

COXO®

潘国慧
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COXO®

C-EXPLORER
SG

USER MANUAL

Dental Ultrasonic Surgical Device  0197



User Manual Ver: 1.1
UI unit Ver:1.0
Control unit Ver:1.0
User Manual No.: AE1498
Revision Date: 2026.03.27

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 $d = 1.2 \times P^{1/2}$	800 MHz to 2.5 GHz $d = 2.3 \times P^{1/2}$
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.			

Contents

1. Safety 1

2. Intended Use 2

3. Contraindication 2

4. Product Configuration 3

5. Product Description 4

6. Installation 5

7. Screen Overview 10

8. Use 12

9. Settings 19

10. Maintenance 21

11. Cleaning, Disinfection and Sterilization 24

12. Troubleshooting 26

13. After-sales Service 28

14. Operating, Transportation and Storage Conditions 28

15. Technical Specifications 29

16. Declared Output Characteristics 30

17. Symbols 31

18. Recycling and Disposal 31

19. EMC 32

Before operating, maintaining, or servicing the device, read this manual thoroughly and retain it for future reference.

The manufacturer reserves the right to update or modify this manual and the related product without prior notice.

This device has a service life of 10 years. The production date can be determined from the batch number.

In the event of a serious adverse event, please report to the manufacturer and the competent authority of the member state immediately.



WARNINGS:

- 1) Using unapproved accessories or making unauthorized modifications may result in personal injury or property damage.
- 2) Only use accessories approved by the manufacturer.
- 3) Do not use product in areas subject to an explosion hazard.
- 4) Do not operate the product in an oxygen - enriched atmosphere.
- 5) To prevent electric shock, use an electrical outlet that is grounded.
- 6) The power plug serves as the main disconnection device. It must remain easily accessible at all times.
- 7) Do not service the control unit or power cord during patient treatment.
- 8) Do not position the device in a way that makes it difficult to operate the disconnection device.
- 9) A damaged power cord or a missing ground wire may cause electric shock. Inspect the power cord before use. The socket must have a grounding contact and comply with national safety regulations.
- 10) Ensure the power supply is functioning correctly. A power failure or voltage fluctuation may cause the surgical motor to stop unexpectedly.
- 11) The user must ensure that the device works properly and is in satisfactory condition before each use.
- 12) Check the coolant containers and lines for absence of leakage.
- 13) If any liquid is detected on the device, do not touch the device and disconnect the device from the mains supply without delay.
- 14) Protect openings of the product from any ingress of liquids. Failure to do so can cause failure of electronic components.
- 15) Do not stick anything in the pump.
- 16) Turn off the device before opening the peristaltic pump. Contact with rotating parts may cause injury.
- 17) After each use, maintain all reusable components according to the instructions.
- 18) The product must be cleaned and serviced according to instructions if it is not to be used for an extended period of time.
- 19) Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers). Before treatment, confirm whether the patient has a cardiac pacemaker or other implanted electronic device.
- 20) If the device exhibits serious malfunction due to improper use or physical damage, stop using it immediately and turn off the power.
- 21) The device operation mode is non-continuous operation. It is recommended to work for 60 sec and stop for 10min.
- 22) Do not remove the motor cable from motor.
- 23) Do not use worn or deformed tips. Do not operate the device when replacing tips.
- 24) After autoclaving the Ultrasonic Handpiece, allow it to cool completely before use.
- 25) Do not perform treatment on metal or ceramic restorations. Ultrasonic vibrations may cause such restorations to break apart.

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 800 MHz $d= 2.3 \times P^{1/2}$ 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 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.			

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.
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.			

02 / 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.

This product is intended for use only by qualified dental surgeons in hospitals or dental clinics.

03 / Contraindication

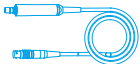
Do not use this device on patients who meet any of the following conditions:

- Patients with hemophilia.
- Patients with pacemakers (or other implanted electronic devices) unless advised otherwise by a physician.
- Patients with heart disease or young children (use with caution).
- Patients with osteoporosis.
- Patients with oral or facial infections, untreated oral mucosal diseases, apical periodontitis, gingivitis, periodontitis, or oral tumors.
- Patients with systemic diseases (e.g., tumors, severe cardiovascular diseases, hematologic disorders, or immune system diseases.)
- Patients with allergies to certain materials or drugs.
- Patients undergoing certain systemic or head and neck therapies (e.g., immunotherapy, chemotherapy, or radiotherapy).
- Patients with mental disorders (use with caution).
- Pregnant or breastfeeding women, and women of childbearing age planning pregnancy (use with caution).

For details of accessories, please refer to the packing list.



Control Unit



Motor Handpiece
(with Motor Cable)



Ultrasonic Handpiece
(with Handpiece Cable)



Foot pedal



Tips



Tip holder



Power Cord



Torque wrench



Fuse



Ultrasonic
Handpiece LED light



Sterilization case



Tube holder



Bracket



Irrigation Hanger



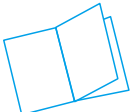
Handpiece Stands



Protective plug



Tube Holder



Instructions for use



Note

- The device meet the EMC requirements of IEC 60601-1-2 standard.
- This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this device can be affected by portable and mobile RF communications device.



WARNINGS:

- The device should not be used in close proximity to or stacked with other device. If they must be used in close proximity or stacked, they should be observed to verify that they work properly in the configuration they are used in.
- Use of accessories and cables other than those sold by the device manufacturers as spare parts for internal components may result in increased the device emissions or reduced immunity.
- Portable and mobile RF communication devices may affect the device performance. Avoid strong electromagnetic interference when used, e.g. near cell phones, microwave ovens, etc.
- Do not use the device in MRI, CT, operating theatres where HF surgical equipment is present, etc.

Number	Name	Length(m)	Shielding
1	Power cord	1.5	NO
2	Motor cable	2.2	NO
3	Ultrasonic Handpiece cable	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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

	Warning		Note
	Caution		Keep dry
	Serial number		Refer to instruction manual/booklet
	Authorized representative in the European Community/European Union		Do not dispose of the product into the ordinary municipal waste or garbage system
	Importer		Do not step on
	Type B applied part		Fragile, handle with care
	Thermoisinfectable		This way up
	Sterilizable in a steam sterilizer (autoclave) at the 134° C		Catalogue number
	Date of Manufacture		Manufacturer
	General symbol for recovery / recyclable		CE Marking
	Batch code		Medical device
	Temporary immersion waterproof		Protective earth
	Alternating current		Foot pedal
	Unique device identifier		Electric fuse
	Stacking limit by number		Power Off
	Power On		

18 / Recycling and Disposal

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

 Ensure that the parts are not contaminated on disposal.

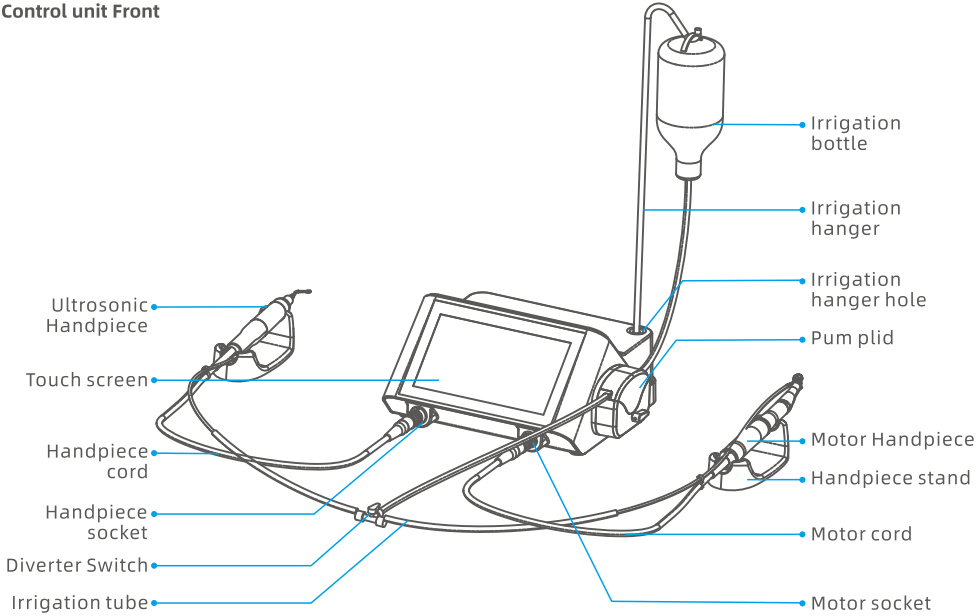
Follow your local and country specific laws, directives, standards and guidelines for disposal.

Medical device

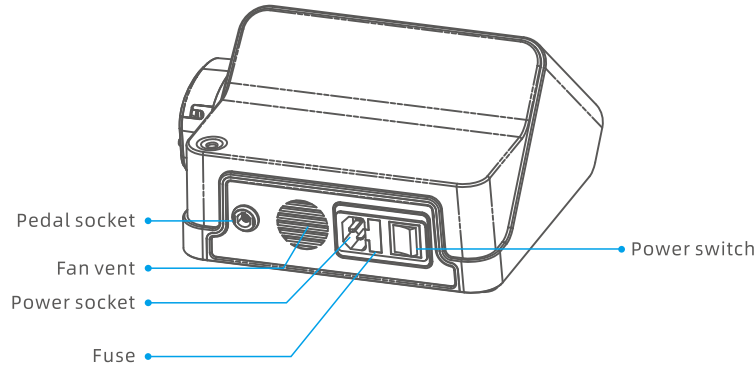
Waste electrical equipment

Packaging

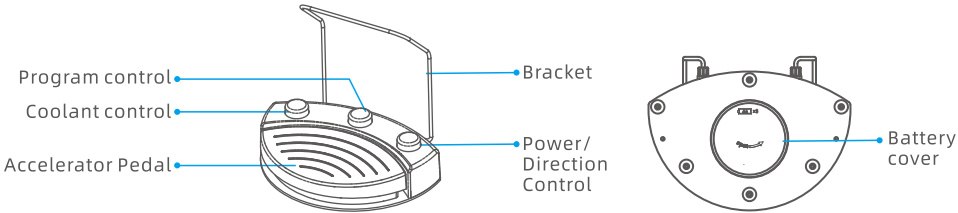
Control unit Front



Rear



Foot pedal (Wireless)



Note

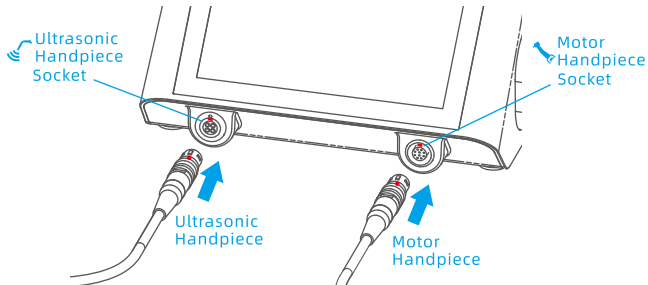
Except for the disposable irrigation tube, all components are supplied nonsterile and transported under nonsterile conditions. Prior to first use, the motor and motor cable, as well as the Ultrasonic Handpiece and Handpiece cable, must be sterilized.

Warning

- Do not operate the device in environments containing explosive gases (e.g., anesthetic gases).
- Do not install the device in locations where it may be exposed to impact or liquid splashes.
- Do not install the device above or near heat sources, ensure installation in a well-ventilated area.
- Do not expose the device to direct sunlight or UV light.
- Handle the device with care to avoid dropping or damaging the device or its components.

6.1 Ultrasonic Handpiece and Motor Handpiece

Align the marking on the handpiece plug with the marking on the main unit socket, and insert the plug smoothly until a “click” is heard. Confirm that the connection is secure.

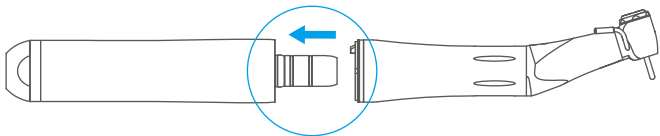


Warning

Make sure the handpiece cord is completely dry before connecting.

6.2 Straight or Contra-angle Handpiece

- The motor can be adapted to all the dental handpiece with interfaces conforming to ISO 3964.
- 1) Attach the handpiece to the motor until the pressing sound indicates that the connection is in place.
 - 2) Rotate the handpiece to make sure that it is connected firmly.



Tip Peak Amplitude (μm)	The peak displacement at the tip of the treatment head in the direction of maximum amplitude. The measurement point shall be within 1 mm from the free end of the tip.	Tip Model	Value (μm)	Power Setting: Level 7
		PS1	60	
		PS2	38	
		PS4	40	
		PS5	34	
		PL3	56	
Excitation Frequency (kHz)	The average frequency of the excitation voltage or current.	Tip Model	Value (kHz)	Power Setting: Level 7
		PS1	30	
		PS2	30	
		PS4	30	
		PS5	30	
		PL3	30	
Derived Acoustic Output Power (mW)	The acoustic power emitted from the tip of the treatment head into water, measured by the hydrophone method.	Tip Model	Value (mW)	Power Setting: Level 7
		PS1	300-2500	
		PS2	300-2500	
		PS4	300-2500	
		PS5	300-2500	
		PL3	300-2500	
Effective Radiating Area (mm²)	The projected solid area at the tip of the treatment head in the direction of vibration amplitude.	Tip Model	Value (mm²)	Power Setting: Level 7
		PS1	3	
		PS2	3	
		PS4	4	
		PS5	4	
		PL3	3	
Power Reserve Index	The ratio of maximum electric power to static (no-load) electric power.	Tip Model	Value	Power Setting: Level 7
		PS1	8	
		PS2	6	
		PS4	6	
		PS5	5.5	
		PL3	5.5	
		PC1	7	

Control unit	
Power Input	100V-240V~ 50Hz/60Hz
Input Power	180VA
Operating mode	Duty cycle: Max.T_ON: 60s, Min.T_OFF: 10s
Fuses	F3.15AT 250V
Coolant flow	20-100ml/min
Classified of protection against Electric Shock	Class I
Protection against electric shock	Type B application section
Degree of Protection(IEC 60529)	IPX0(Control unit) IPX7(Foot Pedal)
Classified by security	Non-AP/APG
Overvoltage category	Class II
Pollution degree	Degree 2
Applied part	Handpiece,Ultrasonic Tip

Ultrasonic Handpiece	
Radial amplitude	<200um
Tranverse amplitude	<30um
Frequency	30±15%kHz
Ultrasonic handpiece cable length	1.8m

Motor Handpiece	
Speed range	300r/min~44000r/min(1:1)
Maximum torque(20:1)	5N·cm~80 N·cm(20:1)
Motor Coupling Type	Complies with ISO 3964
Motor cable length	2.2m

Illumination (LED)	
Type of radiation	LED
Typical color temperature	6,000 K
Rated Voltage of Motor Handpiece LED	d.c.3.3 V
Voltage range of Motor Handpiece LED	2.8 - 3.6 V DC
Rated Voltage of Ultrasonic Handpiece LED	d.c.8.4V
Voltage range of Ultrasonic Handpiece LED	DC 7.8 - 9.0V
Maximal current	100 mA

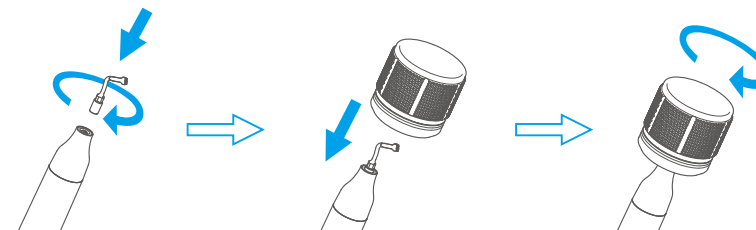
Warning

Changing the handpiece during operation may damage the motor and the handpiece.

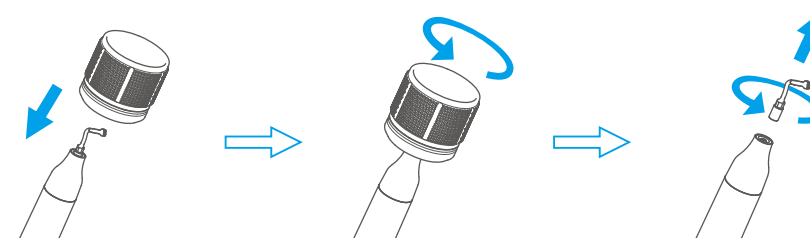
6.3 Ultrasonic Tip

Installation:

- Select the required Ultrasonic Tip and screw it into the Ultrasonic Handpiece.
- 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 Ultrasonic Tip counterclockwise with the Torque wrench.



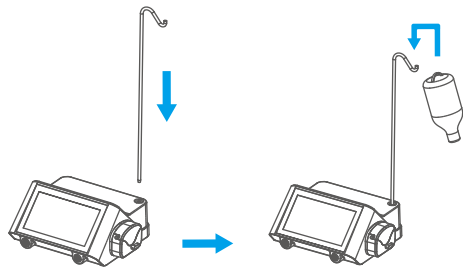
Warning

- 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 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 Tip, as this may lead to breakage during operation or weaken the vibration.
- Do not use Tip that are damaged, bent, or corroded.
- Always ensure that the threaded parts of the Tip are perfectly clean and free of debris.

6.4 Connecting the Irrigation System

Installing the Pole and Irrigation Bottle

Insert the irrigation hanger into the hole and hang the irrigation bottle/bag on the hanger.

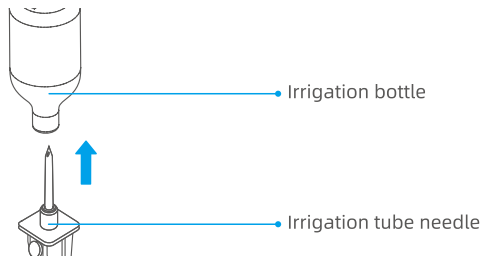


Warning

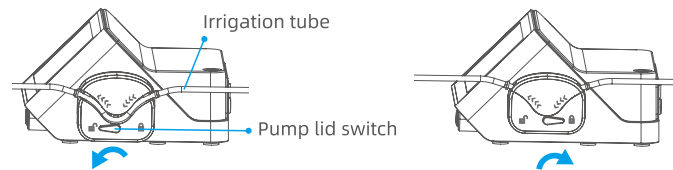
- Use irrigation bottle with a maximal volume of 1.5L only.
- Check the stability of the hanger and the saline bottle/bag.

Installing the Disposable Irrigation Tube

- 1) Insert the Irrigation tube needle into the Irrigation bottle.



- 2) Rotate the pump lid switch counterclockwise to open the pump lid, and correctly install the irrigation tube into the slot of the peristaltic pump.
- 3) Rotate the pump lid switch clockwise to ensure the pump lid is fully closed.



Note

- The disposable irrigation tube and irrigation bottle must be purchased separately. Users can buy only the disposable irrigation tube and irrigation bottle in the market that conforms to CE certification.
Recommended temperature of peristaltic pump tubing: 4 mm inner diameter, 6 mm outer diameter, at least 140 mm in length.
- Inspect the integrity of the irrigation tube before use. Discard immediately if damaged or packaged improperly.

12.2 Error code

Error contents	Causes	Remedy
E1	Internal connection fault in the main unit	Contact your local distributor for repair
E2	Ultrasonic Handpiece error	Check handpiece cable connection, turn off the power, and restart the device. If the error persists, replace the handpiece
E3	Ultrasonic Tip error	Check the tip connection, reinstall it properly, and tighten securely. If the error persists, replace the tip
E4	Ultrasonic Handpiece not connected	Check handpiece cable connection, turn off the power, and restart the device
E5	Motor error	Check motor cable connection, turn off the power, and restart the device. If the error persists, replace the motor
E6	Motor not connected	Check motor cable connection, turn off the power, and restart the device

13 / After-sales Service

- 1) Technical service for this product is provided by the manufacture. If any quality issues arise, the company's after-sales service department will provide support.
- 2) The service life of this device is 15 years. For the production date, please refer to the product label. The Ultrasonic Handpiece with cable and tips can withstand more than 100 sterilization cycles.
- 3) From the date of purchase, the Main unit, Foot pedal, Motor, and Motor cable are covered by a 24-month warranty; the Ultrasonic Handpiece and cable are covered by a 12-month warranty.
- 4) Irreparable damage caused by repairs performed by unauthorized personnel is not covered by the free warranty.
- 5) Upon request, the supplier can provide circuit diagrams, component lists, illustrations, calibration details, or other necessary information to assist qualified technicians authorized by the manufacturer in servicing designated components.

14 / Operating, Transportation and Storage Conditions

Operation Environment	
Environmental Temperature	+5°C - +35°C
Relative Humidity	20% - 80%RH
Atmospheric Pressure	80kPa - 106kPa
Altitude	≤ 2000m
Transport and Storage Environment	
Environmental Temperature	-10°C - +55°C
Relative Humidity	≤ 93%RH
Atmospheric Pressure	50kPa - 106kPa

	Contra-angle spray nozzle clogged	Clean or repair nozzle and nozzle needle
	Tip model without irrigation channel	Use a tip model with irrigation channel
	Tip blocked	Clean irrigation channel of the tip
	Handpiece blocked	Contact your local distributor
	Incorrect irrigation tube specification	Replace with compliant irrigation tube
Excessive motor noise or irregular rotation	Motor not properly inserted	Check that all connections and fittings are secure
Motor noise or irregular rotation	Improper cable connection	Check and secure all connectors
Insufficient power of Ultrasonic Handpiece	Tip not properly installed on handpiece	Remove the tip and reinstall it correctly
	Tip aged, damaged, or deformed	Replace the tip
No light on the straight or Contra-angle handpiece	LED is turned off	Turn on the light
	Handpiece not fully inserted	Reinsert until locked in place
	LED is faulty	Replace the LED light
	LED polarity reversed	Turn the LED 180° and reinstall it
	Handpiece without lighting	Use the handpiece with lighting
Insufficient torque	Incorrect gear ratio setting	Match gear ratio to actual handpiece
	High handpiece resistance	Replace handpiece and recalibrate
Motor overheating	Continuous use or overload	Let the motor cool down before use
Speed too fast or too slow	Incorrect gear ratio	Set correct gear ratio for handpiece
Calibration failed	Handpiece is not 20:1 ratio	Use a 20:1 Contra-angle handpiece
	Handpiece is worn or damaged	Replace with a new one
Liquid overflows from handpiece when pump stops	Peristaltic pump lid not closed	Close pump lid securely

- This product can be repaired on-site by a professional operator or caregiver for simple (e.g., replacement of fuse, LED light, O-ring, etc.)
- If damage to structural components is found, please contact manufacturer for repair.

Warning

- Turn off the device before opening the pump lid!
- Never activate the Foot pedal while the pump lid is open. Moving parts may cause injury.
- When installing irrigation tubes, make sure they are not squeezed and laid loosely.
Do not insert any objects other than the disposable irrigation tube into the pump lid.

4) Select a single irrigation tube or dual-irrigation tube according to the required function, and connect it as follows:

a. Single irrigation tube (single-function use):

Connect the end of the irrigation tube to the required handpiece.

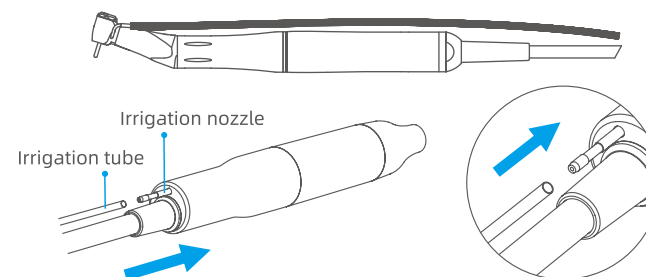
Confirm that the connection is secure and that the tubing and cables are not bent.

b. Dual-irrigation tube (simultaneous Ultrasonic and Implant Functions):

Connect the blue tube end to the nozzle of the Motor Handpiece.

Connect the transparent tube end to the nozzle of the Ultrasonic Handpiece.

Use Tube Holder to organize the irrigation tubes and cables to prevent bending or tangling.



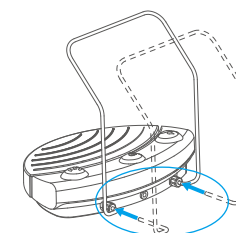
Note

- Open the clamp on the disposable irrigation tube before use.
- For dual-channel tubes, check the diverter switch position; the side indicated is closed.
- Adjust the diverter switch when switching between Piezo and Implant Function.
- Replace the disposable irrigation tube after each use.

6.5 Connecting the Foot pedal

Installing the Bracket

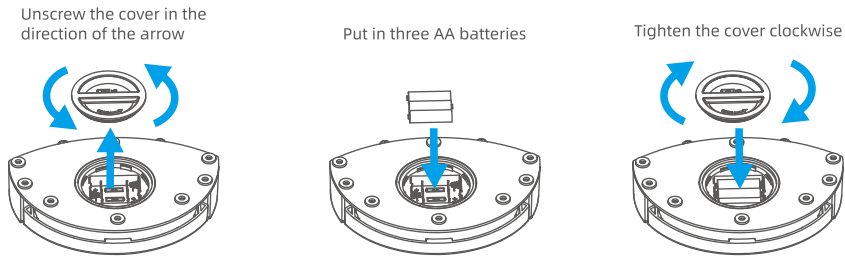
Insert the bracket into the holes on the back of the Foot pedal and tighten the nut.



Installing the Foot pedal

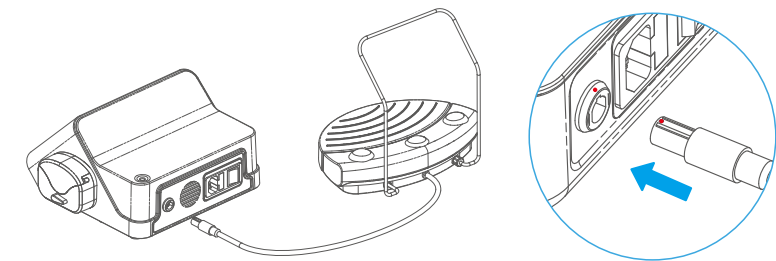
A.Wireless Foot pedal

When using the wireless Foot pedal for the first time, you need to install the batteries. Steps:



B.Wired Pedal

Insert the pedal connector into the jack on the back of the control unit, aligning the mark.



i Note

- The battery specification is AA*3. When installing, distinguish the positive and negative poles.
- When not in use for a long time, please remove the battery.
- Do not mix new and old batteries or different types of batteries.
- When both the wireless and Wired pedals are connected to the device, the Wired pedal takes priority and the wireless pedal is disabled.

6.6 Power

Connect the power cord to the device, then connect it to the net power.
Set the power switch to the “I” position to turn on the power.

Warning

Before use, check whether the power cord is damaged. The socket must be equipped with protective contacts and comply with applicable regulations.

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.	

12 / Troubleshooting

i Note

If the methods in the table do not resolve the issue, please contact your distributor for assistance.

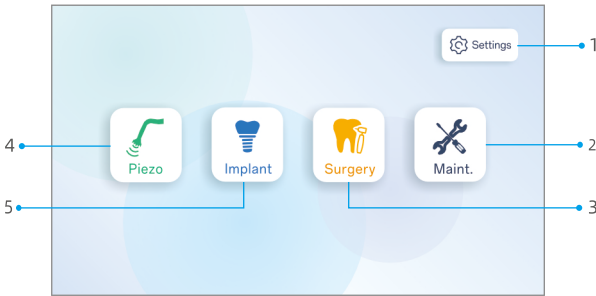
12.1 Troubleshooting

Malfunction	Possible Cause	Remedy
Device fails to power on	Power switch is off	Switch on the power switch on the rear of the device
	Power cord is loose	Check both ends of the power cord and reconnect securely
	Fuse blown	Replace the fuse
Motor does not rotate when Foot pedal is pressed	Wired Foot pedal not connected	Check whether the wired Foot pedal cable is securely connected
	Wireless Foot pedal not paired	Re-pair the Foot pedal (see “9.4 Wireless Foot pedal Pairing”)
	Wireless Foot pedal battery depleted	Replace the battery (see “10.7 Replacing the Wireless Foot pedal Battery”)
	Excessive load	Check whether the Contra-angle handpiece is jammed
	Rinsing mode selected	Switch to another mode
	Ultrasonic mode selected	Switch to Implant mode
Ultrasonic Handpiece emits a sharp noise	Ultrasonic tip not properly installed	Remove the Ultrasonic Tip, reinstall it correctly, and tighten securely
Ultrasonic Handpiece does not work when Foot pedal is pressed	Implant/Surgery Function selected	Switch to Ultrasonic Function
No irrigation or insufficient coolant flow	Coolant flow turned off	Adjust coolant flow
	Diverter valve not in correct position	Adjust diverter valve accordingly
	Diverter valve closed	Open diverter valve
	Pump cover not closed properly	Check and close the pump cover securely
	Irrigation tube bent	Straighten the bent irrigation tube

Pre-Cleaning:	Do a manual pre-cleaning, until the instrument are visually clean. Perform manual pre-cleaning until the instruments are visually clean. Clean the surface of the Motor Handpiece(with cable), Ultrasonic Handpiece(with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench under running water with a soft bristle brush.
Automated Cleaning for Motor Handpiece (with cable), Ultrasonic Handpiece (with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench:	For US/EU: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instruments into the machine on a tray and start the program. • 1 min pre-washing ith 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 Motor Handpiece (with cable), Ultrasonic Handpiece (with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench:	For US/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.
Drying for Motor Handpiece(with cable), Ultrasonic Handpiece (with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench:	Dry the outside of instrument through drying cycle of washer/disinfector. Or use compressed air to blow dry the internal pipes and external surfaces.
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.
Packaging for Motor Handpiece(with cable), Ultrasonic Handpiece (with cable), Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench:	For US: Please the sterilization bags which are approved for its efficacy by FDA. Recommended sterilization bag:SIGMAsterilization Pouch and Roll 510(k)Number:K202462. For EU: Pack the instruments in an appropriate packaging material for sterilization.The packaging material and system refer to EN ISO 11607.
Sterilization for Motor Handpiece(with cable), Ultrasonic Handpiece (with cable), Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench:	For US: Sterilization method: Gravity-Displacement Steam Cycle Sterilization conditions: 135°C,10 minutes Drying Time: 30 minutes For EU: Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) 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

07 / Screen Overview

Main screen



1. Enter the Settings interface
2. Enter the Maintenance interface
3. Enter the Surgery function
4. Enter the Piezo function
5. Enter the Implant function

Piezo Mode Screen



6. Function Status
7. Status Bar:
a. Foot pedal

(Flashing): No Foot pedal connected

:Wired Foot pedal connected

:Wireless Foot pedal is connected. Battery level displayed:

b.Sound

ON OFF

8. Power Adjustment:

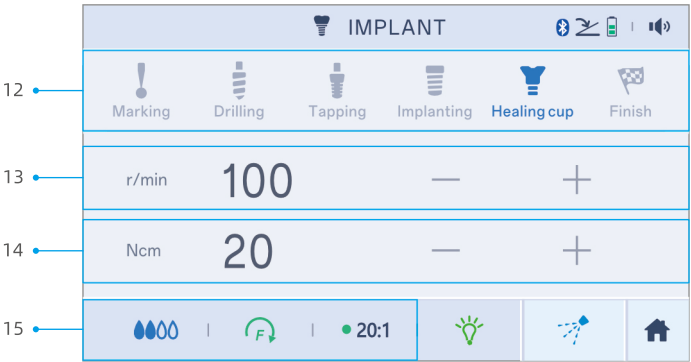
Tap to adjust the power level. Tap **BOOST** again to enter “BOOST” mode.

9. Coolant Adjustment:

Tap to adjust the coolant level.

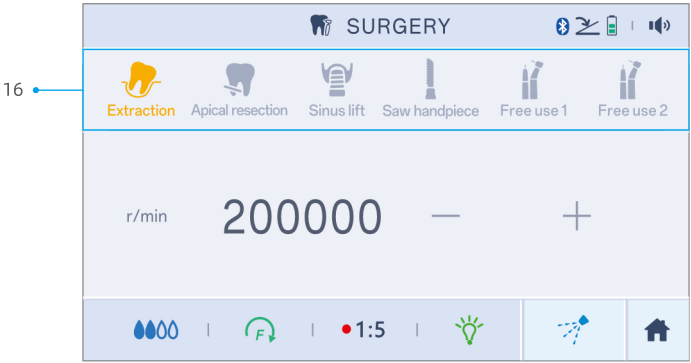
- 10. Mode Switch Button:
Tap to switch to Piezo mode.
- 11. LED Brightness, Rinsing, Settings

Implant Mode Screen



- 12. Implant Step List: Tap to select a step.
- 13. Speed Adjustment: Tap $-$ $+$ to adjust the rotation speed.
- 14. Torque Adjustment: Tap $-$ $+$ to adjust the torque.
- 15. Coolant , Motor Direction, Gear Ratio

Surgery Mode Screen



- 16. Surgery Program: Tap to switch between programs.

11 / Cleaning, Disinfection and Sterilization

Device:	Control unit, Foot pedal and Power cord.
Warning:	Do not use automatic methods to clean and disinfect the Control unit, Foot pedal and Power cord. Do not sterilize the Control unit, Foot pedal and Power cord.
Surface cleaning and disinfection	It is recommended to clean and disinfect the Control unit, Foot pedal and Power cord 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 Unit, Foot Pedal and Power Cord 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:	Motor Handpiece(with cable), Ultrasonic Handpiece(with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench.														
Warning:	Only the Motor Handpiece(with cable), Ultrasonic Handpiece(with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench can be cleaned and disinfected with automated methods. Only the Motor Handpiece(with cable), Ultrasonic Handpiece(with cable), Handpiece Stand, Ultrasonic Tip, Tip Stand 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: <table> <tr> <th>Part name</th><th>Number of time</th></tr> <tr> <td>Motor Handpiece(with cable)</td><td>250</td></tr> <tr> <td>Ultrasonic Handpiece(with cable)</td><td>100</td></tr> <tr> <td>Handpiece Stand</td><td>250</td></tr> <tr> <td>Ultrasonic Tip</td><td>250</td></tr> <tr> <td>Tip Holder</td><td>250</td></tr> <tr> <td>Torque Wrench</td><td>250</td></tr> </table>	Part name	Number of time	Motor Handpiece(with cable)	250	Ultrasonic Handpiece(with cable)	100	Handpiece Stand	250	Ultrasonic Tip	250	Tip Holder	250	Torque Wrench	250
Part name	Number of time														
Motor Handpiece(with cable)	250														
Ultrasonic Handpiece(with cable)	100														
Handpiece Stand	250														
Ultrasonic Tip	250														
Tip Holder	250														
Torque Wrench	250														

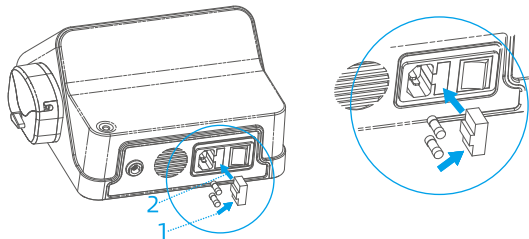
Reprocessing Instructions

Preparation at the Point of Use:	Disconnect the Motor Handpiece(with cable), Ultrasonic Handpiece(with cable), Irrigation Hanger, Handpiece Stand, Ultrasonic Tip, Tip Stand and Torque Wrench. Screw the protection plug to the motor connection.  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.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

10.8 Replace fuse

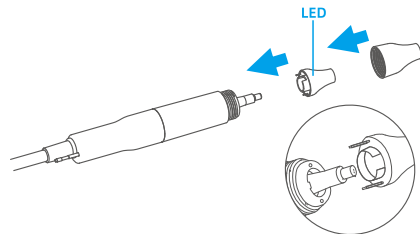
Note

- If the device fails to start, check whether the fuse is blown.
 - Fuse specification: F3.15AL 250V 5×20 mm.
- Disconnect the device from the power source.
 - Use a flathead screwdriver to open the fuse holder located below the power socket.
 - Remove and replace the fuse.
 - Reinsert the holder securely.



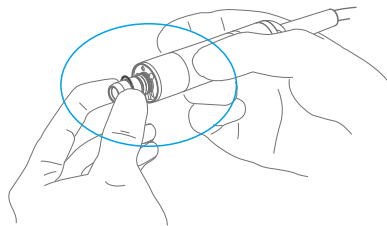
10.9 Replace Ultrasonic Handpiece LED

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



10.10 Replace the O-rings

- Press the O-ring to form a loop.
- Push the O-ring upward and remove it.
- Insert the new O-ring into the groove.



Note

- Do not replace the O-ring while the motor is running.
- Do not use petroleum jelly, oil, or other lubricants, as this may cause malfunction.

08 / Use

8.1 Switching on/off

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

8.2 Functions

The device provides three functions: Piezo, Implant, and Surgery.

8.3 Piezo function

8.3.1 Piezo mode

The Piezo function includes three modes: Bone, Perio, and Endo.

Tap the screen button **Bone** | **Perio** | **Endo** or short press the program button (P) on the Foot pedal from any operating interface to switch between sub-modes.

8.3.2 Power Adjustment

Press the “+/-” buttons to adjust power level (1-7).

Press the “Boost” button to enter Boost level; press again to return to the previous power level.

The Foot pedal can also adjust power:

- Short press  to change power level.
- Long press  to enter or exit Boost level.

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:

Power Level	Applicable Bone Type
Levels 1-2	D4 Low bone density
Levels 3-4	D3 Uniform bone density
Levels 5-6	D2 High bone density
Level 7 & BOOST	D1 Particularly high bone density

8.3.3 Coolant Selection and Rinsing Switch

Press the “+/-” buttons to adjust coolant level (0-7).

Press the  button to perform rinsing, in this mode, the handpiece only supplies water.



The Foot pedal can also perform these functions:

- Short press the coolant button to adjust coolant level.
- Long press the coolant button to perform Rinsing.

Note

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

8.3.4 LED light
Press button  to switch LED light.

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

Select power and coolant level according to the bur Ultrasonic Tips and mode (see table).
Settings highlighted in color are recommended.
Settings without highlights are not recommended.

Tip model: PS1								
mode	PowerCoolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PS2, PS4								
mode	PowerCoolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PS5								
mode	PowerCoolant	1	2	3	4	5	6	7
BONE	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

10.3 Contra-angle Handpiece Cleaning

Tap **Start** under Contra-angle Cleaning to display a function prompt window.
Follow the prompt: place the Contra-angle in a water cup with the handpiece positioned above the water level. To start cleaning, Tap “Start” ; the Contra-angle will immediately begin automatic cleaning, and a cleaning status window will appear.



Contra-angle Cleaning



Remove bur from handpiece,
Only immerse the head in water.

Start

Cancel

During automatic Contra-angle cleaning, a 30-second countdown will be displayed. When the countdown ends, the cleaning is complete. To exit the cleaning function midway, tap “Cancel” .



Note



Cleaning, 30s remaining.

Cancel

10.4 Viewing the Ultrasonic Tip Manual

Tap  under Maintenance to view the Ultrasonic Tip Manual of the device.

10.5 Viewing the Help Center

Tap  under Maintenance to view the device’s mode selection and instructions for use.

10.6 Daily maintenance

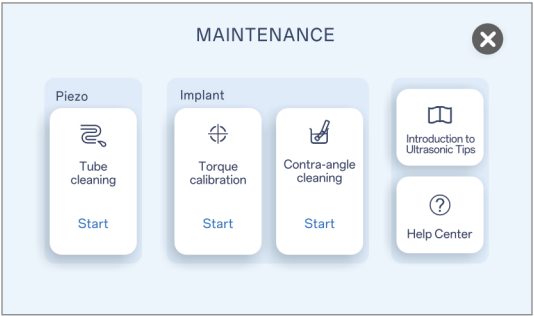
- 1) Regularly check the Ultrasonic Tip for wear and replace it promptly if any issues are found;
- 2) Check the control unit, handpiece, LED, and other components for damage before each use. If any damage is found, stop using the device immediately and contact the manufacturer or authorized dealers for assistance;
- 3) Wipe instrument surface and irrigation hanger with clean water or disinfectant, Note that the instrument cannot be soaked, cleaned or disinfected;
- 4) Keep the control unit away from liquids during the cleaning process;
- 5) Disconnect the power supply before cleaning the control unit.

10.7 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.
-  (Flashing) indicates that the battery level is critically low. Stop operation immediately and replace the battery.
- For detailed battery replacement instructions, refer to Section 6.5 Connecting the Foot pedal.

Tap  to enter the maintenance interface.

In the maintenance interface, you can perform operations such as tube cleaning,torque calibration, and more.



10.1 Tubing Cleaning

The tube cleaning function performs a circulation flush of the Ultrasonic Handpiece tubing to prevent saline crystallization and blockage.

Cleaning should be performed after device use and before handpiece disinfection and sterilization, as follows:

- 1) Replace the irrigation bottle. Distilled or purified water is recommended.
- 2) Tap **Start** under Tube Cleaning, then tap Confirm in the pop-up window. The tube cleaning will start immediately and run for 30 seconds.

 **Note**

After cleaning, remove the irrigation tube from the container and repeat the procedure until the tubing is completely drained.

10.2 Torque Calibration

The Torque Calibration function is to adjust the motor torque deviation, in order to ensure its accuracy.

Tap **Start** under Torque Calibration to automatically start the motor calibration program.

After calibration is completed, the system returns to standby mode. If calibration fails,  Calibration Failed! will be displayed.Refer to Chapter 12. Troubleshooting for the corresponding solution .

 **Caution**

- The motor will run automatically without pressing the Foot pedal during calibration.
- Hold the motor firmly or put it in a safe holder during the calibration.

 **Note**

- The motor handpiece must be attached for calibration.
- Calibration should be carried out only with Contra-angle handpiece with a transmission ratio of 20:1.
- The calibration must be repeated whenever the handpiece is changed.

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							

Tip model: PP1, PP2, PP3, PP4, PP5, PP6								
mode	Power / Coolant	1	2	3	4	5	6	7
ENDO	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

Tip model: PE1, PE2, PE3, PE4								
mode	Coolant	1	2	3	4	5	6	7
PERIO	Power							
	1							
	2							
	3							
	4							
	5							
	6							
	7							
	BOOST							

8.4 Implant function

8.4.1 Implant Mode

Tap  to enter Implant Mode.

Implanting

8.4.2 Select Implant Step

Tap the Implant step icon on the screen to select a step, or short press the Foot pedal Program button (P)to switch steps.

Press and hold the implant step on the screen to change the implant sequence.



Implant Program Icon Description

Icon	Program Name	Description
 Marking	Marking	Mark the implant site
 Drilling	Drilling	Determine drilling direction and depth
 Tapping	Tapping	Prepare the thread
 Implanting	Implanting	Place the implant into the alveolar bone

9.1 Sound

Tap  to turn on or off the sound.

 ON  OFF

9.2 Brightness

Tap  to adjust the screen brightness.

 High  Medium  Low

9.3 Reset

 Warning

Reset all settings will erase all user data and cannot be undone.

The "Reset " function restores the program parameters to their original default values.

Tap **Reset** to start restoring factory settings. The completion message will be displayed once the process is finished.

9.4 Wireless Foot pedal Pairing

 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.

- 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

Before pairing is complete, keep the Foot pedal fully pressed and do not release it.

9.5 Coolant Anti-drip Function

The function is used to prevent coolant dripping when the motor stops. Tap the switch to enable or disable the function.

When Enabled:

When the motor stops, the pump briefly reverses to stop the coolant flow. (A slight delay in coolant output may occur when the motor restarts.)

When Disabled:

The motor and pump stop simultaneously. (Minor dripping may occur, but coolant will flow immediately upon restart.)

Note

- The adjustable speed depends on the handpiece's gear ratio.
- The default parameters for are examples only. In order to avoid risks, the operator should adjust the appropriate parameters according to the actual needs.
- The gear ratio selected must be the same as that of the handpiece.

8.6 Operation

8.6.1 Ultrasonic Handpiece Operation

- Select the Piezo Function main interface.
- Press the Foot pedal to start the handpiece.
- Release the Foot pedal to stop the handpiece,coolant, and light.

8.6.2 Motor Handpiece Operation

- Select the Implant or Surgery main interface.
- Press the Foot pedal to start the motor, which will rotate in the set direction. Release the Foot pedal to stop the motor, coolant, and light.
- The speed of handpiece depends on the pedal pressing force. When pedal is completely pressed,the motor runs at the maximum speed set in the program.
- When the motor encounters resistance equal to the maximum torque set in the program, it stops running.
- When using the implant function, the screen displays the resistance graphically while the motor is running:

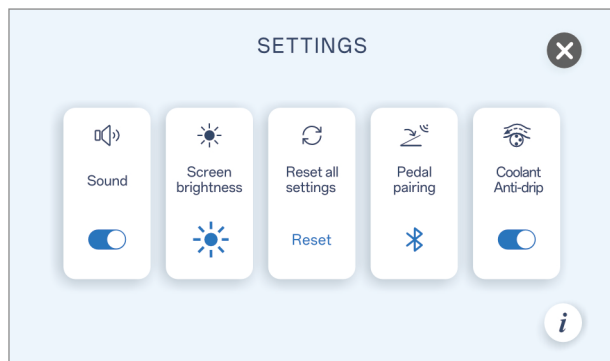
- Green means the limit torque is within 50%,orange means 50%-80%, and red means more than 80%.When resistance reaches the limit torque, the motor stops immediately and two beeping sounds are emitted.

Note

It's recommended to calibrate the Contra-angle before each use. See Chapter 10.2 Torque Calibration for details.

09 / Settings

Tap  Settings to enter the settings and tap  to exit.



 Healing cup	Healing cup	Install the abutment onto the implant or screw in the healing cap
 Free use	Free use	User-defined
 Finish	Finish	Complete the implant procedure

8.4.3 Selection and Adjustment

8.4.3.1 Speed and Torque Adjustment

Tap the “+/-” buttons to adjust Speed or Motor stop Torque.

When connected to a 20:1 Contra-angle handpiece:Speed range: 15-2200 r/min,Torque range: 5-80 N·cm.

8.4.3.2 Coolant Volume and Rinsing

Tap  to select coolant volume level(level 0-4).



Tap  to select coolant volume level(level 0-4).



The Foot pedal can also perform these functions.

- Short press the coolant button  to adjust coolant level.
- Long press the coolant button  to activate rinsing.

Warning

Insufficient coolant may cause tissue damage. Ensure sufficient coolant during use.

8.4.3.3 LED Light

Tap  to adjust motor LED brightness.



8.4.3.4 Motor Direction

Tap the  or pressing the direction button on the Foot pedal to change motor direction.



Warning

For safety reasons, the reverse motor direction is not retained after the device is powered off.

8.4.3.5 Gear Ratio

Tap  20:1 to set the gear ratio.

Warning

Ensure that the selected ratio corresponds to the Contra-angle in use.

8.4.4 Program Presets

Note

- The adjustable speed and torque range depends on the handpiece's gear ratio.
- The default parameters for are examples only. In order to avoid risks, the operator should adjust the appropriate parameters according to the actual needs.
- The gear ratio selected must be the same as that of the handpiece.
- Except motor direction, the device will automatically save the changed parameters.

Default speed, torque, gear ratio, and coolant volume are preset for each step at the factory. Users may adjust within the allowable range.

The preset parameters for implant steps are as follows:

Icon	Speed (r/min)	Torque (N·cm)	Gear Ratio	Coolant	Light
 Marking	200-2200 500 (D)	5-40 10 (D)	20:1/16:1/ 27:1/32:1/ 64:1 20:1 (D)	0-4 2 (D)	0/1/2 2 (D)
 Drilling	200-2200 500 (D)	5-40 10 (D)		0-4 2 (D)	0/1/2 2 (D)
 Tapping	15-100 20 (D)	5-80 25 (D)		0-4 2 (D)	0/1/2 2 (D)
 Implanting	15-100 20 (D)	5-80 40 (D)		0-4 2 (D)	0/1/2 2 (D)
 Healing cup	15-100 20 (D)	5-20 10 (D)		0-4 2 (D)	0/1/2 2 (D)
 Free use	200-2200 500 (D)	5-80 10 (D)		0-4 2 (D)	0/1/2 2 (D)
 Finish	--	--	--	--	--

(D)= Default parameter

Coolant Flow: 0-4 (4 = Maximum)

LED Illumination: 0 = Off, 1 = Low, 2 = High

8.5 Surgery Function

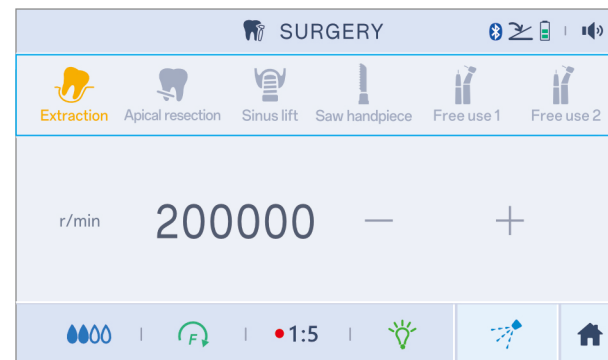
8.5.1 Surgery Mode

Tap  to enter Surgery Mode.

8.5.2 Select Surgery Program

Surgery mode includes 6 programs. There are two ways to select a program:

Tap the screen icon or short press the Foot pedal Program button(P) to switch.



8.5.3 Selection and Adjustment

For Speed, Coolant volume, LED brightness, Motor Direction, Gear Ratio and Rinsing, refer to Section 8.4.3 Selection and Adjustment.

8.5.4 Program Presets

Default speed, gear ratio, and coolant volume are preset for each step at the factory. Users may adjust within the allowable range.

The preset parameters for Surgery Mode are as follows:

Icon	Program Name	Speed (r/min)	Gear Ratio	Coolant	Light
 Extraction	Extraction	1500-220000 150000(D)	1:2/1:3/1:3.3/1:4.2/1:5 1:5(D)	0-4 2(D)	0/1/2 2 (D)
 Apical resection	Apical resection	1500-220000 180000(D)	1:2/1:3/1:3.3/1:4.2/1:5 1:5(D)	0-4 2(D)	0/1/2 2 (D)
 Sinus lift	Sinus lift	1500-220000 200000(D)	1:2/1:3/1:3.3/1:4.2/1:5 1:5(D)	0-4 2(D)	0/1/2 2 (D)
 Saw handpiece	Saw	10000-220000 10000(D)	/	0-4 2(D)	0/1/2 2 (D)
 Free use 1	Free use 1	15-200000 180000(D)	1:1/1:2/1:3/1:3.3/1:4.2/1:5/ 16:1/20:1/27:1/32:1/64:1 1:5(D)	0-4 2(D)	0/1/2 2 (D)
 Free use 2	Free use 2	15-200000 180000(D)	1:1/1:2/1:3/1:3.3/1:4.2/1:5/ 16:1/20:1/27:1/32:1/64:1 1:5(D)	0-4 2(D)	0/1/2 2 (D)

(D)= Default parameter

Coolant Flow: 0-4 (4 = Maximum)

LED Illumination: 0 = Off, 1 = Low, 2 = High