VRN

DS–100

Ultrasonic Bone Surgery Device

OPERATION MANUAL

Guilin Veirun Medical Technology Co.,Ltd.

CONTENT

Statement

Congratulations on becoming a respected customer of Guilin Veirun Medical Technology Co.,Ltd. and welcome to use the DS–100 Ultrasonic Bone Surgery Device, which will bring you a new experience and convenience. This User Manual includes the latest information up to the time of its printing. Guilin Veirun Medical Technology 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.

The use of the device 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

devices.

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,Guilin Veirun Medical Technology Co.,Ltd. will not be responsible for any errors and device damage caused by illegal operation.

Note:

Guilin Veirun Medical Technology Co.,Ltd. does not promise the devices 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 Guilin Veirun Medical Technology Co.,Ltd. or its authorized agent.

1. Introduction

1.1. Overview

Principle of operation

The piezoelectric ceramic transducer converts electrical energy into mechanical energy, and through high–frequency oscillation, the bone tissue at the cutting position is completely destroyed to achieve the purpose of cutting bone tissue.

Mechanism of action

The device uses high–intensity energy ultrasound technology and through the piezoelectric ceramic transducer converts electrical energy into mechanical energy. The use of ultrasound frequency micro–oscillation tip for osteotomy, by high–frequency ultrasound oscillation, the water in the tissue cells in contact is vaporized and protein hydrogen bond breaking, so that the bone tissue to be cut completely destroyed.

1.2. Structure and composition

The device consists of a host (including peristaltic pump), handpiece(including handpiece bracket, silicone handpiece bracket, handpiece connector), foot switch (including plug), tips (including tip bracket), torque wrench, power cord.

The model of each component is shown in the table below.

Device	DS–100
Handpiece	HS–1L
Foot switch	JY01 Single–function foot switch and JY12 Multi–function foot switch
Tips	US1, US2, US4, US5, UL3, UC1

Note:Infusion bottles and tubes are not included in this device.

1.3. Security requirements

Guilin Veirun Medical Technology Co., Ltd. will not be liable for any direct or indirect damages or losses under the following conditions.

(1) If the device is used for purposes other than any of the mentioned uses.

(2) If the operator does not use the device in a manner consistent with the steps and requirements written in the instructions.

(3) If the wiring system in the room where the device is used does not meet appropriate standards and suitable requirements.

(4) If assembly, operation, or repair of the device is not authorized by Guilin Veirun Medical Technology Co., Ltd.

(5) If the environmental conditions in which the device is located or stored do not meet the requirements mentioned in the section on technical requirements in the instruction manual.

⚠ **Danger:** Must be operated by a competent professional.

This device should only be used by specialized, trained personnel (e.g., surgeons). Proper use of this device will not cause side effects; improper use of this device will cause heat to be transmitted to the tissue, which may result in tissue damage.

⚠ **Hazard:** Scope of application.

This device can only be used in the areas of application mentioned in manual (see point 1.5). Failure to follow the instructions for this device will result in injury to the patient, the operator, the device or operational failure.

⚠ **Danger:** Contraindications.

DS–100 may not be used on patients with pace–makers or other implanted electronic devices. The same requirement applies also to the operator.

⚠ **Danger:** Contraindications.

An electrosurgical knife could interfere with correct functioning of the device.

⚠ **Hazard:** Cleaning, disinfection and sterilization of new or repaired devices.

All new or repaired devices are delivered in no sterile conditions.Before being used for treatments,

all new or repaired devices are cleaned, disinfected and sterilized in strict accordance with the requirements of Section 4.

⚠ **Danger:** Use only original Guilin Veirun Medical Technology Co., Ltd. accessories and spare parts.

⚠ **Danger:** Check the condition of the device before treatment.

Always ensure that there is no water underneath the equipment; before each treatment you need to check that the equipment is in normal operation and that its components are effective; if any problem occurs while operating the equipment, do not perform any operation; if there is a problem with the equipment, please contact the authorized technical service center .

⚠ **Danger:** Breakage and wear of the tips.

High–frequency vibration and wear may occasionally result in tip breakage. Tips that have changed shape are highly susceptible to damage during use, and any such tips should never be used. The patient should be instructed to breathe through the nose during treatment to avoid inhaling fragments of dislodged tips.

⚠ **Danger:** Do not install the equipment in a place where there is a risk of explosion.

This equipment must not be operated in areas where flammable gases (anesthetic mixtures, oxygen, etc.) are present.

⚠ **Danger:** Make sure the pump cover of the peristaltic pump is closed.

The foot switch of DS–100 must not be started when the pump cover of the peristaltic pump is open. (Fig.6–B) .Moving parts may damage the operator.

⚠ **Warning:** Contraindication.

Do not perform this treatment on metal or ceramic prosthetic artifacts. Ultrasonic vibrations can cause disintegration of such artifacts.

⚠ **Warning:** Caution.

After autoclaving sterilizing of the handpiece, wait until it have cooled down completely before using.

1.4. Device labelling

1.4.1 Labelling description

A precise description of this labelling and the serial number of the device will enable our after–sales service center to answer your inquiries more quickly and efficiently. The labelling of the device is shown on the back of the device.

1.4.2 Labelling of the device

Each device has its own labelling, on which technical specifications and serial number are indicated. The labelling is on the rear of the device. The remaining data are included in this manual (see 1.7)

1.4.3 Labelling of the handpiece

The serial number and brand of the handpiece is engraved on the shell (Figure 1)

Figure 1

1.4.4 Labelling of foot switch

Figure 2

1.5. Intended use

This device is used in medical facilities for bone cutting, bone trimming and bone collection in oral surgery.

1.6. Contraindications

- Patients with bleeding diseases.
- Patients with cardiac pacemakers.
- Physicians with cardiac pacemakers.
- Patients with active angina pectoris, myocardial infarction within six months, and uncontrolled hypertension and heart failure.
- Patients with respiratory diseases such as asthma and chronic bronchitis.
- Patients with acute infectious diseases.
- Pregnant.

1.7. The main technical parameters

- Waterproof level: IPX0 (device), IPX1 (foot switch)
- Operating mode: Intermittent operation
- Power supply voltage: 100V–240V~ 50Hz/60Hz 120VA
- Fuse: T2AH 250V

- Working frequency: 22.3 kHz~29.6 kHz
- Flow: 25~100 mL/min
- Alarm: Front display show the error (see 5.1 for resolution)
- Handpiece cord: Less than 100 sterilization cycles is recommended.
- Pump tube: Disposable infusion tubes.
- Water Temperature: The recommended temperature of the desalinated water in the infusion bottle or bag is 4℃.
- Size of main unit: 290 mm × 290 mm × 130 mm (L × W × H)
- Weight of main unit: 3kg
- Type of protection against electric shock: Class Ⅰ equipment
- Degree of protection against electric shock: Type B applied part
- Software release version: V1
- Infusion bottle support rod: Infusion bottle support rods shall have a safety factor of 8 and a fracture elongation of not less than 10%.

1.8. Equipment safety classification

- 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), foot switch (IPX1)
- Degree of safety of application in the presence of a Flammable Anesthetic Mixture with air, Oxygen or Nitrous Oxide: Non–AP, APG type equipment.

1.9. Working environment

- Environment temperature: +10℃~ +40℃
- Relative humidity: 30%~75%
- Atmospheric pressure: 70 kPa~106 kPa
- Temperature in the water inlet of water–cooling equipment is not higher than 25℃, and 4℃ normal saline is recommended.

1.10. Side effects, adverse events and the measures that should be taken

If any unintended action occurs while the equipment is in use, immediately cut off the power switch of the equipment and stop using the equipment to ensure safety. When using this equipment, please note that the tip needs enough water to dissipate the heat, otherwise burns may occur, if burns occur, please stop using the equipment immediately and carry out appropriate diagnosis and treatment according to the burns.

1.11 Testing of equipment

- All equipment and components manufactured by Guilin Veirun Medical Technology Co.,Ltd..
- All components were subjected to duty cycles of a certain duration during the test.
- The test emphasized that all the problems are from the failure parts.
- This procedure ensures the function and reliability of all the parts.

2. Installation

2.1. Safety requirements during installation

⚠ **Danger:** The wiring system of the premises where the apparatus is installed and used must comply with the applicable standards and the relevant electrical safety requirements.

⚠ **Danger:** Do not install the apparatus in places where there is a risk of explosion.The apparatus must not be operated in areas where flammable gases (anesthetic mixtures, oxygen, etc.) are present.

⚠ **Danger:** Install the apparatus in a place where it will be protected from blows and from accidental sprays of water or other liquids.

⚠ **Danger:** Do not install the apparatus on or in the vicinity of sources of heat. Install it such a way that there is an adequate circulation of air around it and leave sufficient free space around it.

⚠ **Warning:** Do not expose parts to direct sunlight or UV light.

⚠ **Warning:** This equipment can be handled, but it must be handled with extreme caution.

⚠ **Warning:** Before connecting the cord to the device, make sure that the electrical contacts are perfectly dry. If necessary, dry them with the air syringe.

In order for the operation process to work properly, the equipment must be installed in strict accordance with the requirements of the manual.

2.2. Connecting accessories

⚠ **Warning:** The accessories listed as follow should be connected with the DS–100.

2.3. Install foot switch

Connect the plug of the foot switch to the foot switch socket(Figure 3).

2.4 Install power cable

Plug the output of the power cable into the power socket of the device(Figure 3).

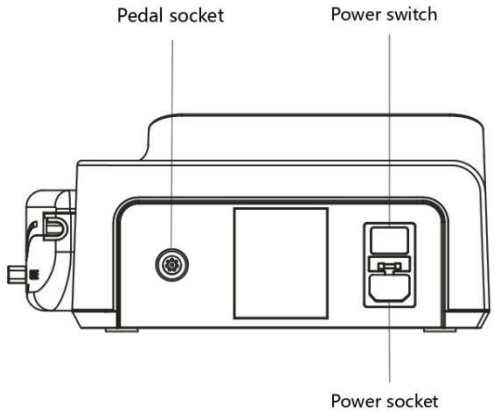
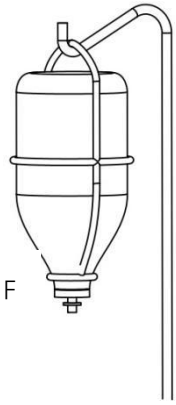


Figure 3

2.5 Install infusion bottle holder

Insert the infusion bottle support rod into the hole behind the device(Figure 4–A).



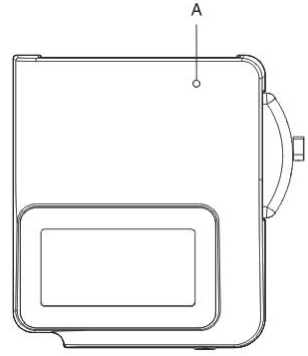


Figure 4

2.6 Install infusion bottle

Hang the infusion bottle(the infusion bottle is purchased physiological saline injection)on the infusion bottle holder(Figure 4–F).

2.7 Connection between pump tube, infusion tube and handpiece.

In sterilizer box, insert the pump tube connector (smaller end) into the handpiece supply tube and the larger end of the pump tube connector into the pump tube.

2.8 Install handpiece

A Place the handpiece on the handpiece silicone bracket

B Insert the handpiece plug into the handpiece socket of the device(Figure 5)

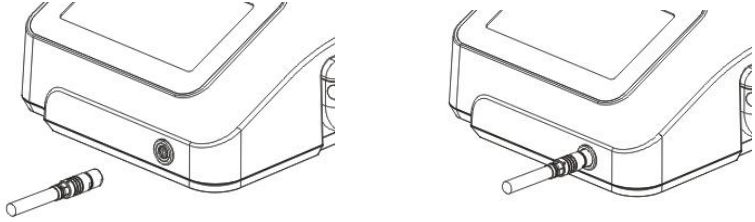


Figure 5

2.9 Installation of pump tube on peristaltic pumps

A Open the pump door(Figure 6–A)and open it as far as possible

B Place the pump tube in the impeller, and the pump tube should be placed in the middle of the impeller and straightened (Figure 6–B)

C Close the pump door completely (Figure 6–C)

⚠ **Danger**: You must ensure that the pump door is completely closed.

The foot switch of DS–100 should never be activated with the peristaltic pump door open. Moving parts can injure the operator.

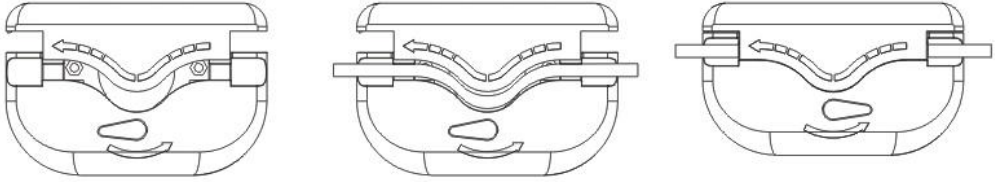


Figure 6

2.10 Bone cutter tip mounted

A Select the tip to be used from the tip bracket in disinfection box

B Screw the tip onto the handpiece(Figure 7)

C Use the torque wrench to screw the tip(Figure 7)till the clattering voice

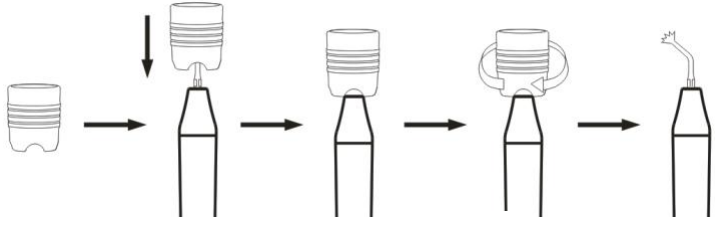


Figure 7

2.11 The effect of the whole device after all the accessories are installed(Figure 8)

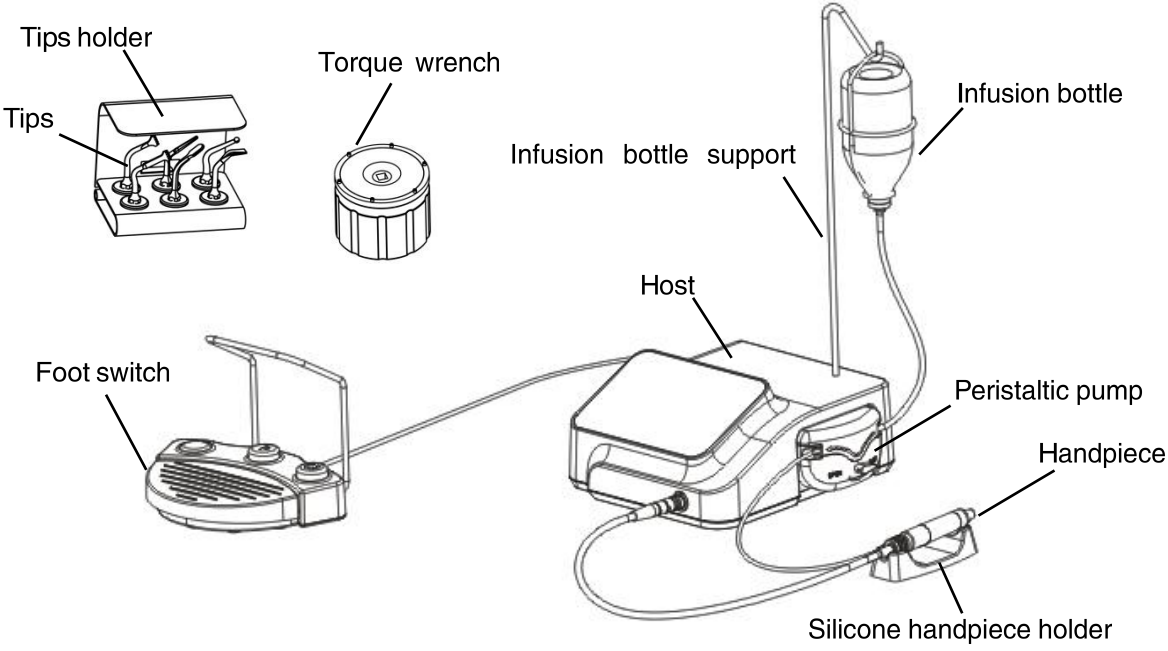


Figure 8

2.12 Turn on the power switch (Figure 3) and when the display is normal, you can use the device. Step down the foot switch, the machine starts to work, and the LED light of the handpiece lights up; Release the foot switch, the device will stop working, and the handpiece LED will go out after 10 seconds.

3. Device function and use

3.1 Panel control

This section illustrates the parts of the front panel of DS–100, which intuitively displays the operator interface, allowing the operator to better use the machine.

(1) Schematic of bone cutting function:

Figure 9

(2)Schematic of periodontal function:

Figure 10

(3)Schematic of root function:

Figure 11

(4) Schematic of cleaning function:

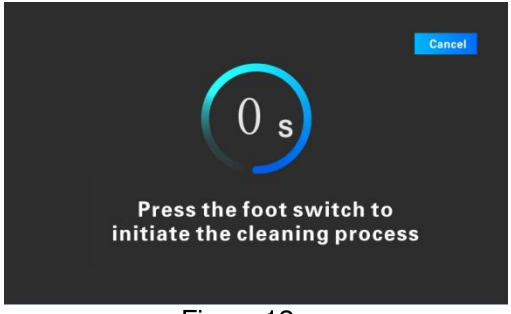


Figure 12

(5) Schematic of alarm interface:

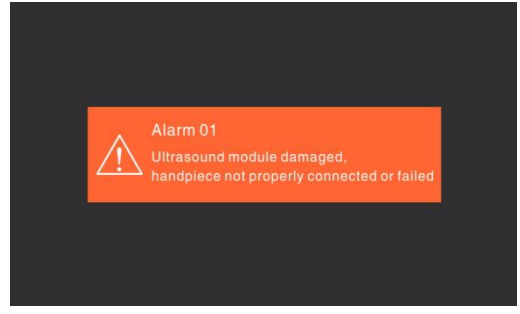


Figure 13

3.2 Description of display

DS–100 has bone cutting, periodontal, root canal and cleaning functions. First set the specific functions through the operation interface, then set the appropriate power output and water output gear. When stepping down the foot switch to start work, the power and water volume cannot be adjusted.

A) Bone cutting function (Figure 9)

Click "Bone cutting" on the operation interface to switch, in the bone cutting treatment function, the power and water volume that can be adjusted by clicking on the power and water volume adjusting area.

1) Power 7–12: for very high bone density/large cortical bone

2) Power 5–9: for high bone density/large cortical bone

3) Power 4–8: for uniform bone density/good cortical bone

4) Power 1–5: for low bone density/poor cortical bone

B) Periodontal function (Figure 10)

Click "Periodontal" on the operation interface to switch, in the periodontal treatment function, the power and water volume that can be adjusted by clicking on the power and water volume adjusting area.

C) Root function (Figure 11)

Click "Root Canal" on the operation interface to switch, in the root treatment function, the power and water volume that can be adjusted by clicking on the power and water volume adjusting area.

D) Cleaning function (Figure 12)

Click "Clean" on the operation interface to switch. Under the cleaning function, press and hold the foot switch to start cleaning. At this time, the host only outputs water without making the handpiece output ultrasonic vibration. In this mode, the brine needs to be replaced with desalted clean water to achieve the purpose of cleaning the waterway! (Cleaning time shall not be less than 20s).

3.3 Safety requirements during use

⚠ **Danger:** Contraindication

DS–100 may not be used on patients with pacemakers or other implanted electronic devices, and the same requirement applies to the physician.

⚠ **Danger:** Breakage and wear of inlay.

The high–frequency vibrations and wear may, very occasionally, lead to breakage of the tip. Tips of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such tips should definitely not be used. It is necessary to instruct the patient to breathe through his nose during the treatment in order to avoid ingestion of the broken fragment of the tip.

⚠ **Danger:** Control of infections.

For maximum safety of both the patient and the operator, clean, disinfect and sterilize the handpiece, the tips , the torque wrench and handpiece holder after each treatment.

⚠ **Warning:** Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could lead to decrementing of such artifacts.

⚠ **Warning:** Contraindication.

After autoclave sterilizing of the handpiece, wait for it to cool down completely before using it.

⚠ **Danger:** The electrical contacts inside the cord connector must be dry.

Before connecting the handpiece to the device, make sure the electrical contacts of the connector are perfectly dry, in particular after the autoclave sterilization cycle. If necessary, dry the contacts by blowing air onto them with the syringe.

⚠ **Warning:** For correct operation, it is necessary to step on the foot switch and activate it before using the tip for treatment, where the electronic circuitry can be used to find the optimum oscillating point without any hindrance, thus obtaining the best performance.

⚠ **Warning:** For spray treatments, use only tips through which liquid can pass.

3.4 System protection and warning

In order to ensure the normal use of the device and to avoid injury to the patient due to misuse or negligence, the device is equipped with a system protection function to remind the user of the safe use of the device. Specific warning messages on the display are as follows: (see section 3.1 Figure 13).

Alarm 01.

① Abnormal internal resistance of the handpiece.

② Damage occurs to the ultrasound module.

③ The handpiece is not connected or has failed.

④ The tip is not tightened or is worn or damaged.

⑤ Handpiece failure.

3.5 Instruction for use

a. Open the air inlet on the disposable infusion tube.

b. Use torque wrench to tighten the tip.

c. The steps to correctly use the torque wrench are as follows:

① Hold the body of the handpiece firmly.

⚠ **Warning:** Do not grip the end part of the handpiece or the cord, only the plastic casting and do not turn it while fastening the tip in place

② Turn the wrench in a clockwise direction until the cultch engages (till making clicking sound).

③ The tip is now correctly tightened in place.

d. Ensure that the handpiece is correctly connected to the handpiece connector.

e. Check the selected function on the display screen. If the required function is different from the selected one, adjust the corresponding mode touch key (see 3.1 Panel control) to switch.

f. Check the selected power on the display screen. If the required power level is different from the selected power level, reset it with the "+" and "–" keys of power.

g. Check the selected water volume on the display screen. If the required water volume level is different from the selected one, reset the "+" and "–" keys of the water volume.

3.6 Rules for keeping the device in proper working order

1) Check the state of wear of the tips periodically and replace any for which a drop in performance is noted;
2) Do not alter the shape of the tips by bending or filling them;
3) Replace any tip that has become deformed or damaged by impacts;
4) Always make sure that any threaded parts and their contact surfaces are perfectly clean;
5) If an tip becomes too worn, the device will stop working.

3.7 Fuse replacement

⚠ **Danger:** Switch off the apparatus.

Press the power switch (see Figure 4) to turn off the device and disconnect the power cord from the mains while performing the following maintenance activities.

1) Insert the flat tip of a screwdriver into the recess in the fuse compartment below the power socket and use it as a lever.
2) Pull out the fuse compartment.

⚠ **Danger:** Replace the fuses, using fuses of the type indicated on the identification label on the bottom of the apparatus.

3) Put the compartment back into place.

3.8 Disposal procedures and precautions

⚠ **Danger:** Medical waste

Define medical waste according to the following points and replace it promptly.

- Tips, when deteriorated or damaged.
- Infusion tubes, after each treatment.
- Pump tubes, Disposable infusion tubes.
- Torque wrench, when aged or damaged.

3.9 Tips

3.9.1 Sharp tips

The sharp edges of these tips can be used to treat bone structures efficiently and effectively. Sharp tips are used in osteotomy and osteoplasty when a fine and well–defined cut in the bone structure concerned it required, there are also tips with sharp edges for osteoplasty techniques and for removing bone fragments.

3.9.2 Smoothing tips

The smoothing tips have surfaces shaped in such a way that they can be used to work the bone structures with precision and in a controlled manner. Smoothing tips are used in osteotomy when it is necessary to prepare difficult and delicate structures such as those for preparing a maxillary sinus window or to complete preparation of the site of an implant.

3.9.3 Blunt tips

Blunt tips are used for separating the soft tissues, for example for detaching schneider ' s membrane or for lateralizing nerves. In periodontology, these tips are used to smooth the root surfaces.

4. Cleaning, disinfecting and sterilizing

4.1 Cleaning function – clean of the waterway system

⚠ **Warning:** Failure to clean the water system will result in salt crystals that will severely damage the device.

⚠ **Warning:** The handpiece and handpiece cord cannot be separated.

1) Replacement of the infusion bottle or bag, the recommended fluid for which is desalted water;

2) Check that the water system is properly installed;

3) Adjust the mode to the cleaning function (see 3.1 Schematic of cleaning function);

4) Step on the foot switch to start the cleaning cycle, ensure that the cleaning lasts more than 20s, then take the pump tube out of the water surface, and continue to step on the foot switch to drain the water in the tube;

5) After the cleaning operation is completed, dry the parts that have gone through the cleaning cycle.

4.2 Clean the enclosure of the equipment

⚠ **Danger:** The enclosure of the equipment is not impermeable to liquids. Do not spray liquids

directly onto the surface of the component enclosure.

⚠ **Danger:** The enclosure cannot be sterilized at high temperatures.

1) Perform the following steps after each treatment.
2) Remove the tip from the handpiece.
3) Clean and disinfect the case surface, wiring and connectors with a damp cloth containing a mild detergent or 70%~80% (v/v) ethanol disinfectant. Refer to the manufacturer's instructions for disinfection and allow to dry in air after disinfection.

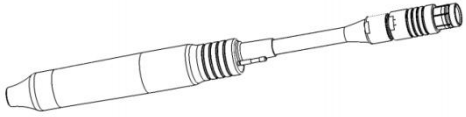
Note: Only 70%~80% (v/v) ethanol disinfectant is recommended for disinfection, some disinfection methods with other sanitizers may discolor or cause damage to the plastic material.

4.3 Reprocessing

⚠ **Warning:** Use only autoclavable steam sterilization.

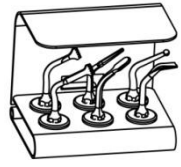
To avoid bacterial or viral infection, do not use any other sterilization methods (e.g., dry heat, radiation, gas, cryo–plasma, etc.). Clean, disinfect and sterilize the following components after each treatment:

1) Handpiece (see below)



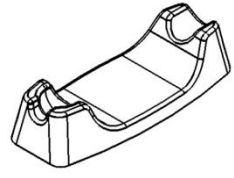
2) Tips (see right)

3) Tips holder (see right)

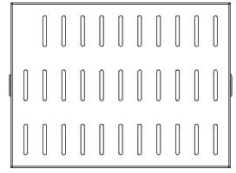


4) Torque wrench (see right)

5) Silicone handpiece holder (see right)



6) Sterilization box (see right)



The above parts can withstand 134℃, 2.2 bar high temperature steam sterilization for 4 minutes.

4.4 Autoclave sterilization of handpiecs

⚠ **Warning:** The handpiece and handpiece cord cannot be separated.

⚠ **Warning:** Do not immerse the handpiece in any sterilizing liquid as this may cause damage.

⚠ **Warning:** Do not sterilize the handpiece with tips attached.

⚠ **Warning:** The handpiece plug must be dry where it meets the handpiece socket.

After sterilization, before connecting the handpiece to the main unit, make sure that the electrical connections of all connectors are completely dry, if necessary by blowing connectors with a hot air.

⚠ **Warning:** After the sterilization process, make sure the handpiece is completely dry before use.

Note:70%~80% (v/v) ethanol disinfectant is recommended to sanitize the handpiece. Sterilizing with other sanitizing solutions may cause discoloration or damage to the plastic material.

1) Clean the handpiece carefully and pay special attention to the threads of tips for damage.
2) Disinfect the handpiece with a damp cloth containing a mild detergent or 70% ~80% (v/v) ethanol disinfectant.
3) Drying the joints by blowing them with a hot air blower.
4) The handpiece is individually sealed into a disposable package (without any tips inside).
5) Autoclave handpiece.

After sterilization, before connecting the handpiece to the main unit, make sure that the electrical connections of all connectors are completely dry, if necessary by blowing the connections with a hot air blower.

4.5 Autoclave sterilization of tips

1) Wash the tip in distilled water (in an ultrasonic tank is preferred)
2) Drying the tip
3) Disinfect the tip with 70% ~80% (v/v) ethanol disinfectant and carefully dry it completely

⚠ **Warning:** Ensure that the inside and outside of the tip are dry before starting the sterilization process, if necessary, by blowing on the connector with a hot air blower.

4) Sterilize the tip by autoclaving
5) Individually seal the tip into a disposable package.

4.6 Autoclave sterilization of torque wrench

1) Cleaning the torque wrench
2) Disinfect the torque wrench with 70%~80% (v/v) ethanol disinfectant and carefully dry it completely
3) Sterilize the torque wrench by autoclaving
4) Individually seal the torque wrench into a disposable package

4.7 Autoclave sterilization of pump tube

1) Clean the pump tube
2) Disinfect the pump tube with 70%~80% (v/v) ethanol disinfectant and carefully dry it completely
3) Sterilize the pump tube by autoclaving.
4) Individual seal the pump tube into a disposable package

4.8 Autoclave sterilization of pump tube connector

1) Clean the pump tube connector
2) Disinfect the pump tube connector with 70%~80% (v/v) ethanol disinfectant and carefully dry it completely
3) Sterilize the pump tube connector by autoclaving

4) Individual seal the pump tube connector into a disposable package

4.9 Autoclave sterilization of handpiece holder

1) Clean the handpiece holder
2) Disinfect the handpiece holder with 70%~80% (v/v) ethanol disinfectant and carefully dry it completely
3) Sterilize the handpiece holder by autoclaving.
4) Individually seal the handpiece holder into a disposable package

⚠ Caution

We are not responsible for any damage to the torque wrench and root canal wrenches caused directly or indirectly by the use of the above improper methods.

5. Troubleshooting

If the device does not function properly, please read this manual carefully and consult the following forms.

Fault	Possible cause	Solutions

The device display does not show when the switch is turned on	The connector at the end of the power cord is not properly inserted into the socket	Check that the cable is securely plugged in
	The power cord is not energized	Check if the power output is working properly, replace the power cord
	Fuse blown	Replacing the fuse
The device is switched on but does not work, no error is shown on the display	The connector of the foot switch is not properly installed in the socket	Correctly installing the foot switch connector
	The pedals don't work	Contacting your local dealer or our company
The handpiece makes a sharp, rattling noise when it is in operation	The tip is not properly mounted to the handpiece	Remove the tip and retighten

The device is switched on but does not work, the alarm 06 symbol appears on the display	The tip is not properly mounted to the handpiece	Remove the tip and retighten
	The tip is aged, damaged or deformed	Replacing the tip
The device is switched on but does not work, the alarm 01 symbol appears on the display	Handpiece deactivation (alarm 06 when not connected to handpiece)	Replacing the handpiece
	Circuit failure	Contacting your local dealer or our company
No water is atomized and sprayed from the tip during operation	This model is non–vented tip	Replacing the tip with a through–port
	The liquid has run out	Replacing a full fluid bag
	The peristaltic pump cover of the inserted tube is opened	Close the peristaltic pump cover
	The infusion set and pump tube is not properly installed	Check the tube connections

	The tip is blocked	Clearing the water passageway of the tip
	The handpiece is blocked	Contacting your local dealer or our company
The device works normally , but the pump is squeezed	The impeller in the peristaltic pump is under too much pressure	Check that the peristaltic pump tube is properly installed
The pump works normally but when it stops liquid spills from the handpiece	Peristaltic pump cover not closed	Ensure that the peristaltic pump cover is closed
Underpowered	The tip is not correctly fitted to the handpiece (Alarm 06 symbol appears on the display)	Removing the tip and screwing it correctly into the handpiece,
	The tip is aged, damaged or deformed (Alarm 06 symbol appears on the display).	Replacing tips

⚠ Note: If the problem still cannot be solved, please contact your local dealer or our company.

6. Storage, maintenance, transportation

6.1. Storage, maintenance

6.1.1 The device should be carefully and gently placed away from sources of vibration, and installed or stored in a cool, dry and ventilated place.

6.1.2 Do not mix with toxic, corrosive, flammable or explosive items when storing.

6.1.3 The device shall be stored in an environment with relative humidity of 10%~93%, atmospheric pressure of 70 kPa~106 kPa and temperature of –20℃~50℃.

6.1.4 When the device is not in use, the power switch should be turned off, unplugged; when not in use for a long time, it should be energized once a month for five minutes each time.

6.1.5 Power supply cable

⚠ **Danger:** Always check the integrity of the cable, if it is damaged, replace it with a VRN accessory.

6.2. Transportation

1) It should not be mixed with hazardous goods during transportation.

2) It should be prevented from excessive shock and vibration, carefully and gently placed, and avoided inverted during transportation.

3) Avoid exposure to sun or rain or snow during transportation.

7. Repair and maintenance lists

Accessory Description

⚠ **Warning:** The handpiece cannot be separated from the cord.

Name	Quantity	Replacement cycle	Replacement method
Peristaltic pumps	1	10 years	/
Equipment	1	10 years	/
Torque wrench	1	200 sterilization cycles	/
Handpiece complete with cord	1	100 sterilization cycles	/

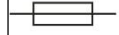
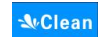
Foot switch	Marking in the packing list	10 years	/
Tip holder	Marking in the packing list	10 years	/
Tips	Marking in the packing list	By wear cycle	See 2.12
Power cord	1	10 years	/
Sterilization box	1	10 years	/
Infusion bottle support rod	1	10 years	/
Silicone handpiece holder	Marking in the packing list	200 sterilization cycles	/

Note: This manual does not list the specifications of the accessories of DS–100 in detail, see the information and packing list with delivery.

8. After service

We offer lifelong maintenance according to the warranty card since the date of sale.We are not responsible for any irretrievable damage caused by the nonprofessional person.

9. Symbols

	Manufacturer's logo		Caution		Type B applied part		Manufacturer		Serial number
	Atmospheric pressure limitation		Refer to instruction manual/book		Humidity limitation		Keep dry		Temperature limit
	This way up		Fragile,hand piece with care		Fuse		Date of manufacture		Use–by date
	Foot switch		"OFF" (power)		"ON" (power)		Do not roll		Do not stack
	Bone cutting function		Periodontal function		Root function		Cleaning function		Medical device

Liquid	Variability in steps of water	Power	Variability in steps of power	IPX1	Degree of protection against ingress of water
UDI	Unique device identifier		Do not dispose of the product into the ordinary municipal waste or garbage system		Sterilizable at up to 134℃ in the steam sterilizer (autoclave) at temperature specified

10. 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	Peristaltic 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 as solvents,which can be used for composting and other biological transformation processes.
4	Handpiece cord		Please put them to the waste sorting recycling bin of organic substances which are not used as solvents,which can be
5	Enclosure		
6	Tube	Remove the tube with nipper pliers.	
7	Infusion bottle	Remove from the main unit.	

			used for composting and other biological transformation processes.
8	Tips	Refer to the section 2.10 in the manual.	Please dispose it in the infectious clinical waste containers.
9	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 substances which are not used as solvents,which can be used for composting and other biological transformation processes.
10	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. Manufacturer's rights

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

12. Declaration of output characteristics

Tip principal amplitude（μm)	The peak displacement of the tip of the treatment head in the direction of	Tip model	Measured mean value（μm)	Set at bone–cutting mode power 12 speeds
		US1	28	
		US2	28	
		US4	36	

	maximum amplitude, and the measuring point is located at the position where the tip of the treatment head is not more than 1mm away from the free end	US5	39	
		UL3	31	
		UC1	41	
Excitation frequency	The average frequency of the excitation voltage or current	Tip model	Measured mean value（kHz)	Set at bone–cutting mode, power 12
		US1	26	
		US2	26	
		US4	26	
		US5	26	

		UL3	26	
		UC1	26	

Derived output sound power and output sound power (mW)	Sound power emitted into the water by the tip of the treatment head, based on measurements made by the hydrophone method	Tip model	Measured mean value (mW)	Set at bone–cutting mode, power 12
		US1	485	
		US2	315	
		US4	470	
		US5	530	
		UL3	510	
		UC1	490	
Main sound output area (mm^2)	The projected area of the solid portion of the tip of the treatment	Tip model	Measured mean value (mm^2)	Set at bone–cutting mode, power 12
		US1	5	
		US2	4	

	head in the direction of the main amplitude of the tip.	US4	4.5	
		US5	4.5	
		UL3	4.5	
		UC1	3.4	
Tip–main amplitude modulation	For systems of the modulated electric excitation power class, the percentage change in the tip main amplitude from the maximum to the minimum value.	Tip model	Measured mean value	Set at bone–cutting mode, power 12
		US1	Not applicable	
		US2	Not applicable	
		US4	Not applicable	
		US5	Not applicable	
		UL3	Not applicable	
		UC1	Not applicable	
Power reserve index	The ratio of maximum	Tip model	Measured mean value	Set at bone–cutting

		US1	2.2	
		US2	2.3	
		US4	2.3	
		US5	2.2	
		UL3	2.1	
		UC1	2.3	
Type of system frequency control	The duty cycle is independent of the load, and the excitation frequency is continuously and automatically adjusted.			
(Note: The above published characteristics of the parameters are based on the Guilin Veirun Medical Technology Co., Ltd. DS–100 standard requirements announced the average value of the test data of the five prototype)				

13. Electromagnetic compatibility

Caution.

1) Unauthorized alteration or modification of the equipment without the express consent of Guilin Veirun Medical Technology Co., Ltd. may result in EMC problems with the equipment or with other equipment.

2) The design and test of DS–100 comply with the relevant operating procedures of electromagnetic compatibility.

3) Note: Flickering due to interference with the root canal function indicator and periodontal function indicator may occur during the electrical fast transient pulse group test, which does not interfere with normal use and recovers spontaneously after completion of the test, as determined by consulting with a clinician with specialized training and experience in the field, including the use of specialized equipment or systems, and is an acceptable risk.

13.1. Requirements of wire installation

Cable name	Cable type	Cable length
Power input wire	Unshielded parallel wires	2 meters
Foot switch input wire	Unshielded parallel wires	2.5 meters
Handpiece tail	Unshielded parallel wires	2 meters

13.2. Electromagnetic compatibility key components

The key EMC components of this device are motherboard chips, IC chips, transformers, power lines, capacitors. The use or replacement of accessories, cables, transducers, etc. that are not matched with the design will lead to a significant reduction in EMC emission and immunity performance. Do not replace machine parts without authorization.

13.3. Guidelines and manufacturers' declarations – electromagnetic emissions

Guidelines and manufacturers' declarations – electromagnetic emissions		
DS–100 is expected to be used in the electromagnetic environment specified below. The customer or user shall guarantee its use in such electromagnetic environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emission GB 4824	Group 1	DS–100 only uses RF energy for its internal functions. Therefore, its RF emission is very low, and the possibility of interference to nearby electronic equipment is very small.
RF emission GB 4824	Class B	DS–100 is suitable for use in all facilities, including domestic facilities and residential public low–voltage

Harmonic emission GB 17625.1	Not applicabl	
Voltage fluctuation/flicker emission GB 17625.2	Complies	

13.4. Guidelines and manufacturers' declarations – electromagnetic immunity

Guidelines and manufacturers' declarations – electromagnetic immunity			
DS–100 is expected to be used in the electromagnetic environment specified below. The customer or user shall guarantee its use in such electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) GB/T 17626.2	± 6kV contact discharge ± 8kV air discharge	± 6kV contact discharge ± 8kV air discharge	The floor should be wood, concrete or tile, and if the floor is covered with a synthetic material, the relative humidity should be at least 30%.

Electrically fast transient pulse clusters GB/T 17626.4	± 2kV to power line ± 1kV to input/output line	± 2kV to power line ± 1kV pair connecting cable	The net power supply shall be of a quality typical of use in a commercial or hospital environment.
Surge GB/T 17626.5	± 1kV differential mode voltage ± 2kV common mode voltage	± 1kV differential mode voltage	The net power supply shall be of a quality typical of use in a commercial or hospital environment.
voltage dips, short interruptions and voltage variations on the power input line GB/T 17626.11	<5% U_T, lasting for 0.5 week (>95% sag on U_T) 40% U_T for 5 weeks (60% sag on U_T) 70% U_T for 25 weeks (30% sag on U_T) <5% U_T, lasting for 5s (>95% sag on U_T)	<5% U_T, lasting for 0.5 week (>95% sag on U_T) 40% U_T for 5 weeks (60% sag on U_T) 70% U_T for 25 weeks (30% sag on U_T) <5% U_T, lasting for 5s (>95% sag on U_T)	The network power supply should have the quality used in typical commercial or hospital environments. If the user of the DS–100 DS–100 needs to run continuously during power interruption, it is recommended that the DS–100 use uninterruptible power supply or battery power supply.

Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	The IF magnetic field shall be characterized by IF magnetic field levels typical of sites in a typical commercial or hospital environment.
Note: U_T refers to the AC network voltage before the test voltage is applied.			

13.5. Guidelines and manufacturers' declarations – electromagnetic immunity

Guidelines and manufacturers' declarations – electromagnetic immunity			
DS–100 is expected to be used in the electromagnetic environment specified below. The customer or user shall guarantee its use in such electromagnetic. environment.electromagnetic			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance

RF conduction GB/T 17626.6 radiofrequency radiation GB/T 17626.3	3Vrms 150kHz ~ 80MHz 3V/m 80MHz ~ 2.5GHz	3Vrms 3V/m	Portable and mobile RF communication equipment shall not be used closer to any part of DS–100 ultrasonic bone tissue surgery equipment than the recommended isolation distance, including cables. The distance shall be calculated by the formula corresponding to the transmitter frequency. recommended isolation distances $d = \left[\frac{3.5}{V1}\right]\sqrt{p}$ $d = \left[\frac{3.5}{E1}\right]\sqrt{p}\,80MHz \sim 80MHz$ $d = \left[\frac{7}{E1}\right]\sqrt{p}\,800MHz \sim 2.5GHz$

			Where, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W), and d is the recommended isolation distance, in meters (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic site a, and in each frequency range b should be lower than the compliance voltage. Interference may occurs in the vicinity of equipment marked with the following symbols. 
Note 1: At 80MHz and 800MHz frequencies, the formula of higher frequency band is used. Note 2: These guidelines may not be appropriate in all cases, and electromagnetic propagation is affected by absorption and emission from buildings, objects and the human body.			

a The strength of fixed transmitting fields, such as base stations of wireless (cellular/cordless) telephones and ground mobile radios, amateur radios, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts, cannot be predicted accurately in theory. In order to evaluate the electromagnetic environment of fixed RF transmitters, the survey of electromagnetic sites should be considered. If the measured field strength of the DS–100 is higher than the RF compliance level of the above application, observe the DS–100 to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or positioning the DS–100. b In the whole frequency range of 150kHz~80MHz, the field strength should be lower than 3V/m.

13.6. Recommended isolation distance between portable and mobile RF communication equipment and DS–100

Recommended isolation distance between portable and mobile RF communication equipment and DS–100
The DS–100 is expected to be used in the electromagnetic environment where the radiation RF disturbance is controlled. According to the maximum output power of communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitter)and DS–100 recommended below.

Rated maximum output power of transmitter/W	Isolation distance corresponding to different frequencies of transmitter/m		
	150kHz ~ 80MHz $d=\left[\frac{3.5}{V1}\right]\sqrt{p}$	80MHz ~ 800MHz $d=\left[\frac{3.5}{E1}\right]\sqrt{p}$	800MHz ~ 2.5GHz $d=\left[\frac{7}{E1}\right]\sqrt{p}$
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 the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum output power of the transmitter provided by the transmitter manufacturer, with Watt (W) as the single digit.
Note 1: At 80MHz and 800MHz frequencies, the formula of higher frequency range is used.
Note 2: These guidelines may not be appropriate in all cases, as electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

DS–100 has passed the test according to YY 9706.102–2021, which cannot be guaranteed to be free from electromagnetic interference in any way. DS–100 should not be used in high electromagnetic environment.