REFINE CE 0123

RF-SN2-M002 Version: 3.1 20250207

Ultrasonic Scaler Instruction Manual

(Series N2000 / N3000)

Please read this manual before operating

Guilin Refine Medical Instrument Co., LTD.

⚠ 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.
• 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.
13.The device must not be used in MRI environment for the device is easily affected by the electromagnetic emission and would not work or work normally.
14.When you meet circumstances where the main unit expires, the misuses lead to the short circuit of the circuit board or accidentally dropping the device results in the damage of components, the device should no longer be reused.

⚠ **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	IPX1	Protected against dripping water
	For indoor use only	24VAC	24VAC power supply socket	134℃	Sterilizable in a steam sterilizer (autoclave) at 134℃
106kPa 70kPa	Atmospheric pressure limitation: 70kPa-106kPa	H_2O 0.01Mpa-0.5MPa	Water entrance pressure: 0.01MPa-0.5MPa	-20℃ +55℃	Temperature limit: -20℃- +55℃
10% 93%	Humidity limitation: 10%-93%		Waste electrical and electronic equipment	CE 0123	CE marking with identification number of the Notified Body
	Fragile, handle with care		Recovery	MD	Medical device
UDI	Unique device identifier	SN	Serial number		

1 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:
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 Intended use

The ultrasonic scaler is intended use in periodontology, for the removal of plaque and calculus, for the cleaning of tooth surfaces and root canals.

1.3 Intended patient population

Adults and pediatrics with the periodontal disease treatment or periodontal cleaning regularly.

1.4 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, pregnant woman and children should be cautious to use the equipment.

1.5 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
4) Applied part of the equipment: Tip
5) Degree of protection against ingress of water: IPX0 (main unit)
6) Degree of protection against ingress of water: IPX1 (foot switch)
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.

1.6 Working condition

1) Environment temperature: +5°C - +40°C
2) Relative humidity: 30% - 75%
3) Atmospheric pressure: 70kPa - 106kPa
4) Temperature of the water at the inlet: not higher than +25°C

1.7 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: "O" 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
Tip thread specifications for compatibility	M3*0.5	M3*0.5	M3*0.6	M3*0.6
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 1.5A	24VAC 50Hz/60Hz 1.5A	24VAC 50Hz/60Hz 1.5A	24VAC 50Hz/60Hz 1.5A
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

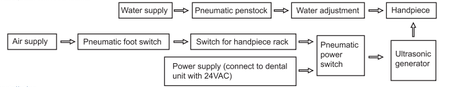
Table 2: Technical Parameters of each model (Serial N3000)

Parameters	N3000	N3000L	V3000	V3000L
Tip thread specifications for compatibility	M3*0.5	M3*0.5	M3*0.6	M3*0.6
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
Input	24VAC 50Hz/60Hz 1.5A	24VAC 50Hz/60Hz 1.5A	24VAC 50Hz/60Hz 1.5A	24VAC 50Hz/60Hz 1.5A
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

2 Installation and adjustment

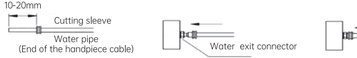
2.1 Working principle

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.

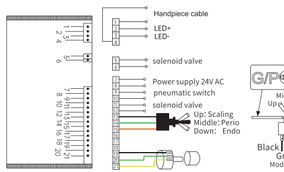


2.2 Installation

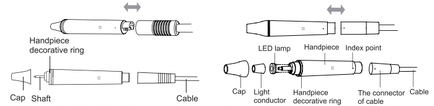
2.2.1 Cutting sleeve use instruction
a) Put the cutting sleeve through the water pipe, keep it 10mm to 20mm away from the entrance.



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.
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" 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.
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.
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.



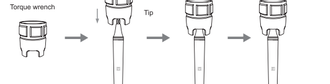
2.3 Instruction for main components of handpiece (showed in picture 2).



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 ternmly.
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.
⚠**Notice:** 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 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.
⚠**Notice:** 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 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.**
⚠**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;
- degration 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)

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.
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 procedures 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.
•Recommended sterilization cycles of handpiece: 300 cycles
•Recommended sterilization cycles of torque wrench and endo wrench: 300 cycles
⚠**Notice:**
a) For cleaning and disinfection, use disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts). Use of other disinfectants may cause discoloration or cracking.
* For details, contact the manufacturer of the disinfectant.
* In this operation manual, disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts) is called by "disinfectant alcohol".
b) Clean the handpiece with compressed air before sterilization.
c) Be sure that the scaling tip has been unscrewed from the handpiece and it cannot be sterilized with others.
d) 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.
e) 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.
f) 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

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℃+55℃.

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.

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.

Fault	Possible causes	Solutions
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.
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.
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 EMC - Declaration of conformity

8.1 Instructions for use

The ME EQUIPMENT or ME SYSTEM is used in hospitals or dental clinics.
Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Warning : Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Warning: The use of cables and accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity.
List of all cables

No	Name	Length	Shielded or not	Detachable or not	Note
1	Potentiometer wire	0.6m	No	Yes	/
2	Toggle switch connecting wire	0.6m	No	Yes	/
3	Handpiece cord	2.0m	No	Yes	/

Replaceable accessories

No	Name	Model	Manufacturer	Connection method	Note
1	Handpiece	HP-3H, HP-5L, HS-7H, HS-7L	GUILIN REFINE MEDICAL INSTRUMENT CO., LTD	Plug	/

Essential performance
The ultrasonic scaler has neither life sustaining functions nor diagnostic of life supporting functions.
The following functions are observed:
- Continuous working of ultrasound
- Continuous working of water flow
- Continuous light on handpiece
When abnormal performance is observed, supplementary measures may be necessary, such as reorientating or relocating the built-in ultrasonic scaler.

8.2 Technical description

8.2.1 All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life:
(1)Portable and mobile RF communications equipment may affect the performance of equipment , use of equipment should be avoided strong electromagnetic interference, and do not closer to mobile phone, microwave oven, etc.
(2)Use of equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
(3)Except for the cables sold by manufacturers of as spare parts of internal components, the use of accessories and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
(4)Use of accessories, transducers and cables other than those specified or provided by the manufacturer together with equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
8.2.2 Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer' s declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity test	**IEC 60601-1-2 Test level**	**Compliance**
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT, 0,5 cycle, At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase, at 0°. 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle, At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase, at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz

NOTE UT is the a.c. mians voltage prior to application of the test level.

Table 3

Guidance and manufacturer' s declaration - electromagnetic Immunity						
	Test frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 test level (V/m)	Compliance level(V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	585	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	450 –470	GMRS 460, FRS 460	FM± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	950					

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	1720	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	15,56 MHz	modulation	7,5	7,5

9 Disposal and Scrapping

The product doesn't contain battery or toxic substances. And there are no components which should be removed specially from the main unit for disposal and scrapping.
After the device is out of its service life, you must not discard it in domestic household waste. Please comply with the Waste Electrical and Electronic Equipment (WEEE) directives and the medical waste disposal regulations of your country.
Torque wrench, endo wrench and handpiece, those which could easily contact to the biological sources and cause biological hazards, shall be detached from the main unit and reprocessed according to the reprocessing treatment in Attachment 2 before the disposal and scrapping.

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)

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

Attachment 2. Table of operating power of the tips

Scaling	
Tip Model	**Power**
GD1	LOW-HIGH
GD2	LOW-HIGH
GD3	LOW-HIGH

Cavity Preparation	
Tip Model	**Power**
SBD1	LOW-HIGH
SBD2	LOW-HIGH
SBD3	LOW-HIGH

Periodontics	
Tip Model	**Power**
PD1	LOW-MID
PD2L	LOW
PD2LD	LOW

Endodontics	
Tip Model	**Power**
ED1	LOW
ED2	LOW
ED3	LOW

GD4	LOW-HIGH
GD5	LOW-HIGH
GD6	LOW-HIGH
GD7	LOW-HIGH
GD8	LOW-HIGH
GD9	LOW-HIGH
GD10	LOW-HIGH
GD11	LOW-HIGH

SBDL	LOW-HIGH
SBDR	LOW-HIGH

PD2R	LOW
PD2RD	LOW
PD3	LOW-MID
PD3D	LOW-MID
PD4	LOW-MID
PD4D	LOW-MID

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

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 product 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.
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

3.1 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.**

3.2 Reusable products must be cleaned, disinfected and sterilized prior to first use. Reprocessing procedures have only limited implications to this device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

⚠ **In case of damage the product should be reprocessed before sending back to the manufacturer for repair.**

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. Preparation at the point of use

Disconnect product. Remove gross soiling of the products with cold water (<40° C) immediately after use. Don't use a fixating detergent or hot water (>40° C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Store the products in a humid surrounding.

6. Transportation

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

7. Preparation for decontamination

The products must be reprocessed in a disassembled state, as far as possible.

8. Pre-Cleaning

Do a manual pre-cleaning, until the products are visually clean. Submerge the products in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

9. Cleaning

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.
Automated Cleaning:
Use a washer-disinfector (WD) meeting the requirements of the ISO 15883 series.
Put the products into the machine on a tray. Connect the products with the WD by using suitable adapter and start the program:
4 min pre-washing with cold water (<40° C)
Emptying
5 min washing with a mild alkaline cleaner at 55° C
Emptying
3 min neutralising with warm water (>40° C);
Emptying
5 min intermediate rinsing with warm water (>40° C)
Emptying
The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

⚠ **Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.**

10. Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).
A disinfection cycle of 5 min disinfection at 93° C has been validated for the product to achieve an A0 value of 5000.

11. Drying

Automated Drying:
Drying of outside of products at 40°C , 5 min through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

12. Functional testing, maintenance

Visual inspection for cleanliness of the products and reassembling if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until products is visibly clean.
Before packaging and autoclaving, make sure that the products have been maintained acc. to manufacturer's instruction.

13. Packaging

Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

14. Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.
Minimum requirements: 3 min at 134 °C (in EU: 5 min at 134 °C)
Maximum sterilization temperature: 138° C
Drying time:
For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.

After sterilization:
a. Remove the product from the autoclave.
b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.
Check that the sterilization wraps or pouches are not damaged.

⚠ **Flash sterilization is not allowed on lumen 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 ISO 14937/ANSI AAMI ISO 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.
•Maximum sterilization temperature 138° C

15. Storage

Storage of sterilized products in a dry, clean and dust free environment with a relative humidity of 10% to 95%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of-20 ° C to +55 ° C, refer to label and instructions for use.

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.

16. 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 devices. 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 (alkaling pH>9 or acid pH<5) can reduce the life span of devices. The manufacturer accepts no liability in such cases.**

⚠ **The devices may not be exposed to temperatures above 138 °C.**

It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

Note: 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.

Shelf life: 10 years, the date of manufacture see product label.

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