Electrosurgical Generator

Operating Manual

Read the contents described in This page carefully when initial use

Declaration

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

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The contents in this manual are subject to changes without any notice, and we will not make any promise and do not take any obligation for the errors in This manual. Any or any part of photocopying, reprinting or translating version are not permitted without permission in written form beforehand.

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

Operation manual is used combining with the technical instructions.

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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;

1、 Characteristics of the product:

1.1 Category of the Device: Category I;

1.2 Model of the Device: Model CF

1.3 Category of Power Supply for the Device: Single phase, supplied from power netting (A.C.220V);

1.4 Rating power of the Device 1100VA±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

Power supply connection: 5A/220V～power frequency: 50Hz

Rating power: 1100VA

Classification: Model CF in category I

Working system: Working system of Intermittent loading continuous operation

Fuse: BGXP5×20 5A 3 pieces

Max. power: 300W with load 800Ω

Protective package: With indications such as keeping with care, upward, moisture proof etc.

Model CF device with function for protection of electricity discharge effect from heart defibrillator Isolated from ground at high frequency of neutral electrode

Disconnection (refer to main power supply)
Connection (refer to main power supply)

Power adding

Power subtracting

Grounding

High voltage connecting terminal, high voltage symbol, dangerous voltage

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±22V， 50Hz±1Hz。
e) Working frequency: 416kHz

3.2 Output rating power:

a）Pure cut: 1W～300W（Load 800Ω）；
b）Blend ：1 W～200W（Load 800Ω）；
c）Spray coag：1W～80W（Load 800Ω）；
d）Soft coag：1W～120W（Load 800Ω）；
e）Bipolar coag：1W～50W（Load 800Ω）；

3.3 Power supply：5A220V∽±10%，50±1%Hz。

3.4 Power consumption of equipment ：≤1100VA。（Cutting function 300W、Bipolar coagulation function 50W output）

3.5 Transportation and storage

a) Ambient temperature range: -40℃～55℃;
b) Relative moisture range: ≤95%；
c) Atmosphere pressure range: 500hPa～1060hPa。

Ⅳ. Expression explanations

4.1 NEUTRAL ELECTRODE

Neutral electrode is an electrode that 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 shuck as burning.

Neutral electrode is also called as plate electrode, skin application plate or spreading electrode.

4.2 Safety system of Nessy neutral electrode

Safety system of neutral electrode is to monitor the area on patient body applied with neutral electrode in order to ensure the applied area no more than 75%. So that, the monitoring of neutral electrode may effectively prevent patient from burning due to untight application, small contacting area, and poor conductivity of applying materials.

The deviation of rating value between high frequency output parameter and the electrotome can be only probably caused due to lower loading resistance, e.g. electrocoagulation electrode is too high, short circuit occurs between application electrode and neutral electrode, or the equipment is in failure.

THIS Electrosurgical Generator is provided with safety system of neutral electrode （NESSY）to monitor the electrical connection between equipment and neutral electrode as well as the condition of neutral electrode applied on body .

V. Names and functions of each part of machine

5.1 Front plate of electronic computer high frequency electrotome

The main controlling sector of electronic computer high frequency electrotome is located on front plate, for the sake of safety, the function sections of electrome CUT, electrocoagulation COAG and bi-electrode BIPOLAR 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), spray coagulation (blue indictor), soft coagulation (blue indictor), bipolar coagulation (blue indicator), bipolar output socket, single polar electrotome output socket as well as skin application plate socket.

Please refer to the following contents for operating

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 corresponding error code, If there is no defect detected, the equipment can be operated then.

a) THIS Electronic equipment has automatic monitoring function for high frequency output parameter, which can monitor the deviation between actual value and the rated valve of high frequency output parameter. When the deviation is too large to ensure the quality requirement of effects concerned (cutting or electrocoagulation), it will send an alarm and /or close high frequency generator. In case that deviation occurs or it is unable to meet the requirements of expected effect, the output error relating to the equipment will be displayed in order to remind operators to check if the deviation is caused by the equipment.

b) The deviation of rating value between high frequency output parameter and THIS electrotome can be only probably caused due to the loading resistance being too low, e.g. electrocoagulation electrode is too high, short circuit occurs between applications or equipment is in failure.

c) Safety system of neutral electrode

THIS series devices are provided with safety system of neutral electrode （NESSY） to monitor the electrical connection between equipment and neutral electrode as well as the condition of neutral electrode applied on body of patient.

When neutral electrode with only one contacting surface is used, it can only detect electric connections between neutral electrodes of the equipment automatically. If the connections are in good conditions, NESSY signal lamp of green flash diode is lightened, all the operating modes can be actuated. If connection is cut off, NESSY signal lamp of red flash diode is lightened; monopole-operating mode should not be actuated at This time.

When neutral electrode with two contacting surfaces is used, it can not only automatically monitor the electric connection between the equipment and neutral electrode, but also monitor the condition of application of neutral electrode on patient’s body. In addition, it can also automatically measure electrical conductivity between the

tow contacting surfaces of neutral electrode and the skin of patient constantly, and automatically compare the results measured with the intensity of high frequency current flowing through the neutral electrode. If the intensity of high frequency current is higher than the corresponding allowable value of conductivity measured, then, NESSY will send video and audio alarm signals, if the conductivity measured between neutral electrode and patient is too weak, the monopole operating mode can not be actuated.

There are numerous varieties of high frequency surgical operation, but up to now, optimum neutral electrode may not be achieved under all operating occasions. In order to ensure customers to have flexibility in selecting the optimum neural electrode, NESSY offers a flexible safety system of neural electrode, which is applicable to the neural electrode selected by the customer in an optimum mode.

Warning

For the sake of safety, only if the condition of modification is notified to all users of equipment appropriately in time, can the setting of NESSY be modified. In addition, for the modification of NESSY, proper records should be made and filed.

Before applying the double- contacting -surface neural electrode onto the body of patient, check if the signal lamp of NESSY green flash diode is lightened.

c) If short circuit occurs low resistance bypass on certain key of the handle of electrode or due to malfunction (such as duo to moisture of electrode handle), or is pressed down in the process of switch-on of power supply, the machine will sound alarm after power supply is switched on and display error code.

d) In the case that short circuit occurs on contactors of foot pedal, and the foot pedal is blocked or pressed down during electrifying, the machine will sound alarm and display error code after electrifying.

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 intermittently and display error code.

e) After electrifying, the equipment will automatically test performance. If certain performance is tested incorrectly, it will sound alarm and display corresponding error code. 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 error code 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.

——In the case that short circuit occurs on the contactors of foot pedal, and the foot pedal is blocked or is pressed down during electrifying, the machine will sound alarm and display error code after electrifying.

——Automatic performance check during startup

After each startup, the equipment tests performance automatically. If it detects certain performance error, it will sound alarm and display corresponding error code. It can also automatically identify following malfunctions of performance of equipment and its accessories connected:

High frequency output voltage check:

—As one operating mode is actuated such as cutting or gentle electrocoagulation, if high frequency output voltage deviates its setting value, the equipment will send out video and audio alarm signals.

Automatic neutral electrode check

——If neutral electrode is disconnected during actuating, or the contacting resistance is too high (only refer to the neutral electrode with double contacting surfaces), and then the equipment cuts off high frequency generator, it sounds alarm and displays error code.

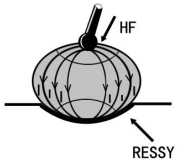
5.2.2 Polar plate test

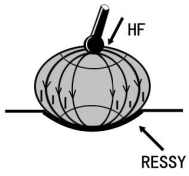
Heat injury caused due to misuse of neutral electrode or without using neutral electrode

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

Warning

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





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 manufacture are used. This requirement is not only suitable for application electrodes including cables and plugs, but also suitable for neutral electrodes including cables and plugs.

When electricity-isolating apparatus is used, ensure that the isolation should not be overloaded and damaged due to higher voltage. This operation manual describes output voltage values for all the cutting and 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 neutral electrode, poor contact of electric connection, cable malfunction, or electricity isolation tissue remained on application electrode. Check them before increasing power.

Connecting socket of neutral electrode

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

THIS Electrotome equipment is equipped with neutral electrode safety system (NESSY), which can automatically monitor the connection between neutral electrode and equipment as well as the condition of application on patient's body. However, the later can only be done by using the neutral electrode with double contacting surfaces. (see "NESSY" in Section 4.4)

Warning

If single-surface neutral electrode is used, NESSY can only monitor condition of electric connection between neutral electrode and equipment, and cannot monitor the

condition of application on patient's body.

The meanings of graphical signs beside of neutral electrode connecting socket are as following:

Common neutral electrode

This device is in conformity with the requirement of Section No. 19.101b of GB9706.4-2009, its application section and isolation from ground meets the requirements of high frequency technology. According to GB9706.4-2009、it is in conformity with requirements for Model CF. In addition, the symbol also indicates that neutral electrode can be left on patient's body when there is no any fabric vibration according to B9706.4-2009.

NESSY= Neutral electrode safety system

Neutral electrode safety system

Electrotome series equipment is provided with safety system of neutral electrode （NESSY） to monitor electric connection between equipment and neutral electrode and condition of the neutral electrode applied on body of patient .

When neutral electrode with only one contacting surface is used, it can only monitor electric connections between neutral electrodes of the equipment automatically. If the connections are in good conditions, NESSY signal lamp of green flash diode is lightened, all the operating modes can be actuated. If connection is cut off, NESSY signal lamp of red flash diode is lightened, homopolar-operating mode should not be actuated at This time.

When neutral electrode with two contacting surfaces is used, it can not only automatically monitor the electric connection between the equipment and neutral electrode, but also monitor the condition of application of neutral electrode on patient's body. In addition, it can also automatically measure electrical conductivity between the tow contacting surfaces of neutral electrode and the skin of patient constantly, and automatically compare the results measured with the intensity of high frequency current flowing through the neutral electrode. If the intensity of high frequency current is higher than the corresponding allowable value of conductivity measured, then, NESSY will send video and audio alarm signal, the homopolar operating mode can not be actuated.

The there are numerous varieties of high frequency surgical operation, but up to now, optimum neutral electrode may not be achieved under all operating circumstance. In order to ensure customers to have flexibility in selecting the optimum neural electrode, NESSY offers a flexible safety system of neural electrode, which is applicable to the neural electrode selected by the customer in an optimum mode.

For the sake of safety, only if the condition of modification is notified to all users of equipment appropriately in time, can the setting of NESSY be modified. In addition, for

the modification of NESSY, proper records should be made and filed.

Before applying the double- surface neural electrode onto the body of patient, check if the signal lamp of NESSY green flash diode is lightened.

Automatic check for neutral electrode

If the connection of neutral electrode is cut off during actuating, or contacting resistance is too high (only refer to separated neutral electrodes), the equipment will cut off high frequency generator, sound alarm and display error code of this error.

5.3 Cutting （ CUT ）function section

5.3.1 Selection keys

Application function will be changed from the functions of pure、 blend by pressing the key once at a time. This device has rapid cutting key directly, press the key when necessary.

5.3.2 Power adding key, subtracting key:

5.3.3 Pure cut

Press adding or subtracting key once when values displayed between 1-40, each press will add or subtract by 1, each press will add or subtract by 5 when values displayed between 40-100, and each press will add or subtract by 10 when values displayed over 100. If the key is pressed down constantly, it adds and subtracts rapidly.

Power range of pure cut is within 1W～300W (load 800Ω)

On the output button of homopolar electrotome handle, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation, This means that cutting has no effect of electrocoagulation.

This is mainly applicable to prostate vaporizing surgical operation（TUR）. Since an automatic power compensating system is designed for the steps of 290W、250W、200W、150W under mode cutting , it is particularly used for prostate vaporizing surgery. It can also operate perfectly under water.

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.

Automatic cutting with high frequency voltage （ CUT）

THIS device is provided with a control system for automatic power compensation circuit to control and regulate cutting to ensure cutting quality selected and for its stability.

Adjustable power limit value in cutting operating mode,

Since THIS device is provided with high frequency voltage automatic control in cutting operating mode, so that there is no need to set power for cutting quality. Adjustable power limit value is mainly to ensure the safety for patients to prevent body tissue from accidental heat trauma and also avoid damages to precise cutting instruments such as needle electrode etc., caused by higher high frequency current when it contacts with other metal apparatus during operation of the device. This damage more likely happens during celioscope surgical operation. It should not to confuse adjustable power limit value with power setting of conventional high frequency surgical operating device. The cutting quality of conventional device directly depends on the settings of power.

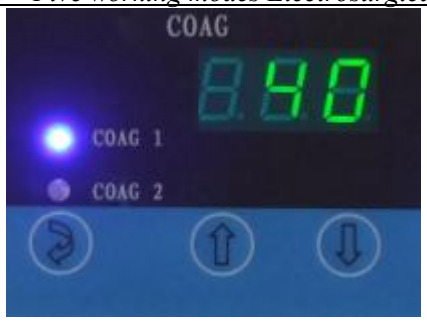
Cutting is especially suitable for those human body with poor electric conductivity. But, since high frequency voltage on electrode applied in cutting mode can reach rather high value, therefore, when cutting in body tissue with poor electric conductivity, instruments with good electric isolating performance must be used for cutting function. It is not recommended to use cutting function for bipolar or sub-bipolar apparatuses, This is because the isolating passages of This kind apparatus is usually small, which cannot be connected to high voltage. It is recommended to use other functions for bipolar or sub-bipolar apparatuses.

5.3.4 Blend Cutting

The power range of blend cutting power is within 1W～200W（load 800Ω）, On the output button of homopolar electrotome handle, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation.

Cutting and blood coagulation can be carried out according to the needs of body tissues during operations. Press down yellow press button on the handle for cutting operation and press down blue press button for blood coagulation, the output power is adjustable with sound reminding. Usually, for the blood vein below 1 mm, there is no need to use hemostasia clamp, and also there are different sounds to distinguish cutting and blood coagulation operation.

5.4 Electrocoagulation function section



5.4.1 Power adding key, subtracting key:

Press adding or subtracting key once when values displayed between 1-40, each press will add or subtract by 1, each press will add or subtract by 5 when values displayed between 40-100, and each press will add or subtract by 10 when values displayed over 100. If the key is pressed down constantly, it adds and subtracts rapidly.

5.4.2 Spray coagulation

Power range of spray coagulation is within1W～80W（Load 800Ω）

It is usually used for blood vein electrocoagulation. If cutting off blood vein within 1-2 mm, nod tow ends of vein with flat end of knife instead of using gauze for dipping blood, cut off in the middle when color is white with a little yellow.

5.4.3 Soft coagulation

Power Range of soft coagulation is within1W～120W（Load 800Ω）

It is usually used for blood vein electrocoagulation. When cutting off blood veins within 1-2 mm, nod tow ends of vein with flat end of knife instead of using gauze for dipping blood, and then cut off in the middle when color is white with a little yellow.

5.5 Bipolar coagulation function section BIPO

5.5.1：Power adding key, subtracting key:

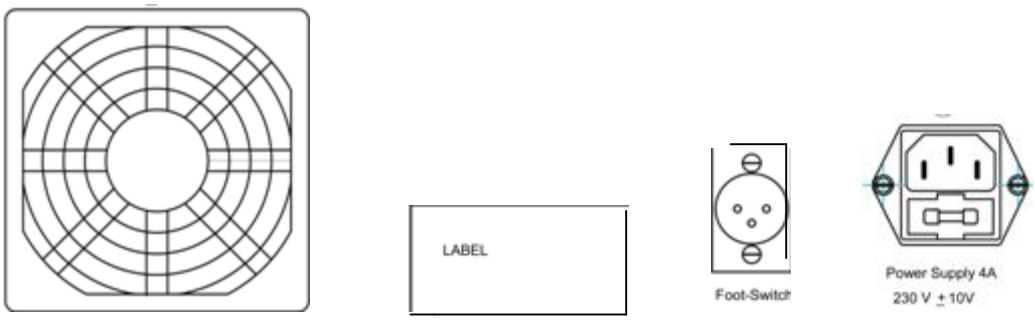
Press adding or subtracting key once when values displayed between 1-40, each press will add or subtract by 1, each press will add or subtract by 5 when values displayed between 40-70. If the key is pressed down constantly, it adds and subtracts rapidly.

5.5.2 Bipolar coagulation: 1W～50W (load 200Ω)

This is suitable for application in orthopaedics, microscopical surgeries. The less tissues are held, the better the effect will be during operation. Too much tissue to be held will affect the result of hemostasia.

Clamp body tissues with bipolar forceps, and output power for electrocoagulation, cut off the output as it leaves from human body, which must be controlled by foot pedal, otherwise, operations mentioned above can not be accomplished.

5.6 Rear Panel



Rear Panel of Apparatus

Rear panel of computerized high frequency electrotome includes: power supply socket, fuse seat, foot pedal socket, grounding connecting terminal, product nameplate and fan.

Power supply fuse of high voltage switch 5A（BGXP5×20）glass tube fuse, 2、3、 fuse 5A （BGXP5×20）glass tube fuse. Since there is an impact current at beginning of max. power output of electrotome, so, 5A fuse is adopted.

5.6.2 A.C power supply socket, rating voltage 5A/220V～, power supply frequency 50Hz

5.6.3 Product nameplate

5.6.4 Foot pedal socket: 5 kinds of unipolar functions, foot pedal and manual control handles are effective simultaneously. Bipolar function will be effective only controlled by foot pedal.

VI. Operation methods

6.1 Disinfecting

Before using the device, connect grounding wire, disinfect head of electrotome, handle ,bipolar forceps，cables and some other components.

Disinfecting methods: wipe dirt with alcohol gauze, and then put it into formalin solution for suffocating under normal temperature of not less than 10 hours.

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 manufacture. 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, handle switch and foot pedal are effective simultaneously.

6.3.2

Bipolarity of This device adopts bipolar forceps output power.

Both bipolar forceps output socket, foot pedal are effective.

Notice:

(1) 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.

6.4 Switch on power supply and observe initial status

①Without inserting skin application plate, accompanied with sound and light alarms after self-examination, it cannot work.

②Inserting the skin application plate, preset it to previous working state after staring up the device, it can work.

Notice: Inserting skin application plate during operation, otherwise it will not work, associated with sound and light alarms.

6.5 This device has functions of pure cut , blend cutting, contact coagulation , spay coagulation, bipolar coagulation,

6.5.1 Pure cut 1W～300W (load 800Ω);

Press down yellow press button at front for monopole output for monopole output, of

which the function has no blood coagulation effect.

This is mainly applicable to prostate vaporizing surgical operation（TUR）. Since an automatic power compensating system is designed for the steps of 290W、250W、200W、150W under mode cutting, it is particularly used for prostate vaporizing surgical operation. It can also operate perfectly under water.

Notice: Notice: During normal surgical operation, one should select a lower power at first, and if it is not 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.

Automatic cutting with high frequency voltage（ CUT）

THIS device is equipped with a control system of automatic open and close circuit to control and regulate cutting for ensuring cutting quality expected and stability.

Adjustable power limit value of cutting operating mode,

Since THIS device is equipped with high frequency voltage automatic control in cutting operating mode, so there is no need to set power for cutting quality. Adjustable power limit value is mainly to ensure the safety for patients to prevent body tissue from accidental heat trauma, and also prevent precise cutting instruments such as needle electrode etc. from damages which is caused by higher high frequency current when it contacts with other metal apparatus under the operation of the device. This damage is more likely to happen during celioscope surgical operation. It should not to confuse adjustable power limit value with power setting of conventional high frequency surgical operating device. The cutting quality of conventional device directly depends on the settings of power.

Pure cut is especially suitable for those human body with poor electric conductivity. But, since high frequency voltage on electrode applied in cutting mode can reach rather high value, therefore, when cutting in body tissue with poor electric conductivity instruments with good electric isolating performance should be used for cutting function. It is not recommended to use cutting function for bipolar or sub-bipolar apparatuses, This is because that the isolating passages of This kind apparatus is usually small, which can not be connected to high voltage. It is recommended to use other functions for bipolar or sub-bipolar apparatuses.

6.5.2 Blend cutting

The power range of blend cutting is within 1W～200W（load 800Ω）, On the output button of homopolar electrotome handle, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation.

Cutting and blood coagulation can be carried out according to the needs of body tissues during operation. Press down yellow press button on the handle for cutting

operation and press down blue press button for blood coagulation, the output power is adjustable with sound reminding. Usually, for the blood veins below 1 mm, there is no need to use hemostasia clamp, and also there are different sounds to distinguish cutting and blood coagulation operation.

6.5.3 Spray coagulation

The power range of spray coagulation is within 1W～80W (load 800Ω)

It is usually used for blood vein electrocoagulation. If cutting off blood vein within 1-2 mm, nod tow ends of vein with flat end of knife instead of using gauze for dipping blood, cut off in the middle when color is white with a little yellow. Press This key to select one of coagulation modes as following:

6.5.4 Soft coagulation

The power range of soft coagulation is within 1W～120W (load 800Ω)

Since this function controls strictly the output voltage, it is called low voltage electrocoagulation, therefore, it is mainly used for celioscope surgical operation, which can carry out blood coagulation and separation with celioscope.

This automatic electrocoagulation function section is coagulating mode, which can be actuated by pressing blue press button on the electrode handle or blue pedal at foot pedal switch. The actuating status is indicated by the flashing tri-angle symbol on the top of the automatic electrocoagulation section and the sounding signal simultaneously.

6.5.5 Bipolar coagulation: 1W～50W (load 200Ω);

This is suitable for application in orthopaedics, microscopical surgeries. The less tissues are held, the better the effect will be during operation. Too much tissue held will affect the result of hemostasia.

The output power will electro-coagulate when bipolar forceps clamp body tissues, cut off output as it leave away from human body, which must be controlled by foot pedal, otherwise, operations mentioned above can not be accomplished.

6.5.6 Foot Pedal:

This device adopts two feet pedals that control all functions. It is effective in monopole mode and handle simultaneously.

The design mentioned above is easy for operation; the customers of This device can use it safely and intuitionally free from occurring accidents.

VII. Precautions:

*Ca*bles of handle, skin application plate and bipolar electrode are made of special high frequency cable, please contact with manufacture 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 one-off skin application plate.

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

Only compatible accessories or eligible accessories tested by manufacture 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.（*6.8.2 aa in GB9706.4*）

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 (Neutral electrode)

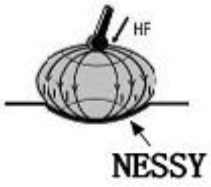
The whole area of polar plate (electrode plate) must closely attach to the body of patient (beneath buttocks), and should be as close as possible to operation area. 6.8.2 bb）1）in GB9706.4

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

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

The electrode plates are divided into metal electrode plate, one-off electrode plate and tow kinds of polar plates

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



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 GB9706.4

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 3GB9706.4

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 GB9706.4

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 GB9706.4

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 s.

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 GB9706.4

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 electrocoagulate 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 fine structure or smaller veins in smaller diameter.

7.11Lower power output should be selected as far as possible to reach expected aim. 6.8.2 bb）7）in GB9706.4

7.12Under normal operation setting, if the output runs down quickly or surgical device doesn't work normally, that probably means the poor contact of neutral electrode (skin application plate) or improper use. 6.8.2 bb）8）in GB9706.4

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 GB9706.4

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 electrotomy 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 GB9706.4

7.15 The disturbance from the operation of high frequency can probably bring about disadvantage to the operations of other medical electronic equipment. B9706.4 中 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 GB9706.4

7.17 Under normal operation of the instrument:

7.17.1 The working life of handle is 50 times, which is probably damaged after expiry. The blade can be used repeatedly.

7.17.2 Metal skin application plate can be use repeatedly within three months period. On-off skin application plate 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 Bipolar forceps cable and cable plug and socket can be used for 25 times; the usage exceeding its time limit may cause damages. Replace it as the isolation layer coming off from the surface of bipolar forceps.

7.17.4 Foot pedal can be used permanently

7.17.5 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

Replace when handle press button (such as handle in normal open), handle lead are damaged.

Handle is made of special high frequency cable and handle shell, blade is made of stainless steel. Handle lead plug and electrotome output are pressed by mouldings, three- core 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 Skin application plate, plate lead and connection of the machine

Replace it if there is cauterization sign on skin application plate and replace it if contacts of plug and socket are in poor condition.

Cables of metal polar plate, one-off skin application plate, and tow bipolar plates, skin application plate leads are made of special high frequency cable. At rear parts of metal polar place and one-off skin plate, there is a rectangular place for sockets for inserting skin application plate lead, pull it out in reverse direction.

The plug for connecting skin application plate blade and machine is Φ6.5mm, insert Φ6.5mm plug into the socket of PATILENT PLATE, Pull it out in reverse direction.

7.19.3 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.

7.19.4 Connection of foot pedal and machine

Foot pedal is in normal open; replace lead when it is broken.

Lead of foot petal is made of special high frequency cable. There is foot pedal socket at rear part of machine. A gap is located at the front of plug, level the gap of socket and insert it into the socket by pushing it rear end. Remove it by holding the front part of plug and press down the square lock and take it out.

7.19.5 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.

7.19.6 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.

7.19.7 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 positioning locks within dustproof cover, hold one side of dustproof cover with hand, take off it 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 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.

The working life period of machine is 6 years form the date of delivery

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 skin application plate 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±1Hz, 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 within the range of 220V±10% and power frequency of 50±1Hz, please use power stabilizer. Do not run the machine idly during operations to avoid accident.

7.25 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.

7.26 Accidental heat injury to body tissues

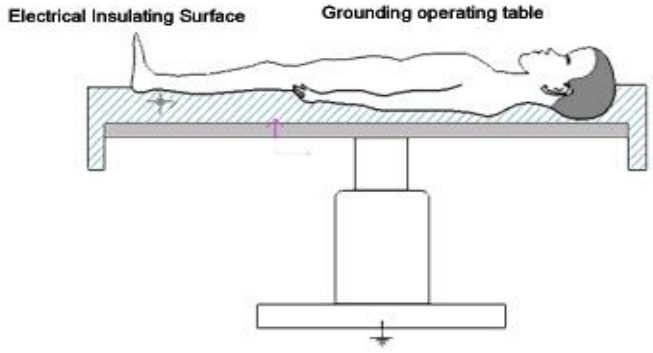
Usually, high frequency surgical operation always has a couple of risks for patients, medical staffs and environments. To avoid these risks during operation, surgeon and his assistant should aware these risks and avoid the happenings of accidents pursuant to regulations.

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 with 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 probably will happen on patient's body.

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

- Pressing down foot pedal accidentally;

- Pressing down manual push button accidentally;
- Malfunctions of foot pedal, manual switch or cable;
- Electricity conductive liquid (such as blood, amniotic fluid, urine, physiological saline, washing liquid etc.) penetrates in foot pedal or manual switch
- Malfunctions in high frequency operation device

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

- Do not put electrode on the body of patient or by the side of patient at random absolutely, so as the electrode may contact directly with patient or contact through conductive object and wet cloth indirectly.
- Fix firmly the electrode lead and do not let it contact with patient, and also not contact with other leads.
- Set sound signal loudly enough to hear, which can prompts working conditions of high frequency generator.
- For some of operations such as celioscope surgical operation, even under non-working condition, cutting electrode or electrocoagulation electrode will inevitably contact with patient, special attention should be paid at This time. If electrodes mentioned above are actuated accidentally due to some errors, do not take them out of body without special monitoring. Otherwise, all parts contacting with the working electrodes will be burnt. Therefore, when This accident happens, cut off power supply of high frequency operation device immediately, and then, manages to take the electrodes out of body.

7.26.3 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 neutral electrode, 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 , blend、 spray coag, soft coag, bipolar coagulation (see appendix 1)

8.2 High frequency drain current

8.2.1 Neutral Electrode (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 GB9706.4 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 bipolar 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 CF	
		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	D.C.	≤0.01mA	≤0.05mA
	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 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.

XI. Transportation and Conditions for Storing

11.1 Transportation will be carried out according to contract.

11.2 Well-packed electrotomes should be stored in a room under the temperature from minus 40℃～55℃ with relative moisture not more than 95%, no corrosive gas as well as in good ventilation.

Ⅻ Malfunctions

Field processing of common malfunctions(No need to remove the cover of its mainframe)

1. Starting up without display

   Check the patch board, power socket. And the fuse is burned or not. Replace it.

2. Starting up with - - 8

   Electrosurgical pad alarms. Bipolar electrosurgical pad stops alarming when it is sticked on the body of the patient. If it still alarms, turn to Maintenance &Processing Methods 2

3. Starting up with - - 7

   Before switching on, the key on the panel ,electrosurgical pencil and footswitch cannot be pressed down. Then check the electrosurgical pencil and footswitch, unplug the pencil and footswitch. Plug the electrosurgical pad into its jack, if its work well, that is the problem of electrosurgical pencil or footswitch.

4. Starting up with normal display, when outputs, it shows - - 5

   Change a new electrosurgical pencil.

5. Starting up with normal display, but when outputs, - - 4 shows up

   The bipolar light is on, turn it off, change a new electrosurgical pencil, then it can work.

6. Starting up with normal display; press the output key on the electrosurgical pencil, the output light is off, and there is no power; but press footswitch , it outputs well.（Tell the doctor to plug the endoscopic cord into the socket next to during the endoscopic surgery）. Please turn to Maintenance &Processing Methods 7.

7. Starting up with normal display, and the lights of electrosurgical pencil and footswitch is on, but no power outputs.

   Please check whether the fuse is burned, just replace it.

8. Starting up with normal display, but the output power is unadjustable.

   Please refer to Maintenance &Processing Methods 8.

9. Starting up with normal display, but only the cutting modes have power outputting, coagulation modes have no output power.

   Change a new electrosurgical pencil, if it's still can not be resolved, turn to Maintenance &Processing Methods 9.

10. Starting up with normal display, but the coagulation modes have no outputs, cutting modes have.

    Change a new electrosurgical pencil.

11. The output sound is too low or too high

A sound adjustment knob is on the back board of the generator, adjust the knob for normal sound. No sound adjustment knob turn to Maintenance &Processing Methods 11.

12. Alerting sound is too high

Maintenance &Processing Methods 12

13. Footswitch has no power outputting

Change a new footswitch. If it doesn't work, turn to Maintenance &Processing Methods 13.

14. When press footswitch, cutting area shows - - 4, alarming.

The bipolar light may be on, press it off.

15. Before plug the electrosurgical pad, the generator gives no alarms.

The bipolar light may be on, press it off. If it doesn't work, turn to Maintenance &Processing Methods14.

Maintenance &Processing Methods

1. Starting up with no display

   Take apart the cover of the mainframe, observing whether the flat cable or any other cables are loosen, or chip drops out. Connect the power source, turn the switch on, measuring the AC input(J13) with AC Voltmeter, to make sure if there is 220V voltage.

2. Starting up with - - 8

   Make pliers or forceps or some other metal objects touch the two metal objects at the side of pole plate on the mainframe at the same time. If there is no alarm, the generator has no malfunction. It's the problem of electrosurgical pad or its cable. Change a new set.

   If it still alerts, turn off the power source, remove the cover of the generator, take apart the main board, find out whether pole plate(T3) transformer is weak jointing .

3. Starting up with - - 7

   Change a new electrosurgical pencil or foot switch.

4. Starting up with normal display, when outputs, it shows - - 5

   Change a new electrosurgical pencil.

5. Starting up with normal display, but when outputs, - - 4 shows up

   It works under bipolar modes. please transfer working modes to monopolar, then it can work.

6. Starting up with normal display; press the output key on the electrosurgical pencil, the output light is off, and there is no power; but press footswitch , it outputs well.

   Take apart the cover of the mainframe, check whether R49(electric resistance 100Ω)

is burned, then change it. If R49 is ok, change a new electrosurgical pencil.

7. Starting up with normal display, and the lights of electrosurgical pencil and footswitch is on, but no power outputs.

   First check the fuse, if it was burned, remove the cover of the generator, observing the choke,

   Check its good or burned, change one. Then check DP9C(high voltage bridge rectifiers), if it was burned, replace it.

8. Starting up with normal display, but the output power is unadjustable.

   Remove the cover, check whether J1（flat cable）is loosen.

9. Starting up with normal display, but only the cutting modes have power outputting, coagulation modes have no output power.

   Change a new electrosurgical pencil, if this can not be resolved, change the photocoupler (7Y-3) on the left.

10. Starting up with normal display, but the coagulation modes have no outputs, cutting modes have.

    Change a new electrosurgical pencil.

11. The output sound is too low or too high

    A sound adjustment knob is on the back board of the generator, adjust the knob for normal sound.

    If there is no sound adjustable knob, remove the cover, adjust (W1)potentiometer10K on the left of the main board.

12. Alerting sound is too high

    Adjust the sound potentiometer, turn down counterclockwise.

13. Footswitch has no power outputting

    Change a new footswitch. Remove the cover, check whether flat cable(J2) is loosen.

14. Before plug the electrosurgical pad, the generator gives no alarms.

Take apart the cover, check whether the electrosurgical pad potentiometer(CW4) is loosen, twist up and down, if it's not loosen. Don't regulate the area of electrode potentiometer till it alerts.