



Model: 2000Y Argon Electrosurgical Generator

Operating Manual

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Read the contents described in this page carefully
when initial use

Declaration
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The contents in this manual may change as the changes of the national standards, we do not inform to the products which had been sold. We have the final interpretation for the contents in the manual.

The manual is intended as a guide for serving the 2000Y Argon Electrosurgical Generator only.

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

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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.

I. 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, power supply(A.C.220V);
- 1.4 Rating power of the Device: $1100\text{VA} \pm 10\%$;
- 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: $\leq 1100\text{VA}$

Classification: Model CF in category I

Working system: Working system of Intermittent loading continuous operation

Fuse: BGXP5 $\times$ 20 5A 3 pieces

Max. power: 300W with load 500 Ω

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)



Power adding



Power subtracting



Grounding connection (refer to main power supply)



High voltage connecting terminal, high voltage symbol, dangerous voltage

III. Technical parameters:

3.1 Normal operation

- a) Environmental temperature range: $5^{\circ}\text{C} \sim 40^{\circ}\text{C}$
- b) Relative moisture range: ≤ 80 ;
- c) Atmosphere pressure range: $86.0 \sim 106.0\text{kPa}$;
- d) Power supply: $220\text{V} \pm 22\text{V}$, $50\text{Hz} \pm 1\text{Hz}$ 。
- e) Working frequency: 416KHz

3.2 Rated output power:

3.2.1 the argon electrosurgical unit part

- a) pure: 300W (Load 500Ω) ;
- b) blend1: 200W (Load 500Ω) ;
- c) blend2: 150W (Load 500Ω) ;
- d) spray coag: 80W (Load 500Ω) ;
- e) forced coag: 120W (Load 500Ω) ;
- f) soft coag: 120W (Load 500Ω) ;
- g) bipolar coag: 120W (Load 200Ω) ;
- h) bipolar forced: 120W (Load 200Ω) ;

3.2.2 Argon system part

- a) Argon output flow range: $0.1\text{L/min} \sim 5\text{L/min}$
- b) Argon input monitoring pressure: $0 \sim 1\text{Mpa}$
- c) All argon cut modes: $0.1\text{L/min} \sim 5\text{L/min}$
- d) All argon coag modes: $0.1\text{L/min} \sim 5\text{L/min}$
- e) Argon purity: $\geq 99.99\%$
- f) Argon flow regulative precision: $(0.1\text{L} \sim 2\text{L}) 0.1\text{L}$ step; $(2\text{L} \sim 5\text{L}) 0.5\text{L}$ step.
- g) Gas supply: AL4 gas cylinder, filling capacity 9.5Mpa
- h) Argon input pressure: $0.2\text{Mpa} \sim 0.65\text{Mpa}$

3.3 Power supply: 5A $220\text{V} \pm 10\%$, $50 \pm 1\%$ Hz。

3.4 Power consumption of equipment : $\leq 1100\text{VA}$ 。(Cutting function 300W 、Bipolar coag function 120W output)

3.5 Transportation and storage

- a) Ambient temperature range: $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$;
- b) Relative moisture range: $\leq 95\%$;
- c) Atmosphere pressure range: $500\text{hPa} \sim 1060\text{hPa}$ 。

IV Expression explanations

4.1 Power peak value system PPS

Initial cut-in is a specific issue during cutting process, especially when the cutting pole is pressed tightly onto the tissues of human body before high frequency

generator is started. This is because that cutting pole contacts with the surface of tissues at this time, so that the resistance is rather low. For example: prostate surgical removal (TUR) through urethra and endoscope polypus removal operation are the cases just like this. Under this condition, the power supplied from high frequency generator must be higher than that of under normal condition in order to make initial cut-in more quickly, otherwise, electro-coagulating putrescence in large area on tissue would be more likely to occur at cutting point. Kangwei Electrotome equipment is provided with automatic compensation system, which can identify low impedance load, and enable the high frequency generator to provide enough power momentarily in order to ensure the quality set for cutting and desired high frequency i.e. electric arc intensity. In addition, low impedance load can also be ensured. This kind of equipment can limit average power within relative low magnitude, which is an improvement for preventing patient from suffering accidental heat trauma.

4.2 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 such as burning.

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

4.3 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 Kangwei 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.

2000Y argon electrosurgical units 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.

V. Names and functions of each part of the machine

5.1 Front panel of 2000Y Argon Electrosurgical Generator

The main controlling sector of 2000Y Argon Electrosurgical Generator is located on the front plate, for the sake of safety, the function sections of monopolar cut, monopolar coagulation, bipolar coag, argon cut and argon coagulation functions can not be actuated simultaneously, but they can be adjusted individually, which includes: power, flow display (green digital code tube), alarm display (red indicator), output display (yellow indicator) (blue indicator), power switch, power adjusting push button, options, pure (yellow indicator), blend1 (yellow indicator), blend2 (yellow indicator), spray coag (blue indicator), forced coag (blue indicator), bipolar coag (blue indicator), bipolar output socket, monopolar output (handle), neutral electrode output socket (plate), argon pencil output socket as well as argon probe output socket.

Please refer to the following contents for operating.

5.2 Functional 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) 2000Y Argon electrosurgical Generator has automatic monitoring function for high frequency output parameter, which can monitor the deviation between actual value and the rated value 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 electrosurgical generator 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

2000Y Argon electrosurgical unit 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 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 two 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 due 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 due 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.

2000Y Argon electrosurgical unit 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 BF. 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 GB9706.4-2009.

NESSY= Neutral electrode safety system

Neutral electrode safety system

CV-2000Y Argon electrosurgical unit 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 monopolar 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 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 Mode select keys

you can select pure cut, blend1 or blend2 when you press the corresponding key.

5.3.2 Power adding key, subtracting key:

Press adding  or subtracting key  to adjust the outputs, 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 or subtracts rapidly.

5.3.3 Pure cut (high-energy cut)

Power range of pure cut is within 1W~300W (load 500 Ω)

On the output button of disposable handle or argon pencil, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation, this means that pure cut 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 pure cut, it is particularly used for prostate vaporizing surgery. It can also operate perfectly under water.

5.3.4 Blend1

Power range of blend1 is within 1W~200W (load 500 Ω), it has power peak system (PPS). This function has 90% cutting effect and 10% electrocoagulation effect during operations.

5.3.5 Blend2

The power range of blend2 is within 1W~150W (load 500 Ω), blend2 can be used with argon gas simultaneously, named as argon cut. This function has 50% cutting effect and 50% electrocoagulation effect during operations. When blend2 be used cooperatively with argon gas, coagulation effect will be up to 80%.

Attention: blend2 is cutting mode, It outputs by the yellow button on the electrosurgical pencil or the yellow footswitch pedal, And with audible and visual indication.

5.4 Coagulation Section



you can select spray coag, forced coag, soft coag modes when press the corresponding key.

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 coag

Power range of spray coag is within 1W~80W (load 500 Ω). Spray coagulation is more applicable to the use of argon electrocoagulation. Spray coag can use common electrosurgical pencil and argon pencil for outputting. If it outputs with argon probe, the footswitch must be used.

The argon flow should be set before using. For digestive operation, argon flow is 1-2L/min, outputs is 20-40W; For open surgeries, argon flow is 3-4L/min, outputs is 40-60W.

5.4.3 Forced coagulation (powerful coagulation)

Power Range of forced coag is within 1W~120W (500 Ω in load)

Forced coag is often applicable to open surgeries and endoscopic surgeries.

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.

When it is used to endoscopic surgeries, it should cooperate with double footswitch.

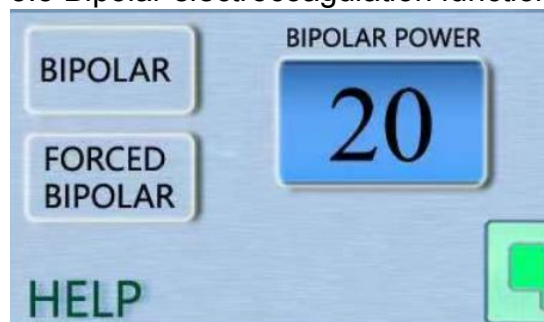
Attention: forced coag is coag mode, It outputs by the blue button on the electrosurgical pencil or the blue footswitch pedal, And with audible and visual indication.

5.4.4 soft coag 1W~120W (500 Ω in load)

The output voltage of soft coag is strictly controlled, it is called low-voltage coagulation. It is mainly used in endoscopic surgery, and coagulation and separation can be performed in the endoscopic surgeries. It has good coagulation effect for single blood spot. It can be used with bipolar forceps, general electrode or ball electrode.

Recommended use power: 30W-60W.

5.5 Bipolar electrocoagulation 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 40-50. If the key is pressed down constantly, it adds and subtracts rapidly.

5.5.2 Bipolar coagulation: 1W~120W (load 200 Ω)

For bipolar output, it is controlled by footswitch.

This is suitable for application in orthopaedics, microscopical and brain 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.

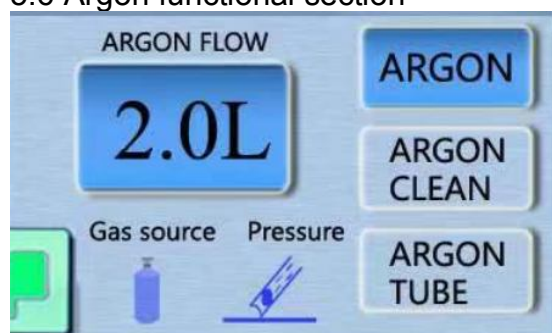
Attention: bipolar coag is coag mode, It outputs by the blue footswitch pedal, And with audible and visual indication.

5.5.3 Bipolar forced coag 1W~120W (load 200 Ω);

It is suitable for laparoscopic surgery with bipolar clamp to separate the lesion from the surrounding tissue. The thermal energy dispersion range of bipolar forced coagulation is small, which is relatively safe. It has the function of impedance monitoring and automatic stop output. Energy output was interrupted by an audible cue upon detection of tissue dryness.

Note: The bipolar forced coagulation function must be started by bipolar foot switch.

5.6 Argon functional section



5.6.1 The unit of Argon flow is L/min, argon flow range is 1L/min to 5L/min, flow error should not be more than ± 1 L/min.



5.6.2 Argon flow add-subtract key  , (0.1-2L) 0.1 step; (2L-5L) 0.5 step. Argon flow has nothing to do with outputs, it can be adjusted according to different operations.

Attention: Argon cut or argon coag modes can be controlled by the yellow or blue pedal of the footswitch, or controlled by the yellow or blue button on the argon pencil. And with audible and visual indication.

5.6.3 Argon gas inputs to pressure meter to achieve the purpose of gas supply. Turn on the switch of argon gas cylinder. Check the pressure meter on the reducing valve, if the displays is during 1-9.5MPa. It can work normally. If the display is less than 1MPa, please replenish argon gas.

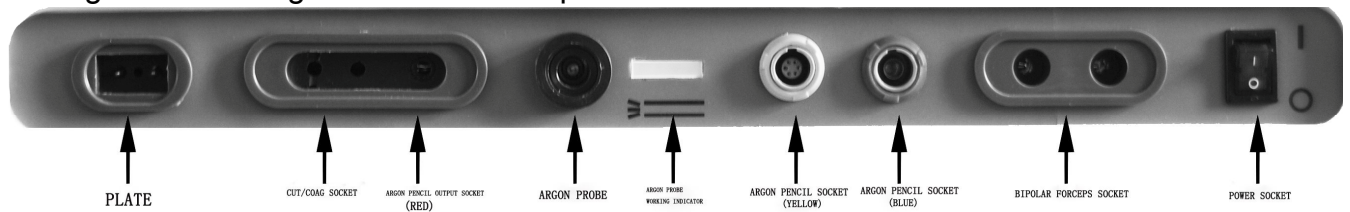
5.6.4 Stop argon supply: if using common electrosurgical pencil, argon gas stops automatically. When using argon pencil, argon gas outputs automatically.

Warning:

Pay much attention to the followings when using Argon Electrosurgical Generator

1. as contraindications, argon electrosurgical Generator can not be used in cardiac surgery and abdominal surgery.
2. This unit do not supply the accessories which connects endoscopics.
3. When argon electrosurgical generator is not used, place the electrode nozzle in a clean, dry, non-conductive, visible place, so as not to cause burns or cause fire in contact with the curtain fabric in contact with the patient.
4. Clinical report recommends: It must be careful when using argon electrosurgical generator for small intestine wall operation, damage degree of lower tissue during argon coagulating produces tiny eschars are not clear, but it will appear tissue crack complication after the operation.
5. During argon arc coagulates tissues, it may produce air embolism. Although in the research of liver and gallbladder coagulation, tiny air embolism are not happened has observably cilinical significance. But surgeons and anesthesiologists should realize that if they do not follow the prevensions below, it may appear harmful air embolism.
 - a)Shorten the operation time when using argon arc for coagulation.
 - b)Do not make spray nozzle contact with opening blood vessels or tissues surface directly.
 - c)We should keep argon flow to the lowest level which can produce the coagulation effect that needed.
 - d)Do not make argon stay at argon pencil tips more than 5 minutes when tissues are not be cutting and coagulating.
 - e)Operators should clear adhesive tissue on the spray nozzle in time, If find that argon continues outputs for a long time underwork condition, although activating signal have already stopped, operators should immediately remove argon pencil from the patients, closed the main unit power and cylinder valve, to make sure the gas supply were cut off. Before put into use, we should find the reason that make the malfunction.

5.7 Argon electrosurgical Generator output section



5.7.1 Neutral electrode socket(plate): 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 monopolar and argon operating mode can not be actuated.

Attention: Neutral Electrode should be checked whether in good condition, replace it if there are problems. The disposable neutral eletrode can be used only one time, please do not use repeatedly.

5.7.2 Monopolar electrosurgical pencil socket(CUT/COAG / power output SOCKET)

2000Y Argon Electrosurgical generator can be used as a common electrocautery without argon gas, electrosurgical pencil can be plugged into this socket. Then Argon is closed. The red hole is high voltage ouput for argon pencil, you can plug the red tip of argon pencil into this hole.

Attention: please close the argon gas when it was not be used, in case of interference appears when using electrosurgical generator.

5.7.3 Bipolar output socket: when using the bipolar functions of Argon electrosurgical generator, just plug the bipolar cable to the socket, and cooperate with footswitch. (argon gas is not be used under bipolar mode)

5.7.4 Argon probe socket: the argon probe mainly used in the digestive surgeries for coagulation, long 2.5m, external diameter is 2.5mm. it controlled by footswitch.

5.7.5 Argon pencil socket: there are four buttons on the argon pencil, power add, power substract, argon cut(yellow), argon coag button(blue).

5.7.6 Power switch

5.8 Rear Panel



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

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.

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

5.8.3 Foot switch socket: 6 kinds of unipolar functions, foot pedal and manual control handles are effective simultaneously. Bipolar function will be effective only controlled by foot pedal.

5.8.4 Argon gas input socket:

The unit supply with AL4 Argon gas cylinder, the capacity is 9.5MPa, the purity of argon gas is more than 99.99 %. A intake tube. Argon inducing valve. Before connecting the argon inducing valve, check whether there is dusty or not, if necessary, make it clean. Then using a wrench to tighten the pressure valve and the air interfaces of the cylinder, connects valve export and argon gas input socket with a plastic tube, turn on the switch, check the pressure gauge.

VI. Operation methods

6.1 Disinfecting

Before using the device, connect grounding wire, disinfect head of electrotome, handle ,bipolar forceps, argon pencils, argon probe, 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, blend1, blend2, , spray coag, forced coag, bipolar coag. Argon pencil use cooperatively with Blend2, argon coagulation cooperate with spray coagulation.

6.5.1 Pure cut (high-energy cut)

Power range of pure cut is within 1W~300W (load 500 Ω)

On the output button of disposable handle or argon pencil, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation, this means that pure cut 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 pure cut, it is particularly used for prostate vaporizing surgery. It can also operate perfectly under water.

Attention: when do operations, we should choose the smallest power output for cutting effect, if it is not enough, then increase the power output gradually. First, using surgical blade to cut a 2-3mm incision, dry the blood with a gauze, at the same time, continuesly cutting with electrosurgical generator for cutting and coagulating. If the cutting

tissues appears yellow, it shows the output power is higher, you can increase the cutting spread or lower the output power. If the cutting tissues appear white with a little yellow, it's the best effect, and it has less tissue damage.

2000Y Argon electrosurgical generator is equipped with closed loop control circuits for controlling and adjusting cutting to make sure the selected cutting status and remain stable.

6.5.2 Blend1

Power range of blend1 is within 1W~200W (load 500 Ω)

Blend1 cooperates with polypus snare, cutting and coagulation circularly output with audible and visual alarm. It activated by double footswitch.

6.5.3 Blend2

The power range of blend2 is within 1W~150W (load 500 Ω)

Blend2 is cooperate with argon pencil for cutting. There are three adapter connectors on the argon pencil, plug them into the correct sockets according to the colors of the connectors and sockets on the front panel.

Press the yellow button on the argon pencil for cutting, during the operation, adjust the argon flow according to the human tissues(using the triangle button on the argon pencil to adjust the argon flow). When power outputs, with audible and visual alarm.(blend2 can also cooperate with common electrosurgical pencil for cutting.)

Attention: blend2 is cutting mode, It outputs by the yellow button on the electrosurgical pencil or the yellow footswitch pedal, And with audible and visual indication.

6.5.4 Spray coag

Power range of spray coag is within 1W~80W (load 500 Ω). Spray coagulation is more applicable to the use of argon electrocoagulation. When using argon probe(blue cable standard supply), plug the connector to the socket. It controlled by double footswitch.

Spray coag can use common electrosurgical pencil and argon pencil for outputting.

The argon flow should be set before. For digestive operation, argon flow is 1-2L/min, outputs is 20-40W; For open surgeries, argon flow is 3-4L/min, outputs is 40-60W.

6.5.5 Forced coagulation (powerful coagulation)

Power Range of forced coag is within 1W~120W (500 Ω in load)

Forced coag is more applicable to open surgeries and endoscopic surgeries.

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.

When it is used to endoscopic surgeries, it should cooperate with double footswitch.

Attention: forced coag is coag mode, It outputs by the blue button on the electrosurgical pencil or the blue footswitch pedal, And with audible and visual indication.

6.5.6 soft coagulation (powerful coagulation)

Power Range of forced coag is within 1W~120W (800 Ω in load)

The output voltage of soft coag is strictly controlled, it is called low-voltage coagulation. It is mainly used in endoscopic surgery, and coagulation and separation can be performed in the endoscopic surgeries. It has good coagulation effect for single blood spot. It can be used with bipolar forceps, general electrode or ball electrode.

Recommended use power: 30W-60W.

6.5.7 Bipolar coagulation: 1W~120W (load 200 Ω);

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.

6.5.8 Bipolar forced coag 1W~120W (load 200 Ω);

It is suitable for laparoscopic surgery with bipolar clamp to separate the lesion from the surrounding tissue. The thermal energy dispersion range of bipolar forced coagulation is small, which is relatively safe. It has the function of impedance monitoring and automatic stop output. Energy output was interrupted by an audible cue upon detection of tissue dryness.

Note: The bipolar forced coagulation function must be started by bipolar foot switch.

6.5.7 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(the part of Argon electrosurgical Generator):

Cables 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)

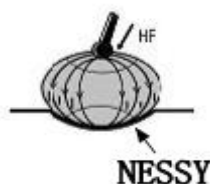
The whole area of polar plate (electrode plate) must closely attach to the body of patient (beneath buttocks), and should be as close as possible to operation area. 6.8.2 bb) 1) in GB9706.4

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 limiter. 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 from 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 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 heated in first. If high through same distance, then tissues of human body will electrocoagulate



human body are always smallest diameter section at frequency current passes diameters (a) over a longer

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.

7.11 Lower power output should be selected as far as possible to reach expected aim.

6.8.2 bb) 7) in GB9706.4

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 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 $\Phi 6.5\text{mm}$, insert $\Phi 6.5\text{mm}$ plug into the socket of PATIENT 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.

7.20 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.

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 $220V \pm 10\%$ and power frequency of $50 \pm 1\text{Hz}$, 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 $220V \pm 10\%$ and power frequency of $50 \pm 1\text{Hz}$, 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.

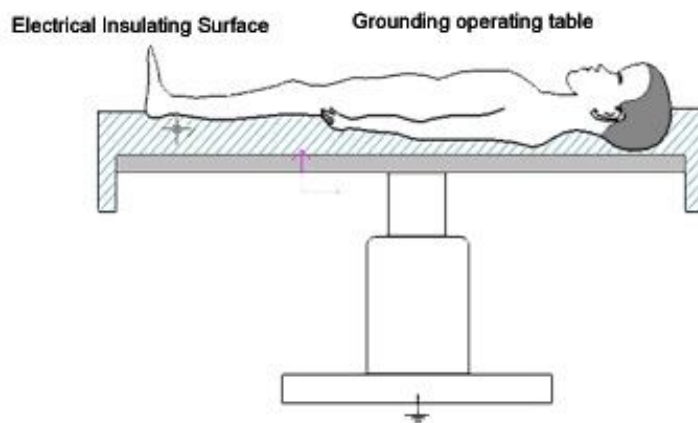
7.26.1 Accidental heat injury to body tissues due to drain current of high frequency

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 electric burn probably will happen on patient's body.

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

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

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

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

monitoring. Otherwise, all parts contacting with the working electrodes will be burnt.

Therefore, when this accident happens, cut off power supply of high frequency operation device immediately, and then, manages to take the electrodes out of body.

7.26.3 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, blend1, blend2, spray coag, forced coag, soft coag bipolar coag, bipolar forced coag.

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 200 Ω 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 from 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.

Warning:

Pay much attention to the followings when using Argon Electrosurgical Generator

1. This unit do not supply the accessories which connects endoscopics.
2. When argon electrosurgical generator is not used, place the electrode nozzle in a clean, dry, non-conductive, visible place, so as not to cause burns or cause fire in contact with the curtain fabric in contact with the patient.
3. Clinical report recommends: It must be careful when using argon electrosurgical generator for small intestine wall operation, damage degree of lower tissue during argon coagulating produces tiny eschars are not clear, but it will appear tissue crack complication after the operation.
4. During argon arc coagulates tissues, it may produce air embolism. Although in the research of liver and gallbladder coagulation, tiny air embolism are not happened has observably cilinical significance. But surgeons and anesthesiologists should realize that if they do not follow the prevensions below, it may appear harmful air embolism.
 - a) Shorten the operation time when using argon arc for coagulation.
 - b) Do not make spray nozzle contact with opening blood vessels or tissues surface directly.
 - c) We should keep argon flow to the lowest level which can produce the coagulation effect that needed.
 - d) Do not make argon stay at argon pencil tips more than 5 minutes when tissues are not be cutting and coagulating.
 - e) Operators should clear adhesive tissue on the spray nozzle in time, If find that argon continues outputs for a long time underwork condition, although activating

signal have already stopped, operators should immediately remove argon pencil from the patients, closed the main unit power and cylinder valve, to make sure the gas supply were cut off. Before put into use, we should find the reason that make the malfunction.

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		$\leq 0.5\text{mA}$	$\leq 1\text{mA}$
Shell Drain current		$\leq 0.1\text{mA}$	$\leq 0.5\text{mA}$
Patient Drain current		$\leq 0.01\text{mA}$	$\leq 0.05\text{mA}$
Patient Drain current added with voltage of network on application section		$\leq 5\text{mA}$	_____
Patient assistant	D.C.	$\leq 0.01\text{mA}$	$\leq 0.05\text{mA}$
	A.C.	$\leq 0.1\text{mA}$	$\leq 0.5\text{mA}$
High frequency drain current		$\leq 150\text{mA}$	_____

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 $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$ with relative moisture not more than 95%, no corrosive gas as well as in good ventilation.

Precautions:

- 1、 Argon pencils'connectors should be plugged into the correct socket with the same color. The connectors can not be disassembled, because it can not be recovered.
- 2、 Argon operation: Standard supply AL4 Argon bomb, the filling capacity is 9.5Mpa. Open the bomb switch, check whether the pressure meter on the reducing valve indicates between 1.0-9.5Mpa, if not, ask the service person to deal with. Please fill with argon gas if its lower than 1.0Mpa.
- 3、 Argon supply: When switch on, Argon flow display window should have digital display.
- 4、 Manual argon clear function: it is necessary to clear argon circuit during operation(for example: if spray nozzle blocked), press argon clear button, Argon will get through continuesly for 3seconds(15L/min), argon erupts from argon pencil or argon probe, at the same time check whether pressure meter indicates 0.2Mpa, if not, ask the service person to deal with.
- 5、 Flow setting: Preset aron flow for cutting or coagulation before operation. Adjust Argon flow by the button on the panel, argon flow can be adjusted during operation. Argon flow for argon probe is 1-1.3L/min; Argon flow for Argon pencil is 2.5-4L/min.
- 6、 Argon supply switch: When do outputs under the condition of argonless, there is not argon outputs when starting cutting or coagulation.
- 7、 Argon cutting output: When hand control or foot control for cutting siganal inputs, preset well argon flow for cutting, do cutting outputs, at this time, cutting indicator light is on(yellow).
- 8、 Argon coagulation output: When hand control or foot control for coagulation siganal inputs, preset well argon flow for coagulation, do coagulation outputs, at this time, coagulation indicator light is on(blue).
- 9、 Output pressure display: Argon pressure gauge displays working pressure of the unit.
- 10、 Argon inflation: Pressure gage on the reducing valve indicates argon pressure of the argon bomb, we can know the usage condition of argon gas. When argon pressure is less than 1.0Mpa, the argon bomb should be inflated with argon gas.
- 11、 After each operation, the argon valve on argon bomb should be closed, and also check argon pressure to inflate the bomb in time.



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