A4 / 07.17







EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 034026 0018 Rev. 01

Manufacturer:

Micromed Medizintechnik GmbH

Eisenbahnstraße 84 78573 Wurmlingen GERMANY

Product Category(ies): HF-surgery units, accessories, surgical instruments, suture and non-active orthopaedic implants

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713175715

Valid from: Valid until: 2020-04-27 2024-05-26

Date, 2020-04-27

Christoph Dicks Head of Certification/Notified Body

A4 / 07.17







Certificate No. Q5 034026 0020 Rev. 00

Holder o Facility(i	f Certificate:	Micromed Medizintechnik GmbH Eisenbahnstraße 84 78573 Wurmlingen GERMANY Micromed Medizintechnik GmbH	
i uointy(i		Eisenbahnstraße 84, 78573 Wurmlingen, GERMANY	
Certifica	tion Mark:	tuv-sud.com/ps-cert	
Scope of	f Certificate:	Design and development, production and distribution of electrosurgical units, accessories, surgical instruments, sutures and non active implants	
Applied Standard(s):		EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016	
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.			
Report No.:		713175715	
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Date,	2020-02-17	C.D.L. Christoph Dicks Head of Certification/Notified Body	

TUV®



Manual Instructions MDV touch 300

ENGLISH





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1. Introduction

Our products are exclusively intended for professional use by appropriately trained and qualified personnel and may only be acquired by them.

An electrosurgical unit is a generator used to transform electronic energy into high-frequency alternating current (HF current). When this current flows through human tissue, it creates heat which is used for cutting and for coagulation of the tissue. The MDV touch 300 is a versatile and compact electrosurgical unit which complies with a high safety standard and unites economy with operative flexibility. It offers the following application modes:

For monopolar surgical use

- Pure cut
- Blend cut
- Polypectomy mode
- Cutting in water environment (TUR)
- Soft coagulation
- Forced coagulation
- Spray coagulation
- Monopolar coagulation in water environment (TUR)

For bipolar use:

- Bipolar cut
- Bipolar Cutting in water environment (TUR)
- Bipolar coagulation
- Bipolar coagulation in water environment (TUR)
- Bipolar coagulation (mode "bipolar forceps AUTO start")
- Bipolar vessel sealing

Benefits of the MDV touch 300:

- Simple, intuitive and safe operation
- Current terminal for optional wireless foot switch, max. 0.5 A
- Display-supported neutral electrode safety system helps interactively when applying the neutral electrode
- Nine storage locations for individual program settings
- Two monopolar multifunction terminals for 3-pin standard or Micromed plug
- Tone signal with scope for control of the volume and an alarm tone in case of faults without facility for switching off
- Coloured illumination of the LCD display in red, yellow, blue or green to indicate different operating modes or error statuses
- Facility for tracing output and impedance at the LCD display in the patient circuit on activation
- Worldwide application possible through connection scope from 100 to 260 volts, 50 to 60 Hz
- Successful vessel sealing is confirmed visually and acoustically
- USB-connection for service



1.1 Monopolar operation

In the monopolar mode, HF current is applied to the tissue using an active electrode. The cutting or coagulation effect is caused by a high concentration of current, i.e. a high current density over the small surface of the active electrode. This generates an increase in temperature, causing the water from the tissue immediately surrounding the active electrode to vaporize. Depending on the intensity of the HF current, this causes bleeding to stop or generates a cut in the tissue.

The HF current flows from the active electrode to the neutral electrode and is distributed over its large surface. This reduces the density of the current in this area, and generally prevents unwanted thermal effects at the position of the neutral electrode. The current flows back to the electrosurgical unit through the neutral electrode.



1.2 Bipolar operation



In the bipolar mode, the current path is limited only to tissue located between the two electrodes of a bipolar instrument.

Use of the neutral electrode is not necessary. Bipolar application does not entail any risk of the current flowing through the patient's body. Consequently, there is no danger of burns due to a poorly or incorrectly positioned neutral electrode.

Bipolar coagulation is therefore safer than the monopolar method and is particularly recommended for patients with pacemakers or for operations on organs with a small diameter.

2. Scope of delivery

150-300-002	MDV touch 300	
151-002-200	Power cable	
	Operating instructions	
	Test protocol	



3. Scope

The use of electrosurgical equipment is predominantly in the following areas:

- General surgery
- Traumatology
- Cardiac and Thoracic surgery
- Vascular surgery
- Urology
- ENT
- Gynaecology

3.1 Intended use

An electrosurgical unit is a generator, which converts electronic energy into high frequency alternating current (RF) power. When this current flows through biological tissue, it generates heat, which is used to cut and coagulate the tissue. The device has both, monopolar and bipolar application modes. In the monopolar mode, RF current is applied to the tissue with an active electrode.

The high current concentration heats the tissue slowly, this process leads to a temperature increase which causes the water of the intra- and extracellular fluids to evaporate, depending on the intensity of the HF current, this leads to a stoppage of bleeding or to a cut in the tissue.

In monopolar RF technology, the current introduced by the surgical site flows back from the small area active electrode to the large area neutral electrode and back to the RF device. It should be noted that there is a high conductivity between the neutral electrode and the body in order to avoid a temperature increase at the current exit point.

In the bipolar operating mode, the neutral electrode is no longer required, the current flow is only limited to the tissue that is located between the two electrodes.

3.2 Contraindications

HF surgical devices should not be used with simulators such as bone stimulators. It also discourages the use of electrosurgical devices when pacemakers, such as cardiac pacemakers, are in use.



4. Structure and basic components of the system



Front view of the MDV touch 300



Rear view of the MDV touch 300



The housing of the MDV touch 300 is made of metal and plastic. As no openings are available for ventilation, the unit is simple to clean (refer to 11.1).

Located on the front of the unit are:

(1) Terminal for a neutral electrode

Connections for

- (2) a bipolar instrument (Bipolar2): 2-pin standard or Micromed plug
- (3) a bipolar instrument (Bipolar1): 2-pin standard or Micromed plug
- (4) a monopolar instrument (Monopolar2): 3-pin standard or Micromed plug
- (5) a monopolar instrument (Monopolar1): 3-pin standard or Micromed plug

(6) LCD touchscreen display

(7) Main switch (on/off)

Located on the back of the housing are:

(8) Earthing pins

- (9) Volume controller
- (10) Rating plate with manufacturer's information regarding serial number, mains voltage, output and fuses

Connections for:

- (11) foot switch for monopolar mode (mono1)
- (12) foot switch for monopolar mode (mono2)
- (13) foot switch for bipolar mode (bi1)
- (14) foot switch for bipolar mode (bi2)
- (15) USB-connection for service
- (16) Current terminal for optional wireless foot switch, max. 0.5 A

(17) Terminal for a power supply cable (100-260 V, 50-60 Hz)

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4.1 Main menu of MDV touch 300



- **(18)** Settings and status of foot switch
- (19) Name of program
- (20) Recognition and status of the neutral electrode
- (21) Settings and status of the lock, which is used to save individual programs (see chapter 7.8 "Saving the program against changes")
- **(22)** Input for program selection
- MONOPOLAR 1:
 - (M1) Input for changing the power level and display (CUT and COAG)
 - (M2) Input for selection of the operating mode and display (CUT and COAG)
- MONOPOLAR 2:
 - (M3) Input for changing of the power level and display (CUT and COAG)
 - (M4) Input for selection the operating mode and display (CUT and COAG)
- BIPOLAR 1:
 - (B1) Input for changing the power level and display
 - (B2) Input for selection of the operating mode and display
- BIPOLAR 2:
 - (B3) Input for changing the power level and display
 - (B4) Input for selection of the operating mode and display



4.2 Overview of symbols for operating modes and settings

Symbol	Meaning
	Increase output
	Reduce output
	Pure cut
	Blend cut
	Polypectomy mode
Ø	Monopolar cutting in water environment (TUR)
<u></u>	Soft coagulation
3 4	Forced coagulation
	Spray coagulation
Ø	Monopolar coagulation in water environment (TUR)
e	Bipolar Cutting
Ø	Bipolar Cutting in water environment (TUR)
	Bipolar coagulation
É	Bipolar cut with coagulation
auto	Bipolar coagulation (Mode "Bipolar Forceps" AUTO Start")
E Contraction of the second se	Bipolar vessel sealing





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Status of the foot switches			
Symbol	Status	Meaning	
	Foot switch 1 Foot switch 2 Foot switch 3 Foot switch 3 Foot switch 4 Foot s	 There is a footswitch connection for each output: MONOPOLAR1- connections can be controlled with foot switch 1 MONOPOLAR2- connections can be controlled with foot switch 2 BIPOLAR1- connections can be controlled with foot switch 3 BIPOLAR2 – connections can be controlled with foot switch 4 	

Status of the neutral electrode			
Symbol	Status	Meaning	
	~	Non divided neutral electrode is detected	
NEUTRAL TYPE	~ 9	Divided neutral electrode is detected	
	 alarm	Neutral electrode not detected or not connected	



Mains connection			
Supply voltage	100-260 Volt, 50 - 60 Hz.		
Nominal frequency	500 kHz		
Output power in monopolar operation			
Pure cut	300 W at 500 Ω		
Blend cut	250 W at 500 Ω		
Polypectomy mode	80 W at 250 Ω		
Cutting in water environment (TUR)	250 W at 500 Ω		
Soft coagulation	140 W at 250 Ω		
Forced coagulation	160 W at 500 Ω		
Spray coagulation	80 W at 1500 Ω		
Coagulation in water environment (TUR)	160 W at 500 Ω		
Output power in bipolar operation			
Bipolar cut	140 W at 250 Ω		
Bipolar cutting in water environment (TUR)	230 W at 100 Ω		
Bipolar coagulation (Mode "Bipolar forceps")	100 W at 100 Ω		
Bipolar coagulation in water environment (TUR)	160 W at 100 Ω		
Bipolar coagulation (Mode "Bipolar Forceps" AUTO Start")	100 W at 100 Ω		
Vessel sealing	120 W (peak: 200W) at 100 Ω		
Safety measures			
Туре	CF		
Protection class	1		
Equipotential connection	Yes		
Safety	In accordance with DIN EN ISO 60601-1		
Electromagnetic compatibility	In accordance with DIN EN ISO 60601-1-2		
Safety of high-frequency surgical units	In accordance with DIN EN ISO 60601-2-2		
Miscellaneous			
Operating temperature	+10° C to +40°C		
Humidity during operation	30-75%		
Air pressure during operation	700-1060hPa		
Storage temperature	-10° C to +60°C		
Storage humidity	10-85%		
Air pressure in storage	500-1060hPa		
Dimensions (L/W/H)	355 x 348 x 170 mm		
Weight	9.5 kg		

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6. Accessories



6.1 Accessories for the monopolar operating mode

Handles for monopolar electrodes can be connected to the unit using a 3-pin standard-, Micromed plug or using the 4 mm plug (banana plug) with only one contact.





Micromed monopolar plug

3-pin standard plug

Neutral electrode

Micromed cable for the neutral electrode 110-296-500



The MDV touch 300 reliably detects neutral electrodes with undivided and divided contact surfaces. Comparison of the electrode detected by the machine and the used electrode provides a direct indication of correct adhesion of the neutral electrode. Both single-use and reusable neutral electrodes can be used.



Micromed recommends use of the single-use safety neutral electrode with double divided contact surface (110-300-002) for maximum safety!





6.2 Accessories for the bipolar operating mode

Bipolar instruments are connected to the electrosurgical unit using a 2-pin standard or Micromed plug. When a bipolar Seal cut coagulation instrument is connected, the unit must be set to maximally 80 Watt output power. The set power may not exceed 80 Watt.



Micromed bipolar plug

2-pin plug for bipolar instruments



Adapter for vessel sealing instruments with switching function from other manufacturers

6.3 Foot switch

The following foot switch can be used:



7. Commissioning the unit

7.1 Before starting work

Before starting surgery, the MDV touch 300 electrosurgery unit is connected via the supply cable to the mains socket with PE conductor. The current cable may only be attached or removed when the device is switched off. The connecting socket for the power cable is located at the back of the housing.



Foot switches are connected at "mono1", "mono2", "bi1" or "bi2" . The terminals are located at the back of the housing.

Handles and electrodes are connected correspondingly at the front of the housing to "MONOPOLAR1", "MONOPOLAR2", "BIPOLAR1" or "BIPOLAR2".



7.2 Switching on



The system is switched on by actuating the main switch (ON/OFF). However, high-frequency current only flows once a button is activated at the handle or foot switch.

Consequently, accessories can also be connected to the unit when it is switched on. However, extreme care should always be taken when doing so!

Always ensure that the system is not inadvertently activated during installation by pressing the foot switch or the button in the handle.



7.3 Foot switch settings

After connecting the foot switch on the back, the "Auto-detection"-Symbol appears on the screen. The symbol indicates which foot switch was connected.

It is important to ensure that the instruments are connected to the connectors, which are selected by footswitch. For example: In Monopolar 1 connected instruments can only be operated with the settings <u>MONO1</u> of the foot switch.

Example:

The "auto-detection"-Symbol is displayed on Monopolar1, which means that the foot switch is connected to "Mono1" on the back of the unit.



7.4 Handles with buttons

Activating the handle with buttons takes place independently of the foot switch settings. These cannot be activated using the foot switch.

7.5 Neutral electrode settings and attachment

In the monopolar operating mode, a neutral electrode is required.



After attaching the neutral electrode to the patient, the HF unit recognizes the neutral electrode automatically (cf. illustration on the left and chapter 4.2 "Overview of symbols for operating modes and settings"). The MDV touch 300 recognizes neutral electrodes with divided and undivided contact surfaces.



Please note the following information when attaching the neutral electrode.

Application information for single-use neutral electrodes

- When using single-use products, always pay attention to the use-by date. Do not use electrodes which are over this date!
- Neutral electrodes designed for single use must not be used a second time!
- The electrode must not be attached to surfaces with a high amount of hair growth. If necessary, shave the relevant area before attaching.
- The neutral electrode must be attached in such a way that its entire surface adheres to the patient's body.



- After every change of the patient's position, check that the neutral electrode is adhering correctly and also check the cable routing.
- As soon as the electrode has been attached, it must not be pulled off and attached again. Should the electrode have to be repositioned, use a new neutral electrode.
- The neutral electrode must not come into contact with fluids and must not be coiled round.
- Do not apply any additional electrically conductive gel to the neutral electrode.
- When performing surgery on small children, special electrodes suitable for children or babies must be used (see manufacturer's instructions)
- Never under any circumstances use damaged products!
- When removing the neutral electrode, never pull on the cable!
- When pulling off single-use electrodes, ensure that the patient's skin is not damaged. Avoid any abrupt movements.

Application information for reusable neutral electrodes

- The neutral electrode must be wiped with disinfectant before repeated use. To disinfect reusable rubber neutral electrodes, we recommend the products Incidin perfekt, Minutil and Incidur F from Ecolab.
- The neutral electrode must be attached in such a way that its entire surface adheres to the patient's body. A rubber band provided for this purpose can be used to ensure better adhesion.
- When attaching the neutral electrode, ensure that the long side is pointing towards the operation field.
- After each change in the patient's position, check the correct adhesion of the electrode and the connecting cable!
- The electrode must not be attached to surfaces with a high amount of hair growth. If necessary, shave the relevant area before attaching.
- The electrode must not be wet or coiled round.
- Fluids between the patient's skin and the neutral electrode must be avoided.
- Do not apply any additional electrically conductive gel to the neutral electrode.
- When performing surgery on small children, special electrodes suitable for children or babies must be used (see manufacturer's instructions)
- When removing the neutral electrode, never pull on the cable!
- Never under any circumstances carry out repairs on the neutral electrode! Please note that rubber electrodes lose their conductive capability if active substances are eroded due to cleaning of the material. This type of electrode considerably increases the risk of burns. Always ensure that not only the unit but also the reusable neutral electrode is included in regular maintenance inspections.



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Areas for attaching the neutral electrode

- Attach the neutral electrode to clean, dry skin.
- The electrode must be attached close to the operation area, but with a minimum direct distance from the operating field of 20 cm.
- Attach over tissue with a good supply of blood without dips or curves in the skin, for instance on the upper arm or thigh. (cf. picture below)
- Do not attach the neutral electrode to projecting surfaces.
- Do not attach above bones, scars, cuts or scratches.
- The electrode must not be attached to surfaces with a high amount of hair growth. If necessary, shave the relevant area before attaching.
- Do not attach above particularly adipose areas such as the abdomen or buttocks.
- The neutral electrode must not be attached above implants.
- Electrodes of monitoring systems must be placed at a distance of at least 20 cm from the operation area and from the position of the attached neutral electrode

Correct attachment of the neutral electrode in adult patients:



Correct attachment of the neutral electrode in children



Attachment in patients with pacemakers

→ Note! Consult the treating cardiologist!





RIGHT

WRONG!



7.6 Setting the operating mode and power level

Operating mode

MDV touch 300 has four different operating modes for monopolar cutting, four for monopolar coagulation, two for bipolar cutting and four for bipolar coagulation applications (for details, see chapter 4.2 "Overview of symbols for operating modes and settings"). The selection of all modes takes place according to the same principle. Touch the field showing the operating modes. The selection menu then opens.

The required operating modes must be selected by touching. To save and return to the main menu, select the "Exit" field.



Menu example: Selection of operating modes (MONO2 – CUT)

Power setting

To set the required power level, touch the power display. The menu for power level selection appears.



Use the arrow keys in order to set the required power setting.

To save and return to the main menu, select the "Exit" field.

Menu example: Power setting (MONO2- COAG)

When the unit is next switched on, the last used settings will appear. If you want to save individual settings against changes the lock function can be used. For more information about the lock function see chapter 7.7 "Saving and accessing the program" and 7.8 "Saving the program against changes".

Bipolar vessel sealing:

The function "vessel sealing" must be set. This function is activated with the footswitch. The footswitch must remain pressed, until the notice "vessel sealing finished" is shown in the display and an acoustic signal is sounded.



7.7 Saving and accessing the program

Touching the "PROG" field causes a selection of saved programs to appear.

To select the required program, touch the relevant line. The program you are located in is highlighted in grey.

In the main menu, the number of the accessed program and the name are displayed

PROGRAM1 DR MULLER

To change the program name, touch the field with the name. In our example, this is: DR MULLER. A window opens with a keypad. The maximum symbol length is 15 characters. To save the name, press "Enter" and to quit without saving, press "Esc".



Every change of the settings is automatically saved in the program you are currently in. In order to save individual settings in a new program, initially select a free storage location. Settings and the name of the program can then be changed at will.

7.8 Saving the program against changes

By touching the lock on the display, the current program will be protected against changes. Nevertheless, it is possible to change settings during surgery. Once the device is switched off, the settings at the time of activation of the lock symbol will be restored.

7.9 Switching off

After terminating the operation, switch off the system at the main switch and pull out the plug. After switching off the system, all electrodes and forceps must be disconnected from the cable and the electrode cable from the unit.

Nr		Ø
1	DR. MULLER	1
2	Name 2	
3	Name 3	
4	Name 4	
5	Name 5	
6	Name 6	
7	Name 7	
8	Name 8	
9	Name 9	



7.10 Menu design

When a handle or a foot switch is activated, the activated channel lights up yellow (for CUT) or blue (for COAG), a signal sounds and a dot appears next to the selected operating mode. In the case of faults, the display lights up red and a signal also sounds.

Examples of menu illumination:



Standby mode



"MONOPOLAR2 - CUT" mode



Display: "Process is completed" – Biseal mode



Display: Error!



7.11 Operating errors

In the case of an operating error, the following display appears:



The following error messages can occur:

	•	
Error - display	Cause of error	Remedying errors
NE Error - No 1	Neutral electrode not connected, not known, or NE is defective	Check the terminal, touch the NE symbol on the touchscreen for detection, where applicable exchange NE and/or connecting cable.
Mono1 - Cut hand	Cut button on handle in terminal Mono 1	
Mono1 - Coag hand	Coag button on handle in terminal Mono 1	Check the terminals, check the settings, exchange accessories if necessary. If
Mono2 - Cut hand	Cut button on handle in terminal Mono 2	error persists, inform specialist personnel.
Mono2 - Coag hand	Coag button on handle in terminal Mono 2	

If one or more numerical codes are displayed, or if the device is indicating any other recognizable defects, please refer to info@micromed.com.

HF current does not flow when the foot switch is actuated. The system only reacts with a tone signal and the display changes colour.

Please check:

- → that all terminals have been <u>correctly</u> connected
- the settings of the foot switch
- → whether the neutral electrode has been recognized

The neutral electrode is not at all or not correctly detected

Check all terminals and touch the field with the symbol of the neutral electrode for detection of the NE. If the neutral electrode is still not recognized, exchange it where appropriate.

It is not possible to switch the machine on or off.

Check whether the power cable has been correctly connected and that the socket is intact. If the error persists, inform the specialist personnel.

The system works perfectly, but the settings cannot be saved.

Inform the specialised personnel.





8. Guideline value for power settings



When performing the power settings, the user should generally take into account the cutting speed, geometry of the electrode and properties of the tissue.

Monopolar cutting:

	Recommended settings
Smooth cuts with thin needle electrode	5 - 40 W
Cutting with knife electrode, lancet or wire loop	50 - 175 W
Cutting in water environment (TUR)	80 - 150 W

Monopolar coagulation:

	Recommended settings
Coagulation of large surfaces	60 W
Coagulation of small surfaces	40 W

Bipolar application:

	Recommended settings
Coagulation	30 - 60 W
Blend Cut	40 - 60 W
Cutting in water environment (TUR)	50 - 75 W
Vessel sealing	50 - 120 W

The recommended settings serve as guideline values only and must be adjusted to the relevant situation. In the event of unfavourable conditions, these values may deviate!





9. Protective measures and warnings

Please observe also the instructions provided on working with the neutral electrode in chapter 7.5 the operating instructions with the accessories and the applicable safety measures!

Before any procedure, check the cables, accessories (handles, electrodes, forceps) and foot switches for any signs of visible irregularity. Do not use cables or instruments with broken or defective insulation. These can result in burns if they come into contact with the skin!

The unit should only be operated at a mains socket with protective earth contact. When performing electrosurgical procedures, the risk of burns must be kept as small as possible. For this, the following safety measures must be observed:

!	All plug-in connections may only be carried out with compatible accessories.
!	Use the greatest care when working with the neutral conductor!
!	Protect the patient from contact with earthed metallic elements (OP table, infusion stand etc.) during use.
!	Avoid contact between supply cables and patients, other cables or instruments! Ensure that there are no loops in the cables of handles and electrodes or fixture to the OP table.
!	Avoid small-area skin-to-skin contact in the patient (e.g. a finger making contact with the thigh).
!	Avoid contact between HF instruments and non-insulated instruments.
!	Prevent the penetration of fluids between the patient's body and the neutral electrode.
!	The output power should not be set higher than is absolutely necessary for the procedure.
!	Do not touch the patient during activation of the coagulation or cutting current. Should this be necessary, a piece of fabric can be used for insulation purposes.
!	In patients connected to monitoring devices (ECG), the monitoring electrodes must be attached at the greatest possible distance to the application areas of the electrosurgical electrodes.
!	The use of highly flammable narcotic substances and oxidizing gases (N20 or O2) should be avoided. Should this be necessary, take particular precautions.

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!	Exclusively non-flammable disinfectants must be used. If alcohol-based solutions are required, wait before performing surgery until these have completely evaporated. Bear in mind that disinfectants can flow down and collect in recesses of the body. A spark from the active electrode can cause combustion of the fluid in normal use.
!	Sparks from the active electrode can set bandages (textiles), metabolic gases and combustible fluids alight.
!	In the case of procedures involving high-frequency current applied to body parts with a minimal cross-section, the bipolar technique should be used in order to prevent the risk of unintentional coagulation.
!	In the case of procedures on body parts with a close link to the remainder of the body, the bipolar technique should be used for safety reasons.
!	The frequently used indirect coagulation mode should only be used with well insulated forceps. We recommend forceps with specially insulated grip areas (ask your Micromed contact).
!	Surgical gloves do not afford the surgeon sufficient protection from burns!
!	During surgery, pacemakers are at risk of destruction. We recommend consulting the treating cardiologist and/or an authorized representative of the pacemaker manufacturer. As a rule, in such cases bipolar application technology is advisable. Electrosurgical procedures are prohibited on outpatients with pacemakers.
!	A marked drop in power at a normal setting can be an indication of incorrect application of the neutral electrode.
!	Soiled electrodes can bring about a drop in the quality of the unit. This applies particularly to gentle and bipolar coagulation. To prevent the tissue adhering to the active electrode (monopolar or bipolar), it is advisable to wait for a moment after coagulation of the tissue and to interrupt the current flow to allow the active tip to cool before separating the electrode from the tissue.
!	High-frequency creep currents can cause burns in areas distant from the application site through conductive connections.
!	To remove the cable from the unit, always hold the plug! Never pull on the cable, as this can result in damage to the cable insulators, burns on the skin or also fire.
!	Instruments which are temporarily not required during the procedure must be placed away from the patient on the instrument table or a similar surface.
!	Reusable electrosurgical instruments which are connected to the unit are generally not delivered in a sterile condition!





Electromagnetic safety

In the development of electrosurgical units, Micromed attaches particular importance to the stringent electromagnetic emission regulations. Consequently, the solutions we supply have a correspondingly minimal emission level for the required output. Measurements confirm the high level of electromagnetic safety offered by Micromed electrosurgical units.

Under typical working conditions based on an 8-hour day, a field occurs at a distance of 5 to 15 cm from the cables. At a distance of 20-40 cm, the value drops well below the prescribed limit.

Electromagnetic fields occur primarily around the cable. The electrosurgical unit itself does not constitute a significant emitting element.

10. Review of the technical status

Before any procedure, check the cables, accessories (handles, electrodes, forceps) and foot switches for any signs of visible irregularity. Do not use cables or instruments with broken or defective insulation. These can result in burns if they come into contact with the skin!

10.1 Mechanical faults

If damage occurs to switches, connecting sockets, houses or the touch screen, or if the unit is dropped on the floor, please contact your authorized dealer for advice on further use. The dealer can arrange for a detailed technical check to be performed.

The manufacturer accepts no liability for calibration work or repairs to the unit carried out by the user.

10.2 Recurring safety inspections

A safety inspection of the electrosurgical system is required every two years. The manufacturer only permits the use of units for which an up-to-date inspection by suitably trained personnel can be verified.

All information relating to the inspections (date, inspecting staff member, result etc.) must be recorded in the unit's log book.

10.3 Servicing and manufacturer address

Micromed Medizintechnik GmbH Eisenbahnstr. 84 78573 Wurmlingen, Germany Tel. +49 7461 96 48 55 - 0 Fax: +49 7461 96 48 55 - 95 Email: info@micromed.com Web: www.micromed.com



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11. System maintenance work

11.1 Cleaning

The electrosurgical unit can be wiped using a cloth dampened with standard disinfectant, and so kept clean using the simplest possible method. Avoid allowing cleaning fluid and disinfectant to penetrate into the unit.

11.2 Fuses

The fuse sockets are located on the back of the unit. The unit works with two fuses of 6.3 A each.

Exchanging the fuses:

- Disconnect the unit from the mains
- Release the fuse from the retainer using a flat blade screwdriver
- Exchange the fuse

After an exchange of fuses, the unit must be checked by suitably qualified personnel.

11.3 Transport

Prevent mechanical damage and moisture. If the unit has been stored for a long period in a cold environment, wait before removing the protective packaging until the unit has reached room temperature. During transportation, the standard safety measures additionally apply. Only ever transport the unit in its original packaging.

11.4 Environmental directives

From the implementation date of the European directive 2002/96/EU as national legislation, the following regulations apply:

- Electrical and electronic units must not be disposed of with normal household waste.
- The consumer is required by law to return electrical and electronic devices at the end of their service life to designated public collection points or to the place of purchase.

Disposal details are set out by the applicable local legislation in the relevant country. The symbol on the product, the instructions for use or the packaging indicates the relevant applicable legislation. By sending end-of-life devices for reuse, material recycling or other forms of utilization you are making a major contribution to environmental protection. Please also send the unit packaging for environmentally responsible recycling after the end of the product's life.







12. Warranty card



We grant a on all electrosurgical devices



2-year warranty

We grant a warranty in accordance with the statutory and country-specific regulations on all electrical medical products (verification required in the form of an invoice or delivery note). The warranty period is two years. In the event of material or production errors, we provide free repair of the unit. Any attempt to carry out independent repairs will render the warranty cover null and void.

Damage caused by incorrect handling, overloading or normal wear and tear is not covered under the terms of the warranty.

In the event of a warranty claim and resulting repair, please enclose a copy of the invoice or delivery note (or lot number) with the unit.



Manufacturer and aftersales service address:

Micromed Medizintechnik GmbH Eisenbahnstr. 84 78573 Wurmlingen Tel. +49 7461 96 48 55 - 0 Fax: +49 7461 96 48 55 - 95 Email: info@micromed.com Web: www.micromed.com



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MDV touch 300

Elektrochirurgiegerät Electrosurgical unit



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MDV touch 300

- Einfache, interaktive und sichere Bedienung am Touch Display
- Neue, weiterentwickelte CUT COAG Funktion
- Automatische Leistungsregelung
- Individuell einstellbare Speicherprogramme
- 4 Multifunktionsbuchsen für Zubehör unterschiedlicher Hersteller
- Instrumentenerkennung im Bipolar-Modus
- AutoStart Funktion
- Leistung und Impedanz werden bei Aktivierung auf dem LCD-Display angezeigt
- Akustische und optische Bestätigung nach abgeschlossener Gefäßversiegelung
- Weltweit einsetzbar: 100-260 Volt, 50-60 Hz
- Erkennung des Fußschalters: Anzeige der angeschlossenen Pedale auf dem Display

Technische Daten · Technical Data

_	Easy,	interactive	and safe	operation	at touch	display
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- Newly developed CUT COAG function
- Automatic adjustment of power output
- Individual saving programs for settings
- 4 multifunction sockets for accessories of various manufacturers - Instrument recognition in bipolar mode
- AutoStart function
- Power output and impedance displayed on LCD screen upon activation
- Acoustic and optic confirmation after completed vessel sealing
- Worldwide use: 100-260 Volt, 50-60 Hz
- Foot switch detection: Connected pedals showing on display

Monopolares Glattes Schneiden	Monopolar pure cutting	300 Watt, 500 Ω
Monopolares Verschorftes Schneiden	Monopolar blend cutting	250 Watt, 500 Ω
Monopolarer Polypektomie Modus	Monopolar polypectomy mode	80 Watt, 250 Ω
Monopolares Schneiden TUR	Monopolar cutting TUR	250 Watt, 500 Ω
Monopolare Schonende Koagulation	Monopolar soft coagulation	140 Watt, 250 Ω
Monopolare Starke Koagulation	Monopolar forced coagulation	160 Watt, 500 Ω
Monopolare Sprüh Koagulation	Monopolar spray coagulation	80 Watt, 1500 Ω
Monopolare Koagulation TUR	Monopolar coagulation TUR	160 Watt, 500 Ω
Bipolare Koagulation	Bipolar coagulation	100 Watt, 100 Ω
Bipolares Schneiden	Bipolar cutting	140 Watt, 250 Ω
Bipolare Gefäßversiegelung	Bipolar vessel sealing	120 Watt, 100 Ω
Bipolares Schneiden TUR	Bipolar cutting TUR	230 Watt, 100 Ω
Bipolare Koagulation TUR	Bipolar coagulation TUR	160 Watt, 100 Ω
Тур	Туре	CF
Klassifizierung	Classification	ll b
Abmessungen	Dimensions	380x370x170 mm
Nennfrequenz	Nominal frequency	500 kHz
Gewicht	Weight	9,5 kg
Gewährleistung (Monate)	Warranty (months)	24
Netzanschluss	Mains supply	100-260 Volt, 50-60 Hz
Schutzklasse	Protective class	1
Potenzialausgleichanschluss	Equipotential connection	Yes
Sicherheitssystem	Safety system	SUNY



150-300-002

Elektrochirurgiegerät MDV touch 300 Electrosurgical unit MDV touch 300



Koagulation

Coagulation

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Schneiden Cutting

Gefäßversiegelung Vessel sealing

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Elektrochirurgiegerät MDV touch 300 Electrosurgical unit MDV touch 300

Schneiden TUR Cutting TUR

Koagulation TUR Coagulation TUR

AutoStart AutoStart