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REFINE

CE 1434

Ultrasonic Scaler Instruction Manual

(Seriel 2000/3000)

Please read this manual before operating

Guilin Refine Medical Instrument Co., LTD.

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⚠ Safety Precautions

⚠ WARNING: If you neglect these safety precautions, you may cause personal injury such as electric shock, fire or damage to the product.

1.Use a separate, grounded power outlet. Never use wet hands to unplug the power cord.

2.Please do not use other than the specified voltage.Before connecting the built-in ultrasonic scaler without transformer to power supply, please check the output voltage is 24VAC, in case of connecting to wrong power supply and that may break the unit.

3.Keep the scaler clean before and after operation. The scaling tip, wrench and handpiece must be sterilized before each treatment.

4.The tip must be tightened to the handpiece with torque wrench. While scaler is working, the heat of scaling tip may become higher if there is no water flowing out, make sure the irrigation is good.

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

6.Don't screw the scaling tip while stepping on the foot switch.

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

8.While scaler is working, the heat of scaling tip will become higher if there is no water flowing out, make sure the irrigation is good.

9.Don't knock or rub the handpiece. Do not pull the cable while the device is working, to avoid damage to the cable.

10.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 our scaling tip.

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

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

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• The changed components are original of our company and operated correctly according to instruction manual.

12.This product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.

⚠ **WARNING:** No modification of this equipment is allowed.

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

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Symbol instruction

Symbol	Instruction	Symbol	Instruction
	Warning, Caution and Important! Check the Instruction Manual		Consult the accompanying documents
	Date of manufacture		Manufacturer
	According to the type of protection against electric shock: CLASS II EQUIPMENT		According to the degree of protection against electric shock:Type B applied part
IPX1	Protected against dripping water		Used indoor only
24VAC	24VAC power supply socket		Can be autoclaved
	Atmospheric pressure for storage		Water entrance pressure:0.01MPa-0.5MPa
	Temperature limitation for storage		Humidity limitation for storage
	Appliance compliance WEEE directive, Dispose as required by the law.	CE 1434	CE Mark

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1 Product introduction

1.1 Product overview

The built-in ultrasonic scaler is used along with dental unit for teeth cleaning and root canal treatment. They are also indispensable equipments for tooth disease prevention and treatment. The ultrasonic scaler is intended to be built in a dental unit which shall comply with IEC 60601-1 and IEC 80601-2-60. The product supposes to be used in hospital and dental clinic, should be used by trained and qualified dentist.This Ultrasonic Scaler is used for the dental calculus elimination and root canal treatment. The ultrasonic scaler is composed of main unit, handpiece (ultrasonic transducer), cable, scaling tip, transformer (optional), foot switch (optional), water pipe and torque wrench.

The ultrasonic scaler has following features:

1) Detachable handpiece can be autoclaved under 134 °C and 0.22 Mpa.

2) Automatic frequency tracking ensures that the device always works on the best frequency, stable and efficient performance.

1.2 Contraindications:

1) The hemophilia patient is forbidden to use this equipment.

2) The patients or doctors with heart pacemaker are forbidden to use this equipment.

3) The heart disease patient, pregrant woman and children should be cautious to use the equipment.

1.3 Equipment safety classification

1) Operating mode: Continuous operation

2) Type of protection against electric shock: Class II

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

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4) Applied part of the equipment: Tip

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

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

7) 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.

1.4 Working condition

1) Environment temperature: +5°C - +40°C

2) Relative humidity: 30% - 75%

3) Atmosphere pressure: 70kPa - 106kPa

4) Temperature of the water at the inlet: not higher than +25°C

1.5 Model and technical Parameters (For specific models, see packing labels.)

Note 1: In addition to the above, the electronic components used to clarify their electrical properties are exactly the same.

Note 2: Function Annotation: "G" means "Scaling Function" ; "P" means "Periodontal Function" ; "E" means "Endodontic Function".

Note 3: Do not replace the fuse of main unit, to avoid safety risks.

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Table 1: Technical Parameters of each model (Serial 2)

Parameters	N2000	N2000L	V2000	V2000L
Compatible Brand	EMS	EMS	Satelec	Satelec
Handpiece	HP-3H (without LED lamp, Detachable)	HP-5L(with LED lamp, Detachable)	HS-7H(without LED lamp, Detachable)	HS-7L(with LED lamp, Detachable)
Function	G, P	G, P	G, P	G, P
Potentiometer	Carbon-film potentiometer (circular)	Carbon-film potentiometer (circular)	Carbon-film potentiometer (circular)	Carbon-film potentiometer (circular)
Size (mm)	75*56*34mm	75*56*34mm	75*56*34mm	75*56*34mm
Weight of main unit	0.125kg	0.125kg	0.125kg	0.125kg
Power input	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A
Fuse of main unit	T1.6AL 250V	T1.6AL 250V	T1.6AL 250V	T1.6AL 250V
Primary tip vibration excursion	<200μm	<200μm	<200μm	<200μm
Tip vibration frequency	28kHz±3kHz	28kHz±3kHz	28kHz±3kHz	28kHz±3kHz
Output power of tip	3W-20W	3W-20W	3W-20W	3W-20W
Half-excursion force	0.5N-5N	0.5N-5N	0.5N-5N	0.5N-5N
Water entrance pressure	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa

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Table 2: Technical Parameters of each model (Serial 3)

Parameters	N3000	N3000L	V3000	V3000L
Compatible Brand	EMS	EMS	Satelec	Satelec
Handpiece	HP-3H (without LED lamp, Detachable)	HP-5L(with LED lamp, Detachable)	HS-7H(without LED lamp, Detachable)	HS-7L(with LED lamp, Detachable)
Function	G, P, E	G, P, E	G, P, E	G, P, E
Potentiometer	Push-pull potentiometer	Push-pull potentiometer	Push-pull potentiometer	Push-pull potentiometer
Size (mm)	75*56*34mm	75*56*34mm	75*56*34mm	75*56*34mm
Weight of main unit	0.125kg	0.125kg	0.125kg	0.125kg
Power input	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A
Fuse of main unit	T1.6AL 250V	T1.6AL 250V	T1.6AL 250V	T1.6AL 250V
Primary tip vibration excursion	<200μm	<200μm	<200μm	<200μm
Tip vibration frequency	28kHz±3kHz	28kHz±3kHz	28kHz±3kHz	28kHz±3kHz
Output power of tip	3W-20W	3W-20W	3W-20W	3W-20W
Half-excursion force	0.5N-5N	0.5N-5N	0.5N-5N	0.5N-5N
Water entrance pressure	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa

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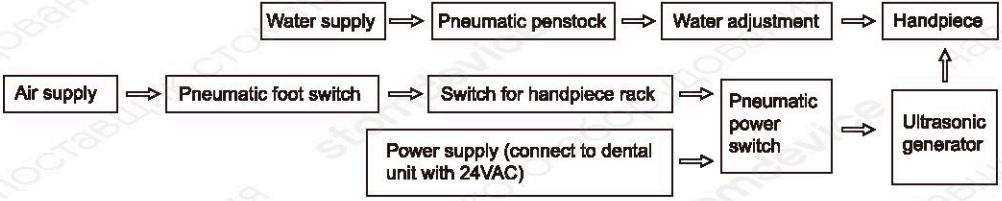
2 Installation and adjustment

2.1 Working principle

2.1.1 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).

2.1.2 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 opened the LED lamp on the top of the handpiece with LED shines.

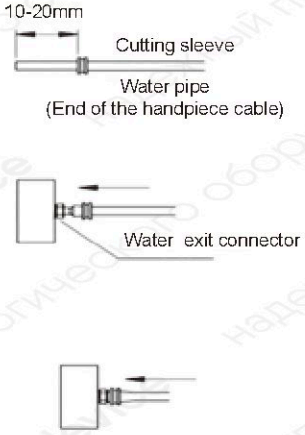


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2.2 Installation

2.2.1 Cutting sleeve use instruction

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 6 mm if repeat the above operation.

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

⚠ Notice:

a) Please connect power and pneumatic switch (or foot switch) showed as picture 1.
b) The No.7 lead and No.8 lead should be connected with 24VAC, and this circuit isn't allowed to act as switch circuit.
c) The No.9 lead and No.10 lead should be connected with pneumatic switch (or foot switch) directly, and this circuit isn't allowed to do the short circuit.
d) Wires 11 and 12 are the solenoid valve drive wires and are not normally used. This outputs 30V DC, must not be connected to a power supply or switch and must not be shorted.
e) Pins 13, 14 and 15 of the N3000 series are for mode selection (black, green and orange wires) and are connected to the toggle switch, the black wire marked "G/P" is for ultrasonic scaling or periodontal treatment mode, the middle of the orange wire is empty and the green wire marked to the position marked "E" for root canal scaling mode.
f) Pins 19, 20 and 21 are connected to a potentiometer for power adjustment. The potentiometer increases power when adjusted clockwise and decreases power when adjusted counterclockwise.
g) The followings should be noticed during installation.

① Pneumatic power switch, pneumatic penstock and pneumatic foot switch are equipped by manufacturers of the dental unit or the end-users.

② The manufacturers of dental unit, the dealers or end-users of the equipment need to drill holes in salver of dental unit so as to fix potentiometer and fetch out the silica gel pipe of handpiece pipe.

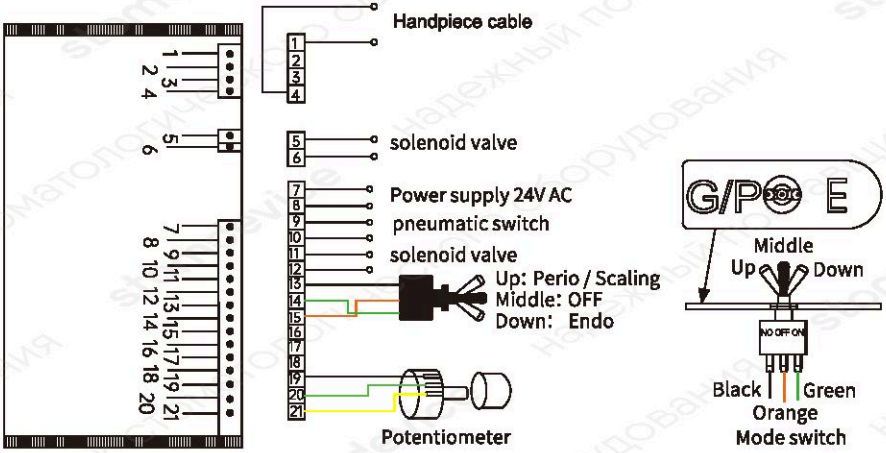
③ Keep enough space for dispersing heat of ultrasonic generator.

④ Built-in ultrasonic scaler without transformer occupies some space, and works with current 24VAC, power ≥20W.

⑤ Before turning on the scaler, turn the potentiometer knob to the minimum and the water control switch to the maximum.

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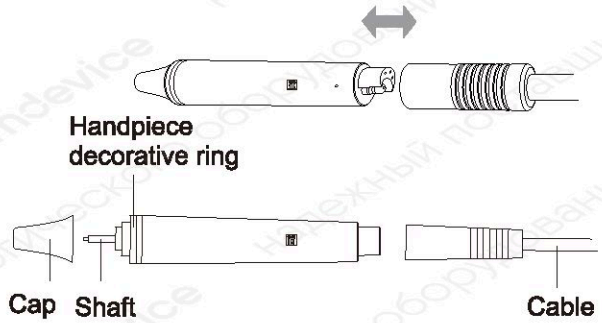
⑥ The frequency of ultrasonic scaler is extremely high. Under normal water supply, a light touch and a certain to-and-fro motion will eliminate the tartar without obvious heat. Overexertion and longtime lingering are forbidden.



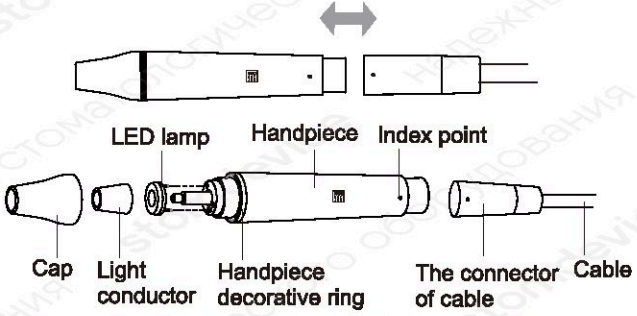
picture 1

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

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Picture 2-A The detachable handpiece without LED lamp



Picture 2-B The detachable handpiece with LED lamp

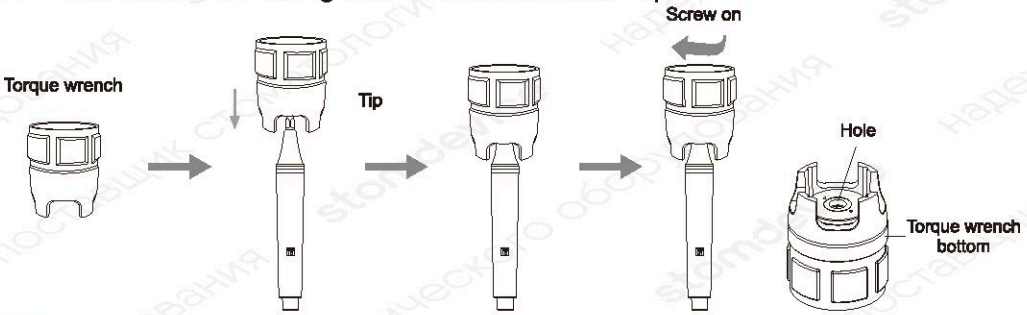
a) Cap: The Cap can be removed. You can screw out the Cap and clean the pole with alcohol termly.

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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 of the main unit.
f) LED lamp, Light conductor (The models that the handpiece with LED lamp): Clean them with purified water and sterilize them under the high temperature of 134°C and high pressure of 0.22Mpa.

Note: The connection of handpiece and the plug must be kept dry.

2.4 Instruction for using the wrench to install tip



Picture 3

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

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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
•Take the tip into the torque wrench then install or uninstall the scaling tip as picture 3 showed.
•Installation: Hold the handpiece and turn the tip toward clockwise direction with the torque wrench. Turn one more circle when the tip stops, then the tip is installed.
•Uninstallation: Hold the handpiece, turn the wrench toward anti-clockwise direction.

⚠ **Note:** The connection of handpiece and the plug must be kept dry.

3 Function and Operation

3.1 Scaling function

3.1.1 Choose the scaling tip according to the requirement, and fix the scaling tip with the wrench. (see picture 3) Please select a suitable power when using different type of tips (refer to "TABLE OF OPERATING POWER OF THE TIPS").
3.1.2 The handpiece can be handled in the same gesture as a pen in hand.
3.1.3 Vibrating intensity: Using the potentiometer to 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.
3.1.4 Step on the foot switch, the tip begins to vibrate, and the LED lamp (model with LED) on the top of the handpiece lights up. Release the foot switch, the LED lamp keep shining for 10 seconds.
3.1.5 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, overexertion and overstay are forbidden.
3.1.6 Water volume adjustment: Step on the foot switch, and the tip begins to vibrate, then turn

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the water control switch to fine spray to cool down the handpiece and clean the teeth.
3.1.7 After finishing operation, keep the machine working for 30 seconds with the water supply to clean the handpiece and the tip.
3.1.8 Unscrew the scaling tip and sterilize it.

⚠ **Be sure not to make the end of the tip touch the teeth vertically, and not use too much force when the tip touch the surface of the teeth, in case of hurting the teeth and damaging the tip.**

⚠ **Note:** Don't screw the scaling tips when stepping on the foot switch, while the machine is working.

3.2 Endodontic function (The models with endodontic function)

3.2.1 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) Pull out the main pole of the power potentiometer to switch to endo function (when push it in, switch to scaling function), then turn the potentiometer toward anticlockwise direction to the minimum grade.
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.

3.2.2 Notice ⚠

a) When fixing endo chuck, it must be screwed down.
b) The screw cap on the endo chuck must be screwed down.

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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, disinfecting and sterilizing

4.1 Please conform to the recommendations of the manual "Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing" delivered with your product regarding the procedure of cleaning, disinfecting, sterilizing and packing of the components. Follow present-day regulations enforced in the country about reprocessing. The use of scouring powder or an abrasive sponge will damage its surface.
4.2 The handpiece, scaling tips, endochuck, torque wrench, endo wrench, LED lamp and Light conductor can be sterilized(the handpiece with LED lamp). The cable and water pipe cannot be sterilized.

⚠ Notice:

a) Clean 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 and sterilization. Don't smear any protective oil on the surface of handpiece.
d) There are some waterproof "O" rings at the end of the handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce their using life. Change a new one once it is damaged or worn excessively.
e) The following sterilizing methods are forbidden:
•Boil in water.
•Dip in iodine, alcohol and glutaraldehyde.
•Bake in oven or microwave oven.

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Notice: We are not responsible for any damage caused in the above items.

5 Transportation, storage and maintenance

5.1 Transportation

5.1.1 Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.
5.1.2 Don't put it together with dangerous goods during transportation.
5.1.3 Avoid solarization and getting wet in rain or snow during transportation.

5.2 Storage

5.2.1 Don't store the machine together with the articles that is combustible, poisonous, caustic, or explosive.
5.2.2 This equipment should be stored in a room where the relative humidity is 10%-93%, atmospheric pressure is 70kPa-106kPa, and the temperature is -20°C-+40°C.

5.3 Maintenance

5.3.1 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.
5.3.2 Please turn off the electrical source if not use it, if not use for a long time, please make the machine get through to the power and water once 3 months for five minutes.

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6 Trouble shooting

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.

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Fault	Possible causes	Solutions
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.
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. (The models that with Endodontic function)	The screw hasn't been screwed.	Screw it tightly.
	Endochuck is damaged.	Change a new endochuck.

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Fault	Possible causes	Solutions
LED light don't work (The models that the handpiece without LED lamp)	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. (The models that with Endodontic function)	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 Environmental protection

Please dispose according to the local laws.

8 European authorized representative

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

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9 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.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The models Ultrasonic Scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the models Ultrasonic Scaler should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The models Ultrasonic Scaler 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.</td></tr>
<tr><td>RF emissions CISPR11</td><td>Class B</td><td rowspan="3">The models Ultrasonic Scaler are suitable for being used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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Guidance & Declaration — electromagnetic immunity			
The models Ultrasonic Scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the models Ultrasonic Scaler 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	±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.

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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 Ultrasonic Scaler requires continued operation during power mains interruptions, it is recommended that the models Ultrasonic Scaler is 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.			

Guidance & Declaration - Electromagnetic immunity
The models Ultrasonic Scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the models Ultrasonic Scaler should assure that it is used in such an environment.

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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 Ultrasonic Scaler, 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 1 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.			

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[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 Ultrasonic Scaler are used exceeds the applicable RF compliance level above, the model Ultrasonic Scaler should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Ultrasonic Scaler.
[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 Ultrasonic Scaler

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

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For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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 apply 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.

10 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.

(The date of production can be found in the label of the package. Product lifetime: 10 years)

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Attachment 1. Table of operating power of the tips

Scaling	
Tip Model	Power
G1	LOW-HIGH
G2	LOW-HIGH
G3	LOW-HIGH
G4	LOW-HIGH
G5	LOW-HIGH
G6	LOW-HIGH
G7	LOW-HIGH
G8	LOW-HIGH
G9	LOW-HIGH
G10	LOW-HIGH
G11	LOW-HIGH

Cavity Preparation	
Tip Model	Power
SB1	LOW-HIGH
SB2	LOW-HIGH
SB3	LOW-HIGH
SBL	LOW-HIGH
SBR	LOW-HIGH

Periodontics	
Tip Model	Power
P1	LOW-MID
P2L	LOW
P2LD	LOW
P2R	LOW
P2RD	LOW
P3	LOW-MID
P3D	LOW-MID
P4	LOW-MID
P4D	LOW-MID

Endodontics	
Tip Model	Power
E1	LOW
E2	LOW
E3	LOW
E3D	LOW
E4	LOW
E4D	LOW
E5	LOW
E5D	LOW
E6	LOW
E7	LOW
E8	LOW
E9	LOW
E10	LOW
E10D	LOW
E11	LOW
E11D	LOW
E14	LOW
E15	LOW

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Attachment 2. Table of operating power of the tips

Scaling	
Tip Model	Power
GD1	LOW-HIGH
GD2	LOW-HIGH
GD3	LOW-HIGH
GD4	LOW-HIGH
GD5	LOW-HIGH
GD6	LOW-HIGH
GD7	LOW-HIGH
GD8	LOW-HIGH
GD9	LOW-HIGH
GD10	LOW-HIGH
GD11	LOW-HIGH

Cavity Preparation	
Tip Model	Power
SBD1	LOW-HIGH
SBD2	LOW-HIGH
SBD3	LOW-HIGH
SBDL	LOW-HIGH
SBDR	LOW-HIGH

Periodontics	
Tip Model	Power
PD1	LOW-MID
PD2L	LOW
PD2LD	LOW
PD2R	LOW
PD2RD	LOW
PD3	LOW-MID
PD3D	LOW-MID
PD4	LOW-MID
PD4D	LOW-MID

Endodontics	
Tip Model	Power
ED1	LOW
ED2	LOW
ED3	LOW
ED3D	LOW
ED4	LOW
ED4D	LOW
ED5	LOW
ED5D	LOW
ED6	LOW
ED7	LOW
ED8	LOW
ED9	LOW
ED10	LOW
ED10D	LOW
ED11	LOW
ED11D	LOW
ED14	LOW
ED15	LOW

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Attachment 3. Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing

1. BEGINNING WORK!

1.1 Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.

1.2 To prevent injury to people and damage to property, please heed the corresponding directives.

1.3 The instructions in this manual are only applicable to the equipment which it was delivered with.

2. INTRODUCTION

2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.

2.2 The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer's medical and dental instruments are based on the potential risk of infection associated with their use.

2.3 It is recommended to use steam sterilization.

2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.

2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.

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2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

3. REPROCESSING - INSTRUCTIONS FOR REUSABLE PRODUCTS

The instructions are binding for the reprocessing of all reusable products (Here after called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

Important: Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used.

Reusable products must be cleaned and sterilized prior to first use. They must be replaced after the number of operations specified by the manufacturer. Disposable products (single use) cannot be reused.

4. PREPARATION - Basic principles

4.1 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.

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

5. POST-OPERATIVE TREATMENT

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

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Steps:

1.Rinse away any surface soiling on the product with distilled deionized water or with a cleaning agent.

2.Rinse through all lumina (e.g. irrigation and aspiration connection) at least 3 times in the normal direction of flow (no back rinsing) using a disposable syringe (min. volume 50 ml) filled with distilled/deionized water applied to the back nozzle.

3.An aldehyde-free cleaning and disinfection solution that is compatible with the products may also be used as an alternative rinsing solution. In such cases, it is necessary to rinse thoroughly afterwards at least 3 times with distilled, or deionized water.

6. CLEANING/DISINFECTION:

6.1 MECHANICAL REPROCESSING

Disinfection must be performed no later than 2 hours after the cleaning phase.

A machine cleaning and disinfection method should always be used for cleaning / disinfection because of the increased effectiveness of this method.

6.2 MECHANICAL CLEANING AND DISINFECTION

6.2.1 Thermal disinfection should be used if this function is available on your disinfector. Use if possible a disinfecting cycle compliant with the standard EN ISO 15883.

6.2.2 Note that there is a risk of disinfectant residue on products when using chemical disinfectants.

6.2.3 Ensure the following criteria are met when selecting a disinfector system:

•Disinfector is proven effective through testing (e.g. FDA approved or CE marked/EN ISO 15883 compliant).

•Disinfector has suitable baskets to hold small fragile products and has rinsing connections for the

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attachment to product lumina.

•The cleaning program is suitable for products to be processed and the rinsing cycle is sufficient.

•Only low microbe count (<10 cfu/ml) distilled or deionized water is used for all rinsing steps. (E.g. Aqua purificata, as per the specifications of Pharm. Eur. or USP).

•Air used for drying is HEPA filtered.

•Disinfector is serviced and checked on a regular basis.

6.2.4 Ensure the following criteria are met when selecting a cleaning and disinfection agent:

•Chemicals are compatible with products.

•With non-thermal disinfection, a suitable disinfectant with tested effectiveness (e.g. FDA approved or CE marked), that is compatible with the cleaning agent, must be used.

⚠Concentrations and contact times specified by the manufacturer of the cleaning and disinfection agent must be followed. Only freshly prepared solutions may be used.

6.2.5 Steps for mechanical cleaning and disinfection with a disinfector

1) Load the WD with the instruments on the tray and start the WD with a full load. Run the cleaning cycle of the "surgical instrument" programme in accordance with the manufacturer's instructions.

Instrument cleaning program:

- pre-wash (5 minutes, ambient temperature water)
- cleaning (5 minutes, 0.5% neutral pH detergent, 40˚C)
- rinse I (1 minute, ambient temperature water)
- rinse II (1 minute,ambient temperature water)
- disinfection (2.5 minutes, pure water 93˚C)

2) Immediately after the cleaning cycle, interrupt the program and unload the samples.

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3) After cleaning in the WD, examine the instruments visually.

4) Carefully place the products in the disinfection basket. Fastening of the products is only permissible if they are freely moveable in the fixture. The products are not permitted to make contact with one another.

5) Using a suitable rinsing adaptor, connect the product lumina to the rinsing connections of the disinfector.

6) Start the program.

7) Remove the products from the disinfector and start the inspection (see section Inspection and maintenance) after the program ends.

8) Wrap the products directly following disinfection and drying (see section Packaging and sterilization). If necessary, repeat drying of the product in a clean place.

7. INSPECTION AND MAINTENANCE

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

8. PACKAGING AND STERILIZATION

⚠ **Do not exceed the maximum number of sterilization cycles.**

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

•Compliant with EN ISO 11607,

•Resistant to 138°C, with adequate steam permeability,

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•Maintained on a regular basis.

If double, single-use sterilization packaging (double bag) is to be used, this must also comply with EN ISO 11607 and be suitable for steam sterilization (temperature resistant to 138°C with adequate steam permeability).

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

•Fractional pre-vacuum procedure (steam sterilization with repetitive pre-vacuum.)

•Steam sterilizer in accordance with EN 13060 or EN 285 validated in compliance with EN IS0 17665,

•Maximum sterilization temperature 138°C,

•Sterilization time at least 3 min. at 134°C (fractional pre-vacuum procedure),

•Sterilization at 134°C for a maximum of 20 minutes is permissible.

⚠ The hot-air sterilization and radio-sterilization procedure may not be used (as it causes the destruction of products).

⚠ The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization). In such cases, please observe the respective valid standards (EN IS0 14937/ANSI AAMI IS0 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

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9. SERVICE LIFE

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in aging of the products.

If the number of permissible re-sterilization cycles is restricted, this will be pointed out in the product specific instructions.

The use of ultrasound baths and strong cleaning and disinfection fluids (alkaline pH > 9 or acid pH< 5) can reduce the life span of products. The manufacturer accepts no liability in such cases.

The products may not be exposed to temperatures above 138°C.

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After service and Warranty Instruction

1 Period validity:

Two year's free repair for the main unit, one year's free repair for the handpiece from the date of purchase. Lifetime maintenance.

2 Range of warranty:

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

3 The followings are beyond our warranty:

1) The damage caused by disobeying the operation instruction or lack of the needed condition.
2) The damage caused by unsuitable operation or disassembly without authorization.
3) The damage caused by unadvisable transportation or preservation.
4) There isn't the seal of distributor or the warranty card isn't filled in completed.

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After service and Warranty Instruction

Name of Customer	
Address	
Post Code	
Tel	
E-mail	
Purchase Date	
Distributor	
Model	
Product No.	
Handpiece No.	
Production Date	