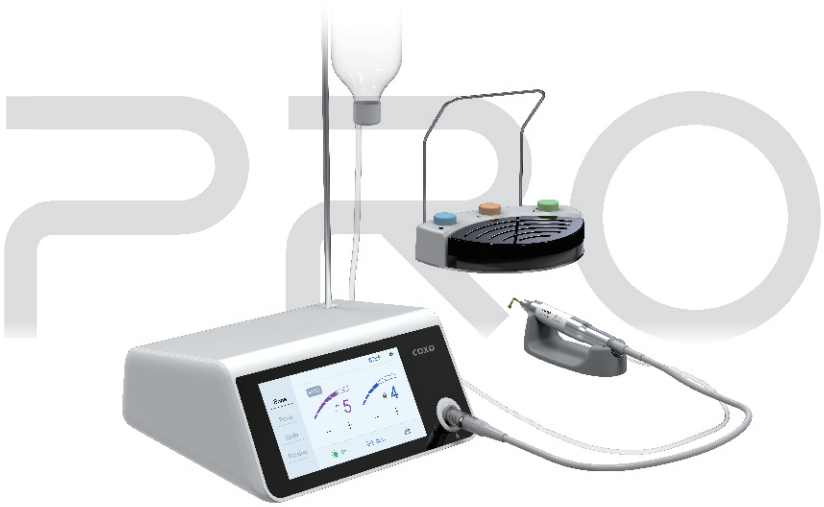
COXO®

USER MANUAL

Dental Ultrasonic Surgical Device



C-EXPLORER PRO

CE 0197

Foreword

The purpose of this manual is to make the operator knowledgeable of the safety precautions, the installation procedures, and the instructions for a correct use and maintenance of the device and its accessories. Please read this manual carefully before use.

The manufacturer shall be under no liability, expressed or implied, and shall have no responsibility for any direct, indirect or other damages and personal injury arising out in connection with any practice in the use of the device and its accessories.

In the event of a serious adverse event, please contact your distributor or importer or EU representative or manufacturer immediately. The manufacturer will deal with it immediately.

The manufacturer is committed to continuously update its products with possible modifications to device components.

Contents

1 Safety

Carefully read this manual before proceeding with the installation, use, maintenance, or other operations on the device. Always keep this manual within reach.

1) The device must be used exclusively by specialized and appropriately trained personnel such as a Surgeon;

2) Use the device only for the intended use, otherwise may cause serious injuries to the patient, the operator, and damages/breakdowns to the device;

3) All new and repaired accessories are supplied in non-sterile conditions. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions given in the Cleaning and Sterilization Manual;

4) Use the original accessories only;

5) Protect openings of the product from any ingress of liquids;

6) Before every treatment, always check that the device works perfectly and that the accessories are efficient. In case you encounter operating abnormalities, do not perform the treatment. Contact an Authorized Service Center if the abnormalities concern the device;

7) The device cannot operate in environments where anesthetic or flammable mixtures are present;

8) The device has electromagnetic interference, so please do not use it around patients with cardiac pacemaker or electronic surgery;

9) An electrical scalpel or other electron-surgical units near the device may interfere with its correct operation;

10) Do not use the Tip which has been damaged, bent or corroded;
Do not change the Tips when the device is working;

11) Check device status before each treatment;

12) Parts that rotate when the pump is running may injure the patient, user and third parties. Do not reach into the pump. Turn off the device when the pump is open;

13) Allow reusable, autoclavable items (the Handpiece, the Dental Ultrasonic Surgical Device Handpiece Tip, the torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated;

14) Do not perform treatments on prosthetic artifacts made of metal or ceramics. The ultrasonic vibrations could lead to the de-cementing of the artifacts.

15) To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

16) Do not make any modifications to this device.

2 Intended use

This product is intended only for use in the field of dentistry, for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal, gap, gingiva, bone, jaw, extractions, implantations).

Does not include soft tissue cutting.

3 Contraindications and indications

3.1 Contraindications

Do not use on the following patients:

- Those with medical complications or allergies;
- Those who have preexisting conditions (E.g. Cardiac, Pulmonary, Renal disturbance or High blood pressure);
- Those who are pregnant or lactating;
- Patients with cardiac pacemakers and infants.

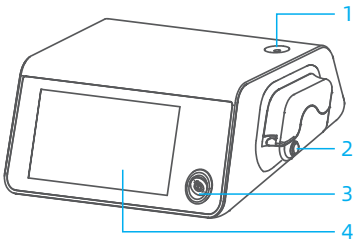
3.2 Indications

- Endodontic disease;
- Dental implant:
  -implant socket preparation;
  -Sinus Floor Elevation;
- Pull a tooth;
- Periodontal disease.

4 Description

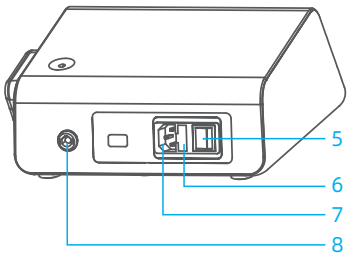
4.1 Control unit

Front



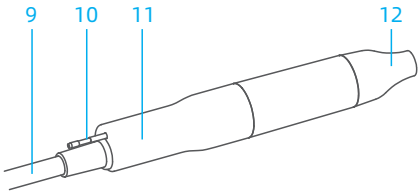
1. Irrigation hanger hole
2. Pump lid button
3. Handpiece socket
4. Touchscreen

Rear



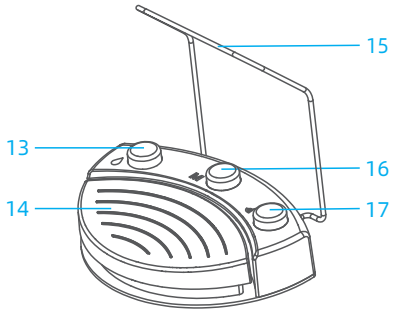
5. Power switch
6. Fuse
7. Power socket
8. Foot pedal socket

4.2 Handpiece (including handpiece cord)



9. Handpiece cord
10. Irrigation nozzle
11. Handpiece
12. Handpiece cap

4.3 Foot pedal



13. Blue: Coolant
14. Black: Operation
15. Bracket
16. Orange: Mode
17. Green: Ultrasonic power

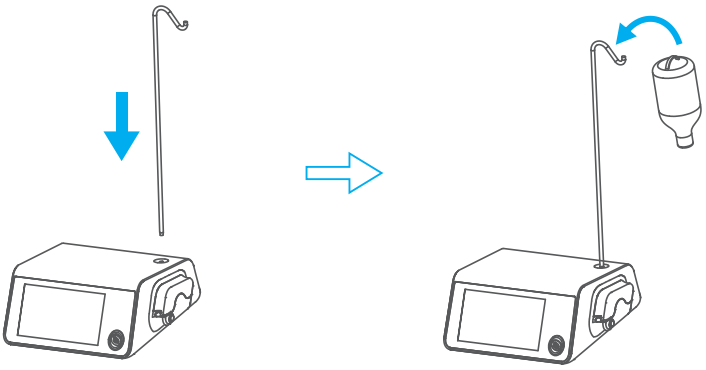
5 Installation

WARNING

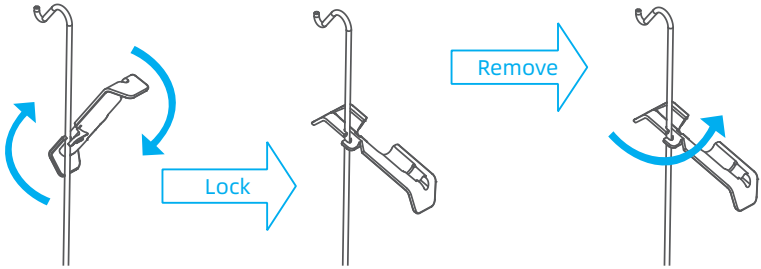
- The device cannot operate in environments where anesthetic or flammable mixtures are present;
- Install the device in a place protected against collisions or against accidental sprays of water or liquids;
- Do not install the device above or near heat sources;
- Foresee adequate air circulation around the device when installing it. Leave adequate space, especially near the fan placed on the back part of the device;
- Do not expose the device to direct sunlight or to sources of UV light;
- The device can be transported, but it must be handled with care when it is displaced;
- Control unit and power cord shall not be serviced or maintenance during normal treatment;
- Not to position the device to make it difficult to operate the disconnection device.

5.1 Irrigation hanger

Insert the irrigation hanger in the hole and hang the irrigation bottle on the hanger.

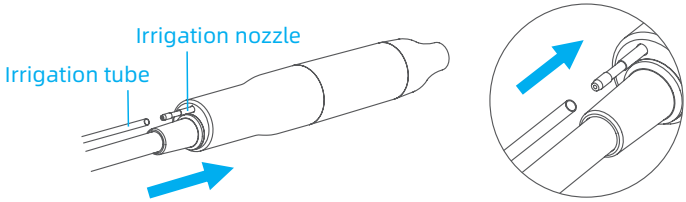


5.2 Handpiece holder



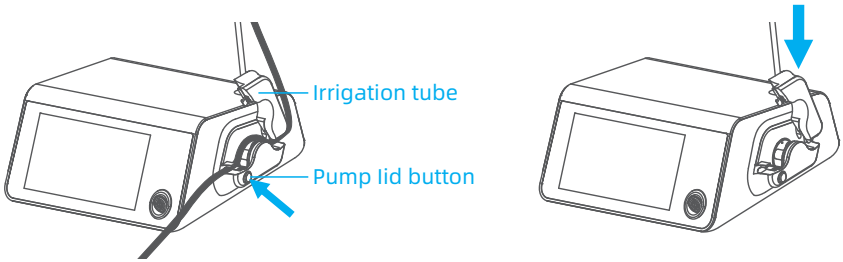
5.3 Irrigation tube

1) Connect the irrigation tube with irrigation nozzle on the handpiece;

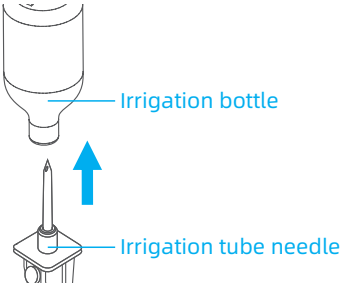


2) Press the button to open the pump lid, and position the irrigation tube in the pump;

3) Close the pump lid completely;



4) Insert the irrigation tube needle into the irrigation bottle.



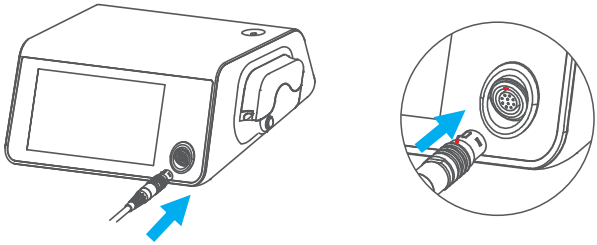
NOTE

- The Dental Ultrasonic Surgical Device is used with the irrigation bottle and irrigation tube.They need to be purchased by the user.Irrigation bottle and irrigation tube must be with the CE mark and FDA Clearance.
- The use of unqualified irrigation tube may cause abnormal installation, small cooling water, pipe explosion and other phenomena.
- Irrigation tubes are disposable and must be replaced after each use.
- Do not use the sterilized irrigation tube package if it is found to be damaged or expired.

Accessories	Specification
Irrigation bottle	Sodium Chloride 0.9%, 500mL~1000mL
Irrigation tube	Pump pipe size: L (120mm~130mm); Inner diameter: 4mm; Outer diameter: 6mm; Outlet pipe size: L 120mm, outer diameter 3mm, inner diameter 1.2mm.

5.4 Handpiece cord

Align the markers to connect the handpiece cord to the device.



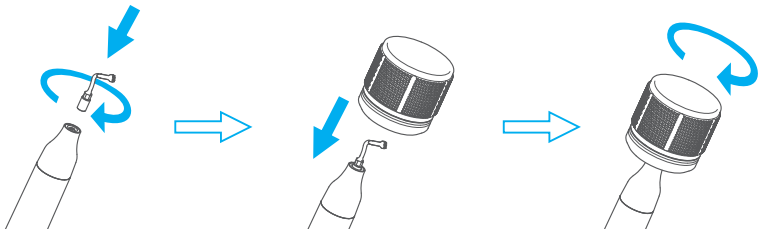
WARNING

Make sure the handpiece cord is completely dry before connecting.

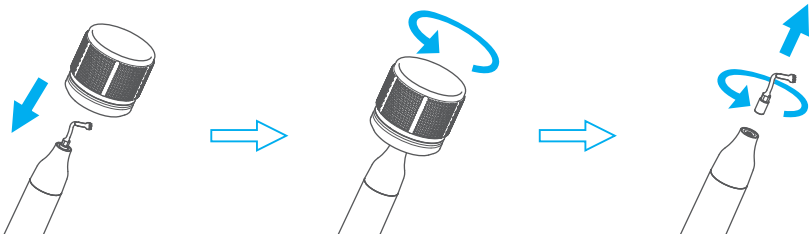
5.5 Ultrasonic Tip

Installation:

- Lightly screw the tip into the handpiece by hand;
- Then, use the torque wrench to rotate the tip clockwise until a "click" is heard and it can no longer be turned.



Disassembly: Rotate the tip counterclockwise with the torque wrench.



WARNING

- Use only the original ultrasonic tip, for detailed usage of the ultrasonic tip, please refer to the Ultrasonic Tip User Manual.
- Ultrasonic Tip can be CE certified separately, users can buy the ultrasonic tip in the market that conforms to CE certification.It is recommended to purchase CE marked product.
- Inspect the ultrasonic tip for wear and integrity before and during each use. If the titanium nitride coating is visibly worn, the tip must be replaced, as excessive wear will reduce cutting efficiency;
- Do not attempt to sharpen or bend the ultrasonic tip, as this may lead to breakage during operation or weaken the vibration;
- Do not use ultrasonic tip that are damaged, bent, or corroded;
- Always ensure that the threaded parts of the ultrasonic tip are perfectly clean and free of debris.

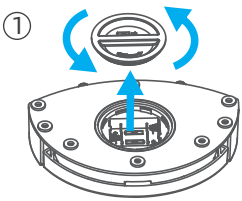
5.6 Foot pedal

This device is equipped with a wireless foot pedal and is also compatible with a wired foot pedal.

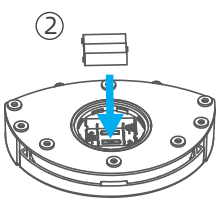
5.6.1 Wireless foot pedal

Install batteries in the wireless foot pedal before first use. The installation steps are as follows:

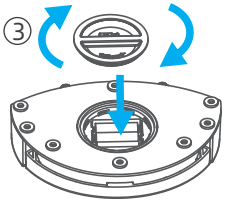
Twist the battery cover in the direction of the arrow.



Insert three AA batteries.



Turn the battery cover clockwise to tighten it.

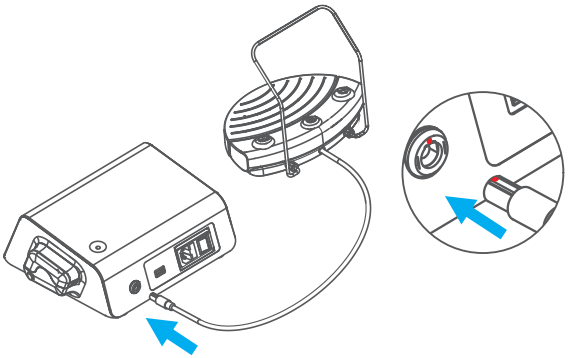


WARNING

The wireless Foot Pedal requires 3 AA batteries. Ensure correct polarity during installation. Remove the batteries if not used for a long period to prolong battery life.

5.6.2 Wired foot pedal

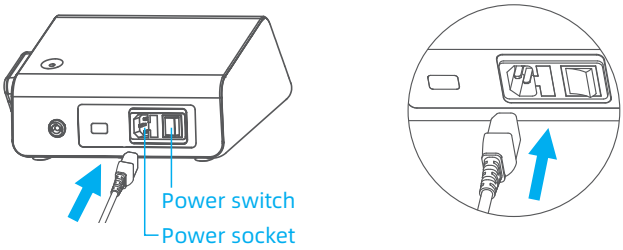
Connect the bracket to the foot pedal, and then lock the nut;
Align the marker points to connect the foot pedal with the device.



5.7 Power cord

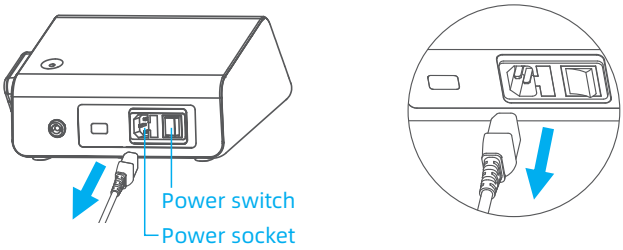
Connect Power

Connect the power cord to the device, then connect it to the net power.



Disconnect Power

Connect the power cord to the device, then connect it to the net power.

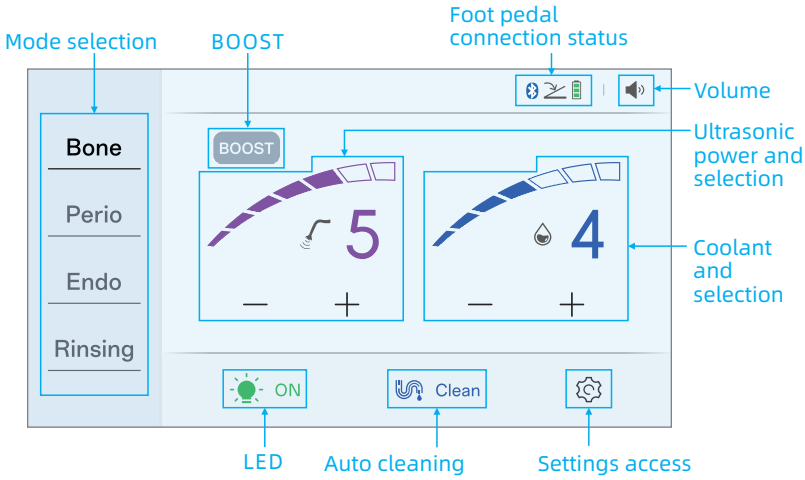


6 Use

6.1 Switching on/off

Press the power switch to turn the device on or off.

6.2 Main interface



6.3 Selection

1) The device supports four modes: BONE, PERIO, ENDO, and RINSING.
2) The mode, ultrasonic power, and coolant levels can be selected by using the touchscreen or the foot pedal.
3) The LED light can be turned on or off via the touchscreen.

NOTE

The standard ultrasonic tips are only compatible with the BONE mode.
For BONE mode, it is recommended to select the power and coolant levels for each ultrasonic tip according to the table below:

Level 1	Low bone density
Level 2-3	Uniform bone density
Level 4-5	High bone density
Level 6-7	Very high bone density
BOOST	Particularly high bone density

Both power level and coolant level can be adjusted. The recommended ultrasonic tips, power levels, and coolant level settings are listed below. (The highlighted power and coolant settings are recommended; blank entries indicate settings that are not recommended due to lower effectiveness.)

Tip model: PS1								
Mode	Coolant / Power	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PS2								
Mode	Power \ Coolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PS4								
Mode	Power \ Coolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PS5								
Mode	Power \ Coolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PL3								
Mode	Power \ Coolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PC1								
Mode	Power \ Coolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

6.3.1 Mode

Press mode button or press the button M of foot pedal to select the working mode.

6.3.2 Ultrasonic power

Press "+" / "-" buttons which aside to the symbol  or press the button  of foot pedal to select the ultrasonic power.

6.3.3 Coolant

Press "+" / "-" buttons which aside to the symbol  or press the button  of foot pedal to select the coolant.

CAUTION

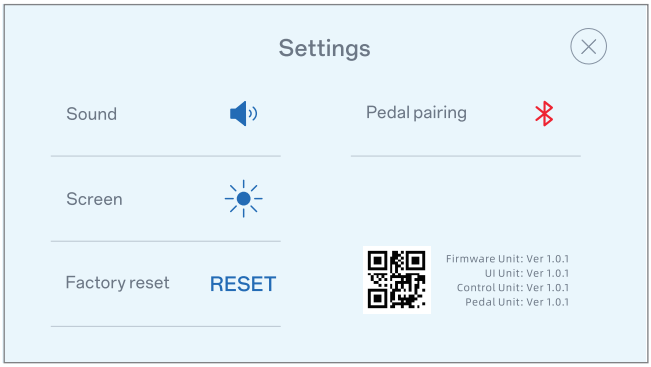
In BONE Mode, coolant cannot be turned off. The minimum setting is Level 1.

6.3.4 LED light

Press button  to switch LED light.

ON	LED light stays on permanently.
AUTO	LED light will automatically turn on when the device starts and turn off 3 seconds after the device stops running.
OFF	LED light stays off permanently.

6.4 Displayed in the settings interface



The device allows adjustment of sound and brightness settings, wireless foot pedal pairing, and factory reset.

- Tap the on the screen to enter the settings interface, and tap the to exit. "Factory reset" can reset the program parameters to the original factory values.
- Press to enter the settings screen. Then, press RESET , and all user-configured data will be cleared and cannot be recovered.

6.5 Foot pedal pairing

The status bar icon at the top of the main interface indicates the foot pedal's connection status:

	(Flashing) indicates no foot pedal is connected.
	Indicates a wired of foot pedal is connected.
	Indicates a wireless foot pedal is connected.

- Click the button and follow the on-screen instructions.
- After successful pairing, the interface will display confirmation .
- If pairing fails, follow the instructions to retry.
- To cancel the pairing, click to disconnect the foot pedal.

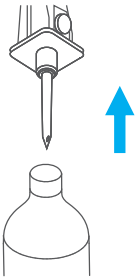
NOTE

- The wireless foot pedal must be paired before use. It is usually pre-paired at the factory.
- If not detected, check the battery and try re-pairing.
- Pairing is required again if the foot pedal is replaced.

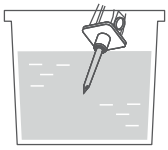
6.6 Auto cleaning

The Clean function allows to perform a cleaning cycle of the irrigation circuit. This function must be performed when you have finished using the device and before cleaning, disinfecting, and sterilizing all the parts.

1) Remove the irrigation needle from the irrigation bottle.



2) Place the irrigation needle in distilled or deionized water in an open container.



3) Start Auto-Cleaning by pressing the button Clean to start a 30-second irrigation tube cleaning cycle.

NOTE

After cleaning, take the irrigation needle out of the container and repeat this process until the water in the line is drained.

7 Cleaning, disinfection and sterilization

Device:	Control unit, Foot pedal, Irrigation hanger.
Warning:	Do not use automatic methods to clean and disinfect the Control unit, Foot pedal, Irrigation hanger. No need to sterilize the Control unit, Foot pedal, Irrigation hanger.
Surface cleaning and disinfection	It is recommended to clean and disinfect the Control unit, Foot pedal, Irrigation hanger surfaces with 75% alcohol at least once a month; • Soak the cloth in a 75% alcohol container and wring it out to remove excess water. • Wipe the surface of the control box and foot switch at least 3 times with a wet rag, paying special attention to gaps and hidden areas of activity, wipe until it is visually clean.
Device:	Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench
Warning:	Only the Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench can be cleaned and disinfected with automated methods. Only the Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench need to be sterilized with a steam sterilization process.
Advice:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function/wear of the device. There is no limit of maximum allowable reprocessing cycles. The device should no longer be reused in case of signs of material degradation.In case of damage the device should be reprocessed before sending back to the manufacturer for repair. The components should be reprocessed after each use.The following are the manufacturer's recommended processing times:

Part name	Number of time
Handpiece	100
Ultrasonic tip	100
Handpiece holder	250
Handpiece stand	250
Tip holder	250
Torque wrench	250

Reprocessing Instructions	
Preparation at the Point of Use:	Disconnect the Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench.Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding, if required.
Cleaning:	Regarding cleaning/disinfection, rinsing, and drying, a distinction should be made between manual and automated reprocessing methods. Preference is given to automated methods due to their superior standardization and industrial safety. Automated Cleaning: Use a washer-disinfector that complies with the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program: • 4 min pre-washing with cold water (<40°C) • Emptying • 5 min washing with a mild alkaline cleaner at 55°C • Emptying • 3 min neutralizing with warm water (>40°C) • Emptying • 5 min intermediate rinsing with warm water (>40°C) • Emptying If manual repetitive processing methods must be used, please verify before use.
Transportation:	Safely store the device in a humid surrounding and transport it to the reprocessing area to avoid any damage and contamination to the environment.
Pre-Cleaning:	Do a manual pre-cleaning, unitl the instrument are visually clean. Clean the surface of the Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench under running water with a soft bristol brush.
Manual Cleaning for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For US):	Recommend using 3M mutienzyme cleaning agent at a concentration of 5mL/1L distilled water. • Soak the soft cloth in detergent and wring it out. • Remove any liquid residue with a lint-free cotton cloth, then dry at 30°C. • Checked that if the devices were clean or broken after cleaning. If the cleaning is not good enough, repeat the cleaning procedure.

Automated Cleaning for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For EU):	Use a washer-disinfector meeting the requirements of the IS0 15883 series. Put the instruments into the machine on a tray and start the program. • 1 min pre-washing with cold water (<40°C) • Emptying • 10 min washing with a mild alkaline cleaner at 55°C • Emptying • 1 min rinsing • Emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr Weigert). Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Automated Disinfection for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For EU):	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.
Manual Drying for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For US):	Use compressed air to blow dry the internal pipes and external surfaces separately.
Automated Drying for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For EU):	Dry the outside of instrument through drying cycle of washer/disinfector.If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling, if required. All instruments should be checked again for dryness. After cleaning and disinfection, a thorough inspection and maintenance ensures that the instruments are fit for use. - Check that the instrument has no dents, cracks, deformations, scratches, etc; - Check all markings on the instrument for clear visibility. Discard and replace any components as necessary. Do not use the device with following defects: material deformation, cracks on the instruments, brittle or other change in the material, etc.
Packaging for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For US):	Please the sterilization bags which are approved for its efficacy by FDA. Recommended sterilization bag:SIGMA Sterilization Pouch and Roll 510(k)Number: K202462.
Packaging for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For EU):	Pack the instruments in an appropriate packaging material for sterilization.The packaging material and system refer to EN ISO11607.
Sterilization for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For US):	Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN ISO 17665) under consideration of the respective country requirements. Following sterilization parameters are commonly used: 135°C, 3 min. **Drying time:** For steam sterilization, we recommend a drying time of 16 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. **After sterilization:** Remove the product from the autoclave. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged.

Sterilization for Handpiece, Handpiece holder, Handpiece stand, Tip holder, Ultrasonic tip and Torque wrench (For EU):	Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN ISO 17665) under consideration of the respective country requirements. Following sterilization parameters are commonly used: 134 °C, 5 min (standard program in EU) **Drying time:** For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. **After sterilization:** Remove the product from the autoclave. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.
Reprocessing validation study information	The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.

Additional Instructions: None

It is the duty of the user to Make sure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

8 Maintenance

8.1 Daily maintenance

1) Check the control unit, handpiece, LED, and other components for damage before each use. If any damage is found, stop using the device immediately and contact the manufacturer or authorized dealers for assistance;

2) Wipe the surface of the instrument with clean water or disinfectant. Do not soak; Note that the instrument cannot be soaked, cleaned or disinfected;

3) Keep the control unit away from liquids during the cleaning process;

4) Disconnect the power supply before cleaning the control unit.

CAUTION

- This equipment does not contain self-maintenance parts, equipment maintenance should be carried out by the designated professionals, if the fault is not rectified, please contact the local dealer or the company;
- Must use the original parts, please contact the local dealer or the company to purchase. Do not use accessories of other brands to avoid damage to the equipment or other dangers.

8.2 Replace wireless foot pedal battery

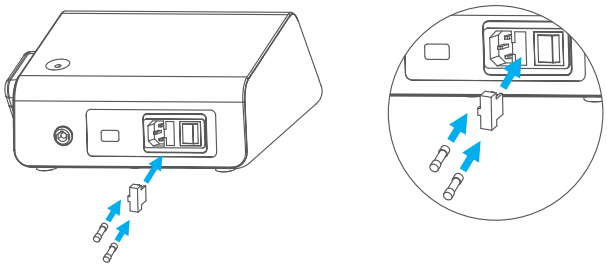
The wireless foot pedal is powered by battery power is displayed in the status bar on the screen. means the battery is low,please replace in time. (twinkle)means the battery is extremely low,please stop working immediately and replace the battery.

8.3 Replace the fuse

CAUTION

- If the device does not work, please check whether the fuse is fused;
- Turn off the power switch before replacing the fuse, and disconnect the power cord from the net power.

Use tools (such as screwdriver) to pry out the fuse and replace it;

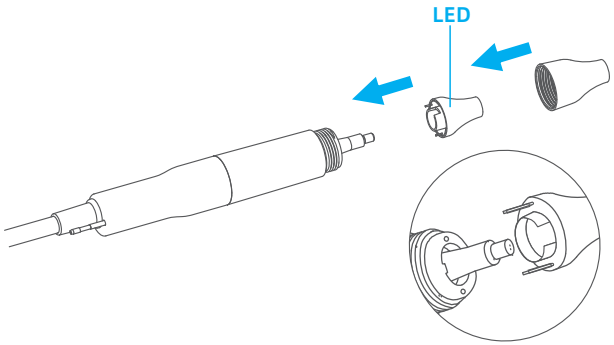


8.4 Replace LED

CAUTION

- Heated LED may cause burns;
- Do not touch the LED immediately after use; allow them to cool down before handling.

1) Turn the handpiece cap counterclockwise;
2) Pull out the LED, replace it and tighten the handpiece cap;



9 Troubleshooting

If the device is not functioning properly, please refer to the following:

Issue	Possible Cause	Solution
No display on the screen when the power switch is turned on	Power cord is not properly connected to the socket	Check and secure the power cord connection
	Faulty power cord	Check the power output; replace the cord if necessary
	Blown fuse	Replace the fuse
Power is on but the device does not work, and no error is displayed	Wired foot pedal connector is not properly plugged in	Ensure the foot pedal is properly connected
	Foot pedal malfunction	Contact your local distributor
Sharp noise from the handpiece during operation	Ultrasonic tip is not correctly installed on the handpiece	Remove and reinstall the ultrasonic tip securely
Error E1 displayed	Internal short circuit in the handpiece	Ensure the handpiece is dry; if the issue persists, replace the handpiece
	Handpiece overheating	
	Moisture inside the handpiece	
Error E2 displayed	Ultrasonic tip is not tightly fastened	Tighten the ultrasonic tip; if issue persists, replace the ultrasonic tip
	Worn or deformed ultrasonic tip	

Error E3 displayed	Handpiece not properly connected to the device	Check and secure the connection; replace handpiece if needed
Error E4 displayed	Internal connection fault in the device	Internal connection fault in the device. Please contact your local distributor for repair
No liquid is coming out from the ultrasonic tip during operation	The selected ultrasonic tip model does not have a water outlet	Use a ultrasonic tip model with a water outlet
	Liquid has run out	Replace with a new liquid pack
	The pump cover of the irrigation tube is open	Close the pump cover
	Irrigation tube are not properly installed	Check the connection of the irrigation tube
	Ultrasonic is clogged	Clean the water channel of the ultrasonic tip
	Handpiece is clogged	Contact your local distributor
Device operates, but peristaltic pump is being compressed	Excessive pressure on the pump rotor	Check that the pump tubing is installed correctly
Liquid leaks from handpiece after pump stops	Pump cover is not tightly closed	Ensure the pump cover is securely closed
Insufficient power	Ultrasonic tip is not properly installed	Remove and securely fasten the ultrasonic tip to the handpiece
	Ultrasonic tip is aged, damaged, or deformed	Replace the ultrasonic tip

If the method in the above table still fails to solve the problem, please contact the dealer for assistance.

10 Technical specifications

Power supply voltage	100-240V~ 50/60Hz
Operation mode	Duty cycle: Max. 60s on / Min. 10s off
Fuses	F3.15AL 250V 5*20mm
Radial amplitude	20-200μm
Transeverse amplitude	< 10μm
Frequency	24kHz - 36kHz
Coolant flow rate	0-100 mL/min
Degree of protection	IPX1(Control unit) IPX7(Foot pedal)
Application part	Handpiece and Ultrasonic tip
Classification of protection against electric shock	Class I
Protection against electric shock	Type B applied part
Types of system frequency control	Continuous and automatic adjustment of excitation frequency
operating environment	Ambient temperature range: +5℃ - +35℃ Relative temperature range: 20%RH - 80%RH Atmospheric pressure range: 80kPa - 106kPa Water temperature of water-cooled device inlet, not higher than 25℃
Storage environment	Ambient temperature range: -10℃ - +55℃ Relative temperature range: ≦93%RH Atmospheric pressure range: 80kPa - 106kPa
ALT	≥2000m
Overvoltage category	Class II
Pollution degree	Degree 2

Illumination(LED)

Light source type	LED
Color temperature	6000K
Rated Voltage	d.c.12V
Voltage range	DC 11V - 14V
Maximum current	100 mA

11 Recycling and disposal

The device and its packaging are designed to be as environmentally friendly as possible.

In accordance with the principles, standards, and requirements of the country (region) in which you are located. When disposing of the old electrical instrument ensure that pollution is not produced in the process of waste disposal.

12 After-sales service

1) The device has a service life of 15 years. The production date is shown on the product label.The recommended number of repeated sterilization use of this product is 100 times.
2) From the date of purchase, with a valid warranty card:
   - The Control Unit is covered by a 2-year warranty and lifetime maintenance.
   - The Handpiece is covered by a 1-year warranty.
3) Damage caused by unauthorized repair is not covered under warranty.
4) Upon request, the supplier can provide circuit diagrams, component lists, schematics, calibration procedures, or other technical documentation needed for qualified personnel to repair designated components.

13 Symbols

	General Warning		Caution
	Refer to instruction manual/booklet		Note
	Type B applied part		Alternating current
	Thermo disinfectable	IPX7	Temporary immersion waterproof
	Sterilizable in a steam sterilizer (autoclave) at the 134° C		Do not dispose of the product into the ordinary municipal waste or garbage system
	Keep dry		This way up
	Fragile, handle with care		Stacking limit by number
	Do not walk or stand here		Foot pedal
SN	Serial Number	UDI	Unique device identifier
LOT	Batch code		Protective earth; protective ground
	“ON” (power)		“OFF” (power)
REF	Catalogue number		Manufacturer
CE 0197	CE Marking		Date of Manufacture
EU REP	Authorized representative in the European Community /European Union	MD	Medical device

14 Guidance and manufacturer's declaration

This instrument needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this instrument can be affected by portable and mobile RF communications instrument.

CAUTION

- Do not use a mobile phone or other instruments that emit electromagnetic fields, near the instrument. This may result in incorrect operation of the instrument.
- This instrument has been thoroughly tested and inspected to assure proper performance and operation!
- This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.

Number	Name	Length(m)	Shielding
1	Power cord	1.5	NO
2	Foot pedal line	1.8	NO
3	Handpiece cord	1.8	NO

Guidance and manufacture's declaration – electromagnetic emission

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions **CISPR 11**	Group 1	The instrument use RF energy only for its internal function. 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 instrument is suitable for use in all establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.
Harmonic emissions **IEC 61000-3-2**	Class A	
Voltage fluctuations / flicker emissions **IEC 61000-3-3**	Complies	

Guidance and manufacture's declaration – electromagnetic emission

The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of instrument 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**	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst **IEC 61000-4-4**	±2kV for power supply lines ±1 kV for Input/ output lines	±2kV for power supply lines ±1 kV for Input/ output lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge **IEC 61000-4-5**	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2 kV common mode	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ± 2 kV common mode	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**	100% U_T (100% dip in U_T) for 0.5 cycle 100% U_T (100% dip in U_T) for 1 cycle 30% U_T (70% dip in U_T) for 25/30 cycles 100% U_T (100% dip in U_T) for 250/300 cycle	100 % U_T (100% dip in U_T) for 0.5 cycle 100 % U_T (100% dip in U_T) for 1 cycle 30 % U_T (70% dip in U_T) for 25/30 cycles 100 % U_T (100% dip in U_T) for 250/300 cycle	Mains power quality should be that of atypical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that device be powered from a unit eruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field **IEC 61000-4-8**	3A/m	3A/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 a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF **IEC61000-4-6**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3V/m 80 MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF **IEC 61000-4-3**	385MHz - 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9of IEC 60601-1-2:2014)	385MHz - 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC60601-1-2:2014)	**Recommended separation distance:** $d= 1.2\times P^{1/2}$ $d= 1.2\times P^{1/2}$ 80 MHz to 800MHz $d= 2.3\times P^{1/2}$ 800 MHz to 2.5GHz where 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: 

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 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 instrument is used exceeds the applicable RF compliance level above, the instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the instrument.

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

Recommended separation distances between portable and mobile RF communications equipment and the instrument.

The instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the instrument 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 $d= 1.2\times p^{1/2}$	80 MHz to 800 MHz $d= 1.2\times P^{1/2}$	80 MHz to 800 MHz $d= 2.3\times P^{1/2}$
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 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.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: 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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