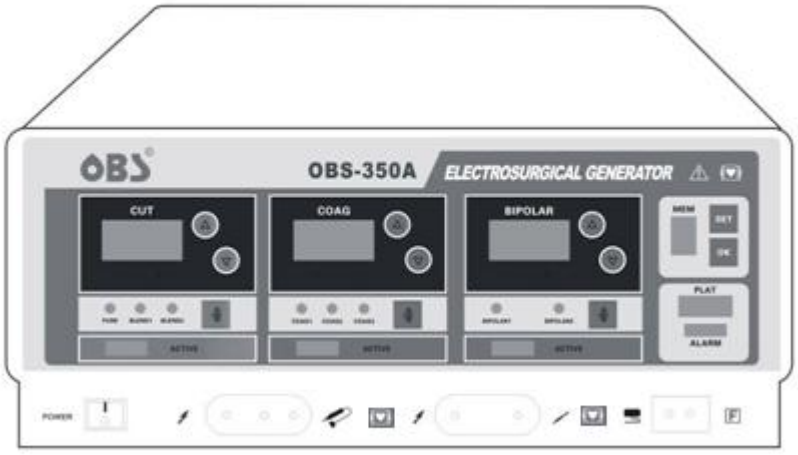
Electrosurgical Generator – Model OBS-350A

Instruction for Use

Revision: 20181018OBS350A



Electrosurgical generator

BAISHENG MEDICAL CO., LTD.

Read the contents described in this page carefully when initial use

- Welcome to use Electrosurgical Generator– Model OBS-350A

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the OBS-350A only.

Notice: Power supply should be cut off before opening the enclosure of this machine.

Equipment Covered in this Manual
Electrosurgical generator: OBS-350A
Reference No.: 2016OBS350A

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CONVENTIONS USED IN THIS GUIDE

WARNING
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION
Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE
Indicates an operating tip, a maintenance suggestion, or a hazard that may result in product damage.

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SECTION one

Introducing the OBS-350A

Indication for use

The Electrosurgical Generator (OBS-350A) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the surgical operation area.

SAFETY

The safe and effective use of electrosurgery depends to a large degree on factors solely under the control of the operator. There is no substitute for a properly trained and vigilant medical staff. It is important that they read, understand, and follow the operating instructions supplied with this electrosurgical equipment.

Physicians have used electrosurgical equipment safely in numerous procedures. Before starting any surgical procedure, the surgeon should be familiar with the medical literature, complications, and hazards of using electrosurgery in that procedure.

To promote the safe use of the OBS-350A, this section presents the warnings and cautions that appear throughout this user's guide. It is important that you read, understand, and follow the instructions in these warnings and cautions so that you can operate this equipment with maximum safety. It is also important that you read, understand, and follow the instructions for use in this user's guide.

WARNINGS:

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the OBS-350A Electrosurgical Generator only.

Hazardous Electrical Output - This equipment is for use only by trained, licensed physicians.

Danger: Fire / Explosion Hazard - Do not use the OBS-350A in the presence of flammable materials.

Fire / Explosion Hazard - The following substances will contribute to increase fire and explosion hazards in the operating room:

• Flammable substances (such as alcohol based skin prepping agents and tinctures)

• Naturally occurring flammable gases which may accumulate in body cavities such as the bowel

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Do not position me equipment to make it difficult to operate the disconnection device.

• Oxygen enriched atmospheres

• Oxidizing agents (such as nitrous oxide [N_20] atmospheres).

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

Electric Shock Hazard - Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

Electric Shock Hazard - Always turn off and unplug the generator before cleaning.

Fire Hazard - Do not use extension cords.

Patient Safety - Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.

The instrument receptacles on this generator are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow, and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

WARNINGS:

Use electrosurgery with caution in the presence of internal or external devices such as pacemakers or pulse generators. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.

If the patient has an Implantable Cardioverter Defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activation of ICD.

Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

For all operation modes, any associated equipment and active electrodes must be rated to with stand the combination of output voltage. Vpeak and crest factor as stated in the table on Page 49

The generator is equipped with a **contact quality monitoring system (CQMS)** (which monitors the status of the ESU pad connection, when a ESU pad connection breaks, the alarm will be activated with RED ALARM indicator and audible alarm sound). The function of the **CQMS** is to monitor and confirm the total resistance between a split ESU pad and patient is within the preset safety range, when the resistance is more than 113ohms, the alarm will be activated with RED ALARM indicator and audible alarm sound, **this function is available to split ESU pad only.** Proper application and visual inspection of the patient return electrode is required for safe operation.

In some circumstances, potential exists for alternate site burns at points of skin contact (e.g.,between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the return electrode that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated output generators.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin-to-skin contact points, such as fingers touching leg, when positioning the patient.
- Place 5 to 8 cm (2 to 3 in.) of dry gauze between contact points to ensure that contact does not occur.
- Position the return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
- In addition, place ESU pads according to the manufacturer's instructions.

Selecting a suitable application site

 Solid ESU pad (Only connection status monitoring);  Split ESU pad (both connection status and contact resistance monitoring)

Apply the ESU pad as closely as possible to the surgical field, preferably the thigh or upper arm. In any case, the application site must be a convex skin surface which is either muscular or has good circulation.

The activated electrosurgical generator may affect the performance of active implants (e.g. cardiac pacemakers, internal defibrillators) or damage them. In the case of patients wearing active implants, consult the manufacturer of the implant or the competent department of your hospital prior to performing surgery. Do not position the ESU pad above cardiac pacemakers, internal defibrillators or other active implants.

The ESU pad should be closer to the site of intervention than ECG electrodes.

The ESU pad must not be applied on or over the following locations:

- on scars
- on inflamed skin
- on bony parts of the body
- over metal implants
- over severely adipose subcutaneous tissue

CAUTION

Non-compatible or solid return electrode

If a non-compatible return electrode is used, the unit may not monitor the contact of the return electrode to skin as expected.

When applying a solid ESU pad, the contact between ESU pad and skin is not monitored. If contact between ESU pad and skin is inadequate, the unit does not emit any visual and acoustic signal.

Risk of burns for the patient under the ESU pad

- Check the ESU pad's instructions for its suitability with the OBS-350A generator.
- Use only suitable ESU pad.
- When applying a solid ESU pad: Regularly check the EUS pad for good skin contact.

WARNINGS:

Potential for alternate site burns increases if the ESU pad is compromised. OBS recommends the use of split ESU pads and OBS generators with a contact quality monitoring system.

The entire area of the ESU pad should be reliably attached to the patient's body and as close to the operating field as possible.

The cables to surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored so that they are isolated from the patient.

Do not wrap the accessory cords or ESU pad cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application if HF surgery. There is a risk of pooling flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluids pooled in these areas should be mopped up before HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases.

Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in Normal Use of the HF surgical equipment.

CAUTIONS:

At no time should you touch the active electrode or bipolar forceps. A burn could result.

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Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow adequate cooling.

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Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

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Non-function of the generator may cause interruption of surgery. A backup generator should be available for use.

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Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active

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When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

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The use of high frequency current can interfere with the function of other electromagnetic equipment.

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When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes. Monitoring systems incorporating high frequency current-limiting devices are recommended.

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Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

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To avoid the possibility of an electrosurgical burn to either the patient or the physicians, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.

The patient should not come in contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.

Remove any loose fitting jewelry from the patient before activation.

Examine all accessories and connections to the electrosurgical generator before use. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

When not using active accessories, place them in a holster or in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

Avoid HF output settings where maximum output voltage may exceed rated accessory voltage. Refer to the accessory's voltage rating. Choose only accessories that will withstand each mode and power setting.

To avoid incompatibility and unsafe operation, use suitable cables, accessories, active and neutral electrodes, including values for the highest allowed H.F. peak voltage.

Connected accessories need be rated for at least the maximum peak output voltage of the H.F. generator set at the intended output control setting in the intended operating mode.

The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a safety hazard at low power settings.

Apparent low output or failure of the OBS-350A to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.

Contraindications

There are no known contraindications.

NOTICES:

If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

KEY FEATURES

The OBS-350A includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.

It includes the following features:

- Three Cut modes: Pure cut, Blend 1 and Blend 2
- Three COAG modes: COAG1(spray), COAG2(forced) and COAG3(soft)
- Two bipolar modes: Bipolar1(macro) and Bipolar2(micro)
- Memory: 10 memory Presets, the unit automatically reset to the last activated Preset setting;
- ESU pad sensing:
  This function can detect the continuity between ESU generator and a split ESU pad which shall be adhered to the patient skin, when Power On, the ESU pad sensing current flows from the unit to one side of the ESU pad, and then pass through patient to reach the other side, after that return to the unit, so the connection on both end connectors of the ESU pad cable can be detected. If there was a disconnection on either end, the Alarm would be activated with visual and audible prompt.
- CQMS (contact quality monitoring system): During **monopolar** electrosurgery, a patient **Split** ESU pad is always required to safely recover the current that flows through the patient's body and return it to the generator. A reduction in surface area contact or poor conductivity between the patient and the ESU pad can cause the current to become concentrated, potentially resulting in burns at the ESU pad site.
  The OBS-350A generator uses the CQMS to monitor the quality of electrical contact between the patient ESU pad and the patient. The CQMS function is designed to

minimize the risk of burns at the ESU site due to a reduction in patient contact area during monopolar electrosurgery.

- How the CQMS works

  The CQMS continuously measures the resistance at the ESU pad site and compares it to a standard value of safe resistance (less than 113ohms), thus under the condition of ESU pad releases or shrinks, the contact area to skin would be reduced, and the contact resistance increased, when the resistance is above 113ohms, the alarm will be activated by Red of "ALARM" indicator as well as Error code(Err--0) displayed on the CUT screen, in the same time a continuous alarm voice(> 65db) initiated, and the generator will stop output simultaneously, the alarm cannot be disabled unless the ESU pad adhered in a good condition again.
- Power ON self diagnostics: In the self diagnosis process after Power ON, all working modes and functions operating are simulated and monitored by software control to determine whether they are performed normally, followed by transmitting of corresponding test data to the display module through the control module. If failure occurs, the respective code will be displayed accordingly as prompt and alarm voice delivered simultaneously, which disables all subsequent operations automatically.
- ***Power peak value system (PPS)***
- PPS: The Peak Power System
  - For optimal support during the initial cutting stage, especially low-contact impedance situations, allowing the electrode to start in contact with target tissue;
  - This feature allows the delivery of an above average output during the initial incision phase, if needed;
  - As a result, any delay at the start of a procedure is minimized, which reduces excessive COAG necrosis at the point of the cutting site;
  - Specifically, before activation of the unit, when the cutting electrode is pressed firmly against the tissue to be cut, the electrode has a relatively extensive contact and thus, lower resistance with the tissue such as TUR or endoscopic polypectomy;
  - In summary, this function detects low-resistance loads and as needed briefly provides sufficient output to ensure the high frequency voltage necessary for the cutting quality selected or the intensity of the electric arcs even with low-resistance loads.
  - This kind of unit can limit average power within relative low magnitude, which is an improvement for preventing patient from suffering accidental heat trauma.
  - Pure CUT, Blend CUT and Bipolar modes are equipped this PPS function.
- Standard connectors: These connectors accept the latest monopolar and bipolar instruments.

NOTICE:

It is recommended that you use a split return electrode while using the OBS-350A CQMS.

To avoid the possibility of a burn to the patient, when using a split pad do not activate the unit if the solid pad indicator is illuminated green or the red alarm indicator remains illuminated red. This could indicate improper pad placement or a faulty NEM circuit.

- Power ON self diagnostics: In the self diagnosis process after Power ON, all working modes and functions operating are simulated and monitored by software control to determine whether they are performed normally, followed by transmitting of corresponding test data to the display module through the control module. If failure occurs, the respective code will be displayed accordingly as prompt and alarm voice delivered simultaneously, which disables all subsequent operations automatically.

ACCESSORIES and Components Applied

- Accessories and components list:
- ✓ Electrosurgical pencil
- ✓ Electrosurgical pad (also named neutral electrode, return electrode, neutral pad…)
- ✓ Electrosurgical bipolar forceps
- ✓ Footswitch for Monopolar procedures
- ✓ Footswitch for Bipolar procedures

- Compatibility requirements:
- ✓ First, the accessories shall be Legally marketed in Europe;
- ✓ Electrosurgical pencil (3pin-9/5mm)
- ✓ Electrosurgical pad (2pin-6mm)
- ✓ Electrosurgical bipolar forceps(2pin-22mm)
- ✓ Associated equipment and accessories used must be rated to withstand the combination of the Vpeak rating and Crest Factor for the following RF modes, Blend, Pinpoint and Spray.When using PURE Cut mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1001Vpeak max.
- ✓ When using Blend mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1029Vpeak max.
- ✓ When using Coagulation mode, associated equipment and active accessories

should be selected that have a rated accessory voltage equal to or greater than 2321 Vpeak max.

- ✓ When using Bipolar mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 398Vpeak max.
- ✓ To avoid incompatibility and unsafe operation, we recommend using the OBS accessories with the OBS-350A.

APPLICATION SPECIFICATION

Operating Conditions:

RF energy is generated and passed through an interconnecting cable to an accessory where the energy is delivered to cut, coagulate and ablate tissue.

Description:

• The OBS-350A High Frequency Electrosurgical Generators models are intended to be used for all electrosurgical cut, blend, coagulation and bipolar procedures.

Medical Purpose / Indication

• Removal and destruction of skin lesions

• Electrosurgical cutting, blending, coagulation and bipolar procedures of tissue to aid surgeon or physician in performing required procedures.

Site Condition:

Ambient luminance range	100 lx to 1,500 lx
Viewing distance	20 cm to 200 cm
Viewing angle normal to the display	± 30˚

Site of use:

• Site of use: Human Tissue

Patient population:

• Age: newborn to geriatric

•Weight: >2.5 kg

• Health: no restrictions

• Nationality: no restrictions

• Patient state: alert, relaxed maybe sedated, possible local anesthesia

– Patient should not be User

Intended User Profile:

• Education: Trained physician, physicians assistance, clinicians

- No maximum

• Knowledge:

- Minimum:

•understands electrosurgery and electrosurgical techniques

• read and understand supplied “User’s Guide” (accompanying document)
• understands hygiene
- No maximum
• Language understanding:
- Languages as specified in the marketing distribution plan
• Experience:
- Minimum:
• Some training on techniques or training under surveillance/supervision
• Other: no special experience needed
• No maximum
• Permissible impairments:
- Mild reading vision impairment or corrected vision to 20/20
- impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz.

SECTION 2

Controls, Indicators and Receptacles

A. Front panel:

The front panel will be designed to be extremely easy to use and all labels will be in clear English. The front panel is separated into three distinct sections, BIPOLAR, CUT and COAG. The explanation of these sections and the rest of the front panel as following illustration. The front panel keyboard functions are outlined in Table 1

A-1. Power display control:

The UP arrow when pressed will increase the desired power setting up to the maximum power. The DOWN arrow will decrease the desired power setting down to the minimum power. When the UP or DOWN key is pressed and held, the power display will change slowly at first, then quickly until the button is released.

A-2. Colors and modes:

Each of the three sections is color coded for keys and indicator bars. CUT is yellow, COAG and BIPOLAR are blue. Only one mode per section can be activated at a time.

A-3. Indicator bars:

Each of the three sections contains an indicator bar for activating status and operating modes light, whenever the section is activated by handswitch or footswitch, this bar will light for the duration of the activation. BIPOLAR and COAG will light up as blue, CUT will light up as yellow. The intended mode switching will light corresponding color. BIPOLAR and COAG will light up as blue, CUT will light up as yellow.

A-4. Output receptacles:

There are three output receptacles on the front panel from left to right by turn are monopolar, bipolar, return electrode. The monopolar receptacle is controlled by both the CUT and COAG sections, the bipolar output receptacle is controlled by the bipolar section and is only active when the bipolar handpiece is activated or bipolar footswitch is activated. The return electrode receptacle is for neutral pad connection when monopolar choosed. See following table 1 for illustration explanation.

A-5. Power:

A rocker switch on the lower left corner of the front panel is the AC line input switch for the generator. Pressing the switch in the “I” position will power the generator on and pressing the switch in the “O” position will power the generator off.

A-6. Memory function

Pressing the “set” button can preserve the current operation parameter. For example, when conduct a specific surgery, the proper parameter adjusted can also apply to another same type one, then press “set” , the MEM screen will display Arabic numerals, and then press “OK”, this parameter is preserved successfully. When power on next time, you just remember the corresponding Arabic numerals and press “set” to choose it. This function can remember 10 parameters.

A-7. Previous settings:

As long as the last parameter setting had been activated, which would present on the front panel when the generator powered on next time. This memory will be automatic and transparent to the user.

A-8. Cut modes:

There are three cut modes: Pure cut, Blend 1 and Blend 2, which can be chose by the relevant switch button circularly that control the type of waveform available from the monopolar output receptacle.

A-9. Coag modes:

There are three coag modes: COAG 1(spray coag), COAG 2(force coag) and COAG 3(soft coag), which can be chose by the relevant switch button circularly that control the type of waveform available from the monopolar output receptacles.

A-10. Bipolar modes:

There are two bipolar modes: Bipolar 1(macro bipolar) and Bipolar 2(micro bipolar), which can be chose by the relevant switch button circularly that control the type of power curve available from the bipolar output receptacle.

A-11. PLAT ALARM:

The PLAT alarm (to reflect the function of CQMS) indicator is on the lower right of the front panel. The PLAT ALARM indicator consist of “PLAT” contact quality display bar and “ALARM” lighten bar. As the following illustration described.

Picture 1

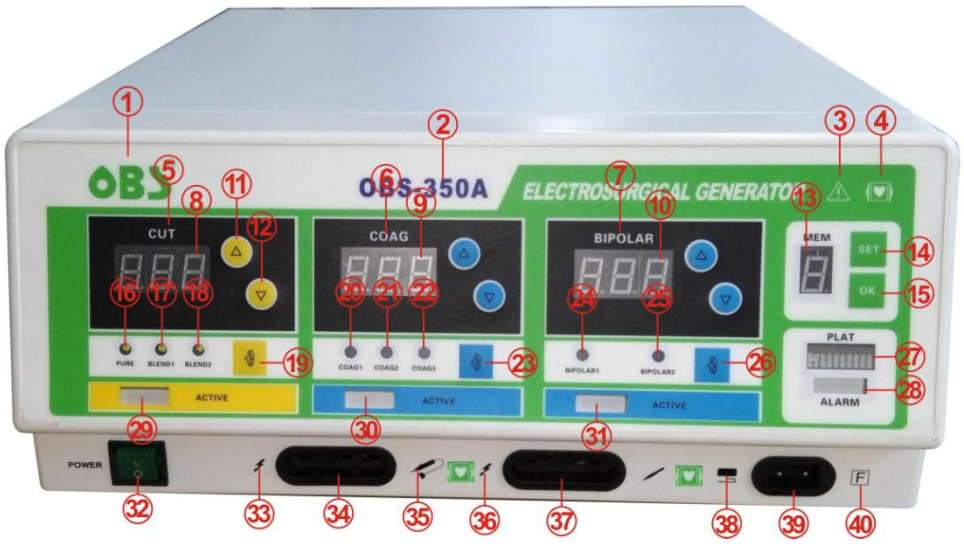
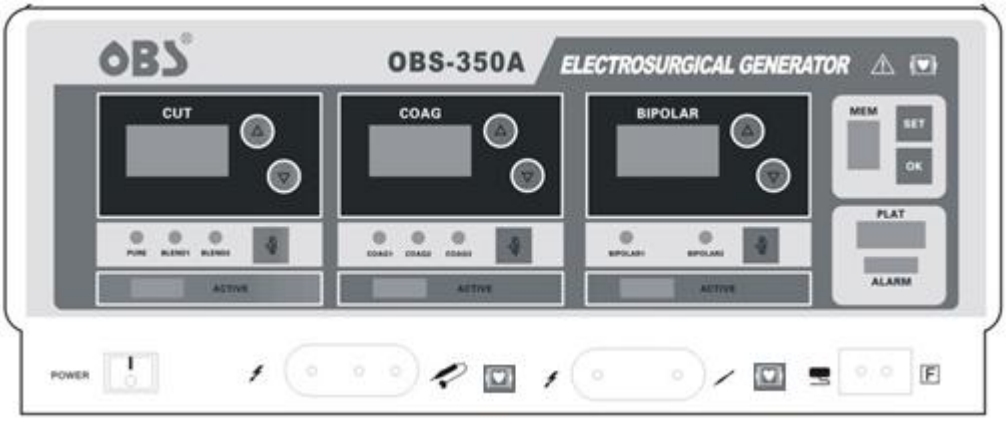


Table 1: Illustration explanation of Front panel			
1	Registered trade mark	**21**	COAG 2 indicator
2	Model	**22**	COAG 3 indicator
3	Symbol for caution	**23**	COAG modes switching button
4	Defibrillation-proof type CF applied part	**24**	BIPOLAR 1 indicator
5	Mode: CUT	**25**	BIPOLAR 2 indicator
6	Mode: COAG	**26**	BIPOLAR modes switching button
7	Mode: BIPOLAR	**27**	Contact quality display bar
8	CUT POWER display	**28**	ALARM indicator
9	COAG POWER display	**29**	CUT operating indicator
10	BIPOLAR POWER display	**30**	COAG operating indicator
11	POWER increase button	**31**	BIPOLAR operating indicator
12	POWER decrease button	**32**	POWER ON/OFF
13	Memory mode	**33**	ESU pencil connection
14	Memory mode setting	**34**	ESU pencil receptacle
15	Memory setting confirmation	**35**	Dangerous voltage
16	PURE cut indicator	**36**	Bipolar forceps connection
17	BLEND 1 indicator	**37**	Bipolar forceps receptacle
18	BLEND 2 indicator	**38**	Neutral pad connection
19	CUT mode switching button	**39**	Neutral pad receptacle
20	COAG 1 indicator	**40**	Output is isolated to ground

Picture 2



OBS®	Registered trademark	⚠	Caution
— ○	Disconnection (refer to main power supply) Connection (refer to main power supply)		
△	Power adding	▽	Power subtracting
↯	Caution High Voltage		Monopolar handpiece receptacle
	Bipolar handpiece receptacle		Electrosurgical pad receptacle
SN	SERIAL NUMBER		CONSULT INSTRUCTIONS FOR USE
	Defibrillator Proof Type CF Equipment	F	RF Isolate – patient connections are isolated from earth at high frequency
	Mandatory: Refer to instruction manual/guide		Do not dispose of this device in the unsorted municipal waste stream.

B. Rear panel

B-1. Footswitch connector

There are two footswitch connectors mounted on the rear panel labeled BIPOLAR FOOTSWITCH and MONOPOLAR FOOTSWITCH, each connector controls the corresponding output receptacle on the front panel. Foot pedal and manual control handles are effective simultaneously. Bipolar function will be effective only controlled by foot pedal.

B-2. Volume control knob

A volume control knob is mounted on the rear panel, the knob controls the volume of the activation tones of the generator. It does not affect the volume of the alarm tones of the generator

B-3. AC line receptacle

An AC line receptacle is mounted on the rear panel of the generator with the function of Voltage Converter (120V/230V), the receptacle is designed to meet the matching connector available on the standard detachable line cords. power supply frequency 60Hz/50Hz.

B-4. Rewirable fuse

There have two rewirable fuses, one for Zero line and the other for Fire line. The fuse can be replaced with a specification of 8A, Φ5×20.

Picture 3

Table 2: Illustration explanation of Rear panel			
1	Thermovent	**5**	Loudspeaker
2	Bipolar footswitch receptacle	**6**	Label
3	Monopolar footswitch receptacle	**7**	Non-ionizing radiation
4	Equipotentiality	**8**	AC line receptacle
9	Rewirable fuse		

SECTION 3

GETTING STARTED

INITIAL INSPECTION

When you first unpack your OBS-350A, inspect it visually:
• Look for any signs of damage.
• Verify that the shipping package contains all items listed on the packing list.
Do not use any damaged equipment.

INSTALLATION

Place the OBS-350A on any flat surface with a tilt angle not more than 10°. The unit relies on natural convection cooling. Do not block its bottom or rear vents. Ensure that air flows freely on all sides of the unit.

WARNING:

Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

FUNCTION CHECKS

Upon initial installation of the unit, perform the tests listed below. Refer to the figures in the previous chapter for the location of connectors and controls.

WARNING:

At no time should you touch the active electrode or bipolar forceps. A burn could result.

Setting Up the Unit

1. Verify that the Power Switch is in the Off (O) position and that no accessories are connected to the unit.
2. Connect a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.
3. Connect a two-button monopolar pencil to the appropriate receptacle.
4. Do not connect a patient return electrode at this time.
5. Turn the unit on by switching the power switch to the ON (|) position.

Checking the Return Electrode Alarm

Press the COAG button of the pencil. Verify that an alarm sounds for three seconds and the ALARM indicator light illuminates, indicating that no ESU pad is connected to the unit.

Confirming Modes

Confirm that you can select each mode and adjust the power up and down.

Checking Bipolar Mode (with bipolar footswitch)

1. Plug in the Bipolar footswitch.
2. Press the pedal on the Bipolar footswitch. Verify that the Bipolar mode activation indicator illuminates and that the system generates the Bipolar activation tone.
3. While activating the Bipolar mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
4. Confirm that releasing the pedal returns the unit to an idle state.

Checking Monopolar Mode (with monopolar footswitch)

1. Plug in the Monopolar footswitch.
2. Connect a solid ESU pad to the ESU pad receptacle, the PLAT bar is full green.
3. Press the Cut pedal (yellow) on the footswitch. Verify that the Cut mode activation indicator illuminates and that the system generates the Cut activation tone.
4. While activating the Cut mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
5. Press the Coag pedal (blue) on the footswitch. Verify that the Coag mode activation indicator illuminates and that the system generates the Coag activation tone.
6. While activating the Coag mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

Checking Monopolar Mode (with handswitch)

1. Connect a handswitching handpiece to the Monopolar handpiece receptacle.
2. Connect a solid ESU pad to the ESU pad receptacle, the PLAT bar is full green
3. Activate, one at a time, the Cut and Coag handswitching controls. Verify that each control causes the correct indicator and tone to sound.

PERFORMANCE CHECKS

After the unit has passed the preliminary functional test, it is ready for performance testing. A qualified biomedical engineer who is thoroughly familiar with electrosurgical devices should conduct this testing. The testing should include checking all modes of operation for proper function and power output.

a) Power ON self diagnostics: In the self diagnosis process after Power ON, all working modes and functions operating are simulated and monitored by software control to determine whether they are performed normally, followed by transmitting of corresponding test data to the display module through the control module. If failure occurs, the respective code will be displayed accordingly as prompt and alarm voice delivered simultaneously, which disables all subsequent operations automatically.

Error code:

- Err--2: CUT malfunction
- Err--3: COAG malfunction
- Err--4: Bipolar malfunction

b) ESU pad test

A solid ESU pad is connected normally, the PLAT bar illuminates full green, otherwise the ALARM indicator will light red as well as audible alarm sound. The output will be cut off simultaneously. But the contact quality with patient cannot be monitored, there is a critical risk of accidental heat trauma of body tissue at working point and adhering area, so that the whole surface of ESU must be applied to the fleshy muscle on patient's body as close and reliable as possible.

Note: A split ESU pad is recommended to connect use with OBS-350A

WARNING:

If single-surface neutral electrode is used, NESSY can only monitor condition of electric connection between neutral electrode and equipment, and cannot monitor the condition of application on patient's body.

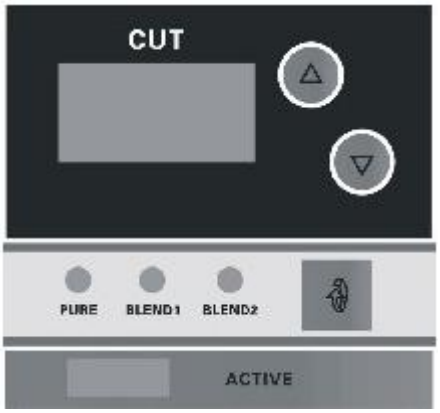
A split ESU pad is connected normally and with a good adherence to patient, the PLAT bar illuminates full green, if not connect well, the ALARM indicator will light red as well as audible alarm sound; if connected well, but without a well adherence, the color of PLAT bar will change from green to orange to red with the reducing of adherence, when the contact resistance is more than 113ohms, the PLAT bar will be full red, and ALARM indicator will light red as well as audible alarm sound, the output will be cut off simultaneously. This is the function of CQMS mentioned above.

WARNING:

For preventing heat injury caused by misuse or malfunctioned system during operations, accessories in good condition must be used. Only compatible accessories or eligible accessories tested by manufacturer are used. This requirement is not only suitable for application electrodes including cables and plugs, but also suitable for neutral electrodes including cables and plugs.

When electricity-isolating apparatus is used, ensure that the isolation should not be overloaded and damaged due to higher voltage. This operation manual describes output voltage values for all the cutting and coagulation operation modes, the isolating intensities can be found in the technical data of the apparatus. If there is any question, please contact with the manufacturer for technical data. All the isolations of electrode, handle of electrode, cable and plug etc. should be kept in good conditions.

c) CUT function section



Electrotomy selection keys

Application function will be changed from the functions of PURE, BLEND1 and BLEND2 by pressing the “ ”key once at a time.

Power adding key, **subtracting key:**

Pure CUT

Press adding or subtracting key once when values displayed between 0-350W(load 500 Ω), each press will add or subtract by 5 increments, If the key is pressed down constantly, it adds and subtracts rapidly.

Blend CUT 1

Press adding or subtracting key once when values displayed between 0-250(load 500 Ω), each press will add or subtract by 5 increments, If the key is pressed down constantly, it adds and subtracts rapidly.

Blend CUT 2

Press adding or subtracting key once when values displayed between 0-150(load 500 Ω), each press will add or subtract by 1 increment, If the key is pressed down constantly, it adds and subtracts rapidly.

NOTICE

During normal surgical operation, one should select a lower power at first, and if it is not higher enough, increase the power gradually. Cut an incision in 2-3 mm in depth with steel sheet knife, dip blood dry with gauze, and then cut with electrotome along the incision, dry it with gauze. If the cut tissue assumes yellow color, that means the power is rather high, increase cutting speed or decrease power output. The optimum effect is that the incision assumes white and a bit yellow color after cutting. This is the right time for a good hemostasia and a slight burn to the tissues of human body.

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d) COAG function section

Electrotomy selection keys

Application function will be changed from the functions of COAG1, COAG2 and COAG3 by pressing the "  "key once at a time.

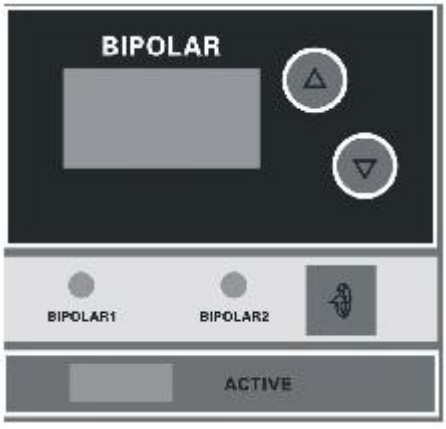
Power adding key, **subtracting key:**


COAG 1 (**Spray**)
Power range of Spray Coagulation is within 0W～120W (load 500Ω)
It is mostly suitable for argon gas ion Coagulation and argon gas.

COAG 2 (**Forced**)
Power Range of Forced coagulation is within 0W～100W (load 500Ω)
It is usually used for blood vein coagulation. When cutting off blood veins within 1-2 mm, nod tow ends of vein with flat end of knife instead of using gauze for dipping blood, and then cut off in the middle when color is white with a little yellow.

COAG 3 (**Soft**)
Power range of Soft coagulation is within 0W～50W (load 500Ω).
Since this function controls strictly the output voltage, so it is called low voltage coagulation, therefore, it is mainly used for celioscope surgical operation and can carry out blood coagulation and separation with celioscope.
This automatic coagulation function section is in coagulating mode, which can be actuated by pressing blue button on the electrode handle or blue pedal on foot pedal switch. The actuating status is indicated by the “ACTIVE” COAG operating indicator and the sounding signal simultaneously.

e) Bipolar application function section BIPOLAR



Power adding key, subtracting key:


Bipolar 1 (Macro): 0W～150W（load 100Ω）
The bipolar 1 can be used on artery and tissue bundles up to and including 7mm in diameter. It provides precise energy delivery and electrode pressure to artery for a controlled time period to achieve a complete and permanent tissue fusion. It has been optimized to produce minimal sticking, charring, or thermal spread to adjacent tissue.
-Bipolar 1(0~150w): 1w increments for each adding

Bipolar 2(micro): 0W～100W (load 100Ω)
This is suitable for application in orthopaedics, microscopical surgeries. The less tissue are held, the better effect will be achieved during operation. Too much tissue to be held will affect the result of hemostasia. Clamp body tissues with bipolar forceps, and output power for coagulation, cut off the output as it leaves from human body, which must be controlled by foot pedal, otherwise, operations mentioned above cannot be accomplished.
-Bipolar 2(0~100w): 1w increment for each adding

SECTION 4

DURING USE

INSPECTING THE GENERATOR AND ACCESSORIES

Before each use of the OBS-350A, verify that the unit and all accessories are in good working order:

- Inspect for damage to the Electrosurgical Generator and all its connections.
- Verify that the appropriate accessories and adapters are present.
- Inspect all cords and connectors for signs of wear, damage, and abrasion.
- Verify that no errors occur when you turn on the unit.
- Initial operation: During the process of developing and manufacturing this high frequency operating device, we have taken into consideration of the legalized technical regulations and existing precautionary regulations on professional safety and accidents. Thus, when the device is used according to applications, patients, operators and the third parties will be protected to prevent them from damages to life and health within the allowable application ranges. Before delivering, functions and safety performances of each device has been tested by the manufacturer. For ensuring reliable and safe performances of the device after transportation and installation in site, operators can run this device only after manufacturer or supplier have tested performances on the spot and explained to the right party how to operate this device according to operation manual.
- When electricity-isolating apparatus is used, it is to ensure that the isolation should not be overloaded and damaged due to higher voltage. This operation manual describes output voltage values for all the cutting and coagulation operation modes, their isolating intensities can be found in the technical data of apparatus. If there is any question, please contact with the manufacturer for technical data.
- Accessories in good condition must be used in surgical operation
  Only compatible accessories that are legible marketed or supplied by manufacturer can be used. This requirement is not only suitable for application electrodes including cables and plugs, but also suitable for neutral electrodes including cables and plugs.
- All the isolations of electrode, handle of electrode, cable and plug etc. should be kept in good conditions

SETUP SAFETY

WARNINGS

Hazardous Electrical Output - This equipment is for use only by trained, licensed physicians.

Electric Shock Hazard - Connect the generator power cord to a properly grounded receptacle.
Do not use power plug adapters.

Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

Fire Hazard - Do not use extension cords.

Patient Safety - Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.

Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

If the patient has an Implantable Cardioverter Defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activation of ICDs.

In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the patient return electrode that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated output generators.

To reduce the potential for alternate site burns, do one or more of the following:

• Avoid skin-to-skin contact points, such as fingers touching leg, when positioning the patient.

• Place 5 to 8 cm (2 to 3 in.) of dry gauze between contact points to ensure that contact does not occur.

• Position the return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.

• In addition, place return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised. OBS recommends the use of split return electrodes and OBS generators with a contact quality monitoring system.

CAUTIONS:

At no time should you touch the active electrode or bipolar forceps. A burn could result.

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Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow adequate cooling.

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Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

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Non-function of the generator may cause interruption of surgery. A backup generator should be available for use.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active.

When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

NOTICE:
If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

SETTING UP

1. Verify that the generator is Off by pressing the power switch Off (O).

2. Place the generator on a stable flat surface, such as a table, platform, or medical cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes. Provide at least 10 to 15 cm (4 to 6 in.) of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when you use the generator continuously for extended periods of time.

3. Plug the generator power cord into the AC Power Cable Receptacle on the rear panel.

4. Plug the generator power cord into a grounded receptacle.

5. Turn on the generator by pressing the power switch On (|). Verify the following:

• All visual indicators and displays on the front panel illuminate.

• Activation tones sound to verify that the speaker is working properly.

6. If the self-test is successful, a tone sounds. Verify the following:

• A Cut mode is selected; a Coag mode is selected.

• Each display shows a power setting. The unit automatically powers up to the last selected preset settings.

• The Patient Return Electrode Alarm Indicator illuminates red.

If the self-test is not successful, an alarm tone sounds. An error code will appear in the Bipolar display, in most cases, the generators disabled. Note the

error code and refer to **Troubleshooting**. Once the self-test is successful, connect the accessories and set the generator controls. Refer to Preparing for Monopolar Surgery or Preparing for Bipolar Surgery later in this section.

NOTICE:

It is forbidden to contact directly the handle bipolar forceps and various accessories with medical solutions, and even to immerse them into medical solutions and other solutions.
Cables of handle, skin application plate and bipolar electrode are made of special high frequency cable, please contact with manufacture if replacements are necessary

7. This device has functions of PURE cut, Blend1 and Blend2, COAG1, COAG2 and COAG3, Bipolar1 and Bipolar2 for the selections during surgical operations.

PREPARING FOR MONOPOLAR SURGERY

Monopolar surgery requires a return electrode.

Applying the Return Electrode

To maximize patient safety, OBS recommends using a split ESU pad and a OBS generator with a contact quality monitoring system (CQMS).

The whole area of polar plate (electrode plate) must closely attach to the body of patient (beneath buttocks), and should be as close as possible to operation area. Effective contact surface i.e. electric conductivity between neutral electrode and patient should be equal to high frequency capacity applied namely the intensity of high frequency current. Here, effective contacting surface means neutral electrode surface contacting electric conduction contacting with patient's skin during operations.

If it is misused or even not used, then there would be a great risk to tissues of human body by accidental heat trauma at point of neutral electrode as well as on the other parts of patient. The electrode plates are divided into metal electrode plate, one-off electrode plate and two kinds of polar plates.

Metal electrode plate must be enclosed in two layers with gauzes, wet it with physiological saline before using. Whole area of it should closely attach to the body of patient (beneath buttocks), and should be as close as possible to operation area to form a good circuit. Electrical conducting glue of on-off skin application plate is adhered to the body of patient (beneath buttocks).

Patient should not touch any metal parts (such as: operating-table, bracket etc.) that are connected with grounding or the metal parts with considerable capacitance of grounding. Thus, it is suggested to use antistatic plate.
To avoid skin-to-skin contacting (i.e. arm to body of patient), put a piece of dry gauze in between the contacting points of four limbs or skin while lying, there should be put a piece of dry gauze in between to isolate them each other.

NOTICE:

The OBS CQMS system recommends that you use a split return electrode. Before activation, pad placement and visual verification of the split return electrode (split pad) indicator on the front panel is recommended. After connecting the split pad to the generator and placing the split pad securely to the patient, give the unit 0.5 to 1 seconds to recognize the split pad. The split pad indicator will illuminate green. If the split pad and cord are attached to the generator without secure contact to the patient, the alarm indicator will illuminate red.

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In order to prevent influences to other instruments or electrifying of machine's body due to induction, grounding should be connected with this machine.

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If low frequency current produced from high frequency surgery device is too strong, or stronger low frequency flows into high frequency surgery device from another voltage source, electric shock will happen at this time.

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Don't open the cover of the device during operation for fear of high voltage of the device. Don't insert any metal pieces into holes. Don't let any liquid flow into the machine to avoid accidents.

.....

Don't do "polar plate test" with handle and electrode, because the polar plate is a product of thin metal polar plate or one-off skin application plate.

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Under normal operation setting, if the output runs down quickly or surgical device doesn't work normally, that probably means the poor contact of neutral electrode (skin application plate) or improper use.

Refer to the manufacturer's instructions for application site and placement procedures. When using metal plate return electrodes, use a conductive gel specifically designed for electrosurgery. Select a return electrode site with good blood flow. While a properly applied electrode results in minimal tissue heating beneath the electrode, a good blood flow helps carry heat away from the site.

1. Connect the cable to the Return Electrode receptacle on the front of the unit. The unit will automatically sense the presence of a split or solid return electrode and, if a split return electrode is used, will constantly monitor the resistance at the contact between the electrode and the patient.
2. Adjust the Blend setting to the desired amount of hemostasis. Adjustment is performed by pressing the up or down buttons next to the Blend display.
   Select the desired power settings for Cutting. Adjustment is performed by pressing the up or down buttons next to the Cut display.
   Select the mode of operation for Coagulation. Select the desired power setting for Coagulation. Adjustment is performed by pressing the up or down buttons next to the COAG display.

Connecting Accessories

Connect a 3-pin monopolar device into the monopolar receptacle on the front of the unit.

If footswitching control capabilities are preferred, connect the monopolar footswitch to the appropriate footswitch connecting socket on the rear of the unit.

If you are using…	Connect it to…
Standard 3-pin handswitching pencil	Monopolar handswitching receptacle
Footswitching pencil	Monopolar footswitching receptacle

To activate the Monopolar mode, depress the cut or coag button on the monopolar handpiece or the cut or coag pedal on the monopolar footswitch.

PREPARING FOR BIPOLAR SURGERY

1. Connect a Bipolar cable to the Bipolar receptacle on the front of the unit.
2. Connect a forcep instrument to the bipolar cable.
3. Connect the bipolar footswitch to the bipolar footswitch connecting socket located on the rear of the unit. To activate the Bipolar mode, depress the pedal on the bipolar footswitch.
4. During operation, high frequency current probably flows through less part of section of limbs. To avoid unnecessary coagulation, it is better to use bipolar electrode technology.

   Generally speaking, as compared with monopole COAG technology, bipolar COAG technology is preferable. Bipolar COAG technology is particularly suitable for COAG in long and narrow organs. High frequency current passes through tissues of human body are always heated in smallest diameter section at first. If high frequency current passes through same diameters (a) over a longer distance, then tissues of human body will be coagulated along whole distance. If diameter of tissues around coagulation electrode point is less than that of electrode point, then there should be coagulation beside the action point (b). Under all circumstance, it is to ensure that the high frequency should not pass through tissue structure or smaller veins in smaller diameter.

5. Bipolar forceps, Bipolar forceps lead and connection of machine
Replace when isolation of bipolar forceps is fallen off, poor contact between bipolar forceps and lead consent, weak connection of lead. Bipolar forceps is made of stainless steel coated with plastic painting. Bipolar forceps plug and bipolar forceps output socket are pressed by moldings. Insert two plugs at will into output socket in parallel, pull out it by holding rear part of socket in parallel. Connect bipolar forceps and bipolar forceps lead, there is a parallel stainless steel at rear part of bipolar forceps, and a socket at front part of bipolar forceps (pressed by moldings), insert bipolar forceps. Remove it by holding middle part of bipolar forceps.

SETTING AND RECALLING MEMORY PRESETS

The OBS-350A incorporates 10 user-defined memory preset settings for easy recall of frequently used settings in all three modes.

Memory
The Memory feature allows the OBS-350A (unit) to display the last selected Preset when the generator is turned on. When activated by the handpiece or footswitch, the unit will operate in that particular mode and power setting.

All new settings must be saved as a Preset to be available at startup or as a Preset selection (0 through 9) when using the unit.

Memory Function Overview
• The unit powers up with the last selected preset (0-9).
• Recall and Set membrane switches are disabled during activation.
• During activation, the activated mode can be adjusted up and or down a maximum of following steps for power increments.

- Pure cut and Blend 1: 5W increments for each adding.
- Blend 2: 1W increments for each adding.
- COAG1, COAG2 and COAG3: 5W increments for each adding.
- Bipolar1: 1W increments for each adding.
- Bipolar2: 1W increments for each adding.

Setting Your Presets

- Select the desired preset (0-9) by pressing the “SET” button.
- Select the desired power (Cut, Coag, and Bipolar) to be stored by using the power output up and down membrane switches.
- Once all of the settings are selected, depress the “SET” button to choose a number from 0 to 9 and then press “OK” for confirmation.
- To recall a Preset, repeatedly press the “SET” button by turn and stop when the preset number (0~9) emerged.

Memory Feature (Last Selected Preset)

The Memory feature allows the unit to display the last selected power preset when the generator is turned on.

NOTICE:

The OBS-350A incorporates 10 factory-set presets that are all set to zero and can be reset to your preferred settings.

To have a setting selection available at startup or to be one of the 10 user-defined presets, the adjustment to the mode and/or power settings must be saved by pressing the “OK” button.

Examples:

Examples1 through 3 explain how the Memory features work and what happens when the power and/or mode is adjusted but not saved as one of the 10 Preset selections.

Example 4 explains what happens when the power and/or mode is adjusted and saved as a new Preset setting:

- Example1: The physician performs a surgical procedure using Preset 5. The Preset has been stored with the following mode and power:

• The mode is set to PURE cut
• The power setting for Cut is 100 watts
• The power setting for COAG2 is 30 watts
• The power setting for Bipolar1 is 60 watts.

The procedure is completed and the unit is switched off.
The next time the unit is switched on, the number 5 Preset will be displayed and available when the unit is activated. The number 5 Preset will be the same as the modes and settings indicated above.

- Example2: The physician performs a surgical procedure using Preset 5 (same as Example1 Preset values). He adjusts the power settings for each mode but does not store the new settings into the Preset. The next time the unit is switched on, the number 5 Preset will be displayed and available when the unit is activated. The number 5 Preset will be the same as the modes and settings indicated in Example1.

- Example3: The physician performs a surgical procedure using Preset 5 (same as Example1 Preset values). He changes the settings by selecting the BLEND1 mode. The displayed power will remain at 100 watts. The physician then adjusts the power to 150 watts. He resumes the procedure now using BLEND1 at 150 watts. He then switches the mode back to PURE cut. The power output returns to 100 watts as stored in the example2 Preset. The physician switches again to the BLEND1 mode and the output power returns to the temporary memory of 150 watts as previously selected. The procedure is completed without saving any modes or power settings. The next time the unit is switched on, the number 5 Preset will be displayed and available when the unit is activated. The number 5 Preset will be the same as the modes and settings indicated in Example 1.

- Example4: The physician performs a surgical procedure using Preset 5 (same as Example1 Preset values). He adjusts the power settings for a Cut mode, a COAG mode, and a Bipolar mode and presses the “OK” button to save the new settings as Preset number 5. The next time the unit is switched on, the number 5 Preset will be displayed and available when the unit is activated. The number 5 Preset will now be the last saved Preset settings for Preset 5.

ACTIVATING THE UNIT

NOTICE:

Review Activation Safety issues before activating the unit. When you turn on your unit remember the following feature:
TheOBS-350A will power up to the modes and settings displayed when the unit was last activated. For example, if you set Pure cut mode at 50 watts and activate the unit, then turn the unit off, it will automatically return to pure cut mode at 50 watts when you turn it on again. Similarly, if you set Spray mode at 40 watts and activate the unit before you turn it off, it will return to Spray mode at 40 watts when you turn it on again.

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1. Monopolar Cut - select the mode of operation for Cut: PURE, Blend I or Blend II, then select the desired Cut power settings by pressing the up and down buttons next to the Cut power display.
2. Monopolar Coag - select the mode of operation for coagulation: COAG1,2 or 3, then select the coagulation power settings by pressing the up and down buttons next to the Coag power display.
3. Bipolar – select the mode of operation for bipolar1 or bipolar2, then adjust the Bipolar power settings by pressing the up and down buttons next to the Bipolar power display.
5. Activate the generator by pressing the appropriate button on the handpiece or pedal on the footswitch.

NOTICE:

Monopolar and bipolar footswitching operations are controlled by independent foot controls.

ACTIVATION SAFETY

WARNINGS

Do not wrap the accessory cords or patient return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

Danger: Fire/Explosion Hazard - Do not use the OBS-350A in the presence of flammable anesthetics.
Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room:
• Flammable substances (such as alcohol based skin prepping agents and tinctures)
• Naturally occurring flammable gases that may accumulate in body cavities such as the bowel
• Oxygen enriched atmospheres
• Oxidizing agents (such as nitrous oxide [N2O] atmospheres).

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow, and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

Use electrosurgery with caution in the presence of internal or external devices such as pacemakers or pulse generators. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the device manufacturer or hospital Cardiology

Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.(The disturbance from the operation of high frequency can probably bring about disadvantage to the operations of other medical electronic equipmen）High frequency operation device generally produces high frequency voltage and current, which will disturb other electronic equipment. When sensible electronic equipment is arranged in operating room, these issues should be taken into account. In principle, sensible electronic equipment should be placed as far as possible from high frequency operation equipment, especially for the place of the cable to transmit high frequency current. In addition, the action of high frequency current cable is just like broadcasting antenna, of which the length should not exceed actual requirement, and absolutely should not be placed in parallel with sensible electronic equipment, and also be too near each other.)

CAUTIONS:

The use of high frequency current can interfere with the function of other electromagnetic equipment.

When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes.

Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

To avoid the possibility of an electrosurgical burn to either the patient or the physicians, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.

Remove any jewelry from the patient before activation.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means.

Examine all accessories and connections to the electrosurgical generator before use. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

When not using active accessories, place them in a holster or in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

SECTION 5

MAINTAINING The OBS-350A

OBS recommends that you complete periodic inspection and performance testing. Perform inspections and performance testing every six months. A qualified biomedical technician should conduct this testing to ensure that the unit is operating effectively and safely.

CLEANING

After each surgical operation, clean accessories by absorbent cotton, gauze dipping with salt water or alcohol, store it properly; keep it in good ventilated room without corrosive gas after arrangement. Carefully examine if the machine and accessories normal and effective before next operation.

WARNINGS

Electric Shock Hazard - Always turn off and unplug the generator before cleaning.

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the OBS-350A Electrosurgical Generator only.

NOTICES:

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

1. Turn off the generator, and unplug the power cord from the wall outlet.

2. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth.
Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. Do not sterilize the generator.

PERIODIC INSPECTION

The machine should be operated idly under normal temperature for more than 20 hours each month, and check if the accessories operate correctly. The machine should be examined by professionals at least 4 times each year, mainly including removing dust in the machine, checking if the machine works normally, safety inspection, condition of isolation, and checking if the accessories are correct and effective. Every six months, visually inspect the OBS-350A for signs of wear or damage.

Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair;

In particular, look for any of the following problems:
• Damage to the power cord
• Damage to the power cable receptacle
• Obvious damage to the unit
• Damage to any receptacle
• Accumulation of lint or debris in or around the unit

FUSE REPLACEMENT

Fuses for the unit reside directly below the Power Cable Receptacle on the rear of the unit. To replace the fuses, follow this procedure:

1. Unplug the power cord from the wall outlet.
2. Remove the power cord from the Power Cable Receptacle on the rear panel.
3. To release the fuse drawer, insert a small flathead screwdriver into the slot on the drawer below the power cord receptacle. Then, slide the drawer out.
4. Remove the two fuses and replace them with new fuses with the same values.
5. Insert the fuse holder into the Power Cable Receptacle.

NOTICES:

If the unit does not display an error and does not power on, check fuses

SECTION 6

TECHNICAL SPECIFICATIONS

PERFORMANCE CHARACTERISTICS

Basic property:

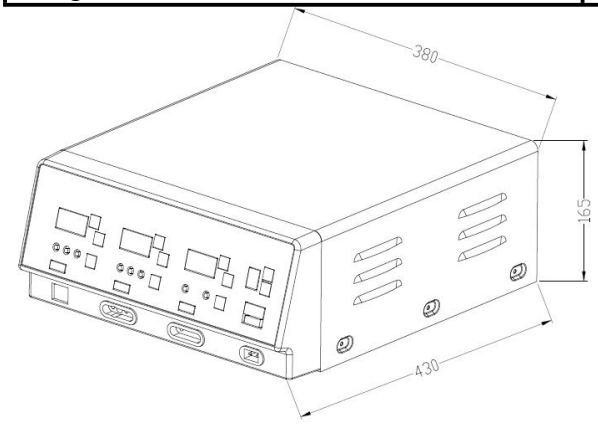
Category of the Device:	Class I Equipment (IEC 60601-1)
Type:	Type CF Equipment Defibrillator Proof
Duty Cycle:	Intermittent loading continuous operation(10s/30s)
Max. power:	350W
Non-permanently installed device	
Working frequency:	(330~460)kHz
Software version of the equipment:	Version: 1.1

Input power:

Input Voltage:	120/230V~VAC
Mains line frequency:	60Hz/50Hz
Power consumption:	880VA
Fuse(two):	F8AΦ5X20

Dimensions and Weight:

Width:	380mm	Depth:	430mm
Height:	165mm	Weight:	7kg



Operating Parameters:

Ambient temperature range:	5~40 ℃
Relative humidity:	≤80%
Atmospheric pressure:	86.0~106.0 Kpa.
Warm-up time:	If transported or stored at temperatures outside the operating temperature range, allow one hour for the generator to reach room temperature before use.

Transport and Storage:

Ambient temperature range:	-40℃ to +55℃
Relative humidity:	RH≤80 %
Atmospheric pressure:	50kPa to 106kPa

OUTPUT CHARACTERISTICS

Maximum Output for Monopolar and Bipolar Modes

Power readouts agree with actual power into rated load to within 20% or 5 watts, whichever is greater.

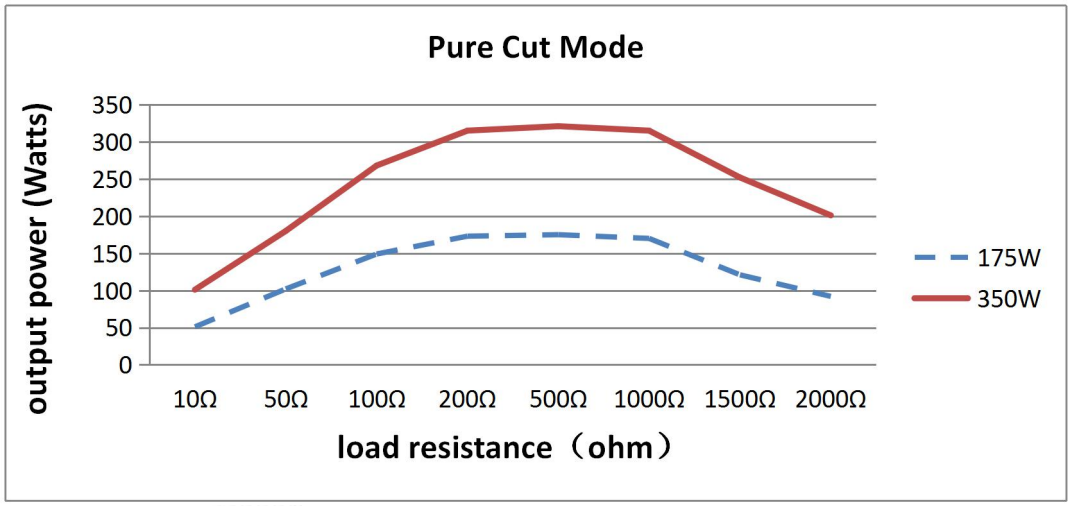
Mode	Output power	Output frequency	Repetition Rate	Vpeak max	Crest Factor (Rated Load)
PURE	350W, Load:500Ω	431Khz±50KHz	N/A	1001	1.7
Blend1	250W, Load:500Ω	431Khz±50KHz	27KHz ±5KHz repetition	1029	2.2
Blend2	150W, Load:500Ω	431Khz±50KHz	25KHz ±5KHzrepetition	801	2.5
COAG1	120W, Load:500Ω	431Khz±50KHz	28KHz ±5KHzrepetition	2321	7.2
COAG2	100W, Load:500Ω	431Khz±50KHz	29KHz ±5KHzrepetition	2177	6.7
COAG3	50W, Load:500Ω	431Khz±50KHz	30KHz ±5KHzrepetition	1380	4.7
Bipolar1	150W, Load:100Ω	431Khz±50KHz	25KHz ±5KHzrepetition	398	1.7
Bipolar2	100W, Load:100Ω	431Khz±50KHz	25KHz ±5KHzrepetition	347	1.7

OUTPUT POWER CURVES:

Half and Full output power versus load impedance

- **Pure cut**

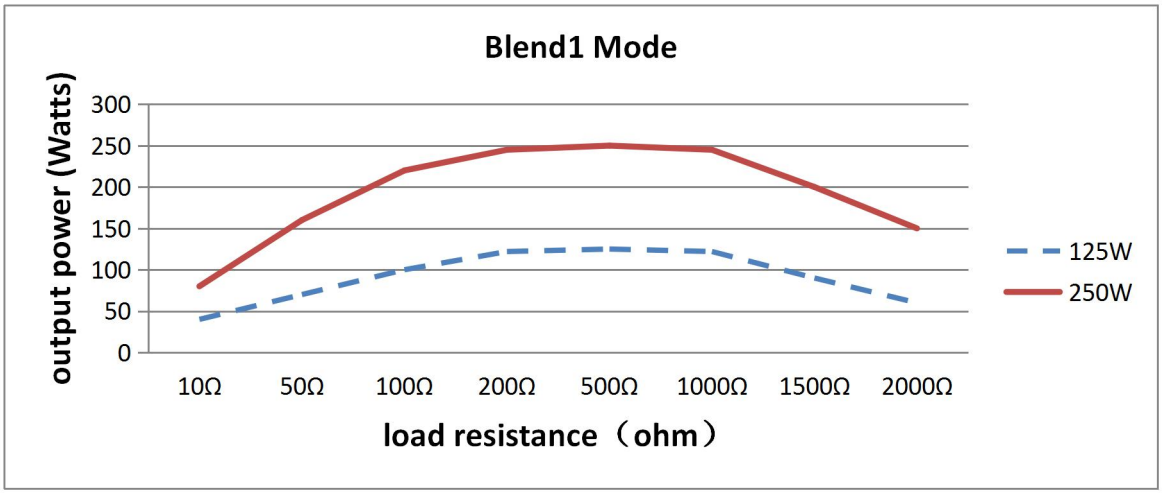
Figure 6-1



--------- Half setting 175W; ——— Full setting 350W

- **Blend cut I**

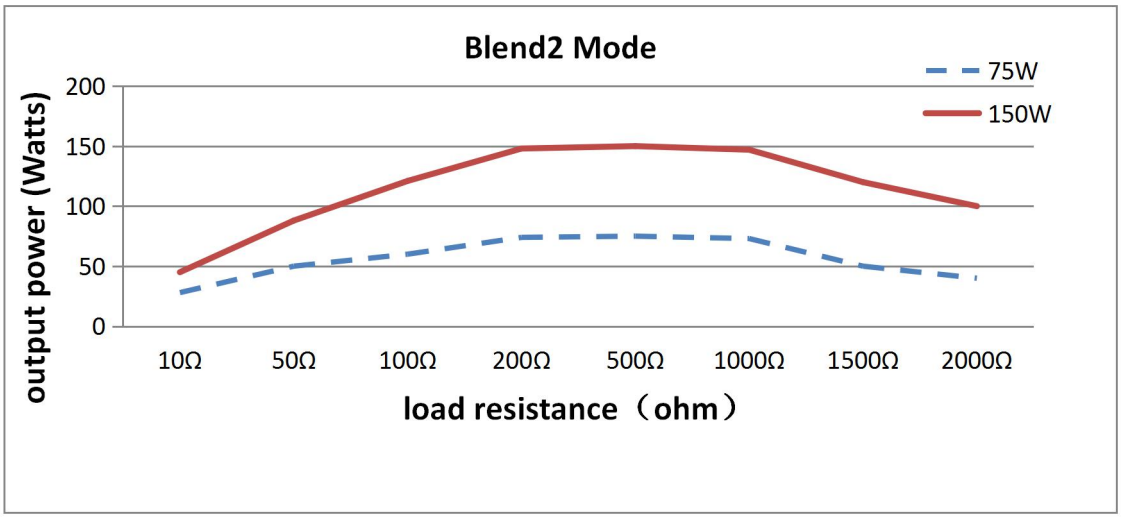
Figure 6-2



--------- Half setting 125W; ——— Full setting 250W

➢ **Blend cut II**

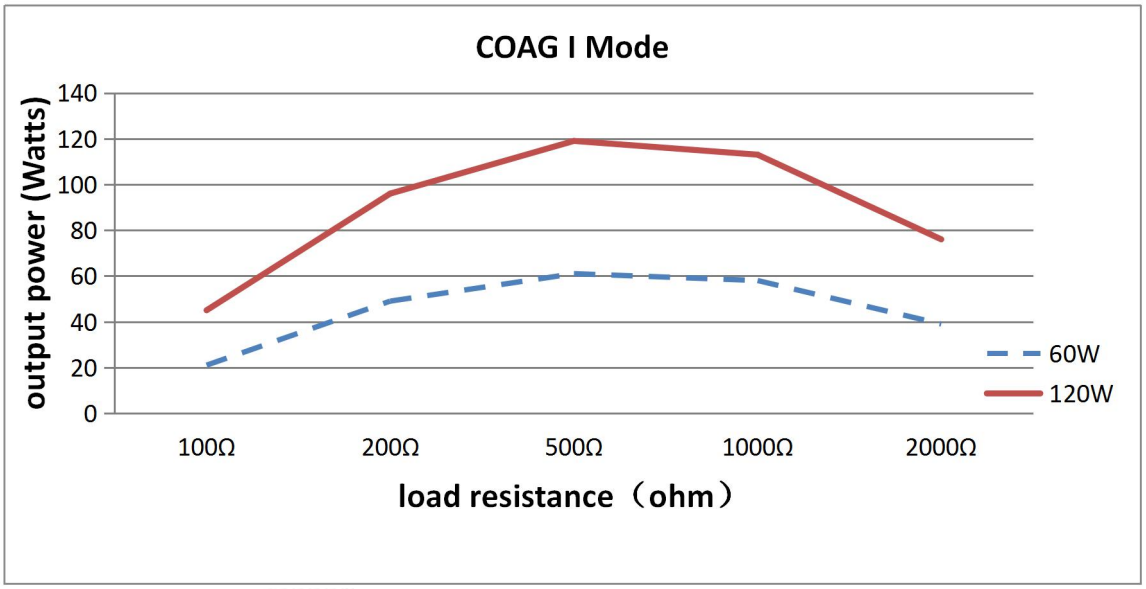
Figure 6-3



--------- Half setting 75W; ——— Full setting 150W

➢ **COAG I**

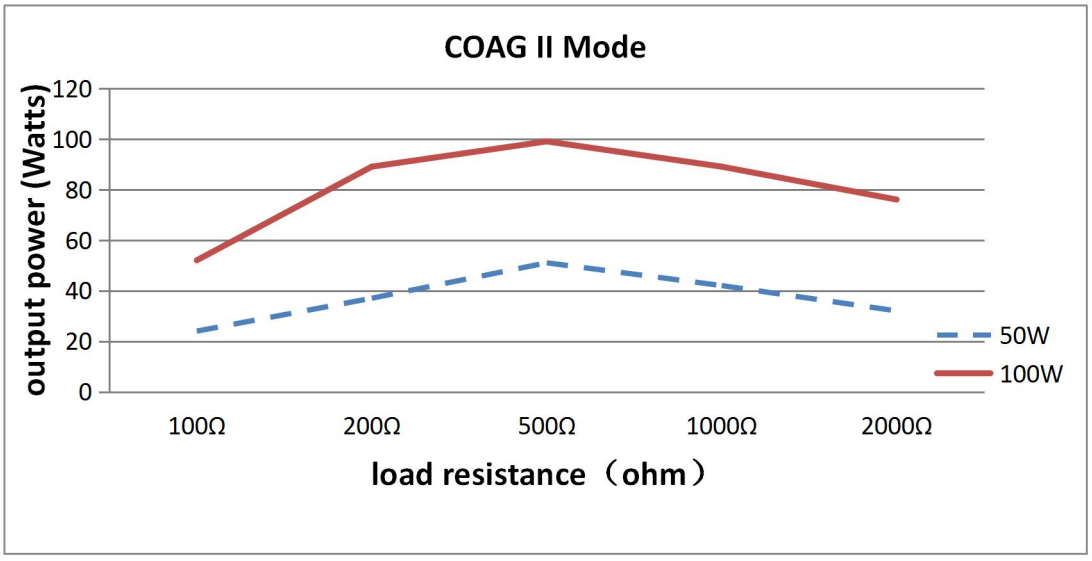
Figure6-4



--------- Half setting 60W; ——— Full setting 120W

- **COAG II**

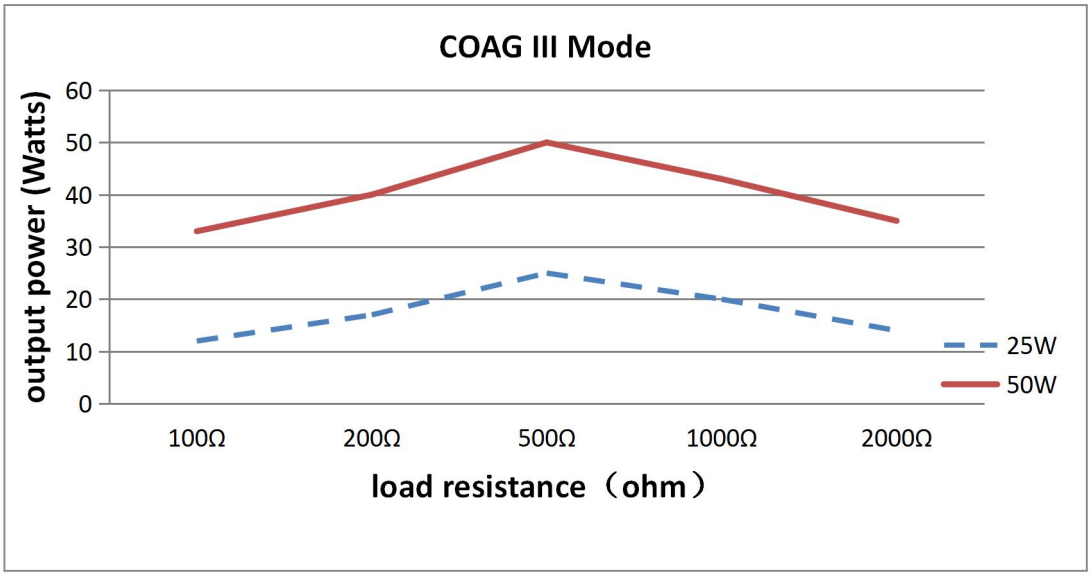
Figure 6-5



--------- Half setting 50W; ——— Full setting 100W

- **COAG III**

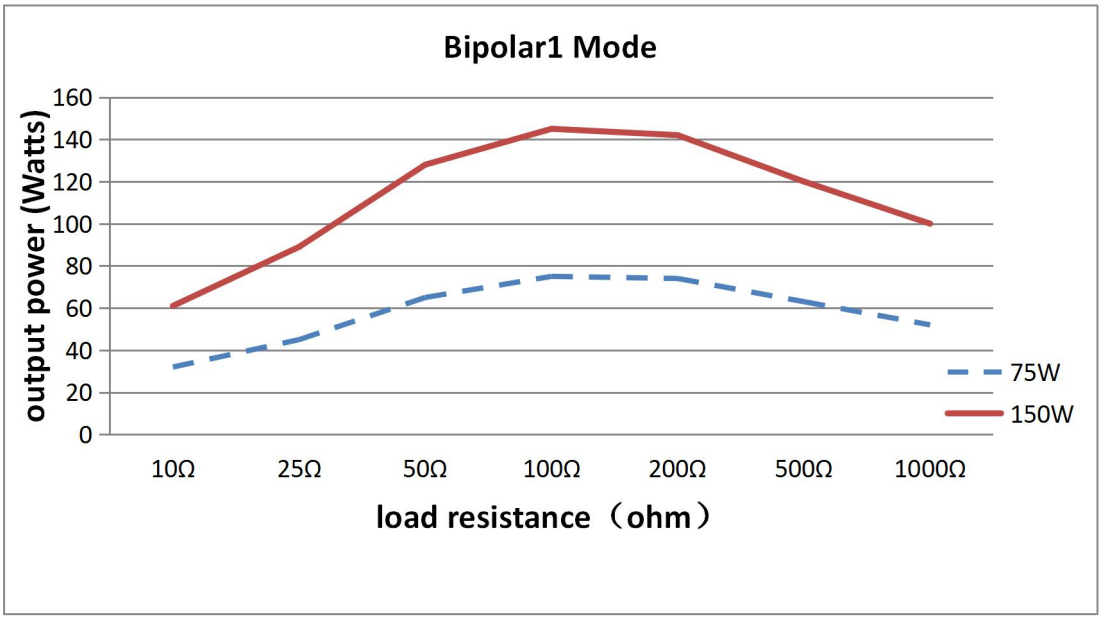
Figure 6-6



--------- Half setting 25W; ——— Full setting 50W

➢ **Bipolar I**

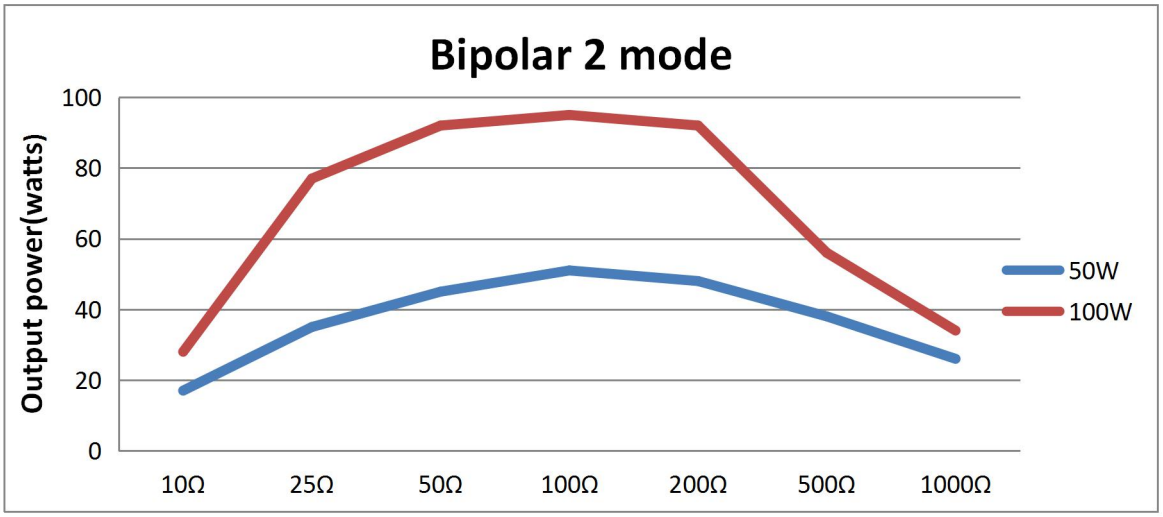
Figure 6-7



Half setting 75W; Full setting 150W

➢ **Bipolar II**

Figure 6-8



Half setting 50W; Full setting 100W

TROUBLESHOOTING

1. When there are sound prompts such as, no power output or audio and light alarm during operation of this machine, the machine cannot operate normally, please stop the machine and check if high voltage fuse is damaged. If the high voltage fuse is not damaged, please check if skin application plate and cable are in good condition; replace them if they are damaged.

2. Please note that when the machine output power, please ensure that power lead of the machine should well contact with power network.

3. Do not run the machine idly during operations to avoid accident.

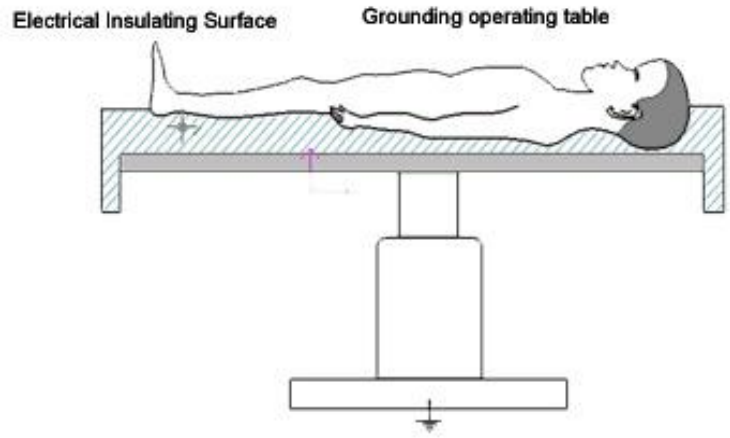
4. If power supply is not within the range of 120V/230V and power frequency of 60Hz/50Hz, please use power stabilizer.
Note that when the machine output power, please ensure that power lead of the machine should well contact with power network. If power supply is not 120V/230V or power frequency of 60Hz/50Hz, please use power stabilizer. Do not run the machine idly during operations to avoid accident.

5. Before operating the device, disinfect the head of electrotome, handle, bipolar forceps，cables and some other components and sections.
Disinfecting methods: wipe dirt with alcohol gauze, and then put it into formalin solution for suffocating under normal temperature for not less than 10 hours.

6. Accidental heat injury to body tissues
Usually, high frequency surgical operation always has a couple of risks for patients, medical staffs and environments. To avoid these risks during operation, surgeon and his assistant should aware these risks and avoid the happenings of accidents pursuant to regulations. Accidental heat injury to body tissues due to drain current of high frequency
During high frequency surgical operation, patient inevitably conducts the high frequency current to ground electric level. If the patient contacts with conductive object at this time, then high frequency current will be produced at the contacting point between patient and object, which causes heat putrescence. Not only is the metal the electric conductive substance, but also the wet cloth.

Warning

During high frequency surgical operation, patient must be isolated from conductive object. The black elastic mantle on operating table has certain conductivity for distributing electric charge. Therefore, it is not suitable to ensure the required isolation between patient and the metals on operating table. Therefore, a medium layer for isolating should be laid between patient and black mantle, such as dry covering cloth.



If this medium layer is getting wet during operation, such as due to sweating, washing liquid, urine etc., waterproof plastic membrane should be used to prevent medium layer from getting wet. Catheter should be used to drain urine out.

7. Heat injury due to accidentally starting up high frequency generator

If the high frequency generator is started accidentally, and there is a contact between electrode and patient or a contact through conductive object or wet cloth, then electric burn probably will happen on patient's body.

For example, accidental startup of machine will possibly happen due to following reasons:

● Pressing down foot pedal accidentally;

● Pressing down manual push button accidentally;

● Malfunctions of foot pedal, manual switch or cable;

● Electricity conductive liquid (such as blood, amniotic fluid, urine, physiological saline, washing liquid etc.) penetrates in foot pedal or manual switch

● Malfunctions in high frequency operation device

In order to avoid heat burning due to accidental startup of high frequency, pay attention to following rules in operation:

● Do not put electrode on the body of patient or by the side of patient at random absolutely, so as the electrode may contact directly with patient or contact through conductive object and wet cloth indirectly.

● Fix firmly the electrode lead and do not let it contact with patient, and also not contact with other leads.

● Set sound signal loudly enough to hear, which can prompts working conditions of high frequency generator.

● For some of operations such as celioscope surgical operation, even under non-working condition, cutting electrode or electrocoagulation electrode will inevitably contact with patient, special attention should be paid at this time. If electrodes mentioned above are actuated accidentally due to some errors, do not take them out of body without special monitoring. Otherwise, all parts contacting with the working electrodes will be burnt. Therefore, when this accident happens, cut off power supply of high frequency operation device immediately, and then, manages to take the electrodes out of body.

7.1 Heat injury due to output error of the device

The risk of Heat injury is in direct proportion with the intensity and time of cutting or set on the device.

Intensity of cutting or electrocoagulation should be set according to the applications, and the exciting time should be just enough for the use.

For example, according to standard settings, if the effect is not so good, the reason for this is probably the poor adhesiveness of neutral electrode, poor contact of electric connector, cable failure, or remnants of electric isolation on electrode. Check them before increasing power.

7.2 Heat injury due to heating electrode

During the process of cutting or electrocoagulating, cutting electrode or electrocoagulation electrode will be very hot due to electric arc and tissue temperature. Not long after cutting or electro-coagulating, if hot electrode contact with body tissue, it will accidentally injure tissues. Special attention must be paid during celioscope surgical operations such as pelvic cavity oviduct electrocoagulating or celioscope surgical polypus resection operations.

7.3 Stimulating nerve and muscle

A known risk of high frequency operation is the accidental electric stimulation to the nerve and muscle of patient. This stimulation comes from the effect of low frequency current, and low frequency current is possibly caused by low frequency current source, or caused by electric arc between applying electrode and patient's tissues.

A.C.with frequency over 300KHZ will not stimulate nerves and muscles.

During the process of cutting, powerful electrocoagulation and ejecting electro-coagulation, the electric arc between applying electrode and body tissues will make parts of high frequency current commutated to produce component of low frequency current that is forced to some extent, this component will stimulate parts of human body structure liable to stimulation, such as nerves and muscles.

When high frequency operation is made on body structure liable to stimulation, muscle contraction must be taken into consideration. For example, this condition will happen in the operations of bladder celioscope surgery around foramen obturatum muscle nerve or operation of facial nerve section.

8. Error code of Power ON self diagnostics

- Err--2: CUT malfunction
- Err--3: COAG malfunction
- Err--4: Bipolar malfunction

If any one of the above Error code proposed, please contact the local supplier or OBS for after-sales services.

MEASURES TO BE TAKEN DURING OPERATION OF THE DEVICE:
1. Connect perfectly the grounding cable.
Power supply of the device should be connected with main bus through three terminals; the longer terminal in the middle is the terminal grounding, which should be grounded during operation.

2. Before operating the device, disinfect the blade of electrotome, handle, bipolar forceps，cables and some other components and sections.
Disinfecting methods: wipe dirt with alcohol (brine) gauze, and then put it into formalin solution for suffocating under normal temperature for not less than 10 hours.

The guarantee period of machine is 1 years from the date of delivery

EC Representative

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