ES-100V

Electrosurgical Generator

User Manual

Introduction

The manual applies only to the company's Electrosurgical Generator (hereinafter referred to as "surgical generator"), which is only used in medical institutions and is only used by medical staff who have been trained and qualified in surgery and specific techniques. For other technical information about the surgical generator, please refer to the after-sales service manual of the company's Electrosurgical Generator.

Note
This surgical generator can be only used by medical staff who have been trained and qualified in surgery and specific techniques.

Overview of the manual
Product name: Electrosurgical Generator;
Model: ES-100V;
Date of manufacture: please refer to the brand tag of the surgical generator;
Expiration date: 6 years;

Instructions for use of the manual

Warning
It indicates a potentially hazardous condition which, if not avoided, will result in death or serious injury.

Note
It indicates a hazardous condition which, if not avoided, will result in mild or moderate injuries.

Important note
It refers to the tips and suggestions for the generator operation.

Caution
It indicates a condition that affects the quality of the product, which, if not avoided, will do damage to the product.

Description
It refers to explanation.

Contents

Part One Introduction to Electrosurgical Generator;

Contents of this part include:

For the safety of the medical staff and patients, medical staff should read this manual carefully to have an in-depth knowledge of this surgical generator.

1.1 Introduction to the surgical generator

ES-100V Product is a multi-functional high frequency surgical generator with 6 kinds of operating modes, including 3 kinds of monopolar electrosurgical excision modes, 2 kinds of monopolar electro-coagulation modes and 1 kind of Bipolar modes. It provides great convenience for a variety of surgeries with the help of the electrotome. At the same time, the built-in return electrode monitor system is capable of monitoring high frequency leakage current, thus providing safety assurance for surgery.

It has the following features:

●3 kinds of monopolar electrosurgical excision modes: pure cut, blend cut 1, blend cut 2;

●2 kinds of monopolar electro-coagulation modes: spray coagulation, forced coagulation;

●1 kinds of Bipolar output modes: standard mode;

●Manual switch and foot switch;

●The recently used mode, power and other parameters can be invoked when starting up;

●Volume control function;

●Intermittent cutting alternating with blood coagulation.

1.2 Software description

Software name: High frequency surgical generator t firmware

Software version: V1.0

Software functions: please refer to the introduction to each controller in part two.

1.3 Monopolar mode

● The monopolar modes of this surgical generator include monopolar electrosurgical excision mode and monopolar electro-coagulation mode, among which the electrosurgical excision modes include pure cut, blend cut 1, blend cut 2 and their respective output powers are adjustable.

◆ Pure cut: Unmodulated sine wave. Clean and precise tissue cutting can be performed if there is no need for hemostasis.

◆ Blend cut 1: The first sine wave to be modulated. It is used when the cutting speed is a bit slow and there is only a small amount of bleeding needed to be treated.

◆ Blend cut 2: The second sine wave to be modulated. Compared with blend cut 1, it is used when the cutting speed is a little bit slower and a better hemostasis effect is needed.

● Monopolar electro-coagulation modes include spray coagulation, forced coagulation and their respective output powers are

adjustable.

◆ Spray coagulation: non-contact efficient surface electro-coagulation with shallow penetration. The tissue removal is achieved by evaporation and a knife-shaped or a spherical electrode is usually adopted for blood coagulation.

◆ Forced coagulation: non-contact blood coagulation, but the output peak voltage is lower than that of the spray coagulation. It applies to blood coagulation of small area.

In regard to the output features of the monopolar mode, please refer to part nine-technical features.

1.4 Bipolar mode

●The Bipolar mode only has the standard mode.

◆Standard: Suitable for most Bipolar applications. Keep the voltage low to prevent sparks.

Regarding the output characteristics of the Bipolar mode, see Part 9-Technical Features.

1.5 Structure and composition

The Electrosurgical Generator is composed of a host, a power cord, a pedal, an electrode, and a neutral plate.

1.6 Range of application

Electrosurgical generator is a general electrosurgical generator designed to generate radio frequency (RF) current, which is used for the cutting and coagulation of the target tissues through the accessory generators during opening and laparoscopic surgery.

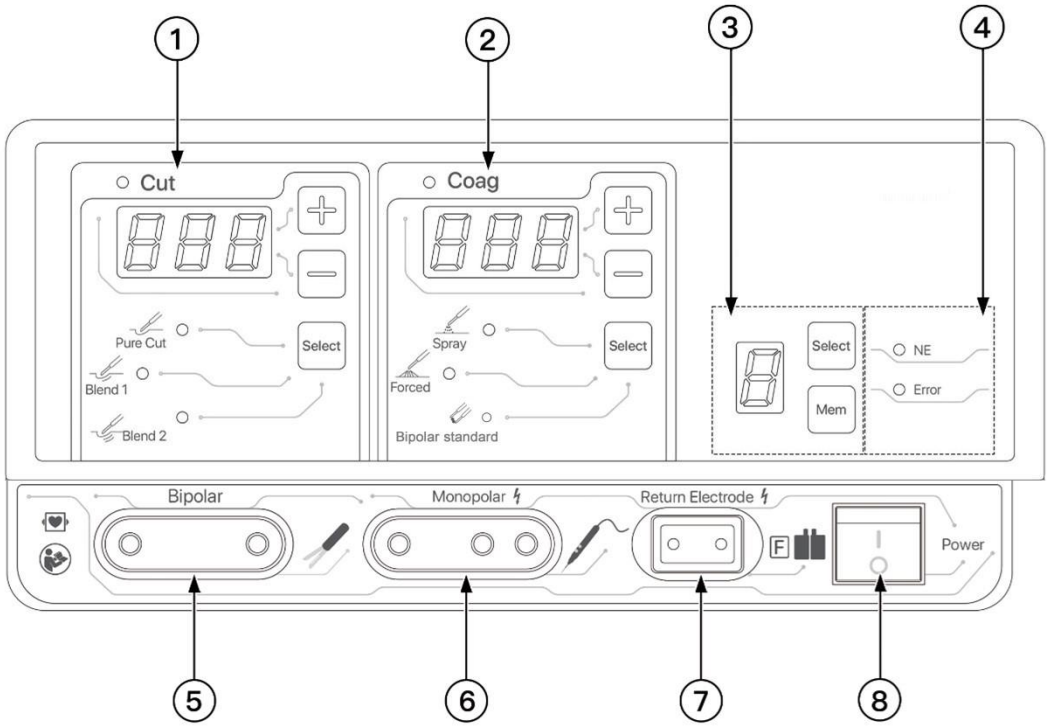
1.7 Contraindication

Electrosurgical Generator belongs to surgical products, and its contraindication is related to particular electrosurgical operations. There are no absolute contraindications for the generator itself. Patients with implantable cardiac pacemakers or other metal implants should be treated with caution and high-frequency current should be avoided to flow near the implants.

Part two front panel, back panel, figures and symbols

Contents of this part include:

2.1 Front panel



①Monopolar electro-coagulation controller

In the monopolar electro-coagulation mode, there are different mode selections and power value settings.

②Monopolar/Bipolar electrosurgical excision controller

In the monopolar/bipolar electrosurgical excision mode, there are different mode selections and power value settings.

③Memory controller

Memorize 9 groups of selected modes and their power value settings.

④Return electrode monitor (REM) system controller

The setting of return electrode monitor system is realized by cooperating with the return electrode.

⑤Bipolar output interface

⑥Monopolar output interface

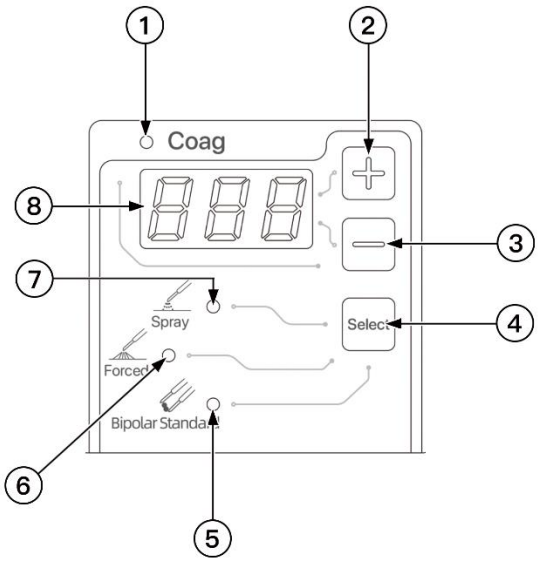
⑦Return electrode interface

⑧Power switch

Generator power switch.

" | " means "on" and "○" means "off".

2.2 Bipolar controller

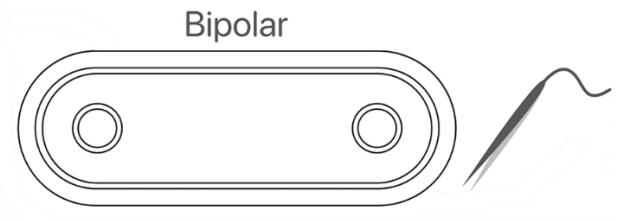


①Indicator light in the electro-coagulation mode
If the indicator light is on, it means that the electro-coagulation mode has been selected.
②Power amplification button in the electro-coagulation mode
Press the button to increase the power (P) of the selected mode, P < 50, 1 W/ time, P≥ 50, 5 W/ time. Long press on the button and the power will keep increasing.
③Power reduction button in the electro-coagulation mode
Press the button to reduce the power (P) of the selected mode, P < 50, 1 W/ time, P≥ 50, 5 W/ time. Long press on the button and the power will keep decreasing.
④Electro-coagulation mode selection button
Press this button to select from three different electro-coagulation modes and the indicator light of the selected mode will be on.

⑤Indicator light in the Bipolar Standard coagulation mode

If the indicator light is on, it means that the Bipolar Standard coagulation mode has been selected and the rated output power is 60W.
⑧Electro-coagulation power output display screen
Display the output power (W) set for a certain selected electro-coagulation mode.

2.3 Bipolar output interface

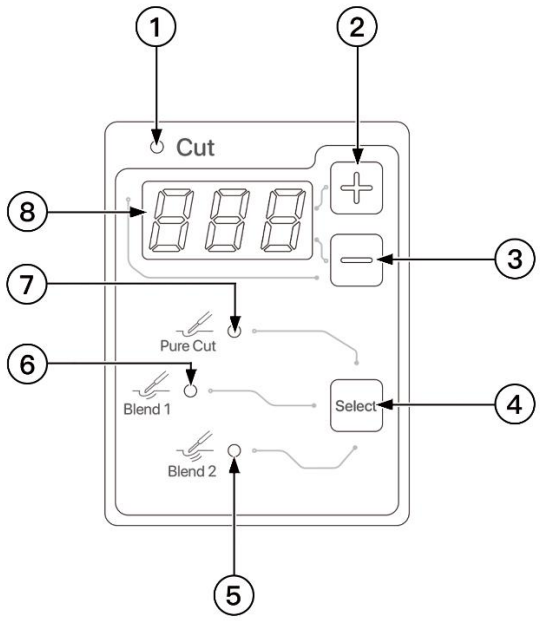


This interface only supports two-pin Bipolar generator accessories. Bipolar generators can be connected to this gang socket for Bipolar electro-coagulation. Bipolar foot switch can be used to start the Bipolar electro-coagulation mode.

Note
The interface is limited to Bipolar generator accessories that shall meet the requirements of part nine. The use of substandard accessories may result in the failure to plug and start up, REM alarm, abnormal output and so on.

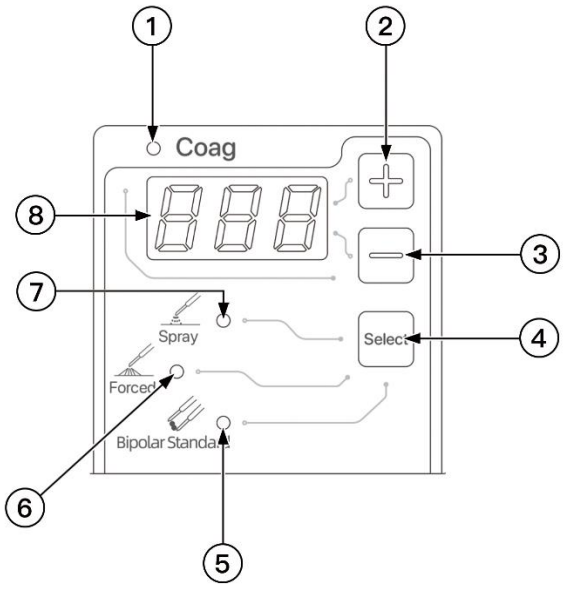
Objects such as tweezers, metal needles are not allowed to insert into this output interface, which might lead to electric shock.

2.4 Monopolar electrosurgical excision controller



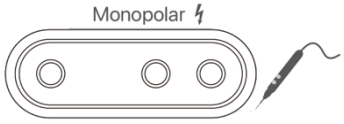
①Indicator light in the electrosurgical excision mode
If the indicator light is on, it means that the electrosurgical excision mode has been selected.
②Power amplification button in the electrosurgical excision mode
Press the button to increase the power (P) of the selected mode,, 1 W/ time. Long press on the button and the power will keep increasing.
③Power reduction button in the electrosurgical excision mode
Press the button to reduce the power (P) of the selected mode , 1 W/ time. Long press on the button and the power will keep decreasing.
④Electrosurgical excision mode selection button
Press this button to select from four different electrosurgical excision modes and the indicator light of the selected mode will be on.
⑤Indicator light in the blend cut 2 mode
If the indicator light is on, it means that the blend cut 2 mode has been selected and the rated output power is 100W.
⑥Indicator light in the blend cut 1 mode
If the indicator light is on, it means that the blend cut 1 mode has been selected and the rated output power is 100W.
⑦Indicator light in the pure cut mode
If the indicator light is on, it means that the pure cut mode has been selected and the rated output power is 100W.
⑧Electrosurgical excision power output display screen
Display the output power (W) set for a certain selected monopolar electrosurgical excision mode.

2.5 Monopolar electro-coagulation controller



①Indicator light in the electro-coagulation mode
If the indicator light is on, it means that the electro-coagulation mode has been selected.
②Power amplification button in the electro-coagulation mode
Press the button to increase the power (P) of the selected mode, 1 W/ time, Long press on the button and the power will keep increasing.
③Power reduction button in the electro-coagulation mode
Press the button to reduce the power (P) of the selected mode, 1 W/ time, Long press on the button and the power will keep decreasing.
④Electro-coagulation mode selection button
Press this button to select from three different electro-coagulation modes and the indicator light of the selected mode will be on.
⑥Indicator light in the forced coagulation mode
If the indicator light is on, it means that the forced coagulation mode has been selected and the rated output power is 60W.
⑦Indicator light in the spray coagulation mode
If the indicator light is on, it means that the spray coagulation mode has been selected and the rated output power is 90W.
⑧Electro-coagulation power output display screen
Display the output power (W) set for a certain selected electro-coagulation mode.

2.6 Monopolar output interface



Monopolar output interface

The monopolar handle can be connected to the interface for electrosurgical excision or monopolar electro-coagulation. Monopolar foot switch or the switch on the monopolar handle can be used to start the electrosurgical excision or monopolar electro-coagulation modes. In regard to the operation of the monopolar handle, please refer to part five.

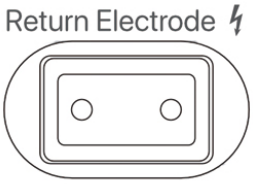
Warning

Objects such as tweezers, metal needles are not allowed to insert into this output interface, which might lead to electric shock.

Note

This interface is limited to monopolar generator accessories that shall meet the requirements of part nine. The use of substandard accessories may result in the failure to plug and start up, REM alarm, abnormal output and so on.

2.7 Return electrode interface



Monopolar cut or electro-coagulation requires the use of appropriate return electrodes, which have to be connected to the generator and be attached to the patient as well.

Important note

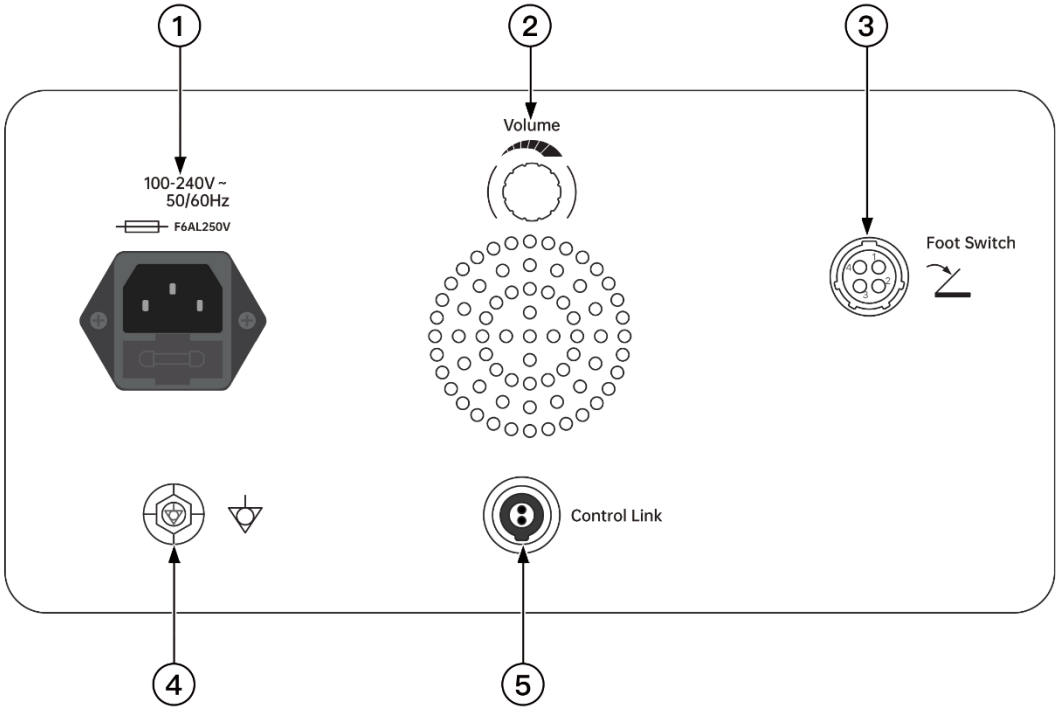
The generator is equipped with return electrode security system - the "return electrode detection function", which can automatically monitor the connection between the return electrode and the generator and the contact area on the patient.

Objects such as tweezers, metal needles are not allowed to insert into this output interface, which might lead to electric shock.

Note

This interface is limited to return electrode generator accessories that shall meet the requirements of part nine. The use of substandard accessories may result in the failure to plug and start up, REM alarm, abnormal output and so on.

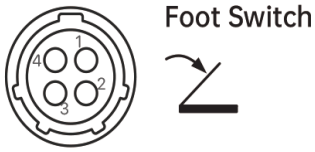
2.8 Back panel



①Power input module
②Audio frequency and volume knob
To control the volume of the sound signals. Turn clockwise to increase the volume and turn counterclockwise to decrease the volume.
③Foot switch socket
④Equipotential earth terminal
Connect the equipment to the ground.
⑤Interlink cable receptacle
for smoke-evacuation control

Warning
It is not allowed to mute the volume of the equipment, which may result in the failure for the surgical staff to notice the accidental start-up of the equipment or the REM alarm information.

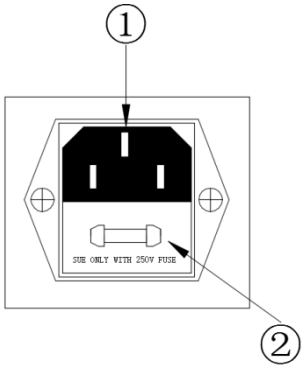
2.9 Foot switch socket



Monopolar and Bipolar foot switch socket
Use together with the monopolar foot switch.

Note
Foot switch socket belongs to generator accessory and it shall meet the requirements in part nine. The use of substandard accessories may result in the failure to plug and start up, REM alarm, abnormal output and so on.

2.10 Power input module



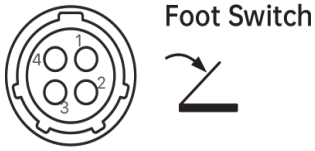
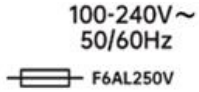
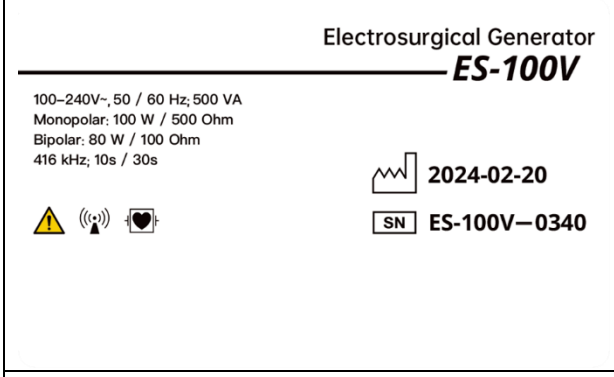
The power input module consists of the power line socket and the fuse (protective tube) drawer.
①Power line socket
Use together with the power line plug of the surgical generator.
②Fuse (protective tube) drawer
There are 2 tubular fuses in this drawer. Please refer to part seven for more information about disassembly,examination, maintenance and replacement.

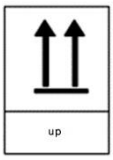
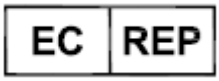
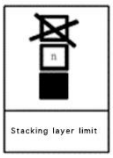
The use of power line that is not supplied by the manufacturer may result in electric shock and fire.

Caution
The use of fuse that is not supplied by the manufacturer may do damage to the product.

2.11 Figures and symbols

Figures and symbols	Description	Application
	Dangerous voltage	External marking
	Symbol for patients whose circuits are of high frequency insulation	External marking
	CF applied part/defibrillation-proof	External marking
	Attention! Please read the attached file	External marking, package marking
	Equipotential	External marking
	Non-ionizing radiation	External marking
	Recycling of waste electronic and electrical products	External marking
	Monopolar socket with manual switch	External marking
	Bipolar electrode socket	External marking
	Return electrode socket	External marking

	Monopolar and Bipolar foot switch socket	External marking
	Volume control	External marking
	Power input and fuse information	External marking
	Brand tag information	External marking
	There are fragile articles in the transport package. Please handle with care	Package marking
	The transport package should be kept out of the rain	Package marking
	The maximum weight that the transport package could bear	Package marking
	Do not roll the transport package during handling	Package marking

	The transport package should be kept straight up in transportation	Package marking
	Please refer to the manual for the use of the generator and precautions	Package marking
	Manufacturer	Package marking
	EU authorized representative	Package marking
	Manufacture Date	Package marking
	Consult instruction for use	Package marking
	Warning	Package marking
	The maximum number of layers that can be stacked for the same transport packages	Package marking
ES-100V	Specification and model of the surgical equipment	External marking
Monopolar	Monopolar output interface	External marking
Return Electrode	Return electrode interface	External marking
Power	Power	External marking

℞ Only	Must be purchased by prescription	External marking

Part three safety guidelines for the surgical generator

Contents of this part include:

Before using the Electrosurgical Generator, please have a careful reading of all the warnings,attentions and cautions, important tips and other notes in this surgical generator manual.

3.1 Overview of the safety guidelines

3.1.1 Training

Warning
1)Unqualified medical staff are not allowed to use this surgical generator, which may cause electric shock and burns to the patients and the medical staff. 2)Unqualified medical staff use this surgical generator may lead to death or serious injury. 3)Unqualified medical staff may cause damage to the surgical generator and the peripheral electronic generators. 4)Medical staff are supposed to read medical literature on topics of techniques, complications, and dangers before using the generator. 5)Patients with implantable cardiac pacemakers or other metal implants are the relative contraindications for this surgical generator and they should be treated with caution by the medical staff to avoid the high-frequency current flowing near the implants.

3.1.2 Fire and explosion

Warning
1) Danger of fire and explosion Medical staff should pay attention to the following substances which will increase the risk of fire and explosion during the surgery. a)Flammable organic solvent and solution (medical alcohol, tincture, etc.) b)Oxygen-enriched environment. Attention should be paid to the examination of the oxygen-enriched environment before and during the operation. To check if there is leakage at the oxygen tube connections and ensure that the room is not in an oxygen-enriched environment before performing the operation. c) To avoid the risk of fire, medical staff should pay attention to flammable substances such as oxidants in the operating room. 2)To avoid the risk of explosion, no flammable and combustible organic reagents (such as anesthetics) or other similar substances shall be stored in the electrosurgery operating room.

3.1.3 Maintenance

If there is any problem with the surgical generator, please contact the manufacturer for after-sales service and do not remove the shell without permission, in case it may lead to electric shock.

3.2 Pre-surgery guidelines

3.2.1 Accessories activation

Note

1)Accessories shall meet the requirements of the manufacturer to ensure the normal operation of the generator.
2)Before using the accessories, please check the manual for all warnings, attentions and cautions, important tips and notes related to the accessories. Meanwhile, please have a careful reading of the accessories product manual.
3)Accessories marked with "disposable" cannot be reused and they shall be handled in accordance with the "Medical Waste Regulations" and the local laws on the handling of the medical waste.
4)The generator carries out a eight-second self-examination when starting up, and a start-up test for the surgical electrode at this moment is not allowed because it may cause damage to the accessories or the generator.

1)To avoid the risk of the surgery, interfaces and wires of the accessories should be checked in advance to ensure that they are intact and in good condition, and then connect the host machine and make sure that their performances can meet the requirements. There will be no sparks, electric arcs and abnormal turning on and off for the testing electrode. Please set the output power to the minimum when testing the accessories.
2)Make sure that the accessories are in a dry condition to avoid electric shock.
3)Electrode is not allowed to touch the generator or other generator shells or metal objects when examining the accessories.
4)Any modification to the accessories is strictly prohibited.
5)Surgical generator failures may lead to an unexpected increase in the output power. In case of failure, the generator should stop working to avoid potential surgical risk.
6) Auxiliary generators and surgical accessories should adopt a rated voltage that is higher than or equal to the maximum output voltage of the surgical generator. Do not use setting when its maximum output voltage exceeds the rated voltage of the accessories.

3.2.2 Return electrode

Note

The selection of monitoring return electrode shall be performed in accordance with the related requirements in Part nine to ensure its

compatibility with the monitor of the generator. If compatible monitoring returen electrode is not adopted, REM alarm may be disabled when a safe contact is lost between the return electrode and the patient.

1)Return electrode compatible with the REM are recommended to ensure that sound and light alerting signals are available in the absence of safe contact between the return electrode and the patient. Please read the manual of return electrode in detail to understand the significance of the change in the number of the REM indicator lights. Meanwhile, the return electrode should be properly placed to avoid burns.
2)To prevent burns caused by return electrodes, proper use and placement of return electrode is necessary for the safe and effective use of the generator. The entire surface area of the return electrode should be securely attached to the patient's body and in complete contact with the skin tissue and as close to the surgical site as possible. Reducing the size of the return electrode plate will lead to burns caused by the increase in the electric current density and it is therefore strictly prohibited.
3)If only Bipolar is required, do not attach the return electrode plate, in case it may influence the surgical effect to tissues that require Bipolar surgical treatment.
4)REM will be disabled and send no sound and light altering signals, if non-REM return electrode plate is used.

3.2.3 Host machine of the surgical generator

Note

1)Do not stack the surgical generator with other surgical generators or other electrical generators.The vents at the rear or lower part of the generator must be kept clear, otherwise the generator cannot dissipate heat, and as a result of which the host machine will shut down for a short time.
2)If the electrotome smoking device and other electrical generators are operated at the same time with the surgical generator, please pay attention to the distance between them to ensure that the sound information of the surgical generator will not be blocked. Meanwhile, please check whether the surgical generator is interfered with or interferes with other generators. If there is interference, contact the manufacturer for after-sales service.
3) To avoid suspension of the operation because of surgical generator failure, a backup generator should be prepared in advance.

1)The host machine carries out a eight-second self-examination when starting up, and the sequence of the self-examination is monopolar electrosurgical excision controller, monopolar electro-coagulation controller, Bipolar controller and REM. After self-examination, if the failure indicator light and the indicator light of the electrode plate are not on,it means that it passes the self-examination.But if it fails to pass the self-examination, the output power will be inaccurate. In this case, the generator cannot be used.
2)The power plug is not allowed to insert into the adapter or the terminal block of poor contact, which may lead to electric shock.
3)Use power line that is supplied by the manufacturer. To replace it or change the length of it may cause fire and it is therefore strictly prohibited.
4)All kinds of interfaces of the host machine can not be modified or expanded, which may lead to electric shock.
5)Surgical generator failure will lead to an unexpected increase in input power. In case of failure, please use the backup generator immediately.

Caution

1)Whether the equipotential is connected to the hospital equalizer. Please follow the local regulations.
2)Please pay attention to the power supply parameters. Incorrect power supply access will lead to burnout of the product.

3.2.4 Others

Note

1)Patients should not be in contact with metal parts that are grounded or having obvious capacitance to ground. Anti-static materials should be adopted for this purpose.
2)Medical staff should wear surgical gloves to prevent users from contacting the return pathway.of the radio frequency energy.
3)As with other sources of energy, by-products such as tissue fumes and aerosols may have carcinogenic and infectious health problems. Appropriate protective measures, such as effective fume extractor, should be taken.

3.3 Guidelines for the ongoing surgery

3.3.1 Power settings

Note
For power settings, please refer to part four for more information. There is no coefficient ratio for the power set value of this surgical generator and the displayed value on the instrument is the set value. Be careful in increasing the power value.
1)Power settings must take place after the activation of the accessories. 2)To choose the lowest possible output power for the desired effect. For some devices or accessories, safety risks may occur at low power settings. 3)For Electrosurgical Generator that functions under normal operating settings, when the output is reduced or interrupted, it may be due to incorrect application of the return electrode or poor connector contact. Check the condition of the return electrodes and their connectors before selecting the high-frequency output power.

3.3.2 Bipolar tweezers

Caution
The Bipolar output cannot be started when the Bipolar tweezers has not yet touched the patient's tissue, or it will do damage to the generator.

3.3.3 Contact with metal objects

1)Activated electrodes are prohibited from contacting any metal objects, or it will cause serious surgical risks. 2)Patients should not contact metal objects that are grounded or have great capacitance to the ground, such as the operating table supports. Therefore, anti-static baffles are recommended. 3)There are risks for patients with implantable cardiac pacemakers or other metal implants, because it may interfere with or even damage the pacemaker. If there is any doubt, please give appropriate and effective advice.

3.3. 4 Activated accessories

1)The activated surgical electrode wires should be placed away from contact with the patient and other wires. Active electrodes that are not used for the moment should be stored in isolation from the patient.

2)Activated surgical electrode is not allowed to get close to combustible materials, which may cause fire.
3)Activated electrodes that are not used for the moment should be placed in the protective sheath or a place that is clean, dry, non-conductive, readily accessible and available, with no combustible materials and no contact with patients.
4)When the operating mode changes, the output of the active electrode may also change with it.
5)When the high-frequency currents can flow through relatively small sections of the body in the surgery, the use of Bipolar techniques can avoid unnecessary coagulation.
6)When Electrosurgical Generator and physiological monitoring generator are applied to a patient at the same time, monitoring electrode of any type should be kept away from the high-frequency electrode as far as possible. Needle-shaped monitoring electrode is not recommended. In all cases, a monitoring system with a high frequency current limiter is recommended.

3.3. 5 Return electrode

1)The entire surface area of the return electrode should be in full contact with the patient when performing operations with high power and long duration. To protect the patients from burns, please make sure that the return electrode is in close contact with the skin tissue, and pay attention to the REM light and sound alerting signals.
2)Under normal settings, if the output power of the surgical generator is significantly reduced, or the generator just does not function normally, it indicates that the return electrode has application failure or poor connection contact.
3)Ensure that the return electrode is closer to the patient healing area than the patient is to any reference contact point on the ground, such as the monitoring electrode.

3.3. 6 Others

1)Skin contact between doctors and patients should be avoided, and doctors are advised to use insulating gloves. It is also important for the patients to prevent skin-to-skin contact (e.g. between limbs), and insert dry gauze if necessary.
2)Neuromuscular stimulation can lead to risks, especially in the case of electric arcs between the active electrode and the tissue.
3) Please confirm that the expected set value is accurate before invoking the data.The group memory function can be used after

the confirmation.
4)If electrosurgery is performed on the posterior area of the chest, flammable anesthetics and oxidizing gases such as Nitrous Oxide (N_2O) and oxygen are prohibited, unless these reagent haven been removed (before the operation).
Use non-flammable reagents to clean and disinfect if possible.
The use of flammable reagents for cleaning and disinfection is also permitted, but these reagents have to be vaporized before the high-frequency surgery. There is a risk of accumulation of flammable reagents in the patient's body or in concave parts (such as the navel) and in cavities (such as the vagina). Remove any accumulated fluid before use. It is also important to be aware of the risk of gas ignition in the body. In an oxygen-rich environment, certain materials such as cotton, wool and gauze, can be ignited by sparks generated during normal operation of Electrosurgical Generator.

3.4 Post-surgery guidelines

Warning

1. After the operation, please turn off the power switch and unplug the power plug before cleaning the generator.
2. Accessories marked with "disposable" should not be sterilized for reuse.

Part four Preparation before the surgery

Contents of this part include:

Note
Please read the manual of the surgical generator and accessories for all the warnings,attentions and cautions, important tips and other notes.

Warning
Please have an extra set of generator for.electrosurgery.

4.1 Host machine preparation

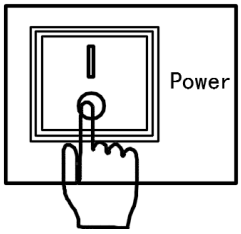
Important note
For more information about the host machine, please refer to part two.

Note
Please read the manual of the surgical generator and accessories for all the warnings,attentions and cautions, important tips and other notes.

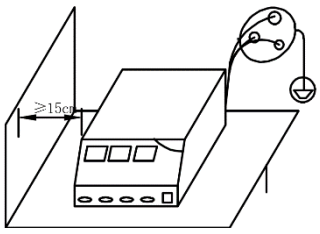
Before performing this step, please refer to 3.2 pre-surgery guidelines -- the host machine for more information, and follow the safety guidelines.

Caution
1)Whether the equipotential is connected to the hospital equalizer. Please follow the local regulations. 2)Please pay attention to the power supply parameters. Incorrect power supply access will lead to burnout of the product.

Self-examination of the surgical generator

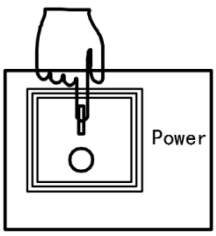


1. Switch to "○" to ensure that the power of the surgical generator is off;



2. Place the surgical generator on a firm surface and pay attention to the clearance around it. Generally, clearance around and on the top of it greater than 15cm is the best cooling clearance;

3.Insert the power line supplied by the manufacturer into the corresponding interface of the back panel, and plug into the socket with ground wire.



4. Switch to "|". Along with the sound prompt, the REM display screen, electrode plate indicator light, failure indicator light as well as the indicator light of the electrosurgical excision controller are all on, indicating that the power supply has been connected and the self-examination process has been entered.

5.The self-examination process is as follows. Please confirm whether the generator is working normally or not:

After connecting it to the power supply,

1) Self-examination of the electrosurgical excision controller:

When the sound prompts, 10 lights of REM display screen emit green light; indicator light of electrode plate and the failure indicator light emit red light; and indicator lights of electrosurgical excision controller all emit yellow light; the display screen shows "888". All these last for 2s and the lights of electro-coagulation controller and Bipolar controller shall be off, which indicates that it passes the self-examination of the electrosurgical excision controller.

2) Self-examination of the electro-coagulation controller:

When the self-examination of the electrosurgical excision controller is finished, the sound prompts again. 10 lights of REM display screen emit green light; indicator light of electrode plate and the failure indicator light emit red light; and indicator lights of electro-coagulation controller all emit blue light; the display screen shows "888". All these last for 2s and the lights of electrosurgical excision controller and Bipolar controller shall be off, which indicates that it passes the self-examination of the electro-coagulation controller.

3) Self-examination of the Bipolar controller:

When the self-examination of the electro-coagulation controller is finished, the sound prompts again. 10 lights of REM display screen emit green light; indicator light of electrode plate and the failure indicator light emit red light; and indicator lights of Bipolar controller all emit blue light; the display screen shows "888". All these last for 2s and the lights of electrosurgical excision controller and electro-coagulation controller shall be off, which indicates that it passes the self-examination of the Bipolar controller.

4) Return electrode monitor system (REM) controller

When the self-examination of the Bipolar controller is finished, the sound prompts again and the REM self-examination process has been entered. If the return electrode interface is not connected or connected but does not attach to the tissue, then it indicates that something goes wrong with the electrode plate. In this case, the indicator light of electrode plate should emit red light and give out two sound prompts.

5) Electrosurgical excision controller, electro-coagulation controller and Bipolar controller normally display a set of powers.The first power is preset by the manufacturer and the default is generally 1W. The recently used power could be automatically invoked later.

Important note
If it has passed the self-examination, then it indicates that the host machine is operating normally. Please refer to 4.2/4.3 for the preparation of the accessories.

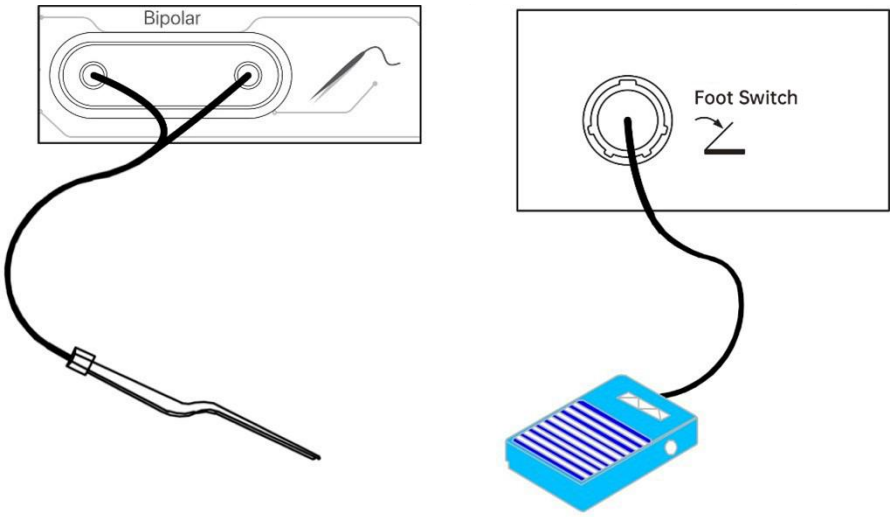
4.2 Bipolar surgical preparation

Important note
Bipolar surgical electrode of the surgical generator must be used together with Bipolar foot switch.

4.2.1 Connection of the Bipolar generator accessories

Note
Please read the manual of the surgical generator and accessories for all the warnings,attentions and cautions, important tips and other notes.

Warning
Before performing this step, please refer to 3.2 pre-surgery guidelines -- accessories activation for more information and follow the safety guidelines.



1. Connect Bipolar electrode plug to the "Bipolar" interface;
2. Connect the plug of foot switch to the corresponding interface(4-pin).

4.3 Monopolar surgical preparation

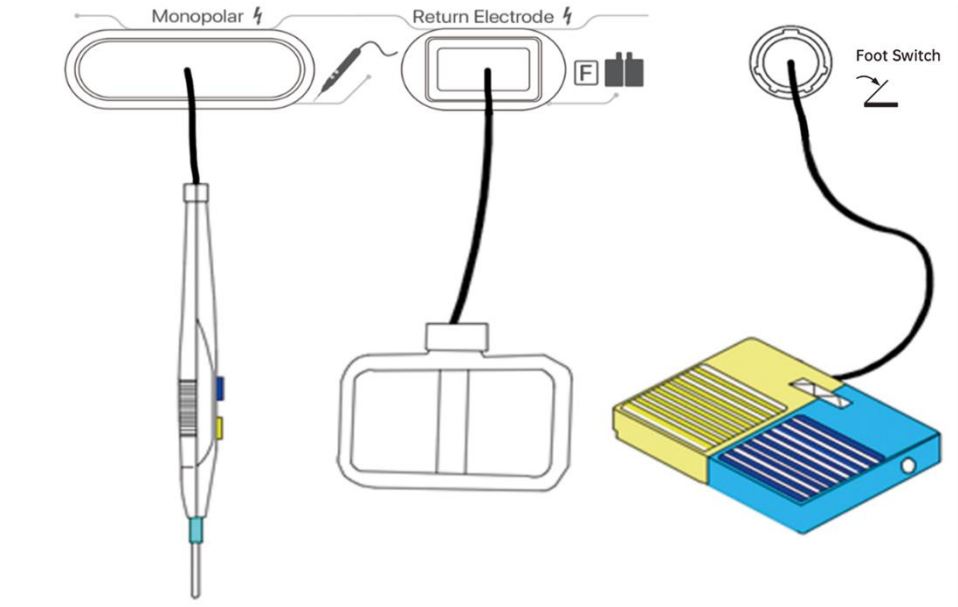
Important note
The monopolar surgical electrode of this surgical generator must be used together with the monopolar foot switch. You can also choose a monopolar surgical electrode with a manual switch.

Note
Please read the manual of the surgical generator and accessories for all the warnings,attentions and cautions, important tips and other notes.

Before performing this step, please refer to 3.2 pre-surgery guidelines -- accessories activation for more information and follow the safety guidelines.

Caution
When two monopolar handles are connected at the same time, they can output simultaneously, but the distribution of output power is related to the impedance of the distance between the two electrodes and the negative electrode plate. Attention should be paid to the position of the return electrode.

4.3.1 Connection of the monopolar generator accessories



1. Monopolar surgical accessory is connected to the "Monopolar" interface. The negative electrode plate is connected to the "Return Electrode" interface.
2. Connect the plug of foot switch to the corresponding interface(4-pin).

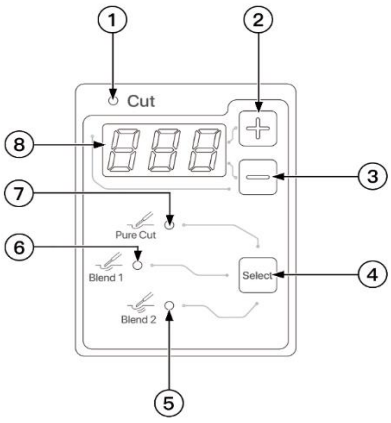
4.3.2 Attach the return electrode to the patient

Before performing this step, please refer to 3.2 pre-surgery guidelines -- return electrode for more information and follow the safety guidelines.

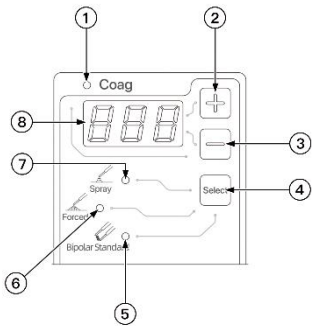
1.The entire surface area of the return electrode should be securely connected to the patient's body. The return electrode must be in full contact with the skin tissue.

2. When the return electrode is in full contact with the tissue, the REM controller will sound twice, and the indicator light of the electrode plate which is originally red should be off at the moment

4.3. 3 Monopolar output setting and testing



Monopolar electrosurgical excision controller (Please refer to 2.4 for more information)



Monopolar electro-coagulation controller (Please refer to 2.5 for more information)

Note

The output power should be set to the lowest value when testing the electrode.

4.3.3.1 Monopolar electrosurgical excision mode

1. Press the ④ "select" button to select the mode needed for the surgery. The corresponding light of the selected mode will emit yellow light.The corresponding modes of the indicator lights are as follows: pure cut-⑦, blend cut 1-⑥, blend cut 2-⑤;

2.Select a certain monopolar electrosurgical excision mode, and press down② to increase the power of the current selected mode.Long press on the button and the power will keep increasing. Press down ③ to reduce the power of the current selected mode. Long press on the button and the power will keep decreasing. Please refer to 2.4 for more information about the maximum power output. Select "pure cut", for example, and then the indicator light ⑦ will emit yellow light. The maximum power can be adjusted to 200W.

4.3.3.2 Monopolar electro-coagulation mode

1. Press the ④ "select" button to select the mode needed for the surgery. The corresponding light of the selected mode will emit blue light.The corresponding modes of the indicator lights are as follows: spray coagulation-⑦, forced coagulation-⑥ and Bipolar -⑤;

2.Select a certain monopolar electro-coagulation mode, and press down② to increase the power of the current selected mode.Long press on the button and the power will keep increasing. Press down ③ to reduce the power of the current selected mode. Long press on the button and the power will keep decreasing. Please refer to 2.5 for more information about the maximum power output.

Select "spray coagulation", for example, and then the indicator light ⑦ will emit blue light. The maximum power can be adjusted to 90W.

4.4 Parameter memory preparation

Automatic memory: the generator automatically memorizes the recently used mode and power, and the most recently used parameters can be invoked by default when starting up.

Important note
1. Automatic memory cannot be used when the surgical generator is first used or when the parameters change from the previous operation. This is because the automatic memory function can only be used after satisfying two conditions. First, it must be the parameters used last time. Second, the parameters of this operation must be exactly the same as the previous one. 2.The automatic memory function need not to be set and it can be completed automatically by the surgical generator itself.

Part five the ongoing surgery

Contents of this part include:

5.1 Check the connection of power and accessories
5.2 Check the connection of return electrode
5.3 Mode selection, power setting and power change
5.4 Surgical electrode activation
5.5 Indicator lights activation
5.6 Volume control
5.7 Response to the alarm information

Note
Please read the manual of the surgical generator and accessories for all the warnings,attentions and cautions, important tips and other notes.

1. Please have an extra set of generator for electrosurgery. 2. Surgical generator failure will lead to an unexpected increase in input power. In case of failure, please use the backup generator immediately. 3. Medical staff should follow the instructions strictly during the operation to avoid accidents.If the generator is used correctly, medical staff should take reasonable emergency measures immediately to deal with accidents caused by other uncontrollable factors. If the surgical generator goes wrong, backup generator can be used. If accident occurs to the staff, appropriate clinical emergency treatment should be taken immediately.

5.1 Check the connection of power supply and accessories

Before performing this step, please refer to 3.2 pre-surgery guidelines -- accessories activation for more information and follow the safety guidelines.

Before starting the surgical electrode, please check once again whether the power supply and accessories are connected normally.To reduce abnormal conditions, make sure that there is no crossing or twining between the accessory wires.

5.2 Check the connection of return electrode

Before performing this step, please refer to 3.2 pre-surgery guidelines -- return electrode for more information and follow the safety guidelines.

If monopolar mode is used, make sure the return electrode is normally connected before starting the surgical electrode.

5.3 Mode selection, power setting and power change

To prevent burns where return electrodes are used, the lowest possible output setting should be adopted to ensure proper treatment of the patient and/or to limit the duration of activation.

5.3.1 Mode selection and power setting

If no group memory preparation is made, the mode and power should be selected and set according to the description in 4.2 ~ 4.3.

5.3. 2 Power change

If the output power value needs to be changed in use, stop the surgical electrode and reset the value according to description in 4.2 ~ 4.3.

To avoid abnormal conditions during the operation, please stop the surgical electrode before making power changes.

5.4 Surgical electrode activation

5.4.1 Monopolar mode electrode activation

If the monopolar surgical electrode is equipped with a manual switch, it can be started with the manual switch or the monopolar foot switch. The corresponding relationship between the manual switch and foot switch buttons and the operating modes is as follows: yellow button-- electrosurgical excision mode, blue button-- electro-coagulation mode.

5.4. 2 Bipolar mode electrode activation

The surgical generator only supports the foot switch to start the Bipolar mode. Press the Bipolar foot switch to start the Bipolar mode.

5.5 Indicator lights activation

Mode	Manual control	Foot control	Indicator light activation
Monopolar electrosurgical excision	Press the yellow handle button	Step on the yellow monopolar pedal	The start-up tone could be heard and the relevant indicator lights of electrosurgical excision mode emit yellow light
Monopolar electro-coagulation	Press the blue handle button	Step on the blue monopolar pedal	The start-up tone could be heard and the relevant indicator lights of electro-coagulation mode emit blue light
Bipolar	/	Step on the Bipolar pedal	The start-up tone could be heard and the relevant indicator lights of Bipolar mode emit blue light

5.6 Volume control

It is not allowed to mute the volume of the generator, which may result in the failure for the surgical staff to notice the accidental start-up of the generator or the REM alarm information.

To control the volume of the sound signals. Turn clockwise to increase the volume and turn counterclockwise to decrease the volume.

5.7 Response to the alarm information

Important note
After the self-examination is completed, REM self-examination will give out two sound prompts of "beep", and the indicator light of the electrode plate will emit red light, which is a normal phenomenon and it indicates that the return electrode is not connected with the tissue.

5.7.1 REM sound and light alerting signals

When the return electrode is fully connected to the tissue and conform to the preset in 4.3.2, the electrode plate indicator light of REM controller should be off at the moment and the green bar of REM display screen should be full, indicating that the monopolar mode allows output at this time. If something goes wrong, the electrode plate indicator light of REM controller will emit red light and give out two sound prompts of "beep" at the same time.

The sound and light alerting signals will be prompted by the following situations

1. The surgical generator is not connected with the return electrode during the surgery;
2. The contact area between the return electrode and tissue decrease or in poor contact during the surgery;
3. Line fault of the return electrode results in the resistance exceeding 150Ω during the surgery.

5.7.2 Non-REM return electrode

REM altering signals will be disabled if non-REM return electrodes are used.

5.7.3 Error code

In the process of self-examination and using of the generator, if the cutting area displays "ERR", and the coagulation area displays digital code, then it indicates that something goes wrong with the generator. Please refer to 7.2 common error code for more information.

5.7.4 Fault alarm

If there is any indication of the failure of the surgical generator, please use the backup generator and check the generator once again after the surgery.

Part six Post-surgery

Contents of this part include:

6.1 Prepare for the next use

6.2 Storage of the surgical generator

Note
Please read the manual of the surgical generator and accessories for all the warnings,attentions and cautions, important tips and other notes.

6.1 Prepare for the next use

Note

Accessories marked with "disposable" cannot be reused and they shall be handled in accordance with the "Medical Waste Regulations" and the local laws on the handling of the medical waste.

Note

When cleaning the surgical generator, liquid should be kept away from flowing into the inside of the generator.

1. To avoid the danger of electric shock, please ensure that the power plug has been unplugged before removing the accessories of surgical generator.
2. For reusable accessories, it is important to pay attention to the methods of cleaning, disinfection, packaging and sterilization and the number of times for repeated use and other restrictions, and they should be used in strict accordance with the instructions.

6.1.1 Remove the accessories

1. Turn off the surgical generator: press the power switch "O" and unplug the power plug;
2. If return electrodes are attached to the tissues of patient, first remove the return electrodes, and then remove all accessories from the host machine;
Accessories marked with "disposable"shall be handled in accordance with the "Medical Waste Regulations" and the local laws on the handling of the medical waste;
For reusable accessories, they should be cleaned and disinfected according to the manufacturer's instructions.
3. Remove foot switch and put it away.

6.1.2 Cleaning

1. Please ensure that the power plug of the surgical generator has been unplugged before cleaning;
2.When cleaning and disinfecting the generator, only incombustible reagents and wet cloth can be used to scrub the surface of surgical generator and the power line;
3. The foot switch is waterproof and it can be cleaned and disinfected with water or 75% alcohol.

6.2 Storage of the surgical generator

The non-operating temperature for this surgical generator is 5℃ ~ 40℃. If the storage environment does not meet the requirement of the non-operating temperature, it shall be stored at room temperature for more than 1h before use. If the surgical generator has been stored for more than 1 year, it should be examined by a professional electrician before use. Please refer to 8.1 for details.

Part seven Fault analysis and troubleshooting

Contents of this part include:

Important note
If the cause of failure is not identified through the troubleshooting method in this manual, please contact the manufacturer for after-sales guidance, and return the defective products to the factory for troubleshooting and maintenance if necessary.

Warning
For generator failure that needs to be solved by the manufacturer, please contact the manufacturer for after-sales service and do not disassemble the machine without permission, which may lead to electric shock.

7.1 Fault analysis and troubleshooting

Phenomenon	Analysis	Troubleshooting
When the switch is turned on, the indicator light is off.	1) 100-240V 50/60HZ power is unplugged; 2)Loose plug.	1)To check whether the power supply is normal; 2)Replug.
Sudden outage during testing or use	1)Power cut in the operating room; 2)Loose plug.	1)Use emergency power supply; 2)Replug.
When the switch is turned on, the indicator light goes on and off.	1)Loose plug; 2)The circuit from the power line to the switch is damaged.	1)Replug; 2) Please contact the manufacturer for after-sales service.
When the switch is turned on, the indicator light is off and abnormal noise could be heard from power line connection of the generator.	The fuse is burnt out	Replace the fuse according to the description in 8.2.
Electrode boot failure	1)Circuit failure of electrode accessories; 2)Damaged manual switch and foot switch; 3) Host program or motherboard or other damage.	1)Replace electrode accessories; 2)Replace the electrode accessories or foot switch; 3)Please contact the manufacturer for after-sales service.
The electrode can be started, but with no output	1)The output power is set too low; 2)Damaged electrode accessories or foot switch; 3)REM has alarm information; 4)Host program or motherboard or other damage.	1)To check the output power setting and restart after resetting; 2)Replace the electrode accessories or foot switch; 3)To check whether the return electrode is in full contact with the tissue. If not, please make sure that the two are fully attached and then restart for test. If REM alerting signals keeps prompting, please replace the return electrode and test again; 4) Please contact the manufacturer for after-sales service.
Interference failures	1)Power supply grounding failures; 2)There are interfering electrical generators in the surgical generator accessories.	1)Check the power supply grounding for maintenance; 2)If possible, turn off the electrical generator and keep them away from the surgical generator. If it must be used and

		attached to the surgical generator, please contact the manufacturers of both sides to solve the problem.

7.2 Common error code

Error code (ERR)	Description	Troubleshooting
0～7	Micro-controller failure	Please contact the manufacturer for after-sales service.
8	Software failure	Restart and see if it is working normally. If the problem is not solved, please contact the manufacturer for after-sales service.
9	The manual or the foot switch of electrosurgical excision may get stuck	Remove the manual switch or the foot switch and restart. If the problem is solved, it means that the manual switch or the foot switch is damaged. If the problem is not solved, please contact the manufacturer for after-sales service.
10	The manual or the foot switch of electro-coagulation may get stuck	Remove the manual switch or the foot switch and restart. If the problem is solved, it means that the manual switch or the foot switch is damaged. If the problem is not solved, please contact the manufacturer for after-sales service.
11	Panel buttons may get stuck	Please contact the manufacturer for after-sales service.
12	No high-frequency output	Please contact the manufacturer for after-sales service.
13	Power failure	Please contact the manufacturer for after-sales service.
14	Dose failure	Please contact the manufacturer for after-sales service.

The display screen in the electrosurgical excision mode shows "ERR"; The display screen in the electro-coagulation mode shows "code"

Part eight Maintenance and repair

Contents of this part include:

Description
Disassemble the machine or replace the accessories without the authorization of the manufacturer. In this case, the manufacturer shall not be responsible for warranty and the resulting consequences.

Warning
Without the authorization of the manufacturer, it is not allowed to disassemble the machine, which may affect the warranty service and have the risk of electric shock.

8.1 Care and maintenance

Warning
1. Surgical generator repairman must be experienced electricians or senior electronic engineers who have been trained in the Electrosurgical Generator. Non-professional workers are allowed to examine and repair the generator. 2. If defects that may endanger patients, employees or the third parties are found during the safety check, the generator can only continue to be used after these defects are eliminated by professional technical maintenance workers.

8.1.1Check frequency and check items of the surgical generator

Frequency: ≥1/year

Items:

Label and manual;

Check with naked eyes whether the generator and accessories are damaged or not;

Check the electrical safety performance according to standard EN60601-1:2006+A1:2013+A2:2021 and EN60601-2-2:2018;

Check the grounding conductor;

Check electric leakage;

Performance test of all the switches and controller indicator lights of the generator;

Check the monitoring device;

Measure the power output of the electrosurgical excision mode;

Measure the power output of electro-coagulation mode.

All the results must be included in the medical products profile.

8.1.2 Check the power line, electrode wire and foot switch wire

Check the power line, electrode and connection cable before use to see whether there is cracking, wearing and aging of the cable. If found, replace it immediately.

8.1.3 Fuse replacement

Replace the fuse when it is burnt out based on the description in part 7 fault analysis and troubleshooting. Refer to 8.2 for more details about the replacement.

8.1.4 Cleaning and disinfection of the product and accessories

Refer to 6.1 prepare for the next use.

8.2 Repair

8.2.1 Accessories replacement

Description
Contact the manufacturer for after-sales service when the foot switch or reusable surgical electrode is damaged.

Note
Use or replace the fuse and power line that is supplied by the manufacturer.

1. For fuse replacement:
The fuse is installed on the back panel of the host machine and integrated with the power socket. Unplug the power line and gently pull the fuse installation part with your hand or small screwdriver. Pull out the fuse box and replace it. Insert the replaced fuse into the fuse installation part in parallel to the center of the fuse box. The replacement is then completed. After the replacement, connect the power line and start the machine. Check whether the indicator lights on the front panel are working normally. If so, the replacement is successful. If not, please unplug the power line and check whether the installation is successful. If it is properly installed, but it still cannot be powered on after repeatedly starting the machine, please contact the manufacturer for after-sales service.
2. For power line replacement:
Please contact the manufacturer to replace the power line.
3. Others
Replacement of other accessories is more complex. Please contact the after-sales service center.

8.2.2 Depot Repair

1. Warranty Statement
Normally, if you do not purchase our warranty service, the default warranty period of the product is 1 year from the date of purchase. Expense may be incurred for the maintenance and repair when the warranty expires.
The following conditions are not covered by the warranty:
1) Appearance damage after use for a period of time;
2) Improper storage and maintenance; water, oil and other abnormal conditions;
3) Drop and broke the generator; damage caused by connecting to improper power supply;
4)Dissemble the machine without the authorization of the company;
5)The warranty card is lost.
2. Depot Repair
a) First of all, please contact the after-sales service center by phone

or other means to confirm the hospital department information, product information and product failure information with the after-sales service center. When troubleshooting is possible, it saves time and economic cost for both parties to adopt the way of non-return-to-depot;
b) For products needed to be returned to the factory for maintenance after confirming with the after-sales service center, please pack and transport the product to the factory according to the requirements of transportation in part 9;
c) If the original packaging of the surgical generator is damaged, please use other packaging materials and ship the product with the approval of the after-sales service center;
d) Please ship the product after paying the freight.

8.3 Scrapping of the generators and accessories

The scrapping of the surgical generator and related accessories should be handled in accordance with the "Medical Waste Regulations" and the local laws on the handling of the medical waste and electronic generators!

8.4 After-sales service center

Part nine Technical features

Contents of this part include:

9.1 Performance features

9.1.1 Appearance

1.The appearance should be neat and with uniform color, and no obvious scratches, damage and deformation.
2.The words and markings should be clear.
3. The control mechanism should be safe and reliable with no loose fasteners

9.1.2 Performance

1.Maximum power output
The maximum power output of the product in each output mode is shown in the table below, and the error range is not more than ±20%.
2. Modulation frequency
The modulation frequency of the product in each output mode is shown in the following table, and the error range shall not be greater than ±10%.
3. Maximum output voltage
The maximum output voltage of the product in each output mode shall not be greater than the maximum output voltage shown in the following table.
4. Peak factor
The peak factors of the product in each output are shown in the table below, and the error range is not more than ±20%.

Mode			Maximum output Power (W)	Load Impedance (Ω)	Modulation frequency （kHz）	Maximum output Voltage (V)	Peak Factor
Monopolar Mode	Eectrosurgical excision Mode	Pure cut	100	500	——	1200	1.8
		Blend cut 1	100	500	20	1300	2.0
		Blend cut 2	100	500	20	1200	2.0
	Electro-coagulation Mode	Spray-coagulation	90	500	12-24	4800	6.3
		Forced coagulation	60	500	25	4800	6.2
Bipolar		Standard	60	100	20	700	700

9.1.3 Frequency

The frequency of each model and mode is 416kHz, and the error range should not exceed ±10%.

9.1.4 Alarm information

When using monitoring return electrode (return electrode monitoring circuit is the REM test), the resistance of the contact area is greater than or equal to 150 Ω, and the generator will give out sound and light alerting signals.

9.1.5 Security features

1. Classified by type of the electric shock protection: typeI
2.Classify by the degree of protection against electric shock: CF applied part
3.Classify by the degree of protection against harmful liquid intake: common generator that does not prevent liquid intake
4.Classified by the degree of safety for use in the case of flammable anesthetic gas mixed with air or oxygen or flammable anesthetic gas mixed with nitrous oxide: generator cannot be used in the presence of flammable anesthetic gas mixed with air or oxygen or flammable anesthetic gas mixed with nitrous oxide
5. Classified by mode of operation: continuous operation with intermittent loading
6.Rated voltage and frequency of the generator: 100-240V~, 50/60Hz
7.Input power of the generator: 500VA
8. Whether the generator has protection against the defibrillation and discharge effect: Yes
9. Whether the generator has signal output and input: no
10. Permanently installed generator or non-permanently installed generator: non-permanently installed generator

9.1.6 Fuse

Fuse specification: F6AL250V

9.1.7 Surgical accessories

Surgical accessories should satisfy the requirements of medical generator regulations and standards. The following requirements should also be satisfied:

Name	Requirements	Recommendations
Monopolar electrode	1)Interface: 4mm 3 pins 2)The line length shall meet the relevant technical requirements	Contact the manufacturer for after-sale service
Bipolar electrode	1)Interface: 4mm 2 pins 2)Tweezers size and line length shall meet relevant technical requirements	
Return electrode	1)Interface: REM plug 2) Size and line length shall meet relevant technical requirements	
Monopolar and Bipolar foot switches	1)Interface: Monopolar-4 pins, Bipolar-3pins 2)The line length shall meet the relevant technical requirements	

9.1.8 Packaging

1. Size

Length × width × height: 520×480×380 (mm)

2. Gross weight

10（kg）

3. Packing list

Number	Name	Unit	Quantity	Remarks
1	Host machine	Piece	1	
2	Power line	Piece	1	
3	Certificate of soundness	Copy	1	
4	Warranty card	Copy	1	
5	Product manual	Copy	1	
6	Fuse tube	Piece	2	
7	Packing list	Copy	1	
8	Hand-held electrosurgical pencil	Piece	1	
9	Monopolar electrode	Piece	1	
10	Hand-held tweezers line	Set	1	
11	Tweezers	Piece	1	
12	Negative electrode plate cable	Set	1	
13	Negative electrode plate	Piece	1	
14	Monopolar foot switch	Set	1	

Important note
After receiving the generator, please check whether the contents in the box are complete according to the list. If not, please contact the after-sales service center. Please take good care of the accessories in the box, or it will affect the fuse replacement and warranty service of the generator.

9.1.9 Storage and transportation

1. Conditions for storage and transportation

Ambient temperature: 5℃ ~ 40℃

Relative humidity: no more than 80%

Atmospheric pressure: 700hPa ~ 1060hPa

2. Methods of storage and transportation

Storage and transportation shall be conducted in accordance with the symbols and markings of the packaging box.

9.2 Available power value

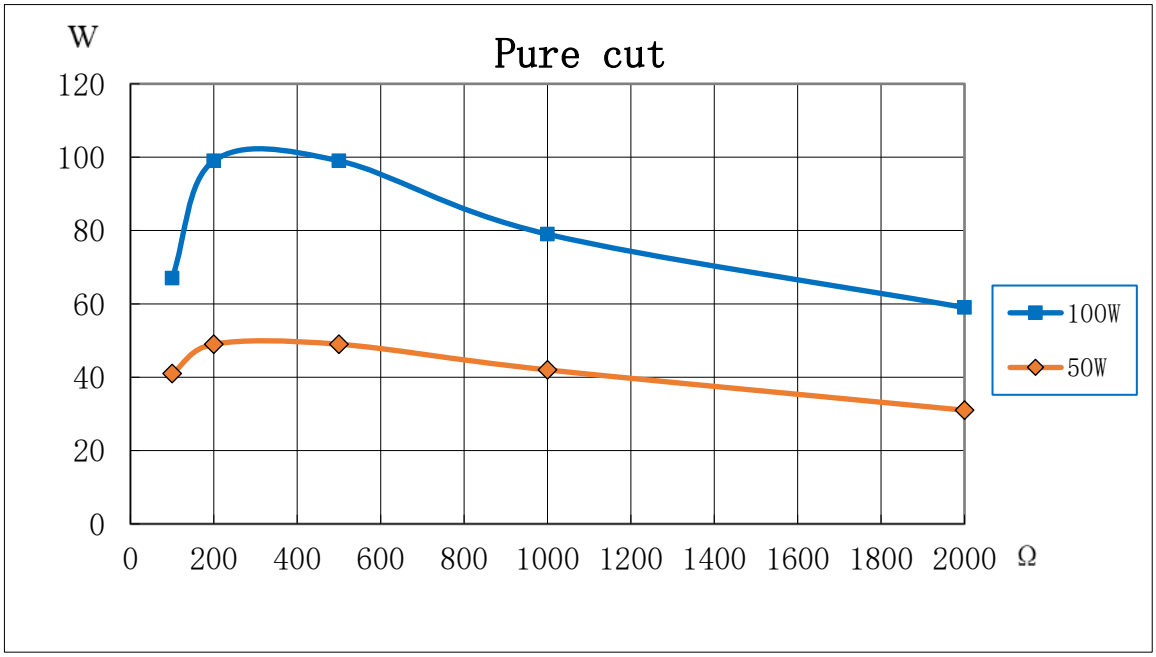
	Available power value (W)									
Monopolar electrosurgical excision: pure cut	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
	31	32	33	34	35	36	37	38	39	40
	41	42	43	44	45	46	47	48	49	50
	51	52	53	54	55	56	57	58	59	60
	61	62	63	64	65	66	67	68	69	70
	71	72	73	74	75	76	77	78	79	80
	81	82	83	84	85	86	87	88	89	90
	91	92	93	94	95	96	97	98	99	100
Monopolar electrosurgical excision: blend cut 1	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
	31	32	33	34	35	36	37	38	39	40
	41	42	43	44	45	46	47	48	49	50
	51	52	53	54	55	56	57	58	59	60
	61	62	63	64	65	66	67	68	69	70
	71	72	73	74	75	76	77	78	79	80
	81	82	83	84	85	86	87	88	89	90
	91	92	93	94	95	96	97	98	99	100
Monopolar electrosurgical excision: blend cut 2	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
	31	32	33	34	35	36	37	38	39	40
	41	42	43	44	45	46	47	48	49	50
	51	52	53	54	55	56	57	58	59	60
	61	62	63	64	65	66	67	68	69	70
	71	72	73	74	75	76	77	78	79	80
	81	82	83	84	85	86	87	88	89	90
	91	92	93	94	95	96	97	98	99	100
Monopolar electro-coagulation: Spray coagulation	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
	31	32	33	34	35	36	37	38	39	40
	41	42	43	44	45	46	47	48	49	50
	51	52	53	54	55	56	57	58	59	60
	61	62	63	64	65	66	67	68	69	70
	71	72	73	74	75	76	77	78	79	80

	Available power value (W)									
	81	82	83	84	85	86	87	88	89	90
Monopolar electro-coagulation: forced coagulation	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
	31	32	33	34	35	36	37	38	39	40
	41	42	43	44	45	46	47	48	49	50
	51	52	53	54	55	56	57	58	59	60
Bipolar: standard mode	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
	31	32	33	34	35	36	37	38	39	40
	41	42	43	44	45	46	47	48	49	50
	51	52	53	54	55	56	57	58	59	60

9.3 Curve graph of output power to the resistance

9.3.1 Monopolar pure cut

Functional relationship between power output and load impedance at full and half power.

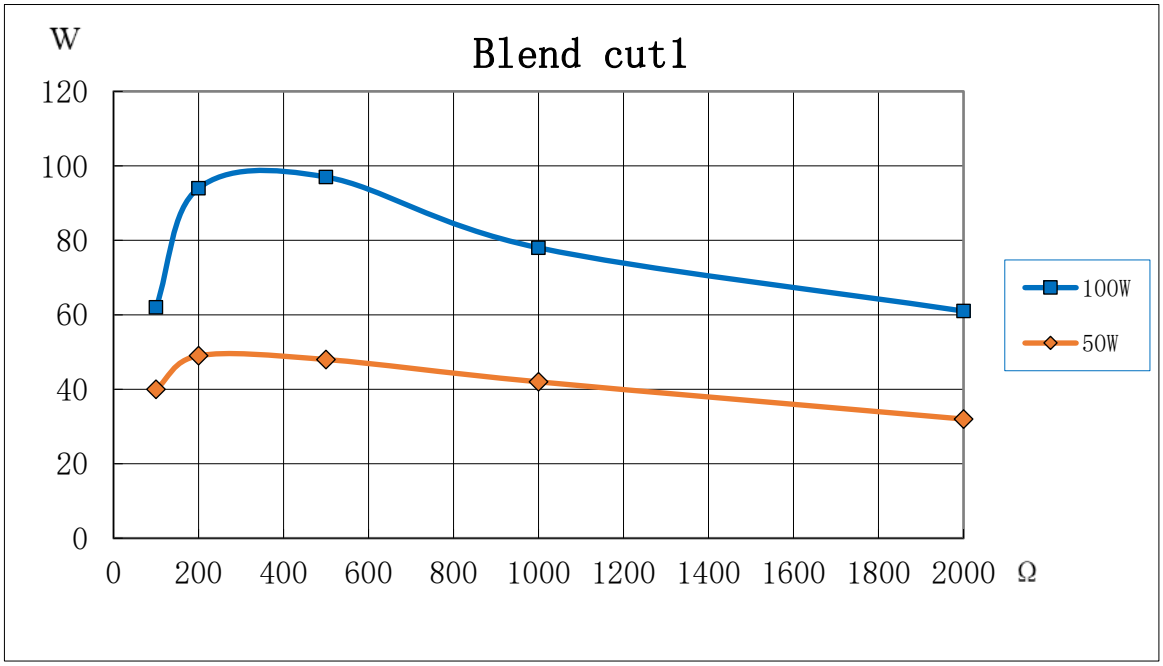


X: impedance (Ω), y: power (W)

full power, half power

9.3.2 Monopolar blend cut 1

Functional relationship between power output and load impedance at full and half power.

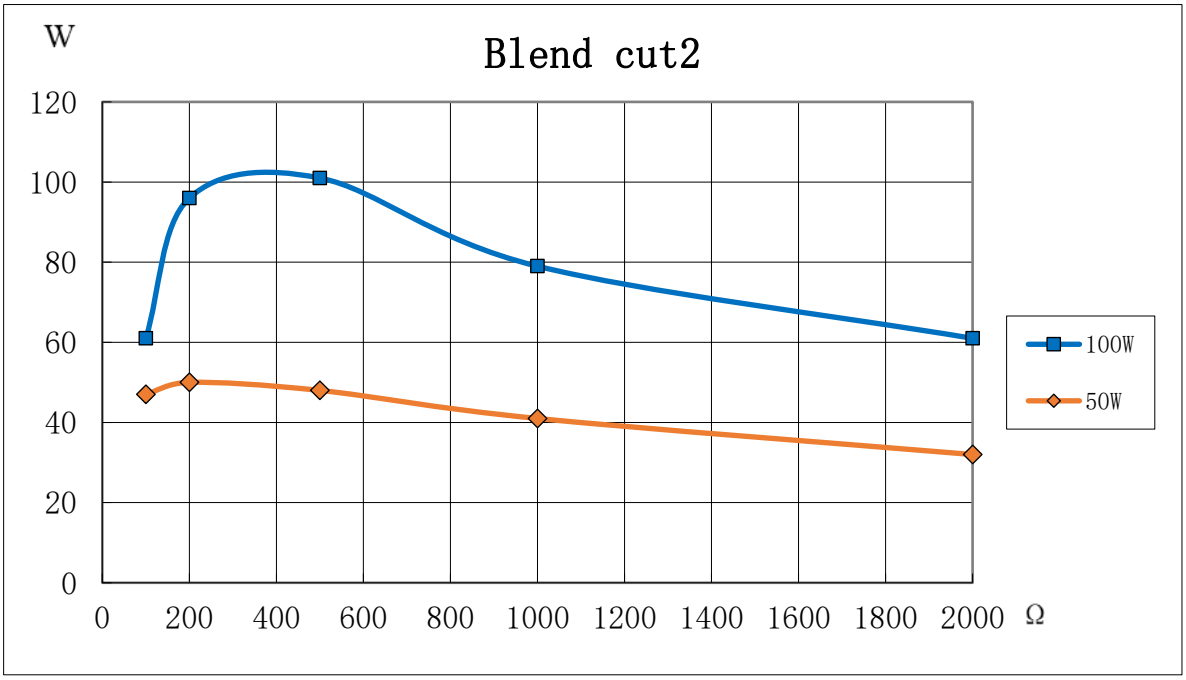


X: impedance (Ω), y: power (W)

full power, half power

9.3.3 Monopolar blend cut 2

Functional relationship between power output and load impedance at full and half power.

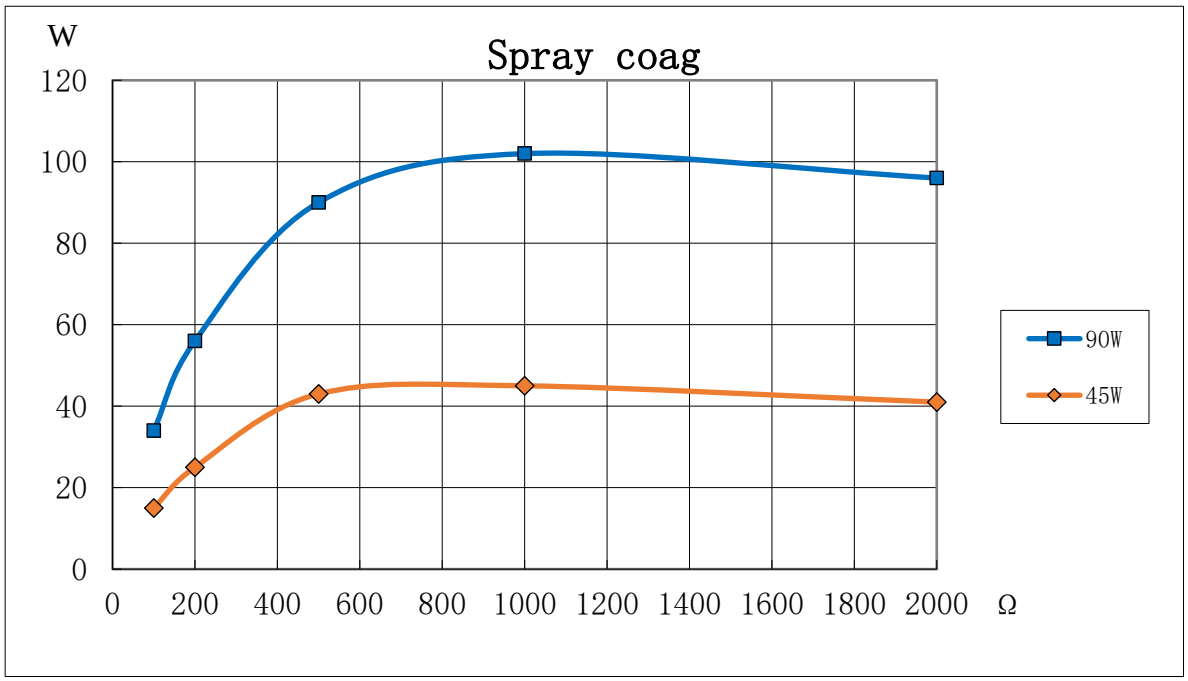


X: impedance (Ω), y: power (W)

full power, half power

9.3. 4 Monopolar spray coagulation

Functional relationship between power output and load impedance at full and half power.

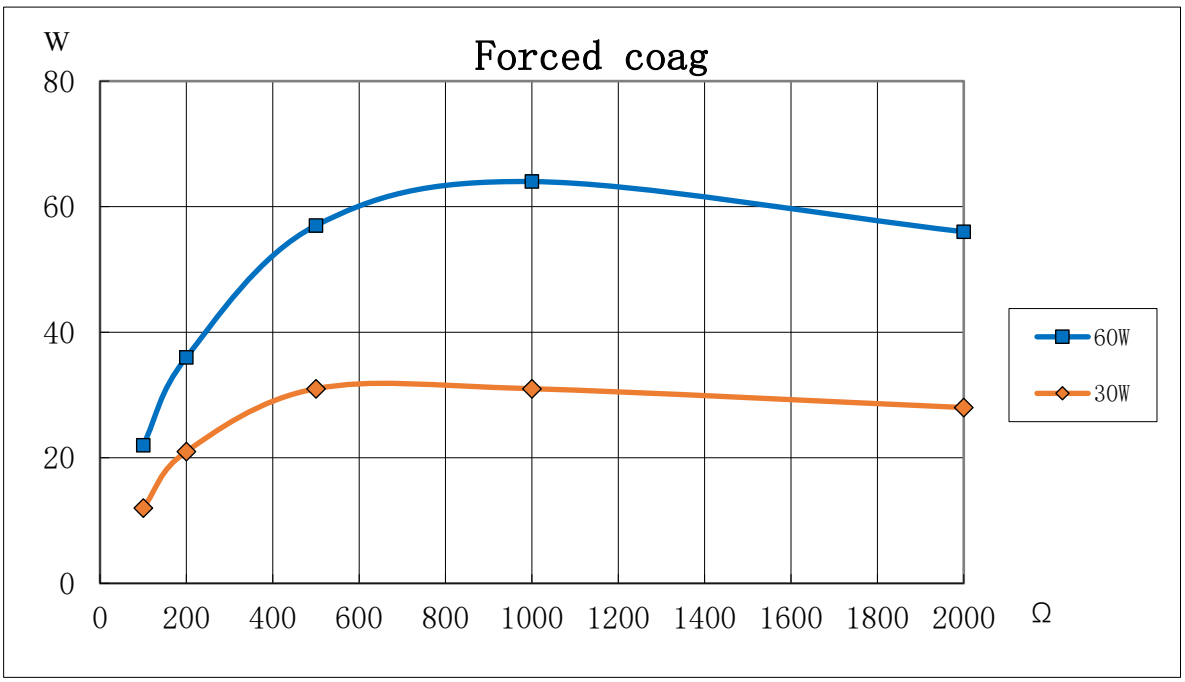


X: impedance (Ω), y: power (W)

full power, half power

9.3. 5 Monopolar forced coagulation

Functional relationship between power output and load impedance at full and half power.

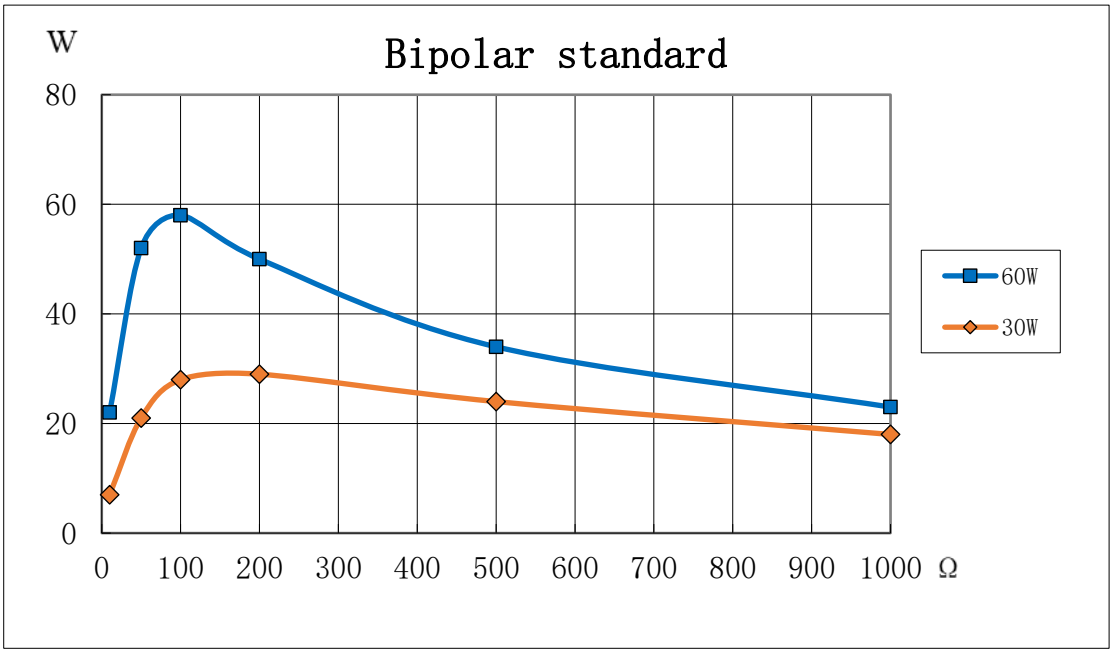


X: impedance (Ω), y: power (W)

full power, half power

9.3. 6 Bipolar standard mode

Functional relationship between power output and load impedance at full and half power.



X: impedance (Ω), y: power (W)

full power, half power

Part ten Electromagnetic compatibility

Contents of this part include:

The information in this section, such as the isolation distance, is general information specifically designed for this product model. The content provided, while not ensuring trouble-free operation of the generator, provides such reasonable assurance. This information may not be applicable to other medical electrical generators; Aging generators may be particularly vulnerable to interference.

Warning
The generator/system is intended for use by medical professionals only. The generator/system may cause radio interference or may interrupt the operation of nearby generators. Supplementary measures may be necessary, such as readjusting or resetting the direction or shielding sites of the generator.

Precautions

1. Interference from the generator may adversely affect the operation of other electrical generators. In case of interference, the unit should use a separate socket or be placed in another room.
2. Medical electrical generator requires special precautions regarding electromagnetic compatibility (EMC), and shall be installed and put into use according to the EMC information provided in this document and the product manual of the other parts of the generator.
3. Portable and mobile radio frequency communication generators will affect the operation of the medical electrical generators.
4. Do not use power lines and accessories other than those specified in the manual. The use of other power lines and or accessories may adversely affect the safety, performance and electromagnetic compatibility of the generator (with increased electromagnetic emission and reduced immunity).
5.Care should be taken if the generator is located near or stacked with other generators; If this is inevitable, observe the generator to ensure that it is working normally.

Warning: Don't near active HF surgical generator and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this generator adjacent to or stacked with other generator should be avoided because it could result in improper operation. If such use is necessary, this generator and the other generator should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this generator could result in increased electromagnetic emissions or decreased electromagnetic immunity of this generator and result in improper operation."

Warning： Portable RF communications generator (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the generator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this generator could result.

Note： The emissions characteristics of this generator make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this generator might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the generator.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
Electrostatic discharge (ESD)	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

IEC 61000-4-2	air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz

	80 % AM at 1 kHz	80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications generator)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710 745	704 – 787	LTE Band 13,	Pulse modulation	0,2	0.3	9

	780		17	217 Hz			
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28

	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

Table 4: recommended safe distance

Recommended isolation distance between portable and mobile radio-frequency communication generators and the High frequency surgical generator			
High frequency surgical generators are intended for use in electromagnetic environment with the radio-frequency interferences controlled. Based on the maximum power output of the communication generator, the purchaser or user of the Electrosurgical Generator may prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication generator < transmitter > and the Electrosurgical Generator as recommended below			
Rated power of the transmitter （W）	Safe distance (m) based on the power of the transmitter		
	150 k Hz – 80 MHz $d=1.2\sqrt{P}$	80 MHz – 800 MHz $d=1.2\sqrt{P}$	800 MHz – 2.5 GHz $d=2.3\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the maximum power output of transmitters not listed in the above table, d is the recommended isolation distance and the unit is in meters (m).The formula of transmitter frequency in the corresponding column can be used. P is the maximum rated output power of the transmitter provided by the transmitter manufacturer and the unit is in watts (W). Note 1: At 80 MHz and 800 MHz, formulas for higher frequency bands should be used. Note 2: these guidelines may not apply to all cases. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.			

Warning

1.In addition to the transducers and cables sold by the manufacturer of the generator or system as spare parts for internal components, the use of non-specified accessories, transducers and cables can result in increased emission or reduced immunity of the generator or system.
The following type of cable must be used to ensure compliance with the standards of disturbing radiation and immunity to interference:

Cable	Length (m)
Power line	1.9
Double-feet switch cable	3.0
One-foot switch cable	2.8

2. The generator or system shall not be used close to or stacked with other generators. If this is inevitable, observe the generator to ensure that it is working normally.
3. Active medical generators should follow the special EMC precautions and therefore they must be installed and used in accordance with these guidelines.
4. Portable and mobile radio frequency communication generators will affect the operation of the medical electrical generators.
Basic performance description: in monopolar electrosurgical excision mode, monopolar electrode-coagulation mode and Bipolar mode, the set value of the generator is the actual output power, and the maximum RF output value shall not exceed ±20% of the set value.

Exceptional situations

Increase the number of generators intended to use radio-frequency energy for diagnostic or therapeutic purposes:
Guidelines for avoiding, identifying and resolving harmful electromagnetic effects on other generator caused by the use of the generator.

Warning

The generator or system may be interfered with by other generators even if they meets the standards of emission.

ES-100V