Miconvey

K500
Ultrasonic Surgical Generator
User Manual

CONTENTS

Preface

I. Use Advice

This manual and the equipment are only for qualified Biomedical Service Personnel use. It is intended only as a guide for technical maintenance of the Ultrasonic Surgical Generator.

This manual is designed to provide instructions for use of the Ultrasonic Surgical Generator. Failure to properly follow the instructions may lead to serious surgical consequences.

II. Version Statement

1. The 02 version is revised in March 2024.
2. Document No.:507012307.
3. The service life of the generator is 8 years.

III. Terms

[Warning]

It indicates potential hazardous situation that may result in death or serious injury of personnel.

[Precautions]

It indicates a situation that may result in minor or moderate injury of personnel.

[Note]

It indicates a hazard which may result in product damage.

[Note matters]

It indicates “tips on operation or suggestions on maintenance”.

IV. Symbol Agreement Used by the Generator Panel

The graphic symbols of front panel include:

The graphic symbols of back panel include:

See “Chapter Three System Introduction-- Generator" for the meaning.

1. Indications and Contraindications

I. Intended purpose

The main function of the generator is to provide electrical energy with ultrasonic frequency, and control the output of the electric power to the hand piece handpiece by activating the foot switch or hand piece switch. Set output energy by operation of the front panel of the generator, and observe the working condition of the system, providing different energy at different gear.

II. Indications

Surgical ultrasound equipment is a medical device that uses ultrasound technology to perform tissue cutting and hemostasis. It cuts tissue through high-frequency ultrasound vibration, while using the generated heat to coagulate blood vessels, achieving hemostasis. Therefore, the design goal is to improve the efficiency and safety of surgery. Based on the prominent features, Ultrasound surgical system is used in so many different kinds of procedures that it would not be practical or beneficial to define the specific clinical condition associated with them.
At present, only the common types of surgeries can be listed, but the applicable clinical conditions go far beyond these.
1. General surgery: such as total thyroidectomy, lobectomy, fundoplasty, splenectomy, appendectomy, colorectal cancer surgery, hemorrhoidectomy, etc;
2. Gynecology: such as subtotal and total hysterectomy, removal of endometriotic lesions;
3. Urology: such as adrenalectomy.

III. Tarket population

Patients who require dissection and hemostasis of tissue during open and laparoscopy surgery, except for children and pregnant women.

IV. Contraindications

1. The instruments are not indicated for incising bone or contraceptive tubal occlusion..
2. The instruments are not intended for brain surgery.
3. Pure vascular closure > 5mm blood vessel.

2. Working Principle And System Components

I. Working Principle

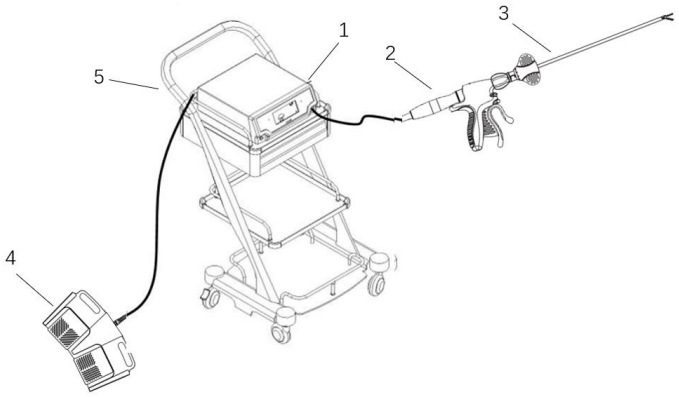
The Ultrasonic Surgical Generator makes the transducer oscillate at the ultrasonic frequency of 55.5khz ± 1KHz, and then the amplitude is amplified by the shaft, so that the water in the tissue vaporizes, the protein hydrogen bond in the tissue breaks and the cells disintegrate, thus cutting the tissue. At the same time, the protein coagulates causing that the small lumen and the large lumen are closed to achieve coagulation.

The generator main controller adopts DSP, CPLD and ARM controllers. CPLD realizes complex logic transformation. DSP realizes data calculation processing such as current, voltage and impedance and controls the waveform producer to generate basic output waveform. It outputs the required power signal through the power drive circuit and output transformer, and outputs it to the handpiece for converting electrical energy to mechanical energy. The conversion ultimately drives the scalpel vibration to achieve cutting and hemostasis. At the same time of output, the DSP monitors and feedback the current and voltage signals whether it reaches the preset value, and changes the drive signal by calculating the error and a certain algorithm, thereby achieving stable output.

II. System Components

The system is mainly comprised of five parts: Ultrasonic Surgical Generator,
Ultrasonic Surgical Handpiece, Disposable Ultrasonic Surgical Scalpel /Ultrasonic Open Surgery Scissors, foot switch and cart(optional).

See Figure 1 for schematic diagram of the system components:



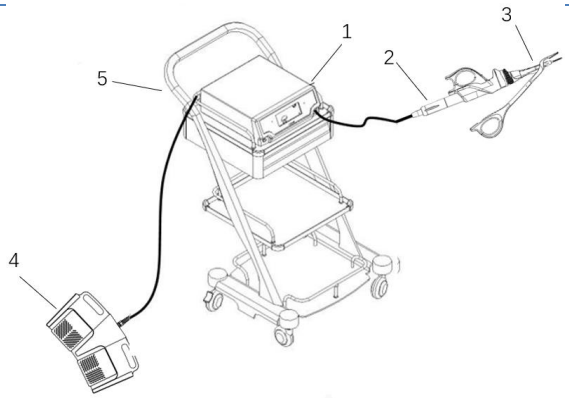


Figure 1 Schematic diagram of the Ultrasonic Surgical System

1. Ultrasonic Surgical Generator	2.Ultrasonic Surgical Handpiece	3.Disposable Ultrasonic Surgical Scalpel /Ultrasonic Open Surgery Scissors	4. Foot switch(optional)	5.Cart(optional)

1) Ultrasonic Surgical Generator K500(“Generator” for short)

The generator supplies the handpiece with electrical energy and facilities selection of power levels, system monitoring and system diagnostics. Power is delivered by activating the foot switch or instrument switch.

2) Ultrasonic Surgical Handpiece (“Handpiece” for short)

The handpiece contains an electroacoustic transducer that converts the electrical energy supplied by the generator to mechanical motion. The transducer is connected to an amplifier which amplifies the motion produced by the transducer and relays it to the scalpel/scissors.

3) Disposable Ultrasonic Surgical Scalpel (“Scalpel” for short) /Ultrasonic Open Surgery Scissors (“Scissors” for short)

The mechanical motion from the handpiece advance to the scalpel/scissors, transmitting ultrasonic energy which enables hemostatic cutting and/or coagulation of tissue.

4) Foot switch

The foot switch is optional. The foot switch is required if the system will be used with coagulating shear or instruments without the hand switching adaptor.

5) Cart

The cart is optional. It is designed to put on AUTOFORCE Ultrasonic Surgical Generator. The cart requires assembly; instructions are included with the cart.

3. System Introduction

I. Ultrasonic Surgical Generator

The generator delivers two power levels: minimum (MIN) and maximum (MAX). The minimum power level can be adjusted by the user from Level 1 to 5. The maximum power level is always Level 5. With all instruments, use a higher generator power level for greater tissue cutting speed and lower generator power level for greater coagulation. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors including the power level selected, instrument characteristics, grip force (when applicable), tissue tension, tissue type, pathology, and surgical technique.

The Front Panel

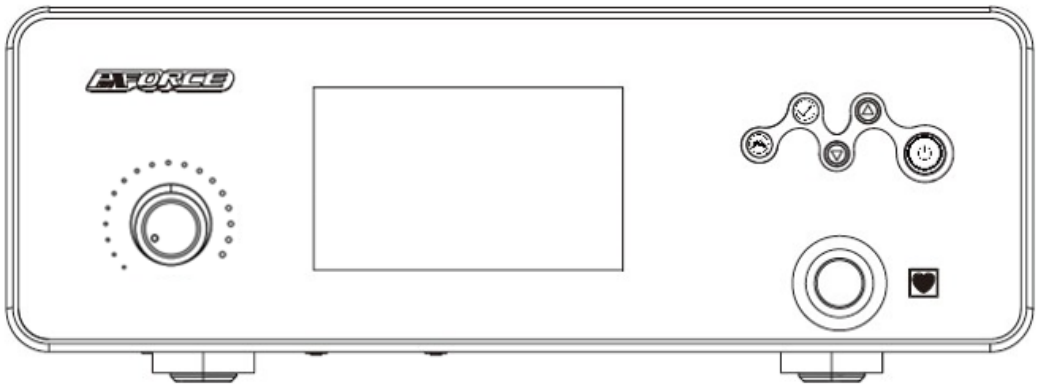


Figure 2 Front Panel

1) Button for Standby and Ready mode

Push this button to toggle between Standby and Ready modes. Upon power-up, the system defaults to Standby mode enabled.

2) Increase/decrease power level

Push this button to increase or decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the graphic display. The power level may be adjusted when the generator is in Ready or Standby mode.

3) **MIN** Low power indication

Indicates the user-settable MIN power level setting. When this power level is activated (by foot switch or instrument switch), the MIN indicator will flash. The system defaults to MIN power level 3. Refer to the instruments' package inserts for the recommended MIN power level.

4) **MAX** High power indication

Indicates the maximum power level setting. This setting is always "5".When this power level is activated (by foot switch or instrument switch), the "MAX" indicator light flashes.

5)  Button for test

In the ready state, press this button to start the test of the handpiece and the scalpel/scissors. Confirm that the installed handpiece and the scalpel/scissors are normal or not.

6)  Hand activation

Press the button to enable or disable the Hand Activation mode， while the LED is flickering it is enable. Upon power-up, the system defaults to Hand Activation mode disabled. If the foot switch in installed, the foot switch is always enabled.

7) LCD

In Ready or Standby modes, this display indicates the minimum (user-settable level 1 to 5) and maximum (level 5) power levels. If a system or component problem exists, error message will appear on the display.

8)  Handpiece receptacle

This receptacle is used to connect the handpiece to the generator.

9)  Volume

Turn this knob to adjust the volume of the activation tones. A tone will sound indicating the volume level selected.

10)  Type symbol

Type CF Applied Part

Back Panel

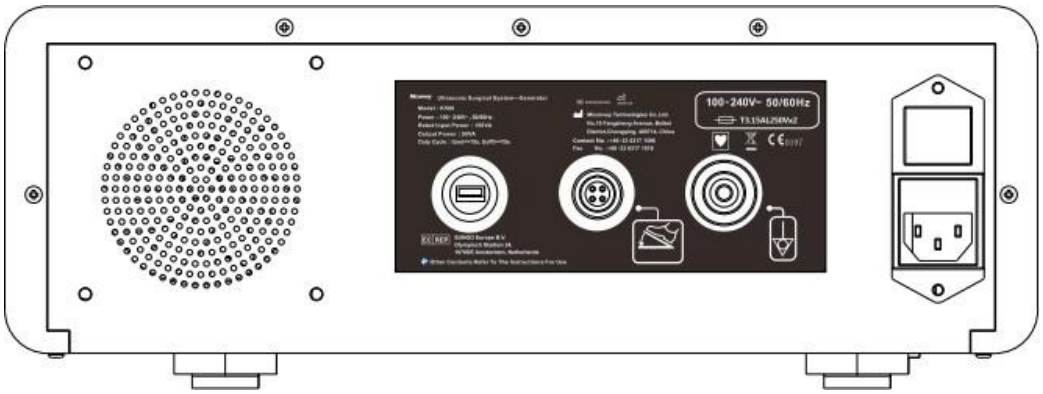


Figure 3 Back Panel

1) Foot switch receptacles

Identical receptacles allow connection of one foot switch for user convenience.

2) Power cord receptacle and switch

This receptacle is used to attach the power cord to the generator. " | " indicates power on and " ○ " indicates power off. Please find Chapter 9- System Specification.

3) Potential equalization terminal

This terminal provides a means for connection to a Potential Equalization Conductor..

4) Dangerous

Make sure the power range in the specified range.

5) USB interface

Warning

It should only be used for upgrade generator by designated engineer of factory, don't be connected with any other USB device, especially USB HOST device as computer.

II. Disposable Ultrasonic Surgical Scalpel/Ultrasonic Open Surgery Scissors and Ultrasonic Surgical Handpiece

The scalpel/scissors is used together with the generator.

The mechanical motion from the handpiece advances to the scalpel/scissors, transmitting ultrasonic energy which enables hemostatic cutting and/or coagulation of tissue.

1) Use the torque wrench to connect the shear with the handpiece, avoid direct screwing by hand. Find finished installation in Figure 4.

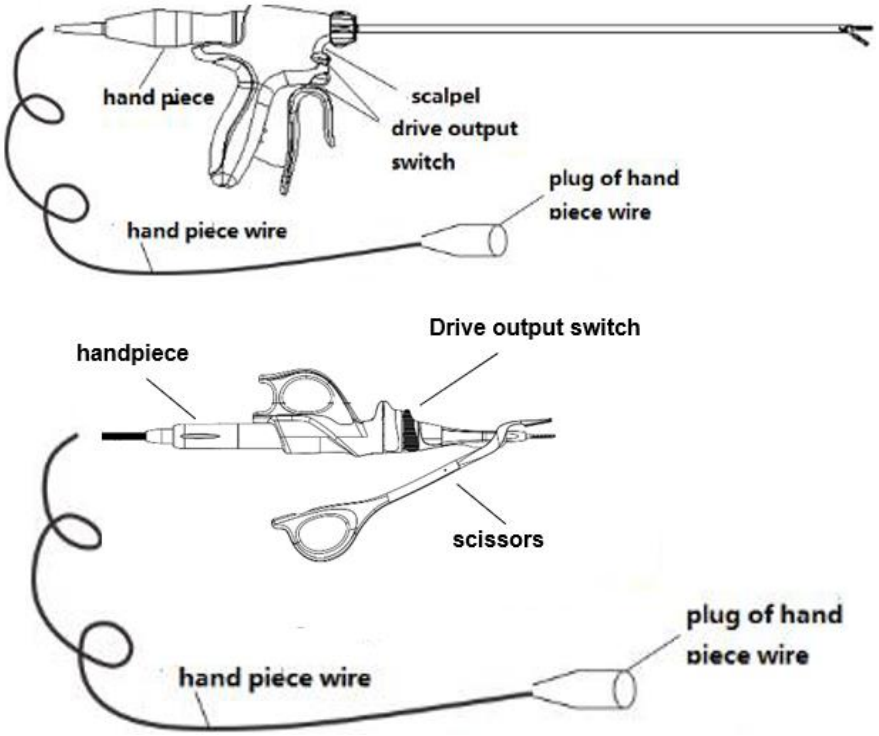


Figure 4 Connection between handpiece and scalpel/scissors

2) The connection between handpiece and generator is as shown in Figure 5

Connect the plug to the generator receptacle.

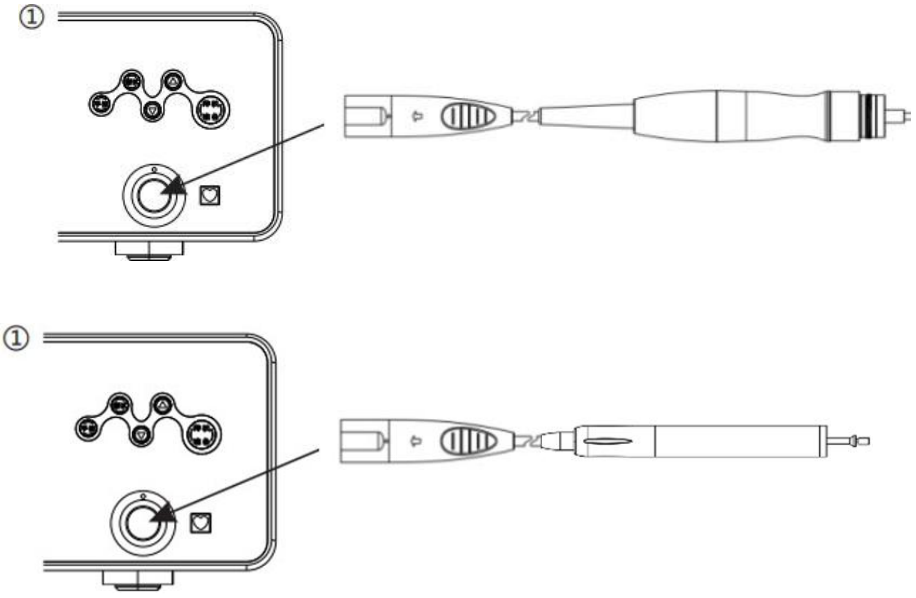


Figure 5 Connection between handpiece and generator

3) Power output of scalpel/scissors

There are two activating output switches “MIN” and “MAX” on the scalpel/scissors, wherein the “MIN” controls the low power level output, and the "MAX" controls the high power level output.

III. Foot Switch

1) Structure of foot switch is as shown in Figure 6

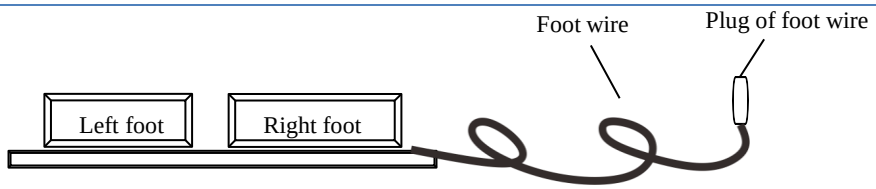


Figure 6 Schematic diagram of foot switch

2) Connection between foot switch and generator

As shown in Figure 7, connect the plug of foot wire into the foot switch receptacles on the back panel of the generator.

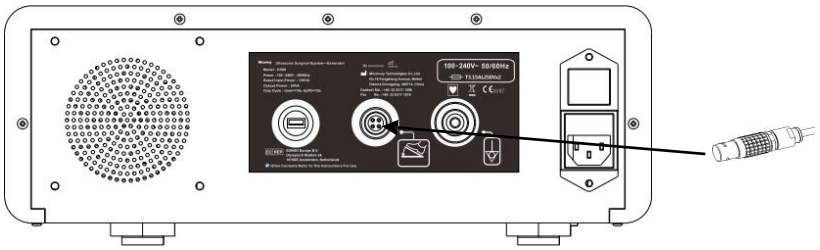


Figure 7 Connection between foot wire plug and generator

3) Motivation control of foot

The left side controls “MIN” power output and the right side controls "MAX" power output. When pressing is effective, the corresponding indicator light flashes and continuous output warning sounds can be heard.

4. System Setup and Operation

I. Unpacking

The Ultrasonic Surgical System includes several components that are purchased separately. Upon receiving the ordered components, please check for visible shipping damage. If there are any damage, please contact us or our local representative.

The components of Ultrasonic Surgical System may include the following parts (see Chapter 9---System Specification):

Ultrasonic Surgical Generator ------- includes the generator, power cord, and user manual.

Ultrasonic Surgical Handpiece ------includes handpiece and test tip.

Foot switch ------includes the foot switch and cable.

Ultrasonic Open Surgery Scissors/ Disposable Ultrasonic Surgical Scalpel-----individual and aseptic packaging.

II. System Start up

[Caution]

The AUTOFORCE Ultrasonic Surgical System includes components that are shipped non-sterile (e.g. handpiece). Sterilize products as required before beginning system setup. Refer to individual package inserts for cleaning and sterilization instructions.

Warning

Ultrasonic Surgical System must be operated within the required ambient operating conditions. Refer to Chapter 9 ---*System Specification*.

1) Confirm that the generator power switch is OFF during setup.

2) Secure the generator on its cart or on another suitable fixture.

3) Fix the cart in the appropriate place, press down the brake to fix the cart.

4) Connect the line cord into the AC inlet located on the generator's rear panel and into an appropriately grounded outlet. If the power cord is wrapped around the cart handle, it must be completely removed from the cart handle prior to plugging it into the power outlet.

Warning

Verify that the outlet voltage correctly corresponds to the generator's requirements. *(See Chapter 9--- System Specification*). Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

5) Attach the foot switch cable to the foot switch.

[Note]

Confirm that the connector and receptacle are dry and clean.

Ensure the collar is finger-tight to prevent inadvertent activation because of fluid ingress.

6) Connect the instrument to the handpiece following instructions in their package inserts.

7) Connect the handpiece to the receptacle on the front panel. Align the red dot on the connector with the red dot on the generator. Ensure the handpiece connector is dry and clean before connecting the handpiece to the generator. Fully insert the handpiece connector to assure complete, proper connection to the generator.

[Caution]

To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance form obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.

Warning:

System power supply must have a reliable protection to the ground to ensure the electrical safety.

III. System Operation

1) Self-testing

Turn the generator power switch on and the generator conducts a series of self-testing to the system hardware, which include: five buttons on the front panel, two switches for foot and instrumental manual control, the system power, and the output circuits of system, etc. Do not operate the generator during the self-testing process.

2) Standby mode

When the initiation sequence is complete, the system will go to Standby., a short "beep" sound will be heard, and the display is as following:

The self-testing process lasts for approximately 5 seconds, if the system detects a faulty generator or incorrect handpiece, error message will appear on the LCD and an audible alarm will sound. Refer to Chapter 5-System Troubleshooting.

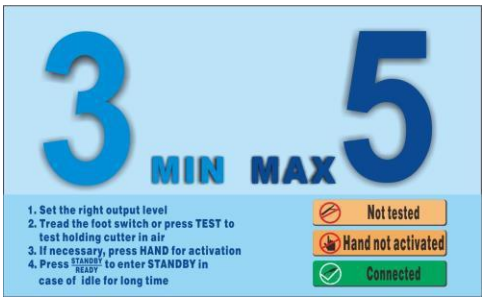
3） Handpiece connection

Install handpiece and scalpel/scissors, connect handpiece and generator with the special cable. Note that the red parker on connector must be upward.

When connect handpiece to generator, generator display handpiece used times, showing as following:

4）Ready mode

Place the generator in Ready mode by pressing the button. In this moment, the system automatically and continuously detects whether the connection of handpiece is normal. Under normal mode, the display showing as following:



If the handpiece is not connected normally, there will be an audible alarm, and the error will be indicated as following:

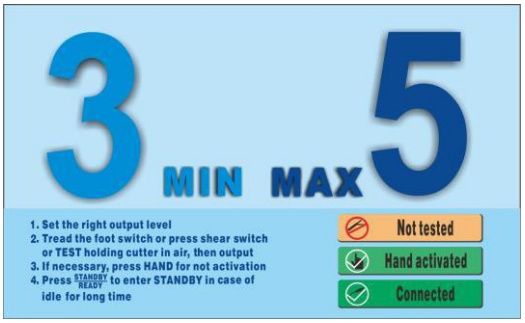
Fix the problem as shown in the interface. If the problem is solved, the previous surface will be displayed.

5) Power level setup

Upon startup, the generator defaults to power level 3(MIN) and 5 (MAX). The minimum (MIN) power level is user-settable from power levels 1 to 5. To adjust the power level, depress the and buttons on the right side of the LCD. Set the power level based on surgeon preference or the recommendations provided in the instrument's package insert.

6) Hand control switch

When requiring operating the hand control switch of scalpel/scissors, press the button to enable hand activation, and the display is as following:

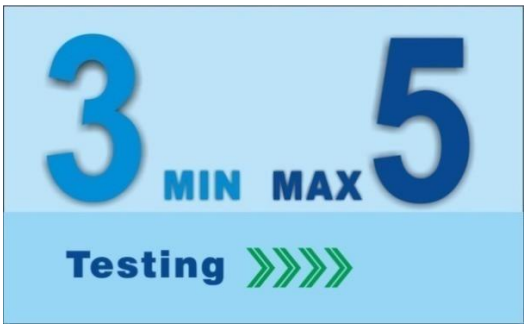


7) Output control

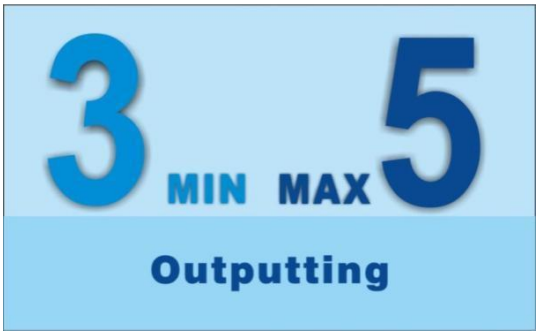
The ultrasonic power output can be activated by pressing down the foot switch or instrument switch.

8) Test and output control

Each time the generator is activated after exiting Standby, hold the instrument in the air and depress the MIN or MAX power level on the foot switch or instrument switch. “Testing” will appear on the LCD and a rapid two-tone pulse will sound while the test is occurring:



During this 5 second period, a system check is being performed, if the system is operating properly, the activation tone corresponding to the power level activated will be heard when the check is complete and the corresponding power figure flashes.

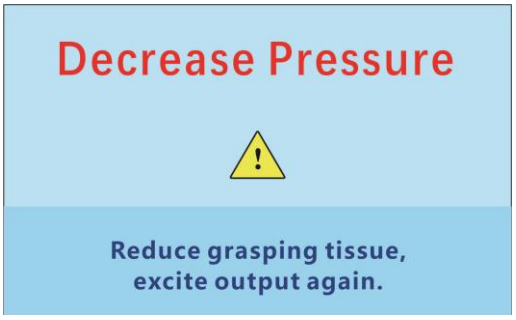


It indicates that all parts work well and the surgery can be performed. Stop the activation by foot or instrument switch, and the generator displays as following:

Operate the instrument on the target tissue by pressing the footplate or the instrument switch.

If the system senses a generator, handpiece or scalpel/scissors fault during testing or use, an audible alarm will sound and the error message will appear on the screen.

If one of the two errors emerges 3 times continuously, an audible alarm will sound and the error message will appear on the screen, such as following:



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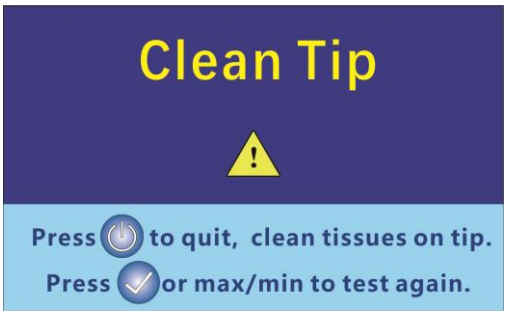

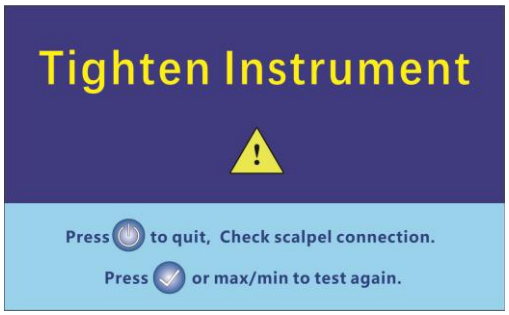

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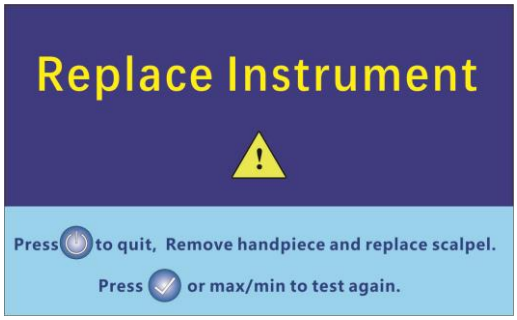
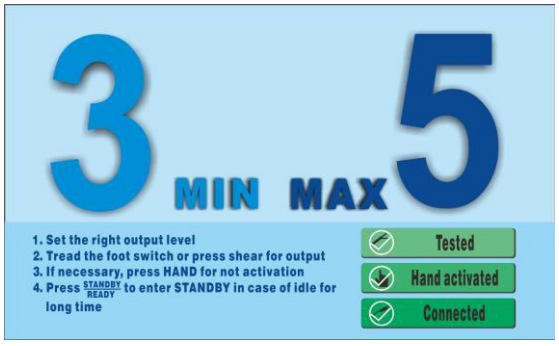


9) Test

In the ready mode, also can press the  button to test the handpiece and scalpel/scissors, the jaw of scalpel/scissors shall be opened, and if the system is normal, it displays as following. Then the surgery can be performed.



10) Standby mode

To avoid internal heat, press the  button to place the generator into standby mode in case of long-time no use.

11) Ready->Standby mode

While exiting standby mode and back to ready mode, the instrument test shall be conducted according to the step7、step8 or step9) to ensure the safety of surgery.

[Note]

Refer to package inserts provided separately for information about the Handpiece, Shear, Test Tip prior to using the system.

Warning

1) **To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects during the system check. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check.**
2) **Place the generator in Standby mode before removing or replacing an instrument, hand switching adaptor or handpiece or when the system is not in use.**
3) **All parts of the ME EQUIPMENT are not serviced or maintained while in use with patient.**
4) **Long time activation of scalpel/scissors may result in high temperature in the tip of scalpel/scissors, it may exceed 80℃, which depends on how long the activation is and which level of output is selected. And the heat in normal operation is necessary for clinical benefit and can help the coagulation. But overheat should be avoided. Please take cautions in long time activation to avoid injuries caused by high temperature on scalpel/scissors. Surgeons can reduce the time period of each activation or reduce the tissue to be cut each time.**
5) **During long time use in operation, the temperature of handle of the scalpel/scissors may exceed 41℃ in some area, at that circumstances, users should avoid holding the handle for longer than 10 mins. Users can stop using for a little time or cool the handle by other means.**

[Note]

1) **The foot switch or instrument switch must be depressed until the system check is completed. If the switch is released prematurely, the check will reinitiate at the next activation.**
2) **The system check will also be performed whenever the handpiece is removed and replaced or TEST is pressed.**
3) **The hand activation button on the generator control panel must be illuminated for the instrument switches to be active, and information** 

will be displayed on the display screen.

**To deactivate the instrument switches, depress the hand activation button, and 

is displayed. (if the hand activation button is not illuminated, instrument switches will be inactive).**

4) If replace the handpiece, please press button to retest on Ready Mode.

IV. System Shut Down

1) Turn the generator power switch off and remove power cord from outlet.

2) Disconnect the handpiece and instrument, and process them as indicated in their respective package inserts.

3) Clean the generator and cart and disinfect the foot switch following hospital protocol (for recommendations, refer to Chapter 6- Product Maintenance)

4) Wrap foot switch cable and the power cord for storage.

5. System Troubleshooting

The generator supports a series of alarms and error massage to help in the identification and troubleshooting of component problems. These guides are meant as an adjunct to, but not a substitute for clinical judgment and observations.

I. Audible Indicators and Alarms

Tone	Possible cause and corrective action
No tone when system is activated	Foot switch or instrument switch is fault.
	Foot switch or handpiece cable is fault.
	If it happens when use instrument, maybe hand activation is disabled
Activation (brief pulses)	System is being activated or is in Test mode. System is operating properly. MIN and MAX power have unique tones.
Short alarm tone	1） Foot switch , instrument switch, or any switch on panel is pressed down， while generator is power on testing 2） The instrument may not be tightened properly 3） Instrument is in contact with too much tissue 4） Tissue may have collected in the distal end of instrument shaft 5） The instrument is bad 6) no handpiece connected with generator

II. Fault Instruction

1) Fault information and solutions provided in the process of power-on self-testing of the generator:

Fault mark	Cause of fault	Troubleshooting
	Fault of "  "button on the front	Check whether the "  "button is pressed

	panel	
	Fault of "  "button on the front panel	Check whether the"  "button is pressed
	Fault of "  "button on the front panel	Check whether the "  "button is pressed
	Fault of "  "button on the front panel	Check whether the "  "button is pressed
	Fault of "  "button on the front panel	Check whether the "  "button is pressed
	Fault of foot “MIN” switch	Check whether the foot “MIN” switch is pressed
	Fault of foot “MAX” switch	Check whether the foot “MAX” switch is pressed
	Fault of instrument “MIN” switch	Check whether the instrument “MIN” switch is pressed
	Fault of instrument “MAX” switch	Check whether the instrument “MAX” switch is pressed
	Fault of power module of generator	Check the output of power module in generator
	Fault of power output circuit of generator	Check the power circuit part
	Fault of output wire of handpiece	Check handpiece
	Fault of communication wire of handpiece	Check handpiece

2) Indicating message and solutions under other condition

Indicating message or error message	Cause of indicating message	Troubleshooting
	The instrumental hand activation is disabled. No alarm sound and effect on output control by instrument switch.	Press  button on the front panel of the generator to activate the instrument switch.
	Turn into Ready mode from Standby mode, and the foot or instrument switch or  button is not activated for testing.	Point the instrumental scalpel/scissors to the air, then activate foot or instrument switch, or press  button on the front panel of the generator.
	The plug of handpiece is not fully connected with the generator.	Confirm that the handpiece connector is fully inserted and properly oriented.
	Power module of the generator is faulty.	Check the output of power module in generator
	The installation of scalpel/scissors and hand piece is loose.	Tighten the scalpel/scissors and handpiece by use special wrench.
	Clamp too much tissue or cutter head blockage, adhesion	Reduce jaw tissue or clean cutter head
	Instrument is bad	Replace the instrument with a new
	Tissue may have collected in the distal end of instrument shaft	Carefully remove tissues from distal end of instrument sheath

6. Product Maintenance

I. Generator and Cart Cleaning

Cleaning generator and cart following hospital protocol. Before cleaning, turn off the generator main power and unplug the power cord from the grounded electrical outlet.

Warning

Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.

Proceed with cleaning as follows:

1) **Prepare a neutral PH detergent or neutral PH enzymatic detergent according to the detergent of manufacturer's directions.**
2) **Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean all surfaces.**
3) **Rinse thoroughly using a soft, clean cloth lightly moistened with warm tap water.**
4) **Dry with a clean and soft cloth.**

II. Foot Switch Cleaning

The foot switch and cable should be cleaned after each use as follows:

1)Disconnect the foot switch from the generator.

2)Prepare a neutral PH enzymatic detergent according to the detergent manufacturer's directions.

3)With the cable securely attached to the foot switch, soak the foot switch and cable in detergent solution for two minutes.

[Note]

Keep the foot switch cable connector that connects to the generator dry at all times to prevent inadvertent activation.

4)After soaking, use a soft-bristled brush to manually clean the foot switch and cable keeping them immersed in the detergent solution.

5) Thoroughly rinse the foot switch and cable - with the cable securely attached to the foot switch – with warm, running tap water for at least one minute.

6) Dry all surfaces with a clean and soft cloth.

III. Handpiece Maintenance

Wrap handpiece and cables with a disposable sterile protective sleeve (size: 12x200cm or above) before each use.

1)Shut off the power, remove the scalpel/scissors, and place it properly.

2)Disconnect the generator from handpiece.

3)Wipe the handpiece and cable with medicinal alcohol.

4)If not used, put the handpiece into the package.

Warning

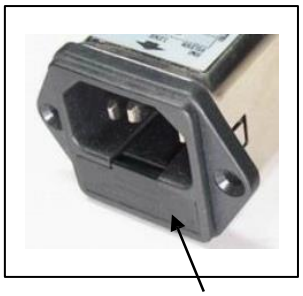
Do not clean the handpiece by ultrasonic cleaner.

IV. Fuse Replacement

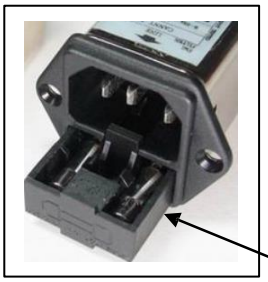
If the generator fails to start, check whether the fuse in the power socket is fused. If it is fused, change it with the same model and parameter (250V /T3.15A, size 5.2mmx20mm).

The operating steps are as follows:

1)Use a straight screwdriver with proper size to pry the fuse box in the power socket.



Fuse box



Fuse box opened

2)Test whether the two fuses in the box are fused by multimeter, change them if they are fused.

3)Close the fuse box after changing the fuse, and recover it to the original state.

V. Equipment Disposal

Some internal components of the generator, foot switch and foot switch cable contain lead. Disposal should be performed according to local requirements regulations.

7. Safety and Function Test

Test the handpiece, generator, and foot switch for safety and function according to hospital protocol. Refer to individual package inserts for safety and function testing for other multi-patient use components.

I. Safety Test

Generator: A qualified hospital technician should perform a leakage current test.

Foot Switch: Examine the footplate, cable connectors, and cable for cracks or other damage and replace if damaged.

Other components: Examine the components by following the instructions in their individual package inserts.

II. Function Test

It's recommended to check the output of the generator at regular intervals.

1) Perform complete instrument preparation and handpiece attachment as described in Chapter 4 System Setup and Operation.

2) Press  button to leave Standby mode and enter Ready mode.

3) Press  to verify that MIN Power Level 3 and MAX Power Level 5 are displayed

4) Push the Increase and Decrease Power Level button up and down to confirm the MIN Power Level changes from 1 to 5.

5) Press  to enable hand activation.

6) Hold the handpiece so that the distal portion is in the air and press  . A three-second system check will be performed - "Testing" will appear on the LCD. After testing, the symbol 

will be displayed.

7) Step on the MIN/MAX foot switch pedal, verify that the MIN/MAX Power Level indicator on the control panel flashes and that the corresponding tone is heard.

Warning

To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system

8. Warnings and Precautions

I. System

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- The ME equipment should be used in the hospital.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocation or re-orienting the equipment.
- Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Safe and effective ultrasonic surgery is dependent not only upon equipment design, but also, to a large extent, upon factors under control of the operator. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- To avoid user or patient injury in the event that accidental activation occurs, the AUTOFORCE Ultrasonic

Surgical System instrument blades should not be in contact with the patient, drapes, or flammable materials while not in use. During prolonged activation in tissue, the instrument blade, clamp arm and distal end of the shaft may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.

- To avoid user or patient injury, the Ultrasonic Surgical System should not be used prior to biomedical evaluation if it shows signs of damage or is suspected of being dropped or having fluids spilled on it.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Product manufactured or distributed by companies other than MICONVEY may not be compatible with the AUTOFORCE Ultrasonic Surgical System. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- The system including the handpiece is not Magnetic Resonance safe and is not Magnetic Resonance compatible.
- To reduce the risk of interference, electrosurgical systems and the AUTOFORCE Ultrasonic Surgical System should be plugged into separate electrical power circuits. Locate the AUTOFORCE Ultrasonic Surgical System, including the handpiece cable, at least approximately 1m from electrosurgical systems and their handpiece (e.g. pencil) cables.
- Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. It is possible to create sparks by hitting other metal instruments. Sparks may ignite flammable gases such as bowel gas.
- The system must be operated within the required ambient operating conditions. *(Refer to Chapter 9-System Specification.)*
- To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.
- Verify that the outlet voltage correctly corresponds to the generator's requirements. *(Refer to Chapter 9 -System Specification)*. Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.
- The AUTOFORCE Ultrasonic Surgical System includes components that are shipped non-sterile (e.g.Handpiece). Sterilize products as required before beginning system setup. Refer to individual

package inserts for cleaning and sterilization instructions.

- To avoid user or patient injury, ensure that the instruments is clear of other instruments, drapes, the patient, or other objects before pressing TEST and during the system check. Safety measures(in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check and while in Test mode.
- To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.
- Do not simultaneously touch the patient and generator.
- Place the generator in the Standby mode before removing or replacing an instrument or handpiece or when system is not in use.
- Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.
- In case of system failure, ensure the availability of the appropriate backup equipment relevant to the specific procedure.
- Do not open the shell of generator without permission, to avoid possible electric shock hazard. Any maintenance and upgrade to the instrument must be conducted by service personnel trained and authorized by MICONVEY TECHNOLOGIES CO., LTD.
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Please contact Miconvey if there is any accident related to cybersecurity occurs.

II. Scalpel/scissors

- The scalpel/scissors should not be output continuously for a long time, otherwise it may cause excessive heating

  of the components or the scalpel/scissors. In principle, it should not exceed 15s at a time.

- During prolonged activation in tissue, the instrument blade and the distal 7cm of the shaft may become

  hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.

  [Note]

  Please refer to individual package inserts for additional warnings and precautions.

9. System Specification

I. Required Components

Ultrasonic Surgical Generator: K500

Ultrasonic Surgical Handpiece: QUHP35, QUBP55, the cable length is 2.9m

Disposable Ultrasonic Surgical Scalpel: Gamma sterilization (QUHS36S, QUHS23S, QUHS14S), EO sterilization (QUHS45S-H, QUHS36S-H, QUHS23S-H, QUHS14S-H).

Ultrasonic Open Surgery Scissors: EO sterilization (SAF09D, SAF17D).

Foot Switch: QFS02, the foot switch cable is connected firmly and cannot be disassembled, and the cable length is 2.9m.

Power Cord: 100V-240V rated current of 10A, cable length maximum 2.9m.

Fuse: 2 x 250V/T3.15A

II. System Specification

Electric Shock Protection Degree: applied part of CF type

Electric Shock Protection Type: Class I

Safety Standard: EN60601-12006/A1: 2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Harmful Immersion Protection: ordinary equipment

Protection Degree: Foot switch: IPX8

Power: Power voltage: 100-240VAC, Power frequency: 50/60Hz

Rated Input Power: 150VA

Output Power: 50VA

Working Condition:

Temperature: 10 ℃-30 ℃

Relative humidity ≤70%;

Air pressure range: 860hPa-1060hPa

Transportation and Storage Condition:

Temperature: -20 ℃ ~ + 50 ℃

Humidity: ≤95%

Air pressure range: 700hPa-1060hPa

Weight of Generator (without packaging): normal 7kg

Total Volume of Generator(W*D*H): 372.8mm *368.6mm *123.6mm

Disposal: some components and parts such as foot switch, and foot switch wire contain lead, which shall be disposed according to local requirements and regulations.

AP / APG Category: Non-AP/APG type equipment.

Date of Manufacture: Find the back panel of the generator for the date of manufacture

Warning

To ensure the safety and stability of the system and other equipment, please use the required power cord. Otherwise it may cause instability of the equipment and other equipment.

Handpiece is the matched part of the system. Using other company parts or cables may cause system failure and even patient injury.

10. Electromagnetic Compatibility Statement

1.This chapter provides special tips on electromagnetic compatibility. The product shall be installed and used according to the electromagnetic compatibility information in this chapter.
2.Portable and mobile radio frequency communication equipment may affect the use of this product. When using this product normally, it is recommended to stay away from portable and mobile radio frequency communication equipment or turn it off.
3.The connecting cable provided by our company must be used.
4.Warning: in addition to the accessories provided by the company, the use of other manufacturers' accessories may increase the emission or reduce the immunity of the product, give an alarm or be unusable.
5.See table 3.
6.This product should not be used close to or stacked with other equipment with the same or similar working frequency. If it must be used close to or stacked, observe and verify that it can operate normally under its used configuration.
7.See table 4.
8.The basic performance is that the equipment can continuously provide ultrasonic output without unexpected change in working mode.
9.See table 5 and table 6.
10.In order to ensure the normal use of this product and ensure that its emission is not increased and its immunity is not reduced, please select the connecting cable and relevant accessories provided by our company.

Cable name	Length (m)	Is it shielded
Handle cable	2.9m	yes

The use of accessories, transducers or cables other than those specified with this product may increase the emission of equipment or system or reduce the immunity.

Table 3

Guidance and manufacturer's declaration - electromagnetic emissions.		
The product is intended for use in the electromagnetic environment specified below. The customer on the user of the product should assure that it is used in such an environment：		
Emissions test	Compliance	Electromagnetic environment - guidance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1	The product uses 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.
Terminal disturbance voltages CISPR 11	Class A	The product only applies to the usage in facility that is not directly connected to the public low voltage power-supply network of non-household and household residence.
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable	

Table 4

Guidance and Declaration-electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer on the user of the product should assure that it is used in such an environment：			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guideline
ELECTROSTATIC DISCHARGE IEC 61000-4-2:2008	±8 kV contact discharge ±15 kV, ±8 kV, ±4 kV, ±2 kV air discharge	±8 kV contact discharge ±15 kV, ±8 kV, ±4 kV, ±2 kV air discharge	Floors shall be wood, concrete, or ceramic tiles. If the floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients / bursts IEC 61000-4-4:2012	±2 KV for power supply lines ±1 KV for Input/output lines	±2 KV for power supply lines ±1 KV for Input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surges IEC 61000-4-5:2005	±1 kV line to line ±2 kV line to GND	±1 kV line to line ±2 kV line to GND	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips/Voltage interruptions IEC 61000-4-11:2004	0% UT: 0.5 cycle at 0°, 45°,90°,135°,180°,225°, 270°and 315° 0 % UT：1 cycle and 70 % UT：25/30 cycles Single phase: at 0° 0 % UT：250/300 cycle	0% UT: 0.5 cycle at 0°,45°,90°,135°,180°, 225°, 270°and 315° 0 % UT：1 cycle and 70 % UT：25/30 cycles Single phase: at 0° 0 % UT：250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields （50Hz/60Hz） IEC 61000-4-8:2009	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.			

Table 5

Guidance and Declaration-electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer on the user of the product should assure that it is used in such an environment：			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -Guideline
Conducted disturbances induced by RF field IEC 61000-4-6:2013 IMMUNITY to proximity fields from RF wireless communications equipment IEC 60601-1-2:2014	3 V（effective value） 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.7 GHz	3 V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance： d=1.2 $\sqrt{P}$ d=1.2 $\sqrt{P}$ 80MHz ~ 800MHz d=2.3 $\sqrt{P}$ 800MHz ~ 2.7GHz 式中： 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：adopt formula with higher frequency on the frequency points 80MHz and 800MHz. NOTE 2：these guidelines may not suitable for all cases. The electromagnetic propagation is effected by absorption and reflection of building, object, and human body.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and ground mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. Due to its emission characteristics, this equipment is suitable for industrial sites and hospitals (CISPR 11 class a). If it is used in residential environment (CISPR 11 class B is generally required), this equipment may not provide sufficient protection for RF communication services. Users may need to take mitigation measures, such as changing its location or adjusting the direction of the equipment.			

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

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the product			
The product is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters), 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		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.7GHz $d = 2.3\sqrt{P}$
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.			

Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This handpiece has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this handpiece as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Test specification for ENCLOSURE PORT IMMUNITY TO RF wireless communications equiment

The function of basic system performance includes the following contents

1) "Standby" mode indication;

2) "Ready" mode indication;

3) Power level setting and figure display;

4) Have two optional power output which can set the "MIN" power level output (one to five power gear) and fixed power level output (gear five).

Warranty

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the People's Republic of China.

MICONVEY warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below.

MICONVEY obligation under this warranty is limited to the repair or replacement, at its option, of anyproduct, or part thereof, which has been returned to MICONVEY or its Distributor within the applicable time period shown below and which examination disclosed, to MICONVEY's satisfaction to be defective.

This warranty does not apply to any product or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by MICONVEY, (2) repaired or altered outside MICONVEY's factory in a way so as to, in MICONVEY's judgment, affect its stability or reliability,

(3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

MICONVEY's products are warranted for the following periods after delivery to the originalpurchaser:

Handpiece	Nine (9) months, Parts and Labors
Generator	One (1) year, Parts and Labors
Carts	One (1) year, Parts and Labors
Foot Switch and Cable	One (1) year, Parts and Labors

Unless superseded by applicable local law, this warranty is in lieu of all other warranties, express or implied, including the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of MICONVEY and is a purchaser's exclusive remedy. In no event shall MICONVEY be liable for special, incidental or consequential damages including, without limitation, damages resulting from loss of use, profits, business or goodwill, other than as expressly provided by a specific law. MICONVEY neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any products of MICONVEY TECHNOLOGIES CO., LTD. There are no warranties that extend beyond the terms hereof.

MICONVEY reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

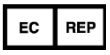
Symbols

I. LABEL

MANUFACTURER

DATE OF MANUFACTURE

SERIAL NUMBER



SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

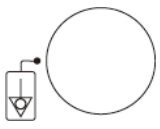
CONSULT INSTRUCTION FOR USE

ELECTRICAL AND ELECTRONIC EQUIPMENT. RETURN WASTE TO A COLLECTION SYSTEM OR TREATMENT AND RECYCLING FACILITIES. APPLICABLE IN THE EU. FOLLOW DECONTAMINATION INSTRUCTIONS BEFORE RETURNING WASTE.

TYPE CF APPLIED PART

NOTIFIED BODY

FOOT SWITCH RECEPTACLES



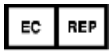
EQUIPOTENTIAL TERMINAL

II. PACKAGE

MANUFACTURER

CONSULT INSTRUCTION FOR USE

MADE FROM 100% RECYCLED FIBRES



SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

NOTIFIED BODY

TEMPERATURE LIMITATION

FRAGILE

THIS END UP

KEEP DRY

DO NOT CRUSH

Unit of after-sales service: MICONVEY TECHNOLOGIES CO., LTD.

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EC REP 【Authorized representative in the European Community】

Name: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

MICONVEY TECHNOLOGIES CO., LTD.