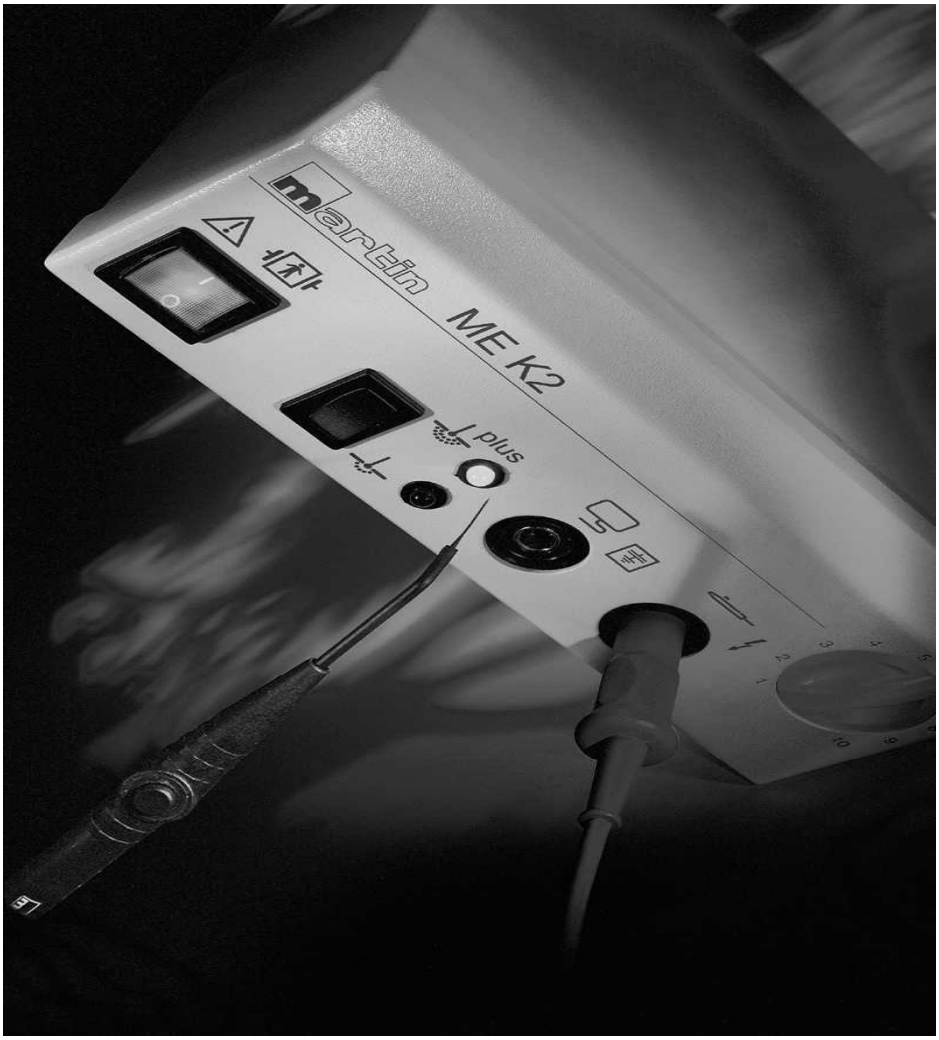
Operating Instructions



Martin Electrosurgical Unit ME K2

1 Product Liability

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 or has been used in accordance with these Operating Instructions.

2 Specifications

Parameters	**Value/Unit**
Power supply/requirements	220–240 V; 100–127 V
Power input	60 VA
Mains frequency	50-60 Hz
Class of protection	I
Classified acc. to MDD / Medical Devices Act	II b
NF and HF leakage currents	in accordance with EN 60 601, Part 2-2
Interference suppression	Limit values in accordance with EN 55011 and EN 60 601-2-2 Immunity to interference according to IEC 801
Type of equipment (degree of protection)	BF
HF nominal frequency	500 kHz
Continuous duty with intermittent loading (*)	10/30 s

(*) Load/no-load ratio

2.1 Crest Factor (**)

Type of Current	**Value**
COAGULATION	3.9
COAGULATION plus	3.9

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

2.2 HF Power

Type of Current	Watts	at Ohms
COAGULATION	15	1000
COAGULATION plus	15	1000

2.3 Weight and Dimensions

Parameter	Value/Unit
Weight	2.8 kg
Height	78 mm
Width	200 mm
Depth	185 mm

2.4 Certification

CE 0297 Marked in conformity with 93/42/EEC

3 Technical Description

Martin's electrosurgical unit ME K2 incorporates highly advanced power electronic components and has been designed in accordance with VDE 0750 and IEC 601 provisions and regulations.

The MARTIN ME K2 is characterized by the following main features:

- Successful treatment of many epidermal anomalies by using the proper type of current.
- Thanks to its special performance characteristics, the unit can be used either in monopolar or monoterminal mode.
- Depending on specific working requirements, the user can choose between two types of high-frequency current: one for “coagulation+”, and one for “coagulation” (hemostatic effect).
- In addition to the footswitch, a handle without finger switch can be connected. This connector jack is to be used also for a handle with finger switch.
- The output power is infinitely adjustable.

4 User's Inspection

Warning

- **Explosion hazards!**
- **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 that are 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 any damage or loss occurred, the user/buyer is required to immediately notify either the seller or the carrier to this effect; otherwise the buyer shall have no right to claim compensation. In said event, a certificate of loss must be established immediately and 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 Preventing Accidental Burns

If the MARTIN ME K2 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 be large). Be sure also to use only approved and non-defective accessories. Accessories that are in any way defective must be removed at once. Always carry out appropriate checks prior to setting the unit into operation!

If you use the Martin ME K2 in connection with a neutral electrode, please observe the following safety requirements:

Be sure to connect all electrodes and cables in the proper manner. In particular, it is important to

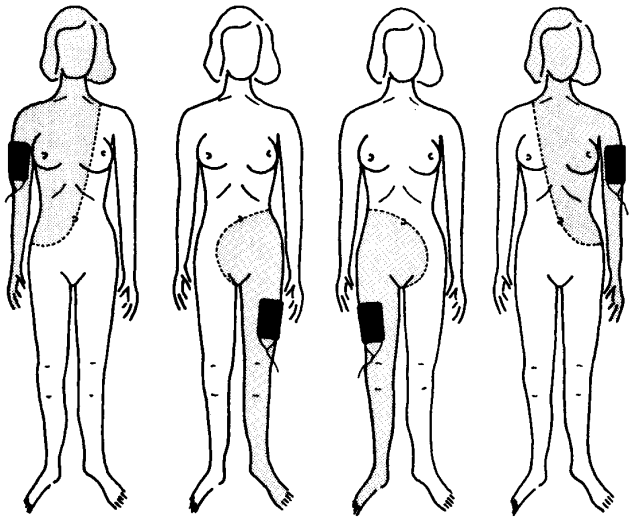
- attach the neutral electrode as close to the operating site as possible and to fix it properly in place on the patient's skin (electrode must be fully in contact with the patient's skin; use rubber band);
- make sure that the neutral electrode maintains full skin contact while the high-frequency current 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 run loop-free in such a way that they will not come into contact with either 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 in longitudinal or diagonal direction but NOT in transverse direction (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 set the unit to the lowest possible output power value required for the respective application.

NOTE:
If HF power output is too low at a normal setting, this can have various reasons; for example, the neutral electrode may not be applied properly, the connectors may have insufficient contact, wire breaks may have occurred below the insulating sheath, or electrodes may have become encrusted. Check accordingly and replace defective parts if required.

- 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 likewise 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 the 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 all 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 that output power increases accordingly when rotating the power adjuster in the corresponding direction.
- Check actual maximum output power against the specified maximum value at all outputs, for all available operating modes and for all nominal load resistances indicated in Section 2.
- Check for acoustic and visual signals upon 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 report attached, which was 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 must be carried out only by MARTIN's qualified servicemen or by a service representative that has been specially authorized to carry out such work.

In case you need information of a technical nature, please use the following hotline:

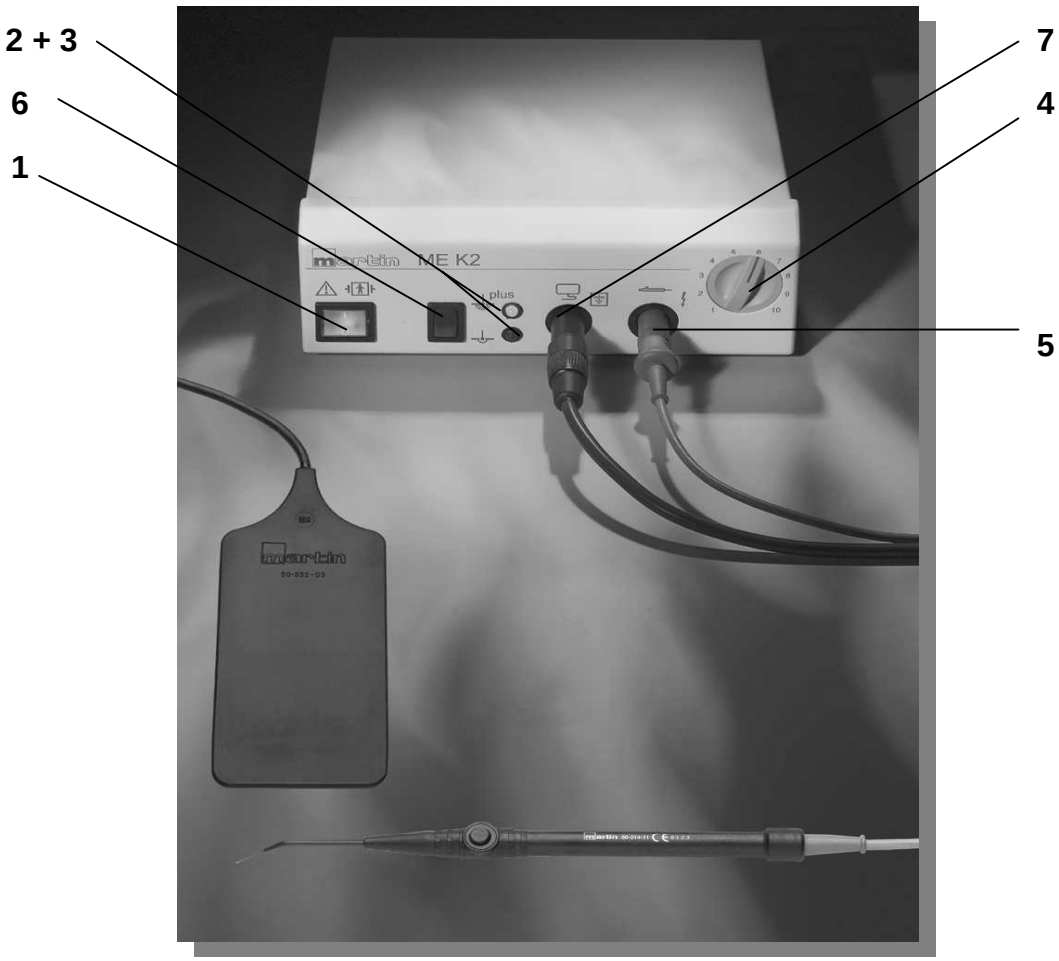
Martin Medizin-Technik
Hotline

Technical Service
Tel.: (+49)7461-706-343
Fax: (+49)7461-706-190
E-mail: msc@martin-med.com

Our Technical Service representatives are available Monday through Friday from 8 a.m. to 5 p.m.

In case you have any questions concerning maintenance contracts and training courses, please contact our Technical Service Manager (Tel. (+49)7461-706-332).

8 Operator Controls and Indicators



1 Power switch (ON/OFF)

2 COAGULATION plus indicator

3 COAGULATION indicator

4 Power adjuster

5 Connector jack for handle

6 COAGULATION+/COAGULATION selector button

7 Neutral-electrode connector jack

8 Footswitch connector socket

9 Power-cord connector socket

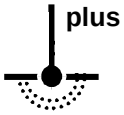
10 Line fuses

For positions 8, 9 and 10, see rear panel

9 Description of Symbols/Pictographs Used

„Forced“ coagulation

Highly modulated HF current of a high voltage; used for fulguration or coagulation. Suitable for treating telangiectasias, spider veins and rosacea.



„Forced“ coagulation plus

Highly modulated HF current of a high voltage with an initial voltage peak. Suitable for treating telangiectasias, spider veins and rosacea. Can also be used as a “cleaning peak” to prevent tissue from sticking to the electrode.

Electrode handle connection

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

Symbol indicating classification/type of equipment ("BF" meaning that device is defibrillator-proof).

WARNING!

OBSERVE OPERATING INSTRUCTIONS!

WARNING! HIGH-FREQUENCY CURRENTS!

Warning label indicating presence of high voltages.

10 Electrosurgery - How It Works

The basic principle behind high-frequency surgery (or electrosurgery) is a rather simple one:

At tissue temperatures of more than 100 °C, the cell sap evaporates. Moreover, 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.

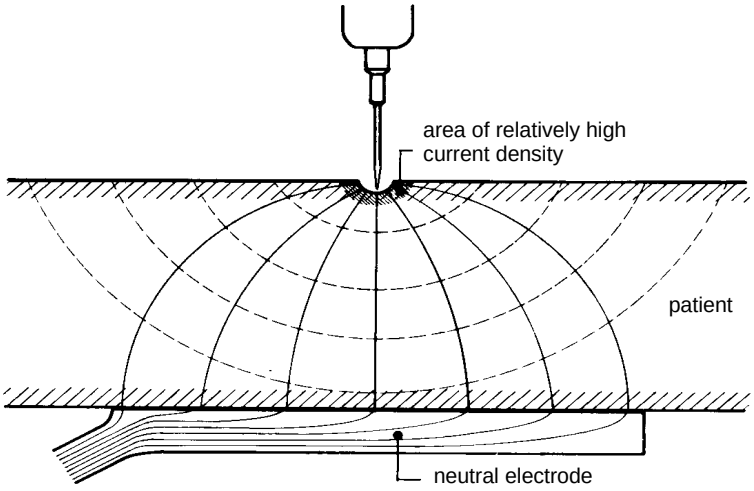
The principle of generating heat in the tissue by using high-frequency currents is illustrated in the diagram shown below:

From a large-surface **neutral electrode**, the HF current flows to a small-surface **active 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/dissection 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 and that, moreover, the heat is distributed over a larger area. These types of electrode are therefore ideal for coagulation.

High-frequency currents of more than 300 kHz are therefore required in order to prevent a Faraday effect with 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).



11 Getting the ME K2 Started

The system is ready for use as soon as

- the unit has been connected to the power supply system (see Section 6);

- the electrode handle (with the active electrode) has been connected to the unit;

- the power switch (1) has been set to ON.

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 indicator (3) must now light up and the corresponding acoustic signal must be heard in addition.

Please note!

If HF current activation is indicated optically (symbol illuminated) or acoustically despite the fact that no footswitch or electrode handle has been connected, the unit is probably defective and must be checked. If, in contrast, malfunction is indicated after the foot switch or electrode handle has been properly connected, this means that either the foot switch, the handle or the connecting cable of the handle is probably defective. In such a case, check these components and replace as required.

If the footswitch is used to activate the HF current, the handle without a finger switch must be connected to the connector jack (5).

When connecting the footswitch (socket (12)), be sure to insert the connector 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 connector socket.

When connecting the active electrodes, 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 results achieved. In other words: A relatively low power output (or power setting) may be sufficient to produce the desired coagulation effect if the current is applied long enough.

14 Types of Current Available

The MARTIN ME K2 allows the user to select between two different, highly modulated HF currents.

Highly modulated HF current with high voltage peaks allowing “forced” coagulation (also called “spray coagulation”. The initial overcurrent ensures that the active electrode is kept clean (i.e. free from tissue particles adhering to it). **When using contact coagulation, this type of current is highly suitable for treating spider veins, rosacea, telangiectasias and spider nevi.**

Highly modulated HF current with high voltage peaks allowing “forced” coagulation (also called “spray coagulation”. **When using contact coagulation, this type of current is highly suitable for treating spider veins, rosacea, telangiectasias and spider nevi.**

15 Application & Start-Up

1. Connect the power cord to the unit's connector socket (9) provided on the rear panel and to the duly installed supply system.

2. Connect the neutral electrode and the handle with finger switch to the appropriate connector jack (7 and 5); see Section 8.

3. Switch on the unit using the power switch (1).

4. Press the selector button (6) to select the required type of current (COAGULATION+ or COAGULATION).

5. Insert the required treatment electrode into the handle.
   Use an adapter if required.

The patient lies on a treatment couch or sits in a treatment chair.

Required treatment accessories:

Isopropanol, swabs, loupe/telescopic spectacles, rubber gloves, medicated ointment, anatomic forceps.

For very pain-sensitive patients, use of a skin-anesthetizing ointment may be indicated. Ensure good lighting conditions, e.g. by using a luminous magnifier.

Safety check:

Upon pressing the button on the treatment handle, a beep should be heard and the blue spray-coagulation indicator must light up. To avoid contact with the patient, be sure to hold the electrode in the air when performing this check.

16 Intended Use

The unit has been designed for the therapy of thread veins, couperosis, teleangiectasiae, spider naevi, pigment anomalies, aging spots etc.

17 Troubleshooting

Please 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 company, the serviceman 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/company performing the work. Whenever repair work or modifications have been carried out by a third party, the equipment or parts repaired must be additionally labeled with the repairer's identification mark.

18 Maintenance of Accessories

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

19 Sterilization and Disinfecting

Disinfection 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) articles.

20 Warranty

The period of warranty for this unit is 24 months, beginning on the day of delivery to the end-user.

Within this period of warranty, we will remedy free of cost - either through our service points / authorized dealers or directly in the factory - any defects that have been demonstrably caused by a manufacturing defect or by the use of defective materials.

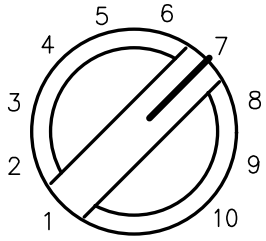
21 Accessories

The unit may be used only in connection with safety-related accessories, wearing parts and disposable articles that have been approved and found to be reliable by a recognized body authorized to test the fully-assembled unit in its ready-for-use condition. Note that any use of non-approved accessories supplied by third parties may represent a source of danger! Be sure to contact the respective manufacturer in all cases of doubt.

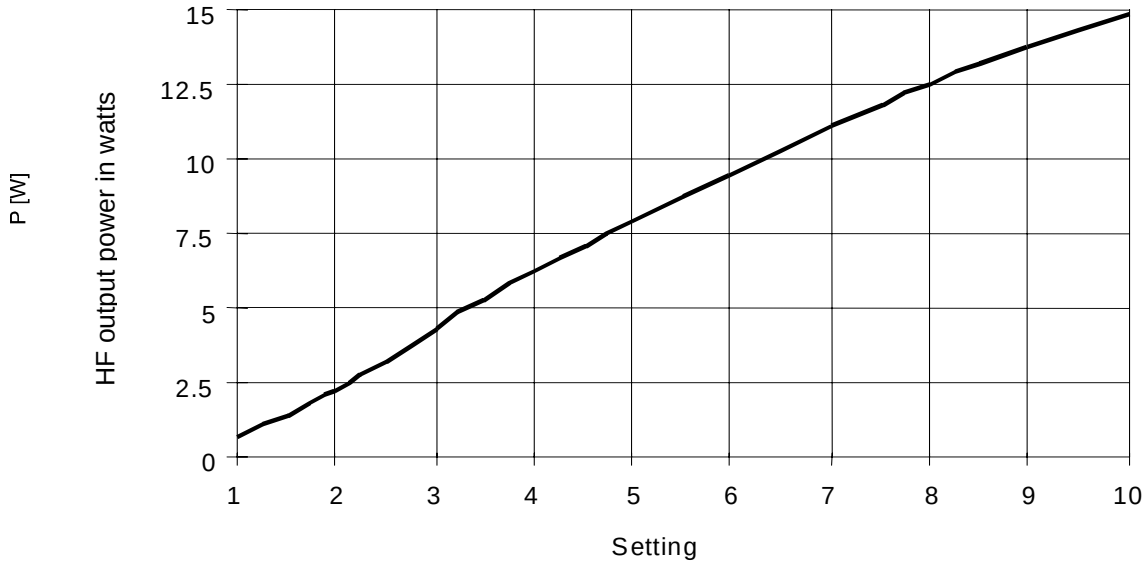
For accessories especially certified for use with electrosurgical units of the ME series, please refer to our accessories catalog, order number 90-767-08.

22 Diagrams

Power adjuster settings:

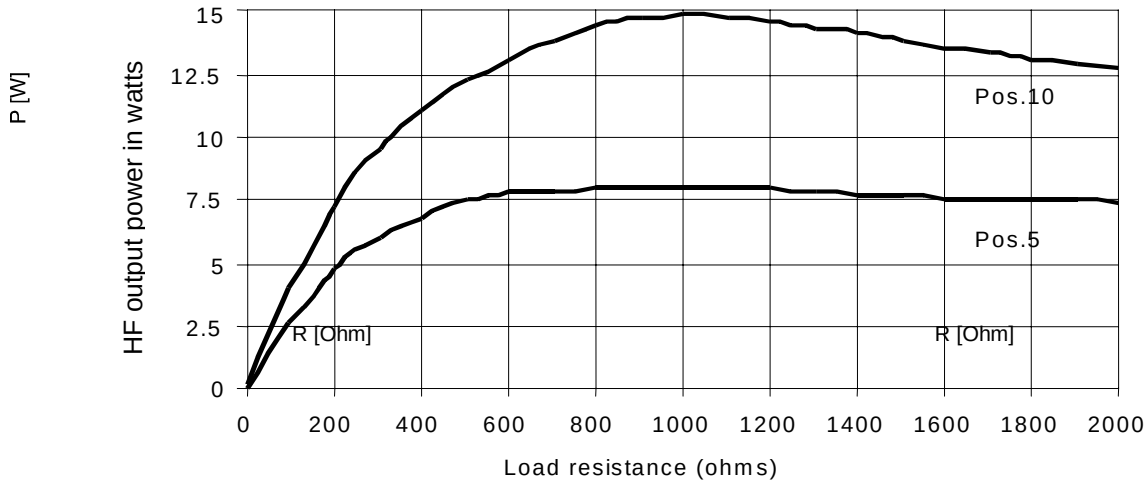


ME K2 Coagulation and Coagulation Plus

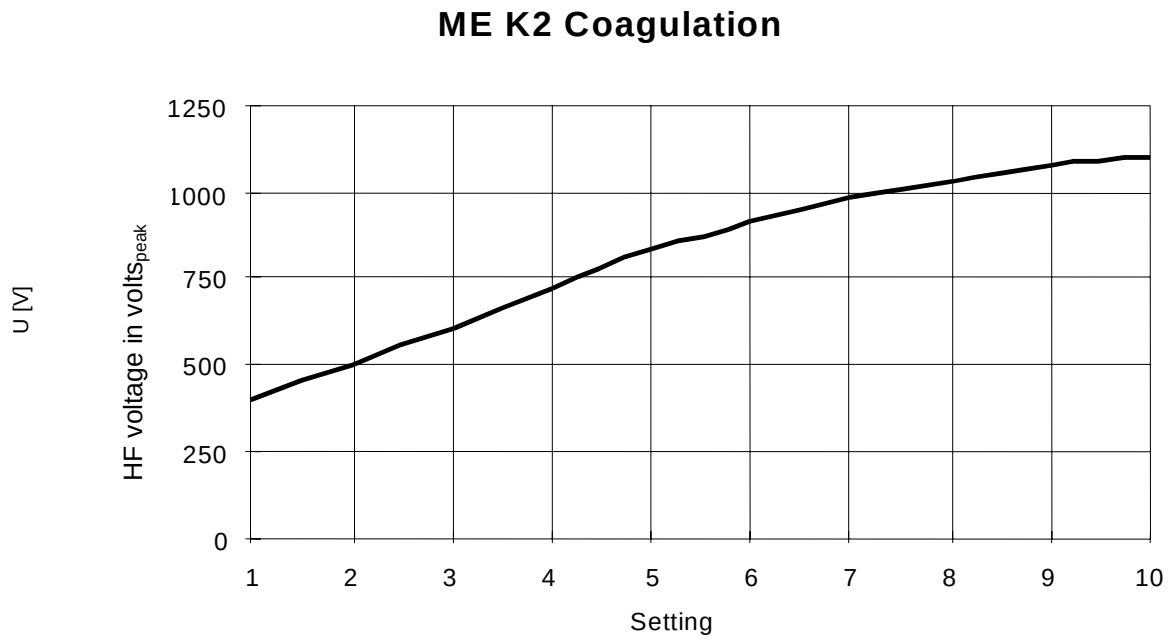


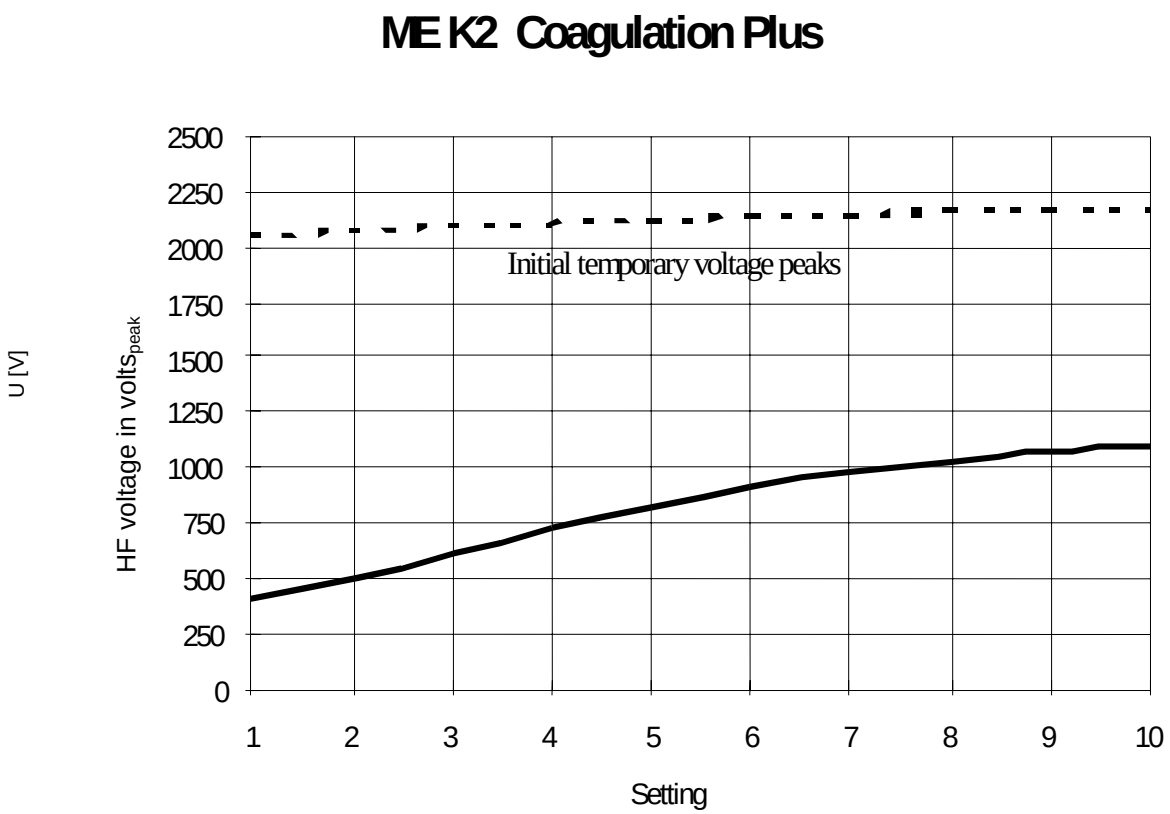
HF power diagram:

ME K2 Coagulation and Coagulation Plus



HF voltage diagrams:





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