



N1 N2

Built-in ultrasonic piezo scaler

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Certificated



EN ISO 9001:2008

EN ISO 13485:2003+AC:2007

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1. The installation and components of equipment

1.1 Instruction

The “Woodpecker” built-in ultrasonic piezo scaler UDS-N1 and UDS-N2 made in Guilin Woodpecker Medical Instrument Co., Ltd. are used along with dental unit for teeth cleaning. They are also indispensable equipments for tooth disease prevention and treatment.

1.2 Components

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

1.2.2 Product performance and structure

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

1.2.3 Scope of application

Ultrasonic piezo scaler is used for the dental calculus elimination.

1.3 The main technical specifications

1.3.1 Technical specifications of ultrasonic piezo scaler

a) Power Input: With transformer 220V to 230V~ 50Hz/60Hz 150mA
Without transformer 24V~ 50Hz/60Hz 1.3A

b) Output primary tip Vibration excursion: $\leq 100 \mu m$

c) Output half-excursion force: $< 2N$

d) Output tip Vibration frequency: UDS-N1 30kHz \pm 3kHz
UDS-N2 28kHz \pm 3kHz

e) Output power: 3W to 20W

f) Water pressure: 0.01MPa to 0.5MPa

g) Weight of main unit: 0.2kg

h) Weight of transformer: 1.0kg (optional)

i) Operating mode: Continuous operation

j) Type of protection against electric shock: Class II equipment

k) Degree of protection against electric shock: Type B applied part

l) Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)

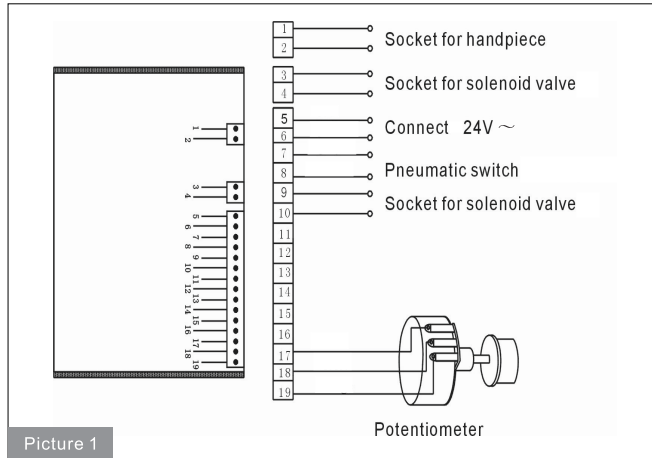
m) Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment can not be used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

1.3.2 Working condition

- a) Environment temperature: 5°C ~ 40°C
- b) Relative humidity: ≤ 80%
- c) Atmospheric pressure: 70kPa to 106kPa

1.4 Installing and connecting of the components

1.4.1 The installation and connecting illustration of the equipment's components are showed as picture 1.



Picture 1

Notice:

- a) Please connect power supply and pneumatic switch (or foot switch) showed as picture 1 .
- b) Lead NO.5 and lead NO.6 should be connected with 24V~, and this circuit is disallowed to act as switch circuit.
- c) Lead NO.7 and lead NO.8 should be connected with pneumatic switch directly, and this circuit acts as switch circuit and is disallowed to do short circuit.

1.4.2 The followings should be noticed during installation.

- a) Pneumatic power switch, pneumatic penstock and pneumatic foot switch are equipped by manufacturers of the dental unit or the end-users.

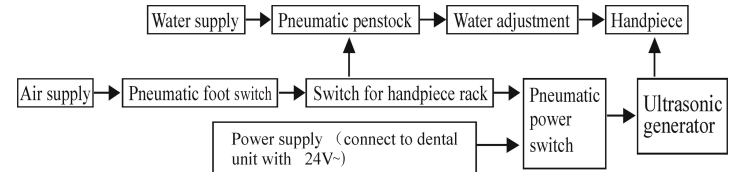
- b) The manufacturers of dental unit, the dealers or end-users of the equipment need to dig holes in the salver of dental unit so as to fix potentiometer and fetch out the silicagel pipe of handpiece cable.
- c) Make sure to keep proper space for dispersing heat of ultrasonic generator.
- d) Built-in ultrasonic scaler without transformer occupies a less space, and works with voltage 24V~, power ≥ 20W.
- e) Turn the potentiometer knob to the minimum and the water control switch to the maximum before turning on the scaler.
- f) The frequency of ultrasonic piezo scaler is extremely high. Under normal working state of the scaling tip, a light touch and a certain to-and-fro motion will eliminate the tartar without obvious heat. Overexertion and longtime lingering are forbidden.

2. Product function and usage

2.1 Working principle

2.1.1 Summarization: the built-in ultrasonic scaler consists of ultrasonic generator (circuit), cable, handpiece (transformer), scaling tip, pneumatic switch (the switch for both of the pneumatic penstock and the circuit after commutating and filtering, is controlled by pneumatic foot switch of dental unit and switch of handpiece rack of ultrasonic scaler at the same time) and switch for handpiece rack (it controls the air supply which gets through to the pneumatic penstock and pneumatic power switch. The air supply is off when handpiece is in the rack and air supply is on when handpiece is out).

2.1.2 Chart of working principle:



The air supply is on when the handpiece is pulled out from the rack. Step on the foot switch, pneumatic power switch, pneumatic penstock, ultrasonic generator, handpiece and scaling tip all start working at the same time, and water supply is on.

2.2 Scaling function

2.2.1 Instruction of wrench (UDS-N1)

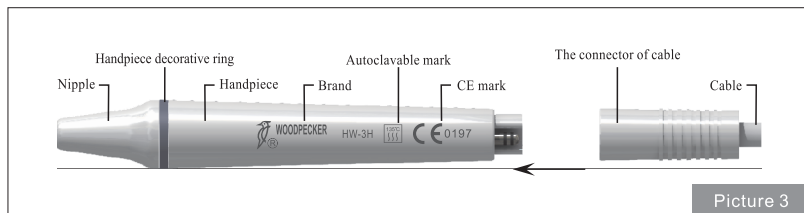
- a) Screw the tip on the handpiece.
- b) Put the tip inside the wrench's hole.
- c) Screw or unscrew the tip as picture 2 showed.



Picture 2

2.2.2 Instructions for main components of detachable handpiece <UDS-N1> (showed in picture 3)

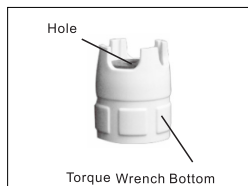
- a) Nipple: The nipple can be removed. You can termly scerw off the nipple and clean the pole with alcohol.
- b) Handpiece decorative ring: The seal can termly be removed and cleaned with alcohol.
- c) Handpiece: The main part of the whole machine, can be autoclaved under the high temperature and pressure.
- d) Symbol: Denote that "Can be autoclaved to the high temperature (135°C) and the high pressure (0.22MPa) "
- e) The connector of the cable: Connect the handpiece with water source and power supply of the main unit.



Picture 3

2.2.3 Instructions for torque wrench <UDS-N2> (showed in picture 4)

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



Picture 4

b) Operation

- ① Take the tip into the torque wrench as picture 5 showed.



Picture 5

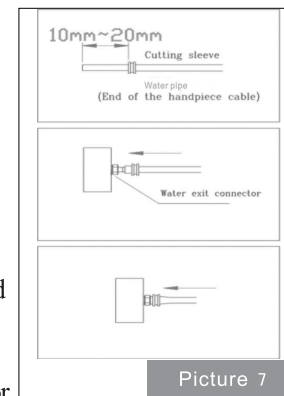
- ② Screw and unscrew the tip as picture 6 showed.
 - 1.Screw: Hold the handpiece tightly, screw the tip with the torque wrench towards clockwise direction, half more circles after the tip stops, then the tip is installed.
 - 2.Unscrew: Hold the handpiece tightly, screw the tip with the wrench towards anti-clockwise direction.



Picture 6

2.2.4 Instructions for cutting sleeve (showed in picture 7)

- a) Hitch the cutting sleeve into the water pipe, keep it 10mm to 20mm from the front.
- b) Hitch the water pipe till the middle of the water connector (about 3mm), then push the cutting sleeve forward the front of the water connector.
- c) Pinch the cutting sleeve and the water pipe with your fingers, push them forward simultaneously until they are fully wrapped into the water connector and the cutting sleeve is in the middle of the water connector.



Picture 7

Notice: Cut off the forepart of the water pipe about 6mm before repeating the above operation.

3. Sterilization and maintenance

3.1 Sterilization of tips and wrench

All the tips and the wrench can be sterilized under the high temperature and pressure.

3.2 Cleaning of tips and wrench (UDS-N1)

The tips and wrench can be cleaned by ultrasonic cleaner.

3.3 Sterilization of detachable handpiece (UDS-N2)

3.3.1 The degree of temperature/ pressure autoclaved:

- a) 121°C/1bar(0.1MPa)
- b) 135°C/2.2bar(0.22MPa)

3.3.2 Pull out the handpiece and unscrew the tip after operation.

3.3.3 Pack the handpiece with sterile gauze or sterile bag before sterilization.

3.3.4 Reuse handpiece after it cools naturally in case of getting scald.

3.3.5 Notice:

- a) Clean the cleaning liquid in the handpiece with compressed air before sterilization.
- b) Be sure that the scaling tips has been unscrewed from the handpiece.
- c) Please check whether the handpiece's exterior has been damaged during the operation or sterilization. Don't smear any protective oil on the surface of handpiece.
- d) There are two waterproof "O" rings at the end of the handpiece. Please lubricate them with dental lube frequently, as sterilization and pulling and inserting repeatedly will reduce their life-span. Change it once it is damaged or worn excessively.
- e) The following sterilizing methods are forbidden:
 - ① Boiled in liquid.
 - ② Dip in disinfectant such as iodine, alcohol and glutaraldehyde
 - ③ Baked in the normal oven or microwave oven.

3.4 Sterilization of torque wrench (UDS-N2)

3.4.1 The torque wrench can be sterilized under the high temperature and pressure.

3.4.2 The followed sterilizing methods are forbidden :

- a) Boiled in the liquor.
- b) Dip in disinfectant such as iodine, alcohol and glutaraldehyde
- c) Baked in the normal oven or microwave oven.

Notice: We are not responsible for any damage directly or indirectly made by any way mentioned above.

3.5 Cleaning of tips and torque wrench (UDS-N2)

The scaling tips and torque wrench can be cleaned by ultrasonic cleaner.

3.6 Troubleshooting and notes

Fault	Possible causes	Solutions
The scaling tip doesn't vibrate when stepping on the foot switch	The plug in loose or wrong contact	Connect as picture 1 showed
	Handpiece and the connector of cable are connected Irrelevantly(UDS-N2)	Pull out handpiece and insert it again
	Scaling tips is loose	Screw down with wrench
	There is some water between the handpiece and the connector of cable (UDS-N2)	Dry the connect point
	There is something wrong with detachable handpiece(UDS-N2)	Send it to our company to repair
The scaling tip vibrates, but there is no water flowing out	Water supply of the dental unit is off	Check the water supply of the dental unit
	There is no water coming from the cable(UDS-N2)	Clean the water pipe of the cable with multi-function syringe
	There is no water coming from the handpiece	Clean the water line of the handpiece with multi-function syringe

Fault	Possible causes	Solutions
The handpiece generates heat	The amount of spouting water is too little	Turn the water control switch to a higher grade
The amount of spouting water is too little	The water pipe of dental unit is jammed	Clean the water pipe
	The water pipe of cable is jammed (UDS-N2)	Clean the water pipe of the cable with multi-function syringe
	The water pipe of handpiece is jammed	Clean the water pipe of the handpiece with multi-function syringe
	The water pressure is not high enough	Enhance the water pressure
The vibration of the tip becomes weak	The tip hasn't been screwed tightly	Screw the scaling tip tightly
	The tips too loose which caused by vibration	Screw the scaling tip tightly
	The tip is damaged	Change a new one
The potentiometer is failure	The potentiometer is damaged	Change a new one
There is wter seeping from the coupling between the handpiece and cable	The waterproof "O" ring is damaged (UDS-N2)	Change a new one

If the problem still exist, please contact local dealer or manufacture.

4. Notice



4.1 Notice when using equipment

- 4.1.1 Keep the scaler clean before and after each operation.
- 4.1.2 The handpiece, scaling tip and torque wrench must be sterilized before operation.
- 4.1.3 Don't screw the tip when stepping on the foot switch.
- 4.1.4 The tip must be fastened and there must have fine spray or drip coming out from the tip when operating.
- 4.1.5 Change it when the tip is damaged or worn excessively. Don't twist or rub the tip.
- 4.1.6 Don't use impure water and don't use brine instead of pure water.

- 4.1.7 Keep the connector of handpiece and the socket of the cable dry before installing the handpiece.(UDS-N2)
- 4.1.8 Don't pull the cable forcibly in case of the handpiece falling off from the cable.(UDS-N2)
- 4.1.9 The internal screw thread of the scaling tips produced by some other manufacturers, maybe coarse, rusty and collapsed. This will damage the external screw thread of the handpiece irretrievably.
- 4.1.10 Make sure that the output voltage of the dental unit is 24V~ before connecting. A wrong power supply may break the unit.
- 4.1.11 Manufacturers of dental unit or the end-users are disallowed to disconnect the built-in ultrasonic scaler, in case of influencing the function of scaler. If you have any special request, please contact our company.

4.2 Contraindication

- 4.2.1 The hemophilia patient is forbidden to use this equipment.
- 4.2.2 The patients or doctors with heart pacemaker are 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 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 $\leq 80\%$, atmospheric pressure is 50kPa to 106kPa, and the temperature is -10°C to $+50^{\circ}\text{C}$.
- 4.3.4 After the operation, please turn off the power supply. If not use for a long time, please make the machine get through to the power and water once per month for five minutes.

4.4 Transportation

4.4.1 Excessive impact and shake should be prevented during the transportation.

Lay it carefully and lightly.

4.4.2 Don't put it together with dangerous goods during transportation.

4.4.3 Avoid solarization and getting wet in rain and snow during transportation.

5. After service

Two years' warranty for the main unit, one year's warranty for the other spare parts (except the expendable parts) from the date of purchase.

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

- I. The maintenance, repair and modification are made by the manufacturer or the authorized dealer;
- II. The exchanged components are original of "WOODPECKER" and operated according to instruction manual.

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

6. Symbol instruction



Trademark



Class II



Alternating current



Used only indoor

IPX0

Ordinary equipment



Type B



Notice! Please read Instruction before use



CE marked product



Date of manufacture



Manufacturer



FDA marked product



Authorised Representative in the EUROPEAN COMMUNITY



Appliance compliance WEEE directive



Atmospheric pressure for storage



Temperature limitation



Humidity limitation

EN ISO 9001:2008

Certificated by international quality control system of ISO

EN ISO 13485:2003+AC:2007

Certificated by medical instrument manufacturer quality control system of ISO

7. Environmental Protection

There is no harmful factor in our product. You can deal with it based on the local law.

8. For technical data, please contact




Wellkang Ltd (www.CE-marking.eu)
29 Harley St., London W1G 9QR, UK

9. EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model UDS-N1 and UDS-N2 is intended for using in the electromagnetic environment specified below. The customer or the user of the model UDS-N1 and UDS-N2 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model UDS-N1 and UDS-N2 uses 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	The model UDS-N1 and UDS-N2 is 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.

Guidance & Declaration — electromagnetic immunity			
The model UDS-N1 and UDS-N2 is intended for using in the electromagnetic environment specified below. The customer or the user of the model UDS-N1 and UDS-N2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 2 kV common mode	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 model UDS-N1 and UDS-N2 requires continued operation during power mains interruptions, it is recommended that the model UDS-N1 and UDS-N2 should be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The model UDS-N1 and UDS-N2 are intended for using in the electromagnetic environment specified below. The customer or the user of the model UDS-N1 and UDS-N2 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	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the model UDS-N1 and UDS-N2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \times P^{1/2}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2 \times P^{1/2}$ 80 MHz to 800 MHz $d=2.3 \times P^{1/2}$ 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 is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a 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 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not be applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>^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 model UDS-N1 and UDS-N2 are used exceeds the applicable RF compliance level above, the model UDS-N1 and UDS-N2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model UDS-N1 and UDS-N2.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

**Recommended separation distances between
portable and mobile RF communications equipment and the model UDS-N1 and UDS-N2**

The model UDS-N1 and UDS-N2 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model UDS-N1 and UDS-N2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model UDS-N1 and UDS-N2 as 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 $d=1.2 \times P^{1/2}$	80MHz to 800MHz $d=1.2 \times P^{1/2}$	800MHz to 2.5GHz $d=2.3 \times P^{1/2}$
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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not be applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.