

Endovapor^{®2}

Multi Radio Frequency System

User Manual



Radio Frequency Electrosurgical Unit

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1 Legal Notes

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The manufacturer is grateful for information about any errors or inconsistencies in this document.

Due to continuous improvement of our products, we reserve the right to make technical changes that do not affect functionality and basic safety.

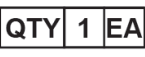
1.1 Liability

All procedures, notes and warnings described in this manual do not release the operator/user from his or her responsibilities regarding clinical judgment, experience and best clinical practice.

2 General Description

The joimax® Endovapor®2 is a compact high performance, high frequency energy source that can be used for a variety of RF surgical applications. It represents a radio wave technology with high surgical precision, versatility and safety. All device settings are pre-programmed for numerous standard procedures and can be customized to preferences. Inside the device, micro controllers ensure optimum integrated electric arc regulation, while self-checking programs such as the neutral electrode contact check, continuously ensure maximum safety. Four separate outputs can be individually configured.

3 Signs and Symbols

	Please note!
	Warning!
	Separate collection of electrical and electronic devices (in accordance with directive 2012/19/EU, WEEE)
	CE mark of the manufacturer according to MDD 93/42/EEC
	Manufacturer
	Date of manufacture
	Follow Instructions for Use
	Item number
	Serial number
	Quantity one each
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Certification mark of CSA Group (Canada)
	On/Off button
	Neutral electrode isolated from ground for RF
	Defibrillation-proof type CF applied part
	Alternating current
	Non ionizing electromagnetic radiation (During activation of the RF device, RF energy in the radio frequency range 9 kHz to 400 GHz is applied, which produces electromagnetic radiation)
	Dangerous voltage
	Equipotential (potential equalization)
	Foot switch connector

	Fiber-optic signal input
	Fiber-optic signal output
	Ethernet connector
	USB connector
	Audio In
IOIOI	Serial interface (UART communication interface)
IP21	Ingress protection class according to IEC 60529: 2: Protected against solid foreign objects of 12,5 mm Ø and greater 1: Protected against vertically falling water drops
IPX8	Ingress protection class according to IEC 60529: X: Not required to be specified 8: Protected against the effects of continuous immersion in water
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain
	Keep away from sunlight
	Non-sterile
MD	Medical Device

3.1 Device Label

Endovapor® 2

REF JEVD0201
SN 35201369

Date of manufacture 2021-04

Caution

Follow instructions for use

Dispose of properly

Non-ionizing Electro-magnetic radiation

IP21 ingress protection class

NETZSPANNUNG LINE VOLTAGE 220-240 V~
NETZFREQUENZ LINE FREQUENCY 50/60 Hz
NETZSTROM INPUT CURRENT 5.0 A
SICHERUNG LINE FUSE T 5.0 A H
SCHUTZKLASSE CLASS I
MONOPOLAR 350 W / 500 Ohm
BIPOLAR 120 W / 50 Ohm
FREQUENZ FREQUENCY 350 kHz / 1 MHz
BETRIEBSART OPERATING MODE INT 10s / 30s

joimax®

CE 0123

R_{only}

(01)04250337103967(11)210414(21)35201369

joimax® GmbH - Amalienbadstraße 41
RaumFabrik 61 - 76227 Karlsruhe
Germany - www.joimax.com

Rev. 01_2019/007

joimax®

Foot Switch Endovapor® 2

REF REFUSS01
SN 00001

joimax® GmbH
Amalienbadstraße 41, RaumFabrik 61
76227 Karlsruhe - Germany

P/N 1285276 [MKF 2 1S/1S-MED-AP GP26]
25 V AC / 60 V DC
IPX8

MD

(01)04250337108405(11)200317(21)00001

CE 0123

R_{only}

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⚙

Ⓢ

US

4 Intended Purpose and Characteristics

**Warning:**

The device must be used only for its intended purpose described in this manual!

4.1 Intended Purpose

The joimax® Endovapor®2 is intended exclusively for the generation of electrical power for monopolar and bipolar cutting and coagulation of soft tissue excluding all soft tissue structures of the central nervous system, namely spinal cord and meninges, during open or minimally invasive surgical procedures.

Indications for use

The Endovapor®2 is intended to be used in the following areas:

- Orthopedics
- Spinal surgery

Contraindications

The RF device must not be used if, in the opinion of an experienced physician or according to current literature, such use would cause a hazard to the patient, e.g. due to the general state of the patient's health, or if there are other contraindications.

Intended patient population

The Endovapor®2 is intended to be used on adult patients of all genders with appropriate indications (except pregnant women). The use of the Endovapor®2 is at the discretion of the respective user on the basis of his training and experience.

Intended users

The Endovapor®2 is intended for use by medical professionals (e.g. surgeons).

It must be operated under the supervision of qualified and authorized personnel. Users are required to be trained and familiar with the basic principles, application rules, and risks of the device in order to reliably avoid a risk to the patient, user, and others.

Intended use environment

The Endovapor®2 is intended for use in operating rooms.

The control unit is intended to be positioned stationary outside of the sterile patient environment, e.g. on a medical cart or table that is suitable in terms of tilting stability and weight of the device.

4.2 Characteristics

Performance Characteristics

The Endovapor®2 is a smart all-in-one RF generator. It features a clearly understandable operating design and innovative functionalities. It includes pre-programmed device settings for numerous standard procedures and joimax® special spine procedures. Four separate outputs can individually be configured.

The Endovapor®2 display is made of flat, wipe-resistant, shatter- and scratch-proof safety glass. The glass touchpad guarantees easy handling and hygienic cleaning.

With the triple action foot switch of the Endovapor®2, all indications and modes will be activated: Yellow pedal for CUT function, Blue pedal for COAG function and Black push button for selecting the active port.

Principles of Operation

An electrosurgical generator delivers power to tissue for cutting and coagulation in surgeries, by supplying radio-frequency electrical current to electrosurgical accessories such as probes or tweezers. The alternating electrical current is transformed to thermal energy within tissue to achieve the target effect.

In monopolar delivery technique one large area neutral electrode (grounding pad) is applied to the patient, the active electrode is the electrosurgical instrument. Current passes from the

active electrode into the target tissue, through the patient using the least resistant direct path to the neutral electrode. The thermal effects takes place at the tip of the active electrode, which is the location of highest current density and resistance.

Instruments for bipolar modes contain both electrodes in close proximity at the application area. The radio-frequency electrical current passes locally through the tissue. This type of application does not require the use of a neutral electrode.

Key Components

Control Unit	Foot switch	Neutral electrode cable
		
The control unit of the system generates the operating voltage via an oscillator and outputs it at the front connectors after power amplification. It includes a glass front with control elements for adjustment of device settings.	The foot switch is the main control element of the system. It is used to activate the power output of the control unit and switch between different connectors.	The neutral electrode cable serves as reusable connection cable for single-use neutral electrodes.

4.3 Clinical Benefits

The application of minimal invasive surgical methods is favorable compared to open surgery in terms of the following clinical benefits: smaller incision, less trauma /less scarring/better cosmesis, reduced blood loss, reduced infection, less postoperative pain, improvement of pain and mobility, faster recovery time/reduced hospital stay, fewer overall complications and improved quality of life.

Endoscopic spinal surgery clearly profits from a RF device for cutting and coagulation of soft tissue in terms of the following clinical benefits: reduced blood loss and reduced duration of the surgical operation.

5 Scope of Delivery

After delivery of the joimax® Endovapor®2, the packaging must be checked for external damage. If any components are damaged or missing, please contact joimax® customer service.

Item number	Item description		
JEVS0201	joimax® Endovapor®2 System <i>for mains voltage 220 – 240 V; incl. Foot Switch, Neutral Electrode Connecting Cable, Neutral Electrode</i>		
	List of components:		
	Item number	Item description	Quantity
	JEVD0201	joimax® Endovapor®2 Device (power rating 220 - 240 V)	1
	REFUSS01	Foot switch joimax® Endovapor®2	1
	JEVNC0001	joimax® Neutral Electrode Connecting Cable, Connecting Cable international	1
JEVS0202	JEVN0001	joimax® Neutral Electrode, Easy Universal, without Connecting Cable, Disposable	5
	joimax® Endovapor®2 System <i>for mains voltage 100 – 127 V; incl. Foot Switch, Neutral Electrode Connecting Cable, Neutral Electrode</i>		
	List of components:		
	Item number	Item description	Quantity
	JEVD0202	joimax® Endovapor®2 Device (power rating 100 – 127V)	1
	REFUSS01	Foot switch joimax® Endovapor®2	1
JEVS0204	JEVNC0001	joimax® Neutral Electrode Connecting Cable, Connecting Cable international	1
	JEVN0001	joimax® Neutral Electrode, Easy Universal, without Connecting Cable, Disposable	5
	joimax® Endovapor®2 System <i>for mains voltage 220 – 240 V; incl. Foot Switch</i>		
	List of components:		
	Item number	Item description	Quantity
	JEVD0201	joimax® Endovapor®2 Device (power rating 220 – 240V)	1
JEVS0203	REFUSS01	Foot switch joimax® Endovapor®2	1
	joimax® Endovapor®2 System <i>for mains voltage 100 – 127 V; incl. Foot Switch</i>		
	List of components:		
	Item number	Item description	Quantity
	JEVD0202	joimax® Endovapor®2 Device (power rating 100 – 127V)	1
	REFUSS01	Foot switch joimax® Endovapor®2	1

6 Safety and Warning Notes

6.1 General Safety and Warning Notes

**Warning:**

This device must be used by trained professionals only!

Warning:

Never touch the patient and any signal input or output connectors on the device at the same time!

Warning:

Installation of the device on a medical trolley with multiple-socket outlet leads to the establishment of a ME system and can lead to a reduced level of safety. The requirements regarding ME systems of IEC 60601-1 must always be observed!

Warning:

The device is not intended for use in explosive areas (e.g. in the presence of anesthetic gas)!

Warning:

Keep these instructions for use in a conspicuous place near the device!

Warning:

Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:

Mechanical stress, such as from falling, can damage or destroy the device!

Warning:

Never use the device with the housing open.

Warning:

Do not use needle electrodes for monitoring while using the device and attach electrodes and cables of physiological monitoring devices without protective resistors or RF chokes as far away from the RF electrodes as possible.

Warning:

For patients with electrically conductive implants, a possible hazard exists caused by concentration or re-direction of RF currents.

Warning:

When not in use, the connected accessories must never be placed on the patient and must always be removed from the patient and be placed in a safe place to avoid danger from unintended activation.

Warning:

Always use non-conductive irrigation fluid with monopolar programs and conductive irrigation fluid with bipolar modes for proper functionality of the device and to avoid potential hazards for the patient.

6.2 Additional Notes regarding MRI (Magnetic Resonance Imaging) and CT (Computer Tomography)

**Warning:**

Do not use the Endovapor®2 Control Unit during MRI or CT scans.

Due to energetic interactions of magnetic fields and X-rays with the material of the electrical components, the control unit may be damaged. Unforeseeable side effects may occur.

6.3 Additional Notes regarding Patients with Pacemakers

**Warning:**

Use of the device at patients with pacemakers or other active implants may lead to malfunction or destruction of the implant, which can endanger the life of the patient or result in irreversible injuries to the patient.

- *In the case of patients with pacemakers, consult the cardiologist before carrying out RF surgery.*
 - *If possible, use bipolar RF methods.*
 - *When using monopolar RF methods, attach a RF neutral electrode.*
 - *Set the demand pacemaker to a fixed frequency.*
 - *Ensure that the pacemaker does not come into contact with the RF electrode.*
 - *Keep a fully operational defibrillator within reach.*
 - *Carry out a postoperative pacemaker check.*
 - *When in doubt, seek appropriate professional advice.*
-

6.4 Additional Notes regarding Patient Positioning

**Warning:**

Always make sure blood circulation is not impaired when positioning and sedating the patient.

Warning:

When positioning the patient ensure

- *To position patients so that they are not touching any metal parts that are grounded or have considerable capacitance relative to ground (e.g. operating table brackets). If necessary, place anti-static cloths between the patient and the bedding.*
 - *That the patient does not touch any wet clothes or bedding.*
 - *To place anti-static cloths between areas with heavy sweating and skin-to-skin contact areas on the patient's torso.*
 - *That the patient is resting on a suitable surface in order to prevent pressure necrosis.*
 - *To drain urine via a catheter.*
-

6.5 Additional Notes regarding Ignition and Explosions

**Warning:**

Use exclusively non-flammable cleaning agents, disinfectants and solvents (for adhesives). If you use flammable cleaning agents, disinfectants or solvents, ensure that they have fully evaporated before using RF surgical equipment.

Warning:

Ensure that no flammable liquids collect beneath the patient or in body cavities (e.g. the vagina). Suction and/or flush body cavities before activating the device.

Warning:

Ensure that no ignitable endogenous gases are present.

Warning:

Ensure that all materials saturated with oxygen (e.g. cotton or gauze) are kept far away from the RF environment, so that they cannot ignite.

6.6 Additional Notes regarding Endoscopic Equipment

**Warning:**

If the device is used stacked in combination with endoscopic equipment, always position the camera control unit above the electrosurgical unit. Ensure that cables of active electrosurgical accessories are not positioned close to the camera control unit or the camera head cable.

Warning:

Never touch the connected endoscope with an activated electrosurgical electrode.

6.7 IT Security Requirements

**Warning:**

Good physical security must be provided to prevent unauthorized physical access to the device.

Warning:

This device must only be used by trained and authorized professionals.

Warning:

Service activities must only be carried out by authorized service personnel.

Cybersecurity considerations were made in accordance with the nature of the device, including the device type and the use environment (operating room) during its lifetime.

The Endovapor®2 software is embedded into the Endovapor®2 control unit (closed system). All external digital interfaces (providing service features) are deactivated during the use of the device or secured by using dedicated communication protocols if an interface is activated. The system does not provide any network functionality.

Therefore, no requirements concerning hardware and IT network characteristics are necessary to run the software as intended, because no external connection/interaction is foreseen.

The healthcare provider is responsible to provide good physical security to prevent unauthorized physical access to the system. The following common best practice security controls ("security hygiene") in the operating environment are recommended to be followed:

- Ensure regulated and authenticated physical access via suitable technical measures (e.g. badges)
- Define roles and access rights, including those for physical access to medical devices
- Provide security awareness training
- Ensure that prescribed maintenance is done as required, including installation of security patches/updates

Contact the joimax® technical support for further information provided on device cybersecurity.

Cybersecurity Vulnerability Reporting

If you detect a cybersecurity weakness or vulnerability of the device or if a cybersecurity incident takes place involving the device, contact joimax® technical support. Depending on the actual event, joimax® technical support will advise which steps to take.

Security Patches/Updates

Security patches/updates are provided by joimax® and may only be installed by authorized personnel. The Endovapor®2 does not allow additional software for malware detection or anti-virus.

6.8 Residual Risks and Undesirable Side-Effects

When using the product, residual risks exist and may lead to the following side-effects for patient, user or third parties: electric shock, burns, bacterial or viral infection, injuries (e.g. nerve damages, cuts, tissue necrosis, irritation or intoxication), delay of the surgery and discontinuation or change of clinical intervention.

7 Installation and Commissioning

**Warning:**

Examine the device, the accessories, and all electrical connections for function and damage prior to use! Defects in cables, connectors, housings or loose parts can impair performance and safety and must be rectified immediately!

Warning:

This device must be installed and commissioned by authorized personnel only. Improper installation could cause damage to the user, the patient, or others, and might damage the device or other medical equipment.

Warning:

Place the device in a way that allows easy disconnection from the mains!

Warning:

The ambient temperature must not exceed +40 °C (+86 °F) during operation!

Warning:

Place the control unit on a clean, flat surface. Ensure that you keep sufficient space behind the device for efficient airflow. Make sure that a minimum distance of 15 cm (6") is maintained between the back of the device and other objects. All ventilation openings must not be obstructed.



The device is recommended to be installed in the joimax® endoscopic trolley.

Keep the original packaging for possible shipment of the device.

The device and all accessories must be checked immediately upon receipt for completeness and obvious damage. Damages may be claimed only if the manufacturer is notified immediately (within a 24-hour period).

If the RF device was previously stored or transported at temperatures below +10 °C (+50 °F) or a relative humidity above 75%, non-condensing, it will take approximately three hours to adjust to room temperature.

7.1 Connection of the Device

**Warning:**

To avoid the risk of electric shock, this equipment must always be connected to potential equalization and a power supply with protective earth!

Warning:

Only joimax® accessories (cables etc.) may be used for connection!

Warning:

Always keep cables out of passage areas in order to reduce the risk of stumbling.

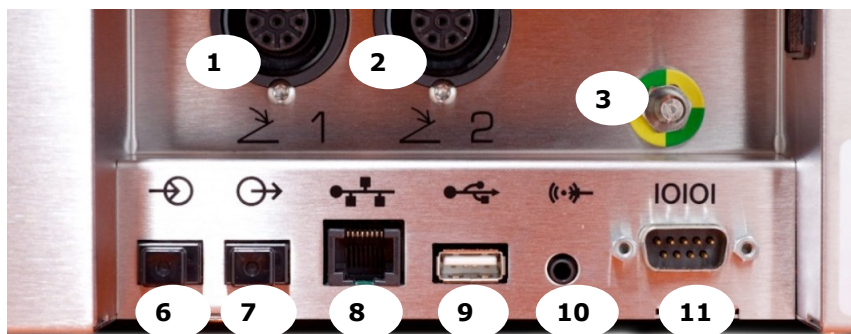
Warning:

Make sure all connectors are free of coarse soiling before insertion.

Warning:

Before connecting and launching the system, all components must be visually inspected for integrity. Damaged parts must be replaced. This must be done by experts.

Rear Panel



1.	Foot switch socket connector 1	7.	Fiber-optic signal output connector
2.	Foot switch socket connector 2	8.	Ethernet connector
3.	Potential equalization connector	9.	USB connector
4.	IEC power cord connector	10.	Audio In (not occupied)
5.	Power switch	11.	UART communication interface
6.	Fiber-optic signal input connector		

Front Panel



12.	Monopolar 1: Socket connector for monopolar instruments with hand or foot switch*
13.	Monopolar 2: Socket connector for monopolar instruments with hand or foot switch*
14.	Socket connector for neutral electrode*
15.	Bipolar 3: Socket connector for bipolar instruments with foot switch, hand switch or AUTOSTART*
16.	Bipolar 4: Socket connector for bipolar instruments with foot switch, hand switch or AUTOSTART*

* Applied part type CF according to IEC 60601-1

7.1.1 Connecting the Control Unit to a Power Supply Network and Potential Equalization



Warning:

Always connect the device to a buffered power supply and make sure that the nominal voltage and power values on the device label are respected. Check the power supply cable prior to use!



Respect the requirements of section 8.6.7 of IEC 60601-1 regarding medical electrical systems.

1. Connect the potential equalization plug to the grounding via appropriate cable.
2. Use the original power cord to connect the power inlet with the mains supply. Set the appropriate output frequency.
3. Set the power switch to position "I".



For safe disconnection of the device from mains power supply, set the power switch at the backside of the device to position "0" and unplug the power cord from the mains connection.

7.1.2 Connecting Accessories



Warning:

Do not prematurely open the sterile packaging of accessories and do not use them if the sterile packaging is visibly damaged or otherwise compromised.

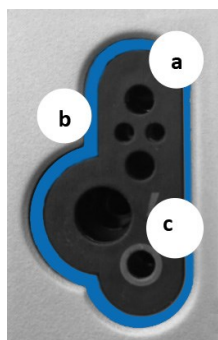


Before connecting instruments, ensure that the following conditions are met:

- Combinations of accessories not mentioned in the user manual may be used only if they are explicitly designed for the intended purpose. Always observe performance characteristics and safety requirements.
- The insulation of the accessories (e.g. RF cables and instruments) must be sufficient for the maximum peak output voltage (see IEC 60601-2-2).

Monopolar Instruments

Monopolar connection sockets (left)



- a 3-Pin US type
- b Bovie (foot switched)
- c 4 mm (0,16 ") socket (foot switched)

1. Connect the monopolar handpiece to one of the two monopolar socket connectors. If using a handpiece without buttons, connect a foot switch.

Neutral Electrodes



Warning:

Ensure compliance with the specifications for correct attachment of the neutral electrode with regard to size, adhesive properties and full-surface contact of the complete electrode.



It is recommended to always use the largest possible electrode.

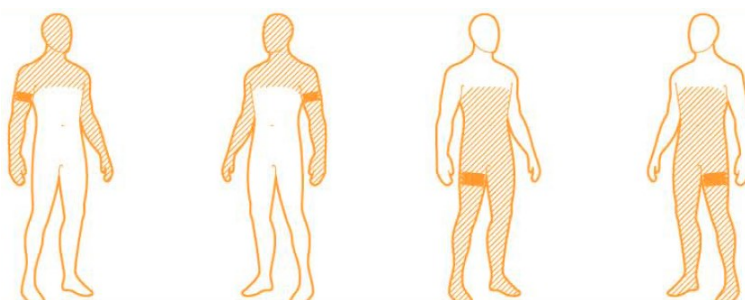
joimax® recommends using split neutral electrodes, since only this type of electrode allows the RF device to detect detachment of the neutral electrode if this occurs.

The maximum output power of monopolar current types is reduced to 50 W when a children's electrode is selected.

Read the instructions on the use of the neutral electrode in the user guide and the information on the package of the neutral electrode.

The following points should be considered to prevent a rise in temperature at the neutral electrode:

- *Sufficiently large contact surface between the neutral electrode and the patient's body.*
- *High electrical conductivity between the neutral electrode and the patient's body.*
- *Select the application point for the neutral electrode so that the current paths between the active and neutral electrodes are as short as possible and run longitudinally or diagonally through the patient's body (because muscles are more conductive in the direction of the fibrils).*

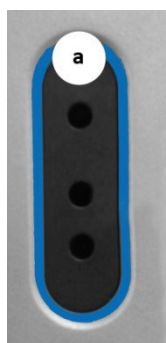


- *For surgery in the thoracic region, do not run the current path transversely across the patient's body and ensure that the patient's heart is never in the current path.*
- *Depending on the surgical site, apply the neutral electrode to the nearest upper arm or thigh if possible, but never closer than 20 cm (7.9 ").*
- *In the case of self-adhesive disposable electrodes, comply with any further manufacturer instructions regarding the point of application.*
- *Ensure that the application area is free of scar tissue, bony protuberances, surface hair and ECG electrodes.*
- *Ensure that there are no implants (e.g. bone nails, bone plates or endoprosthesis) in the current path.*
- *Ensure that no short circuits can occur at the neutral electrode connection.*
- *Avoid areas where fluids may collect.*

Use split neutral electrodes with a sufficiently large surface area (patient age and max. output power during operation have to be considered).

Connection socket for neutral electrode (left)**a** Neutral (US type)

1. Plug the neutral electrode cable into the socket for the neutral electrode.
2. Select the corresponding neutral electrode type on the touch display.

Bipolar InstrumentsBipolar connection sockets (right)**a** 2-Pin US-Type (28.58 mm / 1.13 ")

1. Connect the bipolar handpiece to the instrument (e.g. forceps).
2. Connect the bipolar handpiece to one of the two bipolar socket connectors.
3. For bipolar handpieces without buttons, use AUTOSTART or connect a foot switch.

7.1.3 Connecting the Foot Switch

The foot switch is used to activate the device's operating modes. Connect the foot switch to one of the two socket connectors for foot switches.

- 👉 The RF device automatically detects the connected foot switch and indicates this on the front panel display, including the selected socket connector.

Use the black changeover switch to switch between two selected monopolar and/or bipolar socket connectors. Foot switches without a black changeover switch cannot be used.

7.2 Functional Test



Damage to the device can lead to an undesirable increase in output power due to improper operation of the device.

Certain devices or accessories can pose a risk at low power settings. For example, in argon coagulation, the risk of gas assemblage increases when there is insufficient RF power to rapidly create an impermeable scab layer on the target tissue.

7.2.1 Auto Test Function

The RF device automatically performs cyclic testing during operation. If any problem occurs, see chapter 14.

7.2.2 Functional Testing

Perform the following functional test before putting the device into service:

- 1) Connect the neutral electrode and attach it securely where suitable.
 The EASY neutral electrode indicator changes to green.
- 2) Remove the neutral electrode.
 The indicator changes to red, acoustic signals sound.
- 3) Connect the neutral electrode. Connect a monopolar RF handpiece to a monopolar socket connector if there is a green EASY indicator and use the handpiece and foot switch to individually activate "Cut" and "Coag".
- 4) Check the settings on the display.
- 5) Now change to the bipolar output and connect bipolar forceps.
- 6) Select a mode with AUTOSTART, grasp moist gauze with the forceps, and check the display.
- 7) Now change to a mode without AUTOSTART and use the foot switch to activate the bipolar output. Check the settings and indicators in the bipolar section.



The neutral electrode used for this test may not later be used for an operation.

7.2.3 Behavior in the Event of Malfunctions



In the event of malfunction of the device or changes in its performance that may affect safety (e.g. deviations from the permissible operating conditions) have the faults corrected immediately.

The RF device can be switched off at any time by using the power switch as an emergency stop switch.

Proceed as follows in case of malfunctions:

1. Immediately disconnect the patient from the RF device.
2. Inspect the RF device and perform a functional test.
3. Contact the joimax® technical support.
4. Report any serious incident to joimax® GmbH and the competent authority having jurisdiction in your locale, see Chapter 19.

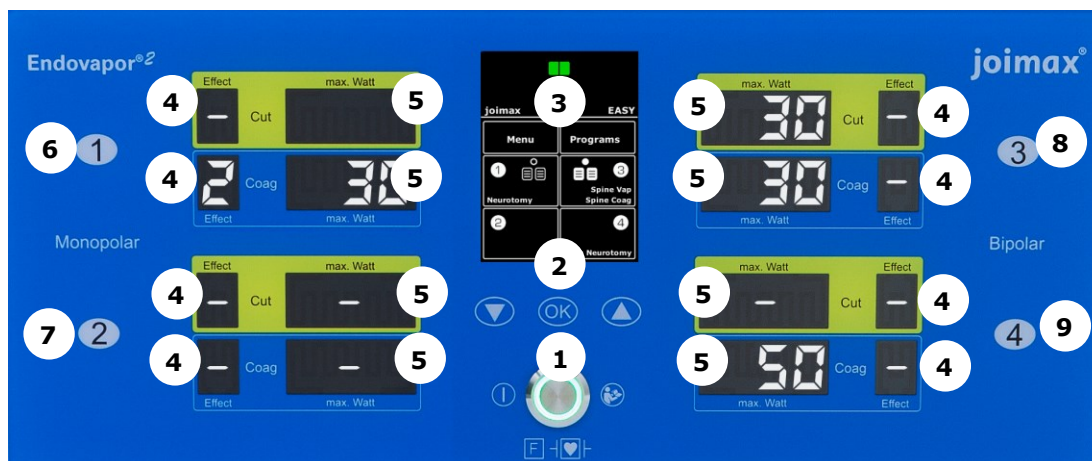
8 Operation



For protection of personnel, joimax® recommends the usage of a fume vent, to withdraw electrosurgical fumes.

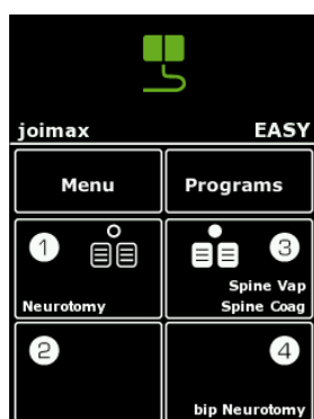
8.1 Control Elements

Front Panel



1.	Button "On/Off"	6.	Activation indication Monopolar 1
2.	Operating and confirmation buttons "OK", "Up" and "Down"	7.	Activation indication Monopolar 2
3.	Touch display	8.	Activation indication Bipolar 3
4.	Button "Effect"	9.	Activation indication Bipolar 4
5.	Button "max. Watt" (maximum output power)		

A touch display is located in the center to control the menu.



The button "Neutral electrode" for neutral electrode settings is located in the upper part of the display.

The program name, the neutral electrode type, as well as the buttons "Menu" and "Programs" are displayed in the middle of the display.

The "Socket menu" -for setting the mode and foot switch for the four sockets - is located in the lower part of the display.

If the display is locked, the "Key lock" button is displayed instead of the "Menu" button. To unlock, tap on any control element, tap "Unlocking" and then "OK".

8.2 Starting the Device



Warning:

Make sure that the device is turned on only after checking the power connector and after ensuring that the device is completely wired.

1. Power up the RF device using the power switch on the back.
2. Switch the RF device on using the "On/Off" button at the front.
 - ↪ The RF device performs a self-testing: All user interface components light up.
 - ↪ Full functionality of the loudspeaker is indicated by the start melody.
3. Check all controls and indicators for proper operation:
 - Power switch
 - Touch display
 - "Effect" button
 - "max. Watt" button
 - Activation indication for monopolar and bipolar socket
4. Instructions for use are shown.
 - ↪ The main screen appears, and the RF device is ready for use.
 - ↪ The parameters of the most recently selected modes appear on the display.

8.3 Shutting Down the Device



For full disconnection from the power supply, the mains switch at the rear of the device must be switched to position "0".

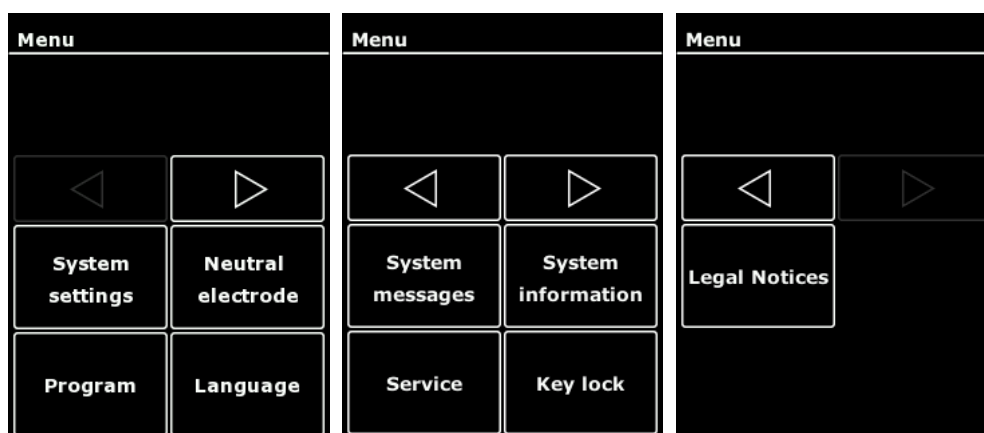
1. The control unit is shut down by pressing the "On/Off" button at the device front.
2. Press the "On/Off" button again to restart the device.

8.4 Device Settings



Set the level of the acoustic signal that sounds when the electrode is activated so that it is always clearly audible.

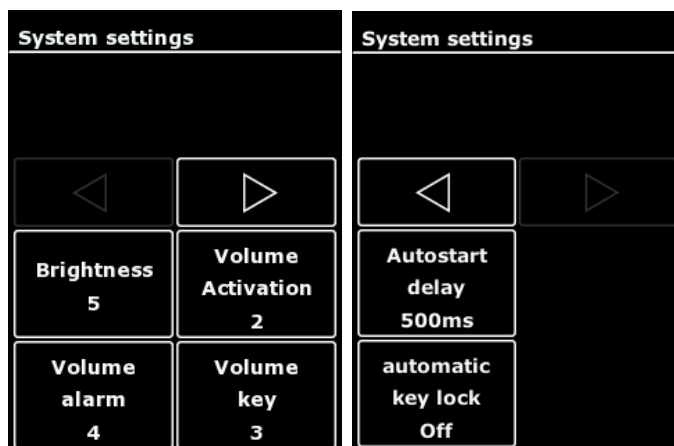
Press the "Menu" button to show the following menu dialogs:



Switch to the required function with the horizontal arrow keys, and press the appropriate selection button to open the menu.

Press the "OK" button to return to the main screen.

8.4.1 System Settings



The "System settings" include settings for brightness, volume of the activation tone, alarm tone and key tone, AUTOSTART delay as well as automatic key lock.

1. Tap the desired parameter.
2. Change the setting in single steps using the "Up" and "Down" buttons.
3. Confirm the selection with the "OK" button.

- or -

To return to the main screen without changing the selection, tap any button outside the selection menu.

8.4.2 Neutral Electrode

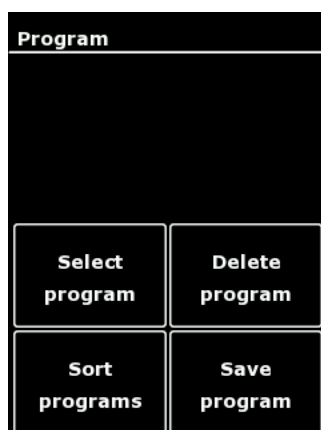
In the "Neutral electrode" menu the connected neutral electrode type is selected and the contact quality is displayed.

8.4.3 Programs



The Program name is displayed red, if settings of the program are changed by the user but not saved.

In the "Program" menu it is possible to select, delete, sort and save programs. You can also enter the "Program" menu via "Programs" on the main screen of the touch display.



Select Program

1. Tap "Select program" to enter the program list.
 - ↳ A list of saved programs appears.
 - ↳ The currently loaded program is visualized by the blue arrow.
 2. Select the desired program by using the "Up" and "Down" buttons.
 3. Confirm the selection with the "OK" button.
 - ↳ The main screen is displayed.
- or -
- To return to the main screen without changing the selection, select "Back" or tap any button outside the selection menu.

Delete Program

1. Tap "Delete program" to enter the program list.
 - ↳ The system displays a red highlighted list of stored programs.
 - ↳ The currently loaded program is visualized by the blue arrow.
 2. Select the program to be deleted with the "Up" and "Down" buttons.
 3. Confirm the selection with the "OK" button.
 - ↳ The main screen is displayed.
- or -

To return to the main screen without changing the selection, select "Back" or tap any button outside the selection menu.

Sort Program

1. Tap "Sort program" to sort the programs alphabetically, by favourites or by storage date.
 2. Select the required order by tapping on the desired parameter.
- ☞ The "Program" dialog is displayed.

Save Program

1. Tap "Save program" to save the current setting under the same or another program name.
2. Choose "Save" to maintain the same program name for the current setting.
- or -
Select "Save As" to save a new program name for the current setting.

8.4.4 Language

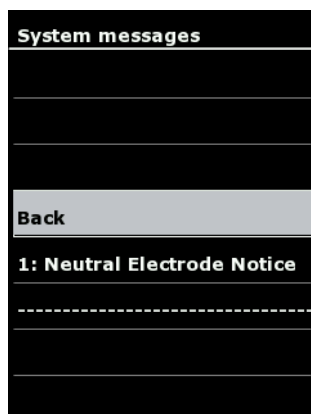
Tap "Language" to select one of the following languages:

German, English, Spanish, French, Italian, Polish, Portuguese, Hungarian, Russian, Turkish and Czech.

8.4.5 System Messages

In the "System messages" dialog, it is possible to open the saved system messages which have occurred since switching on the RF device.

These messages are not saved when switching off the RF device.



1. Select a system message.
2. Tap "OK" to open the system message again.
3. Press again "OK" to return to the overview.
4. To return to the main screen without changing the selection, tap any button outside the selection menu.

8.4.6 System Information

The "System information" dialog displays various system parameters such as version, serial number and TSI dates for Endovapor®2.

8.4.7 Service

In the "Service" dialog contact information is displayed, after entering a password, you can use the dialog to access additional options.

With the password **001224** you enter the service level.



Save device setting

With the function "Backup device" device settings can be saved on a USB storage, e.g. the joimax® USB sticks JMUSB20 (4GB) or JMUSB10 (16GB). This includes all stored programs and system settings.

Transfer device settings

Use "Restore device" to transfer saved device settings from a USB storage to the Endovapor®2.

Save logfiles

Use "Safe logfiles" to save logfiles on a USB storage.

Reset to factory settings

The "Reset to default" function allows you to reset all settings and programs to factory settings.

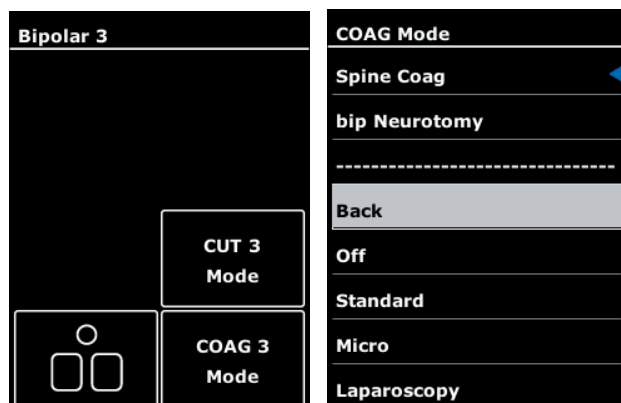
8.4.8 Key Lock

Tap "Key lock" to lock the touch display. To unlock, tap on any control element, tap "Unlocking" and then "OK".

8.4.9 Legal Notices

The license agreement for the operating system can be viewed in the "Legal Notices" dialog.

8.5 Selecting Modes

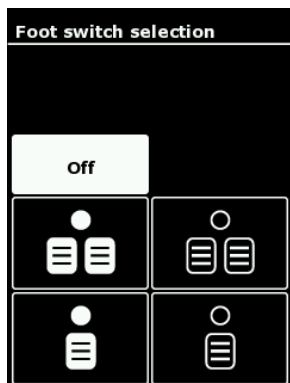


- To select the mode, select the respective socket in the "Socket menu" on the main screen.
 - ↳ A menu appears to select the foot switch assignment as well as the modes for cutting or coagulation.
- Tap on the desired mode type.
 - ↳ A selection screen appears for the available modes.
 - ↳ The active mode is indicated by a blue arrow.
- Select the required mode using the "Up" and "Down" buttons.
 - or -
 - Deactivate the mode by selecting "Off".
- Confirm the selection with the "OK" button.
 - ↳ The overview to select the foot switch assignment, as well as the modes for cutting or coagulation re-appears to select other settings.
 - or -
 - To return to the main screen without changing the selection, select "Back" or tap any button outside the selection menu.

8.6 Assigning the Foot Switch



Handpieces and instruments with activation buttons do not need assignment.



1. Select the desired socket in the "Socket menu" on the main screen.
2. Tap on the "Foot switch" button.
3. Select the required foot switch by pressing the corresponding button.
- or -
- Deactivate the foot switch using the "Off" button.
4. Confirm the selection by pressing the "OK" button.
- or -
- To return to the main screen without changing the selection, tap any button outside the selection menu.

Use the black changeover button to switch between two selected monopolar and/or bipolar sockets.

8.7 Setting Power Output and Effect



All selection windows are closed after 15 seconds without application of the modification.

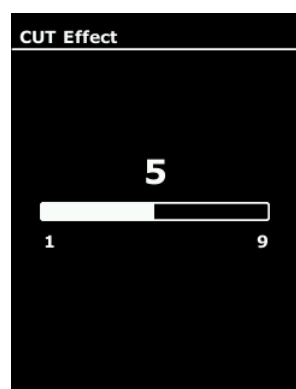
A change in the currently loaded mode, such as by adjusting the power is indicated by a red glowing mode name.

To prevent inadvertent (thermal) tissue damage during operations on body parts with small cross sections and in areas with high resistance (bones or joints), the use of bipolar methods is recommended for these areas.

During RF surgical operations (especially when an arc is formed), part of the RF current is converted into a low-frequency current. This current can trigger muscle contractions in the patient:

- *To minimize the risk of injury to the patient, set the power and the effect as low as possible.*
- *For usage in spine surgery use the joimax® spine modes.*

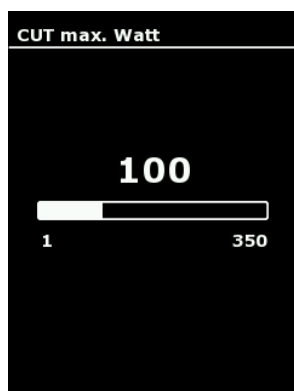
The activation indications and buttons to set the output power and the effect are allocated next to the corresponding sockets. The effect of electrosurgical cutting or coagulation can be set using the button "Effect". To change the output power, use the "max. Watt" button.



1. To select the effect, select the icon below the "Effect" button.
2. Use the "Up" and "Down" buttons to adjust the power level.
3. Confirm your selection by pressing the "OK" button.

- or -

To return to the main screen without changing the selection, tap any button outside the selection menu.



1. To select the maximum power, select the icon below the "max. Watt" button.
 2. Use the "Up" and "Down" buttons to adjust the power level.
 3. Confirm your selection by pressing the "OK" button.
- or -
- To return to the main screen without changing the selection, tap any button outside the selection menu.

8.8 Activating and Deactivating Sockets

To activate a socket, plug a handpiece into the socket and select at least one mode.

➡ The selection field and the activation indication light up.

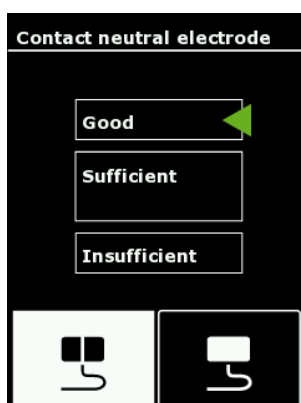
When detaching the instrument, the activation indicator lights up no longer.

To deactivate a socket, select "Off" in CUT and COAG mode.

8.9 Selecting the Neutral Electrode



When using the "EASY" and "BABY" mode, no non-split electrodes are accepted. Using the "MONO" mode, non-split electrodes are accepted.



1. Press the neutral electrode symbol in the upper segment of the display to select the neutral electrode.
- or -
- Alternatively, tap on "Menu" and "Neutral electrode" to select the neutral electrode.
- ➡ The "Neutral electrode" menu with a display of contact quality as well as selection of the neutral electrode types is shown.
- ➡ The selected neutral electrode type is highlighted in white.
2. Select the type of connected electrode by selecting the icon for split or non-split neutral electrodes.
3. In the selection of split neutral electrodes there is also a reduced power mode for children electrodes available.
4. Confirm your selection by pressing the "OK" button.

- or -

To return to the main screen without changing the selection, tap any button outside the selection menu.

➡ The selected type of neutral electrode in connection with a colour-indicator for the contact quality is shown in the status bar.

8.10 EASY Neutral electrode monitoring

The EASY monitoring function measures changes in the resistance between the patient and the RF device before and during RF activation. If necessary, it generates visual and audible alarms to request staff intervention. This requires using a split neutral electrode with appropriate contact areas and suitable contact resistance, attached to the patient according to the manufacturer's instructions. The EASY system does not monitor the currents through the individual contact surfaces of the split neutral electrode.

For the modes "Resection" and "Moderate Coagulation" an electrode with a surface area of at least 90 cm² (13.95 sqin) must be used. If an error message is generated, the display changes from green via yellow to red, depending on the type of fault.

The type of neutral electrode and its contact quality are selected and/or shown in the menu. Faults related to the neutral electrode are shown on the display.

Depending on the contact quality, different icons are shown for neutral electrodes:

Icon / Button	Description	Icon / Button	Description
	Split neutral electrode contact quality OK (green)		Non-split neutral electrode contact quality OK (green)
	Split neutral electrode contact quality not optimum (yellow)		Non-split neutral electrode not detected, not connected, or just insufficient contact quality (red)
	Split neutral electrode not connected or contact quality insufficient (red)		Display the contact quality

9 Mode Overview



The information and data regarding settings, application points, application duration and instrument use are based on clinical practice. However, these are only basic guidelines which must be tested for suitability by the operator. Depending on individual conditions, it may be necessary to deviate from the provided data.

Medical practice is continuously evolving as a result of R&D and clinical experience. This may also make deviations from the provided data necessary.

9.1 Monopolar Modes

9.1.1 Monopolar Coagulation Modes

Monopolar coagulation
Neurotomy
Moderate
Forced coag
Forced mixed
Forced cutting
Spray
Laparoscopy
Resection

Neurotomy

This mode is used in minimal invasive spinal surgery for endoscopic treatment of the facet joint for denervation and surface coagulation.

Suitable instruments

joimax® Legato® handpiece and probe monopolar

Moderate

This mode is used with contact coagulation to stop haemorrhagic oozing, for haemostasis of relatively large tissue areas, and for small-area coagulation. Tissue carbonization is prevented and electrode adhesion to the tissue is strongly reduced. Greater coagulation depth is achieved in this mode than in other coagulation modes. The degree of surface scabbing can be controlled by adjusting the "Effect" setting in the range of 1 to 3.

Suitable instruments

Electrodes with large contact areas, such as ball electrodes

Forced coag

This mode is used for contact coagulation with low tissue penetration, preferably using fine electrodes and electrodes with small contact areas. It achieves a high degree of coagulation with low cutting tendency.

Suitable instruments

Ball electrodes, knife electrodes, spatula electrodes

Forced mixed

This mode is used for contact coagulation with low tissue penetration, preferably using fine electrodes and electrodes with small contact areas. It achieves a high degree of coagulation with moderate cutting tendency.

Suitable instruments

Knife electrodes, spatula electrodes, insulated monopolar forceps

Forced cutting

This mode is used for contact coagulation with low tissue penetration, preferably using fine electrodes and electrodes with small contact areas. It achieves good hemostasis with very good cutting tendency.

Suitable instruments

Knife electrodes, spatula electrodes, needle electrodes

Spray

This mode is used with non-contact surface coagulation using an arc, for hemostasis in parenchymal tissue and in poorly accessible crevices.

Suitable instruments

Ball electrodes, knife electrodes, spatula electrodes, needle electrodes

Laparoscopy

This mode is used in laparoscopy and arthroscopy for monopolar coagulation.

Suitable instruments

Arthroscopy electrodes, laparoscopy electrodes

Resection

This mode is used for monopolar hemostasis in gynaecology and urology.

Suitable instruments

Resectoscope (monopolar), resection snare, rollerblade electrode

9.1.2 Monopolar Cutting Modes

Monopolar Cutting
Standard
Micro
Dry
Resection
Laparoscopy

Standard

In this mode a high-performance RF current with a low crest factor is used for cutting biological tissue. Endovapor®2 quickly adjusts the power output to the minimum required level in response to variations in tissue type and changes in the cutting area or speed.

Suitable instruments

Needle electrodes, knife electrodes, spatula electrodes, sling electrodes

Micro

This mode is used for electrosurgical cutting using micro-electrodes. It enables extremely fine control of the power level and precise work.

Suitable instruments

Micro needle electrodes

Dry

This mode is used for monopolar dry cutting. A large, controlled arc is generated, which allows significantly deeper coagulation to be obtained.

Suitable instruments

Knife electrodes

Resection

This mode is used in gynaecology and urology. The arc control of Endovapor®2 generates the cutting effect with simultaneously minimized output power. This facilitates direct cutting and prevents electrode adhesion.

Suitable instruments

Resectoscope (monopolar), resection snare, rollerblade electrode

Laparoscopy

This mode is used in laparoscopy and arthroscopy for monopolar cutting.

Suitable instruments

Arthroscopy electrodes, laparoscopy electrodes

9.2 Bipolar Modes**9.2.1 Bipolar Coagulation Modes**

Bipolar Coagulation
Spine Coag
Bipolar Neurotomy
Standard
Micro
Laparoscopy
Standard AUTO
Forced
Bipolar Scissors

Spine Coag

This mode is used in minimal invasive spine surgery for endoscopic dissection and coagulation of tissue and for hemostasis.

Suitable instruments

joimax® Vaporflex® handle and probe bipolar, joimax® Legato® handpiece and probe bipolar, joimax® Vaporace® hand piece, cable and probe bipolar (not yet for CE market)

Bipolar Neurotomy

This mode is used in minimal invasive spinal surgery for endoscopic treatment of the facet joint for denervation and surface coagulation.

Suitable instruments

joimax® Vaporflex® handle and probe bipolar, joimax® Legato® handpiece and probe bipolar, joimax® Vaporace® hand piece, cable and probe bipolar (not yet for CE market)

Standard

This mode is used for arcless contact coagulation with forceps.

Suitable instruments

Bipolar forceps

Micro

This mode is used for arcless contact coagulation with micro forceps. It enables extremely fine control of power output down to 0.1 W and precise work for tightly restricted bipolar contact coagulation.

Suitable instruments

Bipolar forceps, micro forceps

Laparoscopy

This mode is used for coagulation in combination with bipolar laparoscopic instruments.

Suitable instruments

Laparoscopic instruments

Standard AUTO

This mode is used for arcless contact coagulation with forceps. Activation starts automatically on contact with tissue.



This mode is visualized with the symbol "AUTOSTART" in the socket menu. The adjustable delay time can be set under "Menu", "System settings", "Autostart delay".



Setting the AUTOSTART mode can result in unintentional coagulations, e.g., when bipolar forceps are used for gripping while the AUTOSTART mode is on.

Suitable instruments

Bipolar forceps

Forced

This mode is used for forced coagulation with forceps.

Suitable instruments

Bipolar forceps

Bipolar scissors

This mode is used with bipolar scissors. It can be used for coagulation before or during cutting, point coagulation, coagulation of cuts and surface coagulation.

Suitable instruments

Bipolar scissors

9.2.2 Bipolar Cutting Modes

Bipolar Cutting
Spine Vap
Bipolar Cutting
Bipolar Scissors

Spine Vap

This mode is used in minimal invasive spine surgery for endoscopic vaporisation of tissue.

Suitable instruments

joimax® Vaporflex® handle and probe bipolar, joimax® Vaporace® hand piece, cable and probe bipolar (not yet for CE market)

Bipolar Cutting

This mode is used for cutting with bipolar laparoscopic instruments.

Suitable instruments

Bipolar instruments

Bipolar scissors

This mode is used with bipolar scissors. It can be used for coagulation before or during cutting, point coagulation, coagulation of cuts and surface coagulation.

Suitable instruments

Bipolar scissors

10 Processing



Warning:

The Endovapor®2 Control Unit and Foot Switch are not suitable for sterilization and must not be sterilized.

Warning:

Before cleaning or disinfection, turn off the device and disconnect it from the power source. Also, disconnect it from all other devices connected to a power source.

Warning:

Check the components and all accessories after processing and prior to each use for damage and for proper operation.



Always respect locally applicable regulations and hygiene procedures of the hospital. Prepare the accessories (e.g. surgical handpieces, instruments, active electrodes, neutral electrodes and cables) as described in the corresponding operating manuals.

10.1 Cleaning and Disinfection of the Control Unit and Foot Switch



Warning:

Ensure no liquid enters the Endovapor®2 Control Unit or Foot Switch during cleaning and disinfection.

Warning:

Before cleaning or disinfection, disconnect all components from the Endovapor®2 Control Unit and disconnect the control unit from its power source.

Warning:

In case of severe soiling, the front panel of the control unit can be carefully cleaned with a cotton swab soaked in alcohol. Do not use any sharp objects for cleaning!



For effective wipe disinfection of the Endovapor®2 Control Unit and Foot Switch, use of Mikrozid® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

Pay particular attention to the connectors at the front of the control unit. Make sure to let them dry thoroughly before connecting any components.

The surfaces of the Endovapor®2 Control Unit and Foot Switch can be cleaned and disinfected with a suitable alcohol-free varnish- and plastic-friendly cleaning and disinfection detergent using the following procedure:

- 1) Turn off the device.
- 2) Disconnect all components from the control unit (e.g. accessories, foot switch) and disconnect the control unit from the power supply.
- 3) Wipe the surfaces of the control unit and the foot switch with a clean, soft cloth, moistened with a suitable detergent or disinfectant.
- 4) Wipe the surfaces again with a sponge or a soft cloth moistened with clean water.
- 5) Dry the surfaces with a clean and lint-free cloth.

10.2 Processing of the Neutral Electrode Connecting Cable


Warning:

The joimax® Neutral Electrode Connecting Cable is not suitable for ultrasonic cleaning.

Warning:

Immediately after use (within a maximum of 2 hours), coarse soiling must be removed from the cable by applying the pre-treatment steps according to chapter 10.2.1.

10.2.1 Pre-treatment


Warning:

To remove soiling manually, use a soft brush or a clean soft cloth designed exclusively for this purpose. Never use a metal brush, steel wool or any sharp objects for cleaning.

Warning:

Do not use abrasive cleaners, waxes or solvents for cleaning.

- 1) Disconnect the neutral electrode from the cable and dispose of it.
- 2) Disconnect the cable from the control unit.
- 3) Remove coarse soiling from the cable by rinsing it with cold running tap water.

10.2.2 Cleaning and Disinfection



joimax® recommends the use of neutral to slightly alkaline cleaning agents or combined cleaning agents and disinfectants without critical ingredients (depending on the concentration). Alcoholic and/or aldehydic ingredients should preferably be used.

Strong alkaline cleaners (pH > 11.5) must be avoided.

joimax® has demonstrated that the products can be effectively cleaned/disinfected using a machine process (5 min at 90 °C / 194 °F) with an alkaline cleaning agent and surfactant additive (Neodisher® MediClean, Chemische Fabrik Dr. Weigert). This applies in the following conditions: The described cleaning and disinfecting method is applied when cleaning/disinfecting. Cleaning agents must offer the proven effectiveness and be compatible with the system (disinfectant and cleaning agent) used in the specified test.

When selecting the disinfectant, make sure that:

- the disinfectant has proven effectiveness (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883)
- if possible, a tested program for thermal disinfection (A0 value > 3000, i. e. at least 5 min at 90° C/194° F) is used
- the used program is suitable for the cable and contains sufficient rinsing cycles
- for rinsing only sterile or low-germ (max 10 germs/ml) and endotoxin-poor (maximum 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used
- the air used for drying is filtered
- the disinfectant is regularly maintained and checked

When selecting the detergent, make sure that:

- it is suitable for the cleaning of medical products made of metals and plastics
- if thermal disinfection is not used, in addition, a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA approval or CE marking) is used and that it is compatible with the cleaning agent used

Procedure:

- 1) Perform the pre-treatment according to chapter 10.2.1.
- 2) Place the neutral electrode cable in the disinfectant.
- 3) Make sure that the cable does not touch other components. Loosely insert the cable; it must not be kinked or squashed.
- 4) Start the program.
- 5) At the end of the program, remove the cable from the disinfectant.
- 6) Inspect, dry and pack the cable immediately after removal in a clean place.

10.2.3 Inspection

After cleaning and disinfection, check the cable for damaged surfaces, chipping or any remaining soiling and cleaning and disinfection agents.

10.2.4 Packing

Put the cable in disposable packaging (single or double) and/or sterilization containers that meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607-1; 11607-2
- suitable for steam sterilization (temperature resistance up to at least 141° C (286° F), sufficient vapour permeability)
- adequate protection of the neutral electrode cable or sterilization packaging against mechanical damage
- regular maintenance according to the manufacturer's instructions (sterilization container)
- cleared by the FDA (No. K953776, K973827)

10.2.5 Sterilization



Warning:

The neutral electrode cable must be sterilized before first and every use.

Warning:

An uncleaned neutral electrode cable must not be sterilized as the effectiveness of the sterilization is only guaranteed after cleaning and disinfection. Make sure the neutral electrode cable is clean before sterilization!

Warning:

Other autoclave settings and cycles than specified may have negative effects on the sterilization result and the function of the neutral electrode cable.

Warning:

Please note that overloading the sterilizer may reduce the sterilization result. Observe the manufacturer's instructions for maximum loading of the sterilizer.



It is the responsibility of the user to carry out the recommended sterilization procedures with regard to achieving the desired or required sterilization effect.

Applicable national legal regulations must be observed.

It is not recommended to use other sterilization methods (such as flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, plasma sterilization).

When selecting the steam sterilizer, make sure that:

- the steam sterilizer has proven effectiveness (according to EN 13060/EN 285 or ANSI AAMI ST79, for USA: FDA clearance)
- the steam sterilizer is validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))

The joimax® Neutral Electrode Connecting Cable can be sterilized using the following procedures:

AUTOCLAVE / STEAM STERILIZATION
FRACTIONATED VACUUM / DYNAMIC AIR REMOVAL Temperature: 132 °C / 270 °F Holding time: min. 3 minutes Drying time: min. 20 minutes Temperature: 121 °C / 250 °F Holding Time: min. 20 minutes Drying Time: min. 20 minutes GRAVITY DISPLACEMENT Not recommended

10.2.6 Storage

After sterilization, the cable must be stored dry and dust-free in the sterilization packaging.

10.3 Processing of Accessories

Follow the instructions for reprocessing in the corresponding user manuals.

11 Technical Data

11.1 Endovapor®2 Control Unit

Insulation type / classification		
EMC	IEC 60601-1-2	
Level of protection provided by the housing	IP 21	
Protection class according to IEC 60601-1	I	
Applied part type according to IEC 60601-1	CF	
Applied standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-2, IEC 62304, IEC 62366-1	
Risk classification	IIb	
Power supply	JEVD0201	JEVD0202
Mains voltage	220 V – 240 V ~	100V – 127 V ~
Power consumption in standby	3 W / 40 VA	3 W / 40 VA
Current consumption in standby	200 mA	400 mA
Maximum power consumption (at 350 W)	700 W / 1150 VA	700 W / 1150 VA
Maximum current consumption (at 350 W)	5 A	10 A
Line fuses	2 x T 5.0 A H	2 x T 10.0 A H
Line frequency	50 / 60 Hz	50 / 60 Hz
Terminal for potential equalization	√	√
Dimensions and weight		
Dimensions (W/H/D)	433 x 173 x 475 mm / 17 x 6.8 x 18,7 "	
Weight	approx. 12,5 kg / 26.7 lb	
Programs		
Number of storable programs in the device	350	
Default programs, factory set	√	
Individually programmable	√	
Program number and data shown on the display	√	
Neutral electrode monitoring		
EASY (Electrode Application System)	√	
Display indication of one-piece or split or Baby electrode in the main and neutral electrode menu	√	
Contact resistance between individual sections of split neutral electrodes shown on display with column for control	√	
Lead resistance shown on the display when a one-piece neutral electrode is used	√	
Maximum allowable resistance between the sections of a split electrode	300 Ω	
Warning signal for hazardous conditions beneath the neutral electrode	Visual, acoustic	
Warning messages on display:	Text messages with further information	
Safety features		
ISSys (Integrated Safety System)	√	
Continuous monitoring of RF leakage current with fault indication	Text messages with further information	
Dosage monitoring with fault indication on the display	√	
Continuous self-test	√	
Continuous status indication on the display	√	
Operating errors shown on the display	Text messages with further information	

System faults shown on the display		Text messages with further information	
Documentation			
Data acquisition and storage in the device		System information with date	
Fault states		√	
Operating errors		√	
Data retrieval via the display		Text messages with further information	
Communication			
USB interface for software updates		√	
External PC interface, UART, using joimax® software. Service support using joimax® software		√	
Capacitive Touchoperation, 3,5" TFT-Display, 4 LCD Display, 7 PCT Buttons		√	
Service support			
Network port for service support		√	
Service support by service programs integrated in the device		√	
Service support via ISSys		√	
Cooling			
Convection		√	
Temperature-controlled fan		√	
Duty factor			
Intermittent		10 s / 30 s (on/off)	
Characteristics			
Max. CUT Power (at 500 Ω)		350 W	
Max. COAG Power (at 50 Ω)		120 W	
Monopolar sockets		2 x international	
Bipolar sockets		2 x international	
Connection for foot switch		2 x	
AUTOSTART		√	
Bipolar hand switch		√	
Environmental conditions		Operation	Transport & storage
Temperature		+10 °C to +40 °C +50 °F to +104 °F	-15 °C to +50 °C 5 °F to +122 °F
Relative humidity		30 to 75%, non-condensing	0 to 90%, non-condensing
Atmospheric pressure		700 to 1060 hPa	500 to 1060 hPa
Operating altitude (max)		3000 m a. sea level	---
Special conditions		---	Keep the device dry and protected from sunlight.
Acoustic signals			
Mode	Category	Frequency (Hz)	Signal type
Monopolar Cut	Activation tones	635	Continuous sound
Monopolar Coag	Activation tones	475	Continuous sound
Bipolar Cut	Activation tones	565	Continuous sound
Bipolar Coag	Activation tones	505	Continuous sound
Error	Alarm tones	-	Signal tone
Warning	Alarm tones	-	Signal tone
Note	Alarm tones	-	Signal tone

11.2 Endovapor® 2 Foot Switch

General		
Applied standards	IEC 60601-1, IEC 60601-1-2IEC 60601-1-6, IEC 60601-2-2, IEC 62304, IEC 62366-1	
Risk classification	I	
Housing	Unbreakable, self extinguishing thermoplast	
Protection	IPX8 according to IEC 60529	
Switching		
System	Reed contact: 1S, 2S, 1W Micro switch: 1PW Hall sensor: HS 0-10 V, 0(4)-20 mA	
Voltage	max. 25 VAC / 60 VDC	
Current	Reed contact: max. 1 A Micro switch:max. 5 A Hall sensor: max. 60 mA	
Capacity	Reed contact: max. 20 VA Micro switch: max. 1250 VA	
Environmental conditions	Operation	Transport & Storage
Temperature	-10 °C to +60 °C +14 °F to +140 °C	-25 °C to +70 °C -13 °F to +158 °F
Relative humidity	10 % - 100 %	0 % - 100 %
Atmospheric pressure	800 hPa - 1060 hPa	500 hPa - 1100 hPa
Operating altitude (max)	2000 m a. sea level	---
Special conditions	---	Keep the device dry and protected from sunlight.

11.3 Modes



The max. values are not necessarily created at rated load resistance.
The RF power is subject to a tolerance limit of $\pm 20\%$.

Only select associated equipment and active accessories with rated accessory voltage greater than or equal to the maximum RF peak voltage.

Description	CCS	Endova por®2 CONT- ROL	Form of RF voltage	Crest factor	Max. power output		Peak voltage	Max. current	Default values	
					Effect	Power range			Effect	Max. Watt
Modes Monopolar Coagulation										
Neurotomy			sinusoidal modulated	6.2	1 2 3	1 W - 60 W	2,3 kVp 2,5 kVp 2,8 kVp	0.35 Arms	2	30
Moderate			sinusoidal constant	2.1	1 2 3	1 W - 120 W	250 Vp	1.3 Arms	2	60
Forced coag			pulsed modulated	7.8	---	1 W - 80 W	3.5 kVp	0.3 Arms	---	50
Forced mixed			sinusoidal modulated	6.2	1 2 3	1 W - 120 W	2.3 kVp 2.5 kVp 2.8 kVp	0.5 Arms	2	60
Forced cutting			sinusoidal modulated	3.3	1 2 3 4	1 W - 250 W	1.5 kVp 1.5 kVp 1.3 kVp 1.3 kVp	0.71 Arms	2	80
Spray			pulsed modulated	10.0	1 2 3 4	1 W - 120 W	3.0 kVp 3.8 kVp 4.6 kVp 5.0 kVp	0.5 Arms	2	80
Laparoscopy			sinusoidal modulated	5.6	---	1 W - 120 W	1.8 kVp	0.5 Arms	---	60
Resection			sinusoidal modulated	6.5	---	1 W - 120 W	2.6 kVp	0.5 Arms	---	60
Modes Monopolar Cutting										
Standard	Yes	Yes	sinusoidal constant	1.5	1 2 3 4 5 6 7 8 9	1 W - 350 W	400 Vp 450 Vp 560 Vp 650 Vp 650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	0.84 Arms	5	100
Micro	Yes	Yes	sinusoidal constant	1.5	1 2 3 4 5 6 7 8 9	1 W - 50 W	280 Vp 340 Vp 380 Vp 400 Vp 400 Vp 400 Vp 450 Vp 450 Vp 450 Vp	0.32 Arms	5	20
Dry	Yes	Yes	sinusoidal modulated	3.6	1 2 3 4 5 6 7 8 9	1 W - 200 W	1.4 kVp 1.4 kVp 1.4 kVp 1.4 kVp 1.5 kVp 1.6 kVp 1.6 kVp 1.6 kVp 1.6 kVp	0.64 Arms	5	100

Description	CCS	Endova por®2 CONT- ROL	Form of RF voltage	Crest factor	Max. power output		Peak voltage	Max. current	Default values	
					Effect	Power range			Effect	Max. Watt
Resection	Yes	Yes	sinusoidal constant	1.5	1 2 3 4 5	250 W	650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	0.71 Arms	2	---
Laparoscopy	Yes	Yes	sinusoidal constant	1.5	1 2 3 4 5 6 7 8 9	1 W - 200W	400 Vp 450 Vp 560 Vp 650 Vp 650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	0.64 Arms	5	100
Modes Bipolar Coagulation										
Spine Coag			sinusoidal constant	1.7	---	1 W - 60 W	150 Vp	1.1 Arms	---	30
Bipolar Neurotomy			sinusoidal modulated	5.0	---	1 W - 100 W	500 Vp	1,2 Arms	---	50
Standard			sinusoidal constant	1.7	---	1 W - 120 W	150 Vp	1.55 Arms	---	40
Micro			sinusoidal constant	1.7	---	0.1 W - 20 W	150 Vp	0.64 Arms	---	10
Laparoscopy			sinusoidal constant	1.7	-	1 W - 120 W	150 Vp	1.55 Arms	---	50
Standard AUTO			sinusoidal constant	1.7	---	5 W - 120 W	150 Vp	1.55 Arms	---	40
Forced			sinusoidal modulated	5.5	---	1 W - 100 W	550 Vp	1.42 Arms	---	70
Bipolar scissors			sinusoidal constant	1.5	---	1 W - 120 W	200 Vp	1.27 Arms	---	40
Modes Bipolar Cutting										
Spine Vap			sinusoidal modulated	3.7	---	1 W - 60 W	550 Vp	0.9 Arms	---	30
Bipolar cutting	Yes	Yes	sinusoidal constant	1.4	---	1 W - 200 W	400 Vp	1.64 Arms	---	100
Bipolar scissors			sinusoidal constant	1.5	---	1 W - 120 W	200 Vp	1.27 Arms	---	40

11.4 Power Output Diagrams

Monopolar Coagulation: Neurotomy

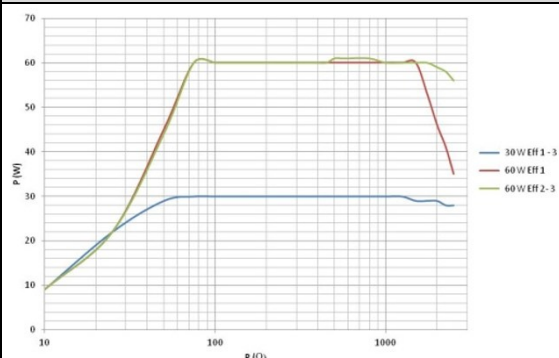


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Neurotomy" = 30 W and 60 W.

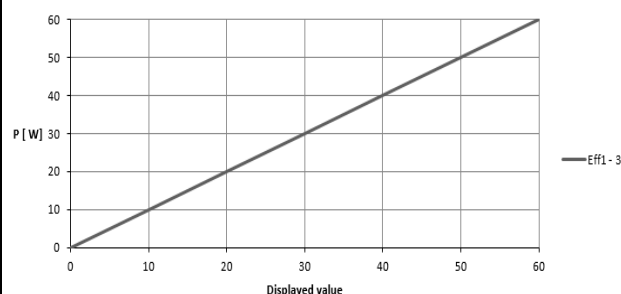


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Neurotomy".
Rated load resistance = 500 Ω .

Effect	U (Vp)
1	2300
2	2500
3	2800

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Coagulation: Neurotomy" (idle mode).

Monopolar Coagulation: Moderate

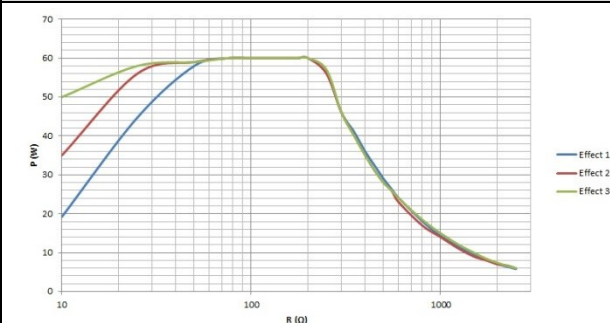


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Moderate" = 60 W.

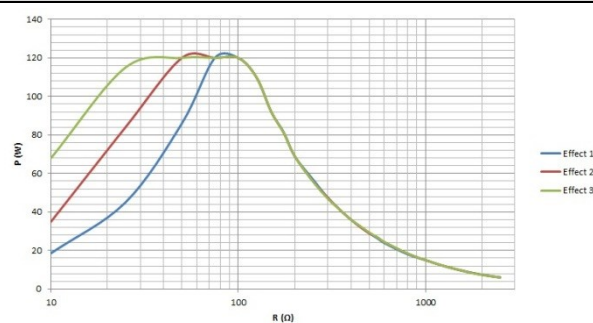


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Moderate" = 120 W.

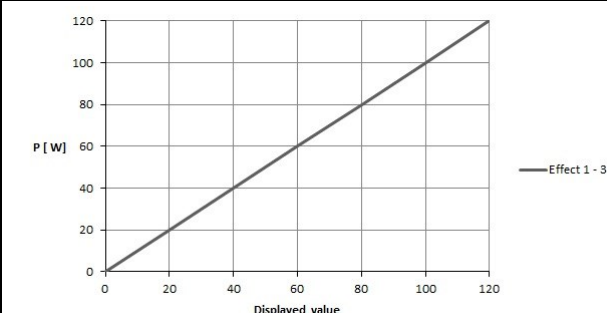


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Moderate".
Rated load resistance = 75 Ω .

Effect	U (Vp)
1	250
2	250
3	250

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Coagulation: Moderate" (idle mode).

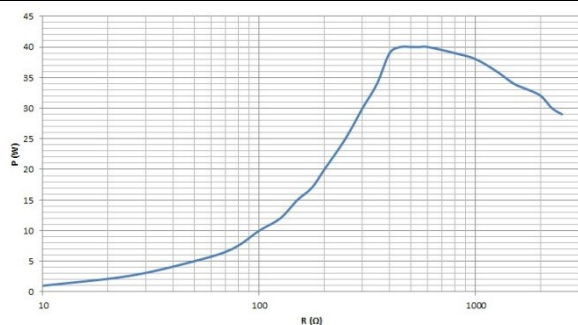
Monopolar Coagulation: Forced coag

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Forced coag" = 40 W.

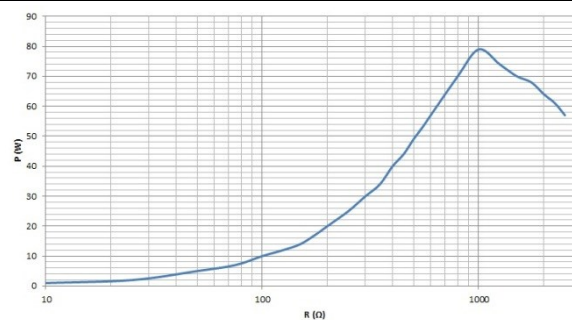


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Forced coag" = 80 W.

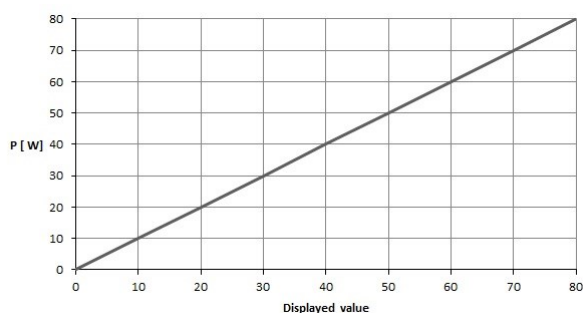


Diagram of power output P [W] as a function of the setting "Monopolar: Coagulation: Forced coag".

Rated load resistance = 1000 Ω .

RF output voltage U [Vp] for the setting "Monopolar Coagulation: Forced coag" (idle mode) = 3500 Vp.

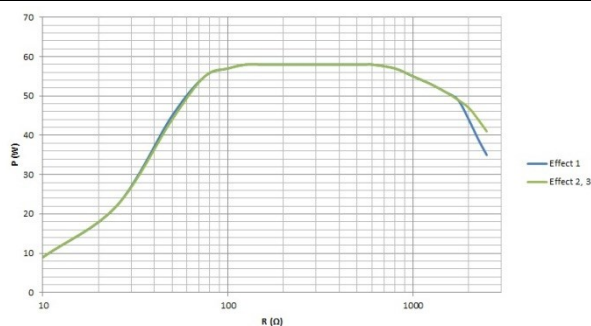
Monopolar Coagulation: Forced mixed

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Forced mixed" = 60 W.

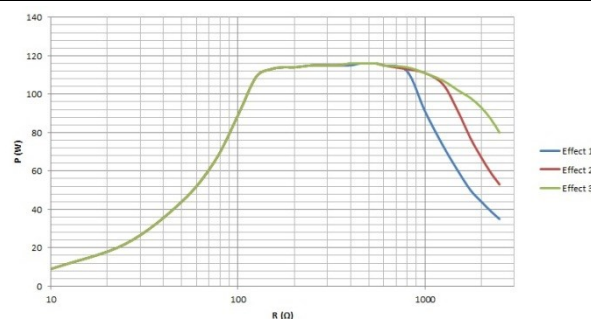


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Forced mixed" = 120 W.

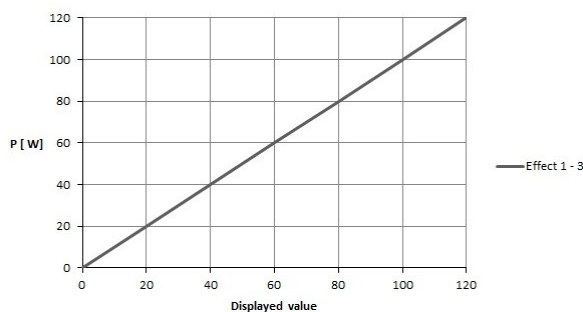


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Forced mixed".

Rated load resistance = 500 Ω .

Effect	U (Vp)
1	2300
2	2500
3	2800

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Coagulation: Forced mixed" (idle mode).

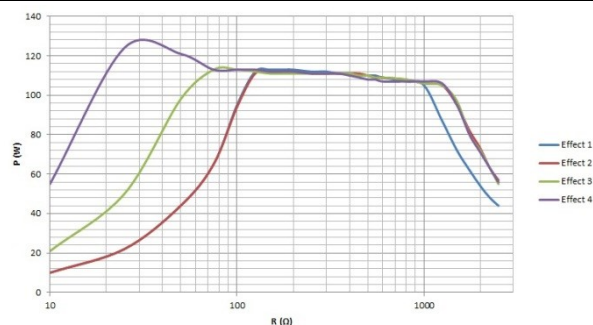
Monopolar Coagulation: Forced cutting

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Forced cutting" = 125 W.

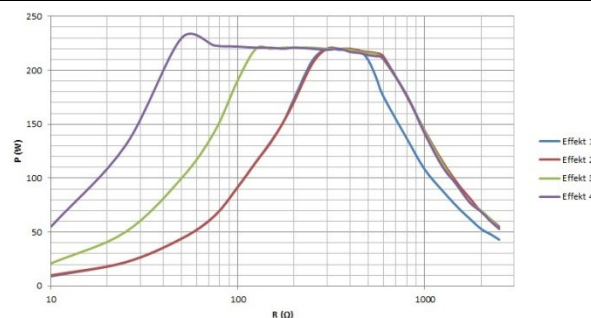


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Forced cutting" = 250 W.

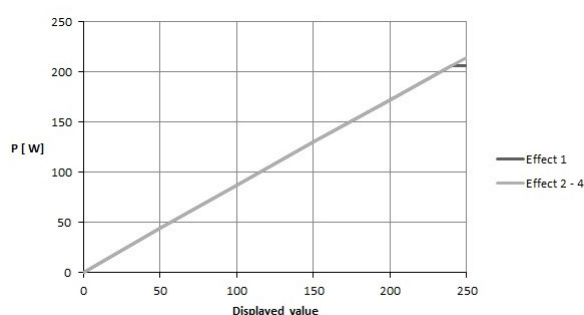


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Forced cutting"

Rated load resistance = 500 Ω .

Effect	U (Vp)
1	1500
2	1500
3	1300
4	1300

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Coagulation: Forced cutting" (idle mode).

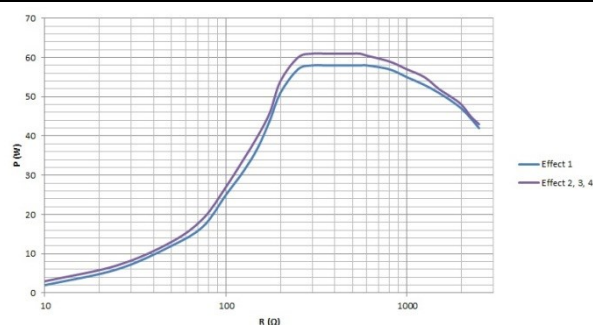
Monopolar Coagulation: Spray

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Spray" = 60 W.

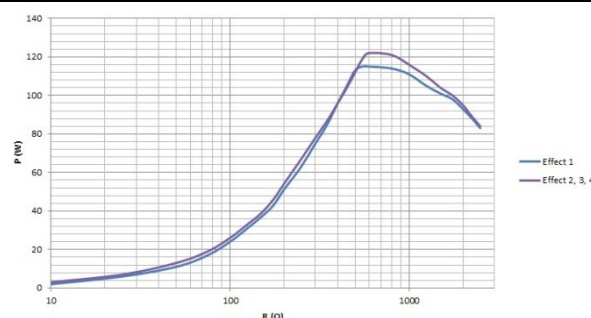


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Spray" = 120 W.

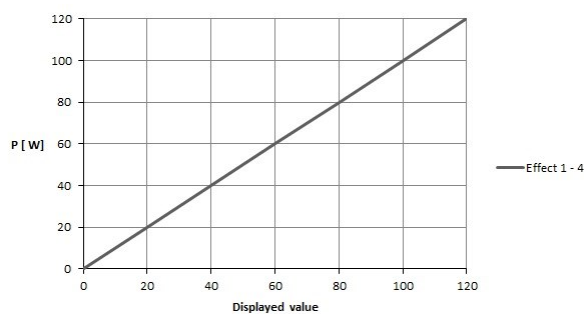


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Spray".
Rated load resistance = 500 Ω .

Effect	U (Vp)
1	3000
2	3800
3	4600
4	5000

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Coagulation: Spray" (idle mode).

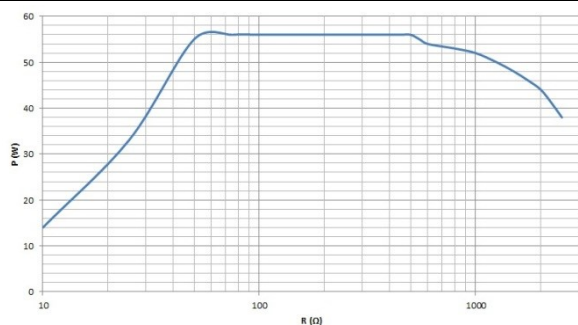
Monopolar Coagulation: Laparoscopy

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Laparoscopy" = 60 W.

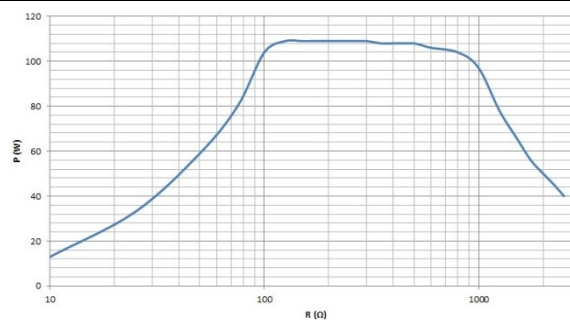


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Laparoscopy" = 120 W.

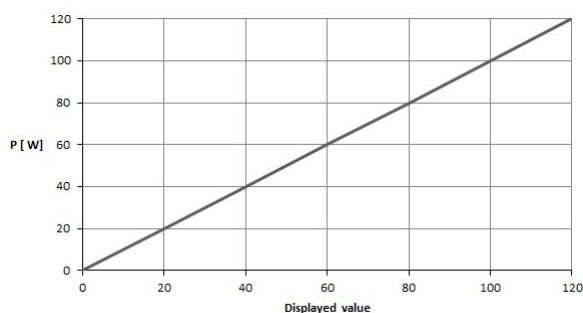


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Laparoscopy". Rated load resistance = 500 Ω .

RF output voltage U [Vp] for the setting "Monopolar Coagulation: Laparoscopy" (idle mode) = 1800 Vp.

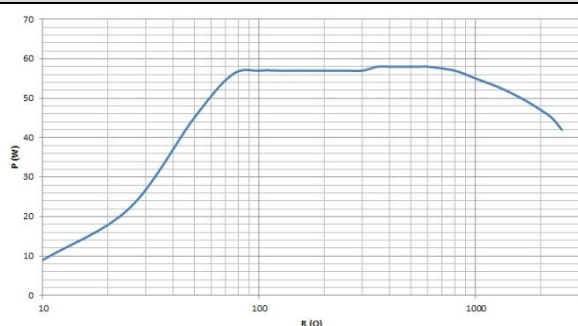
Monopolar Coagulation: Resection

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Resection" = 60 W.

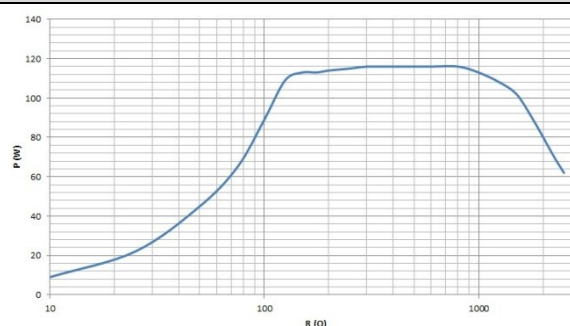


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation: Resection" = 120 W.

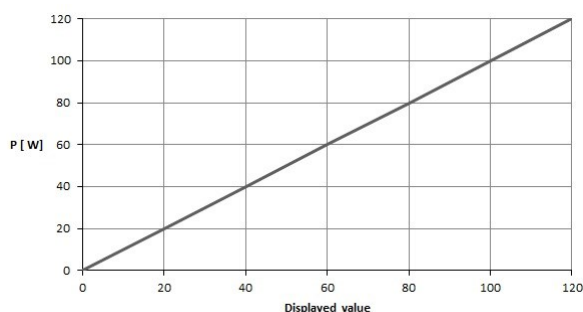


Diagram of power output P [W] as a function of the setting "Monopolar Coagulation: Resection". Rated load resistance = 500 Ω .

RF output voltage U [Vp] for the setting "Monopolar Coagulation: Resection" (idle mode) = 2600 Vp.

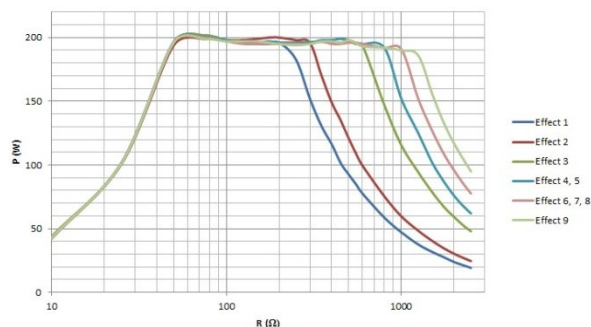
Monopolar Cutting: Standard

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Standard" = 175 W.

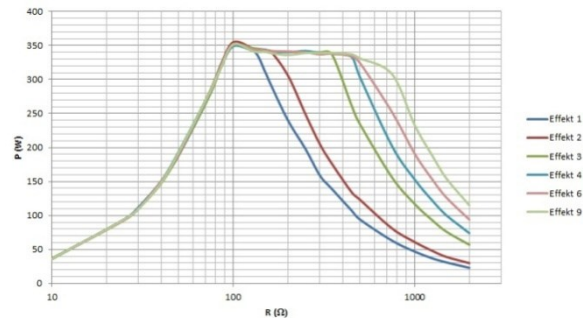


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Standard" = 350 W.

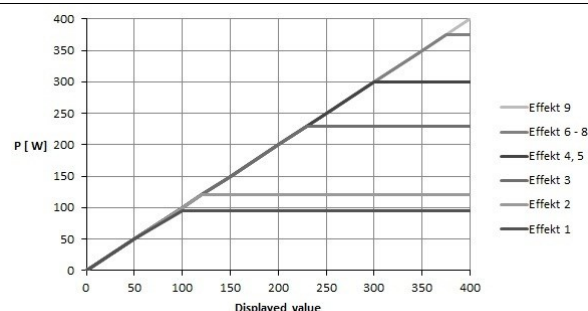


Diagram of power output P [W] as a function of the setting "Monopolar Cutting: Standard". Rated load resistance = 500 Ω .

Effect	U (Vp)
1	400
2	450
3	560
4	650
5	650
6	700
7	700
8	700
9	750

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Cutting: Standard" (idle mode).

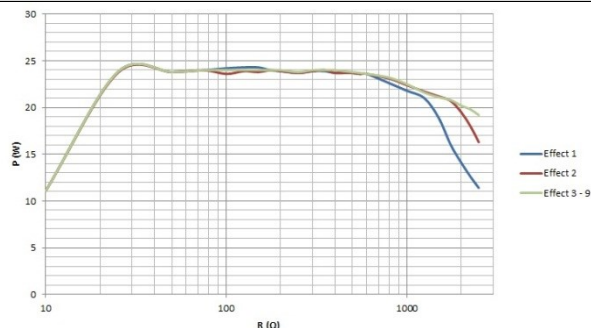
Monopolar Cutting: Micro

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Micro" = 25 W.

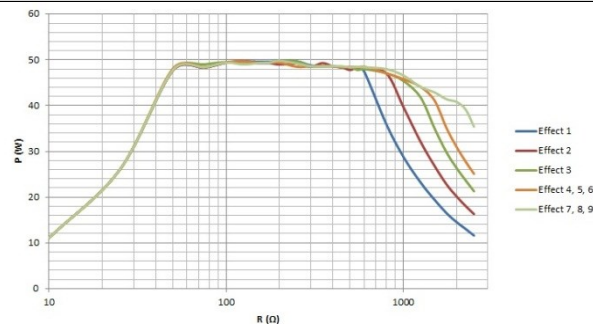


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Micro" = 50 W.

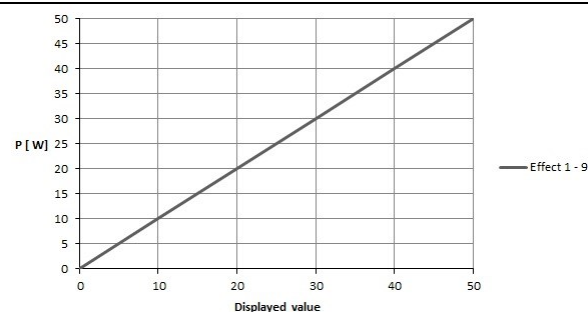


Diagram of power output P [W] as a function of the setting "Monopolar Cutting: Micro". Rated load resistance = 500 Ω .

Effect	U (Vp)
1	280
2	340
3	380
4	400
5	400
6	400
7	450
8	450
9	450

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Cutting: Micro" (idle mode).

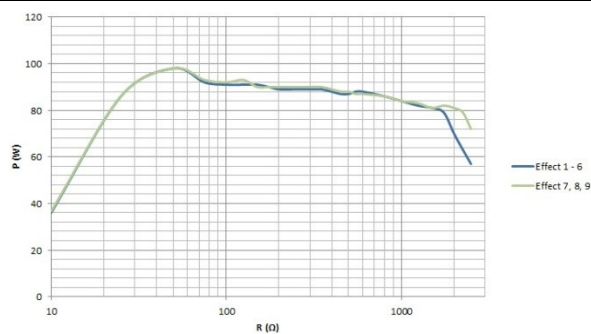
Monopolar Cutting: Dry

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Dry" = 100 W.

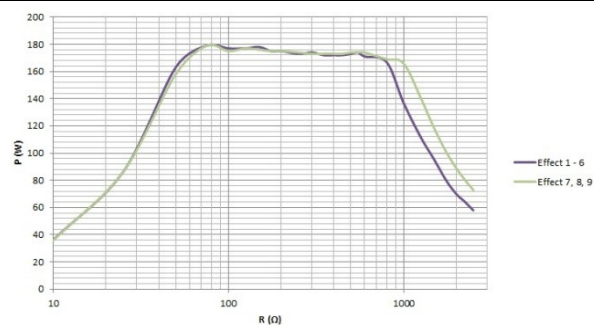


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Dry" = 200 W.

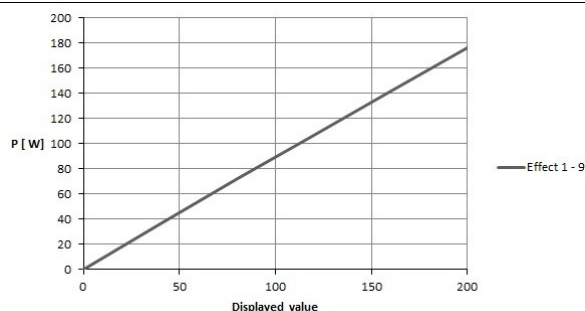


Diagram of power output P [W] as a function of the setting "Monopolar Cutting: Dry". Rated load resistance = 500 Ω.

Effect	U (Vp)
1	1400
2	1400
3	1400
4	1400
5	1500
6	1600
7	1600
8	1600
9	1600

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Cutting: Dry" (idle mode).

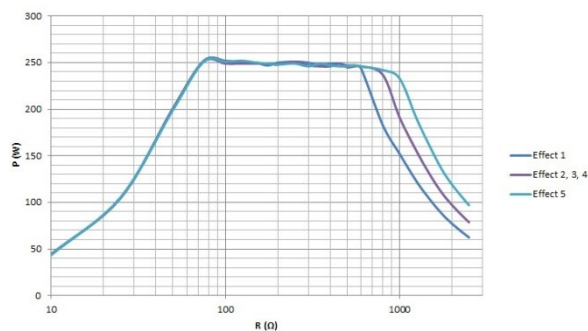
Monopolar Cutting: Resection

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Resection".

Effect	P (W)
1	250
2	250
3	250
4	250
5	250

Table of power output P [W] as a function of the setting "Monopolar Cutting: Resection". Rated load resistance = 500 Ω.

Effect	U (Vp)
1	650
2	700
3	700
4	700
5	750

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Cutting: Resection" (idle mode).

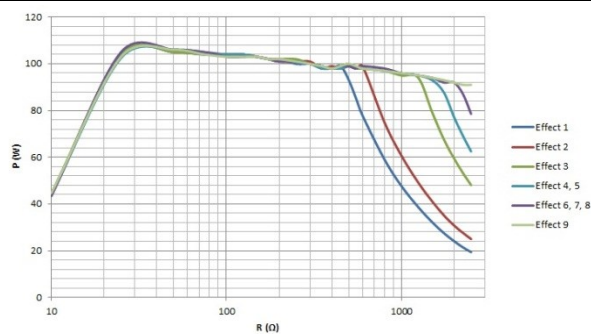
Monopolar Cutting: Laparoscopy

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Laparoscopy" = 100 W.

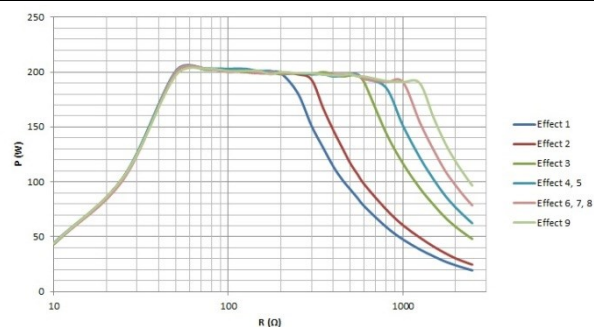


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting: Laparoscopy" = 200 W.

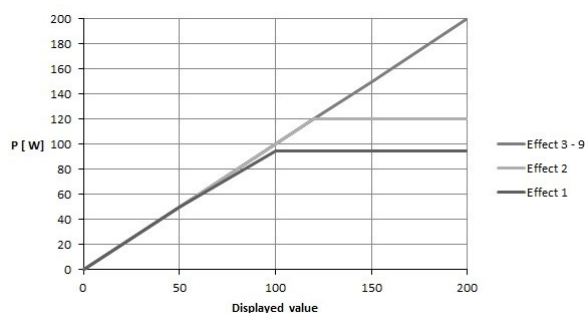


Diagram of power output P [W] as a function of the setting "Monopolar Cutting: Laparoscopy". Rated load resistance = 500 Ω .

Effect	U (Vp)
1	400
2	450
3	560
4	650
5	650
6	700
7	700
8	700
9	750

Table of RF output voltage U [Vp] as a function of the setting "Monopolar Cutting: Laparoscopy" (idle mode).

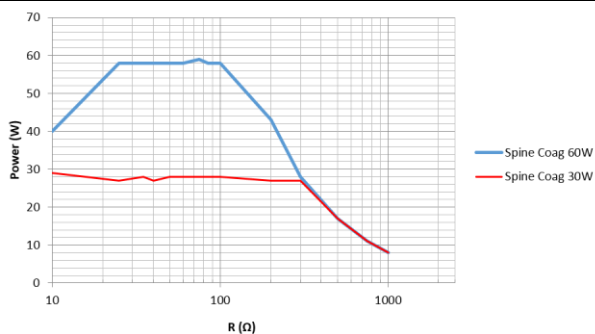
Bipolar Coagulation: Spine Coag

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Spine Coag" = 30 W and 60 W.

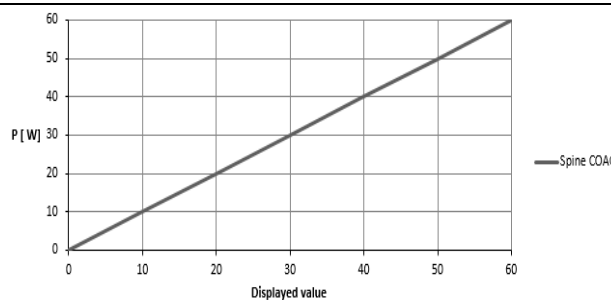


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Spine Coag". Rated load resistance = 50 Ω .

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Spine Coag" (idle mode) = 150 Vp.

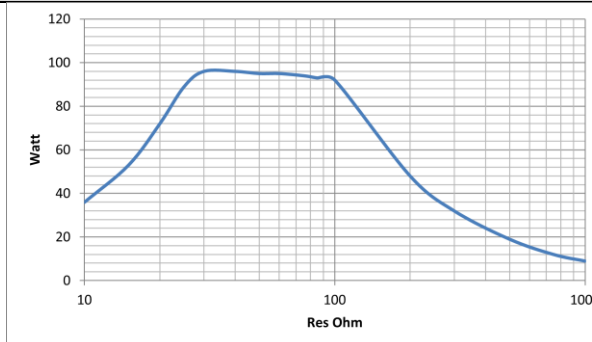
Bipolar Coagulation: Bipolar Neurotomy

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Bipolar Neurotomy" = 100 W (max. setting).

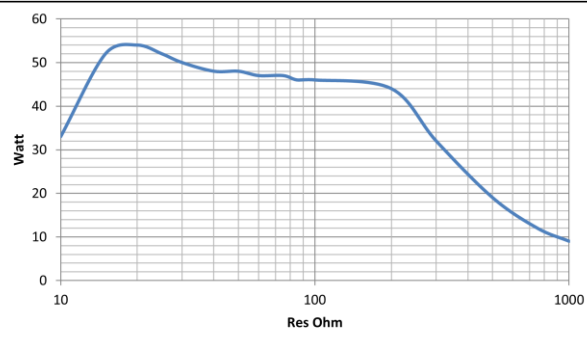


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Bipolar Neurotomy" = 50 W (half setting).

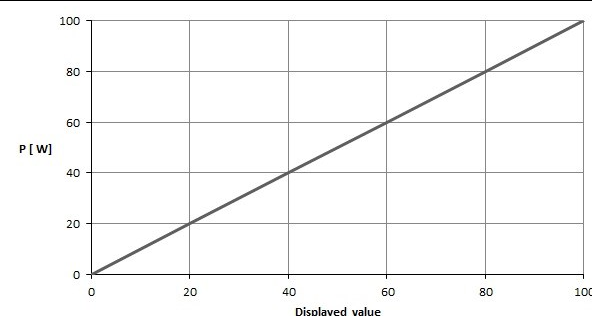


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Bipolar Neurotomy". Rated load resistance = 75 Ω.

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Bipolar Neurotomy" (idle mode) = 500 Vp.

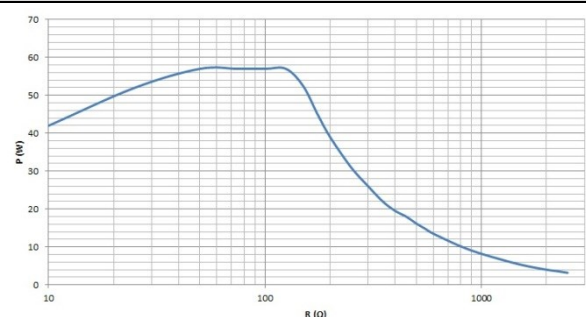
Bipolar Coagulation: Standard

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Standard" = 60 W.

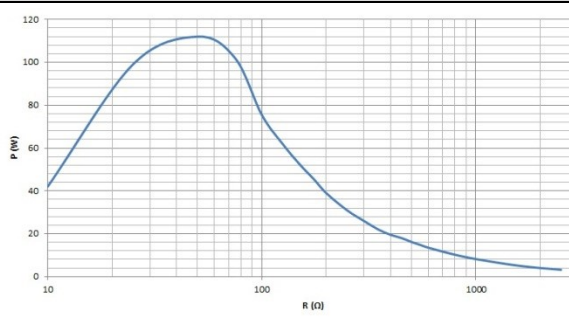


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Standard" = 120 W.

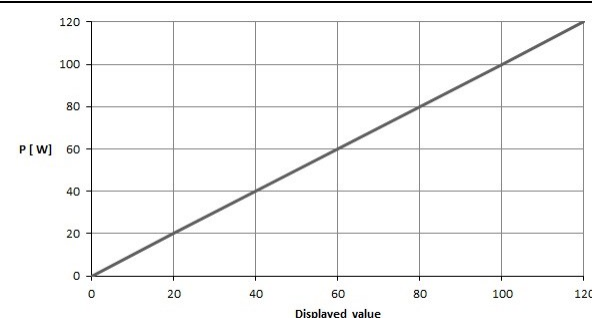


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Standard". Rated load resistance = 50 Ω.

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Standard" (idle mode) = 150 Vp.

Bipolar Coagulation: Micro

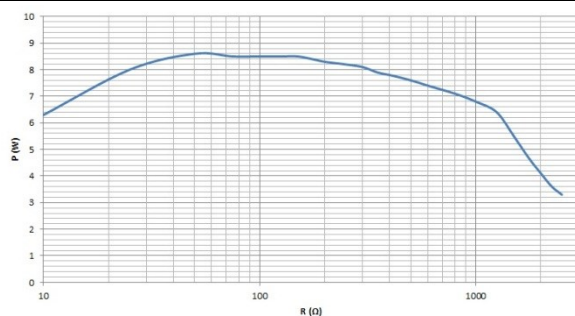


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Micro" = 10 W.

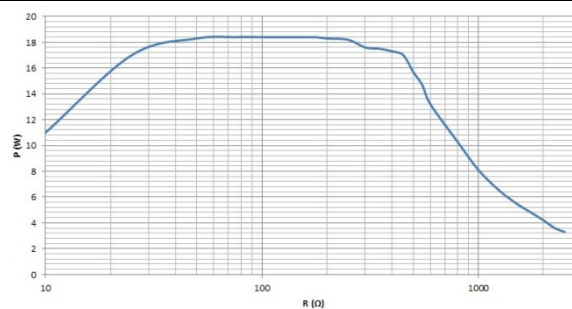


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Micro" = 20 W.

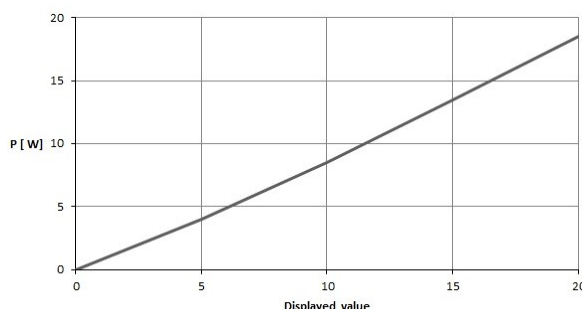


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Micro". Rated load resistance = 50 Ω .

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Micro" (idle mode) = 150 Vp.

Bipolar Coagulation: Laparoscopy

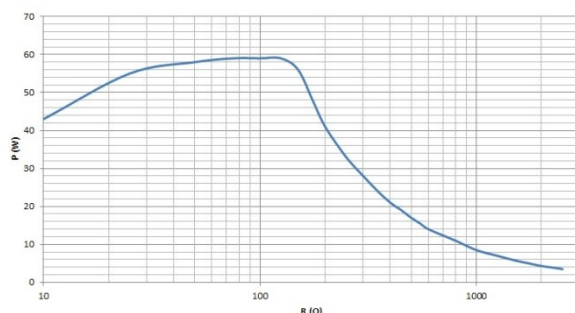


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Laparoscopy" = 60 W.

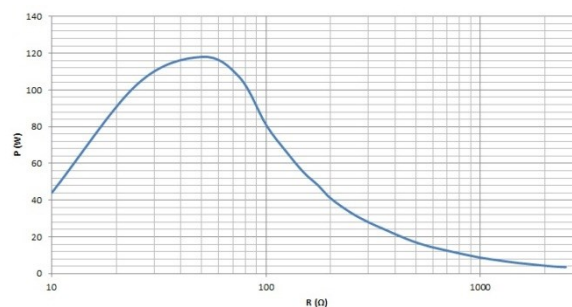


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Laparoscopy" = 120 W.

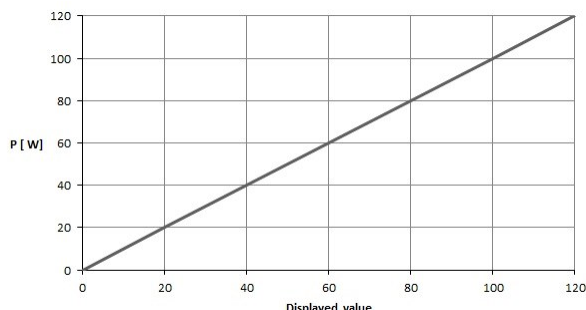


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Laparoscopy". Rated load resistance = 50 Ω .

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Laparoscopy" (idle mode) = 150 Vp.

Bipolar Coagulation: Standard AUTO

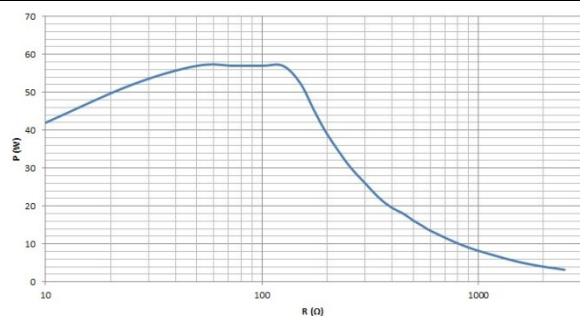


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Standard: Standard AUTO" = 60 W.

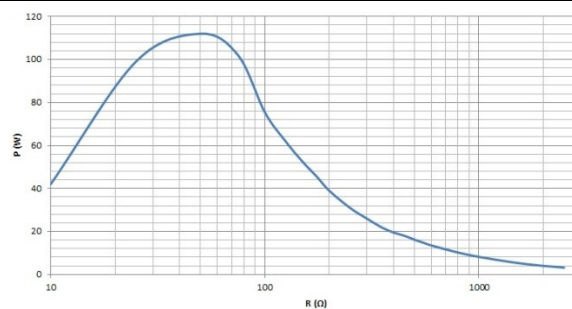


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Standard AUTO" = 120 W.

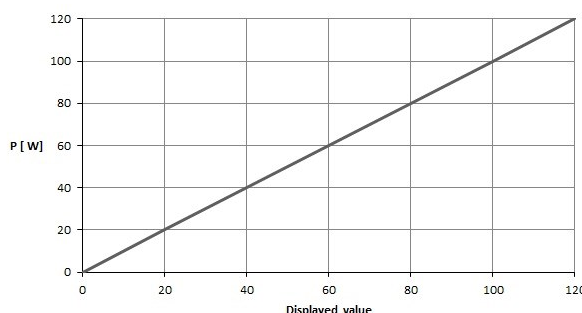


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Standard AUTO". Rated load resistance = 50 Ω.

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Standard AUTO" (idle mode) = 150 Vp.

Bipolar Coagulation: Forced

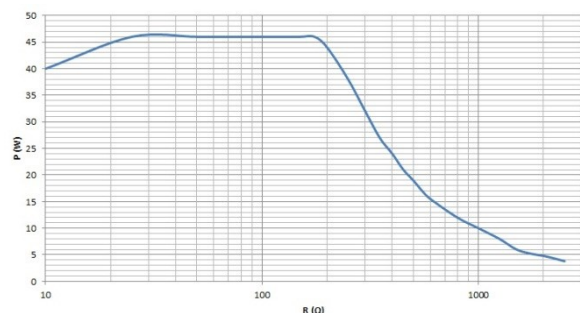


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Forced" = 50 W.

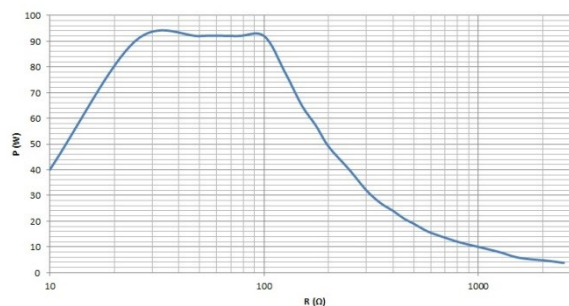


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Forced" = 100 W.

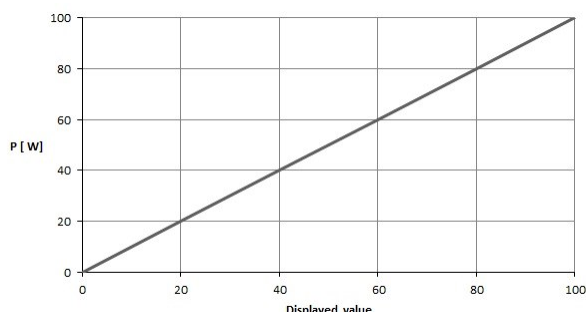


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Forced". Rated load resistance = 50 Ω.

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Forced" (idle mode) = 550 Vp.

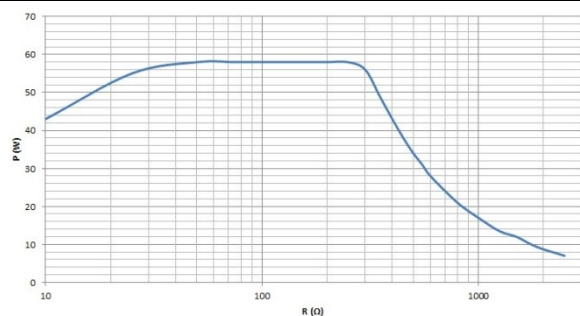
Bipolar Coagulation: Bipolar scissors

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Bipolar scissors" = 60 W.

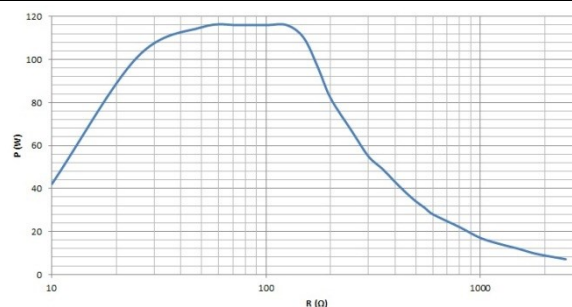


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation: Bipolar scissors" = 120 W.

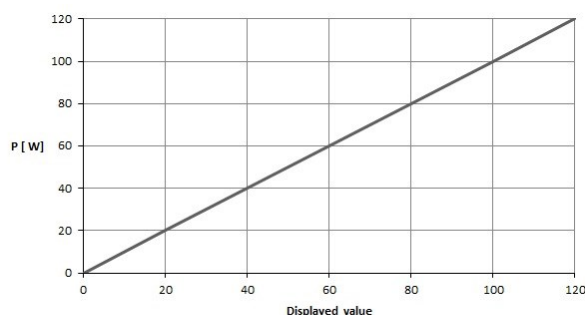


Diagram of power output P [W] as a function of the setting "Bipolar Coagulation: Bipolar scissors" Rated load resistance = 75 Ω.

RF output voltage U [Vp] for the setting "Bipolar Coagulation: Bipolar scissors" (idle mode) = 200 Vp.

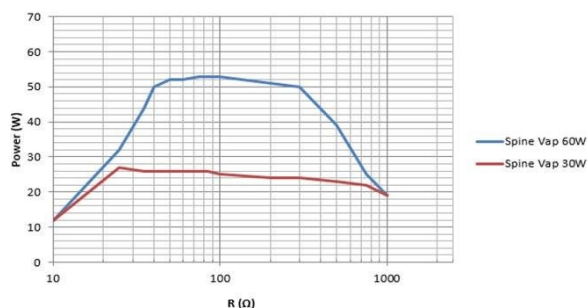
Bipolar Cutting: Spine Vap

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting: Spine Vap" = 30 W und 60 W.

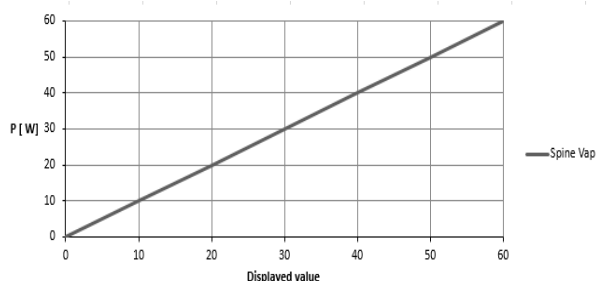


Diagram of power output P [W] as a function of the setting "Bipolar Cutting: Spine Vap". Rated load resistance = 75 Ω.

RF output voltage U [Vp] for the setting "Bipolar Cutting: Spine Vap" (idle mode) = 550 Vp.

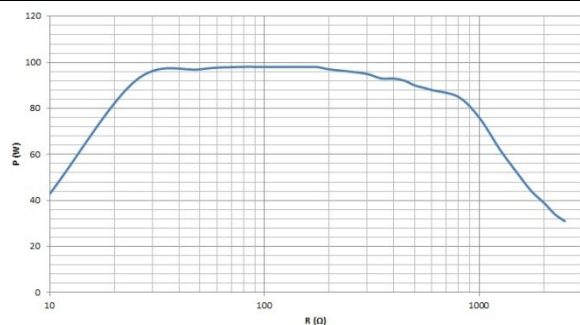
Bipolar Cutting: Bipolar Cutting

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting: Bipolar Cutting" = 100 W.

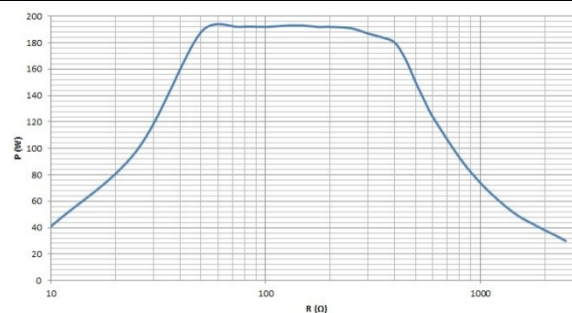


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting: Bipolar Cutting" = 200 W.

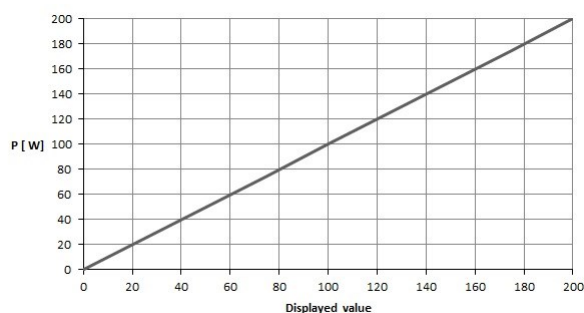


Diagram of power output P [W] as a function of the setting "Bipolar Cutting: Bipolar Cutting". Rated load resistance = 75 Ω.

RF output voltage U [Vp] for the setting "Bipolar Cutting: Bipolar Cutting" (idle mode) = 400 Vp.

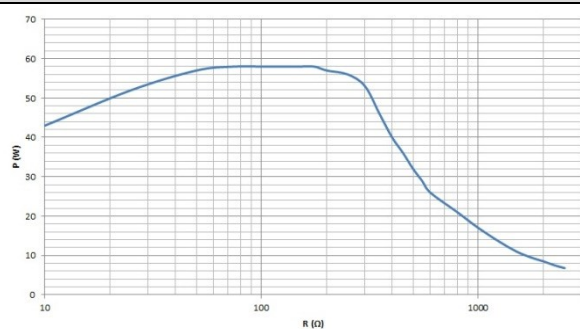
Bipolar Cutting: Bipolar scissors

Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting: Bipolar scissors" = 60 W.

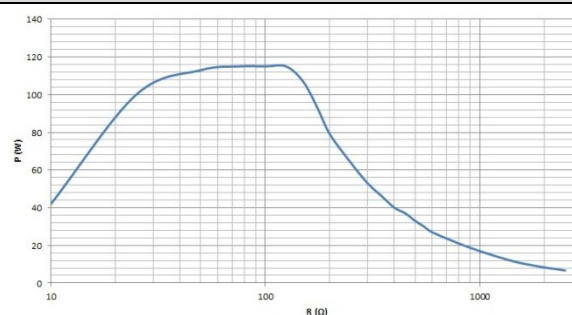


Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting: Bipolar scissors" = 120 W.

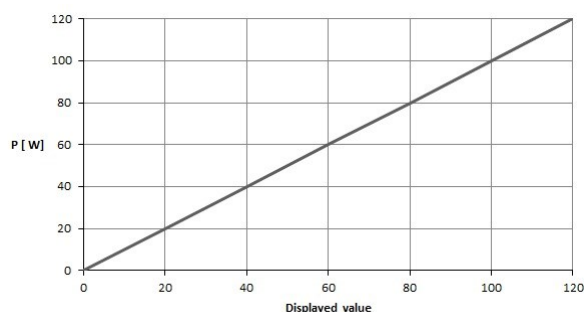


Diagram of power output P [W] as a function of the setting "Bipolar Cutting: Bipolar scissors". Rated load resistance = 75 Ω.

RF output voltage U [Vp] for the setting "Bipolar Cutting: Bipolar scissors" (idle mode) = 200 Vp.

12 EMC Notes

**Warning:**

The Endovapor®2 mandates special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Warning:

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:

Use of this device adjacent to or stacked with other devices should be avoided, because it might result in improper operation. If the Endovapor®2 must be used in a stacked configuration or adjacent with other electronic devices, this device and the other devices must be observed to ensure normal operation.

Warning:

This product may emit radio frequency energy and, if not installed and used according to the instructions, may cause harmful interferences to other devices in the vicinity. If this product interferes with other devices, the user is encouraged to try the following in order to correct the interference:

- Increase the distance between interfering components.
- Consult the manufacturer of the other device for help.

Warning:

Portable RF communications equipment should be used no closer than 30 cm (12") to any part of the Endovapor®2. Otherwise, the performance of this equipment might be impaired.

Warning:

Magnetic field sources, e.g. RFID systems, should be used no closer than 15 cm (5,9") to any part of the Endovapor®2. Otherwise, the performance of the Endovapor®2 might be impaired.

Warning:

Electromagnetic fields are generated during normal use of the RF device. This can adversely affect other devices. Ensure that no electronic devices are placed in the vicinity of the RF device. It may be necessary to take appropriate measures, such as re-orienting or arranging the equipment or installing a shield.



This equipment has been tested and found to comply with the requirements regarding electromagnetic compatibility (EMC) according to IEC 60601-1-2. The customer or user of the Endovapor®2 has to ensure that it is operated in such environments.

The Endovapor®2 is suitable to be used in combination with RF surgical equipment. The device was tested according to IEC 60601-2-2, BB.4 and can withstand the emissions produced by such equipment.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 group 1, class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The Endovapor®2 is suitable for use in professional healthcare facility environments according to IEC 60601-1-2.

Phenomenon	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions	Group 1	The Endovapor®2 must emit electromagnetic energy in order to perform its intended function. Nearby electronic devices may be affected.
	Class A	The characteristics of this device determined by its emissions allow its use in the industrial sector and in hospitals. When used in domestic areas, this device does not provide adequate protection against RF communication equipment. The user may be required to take corrective action such as re-arrangement of the device.
Harmonic distortion	Class A and D	
Voltage fluctuations and flickers	Compliant	

Phenomenon	Basic EMC standard or test method	Immunity test levels	Compliance levels	Electromagnetic environment – guidance
Enclosure Port				
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Endovapor®2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2√P d= 1.2√P 80 MHz to 800 MHz d= 2.3√P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table "Enclosure port immunity to RF wireless communication equipment" below		Minimum distances between the Endovapor®2 and wireless communication equipment as specified in table "Enclosure port immunity to RF wireless communication equipment", must not be undercut.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Compliance levels	Electromagnetic environment – guidance
Immunity to proximity magnetic fields	IEC 61000-4-39	30 kHz, Modulation, CW 8 A/m 134.2 kHz, 2.1 kHz, PM 65 A/m 13.56 MHz, 50 kHz, PM 7.5 A/m	30 kHz, Modulation, CW 8 A/m 134.2 kHz, 2.1 kHz, PM 65 A/m 13.56 MHz, 50 kHz, PM 7.5 A/m	Minimum separation distance between Endovapor®2 and magnetic field sources must be at least 15 cm (5,9").
Input AC power port				
Electrical fast transients/bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV	±0.5 kV, ±1 kV	
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2kV	±0.5 kV, ±1 kV, ±2kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Endocvapor®2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Voltage dips	IEC 61000-4-11	0% U T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Endocapor®2 requires continued operation during power mains

Phenomenon	Basic EMC standard or test method	Immunity test levels	Compliance levels	Electromagnetic environment – guidance
Voltage interruptions	IEC 61000-4-11	0% U T 250/300 cycle	0% U T; 250/300 cycle	interruptions, it is recommended that the Endovapor®2 be powered from an uninterruptible power supply or a battery.
Signal input/output parts port				
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients / bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency	±1 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-ground	IEC 61000-4-5	±2 kV	±2 kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Endovapor®2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Enclosure port immunity to RF wireless communication equipment							
Test frequency (MHz)	Band	Service	Modulation	Max. Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
810	800 -	GSM 800/900,	Pulse modulation	18	2	0.3	28

Enclosure port immunity to RF wireless communication equipment							
Test frequency (MHz)	Band	Service	Modulation	Max. Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
870	960	TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Hz				
930							
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	03	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	03	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

13 Service / Maintenance


Warning:

Do not use the device during service activities.

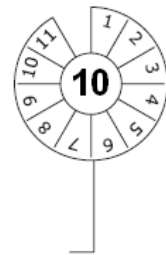


joimax® GmbH recommends performing a function and safety inspection at regular intervals according to EN 62353 or to other corresponding country-specific regulation.

The Endovapor®2 is low maintenance. Regardless of the Endovapor®2 being low maintenance, regular service can contribute to early detection of defects and faults and, thus, extend the operating life of the device.

An operating life of 10 years is specified for the Endovapor®2. Any use beyond this depends on the results of the safety inspections.

joimax® GmbH recommends an inspection to be performed at least once a year. The inspection should be documented with an inspection-label on the device. The next technical safety inspection date of Endovapor®2 can be displayed in the device settings menu. A warning message appears during system start-up if a technical safety inspection is due. Further work is still possible, confirm this with "OK".



Next inspection

13.1 Replacing the Fuse


Warning:

Always observe the specifications on the device label and follow the instructions below when replacing the fuse. Non-observance may result in malfunction of the device and possible injury.

Warning:

Always disconnect the device from the power supply when performing service activities.

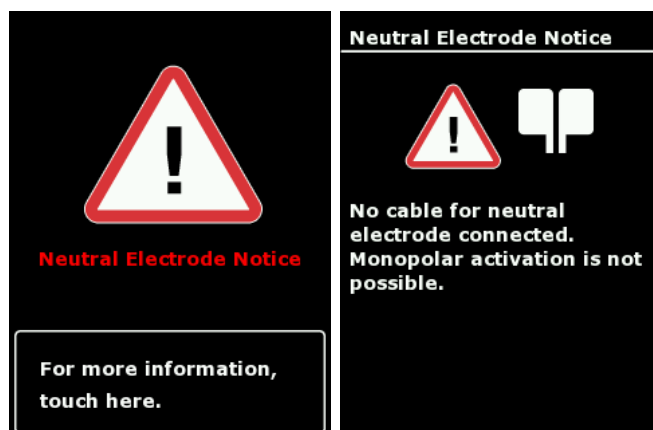


- 1) Turn off the device via the power switch at the backside of the control unit.
- 2) Unplug the power cord from the control unit.
- 3) Open the fuse holder.
- 4) Check the type of replacement fuse on the device label and replace the defective fuses.
- 5) Plug the power cord into the control unit.
- 6) Turn on the device via the power switch at the backside, press the button "On/Off" at the device front and check the function of the device.

14 Troubleshooting

14.1 System Information

A warning message appears on the display when a system fault occurs.



Further information on the cause and corrective measures regarding this fault can be shown by pressing the lower area of the screen.

System information has three different categories:

- Notice (grey screen)
- Warning (orange screen)
- Error (red screen)



While an error is present, the power output cannot be activated.

Error message	Description
Confirmation of AUTOSTART Mode	You have selected an AUTOSTART mode. Setting the AUTOSTART mode can result in unintentional coagulations, e.g. when bipolar forceps are used for gripping while the AUTOSTART mode is on.
AUTOSTART Error	The instrument is in contact with tissue. AUTOSTART cannot be selected. ► Remove the instrument from tissue contact!
Neutral Electrode Error	Wrong neutral electrode connected. The selection does not match the neutral electrode connected. ► Connect the neutral electrode which matches the selected mode, or change the mode to match the neutral electrode.
Neutral Electrode Error	No neutral electrode connected. ► Connect a neutral electrode!
Neutral Electrode Error	Poor contact with the patient. The resistance between the neutral electrode and the patient is too high. ► Establish better contact of the neutral electrode!
Neutral Electrode Warning	Poor contact with the patient. The contact resistance between the neutral electrode and the patient is increasing. ► Establish better contact of the neutral electrode!
Neutral Electrode Notice	No cable for neutral electrode connected. The cable for neutral electrode has been removed. Monopolar activation is not possible.
Mode Error	No mode selected. No mode was selected for this type of activation. ► Select the desired mode or change the foot switch assignment.

Error message	Description
Mode Error	This mode is not allowed for baby neutral electrodes. ► Use split neutral electrodes with a large conductive surface for this mode.
Mode Error	This mode is not allowed for this socket. The current mode remains active. ► Choose another socket for this mode.
Mode Error	The Standard mode cannot be changed. ► Save mode under different name.
Foot Switch Error	No compatible foot switch. The connected foot switch is not compatible with this device. ► Connect a compatible foot switch with a black button!
Foot Switch Error	The foot switch has not been assigned to a socket yet. ► Assign a socket to the foot switch using the "Pedal" button!
Foot Switch Error	Fault on foot switch connection. ► Check the foot switch.
Foot Switch Note	The assignation of the foot switch has been changed. The black button on the foot switch enables switching from socket A to B and back. The active foot switch assignation is displayed in the form of a filled dot.
Foot Switch Warning	Second foot switch assignment has not been set. The current assignment remains active. ► To allocate the second foot switch assignment press the "Pedal" push button on the desired socket.
Hand Switch Error	Fault on hand switch connection. ► Check the handpiece and the connection cable. Please replace them if damaged! ► Instruments with a pin must be connected to the assigned socket!
Temperature Warning	The temperature of the device is higher than normal. This leads to a reduction of the maximum power.
Limitation of Continuous Activation	The maximum activation time has been exceeded. ► Please only activate the generator in short intervals, in order to avoid harming the patient and damaging the connected instruments or the generator.
Mains Voltage Error 22	The mains voltage is too low. ► Please ensure constant mains voltage! ► If necessary, connect a UPS (Uninterrupted Power Supply)!
Activation Error	While switching on the device, there is an activation by foot switch, handpiece or AUTOSTART. ► Check the handpieces or foot switches for malfunctions! ► Disconnect the handpieces / foot switches from the device!
Activation Error	There is an activation while connecting the foot switch or handpieces. ► Check the handpieces or foot switches for malfunctions! ► Disconnect the handpieces / foot switch from the device!
Activation Error	There is no instrument connected on the activated socket. ► Connect an instrument on the designated socket!
Activation Warning	The mode for safety inspections (TSI) is active. Activation is not possible. ► Quit this mode before activating again!
TSI Endovapor®2 Warning	The annual Technical Safety Inspection (TSI) for Endovapor®2 is due. ► Please contact the joimax® technical support
Internal Error 4177	► If this message appears, please contact the joimax® technical support.

14.2 EASY Neutral Electrode Monitoring



See chapter 8.10 for more information about the EASY neutral electrode monitoring.

EASY- Symbol	Indication	Cause	Corrective measures
Flashes yellow	–	Significant increase of the resistance. Depending on the indication, this might cause heating below the neutral electrode.	▶ Check proper fixation of the neutral electrode. An interruption of the application is not necessary.
Switches from green to continuous red	An acoustic signal sounds and a warning message appears on the display.	A significant problem occurs, when the monopolar power output is activated.	▶ Check the neutral electrode cable for proper connection or external damage. ▶ Check the neutral electrode and neutral electrode cable.
	An acoustic signal sounds and a warning message appears on the display.	Loosened electrode.	▶ Re-attach the neutral electrode. If the error persists, replace it.

15 Warranty

**Warning:**

Do not open the Endovapor®2. Unauthorized opening, repair, or modification of the device releases joimax® GmbH from any liability for the operating safety of the device and results in any claims becoming void, even during the warranty period.

Warning:

In case of return of equipment or accessories, original packaging material must always be used!

Warning:

*To protect your staff and the joimax® GmbH employees, please clean the device and its accessories and disinfect it before sending it.
Should this be impossible due to temporal constraints, please prepare the unit as much as possible and label it accordingly.*

The warranty period for the joimax® Endovapor®2 depends on the legal regulations of the specific country. Failure due to faulty material and/or poor processing must be rectified by the manufacturer free of charge within this period.

Transport costs and shipment risks are excluded hereof.

In addition, the details in our general terms and conditions apply.

To facilitate quick processing of service requests, we ask you to send the product with the following information:

- Model/Item number (REF)
- Serial number (SN)
- A description of the error as accurate as possible
- Invoice of the device if available
- Contact person for questions

16 Consumables / Accessories


Warning:

Only the consumables/accessories from joimax® GmbH listed below are to be used with the Endovapor®2. Use of accessories and cables other than those specified or provided by the manufacturer may result in improper operation.

Warning:

Make sure to follow the instructions for use of accessories to be used with the device (e.g. handpieces, RF probes etc.).

Consumables



All consumables are provided by joimax® GmbH. Replacements for all consumables can be ordered from joimax® GmbH or via the respective local joimax® distributor.

Item number	Description
JEVN0001	joimax® Neutral Electrode, Easy Universal, without Connecting Cable, Disposable

Accessories

Item number	Description
JEVNC0001	joimax® Neutral Electrode Connecting Cable, Connecting Cable international

17 Compatibility


Warning:

When using the joimax® Endovapor®2 Spine mode modes

- Neurotomy
- Spine Vap
- Spine Coag
- Bipolar Neurotomy

only original joimax® RF instruments may be used.



Operating conditions of RF instruments (e.g. handpieces and probes) used in combination with the device may differ. Follow the respective instructions for use, which are provided with connected accessories.

joimax® RF instruments and accessories are specially designed to be used with the joimax® Endovapor®2 System:

Item number	Description
JVUH10010	Vaporflex® Handle
JVC35010	Vaporflex® Cable L 3.5 m
JVC35020	Vaporflex® Cable L 3.5 m
JVHS32030	Vaporflex® Shaft 320
JVHS28030	Vaporflex® Shaft 275
JVHS27527S	Vaporflex® Irrigation Shaft 275
JVP32024	Vaporflex® Probe 320, Ball Tip, Bipolar

JVP27525S	Vaporflex® Probe 275, Ball Tip, Bipolar
JVP28024	Vaporflex® Probe 275, Ball Tip, Bipolar
JBPH352505	Legato® Handpiece bipolar
JBPH352506	Legato® Handpiece bipolar
JMPH352504	Legato® Handpiece monopolar
JBPP27020	Legato® Probe, Ball Tip, bipolar, straight
JBPP27025	Legato® Probe, Ball Tip, bipolar, angled
JMPP27025	Legato® Probe, Ball Tip, monopolar, angled
JMPP27025*	Legato® Probe, Ball Tip, monopolar, straight
JVAH10010	Vaporace® Hand piece for joimax® Endovapor®2 (not yet for CE market)
VBFC8030	Cable for Bipolar Instruments, L 3,0 m, Plug joimax® Endovapor®2 (not yet for CE market)
JVAPA15035	Vaporace® Probe bipolar, Area 150 mm – 3.5 mm (not yet for CE market)
JVAPA27035	Vaporace® Probe bipolar, Area 270 mm – 3.5 mm (not yet for CE market)
JVAPA35035	Vaporace® Probe bipolar, Area 320 mm – 3.5 mm (not yet for CE market)



Detailed information regarding joimax® RF instruments and accessories can be found in the data sheet RF program and in the product catalog. Modifications are subject to change.

For further information and new products directly contact the joimax® customer service or your joimax® representative.

When using accessories made by other manufacturers, the user must ensure that only compatible accessories are used. Device accessories and instruments must be designed for the maximum RF peak voltage of the RF device.

The following maximum lengths of accessory cables must be observed:

Bipolar accessory:	max. 3.5 m
Monopolar accessory:	max. 3.5 m
Neutral electrode:	max. 4.5 m
Foot switch:	max. 4 m

18 Disposal of the Device



Warning:

This symbol indicates that medical devices must be disposed of separately from household waste. Dispose of electrical waste in accordance with the applicable national and local regulations.



Warning:

This symbol must be affixed to the waste container or the device when discarding it.



Dispose of packing material, unless it is contaminated, in accordance with national and local regulations.



According to the implementation of European law into national laws and regulations, you are obliged to properly dispose of medical devices.

Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier. "Medical waste" is classified according to dangerous goods law (for transportation) by UN number UN 3291.

19 Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to joimax® GmbH and the competent authority having jurisdiction in your locale. Please notify us at the following telephone number:

For the US	+1 949-859-3472	(24-hour availability)
For all other countries	+49 (0)721 25514 – 999	(24-hour availability)

Thank you for your support!

CE 0123

REF IFUENDO2EN

Document-ID: TD_ENDO_14_GA_002

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