Contents

1	Symbol instruction ······1
2	Acquaintance of the product and its parts2
3	Product structure, scope of application and contraindication ··· 6
4	Components······7
5	Technical specifications7
6	Usage8
7	Cleaning, disinfection and sterilization12
8	Precautions15
9	Maintenance ······17
10	Storage and transportation18
11	After sales service·····19
12	Environmental protections19
13	EMC-Declaration of conformity22

Recommended separation distances between

portable and mobile RF communications equipment and the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2, P9-3.

The models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9, P9L,P9–2,P9–3 are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7, P7L,P9,P9L,P9–2,P9–3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9–2,P9–3 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter			
power	m			
of transmitter	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz	
W	d=1.2×P ^{1/2}	$d=1.2 \times P^{1/2}$	$d=2.3 \times P^{1/2}$	
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 1 At 80 MHz and 800 MHz. the separation distance for 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.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance & Declaration - Electromagnetic immunity

The models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3 are intended for use in the electromagnetic environment specified below. The customer or the user of the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3 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	3 Vrms 150 MHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 x P1/2 80 MHz to 800 MHz d=2.3 x P1/2 800 MHz to 2.5 MHz 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 end 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.

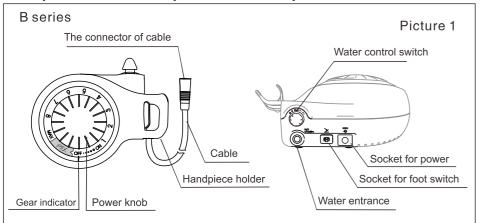
1 Symbol instruction

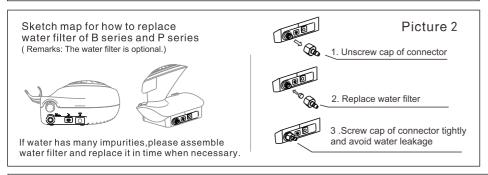
		I	
			Caution
	Class II equipment		Follow instructions for use
†	Type B applied part	30VDC	30VDC input
~	Alternating current	H ₂ O • • • • • • • • • • • • • • • • • • •	Water control switch
2	Foot switch	H₂O 0.1-0.5MPa	Water entrance 0.10MPa~0.5MPa (1bar~5bar)
凸	Use indoor only	A	Appliance compliance with WEEE directive
134°C \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Autoclavable	IPX0	Ordinary equipment
س	Date of manufacture	IPX1	Drop-proof
SN	Serial number	<u></u>	Manufacturer
C € 0197 CE marked product		EC REP	Authorised representative in the European Community

^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 can not 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 models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3 are used exceeds the applicable RF compliance level above, the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

2 Acquaintance of the product and its parts





Sketch map for how to connect foot switch, adapter, waterway to

Foot switch

Water entrance

Socket for foot switch

Socket for power

Power cord plug

Guidance & Declaration-electromagnetic immunity

The models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L, P9–2,P9–3 are intended for use in the electromagnetic environment specified below. The customer or the user of the models B5,B5S,B5L,P4,P5,BD2,P5L, B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9–2,P9–3 should assure that it is used in such an environment.

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	±2kV for power supply lines ±1 kV for Input/output lines	± 2kV for power supply lines	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% 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	<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 models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3 require continued operation during power mains interruptions, it is recommended that the models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9-2,P9-3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

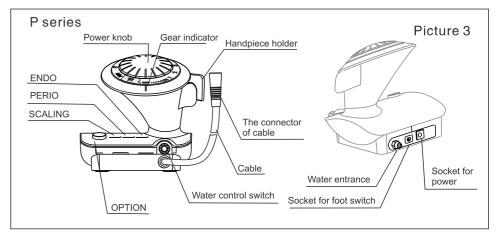
NOTE U τ is the a. c. mains voltage prior to application of the test level.

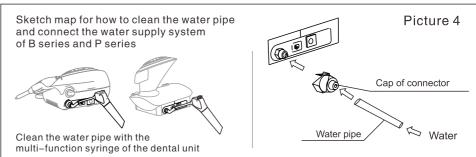
13 EMC – Declaration of conformity

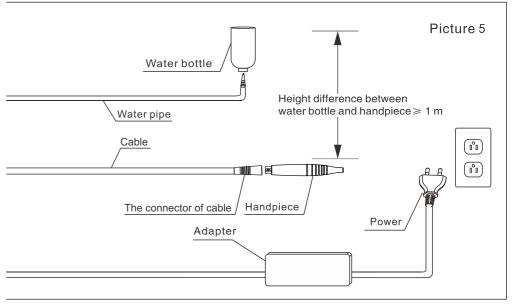
Guidance and manufacturer's declaration-electromagnetic emissions

The models B5,B5S,B5L,P4,P5,BD2,P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L, P9–2,P9–3 are intended for use in the electromagnetic environment specified below. The customer or the user of the models B5,B5S,B5L,P4,P5,BD2,P5L, B6,B6S,B6L,P6,P7,P7L,P9,P9L,P9–2,P9–3 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The models B5,B5S,B5L,P4,P5,BD2, P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L, P9–2,P9–3 use 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	The models B5,B5S,B5L,P4,P5,BD2, P5L,B6,B6S,B6L,P6,P7,P7L,P9,P9L,	
Harmonic emissions IEC 61000-3-2	Complies	P9–2,P9–3 are suitable for use in domestic establishment and in establishment directly Not connected	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	to a low voltage power supply network which supplies buildings used for domestic purposes.	

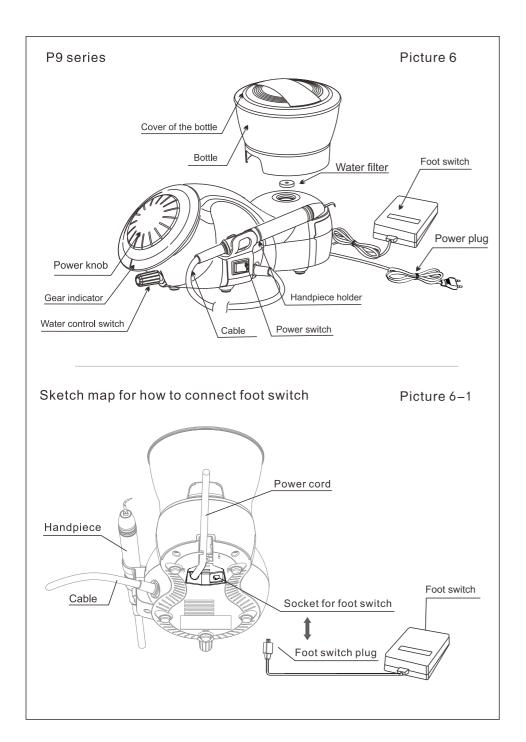


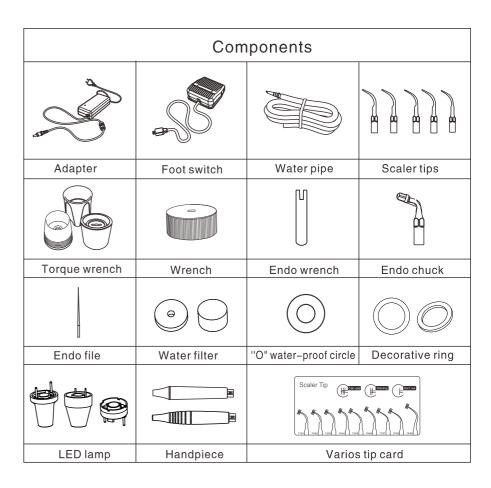




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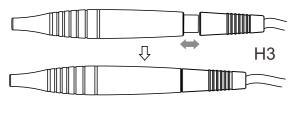
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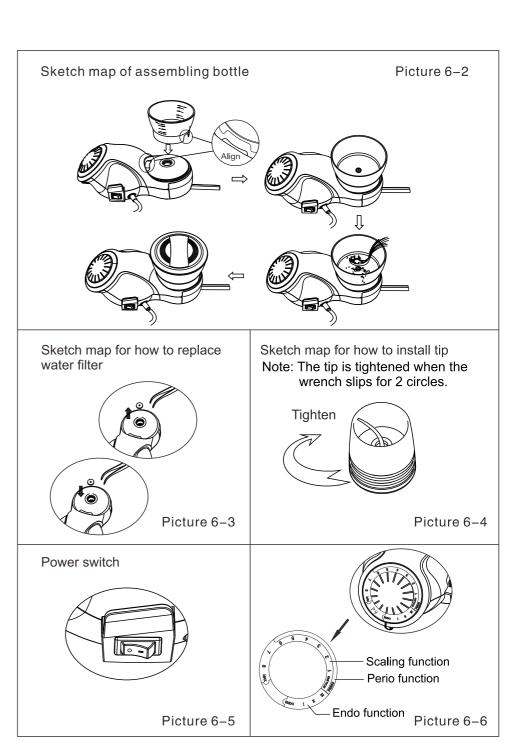
Scaler handpieces match the corresponding scaler models Scaler handpiece The corresponding scaler models No BD2/P9-2 D2 D3 2 P9-3 B5/B6 3 H1 P4/P6 4 H2 Н3 5 P5/P7/P9 HS1 B5S/B6S 6 7 L1 B5L/B6L P5L/P7L/P9L 8 L3 P5L periodontal version/P7L periodontal version/ 9 Golden L3 P9L periodontal version

Sketch map for how to connect detachable handpiece (Take H3 handpiece for example)

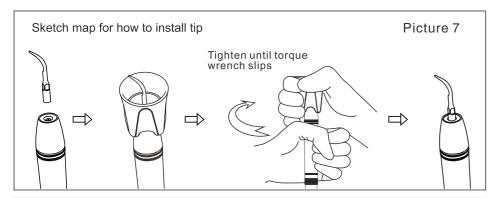


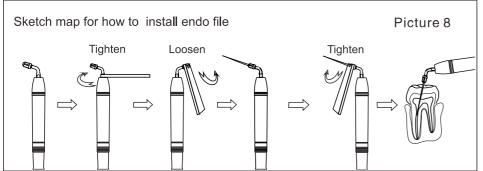
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Picture 10



5





3 Product structure, scope of application and contraindication

3.1 Product performance and structure

Ultrasonic scaler is composed of electrocircuit, waterway and ultrasonic transducer.

3.2 Intended use

A powered device utilizing a vibrating ultrasonic tip to remove calculus and other accretions from tooth surfaces during dental cleaning, periodontal therapy and root canal treatment.

- 3.3 Contraindication
- 3.3.1 The hemophilia disease patients or patients with thrombocytopenia purpura are forbidden to use this equipment.
- 3.3.2 The patients or doctors with heart pacemaker are forbidden to use this equipment.
- 3.3.3 The heart disease patients, pregnant women and children should be cautious to use the equipment.

11 After sales service

- 11.1 We offer 15 months free repair to the equipment based on warranty card from the date when it is sold to the end user. Lifetime maintenance.
- 11.2 The repair of the equipment should be carried out by our professional technician. Irretrievable damage caused by the nonprofessional technician, and damage accidentally or deliberately caused by operators, are out of the range of warranty.

12 Environmental protections

- 12.1 You can deal with it based on the local law.
- 12.2 We reserve the right to change the design of the equipment, product technique, accessories, instruction manual and the content of original packing at any time without notice. If there are some differences between picture and real equipment, take the real equipment as the norm.

- 9.2 Notes
- 9.2.1 [Note 1] Adjust the water control switch according to the direction shown can control the water volume.
- 9.2.2 [Note 2] Clean the water pipe with the multi–function syringe of the dental unit (Picture 4).
- 1) Cut the water pipe at a distance of 10cm to 20cm from the water entrance.
- 2 Turn on the electricity and get through the electricity.
- 3 Connect the multi-function syringe of dental unit to water pipe.
- 4 Disassemble the tip.
- ⑤ Turn on the power and step on the foot switch to start the scaler.
- ⑥ Tum on the switch of the multi-function syringe, press the water into the machine and the impurity blocked in the water pipe can be eliminated.
- 9.2.3 [Note 3] If the scaler tip has been screwed tightly and there is good spray too, the following phenomena show that the scaler tip is damaged:
- 1 The vibrating intensity and the water atomization degree become weak obviously.
- 2 During treatment, it produces the sound like "buzz" from the scaler tip.
- 9.3 If not use for a long time, please make the machine get through the electricity and water once per month for five to ten minutes.

10 Storage and transportation

- 10.1 Environmental conditions of storage and transportation:
- a). Relative humidity: 0 to 80%
- b). Atmospheric pressure: 50kPa to 106kPa
- 10.2 Prevent excessive shock and vibration in transportation, be sure to handle with care and avoid inversion.
- 10.3 Don't mix with dangerous goods during transportation.
- 10.4 Avoid the sun, rain or snow during transportation.
- 10.5 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and install or store in a cool, dry and ventilated place.
- 10.6 Don't store the machine with the articles that are combustible, poisonous, caustic and explosive.

4 Components

Product components are subject to the packing list.

5 Technical specifications

5.1 Performance technical specifications

Adamtanlanast	B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L: 100-240V~ 50/60Hz 0.7A- 0.4A		
Adapter Input	P9/P9L/P9-2/P9-3: 230V~ 50/60Hz 150mA; 110V~ 50/60Hz 300mA		
Main unit input	B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L: 30V===1.2A		
	B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L: 250V/T 1.6AL		
Main unit fuse	P9/P9L/P9-2/P9-3: F1(250VT 0.3AL) F1(250VT 0.5AL) F2(250VT 0.3AL) F2(250VT 0.5AL) F3(250VT 1.6AL) F3(250VT 1.6AL)		
Output power	3W~ 20W		
Output tip vibration frequency	28kHz±3kHz		
Output half-excursion force	<2N		
Output primary tip vibration excursion	≤200μm		
Water pressure	B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L: 0.1MPa~0.5MPa(1bar~5bar)		
Water flow rate	P9/P9L/P9-2/P9-3: 0~50ml/min		
Operating mode	Continuous operation		
Electric shock protection type	Class II		
Classification 93/42/EEC	Class II a		
Degree of protection	B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L:B		
against electric shock	P9/P9L/P9-2/P9-3: BF		
Degree of protection against harmful ingress of water	Ordinary equipment (IPX0), Foot switch(IPX1)		
Degree of safety of application in the presence of a Flammable Anesthetic Mixture with air or with Oxygen or Nitrous Oxide	Equipment not suitable for being used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.		

- 5.2 The conditions of working environment:
- 5.2.1 Environmental temperature:+10°C to +40°C
- 5.2.2 Environmental humidity: 0 to 80%
- 5.2.3 Atmospheric pressure: 700hPa to 1060hPa

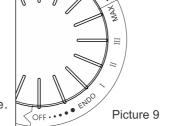
6 Usage

- 6.1 Open the packaging, make sure that all the parts and accessories are complete according to the packing list. Take the main unit out of the box and put it on a stable plane.
- 6.2 Turn the water control switch to the max based on symbol as shown in 9.2.1[Note 1].
- 6.3 Insert the plug of the foot switch to its socket.
- 6.4 Different operations of B, P, P9 series scalers
- 6.4.1 Operations of B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L
- 6.4.1.1 Connect one end of the water pipe to the water entrance, lock the water pipe tightly with locknut, and connect the other end to the pure water source.
- 6.4.1.2 Connect the handpiece with the cable (Picture 10), select a suitable scaler tip as you need and screw it on the handpiece tightly by the torque wrench (Picture 7).
- 6.4.1.3 Turn off the main unit power, then insert the plug of the power source, and then get through to the power.
- 6.4.1.4 Turn on the power button, and start the machine.
- 6.4.1.5 Function selection of P4/P5/BD2/P5L (with Scaling, Perio, Endo functions) and B6/B6S/B6L/P6/P7/P7L
- A). Function selection of P4/P5/BD2/P5L (with Scaling, Perio, Endo functions)

Tum the power knob to the corresponding area as required.

1 ENDO function

Turn the power knob to ENDO and the power is turned on. The machine enters into ENDO mode. Adjust power at " | | | | | MAX" area as required (Picture 9).



9 Maintenance

9.1 Troubleshooting and notes

Fault	Possible cause	Solutions
The scaler tip doesn't vibrate	The power pipe plug of B5/ B5S/B5L/ P4/P5/BD2/ P5L/B6/ B6S/B6L/P6/P7/ P7L is in loose contact.	Make the plug insert to the socket well.
and there is no water flowing out	The foot switch is in loose contact.	Insert the foot switch to its socket tightly
when stepping on the switch.	The fuse of transformer of B5/ B5S/ B5L/P4/P5/BD2/P5L/B6/ B6S/B6L/ P6/P7/P7L is broken.	Contact our dealers or us.
	The fuse in the main unit is broken.	Contact our dealers or us.
The scaler tip doesn't vibrate	The tip is in loose contact.	Screw the tip on the handpiece tightly (Picture 7).
but there is water flowing out when stepping on the	The connect plug between the handpiece and the circuit board is in loose contact.	Contact our dealers or us.
switch.	Problem of handpiece.	Contact our dealers or us.
	The water control switch is not on.	Turn on the water control switch [note 1]
	There is impurity in the solenoid valve of B5/B5S/B5L/ P4/P5/BD2/P5L/B6/B6S/B6L/ P6/P7/P7L.	Contact our dealers or us.
The scaler tip vibrates but there is no spray	The water system of B5/B5S/ B5L/ P4/P5/BD2/ P5L/B6/B6S/ B6L/P6/ P7/P7L is blocked.	Clean the water pipe by multi-function syringe [note2].
when stepping on the switch.	There is air in the water pipe.	B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L: disassemble the scale tip, and turn the water control switch to maximum. Meanwhile, make water pressure higher to 0.5MPa max.
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	P9/P9L/P9-2/P9-3: Step on the foot switch, turn the water control switch to maximum, and disassemble the handpiece. If necessary, disassemble bottle and assemble it again.
	Water single pass of B5/B5S/ B5L/ P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/ P7L is blocked	Replace water filter (Picture 2).
There is still water flowing out after the power is off.	There is impurity in the solenoid valve of B5/B5S/B5L/ P4/P5/BD2/P5L/B6/B6S/B6L/ P6/P7/P7L.	Contact our dealers or us.
The handpiece generates heat.	The water control switch is in a low grade	Tum the water control switch to a higher grade [note 1].
The amount of spouting water is too little.	The water pressure for B5/ B5S/B5L/ P4/P5/BD2/P5L/B6/ B6S/B6L/P6/P7/ P7L is not high enough.	Make the water pressure higher.
	The water pipe of B5/B5S/B5L/ P4/ P5/BD2/P5L/B6/B6S/B6L/ P6/P7/ P7L is blocked.	Clean the water pipe by multi-function syringe [note 2].
The vibration of the tip becomes	The tip hasn't been screwed on the handpiece tightly.	Screw the tip on the handpiece tightly (Picture 7).
weak.	The tip is loose because of vibration.	Screw the tip tightly (Picture 7).
	The tip is damaged. 【Note 3】	Change a new one.
The joint of the handpiece and cable has water leakage.	"O" shape water-proof rubber circle is broken.	Change a new one.
The endo file	The screw is loosen	Tighten it (Picture 8)
doesn't vibrate	The endo chuck is damage	Change a new one
There is noise coming from the endo chuck	The screw is loosen	Tighten it (Picture 8)

If the problem still can't be solved, please contact with local dealer or manufacturer.

- 8.11 After operating, turn off power (turn the power switch to OFF), then pull out the plug, and cut off power supply.
- 8.12 Performing endo function under the scaling status (the blue area) is forbidden for P9/P9L/P9–2/P9–3.
- 8.13 Please check the water filter of P9/P9L/P9-2/P9-3 routinely, replace if necessary (Picture 6-3).
- 8.14 Put the liquid into the bottle of P9/P9L/P9–2/P9–3 and close it with its cover after the bottle is properly installed on the main unit.
- 8.15 Use P9/P9L/P9-2/P9-3 only after the bottle is closed with its cover.
- 8.16 After stopping operation, let P9/P9L/P9-2/P9-3 continuously work under condition of water getting through for 20 to 30 seconds to clean the water circuit, and then clean the connection of bottle.
- 8.17 If don't use P9/P9L/P9–2/P9–3 for a long time, please install the dry and clean bottle on the main unit and close its cover, in case the dust fly into the connection of bottle.
- 8.18 We are only responsible for the safety of machine in the following conditions:
- I. The maintenance, repair and modification are made by the manufacturer or the authorized dealer.
- II. The changed components are original and operated according to instruction manual.
- 8.19 Please use our T series tips for B5/B5L/P4/P5/P5L/B6/B6L/P6/P7/P7L/P9/P9L and use S series tips for B5S/BD2/B6S/P9–2/P9–3. If forcibly use other tips which may not match the scaler, it may result in damage beyond repair.
- 8.20 Please use our power supply or same model power supply.
- 8.21 The 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 effected by electromagnetic interference.

Avoid using the device in high electromagnetic environment.

2 SCALING function

Turn the power knob to SCALING area and the indicator turns blue.

The machine enters into SCALING mode.

3 PERIO function

Turn the power knob to PERIO area and the indicator turns blue. The machine enters into PERIO mode. It is suggested that the maximum power should not exceed 6–7 grade of green area under PERIO mode.

B). Function selection of B6/B6S/B6L/P6/P7/P7L

Press the function button to choose scaling, periodontal or endo mode.

a). Scaling function.

After start the machine, the default initial state is scaling function, and SCALING indicator lights.

- b). Periodontal function
- ① Press "OPTION" button, switch to periodontal function, then PERIO mode indicator lights.
- ② After switching to periodontal function, select the right tips, and use torque wrench to fix it on the handpiece.
- 3 Adjust the frequency based on current status, it can be periodontal scaling after adjusting the right frequency.
- c). Endo function (Picture 8)
- ① Press "OPTION" button, switch to endo function, and ENDO indicator lights.
- ② Use endo wrench to fix endo chuck to handpiece. (Picture 8)
- 3 Loosen the nut of endo chuck.
- ④ Insert endo file in the front hole of the endo chuck and use endo wrench to tighten the nut so as to clamp the file.
- ⑤ Put the endo file into patient's root canal slowly, start the foot switch can conduct ultrasonic root canal therapy. During clinical treatment, adjust the frequency according to actual situation.

Note: Must put the endo file into root canal before starting the foot switch.

- 6.4.2 Operations of P9/P9L/P9-2/P9-3
- 6.4.2.1 Install the bottle:
- 1 Clean the connection interface of the bottle.
- 2 Install the bottle to the main unit (Picture 6–2).
- ③ Put proper volume of pure water or special liquid medicine, such as Hydrogen Peroxide, Chlorhexidine, Sodium Hypochlorite into the bottle.

Note: The liquid medicine can not be lower than the lower limit to insure flowing smoothly, and can not be higher than the upper limit to insure safety.

- 4 Install the cover (Picture 6–2).
- 6.4.2.2 Connect the handpiece with the cable (Picture 10). Hold the handpiece in the same gesture as a pen in hand.
- 6.4.2.3 Select a suitable scaler tip as you need and screw it on the handpiece (Picture 6–4).
- 6.4.2.4 Connect the power and press the power switch. The power is connected when it shows blue color (Picture 6–5).
- 6.4.2.5 Adjust the power knob as you need, step on the foot switch and start the machine (Picture 6–6).
- 6.4.2.6 Function selection: Adjust the power knob to select the needed function.
- a). Scaling function
- 1 Adjust the power knob until the blue indicator lights.
- ② Select a suitable scaling tip according to your need and screw it on the handpiece tightly by the torque wrench (Picture 6–4).
- b). Perio function (Picture 6–6)
- ① Adjust the power knob until the blue indicator lights, and place the power indication in the light blue area.
- ② Select a suitable perio tip for periodontics treatment. Adjust the suitable power within the light blue area.
- c). Endo function (Picture 6-6)
- 1 Adjust the power knob until the green indicator lights.
- 2 Screw the endo chuck on the handpiece with endo wrench.

7.2.9 Processing limit

- 7.2.9.1 The medical devices have been designed for a large number of cleaning, disinfection and sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the medical device. The maximum number of sterilizations for ultrasonic scaler handpiece and ultrasonic scaler tip is 250 times.
- 7.2.9.2 When obvious damage is found on the surface during the inspection of ultrasonic scaler handpiece and ultrasonic scaler tip, don't continue cleaning, disinfection and sterilization.

8 Precautions 🗥

- 8.1 Please keep the scaler clean.
- 8.2 The handpiece, scaler tip, endo chuck, endo file, endo wrench and torque wrench must be sterilized before each treatment.
- 8.3 Don't screw or unscrew handpiece and scaler tip when stepping on the foot switch.
- 8.4 The scaler tip must be fastened by torque wrench and there must be fine spray coming from the tip when operating.
- 8.5 Change a new one when the tip is damaged or worm excessively.
- 8.6 Don't twist the tip or rub it.
- 8.7 Please use purity water source and be sure not to use normal brine instead of purity water source for B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/ P7/ P7L.Choose the liquid according to clinic treatment for P9/P9L/P9-2/P9-3.
- 8.8 If use non-pressure water for B5/B5S/B5L/P4/P5/BD2/P5L/B6/B6S/B6L/P6/P7/P7L, the water should be one meter higher than the head of the patient.
- 8.9 When the scaler is operated, please don't pull the handpiece forcibly in case of the handpiece or handpiece cord damage.
- 8.10 Don't knock or rub the handpiece.

- b). The sterilization bag can with stand high temperature of 134° C and has sufficient steam permeability.
- 7.2.6 Sterilization
- 7.2.6.1 Use only the steam sterilization procedures for sterilization, and other sterilization procedures are prohibited.
- 7.2.6.2 Only the moistheat sterilization method required by ISO17665 standards is allowed to sterilize the medical device.
- 7.2.6.3 Sterilization parameters and conditions
- a). Sterilization temperature: 132–134 °C.
- b). Sterilization times: 4 minutes.
- c). Dry times: 20 minutes.
- 7.2.6.4 Precautions
- a). Only products that have been effectively cleaned and disinfected are allowed to be sterilized:
- b). Before using the sterilizer for sterilization, read the instruction manual provided by the equipment manufacturer and follow the instructions;
- c). Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
- d). 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.
- 7.2.7 The sterilization package of ultrasonic scaler handpiece and ultrasonic scaler tip shall be protected well during storage after sterilization to prevent the medical device from pollution.
- 7.2.8 In the process of transportation, the medical device only needs to be ensured that its package is intact to prevent it from pollution.

- 3 Loosen the nut of endo chuck.
- 4 Insert the endo file into the front hole of endo chuck and use endo wrench to tighten the nut so as to clamp the file.
- ⑤ Put the endo file into the patient's root canal slowly, step on the foot switch and conduct the ultrasonic root canal therapy. Power and water can be adjusted according to actual needs during clinical treatment.

Note: Don't step on the foot switch before putting the endo file into the root canal.

- 6.5 Vibration intensity: Adjust the vibration according to the requirement. Generally adjust to 3 to 4 grade, but also adjust vibration intensity according to the patient's sensitivity and hardness of dental calculus at any time during the clinical treatment.
- 6.6 Water volume adjustment: Step on the foot switch and the tip vibrates, and then turn the water control switch to form good spray to cool handpiece and clean teeth.
- 6.7 Generally, hold the handpiece in the gesture as a pen in hand.
- 6.8 In clinical treatment, don't use the point of tip to contact with the teeth vertically, so as not to damage teeth and tip.
- 6.9 The normal frequency is extremely high. Under the normal working status of scaler tip, a light touch and a certain to-and-fro motion will eliminate the tartar without heating. Overexertion and long-time lingering are forbidden.
- 6.10 After finishing operation, keep the machines working for 20–30 seconds on the water supply condition in order to clean the handpiece and tips.
- 6.11 Uninstall the tip, sterilize handpiece, tips, endo chuck, endo file and torque wrench.

Note: Please don't pull out the handpiece and tips when the foot switch is stepped on and the machine is producing ultrasonic vibration.

7 Cleaning, disinfection and sterilization

7.1 Cleaning and disinfecting undetachable handpiece

Handpiece can be cleaned and disinfected by a non-corrosive disinfectant with neutral PH value. Do not disinfect in high temperature and pressure.

- 7.2 Cleaning, disinfecting and sterilizing detachable handpiece
- 7.2.1 Processing principles
- 7.2.1.1 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.
- 7.2.1.2 Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.
- 7.2.2 Cleaning
- 7.2.2.1 The cleaning of ultrasonic scaler handpiece and ultrasonic scaler tips should be performed no later than 12 hours after operation.
- 7.2.2.2 Pre-cleaning
- a). Flush the device under flowing water and brush the contaminant with a soft brush for no less than 1 min. Wipe the surface and groove of the device with a lint–free soft cloth for no less than 2 min until all residue visible has been removed.
- b). Place the device into the specified sterilization container, and then put the container into the rapid automatic washer–disinfector.
- 7.2.2.3 Automated cleaning
- a). It is recommended to use a washer–disinfectorin in accordance with EN ISO15883.
- b). Cleaning agent: ENDOZIME AW Plus W/APA. Dilution ratio: 1:270
- c). Time of cleaning: 5 minutes
- d). Temperature: 15-60°C

7.2.2.4 Precautions:

- a). The cleaning agent used here must be compatible with the ultrasonic scaler handpieces and only freshly prepared solutions can be used.
- b). The water temperature should not exceed $45\,^{\circ}$ C, otherwise the protein will solidify and it is difficult to remove.
- 7.2.3 Disinfection
- 7.2.3.1 Disinfection must be performed no later than 2 hours after the cleaning phase.
- 7.2.3.2 Automated disinfection
- a). The thermal automated disinfection method is adopted.
- b). Stipulated disinfection temperature: 90℃.
- c). Disinfection time: 6 minutes.
- d). Select the sterilizer meets the requirements of ISO15883 standards.

7.2.3.3 Precautions

Before use, you must carefully read the instruction manual provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

- 7.2.4 Inspection and maintenance
- 7.2.4.1 Check the ultrasonic scaler handpiece and its accessories. If there is still visible stain on the handpiece and its accessories after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
- 7.2.4.2 Check the surface of ultrasonic scaler handpiece. If there is obvious damage, breakage, falling off, corrosion or bending, it must be scrapped and cannot be used again.

7.2.5 Packaging

In order to make ultrasonic scaler handpiece and ultrasonic scaler tips not easy to be polluted after sterilization, meanwhile the package needs not to be damaged during moistheat sterilization process, select the sterilization bag that meets the following two conditions to pack ultrasonic scaler handpiece and ultrasonic scaler tips.

a). The sterilization bag used conforms to ISO 11607;