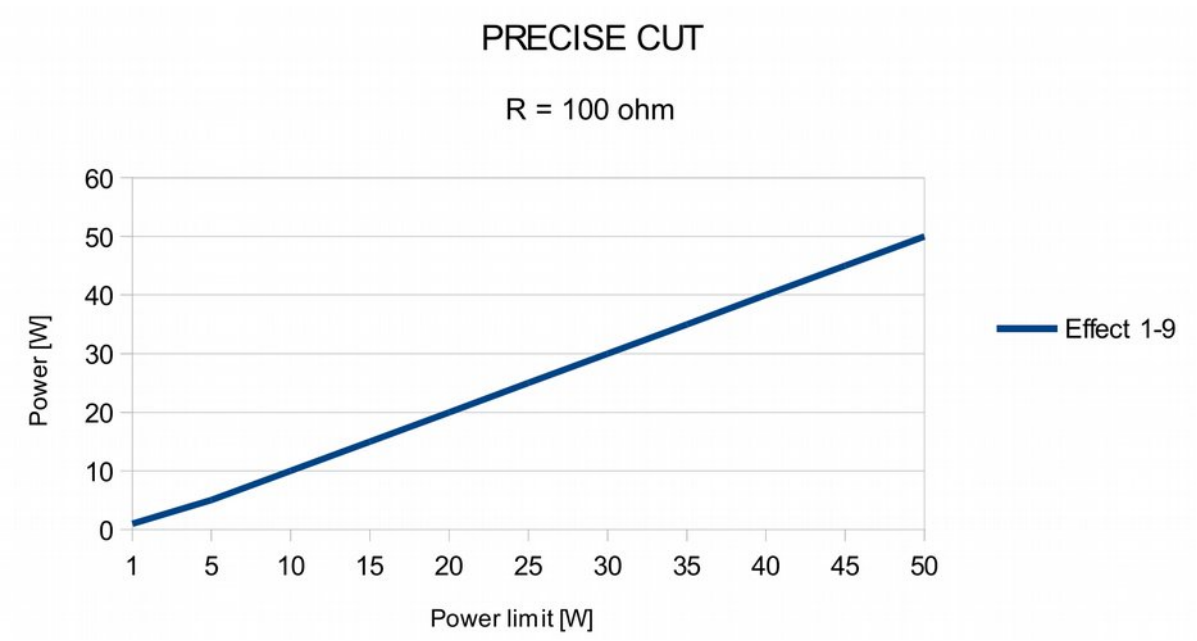
IMPORTANT NOTICE

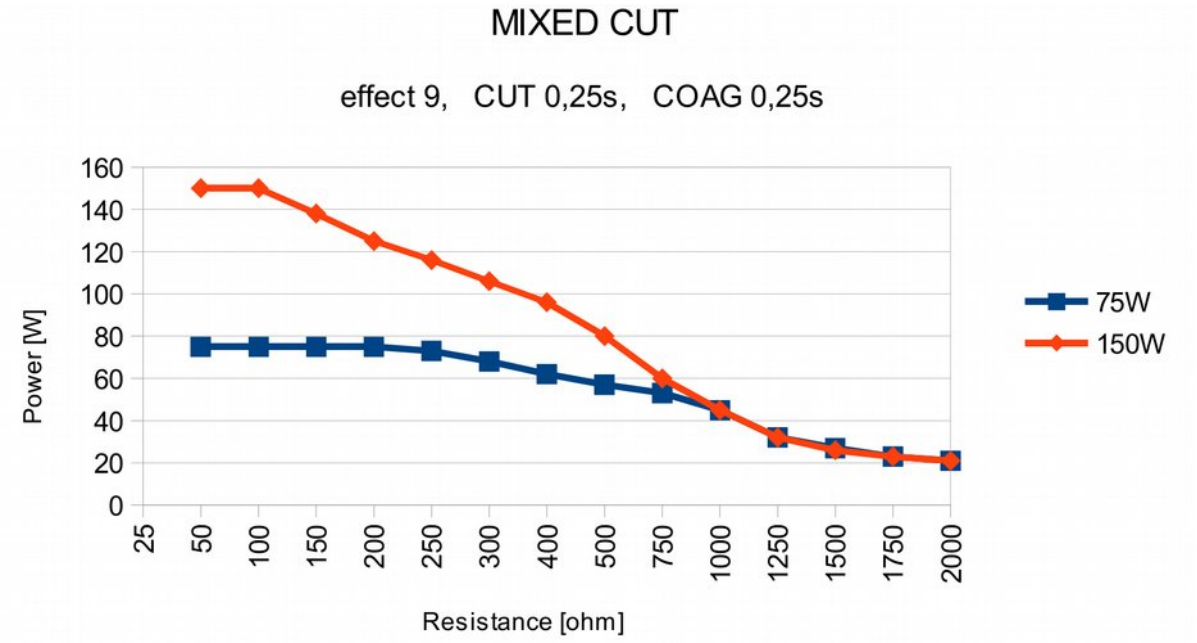
The presented graphs could change with the development of our products.

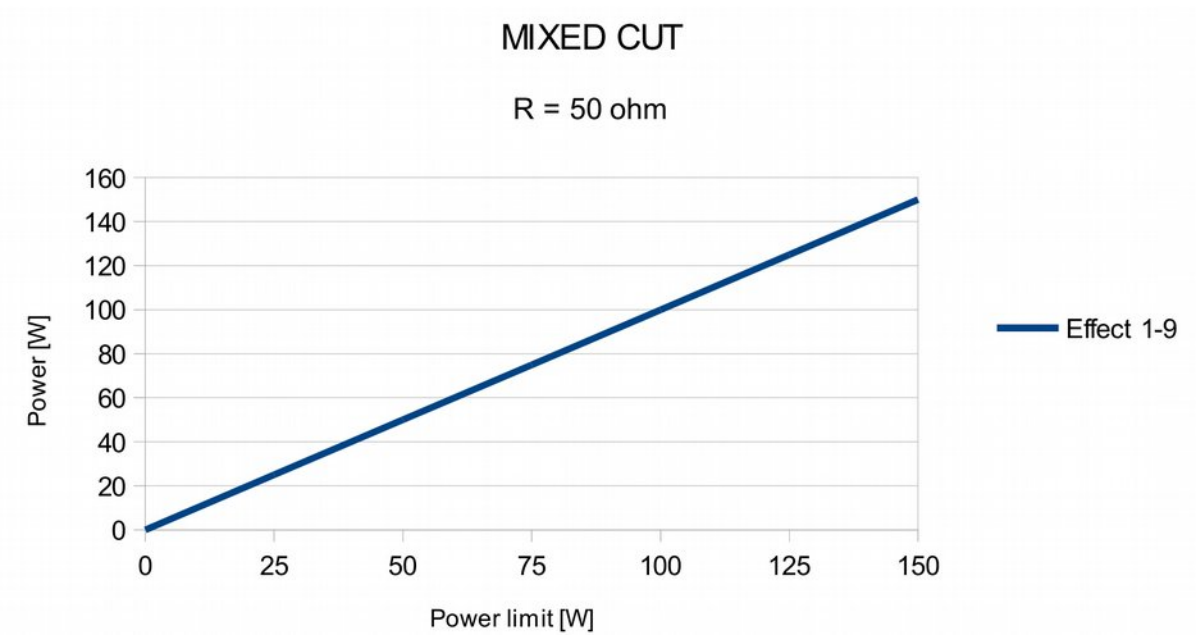


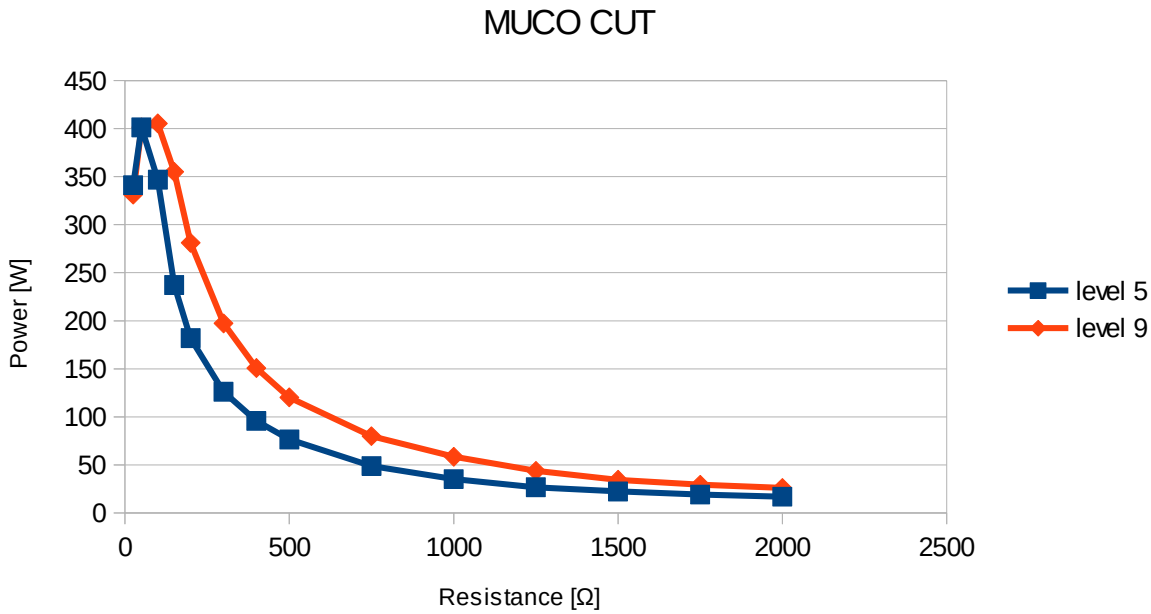

MONO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
0
50
100
150
200
250
300
350
Power limit [W]
Effect 1-9

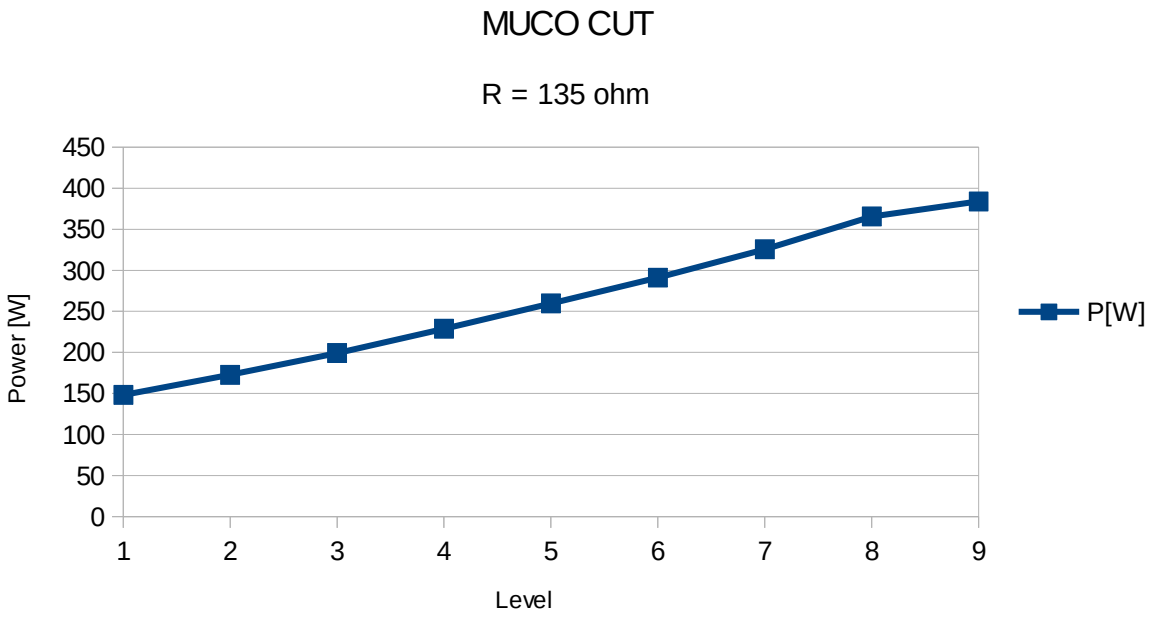

PRECISE CUT
effect 9
Power [W]
60
50
40
30
20
10
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
25W
50W

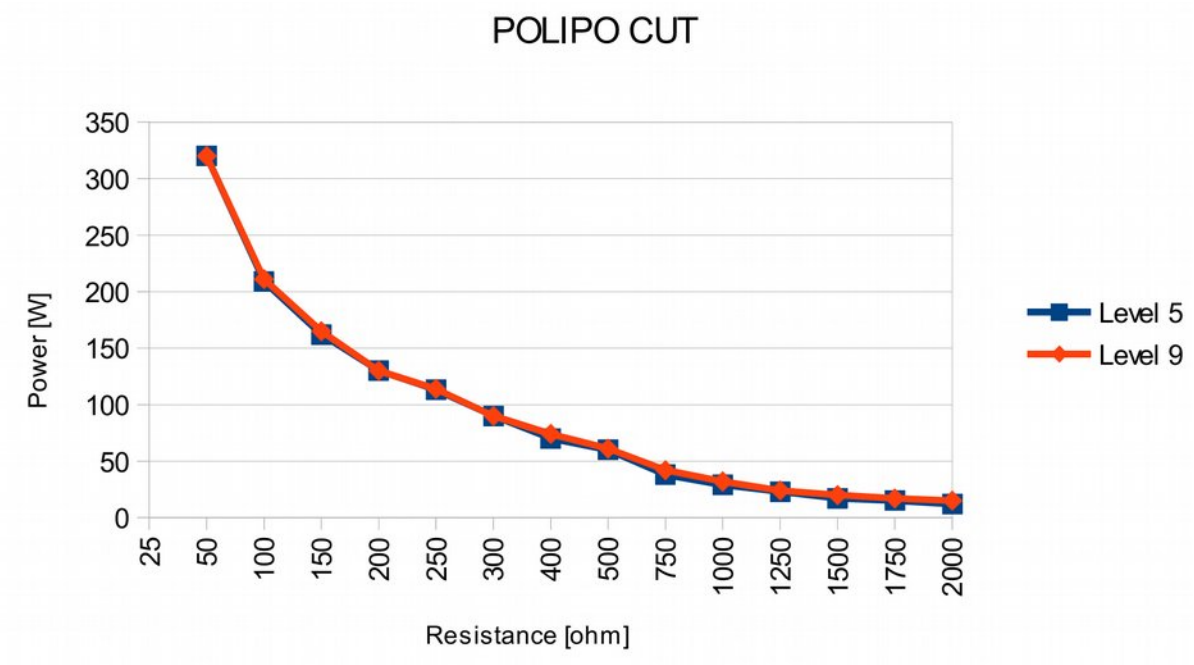

PRECISE CUT
R = 100 ohm
Power [W]
60
50
40
30
20
10
0
1
5
10
15
20
25
30
35
40
45
50
Power limit [W]
Effect 1-9

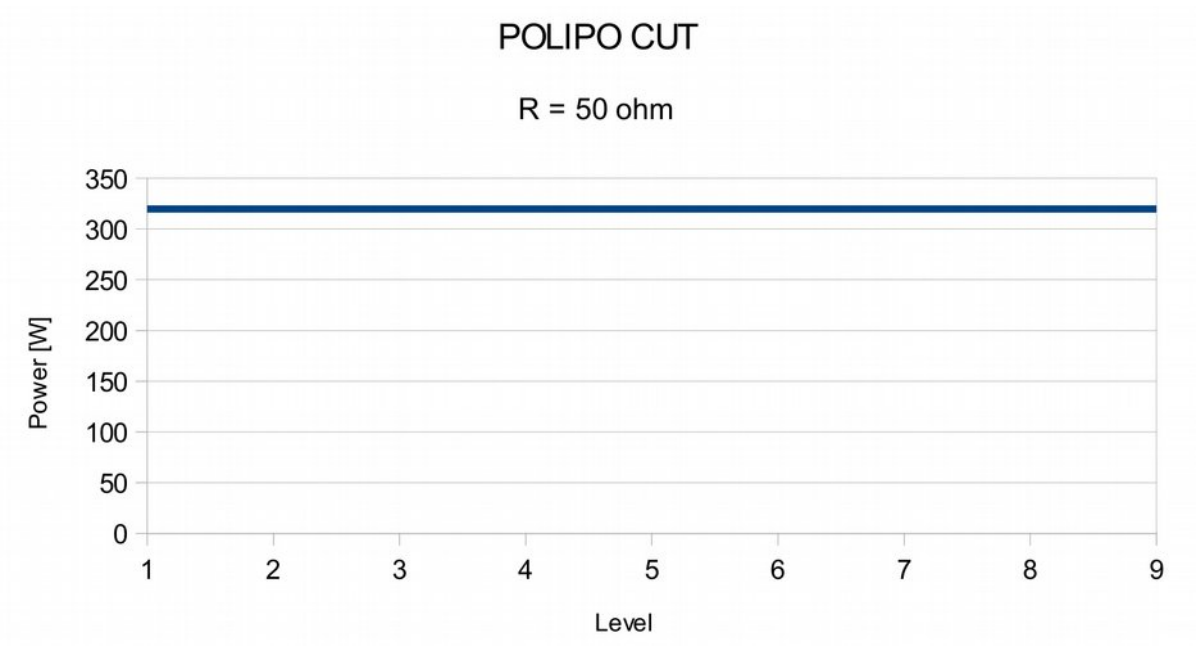

MIXED CUT
effect 9, CUT 0,25s, COAG 0,25s
Power [W]
160
140
120
100
80
60
40
20
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
75W
150W

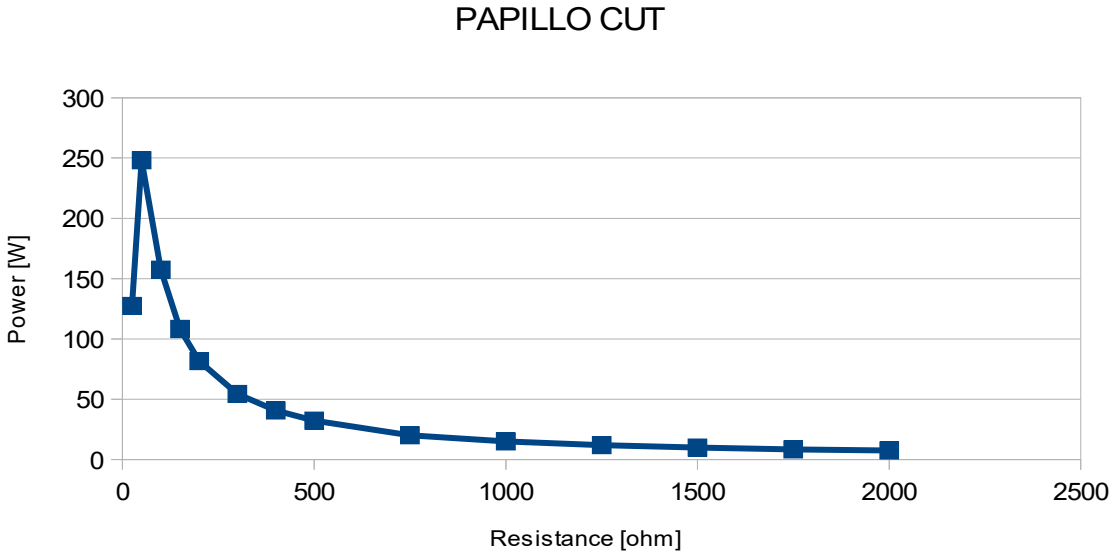

MIXED CUT
R = 50 ohm
160
140
120
100
80
60
40
20
0
Power [W]
0
25
50
75
100
125
150
Power limit [W]
Effect 1-9


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

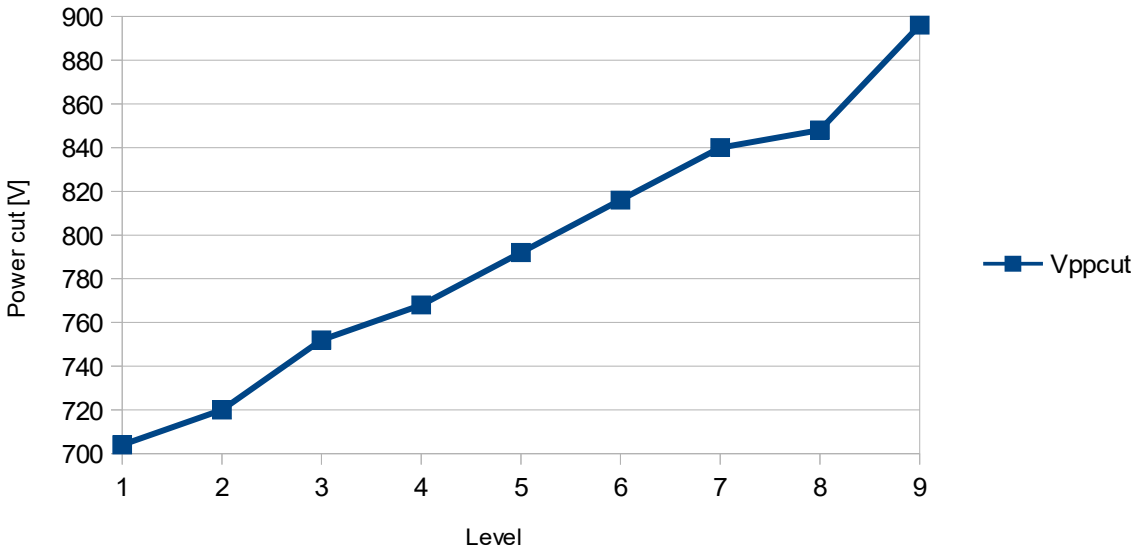

MUCO CUT
R = 135 ohm
Power [W]
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Level
P[W]


POLIPO CUT
Power [W]
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]
Level 5
Level 9

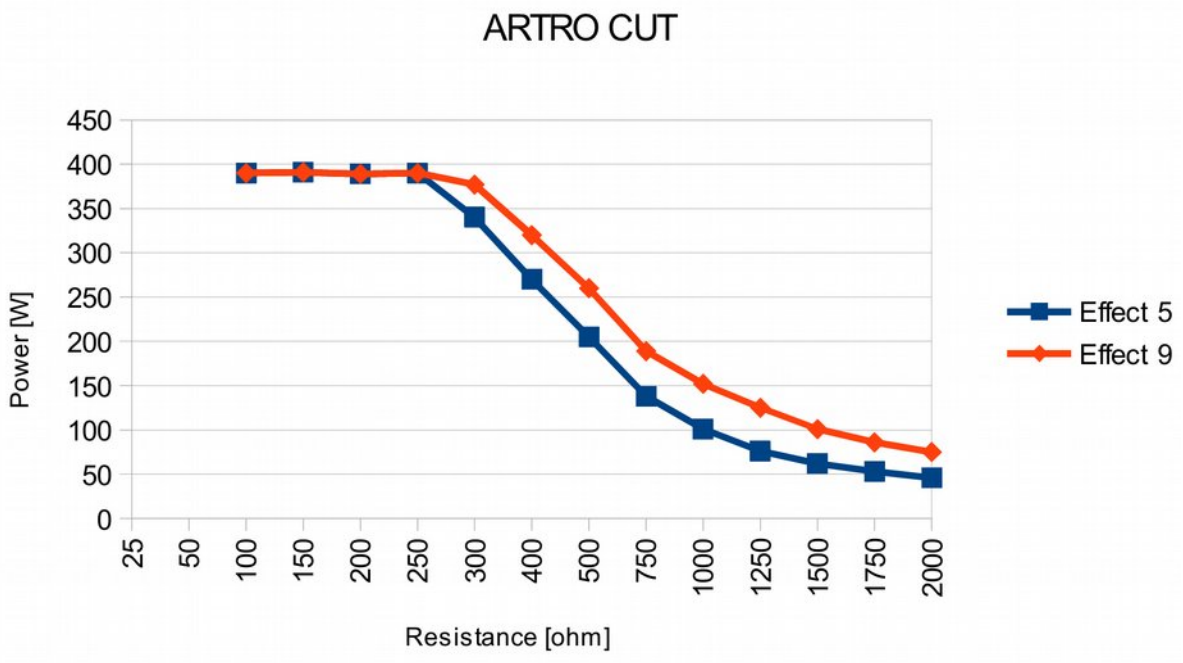

POLIPO CUT
R = 50 ohm
Power [W]
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Level

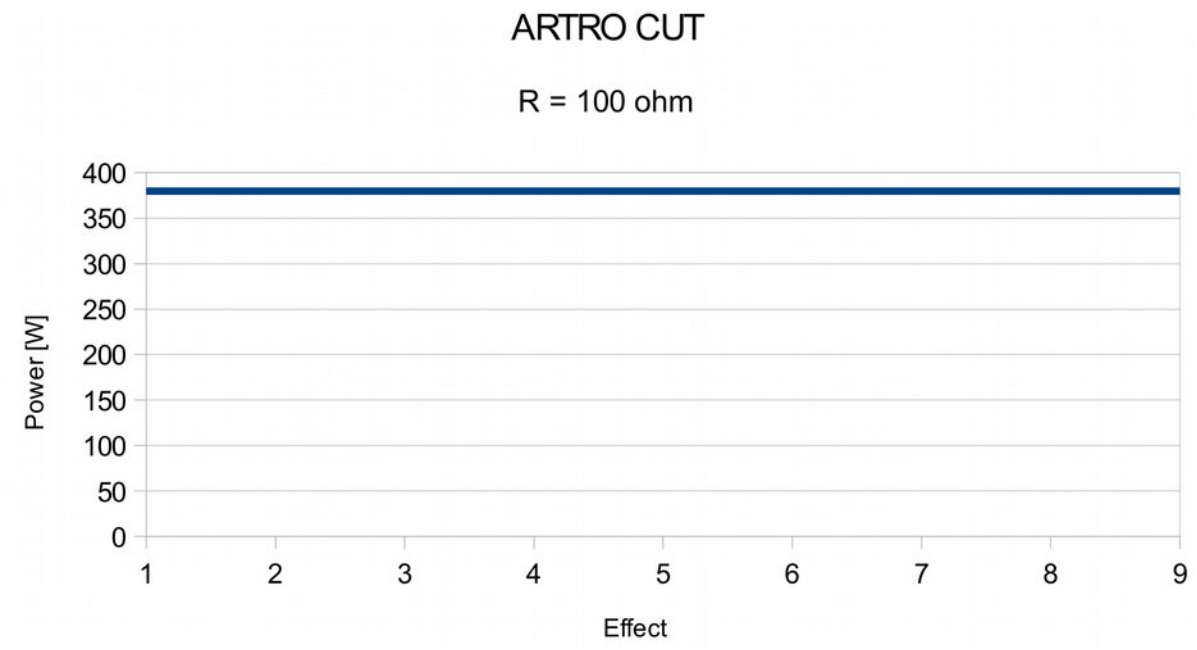

PAPILLO CUT
Power [W]
300
250
200
150
100
50
0
0
500
1000
1500
2000
2500
Resistance [ohm]

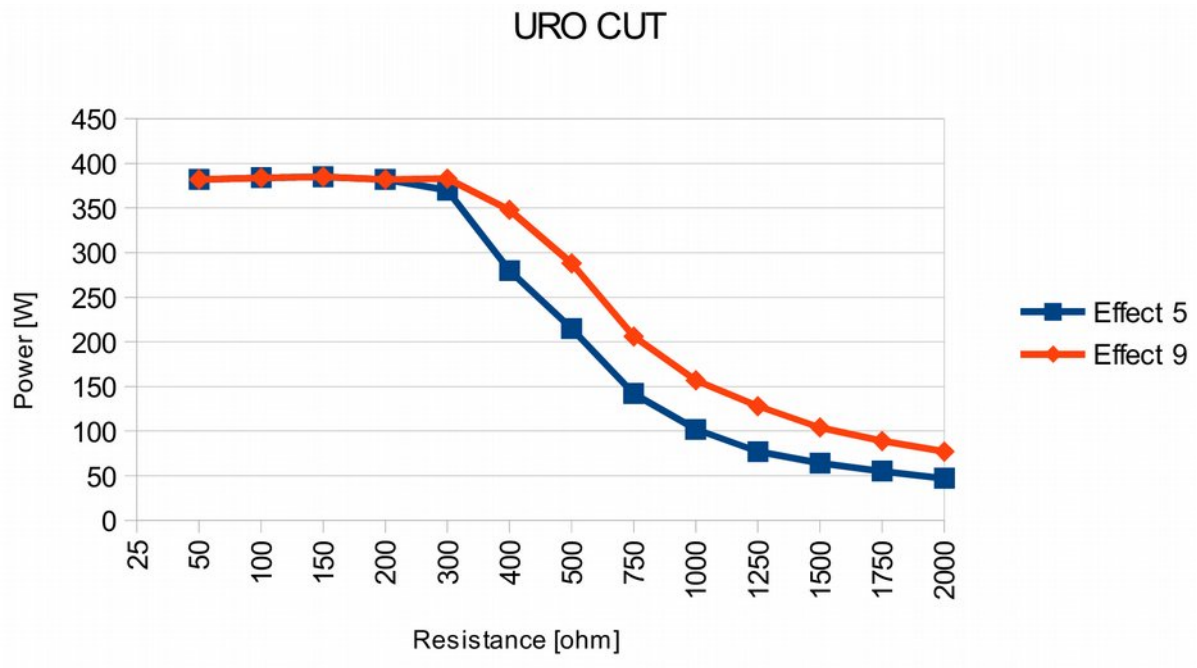
PAPILLO CUT

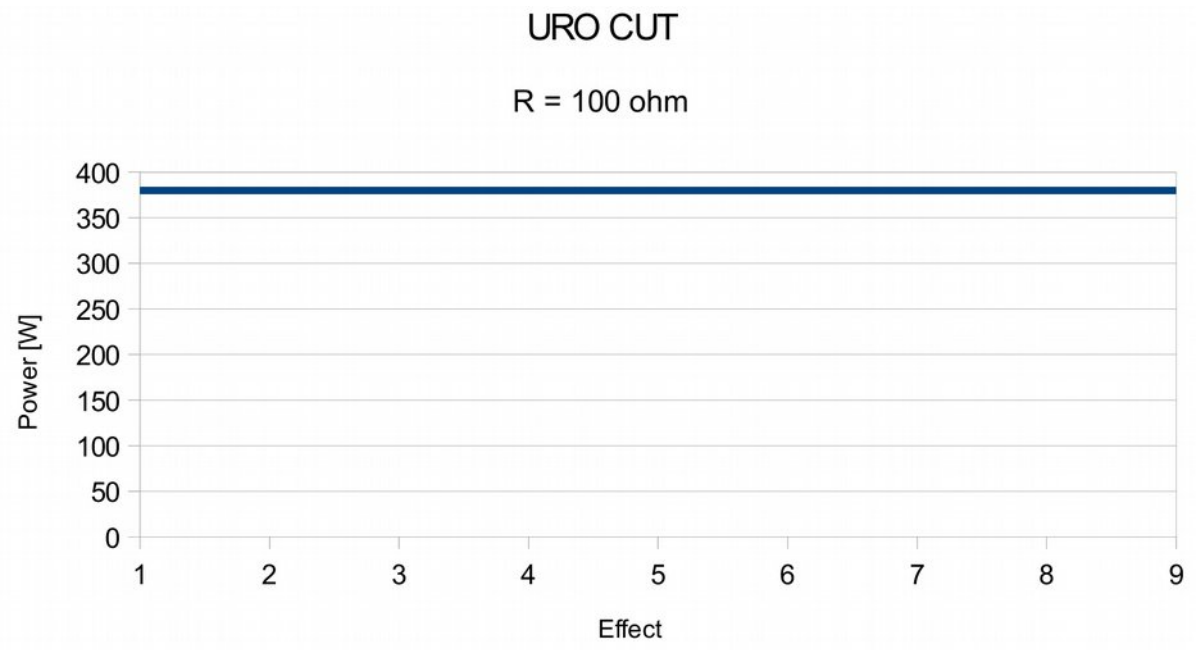


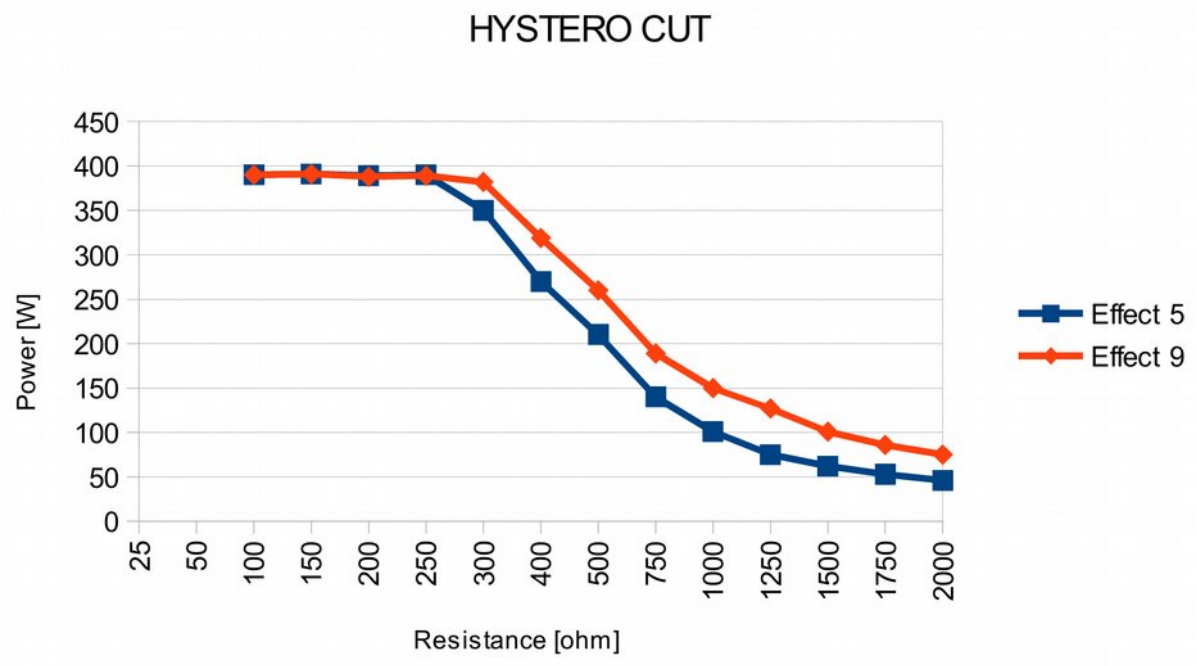
ARTRO CUT

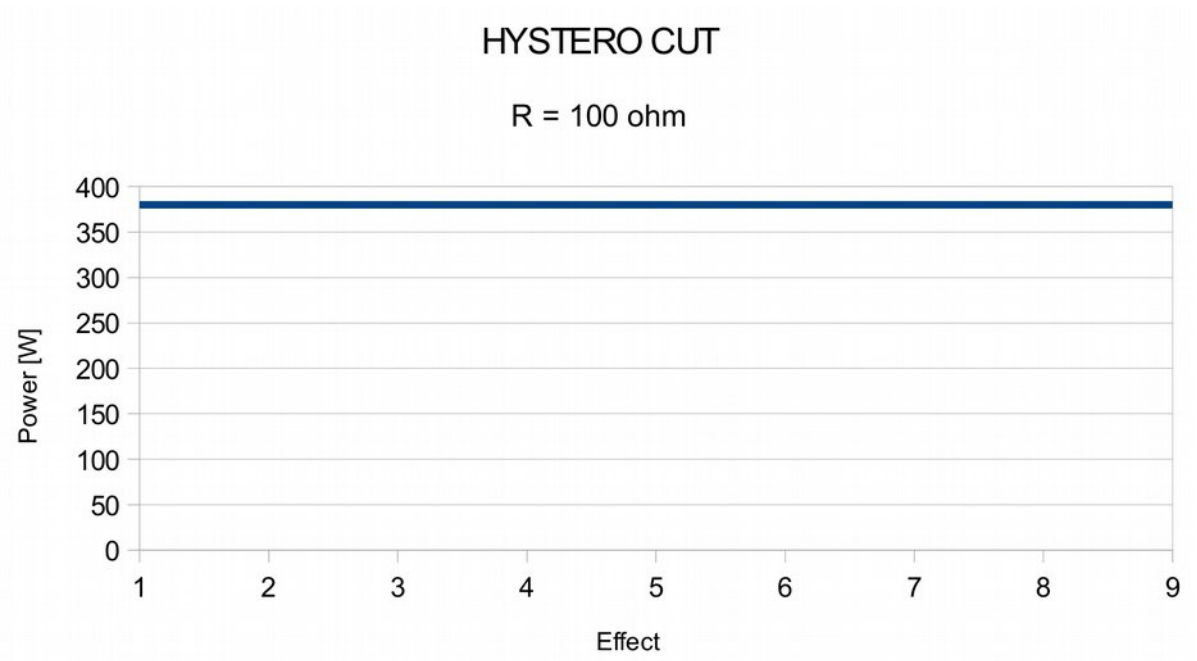


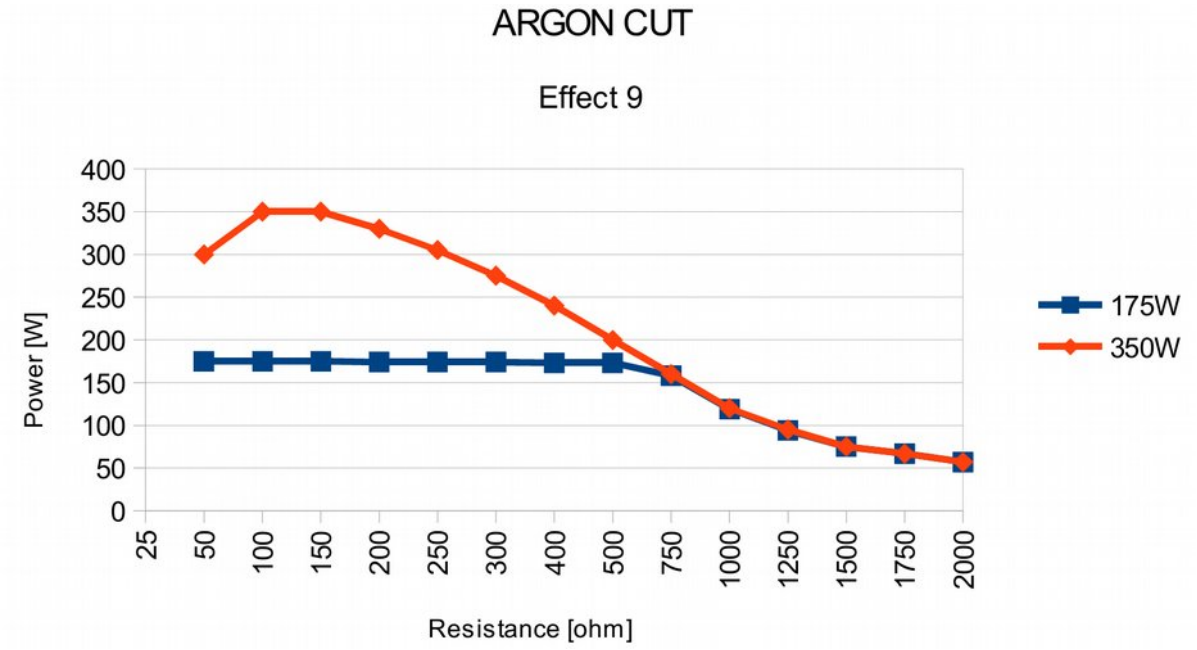

ARTRO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect


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

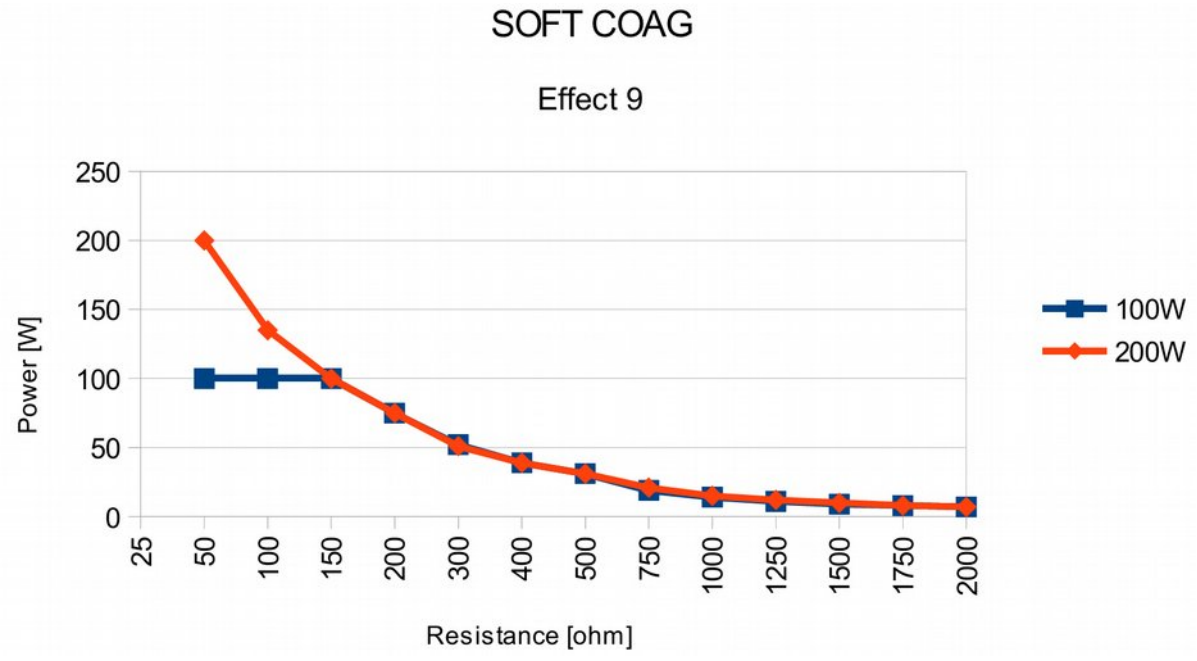

URO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

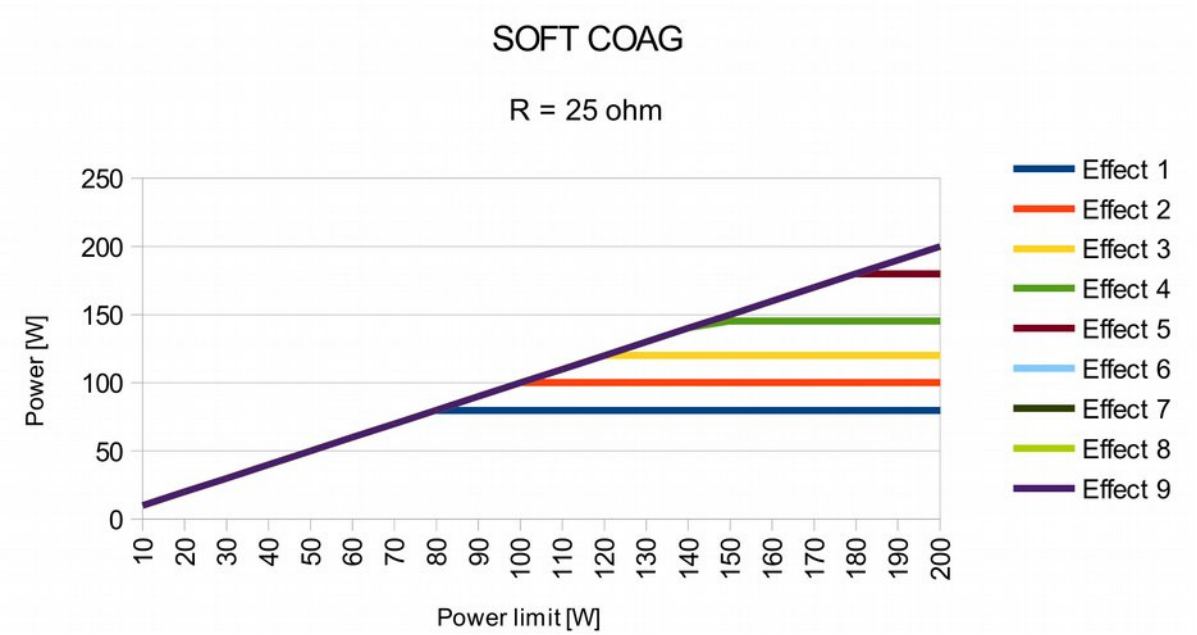

HYSTERO CUT
Power [W]
450
400
350
300
250
200
150
100
50
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

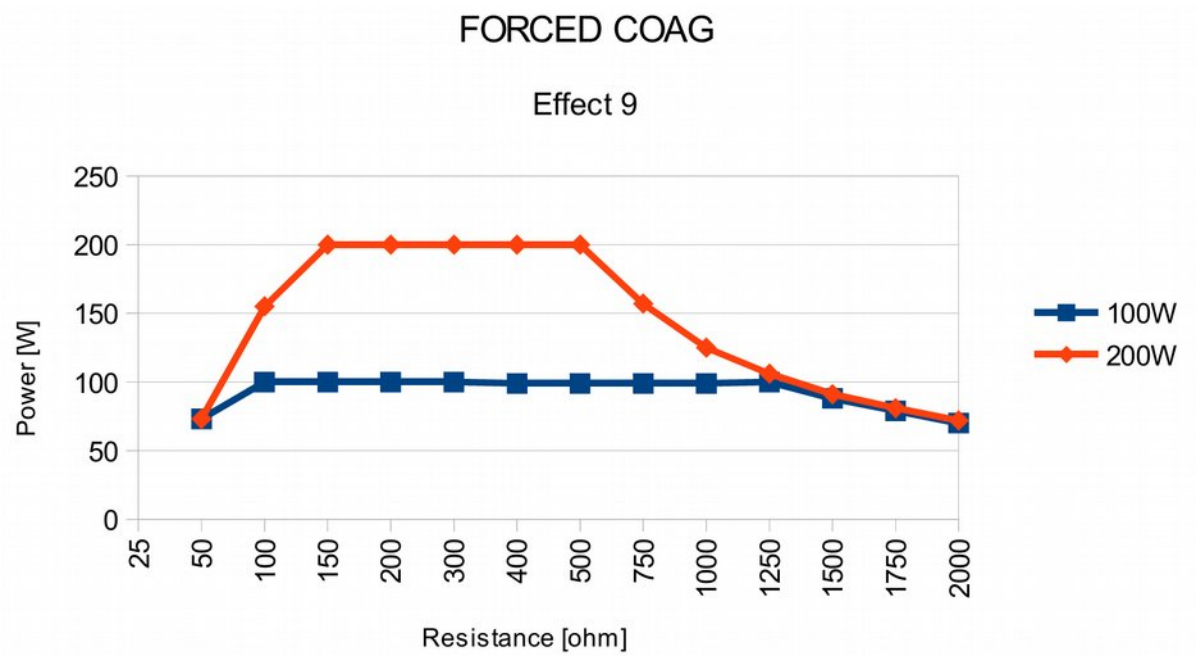

HYSTERO CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

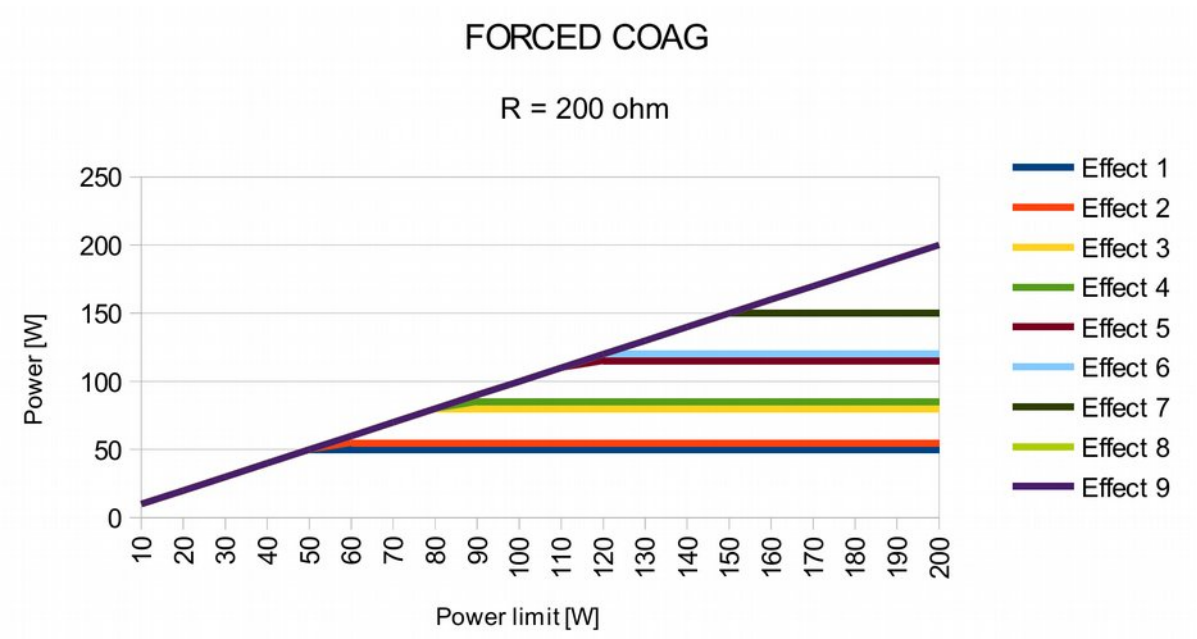

ARGON CUT
Effect 9
Power [W]
400
350
300
250
200
150
100
50
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
175W
350W

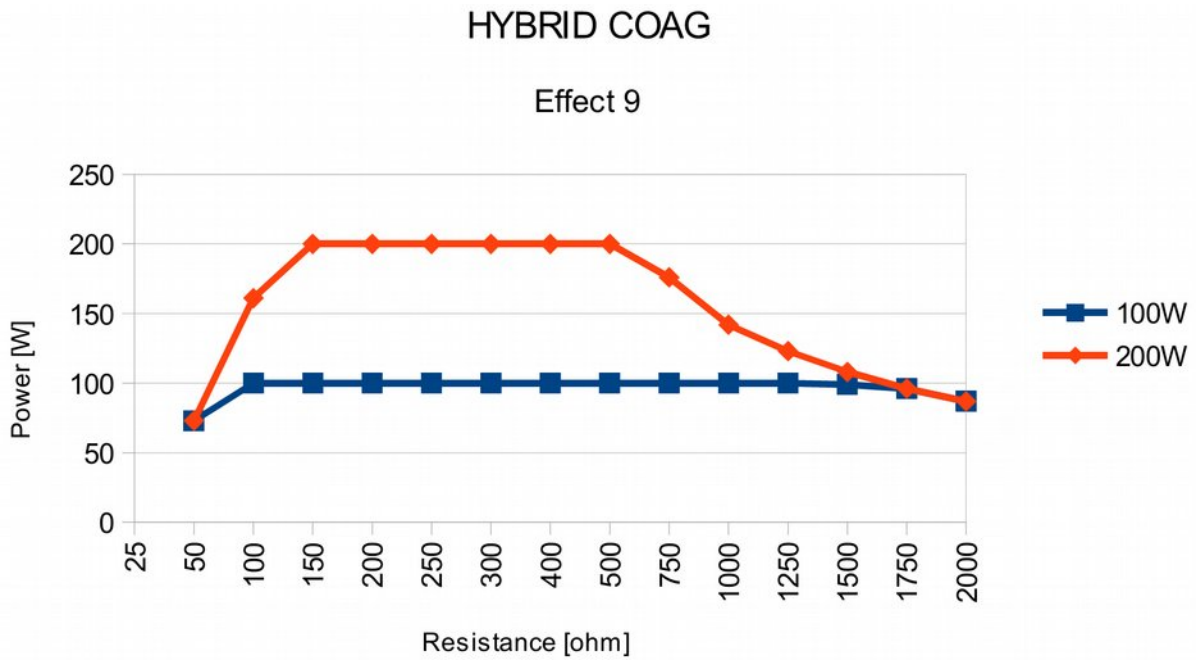

ARGON CUT
R = 100 ohm
Power [W]
400
350
300
250
200
150
100
50
0
1
50
100
150
200
250
300
350
Power limit [W]
Effect 1-9

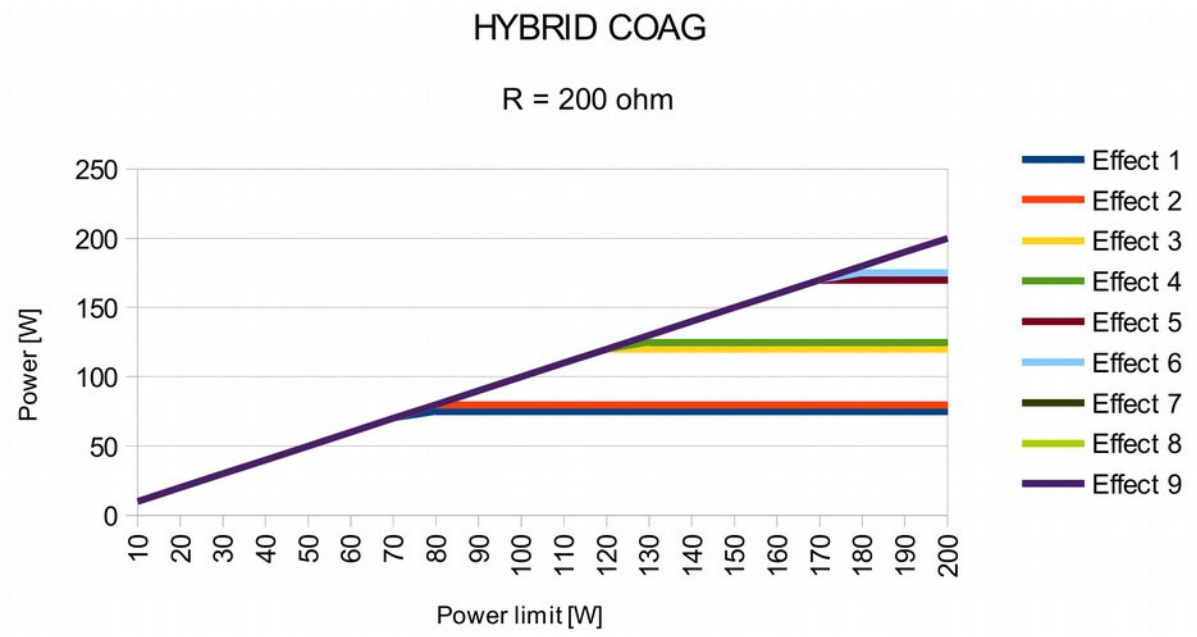

SOFT COAG
Effect 9
Power [W]
250
200
150
100
50
0
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
100W
200W

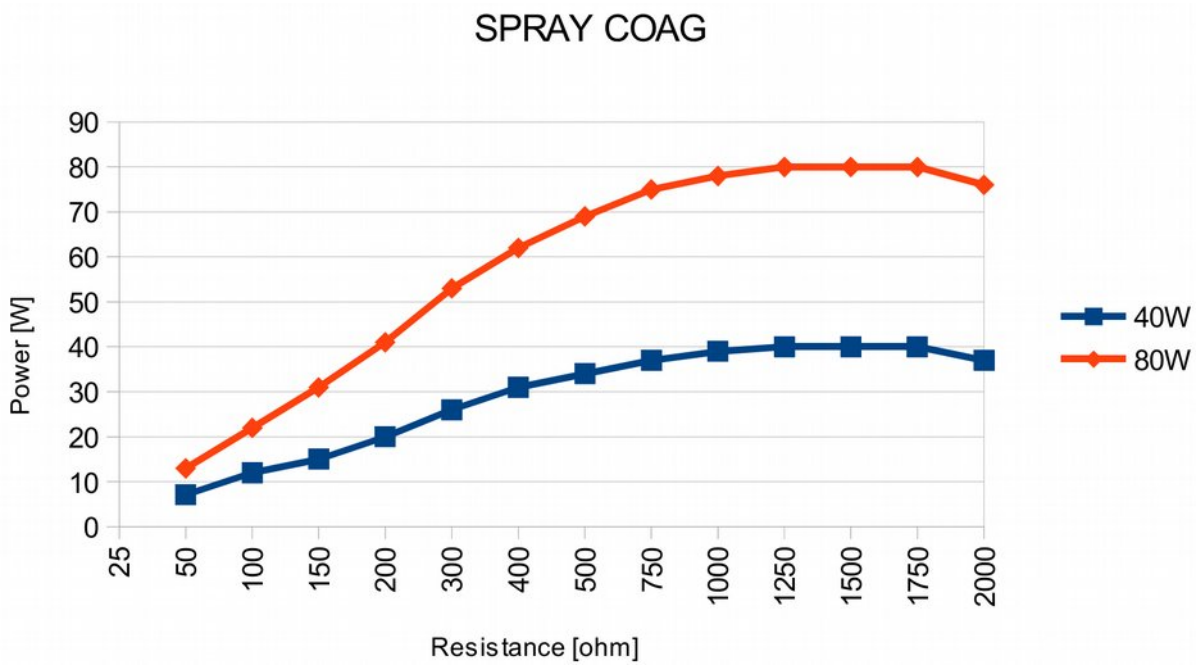

SOFT COAG
R = 25 ohm
Power [W]
250
200
150
100
50
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
150
160
170
180
190
200
Power limit [W]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9

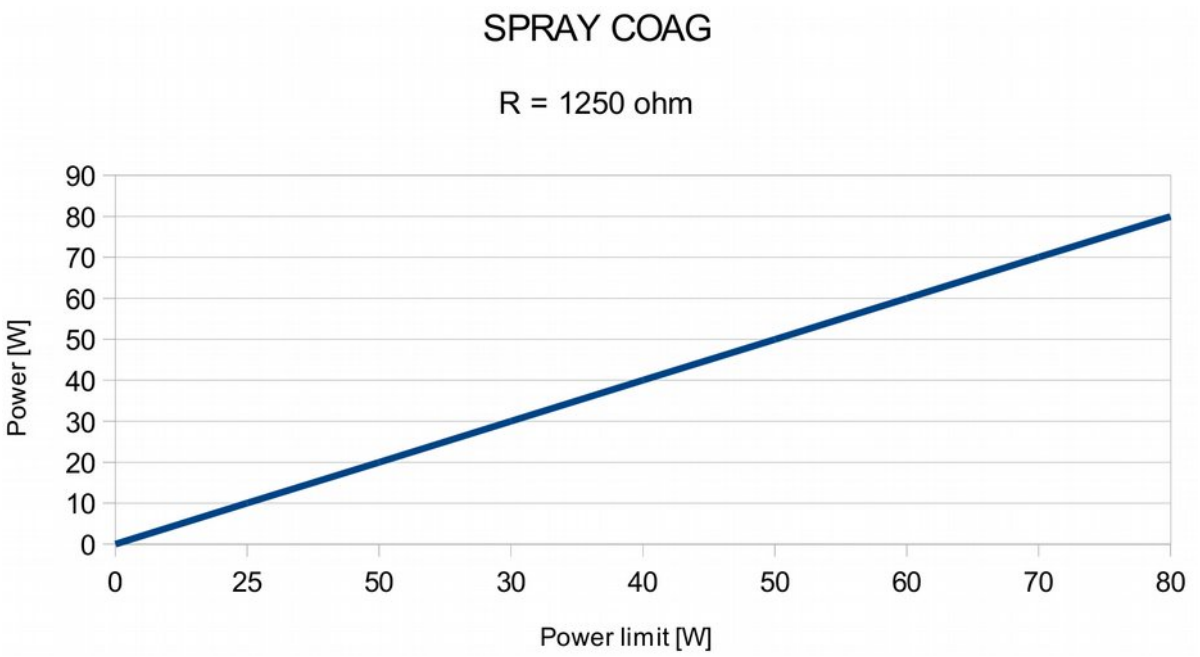

FORCED COAG
Effect 9
Power [W]
250
200
150
100
50
0
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
100W
200W

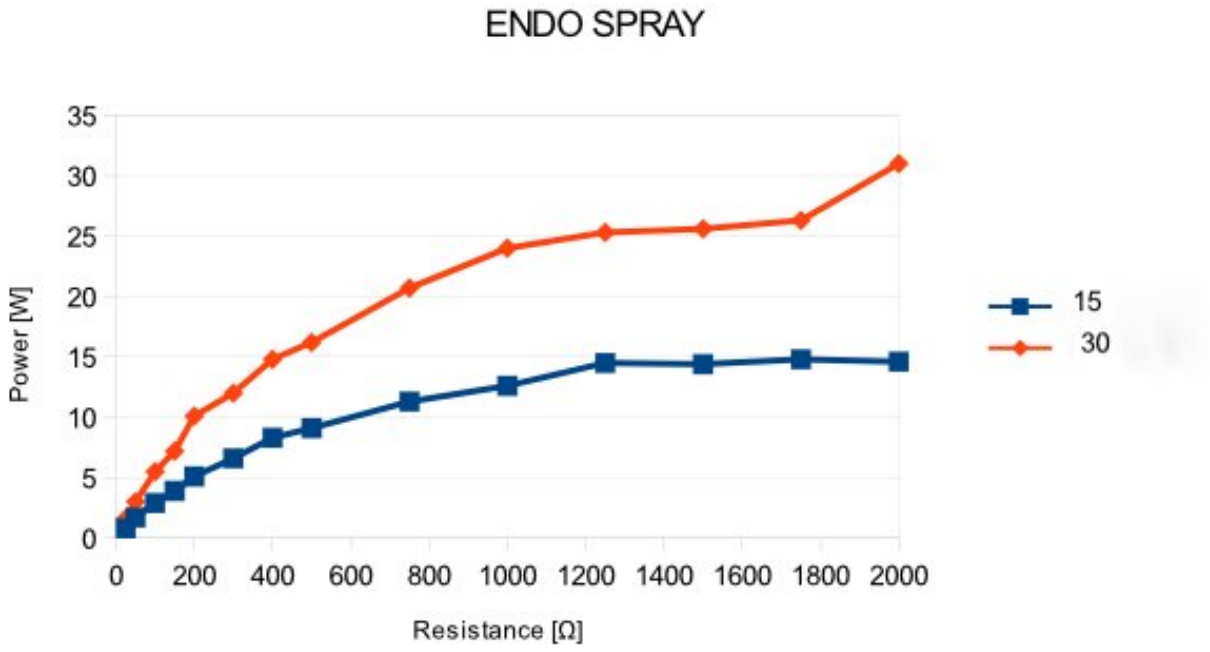

FORCED COAG
R = 200 ohm
Power [W]
250
200
150
100
50
0
10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200
Power limit [W]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9


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]
Power limit [W]
Effect 1
Effect 2
Effect 3
Effect 4
Effect 5
Effect 6
Effect 7
Effect 8
Effect 9

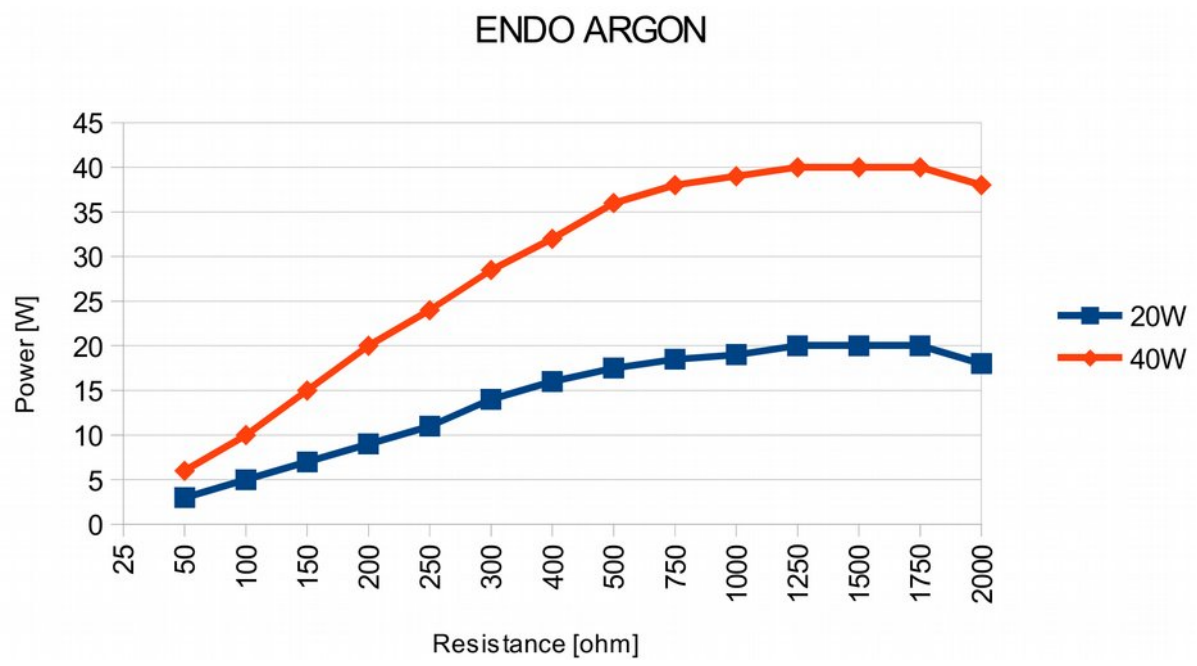

SPRAY COAG
Power [W]
Resistance [ohm]
40W
80W


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]

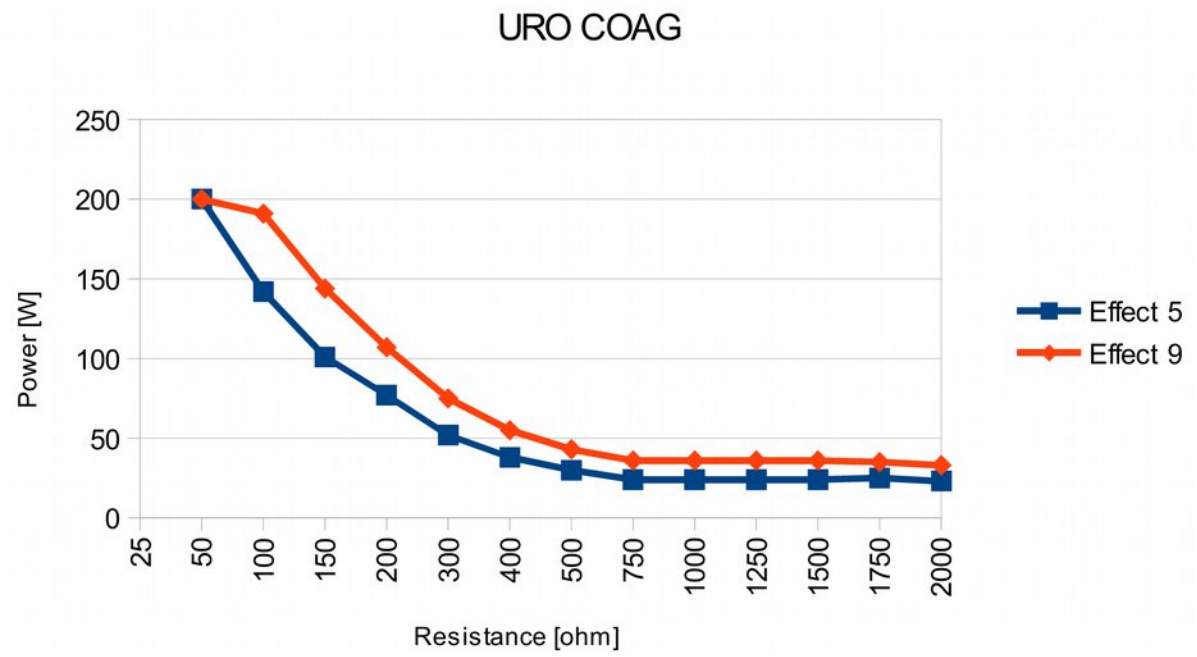

ENDO SPRAY
Power [W]
35
30
25
20
15
10
5
0
0
200
400
600
800
1000
1200
1400
1600
1800
2000
Resistance [Ω]
15
30

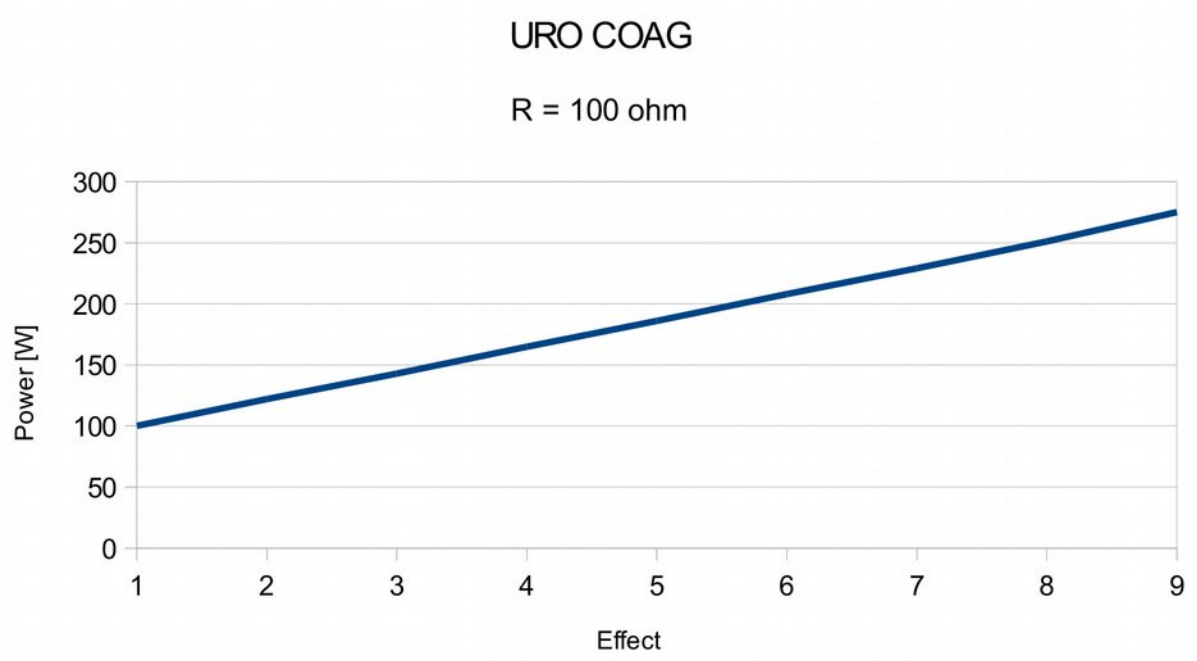

STANDARD ARGON
Power [W]
90
80
70
60
50
40
30
20
10
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
40W
80W

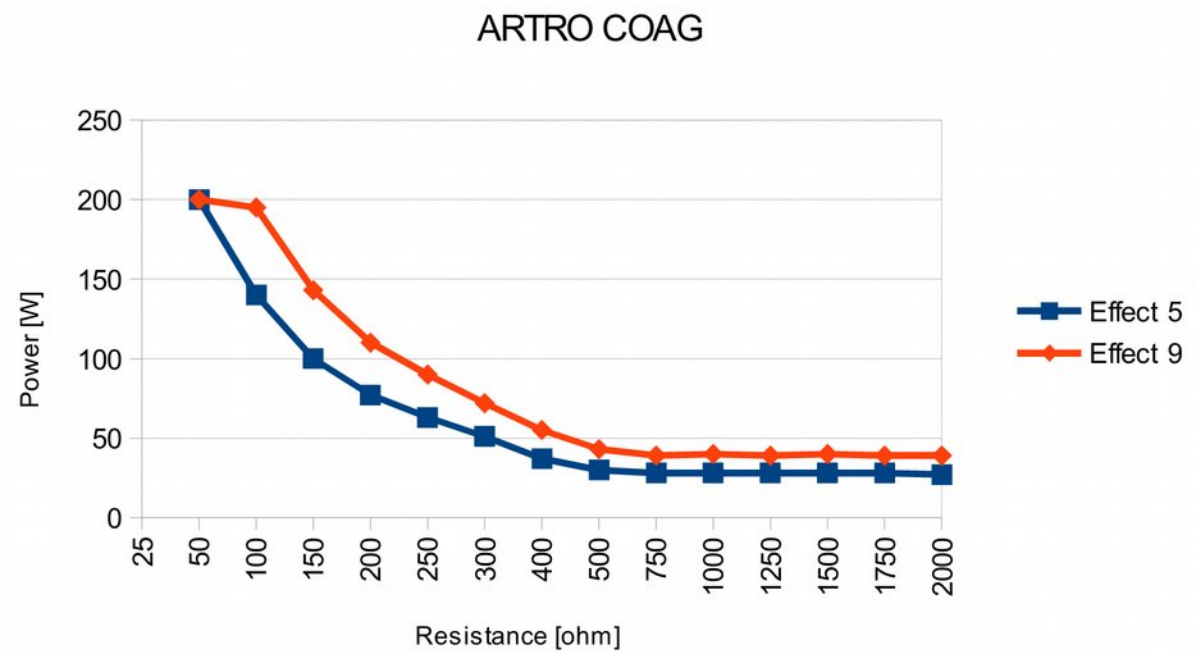

STANDARD ARGON
R = 1250 ohm
Power [W]
90
80
70
60
50
40
30
20
10
0
0
10
20
30
40
50
60
70
80
Power limit [W]

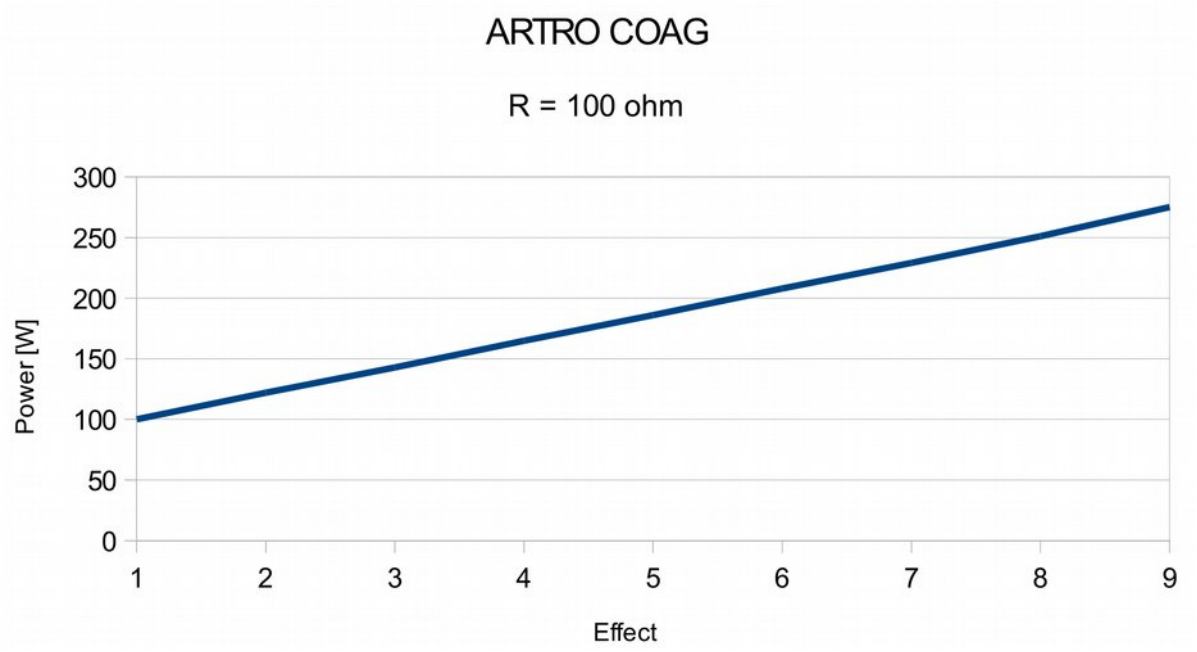

ENDO ARGON
Power [W]
45
40
35
30
25
20
15
10
5
0
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
20W
40W

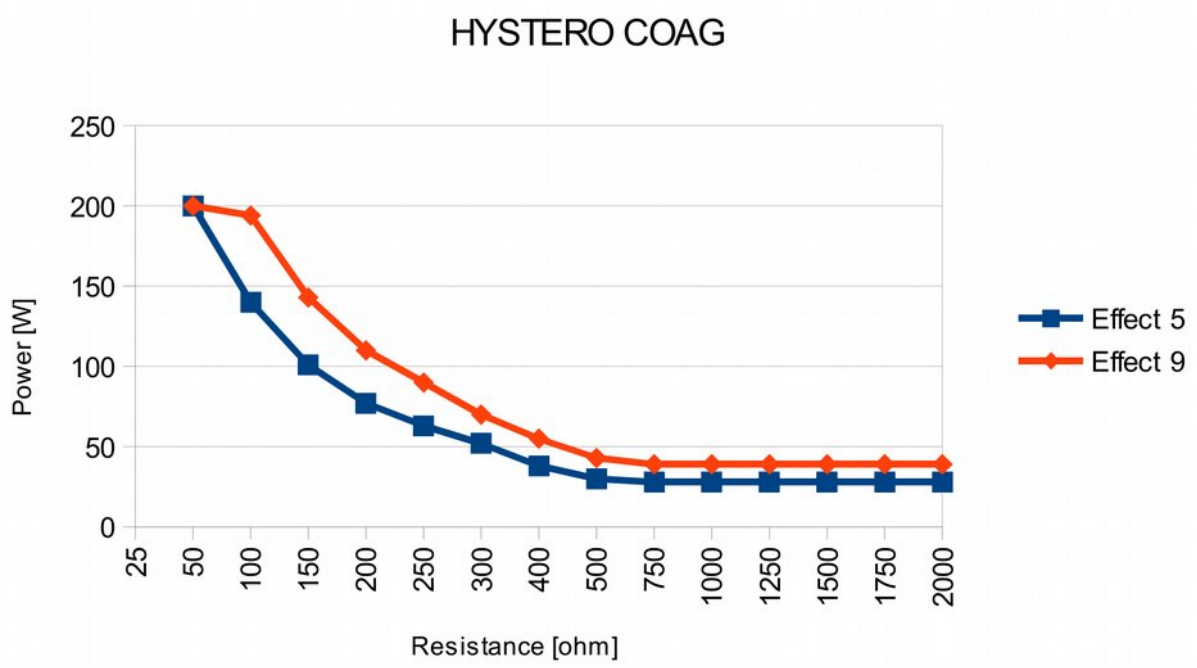

ENDO ARGON
R = 1250 ohm
Power [W]
45
40
35
30
25
20
15
10
5
0
0
5
10
15
20
25
30
35
40
Power limit [W]

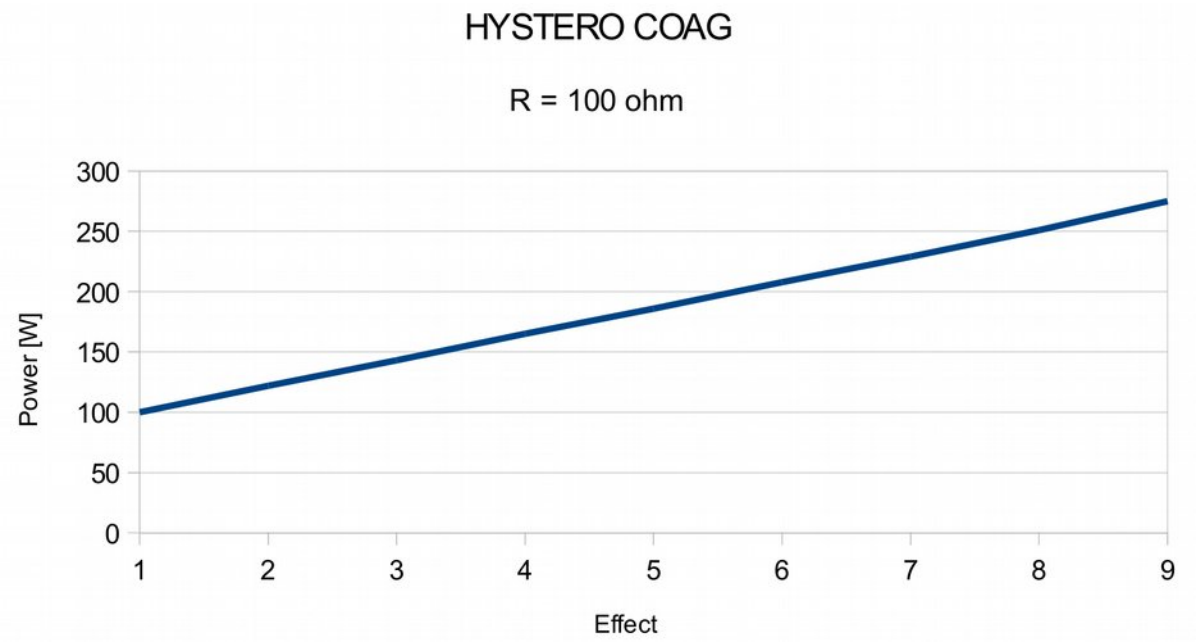

URO COAG
250
200
150
100
50
0
Power [W]
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

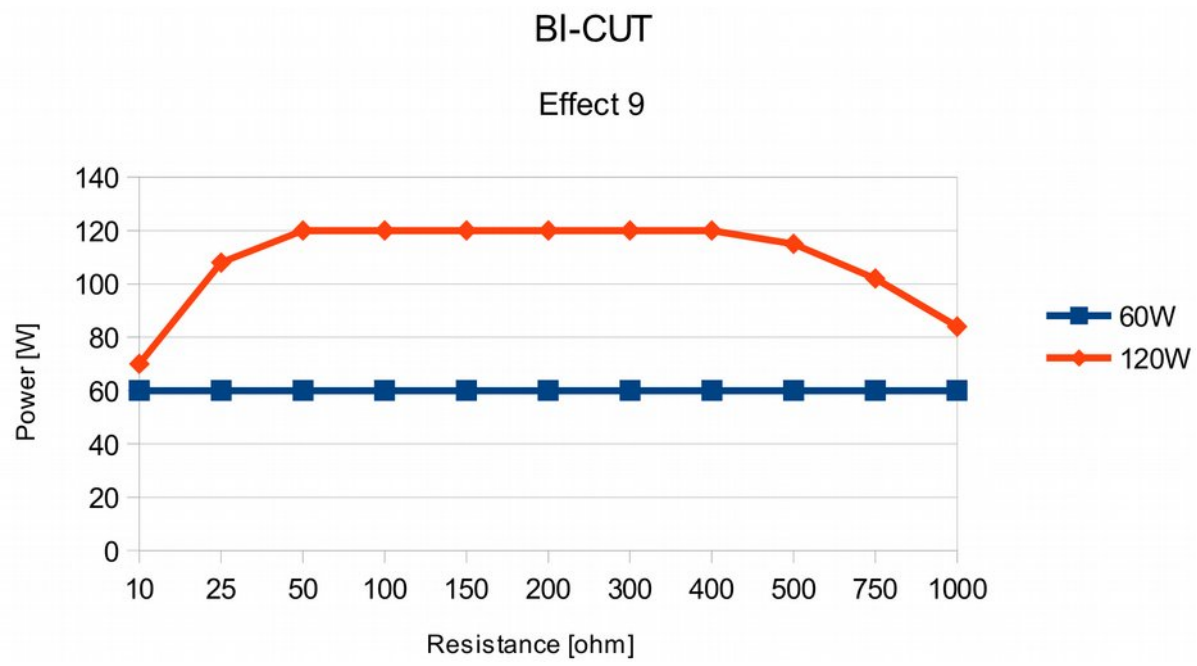

URO COAG
R = 100 ohm
300
250
200
150
100
50
0
Power [W]
1
2
3
4
5
6
7
8
9
Effect

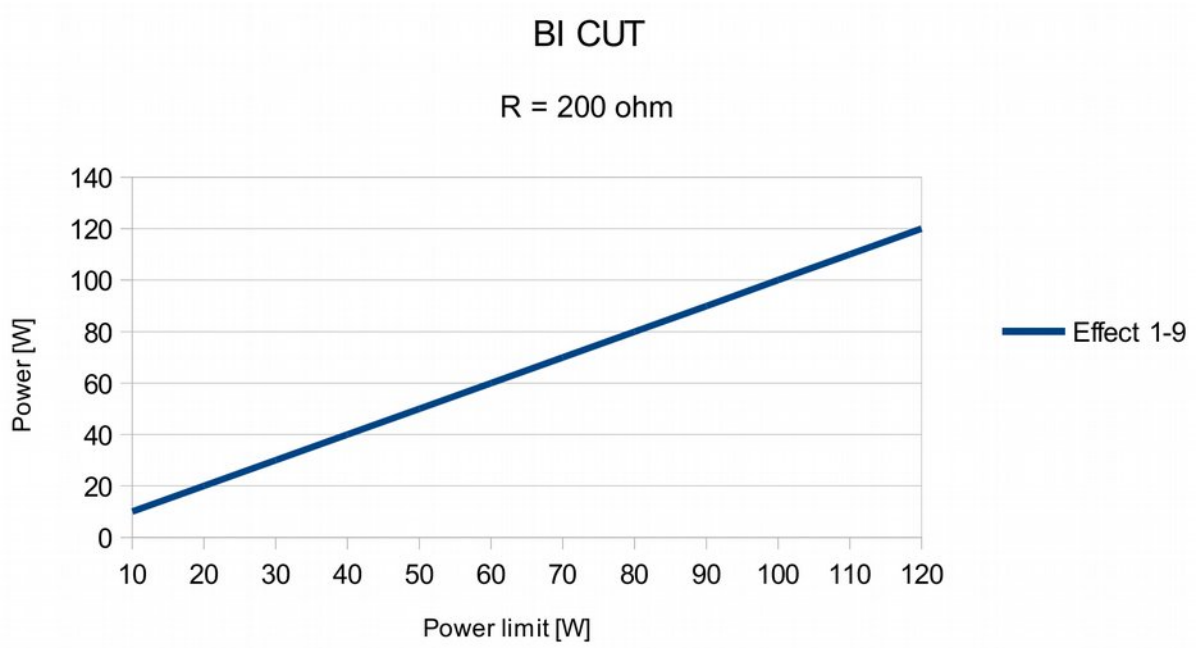

ARTRO COAG
250
200
150
100
50
0
Power [W]
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

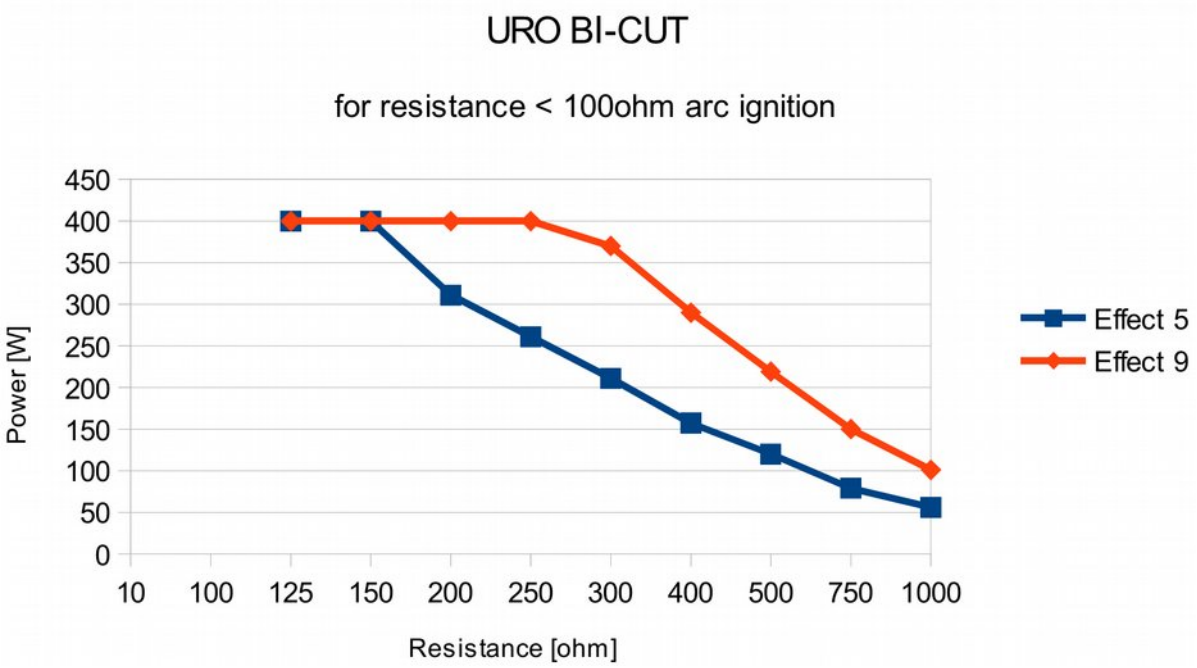

ARTRO COAG
R = 100 ohm
300
250
200
150
100
50
0
Power [W]
1
2
3
4
5
6
7
8
9
Effect

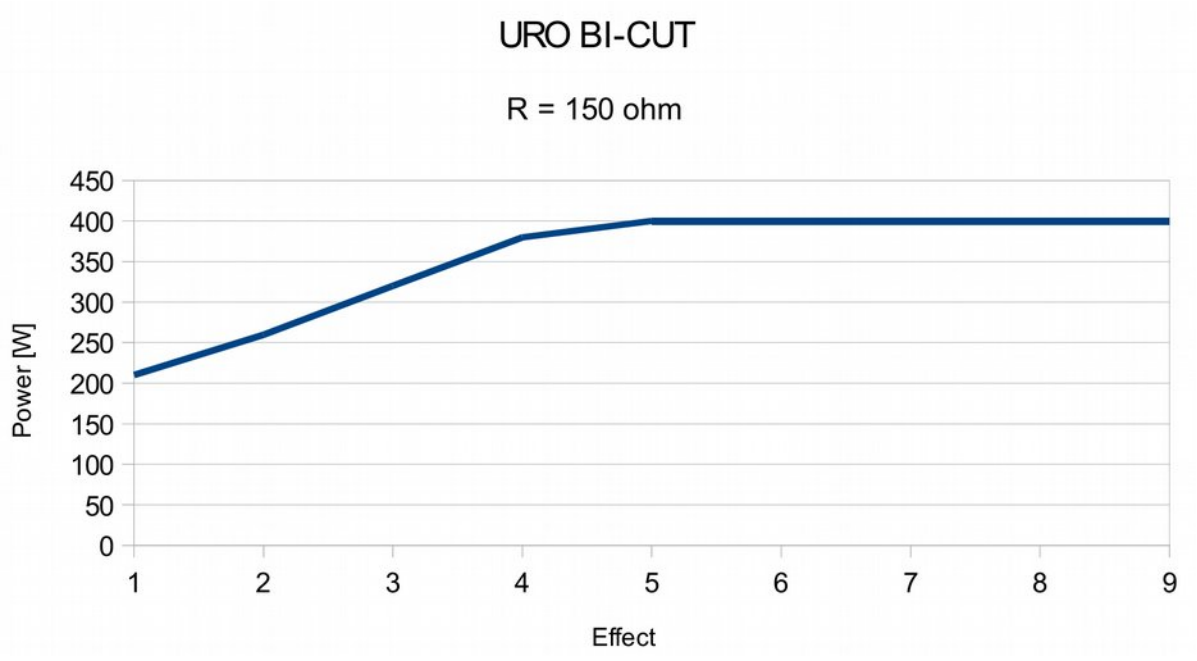

HYSTERO COAG
250
200
150
100
50
0
Power [W]
25
50
100
150
200
250
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

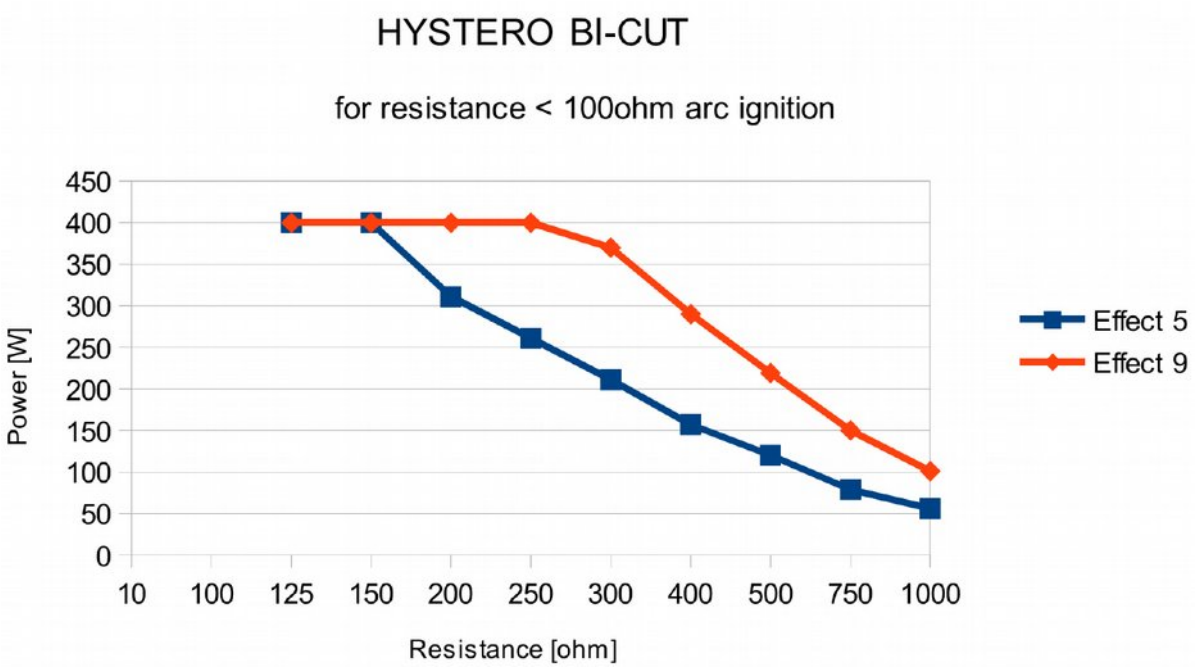

HYSTERO COAG
R = 100 ohm
300
250
200
150
100
50
0
Power [W]
1
2
3
4
5
6
7
8
9
Effect

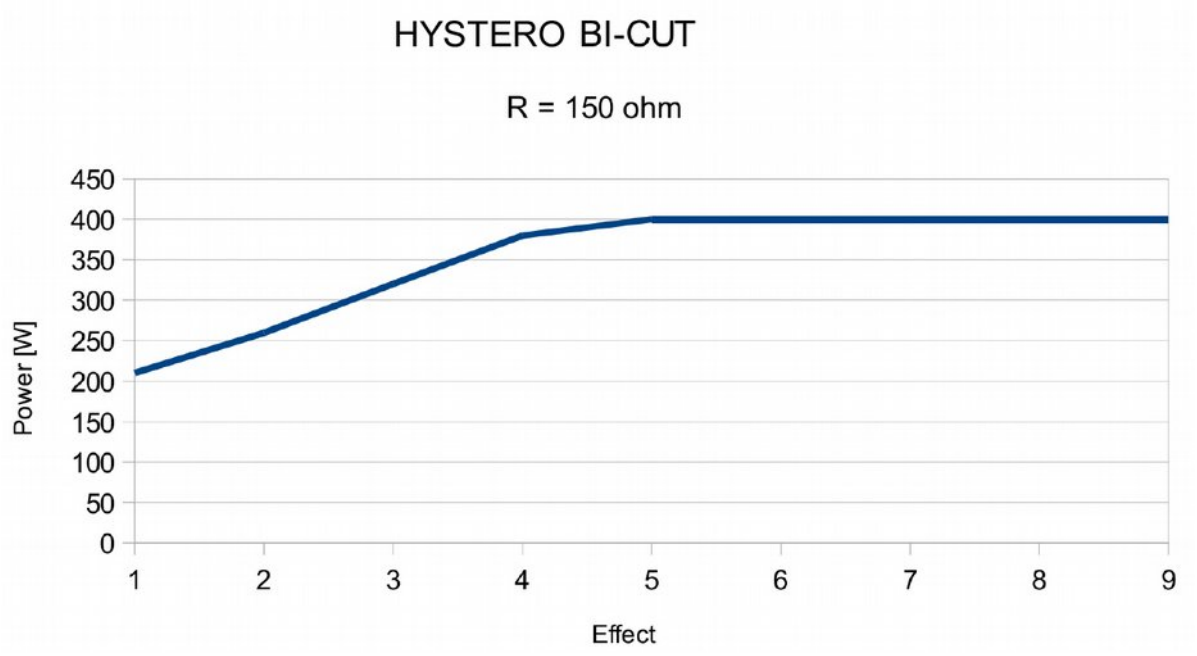

BI-CUT
Effect 9
Power [W]
140
120
100
80
60
40
20
0
10
25
50
100
150
200
300
400
500
750
1000
Resistance [ohm]
60W
120W

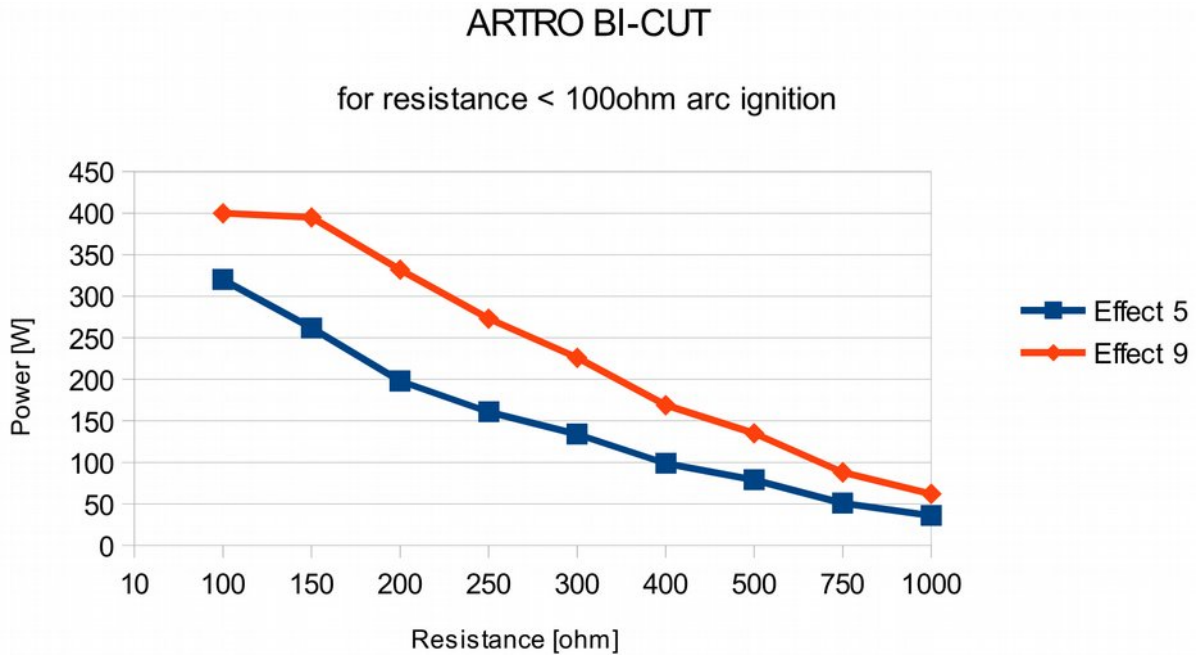

BI CUT
R = 200 ohm
Power [W]
140
120
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
110
120
Power limit [W]
Effect 1-9

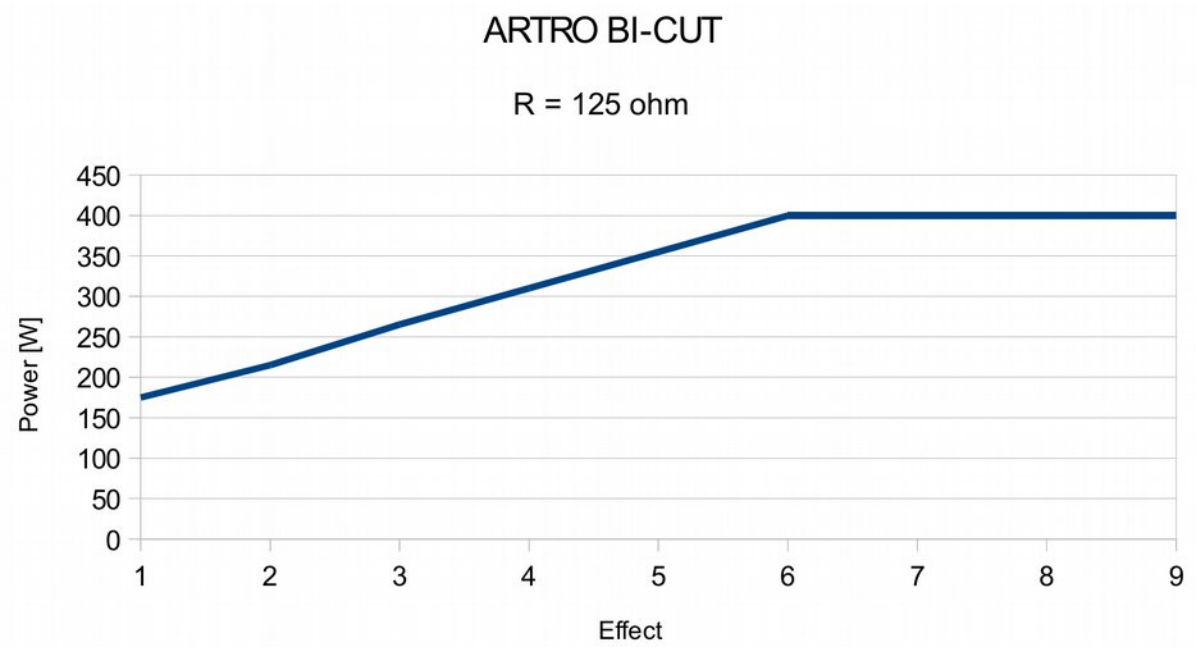

URO BI-CUT
for resistance < 100ohm arc ignition
Power [W]
450
400
350
300
250
200
150
100
50
0
10
100
125
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9

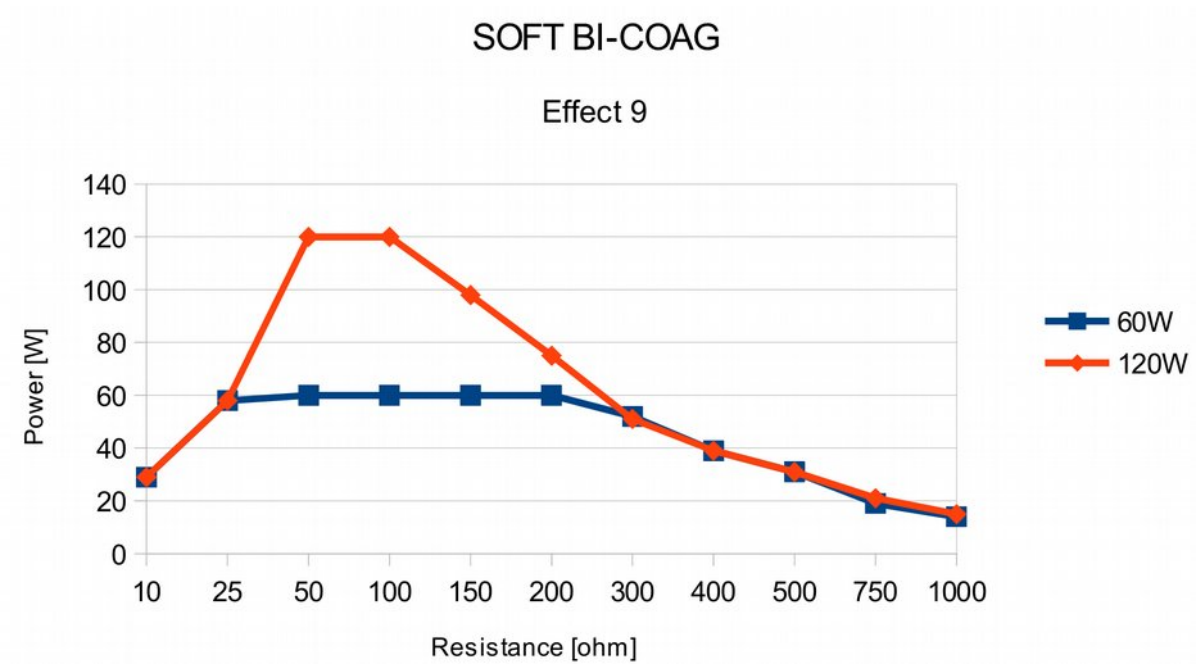

URO BI-CUT
R = 150 ohm
Power [W]
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

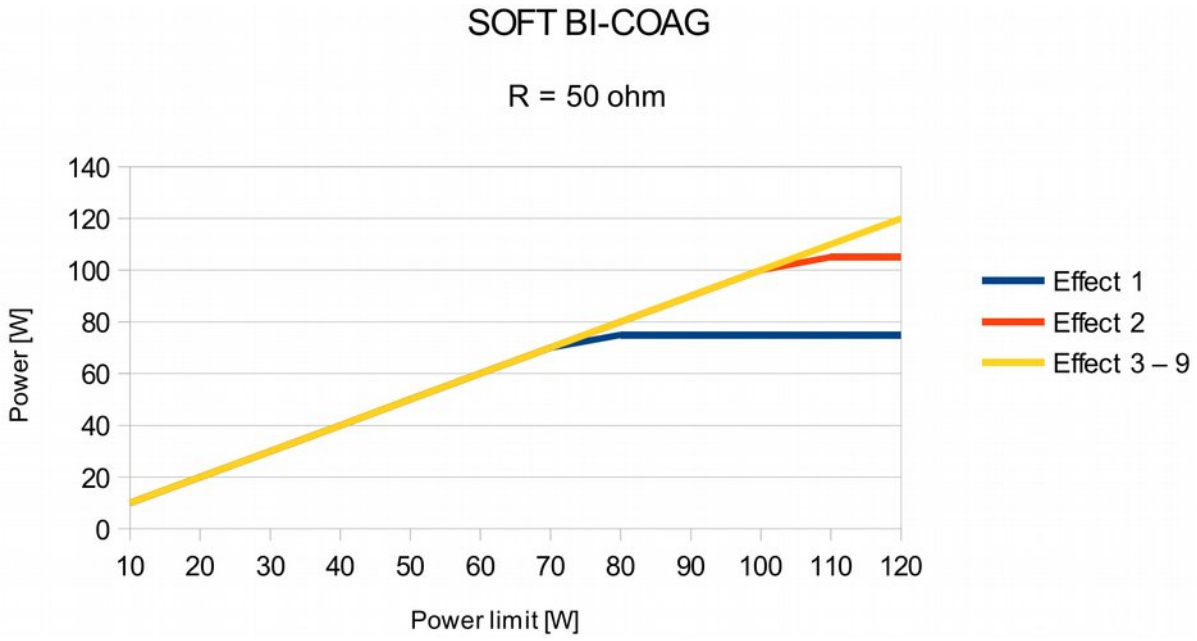

HYSTERO BI-CUT
for resistance < 100ohm arc ignition
Power [W]
450
400
350
300
250
200
150
100
50
0
10
100
125
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9

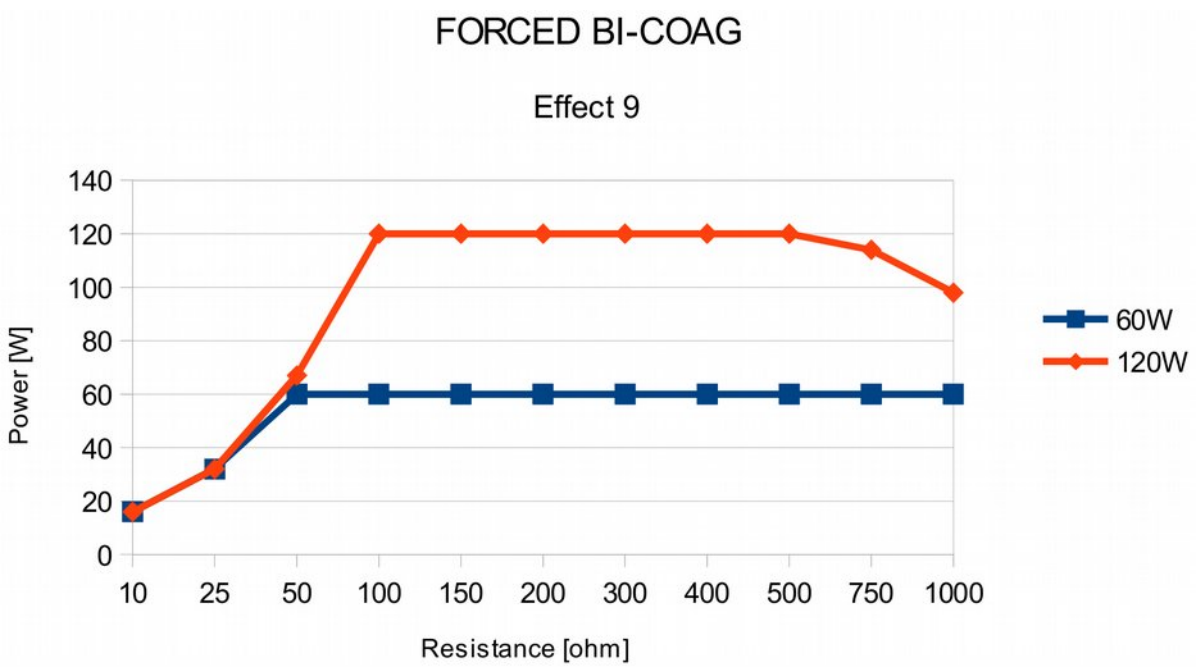

HYSTERO BI-CUT
R = 150 ohm
Power [W]
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

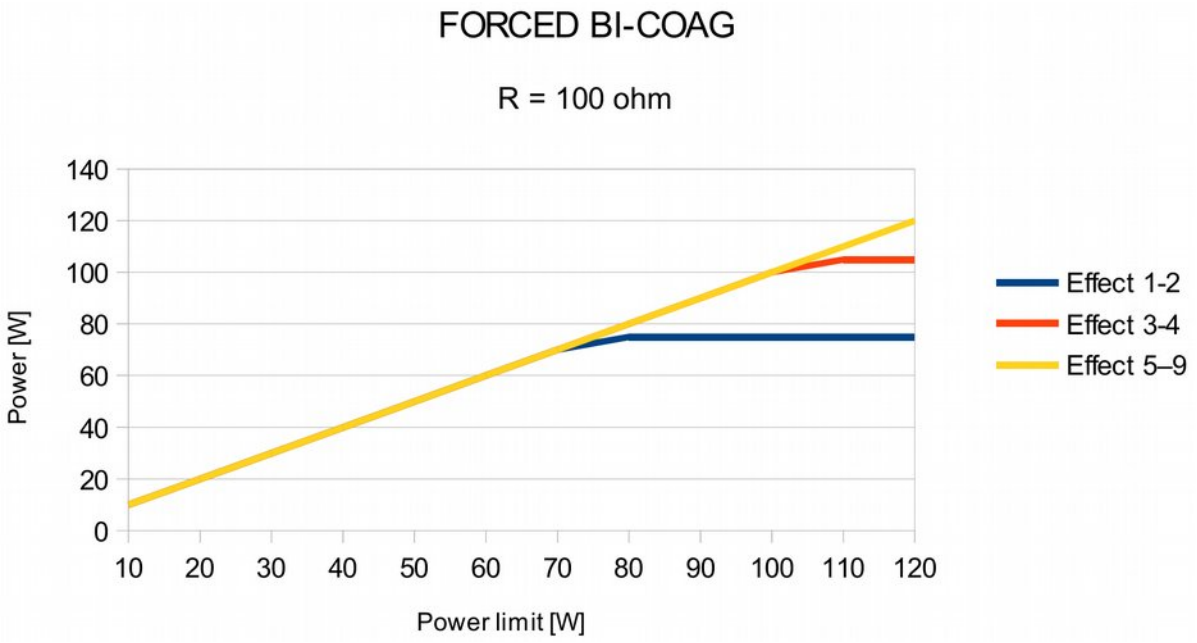

ARTRO BI-CUT
for resistance < 100ohm arc ignition
Power [W]
450
400
350
300
250
200
150
100
50
0
10
100
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9

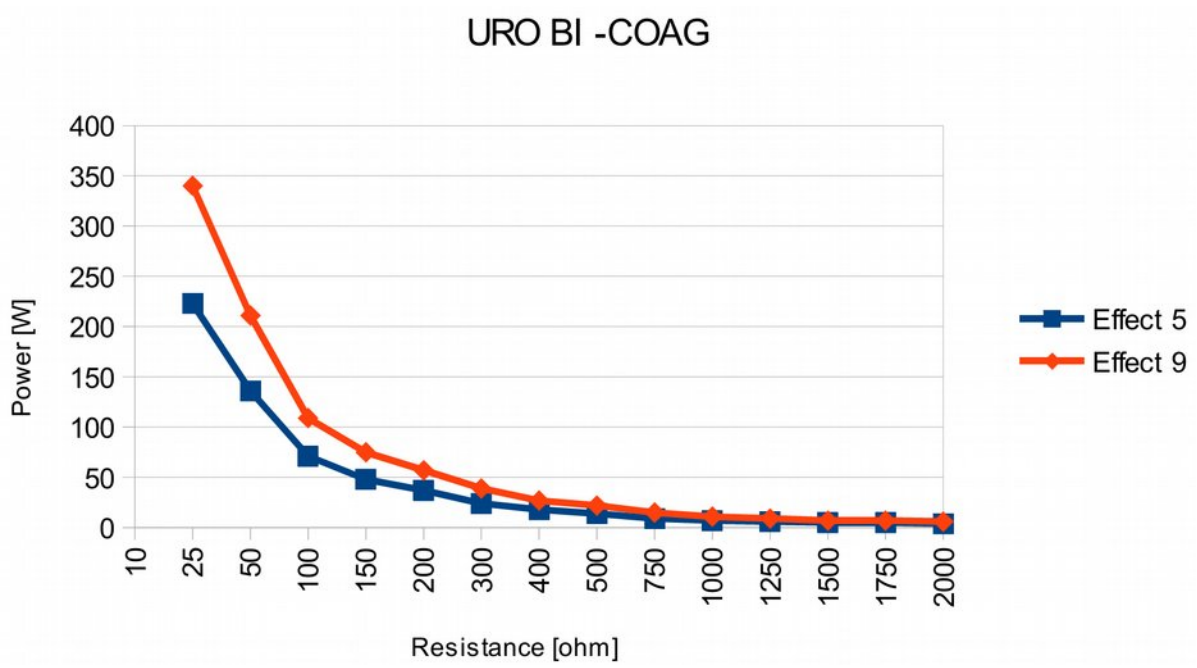

ARTRO BI-CUT
R = 125 ohm
Power [W]
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

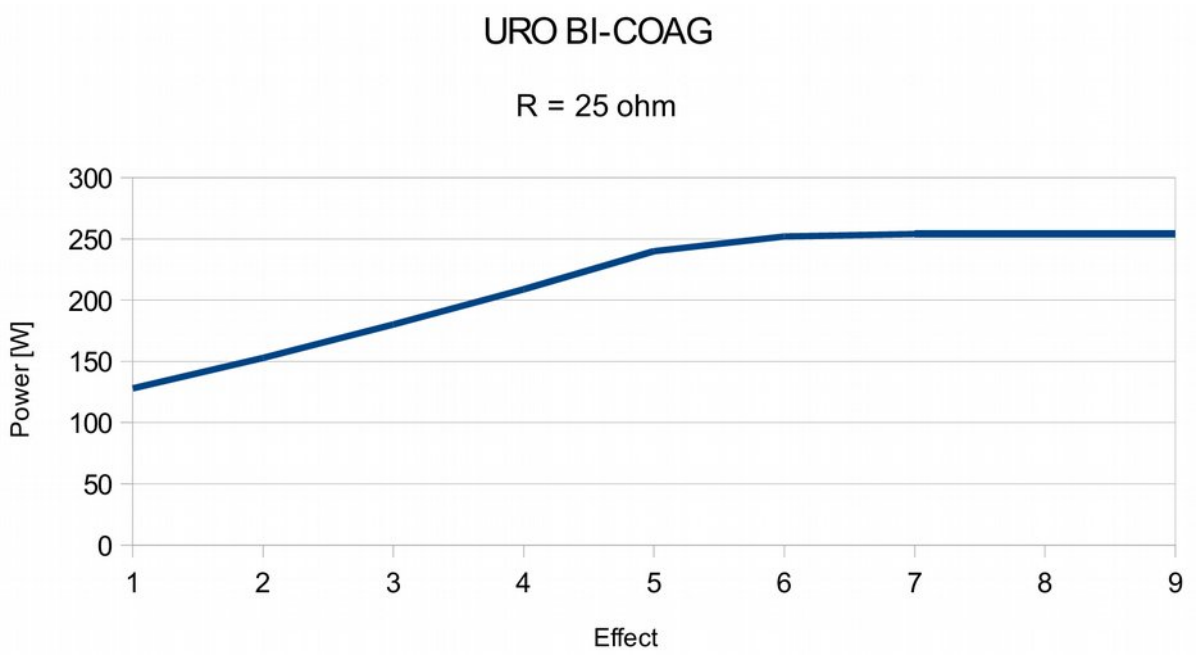

SOFT BI-COAG
Effect 9
Power [W]
140
120
100
80
60
40
20
0
10
25
50
100
150
200
300
400
500
750
1000
Resistance [ohm]
60W
120W

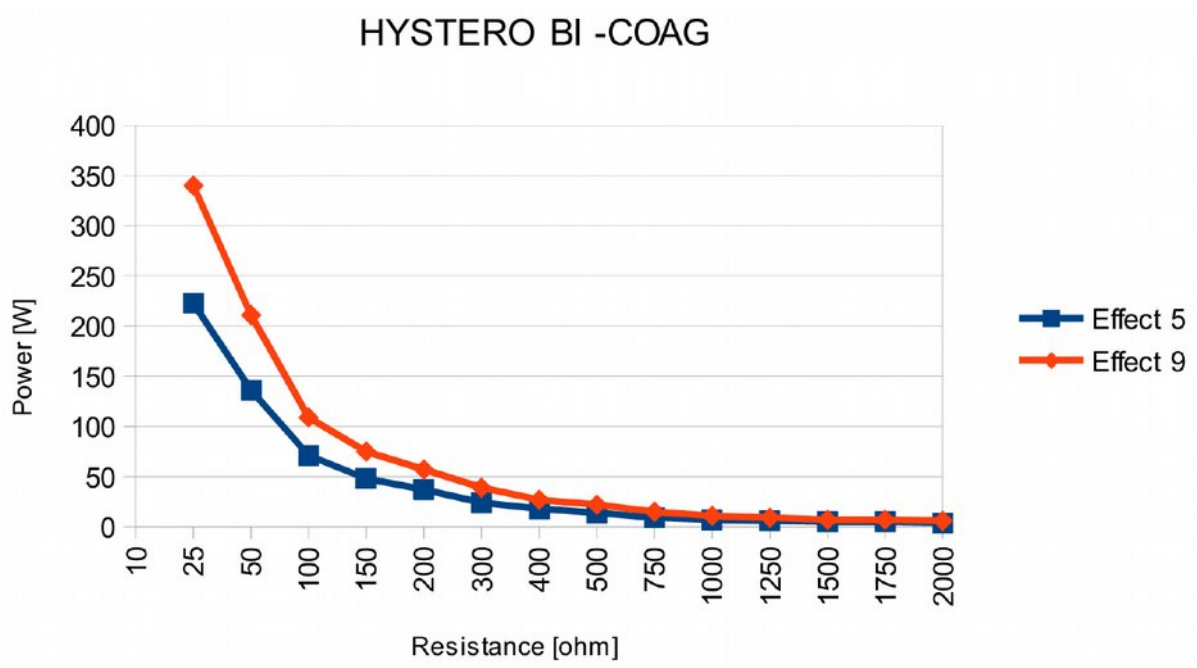

SOFT BI-COAG
R = 50 ohm
Power [W]
140
120
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
110
120
Power limit [W]
Effect 1
Effect 2
Effect 3 – 9

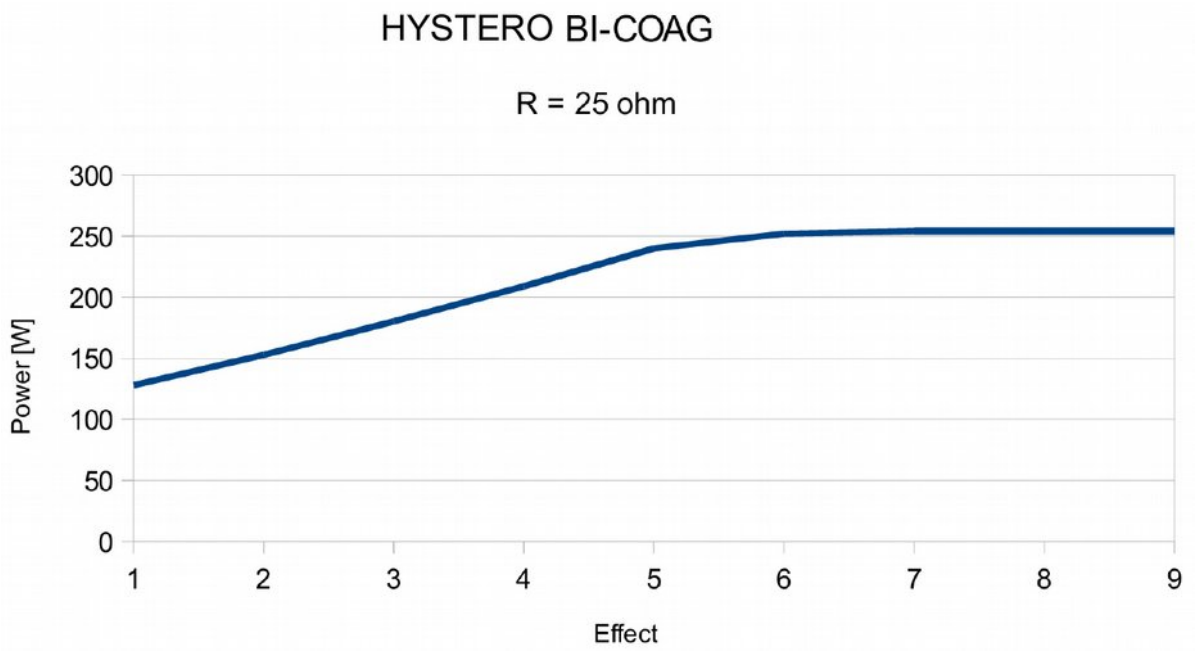

FORCED BI-COAG
Effect 9
Power [W]
140
120
100
80
60
40
20
0
10
25
50
100
150
200
300
400
500
750
1000
Resistance [ohm]
60W
120W

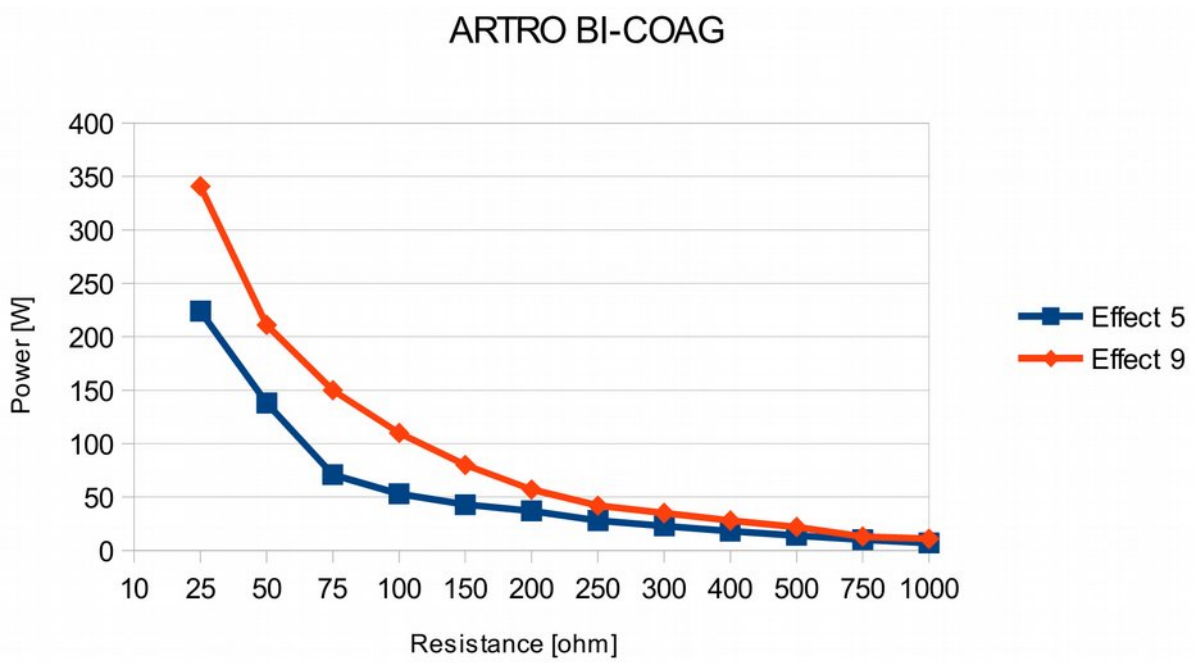

FORCED BI-COAG
R = 100 ohm
Power [W]
140
120
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
110
120
Power limit [W]
Effect 1-2
Effect 3-4
Effect 5–9

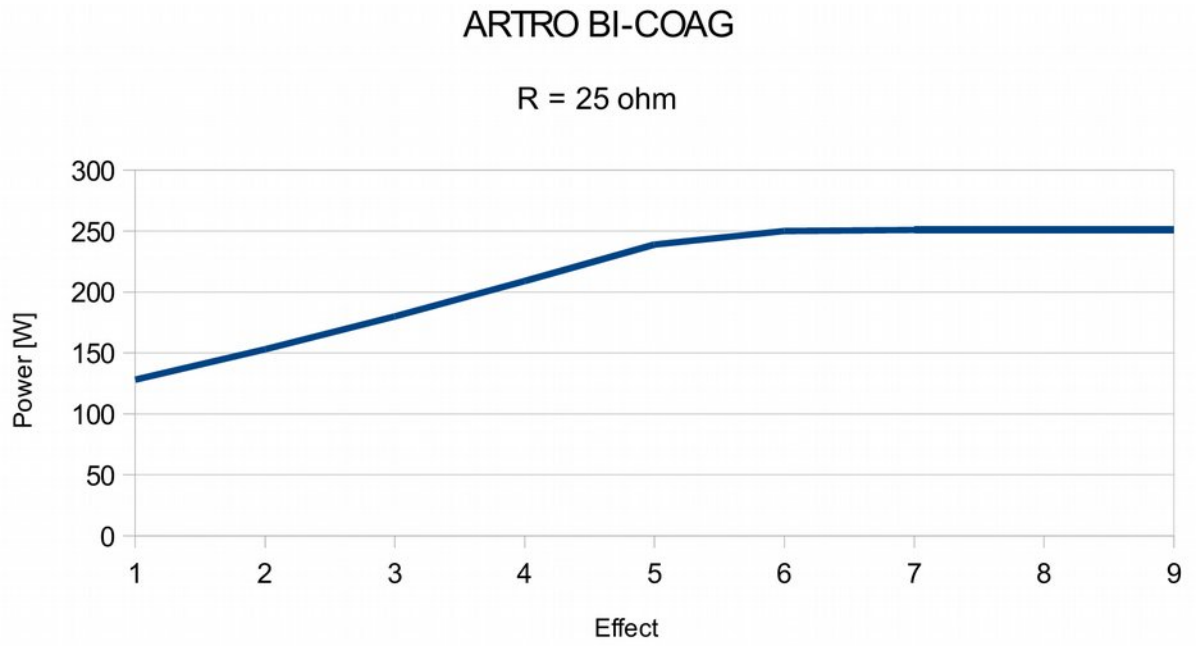

URO BI -COAG
Power [W]
400
350
300
250
200
150
100
50
0
10
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

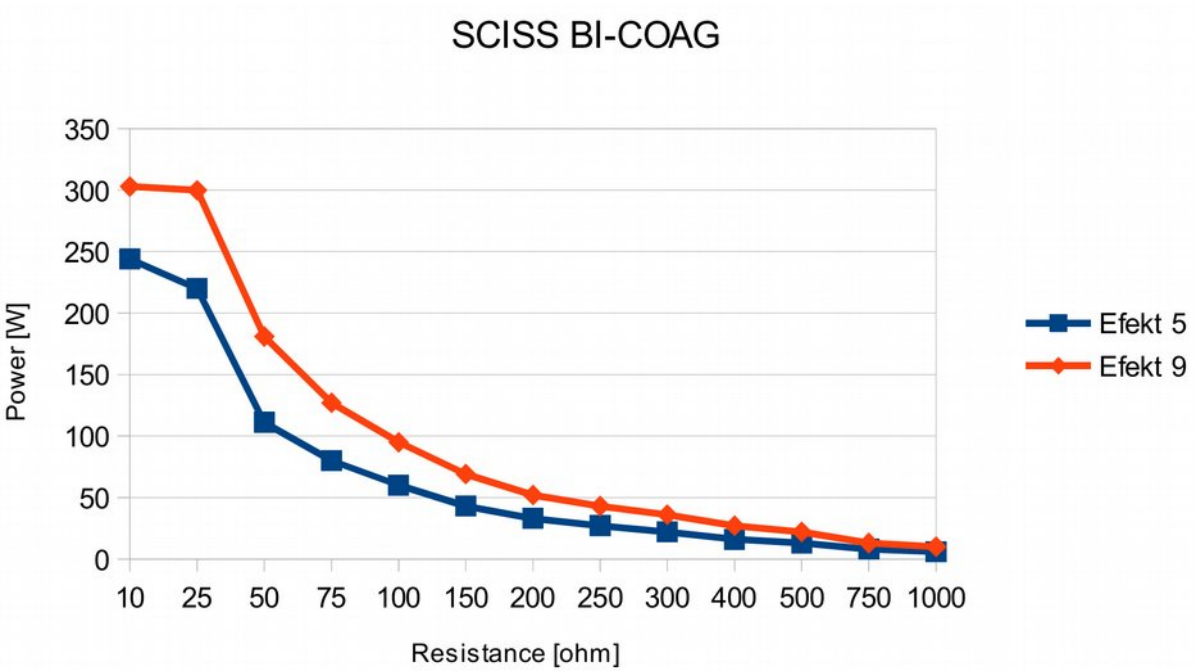

URO BI-COAG
R = 25 ohm
Power [W]
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

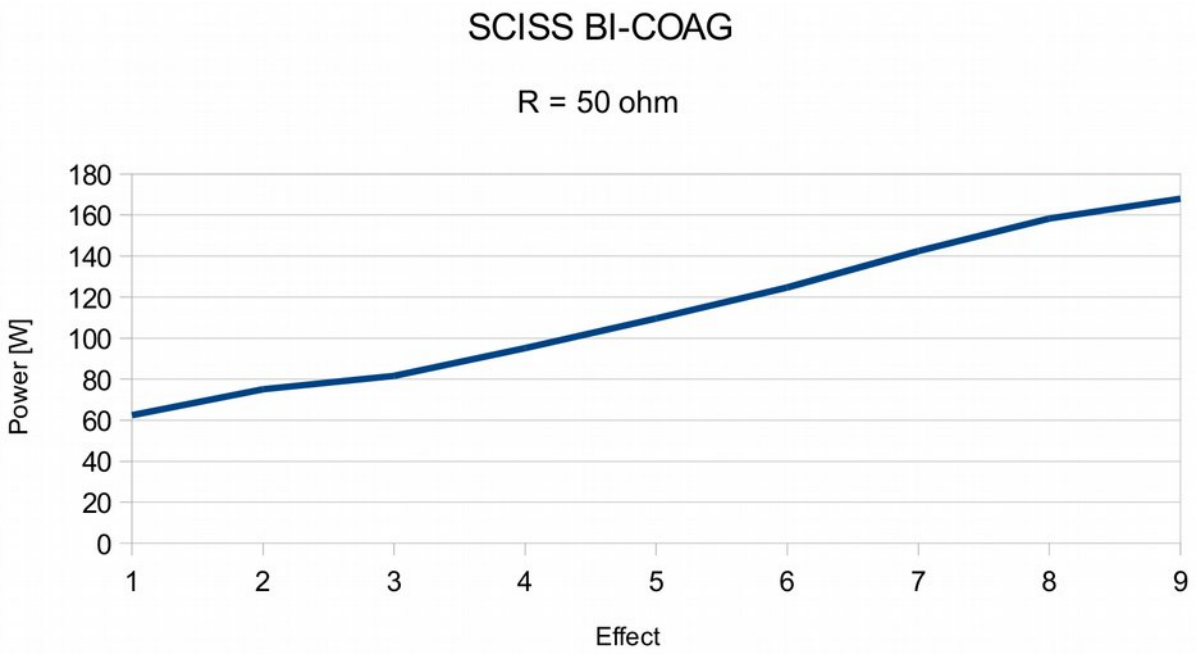

HYSTERO BI -COAG
Power [W]
400
350
300
250
200
150
100
50
0
10
25
50
100
150
200
300
400
500
750
1000
1250
1500
1750
2000
Resistance [ohm]
Effect 5
Effect 9

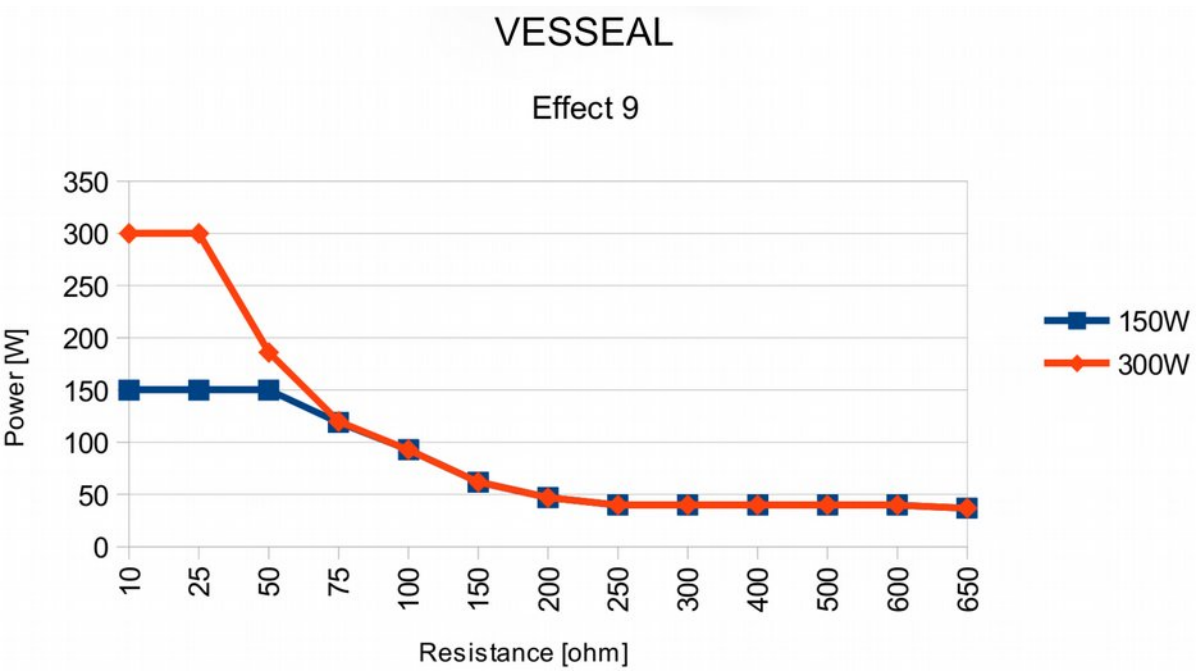

HYSTERO BI-COAG
R = 25 ohm
Power [W]
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
Effect

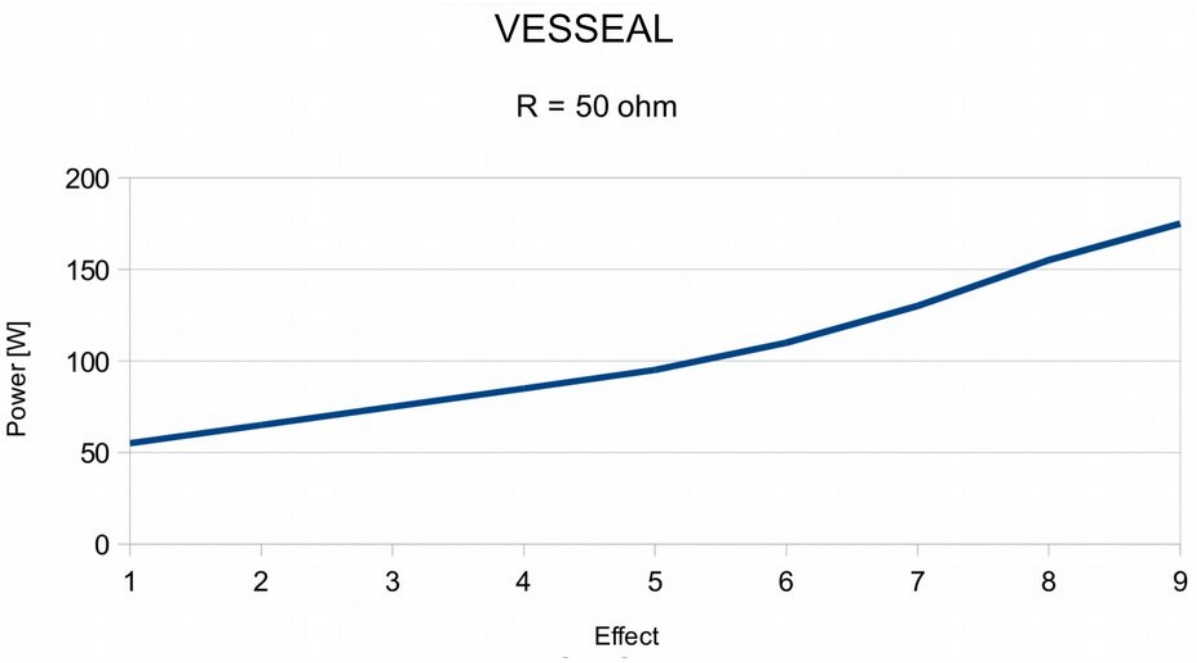

ARTRO BI-COAG
Power [W]
400
350
300
250
200
150
100
50
0
10
25
50
75
100
150
200
250
300
400
500
750
1000
Resistance [ohm]
Effect 5
Effect 9


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
350
300
250
200
150
100
50
0
Power [W]
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
180
160
140
120
100
80
60
40
20
0
Power [W]
1
2
3
4
5
6
7
8
9
Effect


VESSEAL
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


VESSEAL
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
The HF 16-2000-700 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

IMPORTANT NOTICE

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 marked otherwise, the electrosurgical accessories offered may be steam sterilised at up to 134°C and a pressure of 0.2 MPa (2 Bar). When using different accessories, please observe the manufacturer's recommendations.

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

IMPORTANT NOTICE

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

WARNING

In order to avoid mechanical damage, do not dry electrode handles in compressed air under a pressure higher than 0.3 MPa (3 bar).

12.1.3 Autoclave sterilization

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

RECOMMENDATION

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

12.1.4 Formaldehyde sterilisation

CAUTION

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		
The HF 16-2000-700is intended for use in the electromagnetic environment specified below. The customer or the user of the HF 16-2000-700 should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The HF 16-2000-700 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. When HF 16-2000-700 is not activated, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The HF 16-2000-700 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/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
HF 16-2000-700 is intended for use in the electromagnetic environment specified below. The customer or the user of the HF 16-2000-700 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations in 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 mains power interruptions, it is recommended that the HF 16-2000-700 is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
HF 16-2000-700 is intended for use in the electromagnetic environment specified below. The customer or the user of the HF 16-2000-700 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 **HF 16-2000-700**, 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	3 V_{RMS} 150 kHz to 80 MHz	3 V_{RMS}	D = 1.2 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	D = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz

			Where *P* is the maximum output power rating of the transmitter in watts W according to the transmitter manufacturer and *d* is the recommended separation distance in metres 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 which HF 16-2000-700 is used exceeds the applicable RF compliance level above, normal functioning of the HF 16-2000-700 should be verified. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HF 16-2000-700.

[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 HF 16-2000-700

HF 16-2000-700 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of HF 16-2000-700 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and HF 16-2000-700 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

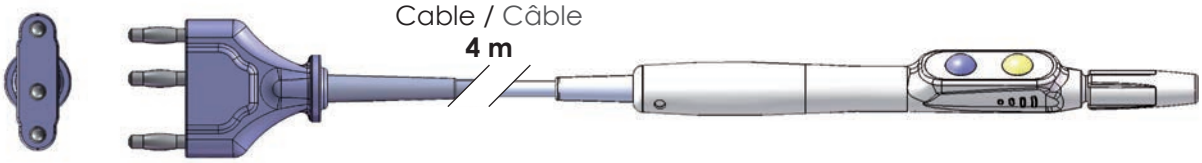
Since the transposition of the 2002/96/EU directive into the national legislation, the following rules have come into force:

- Electric and electronic equipment must not be disposed of with domestic waste.
- The user is obliged to dispose of a broken or redundant electrical or electronic device at a dedicated collection point, place 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 are helping to protect the natural environment.

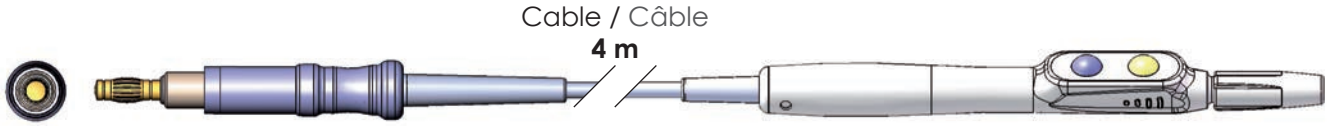
TACTILEC:
Reusable pencil with control buttons
Manches réutilisables à commandes manuelles

Reusable pencil with 2 buttons and international 3 pins plug
Manche réutilisable à commandes manuelles prise internationale



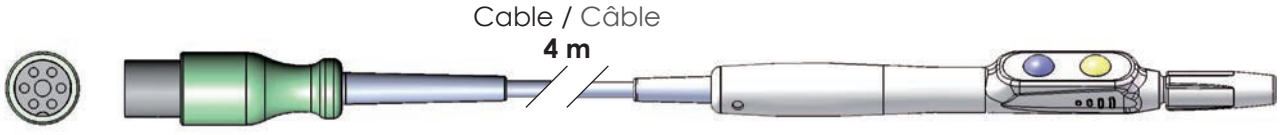
V11MCT9N	**chuck** / *mandrin*	Electrode Ø 2.4 mm	Class IIb = 1 Accessoires HF - NU U = 6.25 kVp T° 95°C max 134°C
V11MCT94N	**chuck** / *mandrin*	Electrode Ø 4 mm	

Reusable pencil with 2 buttons and 5mm plug
Manche réutilisable à commande manuelle prise ronde 5 mm



V11MCT10N	**chuck** / *mandrin*	Electrode Ø 2.4 mm	Class IIb = 1 Accessoires HF - NU U = 6.25 kVp T° 95°C max 134°C
V11MCT14N	**chuck** / *mandrin*	Electrode Ø 4 mm	

Reusable pencil with 2 buttons and Lamidey plug
Manche réutilisable à commandes manuelles prise Lamidey



V11MCT8N	**chuck** / *mandrin*	Electrode Ø 2.4 mm	Class IIb = 1 Accessoires HF - NU U = 6.25 kVp T° 95°C max 134°C
V11MCT84N	**chuck** / *mandrin*	Electrode Ø 4 mm	

Accessories

Accessory	Code No.	Name of Item	Specification
	FS01-01R	Single Foot Switch	3pin Plug Cable 4m
	FS02-01R	Double Foot Switch	4pin Plug Cable 4m
	PL02-01R	Silicon Patient Plate	240mm x 150mm 6.3Pie Plug Cable 3m
	PL02-02R	Silicon Patient Plate	165mm x 90mm 6.3Pie Plug Cable 2m
	PL02-03R	Silicon Patient Plate	110mm x 80mm 6.3Pie Plug Cable 2m
	PL02-04R	Silicon Patient Plate	240mm x 150mm ValleyLab Type Plug Cable 3m
	PL02-05R	Silicon Patient Plate	165mm x 90mm ValleyLab Type Plug Cable 2m
	PL02-06R	Silicon Patient Plate	110mm x 80mm ValleyLab Type Plug Cable 2m
	PL03-02D	Disposable Patient Plate	Adult Dual (120㎖)
	PL03-03D	Disposable Patient Plate	Pediatric Dual (66㎖)
	HD01-01R	Monopolar Handle & Cable	Silicon Cable 4ø 3m
	HD01-02R	Monopolar Handle & Cable	Silicon Cable 4ø 3m
	HD02-01D	Disposable Twin Button Handle	3pin Plug Cable 3m
	CA01-01R	Bipolar Forcep Cable	2pin Plug Cable 3m EN Type Connector
	CA01-02R	Bipolar Forcep Cable	2pin Plug Silicon Cable 3m EN Type Connector
	CA01-03R	Bipolar Forcep Cable	2pin Plug Silicon Cable 3m EU Type Connector
	CA01-04R	Laparoscopy Bipolar Connecting Cable	Silicon Cable, 3m
	CA01-06R	Bipolar Sealer Cable	Silicon Cable 4Ø, 3m
	CA01-07R	Vessel Sealing Cable	2pin Plug Silicon, Cable 3m, EU Type connector
	CA03-01R	Ground Cable	Cable 4ø, 3m

Accessories

Accessory	Code No.	Name of Item	Specification
	CA08-01R	Monopolar Connecting Cable	3Ø Connector, 4m
	CA08-02R	Monopolar Connecting Cable	4Ø Connector, 4m
	CA08-03R	Monopolar Connecting Cable	4.2Ø Connector, 4m
	CA02-02R	Patient Return Plate Cable	6.3Pie Plug Silicon Cable 3m
	CA02-03R	Patient Return Plate Cable	ValleyLab Type Plug Silicon Cable 3m
	BF01-01R	Bipolar Forceps	Bayonet 17.8cm 1.0 Tip
	BF01-02R	Bipolar Forceps	Bayonet 15.2cm 1.0 Tip
	BF02-01R	Bipolar Forceps	Straight 9.0cm 0.5 Tip
	BF02-02R	Bipolar Forceps	Straight 12.1cm 1.0 Tip
	BF02-03R	Bipolar Forceps	Straight 17.8cm 1.0 Tip
	BF03-01R	Bipolar Forceps	Angled 9.0cm 0.5 Tip
	BF03-02R	Bipolar Forceps	Angled 17.8cm 1.0 Tip
	EL01-02D	Electrode	Knife 2.4 * 70mm Black
	EL02-02D	Electrode	Ball 5mm Black
	EL03-02D	Electrode	Loop 6mm Black
	EL04-02D	Electrode	Needle 2.4 * 70mm Black
	EL04-04D	Electrode	Needle Angled 45º 2.4 * 70mm Black
	CT01-01R	CART	W390 x D480 x H850
	HD03-02D	Sens Probe	3 Pin Plug Cable 3m
	HD03-01D	Sens Probe	2 Pin Plug Cable 3m

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To whom it may concern

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CLARIFICATION LETTER

We, **ACKERMANN INSTRUMENTE GMBH**, manufacturer of endoscopic instruments and devices, located at Eisenbahnstrasse 65-67, 78604 Rietheim-Weilheim in Germany, hereby declare that upon being awarded the tender 21093931 "Achiziția Dispozitivelor medicale conform necesităților IMSP Spitalul Clinic de Traumatologie și Ortopedie (listă suplimentară 24)", a grounding/earth cable in length of 5m will be supplied for the High Frequency Surgical Units as offered in the tender.

Our local partner Ericon SRL and ourselves remain at your disposal for any further information which you may require.

Yours faithfully,

Ackermann
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D - 78604 Weilheim / Germany
Tel.: +49-7461/96 61 70 · Fax 96 61 770

Your Ackermann Team