OBS Electrosurgical Generator and Accessories

Model OBS-100A

Instruction for Use

Revision: BSG20100301

Electrosurgical Generator

BAISHENG MEDICAL CO.,LTD.

Read the contents described in this page carefully when initial use

- Welcome to use OBS Eletrosurgical Generator and accessories– Model OBS-100A

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

BAISHENG MEDICAL CO.,LTD.

Add: No.11, Fusheng Rd,XinHui District,JiangMen,GuangDong,China
Tel：+86-750-6628113　　Post code：529100

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Electric circuit diagram, list of elements etc. are promised only to offer to the authorized and qualified technicians and Technology Supervision Department concerned;
Standard Implemented: EN 1041-2008

I. Characteristics of the product:

1.1 Category of the Device: Category I;
1.2 Model of the Device: Model BF
1.3 Category of Power Supply for the Device: Single phase, supplied from power netting (A.C.220-240 V);
1.4 Rating power of the Device :100W±10%;
1.5 Type for application part of the Device: Isolated from ground at high frequency;
1.6 The device is provided with protection for discharge effect of defibrillator;
1.7 The device is categorized as common equipment;
1.8 Operating mode of the device: Intermittent loading continuous operation;
1.9 Non-permanently installed device.

II. Sign

Manufacturer: Baisheng Medical Co.,Ltd.

Type of sign： OBS Electrosurgical Generator – Model OBS-100A

Power supply connection: 3A/220-240V ～
power frequency: 50/60Hz
Rating power: 100W
Classification: Model BF in category I
Working system: Working system of Intermittent loading continuous operation
Fuse: F5AΦ5X20
Max. power: 100W
Protective package: With indications such as keeping with care, upward, moisture proof etc.

III. Technical parameters:

3.1 Normal operation

a) Environmental temperature range: 5℃～40℃
b) Relative moisture range: ≤80%；
c) Atmosphere pressure range: 86.0～106.0kPa；

d) Power supply: 220V±10V， 50/60Hz
e) Working frequency: 360～460kHz

3.2 Output rating power:
a）Pure cut : 5W～100W（Load 500Ω）；
b）Blend cut: 5W～50W（Load 500Ω）；
d）Forced Electrocoagulation: 5W～80W（Load 500Ω）；
e）Soft Electrocoagulation: 5W～40W（Load 500Ω）；

3.3 Power supply： 220V∽±10V，50/60Hz。

3.4 Power consumption of equipment ：≤150W。（Cutting function 100W、electrocoagulation function 80W output）

3.5 Transportation and storage
a) Ambient temperature range: 一40℃～70℃;
b) Relative moisture range: ≤80%；
c) Atmosphere pressure range: 500hPa～1060hPa。

Ⅳ. Expression explanations

4.1 Electrosurgical Pencil

Electrosugical Pencil is also called Active Electrode. There are two kinds of Electrosurgical Pencil. They are hand control and foot control. Hand control pencil is Electrosurgical Pencil on which there are two buttons. One is yellow button which used for controling cutting, another is blue button which used for controling coagulation. Foot control pencil is Electrosurgical Pencil on which there is no button. It is actived by Footswitch.

4.2 Electrosurgical Pad

It is used to contacts in a larger area with physical body of patients to offer high frequency current circuit in low current density to prevent human body tissue from the physical effects such as burning.

Electrosurgical Pad is also called as plate electrode, electrosurgical pad,skin application plate, spreading electrode or grounding pad.

4.3 Footswitch

There are two kinds of footswitch, bipolar footswitch and monopolar footswitch. Bipolar

footswitch is used to active bipolar forceps. Monopolar footswitch is used to active endoscopic cutting, endoscopic coagulation, foot control pencil cutting and coagulation.

4.4 Pad Cable

It is used to connect Electrosurgial Pad and Generator together. It is made of special material which used in medical instruments.

4.4 Bipolar

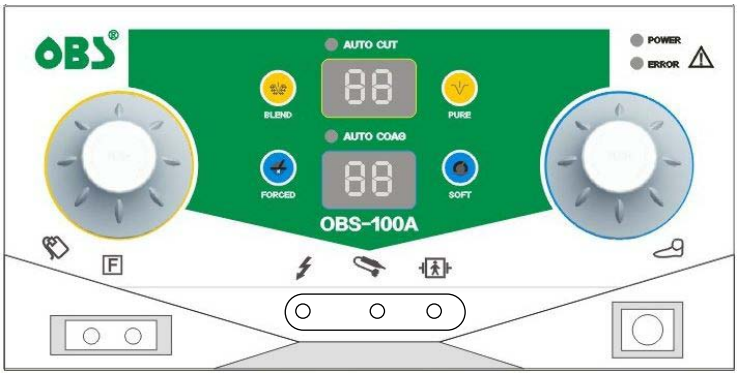
It is also called bipolar forceps which used for coagulation during operation. It can be actived by bipolar footswitch.

V . Names and functions of each part of machine

5.1 Front plate of eletrosurgical generator

The main controlling sector of electrosurgical generator is located on front plate, for the sake of safety, the function sections of electrome CUT, electrocoagulation COAG can not be actuated simultaneously, but they can be adjusted individually, which includes: power display (green digital code tube), alarm display (red indicator), output display (yellow indicator) (blue indictor), power switch, power adjusting push button, options, pure cut(yellow indicator), blend cut (yellow indicator), forced electrocoagulation (blue indictor), soft electrocoagulation (blue indictor), Electrosurgical Pencil output socket as well as Electrosurgical Pad socket.

Please refer to the following contents for operating



Registered trademark

Isolated from ground at high frequency of neutral electrode

Disconnection (refer to main power supply)

Connection (refer to main power supply)

Power adjust knob

See instruction for use

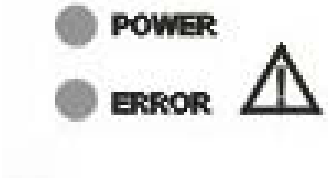
Site is a source of high voltage

Model BF device with function for protection of electricity discharge effect from cardiac defibrillator

electrosurgical pencil connection

electrosurgical pad connection

5.2 Function section



5.2.1 Malfunction alarms

Once switching on, the equipment can automatically examine each function. If any defect is detected out of equipment or its accessories, it will send out alarm and display the defect with red light, If there is no defect detected, the equipment can be operated then.

Warning

Only if its functions are completely set, can it be actuated, if an unset or incompletely set function section is attempted to actuate, the equipment will sound alarm and display red

light.

d) After electrifying, the equipment will automatically test performance. If certain performance is tested incorrectly, it will sound alarm and display corresponding red light. It can automatically identify the following errors of performance of the equipment as well as accessories connected:

——If short circuit occurs on certain key on the front plate or it is pressed incorrectly during electrifying, sound alarm and red light will indicate that malfunction after electrifying.

——If short circuit or low resistance bypass occurs on certain key on the handle of electrode due to malfunction (such as duo to moisture of electrode handle), or it is pressed down in the process of electrifying, the machine will sound alarm after electrifying.

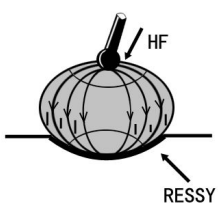
5.2.2 Polar plate test

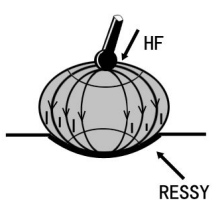
Heat injury caused due to misuse of electrosurgical pad or without using electrosurgical pad

If electrosurgical pad is used improperly, or even not used, there must be a critical risk of accidental heat trauma of body tissue at working point of electrosurgical pad and other parts of patient's body. So that the whole surface of electrosurgical pad must be applied to the fleshy muscle on patient's body as close and reliable as possible.

Warning

Effective contacting surface i.e. electric conductivity between electrosurgical pad and patient should be equal to high frequency capacity applied namely the intensity of high frequency current. Here, effective contacting surface means electrosurgical pad surface contacting electric conduction contacting with patient's skin during operations.





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

When electricity-isolating apparatus is used, ensure that the isolation should not be overloaded and damaged due to higher voltage. This operation manual describes output voltage values for all the cutting and electrocoagulation 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.

The risk of Heat injury caused by output error of equipment is in direct proportion to the cutting set for equipment or intensity of electrocoagulation and time.

Cutting or intensity of electrocoagulation should be set according to the application, and the time for actuation should be just enough for operation. For example, when the effect is not good enough according to standard setting, the reason is probably the poor adherence of electrosurgical pad, poor contact of electric connection, cable malfunction, or electricity isolation tissue remained on application electrode. Check them before increasing power.

Connecting socket of electrosurgical pad

Appropriate electrosurgical pad must be used for monopolar cutting and /or electrocoagulation, it should be not only connected with equipment but also be applied on body of patient carefully.

The meanings of graphical signs beside of electrosurgical pad connecting socket are as following:

Common electrosurgical pad

This device is in conformity with the requirement of Section No. 19.101b of EN60601-1,EN60601-2-2and EN60601-1-2, its application section and isolation from ground meets the requirements of high frequency technology. According to EN60601-1,EN60601-2-2and EN60601-1-2,it is in conformity with requirements for Model BF. In addition, the symbol also indicates that electrosurgical pad can be left on patient’s body when there is no any fabric vibration according to EN60601-2-2.

Automatic check for electrosurgical pad

If the connection of electrosurgical pad is cut off during actuating, or contacting resistance is too high (only refer to separated electrosurgical pads), the equipment will cut off high frequency generator, sound alarm and display red light.

5.3 Cutting （ CUT ）function section

5.3.1 Electrotomy selection keys

Application function will be changed from the functions of pure cut and blend cut by pressing the Power Adjust Knob once at a time.

5.3.2 Power adjust knob:

5.3.3 Pure cut

.The pure cut only have the fuction of cuting. The thermal damage degree is minimum for tissues surrouding by using pure cut..

Power range of pure cut is within 5W～100W (load 500Ω)

5.3.4 blend cut

The blend cut with the funtion of cut and coagulation. It can avoid bleed when cut rapidly and clotting no enough. It is suitable for cuting tissues which will bleed easily.

Power range of blend cut is within: 5~50W (load 500Ω)

On the output button of hand controled electrosurgical pencil, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation.

Notice: During normal surgical operation, one should select a lower power at first, and if it is not higher enough, increase the power gradually. Cut an incision in 2-3 mm in depth

with steel sheet knife, dip blood dry with gauze, and then cut with electrotome along the incision, dry it with gauze. If the cut tissue assumes yellow color, that means the power is rather high, increase cutting speed or decrease power output. The optimum effect is that the incision assumes white and a bit yellow color after cutting. This is the right time for a good hemostasia and a slight burn to the tissues of human body.

5.4 Electrocoagulation function section

5.4.1 Power adjust knob:

5.4.2 Forced coagulation

It is one of monoterminal mode. By using the electrode held slightly away from the surface being treated, resulting in sparking to the surface.When using this fuction, user must precisely position the point of active electrode to the area being treated or the eletrical arc may divert to adjacent tissue areas.If desired, user can quickly coagulate broad areas by holding the electrode further from the skin.

Power range of Forced coagulation is within 5W～80W (load 500Ω).

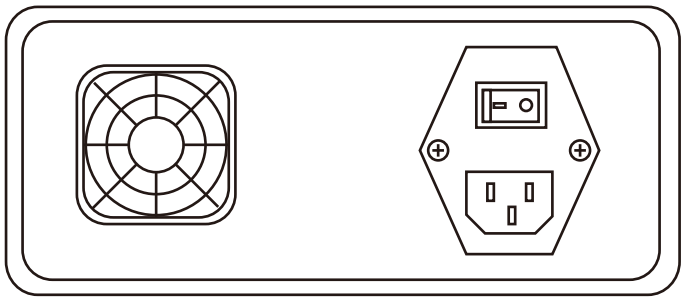
5.4.3 Soft coagulation

It is one of monoterminal mode. Olso call “desiccation”.The electrode either touches, or is inserted into the tissue to coagulate. It is suitable for precise tissue coagulation.

Power range of Forced coagulation is within 5W～40W (load 500Ω).

This electrocoagulation function section is in coagulating mode, which can be actuated by pressing blue button on the electrode handle The actuating status is indicated by the flashing triangle symbol on the top of the automatic electrocoagulation section and the sounding signal simultaneously.

5.6 Rear Panel



Rear Panel of Apparatus

Rear panel of OBS-100A includes: power supply socket, fuse seat and fan.

5.6.2 power supply socket, rating voltage 5A/220-240V～, power supply frequency 50/60Hz

VI. Operation methods

6.1 Sterilization
Before using the device, sterilize the reusable electrosurgical electrodes and accessories. The other components and disposable accessories don't need to be sterilized.
Sterilization methods: Put the electrodes into a container which can be sterilized together . Perform sterilization by using steam according to the autoclave instruction : 134℃±4℃,20min-35minutes,2 bar.

6.2 Plug power cord into Power Supply Socket on the rear of OBS-100A and connect electric outlet.
6.3 Insert the 3 pins plug of Electrosurgical Pencil into the output socket.
6.4 Insert the plug of Pad cable into the pad socket and connect the another terminal with Electrosurgical Pad.
6.5 Turn the on/off switch to the "on"("I") position.
6.6 Adjust the power output for the selected mode to the desired wattage using Adjust Knob on the front panel.
6.7 The selected output will be sent to the accessory electrode upon pressing pencil activation button(yellow or blue one). Activation is indicated by the blue light and a continuous audible tone.
6.8 When the procedure is complete, turn the on/off switch to "off"("O") position.

6.2 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.

6.3 Output terminal

6.3.1 Monopole of this device adopts handle output power. Handle output socket and handle switch are effective simultaneously.

Notice:

(1) It is forbidden to contact directly the handle and various accessories with medical solutions, and even to immerse them into medical solutions and other solutions.

6.4 Switch on power supply and observe initial status

①Without inserting Electrosurgical Pads, accompanied with sound and light alarms after self-examination, it cannot work.

②Inserting the Electrosurgical Pads, preset it to previous working state after staring up the device, it can work.

Notice: Inserting Electrosurgical Pads during operation, otherwise it will not work, associated with sound and light alarms.

6.5 This device has functions of pure cut, blend cut, forced electrocoagulation , soft electrocoagulation , two cutting functions and two electrocoagulations. for the selections during surgical operations.

VII. Precautions:

Cables of Electrosurgical Pencil and Electrosurgical Pad are made of special high frequency cable, please contact with manufacturer if replacements are necessary

7.1 In order to prevent influences to other instruments or electrifying of machine’s body

due to induction, grounding should be connected with this machine.
If low frequency current produced from high frequency surgery device is too strong, or stronger low frequency flows into high frequency surgery device from another voltage source, electric shock will happen at this time.

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

7.3 Don't do "polar plate test" with handle and electrode, because the polar plate is a product of thin metal polar plate or disposable electrosurgical pad

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7.4 Accessories in good condition must be used in surgical operation。

Only compatible accessories or eligible accessories tested by manufacturer can be used. This requirement is not only suitable for application electrodes including cables and plugs, but also suitable for electrosurgical pads including cables and plugs.（*6.8.2 aa in* EN60601-1,EN60601-2-2and EN60601-1-2）

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 electrocoagulation 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.

All the isolations of electrode, handle of electrode, cable and plug etc. should be kept in good conditions.

7.5 Polar Plate (Electrosurgical pad)

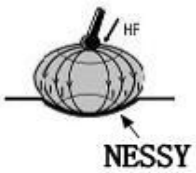
The whole area of Electrosurgical Pad must closely attach to the body of patient (beneath buttocks), and should be as close as possible to operation area. 6.8.2 bb）1）in EN60601-1,EN60601-2-2and EN60601-1-2.

Effective contact surface i.e. electric conductivity between electrosurgical pad and patient should be equal to high frequency capacity applied namely the intensity of high frequency current. Here, effective contacting surface means electrosurgical pad surface contacting electric conduction contacting with patient's skin during operations.

If it is misused or even not used, then there would be a great risk to tissues of human body by accidental heat trauma at point of electrosurgical pad as well as on the other parts of patient.

The Electrosurgial Pads are divided into metal electrosurgical pad, disposable

electrosurgical pad and two kinds of polar pads
Metal electrosurgical pad must be enclosed in two layers with gauzes, wet it with physiological saline before using. Whole area of it should closely attach to the body of patient (beneath buttocks), and should be as close as possible to operation area to form a good circuit. Electrical conducting glue of disposable electrosurgical pad is adhered to the body of patient (beneath buttocks).



7.6 Patient should not touch any metal parts (such as: operating-table, bracket etc.) that are connected with grounding or the metal parts with considerable capacitance of grounding. Thus, it is suggested to use antistatic plate. 6.8.2 bb）2）in EN60601-1,EN60601-2-2and EN60601-1-2.

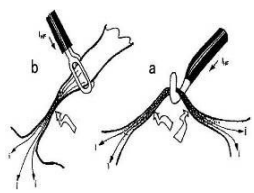
7.7 To avoid skin-to-skin contacting (i.e. arm to body of patient), put a piece of dry gauze in between. 6.8.2 bb）in 3 EN60601-1,EN60601-2-2and EN60601-1-2.
Between the contacting points of four limbs or skin while lying, there should be put a piece of dry gauze in between to isolate them each other.

7.8 In the case when high frequency surgical device and physiological monitor are used on one patient at same time, all monitoring electrode should be far away as possible from the place of operation electrode. It is not recommended to use needle type monitoring electrode.
Under any circumstance, it is recommended to use the monitoring system that has high frequency current limitator. 6.8.2 bb）4) in EN60601-1,EN60601-2-2and EN60601-1-2.
Electrocardiogram （ECG）electrode should not be used within the range of 15 mm in operating area.

7.9 Operation electrode cable should be placed away from patients or other cables to avoid contacting
Operation electrode that is not used temporarily should be placed away from patients. 6.8.2 bb）5）in EN60601-1,EN60601-2-2and EN60601-1-2.
Just like using bistoury, high frequency operation has also a potential risk with carelessness. Be careful and cautious when using cutting electrode and electrocoagulation electrode. Place them aside during breaks to prevent patients or other

persons form touching.
The reason of the accidents happened in the past is that the electrode entering into the layer of coving fabric and penetrated into patient's skin without attention in time, which caused electric burns.

7.10 During operation, high frequency current probably flows through less part of section of limbs. To avoid unnecessary coagulation, it is better to use bipolar electrode technology. 6.8.2 bb）6）in EN60601-1,EN60601-2-2and EN60601-1-2.
General speaking, as compared with monopole electrocoagulation technology, bipolar electrocoagulation technology is preferable. bipolar electrocoagulation technology is particularly suitable for electrocoagulation 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 electrocoagulated along whole distance. If diameter of tissues around electrocoagulation electrode point is less than that of electrode point, then there should be electrocoagulation 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.

7.11 Lower power output should be selected as far as possible to reach expected aim. 6.8.2 bb）7）in EN60601-1,EN60601-2-2and EN60601-1-2.

7.12 Under normal operation setting, if the output runs down quickly or surgical device doesn't work normally, that probably means the poor contact of electrosurgical pad (skin application plate) or improper use. 6.8.2 bb）8）in EN60601-1,EN60601-2-2and EN60601-1-2.

7.13 When surgical operation is carried out on chest or head, flammable anaesthetic, laughing gas and oxygen are avoided for using unless the anaesthetic gas is taken out or anti- anaesthetic is used. Before high frequency operation, flammable cleanser or agglomerant should be vaporized off.
Scour all flammable liquid beneath the body of patient or in concave (bellybutton) and

coelome of body (vagina) before using the device, pay close attention to the risks of flammable gas. For certain materials, such as absorbent cotton full of oxygen, gauze, possibly catching fire by sparks during normal operation of device. 6.8.2 bb）9） in EN60601-1,EN60601-2-2and EN60601-1-2.

The electrodes of high frequency surgical operation device will certainly generate spark or arc during operations, which may ignite flammable liquid, gas or steam. During high frequency operation, it is ensure that all anaesthetic, skin cleanser and disinfecting agent are non-flammable. No any flammable gas existing there should be ensured; otherwise, there must be the risk of explosions.

Therefore, flammable gas should be taken out of coelome or spayed out with CO2 from the affected coelome before surgical operations; operations can only be done after eliminating the flammable gas.

When carrying out electrosugical operation for prostate through urethra, H2O molecule in electric arc between cutting ring and washing liquid will be decomposed into H2 and O2. These gases will gather at top of bladder and become high potential explosive mixtures. If cutting operation is carried out with these mixtures, dangerous explosion will occur.

7.14 When patient is using heart pacemaker or pacemaker electrode, there is a risk existing there, the working condition of pacemaker is possibly disturbed or damaged. Please consult with persons form heart division for assistance. 6.8.2 bb）10）in EN60601-1,EN60601-2-2and EN60601-1-2.

7.15 The disturbance from the operation of high frequency can probably bring about disadvantage to the operations of other medical electronic equipment. EN60601-2-2 6.8.2 cc）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.
In consideration of the disturbance to other sensible electronic equipment, this device is equipped with a special generator, which produces less disturbing electrical level compared with conventional high frequency operation device.

7.16 Operator should examine each accessory before each operation, especially check the damages of electrode cable isolation 6.8.2 dd）in EN60601-1,EN60601-2-2and EN60601-1-2.

7.17 Under normal operation of the instrument:
7.17.1 The working life of reusable electrosurgical pencils is 30 times, which is probably damaged after expiry. Disposable electrosurgical pencils are forbided to be reused.
7.17.2　Metal electrosurgical pad can be use repeatedly within three months period. Disposable electrosurgical pad can only be uses once. Lead of skin application plate can be used repeatedly within three months. Replace it as surface is damaged. The usage exceeding its time limit may cause damages.
7.17.3 Replace if exterior of power supply cable of machine is damaged

7.18 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.

7.19 Descriptions for assembling and un-assembling methods of removable components and accessories as well as wearing materials

7.19.1 Handle and blade of electrosurgical pencil
Replace when handle press button (such as handle in normal open), handle lead are damaged.
electrosurgial pencils are made of special high frequency cable and handle shell, blade is made of stainless steel. Handle lead plug and handle output are pressed by mouldings, three- pins plug is inserted parallelly into output socket. Remove the handle, hold the rear end of plug and pull it out parallelly. Connect blade and handle, align rear end of blade with handle, insert blade. Remove blade; pull it off by holding middle part of blade.

7.19.2 Electrosurgical pad, pad cable and connection of the machine

Replace it if there is cauterization sign on electrosurgical pad and replace it if contacts of plug and socket are in poor condition.

Cables of metal electrosurgical pad, disposable electrosurgical pad are made of special high frequency cable. At rear parts of metal electrosurgical pad disposable electrosurgical pad, there is a rectangular place for sockets for inserting electrosurgical pad cable, pull it out in reverse direction.

7.19.3 Fuse

Fuse is fixed at rear plate of machine, and integrated with power supply socket, pull off power supply cable, pull fuse fixture slightly with hand, take fuse box out for replacement. Insert the replaced fuse parallelly into fuse fixture to finish replacement.

7.19.4 Power supple lead

Replace when tow terminals of power lead are in poor contact condition or damaged, and surface of it is damaged. Power lead has two ends, one end is a plug in type of round outer three-core for power network, the other end is a plug in type of square inner three-core for power supply of the machine, which is inserted parallelly into power supply socket on rear plate of the machine, hold the front end of plug and take it off when removing.

7.19.5 Dustproof cover of fan

The machine is equipped with a fan for lowering temperature, the fan is fixed with a dustproof cover, and there is much of dust accumulated after operating for a long time. There are 4 screws within dustproof cover, open them with screwdriver, take off dustproof cover with force, wash and clean it with sponge, put it under natural condition for drying after cleaning, and replace it within dustproof cover, relocate it into the original place parallelly.

7.20 Safety regular maintenance

The machine should be operated idly under normal temperature for more than 20 hours each month, and check if the accessories operate correctly.

7.21 The machine should be examined by professionals at least 2 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.

7.22 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 electrosurgical pad and cable are in good condition; replace them if they are damaged.

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

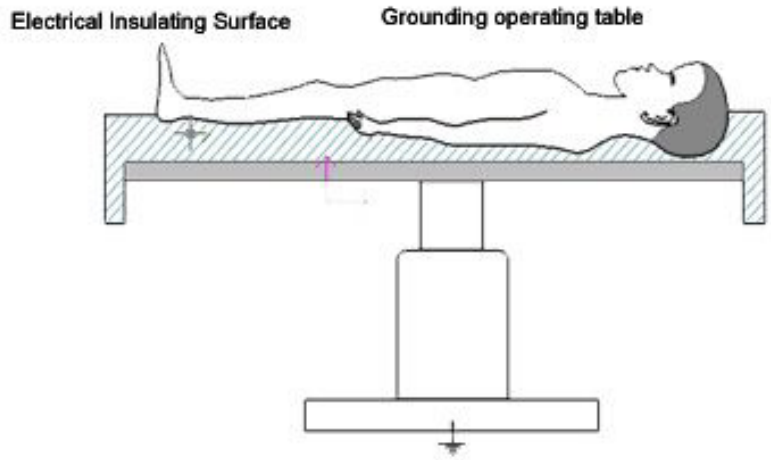
★Do not run the machine idly during operations to avoid accident.

7.24 If power supply is not within the range of 220V±10% and power frequency of 50/60Hz, please use power stabilizer.

7.25 Before operating the device, disinfect the head of electrosurgical pencil, handle cables and some other components and sections.
Sterilization methods: Put the electrodes into a container which can be sterilized together . Perform sterilization by using steam according to the autoclave instruction : 134℃±4℃,20min-35minutes,2 bar.

7.26 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.
7.26.1 Accidental heat injury to body tissues due to drain current of high frequency
During high frequency surgical operation, patient inevitably conducts the high frequency current to ground electric level. If the patient contacts with conductive object at this time, then high frequency current will be produced at the contacting point between patient and object, which causes heat putrescence. Not only is the metal the electric conductive substance, but also the wet cloth.

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



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

7.26.2 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 manual push button accidentally;
- Malfunctions of manual switch or cable;
- Electricity conductive liquid (such as blood, amniotic fluid, urine, physiological saline, washing liquid etc.) penetrates in 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 electrodes on the body of patient or by the side of patient at random absolutely, so as the electrodes 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 electrodes or electrocoagulation electrodes 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.

7.26.3 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 electrosurgical pad, poor contact of electric connector, cable failure, or remnants of electric isolation on electrode. Check them before increasing power.

7.26.4 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.

7.26.5 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.

VIII.Output data

8.1 pure cut, blend cut, forced electrocoagulation , soft electrocoagulation ,

8.2 High frequency drain current
8.2.1 Electrosurgical pad (skin application plate) isolated from ground in high frequency
The application parts should be isolated with ground under both conditions of high frequency and low frequency, which the isolations should be tested according to the following requirements, the drain current of high frequency should not exceed 150mA as each electrode flowing through 200Ω non-inductive resistance .

Following tests carried out to check if they meet requirements:

During testing, electrode cables and electrodes of the device should be arranged according to the instructions in EN60601-1,EN60601-2-2and EN60601-1-2. Fig. 4 102
The space between electrode cables is 0.5m, put them on an isolated surface 1 m form ground surface or any conductive plane, without no load on output end, all the metal shells of II class equipment and internal power supply equipment should be earthed.
Equipment with external isolation should be placed on the grounding metal plate, of which the area at least equal to the area of equipment's bottom (See Fig. 104).
Set max. operating output of each working mode of equipment, and measure high frequency drain current of each electrode in turn.

8.2.2 Application of bipolar electrode: any application section specially designed for dipolar application must be isolated with ground and other application section under high frequency and low frequency.

IX. Special parameters for safe application

Continuous drain current and patient assistant current

Drain current	Model BF	
	Normal Condition	Single Failure Status
Grounding Drain current	≤0.5MA	≤1mA
Shell Drain current	≤0.1mA	≤0.5mA

Patient Drain current		≤0.01mA	≤0.05mA
Patient Drain current added with voltage of network on application section		≤5mA	————
Patient assistant current	D.C.	≤0.01mA	≤0.05mA
patient assistant current	A.C.	≤0.1mA	≤0.5mA
High frequency drain current		≤150mA	————

X. Measures to be taken during operation of the device:

10.1 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.

10.2 Before operating the device, disinfect the blade of electrosurgical pencil, handle, cables and some other components and sections.

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XI. Transportation and Conditions for Storing

11.1 Transportation will be carried out according to contract.

11.2 Well-packed electrosurgical generator should be stored in a room under the temperature from

minus 40℃～70℃ with relative moisture not more than 80%, no corrosive gas as well as in good ventilation.

CE 1023

XII. EC Representative

Wellkang Ltd t/a Wellkang Tech Consulting

Suite B. 29 Harley street LONDON WIG 9QR England. United Kingdom

CE 1023

EC Representative

Wellkang Ltd t/a Wellkang Tech Consulting
Suite B. 29 Harley street LONDON WIG 9QR England. United Kingdom