

Radiofrequency Surgical Unit (Model: CCS- 2000RF)

Operating Manual



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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 before hand.

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; Standard Implemented: YZB/State 0115-2016

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 $1100\text{VA} \pm 10\%$;
- 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: $5\text{A}/220\text{V} \sim$ power frequency: 4MHz

Rating power: 1100VA

Classification: Model CF in category I

Working system: Working system of Intermittent loading continuous operation

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

Max. power: 150W with load 700 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)
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

- Environmental temperature range: 5°C ~ 40°C
- Relative moisture range: ≤ 80 ;
- Atmosphere pressure range: 86.0 ~ 106.0 kPa;
- Power supply: 220V $\pm$ 22V, 4MHz $\pm$ 1% MHz。
- Working frequency: monopolar: 4MHz; bipolar: 1MHz

3.2 Output rating power:

- a) Pure cut: 1W~150W (Load 700 Ω) ;
- b) Blend : 1 W~100W (Load 700 Ω) ;
- c) Ablation: 1W~100W (Load 700 Ω) ;
- d) spray coag: 1W~80W (Load 700 Ω) ;
- e) Forced coag: 1W~100W (Load 700 Ω) ;
- f) Bipolar coag: 1W~120W (Load 200 Ω) ;

3.3 Power supply: 5A 220V φ $\pm 10\%$, 4MHz.

3.4 Power consumption of equipment : $\leq 1100VA$ 。 (Cutting function 150W、Bipolar coagulation function 120W output)

3.5 Transportation and storage

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

IV. Names and functions of each part of machine

4.1 Front panel of radiofrequency surgical unit

The main controlling sector of radiofrequency surgical unit is located on the front panel, for the sake of safety, the function sections of CUT, COAG and BIPOLAR function 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), forced coagulation (blue indictor), bipolar coagulation (blue indicator), bipolar output socket, single polar electrotome output socket as well as patient plate socket.

Please refer to the following contents for operating.

4.2 Function section

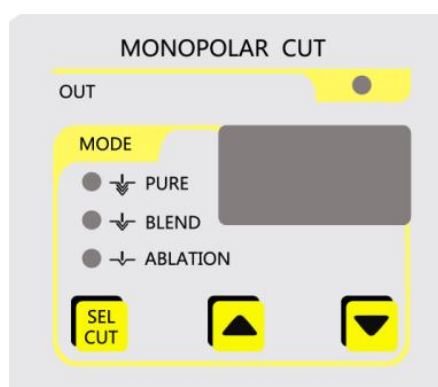


4.2.1 Malfunction alarms

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 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 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.

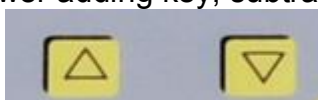
4.3 Cutting （ CUT ） function section



4.3.1 Selection keys

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

4.3.2 Power adding key, subtracting key:



4.3.3 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~150W (load 700 Ω)

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.

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.

4.3.4 Blend Cutting

The power range of blend cutting power is within 1W~100W (load 700 Ω), On the output button of monopolar 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.

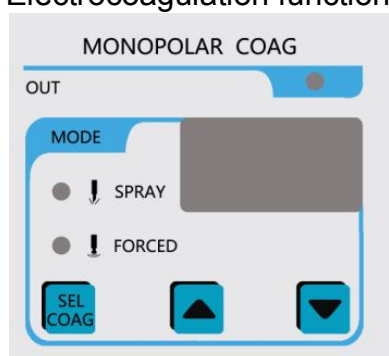
4.3.5 Ablation

The power range of ablation is within 1W~100W (load 700 Ω), it has power peak system (PPS).

On the output button of monopolar electrotome handle, the press button in yellow controls cutting operation, and the press button in blue controls electrocoagulation, which is usually called electric burn, which suitable for symptoms such as gynecology, cervical erosion etc., and suitable for small operation for electric burn treatment, it can also be used for cutting operations with function of blood coagulation just only in lower power, this is suitable for the surgical operations that require higher requirements for blood coagulation.

The ablation function of Kangwei electrosurgical generator is mainly used for celioscope surgical operation. Since this function strictly controls the output voltage, so it is called low voltage cutting, therefore, this is mainly used for celioscope surgical operation. It has about 60% of blood coagulation effect during celioscope cutting.

4.4 Electrocoagulation function section



4.4.1 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.

4.4.2 Spray coagulation

Power range of spray coagulation is within 1W~80W (Load 700 Ω)

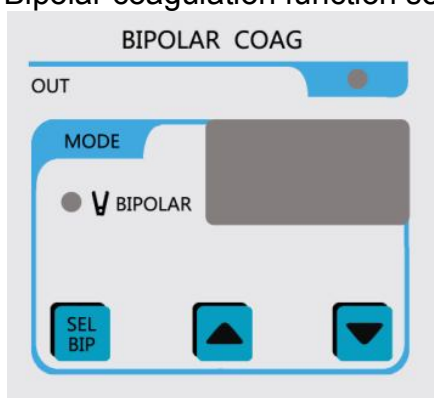
It is usually used for blood vein electrocoagulation. If cutting off blood vein within 1-2 mm, nod tow ends of vein with flat end of knife instead of using gauze for dipping blood, cut off in the middle when color is white with a little yellow.

4.4.3 Forced coagulation

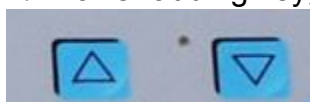
Power Range of forced coagulation is within 1W~100W (Load 700 Ω)

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.

4.5 Bipolar coagulation function section BIPO



4.5.1: Power adding key, subtracting key:



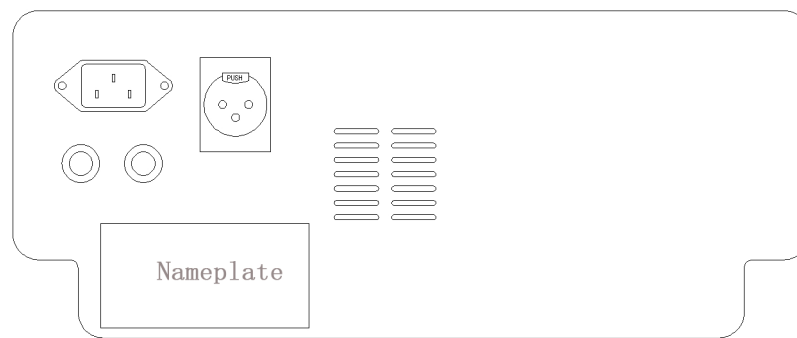
Press adding or subtracting key once when values displayed between 1-40, each press will add or subtract by 1, each press will add or subtract by 5 when values displayed between 40-100, and each press will add or subtract by 10 when values displayed over 100. If the key is pressed down constantly, it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

4.5.2 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 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.

4.6 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.

4.6.1 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.

4.6.2 A.C power supply socket, rating voltage 5A/220V~, power supply frequency 4MHz

4.6.3 Product nameplate

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

V Operation methods

5.1 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.

5.2 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.

5.3 Output terminal

5.3.1 Monopole of This device adopts handle output power. Handle output socket, handle switch and foot pedal are effective simultaneously.

5.3.2

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.

5.4 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.

5.5 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.

VI Precautions:

Cables of handle, skin application plate and bipolar electrode are made of special high frequency cable, please contact with manufacture if replacements are necessary

6.1 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.

6.2 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.

6.3 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.

6.4 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.

6.5 Neutral electrode(Antenna board)

Neutral electrode can be used near or under the patient body, then you can do operation on the infected part.

6.6 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

6.7 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.

6.8 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.

6.9 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 s.

6.10 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



human body are always smallest diameter section at frequency current passes 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.

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

6.8.2 bb) 7) in GB9706.4

6.12 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

6.13 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.

6.14 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 from heart division for assistance. 6.8.2 bb) 10) in GB9706.4

6.15 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.

6.16 Operator should examine each accessory before each operation, especially check the damages of electrode cable isolation 6.8.2 dd) in GB9706.4

6.17 Under normal operation of the instrument:

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

6.17.3 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.

6.17.4 Foot pedal can be used permanently

6.17.5 Replace if exterior of power supply cable of machine is damaged

6.18 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.

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

6.19.1 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.

6.19.2 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.

6.19.3 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.

6.19.4 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.

6.19.5 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.

6.19.6 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.

6.20 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.

6.21 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.

6.22 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.

6.23★ 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.

6.24 Before operating the device, disinfect the head of electrotome, handle, bipolar forceps, cables and some other components and sections.

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

6.25 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.

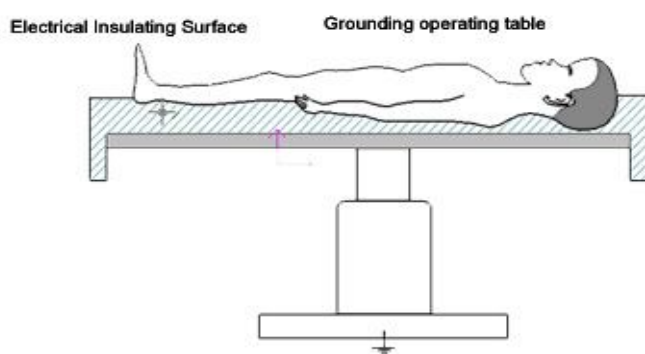
6.26 Accidental heat injury to body tissues due to drain current of high frequency

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.

6.26.1 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.

6.26.2 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.

6.26.3 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.

6.26.4 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.

VII Output data

7.1 Pure , blend、ablation, spray coag, forced coag, , bipolar coag (see appendix 1)

7.2 High frequency drain current

7.2.1 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.

7.2.2 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.

VIII 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		$\leq 150\text{mA}$	_____

IX Measures to be taken during operation of the device:

9.1 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.

9.2 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.

X Transportation and Conditions for Storing

10.1 Transportation will be carried out according to contract.

10.2 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.

Maintenance

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 stucked 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

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.

