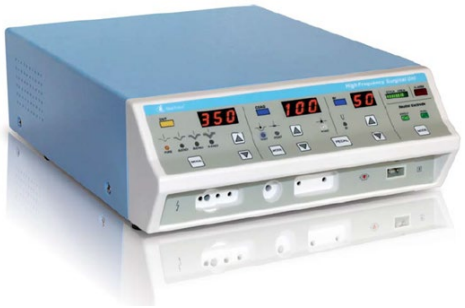
Kalstein

Model YR02145

High-Frequency Electrosurgical Unit

Instruction Manual



Thank you very much for purchasing our High-Frequency Electrosurgical Unit Model YR02145.

Please read the “Operating Instructions” and “Warranty” before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the “Warranty” at a hand place for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

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Table of Contents

Overview

Instrument Description

This electrosurgical unit consists of a main unit and high-frequency accessories which are used on patient's intended part to generate surgical effect. Usually the high- frequency accessories include hand-operated/foot-operated and dual-electrode high- frequency accessories, surgical neutral electrode and foot switch.

Intended Purpose

This equipment is intended for tissue cutting or coagulation in surgical operation byusing high frequency current.

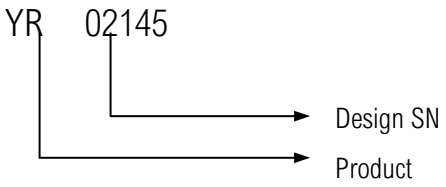
Application Scope

This equipment is applicable to general surgery, urology surgery and brain surgery.

Its specific performance is described below:

- Class-I CF type equipment
- Equipment operation model: intermittent on-load consecutive operation 10 seconds/30 seconds
- Cut (pure cut, blend cut 1, blend cut 2 and blend cut 3) and coagulation (soft coagulation and point coagulation. Dual-electrode tweezer-based coagulation mode.
- Neutral-electrode plate paste area detection system
- Start-up volume adjustment (except alarm)

Model Number Composition and Meaning



Service life 8 years

Date of manufacturing As indicated on external packaging

Unpacking and Installation

Unpacking

Unpack and take the electrosurgical unit out of the packaging box with care. Keep thecardboard and packing materials for use in future handling or return.

In case of any failure or question, do not dismantle the equipment for repair, but contact themanufacturer or your local dealer immediately.

Power supply

Operating Power AC220V 50/60Hz, grounded reliably

Operating Environment

Temperature: 10-40℃

Humidity: ≤80%RH

Atmospheric pressure range: 86.0 kPa~106.0kPa

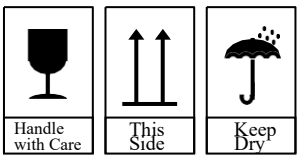
Clean and well-ventilated indoor location free of aggressive and inflammable materials

Handling

Temperature: -40 ~ +55℃ Humidity: 10~85%RH

Atmospheric pressure range: 86.0 kPa~106.0kPa

Strong shock and collision shall be avoid during shipping or operation. Preventexposure to rain.



Installation

- Unpack the product, check all accessories for any damage.
- Connect the power cable and the neutral electrode and electrosurgical unit. Place a wet soapon the electrode plate.
- Power the equipment on to a proper power (less than 50W) and start electrosurgical unit,spark should be generated at the soap.
- Ensure the power is output, disconnect the accessory and deliver the overall unit to user.

Instrument Description

Overall Dimensions and Weight

Packaging Dimensions (mm): 516*616*460Gross

Weight (kg): 21.4

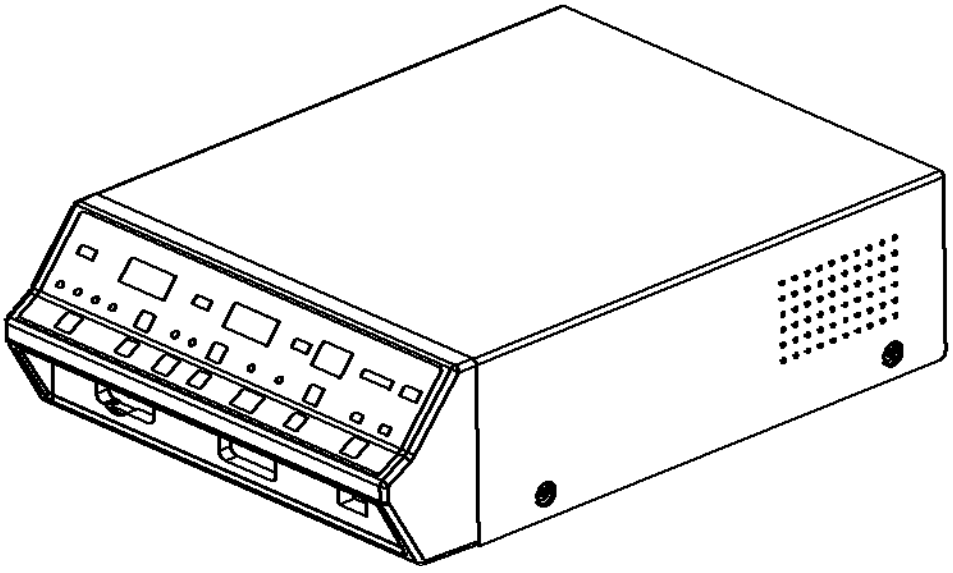
Overall Dimensions (mm): 495*395*205Net

Weight (kg): 14.4

Accessories Attached

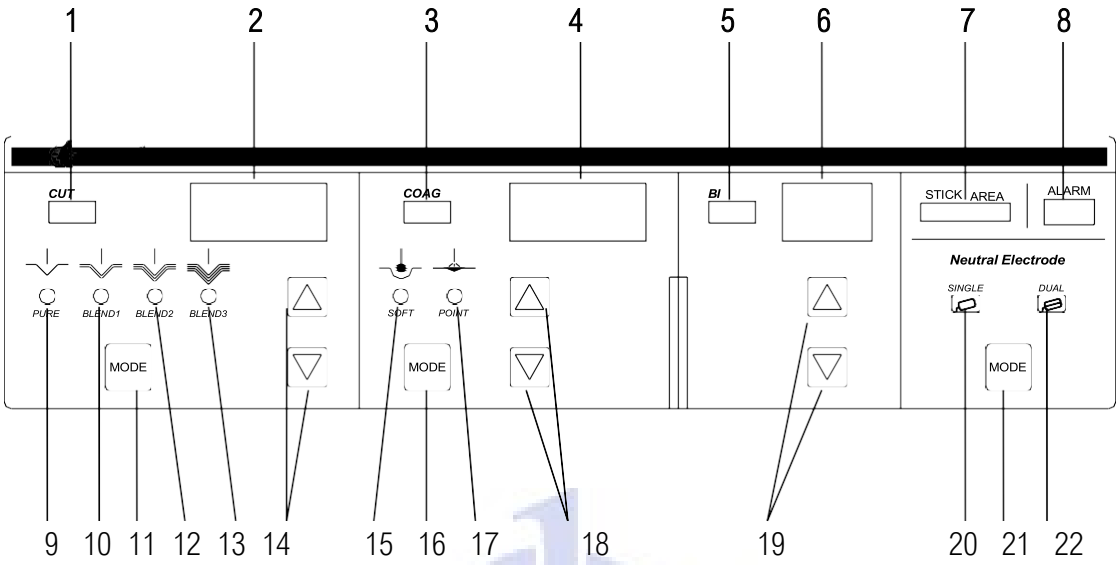
Order No.	Name	Quantity
7SB-EB03NO-SDB	Hand-operated knife (including operation electrode)	1
7SB-EB05NO-JDB	Foot-operated knife (including operation electrode)	1
7RB-EB03JB-005	Dual-sheet flexible neutral electrode plate	1
7DP-USAL-003	Flexible electrode plate connectingwire	1
1WC-10A250-SW1	Power cable	1
NGD-020	Foot switch	1
1WC-03PIN-002	Tweezers connecting wire	1

View of Overall Unit



Control and Display Description

Panel Description



Operation Status

1 Cut Start-Up Indicator

Cut Power Setting Display Window

3 Single-Electrode COAG Start-Up Indicator

4 Single-Electrode COAG Power Setting DisplayWindow

5 Dual-Electrode COAG Start-Up Indicator

6 Dual-Electrode COAG Power Setting DisplayWindow

7 electrode plate Paste Area Indication Window(LED Window)

8 Warn Indicator

9 Pure Cut Indicator

10 Mix Cut 1 Indicator

11 Cut Mode Selection Key

12 Mix Cut 2 Indicator2

13 Mix Cut 3 Indicator

14 Cut Power Setting Up/Down Keys

15 Soft COAG Indicator

16 Single-Electrode COAG Mode Selection Key

17 Point COAT Indicator

18 Single-Electrode COAG Power Setting Up/DownKey

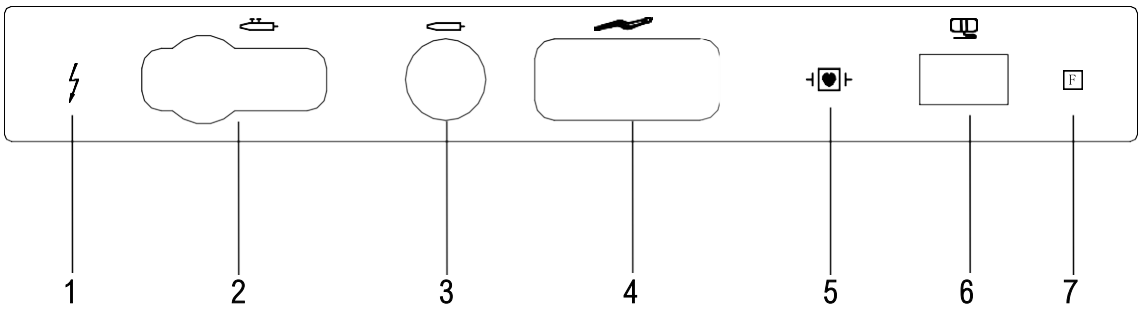
19 Dual-Electrode COAG Power Setting Up/DownKeys

20 Single-electrode plate Mode Indicator

21 Electrode plate selection key

22 Dual-electrode plate Mode Indicator

Accessory Connection Description



1 Risk of high voltage with output socket!2

Hand-operated knife socket

3 Foot-operated knife socket4

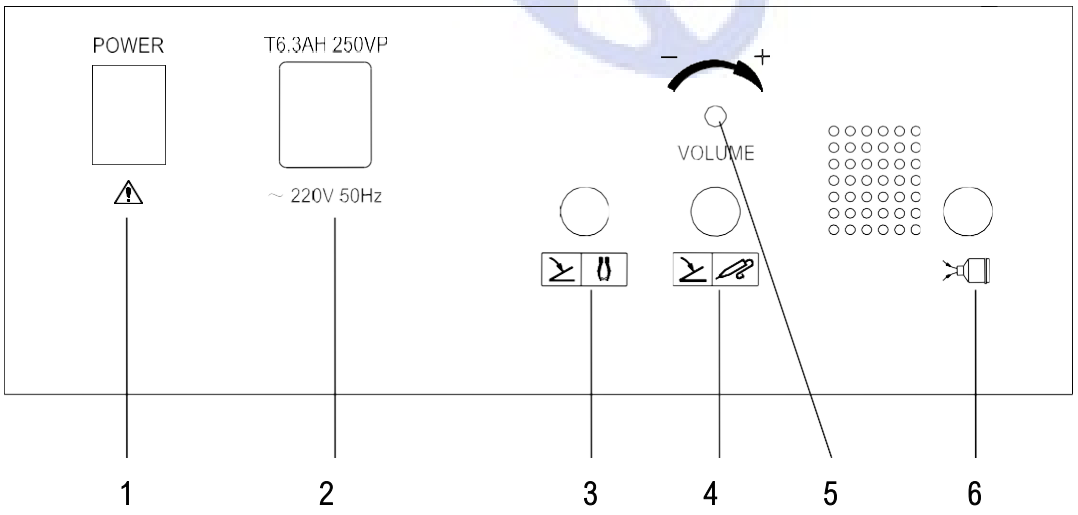
Tweezers socket

5 CF type ICD equipment

6 Electrode plate socket

F 7 Fully suspended tuning balance output

Rear Panel Description



1 Power switch

2 Power socket (including fuse)

3 Dual-electrode foot switch

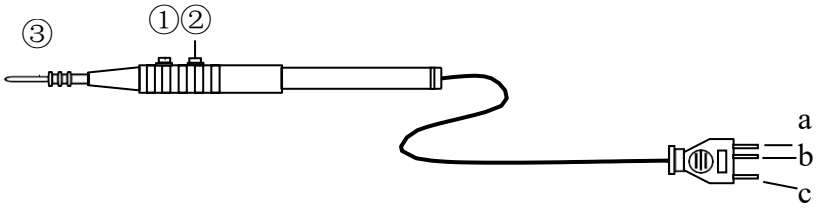
4 Single-electrode foot switch socket

5 Volume potentiometer

6 Smoke extractor socket

Accessory Description

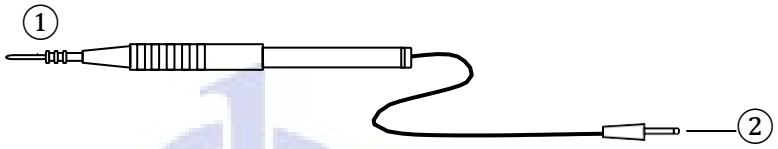
Hand-operated knife



①Cut Button ②COAG Button ③Blade
a) Cut terminal b) COAG terminal c) Public terminal

- Hand-operated blade (3) is connected to public terminal c) of the socket
- Press cut button (1) to connect cut terminal a) of the plug to public terminal c).
- Press COAG button (2) to connect cut terminal ab of the plug to public terminal c).

Foot-operated knife



①Blade ②Plug

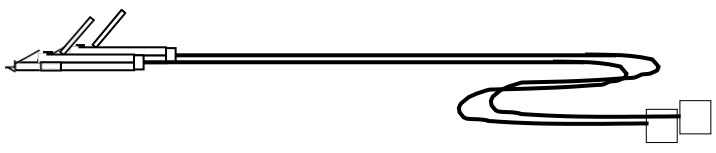
- Foot-operated blade (1) is connected to public terminal c) of the socket

Foot switch

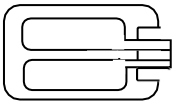
①Cut treadle ②COAG treadle ③Plug
a) Cut terminal b) COAG terminal c) Public terminal

- Press cut treadle (1) to connect cut terminal a) of the plug to public terminal c).
- Press COAG treadle (2) to connect COAG b) of the plug to public terminal c).

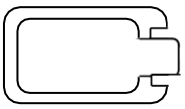
Neutral electrode connecting wire



Dual-sheet flexible electrode plate



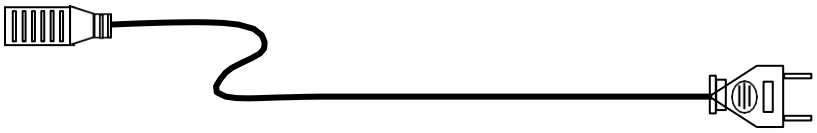
Single-sheet flexible electrode plate



Smoke extractor connecting wire

Tweezers

Tweezers connecting wire



Note:

- Rate voltage for accessories shall be ≥4000V, and the maximum output voltage shall not be larger than the rated voltage during operation.
- Any third-party accessory shall be first ensured to be consistent with the original one in dimension, and then match the equipment as verified in consistency test before it is used in place of the original.

Preoperative Preparation

Environmental requirements

During operation, the electrosurgical unit shall be kept a certain distance away from any other electronic equipment in operating room to minimize the EMI generated thereby. No object shall be placed onto the electrosurgical unit, nor shall the electrosurgical unit be placed onto any object, so as to ensure good heat dissipation.

Accessory Selection and Installation

Connection of power cable: First connect one end of the power cable to the equipment,and then connect the plug to a AC220V 50/60Hz three-phase power socket which is grounded reliably.

Accessories shall be selected based on power output mode:

Hand-control mode: Connect plugs of hand-operated unit and neutral electrode plate to thecorresponding sockets.

Foot-control mode: Connect plugs of foot-operated unit, foot switch and neutral electrodeplate to the corresponding sockets.

Use of Neutral Electrode

Classification of neutral electrode

Disposable flexible neutral electrode is classified into single-sheet and dual-sheet types.

Use of single-sheet flexible neutral electrode

Connect plug at one end of neutral electrode connecting wire to the position specified for accessory connection, and the electrode mode indicator lamp turns on; attach the neutral electrode with the clamp at the other end, and then attach the neutral electrode uniformly tothe patient's skin. In case that the neutral electrode get loose during operation, the visual and audible alarm would be activated and power output would be ceased.

Warn:

- During operation, when single-sheet flexible neutral electrode is used, the medical staffmust always pay attention to pasting of the electrode to prevent fall of it and burn to the patient caused thereby.
- **In case of any failure in use of any incompatible neutral electrode, alarm would not be activated. The neutral electrode can be monitored when the resistance in it is between 10~125Ω.**

Use of dual-sheet flexible neutral electrode

Connect plug at one end of neutral electrode connecting wire to the position specified for accessory connection, and attach the neutral electrode with the clamp at the other end, and then attach the neutral electrode uniformly to the patient's skin.

The electrode mode indicator turns on at this moment, and the paste area indicator turns on as well by the certain levels (generally 2~9 levels) depending on the patient's body resistance andthe paste area. After the neutral electrode is insured to be fully attached to the body, start output of cut or COAG mode, and data on paste area will be stored in the equipment. During operation, in case that the neutral electrode falls down or turns up, making paste area increased

by 30%, alarm will be activated and power output will be ceased till the neutral electrode is re-attached properly.

Power-On

Switch on the power and equipment model and version ID will be displayed on the screen.The equipment will start the last use status (mode setting and power setting).

Operations during Operation

Mode Setting

Cut mode category: Pure cut 0-350W
Mix cut 1 0-300W Mix cut 2 0-200W Mix cut 3 0-150W
COAG mode category: Soft COAG 0-100W
Point COAG 0-100W
Dual-electrode COAG 0-50W

Select operation mode as required for the operation by using the selectionkeys, and related indicator lamp will turn on.

Power regulation

After mode setting is finished, press cut/COAG Power regulation key to set output power, the related set value will be displayed on the power display window on the panel.

Press down and hold power setting key for 3 seconds to increase power up.

Caution: For the initial use, be sure to start with small power output.

Output Start-up

Cut and COAG outputs are controlled respectively by cut/COAG keys on hand- operated or cut/OCAG treadle on foot switch. Cut is controlled by yellow key/treadle, while COAG by blue key/treadle.

When cut is started, the cut indicator turns on, and a sound of 750Hz is generated. When COAG is started, the COAG indicator turns on, and a sound of 250Hz is generated. Hand-operated unit and foot-operated unit share one output channel, so cannot be operated at the same time.

Stop Operation

Release the key/foot switch to cease power output.

Upon completion of operation, press POWER button to switch off power supply. Remove all accessories, and dispose any disposable accessories in accordance withrelated instructions. Any other accessories shall be cleaned and disinfected.

Post-Operation Maintenance

Cleaning and Disinfection of Accessories

* Clean the unit with medical cotton soaked with medical alcohol of 70%.
* Application accessories such as hand-/foot-operated knife and related connecting leads shall be disinfected with epoxy ethane before use, and their integrity shall be checked after disinfection.

* Power cable, foot switch and their connecting lead shall be kept clean.
* **For purpose of energy conservation and environment protection, any disposable accessories shall be collected together and disposed by related department insteadof being rejected freely.**
* Non-disposable accessories shall be cleaned and disinfected and then kept properly for future reuse.

Caution: Do not clean or disinfect hand-operated/foot-operated knife by soaking itinto detergent or disinfectant.

Replacement of Fuse

* Keep the power switch at position "O" and disconnect power cable from the main unit,and leave the equipment power-off for more than 10 minutes.
* Unscrew cover of the fuse holder with a flat-head screwdriver.
* Mount two fuses of the same specification as the original ones into the holder.
* Re-screw the top of fuse holder with a flat-head screwdriver.

Safety Considerations

*The electrosurgical unit shall be operated only by trained and approved medical staff, who shall read this manual carefully prior to use of it to prevent any safety hazardcaused by improper operation.

*Power supply to the electrosurgical unit shall be connected via a three-phase socked which is grounded reliably, so as to ensure safe and reliable operation of the electrosurgical unit, and to prevent electric shock.

*In case of surgical operation on chest or brain, any flammable narcotic and oxidizinggas such as (N2O) and oxygen shall be avoided unless they can be removed prior to operation. Where possible, flame-retardant reagent shall be used for cleaning and disinfection. Flammable agent may be used as solvent of bonding agent for cleaning and disinfection, but shall be removed by vaporization prior to operation. There is risk of

accumulation of flammable agent in patient's body or any hole (e.g. navel)/cavity (e.g. vagina). Any liquid accumulated shall be removed prior to use of any high-frequency operating equipment. In addition, risk of inflammation of gas inside body shall be prevented as well. Some materials, such as cotton, wool and gauze, when exposed to oxygen, may be ignited by spark generated in operation of high-frequency operating device.

*Integrity of accessories shall be checked prior to operation.

a. Check whether the accessories are securely connected to the equipment, and any flexible neutral electrode board is reliably attached to the connecting wire.

b. Test insulation performance of the accessories and check whether any sheath thereof is damaged.

* Any patient who carries cardiac pacemaker or any other active implant may be subject to risk of interference thereto or damage thereof. For any question, consult related pacemaker manufacturer or experienced surgeon.

*Contact between patient's skins (e.g. between patient's arm and body) shall be prevented,such as by attachment of dry gauze.

*The neutral electrode board must be properly connected and attached to the patient'sskin by sufficient area, as detailed below.

*Use as low output power as possible to meet intended performance. Some devices or accessories in low power setting may cause safety hazard. For example, In case of coagulation with beam of argon, if high-frequency power is insufficient to generate a quickly enclosed eschar at target tissue, risk of air embolism may be caused.

* Output power of electrosurgical unit shall not be increased blindly, and as low output power as possible shall be used instead to meet the intended purpose. Output powerof single-electrode electrosurgical unit shall be kept between 30~70W, or larger for special operations such as amputation, but not higher than 200W anyway. In case thatthe output power required in an operation is substantially larger than the general power, setup of the neutral electrode, integrity of the electrode and blade cable, equipment condition and patient's suspension shall be checked immediately till the power is recovered to the normal level. Where normal output power is unpredictable, try to gradually increase the output power till it is proper. Prior to start-up and after end of operation, the output power shall kept at low level to prevent abrupt application of large power onto the patient.

* The patient shall be prevented from contacting any metal part grounded (e.g. operating table bracket), and for this purpose it is recommended to use anti-static isolating plate.During the operation, the medical staff must wear well-insulated rubber gloves to prevent burn.

* Any disinfectant, cleaning agent or patient's liquid may cause the patient contact any metal and thereby cause burn. Therefore the bedding, bed cushion and the patient shall be kept dry.
* For operation where high frequency current passes body part in small section area, it is recommended to use dual-electrode technique (mode) to prevent unexpected coagulation.
* Where both high-frequency operating equipment and physiological monitoring equipment are used on the patient, any monitoring electrode shall be kept as far away from operating electrode and neutral electrode as possible, and it is recommended not to use needle-shape monitoring electrode. In all cases, it is recommended to use monitoring system with high frequency current limiting device.
* Contact of operating electrode/neutral electrode with patient or any other lead wire shall be prevented, and any operating electrode not in use shall be kept away from patient.
* In case that any high-frequency operating equipment which function normally inproper settings has descending output power or fails, it may mean that the neutral electrode is used improperly or in poor contact. In such case, prior to application of higher output power, operation and connection of the neutral electrode shall bechecked.

*In case that the patient has any metal part (steel ring or nail) implanted in body, the high-frequency current shall be such routed to bypass the metal part, so as to prevent heating by high-frequency eddy current and thereby burn to the patient's internal tissue.

*Prevent any naked part of body from contacting neutral electrode or blade in operation, since the same generates high-frequency radiation and thereby cause irritation or painof burn.

*Any accessory (hand-operated knife, foot-operated knife, electrode plate) applied for the electrosurgical unit is wearing part, and shall be checked carefully prior to and during operation to prevent its malfunction and burn or interference with operation caused thereby.

* Interference generated by high-frequency operating equipment may have adverse effecton operation of other medical electrical equipment.

* Protection against burn caused by neutral electrode of electrosurgical unit

Burn by neutral electrode is common accident in operation with electrosurgical unit, and the unit operator must apply correct attachment method to prevent occurrence of the accident. Disposable single-sheet and dual-sheet flexible neutral electrodes are used in this equipment. How to use them is described in Section Use of Neutral Electrode, and additional instructions are given below.

A. Disposable neutral electrode shall not be re-used as adhesive on it may fall out during repeated use and tends to cause burn.

B. It is recommended to use dual-sheet flexible neutral electrode as much as possible, since the equipment is furnished with a circuit electrode monitoring system which continuously monitors electrode-skin contact area so that theelectrosurgical unit operates only when the contact area is large enough; in case of small contact area, alarm will be activated and power output will be ceased toensure safety much better than single-sheet electrode.

C. In addition to the consideration that neutral electrode must be in close and uniform contact with patient's skin by sufficient area, the following points shall be paid attention to as well in use of neutral electrode.

a) The neutral electrode shall reliably attached to the patient's body by its full area and as close to the operated part as possible, so as to not only minimize operating impedance of electrical knife, but also reduce required output power of the unit and thereby minimize risk of burn (as stated above, risk of knife increaseswith rise of output power), as neutral electrode located close to unit tip will largely increase area of high frequency current channel and distribution of strong EMF and high potential on patient's body, and thereby increase risk of burn by neutral electrode in multi-point grounding as stated below.

b) Neutral electrode shall be fixed at smooth, dry and fleshy part without extruding bone, so as to ensure good contact. Muscle has lower impedance and better electric conductivity than fat, and thereby reduce heating. Part with extruding bone makes it hard to ensure sufficient contact area and impairs uniformity of contact, and thereby results in high current density and increase risk of burn.

* Protection against burn not caused by neutral electrode of electrosurgical unit

a) During operation, even though neutral electrode is located properly, patient may still be subject to risk of burn which is not caused by neutral electrode, andcalled as non-neutral electrode burn.

b) The reason for non-neutral electrode burn is that patient's body is grounded at multiple points.

For example, a) Metal bed is located on concrete floor in operating room, and two or more parts of patient contact the bed.

b) Cable of any accessory is lain on wet floor and contacts patient's skin without isolation.

c) The electrosurgical unit operator does not wear insulated rubber gloves and is in poor insulation to the ground.

In any of the aforesaid cases, high frequency current forms a loop between the grounding points and thereby results in burn.

* Low-frequency spark

a) Human's nerve and heart are sensitive to low-frequency current and excessively large low-frequency leakage current may cause severe shock to patient or even be life-threatening, so low-frequency leakage current in the equipment itself has been strictly restricted, but any external low-frequency current is uncontrollable to it.

b)Any external connecting cable (neutral electrode and blade cable, including plug, socket and adapter) may generate arc strike in case of poor contact or fault in internal lead, which may results in larger low-frequency current and thereby cause burn to patient.

c) Low-frequency burn often occurs inside body rather than on the surface. In case that patient **shakes seriously during operation, the equipment must be shut down and the cable must be checked for any breakage, rust or looseness in connector.**

Therefore it is absolutely essential to ensure reliable connection of the externalcable ((neutral electrode and blade cable, including plug, socket and adapter).

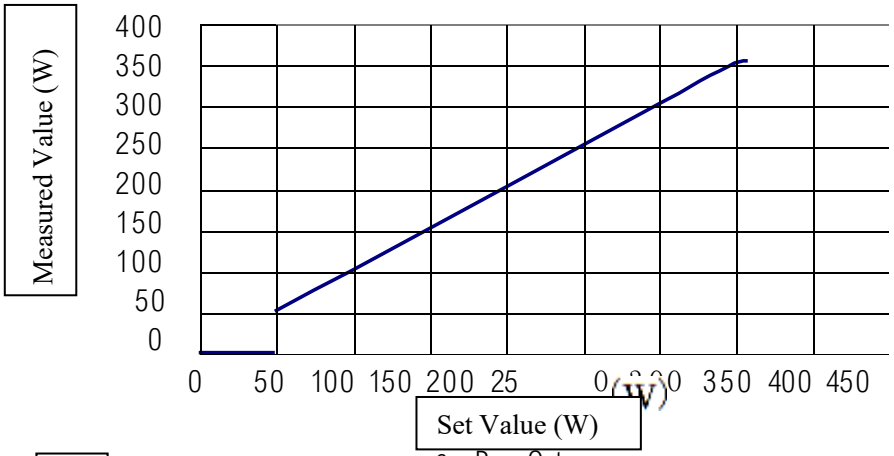
*** Failure in electrosurgical unit may cause unexpected increase of output power. Our high-frequency operating equipment has undergone strict safety testing beforefactory delivery and meets related national standards, and can be safely used by users.**

Technical Data

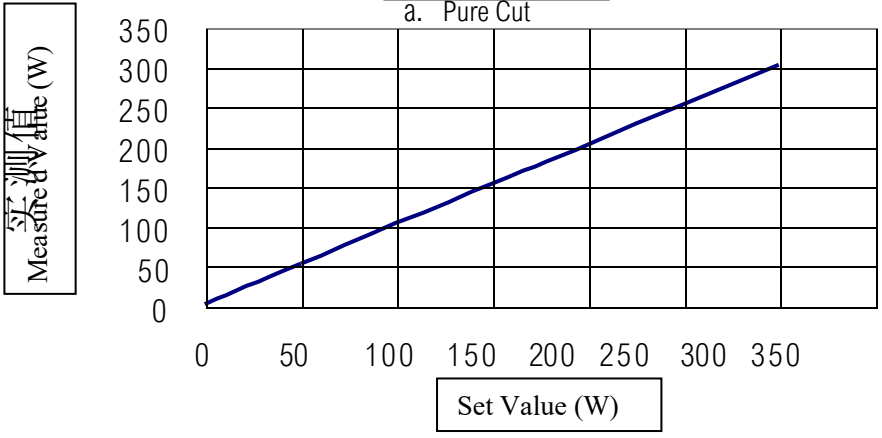
Output Parameters

	MAXIMUM POWER (W)	RATED LOAD (Ω)	Duty cycle	MAXIMUM OPEN CIRCUIT VOLTAGE PEAK VALUE (V)
Pure Cut	350	500	100%	900
Mix Cut 1	300	500	68%	1800
Mix Cut 2	200	500	56%	1360
Mix Cut 3	150	500	24%	1570
Soft COAG	100	500	16%	1960
Point COAG	100	500	16%	1960
Dual-Electrode COAG	50	100	100%	306

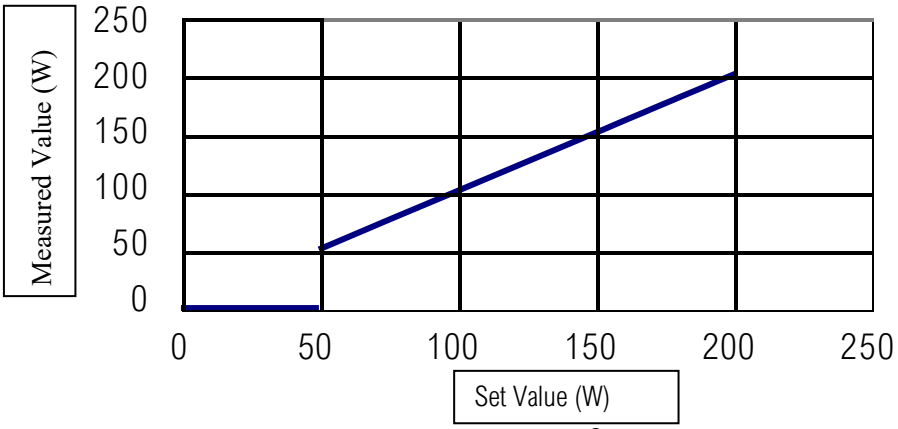
Curves of Set Power and Actual Measured Power in Various Modes



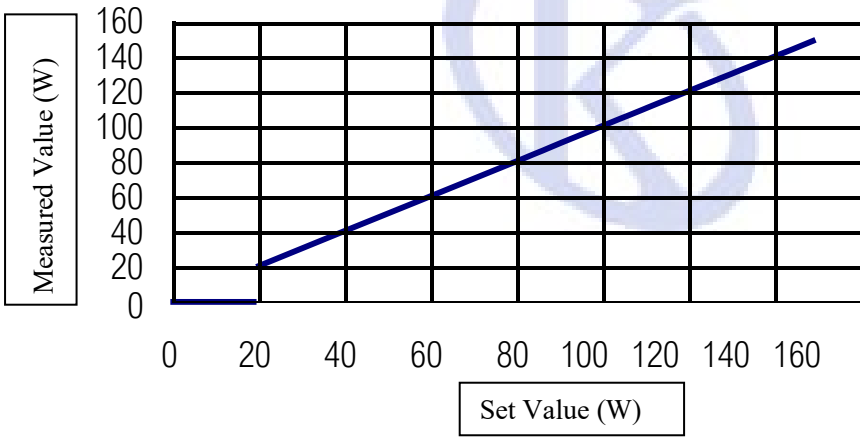
a. Pure Cut



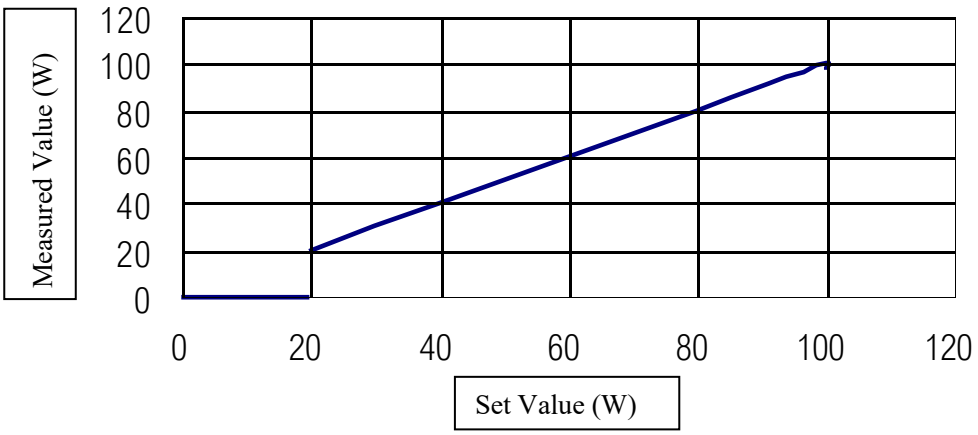
b. Mix Cut 1



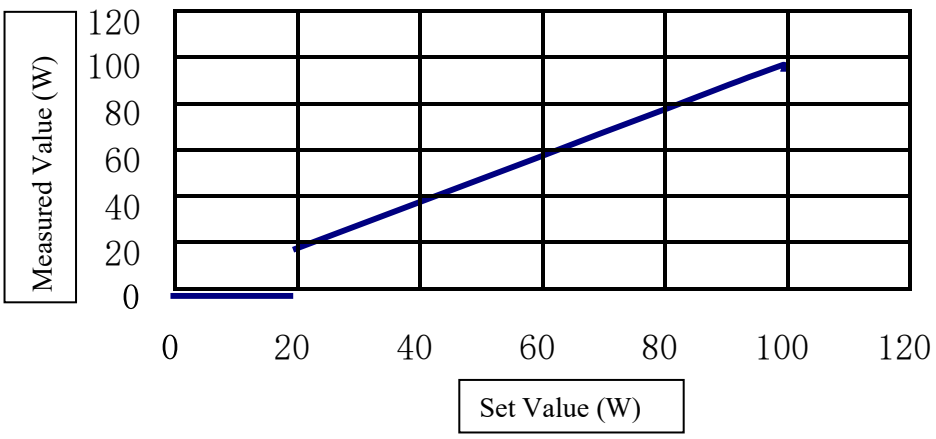
c. Mix Cut 2



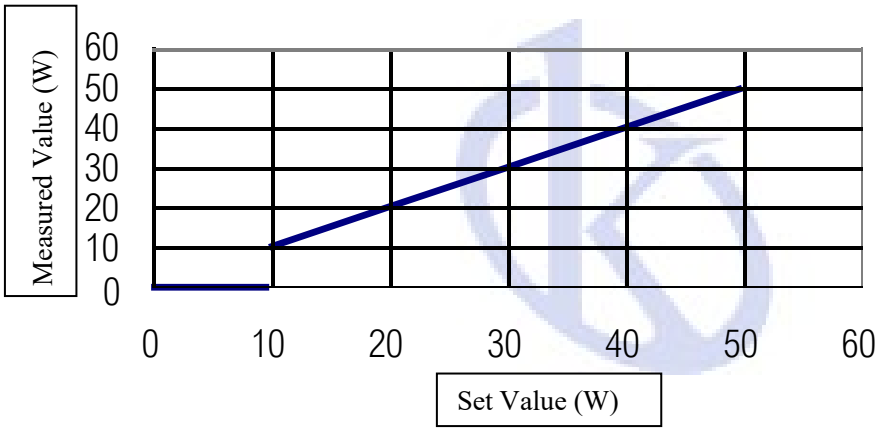
d. Mix Cut 3



e. Soft COAG



f. Point COAG

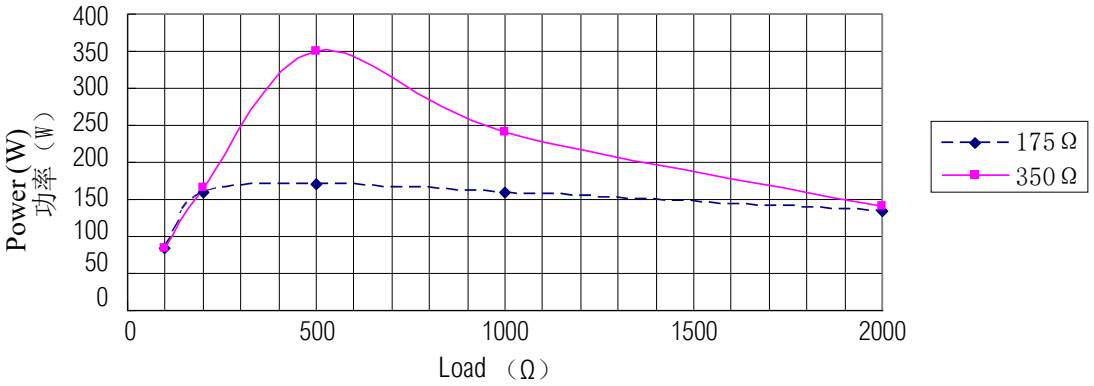


g. Dual-Electrode COAG

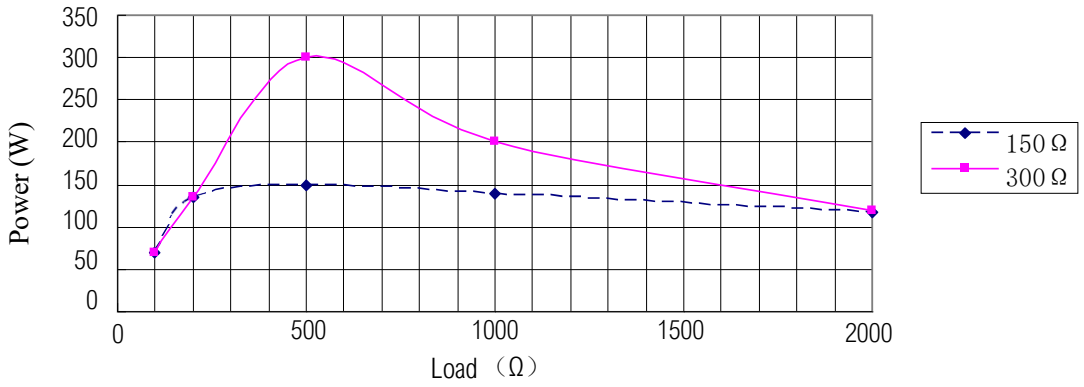
Load Power Curves in Various Modes

Variation curves of output power P as the function of load RL in full power and half power in various modes are given below.(full power set in full line while semi-power setin dotted line)）

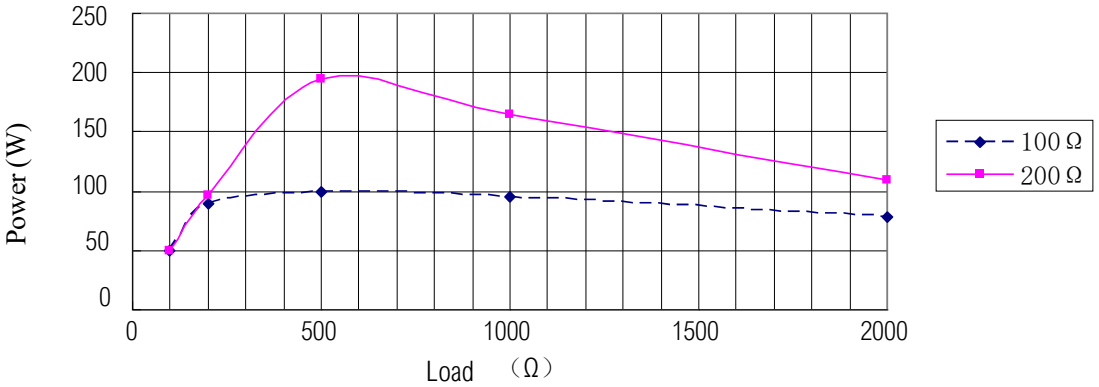
a. Pure Cut



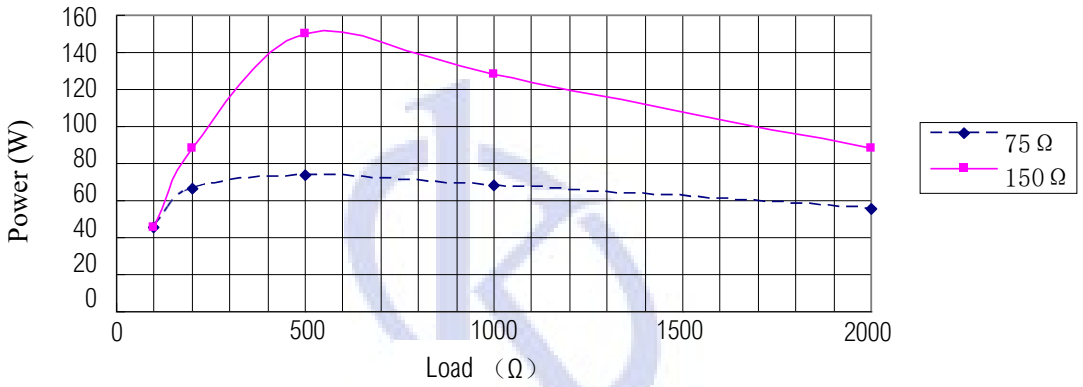
b. Mix Cut 1



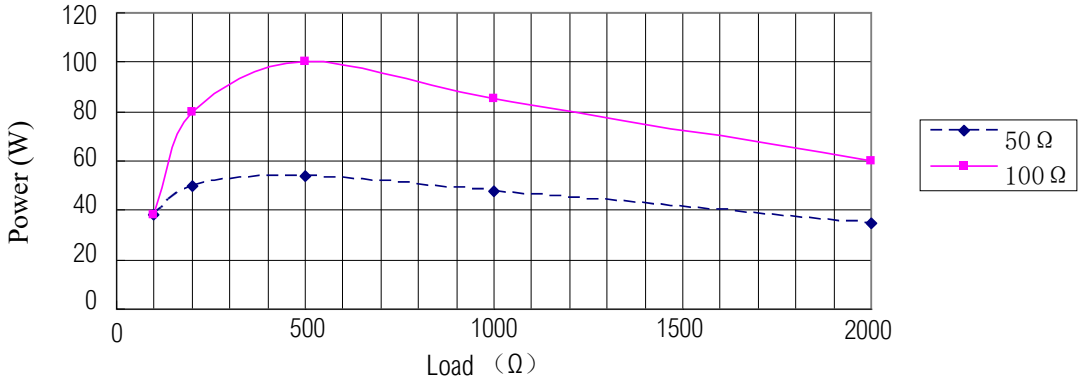
c. Mix Cut 2



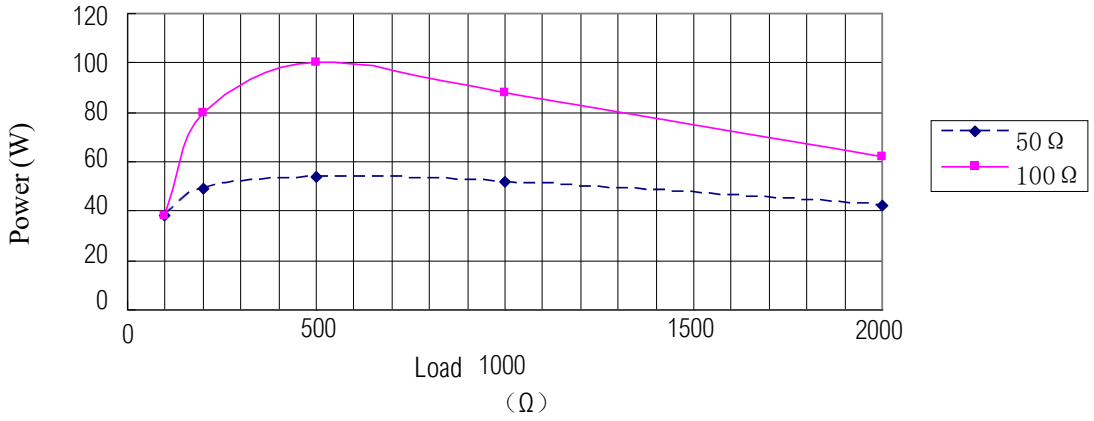
d. Mix Cut 3



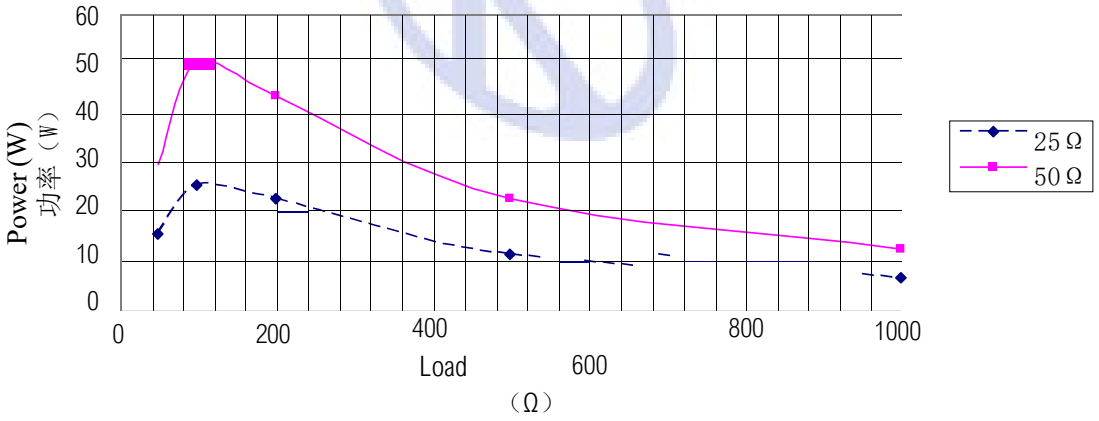
e. Soft COAG



f. Point COAG

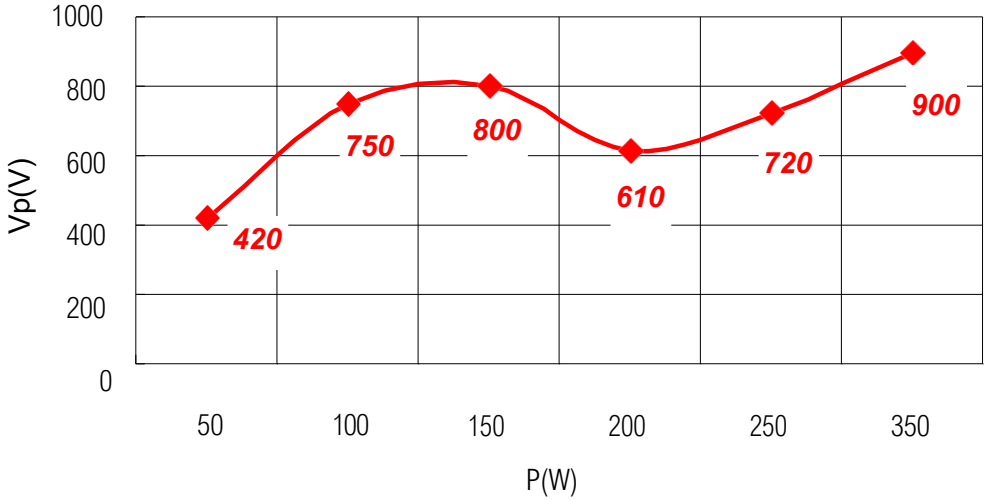


g. Dual-Electrode COAG

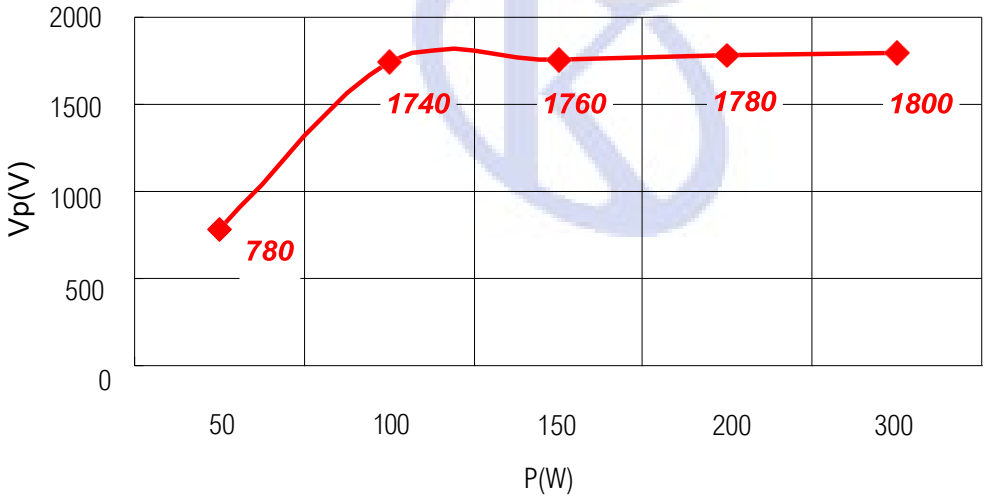


Output Power and Voltage Peak Curves in Various Modes

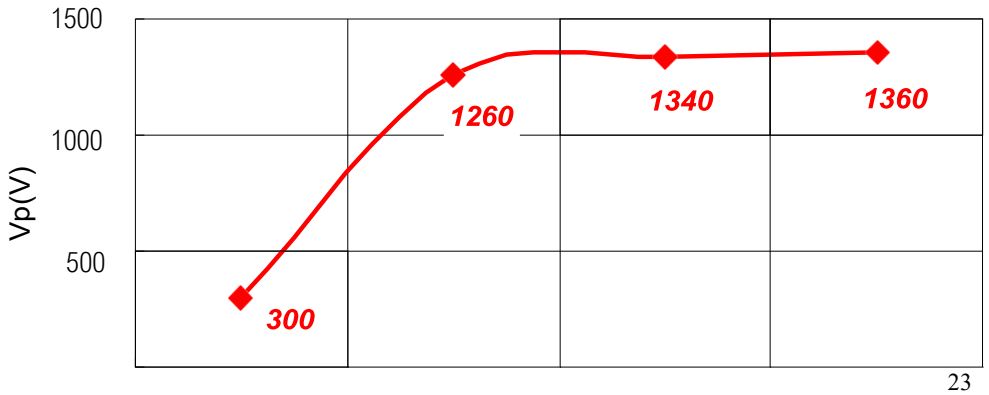
a. Pure Cut

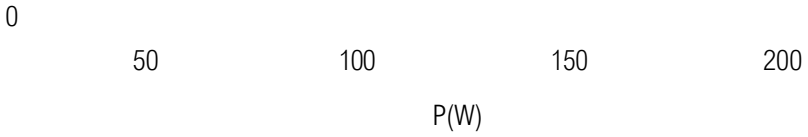


b. Mix Cut 1

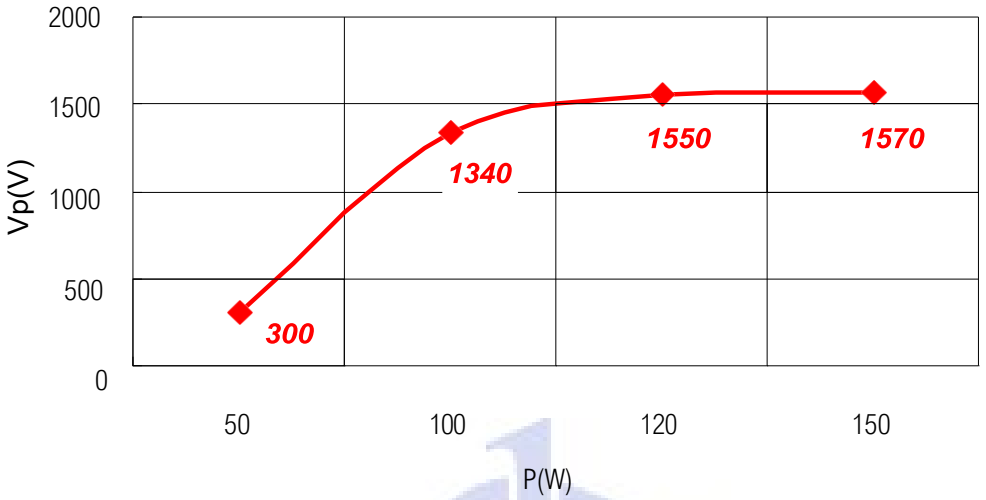


c. Mix Cut 2

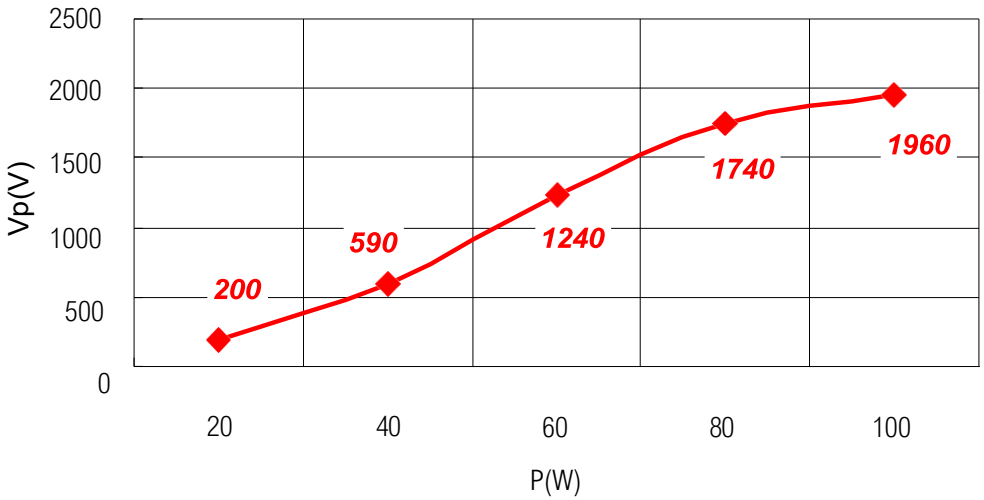



0
50
100
150
200
P(W)

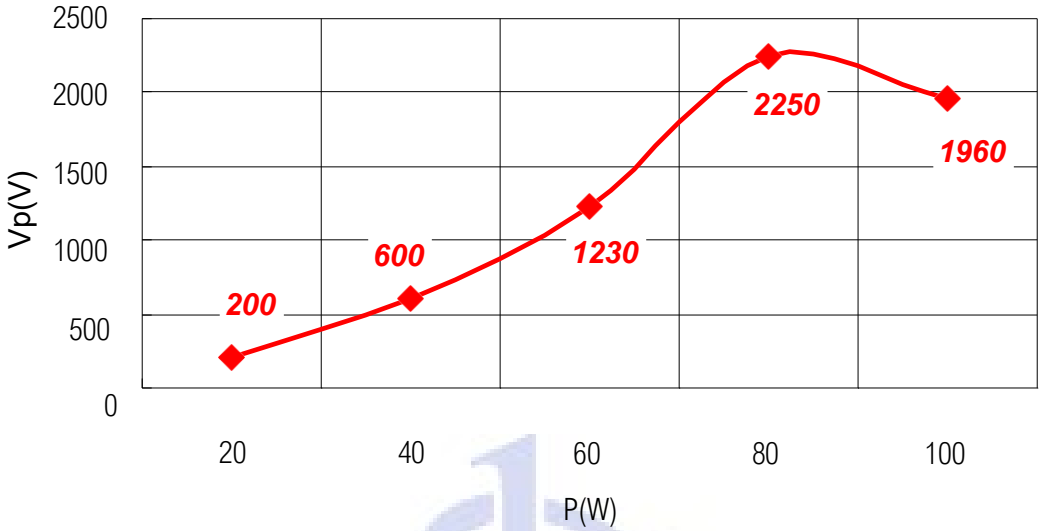
d. Mix Cut 3



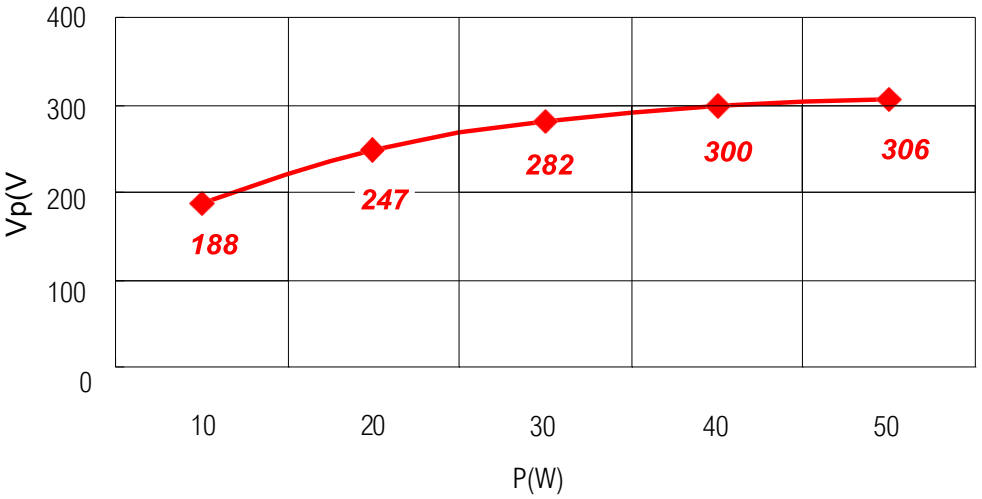
e. Soft COAG



f. Point COAG



g. Dual-Electrode COAG



Safety Indexes

This equipment is in compliance with related national safety standards.The neutral electrode is isolated from the ground in case of high frequency.

To-earth leakage current <150mA

Low-Frequency Leakage Current：To ground <0.5mA

Enclosure <0.1mA

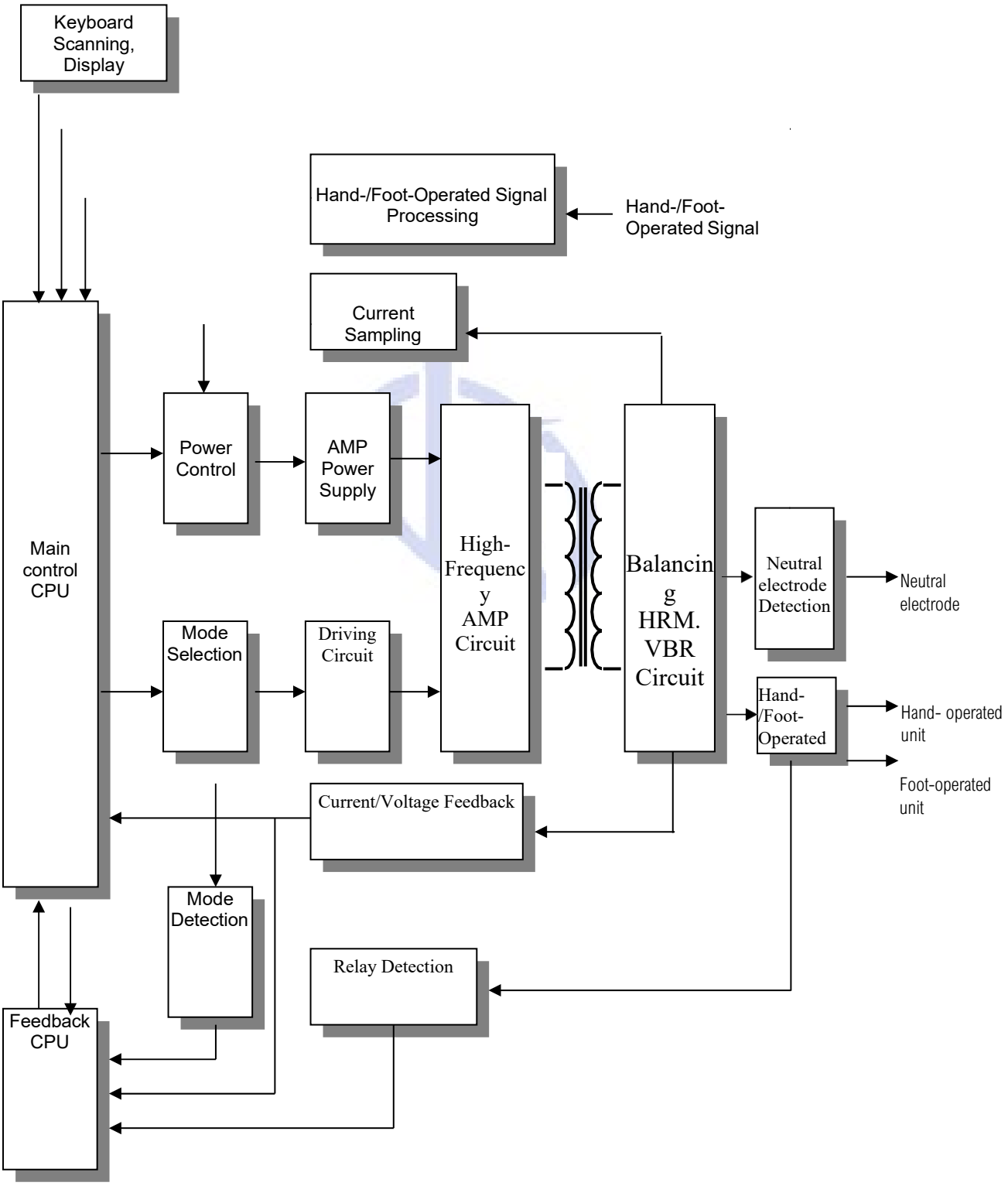
Patient <0.01mA

Product Classification

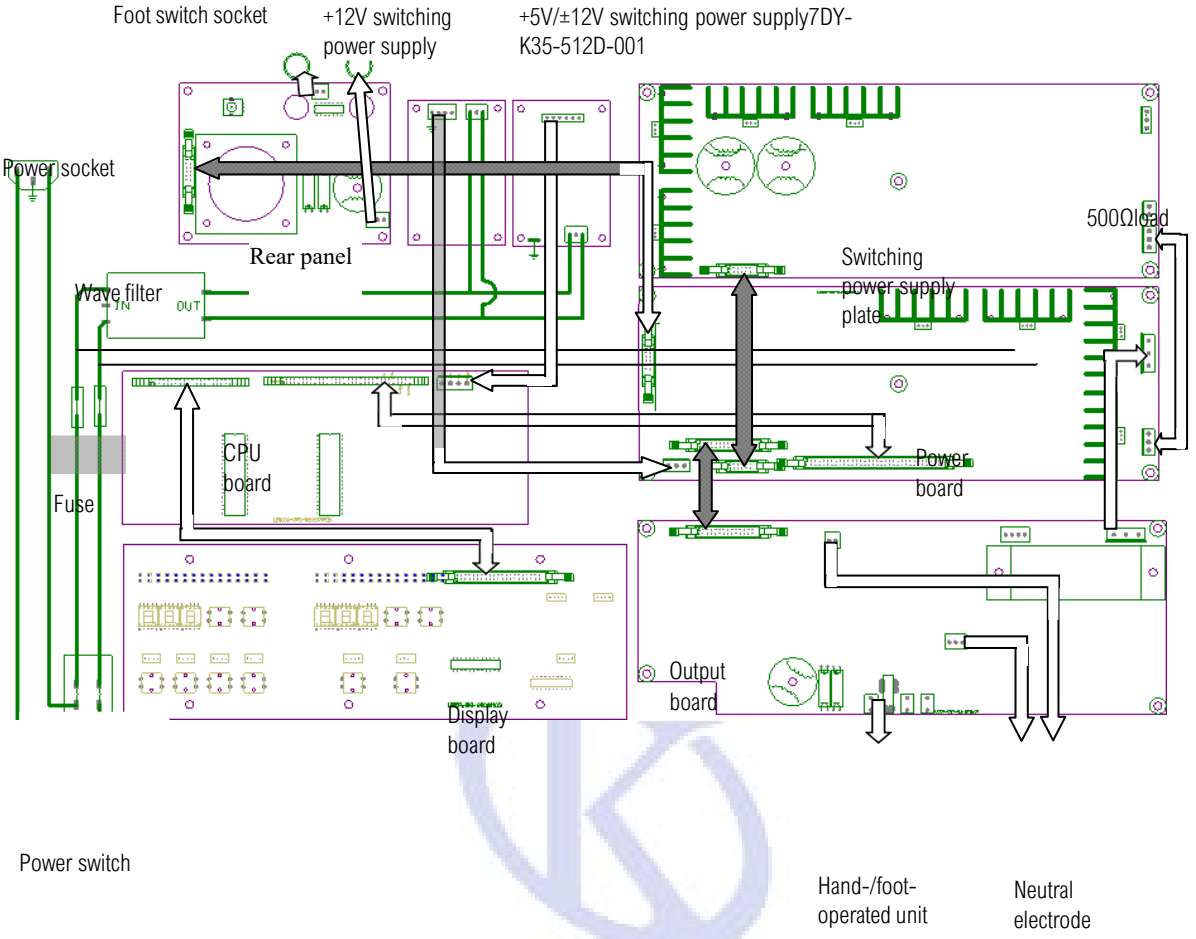
- Product class: CLASS I
- Product type's type: CF
- Power supply: AC220V, 50/60Hz
- Rated input power: 5A
- Applied part of equipment: Output circuits of surgical blade and neutral electrode
- The equipment provides protection against ICD discharge effect
- The equipment is general-purpose equipment
- Equipment operation model: intermittent on-load consecutive operation 10/30s
- Portable equipment

Circuit Description

Main Unit Principle Block Diagram



Main Unit Wiring Diagram



Note: 7DY-K20-12-001 switching power output voltage: +12V
7DY-K35-512D-001 switching power output voltage: +5V±12V

Operating Principle

Press POWER button to power the equipment on, and the electrosurgical unit is ready for operation and the control circuit is under the operator's control (mode, power etc.).During the course of standby and operation, main CPU will keep on detecting signals from electrode plate,and give warn and disable start-up in case of open circuit on the electrode plate or any other exception. If the signals from Electrode plate are normal, control board will give mode signals and sends a pulse width modulation power signal to power supply board and a audible prompt signal to rear panel (not marked in the block diagram). The power circuit receives mode signalsfrom control circuit, and sends to power amplifier circuit modulation signals in a certain cycle and width through mode selection and generation circuit, which is phase split into amplification gate signal by high-frequency transformer. At the same time, control board sendsto power supply board pulse width modulation signals corresponding to the power as set, and supplies stable and isolated DC power to the amplifier through switching circuit and high- frequency transformer. Current sampling circuit is connected at output terminal, where sampling signals are sent to comparator control circuit to limit short circuit current.

During output of power of electrosurgical unit, main control CPU and monitoring CPU detect the high-

frequency voltage, current and power signals at the output terminal on a real-timebasis to achieve safe redundancy, and, at the same time, by using software calculation and compensation, make the electrosurgical unit output appropriate power in different impedance to ensure safe and reliable operation of the electrosurgical unit.

CPU board circuit

CPU board mainly consists of two CPU - U2 functions as main control chips to receive start-up signal and electrode plate mode signal, send mode signal and power-controlling PWM signal, and operate 7219 on display board to control various lamps and scan keyboard; main control CPU also receives power, voltage and current feedback signals and controls output of final power; U10 Acts as feedback chips to receive feedback signals from relay, as well as power/voltage/current feedback signals, and gives warn in case of exception. These CPU chips are connected by means of CAN bus.

CPU board performs AC-DC conversion of voltage and current from output board through AD536, and composites power value through AD633.

CPU board is also furnished with neutral electrode detection circuit. Signals from CPU

board to power board are isolated with opto-coupler 521.

Display Board Circuit

Display Board operates to receive signals from main control ships on control board, and drives lamps and keys and controls display of digital tube with a piece of MAX7219 chip.

Switching Power Supply Board Circuit

Switching power supply board mainly acts an AMP power supply based on principle of switching power supply. It receives a PWM signal from CPU board and converts it into DC signal and then send it to U1001 (UC3825 high-speed PWM controller) to generate two non- overlapped alternating square waves, which are sent to coils T1001 and T1002 by U1003 and U1004 (7667) and then are used to drive four VMOS tubes (IRF840) via coils. On theother hand, AC220V power is converted into DC power through bridge-type rectifying circuit (BR1001) and filtering circuit, and then transferred alternatively through bridge circuit consisting of four VMOS tubes (840) and output by transformer T1003, and rectified bydiode (U860), and finally output by L and C filters as DC voltage required for power amplifier.

CPU/Power Board Circuit

Power board operates primarily to output appropriate power tube driving signal based on modeactivated by CPU board, in addition to amplification power supply on power supply board to output power. Power driving signal consists of VMOS tube (IRF520) and driving coils T2001 and T2002. Power driving circuit is a full-bridge power amplifier circuit consisting of four VMOS tubes (840). The power board is also furnished with a circuit which limits short circuit current and high-frequency leakage current by sending signals to power board in case of over- range current so as to reduce voltage in amplification circuit.

Output Board Circuit

Output board operates primarily to output power output from full-bridge amplifier through power coil T5001 to resonant circuit consisting of LC, and to the terminal through neutral electrode and electrosurgical unit tip. The high-voltage output is furnished with current sampling circuit, high-frequency leakage current sampling circuit, voltage sampling circuit andneutral electrode resistance sampling circuit, respectively sending signals to power board and CPU board for analysis.

The output board also generates hand-operated unit start-up signals passing through coil T5008and separated by opto-couplers O5001 and O5002.

Rear Panel Circuit

Rear panel operates to generate an oscillation from NE555, which passes through coil T7001 and opto-couplers O7001 and O7002 to generate foot-operated unit start-up signals.

Rear panel also contains a LM386 sound-generating circuit.

Maintenance Technique

Daily Accessory Inspection

* Cable of any accessory shall not have a deteriorated insulating layer and thelead shall not have an obvious line made by folding.
* Any cable connector shall be connected securely and firmly.

Warranty

We provide warranty for the main unit and foot switch.

* The warranty for main unit is valid for a period of one year starting from the date of purchase.
* Warranty for foot switch is valid for a period of two year starting from the date of factory delivery (one year of operation) provided that related instructions on storage and operation are observed.
* We are not liable for any failure or damage of any instrument/device resulted from user's improper use within validity of warranty.
* During validity of warranty, user shall not open the main unit enclosure or dismantle the foot switch without authorization, or otherwise the warranty will become invalid.
* After the warranty is invalid, related repair and maintenance service will be charged.
* Related equipment drawings and some necessary technical data will be provided for the maintenance agent and staff trained and approved by us.

Trouble Shooting

As the electrosurgical unit system is complicated, any trouble shooting activity shall be performed in accordance with the following procedure:

1.It should be determined whether the trouble is caused by failure in the equipment or personal improper operation.

For example, the neutral electrode is not reliably attached to patient's body,which will activate alarm and cause start-up failure.

2.It should be determined whether the trouble is caused by failure in the equipment or damage of any accessory.

For example, the equipment fails to start mostly because there is a problem with the hand-operated unit switch or foot switch.

3.It should be determined whether the trouble is caused by failure in the equipment or any external breakdown. Related instructions are tabulated innext section.

4. It should be determined in what part of the equipment there is a fault.

Any Internal fault in the equipment shall be removed by any well-trained

personnel.

Regular Testing

User shall regularly carry out some necessary performance and safety tests.

* Power test (on a semi-annual basis)

*Low-frequency leakage current test (on a semi-annual basis)To-earth leakage current <0.5mA

Patient leakage current <10μA

* High-frequency leakage current test (on a semi-annual basis) <150mA

Common Fault Table

External Fault Table

Phenomenon	Cause	Handling Method
No display is output when the power supply is switch on	◆ No 220V voltage is output atthe power socket ◆ The fuse is loose or broken.	◇ Check grid power supply ◇ Tighten or replace fuse (If the problem remains after replacement, it may be caused by any internal fault.)）
Alarm is activated	◆ Neutral electrode] plug is not connected reliably ◆ Neutral electrode clamp does not hold electrode conductor securely	◇ Connect neutral electrode reliably or replace neutral electrode. ◇ Hold electrode conductor securely
The equipment fails to be started from hand-operated unit	◆ Hand-operated unit switch is in poor contact	◇ Replace hand-operated unit
The equipment fails to be started from foot switch	◆ Foot switch is in poor contact ◆ Foot switch is not connected reliably	◇ Replace foot-operated switch ◇ Re-connect the plug
Dual-sheet neutral electrode fails to be switched automatically	◆ Plug on electrode connectingwire is damaged	◇ Replace electrode connecting wire
Connect hand-operated unit and the equipment is started	◆ Hand-operated unit is constantly close	◇ Replace hand-operated unit
Output electrode cable overheats or output power is obviously low	◆ The cable is folded or any connector gets loose	◇ Replace related accessory or tightenthe connector
Enclosure of equipment is electrified	◆ The power cable is not grounded properly or grid power cable inside equipment falls out	◇ Ground power cable properly or re-connect grid power cable

Internal Fault Table

Phenomenon	Cause	Handling Method
Alarm is activated	◆ Neutral electrode plug is in poor contact ◆ Soft neutral electrode clamp is in poor contact	◇ Replace electrode connectingwire ◇ Replace electrode connectingwire
Dual-sheet neutral electrode fails to be switched automatically	◆ Switch in neutral electrode socket is damaged ◆ Wire connecting neutral electrode socket falls off outputboard	◇ Replace socket ◇ Connect the connecting wire reliably
Digital tube fails	◆+5V switching power supply is damaged ◆ Connector between +5V switching power supply anddisplay board falls off ◆Display board or CPU board is damaged	◇ Replace 5W switching power supply ◇ Connect the connecting wire reliably ◇ Replace display board or CPUboard
Hand-operated unit fails to operate while foot switch can operate	◆ Optical-isolator in hand-operatedunit isolating circuit is damaged	◇Replace output board
Foot switch fails to operate while hand-operated unit can operate	◆ Optical-isolator in foot-operatedunit isolating circuit s damaged	◇Replace rear panel
Both hand-operated unit and foot switch fail to operate	◆ If relays JD5002 and JD5003 on Output board act, it can be determined that CPU fails to receive start-up signal ◆ If relay on Output board fails to act, it can be determined that power board fails to send start-up signal	◇ Replace CPU board ◇Replace power board
High-frequency leakage current increases	◆ Too heavy dust is accumulated or the equipment is affected with	◇ Clean, dry and re-coat the equipment

	damp.	
The equipment can be started but fails to outputpower	◆ Switching power supplyfails to supply AMP power ◆ Power tube fails to output driving waveform ◆ Resonance circuit is damaged	◇ Replace power supply board ◇ Replace power board ◇ Replace output board
Output power is in significant deviation	◆ Storage is damaged	◇ Replace CPU board

Guide and Statement

Guide and Manufacturer's Statement - EMR		
This equipment shall be operated in the following electromagnetic environment. Theuser shall ensure this equipment to be operated in such environment.		
Emission Test	**Emission Test**	**Emission Test**
Radio Emission GB4824	Group 1	YR02145 uses radio frequency energy only for its internal functions during test in standby. Therefore, it emits extremely low RF energy andwill cause no interference to the adjacent electrical equipment.
Radio Emission GB4824	Class A	This equipment is applicable to any facility not directly connected to non-domestic andresident-shared public LV power grid.
Harmonic Emission GB17625.1	NA	
Voltage Fluctuation/Flash Emission GB17625.2	NA	

Guide and Manufacturer's Statement - EMI			
This equipment shall be operated in the following electromagnetic environment. Theuser shall ensure this equipment to be operated in such environment.			
Immunity Test	IEC 60601 Test Level	Compliant Level	EME - Guide
ESD GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The floor shall be constructed of wood or concrete or tiled. In case of floor covered with composite material, the relative humidity shall be at least 30%.
EFT GB/T 17626.4	±2kV to power cable ±1kV to input/output cable	±2kV to power cable ±1kV to input/output cable	The grid power shall be applicable for typical commercial or medical environment.

Surging GB/T17626.5	±1kV cable to cable ±2kV cable to earth	±1kV cable to cable ±2kV cable to earth	The grid power shall be applicable for typical commercial or medical environment.
Voltage dip, short interruptionand voltage variation in power input line GB/T17626.11	<5% U_T, continuous for 0.5 cycle (voltage dip >95%in U_T) 40% U_T, continuous for 5 cycle (voltage dip of 60% in U_T) 70% UT, continuous for 25 cycles (voltage dipof 30% in UT) <5%U_T, continuousfor 5s (voltage dip >95%in U_T)	<5% U_T, continuous for 0.5 cycle (voltage dip >95%in U_T) 40% U_T, continuous for 5 cycles (voltage dip of 60% in U_T) 70% UT, continuous for 25 cycles (voltage dip of 30% in UT) <5%U_T, continuous for 5s (voltage dip >95%in U_T)	The grid power shall be the one used for typical commercial or medical environment. If Anaeston05 user needs touse Anaeston05 during power outage, It is recommended to connectAnaeston05 to a UPS or use battery.
Power frequency magnetic field (50/60Hz) GB/T17626.8	3 A/m	3 A/m	In commercial or medical environment, the power supply shall have its frequency and magnetic field kept at a specific level.
Caution: Prior to test, UT refers to AC voltage.			

<table>
<tr><th colspan="4">Guide and Manufacturer's Statement - EMI</th></tr>
<tr><td colspan="4">This equipment is intended to operate in the following EMI environments, and itspurchaser or user shall ensure to operate it in these EMI environments.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliant Level</td><td>EM Environment - Guide</td></tr>
<tr><td>RF Transmission GB/T 17626.6
RF Radiation GB/T 17626.3</td><td>3V (effective value)
150kHz-80Mhz
3V/m
80 MHz～2.5 GHz</td><td>3V (effective value)

3V/m</td><td>Any portable or mobile RF communication equipment shall be operated at a distance away from any part (including cable) of the equipment not shorter than the recommended, calculation of whichshall be based on the formula specific for the transmitter frequency.
Recommended Distance
d=1.2 $\sqrt{P}$
d=1.2 $\sqrt{P}$ 80MHz～800MHz
d=2.3 $\sqrt{P}$ 800 MHz ～2.5 GHz
Where,
P: the maximum rated output power (in Watt) of transmitter provided by its manufacturer.
d: the recommended distance (in meter).
The field strength of fixed radio frequency transmitter is determined based on the survey at EMI location*, and each frequency range * should be lower than Compliance Level.
Interference may be caused nearany equipment attached with thefollowing labels.
  </td></tr>
<tr><td colspan="4">Note 1: For frequency of 80MHz and 800MHz, a formula in respect of high frequencyshould be used.
Note 2: These guidelines may not be applicable to all circumstances, as transmission ofEMI may be affected by absorption and reflection of buildings, objects and human body.</td></tr>
</table>

*Field strength of fixed transmitter, such as: wireless telephone (cellular or cordless) and ground mobile radio base station, amateur radio, FM/AM radio broadcasting and TV broadcasting, is unpredictable in theory. Evaluation of EMI of fixed RF transmitter shall take into consideration measurement on the EMI field. If the field strength measured at the location where this equipment is installed is higher than the RF allowable level, this equipment shall be monitored to verify its normal operation. If any performance defect is detected, necessary remedial measure shall be taken, such as re-locating or re-orienting this product.
* In the frequency range of 150KHz～80MHz, field strength should be lower than 3 V/m.

Recommended separation distance between portable/mobile RF communicationequipment and this equipment

This product is intended to operate in EME with controlled RF radiation interference. Based on the maximum output of communication equipment, purchaser or user of thisequipment shall maintain the minimum distance between portable/mobile RF communication equipment (transmitter) and this equipment so as to prevent EMI.

Maximum rated output power of transmitter W	Distance based on frequency of transmitter /m		
	150kHz-80Mhz $d=1.2\sqrt{P}$	80MHz～800MHz $d=1.2\sqrt{P}$	800 MHz ～2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum output values of emitter which are not listed above, the recommended distance d in meter shall be determined based on the formula as provided in the column of emitter frequency. Here P is the maximum rated outputpower in watt (W) provided by the manufacturer.
Note 1: The formula for higher frequency band shall be applied for frequency range of80 MHz ~ 800 MHz.
Note 2: These guidelines may not be applicable to all circumstances, as transmission of EMI may be affected by absorption and reflection of buildings, objects and humanbody.

Warn:

1) Power cable used for YR02145 shall be CCC certified.

2) Apart from the energy converter and cables supplied as spare parts by the equipmentor system manufacturer, use of any other accessory, converter or cable may cause increase of EMI generated by the equipment or system or reduction of interference immunity.

3) This equipment shall not be operated near or in stack with any other equipment unless it is verified that it can operate normally in its existing configuration.

⚠ Warn: This equipment has to emit electromagnetic energy to achieve its intended function, which may affect any electronic equipment nearby. User should pay attentionto operation of the electronic equipment nearby. In case of any anomaly, immediately take proper action to move the equipment away or provide proper screen.

4) Any portable or mobile RF communication equipment may affect operation of thisequipment. .