VRN

DA–20

Ultrasonic Scaler

User Manual

CE 0123

Guilin Veirun Medical Technology Co.,Ltd.

CONTENT

Copyright & Declaration

This document is an English translation of the original Chinese version.

Congratulations on your purchase of DA–20 Ultrasonic Scaler from Guilin Veirun Medical Technology Co.,Ltd. It will bring you a new experience and convenience.

The manual is compiled in accordance with the relevant laws and regulations of China and the specific conditions of the DA–20 manufactured by Guilin Veirun Medical Technology Co.,Ltd. The manual includes the latest information as of the time of printing. Guilin Veirun Medical Technology Co.,Ltd. is solely responsible for the revision and explanation of the simplified Chinese version of the manual, and reserves the right to change the relevant content after the manual is printed without prior notice.The pictures involved in this manual are schematic diagrams and are for reference only. If the pictures do not match the actual product, the actual product shall prevail.

The operator must strictly follow this manual to operate. Otherwise, Guilin Veirun Medical Technology Co.,Ltd. shall not be responsible for any errors and equipment failures caused by illegal operations.

NOTICE：**Guilin Veirun Medical Technology Co.,Ltd. does not promise that the device will be used for a certain special purpose and make any implied guarantee for its marketability and applicability.**

If you need after–sales service support, please contact Guilin Veirun Medical Technology Co.,Ltd. or an authorized agent.

1. Introduction

1.1. Overview

DA–20 adopts piezoceramic ultrasonic technology, which uses high–frequency and high–energy vibrations generated by ultrasonic waves to clean the surface of the teeth, break up calculus and stains in the periodontal pockets by tips, and then the rubble and plaque are washed down by the water spray produced by the device. It is designed for gingival, subgingival cleaning and root canal washing and has the function of automatic water supply.It has following characteristics:

- The handpiece can be sterilized at 134℃ temperature and 0.22 MPa pressure.
- The wireless foot switch is used to remotely control the unit, which is more convenient to operate. At the same time, wired foot switches can also be selected according to user needs.
- High–brightness LED, which can improve the efficiency of clinical operation, and it can also use ordinary plug–in handpiece that has high compatibility.
- The product service life is 10 years.

1.2. Equipment description

The product is mainly composed of function control circuit, power supply circuit, irrigation system, tip, handpiece, and foot switch.

1.3. Intended use

The product is intended use for removing tartar, plaque on the surface of teeth and in periodontal pockets, cleaning and washing root canals.

1.4. Contraindications

- Patients with hemophilia is forbidden.
- Patients with heart pacemaker is forbidden.
- Doctors with heart pacemaker is forbidden.

- Use with caution in patients with heart disease, pregnant women and young children.

1.5. Technical parameters

- Input Voltage：230 V～，50 Hz
- Input Power：35 VA
- Batteries of wireless foot switch：AA Batteries×2
- Receiving sensitivity: –114 dB, receive frequency：2.4 G–2.5 G
- Tip amplitude： minimum,1 μm, deviation –50%
  maximum, 100 μm, deviation +50%
- Half deflection force：minimum, 0.1 N, deviation –50%
  maximum, 5 N，deviation +50%
- Vibration frequency of tip：18 kHz～45 kHz

Note：The vibration frequencies of different types tips are different, but they are all distributed within the described range.

- Output Voltage of tip：3 W～20 W
- Fuse：T1AH250V
- Weight：1.8 kg
- Software version: V1
- Operation modes：continuous running
- Protection against electric shock rating：Class Ⅱ equipment
- Protection against electric shock degree：Type B applied part
- Ingress protection rating：Ordinary equipment (IPX0), Wired foot switch is waterproof equipment（IPX1），Wireless foot switch is waterproof equipment（IPX4）
- Degree of safety 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：10 dbm

Radio Frequency Interface Requirements – Related to European installation

Note: This equipment has been tested and found to comply with the limits for a 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 2402~2480MHz 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.

- Software version：V1

1.6. Operation environment

a）Ambient temperature：5 ℃~ 40 ℃
b）Relative humidity：≤80%
c）Atmospheric pressure：70 kPa~106 kPa

d) Applicable range of power supply voltage ： 230 V ~

1.7. Side effects, adverse events and measures

According to the results of many years of clinical treatment with similar equipment, there are no serious side effects except that the enamel of the treatment site may leave a few scratches that can be recovered.

If any unexpected action occurs during the use of this device, please immediately power off it to stop the device to ensure safety.When using the device, pay attention that the tip needs enough water to dissipate heat, otherwise may burn the patients. If burns occur, please stop using the device immediately and perform corresponding diagnosis and treatment according to the burns.

2. Installation

2.1. Front/Back view

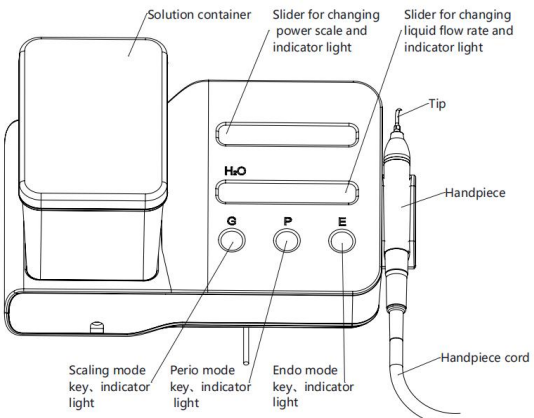


Figure 2.1

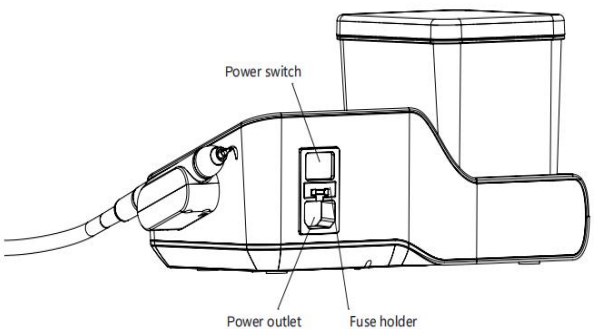


Figure 2.2

Figure 2.1：
Solution container：Storage solution for scaling.
Slider for changing power scale and indicator light：it used for changing power scale and displays the power scale of the current working state.
Slider for changing liquid flow rate and indicator light：it used for changing liquid flow rate at the tip and displays the flow rate of the current working state.
Tip：used in conjunction with ultrasonic scaler for cleaning and reshaping the surface of teeth, root canals and other parts
Handpiece：used in conjunction with scaler with water spray function
Handpiece cord：used to connect hanpiecee and unit
Endo mode key, indicator light：switching the endo mode, the light is on to indicate that the ultrasonic scaler is in endo state.
Perio mode key, indicator light：switching the perio mode, the light is on to indicate that the ultrasonic scaler is in perio state.
Scaling mode key, indicator light：switching the scaling mode, the light is on to indicate that the ultrasonic scaler is in Scaling state.
Figure 2.2：
Power switch: switching the power state
Power outlet: power input
Fuse holder: place the fuse
2.2. Connection of the accessories
Insert the USB connector of the foot switch in the drawing position

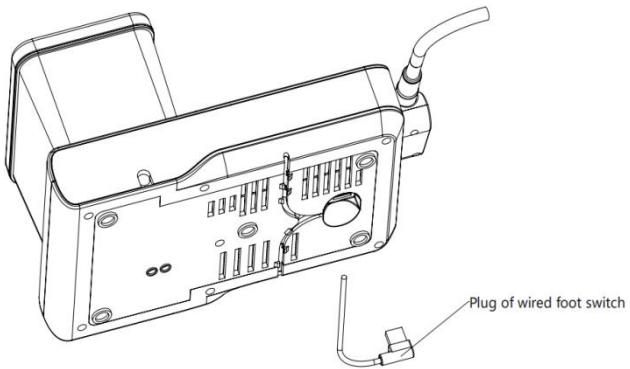


Figure 2.3

Socket of wired foot switch is at the bottom of the device, it will be inserted into the forward or backward of the wire groove firstly according to the user's needs.

2.3. Solution container installation

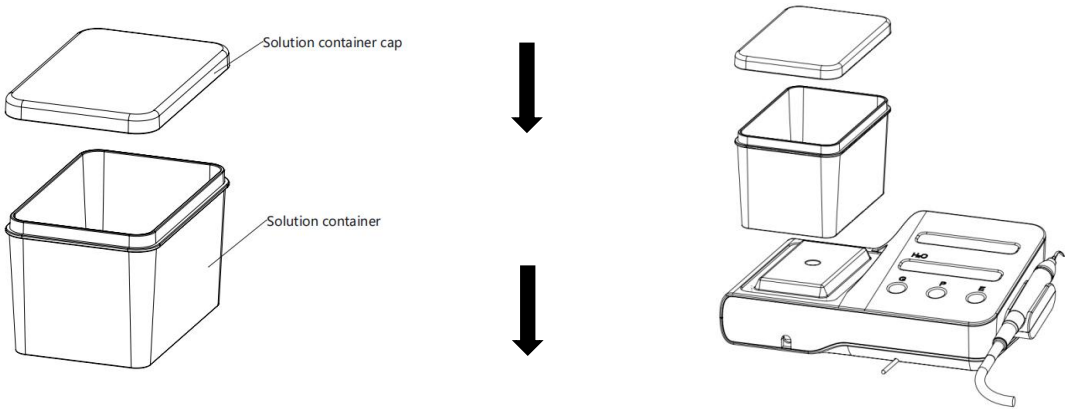


Figure 2.4

2.4. Handpiece installation

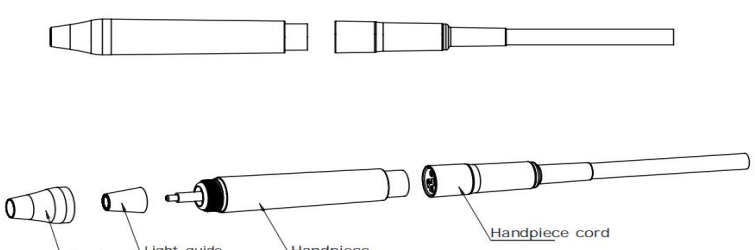


Figure 2.5

2.5. Tip installation

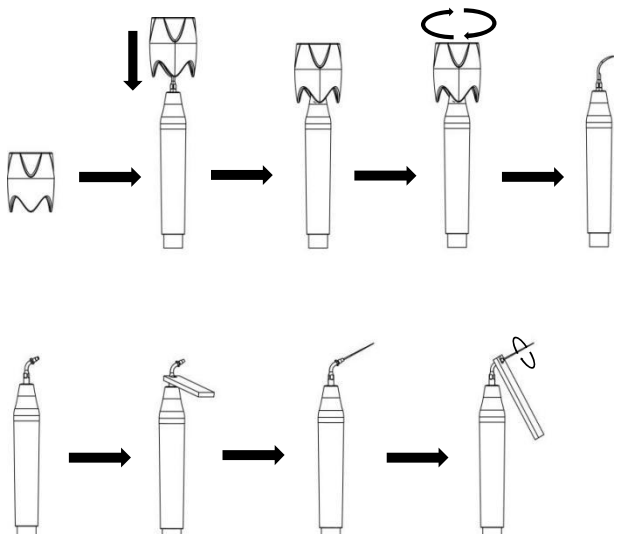


Figure 2.6

2.6. Matching code for wireless foot switch

1) Press and hold the three keys "G", "P" and "E" at the same time until the indicator light of liquid slider starts to flash slowly under the device is power on.
2) Keep foot switch pressed and insert two AA batteries (operate when indicator light of liquid slider starts to flash slowly at the same time) ,and then foot switch will enter matching mode and it should keep pressed state for 3 seconds after it is power on.
3) Loosen foot switch and restart, and the device can be controlled by wireless foot switch.

4) Press and hold the three keys "G", "P" and "E" at the same time when these three modes are at 10 scales , and the device will cancel all match.
5) Press and hold the three keys "G", "P" and "E" at the same time when the liquid flow rate is 10 scales, the device will enter the calibration mode of liquid flow rate. Don’t enter this mode under normal circumstances. If necessary, please contact the dealer or contact the manufacturer.

Note: Tear off the membrane behind the sticker and stick it on the bottom of foot switch for waterproofing

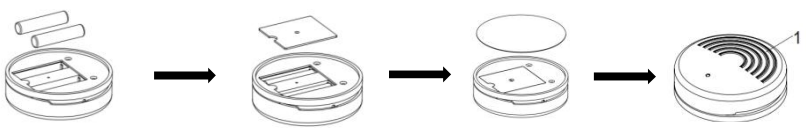


Figure 2.7 Press "1" to start the device.

3. Operating instruction

3.1. Major components of handpiece

Conehead：it can be unscrewed, users can take out the conehead regularly and clean the main pole with alcohol.
Light guide：it can be cleaned with alcohol.
Handpiece：it is the important parts of the device, which can be at high temperature and high pressure environment.
Handpiece cord：it is used for connecting the handpiece and irrigation system and circuit of the unit .

NOTICE：Please keep the handpiece and socket dry.

3.2. Torque wrench

1) The design of torque wrench adopts a special structure, which can ensure the user can effectively load and

unload the tip and protect the user's hand during use, and it can avoid be scratched by the tip when load and unload the tip(See Figure 2.6).

2) Put the tip into the wrench and hold the handpiece tightly, rotate the tip in a clockwise direction till the tip does not turnround anymore, and then it is installed.
3) Unload the tip: Hold the handpiece and rotate the tip in a counter–clockwise direction by wrench to remove it.
4) Once after using, please put the wrench into sterilization cabinet to sterilize.
5) After sterilization, due to the high surface temperature of the torque wrench, the wrench needs to be cooled before it can be used again to avoid burns.
6) When the torque wrench is not in use, place it in a ventilated and dry place and keep it clean.

3.3. Scaling function for gingiva and subgingival

1) Open the package and check whether the accessories of the product are complete according to the packing list. Take out the device from the box and place it on a stable surface facing the operator.
2) Set the slider for changing liquid flow rate to the max scale.
3) Insert the battery into the wireless foot switch or insert the plug of the wired foot switch into the foot switch socket(See Figure 2.3 and Figure 2.7).
4) Open the solution container cap, put a proper amount of pure water into container, close the cap, and install the container to the installation position of container on the device(Figure 2.4).
5) Fasten the tip to the handpiece with torque wrench (See Figure 2.6), and then correctly connect the handpiece with the handpiece cord socket. Before installing the handpiece, dry the connection end of the handlpiece and the socket thoroughly(Figure 2.5).
6) Power off the device, then connect the output of the power cord to the device, and then connect the input of the power cord to the electric supply(See Figure 2.2).
7) Power on the device, and the “G” indicator light and the first 3 power indicator lights will light up at this time.
8) The operator selects the "G" and "P" modes according to the series of the tips, and the power of the tip is shown

in the attached table.

9) The frequency is relatively fast when the product is working normally, ensure that the device has normal water output, only light touch and reciprocating movement at a certain speed can be used to eliminate dental calculus, and there is no obvious feeling of heating at the tip; Excessive local force or staying for too long when cleaning teeth.
10) Vibration intensity: adjust the vibration intensity according to your needs. Generally, user can adjust it to a medium vibration intensity. User can also adjust the vibration intensity at any time during the clinical process according to the patient's sensitivity and the hardness of the calculus.
11) Liquid flow rate: step on the foot switch, the tip will vibrate, slide the liquid slider to make the liquid into a semi–atomized state to cool the tip and clean the teeth.
12) Generally use the pen position to hold the handpiece.
13) During scaling, do not make the tip be in vertical contact with the teeth, and do not apply heavy pressure to avoid damage to the teeth and tip.
14) After completing scaling, keep working for 30 seconds under the water supply to clean the handpiece and tip.
15) Remove the tip and then pull out the handpiece for sterilization.

NOTICE:

1) Please do not pull out the handpiece when stepping on the foot switch and the tip vibrates.

2) If do not use the wireless foot switch for a long time, please remove the battery.

3) Please do not move or turn over the device when it is working.

3.4. Endo function

1) Fix the holder of endo file to the handpiece with endo wrench (See Figure 2.6).
2) Unscrew the nut of the holder .

3) Insert the endo file into the hole in front of the holder.
4) Tighten the nut of the endo file with endo wrench.
5) Press "E", the "E" indicator lights up.
6) When the Endo function is selected, slowly extend the endo file into the patient's root canal, step on the foot switch and start the root canal washing. Adjust the power of root canal washing as needed.

NOTICE:

1) Tighten the endo tip.
2) Tighten the nut of the holder.
3) Do not apply heavy pressure when root canal washing.
4) Do not step on the foot switch when the endo file is not placed in the root canal.
5) It is recommended that the power adjustment start from the 1st scale and slowly increase to the 3rd scale when using the Endo function.
6) Please do not move or turn over the device when it is working.

3.5. Wireless foot switch

3.5.1. Operating

1) Put 2 AA batteries into the wireless foot switch in the direction indicated by the positive and negative poles, install the battery cover and glue the waterproof rubber pad, and tighten the cover screws.
2) Place the wireless foot switch flat on the ground.
3) After matching with ultrasonic scaler, power on the device and then user can use the wireless foot switch to control the device.
4) Within 5 meters of the ultrasonic scaler, the vibration of the device can be controlled by the wireless foot switch at any position. Please be careful not to have large obstacles between the foot switch and the device, so as not to affect the wireless transmission.

3.6. Automatic water supply

3.6.1. Operating：

1) Pull out the container installed on the device vertically upwards.
2) Open the cap of container, add enough pure water, and then close the cap tightly.
3) Clean bottleneck and socket connection of container.
4) Insert the container vertically into the container interface of automatic water supply on the device.

NOTICE：

1) Make sure that the air vent and water outlet are not blocked.
2) Check if the gasket in the cap is fine. If the gasket is deformed or falls off, please replace and install it in time.
3) Please clean the connection of the container before each use.
4) Please add liquid in time to keep the liquid path unblocked when the liquid in the container is lower than the lower limit.

3.7. Precautions

1) Keep the device clean and dry before or after use.
2) Prohibit suspended or inverted device.
3) Before each use, please let the device work for 30 seconds under the condition of water to remove the residual water in the pipeline.
4) The operator should be equipped with adequate protection (such as goggles, mask, etc.) to prevent cross–infection.
5) Using the product must comply with the requirements of the relevant operating specifications and relevant laws and regulations of the medical department, and it is limited to trained doctors or technicians.
6) Before each use, please sterilize the tip, wrench and other accessories.

7) Don’t tighten or loosen the tips when the handpiece is activated.
8) Tighten the tips.
9) When the tip is damaged or worn, the vibration intensity will decrease. The operator should replace the tip with a new one according to the clinical situation.
10) Don’t bend or sharpen the tips.
11) Don’t use unclean water, and do not use normal saline instead of pure water sources.
12) Don’t pull the tail wire forcefully during the use to avoid damage to the tail wire.
13) Don’t beat and scrape the handpiece in a hurry.
14) After using the device, power off the device and pull out the power plug.
15) Our company specializes in producing medical devices and we're responsible for its security only when the device maintained, repaired and modified by URIT or Distributor authorized by the our Company, and the replacement accessories are made by our Company and operating follow the user manual.
16) The internal thread of the tips produced by some manufacturers is rough, rusty, chipped or adopts other standard threads. When used with the handpiece, it is easy to damage and slip the teeth, and even cause irreparable damage to the product. Please use the original tip.
17) When the operator uses a different series of tips, it needs to adjust the working mode accordingly to avoid breaking the tip.
18) Don’t move or flip the device during use.

4. Reprocessing

The instructions provides instructions for cleaning, sterilization and packaging of Ultrasonic Scaler intended to be reprocessed in medical facilities.Reprocessing components include tip,wrench and handpiece.

The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in

order to eliminate the risk of product reuse related infection.Decisions regarding cleaning or sterilizing dental instruments are based on the potential risk of infection associated with their use.

It is recommended to use steam sterilization. Remember that sterilization cannot be achieved unless the elements of the assembly are cleaned first.

If there is anything in the following instructions that is not clear, do not hesitate to contact.

We encourage you to report adverse events related to device reprocessing. Report such events directly to Guilin Veirun Medical Technology Co., Ltd.

4.1Reprocessing instructions for reusable products

The instructions are binding for the reprocessing of Ultrasonic Scaler. When necessary, additional product–specific instructions are included with the product to provide additional information.

Before use, carefully read the operating instructions of Ultrasonic Scaler and devices with which the product will be used.Reusable products must be cleaned and sterilized prior to first use. They must be replaced after the number of operations specified by the manufacturer. Disposable products (single use) cannot be reused.

4.2Preparation

It is only possible to carry out effective sterilization after the completion of effective cleaning. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product–specific procedures are used for cleaning and sterilization, and that the validated parameters are adhered to during every cycle.Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.

4.3Initial treatment at the point of use

The treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. Additional information, where necessary, is provided in the respective product–specific usage instructions.

Steps

1) Completely disassemble the tips and handpiece from Ultrasonic Scaler, if applicable. Rinse away any surface soiling of them with distilled deionized water or cleaning agent.
2) Rinse through all lumina (e.g. irrigation and aspiration connection) at least 3 times in the normal direction of flow (no back rinsing) using a disposable syringe (min. volume 50 ml) filled with distilled/deionized water applied to the back nozzle.
3) An aldehyde–free cleaning and disinfection solution that is compatible with the products may also be used as an alternative rinsing solution. In such cases, it is necessary to rinse thoroughly afterwards at least 3 times with distilled, or deionized water.

4.4Cleaning

Preparation

When selecting the cleaning agent to be used, ensure that:

•These are fundamentally suitable for the cleaning of the products and compatible with one another,

• The chemicals used are compatible with the products.

⚠ It is absolutely essential that the concentrations and contact times specified by the manufacturer of the cleaning agent are adhered to. Only freshly prepared solutions may be used. The solution is not permitted to foam.Only sterilized or low microbe count distilled/deionized water (< 10 cfu/ml) can be used for all rinsing steps.

Steps for manual cleaning

1) Completely disassemble the handpiece and instruments, if applicable.
2) Place the products in 75% ethyl alcohol for at least 3mins.
3) Remove any externally–attached soiling by brushing carefully with a soft brush or a soft cloth for at least 3 mins.
4) Rinse the products vigorously at least five times, each time with fresh distilled or deionized water (each product lunmen with at least 50 ml of water). Repeat the cleaning process if the last rinsing does not run clear, or if stains are still visible on the product.

⚠ The product adopts manual cleaning and it has been verified. Please do not modify the cleaning method without authorization, such as using disinfector for automated cleaned.

Notice: No automatic cleaning for the product.

4.5Drying

After cleaning, put the handpiece, wrench and tips into the oven for drying.The recommended drying condition is 138℃ for 20 minutes.

4.6Inspection and maintenance

⚠ If stains are still visible on the product after cleaning, the entire cleaning procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or bent out of shape must be disposed of (no further use is permissible).

4.7Packaging

Only cleaned products are permitted to be sterilized. Prior to sterilization, the products need to be placed in a suitable sterilization container:

- Resistant to 138℃, with adequate steam permeability,
- Maintained on a regular basis.

If single–use sterilization packaging is to be used, this must be suitable for steam sterilization (temperature resistant to 138 ℃ with adequate steam permeability).The material of sterilization packaging is made of medical paper and PET/CPP. The packaging material complies with the requirements of EN ISO 11607–1.

Steps

1) Select a suitable sterilization packaging according to the size of the sterilized item and put the items in.
2) Place the sharp and specially shaped devices in the correct position for safe removal when opened.
3) Affix the strip of sterilization packaging(the strip of the packaging is sticky and it does not require additional processing for sealing such as heat sealing) and mark the sterilization time.
4) Put the sealed sterilization packaging rightly into steam sterilizer.
5) Pay attention to the color–changing: if sterilization is really implemented, it will turn black /grey from initial blue under steam sterilization.
6) Open the strip along the direction printed on the packaging and then takes the items out.

4.8Sterilization

The handpiece and tips can withstand 250 reprocessing cycles.Do not exceed the maximum number of reprocessing cycles.

Use only the following listed steam sterilization procedures for sterilization; other sterilization procedures are not permissible:

- Steam sterilizer in accordance with EN 13060 validated in compliance with EN IS0 17665,
- Maximum sterilization temperature 138℃.

Steps for sterilization

1.Sterilization at 134℃ for 4 minutes.

2.Sterilization at 134℃ for a maximum of 20 minutes is permissible.

The hot–air sterilization and radio–sterilization procedure may not be used (as it causes the destruction of products). The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).

4.9Service life

The handpiece and tips have been designed for 250 reprocessing cycles.Ultrasonic Scaler has 10 years service life and tips have 5 years service life from start with production, if it exceeds reprocessing cycles or service life, it should be not used any more. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products.The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling pH > 9 or acid pH < 5) can reduce the life span of products. The manufacturer accepts no liability in such cases. The products may not be exposed to temperatures above 138℃.

4.10Storage and transportation

After sterilization, keep sterilization packaging and stored it in the following environment to avoid infection and sterilization failure:

- Temperature:–20 ℃ to 55 ℃,
- Humidity:≤95%,
- Atmospheric pressure:70kPa~106 kPa.

⚠ The product can keep sterile for 6 months in sterilization packaging, when exceed the 6 months，it shall

be reprocessed again before use.

After reprocessing, it is necessary to confirm that the products can work normally before use. If products with visible damage, chip/flake loss, corrosion, rust or bent out of shape must be disposed of (no further use is permissible).

5. Troubleshooting

Error	Possible causes	Solutions
Turn on the power switch, there is no indicator light on the panel	Poor contact of power plug	Plug in the power plug tightly
	Internal fuse not working	Contact your local dealer or our company
There is no vibration or no water spray at the tip after stepping on foot switch	Poor contact of wired foot switch	Plug in the plug of foot switch tightly
	Batteries are out of power of wireless foot switch	Change new batteries
	Foot switch not working	Match the foot switch again (please refer to paragraph 2.6)
After stepping on the foot switch, the tip does not vibrate but there is water spray at the tip	Tip loose	Fasten the tip using the wrench
	Faulty handpiece	Pull out handpiece and contact your local dealer or our company
	Faulty handpiece cord or inside circuit	Contact your local dealer or our company
There is water spray at the tip after power off	Faulty electromagnetic valve	Contact your local dealer or our company
Handpiece overheating	Spray is set up too small	Adjust the spray
Handpiece overheating seriously	Faulty handpiece	Pull out handpiece and contact your local dealer or our company
Inadequate amount of spray	Spray is set up too small	Adjust the spray
	The water circuit is blocked	Unblock the water circuit by three–ways syringe

Weak tip vibration	Tip loose	Fasten the tip using the wrench
	There is not dry between the base of the handpiece and its cord	Dry the connector between the base of the handpiece and its cord by hot air
	Worn or bent tip	Replace the tip
Water is leaking between the base of the handpiece and its cord	Wear of the seal	Replace the seal
There is no vibration or noisy at root canal file	Loose clamping nut	Tighten clamping nut
	Damaged root canal holder	Replace root canal holder

NOTICE：If the fault still cannot be resolved, please contact your local dealer or our company.

6. Storage, maintenance and transportation

6.1. Storage and maintenance

- The device should be handled with care, far away from the earthquake source, and should be installed or stored in a cool, dry and ventilated place.
- Do not mix with toxic, corrosive, flammable and explosive materials during storage.
- When the product is not used for a long time, it should be connected to water and electricity once a month, each time for 5 minutes.
- Store temperature from –20 ℃ to 55 ℃,relative humidity ≤95%，atmospheric pressure from 70 kPa to 106 kPa.

6.2. Transportation

- Transport should not be mixed with dangerous goods.
- Avoid excessive shock and vibration during transportation, handle with care and avoid upside–down.
- Keep away from rain, sunlight or snow during transportation.

7. Maintenance

Maintenance list as follow:

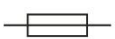
No.	Name	Replacement cycle	Replacement Method
1	Main board	/	/
2	Touch keyboard	/	/
3	Handpiece	250 reprocessing cycle	See article 2.4
4	Handpiece cord	/	/
5	Tips	250 reprocessing cycle/5 years/abrasion	See article 2.5
6	Torque wrench	250 reprocessing cycle	/
7	Endo wrench	250 reprocessing cycle	/
8	Endo tips	250 reprocessing cycle	See article 2.5
9	Liquid pipe(4mm×6mm)	/	/
10	Power cord	/	/
11	Electromagnetic valve	/	/
12	Wireless foot switch	/	/
13	Wired foot switch	/	/

NOTICE：There doesn't exhaustively list the accessories and specifications of DA-10. Please refer to the random delivery materials and packing list for details.Should your product need serviced and repairs,please send it to your dealer or to an authorized repair center.We decline responsibility for the safety of the device and declare the warranty null and void if service or repair is carried out by an unauthorized third party or if non-genuine spare parts are used.

8. After–sale service

This device is guaranteed by the warranty card from the date of sale, and is responsible for lifetime maintenance. Irreparable device damage caused by non–designated dedicated maintenance personnel is not covered by the free warranty.

9. Symbols description

Symbol	Description	Symbol	Description
	Manufacturer's logo		Fuse
	Caution		AA batteries
	Refer to instruction manual/ booklet		Manufacturer
	“ON” (power)		“OFF” (power)
	Date of manufacture		Use by date
	Temperature Limit		Atmospheric pressure limitation

Symbol	Description	Symbol	Description
	Humidity limitation		Serial number
	This way up		Fragile, handle with care
	Keep away from rain		CLASS II equipment
	Type B applied part		Medical device
	Sterilisation at 134℃ in an autoclave		Slider adjustment direction
Liquid	Slider for changing liquid flow rate	Power	Slider for changing power scale
	Foot switch	IPX1 IPX4	Ingress protection rating
	Do not roll		Stacking limit by number
CE 0123	CE marking	UDI	Unique device identifier

Symbol	Description	Symbol	Description
EC REP	Authorized representative in the European Community/European Union		Do not dispose of the product into the ordinary municipal waste or garbage system

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.
2	Transformer		
3	Pump		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
4	Solenoid valve		

			as solvents,which can be used for composting and other biological transformation processes.
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.	
9	Water bottle	Remove from the main unit.	
10	Tips	Refer to the fig.9 in the manual.	Please dispose it in the infectious clinical waste containers.
11	Foot switch	/	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
12	Handpiece	Remove from the handpiece cord.	

			substances which are not used as solvents,which can be used for composting and other biological transformation processes.

⚠ Note:

(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. Manufacturer's rights

The company reserves the right to modify the design, technology, accessories, user manual content and packing list content of the product at any time without notice. In case of discrepancies, the actual product shall prevail.

12. Electromagnetic compatibility

⚠ **NOTICE:**

1）Without the express consent of Veirun, unauthorized changes or modifications to the device may cause electromagnetic compatibility(EMC) problems of the device or other device.

2）The design and test of device comply with the operating regulations related to EMC.

3）The ME EQUIPMENT is suitable for hospital and clinics.

4）The third conductor in the POWER SUPPLY CORD is only a functional earth.

Warning： Even if other devices meet the launch requirements of the corresponding national standards,the device or system may interfere with other electronic devices.

Warning： 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.

Warning： 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.

Warning: 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.

Warning： 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.

Note： The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

12.1. Cable length

Cable name	Type	Length

Power cord	Unshielded parallel line	1.8 m
Input line of foot switch	Unshielded parallel line	2.5 m
Handpiece cord	Unshielded parallel line	2 m

12.2. Key components of EMC

The product key components of EMC are the scaler's main board chip, touch board chip, transformer and diaphragm pump. The use or replacement of accessories, cables, transducers, etc. that are not designed to match will cause the electromagnetic emissions and immunity performance to be significantly reduced.Do not replace device parts without authorization.

12.3. Necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

1) It is suitable for used in domestic establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purpose.
2) Floors should be wood, concrete or ceramic tile. If floors are cover with synthetic material, the relative humidity should be at least 30%.
3) Main power quality should be that of a typical commercial or hospital environment.
4) If the user requires continued operation during power mains interruptions, it is recommended that it be powered for an uninterrupted power supply or a battery.

12.4. Electromagnetic emissions

Guidance and manufacturer’s declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

12.5. Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	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; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25cycles; Single phase: at 0°.

	0 % UT; 250/300 cycle	0 % UT; 250 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance level** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820,	Pulse modulation 18 Hz	28	28
	870					
	930					

			CDMA 850, LTE Band 5			
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Guidance and manufacturer's declaration - electromagnetic Immunity				
	Test Frequency	**Modulation**	**IEC 60601-1-2 Test Level** (A/m)	**Compliance level** (A/m)
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

DA–20 has passed test according to the standard IEC 60601–1–2, but it cannot guarantee in any way that it is not affected by electromagnetic interference. DA–20 should be avoided using in high electromagnetic environments.

13. Index：Table of tip power for use

Model	Gear	Irrigation flow	Treatment type
G1	1-10(G)	YES	Supragingivale scaling
G2	1-10(G)	YES	Supragingivale scaling
G4	1-6(G)	YES	Supragingivale scaling
P1	1-10(P)	YES	Subgingival scaling
P4	1-10(P)	YES	Subgingival scaling
E14	1-3(E)	YES	Root canal washing

Manufacturer Information
Product Name：Ultrasonic Scaler
Model：DA–20

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