COXO®

Dental Ultrasonic Surgical Device

User Manual



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EU REP **Lotus NL B.V.**

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C-EXPLORER

CE 0197

			electromagnetic site survey should be less than the compliance level in each frequency range 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.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

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 COXO 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.

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

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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 inU_T) for 25/30 cycles 100% U_T (100% dip in UT)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 inU_T .)for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the instrument requires continued operation during power mains interruptions, it is recommended that the instrument 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to table 9of IEC 60601-1-2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7GHz 385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to table 9 of IEC60601-1-2:204)	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. Recommended separation distance $d=1.2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=1.2\times P^{1/2}$ 800 MHz to 2,5 GHz 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

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.

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.		
Emission 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 emission 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 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**
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.

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 andappropriately 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 Hadpiece, 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.

2. Intended use

Dentistry and oral surgery (implant site preparation, bone cutting, maxillary sinus floor (mucus membrane) elevation, osteoplasty, bone resection in radectomy, periodontal operation, prosthesis maintenance, surgical endodontic procedure.

3. 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.

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) Press the button (i) to inquire about the device information;
2) Please refer to the product label for manufacturing information;
3) The service life of this device is 10 years;
4) The Control unit and Pedal are guaranteed for 2 years from the date of purchase, and the Handpiece (including pipeline) are guaranteed for 1 year;
5) The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void.

13. Symbols

	Warning/Caution		Consult instructions for use.
	Type B applied part		Alternating current
	Autoclave	SN	Serial number
	Indoor use		Special disposal of waste electrical and electronic equipment
IPX6	Continuous immersion waterproof		Protective ground
	Recyclable packaging materials		Vertical up
	Fragile		Keep dry
	Stacking restriction		No trampling
CE 0197	CE Marking		

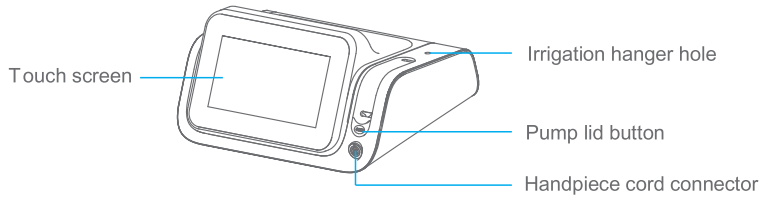
10. Technical specifications

Power supply voltage	100-240V~ 50/60Hz 150VA
Operation mode	Run intermittently, work for 60 seconds and stop for 10 seconds.
Fuses	2×3.15AT 250V
Frequency	24kHz - 36kHz
Pump capacity	0 - 100 mL/min
Degree of protection	IPX1 (Control Unit) IPX7 (Pedal)
Application part	Handpiece and Dental Ultrasonic Surgical Device handpiece 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℃-+40℃ Relative temperature range: 20%RH -80%RH Atmospheric pressure range: 86kPa-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: 50kPa-106kPa

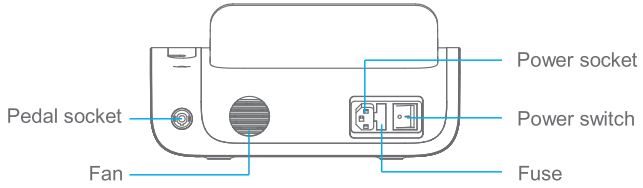
4. Description

4.1 Control unit

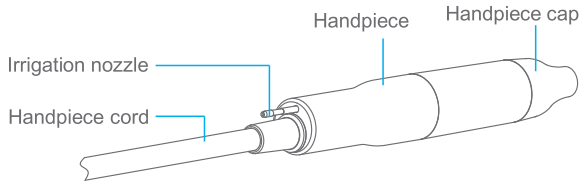
Front



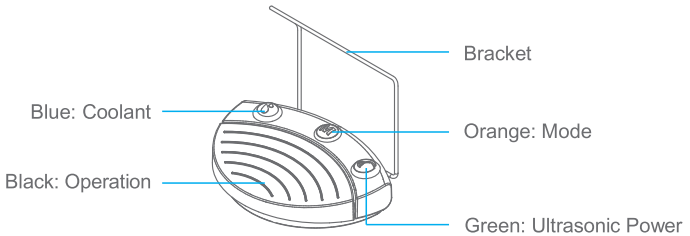
Rear



4.2 Handpiece (including Handpiece cord)



4.3 Pedal



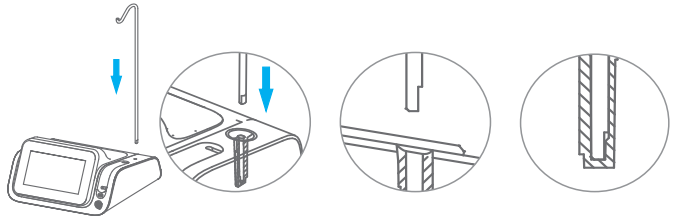
5. Installation

⚠ WARNING:

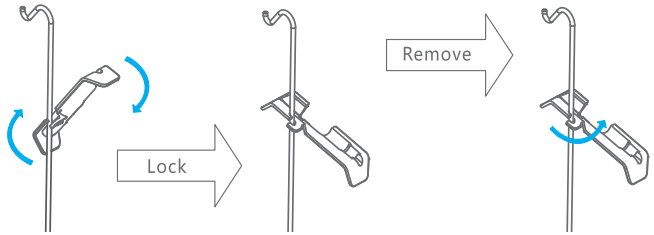
- The device cannot operate in environments where anesthetic or flammable mixtures are present;
- Install the device in a place protected against collisions or against accidentalsprays of water or liquids;
- Do not install the device above or near heat sources;
- Foresee adequate air circulation around 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.

➢ Irrigation Hanger

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



➢ Handpiece Holder



➢ Irrigation Tube

1) Connect the Irrigation tube with Irrigation nozzle on the handpiece;
2) Press the "OPEN" button and open the pump lid;
3) Position the Irrigation tube in the pump;
4) Close the pump lid completely;
5) Insert the Irrigation tube needle into the Irrigation bottle.

9. Troubleshooting

Malfunction	Cause	Solution
Error E1	Excessive Dental Ultrasonic Surgical Device Handpiece Tip load	After the load is removed, restart.
	Handpiece overheating	When the Handpiece is cooled, restart.
	Handpiece failure	Contact the dealer.
	Control Unit failure	Contact the dealer.
Error E2	Dental Ultrasonic Surgical Device Handpiece Tip is not tightened.	Check and try again.
	Dental Ultrasonic Surgical Device Handpiece Tip broken, worn-out, or deformed	Replace the Dental Ultrasonic Surgical Device Handpiece Tip with a new one.
	Handpiece failure	Contact the dealer.
Error E3	Handpiece is not connected.	Connect the Handpiece.
	Handpiece failure	Contact the dealer.

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

8. Maintenance

8.1 Daily maintenance

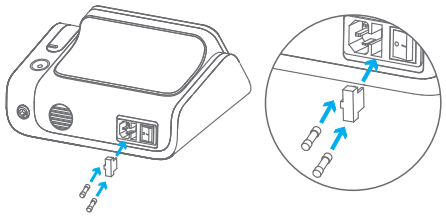
1) Check whether control unit, Handpiece, LED and other parts are damaged before each use. If so, please stop using it immediately and contact our company or authorized dealers for help;
2) Wipe instrument surface with clean water or disinfectant, do not soak.
3) During cleaning process, keep the control unit from liquid;
4) Disconnect the power when cleaning control unit.

8.2 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;

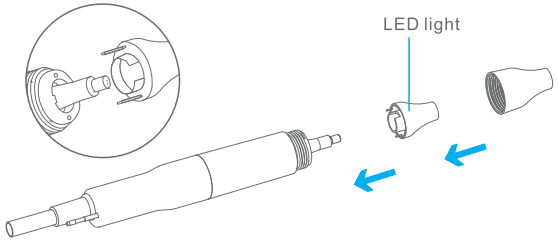


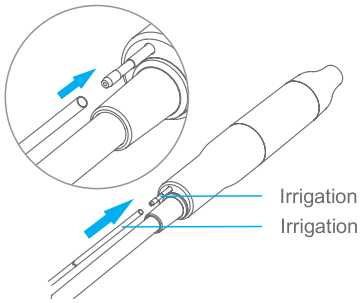
8.3 Replace LED Light

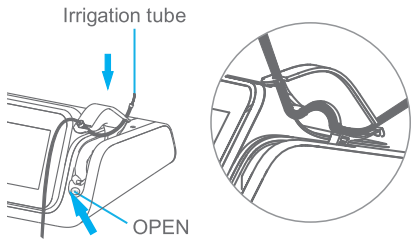
⚠ CAUTION:

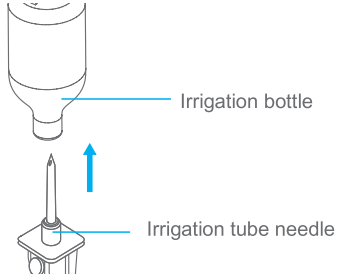
- Heated lamp beads may cause burning;
- Do not touch the lamp beads after work, but allow them to cool down.

1) Turn the Handpiece cap counterclockwise;
2) Pull out the lamp bead, replace it and tighten the Handpiece cap;







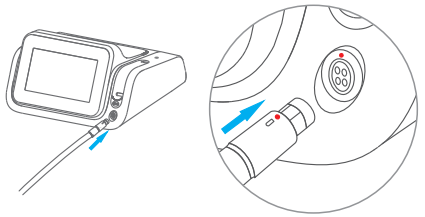


⚠ WARNING:

- The irrigation tube and bottles mentioned above need to be purchased separately. It is recommended to purchase the ones which registered by the Food and Drug Administration.
- Irrigation tubes are disposable and must be replaced after each use.

➢ Handpiece Cord

Align the marker points to connect the Handpiece cord with the device.



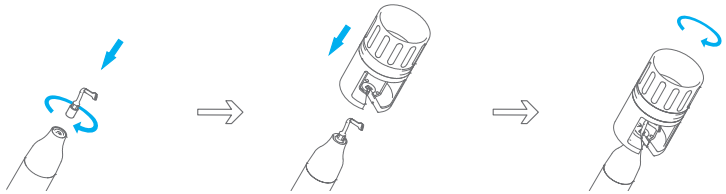
⚠ WARNING:

Make sure the handpiece cord is completely dry before connecting.

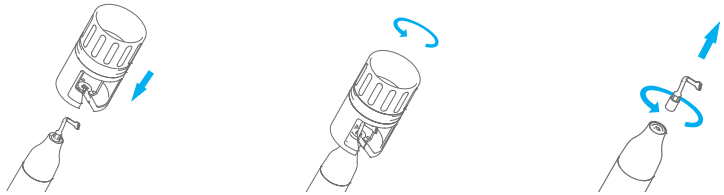
➢ Dental Ultrasonic Surgical Device Handpiece Tip

Installation:

- lightly screw in the Tip by hand;
- Rotate the Tip clockwise with the torque wrench until it makes a click sound and cannot rotate any further.



Disassembly: Rotate the Tip counterclockwise with the torque wrench.



⚠ WARNING:

- Use the original Dental Ultrasonic Surgical Device Handpiece Tip only;
- Check the condition of wear of the Tip and that it is intact before and during every use. When the titanium nitride coating is visibly worn out, the insert must be replaced. Use of an overly worn out insert reduces its cutting efficiency;
- Do not attempt to sharpen or bend the Tip as this may cause the Tip to break during operation, or the vibration may be weakened;
- Do not use a Tip which has been damaged, bent or corroded;
- Always check that the threaded parts of the Tip are perfectly clean.

	Use a washer-disinfector meeting the requirements of 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.
Disinfection:	Automated Disinfection: 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 instrument to achieve an A0 value of 3000.
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion Maintenance is not required. Instruments oil must not be used
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to GB/T 19633.
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 13060) under consideration of the respective country requirements. Minimal requirements: 3 min at 134 °C. In EU, 5 min at 134 °C is required. Maximal sterilization temperature: 137°C. • Flash sterilization is not allowed on lumen instruments. • Sterilisable times: 100.
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 ensure 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.	

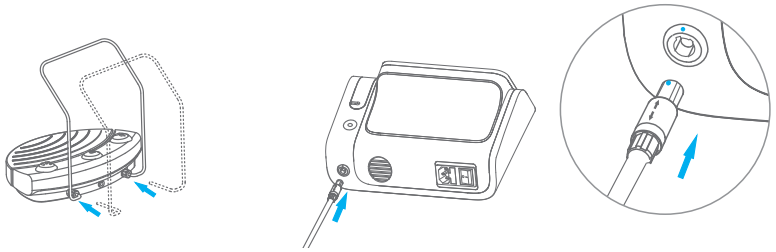
7. Cleaning, disinfection and sterilization

Instrument:	Control unit, Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip, Handpiece holder, Handpiece stand and Irrigation hanger. The procedure for cleaning, disinfection and sterilization applies only to Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip , Handpiece holder, Handpiece stand and Irrigation hanger.
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 instrument. There is no limit of maximum allowable reprocessing cycles. The instrument should no longer be reused in case of signs of material degradation. In case of damage the instrument should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use:	Remove Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip, Handpiece holder, Handpiece standand Irrigation hanger. 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.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The instruments must be reprocessed in a disassembled state. Only Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip, Handpiece holder, Handpiece stand and Irrigation hanger can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize Control unit. The Control unit cannot be cleaned and disinfected in a washer/disinfector. For these parts, only general wipe decontamination is possible!
Decontamination of other parts than Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip, Handpiece holder, Handpiece stand and Irrigation hanger:	After operation, take out Control unit on the workbench Soak a soft cloth completely with distilled water or deionized water, decontamination and wipe all the surfaces of these components, until the surface of the parts the components are visually clean. For decontamination, soak a dry soft cloth with 75% alcohol wipe all surfaces of Control unit with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectant swipe the surface of the component with a dry soft lint-free cloth.
Pre-Cleaning:	Following instruction is only relevant for Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip, Handpiece holder, Handpiece stand and Irrigation hanger. Not use automated cleaning, disinfection and sterilization for other parts than Handpiece, Dental Ultrasonic Surgical Device Handpiece Tip, Handpiece holder, Handpiece standand Irrigation hanger in this system! Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surface with a soft Bristol brush.
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning:

➢ Pedal

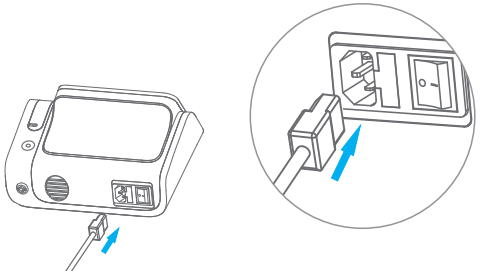
Connect the bracket to the pedal, and then lock the nut;

Align the marker points to connect the pedal with the device.



➢ Power Cord

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

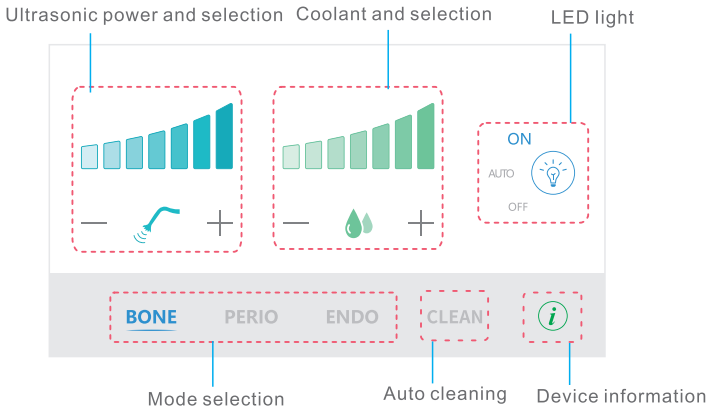


6. Use

6.1 Switching on

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

6.2 Main Interface



6.3 Selection

1) The device contains 3 modes: BONE, PERIO and ENDO.
2) Mode, Ultrasonic power and coolant can be selected by touching the screen or pressing pedal.
3) LED light can be selected by touching the screen.

6.3.1 Mode

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

6.3.2 Ultrasonic Power

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

NOTE:
For BONE, it is recommended to select thelevel according to the following table:

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

6.3.3 Coolant

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

CAUTION:
Treatment without coolant is possible only with the ENDO and PERIO functions, setting the coolant level on “0”.

6.3.4 LED light

Press button to switch LED light.

ON AUTO OFF	LED light stays on permanently.
ON AUTO OFF	LED light is switched on by pressing the pedal, and automatically switches off 3 seconds after the pedal is released.
ON AUTO OFF	LED light stays off permanently.

6.4 Working

Press the pedal to start working, and release to stop.

NOTE:
Mode, Ultrasonic power and coolant buttons are not available in the work, except for LED light.

6.5 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) Place the Tip of the Handpiece into the water.
4) Start Auto Cleaning by pressing the button CLEAN and pressing the pedal.
5) It can be stopped anytime by releasing pedal.

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