Electrosurgical and Cosmetic Unit ME K3

Instructions for Use

KLS martin GROUP

Table of Contents

1 Warranty

Martin will accept no liability for the safety, reliability and proper functioning of this unit unless:

- any extensions, resettings, modifications or repairs that may become necessary are carried out by persons duly authorized by Martin to perform such work;
- all electrical installations of the room where the unit is used have been carried out in accordance with IEC regulations;
- the unit is used in accordance with these Operating Instructions.

2 Specifications

Parameters	**Value/Unit**
Power supply/requirements	220–240 V; 100–127 V Can be set via soldering jumper inside unit; to be carried out only by Technical Service
Power input	without HF output approx. 18 VA at max. output approx. 140 VA
Mains frequency	50–60 Hz
Protection class	I
Classification acc. to MDD / Medical Devices Act	II b
Type of applied part (class of protection)	BF; defibrillation-proof
HF nominal frequency	450 kHz
Modulation frequency	35/90 kHz
Continuous duty with intermittent loading	10/30 s (*)

(*) Load/no-load ratio

2.1 Crest Factor(**)

Type of Current	**Value**
INDICATION-RELATED COAGULATION	4.6
BIPOLAR COAGULATION	1.5
CUT I	1.5
CUT II	2.2

(**) Crest factor = ratio of peak voltage to effective (r.m.s.) voltage

2.2 HF Power: Macro Current

Type of Current	Watts at Ohms
COAGULATION: FREE SETTINGS	30 ± 20% 1200
COAGULATION: TELANGIECTASIAS	5 ± 20% 1200
COAGULATION: OVERPIGMENTATION	3 ± 20% 1200
COAGULATION: FIBROMAS	24 ± 20% 1200
BIPOLAR COAGULATION	50 ± 20% 75
CUT I	50 ± 20% 900
CUT II	50 ± 20% 900

2.3 HF Power: Micro Current

(separately selectable via MICRO button)

Type of Current	Watts at Ohms
COAGULATION: FREE SETTINGS	10 ± 20 % 1200
BIPOLAR COAGULATION	15 ± 20 % 75
CUT I	15 ± 20 % 900
CUT II	15 ± 20 % 900

2.4 Weights and Dimensions

Parameter	Value/Unit
Weight	6.8 kg
Width	410 mm
Height	132 mm
Depth	270 mm

Design:
The functional groups can be easily replaced. Overall design complies with VDE 0750 Part 1/05.82 (= IEC 601-1/1977) and VDE 0750 Part 202/09.84 (= IEC 601-2-2)

2.5 Certification

CE 0297 conforms to 93/42/EEC

3 Technical Description

Martin's electrosurgical unit KREISZ ME K3 incorporates highly advanced power electronic components and has been designed in accordance with VDE 0750 and IEC 601 provisions and regulations.

The KREISZ ME K3 is characterized by the following main features:

- High output power enables the successful treatment of many epidermal anomalies.
- Thanks to its special performance characteristics, the unit can be used in monopolar (or monoterminal) mode.
- In line with the specific working requirements, the monopolar HF current can be optionally used either for cutting or for coagulation (hemostatic effect).
- The unit provides a monopolar jack allowing connection of a handle without finger switch (to be used in conjunction with a footswitch) or connection of a handle with finger switch.
- Bipolar coagulation is possible with the footswitch. A separate socket is available for footswitch connection.
- The MICRO function enables power reduction for difficult indications.
- The output power is adjustable in 10-step increments/decrements with the Up/Down keys.

4 User's Inspection

Warning

- **Explosion hazard!**
- **Note that the unit has NOT been designed for use in potentially explosive atmospheres. Since sparking occurs on the active electrodes, this may ignite flammable gases if present. So always ensure that any cleansing, degreasing or disinfecting agents applied have evaporated completely before using the unit.**

IMPORTANT NOTES

- Improper use of electrosurgical equipment or non-observance of safety requirements may lead to severe damage or injuries.
- So carefully read these Operating Instructions prior to using the unit, thus familiarizing yourself with the working principles of the system. Moreover, it is important to have a good understanding of electrosurgical techniques and associated basics.

DAMAGE CAUSED IN TRANSIT

The unit as well as its accessories must be checked for potential defects and transport damage/loss immediately upon receipt of the goods.

COMPENSATION CLAIMS

In case of damage or loss, compensation claims can only be recognized if the user/buyer immediately notifies either the seller or the carrier to this effect. The damage or loss must be established at once and the report must be submitted either to a MARTIN representative or to MARTIN directly so that the compensation claims involved can be duly filed with the insurer.

RETURNING THE GOODS

If the device delivered needs to be returned either to MARTIN or a MARTIN service point (authorized dealer), always use the original shipping carton if possible. Moreover, please include accompanying documents containing the following information:

Buyer’s name and address, type and equipment number, description of defect(s).

5 Measures for the Prevention of Accidental Burns

If the KREISZ ME K3 is used in monoterminal mode (which represents the usual mode of operation), particular care must be used to avoid any small-area contact between the patient and those metal parts of the patient's chair which carry a frame potential, since considerable heat may develop in such places (so contact areas should always be large). Be sure also to use only approved and non-defective accessories. Accessories that are in any way defective must be removed from service at once. Always carry out appropriate checks prior to putting the unit into operation!

If you use the KREISZ ME K3 in conjunction with a neutral (i.e. dispersive) electrode, please observe the following safety requirements:

Be sure to apply the electrode(s) and electrode lead(s) correctly. In particular, it is important to

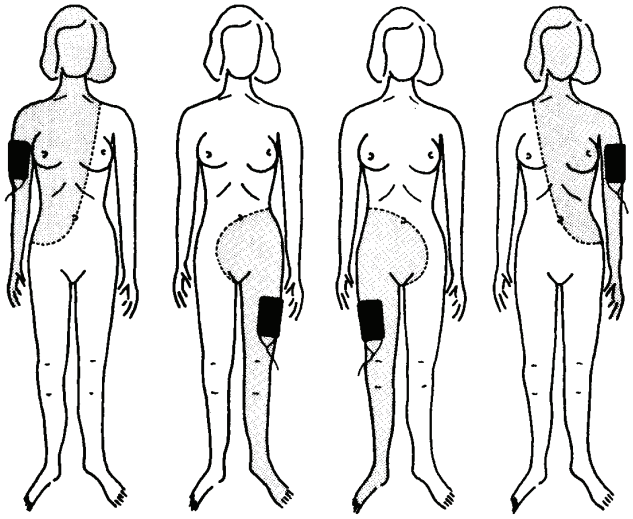
- attach the neutral electrode as close to the operating site as possible and fix it properly in place on the patient's skin (electrode must make full contact with the patient's skin; use rubber band to secure electrode in place).
- make sure that the neutral electrode maintains full skin contact while the high-frequency current is being applied. When attaching the neutral electrode to extremities, take care not to disturb the blood circulation in any way.
- make sure that the high-frequency electrode leads are guided loop-free in such a way that they will not make contact with the patient or other cables. This is particularly important with regard to the neutral electrode. Note that only the leads provided by the manufacturer may be used.
- make sure that the paths of the current flowing through the patient's body are kept as short as possible, running longitudinally or diagonally but NOT transversally (particularly so in the thoracic region). If metal parts are present on or in the patient's body, either remove them, insulate them or take particular care when applying the current (avoid contact).

When performing high-frequency surgery, be sure to observe the following rules:

- Always select the lowest possible output power required for the application.

- **Note:**
  If the effect achieved with a given power output setting is insufficient, there can be various reasons for it. For example, the neutral electrode may not be attached properly, the connectors may make insufficient contact, wire breakage may have occurred below the insulating sheath, or electrodes may have become encrusted. Check accordingly and replace defective parts if necessary.

- After repositioning the patient, always check the electrodes and leads for proper application/routing:



- Using HF surgical devices necessarily means that sparking will occur on the active electrode. So please take care that any flammable substances that may be present – such as cleaning and disinfecting agents, or solvents used in bonding agents – will have evaporated completely before using your HF surgical unit. Also note that materials saturated with oxygen (such as cotton wool or gauze/mull) may also get ignited by the sparks generated in the normal operation of the HF unit.
- The HF unit may not be used in combination with other devices unless the manufacturer has given permission to do so.
- Operating this HF unit may cause interference with other electromedical equipment.

5.1 Cardiac Pacemakers

Patients with cardiac pacemakers or pacemaker electrodes are potentially endangered insofar as malfunction or damage may be caused in the pacemaker. In cases of doubt, please contact your cardiologist for advice. When treating outpatients, always verify whether or not the patient is wearing a pacemaker. Whenever HF surgery is to be performed on patients equipped with a pacemaker, use a suitable monitoring system during the operation and keep a defibrillator at hand.

6 Connecting the Unit to the Power Supply System

The unit may be connected only to a duly installed and grounded socket. Before switching on the unit for the first time, verify that the mains voltage supplied is in accordance with the voltage indicated on the rating plate (located on the rear side of the unit).

The line fuse is located in the unit's connector socket assembly (on rear side).

7 Regular Safety Checks

At least every 24 months, fully qualified technicians with sufficient practical experience must perform the following checks and tests on the unit so its safety and reliability are assured.

- Visual inspection: check the unit and its accessories for mechanical and functional damage or defects.
- Check that all safety labels are fully readable.
- Check the fuses for compliance with rated current and prearcing time/current characteristic.
- Perform functional test in accordance with the Operating Instructions.
- Check power adjuster for proper functioning: output power must increase/decrease accordingly when rotating the adjuster both ways.
- Check actual maximum output against the specified maximum value at all outputs, for all available operating modes and for the nominal load resistances indicated in section 2.
- Check for acoustic and visual signals during current activation.
- Carry out electrical checks in accordance with the Test Report sheet for periodic safety checks.

Leakage currents may not exceed 1.5 times the value measured first and at the same time not exceed the limit either.

The values measured first are available from the test reports attached, which were established when the unit was first installed.

We recommend the user to record all safety checks and related results in an equipment log.

If the unit is not fully reliable and/or safe to operate, it must either be repaired or the user must be informed of the potential hazards involved in operating the unit.

PLEASE NOTE:

The above checks may be carried out only by qualified service technicians or by a service representative that has been specially authorized to carry out such work.

Hotline

a) Should you have any questions on how to handle the unit/product or on its clinical application, please do not hesitate to contact the

   product management
   Tel: +49 7461 706-243
   Fax: +49 7461 706-190

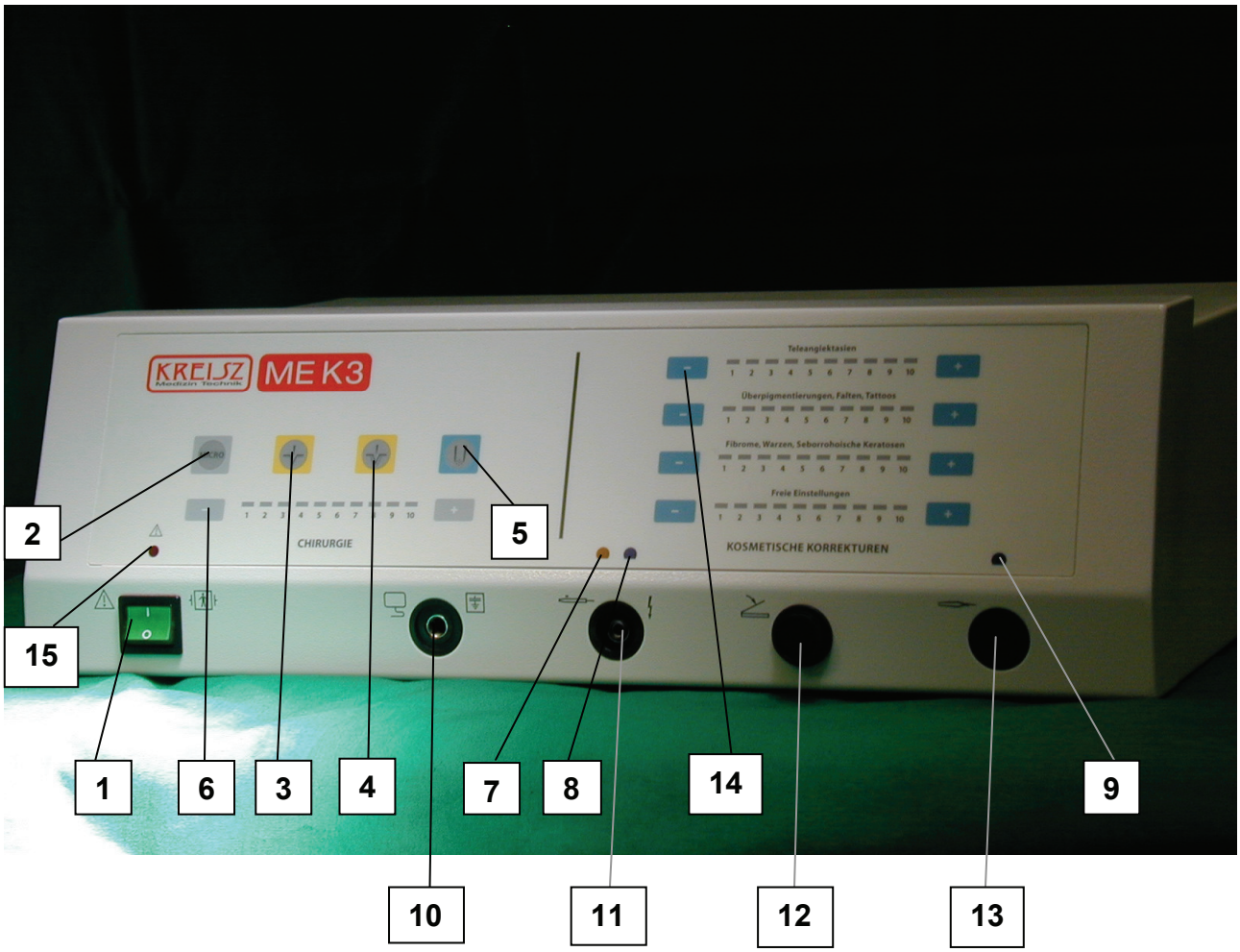
b) Should you have any technical questions please turn to our

   Martin Service Center:
   Tel: +49 7461 706-343
   Fax: +49 7461 706-203
   E-Mail: msc@klsmartin.com

Our service representatives are available Monday through Friday from 8 a.m. to 5 p.m. (CET).

Should you have any questions concerning maintenance contracts or training courses, please contact our Technical Service Manager on +49 74 61 706-332, or send an e-mail to: msc@klsmartin.com.

8 Operator Controls and Indicators



1 Power switch (ON/OFF)
2 MICRO selector switch
3 CUT I current selector switch
4 CUT II current selector switch
5 Bipolar coagulation current selector switch
6 Power adjusting buttons (Up/Down keys) for surgical applications, ten stages
7 CUTTING indicator
8 COAGULATION/FULGURATION indicator
9 BIPOLAR COAGULATION indicator
10 Neutral electrode (NE) connector jack
11 Connector jack for handle with finger switch
or handle without finger switch (for current activation via footswitch)
12 Footswitch connector socket
13 Bipolar coagulation connector socket
14 Power adjusting buttons (Up/Down keys) for indication-related applications, ten stages
15 “Equipment fault“ indicator

Rear side:
(no illustration)

16 Power cord connector socket
17 Line fuses
18 Equipotential bonding connector
19 Rating plate

9 Description of Symbols/Pictographs Used

CUT I

Non-modulated HF current with a high effective output at a relatively low voltage.
This type of current provides a sharp cut without any (or with just a little) spark formation, so no additional eschar formation occurs on cutting surfaces.

CUT II

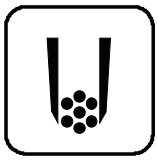
Slightly modulated HF current for cutting, with just a little eschar formation on the cutting surfaces.

No pictograph

Output power adjustment with UP/DOWN KEYS

Indication-related coagulation

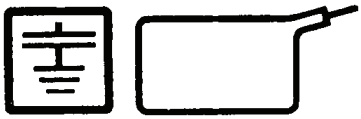
Very strongly modulated HF current with a very high voltage, to be used for fulguration or coagulation. Suitable for treating telangiectasias, spider bursts, rosacea, etc.



Bipolar coagulation requires no neutral/dispersive electrode because the instrument used ensures that the current path is kept as short as possible (from tip to tip). Low power requirements and highly limited coagulation zones ensure the highest possible degree of application safety.

Connectors for electrode handles.

Monopolar and bipolar coagulation with the footswitch.
After selecting the footswitch by pressing this key, the selected coagulation current can be activated with the single-pedal footswitch and applied to the tissue through the monopolar or bipolar instrument connected. Upon activation, the appropriate indicator will light up and an activation alarm signal will be sounded in addition. Releasing the footswitch stops HF activation.



Neutral electrode connection. Neutral electrode connected to ground when HF current is used (capacitance grounding).

Symbol indicating classification/type of equipment or applied part ("BF" meaning that device is defibrillation-proof).

ATTENTION!

OBSERVE OPERATING INSTRUCTIONS!

CAUTION! HIGH-FREQUENCY CURRENT OUTPUTS!

Warning label indicating presence of high voltages.

10 Electrosurgery – How It Works

The working principle behind high-frequency surgery (or electrosurgery) is easily explained:

At tissue temperatures above 100 °C (212 °F), the cell sap evaporates and the tissue cells are blasted open by the vapor pressure generated, which leads to tissue separation. If, in contrast, the tissue temperature remains below 100 °C, a coagulative (or hemostatic) effect is generated in the cells.

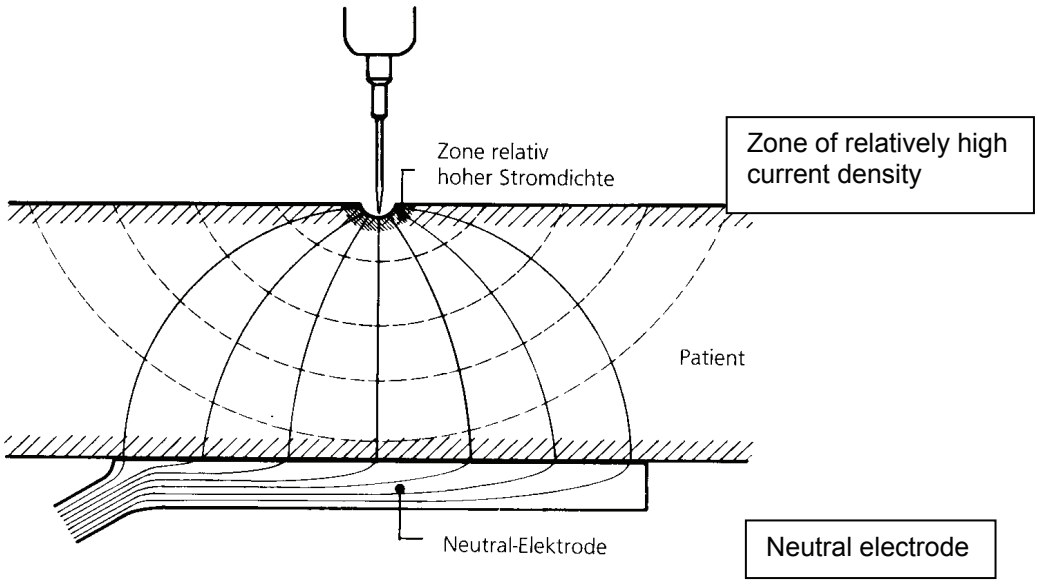
The principle of generating heat in the tissue by using high-frequency currents is illustrated in the diagram shown below:

From a small-surface **active electrode**, an HF current flows to a large-surface **neutral electrode**, transmitted either over or through the patient's body. This leads to a high current density – i.e. current per unit area (A/mm²) – in the area around the active electrode. As soon as certain threshold values are reached or exceeded – if, in other words, the dosage is high enough –, heat loss/dissipation will occur. Heat will thus be transferred to the surrounding tissue to generate the required treatment conditions.

Thin, needle- or lancet-type active electrodes produce a very high current density and, accordingly, high tissue temperatures. These types of electrode are therefore ideal for cutting purposes.

In contrast, large-surface ball or plate electrodes produce comparatively lower current densities in the patient's body, which means that less heat is generated in the tissue and distributed over a larger area. Therefore, these types of electrode are ideal for coagulation.

High-frequency currents of more than 300 kHz are required in order to prevent a Faraday effect with the corresponding irritation of the nerves and muscles of the current paths and to optimize the general conditions for electrotherapy (e.g. achieve better capacitive current conduction from the electrodes through the dry – and thus poorly conductive – skin to the tissue).



10.1 Working Principle and Intended Use

10.1.1 Monopolar working principle

The KREISZ ME K3 HF electrosurgical unit is a power generator that converts mains-supplied electric energy into a high-frequency current. This HF current is then conducted to a pointed active electrode via an electrode lead and a handle. At the point of contact, a high field density is generated in the surrounding tissue – i.e., a small-area energy concentration that produces the desired electrosurgical effect in the region where the active electrode is applied. Subsequently, the energy flows through the patient's body to the large-surface neutral electrode, whereby the power density steadily decreases. Thus, as intended, no thermal effect is produced in the region where the neutral electrode is attached. The circuit is then closed via the neutral electrode lead.

The HF generator can be activated either with the footswitch or with the finger switch if a surgical handle featuring such a switch is used.

10.1.2 Bipolar working principle

Through special design measures (insulation), bipolar instruments can be built which incorporate both an active and a neutral electrode arranged directly opposite each other. Thus, the path of the HF current is kept as short as possible, extending just from one tip of the instrument to the other. This ultrashort current path also means delimited coagulation zones at low power requirements.

10.1.3 Intended use

The KREISZ ME K3 is an electrosurgical generator intended for the electrosurgical cutting and coagulating of living human and animal tissue.

11 Start-Up

To have the system ready for use, connect it to the power supply (see section 6), then connect the electrode handle (complete with active electrode) to the unit and set the power switch (1) to ON.

Upon pressing the power switch, the unit routinely performs a self-test in which all safety-related components are checked for proper functioning.

The self-test takes approximately 10 seconds. During this period, all indicators will light up one after the other.

Warning!

Do not operate any controls either on the unit or the handle during the self-test! Also do not operate the footswitch because the system would interpret this as an error.

12 Functional Test

Prior to using the unit, always perform the following functional check: Activate the HF current by means of the footswitch or finger switch (handle). The corresponding indicator must now light up and the acoustic signal must be heard in addition.

Attention!

If HF current activation is indicated optically or acoustically despite the fact that no footswitch or electrode handle has been connected, the unit is defective and must be checked. If the same thing happens after the footswitch or electrode handle has been properly connected, this means that either the footswitch, the handle or the connecting cable of the handle is defective. In such a case, check these components immediately and replace as necessary!

If the footswitch is used for HF current activation, the handle without a finger switch must be connected to the connector jack 11.

When connecting the footswitch (socket 12), be sure to insert the plug properly into the socket. The lug provided on the inner side of the plug must properly engage with the corresponding notch provided on the socket.

To connect an active electrode, proceed as follows: Insert the appropriate electrode into the handle from the front, then fix the electrode in place by rotating the screwed cap clockwise.

13 Dosage

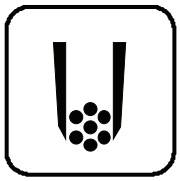
Selecting the proper dosage – i.e. the appropriate HF output power – is crucial for a successful therapy. According to Joule's law, the time factor is one of the most important factors in determining the heat generated by a given electric output power. This means in practice that both parameters – output power *and* time – will have a bearing on the coagulation result. In other words, you can also use a lower power output (or power setting) to produce the desired coagulation effect provided the current is applied correspondingly longer.

14 Types of Current Available

As a high-end electrosurgical unit, the KREISZ ME K1 allows you to select among various HF currents ranging from completely unmodulated currents (for cutting) to highly modulated currents (as required for fulguration).

Unmodulated HF current for optimal cutting results. By eliminating (filtering out) any modulations in the high-frequency current oscillations, the formation of sparks at the active electrodes is minimized, thus reducing the risk of burns on the cutting surfaces to an absolute minimum.

Slightly modulated HF current offering one of the main advantages of the electrocut in a particularly perfect manner: an excellent view of the surgical field, enabled by a complete (or nearly complete) absence of hemorrhages due to the hemostatic effect. At the same time, the experienced and skilled surgeon will be able to use this current also for the application of burn-free (carbonization-free) cuts.



Local contact coagulation in the area of the bipolar electrode tips. Bipolar coagulation requires no neutral electrode. Thanks to the special instrument used, the current path is limited to the shortest possible distance (just from one tip of the instrument to the other). Low power requirements and defined coagulation zones guarantee extremely safe working.

No pictograph Output power adjustment with UP/DOWN KEYS

Highly modulated HF current with high voltage peaks allows forced coagulation, also known as “spray coagulation”. **In contact mode, this type of current is highly suitable for treating spider veins, rosacea, telangiectasias, spider nevi, pigment disorders, senile speckles, etc.**

15 Cutting

IMPORTANT NOTE

- This function is intended for minor surgical interventions. Note that the unit may only be used for this purpose by specially trained persons such as surgeons, dermatologists, etc. This function must not be used for cosmetic applications!

16 Application

The therapy of spider bursts, rosacea, telangiectasias, spider nevi, pigment disorders, senile speckles, etc., with the KREISZ ME K3 has been developed in cooperation with Mr. Stefan Kreisz. Mr. Kreisz himself will provide the legally required user instruction and familiarize you with this special treatment technique. Please contact Mr. Kreisz through the following address:

Stefan Kreisz
Klaushager Weg 44

D-13467 Berlin
Germany

Phone: (+49) 30 405 33 989
Fax: (+49) 30 405 39 876

17 Troubleshooting

IMPORTANT NOTE

- The unit may be repaired only by us or by a person/agent that has been expressly authorized by us to carry out such work.

If repair work has been carried out by an authorized person or firm, the service technician is required to issue to the user/owner a certificate detailing about the nature and scope of the repair work done. Such certificate must show the date when the work has been carried out and must be signed, giving full particulars as to the person/firm performing the work. In all cases where repair work or modifications have been carried out by a third party, the equipment or parts modified or repaired must be additionally labeled with the repairer's identification mark.

18 Care of Accessories

To ensure good surgical results, the active electrodes must be kept clean and bright at any time.

19 Sterilization and Disinfecting

Disinfect by using ...	**common disinfectants containing solvents**	**autoclave (steam sterilization at 134 °C)**
Unit	X	–
Handle	X	X
Active electrodes	X	X
Rubber neutral electrodes	X	X (120 °C)

Note:

Never sterilize or reuse accessories marked as disposable (single-use) products!

20 Warranty

Martin's Standard Terms of Business shall apply (as revised and updated from time to time).

Accessories are consumables and as such not covered by warranty.

We will remedy free of cost – either through our Technical Service or directly in the factory – any defects that have been caused by a manufacturing defect or by the use of defective materials. Such repair shall not extend the warranty period granted for this unit.

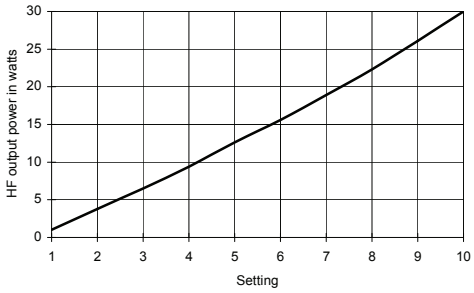
21 Accessories

The unit may only be used in combination with accessories, wearing parts and disposables that have been certified as safe for use by a testing authority and for which a Declaration of Conformity has been issued. The use of untested accessories from other manufacturers may pose a hazard. In cases of doubt, please contact the manufacturer.

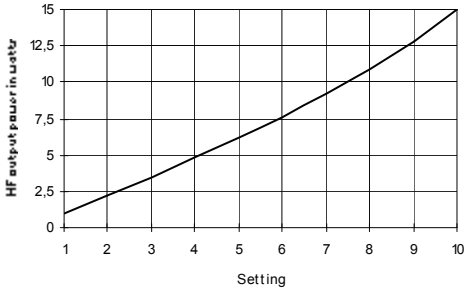
For accessories specially certified for use with KLS Martin electrosurgical units, please refer to the KLS Martin Accessories Catalog, which is available from Gebrüder Martin or can be directly downloaded via www.klsmartin.com.

22 Diagrams

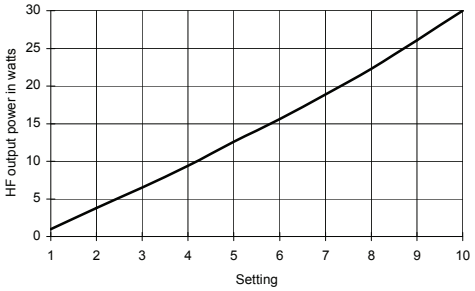
ME K3 Cut 1 + 2, Macro



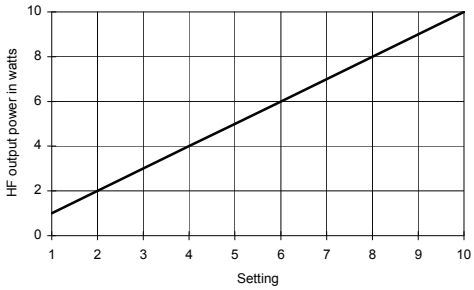
ME K3 Cut 1 + 2, Micro



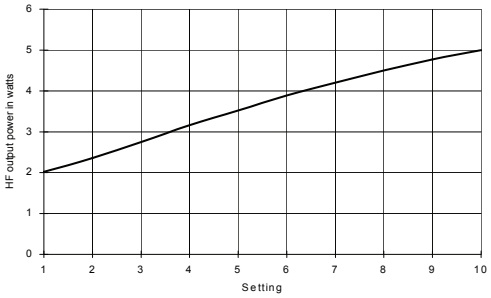
ME K3 Coagulation, Free Setting, Macro



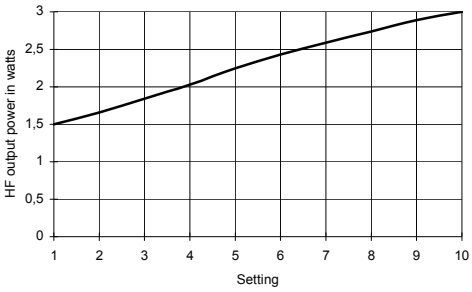
ME K3 Coagulation, Free Setting, Micro



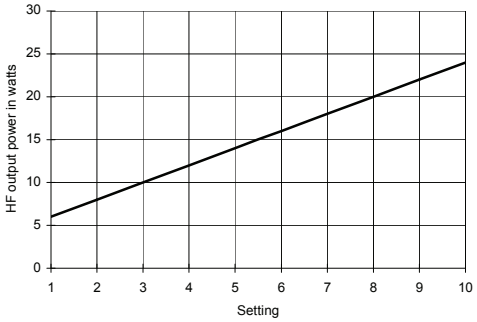
ME K3 Coagulation, Telangiectasias



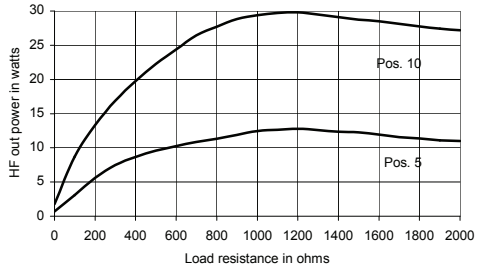
ME K3 Coagulation, Overpigmentation



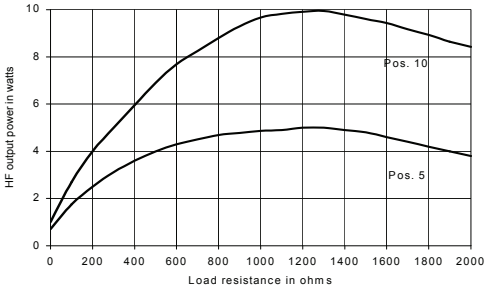
ME K3 Coagulation, Fibromas



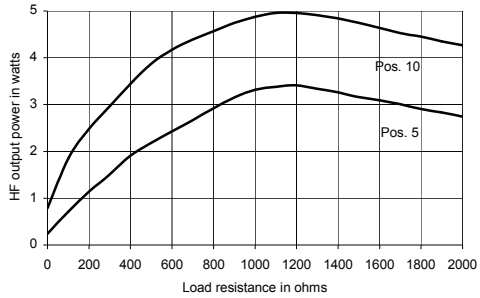
ME K3 Coag, Free Setting, Macro



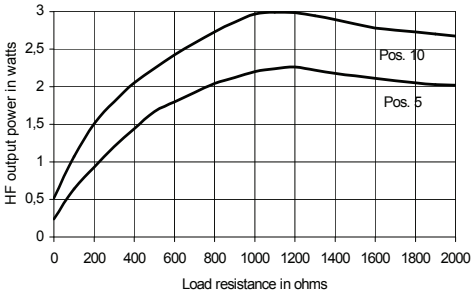
ME K3 Coag, Free Setting, Micro



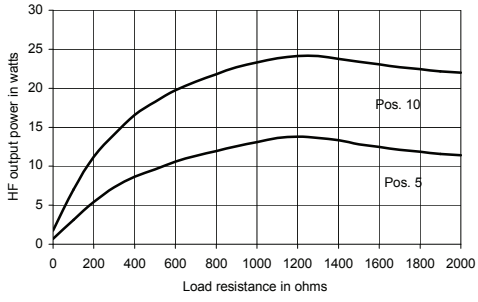
ME K3 Coag, Telangiectasias



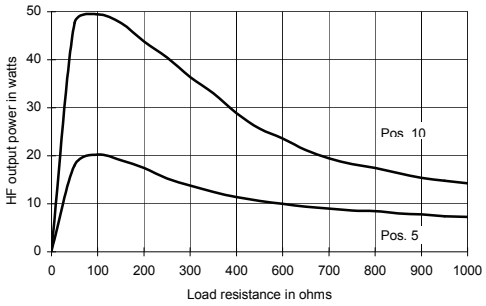
ME K3 Coag, Overpigmentation



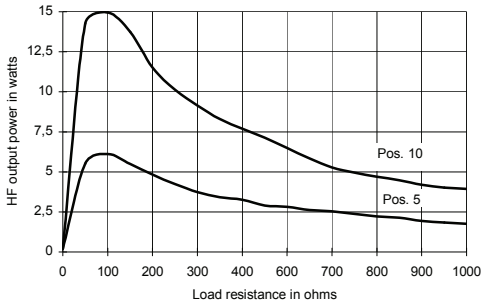
ME K3 Coag, Fibromas ...



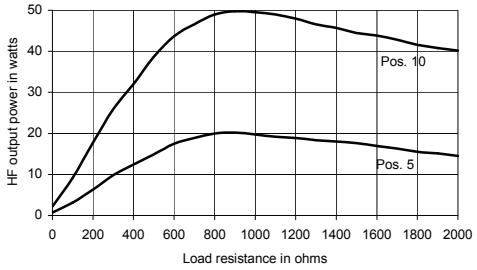
ME K3 Bipolar Coag, Macro



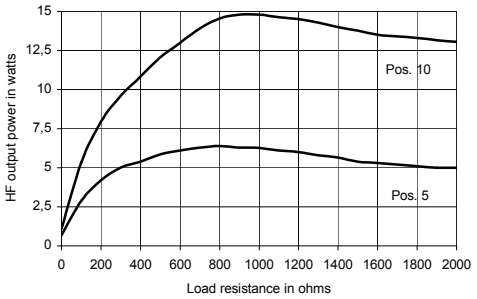
ME K3 Bipolar Coag, Micro



ME K3 Cut 1 + 2, Macro

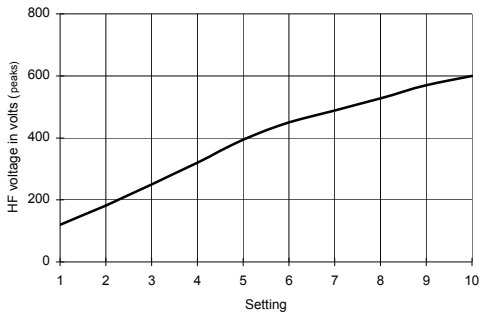


ME K3 Cut 1 + 2, Micro

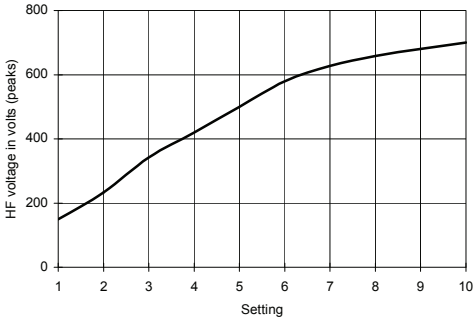


KREISZ ME K3 – Voltage Diagrams:

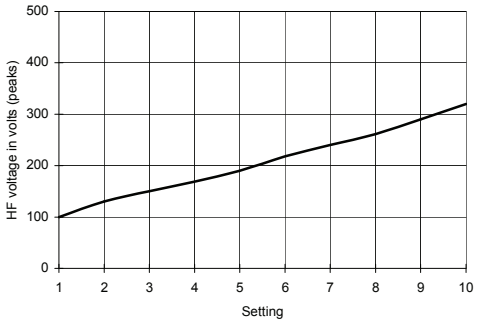
ME K3 Cut 1



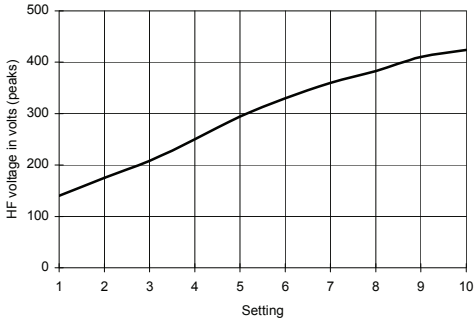
ME K3 Cut 2



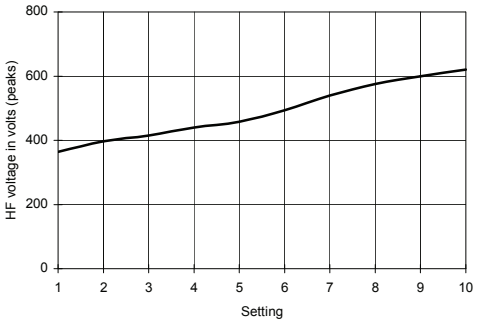
ME K3 Cut 1, Micro



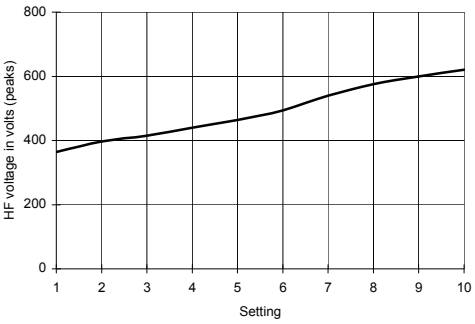
ME K3 Cut 2, Micro



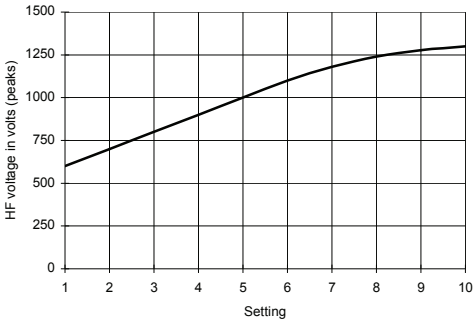
ME K3 Coagulation, Telangiectasias



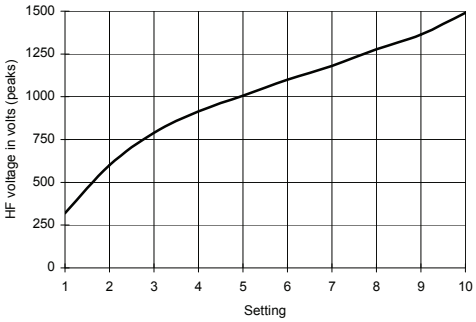
ME K3 Coagulation, Overpigmentation



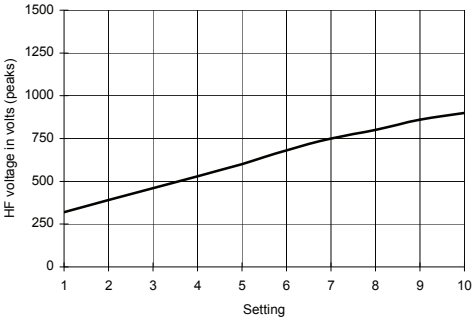
ME K3 Coagulation, Fibromas



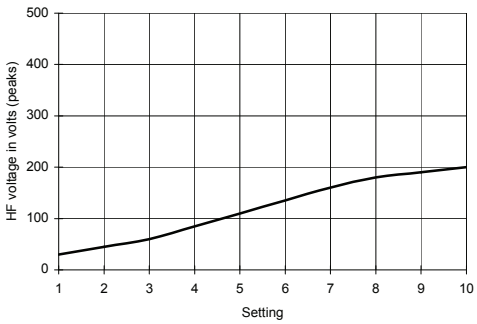
ME K3 Coagulation, Free Setting



ME K3 Coagulation, Free Setting, Micro



ME K3 Bipolar Coag



KLS Martin Group

Karl Leibinger GmbH & Co. KG
78570 Mühlheim · Germany
Tel. +49 74 63 838-0
info@klsmartin.com

KLS Martin France SARL
68000 Colmar · France
Tel. +33 3 89 21 66 01
france@klsmartin.com

KLS Martin L.P.
Jacksonville, Fl 32246 · USA
Office phone +1 904 641 77 46
usa@klsmartin.com

KLS Martin GmbH + Co. KG
79224 Umkirch · Germany
Tel. +49 76 65 98 02-0
info@klsmartin.com

Martin Italia S.r.l.
20059 Vimercate (MB) · Italy
Tel. +39 039 605 67 31
italia@klsmartin.com

Orthosurgical Implants Inc.
Miami, Fl 33186 · USA
Office phone +1 877 969 45 45
sales@orthosurgical.com

Stuckenbrock Medizintechnik GmbH
78532 Tuttlingen · Germany
Tel. +49 74 61 16 11 14
verwaltung@stuckenbrock.de

Nippon Martin K.K.
Osaka 541-0046 · Japan
Tel. +81 6 62 28 90 75
nippon@klsmartin.com

Gebrüder Martin GmbH & Co. KG
Representative Office
121471 Moscow · Russia
Tel. +7 (499) 792-76-19
russia@klsmartin.com

Rudolf Buck GmbH
78570 Mühlheim · Germany
Tel. +49 74 63 99 516-30
info@klsmartin.com

Martin Nederland/Marned B.V.
1270 AG Huizen · The Netherlands
Tel. +31 35 523 45 38
nederland@klsmartin.com

Gebrüder Martin GmbH & Co. KG
Ein Unternehmen der KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
Postfach 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax 706-193
info@klsmartin.com · www.klsmartin.com

06.09 · 90-148-52-21 · Printed in Germany · Copyright by Gebrüder Martin GmbH & Co. KG · Alle Rechte vorbehalten · Technische Änderungen vorbehalten
We reserve the right to make alterations · Cambios técnicos reservados · Sous réserve de modifications techniques · Ci riserviamo il diritto di modifiche tecniche