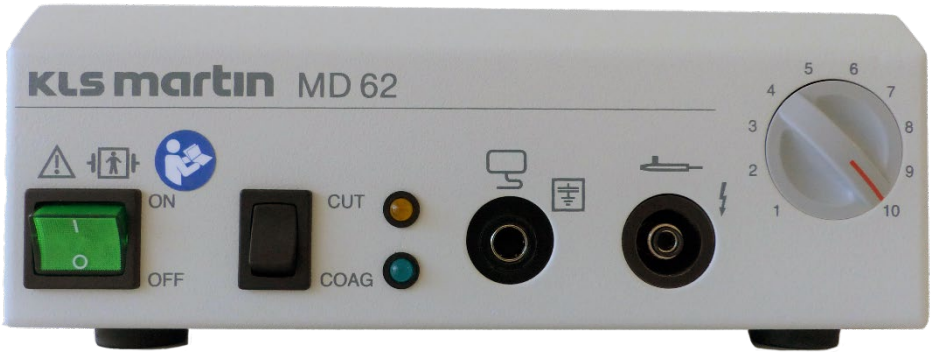
KLS martin GROUP



English

Electrosurgical unit MD 62

Instructions for Use

CE 0297

REF 90-633-52-30 / Revision 09
Date of Release: 2023-11

www.klsmartin.com

Brief Instructions for Use MD 62

For the allocation of the position numbers, see Chapter 4.1 Technical Specification, page 12

? V

Connection to the network after the voltage check

Power switch to ON

Connection of the neutral electrode

No neutral electrode = monoterminal application

Connect the neutral electrode to the socket (5)

Connect the HF activation via finger switch

Connect the handle with the finger switch to the socket (6)

Select the type of current using the switch (2)

Set the output power using the control unit (7)

Activate cutting or coagulation; the activation light CUT or COAG lights up and the activation signal sounds

HF activation via foot switch

Connect the handle without a finger switch to the socket (6)

Connect the foot switch to the socket (8) on the back of the device

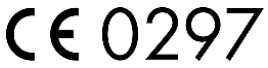
Select the type of current using the switch (2)

Set the output power using the control unit (7)

Activate cutting or coagulation; the activation light CUT or COAG lights up and the activation signal sounds

Symbol Explanation

The following symbols are either part of these Instructions for Use and/or of the product label.

	**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.
	Instructions for Use
	Follow Instructions for Use
	Catalogue number
	Serial number
	Date of manufacture
	Manufacturer
	CE marking of conformity
	Warning; Electricity!
	Dangerous voltage
	Non-ionizing electromagnetic radiation
	Protective earth (ground)

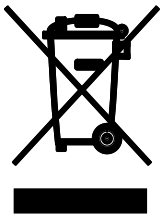
	Do not dispose this product into the ordinary municipal waste.

Table of Contents

1 Product Liability and Warranty

1.1 General Information

We thank you for buying one of our products.

This product bears the CE-marking, which means that it satisfies the essential requirements laid down in the EC Directive concerning medical devices.

We are the manufacturer of this product:

KLS Martin SE & Co. KG

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

1.2 Scope of Delivery

HF generator

- Electrosurgical unit MD 62
- Mains cable
- Instructions for Use

1.3 Intended Use

The device is primarily intended for electrosurgical application in dentistry and is used for electrosurgical cutting or coagulation of living human tissue.

Further areas of use could be dermatology or minor cosmetic surgery. In any case, the device must be operated or used in the manner described. Operation or use that deviates from this description may result in danger for the patient, user, or third parties.

The structure of the device corresponds to DIN EN 60601-1 and DIN EN 60601-2-2.

The operator may use the device only if a function check has been performed before at the operating site by KLS Martin or a person authorized by KLS Martin. In addition, a responsible person designated by the operator must have been instructed in the proper handling, application, and operation as well as in permissible combinations with other medical devices, objects and accessories. This responsible, instructed person then trains staff to operate the device for the operator. We recommend recording the instructions in a medical device book. The medical device book can be obtained from KLS Martin.

The device may be used only by persons trained in how to use it properly and safely. 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 application modes of electrosurgery.

The operational safety of the unit must be verified at regular intervals, see Chapter 9 Safety Check (SC**)**, page 32.

If the device is not functionally reliable and/or safe to operate, it must be marked as such and withdrawn from service. A technical check is mandatory in any such case.

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.

As part of the warranty, all of the defects caused by material or manufacturing faults will be remedied by our customer service team or remedied directly in the plant free of charge. This does not extend the warranty period for the device.

Important Information

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

If the repair is carried out by a person or firm specially authorized by KLS 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 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. Even after this period, changes to this product are not permitted and will result in the loss of the ability to make liability claims against KLS Martin.

1.5 User’s Inspection

Check the delivery immediately after you receive it to ensure it is complete and in good condition. Any transport damage must be reported immediately.

1.6 Hotline

Should you have any questions on how to handle the device or product or use it for clinical applications, please do not hesitate to contact the Product Management:

Phone: +49 7461 706-0

E-mail: info@klsmartin.com

If you have any technical questions, please contact the Martin Service Center:

Phone: +49 7461 706-343

E-mail: service@klsmartin.com

If you have any questions about maintenance contracts and training sessions, please contact the Head of Technical Service:

Phone: +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. The serial number is indicated on the rating plate, see Chapter 4.1 Technical Specification, page 12.

2 Notes on this Document

⚠WARNING

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

Improper handling and care as well as use other than intended can lead to premature wear and/or pose a risk for patients and users.

- Every user is required to read this document completely and follow it carefully.
- In particular, be sure to heed all cautions, warnings and danger notices.
- Keep this document accessible to users at all times.
- This text refers to male, female and non-binary individuals equally. Reference to various genders is avoided purely for reasons of improved readability.

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 serious injury!

Indicates a situation which, if not avoided, **could** result in 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

We can provide a service manual on request. The service manual helps persons or companies authorized by us with the maintenance and repair of the device. It also contains order information for all assemblies that are available as replacement parts.

3 Working Principles

3.1 Monopolar Working Principle

The electrosurgical unit MD 62 is a generator in which electrical energy from the grid is converted into high-frequency current. In monopolar use, the HF current is introduced into the operation field via an active electrode on a handle or other surgical instrument. A high energy concentration is generated in a small area at the application site of the active electrode in the area of tissue surrounding the contact point, causing the desired electrosurgical effect. Over the course of further energy transport through the patient, the current concentration is decreased via the neutral electrode or capacitively via the patient's chair. The thermal effect is therefore intended to occur on the active electrode only.

The HF generator is activated optionally via a foot switch or finger switch on the handle.

3.2 Indication for Periodontology

The electrosurgical unit MD 62 has significantly expanded the range of therapeutic instruments available to dentists in the field of periodontology. Publications by internationally renowned authors report excellent treatment success in the following indications:

- Gingivectomy
- Gingivoplasty
- Opening an acute or subperiosteal abscess
- Extension of tooth crowns (aesthetic indication) or anchor teeth for bridges (static indication) that are too short
- Operation on abnormal lips or lingual frenula
- Removal of deep muscles or ligaments in the oral vestibule
- Problems with tooth eruption
- Surgery to remove abnormal mucous membrane growth following the extraction of a tooth or other surgery
- Surgical removal of neoplasms of the mucous membrane
- Opening the mucous membrane during plastic bone corrections
- Mucous membrane periosteal opening during apicoectomy, during surgery on jaw cysts, surgery to remove displaced teeth and broken or retained root residue
- Surgery on tumors
- Biopsy
- Desensitizing of exposed tooth necks
- Creation of a subgingival channel to prepare for taking precise impressions in prosthetics
- Hemostasis using the HF current

- Treatment of periodontal pockets
- Sterilization of root canals
- Excision of lip fibromas
- Removal and leveling of hypertrophic gums

NOTICE

This information does not represent recommendations from the manufacturer. As the manufacturer of the device, KLS Martin explicitly states that decisions on treatment lie with the doctor.

4 Commissioning

4.1 Technical Specification

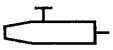
The use of this high frequency generator ensures clean and smooth tissue separation in the **cutting** function and effective hemostasis of bleeding vessels in the **coagulating** function. Matching accessories are available for each case-specific use.

The device is a modern electrosurgical unit with a power range of up to 50 W. The main field of application is what is known as monoterminal application. At the same time, this device can also be used to carry out minor monopolar surgery (using an applied neutral electrode) in other specialisms.

Fig. 4-1: Front of the device

1. Power switch ON/OFF
2. Selection switch CUT/COAG
3. Activation light for coagulation COAG
4. Activation light for cutting CUT
5. Connection socket for optimal use of a neutral electrode

6. Connection socket for a handle with and without switch
7. Output power controller



Connection for electrode handles

Symbol for classification of the unit as class BF (the unit is safe to be used with a defibrillator)

Unit is earthed for high frequency and can therefore be operated in monoterminal mode

Follow Instructions for Use

Dangerous voltage

Foot switch connection

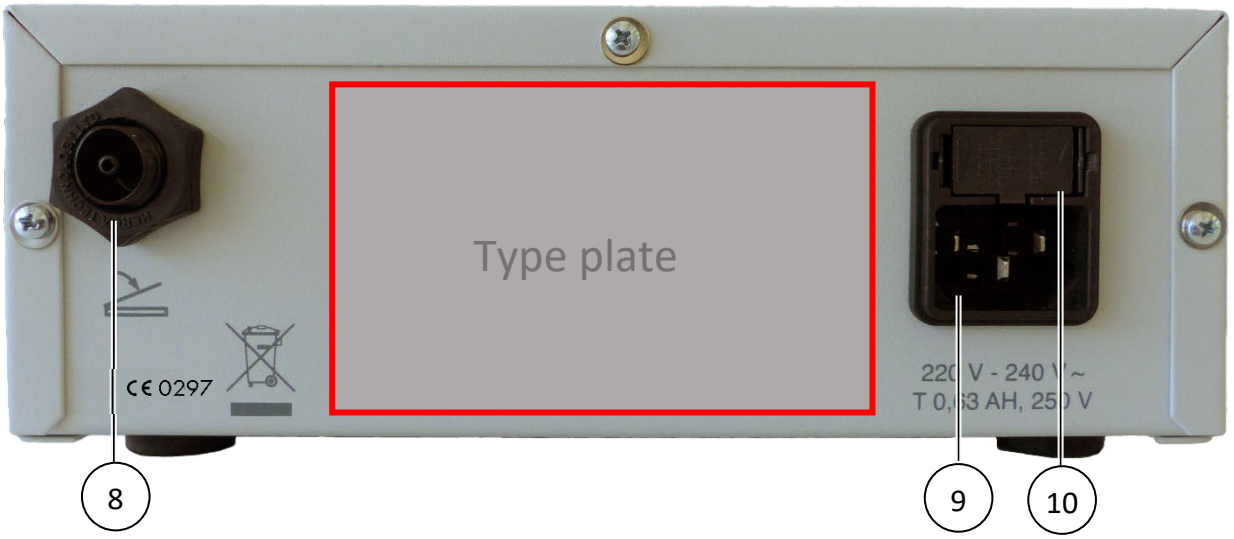


Fig. 4-2: Rear of the unit

8. Connection socket for the pneumatic foot switch
9. Connection socket for the mains cable
10. Mains fuses
    110 – 127 V: T1,25 AH
    220 – 240 V: T0.63 AH
    G 5 x 20 mm

4.2 Installation

The unit should be installed securely on a flat surface.

- Ensure that the cables that are connected (accessories, mains cable) do not compromise structural stability.
- Do not cover the unit as this prevents the dissipation of heat and emission of the activation sound.

4.3 Mains Connection

Before first switching the unit on, make sure that your mains supply matches the voltage setting of the device indicated on the label (next to the power input). If the voltages do not match, please contact the Martin Service Center.

Any switching to another supply voltage required may only be carried out on site by a person authorized by KLS Martin. Unauthorized persons may not open the unit!

The unit is available for the following voltage range:

- 220 – 240 V: T0.63 AH

⚠WARNING

Danger of electric shock!

To avoid the risk of electric shock, be sure to connect the device only to a power supply system incorporating a protective conductor.

Connect the unit to the power outlet using the mains cable. Switch the power switch (10) on the front of the unit to “I”.

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.

No special measures are required to decommission the unit.

4.4 Switching On/Off

- Connect the unit to the mains supply.
- Connect all necessary accessories.
- Switch the unit on using the power switch (1, Fig. 4-1 Front of the device, page 12).
- Carry out the function test and preliminary test.
- Select the current type CUT or COAG using the selection button (2, Fig. 4-1 Front of the device, page 12).
- Set the output power using the controller (7, Fig. 4-1, Front of the device, page 12). The dose should be selected based on the user’s experience or on the results of the preliminary test. Working speed is another parameter that impacts the effect.
- Activate the unit using the finger switch on the electrode handle or using the foot switch.

- After the end of use, switch the unit off using the power switch (1, Fig. 4-1, Front of the device, page 12).

⚠WARNING

The desired surgical effect is achieved only when the HF power is selected correctly, otherwise there is a risk of danger to the patient.

Set the HF power as low as possible for the desired surgical effect. 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 cutting is not achieved and local coagulation results where it is not desirable or even dangerous.

The 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 Operation

5.1 Functional Check

Check that the unit is in good and safe condition before use.

- Connect the unit to the power supply.
- Power switch to ON.
- Connect the accessories:
- Electrode handle
  - Connect the foot switch (if intended for operation)
  - Connect the neutral electrode (if intended for operation)

NOTICE

The active electrodes are inserted into the electrode handle from the front and attached in this way.

⚠WARNING

Danger of uncontrolled current flow with the risk of danger to the patient!

The unit should not be activated when connecting or replacing electrodes.

- Activate the unit (push the finger button on the electrode handle or the foot button).
- Activate the current type CUT or COAG.
  - The signal sounds and the optical displays are active accordingly.
- If the HF current activation emits an optical or acoustic signal and no foot switch or electrode handle is connected, the unit is defective and must be checked. If the error occurs after the foot switch or

electrode handle is connected, then either the foot switch, the electrode handle or the electrode handle connection cable is defective. Check these parts immediately and replace them if necessary!

- To prevent overheating damage to the unit, the period of time for which it is used (10 s activation/30 s break) must be taken into account.
- An overheated unit can result in thermal cutout as a result of the excess temperature. If this happens, let the unit cool before trying to activate it again.

5.2 Recommended Preliminary Test

There are many significant advantages when electrosurgery with the MD 62 is applied skillfully. The most important requirement to achieve the desired results, however, is full mastery of the treatment technique.

Practicing on a model with the various treatment electrodes is therefore highly recommended to prevent failure.

The test below is used to check whether the treatment chair is sufficiently grounded capacitively. If the desired performance is not achieved, an improvement can be made using the neutral electrode which needs to be placed in the patient for this purpose.

Raw, lean beef is most suitable as a test tissue. Coagulation effects can be clearly identified by the white discoloration that occurs as a result.

The test setup is shown in the diagram below. The person performing the test needs to sit in the treatment chair. In this arrangement, the electrical conditions in the model are approximately the same as those for the patient. The safety precautions for handling electrosurgical units must be complied with.

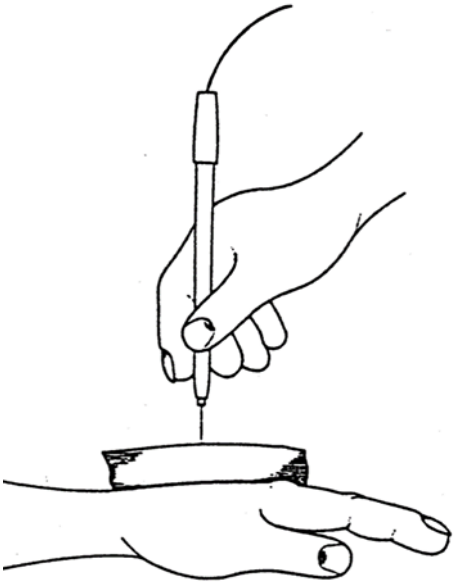


Fig. 5-1: Test setup

⚠CAUTION

Danger of high frequency burns!

It is important to ensure that there is no contact with grounded metal parts during the preliminary test described and when treating patients. The high frequency current could cause high frequency burns at these conduction points, some of which are small in area.

5.3 Dosing

The correct dosing of the high frequency power applied is critical to the success of treatment. According to Joule's law, one of the most critical factors when calculating the electrical power converted to heat is the time factor. That means that correct dosing, and hence the prevention of burns during cutting, depends on the speed that the electrode moves in the tissue.

Many authors recommend taking into account the precise scale values on the unit's dose regulator. However, the dose setting on the unit is overestimated here: pulling of the electrodes through the tissue as quickly as possible is more conclusive. A mid-range setting of the dose regulator to level 4 or 5 is sufficient. This meets the requirement for sufficiently rapid electrode movement.

5.4 Safety Aspect

An error in an electrosurgical unit can result in an unwanted increase in output power. To prevent this, a protective circuit to prevent overdosing is integrated into the unit.

5.5 Faults

If the HF activation signal sounds when the foot switch or electrode handle is connected without one of the operating elements being activated then one of these accessories is defective. This accessory must not be used. It must be replaced.

If the HF activation signal sounds and the foot switch and electrode handle are not connected then the device is defective and should not be operated. A technical check is mandatory in any such case.

In the event of a technical defect or if a technical defect is suspected, the unit must undergo technical inspection.

- Contact the Martin Service Center (see Chapter 1.6 Hotline, page 9).

5.6 Maintenance

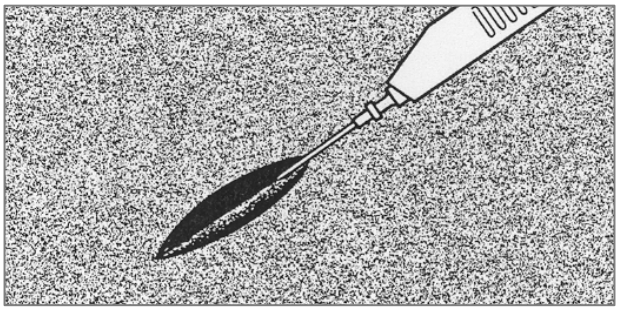
During use, no maintenance work may be performed on the MD 62.

6 Application

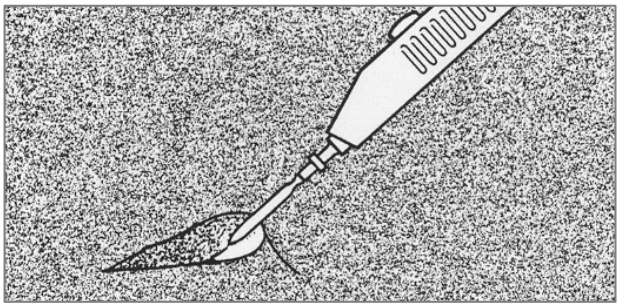
6.1 Cutting

Active electrodes in the form of needles and wire loops are used for cutting. The selection of the various electrode shapes depends on the intended cutting effect.

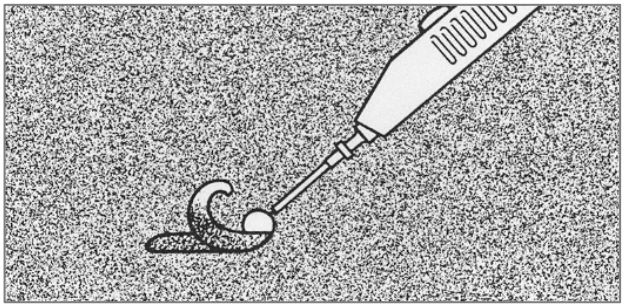
Needle or wire loop electrodes with cross sections that are as thin as possible are most suitable for smooth cuts with no sloughing of the cutting surfaces. They also facilitate rapid cutting, thus preventing the cutting surfaces from sloughing.



Electrodes with needles or wire loops with a thick cross section make cutting more difficult and cause a more or less significant sloughing of the cutting surfaces. The advantage of this cutting technique lies in the optimal hemostasis, but primary healing is not achieved in all cases.



The use of wire loop electrodes in various shapes is recommended for tissue removal and biopsies. Gradual removal leads to excellent remodeling of the gums.



6.2 Coagulation

Coagulation has a very broad range of indications in general surgery. All forms of active electrodes and even surgical instruments are used.

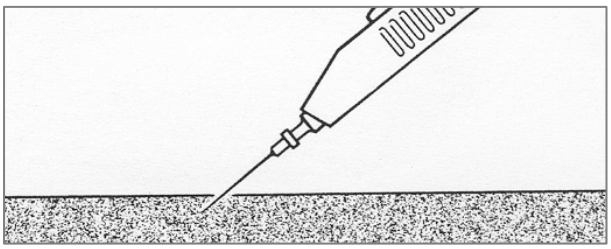
This method of working is less commonly used in dental practices. It should be noted that a coagulation effect can be achieved even at low HF power and over a long coagulation period.

⚠CAUTION

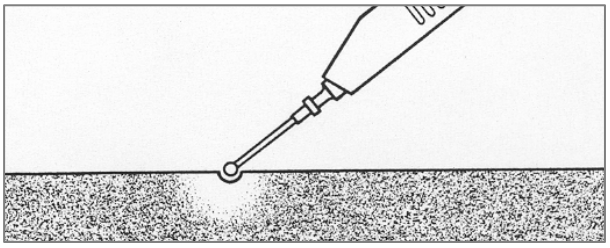
Heat damage with the risk of danger to the patient!

Heat damage to the jaw bone and roots of the teeth cannot be ruled out with certainty during coagulation.

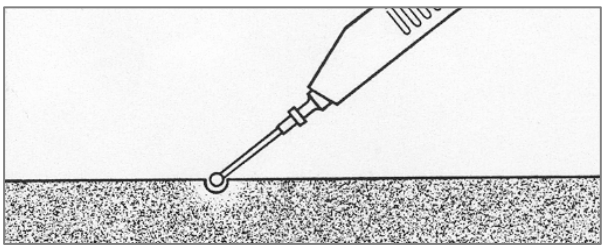
Hemostasis over the smallest possible coagulation area is carried out with fine needle electrodes.



Besides the selection of electrodes, the extent of the coagulation area can be controlled by the dosing: When dosing is low, coagulation occurs slowly and extends relatively widely.

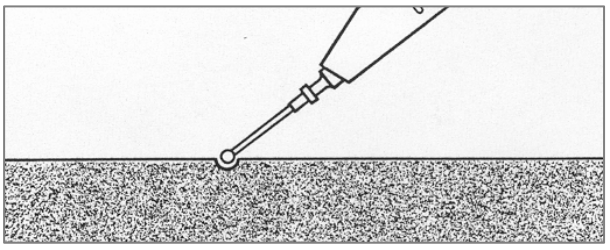


When dosing is high, coagulation occurs quickly and is very limited. The tissue in the area around the coagulation electrode dries out and the current flow reduces because of the resulting increase in resistance.

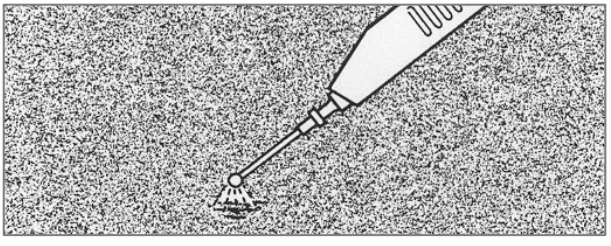


Keep electrodes clean.

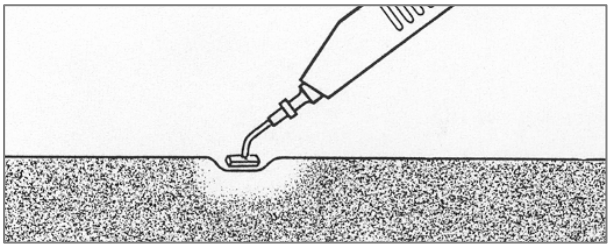
An insulating crust made of burned tissue and blood residue forms on the surface of contaminated electrodes. Sparks form and the contact surface carbonizes.



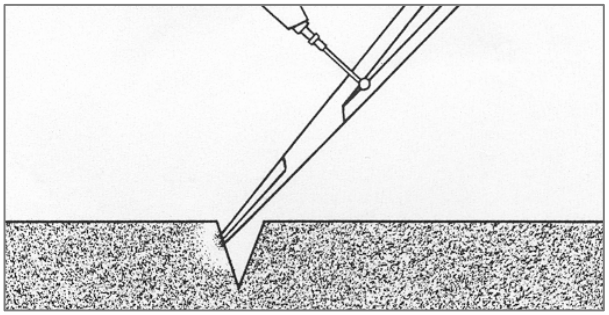
The current may only be activated once the electrode has been placed on the tissue. If the HF current is activated too early, sparks will fly from the minimal air gap between tissue and electrode and create an insulating crust.



Ball or plate electrodes can be used for hemostasis in areas of leakage and to carbonize entire sections of tissue in tumor surgery.



Bleeding vessels can be sealed quickly and safely using coagulation. The bleeding vessel is gripped with tweezers or a clamp and the instrument is rendered live by contact with the active electrode. This results in coagulation at the transition point to the body.



Insulation between the instrument (tweezers) and the user must be ensured when working in this way.

6.2.1 Connection of the Neutral Electrode

⚠WARNING

No warning signal!

A non-split cannot be monitored. In case of insufficient contact, **no warning signal** will be triggered.

Electrodes and wires must be applied carefully. The following must be taken into account in particular:

- The entire surface of the neutral electrode must be applied securely against the patient's body as close to the operation field as possible.
- Secure contact of the neutral electrode must be ensured for the total duration of the high frequency application. When applying the neutral electrode to a limb, perfusion must not be affected. **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 wires must be applied carefully. The leads supplying the high frequency electrodes must be guided without loops so they do not come into contact with either the patient or other leads. Only the wires intended by the manufacturer for use with the unit may be used.
- The leads supplying the high frequency electrodes must be guided without loops so they do not come into contact with either the patient or other leads. This applies to the neutral electrode in particular. Only the wires intended by the manufacturer for use with the unit may be used.
- The current paths in the body must be as short as possible and run in the longitudinal or diagonal direction of the body. The current paths may not run across the body, and under no circumstances through the chest. Any metal parts in or on the body should be removed if possible, insulated, or paid special attention to.
- After any repositioning of the patient, the electrodes and their wires must be checked to ensure they are attached correctly.
- Do not apply the neutral electrode above implants or other metal parts, nor above bone protrusions or scarred tissue. If necessary, prepare the application site by cleaning and degreasing it. Hair must be removed. For removal do not use substances (e.g. no alcohol) that desiccate the skin.

- For removal of the neutral electrode, do not pull at the cable or the connector strap. Quick removal of adhesive electrodes may hurt the skin.

⚠WARNING

Risk of burning from the improper handling of the neutral electrode!

The risk of burns under the neutral electrode is particularly high if monopolar cutting currents with particularly high power and longer duration of activation are used.

Secure contact of the neutral electrode must be ensured for the total duration of the high frequency application. The neutral electrode must butt against the patient's body as close to the operation field as possible, reliably, and with its whole surface.

6.2.2 Working with the Active Electrode

Compliance with the following rules must be ensured when using high frequency surgery:

- Contact between the active electrode and metal parts (implants, fillings, crowns etc.) must be avoided during HF activation.
- In the event of insufficient power transfer/efficacy and in the event of electromagnetic incompatibility, we recommend the use of a neutral electrode (Item no. 80-332-03-04).
- When simultaneously using electrosurgery and monitors on the same patient, only monitoring electrodes whose leads comprise protective resistors or HF chokes may be used. Needle electrodes may not be used for monitoring. The active surgery electrode may not be used near to the ECG electrodes (distance of at least 15 cm).
- High frequency power should be set as low as possible for the application in question.

Note

An insufficient effect on the active electrode with the usual settings could be caused by the following:

- Poor contact of the neutral electrode with the patient's body
- Poor contact in plug-in connections
- Cables broken beneath the insulation or encrusted electrodes
- Insufficient earthing of the patient's chair
  - A neutral electrode should be connected in this case. We recommend that a neutral electrode is generally used to ensure the most effective possible operation.

These points must be checked and any defective parts replaced.

7 Safety measures

7.1 General Information

⚠WARNING

Non-compliance with the safety measures listed below may result in serious or even fatal injury to the patient or user.

The device may be used only by persons trained in how to use it properly and safely. 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 application modes of electrosurgery.

⚠WARNING

Danger of injury as a result of the power being set too low!

It should be kept in mind that power settings that are too low may also pose a risk, e.g. if cutting is not achieved because of insufficient power and hence local coagulation occurs where it is not required or is even dangerous

- Set the HF power as low as possible for the desired surgical effect, but no lower.

7.2 Other Safety Precautions

- The use of flammable anesthetic drugs, laughing gas (N_2O), and oxygen should be avoided. The use of electrosurgical units is always associated with sparking on the active electrode. Flammable substances used as detergents or disinfectants or as solvents must be allowed to evaporate prior to using electrosurgery. There is a danger of flammable liquids accumulating underneath the patient, in pits such as the navel or in body cavities such as the vagina. Liquid that has accumulated in such places must be wiped off before using the electrosurgical unit. There is a danger of ignition of endogenous gases. Materials saturated with oxygen, such as cotton and gauze, may catch fire from the sparks that occur during the intended use of the electrosurgical unit.
- The unit should only be combined with other units by the manufacturer or with the latter’s consent.
- Other electromedical devices may be disrupted by the operation of the electrosurgical unit.

⚠WARNING

Risk of electric shock as a result of touching live parts!

If the high frequency current is activated when using the electrode or when replacing an electrode, a high voltage will be generated on contact with the electrode by the patient or user and there is a risk of an electric shock.

- Never activate the high frequency current when using the electrode or when replacing an electrode.

⚠WARNING

There is a risk of burns resulting from the use of insufficiently insulated instruments when working with monopolar coagulation currents.

If instruments and active electrodes are insufficiently insulated, there is a risk that the user will be exposed to HF voltages. Surgical gloves provide no defined electrical insulation. They do not protect against potential voltage breakthroughs.

- In case of indirect application via a hand-held instrument (surgical tweezers), this should be insulated so as not to expose the user to the HF voltage transmitted to the instrument.

⚠WARNING

Risk of burns caused by high HF current concentration!

The hazard potential of electrosurgery increases with the power applied. The following should therefore be noted:

- High frequency power should be set as low as possible for the application in question.
- Insufficient effect at the usual setting may be caused by incorrect positioning of the neutral electrode, poor contact in plug connections, cables broken beneath the insulation, or encrusted electrodes for example. This must be checked before the HF power settings are increased.
- A defect in the electrosurgical unit may cause an unwanted increase in output power. To prevent this, a protective circuit to prevent overdosing is integrated into the unit.

HF current is emitted in line with the preset current types and the power setting. The selected working channel is activated when an activation button is actuated on the handle or foot switch. At the same time, a different activation sound is emitted after cutting or coagulation and the associated activation light (3) or (4) lights up.

⚠CAUTION

Risk of malfunction, risk of injury!

Improper handling by the user may lead to failure of the unit and injuries. Therefore, please note:

- In the case of long-lasting HF current application with high power, the surface of the unit can heat up significantly.
- The accessories must be suitable at the minimum for the voltages listed in Chapter 12 Technical Data, page 35.

Only accessories with no defects may be used.

⚠CAUTION

Risk of malfunction, risk of injury!

If the HF activation signal sounds when the double switch or handle is connected without one of the operating elements being actuated then one of these accessories is defective.

This accessory must not be used. It must be replaced.

7.3 Unit-specific Safety Measures for Use in enDtistry

Electrosurgical units are high frequency generators that generate high voltages and currents to carry out their intended use. To avoid hazards to the patient, the user, or third parties, the method must be applied carefully and the operating and safety precautions must be strictly observed.

⚠CAUTION

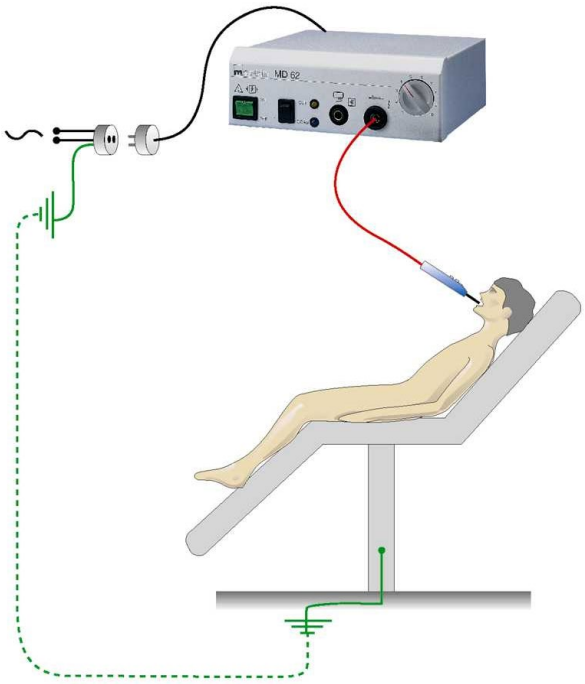
Risk of injury caused by the generation of heat!

Failure to comply with the following safety precautions can lead to injuries caused by burning and jeopardize the outcome of treatment.

When using the monoterminal treatment method that is standard with the MD 62 electrosurgical unit, it is necessary to ensure in particular that there are no small contact areas between the patient and metal parts leading to a grounding potential on the treatment chair. Heat can be generated at these areas.

- Attach neutral electrodes to the patient in such a way that safe contact over a large surface is ensured for the entire duration of the high frequency application.
- Inform the patient.
- Check the measure.

If a grounded patient chair is available, monoterminal application is possible. In this case, no neutral electrode is necessary. It is necessary to ensure that an adequate form of earthing is provided. If this is not the case, a neutral electrode must be used.



- The following cases may lead to the failure of the unit or to thermal cutout:
  - An insufficient effect at the usual setting may be caused by a lack of or insufficient earthing of the treatment chair.
  - Activating the unit over an extended period of time without actually working with it is not permitted.
- The connection cable to the electrosurgical handle should be guided in such a way that it does not come into contact with the patient or grounded metal parts.

- The electrosurgical handle may not be placed in or on the patient. Otherwise there is a risk of possible uncontrolled activation. Metal parts on or in the patient, including jaw implants and metal crowns, may conduct current on HF activation. This means a possible risk to patients and to the proper function of these parts.

Compliance with the following rules must be ensured when using high frequency surgery:

- High frequency power should be set as low as possible for the application in question.
  An insufficient effect at the usual settings could be caused by the following, for example:
  - Poor contact of the neutral electrode
  - Poor contact in plug-in connections
  - Cables broken beneath the insulation or encrusted electrodes
- This must be checked and any defective parts must be replaced.
- The use of electrosurgical units is always associated with sparking on the active electrode. Flammable substances must be allowed to evaporate prior to using electrosurgery. Flammable substances that have accumulated must be wiped off before using the electrosurgical unit. Materials saturated with oxygen, such as cotton and gauze, may catch fire from the sparks that occur during the intended use of the electrosurgical unit.
- The unit should only be combined with other units by the manufacturer or with the latter’s consent.
- Other electromedical devices may be disrupted by the operation of the electrosurgical unit.
- Radios and cell phones or other emitters in the immediate vicinity may affect the safe operation of the unit.

The principle of electrosurgery is based on the fact that thermal effects (cutting, coagulation) are generated on a small active electrode. The high frequency current used flows from this active electrode to a large neutral electrode applied to the patient. The relevant lead or return cable to the HF generator closes the circuit.

In the version of monoterminal application in dentistry, this property is used to ensure that high frequency currents can flow in a capacitive manner. The patient in the treatment chair forms a capacitor of this type. The current is then guided from the active electrode to the treatment chair and from there to the generator in a capacitive manner.

7.4 Patient Positioning

⚠WARNING

Risk of burning from vagrant currents!

Electrosurgical units are high frequency generators that generate high voltages and currents to carry out their intended use.

The risk of burns is particularly high where high-power monopolar cutting and contact coagulation currents are used, while it is very low in purely bipolar application. The bipolar technique should be the method of first choice for this reason. In order to prevent formation of shunts for HF current or concentrated leakage current paths, it is mandatory to comply with the following instructions when placing the patient on the operating table:

- The patient must be positioned insulated 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. Further dry cloth layers should be used where appropriate.
- Areas with increased perspiration, extremities touching the trunk or skin-on-skin contact should be kept dry by temporarily covering them with drapes (arm-trunk, leg-leg, breasts).
- The neutral electrode should be placed as close as possible to the operation field. For surgery on the trunk, the upper arms and upper legs are good application positions.

The above-mentioned requirements for insulation must also be fulfilled if the patient is repositioned during the operation.

7.5 Working with the Active Electrode

⚠WARNING

Risk of burns upon contact of the active electrode with metallic parts!

If the active electrode is allowed to get in contact with metal parts, shunts or concentrated leakage paths can be created for the HF current. These can cause burns.

Contact between the active electrode and metal parts (implants, endoprostheses etc.) during HF activation must be avoided.

⚠WARNING

Risk or burns resulting from defective active electrodes!

Active electrodes with insulation defects can lead to a risk of burning for patients and users. Therefore, please note:

- Active electrodes, their sockets and lines must be examined for defects of the insulation before being connected.
- Do not place the leads to the active electrode over the patient or over leads from other electromedical units.
- If current types with high output voltages are to be used, it is necessary to check whether the accessories associated with the active electrode are suitable for the possible voltage load.

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

⚠WARNING

Risk of electromagnetic interference with physiological monitoring devices!

- When simultaneously using HF surgery and monitors on the same patient, only monitoring electrodes whose leads comprise protective resistors or HF chokes may be used. Needle electrodes may not be used for monitoring.
- The active electrode may not be used in the vicinity of sensor electrodes on the monitors (e.g. ECG electrodes). Please keep a distance of at least 15 cm.
- No warning signal sounds when incompatible active electrodes are used.

High frequency power should be set as low as possible for the application in question. Insufficient effect at the usual setting may be caused by incorrect positioning of the neutral electrode, poor contact in plug connections, cables broken beneath the insulation, or encrusted electrodes for example. This must be checked and any defective parts must be replaced.

7.6 Gases in the Operation Area

⚠WARNING

Risk of explosion and risk of fire!

Materials saturated with oxygen, such as cotton and gauze, may catch fire from the sparks that occur during the intended use of the electrosurgical unit. The use of electrosurgical units is always associated with sparking on the active electrode.

There is the additional risk of accumulation of flammable liquids under the patient or in anatomical cavities and recesses. Therefore, please note:

- If possible do not use flammable substances for cleaning or disinfection.
- Flammable substances used as detergents or disinfectants or as solvents must be allowed to evaporate prior to using HF surgery and removed by means of ventilation.
- Accumulation of flammable liquid under the patient, in depressions such as the navel, or in body cavities such as the vagina must be wiped away before any electrosurgical unit may be used.
- In case of increased concentrations of oxygen and/or nitrous oxide in the area of the operation field, special care must be taken.

Bubbles of pyrolysis and electrolysis gas in body cavities should be removed by appropriate irrigation to avoid significant accumulation.

7.7 Use of two Electrosurgical Units 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 units:

- Only type CF electrosurgical units with applied parts by KLS Martin may be used.
- The MD 62 may not be used together with another electrosurgical unit.
- Each unit that is operated in monopolar application requires a neutral electrode separately attached to the patient. The instructions for the proper insertion of the neutral electrode must be followed.
- Exclusively bipolar application of a unit obviates the need to insert 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.

7.8 Impact on other Devices in the Medical Practice

The intended use of high frequency current in electrosurgery can interfere with other devices (e.g. treatment chair, telephone, PC, dimmer switch) when the MD 62 is being operated.

The following measures may alleviate this interference by returning the HF current from the patient to the electrosurgical unit in other ways:

- Connecting the unit to another power outlet
- Using a neutral electrode
- Using a conventional mains filter on the PC and telephone system

If problems still occur, please contact the Martin Service Center, see Chapter 1.6 Hotline on page 9.

7.9 General Safety Precautions

The unit should only be combined with other electromedical units by the manufacturer or with their consent.

Other electromedical devices may be disrupted by the operation of the electrosurgical unit.

Exclusively bipolar application of a unit obviates the need to insert the neutral electrode for this unit.

7.10 Combination with other Devices

⚠CAUTION

Risk caused by combination with other electromedical devices!

The unit should only be combined with other electromedical units by the manufacturer or with their consent. The following should be taken into account:

- Other electromedical devices may be disrupted by the operation of the electrosurgical unit.
- Additional equipment that is connected to the device must demonstrably meet the corresponding IEC specifications.
- Anyone who connects additional units to the input or output section is the system configurator and is therefore responsible for compliance with the applicable version of standard IEC 60601-1.

The Martin Service Center can provide information on this if you have any questions.

7.11 Risks Associated with Accessories

⚠CAUTION

Risk of injury from defective accessories!

Using a accessories that are not fully functional, damaged or defective can pose a hazard to patients or users and compromise the proper functioning of the electrosurgical unit.

- Accessories to electrosurgical units must always be kept in perfect functional condition.
- The use of uncertified accessories by other manufacturers may constitute a source of danger. In case of doubt, contact KLS Martin.
- Accessories marked for single use may not be recycled or reused.

Any unusable accessories must be discarded.

8 Cleaning and Disinfection

The responsibility for cleaning and disinfection lies with the operator/user of the product. Be sure to observe your national/local regulations, including potential restrictions.

⚠WARNING

Danger of serious physical injury due to damaged accessories!

A non-functional device and defective accessories can pose a risk to the patient or user and can impair the intended functions of the device.

- Be sure to maintain the unit and its accessories in perfect operating condition. Perform a visual inspection and check the system for insulation damage, cleanliness and integrity.

A unit or accessories found to be unfit for use must be withdrawn from service.

- Never sterilize the unit.
- Always disconnect the unit from the supply before cleaning and disinfecting it.
- No liquid must be allowed to enter the unit. Therefore clean and disinfect it with care. Do not use sprays!
- Never clean the unit with abrasive cleaners, disinfectants or solvents that could scratch the housing or damage the device in other ways.
- For surface cleaning and surface disinfection, use the procedure recommended by your hospital or use another nationally recognized and approved method.
- When disinfecting accessories (by surface disinfection or immersion), be sure to observe the instructions of the manufacturer of the disinfectant regarding material compatibility, dosage and exposure time.
- Accessories not suitable for sterilization, such as the foot switch, must be cleaned with a disinfecting detergent.
- All disinfectant residues must be completely removed before putting the unit in operation.
- If accessories must be disinfected or sterilized, be sure to observe the respective Instructions for Use.

9 Safety Check (SC)

At least every 24 months, the following checks and tests must be performed on the device by persons who have the necessary training, knowledge and practical experience to carry out such safety checks competently and independently.

NOTICE

The device may only be checked by qualified service personnel from KLS Martin or by agents that are expressly authorized to do so.

- Inspect the unit and accessories for mechanical damage that may impair the function.
- Check the safety-related labels to ensure they are legible.
- Check the unit safety fuses for rated current and melting characteristics.
- Carry out a function check according to the Instructions for Use.
- Check the change in energy output depending on the direction of rotation of the power controller.
- Carry out a comparison between the target and actual value of the maximum energy output at all outputs for the operating types available at the nominal load resistances indicated (see Chapter 12 Technical Data on page 35).
- Check the acoustic and optical warning for the power output.
- Electrical check is carried out according to the test report for regular safety checks.
- Leakage currents may not be more than 1.5 times the value initially measured and simultaneously no greater than the limit value.
- The initially measured values can be found in the attached test reports from the initial installation.
- We recommend entering the safety checks in a medical device book and recording the results of the checks.
- If the device is not functionally reliable and/or safe to operate, it must be marked as such and withdrawn from service. A technical check is mandatory in any such case.

NOTICE

A service manual is available on request which contains technical details and a description of the safety checks (SC). The service manual supports persons or companies authorized by KLS Martin with the maintenance and repair of the device. The service manual also contains all assemblies that are available as replacement parts.

10 Troubleshooting

Fault	Cause	Remedy
Control light for the power switch (1, Fig. 4-1, page 12) does not light up.	Mains supply (fuse) interrupted.	Check the supply. Switch on the fuse.
	Mains cable not inserted.	Insert mains cable. Replace the mains cable if it is defective.
	Control light defective.	Contact Martin Service Center.
	ON/OFF switch in the OFF position.	Set switch to ON.
High-frequency current cannot be activated.	Foot switch or electrode handle defective.	Replace accessories.
	Plug connection to the foot switch/electrode handle defective or insufficiently well inserted.	Connect accessories correctly. Replace parts on the accessories if the plug connection is defective. Contact the Martin Service Center in the event of a defect in the plug connection on the unit.
	Unit overheated, thermal cutout occurs as the treatment location may not be suitable for monoterminal application	Allow the unit to cool. Use a neutral electrode Use a grounded treatment chair
Unit does not have a working effect in CUT or COAG.	Output power set is too low	Carefully increase the output power using the control unit (7, Fig. 4-1, page 12)
	Active electrode is dirty.	Clean the electrode. Replace the electrode.
	Treatment location is not suitable for monoterminal operation.	Use a neutral electrode. Use a grounded treatment chair.

11 Accessories

The unit may only be used with accessories, wear parts and single use articles whose safety of use has been demonstrated by a declaration of conformity.

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!

Improper handling by the user may lead to failure of the unit and injuries. Therefore, please note:

- Accessories should always be visually inspected before use.
- The use of accessories made by other manufacturers may constitute a source of danger. In case of doubt, contact KLS Martin.
- The accessories must be suitable at the minimum for the voltages listed in Chapter 12 Technical Data, page 35.

Only accessories with no defects may be used.
Any unusable accessories must be discarded.

⚠CAUTION

Danger of injury from the use of non-approved accessories and cables!

The use of accessories or cables other than those specified or provided by KLS Martin can result in increased electromagnetic interference emission or reduced electromagnetic interference immunity of the unit, and to faulty operation.

In case of doubt, contact KLS Martin.
Radios, cell phones, or other emitters in the immediate vicinity of the unit may affect the safe operation of the latter. For minimum distances from emitting devices see section 14 “Guidelines and Manufacturer’s Declaration Regarding Electromagnetic Compatibility (EMC)

Guidelines and Manufacturer’s Declaration Regarding Electromagnetic Compatibility (EMC)”, page 39.

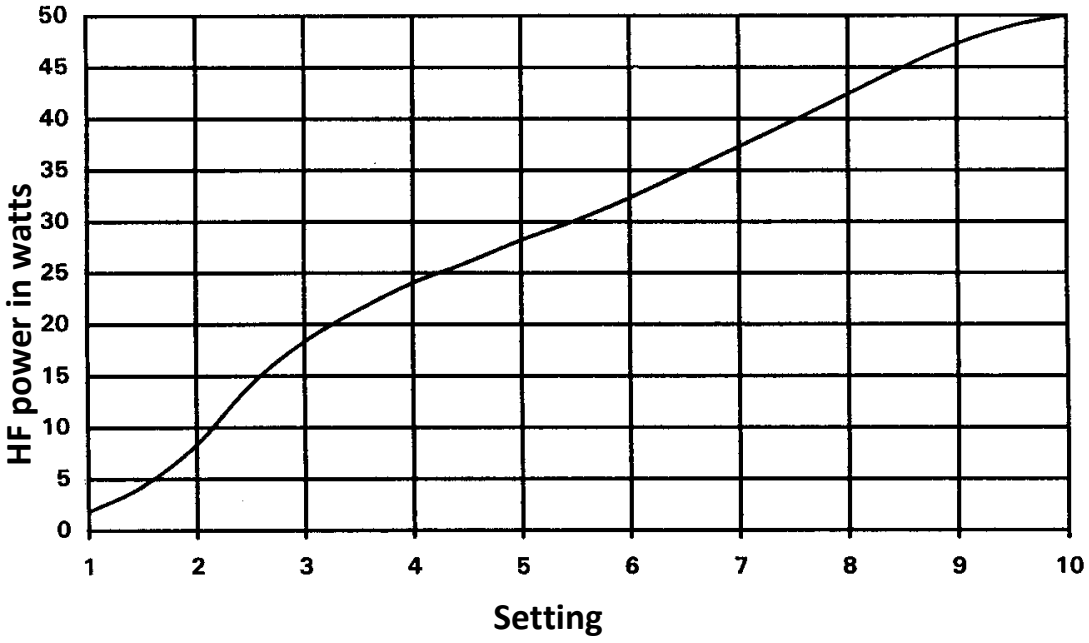
12 Technical Data

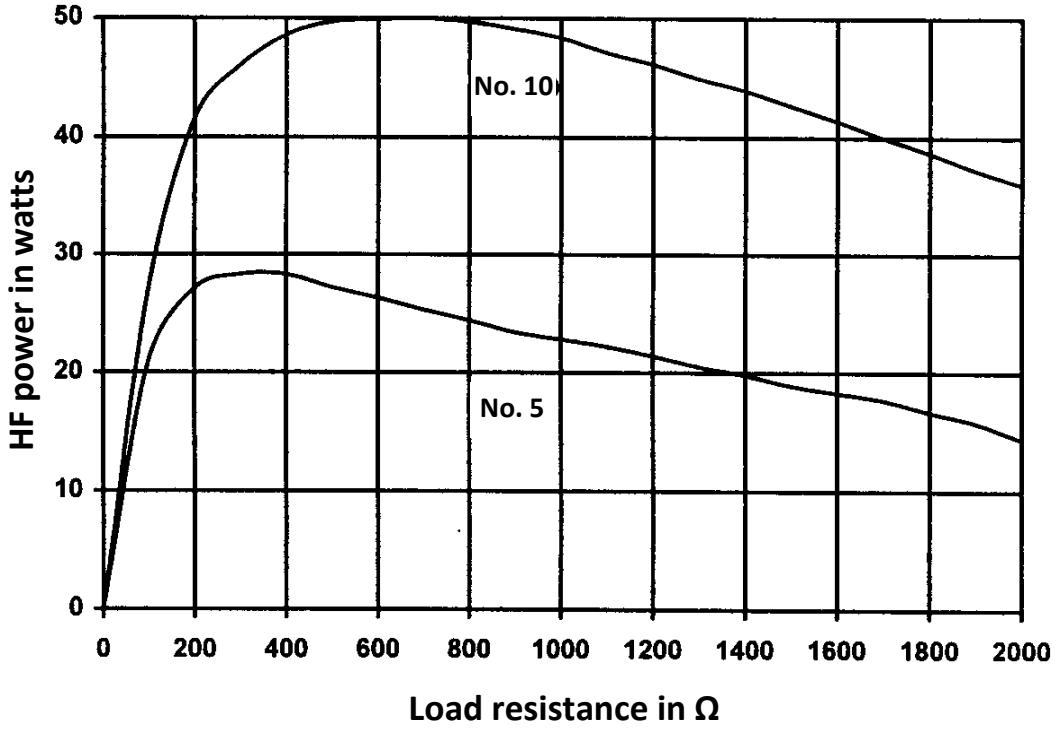
Designation	Electrosurgical unit MD 62			
Mains connection	220 – 240 V; 50/60 Hz			
Power consumption	125 VA			
Protection class	I			
IP classification	IP2X			
Type	BF			
Nominal frequency	1,000 kHz			
Pulse frequency during modulation	500 kHz			
DAB (ratio between load and pause times)	10 s/ 30 s			
HF output sizes				
Current type	**Power**	**Crest factor**	**Voltage**	**max. current**
Coagulation	30 W at 1,200 Ω	3.6	1,900 V_{max}	210 mA
cutting	50 W at 600 Ω	2.3	1,200 V_{max}	360 mA
Operating mode	Intermittent INT 10 s/30 s corresponds to 25% duty factor			
Line fuses	220 – 240 V: T0.63 AH G 5 x 20 mm			
Weight	2.8 kg			
Electromagnetic compatibility	Limits according to DIN EN 60601-1-2 with the restrictions according to DIN EN 60601-2-2			
Dimensions W x H x D	78 X 200 185 mm			
Environmental conditions for transport and storage	Ambient temperature Relative humidity Air pressure	-25 °C up to +70 °C 10 – 100% 500 – 1.060 hPa		
Environmental conditions for operation	Ambient temperature Relative humidity Air pressure	+10 °C up to +40 °C 30 – 75% 700 – 1.060 hPa		
CE 0297	Compliant with 93/42/EEC			

13 Diagram

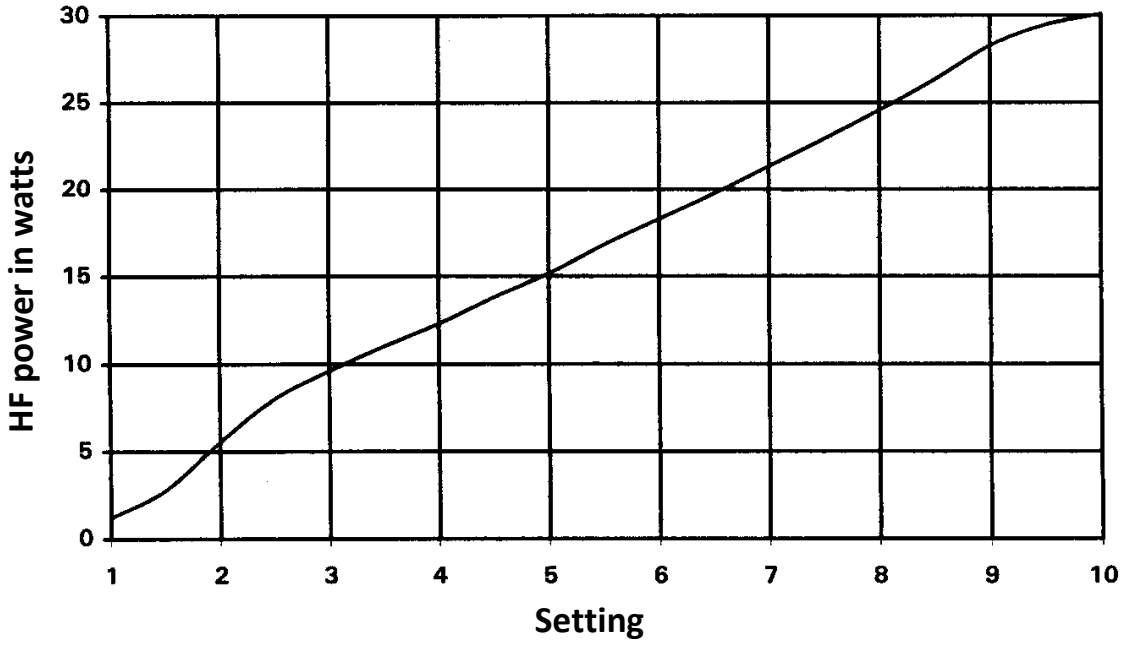
13.1 Power Diagrams

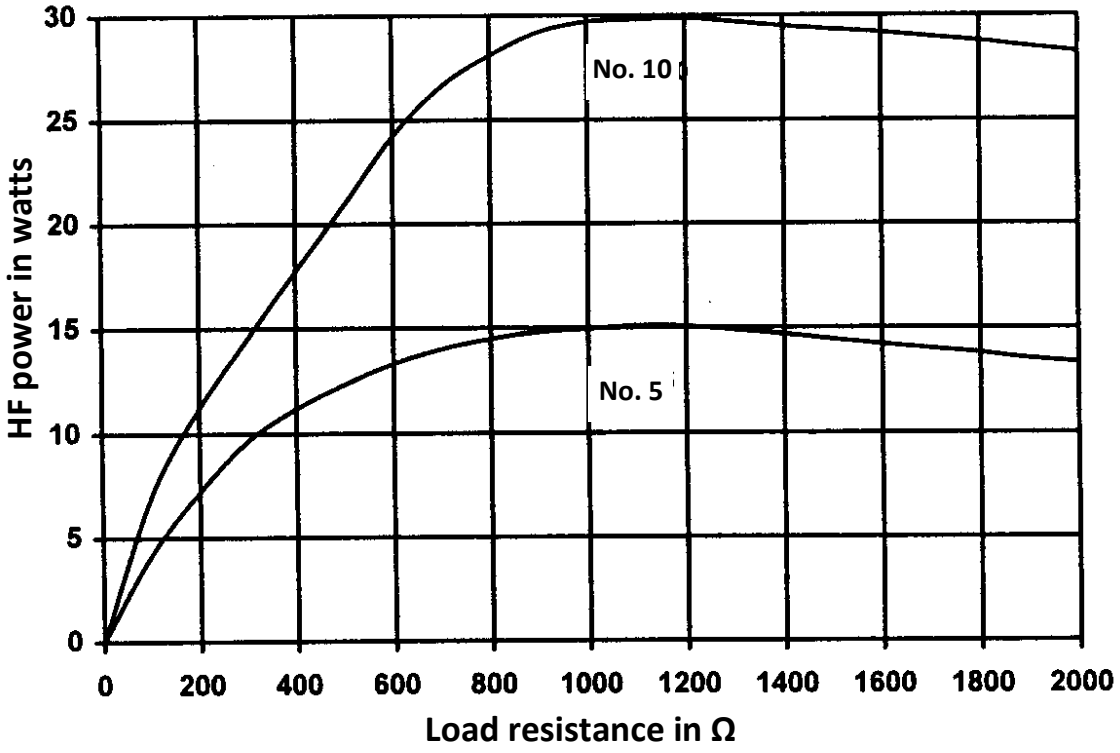
Cutting





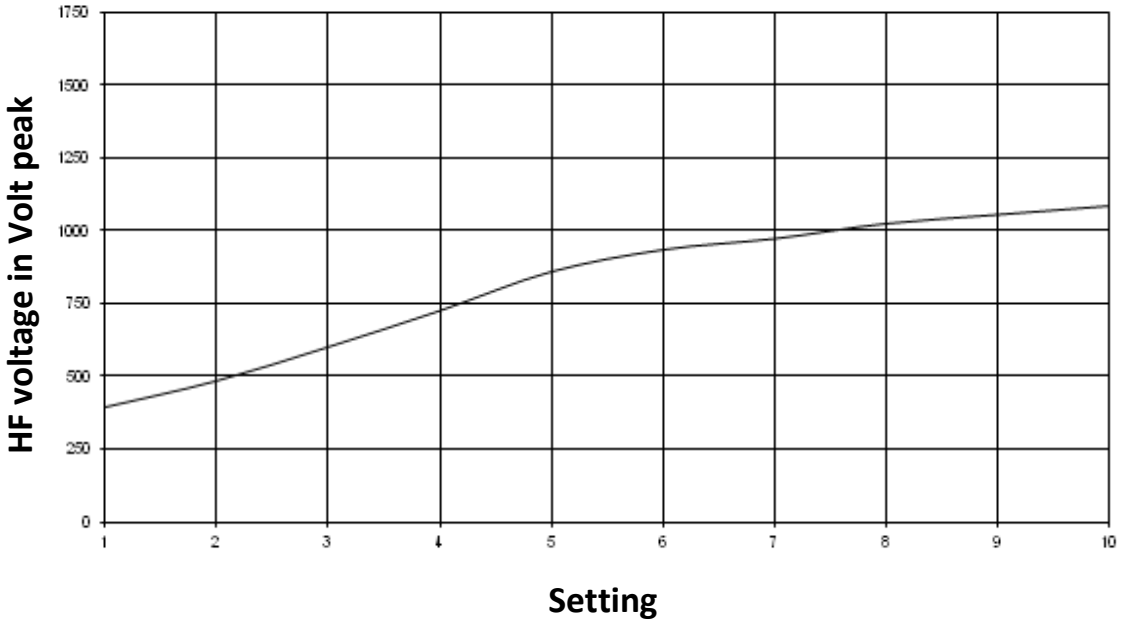
Coagulation



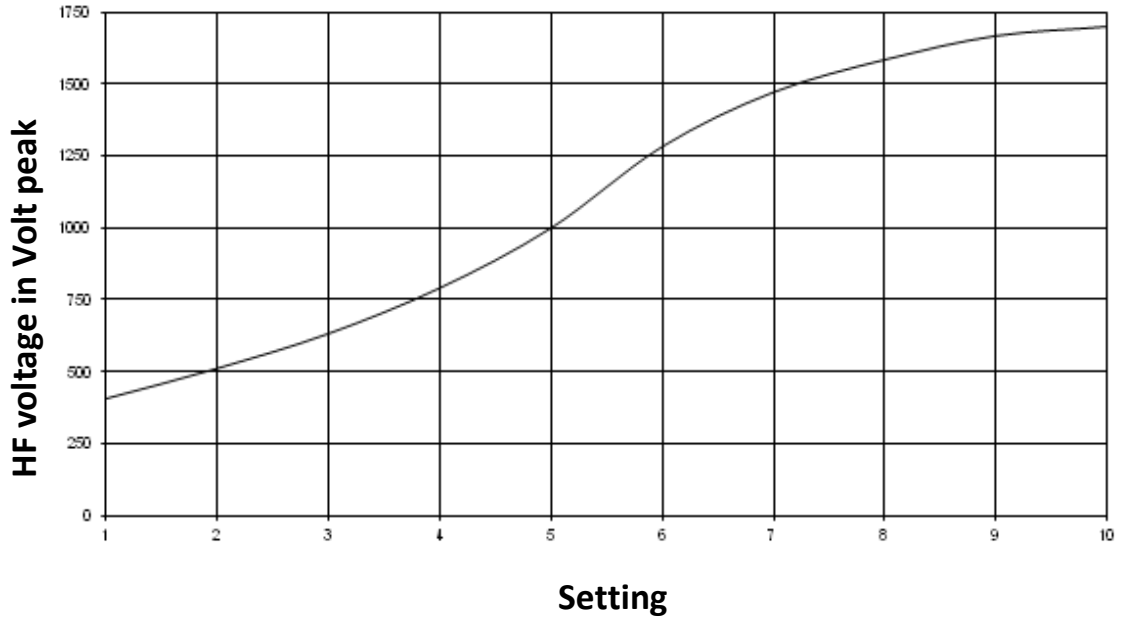


13.2 Voltage Diagrams

Cutting



Coagulation



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

Regarding EMC, medical electrical devices are subject to special safety measures, and they must be installed and operated according to the EMC regulations laid out in this document.

⚠CAUTION

Danger from incorrect operation with the stacking of devices!

Use of this device directly next to or stacked upon other devices should be avoided, as this could result in faulty operation. If use as described above is still required, this device and the other devices should be monitored closely to ensure that they operate properly and safely.

⚠CAUTION

Risk of malfunction as a result of the use of unauthorized accessories and unauthorized leads!

The use of any accessories and leads other than those specified or provided by the manufacturer of this device may result in increased transmission of electromagnetic interference or reduced electromagnetic immunity of the device and may lead to faulty operation. In cases of doubt, consult KLS Martin.

Guidance and manufacturer's declaration – Electromagnetic emission		
The electrosurgical unit MD 62 is intended for use in an electromagnetic environment as specified below. The user must ensure that it is used in such an environment.		
Test for emission of electromagnetic interference	**Compliance level**	**Electromagnetic environment – Guidance**
HF emissions according to CISPR 11	Group 2	The device uses electromagnetic energy exclusively for the performance of its internal functions. This may cause interference in nearby electronic equipment.
HF emissions according to CISPR 11	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.
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The device is intended for use in an electromagnetic environment as specified below. The user of the device must ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
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 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	The quality of the supply voltage should be that of a typical commercial or hospital environment.
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 be that of a typical commercial or hospital environment.
Voltage dips, short power interruptions and supply voltage fluctuations according to IEC 61000-4-11	0% U_T (100% dip in U_T) for ½ period at 0.45, 90, 135, 180, 225, 270 and 315 degrees 0% U_T (100% dip in U_T) for 1 period 70% U_T (30% dip in U_T) for 25/30 periods, single-phase at 0 degrees 0% U_T (100% dip in U_T) for 250/300 periods	0% U_T (100% dip in U_T) for ½ period at 0.45, 90, 135, 180, 225, 270 and 315 degrees 0% U_T (100% dip in U_T) for 1 period 70% U_T (30% dip in U_T) for 25/30 periods, single-phase at 0 degrees 0% U_T (100% dip in U_T) for 250/300 periods	The quality of the supply voltage should be that of a typical commercial or hospital environment. If during activation of HF output power any perceptible problems with the power supply should occur, it is recommended to feed the device from an uninterruptible power supply.
Supply-frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at mains frequency should conform to the typical values as found in industrial or hospital environments.
Note	U_T is the AC mains voltage prior to application of the test levels.		

Guidance and manufacturer's declaration – Electromagnetic immunity			
The device is intended for use in an electromagnetic environment as specified below. The user of the device must ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
HF conducted disturbances according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff}[a] in ISM frequency bands 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff}[a] in ISM frequency bands 150 kHz to 80 MHz	Portable or mobile radio equipment should be used no closer to the device (including cables) than the recommended separation distance of 30 cm (12"). Field strengths from stationary radio emitters, as determined by an electromagnetic site survey[b], 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. 
HF radiated disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Note	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz.

[b] Field strengths from stationary transmitters, such as base stations for radio (cellular/cordless) telephones and mobile land radio units, amateur radio stations and AM and FM radio and TV stations, cannot be predicted precisely by theory. The field strength of stationary emitters such as e.g. base stations of wireless phones and mobile radios, amateur radio stations, AM and FM radio- and TV stations can, theoretically, not be predicted reliably. 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.

Recommended separation distances between portable and mobile HF telecommunications equipment and the MD 62			
Requirements for high-frequency wireless communication equipment			
Frequency band (MHz)	**Test frequency (MHz)**	**Modulation**	**Compliance level (V/m)**
380 – 390	385	Pulse[a] – 18 Hz	27
430 – 470	450	FM ± 5 kHz sweep or pulse[a] – 18 Hz	28
704 – 787	710, 745, 780	Pulse[a] – 217 Hz	9
800 – 960	810, 870, 930	Pulse[a] – 18 Hz	28
1700 – 1990	1720, 1845, 1970	Pulse[a] – 217 Hz	28
2400 – 2570	2450	Pulse[a] – 217 Hz	28
5100 – 5800	5240, 5500, 5785	Pulse[a] – 217 Hz	9
Note	A minimum safety distance of 30 cm (12”) between portable HF communication equipment emitting in the respective frequency band and the KLS Martin MD 62 should be observed. This includes e.g. cell phones and WIFI, RFID and Bluetooth devices. Non-observance may result in reduction of the performance features of the device.		
[a] Pulse modulation is defined as a square wave signal with 50 % duty cycle.			

15 Environmental Information

15.1 Packaging

KLS Martin will take back the full packaging upon request. Whenever possible, parts of the packaging will be recycled.

If you do not wish to make use of this offer, you can dispose of the packaging as paper and household waste.

15.2 Ecological Aspects of Operation

Whenever the unit is not used for an extended period of time due to treatment pauses, we recommend you to switch it off for safety as well as economic reasons (energy saving).

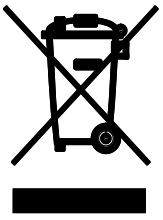
If single-use products are used for treatment, please note that they may only be discarded in the general household or problematic waste after careful cleaning, disinfection and, if necessary, sterilization. Infected sharp parts on single-use products are treated like other sharps (cannulas, needles and scalpels) in accordance with the applicable regulations (disposal in leak-proof and puncture-resistant containers).

When vaporizing tissue, you should ensure that you do not inhale the concentrated combustion products that are generated during proper use over an extended period of time. During regular proper of the unit, no pollutants other than the above-mentioned combustion products will be formed.

A smoke evacuator can be used to aspirate the smoke generated.

15.3 Disposal of the Device

In designing the device, we tried to avoid using composite materials wherever possible. This design approach ensures that it can be recycled to a large degree after the end of the device's service life. We therefore offer to take the device 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 2012/19/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.

KLS Martin SE & Co. KG
A company of the KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

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