

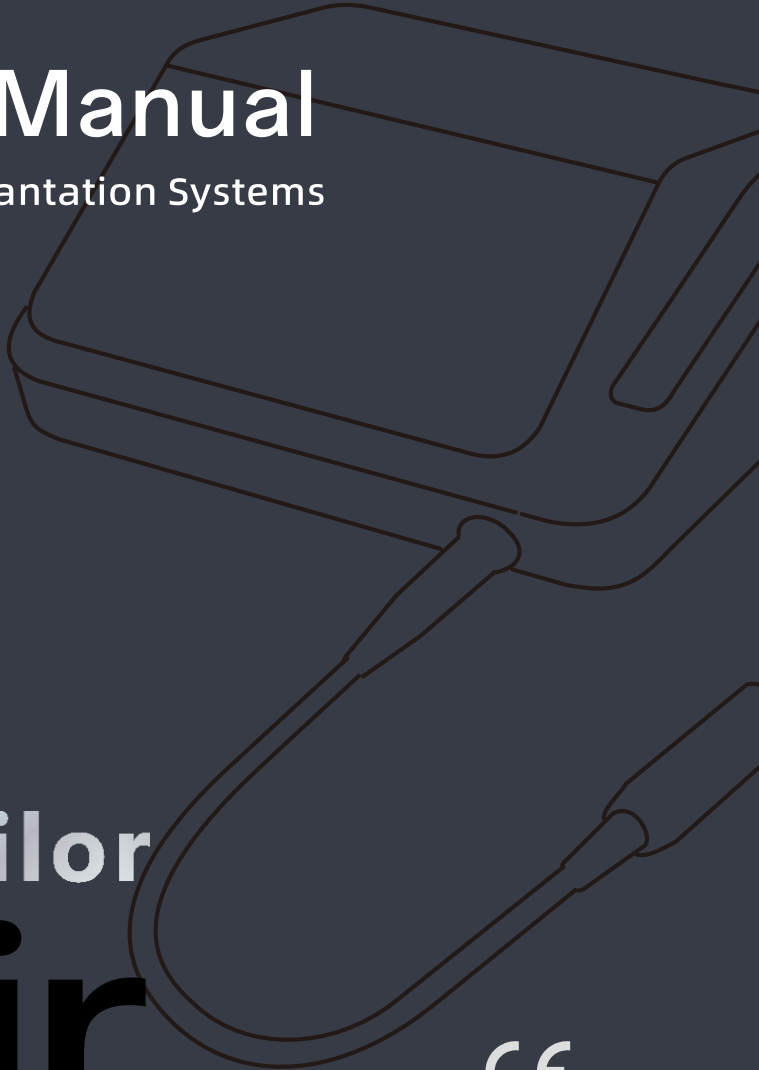
COXO[®]

User Manual

Dental Implantation Systems

C-Sailor
Air

CE 0197



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1. Safety

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

The manufacturer has 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.



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 device 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). Ask patients if they have a cardiac pacemaker or other system implanted before you start the treatment!
- 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 1 min and stop for 10 min.
- 22) Do not remove the motor cable from motor.

2. Intended Use

- 1) This device 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, gingival, bone, jaw, extractions and implantations).
- 2) The device is intended for use by suitably qualified and trained medical, technical and specialist staff only.


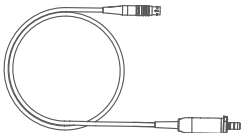
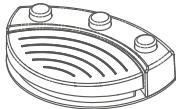
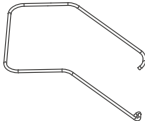
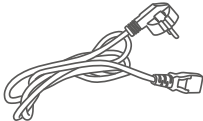





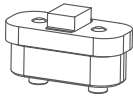
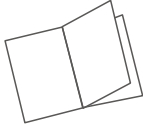
3. Contraindication

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

- Patients with systemic diseases (such as cancer, severe cardiovascular conditions, blood disorders, or immune system diseases.)
- Patients undergoing ongoing systemic treatments (such as anticoagulant therapy, chemotherapy, or radiotherapy.)
- Patients with insufficient bone volume or poor bone quality.

4. Product Configuration

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

 <p>Control Unit</p>	 <p>Motor</p>	 <p>Foot Pedal</p>
 <p>Bracket</p>	 <p>Power Cord</p>	 <p>Irrigation Hanger</p>
 <p>Tube Holder</p>	 <p>Fuse</p>	 <p>Handpiece Stand</p>
 <p>Protective plug</p>	 <p>LED lamp</p>	 <p>Instructions for use (IFU)</p>

* Note:

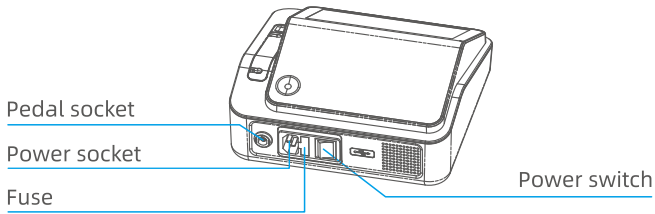
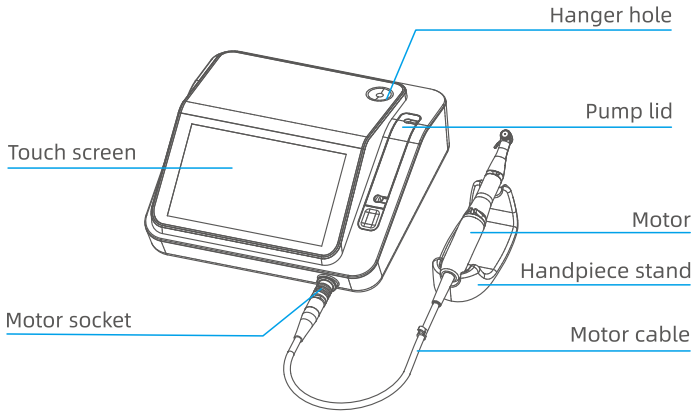
- 1) The contra-angle handpiece can be CE certified separately. Users can buy the contra-angle handpiece in the market that conforms to CE certification and the connection interface conforms to ISO 3964 standard.
- 2) Recommend using the contra-angle handpiece of our company.
- 3) The irrigation tube can be CE certified separately. Users can buy the Irrigation Tube in the market that conforms to CE certification. The Irrigation Tube compatible with this product is as follows:

Pump pipe: Length 125-130 mm; outer diameter 6 mm; inner diameter 4 mm.

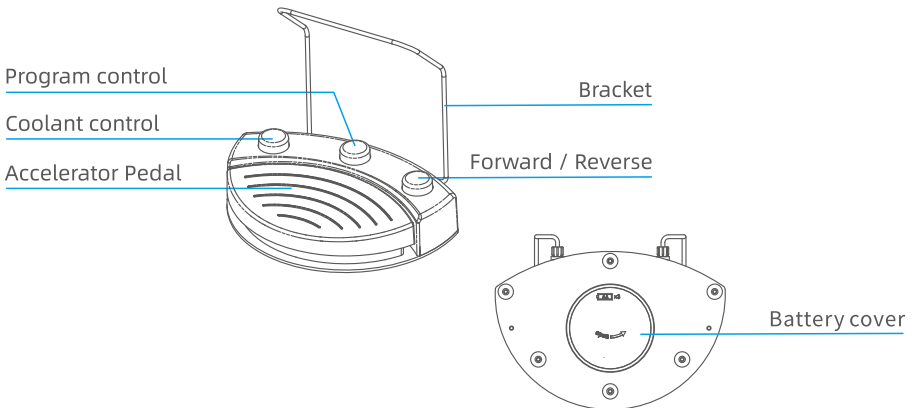
Water outlet: Outer diameter 3 mm; inner diameter 1.2 mm.

5. Product Description

Control unit



Foot Pedal (Wireless)



6. Installation



Note

Except for the irrigation tube, all other components are not sterile during transportation. Sterilize the motor and motor cable before the first use.

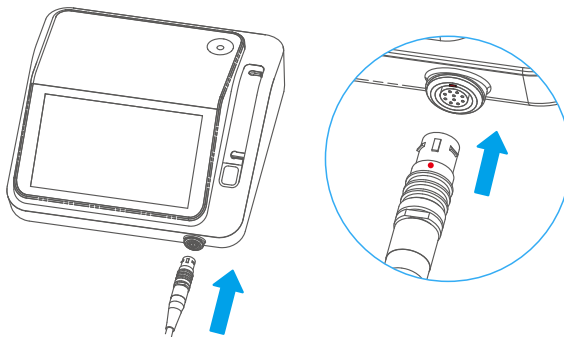


Warning

- 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.
- Ensure 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 UV light.

6.1 Motor

Align the marker points to connect the motor cable with the device.





Note

After motor is connected, the status bar of the screen will display the motor status:



: motor is connected.



(twinkle) : motor is undetected.

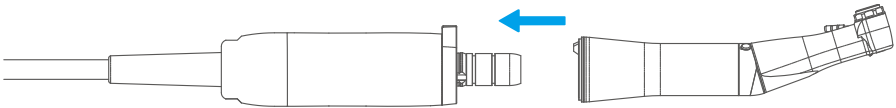


(twinkle) : motor failed.

6.2 Straight or Contra-angle Handpiece

The motor can be adapted to all the dental handpiece with interfaces conforming to ISO 14457/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.

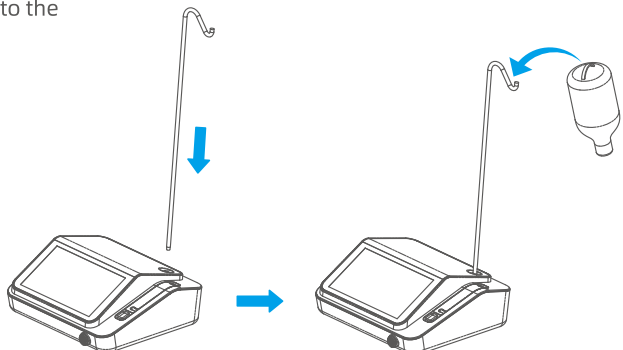


Warning

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

6.3 Irrigation Hanger

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.

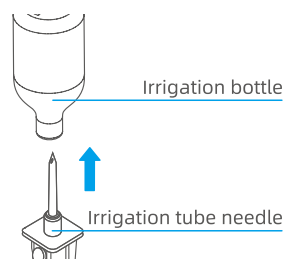
6.4 Irrigation Tube



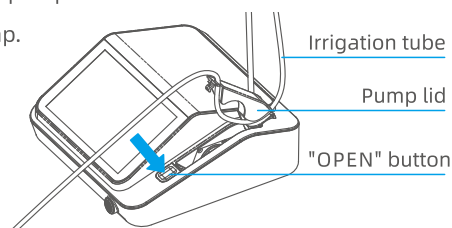
Note

- The irrigation tube and bottle shall be purchased separately. Use CE-certified irrigation tubes (see **Chapter 4** for details).
- Use 0.9% normal saline injection that conform to the requirements for coolant.
- Inspect the integrity of the irrigation tube before use. Discard immediately if damaged or packaged improperly.

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



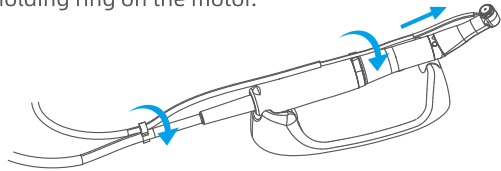
- 2) Press the "OPEN" button and open the pump lid.
- 3) Position the irrigation tube in the pump.
- 4) Close the pump lid completely.



Warning

- Turn off the device before opening the pump lid!
- When installing irrigation tubes, make sure they are not squeezed and laid loosely.

- 5) Route the Irrigation tube from the control unit along the motor cable and connect it to irrigation nozzle on the handpiece.
- 6) Place the Irrigation tube into the holding ring on the motor.



i Note

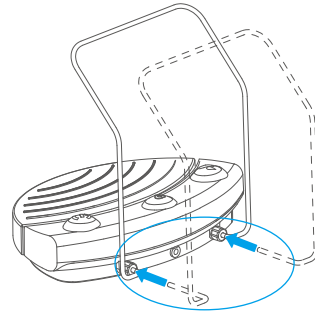
- Before use, make sure to open the clamp on the irrigation tube.
- The irrigation tube must be replaced after each use.

6.5 Foot Pedal

The device is compatible with both wireless and corded pedals.

6.5.1 Bracket

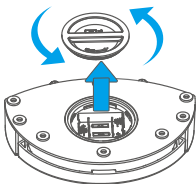
Insert the bracket into the holes on the back of the pedal and tighten the nut.



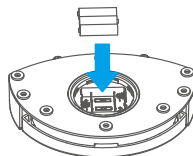
6.5.2 Wireless Pedal

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

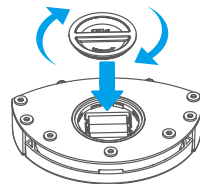
Unscrew the cover in the direction of the arrow



Put in three AA batteries



Tighten the cover clockwise



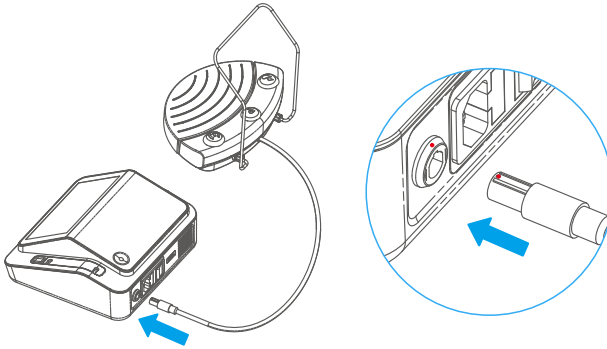


Note

- Generally, the wireless pedal has been paired before delivery. If you need to re-pair, please refer to **Chapter 11.3 Pedal pairing**.
- 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.

6.5.3 Corded Pedal (When applicable)

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



Note

When both the wireless and corded pedals are connected to the device, the corded pedal takes priority and the wireless pedal is disabled.

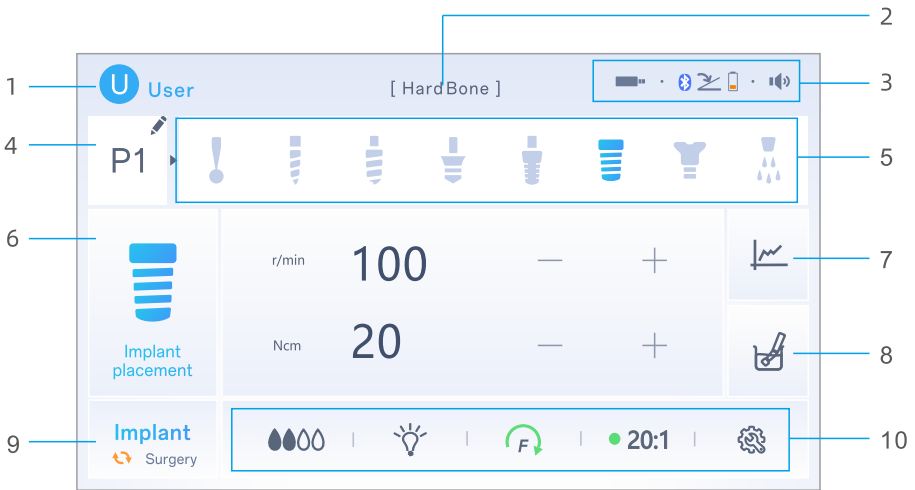
6.6 Power











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

Press the power switch to turn on the device.

7. Screen Overview

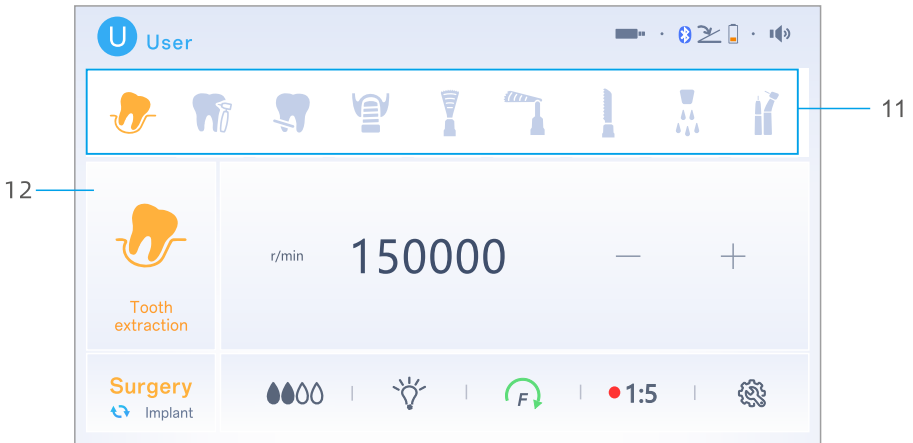
Implant Mode Screen



- 1. User Avatar and Name:** Tap to enter user selection screen.
- 2. Program Note Name:** Displays the note name of the current program.
- 3. Status Bar:**
 - a. Motor**
 -  : Motor is connected
 -  (twinkle) : Motor is undetected
 -  (twinkle) : Motor failed
 - b. Pedal**
 -  (twinkle) No pedals is connected.
 -  Cored pedals is connected.
 -   Wireless pedal is connected. Battery level displayed: 
 - c. Sound**
 -  Sound on  Sound off
- 4. Implant Program:** Tap to switch programs; Long press to edit Implant steps.
- 5. Step List:** Displays all the steps under the program.

6. **Current Step:** Tap to switch between steps.
7. **Clinic Data:** Record the speed and torque curve of the "Implant placement " step, and the parameter records of each step.
8. **Contra-angle Cleaning**
9. **Mode Switch**
10. **Other Controls:** Includes Coolant , LED brightness, Motor direction, Gear ratio and Settings.

Surgery Mode Screen



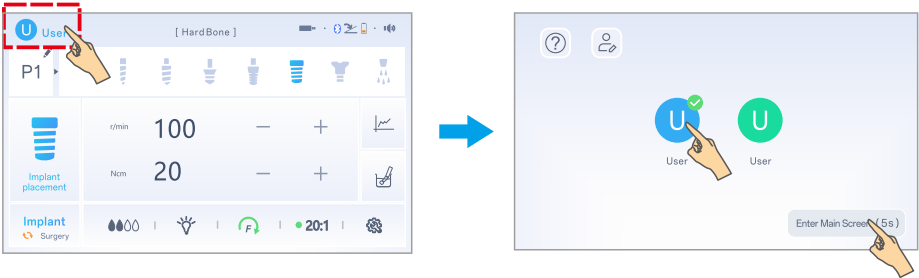
11. **Surgery Program**
12. **Current Program:** Tap to switch between programs.

8. Managing User Profiles


The device supports up to three user profiles, each storing personalized settings for Implant and Surgery modes.

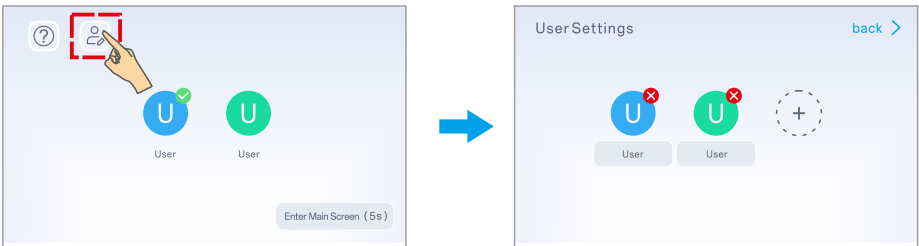
8.1 Switch Users



- Tap the user avatar to enter the user selection screen.
- Tap another user's avatar to switch users.
- Wait 5 seconds or tap a button to enter the main screen.



8.2 Create, Delete, and Rename Users

- Tap the  to enter the user settings.



- Tap  to delete a user.
- Tap  to create a new user.
- Tap the input box to type in the new name.



Caution


- Deleting a user will permanently erase all associated settings. This action cannot be undone.
- At least one user must remain. If all three users are deleted, the system will automatically create a default user.

9. Implant Mode

The device contains two modes: implant and surgery, and you can switch by pressing



9.1 Select Implant Program

- The device contains 5 implant programs, from P1 to P5.
- Tap  to select the program. The list on the right shows all the steps under the program.

9.2 Select Implant Step

- Tap the step icon or enlarged step icon to select implant step.
- You can also switch steps by pressing the program button (P) of the pedal.



Note

Users can edit the program by combining steps as needed. See **Chapter 9.5 Edit Implant Steps for details.**

9.3 Selection and Adjustment



Note


Except motor direction, the device will automatically save the changed parameters.

9.3.1 Coolant Volume



Warning

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

- Tap the  or pressing the coolant button on the foot pedal to select coolant volume level.



Off



Level 1



Level 2




Level 3



Level 4

9.3.2 LED Light

- Tap  to adjust motor LED brightness.



High



Low



Off

9.3.3 Motor Direction

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



Forward



Reverse



Warning

Reverse direction is not saved for safety reasons.

9.3.4 Gear Ratio


- Tap  to set the gear ratio.



Warning

Make sure the selected ratio matches the contra-angle being used.













9.3.5 Speed

- Tap  to set the desired speed, which is the maximum motor speed during operation.

9.3.6 Limit Torque

- Tap **+/-** to set the desired torque, which is the limit torque during operation.

Default parameters of the implant step:

Icon	Name	Speed (r/min)	Torque (N·cm)	Gear Ratio	Coolant
	Round bur	200-2000 500 (D)	5-40 10 (D)	16:1/20:1/ 27:1/32:1/ 64:1 20:1 (D)	0-4 2 (D)
	Lance drill	200-2000 500 (D)	5-40 10 (D)		0-4 2 (D)
	Pilot drill	200-2000 500 (D)	5-40 10 (D)		0-4 2 (D)
	Twist drill	200-2000 500 (D)	5-40 10 (D)		0-4 2 (D)
	Profile drill	200-2000 500 (D)	5-40 10 (D)		0-4 2 (D)
	Screw press	15-100 20 (D)	5-80 25 (D)		0-4 2 (D)
	Implant placement	15-100 20 (D)	5-80 20 (D)		0-4 0 (D)
	Healing cap	15-100 20 (D)	5-20 10 (D)		0-4 0 (D)
	Saw handpiece	10000-40000 30000 (D)	/	/	0-4 2 (D)
	High speed	10000-200000 10000 (D)	/	1:2/1:3/1:3.3 /1:4.2/1:5 1:4.2 (D)	0-4 2 (D)
	Low speed	2000-40000 2000 (D)	/	1:1/4:1/10:1/ 16:1/20:1 1:1 (D)	0-4 2 (D)
	Rinsing	/	/	/	0-4 4 (D)

(D) = Default parameter

Coolant Flow: 0-4 (4 = Maximum)



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.

9.4 Operation



Note

It's recommended to calibrate the contra-angle before each use. See **Chapter 11.4 Calibration** for details.

- Press the foot pedal to start the motor. The motor rotates according to the programmed direction.
- The rotation speed increases with the pedal pressure. When fully pressed, the motor runs at maximum preset speed.
- When the motor is running, resistance is displayed on screen with color indicators:



- Green: $\leq 50\%$ of limit torque
- Orange: 50-80% of limit torque
- Red: $>80\%$ of limit torque

- When resistance reaches the limit torque, the motor stops immediately and two beeping sounds are emitted.

9.5 Edit Implant Steps

Users can customize each program by adding, removing, or replacing steps (Max: 8 steps/program).


- Long press  to enter Edit Screen.

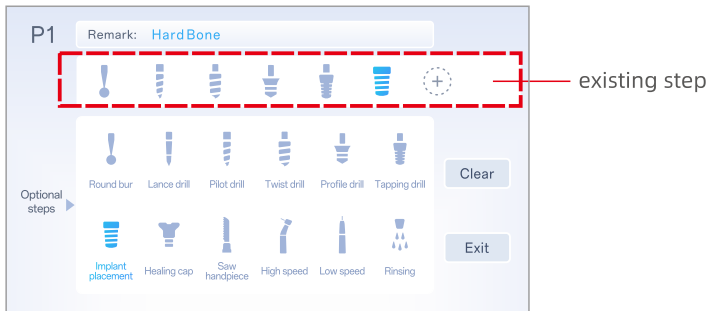


9.5.1 Remark Name

- Tap the input box and type in the new note name.
- The note name will be displayed next to the status bar.

9.5.2 Clear, Add and Replace Steps

- **Clear:** Tap **Clear** to remove all.
- **Add:** Tap  , select from optional step icons.
- **Replace:** Tap an existing step, then select a new one.



Note

- Each program can contain a maximum of 8 steps. Additional steps cannot be added once the limit is reached.
- Each program requires at least one step. If all steps are deleted, add a new step to save the program.

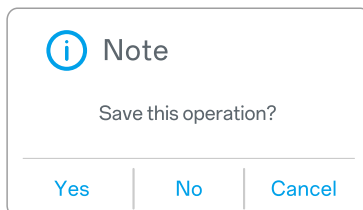
9.5.3 Saving and Exiting

- Tap the **Exit** button. A confirmation popup will appear.

Yes: Save all changes made.

No: Discard changes and keep the original program.

Cancel: Return to the edit screen.



9.6 Document


The device automatically records the speed and torque curve of the "Implant placement" step, and the parameter records of each step.

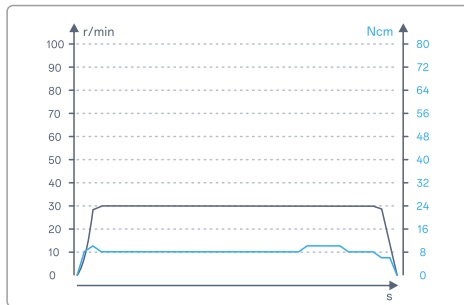


Note

- Only the latest implant data is stored. If you need to save it, please transfer it to an external USB device.
- Data is cleared when the device shuts down.
- USB storage device uses FAT32 format, and the usable capacity is not less than 2MB.
- This curve is only update after completing the Implant Placement step.

9.6.1 Clinic Data

- Tap  to enter the Clinic Data Screen.
- Tap the curve chart to enlarge the view:



Left Y-axis (Gray): Speed curve

Right Y-axis (Blue): Torque curve

- The table displays the following information:

No. Step number



Step Name



(Max)

Max Actual Speed (r/min)



(Max/Preset)

Max Actual Torque / Preset Torque (N·cm)



Coolant volume Level (0-4)




Gear Ratio

- Tap **Export** to continue the operation.

9.6.2 Save

The screenshot shows a form for saving patient information. It includes fields for No. (patient 1), Date (2025-1-1), Name (001), and Birthday (1985-1-1). There are radio buttons for Bone Density (D1, D2, D3, D4, Other) and Tooth Numbering System (FDI, ADA). A tooth numbering diagram is displayed below, showing teeth 18-28 and 48-38. A blue bar is present on tooth 25. An export icon is visible on the right side of the form.

- Enter patient or procedure information as prompted.
- Insert a USB storage device.
- Tap  to export the data.

If successful: “Implant data saved successfully” will be displayed.

If failed: Check the USB device is properly inserted.

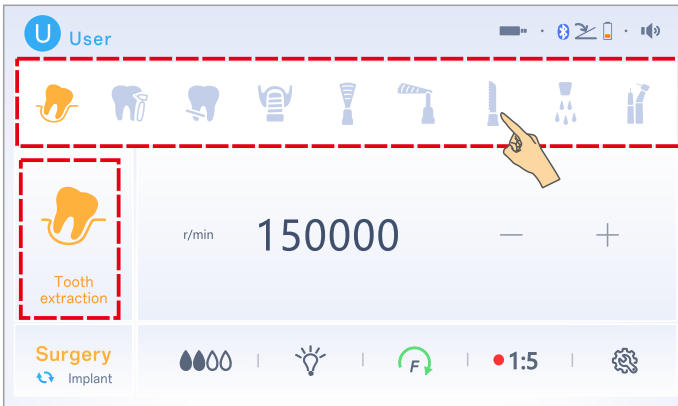
10. Surgery Mode

The device contains two modes: implant and surgery, and you can switch by pressing



10.1 Select Surgery Program

- Tap the step icon or enlarged step icon to select implant step.
- You can also switch steps by pressing the program button (P) of the pedal.









10.2 Selection and Adjustment

Please refer to **Chapter 9.3 Selection and Adjustment** for details.

Default parameters of the surgery step:



Icon	Name	Speed (r/min)	Gear Ratio	Coolant
	Tooth extraction	10000-170000 150000 (D)	1:2/1:3/1:3.3/1:4.2/1:5 1:4.2 (D)	0-4 2 (D)
	Restoration	10000-200000 170000 (D)	1:2/1:3/1:3.3/1:4.2/1:5 1:5 (D)	0-4 2 (D)
	Apical resection	10000-170000 10000 (D)	1:2/1:3/1:3.3/1:4.2/1:5 1:4.2 (D)	0-4 2 (D)

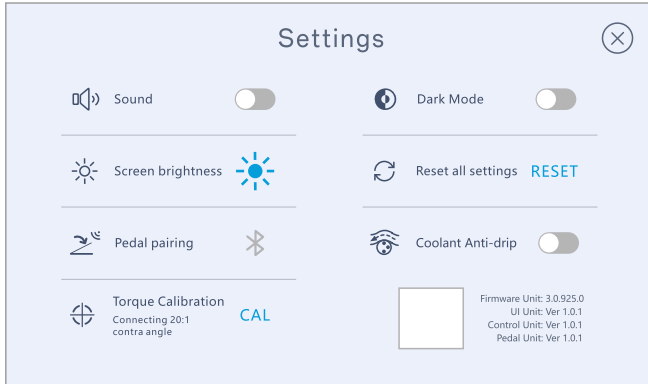
	Sinus lift	10000-200000 200000 (D)	1:2/1:3/1:3.3/1:4.2/1:5 1:5 (D)	0-4 2 (D)
	Sagittal saw	10000-40000 30000 (D)	/	0-4 2 (D)
	Swinging saw	10000-40000 30000 (D)	/	0-4 2 (D)
	Reciprocating saw	10000-40000 30000 (D)	/	0-4 2 (D)
	Rinsing	/	/	0-4 4 (D)
	Other	300-40000 8000 (D)	1:2/1:3/1:3.3/1:4.2/1:5:1 /3.2:1/3.4:1/4:1/10:1/16:1 /20:1 1:1 (D)	0-4 2 (D)

(D) = Default parameter

Coolant Flow: 0-4 (4 = Maximum)

11. Settings

- Tap  to enter the settings and tap  to exit.



11.1 Sound

- Tap  to turn on or off the sound.



Sound on



Sound off

11.2 Brightness

- Tap  to adjust the screen brightness.



High



Medium




Low

11.3 Pedal Pairing






Note

- The wireless pedal can be used only after it is paired with the control unit. Generally, it has been paired before delivery and can be used directly.
- If the control unit does not detect the wireless pedal, in addition to checking the battery, you can try to pair again.
- If you replace the wireless pedal, re-pair it with the control unit.

- Tap  and follow the prompts.
- Press and hold the wireless pedal during pairing.

After pairing:

- If successful, the screen will display .
- If unsuccessful, try pairing again.
- If pedal is paired but not connected to the control unit, the screen will display .
- To cancel pairing, tap the  button.

11.4 Torque Calibration

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

- Attach the 20:1 contra-angle handpiece.
- Tap **CAL** to start calibration.
- If calibration fails, repeat the process or see **Chapter 14. 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.



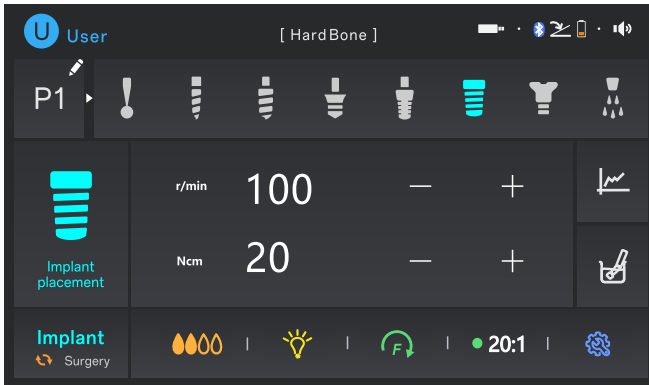
Note

- The 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.

11.5 Dark Mode

Dark Mode provides a dark background interface for low-light environments.

- Tap the switch to enable or disable. Dark mode is shown below:



11.6 Factory reset

This function restores all program parameters to the factory default settings.

- Tap **RESET** to begin. When the reset is complete, it will be displayed OK.



Warning

Performing a reset will delete all data under the current user account and cannot be undone.

11.7 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.
(Note: A slight delay in coolant output may occur when the motor restarts.)

When Disabled:

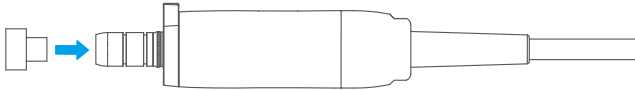
The motor and pump stop simultaneously.
(Note: Minor dripping may occur, but coolant will flow immediately upon restart.)

12. Cleaning, Disinfection and Sterilization



Caution

- The protective plug must be installed before sterilized.
- Screw the protective plug into the motor.



Device:	Motor and motor cable
Advice	Reprocessing procedures have only limited implications to this dental instruments. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation or malfunction. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use:	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.
Preparation for Decontamination:	If applicable, the devices must be reprocessed in a disassembled state, as far as possible.
Pre-Cleaning:	Do a manual pre-cleaning, until the instruments are visually clean. Do not put a motor and motor cable into a container containing a cleaning solution. If the internal liquid is not cleaned and the drying is incomplete, the internal parts may be corroded.

<p>Automated Cleaning: (For EU)</p>	<p>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.</p> <p>Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series.</p> <p>Put the instrument into the device on a tray. 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</p> <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</p> <p>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.</p>
<p>Manual Cleaning: (For US)</p>	<p>Recommend using 3M mutienzyme cleaning agent at a concentration of 5mL/1L distilled water.</p> <ul style="list-style-type: none"> ● Soak the soft cloth in detergent and wring it out. ● Wipe the outer surface of the motor and motor cable with the soft cloth. ● Wipe the outer surfaces of the motor and motor cable with a clean, damp cloth until all visible contaminants and cleaning agents are removed. ● Remove any liquid residue with a lint-free cotton cloth, then blow dry with compressed air. ● Checked that if the devices were clean or broken after cleaning. If the cleaning is not good enough, repeat the cleaning procedure. ● Do not put a motor and motor cable into a container containing a cleaning solution. If the internal liquid is not cleaned and the drying is incomplete, the internal parts may be corroded.
<p>Automated Disinfection: (For EU)</p>	<p>Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN15883).</p> <p>A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93°C .</p>
<p>Manual Disinfection: (For US)</p>	<p>Wipe disinfection is recommended to ensure that the disinfectant is used for a limited period of time.</p> <p>Place a lint-free cotton cloth into a container of 75% alcohol and wet it completely, pick it up and twist it gently to dry it. Wipe down the motor and cable at least 3 times, making sure that all surfaces have been wiped down with a damp cloth.</p> <p>Do not soak in disinfectant containers for disinfection.</p>

Automated Drying: (For EU)	Automated Drying: Drying the instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel.
Manual Drying: (For US)	Use compressed air to blow dry the internal pipes and external surfaces separately.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling, if required. 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.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607. (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.
Sterilization: (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. 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 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After sterilization: a. Remove the product from the autoclave. b. 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.
Sterilization: (For US)	Sterilizable parts: Motor and motor cable Sterilization method: Gravity-Displacement Steam Cycle Sterilization conditions: 135°C, 10 minutes Drying Time: 30 minutes
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.	

13. Maintenance

13.1 Routine Maintenance



Note

After using the device, follow the instructions below for routine maintenance.

Components	Routine maintenance method
Cables	Inspect the power cord, motor cable, and foot pedal cable at least every 6 months. If any of the cable coatings show signs of wear, contact the manufacturer or an authorized dealer for assistance.
Control unit	Before use, check the unit to see if there is any liquid leakage or damage. If so, stop using it immediately and contact manufacturer or an authorized dealer for assistance.

- After each use, wipe the control unit, foot pedal, irrigation hanger, and cable surfaces with a damp cloth.
- Use a disposable soft cloth and approved disinfectant to clean all visible surfaces
- For motor and motor cable sterilization, refer to **Chapter 12 Cleaning, Disinfection, and Sterilization**.

13.2 Replace Wireless Pedal Battery

- The wireless foot pedal is powered by 3 AA batteries. Battery status is shown on the screen:



Battery low




(twinkle) Battery extremely low – Stop operation and replace immediately.

For pairing instructions, see **Chapter 11.3 Pedal Pairing for details**.

For replace the battery, see **Chapter 6.5.2 Wireless pedal for details**.

13.3 Contra-angle Handpiece Cleaning

- 1) Tap  and follow the prompts.
- 2) Remove the bur from the contra-angle handpiece. Immerse only the handpiece head in clean water.

3) Tap "Start" to begin the cleaning process.


i **Contra-angle Cleaning**

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

Start | Cancel

4) The cleaning cycle lasts 30 seconds. You may tap "Cancel" to stop the process at any time.

i **Note**

 Cleaning, 4 s remaining

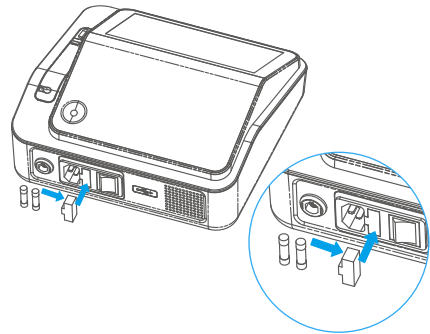
Cancel

13.4 Replace Fuse

i **Note**

- If the device fails to start, check whether the fuse is blown.
- Fuse specification: F3.15AL 250V 5*20mm.

- 1) Disconnect the device from the power source.
- 2) Use a flathead screwdriver to open the fuse holder located below the power socket.
- 3) Remove and replace the fuse.
- 4) Reinsert the holder securely.



13.5 Replace LED

i **Note**

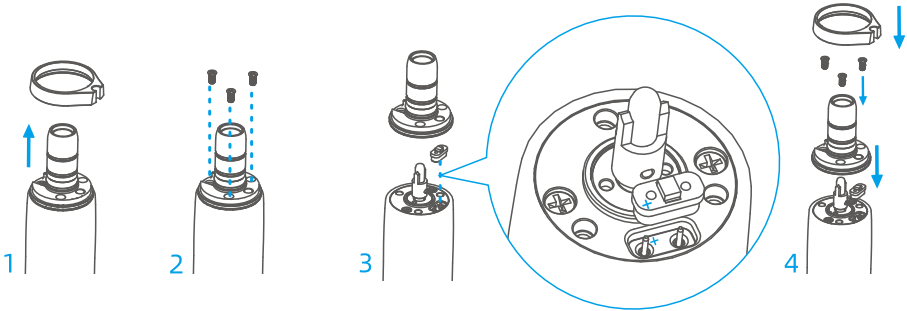
- LEDs operate on DC voltage only. Connect with correct polarity.
- If the LED does not light up, turn it 180° and reinstall.



Caution

Do not touch the LED immediately after use—it may be hot and cause burns.

- 1) Rotate to remove the retaining ring.
- 2) Unscrew the LED mounting screws.
- 3) Remove the damaged LED. Insert the new LED and tighten the screws.
- 4) Reattach the retaining ring.



13.6 Replace the O-rings



Note

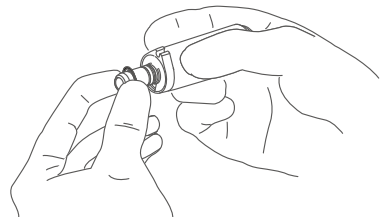
Do not replace the O-ring while the motor is running.



Caution

Do not use petroleum jelly, oil or other grease in this device as this may cause malfunctions.

Remove the O-ring and replace the new one.



14. Troubleshooting



Note

The motor is not user-serviceable and must be returned to the manufacturer.



Caution

The motor is not user-serviceable and must be returned to the manufacturer.

Malfunction	Possible Cause	Remedy
Device won't power on	The unit is switched off	Switch on the power switch on the rear of the device
	Power cord unplugged	Plug in the power cord
	Fuse is blown	Replace the fuse (see Chapter 13.4)
Pedal does not respond	The battery has run down	Replace with 3 new AA batteries
	Wireless pedal not connected device	Re-pair pedal (see Chapter 11.3)
	Poor contact of corded pedal	Reconnect
Motor not running	Motor cable is loose	Reconnect and check that the connection is in place
	Handpiece is jammed or overloaded	Remove and inspect the handpiece
	"Rinsing" program is selected	Select the other program.
Motor noise or irregular rotation	Improper cable connection	Check and secure all connectors
No coolant or insufficient coolant	No coolant flow pre-selected	Pre-select coolant flow
	Pump lid is not closed	Close completely
	Irrigation tube clamp is closed	Open clamp
	Irrigation tube is kinked	Check and straighten out the bend
	Contra-angle handpiece nozzle is blocked	Clean and dredge
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 (see <i>Chapter 11.4</i>)
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

- 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.

15. After-sales Service

15.1 Warranty

This product is supported by the manufacturer, which provides professional technical assistance in the event of device-related issues.

- The control unit, foot pedal, motor, and motor cable are covered by a 36-month warranty from the date of purchase.
- After the warranty period, replacements for damaged or worn parts can be purchased directly from the manufacturer or an authorized distributor.

15.2 Disclaimer

The manufacture will not be responsible for accidents, unit damage, or bodily injury resulting from:

- Repairs performed by personnel not authorized by the manufacturer.
- Any unauthorized modifications, alterations, or changes to the product.
- Maintenance or repair using non-original parts or components not specified by manufacturer.
- Operating the device outside the instructions and safety precautions outlined in this manual.
- Use in non-compliant environmental or electrical conditions, including improper power supply.
- Damage resulting from natural disasters such as fire, flood, lightning, or earthquake.

16. Operating, Transportation and Storage Conditions

Operating environment

Environmental temperature	+5 °C - +35 °C
Relative humidity	20% - 80%RH
Atmospheric pressure	80kPa - 106kPa

Transport and storage conditions

Environmental temperature	-10°C - +55°C
Relative humidity	≤93%RH
Atmospheric pressure	50kPa - 106kPa

17. 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

18. Technical Specifications

Control unit

Power Input	100V-240V~ 50Hz/60Hz
Input power	250VA
Operating mode	Non-continuous operation Duty cycle: Max.T_ON: 40s, Min.T_OFF: 10min
Classified of protection against Electric Shock	Class I
Protection against electric shock	Type B application section
Degree of Protection(IEC 60529)	IPX7 (foot pedal)
Classified by security	Non-AP/ APG
Altitude	≤2000m
Overvoltage category	Class II
Pollution degree	Degree 2
Applied part	Motor
Maximum torque(20:1)	80 N·cm

Motor

Speed range	300r/min~40000r/min
Motor shaft coupling	Meet the requirements of ISO 3964
Motor cable length	1.8m
Material	Aluminum alloy, Stainless Steel
































Foot pedal

Model number	FS-3
Degree of Protection (IEC 60529)	IPX7
Cable length	1.8m

Illumination (LED)

Light source type	LED
Color temperature	6,000 K
Voltage range	DC 2.8 - 3.6 V
Maximum current	100 mA

19. Symbols

	General warning		Caution
	Note		Refer to operating instructions
	Thermo disinfectable	IPX7	Temporary immersion waterproof
	Type B applied part		Sterilizable in a steam sterilizer at 134°C
	This way up		Keep dry
	Fragile, handle with care		Do not dispose of the product into the ordinary municipal waste or garbage system
	Serial number		Protective earthing
	Alternating current		Foot pedal
	Power On		Power Off
	Date of manufacture		Manufacturer
	Medical device		Unique device identifier
	Electric fuse		CE Mark
	Catalogue number		Authorized representative in the European Union
	Keep away from sunlight		Protect from heat and radio-active sources
	Importer		Do not walk or stand here
	Stacking limit by number		General symbol for recovery / recyclable

20. EMC



Note

- The device meet the EMC requirements of IEC 60601-1-2 standard.
- The user shall install and use according to the EMC information provided in the delivered file.
- 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.
- The guidelines and manufacturer's statement are attached.



Caution

- 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.

Number	Name	Length(m)	Shielding
1	Power cord	1.5	No
2	Foot pedal cable	1.8	No
3	Motor cable	1.8	No

Guidance and manufacturer's declaration- electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device use RF energy only for their internal unction. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are 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, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power 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 line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	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 an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	CW 8A/m for 30kHz Pluse modulation 2.1kHz, 65A/m for 134.2kHz Pluse modulation 50kHz, 7.5Am for 13.56MHz	CW 8A/m for 30kHz Pluse modulation 2.1kHz, 65A/m for 134.2kHz Pluse modulation 50kHz,7.5Am for 13.56MHz	
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered.</p> <p>Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = [6/d] \times P$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.</p>
Radiated RF IEC 61000-4-3	6 Vrms in ISM and amateur Radio bands	6 Vrms in ISM and amateur Radio bands	
	3 V/m, 10V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1)	3 V/m, 10V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1)	

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User Manual Ver: 1.1

UI unit Ver:1.0

Control unit Ver:1.0

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