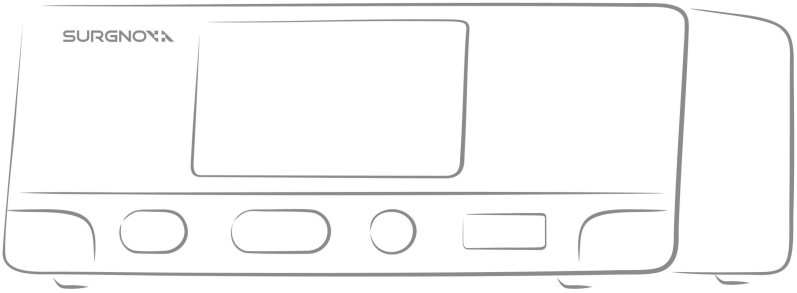
VariCure™

SURGNOVA
HEALTHCARE TECHNOLOGIES

Ultrasonic Surgical & Electrosurgical System





User's Guide

Contents

Preface 1
Warranty 1
1 Important Information for Clients 1
1.1 Special Reminders 1
1.2 Terms 1
1.3 Safety Marks and Definitions 1
1.4 Symbol Description 2
1.5 Warnings and Caution 3
1.5.1 General Warnings and Caution 3
1.5.2 Warnings and Cautions of Ultrasonic Scalpel 5
1.5.3 Warnings and Cautions of Electrosurgical 5
2 System Review 6
2.1 System Composition 6
2.2 Intended Use 7
2.3 Intended Patient Population 7
2.4 Contraindications 7
2.5 Clinical benefits 7
2.6 Working Principle 7
2.7 Working Conditions 7
2.8 Accessory List 8
2.9 Introduction of Panels 8
2.9.1 Front Panel 8
2.9.2 Rear Panel 9
2.10 Introduction of Interfaces 9
2.11 System Settings 12
2.12 Foot Switch 13
3 Instructions 13
3.1 Basic Requirements 13
3.2 Examination before Use 13
3.3 Power Cord Connection 14
4 Instructions of Ultrasonic Scalpel 14
4.1 Connection of Equipment 14
4.2 Connection of Ultrasonic Scalpel and Interface Display 15
4.3 Ultrasonic Scalpel Activation 16
4.4 Completion of Use 17
5 Instructions of Electrosurgical 17
5.1 Connection of Equipment 18
5.1.1 Accessories Connection and Interface Display 18
5.1.2 Accessory Activation 19
5.2 Use of Equipment 21
5.2.1 Instructions 21
5.2.2 Parameter Settings of Electrosurgical 21
5.2.3 Mode Switching 22
5.2.4 Change of Modes And Power Set Values 23
5.2.5 Output at Power-on 23
5.2.6 Output Interface at Power-on 23
5.2.7 Alarm Prompts 23
5.2.8 Completion of Use 23
6 Troubleshooting 23
6.1 Instructions 23

6.2 Ultrasonic Scalpel 23
6.3 Electrosurgical 24
6.4 System Failure 24
7 Technical Parameters 24
7.1 Safety Class 24
7.2 Ultrasonic Scalpel 25
7.3 Electrosurgical 25
7.4 Power Output Curve of Electrosurgical 28
7.5 Optional Accessory Parameters of Electrosurgical 32
7.6 Product Standard 35
7.7 EMC Information 35
8 Transport and Storage 38
8.1 Transport Conditions 38
8.2 Storage Conditions 38
9 Cleaning 38
9.1 Cleaning of the Energy Generator 39
9.2 Cleaning of the Foot Switch 39
10 Maintenance and Repair 39
10.1 Maintenance 39
10.2 Repair 39
10.2.1 Replacement of Fuse 39
10.2.2 Replacement of Power Cord 39
11 Disposal 39
Attachment I Brief Instructions 40
Ultrasonic Scalpel 40
Electrosurgical 41
Attachment II User Manual of Ultrasonic Scalpel Accessories 42
Instructions of Ultrasonic Transducer 42
Instructions of Ultrasonic Scalpel 44
Attachment III User Manual of Electrosurgical Accessories 46
Instructions of Electrosurgical Pencil 46
Instructions of Electrosurgical Pencil Electrode 46
Instructions of Laparoscopic Electrode 47
Instructions of Bipolar Instruments 48

Preface

This User's Guide is a manual intended to help our users and operators safely and effectively utilize the equipment, which should be only for the use of qualified medical professionals that possess specific professional skills and have undergone related surgical trainings.

The equipment described in this User Manual refers to ultrasonic surgical & electrosurgical system produced by Surgnova Healthcare Technologies (Zhejiang) Co., Ltd (hereinafter referred to as "Surgnova"), which mainly consists of the following seven models: SC100ES / SC200ES / SC300ES / SC200 / ES100 / ES200 / ES300.

Safe and effective use of the equipment depends on not only design of the equipment, but use of operators as well. Please read through all "instructions, warnings and cautions" provided in this User Manual. Do not attempt to operate the equipment before reading through and understanding this User Manual.

Warranty

Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. is committed to providing quality assurance for the product in the warranty period, including material and process defects. During the warranty period, Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. reserves its right to decide whether to repair the damaged equipment or to replace it for free. Any damage, if caused by accident, misuse, or unauthorized modification, does not apply to this warranty.

1 Important Information for Clients

1.1 Special Reminders

This User Manual describes the correct operation and maintenance of the ultrasonic surgical & electrosurgical system, and recommended methods of cleaning, disinfection, and sterilization. Any incorrect operation during use may cause equipment damage or personnel injury. Surgnova will not be responsible for any personnel injury or equipment damage if they were caused by use of the equipment not as this User Manual instructs.

1.2 Terms

Term	Description
CQM	A CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE. A MONITORING NE is also known as a split or divided plate since the conductive area is split into two or more parts.
Neutral Electrode	Electrode intended to provide an electrical return path for the MONOPOLAR application of HIGH FREQUENCY current with such a low current density in the PATIENT'S tissue that effects such as excessive rise in temperature or unwanted burns are avoided.
Ultrasonic	Sound with a frequency greater than the upper limit of human hearing (greater than 16 kHz).
Ultrasonic Surgical & Electrosurgical Generator	A device, which generates energy acting on patients for therapeutic purpose.
Ultrasonic Transducer	A device, which converts electric energy into mechanical energy in ultrasound frequency range.
Applied Part	The part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function.
Handswitching Electrosurgical Pencil	It is composed of electrosurgical pencil and electrosurgical electrode.

1.3 Safety Marks and Definitions

Safety information contained in this User Manual helps users identify potential risks and avoid them. This User Manual highlights potential risks with four marks, namely, Danger, Warning, Caution and Note.

Danger	Indicates high risks that may cause death or serious injury if not avoided.
Warning	Indicates risks that may cause serious equipment damage or casualty if not avoided.
Caution	Indicates the potential safety risks that may cause equipment damage or personnel injury if not avoided.

Note	Indicates annotation to operation or recommendation on maintenance; mistakes may be caused if they are not followed.

This User Manual provides safety information related to equipment use. Please read through and understand all instructions before use. If information like danger, warning, Caution and Note related to the equipment is not followed correctly, personnel injury, equipment dysfunction and invalidity of warranty may be caused.

1.4 Symbol Description

All symbols used on the equipment and labels and their meanings are contained in the table below:

	Defibrillation-proof type CF applied part		Floating ground
	Do not reuse		Air pressure limitation
	Equipotentiality		Protective earth (grounded)
	Dangerous When used with flammable anesthetic, there could be an explosion danger.		Non-ionized electromagnetic radiation
	Follow this User Manual	REF	Catalogue number
LOT	Batch code	SN	Serial number
	Country of manufacture		Manufacturer
	Fragile		Do not use if package is damaged and consult instructions for use.
	This way up		Keep dry
	Temperature limit		General warning sign
	Type CF applied part		Humidity limitation
	Warning, electricity		Use-by date
EU REP	Authorized representative in the European Community	GB REP	Authorized representative in the United Kingdom
	Sterilized using ethylene oxide; single sterile barrier system.	**Rx Only**	Caution: Federal law prohibits dispensing without prescription
CE	European union approval		(WEEE) Waste Electrical and Electronic Equipment

UK CA	United Kingdom approval	MD	Medical device

Note	Please get familiar with and understand meanings of the above symbols before operating the equipment.

1.5 Warnings and Caution

1.5.1 General Warnings and Caution

Warning	Before using the equipment, please first check whether all the components are complete and operational. Do not use upon any damage and replace the damaged component(s) in time.
Warning	Do not place the equipment close to/on any other device when using, or improper operation may be caused.
Warning	The equipment should be placed where power supply can be easily cut off in normal operation.
Warning	Failures of the equipment may lead to unpredictable amplification of output power.
Warning	The equipment should be plugged in medical power socket to ensure the reliability of its protective earth. Any damage to protective earth may lead to electric shock and result in injuries of patients and surgical personnel.
Warning	Check whether surgical electrodes and cables are damaged before each use. Current will leak out from cracks caused by ruptures or scratches, which lowers current density at Notes of the electrodes and causes burns in other parts.
Warning	If the energy generator is in a humid environment, no matter it is caused by pipeline leakage or liquid spraying, pull the power cord off from the power socket before handling the energy generator.
Warning	When the equipment is used together with electrodes or probes of monitoring, stimulating, and imaging equipment, even though the equipment is battery powered, insulated or its line frequency is isolated, high-frequency current channel will still be in existence. Putting these electrodes/probes away from the surgical site/neutral electrode as far as possible will avoid burns to a large degree, however, such risks cannot be eliminated.
Warning	Upon any unintended output power drop or interruption during normal use, check whether the neutral electrode is partly/totally disconnected, and whether the connector is in poor contact.
Warning	The equipment should be connected to patients when used, and the patient area should be isolated from the ground. Patients should not contact any metal which is grounded or which has considerable capacitance to the ground (e.g., operating table bracket). Antistatic separator is recommended to be used. Placement site of the neutral electrode should avoid any metal implant. Use with cautions if the metal implant cannot be avoided.
Warning	The equipment is not recommended to be used when internal/external pacemaker has been placed. Interference generated by the equipment will cause the pacemaker and other devices to enter the asynchronous state or cause total function loss of the pacemaker. When planning to use any electrosurgical device on a patient placed with cardiac pacemaker, please consult a cardiologist, and contact the pacemaker manufacturer before the operation.
Warning	For a patient with an implantable cardioverter defibrillator (ICD), instructions should be provided by the ICD manufacturer before performance of any operation related to the equipment. Electrosurgery may cause multi-boot to an ICD.
Warning	In case of leakage of flammable anesthetic, do not use the equipment to avoid explosion and other risk situations.
Warning	Correct sticking of the neutral electrode is key to the safe and effective use of high-frequency electrosurgical, especially in the aspect of preventing electrode plate from sticking to the burned site of the skin. Ensure that the neutral electrode is stuck to the patient reliably and as close to the surgical site as possible.
Warning	Prevent skin-to-skin contact (between the limbs of a patient). Dry gauze is recommended to be placed where skin-to-skin contact is likely to occur. During the operation, pay continuous attention to whether the electrode plate of the neutral electrode is overheated. Before selecting the high-power output, ensure that the neutral electrode is well stuck and the connector is well connected. Prevent the electrode plate from contacting any skin except the sticking site to avoid accidental burns. Dry gauze is recommended to be placed where skin contact is likely to occur.
Warning	Before the operation, flammable effusion on the patient's body or in grooves (e.g., belly button) and concave (e.g., vagina) should be cleaned.
Warning	When filled with oxygen, materials such as cotton, wool and gauze may be ignited by sparks generated in abnormal situations of the equipment electrodes.

Warning	Do not amplify output power without limit. It is suggested that achieving the expected therapeutic effect be taken as the precondition and the power be as small as possible.
Warning	When high-frequency surgical equipment is used in the single user mode, the surgical electrode and the neutral electrode should be used at the same time. If there is any suspicion of energy output after closing the output, turn off the main power supply at once and disconnect the surgical electrode from the energy generator.
Warning	Electromagnetic interference generated in normal operation of the equipment may make negative impact on the normal operation of other equipment; upon such a situation, increase the distance between the equipment and the cables and plug power plug of the equipment into sockets of various branches.
Warning	Enough distance should be kept between monitoring electrode and activated electrode when the high-frequency surgical equipment and the physiological monitoring equipment are utilized at the same time. Needle-like monitoring electrode is not recommended.
Warning	Studies have shown that smoke generated during electrosurgery can be potentially harmful to patients and the surgical personnel. These studies recommend adequately ventilating the smoke by using a smoke evacuator or other means.
Warning	Jewelry may concentrate electrosurgical current if it is near the electrosurgical site because the electrosurgical current will go through, e.g., the path between the electrosurgical part and the neural electrode. Meanwhile, loose jewelry may also contact an object to generate an alternative current path. Any of the conditions may cause shock or burns to patients. Jewelry and metal should thus be taken off, or wrapped up with dry gauze.
Warning	The use of any accessory, sensor, and cable, other than designated by the manufacturer, may result in increased electromagnetic radiation or decreased electromagnetic immunity, which causes improper operation.
Warning	Output power should be as low as possible on the premise that the intended use has been met. But some equipment or accessory may have unacceptable risks under low power settings. E.g., when argon beam coagulates, risk of gas embolism will rise if the high-frequency power is not enough to cause fast scabbing of the target tissue.
Warning	In case of surgery in the chest or head area, do not use flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen, unless these drugs are sucked. Inflammable detergents and disinfection products should be used.
Warning	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Electro Surgical System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Warning	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning	The Ultrasonic Surgical & Electrosurgical System emit electromagnetic energy in order to perform its intended function. So the function of other electronic equipment near the Ultrasonic Surgical & Electrosurgical System would be affected. Based on requirements of EN60601-1-2, when Ultrasonic Surgical & Electrosurgical System is switched on but the high frequency output is not energized and with all the electrode cables attached to the Ultrasonic Surgical & Electrosurgical System. Under these test conditions, the Ultrasonic Surgical & Electrosurgical System shall comply with the CISPR 11 Class A Group 1 limits requirement.
Warning	Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and improper operation.
Warning	The instructions for use shall explain that protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.
Warning	Ultrasonic Scalpel and Electrosurgical cannot be used simultaneously.
Warning	If any serious incident has occurred in relation to the product, the user and/or patient should report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Warning	Do not allow the body to directly contact the application end and negative pads.
Warning	Unauthorized modification of the equipment is not allowed.

Caution	Patients cannot contact any grounded metal (e.g., operating table and bracket). Direct skin contact of patients should be avoided when using the equipment.
Caution	When the equipment and physiological monitoring equipment are used on a patient at the same time, sensor of the latter cannot resist impact of the high-frequency current stably. Thus, it should be placed as far from the high-frequency surgical electrode as possible. Use of monitoring electrode is not recommended.
Caution	Under the condition when therapeutic needs are ensured, power output should be as low as possible.

Caution	When using the equipment, high-frequency radiation may interfere with other electrical equipment.
Caution	No part of the equipment can be maintained by user itself. When equipment failure happens, please contact the after-sale service immediately or send the equipment return to depot in case of electric hazards.

1.5.2 Warnings and Cautions of Ultrasonic Scalpel

Warning	Heat generated by the equipment can become ignition source. So please keep the equipment away from flammable material and oxygen rich environment.
Warning	When the ultrasonic scalpel of the product is applied, users are only limited to medical personnel that have undergone ultrasonic surgery and electrosurgery trainings.
Warning	During the operation, the ultrasonic transducer may heat up. When it gets overheated, stop using the equipment from being burned.
Warning	During the operation, the ultrasonic transducer cables should be isolated from patients and other surgical electrodes.
Warning	To avoid accidental power-on that injures operators and patients, ultrasonic scalpels must not contact with patients, surgical towels or flammable substance when not used.

Note	Cautions in use of ultrasonic scalpel accessories may refer to "Attachment II: User Manual of ultrasonic scalpel accessories".

1.5.3 Warnings and Cautions of Electrosurgical

Warning	If output power is obviously low or the equipment cannot work normally when set value is normal, the neutral electrode may be stuck incorrectly or connection problems of the high-frequency electrosurgical electrode may exist. Do not increase power before checking obvious connection problems or the correctness of sticking. After the neutral electrode is stuck, whenever the patient is moved again, check the connection between the patient and the neutral electrode again.
Warning	Unless a compatible monitoring neutral electrode is used with the CQM, loss of safe contact between the neutral electrode and the patient will not result in an alarm.
Warning	A warning that failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.
Warning	For associated equipment and active accessories, including separately supplied parts thereof, the rated accessory voltage may exceed rated accessory voltage.
Warning	Check all accessories of and their connection with the energy generator before use, and make sure that performance of accessories meets the requirements. Arc, spark, accessory failure, or accidental surgical effects may be caused by improper connection.
Warning	The patient leads should be positioned in such a way that contact with the patient or other leads is avoided.
Warning	Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
Warning	It is recommended to use monitoring systems incorporating high frequency current-limiting devices.
Warning	Avoid HF output settings where maximum output voltage may exceed rated accessory voltage.
Warning	Do not use the high frequency accessories when thers is visibly exposed metal of the active electrode shaft where it connects with the active handle, poor electrical connection between the active handle and active electrode shaft or poor fit between the active handle and active electrode shaft.
Warning	Smoke will be generated during the use of this product and smokeplume extraction is recommended to be used in the procedure.

Caution	High-frequency electrosurgical in operation may cause interference to other electronic equipment (e.g., monitors). Thus, enough distance should be kept between the high-frequency electrosurgical and other electronic equipment.

Note	Cautions in use of electrosurgical accessories may refer to "Attachment III: User Manual of electrosurgical accessories".
Note	For surgeries with relatively small cross section of surgical site, since high-frequency current may flow through all parts of the body during the operation, use of bipolar technology may avoid undesired tissue

	injury.
Note	When the generator outputs energy, it should generate corresponding prompt sounds according to different output modes.
Note	When using a manual electrosurgical pen and laparoscopic electrodes, the energy generator supports the neutral electrode contact quality detection function (REM function）.

2 System Review

2.1 System Composition

According to functions, the system can be divided into the ultrasonic scalpel and the high-frequency electrosurgical. According to types of instruments, the system can be divided into energy generator, applied part and accessories.

Applied part is the part of equipment that in normal use necessarily comes into physical contact with the patient, which including ultrasonic scalpel, handswitching electrosurgical pencil (Electrosurgical Pencil, Electrosurgical Electrode), laparoscopic electrode, bipolar instruments (Bipolar Coagulation Forceps and Bipolar Instruments).

Compositions of the generator, the ultrasonic scalpel, and the high-frequency electrosurgical are as follows:

Table 2-1: Instructions of generator and accessory composition

No.	Name	Model
1	Ultrasonic Surgical & Electrosurgical Generator	SC100ES / SC200ES / SC300ES / SC200 / ES100 / ES200 / ES300
2	Foot Switch	SJ-B03
3	Power Cord	Power cord complying with European standards, 2m, allowable current: 250VAC/10A; Power cord complying with British standards, 2m, allowable current: 250VAC/10A; Power cord complying with Italian standards, 2m, allowable current: 250VAC/10A.

Table 2-2: Instructions of ultrasonic scalpel accessories

No.	Name	Model
1	Ultrasonic Transducer	SC100T / SC150T
2	Ultrasonic Scalpel	SC13C / SC21C / SC35C / SC43C / SC13C+ / SC21C+ / SC35C+ / SC43C+/ SC13E / SC21E / SC35E / SC43E / SC09S / SC09S2 /SC17S2

Table 2-3: Instructions of high-frequency electrosurgical accessories

No.	Name	Model
1	Electrosurgical Pencil	SCPen / SCPenE /SCPenR / SCPenS
2	Electrosurgical Electrode	SCPenK0069 / SCPenK0150 / SCPenN0069 / SCPenN0150 / SCPenB0140-1 / SCPenB0140-2 / SCPenL0150
3	Laparoscopic Electrode	SCHookL0330 / SCHookL0450 / SCHookLS0360 / SCHookLS0450
4	Bipolar Coagulation Forceps	SCForceps0115-1/ SCForceps0115-2/ SCForceps0115-3/ SCForceps0115-4/ SCForceps0200-1/ SCForceps0200-2/ SCForceps0200-3/ SCForceps0200-4
5	Bipolar Instruments	AG52323CM / AG53723CM / AG54423CM / AG52320SM / AG53720SM / AG54420SM / AG22121KM

Caution	The above seven models of Ultrasonic Surgical & Electrosurgical Generator, SC300ES contains the ultrasonic and electrosurgical. And its circuit board and external interface are also the most complete of all models. Compared with SC300ES, Other models of Ultrasonic Surgical & Electrosurgical Generator may delete circuit board, external interface, and software function. SC300ES, SC200ES and SC100ES has ultrasonic and electrosurgical function. They have the same hardware. But for the software on the control board and electrosurgical power limit is different. ES300, ES200, ES100 only has electrosurgical function, they have the same hardware. But for the software on the control board and electrosurgical power limit is different. SC200 only has ultrasonic function.

2.2 Intended Use

The product includes electrosurgical and ultrasonic scalpel. The electrosurgical is mainly used to cut and coagulate human soft tissue in clinical operations. The ultrasonic scalpel is used to cut, dissect, and coagulate tissue; it may be applied for sealing vessels up to and including 7 mm in diameter; it is indicated for use in open and endoscopic general surgical procedures, and other procedures where bleeding control and minimal thermal injury to tissue are desired.

2.3 Intended Patient Population

Ultrasonic Surgical & Electrosurgical System is designed for patient who meets the intended use.

2.4 Contraindications

The product is prohibited to the following conditions:

Ultrasonic scalpel:

- Cutting bones;
- Tubal ligation aiming at contraception;
- When the surgery using ultrasonic scalpel conflicts with the best interests of the patient.

Electrosurgical:

- Patients that have been implanted with cardiac pacemaker, metal implant and ICD are prohibited to use the equipment or should consult a cardiologist;
- This product is not suitable for infants.

2.5 Clinical benefits

- Ultrasonic Surgical mode (US Energy)：
  - Increase hemostasis success rate
  - Increase operation success rate
  - Less intraoperative blood loss
  - Less surgical time
  - Less length of hospital stay
- Electrosurgical mode (RF Energy)：
  - Increase operation success rate
  - Less intraoperative blood loss
  - Less surgical time
  - Less length of hospital stay
  - Less drainage time

2.6 Working Principle

When the equipment is switched to the ultrasonic scalpel, electric energy in the energy generator being converted into mechanical energy through the ultrasonic transducer makes the ultrasonic scalpel jaws generate vibration with the frequency of around 55.5 kHz and the amplitude of no higher than 100μm. When the vibrating ultrasonic scalpel jaws contact with tissue, protein hydrogen bonds in tissue are opened and tissue protein cells deform to form viscous solids. The effect of cutting and hemostasis is gained at the cost of minimal tissue injury.

When the equipment is switched to the high-frequency electrosurgical, cutting with the high-frequency electrosurgical generates a large amount of heat energy, which causes explosive evaporation of tissue under the electrode and splits out a non-bleeding, narrow and flat incision with a depth of several millimeters; meanwhile, blood in the vessel coagulates to a certain depth, which takes the place of ligation to stop the incision from bleeding.

2.7 Working Conditions

The working conditions of the equipment refers to the following Table 2-4 & Table 2-5.

Table 2-4: Power Supply Condition

Voltage input range	100V -240V AC
Fuse voltage	T6.3AH 250VAC
Frequency	50Hz / 60Hz

Table 2-5: Working Environment

Temperature	5°C ~ 40°C

Humidity	20% RH ~ 80% RH (No-condensation)
Air pressure	700hPa ~ 1060hPa

2.8 Accessory List

Object	Quantity	Note
Ultrasonic Surgical & Electrosurgical Generator	1	
Double-Control Foot Switch	1	The SC200 is not equipped with the foot switch, other models are equipped with foot switch as standard.
Power Cord	1	Optional
User's Guide	1	
Certificate	1	
Packing List	1	

2.9 Introduction of Panels

2.9.1 Front Panel

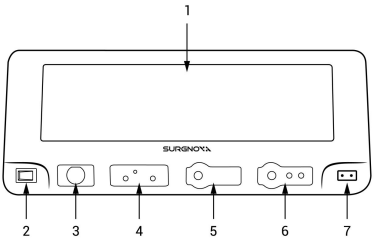


Figure 2.1: Front panel

No.	Feature	Description
1	Interface Display Touch Screen	Equipment parameters can be displayed, set, and modified on the screen.
2	Power Switch	Power control switch: the equipment is turned on by pressing "I" and turned off by pressing "O".
3	Ultrasonic Transducer Socket	The ultrasonic transducer can be connected to the ultrasonic transducer socket.
4	Bipolar Instruments Socket	The bipolar instruments can be connected to the bipolar instruments socket.
5	Laparoscopic Electrode Socket	The monopolar instruments can be connected to the laparoscopic electrode socket.
6	Handswitching Electrosurgical Pencil Socket	The monopolar instruments can be connected to the handswitching electrosurgical pencil socket.
7	CQM Socket	The neutral electrode can be connected to the CQM socket.

2.9.2 Rear Panel

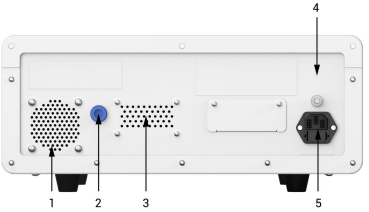


Figure 2.2: Rear Panel

No.	Feature	Description

1	Ventilation Panel	Device Cooling.
2	Foot Switch Socket	Attach the Foot Switch.
3	Speaker	Identify the device running feedback sound.
4	Equipotential Terminal	Connect different pieces of equipment together to maintain equal grounding.
5	Power Cord Input Jack	Attach the Power cord.

2.10 Introduction of Interfaces

Note	The interfaces in the manual are based on the model ES300, for reference only, and they will be different for different equipment models. Please refer to the actual interfaces of the equipment.

The main interface is composed of four parts: Electrosurgical Pencil, Laparoscopic Electrode, Bipolar Instruments and Ultrasonic Scalpel. The Ultrasonic Scalpel has two levels: the MAX level and the MIN level. Other interfaces support mode selections and output power settings when using high-frequency surgical instruments.

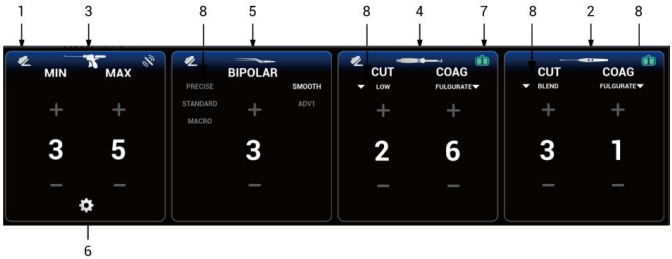


Figure 2.3: Instructions of the main interface

No.	Icon and Display	Description
1	Foot Switch Icon	Displaying the connection status of the foot switch; icons of different colors mean different statuses: The foot switch has not been connected or not selected. Select the activation channel by touching the icon; The foot switch icon turns into white, indicating the foot switch of selected channel is ready to be activated.
2	Handswitching Electrosurgical Pencil Icon	Standing for the monopolar instrument channel. The background turns from gray to blue after the monopolar instrument being inserted.
3	Ultrasonic Scalpel Icon	Standing for the ultrasonic scalpel channel. The background turns from gray to blue after the ultrasonic scalpel being inserted.
4	Handswitching Electrosurgical Pencil Icon	Standing for the monopolar instrument channel. The background turns from gray to blue after the monopolar instrument being inserted.
5	Bipolar Instruments Icon	Standing for the bipolar instruments channel. The background turns from gray to blue after the bipolar instruments being inserted.
6	System Settings Icon	Entering the system settings interface by touching the icon.
7	Neutral Electrode Display	Displaying neutral electrode contact quality: The neutral electrode is well contacted; Neutral electrode has not been connected or is abnormally contacted.
8	Mode Display	Displaying the Mode when activated.



Figure 2.4: Instructions of the electrosurgical interface

No.	Icon and display	Description
1	Power Value	Displaying power value of the monopolar instrument under the “cutting" mode.
2	Power Value	Displaying power value of the monopolar instrument under the "coagulating" mode.
3	Mode Display	Displaying the mode selected.
4	Power Decreasing	You may reduce power settings to the level you need by touching the button (ranges vary from mode to mode).
5	Power Increasing	You may increase power settings to the level you need by touching the button (ranges vary from mode to mode).
6	Drop-down button	You may select the submode under the “cutting” and" coagulating" modes accordingly.



Figure 2.5: Instructions of the laparoscopic electrode interface

No.	Icon and display	Description
1	Power Value	Displaying power value of the monopolar instruments when activated.
2	Mode Display	Displaying the mode selected.
3	Power Decreasing	You may reduce power settings to the level you need by touching the button (ranges vary from mode to mode).
4	Power Increasing	You may increase power settings to the level you need by touching the button (ranges vary from mode to mode).



Figure 2.6: Instructions of the bipolar instruments interface

No.	Icon and display	Description
1	Power Value	Displaying power value of the bipolar instruments when activated.
2	Mode Display	Displaying the mode selected.
3	Power Decreasing	You may reduce power settings to the level you need by touching the button (ranges vary from mode to mode).
4	Power Increasing	You may increase power settings to the level you need by touching the button (ranges vary from mode to mode).



Figure 2.7: Instructions of figures of the ultrasonic scalpel interface

No.	Icon and display	Description
1	Power Decreasing	You may reduce power settings to the level you need by touching the button.
2	Power Increasing	You may increase power settings to the level you need by touching the button.
3	MIN	MIN means the minimum power level settings. When the power level is enabled (through foot switch or manual switch), the MIN indicator will be highlighted. The system default MIN power level is 3, ranging from 1 to 4.
4	MAX	MAX means the maximum power level settings. When the power level is enabled (through foot switch or manual switch), the MAX indicator will be highlighted. The system default MAX power level is 5, ranging from 4 to 5.
5	Ultrasonic Scalpel Cutting Sound	Ultrasonic scalpel cutting sound can be turned on or off by touching the icon. When using ultrasonic scalpel for cutting, the device will make quick sounds when the tissue is about to be cut off if the founction is turned on. The sound will not be emitted if the function is turned off.

2.11 System Settings

You may enter the system settings interface by touching the System Settings Icon on the Ultrasonic Scalpel part of the main interface and select the item to be set by touching the upper buttons. The background of the currently selected button will turns blue. You may return to the previous menu by touching the Return button on the right.

Volume: You can adjust the system volume by touching the volume icon and entering the following interface.

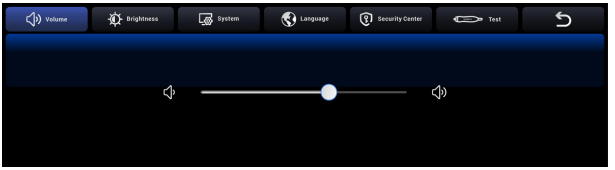


Figure 2.8: Interface of volume setting

Brightness: You can adjust the screen brightness by touching the brightness icon and entering the following interface.

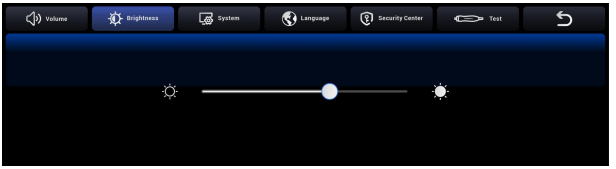


Figure 2.9: Interface of brightness setting

System information: Medical personnel can view advanced information of the system. With the information, they can determine whether to order a new handle, and get to know the current software version.



Figure 2.10: Interface of system information

Language setting: Chinese is the default language. Users can select Chinese or English. The selected option will be highlighted.

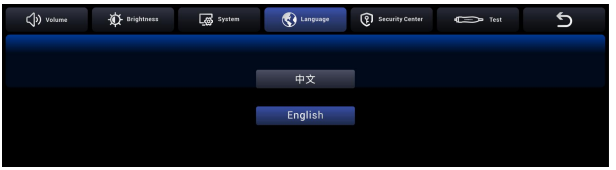


Figure 2.11: Interface of language setting

Advanced Setting: This setting is only available for maintenance personnel.

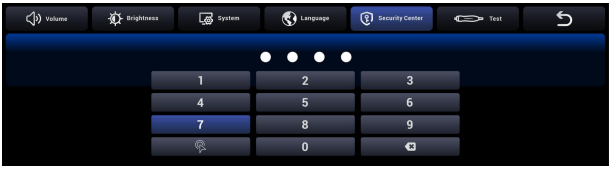


Figure 2.12: Interface of security center

Handle test: Test operation of the transducer to see if the handle functions normally. The test result will be displayed on the screen.

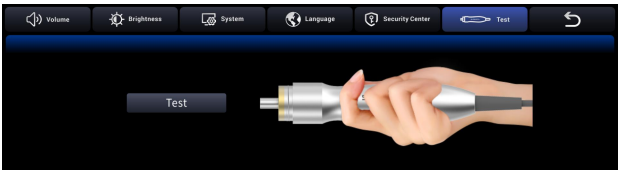


Figure 2.13: Interface of handle test

2.12 Foot Switch

The medical foot switch used in conjunction with the equipment is SJ-B03 foot switch.

The left and right channels of the foot switch are used to cut (yellow) and coagulate (blue), respectively. When output of energy is needed, the operator should keep the feet upon the pedals of the foot switch continuously to connect the switch; when it is time to cut off the energy, the operator should disconnect the switch by removing the feet.

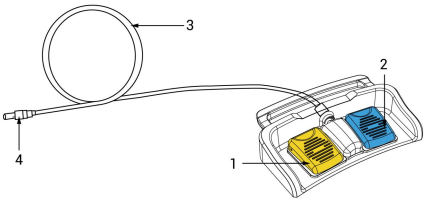


Figure 2.12: Features of the foot switch and instructions

No.	Feature	Description
1	MIN / Cut (Yellow)	Activating the MIN level energy of the generator/Cut.
2	MAX / Coag (Blue)	Activating the MAX level energy of the generator/Coagulate.
3	Connecting Cable	Connecting cable of the foot switch.
4	Connector	Connector between the foot switch and the energy generator.

Warning	Stop using the Foot Switch when it deforms or breaks. Replace it with a new one.
Warning	As a kind of magnetic relay switch, the foot switch cannot be placed in strong magnetic or high voltage environment.
Warning	Stop using the Foot switch when the cables and mechanical parts loose or break. Replace it with a new one.

Note	Foot switch connecting cables support output of 24VDC rated voltage and 0.1A rated current.
Note	Structure of the foot switch mainly includes connector, connecting cable and mechanical switch. The connector is error proofing designed.

3 Instructions

3.1 Basic Requirements

Users of the product must be doctors or medical personnel under the surveillance of the doctors. Users must have enough clinical procedure trainings.

3.2 Examination before Use

The equipment should be examined according to the following suggested content before being put into use.

Danger	Do not snip the neutral electrode off to shrink the size, or high current density will cause burns to patients.

Warning	Only when the equipment completes self-test smoothly can it be used, or the output power will be inaccurate.
Warning	The power socket connecting to the power cord must have protective earth. Do not use a power plug adapter. Do not use lengthened wire.
Warning	Do not connect any wet accessory to the equipment.
Warning	Make sure that connection of all accessories and adapters are correct and no metal parts are exposed.
Warning	When using the equipment according to the specified procedures of this User Manual, the use should be stopped upon any failure or uncertainty.
Warning	The doctor should place the neutral electrode correctly; upon any incorrect placement of the neutral electrode or any poor contact with the patient, the energy generator will make an alarm and stop outputting.
Warning	The distance between the ECG electrode and the surgical site should be more than 15cm.
Warning	Wires of the application end and the neutral electrode should not be coiled on conductive metal devices.
Warning	Wires of the application end and other electrical equipment should not be bound together.
Warning	For some surgeries where high-frequency current may flow through the part of body with relatively small cross section, the bipolar technology had better be used to prevent undesired tissue injury.
Warning	Under the high-frequency electrosurgical, when using handswitching electrosurgical pencil or laparoscopic electrode, the CQM neutral electrode must be used to ensure the patient's safety to the largest extent.

Caution	Do not put any equipment on the top of the equipment, or put the equipment on the top of any other electrical equipment, because such kind of placement is neither stable nor good for sufficient heat dissipation.
Caution	When the equipment is used in conjunction with the smoke evacuator, the smoke evacuator should be put away from the equipment to a certain distance and the equipment's sound volume controller should be adjusted to such a degree that proper start-up tone can be heard.
Caution	Before using the accessories, read the accompanying warnings, cautions and instructions provided with the electrosurgical accessories. Specific instructions are not included in the manual.
Caution	Connect the accessories to the sockets correctively. Especially the bipolar instruments can be connected to the bipolar socket only. Improper connection of accessories will cause accidental equipment start-up or the CQM contact quality monitor to make an alarm.
Caution	Before testing the accessories, power should be set to the MIN value.

3.3 Power Cord Connection

1. Insert the power cord into the power input jack in the rear panel of the energy generator.
2. Insert the plug of the power cord into the grounded socket for medical purpose.

Warning	Each of the equipment is equipped with 4 power cords that comply with different national standards respectively; use the power cord complying with local power standard when making a connection. Do not use a power plug adapter.
Warning	Connect the power cord to a wall socket with specified voltage, or the product may be damaged.
Warning	The power cord must be connected to the correctly grounded socket.

Note	Make sure that the power cord plug is totally inserted into the power input jack in the rear panel of the energy generator.
Note	To ensure stability of power connection of the equipment, it is recommended that the power cord accompanying the equipment be used all the time.

4 Instructions of Ultrasonic Scalpel

4.1 Connection of Equipment

1. Connection to the foot switch: insert the connector at the end of foot switch cable into the foot switch socket in the rear panel of the energy generator.
2. Connection to the ultrasonic transducer: insert the ultrasonic transducer connector into the ultrasonic transducer socket on the

front panel of the energy generator and make sure that the connection is firm and reliable.

3. Connection to the ultrasonic scalpel: connect the ultrasonic scalpel matching with the machine to the ultrasonic transducer and have it tightened.

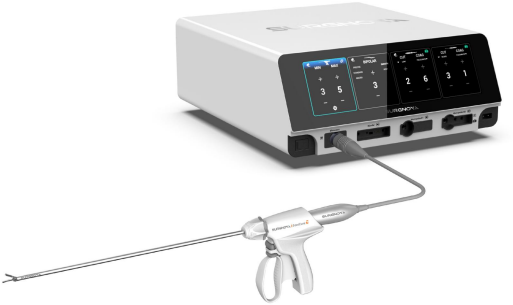


Figure 4.1: Connection of ultrasonic scalpel

Warning	Check whether the ultrasonic scalpel energy generator and the accessories are damaged or not before carrying out system connection. Please do not use any component or equipment that has been damaged.

Note	The foot switch connector with lock catch is loose-proof. After being inserted, the connector locks automatically.

4.2 Connection of Ultrasonic Scalpel and Interface Display

1. After connecting to the transducer, the interface displays a GIF prompt for the insertion of the ultrasonic scalpel (not applicable to SCXXE).

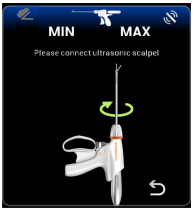


Figure 4.2: Interface of transducer connection

2. After being connected, the ultrasonic scalpel needs a self-test. The interface displays that the ultrasonic scalpel jaws should be opened, then the MAX or MIN level button of the ultrasonic scalpel should be pressed for a 2-second duration.



Figure 4.3: Ultrasonic scalpel self-test

3. There will be a prompt tone during the self-test, suggesting the self-test is under way; upon completion of self-test, there will be a prompt tone, suggesting the self-test has been completed or failed. Upon a successful self-test of the ultrasonic scalpel, the screen will return to the main interface.



Figure 4.4: Screen display of a successful ultrasonic scalpel self-test

Upon a failed ultrasonic scalpel self-test, a prompt box for self-test failure will pop up, as is shown below:

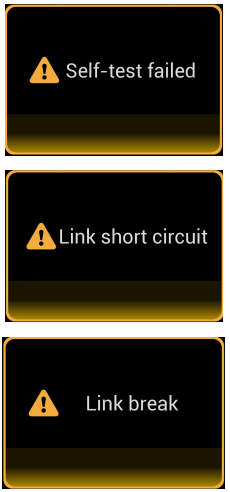


Figure 4.5: Prompt box for ultrasonic scalpel self-test failure

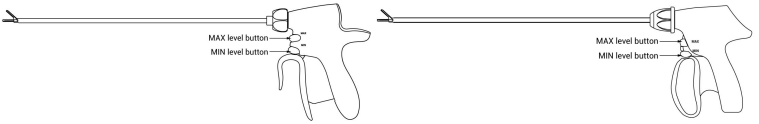
4. Set the MIN/MAX parameter as needed; the energy generator should be workable when the setting completes. Energy output on the MIN or MAX should be realized with the handle or foot switch according to needs.

Warning	When using the equipment according to the above operation procedures, the use should be stopped upon any failure or uncertainty. The failures can be settled by consulting this User Manual or after-sales service.

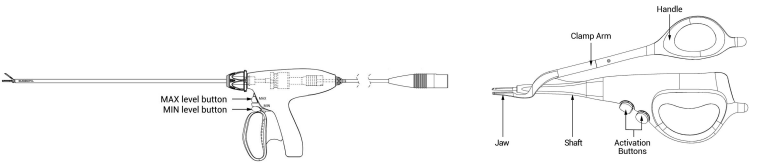
Caution	When using the ultrasonic transducer and the ultrasonic scalpel, operate gently to avoid any irreversible results caused to their performances and properties.

4.3 Ultrasonic Scalpel Activation

Method I: Press the MAX/MIN level button on the ultrasonic scalpel to activate the MAX/MIN level.



(a)Ultrasonic scalpel SCXXC (b)Ultrasonic scalpel SCXXC+



(c)Ultrasonic scalpel SCXXE (d)Ultrasonic scalpel SC09S SCXXS2

Figure 4.6: Diagram of ultrasonic scalpel

Method II:

1. Touch the foot switch button on the top of the ultrasonic scalpel channel to turn it into white and solid.

2. Step on the yellow pedal on the foot switch to activate the MIN level and step on the blue pedal on the foot switch to activate the MAX level. The activated level will be highlighted while the border of the ultrasonic scalpel interface turns light blue.



Figure 4.7: MAX level of ultrasonic scalpel is activated



Figure 4.8: MIN level of ultrasonic scalpel is activated

4.4 Completion of Use

1. Turn off the equipment.

2. Pull off all accessories from the front panel.

3. Remove and store the foot switch reasonably.

5 Instructions of Electrosurgical

The product provides the following working modes for users to select.

Monopolar Insturments	Low pure cut mode: applicable to cutting of fine tissues and endoscopic surgery.
	Pure cut mode: applicable to fine non-invasive cutting.
	Blend mode: providing good coagulant effect when cutting.
	Soft mode: applicable to the coagulation of endoscopic surgery and other fine tissues.
	Fulgurate mode: applicable to the superficial coagulation of most surgeries and laparoscopic surgeries.
	Spray mode: applicable to large area of tissue bleeding, and only forming a scab in superficial tissue structure.
	Share soft mode: applicable to the coagulation of endoscopic surgery and other fine tissues, handswitching electrosurgnical pencil and laparoscopic electrode channel can be activated synchronously.

	Share fulgurate mode: applicable to the superficial coagulation of most surgeries and laparoscopic surgeries, handswitching electrosurgnical pencil and laparoscopic electrode channel can be activated synchronously.
	Share spray mode: applicable to large area of tissue bleeding, and only forming a scab in superficial tissue structure, handswitching electrosurgnical pencil and laparoscopic electrode channel can be activated synchronously..
Bipolar Instrumnts	Precise mode: applicable to neurosurgery, ophthalmology and other microsurgeries.
	Standard mode: applicable to neurosurgery and general surgeries.
	Macro mode: applicable to open and endoscopic surgeries.
	Smooth mode: applicable to superficial coagulation of delicate, fragile tissues and control of minor bleeding in most surgeries.
	Advance mode: applicable to seal tissue bundles and vessels to control bleeding.

5.1 Connection of Equipment

5.1.1 Accessories Connection and Interface Display

1. **Connection of handswitching electrosurgical pencil and interface display:** Insert the monopolar instrument into the corresponding handswitching electrosurgical pencil socket of the energy generator. Upon the insertion of the monopolar instrument, the background of handswitching electrosurgical pencil channel will turn blue.



Figure 5.1: Handswitching electrosurgical pencil socket and interface display

2. Connection of laparoscopic electrode and interface display: Insert the monopolar instrument into the corresponding laparoscopic electrode socket of the energy generator. The background of Laparoscopic Electrode channel will turn blue.

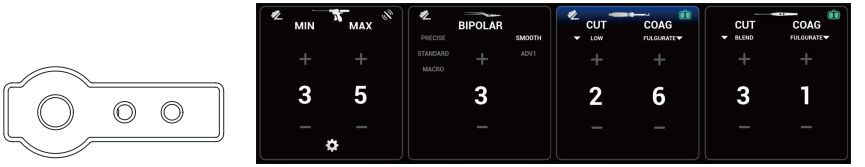


Figure 5.2: Laparoscopic electrode socket and interface display

3. Connection of bipolar instruments and interface display: Insert the bipolar instruments into the corresponding bipolar instruments socket of the energy generator. Upon the insertion of the bipolar instruments, the background of bipolar instruments channel on the main interface will turn blue.

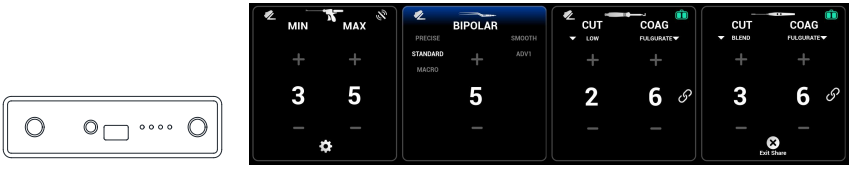


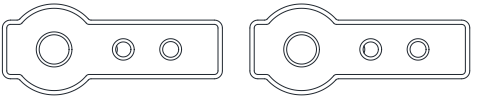
Figure 5.3: Bipolar instruments socket and interface display

4. **Connection of neutral electrode and interface display:** Insert the neutral electrode into the corresponding CQM socket of the energy generator. If the neutral electrode is inserted and well contacted, the neutral electrode icon of the main interface will turn green.



Figure 5.4: CQM socket and interface display

5. Connection of monopolar instrument in share modes and interface display: Insert the two monopolar instruments into the handswitching electrosurgical pencil and laparoscopic electrode socket of the energy generator respectively. After the two instruments are inserted and well contacted, the main interface will display as follows.



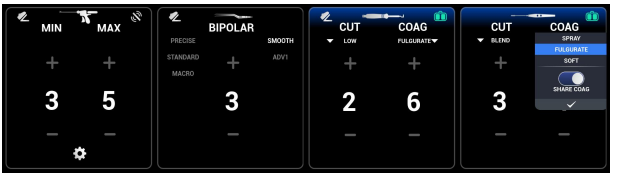


Figure 5.5: Monopolar instrument in share modes and interface display

5.1.2 Accessory Activation

1. **"Cutting" activation of handswitching electrosurgical pencil:**

Method I: Press the yellow button on the handswitching electrosurgical pencil.



Figure 5.6: Diagram of handswitching electrosurgical pencil

Method II: Touch the foot switch button on the top of the handswitching electrosurgical pencil channel to turn it into white and solid; and then step on the yellow pedal of the foot switch to activate it.

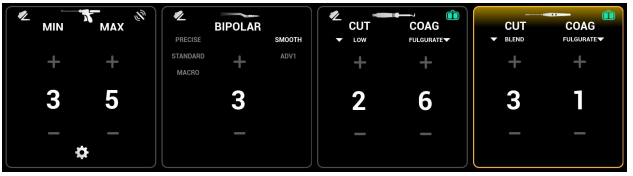


Figure 5.7: "Cutting" activation of handswitching electrosurgical pencil

2. **"Coagulating" activation of handswitching electrosurgical pencil:**

Method I: Press the blue button on the handswitching electrosurgical pencil.

Method II: Touch the foot switch button on the top of the handswitching electrosurgical pencil channel to turn it into white and solid; and then step on the blue pedal of the foot switch to activate it.

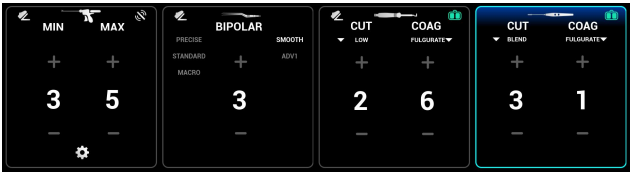


Figure 5.8: “Coagulating” activation of handswitching electrosurgical pencil

3. **Laparoscopic electrode activation:** Connect to the foot switch. Then touch the foot switch button of the laparoscopic electrode channel to turn it into white and solid; and step on the yellow pedal of the foot switch to activate it.



Figure 5.9: “Cutting” activation of laparoscopic electrode in laparoscopic mono-cut mode

4. Bipolar instruments activation:

Method I: Press the activation button on the bipolar instruments.

Method II: Connect to the foot switch. And touch the foot switch button on the top of the bipolar channel to turn it into white and solid; then step on the blue pedal of the foot switch to activate it.

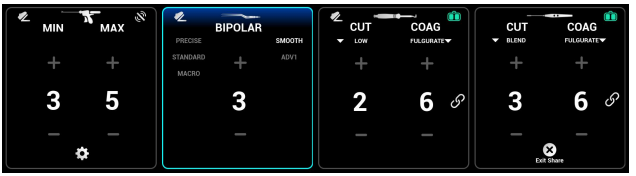


Figure 5.10: Bipolar instruments activation in default mode

5. Monopolar instruments activation in share mode:

Step I: Connect to the foot switch or use the activation button on the instruments.

Step II: Take “FULGURATE” in share coagulating mode for example, choose “FULGURATE” in the interface, touch the icon “SHARE COAG”

, then touch “ √ ” button to enter share mode.

Step III: Press the activation button on the instruments or pedal on the foot switch to activate.

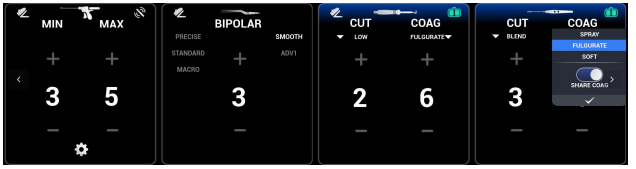


Figure 5.11: Monopolar instruments activation in share mode 1



Figure 5.12: Monopolar instruments activation in share mode 2

Warning	When activating the handswitching electrosurgical pencil, please ensure the good connection and contact of the neutral electrode.
Warning	When activating the laparoscopic electrode, please ensure the good connection and contact of the neutral electrode.

Note	The border of the activated channel will be highlighted.

5.2 Use of Equipment

5.2.1 Instructions

Instructions of quick settings:

1. Insert the power cord of the equipment into the socket on the rear panel.
2. Insert the plug of the power cord into the grounded wall socket.
3. Connect the equipment to power supplies to confirm if the self-test completes smoothly.

Note	If you are not familiar with how to set the equipment, please refer to the follow-up detailed instructions on settings.

Instructions of monopolar instruments:

1. Connect the pedal to the foot switch socket on the rear panel. (This step can be omitted if the manual control switch is used.)
2. Connect the monopolar instrument to the corresponding socket on the front panel.
3. Stick the neutral electrode on the patient, and the neutral electrode socket on the front panel.
4. Select the foot switch option of the corresponding channel on the interface, and set mode and value of the corresponding channel. (When the sharing mode is enabled, the parameters of the dual channels are modified synchronously.)

Warning	Only foot switches equipped by Surgnova can be used on the equipment.

Instructions of bipolar instruments:

1. Connect the pedal to the foot switch socket on the rear panel. (This step can be omitted if the manual control switch is used.)
2. Connect the bipolar instruments to the corresponding socket on the front panel.
3. Select the foot switch option of the bipolar instruments channel on the interface, and set corresponding mode and value.

Note	Use bipolar instruments alone without the neutral electrode.

5.2.2 Parameter Settings of Electrosurgical

1. Press the power switch to (O) to confirm that the equipment has been turned off.
2. Place the equipment on a stable and firm platform.
3. Insert the power cord into the socket on the rear panel.
4. Insert the power cord plug into the grounded socket.
5. Press the power switch to (I) to connect the electrosurgical to power supplies. Confirm the following items: All visible indicators and display screens are on; The start-up tone sounds, proving that the loudspeaker is working normally.

If self-test is successful, there will be a prompt tone.

If self-test is not successful, there will be an alarm tone. Once self-test succeeds, connect the accessories and set function parameters.

Parameter settings of bipolar instruments:

1. Select the bipolar instruments parameter settings section on the LCD screen, and select the specific mode and set the specific power value.

2. White the foot switch icon on the LCD screen.
3. See the figure for the way of operation.
4. The function can be put into use.

Monopolar surgeries:

1. Connect the foot switch to the foot switch socket on the rear panel.
2. Connect the monopolar device to the monopolar device socket on the front panel.
3. Connect the neutral electrode to the neutral electrode socket on the front panel.
4. Stick the neutral electrode on the patient correctly and ensure that it is well stuck.
5. Select the monopolar mode parameter settings section on the LCD screen, and select the specific mode and set the specific power value.
6. Lighten the needed monopolar pedal channel button on the LCD screen.

Warning	Confirm whether the power set value is correct before the surgery. Use the minimum power and the shortest duration needed to achieve the effect.
Warning	Do not increase power set value when the surgical electrodes (laparoscopic electrode, handswitching electrosurgical pencil and bipolar instruments), the neutral electrode and their connections have not been examined. To minimize possibility of burns, surgical electrodes should be used for the shortest duration that is necessary for attaining the anticipated operation effect, especially for pediatric patients, neonatal patients and patients that need fine tissue surgeries.
Warning	To avoid burning patients, close contact between the neutral electrode and the skin should be ensured. Check the neutral electrode regularly; and check it after rearranging patients and during starting up the equipment for a long time.
Warning	If the needed power set value is higher than that has been anticipated, or the patient has been rearranged, please check whether sticking of the patient's circuit electrode plate is still reliable and check connection of all the connecting cables at the same time.
Warning	When placing the surgical electrode cable, prevent it from contacting with the patient or other cables. Surgical electrodes that are not used at the moment should be isolated from the patient.
Warning	The equipment should not be started before the forceps contacting with the patient, or the product may be damaged.

Note	If the foot switch is not needed in turning on the equipment, do not connect it.
Note	The screen indicates whether the neutral electrode is connected correctly.
Note	The equipment supports nine working modes for users to select: low-voltage cutting, pure cutting, blended cutting, dry coagulation, electrocautery, spray coagulation, precise bipolar, standard bipolar and strong bipolar.

5.2.3 Mode Switching

Switching between the monopolar cutting and coagulation:

1. Press the needed cutting/coagulation mode start button to switch if there is a need for switching between the two modes. The border of the selected mode will be lightened.
2. After setting power value and mode, press the start button to activate it.
3. When switching between the cutting and coagulation modes, power set value of the original mode will remain the same; stop activating to set the value again.

Switching between the cutting and coagulation subschemas:

1. After confirming the selected subschema, mode name and icon can be seen on the interface.
2. Click the mode box on the main interface to enter the subschema.
3. After entering the subschema, there will be three modes for choosing.
4. When switching between subschemas, the previous set value will be remained.

Note	After restarting the equipment, the previous set mode and power value will be displayed on the interface.
Note	When the equipment is outputting power, the mode and power value cannot be changed.
Note	Upon completion of parameter setting, users can click the return button area to confirm.

5.2.4 Change of Modes And Power Set Values

Click the needed mode on the main interface.

Note	After restarting the equipment, the previous set mode and power value will be displayed on the interface.

5.2.5 Output at Power-on

Control the start-up of the handswitching electrosurgical pencil by using the manual switch or the foot switch. If the bipolar coagulation forceps or the foot-controlled type laparoscopic electrode be used, the foot switch is necessary.

Warning	To reduce the possibility of heterotopic burns caused by high-frequency leakage current, activation of the equipment for a long time and unnecessary activation should be avoided.
Warning	Do not start the equipment before the bipolar instruments contact with the patient.

5.2.6 Output Interface at Power-on

When the equipment outputs energy, the corresponding mode on the interface will be highlighted, accompanying start-up tone.

5.2.7 Alarm Prompts

CQM alarm prompts:

The alarm tone will ring once and the interface will indicate the alarm. After the alarm condition is corrected, energy output will be started and the interface will indicate the problem solved.

The following conditions will cause CQM alarm:

1. After the power-on self-test is completed, because the neutral electrode has not been connected or stuck on the patient, the CQM will alarm once and the indicator will be red.
2. When the equipment starts, the laparoscopic electrode or the handswitching electrosurgical pencil has been connected, but the neutral electrode has not been connected to the equipment.
3. The connection between the neutral electrode and the patient is not good.
4. The contact area shrinks due to movement, loosening, effusion or dry contact gel.
5. Excessive resistance caused by damaged wire of the neutral electrode.

Note	Upon any equipment failure or abnormal CQM status, the screen displays failure data and the equipment makes an alarm tone and stops energy output.

5.2.8 Completion of Use

1. Turn off the equipment.
2. If the neutral electrode is stuck on the patient, please take it off.
3. Pull off all accessories from the front panel.
4. Remove and store the foot switch reasonably.

6 Troubleshooting

6.1 Instructions

When failures occur, popup windows with corresponding error messages will be shown on the screen.

6.2 Ultrasonic Scalpel

During the operation of the equipment, any of the following failures will stop the equipment from outputting ultrasonic energy, make it provide a sound prompt and display the corresponding error message in the display window on the front panel.

Table 6-1: Error messages and description of ultrasonic scalpel

Error messages	Description	Possible Reasons and Troubleshooting
Abnormal power supply, please restart the device.	Abnormal power supply voltage of the ultrasonic module of the energy generator.	Power off and restart the system. Contact the manufacturer if the problem remains.
Overheating mainboard, please restart the device.	Abnormal temperature of the ultrasonic module of the energy generator.	Power off and restart the system. Contact the manufacturer if the problem remains.

Abnormal power supply, please restart the device.	Abnormal supply voltage of the ultrasonic module of the energy generator.	Power off and restart the system. Contact the manufacturer if the problem remains.
Self-test failure, please replace the ultrasonic transducer.	Test failure of the ultrasonic transducer.	Replace the ultrasonic transducer with a new one.
Ultrasonic Overused	The number of uses of the ultrasonic transducer is exhausted.	Replace the ultrasonic transducer with a new one.
Self-test failure, please replug ultrasonic scalpel.	Test failure of the ultrasonic scalpel.	Reconnect the transducer and the scalpel head, and test again.
Power output break, please replace transducer and restart the device.	Disconnection of the ultrasonic transducer output cable.	Check whether the connection of the ultrasonic transducer interface is reliable.
Power output short circuit, please replace transducer and restart the device.	Short circuit of the ultrasonic transducer output cable.	Replace the transducer.
Overpressure, please open the jaw.	Excessive pressure at the jaws of ultrasonic scalpel.	Open the jaw and activate again.
Frequency locking failure, please reclamp tissue or wipe ultrasonic scalpel. (Code: AA)	Excessive pressure at the jaws of ultrasonic scalpel.	Open the jaw and activate again.
Possible damage of ultrasonic scalpel, please self-test again or replace the scalpel after wiping.	Possible damage of ultrasonic scalpel.	Replace the ultrasonic scalpel with a new one.

6.3 Electrosurgical

During the operation of the equipment, any of the following failures will stop the equipment from outputting electrsugical energy, make it provide a sound prompt and display the corresponding error message in the display window on the front panel.

Table 6-2: Error messages and description of Electrosurgical

Error messages	Description	Possible Reasons and Troubleshooting
Abnormal output power, please restart the device.	Abnormal output power	Power off and restart the system. Contact the manufacturer if the problem remains.
Abnormal FRAM, please restart the device.	FRAM abnormality	Power off and restart the system. Contact the manufacturer if the problem remains
REM PAD CONTACT QUALITY	Poor contact of neutral electrode	Connect REM pad, check connection at patient site, or replace REM pad

6.4 System Failure

During the operation of the equipment, any of the following failures will stop the equipment from outputting energy, make it provide a sound prompt and display the corresponding error messages in the display window on the front panel.

Table 6-3: Error messages and description of system failure

Error Messages	Description	Possible Reasons and Troubleshooting
Abnormal fan speed, please restart the device.	Abnormal fan speed	Power off and restart the system. Contact the manufacturer if the problem remains.
Overheating chassis, please restart the device.	Chassis over temperature alarm	Power off and restart the system. Contact the manufacturer if the problem remains.
Inner communication error, please restart the device.	Inner communication error	Power off and restart the system. Contact the manufacturer if the problem remains.

7 Technical Parameters

7.1 Safety Class

Table 7-1: Safety class

Electric shock protection class	Class I
Degree of protection against electric shock (bipolar instruments,	Defibrillation-proof type CF applied part

laparoscopic electrode, handswitching electrosurgical pencil)	
Degree of protection against electric shock (ultrasonic scalpel)	Type CF applied part
Ultrasonic scalpel operation	continuous operation （continually）
Electrosurgical operation	Intermittent loading and continuous operation (run for 10 seconds / pause for 30 seconds)
Ingress protection rating	IPX0 for Generator, IPX8 for foot switch
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Non-AP/APG equipment
Software Version	ES_ Firm Ware, Version: P1 US_ Firm Ware, Version: P1 HMI_ Soft_Ware, Version: P1

Note	The defibrillated recover time is 1s.

7.2 Ultrasonic Scalpel

Amplitude

Main amplitude at the distal Note and tolerance (unit: μm): no more than 100μm.

Lateral amplitude at the distal Note: no more than 5μm.

Excitation Frequency

55.5kHz, tolerance: ±1kHz

Power

Static (No-Load) Electric Power	≤20W
Maximum Electric Power	≤45W
Index of Power Margin	>2

Range of power level set

There are two level setting channels on the front panel of the energy generator;

MAX level ranges from 4 to 5, and MIN level ranges from 1 to 4. Default power-on status of the energy generator is 3 for MIN and 5 for MAX.

The energy generator can transmit energy to the ultrasonic scalpel jaws, and control the output interface of the MAX/MIN level as well.

Released output characteristics of the product include main amplitude at the distal Note, excitation frequency, control type (continuous operation and intermittent loading) and index of power margin.

Energy Timely Adjustment Technology

Energy timely adjustment technology provides the generator with the ability to monitor the real-time impedance during use so that the generator auto adjusts the power output and delivers it to the ultrasonic scalpel, as well as provides audible feedback to the user.

Audible feedback: When power is activated, audio feedback is initiated. When the upper impedance threshold is reached, the audio feedback changes into a higher pitch tone.

Frequency Timely Adjustment Technology

With the frequency timely adjustment technology, the generator is able to monitor the phase difference between voltage and current signals and adjust excitation frequency accordingly to control the phase difference within a certain value for the resonance of the transducer.

7.3 Electrosurgical

Table 7-2: Output parameters of electrosurgical

Mode		Load Resistance	Working frequency	Modulation Frequency	Output Voltage (Vpk)	Output Current	Crest Factor
Monopolar	Low Pure Cut	300Ω	390kHz	/	600V	1.25A	1.5±0.2
	Pure Cut	300Ω	390kHz	/	1000V	1.25A	1.5±0.2
	Blend	300Ω	390kHz	27KHz	1650V	1A	2.5±0.2
	Soft	300Ω	390kHz	39kHz	1250V	1.2A	5±0.5

	Fulgurate	300Ω	390kHz	30kHz	2800V	1A	5.5±0.5
	Spray	300Ω	390kHz	25-50kHz	2350V	1A	5.5±0.5
	Share Soft	300Ω	390kHz	39kHz	1250V	1.2A	5±0.5
	Share Fulgurate	300Ω	390kHz	30kHz	2800V	1A	5.5±0.5
	Share Spray	300Ω	390kHz	25-50kHz	2350V	1A	5.5±0.5
Bipolar	Precise	100Ω	470kHz	/	250V	1.7A	1.5±0.2
	Standard	100Ω	470kHz	/	180V	1.7A	1.5±0.2
	Macro	100Ω	470kHz	/	400V	1.7A	1.5±0.2
	Smooth	100Ω	470kHz	/	134V	1.35A	1.5±0.2
	Advance 1	50Ω	470kHz	/	155V	2A	1.5±0.2

The maximum heating factor generated in any 60 second period is $200A^2s$.

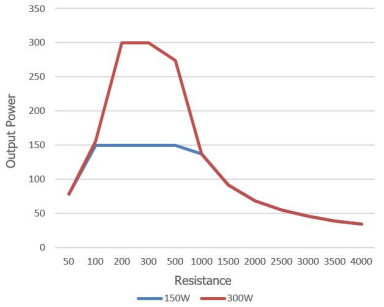
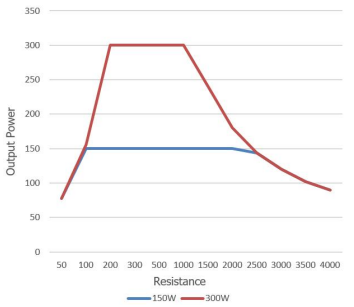
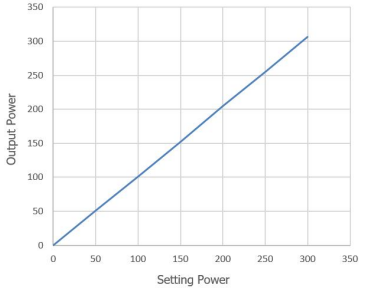
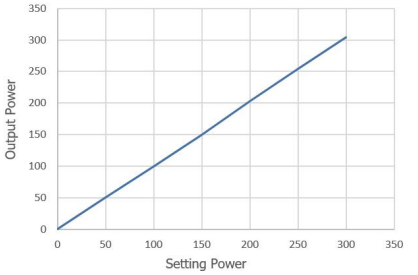
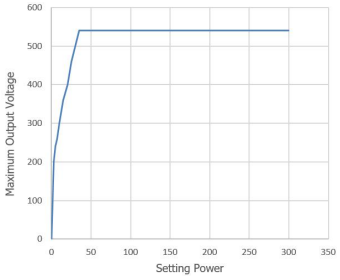
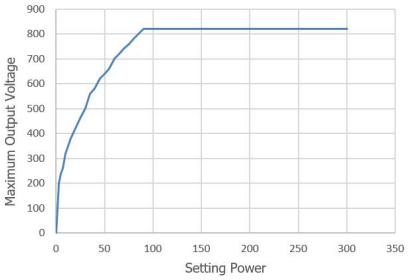
Note	The rated voltage of the electrosurgical pencil should be greater than or equal to 2600V, the rated voltage of the laparoscopic electrode should be greater than or equal to 1490V, and the rated voltage of the bipolar instruments should be greater than or equal to 360V.

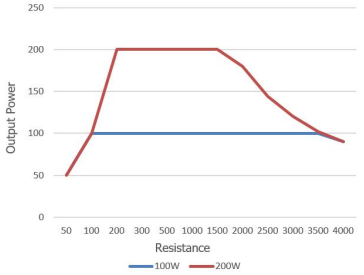
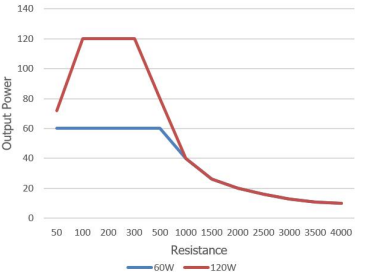
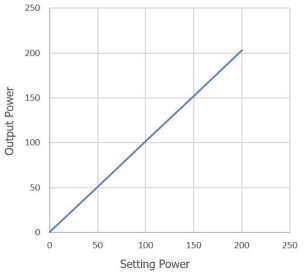
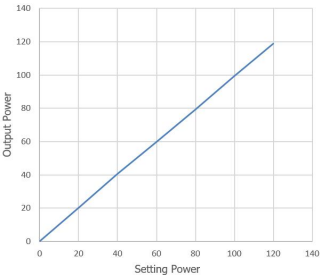
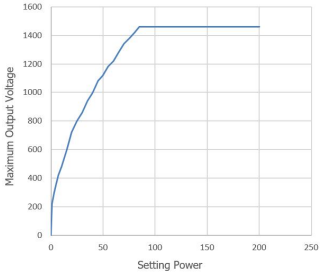
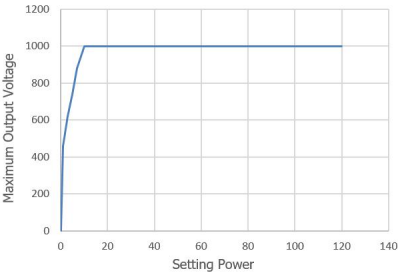
Table 7-3: Maximum Output Power of electrosurgical

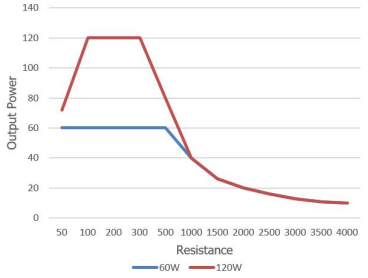
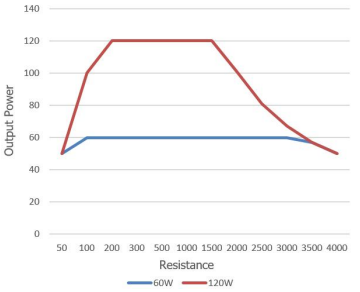
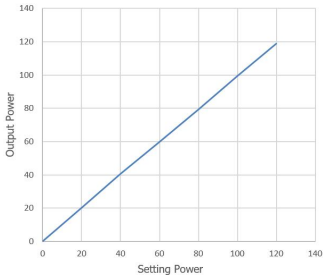
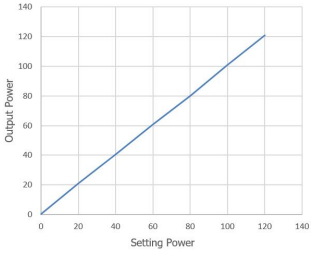
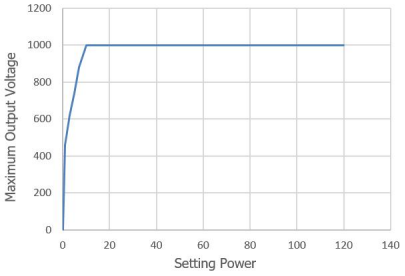
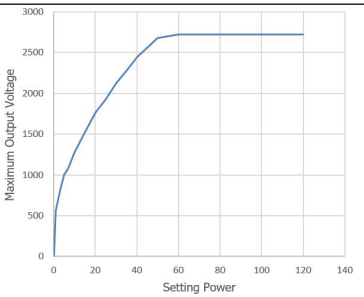
Model	Mode	Maximum Output Power
SC300ES	Low Pure Cut Mode	300W
	Pure Cut Mode	300W
	Blend Mode	200W
	Soft Mode	120W
	Fulgurate Mode	120W
	Spray Mode	120W
	Share Soft Mode	120W
	Share Fulgurate Mode	120W
	Share Spray Mode	120W
	Precise Mode	70W
	Standard Mode	70W
	Macro Mode	70W
	Smooth Mode	70W
	Advance 1 Mode	120W
SC200ES	Low Pure Cut Mode	200W
	Pure Cut Mode	300W
	Blend Mode	200W
	Soft Mode	120W
	Fulgurate Mode	120W
	Spray Mode	120W
	Share Soft Mode	120W
	Share Fulgurate Mode	120W
	Share Spray Mode	120W
	Precise Mode	70W
	Standard Mode	70W
	Macro Mode	70W
	Smooth Mode	70W
	Advance 1 Mode	120W
SC100ES	Low Pure Cut Mode	100W
	Pure Cut Mode	300W
	Blend Mode	200W
	Soft Mode	120W
	Fulgurate Mode	120W
	Spray Mode	120W

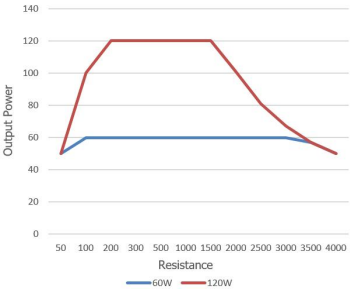
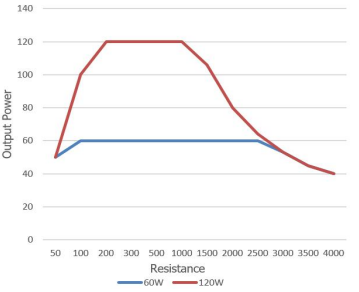
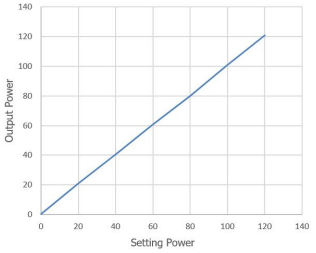
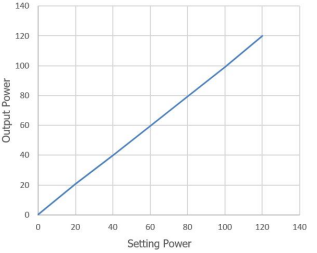
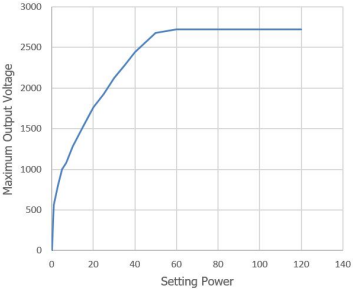
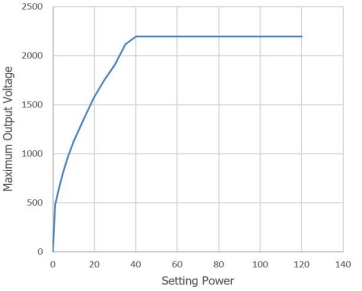
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	Share Fulgurate Mode	120W
	Share Spray Mode	120W
	Precise Mode	70W
	Standard Mode	70W
	Macro Mode	70W
	Smooth Mode	70W
	Advance 1 Mode	120W
ES300	Low Pure Cut Mode	300W
	Pure Cut Mode	300W
	Blend Mode	200W
	Soft Mode	120W
	Fulgurate Mode	120W
	Spray Mode	120W
	Share Soft Mode	120W
	Share Fulgurate Mode	120W
	Share Spray Mode	120W
	Precise Mode	70W
	Standard Mode	70W
	Macro Mode	70W
	Smooth Mode	70W
	Advance 1 Mode	120W
ES200	Low Pure Cut Mode	200W
	Pure Cut Mode	300W
	Blend Mode	200W
	Soft Mode	120W
	Fulgurate Mode	120W
	Spray Mode	120W
	Share Soft Mode	120W
	Share Fulgurate Mode	120W
	Share Spray Mode	120W
	Precise Mode	70W
	Standard Mode	70W
	Macro Mode	70W
	Smooth Mode	70W
	Advance 1 Mode	120W
ES100	Low Pure Cut Mode	100W
	Pure Cut Mode	300W
	Blend Mode	200W
	Soft Mode	120W
	Fulgurate Mode	120W
	Spray Mode	120W
	Share Soft Mode	120W
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	Advance 1 Mode	120W

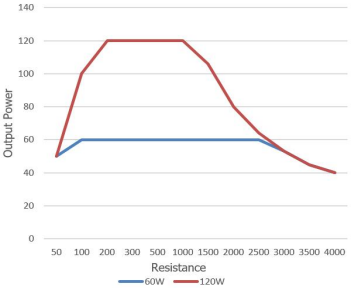
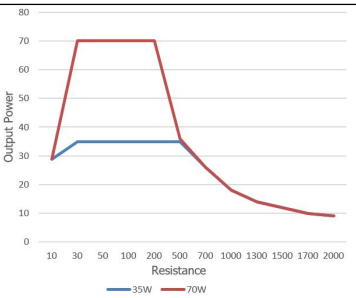
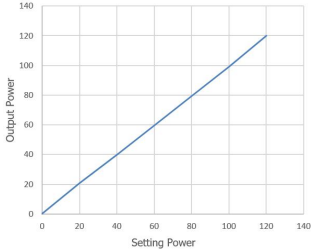
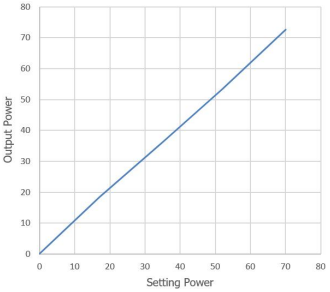
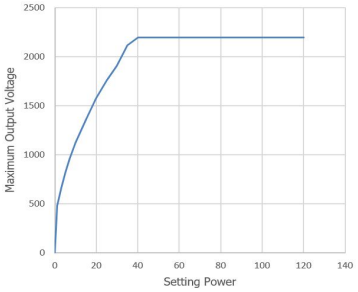
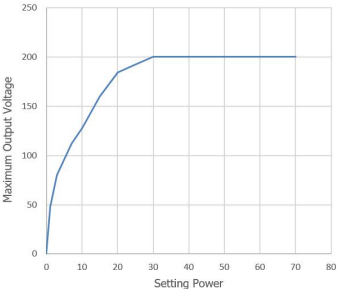
7.4 Power Output Curve of Electrosurgical

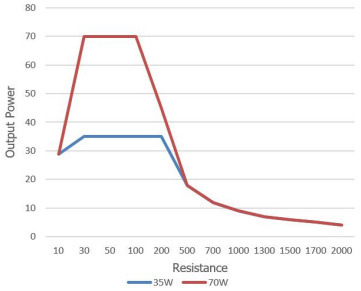
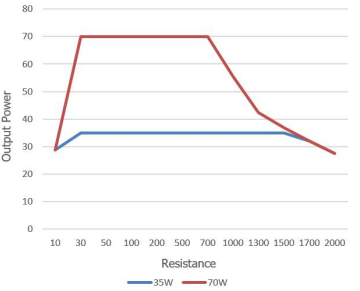
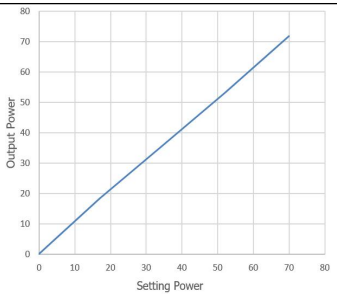
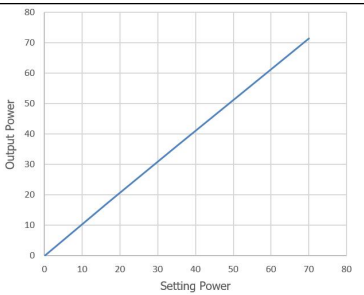
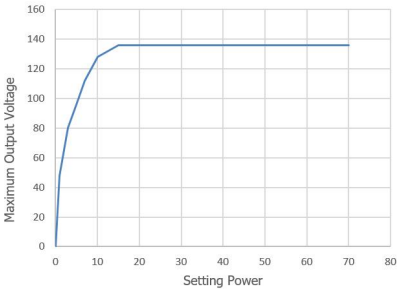
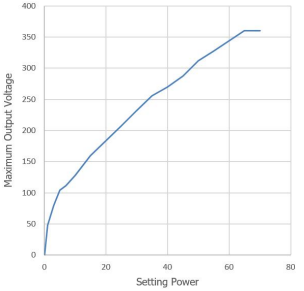
Low Pure Cut Mode	Pure Cut Mode
	
Output Power vs. Resistance	Output Power vs. Resistance
	
Output Power vs. Setting Power (300Ω)	Output Power vs. Setting Power (300Ω)
	
Maximum Output Voltage vs. Setting Power (4000Ω)	Maximum Output Voltage vs. Setting Power (4000Ω)

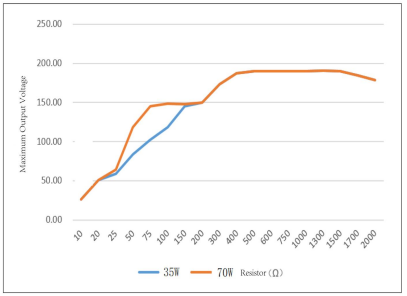
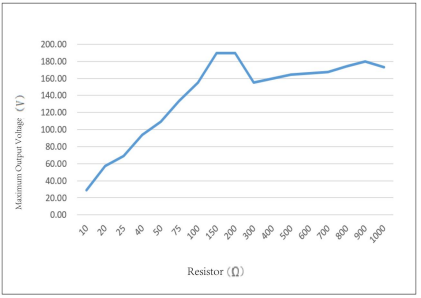
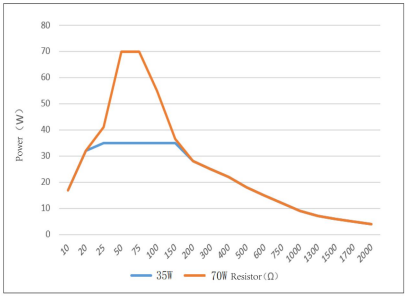
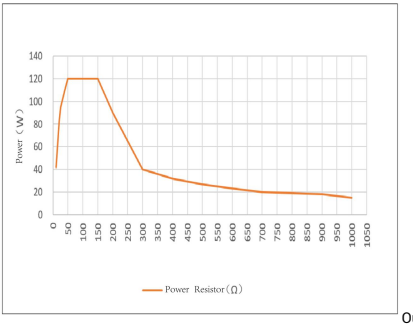
Blend Mode	Soft Mode
	
Output Power vs. Resistance	Output Power vs. Resistance
	
Output Power vs. Setting Power (300Ω)	Output Power vs. Setting Power (300Ω)
	
Maximum Output Voltage vs. Setting Power (4000Ω)	Maximum Output Voltage vs. Setting Power (4000Ω)

Share Soft Mode	Fulgurate Mode
	
Output Power vs. Resistance	Output Power vs. Resistance
	
Output Power vs. Setting Power (300Ω)	Output Power vs. Setting Power (300Ω)
	
Maximum Output Voltage vs. Setting Power (4000Ω)	Maximum Output Voltage vs. Setting Power (4000Ω)

Share Fulgurate Mode	Spray Mode
	
Output Power vs. Resistance	Output Power vs. Resistance
	
Output Power vs. Setting Power (300Ω)	Output Power vs. Setting Power (300Ω)
	
Maximum Output Voltage vs. Setting Power (4000Ω)	Maximum Output Voltage vs. Setting Power (4000Ω)

Share Spray Mode	Precise Mode
	
Output Power vs. Resistance	Output Power vs. Resistance
	
Output Power vs. Setting Power (300Ω)	Output Power vs. Setting Power (100Ω)
	
Maximum Output Voltage vs. Setting Power (4000Ω)	Maximum Output Voltage vs. Setting Power (1000Ω)

Standard Mode	Macro Mode
	
Output Power vs. Resistance	Output Power vs. Resistance
	
Output Power vs. Setting Power (100Ω)	Output Power vs. Setting Power (100Ω)
	
Maximum Output Voltage vs. Setting Power (1000Ω)	Maximum Output Voltage vs. Setting Power (1000Ω)

Smooth Mode	Advance Mode
	
Maximum Output Voltage vs. Resistance	Maximum Output Voltage vs. Resistance
	
Output Power vs. Resistance	Outp ut Power vs. Resistance

7.5 Optional Accessory Parameters of Electrosurgical

1. Rated accessory voltage of the selected accessory should be no less than the equipment's maximum output voltage; see Table 7-2 for maximum output voltages of modes of the equipment.
2. Only neutral electrodes with CQM function that must compatible with the neutral electrode socket of Ultrasonic Surgical & Electrosurgical generator and qualified by CE certificate can be used with the device.
3. Accessories that are certificated and within the validity period should be used in conjunction with the equipment.
4. See the figure below (unit of size in the figure is mm) for the equipment's accessory sizes; please select accessories with proper sizes to connect to the equipment:

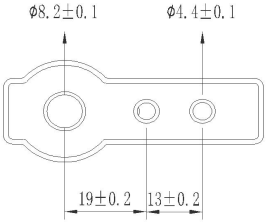


Figure 7.1: Channel interface of handswitching electrosurgical pencil

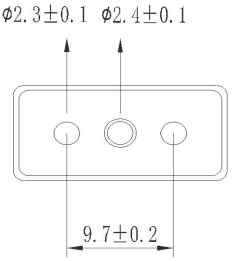


Figure 7.2: Channel interface of neutral electrode

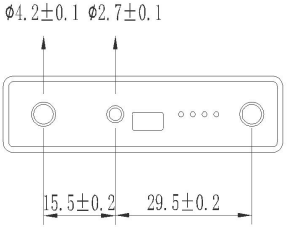


Figure 7.3: Channel interface of bipolar instruments

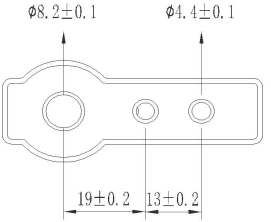


Figure 7.4: Channel interface of laparoscopic electrode

7.6 Product Standard

The equipment has been tested to meet the requirements of the following electrical safety standards:

IEC 60601-1	Medical electrical equipment - Part 1 General requirements for basic safety and essential performance
IEC 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical accessories
IEC 60601-1-2	General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

7.7 EMC Information

Warning	This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver, or radio control products. If you have to do so, the device should be observed to verify normal operation.
Warning	The use of accessories and power cord other than those specified, except for cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Essential Performance:

Ultrasonic scalpel mode:

Main amplitude at the distal Note and tolerance (unit: μm): no more than 100μm; Lateral amplitude at the distal Note: no more than 5μm; Excitation frequency:55.5kHz, tolerance: ±1kHz; Static (No-load) electric power ≤20W; Maximum electric power ≤45W; Index of power margin >2.

Electrosurgical mode: The output power accuracy of this product should meet the following requirements: when the set power is 0, this product has no output; When the designed power is not 0W, the tolerance between the actual output and the designed output is ±20%; the CQM function of the neutral electrode should be normal.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Ultrasonic Surgical & Electrosurgical System is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Ultrasonic Surgical & Electrosurgical System 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.
RF emissions CISPR 11	Class A	The Ultrasonic Surgical & Electrosurgical System is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity

The Ultrasonic Surgical & Electrosurgical System is intended for use in the electromagnetic environment specified below. The user of the equipment should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz repetition frequency ±1 kV for input / output lines	±2 kV for power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV differential mode line-line ±0.5kV, ±1kV, ±2kV differential mode line-ground	±0.5kV, ±1kV differential mode line-line ±0.5kV, ±1kV, ±2kV differential mode line-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T (100 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25/30 cycles at 0° 0 % U_T (100 % dip in U_T) for 250/300 cycle at 0°	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T (100 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25/30 cycles at 0° 0 % U_T (100 % dip in U_T) for 250/300 cycle at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The Ultrasonic Surgical & Electrosurgical System is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrasonic Surgical & Electrosurgical System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	3Vrms 150kHz to 80MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	Portable and mobile RF communications equipment should be used no closer to any part of the Ultrasonic Surgical & Electrosurgical System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $\sqrt{P}$ $\sqrt{P}$ 80MHz a 800MHz $/\overline{P}$ 800MHz a 2,7GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu-facturer and *d* is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.7GHz	3V/m	Field strengths from fixed RF trans-mitter, as determined

			by an electro-magnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ultrasonic Surgical & Electrosurgical System is used exceeds the applicable RF compliance level above, the Ultrasonic Surgical & Electrosurgical System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Ultrasonic Surgical & Electrosurgical System.

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

Recommended separation distances between portable and mobile RF communications equipment and the Ultrasonic Surgical & Electrosurgical System

The Ultrasonic Surgical & Electrosurgical System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ultrasonic Surgical & Electrosurgical System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ultrasonic Surgical & Electrosurgical System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	150 kHz ~ 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz ~ 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz ~ 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
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) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applied.

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

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless

communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency (MHz)	Maximum Power (W)	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E=\frac{6}{d}\sqrt{P}$ Where *P* is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

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

8 Transport and Storage

8.1 Transport Conditions

If the equipment needs to be transported, it should be transported according to the order contract. There is no hard impact, drench or exposure allowed during transport. Hard vibration and damp environment should be avoided as much as possible during transport and movement. And the equipment should be placed on a dry, well-ventilated and horizontal table without direct light.

The requirements for transport environment of energy generator are as follows:

Temperature	-20°C ~ 55°C
Humidity	10% RH ~ 80% RH non-condensing
Air pressure	700 hPa ~ 1060 hPa

8.2 Storage Conditions

The equipment should be stored a well-ventilated indoor environment without corrosive gas or irritating odor. The requirements for storage environment of the generator are as follows:

Temperature	-20°C ~ 55°C
Humidity	10% RH ~ 80% RH non-condensing
Air pressure	700 hPa ~ 1060 hPa

9 Cleaning

Warning	Turn off the energy generator power supply and plug the power cord off from the power socket before cleaning.
Warning	Do not remove the chassis shell of the energy generator when cleaning.
Warning	Check whether there is any damage, crack or appearance deformation before cleansing. Upon any of the above problems, do not clean. Contact the after-sales service unit of Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Warning	Do not have any liquid get into the connector interface on the front panel of the energy generator. Please store

	the equipment and accessories in a clean, dry and non-corrosive environment.

Note	See content of the Attachment for cleaning, disinfection and sterilization of the accessories.

9.1 Cleaning of the Energy Generator

1. Soak a piece of cloth in soft incombustible cleaner; wipe the external surface of equipment with the soaked cloth. Or clean with a soft bristle brush or equivalent.
2. Wipe the external surface with a piece of clean, soft cloth soaked in distilled water.
3. Wipe the external surface with a piece of dry, clean, and soft cloth.

9.2 Cleaning of the Foot Switch

Use soft detergent, e.g., 70% isopropanol solution, to clean the energy generator and foot switch.

Caution	Ensure that any part of the equipment is free from any isopropanol solution residual before the operation.

10 Maintenance and Repair

10.1 Maintenance

This equipment does not require any routine maintenance except cleaning.

Note	There are no maintainable parts by users. Once any failure occurs, you should send the equipment to Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.

10.2 Repair

If the fuse or the power cord is damaged, fixed types provided by Surgnova Healthcare Technologies (Zhejiang) Co., Ltd can be replaced. Other types of fuses or power cords may cause equipment failure.

10.2.1 Replacement of Fuse

When there is a suspected blown fuse, check according to the following procedures and change the fuse:

1. Turn off the energy generator power supply and plug the power cord off from the equipment.
2. Open the fuse drawer below the power input jack in the rear panel of the energy generator. Take out the fuse and check whether it has been blown with a multimeter.
3. Replace the blown fuse with a new one of the same model.
4. Power on the energy generator and turn on the equipment power switch to make sure that power-on self-test can pass.
5. The equipment can be used normally.

10.2.2 Replacement of Power Cord

Upon any damage, the power cord must be replaced. The procedures are as follows:

1. Disconnect the power supply circuit and ensure that no dangerous voltage is on the power cord socket.
2. Pull off the power cord from the socket.
3. Disconnect the power cord from the energy generator.
4. Turn on switch of the power supply circuit and ensure that the socket can work normally.
5. Connect the new power cord to the socket and the energy generator.
6. Turn on power switch of the energy generator.
7. The energy generator can be used normally as soon as power-on self-test passes.

11 Disposal

The equipment should be disposed of at the end of its service life in accordance with the local laws and regulations. Accessories or other disposable consumables that are used in conjunction with the equipment during the operation are recommended to be disposed in accordance with the local laws and regulations.

Attachment I Brief Instructions

Ultrasonic Scalpel

1. Connect the power cord of the energy generator.
2. Press the power switch of the energy generator, ultrasonic function of the energy generator will begin self-testing.

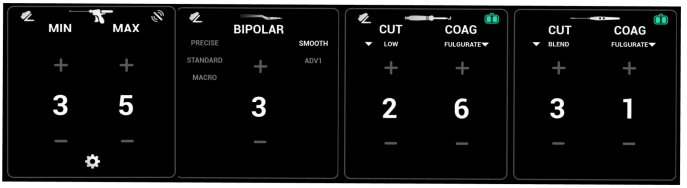


Figure 1: Power-on interface of energy generator

3. Insert the ultrasonic transducer.

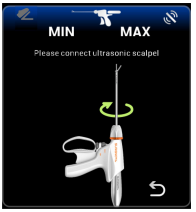


Figure 2: Insert the ultrasonic transducer

4. Connect the transducer to the ultrasonic scalpel (not applicable to SCXXE): use the ultrasonic scalpel torque wrench to connect the transducer to the ultrasonic scalpel. The "click" sound heard in rotating the torque wrench suggests that the transducer has been fastened well to the ultrasonic scalpel. Meanwhile the energy generator panel shows that the transducer has been connected to the ultrasonic scalpel, and prompts that self-test should be triggered by pressing the button.



Figure 3: Ultrasonic scalpel self-test prompt

5. Self-test of transducer and ultrasonic scalpel: activate the MAX/MIN button on the handle (if the foot switch has been connected and its function has been activated, you can also activate the left/right pedal on the foot switch). During self-test, a sound prompt given by the energy generator can be heard. Upon completion of the self-test, the energy generator will make a "jingle" sound, and the panel will display as the figure below. The ultrasonic scalpel is at the operational status at the moment.



Figure 4: Ultrasonic scalpel self-test is successful

6. After the transducer and the ultrasonic scalpel are accessed to the energy generator, the foot switch can be accessed for usage.

Caution	If self-test does not pass, warning and error message will be displayed on the panel. See the descriptions of error messages in "7.2 Ultrasonic Scalpel" for detailed, or contact the manufacturer.

Note	If self-test does not pass, there will be a warning tone and error messages will be displayed on the panel at the same time. To carry out another self-test, pull the transducer off from the ultrasonic generator interface or restart the ultrasonic generator. Contact the manufacturer upon any problem.
Note	During the test, if the scalpel head is bearing too much pressure, the ultrasonic generator panel will display corresponding error messages and there will be a warning tone. Open the jaws and activate again to continue the operation.

Electrosurgical

1. Connect the power supply of the energy generator; turn on the power switch on the front panel.

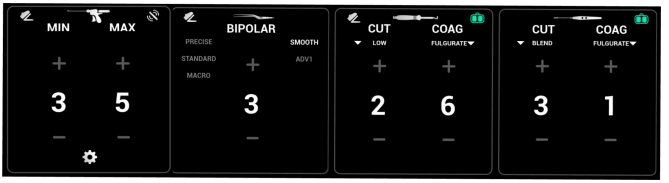


Figure 5: Power-on interface of energy generator

2. Connect the foot switch to the corresponding interface on the rear panel.
3. Connect other accessories as needed:

1) Connect the monopolar instrument: connect the monopolar instrument to the corresponding interface on the front penal.

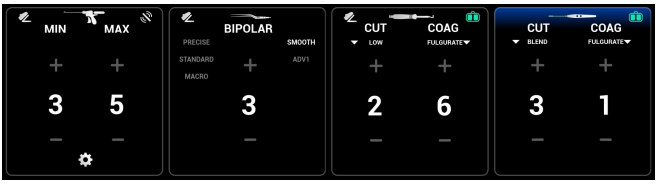


Figure 6: Connection of handswitching electrosurgical pencil channel

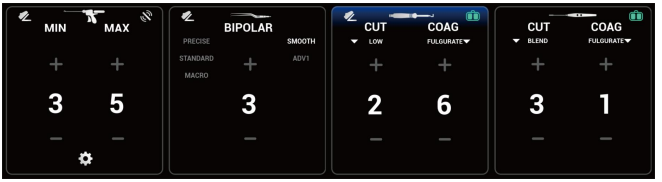


Figure 7: Connection of laparoscopic electrode channel

2) Connect the bipolar instruments: connect the bipolar instruments to the corresponding interface on the front panel.



Figure 8: Connection of bipolar instruments

4. Activate the needed mode: touch the foot switch button icon on the top of the mode channel needed to turn it into yellow and

solid, and then step on the pedal to activate it.

Note	Every time after turning on the equipment, the main interface displays parameters set in the previous time.
Note	To activate the “cutting” mode of the handswitching electrosurgical pencil, step on the yellow pedal of the foot switch; to activate the “coagulating” mode, step on the blue pedal of the foot switch. In default mode, step on the blue pedal of the foot switch to activate the laparoscopic electrode; in the multi-footswitch mode, step on the yellow pedal to activate the laparoscopic electrode. In the laparoscopic mono-cut mode, step on the yellow pedal to activate “cutting” function, and step on the blue one to activate the “coagulation” function. Bipolar coagulation froceps can be activated by stepping on the blue pedal in both default and multi-footswitch modes.
Note	Besides being activated by stepping on the pedals, the “cutting” and “coagulating” modes of the monopolar electrosurgical can also be activated by pressing the yellow and blue buttons on the handswitching electrosurgical pencil, respectively.

Attachment II User Manual of Ultrasonic Scalpel Accessories

Instructions of Ultrasonic Transducer

Product Model:

SC100T, SC150T

Manual cleaning:

1. Wipe the surface of the ultrasonic transducer thoroughly with a sterile gauze to remove rough contaminants.

2. Then wipe the transducer with a sterile gauze soaked in a neutral multi-enzyme cleaner (Metrex EmPower). The following parameters are recommended:

Model	SC100T	SC150T
Cleaning Solution	Metrex EmPower	3M Biofilm Removal Multi-Enzyme Cleaner 70508
Concentration	1:120	5ml/L-10ml/L
Temperature	20°C ~ 40°C	25°C ~ 40°C
Immersion	≥1 min	2min-10min

3. Brush the connecting part of the transducer for 5-10 min with a soft brush.

4. Wipe the surface for 5-10 min with a sterile gauze.

5.Thoroughly rinsing the transducer with purified water for 5-10 min.

Automated cleaning of ultrasonic transducer SC100T:

1. **Pre-Cleaning**: Clean the ultrasonic transducer in the washer disinfector or pre-rinse with purified water. Time of Pre-cleaning: 5-10 minutes, Temperature: Room Temperature.

2. **Cleaning**: Neutral detergents and pH-neutral enzymatic detergents can be used. Time of cleaning: 5-10 minutes, Temperature: Room Temperature. The following parameters are recommended:

Cleaning Solution: Metrex EmPower; Concentration: 1:128 ~ 1:512; Temperature: 20°C ~ 40°C

3. **Rinsing 1**: Purified or deionized water should be used throughout the Hand Piece cleaning process when using Metrex EmPower. Time of Rinsing 1: 5-10 minutes, Temperature: Room Temperature.

4. **Rinsing 2**: Purified or deionized water should be used throughout the Hand Piece cleaning process when using Metrex EmPower. Time of Rinsing 2: 5-10 minutes, Temperature: Room Temperature.

Note: Ultrasonic cleaning agents are not recommended for cleaning ultrasonic transducers.

Drying:

Dry the transducer with a clean, absorbent cloth. If a washer-disinfector without a drying cycle is used, a hot-air dryer may be used but the transducer must not be heated to temperatures above 134°C. The cavities of transducer parts must be blown out with clean, compressed air, up to 20 psi, in order to eliminate the possibility of any residual water remaining.

Sterilization:

Method	Applicable transducer	Parameters	
Pulsation vacuum	SC100T	sterilizer	BIST-A-D360-D-A steam sterilizer manufactured by SHINVA
		temperature	132°C/134°C

		exposure time	at least 4min
		dry time	20~30min
	SC150T	sterilizer	MOST-T 80L steam sterilizer manufactured by SHINVA
		temperature	132°C/134°C
		exposure time	at least 3min
		dry time	0~30min
Low temperature plasma	SC100T	sterilizer	PS-100X Hydrogen peroxide low temperature plasma sterilizer manufactured by SHINVA
		temperature	(50±2) °C
		mode	Full-cycle
		hydrogen peroxide, concentration	56%~63%
	SC150T	sterilizer	PS-200X Hydrogen peroxide low temperature plasma sterilizer manufactured by SHINVA
		temperature	(50±5) °C
		mode	Full-cycle
		hydrogen peroxide, concentration	56%~60%

Warning	The transducer must be cleaned, disinfected and sterilized each time before use.
Warning	Avoid using frictional materials in treating the surface during cleaning, disinfection and sterilization of the ultrasonic transducer.
Warning	Do not clean power plug of the ultrasonic transducer with an alcohol wipe.
Warning	Ensure that no liquid gets into any jack or crack of the ultrasonic transducer.

Caution	Ensure that all parts are free from any liquid residual. If there is any residual, wipe it off with a piece of dry, clean and soft cloth.

Connection:

Insert the ultrasonic transducer connector into the jack in the front panel of the energy generator and make sure that the connection is firm and reliable.

Test:

After connecting the ultrasonic transducer, select the "Handle test" in the settings interface to conduct transducer self-test. If self-test does not pass, a prompt of "Troubleshooting: plug out and insert the transducer to test again" will be displayed. If the problem cannot be solved after three tests, replace the handle; if still not solved, please contact the manufacturer.

Note	Each time when a new ultrasonic transducer replaces the old one, it must be tested.

Working environment, storage and transport environment:

	Temperature	Relative Humidity	Air Pressure
Working Environment	5°C ~ 40°C	20%RH ~ 80%RH, non-condensing	700hPa ~ 1060hPa
Storage and Transport Environment	-20°C ~ 55°C	10%RH ~ 80%RH, non-condensing	700hPa ~ 1060hPa

Warning	Please do not operate the equipment near any volatile solvent, such as methanol and alcohol, since there could be dangerous situations, e.g., explosion.
Warning	Completeness and maneuverability of equipment components, cracks and damages on surface and cables of the ultrasonic transducer should be examined before use. If any, stop the use and have it replaced in time.
Warning	Be careful when operating the ultrasonic transducer. Do not knock on the ultrasonic transducer or fall it to the floor, to avoid any change in resonance frequency caused by damage.
Warning	During the operation, it is suggested to wear protective glasses, filtration mask or set smoke evacuator/fume

	extractor in the operation room.

Caution	After usage count of the ultrasonic transducer has reached the upper limit (99), scrap disposal should be implemented according to the hospital's related regulations.
Caution	SCT100T ultrasonic transducer can only be used in conjunction with Surgnova's ultrasonic generator and ultrasonic scalpel, rather than any other manufacturer's such products.
Caution	No component of the equipment can be repaired by users. In case of electric shock and other risks, please contact after-sales service or return the equipment to the manufacturer upon any equipment failure.

Instructions of Ultrasonic Scalpel

Product Model:

Model	Shaft Length (cm)
SC43C / SC43C+ / SC43E	43
SC35C / SC35C+ / SC43E	35
SC21C / SC21C+ / SC43E	21
SC13C / SC13C+ / SC43E	13
SC09S / SC09S2	9
SC17S2	17

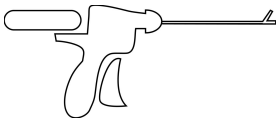
The instruments have a clamp arm and coated curved blade that are designed to work through a 5mm trocar ,through a 5mm reducer cap in a larger diameter trocar , or through an incision without the use of a trocar.

Sterilization:

The product is sterile; all products are sterilized with ethylene oxide and cannot be disinfected or sterilized for a second time.

Test and use:

Test: turn on the energy generator switch and insert the ultrasonic transducer. Fix the ultrasonic scalpel to the fixed end of the ultrasonic transducer scalpel head using the torque wrench and fasten it until the “click” sound is heard. At the moment, the icon below on the front panel flashes blue light:



Use: the ultrasonic scalpel cannot be used until self-test passes. Fasten the trigger to clamp the part to be cut, press the level button or step on the foot switch to output ultrasonic energy.

Warning	Jaws of the ultrasonic scalpel are prohibited to be reversed during cutting, to avoid any damage caused to the jaws.

Caution	During usage, each activation time should not last too long, to avoid wearing tissue pad.
Caution	Do not reuse the ultrasonic scalpel for reusing the product might put patients at increased risk of infection.

Note	When the ultrasonic scalpel cannot pass the test, check whether the connection between the ultrasonic scalpel and the ultrasonic transducer is reliable. Three failed tests suggest that the ultrasonic scalpel is out of order.
Note	The trigger cannot be pulled too tightly when being used, or the ultrasonic generator will stop outputting energy and display fault code, AA.
Note	Ulreasonic Scalpel SCXXE has a built-in ultrasonic transducer and does not require an ultrasonic transucer to be connected.
Note	Ultrasonic Scalpel SCXXE and SCXXC+ are compatible with ultrasonic transducer SC100T. Ultrasonic Scalpel SC09S and SCXXS2 are compatible with ultrasonic transducer SC150T.

Working environment, storage and transport environment:

	Temperature	Relative humidity	Air pressure
Working environment	5°C ~ 40°C	20%RH ~ 80%RH, non-condensing	700hPa ~ 1060hPa

Storage and transport environment	-20°C ~ 55°C	10%RH ~ 80%RH, non-condensing	700hPa ~ 1060hPa

Warning	The equipment can only be sold by doctors or in accordance with a doctor's advice.
Warning	The product is kept in a sterile package. Do not use if package is damaged.
Warning	The product can only be used in conjunction with Surgnova's ultrasonic generator and ultrasonic transducer, rather than any other manufacturer's such products.
Warning	Whenever there is system failure, ensure that standby equipment for a specific surgery is ready.
Warning	Operations involving laser, high-frequency electrosurgical and ultrasonic wave should be fully understood in their performance, to avoid electric shock and burn of patients and medical personnel, as well as causing damage to any other medical device.
Warning	Do not soak the equipment in liquid.
Warning	High-frequency oscillating sound made by resonance of the jaws or the transducer handle is an abnormal status, suggesting that the scalpel head or the transducer handle is running abnormally. The oscillating sound suggests that the transducer handle is being used beyond its service life or connection of the scalpel head is incorrect, which may lead to excessive over temperature of the scalpel head and injure users and patients.
Warning	The ultrasonic scalpel is a disposable product. Used ultrasonic scalpels should be treated according to the hospital's related regulations and procedures and cannot be used repeatedly.
Warning	Temperature of the scalpel head is relatively high. Do not touch it with skin and flammable objects to avoid burns and combustion.
Warning	To avoid accidental power-on that injures operators and patients, ultrasonic scalpel head must not contact with patients, surgical towels or flammable substance when not used.
Warning	During the operation, it is suggested to wear protective glasses, filtration mask or set dedicated smoke evacuator/fume extractor.
Warning	Be careful when operating the ultrasonic scalpel. Do not knock on the ultrasonic scalpel or fall it to the floor, to avoid any damage of the jaws.
Warning	When the jaws open, do not insert the device or pull out Trocar, to avoid damaging the device.
Warning	To avoid injuring users and patients, do not activate any electrosurgical equipment that is close to a SURGNOVA device. Aerosol generated by activating SURGNOVA ultrasonic scalpel in fat tissue is of flammable risks.
Warning	During use of the ultrasonic scalpel, avoid unintended contact between the jaws and surrounding tissue.
Warning	Please do not bend the jaws to avoid jaws failure and injuring users and patients.
Warning	When activated, avoid touching the ultrasonic scalpel with any object and metal/plastic device and equipment, to avoid damaging the scalpel head.
Warning	When there is no tissue between the jaws and tissue pad, keep the jaws open to avoid damaging the tissue pad and the jaws.
Warning	During cutting, blood and tissue may accumulate on the tissue pad and the jaws. Clean the accumulated blood and tissue in time to avoid that temperature of the jaws rises abnormally.
Warning	Special treatment may be needed by device or equipment contacting with body fluid to avoid biological contamination.
Warning	After removing the ultrasonic scalpel, check tissue hemostasis. If hemostasis fails, proper methods should be adopted to stop bleeding.
Warning	The ultrasonic scalpel should not be activated for long time during use, or the scalpel head will be overheated, leading to a failure.
Warning	Only proper ultrasonic scalpel, ultrasonic transducer, foot switch and power cord should be used to ensure compatibility with the ultrasonic generator.
Warning	When Surgnova's ultrasonic scalpel is used on substantial organs, auxiliary measures should be taken to stop bleeding successfully. The cutting should be performed slowly. Do not try to crosscut large area of tissue once, to avoid cutting off great vessels, biliary tract or other tissues.
Warning	Products produced by companies that are not authorized by Surgnova Healthcare Technologies (Zhejiang) Co., Ltd may be incompatible with the SURGNOVA system. Use of such products may lead to unexpected results and injure users and patients.

Attachment III User Manual of Electrosurgical Accessories

Note	Refer to 1.4 "Symbol Description" for symbol identifications on the electrosurgical accessories

Instructions of Electrosurgical Pencil

	Model	Working Length(mm)	Note	Rated Voltage
Product model	SCPen	/	Cable: 2.9m, diameter of compatible electrode: 2.36mm±0.05mm	3500V
	SCPenE	45	Cable: 2.9m	
	SCPenR	40 (Retracted)	Extension: 140mm; Cable: 2.9m	
	SCPenS	40	Evacuation tubing: 52cm; Cable: 2.9m	
Scope of application	The electrosurgical pencil should be used in conjunction with high-frequency surgical equipment and suction device to carry out electrocoagulation and electrosurgical resection in open high-frequency surgeries.			
Usage method	1. Check whether the package is damaged. Do not use if the package is damaged. 2. Take out the electrosurgical pencil from the package. Check product completeness before use. 3. Remove protective cover of the Electrosurgical Electrode and insert it into the Electrosurgical Pencil (if applicable); check whether the electrode inserted into the Electrosurgical Pencil handle is firm. 4. Adjust the working electrode to the required length or connect the smoke evacuation tube to an evacuator (if applicable). 5. Insert the electrosurgical pencil into the corresponding output jack in the ultrasonic surgery energy generator. 6. During the use of the electrosurgical pencil, press the yellow button on the handle to start the "cutting" output, and press the blue button on the handle to start the "coagulating" output.			
Storage and transport environment	Temperature: -20°C ~ 55°C Relative humidity: 10%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa			
Working environment	Temperature: 5°C ~ 40°C Relative humidity: 20%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa			
Sterilization	The product is sterile; all products are sterilized with ethylene oxide and cannot be disinfected or sterilized for a second time.			
Cautions	1. The product is sterile. Do not use if package is damaged. 2. To ensure operational safety, carefully check the completeness before use. Do not use upon situations like broken insulating layer and wire and rusty/loose electrode. 3. To avoid accidental power-on that injures operators and patients, electrosurgical pencils must not contact with patients, surgical towels or flammable substance when not used. 4. The product is a disposable product. Used electrosurgical pencils should be treated according to the hospital's related regulations and procedures and cannot be used repeatedly. 5. Do not reuse the electrosurgical pencil for reusing the product might put patients at increased risk of infection.			

Instructions of Electrosurgical Pencil Electrode

	Model	Shape of electrode	Electrode length (mm)	Electrode thickness/diagram (mm)	Rated Voltage
Product model	SCPenK0069	Knife shape	69	Thickness: 0.5mm	3500V
	SCPenK0150	Knife shape	150	Thickness: 0.5mm	
	SCPenN0069	Needle shape	69	Tip diameter: 0.8mm	
	SCPenN0150	Needle shape	150	Tip diameter: 0.8mm	
	SCPenB0140-1	Spherical shape	140	Sphere diameter: 5mm	
	SCPenB0140-2	Spherical shape	140	Sphere diameter: 3mm	

	SCPenL0150	L shape	146	Line diameter: 1mm	
Scope of application	The electrosurgical pencil electrodes of various models should be used in conjunction with high-frequency surgical equipment and suction device to carry out electrocoagulation and electrosurgical resection in open high-frequency surgeries.				
Usage method	1. Check whether the package is damaged. Do not use if the package is damaged. 2. Take out the product from the package. 3. Remove protective sleeve of the electrode and insert it into the handswitching electrosurgical pencil; check whether electrode inserted into the handle is firm.				
Storage and transport environment	Temperature: -20°C ~ 55°C Relative humidity: 10%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa				
Working environment	Temperature: 5°C ~ 40°C Relative humidity: 20%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa				
Sterilization	The product is sterile; all products are sterilized with ethylene oxide and cannot be disinfected or sterilized for a second time.				
Cautions	1. The product is sterile. Do not use if package is damaged. 2. To ensure operational safety, carefully check the completeness before use. The product cannot be used if the insulating layer is broken, especially. 3. Do not reuse the electrosurgical pencil electrode for reusing the product might put patients at increased risk of infection.				

Instructions of Laparoscopic Electrode

	Model	**Working length (m)**	**Diameter of shaft (mm)**	**Cable Length (m)**	**Rated Voltage**
Product model	SCHookL0330	360	5	3.1±0.1	3500V
	SCHookL0450	450	5		
	SCHookLS0360	360	5	2.9±0.1	
	SCHookLS0450	450	5		
Scope of application	As a monopolar surgical accessory of high-frequency electrosurgical, the laparoscopic electrode should be used in conjunction with ultrasonic electrosurgery energy generator and laparoscope. Minimum inner diameter of device duct of the laparoscope that is used in conjunction should be no smaller than 5mm. After connecting with the usage method, start the ultrasonic electrosurgery energy generator to carry out cutting and blood coagulation on body tissue.				
Product composition	The product is composed of working electrode and connecting cable.				
Usage method	1. Check whether the package is damaged. Do not use if the package is damaged. 2. Connect the Laparoscopic Electrode and the connecting cable. 3. Connect smoke evacuation tube to evacuator (if applicable). 4. Insert the cable connecting plug into the corresponding output jack of the Ultrasonic Surgical & Electrosurgical Generator. 5. Insert the Laparoscopic Electrode into the orifice of the laparoscope that is used in conjunction according to the corresponding laparoscope instructions. 6. During the use of the Laparoscopic Electrode, step on any of the foot switch to start the output.				
Storage and transport environment	Temperature: -20°C ~ 55°C Relative humidity: 10%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa				
Working environment	Temperature: 5°C ~ 40°C Relative humidity: 20%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa				
Sterilization	The product is sterile; all products are sterilized with ethylene oxide and cannot be disinfected or sterilized for a second time.				
Cautions	1. The product is sterile. Do not use if package is damaged. 2. The product should be used in conjunction with ultrasonic electrosurgery energy generator in operation,				

	and is applicable to all related use precautions of ultrasonic electrosurgery energy generator. 3. To ensure operational safety, carefully check the completeness before use. Do not use upon situations like broken insulating layer and wire and loose connector. 4. The monopolar surgical electrode should be used in conjunction with the neutral electrode. Focus on circuit monitoring during the operation to avoid burns. 5. To avoid accidental power-on that injures operators and patients, laparoscopes must not contact with patients, surgical towels or flammable substance when not used. 6. Patients should not contact with any grounded metal/metal with visible earth capacitance (e.g., operating table and bracket). Use of antistatic separator is recommended. 7. Prevent skin-to-skin contact (the limbs of a patient). Thick dry gauze is recommended to be placed where skin-to-skin contact is likely to occur. 8. High-frequency current may interfere with operation of pacemakers. Note that current circuit must not go through active implant products implanted by patients, like pacemakers. Before performing high-frequency operations on such patients, related cardiologists must be on the spot to take/prepare to take proper and effective preventive first-aid measures. 9. The product is a disposable product. Used laparoscope should be treated according to the hospital's related regulations and procedures and cannot be used repeatedly. 10. Please refer to the instructions of integrated system of ultrasonic eletrosurgery used in conjunction for other cautions. 11. Do not reuse the laparoscopic electrode for reusing the product might put patients at increased risk of infection.

Instructions of Bipolar instruments

Bipolar Coagulation Forceps	**Model**	**Shape of handle**	**Electrode length (mm)**	**Electrode thickness/diagram (mm)**		**Cable Length (m)**	**Rated Voltage**
	SCForceps0115-1	Straight	115	Straight, Note: 0.3mm		3.1±0.1	500V
	SCForceps0115-2	Straight	115	Straight, Note: 0.7mm			
	SCForceps0115-3	Straight	115	Curved, Note: 0.3mm			
	SCForceps0115-4	Straight	115	Curved, Note: 0.7mm			
	SCForceps0200-1	Gun shape	200	Straight, Note: 0.3mm			
	SCForceps0200-2	Gun shape	200	Straight, Note: 0.7mm			
	SCForceps0200-3	Gun shape	200	Curved, Note: 0.3mm			
	SCForceps0200-4	Gun shape	200	Curved, Note: 0.7mm			
Bipolar Instruments	**Model**	**Shape of handle**	**Shaft Diameter (mm)**	**Shaft Length (mm)**	**Jaw Length (mm)**	**Cable Length (m)**	**Rated Voltage**
	AG52323CM	Gun shape	5.4	230	23	4±0.2	450V
	AG53723CM	Gun shape	5.4	370	23		
	AG54423CM	Gun shape	5.4	440	23		
	AG52320SM	Gun shape	5.4	230	20		
	AG53720SM	Gun shape	5.4	370	20		
	AG54420SM	Gun shape	5.4	440	20		
	Model	**Shape of handle**	**Tip Width (mm)**	**Total Length (mm)**	**Jaw Length (mm)**	**Cable Length (m)**	**Rated Voltage**
	AG22121KM	Scissor shape	2	210	21	4±0.2	450V
Scope of application	The bipolar instruments are accessories of high-frequency surgical equipment and should be used in conjunction with high-frequency generator to carry out electrocoagulation in open surgeries.						
Product composition	The product is composed of forceps and connecting cable.						
Usage method	1. Check whether the package is damaged. Do not use if the package is damaged. 2. Take out the product from the package. 3. Connect the bipolar instruments and the connecting cable; insert the cable connecting plug into the corresponding output jack of the Ultrasonic Surgical & Electrosurgical Generator.						

	4. Step on any pedal of the foot switch or activation buttons to start the output of bipolar coagulation forceps. Press the activation button to start the output of bipolar instruments.
Storage and transport environment	Temperature: -20°C ~ 55°C Relative humidity: 10%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa
Working environment	Temperature: 5°C ~ 40°C Relative humidity: 20%RH ~ 80%RH, non-condensing Air pressure: 700hPa ~ 1060hPa
Sterilization	The product is sterile; all products are sterilized with ethylene oxide and cannot be disinfected or sterilized for a second time.
Cautions	1. The product is sterile. Do not use if package is damaged. 2. To ensure operational safety, carefully check the completeness before use. Do not use upon situations like broken insulating layer and wire and rusty/loose electrode. 3. To avoid accidental power-on that injures operators and patients, bipolar instruments must not contact with patients, surgical towels or flammable substance when not used. 4. The product is a disposable product. Used bipolar instruments should be treated according to the hospital's related regulations and procedures and cannot be used repeatedly. 5. Do not reuse the bipolar instruments for reusing the product might put patients at increased risk of infection.

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