

10. Statement

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Type 1 / Type 1L / Type 2 Ultrasonic Scaler Operation Instructions

Attachment: Operating Power of Scaling Tips

General Scaling		Cavity Preparation		Periodontics		Endodontics	
Model	Power	Model	Power	Model	Power	Model	Power
G1/GD1	1-10 (G)	SB1/SBD1	1-10 (P)	P1/PD1	1-10(P)	E1/ED1	1-3(E)
G2/GD2	1-10 (G)	SB2/SBD2	1-10 (P)	P2L/PD2L	1-3(P)	E2/ED2	1-3(E)
G3/GD3	1-10 (G)	SB3/SBD3	1-10 (P)	P2LD/PD2LD	1-2(P)	E3/ED3	1-6(E)
G4/GD4	1-10 (G)	SBL/SBDL	1-10 (P)	P2R/PD2R	1-3(P)	E3D/ED3D	1-3(E)
G5/GD5	1-10 (G)	SBR/SBDR	1-10 (P)	P2RD/PD2RD	1-2(P)	E4/ED4	1-6(E)
G6/GD6	1-10 (G)			P3/PD3	1-6(P)	E4D/ED4D	1-3(E)
G7/GD7	1-10 (G)			P3D/PD3D	1-6(P)	E5/ED5	1-6(E)
G8/GD8	1-10 (G)			P4/PD4	1-6(P)	E5D/ED5D	1-3(E)
G9/GD9	1-10 (G)			P4D/PD4D	1-6(P)	E6/ED6	1-6(E)
G10/GD10	1-10 (G)					E7/ED7	1-3(E)
G11/GD11	1-10 (G)					E8/ED8	1-10(E)
						E9/ED9	1-10(E)
						E10/ED10	1-6(E)
						E10D/ED10D	1-6(E)
						E11/ED11	1-6(E)
						E11D/ED11D	1-6(E)
						E14/ED14	1-3(E)
						E15/ED15	1-3(E)

Safety Precautions



Warning: if you neglect these safety precautions, you may cause personal injury such as electric shock, fire or damage to the product.

- 1) Use a separate, grounded power outlet. Never use wet hands to unplug the power cord.
- 2) Please put the power plug into the socket easy to pull out, to make sure it can be pulled out in emergency. Please do not use other than the specified voltage.
- 3) Do not damage, modify, pull, over bend or twist the power cord, do not place heavy objects on the power cord.
- 4) Do not put the product on unstable workbenches, such as shaky tables, bevels or vibrations.
- 5) Keep the scaler clean before and after operation. The scaling tip, wrench and handpiece (detachable) must be sterilized before each treatment.
- 6) The tip must be tightened to the handpiece with torque wrench. While scaler is working, the hear of scaler tip may become higher if there is no water flowing out, make sure the irrigation is good.
- 7) Don't twist or rub the tip. Change a new one when the tip is damaged or worn excessively.
- 8) Don't screw the scaling tip while stepping on the switch.
- 9) Don't use impure water source, and be sure not to use normal brine instead of pure water source.
- 10) If use the water source without hydraulic pressure, the water surface should be one meter higher than the head of the patient.
- 11) Don't knock or rub the handpiece. Do not pull the cable while the device is working to avoid damage to the cable.
- 12) After operating, turn off electrical source, and then pull out the plug.
- 13) The screw thread of scaling tip produced by other manufacturer is maybe coarse, rusty and collapsed, which may damage the screw thread of the handpiece irretrievably. Please use the scaling tip provided by the VOLDENT company.
- 14) The device is only applicable to the corresponding type of power adapter produced by VOLDENT company.
- 15) As a professional manufacturer of medical instruments, we are only responsible for the safety on the following conditions:
 - The maintenance, repair and modification are made by the manufacturer or the authorized dealer.
 - The replacement components are original of VOLDENT company and operated correctly according to instruction manual.
- 16) This product is intended for use in hospital and dental clinics only. The user must be professionally trained and qualified dentists.

Packing List

1 × Ultrasonic Scaler Main Unit	1 × VD-3H Scaler Handpiece (TYPE 1 only)
1 × Power Supply Cable	1 × VD-5L Scaler Handpiece (TYPE 1L, TYPE 2 only)
1 × Foot Switch	5 × Scaler Tip (TYPE 1 only)
1 × Scaler Tip Wrench	10 × Scaler Tip (TYPE 1L, TYPE 2 only)
1 × Endo File Wrench	1 × LED Part (TYPE 1L, TYPE 2 only)
2 × Endo File	1 × Operation Instructions

Recommended Separation Distance between Portable and Mobile RF Communication Device and Ultrasonic Scaler			
This device is intended to be used in electromagnetic environment in which radiated RF disturbances is controlled. According to the maximum output power of the communication device, the customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication device (transmitters) and this device as recommended below.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz ~ 80MHz d=1.2√P	80MHz ~ 800MHz d=1.2√P	800MHz ~ 2.5GHz d=2.3√P
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	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: At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Without the express consent of manufacturer, unauthorized alteration or modification of the device may cause electromagnetic compatibility problems of this or other devices. Warning: this device should not be used close to or stacked with other devices. If it must be used closed to or stacked, it should be observed and verified to work normally under the configuration used.			

8. Environmental Protection

Please dispose according to the local laws.

9. After-Sales Service

- 9.1. After the product is sold, if it cannot work normally due to quality problems, our company will be responsible for the after-sales service with the warranty card. For specific items, please refer to the warranty instructions in the warranty card.
- 9.2. This product does not contain self-repair parts. All product maintenance, adjustment, calibration and modification of technical parameters, etc., can only be performed by our company's or dealer's technicians.
- 9.3. The user must use the original accessories, please contact your local dealer or our company to purchase. It is forbidden to use related accessories of other brands to avoid damage to the equipment or other dangers.
- 9.4. Warranty Period
5 years for the main unit, 1 year for the handpiece from the date of purchase, lifetime maintenance.
- 9.5. Range of Warranty
Within the warranty period of validity, all faults caused by product quality, process structure, etc. belong to the scope of warranty.
The following conditions are not covered by the warranty:
 - a) The faults caused by disobeying the operation instruction or lack of the needed condition.
 - b) The faults caused by unsuitable operation or disassembly without authorization.
 - c) The faults caused by unadvisable transportation or preservation.
 - d) Warranty card without the seller's seal or incomplete filling.

Guidance & Declaration – Electromagnetic Immunity			
This device is intended to be used in the electromagnetic environment specified below. The customers of the users should assure the environment conditions.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2kV for power supply cable, ±1kV for input / output cable	±2kV for power supply cable, ±1kV for interconnecting cable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line to line, ±2kV line to earth	±1kV line to line	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input cable. IEC 610004-411	< 5% U _r (> 95% dip in U _r) for 0.5 cycle, 40% U _r (60% dip in U _r) for 5 cycle, 70% U _r (30% dip in U _r) for 25 cycle, 40% U _r (> 95% dip in U _r) for 0.5 cycle, < 5% U _r ¹ (> 95% dip in U _r) for 5 sec.	< 5% U _r (> 95% dip in U _r) for 0.5 cycle, 40% U _r (60% dip in U _r) for 5 cycle, 70% U _r (30% dip in U _r) for 25 cycle, 40% U _r (> 95% dip in U _r) for 0.5 cycle, < 5% U _r ¹ (> 95% dip in U _r) for 5 sec.	Main power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that this device is powered from and uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 kHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by and electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment market with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 kHz to 2.5 GHz	3 V/m	
Note: U _r is AC network voltage before application of test voltage. At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. ^a Field strength 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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device. ^b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

Symbols

	Caution!		Read instructions		Ground Protection
	Serial Number	IPX1	Water proof grade		Sterilizable at up to 135°C in the autoclave
	Production date		Manufacturer		Used in door only
	Valid period		Degree of protection against electric shock: Type B applied part	220 VAC 120 VAC	220 VAC power supply socket 120 VAC power supply socket
ON/OFF	Power on / off		Water flow adjustment		Foot switch socket
	Appliance compliance WEEE directive, dispose according to laws	H ₂ O 0.01MPa ~ 0.5MPa	Water inlet pressure: 0.01MPa ~ 0.5MPa		Fuse
	Temperature limitation		Humidity limitation		Atmospheric pressure
	Trade mark				

1. Product Introduction

1.1. Overview

Voldent Medical Technology Co., LTD. is a professional manufacturer in researching, developing, producing and distributing ultrasonic scalers. The product is used for tooth cleaning and also an important device for tooth disease prevention and treatment. The ultrasonic scaler is composed of main unit, handpiece, cable, water pipe, tip, torque wrench, foot switch and power adapter.

1.2. Contraindications

- 1) The hemophilia patient is forbidden to use this equipment.
- 2) The patients or doctors with heart pacemaker are forbidden to use this equipment.
- 3) The heart disease patient, pregnant woman and children should be cautious to use this equipment.

1.3. Safety Classification

- 1) Operating mode: continuous operation
- 2) Type of protection against electric shock: Class II
- 3) Degree of protection against electric shock: Type B applied part
- 4) Applied part of the equipment: Tip
- 5) Degree of protection against harmful ingress of water: Ordinary equipment
- 6) Waterproof Level: IPX1
- 7) Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment can not be used in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

1.4. Working Condition

- 1) Ambient temperature: +5°C ~ +40°C
- 2) Relative humidity: 30% ~ 75%
- 3) Air pressure: 70kPa ~ 106kPa
- 4) Inlet water temperature: ≤ +25°C

1.5. Model and Technical Parameters

Table 1 Technical Parameters of each model

Model	Type 1	Type 1L	Type 2
Dimensions (mm)	215mm*155mm*120mm	215mm*155mm*120mm	215mm*155mm*210mm
Main unit weight	1.65kg	1.65kg	1.83kg
Power Apater	Built-in	Built-in	Built-in
Rated Input	220VAC 50Hz/120VAC 60Hz	220VAC 50Hz/120VAC 60Hz	220VAC 50Hz/120VAC 60Hz
Power Input	38VA	38VA	38VA
Waterproof level of foot switch	IPX1	IPX1	IPX1
Main unit fuse	T0.5AL 250VAC	T0.5AL 250VAC	T0.5AL 250VAC
Power supply fuse	----	----	----
Water supply	Outer water source	Outer water source	Water tank
Water inlet pressure	0.01MPa ~ 0.5MPa	0.01MPa ~ 0.5MPa	0.01MPa ~ 0.5MPa
Function	G, P, E	G, P, E	G, P, E
Endo Irrigation Function	Yes	Yes	Yes
Control	Touch control, knob control	Touch control, knob control	Touch control, knob control
Handpiece	VD-3H	VD-5L (LED)	VD-5L (LED)
Tip vibration frequency	28kHz±3kHz	28kHz±3kHz	28kHz±3kHz
Primary tip vibration excursion	<90μm	<90μm	<90μm
Half-excursion force	0.5N ~ 2N	0.5N ~ 2N	0.5N ~ 2N
Output power of tip	3W ~ 20W	3W ~ 20W	3W ~ 20W

Notice:

“G” stands for general scaling, “P” stands for periodontal scaling, “E” stands for endodontics irrigation



Do not replace the fuse of main unit nor the power supply to avoid safety risks.

2. Installation

2.1. Installation Steps

- 1) Unpack the package, make sure that all the parts and accessories are complete according to the packing list. Take the main unit out and put it on the stable plane facing to the operator.
- 2) Insert the plug of the foot switch to the socket on the back of main unit.
- 3) Connect the handpiece to the cable.
- 4) **Type 1 & Type 1L -- Connect one end of the water pipe to the water entrance. The other end to the clean water source.**
Type 2 -- Take out the water tank and cover, insert the water tank to the socket on the top of main unit. Fill the tank with clean water source then cover it.
- 5) Turn the water control knob to the Max.
- 6) Screw the tip to the head of handpiece with torque wrench.
- 7) Connect the main unit to the power supply though the power adapter.
- 8) Step on the foot switch and start operating.

FAULT	POSSIBLE CAUSE	SOLUTIONS
Scaling tip doesn't vibrate but water flow is good.	Poor contact between handpiece and cable or between cable and circuit	Contact the dealer or the service center
	Cable failure	Contact the dealer or the service center
	Handpiece failure	Send the handpiece back to dealer or the service center
Scaling tip vibrates but no water flow	The water adjustment knob is not on.	Turn on the water adjustment knob.
	Handpiece liquid way is jammed.	Send the handpiece back to dealer or the service center
	Cable or the internal liquid way is jammed.	Clean the liquid way with multi-function syringe.
	The electromagnetic valve or the water pump failure	Contact the dealer or the service center
The amount of water flow is too little	The water adjustment is in a low grade.	Turn up the water adjustment knob.
	Water pressure is not enough	Enhance the water pressure.
	Cable or the internal liquid way is jammed.	Clean the liquid way with multi-function syringe.
The vibration of scaling tip is weak	Poor contact of scaling tip	Tighten the scaling tip again
	The coupling between the handpiece and cable is not dry.	Dry it by hot and dry air.
	Scaling tip is damaged.	Change a new scaling tip.
Water leakage from the coupling between the handpiece and cable.	The water proof O-ring is damaged.	Change a new O-ring.
The handpiece generates heart	The amount of water flow is not enough.	Turn up the water adjustment knob.
	The potentiometer failure	Change a new potentiometer.
Unadjustable power intensity	The potentiometer failure	Change a new potentiometer.
Endo file doesn't vibrate.	The screw loose.	Tighten it up.
	The endo chuck is damaged.	Change a new one.
Noise comes from the endo chuck.	The screw loose.	Tighten it up.
LED lamp doesn't work.	Poor contact of LED lamp	Reconnect it.
	LED lamp failure	Change a new one.

In case of any fault that could not be solved by the above methods, please contact your dealer or the nearest service center.

7. EMC Declaration of Conformity

This device 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 this device in high electromagnetic environment.

Guidance & Declaration – Electromagnetic Emissions		
This device is intended to be used in the electromagnetic environment specified below. The customers of the users should assure the environment conditions.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RM emissions CISPR 11	Class B	This device 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

- 2) Handpiece, tip and torque wrench can be autoclaved under high temperature and pressure.
Recommended sterilization program:
134°C, 4 minutes, 3 times of vacuum, drying time 15 minutes.
- 3) After sterilization, the handpiece should be used again after it cools down naturally.



Notice:

- 1) Handpiece, tip and torque wrench need to be autoclaved under high temperature and pressure before each use.
- 2) Clean the remaining liquid on the surface of handpiece, tip and torque with compressed air before sterilization.
- 3) Tip must be removed from the handpiece before sterilization. Tips should be packed separately. It cannot be sterilized with other instruments.
- 4) Do not smear any protective oil on the surface of handpiece.
- 5) There are 2 waterproof seal rings at the end of the handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce the using life. Change a new one once it is damaged or worn excessively.
- 6) The following sterilizing methods are forbidden:
 - a) Boiling in water
 - b) Dip in iodine, alcohol and glutaraldehyde
 - c) Bake in oven or microwave.
 VOLDENT company does not provide warranty in case of any damage caused by above methods.

5. Transportation, Storage and Maintenance

5.1. Transportation

- 1) Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.
- 2) Do not put it with other dangerous goods together during transportation.
- 3) Avoid solarization and getting wet in rain or snow during transportation.

5.2. Storage

- 1) Do not store the device with toxic, corrosive, flammable and explosive materials.
- 2) This device should be stored in an environment with a relative humidity of 10% to 93%, an atmospheric pressure of 70kPa to 106kPa, and a temperature of -20°C to +40°C.

5.3. Maintenance

- 1) This device should be handled with care, away from the source of earthquakes, and should be installed or stored in a cool, dry and ventilated place.
- 2) Turn off the power switch and unplug the power plug when not use. If long time no using, it should be energized and watered once every 3 months, and 5 minutes each time.

6. Trouble Shooting

FAULT	POSSIBLE CAUSE	SOLUTIONS
Scaling tip doesn't vibrate and not water flowing out	Poor contact of power plug	Make the plug insert to the socket well
	Poor contact of foot switch	Insert the foot switch to its socket tightly
	Fuse of the main unit is burnt.	Contact the dealer or the service center
	Poor contact of scaling tip	Tighten the scaling tip again

2.2. Function Instructions and Connection Diagram

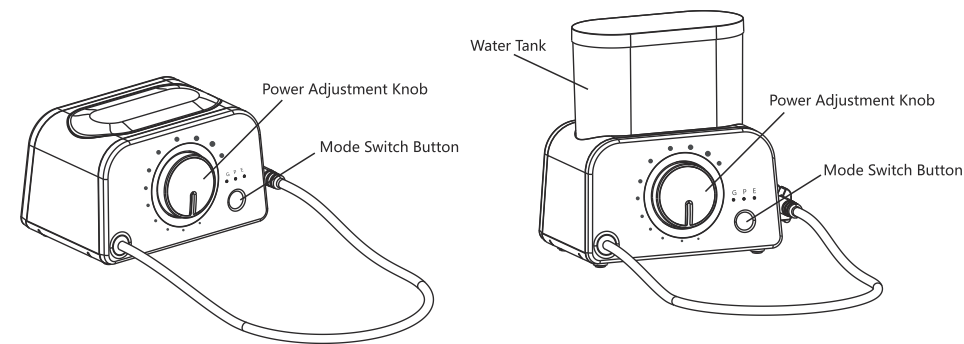


Figure 1 Type 1, Type 2 front view

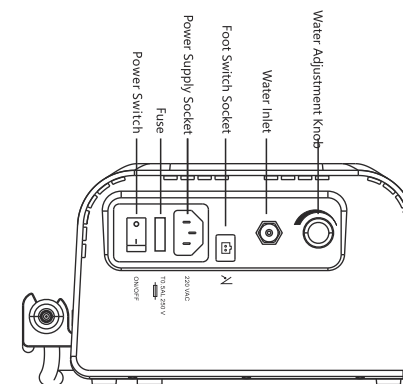


Figure2 Type 1, Type 2 back view

Notice: only Type 1 and Type 1L have external water source interface.

2.3. Handpiece Installation

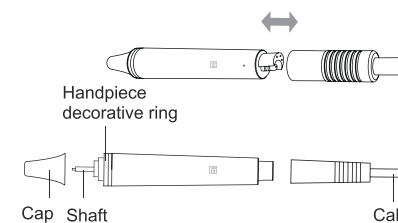


Figure 3 VD-3H handpiece

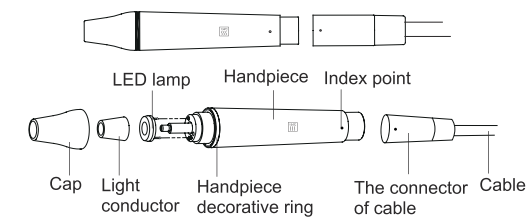


Figure 4 VD-5L handpiece

2.4. Tip Installation

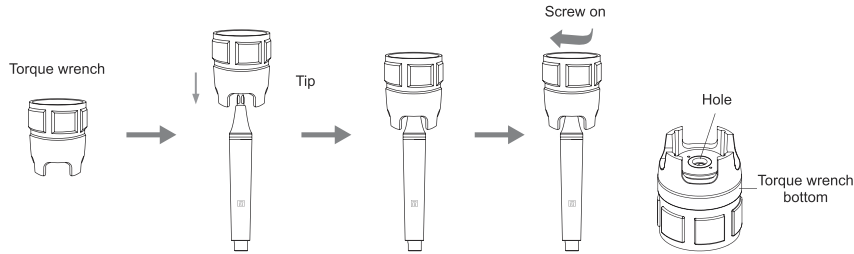


Figure 5 Instruction of using the wrench to install tip

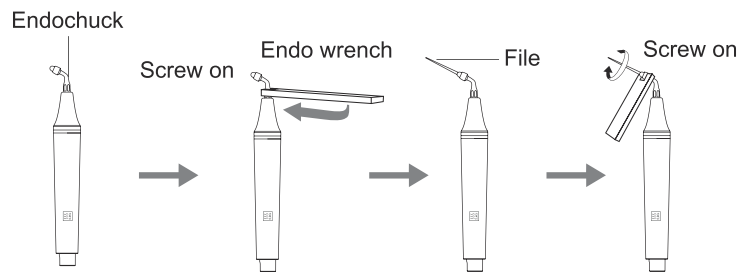


Figure 6 Instruction of using the wrench to install endo file and chuck



Notice: The connector of handpiece and the cable socket must be completely dry.

3. Function and Operation

3.1. General Scaling and Periodontal Scaling Functions

- 1) Turn on the power switch, the power indicator is on. Turn the water adjustment knob to the Max.
- 2) Choose proper scaling tip as requirement. (Refer to Attachment) Install the tip with the torque wrench. (Figure 5)
- 3) Vibration intensity: Select a suitable power level by turning the power adjustment knob as requirement. Usually adjust to the middle grade, and adjust the vibration during the treatment base on the patient's sensitivity and the rigidity of tartar.
- 4) Step on the foot switch, the tip starts to vibrate. **(If Type 2, the LED light on the head of handpiece lights up. Release the foot switch, the LED light keeps on for 10 seconds.)**
- 5) Under normal working condition, the frequency of tip is very high. Slightly touch and a certain to-and-fro motion will eliminate the tartar without obvious heating. Overexertion and overstay are forbidden.
- 6) Water volume: Step on the foot switch, the tip starts to vibrate. Turn the water adjustment knob to get fine spray to cool down the handpiece and clean the teeth.
- 7) After operation, keep the machine working for 30 seconds with water supply to clean the handpiece and the tip.
- 8) Unscrew the scaling tip, unplug the handpiece and sterilize them.



Notice: Be sure no to take the end of tip touch teeth vertically. Do not use much force when the tip touching the surface of teeth in case of damaging the teeth.



Notice: Do not screw the scaling tip when stepping on the foot switch.

3.2. Endodontic Irrigation Function

- 1) Install the endo chuck to the handpiece with endo wrench. (Figure 6)
- 2) Unscrew the screw cap at the top of endo chuck, insert the endo file into the hole of endo chuck, then tighten the cap with endo wrench. (Figure 6)
- 3) Select "E" mode by touching the mode switch button.
- 4) When the device turns to endodontic irrigation mode, the power is at the 1st grade. Put the endo file into the patient's root canal slowly, the step on the foot switch to start the irrigating. During the treatment, turn up the power gradually as needed.



Notice:

- 1) Do not press it too much when the file in the root canal.
- 2) Do not step on the switch until the file is put into the root canal.
- 3) The power level of endodontic irrigation should not be more than 5th grade.

3.3. Water Tank Instructions

- 1) Remove the cover of water tank, add the right amount of pure water to the water tank then recover it.
- 2) When the water level in the water tank is too low, please pay attention to adding water in time to avoid poor water flow.



Notice: In order to obtain the best clinical use effect, do not use excessively worn tip. When the following situations occur, the tip may be damaged or worn out, and the tip should be replaced in time.

- 1) Visually compare the tip with the new unused tip. If there is obvious damage, or the length of the tip is shorter than the new tip by more than 1 mm.
- 2) Water spray is incomplete.
- 3) The vibration amplitude of the tip becomes larger, and there is obvious collision sound.
- 4) Vibration intensity decreased during work, scaling effectiveness and efficiency decrease.

4. Cleaning, Disinfection and Sterilization

4.1. Accessories Cleaning and Disinfecting

- 1) The main unit, power supply and foot switch cannot be cleaned and disinfected. If you need to clean, use a clean cloth to wipe the surface.
- 2) Handpiece, tip and torque wrench can be cleaned with clean water or ultrasonic cleaner.
- 3) Handpiece, tip and torque wrench need to be cleaned before disinfecting and autoclaving.
- 4) Handpiece cap, LED lamp and light guide at the top of handpiece can be screwed out and clean with clean water or alcohol.

4.2. Disinfection

The wrench can be disinfected with any commonly used non-corrosive neutral disinfectant. It can be wiped and disinfected with alcohol or a disinfectant towel. You can also choose an autoclave for high temperature and pressure disinfection.

4.3. Sterilization

- 1) After each use, uninstall the handpiece and tip, pack them into a disinfection bag.