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Product name: Ultrasonic Scaler
Product model: VRN-Q5



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Ultrasonic Scaler VRN-Q5

User Manual

URIT Medical Electronic Co.,Ltd.

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Statement

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Congratulations on becoming a respected customer of URIT Medical Electronic Co.,Ltd. and welcome to use the ultrasonic scaler VRN-Q5 , which will bring you a new experience and convenience. This User Manual includes the latest information up to the time of its printing. URIT Medical Electronic Co.,Ltd. is solely responsible for the revision and interpretation of simplified English version of this User Manual, and reserves the right to make alterations without notice after printing. Some schematic diagrams listed in this User Manual are for reference only. If the picture is inconsistent with the real object, the real object shall prevail.

All information stated in this User Manual is protected by copyright law. Without the prior written consent of URIT Medical Electronic Co.,Ltd. the contents in the User Manual shall not be reproduced, copied or translated into other languages in any form. The use of the product must comply with the requirements of relevant operating procedures and relevant regulations of the medical department, and can only be used by trained doctors or technicians.

The circuit diagrams, parts lists, instructions, calibration instructions and other information provided in the manual can be used by companies or individuals authorized by the company to repair the products.

The clinical benefits of scalers are reduce the PPD by removal of calculus and plaque to improve oral hygiene and prevent or treat periodontal disease and peri-implantitis.

Please carefully read this User Manual before use and properly keep it for future reference. All operations must be carried out in strict accordance with the operating instructions of this User Manual. Otherwise,URIT Medical Electronic Co.,Ltd. will not be responsible for any errors and product damage caused by illegal operation.

Note:

URIT Medical Electronic Co.,Ltd. does not promise the products to be used for certain special purposes, or make any implied guarantee for their marketability and applicability;

If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

If you need the support of after-sales service, please contact URIT Medical Electronic Co.,Ltd. or its authorized agent.

1. Product instruction

1.1 Overview

By employing the full-automatic frequency tracking system, it is available to realize such functions as scaling, periodontal treatment, endodontic irrigating, and automatic water supply; in addition, it has the following features:

- The handpiece can be sterilized under high temperature 134 °C and 0.22 MPa pressure.
- By employing the wireless foot switch to remotely control the operation of the main unit, the operation is more convenient, and the wired foot switch can be selected according to the needs of the user.
- Soft bright LED light, which not only improves the clinical operation efficiency, but also enables the commonly used detachable handpiece to have high compatibility.
- Life time is 10 years.
- Shelf life of the device is 10 years.

1.2 Structure and Composition

The ultrasonic scaler is mainly composed of function control circuit, fluid path, handpiece, tip, power adapter and foot switch (wired or wireless).

1.3 Intended use

This device is a piezo-operated ultrasonic device for use in dental applications. It is mainly used for the treatment of periodontal defects. In addition, the device is used in the area of prophylaxis, peri-implantitis treatment as well as dental hygiene.

Intended patient population: Adults and pediatrics patients with periodontal disease.

Pediatrics: Age levels ranged from 12 to 18 years

Medical condition: The product will be effective and safety in removal of calculus, plaque and other dental stains and root canal cleaning and washing. And the product will benefit the health of the teeth.

Intended user: The Ultrasonic Scaler is intended to be operated by trained dentist.

Place of use: professional dental clinics and hospitals.

1.4 Contraindications

- Patients with cardiac pacemakers
- Patients with gingival malignant tumor
- Patients with active angina pectoris, myocardial infarction within six months, and uncontrolled hypertension and heart failure
- Patients with local oral inflammation in the acute phase (except acute necrotizing gingivitis)
- Patients with bleeding diseases
- Patients with acute infectious diseases
- Pregnant

1.5 Main technical parameters

- Input voltage: 230 VAC, 50 Hz
- Input power: 35VA
- Wireless foot switch battery: AA battery x 2
- Receiving sensitivity: -114 dB (in accordance with China National Telecommunication Law) ; Receiving frequency: 2.4 GHz

band.

- The recommended atmospheric pressure for the products shall be in the range of 70 kPa~106 kPa. Air consumption shall be 0 L/min and the amount of liquid delivered to the operating area of the products shall be at maximum of 50 mL/min at the pressure in the range of 0.01 MPa~0.5 MPa during working. Outlet pressure of water bottle is 0.02 MPa.

- Tip amplitude: Minimum: 1 μm; deviation -50%. Maximum: 100 μm; deviation +50%
- Output half-excursion force: Minimum: 0.1 N; deviation -50%. Maximum: 2 N; deviation +50%
- Tip vibrating frequency: 25 kHz~35 kHz

Note: The tip vibrating frequencies are different of different type tips , but all are distributed within the described range.

- Tip output power: 3 W~20 W
- Fuse: T1AH250V
- Weight of main unit:1.8 kg
- Operating mode: Continuous operation
- Type of protection against electric shock: Class I equipment

- Degree of protection against electric shock: Type B applied part
- Degree of protection against ingress of water: main unit (IPX0), wired foot switch (IPX1), wireless foot switch(IPX4).
- Degree of safety of application in the presence of a Flammable Anesthetic Mixture with air, Oxygen or Nitrous Oxide: Non-AP, APG type equipment.

- Wireless foot switch: transmission frequency: 2.412 GHz~2.462 GHz, modulation type: GFSK, Max. radiation power: 12 dBm.

1.6 Radio Frequency Interface Requirements - Related to European installation

- Note: This equipment has been tested and found to comply with the limits for EN 300 440 V2.1.1 receiver Category 3.
- These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- This equipment is sensitive to other equipment that intentionally generates, radio frequency energy in the 2402~2483.5 MHz that may conduce to the instability to use the Remote Control on it. However there is no guarantee that interference will not occur in a particular installation. If this equipment suffer from the harmful interference from another radio device to radio this can be determined by turning the respective equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Turn off the disturbance equipment
- Increase the separation between the disturbance equipment
- Consult the dealer or an experienced radio/TV technician for help.

1.7 Working environment

- Temperature: 5°C~40°C
- Relative humidity: ≤80%
- Atmospheric pressure: 70 kPa~106 kPa
- Applicative range of power supply and voltage: 230VAC, 50Hz
- The maximum inlet pressure of handpiece: 0.5MPa
- See the specific specifications on the label.

2. Product installation

2.1. Main Unit Front & Rear Schematic Diagram

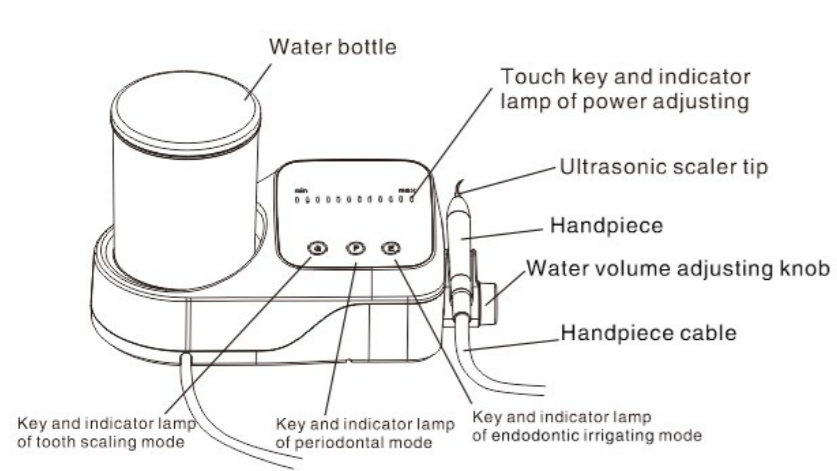


Figure 1 Front Schematic Diagram

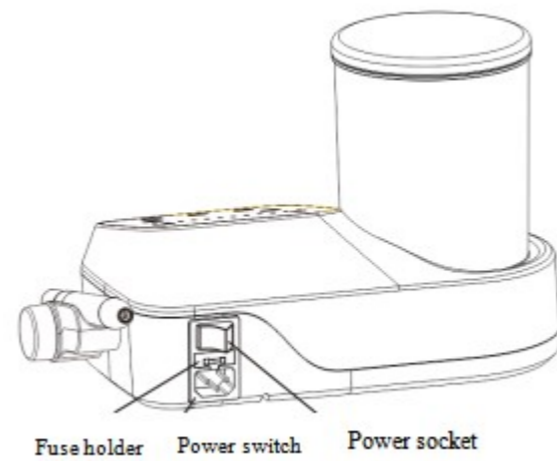


Figure 2 Rear Schematic Diagram

2.2. Schematic Diagram of Connection between Foot Switch and Main Unit

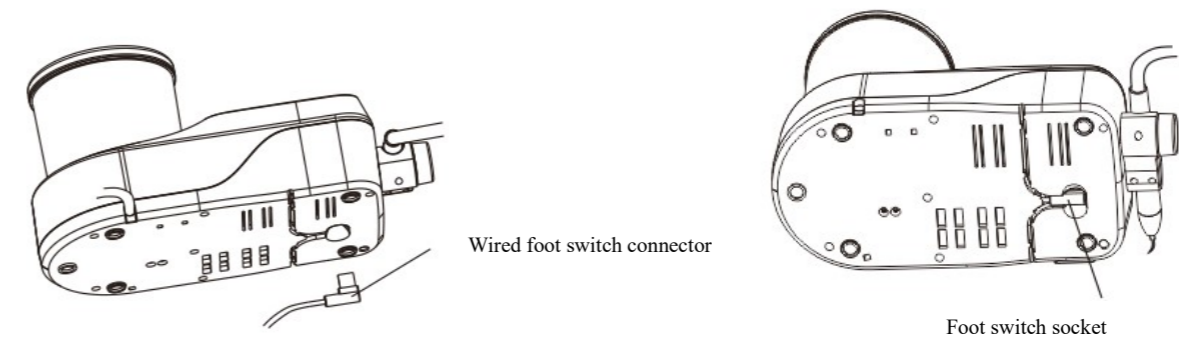


Figure 3

Insert the USB connector of the foot switch into its corresponded interface at the bottom of the main unit according to the drawing position, and clip it into the front or rear wire slot as required by the user.

2.3. Water Bottle Installation Schematic Diagram

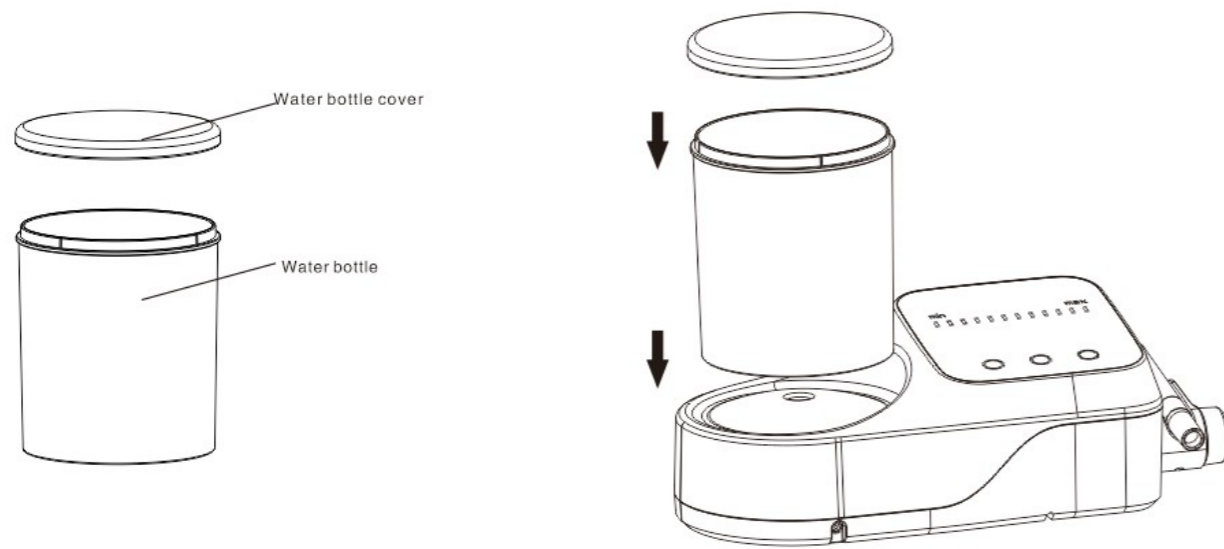


Figure 4

2.4 Handpiece Installation and Connection Schematic Diagram

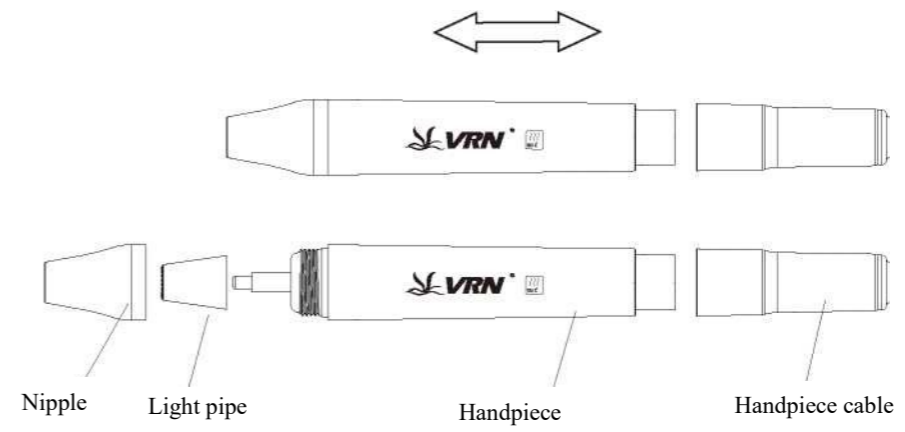


Figure 5

2.5 Assembly and Disassembly Schematic Diagram of Ultrasonic Scaler Tips and File by Wrench

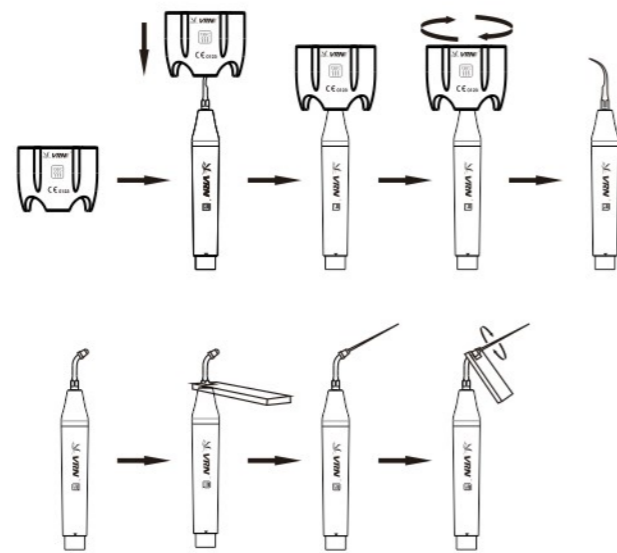


Figure 6

2.6. Wireless foot switch matching

- (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) When the wireless foot switch is depressed, install two sets of AA battery (it shall be operated when the Veirun logo lighting up).
- (3) Release the foot switch, wait for 30 seconds or restart, and the wireless foot switch can control the device.

3. Product function and operation

3.1 Operation of handpiece

- (1) Nipple: It is available to unscrew the nipple, the user can periodically take it out and clean it with alcohol.
- (2) Light pipe: It can be cleaned with alcohol.
- (3) Handpiece: An important part of the instrument, which can be sterilized under high temperature and high pressure.
- (4) Cable socket: Connect the handpiece to the water path and circuit of main unit.

⚠ Note: When connecting the handpiece to the cable socket, please keep them dry. In order to keep the handpiece in good working condition, it is necessary to maintain the handpiece regularly, and use the handpiece on the machine at least once a month, and keep it dry after use.

3.2 Operation of torque wrench

Design with special structure, the torque wrench could not only effectively assemble and disassemble the ultrasonic scaler tips, but also protect the operator's hands. Operation Steps (See Figure 6):


- (1) Insert the ultrasonic scaler tips into the torque wrench.
- (2) Assembly: hold the handpiece tightly, and screw the ultrasonic scaler tips with the torque wrench by clockwise direction until the ultrasonic scaler tips no longer rotated, and the assembly of the ultrasonic scaler tips is completed.
- (3) Disassembly: hold the handpiece tightly, then use the torque wrench to unscrew the ultrasonic scaler tips by counter-clockwise direction, and the disassembly of the ultrasonic scaler tips is completed.
- (4) Please disinfect and sterilize the torque wrench after use.
- (5) After sterilization, the temperature of the torque wrench is very high. It can be used again only after the torque wrench cooled, so as to avoid scalding.
- (6) Please place it in a ventilated and dry place and keep it clean after use.

3.3 Scaling, periodontal treatment function and operation

- (1) After unboxing, check all accessories of the product according to the Packing List. Take out the device from the box, then place it on a stable and flat plane.
- (2) Turn the water volume adjusting knob to its maximum as shown in the Figure 1 (see section 3.5.1 [Note 1]).
- (3) Install the batteries into the wireless foot switch, or plug the wired foot switch connector into the socket (see Figure 7, Figure 3).
- (4) Open the water bottle, pour a proper amount of purified water into the water bottle, then put the cover back, and install the water bottle (see Figure 4).
- (5) Fasten the ultrasonic scaler tips on the hand of the handpiece with torque wrench (see Figure 6), then properly connect the handpiece to the cable socket. Before installing the handpiece, thoroughly dry the handpiece and the cable socket (see Figure 5).
- (6) Set the power switch of the main unit to OFF state, then connect the output terminal of power supply cord to the main unit, and connect the input terminal of power supply cord to mains electricity (see Figure 2).
- (7) Turn on the power switch, the indicator light of key "P" and the first 3 power indicators will light up.
- (8) The operator shall select the operation mode of "G" and "P" according to the series of ultrasonic scaler tips. Please refer to the attached Table for the details of power used by the ultrasonic scaler tips.
- (9) When the product is working normally, the frequency is fast; When water spray from the tip normally, gently contact and reciprocate at a certain speed, so that the dental calculus can be removed, and there is no obvious feeling of fever on the surface of ultrasonic scaler tips; Do not use excessive force locally or stay too long times when scaling teeth.
- (10) Vibration strength: adjust the magnitude of vibration strength according to requirements; Generally, it is recommended that adjust to moderate vibration strength, or adjust it at any time in the clinical process according to the sensitivity of the patients

and the hardness of dental calculus.

- (11) Water volume adjustment: step on the foot switch to generate vibration at the ultrasonic scaler tips, rotate the water volume adjusting knob to form mist, so as to cool the ultrasonic scaler tips and clean the tooth surface.
- (12) Generally, the handpiece is held by the pen holding gesture.
- (13) During clinical scaling and treatment, do not make the top of the ultrasonic scaler tips come into vertical contact with the tooth, and do not apply heavy pressure, so as to avoid damaging the tooth and the ultrasonic scaler tips.
- (14) After clinical scaling and treatment, the handpiece shall be kept working for 30 seconds, the water shall be supplied during this process to clean the handpiece and ultrasonic scaler tips.
- (15) Disassemble the ultrasonic scaler tips and the handpiece for reprocessing so as to avoid cross-infection.

 **Note: Do not pull out the handpiece when the foot switch is depressed and the ultrasonic scaler tips are vibrating. If the wireless foot switch is not used for a long time, please remove its batteries.**

3.4 Endodontic irrigating function and operation

- (1) Use an Endo wrench to fix the file holder on the hand of the handpiece (see Figure 6).
- (2) Unscrew the nut of the file holder (see Figure 6).
- (3) Insert the file into the hole in front of the file holder (see Figure 6).
- (4) Tighten the nuts with the Endo wrench (see Figure 6).
- (5) Press the key "E" and the indicator light of "E" is on.
- (6) When the endodontic irrigating function is selected, only the function indicator light and the first power indicator light are illuminated. When the file is slowly inserted into the patient's root canal, depress the foot switch and start the endodontic irrigating. The power of endodontic irrigating shall be adjusted according requirements.

 **Note:**

- (1) **When installing the file and the nut, they must be firmly tightened.**
- (2) **When the endodontic irrigating is carried out to the root canal, light pressure shall be applied and it is recommended that the power adjustment slowly increase from 1st grade to 3rd grade.**
- (3) **Do not step on the foot switch when the file is not inserted into the root canal.**

3.5 Function and operation of wireless foot switch

3.5.1 Operation

- (1) Install two sets of AA battery into the wireless foot switch according to the direction indicated by the positive and negative electrodes, install the batteries cover plate and attach the waterproof rubber pad;
- (2) Place the wireless foot switch on the ground, and ensure the ground is flat;
- (3) After connecting all wires of the ultrasonic scaler, turn on the power switch, and the wireless foot switch will automatically connect to the ultrasonic scaler.
- (4) Within 5 meters around the ultrasonic scaler, the wireless foot switch could control the ultrasonic scaler.

3.6 Automatic water supply function and use

3.6.1 Operation Steps:

- (1) Vertically pull out the water bottle installed on the ultrasonic scaler.
- (2) Open the water bottle cover, fill it with sufficient purified water, and close the cover.
- (3) Clean the neck of the water bottle, as well as interface connecting to the water bottle.
- (4) Vertically insert the water bottle into the interface of the ultrasonic scaler.

Note:

- (1) **Make sure that the air vent and water outlet are not blocked.**
- (2) **Check if the internal gasket of the cover is well, if the gasket is deformed or falls off, replace and install it in time.**

- (3) **Please clean the interface of the water bottle before use.**
- (4) **If the liquid in the water bottle is lower than the lowest level, please fill liquid in time, so as to keep the water path smooth.**

3.7 Safety precautions:

- (1) Keep the product clean before and after use.
- (2) Do not suspend the product, or place it upside down.
- (3) Before each clinical operation, please keep the product to operate in the presence of water for 10 seconds to remove residual water from the pipeline.
- (4) During operation, the operator shall be equipped with adequate protection (e.g. goggles, face mask, etc.) to prevent them from cross-infection.
- (5) The operation of the product must comply with the requirements of relevant operating procedures and relevant regulations of the medical department, and can only be used by trained doctors or technicians.
- (6) Before first use or after each use, please reprocessing the its accessories such as ultrasonic scaler tips, wrench and handpiece so as to prevent patients from cross-infection.
- (7) Do not assemble or disassemble the ultrasonic scaler tip when the foot switch is pressed and the ultrasonic scaler tip vibrates.
- (8) The ultrasonic scaler tips must be tightened to the handpiece, and there must be water mist during operation (except for the ultrasonic scaler tips working without water).
- (9) If the ultrasonic scaler tips are breaking,damaged or worn, the vibration strength will decrease, and operator shall replace a new one according to the clinical conditions so as to prevent the patient from accidentally swallowing or inhaling debris.
- (10) Please don't bend or polish the ultrasonic scaler tips. The ultrasonic scaler tips is sharp, please be carefully during operation.

- (11) It is prohibited to use unclean water source, or use normal saline instead of pure water source.
- (12) Do not pull the handpiece cable during operating, which can avoid damage to the handpiece cable.
- (13) Do not beat or scrape the handpiece.
- (14) After using the product, turn off the power switch and pull out the power plug.
- (15) Only when the maintenance, repair and modification of the product are carried out by us or dealers, and the replaced parts are the original parts purchased from us and it is operated follow the Operation Manual, we will responsible for the product safety.
- (16) The internal thread of the ultrasonic scaler tips produced by some manufacturers is rough, rusty, cracked or subject to other standards. If the external thread of handpiece is used in combination with the ultrasonic scaler tips that have aforesaid defects, it is easy to damage the thread, result in the loose thread, even cause irreparable damage to the ultrasonic scaler, please use the original ultrasonic scaler tips.
- (17) When the operators use different series of ultrasonic scaler tips, it is necessary to adjust the working mode of the product correspondingly to avoid breakage of ultrasonic scaler tips.
- (18) According to the operating conditions of different ultrasonic scaler tips, it is recommended to set the power and water output in accordance with the requirements of section 13.1.
- (19) The temperature of ultrasonic scaler tips may reach to 75.8°C once water not supplied when continuous operated at the 35°C ambient temperature. Do not touch it until it cools down.
- (20) MR UNSAFE: the device cannot be used in MRI environment.

4. Reprocessing

4.1 Handpiece

Reprocess according to Reprocessing Instructions. Please read the instructions carefully before operating.

Note:

- (1) **Before sterilization, use compressed air to blow and clean the liquid remaining on the handpiece.**
- (2) **Make sure to remove the ultrasonic scaler tip from the handpiece before reprocessing, and sterilize with specified equipment.**
- (3) **During reprocessing process, please pay your attention to the external damage of the handpiece at any time. Do not apply any protective oil to the handpiece surface.**
- (4) **The products have been designed for 250 reprocessing cycles. Do not exceed the maximum number of reprocessing cycles.**
- (5) **It is strictly prohibited to reprocess the handpiece in the following manner:**
 - **Put the handpiece in the solution for stewing.**
 - **Immerse the handpiece with iodine, alcohol, glutaraldehyde and other disinfectants.**
 - **Put the handpiece in oven or microwave oven for high temperature baking.**

4.2 Ultrasonic scaler tips

Reprocess according to Reprocessing Instructions. Please read the instructions carefully before operating.

4.3 Torque wrench and Endo wrench

Reprocess according to Reprocessing Instructions. Please read the instructions carefully before operating.

Note:


We shall not be responsible for any direct or indirect damage to the torque wrench and the Endo wrench caused by the improper use mentioned above.

5. Troubleshooting

5.1 Troubleshooting table

Fault	Possible cause	Solutions
Indicator lamps don't light up	Poor connection of power supply cord	Correctly connect the power supply cord
	Poor connection of wired foot switch	Correctly connect the connector of wired foot switch
No water coming from the handpiece	Poor connection of wired foot switch	Correctly connect the connector of wired foot switch
	The batteries of wireless foot switch run out	Replace the new batteries
	No match of wireless foot switch	Re-match (see section 2.6)
Ultrasonic scaler tips don't vibrate but there is water flowing out	The ultrasonic scaler tip hasn't been screwed on to the handpiece tightly	Screw the ultrasonic scaler tip on the handpiece tightly
	Fault of handpiece	Pull out handpiece and contact us or authorized dealers
	Fault of handpiece cable or inside circuit	Contact us or authorized dealers
There is still water flow out when power off	Fault of solenoid valve	Contact us or authorized dealers
Handpiece generates heat	The amount of water volume is too little	Turn the water volume adjusting knob to a higher grade

Handpiece severely generates heat	Fault of handpiece	Pull out handpiece and contact us or authorized dealers
The amount of water volume is too little	The water volume adjusting knob is a low grade	Turn the water volume adjusting knob to a higher grade
	The water path is jammed	Clean water path with multi-function syringe
The vibration of the ultrasonic scaler tip becomes weak	The ultrasonic scaler tip hasn't been screwed on to the handpiece tightly	Screw the ultrasonic scaler tip on the handpiece tightly
	The connection between the handpiece and the cable isn't dry	Dry it by the hot air
	The ultrasonic scaler tip is excessively damaged	Replace a new one
Water leakage between handpiece and cable.	The handpiece connecting O-ring is damaged	Replace a new one
The file does not vibrate or there is noise	The screw is loose	Tighten it
	The screw is damaged	Replace a new one

 **Note: If the problem has not been solved, please contact us or local authorized dealers.**
5.2 Note

[Note 1]

According to the symbol, rotate the water amount adjusting knob until it can not be rotated, the water amount is minimum at this

time, otherwise, it is the maximum position.

[Note 2]

In the case of ensuring that the ultrasonic scaler tip has been tightened and has been sprayed with water mist, the ultrasonic scaler tip is deemed to have been damaged by the following phenomena:

- (1) The vibrating strength and water atomization degree of the ultrasonic scaler tip are obviously weakened.
- (2) Abnormal noise of "buzzing" is sound when the ultrasonic scaler tip works.

6. Storage, maintenance and transportation

6.1 Storage and maintenance


- Product shall be carefully placed far away from the hypo-center, and shall be installed at a cool, dry, and ventilated place.
- When storing, do not put it together with toxic, corrosive, inflammable and explosive articles.
- In case the product is not used for a long time, it should be electrified once a month, and each time lasts for 5 minutes.
- The product shall be stored at the location as follow:
 - ① Temperature: -20 °C ~ 55 °C,
 - ② Relative humidity: 10% ~ 90%,
 - ③ Atmospheric pressure: 70 kPa ~ 106 kPa.

6.2. Transportation

- During transportation, it shall not be packed with dangerous goods.
- During transportation, excessive shock and vibration shall be prevented, and carefully place, do not place it upside down.
- Protect the product from direct sunlight, rain, or snow during transportation.

7. Product list

No.	Name	Remarks
1	Main unit	/
2	Handpiece	/
3	Ultrasonic scaler tips	/
4	Torque wrench	/
5	Endo wrench	/
6	Endo file	/
7	Connector of water path	/
8	Sterilization box	/
9	Power supply cord	/
10	Water bottle	/
11	Wireless foot switch	/
12	Wired foot switch	/
13	Main software	Sine_wave_STM32codeV1.000

 **Note: The specifications of spare parts of the ultrasonic scaler are not listed in detail in this manual, for details, please refer to the data and packing list come with the product.**

8. Warranty

Since the date of sale, the warranty of this product is effective with its warranty card, and we are responsible for life-long maintenance. The product cannot be disassembled privately. If necessary, please disassemble and repair it under the authorization of the company. The repair is limited to the replacement of the tail line, main board, and water pump.

For the non-repairable damage caused by the maintenance of any non-designated and dedicated maintenance personnel is not covered by the free warranty.

9. Manufacturer's rights

We reserves the right to modify the design, technology, accessories, description and packing list of the products without prior notice at any time. In case of any difference, the actual product shall prevail.

10. Product disposal

No.	Components	Disassemble methods	Dispose methods
1	Printed-wiring boards	Use a Phillips screwdriver to remove the fixing screw, unplug the cable, and remove the items.	Recycle as metals and metal compounds. Please put them to the waste sorting recycling bin of metals. 1.For metals and metal compounds, please put them to the waste sorting recycling bin of metals. 2.For nonmetal, please put them to the waste sorting recycling bin of organic substances which are not used as solvents,which can be used for composting and other biological transformation processes.
2	Transformer		
3	Pump		
4	Solenoid valve		





























5	Handpiece cord		Please put them to the waste sorting recycling bin of organic substances which are not used as solvents,which can be used for composting and other biological transformation processes.
6	Enclosure		
8	PU tube	Remove the PU tube with nipper pliers.	Please dispose it in the infectious clinical waste containers.
9	Water bottle	Remove from the main unit.	
10	Ultrasonic scaler tips	Refer to the section 2.5 in the manual.	1.For metals and metal compounds, please put them to the waste sorting recycling bin of metals. 2.For nonmetal, please put them to the waste sorting recycling bin of organic substances which are not used as solvents,which can be used for composting and other biological transformation processes.
11	Foot switch	/	
12	Handpiece	Remove from the handpiece cord.	



1.Electrical waste products should not be disposed of with household waste.

2.Please recycle where facilities exist. Check with your local authority or retailer for recycling advice if you are unclear.

11. Symbols

	Manufacturer's logo		Caution!		Earth (ground)		Type B applied part		Do not dispose of the product into the ordinary municipal waste or garbage system
	Sterilizable at up to 134°C in the steam sterilizer (autoclave) at temperature specified		Manufacturer		Refer to instruction manual/booklet		Serial number		Keep dry
	Temperature limit		Humidity limitation		Fragile, handle with care		Atmospheric pressure limitation		Date of manufacture
	Use-by date		This way up		Medical device		Foot switch		Fuse
	"OFF" (power)		"ON" (power)		Water volume adjusting knob		Water volume adjusting		Degree of protection against ingress of water
Min	Minimum power	Max	Maximum power		Do not roll		Stacking limit by number		AA battery

12. Electromagnetic compatibility (EMC)

Warning:

- (1) **The ME EQUIPMENT or ME SYSTEM is suitable for hospital or professional dental clinic environment**
- (2) **Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.**
- (3) **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- (4) **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- (5) **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

12.1 Requirements for cable installation

Cable name	Cable type	Cable length
Power input cable	Unshielded parallel cables	1.2m
Input cable of foot switch	Unshielded parallel cables	2.5m
Handpiece cable	Unshielded parallel cables	2m

12.2 Key components of electromagnetic compatibility (EMC)

The key components of electromagnetic compatibility of the product are the main-board chip, touch-panel chip, transformer, and diaphragm pump, in the case of using or replacing non-original accessories, cables and transducers, it may result in obvious decrease of emission and immunity of the electromagnetic compatibility. Do not replace machine parts at random.

12.3 Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The ultrasonic scaler VRN-Q5 is expected to be used in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such electromagnetic environment.		
Emission test	Conformity	Electromagnetic environment-Guideline
RF emissions CISPR11	Group 1	The ultrasonic scaler VRN-Q5 only uses RF energy for its internal functions. Therefore, its radio frequency is low, and the possibility of interference to nearby electronic devices is small.
RF emissions CISPR11	Class B	The ultrasonic scaler VRN-Q5 is suitable for use in all installations, including household installations and the public low voltage supply grid directly connected to the home.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply	

12.4 Guidance and manufacturer's declaration-electromagnetic Immunity

Guidance and manufacturer's declaration-electromagnetic Immunity			
The ultrasonic scaler VRN-Q5 is expected to be used in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such electromagnetic environment.			
Immunity test	IEC 60601 test level	Satisfy	Electromagnetic environment - Guideline
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15kVair	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kVair	The ground shall be wood, concrete or tile; if the ground is covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency	The power supply from the grid shall have the quality to be used in hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2kV common mode	±0.5kV, ±1 kV differential mode ±0.5kV,±1 kV, ±2kV common mode	The power supply from the grid shall have the quality to be used in hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0%UT;0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT;25/30 cycles; Single phase: at 0°. 0%UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0%UT; 250/300 cycle	The power supply from the grid shall have the quality to be used in hospital environment. If the user of the ultrasonic scaler VRN-Q5 needs to operate continuously during power failure, it is recommended that the ultrasonic scaler VRN-Q5 be powered by an uninterruptible power supply (UPS) or the battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	The PFMF shall have the PFMF level characteristics of a typical place in hospital environment.
Conducted RF IEC61000-4-6	3V 0,15MHz-80MHz 6Vin ISM bands between 0,15MHzand80MHz 80% AM at 1 kHz	3V 0,15MHz-80MHz 6Vin ISM bands between 0,15MHzand80MHz 80% AM at 1 kHz	
Conducted RF IEC61000-4-6	3V/m 80MHz-2,7GHz 80%AM at 1 kHz	3V/m 80MHz-2,7GHz 80 % AM at 1 kHz	
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic Immunity							
The ultrasonic scaler VRN-Q5 is expected to be used in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in such electromagnetic environment.							
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430-470	GMRS460, FRS460	FM ±5 kHz deviation 1 kHzsine	2	0.3	28
	710	704-787	LTEBand13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, IDEN820, CDMA 850, LTEBand5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
1970							

12.5 Recommended isolation distance between portable and mobile RF communication devices and ultrasonic scaler VRN-Q5

Recommended isolation distance between portable and mobile RF communication devices and ultrasonic scaler VRN-Q5			
The ultrasonic scaler VRN-Q5 is expected to be used in the electromagnetic environment where radiation RF disturbances are controlled. According to the maximum output power of the communication device, the purchaser or user may prevent electromagnetic interference by maintaining the minimum distance (as recommended below) between the portable and mobile RF communication device (transmitter) and the ultrasonic scaler VRN-Q5.			
Rated maximum output power/W of transmitter	Isolation distance/m corresponding to different frequencies of the transmitter		
	150kHz~80MHz $d = \left[\frac{3.5}{f} \right] \sqrt{P}$	80MHz~800MHz $d = \left[\frac{3.5}{f} \right] \sqrt{P}$	800MHz~2.5GHz $d = \left[\frac{7}{f} \right] \sqrt{P}$
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 the rated maximum output power of transmitter not listed (if any) in above Table, the recommended isolation distanced, in meters (m), can be determined by using the formula in the corresponding transmitter frequency column, where P is the maximum output power of transmitter provided by the transmitter manufacturer, the unit shall be Watts (W).			
Note 1: formulas for higher frequency range are used at frequencies of 80MHz and 800 MHz.			
Note2: these guidelines may not be appropriate for all situations, the electromagnetic transmission is affected by the absorption and emission of buildings, objects and human bodies.			

The ultrasonic scaler VRN-Q5 has passed the test according to the requirements of IEC 60601- 1-2:2004; however, it does not guarantee in any way that it is not affected by electromagnetic interference. The ultrasonic scaler VRN-Q5 shall not be used in high electromagnetic environment.

13. Attachment

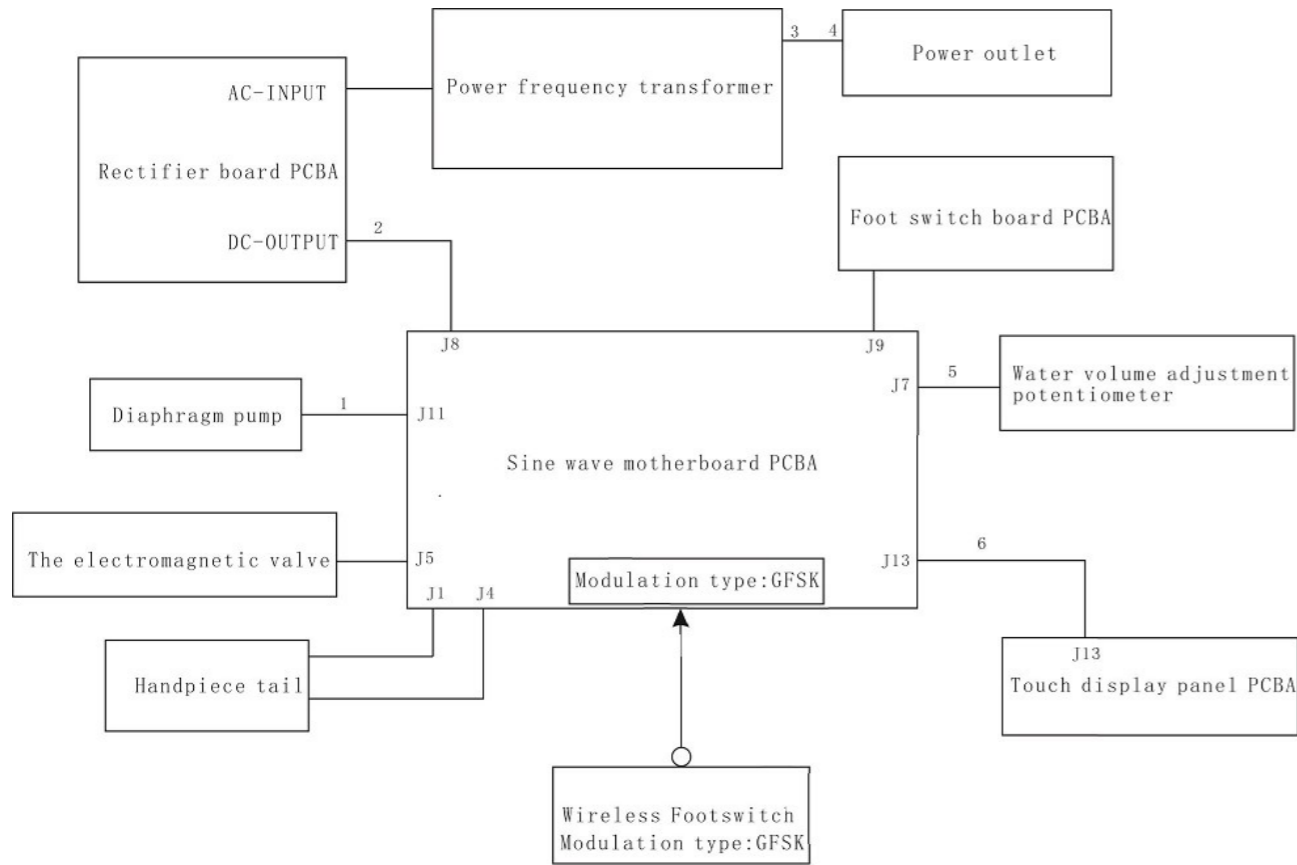
13.1 Attached table: Power table of ultrasonic scaler tips

Scaling		
Model	Grade	Water volume
G1	1-10(G)	Yes
G3	1-10(G)	Yes
G4	1-6(G)	Yes

Implant maintenance		
Model	Grade	Water volume
IM1	1-4(P)	Yes

Periodontal treatment		
Model	Grade	Water volume
P1	1-10(P)	Yes
P11	1-6(P)	Yes
P12	1-6(P)	Yes
P12L	1-6(P)	Yes
P12R	1-6(P)	Yes
P16	1-6(P)	Yes

13.2 Attached figure: Electrical schematic diagram



The control signal is given to the main control board through wired or 2.4 GHz wireless communication. The main control board of the product can control the water pump, solenoid valve and handle work.

13.3 Compatible ultrasonic scaler tips

The Ultrasonic Scaler Tips manufactured by URIT Medical Electronic Co., Ltd. compatible with the VRN-Q5 Ultrasonic Scaler. See the table below for model details:

No.	Model	Material	Thread	Thread length	Tooth pitch	Function
1.	G1	1Cr17Ni2 stainless steel	M3 standard thread	5±0.5mm	0.5mm	For supragingival scaling
2.	G2					
3.	P2L					For periodontal treatment
4.	P2R					
5.	P4					
6.	P13L					
7.	P13R					
8.	P15					
9.	G3	30Cr13 stainless steel	M3 standard thread	5±0.5mm	0.5mm	For supragingival scaling
10.	G4					
11.	G5					For periodontal treatment
12.	P3					
13.	P1					
14.	E1					
15.	E14					For root canal therapy
16.	E15					

17.	P11	TC4 titanium alloy	M3 standard thread	5±0.5mm	0.5mm	For periodontal treatment
18.	P12					
19.	P12L					
20.	P12R					
21.	P16					
22.	IM1					For implant maintenance

 **Warning:**

The internal thread of the ultrasonic scaler tips produced by some manufacturers is rough, rusty, cracked or subject to other standards. If the external thread of handpiece is used in combination with the ultrasonic scaler tips that have aforesaid defects, it is easy to damage the thread, result in the loose thread, even cause irreparable damage to the ultrasonic scaler, please use the VRN original ultrasonic scaler tips .