Instruction Manual for APT Dental Scaler

Guilin Refine Medical Instrument Co., LTD.

RF-APT-M001 Version: 1.1 20230203

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. 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	Instruction	Symbol	Instruction	Symbol	Instruction
	Trademark		Foot switch		Refer to instruction manual/booklet
	Caution	IPX1	Protected against dripping water	134℃	Sterilizable in a steam sterilizer (autoclave) at 134℃
	Recovery		Manufacturer		For indoor use only
	Date of manufacture		Type B applied part		Alternating current
	Power-on button		Power-off button	ON/OFF	Power switch

-20℃ +40℃	Temperature limit: -20℃- +40℃	70kPa 106kPa	Atmospheric pressure limitation: 70kPa-106kPa	10% 93%	Humidity limitation: 10%-93%
	Keep dry		Fragile, handle with care		Waste electrical and electronic equipment
	Class II equipment	G	Scaling mode	P	Periodontal mode
E	Endo mode	A	Air polishing mode	C	Cleaning mode
SN	Serial number	MD	Medical device	UDI	Unique device identifier

Foreword

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

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

a) According to the selected handpiece, automatically switch the working mode.
b) Touch screen to choose function and power.
c) Special chemical solutions such as hydrogen peroxide and chlorhexidine can be used to improve the clinical treatment effect.
d) LED handpiece enables convenient Clinical operation.
e) The automatic frequency tracking system for the best working condition, which brings more stable performance of device.
f) The automatic frequency tracking system for the best working condition, which brings more stable performance of device.
g) Detachable ultrasonic handpiece and air polishing handpiece can be sterilized under high temperature of 134℃ and high pressure of 0.22MPa.

1.2 Model: APT

1.3 Intended purpose

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. The device is supposed to be used at adults and children in hospitals and dental clinics, and should be used by trained and qualified dentist.

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, Transformer.

1.6 Replacement instruction for main accessories.

Name	Model	Replacement instruction
Air polishing handpiece	XP-1 XP-2 (Optional)	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.
Transformer	RFT01	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.
Scaler tip	Refer to 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 it's broken.
Foot pedal	RFS02	Reusable and Durable. Please change a new one as per Instruction Manual when it's broken.
Water tank	/	Reusable and Durable. Please change a new one as per Instruction Manual when it's broken.
Powder tank	/	Reusable and Durable. Please change a new one as per Instruction Manual when it's broken.

1.7 Device safety classification

1) Classified by operation mode: Continuous operating device
2) Type of protection against electric shock: Class II
3) Degree of protection against electric shock: B 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	APT
Dimension(mm) Length×Width×Height	320mm×310mm×120mm
Main unit weight	3kg
Handpiece model	HY-2L, XP-1, XP-2 (Optional)

Control Panel	Touch panel
Water supply	Self water supply
Power supply	AC 220-230V 50/60Hz
Input power	50VA
Main unit fuse	T1.6AL 250V
Foot pedal shell protection Level	IPX1
Tip output features	Frequency: 30kHz±5kHz, Output main vibration offset of tip: 1μm ~ 200μm, semi-offset force: 0.1 ~ 5N, Output power of tip: 3W ~ 20W
Air pressure	5.5bar ~ 7.5bar(0.55MPa ~ 0.75MPa)
Software version	1.0.0

1.9 Operation environment

1) Environment temperature: +5° C-+40° C
2) Relative humidity: 30%-75%
3) Atmosphere pressure: 70kPa-106kPa
4) Cooling water temperature: +5℃ ~ +25℃

2 Installation

2.1 Main unit diagram

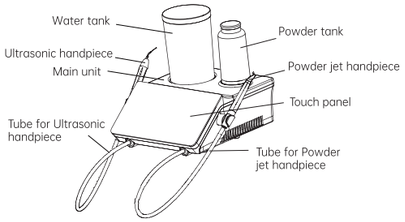


Figure 1 Front of Main Unit

2.2 Back of Main Unit

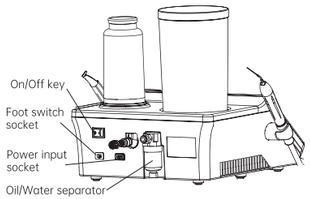


Figure 2 Back of Main Unit

2.2 Touch panel

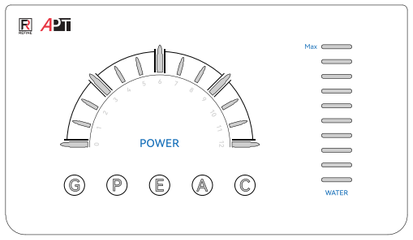


Figure 3 Touch Panel

G: General
P: Periodontal
E: Endodontic
A: Powder jet
C: Clean
POWER: Power adjustment
WATER: Water adjustment

2.4 Handpiece

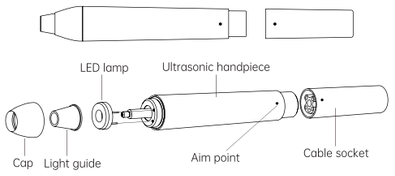


Figure 4 Ultrasonic handpiece

Figure 5 XP-1 handpiece

Figure 6 XP-2 handpiece

2.5 Schematic diagram of tip installation

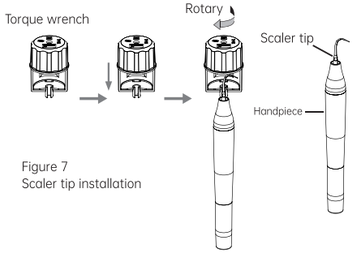


Figure 7
Scaler tip installation

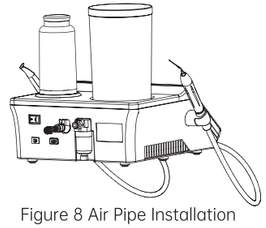


Figure 8 Air Pipe Installation

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 8 Plug the external air pipe connector into the air intake connector on the back of the main unit(as showed 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 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.
2.6.5 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 Turn off the power switch, 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: 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 Foot switch

Choose the mode of foot pedal according to 2.6.4, place it in the flat ground.

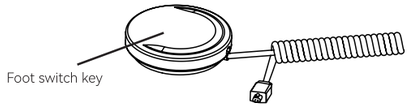


Figure 9 Foot switch

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 General 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 patient's 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, 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.
4) After cleaning, click "A" on the touch panel to stop cleaning.

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 holder does not open properly	Pull the holder out
The tip does not vibrate and there's water spray after power on and stepping on the footswitch	Loose tip	Tighten the tip
	The connection between the tail wire and the circuit board is loosed	Contact local distributor or the manufacturer.
	Handpiece fault	Contact local distributor or the manufacturer.
	cable fault	Contact local distributor or the manufacturer.
The tip does not vibrate and there's water spray after power on and stepping on the footswitch	Water volume not turn on	Turn up the water volume(Note1)
	Impurity in the solenoid valve	Contact local distributor or the manufacturer.
	Water line clogging	Use syringe to Dredge the water line(Note2)
Water leak from handpiece after the machine turned off	Impurity in the solenoid valve	Contact local distributor or the manufacturer.
Handpiece heating	Water volume is too small	Turn up the water volume(Note1)
	Device fault	Contact local distributor or the manufacturer.
Water spray is too small	Water volume is too small	Turn up the water volume (Note1)
	Water line clogging	Use syringe to Dredge the water line(Note2)
Weakened tip vibration	Tip is not tightened.	Tighten the tip
	Tip is loose	Tighten the tip
	Broken tip (Note1)	Replace the tip
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
	The holder does not open properly	Pull the holder out
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.
The nozzle does not spray water but there is gas coming out after power on and stepping on the foot pedal.	Water volume not turn on	Turn up the water volume(Note1)
	Filter clogging	Clean the filter according to article 6
	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.
Power, water indicator shows 1 lamp glitter	Warning 01 means 2 handpieces taken off from the holder	Put the unuse handpiece back to the holder
Power, water indicator shows 2 lamps glitter	Warning 02 means no handpiece taken off from the holder	Take up 1 handpiece

Power, water indicator shows 4 lamps glitter	Warning 04 means air line faulty	Same solution as " The nozzle does not spray gas but there is water spray after power on and stepping on the foot pedal."
Power, water indicator shows 5 lamps glitter	Warning 05 means the powder tank not installed properly	Install the powder tank properly

Note: Please contact local distributor or the manufacturer if the machine still can not work after the procedure as showed above.

4.2 Notes

Note 1: The water volume indicator shows on the touch panel, when choose level 1 means water output turned off.

5 Cleaning, disinfection, and sterilization

5.1 Please conform to the recommendations of the manual "Reprocessing Instructions of Cleaning, Disinfecting and Sterilizing" delivered with your product regarding the procedure of cleaning, disinfecting, sterilizing and packing of the components. Follow present-day regulations enforced in the country about reprocessing. The use of scouring powder or an abrasive sponge will damage its surface.

5.2 The detachable handpiece, scaling tips, endochuck, torque wrench, endo wrench, LED lamp and Light conductor (the handpiece without LED lamp) can be sterilized. The undetachable handpiece, cable and water pipe cannot be sterilized.

⚠ Notice:

a) Clean in the handpiece with compressed air before sterilization.

b) Be sure that the scaling tip has been unscrewed from the handpiece and it cannot be sterilized with others.

c) Please notice whether the outer of the handpiece is damaged during the treatment and sterilization. Don't smear any protective oil on the surface of handpiece.

d) There are two waterproof "O" rings at the end of the handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce their using life. Change a new one once it is damaged or worn excessively.

e) The following sterilizing methods are forbidden:

- Boil in water.
- Dip in iodine, alcohol and glutaraldehyde.
- Bake in oven or microwave oven.

⚠ Notice: We are not responsible for any damage caused in the above items.

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℃ - +55℃.

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, re- place 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.

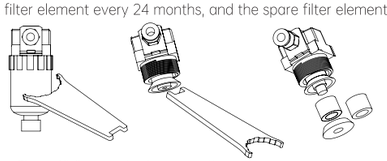


Figure 10 Schematic diagram of filter element replacement

7 Environmental protection, disposal and scapping

The equipment does not contain any harmful components. After the device is out of its service life, please dispose it in accordance with the Waste Electrical and Electronic Equipment (WEEE) directives and the medical waste disposal regulations of your country.

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

9.1 Notice

The ME EQUIPMENT or ME SYSTEM is suitable for hospitals and dental clinics.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

List of all cables

NO	Name	Length	Shielded or not	Detachable or not	Note
1	Power supply cord (input terminal)	1.85m	No	Yes	/
2	Power supply cord (output terminal)	1.45m	No	Yes	/
3	Foot switch cord	2.5m	No	Yes	/
4	Handpiece tail cord	2.0m	No	No	/

Accessories

NO	Name	Model	Connection method	Note
1	Handpiece	XP-1 XP-2 HY-2L	Plug	/
2	Transformer	RFT01	Plug	/

Essential performance

The dental scaler has neither life sustaining functions nor diagnostic of life supporting functions.

The following functions are observed:

- Continuous working of ultrasound
- Continuous working of water flow, air and powder flow when using air polishing system
- Continuous light on handpiece

When the me equipment essential performance is lost or degraded due to em disturbances, the doctor should immediately stop using it to ensure that there is no treatment error. And then remove the source of disturbances or adjust the direction or position of ME EQUIPMENT to ensure ME EQUIPMENT can be used in normal performance condition.

9.2 Technical description

9.2.1 All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

(1) Portable and mobile RF communications equipment may affect the performance of equipment , use of equipment should be avoided strong electromagnetic interference, and do not closer to mobile phone, microwave oven, etc.

(2) Use of equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

(3) Except for the cables sold by manufacturers of as spare parts of internal components, the use of accessories and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

(4) Using in conjunction with accessories, adapters or cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

9.2.2 Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° .0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° .0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° .0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° .0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance level** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380–390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430–470	GMRS 460,FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704–787	LTE Band 13,17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800–960	GSM 800/900,TETRA 800, iDEN 820,CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700–1990	GSM 1800;CDMA 1900; GSM 1900;DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400–2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450,LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
	Test Frequency	**Modulation**	**IEC 60601-1-2 Test Level** (A/m)	**Compliance level** (A/m)
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

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.)

Reprocessing instructions of cleaning, disinfecting and sterilizing

1. Beginning Work!

1.1 Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.
1.2 To prevent injury to people and damage to property, please heed the corresponding directives.
1.3 The instructions in this manual are only applicable to the product which it was delivered with.

2. Introduction

2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.
2.2 The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer's medical and dental products are based on the potential risk of infection associated with their use.
2.3 It is recommended to use steam sterilization.
2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.
2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.
2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

3. Reprocessing - Instructions for Reusable Products

3.1 The instructions are binding for the reprocessing of all reusable products (Here after called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

⚠ **Important: Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used.**

3.2 Reusable products must be cleaned, disinfected and sterilized prior to first use. Reprocessing procedures have only limited implications to this device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

⚠ **In case of damage the product should be reprocessed before sending back to the manufacturer for repair.**

4. Preparation - Basic Principles

4.1 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.
4.2 Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic. This applies especially with regard to the additional requirements for the inactivation of prions.

5. Preparation at the Point of Use

Disconnect product. Remove gross soiling of the instrument with cold water (<40° C) immediately after use. Don't use a fixating detergent or hot water (>40° C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Store the products in a humid surrounding.

6. Transportation

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

7. Preparation for Decontamination

The products must be reprocessed in a disassembled state, as far as possible.

8. Pre-cleaning

Do a manual pre-cleaning, until the products are visually clean. Submerge the products 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.

9. 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 (WD) meeting the requirements of the ISO 15883 series.
Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:
4 min pre-washing with cold water (<40° C);
emptying
5 min washing with a mild alkaline cleaner at 55° C
emptying
3 min neutralising with warm water (>40° C);
emptying

5 min intermediate rinsing with warm water (>40° C)
Emptying
The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

⚠ **Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.**

10. Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).
A disinfection cycle of 5 min disinfection at 93° C has been validated for the product to achieve an A0 value of 3000.

11. Drying:

Automated Drying:
Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

12. Functional Testing, Maintenance

Visual inspection for cleanliness of the products and reassembling if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean.
Before packaging and autoclaving, make sure that the products have been maintained acc. to manufacturer's instruction.

13. Packaging

Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

14. Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.
Minimum requirements: 3 min at 134 ° C (in EU: 5 min at 134 ° C)
Maximum sterilization temperature: 138° C
Recommended sterilization cycles of handpiece: 300 cycles
Recommended sterilization cycles of torque wrench and endo wrench: 300 cycles
Drying time:
For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.
After sterilization:
a. Remove the product from the autoclave.
b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.
Check that the sterilization wraps or pouches are not damaged.

⚠ **Flash sterilization is not allowed on lumen instruments.**

⚠ **The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).** In such cases, please observe the respective valid standards (EN ISO 14937/ANSI AAMI ISO 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

15. Storage

Storage of sterilized products in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

16. Service Life

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However, with every renewed preparation for use, thermal and chemical stresses will result in aging of the devices. If the number of permissible re-sterilization cycles is restricted, this will be pointed out in the product specific instructions.

⚠ **The use of ultrasound baths and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH<5) can reduce the life span of devices. The manufacturer accepts no liability in such cases.**

⚠ **The devices may not be exposed to temperatures above 138 ° C.**

It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

Dental Scaler(APT) "O" ring specification sheet

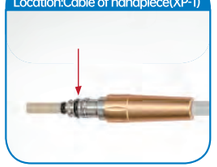
"O" Ring Size:Φ32 x Φ2.8
Location:Powder tank cover

"O" Ring Size:Φ6.75 x Φ1.6
Location:Bottom of powder tank

"O" Ring Size:Φ6.5 x Φ2
Location:Powder tank connector of main unit

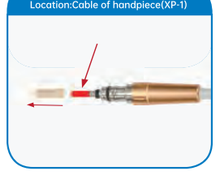
"O" Ring Size:Φ8 x Φ1.5
Location:Quick coupling inlet

"O" Ring Size:Φ11 x Φ1.5
Location:Cable of handpiece(XP-1)



"O" Ring Size:Φ6.75 x Φ1.6
Location:Cable of handpiece(XP-1)

"O" Ring Size:Silicone connection sleeve
Location:Cable of handpiece(XP-1)



"O" Ring Size:Φ5.5 x Φ1
Location:Handpiece(HY-2L)

"O" Ring Size:Φ8.5 x Φ1.8
Location:Water bottle

Note: We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

Shelf life: 10 years, the date of manufacture see product label.

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