Electrosurgical Generator – Model OBS-100B

Instruction for Use

Version No.: 20181018OBS100B

Electrosurgical generator

BAISHENG MEDICAL CO., LTD.

Read the contents described in this page carefully when initial use

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

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-100B only.

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

Equipment Covered in this Manual
Electrosurgical generator: OBS-100B
Reference No.: 20181018OBS100B

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BAISHENG MEDICAL CO., LTD.

CONVENTIONS USED IN THIS GUIDE

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

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

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

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SECTION one

Introducing the OBS-100B

Indication for use

The Electrosurgical Generator (OBS-100B) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform bipolar functions in the surgical operation area.

SAFETY

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

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

To promote the safe use of the OBS-100B, 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:

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

Danger: Fire / Explosion Hazard - Do not use the OBS-100B in the presence of flammable materials.

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

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel

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To avoid the risk of electric shock, this equipment must only be

connected to a supply mains with protective earth.

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

• Oxygen enriched atmospheres

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

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

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

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

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

Fire Hazard - Do not use extension cords.

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

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

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

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

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.

WARNINGS:

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

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

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

For all operation modes, any associated equipment and active electrodes must be rated to with stand the combination of output voltage. Vpeak and crest factor as stated in the table on Page 28

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.

WARNINGS:

The unit is only intended for bipolar application, so there is no need for a patient return pad (ESU Pad).

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 around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide

(N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

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

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

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

CAUTIONS:

At no time should you touch the 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.

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.

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. Monitoring systems incorporating high frequency current-limiting devices are recommended.

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.

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

Remove any loose fitting jewelry from the patient before activation.

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

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

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

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

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

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

Apparent low output or failure of the OBS-100B 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.

When using BIPOLAR 1 mode, the active accessory used should have a voltage rating equal to or greater than 282Vpeak.
When using BIPOLAR 2 mode, associated equipment and active accessories should be selected that have a voltage rating of 307Vpeak.

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.

Contraindications

There are no known contraindications.

NOTICES:

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

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

KEY FEATURES

The OBS-100B includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.
It includes the following features:

- Only Bipolar modes application designed (No need a ESUpad)
- Two bipolar modes: Bipolar1(footswitch control) and Bipolar2(automatic control)
- Memory function: 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.
- Power ON self diagnostics: In the self diagnosis process after Power ON, the bipolar 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 Alarm indicator will be displayed red as prompt and alarm voice delivered simultaneously, which disables the subsequent operations automatically.

NOTICE:

In the Power On self diagnostics process, if the alarm indicator displayed red, indicating that the unit is failure, please contact the local supplier or manufacturer for consult and change another one.

ACCESSORIES Applied

- Accessories and components list:
- ✓ Electrosurgical bipolar forceps
- ✓ Footswitch for Bipolar procedures
- Compatibility requirements:
- ✓ First, the accessories shall be Legally marketed in Europe;
- ✓ 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 Bipolar1 mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 282Vpeak max.
- ✓ When using Bipolar2 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-100B.

OBS Accessories Included:

- Bipolar Forceps with cable 2pcs
- Footswitch 1pcs
- Power cord 1pcs
- Manual 1pcs

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-100B High Frequency Electrosurgical Generators models are intended to be used for all electrosurgical cut, blend, coagulation and bipolar procedures.

Medical Purpose / Indication

• Removal and destruction of skin lesions

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

Site Condition:

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

Site of use:

• Site of use: Human Tissue

Patient population:

• Age: newborn to geriatric

•Weight: >2.5 kg

• Health: no restrictions

• Nationality: no restrictions

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

– Patient should not be User

Intended User Profile:

• Education: Trained physician, physicians assistance, clinicians

- No maximum

• Knowledge:

- Minimum:

•understands electrosurgery and electrosurgical techniques

• read and understand supplied “User’s Guide” (accompanying document)

• understands hygiene

- No maximum

• Language understanding:

- Languages as specified in the marketing distribution plan

• Experience:

- Minimum:

• Some training on techniques or training under surveillance/supervision

• Other: no special experience needed

• No maximum

• Permissible impairments:

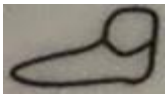
- Mild reading vision impairment or corrected vision to 20/20

- impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz.

SECTION 2

Controls, Indicators and Receptacles

➢ **Table 1 Symbol and mark used.**

	Registered trademark		Caution
	Power ON/OFF		Defibrillator Proof Type CF Equipment
	Footswitch receptacle	F	RF Isolated
	Caution High Voltage	SN	SERIAL NUMBER
	Bipolar handpiece receptacle		CONSULT INSTRUCTIONS FOR USE
	Mandatory: Refer to instruction manual/guide		Do not dispose of this device in the unsorted municipal waste stream.

➢ **Product front view:**

1	Activating indicator	**2**	Output power display
3	Bipolar 1 selecting indicator	**4**	Bipolar 2 selecting indicator
5	Memory group display (from 0 to 9)	**6**	Memory group setting button (0~9)
7	Memory group confirming button	**8**	Power ON/OFF indicator
9	Power On self test alarm indicator	**10**	Clockwise rotation: power adding Anticlockwise rotation: power subtracting Push: bipolar modes switching
11	Bipolar forceps receptacle	**12**	Bipolar footswitch receptacle

➢ **Product Back view**

Table 3: Illustration explanation of Rear panel			
1	Thermovent	**5**	Non-ionizing radiation
2	Equipotentiality	**6**	Rewirable fuse
3	Loudspeaker	**7**	AC line receptacle
4	Label	**8**	Power ON/OFF switch

SECTION 3

GETTING STARTED

INITIAL INSPECTION

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

• Look for any signs of damage.

• Verify that the shipping package contains all items listed on the packing list.

Do not use any damaged equipment.

INSTALLATION

Place the OBS-100B on any flat surface with a tilt angle not more than 10°. The unit relies on natural convection cooling. Do not block its bottom or rear vents. Ensure that air flows freely on all sides of the unit.

WARNING:

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

FUNCTION CHECKS

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

WARNING:

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

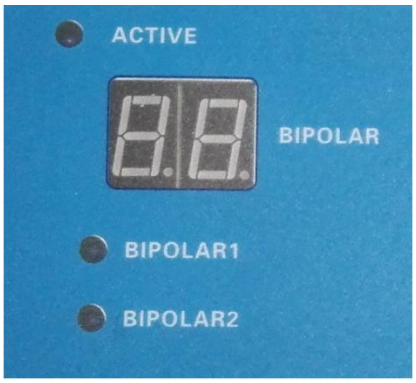
Setting Up the Unit

1. Verify that the Power Switch is in the Off (O) position and that no accessories are connected to the unit.
2. Connect a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.
3. Connect a bipolar forceps to the appropriate receptacle.
4. Turn the unit on by switching the power switch to the ON (|) position.

Confirming Modes

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

Checking Bipolar Mode (with bipolar footswitch)



BIPOLAR1	0W～80W（Load100Ω）
BIPOLAR2	0W～80W（Load 100Ω）
	Clockwise rotation: power add Anticlockwise rotation: power subtract Push: bipolar modes switch

1. Plug in the Bipolar footswitch.
2. Press the pedal on the Bipolar footswitch. Verify that the Bipolar mode activation indicator illuminates and that the system generates the Bipolar activation tone.
3. Confirm that releasing the pedal returns the unit to an idle state.

PERFORMANCE CHECKS

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

a) **Power ON self diagnostics:** In the self diagnosis process after Power ON, the bipolar 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 Alarm indicator will be displayed red as prompt and alarm voice delivered simultaneously, which disables all subsequent operations automatically.

b) **Memory Feature Description and checks**

- The OBS-100B 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 “SET”
- Select the desired mode to be stored by pressing one of the mode knob “  ”
- Select the desired power to be stored by utilizing the power output control knob. “  ”
- Once all the settings are selected, pressing the Presets “OK” 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 “SET” button to toggle through all the presets.

➢ **Checks:**

- choose a intended bipolar output value (Bipolar1:35w as an example), press “SET” to from 0~9 groups and select “1” (as an example) for memory group 1;
- step bipolar footswitch to activate, and then power OFF the unit;
- Power On again, the previously activating value (Bipolar1:35w) will be displayed;
- Press “SET” circularly, the group of memory 1 (Bipolar1:35w) will be displayed the same every time.

WARNING:

For preventing heat injury caused by misuse or malfunctioned system during operations, accessories in good condition must be used. Only compatible accessories or eligible accessories tested by manufacturer are used. This requirement is suitable for application electrodes including cables and plugs. When electricity-isolating apparatus is used, ensure that the isolation should not be overloaded and damaged due to higher voltage. This operation manual describes output voltage values for all the bipolar operation modes, the isolating intensities can be found in the technical data of the apparatus. If there is any question, please contact with the manufacturer for technical data. All the isolations of electrode, handle of electrode, cable and plug etc. should be kept in good conditions.

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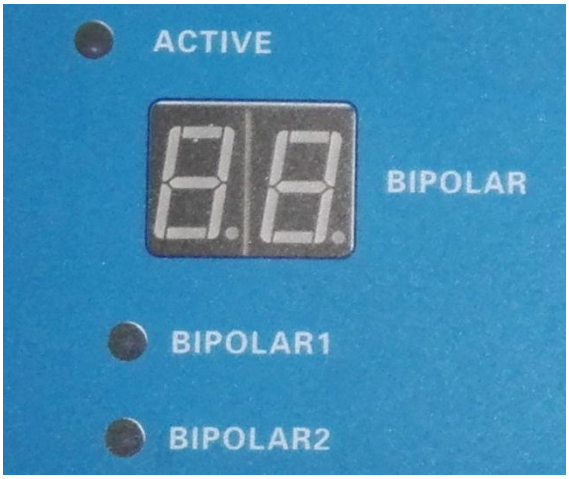
c) Bipolar application function checks



Bipolar selection keys

Application function will be changed from the functions of Bipolar1, and Bipolar2 by pushing the “ ” knob once at a time.

Power increase or decrease knob	
Power adding adjust	Clockwise rotation
Power subtracting adjust	Counterclockwise rotation

Bipolar 1(footswitch control): 0W～80W (load 100Ω)
Bipolar 2 (automatic control): 0W～80W（load 100Ω）

They are suitable for application in orthopaedics, microscopical surgeries., and The less tissue are held, the better effect will be achieved during operation. Too much tissue to be held will affect the result of hemostasia. Clamp body tissues with bipolar forceps, and output power for coagulation, cut off the output as it leaves from human body, which must be controlled by foot pedal, otherwise, operations mentioned above cannot be accomplished.

SECTION 4

DURING USE

INSPECTING THE GENERATOR AND ACCESSORIES

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

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

SETUP SAFETY

WARNINGS

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

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

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

Fire Hazard - Do not use extension cords.

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

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

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

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

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

CAUTIONS:

At no time should you touch the 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 Bipolar mode is selected.

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

If the self-test is not successful, an alarm tone sounds with red Alarm indicator illuminated (see Trouble shooting). Once the self-test is successful, connect the accessories and set the generator controls. Refer to Preparing for Bipolar Surgery later in this section.

NOTICE:

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

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7. This device has functions of Bipolar1 and Bipolar2 for the selections during surgical operations.

PREPARING FOR BIPOLAR SURGERY

1. Connect a Bipolar cable to the Bipolar receptacle on the front of the unit.
2. Connect a forceps instrument to the bipolar cable.
3. Connect the bipolar footswitch to the bipolar footswitch connecting socket located on the front 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. It's better to use bipolar electrode technology.
   Generally speaking, as compared with monopole COAG technology, bipolar COAG technology is preferable. Bipolar COAG technology is particularly suitable for COAG in long and narrow organs. High frequency current passes through tissues of human body are always heated in smallest diameter section at first. If high frequency current passes through same diameters (a) over a longer distance, then tissues of human body will be coagulated along whole distance. If diameter of tissues around coagulation electrode point is less than that of electrode point, then there should be coagulation beside the action point (b). Under all circumstance, it is to ensure that the high frequency should not pass through tissue structure or smaller veins in smaller diameter.
5. Bipolar forceps, Bipolar forceps lead and connection of machine
   Replace when isolation of bipolar forceps is fallen off, poor contact between bipolar forceps and lead consent, weak connection of lead. Bipolar forceps is made of stainless steel coated with plastic painting. Bipolar forceps plug

and bipolar forceps output socket are pressed by moldings. Insert two plugs at will into output socket in parallel, pull out it by holding rear part of socket in parallel. Connect bipolar forceps and bipolar forceps lead, there is a parallel stainless steel at rear part of bipolar forceps, and a socket at front part of bipolar forceps (pressed by moldings), insert bipolar forceps. Remove it by holding middle part of bipolar forceps.

Memory Feature (Last Selected Preset)

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

ACTIVATING THE UNIT

NOTICE:

Review Activation Safety issues before activating the unit. When you turn on your unit remember the following feature:
TheOBS-100B will power up to the modes and settings displayed when the unit was last activated. For example, if you set Bipolar 1mode at 50 watts and activate the unit, then turn the unit off, it will automatically return to Bipolar 1 mode at 50 watts when you turn it on again. Similarly, if you set Bipolar 2 mode at 40 watts and activate the unit before you turn it off, it will return to Bipolar 2 mode at 40 watts when you turn it on again.

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1. Bipolar – select the mode of operation for bipolar1 or bipolar2, then adjust the Bipolar power settings by rotating the power adjustment knob.
2. Activate the generator by footswitch pedal.

NOTICE:

Bipolar footswitching operations are controlled by independent foot controls.

ACTIVATION SAFETY

WARNINGS

Do not wrap the accessory 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-100B in the presence of flammable anesthetics.

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

- ***Flammable substances (such as alcohol based skin prepping agents and tinctures)***
- ***Naturally occurring flammable gases that may accumulate in body cavities such as the bowel***
- ***Oxygen enriched atmospheres***
- ***Oxidizing agents (such as nitrous oxide [N2O] atmospheres).***

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

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

Use electrosurgery with caution in the presence of internal or external devices such as pacemakers or pulse generators. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.(The disturbance from the operation of high frequency can probably bring about disadvantage to the operations of other medical electronic equipmen） High frequency operation device generally produces high frequency voltage and current, which will disturb other electronic equipment. When sensible electronic equipment is arranged in operating room, these issues should be taken into account. In principle, sensible electronic equipment should be placed as far as possible from high frequency operation equipment, especially for the place of the cable to transmit high frequency current. In addition, the action of high frequency current cable is just like broadcasting antenna, of which the length should not exceed actual requirement, and absolutely should not be placed in parallel with sensible electronic equipment, and also be too

near each other.)

CAUTIONS:

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

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

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

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

Remove any jewelry from the patient before activation.

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

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

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

SECTION 5

MAINTAINING The OBS-100B

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.

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.

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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-100B 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

FUSE REPLACEMENT

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

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

NOTICES:

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

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SECTION 6

TECHNICAL SPECIFICATIONS

PERFORMANCE CHARACTERISTICS

Basic property:

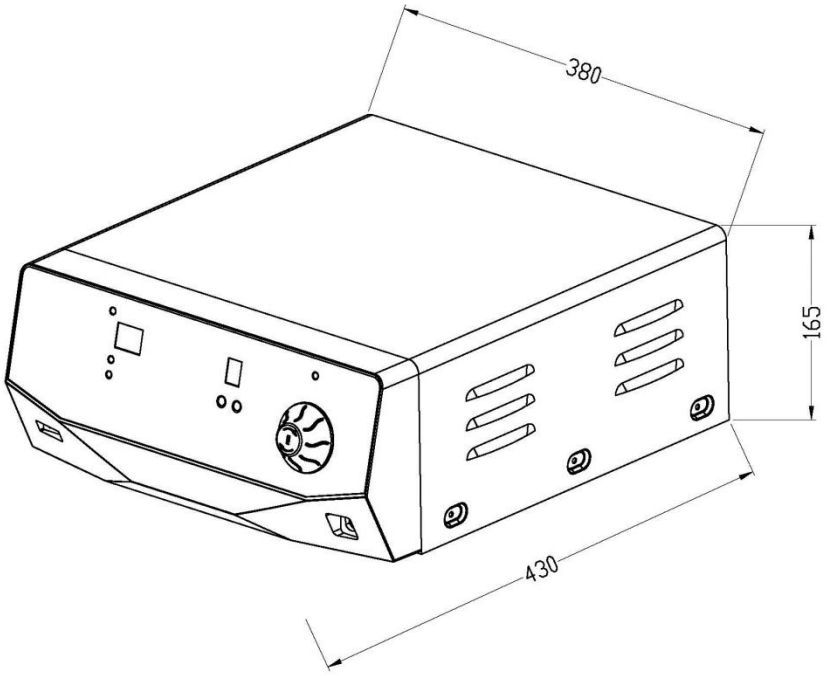
Category of the Device:	Class I Equipment (IEC 60601-1)
Type:	Type CF Equipment Defibrillator Proof
Duty Cycle:	Intermittent loading continuous operation(10s/30s)
Max. power:	80W
Non-permanently installed device	
Working frequency:	(330~460)kHz

Input power:

Input Voltage:	120/230V~VAC
Mains line frequency:	60Hz/50Hz
Power consumption:	200VA
Fuse(two):	F6AΦ5X20

Dimensions and Weight:

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



Operating Parameters:

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

Transport and Storage:

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

OUTPUT CHARACTERISTICS

Maximum Output for Monopolar and Bipolar Modes

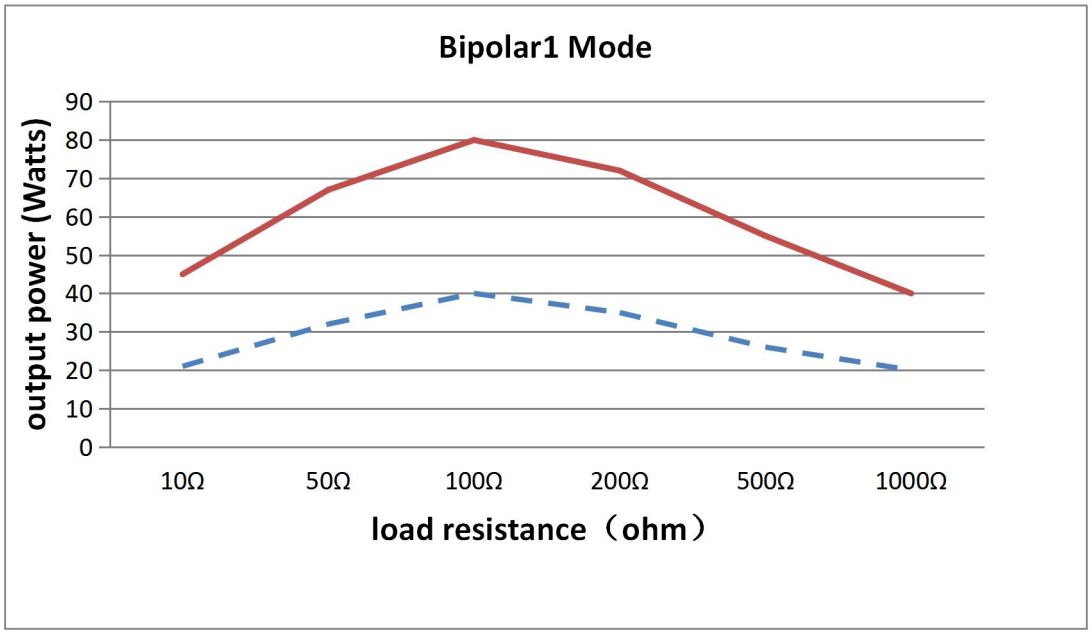
Power readouts agree with actual power into rated load to within 20% or 5 watts, whichever is greater.

Mode	Output power	Output frequency	Repetition Rate	Vpeak max	Crest Factor (Rated Load)
Bipolar1	80W, Load:100Ω	431Khz±50K Hz	27KHz ±5KHzrepetition	282	1.5
Bipolar2	80W, Load:100Ω	431Khz±50K Hz	25KHz ±5KHzrepetition	307	1.7

OUTPUT POWER CURVES:

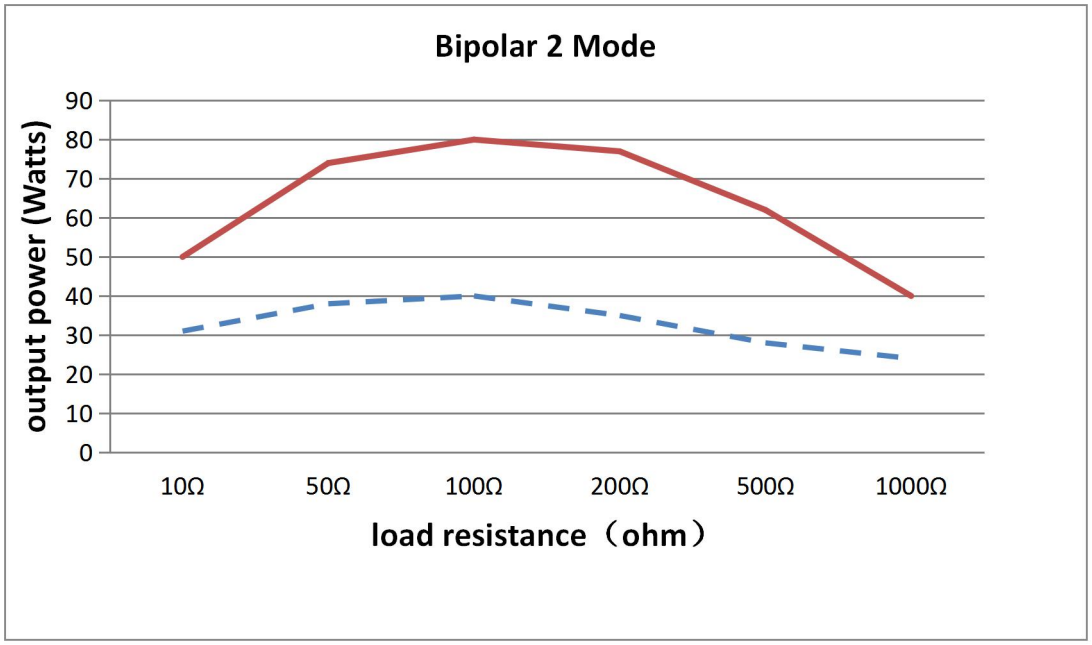
Half and Full output power versus load impedance

- **Bipolar I**



--------- Half setting 40W; ——— Full setting 80W

- **Bipolar II**



--------- Half setting 40W; ——— Full setting 80W

EMC COMPLIANCE

The unit of OBS-100B and its supplied accessories are complied with the requirements of IEC60601-1-2:2007.

NOTICES:

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 Instruction for use.

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Understand that only the Accessories supplied with or ordered from OBS 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-100B.

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The OBS-100B and its accessories are not suitable for interconnection with other equipment. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

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The OBS-100B should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the OBS-100B should be observed to verify normal operation in the configuration in which it will be used.

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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.

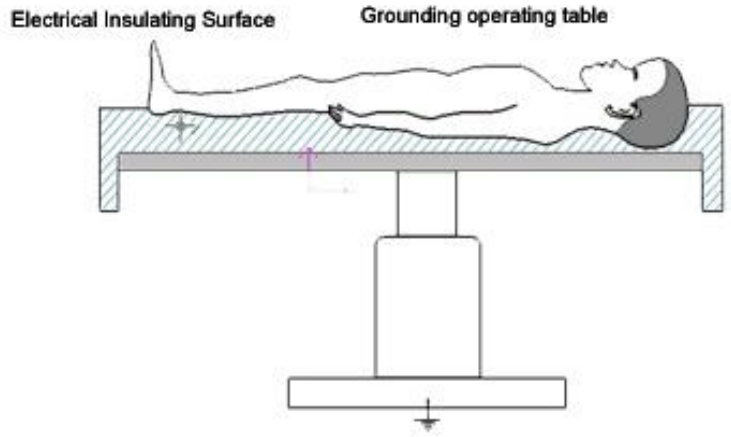
4. If power supply is not within the range of 120V/230V or power frequency of 60Hz/50Hz, please use power stabilizer.
Note that when the machine output power, please ensure that power lead of the machine should well contact with power network. If power supply is not 120V/230V or power frequency of 60Hz/50Hz, 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.
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;
- 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.
- 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 If the Alarm indicator illuminated during Power On self diagnostics, please contact the local supplier or OBS for after-sales services.

MEASURES TO BE TAKEN DURING OPERATION OF THE DEVICE:

1. Connect perfectly the grounding cable.
Power supply of the device should be connected with main bus through three terminals; the longer terminal in the middle is the terminal grounding, which should be grounded during operation.

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

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

EC Representative

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