INSTRUCTIONS FOR USE

CURIS®

4 MHz Radiofrequency Generator

REF 36 01 00 – 01

These instructions for use apply for all devices according to chapter 5.1.

Table of contents

1 Explanation of symbols and abbreviations

	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
MD	Medical Device
	Non-ionizing radiation
	Observe the instructions for use, notice, warning
	Disposal instructions
Ω	Ohm
A	Ampere
AC	Alternating current
CF	Cardiac floating
dB	Decibel
DC	Direct current
Display	Indicator panel on the generator
Err	Error
F	Floating
hPa	Hectopascal
Hz	Hertz
kHz	Kilohertz
mA	Milliampere
MDD 93/42 (EEC)	EU Medical Device Directive
MHz	Megahertz
MPG	Medical Devices Act (Germany)
LF	Low frequency
P	Power
PE	Potential equalization
Peak	Peak
R	Resistance
RaVoR™	Radio frequency volume reduction
RF	Radio frequency
V	Volt
VA	Volt-ampere
Rx only	Sale restricted to attending physicians (USA)

(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.

NOTE

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.

After repositioning the patient, the electrodes and cables must be checked to verify they are correctly applied.

The use of ignitable anesthetics, nitrous oxide (N_2O), 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.

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 or plate-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 tweezers or forceps, 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®

The RF generator CURIS® has a maximum power output of approx. 100 watts and has been designed for monopolar and bipolar electrosurgical applications in ENT, plastic /cosmetic surgery, maxillo-facial surgery, dermatology and for use in doctors' offices. The use in other fields of surgery may be indicated.

CURIS® is intended for electrosurgical cutting and coagulation.

Excluded from its use are applications under liquids and applications requiring higher RF output than the maximum power (see chapter 9, Technical Information) for each mode.

The CURIS® may only be used by persons who have been trained in the proper and safe use of the device. The user manual should be noted in the instruction and application.

Safe use of electrosurgery requires the user to be familiar with the technology and the applications.

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

2.3 Contraindications and side effects

2.3.1 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 or forgoing the use of RF surgery may be necessary 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 section 7 have to be observed in addition.

2.3.2 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 section 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®, mains cable, instructions for use

3.1.2 Claims for compensation

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

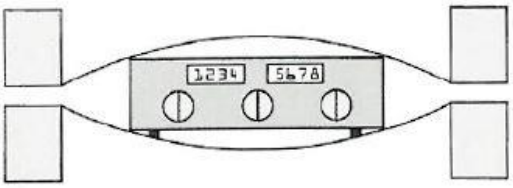
If possible, the original packaging must be used to return a device to Sutter or a Sutter service center. If this is not available, packaging that properly protects the device being returned is mandatory. In case of improper packaging, liability rests exclusively with the sender. The following accompanying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

NOTE

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.

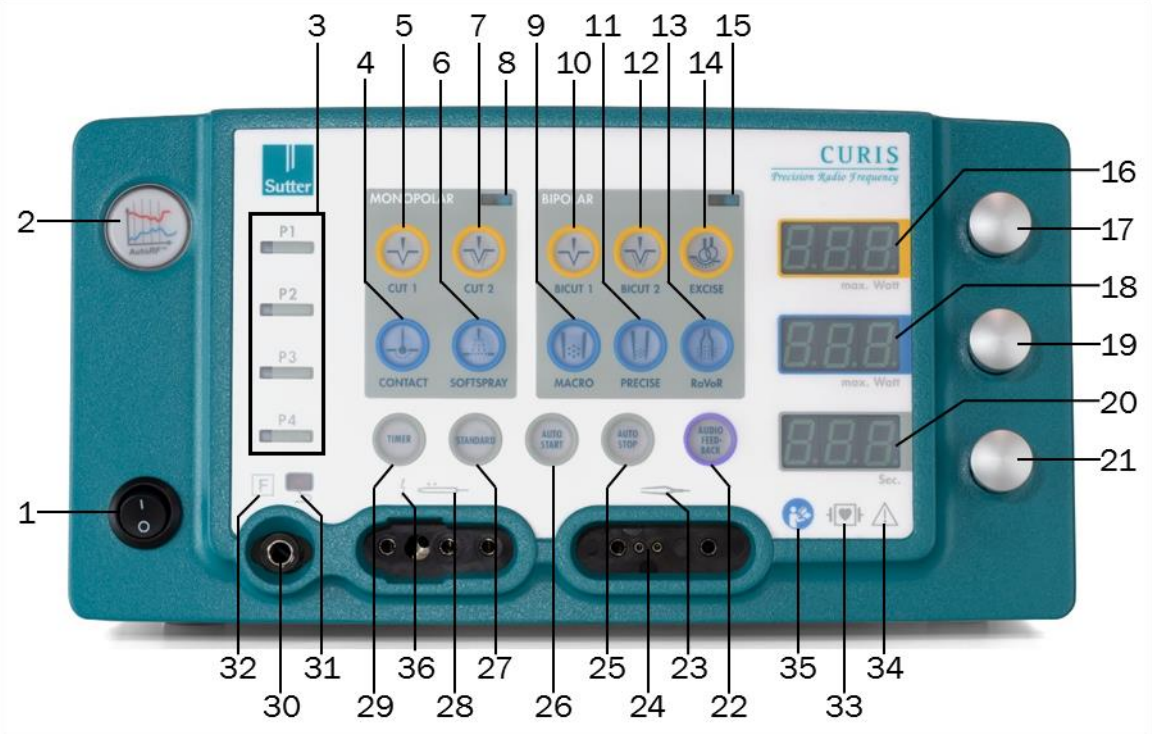
When returning or shipping an RF generator, please ensure that the membrane packaging is correctly inserted.



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 Mains switch

2 “Auto-RF control active” indicator

3 Program memory P1 ... P4 (to store device settings)

4 CONTACT selection button for monopolar contact coagulation

5 CUT 1 selection button for monopolar cutting

6 SOFTSPRAY selection button for contactless monopolar coagulation (spray coagulation)

7 CUT 2 selection button for monopolar cutting with coagulation

8 The indicator lamp lights up during RF output in the MONOPOLAR operating mode.

9 MACRO selection button for bipolar coagulation

10 BICUT 1 selection button for bipolar cutting

11 PRECISE selection button for bipolar coagulation with fine instruments

12 BICUT 2 selection button for bipolar cutting with coagulation

13 RaVoR™ selection button for bipolar RF volume reduction, for instance in snore therapy

14 EXCISE selection button for bipolar cutting with ring forceps

15 The indicator lamp lights up during RF output in the BIPOLAR operating mode.

16 Display of the RF cutting output setting
(operating modes CUT1, CUT2, BICUT1, BICUT2, EXCISE)

17 Rotary knob to select the RF cutting output
(operating modes CUT1, CUT2, BICUT1, BICUT2, EXCISE)

18 Display of the RF coagulation output setting

(operating modes CONTACT, SOFTSPRAY, MACRO, PRECISE, RaVoR™)

19 Rotary knob to set the RF coagulation output

20 Display of the TIMER time

21 Rotary knob to set the TIMER time

22 AUDIO FEEDBACK special function button
(only possible in bipolar coagulation operating modes)

23  Connection socket for bipolar instruments

24 2mm auxiliary contacts of the bipolar instrument jack

25 AUTO STOP special function button (only possible in bipolar coagulation operating modes)

26 AUTO START special function button (only possible in MACRO and PRECISE bipolar coagulation operating modes)

27 STANDARD special function button for working without automatic START, STOP, or TIMER functions

28  Connection socket for monopolar instruments

29 TIMER special function button to set the instrument on time
(only possible in the CONTACT, SOFTSPRAY, MACRO, and PRECISE coagulation operating modes)

30 Connection socket for the neutral electrode

31  "Neutral electrode not connected" indicator (red flashing lamp).

32  Notification symbol "neutral electrode insulated from ground" (F = floating)

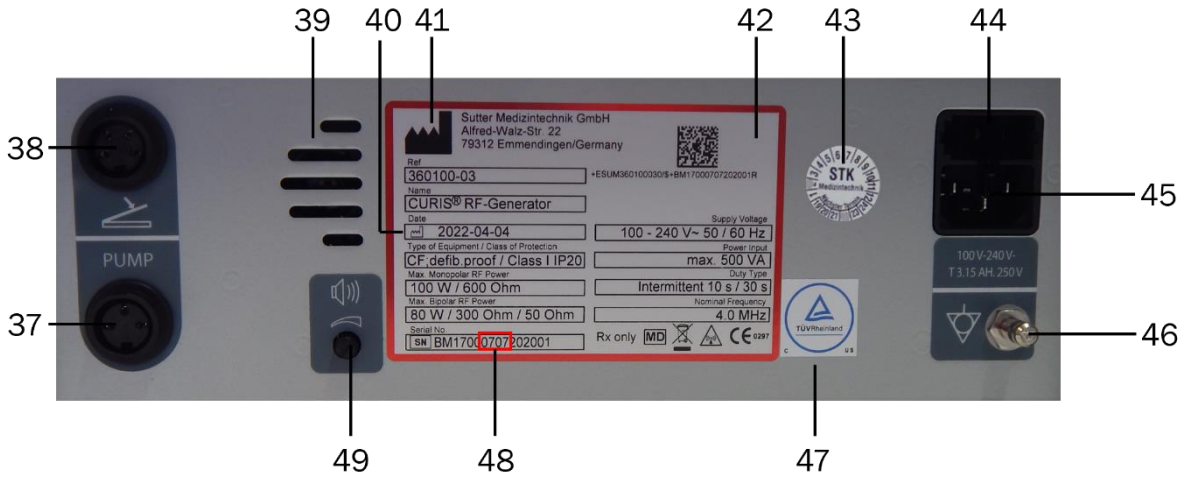
33  Notification symbol for classification of the device (CF).
The device is defibrillator safe.

34  Notification symbol "CAUTION!"

35  Notification symbol "CAUTION! NOTE THE INSTRUCTIONS FOR USE!"

36  Notification symbol "CAUTION – HIGH-FREQUENCY CURRENTS, DANGER HIGH VOLTAGE"

Back of the device



37 PUMP Connection socket for flushing pump

38 Connection socket for foot switch

39 Speaker

40 Manufacturing date

41 Manufacturer

42 Type plate

43 Safety-related inspection seal of approval

44 Device fuse (2x T 3.15 AH 250 V G 5x20mm)

45 Mains cable connection socket

46 PE connection for electric potential equalization

47 TÜV seal of approval

48 Hardware and software version, four characters

49 Volume control

NOTE

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:

BM1700 07 07 19 15xx — Sequential production number

Year of manufacture

Software status code

Hardware status code

Device type

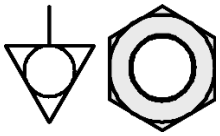
5 Commissioning

5.1 Validity of these instructions for use

These instructions for use are valid for all CURIS® devices with hardware and software according to the hardware and software status (48) on the type plate equal to **"0707"**. The type plate is on the rear of the device.

Pressing the "CUT 1" and "EXCISE" buttons while the device is powering up shows the software version in the bottom two rows of the display: for example, 702 means V 7.02.

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 prescribed for certain operating rooms, for instance for intercardial procedures, and can be established via the potential equalization connection (46). The required connecting cable is not included in the scope of delivery and can be obtained from us if needed.

5.3 Mains supply

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

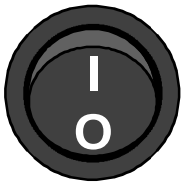
The fuses are located on the rear of the device in the slot (44) on the mains connection socket.

Connect the mains cable to the connection socket (45) 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 (power switch (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 switching on, the red indicators above the neutral electrode indicator light up briefly.

Then all control buttons light up briefly. No line or point is allowed to appear on the output and timer displays at this time. Finally, the three displays light up with “888”. At the same time, the activation indicator lamps for monopolar “cut” and “coag” as well as bipolar “cut” and “coag” light up sequentially; the respective activation tone has to sound simultaneously.

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 neutral electrode to the connection socket on the front of the device (30). One-piece neutral electrodes or neutral electrodes with two partial areas that make it possible to monitor the contact to the patient may be connected.

In monopolar mode, the “Neutral electrode not connected” indicator (31) 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 not connected” indicator only turns off 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.

NOTE

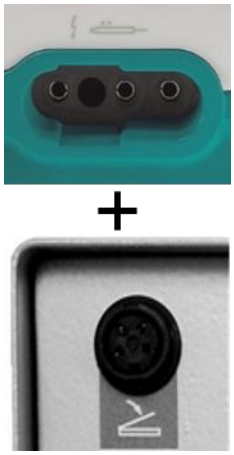
Insufficient contact between the neutral electrode and patient only triggers an acoustic warning signal when a neutral electrode that supports monitoring is used with the contact quality monitor.

5.6.2 Connecting monopolar handles for cutting and coagulation

Connecting **monopolar handles with finger switch**, e.g. Sutter accessory REF 36 07 04:

To use monopolar handles with finger switch, connect the connection cable to the socket (28) on the front of the device (see illustration to the left).

Subsequently activation is realized with the finger switch on the handle.



Connecting **monopolar handles without finger switch**, e.g. Sutter accessory REF 36 02 14:

To use monopolar handles without a finger switch, connect the connection cable to the socket (28) on the front of the device (see illustration, above left) **and** connect the foot switch (REF 36 01 10) to the socket (38) on the back of the device (see illustration, below left).

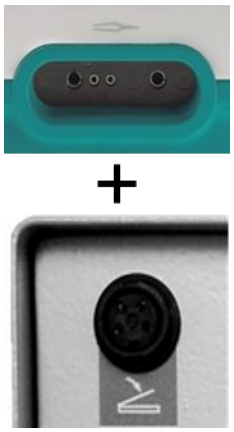
Subsequently the foot switch is used for activation.

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 (23) on the front of the device (see illustration, above left) **and** connect the foot switch (REF 36 01 10) to the socket (38) on the back of the device (see illustration, below left).

The foot switch or, for the coagulation electrodes, the AUTO START function (26) is subsequently used for activation; see chapter 6.1.

Bipolar tweezers 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 the CURIS® 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.

NOTE

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.

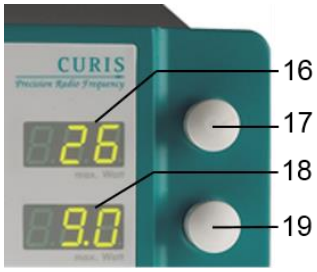
When instruments are detected automatically, programs (buttons P1 through P4) can only be loaded and saved within the parameters assigned to the respective instrument.

5.6.5 Operating mode selection

Select the desired operating mode before using the device.
The CURIS® 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	CONTACT (4)	Contact coagulation, coagulation with depth effect on direct contact between the electrode and tissue.
		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 1 (10)	Smooth cut with no coagulation zone.
		BICUT 2 (12)	Cutting current with coagulation zone.
		EXCISE (14)	For the use of, for example, ring forceps.
	Coagulation blue selection buttons	MACRO (9)	Bipolar coagulation, local contact coagulation in the area of the bipolar electrode pair.
		PRECISE (11)	Bipolar coagulation with fine electrodes, local contact coagulation in the area of the bipolar electrode pair.
		RaVoR™ (13)	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 and STANDARD special functions are not supported with RaVoR™. AUTO STOP cannot be turned off.

5.6.6 Setting the output power



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

Control dial (17) and output display (16) for the CUT operating modes (cutting):
CUT 1, CUT 2, BICUT 1, BICUT 2, EXCISE

Control dial (19) and output display (18) for the COAG operating modes (coagulation):
CONTACT, SOFTSPRAY, MACRO, 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.

NOTE

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 occurs 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!

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 indicator lamp for the operating mode MONOPOLAR (8) or BIPOLAR (15) lights up.

WARNING

The rules for electrosurgery application in chapter 7 “Safety measures” 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!

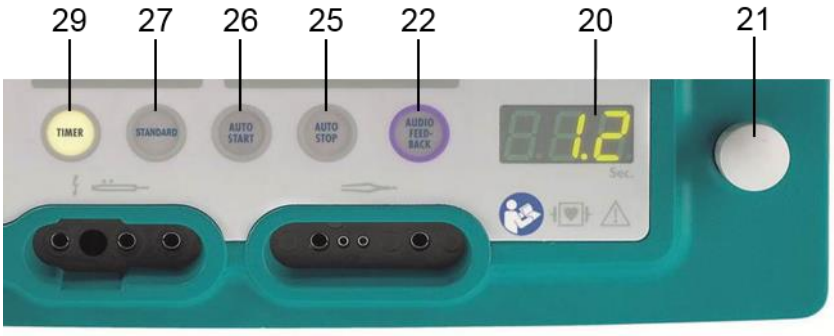
The surface of the device may get very hot during the extended application of RF current.

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 all coagulation modes of the CURIS®. Here the radiofrequency energy is emitted in 50 packets per second. The treatment is gentler on the tissue due to the short breaks.



TIMER (29)

This special function limits the RF output to a maximum activation time selected in advance. The device automatically turns off the electrode after this time. Adjust the time using the rotary knob (21). The display (20) indicates the remaining available time. The TIMER only runs while the RF current is activated; pausing stops the TIMER. The adjustment range is 0.2 ... 60,0 seconds. The TIMER function only works in the coagulation operating modes (both monopolar and bipolar, but not in RaVoR™ mode).

Procedure:

1. Press the TIMER button (29).
2. Set the maximum on time for the RF output using the rotary knob (21).
3. Turn on the electrode.

After the configured time ends, the electrode turns off automatically even if the foot or finger switch is still pressed.

STANDARD (27)

This button turns off all special functions. Then turn the electrode on and off manually (on the handle or using the foot switch).

AUTO START (26)

This special function is only available in the MACRO and 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 seconds using the rotary knob (21).

WARNING

Unintentional RF activation may occur with the CURIS® 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 operating modes cannot be selected when the AUTO START function is selected.

For exclusive bipolar application, nevertheless selecting a bipolar cutting position is recommended in order to prevent unintentional monopolar application. When a bipolar coagulation and a cutting operating mode are selected simultaneously, no cutting current can be produced with activation of the AUTO START function (no selection button for the cutting operating modes is stored and a warning tone sounds when CUT operating modes are activated).

AUTO STOP (25)

This special function is only possible in the coagulation operating modes MACRO, 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 FEEDBACK (22)
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 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 buttons P1 ... P4 (3) until the confirmation signal sounds.

Now the current device settings are stored in the selected program memory slot and the green indicator lamp next to the program memory button light 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 green indicator lamp next to the button shows that the saved settings are active. If the special AUTO START function was also saved, the AUTO START button (26) flashes after loading the saved settings but the function is not active. This function is only active after pressing the AUTO START button (26). This step protects against unintentional activation.

NOTE

A manually selected output setting in a bipolar cutting operating mode cannot be saved for safety reasons! In this case the output setting “0” is always stored in the program. To work with bipolar cutting current, the output first has to be set again using the rotary knob (17).

The green 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 detection, 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.

6.3 Function test

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

1. Pull the plug of the connection cable for the neutral electrode out of the connection socket (30). The red warning lamp (31) flashes. 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. On the other hand, the bipolar current can be activated if selected; in this case, the red warning lamp will not flash.
2. Connect the plug of the connection cable for the neutral electrode to the connection socket (30) again. If a monopolar operating mode is selected, the red warning lamp (31) stops flashing now. If a segmented neutral electrode is used, it must be correctly applied to the patient for the alarm to turn off. This warning lamp does not flash with bipolar operating modes.
3. Connect the connection cable with the monopolar electrode handle to the socket (28). Activate the chosen current with the finger switch on the electrode handle or the foot switch. The operating mode indicator lamps for MONOPOLAR (8) and BIPOLAR (15) 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, then 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.

A medical device record must be maintained 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®.

Any serious-incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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, wetting of the pads serving as high-frequency insulation must be prevented 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 should 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

Electrodes and cables must be applied 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.
- When using disposable adhesive electrodes, ensure that the expiry date has not passed.
- The supply cables to the RF electrodes are routed without loops so that they touch neither the patient nor other cables. This applies in particular to the neutral electrode. 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® 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 disposable adhesive neutral electrode. Continuous monitoring of the patient is only ensured with a split adhesive 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 adhesive electrodes off quickly can cause skin injuries.

7.4 Pacemaker, 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 via endoprostheses is prohibited. Never apply the neutral electrode via 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!

NOTE

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 instruments that generate a high-frequency current, such as the CURIS®, may interfere with other electromedical equipment (such as ECG monitoring) 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® to a different outlet.
- Increase the distance between the CURIS® 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®, 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 bolt (46) 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 54 L/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)
- Silicone neutral electrode with cable (REF 36 02 26)
- Cable for disposable neutral electrodes (REF 36 02 38)
- Foot switch (REF 36 01 10, see chapter 12)
- Foot switch (REF 36 01 14, see chapter 12)
- single-use patient plate, split, for adults and children (REF 29 00 – 5)

Products shown in this IFU are subject to regulatory approval in individual markets. Products may therefore not be available in all markets.

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.

Ask your specialist dealer or the manufacturer in case of doubt.
The cable length of accessories should not exceed 3 m.

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® (for instance connection of a flushing pump or joint connection on one power strip), 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 a bipolar cutting operating mode 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 (17). An output setting > 0 in a bipolar cutting operating mode cannot be stored in a program, but is automatically set to “0” in the program.

NOTE

For safety reasons, leaving the output setting for a bipolar cutting operating mode 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

Disconnect the device from the mains network for cleaning and disinfection. 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 disinfectant residues are fully removed before using the device.

NOTE

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

NOTE

Accessories that cannot be sterilized must be regularly disinfected by wiping (see chapter 8.1; for the disinfection of the foot switch, see chapter 12).

NOTE

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

9 Technical information

9.1 Technical data, standards, certification

Mains supply	100-240 V; 50/60 Hz							
Power consumption	without RF output		approx. 50 VA					
	at max. output power		approx. 500 VA					
Protection class	I							
IP-Code	IP20							
MPG classification	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 (cutting)	max.	100 W	± 20 %	on	600 Ω	1.10 A	4.00 MHz	-
CUT 2 (cutting)	max.	80 W	± 20 %	on	600 Ω	1.10 A	4.00 MHz	33 kHz
CONTACT (coag.)	max.	80 W	± 20 %	on	400 Ω	1.20 A	4.00 MHz	33 kHz
SOFTSPRAY (coag.)	max.	60 W	± 20 %	on	600 Ω	0.90 A	4.00 MHz	33 kHz
BIPOLAR current type								
BICUT 1 (cutting)	max.	80 W	± 20 %	on	300 Ω	1.20 A	4.00 MHz	-
BICUT 2 (cutting)	max.	80 W	± 20 %	on	300 Ω	1.30 A	4.00 MHz	33 kHz
EXCISE (cutting)	max.	80 W	± 20 %	on	300 Ω	1.20 A	4.00 MHz	33 kHz
MACRO (coag.)	max.	80 W	± 20 %	on	50 Ω	2.20 A	4.00 MHz	-
PRECISE (coag.)	max.	50 W	± 20 %	on	50 Ω	1.70 A	4.00 MHz	33 kHz
RaVoR™ (coag.)	max.	40 W	± 20 %	on	50 Ω	1.60 A	4.00 MHz	33 kHz
Operating mode	Intermittent INT 10 s /30 s corresp. 25 % ED							
Mains fuse	2 x T 3.15 AH 250 V G 5x20mm							
Signal level	RF indicator: 40-65 dB(A) adjustable Alarm: 65 dB(A)							
Weight	approx. 5.0 kg							
Dimensions	W x H x D	320 mm x 170 mm x 385 mm						
Standards	IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012 IEC 60601-1-2:2014 IEC 60601-2-2:2017							
CE 0297	Conforming to article 120(3) of Council Regulation (EU) 2017/745 (MDR)							
Environmental conditions for transportation and storage	Ambient temperature Relative humidity Atmospheric pressure	-25 °C to +70 °C 10 % to 100 % 500 hPa to 1060 hPa						
Environmental conditions for operation	Ambient temperature Relative humidity Atmospheric pressure	+10 °C to +40 °C 30 % to 75 % 700 hPa to 1060 hPa						

NOTE

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

9.2 Recurring safety-related inspections

The following inspections must 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 experience gained through practical activity, are able to perform such safety-related inspections properly and who are not subject to any directives in regards to this inspection activity.

NOTE

No maintenance tasks may be carried out on the CURIS® 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.

NOTE

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.

NOTE

We can provide you with instructions for the safety-related inspections and a service manual on request. These assist persons or companies authorized by us with the maintenance/repair of the CURIS®. The service manual also lists all assemblies that are available as replacement parts.

NOTE

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

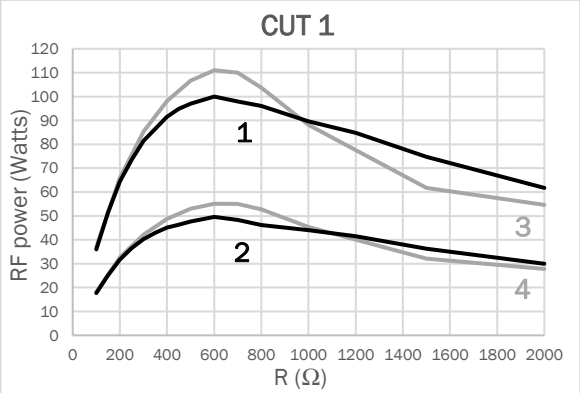
NOTICE

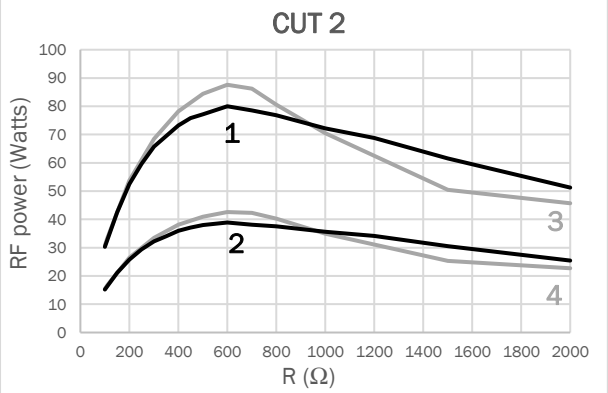
Two 100%/50% output curves are respectively shown in the diagrams – measured with the measurement systems EPM3 (black) and PMS4 (grey).

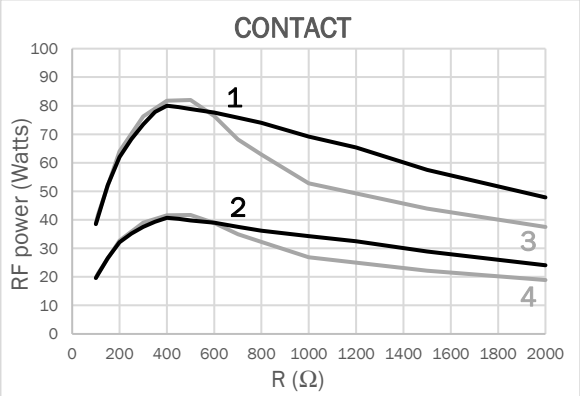
Differences in the measurement results are due to the different measurement concepts of these measurement systems, the complex HF impedance progression of the resistance matrix and the generator control concept. The newly introduced output analysis with the PMS4 measurement system is being carried out because the EPM3 measurement system has become obsolete.

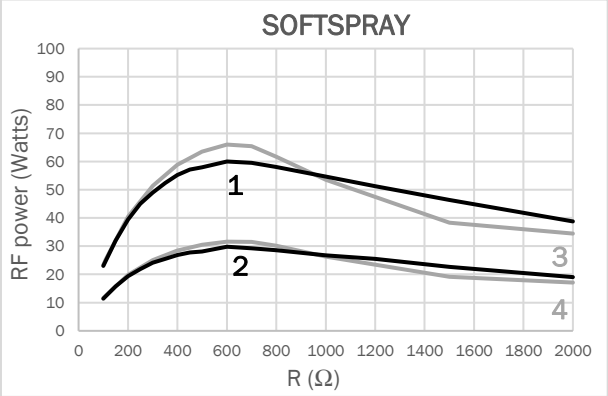
Since there is no underlying physical change to the generator, the deviations of the respective characteristic lines have no influence whatsoever on the application or use.

MONOPOLAR



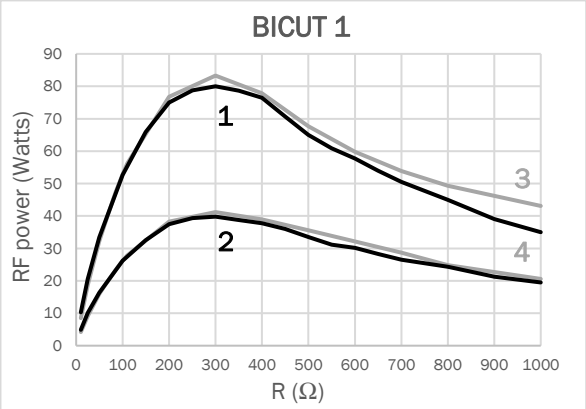


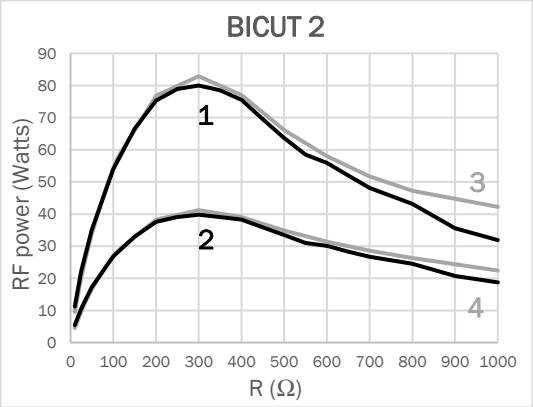


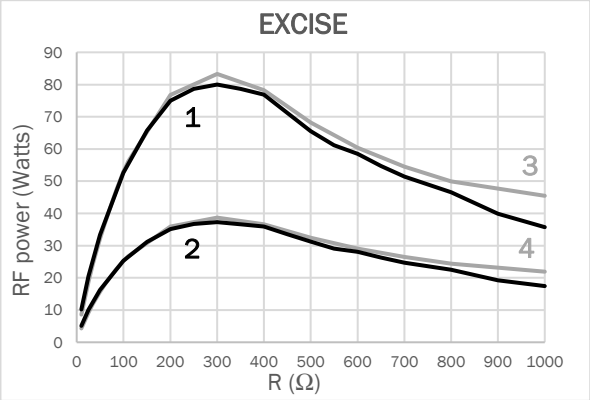


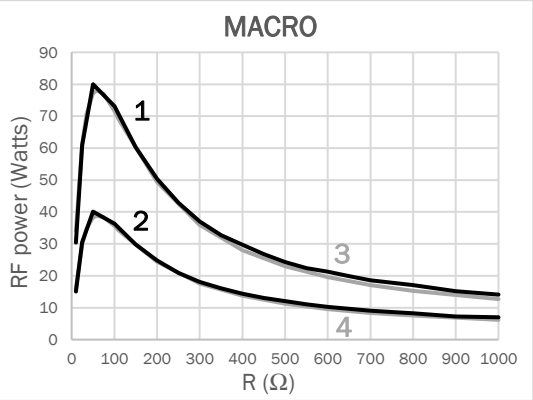
Colour	Curve	Output setting	Measurement system
Black	1	Maximum output (100%)	EPM3
	2	Half output (50%)	
Grey	3	Maximum output (100%)	PMS4
	4	Half output (50%)	

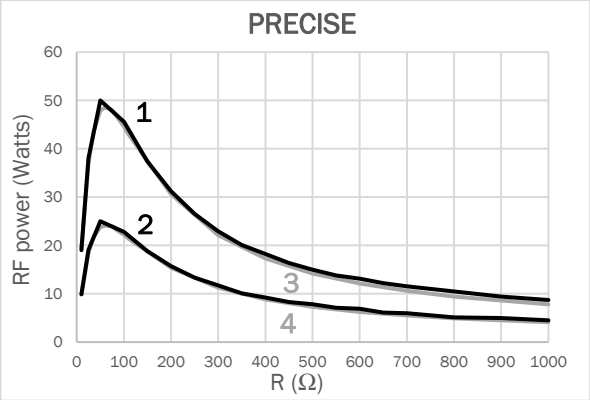
BIPOLAR

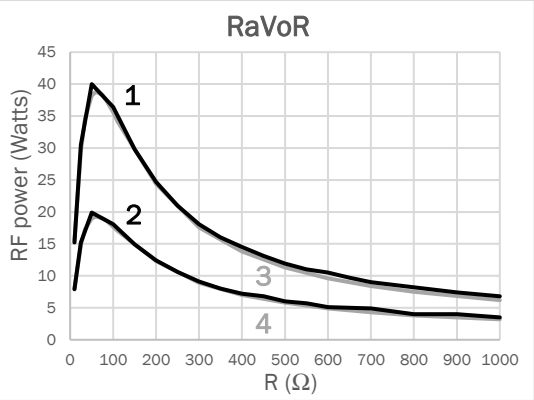










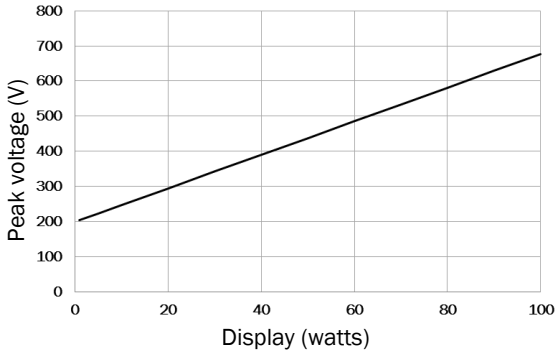


Colour	Curve	Output setting	Measurement system
Black	1	Maximum output (100%)	EPM3
	2	Half output (50%)	
Grey	3	Maximum output (100%)	PMS4
	4	Half output (50%)	

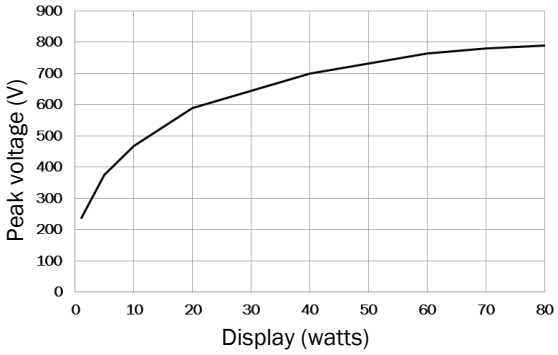
9.3.2 RF voltage

MONOPOLAR

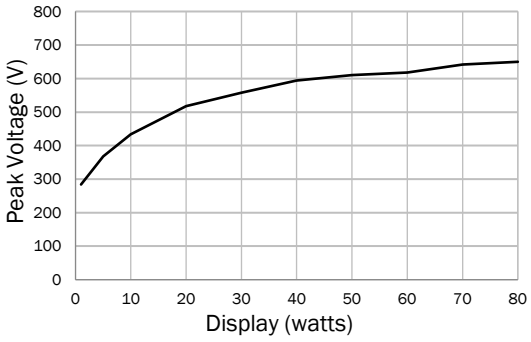
CUT 1



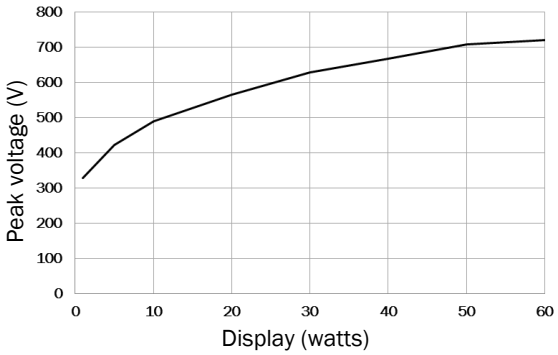
CUT 2



CONTACT

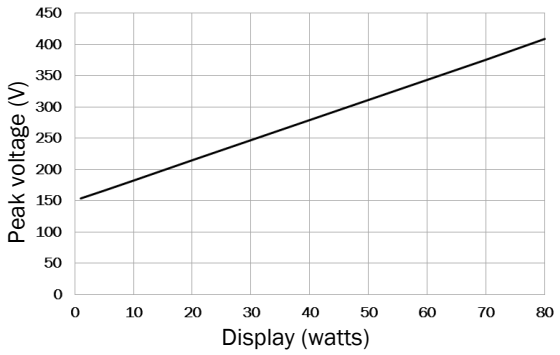


SOFTSPRAY

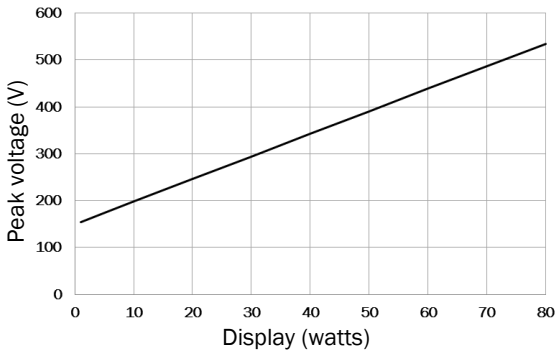


BIPOLAR

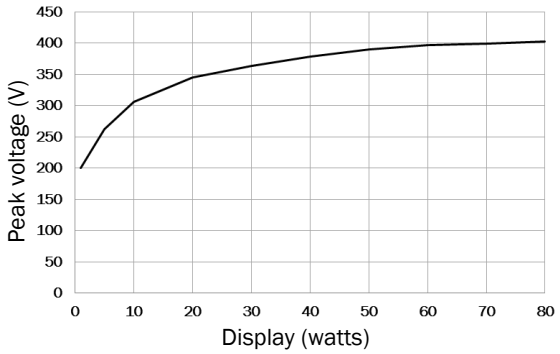
BICUT 1



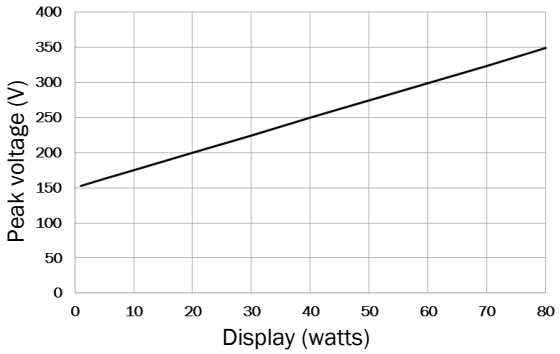
BICUT 2



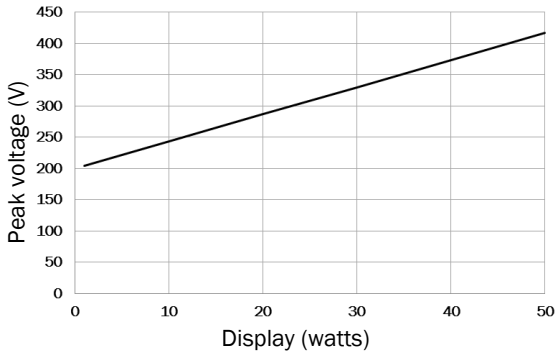
EXCISE



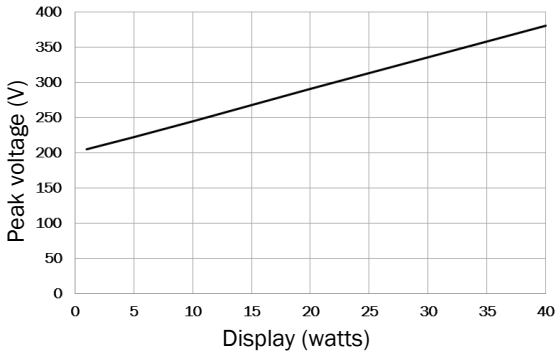
MACRO



PRECISE

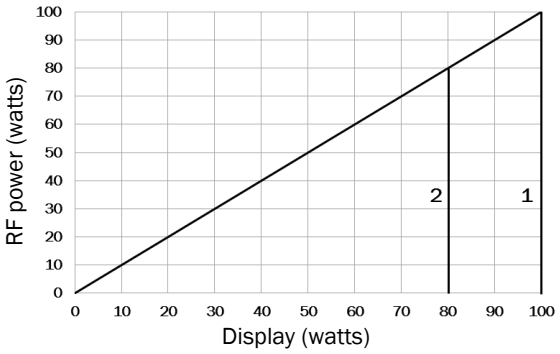


RaVoR



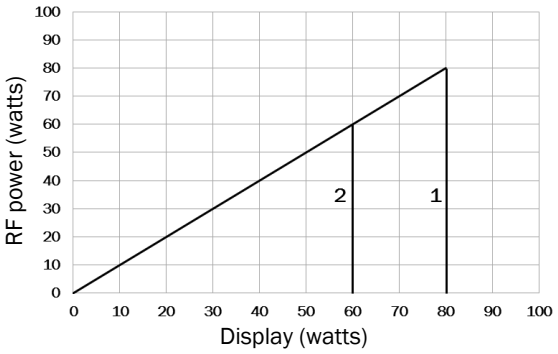
9.3.3 Control characteristic curve

MONOPOLAR CUT



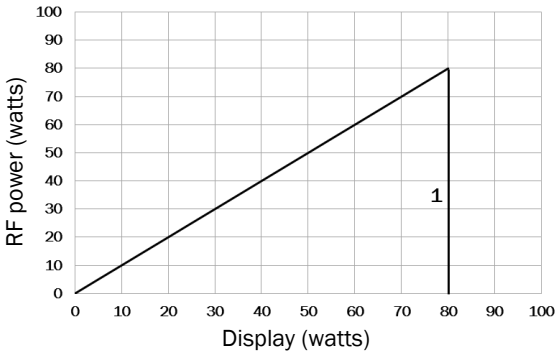
1 = CUT 1 on 600 Ω
2 = CUT 2 on 600 Ω

MONOPOLAR COAG



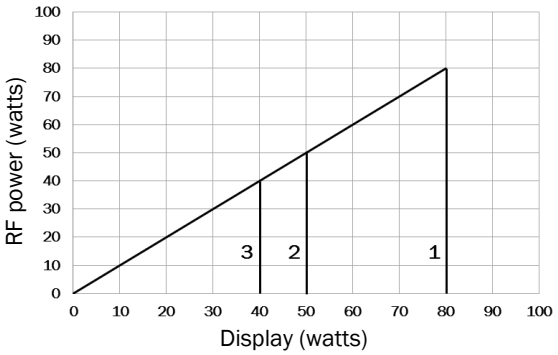
1 = CONTACT on 400 Ω
2 = SOFTSPRAY on 600 Ω

BIPOLAR CUT



1 = BICUT 1, BICUT 2, EXCISE on 300 Ω

BIPOLAR COAG



1 = MACRO on 50 Ω
2 = PRECISE on 50 Ω
3 = RaVoR™ on 50 Ω

9.4 Guidelines and manufacturer declaration for electromagnetic compatibility

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014, section 7: Electromagnetic emissions		
The CURIS® is intended for operation in an electromagnetic environment as specified below. The customer or user of the CURIS® must ensure that it is operated in such an environment.		
Interference resistance tests	**Compliance level**	**Electromagnetic environment – guidelines**
HF emissions according to CISPR 11	Group 2	The CURIS® has to emit electromagnetic energy for its intended function. Interference with devices in the vicinity is possible.
HF emissions according to CISPR 11	Class B	Compliance with the class only in operational readiness without the activation of HF current!
Emission of harmonics according to IEC 61000-3-2	Class A	The CURIS® is suitable for use in all facilities, including residential facilities and those connected directly to the regular, public supply network for residential buildings.
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

Guidelines and manufacturer declaration according to IEC 60601-1-2:2014, section 8.9: Electromagnetic emissions			
The CURIS® is intended for operation in an electromagnetic environment as specified below. The customer or user of the CURIS® 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 covered in ceramic tiles. If synthetic floor coverings are installed, the relative humidity must be at least 30 %.
Fast transient electrical interference/burst 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® requires continuous functioning even in case of energy supply interruptions, supplying the CURIS® 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.
NOTE: U_T is the AC mains voltage prior to application of the test levels.			

<table>
<tr><th colspan="4">Guidelines and manufacturer declaration according to IEC 60601-1-2:2014, section 8.9:
Electromagnetic interference resistance</th></tr>
<tr><td colspan="4">The CURIS® is intended for operation in an electromagnetic environment as specified below. The customer or user of the CURIS® 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.</td></tr>
<tr><th>Interference resistance tests</th><th>Test level according to IEC 60601</th><th>Compliance level</th><th>Electromagnetic environment – guidelines</th></tr>
<tr><td>Conducted HF interference according to IEC 61000-4-6</td><td>3 V_{eff}
150 kHz to
80 MHz

6 V_{eff}[a] in ISM frequency bands
150 kHz to
80 MHz</td><td>3 V_{eff}
150 kHz to
80 MHz

6 V_{eff}[a] in ISM frequency bands
150 kHz to
80 MHz</td><td rowspan="2">Portable and mobile radio devices should not be used closer to the CURIS® (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[b] according to on-site testing.[b].

Interference may occur in the vicinity of equipment marked with the following symbol.

  </td></tr>
<tr><td>Radiated HF interference according to IEC 61000-4-3</td><td>3 V/m
80 MHz to
2.7 GHz</td><td>3 V/m
80 MHz to
2.7 GHz</td></tr>
<tr><td>NOTE</td><td colspan="3">These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">[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®I 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®.</td></tr>
</table>

Recommended separation distances between portable and mobile HF telecommunications devices and the CURIS® according to IEC 60601-1-2:2014, 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® 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 burn-off 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 electric and electronic equipment according to Directive 2002/96/EC (WEEE) and the German Electrical and Electronic Equipment Act (ElektroG)

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

11 Error diagnosis

Error	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	Turn the device 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® can continue in the STANDARD operating mode, then contact Service.
Display of an error message, e.g. Err 42	See listing below	See listing below

Error messages and their meaning

The CURIS® 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.

NOTE

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.

NOTE

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

Error no.	Meaning	Cause	Resolution
Err 41, Err 42	During the power-up test, the device recognized actuation of the yellow and/or blue finger switch of a hand piece connected to the monopolar output.	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, the device recognized actuation of the yellow and/or blue finger switch of a hand piece connected to the bipolar output.	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, the device recognized actuation of the yellow and/or blue foot switch pedal.	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, the device detected the actuation of a button on the operator panel.	Attempting to actuate a button before the power-up test completes, or operator panel defect.	If not caused by activation, the operator panel of the CURIS® 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.

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 CURIS. 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 (10s/30s).	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 foot switch is offered for the CURIS®:

REF 36 01 10 → two-pedal foot switch without flushing pump button, explosion protected, 4 m cable

REF 36 01 14 → two-pedal foot switch without flushing pump button, explosion protected, 4 m cable

Intended use

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

REF 36 01 10

Yellow pedal → cutting mode activation

Blue pedal → coagulation mode activation

REF 36 01 14

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 only manual cleaning, use just a cloth impregnated with water and a mild detergent. Do not use cleaning agents which may damage the plastic surfaces such as detergents, abrasive cleansers or solvent-based cleaners.

NOTE

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

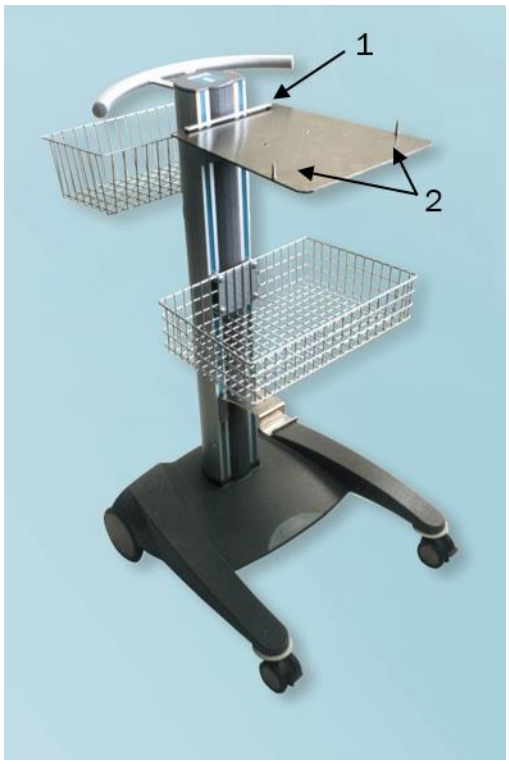
Standards: IEC 60601-1:2005, IEC 60601-2-2:2009, IEC 60529:1989, IEC 60721-3-2:1997;
Class: Class I according to the Council Regulation (EU) 2017/745
Pedals made of break-proof, self-extinguishing thermoplastic material, cast aluminum housing
Connecting cable: permanently connected and sealed control 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
Switching power max. 30 VA; mech. service life: >1 million switching cycles
Approvals: AP compatible
Storage conditions: Temperature: -25 °C to +70 °C; relative humidity: 5 % - 100 %; air pressure: 500 hPa – 1100 hPa

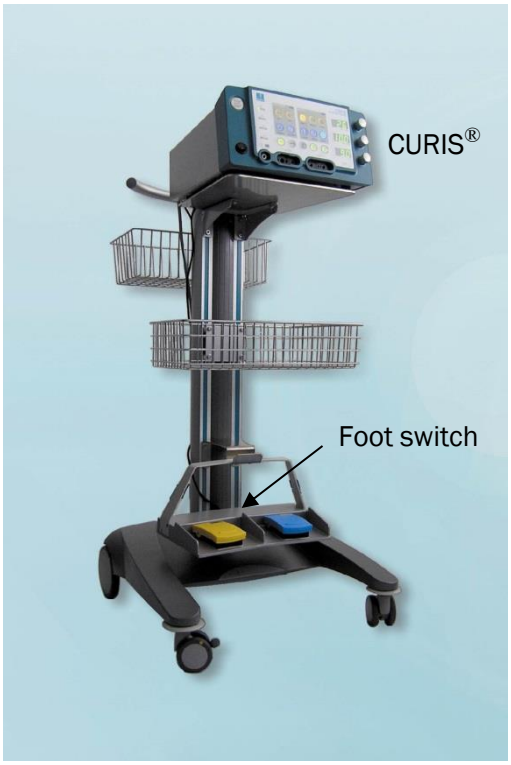
13 Equipment cart (optional)

REF 36 09 00

The equipment cart designed especially for the CURIS® features numerous extras such as storage baskets and a foot switch adapter. It is fully assembled on delivery.

The CURIS® is secured against sliding by engaging in the metal strip (1) on the plate of the cart and sitting on the two metal pins (2).





Notes

Notes

Address of the manufacturer

Distributed by:

Manufacturer:

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