MICROMED®

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MDIII

User Manual Unit MD3

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1. Product Description

The HF-Electrosurgical Unit MD3 is the ideal device for smaller surgical operations. Suitable for diverse ranges of application like surgical-, veterinary-, dermatological-, dental-, gynecological- and cosmetical applications. This device can be used for monopolar, monoterminal and bipolar therapies. A neutral electrode is necessary for the monopolar method. However the patient has to be carried in connection with the ground.
The unit is equipped with 2 cut-modes and 3 coagulation-modes:

Mode	Effect	Performance Values (Watt)	Micro Mode (Watt)
Cut 1	smooth cut	80	30
Cut 2	encrusted cut	70	30
Coagulation 1	contact coagulation	70	30
Coagulation 2	spray coagulation	50	20
Coagulation 1	bipolar coagulation	70	50

The micro switch is used to reduce the maximum output power of the cut function 80 Watt down to 30 Watt when the bipolar mode ist activated, resp. down to 50 Watt in the coagulatin 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 wihout push button. In this case the activison has to be done by a foot switch. The bipolar output can also be activated 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/two-piece single use neutral electrode.

1.1 Product liability

The firm Micromed declares to take responsibility for the safety of Unit MD3 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, fulfills the specification of VDE 0107 or IEC 60364-710
- The unit must be used after the annotations and rules of the user manual.

1.2. 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.

2. Incoming materials inspection

Damage in transit
Please check after you received the unit immediately 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 inforemed immediately. A protocoll of all damages has to be done without delay. Please send this protocoll 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 Startup

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. The electronic connection may only be connected by the supplied cable or by a qualitative comparable cable. The outlet must be a protective contact outlet. It is absolutelty important that cable and outlet do have a protective contact.

4. Hints for safe application

Non observance of the descriped 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, or taken possessions 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 place down far 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, e.g. between must be adjusted as low as possible for the respective application.
- In case of a malfunction exists the danger of an increased transference of HF-performance. Caution! Endangering 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-Cureent, because the function of the pacemaker can be jammed or even completely damaged.

4.2 Placement of patients for monoterminal operations

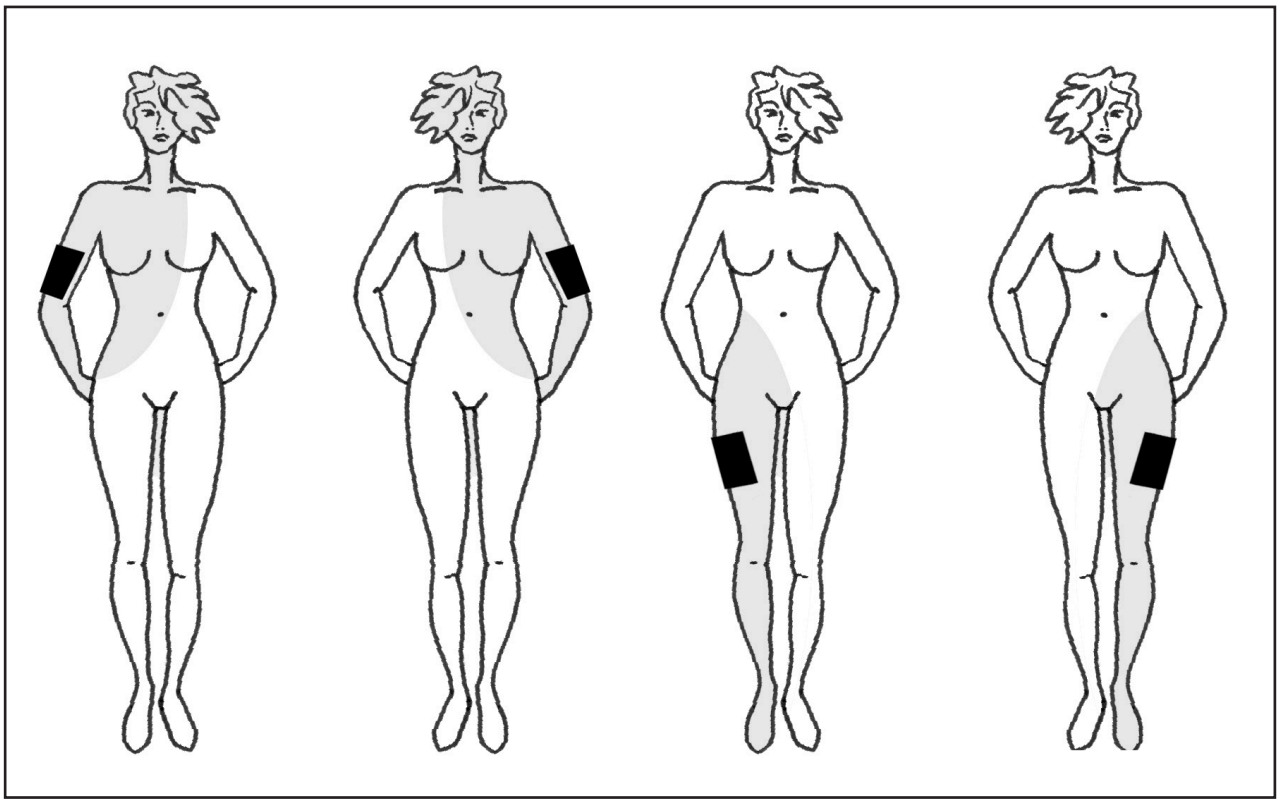
The HF-Unit MD3 is a so called "BF-Type", that means monoterminal apllications are possible.
The therapeutic bensch on which the patient is lying on, must be electricially grounded. The neutral electrode must be always plugged in and placed on the patient's body, otherwise the unit will deliver no power. The restiance values between patient and therapeutic bench must be the same on every spot. If there is the slightest touch between and ground potential leading metal parts, e.g. at the bench on which he is lying, there is the danger of skinn irritation and burnings.
Because of that, it is very important to check before every therapy, that there is no direct contact to ground potential.

4.3 Placement of the patient for monopolar operations

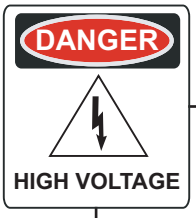
- The patient must be placed on the bench without any ground potential. The neutral electrode is necessary for electrical connection to the patient, because it allows a backflow of electrical current out of the human body.
- The neutral electrode must be placed with its entire surface as close as possible 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 fett and on spots where fluids can flow together.
- Do not use electrode gel.
- The application surface must be clean, dry, free of hair growth and without any injuries.
- The cables shouldn't be in touch wiht the patient, nor have contact to any other cables.

4.4 Neutral electrode

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



Neutral electrode Operation field



- **An alert sound and a red signal will appear, if no plug of an neutral electrode is plugged in.**
- **The neutral electrode shouldn’t be put on apophysis, metal-implants, scared skin, massive cells of fett and on spots where fluids can flow together.**
- **The application area must be dry and clean, and should not include a big crop of hair.**
- **The connection cable of the neutral electrode must not touch the patient or any different cables.**
- **The superveillance 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 to 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 should not be disconnected from the patient by pulling the cable.**
- **Always set the power output for the respective purpose as low as possible.**

4.5 Medical range of application

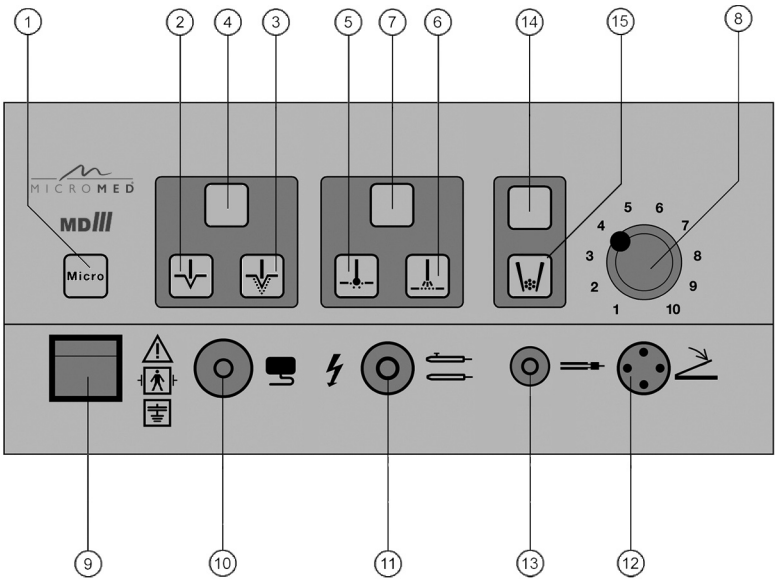
This HF-Unit was conceived for the use up to 80 Watt power output, in the following disciplines:

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

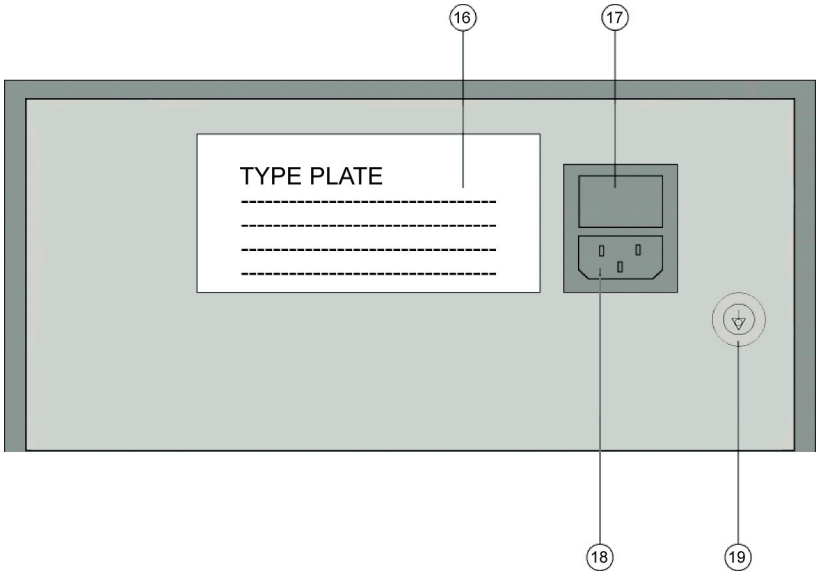
4.6 Function of HF-Units

The HF-Unit produces thermic effects. The highfrequent electrical current heats the histoblasts. The tissue is beeing cut with more than 100°C., thereby all intra,- and extracellularly 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 hight 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.

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	Knop 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	Connection plug bipolar
14	Pilot lamp for Bipolar Coagulation
15	Bipolar Coagulation



16	Type plate
17	Mains fuse, 1,0 Ampere
18	Power plug
19	Potential balance

5.1 Description of user elements

Cut1
creates a smooth cut with less sparkles and less encrustations.

Cut2
creates an encrusted cut with many sparkles. Suitable for very bloody tissue or fett 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.

Bipolar-Coagulation
This kind of coagulaton is working without use of a neutral electrode.
In this mode a low power output to the operating area allows a safe work.

Micro Switch
The micro switch reduces intensely the power output. That hepls to adjust the lower performance range much easier.

Connector (monopolar) for electrode handles: suitable for handles with one/none button.

Connector (bipolar) for forceps and bipolar instruments. Activation by foot switch.

Connector neutral electrode

Connector foot swich to activate monopolar and bipolar jack.

Defibrilator safe for HF-Units in class BF.

Capacitive earth connection between HF-Unit and ground.

Caution! Read user manual!

Caution! High Voltage output.

6. Start Up

The electrical connection of this unit may only be connected with the supplied mains 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 mains voltage on the type plate has to match with the voltage of your electrical system.
The HF-Unit is to activate 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 five 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.
Caution, when the microfunction is turned off, power output will increase enormously, for example from 30 Watt to 70 resp. 80 Watt with level 10. Because of that performance muste be decreased immediatelsy when micromode is turned off.

The power output can only be activated when the one-piece neutral electrode ist plugged in, otherwise an alert will resound and the red signal will be blinking.

6.1 Disturbing emission of HF-Units

The HF-Units produce logically highfrequent and magneic 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.

8. Restoration

The device contains two fuses that resides 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.

9. Specifications

Power Supply Line

Power Supply Line (see type plate)	110-120/220-240 V~
Mains frequency	50-60 Hz
Power consumption	180 VA
Mains fuse 230V	1 Ampere, time-delayed, 2 x

HF-Output max.

Cut I max.	80 Watt, 400 Ohm
Cut II max.	70 Watt,1000 Ohm
Contact-Coagulation	70 Watt, 400 Ohm
Spray-Coagulation	50 Watt,1000 Ohm
Bipolar Coagulation	70 Watt 125 Ohm

HF-Output Micro

Cut I max.	30 Watt, 400 Ohm
Cut II max.	30 Watt,1000 Ohm
Contact-Coagulation	30 Watt, 400 Ohm
Spray-Coagulation	20 Watt,1000 Ohm
Bipolar Coagulation	50 Watt 125 Ohm

General Specifications

Nominal Frequency	700 kHz
Safety Class	I
Type	BF
Classification MPG	II b
Ratio encumbrunce 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

10. 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 4,0 mm, please see HF-Catalogue Micromed
121-XXX-XXX	Electrode Ø 1,6 mm, please see HF-Catalogue Micromed
122-XXX-XXX	Electrode Ø 4,0 mm, 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	Knop for rubber band
152-811-010	Foot switch
129-001-001	Suitcase HF-Unit MD3
140-XXX-XXX	Bipolar Forceps
151-003-001	Accessory Dermatology
151-003-002	Accessory Set Cosmetic Bipolar
151-003-003	Accessory Surgery
151-003-004	Accessory Set Dental
151-003-006	Monopolar ENT Accessory Set
151-003-007	Bipolar ENT Accessory Set

11. Waste disposal

The HF-Electrosurgical units contain no electronic parts and materials which are more 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.

12. 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 statement of the pertaining manufacturers must paid attention.
- 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.

13. 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:

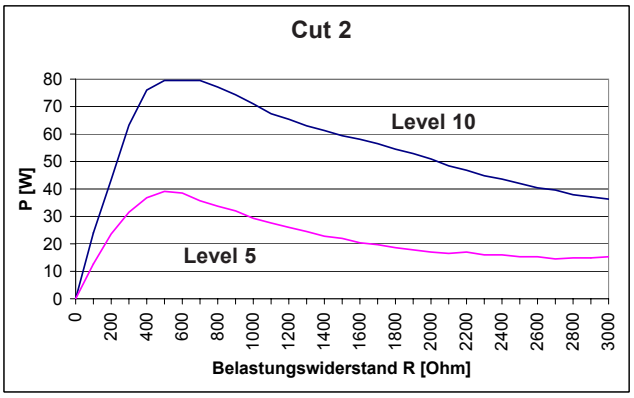
- The resultes from the safety controls have to be documented in the equipment book.
- Visual Control HF-Unit and accessories
- The readability of all-safety relevant epigrams must be checked.
- The fuses must be checked concerning rated current and fusion character.
- Constant energy transference corresponds to the increasing values from the performance setting at the rotary knob.
- The maximum transfered performance must be compared f or 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.

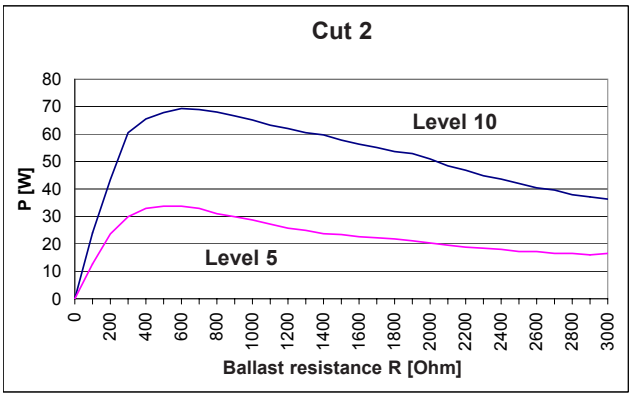
14. Certificates

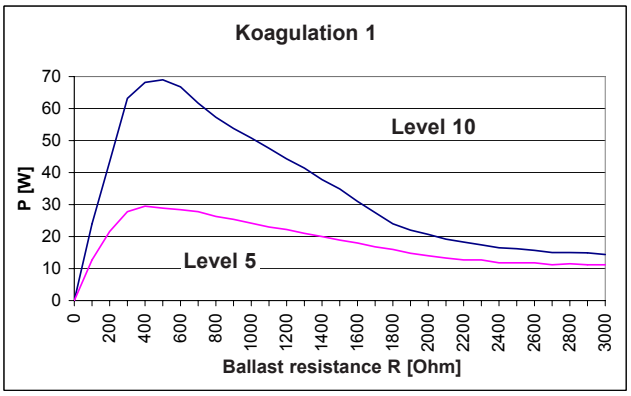
conformable to 93/42/EWG

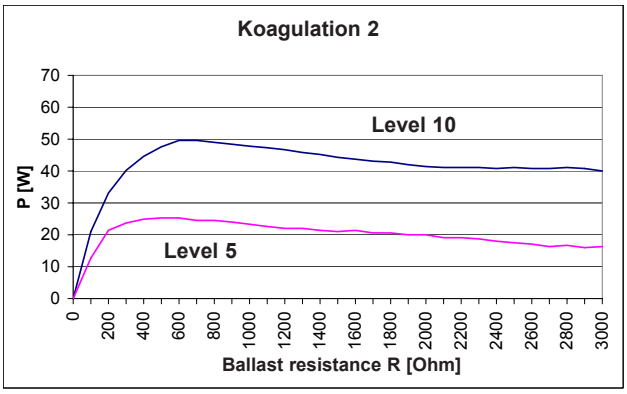
15. Charts of output power

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

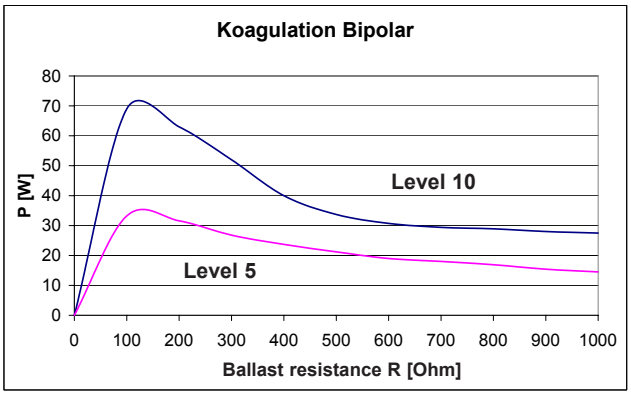




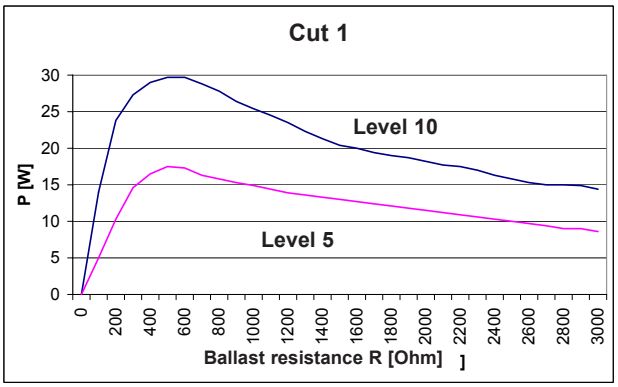


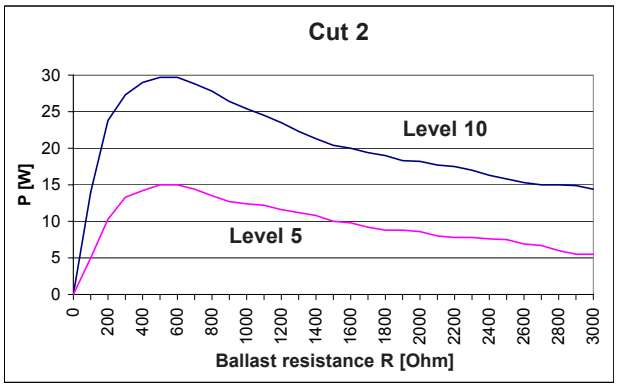


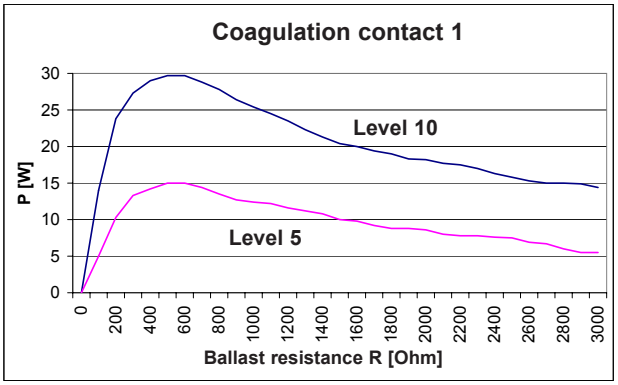
Maximum output power as a function of the power settings.

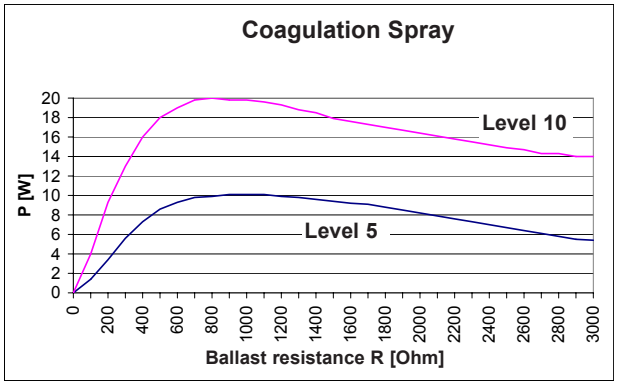


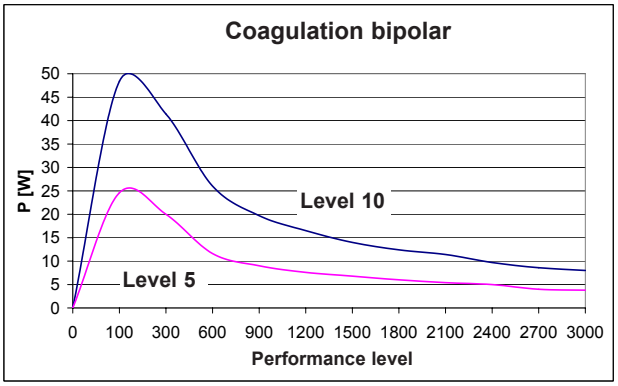
16. Charts of output power with Micro mode





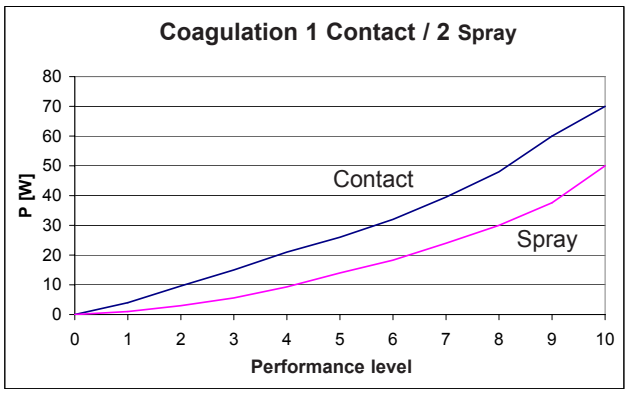


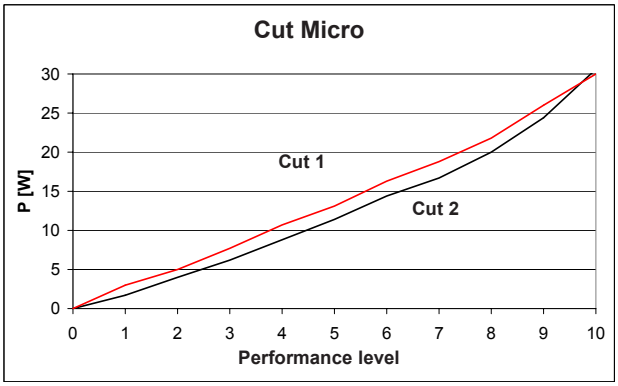


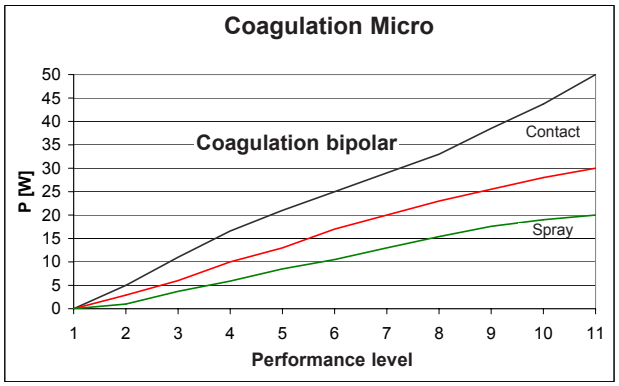


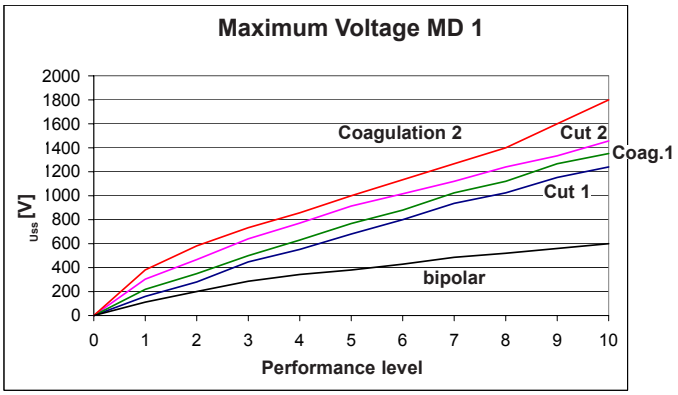
17. Additional Charts

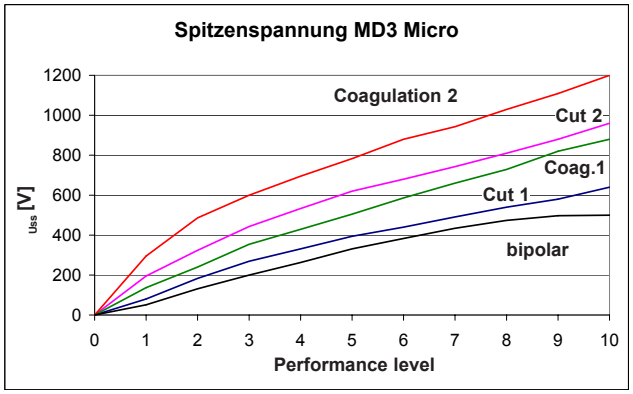
The following charts show the relating power output as a function of the setting concerning a determined resistance of 500 Ohm (Cut1, Coagulation1) resp. 1000 Ohm (Cut2, Coagulation2).











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.
Voltages (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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