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Ultrasonic Surgical System Instruction Manual

(Please Carefully Read This Before Operating)



Guilin Refine Medical Instrument Co., Ltd
RF-MS3-M002 Version: 1.0 Modify: 20221206

Foreword

Before installation, operation, maintenance, or any other conduct on the device, please read this manual carefully. Safety requirements based on the level of risk are listed below the following indications:

Danger (always referring to personnel injury)

Warning (referring to possible property loss)

The manual intends to let users understand the safety requirements, installation, correct instructions for use, and maintenance. Any unexpected problems encountered during the operation shall be reported in time to the after-sale service center of Guilin Refine Medical Instrument Co., Ltd. The manufacturer is NOT responsible for any damage or loss howsoever caused by tampering or modifying the apparatus by any user or unauthorized personnel.

We shall retain our rights to modify apparatus design, product techniques, accessories, instruction manual, and package content at any time without notice.

Guilin Refine Medical Instrument Co., Ltd is committed to continuously upgrading its products, which may entail changes to components of the equipment. If there is any discrepancy between the descriptions contained in this manual and your equipment, please contact the dealer or the REFINE after-sale service for further explanation.

The manual may not be used for purposes other than device installation, operation, and maintenance.

Safety Precautions

Warning: Ignoring the safety precautions may cause injury, fire, or damage to the device by electric shock.

1. Please use an independent power supply socket with ground-connection protection. Do not touch the power plug with wet hands.
2. Please insert the power plug completely into the AD adapter, and do not use other power adapters beyond the specified voltage.
3. Please connect the foot switch before turning on the power switch, and do not hot-plug the foot switch while powering up.
4. The power cable cannot be damaged, modified, dragged, excessively bent, distorted, or put under heavy objects.
5. Please do not place the product on an unstable countertop, such as rickety tables, slopes, or somewhere vibrating.
6. Please keep the equipment clean and clear, and disinfect the handpiece, Ultrasonic Surgical System tips, torque wrench, and other accessories before and after use.
7. The tip must be screwed up to the handpiece with the torque wrench; make sure the Ultrasonic Surgical System tip is working with water spray; evacuate the water inside the rear line of the handpiece every time before using.
8. Please do not twist or burnish the tip. Change a new one when the tip is damaged or excessively worn out.
9. Please do not screw the tip while stepping on the foot switch or the equipment is working.
10. Instead of pure water, please do not use unpurified water sources or normal saline.
11. Please do not hit, scrape, or burnish the handpiece, or pull out the cable while the device is working, to avoid unnecessary damage.
12. Switch off power and unplug after using the device.
13. The internal screw thread of Ultrasonic Surgical System tips produced by some manufacturers are maybe coarse, rusty, or fractured, which will damage the external screw thread of our product irretrievably. Please use our Ultrasonic Surgical System tips.
14. The product is intended for use in hospitals and dental clinics only. The users must be professionally trained and qualified dentists and comply with the related operation standards of the medical department and relevant laws while using. Please prepare enough protective equipment such as goggles and masks to avoid infection when operating.
15. The product will initialize its work setting after powering off, and operators shall release the foot switch in time in case of power cuts.
16. Choose appropriate Ultrasonic Surgical System tips and set compatible power intensity according to different practical requirements (For details, Appendix: Publication of Compatibility Description and Output Characteristics of Ultrasonic Surgical System tips)
17. Do not use the handpiece when is not completely cool after autoclaving.
18. As a professional manufacturer of medical instruments, we are only responsible for safety under the following conditions:
 - The maintenance, repair, and modification are made by the manufacturer or the authorized dealer.
 - The exchanged components are original of our company and operated correctly according to the instruction manual.
19. Guilin Refine Medical Instruments Co., Ltd takes no responsibility for any direct or indirect damage or loss under the following conditions:
 - If the device is used for any purpose beyond the mentioned range of application.
 - If the user does not use the device according to the procedures and requirements written in the manual.
 - If the wiring system of the usage scenario does not meet the appropriate standards and requirements.
 - If any assemble operations, extensions, settings, alterations, or repairs have been carried out by personnel not authorized by REFINE;
 - If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications

Danger:

1. Range of application: The device can only be applied in the range mentioned in the manual (see 1.2). Misconduct may cause injury to patients or operators, and damage or invalid operation to the device.
2. Contraindications: Patients or operators with pacemakers or any electronic implant items cannot use this device, or else the electric scalpel may impact them.
3. Sanitation: As all the new and repaired products shipping without sterilization, please strictly follow section 4 to clean, disinfect, and sterilize the products.
4. Pre-check: While using the device, make sure there is no liquid under it; pre-check whether the device and its components function normally; if any problem is encountered, do not operate it arbitrarily and timely contact the authorized technical service center.
5. Damage and insert abrasion: High-frequency vibration and abrasion may occasionally damage the inserts, and deformed inserts are easy to be damaged while using, which is prohibited to be used. Operators should guide patients on how to breathe to not inhale debris from the inserts.
6. Avoid explosives: Do not place the device where there is at any potential explosion risk, including flammable gas such as anesthetic mixtures, pure oxygen, etc.
7. Close the pump cover: Make sure to close the cover of the peristaltic pump; do not leave the pump cover open when stepping on the foot switch. (Fig.5-Ref. B) The operating components may injure operators.

Symbol Instructions

Symbol	Implication	Symbol	Implication	Symbol	Implication
	Caution		Refer to instruction manual/booklet		Waste electrical and electronic equipment
	Recovery	IPX1	Protected against dripping water		For indoor use only
	Date of manufacture		Manufacturer		Alternating current
ON/OFF	Power switch		Type B applied part		Foot switch
Water	Water intensity	Power	Power intensity	B	Switch to bone cutting function
P	Switch to perio treatment function	E	Switch to endo treatment function	C	Switch to cleaning function
	Temperature limit: -20°C- +40°C		Atmospheric pressure limitation: 70kPa-106kPa		Humidity limitation: 10%-93%
	Keep dry		Fragile, handle with care		Sterilizable in a steam sterilizer (autoclave) at 134°C

1. Product Introduction

1.1 Product overview

The Ultrasonic Surgical System is produced by Guilin Refine Medical Instrument Co., Ltd, and its principle is to convert the sound energy of the ultrasonic frequency source into mechanical vibration through the transducer and utilize the inverse piezoelectric effect to generate ultrasonic oscillation, and then the Ultrasonic Surgical System tip will correspondently be stimulated to resonate. After the Ultrasonic Surgical System tips with different shapes and structures of ultrasonic vibration contact the working area, the ultrasonic vibration is applied to bone tissue through the Ultrasonic Surgical System tips to achieve cutting and breaking.

1.2 Range of Application

The MaxSurgeryIII is a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied to in almost any anatomical situation. This equipment can be used in the following fields:

- a) Oral surgery;
- b) Orthopedic surgery;
- c) Maxillofacial surgery;
- d) Cosmetic surgery;
- e) Neurosurgery;
- f) Otolaryngology.

1.3 Structure and Composition

The product is composed of MaxSurgery III (including a peristaltic pump, a pump tube, a pump tube connector, and a support rod of infusion bottles), a handpiece HB-1L (including a handpiece rack and a handpiece connector), a foot switch RFS05, Ultrasonic Surgical System tips US1/US2/US4/US5/UL3/UC1 (including Ultrasonic Surgical System tips rack), a torque wrench, and an adapter cable.

1.4 Contraindications

- 1) The hemophilia patient is forbidden to use this equipment.
- 2) Patients or doctors with heart pacemakers are forbidden to use this equipment.
- 3) The heart disease patient, pregnant women, and children should be cautious to use the equipment.
- 4) Patients with oral and maxillofacial infections, uncured oral mucosal diseases, periapical diseases, gingival diseases, periodontal diseases, oral tumors and other diseases are prohibited;
- 5) Patients with allergic constitution and a history of drug allergy are prohibited;
- 6) Use cautiously with patients with mental disorders.
- 7) Patients with serious systemic infectious or systemic diseases, such as heart, liver, kidney, hematopoietic system, digestive system, endocrine system and other diseases, should be cautious;
- 8) Pregnant women or lactating women, and fertile women who have recently had a birth plan, should use with caution.

1.5 Working Conditions

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

1.6 Model and Technical Parameters

Table 1 Technical Parameters

Parameters	MaxSurgery III
Size(mm)	290mm*270mm*125mm
Weight of the main unit	3kg
Power Supply	100-240V.a.c. 50Hz/60Hz
Input Power	120VA
The fuse of main unit	2×T1.6AL 250V
Mode of operation	Non-continuous operation, function for 60 sec and pauses for 10 sec
Working frequency	26.0kHz±3.0kHz
Discharge of water	30-125ml/min
Protective system and steady APC running time	Connect without handpiece 10ms, line break 10ms, broken or untight Ultrasonic Surgical System tips < 500ms, ground protection connect 10ms
Waterproof grade	IPX1(main unit), IPX1(foot switch)
Handpiece cable	Recommend to use under 100 reprocessing cycles
Pump tube	Recommend to use under 8 reprocessing cycles
Ultrasonic Surgical System tips holder and pump tube connector	Recommend to use under 1000 reprocessing cycles
Operating modes	B, P, E, C
Control Method	Touch screen
Type of protection against electric shock	Class I
Level of protection against electric shock	Type B applied part
AP or APG equipment	No
Defibrillation discharge effect protection	No
Signal output or input	No
Permanently installing equipment	No
Software edition	V 1.0.0

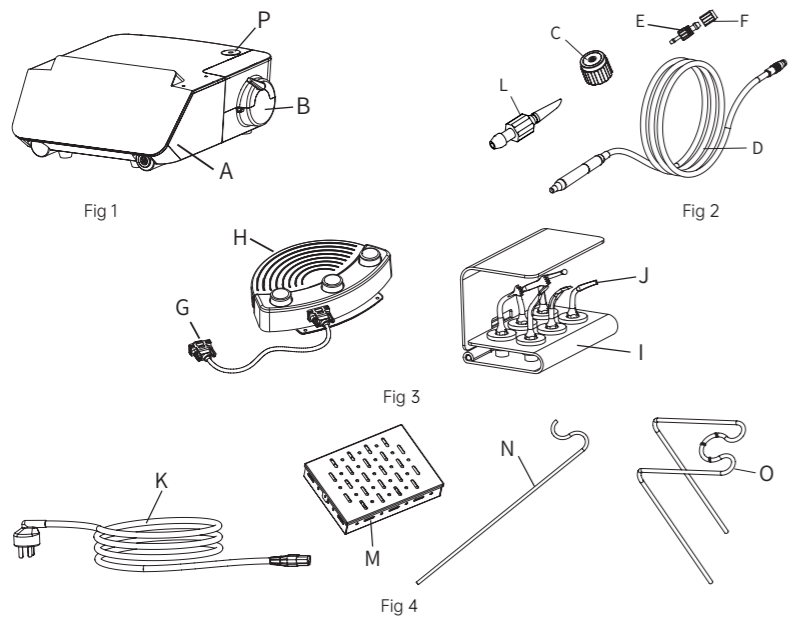
Notice: the definition of operating modes: B (Bone cutting), P (Periodontal Treatment), E (Endodontic Treatment), C (Cleaning)

1.7 Accessory Specification

Accessories/Components	Specifications	Quantity	Replacement	Reference
Main unit	/	See packing list	Can be used long-term, contact the manufacturer if is damaged	Fig1
Handpiece (detachable)	HB-1L	See packing list	Can be used long-term. When the output power decreases significantly or does not work, it should be replaced. It should be returned to the manufacturer for replacement. It is recommended to replace after 100 reprocessing cycles.	Fig2-D
Silicon tube 4*6 (50cm)	/	See packing list	It is recommended to replace after 8 reprocessing cycles.	Fig8-C
Power cable	/	See packing list	Can be used long-term. Replace it when it's cracked or non-conductive.	Fig4-K
Ultrasonic Surgical System tips	see attachment	See packing list	It should be replaced when it has been reused 20 times or worn out.	Fig3-J
Torque wrench	TW-6L	See packing list	It is recommended to replace after 1000 reprocessing cycles. Replace it according to the manual after damage.	Fig2-C

Accessories/Components	Specifications	Quantity	Replacement	Reference
Foot switch	RFS05	See packing list	Can be used long-term. Replace it according to the manual after damage.	Fig3-H
Handpiece rack	/	See packing list	Can be used long-term. Replace it according to the manual after damage.	Fig4-O

Warning: to avoid safety risks, the fuse of the main unit or power supply should not be changed by users.



2 Product Installation

2.1 Safety requirements during installation

Danger: The wiring system of the premises where the apparatus is installed and used must comply with the applicable standards and the relevant electrical safety requirements.

Danger: Do not install the apparatus in places where there is a risk of explosion. The apparatus may not be used in areas where there are inflammable atmospheres (anesthetic mixtures, oxygen, etc.)

Danger: Install the apparatus in a place where it will be protected from blows and from accidental sprays of water or other liquids.

Danger: Do not install the device on or in the vicinity of sources of heat. Install it in such a way that there is adequate circulation of air around it. Leave sufficient free space around it, in particular concerning the fan on the rear. (Fig.5)

Warning: Do not expose the apparatus to direct sunlight or sources of UV light.

Warning: The apparatus is transportable, however, it must be handled with care when it is moved.

Warning: Keep dry around the junctions before connecting cables. Blow-dry it with an air gun if necessary.

2.2 Initial Installation

To ensure perfect operation, the equipment must be installed in strict accordance with the manual.

2.3 Accessory connection

Warning: The accessories listed as follow should be connected with the MaxSurgery III

2.3.1. Installation of Foot switch

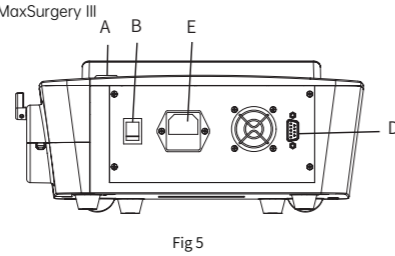
Connect the foot switch to the casting of the device by inserting the plug into the foot switch socket; (Fig5-Ref.D)

2.3.2. Power Supply Connection

Plug the power cable into the connector on the casting of the device and then into the power outlet; (Fig5-Ref.E)

2.3.3. Infusion bottle rod installation

Insert the rod for supporting the bag into the holes provided for it (Fig.5- Ref. A)



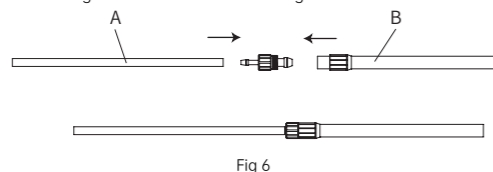
2.3.4. Tubes and Handpiece connection

1) See the sterilize box (Fig4-Ref.M), and insert the smaller end of the pump tube connector into the handle water supply pipe (Fig6-Ref.A)

2) Connect the round end of the infusion bag needle (Fig2-Ref.L) to the other end of the pump tube.

3) Insert the tip of the infusion bag into the saline bag (infusion bag)

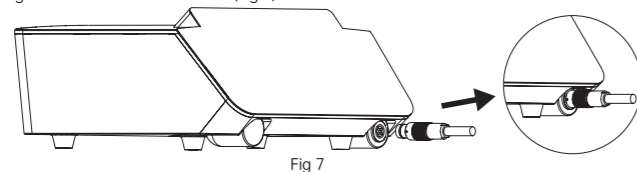
Notice: Disposable infusion tubes and infusion bottles mentioned in the above attachments need to be purchased separately. It is recommended to purchase ones with the registration of the Food and Drug Administration.



2.3.5. Handpiece Installation

1) Put the handpiece on the handpiece rack (Fig.4-Ref. O), and clamp the end of the handpiece tail wire into the small groove of the rack to avoid falling off.

2) Insert the handpiece plug into the socket of the device (Fig.7)



2.3.6. Installation of pump tube on peristaltic pump

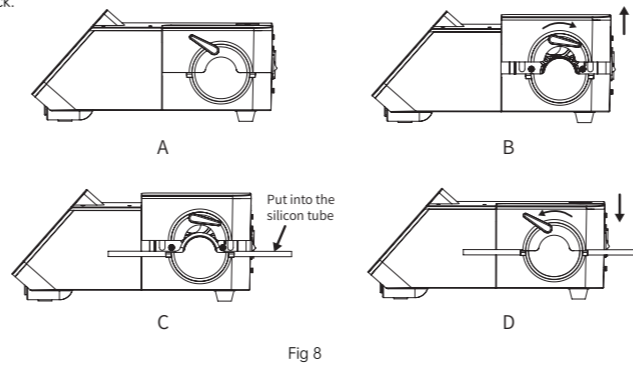
1) Open the pump cover (Fig.8-Ref. A) as wide as possible.

2) Place the pump tube in the impeller (Fig.8-Ref. B)

3) Close the pump cover completely (Fig.8-Ref. C)

Danger: Must make sure the pump cover is completely closed.

The foot switch of the Ultrasonic Surgical System should never be activated with the lid of the peristaltic pump open. The operating parts may hurt the operator. The pump tube shall be installed in the corresponding slot of the peristaltic pump, otherwise, it may cause the stepper motor to block.

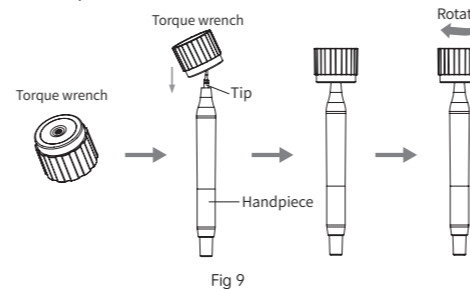


2.3.7. Ultrasonic Surgical System tip installation

1) Choose a Ultrasonic Surgical System tip needed from the sterilize box (see a box full of tips)

2) Screw the tip on the handpiece (Fig.9)

3) Tighten the tip with the torque wrench until you hear a "click" sound.



2.3.8. Turn on the power switch (Fig.5-Ref. B). After the screen displays normally, you can start to operate the device.

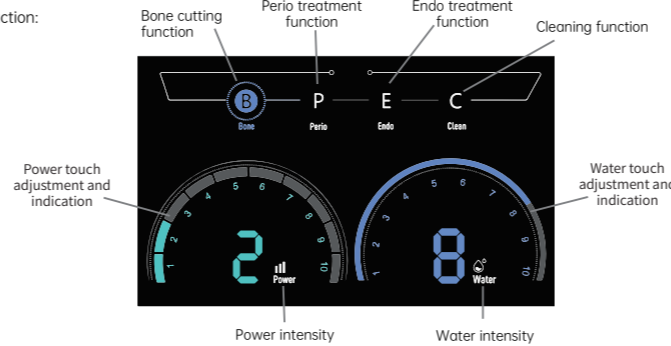
Step on the foot switch to start working, and the LED on the handpiece is on. Release the foot switch to stop working and the LED light will be off in 10 sec.

3 Controls

3.1 Panel control

This section introduces the front operation panel of MaxSurgery III, enabling users to better use the device with an intuitive display operation interface.

Operation panel instruction:



3.2 Descriptions and Functions of the Screen

MaxSurgery III has the functions of bone-cutting (BONE), periodontal treatment (Perio), root canal treatment (Endo), and cleaning mode (Clean).

First, users can set a specific mode through the operation panel, and then set the appropriate power intensity and water output intensity.

Both power intensity and water output intensity cannot be adjusted when the foot switch is stepped on.

A) Bone-cutting, touch the "B" on the screen to switch the mode (Fig.10)

In bone function, both the water and power model are available. Ten power levels as follows:

- ① Power 9-10: D1, Very high bone density
- ② Power 6-8: D2, High bone density
- ③ Power 3-5: D3, Middle bone density
- ④ Power 1-2: D4, Low bone density

B) Periodontal treatment (Perio), touch the "P" on the screen to switch the mode (Fig.10)

In Perio function, both the water and power model are available. (Fig.10)

C) ENDO function, touch the "E" on the screen to switch the mode (Fig.10)

In ENDO function, both the water and power model are available.

D) Cleaning mode (Clean), touch the "C" on the screen to switch the mode (Fig.10)

In cleaning mode, the main unit can be cleaned after stepping the foot switch once (while cleaning, the handpiece does not vibrate and only flushes the tubes and Ultrasonic Surgical System tip)

3.3 Safety requirements during use

Danger: Contraindications.

Do not use the MaxSurgery III on patients with pacemakers or other implantable electronic devices. This requirement also applies to the operator.

Danger: Breakage and wear of the tips.

The high-frequency vibrations and wear may, very occasionally, lead to the breakage of the tip. Tips of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such tips should definitely not be used. It is necessary to instruct the patient to breathe through his nose during the treatment in order to avoid ingestion of the broken fragment of the tip.

Danger: Control of infections.

For maximum safety of both the patient and the operator, clean, disinfect and sterilize the piezo electronic handpiece, the tips, and the torque wrench after each treatment.

Warning: Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could lead to decrementing of such artifacts.

Warning: Contraindication.

After autoclave sterilizing of the handpiece, wait for it to cool down completely before using it.

Danger: The electrical contacts inside the cord connector must be dry. Before connecting the handpiece to the device, make sure the electrical contacts of the connector are perfectly dry, in particular after the autoclave sterilization cycle. If necessary, dry the contacts by blowing air onto them with the syringe.

Warning: To use the device correctly, it is necessary to press the foot switch and start it up without letting the tip rest on the part to be treated. This will allow the electronic circuit to detect the point where resonance of the tip is without any interference, thus enabling optimum performance. If this is not done, contact with the part to be treated or with other surfaces before start-up could cause tripping of the protection systems.

Warning: For spray treatment, use only tips through which liquid is passed.

3.4 Protection systems and alarms

The device has a diagnostics circuit that is used to recognize the tripping of the protection system and of the alarms. These are shown on the display, as follows:

Warn01, Abnormal interior part of handpiece, please make sure it is completely dry or replace a new one.

Warn03, Abnormal cooling fan, please check whether it is spinning or poor-connected.

Warn06, Abnormal output of handpiece, please make sure the handpiece is connected and the Ultrasonic Surgical System tip is tightened.

3.5 Instruction for use

Open the air intake on the drip system; Screw the chosen tip onto the MaxSurgery III handpiece until it is flush against it;

To use the torque wrench correctly (Fig.9) proceed as follow:

① Hold the body of the handpiece firmly;

Warning: Do not grip the end part of the handpiece or the cord, only the plastic casting (Fig.9), and do not turn it while fastening the tip in place; Turn the wrench in a clockwise direction until the clutch engages (till making a clicking sound);

③ The tip is now properly tightened in place;

Make sure that the MaxSurgery III handpiece is correctly connected to the handpiece connector.

Check the display to see the type of power that has been set. If the type of power required is different from the type that has been set, use "B", "P", "E", and "C" on the screen to switch.

Check the display to see the power level that has been set, if the type of power required differs from the level that has been set, touch the screen for resetting power and water intensity, depending on the type of function that has been set.

3.6 Instruction for the major components of the detachable handpiece

3.6.1 Conical head: detachable, can be periodically removed for cleaning the main rod with alcohol.

3.6.2 Handpiece (with tail wire): the transducer, can be autoclaved.

3.6.3 Tail plug: the joint part between the detachable handpiece and waterway system and the circuit of the main unit.

3.6.4 LED light: Can be autoclaved or cleaned with purified water.

3.7 Instructions for torque wrench

The torque wrench adopts a special structural design, which can reasonably and effectively control the strength of screwing and unscrewing tips, ensuring users' better use experience. And it protects users' hands from being scratched by Ultrasonic Surgical System tips during screwing and unscrewing.

a) Take out the torque wrench, screw or unscrew the Ultrasonic Surgical System tip as shown in Fig.9

b) Install Ultrasonic Surgical System tip: hold the handpiece tightly, and use the torque wrench to rotate the Ultrasonic Surgical System tip in the direction shown in Fig.9 until it cannot be rotated anymore, and continue to rotate for another circle, then the Ultrasonic Surgical System tip is tightly installed.

c) Uninstall Ultrasonic Surgical System tip: hold the handpiece tightly, and use the torque wrench to rotate the Ultrasonic Surgical System tip in the counterclockwise direction shown in Fig.4 to remove it.

d) After each use, please put the torque wrench in the disinfecting cabinet for disinfection

e) Wait until the torque wrench is cooled down to avoid scalding due to the high temperature on the surface after disinfection.

f) The torque wrench shall be placed in a ventilated and dry place and kept clean when it is not used.

3.8 Rules for keeping the device in proper working order

3.8.1. Check the state of wear of the tips periodically and replace any for which a drop in performance is noted;

3.8.2. Do not deform the shape of the tips by bending or filling them;

3.8.3. Replace any tip that has become deformed or damaged by impacts;

3.8.4. Always make sure that any threaded parts and their contact surfaces are perfectly clean;

3.8.5. If a tip becomes too worn, the device will stop working.

4 Reprocessing instructions of cleaning, disinfecting and sterilizing

4.1 Beginning Work!

4.1.1 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.

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

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

4.2 Introduction

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

4.2.2 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 products are based on the potential risk of infection associated with their use.

4.2.3 It is recommended to use steam sterilization.

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

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

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

4.3 Reprocessing - Instructions for Reusable Products

4.3.1 During use, it is advisable to use a protective film (or protective cover) to insulate the tail wire and the main unit, so as to reduce the cleaning possibility. The protective film (or protective cover) may be damaged and become invalid, which is hard to recognize and easy to contaminate the instrument once the damage occurs. Therefore, cleaning, disinfection and sterilization shall be carried out for the whole unit.

4.3.2 Before reprocessing, Start the cleaning function -- clean the waterway system.

Warning: Failure to clean the waterway system will cause serious damage to the equipment due to salt crystals.

Warning: The handpiece and the tail wire cannot be detached.

a) Replace the infusion bottle or infusion bag, and the liquid within must be desalted water;

b) Check whether the waterway system is correctly installed;

c) Start the cleaning function (Fig.10)

d) Step on the pedal to start the machine peristaltic pump to flush the inner pipe with water. It is recommended that the continuous flushing and cleaning time should not be less than 25 seconds;

e) After washing and cleaning, you can switch back to the original mode by touching other mode functions and touching the key;

f) After the cleaning operation is completed, dry the parts after the cleaning cycle.

4.3.3 Handpiece (with tail wire), Ultrasonic Surgical System tip, torque wrench, pump tube, pump tube connector, infusion bag needle, power cable, pedal switch, and handpiece rack can be obtained by disassembling the device before reprocessing.

Warning: Only the following accessories can be carry out cleaning, disinfection and sterilization procedure.

a) Handpiece (Fig.2-Ref.D) b) Ultrasonic Surgical System tips (Fig.3-Ref.J) c) Ultrasonic Surgical System tip holder (Fig.3-Ref.I)

d) Torque wrench (Fig.2-Ref.C) e) Pump tube (Fig.6)

f) Pump tube connector (Fig.2-Ref.E)

Danger: The shell cannot be automatic cleaning, disinfection, sterilization.

The shell's surface, infusion bag needle, power cable, pedal switch, and handpiece rack can be clean and disinfect with a damp cloth containing a mild detergent or a disinfectant with a pH of 7, and air dry after disinfection is allowed.

Warning: Handpiece and tail wire cannot be detached.

Warning: Do not immerse the handpiece in any disinfection liquid, which may cause damage.

Warning: Do not leave the Ultrasonic Surgical System tip tightened on the handpiece during disinfection.

Warning: The power connection between then handpiece plug and the socket must be kept dry.

4.3.4 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.

4.3.5 Reusable products must be cleaned, disinfected and sterilized prior to first use. Reprocessing procedures have only limited implications to this device.

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

4.4 Preparation - Basic Principles

4.4.1 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.

4.4.2 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.

4.5 Preparation at the Point of Use

Disconnect product. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixing 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.

4.6 Transportation

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

4.7 Preparation for Decontamination

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

4.8 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.

4.9 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 instrument into the machine on a tray. Connect the instrument 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.

4.10 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 3000.

4.11 Drying:

Automated Drying:

Drying of outside of instrument 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.

4.12 Packaging

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 instrument is visibly clean.

Before packaging and autoclaving, make sure that the products have been maintained acc. to manufacturer's instruction.

4.13 Packaging

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

4.14 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 instruments.

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.

4.15 Storage

Storage of sterilized products in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

4.16 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 (alkaline 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.

5 Transportation, storage, and maintenance

5.1 Transportation

5.1.1. Prevent excessive shock and vibration during transportation, and handle with care.

5.1.2. It should not be mixed with dangerous goods during transportation.

5.1.3. Avoid exposure to sun or rain or snow during transportation.

5.2 Storage

5.2.1. Do not store the machine together with articles that is poisonous, combustible, caustic, or explosive.

5.2.2. This machine should be stored in a room where the relative humidity is 10% - 93%, atmospheric pressure is 70kPa - 106kPa, and the temperature is -20°C - +40°C.

5.3 Maintenance

5.3.1. The device 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. When the device is not in use, turn off the power supply and unplug the power plug. If it is not used for a long time, it should be energized and connected to water and air once a month for five minutes.

Danger: Always make sure the cable is intact. If it is damaged, please replace it with accessories produced by REFINE.

5.4 Fuse replacement

Danger: Switch off the power.

Always turn off the apparatus by means of the switch, and disconnect it from the power outlet before carrying out the following maintenance activities.

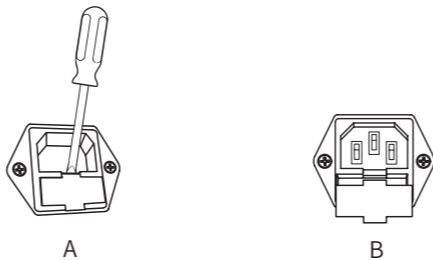


Fig 11

a) Insert a straight screwdriver into the recess in the fuse compartment below the power socket and use it as a lever (Fig.11-Ref.A);

b) Pull out the fuse compartment (Fig.11-Ref.B);

Danger: Replace the fuses, using fuses of the type indicated on the identification label on the bottom of the apparatus;

c) Put the compartment back into place (Fig.11-Ref.B).

6 Troubleshooting

If the device does not seem to be working properly, read the instruction again and then check the following table:

Problems	Possible causes	Solutions
The screen of the device does not display when it's switched on.	The connector on the end of the power cable is plugged into the socket on the rear of the device properly.	Check that the power cable is firmly connected
	The power cable is faulty.	Check that the power outlet is working properly. Replace the power cable.
	The fuses blew out	Replace the fuses.
The device is powered on but does not work with no error displayed on the screen.	The connector of the foot foot switch is not properly plugged into the socket.	Insert the foot switch connector properly
	The foot switch will not work.	Contact the nearest dealer or authorized REFINE service center
A faint whistle can be heard coming from the MaxSurgery III handpiece during operation.	The tip is not correctly tightened onto the handpiece.	Unscrew the tip and screw it back into place correctly.
The device is switched on but will not work, the message Warn01 appears on the display.	The connection joint between the handpiece and tail wire is not completely dry	Dry them completely
	Aging handpiece and abnormal parameters	Replace a new one
	Aging, damage, and deformation of Ultrasonic Surgical System tips	Replace a new one
	Malfunctioning of the tuning circuit.	Contact the nearest dealer or authorized REFINE service center
The device is switched on but will not work, the message Warn03 appears on the display.	The cooling fan connecting terminal falls off	Contact the nearest dealer or authorized REFINE service center
	Aging cooling fan, decreasing parameters	Replace the bag with a full one. Contact the nearest dealer or authorized REFINE service center
	Short circuit of cooling fan caused by liquid	Contact the nearest dealer or authorized REFINE service center
The device is switched on but will not work, the message Warn06 appears on the display.	Abnormal drive circuit of the cooling fan	Contact the nearest dealer or authorized REFINE service center
	The tip is not correctly tightened onto the handpiece	Unscrew the tip and screw it back into place correctly.
No liquid comes out of the tip during operation.	The tail wire is not connected to the device	Check whether it is well-connected
	Aging handpiece, decreasing parameters	Replace a new one.
	Abnormal ultrasonic circuit of the main unit	Contact the nearest dealer or authorized REFINE service center
	The tip is of the type with no through-flow of liquid.	Use an tip of the type with through-flow of liquid.
The bag of liquid is empty	The bag of liquid is empty	Replace the bag with a full one.
	The cover of pump that connected with the water tube is open.	Close the cover.
	The tubes of the drip system and of the pump have not been correctly installed.	Check the connections of the tubes.
	The tip is clogged	Free the passage in the tip through which the water passes.
	The handpiece is clogged	Contact the nearest dealer or authorized REFINE service center

Problems	Possible causes	Solutions
The device is working properly, but the pump is being forced.	Too much pressure by the impeller on the tube in the peristaltic pump.	Check whether the tube in the peristaltic pump has been correctly inserted.
The pump is running correctly but liquid leaks from the hand-piece when it stops	The cover of the peristaltic pump is not closed tightly.	Make sure that the cover of the peristaltic pump is properly closed.
Insufficient power	The tip is not correctly fitted to the handpiece (the message Warn06 appears on the display).	Unscrew the tip and screw it back into place correctly.
	The tip is worn, broken or deformed (the message Warn06 appears on the display).	Replace a new one

Please contact the nearest dealer or our company if the problems remain unsolved.

7 Environmental Protection

Parts	Toxic or harmful substances or elements					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
Main unit	○	○	○	○	○	○
handpiece	○	○	○	○	○	○
Tip	○	○	○	○	○	○
Foot switch	○	○	○	○	○	○
Mechanical elements, including bolts, nuts, washers, etc.	○	○	○	○	○	○

○ : Indicates that the content of the toxic substance in all homogeneous materials of the part is below the limit requirement stipulated in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.

X : Indicates that the content of the toxic substance in at least one of the homogeneous materials of the part exceed the limit requirement specified in SJ/T-11363-2006. (This product meets the RoHS environmental protection requirements of the European Union; at present, there is no mature technology in the world that can replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys). Please dispose according to the local laws or consult with dealer from whom you purchased it about waste disposal.

8 Disposal procedures and precautions

Danger: Medical waste

Medical waste is defined according to the following points, please replace it in time:

- Aging or damage of Ultrasonic Surgical System tips.
- Pump tube, after 8 sterilization cycles.
- Infusion tube, after each treatment.
- Aging or damage of torque wrench.

9 After-sale service

9.1. After the equipment is sold, the manufacturer will be responsible for quality problem according to the warranty card. For specific items, please refer to the warranty instructions in the warranty card.

9.2. This product does not contain self-maintaining parts. All maintenance, adjustment, calibration, and modification of technical parameters of the product can only be carried out by the technicians or special repair shops. If the customer needs to repair by himself, the manufacturer can provide circuit diagrams, component lists, legends, calibration rules, or other information necessary to help the user's qualified technicians repair the equipment parts designated by the manufacturer, but the manufacturer will not bear the consequences arising therefrom.

9.3. The user must use the original accessories, please contact your local dealer or the manufacturer to purchase. It is forbidden to use accessories of other brands to avoid damage to the equipment or other dangers.

9.4. After the handpiece, tips and other accessories are damaged, users should not repair them by themselves. Please purchase new parts and replace them before use. If you need relevant information, please contact the manufacturer.

9.5. The service life of the product is 10 years. See the packaging label for the production date.

10 EMC-Declaration of conformity

EMC conformity is necessary to ensure the safety of devices and systems because there are electromagnetic phenomena of various strength levels in the areas where these devices are normally used. This means that in order to ensure electromagnetic compatibility, the equipment must operate correctly in its intended operating environment. The MaxSurgery III must be installed and used according to the electromagnetic compatibility information in this manual to ensure specific precautions related to electromagnetic compatibility.

Notice:

- Users shall install and use according to the electromagnetic compatibility information provided in the accompanying documents.
- Portable and mobile radio frequency communication equipment may affect the performance of MaxSurgery III ultrasonic bone tissue surgery equipment, and avoid strong electromagnetic interference when using, such as near mobile phones, microwave ovens, etc.

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.
- 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.
- Other electrical equipment used in the same room or adjacent rooms, or portable and mobile RF communication equipment such as mobile phones, walkie talkies, or nearby radio equipment, TV or microwave transmission equipment, may cause the performance of MaxSurgery III to be reduced. If electromagnetic interference (EMI) affects the normal operation of MaxSurgery III, it may be necessary to move MaxSurgery III to another place or take corresponding electromagnetic interference suppression measures.
- MaxSurgery III has special precautions for EMC. It needs to be installed and used according to the information provided in the manual.
- The accessories of our company have been tested according to the requirements of YY 0505-2012 standard and confirmed to meet the Class B radiation standard of Group 1. Please use our original accessories.
- The use of power cord, handpiece tail wire and foot switch connecting wire not designated for the MaxSurgery III may increase its radiation of it or reduce its anti-interference capability. Please use our original accessories. Specific information is shown in the table below.

10.1 Requirements for cord installation

1) Requirements for the device's cords

NO	Name	Length(m)	Shielded or not
1	Power cord	1.8	No
2	Ultrasonic handpiece cord	2.2	No

3	Foot switch cord	2.0	No
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10.2 Key EMC components

The key EMC components of the product are switching power supply, power cord, IC chip. The use or replacement of accessories, cables, transducers, etc. that are not matched with the design will result in a significant reduction of EMC emission and immunity performance. Do not replace machine parts without authorization.

10.3 Guidance and manufacturer's declaration - electromagnetic emissions


Guidance and manufacturer's declaration - electromagnetic emissions		
The MaxSurgery III is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in these conditions:		
Emissions test	Compliance	Electromagnetic environment – Guidelines
RF emissions GB 4824	Group 1	MaxSurgery III uses RF energy only for its internal functions. Therefore, its RF emission is very low, and the possibility of interference with nearby electronic equipment is very small
RF emissions GB 4824	Class B	MaxSurgery III is suitable for use in all facilities, including household facilities and directly connected to the public low-voltage power supply network of the household
Harmonic emissions GB 17625.1	Group A	
Voltage fluctuations/ flicker emissions GB/T 17625.2	Applicable	

10.4 Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The MaxSurgery III is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in these conditions:			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment – Guidelines
Electrostatic discharge (ESD) GB/T 17626.2	±6kV contact ±8 kV air	±6kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst GB/T 17626.4	±2kV power supply lines	±2kV power line ±2kV power line to protective ground (PE) ±1kV pair connecting cable	Mains power quality should be that of a typical commercial or hospital environment
Surge GB/T 17626.5	±1 kV line to line ±2 kV line to ground	±1kV differential mode voltage ±2kV common mode voltage	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	< 5% U _r for 0.5 cycles (>95% dip in U _r) 40% U _r for 5 cycles (60% dip in U _r) 70% U _r for 25 cycles (30% dip in U _r) < 5% U _r for 5s (>95% dip in U _r)	< 5% U _r for 0.5 cycles (>95% dip in U _r) 40% U _r for 5 cycles (60% dip in U _r) 70% U _r for 25 cycles (30% dip in U _r) < 5% U _r for 5s (>95% dip in U _r)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MaxSurgery III requires continued operation during power mains interruptions, it is recommended that the MaxSurgery III be powered from an uninterruptible power supply or a battery
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Notice: U_r is the a.c. mains voltage prior to application of the test level.

10.5 Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The MaxSurgery III is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in these conditions:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidances
Conducted RF GB/T 17626.6	3V (effective value) 150 kHz ~ 80 MHz	3V (effective value)	Portable and mobile RF communications equipment should be used no closer to any part of the MaxSurgeryIII, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance = 3V d=1.2×P ^{1/2} 80MHz~800MHz d=2.3×P ^{1/2} 800MHz~2.5GHz 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, as 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: 
Radiated RF GB/T 17626.3	3V/m 80MHz ~ 2.5GHz	3V/m	

NOTE 1 At 80 MHz and 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 broadcasts and TV broadcasts 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 MaxSurgery III is used exceeds the applicable RF compliance level above, the MaxSurgery III should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MaxSurgery III.

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

10.6 Recommended separation distances between portable and mobile RF communications equipment and the MaxSurgery III.

Recommended separation distances between portable and mobile RF communications equipment and the MaxSurgery III.			
The MaxSurgery III is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MaxSurgery III can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MaxSurgery III are recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150kHz ~ 80MHz d=1.2×P ^{1/2}	80MHz ~ 800MHz d=1.2×P ^{1/2}	800MHz ~ 2.5GHz d=1.2×P ^{1/2}
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) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range is applied.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

MaxSurgery III is used in the above-specified electromagnetic environment, which will work safely and provide the basic information described in Article 7.2

Performance: 1. When Bone, Perio and Endo functions are performed, the working tip on the handle will vibrate and water will flow out. When Clean functions are performed, the working tip on the handle will not vibrate and only water will flow out; 2. Controllable operation of foot switch.

The equipment has passed the test according to YY 0505-2012/EN 60601-1-2:2004, which does not guarantee that it will not be affected by electromagnetic interference in any way. The equipment shall not be used in a harsh electromagnetic environment.

11 Statements

11.1. All equipment and components manufactured by Guilin Refine Medical Instrument Co., Ltd. have been thoroughly inspected and tested.

11.2. During the test, all components withstood a certain working cycle.

11.3. The test emphasizes that any fault is caused by faulty components.

11.4. This step ensures the normal function and reliability of all components.

11.5. The Company reserves the right to modify the product technology, accessories, operation instructions, and product packaging content at any time without notice,

The pictures are for reference only, and Guilin Refine Medical Instrument Co., Ltd. reserves the right of final interpretation.

12 Guarantee

12.1. Before being placed on the market, all REFINE equipment undergoes a thorough final check to ensure that it is in proper working order.

12.2. REFINE guarantees that all its products can be replaced free of charge during the warranty period due to defects in production by the seller or importer of new products purchased from REFINE. See the warranty card for warranty details.

12.3. Throughout the warranty period, REFINE undertakes to repair (or, at their sole discretion, to replace) free of charge any parts that, in their opinion, are faulty. Complete replacement of REFINE products is excluded.

12.4. REFINE cannot accept any liability for direct or incidental damage or personal injury in the following cases:

- (1) If the device is used for any purpose beyond the mentioned range of application;
- (2) If the user does not use the device according to the procedures and requirements written in the manual.
- (3) If the wiring system of the usage scenario does not meet the appropriate standards and requirements.
- (4) If any assemble operations, extensions, settings, alterations, or repairs have been carried out by personnel not authorized by REFINE;
- (5) If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

12.5. Accidental damages due to transport, incorrect use, or carelessness or to connect to power supplies other than as envisaged and damage to the signaling lamps handpiece and all accessories are excluded from the warranty. The warranty will no longer apply if the apparatus has been tampered with or repaired by unauthorized personnel.

12.6. Warning:

The warranty is valid only if the warranty slip enclosed with the product has been completed in full and returned to us or, if appropriate, to your REFINE dealer or importer within 20 days from the date of purchase, as proven by the consignment note/invoice issued by the dealer/importer. In order to benefit from the warranty service, the customer must return the apparatus to be repaired to the REFINE dealer/importer from which it was purchased, at his own expense.

12.7. The apparatus should be returned suitably packed (possibly in its original packing material).

12.8. Accompanied by all the accessories and by the following information:

- (1) Owner's details, including his telephone number;
- (2) Details of the dealer/importer;
- (3) Photocopy of the consignment note/purchase invoice of the apparatus issued to the owner and indicating, in addition to the date, also the name of the 30 apparatus and its serial number;
- (4) A description of the problem.

12.9. Transport and any damages caused during transport are not covered by the warranty. If the problem is caused by a free accident or an accident caused by improper use, the repair of Sharp products shall be charged according to the actual cost.

Appendix: Publication of compatibility description and output characteristics of Ultrasonic Surgical System tips.

Model specification	Type of tips	Working mode	Power intensity	Primary tip vibration excursion (µm)	Primary acoustic output area	Drive frequency (kHz)	Derived output acoustic power(mW)	Type of system frequency control	Secondary tip vibration excursion (µm)	Power reserve index
US1	Sharp	Bone (Bone cutting)	P1	30±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	36±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	42±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
US2	Sharp	Bone (Bone cutting)	P1	28±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	35±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	40±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
US4	Smoothing	Bone (Bone cutting)	P1	26±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	34±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	39±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
US5	Smoothing	Bone (Bone cutting)	P1	27±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	35±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	42±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
UL3	Blunt	Bone (Bone cutting)	P1	26±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	34±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	39±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
UC1	Smoothing	Bone (Bone cutting)	P1	30±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	37±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	43±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
UP1	Sharp	Perio (Perio Treatment)	P1	28±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	35±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	40±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0
UE1	Blunt	Endo (Endo Treatment)	P1	27±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤4	2.0±1.0
			P5	36±10	< 12mm ²	26.0±3.0kHz	200 ~ 600mW	Load independent	≤6	2.0±1.0
			P10	41±10	< 12mm ²	26.0kHz±3.0kHz	200 ~ 600mW	Load independent	≤8	2.0±1.0

Notice:

(1) Sharp Ultrasonic Surgical System tips

The sharp edges of these tips can be used to treat bone structures efficiently and effectively. Sharp tips are used in osteotomy and osteoplasty when a fine and well-defined cut in the bone structure concerned is required, there are also tips with sharp edges for osteoplasty techniques and for removing bone fragments.

(2) Smoothing tips

The smoothing tips have surfaces shaped in such a way that they can be used to work the bone structures with precision and in a controlled manner. Smoothing tips are used in osteotomy when it is necessary to prepare difficult and delicate structures such as those for preparing a maxillary sinus window or to complete preparation of the site of an implant.

(3) Blunt tips

Blunt tips are used for separating the soft tissues, for example for detaching Schneider's membrane or for lateralizing nerves. In periodontology, these tips are used to smooth the root surfaces.

(4) Primary tip vibration excursion: The head of Ultrasonic Surgical System tip shifts in the direction of maximum amplitude on the peak-to-peak value, and the measuring point is located at the position where the head of the Ultrasonic Surgical System tip is not over 1 mm away from the free end (tail end).

(5) Primary acoustic output area: In the direction of the principal amplitude of tips, and the projected area of the solid part of the head of the Ultrasonic Surgical System tip.

(6) Drive frequency: the average frequency of drive voltage or current.

(7) Derived output acoustic power: the acoustic power emitted from the head of the Ultrasonic Surgical System tip under water based on the measurement results of the hydrophone method.

(8) Type of system frequency control: Refer to the percentage change of principal tip amplitude from the max to the min for systems with modulated electric excitation power.

(9) Power reserve index: The ratio of maximum electric power to static (no-load) electric power.