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REFINE

CE 1434

Ultrasonic Scaler Instruction Manual

(MaxPiezo7, MaxPiezo7+)

Please read this manual before operating

Guilin Refine Medical Instrument Co., LTD.

RF-MP7-M001-1.1 2021/05/20

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⚠ Safety Precautions

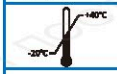
⚠ WARNING: If you neglect these safety precautions, you may cause personal injury such as electric shock, fire or damage to the product.

1.Use a separate, grounded power outlet. Never use wet hands to unplug the power cord.
2.Please put the power plug into the socket easy to pull out, to make sure it can be pulled out in emergency. Please do not use other than the specified voltage.
3.Do not damage, modify, pull, over bend or twist the power cord, do not place heavy objects on the power cord.
4.Do not place the product on unstable workbenches, such as shaky tables, bevels, or vibrations.
5.Keep the scaler clean before and after operation. The scaling tip, wrench and handpiece (detachable) must be sterilized before each treatment.
6.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.
7.Don't twist or rub the tip. Change a new one when the tip is damaged or worn excessively.
8.Don't screw the scaling tip while stepping on the foot switch.
9.Don't use impure water source, and be sure not to use normal brine instead of pure water source.
10.If use the water source without hydraulic pressure, the water surface should be one meter higher than the head of the patient.
11.Don't knock or rub the handpiece. Do not pull the cable while the device is working, to avoid damage to the cable.
12.After operating, turn off electrical source, and then pull out the plug.
13.The screw thread of the scaling tips produced by other manufacturers is maybe coarse, rusty and collapsed, which will damage the screw thread of the handpiece irretrievably. Please use our scaling tip.
14.This equipment is only applicable to the corresponding type of power adapter produced by our company.
15.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.
16.This product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.
17.Indicator light: Other colours: Meaning other than red, yellow, or green, indicated the device ready for use.
18.Statement: the third conductor in the POWER SUPPLY CORD is only a functional earth.

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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
	Foot switch interface		Used indoor only
	Adjustment for the water flow		Can be autoclaved
24VAC	24VAC power supply socket		Appliance compliance WEEE directive, Dispose of as required by the law.
220VAC 110VAC	220VAC power supply socket 110VAC power supply socket	OPTION	Function selection
	Atmospheric pressure for storage	H_2O 0.01Mpa-0.5MPa	Water entrance pressure:0.01MPa-0.5MPa
	Temperature limitation for storage		Humidity limitation for storage
IPX1	Protected against dripping water	EC REP	European authorized representative

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1 Product introduction

1.1 Product overview

Guilin Refine Medical Instrument Co.,Ltd. is a professional manufacturer to research, develope, produce and sell ultrasonic scalers. The product is used for teeth cleaning and also an important device for teeth disease prevention and treatment. The Ultrasonic scaler is composed of main unit, handpiece, cable, water pipe, tip, torque wrench, foot switch, and power supply.

The ultrasonic scaler has following features:

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

1.1.2 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, pregnant 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
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

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1.4 Model and technical Parameters

Parameters	MaxPiezo7	MaxPiezo7+
Size (mm)	180mm*180mm*150mm	180mm*180mm*150mm
Weight of main unit	1.59kg	1.59kg
Weight of power supply	----	----
Rated input	220VAC 50Hz /110VAC 60Hz	220VAC 50Hz / 110VAC 60Hz
Input Power	38VA	38VA
Fuse of main unit	T0.5AL 250V	T0.5AL 250V
Fuse of power supply	----	----
Primary tip vibration excursion	<200μm	<200μm
Tip vibration frequency	28kHz±5kHz	28kHz±5kHz
output power of tip	3W-20W	3W-20W
half-excursion force	0.5N-5N	0.5N-5N
Water entrance pressure	0.01MPa-0.5MPa	0.01MPa-0.5MPa
Handpiece model	HP-3H (Without LED lamp, Detachable)	HP-5L (With LED lamp, Detachable)
Function setting	G, P, E	G, P, E
Touch control	YES	YES
Water bottle	With	With

⚠ **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 mode" ; "P"means "Periodontal mode" ; "E"means "Endodontic mode"

⚠ **Note 3**: Do not replace the fuse of main unit nor the power supply, to avoid safety risks.

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1.5 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

2 Installation and adjustment

2.1 Product installation steps

2.1.1 Unpack the package, make sure that all the parts and accessories are complete according to the packing list, take the main unit out of the box, and put it on the stable plane facing to the operator.

2.1.2 Turn the water control knob to the max, Do not screw it over tight in case of damage.

2.1.3 Insert the plug of the foot switch to the socket.

2.1.4 Connect one end of the water pipe to the water entrance, and the other end to the clean water source.

2.1.5 Connect the handpiece (detachable) to the cable.

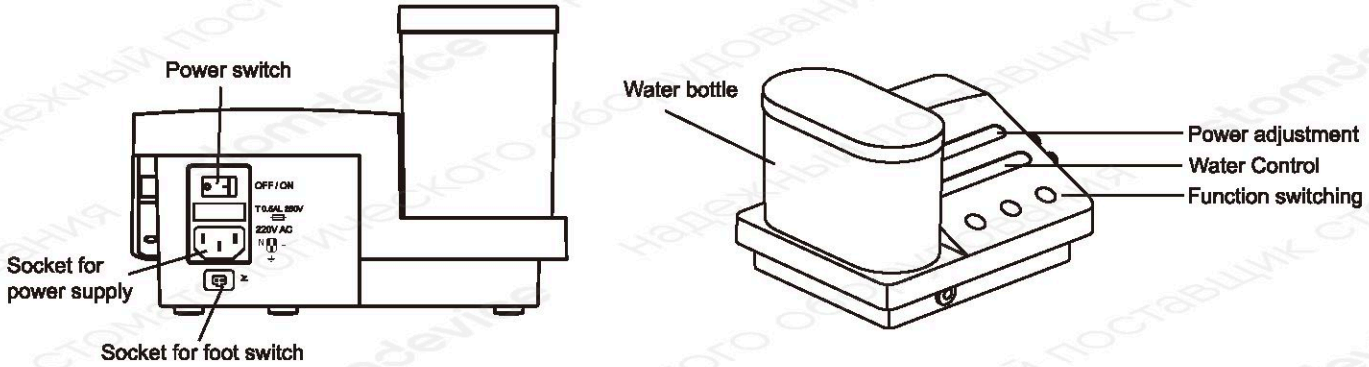
2.1.6 Install the tip on the handpiece and turn on the power switch to start operation.

2.2 The function instructions and the connection diagram

2.2.1 Power adjustment: The models with potentiometer are adjusted by potentiometer, turn on/off the potentiometer to adjust the power; for the models with touch panel, power can be adjusted by finger touch.

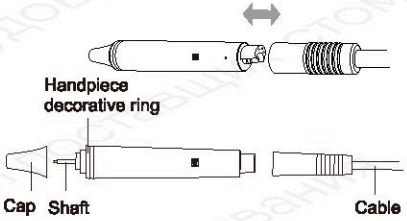
2.2.2 Water adjustment: Water is adjusted by touch panel.

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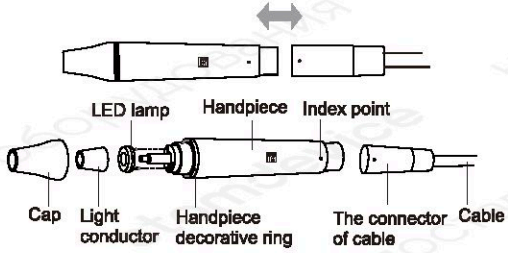


Picture 1 The front view of the main unit (MaxPiezo7, MaxPiezo7+)

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



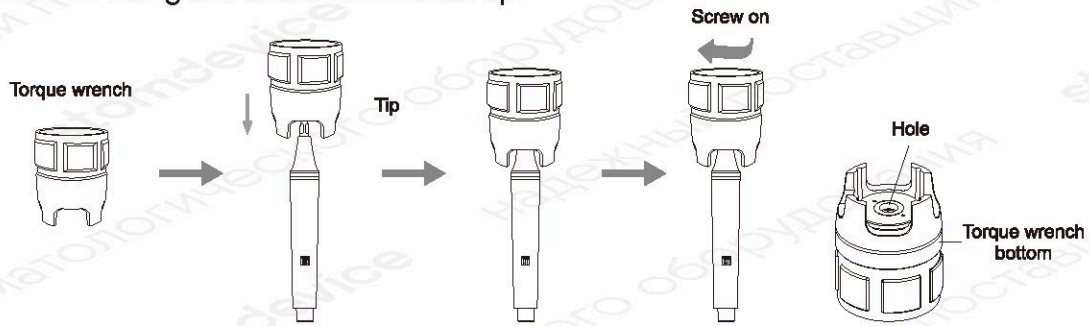
Picture 2-A The handpiece without LED lamp



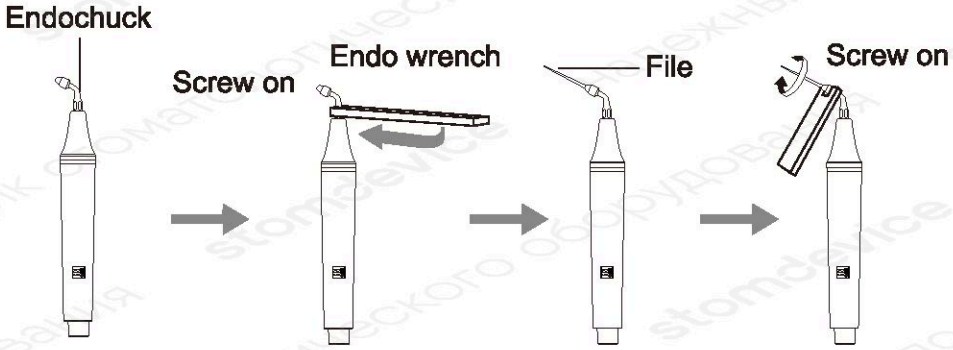
Picture 2-B The handpiece with LED lamp

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2.4 Instruction for using the wrench to install tip



Picture 3



Picture 4

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

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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 (detachable) and the plug must be kept dry.

3 Function and Operation

3.1 Scaling & periodontal treatment function

3.1.1 Turn on the power switch, the power indicator lighted and the machine is ready for work.

3.1.2 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").

3.1.3 The handpiece can be handled in the same gesture as a pen in hand.

3.1.4 Vibrating intensity: 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.

3.1.5 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.

3.1.6 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.

3.1.7 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.

3.1.8 After finishing operation, keep the machine working for 30 seconds with the water supply to clean the handpiece and the tip.

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3.1.9 Unscrew the scaling tip and sterilize it.

⚠ **Note:** Be sure not to make the end of the tip touch the teeth vertically, and not use too much force when the tip touching 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.

⚠ **Note:** When the water is lower than water level lower limit, please open the lid, fill the bottle with adequate purified water and cover the lid.

3.2 Endo function (Root canal treatment)

3.2.1 Fix endochuck to handpiece by endo wrench (See Picture 4).
3.2.2 Unscrew the screw cap on the endochuck.
3.2.3 Put the ultrasonic file into the hole in the front of endochuck.
3.2.4 Screw the screw cap with endo wrench to tighten up the ultrasonic file.
3.2.5 Press option key, turn to endo function.
3.3.6 When ultrasonic scaler turns into endo function, only the first power indicator is on and the power is at the lst grade. Put the ultrasonic file into the patient's root canal slowly, step on the foot switch to start endo treatment. During the treatment, turn up the power gradually according to the needs.

⚠ **Note:**

a) When fixing endochuck,it must be screwed down.
b) The screw cap on the endochuck must be screwed down.
c) Don't press it too much when the ultrasonic file in root canal.
d) Don't step on the foot switch until the ultrasonic file is in root canal.
e) The power range of endo treatment is advised from the lst to the 5th grade.

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

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

5 Cleaning, disinfecting and sterilizing

5.1 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.
5.2 The handpiece (detachable), scaling tips, endochuck, torque wrench, endo wrench, LED lamp and Light conductor (the handpiece with LED lamp) can be sterilized.

⚠ **Notice:**

a) Clean the handpiece (detachable) 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 two 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

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excessively.

e) 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.

6 Transportation, Storage And Maintenance

6.1 Transportation

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

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

6.1.3 Avoid solarization and getting wet in rain or snow during transportation.

6.2 Storage

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

6.2.2 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.

6.3 Maintenance

6.3.1 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.

6.3.2 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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7 Trouble shooting

Fault	Possible cause	Solutions
The scaling tip doesn't vibrate and there is no water flowing out when stepping on the foot switch.	The power plug is in loose contact.	Make the plug insert to the socket well.
	The foot switch is in loose contact.	Insert the foot switch to its socket tightly.
	The fuse in the main unit is broken.	Contact our dealers or us.
The scaling tip doesn't vibrate but there is water flowing out when stepping on the switch.	The tip is in loose contact.	Screw the tip on the handpiece tightly (See Picture 3).
	The connect plug between the handpiece and the circuit board is in loose contact.	Contact our dealers or us.
	Something wrong with the handpiece.	Send the handpiece to our company to repair.
	Something wrong with the cable.	Contact our dealers or us.
The scaling tip vibrates but there is no spray when stepping on the foot switch.	The water control knob is not on.	Turn on the water control knob [note 1].
The vibration of the tip becomes weak.	The tip hasn't been screwed on to the handpiece tightly.	Screw the tip on the handpiece tightly (See Picture 4).
	The tip is loose because of vibration.	Screw on the tip tightly (See Picture 4).
	The coupling between the handpiece and the cable isn't dry.	Dry it by the hot air.
	The tip is damaged [note 2].	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 waterproof "O"ring.
There is water flowing out when turn off the power.	There is impurity in the solenoid valve.	Contact with the local distributor or manufacturer.

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Fault	Possible cause	Solutions
The handpiece generates heat.	The amount of spouting water is too little.	Turn the water control switch to a higher grade [note 1].
	The potentiometer is broken.	Change a new one.
The amount of spouting water is too little.	The water control knob is a low grade.	Turn the knob to a high grade [note 1].
	The water pressure is not enough.	Enhance the water pressure.
	The water pipe is jammed.	Clean water pipe with multi-function syringe [note2].
The vibrating intensity control knob seizes up.	The potentiometer is damaged.	Contact with the local distributor or our company.
The u-file doesn't vibrate.	The screw is loose.	Tighten it.
	Endochuck is damaged.	Change a new one.
There is noise coming from the endochuck.	The screw is loose.	Tighten it.
LED light don't work (Handpiece with LED lamp)	Poor contact	Contact tightly
	Something wrong with LED light	Change a new one
There is no water coming out from the handpiece (automatic water supply mode).	There is air in the water pipe.	Turn the water control to the Max, reinsert the bottle.

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

8 Environmental protection

Please dispose according to the local laws.

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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.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Ultrasonic scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrasonic scaler should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The 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.
RF emissions CISPR11	Class B	The 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity			
The Ultrasonic scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the 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	Floor 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	Main power quality should be that of a typical commercial or hospital environment.

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Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the Ultrasonic scaler requires continued operation during power mains interruptions, it is recommended that the 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 Ultrasonic scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrasonic scaler should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

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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 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.			
[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 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 Ultrasonic scaler. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and the Ultrasonic scaler

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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

⚠ The normal function of the Serial 6 / Serial 5 Ultrasonic scaler may be disturbed by strong Electro Magnetic Interference. If so, simply reset the product to resume normal operation by following the instruction manual. In case the function could not resume, please use the product in other location.

⚠ Without the express consent of manufacture, unauthorized alteration or modification of the equipment may cause electromagnetic compatibility problems of the equipment or other equipment.

⚠ Warning: this device should not be used close to or stacked with other devices. If it must be used close to or stacked, it should be observed and verified to work normally under the configuration used.

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Attachment 1. Table of operating power of the tips (Compatible with EMS)

Scaling	
Tip Model	Power
G1	1-10(G)
G2	1-10(G)
G3	1-10(G)
G4	1-10(G)
G5	1-10(G)
G6	1-10(G)
G7	1-10(G)
G8	1-10(G)
G9	1-10(G)
G10	1-10(G)
G11	1-10(G)

Cavity Preparation	
Tip Model	Power
SB1	1-10(P)
SB2	1-10(P)
SB3	1-10(P)
SBLL	1-10(P)
SBR	1-10(P)

Periodontics	
Tip Model	Power
P1	1-10(P)
P2L	1-3(P)
P2LD	1-2(P)
P2R	1-3(P)
P2RD	1-2(P)
P3/PD3	1-6(P)
P3D	1-6(P)
P4	1-6(P)
P4D	1-6(P)

Endodontics	
Tip Model	Power
E1	1-5(E)
E2	1-5(E)
E3	1-6(E)
E3D	1-3(E)
E4	1-6(E)
E4D	1-3(E)
E5	1-6(E)
E5D	1-3(E)
E6	1-6(E)
E7	1-6(E)
E8	1-10(E)
E9	1-10(E)
E10	1-6(E)
E10D	1-6(E)
E11	1-6(E)
E11D	1-6(E)
E14	1-3(E)
E15	1-3(E)

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Attachment 2. Reprocessing instructions

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.

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s of cleaning, disinfecting and sterilizing

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

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

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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.

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.

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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 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

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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.

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

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(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,
•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

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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.

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 (alkaling 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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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.

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After service and warranty instruction

1 Period validity:

Five 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	

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