

Ultrasonic Scaler Instruction Manual

(Series N2000 / N3000)

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.

- Use a separate, grounded power outlet. Never use wet hands to unplug the power cord.
- 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.
- Keep the scaler clean before and after operation. The scaling tip, wrench and handpiece must be sterilized before each treatment.
- 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.
- Don't twist or rub the tip. Change a new one when the tip is damaged or worn excessively.
- Don't screw the scaling tip while stepping on the foot switch.
- Don't use impure water source, and be sure not to use normal brine instead of pure water source.
- 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.
- Don't knock or rub the handpiece. Do not pull the cable while the device is working, to avoid damage to the cable.
- 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.
- 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.
 - The changed components are original of our company and operated correctly according to instruction manual.
- 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.

Symbol instruction

Symbol	Instruction	Symbol	Instruction	Symbol	Instruction
	Caution		Refer to instruction manual		Date of manufacture
	Manufacturer		Class II equipment		Type B applied part
	Power adjustment		Keep dry		Protected against dripping water
	For indoor use only		24VAC power supply socket		Sterilizable in a steam sterilizer (autoclave) at 134°C
	Atmospheric pressure limitation: 70kPa-106kPa		Water entrance pressure: 0.01MPa-0.5MPa		Temperature limit: -20°C +55°C
	Humidity limitation: 10%-93%		Waste electrical and electronic equipment		CE marking with identification number of the Notified Body
	Fragile, handle with care		Recovery		Medical device
	Unique device identifier		Serial number		

Product Introduction

1.1 Product overview

The 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 at adults and children in hospital and dental clinic, and 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:
- Detachable handpiece can be autoclaved under 134 °C and 0.22 Mpa.
 - Automatic frequency tracking ensures that the device always works on the best frequency, stable and efficient performance.

1.2 Contraindications

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

1.3 Equipment safety classification

- Operating mode: Continuous operation
- Type of protection against electric shock: Class II
- Degree of protection against electric shock: Type B applied part
- Applied part of the equipment: Tip
- Degree of protection against ingress of water: IPX0 (main unit)
- Degree of protection against ingress of water: IPX1 (foot switch)
- 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

- Environment temperature: +5°C - +40°C
- Relative humidity: 30% - 75%
- Atmosphere pressure: 70kPa - 106kPa
- 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.

Table 1: Technical Parameters of each model (Serial N2000)

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
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	<90µm	<90µm	<90µm	<90µm
Tip vibration frequency	28kHz±5kHz	28kHz±5kHz	28kHz±5kHz	28kHz±5kHz
Output power of tip	3W-20W	3W-20W	3W-20W	3W-20W
Half-excursion force	0.5N-2N	0.5N-2N	0.5N-2N	0.5N-2N
Water entrance pressure	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa

Table 2: Technical Parameters of each model (Serial N3000)

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

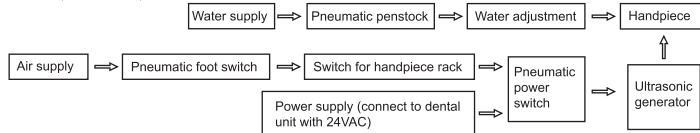
Parameters	N3000	N3000L	V3000	V3000L
Input	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A	24VAC 50Hz/60Hz 1.3A
Fuse of main unit	T1.6AL 250V	T1.6AL 250V	T1.6AL 250V	T1.6AL 250V
Primary tip vibration excursion	<90µm	<90µm	<90µm	<90µm
Tip vibration frequency	28kHz±5kHz	28kHz±5kHz	28kHz±5kHz	28kHz±5kHz
Output power of tip	3W-20W	3W-20W	3W-20W	3W-20W
Half-excursion force	0.5N-2N	0.5N-2N	0.5N-2N	0.5N-2N
Water entrance pressure	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa	0.01-0.5MPa

Installation and adjustment

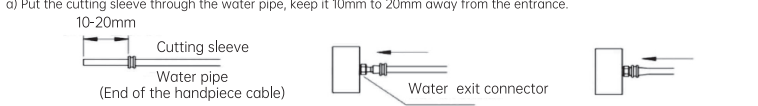
2.1 Working principle

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.



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.

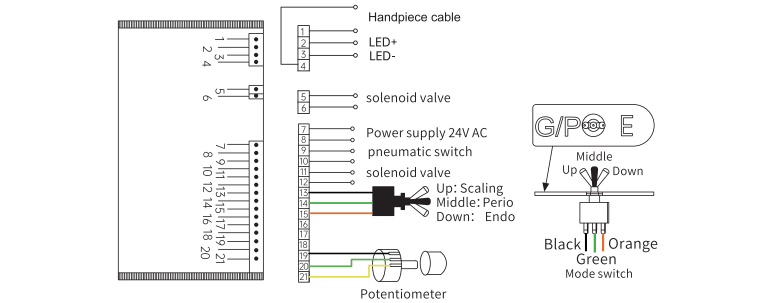


- Put the water pipe in the middle of the water exit connector (about 3mm), then push the cutting sleeve forward to the front edge of the water exit connector.
- Pinch the cutting sleeve and the water pipe with your fingers, push them forward at the same time until they are wrapped into the water exit connector fully. Then the cutting sleeve is in the middle of the water exit connector.

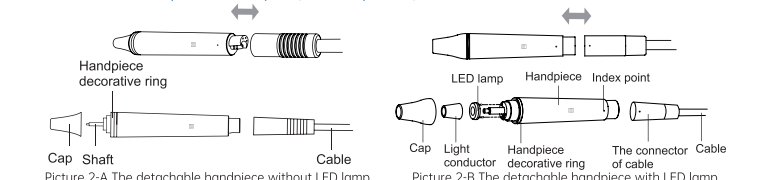
Notice: Cut off the forepart of the water pipe about 6 mm if repeat the above operation.

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

- Please connect power and pneumatic switch (or foot switch) showed as picture 1.
- The No.7 lead and No.8 lead should be connected with 24VAC, and this circuit isn't allowed to act as switch circuit.
- 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.
- 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.
- 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" is for ultrasonic scaling treatment mode, the middle of the green wire marked "P" is periodontal treatment mode and the orange wire marked "E" is for root canal scaling mode.
- 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.
- The followings should be noticed during installation.
 - Pneumatic power switch, pneumatic penstock and pneumatic foot switch are equipped by manufacturers of the dental unit or the end-users.
 - 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.
 - Keep enough space for dispersing heat of ultrasonic generator.
 - Built-in ultrasonic scaler without transformer occupies some space, and works with current 24VAC, power ≥20W.
 - Before turning on the scaler, turn the potentiometer knob to the minimum and the water control switch to the maximum.
 - 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.



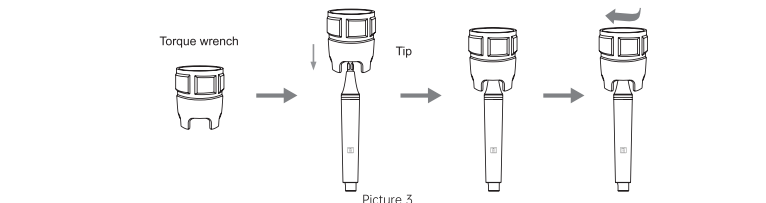
2.3 Instruction for main components of handpiece (showed in picture 2).



- Cap: The Cap can be removed. You can screw out the Cap and clean the pole with alcohol termly.
- Decorative ring: can be disassembled and cleaned with alcohol regularly, can be autoclaved under the high temperature and pressure.
- Handpiece: The main part of the whole handpiece, can be autoclaved under the high temperature and pressure.
- Symbol: Autoclaved (134°C, 0.22MPa)
- The connector of the cable: Connect the handpiece with the water source and power of the main unit.
- 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.

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

2.4 Instruction for using the wrench to install tip



- 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.
- 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.

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

Function and operation

3.1 Scaling function

- 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").
- 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 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.

Notice: 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.

Notice: Do not use tips that have been worn-out to unfit for use. To reach the clinical effect, the operator should replace the tips at these circumstances where:

- obvious damage to be found or being significantly shorter by comparing tips in the use with those unused and/or;
- insufficient flushing performance and/or;
- more tip vibration with obvious collision sound and/or;
- degradation of vibrating intensity and scaling effect.

Notice: 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)

- Usage process
 - Fix endo holder to handpiece by endo wrench.
 - Unscrew the screw cap on the endo holder.
 - Put the ultrasonic file into the hole in the front of endo holder.
 - Screw the screw cap with endo wrench to tight up the ultrasonic file.
 - 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.
 - Step on the foot switch to start endo treatment.
 - 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:

- When fixing endo chuck, it must be screwed down.
- The screw cap on the endo chuck must be screwed down.
- Don't press it too hard when the ultrasonic file is in root canal.
- 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:

- Clean the handpiece with compressed air before sterilization.
- Be sure that the scaling tip has been unscrewed from the handpiece and it cannot be sterilized with others.
- 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.
- 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.
- The following sterilizing methods are forbidden:
 - Boil in water.
 - Dip in iodine, alcohol and glutaraldehyde.
 - Bake in oven or microwave oven.

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

5 Transportation, storage and maintenance

5.1 Transportation

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

5.2 Storage

- Don't store the machine together with the articles that is combustible, poisonous, caustic, or explosive.
- 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 +55°C.

5.3 Maintenance

- 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.

