



INSTRUCTIONS FOR USE

CURIS®II

4 MHz Radiofrequency Generator

REF 36 01 00 – 05



Table of Contents

1	EXPLANATION OF SYMBOLS AND ABBREVIATIONS	1
2	MODE OF ACTION AND INTENDED USE	3
2.1	General information about the mode of action of electrosurgery	3
2.2	Intended use of the CURIS® II	5
2.2.1	Purpose	5
2.2.2	Fields of application	5
2.2.3	Contraindications and side effects.....	5
	Contraindications	5
	Side effects.....	6
3	TRANSPORTATION AND PACKAGING	7
3.1	Receiving inspection.....	7
3.1.1	Transport damage	7
3.1.2	Claims for damages.....	7
3.2	Returns	7
4	FUNCTION AND MEANING OF THE DISPLAY AND CONTROL ELEMENTS.....	8
5	COMMISSIONING	12
5.1	Validity of these instructions for use	12
5.2	Potential equalization connection	12
5.3	Mains connection.....	12
5.4	Turning the device on and off	13
5.5	Self-test.....	13
5.6	Connecting accessories.....	13
5.6.1	Connecting the neutral electrode.....	13
5.6.2	Connecting monopolar handles for cutting and coagulation.....	14
5.6.3	Connecting bipolar accessories.....	15
5.6.4	Bipolar accessories with automatic instrument detection	15
5.6.5	Connecting the irrigation pump	15
5.6.6	Smoke gas evacuation connection	16
5.6.7	Operating mode selection.....	17
5.6.8	Setting the output power	17
6	OPERATION	19
6.1	Special functions.....	19
6.2	Program memory.....	20
6.3	Functional test	21
7	SAFETY MEASURES.....	23
7.1	General information.....	23



7.2	Patient positioning	23
7.3	Application of the neutral electrode and high-frequency current	24
7.4	Pacemakers, active and passive implants	25
7.5	Setting down RF instruments	25
7.6	Risks due to electromagnetic interference	26
7.7	Accessories	27
7.8	Operation with bipolar cutting forms	28
7.9	Risks due to high electric voltage	28
8	CARE INSTRUCTIONS	29
8.1	Cleaning and disinfection	29
8.2	Sterilization of accessories	29
8.3	Accessories that cannot be sterilized	29
9	TECHNICAL INFORMATION	30
9.1	Technical data, standards, certification	30
9.2	Recurring safety-related inspections	31
9.3	Diagrams	32
9.3.1	RF output	32
9.3.2	RF voltage	34
9.3.3	Control characteristic curve	36
9.4	Guidelines and manufacturer declaration for electromagnetic compatibility	37
10	ENVIRONMENTAL NOTICES	41
10.1	Packaging	41
10.2	Environmentally friendly device operation	41
10.3	Device disposal	41
11	ERROR DIAGNOSIS	42
12	FOOT SWITCH (ACCESSORY)	45

Instructions for Use

These instructions for use apply for all devices according to [Chapter 5.1](#).

1 Explanation of symbols and abbreviations

	Temperature limit
	Relative humidity limit
	Air pressure limit
	Medical device
	Non-ionizing radiation
	Warning
	Notice
	Disposal instructions
Rx ONLY	Sale restricted to attending physicians (USA)
	Attention, note the instructions for use
	Manufacturer
	Manufacturing date
	Article number
	Serial number
	This side up
	Protect against moisture
	Caution, fragile
IP21	IP protection class 21
CE	CE marking
°C	Degrees Celsius
%	Percent
Ω	Ohm



A	Ampere
AC	Alternating current
CF	Cardiac floating
cm	Centimeter
dB	Decibel
DC	Direct current
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
Err	Error
GHz	Gigahertz
hPa	Hectopascal
Hz	Hertz
IC	Instrument code (instrument recognition)
kHz	Kilohertz
kV	Kilovolt
m	Meter
max	Maximum
min	Minute
mm	Millimeter
mA	Milliampere
MDR	Regulation (EU) 2017/745 for medical devices
MHz	Megahertz
LF	Low frequency
P	Power
PE	Potential equalization
R	Resistance
RaVoR™	Radio frequency volume reduction
RF	Radio frequency
V	Volt
VA	Volt-ampere

(also see [Chapter 4](#))

2 Mode of action and intended use

2.1 General information about the mode of action of electrosurgery

Electrosurgery is a surgical method that uses electric current to achieve surgical effects. To prevent this current from causing nerve stimulation (electric shocks), alternate current with a sufficiently high frequency (approximately 4 MHz with this device) is used so that nerve stimulation no longer occurs (Nernst equation). Since the frequency is in the range of radio waves, one also speaks of “radio frequency surgery” (RF surgery).

If the current is supplied to the surgical area by an electrode and conducted away from the body again outside the surgical area using a large-scale electrode with no electrosurgical effect, one speaks of **monopolar application**. The electrode in the surgical area is called the active electrode, the current return electrode is called the neutral electrode. If on the other hand the current is conducted away from the body and back to the device by an electrode directly within the surgical area – which is usually symmetrical to the supply electrode – then one speaks of **bipolar application**.



When RF surgery and monitoring screens are used simultaneously on a patient, only monitoring electrodes with supply cables that contain protective resistors or RF inductors may be used. Needle electrodes for monitoring may not be used. Do not use the active surgery electrode in the vicinity of the ECG electrodes (minimum distance 15 cm)!

Compliance with the following general rules is required for RF surgery applications:



Always work with the lowest RF output setting for the desired surgical effect. On the other hand, note that setting the output too low can also constitute a risk, for instance because a first cut is not made due to excessively low output so that local coagulation results where it is not desirable or even dangerous.



NOTICE

An inadequate effect with the usual setting may for instance be due to poor application of the neutral electrode, poor contact in plug connections, cables broken underneath the insulation, or encrusted electrodes. This needs to be checked and defective components must be replaced.



Check the electrodes and lines for correct attachment after repositioning the patient.



The use of ignitable anesthetics, nitrous oxide (N₂O), and oxygen should be avoided. The use of RF devices may generate sparks on the active electrode. Combustible substances used as cleaning agents, disinfectants, or solvents must evaporate before the application of RF surgery. There is a risk that combustible liquids may accumulate under the patient or in body recesses such as the navel or body cavities such as the vagina. Wipe up liquid that has accumulated in these areas before using the RF device. There is a risk that endogenous gases may ignite. Materials saturated with oxygen such

as cotton wool and gauze may be ignited by the sparks that form during the intended use of the RF device.



Combinations with other devices may only be realized by the manufacturer or with the manufacturer's consent.



The operation of the RF device may interfere with other electromedical devices.



When active electrodes will not be used for some time, they must be stored in a location isolated from the patient.



Accessories that are used have to be inspected by the operator at regular intervals.



NOTICE

For further information about electrical safety, we recommend IEC TR 61289 or DIN EN 60601-2-2 Supplement 1.

In principle one differentiates between two electrosurgical effects:

- **Electrosurgical cutting**
- **Electrosurgical coagulation**

Electrosurgical cutting

With **electrosurgical cutting**, a high current concentration occurs at the transition between the electrode and tissue, leading to very rapid heating at that point. This causes water vapor to escape from the tissue. The release of vapor separates the tissue from the electrode, creating an insulating layer. This layer needs to be electrically penetrated by ionizing the steam so the current can continue to flow. Now physical effects occur in this water vapor layer, which has become electrically conductive, leading to tissue separation. If the tissue contains only little or no water, then this cutting process only works moderately or not at all. This method is used to sever or resect tissue using blade or needle-shaped electrodes, or wire or tape loops.

Electrosurgical coagulation

Two active principles are generally differentiated for **electrosurgical coagulation**. When the current from the electrode enters the tissue, the tissue at that point is heated by electrothermal energy conversion (resistive heating). This is used to denature (coagulate) tissue for surgical purposes or to stop major bleeding (hemostasis). This type of electrosurgical coagulation is called contact coagulation, and is carried out using a ball-shaped electrode or the flat side of a blade-shaped electrode.

Another possible application is the targeted destruction of tissue using piercing electrodes, which in this case can postoperatively lead to a desired volume reduction in the tissue (radio frequency volume reduction: RaVoR™).

In the bipolar application, the electrode pair is frequently carried out as forceps with arms insulated from each other, often designed for special preparations.

A different coagulation effect occurs when the voltage on the active electrode is so high that sparks can form from the electrode to the tissue. Low ends form at the ends of these sparks. Within them the temperature is extremely high, but the temperature gradient from the inside to the outside is also extreme so that coagulation only takes place in a thin layer on the surface. This allows large-scale hemostasis with only minor depth damage to the tissue to be achieved. This type of coagulation is called spray coagulation and can be carried out with a needle electrode or the pointed end of a blade electrode.

2.2 Intended use of the CURIS® II

2.2.1 Purpose

The CURIS® II is suitable for electrosurgical cutting and coagulating.

2.2.2 Fields of application

The CURIS® II 4 MHz radiofrequency generator with its output power of max. 120 watts is suitable for monopolar and bipolar electrosurgical procedures in neurosurgery, ear/nose/throat medicine, plastic/cosmetic surgery, oral and maxillofacial surgery, dermatology, and by registered surgeons. Meaningful applications may exist in other specialist fields.

To a significant extent, the field of application and the application method of the products depend on the decision and expertise of the user, that is, the doctor or medical personnel.

The CURIS® II may only be used by persons who have been trained in the proper and safe use of the device. The instructions for use must be observed for training and application.

The safe application of electrosurgery requires the user to be familiar with the technology and forms of application.



Any change to the product or deviation from these instructions for use waives the liability of Sutter Medizintechnik.

2.2.3 Contraindications and side effects

Contraindications

Applications that require a higher RF output than the maximum output specified in the technical data for the respective current type are contraindicated.

In case of procedures on body parts with a small cross-section in proportion to their dimensions (filamentary structures and skin flaps), using bipolar technology is preferred or forgoing the use of RF surgery is indicated to prevent unwanted coagulation in other areas.

No contraindications that apply to the product directly are known at this time. The attending doctor has to decide whether the intended application can proceed, based on the patient's general condition. The safety measures described in [Chapter 7](#) have to be observed in addition.

**Side effects**

No side effects that apply to the product directly are known at this time. Observe the safety measures in order to avoid unwanted effects – see [Chapter 7](#).

3 Transportation and packaging

3.1 Receiving inspection

3.1.1 Transport damage

The device and accessories must be inspected for possible transport damage and defects on receipt.

Scope of delivery: CURIS® II, mains cable, instructions for use

3.1.2 Claims for damages

Claims for compensation can only be asserted if the seller or shipper is notified promptly. A record of damages must be prepared immediately. The record of damages has to be submitted to the nearest Sutter representative or directly to Sutter so that claims for compensation can be reported to the insurer.

3.2 Returns

If possible, the original packaging must be used to return a device to Sutter or a Sutter service center. If this is not available, packaging that properly protects the device being returned is mandatory. In case of improper packaging, liability rests exclusively with the sender. The following accompanying documents must be included:

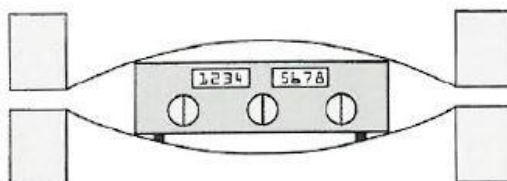
- Name and address of the sender/return recipient
- Model and device number
- Description of the defect
- The version of these instructions for use
- The most recent inspection record for the safety-related inspection
- A notice that the device has been properly disinfected



NOTICE

The packaging of the generator is not intended for transportation together with the foot switch! The foot switch must be packaged separately. Shipping them together may result in transportation damage and Sutter assumes no liability for this.

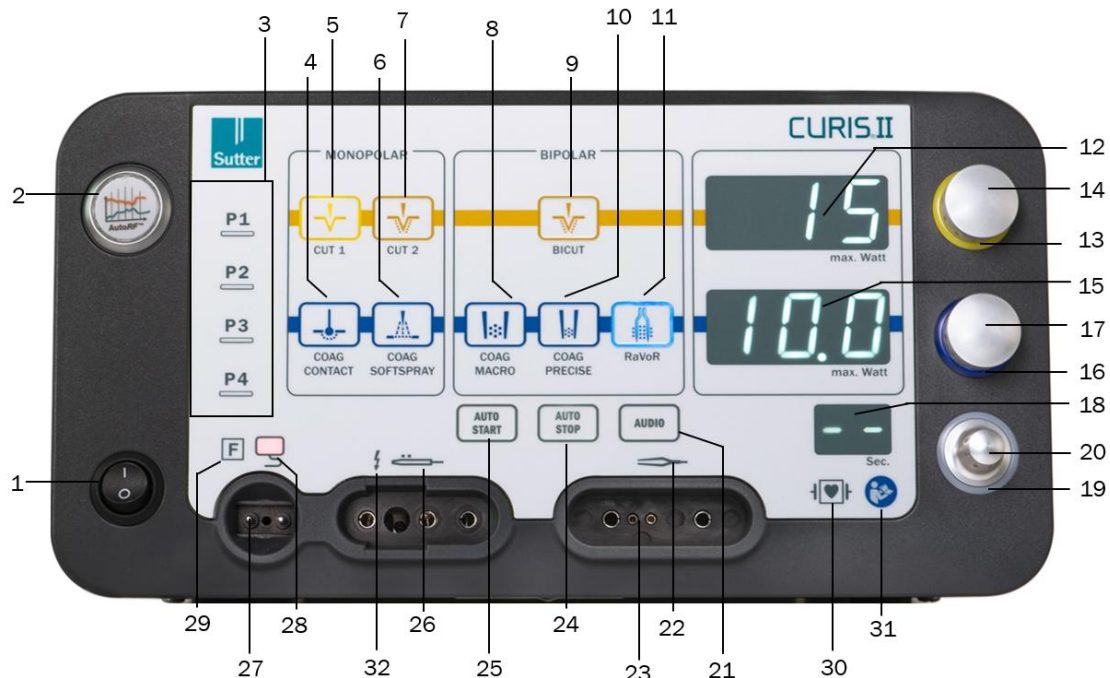
When returning or shipping an RF generator, please ensure that the membrane packaging is correctly inserted.



The packaging can be reordered under the following article number: **98 91 19**

4 Function and meaning of the display and control elements

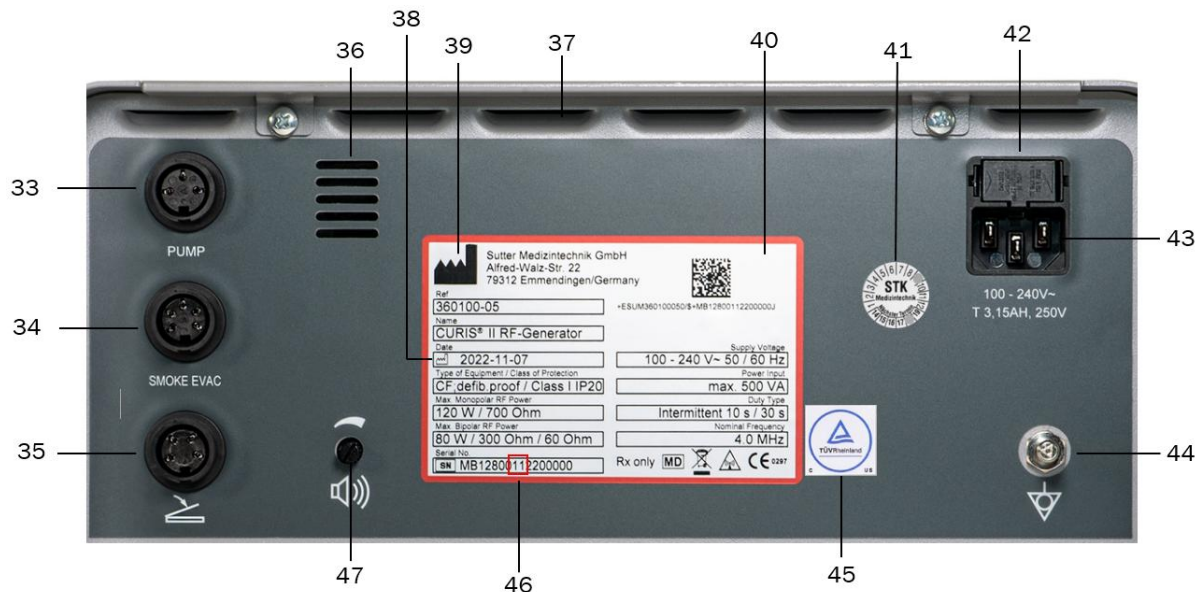
Front of the device



- 1 Power switch
- 2 “Auto-RF control active” indicator
- 3 Program memory P1 ... P4 (to store device settings)
- 4 COAG CONTACT selection button for monopolar contact coagulation
- 5 CUT 1 selection button for monopolar cutting
- 6 COAG SOFTSPRAY selection button for contactless monopolar coagulation (spray coagulation)
- 7 CUT 2 selection button for monopolar cutting with coagulation
- 8 COAG MACRO selection button for bipolar coagulation
- 9 BICUT selection button for bipolar cutting with coagulation
- 10 COAG PRECISE selection button for bipolar coagulation with fine instruments
- 11 RaVoR™ selection button for bipolar RF volume reduction, for instance in snore therapy
- 12 Display of the RF cutting output setting
(for operating modes CUT 1, CUT 2, BICUT)
- 13 The CUT indicator ring lights up when a cutting current is selected, and turns brighter when the RF output of the selected cutting current is delivered.
- 14 Rotary knob to select the RF cutting output
(operating modes CUT 1, CUT 2, BICUT 1, BICUT 2, EXCISE)
- 15 Display of the RF coagulation output setting
(operating modes COAG CONTACT, COAG SOFTSPRAY, COAG MACRO, COAG PRECISE, RaVoR™)
- 16 The COAG indicator ring lights up when a coagulation current is selected, and turns brighter when the RF output of the selected coagulation current is delivered.

- 17 Rotary knob to set the RF coagulation output
(operating modes COAG CONTACT, COAG SOFTSPRAY, COAG MACRO, COAG PRECISE, RaVoR™)
- 18 Display of the AUTO START time
- 19 The indicator ring for AUTO START lights up when the AUTO START special function is selected, and turns brighter when the AUTO START special function is active.
- 20 Rotary knob to set the TIMER time
- 21 AUDIO special function button
(only possible in bipolar coagulation operating modes)
- 22  Connection socket for bipolar instruments
- 23 2 mm auxiliary contacts of the bipolar instrument socket
- 24 AUTO STOP special function button (only possible in bipolar coagulation operating modes)
- 25 AUTO START special function button (only possible in COAG MACRO and COAG PRECISE bipolar operating modes)
- 26  Connection socket for monopolar instruments
- 27 Connection socket for the neutral electrode
- 28  "Neutral electrode status" indicator
Lamp flashing red = neutral electrode not connected
Lamp flashing green = neutral electrode connected
- 29  Notification symbol "neutral electrode insulated from ground" (F = floating)
- 30  Notification symbol for classification of the device (CF).
The device is defibrillator safe.
- 31  Notification symbol "CAUTION! NOTE THE INSTRUCTIONS FOR USE!"
- 32  Notification symbol "CAUTION – HIGH-FREQUENCY CURRENTS, DANGER HIGH VOLTAGE"

Back of the device



- 33  Connection socket for irrigation pump
- 34  Connection socket for smoke gas evacuation
- 35  Connection socket for foot switch
- 36  Speaker
- 37 Ventilation slots
- 38  Manufacturing date
- 39  Manufacturer
- 40 Type plate
- 41 Safety-related inspection seal of approval
- 42 Device fuse (2x T 3.15 AH 250 V G 5x20 mm)
- 43 Mains cable connection socket
- 44  PE connection for electric potential equalization
- 45 NRTL seal of approval
- 46 Hardware and software version, two characters
- 47 Volume control



NOTICE

In the chapters that follow, the numbers in brackets, for example (X), represent the item numbers of the display and control elements in the illustrations of the front and rear of the device.

The serial number encodes the following information about the respective device:

The diagram illustrates the structure of the sequential production number MB12800112200000. The number is broken down into five parts, each with a label:

- MB12800**: Device type
- 1**: Hardware status code
- 1**: Software status code
- 22**: Year of manufacture
- 00000**: Sequential production number

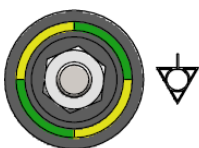
5 Commissioning

5.1 Validity of these instructions for use

These instructions for use are valid for all CURIS® II units with the hardware and software version “11” (46) according to the type plate. The type plate is on the rear of the device.

Simultaneously pressing the “CUT 1” and “BICUT” push-buttons while the device is powering up shows the software version in the bottom two rows of the display. Example: F 1.00.02 means version 1.00.02.

5.2 Potential equalization connection



Potential equalization is a connection of device housings with good electrical conductivity. It is intended to ensure that the devices consistently maintain the same electrical potential, even in case of an electrical defect.

Potential equalization is required in operating rooms where intracardial procedures are performed.

Potential equalization can be established via the potential equalization connection (44) on the rear of the device.

To do so, push the potential equalization cable in firmly until it locks into place. The required potential equalization cable is not included in the scope of delivery.

5.3 Mains connection



WARNING

To exclude the risk of electric shock, this device may only be connected to a mains network with protective conductor.

The device is equipped with a multi-voltage power supply. It can be operated in the following voltage range without switching:

100 – 240 V AC, 50/60 Hz

The fuses are located on the rear of the device in the slot (42) on the mains connection socket.

Connect the mains cable to the connection socket (43) on the rear of the device and the other end of the mains cable to an outlet.

For the all-phase, full disconnection of the device in case of danger, either the connection socket on the device or the outlet where the mains cable is plugged in should be left accessible.

No special measures are required to take the device out of operation.

5.4 Turning the device on and off



Turn the device on and off using the power switch on the front (1).

For the all-phase disconnection of the mains voltage, the mains cable has to be unplugged.

5.5 Self-test

The device performs a self-test after it is switched on. All display elements on the front are turned on during this process. The correct functioning of these elements cannot be checked by the device itself. Therefore they have to be checked by the user as follows:

After the device is switched on, all cutting modes with the indicator ring CUT light up, followed by the five coagulation modes with the indicator ring COAG, and finally the special functions with the indicator ring for AUTO START.

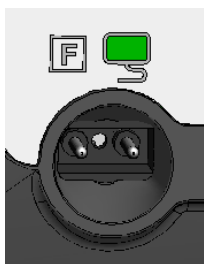
Then all indicator lamps of the program buttons light up. The neutral electrode indicator simultaneously lights up red. Finally, the three displays light up with “888”, the neutral electrode indicator color changes to green, and four different activation signals sound in parallel.

An error in the self-test sequence indicates a device defect. Do not continue using the device. Contact your service partner.

After the internal device test completes successfully, the device is operational with the program that was last used. An error number is displayed if an error is found (see [Chapter 11](#)).

5.6 Connecting accessories

5.6.1 Connecting the neutral electrode

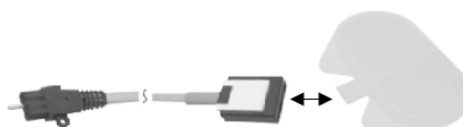


Connect the connector of the neutral electrode connection cable (REF 36 02 37) to the connection socket (27) on the front of the device (see illustration, above left).

Connect neutral electrodes with two partial areas that make it possible to monitor the contact to the patient.

Insert the second end of the cable into the connecting lug of the neutral electrode and engage the locking lever (see illustration, below).

In monopolar mode, the “Neutral electrode status” indicator (28) above the socket



lights up if the neutral electrode is not connected. This indicator does not light up in bipolar mode. If an attempt is made to activate the device in a monopolar operating mode in this state, a loud acoustic warning signal is emitted. RF current cannot be activated.

This has no influence on the bipolar current.

When an electrode with more than one surface is connected, the “Neutral electrode status” indicator lights up green after the safe application state is reached. Since individual warm-up times can be expected here, the additional required time must be taken into account.

NOTICE

Insufficient contact between the neutral electrode and patient only triggers an acoustic warning signal when a neutral electrode that supports monitoring is used with the contact quality monitor.

5.6.2 Connecting monopolar handles for cutting and coagulation



Connecting **monopolar handles with finger switch** (e.g. REF 36 07 04)

To use monopolar handles with a finger switch, connect the connection cable to the socket (26) on the front of the device (see illustration, left).

Subsequently activation is realized with the finger switch on the handle. A connected neutral electrode is required for activation.



Connecting **monopolar handles without finger switch** (e.g. REF 36 02 14)

To use monopolar handles without a finger switch, connect the connection cable to the socket (26) on the front of the device (see illustration, above left) **and** connect the footswitch (e.g. REF 36 01 10) to the socket (35) on the back of the device (see illustration, below left).



Subsequently the foot switch is used for activation.

For all connections, please also note the information in [Chapter 4](#) and the respective instructions for use for the accessories being used.



WARNING

Activating the RF current is not permitted while inserting the electrode and during electrode replacement! Risk of burns!

5.6.3 Connecting bipolar accessories



To use **bipolar instruments**, connect the connection cable to the socket (22) on the front of the device (see illustration, above left) **and** connect the footswitch (e.g. REF 36 01 10) to the socket (35) on the back of the device (see illustration, below left).

The footswitch or, for the coagulation electrodes, the AUTO START function (25) is subsequently used for activation; see [Chapter 6.1](#).

Bipolar forceps with a hand switch can be connected using a special cable.

The neutral electrode is **not** required for bipolar applications.

Connecting the neutral electrode in addition in bipolar mode has no influence on the safety and effectiveness of bipolar applications.

For all connections, please also note the information in [Chapter 4](#) and the respective instructions for use for the accessories being used.

5.6.4 Bipolar accessories with automatic instrument detection

Special accessories that are automatically detected by a coding element can be connected to CURIS® II RF generator. Default settings adapted to the accessories are configured on the generator for this purpose. These can only be changed in part or not at all.



NOTICE

When the instrument is connected, a confirmation tone sounds and the number of the detected instrument code such as "IC 04" is shown on the display. Please check whether the number that is displayed is the same as the instrument number according to the instructions for use. The automatically selected current type and output have to be checked for plausibility.

When instruments are detected automatically, programs (buttons P1 through P4) can only be loaded and saved within the parameters assigned to the respective instrument.

5.6.5 Connecting the irrigation pump



PUMP

Connecting the **CURIS® flow irrigation pump**, REF 35 09 50

Plug one end of the interconnecting cable (REF 93008120) into the connection socket (33) on the back of the CURIS® II (see illustration, left). Connect the other end of the interconnecting cable to the connection socket on the back of the CURIS® flow irrigation pump being used.

For subsequent activation, start a bipolar coagulation mode or press the irrigation button on the footswitch; see [Chapter 12](#). Please note the information in the CURIS® flow instructions for use.



5.6.6 Smoke gas evacuation connection



SMOKE EVAC

Smoke gas evacuation connection

Plug one end of the interconnecting cable (REF 08-200-57-45) into the connection socket (33) on the back of the CURIS® II (see illustration, left). Connect the other end of the interconnecting cable to the connection socket on the back of the smoke gas evacuation unit being used.

For subsequent activation, start a cutting or coagulation mode.

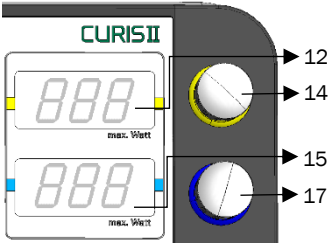
5.6.7 Operating mode selection

Select the desired operating mode before using the device.

The CURIS[®] II has the following operating modes:

MONOPOLAR for monopolar electrodes	Cutting yellow selection buttons	CUT 1 (5)	Smooth cut with no coagulation zone.
		CUT 2 (7)	Cutting current with coagulation zone.
	Coagulation blue selection buttons	COAG CONTACT (4)	Contact coagulation, coagulation with depth effect on direct contact between the electrode and tissue.
		COAG SOFTSPRAY (6)	Spray coagulation, coagulation current with low depth effect for surface coagulation with sparks (fulguration).
BIPOLAR for bipolar electrodes	Cutting yellow selection buttons	BICUT (9)	Cutting current with coagulation zone.
	Coagulation blue selection buttons	COAG MACRO (8)	Bipolar coagulation, local contact coagulation in the area of the bipolar electrode pair.
		COAG PRECISE (10)	Bipolar coagulation with fine electrodes, local contact coagulation in the area of the bipolar electrode pair.
		RaVoR™ (11)	Bipolar radio frequency volume reduction, for instance in snore therapy. In this operating mode, the device operates automatically with the special AUTO STOP function. The AUTO START special function is not available with RaVoR™. AUTO STOP cannot be turned off.

5.6.8 Setting the output power



Set the output power for cutting and coagulation using the control dials on the front of the device.

Control dial (14) and output display (12) for the CUT operating modes (cutting): CUT 1, CUT 2, BICUT
Control dial (17) and output display (15) for the COAG operating modes (coagulation): COAG CONTACT, COAG SOFTSPRAY, COAG MACRO, COAG PRECISE, RaVoR™

The output setting can be adjusted up to a specified maximum value. For the maximum values of the various operating modes, see the technical information in [Chapter 9](#).

**NOTICE**

Always select the lowest output setting for the desired effect. On the other hand, note that setting the output too low can also constitute a risk, for instance because a first cut is not made due to excessively low output so that local coagulation results where it is not desirable or even dangerous.

6 Operation



WARNING

Activating the RF current is not permitted while inserting the electrode and during electrode replacement! Risk of burns! No activation of the footswitch or handle while inserting or changing the electrode.

For activation, turn on the RF current according to the previously selected operating mode by operating the switch on the handle or the foot switch. The RF current is produced according to the previously selected output setting. Activation is accompanied by a continuous tone and the CUT (13) or COAG (16) indicator ring corresponding to the current type lights up.



WARNING

The rules for electrosurgery application in [Chapter 7](#) for patients and users generally have to be observed. In particular, ensure safe application of the neutral electrode and proper positioning of the patient! Only use accessories in flawless condition! The surface of the device may get very hot during the extended application of RF current.

6.1 Special functions

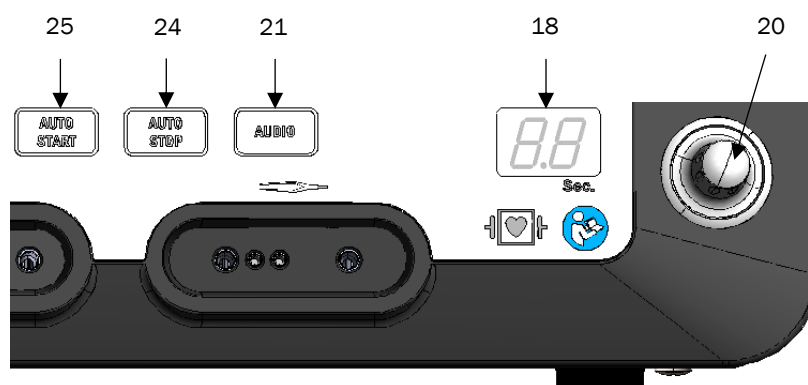
The device is equipped with the following special functions.



The AutoRF™ function monitors and controls the power output of the device depending on the state of the tissue.



p3™ works with various coagulation modes of the CURIS® II. Here the radiofrequency energy is emitted in approximately 50 packets per second. The short breaks make the treatment gentler on the tissue.



AUTO START (25)

This special function is only available in the COAG MACRO and COAG PRECISE bipolar coagulation operating modes. The RF current is turned on and off automatically on contact with tissue. It is turned on with a delay that can be adjusted from 0.0 to 5.0 seconds using the rotary knob (20).



WARNING

Unintentional RF activation may occur with the CURIS® II when using the AUTO START function. Be sure to prevent accidental contact of the bipolar instrument being used with tissue or contact with low impedance, electrically conductive components!

Switching on can also be triggered by contact with metal components (such as trocars, wound retractors, and the two electric poles themselves) or similar low impedance materials (such as liquids). Unintentional RF activation may also occur with tissue contact when bipolar accessories are set down on the patient or during perioperative instrument cleaning.

If one switches to a monopolar operating mode during treatment (also in case of accidental monopolar activation) and an electrical contact is detected between the two bipolar conductors, the AUTO START button flashes after ending the monopolar application and the function is not active. To prevent unintentional activation, the function has to be confirmed by pressing the AUTO START button again.

The bipolar cutting current BICUT cannot be selected when the AUTO START function is selected.

For exclusive bipolar application, nevertheless selecting a bipolar cutting setting is recommended in order to prevent unintentional monopolar activation. When a bipolar coagulation and a cutting operating mode are selected simultaneously, no bipolar cutting current can be produced with selection of the AUTO START function (a selection button for the cutting currents is not provided, and a warning tone sounds when CUT operating modes are activated).

AUTO STOP (24)

This special function is only available in the coagulation operating modes COAG MACRO, COAG PRECISE, and RaVoR™, and is activated automatically when the RaVoR™ operating mode is selected. After automatic bipolar coagulation begins, the tissue dries out more in the primary coagulation phase. This further drying leads to increased electric tissue resistance and therefore automatic deactivation of the generator.

Without the special AUTO START function, the electrode can also be activated using the instrument switch or foot switch.

AUDIO (21)

This special function is only available in the bipolar coagulation operating modes. During cutting and coagulation, the device produces a tone with a pitch that indicates the electric tissue resistance. The pitch of the message tone rises with the resistance as the tissue dries out more.

6.2 Program memory

The device has four program memory slots on the push-buttons P1 ... P4 (3). They are used to store the respective current device settings.

Procedure:

1. Configure the desired device settings (operating mode, output, special function).
2. Press one of the push-buttons P1 ... P4 (3) until the confirmation signal sounds.

Now the current device settings are stored in the selected program memory slot and the white indicator lamp below the program memory button lights up. The device operates with those settings effective immediately. This process can be repeated for the other program memory slots.

To activate the saved settings, briefly press the corresponding program memory button. The white indicator lamp below the button shows that the saved settings are active. If the special AUTO START function was also saved, the AUTO START push-button (25) flashes after loading the saved settings but the function is not active. This function is only active after pressing the AUTO START push-button (25). This step protects against unintentional activation.



NOTICE

A manually selected output setting in the bipolar cutting operating mode BICUT cannot be saved for safety reasons! In this case the output setting “0” is always stored in the program. To work with BICUT, the output first has to be set again using the rotary knob (14).

The white indicator lamp turns off as soon as the device settings are changed. Pressing one of the program memory buttons again until the confirmation tone sounds overwrites the settings stored in this program slot with the new settings.

When bipolar accessories are used with automatic instrument recognition, the function of the program memory buttons is limited (see [Chapter 5.6.4](#)). When using encoded bipolar accessories, settings on the device that have been changed by the user compared to the default settings (to the extent this is possible) cannot be saved.

The program used last is always active after turning on the device.



NOTICE

Only delete user programs after consulting the owner of the RF surgery device!

6.3 Functional test

Before using the device, check all device functions and perform the following functional tests:

1. Pull the plug of the connection cable for the neutral electrode out of the connection socket (27). The neutral electrode indicator (28) flashes red. When attempting to activate a monopolar RF current, an intermittent acoustic warning signal sounds instead of the continuous activation tone. RF current activation is blocked. Bipolar current on the other hand can be activated if selected; the neutral electrode indicator is off in this case.
2. Connect the plug of the connection cable for the neutral electrode to the connection socket (27) again. If a monopolar operating mode is selected, the neutral electrode indicator (28) now lights up green. If a segmented neutral electrode is used, it must be correctly applied to the patient for the alarm to turn off.
3. Connect the connection cable with the monopolar electrode handle to the socket (22). Activate the chosen current with the finger switch on the electrode handle or the foot switch. The

indicator rings for CUT (13) and COAG (16) have to light up according to the current type that is selected and the RF activation signal has to sound.



WARNING

If the RF activation signal sounds without the foot switch or electrode handle connected, the device is defective. Do not operate the device! A technical inspection is required.

If the RF activation signal sounds with the foot switch or electrode handle connected **without** activating one of the control elements, one of these accessories is defective. Continuing to operate this accessory is not permitted! It must be replaced.

7 Safety measures

7.1 General information

RF devices are high-frequency generators that generate high voltages and currents for their intended application. To avoid danger for the patient, operating personnel, or third parties, the device must always be used carefully and strict compliance with the operating and safety instructions is required!

Ensure that disinfectants are fully removed or evaporated before using the device.

Maintain a medical device record according to the operator ordinance.

A defect in an RF device can cause an unwanted increase in the output power. In order to prevent this, a protective circuit against overdosing is integrated into the CURIS® II.

Serious incidents that occur in relation to the product must be reported to the manufacturer and the responsible public authority in the member state in which the user and/or patient resides.

7.2 Patient positioning

For monopolar applications, the electric current supplied to the patient by the RF device via the active electrode can return to the device in two ways to close the electric circuit. The regular path leads through the neutral electrode, which conducts the current from the patient to the device over a large area and therefore without the heating effect that occurs on the active electrode. The second path is an unwanted bypass that can form when the patient is in contact with conductive components that are connected to ground potential. These are all large-scale metal components such as the frames of treatment tables, operating tables, chairs with metal frames, and the housings of electrical equipment supplied by the mains network. The patient must not have any contact with grounded metal components, otherwise there is a risk of point burns at the contact points. Especially the patient's limbs should not be in contact with metal fixtures.

If the patient is lying on an operating table or treatment table with a metal frame, high-frequency insulation to the metallic surface must be ensured by a sufficient number of pads (drapes). If moisture, perspiration, and the like is expected during the operation, prevent wetting of the pads serving as high-frequency insulation with waterproof film where applicable.

The accumulation of fluids under the patient must be prevented under all circumstances. Additional dry cloth layers must be used as needed.

The RF current flowing through the body must reach the neutral electrode along the shortest possible path. Ensure that the current does not leave the body and re-enter it in a different place on the way to the neutral electrode, for example, in case of contact between the hand and thigh or elbow and torso. This current bypass causes a risk of burns at such contact points. Therefore, areas with high levels of perspiration, limbs in contact with the trunk, or skin to skin contact must be kept dry with layers of drapes (arm/torso, leg/leg, mammae).

Ensure that the aforementioned insulation requirements are also met when the patient is shifted to a different position during the operation!

7.3 Application of the neutral electrode and high-frequency current



Attach electrodes and cables carefully. Here the following must be observed in particular:

- The neutral electrode has to be applied as close as possible to the surgical area, reliably, and with its entire surface in contact with the patient's body.
- Secure contact of the neutral electrode must be ensured for the entire RF application duration. The circulation must not be impaired by the application of the neutral electrode to limbs.
- When using disposable neutral electrodes, ensure that the expiry date has not passed.
- The supply cables to the RF electrodes must be routed without loops so that they touch neither the patient nor other cables. This applies for the neutral electrode in particular. Only use the cables intended for the device by the manufacturer.
- The supply lines and the instruments used are designed for the RF voltages of the CURIS® II and these must not be exceeded (see the voltage diagrams in [Chapter 9.3.2](#)).
- The current paths in the body are as short as possible and run lengthwise or diagonal to the body, not crosswise, the latter under no circumstances on the thorax. Any metal components in and on the body must be removed if possible, insulated, or require special attention.
- To ensure continuous application during the entire duration of the operation, we recommend a split single-use neutral electrode. Continuous monitoring of the patient is only ensured with a split neutral electrode.



Monitoring is not possible with a one-piece neutral electrode. **No warning signal** is triggered in case of poor contact!



Applying the neutral electrode to implants and other metal components, or to bony protrusions and scar tissue, is not permitted. The application site may have to be prepared by cleaning and degreasing, and the removal of heavy hair growth. Substances that dry out the skin (such as alcohol) may not be used for removal.



Do not pull on the cable or connecting lug to remove the neutral electrode. Pulling the adhesive surface off quickly can injure the skin.

7.4 Pacemakers, active and passive implants



For patients with metallic implants, RF current paths generally may not pass through these implants. This must be taken into account for the application of the active and neutral electrode. Applying the neutral electrode over endoprostheses is prohibited. Never apply the neutral electrode over metallic implants.



Patients with active implants such as pacemakers or implanted electrodes may be endangered by the application of the RF device. Irreparable damage to the active implant or an impairment of its function are possible effects. Because of these uncertainties, radio frequency should only be used on such patients when there is no equivalent alternative. The guidelines that follow must be observed.

The implant manufacturer's instructions for use have to be observed.

Monitoring such patients with suitable monitoring devices is recommended. Keep a defibrillator and external pacemaker ready for use. Always choose the lowest possible output power setting for the RF device. Do not apply the active electrode of the RF device closer than **15 cm** to the active implant or its electrodes. Carefully follow the instructions for use, such as the application of the neutral electrode!



NOTICE

Use bipolar technology if possible.

7.5 Setting down RF instruments



Do not set down any electrosurgery instruments on the patient during application pauses.

7.6 Risks due to electromagnetic interference



WARNING

The intended use of electrosurgery devices that generate a high-frequency current, such as the CURIS® II, may interfere with other electromedical equipment (such as ECG monitors) and electronic equipment (such as telephones or PCs) during the activation of the HF current.



WARNING

Radio equipment, mobile telephones, or other transmitters operated in the immediate vicinity of the RF generator may impair its safe functioning.

See [Chapter 9.4](#) for the minimum distances from transmitters.

Take the following steps to reduce this interference:

- Connect the mains cable of the CURIS® II to a different outlet.
- Increase the distance between the CURIS® II and the other device (not directly adjacent to each other or stacked).
- If devices are operated next to each other or stacked with the CURIS® II, the functioning of both devices must be monitored.
- Route instrument cables so that they are not close to other devices and their connection cables, to the extent possible.
- Ensure the potential equalization pin (44) is connected to a proper ground.
- Route connection cables so that they are not close to other devices if possible.

7.7 Accessories

Sutter Medizintechnik recommends the following tested accessories:

- Bipolar cable (REF 37 01 54L/R/G/A/S/P)
- Monopolar cable with 4 mm instrument plug (REF 36 01 87)
- Monopolar electrode handle with finger switch for coagulation and cutting (REF 36 07 04)
- Monopolar electrode handle without finger switch (REF 36 02 14)
- Connection cable for disposable neutral electrodes (REF 36 02 37)
- 1-pedal footswitch (REF 36 01 07, see [Chapter 12](#)).
- 1-pedal footswitch with push-button (REF 36 01 08, see [Chapter 12](#))
- 2-pedal footswitch (REF 36 01 14/REF 36 01 10, see [Chapter 12](#)).
- 2-pedal footswitch with push-button (REF 36 01 12, see [Chapter 12](#))
- Disposable neutral electrode, segmented, for adults and children (REF 29 00 - 5)

Product availability depends on regulations in various markets and may vary as a result.



The device may only be used with accessories, wear parts, and disposable products for which safe, unproblematic use is confirmed.

Using untested accessories from other manufacturers may lead to electromagnetic interference emissions or reduced electromagnetic interference resistance of the device and to faulty operation.

If you use accessories from other manufacturers, it is therefore particularly important to ensure that the accessories are in fact suitable. Indicators of legitimate manufacturers and suitable accessories include the following points:

- The manufacturer has a declaration of conformity for the accessory.
- The manufacturer has proof of compatibility for the accessory, or is willing to confirm this for you.
- The accessory includes instructions for use that clearly describe the scope of functionality in easily comprehensible terms.
- The accessory has suitable plug connections that can be connected to the device without excessive force and problems.
- The manufacturer is willing to confirm testing of the accessory according to the international IEC 60601-2-2 standard on request.
- The accessory products are labeled, clearly legible, e.g. with information about the manufacturer and their maximum dielectric strength.
- The manufacturer provides you with additional technical data and specifications on request, and is available for your inquiries during regular business hours.

Please consult your specialist dealer or the manufacturer in case of doubt.



The length of active accessories is not permitted to exceed certain limit values for electromagnetic compatibility (EMC) reasons. If the accessory is too long, it can act like an antenna and therefore cause electromagnetic interference. The length of the active accessory comprises the entire line path – from the connector through the cable to the tip of the electrode.

- For bipolar accessories, the maximum permissible length is 3.3 meters.
- For monopolar accessories, the maximum permissible length is 3.4 meters.



Avoid settings on the device where the maximum output voltage exceeds the rated voltage for the accessory (see the voltage diagrams in [Chapter 9.3.2](#)).



If components form a system together with the CURIS® II, these have to meet the requirements of the respective medical environment. IEC/EN 60601-1 (3rd edition, section 16) in particular must be taken into account. Contact the manufacturers of the components or equipment in case of doubt.

7.8 Operation with bipolar cutting forms

For microsurgery applications in particular, the unintentional activation of a bipolar cutting current (for instance by mixing up the foot switch pedals) may create a hazard for the patient. Therefore, the output setting is always set to “0” initially when the bipolar cutting mode BICUT is selected manually. Even when the generator was last operated in bipolar cutting mode, the output is automatically set to “0” again after the device is switched on. Then the desired output setting has to be chosen with the rotary knob (14). An output setting > 0 in the bipolar cutting mode BICUT cannot be stored in a program, but is automatically set to “0” in the program.



NOTICE

For safety reasons, leaving the output setting for the bipolar cutting mode BICUT at “0” is recommended if using this operating mode is not intended.

7.9 Risks due to high electric voltage

The application of a current type with a high voltage, in particular a monopolar high-voltage coagulation current type, can cause neuromuscular stimulation on the patient.

8 Care instructions

8.1 Cleaning and disinfection

For cleaning and disinfection, turn the device off, disconnect it from the mains network, and remove connected components and accessories. Liquids must not be allowed to get into the interior of the device when applying or spraying cleaning agents and disinfectants.

Clean all exterior surfaces of the device, including the front plate, with conventional cleaning agents that do not contain alcohol.

Disinfect the surfaces of the device and accessories that cannot be sterilized using disinfectants commonly used in medical practices and surgery departments.

Ensure that cleaning agents and disinfectants are fully removed or evaporated before using the device.

Visual inspection: The sockets of all connections and the plugs of the connecting cables must not be soiled in any way.



NOTICE

Always keep accessories for RF devices in flawless functional condition. Non-functional, damaged or defective accessories may pose a hazard for the patient or the user, and can impair the proper functioning of the RF device. Accessories that are not suitable for use must be separated!

8.2 Sterilization of accessories



Be sure to observe the information provided with accessories for their care and reconditioning.

8.3 Accessories that cannot be sterilized



NOTICE

Accessories that cannot be sterilized require regular disinfection by wiping (see [Chapter 8.1](#); for disinfection of the footswitch, see [Chapter 12](#)).



NOTICE

The instructions for use of the CURIS® II do not replace the instructions for use of the accessories.



9 Technical information

9.1 Technical data, standards, certification

Mains connection	100-240 V; 50/60 Hz
Power consumption	Without RF output Approx. 50 VA
	At max. output power Approx. 500 VA
Protection class	I
Protection level	IP20
Classification according to Regulation (EU) 2017/745	II b
LF and RF leakage currents	according to IEC 60601-2-2
Type	CF; defibrillator safe

RF output parameters:

MONOPOLAR current type	Output	On load resistor	Max. HF output current	Nominal frequency	Modulation frequency
CUT 1	max. 120 W	± 20 % on 700 Ω	1.10 A	4.00 MHz	-
CUT 2	max. 90 W	± 20 % on 700 Ω	1.10 A	4.00 MHz	31.25 kHz
COAG CONTACT	max. 90 W	± 20 % on 500 Ω	1.20 A	4.00 MHz	31.25 kHz
COAG SOFTSPRAY	max. 70 W	± 20 % on 700 Ω	0.90 A	4.00 MHz	31.25 kHz

Current type BIPOLAR

BICUT	max. 80 W	± 20 % on 300 Ω	1.20 A	4.00 MHz	31.25 kHz
COAG MACRO	max. 80 W	± 20 % on 60 Ω	2.20 A	4.00 MHz	-
COAG PRECISE	max. 50 W	± 20 % on 60 Ω	1.70 A	4.00 MHz	31.25 kHz
RaVoR™	max. 40 W	± 20 % on 60 Ω	1.60 A	4.00 MHz	31.25 kHz

Operating mode Intermittent INT 10 s / 30 s corresp. 25% ED

Mains fuse 2 x T 3.15 AH 250 V G 5x20 mm

Signal level RF indicator: 40-65 dB(A) adjustable
Alarm: 65 dB(A)

Weight Approx. 5.0 kg

Dimensions W x H x D 313 mm x 166 mm x 408 mm

Standards IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012 + A2:2020
IEC 60601-1-2:2014+A1:2020
IEC 60601-2-2:2017+A1:2023
IEC 60601-1-6:2010+A1:2013+A2:2020

Compliant with Regulation (EU) 2017/745

Environmental conditions for transportation and storage

Ambient temperature -25 °C to +70 °C
Relative humidity 10 % to 90 %
Atmospheric pressure 500 hPa to 1060 hPa

Environmental conditions for operation

Ambient temperature +10 °C to +40 °C
Relative humidity 30 % to 75 %
Atmospheric pressure 700 hPa to 1060 hPa

9.2 Recurring safety-related inspections

The following inspections should be carried out on this device at least every 24 months according to the requirements of IEC 62353. They must be carried out by Sutter or persons/organizations authorized by Sutter that, based on their education, knowledge, and practical experience, are able to perform such safety-related inspections properly and who are not subject to any directives with regard to this inspection activity.



NOTICE

No maintenance tasks may be carried out on the CURIS® II while it is in use.

The following safety-related inspections have been established:

1. Legibility of the type plate and labeling
2. Verification of the valid instructions for use
3. Checking the software version
4. Checking the self-test
5. Verifying the functionality of the control elements on the front
6. Visual inspection of all connections on the device
7. Inspection of reusable accessories (optional)
8. Verifying the functionality of the rotary encoders
9. Verifying the functionality of activation, the activation lamps and the activation tone
10. Verifying the functionality of the two-pedal foot switch
11. Verifying the functionality of neutral electrode monitoring
12. Verifying the functionality of the special function buttons
13. Verifying the functionality of instrument encoding
14. Checking the RF output power settings and RF leakage currents
15. Safety-related inspection according to IEC 60601-1:
 - Protective conductor resistance
 - Grounding current, normal case and first error
 - Housing leakage current normal case, first error protective conductor, first error mains network
 - Patient leakage current normal case, first error protective conductor, first error voltage on application part

Please contact the manufacturer or your specialist dealer for further information.



NOTICE

When measuring output in the megahertz range, parasitic effects have a much greater effect compared to conventional HF devices that work in the range of 300-500 kHz. Therefore the output measuring device that is used must be suitable for 4 MHz even under load (that means the specified limiting frequency has to be significantly higher). Both connections of the output measuring device have to be potential free.



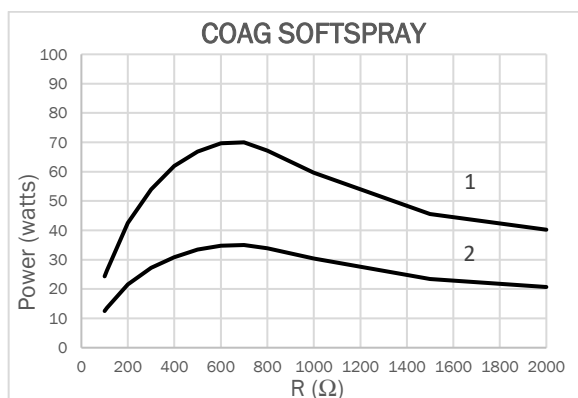
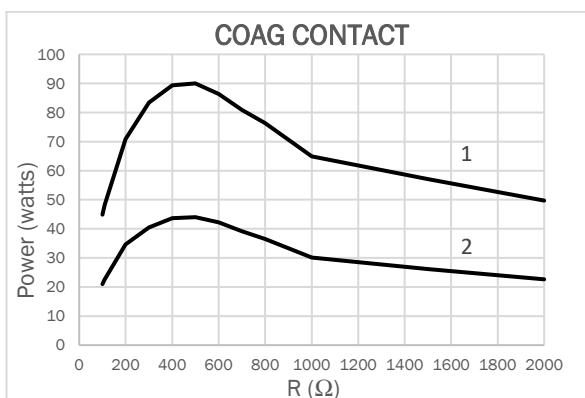
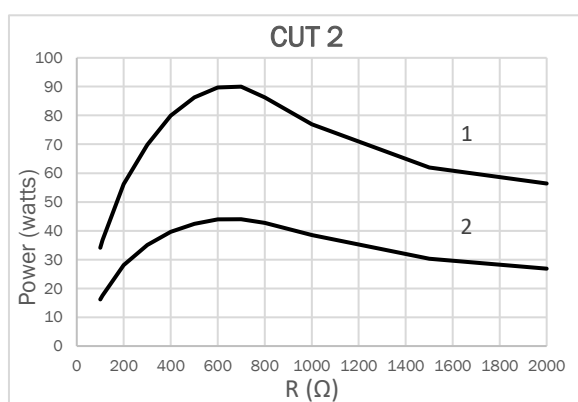
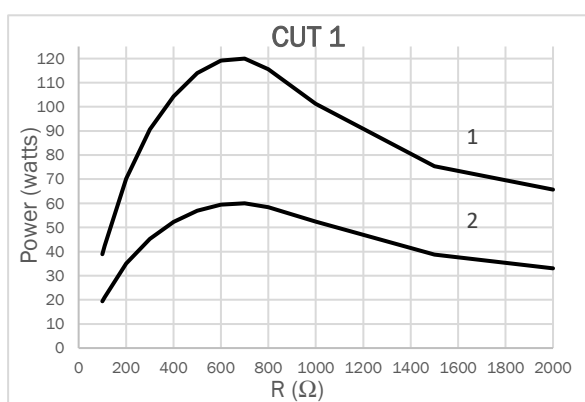
NOTICE

The product may only be repaired by the manufacturer or an agent expressly authorized by the manufacturer. Otherwise the warranty and any possible additional liability claims against the manufacturer are voided.

9.3 Diagrams

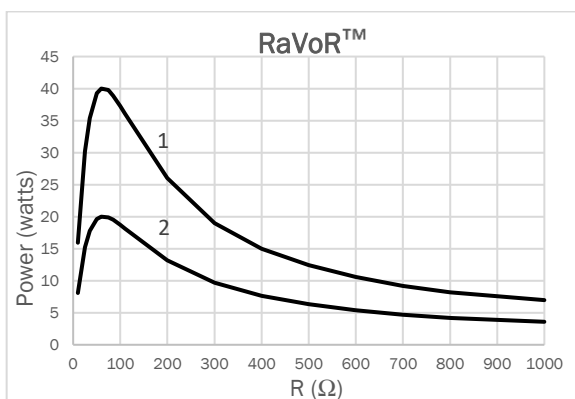
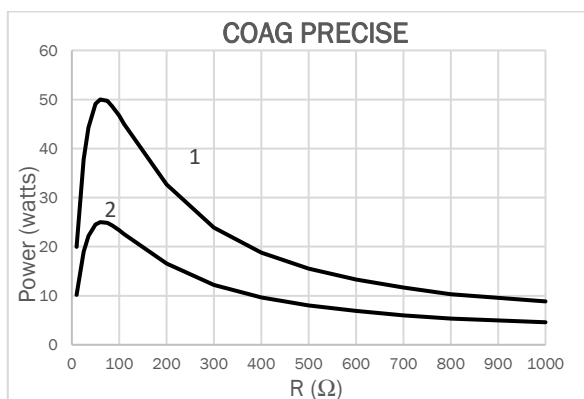
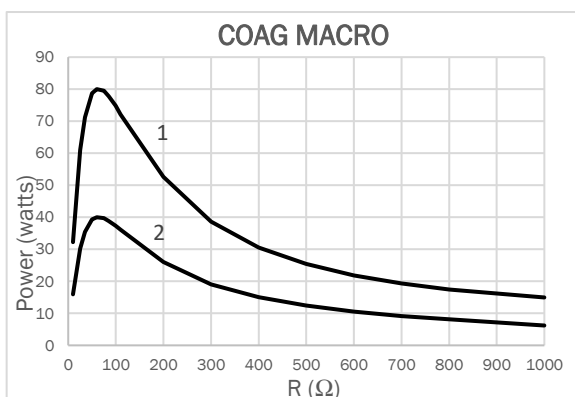
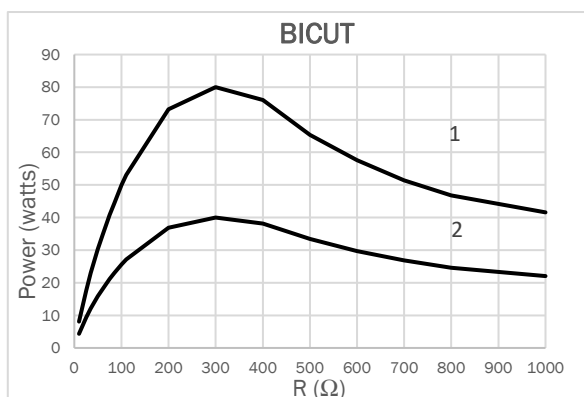
9.3.1 RF output

MONOPOLAR



Curve	Output setting
1	Maximum output (100%)
2	Half output (50%)

BIPOLAR

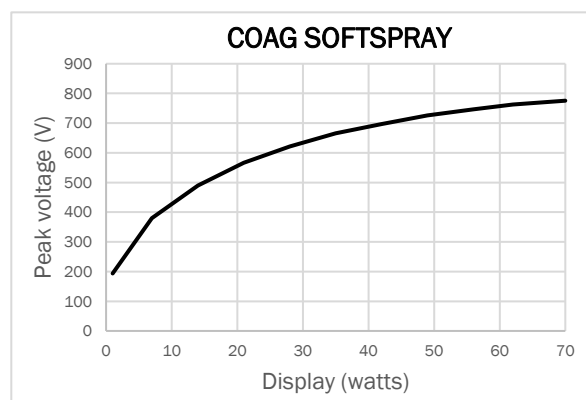
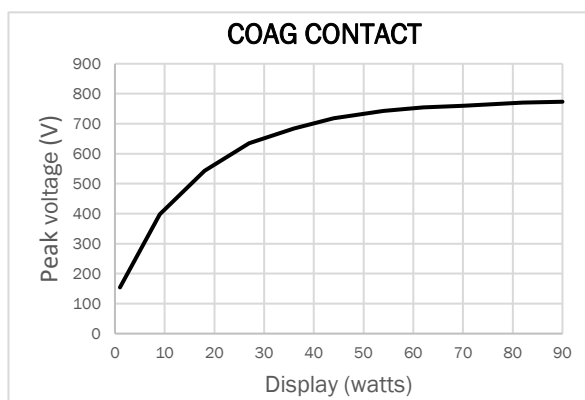
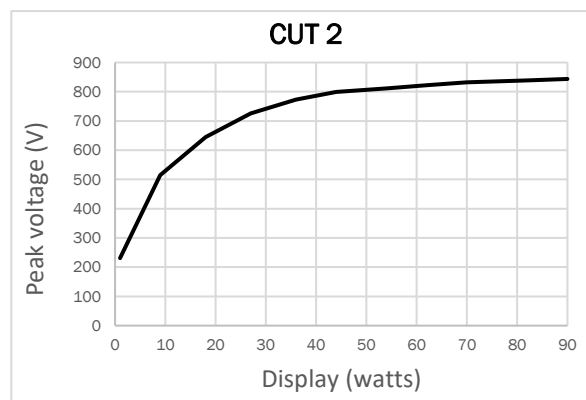
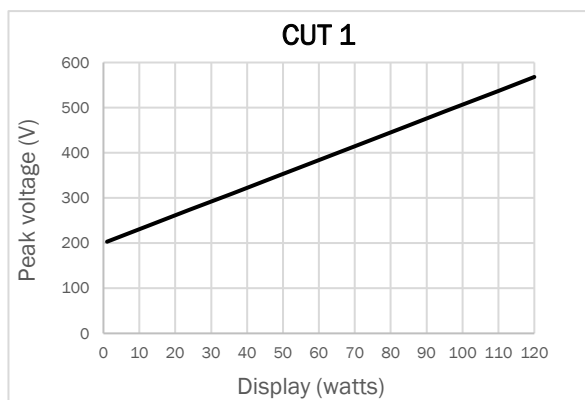


Curve	Output setting
1	Maximum output (100%)
2	Half output (50%)

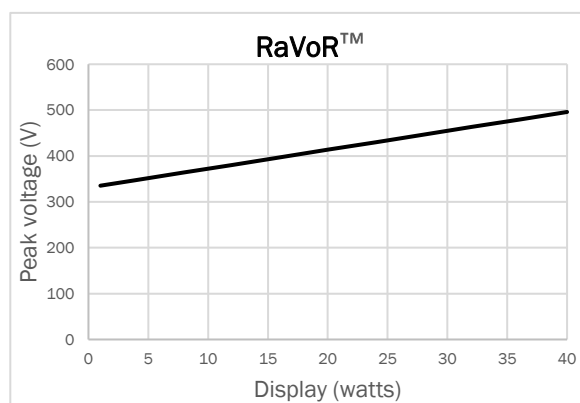
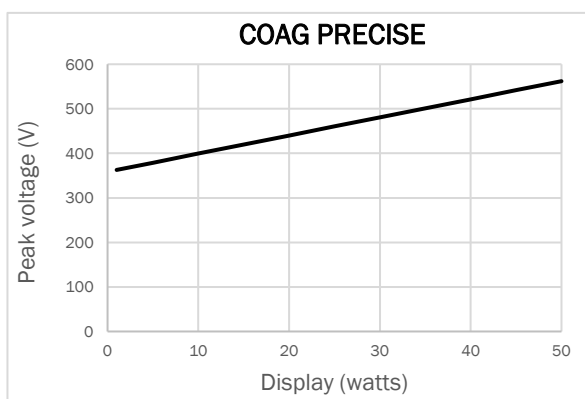
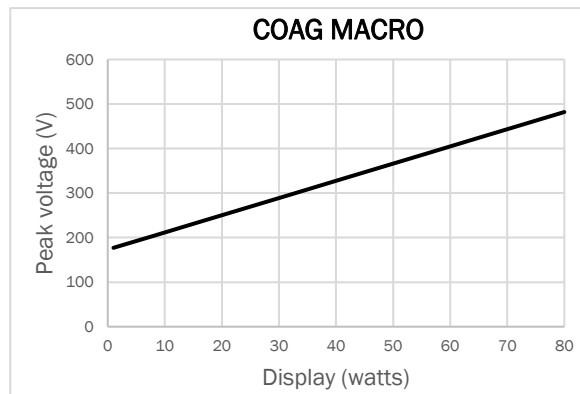
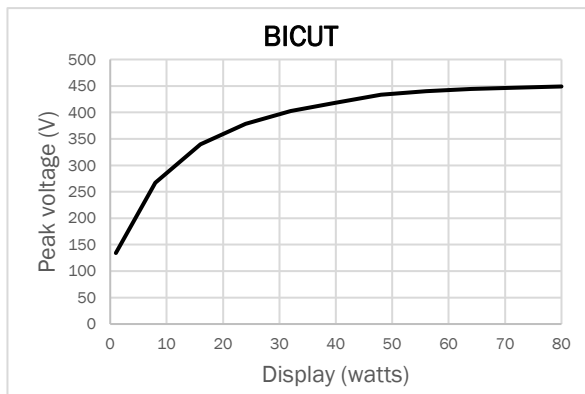


9.3.2 RF voltage

MONOPOLAR

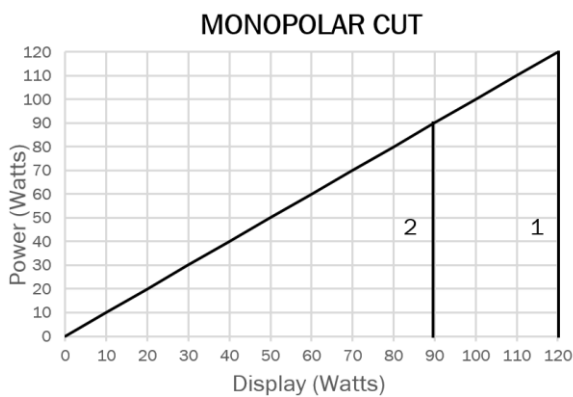


BIPOLAR

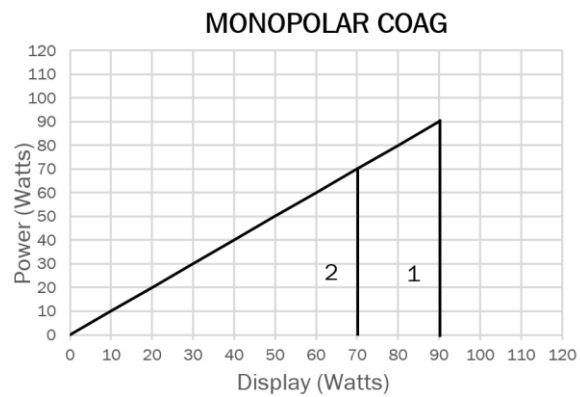




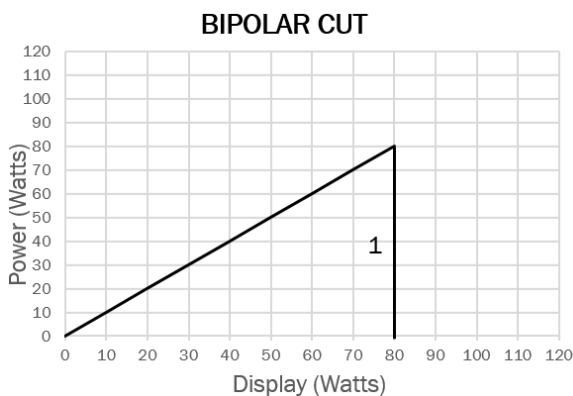
9.3.3 Control characteristic curve



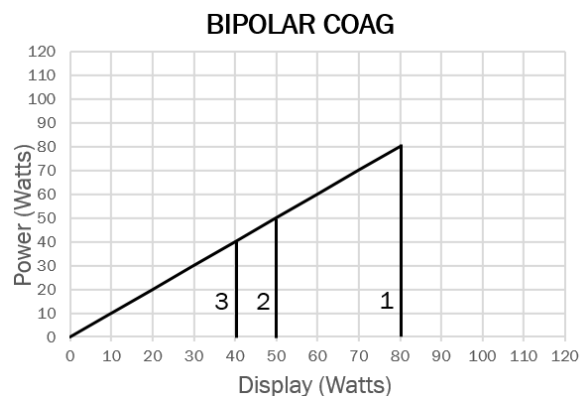
1 = CUT 1 on 700 Ω
2 = CUT 2 on 700 Ω



1 = COAG CONTACT on 500 Ω
2 = COAG SOFTSPRAY on 700 Ω



1 = BICUT on 300 Ω



1 = COAG MACRO on 60 Ω
2 = COAG PRECISE on 60 Ω
3 = RaVoR™ on 60 Ω

9.4 Guidelines and manufacturer declaration for electromagnetic compatibility

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014+A1:2020, Section 7: Electromagnetic emissions		
The CURIS® II is intended for operation in an electromagnetic environment as specified below. The customer or user of the CURIS® II must ensure that it is operated in such an environment.		
Emitted interference tests	Compliance level	Electromagnetic environment – guidelines
HF emissions according to CISPR 11	Group 2	The CURIS® II has to emit electromagnetic energy for its intended function. Interference with devices in the vicinity is possible.
HF emissions according to CISPR 11	Class A	Compliance with the class only in operational readiness without the activation of RF current! The CURIS® II is intended for use in non-residential facilities and facilities connected directly to a public low voltage system that also supplies residential buildings.
Emission of harmonics according to IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	



NOTICE

The emission characteristics of the CURIS® II make the device suitable for use in industrial environments and hospitals (CISPR 11 class A). When used in residential areas (where class B is generally required according to CISPR 11), the CURIS® II may not provide adequate protection against radio services. The user may have to implement corrective measures such as relocating or repositioning the device.



NOTICE

This device is intended exclusively for use by qualified medical personnel.

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014+A1:2020, Section 8.9: Interference resistance test level

The CURIS® II is intended for operation in the electromagnetic environment specified below. The customer or user of the CURIS® II must ensure that it is operated in such an environment.

Interference resistance tests	Test level according to IEC 60601	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or concrete, or surfaced in ceramic tiles. If synthetic floor coverings are installed, the relative humidity must be at least 30%.
Fast transient electrical interference/bursts according to IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a normal commercial or hospital environment.
Impulse voltage/surges according to IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	±1 kV differential mode voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a normal commercial or hospital environment.
Voltage drops, brief disruptions, and fluctuations in the supply voltage according to IEC 61000-4-11	0% U_T (100% drop of U_T) for ½ period at 0, 45, 90, 135, 180, 225, 270, 315 degrees 0% U_T (100% drop of U_T) for 1 period 70 % U_T (30% drop of U_T) for 25/30 periods, single phase at 0 degrees 0% U_T (100% drop of U_T) for 250/300 periods	0% U_T (100% drop of U_T) for ½ period at 0, 45, 90, 135, 180, 225, 270, 315 degrees 0% U_T (100% drop of U_T) for 1 period 70 % U_T (30% drop of U_T) for 25/30 periods, single phase at 0 degrees 0% U_T (100% drop of U_T) for 250/300 periods	The quality of the supply voltage should correspond to a normal commercial or hospital environment. If the user of the CURIS® II requires continuous functioning even in case of energy supply interruptions, supplying the CURIS® II from an uninterruptible power supply is recommended.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the mains frequency should correspond to the typical values found in commercial or hospital environments.
Close range magnetic field according to IEC 61000-4-39	8 A/m 65 A/m 7.5 A/m	8 A/m 65 A/m 7.5 A/m	Close range magnetic fields should correspond to the typical values found in commercial or hospital environments.

NOTE: U_T is the AC mains voltage prior to application of the test levels.

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014+A1:2020, Section 8.9: Electromagnetic interference resistance

The CURIS® II is intended for operation in the electromagnetic environment specified below. The customer or user of the CURIS® II must ensure that it is operated in such an environment. Radio equipment, mobile telephones or other transmitters operated in the immediate vicinity may impair the functioning of the device.

Interference resistance tests	Test level according to IEC 60601	Compliance level	Electromagnetic environment – guidelines
Conducted HF interference according to IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz 6 V _{eff} ^a in ISM frequency ranges from 150 kHz to 80 MHz	3 V _{eff} 150 kHz to 80 MHz 6 V _{eff} ^a in ISM frequency ranges from 150 kHz to 80 MHz	Portable and mobile radio devices should not be used closer to the CURIS® II (including cables) than the recommended separation distance of 30 cm . The field strength of stationary radio transmitters for all frequencies should be lower than the compliance level according to on-site testing. ^b
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Interference is possible in the vicinity of devices that carry the following graphic symbols. 

NOTE These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz

^b The field strength of stationary transmitters such as base stations of mobile telephones and mobile radio devices, amateur radios, AM and FM radio and TV transmitters cannot be theoretically determined exactly in advance. In order to determine the electromagnetic environment in regards to the stationary transmitters, a site survey should be considered. If the measured field strength at the location where the CURIS® II is used exceeds the aforementioned compliance level, the device should be monitored to ensure it is functioning properly. Should unusual performance characteristics be observed, additional measures may be required, such as changing the alignment or location of the CURIS® II.

Recommended separation distances between portable and mobile HF telecommunications devices and the CURIS® II according to IEC 60601-1-2:2014+A1:2020, Section 8.10				
Specification for high-frequency wireless communication equipment				
Frequency band (MHz)	Test frequency (MHz)	Modulation	Compliance level (V/m)	Distance (m)
380 - 390	385	Pulse modulation ^a 18 Hz	27	0.3
430 - 470	450	FM ^b ±5 kHz deviation or pulse modulation ^a 18 Hz	28	0.3
704 – 787	710, 745, 780	Pulse modulation ^a 217 Hz	9	0.3
800 – 960	810, 870, 930	Pulse modulation ^a 18 Hz	28	0.3
1700 – 1990	1720, 1845, 1970	Pulse modulation ^a 217 Hz	28	0.3
2400 - 2570	2450	Pulse modulation ^a 217 Hz	28	0.3
5100 - 5800	5240, 5500, 5785	Pulse modulation ^a 217 Hz	9	0.3
NOTE	The minimum safety distance of 30 cm between portable HF communication devices transmitting in the specified frequency band and the CURIS® II should be maintained. This includes cellular phones, WiFi, RFID, and Bluetooth devices among others. Failure to comply can impair the performance characteristics of the device.			
^a Pulse modulation	Pulse modulation is defined as a square wave signal with a pulse-duty factor of 50%.			
^b FM	Frequency modulation			

10 Environmental notices

10.1 Packaging

The entire packaging can be returned to the seller and is recycled as far as possible. Otherwise dispose of the packaging as waste paper and/or household garbage.

10.2 Environmentally friendly device operation

During the vaporization of tissue, the concentrated, longer-term inhalation of the burn-off that occurs during intended use should be avoided. Hazardous substances other than the aforementioned decomposition products do not develop during the intended use of the device.

A flue gas extraction system may be used for burn-off extraction.

For improved occupational safety and in the interest of energy conservation, we recommend turning off the device during longer treatment pauses.

If disposable products are used, these shall only be disposed of in household garbage or as hazardous waste after careful cleaning, disinfection and if applicable sterilization. Infected, sharp components of disposable instruments are treated like other “sharps” (cannulas, needles, and scalpels) according to the applicable directive (disposal in germ-proof and puncture-proof containers).

10.3 Device disposal

The use of composite materials was largely avoided in designing the device. This enables a high degree of recycling when the device reaches the end of its service life. The requirements of the electronic scrap directive must be met in the course of disposal, or the device has to be returned to the manufacturer/distributor for proper disposal.



Labeling of electrical and electronic equipment according to Directive 2012/19/EU on waste electrical and electronic equipment.

The symbol on the product or its packaging indicates that this product may not be disposed of as regular household garbage.

11 Error diagnosis

Defect	Possible cause	Error rectification
Elements on the front stay dark, device does not function	No mains voltage	Check the mains supply
	The mains cable on the outlet or device is not connected correctly or at all	Check the mains cable connection
	Device not switched on	Switch on the device
	Defective mains fuse	Device defect, service required
	Internal power supply defective	Device defect, service required
Elements on the front work normally, no RF output power	Defective accessory	Replace the accessory
	Defective device	Switching the unit off and on again. Notify Service of any error message that is displayed.
Auto-Start button is flashing	“Auto-Start” has to be acknowledged when loading a program	Press the Auto-Start button. No error.
	The button continues flashing after it is acknowledged.	Disconnect and check the connected accessory. Accessory is in contact with tissue or defective.
	Even though the accessory was removed, the button continues flashing.	Operating the CURIS® II can continue in the STANDARD operating mode, then contact Service.
Display of an error message such as Err 42	See listing below	See listing below

Error messages and their meaning

The CURIS® II RF generator conducts extensive functional tests during the power-on self-test.

All safety-related functions are also checked continuously during operation. In case of errors, the RF energy output is stopped and the error is indicated by an error message.



NOTICE

After an error message is displayed, the device can only be reset by turning it off and back on again.

The messages where resolution by the user is possible are listed below. All other error messages are listed in the service manual.



NOTICE

Contact the manufacturer or specialist dealer if an error message not described here is displayed.

Error no.	Meaning	Cause	Corrective action
Err 41, Err 42	During the power-up test, actuation of the yellow or blue finger switch of a hand piece connected to the monopolar output is recognized.	Activating a finger switch before the power-up test completes, defect in the hand piece or its connection cable, or device defect.	If not caused by actuation, disconnect the hand piece and turn the device off and back on again. If the error is still displayed, there is a device error.
Err 45, Err 46	During the power-up test, actuation of the yellow or blue finger switch of a hand piece connected to the bipolar output is recognized.	Activating a finger switch before the power-up test completes, defect in the hand piece or its connection cable, or device defect.	If not caused by actuation, disconnect the hand piece and turn the device off and back on again. If the error is still displayed, there is a device error.
Err 47, Err 48	During the power-up test, actuation of the yellow or blue pedal of the foot switch is recognized.	Activation of the foot switch before the power-up test was complete, short circuit in the foot switch or its connection cable, or device defect.	If not caused by actuation, disconnect the foot switch and turn the device off and back on again. If the error is still displayed, there is a device error.
Err 51	During the power-up test, actuation of a button on the operator panel is recognized.	Attempting to actuate a button before the power-up test completes, or operator panel defect.	If not caused by actuation, the operator panel of the CURIS® II is defective.
Err 52, Err 152, Err 53, Err 153, Err 55	Instrument recognition calibration error.	Internal hardware error.	Turn the device off and back on, and connect and disconnect the instrument. Contact the manufacturer/specialist dealer if the error remains.
Err 54, Err 154, Err 56	Instrument is not recognized.	Contacting error; internal hardware error.	Turn the device off and back on, and connect and disconnect the instrument. Contact the manufacturer/specialist dealer if the error remains.

Error no.	Meaning	Cause	Corrective action
Err 62, Err 162	An invalid instrument code is identified by the device.	Defective code resistance in the instrument, loose contact, connection and disconnection too fast, or connection of an unapproved coded instrument.	Check if the instrument is approved for the CURIS® II. Disconnect the instrument, turn the device off and on again, reconnect the instrument. Contact the manufacturer/specialist dealer if the error remains.
Err 89	Overheating of the RF output stage noted.	Continuous RF activation for an extended time outside the specification (10 s/30 s).	Turn off the device and let it cool down for a few minutes before turning it on again. If the error is still displayed, there is a device error.

12 Foot switch (accessory)

The following footswitches are offered for the CURIS® II:

REF 36 01 07 → 1-pedal footswitch without push-button, explosion-protected, 4 m cable

REF 36 01 08 → 1-pedal footswitch with push-button, explosion-protected, 4 m cable

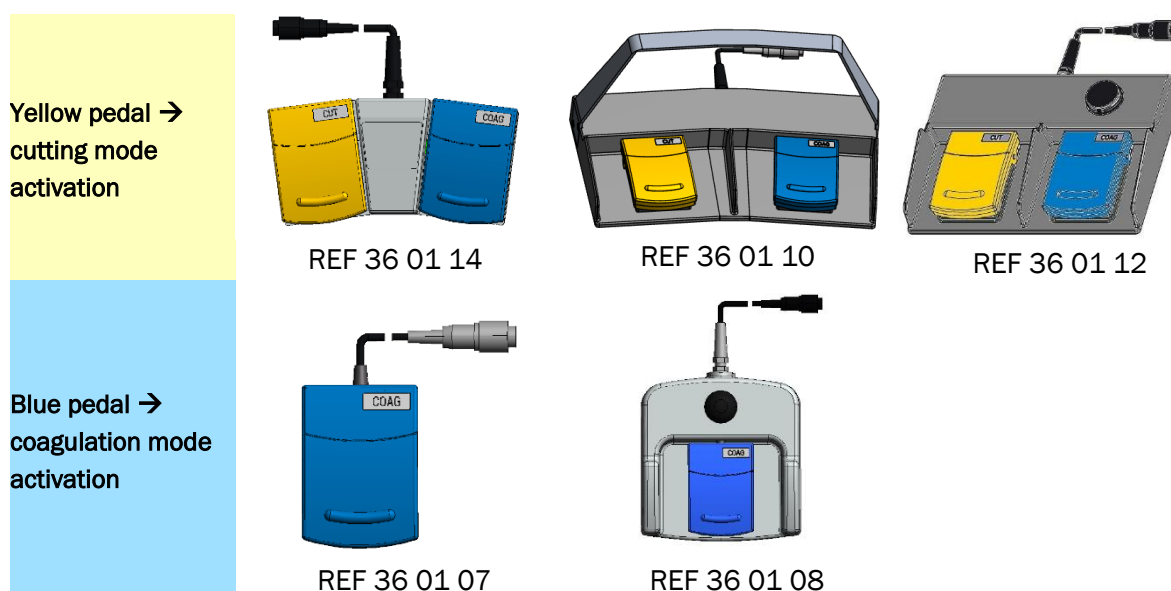
REF 36 01 14 → 2-pedal footswitch without push-button, explosion-protected, 4 m cable

REF 36 01 10 → 2-pedal footswitch without push-button (with holder), explosion-protected, 4 m cable

REF 36 01 12 → 2-pedal footswitch with push-button, explosion-protected, 4 m cable

Intended use

The foot switch serves as a triggering mechanism for the CURIS® II RF generator. It is used to turn the power output of the RF generator on and off.



Maintenance, cleaning, disinfection

When these instructions are followed, the foot switch requires minimal maintenance. Depending on the ambient conditions and frequency of use, regular maintenance and the inspection of the housing and connecting cables for damage and problematic dirt is recommended.

For exclusively manual cleaning, only use a cloth wetted with water and a mild cleaning agent. Never use cleaning agents that may attack the plastic surfaces, such as instrument cleaners, scouring cleaning agents, or cleaners containing solvents.



NOTICE

For safety reasons, always perform a functional test prior to surgical application. Always activate the pedals with the electrosurgery device turned on. To prevent unintentional burns, perform the functional test without electrode cables connected to the electrosurgery device.



Technical data

Standards: IEC 60601-1, IEC 60601-2-2, IEC 60529

Class: Class I according to Regulation (EU) 2017/745

Pedals made of break-proof, self-extinguishing thermoplastic material, housing made of cast aluminum or self-extinguishing thermoplastic material depending on the model

Connecting cable: permanently connected and sealed control cable

Protection class: IP X8 (1 m / 35 min) according to IEC 60529

Switching element: Reed contact

Switching voltage: max. 25 V AC / 60 V DC

Switching current: max. 1 A

Breaking capacity max. 20 VA

Mechanical service life: >1 million switching cycles

Approvals: AP compatible

Environmental conditions for transportation and storage	Ambient temperature	-25 °C to +70 °C
	Relative humidity	5 % to 100 %
	Atmospheric pressure	500 hPa to 1100 hPa
Environmental conditions for operation	Ambient temperature	-10 °C to +60 °C
	Relative humidity	10 % to 100 %
	Atmospheric pressure	800 hPa to 1060 hPa



Notes

[illegible]



Notes

[illegible]



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Changes reserved!

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