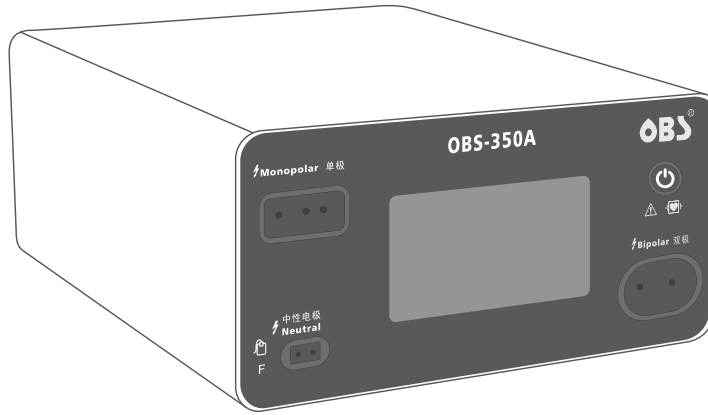
Electrosurgical Generator

OBS-350A

(LCD Version)

Instruction for Use



BAISHENG MEDICAL CO.,LTD.

BAISHENG MEDICAL CO.,LTD.

Read the contents described in this page carefully when initial use

- Welcome to use OBS Eletrosurgical Generator and accessories– Model ***OBS-350A LCD Version***

Declaration

Please check, there is any change for the position of the product.

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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 (LCD Version)
Reference No.: 20231010OBS350A
Issuing date: 2023.10.10

For Information Contact

Manufacturer: **BAISHENG MEDICAL CO., LTD.**
Add: No.11, Fusheng Road, XinHui District,
529100 JiangMen, GuangDong
PEOPLE'S REPUBLIC OF CHINA

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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.

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NOTICE

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

TABLE OF CONTENTS

SECTION 1 INTRODUCTION OF OBS-350A(LCD Version)

1.0 Indication for use

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

1.1 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(LCD Version), 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(LCD Version) Electrosurgical Generator only.

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

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

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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.

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

- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N_2O] 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.

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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.

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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.

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

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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.

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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 Section7 Technical Specifications.

The generator is equipped with a contact quality monitoring system (CQMS) (which monitors the status of the ESU pad connection, when a electrosurgical (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 135ohms, 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.

WARNINGS:

Therefore a warning is necessary to make the user aware that in sensitive structures neuromuscular stimulation can still occur leading to secondary RISKS like injury caused by muscle contractions.

There is potential risk of sensitive structures neuromuscular stimulation that can still occur leading to secondary RISKS like injury caused by muscle contractions during use of the Electrosurgical device.

1.2 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. Ifcontact 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.

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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.

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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.

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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.

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The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) 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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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.

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.

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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.

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Remove any loose fitting jewelry from the patient before activation.

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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.

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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.

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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.

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

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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.

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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.

1.3 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.

1.4 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(Vessel Sealing) 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 135ohms), 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 135ohms, the alarm will be activated by Red of "ALARM" indicator as well as Error code 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.

见6.2故障和处理

• Power peak value system (PPS)

• PPS: The Peak Power System

1) For optimal support during the initial cutting stage, especially low-contact impedance situations, allowing the electrode to start in contact with target tissue;
2) This feature allows the delivery of an above average output during the initial incision phase, if needed;
3) 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;
4) 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;
5) 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.
6) This kind of unit can limit average power within relative low magnitude, which is an improvement for preventing patient from suffering accidental heat trauma.
7) Pure CUT, Blend CUT and Bipolar modes are equipped this PPS function.
8) Standard connectors: These connectors accept the latest monopolar and bipolar instruments.

WARNINGS:

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.

1.5 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.

1.6 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 LABELS AND SYMBOLS

Explanation for used symbols

	Trademark of BAISHENG MEDICAL CO.,LTD		Defibrillator Proof Type CF Equipment
	Equipotential Symbol		Mandatory: Refer to instruction manual/guide
	RF Isolate–patient connections are isolated from earth at high frequency		Protective earth connection
	Neutral electrode		Caution
	Non-Ionization radiation		Fragile
	Manufacturer		Symbol for “Relative humidity limitation”
	Symbol for "temperature limitation”		This way up
	Keep dry		Do not dispose of this device in the unsorted municipal waste stream.
	Horizontal placement		CE marking
	SERIAL NUMBER		

SECTION 3 INSTALLATION AND CONNECTIONS

3.0 Initial inspection

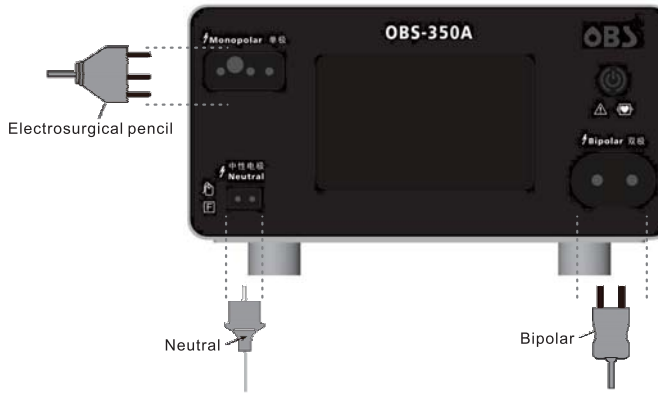
When you first unpack your OBS-350A, inspect it visually:

- 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.

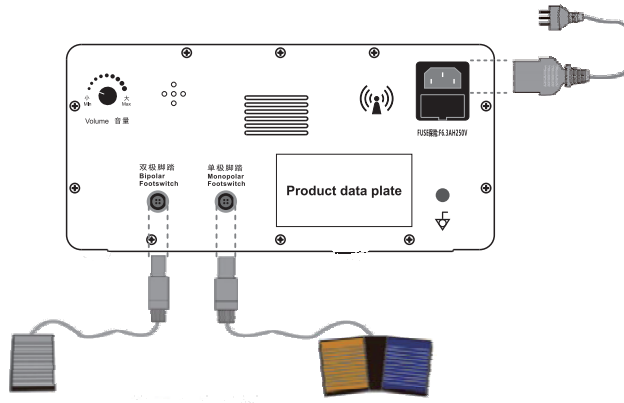
WARNINGS:

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.

front panel



rear panel



3.1 Rear panel

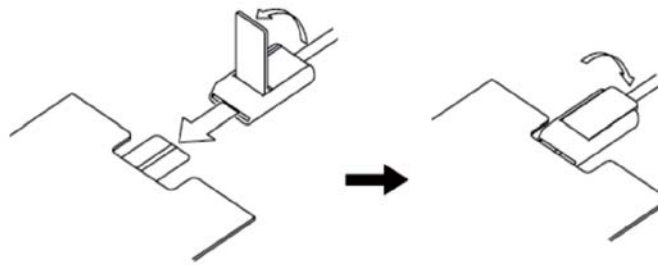
1. Footswitch connector
There are two footswitch connectors mounted on the rear panel labeled BIPOLAR FOOTSWITCH and MONOPOLAR FOOTSWITCH, each connector controls the corresponding output receptacle on the front panel. Foot pedal and manual control handpieces are effective simultaneously. Bipolar function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

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

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.

4. Rewirable fuse
There have two rewirable fuses, one for Zero line and the other for Fire line.

connection of neutral electrode



Connecting the neutral electrode
1.For neutral electrodes with a pre-attached cable consider the following procedure: Insert the neutral electrode plug into the neutral electrode socket (suitable for 2 pin plugs with 2.5 mm pin diameter and pin spacing 10 mm, US standard) on the front panel of the electrosurgical generator (see Picture 1).

2.For neutral electrodes without a pre-attached cable consider the following procedure: Lift the lever-locking arm of the neutral electrode cable “P-cord”, and then position the neutral electrode tab evenly between the clamp jaws. Lock the clamp by fully pressing down the lever-locking arm (see Picture 3). Insert the “P-cord” plug on the electrosurgical generator side into the neutral electrode socket (suitable for 2 pin plugs with 2.5 mm pin diameter and pin spacing 10 mm, US standard) on the front panel of the electrosurgical generator (see Picture 1).

SECTION 4 OPERATION

Before starting an operating procedure, confirm that the connections of the power cord, footswitch, neutral electrode and HF instruments are secure and correct.

DANGER:

If during operation any irregularity will be suspected, do not use the electrosurgical generator and refer to Section 6, “Troubleshooting”. If the irregularity is still suspected after consulting chapter 8, contact OBS. Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.

4.0 Turn on the electrosurgical generator

This switch turns the electrosurgical generator on and off.

NOTE:

1.By using the electrosurgical generator for the first time there will be a default setting of the assigned modes, output power settings and the effects.
2.By switching between the modes, the electrosurgical generator automatically recalls the settings used for each mode individually.
3.By switching on the electrosurgical generator after one or more procedures have been done, the last used mode, effect and output power is presented at the “All screen”. Before starting the procedure, confirm the correctness of the settings.

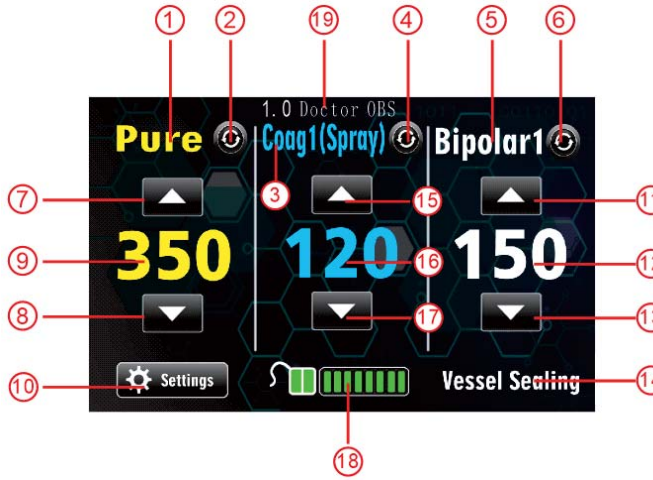
4.1 starting up

When turning on the device, it enters a self check state. Please do not operate the device. After the system self check is normal, it will automatically enter the user operation homepage.

4.2 Shutting down

When shutting down, the device enters the save data state. Please do not operate the device. After the system data is saved, it will automatically enter the standby state. If the device is not used for a long time, please disconnect the power cord from the network power supply

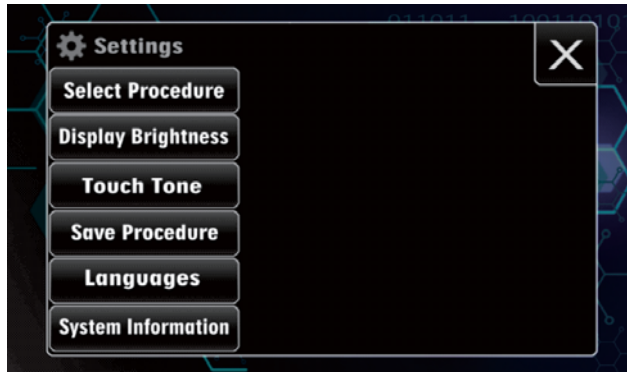
4.3 Operating main interface



1. Indication of currently set Monopolar cut output mode
   Pure cut / Blend cut1 / Blend cut 2
2. Monopolar cut mode switching button
   When this function button is pressed, it switches between pure cut, blend cut 1 or blend cut 2 modes.
3. Indication of currently set monopolar cut output mode
   Coagulation1(Spray coag)/Cogulation2(Forced coag)/Cogulation3(Sofe coag)
4. Monopolar coagulation mode switching button
   When this function button is pressed, the coagulation 1, coagulation 2, or coagulation 3 mode is switched.
5. Indication of the currently set bipolar coagulation output mode
   Bipolar1(vessel sealing)/Bipolar2(Standard coagulation)
6. Bipolar coagulation mode switching button
   When this function button is pressed, the bipolar coagulation 1 or bipolar coagulation 2 mode is switched.
7. Monopolar cut power button
   When the function button is pressed once, the monopolar cut power value increases. When the function button is long pressed, the monopolar cut power value increases continuously and rapidly.
8. Monopolar cut power reduction button
   When the function button is pressed once, the monopolar cut power value decreases. When the function button is long pressed, the monopolar cut power value decreases continuously and rapidly.
9. The currently set output power value of monopolar cut
10. Set menu button
    When you press this function button, you will enter the <Settings Menu Screen>
11. Bipolar coagulation power increase button
    When the function button is pressed once, the bipolar coagulation power value increases. When the function button is long pressed, the bipolar coagulation power value increases continuously and rapidly.
12. Currently set bipolar coagulation output power value

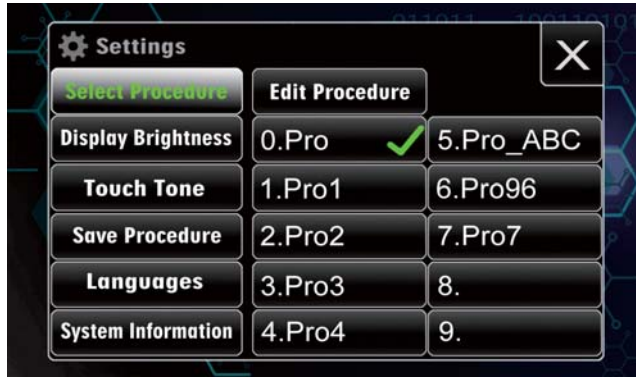
13.Bipolar coagulation power reduction button
When the function button is pressed once, the bipolar coagulation power value decreases. When the function button is long pressed, the bipolar coagulation power value decreases continuously and rapidly.
14. Vessel sealing coagulation mode indication
This icon is displayed when the selected mode is bipolar coagulation 2, otherwise it is not displayed.
15. Monopolar coagulation power increase button
When the function button is pressed once, the monopolar ocoagulation power value increases. When the function button is long pressed, the monopolar coagulation power value increases continuously and rapidly.
16. Currently set output power value of monopolar coagulation
17. Monopolar coagulation power reduction button
When the function button is pressed once, the monopolar coagulation power value decreases. When the function button is long pressed, the monopolar coagulation power value decreases continuously and rapidly.
18. Contact quality monitoring indicator of neutral electrode
When using a split neutral electrode, a green prompt indicates that the neutral electrode is in good contact with the human body, and a red prompt indicates that the neutral electrode has fallen off from the human body.
19. The currently selected program name
Program selection function reference 4.5

4.4 Setting menu screen



1. Choose a program
When pressing this function button, enter the <select program setting screen>
2. Brightness adjustment
When pressing this function button, enter the <Brightness Adjustment Setting Screen>
3. Button sound
When the function button is pressed, the <key sound setting screen> will be entered.
4. Save the program
When this function button is pressed, the <Save Program Settings Screen> will be entered.
5. Language
When pressing this function button, enter the <language setting screen>
6. System information
When pressing this function button, enter the <system information screen>
7. X button
When you press this function button, you will return to the <main operation screen>

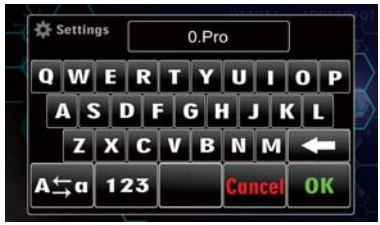
4.5 Select program settings screen



The select program function is to recall a setting saved in the memory, a total of 10 set. To modify and save program settings, refer to 4.9

1.Call the program
Press the button to call the program, such as "0.Pro", the selected program will be called, and the main operation picture will display the value preset for the program. The program name displayed in the main drawing of the operation is updated to the program name, such as "0.Pro".
2.Edit program button
When this function button is pressed, the <Edit Program Settings Screen> will be entered.

4.6 Edit program settings screen



Capital letter input

Lowercase letter input

digital input

1. Capital letter input
If it displays <lowercase letter input screen>, press the key A⇆a to enter the capital letter input screen, press the capital letters "A-Z", and enter the corresponding capital letters for the program name.

2. Lowercase letter input
If it displays <capital letter input screen>, press the key A⇆a to enter the lowercase letter input screen, press the lowercase letters "A-Z", and enter the corresponding lowercase letters for the program name.

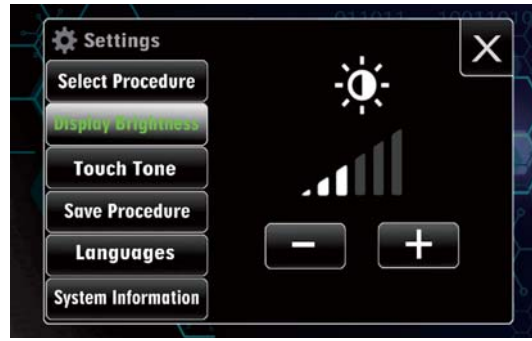
3. Digital or character input
Press the key 123 to enter the digital or character input screen. Press the number "0-9" or the characters "." "-" to enter the corresponding digital or characters for the program name.
Press the key ABC to enter the capital letter input screen.

4. Space
Press the key ▬ and enter a space for the program name.

5. Delete a letter or number or character
Press key ← to delete a letter or number or character.

6. Cancel save
Press the key Cancel to cancel the currently edited program name.
Press the key OK to save the currently edited program name.

4.7 Brightness adjustment setting screen



1. − Button
When this function button is pressed, the screen brightness decreases
2. + Button
When this function button is pressed, the screen brightness increases
3. Button
When this function button is pressed, the screen brightness increases

4.8 Button sound setting screen

1. ON
   When the function button is pressed, the button sound is turned on. The screen displays the icon.
2. OFF
   When the function button is pressed, the button sound is turned off. The screen displays the icon.

4.9 Save program screen

1. NO
   When this function button is pressed, the value set by the current program is not saved.
2. YES
   When this function button is pressed, the value of the current program setting is saved.

4.10 Language setting screen

1. 简体中文Chinese
   When this function button is pressed, the system sets the language to Simplified Chinese font.
2. 英文English
   When this function button is pressed, the system sets the language to English font.

4.11 System information screen

1. Display the model and version number of this device

SECTION 5 DURING USE

5.0 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, handpiece of electrode, cable and plug etc. should be kept in good conditions

5.1 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.

.....

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.

.....

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.

.....

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 of bipolar forceps and various accessories with medical solutions, and even to immerse them into medical solutions and other solutions.

Cables of handpiece, 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.

5.2 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.

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

.....

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.

.....

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 handpiece and electrode, because the polar plate is a product of thin metal polar plate or one-off skin application plate.

.....

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.

5.3 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 thanthat 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.

5.4 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 [N_2O] 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 equipment) 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 6 MAINTAINTION of OBS-350A(LCD Version)

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 flat-head 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.

.....

NOTICE:

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

Fuse replacement in the fuse holder

SECTION 7 TECHNICAL SPECIFICATIONS

7.0 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):	See the remark on rear panel

PURE CUT	(1W~350W, Load: 500Ω)
BLEND 1	(1W~250W, Load: 500Ω)
BLEND 2	(1W~150W, Load: 500Ω)
COAG 1	(1W~120W, Load: 500Ω)
COAG 2	(1W~100W, Load: 500Ω)
COAG 3	(1W~50W, Load: 500Ω)
BIPOLAR 1	(1W~150W, Load: 100Ω)
BIPOLAR 2	(1W~100W, Load: 100Ω)

Dimensions and Weight:

W x H x D	44cm x 37cm x 20cm
Weight	7 kg

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

7.1 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 natural electrode 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.

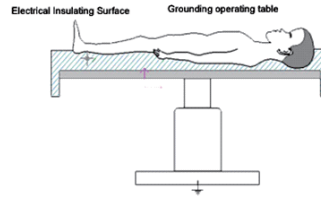
4. If power supply is not within the range of 120V/230V and power frequency of 60Hz/50Hz, please use power stabilizer.
Note that when the machine output power, please ensure that power lead of the machine should well contact with power network. If power supply is not 120V/230V or power frequency of 60Hz/50Hz,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

5. Before operating the device, disinfect the head of electrode, handpiece, 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.

NOTICE:

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.

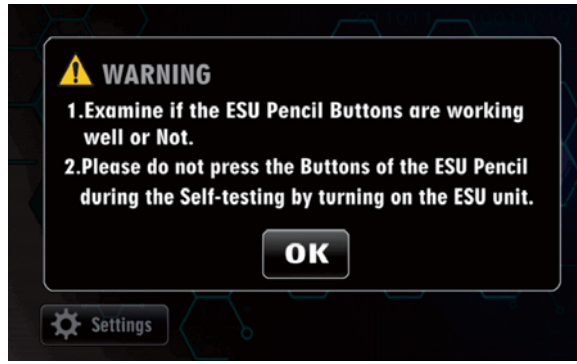
When high frequency operation is made on body structure liable to stimulation, muscle contraction must be taken into consideration. For example, this condition will happen in the operations of bladder celioscope surgery around foramen obturatum muscle nerve or operation of facial nerve section.

7.4 Troubleshooting
1. If the electrosurgical generator cannot work properly, the operation should be stopped immediately.
2. Check whether there is an error screen display
3. If an error screen appears, refer to the information in section 7.5 "Error Screens, Codes and Measures" for fault identification and correction.
4. If the above remedial measures cannot solve the problem, please stop using the electrosurgical generator and contact Baisheng Company for repair.

7. 5 Error screens, codes and actions
7.5.1 Neutral electrode alarm

1. Installation and Connections Check whether the neutral conductor cable is correctly connected to the OBS-350A generator, refer to Section 3 Installation and Connections
2. Check whether the neutral electrode and lead connection clamp are connected normally, refer to Section 3 Installation and Connections
3. If the neutral electrode connecting wire is damaged, replace it with a qualified neutral electrode connecting wire.
4. If the neutral electrode is damaged, replace it with a qualified neutral electrode.

7.5.2 Pencil button alarm



1. Release the pen button and click the OK button.
2. Check whether the pencil and OBS-350A generator are correctly connected, refer to Section 3 Installation and Connections
3. Unplug the pencil, check whether the pencil is damaged, and replace it with a qualified pencil.

7.5.3 Foot button alarm

1. Release the foot switch button and click the OK button.
2. Check whether the foot switch and OBS-350A generator are correctly connected, refer to Section 3 Installation and Connections.
3. Unplug the foot switch, check whether the foot switch is damaged, and replace it with a qualified foot switch.

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 electrode, handpiece, 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.

SECTION 8
ELECTROMAGNETIC COMPATIBILITY (EMC)

8.0 Warning

● The device shall be used in hospitals except for near the RF shielded rooms as for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. The doctor shall be remove the device away from the interference source as the magnetic resonance device and restart it to check the function if normal, when the device failed to perform the surgery.
● Use of the device adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, the device and the other device should be observed to verify that they are operating normally.
● Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
● Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Fullwell gennerator FW-350A, including cables specified by the manufacturer. Otherwise, degradation of the performance of the device could result.
● Recommended applicable accessories list:

Applicable accessories	Maximum lengths of shielded cables
Electrosugical pencil	2m
Electrosugical pads	2m
Electrosugical forceps	2m

Note1: In addition to the specification of accessories provided as above, the use of other specification accessories may result in an increase in the emission of the high-frequency surgical equipment or a reduction in immunity.
a) the compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL;
b) any deviations from this collateral standard and allowances used;
c) * all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.

Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC 60601-1-2.

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

NOTES:

● At 80 MHz and 800 MHz, the higher frequency range applies.
● These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 2: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment.

Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used insuch an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Radiated RF per ISO 9919 clause 36 and ISO 80601-2-61 clause 202.6.2.3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz 20 V/m 80 MHz to 2.5 GHz	N/A 3 V/m 20 V/m	Recommended Separation Distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

a.Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed

RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The following table details the recommended separation distances between portable and mobile RF communications equipment and this device.

Table 4: Recommended Separation Distances

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

OBS®

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