





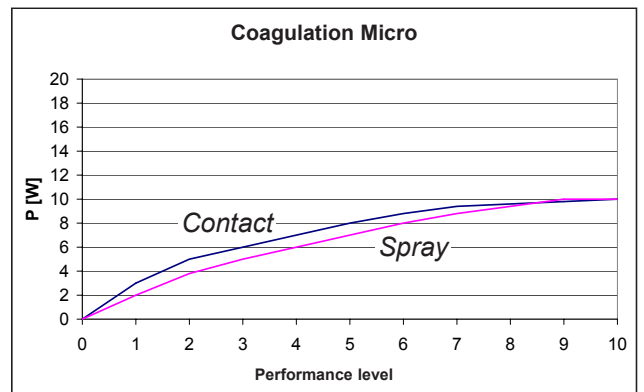
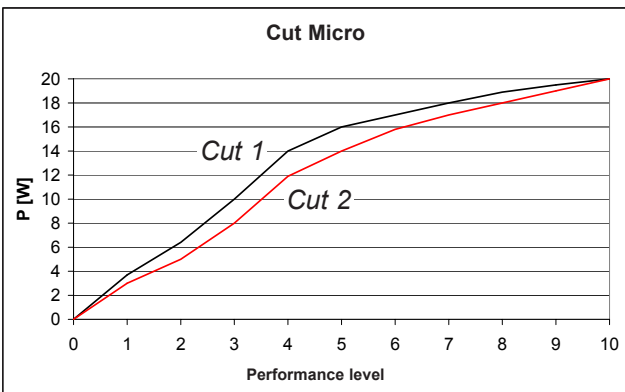
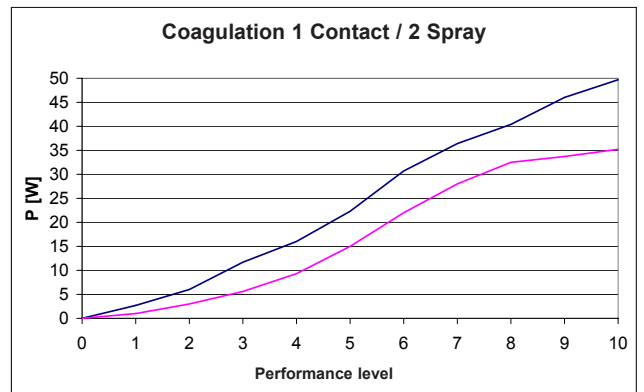
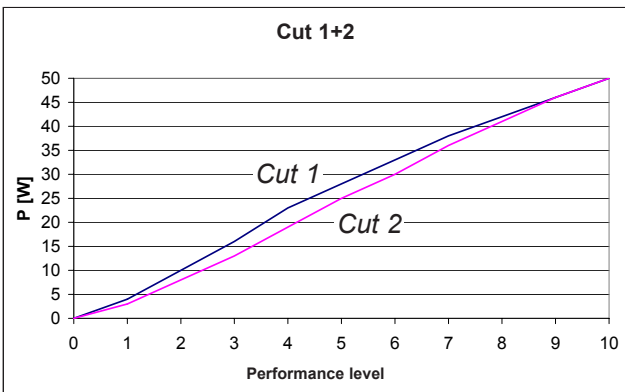
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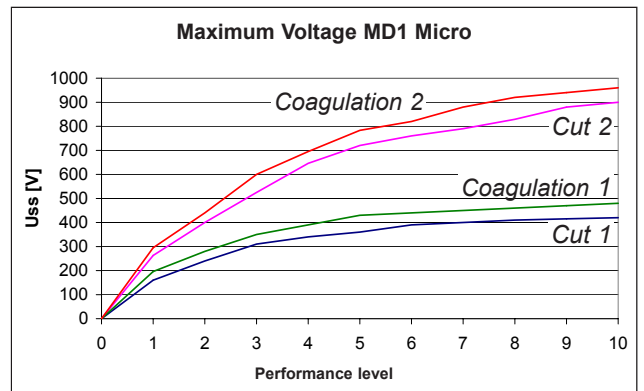
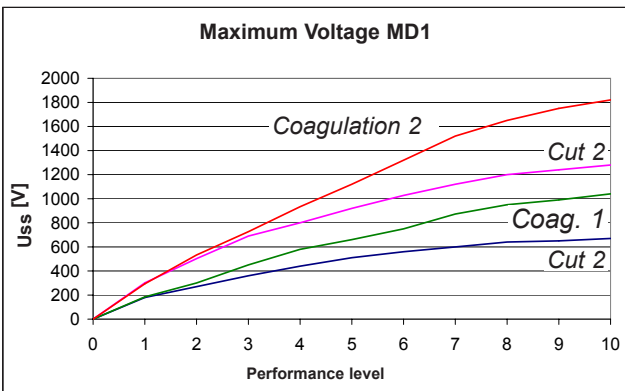


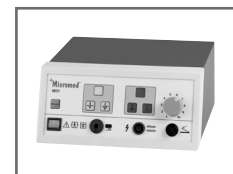
### 18. Additional Charts

The following charts show the relating power output as a function of the setting concerning a determined resistance of 500 Ohm (Cut1, Coagulation1) resp. 1000 Ohm (Cut2, Coagulation).



Maximum output power as a function of the power settings.





## 1. Product Description

The HF-Electrosurgical Unit MD1 is the ideal device for smaller surgical operations. Suitable for diverse ranges of application like surgical-, dermatological-, dental-, and cosmetical applications. This device can be used for monopolar and monoterminial therapies. A neutral electrode is necessary for the monopolar method. The monoterminial mode needs no neutral electrode. However the patient has to be carried in connection with the ground. (see point 4.2).

The unit equipped with 2 cut-modes and 2 coagulation-modes:

Mode	Effect	Performance Values (Watt)	Micro Mode (Watt)
Cut 1	smooth cut	50	20
Cut 2	encrusted cut	50	20
Coagulation 1	contact coagulation	50	10
Coagulation 2	spray coagulation	35	10

The micro switch is used to reduce the maximum output power of the cut function (50 Watt) down to 20 Watt, resp. down to 10 Watt in the coagulation function. The reduction of output power is an advantage, because the range of power can be adjusted more exactly.

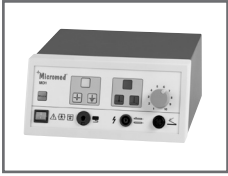
The device is equipped with a special interface for an electrode handle with push button or a handle without push button. In this case the activation has to be done by a foot switch.

The neutral electrode interface is used to connect the small rubber neutral electrode or an electrode cable in connection with an one-piece single use neutral electrode.

### 1.1 Product liability

The firm Micromed declares to take responsibility for the safety of Unit MD1 if the user keeps to the following points:

- Fresh engagements and acts of fixing should be done by Micromed only.
- The electrical installation of the room in which the unit is used, must fulfill the specification of VDE 0107 or IEC 60364-710
- The unit must be used after the annotations and rules of the user's manual.



## 2. Incoming materials inspection

### Damage in transit

Please check immediately after you received the unit if there is any damage in transit or any defects.

### Claim for damages

Claim for damages is valid, if the dealer or the firm Micromed are informed immediately. A protocol of all damages has to be done without delay. Please send this protocol to the dealer or directly to Micromed, in order to work on the settlement of damages.

### Back dispatch

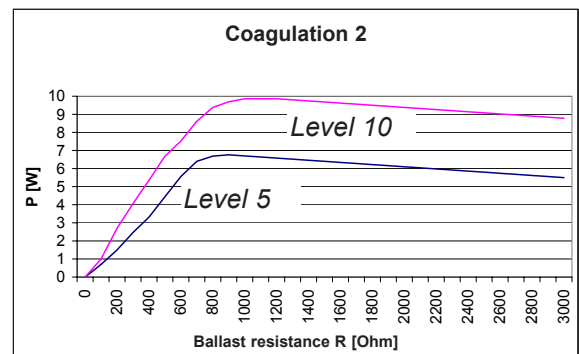
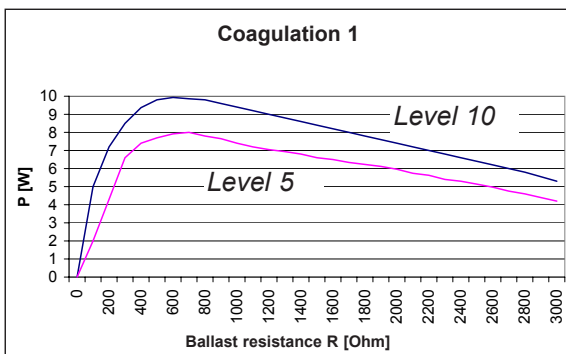
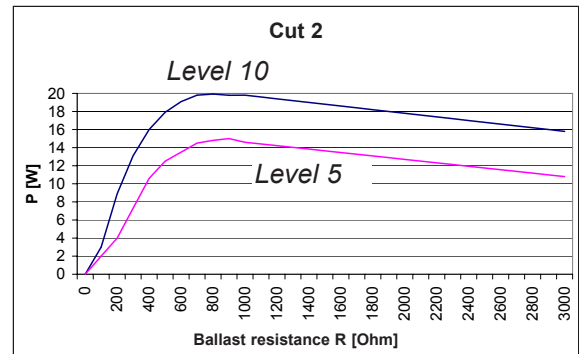
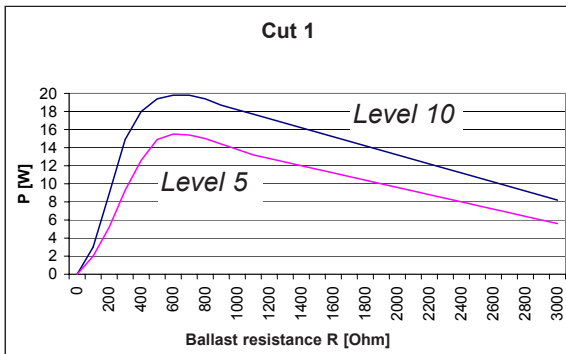
The back dispatch of the unit is done if possible inside the original package to Micromed. Please add the following accompanying documents: Name and address of the despatcher, model number and device number, description

## 3. First Start Up

The operator can only start using the device if the equipment was checked by an acceptance test at the operating place and the responsible person who uses that equipment was instructed in its handling.



## 16. Charts of output power with Micro mode



## 17. Environmental relevantly indications

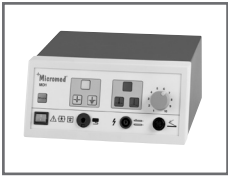
### Packaging

The complete packaging will be taken back by Micromed. If you do not want to make use of hereof, you can dispose of the packaging with the regular household bin.

### Disposal of the device

When producing the device we used sparse composites. This way of production allows a high degree of recycling. We offer you to take back the old device and remove it properly.

We would like to point out that the conditions of the Directives for Electronic Scrap must be adhered to when removing the device.

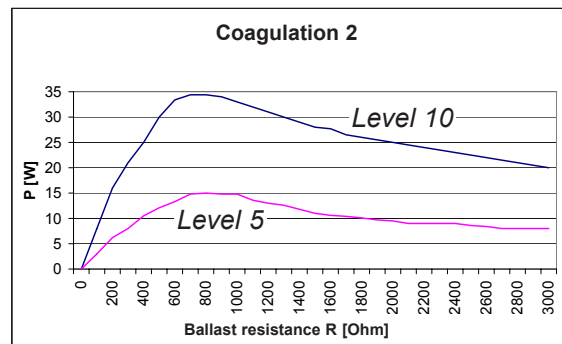
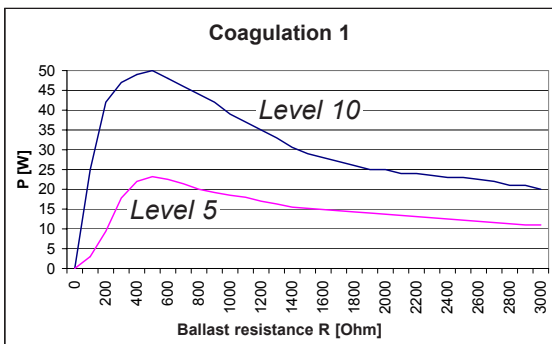
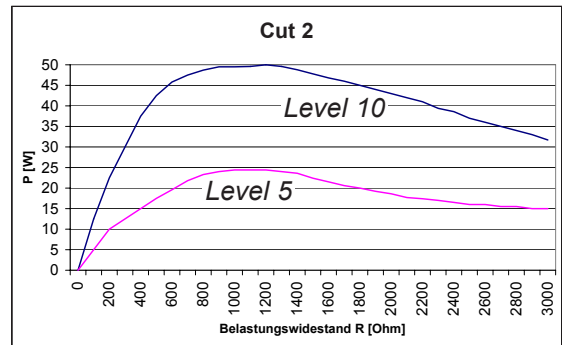
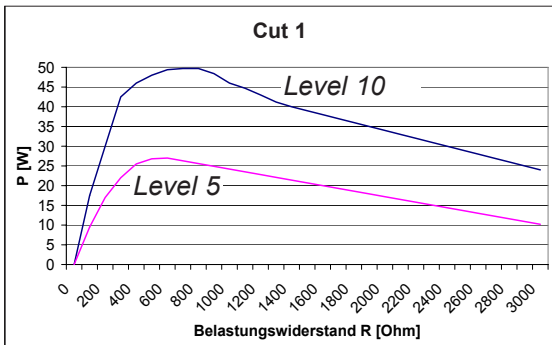


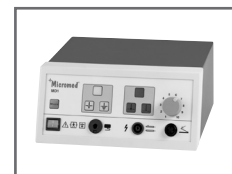
### 14. Restoration

The device contains two fuses that reside inside the power entry module on the backside. To replace those fuses, the power plug must be disconnected from the socket. The fuseholder must be unlocked on both sides, afterwards the fuseholder can be pulled out. Check both fuses, replace the defective one. **The fixing of asserted defects inside the HF-Unit must be done by Micromed.**

### 15. Charts of output power

The upper performance curve describes level 10, the inferior curve the maximum performance at level 5.





#### 4. Hints for safe application

Non observance of the described hints of wrong handling, can cause incidents combined with serious injuries.

The HF-Electrosurgical unit is not determined for operations in areas which are in danger of explosions.

- The use of flammable fluids and gases has to be avoided, and precautions must be taken that those fluids / gases cannot be inflamed by the high frequency voltage.
- You can use this HF-Unit for monopolar and monoterminal therapies.
- The temporary unused active electrode has to be placed far away from the patient. Any contact to close cables must be avoided.
- The performance setting must be adjusted as low as possible for the respective application.
- Skin-to-Skin touching, between body and upper arm must be avoided.
- In case of a malfunction there exists the danger of an increased transference of HF-performance. Caution! Danger due to burnings.



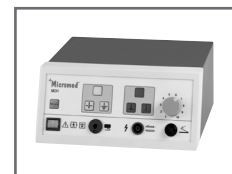


### **4.1 Patients with pacemakers**

The ambulant therapy of patients with pacemakers may not be executed in connection with HF-Current. Please ask every patient before the therapy with HF-Current, if he wears a pacemaker. Patients with pacemakers are endangered by HF-Current, because the function of the pacemaker can be jammed or even completely damaged.

### **4.2 Placement of patients for monoterminal operations**

The bench of therapeutic chair must be connected electrically with the ground potential. The neutral electrode is not necessary to connect the patient electrically. The contact resistance between patient and bench must be on every spot of the surface the same value. If the patient touches directly ground potential leading metal parts, like the therapeutic charts, there is the risk of skin irritations and burnings.



## 11. Disinfection

### HF-Unit

The disinfection of this HF-Unit can be done by the usual wipe- and spray disinfectant. Keep to manufacturer data.

### HF-Accessory


- Cleaning, disinfection and sterilization of HF-Accessories can also be done with the same chemical disinfectant. The instructions of the pertaining manufacturers must be followed.
- The mechanical cleaning can be done up to 95°C.
- The electrode handle MicroPen, connecting cable and the electrodes can be sterilized up to 134°C.
- Sterilization with hot air is not permitted.

## 12. Safety Controls

The safety-relevant controls for this HF-Unit must be done at least every 24 months. The tests have to be done by authorized personnel or directly by Micromed. The following issues must be checked:

- The results from the safety controls have to be documented in the equipment book.
- Visual Control HF-Unit and accessories.
- The readability of all-safety relevant epigrams must be checked.
- The fuses must be checked concerning rated current and fusion character.
- Constant energy transference corresponds to the increasing values from the performance setting at the rotary knob.
- The maximum transferred performance must be compared for all four current types, with or without microswitch to the scheduled value. If necessary the power output must be adjusted once again.
- The test must be processed according to EN IEC 60601-1.

## 13. Certificates

conformable to 93/42/EWG  0123



### 9. Accessory

The HF-Unit may only be used with original Micromed accessories. The accessory must be examined before each operation. Damaged accessory can cause unwanted burnings.

100-001-016	MicroPen, Handle without buttons, for 1,6mm electrodes
100-001-040	MicroPen, Handle without buttons, for 4,0mm electrodes
100-101-016	MicroPen, Handle with one button, for 1,6mm electrodes
100-101-040	MicroPen, Handle with one button, for 4,0mm electrodes
101-020-200	Connecting cable MicroPen, length 2m
101-020-300	Connecting cable MicroPen, length 3m
101-020-400	Connecting cable MicroPen, length 4m
101-020-500	Connecting cable MicroPen, length 5m
120-XXX-XXX	Electrode Ø 4mm, please see HF-Catalogue Micromed
121-XXX-XXX	Electrode Ø 4mm, please see HF-Catalogue Micromed
122-XXX-XXX	Electrode Ø 4mm, please see HF-Catalogue Micromed
110-103-400	Rubber neutral electrode with 4m connecting cable
110-101-075	Rubber band, punched, length 75cm, (material contains latex)
110-101-100	Rubber band, punched, length 100cm, (material contains latex)
110-102-000	Knob for rubber band
152-811-010	Foot switch
129-001-001	Suitcase HF-Unit MD1
151-001-001	Accessory Dental
151-001-002	Accessory Dermatology
151-001-003	Accessory Surgery

### 10. Waste disposal

The HF-Electrosurgical units contain no more electronic parts and materials which are harmful to the environment compared to the usual extent. The construction is built up in a way that facilitates the recycling of different materials like iron, synthetic parts and electronics.

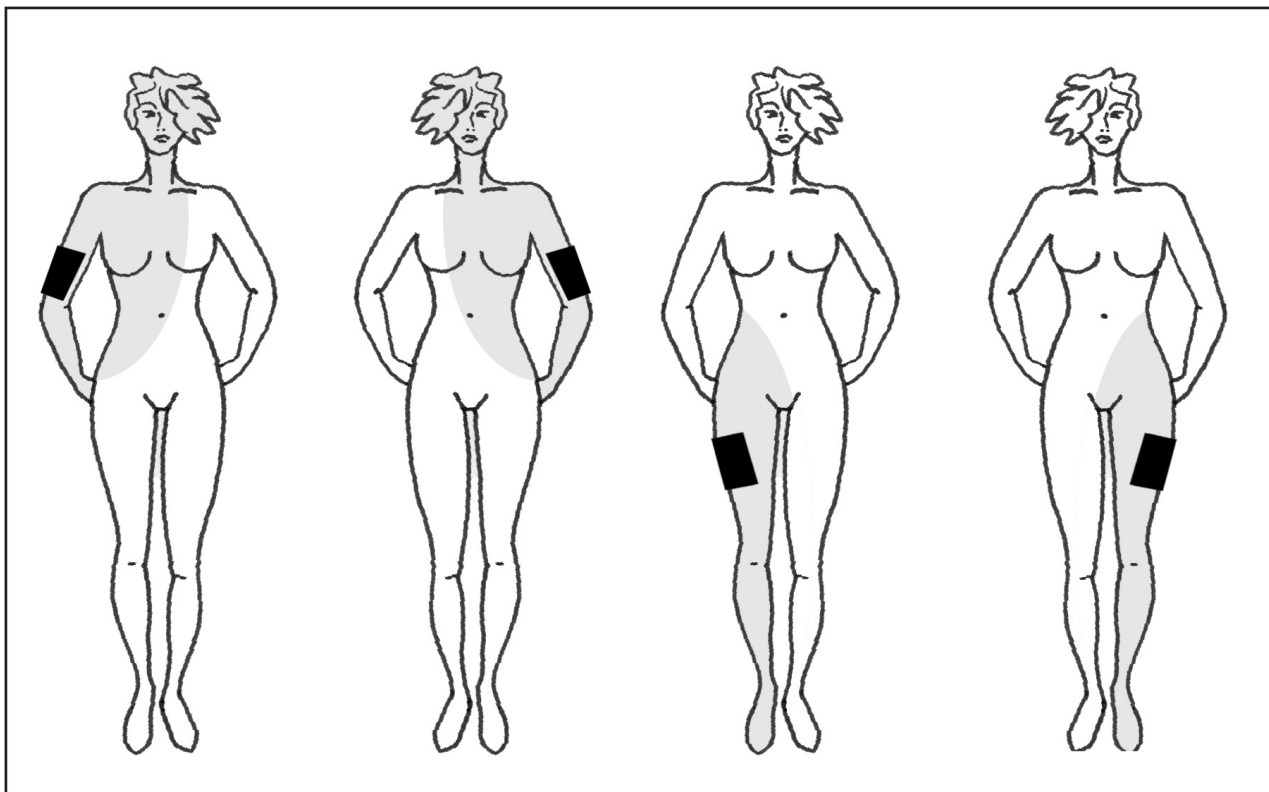


### 4.3 Placement of the patient for monopolar operations

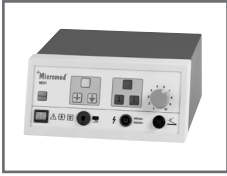
- The patient must be placed on the bench without any ground potential. The neutral electrode is necessary for electrical connection to the patient, because it allows a backflow of electrical current out of the human body.
- The neutral electrode must be placed with its entire surface as close as possible to the treatment area. Furthermore it must be layed on the patient's body absolutely reliable, otherwise the danger of skin irritation and burning exists.
- The neutral electrode shouldn't be put on apophysis, metal-implants, scared skin, massive cells of fat and on spots where fluids can flow together.
- No electrode gel is allowed.
- The application surface must be clean, dry, free of hair growth and without any injuries.
- The cables shouldn't be in touch with the patient, nor have contact to any other cables.

### 4.4 Neutral electrode

The neutral electrode must be put on the skin perfectly with its entire surface. We recommend the hips or the upper arms.



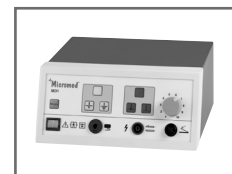
Neutral electrode
  Operation field



## 4.4 Neutral electrode



- The neutral electrode shouldn't be put on apophysis, metal-implants, scared skin, massive cells of fat and on spots where fluids can flow together.
- The surveillance electrodes from connected diagnose units must be placed as far as possible to the neutral electrode and active electrode.
- If there should be a power drain which is too low, which doesn't match with the adjusted performance, please check the operation field and all other connecting cables, incl. special accessories.
- The neutral electrode may not be disconnected from the patient by pulling the cable.
- Always set the power output for the respective purpose as low as possible.



## 8. Specifications

### Power Supply Line

Power Supply Line (see type plate)	110-120/220-240 V~
Mains frequency	50-60 Hz
Power consumption	127 VA
Mains fuse 230V	1 Ampere, time-delayed, 2 x

### HF-Output max.

Cut I max.	50 Watt, 500 Ohm
Cut II max.	50 Watt, 1000 Ohm
Contact-Coagulation	50 Watt, 500 Ohm
Spray-Coagulation	35 Watt, 1000 Ohm

### HF-Output Micro

Cut I max.	20 Watt, 500 Ohm
Cut II max.	20 Watt, 1000 Ohm
Contact-Coagulation	10 Watt, 500 Ohm
Spray-Coagulation	10 Watt, 1000 Ohm

## General Specifications

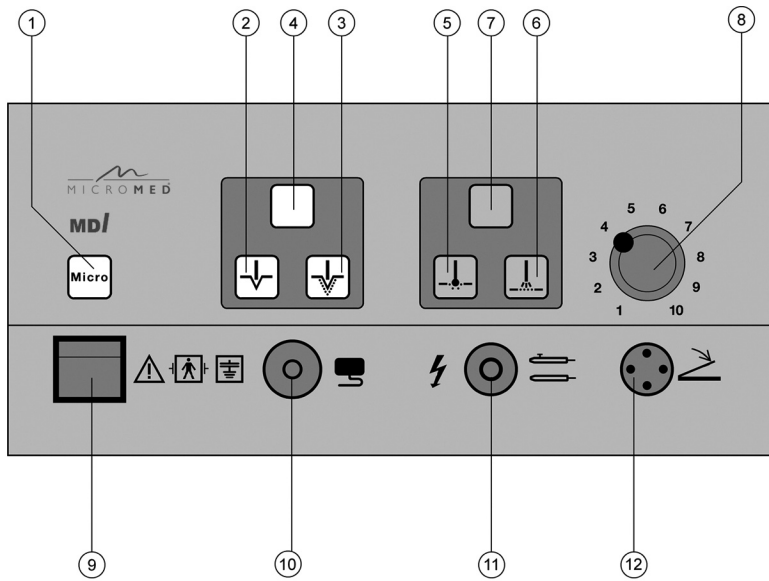
Nominal Frequency	720 kHz
Safety Class	I
Type	BF
Classification MPG	II b
Ratio encumbrance time/break time	10 / 30 sec.
Weight	5,5 kg
Breadth	270 mm
Height	125 mm
Depth	260 mm

## Transport- and storage conditions

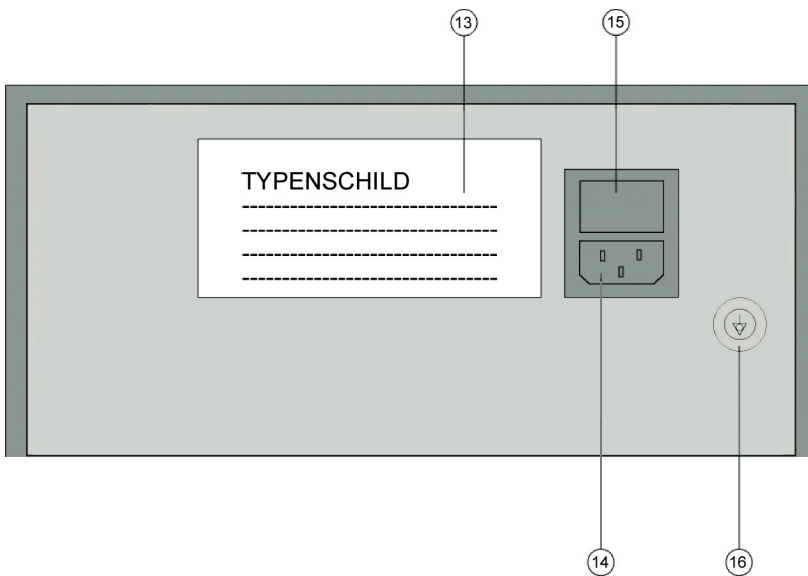
Ambient temperature: -20°C until +70°C  
 Relative humidity: 10% until 100%  
 Air pressure: 500 until 1060hPa



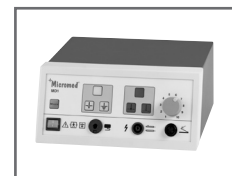
## 5. Hints for operating



- 1 Micro-Button to reduce power
- 2 Cut 1
- 3 Cut 2
- 4 Pilot lamp for Cut
- 5 Coagulation 1
- 6 Coagulation 2
- 7 Pilot lamp for Coagulation
- 8 Knob to adjust performance
- 9 Power-Button On/Off
- 10 Connection plug for neutral electrode
- 11 Connection plug for electrode handle
- 12 Connection plug for foot button



- 13 Type plate
- 14 Mains fuse, 1,0 Ampere
- 15 Power plug
- 16 Potential balance



## 5.1 Description of user elements



**Cut1**  
creates a smooth cut with less sparks and less encrustations



**Cut2**  
creates an encrusted cut with many sparks. Suitable for very bloody tissue or fat cells.



**Contact-Coagulation**  
creates a powerless modulated current for the contact-coagulation.



**Spray-Coagulation (Fulguration)**  
creates a powerful modulated current for spray-coagulation or fulguration



**Micro Switch**  
The micro switch extremely reduces the power output. That helps to adjust the lower performance range more easily.



**Female connector for electrode handles:** suitable for handles with one/no button.



**Connector neutral electrode**



**Connector foot switch**



**Defibrillator safe for HF-Units in class BF.**



**Capacitive earth connection between HF-Unit and ground.**





Attention! Keep to user's manual



Attention! High voltage output!

## 6. Start Up

The electrical connection of this unit may only be connected with the supplied main connection cable to a socket which was correctly installed according to VDE 0107 resp. IEC 60364-710. Before using this machine the first time, the given main voltage on the type plate has to match with the voltage of your electrical system.

The HF-Unit is to be activated by pushing the green power switch (9) with the inscription 01. From now on the green switch is flashing, and the user can choose one of the four types of current. The Micro-button must be pushed, to reduce the power. If you push this button, the micro-switch is flashing green, and the maximum power output is reduced. That allows to adjust the power very precisely.

### 6.1 Disturbing emission of HF-Units

The HF-Units produce logically highfrequent and magnetic fields, which are sent out through the cables and can disturb electronic units around the operation field.

## 7. Guarantee

From the very first day on, beginning at the day of the delivery, we grant a guarantee of 24 months.



## 4.5 Medical range of application

This HF-Unit was conceived for the use up to 50 Watt power output, in the following disciplines:

- General Surgery
- Dental Surgery
- Dermatology
- Container Surgery
- Gynecology
- HNO-, Jaw- and Face Surgery
- Cosmetic applications
- Microsurgery
- Plastic Surgery
- Accident Surgery
- Veterinerian Surgery

## 4.6 Function of HF-Units

The HF-Unit produces thermic effects. The highfrequent electrical current heats the histoblasts. The tissue is being cut with more than 100°C., thereby all intra,- and extracellular fluids and all cell substances get coagulated thermically. This stops all possible bleedings.

In the HF-Surgery there is a distinction between two types of electrical current: "Cut" and "Coagulation". Because of the high current density on the active electrode, it is possible to cut/coagulate the tissue. The current passes through the human body , leaves the body through the neutral electrode, and finally back to the HF-Unit.

## 18. Information about electromagnetic compatibility (EMC)

### Guidelines and manufacturer's information – electromagnetic emission

The unit is intended for service in one of the below mentioned electromagnetic surroundings. The customer or user of has to make sure that this surrounding is given when operating the unit.

Interference emission measurements	Conformity	Electromagnetic surroundings
High frequency emissions according to CISPR 11	Class B	The unit uses high frequency energy exclusively for intern functioning. Its high frequency emission is very low. It is possible that close by electronic units might be disturbed. The unit is suitable for use in all facilities including those in residential areas and such which can be connected directly to a public supply network, which supplies buildings for residential purposes.

### Guidelines and manufacturer's information – Electromagnetic interference immunity

The unit is intended for service in one of the below mentioned electromagnetic surroundings. The customer or user of has to make sure that this surrounding is given when operating the unit.

Interference immunity testing	IEC 60601 test level	Conformity level	Electromagnetic surroundings
Electrostatic discharge according to IEC 6100-4-2	± 6kV Contact discharge ± 8 kV Air discharge	± 8kV Contact discharge ± 15kV Air discharge	Floors should consist of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances Bursts according to IEC 6100-4-5	± 2kV for mains cable ± 1 kV for input and output wiring	± 2kV for mains cable ± 2 kV voltage outer conductor - earth	The quality of the supply voltage should comply with that of a typical business or hospital environment.
Voltagess ( Surges ) according to IEC 6100-4-5	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor earth	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor earth	The quality of the supply voltage should comply with that of a typical business or hospital environment.

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