CE 0197

Ultrasonic surgical system generator

User Manual

B.J.ZH.F. Panther Medical Equipment Co.,Ltd

 Please read the user manual carefully!

All the information contained in this user manual has been confirmed to be correct. This company shall assume no responsibility for any accidental injury or any life-threatening event directly or indirectly caused by improper use or incorrect operation, and all the information contained in this manual is protected by law.

This manual only provides instructions for the use of the system and does not involve surgical technical information.

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Chapter 1 General Description

Product Name:

Ultrasonic surgical system generator (hereinafter referred to as “system”)

Product Model:

System Model: SG100；

Matching Drive Handle Model: HP1；

Matching Cutter Head Model: SE54,SE45,SE36, SE23, SE14.

Fuse Model: F3AL250V.

Fuse Replacement Method: there is a fuse holder in the middle of the back panel power socket. Opening the fuse holder can facilitate fuse replacement. After the replacement is complete, buckle the fuse holder back into the middle of the power socket.

Main machine Dimension: 343mm（length）×330mm（width）×136mm（height）

Main machine weight: 4.6kg

The cable information is shown in table 1:

1 Table 1

Serial No.	Name	Cable length (m)	Shield Yes/No	Remarks
1	Power line	5	No	
2	Ground wire	5	No	
3	Foot Switch wire	3	Yes	
4	Drive Handle wire	3	Yes	

Indications:

This system is indicated for soft tissue cutting when bleeding control and minimal thermal injury is desired. It is also indicated for general, gynecologic in open and Laparoscopic surgery.

It can not be used for the blood vessel with close diameter more than 3mm alone. The product is not applicable to bone removal, dental, tubal ligation and neurosurgery.

Contraindications:

1. A patient with a systemic hemorrhagic disease;
2. A patient unable to withstand surgery due to serious heart, liver or lung insufficiency;
3. A patient with diabetes or with hypertension whose condition is out of control;
4. A patient taking anticoagulants such as aspirin or warfarin should not be operated on until coagulation function returns to normal 2 weeks after medication withdrawal;
5. A patient complicated by a serious infectious disease whose condition is out of control;
6. Any other patient who may have corresponding surgical contraindications.

Operation Environment

Temperature 10 °c — 40 °c, relative humidity ≤ 75%, pressure range: 700hpa — 1060hpa

Product Performance Requirements

1. Resonant frequency: 55.5kHz±1kHz；
2. Primary tip vibration excursion can be adjusted in 5steps (i.e. levels);
   The maximum is 75μm with an error of ±10%;
   The minimum is 45μm with an error of ±10%;
3. Vibration frequency of the tip of cutter head
   55.5kHz±1kHz.
4. Quiescent electrical power is 18W±1.8W；
5. Maximum electrical power is 18W±1.8W；
6. Category to which the equipment belongs: Class I;
7. Classified by the degree of protection against electric shock of the applied part : Type CF
8. Classified by the protection degree against harmful ingress of liquids : Foot switch IPX8；
9. Classified by the use of flammable anesthetic gas mixed with air or by the use of flammable anesthetic gas mixed with oxygen or nitrous oxide: non-AP/APG equipment;
10. Classified by operation mode: intermittent loading continuous operation (intermittent 15s/loading 15s);
11. Rated voltage and frequency of equipment: AC 100-240V 50/60Hz；
12. Input power of equipment: 150VA；
13. Secondary tip vibration excursion of cutter head
    Less than 10 μm.
14. Power reserve index

Power reserve index should be 1-2.

15. Primary acoustic output area

Primary acoustic output area of the tip of cutter head is no more than 3 square millimeters

16. Derived output acoustic power

Derived output acoustic power shall be more than 100 mW.

17. Directivity patterns

Sound pressure at $\theta=0^{o}$ with an error of ±30% : 25×10^{-3}MPa
Sound pressure at $\theta=+45^{o}$ with an error of ±30% : 20×10^{-3}MPa
Sound pressure at $\theta=+90^{o}$ with an error of ±30% : 15×10^{-3}MPa
Sound pressure at $\theta=-45^{o}$ with an error of ±30% : 20×10^{-3}MPa
Sound pressure at $\theta=-90^{o}$ with an error of ±30% : 15×10^{-3}MPa

18. Secondary acoustic output area

Wide surface secondary acoustic output area should be less than $35mm^2$.
Narrow surface secondary acoustic output area should be less than $25mm^2$.

Safety Requirements

Warnings: Warnings are used to alert users that certain errors in the operation of the instrument may result in injury or death to patients.

Cautions: Cautions are used to remind users of the possibility of patient injury or problems such as malfunction or crash of the instrument, damage to the instrument itself or to any other property, which are caused by operating the instrument correctly or incorrectly.

Notes: Include some important and easily overlooked information for users to better understand and apply the instrument.

Warnings：

- Product accessories not manufactured by this company may not be compatible with this system. Use of any product not manufactured by this company may cause unintended consequences or harm to users or to patients.
- Minimally invasive procedures are only intended for medical personnel who have been professionally trained and proficient in minimally invasive techniques. It is known from relevant medical literature and related techniques that the use of any minimally invasive procedure may produce complications .
- It is very necessary to master the theories of operations and techniques for laser, electrosurgery and ultrasonic procedures. Such things can be avoided as electric shock, burn hazard to both patients and medical personnel , and damage to the device or to any other instrument or equipment. Make sure that electrical insulation and grounding are good. The electrosurgical instrument can not be immersed in liquid unless the instrument is designed to be immersed in liquid and its label indicates that it can be immersed in liquid.
- Safety and effectiveness of ultrasonic surgical equipment depend not only on the equipment design, but also on many factors like the system control by the operator. In order to improve the safety and effectiveness of the system, the user manual must be read and understood before use.

- Equipment can not be used in any place where flammable anesthetics formed by air or oxygen mixing with carbon monoxide. Hitting a metal instrument may produce sparks, which may ignite such flammable gases as xenon.
- It is prohibited to use this instrument in an environment with flammable anesthetic gases.
- It is prohibited to use this instrument in the course of nuclear magnetic resonance imaging (MRI) examination or in the course of computed tomography(CT)examination.
- It is prohibited to use this instrument in an environment with any high frequency.
- When energized endoscopes are used with equipment, patient leakage currents may be additive. In which case a type cf applied part energized endotherapy device should be used in order to minimize total patient leakage current.

Chapter 2 Instrument Brief Introduction

Ultrasonic surgical system generator (hereinafter referred to as “system”) consists of a main machine, a drive handle and a foot switch,

Soft-tissue ultrasonic surgical system holder/tip Model: SE54,SE45,SE36, SE23, SE14.

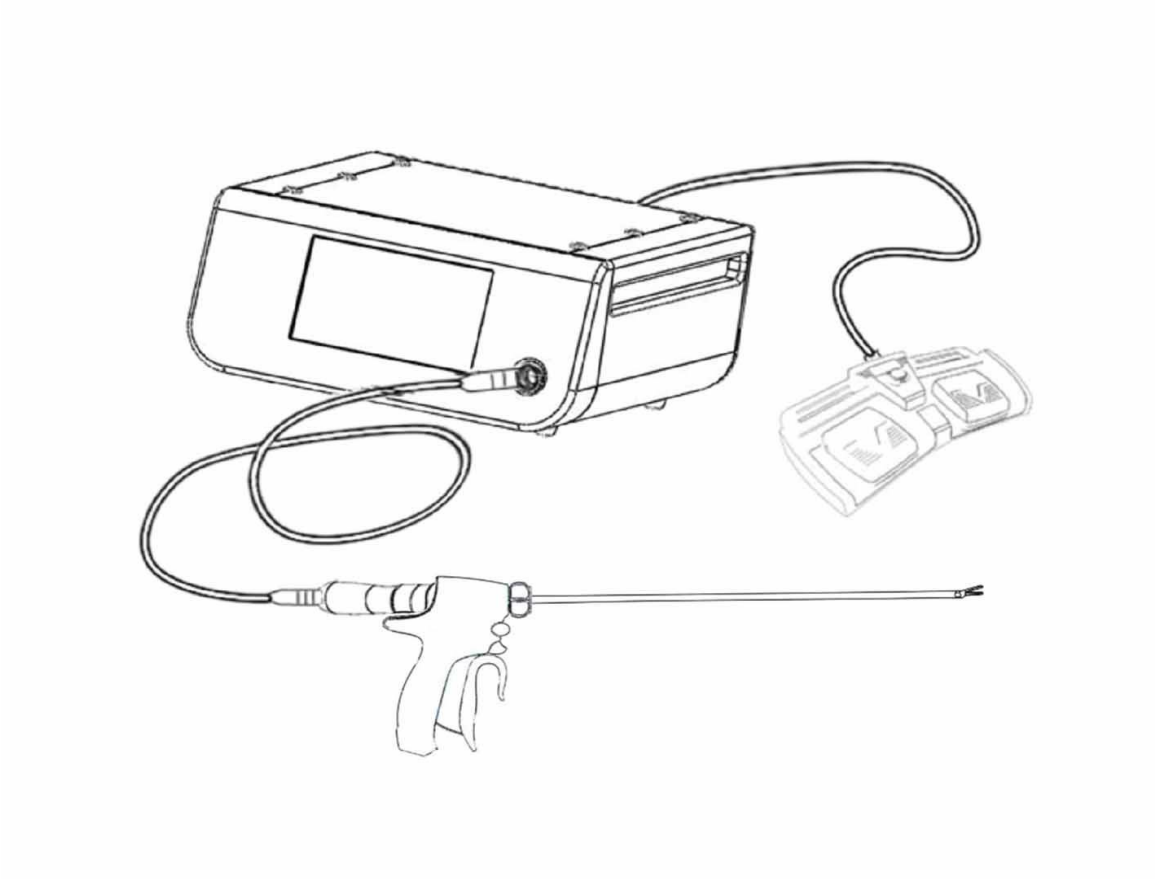

Fig 2-1

2.1 Theory of Operation

Main machine converts electrical energy into mechanical energy and makes the metal cutter head mechanically vibrate at an ultrasonic frequency of 55.5KHz through the ultrasonic frequency generator (drive handle) to vaporize water molecules in tissues, break protein hydrogen bonds, disintegrate cells, cut or to solidify tissues and close blood vessels so as to achieve the purpose of tissue cutting and hemostasis

Ultrasonic surgical system generator uses ultrasonic energy to achieve hemostatic cutting and/or coagulation of soft tissues to control bleeding and reduce thermal injury.

2.2 Product Appearance

Front Panel

Fig 2-2

1. System State Display Column: displays current working state of the machine,the use times of the driving handle and the host.

2. Blood Coagulation Power Level Adjustment Button: click this button to set the power level by adjusting in steps (i.e. levels) 1 to 5.

3. Cutting Energy Indicator.

4. Ultrasonic output interface: the interface connecting the cable of the drive handle. with a mark U/S.

5. System Setup Button: can perform setups for system volume, blood coagulation tones, cutting tones, and for background pictures and languages

6. Switch Changeover Button: changeover button between manual and foot switches.

7. Mode Changeover Button: changeover button between ready and standby modes.

8. Tuning Button.

Back Panel

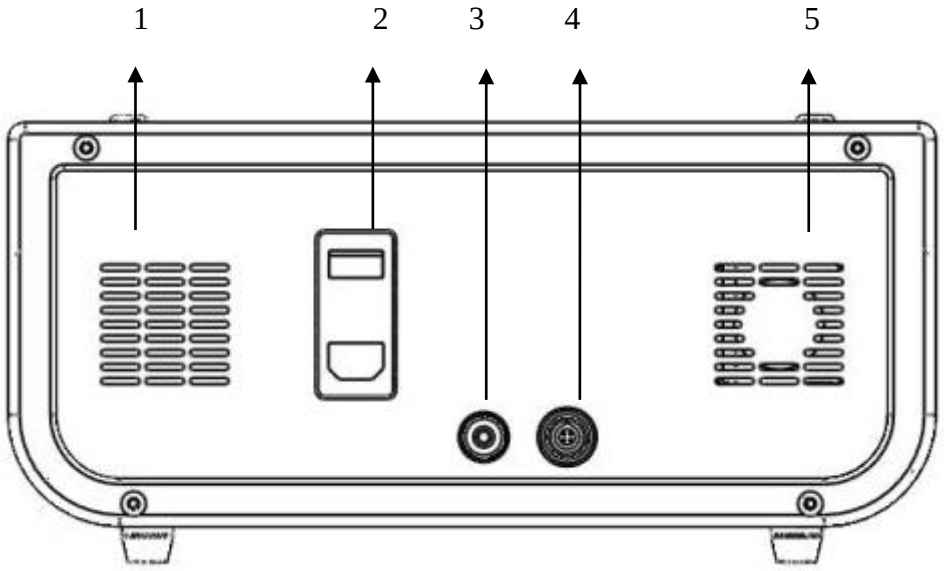

Fig 2-3

1. Speaker.

2. Main Machine Power Supply Socket and Switch

3.Equipotential Terminal

4. Foot Switch Socket with a Mark FS

5. Cooling Fan

Chapter 3 System Installation

3.1 Preparation and Checkout

Warnings:

- Prepare and check this product according to the following instructions before each time use. Other pieces of equipment to be used together with this product shall be checked in accordance with their respective user manuals. Please do not use this product even if any slight abnormality is found, and refer to the content of "troubleshooting"in chapter 8. If there is still any abnormality after referring to chapter 8, please contact our company. Damage or abnormality to the equipment may endanger the safety of patients or of operators, and may lead to more serious damage to the equipment.
- This product has not been sterilized before delivery. Before initial use, cleaning, disinfection and sterilization shall be carried out according to the instructions of "cleaning, disinfection and sterilization".
- If any crack or scratch is found on the cutter bar, please do not use it. Otherwise abnormal output or broken cutter bar may occur.
- Check the pressure mouth for wear, tooth deformation or for other damage. These conditions can result in abnormal output or broken cutter bar.
- Do not use a cutter with exposed metal of its pressure mouth. Otherwise, fall-off of the cutter bar or of the pressure mouth may occur.
- If the connection point inside the drive handle's plug or inside the connection cable's socket blackens, replace the drive handle and the connection cable. Otherwise, the equipment will be short-circuited and cause damage to the main machine.
- When checking or using this product, be sure to wear appropriate personal protective equipment, such as goggles, masks, waterproof protective clothing ,and chemical protective gloves of appropriate size and length that will not expose skin. Otherwise, blood, mucus and other potentially infectious substances from patients will cause infection risk.
- Do not use a cutter if any gap is found between its pressure mouth (white part) and its metal part.

Cautions:

- Please do not exert excessive force when installing or disassembling this product. If the equipment is difficult to install, do not bend or hit any parts by force, but should disassemble and reinstall them. If it is still difficult to install, thoroughly check the equipment and its components for abnormalities. If you observe or suspect that there is something wrong with the equipment or its components, please do not use it and contact our company.
- Check the instrument thoroughly after each use. If any abnormality is found, please do not use this product and contact our company.
- Do not use any component if it is out of shape. Even the original shape is restored, the durability of the component will be weakened. Its continued use will result in more serious instrument damage or inability to remove the instrument from the trocar cannula.
- If the drive handle connection cable is damaged or ruptured, its leakage current will cause burns to the operator or the patient. Replace the cable if the it is damaged.
- Do not use a cutter if its clamping spacer(white part) is visibly worn. Too thin a clamping spacer will reduce grasping force and solidification ability. The clamping spacer(white part) will wear away gradually.
- Do not touch any plug connection point or socket connection point when checking or connecting drive handle and the cutter. The electrostatic charge accumulated by high temperature and high

pressure sterilization may cause electric shocks.

3.1.1 Checkout for the Drive Handle,Connection Cable, and the Cutter

The pressure mouth will be gradually worn out as a result of the ultrasonic vibration of the cutter bar,as shown in Fig 3-1.Ensure that the cutter is checked before each use so as to prevent sudden breakage of the cutter or weakening of the cutting quality and of solidification ability, and replace the cutter with a new one if necessary. Damage to the cutter's pressure mouth can result in abnormal output, aggravated damage to equipment or injury to patients. Do not use any damaged cutter.

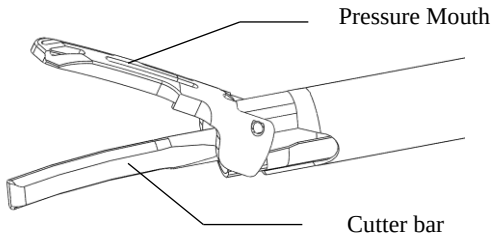

Fig 3-1

1. Confirm sure that the drive handle and the connection cable are free of dust, dislocation, cracks or loosening.If the connection point inside the drive handle socket or inside the connection cable plug blackens,replace the drive handle or the connection cable with a new handle or a new connection cable respectively.
2. Check the inside of the plug for any foreign matter or any liquid. If any liquid is found, dry the liquid by dry gauze with the plug down. If any foreign matter inside, clean the plug by sterile brush. Do not poke or scrape the connection point with the metal tip of the brush . Check and clean the inside of the socket in the same way.
3. After cleaning as described in step 2 above, repeatedly connect and remove the socket and the plug about 10 times. Repeated connection and disassembly of the socket and the plug helps to remove substances attached to the connection point. If a foreign matter solidifies on the connection point, the above operation is a very useful cleaning measure.

4. Confirm the cutter is marked with a clear serial number.

5. Confirm the cutter is free of dust, dislocation, cracks, looseness, dents or bending.

6. Check the entire insulation part of the cannula for peeling, loosening, breakage or crease.

7. Verify the pressure mouth of the cutter is not damaged. Special care shall be taken in the following cases:

1） If the teeth of the pressure mouth are bent or too far apart from each other, insufficient grasping or improper cutting may arise; Please do not use this cutter, replace it with a new one.

2） Make sure stop using the cutter immediately as long as its clamping spacer(white part) is too thin or worn, and replace the cutter with a new one. Failure to do so will result in abnormal output, broken cutter bar or damaged tissues.

3） Do not use a cutter if there is any gap between its clamping spacer (white part) and its metal part.

3.2 System Connection and Installation

3.2.1 Connection and Installation of the Cutter and the Drive Handle

As shown in Fig 3-2

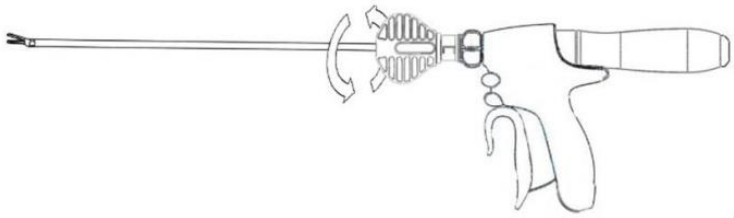

Fig 3-2

Cautions:

- Confirm the cutter and its drive handle are firmly connected. Hand-tightened cutter may lead to unsafely transmitted ultrasonic output, damaged cutter bar, or hot surface of the drive handle.
- Only use a torque wrench to loosen/tighten the cutter. Please do not use other equipment to tighten the cutter. Otherwise, the equipment or the drive handle may be damaged.
- If the cutter does not rotate smoothly, disassemble itself and its matching parts and reinstall, and then screw them together. Excessive screwing force can cause damage to the cutter or to its drive handle.
- Tighten with the torque wrench until a click is heard, which indicates tightness has been achieved.
- Connection of Multiple Time Use Cutter:

1. Insert the drive handle's screw part into the cutter bar's joint. Then rotate the drive handle with your fingers until it is tightened.
2. Install the torque wrench into the cannula's groove and tightly hold both the torque wrench and the drive handle. Then rotate the cutter clockwise with the torque wrench until the torque wrench clicks.
3. When a drive handle has to be replaced during use, check the new drive handle according to "Checkout for the Drive Handle,Connection Cable, and the Cutter and the Cutter Bar", Perform step 1 and step 2 above to connect the new drive handle to the cutter.

- Connection and Installation of Single time use Cutter

1. Remove the disposable cutter from the package.
2. Insert the drive handle's screw part into the cutter bar's joint. Then rotate the drive handle with your fingers until it is tightened.
3. Install the torque wrench into the cannula's groove and tightly hold both the torque wrench and the drive handle. Then rotate the cutter clockwise with the torque wrench until the torque wrench clicks.
4. When a drive handle has to be replaced during use, check the new drive handle according to "Checkout for the Drive Handle,Connection Cable, and the Cutter and the Cutter Bar", Perform step 1 and step 2 above to connect the new drive handle to the cutter.

3.2.2 Connection and Installation of the Main Machine Front Panel

Cautions:

- Please do not touch the pin in the plug of the connection cable. Otherwise, the static electricity on the pin may cause an electric shock.
- Hold the connection cable plug when connecting or removing the connection cable or when removing the waterproof cover from the plug. Pulling the cable can cause damage to the cable or to the internal wires.

As shown in Fig 3-3, insert the drive handle connector plug into the ultrasonic output socket of the main machine, and align one red dot with the other red dot.

Fig 3-3

3.2.3 Connection and Installation of the Main Machine Back panel

Warnings:

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position ME equipment to make it difficult to operate the disconnection device

Cautions:

- When connecting or removing the power plug, be sure that the other end of the power cord is disconnected and that the power switch of the main machine is in the off state.
- Please do not touch the pin in the plug of the connection cable of the foot switch. Otherwise, the static electricity on the pin may cause an electric shock.
- Hold the cable plug of the foot switch when connecting or removing the foot switch. Pulling the cable can cause damage to the cable or to the internal wires.

As shown in Fig 3-4, insert the power cord plug into the power cord socket of the main machine,

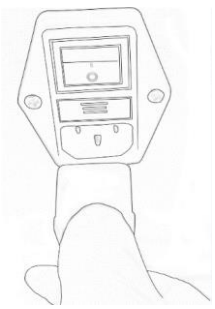

Fig 3-4

As shown in Fig 3-5, insert the foot switch plug into the foot switch socket in the main machine back panel.

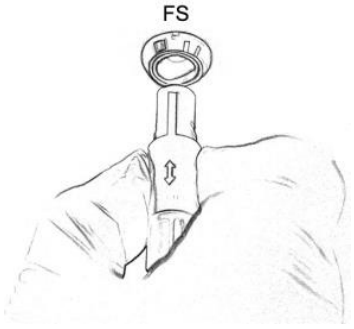

Fig 3-5

Chapter 4 System Checkout

4.1 System Checkout

Cautions:

- Do not carry out ultrasonic output while closing the pressure mouth. Otherwise, the abnormal heat caused by the friction between the pressure mouth and the cutter bar may cause damage to the both or cause their fall-off
- Please do not carry out ultrasonic output when the cutter bar is in contact with other objects. Otherwise, the equipment can be damaged, the head of the cutter bar can fall off, or the metal noise can be caused by friction.
- Please do not touch the cutter bar while output is being carried out.Otherwise burns may occur.
- Please do not use the system and contact our company if you do not hear the ultrasonic output prompt tone when activating the output.
- After connecting the drive handle to and powering up the main machine, if" handle not connected" is prompted in the course of the starting up and initialization of the main machine,it indicates that the drive handle connection cable is not properly inserted.
- The main machine enters “PLEASE TUNE” state after its initialization is successfully completed.Click the “TUNE”button, a few seconds later, if the main machine does not prompt“STANDBY”, but prompts“TUNING FAILED，it is highly possible that the drive handle or the cutter is not working properly. In such a case, immediately replace the drive handle or the cutter with a spare drive handle or with a spare cutter respectively.

4.2 Ultrasonic Output Checkout

Warnings:

- Abnormal noise made during output process may indicate that the equipment or the drive handle has been damaged.The continued use of the damaged equipment will result in the damage or fall-off of the cutter bar.In such a case, it should be replaced with standby equipment.

1. During the checkout, confirm that the cutter bar of the instrument does not touch any other object, and that the pressure mouth is in an open state.
2. Step down the output pedal of the foot switch (maximum value) for about 5 seconds.During this time, confirm that ultrasonic output sound is heard, and that output music is played at the same time. Please refer to “Troubleshooting”in chapter 8 if the ultrasonic output is abnormal.

4.3 Trocar Compatibility Checkout

Warnings:

- The outer diameter of this product’s cannula is 5.5 mm.Use a right sized trocar. It is recommended that these pieces of equipment be confirmed to be compatible with each other before the trocar is used in combination with this product.
- Please do not fall this product off. Excessive force on the pressure mouth or on the head of the cutter bar may result in a broken cutter or failure to open or failure to close the cutter bar. Do not

use any broken cutter,which may be stuck in the sheathing cannula in the course of pulling out or extraction even if it is available to insert the product into the trocar's shealthing cannula.

- When installing a trocar with sharp edges and corners of the opening part , hard contact will cause the fall-off of or other damage of the insulation skin of the cannula.Before use, install this product on the trocar, and verify its insulation skin is not damaged.
- Please do not open the cutter's pressure mouth when inserting the pressure mouth into the trocar, otherwise, mechanical damage to the cutter, trocar or to the interior of the cutter can occur. This product will be unable to grasp tissues correctly if its cutter or pressure mouth is damaged.
- Hold the cutter firmly when extracting this product out of the trocar. Please do not hold its cannula; Otherwise the pressure mouth may get stuck in the trocar, causing damage to the cutter.

1. Close the pressure mouth of the cutter, and carefully insert the instrument cannula into the trocar.
2. Verify that both the cutter and the cutter bar's pressure mouth protrude from the head of the trocar.
3. Make sure the cannula moves smoothly within the trocar.
4. After confirming compatibility, carefully remove the cannula from the trocar.

4.4 Cable Checkout

Cautions:

- Only use the cable provided with this product. Do not use other cables, as doing so can not guarantee the safety of both the cables and this product.
- Firmly install the cable and the drive handle. If the output starts with the cable not securely installed, the operator or the patient may get burned.
- If the cable is found scratched, cracked or peeled, do not use it. Thus the cable will deform or break. The operator or the patient is likely to get burned if the cable falls off during operation. Please confirm safe connection has been achieved. Otherwise, replace the cable or the equipment with a spare cable or with standby equipment respectively.

1. Verify that the cable interface is free of any scratch and any crack.
2. Confirm its connection is firm.

Chapter 5 Instructions for Operation

Warnings:

- Wearing personal protective equipment can protect operators from dangerous chemicals and potentially infectious substances. Appropriate personal protective equipment, such as goggles, masks, waterproof clothing and chemical gloves, shall be worn during operations. Personal protective equipment should be of the right size and long enough to avoid skin exposure.
- To ensure that surgery is successfully completed without being affected by malfunction, standby equipment or appropriate emergency handling should be well prepared.
- In the course of use, if this product has any abnormality or malfunction, stop using and replacing it with standby equipment, and contact our company.
- Ensure that neither the pressure mouth nor the cutter bar is in contact with surrounding tissues before output is activated, otherwise, ultrasonic output can lead to perforation, bleeding, burns or tissue damage
- Whenever possible, try to avoid the cutter's cannula in contact with tissues. If ultrasonic output is carried out for a long time, the temperature of the cannula's surface can rise, resulting in burns at the tissues in contact with the cannula.
- When ultrasonic output is activated, do not touch the cutter bar with any hard objects(such as metal clips or other equipment), please do not grab the cutter bar.
- Accidental contact with the cutter bar should also be avoided. Otherwise, the cutter bar may be overworn or damaged due to ultrasonic vibration.
- Please do not activate ultrasonic output when twisting the cannula to grab hard or thick tissues, or when rotating the rotatable knobs. Otherwise, the cutter bar can come into contact with internal components, resulting in its damage or its head's fall-off.
- Do not increase ultrasonic output too much or too quickly. Otherwise, the result will be patients' injury or reduced durability of the equipment.
- In the course of use, if ultrasonic output stops, the cannula connected with the drive handle and with the connection cable should be immediately extracted from the patient's body , and then be checked according to the instructions for "when ultrasonic output malfunctions". Otherwise, the patient will get injured.
- If the pressure mouth or the cutter bar falls off, please stop using the equipment immediately and take an appropriate method to take out the fallen part.
- When the cutter bar is contaminated by carbonized tissues, wet soft gauze should be used to remove tissue debris. Do not scrape with sharp objects such as a scalpel. Otherwise, the cutter bar may be scratched or broken, and will be likely to fall into the body cavity during the ultrasonic output process.
- Do not activate the output when no object is grabbed between the pressure mouth and the cutter bar, or when it is not certain that the tissues to be grabbed have been completely removed. Otherwise, the friction between the pressure mouth and the cutter bar will produce abnormal heat, causing damage to the both or causing their fall-off.
- Continuous ultrasonic output can make the cutter bar hot. Do not come into contact with any tissue other than targeted issues, otherwise the issue will be burned. The output shall be stopped immediately after tissues are removed. Otherwise, the pressure mouth and the cutter bar's head can be worn out. Extra care should be taken when using the instrument at a higher output.
- Do not use this product unless clear endoscopic images are obtained. Otherwise, the patient will be injured.
- The cutter bar's head of this product is relatively sharp, so the trocar should be inserted and operated carefully.
- Please do not attempt to remove tissues when the pressure mouth cannot be opened smoothly. Excessive force on the cannula can lead to cutter damage. When the pressure mouth is unable to be opened/closed, the equipment shall be stopped immediately and be extracted from the

patient's body to avoid injury.

- When replacing the drive handle, be sure to extract the cutter from the patient's body. After its extraction, remove the plug from the drive handle socket. If the drive handle is being replaced while the cannula is in the patient, the force used for removal can cause the cutter head to press against tissues, causing damage to the equipment or injury to the patient.
- Do not activate ultrasonic output if blood or saline solution is found inside the plug or inside the socket. Otherwise, the equipment will be short-circuited, resulting in damage to the main machine.
- If the connection point inside the drive handle's plug or inside the connection cable's socket blackens, replace the drive handle and the connection cable. Otherwise, the equipment will be short-circuited and cause damage to the main machine.

Cautions:

- Gently hold the control cutter and ensure that the pressure mouth is closed when inserting this product into the trocar, or removing this product from the trocar. If the pressure mouth is open when the product is inserted or removed, the cutter bar will be likely to be damaged, or the product will be unlikely to be removed from the trocar.
- Do not apply excessive force when inserting this product into the trocar or removing the product from the trocar. If insertion is difficult to do, withdraw the product from the trocar and make sure it is not damaged. insertion or extraction of this product by excessive force may result in damage to the equipment or inability to remove the product from the trocar.
- Please do not bend the cannula hard when this product is used in conjunction with the trocar. If the equipment comes into contact with the opening of the trocar cannula, the insulation part of the equipment's cannula can be peeled off or the equipment can be damaged.
- Do not drop or strike this product. In that case, even if the equipment does not appear to be damaged, its durability will be weakened. Please do not use this product and contact our company if the product falls or is struck.
- This product is a precision instrument. Be careful when doing checks, preparations and operations.
- Operate the handle and control the cutter with fingers of one hand, please do not apply excessive force. Holding the cutter with both hands or with palms can cause damage to the equipment.
- Use this product in an environment specified in "Operation Environment".
- This product can only be used in soft tissues, not in cartilages, bones or hard objects. Failure to do so may result in damage to the equipment or inability to remove this product from the trocar.
- During surgery, if any body fluid or tissue debris is found on the surface of the pressure mouth, the cutter bar or of the cannula, it should immediately be wiped with sterile gauze or immediately be soaked in saline solution. If saline solution or blood is found between the cutter bar and the cannula, it should be wiped with sterile dry gauze. Otherwise these substances attached will solidify and affect the pressure mouth's operation, or cause damage to the equipment.
- Do not rotate the pressure mouth unless necessary. Otherwise, the cutter cable can be twisted, resulting in equipment malfunction.
- Although this product is capable of starting up an unlimited time of ultrasonic output, it should also be stopped immediately after tissue cutting. Conduct basic experiments before using this product. The optimal output value and start-up time shall be determined according to the experimental results.
- When stepping down the foot switch, please do not connect the drive handle to the cable or

remove the cable from the drive handle.

- ●Do not wipe the inside of the plug or of the socket with gauze dipped in saline solution. If the solution is attached to the connection point inside the plug or inside the socket, the ultrasonic output shall not be started up or damage to the main machine may occur.
- ●During surgery, if blood or meat crumbs from patients contaminates the inside of the plug or inside of the socket, rinse with sterilized water and wipe dry with dry gauze.
- ●During surgical operation, if saline solution enters the inside of the plug or inside the socket, dry it with dry gauze.
- ●When removing the drive handle plug, straighten the connection cable if it is twisted.
- ●Do not touch the connection points in the plug and in the socket. Otherwise, the static electricity on the connection points may cause electric shocks.

5.1 Procedure for Operation

1. Correctly install and check the system as described in chapters 3 and 4, and then power up the main machine;
2. After the system's successful activation, the words"PLEASE TUNE" appear on the system state column;
3. Set the output power value by adjusting the power level button;

Press the "+" button to increase the power level, and the "-" button to lower the power level. The power level range is 1 ~ 5.

Fig 5-1

The output power values corresponding to levels 1-5 are shown in table 2.

Table 2 Output Power Values Corresponding to Different Power Levels (Unit W Error ±10%)

Power Level	1	2	3	4	5
Output Power Value	6	9	12	15	18

4. Click the tuning button on the touch screen or step down the yellow pedal of the foot switch.Or press the manual switch of MAX button, the system will tune, while the state column prompting" TUNING IN PROCESS, PLEASE WAIT A MOMENT…"

Fig 5-2

If tuning fails, the words"TUNING FAILED" will appear in the system state column and the voice prompt" TUNING FAILED" will sound.

Fig 5-3

If tuning succeeds, the word"STANDBY" will appear in the system state column and a voice prompt will sound.

Fig 5-4

5. In the STANDBY mode, the equipment is in a suspended state, and neither the manual switch nor the foot switch works. Press the "READY" button, the equipment enters the ready state, the word"READY" appears in the system state column, step down the pedal and the equipment will generate corresponding energy; Re-press the ready/standby button, the equipment enters the standby state and does not work even if the foot switch is stepped down .

6. Step down the corresponding pedal or press the corresponding manual button to do cutting and blood coagulation.

Warnings:

- During cutting and blood coagulation, the front half of the pressure mouth shall be used to grab tissues. If only the rear half of the pressure mouth is used to grab tissues, the temperature of the part between the pressure mouth and the cutter bar will rise, leading to damage or fall-off of the cutter bar.

1. When this product is used in conjunction with the endoscope, close the pressure mouth and slowly insert the equipment into the trocar.
2. Operate the cutter to grab the tissues to be cut or to be solidified. Make sure the cutter bar is not contact with any non-targeted tissue.
3. The ultrasonic output is activated by stepping down the appropriate pedal of the foot switch. When the output is made, the main machine will play a set sound tone.

- **Step down the right pedal of the foot switch (color yellow) or press the manual switch of MAX button, the main machine will emit the maximum ultrasonic energy.**
- Step down the left pedal of the foot switch (color blue) or press the manual switch of MIN button (MIN), the main machine will emit the ultrasonic energy with a set power level.

5.2 System Setup

Press the "SET" button to enter the main menu, as Fig 5-5

音量：Volume

语言：Language

背景：Background

切割音效：Cutting Tone

凝血音效：Blood Coagulation Tone

返回：Return

Fig 5-5

Line 1 Volume Settings, press the “+” to increase volume, and press the “-” to reduce volume.

Line 2 Language settings, the system language can be set by clicking English or Chinese.

Line 3 Background Picture Settings, 2 kinds of background pictures can be selected.

Line 4 Cutting Tone Settings, click the triangle on the right to select 7 cutting tones.

Line 5 Blood Coagulation Tone Settings, Click the triangle on the right to select 7 kinds of blood coagulation tones.

5.3 System Operation After Use

Cautions:

- When extracting this product from the trocar, be careful not let mucous membranes or other substances from patients fall into the gap between the trocar and this product.
- Please do not pull the trocar and this product at the same time. Otherwise, the pressure mouth or the cutter bar may damage surrounding tissues, or the equipment itself may be damaged.

1. Power off the main machine.
2. Close the accessories according to the contents of the user manual for the accessories used in conjunction with this product.
3. While holding the trocar, close the equipment’s pressure mouth, and pull it out of the cannula carefully and slowly.
4. This product shall be cleaned and sterilized in accordance with the contents of chapter 6 "cleaning, disinfection and sterilization".

Chapter 6 Cleaning, Disinfection and Sterilization

6.1 General Description

Incident Reports of patients' cross-infection due to improper cleaning, disinfection or sterilization have been documented in the medical literature. It is strongly recommended that relevant personnel be familiar with the regulations and policies of all the following national and local hospitals.

— Procedures for cleaning, disinfection and sterilization in the specific hospital
— Occupational health and safety regulations
— Regulations and policies of national and local hospitals
— Regulations of this user manual
— Mechanical knowledge for this product
— Identification label for the medicament
— Please judge the types and conditions of the methods used for cleaning, disinfection and sterilization from a professional point of view.
— Contact local health institutions to comprehend local standards and regulations.

6.2 Cautions

Cautions

●Before cleaning, thoroughly check the equipment for damage, cracks, or for some part that is not working properly. Do not use any equipment showing signs of damage. Discard and replace the damaged equipment or send it to the service department designated by our company for repair.

●Failure to do cleaning and sterilization as described in this chapter may result in damage to the equipment.

6.3 Cleaning and Disinfection

6.3.1 Cleaning and Disinfection of the Main machine and the Touch Screen

6.3.1.1 Cleaning

Caution: Clean the main machine and touch screen according to the hospital rules. Before cleaning, turn off the main power switch of the main machine and unplug the ground connector.

Warnings:

- The spilling or ejecting liquid soakage into the main machine can cause damage to the equipment or an electric shock.

The cleaning procedure is as follows:

1. Prepare pH neutral detergent or pH neutral enzymatic detergent according to the manufacturer's instructions.
2. Clean all surfaces by hand with clean soft cloth slightly moistened with detergent. Pay special attention to cracks and gaps.
3. Then scrub thoroughly with a piece of clean soft cloth that is slightly moisturized by warm tap water.
4. Wipe dry with clean soft cloth

6.3.1.2 Disinfection

The main machine must be wiped with disinfectant before reuse if it is contaminated with blood or body fluids.The following chemical disinfectants have been confirmed to be feasible for the use of the main machine: sodium hypochlorite solution (0.25% - 0.50%).

Disinfectants should be prepared and used in accordance with the manufacturer's recommendations on use, concentration and contact time

For disinfectants not specified above, their compatibility with the instrument material shall be tested prior to use. A moderate level * of disinfectant should be used at a minimum. It is usually possible to obtain technical data sheets by contacting the manufacturer to help evaluate compatibility.

* “The moderate level” is a category applicable to the United States. Moderate disinfectants can kill viruses, mycobacteria, fungi and propagula.

In the process of decontamination and disinfection, ensure that detergent or disinfectant residue is completely removed after wiping. If there is still residue of detergent or disinfectant, moisten a piece of clean soft cloth with pure water or with deionized water and then wipe the affected area (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations on removing disinfectant residue.

6.3.2 Cleaning and Disinfection of the Drive Handle

6.3.2.1 Cleaning

Caution: The drive handle protective cap and the plug waterproof cap should be kept connected during cleaning and disinfection

The cleaning procedure is as follows:

1. Prepare pH neutral detergent or pH neutral enzymatic detergent according to the manufacturer's instructions.
2. Clean all surfaces by hand with a clean soft cloth slightly moistened with detergent. Pay special attention to cracks and gaps.
3. Then scrub thoroughly with a piece of clean soft cloth that is slightly moisturized by warm tap water.
4. Wipe dry with clean soft cloth

6.3.2.2 Disinfection

The drive handle must be disinfected before reuse if it is contaminated with blood or other liquids.The following chemical disinfectants have been confirmed to be feasible for the use of the drive handle: sodium hypochlorite solution (0.25% - 0.50%).

Disinfectants should be prepared and used in accordance with the manufacturer's recommendations on use, concentration and contact time

For disinfectants not specified above, their compatibility with the instrument material shall be tested prior to use. A moderate level * of disinfectant should be used at a minimum. It is usually possible to obtain technical data sheets by contacting the manufacturer to help evaluate compatibility.

* “The moderate level” is a category applicable to the United States. Moderate disinfectants can kill viruses, mycobacteria, fungi and propagula.

Any process of disinfection involving tools and solutions may affect the wear and tear of the device or the equipment. In some cases, other disinfectants may be required.

In the process of decontamination and disinfection, ensure that detergent or disinfectant residue is completely removed after wiping. If there is still residue of detergent or disinfectant, moisten a piece of clean soft cloth with pure water or with deionized water and then wipe the affected area (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations on removing disinfectant residue.

6.3.3 Cleaning and Disinfection of the Foot Switch

6.3.3.1 Cleaning

Caution: Always connect the foot switch plug to the waterproof cap during cleaning or disinfection

The foot switch and the cable should be cleaned up after each use according to the following steps:

1 Prepare pH neutral detergent or pH neutral enzymatic detergent according to the manufacturer's instructions.

2 Please clean all surfaces by hand with a clean soft cloth slightly moistened with detergent. Pay special attention to cracks and gaps.

3 Then scrub thoroughly with a piece of clean soft cloth that is slightly moisturized by warm tap water.

4 Wipe dry with clean soft cloth

If necessary, the foot switch can be soaked and cleaned according to the following steps:

1. Prepare pH neutral enzymatic detergent as recommended by the manufacturer and soak foot switch and wire assembly (not including the main machine connector) in it.
2. In detergent solution clean the device manually with a soft brush or clean soft cloth. Special attention should be paid to cracks and gaps.
3. Clean thoroughly with a piece of clean soft cloth soaked in warm tap water to remove detergent or wash the foot switch under warm tap water.

4. Wipe dry the device with a piece of clean absorbent cloth.

6.3.3.2 Disinfection

The foot switch must be wiped with disinfectant or soaked in disinfectant before reuse if it is contaminated with blood or body fluids. The following chemical disinfectants have been confirmed to be feasible for the use of the foot switch: sodium hypochlorite solution (0.25% - 0.50%).

Disinfectants should be prepared and used in accordance with the manufacturer's recommendations on use, concentration and contact time

For disinfectants not specified above, their compatibility with the instrument material shall be tested prior to use. A moderate level * of disinfectant should be used at a minimum. It is usually possible to obtain technical data sheets by contacting the manufacturer to help evaluate compatibility.

* “The moderate level” is a category applicable to the United States. Moderate disinfectants can kill viruses, mycobacteria, fungi and propagula.

Any process of disinfection involving tools and solutions may affect the wear and tear of the device or the equipment. In some cases, other disinfectants may be required.

In the process of decontamination and disinfection, ensure that detergent or disinfectant residue is completely removed after wiping. If there is still residue of detergent or disinfectant, moisten a piece of clean soft cloth with pure water or with deionized water and then wipe the affected area (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations on removing disinfectant residue.

Chapter 7 Storage and Disposal

7.1 Storage Conditions and Validity Period

Cautions:

- Please do not store the instrument in direct sunlight or in hot and humid places. Failure to do so may cause equipment damage or risk of infection.
- Please do not store this product in the shipping box. Otherwise there will be risk of infection
- During storage, make sure that the cutter cable is not excessively bent, deformed or twisted, otherwise the cable or internal wires may be damaged.
- Please do not store the equipment in a places with x-rays, radiation energy or strong electromagnetic waves (such as somewhere close to microwave diagnosis and treatment equipment, short-wave diagnosis and treatment equipment,or close to MRI, radio devices, etc.). Otherwise, the result may be the damage to the equipment or risk of infection.
- Any strong impact of this product should be avoided during storage, otherwise the equipment may be damaged.
- The equipment storage conditions: temperature -40°C—+50°C; Humidity≤90%; Pressure range 500hPa—1060hPa. And shall be stored in clean, dry and well ventilated places.

7.2 Discard Disposal

All applicable national and local laws and regulations shall be followed when discarding this product and its components.

Chapter 8 Troubleshooting and Warranty

If the equipment is found to be obviously damaged and unable to function normally, or if other abnormalities are found during the check according to the method described in chapter 4 " system checkout", please do not use this product, and contact our company. The non-fault problems found can be corrected by referring to section 8.1 "troubleshooting guidelines". If these problems can not be solved in accordance with the methods described, please stop using the product and send it to our company for repair.

Warning

● If an instrument is found to be abnormal, do not use the instrument on the patient.

8.1 Troubleshooting Guidelines

Table 3 Troubleshooting Guidelines

Fault Phenomenon	Possible Cause	Solution
There is the prompt of drive handle disconnected after turning on the main machine	Handle plug cable is not properly connected	Re-plug and re-unplug the cable connecting the drive handle and the main machine.
There is still the prompt of drive handle disconnected after re-plugging and re-unplugging	There is a hardened foreign matter on the connection point inside the handle socket or inside the connection cable plug.	Use a sterile cleaning brush to clean the connection point inside the handle plug. Clean the connection point inside the socket in the same way. And then connect and remove the plug and the socket about 10 times.
Tuning Failed	Damage to drive handle or to cutter bar	Replace the drive handle or the cutter with a spare drive handle or with a spare cutter respectively
Ultrasonic output cannot be activated. (with ultrasonic working tone)	Damage to cutter bar(such as cracks)	Replace the cutter with a spare one
	Incorrect connection between drive handle and cutter	Remove and re-install both the cutter and the drive handle with a torque wrench
	Excessive force on cutter bar	Reduce the force on the cutter bar(do not use it on hard tissues or on hard objects)
	A foreign matter or liquid inside plug or socket	If liquid is found, dry the liquid with dry gauze. If a foreign matter is found, please use a sterilization cleaning agent to clean the the connection point as well as the inside of the socket.
Ultrasonic output cannot be activated. (without ultrasonic working tone)	Poor pedal contact of foot switch	Replace the foot switch with a spare one
	Poor contact of manual switch	Replace the cutter with a spare one
	Machine is in a state of standby	Press the "READY"button to deactivate the standby state

8.2 Warranty

This machine cannot be repaired by users themselves, and all maintenance shall be carried out by the technical personnel approved by the company.

Please contact our company before the equipment is returned for repair. When you return the equipment for repair, please attach a description list of the dysfunction and damage of this product, as well as the maintenance card, the name and telephone number of the person most familiar with the machine's malfunction in your company.

Cautions:

- Before the equipment is returned for repair, this product should be thoroughly cleaned and sterilized. If handled improperly, the operator in the hospital or maintenance personnel in this company may get infection.

Warning:

- This company shall assume no responsibility for any damage caused by the following circumstances:

— Damage as a result of the use in combination with any other device produced or sold without this company's permission;

— Damage as a result of being repaired or modified outside this company's factory.

— Damage due to improper use, negligence, or accident;

— Damage due to failure to comply the following: design and use parameters, instructions or guidelines for the use of the product, or the functional, operational or environmental standards for similar products commonly used in the industrial field.

- Warranty Period

Table 4 Warranty Period

Serial No.	Product	Warranty Period
1	Drive Handle	200times
2	Main Machine	24 months

- Contact our company for purchase in the event that any other non-warranty part is damaged.

Chapter 9 Electromagnetic Compatibility

This chapter is a reminder of electromagnetic compatibility. This system SG100 shall be installed and used according to the electromagnetic compatibility information in this chapter.

A portable or mobile radio frequency communication device may affect the use of this system SG100. it is recommended to stay away from portable or mobile radio frequency communication devices or keep them in an off state when using this system SG100 in a normal way,.

Warning: The use of any accessory other than the accessories provided by this company may lead to the increase of emission or to the decrease of immunity of this system SG100.

This system SG100 should not be close to or be superimposed with other equipment with the same or similar frequency. If the stapler is required to do so, it should be observed and verified to be able to operate normally under its used configuration.

Please choose the connection cables and their related accessories provided by this company in order to ensure that the normal use of this system SG100 and that no increase of its emission or no decrease of its immunity

The use of non-specified accessories, transducers or cables in conjunction with this system SG100 may result in increased emission or reduced immunity of the equipment or the system.

Refer to below Table 5 to table 9 for detailed guideline and declaration.

Table 5 Guidelines and Manufacturer's Statement-Electromagnetic Emission-Electromagnetic radiation guidelines

this system SG100 is expected to be used in the following specific electromagnetic environments. Users and buyers of this system SG100 the must ensure that this product is used in such an environment.

Radiation Test	**Conformity**	**Electromagnetic environment-guidelines**
IEC 61000-3-2 Harmonic emission	Not applicable	Used in professional healthcare environment only
IEC 61000-3-3 Voltage fluctuation/Flicker emission	Not applicable	
CISPR 11 Radio-frequency radiation	Complies Class A	this system SG100 is not suitable for interconnecting with other equipment.

Table 6 Guidelines and manufacturer's statement-electromagnetic immunity guidelines

this system SG100 is expected to be used in the following specific electromagnetic environments. Users and buyers of this system SG100 must ensure that this product is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidelines
Electrostatic Discharge(ESD) IEC 61000-4-2	±6kV Contact discharge ±2kV, ±4kV, ±8kV, ±15kV Air discharge	±6kVContact discharge ±2kV, ±4kV, ±8kV, ±15kV Air discharge	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical Fast Transient Burst IEC 61000-4-4	±2kV 100kHz Repetition frequency	±2kV 100kHz Repetition frequency	
Surge IEC 61000-4-5 Line to line Line to Ground	±0.5kV ±1kV ±2kV	±0.5kV ±1kV ±2kV	
Voltage Sag on Power Input Line, short interruption and voltage change IEC 61000-4-11	0%UT;0.5 cycle g) 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° q) 0%UT;1 cycle and 70% UT;25/30 cycles h) Single-phase：on° 0%UT;250/300 cycles h)	0%UT;0.5 cycle g) 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° q) 0%UT;1 cycle and 70% UT;25/30 cycles h) Single-phase：on° 0%UT;250/300 cycles h)	
Power frequency magnetic field IEC 61000-4-8	30A/mg） （50/60Hz）	30A/m （50/60Hz）	The power frequency magnetic field should have the horizontal characteristics of power frequency magnetic field in typical places in a typical commercial or hospital environment.

Note: UT refers to the AC network voltage before voltage is applied.

Table 7 Guidelines and manufacturer's statement - electromagnetic immunity guidelines

this system SG100 is expected to be used in the following specific electromagnetic environments. Users and buyers of this system SG100 must ensure that this product is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidelines
Radio-frequency Conduction IEC 61000-4-6 Radio-frequency Radiation IEC 61000-4-3	3V 150kHz~80MHz 6V in ISM band 3V/m 80MHz-2.7GHz 80%AM,1kHz c)	3V 150kHz~80MHz 6V in ISM band 3V/m	A portable or mobile radio frequency communication device shall be at a distance from any part of this system SG100 (cables included) no shorter than the recommended isolation distance for the device. The specific distance shall be calculated by a formula corresponding to the transmitter frequency **Recommended isolation distance** $d=1.2\sqrt{P}$ 80MHz~800MHz $d=1.2\sqrt{P}$ 800MHz~2.7GHz where, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts(W); and d is the recommended isolation distance, in meters(m). [b] The field strength of the fixed RF transmitter is determined by the electromagnetic field site survey[a] , and should be lower in each frequency range [b] than the coincidentdet level. Interference may occur near devices marked with the following symbol. 

Note 1: The formula for the higher frequency range is adopted at frequencies 80MHz and 800MHz.
Note 2: These guidelines may not be appropriate for all situations, as electromagnetic wave transmission is affected by absorption and emission from buildings, objects and human bodies.

"a" field strengths of fixed transmitters, such as: wireless (cellular/cordless) telephones and base stations for ground mobile radios, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasting and television broadcasting, etc., These field strengths above cannot be predicted accurately in theory. In order to evaluate the electromagnetic environment of a fixed RF transmitter, the survey of electromagnetic field site should be considered. If the field strength in the place where this system SG100 is located is measured to be higher than the RF coincidentdet level for the above application, the device shall be observed and verified to be able to operate normally. If any abnormal performance is observed, supplementary measures, such as redirection or repositioning of the device, may be necessary.
"b" In the whole frequency range of 150kHz-80kHz, the field strength should be less than 3V/m.

Table 8 Recommended isolation distance between a portable or mobile radio frequency communication device and the SG100

this system SG100 is expected to be used in an electromagnetic environment where RF harassment is controlled. According to the maximum output power of the communication device, buyers and users of this system SG100 can prevent electromagnetic interference by maintaining the minimum distance recommended below between a portable or mobile radio frequency communication device (transmitter) and this system SG100.

Rated maximum Output power of the transmitter W	Isolation distances for different frequencies of the transmitter (m)		
	150kHz~80MHz ISM Frequency Band $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.7GHz $d=2.4\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For any rated maximum output power of the transmitter not listed in the table above, the recommended isolation distance d, in meters(m), can be determined by the formula in the corresponding transmitter frequency column, where p is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (w).

Note 1:The formula for the higher frequency range is adopted at frequencies 80MHz and 800MHz.

Note 2: These guidelines may not be appropriate for all situations, as electromagnetic wave transmission is affected by absorption and emission from buildings, objects and human bodies.

Table 9 Test Specifications for Immunity of Surgical Ports to RF Wireless Communication Devices

Test Frequency （MHz）	Frequency Range a） （MHz）	Service a）	Modulation b）	Max Power （W）	Separation Distance（m）	Immunity Test Level （V/m）
385	380-390	TETRA	Pulse Modulation b） 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM c） **Deviation** ±5 kHz Sine 1 kHz	2	0.3	28
710	704-787	LTE Frequency Band 13,17	Pulse Modulation b） 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Frequency Band 5	Pulse Modulation b） 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Frequency Band 1,3,4,25, UMTS	Pulse Modulation b） 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth，WLAN, 802.11 b/g/n, RFID 2450, LTE Frequency Band 7	Pulse Modulation b） 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation b） 217 Hz	0.2	0.3	9
5500						
5785						

Note: The distance between the transmitting antenna and the device or the system can be reduced to 1 meter if the immunity test level requires to to be reached. IEC 61000-4-3 allows a test distance of 1 meter.

a） For some services, only uplink frequencies are included.

b） The carrier shall be modulated using a square wave signal with a 50% duty cycle

c) As an alternative to FM modulation, 50% pulse modulation at 18Hz can be used. Because while it does not represent actual modulation, this would be the worst case scenario.

Chapter 10 Symbols and Meanings

Table 9 Drawing Marks Interpretation

Drawing Mark	Meaning	Drawing Mark	Meaning
	Warning! Caution		Attention! Consult to accompanying documents
	Batch code		Applied part Type CF Can be directly used in the heart
	Storage temperature and humidity	IPX8	Degree of protection against harmful ingress of water
	Manufacture date		Manufacturer information
	Guard against rain		Fragile
	Dangerous Voltage	I	Power on
		O	Power off
	Electrical and electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in EU countries. Follow decontamination instructions before returning waste.	U/S	Ultrasonic output mark: when used together with Soft-tissue ultrasonic surgical system holder/tip, single-use Model SE36, the Ultrasonic output signal frequency: 55.5kHz ± 1kHz; the voltage: 100-2000V AC
		FS	Foot switch mark
	Authorized representative in the European Community	CE 0197	Notified body
	Refer to the user manual		

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