



Dental Scaler Instruction Manual

Precautions

- ⚠ Warning:** If you neglect these precautions, it might cause personal injury such as electric shock, fire or damage to the product.
1. This product is not a home appliance. It is only applicable for hospitals and dental clinics. The use of the product must comply with the requirements of the relevant operating specifications and relevant laws and regulations of the medical department. The user must be a professionally trained and qualified dentist or technician. Adequate protection (such as goggles, mask, etc.) should be equipped during operation to prevent cross-infection.
 2. Please use an independent power outlet with protective grounding. Do not unplug the power cord with wet hands.
 3. Please fully insert the power plug of the device into the power socket, please do not use other power source other than the specified voltage.
 4. Do not damage, modify, pull, bend or twist the power cord excessively, and do not place heavy objects on the power cord.
 5. After using the machine, turn off the power switch and pull out the power plug.
 6. When the equipment recovers after power off, please await the equipment to be stable before stepping on the pedal. The operator should release the pedal in time when the power is off.
 7. Please do not place the product on an unstable workbench, such as a swaying table, an inclined surface, or a location subject to vibration.
 8. This equipment is a reusable product. Keep the equipment clean before and after use. Before each use, the handpieces, tips, torque wrench etc. must be disinfected and sterilized. It is suggested to disinfect and sterilize according to the recommended method in Chapter 5 of this manual.
 9. Do not knock or scrape the handpiece. Do not pull the cable forcefully during the use of the equipment to avoid damages.
 10. Do not bend or polish the tips. The tips must be screwed to the handpiece with a torque wrench, and water spray must be generated during operation.
 11. Before each operation, you should work outside the patient's mouth for more than 10 seconds under the condition of water to drain the water in the pipeline at the back of the handpiece
 12. When the tip is damaged or worn out, the vibration intensity might decrease. The operator should replace a new tip in time according to the clinical situation. It is not recommended to use the tip after the abrasion of tip exceed 2mm or more. You can use the tip comparison indicator to check. If the length is out of the first line, the power remains the same; if it is between the first and second line, the power would decreased to 80%; if it reaches or surpass the second line, the power would drop massively, on the occasion, replacement of tip is recommended.
 13. Do not screw or unscrew the tip while stepping on the foot switch, or when the machine is on working.
 14. The inner thread of the tip manufactured by certain manufacturers are rough, rusty and might break the thread system, which will cause irreparable damage to the scaler. Please use corresponding tips of Refine brand.
 15. Choose the appropriate power according to different types of tips. See Annex Tip power chart There are recommended power and water volume for different types of tip in the system. You can double-click the current mode to choose the tip.
 16. Do not use unclean water
 17. Improper cleaning and treatment of titanium implants, porcelain restorations, etc. can easily cause loosening of the adhesive, cracking of the porcelain restorations, or even cracking of the porcelain. The cleaning or treatment of the oral cavity of such patients should be carefully considered.
 18. Noise will be generated during the scaling process. Those who are sensitive to noise can wear earplugs by themselves.
 19. We will be responsible for the safety only when the maintenance, repair and modification of the machine are carried out by the company or its authorized distributors, the replacement parts are from the company, and the operation is on the basis of instruction manual.

20. This equipment has electromagnetic interference. Do not use it around electronic surgery, and be cautious in an environment with strong electromagnetic interference when using this equipment.
21. This equipment does not contain toxic or hazardous substances, and it can be discarded in accordance with the relevant laws and regulations on discarded medical devices.
22. Do not step on the foot pedal when the cable of the air polish handpiece is removed from the main unit.
23. Before using the ultrasonic handpiece, please make sure that the cable of the air polish handpiece is correctly placed on the handle bracket; similarly, before using the air polish handpiece, please make sure that the cable of the ultrasonic handpiece is correctly placed on the ultrasonic handle bracket.
24. The tip must be tightened.
25. The air polishing handpiece nozzle should not be aimed at people.
26. There might be injury if the powder accidentally sprays into the eyes. We strongly recommend that all personnel (doctors, nurses, patients) wear goggles during air polishing treatment.
27. Please do not unload the powder tank when stepping on the pedal or when the machine is working.
28. Before replacing the air polishing handpiece or the nozzle, please use a syringe to blow the moisture at the joints at both ends (especially the gas interface) to prevent moisture from entering the gas path and avoid clogging of the powder in the pipeline.

Contraindications

1. The hemophilia patient is forbidden to use this equipment
2. The patients or the doctors with heart pacemaker are forbidden to use this equipment.
3. Heart disease patients, pregnant women and children should be cautious to use the equipment.
4. Patients with respiratory diseases such as asthma and chronic bronchitis are not allowed to use this device.

Symbol Instruction

Symbol	Implication	Symbol	Implication	Symbol	Implication
	Trademark		See instruction manual		Grounding protection
	Warning and important notes! See the attached documents		Anti-drip equipment		Sterilizable spare parts under high temperature
	Recycling		Manufacturer		Indoor only
	Date of manufacture		BF type applied part		Alternating current
	Power-on button		Power-off button		Power switch
	Ordinary equipment		Power adjustment		Foot pedal plug
	Storage condition, temperature limit: -20°C ~ +40°C		Storage condition, air pressure limit: 70kPa - 106 kPa		Storage condition, humidity limit: 10% - 93%
	Keep dry		Fragile		Compliance with WEEE directive, Discarded as per regulations
	Boost mode		Anhydrous mode		Clean mode

Forward

Guilin Refine Medical Instrument Co., Ltd. is a high-tech enterprise integrating R&D, production and sales of dental products, with a complete quality assurance system.

1 Product Introduction

1.1 Brief introduction

PT X dental scaler combines ultrasound scaler and air polishing scaler. The main features are:

- 1) According to the selected handpiece, automatically switch the working mode.
- 2) Touch LCD screen.
- 3) Special chemical solutions such as hydrogen peroxide, sodium hypochlorite and chlorhexidine can be used to improve the clinical treatment effect.
- 4) LED handpiece enables convenient Clinical operation.
- 5) The automatic frequency tracking system for the best working condition, which brings more stable performance of device.
- 6) Detachable ultrasonic handpiece and air polishing handpiece can be sterilized under high temperature of 134 and high pressure of 0.22MPa.

1.2 Model: PT X

1.3 Scope of application

This product includes an ultrasonic system and an air polish system. The ultrasonic system is used for periodontal treatment in oral clinical treatment to remove tartar and plaque, root canals cleaning; Air polish system is used to remove plaque and pigment, it can also be used for implants maintenance.

1.4 Device configuration

Please refer to the packing list for device configurations.

1.5 Structure and components

The machine consists of main unit, handpiece (ultrasonic handpiece, air polishing handpiece), cable, bottle, tips, dental air polishing powder, torque wrench and foot pedal, Power cord.

1.6 Replacement instruction for main accessories.

Name	Model	Replacement instruction
Air polishing andpiece	XP-1 / XP-2	Reusable and Durable; Please change a new handpiece when the handpiece is blocked and cannot be dredged, or the sealing performance is reduced, or the ventilation pipe is seriously worn out

Ultrasonic handpiece	HY-2L	Reusable and Durable; Please change a new handpiece when the output power drops significantly or does not work.
Power cord	/	Reusable and Durable; Please replace the power cord when it is cracked or non-conductive
Water pipe	/	Reusable and Durable; Please change a new pipe when the water pipe is cracked and leaked.
Tips	refer to the packing list	Please change a new tip when it is worn out. For details, see point 12 of the Safety Precautions.
Torque wrench	/	Reusable and Durable. Please change a new one as per Instruction Manual when its broken.
Foot pedal	RFS05	Reusable and Durable. Please change a new one as per Instruction Manual when its broken.
Water bottle	/	Reusable and Durable. Please change a new one as per Instruction Manual when its broken
Powder tank	/	Reusable and Durable. Please change a new one as per Instruction Manual when its broken.

1.7 Device safety classification

- 1) Classified by operation mode: Continuous operating device
- 2) Type of protection against electric shock: Class I
- 3) Degree of protection against electric shock: BF type
- 4) Degree of protection against harmful ingress of water: Ordinary equipment (IPX0). Foot pedal is anti-drip device (IPX1)
- 5) Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.8 Main technical specification

Specification	PT X
Main Unit Size (mm) Length*Width*Height	320mm330mm120mm
Main unit weight	4.0kg
Handpiece model	HY-2L / XP-1 / XP-2
Control mode	Touch control
Water supply mode	Water supply
Power adapter input	100VAC - 240VAC 50Hz/60Hz
Input power	200VA
Main unit fuse	T1.6AL 250V
Foot pedal shell protection Level	IPX1
Tip output features	Frequency: 30kHz5kHz; Output main vibration offset of tip 1μm ~ 200μm; Semi-offset force 0.1-5N; Output power of tip 3W-20W
Water inlet pressure	0.1bar-5bar (0.01MPa-0.5MPa)
Air inlet pressure	5.5bar-7.5bar (0.55MPa-0.75MPa)
Water temperature	≤ 45°C

1.9 Operation Environment

Environmental temperature: +5°C - +40°C , Relative humidity: 30% - 75%, Atmospheric pressure: 70kPa - 106kPa, Cooling water temperature: +5°C - +25°C

2 Installation

2.1 Main Unit Diagram

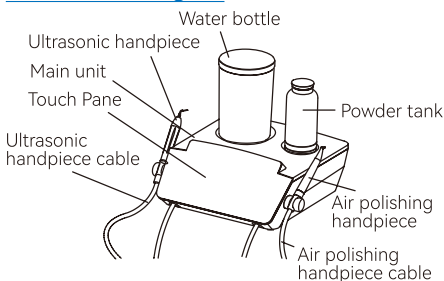


Figure 1 Front view

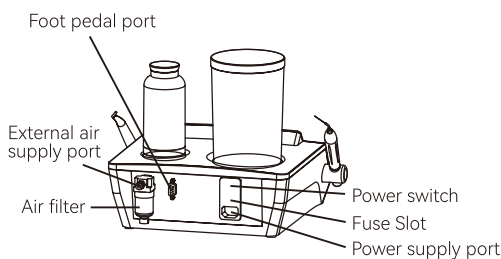


Figure 2 Back view

2.2 Touch panel

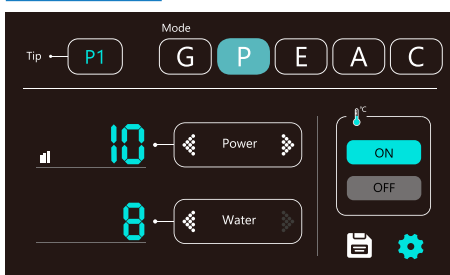
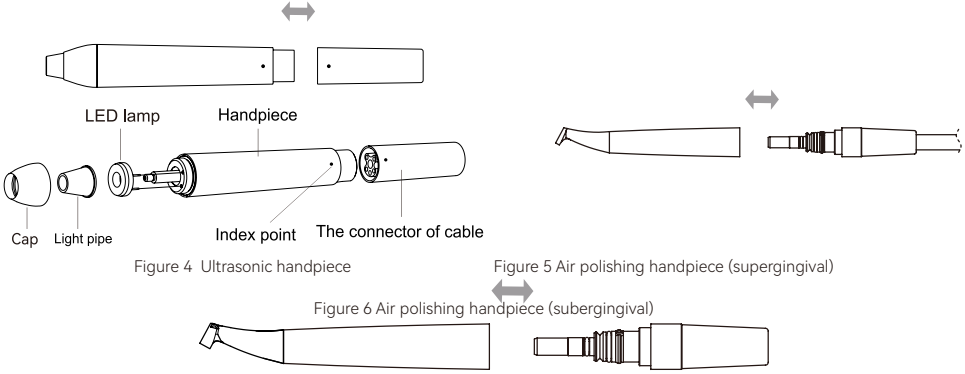


Figure 3 Touch panel diagram

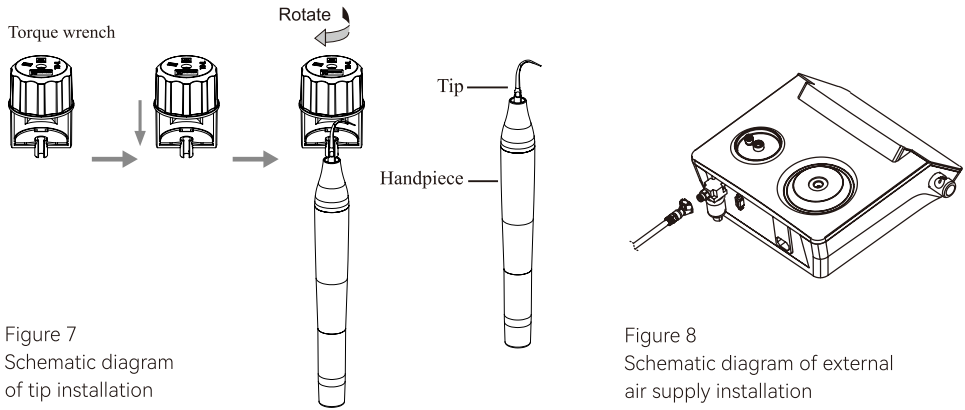
Symbol Implication

Symbol	Implication	Symbol	Implication	Symbol	Implication
	Tip currently in use	G	Scaling mode	P	Periodontal mode
E	Endo mode	A	Air polishing mode	C	Cleaning mode
	Data storage function		Setting		Water hitting switch
	Turn down water vol-ume/ power/air pressure		Turn up water vol-ume / power / air pressure		

2.4 Schematic diagram of handpiece



2.5 Schematic diagram of tip installation



2.6 Installation procedures

- 2.6.1 Open the package, check whether the equipment is complete as per the packing list, and place the main unit on a solid place, facing the operator.
- 2.6.2 Plug the external air pipe connector into the air intake connector on the back of the main unit (as shown in Figure 8).
- 2.6.3 Fill the water bottle with an appropriate amount of water, and fix the water bottle into the sink seat directly above the main unit (it is recommended to smear a layer of petroleum jelly on the O-ring at the bottom of the water bottle to facilitate the plugging and unplugging of the water bottle)
- 2.6.4 Match the pedal (Wired or wireless) as per personal preference.
 - 1) Wired mode: Connect one end to the foot pedal port of the foot pedal, and the other end to the foot pedal port on the main unit.
 - 2) Wireless mode: Remove the pedal battery cover and install 2 AA batteries. Switch on the main unit and the foot pedal can be connected and controlled (when leaving the factory, the Bluetooth foot pedal and the main unit have been paired and connected. If you change the foot pedal, please enter the "System Settings" to match the Bluetooth foot pedal.)
- 2.6.5 Connect the ultrasonic handpiece and the air polishing handpiece into the corresponding cables, and place the handpiece on the brackets on both sides of the main unit. The ultrasonic handpiece is on the left and the air polishing one is on the right.
- 2.6.6 Connect the power cord with the power port on the back of the main unit, and then plug in the 220VAC power, as shown in Figure 2.

Warning 1: When the power cord is connected to the network power supply, it must be connected to a protective ground; When the power cord is connected to the network power supply, do not place or install the product where it is difficult to disconnect the network power supply.

3 Function and Operation

3.1 Multi-functional foot pedal

- 3.1.1 Choose the mode of foot pedal according to 2.6.4, place it in the flat ground
- 3.1.2 The pedal and its functions are shown below:

Button	Operating mode	Function	
		Ultrasonic system	Air polishing system
A	Standard	Vibration + Water	AirPowder + water
B	No-water mode	Vibration	Air only
C(A+)	Boost mode	5-Level increase in Power	5-Level increase in air pressure
D	Cleaning mode	Water only	Water + Air

Note: Under Boost mode, Power or air pressure would be increased by 5 grades, the maximum is the 12th grade. After releasing button

C, it will automatically return to the previously set grade.

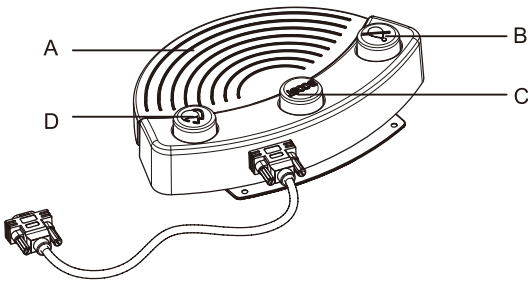


Figure 9
Schematic diagram of multi-function foot pedal

3.2 Ultrasonic system

3.2.1 Scaling

- 1) Turn on the power switch and pick up the ultrasonic handpiece, afterwards the panel will automatically shift to Ultrasonic mode.
- 2) Press the G button to enter Scaling mode.
- 3) Select the tip and tighten it on the handpiece by torque wrench.
- 4) When stepping on the button A, tip vibrates with LED on and water emits; Release the button, vibration and water stop, LED will be off 10 seconds later.
- 5) The handpiece is generally held in a pen-holding position.
- 6) The frequency is extremely high when the machine is on working. It can remove the tartar with the tips softly stroke on the teeth surface like erasing motion. DO NOT stay long or put overmuch pressure on the teeth.
- 7) Vibrating intensity: Adjust the vibrating intensity according to your need. The setting power is level 3, please adjust the vibrating intensity according to the teeth sensitivity and hardness of calculus during clinical application.
- 8) Water volume: Please adjust the volume on the panel.
- 9) During clinical scaling, please keep the side of the tip adapt to the tooth surface horizontally, with light lateral pressure to allow the tip vibrate freely.
- 10) After operation, please keep device working for 30s with water to flush the handpiece and tips; Remove the tip and get it sterilized.

3.2.2 Periodontal treatment

- 1) Use a torque wrench to tighten the periodontal treatment tip to the ultrasonic handpiece. Click the P button on panel to enter the periodontal treatment mode.
- 2) The operation and adjustment methods are similar to Scaling mode.

3.2.3 Endodontic irrigation

- 1) Tighten the endo file to the handpiece by endo wrench.
- 2) Click on the E button and enter the Endo mode.
- 3) The default power is level 1 under Endo mode, operator can adjust the power according to the need in clinical treatment.
- 4) Select the appropriate Endo file and slowly place it into the root canal of the patients teeth. Step on the foot pedal to start ultrasonic endodontic irrigation.
- 5) During clinical cleansing, the file should not be pressed too tightly when it is in the root canal
- 6) Do not step on the pedal before the file is in the root canal.
- 7) The suggested power range for endodontic irrigation is level 1-level 5.

3.3 Air polishing system

- 1) Add appropriate amount of powder to the powder tank (the amount of powder added should be between "Max" and "Min" marked on the the tank), then tighten the upper cover of the powder tank, and fix the powder tank on the main unit.
- 2) Pick up the Air polishing handpiece, afterwards the panel will automatically shift to Air polishing mode.
- 3) Adjust the water volume and air pressure, aim the nozzle at a pool, press the foot button A, and confirm that the nozzle can spray gas, powder and water spray normally before use.
- 4) Before Air polishing treatment, please wear goggles and veil on the face of the patient. Users should wear goggles or a protective mask.
- 5) The handpiece is generally held in a pen-holding position.
- 6) Adjust the water volume and air pressure to an appropriate level. The recommended water volume starts at level 5 and the air pressure starts at level 3. According to the sensitivity of the patient's teeth and hardness of the dental plaque, adjust the water volume and air pressure at any time during the clinical process; increasing the air pressure will enhance cleaning effect, but will weaken the polishing effect; increasing the amount of water will enhance the polishing effect, but will weaken the cleaning effect.
- 7) The nozzle should be aligned with the tooth surface during the cleansing, but avoid direct contact. Keep the nozzle and the tooth surface at a distance of 3-5mm at 30-60 angle. The smaller the angle, the larger the cleaning area; during the cleansing, please Perform a small circular motion on the surface of the tooth.
- 8) The air/powder mixture reflected from the tooth surface should be evacuated by using a strong suction device on the dental unit during treatment.
- 9) After treatment, adjust the water volume to the maximum level, and polish the surface of teeth.

3.4 Cleaning Mode

It is recommended to flush and disinfect the pipeline of the device every day. "Cleaning" mode allows cleaning and disinfection of the pipeline to reduce the accumulation of crystals and the number of bacteria in the pipeline.

- 1) Fill a water bottle with distilled water or demineralized water.
- 2) Pick up the ultrasonic handpiece, point the handpiece at the sink, click the Cleaning button on the screen, and press the button D on foot pedal to start cleaning the pipeline. Then, the pedal can be released.
- 3) After cleaning for 30 seconds, the device will automatically stop the Cleaning mode. You can also press the button D on foot pedal again in the Cleaning mode or click Purge on the screen to stop cleaning.
- 4) After cleaning, put the ultrasonic handpiece back into the bracket. And then, pick up the air polishing handpiece, point the handpiece nozzle at the pool, and click the Cleaning button again, so that the device will automatically blow out the residual powder in the pipeline and release the high pressure gas in powder tank.
- 5) After cleaning for 20 seconds, the device will automatically exit the Cleaning mode. You can also click Purge on the screen to stop cleaning.

3.5 Setting

- 1) Click "ON" / "OFF" to turn on or off the heating function. (According to the actual water output, the water temperature is different).
- 2) Click the "Settings" button at the bottom right corner of the screen to enter the "System Settings" interface
- 3) Click Calibration button, the system will automatically calibrate the air pressure to the value set in the program
- 4) The Bluetooth pedal has been matched to the machine, any subsequent replacement of foot pedal or main unit needs to make new pair.

4 Troubleshooting

4.1 Troubleshooting

Fault	Possible cause	Solutions
The tip does not vibrate and no water comes out after powering on and stepping on the foot switch	Poor contact of power plug	Plug the power supply well
	Poor contact of pedal switch	Plug the foot pedal plug well.
	The fuse is broken.	Replace a T1.6AL 250V fuse
	Out of battery under wireless pedal mode	Replace a new battery
	Poor connection under wired pedal mode	Connect the wire and screw it well
	Main unit fault	Contact local distributor or the manufacturer.
The tip does not vibrate and there is water spray after power on and stepping on the foot pedal.	Loose tip	Tighten the tip
	The connection between the tail wire and the circuit board is loose.	Contact local distributor or the manufacturer.
	Handpiece fault	Contact local distributor or the manufacturer.
	cable fault	Contact local distributor or the manufacturer.
The tip vibrates but there is no water spray after power on and stepping on the foot pedal.	The resistance of the diaphragm pump becomes larger, and the torque of the low water retaining capacity is insufficient	Turn up the water volume.
	Impurity in the solenoid valve	Contact local distributor or the manufacturer.
	Water line clogging	Contact local distributor or the manufacturer.
After power-off, there is still water spray.	Impurity in the solenoid valve	Contact local distributor or the manufacturer.
Handpiece heating	Water volume is too small	Turn up the water volume.
	Device fault	Contact local distributor or the manufacturer.
Water spray is too small	Water volume is too small	Turn up the water volume
	Water line clogging	Contact local distributor or the manufacturer.
Weakened tip vibration	Tip is not tightened.	Tighten the tip
	Tip is loose	Tighten the tip
	Broken tip Note1	Replace the tip
Outlet water temperature is too high (over 45° C)	Thermocouple fault	Contact local distributor or the manufacturer.
The Endo file does not vibrate	The nut is not tightened	Tighten the nut
There is no air spray and water spray after power on and stepping on the foot pedal.	Loose contact of power supply plug.	Plug the power supply plug well.
	Poor connection under wired pedal mode	Connect the wire and screw it well
	Out of battery under wireless pedal mode	Replace a new battery
The nozzle does not spray gas but there is water spray after power on and stepping on the foot pedal.	Nozzle clogging	Dredge the nozzle
	Handpiece clogging	Dredge the handpiece
	Clogging of handpiece tail cord	Remove the tail cord from the main unit, dredge the tail cord or replace it.
	Solenoid valve fault	Contact local distributor or the manufacturer.
There is air flow but no water spray after power on and stepping on the foot pedal.	The resistance of the diaphragm pump becomes larger, and the torque of the low water retaining capacity is insufficient	Turn up the water volume
	Impurity in the solenoid valve	Contact local distributor or the manufacturer.
	Water line clogging	Contact local distributor or the manufacturer.
Leaking air of powder tank	The O-ring on base of powder tank is broken	Unscrew the powder tank base, take out the damaged O-ring, replace the O-ring of the same specification attached, and screw on the powder tank base
	Broken O-ring	Replace the O-ring
	There is powder residue at the thread, so that the screw is not in place.	Remove the residual powder at the thread part.
	The upper cover of powder tank is broken.	Replace the upper cover of powder tank.
	The thread of powder tank is broken so that the screw is not in place.	Replace a powder tank
Water leakage of handpiece	Broken O-ring of handpiece	Replace the O-ring
The air powder scaling efficiency is reduced.	The powder in tank is not enough.	Add powder to the tank.
	Powder residue in pipe, handpiece, or nozzle passage	Clean the passage with a fine needle and blow it off with compressed air.
Touch panel pops up prompt message	No powder tank	Check the powder tank and reinstall.
	Air pressure is too high or too low	Increase the external air pressure input, Input air pressure range requirements: 5.5bar-7.5bar(0.55Mpa-0.75MPa)
	Pick up two handpieces at a time	Before stepping on the pedals, please pick up only one handpiece
	no handpiece has been picked up	Before stepping on the pedals, please pick up only one handpiece
	The handpiece does not match the mode configuration	Please select the correct handpiece and mode

Note: if the problems cannot be solved, please contact local distributor or the manufacturer.

4.2 Notes

Note 1 If the tip is surely tightened and there is water mist spray, the tip is considered to be damaged with the following phenomena:

- 1) The vibration intensity of the tip and the degree of water atomization are significantly weakened.
- 2) The tip makes a harsh click sound during operation.

5 Cleaning, disinfection, and sterilization

5.1 Initial processing

5.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle. Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

5.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

Let the device works for 20-30 seconds at maximum water volume to separately flush the Ultrasonic handpiece, tip, Air polishing handpiece, and nozzle;

Remove the handpieces from the device and rinse away the dirt on the surface of handpieces and their accessories (tip, nozzle and torque wrench) with pure water (or distilled water/deionized water);

Dry the handpieces and its accessories with a clean, soft cloth and place it in a clean tray.

Precautions:

The water used here must be pure water, distilled water or deionized water.

5.2 Cleaning

The cleaning of handpiece and its accessories should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

5.2.1 Automated cleaning

△ The cleaner is proved to be valid by FDA, CE certification or in accordance with EN ISO 15883.

△ There should be a flushing connector connected to the inner cavity of the product. The cleaning procedure is suitable for the handle, and the flushing period is sufficient. But ultrasonic cleaning is not allowed for Ultrasonic handpiece.

△ It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the section Disinfection.

Precautions:

1) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the handpiece.

2) The water temperature should not exceed 45, otherwise the protein will solidify and it is difficult to remove.

5.2.2 Manual cleaning

△ Soak the handpieces and its accessories in a cleaning agent (such as multi-enzyme). The soaking time and concentration should at least reach the time and concentration specified by the detergent manufacturer;

△ Carefully clean the surface of the handpieces and its accessories with a disposable soft cloth or soft brush to remove any visible dirt on the surface;

△ Rinse the handpieces and its accessories under clean running water (desalted water, distilled water or deionized water) for at least 5 times with duration of no less than 60 seconds for each time.

△ Check whether the cleaned parts are clean or damaged. If the cleaning is not complete, repeat the previous cleaning procedures.

△ The intrinsic suitability of the handpieces and its accessories for effective cleaning using the above procedure was verified by a validated facility.

Precautions:

1) The cleaning agent used here must be compatible with the handpieces and only freshly prepared solutions can be used.

2) The water temperature should not exceed 45, otherwise the protein will solidify and it is difficult to remove.

5.3 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Auto- mated disinfection is preferred if conditions permit.

5.3.1 Automated disinfection

If possible, the disinfection cycle should be in accordance with EN ISO 15883. Please ensure that the following standards are met when selecting a sterilizer system:

△ The sterilizer is FDA approved, CE certified or in accordance with EN ISO 15883.

△ Use high temperature disinfection function. The temperature does not exceed 134 °C. The temperature cannot exceed 20 minutes.

△ The sterilizer has a flush connecting piece that is connected to the interior of the handpiece.

△ The cleaning procedure is suitable for the handle and the flushing cycle is sufficient (5-10 minutes).

△ Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

△ The air used for drying must be filtered by HEPA.

△ Regularly repair and inspect the disinfector.

Cleaning and disinfecting steps by using Washer-disinfector

Carefully place the handpieces and its accessories in the disinfection basket. Fastening of the handpieces and its accessories if only permissible if they are freely moveable in the fixture. The handpieces and its accessories are not permitted to make contact with one another.

Use a suitable rinsing adaptor, and attach the handpieces to the rinsing connections of the washer-disinfector so that the surface and internal water lines can be flushed during cleaning process.

Start the program. After the program is finished, remove the handpieces and its accessories from the washer-disinfector, inspect (refer to section Inspection and Maintenance) and packaging (refer to chapter Packaging). Dry the handpieces and its accessories repeatedly if necessary (refer to section Drying).

The intrinsic suitability of the handpieces and its accessories for effective cleaning and disinfection using the above automated cleaning and disinfection procedures was verified by a certified facility.

Precautions:

1) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and pre- cautions.

2) With this equipment, cleaning, disinfection and drying will be carried out together.

3) Cleaning: (a) The water temperature should not exceed 45, otherwise the protein will solidify and it is difficult to remove. (b) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c) The cleaning agent must be compatible with the handpiece. Please follow the concentration and contact time provided by manufacturer.

5.3.2 Manual disinfection

Tools: containers for disinfectant, water guns, air guns, trays

Place the handpieces and its accessories in a disinfectant (e.g. 75% medical alcohol or 2% glutaraldehyde solution) for at least the time specified by the manufacturer.

Remove the handpieces and its accessories from the disinfectant and rinse it with purified water, distilled water or deionized water for at least 5 times for not less than 60 seconds of each time.

Dry the handpieces and its accessories with filtered compressed air (maximum pressure: 3 bar).

After the program is finished, remove the handpieces and its accessories from the washer-disinfector, inspect (refer to section Inspection and Maintenance) and packaging (refer to chapter Packaging). Dry the handpieces and its accessories repeatedly if necessary (refer to section Drying).

Verification of the fundamental suitability of the handpieces and its accessories for effective manual cleaning and disinfection was provided by a verified testing laboratory.

Precautions:

- 1) The disinfectant used to configure the disinfectant must be compatible with the handpieces and cleaning agent, and must be tested effective (e.g., DGHM, FDA approved or CE certified).
- 2) The disinfectant must be used in accordance with the concentration and contact time specified by manufacturer.
- 3) The disinfectant used must be freshly prepared solutions and no foaming is allowed.

5.4 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

- 1) Spread a clean white paper (white cloth) on the flat table, point the handpieces and its accessories against the white paper (white cloth), and then dry the handpieces and its accessories with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the drying is completed.
- 2) It can be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80 - 120 and the time should be 15 - 40 minutes.

Precautions:

- 1) The drying of product must be performed in a clean place.
- 2) The drying temperature should not exceed 138;
- 3) The equipment used should be inspected and maintained regularly.

5.5 Inspection and maintenance

- 1) Check the handpieces and its accessories. If there is still visible stain on the handpieces and its accessories after cleaning/ disinfection, the entire cleaning/disinfection process must be repeated.
- 2) Check the handpieces and its accessories. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.
- 3) Check the handpiece. If the structural parts (O-ring, LED light, light guide, etc.) are broken, please replace it before use. But the replaced parts must be cleaned, disinfected and dried.
- 4) If the service time (number of times) of the Ultrasonic handpiece reaches the specified service life (number of times), please replace it in time.
- 5) Do not use the machine when the machine is being cleaned/disinfected/sterilized.

5.6 Packaging

The disinfected and dried handpieces and their accessories are assembled and quickly packaged in a medical sterilization bag (or special holder, sterile box).

Precautions:

- 1) The package used conforms to ISO 11607;
- 2) It can withstand high temperature of 138 and has sufficient steam permeability;
- 3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;
- 4) Avoid contact with parts of different metals when packaging.

5.7 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

The highest sterilization temperature is 138;

The sterilization time is at least 4 minutes at a temperature of 132 / 134 and a pressure of 2.0 bar - 2.3 bars.

Allow a maximum sterilization time of 20 minutes at 134.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Precautions:

- 1) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
- 2) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

4) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

Fractionation pre-vacuum procedure: a procedure for steam sterilization by repeating pre-vacuum, the procedure used here is steam sterilized by three pre-vacuums.

6 Transport, storage and maintenance

6.1 Transport

6.1.1 Excessive impact and shake should be prevented during transport. Lay it care fully and lightly.

6.1.2 Do not put it together with dangerous goods during transport.

6.1.3 Avoid being exposed to sun, rain, and snow during transport.

6.2 Storage

6.2.1 The device should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry, and ventilated place.

6.2.2 Do not store the machine together with articles that is poisonous, combustible, caustic, or explosive.

6.2.3 This machine should be stored in a room where the relative humidity is 10% - 93%, atmospheric pressure is 70kPa - 106kPa, and

the temperature is -20°C - +40°C .

6.2.4 When the device is not in use, turn off the power supply and unplug the power plug. If it is not used for a long time, it should be energized and connect to water and air once a month for five minutes.

6.3 maintenance

6.3.1 Air filter

1) When water accumulate in the filter, turn the knob at the bottom of the filter counterclockwise to drain the water, and tighten the knob clockwise.

2) Replacement of the filter element: Use a filter wrench to unscrew the transparent cover of the air filter, then use the wrench to unscrew the black nut at the lower end of the filter element, remove the white filter element and discard it into the trash can, replace it with a new filter element, and reinstall the black nut and transparent shell. It is recommended to replace the filter element every 24 months, and the spare filter element is included in the accessory.

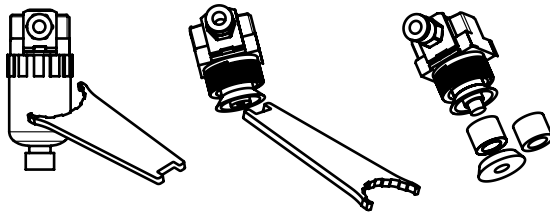


Figure 10 Schematic diagram of filter element replacement

7 Environmental Protection

The instrument contains no hazardous components and can be disposed of and destroyed in accordance with the relevant local regulations.

Part	Toxic or harmful substances or elements					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
Main unit	○	○	○	○	○	○
andpiece	○	○	○	○	○	○
Tip	○	○	○	○	○	○
Nozzle Foot pedal	○	○	○	○	○	○
Mechanical elements, including bolts, nuts, washers, etc.	○	○	○	○	○	○

○: Indicates that the content of the toxic substance in all homogeneous materials of the part is below the limit requirement stipulated in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.
 X: indicates that the content of the toxic substance in at least one of the homogeneous materials of the part exceed the limit requirement specified in SJ/T-11363-2006. Please dispose according to the local laws or consult with dealer from whom you purchased it about waste disposal.

8 After service

8.1 After the equipment is sold, the manufacturer will be responsible for quality problem according to the warranty card. For specific items, please refer to the warranty instructions in the warranty card.

8.2 This product does not contain self-maintaining parts. All maintenance, adjustment, calibration, and modification of technical parameters of the product can only be carried out by the technicians or special repair shops. If the customer needs to repair by himself, the manufacturer can provide circuit diagrams, component lists, legends, calibration rules, or other information necessary to help the user's qualified technicians repair the equipment parts designated by the manufacturer, but the manufacturer will not bear the consequences arising therefrom.

8.3 The user must use the original accessories, please contact your local dealer or the manufacturer to purchase. It is forbidden to use accessories of other brands to avoid damage to the equipment or other dangers.

8.4 After the handpiece, tips and other accessories are damaged, users should not repair them by themselves. Please purchase new parts and replace them before use. If you need relevant information, please contact the manufacturer.

9 EMC-Declaration of conformity

Notice: 1) Without the express consent of Guilin Refine Medical Instrument Co., Ltd., unauthorized changes or modifications to the equipment may cause electromagnetic compatibility problems of this equipment or other equipment.

2) The design and test of the PT X dental scaler conform to the operating regulations of electromagnetic compatibility. Its basic performance is: the tip installed at the front end will vibrate when working, water will spray out, and the front end of the handpiece will emit light at the same time.

3) Note: During the electrical fast transient burst test, there may be situations in which the power cannot be adjusted due to the interference of the touch buttons. This situation will not affect the power output of the whole machine, and it can be restored by itself after the test is completed. Consultation A clinician with professional training experience and field including the use of special equipment or systems to determine that the risk is acceptable.

Warning:

1) The equipment or system should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed to verify that it can operate normally under the configuration used.

2) The operation of the PT X dental scaler at a value lower than the minimum amplitude or minimum value specified in this manual may lead to inaccurate consequences.

3) Except for transducers and cables sold by equipment or system manufacturers as spare parts of internal components, the use of accessories, transducers and cables outside the regulations may result in increased emission of the equipment or system or reduced immunity.

4) The use of accessories, transducers or cables outside of the regulations together with equipment and systems may result in an increase in the emission of the equipment or system or a decrease in immunity.


Guidance and manufacturer's declaration of electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model PT X uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B	PT X is suitable for being used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration - electromagnetic immunity			
The model PT X is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT X should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors 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	± 2 kV for power supply lines ± 1 kV for Input/Output lines	± 2 kV for power supply lines, ± 1 kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line	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 (>95% dip in UT) for 0.5 cycle 40% Ur (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT for 5 cycles 70% UT (30% dip in UT for 25 cycles <5% UT (>95 % dip in UT) for 5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model PT X requires continued operation during power mains interruptions, it is recommended that the model PT X be powered from an uninterruptible power adapter or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE Ur is the ac mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The model PT X is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT X 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 Radiated RF IEC 61000-4-3	3Vrms 150kHz - 80MHz 3V/m 80MHz - 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model PT X, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5\sqrt{P}] \times P^{1/2}$ $d = 1.2 \times P^{1/2}$ 80 MHz - 800 MHz $d = 2.3 \times P^{1/2}$ 800 MHz - 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz - 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
A) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model PT X is used exceeds the applicable RF compliance level above, the model PT X should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model PT X. B) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the model PT X			
The model PT X is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model PT X can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model PT X is recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz ~ 80MHz d=1.2	80MHz ~ 800MHz d=1.2	800MHz ~ 2.5GHz d=2.3
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz - 800 MHz, the separation distance for the higher frequency range applies.

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

PT X has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

10 Statement

Refine reserves the right to modify the product technology, accessories, instruction manual and product packaging content at any time without notice. The product is subject to the actual product, and the pictures are for reference only. The final interpretation right belongs to Guilin Refine Medical Instrument Co., Ltd.

(Refer to the product packaging label for the product production date.)

After service and warranty instruction

1 Period validity:

Five year's free repair for the main unit, one year's free repair for the handpiece from the date of purchase. Lifetime maintenance.

2 Range of warranty:

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

3 The followings are beyond our warranty:

- 1) The damage caused by disobeying the operation instruction or lack of the needed condition.
- 2) The damage caused by unsuitable operation or disassembly without authorization.
- 3) The damage caused by unadvisable transportation or preservation.
- 4) There isn't the seal of distributor or the warranty card isn't filled in completed.

After service and Warranty Instruction

Name of Customer	
Address	
Post Code	
Tel	
E-mail	
Purchase Date	
Distributor	
Model	
Product No.	
Handpiece No.	
Production Date	



Guilin Refine Medical Instrument Co., Ltd.
 No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China
 Tel: +86-773-7796686 Email: refine@refine-med.com
 Website: <http://www.refine-med.com>



MedNet EC-REP GmbH
 Borkstrasse 10 · 48163 Muenster · Germany