English

Electrosurgical Unit ME 411

CE 0297

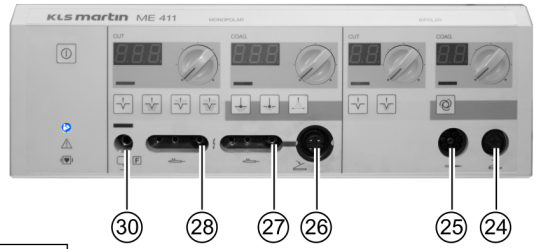
Instructions for Use

REF 90-657-52-31
Revision 4
Date of Release: 2015-12

KLS martin GROUP

Quick Instructions for Use ME 411

For the assignment of the numbering see section 4.2 “Functions of the Control Elements, Connections and Displays”, page 12.



Connect to mains after voltage test

After test runs and acknowledgment, the device is operational

Monopolar operation

Connect neutral electrode to connection socket (30)

Apply the neutral electrode

HF activation via finger switch

Connect handle with finger switch to connection socket (27) or (28)

Select current type

Set power

Activate cutting or coagulation

HF activation via foot switch

Connect handle without finger switch to connection socket (27)

Connect foot switch to connection socket (26)

Select current type

Set power

Activate cutting or coagulation

Bipolar operation

Connect bipolar instrument to connection socket (25)

Connect foot switch to connection socket (24)

Select current type

Set power

Bipolar cutting

Activate bipolar cutting

Deactivate bipolar cutting

Bipolar coagulation

HF activation without Auto-Coag-Stop

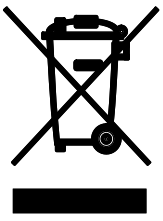
Activate bipolar coagulation

Deactivate bipolar coagulation

HF activation with Auto-Coag-Stop

Activate bipolar coagulation with Auto-Coag-Stop

Symbol explanation

	**Safety alert symbol** CAUTION — Indicates a situation which, if not avoided, could result in minor or moderate injury. WARNING — Indicates a situation which, if not avoided, could result in death or serious injury. DANGER — Indicates a situation which, if not avoided, will result in death or serious injury.
	Observe instructions for use
	Item number (Item no.)
	Manufacturer
NON WOOD	The packaging is “non-wood”, i.e. wood packaging material that is not subject to ISPM 15 and therefore suitable for international shipment.
	Warning: Dangerous high voltage!
	Class I equipment acc. to IEC 60601-1
	CE mark of conformity
	This product may not be disposed of as normal household garbage

Contents

1 Product Liability and Warranty

1.1 General Information

We thank you for having decided to buy a KLS Martin product. This product carries the CE mark, which means that it satisfies the essential requirements laid down in the EC Directive concerning medical devices.

We are the manufacturer of this product:

Gebrüder Martin GmbH & Co. KG

A company of the KLS Martin Group
KLS Martin Platz 1 · D-78532 Tuttlingen · Germany
Postfach 60 · D-78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

1.2 Scope of Delivery

- Electrosurgical unit ME 411
- Mains cable
- Instructions for Use

1.3 Intended Use

The unit is used for electrosurgical cutting or coagulation of live human tissue.

The operator may operate the device only if an on-site functional test has previously been performed by Gebrüder Martin or a person authorized by Gebrüder Martin. In addition, a responsible person designated by the operator must have been instructed in the proper handling, application and operation of the unit, as well as in its permissible combination with other medical devices, objects and accessories. This duly instructed officer shall subsequently be responsible for familiarizing the operator's staff with the unit as the need arises. We recommend documenting all user instructions in a medical device logbook. A copy of the logbook is available from Gebrüder Martin.

The operating safety of the unit must be checked in regular intervals, see section 7 "Safety Checks", page 37.

If the device does not work properly and / or cannot be operated safely, it must be marked as non-operational and put out of operation. A technical inspection must be performed.

1.4 Warranty

Our Standard Terms and Conditions of Sale effective at the time shall apply. Agreements diverging from these Standard Terms and Conditions do not restrict the legal rights of the buyer.

Any warranty exceeding the above provisions shall require a contractual form and shall exclude component-related vandalism, software updates and consumables.

Under this warranty, we will remedy free of charge any defects due to faulty workmanship or the use of faulty materials, either through our Customer Service or directly at the factory. The warranty for the unit is not extended by this.

Important Notices

The product may only be repaired by Gebrüder Martin or a qualified person or firm expressly authorized by Gebrüder Martin to perform such work.

If the repair is carried out by a person or firm specially authorized by Gebrüder Martin, the operator of the product is required to obtain from the repairer a certificate with details about the nature and scope of the repair work done. This certificate must show the date of the repair and the details of the person or firm carrying out the work and must be signed.

In all cases where a party other than the product manufacturer performed the work, repaired products must be additionally marked with the repairer's ID label.

Improper interventions or alterations performed by third parties during the period of limitation shall void any and all warranty claims. Unauthorized actions performed on the product shall invalidate any liability claims against Gebrüder Martin.

1.5 User's Inspection

Immediately upon receipt, the goods must be checked for completeness and potential damage in transit. Notice of any such damage must be given immediately.

1.6 Hotline

- Should you have any questions on how to handle the product or use it for clinical applications, please do not hesitate to contact the Product Management:
  Tel: +49 7461 706-243
  Fax: +49 7461 706-190
- Should you have any technical questions, please do not hesitate to turn to our Martin Service Center:
  Tel: +49 7461 706-343
  Fax: +49 7461 706-408
  E-mail: service@klsmartin.com
- Should you have any questions concerning maintenance contracts or training courses, please contact our Technical Service Manager:
  Tel: +49 7461 706-332
  E-mail: service@klsmartin.com

NOTICE

To answer your technical questions as efficiently as possible, our service technicians require the serial number of the product. Therefore, please have this number at hand when contacting our hotline. It is part of the information provided on the rating plate; see section 4.2 “Functions of the Control Elements, Connections and Displays”, page 6.

2 Notices Concerning this Document

⚠

Non-observance of this document can lead to serious or even lethal patient injury!

Improper handling and care as well as non-intended use can lead to premature wear and / or pose a risk to patients and users!

Be sure to read, understand and follow the instructions given below!

- Every user is required to read this document completely and follow them carefully.
- In particular, be sure to heed all cautions, warnings and danger notices.
- Keep this document accessible to users at all times.

2.1 Symbols Used in this Document

Throughout this document, important information (such as general or safety-related notices) is marked with the following symbols and signal words:

⚠WARNING

Danger of death or serious injury!

Indicates a situation which, if not avoided, **could** result in death or serious injury!

⚠CAUTION

Danger of minor injury!

Indicates a situation which, if not avoided, could result in minor or moderate injury!

NOTICE

Risk of material damage!

Indicates a situation which, if not avoided, could lead to material damage (loss of time, data loss, device / machine failure, etc.)!

2.2 Service Manual

Upon request, we will supply a service manual. It helps persons or companies authorized by us to maintain / repair the unit. The service manual also contains order information for all components that are available as spare parts.

3 Functional Principle

3.1 Monopolar Functional Principle

The electrosurgical unit ME 411 is a generator that converts electrical energy from the grid into a high-frequency current. This high-frequency current is fed to a point-shaped active electrode via a supply line and a handle. This leads to high field line concentration in a small area at the application site of the active electrode in the tissue surroundings of the point of contact. The desired electrosurgical effect is achieved by to this energy concentration in a small area in the area of the active electrode. During further energy transport through the patient up to the neutral electrode applied to a larger area, the concentration of the current is further reduced. Therefore, there is, in accordance with its intended purpose, no thermal effect in the area of the applied neutral electrode. The circuit is closed via the supply cable of the neutral electrode.

The RF generator is activated optionally via foot switch or finger switch on the surgical handle.

3.2 Bipolar Functional Principle

Special constructional measures (insulation) permit design of bipolar instruments where the active electrode and neutral electrode are positioned directly to each other. Here the path of the high-frequency current only leads to one instrument tip to the other. Thus, there result very short current paths and delimited coagulation areas with low power requirements.

4 Commissioning

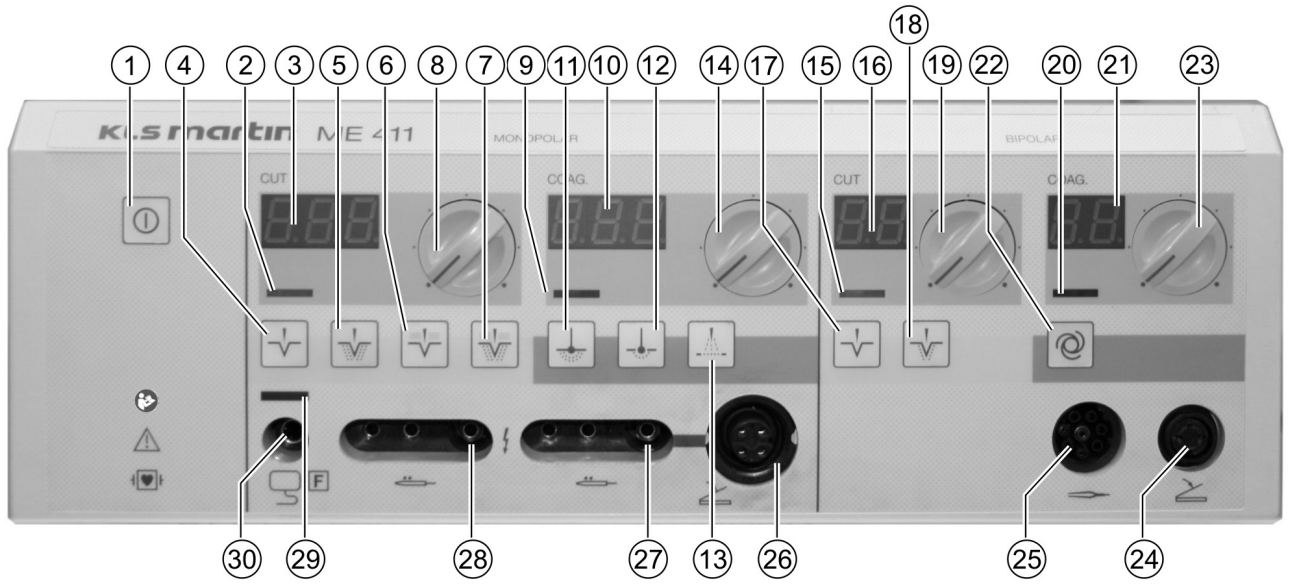
4.1 Technical Specification

The unit is controlled by a micro-processor, can be used universally and has excellent performance data. The unit meets the latest safety standards.

The unit is characterized by the following constructional characteristics:

- Dynamic characteristic control for the automatic setting of an optimal working point for any type of operation.
- Progressive power adjustments for particularly precise settings in the lower power range and high power reserves in the upper adjustment range.
- Advanced safety concept with two parallel micro-processors.
- Easy handling thanks to the clear arrangement of all control elements and their labeling with easy-to-remember function symbols. The power is set via rotary knobs with an additional digital display of the set power in watts. All connections for active electrodes, neutral electrodes and foot switches are located on the front side.
- Four current types for monopolar cutting: Smooth cutting and cutting with eschar in the ambient media air and liquid.
- Three current types for monopolar coagulation: Two coagulation currents with high power for contact coagulation; a forced coagulation current for preparation; and a coagulation current with high crest factor for spray coagulation.
- Extra generator for bipolar cutting and bipolar coagulation. The bipolar generator can be operated synchronously with the monopolar generator for cutting / coagulation.
- Self-test after each switching on of the unit.
- Optical and acoustic signals to indicate RF activation with activation LEDs in different colors and different signal tones for cutting and coagulation.
- Multi-functional interfaces for intelligent accessory components.
- Serial interface for comfortable operation with a KLS Martin Argon Beamer System (MABS).
- Combined connection sockets for KLS Martin coax cables and disposable products.
- The integrated Patient Control System (PCS) by KLS Martin performs continuous application monitoring using a two-surface neutral electrode.
- Safety system according to IEC 60601-2-2 for cases of a unit-related output error.
- Acoustic warning in case of high-frequency activation > 15 s (switch-on time).
- No opening or cooling vents, no cooling fan. Low power loss thanks to high efficiency of the generators.
- Hygiene-friendly foil front plate.
- Practice-oriented, high-quality accessory components.

4.2 Functions of the Control Elements, Connections and Displays



1 ON / STANDBY switch

2 Activation LED monopolar cutting

3 Digital power display monopolar cutting (display of maximum output power in watts)

4 Selection button monopolar cutting 1

5 Selection button monopolar cutting 2

6 Selection button monopolar cutting URO 1

7 Selection button monopolar cutting URO 2

8 Power controller monopolar cutting

9 Activation LED monopolar coagulation

10 Digital power display monopolar coagulation (display of maximum power)

11 Selection button contact coagulation 1

12 Selection button contact coagulation 2

13 Selection button spray coagulation

14 Power controller monopolar coagulation

15 Activation LED bipolar cutting

16 Digital power display bipolar cutting
(display of the maximum power)

17 Selection button bipolar cutting 1

18 Selection button bipolar cutting 2

19 Power controller bipolar cutting

20 Activation LED bipolar coagulation

21 Digital power display bipolar coagulation
(display of maximum power)

22 Selection button bipolar automatic operation

23 Power controller bipolar coagulation

24 Connection socket for double-pedal foot switch for bipolar cutting and bipolar coagulation or for single-pedal foot switch for bipolar coagulation

25 Connection socket for bipolar instruments

26 Connection socket for double-pedal foot switch for monopolar cutting and monopolar coagulation

27 Connection socket for monopolar handle

28 Connection socket for monopolar handle

29 Indicator LED neutral electrode

30 Connection socket for neutral electrode

31 Mains switch

32 Mains fuses (230 V: T4 AH, 115 V: T8 AH, G 5 x 20 mm)

33 Connection socket for mains cable

34 Type plate

35 Speakers

36 Connector for equipotential bonding

37 Serial interface for the Argon Beamer System by KLS Martin (MABS)

Connection for the neutral electrode.
Neutral electrode insulated against ground (floating).

Symbol for classification of the unit (CF). The unit is defibrillation-proof.

WARNING! PLEASE READ INSTRUCTIONS FOR USE!

WARNING! HIGH-FREQUENCY CURRENTS! CAUTION! HIGH VOLTAGE!

4.3 Mains Connection

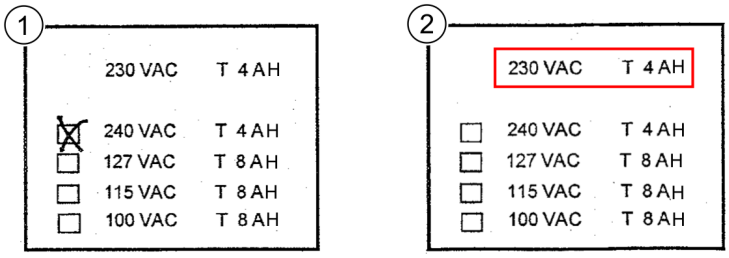
For the assignment of the numbering, see section 4.2 "Functions of the Control Elements, Connections and Displays", page 12.

Before initial switching on of the unit, ensure that your grid complies with the voltage setting of the unit indicated on the label (next to the power input). If the voltages should not match, please contact our Martin Service Center.

Any adjustment to another supply voltage on site may only be carried out by a person authorized to do so by Gebrüder Martin. Unauthorized persons may not open the unit!

NOTICE

In the absence of special labeling (1) the voltage setting corresponds to the basic setting (2 / 230 VAC T 4 AH).



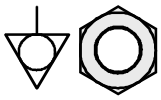
Connect the unit to the power outlet using the mains cable. Set mains switch on the rear side of the unit to position I (rocker up).

In order to be able to completely separate the unit from the grid in the event of danger, either the power socket of the unit or the outlet into which the mains cable is plugged in should remain accessible.

For the decommissioning of the unit, no special measures are necessary.

4.4 Equipotential Bonding Connection

For the assignment of the numbering, see section 4.2 "Functions of the Control Elements, Connections and Displays", page 12.



Equipotential bonding, aka potential equalization, is the conductive electrical connection of the casings of units. It ensures that the units will always, even in case of an electric defect, have the same potential. Equipotential bonding is required for certain operating theaters, e. g. for intercardial operations, and can be realized via the equipotential bonding connection (36). The necessary connection cable is not included in the scope of delivery and can be purchased if required.

4.5 ON / STANDBY

After switching on at the mains switch, the unit is in standby mode (ON / STANDBY).

- The buttons cannot be operated.
- The display fields are dark.

By pressing the ON / STANDBY button, the unit is set to operating mode and performs a self-test.

4.6 Self-Test

For the assignment of the numbering, see section 4.2 "Functions of the Control Elements, Connections and Displays", page 12.

Briefly, the software version of the operating program and characteristics table are shown on the cutting and coagulation display. Then the numeric displays with the control figure **8** as well as all activation LEDs are lit up. Next the individual buttons of the current types and the corresponding channel are activated.

- After successful self-test an acknowledgment signal is sounded.

If the unit indicates an error condition with **Err** and a figure during the self-test process, re-activate the self-test by pressing the ON / STANDBY button (1) again. If the unit indicates an error condition **Err.** again:

- Put unit out of operation
- Inform Martin Service Center

Error messages 41 – 50 may indicate defective accessories. Accessories already activated during self-test will cause an error message.

- During the switching-on process, the unit is automatically set to the previously used operating values.
- Bipolar automatic operation is always disabled when the unit is switched on.

4.7 Monopolar Operation

For the assignment of the numbering, see section 4.2 "Functions of the Control Elements, Connections and Displays", page 12.

4.7.1 Connection of the Neutral Electrode

If the neutral electrode is not connected, the red neutral electrode indicator LED (29) flashes. If you try to activate the unit in this condition using the finger switch or foot switch, the red indicator LED flashes at double intensity, and an acoustic warning signal will be heard. The RF current cannot be activated.

The indicator LED (29) goes dark after reaching a safe application state when a multi-surface electrode (e. g. KLS Martin TWIN-PAD) is connected. As in this case individual run-in times are to be expected, a lead time for the application must be considered.

⚠WARNING

Risk of burns from improper handling of the neutral electrode!

A one-part neutral electrode cannot be monitored. In case of insufficient contact, there will be no warning signal!

4.7.2 Connection of Handles

For monopolar cutting and coagulation, one or two handles with finger switch or a foot switch together with a handle or a finger switch can be connected. Handles with finger switch can be connected to output (27) or (28). The handles have a priority function insofar as the handle connected to output (27) has priority over the handle connected to output (28) (this can be changed if necessary, see section 4.9 "Optional Unit Functions", page 27).

Handles without finger switch or surgical instruments (e. g. resectoscopes) are connected to output (27), the corresponding foot switch to output (26). In this operating mode, a handle with finger switch can be connected to output (28) at the same time. Here, the foot switch function has priority in case of a possible synchronous activation.

Handles with coax plug as well as handles with 3-pin plug can be connected to outputs (27) and (28). For further information, please see the accessories catalog of KLS Martin.

Surgical RF instruments without switch function, such as resectoscopes, must be connected to the right socket (coax) of output (27), as the foot switch acts only on this port.

The desired active electrode must be inserted into the hexagonal guide of the surgical handle until the hexagon of the electrode snaps into place. This prevents rotation of the electrode during the application.

4.7.3 Connecting Accessories for the KLS Martin Argon Beamer System (MABS)

If the ME 411 is operated together with an Argon Beamer System, an Argon Beamer handle (MABS handle) is usually connected to output (27). If necessary, the MABS handle can also be connected to output (28). However, for this purpose the connection configuration must be changed on the MABS basic unit. Such a configuration requires the unit to be connected to the MABS basic device via the serial interface (37).

For further information, please see the Instructions for Use of the KLS Martin Argon Beamer System.

⚠WARNING

Risk of electric shock!

When inserting the electrode and while replacing an electrode, the high-frequency current must not be activated.

4.7.4 Selecting the Current Type

Four different current types are available in the control field **Monopolar Cut** that is marked **yellow** on the front plate.

Cutting 1
Clean cut without eschar formation

Cutting 2
Cutting current with low eschar formation

Cutting Uro 1
Clean cutting under liquids such as TUR

Cutting Uro 2
Cutting current with low eschar formation for cutting under liquids

Three different current types are available in the control field **Monopolar Coag.** that is marked **blue** on the front plate:

Contact coagulation 1
Coagulation with high depth and direct contact between electrode and tissue.

Contact coagulation 2
Coagulation with direct contact between electrode and tissue. Particularly suitable for TUR.

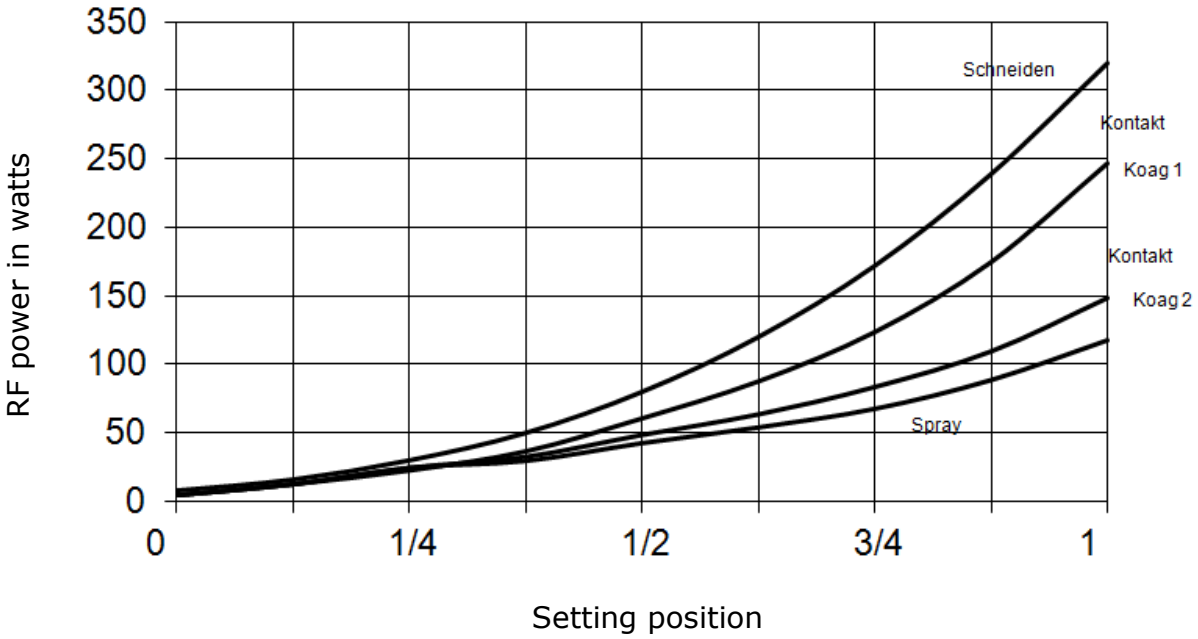
Spray coagulation
Coagulation with high voltage for surface coagulation (fulguration). Particularly suitable for hemostasis in TUR with small-area instruments such as loops.

4.7.5 Power Setting

For setting the cutting power use the power controller (8) with the corresponding power display. For setting the coagulation power use the power controller (14) with the corresponding power display. The power setting is adjusted from a preset minimum value to a maximum value depending on the selected current type (see section 9 “Technical Data”, page 38).

The progressive control characteristic line allows a very precise power increase in the lower range, and a correspondingly more strongly increasing power setting in the high power range. This enables precise adjustment of the lower power range for demanding operations without need for special functions, and to provide sufficient power reserves for applications with high power demands.

Please note that due to this advantage the controller setting in the middle of the adjusting range does not correspond to half of the maximum output power (see figure).



4.7.6 Operation

⚠

Failure to comply with the patient and user rules for the application of electrosurgery explained in section 5 "Safety Measures", page 28, may result in severe and even lethal injury!

- Ensure safe application of the neutral electrode and correct positioning of the patient.
- After prolonged application of RF current at high power, the surface of the unit can heat up significantly.
- Only accessories in flawless working condition may be used.
- During simultaneous activation of two control elements (e. g. blue and yellow button on the handle), the generator is blocked, and there will be no RF power.

Depending on the selected application purpose, the RF current is activated by pressing the yellow button for the cutting current and the blue button for the coagulation current either on the handle or foot switch. The RF current is provided in accordance with the preset current types and the set power. By actuating an activation button, the selected working channel is activated. At the same time, there is an acoustic activation signal that is different for cutting and coagulation, and the corresponding activation LED lights up. The sound of the acoustic signal increases in case of RF activation for more than 15 s. This function can be deactivated using a switch inside the unit (see section 4.9 "Optional Unit Functions", page 27).

If the unit is operated together with a KLS Martin Argon Beamer System via the serial interface (37), this volume increase is disabled when a MABS operating mode is activated.

NOTICE

The serial interface (37) on the rear of the unit is intended exclusively for use with a KLS Martin Argon Beamer System. It does not comply with the Standard V24 / RS-232 and cannot be used for the connection of a PC or similar devices.

4.7.7 Functional Check

All functions of the unit must be checked before using the unit.

The following functional checks must be performed:

- Remove plug of the connection cable for the neutral electrode from the connection socket (30).
  - — The red indicator LED (29) flashes.
  - — Upon attempts to activate the RF current, the acoustic warning signal is sounded.
  - — Activation of the RF current is blocked.
- Re-insert the plug of the connection cable for the one-surface neutral electrode into the connection socket (30).
  - — The red indicator LED (29) must not flash any longer.
  - — In case of a two-part neutral electrode, this must be correctly applied to the patient for the alarm to disappear.
- Connect connection cable with electrode handle to socket (27) or (28).
- Select the individual current types by actuating the finger switch on the electrode handle or the foot switch.
  - — The activation LEDs (2) or (9) assigned to the individual current types must light up, and the RF activation signal must sound.

⚠CAUTION

Risk of malfunction, risk of injury!

If the RF activation signal can be heard when no double foot switch or electrode handle is connected, the unit is defective.

- The unit must not be operated.
- A technical inspection must be performed.

⚠CAUTION

Risk of malfunction, risk of injury!

If the RF activation signal can be heard while the foot switch or electrode handle is connected but none of the control elements is triggered, one of these accessory parts is defective.

- The defective accessory must not be used.
- It must be replaced.

4.8 Bipolar Operation

For the assignment of the numbering, see section 4.2 "Functions of the Control Elements, Connections and Displays", page 12.

4.8.1 Function of the Neutral Electrode

For bipolar application no neutral electrode is required. Even though the indicator LED (29) for the neutral electrode flashes, the RF generator can be activated in this mode.

As a changeover from bipolar to monopolar application during the course of an operation is to be expected, we recommend application of a neutral electrode under all circumstances.

4.8.2 Operation with Hand Switch or Foot Switch

The functions **bipolar cutting** and **bipolar coagulation** are available on the unit. The following accessory components can be connected:

Bipolar coagulation

All bipolar connection cables with small coax plugs (e. g. for bipolar forceps, bipolar RF pliers) can be connected to the middle socket of socket (25). Bipolar coagulation is activated via the foot switch.

The bipolar connection socket (25) allows the connection of bipolar combination instruments for cutting and / or coagulation. This multi-purpose connection socket is already set up for the connection of instruments with coded ID.

A single-pedal foot switch for activating the bipolar coagulation channel can be connected to socket (24).

Bipolar cutting

Instruments for bipolar cutting and coagulation can be connected to socket (25) via a connection cable with multi-purpose plug. Both hand switch and foot switch operation is possible.

- A double-pedal foot switch must be connected to socket (24) for the application types bipolar cutting and bipolar coagulation.

4.8.3 Selecting the Current Type

The following current types are available in the control field **Bipolar** that is marked **yellow** on the front plate:

Cutting 1
Bipolar, clean cutting without eschar formation
(e. g. loop electrodes)

Cutting 2
Bipolar cutting with eschar formation
(e. g. plier electrodes)

One non-adjustable coagulation current type is available in the operating field **Bipolar** that is marked **blue** on the front plate.

Bipolar automatic operation
When pressed, the button (22) has the function to automatically activate the RF current on tissue contact and to deactivate it after the coagulation.

If the button **Bipolar automatic operation** (22) is activated and left in that position, the code of the connected instrument appears in the display (21) for bipolar coagulation. **00** displayed indicates an instrument without coding or the fact that no instrument is connected. **EE** displayed indicates an unknown instrument that is treated like an uncoded instrument.

⚠CAUTION

Unintentional RF activation!

In the function **Bipolar automatic operation** of the unit, there is the possibility of unintended RF activation.

- The bipolar instrument used must never come into unintentional contact with tissue or low-resistance parts.

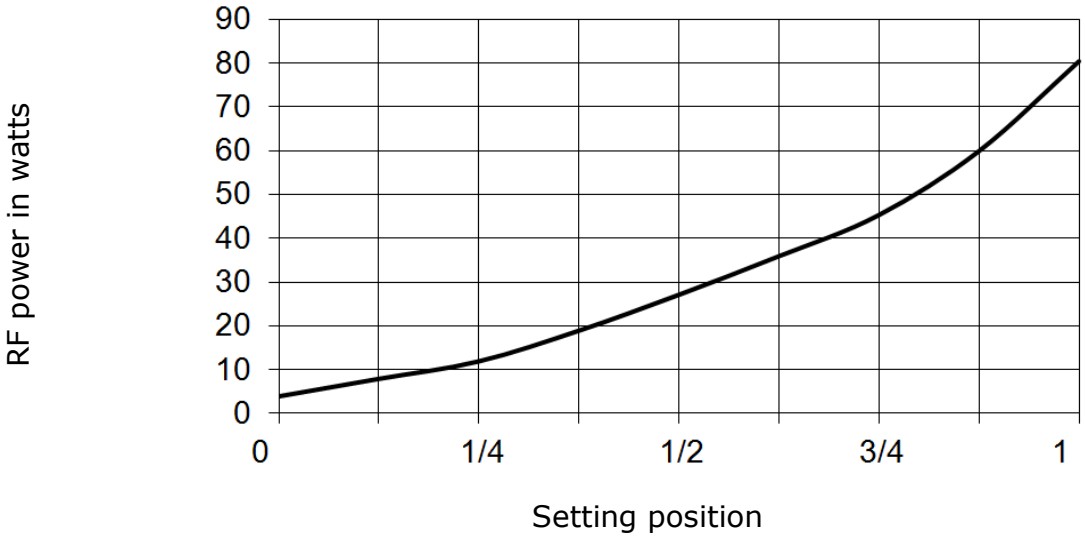
The switching-on process can also be triggered by contact with metal parts (e. g. trocars) or similarly low-resistance materials (e. g. liquids). Unintentional RF activation may also occur if the bipolar instrument is placed on the patient and thus comes into contact with tissue.

To avoid this risk, the function **Bipolar Auto Start** of the units can be deactivated as explained in section 4.9 "Optional Unit Functions", page 27. In this case, only the function **Bipolar Auto Stop** is activated. Here the RF current is deactivated via the impedance of the coagulated tissue. The RF current is then activated manually, for example via the foot switch.

4.8.4 Power Setting

Use the power controller (19) for setting the bipolar cutting power. Use the power controller (23) for setting the bipolar coagulation power. The power setting is adjusted from a preset minimum value to a maximum value (see Technical Data). The progressive control characteristic line allows a very precise power increase in the lower range, and a correspondingly more strongly increasing power setting in the high power range. This enables precise adjustment of the lower power range for demanding operations without need for special functions, and to provide sufficient power reserves for applications with high power demands.

Please note that due to this advantage the controller setting in the middle of the adjusting range does not correspond to half of the maximum output power (see figure).



4.8.5 Operation

Depending on the selected application purpose, the bipolar RF current is activated by pressing the yellow button for the cutting current and the blue button for the coagulation current either on the handle or foot switch. The RF current is provided in accordance with the preset current types and the set power. By actuating an activation button, the selected working channel is activated. At the same time, there is an acoustic activation signal that is different for cutting and coagulation, and the corresponding activation LED (15) or (20) lights up. The sound of the acoustic signal increases in case of RF activation for more than 15 s.

4.8.6 Simultaneous Operation

The monopolar and bipolar functions of the unit can be used simultaneously on a patient. The accessory components and the unit settings can be connected according to the steps described earlier.

Upon simultaneous activation of monopolar and bipolar operating modes, the activation sounds overlap.

⚠ CAUTION

Risk of malfunction, risk of injury!

Connection of a neutral electrode is mandatory for simultaneous operation. The application rules for that mode must be observed (see section 5 “Safety Measures”, page 28).

After prolonged application of RF current at high power, the surface of the unit can heat up significantly.

4.8.7 Functional Check

All functions of the unit must be checked before using the unit.

The following functional checks must be performed:

- As described in section 4.8.1 "Function of the Neutral Electrode", page 22, we also recommend connecting the neutral electrodes even for bipolar mode. If neutral electrodes are connected, the following test must be performed:
  Remove plug of the connection cable for the neutral electrode from the connection socket (30). The red indicator LED (29) flashes. Upon attempts to activate the monopolar RF current, the acoustic warning signal is sounded. Activation of the monopolar RF current is blocked.
- Re-insert the plug of the connection cable for the neutral electrode into the connection socket (30). The red indicator LED (29) must not flash any longer.
- Connect connection cable with instrument for bipolar coagulation to socket (25). Select the desired operating mode using the function buttons (17), (18) and (22).
- Activate the current type via the foot switch. The activation LEDs (15) or (20) must light up, and the RF activation signal must sound.

⚠ CAUTION

Risk of malfunction, risk of injury!

If the RF activation signal can be heard when no foot switch or electrode handle is connected, the unit is defective.

- The unit must not be operated.
- A technical inspection must be performed.

⚠ CAUTION

Risk of malfunction, risk of injury!

If the RF activation signal can be heard while the foot switch or electrode handle is connected but none of the control elements is triggered, one of these accessory parts is defective.

If the RF activation signal can be heard while the foot switch / electrode handle is connected but none of the control elements is triggered, one of these accessory parts is defective.

- The defective accessory must not be used.
- It must be replaced.

4.9 Optional Unit Functions

Upon initial delivery, the unit is set to its basic configuration. The basic configuration corresponds to the most common routine requirements in the operating theater. KLS Martin optionally provides the user with further, additional or modified unit properties. These functions can be selected inside the unit. This technical modification of the unit properties may be performed only by technicians authorized by Gebrüder Martin.

The basic configuration of the unit is shown in bold in the following table.

	On	Off
S1	**Contact coagulation with high crest factor for intense surface coagulation (contact coagulation 1b)**	Contact coagulation with low crest factor for in-depth coagulation (contact coagulation 1a)
S2	Cutting 2, increased eschar formation (2b)	Cutting 2, reduced eschar formation (2a)
S3	**The Power Peak function is deactivated**	When activating the current types CUT 1 and URO CUT 1, the power is briefly overboosted (Power Peak)
S4	**When operating with two monopolar handles, the handle connected to socket (27) has priority over the one connected to socket (28)**	When operating with two handles, both have the same priority, i. e. the one pressed first is activated and the other one has to wait
S5	Unit can only be operated with two-surface neutral electrodes	Unit can be operated with single-surface as well as with two-surface neutral electrodes
S6	**After 15 seconds of uninterrupted RF activation, the volume of the activation signal is increased**	The volume of the activation signals remains unchanged
S7	The visual and acoustic neutral electrode alarms are always triggered simultaneously	The visual neutral electrode alarm is triggered immediately, the acoustic alarm only when trying to activate a monopolar operating mode
S8	**The automatic switching-on function of the bipolar coagulation is available together with the Auto Coag Stop function**	Bipolar coagulation is activated via hand or foot switch, the function bipolar Auto Coag Stop is available.

5 Safety Measures

5.1 General Information

Electrosurgical devices are high-frequency generators designed to create high voltages and currents. In order to avoid hazards to the patient, the operators and third parties, the procedure must be applied carefully, and the operating and safety notes must be strictly observed.

⚠

Failure to comply with the following safety measures may result in serious or even lethal patient or user injury!

⚠**WARNING**

Risk of injury from too low power setting!

Set the RF power for the desired surgical effect to the lowest possible setting. On the other hand, it should also be kept in mind that too lower power settings may also pose a risk, e. g. if due to insufficient power no cutting is achieved and local coagulation results where it is not desirable or even dangerous.

The unit may be used only by persons trained in the proper and safe use of the unit. The Instructions for Use are to be adhered to in instruction and application.

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

5.2 Patient Placement

⚠WARNING

Risk of burns from stray currents!

- The patient must be placed isolated from grounded metal parts. Particular care is required to ensure that the patient's limbs do not touch any metal structures either.
- Ensure the required high-frequency insulation against the operating table by a sufficient number of layers (insulating blankets). Since during the operation moisture, perspiration, etc. are to be expected, a waterproof foil must be used to prevent wetting of these layers which serve as high-frequency insulation.
- Fluid accumulation under the patient must be avoided under all circumstances. Use further dry cloth layers where appropriate.
- Keep areas with stronger perspiration, extremities touching the trunk or skin-on-skin contact apart from each other and dry (arm-trunk, leg-leg, breasts) using insulating blankets.
- The above requirements for insulation must also be fulfilled if the patient is repositioned during the operation.

5.3 Application of the Neutral Electrode

⚠WARNING

Danger of burns from missing warning signal in case of one-piece neutral electrodes!

A one-part neutral electrode cannot be monitored. In case of insufficient contact, there will be no warning signal! The control of the RF output power can be limited for some monopolar cutting currents by one-piece, large-area neutral electrodes that do not come into direct contact with the patient's skin (so-called capacitive neutral electrodes). This can lead to the full power being emitted to the patient.

- We therefore generally recommend using a two-piece disposable neutral electrode that ensures the continuous monitoring of the patient.
- If a monopolar RF current is to be used, then a neutral electrode must be placed on the patient. Also in cases where bipolar application is intended but additional application of monopolar electricity is likely in case of complications, a neutral electrode should at least be kept ready.

⚠WARNING

Risk of burns from improper handling of the neutral electrode!

The risk of burns under of the neutral electrode is particularly high if monopolar cutting or contact coagulation currents with particularly high power and longer duration are used (e. g. TUR-P, endometrium ablation).

In order to minimize the risk of burns or other problems in the area of the neutral electrode, during application of the neutral electrode please mind the following:

- The neutral electrode must butt against the patient's body as close to the operation field as possible, reliably, and with its whole surface. For an operation field on the torso, the upper arms and thighs are good application sites.
- Safe contact of the neutral electrode must be ensured for the total duration of the high frequency application.
- Application of the neutral electrode to a limb must not impair perfusion. Particularly for longer operation times it must be made sure that the patient does not lie on the cable connection clip of the neutral electrode (risk of pressure necrosis).
- Electrodes and cables must be applied carefully. The supply cables to the high-frequency electrodes must be laid out without loops and so that they cannot touch the patient or other cables. Use only cables that are intended for use with the device according to the manufacturer's instructions.
- The current paths in the body should be as short as possible and run in the longitudinal or diagonal direction of the body, not across it, the latter particularly not on the chest. Any metal parts in or on the body should be removed if possible, insulated, or paid special attention to.
- After repositioning of the patient, the electrodes and cables must be controlled for proper attachment.
- For removal of the neutral electrode, do not pull at the cable or the connector strap.

5.4 Working with the Active Electrode

Observe the following rules when using high-frequency surgery:

- When simultaneously using electrosurgery and monitors on the same patient, use only monitoring electrodes whose leads comprise protective resistors or RF reactors. Needle electrodes must not be used for monitoring. The active surgical electrode must not be used near ECG electrodes (minimum distance 15 cm).
- The high-frequency power should be set to the lowest possible setting for the respective application.

NOTICE

An insufficient effect while using the standard setting can, for example, be caused by poorly applied neutral electrodes, insufficient contact in plug connection, cables that are damaged under the insulation or encrusted electrodes. This must be checked, and defective parts must be replaced if necessary.

⚠WARNING

Danger of burns from defective active electrodes!

Application of a current with high voltage, and in particular of a monopolar high voltage coagulation current, may cause neuromuscular stimulation in the patient.

5.5 Use of Two Electrosurgical Devices on One Patient

Basically, due to the increased risk of accidental burns by high-frequency currents two electrosurgical units should be used on one patient only if medical requirements necessitate this.

The following rules are to be observed in the concomitant operation of two electrosurgical devices:

- Only electrosurgical units with type CF application parts by Gebrüder Martin may be used.
- Each unit to be operated in monopolar application requires a neutral electrode separately attached to the patient. It is mandatory to comply with the instructions for proper application of the neutral electrode.
- Exclusively bipolar application of a unit obviates the need for application of the neutral electrode for this unit.
- The expected current paths from each active electrode to the corresponding neutral electrode must not overlap or intersect. To this end, always place each neutral electrode in the immediate vicinity of the operation field.
- The total power of the simultaneously applied currents must not exceed 400 W.

5.6 Work on Patients with Pacemakers or Other Implants

If patients have metallic implants, the RF current paths must, as a general rule, not lead through these implants. This must be considered when applying the active and neutral electrode, i. e. it is not allowed to apply the neutral electrode over endoprostheses.

In patients with active implants such as pacemakers or implanted electrodes, the application of the electrosurgical unit poses a risk. Application could result in irreparable damage to the active implant or impairment of its function. The following guidelines are to be observed.

Such patients are to be monitored using suitable technology. A defibrillator as well as an external pacemaker should be kept ready for use. The output power selected for the electrosurgical unit should be as low as possible. Do not use the active electrode of the electrosurgical unit closer than 15 cm to the implant or its electrodes. Wherever possible, use bipolar technology. The rules of application such as application of the neutral electrode must be carefully followed.

In case of metal parts present in the body, such as hip stems, ensure that they are not exposed to HF currents under any circumstances. HF currents can lead to surface damage (fusing) resulting in a notching effect that can cause fatigue bending fractures of the metal part, even several years later.

5.7 Cable Routing on the Patient

During simultaneous use of the monopolar and bipolar application ensure that the respective lines have a minimum distance of 10 cm to each other. The lines must be laid out loosely and without loops.

5.8 Operation with KLS Martin Argon Beamer System

If the unit is used together with an Argon Beamer System, the safety notes in the Instructions for Use of the MABS must be observed. The correct connection cable can be ordered as item no. 80-181-51-04.

5.9 Putting Down RF Instruments

In the intervals between use, never place RF instruments on the patient.

5.10 Accessories

Consider the following notes when using accessory equipment:

- The accessory equipment must have sufficient dielectric strength. The accessory equipment must be suitable for at least the voltages indicated in section 9 “Technical Data”, page 38.
- The accessory equipment must be in flawless working condition.

5.11 Additional Safety Notes

- During operations on low-diameter body parts, bipolar technology can be used to avoid unintentional coagulation in other areas.
- Use of flammable anesthetics, nitrous oxide (N_2O) and oxygen must be avoided. Sparking on the active electrode will always occur when using electrosurgical devices. Combustible substances that are used for cleaning or disinfection or as solvents must be evaporated before application of electrosurgery. There is the risk of accumulations of combustible liquid under the patient or in depressions such as the navel or in body cavities such as the vagina. Liquid that has accumulated in such areas must be removed before the electrosurgical unit may be used. Always be aware of the possible presence of combustible endogenous gases. Materials saturated with oxygen, such as cotton or gauze, may catch fire from the sparks that occur during the intended use of the electrosurgical device.
- Transurethral resection of the prostate (TUR):
  It is generally known that during transurethral resection of the prostate (TUR), in particular during continuous or long RF application, flammable gases can easily form. These gases may accumulate in the upper area of the bladder. The addition of atmospheric air further increases the risk of an explosion. The contact of RF current with such gas accumulations may result in the potential risk of an unintentional explosion. The gas-air pocket in the bladder should therefore always be kept to a minimum.
- The unit may be combined with other units only by the manufacturer or with the manufacturer's consent.
- The electrosurgical unit may interfere with other electromedical devices.

5.12 Inadvertent emission of HF energy

Certain foot switches have magnetically activated reed contacts and must therefore be kept out of the immediate vicinity of magnetic fields (especially of MRTs).
Otherwise this can lead to unintentional activation of the foot switches. For the same reason, magnets must be kept out of the immediate vicinity of the foot switches.
Further information can be found in the respective instructions for use of the foot switch.

6 Cleaning and Disinfection

The operator / user is responsible for cleaning and disinfecting the device. National regulations regarding cleaning and hygiene are to be complied with.

⚠WARNING

Risk of serious injury from defective accessories!

A non-functional unit or defective accessories can endanger the patient or user, as well as affect the intended functions of the unit.

- The unit and its accessories must always be kept in flawless working condition. Intact insulation, cleanliness and potential damage must be visually ascertained.
- Units and accessories unfit for further use are to be scrapped.

- The unit is not sterilizable.
- For cleaning and disinfection, the unit must be disconnected from the grid.
- When handling cleaning agents and disinfectants, no liquid may enter the unit. Use of spray is not allowed!
- Never clean the unit with scouring agents, disinfectants, or solvents which may scratch the casing or damage the unit.
- For surface cleaning and disinfection, follow the protocols recommended by the hospital or apply another nationally recognized and approved procedure.
- If accessories are to be disinfected (surface disinfection or immersion), the information of the manufacturer of the disinfectants concerning material compatibility, dosage, and exposure time must be respected.
- Non-sterilizable accessories, such as foot switches, must be subjected to disinfecting cleaning.
- Before start-up of the unit, all residual disinfectant must have been reliably removed.
- If accessory parts are to be disinfected or sterilized, the instructions for use of the accessory parts must be observed.

7 Safety Checks

At least every 24 months the device must be subjected to the following controls to be performed by people who, by virtue of their training, knowledge and experience gained from practical activities are able to properly perform such safety checks and who are not obliged to adhere to instructions with regard to such control activities.

NOTICE

The unit may be inspected only by qualified service staff of Gebrüder Martin or by companies expressly authorized to do so.

- Perform a visual check of the unit and its accessories for mechanical damage that may impair the function of the unit.
- Verify readability of safety-relevant labels.
- Check fuse inserts of the device fuse for nominal current and fuse characteristics.
- Test function according to Instructions for Use.
- Check the linear increase or decrease of the output power upon corresponding position of the rotary knob.
- Check the actual maximum output power with the maximum values (±20%) specified in section 9 "Technical Data", page 38 on all RF outputs for all available operating modes under consideration of the indicated nominal load resistors.
- Check acoustic and visual signals during power output.
- Perform electrical check according to test report for periodic safety checks.
- The maximum leakage current value may not be more than 1.5× the initially measured values and may not exceed the limit value either.
- The initially measured values are indicated in the attached test reports from the initial commissioning.
- We recommend entering the safety checks in a medical product log and documenting the test results.
- If the unit is not intact and / or not safe to operate, it must be repaired, or the operator must informed about the danger the unit constitutes.

NOTICE

A service manual that contains technical details and a description of the safety checks is available upon request. The service manual helps persons or companies authorized by us to maintain / repair the unit. The service manual also lists all components available as spare parts.

8 Accessories

The unit may be used only with accessories, wear parts and single-use articles whose safety of use has been demonstrated by a declaration of conformity. Use of uncertified accessories by other manufacturers may constitute a source of danger. In case of doubt, consult the manufacturer.

The accessories certified for electrosurgical units by KLS Martin can be taken from the accessories catalog of KLS Martin which can be requested or directly downloaded from www.klsmartin.com.

⚠ CAUTION

Risk of injury from defective accessories!

The use of accessories by other manufacturers may constitute a source of danger. In case of doubt, contact Gebrüder Martin.

9 Technical Data

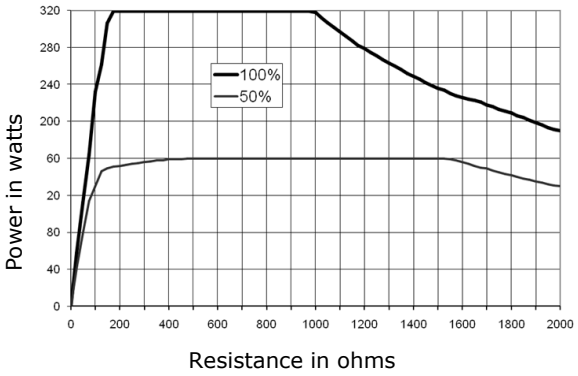
Description	Data electrosurgical unit ME 411
Mains Connection	100 V / 115 V / 127 V / 230 V / 240 V; 50 / 60 Hz adjustable via re-soldering of wire bridges by the Martin Service Center (see section 4.3, page 14)
Power consumption	in Standby mode 1 VA without RF output 42 VA at max. output power 880 VA
Protection class	I
Classification acc. to 93/42/EEC Annex IX	II b
Leakage currents LF / RF	acc. to IEC 60601-2-2
Type	CF; defibrillation-proof
Nominal frequency	400 kHz
Modulation frequency	30 kHz in Cutting 2, Cutting Uro 2 and Contact coagulation 1 65 kHz in Contact coagulation 2 50 kHz in Spray coagulation 30 kHz in Bipolar cutting 2

Description	Data electrosurgical unit ME 411		
RF output variables			
Current type	**RF output (±20%)**	**Crest factor**	**max. RF voltage in Vs (±10%)**
Cutting 1	320 W at 350 Ω	1.8 at 350 Ω	1,420
Cutting 2a	320 W at 350 Ω	2.3 at 350 Ω	2,150
(Cutting 2b	320 W at 800 Ω	2.6 at 800 Ω	2,200
Cutting Uro 1	320 W at 350 Ω	1.8 at 350 Ω	1,430
Cutting Uro 2	320 W at 800 Ω	2.6 at 800 Ω	2,700
(Contact coagulation 1a)	250 W at 200 Ω	1.8 at 200 Ω	620
Contact coagulation 1b	250 W at 200 Ω	3.0 at 200 Ω	1,150
Contact coagulation 2	150 W at 500 Ω	5.4 at 500 Ω	3,080
Spray coagulation	120 W at 1000 Ω	5.5 at 1000 Ω	4,200
Bipolar cutting 1	80 W at 500 Ω	1.8 at 500 Ω	490
Bipolar cutting 2	80 W at 500 Ω	2.1 at 500 Ω	625
Bipolar coagulation	80 W at 100 Ω	1.8 at 100 Ω	215
Information in parentheses represents alternative settings, see section 4.9, page 27.			
Operating mode	Intermittent INT 10 s / 30 s corr. to 25% duty factor		
Mains fuses	230 V: T 4 AH 115 V: T 8 AH G 5 x 20 mm		
Signal level	RF display: 55 dB(A) (adjustable 50 – 60 dB; contact the Martin Service Center) Alarm: 65 dB(A)		
Weight	14.2 kg		
Radio interference suppression	Limit values acc. to IEC 55011 and IEC 60601-2-2 Radio interference immunity acc. to IEC 801		
Dimensions W x H x D	405 x 135 x 380 mm		
Environmental conditions for transport and storage	Ambient temperature Relative humidity Atmospheric pressure	-25 °C to +70 °C (-13 °F to +158 °F) 10 – 100% 500 – 1,060 hPa	
Environmental conditions for operation	Ambient temperature Relative humidity Atmospheric pressure	+10 °C to +40 °C (-13 °F to +158 °F) 30 – 75% 700 – 1,060 hPa	
CE 0297	Compliant with 93/42/EEC		

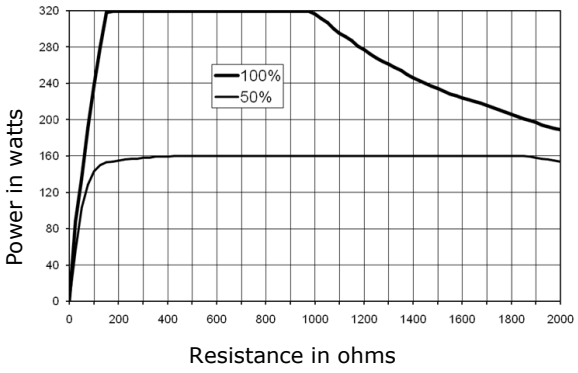
10 Diagrams

10.1 Performance Diagrams

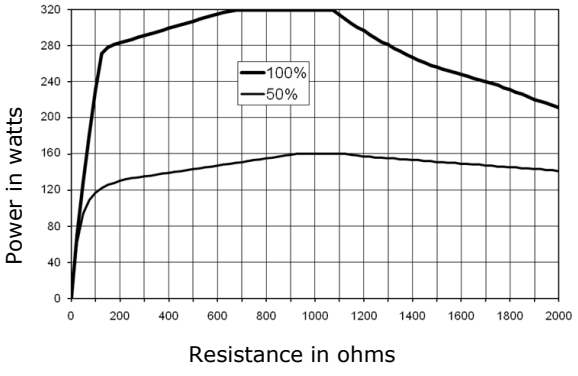
Monopolar cutting 1



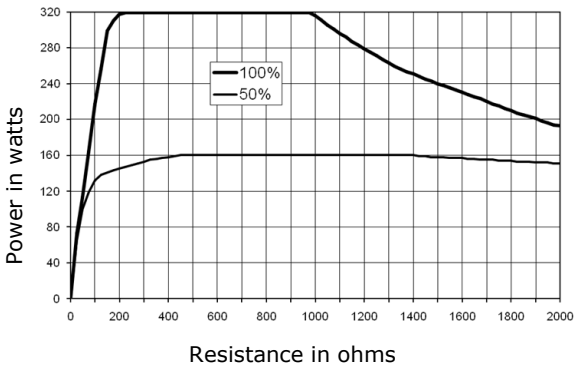
Monopolar cutting 2a



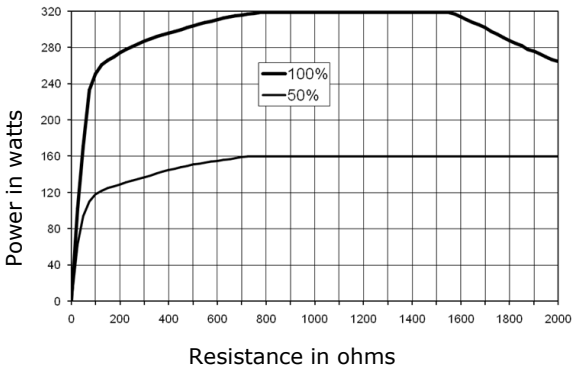
Monopolar cutting 2b



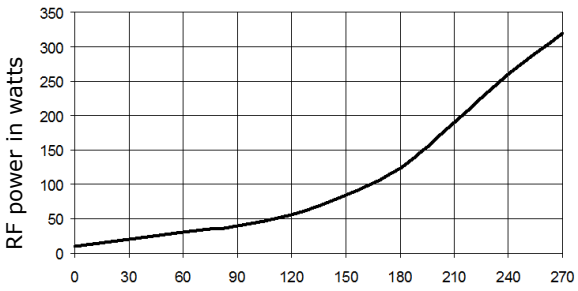
Monopolar cutting Uro 1



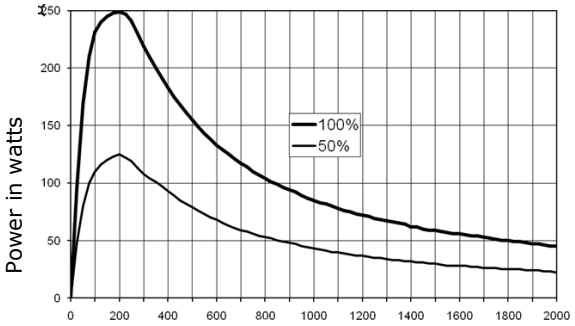
Monopolar cutting Uro 2



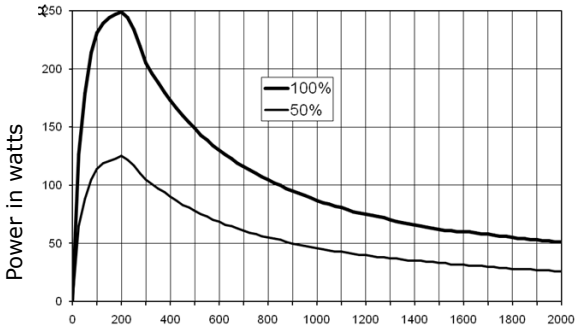
Setting monopolar cutting



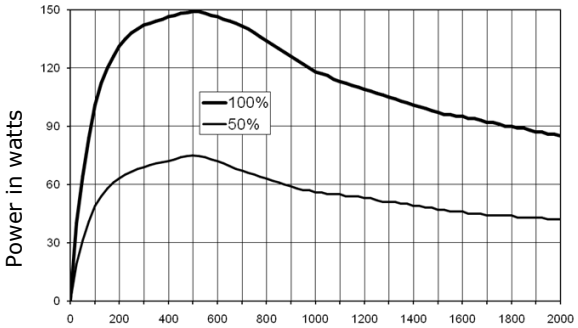
Contact coagulation 1a



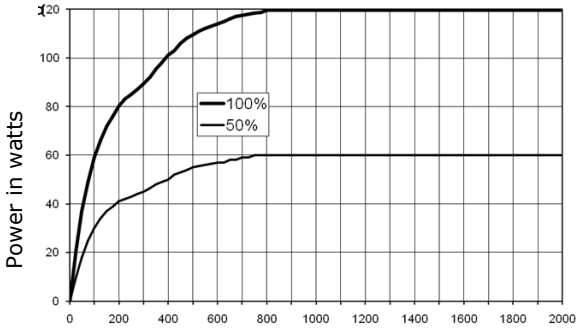
Contact coagulation 1b



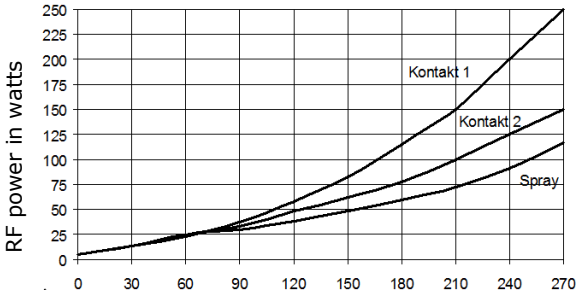
Contact coagulation 2



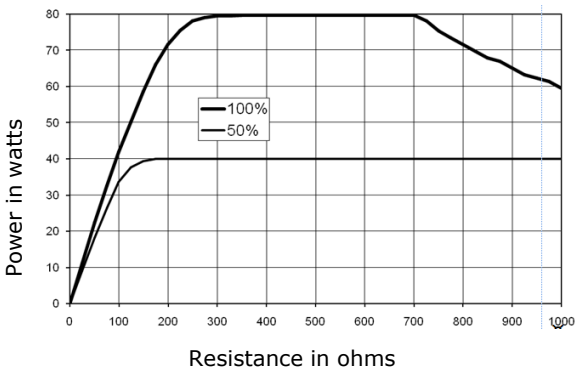
Spray coagulation



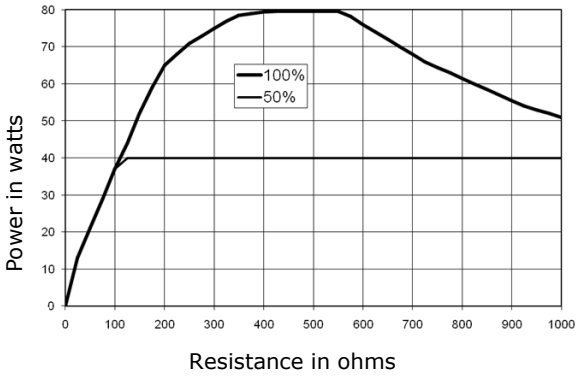
Setting monopolar coagulation current types



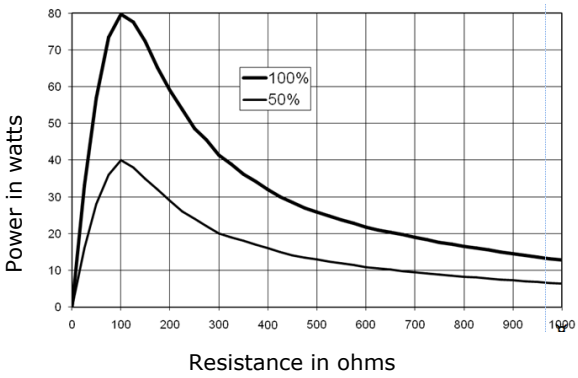
Bipolar cutting 1



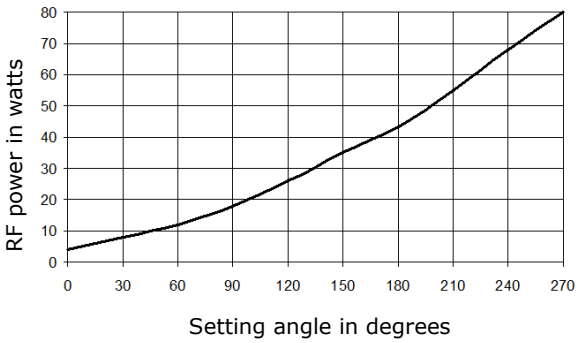
Bipolar cutting 2



Bipolar coagulation



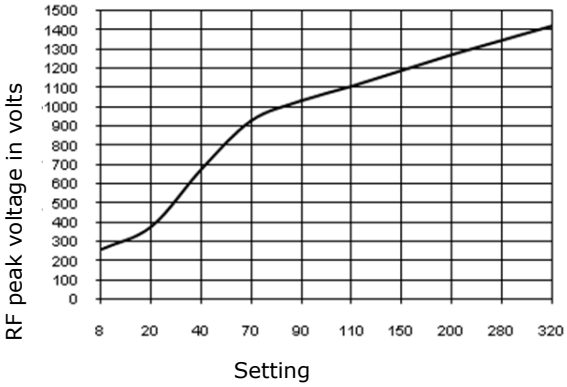
Setting bipolar current types



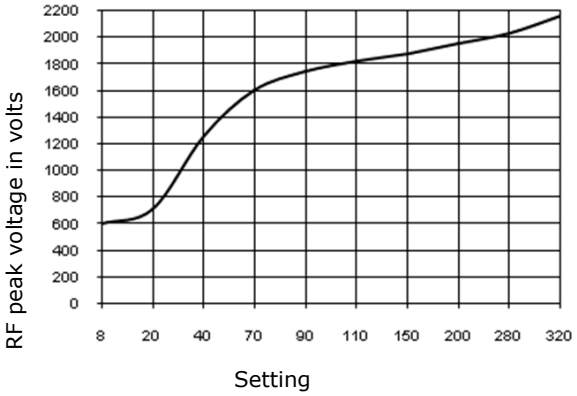
10.2 Voltage Diagrams

RF output voltage depending on the setting

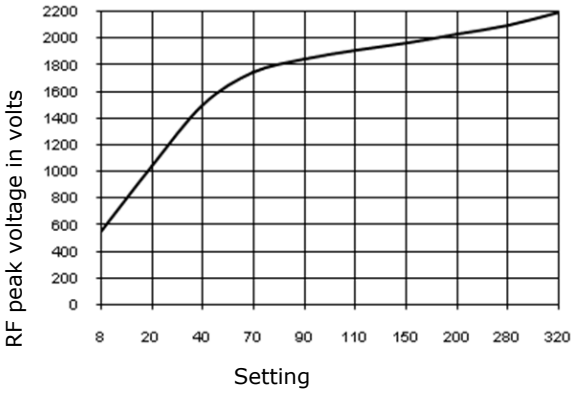
Monopolar cutting 1



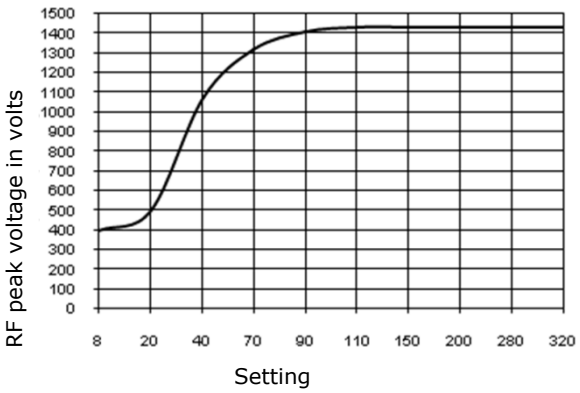
Monopolar cutting 2a



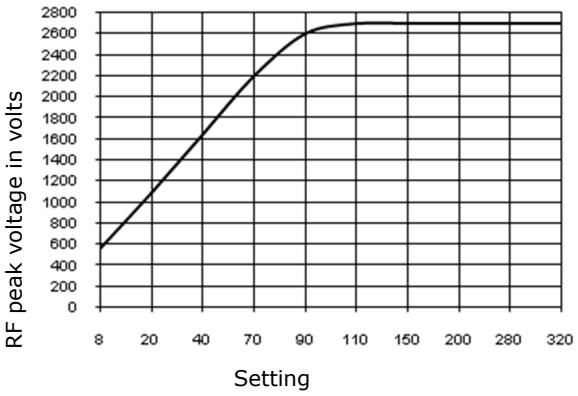
Monopolar cutting 2b



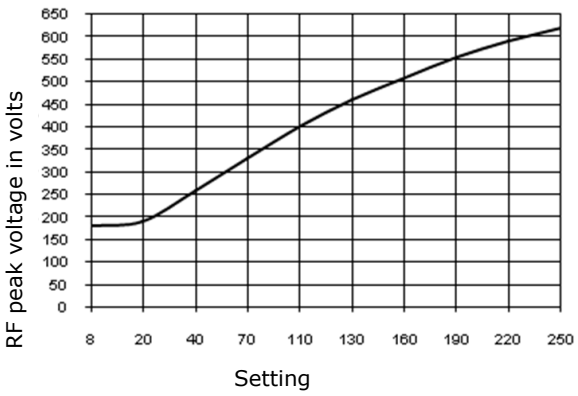
Monopolar cutting Uro 1



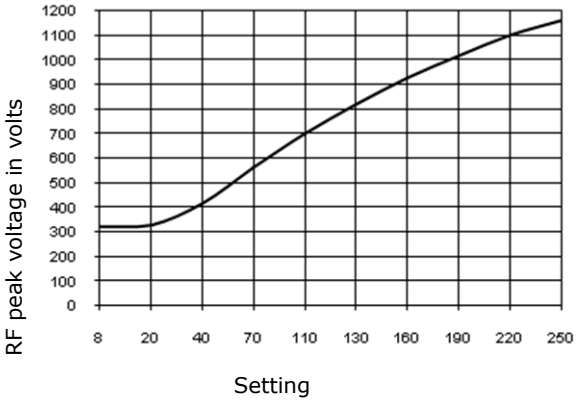
Monopolar cutting Uro 2



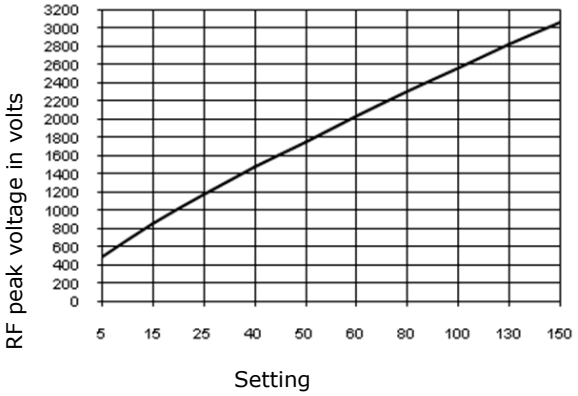
Contact coagulation 1a



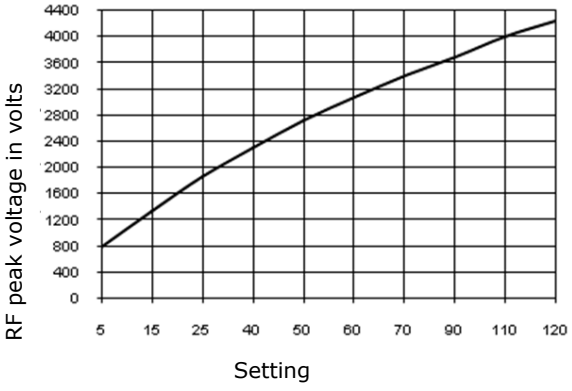
Contact coagulation 1b



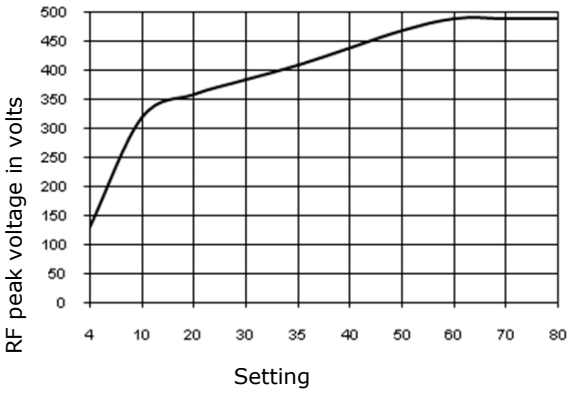
Contact coagulation 2



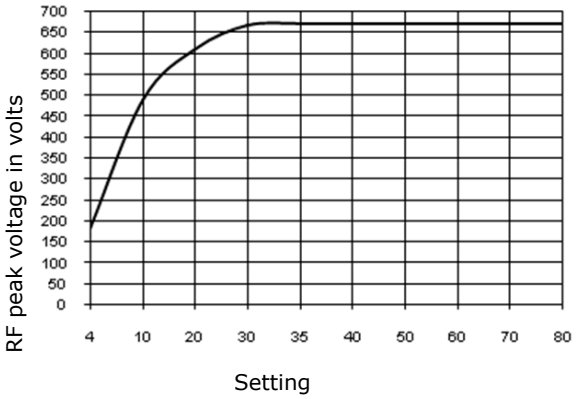
Spray coagulation



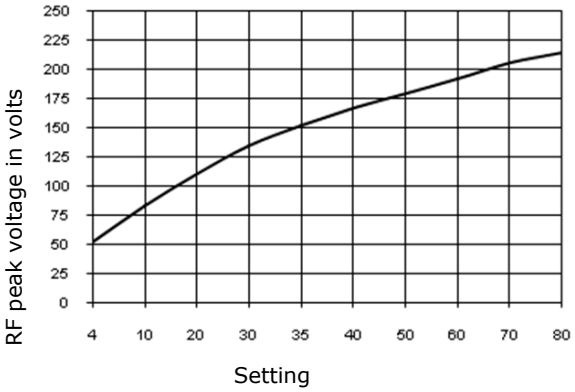
Bipolar cutting 1



Bipolar cutting 2



Bipolar coagulation



11 Guidelines and Manufacturer's Declaration Regarding Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration according to IEC 60601-1-2, clause 6.8.3.201 a) 3) Table 201: Electromagnetic emission		
The device ME 411 is intended for use in an electromagnetic environment as specified below. The user should assure that it is used in such an environment.		
Emission test	**Compliance level**	**Electromagnetic environment – Guidance**
RF emissions according to EN 55011	Group 2	The device uses electromagnetic energy exclusively for the performance of its internal functions. This may cause interference in nearby electronic equipment.
RF emissions according to EN 55011	Class B	The limits of this class are kept only in standby mode (without RF current activation)!
Harmonic emissions according to IEC 61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration according to IEC 60601-1-2, clause 6.8.3.201 a) 3) Table 201: Electromagnetic emission			
The device is intended for use in an electromagnetic environment as specified below. The user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast electrical transients / bursts according to IEC 61000-4-4	±2 kV for mains power lines ±1 kV for input and output lines	±2 kV for mains power lines ±1 kV for input and output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge 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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short power interruptions and supply voltage fluctuations according to IEC 61000-4-11	<5% U_T (>95% dip in U_T) for ½ period 40% U_T (60% dip in U_T) for 5 periods 70% U_T (30% dip in U_T) for 25 periods <5% U_T (>95% dip in U_T) for 5 seconds	0% U_T (100% dip in U_T) for ½ period 40% U_T (60% dip in U_T) for 5 periods 70% U_T (30% dip in U_T) for 25 periods 0% U_T (100% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during mains power interruptions, it is recommended to power the device from an uninterruptible power supply.
Power frequency (50 / 60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration according to IEC 60601-1-2, clause 6.8.3.201 b) Table 204: Electromagnetic immunity

The device is intended for use in an electromagnetic environment as specified below. The user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Conducted RF according to IEC 61000-4-6 Radiated RF according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ for 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio stations and AM and FM radio and TV stations, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level specified above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Recommended separation distances between portable and mobile RF telecommunications equipment and the KLS Martin device according to IEC 60601-1-2 clause 6.8.3.201 b), Table 206

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the device as recommended below, depending on the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (in m)		
Rated maximum output *P* of transmitter in watts	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1:	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 Ecological Information

12.1 Disposal of Packing

Gebrüder Martin will, as a matter of course, take back the full packaging if so desired, to recycle as many parts of the packaging as possible.

If you do not wish to make use of this offer, you can dispose of the packaging with the normal paper or domestic garbage.

12.2 Ecological Aspects of Operation

If the treatment is interrupted and the unit is not being used for an extended period, we recommend you to switch it off for safety as well as economic reasons (energy saving).

If disposable products are used in a treatment, please note that such articles must first be carefully cleaned, disinfected and – where applicable – sterilized before they are disposed of as domestic or hazardous waste. Infected sharp parts of single-use products must be handled like any other "sharps" (cannulas, needles and scalpels) in accordance with valid regulations (disposal via germ-proof and puncture-proof containers).

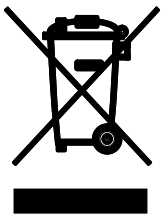
When vaporizing tissue, ensure that you do not inhale the combustion fumes that form by design over a longer period in concentrated form. During regular use of the unit, no pollutants other than these combustion products will be formed.

For removal of such combustion products, a fume suction system can be used.

12.3 Disposal of the Unit

In designing the unit, we tried to avoid using composite materials wherever possible. This allows a high degree of recycling after the lifetime of the unit. We therefore offer to take the unit back for proper disposal and recycling.

Be sure to observe your national/local rules and regulations governing disposal!



Marking of electric and electronic equipment in accordance with Directive 2002/96/EC (WEEE Directive) and the German Electrical and Electronic Equipment Act (ElektroG)

This symbol on the product or its packaging indicates that the product may not be disposed of as normal household garbage.

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