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S6 LED

ULTRASONIC SCALER INSTRUCTION MANUAL

CE 0197



DTE®

Guilin Woodpecker Medical Instrument Co., Ltd.

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1. The installation and components of equipment

1.1 Instruction

Guilin Woodpecker Medical Instrument Co., Ltd. is a professional manufacturer researching, developing and producing ultrasonic scalers. The product is mainly used for teeth cleaning and also an indisensable equipment for teeth disease prevention and treatment.

The ultrasonic scaler S6 LED has scaling, perio functions with the following features:

1.1.1 The handpiece can be autoclaved to high temperature 134°C and high pressure 0.22Mpa.

1.1.2 Automatic frequency tracking ensures that the machine always works on the best frequency and more steadily.

1.1.3 Digital control, easy operation and more efficient for scaling.

1.2 Components

1.2.1 The components of machine are listed in the packing list.

1.2.2 Product performance and structural composition

Ultrasonic scaler S6 LED is composed of electrocircuit, water way and ultrasonic transducer.

1.2.3 Scope of application

Ultrasonic scaler S6 LED is used for the dental calculus elimination and root canal treatment.

1.3 The main technical specifications

Technical description is included in the instructions for use.

1.3.1 Power supply input: 220-240V~ 50Hz/60Hz 150mA

1.3.2 Main unit input: 24V~ 50Hz/60Hz 1.3A

1.3.3 Output primary tip vibration excursion: ≤90μm

1.3.4 Output half-excursion force: ≤2N

1.3.5 Output tip vibration frequency: 28kHz±3kHz

1.3.6 Output power: 3W to 20W

1.3.7 Main unit fuse: T1.6AL 250V

1.3.8 Power supply fuse: T0.5AL 250V

1.3.9 Water pressure: 0.01MPa to 0.5MPa

1.3.10 Weight of main unit: 0.65kg

1.3.11 Operating mode: Continuous operation

1.3.12 Type of protection against electric shock: class II equipment

1.3.13 Degree of protection against electric shock: Type B applied part

1.3.14 Applied part of the equipment: handpiece and tip

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1.3.15 Degree of protection against harmful ingress of water: Ordinary equipment, the foot switch is drip-proof equipment (IPX1)

1.3.16 Degree of safety of application in the presence of a Flammable Anesthetic Mixture with air, Oxygen or Nitrous Oxide: Equipment not suitable for being used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

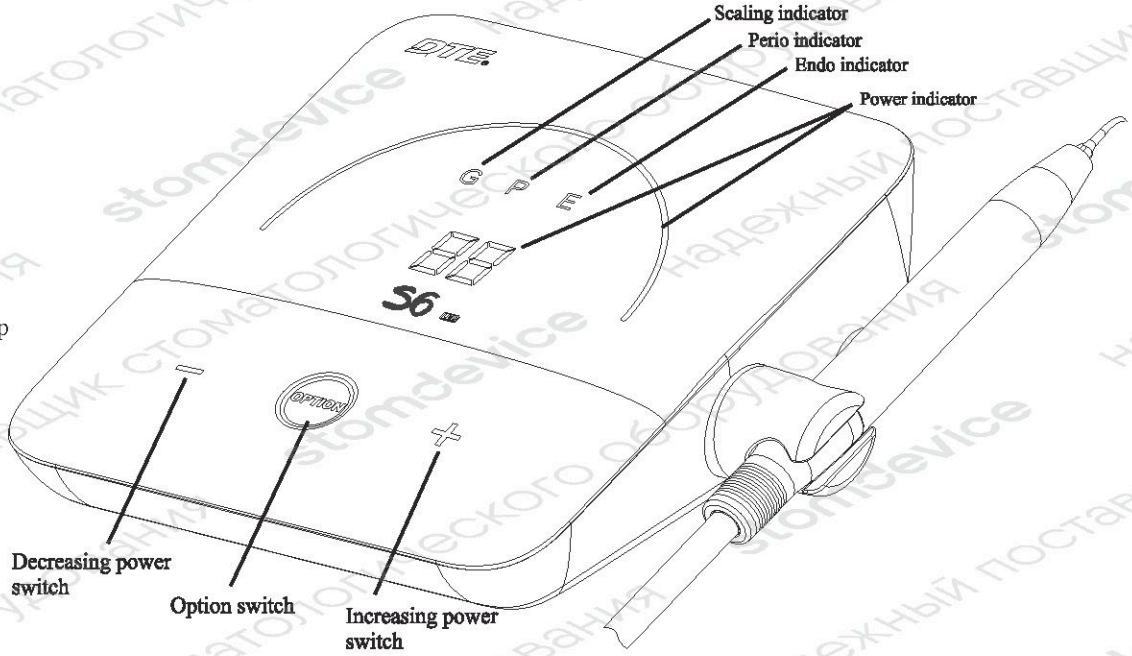
1.3.17 The main unit use a power adapter to connet network power supply, isolation mode from network power supply is transformer isolation and solid insulation of the enclosure.

1.4 Instruction of the main components

Instruction and component sketch map

1.4.1 Front of the main unit sketch

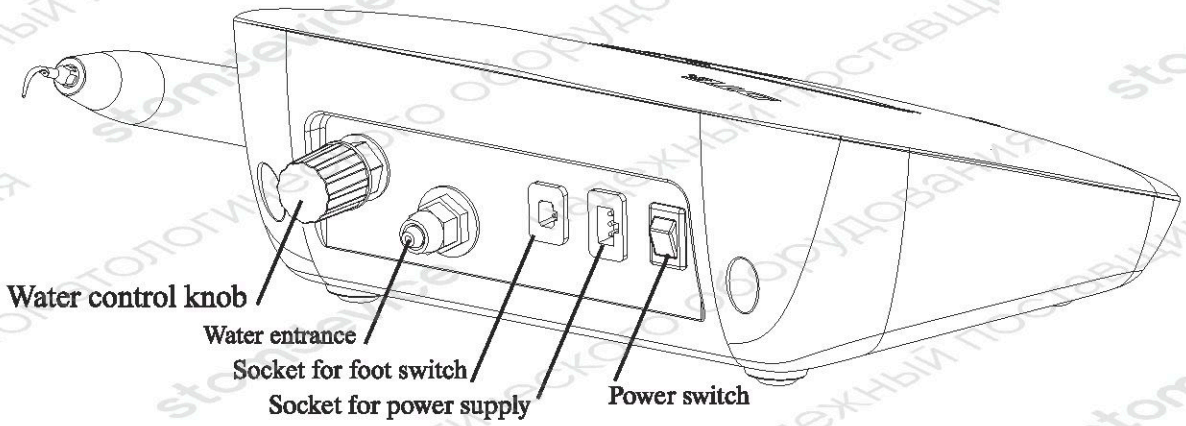
map



Picture 1

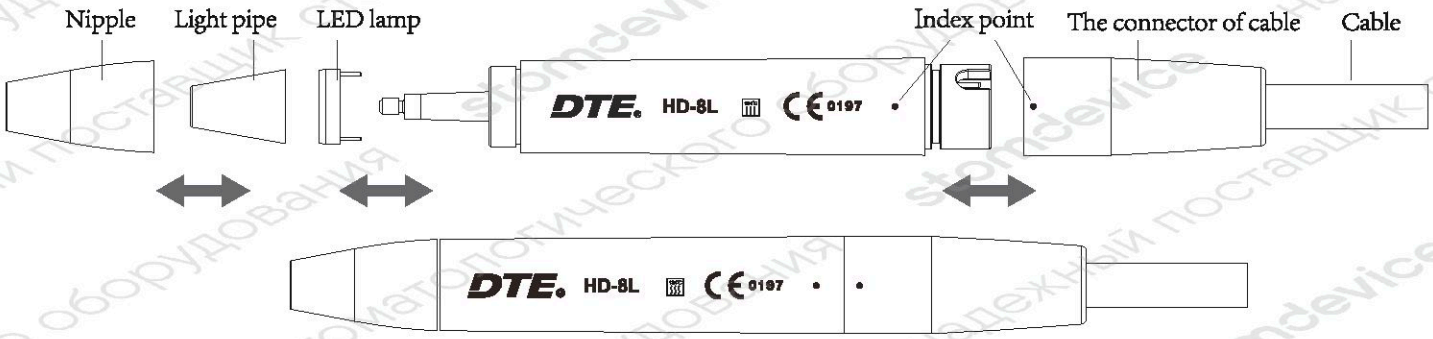
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1.4.2 Back of the main unit sketch map



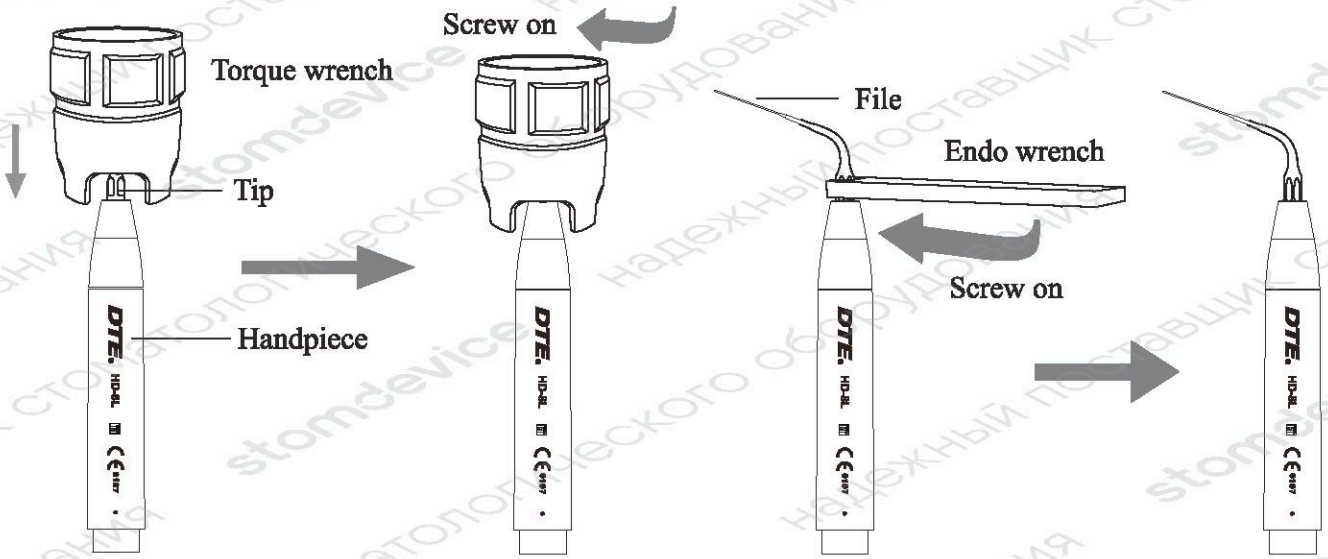
Picture 2

1.4.3 Instruction of using wrench



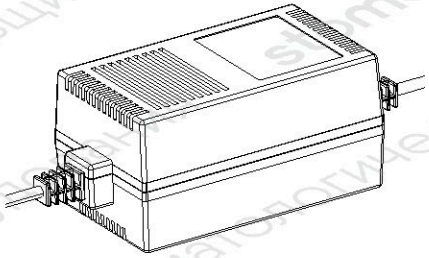
Picture 3

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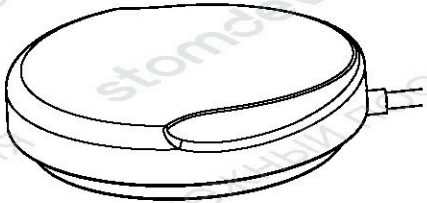


Picture 4

1.4.4 List of removable parts



Picture 5



Picture 6

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Num	Object	Remark	Type No./model No./	Manufacturer/Trademark
1	Detachable handpiece	/	HW-8L	DTE
2	Scaler tips	/	/	DTE
3	Power suplly	See picture 5	ZMN-03	Guilin Woodpecker
4	F2 food switch	See picture 6	F2	Woodpecker
5	Endochuck	/	TD-E1	DTE
6	Torque wrench	/	TD-1L	DTE
7	Endo wrench	/	/	DTE

2. Installation and adjustment

2.1 Operation

2.1.1 Open the packing box, make sure that all the parts and accessories are complete according to the packing list, take the main unit out of the box, and put it on the the stable plane facing to the operator.In addtion,install the device to an operator-friendly position.

2.1.2 Turn the water control knob to the max according to the picture 1 direction, Do not screw it over tight in case of damage. [note 1]

2.1.3 Insert the plug of the foot switch to its socket. (see picture 2)

2.1.4 Connect one end of the water pipe to the water entrance, and the other end to the clean water sourse. (see picture 2)

2.1.5 Before treatment, make sure scaling tip, wrench and handpiece have been sterilized. Choose the scaling tip according to the requirement, and fix the scaling tip with the wrench. (see picture 4)

2.1.6 Turn on the power switch, the power indicator lighted and the machine is ready for work. Touch panel is applied to this machine, power can be adjusted by directly touching the power indicator on the touch panel.

2.1.7 Under normal working condition, the frequency of the tips is very high, light touch and a certain to-and-fro motion will eliminate the tartar without obvious heating, overexetion and overatay are forbidden.

2.1.8 Vibrating intensity: Adjust the vibrating intensity according to your need, usually adjust to the middle grade, and adjust the vibrating during the clinical treatment according to the patient's sensitivity and the rigidity of the tartar.

2.1.9 Step on the foot switch, the tip begins to vibrate, and the LED lamp on the top of the handpiece shines. Release the foot switch, the LED lamp keep shining for 10 seconds.

2.1.10 Water volume adjustment: Step on the foot switch, and the tip begins to vibrate, then turn the water control switch to fine spray to cool down the handpiece and clean the teeth.

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

2.1.12 Be sure not to make the end of the tip touch the teeth vertically, and not use too much pressure when the tip touch the surface of the teeth, in order not to hurt the teeth and the tip.

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2.1.13 After finishing operation, keep the machine working for 30 seconds with the water supply to clean the handpiece and the tip.
2.1.14 Unscrew the scaling tip and sterilize it.
2.1.15 After operating, turn off the power switch to cut off the power, then pull off the plug of power adapter.
Note: Don't screw the scaling tips when stepping on the foot switch, and the machine is working.

3. Maintenance and sterilization

3.1 Sterilization of detachable handpiece

3.1.1 Autoclaved under high temperature, pressure, time:
a) 134°C, 2.0bar~2.3bar (0.20MPa~0.23MPa), 4min.
b) Pull out the handpiece and unscrew the scaling tip and endochuck after each operation.
c) Pack the handpiece with sterile gauze or sterile bag before sterilizing.
d) Reuse handpiece after it cools naturally to avoid scalding hands.
3.1.2 Notice
a) Dry the cleaning liquid in the handpiece with compressed air before sterilization.
b) Be sure that the scaling tip has been unscrewed from the handpiece and it cannot be sterilized with others.
c) Please notice whether the outer of the handpiece is damaged during the treatment or sterilization, don't smear any protective oil on the surface of handpiece.
d) There are two waterproof "o" rings at the end of handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce their service life. Change a new one once it is damaged or worn excessively.
e) The following sterilizing methods are forbidden:
i. Put handpiece into any liquid for boiling.
ii. Dip handpiece in disinfectors such as iodine, alcohol and glutaraldehyde.
iii. Put handpiece into oven or microwave oven for baking.

3.2 Sterilization of tip and Endochuck

3.2.1 Select the temperature, pressure and time of the autoclave sterilizer:
134°C,2.0bar-2.3bar (0.20MPa-0.23MPa), 4min.
3.2.2 Please remove tip and Endochuck after each operation
3.2.3 The surgical tip and Endochuck should be individually wrapped and sterilized with a sterilization towel or bag.
3.2.4 After sterilization, it is necessary to cool the tip before it can be used again so as not to burn the hands.
3.2.5 Before sterilization, please remove the tip from handpiece. Don't sterilize tip with other instrument in the same sterilizer.

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3.3 Disinfection and sterilization of torque wrench and Endo wrench

3.3.1 Torque wrench and Endo wrench can be sterilized with any commonly used non-corrosive neutral disinfectant, or they can be sterilized by autoclaving (Please refer to 3.2.1).

3.3.2 Do not disinfect or sterilize the torque wrench in the following ways:

a) Put it in solution and cook it;

b) Soak with disinfectant such as iodine, alcohol and glutaraldehyde;

c) Bake it at high temperatures in an oven or in a microwave oven.

Note: if the torque wrench is directly or indirectly damaged as a result of the above three disinfecting and sterilizing methods, Woodpecker will not be responsible for the repair.

3.4 The tip is made of 3Cr13 and has obtained Biocompatibility Test Report which shows that it will not result in any unacceptable risk while touching teeth.

3.5 Cleaning of tips, endochuck, torque wrench and endo wrench

The scaling tip, endochuck, torque wrench and endo wrench can be cleaned by ultrasonic cleaner.

3.6 Troubleshooting and notes

3.6.1 Troubleshooting

Fault	Possible cause	Solutions
The scaling tip doesn't vibrate and there is no water flowing out when stepping on the foot switch.	The power plug is in loose contact.	Make the plug insert to the socket well.
	The foot switch is in loose contact.	Insert the foot switch to its socket tightly.
	The fuse in the adapter or main unit is broken.	Contact our dealers or us.
The scaling tip doesn't vibrate but there is water flowing out when stepping on the switch.	The tip is in loose contact.	Screw the tip on the handpiece tightly (See Picture 4).
	The connect plug between the handpiece and the circuit board is in loose contact.	Contact our dealers or us.
	Something wrong with the handpiece.	Send the handpiece to our company to repair.
	Something wrong with the cable.	Contact our dealers or us.

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Fault	Possible cause	Solutions
The scaling tip vibrates but there is no spray when stepping on the foot switch.	The water control knob is not on.	Turn on the water contrl knob [note 1].
The vibration of the tip becomes weak.	The tip hasn't been screwed on to the handpiece tightly.	Screw the tip on the handpiece tightly (See Picture 4).
	The tip is loose because of vibration.	Screw on the tip tightly (See Picture 4).
	The coupling between the handpiece and the cable isn't dry.	Dry it by the hot air.
	The tip is damaged [note 2].	Change a new one.
There is water seeping from the coupling between the handpiece and cable.	The waterproof "O"ring is damaged.	Change a new waterproof "O"ring.
There is water flow out when turn off the power.	There is impurity in the solenoid valve.	Contact with the local distributor or manufacturer.
The handpiece generates heat.	The amount of spouting water is too little.	Turn the water control switch to a higher grade [note 1].
	The potentiometer is broken.	Change a new one.
The amount of spouting water is too little.	The water control knob is a low grade.	Turn the knob to a high grade [note 1].
	The water pressure is not enough.	Enhance the water pressure.
	The water pipe is jammed.	Clean water pipe with multi-function syringe [note2].
The vibrating intensity control knob is seized up.	The potentiometer is damaged.	Contact with the local distributor or our company.
The u-file doesn't vibrate.	The screw is loose.	Tighten it.
	Endochuck is damaged.	Change a new one.
There is noise coming from the endochuck.	The screw is loose.	Tighten it.
LED light don't work	Poor contact	Contact tightly
	Something wrong with LED light	Change a new one

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Fault	Possible cause	Solutions
There is no water coming out from the handpiece (automatic water supply mode).	There is air in the water pipe.	Turn the water control to the Max, reinsert the bottle.

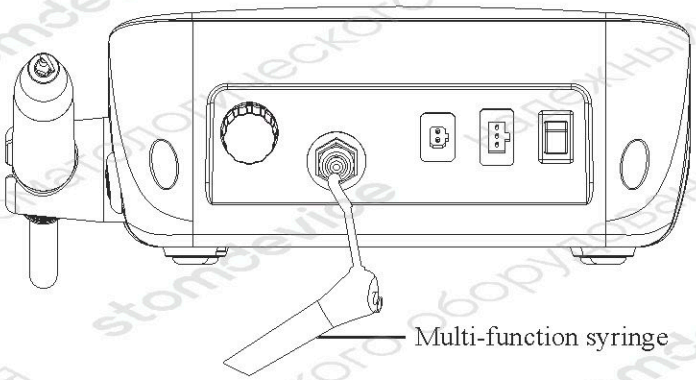
If the problem still can't be solved, please contact with local dealer or manufacturer.

Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

3.6.2 Notice ⚠

[Note 1] The water control knob can adjust the water volume according to the symbol.

[Note 2] To clean the water pipe with the multi-function syringe of the dental unit (see picture 7):



Picture 7

a) Snip the water pipe at a distance of 10cm to 20cm from the water entrance.

b) Turn on the power switch, get through to the power.

c) Connect the multi-function syringe of the dental unit to the water pipe.

d) Screw off the scaling tip or pull out the handpiece.

e) Step on the foot switch.

f) Turn on the switch of the multi-function syringe, press the air or water into the water pipe to clean and eliminate the impurity.

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[Note 3] If the scaling tip has been screwed on tightly and there is fine spray too, the following phenomena show that the scaling tip is damaged:

a) The vibrating intensity and the pulverization degree become weak obviously.

b) During operating, there is some buzz when the scaling tip is working.

[Note 4] If the power cable connected to the grid electricity end of the power adapter is damaged, as the power cable is not removable, for your safety, please contact a professional for replacement.

4. Precaution

4.1 Usage notice

4.1.1The use of the product must comply with the relevant regulatory requirements of the medical regulatory authorities, and should only be used by trained doctors or technicians.

4.1.2 Keep the scaler clean before and after operation.

4.1.3 The scaling tip, wrench and handpiece must be sterilized before each treatment.

4.1.4 Don't screw the scaling tip when stepping on the foot switch.

4.1.5 The scaling tip must be fastened. There must be fine spray coming out from the tip when operating.

4.1.6 Change a new one when the tip is damaged or worn excessively.

4.1.7 Don't twist or rub the tip.

4.1.8 While scaler working, the heat of scaling tip will become higher if there is no water flowing out. Please keep the water flow smoothly.

4.1.9 Don't use impure water source, and be sure not to use normal saline instead of pure water source.

4.1.10 If use the water source without hydraulic pressure, the water surface should be one meter higher than the head of the patient.

4.1.11 Don't knock or rub the handpiece.

4.1.12 Please put the power plug into the socket easy to pull out, to make sure it can be pull out in emergency.

4.1.13 When using the equipment, please keep the water get through smoothly, otherwise patient's tooth surface would be injured by overheat in the handpiece.

4.1.14 After operating, turn off electrical source, and then pull out the plug of power adapter.

4.1.15 As a professional manufacturer of medical instruments, we are only responsible for the safety on the following conditions:

I.The maintenance, repair and modification are made by the manufacturer or the authorized dealer.

II. The changed components are original of "DTE" and operated correctly according to instruction manual.

III. Maintenance is forbidden while the device is used for treatment.

4.1.16 The screw thread of the scaling tips produced by other manufacturers maybe coarse, rusty and collapsed, which will damage the screw thread of the handpiece irretrievably. Please use "WOODPECKER" brand scaling tip.

4.1.17 Please select a suitable power when using different type of tips (refer to "TABLE OF OPERATING POWER OF THE TIPS").

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4.2 Contraindication

4.2.1 The patient who has hemophilia is not allowed to use this equipment.
4.2.2 The patient or doctor who with heart pacemaker is forbidden to use this equipment.
4.2.3 The heart disease patient, pregnant woman and children should be cautious to use the equipment.

4.3 Storage and maintenance

4.3.1 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and is installed or kept in a cool, dry and ventilated place.
4.3.2 Don't store the machine together with the articles that are combustible poisonous, caustic, or explosive.
4.3.3 This equipment should be stored in a room where the relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa to106kPa, and the temperature is -20°C ~ +55°C.
4.3.4 Please turn off the power switch and pull out the power plug when the equipment is not used. If the machine is not used for a long time, please make it get through to the power and water once per month for five minutes.

4.4 Transportation

4.4.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.
4.4.2 Don't put it together with dangerous goods during transportation.
4.4.3 Avoid getting it exposed to sun, rain or snow during transportation.

4.5 Working condition

4.5.1 Environment temperature: +5°C to +40°C
4.5.2 Relative humidity: 30%~75%
4.5.3 Atmosphere pressure: 70kPa to 106kPa
4.5.4 A temperature of the water at the inlet: not higher than +25°C

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5. After service

Within one year from the date of sale, the device enjoys one year free repair by providing warranty card.

The repair of the equipment should be carried out by professional technician. We are not responsible for any irretrievable damage caused by non-professional person.

6. Symbol instruction

DTE®	Trademark	IPX0	Ordinary equipment
~	Alternating current	IPX1	Drip-proof
	Date of manufacture		Manufacturer
	Class II equipment		Type B applied part
	Foot switch interface		Used indoor only
H/O	Adjustment for the water flow	134°C	Can be autoclaved
H_2O 0.01-0.5MPa	Water entrance pressure	CE 0197	CE marked product
	Follow instructions for use		Appliance complies with WEEE directive
106kPa 70kPa	Atmospheric pressure for storage	+55°C -20°C	Temperature limit for storage
93% 10%	Humidity limit for storage		
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		

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7. Environmental protection

Please dispose according to the local laws or consult with dealer from whom you purchased it about waste disposal.

8. Manufacturer's right

We reserve the rights 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.

9. European authorized representative

EC REP MedNet GmbH
Borkstrasse 10 · 48163 Muenster · Germany

10. EMC - Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The models S6 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models S6 LED should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models S6 LED use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The models S6 LED are suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity			
The models S6 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models S6 LED should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

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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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models S6 LED require continued operation during power mains interruptions, it is recommended that the models S6 LED be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance & Declaration - Electromagnetic immunity			
The models S6 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models S6 LED should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models S6 LED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=[3,5/V1]×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). [b] Field strengths from fixed RF[a] transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol:
NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models S6 LED are used exceeds the applicable RF compliance level above, the model S6 LED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models S6 LED. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and the models S6 LED			
The models S6 LED are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models S6 LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models S6 LED are recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,5GHz d=2.3×P1/2
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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer. NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

11. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

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