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COXO®

徐宝悦
2026-6-6

PT Master

USER MANUAL

Dental Scaler and Air Polisher



CE 0197

Guidance and manufacture's declaration – electromagnetic immunity			
The model PT Master is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT Master 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	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	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 model PT Master, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E=[6/d]xP^{1/2}$ 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.
	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Radiated RF IEC 61000-4-3	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 IEC 60601-1-2:2014+A1:2020)	

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Guidance and manufacture's declaration – electromagnetic immunity			
The model PT Master is intended for use in the electromagnetic environment specified below. The customer or the user the model PT Master 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,±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 line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±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	<5 % UT for 0.5 Period (>95% interruption) 40 % UT for 5 Period (>60% interruption) 70% UT for 25 Period (>30% interruption) <5 % UT for 5s (95% interruption)	<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 a typical commercial or hospital environment. If the user of the instrument requires continued operation during power mains interruptions, it is recommended that the instrument be powered from a unit eruptible power supply or a battery.
Power frequency(50/60 Hz)magnetic field IEC 61000-4-8	30A/m	30A/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.			

17. Recycling and disposal of waste



The device and its packaging are designed to be as environmentally friendly as possible.
In accordance with the principles, standards, and requirements of the country (region) in which you are located. When disposing of the old electrical instrument ensure that pollution is not produced in the process of waste disposal.

18. Guidance and manufacturer's declaration -- EMC

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

⚠ Caution

Do not use a mobile phone or other instruments that emitelectromagnetic fields, near the instrument. This may result in incorrect operation of the instrument.

This instrument has been thoroughly tested and inspected to assure proper performance and operation!

This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.

Number	Name	Length (m)	Shielding
1	Power cord	1.5	No
2	Adapter cable	1.5	No
3	Handpiece cord	1.8	No
4	Wired pedal cable	1.8	No

Guidance and manufacture's declaration – electromagnetic emission		
The model PT Master is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT Master should assure that it used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The model PT Master use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The model PT Master is suitable for use in all establishments other than domestic and those directly connected to the public lowvoltage 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	

1. Safety

⚠ Warning

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

1) Do not handle the power cord with wet hands. Wet hand contact with electricity may result in an electric shock.
2) Keep away from explosive substances and flammable materials.
3) If the product overheats or smells of burning, immediately turn off the power and disconnect the main power cord.
4) Be careful not to get water or liquid disinfectant in the Control Unit. This could cause short circuits and lead to fire and/or electric shock.
5) Connect to a public water system that provides drinkable water at a water pressure between 0.1 and 0.3 MPa. Using with an incorrect water pressure may result in insufficient water supply, inoperability, or malfunction.
6) Always use the water supply. Insufficient water supply results in overheating, which may damage the surface of the patient's tooth.
7) During use, both the operator and the assistant should always wear protective glasses and protective face masks. Also, continuously vacuum and collect ejected powder during use. If any powder gets into the eyes, eyes wash out immediately with copious amount of water and consult an ophthalmologist.
8) Set the supply air pressure to 0.55 - 0.75 MPa and use clean, dry air. Using with the incorrect pressure may result in insufficient spray pressure (power), inoperability or malfunction.
9) Do not spray directly onto the cement in the root canal, decalcified enamel, filling, margin of a prosthesis or filling.
10) Make sure the compressed air supply is clean and dry. Water or oil content mixed in the air supply may cause solidification of the cleaning powder inside the product.
11) The device must be used within the scope mentioned in this manual. If the user fails to operate the device in accordance with the manual or uses the device for otherpurposes, the Company or the authorized Distributor shall not be liable.
12) The use of the device is restricted to qualified medical and technical personnel and trained professionals.
13) Do not make any modifications to this device.
14) Use the original parts and contact the manufacturer or authorized dealer for purchaseand replacement if the parts are damaged.
15) Please check the integrity of the nozzle and the tightness of the package. Do not use it if it is damaged.
16) Keep the device clean before and after use.
17) Allow the device torun under water for 10 seconds before each operation to remove residual water in the pipe.

18) The Scaler Tips must be tightened during use. When the Scaler Tips is damaged or worn, the vibration intensity will decrease. The user should replace the Scaler Tips in time.

19) Do not bend or polish the Scaler Tips

20) Be very careful to ensure cleaning powder does not enter the patient's mucosal areas (eyes, nose, etc.) other than the oral cavity. Also, protect the face with a towel or protective glasses, etc., to prevent the cleaning powder from getting into the patient's eyes.

21) Before connecting the handpiece cord, Chamber and handpiece, be sure to blow off all water from the connections with dry air. Failure to do so may result in moisture entering the air supply, causing solidification of the cleaning powder inside the product.

22) Do not use unclean water sources.

23) Do not pull hard on the handpiece cord to avoid damage.

24) Do not knock or scratch the handpiece.

25) The device has electromagnetic interference and should not be used in the vicinity of a pacemaker or electronic surgery.

26) Both electromagnetic fields and unstable voltages can interfere with the normal operation of the device.

27) In order to avoid electric shock injury, the device must be connected to the power supply network with protective ground.

28) The device isn't intended used in areas such as emergency rooms of operating theatres.

29) Time to contact unit enclosure, power supply cord, power switch, rotary knob, screen, foot pedal, adapter and applied part is less than 1min.

30) Control unit and power cord shall not be serviced or maintenance during normal treatment.

31) The device has a service life of 10 years and the date of manufacture is detailed on the label.

15. Symbols

	Caution		Warning
	Note		Refer to operating instructions
	Type B applied part		Thermo disinfectable
	Keep dry		Fragile, handle with care
	This way up		Sterilizable in a steam sterilizer at 134°C
	Direct current		Indoor use only
	Do not dispose of the product into the ordinary municipal waste or garbage system		Serial number
	Foot pedal		Alternating current
	Batch code		Catalogue number
	CE Marking		

16. After-sales service

1) The control unit and handpiece are guaranteed for 24 months from the date of purchase, and the accessories (adapter) are guaranteed for 6 months. The rest of wearing parts and accessories are not guaranteed.

2) The following conditions are not covered by the free warranty:

- Damage caused by human causes;
- Force majeure causes damage;
- User's unauthorized alteration, dismantling or maintenance;
- Any damage caused by not using and maintaining according to the instructions;
- Failure or damage caused by forced use of the product beyond the normal conditions of use.

3) The supplier can provide, upon request, circuit diagrams, component lists, notes, calibration specifications, or other information necessary to assist the user's qualified technicians in the repair of parts of the equipment which are designated as repairable by the manufacturer.

13. Operating, transportation and storage conditions

Operating environment

Ambient temperature	+5°C-+40°C
Relative humidity	20%RH-80%RH
Air pressure	80kPa-106kPa
ALT	≤2000m

Transport and storage environment

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

14. Technical specifications

Adapter	Input: AC100-240V50/60Hz
	Output: DC29.5V, 4.8A
Input power	150VA
Operating mode	Continuous operation
Degree of Protection(IEC 60529)	Control unit (IPX1)
	Foot pedal (IPX4)
Classified by how safe it is to use in thecase of flammable anesthetic gas mixed with air or nitrous oxide	Non-AP/APG type
Application part	Handpiece: aluminium (6063) Ultrasonic Tip: stainless steel (304)
Protection against electric shock	Type B
Classification of protection against electric shock	Class I (Adapter)
Scaler Tips vibration offset	< 150μm
Scaler Tips vibration frequency	24-36kHz
Half offset force	⩾ 0.5 N
Output power of tip	3-20W
Input pressure	0.55-0.8 Mpa
Water Input pressure	0.1-0.5Mpa
Weight	3.7kg
Control unit size	L×W×H: 30cm×26cm×13cm
Overvoltage category	Class II
Pollution Degree	Degree 2

2. Intended use

Tooth surface cleaning, removal of plaque or calculus, tooth resection, expansion or cleaning of root canal, removal of foreign substances, root canal obturation, enhancing adhesion of fixed restorations, incision or removal of periodontal tissue;
This device is only used in dental clinics or hospitals.

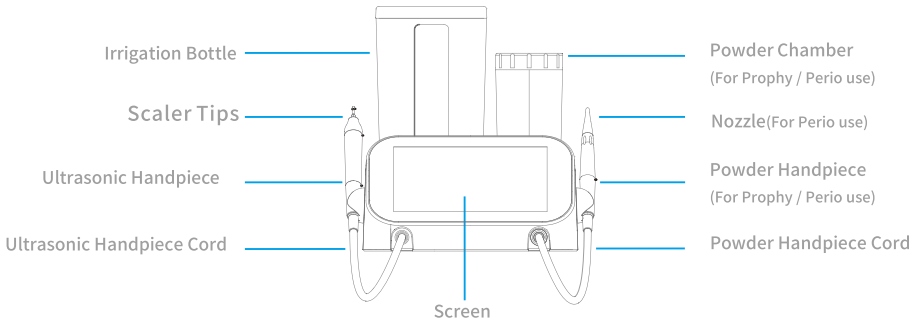
3. Contraindications

Do not use on the following patients:

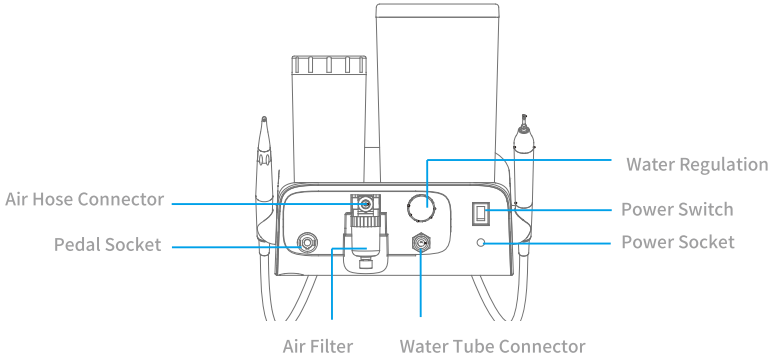
- Users who have pacemakers (or other electrical equipment) and are warned not touse small appliances (such as electric razors, hair dryers, etc.)
- Hemophilia patients;
- pregnant women, children, photoallergies and patients with retinal history;
- Patients with respiratory diseases such as asthma and chronic bronchitis;
- Those who have preexisting conditions (E.g. Cardiac, Pulmonary, Renal disturbance or High blood pressure)

4. Description

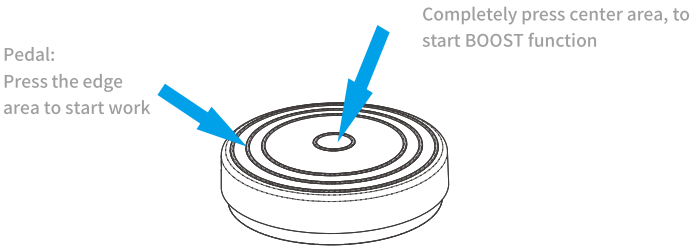
Front



Rear



Foot Pedal



No sand of blasting	Powder handpiece is blocked	Use a needle to clean the passage and blow it clean with compressed air (Detail in “unclogging guide”)
	Powder chamber is blocked	Use a needle to clear the outlet and intake of the powder chamber,blow it clean with compressed air (Detail in “unclogging guide”)
	Control unit internal pipeline is blocked	Use a needle to clear the outlet and intake of the powder chamber (Detail in “unclogging guide”)
	Powder handpiece tube is blocked	Use a needle to clear the outlet and intake of the powder chamber (Detail in “unclogging guide”)
	Solenoid valve failure	Contact your local distributor
	No air supply	Check the air source connection
After the sandblast is over, there is still a gas spray at the outlet of the handpiece	Sand -stop valve failure	Check the gas supply and confirm whether it is satisfied with the rated gas supply

12. Troubleshooting

Malfunction	Cause	Remedy
Non-functional device	Power cord not plugged in properly	Check the power plug
	The power switch is not turned on	Turn on the power
The pedal doesn't work when press it	Bad contact of wired pedal	Reconnect
	The battery has run down	Replace the battery
	Wireless pedal failure	Re-pair
Air/water leakage of handpiece	The spare O-ring is damaged	Replace the O-rings
Ultrasonic handpiece overheating	Insufficient coolant	Increase irrigation volume
The ultrasonic handpiece LED light is not on	LED light damage	Replace LED lights
Abnormal working of the Scaler Tips (such as reduced vibration, no water coming out, etc.)	The Scaler Tips is loose	Tighten it with torque wrench
	The Scaler Tips is damaged	Replace with a new one
	Blocked waterways cause tips not to come out of the water	Unblocking with three guns
Low efficiency of blasting	Insufficient powder	Increase the powder
	Residue of sand in the powder handpiece	Use a needle to clean the passage and blow it clean with compressed air
	Powder absorbs moisture and clumps	Replace with a new powder
	Air source pressure is too low	Ensure that the pressure meets the requirements of the machine
Air leakage of powder chamber	There is powder residue at the mouth or cap thread or the thread is not screwed in place	Clean the remaining powder and blow dry with compressed air
Irrigation bottle leaks	The spare O-ring is damaged	Replace O-ring
The control unit bottom leaks sand	Sand tube of the control unit bottom is broken	Contact your local distributor to replace the sand tube (Details in 12.3)

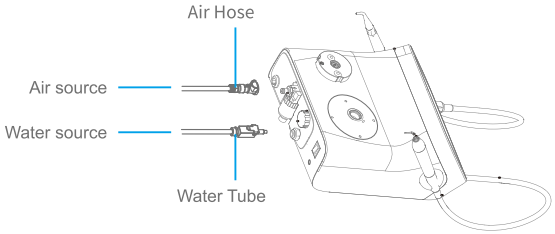
5. Installation

Caution

- If any parts are damaged, it is recommended to buy the original parts.
- Please do not to position the device to make it difficult to operate the disconnection device.

5.1 Air hose and water tube

Insert one end of the air hose / water tube to the control unit and the other end to the air / water source.



Note

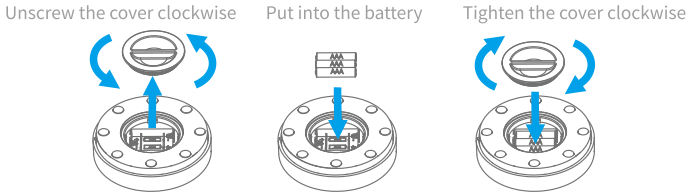
- Input pressure range is required to be 5.5bar-8.0bar (0.55 Mpa-0.8 MPa);
- Input water pressure range is required to be 1.0bar -5.0bar (0.1MPa-0.5 MPa).

5.2 Pedal

The pedals of this product are wireless and wired pedals. You can choose a wired or wireless connection according to the user's needs.

5.2.1 Connect wireless pedal

1) The first time you use the wireless pedal, you need to install batteries. The battery installation method is as follows:



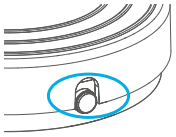
Note

- Battery specification is AAA * 3. When installing, pay attention to distinguish the positive and negative poles.
- When installation and use of wireless pedals, you must remove the pedal connection line.

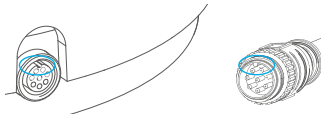
2) Generally, the wireless pedal has been paired before delivery. If you need to re-pair, please refer to “6.3 Pedal pairing".

5.2.2 Connect wired pedal

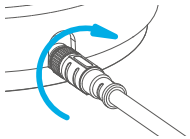
1) Take out the pedal and pull out the glue plug behind the pedal.



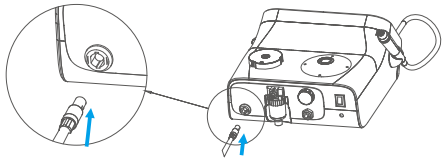
2) Align the concave point above the pedal connector with the convex point of the pedal connection cable, insert the connection line into the pedal.



3) Tighten the screws on the foot of the connection clockwise to fix the screws.

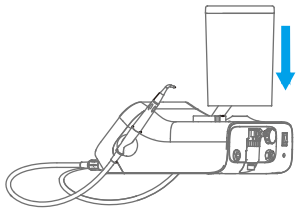


4) Align the marker points to connect the pedal with the device.



5.3 Irrigation bottle

Insert the irrigation bottle containing water directly into the bottle interface.

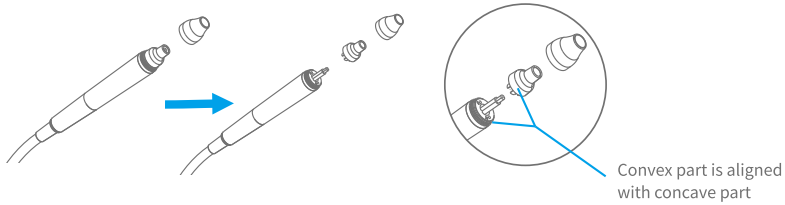


Note

- Do not exceed the maximum scale of irrigation bottle.

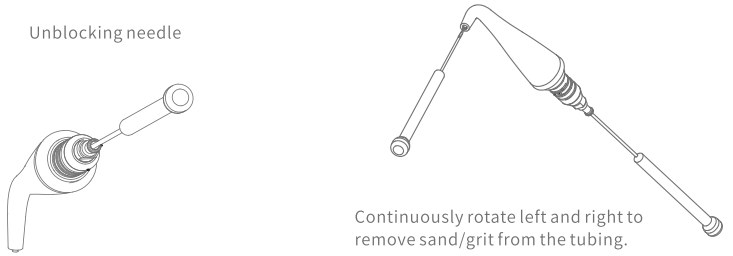
11.6 Replace LED light

- Turn the handpiece cap counterclockwise;
- Pull out the lamp bead, replace it and tighten the handpiece cap.



11.7 Unblocking

This product is equipped with unblocking needles (long/short) for clearing blockages in the handpiece. Insert the unblocking needle into the clogged area, rotate and move it left and right to remove the blockage, and finally blow it clean with compressed air.

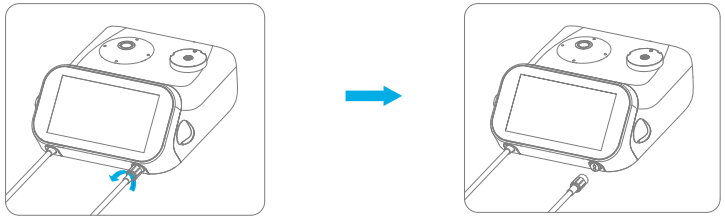


11.8 Replace spare O-ring

When there is water leakage in the handpiece and air leakage in the air filter, check the O-ring in time. If damaged, replace it in time.

11.5 Replace the power handpiece tube

Power handpiece tube has sand hose. Long time using will cause internal damage, improper use will lead to internal hose blockage, must to replace the handpiece tube.



Note

The handpiece tube is easy to be damaged. For a long time, the internal sand -pass hose is damaged. The handpiece tube needs to be replaced.

Each handpiece tube is expected to spray sand and teeth more than 400 times.

Caution

In order to avoid tube blockage, should click the cleaning sign on the screen to clean the pipeline after use. (For details, see 10. Clean pipes)

Note

If no sand during use, please remove the powder handpiece first and step on the foot pedal to determine whether the handpiece tube is blocked or the powder handpiece is blocked:

① After removing the handpiece and start device, the tube still does not sand out——the powder handpiece tube is blocked. Please remove the powder handpiece tube and contact your local dealer to dredge or replace it.

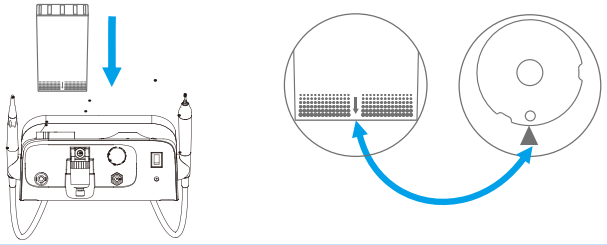
② After removing the handpiece and the tube sand flow as usual——The powder handpiece is blocked.Please use a needle to clean the passage and blow it clean with compressed air.

5.4 Powder Chamber

- Connection: First, the arrow at the bottom of the powder chamber is directed at the triangular icon of the control unit and then directly inserted.
- Disconnection: After pressure relief, pull it upward.

Note

- Do not exceed the maximum scale of irrigation bottle.



Note

- The amount of powder should be controlled between MIN and MAX;
- Please keep the powder chamber and powder dry;
- It is easy to be damp if powder exposed to the air for a long time,and using damp sand is easy to cause blocking;
- The powder chamber should be kept dry, otherwise the powder is easy to be damp and caked;

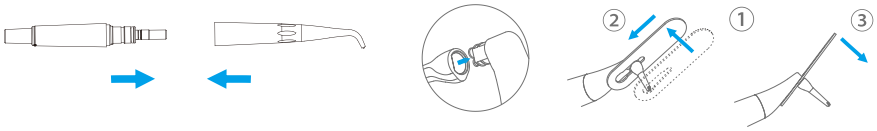
5.5 Powder handpiece

5.5.1 Powder handpiece

- Use air to dry the connection between the Handpiece and Handpiece HosePlug;
- Push the powder handpiece straight into the handpiececord.

5.5.2 Nozzle (For Perio use)

- Connection: Insert handpiece head in the direction of nozzle "D" head;
- Disconnection: Use the spanner wrench to pry it out.



Caution

- The nozzle is disposable and prohibited from secondary use.

5.6 Ultrasonic handpiece

5.6.1 Ultrasonic handpiece

- Connection: Align the dots on the ultrasonic handpiece and handpiece cord, then push handpiece straight into the connector;

> ⚠ Caution
>
> - The nozzle is non-sterile and needs to be disinfected with medical alcohol for 5 minutes before use;
> - The nozzle is disposable and prohibited from secondary use.

- Disconnection: Hold the ultrasonic handpiece and handpiece cord, then pull the handpiece out.

5.6.2 Scaler Tips

- Connection: Hold the handpiece and screw in the Scaler Tips, and then insert it into the torque wrench, finally rotate clockwise.
- Disconnection: Hold the handpiece tightly, insert the Scaler Tips into the torque wrench, and then rotate counterclockwise.



5.7 Adapter

Connect Power ③→②→①

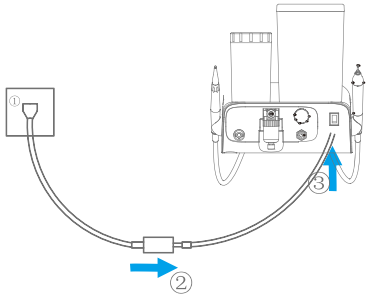
Connect the adapter to the device,

then connect it to the net power.

Disconnect Power ①→②→③

Disconnect the net power supply,

then disconnect the adapter from the device.



> ℹ Note
>
> - Please be careful not to touch the appliance with wet hands.

> ℹ Note
>
> - It is recommended that the water filter in the primary filtration bin (position A) be replaced every 12 months and the water filter in the secondary filtration bin (position B).

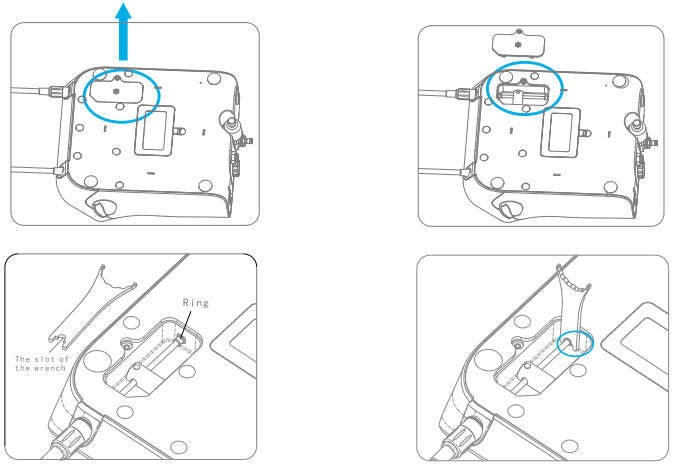
> ⚠ Caution
>
> Be sure to install water filters before use!

11.4 Replace the sand tube

The sand stop valve warehouse at the bottom of the host has sand -stop valves and sand tubes; the sand tube is easy to be damaged. After a long period of use, the operation of the sand -stop valve will damage the sand tube; the sand tube is required after damage.

Disassembling: Turn the screw to open the lid, remove the sand tube ring, use the slot of the wrench to catch on the tube ring and pry out the ring, then remove the damaged sand tube.

Installation: The sand -passing tube passes through the sand -stop valve, installs the tube ring, and then butt the sand through tube joint, and toggle the tube ring over the joint.



> ℹ Note
>
> - When the sand powder leaks at the bottom of the device, it means that the sand tube has been damaged and the sand tube needs to be replaced to continue to use.
> - The life of the sand tube: use once a day, it is expected to be used for more than 5 years; 5 times a day, and can be available for more than 1 year.

11. Maintenance

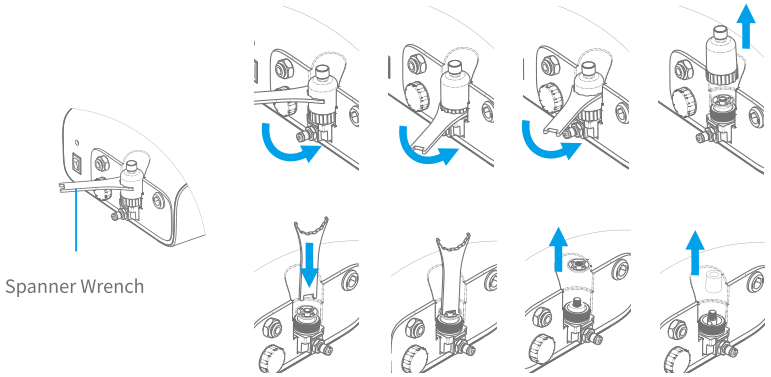
The following maintenance of this product may be performed by a qualified physician or nurse practitioner.

11.1 Replace the wireless pedal battery

The wireless pedal is powered by battery, and the battery power is displayed at the status bar at the top of the screen. If is displayed, it should be replaced in time. means that the electricity is extremely low, and the battery needs to be stopped immediately and replaced the battery. For the specific replacement method, see " 5.2.1 connect wireless pedal".

11.2 Replace Air filter

Air filter is mainly used to remove dirt, rust slag, dust, oil, moisture in the air. It is recommended to replace once every 24 months.



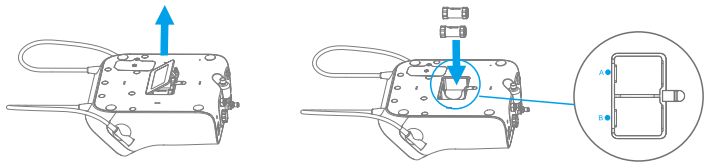
Spanner Wrench

11.3 Replace water filter

Water filters are mainly used to remove suspended matter, chlorine, organic impurities, color, odor, etc. to avoid device failure. If external water is used frequently, it is recommended the filter monthly and replace it if it is found to be very dirty.

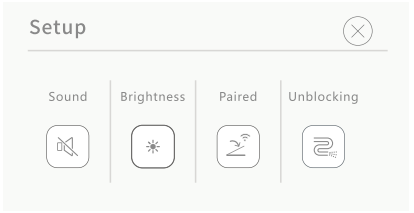
Disassembling:open the lid and remove it upwards.

Installation: Open the lid at the bottom of the host and install the water filter in the direction shown in the picture.



6. Settings

Press to enter the settings and press to exit.



6.1 Sound

- Press to turn on or off the sound;
- : sound is on; : sound is off.

6.2 Brightness

Press to select the screen brightness.

6.3 Pedal pairing

- The icon at the top of screen shows the status of foot pedal:

(twinkle) No pedals is connected.

Wired pedals is connected.

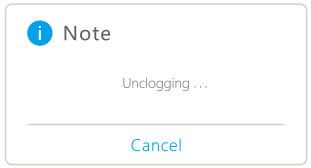
- To use the wireless foot pedal, it must be paired with the main unit in advance. Press the button on the settings screen and follow the on-screen instructions.
- Once pairing is successful, the screen will automatically return to the settings interface, and the interface will show that the foot pedal is paired .
- If pairing fails, follow the prompts to retry.
- To cancel the pairing, press the button to disconnect the foot pedal.

Note

- Do not release the foot pedal during the pairing process;
- After each device restart, step on the working pedal of the wireless foot pedal to activate it, so that it can automatically connect to the main unit.

6.4 Tube unclog

- Press  to turn on tube unclog;
- Press “Cancel” to turn off the tube unclog.



Note

- Please refer to “Unclogging Guide”.

Drying:	Automated Drying: Drying the products through drying cycle of washer/disinfector. If needed, additional manual drying can be perfo rmed through lint free towel. Insufflate cavities of products by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the products and reassembling, if required. All products should be checked again for dryness. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use. -Check that the product has no dents, cracks, deformations, scratches, etc.; -Check all markings on the product for clear visibility. Discard and replace any components as necessary. Do not use the device with following defects: material deformation, cracks on the product, brittle or other change in the material, etc.
Packaging:	Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
Sterilization:	Sterilization of products by applying a fractionated pre -vacuum steam sterilization process (according to EN 285/EN ISO 17665) under consideration of the respectiv e country requirements. Following sterilization parameters are commonly used: 134 °C, 5 min (standard program in EU) Drying time: For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After sterilization: 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. c. Check that the sterilizat ion wraps or pouches are not damaged.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
Reprocessing validation study information:	-Foshan COXO _Cleaning Disinfection Validation Report, Report No.: MDS-RECD-230809-222 -Foshan COXO _Sterilization Validation Report, Report No.: MDS -RES-230809-223 -Foshan COXO _Sterilization Validation Report, Report No.: MDS -RES-230809-224

	cloth.
Pre-Cleaning of Powder Handpiece, Ultrasonic handpiece, Scaler Tips, Spanner wrench, and Torque wrench:	Following instructions are only relevant for powder handpiece, ultrasonic handpiece, scaler tips, spanner wrench, and torque wrench! Not use automated cleaning, disinfection and sterilisation for other parts than powder handpiece, ultrasonic handpiece, scaler tips, spanner wrench, and torque wrench in this system! Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the EN ISO 15883 series. The products in the washer-disinfector are arranged in such a way that there is no rinsing shadow and the water drains off quickly. Start the program: • 4min pre-washing with cold water (<40°C); • emptying • 5min washing with a mild alkaline cleaner at 55°C • emptying • 3min neutralising with warm water (>40°C); • emptying • 5min intermediate rinsing with warm water (>40°C) • Emptying The automated cleaning processes have been validated by using 0.5% neodisher MediC/ean 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 valida te it prior to use.
Disinfection:	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to AO value (see EN ISO 15883). A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an AO value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93°C.

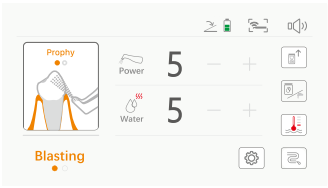
7. Blasting system

7.1 System selection

- When taking down the powder handpiece from the handpiece holder, automatically enter the blasting system;
- you can also press Piezo to switch when the handpieces are not taken down.
- After power-on or when the powder handpiece is returned to the holder, continuous air purging starts automatically. Air purging stops automatically when the powder handpiece is taken down. This function reduces residual water and powder inside the handpiece and lowers the risk of clogging.

7.2 Mode selection

The system contains two modes: Prophy and Perio. Press any position in the following icon to switch modes.







7.3 Power adjustment

Press the "+" or "-" on the right side of the Power to adjust the power.

7.4 Irrigation mode selection and volume adjustment

Blasting system can use bottle or tap water, and press to switch. The selected mode is displayed on the screen as an icon.

: Bottle water : Tap water

7.4.1 Bottle water

Press "+" or "-" on the right side of the Water to adjust the irrigation volume.

7.4.2 Tap water

Adjust irrigation volume through water adjust knob on the back of the control unit.

7.5 Heating

1) Press the button to turn on/off the heating function.
2) The heating temperature is adjustable across 5 levels (0–4). The outlet water temperature ranges from approximately 20°C to 40°C:

- Level 0: Heating function OFF;
- Levels 1–4: heating and water output are enabled, with temperature increasing progressively as the level increases.

3) Actual outlet water temperature may vary depending on the selected level and water flow rate. Adjust according to your usage needs.

 Heating function enabled

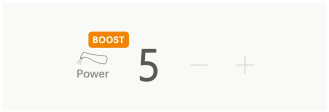
 Heating function disabled

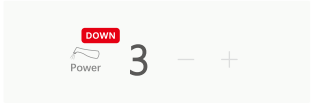
Note

- If the water temperature becomes too high during heating, a pop-up message "Heating function failed" will appear on the screen. In this case, turn off the heating function and continue working. Wait for a while before turning the heating function back on.
- Before surgery, it is recommended to turn on the heating function in advance for preheating. The preheating time is approximately 1 minute. After preheating is complete, the handpiece will deliver hot water within about 30 seconds.
- After adjusting the water flow rate or heating level, wait until the water temperature stabilizes before use. It is recommended to increase the water flow and heating level gradually to reduce the risk of scalding.
- As some heat is dissipated when water flows through the tubing, the actual outlet water temperature may be lower than the set temperature. Additionally, heating performance may be affected by ambient temperature and other factors. Variations in heat loss rate and final temperature may cause fluctuations in the outlet water temperature, which is a normal phenomenon.

7.6 Working

1) Press the pedal to start working, and release to stop ; (First use after power on, need to wait a few seconds before water);
2) Power level and irrigation volume can be adjusted during working;
3) Press the accelerator pedal hard to start BOOST function that can increase blasting power;
4) If the actual power is lower than the set value, the system will automatically detect.





Note

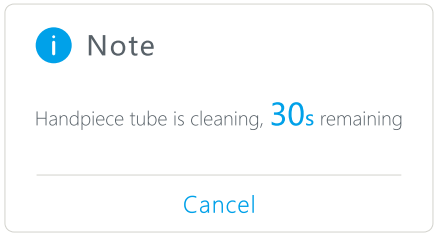
- Blasting recommendation use 5 ~ 7 gear

10. Cleaning, disinfection and sterilization

Device:	Dental Scaler and Air Polisher The procedure for cleaning, disinfection and sterilization applies only to the accessories powder handpiece, ultrasonic handpiece, scaler tips, spanner wrench, and torque wrench.
Advice:	Reprocessing procedures have only limited implications to this dental instrument. 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 allowed reprocessing. The device should no longer be reused in case of signs of material degradation. In case of damage the devi ce should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use:	Disconnect the handpiece and scaler tips. Remove gross soiling from the device with cold water (<40°C) immediatel y after use, if applicable. 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.
Transportation:	Safely store the device in a humid surrounding and transport it to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state, as far as possible. Only powder handpiece, ultrasonic handpiece, scaler tips, spanner wrench, and torque wrench can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the control unit. The control unit cannot be cleaned and disinfected in a washer/disinfector. For these parts, only a general wipe decontamination is possible!
Decontamination of other parts than Powder Handpiece, Ultrasonic handpiece, Scaler Tips, Spanner wrench, and Torque wrench:	After operation, take out the control unit on the w orkbench. Soak a soft cloth completely with distilled water or deionized water, and wipe all the surfaces of these components, until the surface of the components is visually clean. For decontamination, soak a dry soft cloth with 75% alcohol or other disinfects which are approved for its efficacy by VAH/DGHM-listing, CE marking, FDA and Health Canada Approval. Wipe all surfaces of control unit and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectants. Wipe the surface of the component with a dry soft lint-free

9. Auto-Cleaning

1) Auto cleaning is to prevent blockage or rust on metal parts .So, the auto should be clean before each use and after each treatment;
2) Before ultrasonic tube cleaning, bottle water must be installed; Before cleaning the blasting tube, compressed air should be connected and water should be on;
3) Place the tip of the handpiece into the container to catch water;
4) Press the button and start auto-cleaning;
5) Auto-Cleaning takes about 30 seconds and can be cancelled at any time during the cleaning process.

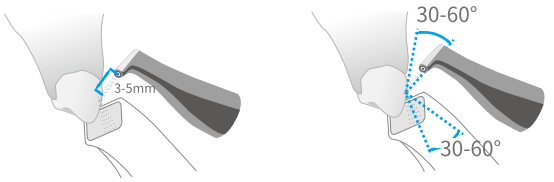


Note

- Ultrasonic handpiece and powder handpiece cannot be cleaned at the same time; Only bottle water supply can be used for auto-cleaning function;
- The water supply for the cleaning function is determined by the currently selected water supply mode.
- To avoid tube blockage caused by powder, it is recommended to perform tube cleaning before and after each air polishing treatment.
- Do not use water containing cleaning solutions to clean the tubing.

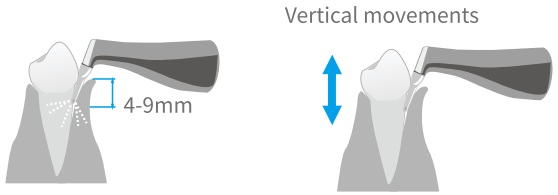
7.6.1 Prophy mode

1) Before treatment, adjust the power level and the irrigation level before using on the patient;
2) Keep the nozzle at a distance of 3- 5mm from the tooth surface and at an angle of 30 - 60 degrees.



7.6.2 Perio mode

1) Insert the nozzle tip deeper than 3mm into the periodontal pocket;
2) Keep the nozzle at a distance of 4 - 9mm from the tooth surface and moving at a vertical direction;



Note

- Powder may not be sprayed efficiently into the periodontal pocket if the depth is less than 3mm.
- Never point the nozzle directly toward the oral mucous membrane or in periodontal pockets.
- Users should wear a protective mask.

7.6.3 Releasing residual pressure

The chamber cap cannot be opened after operation due to buildup of air pressure inside the chamber increasing during operation. Release the pressure remaining in the chamber before putting powder in the chamber or removing the chamber from the control unit.

1) Take the powder handpiece out of the handpiece holder.
2) Place the handpiece into the container to catch powder and water.
3) Press the button and start to release.

Note

- During pressure relief, it is recommended to point the handpiece nozzle downward to avoid injury caused by ejected air or residual powder.

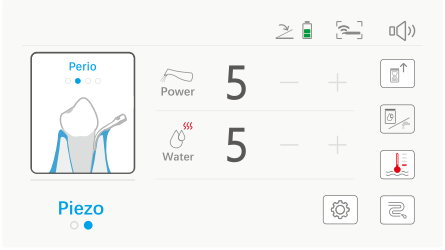
8. Ultrasonic system

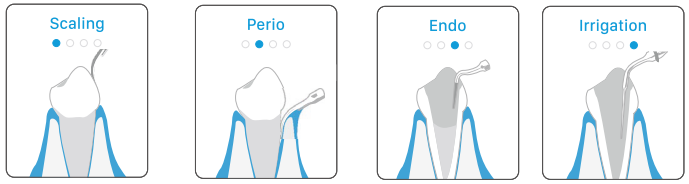
8.1 System selection

- When taking down the ultrasonic handpiece from the handpiece holder, automatically enter the ultrasonic system;
- you can also press Blasting to switch when the handpieces are not taken down.

8.2 Mode selection

The system contains four modes: Scaling, Perio, Endo and Irrigation. Press any position in the following icon to switch modes.





8.3 Power adjustment

Press the "+ " or "-" on the right side of the Power to adjust the power.

8.4 Irrigation volume adjustment

1) During ultrasonic operation, either internal or external water supply can be used. The ultrasonic power and water flow rate can be selected as needed, and the heating function of the water supply can be adjusted to the desired level;
2) Press "+ " or "-" on the right side of the Water to adjust the irrigation volume.

8.5 Heating

1) Press the button to turn on/off the heating function.
2) The heating temperature is adjustable across 5 levels (0–4). The outlet water temperature ranges from approximately 20°C to 40°C:
   - Level 0: Heating function OFF;
   - Levels 1–4: heating and water output are enabled, with temperature increasing progressively as the level increases.
3) Actual outlet water temperature may vary depending on the selected level and water flow rate. Adjust according to your usage needs.

Heating function enabled Heating function disabled

Note

- If the water temperature becomes too high during heating, a pop-up message "Heating function failed" will appear on the screen. In this case, turn off the heating function and continue working. Wait for a while before turning the heating function back on.
- Before surgery, it is recommended to turn on the heating function in advance for preheating. The preheating time is approximately 1 minute. After preheating is complete, the handpiece will deliver hot water within about 30 seconds.
- After adjusting the water flow rate or heating level, wait until the water temperature stabilizes before use. It is recommended to increase the water flow and heating level gradually to reduce the risk of scalding.
- As some heat is dissipated when water flows through the tubing, the actual outlet water temperature may be lower than the set temperature. Additionally, heating performance may be affected by ambient temperature and other factors. Variations in heat loss rate and final temperature may cause fluctuations in the outlet water temperature, which is a normal phenomenon.

8.6 Working

1) Press the pedal to start working, and release to stop;
2) Power level and irrigation volume can be adjusted during working;
3) Press the accelerator pedal hard to start BOOST function that can increase ultrasonic power;



4) After the operation is complete, let the device run under water for 30 seconds to flush Scaler Tips.