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VRN- A8/VRN-A8Plus

Ultrasonic Scaler

OPERATION MANUAL

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Copyright and statement

Copyright © URIT Medical Electronic Co., Ltd.

Congratulations to become valued customers of URIT Medical Electronic Co., Ltd. Thanks for using VRN-A8 / VRN-A8Plus Ultrasonic scaler. It will bring you the new experiences and conveniences.

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Read the instruction manual originally delivered with each of the components before using this product and follow the instruction manual to operate. Otherwise, URIT Medical Electronic Co., Ltd. Dose not take any responsibility for any errors and damage o the product because of violation operation.

Note:

URIT Medical Electronic Co.,Ltd does not promise any implied guarantee to the product special use for merchantability and applicability.

If you need after-sale service support, please contact with authorization dealer or manufacturer.

Warning

The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

The device requires no calibration.

The device is not repairable and contains no user serviceable parts.

No modification of this equipment is allowed.(3rd Edition)

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons.

1.Products overview

1.1 Overview

VRN-A8 / VRN-A8 Plus Ultrasonic scaler has the function of scaling. periodontal treatment and root canal irrigation, and has the following characteristics:

- With 2 routes of water supply systems, convenient to operate;
- Hydraulic routing is made by the antibacterial materials. The clinical fluids, such as hydrogen peroxide, chlorhexidine, sodium hypochlorite can be filed into the automatic water supply system, which significantly improve the performance of periodontal therapy and root canal irrigation.
- Handpiece can be autoclaved under 133℃(± 2℃) and 193 kPa~201 kPa.
- Automatic frequency tracking system ensures the best working status, performance is much more stable.

- The built-in PC chip with intelligent control of power make the treatment more comfortable.
- The evolutionary wireless foot switch remotes the main unit, and the cord switch can also be selected according to user needs.
- High brightness LED light improves the clinical efficiency; the main unit can also fit the regular detachable handpiece.

Operating life of the scaler is 10 years.

1.2 Product components

The device is composed of electronic controlling circuit, waterway, handpiece and tips.

1.3Product scope

An ultrasonic scaler is a device intended for use during dental cleaning and periodontal(gum)therapy to remove calculus deposits from teeth to prevent periodontitis by application of an ultrasonic vibrating scaler tip to the teeth.

1.4 The technical specification

- Working conditions:
- Temperature:5℃~40℃ Relative humidity≤80% Atmospheric pressure:70 KPa–106 KPa
- Power supply:
Adaptor Input:100–240Vac,50–60Hz,
Power consumption:30Vdc,1.3A
For main unit:30 Vdc, 1.3A

- Wireless control foot pedal battery:1.5VX2
- Receiving sensitivity:–114dB
- Primary vibration excursion of the tip: Minimum, 1 u m, Deviation–50%
Maximum,100u m, Deviation+50%
- Output half–excursion: Minimum,0.1N, Deviation–50%Maximum,2N,Deviation +50%
- Vibration frequency of the tip:18 kHz–60kHz
- Input Power:30VA–48VA
- Ultrasonic output power:3W–20W
- Fuse: 125V1.5A
- Water pressure:0.1bar–5 bar(0.01MPa–0.5MPa)
- Weight of main unit:0.75kg
- Weight of adapter:0.25kg
- Size:330mm x 245mm x 190mm
- Operating mode: Continuous operation
- Type of protection against electric shock: Class II Equipment
- Degree of protection against electroshock: Type B applied part
- Degree of protection against harmful ingress of water:
Ordinary equipment(IPx4), Protection Degree against water(used on the wireless control foot pedal)(IPx6)
- Safety degree of the application the presence of a Flammable Anaesthetic Mixture with air or with Oxygen or Nitrous Oxide: Equipment Not suitable for being used in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide

1.5 Components and function

1.5.1 Install instruction

a) The Front And back sketch map of the main unit

FIGURE 1

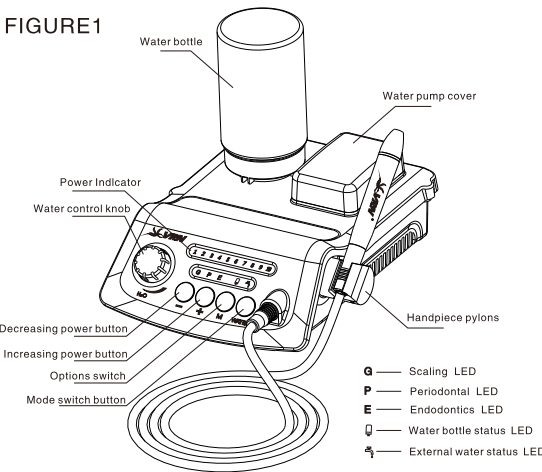
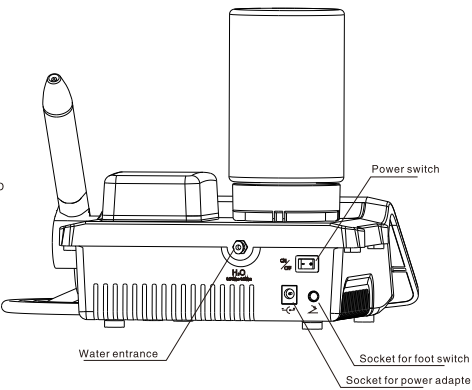
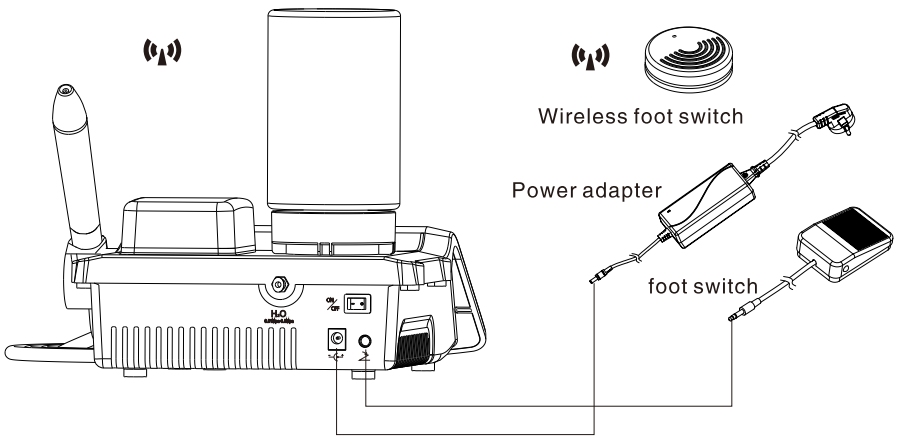


FIGURE 2



b) Main unit, foot switch and adapter connection

FIGURE 3



c) Water way connection



FIGURE 4

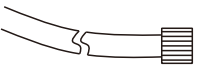


FIGURE 5

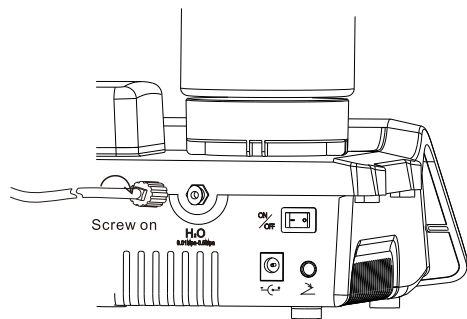


FIGURE 6

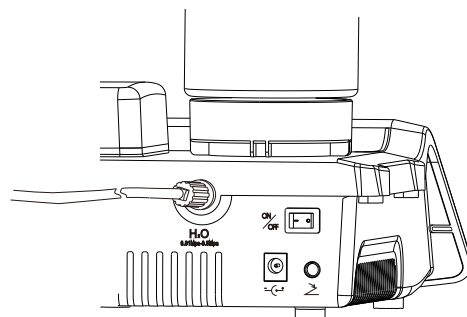


FIGURE 7

d) Detachable handpiece connection(LED Handpiece or Standard Handpiece)

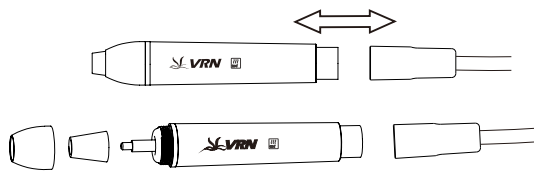


FIGURE 8

e) Installation of tip and endochuck with wrench

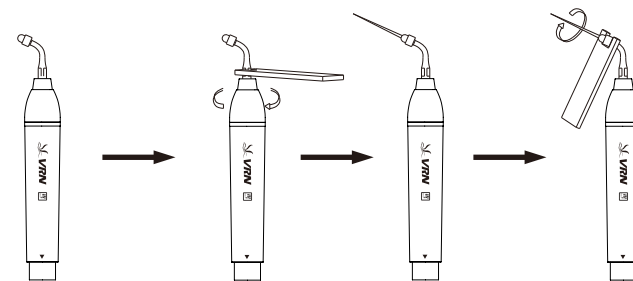
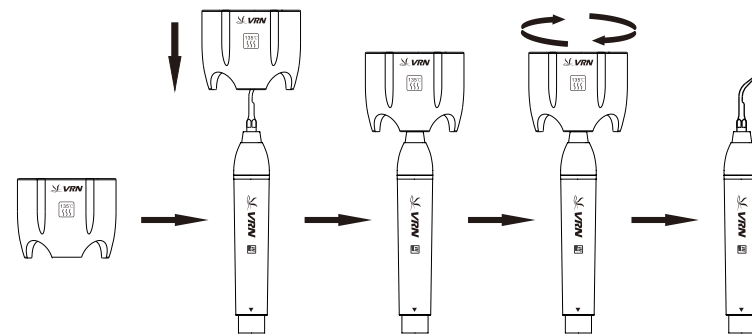


FIGURE 9

f) Installation for the battery of wireless control foot switch

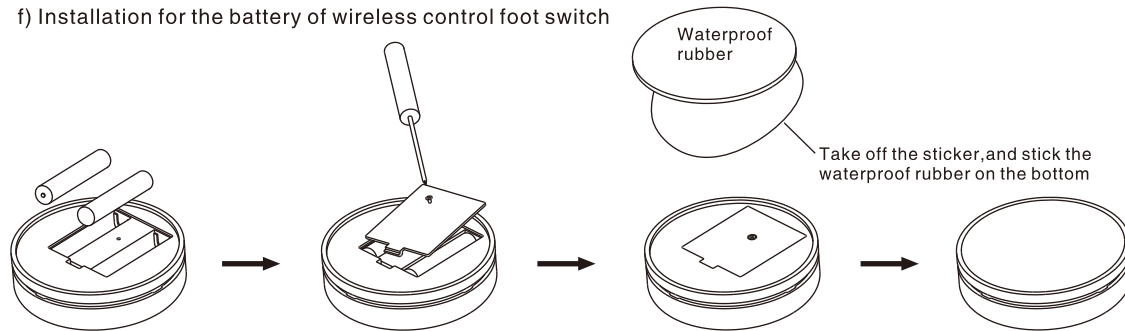
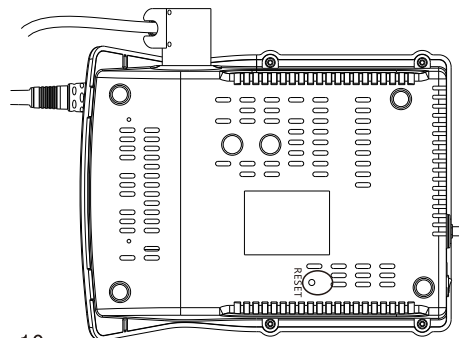


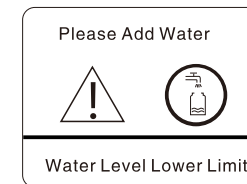
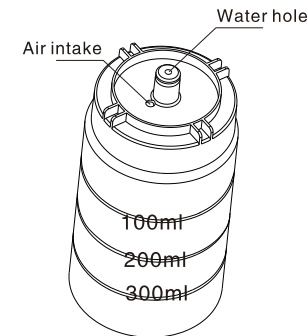
FIGURE 10

g) Wireless foot switch code reset process

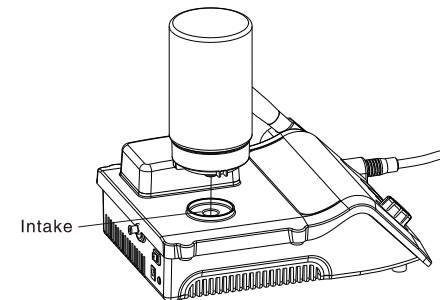


- 1) In case the equipment is electrified, long press the three keys of "G" "P" "E" until their power indicators light up, then release the three keys.
- 2) Ensure the foot is depressed, then install two sets of size AA battery (it shall be operated when the power indicators are lighting up).
- 3) Release the foot switch, wait for 30 seconds or restart, and the wireless foot switch can control the instrument;

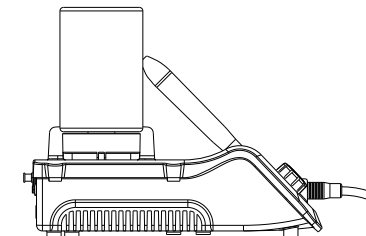
h) Water bottle installation



1. Fill up the water or clinical fluids, then tighten the cap
2. Insert the water bottle



3.OK



2.Products function and operation

2.1.1 Operation

1)After opening the pack, check that whether 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.

2)Turn the water control knob to the maximum based of symbol as shown(see 3.5.2[note]1)

3)Install the battery of wireless control foot switch, or insert the plug of the cord foot switch to the main unit.(Figure 8, Figure 3)

Liquid route installation:

- Automatic water supply

Fillup appropriate amount of purified water into the water bottle , and then insert the water bottle of the main unit .

- External water supply

Connect one end of the water tube to the water entrance, and the other end to the purified water source, which can be the dental unit or other water source.(Figure 4)

4)Screw the scaling tip tightly to the handpiece by wrench, and then connect the handpiece and the connector of cable correctly. Before the installation of handpiece, please make sure the end of handpiece and the connector of the handpiece is dry.

5)Make sure that the power switch to the main unit is off. Insert the plug the power source of the main unit, and then connect the power.

6) Turn on the power switch to the main unit, and the function indicator and fist four power indicators is on.

7)Choose the automatic water supply or external water supply as need.

8)The normal frequency is extremely high. At the normal working state of the scaling tip. a light touch and a

certain to-and-fro motion will eliminate the tartar without heating. Overexertion and long-time lingering are forbidden.

9)Vibration intensity: Adjust the vibration intensity as need; generally the middle grades suitable for most of time. According to patient's different sensitivity and the rigidity of the tartar, adjust the vibrating intensity during the clinical treatment.

10)Water volume adjust: Step on the foot switch, and the tip begins to vibrate, and then turn the water control knob to form fine spray to cool down the handpiece and clean the teeth.

11)The handpiece can be handled in the same gesture as a pen in hand.

12)During the clinical treatment. be sure not to make the end of tip touch the teeth vertically and not to make the tip overexert on the surface of the teeth in case of hurting the teeth and damaging the tip.

13)After finishing operation, keep the device working for 30 seconds on the water supply condition in order to clean the handpiece and the scaling tip.

14)Unscrew the scaling tip and pull out the handpiece then sterilize them.



Notice: Do not pull out the handpiece when the foot switch is stepped on and the device is producing ultrasonic vibration.

Please uninstall the battery if not using the wireless control foot pedal for long time.

2.1.2 Instruction for main components of detachable handpiece(See figure 8)

Seal: Could be cleaned by alcohol

Handpiece: The main part of the whole handpiece can be autoclaved under the high temperature and pressure.

The connector of the cable: Connect the handpiece with the water source and power supply of the main unit.

Notice: Keep dry when the detachable handpiece connects to the connector of the cable.

2.1.3 Instruction of wrench using(See figure 9)

The wrench's structure is designed in special way which can control the strength of the scaling tips installation properly and correctly. It also can guarantee the operator screw or unscrew the scaling tip effectively and keep their hands away from being scratched.

Operation step:

- 1)Align the legs of the wrench to the tip.
- 2)Install he tip: Grip the handle, rotate the tip in a clockwise direction is the tip does not turn round anymore, and then it is installed.
- 3)Unloading the tip: Grip the handle and rotate the tip n a counterclockwise direction by wrench to remove it.
- 4)Once after using, please put the wrench into disinfection cabinet to disinfect.
- 5)After disinfecting, the surface temperature of the wrench is too high to be used again, so user must wait until it is cool down, for avoiding hurt.
- 6)When do not use please put the wrench in a cool. dry and ventilated place, and keep it clean.

2.2 Endodontics function

Operation step:

- 1)Fix endochuck to handpiece by endo wrench.
- 2)Unscrew the screw cap on the endochuck.
- 3)Put the ultrasonic file into the hole in the front of endochuck.
- 4)Screw the screw cap with endo wrench to tighten up the ultrasonic file.
- 5)Press the function button, turn to endo function.

6)When ultrasonic scaler is on endo function, only function indicator and first power indicator are bright.

Put the ultrasonic file into the patient's root canal slowly, and step on the foot pedal to start endo irrigation.

During the treatment, turn up the power gradually according to the needs.



Notice:

- 1)When fixing endochuck, it must be screwed down.
- 2)The screw cap on the endochuck must be screwed down.
- 3)Do not press it too much when the ultrasonic file in root canal.
- 4)Do not step on the foot pedal until the ultrasonic file is in root canal.
- 5)The power range of endo treatment is advised from the 1st to the 5th grade.

2.3 Wireless control foot switch function

2.3.1 Installation

Put 2 AA batteries into wireless control foot switch, stick the waterproof rubber on the bottom after covering the battery cover.

Leave the wireless control foot switch on the flat ground.

After installing the ultrasonic scaler, turn on the ultrasonic scaler power.

The wireless control foot switch will identify to the main unit automatically.

2.3.2 Usable range

Within any distance of 5 meters, the wireless control foot switch could fully operate the ultrasonic scaler vibrating.

2.4 Automatic water supply system

2.4.1 Operation

- 1)Open the water cap, fill up the purified water, and then tighten the water cap.

2)Clean the water hole of the water bottle and the intake of the main unit.

3) Insert the water bottle to the main unit.

4)Press the model switch button "WATER"to choose the automatic water supply.

2.3.2 Notice

1)Make sure the air intake and water hole of the water bottle is not blocked.

2)Check the water proof "O–ring"on the water hole part is not damaged. If the "O–ring" is damaged or failing, please replace it immediately.

3)Make sure that the water cap is tight in case of water leaking.

4)Clean the water hole of the water bottle before each use.

5)When change the liquid inside of water bottle, please turn the water control knob to the maximum and run the device for 30 seconds in order to maintain and clean the current liquid route. Then start to do the treatment.

6)When the liquid inside the water bottle is low, please fill up the liquid to ensure the regular working.

3. Sterilization and maintenance

3.1 Sterilization of detachable handpiece

Handle disinfection can refer to cleaning, disinfecting and sterilizing instructions, please read the instructions before disinfection, and operate according to the instructions.

3.1.1 Autoclaved under high temperature/pressure:

Handle disinfection can refer to cleaning, disinfecting and sterilizing instructions.



Notice:

1)Dry the cleaning liquid in the handpiece with compressed air before sterilization.

2)Be sure that the scaling tip has been unscrewed from the handpiece and it can not be

sterilized with others.

3)Please check whether the outer of the handpiece is damaged during the irrigation or sterilization, and do not apply any protective oil on the surface of handpiece.

4)There are 2 waterproof O–ring at the end of handpiece. Since sterilization and repeated pulling and inserting will reduce its using life, please lubricate them with dental lube frequently. Change the new O–ring if it is damaged or worn excessively.

5)The sterilization parts can be sterilized over 250 times.

6)The following sterilization methods are forbidden:

- Put handpiece into any liquid for boiling;
- Dip handpiece in disinfectors such as iodine, alcohol and glutaraldehyde;
- Put handpiece into oven or microwave oven for baking.

3.2 Sterilization of tips and endochuck

All he scaling tips and endochuck can be autoclaved under high temperature and pressure.

For disinfection methods, please refer to cleaning, disinfecting and sterilizing instructions.

3.3 Sterilization of wrench and endo wrench

1)The wrench and endo wrench can be sterilized under high temperature and pressure.

2)The following sterilization methods for wrench are forbidden:

- Braise in liquor;
- Dip in iodine, alcohol or glutaraldehyde;
- Torrefy in oven or microwave oven.



Notice:

We are not responsible for any damage of the torque wrench directly or indirectly made by any way in the above items.

3.4 Troubleshooting and notes

3.4.1 Troubleshooting

Fault	Possible cause	Solutions
The scaling tip doesn't vibrate and there is no water flowing out when stepping on the foot Switch	The power plug is in loose contact	Make the plug insert to the socket well
	The foot pedal is in loose contact (wire foot Switch)	Insert the foot switch to its socket tightly
	The fuse in the main unit is broken	Contact the dealers or us
	The battery for wireless control foot Switch died	Change the new batteries
The scaling tip does not vibrate but there is water flowing out when stepping on the foot Switch	The tip is in loose contact	Screw the tip on the handpiece tightly
	The connect plug between the handpiece and the circuit board is in loose contact	Contact the dealer or us
	Handpiece problem	Send the handpiece to dealer or us to repair
	Cable problem	Contact the dealer or us
The scaling tip vibrates but there is no spray when stepping on the foot Switch	The water control knob is not on	Turn on the water control knob [note 1]
	There is impurity in the electric-magnetic valve	Take the electric-magnetic valve apart or contact the dealer or us
	The water system is blocked	Clean the water pipe by multi-function syringe [note 2]
There is still water flowing out after the power is off	The electric-magnetic valve problem	Contact the dealer or us
The handpiece generates heat	The water control knob is in a low setting	Turn the water control knob to a higher grade [note 1]

Fault	Possible cause	Solutions
The amount of spouting water is too little	The water control knob is in a low setting	Turn the water control knob to a higher grade [note 1]
	The water pressure is not high enough	Make the water pressure higher
	The water system is blocked	Clean the water pipe by multi-function syringe [note 2]
The vibration of the tip becomes weak	The tip has not been screwed on to the handpiece tightly	Screw the tip tightly
	The coupling between the handpiece and the cable is not dry	Dry it by the hot air
	The tip is damaged [note 3]	Change the new scaling tip
There is water leaking from the coupling between the handpiece and the cable	The waterproof O-ring is damaged	Change the new waterproof O-ring
The U-file does not vibrate	The screw is loose	Tighten it
	Endochuck is damaged	Change the new endochuck
There is noise coming from the endochuck	The screw is loose	Tighten it
Handpiece no water coming (water supply mode)	Liquid Road tube full of air	Screw water valve to maximum, and reinsert automatic water bottles
LED does not light	Poor contact	Check circuit
	LED burn out	Replacing the LED
	LED wrong installation	LED "+" matches the handpiece "+" tag



Notice:
If the problem still cannot be solved, please contact with local dealer or manufacturer.

3.4.2 Notes

[note 1]

Turn the water control knob as symbol shown. It comes to the min, on the contrary direction, it comes to the max.

[note 2]

- 1)Clean the water pipe with the multi-function syringe of the dental unit;
- 2)Disconnect the water pipe from main unit;
- 3)Get through to the power and turn on the power switch;
- 4)Connect the multi-function syringe of dental unit to the water pipe;
- 5)Disassemble the tip or handpiece;
- 6)Step on the foot switch;
- 7)Turn 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.

[note 3]

If the scaling tip has been screwed on tightly and there is fine spray too, the following phenomena show that the scaling tip is damaged:

- 1)The vibration of tip and the spray from the tip are apparently weakening.
- 2)The noise or droning sound from tip when operation.

3.5 TROUBLESHOOTING FOR THE ELECTROMAGNETIC VALVE

If the water is not clean or the electromagnetic valve works too long, there will be the scale and impurity generated on the inside wall and valve plug. It will Cause the water way to be blocked, and could repair as following steps:

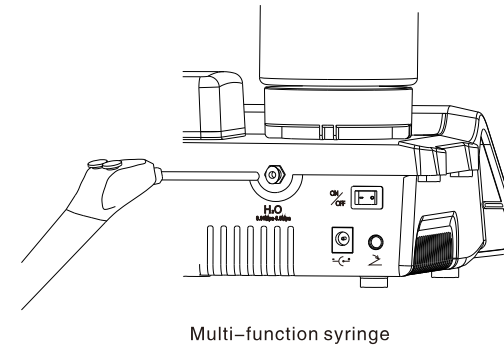
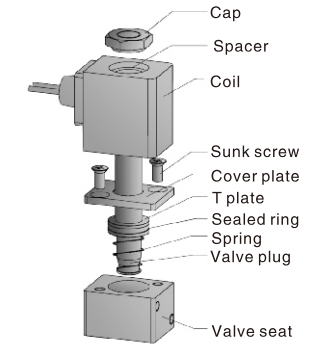


FIGURE 11



- 1)Follow the [note2]
- 2)Uninstall the electromagnetic valve by following steps:
 - a)Turn off the power, and unplug the power cable;
 - b)Unscrew the cap, and move out the hood of main unit;
 - c)Unscrew the cap on the electromagnetic valve, and Uninstall the electromagnetic valve as shown on Figure;
 - d)Take out the valve plug. and clean out the impurity on the inside wall;
 - e)Install The parts as shown on the figure.
 - f)Ensure the water way is working by repeat [note 2].

4. Precaution

4.1 Notice when using equipment

(Do not allow Service or maintenance the equipment where used in patient)

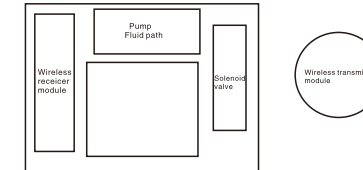
- 1) Keep the scale clean before and after operation.
- 2) The Handpiece, scaling tip, wrench, endo wrench and endo chuck must be sterilized before each treatment.
- 3) Do not screw or unscrew scaling tip and endo chuck when stepping on the foot switch.
- 4) The scaling tip must be fastened and there must be fine spray or drip coming out from the when operating.
- 5) Change a new one when the tip and ultrasonic file are damaged or worn excessively.
- 6) Do not twist or rub the tip and endochuck.
- 7) If use the water source without hydraulic pressure, the water surface should be 1 meter higher than the head of the patient.
- 8) Ensure the power connection is firm before installing the device; otherwise it could cause the device function.
- 9) Do not pull the cable forcibly in case of the handpiece falling off from the cable.
- 10) Do not knock or rub the handpiece.
- 11) After operation, turn off power, and unplug the power cable.
- 12) We are only responsible the safety on the following conditions:
 - The maintenance, repair and modification are made by the manufacturer or the authorized dealer.
 - The spare components are original of "VRN" and are operated according to instruction manual.
- 13) The internal screw tread of the scaling tips produced by some manufacturers may be coarse, rusty and collapsed. This will damage the external screw thread of the handpiece irritably;
- 14) This model only matches the adapter of our company.

15) Ultrasonic Scaler Only by professional and technical qualifications of doctors to operate.

16) Ultrasonic Scaler use when away from strong electromagnetic interference devices.

17) Appliance coupler is considered as disconnect device, please do not place the equipment in difficulty operation position.

18) Schematic:



4.2 Contraindication

- Approval of a suitably qualified medical practitioner should be sort prior to use with haemophiliacs, or pregnant women, or children.
- Ultrasonic oscillations may prevent cardiac pacemakers and defibrillators. From functioning properly. Therefore, we recommend that patients with a cardiac pace maker or a defibrillator should not be treated with this product.
- Scaling generates an aerosol; patients with high-risk infectious diseases should not be treated as it may put others at risk.

4.3 Storage and maintenance

- The device should be handled carefully and light. Be sure that it is far from the vibration, and installed or kept in a cool, dry and ventilated place.
- Do not store the machine together with the articles that are combustible, poisonous, caustic, and explosive.

- This device should be stored in a room where the relative humidity is $\leq 90\%$, atmospheric pressure is 70 kPa to 106 kPa, and the temperature is -20°C to $+55^{\circ}\text{C}$.

- If not use for a long time, please make the machine get through to the power and water once per month for five minutes.

4.4 Transportation

- Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and do not invert it.

- Don't Put It Together with dangerous goods during transportation.

- Avoid solarization and getting wet in rain or snow during transportation.

5.Packing list

No.	Name	Specification/Model
1	Motherboard	/
2	Control panel	/
3	Detachable handpiece	/
4	Handpiece cable	/
5	Tips	5 Tips
6	Wrench	/
7	Endo wrench	/
8	Handpiece seal	
9	Waterproof "O" ring	3.5mmx1.5mm
10	multi-function syringe	/
11	Water pipe	4mmx6mm
12	Power adapter	30V
13	electric-magnetic valve	/
14	Wireless control foot switch	/
15	Wired foot switch(option)	/

Note: This instruction manual did not detail the specification parts of ultrasonic scaler; please check the promotion documents and "packing list" along with the packing.




















6.After service

According to the warranty card, we offer the life time repair since the product is purchased.

The repair of the device should be carried out by our professional technician.

We are not responsible for any irretrievable damage caused by the non-professional person.

7.Symbol instruction

	Manufacturer's logo		Caution! Read the operation instruction		Class II equipment		Applied part type B
	Disposal		Manufacturer		Used indoor only		Serial number
	Autoclavable		Storage Humidity		Storage Temp		Keep dry
	Fragile		Refer to instruction manual/booklet		Water supply		up
IPX6	Waterproof rating of water resistance		Electrical Outlet		Foot switch connection		Production date
IPX4	Waterproof grade is splash proof						

8.Environmental Protection

No harmful factor in this product, and deal with it based on the local regulation.

9.Manufacturer' s right

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

10. EMC Declaration

Guidance and manufacturer's declaration--electromagnetic emissions		
The models VRN-A8/VRN-A8Plus Dental Ultrasonic SandBlasting Scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the VRN-A8/VRN-A8Plus Dental Ultrasonic SandBlasting Scaler should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic emissions--guidance
Radiated Emission EN 60601-1-2: 2015 EN 55011:2016+A1:2017	Class B	The models VRN-A8/VRN-A8Plus Dental Ultrasonic SandBlasting Scaler 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.
Conducted Emissions EN 60601-1-2: 2015 EN55011:2016+A1:2017	Class B	The models VRN-A8/VRN-A8Plus Ultrasonic Periodontal Therapy System are suitable for used in domestic establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Current EN 60601-1-2: 2015 EN 61000-3-2:2014	Test configuration and procedure see clause 7.1 of standard EN 61000-3-2: 2014	
Voltage Fluctuations/ Flicker Emissions EN 60601-1-2: 2015 EN 61000-3-3:2014	Test configuration and procedure see clause 5 of standard EN 61000-3-3: 2013	

Guidance and Manufacturer's Declaration--Electromagnetic Immunity

Guidance and manufacturer's declaration--electromagnetic immunity		
The models VRN-A8/VRN-A8Plus Ultrasonic Periodontal Therapy System are intended for use in the electromagnetic environment specified below. The customer or the user of the VRN-A8/VRN-A8Plus Ultrasonic Periodontal Therapy System should assure that it is used in such an environment.		
Immunity Test	Compliance	Electromagnetic emissions--guidance
Electrostatic Discharge EN60601-1-2:2015 EN61000-4-2:2009	± 15kV for air discharge ± 8kV contact discharge	Floors should be wood, concrete or ceramic tile. If floors are covers with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst	± 2kV a.c.pwoer lines	Main power quality should be that of a typical commercial or hospital environment.
Surge Test EN60601-1-2:2015 EN61000-4-5:2014	± 1kV a.c pwoer line(s) to line(s)	Main power quality should be that of a typical commercial or hospital environment.

Immunity Test	Compliance	Electromagnetic emissions–guidance
Conducted Disturbance Induced by Radio–frequency Fields	comply with the requirements of clause 8.9 of EN60601–1–1–2: 2015 at immunity test levels of 3Vrms and 6Vrms over the frequency range beginning at the start frequency and extending to 80MHz	For AC power input lines: EUT is placed on an insulating support of 0.1m high above a ground reference plane. It must be 0.3m away from the CDN (coupling and decoupling network) of which the bottom is made of metallic material and placed above the ground reference plane shall be between 30 and 50mm (where possible). The disturbance signal amplified by amplifier is injected to EUT through CDN. For Signal Line and Control Line: EUT is placed on an insulating support above a ground reference plane. The EM clamp is directly placed on the ground reference plane with its metallic bottom contacting the plane. Gables between EUT and auxiliary equipment are put through the EM clamp. The disturbance signal amplified by amplifier is injected to EUT through EM clamp. Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.
Voltage Dips and Interruptions	100%/10ms, 20ms 30%/500 ms	EUT is connected to the simulator according to the test photo. When conducting this, the power supply shall be set at the minimum and maximum rated input voltages and test voltage changes shall be step changes at the phase angle of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.

Immunity Test	Compliance	Electromagnetic emissions–guidance
Radiated, Radio–frequency, electromagnetic field	comply with the requirements of clause 8.9 of EN60601–1–2: 2015 at immunity test levels	EUT and its auxiliary instrument are placed on a turntable which is 0.8 meter above ground. Transmitting antenna mounted on an antenna mast is set 3 meter away from the EUT. During the test, each of the four sides of EUT will face the transmitting antenna with the turntable cycled. Both horizontal and vertical polarization of the antenna are set on test and measured individually? In order to judge the performance of the EUT, a set of monitor system is used. Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.