TEKNO GERMANY SHAVER TM 940

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CE 0483

Copyright Information

Table 0. Basic data on the device and its place of installation.

	Control Unit	Handpiece	Footswitch
Device Reference / Article Number:			
Device Serial Number:			
Place of installation:			
Date of installation:			
Person trained in use of the device:			

Please fill in the data above and keep the operating instruction for future reference.

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1 PRECAUTIONS

- The operating instruction indicates how to operate, maintain and service the equipment, so that its working life is as long as possible. Proper service is essential for a long-term trouble-free operation of the device.
- Staff operating the device should familiarize themselves with the contents of this manual before installation and use of the device, and those who have access to it.
- The device can only be operated by doctors or assisting staff with appropriate qualifications.
- The device is made up in I safety class.
- CAUTION: To avoid risk of electric shock the device has to be connected only to a supplying network with protective earthing.
- Before connecting the device to the power outlet, make sure that the parameters of the power grid are identical to those in the device specifications. Supply voltage, frequency and power consumption are specified in the remainder of the documentation and on the rear panel of the device.
- Do not expose the device to strong humidity or rain.
- Do not squeeze, pull and bend the cable of Shaver Handpiece and Shaver Footswitch.
- WARNING! Never use the device in the environments of flammable anaesthetic gases or in oxygen rich environment.
- If flammable gases (including anaesthetics gases) are released in the vicinity of the device, the latter should be immediately switched off and unplugged from the power socket.
- To avoid overheating the device, ensure that adequate ventilation is provided before starting the device. It is recommended to maintain a min. 15 cm clearance from the left, right and rear sides of the device.
- Under no circumstances open the cover of the device when it is connected to power. Electric voltage inside the unit can reach 0.4 kV. Electric shock may result in permanent disability or death.
- NEVER place the device near hot surfaces or areas subject to vibration or shock.
- Repairs of the device, other than those specified in this operating instruction, can be performed only by manufacturer or by an authorized service provider specified by the manufacturer. The only repair that the user can perform, after familiarizing themselves with the contents of the operating instruction: changing fuses for the electric power connection.
- Service address can be found in the last page (*service provider data)* of the operating instruction.
- The device must not be serviced and maintained while in use with the patient.

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- WARNING!!! Temperature of Shaver Handpiece enclosure in most unfavourable conditions could reach the value of 50°C. Avoid touching the patient with the Shaver Handpiece and never place it on top of the patient, as doing so may result in burns to the patient. Never use a device with a closed valve, the liquid flowing through the Shaver Handpiece channel cools its enclosure.

- Running the shaver blade or shaver bur without flow may cause damage to the handpiece or may cause the shaver hub to melt due to excessive heat.

- In case of any disturbances or malfunctions in the functioning of the device, immediately turn it off using the power switch located on the rear panel.

- WARNING!!! Device during normal use works in conjunction with other electrical devices in medical system. When combining or modifying medical system, requirements of IEC/EN 60601-1 should be fulfilled. Detailed information and guidance can be found in point *4.1 Medical systems* of the instruction.

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in user manual. Portable and mobile RF communications equipment can affect medical electrical equipment. The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Taking into account the above guidance, the manufacturer feels responsible for the safety and reliability of the device.

The manufacturer does not assume responsibility for damages which have arisen through abuse or incompatible with the intended operation of the device.

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2 CLASSIFICATION OF THE DEVICE AND ITS INTENDED USE

2.1 Intended use of the device

Shaver System TM 940 has been specifically designed for driving of blades and surgical cutters, which are used during treatments of orthopaedic reconstruction by using an endoscopic method named arthroscopy. Arthroscopic Shaver System consists of: Shaver Control Unit tk 39802-01, Shaver Handpiece tk 39802-02 and Shaver Footswitch tk 39802-03.

It is not necessary to use the Shaver Footswitch during the treatment. Activating the basic functions via footswitch facilitates the operation of the device, that makes its usage more convenient and faster.

Table 1. The Shaver Control Unit tk 39802-01 cooperates with the followings.

Pos.	Specification	Ref. /Art. No.
1	Shaver Handpiece	tk 39802-02
2	Shaver Footswitch	tk 39802-03

The device can be used only for medical treatments, such as: arthroscopy.

It is the user's responsibility to use the device properly as intended. Not complying to the operating instruction may result in danger for the patient or any of users.

2.2 Contradictions

There are no known clinical contraindications for the use of the device.
The surgeon as an operator is able to decide to exclude the used of the shaver system in a given arthroscopic treatment, based on the patient's condition, condition or other factors affecting the safety and effectiveness of the system.

There are no known side effects that could adversely affect the patient's health and safety. The use of the device is not recommended when the arthroscopic treatment is contraindicated or when the ambient conditions are outside the acceptable range defined by the manufacturer of the products in the point 8 of the operating instruction.

2.3 Products and optional accessories

Table 2. Products and accessories.

Pos.	Specification	Ref. /Art. No.	Qty
1	Shaver Control Unit: Console, IFU, power cord, fuses	tk 39802-01	1
2	Shaver Handpiece	tk 39802-02	1
3	Shaver Footswitch	tk 39802-03	1
4	Power cord with EU plug (IEC/EN 60320-1/C13)	tk 754-9990	1
5	Operating instruction	-	1
6	Spare fuses	According to *Table 10.*	2

The device is supplied in a package that should be kept for possible future transport.
Only proper packing of the device in its original packaging ensures safe transport.

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2.4 Device classification

The Arthroscopic Shaver System has been classified **as Class IIa** in accordance with rule 9 of Annex IX of Directive MDD/93/42/EEC.
Cited standards are specified in *Table 3.*

Table 3. List of standards, to which the manufacturer referred to during conformity assessment.

No.	Standard	Description
1	DIN EN 60601-1+A1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2	DIN EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	DIN EN ISO 14971	Medical devices. Application of risk management to medical devices
4	DIN EN 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
5	DIN EN 62366-1	Medical devices -- Application of usability engineering to medical devices
6	DIN EN 62304	Medical device software -- Software life cycle processes
7	DIN EN ISO 17664	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
8	DIN EN ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
9	DIN EN ISO 10993-18	Biological evaluation of medical devices -- Part 18: Chemical characterization of materials
10	DIN EN ISO 15223-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
11	DIN EN 1041	Information supplied by the manufacturer of medical devices

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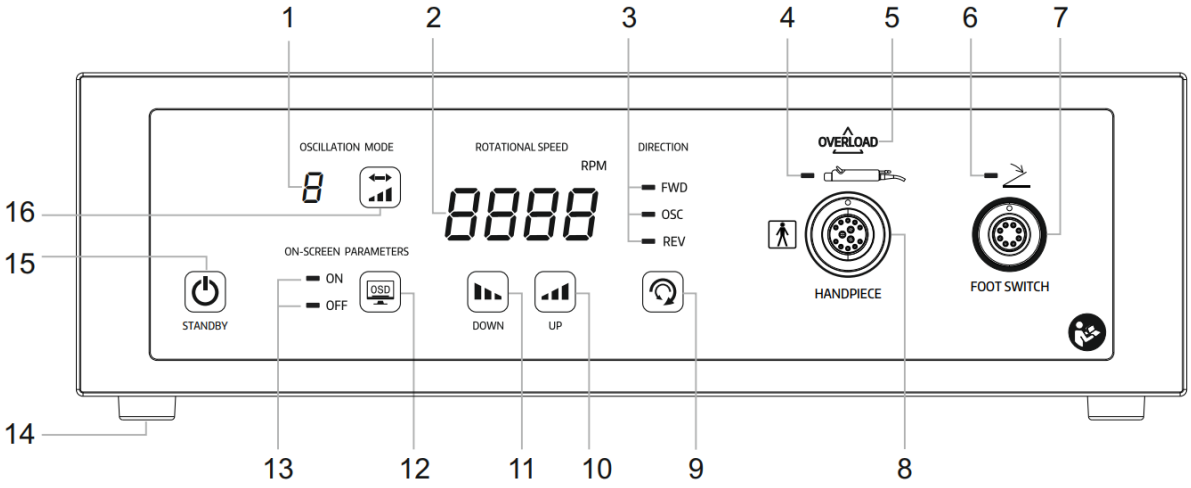
3 DESCRIPTION OF THE COMPONENTS

3.1 Front panel description



Description:

1. **Display window „OSCILLATION MODE"** – displays the actual oscillation mode number.
2. **Display window „ROTATIONAL SPEED"** – displays the rotational speed value and messages.
3. **Indicators „DIRECTION"** – indicates the direction mode of rotation the shaver blade in Shaver Handpiece
   - - FWD – clockwise rotation,
   - - OSC – oscillation mode,
   - - REV – counter clock rotation.
4. **Indicator „HANDPIECE"** – visual indication of Shaver Handpiece connection to the "Handpiece" socket.
5. **Indicator "OVERLOAD"** – visual indication of Shaver Handpiece motor overload.
6. **Indicator „FOOT SWITCH"** – – visual indication of Shaver Footswitch connection to the "Foot switch" socket.
7. **"FOOT SWITCH" socket** – socket for connection the Shaver Footswitch.
8. **"HANDPIECE" socket** – socket for connection the Shaver Handpiece .
9. **"DIRECTION" button** – function key to switch direction mode of rotation the shaver blade in the Shaver Handpiece.
10. **"SPEED UP" button** – stepwise increase of the speed to the next higher level of rotational speed.
11. **"SPEED DOWN" button** – stepwise reduction of the speed to the next lower level of rotational speed.
12. **"OSD" button –** illuminated, indicates connection to the appropriate device.
13. **Indicators „ON-SCREEN PARAMETERS"** – visual indication the status of the function:
    – ON – active,
    – OFF – inactive.
14. **Rubber feet** of the device.
15. **"STANDBY" button** – switches the device from a „STANDBY" state of energy saving/sleep to a working state and vice versa.
    - the „Standby" indicator blinks at a frequency of 0.5Hz- this means that the device is on a „Standby" state
    - the "Standby indicator illuminates continuously – the device is switched on and working properly.
16. **"OSCILLATION MODE" button** – oscillation mode change button.

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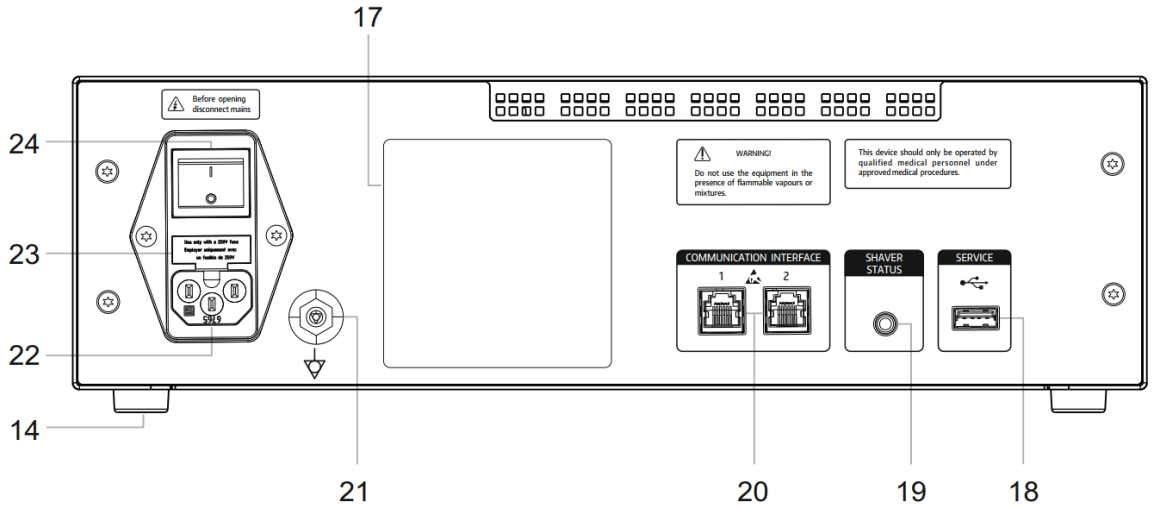
3.2 Rear panel description



Description:

14. **Rubber feet** of the device.
17. **Device label** – contains information on the device type, wattage, power supply fuses, serial number and date of manufacturing.
18. **"SERVICE"-** service socket – for service only.
19. **"SHAVER STATUS"** – mini-jack socket – information about the Shaver Handpiece work status.
20. **"COMMUNICATION INTERFACE"** – RJ 11 socket – dedicated to connection to apropiate device.
21. **POAG stud for the equipotential bonding system** - connector for equalising the electrical potential of the housing of the Shaver Control Unit with the potential of other devices**.**
22. **Power cable socket** - power cable socket with fuse drawer. The nominal values for fuses are specified on the device label. It is imperative to disconnect the power cord during maintenance, cleaning or replacement of fuses.
23. **Fuse drawer** - where protecting the device power supply fuses are installed. Changing the fuses is described in point 7.1.
24. **Power switch** – double pole ON/OFF switch used to enable and disable power to the device.

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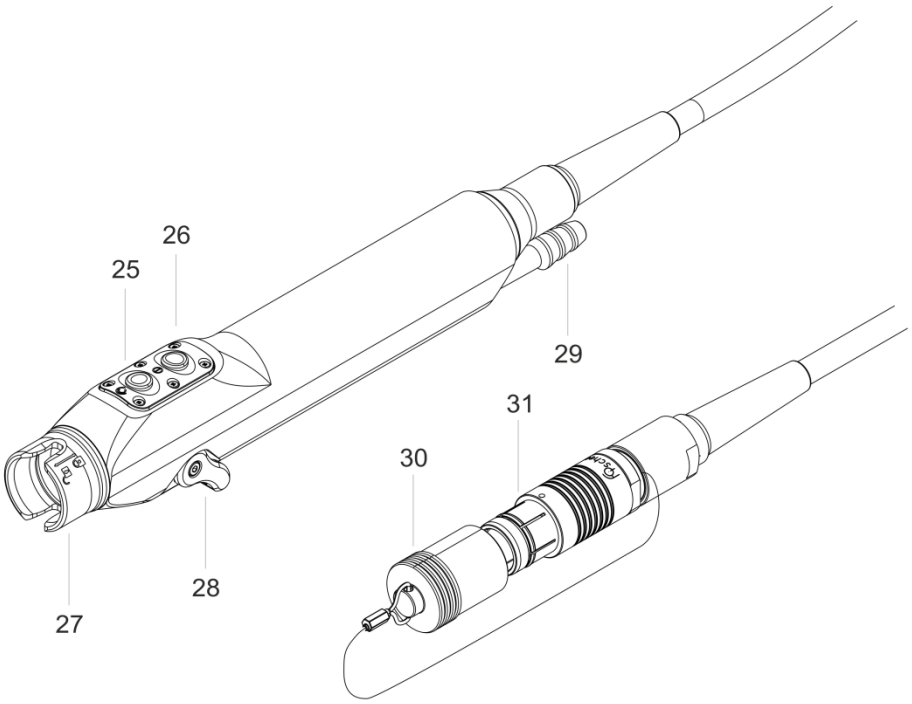
3.3 Shaver Handpiece description



Description:

25. "**DIRECTION" button** – function key to switch direction mode of rotation of the Shaver blade in she Shaver Handpiece (long press switches mode of oscillation).
26. **ON/OFF button** – turning on/off the motor in the Shaver Handpiece (long press activates „WINDOW SIZE" function).
27. **Head –** the part securely engaging the shaver blade in Shaver Handpiece.
28. **Suction control lever** – to regulate the extraction of saline solution from the operative site.
29. **Aspiration port** – to connect the tube of the vacuum pump onto this nozzle, to suck the saline solution from operating field through off the Shaver Handpiece.
30. **Protective cap for the plug** – protects the plug during cleaning, disinfection and sterilization process.
31. **Plug**–connection to attach the Shaver Handpiece to the Shaver Control Unit. An integrated lock at the plug protects the cable of the Shaver Handpiece from being pulled out by accident.

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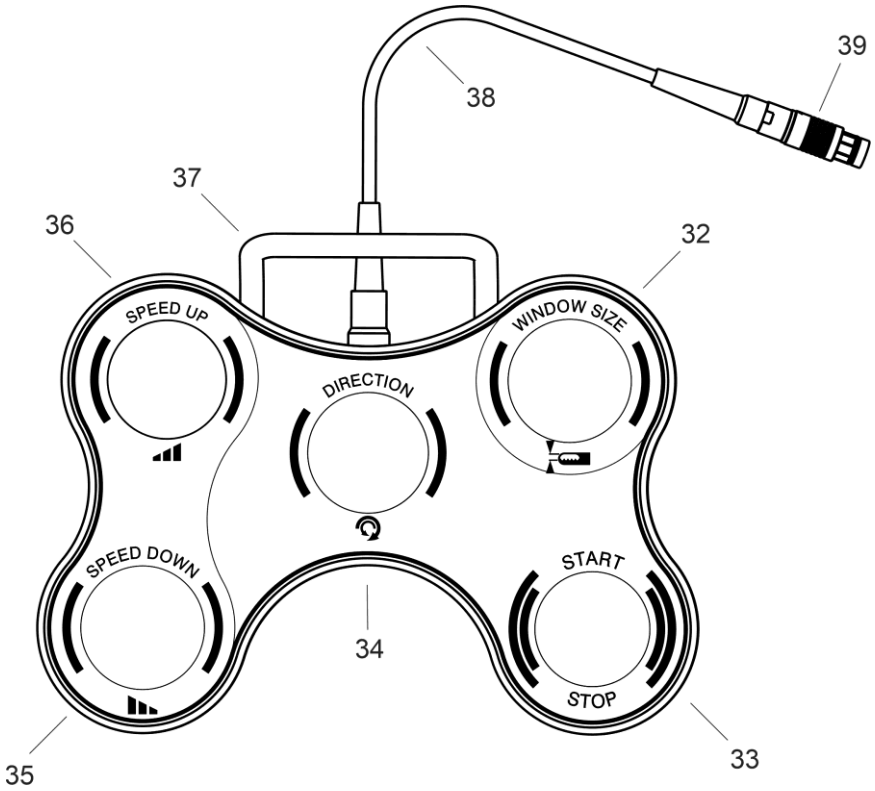
3.4 Shaver Footswitch description



Description:

32. **"WINDOW SIZE" button** – window size calibration function.
33. **START/STOP button** – turning on/off the motor in the Shaver Handpiece.
34. **"DIRECTION" button** – function key to switch direction mode of rotation the shaver blade in the Shaver Handpiece.
35. **"SPEED DOWN" button** – stepwise reduction of the speed to the next lower level of rotational speed.
36. **"SPEED UP" button** – – stepwise increase of the speed to the next higher level of rotational speed.
37. **Handle** – used for lifting and carrying the Shaver Footswitch.
38. **Cable** – connection between the Shaver Footswitch and the Shaver Control Unit, serves to transmit the selected functions of the individual Shaver Footswitch buttons.
39. **Plug** – connection to attach the Shaver Footswitch to the Shaver Control Unit. An integrated lock at the plug protects the cable of the Shaver Footswitch from being pulled out by accident.

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4 INSTALLATION AND STARTING OF THE DEVICE

4.1 Medical systems

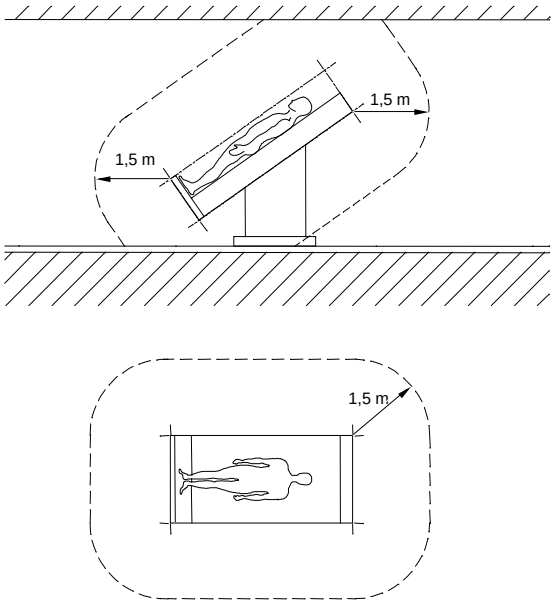
WARNING!

The device is designed to work in conjunction with other electrical devices in a medical system. The combination of the medical system can only be performed by qualified person. Installation of medical systems and their modifications during normal use are permitted with caution to requirements. Legal requirements and Clause 16 of EN 60601-1 technical requirements have to be fulfilled.

WARNING!

In addition to this operating instruction also follow the instructions of the product used in combination with this product.

In the patient environment may be located only medical electrical devices provided by the manufacturer for such use. Electrical equipment outside the patient environment must meet certain safety requirements according to IEC or ISO. Patient environment in accordance with IEC / EN 60601-1 is defined as the area around the patient according to shown below.



WARNING!

When the device is used with other equipment, leakage currents may be additive causing hazard to the patient. When selecting the system components basic safety requirements shall be fulfilled:

- After medical system installation or modification, leakage currents shall be measured to ensure that the limit values according to EN 60601-1 are not exceeded. Leakage currents can be reduced by means of separating transformer or additional protective earth terminal to system ground.
- To connect the device with non-medical devices, the device and the non-medical devices have to be powered through a medical separating transformer.
- To connect the device with a non-medical device in non-medically used room through a long cable, a separation device should be used between the device and the non-medical device.

WARNING!

If a multiple socket-outlet is used, it shall not be placed on the floor.

WARNING!

Connection of additional medical, non-medical devices or multiple socket outlets to medical system requires re-analysis and safety checks on compliance with the requirements of IEC/EN 60601-1.

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WARNING!
Any modifications of medical systems contrary to this operating instruction, could result in exceeding allowable safe limits of leakage currents and will cause hazard to the patient.

WARNING!
During operation of the device, do NOT touch the patient and any signal connector of the device at same time, or other devices in patient environment.

4.2 Device installation

This chapter describes the correct installation and start-up of the device. The first step is the correct installation of the Shaver Control Unit, Shaver Handpiece and Shaver Footswitch. If the subsequent steps described in chapters 4.1. to 4.4. have been followed correctly, the device is now ready for use and the Shaver blades can be attached.

Attention: When the Arthroscopic Shaver System is not in active use, protect the device against inadvertent actuation of the Shaver Footswitch and the Shaver Handpiece!

Before installation, make sure that the device has sufficient ventilation by maintaining a minimum distance of 15 cm from the right, left and rear sides of the device.

Device installation:

- the only intended position of the Shaver Control Unit is horizontal, in which the device is placed on a flat surface on its four rubber feet (14). In addition, adequate ventilation around the Shaver Control Unit must be provided,
- the place of installation should be a flat, dry and clean surface. This can be a table, shelf of an endoscopy trolley or other elements meant for installation of medical devices.

Connecting the device to power:

- connect, using an appropriate lead, the equipotential bolt located on the rear of the Shaver Control Unit to an equipotential strip. The cable insulation should be yellow-green,
- connect the power cord provided with the device to the socket (22) on the back of the Shaver Control Unit,
- plug the power cord into the power socket. The voltage should be within the range indicated on the device label.

Turn on the device:

- A properly installed and connected device should be started using the "ON/OFF" switch (24) located on the rear panel.

The “STANDBY” button (15) will start flashing at a frequency of 0,5Hz, indicating that the device has switched to standby mode.

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4.3 Connection of Shaver Handpiece to Shaver Control Unit

NOTE!

The device is compatible only with Shaver Handpiece according to the specification in point 2.1.

- The plug (31) at the end of the cable of the Shaver Handpiece has to be connected to the socket “HANDPIECE” (8) at the front panel of the Shaver Control Unit.
- The plug (31) of the Shaver Handpiece is marked with a notch and a red dot. When connecting the plug, make sure that the red dot on the plug is in the same position as the red dot on socket (8) of the Shaver Control Unit. The pins inside the plug (31) might otherwise get damaged.
- When the Shaver Control Unit is activated (see point 4.5.) the Shaver Handpiece is ready for use. The Shaver Handpiece can be operated by means of buttons localized on Shaver Handpiece and/or the buttons on Shaver Footswitch.
- To avoid damage, make sure to pull at the plug (31) itself not the cable or elastic cover when removing the plug (31) form the socket (8).

NOTE!

Both the blinking indicator of socket „HANDPIECE” (4) and sound message indicate the failure found by control unit. Detailed information about troubleshooting can be found in point *7.4. Basic troubleshooting of the device*. For more information, please contact the manufacturer of this device or your local distributor.

The maximum speed of the Shaver System is 10000 RPM.

Attention! Make sure, before removing plug (31) from the socket (8) of the Shaver Control Unit that Shaver Handpiece motor has been stopped. Shaver Handpiece should be hold only by its case during operation.

4.4 Connection of Shaver Footswitch to Shaver Control Unit

NOTE!

The device is compatible only with Shaver Footswitch according to the specification in point 2.1.

- The plug (39) at the end of the Footswitch cable has to be connected to the “FOOT SWITCH” (7) socket at the front panel of the Shaver Control Unit.
- The plug (39) of the Shaver Footswitch is marked with a notch and a red dot. When connecting the plug, make sure that the red dot on the plug is in the same position as the red dot on the socket (7) of the Shaver Control Unit. The pins inside the plug might otherwise get damaged during connection.
- To avoid damage, make sure to pull at the plug (39) itself and not the cable when removing the plug. When the Shaver Control Unit is activated (see point 4.5.), the Shaver Handpiece can be operated via the Shaver Footswitch.

NOTE!

Both the blinking indicator of socket „FOOT SWITCH” (6) and sound message indicate the failure found by control unit. Detailed information about troubleshooting can be found in point *7.4. Basic troubleshooting of the device*. For more information, please contact the manufacturer of this device or your local distributor.

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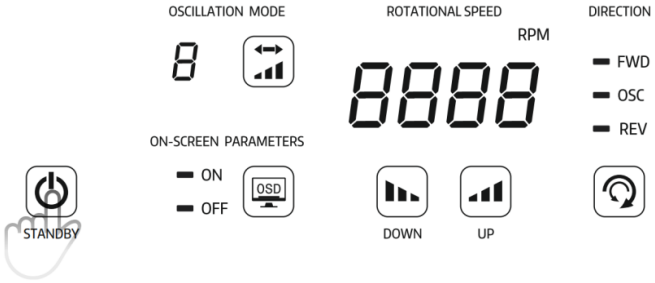
4.5 Starting the device

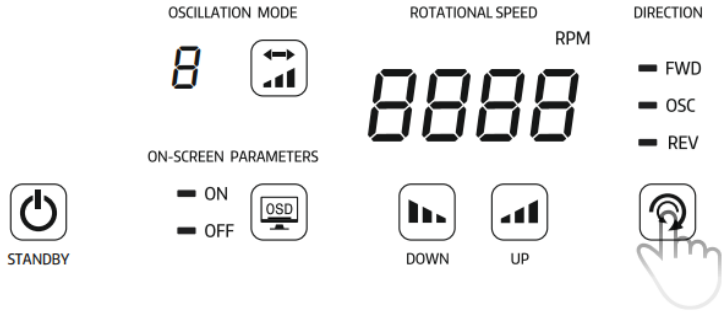
Once the device is in standby mode (see point 4.2.), press the “STANDBY” button (15) – the last used settings are reloaded.



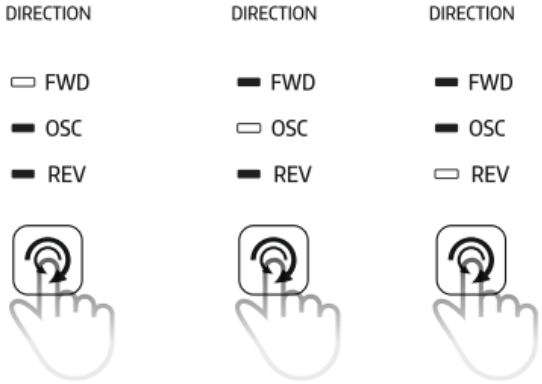
Device is ready to work – „Ready” mode.

4.6 Operation

- To start the treatment, a Shaver-compatible blade should be used. Use compatible single or reusable Shaver blades or burs. The reusable Shaver blade requires cleaning, disinfection and sterilization processes before each treatment in accordance with the manufacturer's instructions.
- Place the sterile Shaver blade in the Shaver Handpiece.
- For chosen direction mode (FWD,OSC,REV) only illuminated buttons are active.
- The user has the possibility to choose the direction of rotation of the blade inserted into the Shaver Handpiece. To change the direction of rotation, press the button “DIRECTION” (9).



- Active direction mode of rotation is signalled by illuminated indicator (3), additionally the operating direction is displayed in the display window (2):



FORWARD	OSCILLATION	REVERSE
		

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- Depending on the selected oscillation mode, the shaver blade is driven at different rotational speeds and frequencies of oscillation. The change of oscillation mode is activated by pressing the button “OSCILLATION MODE” (16).
- Available oscillation modes were described in table 4.

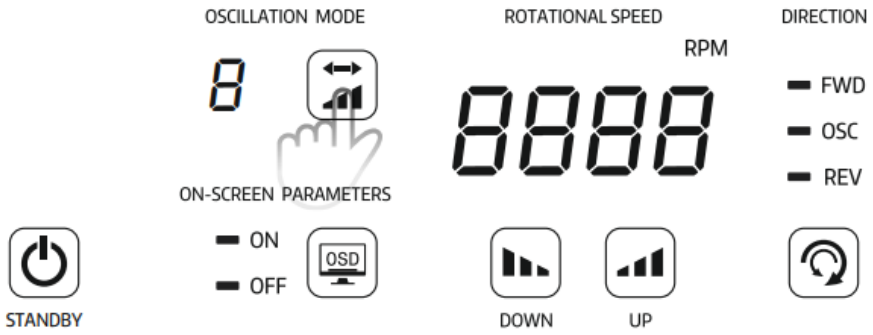
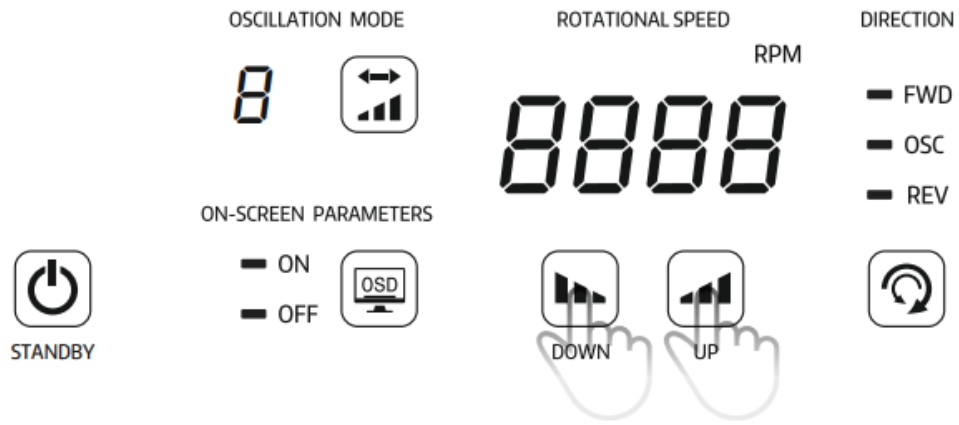


Table 4. Description of oscillation mode.

Oscillation mode No.	Oscillation mode	Description	
		Range of rotational speed [RPM]	Frequency of oscillation
1	Mild	500÷3500	Depend on rotational speed and oscillation mode
2	Normal	500÷3500	
3	Aggressive	500÷3500	
4	Slow	500÷3500	Constant for selected oscillation mode
5	Standard	500÷3500	
6	Fast	500÷3500	
7	Soft CUT mode	2100	Constant for selected oscillation mode
8	Fast CUT mode	2500	
9	BARRACUDA mode	3000	

The change of rotational speed is activated by pressing buttons: „UP” (10) – increasing the speed value and „DOWN” (11) – decreasing the speed value. The equivalent buttons are located on the Shaver Footswitch (35) and (36). The value of rotational speed can be changed in the range 500÷10000 RPM for the FWD and REV directions. In oscillation mode, the maximum rotational speed is limited and amounts 3500 RPM. The active rotational speed value is displayed in the display window (2).



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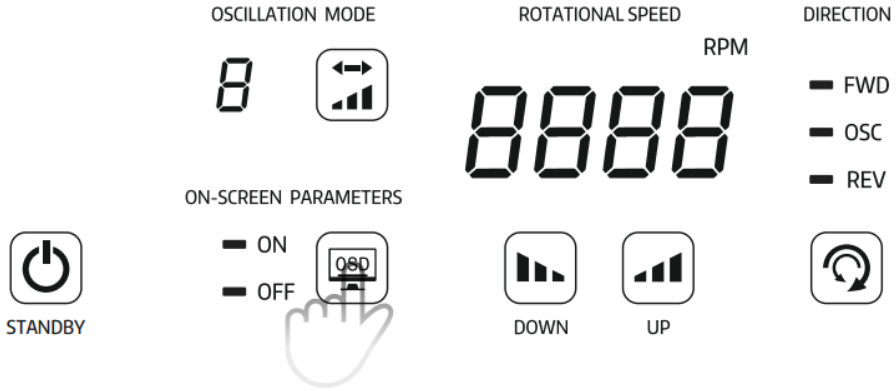
4.7 OSD Function

NOTE!

The OSD function enables activation / deactivation of the connection with appropriate device. For more information, please contact with manufacturer of this device or your local distributor.

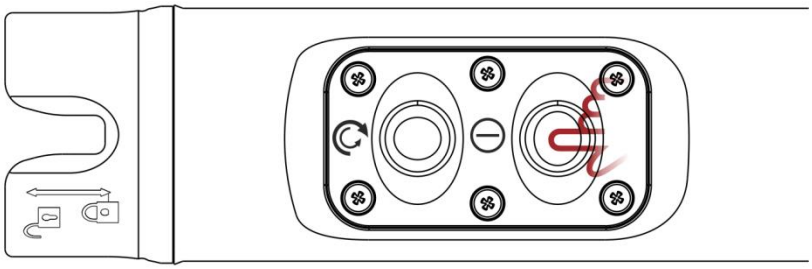
- The “COMMUNICATION INTERFACE” socket is located on the rear side of the Shaver Control Unit. Please connect Shaver Control Unit with compatible device by means of appropriate signal cable.
- By pressing the “OSD” button (12), the activation / deactivation of connection with appropriate device.
- The status of OSD function is signalized (activation/deactivation) by two indicators: ON/OFF (13).



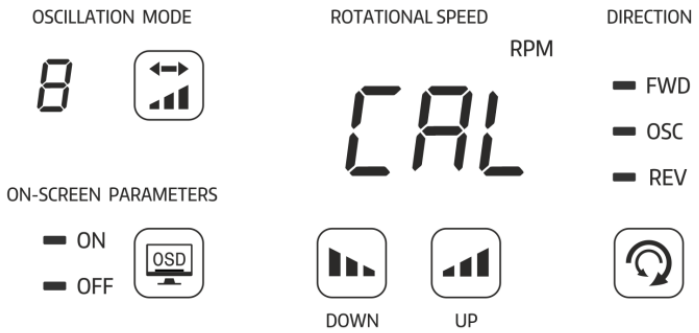
4.8 Window size function

Window size function is available only in oscillation mode.

- Press and hold ON/OFF (26) button on Shaver Handpiece.



- After 2 seconds the blade starts rotating slowly. In display window (2) appears message **CAL** to inform about calibration of window size. When the desired blade window position is located, release the ON/OFF button. Each time when the Shaver Handpiece stops, the blade window will return to this location.



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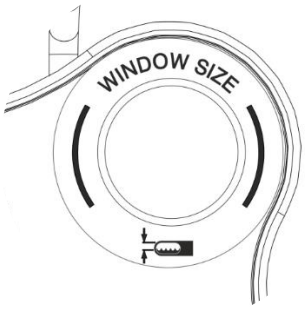
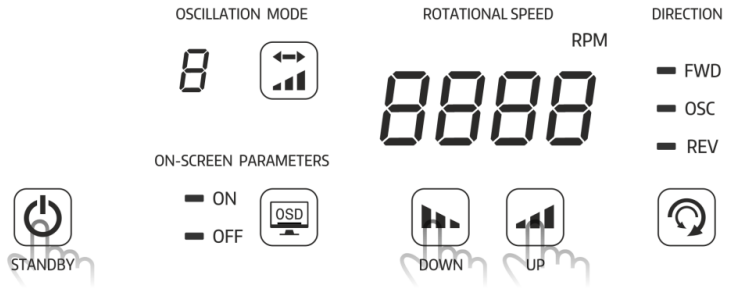
Alternatively, that function can be activated by the Shaver Footswitch. Press and hold the “WINDOW SIZE” footswitch button (32). The blade starts rotating slowly. When the desired blade window position is located release the “WINDOW SIZE” button. When the handpiece stops, the blade window will return to this location.

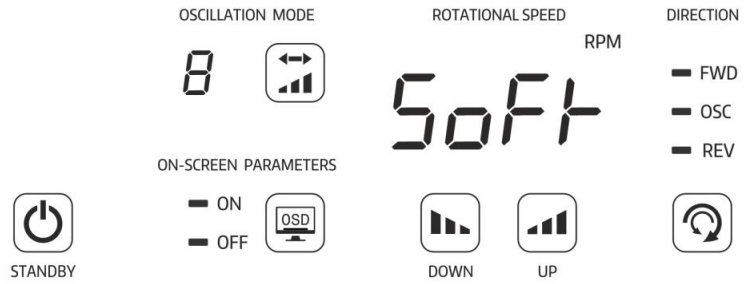


4.9 Software version

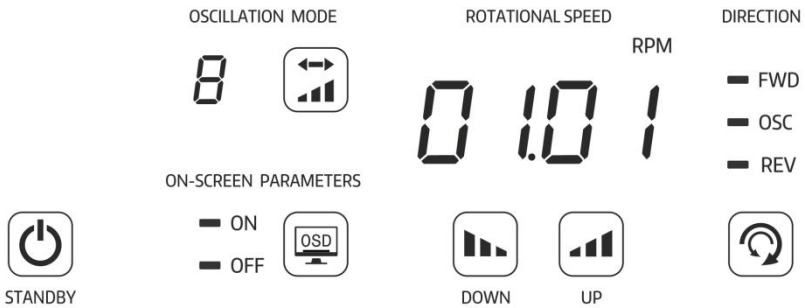
Software version can be displayed only if the device is in „Standby” mode. Simultaneously pressing „STANDBY” (15), „SPEED DOWN” (11) and „SPEED UP” (10) buttons let to display (2) current software version.



In display (2) will appear the message **SOFt** lasting 2 seconds. In this time, the „STANDBY” (15) button is illuminated continuously.



Next, the display (2) shows number of current software version – the message will be active only by 6 sec.



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4.10 Shut down the device

After the surgery, turn off the device with the "STANDBY" (15) button and disconnect all components/accessories. Decontaminate the device and its accessories according to chapter *6. Maintenance and care*.

5 OPERATION OF THE COMPONENTS

5.1 Shaver Control Unit

Unauthorized removal of the seal voids all warranty claims and results in the manufacturer disclaiming all liability for subsequent defects and/or restrictions of use. The same applies if the Shaver Handpiece and the Shaver Footswitch are opened by unauthorized personnel.

Ventilation: always ensure good ventilation at the rear panel of the Shaver Control Unit to prevent heat accumulation. Make sure to keep a distance of at least 15 cm between the rear panel of the Shaver Control Unit and the back wall of the instrument tower.

Protection: Unintentional opening of the Shaver Control Unit is prevented by an anti-tamper seal.

Power supply: device works at a voltage range of 100 to 240 VAC (50 or 60 Hz). Prior to initial start-up, make sure that all necessary fuses are present in the fuse box. The device is supplied with spare fuses. These must be installed as explained in chapter 7.1. The power cable should be connected to the socket (22) at the rear panel of the device.

Initial start-up: switch the device on by turning the “POWER ON/OFF” switch (24) on the rear panel of the Shaver Control Unit into "ON" position. Press the “STANDBY” button (15), interface will switch itself on and perform a brief self-test, after which the last used settings are reloaded.

Keyboard: the keyboard on the front panel of device can be used to set Shaver Handpiece working parameters: direction of rotation, rotational speed, oscillation mode etc. The “STANDBY” (15) button on the front panel allows the device to be switched off into stand-by mode - without entirely cutting off the power supply. Blinking “STANDBY” button or LED lit continuously (15) while all other buttons are dimmed indicates that the device is in stand-by mode. If you wish to turn off the device completely, turn the main “POWER ON/OFF”(24) switch on the rear panel into “OFF” position.

5.2 Shaver Footswitch

The Shaver Footswitch allows to control the operation of Shaver Handpiece and to regulate the operating parameter of the device: rotational speed, direction of rotation, oscillation mode. The user has the option to change the settings of the Shaver Footswitch buttons functions, in accordance with the information in point *5.3.3.1 Configuration of the buttons function.* In default settings the Shaver Handpiece is activated during the button “START/STOP” is continuously pressed, its release causes immediate stop the motor operation.
Button “DIRECTION” (34) is used to select direction mode of shaver blade engaged to the Shaver Handpiece. The rotational speed might be increased or decreased by buttons (35) and (36) on the Shaver Footswitch.

ATTENTION!

Blinking indicator „FOOT SWITCH” (6) indicates the wrong Shaver Footswitch position or failure of at least one button.

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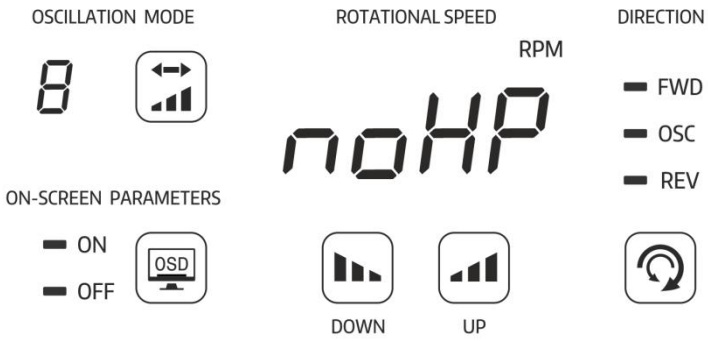
5.3 Shaver Handpiece

Shaver Handpiece has got two built in functional keys, that operate the device function. In addition, Shaver Handpiece is equipped with suction control lever, by means of which the liquids flow is controlled.
The simultaneously controlling operation of the device is possible by both: Shaver Handpiece and Shaver Footswitch.

NOTE!

The message: **noHP** appearing in the display window means, that the connection between Shaver Handpiece and the Control Unit was not detected.

Blinking indicator „HANDPIECE" (4) indicates the failure of least one button.



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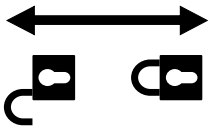
5.3.1 Installation of the shaver blade

NOTE!

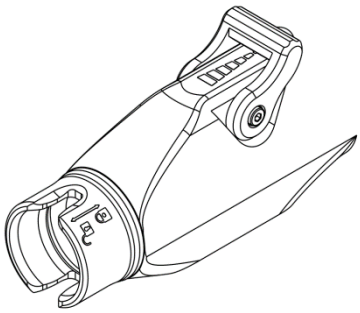
For the selection of compatible blades please contact the manufacturer of this device or your local distributor.

Follow these steps to properly install shaver blades in the Shaver Handpiece head:

- To start the treatment, a compatible blade should be used. Use compatible single or reusable shaver blades or burrs. The reusable shaver blade requires cleaning, disinfection and sterilization processes after each treatment in accordance with the manufacturer's instructions.
- Place the sterile shaver blade in the Shaver Handpiece head. Slide the shaver blade or shaver bur into the Shaver Handpiece head until perceptible resistance. Slight rotating motion of the blade facilitate its correct insertion in Shaver Handpiece head.
- Depending on shaver blades used, its locking in the head is done automatically or by moving the latch element towards the head in accordance with symbol on the Shaver Handpiece head.



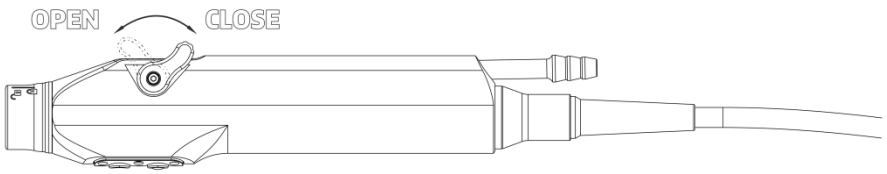
- Check that the blade is properly attached, to do this gently pull the blade.
- After the treatment open the latch and withdraw the blade. To avoid dropping the shaver blade, it should be pulled only when the Shaver Handpiece is in upright position,
- It is recommended to operate the shaver blade in range of rotational speed dedicated for it. The information about maximum rational speed is in the instruction for use provided with the blades.



5.3.2 Suction control lever

Suction control lever (28) regulate the force of liquid flow. The tube should be connected to the aspiration port (29), to ensure proper drainage of the saline solution containing tissue residues from operation field. After assembling make sure the tube is properly and tight mounted on aspiration port by gentle pulling.

Shaver Handpiece can be operated by the right-handed and left-handed user. Depending on user preferences about holding the Shaver Handpiece, the suction control lever can be toward up or down. The user should take care the suction control lever should be easy to reach so as have complete control of liquid flow. Flow intensity depends on suction control lever position. To increase force of flow, the suction control lever should be moved towards Shaver Handpiece head, or to decrease, the lever should be moved towards aspiration port. The regulation of flow intensity between these two positions is no gradual.



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5.3.3 Shaver Handpiece buttons

Shaver Handpiece can be operated by two functional buttons built in, located in nearby of Shaver Handpiece head. Start and stop of device working are indicated in display window by accordingly messages: **run** and **stop**.

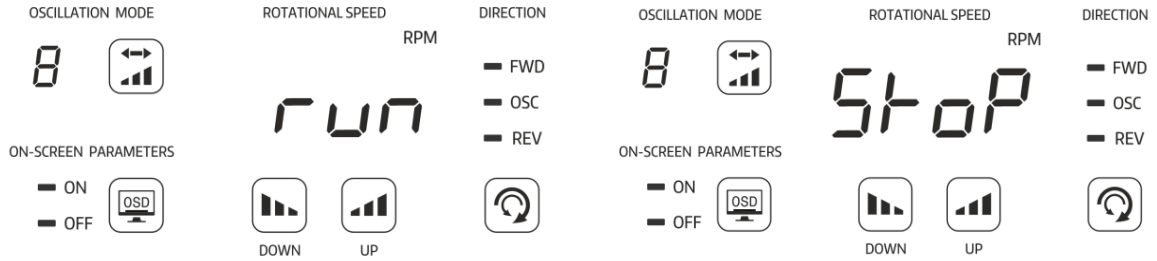
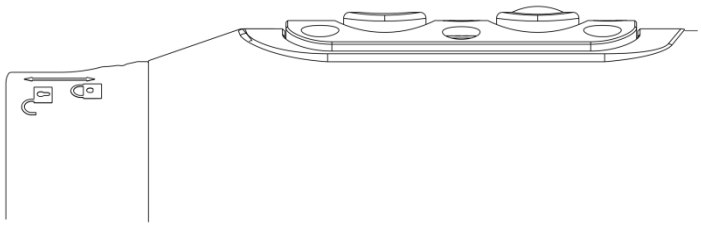


Table 5. Description of Shaver Handpiece buttons.

Button		Description
Short press of ON/OFF button		Turning the Shaver Handpiece motor on/off
Long press of ON/OFF button		Initialization of window size function
Short press of DIRECTION button		Switching direction of rotation of the Shaver blade
Long press of DIRECTION button		Changing the oscillation mode for “OSC” Changing the RPM speed level for “FWD” and “REV”.

The Shaver Handpiece buttons differ in shape to facilitate the operation of the device.



Pressing of any button during Shaver Handpiece is running causes it to stop. The user has the option to change the settings of the Shaver Handpiece button functions, in accordance with the information in point *5.3.3.1 Configuration of the buttons function.*

ATTENTION!
If during the operation of the device using the Shaver Footswitch, any of the Shaver Handpiece button is activated, the device control will be automatically redirected to the Shaver Handpiece.

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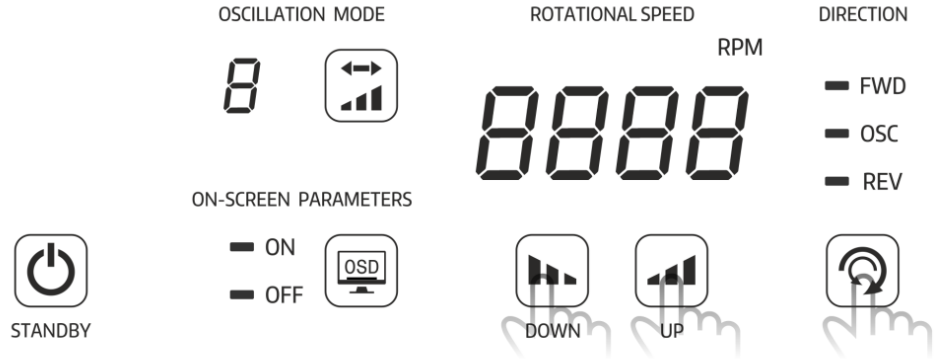
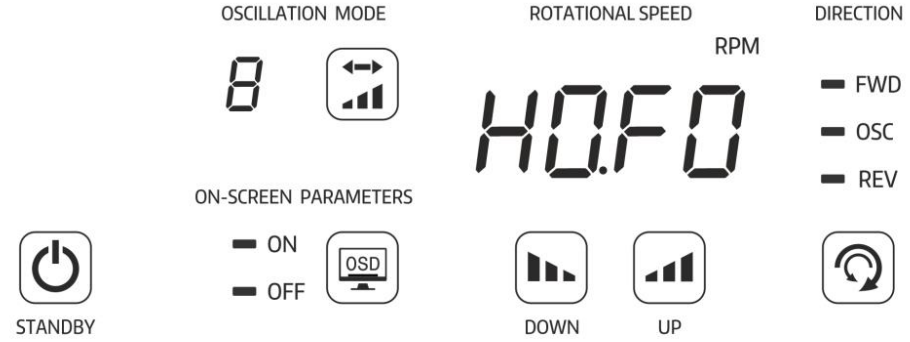
5.3.3.1 Configuration of button-functions

Functions of Shaver Handpiece buttons are modified only in „Standby" mode. The simultaneously pressing the buttons „SPEED UP" (10), „SPEED DOWN" (11), and „DIRECTION" (9) by 4 seconds activates option to configure key functions.



In display window appears the information about functional strategy of the buttons. The button „STANDBY" (15) is still illuminated.



By using buttons:

- „SPEED DOWN" (11) change the functionality strategy of Shaver Handpiece buttons (H0, H1, H2),
  - H0: dual functionality for the buttons:
    - Button ON/OFF (26) – short press activates function ON/OFF.
    - Button ON/OFF (26) - long press activates window size function, it is stopped by releasing the button ON/OFF.
    - Button DIRECTION (25) - short press activates direction mode function: FWD, OSC, REV.
    - Button DIRECTION (25)- long press activates oscillation mode function and change the mode in loop from 1 to 9 for "OSC" or change of RPM level for "FWD" and "REV" from 500 to 10000 (if the last value is exceeded, the next loop will start from 3000 RPM). Releasing the button stops further change.
  - H1: single functionality for the buttons:
    - Button ON/OFF (26) – activates function ON/OFF.
    - Button DIRECTION (25) – activates direction mode function (FWD, OSC, REV).
  - H2: no functionality for the buttons/ operating by buttons is unavailable.

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- „SPEED UP" (10 change the functionality strategy of Shaver Footswitch buttons (F0, F1), where:
  - F0: Activation of the Shaver Handpiece comes by continuously pressing button START/STOP (33) on the Shaver Footswitch, releasing the button stops the device work,
  - F1: Activation of the Shaver Handpiece comes by push the button START/STOP (33) on the Shaver Footswitch, next push of the button stops the device work.

Pressing the button „STANDBY) (15) automatically accepts the configuration and returns to „Standby" mode.
Default settings for the Shaver Handpiece buttons are H0, for Shaver Footswitch is F0.

6 MAINTENANCE AND CARE

6.1 General information

The Handpiece must be cleaned, disinfected and sterilized prior to every use. The Shaver Control Unit and the Shaver Footswitch must also be cleaned and disinfected, but they do not require sterilization. This also applies to the very first use after delivery, because all components of the Shaver Control Unit are supplied in non-sterile condition and without having been disinfected. Thorough cleaning and disinfection are essential preconditions for an effective sterilization.
The division/entity in charge of reprocessing has to make sure that:

- validated cleaning, disinfecting and sterilization methods are used,
- the washer /disinfector and the sterilizer are checked and serviced in regular intervals,
- the validated parameters are followed during every reprocessing procedure.

Safety precautions!
Using methods of cleaning, disinfection and sterilization other than those described in these instructions, the division/entity takes sole responsibility for demonstrating the effectiveness of his method of reprocessing and the sterility of the product itself. In this case, the manufacturer is not responsible for the product.

Attention!
In addition to the above, the country specific legal provisions regarding reprocessing of medical devices have to be observed!

Safety precautions!
Always wear protective clothing during the reprocessing of contaminated medical instruments, i.e., eye and mouth protectors, chemical-resistant gloves and moisture repellent clothes. Blood, residual tissues and other infectious materials pose an increased risk of infection.

6.2 Cleaning and disinfection of the Shaver Control Unit and the Shaver Footswitch

Always make sure to remove the power cable from the plug and the power cable socket (22) on the rear panel of the Shaver Control Unit prior to cleaning. During the cleaning process, the device must not be connected to the power supply in any way.
The Shaver Control Unit and Shaver Footswitch must be cleaned and disinfected after every use. To remove dust and other dirt or contamination use a clean cloth moistened with cleaning and disinfectant solution. Make sure that the cloth is just moist and not soaking wet to prevent moisture from entering the sockets (7) and (8) of the Shaver Control Unit.
When choosing the cleaning and disinfection solution, make sure:

- to use a product that is suitable for wet wipe disinfection of metal and plastic components,
- to choose a product with proven suitability (e.g. authorized by the FDA or provided with a CE mark), for example Microbac forte, Velox AF or other.
- that the detergent is compatible with the disinfectant,
- that both agents are compatible with the Shaver Control Unit and its accessories (see chapter 6.3.11. Material compatibility).

The concentration and immersion time indicated by the manufacturer of the detergents and disinfectants have to be strictly observed.

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6.3 Cleaning, disinfection and sterilization of Shaver Handpiece

6.3.1 General information

These reprocessing instructions are provided in accordance with EN ISO 15883, EN ISO 17664, EN ISO 17665, EN 285, EN ISO 11607, AAMI ST79, AAMI ST81, AAMI TIR12.
Give preference to mechanical cleaning and disinfection of the Shaver Handpiece in the washer /disinfector. Manual reprocessing (including ultrasonic bath) should only be chosen if mechanical reprocessing is not an option. Manual cleaning and disinfection may only take place if the division/entity in charge is in possession of an officially approved device and product specific process validation and they are prepared to assume responsibility for the process.

CAUTIONS!

In case of automatic cleaning the pre-cleaning is absolutely required!

Reusable instruments, such as shaver blades, must be reprocessed as indicated in the instruction pamphlet enclosed with the instruments or according to the information provided by the manufacturer. Before, start procedure please make sure that, you possess equipment and accessories from the table below:

Table 7. Equipment and accessories to reprocess Shaver Handpiece.

Equipment and Accessories	Description
Personal Protective Equipment (PPE)	– Gloves – protect hands – Gowns/aprons– protect skin and/or clothing – Masks and respirators – protect mouth/nose – Googles – protect eyes – Face shield – protect face, mouth, nose and eyes
Cleaning instruments	– Soft clean brushes (channel cleaning brush ø5 mm, minimal length 30 cm is recommended) – Lint free clothes
Cleaning device	– Ultrasonic bath – Automatic washer-disinfector – Autoclave
Detergents	Recommended: – Detergent for use in washer - Neodisher MediClean forte – Detergent for use for manual cleaning - Korsolex

WARNING!

- To minimize the risk of infection, clean, disinfect and sterilize the Shaver Handpiece prior to the first use and every use thereafter.
- Ensure suction control lever (33) is completely open (in the MAX position) during sterilization.
- Remove all accessories before cleaning and sterilization process.

CAUTIONS!

- Do not leave the Shaver Handpiece in solutions longer than necessary. This may accelerate normal product aging.
- Protective cap must be always installed before cleaning and sterilization to protect connection pins from moisture, which could damage connectors.

6.3.2 Limits on reprocessing

Proper processing has a minimal effect on the Shaver Handpiece. End of life is normally determined by wear and damage due to use.
Damage by improper processing will not be covered by the warranty.

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6.3.3 Point of use

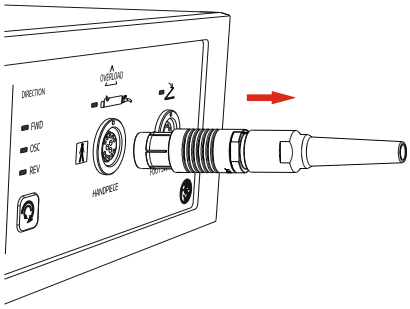
Keep the device moist (in sterile distilled water) after use to prevent soil from drying.
Do not use a fixating detergent or hot water (temperature should be less than 40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.

6.3.4 Containment and transportation

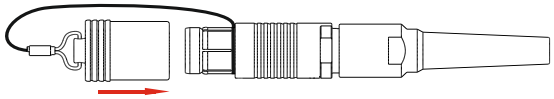
It is recommended that devices are reprocessed as soon reasonably practical following use.

6.3.5 Preparation for cleaning

Disconnect the Shaver Handpiece cord and detach accessories from equipment prior to cleaning- when removing the Shaver Handpiece from the Shaver Control Unit, make sure to pull it out by holding the plug (31) not by the cable. Seal the plug with protective cap (30).



Ensure that the protective cap is securely attached to the cable connector for Shaver Handpiece.

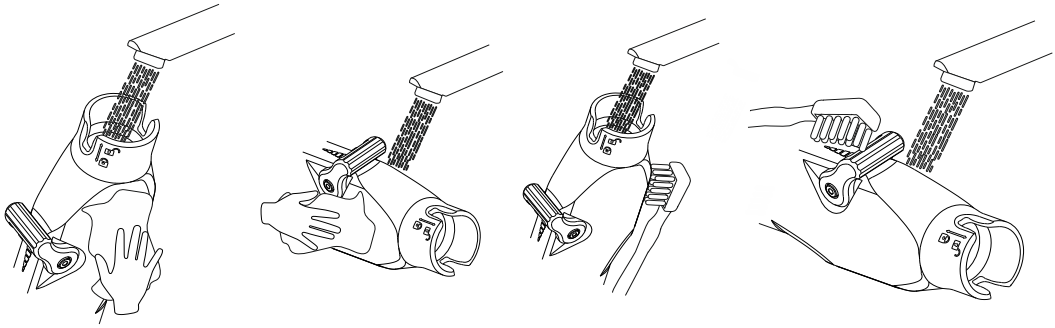


Remove dried-on soil and gross debris from devices, especially from areas such as joints and crevices.

6.3.6 Automatic washing and disinfection

6.3.6.1 Pre-cleaning

- Remove all traces of blood, debris and stains.
- Use a clean, soft brush or a soft clean cloth with tap water or a cleaning detergent solution to remove any contamination from the Shaver Handpiece. Always avoid any harsh materials that can scratch or mar the surface.
- If using a cleaning detergent, make sure that this is free of aldehyde (risk of protein fixation) and suitable for disinfecting the materials involved (see point *6.3.11. Material compatibility*). Choose a product with proven suitability (e.g., approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark).



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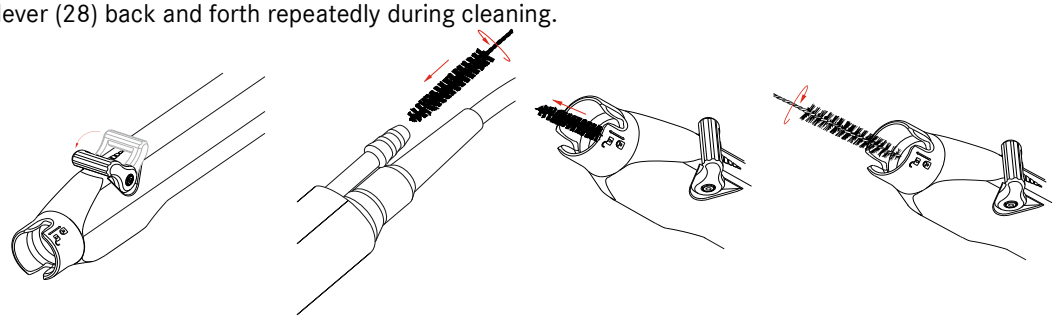
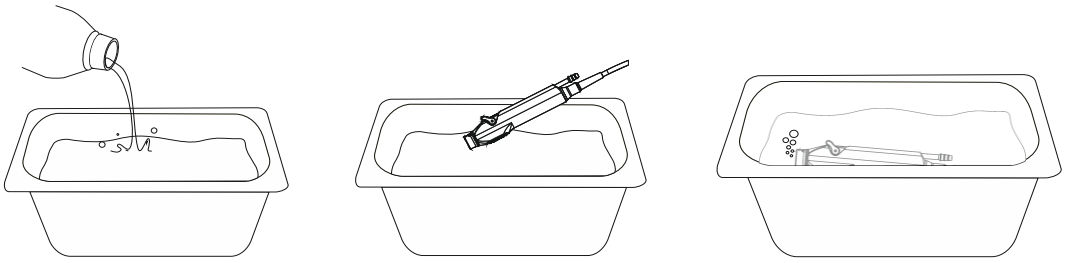
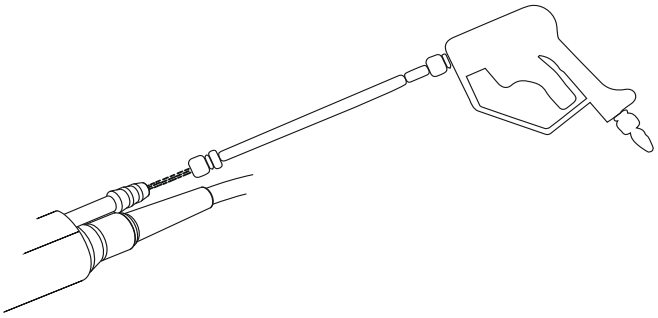
- For pre-cleaning the inner lumens choose a brush with matching diameter to ensure that the full depth of the area is reached. This applies to the suction channel and the internal of Shaver Handpiece head. Place the suction control lever (28) in the fully open position. Clean the suction tube thoroughly with a cleaning brush until debris will be removed. Move suction control lever (28) back and forth repeatedly during cleaning.



- Next, place the Shaver Handpiece into an ultrasonic bath filled with cleaning solution (recommended: Neodisher Mediclean forte 0,5%, 10 min, 40°C, 35 kHz). Place the Shaver Handpiece in upright position, with the head (27) facing downwards. The Shaver Handpiece and the cable must be completely covered by cleaning solution. Agitate the device to remove air. The suction control lever (28) must be set in open (MAX) position, when choosing the cleaning solution, make sure that:
  - the solution is suitable for cleaning instruments with metal and plastic components,
  - all chemicals contained in the solution are compatible with the medical devices (see point *6.3.11. Material compatibility)*
  - the solution is suitable for ultrasonic baths (i.e. no foaming).



- Rinse the entire Shaver Handpiece. Keep the head of the Shaver Handpiece pointed downward. Rinse all lumens, e.g. the suction channel and the interior of Shaver Handpiece head (27) with a water pistol with cold water for at least 10 seconds (static water pressure: 2 bar). Make sure that the suction control lever (28) is in open (MAX) position to prevent any contamination from remaining in the head (27) or in the suction channel (29).



NOTE!
Please note that the above pre-cleaning process and the cleaning agents used merely serve to protect the person carrying out the reprocessing procedure. This does not in any way replace the disinfection cycle which is absolutely essential.

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Attention!
For manual removal of contamination, only use soft brushes and soft clean clothes that are intended for this purpose. The use of metal brushes and steel wool is not permitted as these would damage the surface. Take great care when cleaning the Shaver Handpiece, especially when cleaning the head interior and the suction channel. In absence of an ultrasonic bath, an ordinary bath is acceptable in exceptional cases, in which case a minimum immersion time of 20 minutes must be observed.

The suitability of these medical devices for effective pre-cleaning was tested and proved by an independent test laboratory. The detergent Neodisher Mediclean forte (0.5 %) (Dr. Wiegert GmbH & Co. KG, Hamburg) was used. The above work flow was determined by the tests in the test laboratory.

6.3.6.2 Automatic cleaning and disinfection

When choosing the washer/disinfector, make sure that:

- the suitability of the washer/disinfector has been proven (e.g. authorized by the FDA or provided with a CE mark pursuant to EN ISO 15883),
- a program for thermal disinfection is available (A_0 value> 3000 or - in older devices - a minimum hold time of 5 minutes at 90°C).
- the program is suitable for these medical devices and that it comprises a sufficient number of rinsing cycles,
- the final rinse is done with sterile water, almost sterile water or water with a low content of Endotoxin (max. number of Endotoxin units: 0,25/ml) (e.g. processed water),
- the air used for drying is filtered,
- the washer / disinfector is serviced and checked in regular intervals.

When choosing the detergent, make sure that:

- it is suitable for cleaning medical devices with metal and plastic components,
- if thermal disinfection is not an option, a suitable disinfectant with proven suitability (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark) must be used.
- The disinfectant must be compatible with the detergent, all chemicals used during the process must be compatible with the present medical devices (see point *6.3.11. Material compatibility).*

NOTE!

- The concentrations specified by the manufacturers of the detergents and disinfectants have to be strictly observed.

Work flow:

1. Loosely coil up the cable of the Shaver Handpiece with a diameter of 30 cm.
2. Load the Shaver Handpiece in the washer /disinfector. Make sure that the Shaver Handpiece does not touch any other instruments and that the head (27) is facing downwards. It can be placed in vertical or diagonal position.
3. The aspiration port (29) of the suction channel must be connected to a flexible tube at the basket (a rack for MIS – instruments). Make sure that the suction control lever (28) is in open (MAX) position.

Table 8. Parameters for each stage of automatic cleaning process.

Stage of automatic cleaning process	Time	Water temperature	Detergent
Pre-cleaning	2 min	Cold	–
Cleaning	5 min	55°C	0,5% Neodisher Mediclean forte (Dr. Weigert)
Rinsing	3 min	Cold deionized water	–
Rinsing	2 min	Cold deionized water	–

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4. Perform thermal disinfection: min. cycle parameters: 5 min. at 90°C, A_0 value> 3000
5. Once the entire cycle is completed, remove the Shaver Handpiece from the washer /disinfector.
6. Check the Shaver Handpiece to make sure that it is ready for use. Wrap immediately after removal from the washer /disinfector (see point *6.3.8. Inspection/lubricants* and *6.3.9. Packaging)*. If the Shaver Handpiece is still wet, dry at a clean place.
7. Visually inspect the device, including all internal surfaces for damage and reaming soil. If any damage is detected, consult to your distributor for clues. It is recommended to inspect lumens by special magnifying scope to see the inner surface of the lumen. Repeat cleaning if soil is visible and reinspect. If the device still would not be clean enough, please inform distributor about this problem.

The suitability of these medical devices for effective automatic cleaning and disinfection was tested and proved by an independent test laboratory. A washer /disinfector G7836 CD (Co. Miele & Cie. KG, Gutersloh, Germany) and the detergent Neodisher Mediclean forte (0.5 %)(Dr. Wiegert GmbH &Co. KG, Hamburg) were used. The above work flow was determined by the tests in the test laboratory.

6.3.7 Manual cleaning and disinfection

Manual reprocessing (including ultrasonic bath) should only be chosen if mechanical reprocessing is not an option. Manual cleaning and disinfection may only take place if the division/entity in charge is in possession of an officially approved device and product specific process validation and if they are prepared to assume responsibility for the process.
When choosing the detergent, make sure that:

- it is suitable for cleaning medical devices with metal and plastic components,
- its suitability has been proved (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark),
- all chemicals used are compatible with the present medical device (see point *6.3.11. Material compatibility)*.

We recommend a combined solution for cleaning and disinfection, for example Korsolex plus (Co. Bode Chemie). The concentration and immersion time specified by the manufacturers of the detergents and disinfectants have to be strictly observed. Use sterile water, almost sterile water or water with a low content of Endotoxin (max. number of Endo-toxin units: 0.25/ml) (e.g. processed water) only. The air used for drying must be filtered.

- Use a clean, soft brush or a soft clean cloth with tap water or a cleaning detergent solution to remove any contamination from the Shaver Handpiece. Always avoid any harsh materials that can scratch or mar the surface.
- If using a cleaning/disinfected detergent, make sure that this is free of aldehyde (risk of protein fixation) and suitable for disinfecting the materials involved (see point *6.3.11. Material compatibility)*. Choose a product with proven suitability (e.g. approved by the German Association for Hygiene and Microbiology (DGHM) or the Association for Applied Hygiene (VAH), authorized by the FDA or provided with a CE mark).
- Remove all traces of blood, debris and stains.
- Scrub interfaces several times using a twisting action if possible.
- Scrub interiors of the head and suction channel with a tight-fitting brush oscillating the brush and move from the front to rear of the device - feed the wire end of a cleaning brush through the cannulation Shaver Handpiece. Pull the brush completely through and repeat until all debris is removed.
- Clean the interior of the head and suction channel using the cleaning brush with suitable diameter. Next, in open position of suction control lever, lead the cleaning brush from head side to the suction channel. Drag the brush by whole the suction channel. Repeat the action by leading the cleaning brush from aspiration port side.
- Manipulate all moving parts of the Shaver Handpiece to ensure all debris is removed. If not, clean again until all debris will be removed.
- Immerse the Shaver Handpiece in a bath filled with cleaning/disinfectant solution. Make sure that the Shaver Handpiece is in upright position, with the head (27) facing downwards. The Shaver Handpiece and the cable must be completely covered with cleaning solution. Make sure, that the suction control lever (28) is in open (MAX) position.

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- A minimum immersion time is 20 minutes and the process must be observed. If you use ultrasonic bath the processes parameters are the followings: t=10 min, T=40°C, frequency: 35 kHz
- The concentration and immersion time specified by the manufacturers of the detergents and disinfectants have to be strictly observed.
- Lift the Shaver Handpiece out of the bath and rinse with sterile or almost sterile water for at least 10 minutes. The head (27) of the device should be pointed downward. Make sure that the head (27) and the suction channel are completely free of residues of tissue and chemicals.
- Thoroughly dry all surfaces using a sterile, lint free wipe immediately after rinsing. After flushing operation is complete, it is recommended that forced air be used through all channels to remove water droplets. Ensure that the head and the suction canal is free of any residual moisture
- Visually inspect the Shaver Handpiece, if soil remains, repeat the manual cleaning procedure, focusing on those areas.
- Check the Shaver Handpiece to make sure that it is ready for use and wrap immediately (see point *6.3.8. Inspection/lubricants* and *6.3.9. Packaging)*. If the Shaver Handpiece is still wet, dry at a clean place.

6.3.8 Inspection / lubricants

After cleaning and disinfection, remove the protective cap (30) from the plug (31) and check the Shaver Handpiece for corrosion, damaged surfaces, spalling and visual contamination. Discard damaged Shaver Handpieces (see point *6.4. Reusability*). In case of residual contamination, repeat the complete cleaning and disinfecting process. The inside of the Shaver Handpiece must not be moistened with any type of lubricant!

6.3.9 Packaging

Place the protective cap (30) back onto the plug (31). The suction control lever must be open (MAX position) when the Shaver Handpiece is sterilized. Make sure that the suction control lever is in correct position, before the device will be put to the wrap. Loosely coil up the cable of the Shaver Handpiece with a diameter of 30 cm. Wrap the Shaver Handpiece in disposable sterilization pouches (single or double) and/or in a sterilization container, according to the following conditions:

- EN ISO 11607/ ANSI AAMI ISO 11607,
- suitable for steam sterilization (heat resistant up to 141°C, sufficient permeability),
- the Shaver Handpiece is adequately protected from mechanical damage,
- sterilization containers must be serviced in regular intervals according to the instructions of the manufacturer.

If sterilization bag is used, select its appropriate size to avoid damage the seal. The Shaver Handpiece has to be thoroughly dry before wrapping in a peel pouch. The moisture inside the peel pouch causes damages during sterilization.

6.3.10 Sterilization

Use the below described method of sterilization only. All other methods are prohibited.
It is critical to properly clean all reusable devices prior to sterilization. Sterilization does not eliminate the need for proper cleaning of devices. Sterilization compatibilities, cleaning handling and storage of instrumentation are the responsibility of qualified facility/user personnel.

Shaver Handpiece must be sterilized by steam, using the following methods only:

Table 9. Parameter of sterilization process.

Sterilization Method	Wrapping	Temperature	Cycle Time	Dry Time
Pre-vacuumed sterilizer	Wrapped	134°C	3 min.	10 min.

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- sterilization method: fractionated vacuum
- steam sterilizer according to DIN EN 13060/DIN EN 285,
- validated according to ISO 17665 (Start-up and product specific performance assessment),
- the temperature during sterilization must not exceed 138°C (280°F plus tolerance) according to EN ISO 17665 (earlier DIN EN 554/ANSI AAMIISO 11134),
- sterilization time (hold time of the sterilization temperature):
  - fractionated vacuum: at least 3 minutes at 134°C (273°F),

The Shaver Handpiece has to cool down at room temperature.

Do not use while still warm.
Accelerated cooling with water or a wet cloth is not permitted.

Not suitable for flash sterilization! Do not use hot air, radio or plasma sterilization. Not suitable for sterilization with formaldehyde or ethylenoxide.

ATTENTION! Shaver Control Unit and Shaver Footswitch cannot be sterilized.
ATTENTION! A reduction of the indicated drying time during the sterilization process can cause irreversible damage or reduce the performance.
ATTENTION! Do not exceed the maximum sterilization temperature during the sterilization process. This can cause irreversible damage or reduce the performance.
CAUTION! Check, if the Shaver Handpiece plug had any contact with liquids, remove moisture using dry compressed air. Only dry connectors may be plugged to Shaver Control Unit.

6.3.11 Material compatibility

Make sure that the chosen detergents and/or disinfectants do not contain any of the below listed chemicals:

- organic, mineral or oxidizing acids (lower limit for the pH-value: 5.5),
- strong bases (upper limit for the pH- 11, alkaline products are recommended),
- organic solvents (e.g. ether, ketone, benzine),
- oxidants (e.g. peroxides),
- halogens (chlorine, iodine, bromine),
- aromatic and halogenated hydrocarbon.

Do not use metal brushes or steel wool for cleaning the Shaver Handpiece. Do not exceed a temperature of 138°C (280°F).

6.4 Reusability

The individual components can be reused as long as they perform adequately and the instruments can be fixed properly, provided that they are used with due care and reprocessed, inspected and packed correctly. Any (further) use of damaged or contaminated instruments is on the sole responsibility of the user. The durability of the product largely depends on careful handling during use and reprocessing, which is why the number of possible reprocessing cycles cannot be determined.
Before each re-use, verify that the device does not show any signs of mechanical damage that may affect its proper and safe operation. In the event of discovering any disturbing damage, report it to the manufacturer's service department.

The manufacturer declines all liability in case of non-observance of these instructions.

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7 INSPECTIONS, SERVICE, TECHNICAL SUPPORT

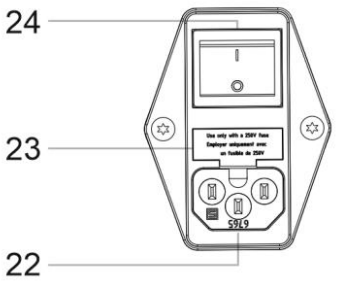
7.1 Replacing fuses

WARNING!

Follow these steps before replacing the fuses:

- turn the device off using the power switch “POWER ON/OFF” (24) located on the rear panel,
- disconnect the power cord from the power socket and then from the socket of the device (22). When equipment was switched on, please wait 3-4 minutes for disconnecting.

Replacing fuses is to be performed only if they are damaged.
Use only such fuses as indicated in *Table 10.*



To replace the fuses:

- remove defective fuses. Fuses are located in the drawer (23) installed in the appliance inlet of the device,
- new time-delay fuses, the values of which should be selected on the basis of Table 10, should be inserted in the slots in the fuse drawer:

Table 10. Values of fuses intended for specific models of the Shaver Control Unit of Shaver System.

Pos.	Shaver Control Unit	Value and type of fuse
1.	tk 39802-01	2x T 1,25A L 250 V

- Slide the fuse drawer (23) into the appliance inlet of the device. Proper installation will be signaled by an audible “click” - the sound of latches closing in the drawer locking mechanism.
- Connect the power cord. The device can be restarted.

7.2 Periodic inspections of the device

For long-lasting and trouble-free operation of the device, the manufacturer imposes obligatory inspections, which should take place at intervals of no less than every 12 months (once a year).

The inspection must be conducted by the manufacturer or its authorized service provider. See *service provider data* in the last page.

The inspection consists of:

- checking the technical state of the device,
- cleaning the interior of collected dust and other contaminants,
- measurement of operational parameters,
- performance of an electrical safety test in accordance with EN 60601-1,
- software update.

Each inspection involves a subsequent report, whose copy will be delivered to the client with the device. If malfunctions are found during the inspection, the inspector will prepare an offer for removal of such defects, which will be sent to the customer by e-mail or fax.

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7.3 Warranty and post-warranty service

The device manufacturer provides warranty and post-warranty service under the following conditions:

- a damaged device should be sent in its original packaging directly to manufacturer (address can be found in the last page *service provider data*) or to local manufacturer's distributor, together with a detailed description of the malfunction. The service provider has the right to refuse warranty repairs of a device improperly packaged or in non-original packaging,
- under no circumstances repairs should be carried out by unqualified personnel. Only the manufacturer and/or authorized service partners are authorized to perform them. The device is protected from unauthorized opening by the warranty seals. A damaged or broken seal voids the warranty and implies to the manufacturer refusing any responsibility for any subsequent malfunctions and/or limitations in the functioning of the device,
- the manufacturer's warranty does not cover damage caused by random events such as flooding, fall, power surge caused by a storm, burning in a fire etc.,
- warranty repairs may be carried out solely by the equipment manufacturer or an authorized service provider, whose address is given by the manufacturer,
- before shipping, decontaminate the device and its accessories according to chapter *6 "Maintenance and care"* in order to protect the service personnel. Manufacturer and authorized service provider has the right to reject contaminated products for repair.

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7.4 Basic troubleshooting of the device

Table 11. Specification of the most common problems associated with using the device and methods of their detection and elimination.

Symptom	Probable cause	Correction/prevention
The Shaver Control Unit does not work	power cord is not connected	connect power cord to the power cable socket (22)
	no power at place of installation	make sure that the voltage in the power grid is correct
	damaged or missing fuse	check fuses (See point 7.1.)
	“ POWER ON/OFF” (24) switch was not actuated	after installation actuate “ POWER ON/OFF” (24) switch at the rear panel of the Shaver Control Unit
The shaver Handpiece does not work	the Shaver Handpiece was not connected to the Shaver Control Unit	connect the Shaver Handpiece to the socket “ HANDPIECE” (8) or check that the Shaver Handpiece is properly locked in place
	Shaver blade is blocked in the Shaver Handpiece	replace the Shaver blade for a well-functioning one
The Shaver Footswitch does not work	The Shaver Footswitch has not been connected to the Shaver Control Unit	connect the Shaver Footswitch to the socket “ FOOT SWITCH” (7) or check that the Shaver Footswitch is properly locked in place
The Shaver Handpiece overheats	prolonged overloading of the Shaver Handpiece	remove the Shaver Handpiece from the connection socket at the Shaver Control Unit and allow to cool down to room temperature. Make sure if installed Shaver blade not cause the Shaver Handpiece overloading.
Indicator of „HANDPIECE” socket (4) blinks	Short-circuit of Shaver Handpiece buttons	Pull out Shaver Handpiece plug from the socket. Make sure, the buttons are not pressed. Connect again the Shaver Handpiece do the socket “ HANDPIECE” (8)
Indicator of „FOOT SWITCH” socket (6) blinks	Short-circuit of Shaver Footswitch buttons	Pull out Shaver Footswitch plug from the socket. Make sure, the buttons are not pressed. Connect again the Shaver [illegible]
	The Shaver Footswitch is overturned	Make sure, the Shaver Footswitch is in correct position
	Shaver Footswtich is out of calibration	Connect the footswitch to the control unit tk 39802-01. Press simultaneously and hold on DIRECTION and SPEED UP buttons. Footswitch LED starts to blink. Keep both buttons pressed until the LED is lit continuously.

Any anomalies or defects not included in the aforementioned table must be reported to the manufacturer's service department. Until all defects of the device are removed, it should be excluded from operation and marked accordingly.

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CE 0483

8 TECHNICAL SPECIFICATIONS

Table 12. Arthroscopic Shaver System technical specification.

Parameter	Shaver Control Unit (tk 39802-01)
Power consumption	20 VA (at power supply 100 VAC) 35 VA (at power supply 240 VAC)
Supply voltage	100-240V AC
Power frequency	50/60 Hz
Protection class	Class I, application part type BF
Weight	4,8 kg
External dimensions	D: 250 mm x W: 330 mm x H: 96 mm
Fuses	According to *Table 10.*
Ambient temperature	During operation: +10°C to +40°C
	During storage and transport: -20° C to +45°C
Maximum relative humidity	During operation: 70%
	During storage and transport: 70%
Protection against harmful ingress of water or particulate or particulate matter	IP X0 Not protected against water / moisture
Do not use in the environment of flammable anesthetic gases.	
All electromagnetic compatibility standards were applied and the device was tested accordingly. However, some devices may interfere with the Shaver Control Unit. It is recommended to keep such devices away from the Shaver Control Unit.	
The CE mark on the device label certifies compliance with all European requirements and with Directive MDD/93/42/EWG.	

Table 13. Shaver Handpiece technical specification.

Parameter	Shaver Handpiece tk 39802-02
Length	164 mm
Weight	325 g (without cable)
Speed	500 – 10000 rpm (±10%)
Cable length	3,2 m
Sterilization method	Steam sterilization
Ambient temperature	During operation: +10°C to +40°C
	During storage and transport: -20° C to +45°C
Maximum relative humidity	During operation: 100%
	During storage and transport: 90%
Protection against harmful ingress of water or particulate or particulate matter	IP X7 Protection against the effects of immersion up to 1 meter of water by 30 minutes
The CE mark on the device label certifies compliance with all European requirements and with Directive MDD/93/42/EWG.	

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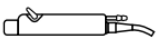
Table 14. Shaver Footswitch technical specification.

Parameter	Shaver Footswitch tk 39802-03
Weight	2,45 kg
Cable length	3,2 m
Dimensions	28 x 280 x 215 mm
Ambient temperature	During operation: +10°C to +40°C
	During storage and transport: -20° C to +45°C
Maximum relative humidity	During operation: 100%
	During storage and transport: 90%
Protection against harmful ingress of water or particulate or particulate matter	IP X8 Protection against the effects of continuous immersion in water
The CE mark on the device label certifies compliance with all European requirements and with Directive MDD/93/42/EWG.	

9 LABELS AND MARKINGS

9.1 Symbols and their meanings

Table 15. Summary of symbols and their meanings.

Symbol	Description/meaning	Symbol	Description/meaning
	Follow instructions for use		Information relating to the disposal of electronic equipment in the EU
	Type BF applied part	IP	Symbol for tightness class
	STANDBY – switches the device from a standby state of energy saving/sleep to a working state and vice versa		Warning symbol, drawing attention to the existence of specific risks and precautions associated with the use of the product - please refer to the instructions for use.
	OSCILLATION MODE – button oscillation mode change button.		OVERLOAD- visual indication of Shaver Handpiece motor overload
	OSD – button activation/deactivation of - connection to the apropiate device		Shaver Handpiece socket
	DIRECTION – button function key to switch direction of rotation of the Shaver blade in the handpiece		Shaver footswitch socket
	SPEED DOWN - button stepwise reduction of the speed to the lower level of rotational speed		Symbol for year of production

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Symbol	Description/meaning	Symbol	Description/meaning
UP	SPEED UP – button stepwise increase of the speed to the next higher level of rotational speed		Symbol for the manufacturer of the device
FWD	Clockwise rotation of Shaver Handpiece motor	REF	Device reference / article number
OSC	Oscillation mode	CE xxxx	Mark of conformity with European Community directives. XXXX - identification number of the notified body involved in the conformity assessment procedure
REV	Counterclockwise rotation of Shaver handpiece motor		Equipotential (equalising potential)
ON	Symbol - ON	+40°C +10°C	Limit of permitted temperatures
OFF	Symbol - OFF		Fragile! Careful!
SN	Device serial number		Protect from moisture!
	ON/OFF button on Shaver handpiece When short pressed turns the shaver handpiece motor on/off When long pressed initialized „WINDOW SIZE" function		This way up, do not turn over!
	DIRECTION button on Shaver handpiece When short pressed switch direction of rotation of the Shaver blade When long pressed change the oscillation mode		WINDOW SIZE – function key to calibrate window size.
MD	Medical Device	UDI	Unique device identifier

9.2 Packaging label

Label contains information about the contents of the package such as: device type, serial number, reference / article number, manufacturer's name and address.

9.3 Device label

Label includes necessary information regarding: device type, manufacturer data, date of production, supply voltages, power consumption and type of fuses. It also identifies the device by reference / article and serial number.

Under no circumstances the label should be removed or destroyed.
An illegible label makes it impossible to identify significant parameters. A device without a label or with a damaged label, which does not contain data identifying the product, is not subject to the manufacturer's warranty.

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9.4 Disposal of used electronic products

Before disposal, the device should be free from biological impurities in accordance with point *6. Maintenance and care.*

In the European Union

The current EU-wide legislation, implemented in each member state, requires that all electrical and electronic equipment marked with this symbol is disposed separately of other waste. This includes electronic devices or electrical accessories such as cables, electronics, etc. When disposing of such products, please follow the advice of your local authorities. The symbol shown on electrical and electronic products only applies in current EU member states.

Outside the European Union

When disposing of used electronic and electrical products outside the European Union, please contact your local authorities to obtain information on the proper method of disposal.

10 INFORMATION ABOUT POTENTIAL ELECTROMAGNETIC INTERFERENCES

WARNING!

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING!

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

WARNING!

The device and its accessories should be observed to verify that it is operating normally. Please take special attention and do not use the device and remove the source of EM disturbances if any of following symptoms occurs:

- Working parameters not changed without user intervention.
- Rotation of Shaver Handpiece not activated without user intervention.

Further work with the product is possible after removing the source of electromagnetic interference.

WARNING!

The use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased emissions or decreased electromagnetic immunity of the device and result in improper operation.

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Table 16. Guidance and manufacturer's declaration – Electromagnetic emissions.

EMC – guidance and manufacturer's declaration (EN 60601-1-2:2015) Arthroscopic Shaver system (ASS) consist of Shaver Control Unit tk 39802-01, Shaver Handpiece tk 39802-02, Shaver Footswitch tk 39802-03		
The arthroscopic Shaver system is intended for use in the electromagnetic environment specified below. The customer or the user of the ASS device should assure that it is used in such an environment.		
The arthroscopic Shaver system is intended to be used in hospital in medical treatment area (professional healthcare facility environment) where in its vicinity a high-powered medical electrical equipment (HF surgical equipment) may be used, except of an me system for magnetic resonance imaging, where the intensity of EM disturbances is high. EM environment is classified as special environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Classification according to CISPR 11	Group 1	The ASS device uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The ASS device is suitable for use in all establishments, other than domestic and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes. The ASS device is not intended to be used in vicinity of an me system for magnetic resonance imaging, where the intensity of EM disturbances is high
Harmonic emissions IEC 61000-3-2	Class A; Complies	
Voltage fluctuations IEC 61000-3-3	Complies	

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Table 17. Guidance and manufacturer's declaration – Electromagnetic immunity.

The ASS device is intended for use in the electromagnetic environment specified below. The customer or the user of the should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV, 100kHz for power supply lines ±1 kV, 100kHz Connection cables NF, SN	±2 kV, 100kHz for power supply lines ±1 kV, 100kHz Connection cables NF, SN	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line-to-line, ±2 kV line-to-ground	±1 kV line-to-line, ±2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 40% U_T; 5 periods 70% U_T; 25 periods 0% U_T ; 250 periods (5 sec)	0% U_T; 0,5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 40% U_T; 5 periods 70% U_T; 25 periods 0% U_T ; 250 periods (5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ASS device requires continued operation during power mains interruptions, it is recommended that the ASS device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the mains voltage prior to application of the test level.			

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Table 18. Guidance and manufacturer's declaration – Electromagnetic immunity.

The ASS device is intended for use in the electromagnetic environment specified below. The customer or the user of the ASS device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the ASS device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3,000 V	$d=1{,}16\sqrt{P}$
	6 Vrms in ISM bands between 150 kHz and 80 MHz; 80% AM at 1 kHz)	6,000 V	$d=2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10,000 V/m	$d=0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d=0{,}7\sqrt{P}$ 800 MHz to 2,7 GHz d=0,3m where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, **a)** should be less than the compliance level in each frequency range. **b)** Interference may occur in the vicinity of equipment marked with the following symbol: 
	From 9 V/m to 28 V/m for 380MHz to 5800MHz (wireless communication equipment)		
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Fidel strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land			

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The ASS device is intended for use in the electromagnetic environment specified below. The customer or the user of the ASS device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASS device is used exceeds the applicable RF compliance level above, the ASS device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ASS device. b) Over the frequency range 150 kHz to 80 MHz, Fidel strengths should be less than 3 V/m. c) 380MHz to 5800MHz wireless communication equipment works within specified ranges: 380MHz to 390MHz, 430 MHz to 470 MHz, 704 MHz to787 MHz, 800 MHz to 960 MHz, 1700 MHz to 1990 MHz, 2400 MHz to 2570 MHz, 5100 MHz to 5800 MHz .			

Table 19. Recommended separation distances between portable and mobile RF communications equipment and the ASS device.

The ASS device is Intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ASS device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASS device as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**			
	150 kHz to 80MHz $d=1{,}16\sqrt{P}$	150 kHz to 80MHz in ISM bands $d=2\sqrt{P}$	80 MHz to 800 MHz $d=0{,}35\sqrt{P}$	800 MHz to 2,7 GHz $d=0{,}70\sqrt{P}$
0,01	0,12	0,2	0,035	0,07
0,1	0,37	0,63	0,11	0,22
1	1,2	2	0,35	0,7
10	3,7	6,3	1,1	2,2
100	12	20	3,5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1:** At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

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Table 20. Guidance and manufacturer's declaration – Immunity to HF Surgical Equipment.

The ASS device is intended for use in the electromagnetic environment specified below. The customer or the user of the ASS device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Effects of HF surgical equipment emissions according to Annex BB of IEC 60601-2-2.	Emissions produced by HF surgical equipment	The immunity test of ASS device, power cord were performed. The monopolar HF surgical signal was applied to Shaver Control Unit tk 39802-01, power cord, Shaver Footswitch tk 39802-03 and Shaver Handpiece tk 39802-02 cable. No influence on ASS device was notice.	Before use HF surgical equipment must be installed according to its user manual. Operator must be sure that the EM disturbances produced by HF surgical equipment does not affect the other ASS devices located in treatment room including video monitor. HF surgical equipment can cause slight interference on the monitor display.

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Pos.	Specification	Art. No.
1	Control Unit	tk 39802-01
2	Handpiece	tk 39802-02
3	Footswitch	tk 39802-03

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ÄNDERUNGSVERZEICHNIS

(Vor Ausdruck / Versand / Veröffentlichung der GebA löschen – nur für interne Zwecke)

Datum	Version	Beschreibung der Änderung	Geändert durch	Freigabe durch
26.03.2024	1	Ersterstellung	J. Kaeding	FRM-149

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