

Ultrasonic Scaler

Operating Manual Version V1.0

Model:

CE 2460



Introduction

Periodontal ultrasonic treatment instrument has multi-application in dental clinical treatment, it can be widely used in periodontology, endodontology and prevention of oral science, and it has different working tips, can be used with different flushing fluid according to clinical treatment requirement.

In order to master operation of Periodontal ultrasonic treatment instrument, read safety precautions and important notices in this operation manual carefully before using, keep this operation manual well for future reference.

People oriented technology, hope patients can be benefit from its unique advanced technology by using the product.

Last revision date: 23 June 2019

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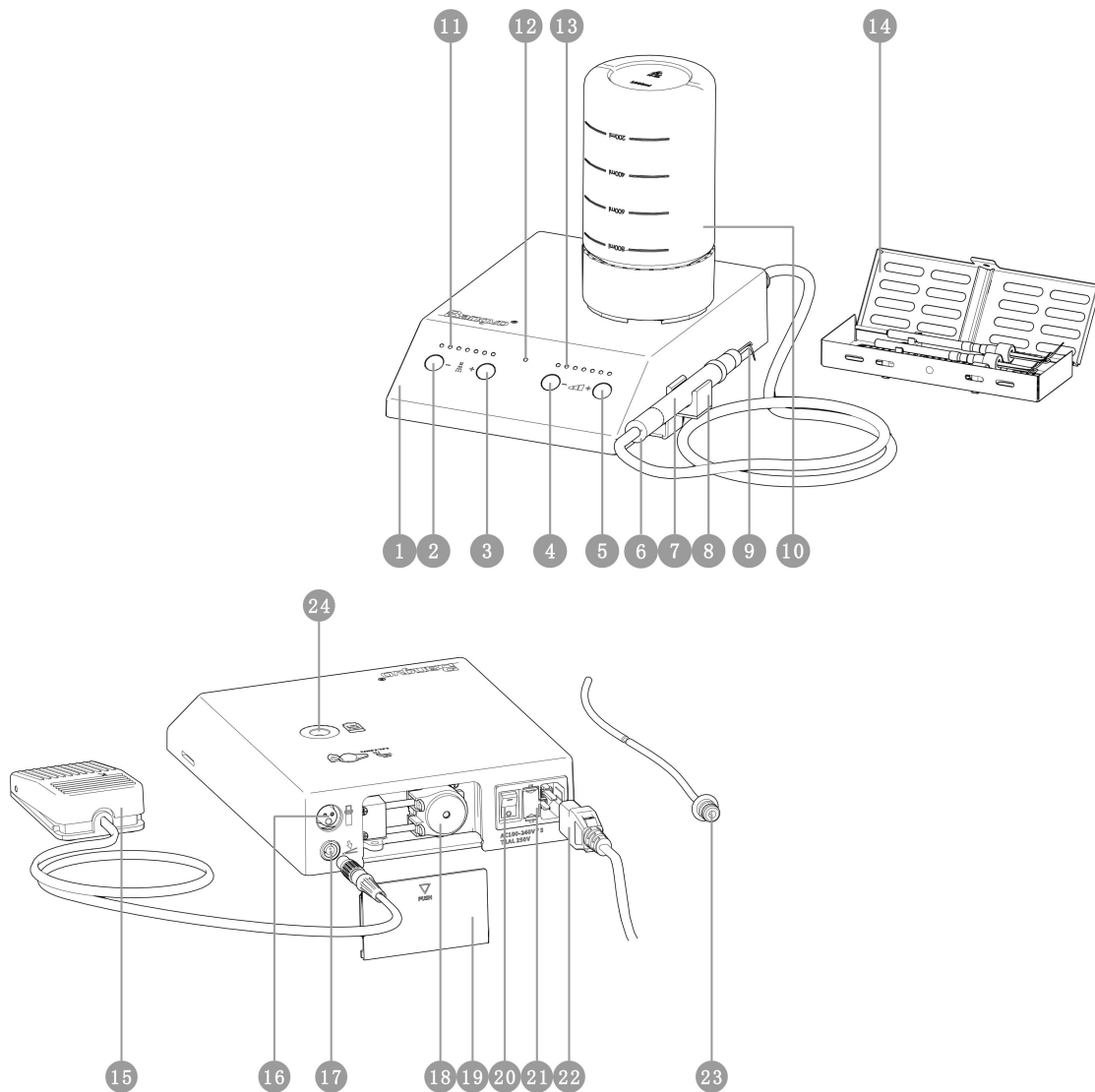
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A Composition of product

Product name: Ultrasonic Scaler

Model:

It is composed of main unit, handle, cable, water (fluid) supply components, foot pedal, and power line.



1.Main unit 2.(Flow -) switch 3.(Flow+) switch 4.Power switch

5.Power 6. handle cable 7. Handle 8. Handle holder 9. Ultrasonic tip

10. Flushing fluid bottle 11. Flow rate indicator 12. water way/status indicator
13. indicator light 14. root canal file box 15. Foot pedal
16. Handpiece socket 17. Foot pedal switch socket 18. Water pump
19. Water pump tank cover 20. Power switch socket 21. Fuse box
22. Power line 23. pumping adapter 24. Flushing fluid bottle base

B Product clinical feature

ultrasonic scaler can provide lower amplitude (10 μ m) and higher vibration frequency (41.5KHz) than most of ultrasonic scalers in the world now.

Working tips are made of titanium alloy, it moves in a circular motion with 41.5KHz high frequency, (41500 vibrations per second), its minimum amplitude is about 10 μ m, which is a quarter of a diameter of human hair, this make patients feel comfortable during treatment.

Unique fluid supply system can introduce flushing fluid of external fluid supply container or dental chair fluid supply system.

Water pump driving system is separated from fluid supply system, which keeps flushing fluid clean during the transportation to treated area.

Connection, usage and replacement of handle cable, working tips is easy, simple and convenient.

C Application

Ultrasonic scaler applies to cleaning, trimming of oral cavity such as tooth surface and root canal.

D Contraindications and special attention



D1 Contraindications

- 1) It is contraindicated for hemophilia patients.

- 2) It is contraindicated for patients with cardiac pacemaker or defibrillator.
- 3) It is contraindicated for doctors with cardiac pacemaker or defibrillator.
- 4) Heart disease patients, pregnant woman and children should use with caution.

D2 Special attention

- 1) When replacing accessories and spare parts, use replacement parts provided by Bangvo, to avoid accident.
- 2) The product only can be used by qualified person who is trained professionally (such as dentist, dental hygienist), to avoid accident.

E Fluid supply tube cleaning

Distilled water, deionized demineralized water



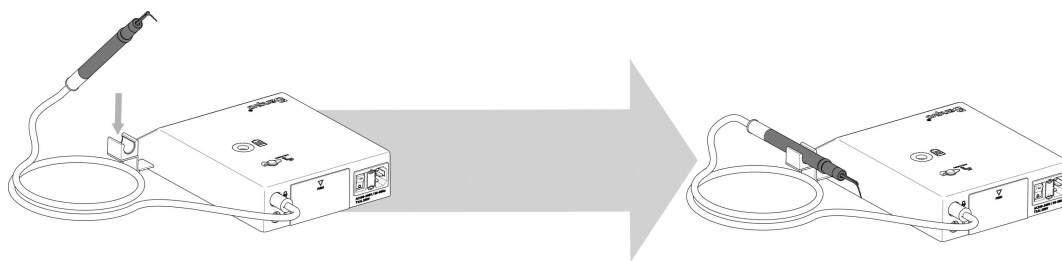
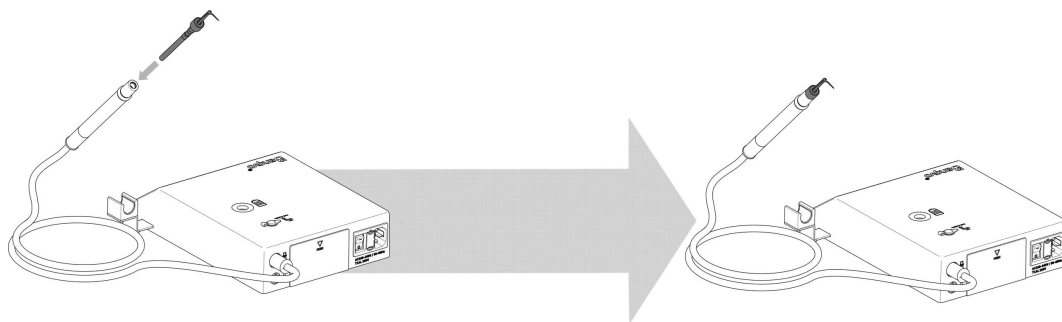
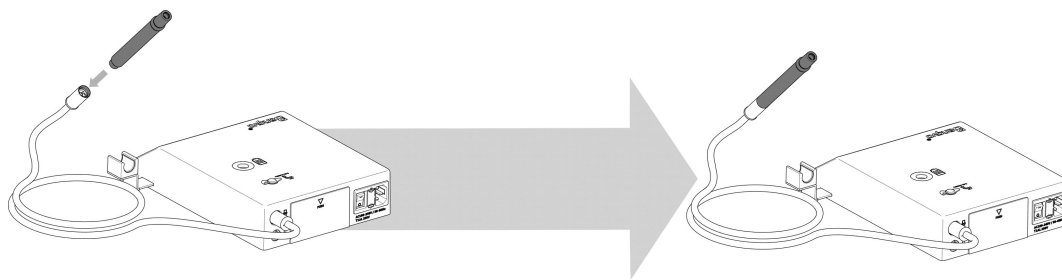
Different flushing fluid may react, it may cause damage for fluid supply tube or other unknown risk.

Clean tube before use different flushing fluid is necessary.

F Installation steps

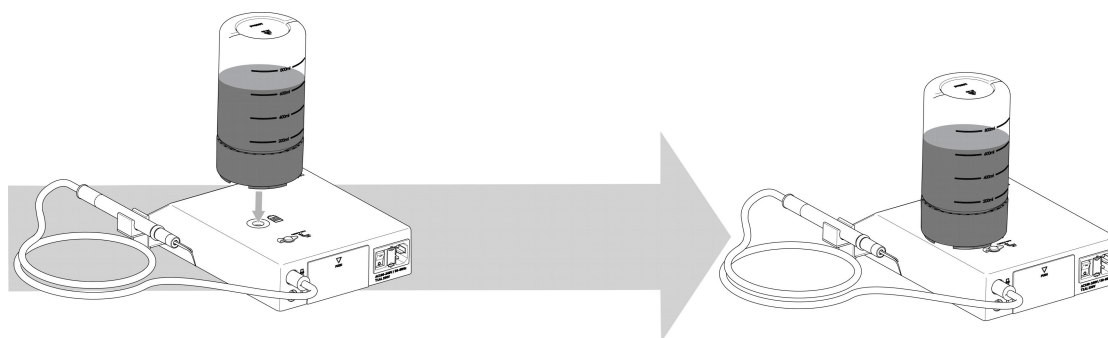
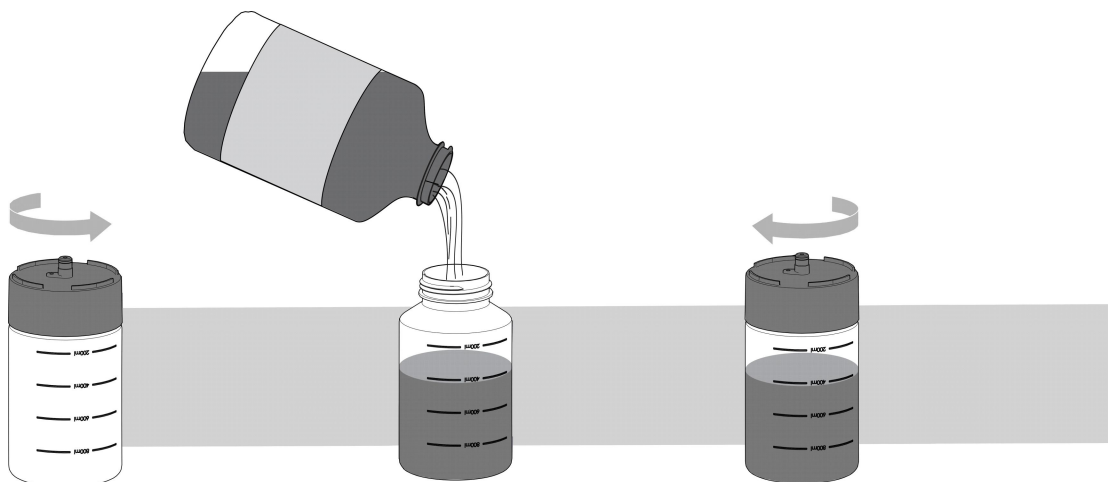
F1 Installation of handle, handle cable, handle holder and working tip





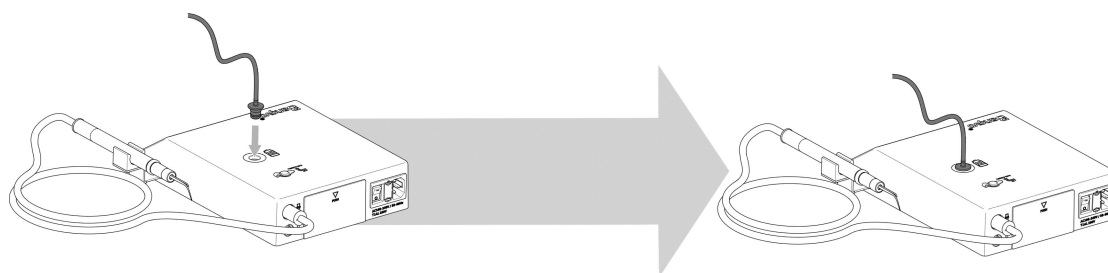
F2 Fluid supply system installation

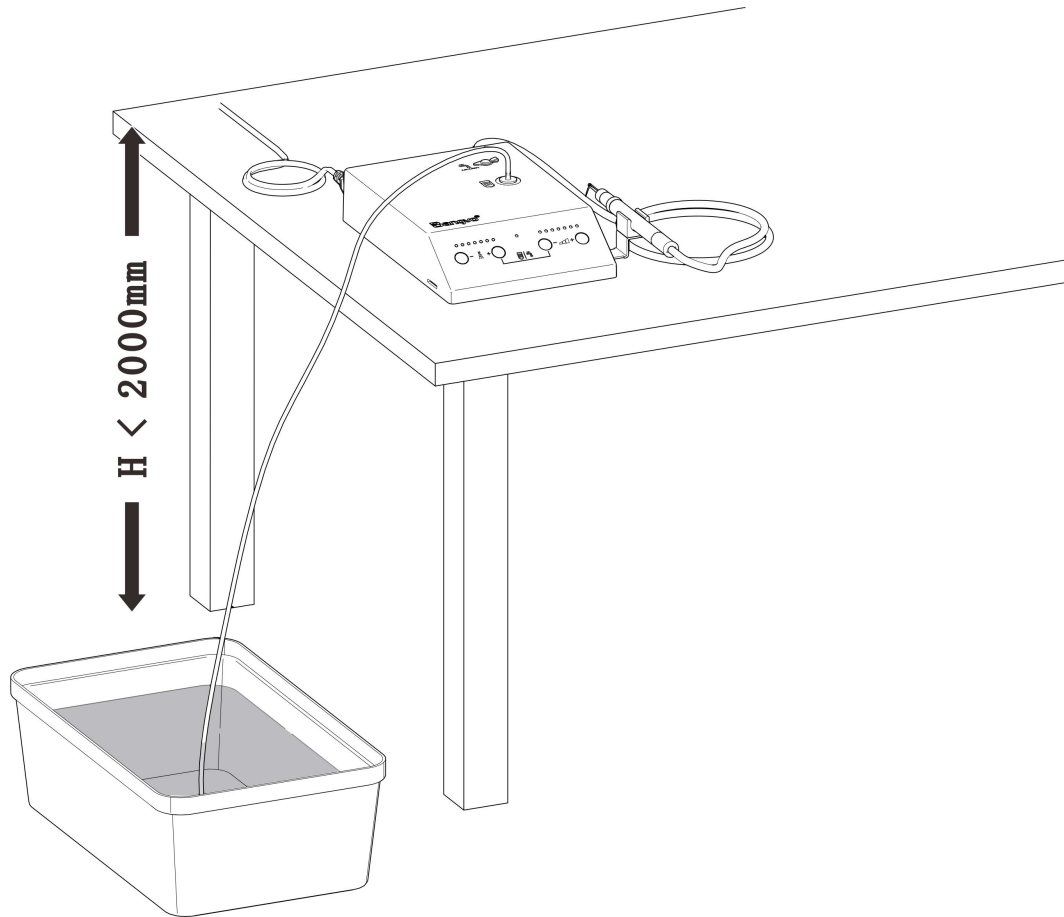
F2.1 Flushing fluid bottle



Check the seal ring of cap is intact before installing flushing fluid bottle.

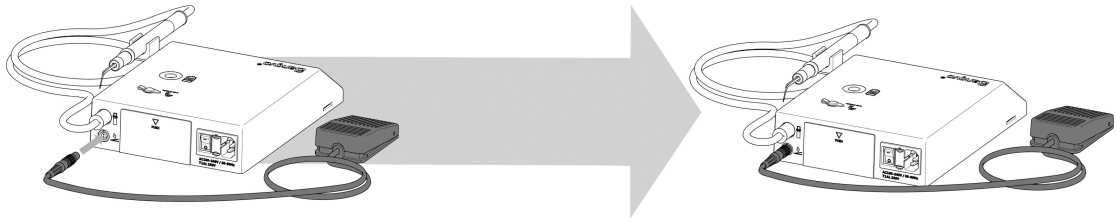
F2.2 Other fluid storage supply system



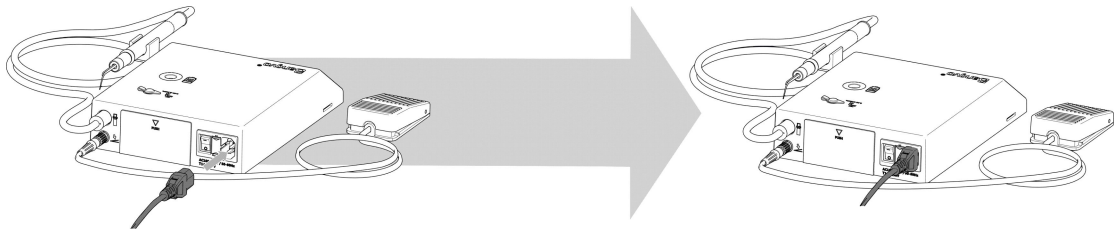


The vertical distance between main unit and fluid storage container should be less than 2 meters.

F3 Foot pedal installation.



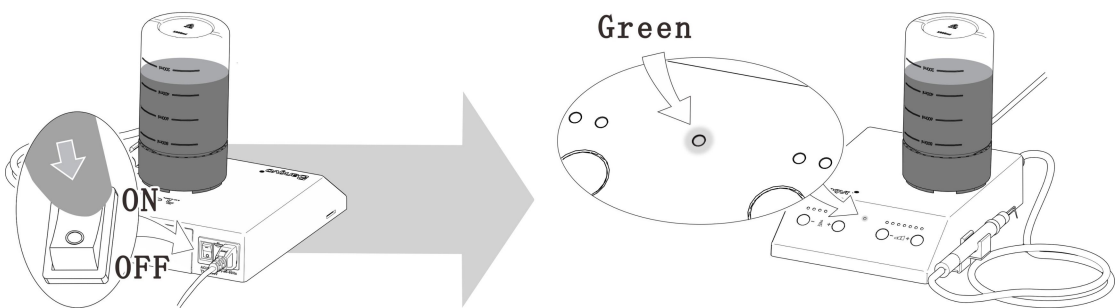
F4 Installation of power line



Attention: Input power of the unit is single-phase alternating current, the scope is 100V~240V, make sure input power voltage is consistent with the unit' s voltage, and with good grounding.

G Operation

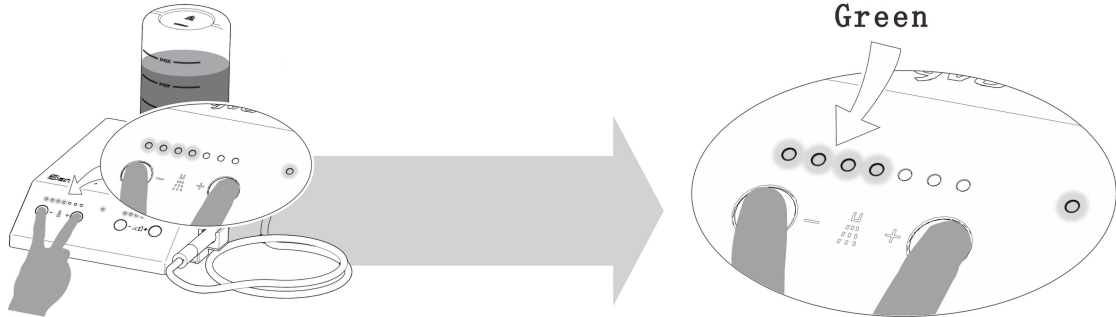
G1 Main unit start



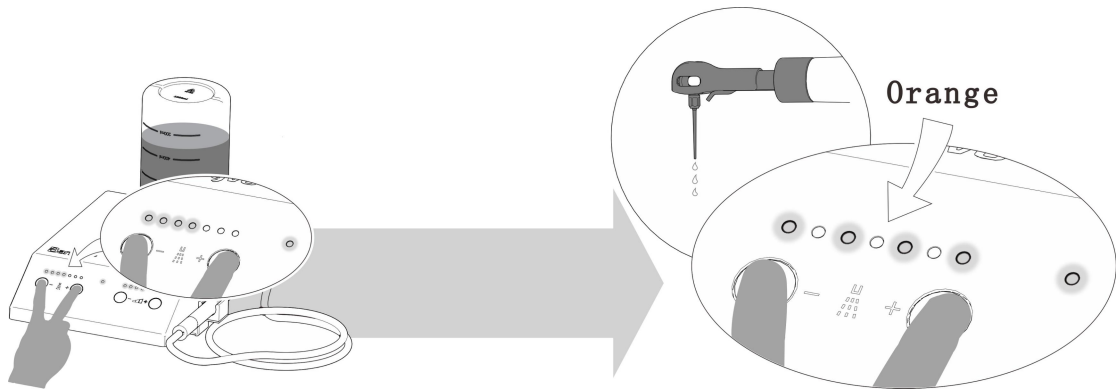
- 1) Main unit in idle mode, status indicator is green, and keeps on;
- 2) Main unit in working mode, status indicator is green, and blinking;

G2 Fluid supply system option

When in flushing fluid bottle mode, check the margin of flushing fluid repeatedly to supplement in time.



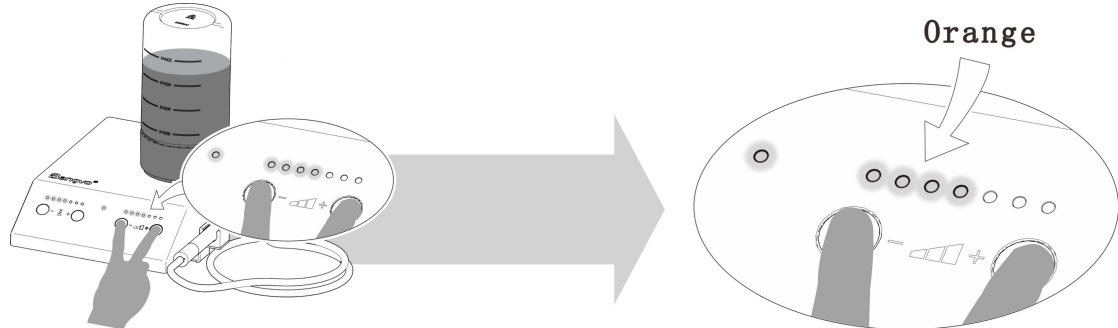
Choose flushing fluid bottle continuous supply mode, fluid infusion volume indicator is green and lighting up continuously.



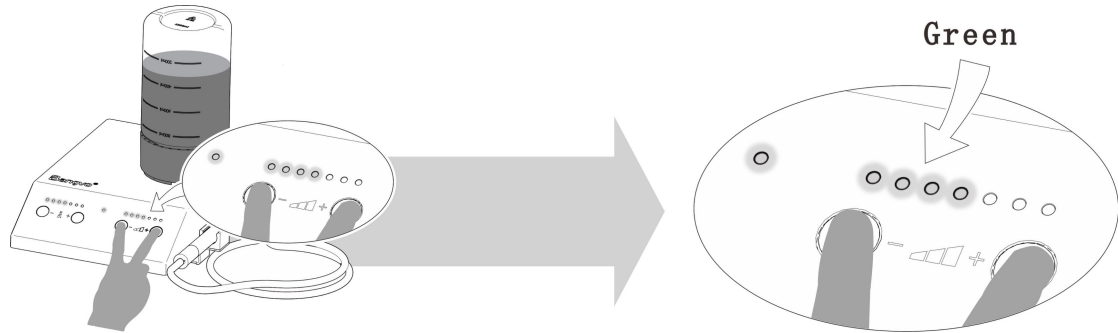
Choose flushing fluid bottle intermittent supply mode, fluid infusion volume indicator is orange, and lighting up interally.

G3 Choose tip and working mode

Choose suitable working tip and mode according to your requirement, default mode is standard working mode.



Choose standard working mode, power indicator shows green, and lights up continuously.

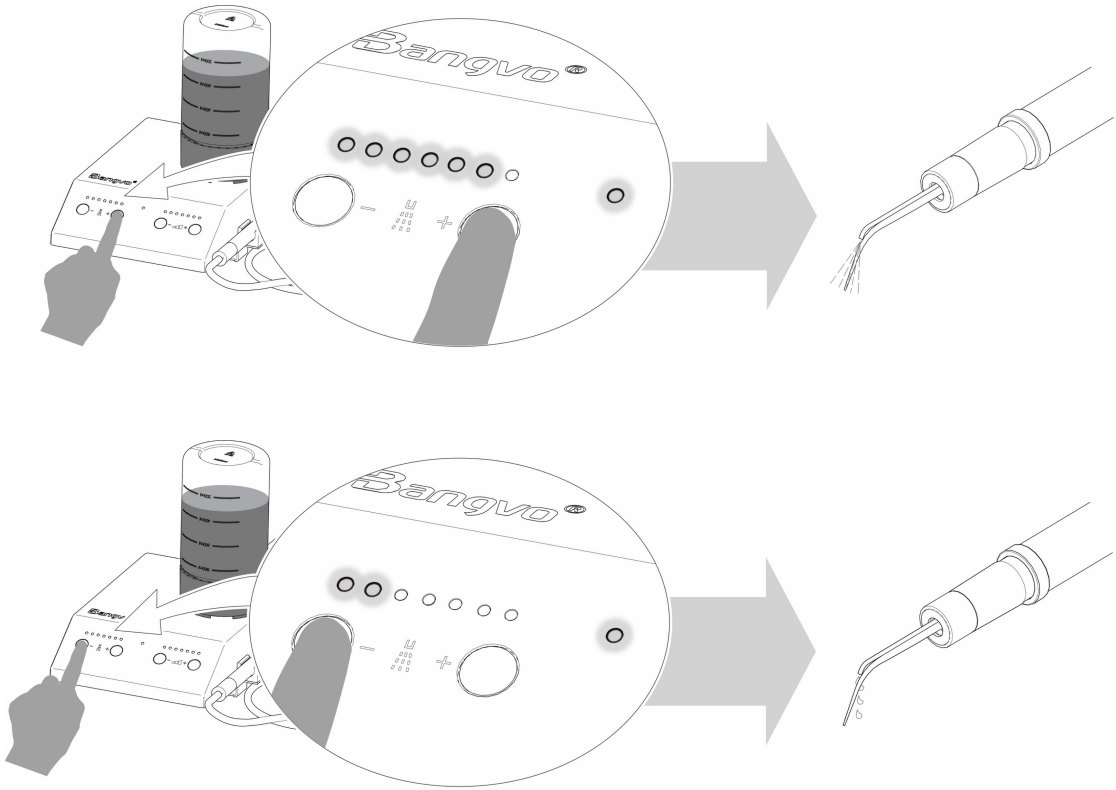


Choose comfort working mode, power indication shows green, and lights up continuously.

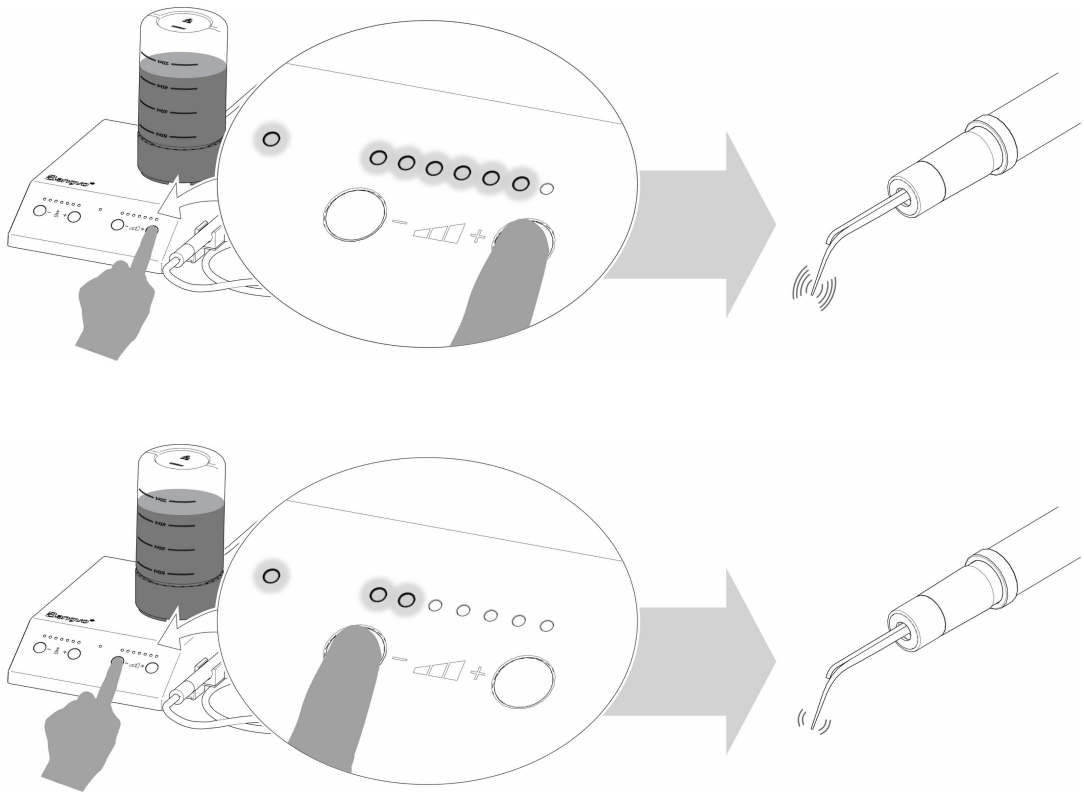


The mode is special for Model.S200 ultrasonic scaler. L200 is not applicable.

G4 Adjust fluid supply volume of working tip

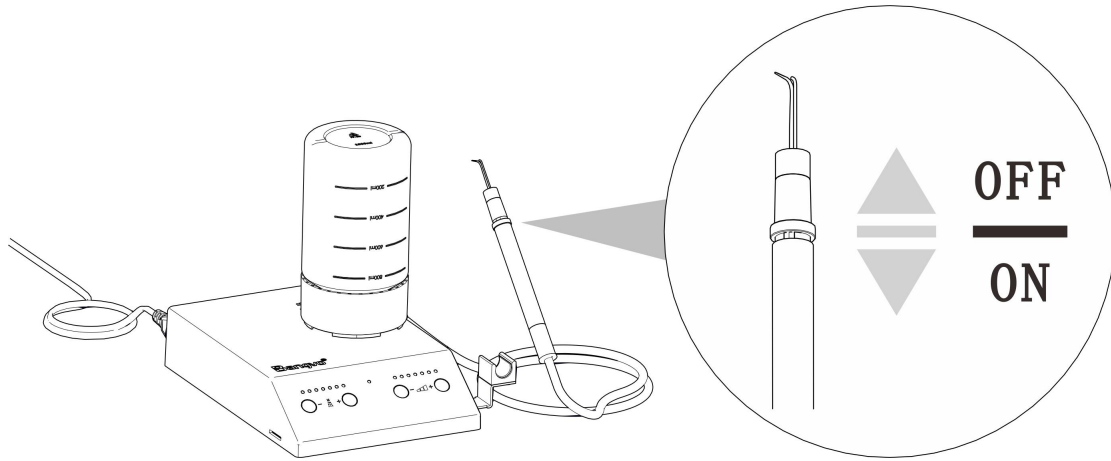


G5 Adjust vibration intensity of working tip

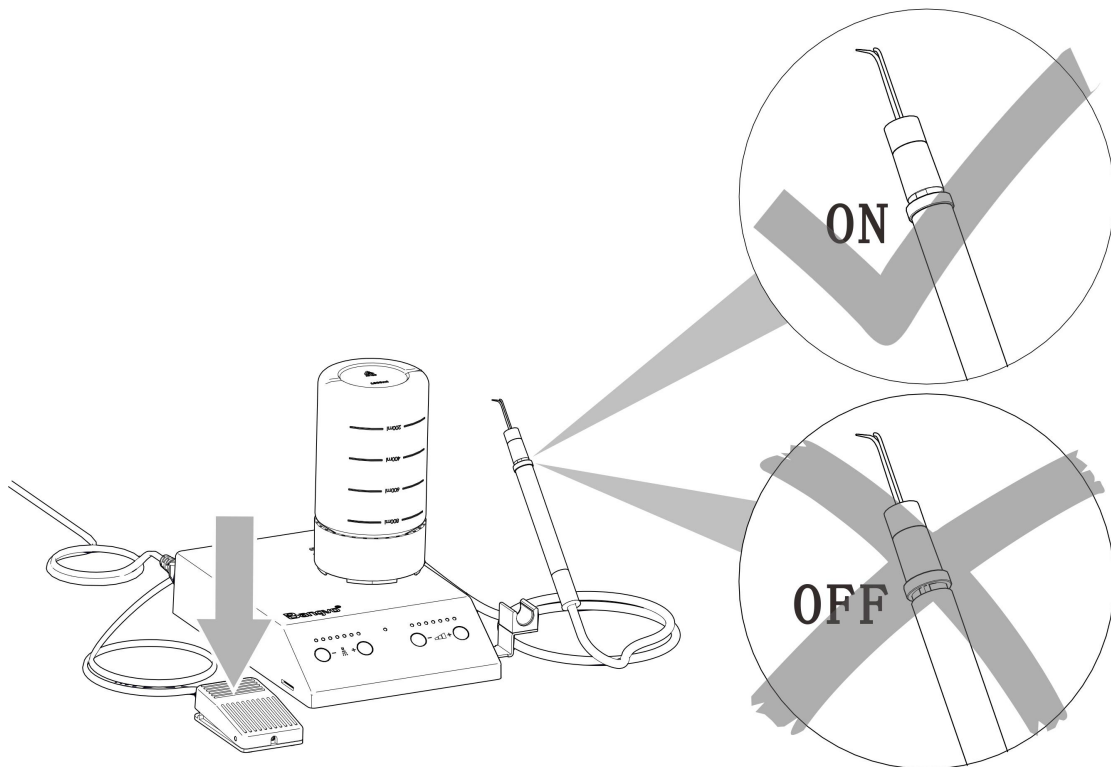


G6 Main unit

G6.1 Use finger control switch to control handle.

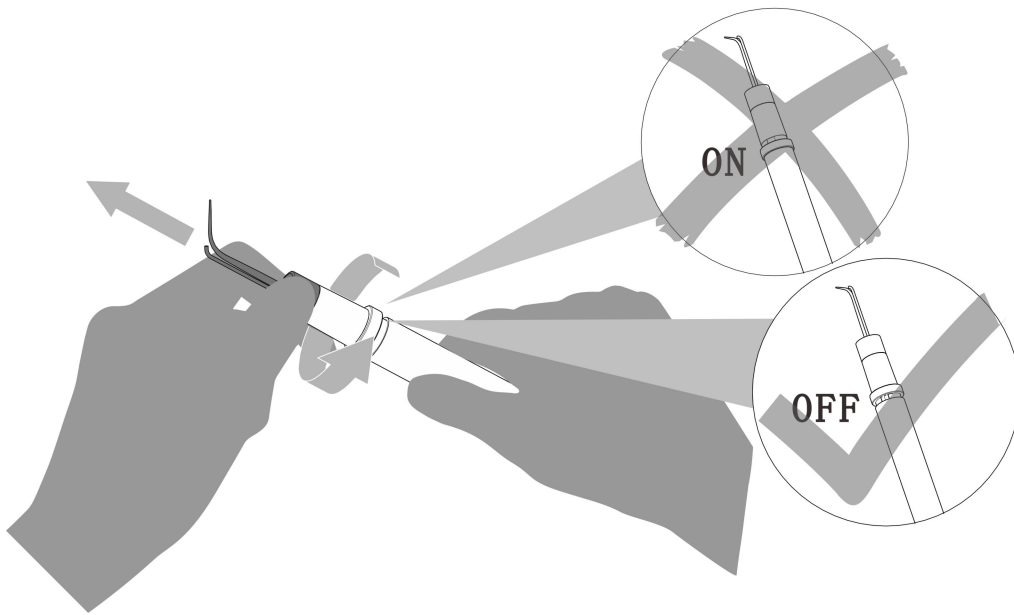



G6.2 Use foot pedal to control.



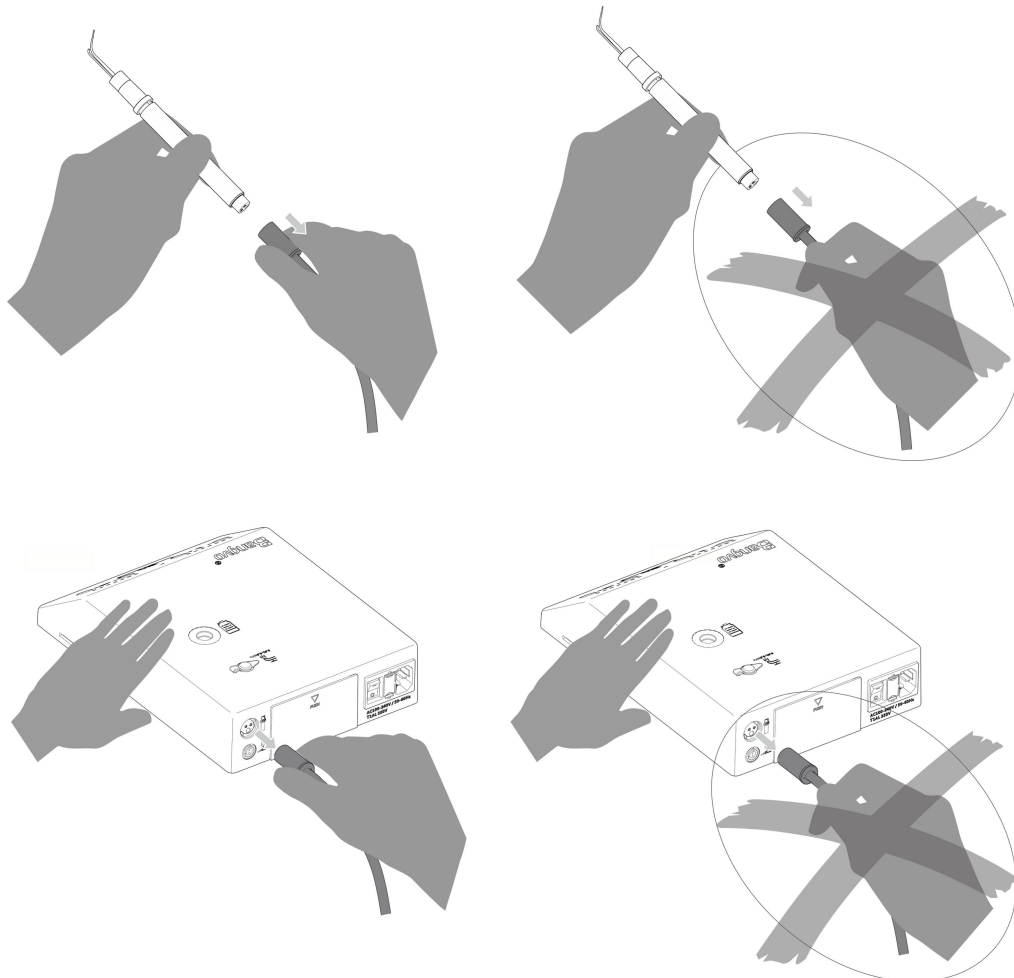
Finger control switch must be on before operation, and use foot pedal to control.

G7 Tip replacement

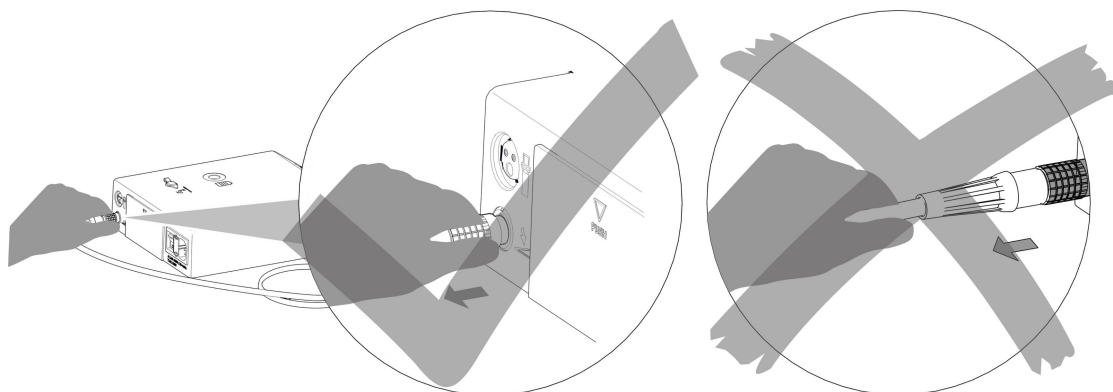


 Finger control switch must be off before replacement.

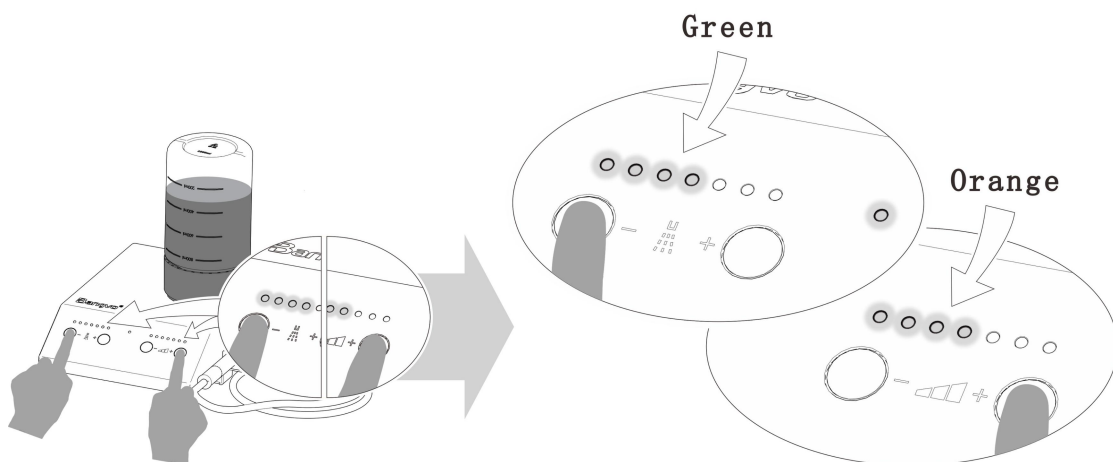
G8 Handle and handle cable disassembly



G9 Foot pedal disassembly



G10 Restore factory setting



H Cleaning and disinfection

For the instrument is in use, we suggest to clean and disinfect the instrument and accessories every day, to reduce crystal deposition and bacteria quantity in tube.

H1 Fluid supply tube

Fluid supply tube needs to be cleaned after each treatment period is finished or change different flushing fluid during treatment.

Use distilled water or dermineralized water, adjust flow to the maximum, put handle on top of sink, turn on handle, and last no shorter than 30s. After fluid supply is cut off, turn on main unit and keep it working for 15s, to empty residual liquid left in tube, handle and tip.

H2 Working tip

Tips can be put into disinfection box to be disinfected by autoclave sterilization, they can bear 135°C/2.2bar (0.22MPa) high temperature high pressure disinfection. Or use other medical oral disinfectant to do immersion disinfection.

H3 Handle and handle cable

Use alcohol, suds or other detergent to wipe handle, it can bear 135 °C /2.2bar (0.22MPa) high temperature high pressure disinfection.

Handle can' t be soaked in liquid, alcohol, suds or other detergent.

Any chemicals contain histochoice tissue fixative, such as glutaraldehyde, formalin, is not allowed to use for cleaning and disinfection for handle and handle

cable.

H4 Main unit shell

Surface of main unit only can be wiped by alcohol, detergent or suds. Strong dissolution reagent, such as lacquer thinner (banana oil), gasoline, is not allowed to swipe main unit surface.

I 常见故障现象及排除 Common faults and troubleshooting

I1 常见故障现象 Common faults

Fault phenomena	Reason	Solution
Leaking in gap between handle and handle cable socket end.	Seal ring of tube at the handle cable socket end is damaged.	Contact Bangvo
Leaking in gap between handle and working tip.	O-ring in tip is aging or damaged.	Contact Bangvo
Main unit indicator light does not light after power on.	Power fuse is burned, or poor contact between socket.	Take it out from main unit power socket, replace fuse, and check power plug and socket. (see J2.1 for ref.)
Motor pump works normally, but no flushing fluid flows.	Fluid supply pump components are damaged.	Replace fluid supply components (see J2.2 for ref.)
	Directions of inlet and outlet are installed oppositely.	Re-install fluid supply components (see J2.2 for ref.)
	Handle and its cable or tube in tip is obstructed.	Contact Bangvo
Vibration of tip is weakened or doesn't	Liquid enters into handle.	Swing handle and remove liquid in it.

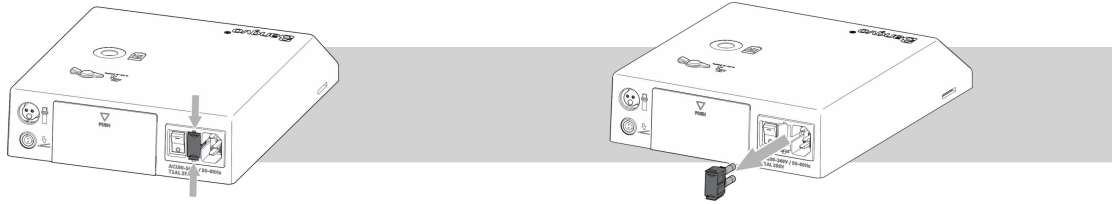
work or makes abnormal noise.	Magnetic bar is aged, cracked or damaged.	Contact Bangvo
	Tip is worn seriously, out of shape or damaged.	Contact Bangvo



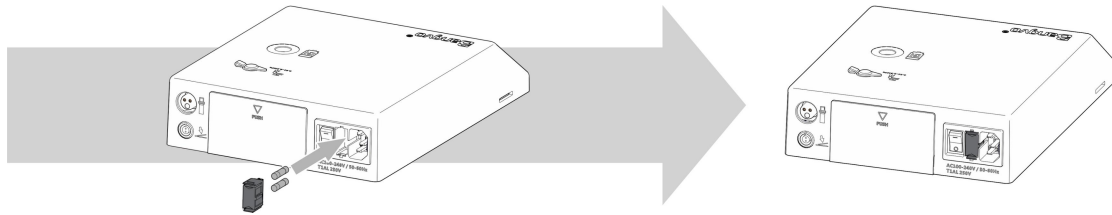
Attention: If fault still can't be solved according to the methods mentioned in manual, please contact Bangvo, do not repair it by yourself.

I2 Common trouble shooting

I2.1 Replace power fuse



disassemble fault power fuse

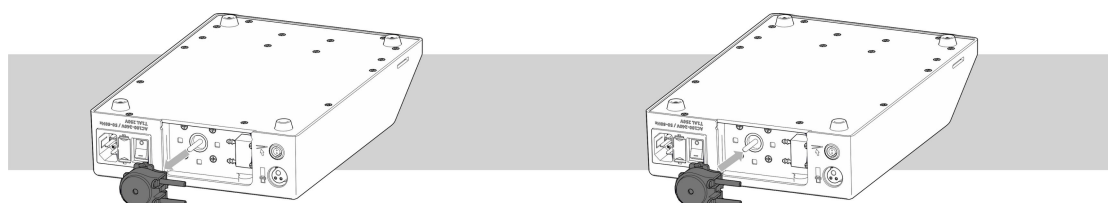
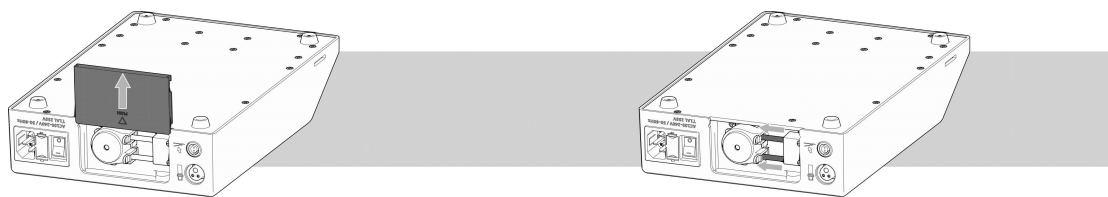


install new power fuse

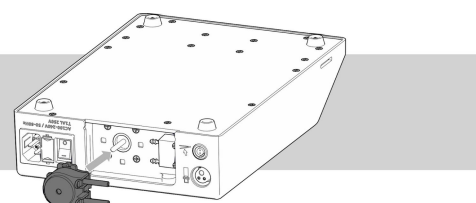


Attention: power fuse specification: AC slow blow fuse, model No. T1A/AC250V, replace fuse according to standards.

12.2 更换供水水泵组件 fluid supply pump components replacement



disassemble fault pump component



install new pump component



J Storage, maintenance and transportation

Before scrap, all the original packages need to be remained, in case use them for transportation and storage.

J1 Storage and maintenance

1) Keep away from and do not mix with toxicants, corrosives, inflammables and explosives when storage the product.

2) Handle the product with care, keep away from vibration, and put it or keep it in a cool ventilated dry place.

3) The product should be stored in an environment, relative humidity isn't more than 80%, atmospheric pressure is 50kPa ~ 106kPa, temperature is -10°C ~ 50°C.

4) Power switch should be turned off, and pull the plug when the product is not in use. Long-term use, please electrify it and keep liquid supply once per month, 5 minutes per time.

J2 Transportation

1) The product should be put into original package to transport to avoid damage.

2) Handle with care, and prevent excessive shock and vibration during transportation.

3) Do not mix with dangerous cargo during transportation.

4) Avoid solarization, rain and snow during transportation.

K Environment protection

The left flushing fluid and used flushing fluid should be put into sealed container or , and do liquid waste treatment. If distilled water or other harmless liquid is used as flushing fluid, it can be pour into sink directly without any treatment.

Treatment and destroy of the product should be proceeded according to local law and regulations.

L EMC



Attention

S1/L1 ultrasonic scaler is compliant with YY0505 standard for EMC related requirements.

User should install and use the produce according to EMC information provided by manufacturer.

Portable and movable RF communication equipment can influence performance of S1/L1 ultrasonic scaler, avoid strong electromagnetic interference, such as near to movable phone, microwave oven.



For details see attached Guide and declaration of manufacturer

Warning

S1/L1 ultrasonic scaler should not be close to or stacked with the other devices. If being used with other devices, please observe and verify that it can work normally with chosen configuration.

Class A device is intended to use in industrial environment, due to conducted disturbance and radiation disturbance of S1/L1 ultrasonic scaler, make sure EMC may have potential difficulties in the other environment.

Except original cable produced by manufacturer of S1/L1 ultrasonic scaler, use the other accessory and cable may cause emission increase or immunity reduce.

Circuit Form

No.	Name	Cable Length (m)	Shielding	Remark
1	power line	3.0	N	/
2	handle cable	2.0	N	/
3	foot pedal cable	2.0	N	/

L1 Attachment- Guide and Declaration of manufacturer

Guide and Declaration of manufacturer-EME		
S1/L1 ultrasonic scaler is intended to use in below electromagnetic environment, buyer or user should make sure it is used in such electromagnetic environment.		
Emission Test	Conformity	Electromagnetic environment-Guide
radio-frequency emission GB 4824	Group 1	S1/L1 ultrasonic scaler only use radio frequency energy for its internal function. So, it has low RF frequency, and low possibility of generating interference with electronic devices nearby.
radio-frequency emission GB 4824	Class A	S1/L1 Periodontal ultrasonic scaler is suitable for non-domestic and all facilities that connect residential public low voltage supply network indirectly
harmonic emission GB 17625.1	NA	
voltage fluctuation/twinkle emission GB 17625.2	NA	

Guide and Declaration of manufacturer-EMI


S1/L1 ultrasonic scaler is intended to use in below electromagnetic environment, buyer or user should make sure it is used in such electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Coincidentdet Level	Electromagnetic-guide
Electro-Static discharge (ESD) GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	± 6 kV contact discharge ±8 kV air discharge	Ground should be woody, concrete, ceramic, if ground was covered by synthetic material, the relative humidity should be at least 30%.
Electrical transient(EFT) GB/T 17626.4	±2kV to power line ±1kV to input/output line	±2kV to power line	Mains should have quality for typical commercial or hospital environment.
Surge GB/T 17626.5	± 1kV difference-mode voltage ± 2 kV common mode voltage	±1kV difference-mode voltage ±2 kV common mode voltage	Mains should have quality for typical commercial or hospital environment
Power supply input wire voltage sag, short interruption, and voltage change GB/T 17626.11	<5 % U_T , last 0.5 cycle (at U_T , >95% sag) 40 % U_T , last 5 cycle (at U_T , 60% sag) 70 % U_T , last 25 cycle (at U_T , 30% sag) <5 % U_T , last 5s (at U_T , >95% sag)	<5 % U_T , last 0.5 cycle (at U_T , >95% sag) 40 % U_T , last 5 cycle (at U_T , 60% sag) 70 % U_T , last 25 cycle (at U_T , 30% sag) <5 % U_T , last 5s (at U_T , >95% sag)	Mains should have quality for typical commercial or hospital environment. If user of S1/L1 ultrasonic scaler requires continuous working during power interruption, Uninterruptible power supply or battery powered is recommended for the

			product.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	Power frequency magnetic field should have typical place characteristics in typical industrial or medical environment.
Remark: U_T means AC voltage before applied test voltage.			

Guide and Declaration of manufacturer-EMI

S1/L1 ultrasonic scaler is intended to use in below electromagnetic environment, buyer or user should make sure it is used in such electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Coincidentdet Level	Electromagnetic-guide environment
<p>Radio-frequency conduction</p> <p>GB/T 17626.6</p> <p>Radio-frequency radiation</p> <p>GB/T 17626.3</p>	<p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>3 V/m</p> <p>80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and movable RF communication device should not be closer to any part of S1/L1 ultrasonic scaler than recommended distance, including cable, when they are working. The distance should be calculated by relevant transmitter frequency formula.</p> <p>In recommended isolation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>P—According to the maximum rated output of transmitter provided by transmitter manufacturer, the unit is watt.</p> <p>Recommended isolation distance, the unit is m.</p> <p>Field intensity of stationary RF transmitter is determined by survey ^c of electromagnetic field, in each frequency range, ^d should be lower than coincidentdet level.</p> <p>Interfere may appear when near to the devices with below symbol.</p> <div style="text-align: center;">  </div>
<p>In frequency 80MHz and 800MHz use higher frequency formula.</p> <p>The guide may not be suitable for all conditions, electromagnetic propagation is affected by buildings, objects, absorption and reflection of human body.</p>			

A Stationary transmitter, such as wireless (cellular system, cordless) telephone, movable ground radio base station, amateur radio, amplitude and FM radio, videocast, their field intensity can't be foreseen accurately. In order to evaluate electromagnetic environment of stationary RF transmitter, survey of electromagnetic field should be considered. If field intensity of S1/L1 ultrasonic scaler is higher than above applicable RF coincident level, observe and verify if it can work normally. If there has abnormal performance, supplement measure is necessary, such as re-adjust direction or position of the product.

B In frequency range 150KHz ~ 80MHz, field intensity should be lower than 3 V/m.

**Recommended isolation distance between portable and movable RF communication device
and periodontal ultrasonic treatment instrument**

S1/L1 ultrasonic scaler is intended to use in RF radiation disturbance controlled electromagnetic environment. According to the maximum rated output, as recommended in below, buyer or user can prevent electromagnetic interference by maintain the minimum distance between portable and movable RF communication device (transmitter) and device or system.

W Max. Rated output of transmitter W	Isolation distance for different frequency/m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
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 unlisted the maximum rated output above, recommended isolation distance is d, the unit is m, formula in relevant transmitter frequency column can be used to confirm, here P is the maximum rated output provided by transmitter manufacturer, the unit is W.













In frequency 80 MHz and 800 MHz, use higher frequency range formula.




The guide may not be suitable for all conditions, electromagnetic propagation is affected by buildings, objects, absorption and reflection of human body.

M Accessories and serial No.


Name	Specification
Ultrasonic working tips	SS02/SR03/SL04/PS02/PR04/PL05/PR06/PL07/P10
handle (black)	/
handle cable (black)	2m
foot petal	2m
power line	3m
disinfection box	/
flushing fluid bottle	/
Operating manual	/
disk	/

N Symbol description

Symbol	Description
	registered trademark
	type B applied
	Refer to Operating instructions
	Indicates this device is in compliance with MDD 93/42/EEC. 2460 is the Notified Body Number
	Date of manufacture
	Manufacturer ID
	Authorized Representative in the European community
S1/L1	product model No.
	serial number
	Compliance with WEEE Standard
	attention
	output power regulation
	output flow regulation

	connector for flushing fluid bottle
	handle cable connector
	foot pedal connector
IPX4	waterproof grade of equipment
AC100-240V / 50-60Hz	voltage and frequency of input power
T1AL 250V	fuse specification

O Technical parameter

Power type:	single-phase power with grounding (L+N+PE)
Power voltage:	AC 100~240V 50~60Hz
Security type:	Class I , type B 
Power:	Max. 50VA
Maximum power output:	8.5W
Fuse:	T1A, AC 250V
Frequency:	41.5kHz ±2%
Amplitude:	10~100μm
Half polarization force:	0.5 N ±50%
Flushing dose:	0~80mL/min
Main unit outer size:	272×190×62.5MM
Weight:	4.6 kg
Service life:	5years

P License

Production licence: Guangdong Food and Drug Administration No.20112104

CE certification No. : 11856-2017-CE-RGC-NA-PS Rev. 0.0

Registration No.: Guangdong Medical Device Registration No.20172231316:

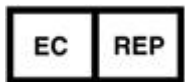
Add:Room 201, Building A, Jinke industrial park, No. 310 Wuh
e avenue, Luhu community, Guanhu street,Longhua District,S
henzhen

TEL: 0755-86218029 FAX: 0755-25851860

Website: www.bangvo.com E-mail: bv@bangvo.com

Contact: Mr Huang Mobile: 13808803541

CGI Business Trading and Consulting e.K



Add: Hans-Bethe-Str.1, 60438 Frankfurt am Main, Germany

Tel: +49 -69 1752 6970 Fax: +49-(0)-69-1534 6558

Email: cgi-trading-consulting@hotmail.com

Q Warranty notes

The manufacturer provide 12 months free guarantee period for the product from the date of user' s acceptance. Damage caused by human error or negligence is not included in the scope of warranty. During warranty period, user can send main unit or components with warranty card to the manufacturer or local agent to handle.



Attention: The manufacturer assumes no responsibility for below situations.

- 1) User doesn't operate the product according this manual strictly.
- 2) Modify, repair the product and change the technical parameter without

authorization.

3) Bend, sharpen, refit shape and structure without authorization.

4) Use accessories or components which are not provided by the manufacturer.

The manufacturer reserves the right to improve, change design or stop producing the product, no need to inform the user.