# Electrosurgical Generator

## User Manual

# *OBS-100C*


## OBS Electrosurgical Generator

Made in China

Printed in China

Version No.: 20181018-OBS100C

**BAISHENG MEDICAL CO., LTD.**

**Read the contents described in this page carefully when initial use**

- Welcome to use Electrosurgical Generator– Model OBS-100C

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-100C only.

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

**Equipment Covered in this Manual**
Electrosurgical generator: OBS-100C
Reference No.: 2016OBS100C

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**BAISHENG MEDICAL CO., LTD.**

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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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**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-100C*

**This section includes the following information:**

- ✧ ***Indication for use***
- ✧ ***Key Features***
- ✧ ***Compatible Accessories Requirements***
- ✧ ***Accessories Included***
- ✧ ***Safety***
- ✧ ***Contraindications***

## *CAUTIONS:*

Read all warnings, cautions, and instructions provided with this generator before using.

Read the instructions, warnings, and cautions provided with electrosurgical accessories before using. Specific instructions are not included in this manual.

## ✧ *Indication for use*

**The OBS-100C Electrosurgical Generator is intended to be used for electrosurgical cut, blend, coagulation, fulguration, and bipolar procedures.**

## ✧ *Key Features*

OBS-100C Electrosurgical Generator with state-of-art technology offers superb performance on the electro-surgery, and shows remarkable safety, reliability and convenience.

Key features of OBS-100C are as follows:

- Two levels of coagulation: pinpoint coagulation and fulguration
  - Pinpoint coagulation provides precise control of bleeding in localized areas.
  - Fulguration provides greater control of bleeding in highly vascular over surface areas.
- Memory: The unit incorporates as many as ten user-defined presets for easy recall of frequently used settings. The unit will reset to the last activated Preset setting when Power ON.
- Isolated RF output for Cut, Blend and Coag modes
  - This minimizes the potential of alternate site burns.
- Ground Referenced RF output for Fulguration modes
- Standard connectors: These connectors accept the latest monopolar and bipolar instruments.
- An ESU pencil with power handpiece that control can be attached.

## ✧ *Compatible Accessories Requirements*

➢ 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.When using PURE Cut mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 650Vpeak max.

- ✓ When using Blend mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 801Vpeak 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 307Vpeak max.
- ➢ To avoid incompatibility and unsafe operation, we recommend using the following OBS accessories with the OBS-100C:

## ✧ *Accessories Included*

Electrosurgical Pencil, disposable 2pcs
Bipolar Forceps with cable, reusable 1pc
Disposable Electrosurgical Pad 2pcs
Cable for Electrosurgical Pad, reusable 1pc
Foot switch 1pc
Power cord 1pc
Manual 1pc

## ✧ *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-100C 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.

## ✧ *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-100C, this section presents the warnings and cautions that appear throughout this user manual. 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 manual.

### *WARNINGS:*

**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-100C in the presence of flammable materials.

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**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 which may accumulate in body cavities such as the bowel
• 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.

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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.

---

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.

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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.

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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.

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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.

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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 patient return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised.

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The entire area of the neutral electrode 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 return electrode 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 ($N_2O$) 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.

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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.

.....

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.

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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.

.....

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.

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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.

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.

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.

**NOTICE**

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

## ✧ *Contraindications*

There are no known contraindications.

# *SECTION 2*

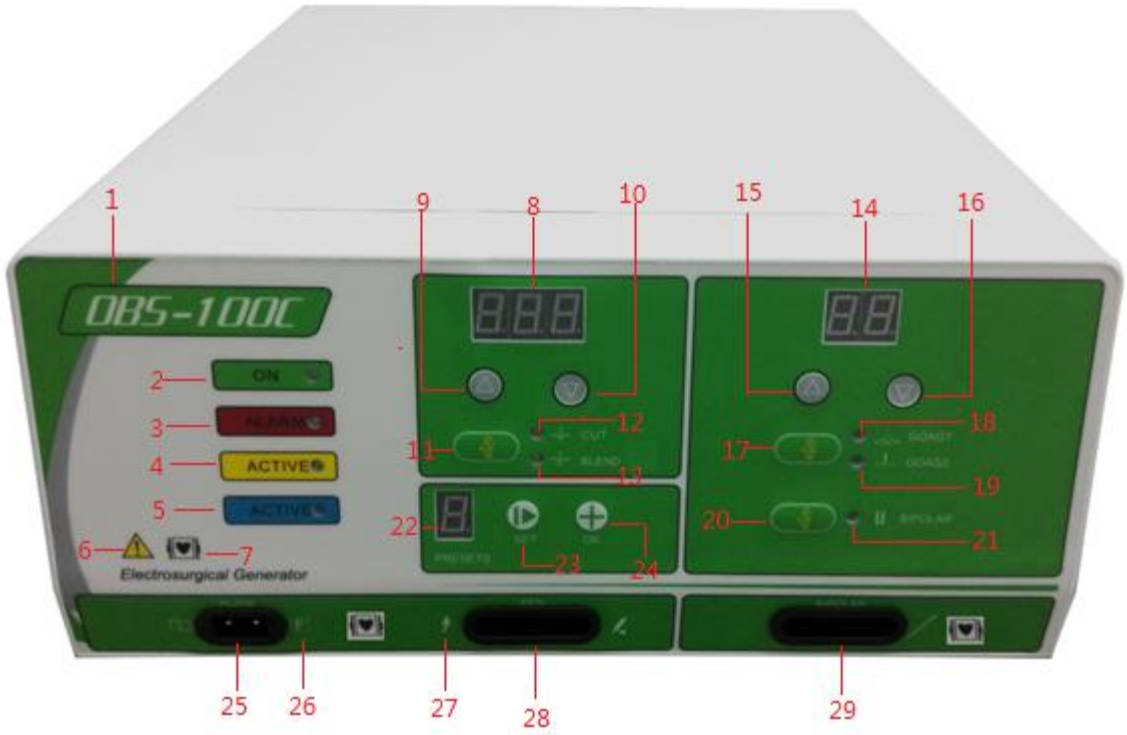
## *Controls, Indicators and Receptacles*

**This section includes the following information:**

- ✧ ***The Front Panel Controls, Indicators and Receptacles***
- ✧ ***The Rear Panel Controls, Indicators and Receptacles***
- ✧ ***Labeling and Symbol used***

## ✧ *The Front Panel Controls, Indicators and Receptacles*

Figure 2-1: Layout of controls, indicators, and receptacles on the front panel




| **Table2-1**: Illustration explanation of Front panel | | | |
|---|---|---|---|
| **1** | Model mark | **16** | POWER decrease button |
| **2** | Power on indicator | **17** | Coagulation or Bipolar selection |
| **3** | Fault indicator | **18** | Coagulation operating indicator |
| **4** | Cut mode indicator | **19** | Bipolar operating indicator |
| **5** | COAG mode indicator | **20** | Fulguration selection button |
| **6** | See instructions | **21** | Fulguration operating indicator |
| **7** | Defibrillation-proof type CF applied part | **22** | Memory mode display |
| **8** | CUT POWER display | **23** | Memory mode setting |
| **9** | POWER increase button | **24** | Memory setting confirmation |
| **10** | POWER decrease button | **25** | Neutral pad receptacle |
| **11** | Cut or Blend selection | **26** | RF isolation |
| **12** | Cut operating indicator | **27** | Caution high voltage |
| **13** | Blend operating indicator | **28** | ESU pencil receptacle |
| **14** | COAG and Bipolar power display | **29** | Bipolar accessory receptacle |
| **15** | POWER increase button | | |

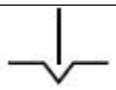
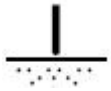
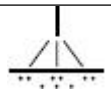
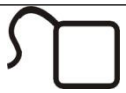
## ✧ *The Rear Panel Controls, Indicators and Receptacles*

Figure 2-2: Layout of controls, indicators, and receptacles on the rear panel


| **Table 2-2:** Illustration explanation of Rear panel | | | |
|---|---|---|---|
| **1** | Volume control knob | **4** | AC line receptacle |
| **2** | Essential label | **5** | Rewirable fuse |
| **3** | Footswitch receptacle | **6** | Power ON/OFF |

## ✧ *Labeling and Symbol used*

### *For the OBS-100C Electrosurgical Generator*

| | | | | |
|---|---|---|---|---|
|  |  |  |  |  |
| Registered trademark | POWER ON/OFF | Grounding | Caution – high voltage | CF defibrillation |
|  |  |  |  |  |
| Isolated from ground | Caution | CONSULT INSTRUCTIONS FOR USE | SERIAL NUMBER | Output mode selection |
|  |  |  |  |  |
| Cut mode | Blend mode | Coagulation mode | Bipolar mode | Fulguration mode |
|  |  |  |  |  |
| Select next preset | Set new preset | Patient return electrode | Monopolar handpiece receptacle | Bipolar forceps Receptacle |
|  | Mandatory: Refer to instruction manual/guide |  | Do not dispose of this device in the unsorted municipal waste stream. | |

# *SECTION 3*

## *Getting Started*

**This section includes the following information:**

- ✧ ***Initial Inspection***
- ✧ ***Installing the Unit***

## ✧ *Initial Inspection*

When you first unpack your OBS-100C, inspect it visually:

- Verify the outer package integrity and information marked
- Verify the integrity of the inner unit pertaining to the impact, deformation, damage and symbol information

If the unit is damaged, notify OBS Customer Service immediately.
Do not use any damaged equipment.

## ✧ *Installing the Unit*

Place the OBS-100C 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 proposed in this User manual.***

# *SECTION 4*

## *USING the OBS-100C*

**This section includes the following information:**

- ✧ ***Inspecting the Generator and Accessories***
- ✧ ***Setup Safety***
- ✧ ***Setting Up***
- ✧ ***Preparing for Monopolar Surgery***
- ✧ ***Preparing for Bipolar Surgery***
- ✧ ***Activation Safety***
- ✧ ***Activating the Unit***

## *CAUTIONS*

Read all warnings, cautions, and instructions provided with this generator before use.

Read the instructions, warnings, and cautions provided with compatible electrosurgical accessories before use. Specific instructions are not included in this manual.

## ✧ *Inspecting the Generator and Accessories*

Before each use of the OBS-100C Electrosurgical Generator, verify that the unit and all specified accessories are in good working order:

- Inspect for damage to the Electrosurgical Generator and all its connections.
- Verify that the appropriate accessories adapters integrity, of which parameters shall be compatible with our OBS-100C. Please refer to "Section 1- Compatible Accessories Requirements" for details.
- Only a solid ESU pad(solid patient return electrode) is available because of the ESU pad connection check function only applicable to a solid ESU pad, if a split ESU pad connected, the Fault indictor will always be light.
- Inspect all cords and connectors for signs of wear, damage, and abrasion.

## ✧ *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.***

---

***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.***

---

***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.***

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***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.***

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***Potential for alternate site burns increases if the return electrode is compromised.***

## *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.***
***Connect the power cord to a wall outlet having the correct voltage. Otherwise product damage may result.***

## ✧ *Setting Up*

**1.** If the unit is not already installed refer to Section 3 of this manual for the installation procedure.

**2.** Turn on the generator by pressing the power switch ON (|) of the rear panel.
Verify the following:

- The visual indicator of "On" on the front panel illuminate Green.
- The visual indicator of "Fault" on the front panel illuminate Red with the alerts of 2 beeps(when a solid ESU pad connected, the "Fault indicator will extinguish")
- Activation tones sound to verify that the speaker is working properly.

**3. Preset display**

The unit resets to the last activated Preset setting. The Preset display will display a number from 0 to 9 when press the "▶|" key by turns if preserved previously. The power display will show the power level for the last used Preset setting.

**4.** Connect the accessories and set the generator controls. Refer to Preparing for Monopolar Surgery or Preparing for Bipolar Surgery as the following.

**5.** Output terminal

- Monopolar of this unit adopts handle output power. Handle output socket, handle switch and foot pedal are effective simultaneously.
- Bipolar of this device adopts bipolar forceps output power, both bipolar forceps output socket, foot pedal are effective.

**6.** This device has functions of pure cut, blend cut, COAG, fulguration and bipolar COAG;

### *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.***

- **OBS-100C Memory Feature Description**

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- The OBS-100C incorporates 9 user-defined Presets for easy recall of frequently used settings.
- Storing and Recalling Preset Settings

- Select the desired preset number (0-9) by pressing the Recall button. "  "
- Select the desired mode to be stored by pressing one of the mode membrane switches " 

"
- Select the desired power to be stored by utilizing the power output control knob. "  " and "  "
- Once all the settings are selected, pressing the Presets "Set" Button for save. "  "

- To indicate the settings have been stored, there is a different voice to sound 2 times for prompt.

- To recall a preset simply press the Presets "Recall" button to toggle through all the presets.

## *NOTICE:*

***The unit will reset to the last activated Preset setting no matter whether the setting was saved or not.***

"  " ***indicates power increase;*** "  " ***indicates power decrease***

---

## ✧ *Preparing for Monopolar Surgery*

**Cut, Blend, and Coagulation modes require a patient return electrode.**

**Applying the Patient Return Electrode:**

- ➢ 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(patient return electrode);  Split ESU pad

**(*A solid ESU pad is required to connect with our OBS-100C)**

- 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 split return electrode**

If a non-compatible return electrode is used, such as the Vp of return electrode is less than the unit, there may be risk of burnt or electric shock.

When applying a split ESU pad, there is a visual and acoustic signal for "Fault" alarm, the unit stops output.

Risk of burns for the patient under the ESU pad

- Check the ESU pad's instructions for its suitability with the OBS-100C generator.
- Use only suitable ESU pad.

## *WARNINGS:*

Potential for alternate site burns increases if the ESU pad is compromised.

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.

**Connecting Accessories**

- Plug the handpiece into the monopolar output on the lower middle of the front of the unit. "  "

- The plug is designed to fit in only one direction. Plug the smaller round connector from the handpiece into the receptacle on the bottom of the unit.
- The three button handpiece is designed to give the doctor complete fingertip control of the power settings.

- Slide the desired active electrode into the handpiece until it is firmly seated.
- Slide the handpiece from above into another prepared holder near to the unit.
- Plug the male end of the ESU pad cable into the Patient Plate receptacle located to the lower left of the front of the unit. "  "

## *NOTICE:*

***A return electrode is not required for the fulguration mode.***

---

***There is two beeps voice prompt and then the "Fault" indicator will be illuminated Red when the return electrode is disconnected, but the unit can output normally under the Fulguration mode.***

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***There is two beeps voice prompt and then the "Fault" indicator will be illuminated Red when the return electrode is disconnected, and the unit stops output under the other mode of monopolar.***

---

- An optional footswitch may be used with monopolar procedures. If the footswitch is utilized, plug the footswitch cable into the footswitch receptacle. While using a footswitch the output will be delivered via the handpiece.
- The activation button on the handpiece will continue to function while a footswitch is connected to the unit.
- Choose the Monopolar mode of operation by pressing the desired membrane switch on the front panel. Monopolar modes include Cut, Blend, Coagulation, and Fulguration.
- Set the output power either by using the up and down membrane switch on the front of the unit or by the up and down buttons on the handpiece (if a fingerswitch handpiece used). When power level adjustment is being made by the handpiece an audible tone will sound to indicate that the power level has been changed.

- Depressing and holding the up or down buttons will cause the power settings to change more rapidly for quick adjustment of the output power.
- Power adjustment increments:

- **Fulguration**(the max output 35watts)
  0-10 range: 0.1watt increments
  10-35range: 1.0 watt increments
- **Cut, Blend, Coagulation**
  1.0 watt increments

## *NOTICE:*

***The output settings cannot be adjusted when the unit is being activated.***

- The unit is now ready to perform surgery. Refer to Activating the Unit later in this section.

## *NOTICE:*

***The parameter of accessories compatibility***

- ✓ Associated equipment and accessories used must be rated to withstand the combination of the Vpeak rating and Crest Factor for the following RF modes:
- ✓ When using PURE Cut mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 650Vpeak max.
- ✓ When using Blend mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 801Vpeak max.
- ✓ When using Coagulation1 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 Coagulation2 (Fulguration) mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 2177 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 307Vpeak max.
- ✓ To avoid incompatibility and unsafe operation, we recommend using the OBS accessories with the OBS-100C.

## ✧ *Preparing for Bipolar Surgery*

- Insert the two connectors from the bipolar cable into the bipolar accessory receptacle.
- Connect the desired forceps to the operating end of the bipolar cord.
- Plug the footswitch cable into the footswitch receptacle. A footswitch is required to activate the Bipolar mode.

### *NOTICE:*

***The patient return electrode is not utilized during bipolar procedures.***

***The is only one Footswitch receptacle for both monopolar and bipolar***

- Select the Bipolar mode by pressing the membrane switch on the front of the unit.

- Set the output power either by using the up and down membrane switch on the front of the unit or by the up and down buttons on the handpiece. When power level adjustment is being made by the handpiece an audible tone will sound to indicate that the power level has been changed. Depressing and holding the up or down buttons will cause the power settings to change more rapidly for quick adjustment of the output power.

- Power adjustment increments:
  **Bipolar**(the max output 80watts)
  0-10 range: 0.1watt increments
  10-80range: 1.0 watt increments

### *NOTICE:*

***The output settings cannot be adjusted when the unit is being activated.***

- The unit is now ready to perform surgery. Refer to Activating the Unit later in this section.

## ✧ *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 OBS100C Electrosurgical Generator 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.***

## *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 loose fitting 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.***

## ✧ *Activating the Unit*

### *Monopolar Activation*

**1.** If the unit is not already set up, follow the set up procedure to prepare the unit for operation.

**2.** Remove the handpiece from the holder. Place the handpiece in the desired position.

**3.** To activate the unit, depress the activation button on the handpiece or depress the pedal on the footswitch. While the unit is activated, the appropriate audible tone is sounded and one of the related activation LEDs will illuminate.

**4.** When the procedure is completed, turn the unit off.

**5.** Return the handpiece to the holder. The handpiece or electrode should be disposed after each procedure. If contamination has occurred to the handpiece, the handpiece should be sterilized.

### *NOTICE:*

***When sterilizing the handpiece of reusable follow the manufacturer's sterilization instructions that accompany the handpiece.***

### *Bipolar Activation*

**1.** If the unit is not already set up, follow the set up procedure to prepare the unit for operation.

**2.** Place the forceps in the desired position.

**3.** To activate the unit depress the footswitch pedal. While the unit is activated, an audible tone is sounded and the blue activation LED will illuminate.

**4.** When the procedure is completed, turn the unit off.

**5.** Remove the forceps from the bipolar cord and sterilize.

### *NOTICE:*

***When sterilizing the forceps of reusable follow the manufactures sterilization instructions that accompany the forceps.***

# *SECTION 5*

## *Maintaining the OBS-100C*

**This section includes the following topics:**

- ✧ ***Cleaning***
- ✧ ***Periodic Inspection***

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 normal saline (0.9%) or alcohol (75%), 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.***

## *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*

- Every six months, visually inspect the OBS-100C Electrosurgical Generator for signs of wear or damage.

- 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

# *SECTION 6*

## *Repair Policy and Procedures*

**This section includes the following information:**

- ✧ ***The Manufacturer's Responsibility***
- ✧ ***Returning the Generator for Service***

## ✧ *The Manufacturer's Responsibility*

Baisheng Medical is responsible for the safety, reliability, and performance of the generator only under the following circumstances:

- The user has followed the installation and setup procedures in this user'manual.
- Persons authorized by OBS performed assembly operation, readjustments, modifications, or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.
- Equipment use is in accordance with the Baisheng Medical instructions for use.

## ✧ *Returning the Generator for Service*

Before you return the generator, call your OBS representative for assistance. If instructed to send the generator to OBS, first obtain a Returned Goods Authorization Number. Then clean the Generator and ship it to OBS for service.

**Step 1 – Obtain a Returned Goods Authorization Number**

Call the OBS Customer Service Center to obtain a Returned Goods Authorization Number.

Have the following information ready when you call:

- Hospital / clinic name / customer number
- Telephone number
- Department / address, city, state, and zip code
- Model number
- Serial number
- Description of the problem
- Type of repair to be done

**Step 2 – Clean the Generator**

Complete the process according to Section 5-Cleaning

**Step 3 – Ship the Generator**

**A.** Attach a tag to the generator that includes the Returned Goods Authorization Number and the information listed as Step 1.

**B.** Be sure the generator is completely dry before you pack it for shipment.

**C.** Ship the generator, prepaid, to the address given to you by the OBS Service Center.

# *SECTION 7*

## *Technical specifications*

## *Performance characteristics*

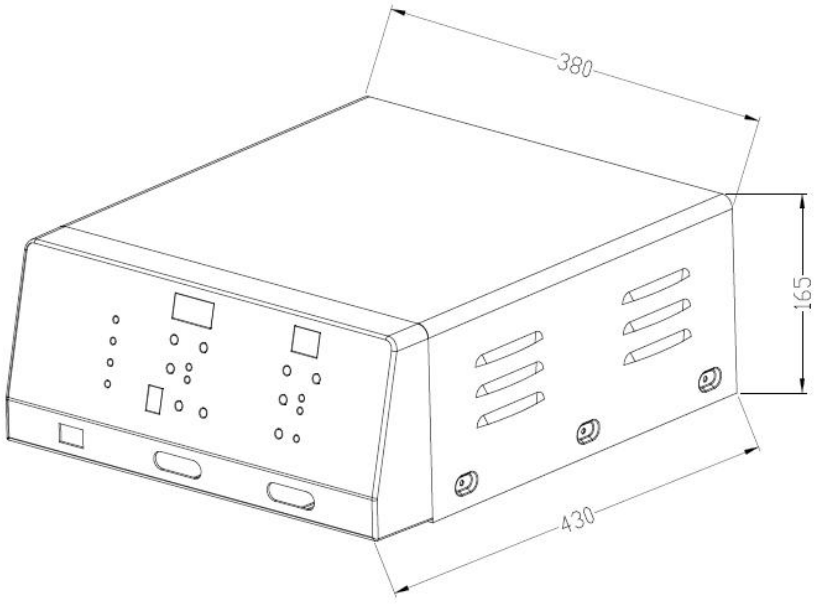
### *Input power*

| | |
|---|---|
| **Input voltage:** | **120/230Va.c** |
| **Mains line frequency:** | **60/50Hz** |
| **Power consumption:** | **300VA** |
| **Fuse(two):** | **6A, Φ5×20.** |

### *Duty Cycle*

Under maximum power settings and rated load conditions (Cut, 100 watts with 500 Ω load), the generator is suitable for activation times of 10 seconds on, 30 seconds off for one hour.

### *Dimensions (mm) and Weight (kg): Weight: 7kg*



### *Operating Parameters*

| | |
|---|---|
| **Ambient temperature range** | **+5° to +40° C** |
| **Relative humidity** | **No more than 80%** |
| **Atmospheric pressure** | **86kPa to 106kPa** |
| **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° C** |
| **Relative humidity** | **10% to 100%, including condensation** |
| **Atmospheric pressure** | **50kPa to 106kPa** |

### *High Frequency (RF) Leakage Current*

| | |
|---|---|
| **Bipolar RF leakage current** | **< 11.34 mA** |
| **Monopolar RF leakage current (additional tolerance)** | **< 7.56 mA** |

# *STANDARDS AND IEC CLASSIFICATIONS*

### *Class I Equipment (IEC 60601-1)*

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

### *Type CF Equipment (IEC 60601-1) / Defibrillator Proof*

The OBS-100C Electrosurgical Generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF equipment.

### *Drip Proof (IEC 60601-2-2)*

The generator enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wet, are likely to affect adversely the safety of the generator.

### *Electromagnetic Interference*

When other equipment is placed on or beneath an activated Baisheng Medical electrosurgical generator, the OBS-100C Electrosurgical Generator operates without interference. The generator minimizes electromagnetic interference to video equipment used in the operating room.

### *Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2)*

The OBS-100C Electrosurgical Generator complies with the appropriate IEC 60601-1-2 and IEC 60601-2-2 specifications regarding electromagnetic compatibility.

### *Voltage Transients (Emergency Generator Mains Transfer)*

The OBS-100C Electrosurgical Generator operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

## *EMC COMPLIANCE*

Special precautions should be taken regarding the OBS-100C. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Understand that only the Accessories supplied with or ordered from Baisheng Medical should be used with your device. The use of accessories, transducers, and cables other than those specified, may result in increased Emissions or decreased Immunity of the OBS-100C.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The OBS-100C should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the OBS-100C should be observed to verify normal operation in the configuration in which it will be used.

**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 | 100W, Load:500Ω | 431Khz±50KHz | N/A | 650 | 1.7 |
| Blend | 100W, Load:500Ω | 431Khz±50KHz | 25KHz ±5KHz repetition | 801 | 2.2 |
| COAG1 | 60W, Load:500Ω | 431Khz±50KHz | 28KHz ±5KHzrepetition | 2321 | 7.2 |
| COAG2 | 35W, Load:500Ω | 431Khz±50KHz | 29KHz ±5KHzrepetition | 2177 | 6.7 |
| Bipolar | 80W, Load:100Ω | 431Khz±50KHz | 25KHz ±5KHzrepetition | 307 | 1.7 |

## *OUTPUT POWER CURVES*

The curves that follow depict the changes for each mode at specific power settings.

**Monopolar Cut Curves**

For each output power vs. impedance curve, the upper curve represents readings taken at full power; the lower curve, readings taken at half power.

Figure A-1 **Half and Full output power versus load impedance of CUT mode**

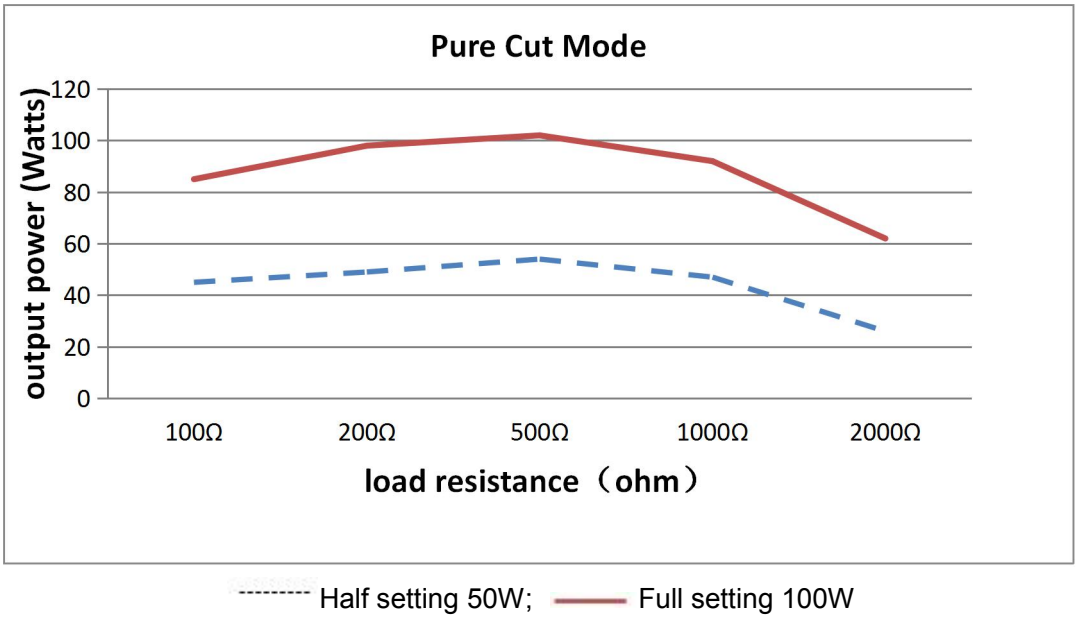
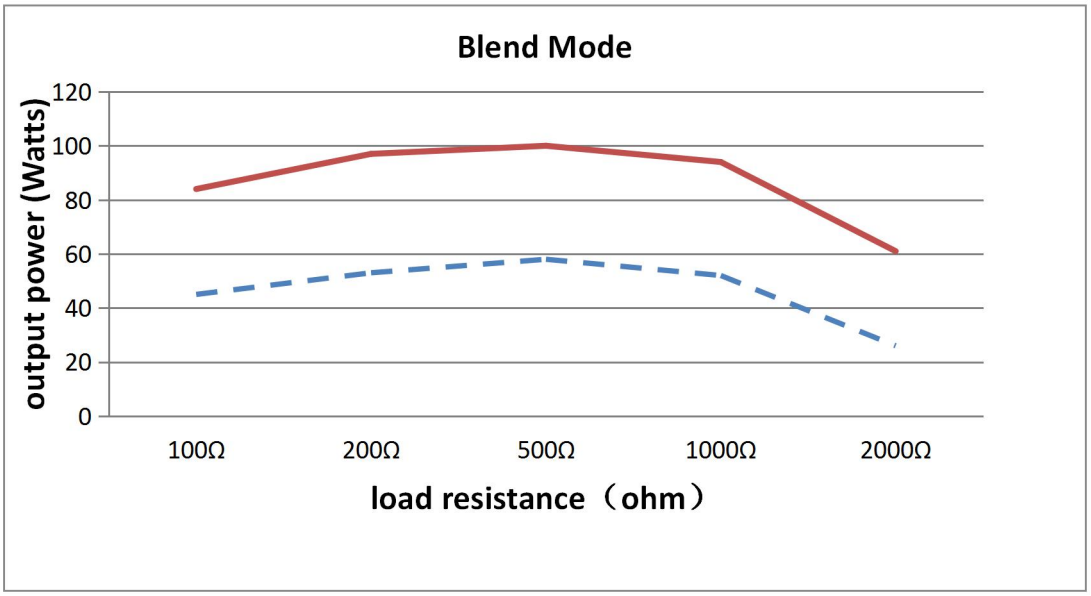
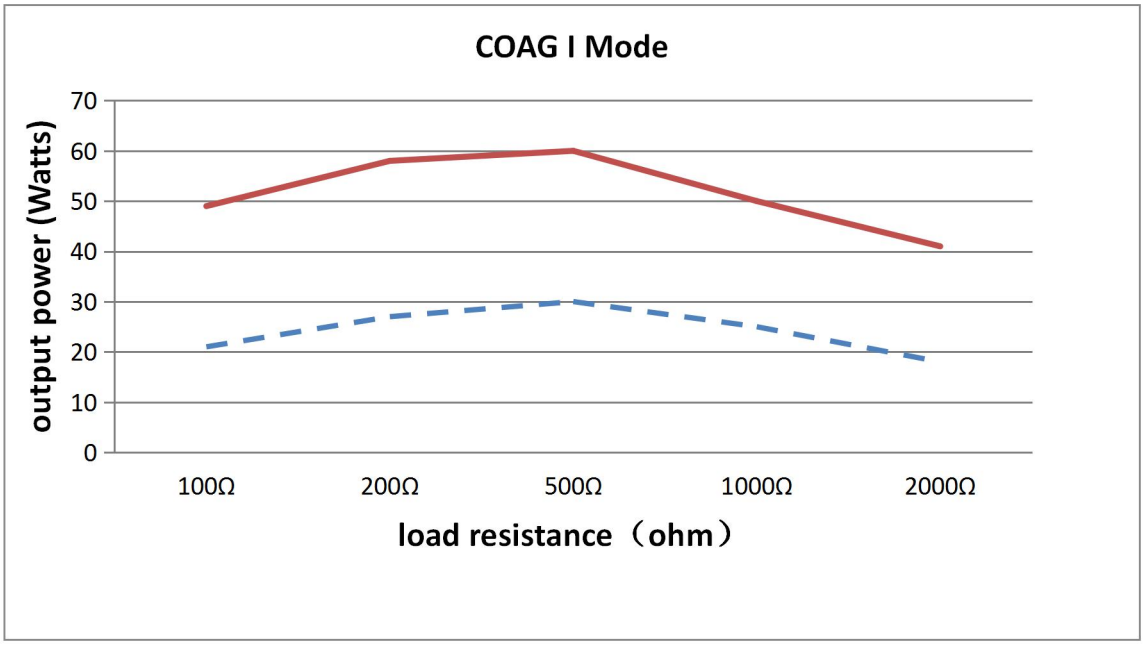


Figure A-2 **Half and Full output power versus load impedance of Blend mode**




Half setting 50W; Full setting 100W

Figure A-3 **Half and Full output power versus load impedance of COAG1 mode**




Half setting 30W; Full setting 60W

Figure A-4 **Half and Full output power versus load impedance of Fulguration mode**

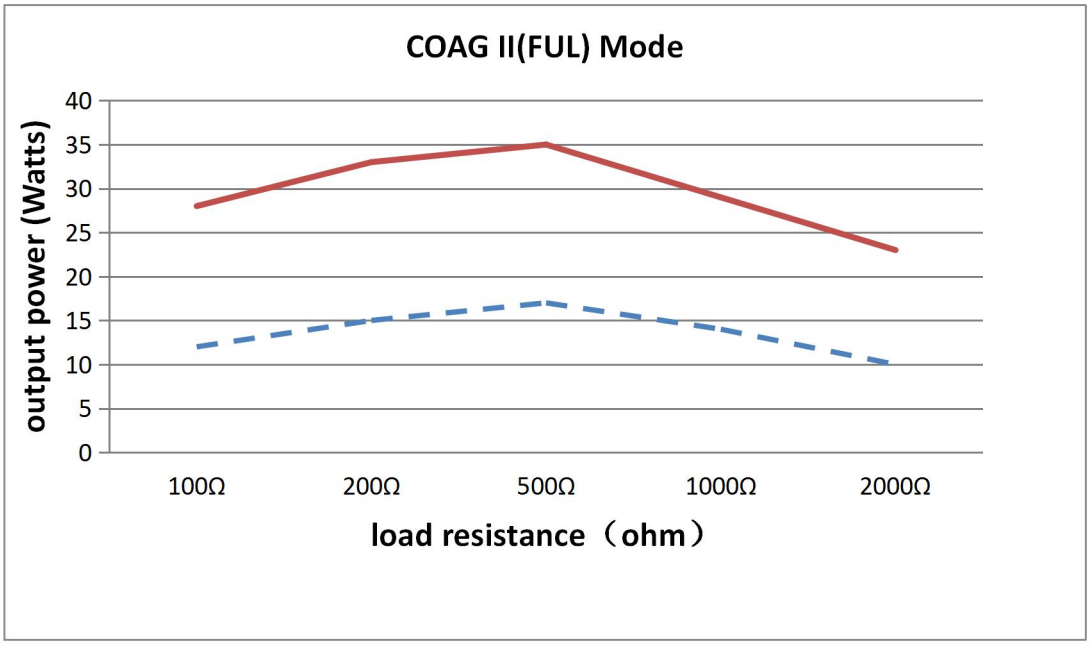
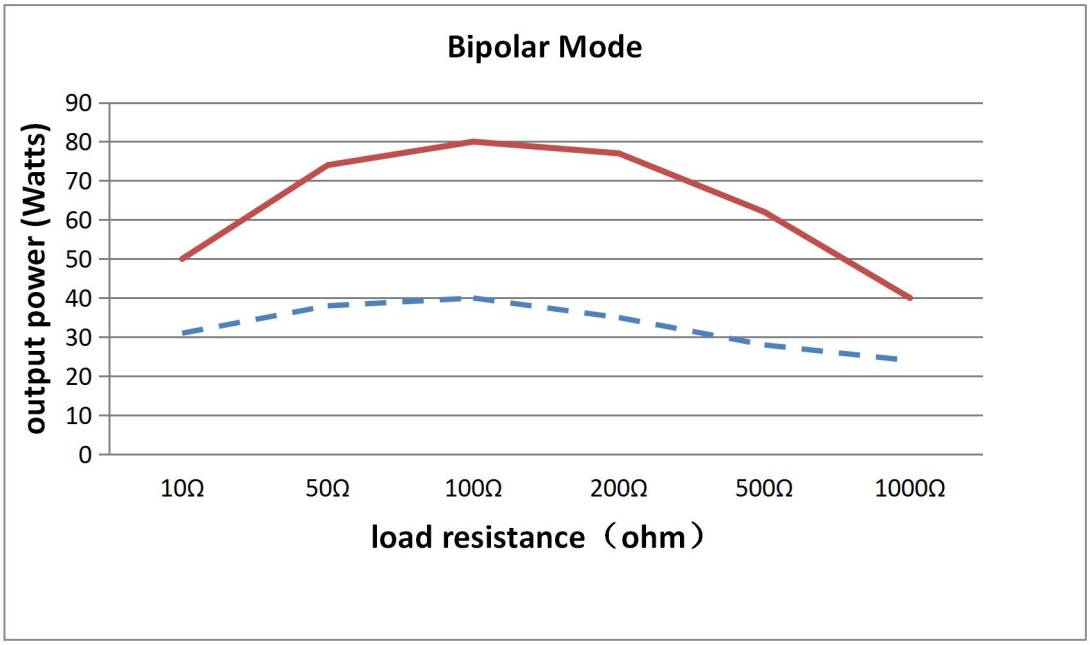



Figure A-5 **Half and Full output power versus load impedance of Bipolar mode**



## 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.

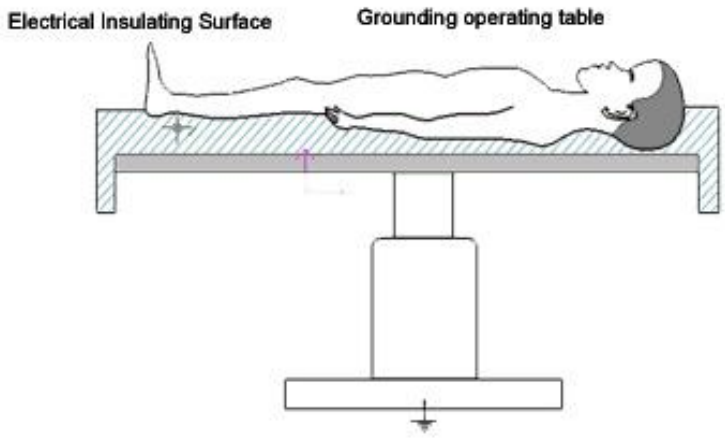
4. If power supply is not within the range of 120V/230V and power frequency of 60Hz/50Hz, please use power stabilizer.
Note that when the machine output power, please ensure that power lead of the machine should well contact with power network. If power supply is not 120V/230V or power frequency of 60Hz/50Hz,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

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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.

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

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