Symbols Used

	UL Classification Mark for the United States and Canada.		**Danger of catching fingers** Do not put your fingers in rotating parts
	Protective earth (ground)		**Water cooling - irrigation**
	Connector for potential equalization lead		**Follow instructions for use**
Rx Only	**Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.**		**Materials to be recycled** The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force.
	Device of type B		**Electrical or electronic materials to be recycled**
	CAUTION! Dangerous voltage		**Component sensitive to electrostatic discharge**
	CAUTION! Refer to the accompanying documents	135°C	**Sterilizable in autoclave up to the specified temperature**

Manufactured for:
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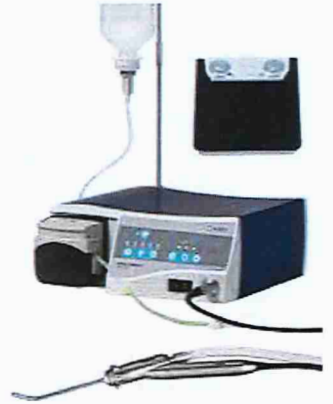
INSTRUCTIONS FOR USE

Entellus Medical Shaver System

1. SYSTEM DESCRIPTION

The Entellus Medical Shaver System offers you cutting-edge technology and features in a compact size. Fitted with the Shaver System Handpiece, the system is easy to use and has a high performance and reliability level consistent with the Entellus Medical product portfolio. All the system's functions can be viewed and accessed quickly via the keys on the Control Unit or Foot Pedal. The Shaver System motor can be programmed in two modes -- continuous rotation or oscillating rotation based on preference. The Handpiece, with an integral micro-motor, is characterized by its lightness, precision and handling comfort. Its unique ergonomics in addition to its integral irrigation system ensure ease of handling and efficient performance. The Handpiece is coupled to a brushless motor without sensors which is renowned for its power and reliability.



The Entellus Medical Shaver System includes:

- 1 Control Unit
- 1 Handpiece with cable, sterilizable
- 1 multifunction Foot Pedal with 2 buttons
- 1 Irrigation Stand
- 1 set of 10 Irrigation Lines with 2 flow rate ranges
- 1 set of 10 Irrigation Clips
- 1 Cleaning Brush
- 1 Power Cord

2. INDICATION FOR USE

The Entellus Medical Shaver System has been designed for shaping bone and for the resection of soft and hard tissues as part of surgical procedures in the areas of otorhinolaryngology.

3. CONTRAINDICATIONS

None known

4. WARNINGS AND PRECAUTIONS

4.1 Warnings, precautions for use

Technical specifications, illustrations and dimensions contained in this document are given only as a reference. They correspond to the software V1.3X. The manufacturer reserves the right to bring technical improvements to his equipment without modifying the present instructions.

Do not use this device in the presence of a flammable gas.

The device and its accessories should be used only by trained and competent medical personnel, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and the present user manual. According to these measures, the user has the following obligations:

- To only use devices in perfect working condition. In the event of irregular operation, excessive vibrations, abnormal over-heating or other signs suggesting mal-functioning of the device, work must be suspended immediately. In this case, contact a repair center approved by Entellus Medical.
- Make sure that the device is used only for the purpose for which it is intended, protect yourself, patients and third parties from all danger and avoid contamination by the product.

The device and its accessories are designed solely for medical treatment. Any use not in conformance with the intended use is unauthorized and may prove dangerous.
Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Never submerge the Shaver System Control Unit in disinfection solutions.

Install the Control Unit on an appropriate mounting to prevent risks of injury or infection for yourself, the patient or third parties. Use only Entellus Medical accessories and/or spare parts. The use of other products, accessories or parts could void the guarantee and/or endanger the patient or the operator.

To avoid the risk of electrical shock, this equipment must only be connected to a supply main with ground.

Use the enclosed power supply cord (Hospital grade, UL classified).

Do not lift the pedal by its connection cable!

Danger of electrocution. Never open the device when it is connected to the mains power outlet.

4.2 Environmental protection and indications for device disposal

This equipment must be recycled. The disposal and/or recycling of materials must be performed in accordance with the legislation in force. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards.

The user can return the device to Entellus Medical or call directly on a firm accredited for the treatment and recovery of this type of equipment.

4.3 Precautions regarding electromagnetic compatibility (EMC)

Regarding the EMC, and in order to maintain basic safety and the essential performances (refer to the chapter 10 for more information) for the expected service life of 10 years, the medical electrical equipment requires special precautions and must be installed and put into operation in accordance with the appropriate information provided in the service manual and in the present document. The Shaver System Control Unit complies with the EMC requirements according to EN 60601-1-2: 2014. Radio transmit-ting equipment, cellular phones, etc. should not be used in the immediate vicinity of the device, since this could affect its operation. Special precautions should be taken when using strong emission sources such as high-frequency surgical equipment and other similar equipment, to ensure that HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or Entellus Medical.

WARNING: The use of the Control Unit adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Control Unit and other equipment should be observed to verify that they are operating normally.

Pins of connectors identified with the ESD warning control symbol should not be touched and connections should not be made to these connectors unless ESD precaution procedures are used.

WARNING: Use of accessories, transducers and cables other than those specified or provided by Entellus Medical could result in increased electromagnetic emissions or a decreased electromagnetic immunity of the equipment and result in improper operation.

See "Accompanying documents EMC" at the end of this manual.

5. CONTROL UNIT

5.1 Technical data

Subject to modifications of the models and technical amendments.
Environmental conditions:

	Work	Transport	Storage
Temperature	+10°C (+50°F) to +30°C (+86°F)	-25°C (-13°F) to +70°C (+158°F)	+10°C (+50°F) to +30°C (+86°F)
Relative humidity (including condensation):	20% to 80%,	10% to 100%,	20% to 80%,
Atmospheric pressure:	700 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

Control Unit

Supply voltage:
100 - 240 Vac / 2A – 1A / 50-60 Hz.
Fuses:
2 fuses T 2.5 AH 250 VAC.
Motor power supply:
1 push-pull type connectors / <50 Vdc.
Electrical insulation class:
Class I
Applied parts:
Type B.
Protection class:
IP 41 as per CEI 529.
Size / Weight:
(W x H x D) 261 x 110 x 300 mm
(height with irrigation stand: 520 mm) / 4.1 kg.

Fig. 1

Irrigation Pump

Delivery from ca. 5 to 90 ml/min,

4 + 4 irrigation flow rate values (with two-speed irrigation line).

Irrigation Stand

Stainless steel.

Foot Pedal, multifunction

Protection class:
IPX8 as per CEI 529.
Functions:
Drill motor forward/reverse selection,
shaver rotation continuous/oscillating,
speed control irrigation pump start/stop and flow rate selection.
Size / Weight:
(W x H x D) 160 x 55 x 170 mm / 0,830 kg.

Cable

Length 295 cm ±5 cm.

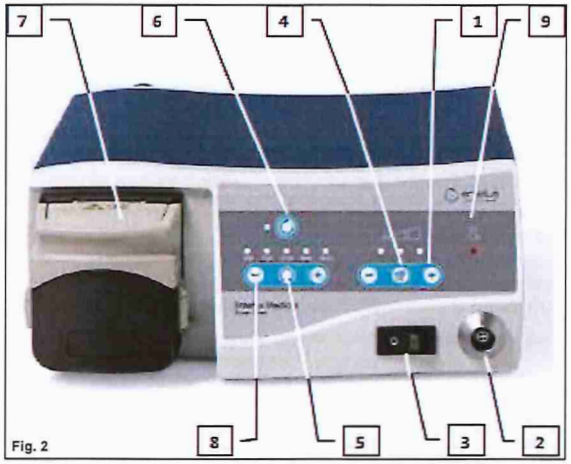


Fig. 2

Compliance criteria

General requirements:	Requirements according to the EUT:
The following deteriorations associated with essential performance* and safety shall not be allowed: - component failure; - changes in programmable parameters; - reset to factory defaults; - change of operating mode; - false alarms; - cessation or interruption of any intended operation, even if accompanied by an alarm; - initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm; - error of a displayed numerical value sufficiently large to affect diagnosis or treatment; - noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring; - artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring; - failure of automatic diagnosis or treatment, even if accompanied by an alarm; The equipment or system may exhibit deterioration of performance that does not affect basic safety or essential performance.	Essential performance*: - Motor shall remain inactive when the foot control is released. - Motor shall remain active when the foot control is engaged. - Variations in speed and incorrect functioning do not represent unacceptable risks - No unintentional start of motor - In the case of a ESD (±15 kV), the system failed that requires a restart of the EUT does not represent an unacceptable risk

* Essential performance = performance necessary to achieve freedom from unacceptable risk.
The manufacturer shall identify which functions are essential performances. Equipment that does not perform properly could result in an unacceptable risk for patients, operators, or others. All features or functions that must perform properly to prevent harm to the patient, operator or others are important. When a failure to perform would result in an unacceptable risk for the patient, operator or others, then those features or functions are seen as essential performance. Essential performance = performance necessary to achieve freedom from unacceptable risk.

ESD Information
The accessible pins of connectors should not be touched by staff with their fingers or with a hand TOOL, unless proper precautionary procedures have been followed. These connectors are identified by the ESD warning symbol.
Here is a non-exhaustive list of preventive measures to be taken to prevent the build-up of electrostatic charges:

- Use: air conditioning, humidification, conductive floor coverings, non-synthetic clothing.
- Allow static charges from your body to flow to the metal frame of the Shaver System or to ground or a large metal object;
- connect your body to the Shaver System or to ground by means of a wrist strap.
- Before connecting or disconnecting the connector, touch a metallic surface of the Shaver System to eliminate any static electricity.

It is recommended that Shaver System users undergo basic training in the procedures relating to ESD precautions.
The basic training should include:

A) An introduction to the physics of electrostatic charges, the voltage levels that can occur in normal practice and the damage that can be done to electronic components.
B) An explanation of the methods to be used to prevent the build-up of electrostatic charges.
C) An explanation of how and why charges from your body should be discharged to ground or to the frame of the EQUIPMENT or SYSTEM.

UL Conformity
Classified by Underwriters Labo-ratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI/IEC/EN ES60601-1 (2012, 3.1 ed.) and CAN/CSA C22.2 No 60601-1 (2014).

Essential Performances according to EN IEC 60601-1
Reliable activation/deactivation of the motor using the foot control. Variations in the device speed and incorrect functioning do not represent unacceptable risks.

11. GENERAL TERMS OF GUARANTEE

Entellus Medical endeavors to provide its customers with products and devices of impeccable quality, which it guarantees within the limits of the present general terms and the particular agreements signed, against any operating fault, material or manufacturing defect. The guarantee period is 12 months from the date of invoice. In general, the guarantee does not exempt the customer from the obligation of obtaining information from Entellus Medical in case of doubt and in particular when the product is used in conditions not explicitly provided for originally.

In the event of claims, the manufacturer or its authorized representative shall perform product repair or replacement free of charge, after analyzing the justification for the claim. All other claims of whatsoever kind, and in particular claims for damages, are excluded. Entellus Medical shall not be held responsible for damage or injury and the consequences thereof, resulting in particular from: excessive wear, inappropriate use, failure to comply with operating instructions, assembly instructions or maintenance instructions, exceptional environmental, chemical, electrical or electrolytic influences, faulty air or water seals or electrical connections. In any case the guarantee becomes null and void in the event of inappropriate servicing, use of non-recommended parts, accessories or consumables, or modifications to the product carried out by third parties not authorized by Entellus Medical. In case of dispute as so whether or not the defect exists, it shall be incumbent on the customer to prove the existence of the defect. Guarantee claims shall be taken into consideration only upon presentation, with the product, of a copy of the invoice or delivery slip on which should appear clearly the date of purchase and the product reference and serial number.

Guidance and manufacturer's declaration – electromagnetic immunity

The Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the Shaver System should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Professional healthcare facility environment – guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V	When using portable and mobile RF communications equipment, be sure to respect the recommended separation distance from all parts of the Shaver System, including cables. (Separation distance is calculated using the equation applicable to the frequency of the transmitter). **Recommended separation distance** $d = 1.2\ P\ \sqrt{}$ $d = 1.2\ P\ \sqrt{}$ 80 MHz to 800 MHz $d = 2.3\ P\ \sqrt{}$ 800 MHz to 2.7 GHz 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m	

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] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted 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 Shaver System is used exceeds the applicable RF compliance level above, the Shaver System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Shaver System.

[b] Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Shaver System

The Shaver System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Shaver System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Shaver System 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		
	150 kHz to 80 MHz $d = 1.2\ P\ \sqrt{}$	80 MHz to 800 MHz $d = 1.2\ P\ \sqrt{}$	800 MHz to 2.5 GHz $d = 2.3\ P\ \sqrt{}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

5.2 Set-up

5.2.1 Unpacking and checking

1. When unpacking the cardboard box, check its content against the packing list. If items are missing or if the equipment is damaged, notify the sender immediately. If the shipment box is damaged, notify the carrier.
2. After unpacking, keep the shipment box and the packing materials. They could be useful for returning the device.

5.2.2 Preparation

1. Place the Shaver System Control Unit in the non-sterile area, on a table, on a cart or on any other surface, out of reach of the patient, with the main switch and power cord always accessible. The Control Unit must never be placed on the floor.
2. The Control Unit is powered by the mains (100 to 240 Vac). It is protected by 2 fuses located in box **12 (Fig. 1)**. Check that the main switch **3 (Fig. 2)** is on position **0** and connect the power cord to connector **13 (Fig. 1)**.
3. Connect the pedal cable to output **11 (Fig. 1)** provided on the rear panel, making sure to align the red marks on the connector and the plug.
4. Connect the Handpiece motor cable to output **2 (Fig. 2)** ensuring to align the red marks.
5. Align and insert the Irrigation Stand in the support **10 (Fig. 1)** provided at the rear of the Control Unit and suspend the saline bag there.

Before performing any operation on the device, touch a metallic surface to eliminate any static electricity.

Attach the ground wire to the potential equalization connector **14 (Fig. 1)**. The purpose of the potential equalization connector is to equalize potentials between different metal parts that can be touched simultaneously, or to reduce differences of potential which can occur during operation between the bodies of medical electrical devices and conductive parts of other objects.

5.2.3 Use of the Irrigation Line

1. Check the integrity of the irrigation line packaging and the use-by date. **Only Entellus Medical lines ensure trouble-free operation.**
2. Remove the disposable sterile irrigation line from its bag. **Use a new Irrigation Line for each patient, a reuse could lead to a cross contamination.**
3. Connect the flexible hose to the spray tube of the Handpiece.
4. Install the white or green silicone segment on the irrigation pump and close the pump cover. Check the "V" location in the chuck mechanism **(Fig. 3)**.

Caution: Risk of hose perforation.

Caution!
Do not operate the pump when the cover is open. Danger of catching fingers!


Fig. 3

5. Remove the spike protection, and perforate the saline bag.
6. Attach the irrigation line to the motor cable using the provided irrigation clips.

Irrigation line with 2 flow rates (Fig. 4):

- 100% Flow rate using the white silicone segment: From ca. 10 to 90 ml/min.
- 50% Flow rate using the green silicone segment: From ca. 5 to 50 ml/min.

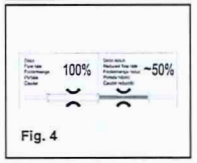


Fig. 4

5.3 Use

5.3.1 Power up

At power-up (switch **3 Fig. 2** in position **1**), a green light will turn on inside the switch.
Various keys located under a watertight membrane can be used to select the work mode and to perform the appropriate adjustments depending on the planned operation. Each selected mode corresponds to a specific LED.

Note: The active state of keys **4** to **6** is shown by an illuminated LED above the corresponding key.
The software version is indicated during unit initialization by the blinking LED **5**.

5.3.2 Continuous irrigation synchronized with the motor

Press this key **4** to activate and deactivate the function of simultaneous pump starting and stopping with the selected motor. It is symbolized by a green LED. This function is also controlled by the left Foot Pedal button.

Remark: When irrigation is stopped, the pump's direction of rotation is reversed to "suck up the drop"

5.3.3 Adjustment of the irrigation flow

A press on the key **1** - or + respectively reduces or increases the irrigation flow. The flow is symbolized by LEDs (1 to 3) located above the keys.

5.3.4 Configurable option

Memorize last adjustments before Control Unit is switched off:

To activate or deactivate the memorization, proceed as follows:

1. Activate motor rotation in clockwise direction using key **6**.
2. Press key **6** for 5 seconds until beep.

Keyboard beep on each button press on keyboard or foot pedal.

To activate or deactivate the keyboard beep press key **4** for 5 seconds until beep.

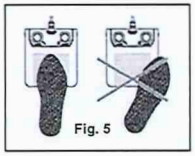


Fig. 5

5.3.5 Foot Pedal

The pedal functions allow the surgeon to change setting without the assistance of another person.

Remark: The Foot Pedal must always be connected.

For good pedal stability and operation, make sure to place your foot correctly in the center of the pedal (**Fig. 5**)!


Fig. 6

Left dual-function button for irrigation control (Fig. 6):

a. Long press on the button: Activation or deactivation of the irrigation.
b. Short press on the button: Change in flow rate in steps in increasing order if irrigation is activated.

Right dual-function button for motor control (Fig. 6):

a. Long press on the button: (ca. 1sec.): Swap between **«continuous rotation clockwise»** and **«oscillating mode»**.
b. Short press on the button: Speed increase in steps. In **«oscillating mode»**: speed increase in 500 rpm steps (frequency, 0.5Hz.)

Variable speed drive (rocker switch):

Variable motor speed control.

5.3.6 Power down

To switch off the Control Unit, turn the switch **3 Fig. 2** in position **0**.

6. HANDPIECE

The Handpiece is designed to drive various types of Shaver surgical blades. The Handpiece is connected to the Control Unit by a specific cable.
The Handpiece is provided "nonsterile". Clean, lubricate and sterilize the Handpiece with the cable before first use.

6.1 Technical data

Subject to modifications of the models and technical amendments.

Environmental conditions:

	Work	Transport	Storage
Temperature	+10°C (+50°F) to +30°C (+86°F)	-25°C (-13°F) to +70°C (+158°F)	+10°C (+50°F) to +30°C (+86°F)
Relative humidity (including condensation):	20% to 80%,	10% to 100%,	20% to 80%,
Atmospheric pressure:	700 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

Type: Direct current, brushless and sensorless.
Power supply: 0 - <50 Vdc 4.5 A max.

Parts applied: All housing surfaces of Handpiece are considered "applied parts" of type B.

Motor torque: Max. 15 mNm.

Speed:
- In continuous rotation 500 to 8,000 rpm +/- 5%.
- In oscillating mode 500 to 5,000 rpm, +/- 5%.

Noise level: As per ISO 11498: < 62 dBA at 45 cm.

Period of operation: To avoid overheating of the applied parts and the associated risk of burn injuries of patient or surgeon, the following rules must be respected:

a. Limit the maximum speed of rotation based on the intended use.
b. Adequate irrigation is mandatory.
c. Duty cycle: For room temperature up to 30°C (86°F), the motor under full load is rated for intermittent operation with a maximum ON time of 2 minutes followed by a minimum OFF time of 20 minutes.

When the Handpiece external surface temperature rises more than ca. 21°C (69,8°F) above the ambient temperature, an alarm will ring (see section 9 for further explanations). The Handpiece can still be used for a short period but under the surgeon's full responsibility. In this case beware of not touching the patient with the Handpiece (high risk of burn injuries).

Size / Weight: Diameter 18 mm, length 140 mm, angle 15° / 198 g without cable and without tool.

Motor / cable: Push-pull type connector at Shaver System end, length 295 cm ±5 cm.

Tools: Single use and reusable straight and curved shaver blades.

6.2 Connection

Before connecting the specific motor cable, check the cleanliness of the rear of the Handpiece and the cable plug. The Handpiece should be properly oriented (align the cable reference with the reference on the motor). Insert the plastic connector in position. Tighten the connector nut as far as possible.

Irrigation:
Connect the irrigation line to the Handpiece up to a firm stop. Attach the irrigation line to the motor cable using the provided irrigation clips.

Suction:
Connect the suction hose of inner diameter 4 to 8 mm on the Handpiece. Insert the suction hose into the apertures of the mounting clips already installed on the motor cable.

Surgical shaver blades:
The blades for the Handpiece are sterile disposable instruments or reusable and sterilizable instruments. These tools are used exclusively with the Handpiece. There are various blades, depending on the planned operation. Refer to the tools' documentation.

⚠ **Important note: Never insert an instrument on a rotating micro-motor.**

Before using the Handpiece, operate it at moderate speed without blade for a few seconds, so as to spread the lubricant and remove any excess.

10. DOCUMENTS ACCORDING TO EN 60601-1-2: 2014, CHAPTER 5

Guidance and manufacturer's declaration – electromagnetic emissions

The Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the Shaver System should ensure that it is used in such an environment.

Emissions test	Compliance	Professional healthcare facility environment – guidance
RF emissions CISPR 11	Group 1	The Shaver System uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Shaver System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The Shaver System is intended for use in the electromagnetic environment specified below. The customer or the user of the Shaver System should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Professional healthcare facility environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV air	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines, 100 kHz repetition frequency	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines, 100 kHz repetition frequency	Not applicable[1]	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to ground	±2 kV common mode	
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Shaver System requires continued operation during mains power interruptions, it is recommended that the Shaver System be powered from an uninterruptible power supply or a battery.
	0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0°	0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0°	
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycles	0% UT; 250/300 cycles	
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	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 AC mains voltage prior to application of the test level.

[1] NA: cables shorter than 3 metres

For all servicing and repairs, we recommend that you contact Entellus Medical.

Entellus Medical recommends users to have their dynamic instruments checked or serviced once to twice a year depending of the usage frequency.

Hygiene

For the safety of the repair center's personnel, the instrument should be cleaned and sterilized completely before being returned for repair. If that proves impossible, for example because a disinfection or sterilization would make the instrument completely unusable, clean the instrument as carefully as possible and mark it accordingly to indicate that it has not been decontaminated.

9. MALFUNCTIONS AND ERRORS

Use the table below to solve any problem encountered. If the problem is solved, stop using the product and contact Entellus Medical.

9.1 Control Unit

Message	Description	Recommended action
An acoustic signal is emitted when control unit is powered-up	This indicates that the pedal cable is not connected to the control unit or that the connection is defective.	Connect the pedal cable to the (outlet **11**) provided at the rear of the unit; check that the plug is connected correctly.
When rocker pedal is depressed, an acoustic signal is emitted. The 5 speed LEDs are flashing and an acoustic signal is emitted. 	The motor is not connected or The device has identified a motor cable defect. or Motor average current too high; motor speed of rotation too low or motor blocked. or The device has identified a motor defect; phase-to-phase short circuit in the motor or the motor cable or The Handpiece or cable is unsuitable.	Connect motor cable use a new motor cable Restarting as soon as the pedal is released; further pedal rocker movement required. Change the motor and/or the cable. If the error persists, contact Entellus Medical. Connect a Handpiece with its cable
 **Alarm 9** The red LED is turned on and an acoustic signal is emitted.	The motor external surface temperature rose more than ca. 21°C (69,8°F) above the ambient temperature. The alarm is ringing every 5 seconds.	We recommend to stop working and to wait until motor temperature reduces and alarm stops or to change the micromotor. The micromotor can still be used for a short period but under the surgeon's full responsibility. In this case beware of not touching the patient with the micromotor/ Handpiece (high risk of burn injuries).
 The 3 irrigation LEDs are flashing and an acoustic signal is emitted.	The irrigation pump is blocked or the pump electronic is short-circuited.	Press key **4**. If the error persists, contact your accredited Entellus Medical.

9.2 Handpiece

Problem	Solution
The Handpiece is not working	Make sure that the cable is properly connected to the Handpiece and the Control Unit. Make sure that the Control Unit is turned on and the Handpiece is selected. Check the condition of the motor power cable and the Handpiece (broken contact or severed cable).
Impossible to insert the blade	Check the condition of the blade. Without a blade, check the freedom of movement of the clamping ring. To do so, push it up to a firm stop and release. It should return to its initial position. Check that there is no part or other dbri retained inside.
The clamping ring is not free to move	Check the external and internal cleanliness of the clamping system. Lubricate with "*Lubrifluid*" before sterilization.
The 360° orientation system is not free of movement or the auto blocking system of the blade is failing	Check external and interior cleanliness of the clamping ring and orientation system. Lubricate with "*Lubrifluid*" before sterilization.
The blade is inserted, but it does not rotate	Remove the blade and check that the drive is not broken. Check that the blade is correctly in position.
The suction pump operates, but there is zero or little suction	Check that the hose is not clogged or kinked. See the blade operating instructions. Clean the suction channel of the Handpiece with a soft-bristle brush.
The irrigation pump operates, but the irrigation fluid does not flow	Check that the irrigation line is properly connected and that the flow rate setting is adequate. Check that the blade is not clogged. Check that the Handpiece duct is not clogged. This should be done without a tool.

6.3 Blade insertion and removal on the Handpiece

1. Gently insert the blade in the Handpiece up to a firm stop; the clamping ring should retract and then return to its initial position. Pull the blade slightly to check that it is correctly attached. If the blade is not correctly attached, remove it and start insertion again.
2. Pull the clamping ring to the rear and remove the blade.

Note: The blade consists of two separate parts. If the internal part remains held in the Handpiece, pull on this component axially to withdraw it.

360°orientation system:

Turn the orientation crown to choose the proper shaver blade position. The auto blocking system maintains the shaver blade in its position.

6.4 SHAVER Mode

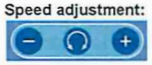
Oscillating rotation is selected by default upon power up of the control unit.

Direction of rotation

A press on key **6** activates the continuous rotation mode. The corresponding speed is displayed by green LEDs and the blue numbers (500 to 8,000).

A press on key **5** activates the oscillating rotation mode. The corresponding speed is displayed by green LEDs and the white numbers (500 to 5,000).

Speed adjustment:



A press on key **8** - or + respectively reduces or increases the speed of rotation.

Remark: When keys **1** or **8** are held pressed down, the values are scrolled automatically.

7. CLEANING / MAINTENANCE / STERILIZATION

7.1 General indications

⚠ **Do not place the Handpiece in an ultrasonic bath.**

⚠ **Never rinse instruments in cold water to cool them.**

⚠ **Never submerge the Handpiece in disinfection solutions.**

⚠ **Do not place stainless steel instruments or motors in physiological saline solutions (NaCl solution), because prolonged contact may cause corrosion.**

Customary precautions:

Hospital procedures must be followed. The universal precautions must be complied with by hospital personnel working with contaminated or potentially contaminated medical instruments. Pointed and sharp instruments should be handled with great caution.

Agents required for cleaning:

- Detergents:

Enzymatic detergent recommended for cleaning surgical instruments in washer / disinfector. For example a detergent containing proteolytic enzymes.

Detergents should be used in the concentration, temperature and duration recommended by the detergent manufacturer.

To remove physiological liquid inside the instrument or the spray tube, use the "*Aquacare*" or a water gun.

⚠ **Do not use detergents that are corrosive or contain chlorine, acetone or bleach, aldehydic products or alcohols.**

- Lubricant:

Exclusively use "*Lubrifluid*".

- Brush / cleaning gun:

The brushes should be non-aggressive to avoid damaging the device. Preferably use nylon brushes with flexible hairs or soft bristles. Use the cleaning gun with the appropriate nozzles for the various ducts.

Storage:

Entellus Medical strongly advises storing only sterilized devices so as to reduce the risks of corrosion.

Ambient conditions of storage after sterilization:

- Store the equipment in a clean, dry place at ambient temperature (10–30°C (50–86°F), 20–80% humidity).
- Do not expose the equipment to direct sunlight.
- Do not expose the equipment to permanent X-ray irradiation.
- Do not store the equipment in places that could be reached by liquid splashes.
- Do not store the equipment in the following ambient conditions:
  - Dust
  - Saline or sulphurous atmosphere
- Do not store the equipment in a location where there is a risk of release of flammable gases.

Preliminary cleaning precautions:

This operation is important to facilitate the subsequent cleaning stage (it prevents dirt from drying and sticking to the equipment).

Cleaning precautions:

Complete cleaning can lower the initial microbial load, eliminate organic matter and prevent biofilm formation. This stage is essential and influences the quality of the disinfection procedure as a whole. Cleaning combines the physicochemical action of the product and the mechanical action of brushing and rinsing.

Sterilization precautions:

The shelf life of stored sterilized instruments depends on the type of packaging used and the storage conditions (refer to the DIN 58953 standard, section 9, or the existing local regulations).

Since no reprocessing methods have been validated for removal of transmissible spongiform encephalopathy (TSE) agents from medical devices, this device should not be used for patients with known or suspected TSE agent disease, including CJD and vCJD. Entellus Medial recommends incineration of devices that have directly contacted patients suspected or confirmed with TSE/CJD diagnosis.

The instructions of the sterilizer manufacturer concerning operation and the load configuration should be complied with explicitly.

⚠ **Do not exceed a temperature of 138°C (280°F).**

Before re-using, the instrument must be allowed to cool to ambient conditions, without forced cooling.

Packing for sterilization:

Separate packing:

Wrap the instrument with its cable immediately after cleaning in an individual packing such as a paper/plastic pouch or sterilization wrap, for steam sterilization. Make sure that the cable does not touch the sides of the sterilizer.

Or

Packing in stiff boxes and trays with defined, pre-configured lids and apertures and wrap the stiff boxes or tray.

FDA approved sterilization wraps or container must be used.

The Handpiece is delivered "nonsterile". Before it is used, please comply with the present section. The cycles described below are compatible with the Handpiece and its cable:

- Clean, lubricate and sterilize the instrument with the cable before first use.
- Clean, lubricate and sterilize the instrument with the cable before each further use.
- After each use, perform cleaning maintenance and sterilization of the Handpiece as quickly as possible.

As soon as you have finished using the Handpiece, proceed as follows:

- Disconnect the motor power cables from the Control Unit.
- Do not disconnect the power cable on Handpiece side.
- Disconnect the irrigation and suction lines from the Handpiece.
- Separate the surgical shaver blade from the Handpiece, and treat it in accordance with the local regulations in force concerning the disposal of contaminated wastes.

For instruction per instrument see section 7.2 to 7.4.

7.2 Control Unit and Foot Pedal

Use enzymatic detergents with a neutral pH (6.0-8.0). Spray the outside to clean residues. Soak a clean cloth and carefully clean the surfaces and also under the pedal's rocker switch (see **Fig. 7** and **Fig. 8**).

⚠ **The Control Unit and the Foot Pedal are not sterilizable!**

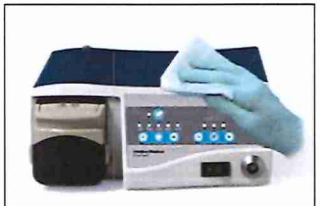


Fig. 7

Fig. 8

7.3 Handpiece

7.3.1 Preliminary cleaning

⚠ **It should be performed as soon as possible after the surgical procedure.**

⚠ **Preliminary cleaning should be followed by manual cleaning.**

⚠ **Never submerge the Handpiece in disinfection solutions.**

- Spray (2 sec.) the interior of the suction channel and then the irrigation channel in the direction of their use with "*Aquacare*" to remove physiological saline solution from the duct.
- Place the Handpiece under running tap water (tip upwards) and rinse with cold water for at least 10 seconds to clean the inside of the Handpiece. Close suction channel several times with finger. Follow by a 10 seconds rinse with the tip downward through the suction port (see **Fig. 9** to **Fig. 11**).
- Clean the outside and inside with water and brush/swab until visually clean.
- Spray (4 sec.) the irrigation channel in the direction of its use with "*Aquacare*" to rinse it.
- Wipe the cable and the Handpiece with non-woven towelettes.
- Perform manual cleaning.

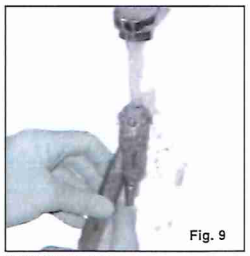


Fig. 9

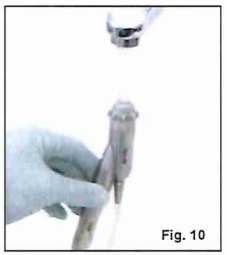


Fig. 10

Fig. 11

7.3.2 Cleaning

Manual cleaning:

Hold the Handpiece with the front end directed downward and wash it with the cable abundantly with detergent solution (max. temperature 35°C (95°F)) as follows:

- Without clamping, rub the whole cable with a non-woven towelettes that is soaked with detergent, one to-and-fro movement.
- Brush the outside of the Handpiece with a soaked soft nylon brush (especially in the corner, edges and openings) for 30 seconds.
- Clean the interior of the Handpiece on the drive side with the swab for 30 seconds (take care not to scratch or damage the interior of the part).
- Rinse the cable for 20 seconds with cold tap water.
- Rinse the inside and outside of the Handpiece with tap water for at least 20 seconds. Hold the device with the front end directed downward.
- Check the freedom of movement of the closing collar. To do this, push it several times to full stop and release it. It must always return to the starting position.
- With a water gun or "*Aquacare*" rinse the irrigation channel thoroughly.
- Blow clean air in the irrigation channel, in the suction port and in the nose to dry the inside of the Handpiece. Dry the exterior of the Handpiece and its cable by wiping with a clean and dry non-woven towelettes.
- If the instrument is not immediately sterilized, perform a dynamic drying under ventilation at about ~100°C (212°F), for a minimum of 25 minutes.

7.3.3 Inspection, lubrication and testing

Carefully inspect each part to make sure that all visible contamination has been eliminated. Check in particular that the ducts are clear. Where there is contamination, repeat the cleaning process.

After each cleaning operation and before each sterilization, lubricate the instrument with "*Lubrifluid*" from Entellus Medical as follows:

- To absorb any excess lubricant, apply a cloth over the instrument's apertures. Insert the tapered end of the "*Lubrifluid*" spray in the tip of the Handpiece and squirt for about 0.5 second.
- Then leave the Handpiece to rest upright with the tip downward for at least 5 minutes.
- Check the freedom of movement of the attachment ring. To do this, push it several times to full stop and release it. It must always return to the starting position.
- Check the freedom of movement of the orientation crown (in both directions of rotation).

7.3.4 Sterilization

Sterilization by steam / moist heat is the recommended method for the Handpiece and its cable. The following table for the sterilization parameters, using a B type cycle with Pre-Vac, is recommended to provide a sterility assurance level (SAL) of 10^{-6}:

Temperature	135°C (275°F)
Pressure	2.2 bar (31.9 PSI)
Time	3 minutes
Drying	15 minutes[1]

[1] Refer to sterilizer manufacturer recommendations for drying times per load configuration.

8. MAINTENANCE

Control Unit

Entellus Medical recommends users to have the Control Unit checked at least once a year.

Change of fuse:

- In case of power supply problems, check the fuses.
- To change the fuse, open the box **A (Fig. 12)** located on the back of the unit and extract the fuse by pulling it. Insert new fuse and close the box **A (Fig. 12)**.
- If a fuse fails a second time, have the device checked by an accredited Entellus Medical representative.

Fig. 12

Handpiece

No component of the Handpiece may be changed by the user.

⚠ **Never disassemble the Handpiece or its cable.**