UDS-N6 LED

ULTRASONIC SCALER INSTRUCTION MANUAL

Please read this manual before operating

CE 0197

WOODPECKER

Guilin Woodpecker Medical Instrument Co., Ltd.

Contents

1. The installation and components of equipment

1.1 Instruction

Guilin Woodpecker Medical Instrument Co., Ltd. is a professional manufacturer in 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 built-in ultrasonic scaler UDS-N6 LED is 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 Components and scope of application

a) Ultrasonic scaler is composed of elect circuit, water way and ultrasonic transducer.

b) This model is used for the dental calculus elimination and root canal treatment.

1.3 The main technical specifications

1.3.1 Technical specifications of ultrasonic scaler

a) Power input:

With transformer 220-240V~ 50Hz/60Hz 150mA

Without transformer 24V~ 50Hz/60Hz 1.3A

b) Output primary tip Vibration excursion: ≤100μm

c) Output half-excursion force: <2N

d) Output tip Vibration frequency: 28kHz±3kHz

e) Output power: 3W to 20W

f) Water pressure: 0.01MPa to 0.5MPa

g) Weight of main unit: 0.2kg

h) Main unit fuse: T1.6AL 250V

i) Weight of transformer: 1kg (optional)

j) Operating mode: Continuous operation

k) Type of protection against electric shock: Class II

l) Degree of protection against electric shock: Type BF applied part

m) Applied part of the equipment: handpiece and tip

n) Degree of protection against harmful ingress of water: Ordinary equipment

o) Degree of protection against harmful ingress of water: protection degree against water (used on foot switch):IPX1

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

1.3.2 Working condition

a) Environment temperature: +5°C to +40°C

b) Relative humidity: 30% ~75%

c) Atmosphere pressure: 70kPa to 106kPa

d) A temperature of the water at the inlet： not higher than +25°C

2 Installing of the equipment

The main components of this equipment and installation are showed as picture 1.

2.1 Please connect power supply and pneumatic switch (or foot switch) showed as picture 1.

2.2 The No.2 lead and No.3 lead should be connected with 24V~, and this circuit isn't allowed to act as switch circuit.

2.3 The No.4 lead and No.5 lead should be connected with pneumatic switch (or foot switch) directly, and this circuit isn't allowed to do the short circuit.

2.4 Potentiometer installation instruction

2.4.1 Affix the accompanying power adjustment dial to the corresponding position on dental unit panel so that the dividing line between "10" and "1" is vertically downwards.

2.4.2 Insert the washer into the potentiometer, and then load the potentiometer into the corresponding position of dental unit vertically downwards according to the wiring.

2.4.3 Put the flat washer and nut into the potentiometer and tighten it, and then turn the potentiometer to the left.

2.4.4 Align the tick mark on the aluminum alloy knob with the "1" on the power adjustment dial to load the aluminum alloy knob.

2.5 Slide switch installation instruction (Only for device with Endo function)

2.5.1 Remove the built-in outer nut and washer on the toggle switch, and insert the toggle switch into the corresponding position of the dental chair according to the wiring sequence of yellow, red and green.

2.5.2 Place the washer and nut into the toggle switch in turn and tighten the nut.

2.5.3 Affix the accompanying toggle switch label to an obvious position near toggle switch.

2.6 The followings should be noticed during installation:

2.6.1 The manufacturers of dental unit, the dealers or end-users of the equipment need to dig holes in salver of dental unit so as to fix potentiometer and fetch out the silica gel pipe of handpiece pipe.

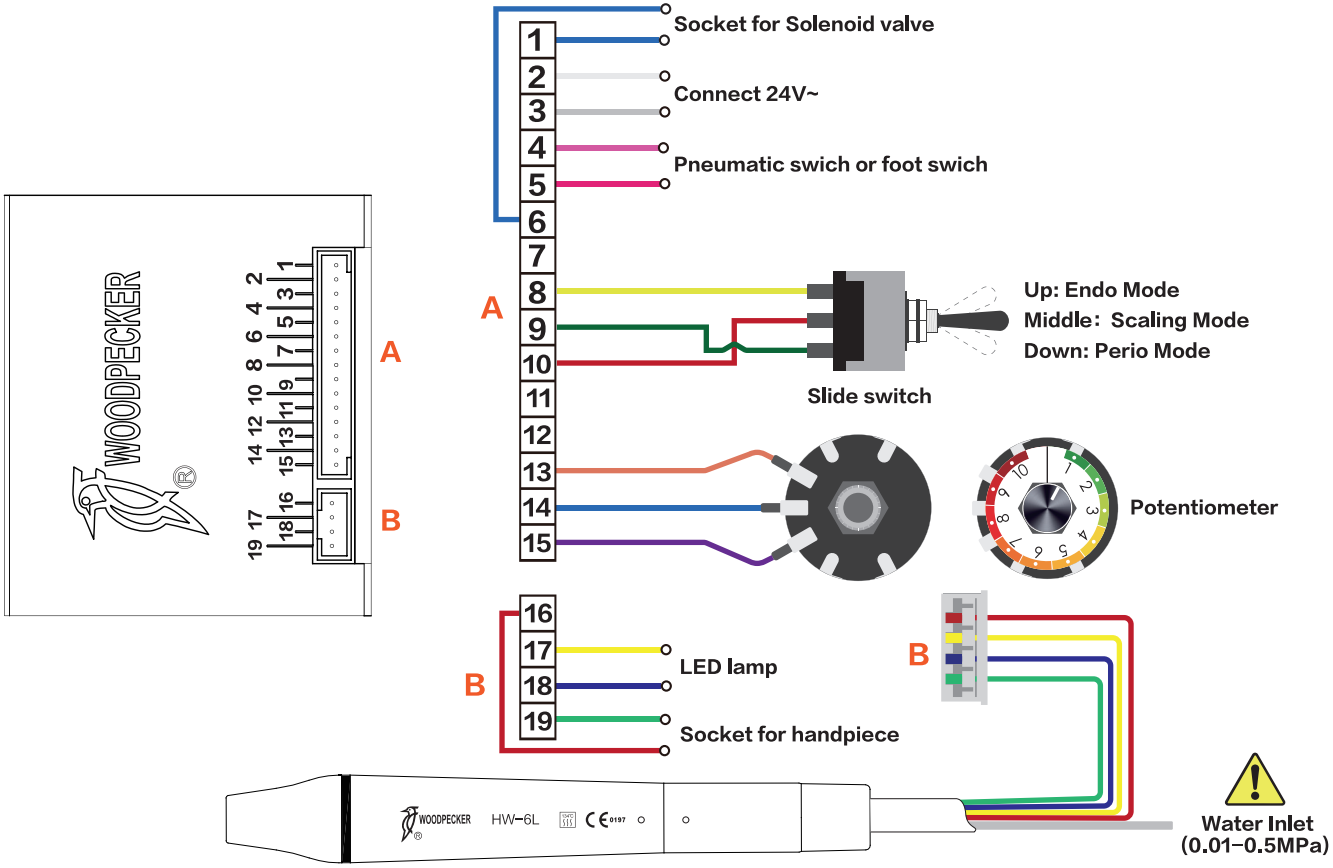
2.6.2 Keep enough space for dispersing heat of ultrasonic generator.

2.6.3 Built-in ultrasonic scaler without transformer occupies a little space, and works with current 24V~, power ≥20W.

2.6.4 Before turning on the scaler, turn the potentiometer knob to the minimum and the water control switch to the maximum.

2.6.5 The frequency of ultrasonic scaler is extremely high. Under normal water supply, a light touch and a certain to-and-fro motion will

eliminate the tartar without obvious heat. Overexertion and longtime lingering are forbidden.



Notice: For device without Endo function, there is no slide switch.

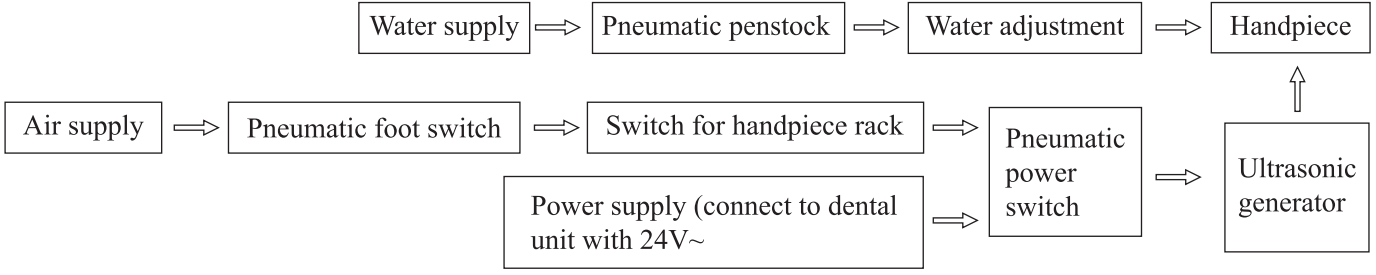
picture 1

3. Product function and usage

3.1 Working principle

3.1.1 Summarization: the built-in ultrasonic scaler is consist of ultrasonic generator (circuit), cable, handpiece (energy-transformed instrument), scaling tip, pneumatic switch (the power switch of pneumatic penstock and the circuit's commutating and filtering, is controlled by pneumatic foot pedal of dental unit and switch for handpiece rack of ultrasonic scaler at the same time) and switch for handpiece rack (it controls the air supply which gets through pneumatic penstock and pneumatic power switch. And the air supply is off when handpiece is in the rack and on when handpiece is out).

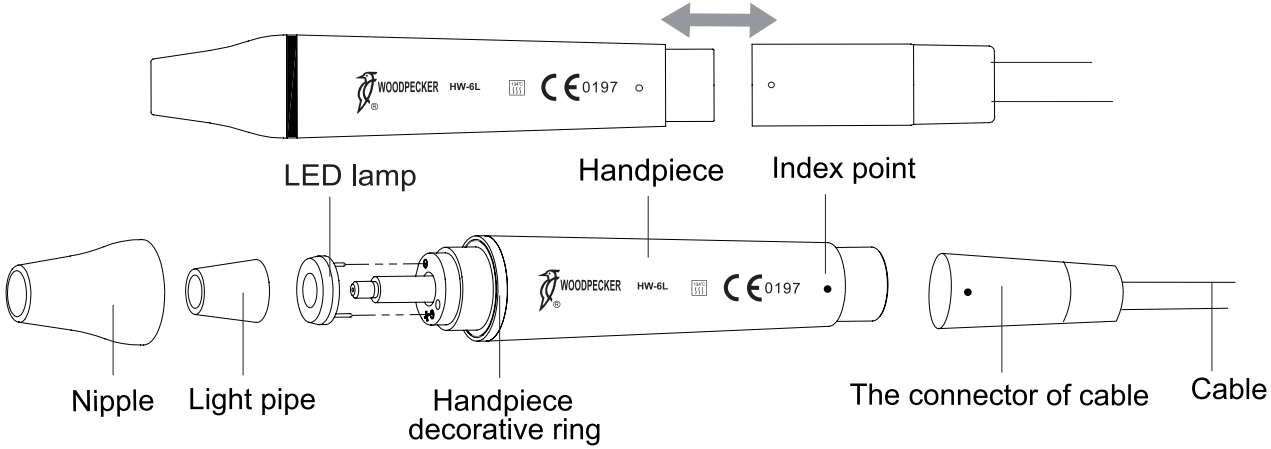
3.1.2 Chart of working principle:



The air supply is on when the handpiece is 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 opens, the LED lamp on the top of the handpiece shines.

3.2 Scaling function

3.2.1 Instruction for main components of detachable handpiece (showed in picture 2).



picture 2

a) Nipple: The nipple can be removed. You can screw out the nipple and clean the pole with alcohol termly.

b) Decorative ring: can be disassembled and cleaned with alcohol regularly, can be autoclaved under the high temperature and pressure.

c) Handpiece: The main part of the whole handpiece, can be autoclaved under the high temperature and pressure.

d) Symbol: Autoclaved (134°C,0.22MPa)

e) The connector of the cable: Connect the handpiece with the water source and power supply of the main unit.

f) LED lamp,Light pipe: Clean them with purified water and sterilize them under the high temperature of 134°C and high pressure of 0.22Mpa.

3.2.2 Instruction for using torque wrench (showed in picture 3)

a) The torque wrench's structure is designed in special way which can control the strength of the scaling tip 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.

b) Operation

(b1). Take the tip into the torque wrench as picture 4 showed.

(b2). Install Endochuck and Endo files as Picture 5 showed. (Only applicable to device with Endo function)

Ⅰ Installation: Hold the handpiece turn the tip toward clockwise direction with the torque wrench. Turn one more circles when the tip stops, then the tip is installed.

Ⅱ Uninstallation: Hold the handpiece, turn the wrench toward anti-clockwise direction.

3.2.3 Cutting sleeve use instruction (showed as picture 6)

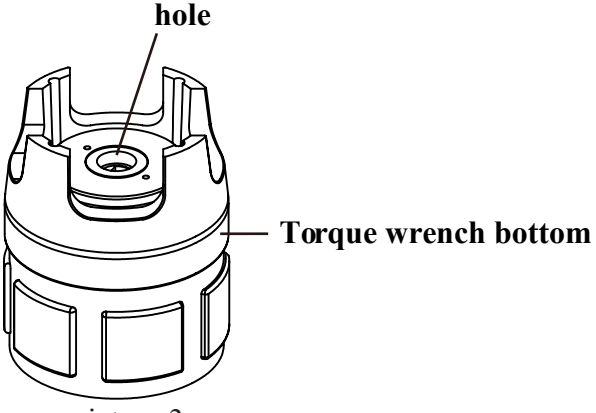
a) Put the cutting sleeve through the water pipe, keep it 10mm to 20mm away from the entrance.

b) Put the water pipe in the middle of the water exit connector(about 3mm), then push the cutting sleeve forward to the front edge of the water exit connector.

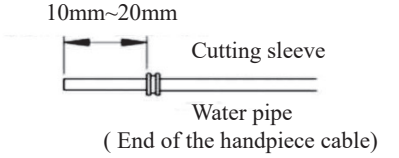
c) Pinch the cutting sleeve and the water pipe with your fingers, push them forward at the same time until they are wrapped into the water exit connector fully. Then the cutting sleeve is in the middle of the water exit connector.

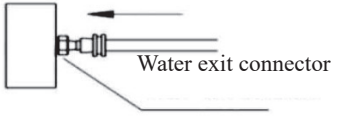
Notice:

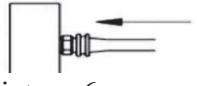
Cut off the forepart of the water pipe about 6mm if repeat the above operation.



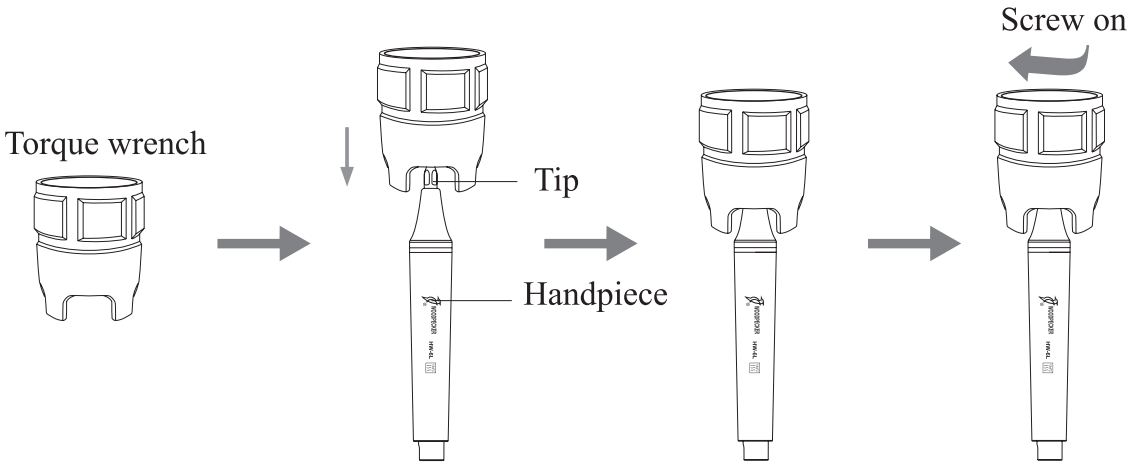
picture 3



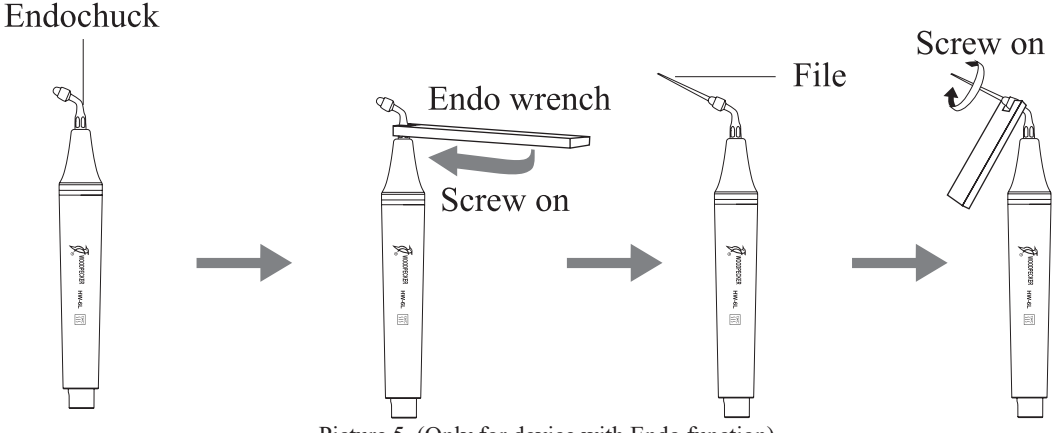




picture 6



Picture 4



Picture 5 (Only for device with Endo function)

3.3 Endo function (Only for device with Endo function)

3.3.1 Usage process

a) Fix endo holder to handpiece by endo wrench.
b) Unscrew the screw cap on the endo holder.
c) Put the ultrasonic file into the hole in the front of endo holder.
d) Screw the screw cap with endo wrench to tight up the ultrasonic file.
e) Switch the slide switch knob to the Endo mode (i.e. switch to the top position), and then turn the power potentiometer to the minimum gear.
f) Step on the foot switch to start endo treatment.
g) Use for endo function when step on foot switch. During the treatment, turn up the power gradually according to the needs.

3.3.2 **Notice:**

a) When fixing endo chuck, it must be screwed down.
b) The screw cap on the endo chuck must be screwed down.
c) Don't press it too hard when the ultrasonic file is in root canal.
d) Don't step on the foot switch until the ultrasonic file is in the root canal.

4. Cleaning, Disinfection and Sterilization

The cleaning, disinfection and sterilization of handpiece, tip, and wrench (include torque wrench and Endo wrench) are as follow.

Unless otherwise stated, they will be hereinafter referred to as "products".

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

Do not clean the handpiece with ultrasound cleaning machine.

This device shall not be exposed to high temperature above 138℃.

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for handpiece is 600 times. For tips, it is 300 times. And for wrench, it is 1000 times.

4.1 Initial processing

4.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/ disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic,especially with regard to the additional requirements for the inactivation of prions.

4.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Let the Ultrasonic Scaler works for 20-30 seconds at maximum water volume to flush the handpiece and tip;

2. Remove the handpiece from the Ultrasonic Scaler, and rinse away the dirt on the surface of product with pure water (or distilled water/ deionized water);

3. Dry the product with a clean, soft cloth and place it in a clean tray.

Notes

a) The water used here must be pure water, distilled water or deionized water.

4.2 Preparation before cleaning

Steps：

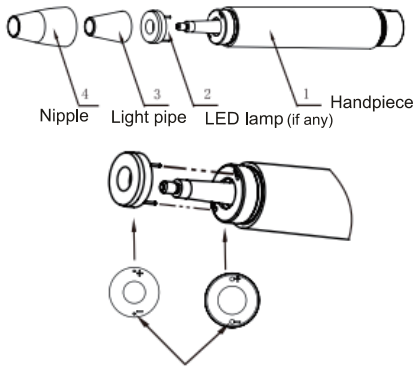
Tools: Endo wrench or torque wrench, tray, soft brush, clean and dry soft cloth

1. Remove the tip from product with Endo wrench or torque wrench provided by Guilin Woodpecker Medical Instrument Co., Ltd, and then put the tip and wrench into a clean tray.

2. Unscrew the nipple of product counterclockwise, remove the sealing ring, light pipe(if any） , and LED lamp(if any), and put them in the tray.

3. Use a clean soft brush to carefully brush the joints between product and the connector of cable, front thread, horn, nipple, seal ring, light pipe(if any) and LED lamp(if any) until the dirt on surface is not visible. Then use soft cloth to dry the product and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps



4.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

4.3.1 Automated cleaning

•The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

•There should be a flushing connector connected to the inner cavity of the product.

•The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

•Do not clean the product with ultrasound.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Notes:

a) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.

b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

c) After cleaning, the chemical residue should be less than 10mg / L.

4.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

4.4.1 Automated disinfection-Washer-disinfector

•The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

•Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

•The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector

1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

Notes:

a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4)During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000;

(d2)Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600

(d3) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and A0>3000

e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f) After cleaning, the chemical residue should be less than 10mg / L.

g)The air used for drying must be filtered by HEPA.

h) Regularly repair and inspect the disinfector.

4.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time should be 15~40 minutes.

Notes:

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

4.6 Inspection and maintenance

In this chapter, we only check the appearance of the product. After inspection, if there is no problem, the handpiece should be immediately reassembled, installing the sealing ring, LED, light guide, and cone head in sequence to the handpiece, and then tighten the cone head clockwise.

4.6.1 Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

4.6.2 Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

4.6.3 Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

4.6.4 If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

4.7 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

Notes

a) The package used conforms to ISO 11607;

b) It can withstand high temperature of 138 °C and has sufficient steam permeability;

c) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

d) Avoid contact with parts of different metals when packaging.

4.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

- The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;
- The highest sterilization temperature is 138 ° C;
- The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.

• Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Notes:

a) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

b) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

c) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

d) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

4.9 Storage

1 Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2 After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

4.10 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation.
3. Avoid exposure to sun or rain or snow during transportation.

The cleaning and disinfection of main unit are as follows.

• Before each use, wipe the surface of the connector of cable and cable with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.

• Before each use, please let the Ultrasonic Scaler works for 20-30 seconds at maximum water volume, then install the handpiece.

• After each use, please let the Ultrasonic scaler works for 20-30 seconds at maximum water volume, then remove the handpiece.

• After each use, wipe the surface of the connector of cable and cable with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

5. Contraindication

5.1 The hemophilia patient is forbidden to use this equipment.
5.2 The patients or doctors with heart pacemaker are forbidden to use this equipment.
5.3 The heart disease patient, preganant woman and children should be cautious to use the equipment.

6. Troubleshooting

Fault	Possible causes	Solutions
The scaling tip doesn't vibrate when stepping on the foot switch.	The plug is in loose or wrong contact.	Connect as picture 1 showed.
	Handpiece and the connector of cable connect irrelevantly.	Pull out handpiece and insert it again.
	Scaling tip is loose.	Screw it on tightly with torque wrench.
	There is some water between the handpiece and the connector of cable.	Dry the connect point.
	There is something wrong with detachable handpiece.	Send it to our company to repair.
The scaling tip vibrates, but there is no water flowing out.	Water supply of dental unit is off.	Check the water supply of the dental unit.
	There is no water coming out from the cable.	Clean the water pipe of the cable with multi-function syringes.
	There is no water coming out from the handpiece.	Clean the water pipe of the handpiece with multi-function syringes.
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.	Clean the water pipe of the cable with multi-function syringe.
	The water pipe of handpiec 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 down the scaling tip.
	The tip vibrates loose.	Screw down the scaling tip.
	The tip is damaged.	Change a new one.

Fault	Possible causes	Solutions
There is water seeping from the coupling between the handpiece and cable.	The waterproof "O" ring is damaged.	Change a new "O" ring.
The potentiometer is failure.	The potentiometer is damaged.	Change a new one.
The U-file doesn't vibrate. (If there is U-file)	The screw hasn't been screwed.	Screw it tightly.
	Endochuck is damaged.	Change a new endochuck.
LED light don't work	Poor contact	Contact tightly
	Something wrong with LED light	Change a new one
	LED lamp installed backwards	Please install the "+" of the LED lamp to the "+" of the handpiece
There is noise coming from the endochuck. (If there is endochuck)	The screw cap hasn't been screwed tightly.	Screw it tightly.

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

7. Precaution

Notice when using equipment

7.1 Keep the scaler clean before and after operation.

7.2 The handpiece, scaling tip, torque wrench, endo wrench and endochuck(If there are) must be sterilized before each treatment.

7.3 Don't screw or unscrew the scaling tip when stepping on the foot pedal.

7.4 The scaling tip and endochuck(If there is) must be fastened and there must be fine spray or drip coming from the tip when operating.

7.5 Change a new one when the tip is damaged or worn excessively. Don't twist the tip or rub the tip.

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

7.7 Don't use impurity water source and be sure not use normal brine instead of pure water source.

7.8 Ensure the connector of handpiece and the socket of the cable dry before installing the handpiece.

7.9 Don't pull the cable forcibly in case of the handpiece falling off the cable.

7.10 The internal screw threat of the scaling tips produced by some other manufactures, may be coarse, rusty and collapsed. This will damage the external screw threat of the handpiece irretrievably. Please use "WOODPECKER" brand scaling tips.

7.11 Before connecting the built-in ultrasonic scaler without transformer to power supply, please check the output voltage is 24V~, in case of connecting to wrong power supply and that may break the unit.

7.12 Manufacturers of dental unit or the end-user aren't allowed to disconnect the built-in ultrasonic scaler, in case of affecting function of scaler.

If you have any special request, please contact with us.

(1). WARNING: No modification of this equipment is allowed.

(2). WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

8. Storage and maintenance

8.1 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.

8.2 Don't store the machine together with the articles that is combustible, poisonous, caustic, or explosive.

8.3 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.

8.4 Please turn off the electrical source if not be use it, if not use for a long time, please make the machine get through to the power and water once per month for five minutes.

9. Transportation

9.1 Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.

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

9.3 Avoid solarization and get wet in rain or snow during transportation.

10. After-service

We offer two year free repair to the equipment according to the warranty card.

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

11. Environmental Protection

Please dispose according to the local laws.

12.European authorized representative

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

13. 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.

14. Symbol instruction

WOODPECKER	Trademark		Follow Instructions for Use
IPX0	Ordinary equipment	~	Alternating current
106kPa 70kPa	Atmospheric pressure for storag		Date of manufacture
	Manufacturer		Class II equipment
	Type BF applied part	134°C	Can be autoclaved
	Used indoor only		Appliance compliance WEEE directive
CE 0197	CE marked product	93% 10%	Humidity limitation for storage
+55°C -20°C	Temperature limitation for storage		

15. EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The models UDS-N6 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models UDS-N6 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 UDS-N6 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 UDS-N6 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 lEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions lEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity			
The models UDS-N6 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models UDS-N6 LED should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) lEC 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 lEC 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 UDS-N6 LED require continued operation during power mains interruptions, it is recommended that the models UDS-N6 LED be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field lEC 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.			

Guidance & Declaration - Electromagnetic immunity			
The models UDS-N6 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models UDS-N6 LED should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF lEC 61000-4-6 Radiated RF lEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specification s for ENCLOSUR E PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the models UDS-N6 LED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 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 d 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 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 UDS-N6 LED are used exceeds the applicable RF compliance level above, the model UDS-N6 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 UDS-N6 LED. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the models UDS-N6 LED

The models UDS-N6 LED are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models UDS-N6 LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models UDS-N6 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.

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for more information

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