

Figure, Sign, Abbreviation



Indicate danger, warning and precaution



BF mode safety type equipment (back-panel)



Protective Earthing (within the apparatus)



Dangerous Voltage (within the apparatus)

F2AL250V

Fuse's mode and specification (back-panel)



Fuse (the same as the above-mentioned fuse)

(back-panel)

IPX1

Prevent Dripping



Fragile Goods



Avoid Rain

42kgmax



Limit of piling up weight: 42kg



Turn off the power



Turn on Power



Upward



This product is prohibited to use in the operation room.



**It must adopt the net power socket with protecting earthing line,
And ensure the earthing is well.**

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I.Overview

Introduction
Product features
Application scope and contraindication
Application environment conditions
Effect on environment and energy
Safety precautions

Introduction

Company Introduction

EG Medical is a sino-foreign hi-tech joint venture, mainly invested by foreign founds, specialized in the design, research and development, manufacture, marketing and service of medical facilities. The company has being acting on a quality policy of "practicality, innovation, high-quality and high-efficiency", pursuing insistently a modern mode of management and strictly implementing the national state and industrial standards. It was appraised as "High-tech Enterprise" in 1999 and again in 2003 as foreign funded "Advanced Technology Enterprise".Later, it obtained ISO9001 2000 International Quality System certificate, TUVPS and China Medical Apparatus (CMD) Quality System certification. Wearnes Medical has become a well-known key enterprise of our country for manufacturing medical facilities, and will be innovating and pursuing excellence continuously in the future, for achieving perfect qualities to serve for health and repay our society.

Product Introduction

9651B series of HF operative electrocautery are new medical apparatus. The apparatus, high quality and low cost, applied widely in clinics and enabling a quick economical recompense, is appraised in medical field as the "Penicillin" for treating diseases on body surface and in cavity. The product has had ready markets in 28 provinces, municipalities and autonomous regions, and received favorable comments from many medical units since it came into the market in 1997.It is attractive in appearance, reasonably designed and reliable. It is designed to automatically adapt to wide-range mains voltage and therefore is widely appreciated

by the hospitals of all levels, especially health centers and clinics in towns and villages and privately-owned clinics.

Product Features:

- (1) Import integral circuit and control chip to ensure the normal application of the Apparatus;
- (2) Spherical electrodes, needle-shape electrodes and knife-shape electrodes, easily-used operating handles, excellent quality;
- (3) Integrating several new technologies to ensure the integral features of quick startup, high efficiency, long-fire life and stability;
- (4) New technology related to switching power supply to save the necessity of external AC voltage stabilizer; normal application is enabled in area with unstable power supply(198V~242V);
- (5) Touch switch for function selection, high efficiency and convenience.

Application scope and contraindication

- (1) Dermopathy: condyloma acuminatum, plantar wart, flat wart, verruca vulgaris, sebaceous gland tumor, aestates and etc.
- (2) Anorectal diseases: internal and hemorrhoid hemorrhoid etc
- (3) Gynecopathy: Class I, II and III cervical erosion, cervical polyp, Nabothian cyst, labia minora lipoma and etc.
- (4) Five sense organs: chronic hypertrophic rhinitis, nasal polyp, nasal cavity hemangioma and etc.



Contraindication:

- Forbidden to apply this apparatus on patient with hemorrhagic tendency in their bodies.
- Forbidden to apply this apparatus on patients with implanted cardiac pacemakers and pacemakers.
- Forbidden to apply this apparatus on patients during the period of acute infection.
- Forbidden to apply this apparatus on patients of cardio-pulmonary function insufficiency and other high risk diseases.
- Forbidden to apply this apparatus on patients during the period of Gestation.

Application environment conditions

- (1) Ambient temperature: $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$;
- (2) Relative humidity: 30%~85%;
- (3) Atmospheric pressure: 50kPa~106kPa;
- (4) Power supply: a.c. $220\text{V} \pm 22\text{V}$, $50\text{Hz} \pm 1\text{Hz}$;
- (5) Application of this apparatus in operating room is forbidden.

Influence on environment and energy

Keep the apparatus away from other devices when working, as the electromagnetic wave transmitted from operating electrodes and connecting wires of handles may possibly cause electromagnetic interference with medical electric instrument such as monitors and etc.



Safety precautions

- (1) The apparatus should be preheated to dispel humidity at least half an hour, before it is reused after a long-fire time non-use.
- (2) Cables of operating electrodes should be placed properly to avoid contact with patients or other conducting wires during application of this apparatus and the operating electrodes without immediate use should be placed away from patients.
- (3) Switch off power prior to replacement of electrodes to prevent electric shock hazard.
- (4) Foot switch should be placed on the floor where there is no water log.
- (5) "Operating" indicator is on and the apparatus beeps (when volume switch set to "High") to indicate the entire unit is operational, when the electrodes must be prevent approaching position not to be treated.
- (6) This apparatus should not be used together with flammable doanesthetic, laughing gas, oxygen, flammable disinfectant or other flammable gas or fluid. Before the electrodes contact the body of a patient, completely swab up the flammable fluid remaining in the exacatin (such as umbilical region and cavity etc) of the patient. Risk from other fire sources shall be also prevented during application of this apparatus.
- (7) Electrode handles should be placed on the handle support if not used immediately; if not to use for a long-fire time, the electrode handles should be stored in a clean and sanitary place to avoid damage or pollution.

II. Main structure and mode of operation

Main structure of complete unit

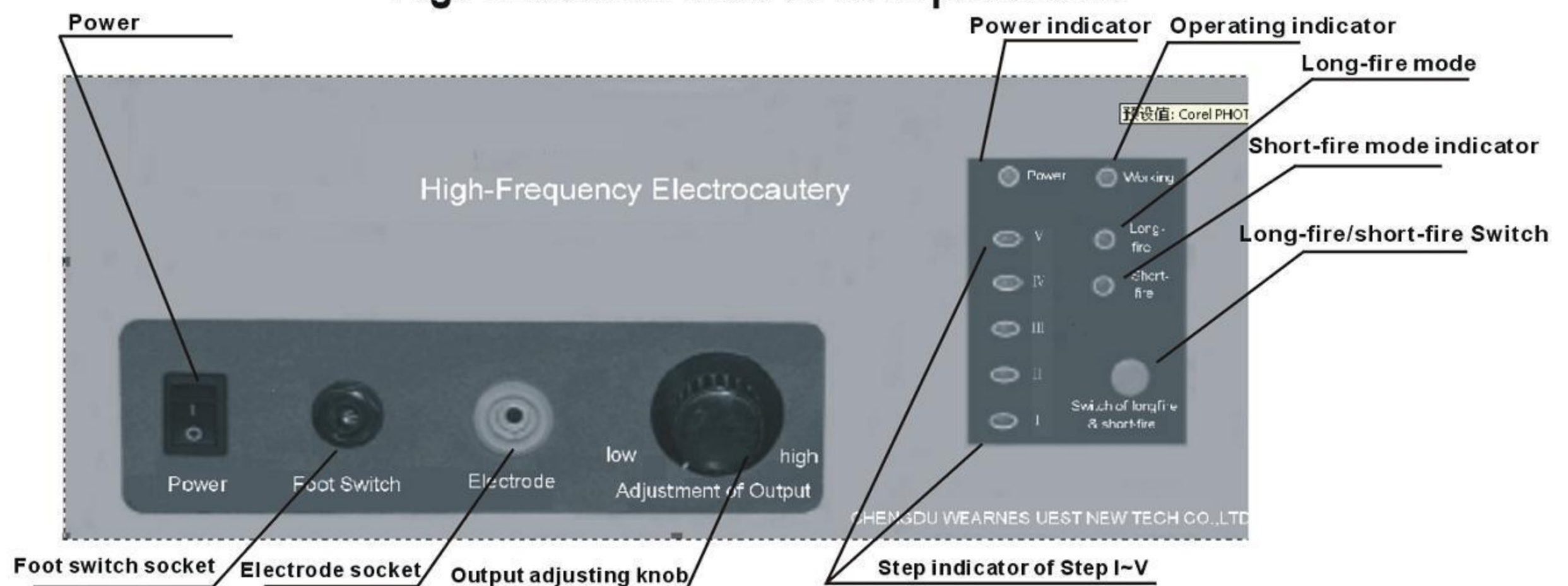
Mode of operation

Main structure of complete unit

9651B series mainly consists of main unit, foot switch and operation electrodes, connecting wires and handles (these instructions are based on 9651B1, methods of application for 9651B, 9651B2 and 9651B3 are the same). The complete external view of 9651B1 is shown as following Fig. 1; Fig. 2, front panel; Fig. 3, back panel; Fig. 4, operating electrodes; Fig. 5, 9651B External View of Complete Unit.



Fig. 1 External View of Complete Unit



**9651B series of High-Frequency Electrocautery
Fig. 2 Front Panel**

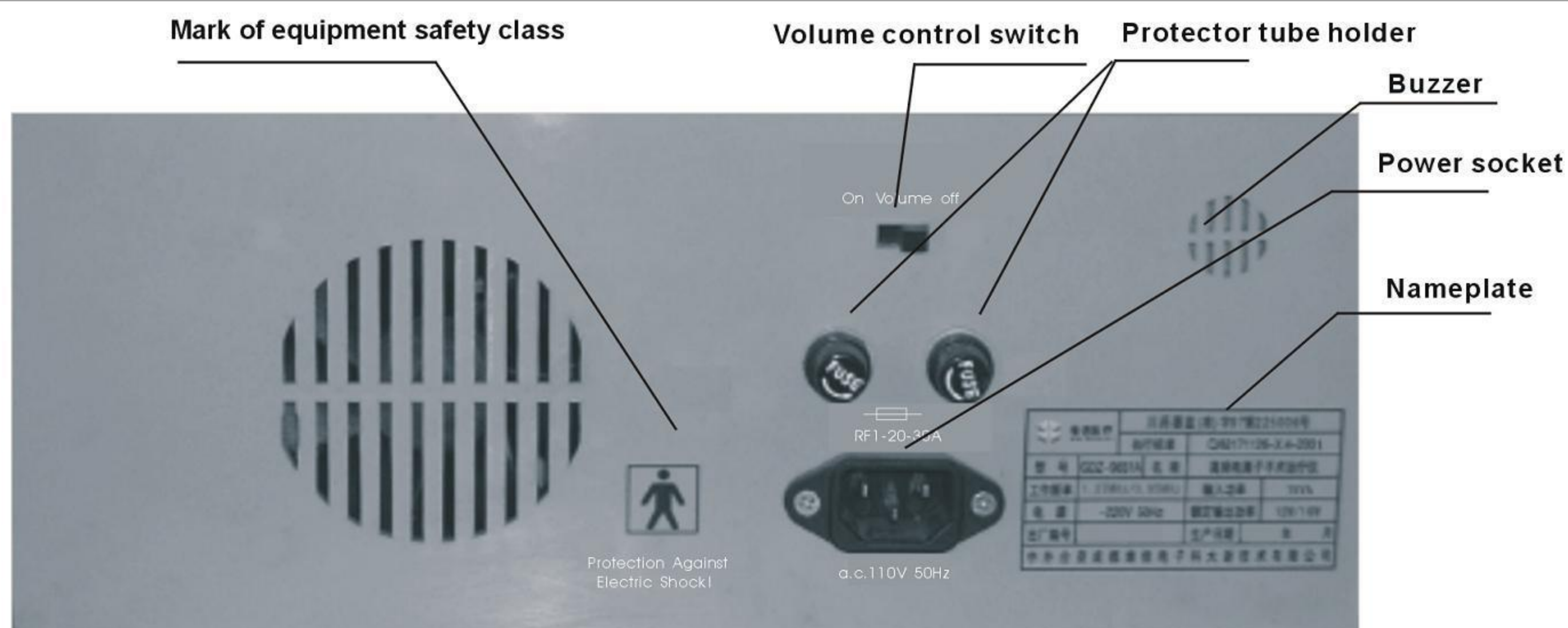


Fig. 3 Back Panel

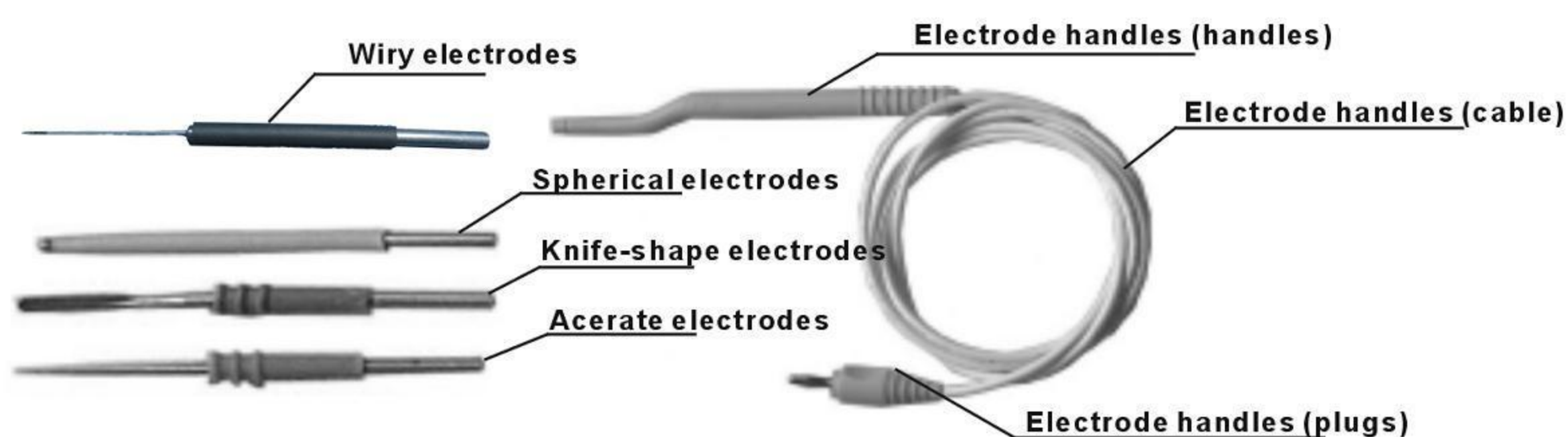


Fig. 4 Operating electrodes



Fig. 5 9651B External View of Complete Unit

Mode of operation

Mode of operation

(1) Principle Diagram(as shown in Fig. 6)

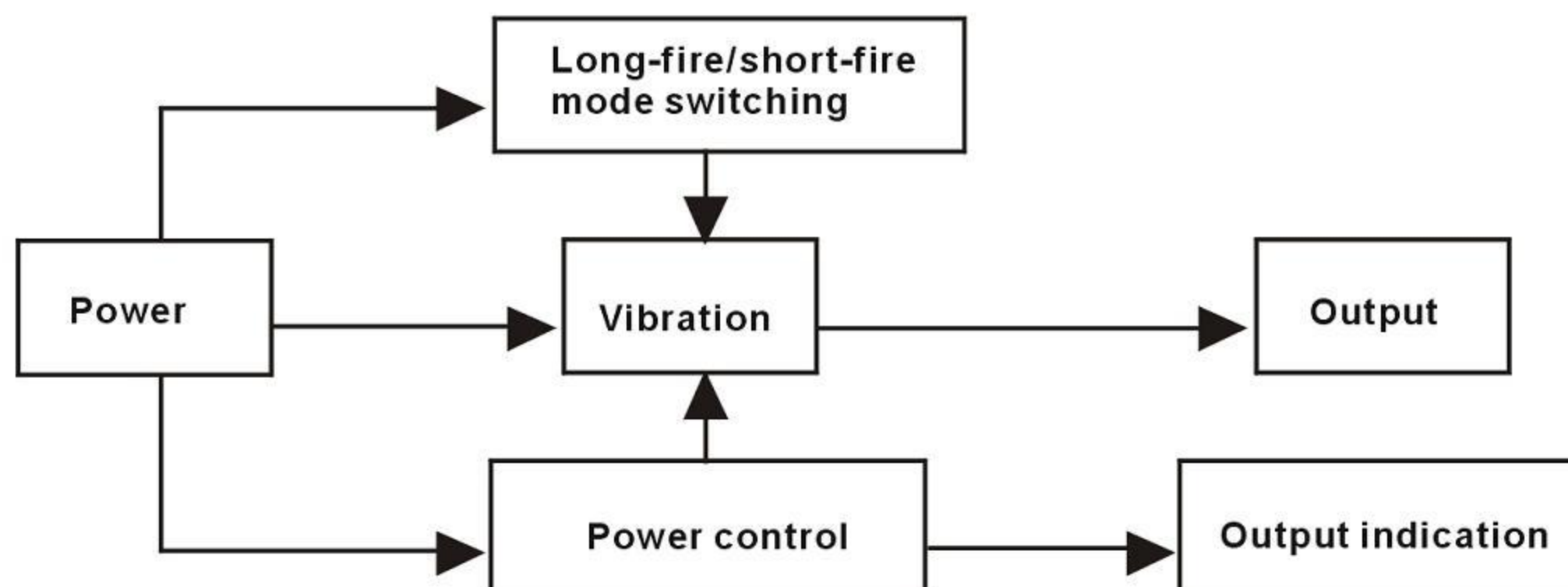


Fig. 6 Principle Block Diagram

(2) Mode of operation

The power circuit transforms AC voltage into DC voltage by stepping down transformation and supplies power to other circuits. Power control circuit controls Vibration output amplitude and status indicating. Operating frequency of control Vibration circuit for long-fire/short-fire mode switching circuit. Vibration circuit produces therapeutic waveform with the output circuit being buffer step up circuit.

(3) Alarming system

When outputting, the apparatus will send out acoustic alarm indicating output is Ongoing.

III. Major Technical Indexes

Major Technical Parameters
Exterior & Installation Dimension
Weight of the Unit

Major technical parameters

(1) Power supply: a.c.198V~a.c.242V, 50Hz $\pm$ 1 Hz

(2) Operating frequency: 1.27MHz $\pm$ 0.127MHz (without inductive load 500 Ω)

(3) Rated input power: 240VA

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- (4) Output is in the form of modulated wave.
 - (5) Output power: by adjustable steps of Step I, II, III, IV and V. Maximum output power: $40W \pm 20\%$ Mixing-cut mode , $30W \pm 20\%$ of Bloodt-clotting mode
 - (6) Mode of Operation: Continuous Operation
 - (7) Protection against Electric Shock: I
 - (8) Degree of protection against Electric Shock: BF mode
 - (9) It is normal apparatus.

Outline dimensions and installation dimensions

322mm(length)×240mm(width)×148mm(height)

Total weight of unit

Gross weight: 5kg

Net weight: 3.5kg

IV. Installation and commissioning

Installation

Commissioning and test application

Inspection & Acceptance

Installation

(1) Installation environment

Prerequisite ambient temperature for installation: $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$; relative humidity: 30%~85%; atmospheric pressure: 50kPa~106 kPa; supply power: a.c. $220V \pm 22V$, $50\text{Hz} \pm 1\text{Hz}$, dustproof and well-ventilated environment with no corrosive and flammable gas.

(2) Installation method

- ◆ Open the accessory box and check the parts and accessories against the packing list. Notice the distributor immediately in case of any damage;

- ◆ proper electrodes are selected based on the situation of the patient to be treated, and installed as shown in Fig.4; cleaning and disinfection is conducted by common method; the selected knife-shape electrodes, spherical electrodes, wiry electrodes or needle electrodes are directly inserted in the front ends of handles.

Commissioning and test run

Connect one electrode to the handle and electrified; adjust the power to the proper step in accordance with the operating procedures and then perform a simulative operation on a piece of pork or soap to observe the effect.

Acceptance

- (1) Apparatus and accessory should be checked against packing list, all of them should be in good order;
- (2) Inspect the functions under long-fire/short-fire modes and the five steps; if Operating normally under all the conditions, the product is qualified and acceptable.

V. Operation method

Preparation before operation

Operating procedures

Recommended treatment of diseases and treatment methods

Preparation before operation



Safety precautions

(1) Safety precautions

For proper use of this apparatus, attention should be paid to the following aspects before application:

- ◆ Before using such apparatus for the first time, the operator should have an exercise on a piece of wet soap to have experience on the characteristics of ionization/coag and cut modes, practicing the treating skill; operation on patient may be permitted until becoming very skillful.
- ◆ During treating, the doctor must wear rubber gloves on both hands.

- ◆ In case of any contamination on the electrodes which may impact the power output, stop the apparatus to remove the contamination.
- ◆ For ablating, the electrodes shall be checked beforehand, if becoming blunt, they must be grinded or replaced.
- ◆ During treating, the electrode moving should be in proper speed based on the ablating status; if too fast, no spark is generated as there is no time gap and the ablating force and therapeutic effect is reduced accordingly.
- ◆ In long-fire mode, the electrode are placed near, but not close to, the human tissue; in short-fire mode, the electrode should enter the focus in proper and uniform speed (such as destroying dilatation capillary, sudoriferous gland and etc), i.e. there must a proper interval. This apparatus may operate effectively only under the skillful practice of such interval.
- ◆ Be cautious to use on diabetics. Be cautious to use on scar diathesis patients. Be cautious to use on woman in mensdtrual period.

(2) Power supply and environment check

Check and confirm the power is at a.c.198V~a.c.242V and make sure there's protective earthing wire and well-ventilated environment.

(3)Apparatus Arrangement, Parts, Accessory Connection and Installation
InspectionPlace the apparatus on the proper position; connect the foot switch to the front panel of the main unit; connect the electrode handle cable to the output interface on the front panel; and mount the selected electrodes on the handles with the reliable connection ensured.

(4) Handles and electrodes disinfection

- A .Before application, the handles must be cleaned and disinfected with medical alcohol and dried.
- b. After each use, the electrodes shall be sterilized under high temperature and high pressure (pressure: 102.9kPa; temperature: 121℃; lasting for 20~30min).

Operating steps



Only mains socket-outlet with protectire earth conductor is allowed and the protectire earth conductor must be ensured in good condition.

- (1) Plugging the power plug of the main unit into the network power socket;
- (2) Insert the well-mounted handle plug into the " Electrode " socket of the apparatus.

- (3) Turn on the " Power " switch. The power indicator is on, and the operating mode indicator and output step indicator display, in the same time, the preset operating mode and status of the apparatus.
- (4) To conduct the treatment, the foot switch must be used. Insert the foot switch plug into the " Foot switch " socket on the panel. If foot switch is not stepped, " perating " indicator off, no beep heard and no output from the electrode; when stepping down the " Foot switch " , " Operating " indicator is on, beeping alarm is heard and there is output from the electrode. Unplugging the " Foot switch " plug, " Operating " indicator is off, no beeping is heard and there is no output from the electrode. The beeping volume may be adjusted by turning the " Volume adjuster " on the back panel (turning to " Mute " position, it is in a mute status).
- (5) To select the appropriate output step, turn the " Output adjusting " knob. During treating, the power should start from the lower step and adjusted up gradually.

Recommended treatment of diseases and treatment methods

(1) Treatment of dermatosis

- ◆ Plantar wart, flat wart, verruca vulgaris, sebaceous gland tumor, aestates and etc.
- a. Traditional disinfection, local infiltration narcotization. For gentle, superficial and dispersal impairments, narcotization may be cancelled based on the tolerance.
- b. To proceed with the treatment, pinch the part around the impairment with left thumb and forefinger so as to mitigate the pain.
- c. Generally, Cut mode is adopted(Coa mode may be also used) and the common steps are Step II~V; wiry or knife-shape electrode is used to gently touch or approach the impairment, ablating point by point or vaporizing. Doctor may select the power step based on the nature, size and depth of skin impairment, his experience and the characteristics of Coa and Cut modes. General principle is to increase output for serious impairment, select Coa mode if bleeding is liable bleeding while select Cut mode if no liable beeding; Coa mode is usually used for coagulation, charring and vaporization while Cut mode for ablating. For certain impairments, combination of Coa and Cut modes is adopted. When adopting Cut mode to treat verruca vulgaris, there will be bleeding when erasing when the charring layer after the verrucosus impairment is vaporized. Then turn to Coa mode and increase the output; touch the bleeding position quickly for several times to arrest bleeding and form coverage.

-
- d. For the purpose of radical treatment during treating, the doctor may use isotonic sodium chloride cotton balls to clean the treated location so as to check if the impairment is completely dispelled.
 - e. Sometimes non-conduction may occur in the charred layer due to lack of water, which is unfavorable in sparking and evaporation when gently touching this location; then isotonic saline cotton balls may be used to clean to clean off or wet the charred layer before resume the treating.
 - f. If the impairment area is large, dispersal and deep below the true skin, treating in several times is necessary and the treated radius at each time should be controlled within 1~2mm with distance between the treated patches not less than 1mm so as to prevent forming of scar; in such case, spherical electrode may be used for the treatment.
 - g. The treatment is finished when confirming the impairment is totally dispelled; wound surface should not wiped any more as remaining of the coagulation layer is favorable to scabbing.
 - h. After the treatment, the superficial and small-size wound surface on head and face may be applied with scald ointment, where bandaging is not necessary. For other locations, bandaging is necessary and dressing should be changed every 2~3 days
 - i. After decrustation, temporary chromatosis may occurs in some cases which usually disappears after 1~6 months or longer in individual cases. The patients must be instructed not to be insolated within 1month or apply floury cosmetics, and let the crust at the treated position come off naturally.

◆ Cauliflower excrescence

- a. Select Cut mode and adjust the step to Step IV~V.
 - b. Conduct traditional disinfection, apply superficial narcotization at mucous membrane position or local narcotization at dermal position.
 - c. Instruct the patient to inspire with mouth and expire with nose during treating operation so as to ensure the treating smoothness and safety. Conduct traditional disinfection and apply superficial infiltration narcotization on concha with several drops of 1~2/100 Tetracaine in 1:1000 adrenalin cotton sheet.
 - d. Do not remove the charred layer formed from the vaporized surface of wound so as to forming of scab. Just local wiping with iodine and fluorine is sufficient after the operation.
- (2) Therapeutic method for diseases related to eye, ear, nose and throat

◆ Chronic pachismus rhinitis

- a. Select wiry electrodes and determine the proper length based on the situation; bend the electrode to proper angle based on the situation of the affected region.
- b. Adopt long-fire mode and adjust the step to Step IV~V.

- C. Instruct the patient to inspire with mouth and expire with nose during treating operation so as to ensure the treating smoothness and safety. Conduct traditional disinfection and apply superficial infiltration narcotization on concha with several drops of 1~2/100 Tetracaine in 1:1000 adrenalin cotton sheet.
- d. Place the right little finger at the outer lower part of the patient's nasal ala so as to support the wrist holding the handle, align the electrode to the tissue to be destructed and then step down the foot switch. Note! Release the foot switch immediately if the patient shakes during the operating, to prevent injury.
- e. Adjust the distance between the electrode and the tissue based on the size of the spark. Generally, the spark is small when the electrode is about 1mm from the tissue and it will be large if 2~3mm to the tissue. In case of bleeding, the electrode may be drawn back a little from the tissue and only let the larger spark stay for a moment at the bleeding position.
- f. Place the electrode near the hypertrophic mucosa and vaporize it from down to up(or from the front edge to the back edge) till 1/3~1/2 of the concha thickness is left.
- g. Use absorbable gelatin sponge to fill the wound surface after the operation and instruct the patient not to blow his/her nose within one week; the wound surface generally heals in two weeks.
- h. In case of excessive excretion and emphysema in nasal cavity after operation, the doctor may take it out carefully.

◆ Nasal polyp

Therapeutic methods and treatment after operation is same as those for “chronic hypertrophic rhinitis” To treat large polypi, remove by hitching or excise the polypi and then vaporize the root with Coa. To treat small size polypi, directly vaporize it with Cut.

(3) Therapeutic methods for anorectal diseases

◆ External hemorrhoid

- a. Traditional disinfection and local narcotization with 5/100 dolocaine.
- b. Select Cut mode and adjust the step to Step II~IV.
- c. Vice the hemorrhoid basal part with a hemostat and ablate the external hemorrhoid along the hemostat; release the hemostat and further vaporize the residual root in long-fire mode and arrest the bleeding. For a larger external hemorrhoid, stitching of 1~2 needles with silk thread may be necessary.
- d. For a thrombus type external hemorrhoid, vice the thrombus with a hemostat, take basal part of the thrombus type external hemorrhoid as the center and apply a radial incision in short-fire mode; take out the incision with a hemostat and then burn the basal part of the thrombus type external hemorrhoid with long-fire to remove the residual part and arrest the bleeding.

-
- e. Change the dressing in a hip bath manner every day after the operation. About 2 weeks need for recovery.

◆ Internal hemorrhoid

- a. Traditional disinfection and local narcotization with 5/100 dolicaïne
- b. Select Cut mode and adjust the step to Step III.
- c. Vice the haemorrhoid with a hemostat and ablate the hemorrhoid along the hemostat; use “3~0” gut string to stitch a “8” shape tie along the lower edge of the hemostat; after operation, inject methylene blue reagent in the haemorrhoid basal part(number of haemorrhoids removed each time should not exceed 3).
- d. Insert ointment gauze strips in the anal canal after operation, suppress excrement within 24 hours; change dressing by hip bath after excrement; recovery needs about 2 weeks.



Patient without procreation history would not have a natural accouchement but a caesarean birth as the elasticity of the unerine neck might be reduced.

(4) Therapeutic methods for gynecological diseases

◆ Cervical erosion

- a. Choose the operation on a day 3~7 days after catamenia finishes.
- b. Common gynecological check and confirm there is no acute colpitis or pelvic inflammation
- c. Common cervical smear check to confirm there is no canceration
- d. Select Coa mode and adjust the step to Step V.
- e. Select spherical electrodes
- f. Conduct traditional disinfection and expose the neck of uterus
- g. Place the electrode near the anabrosis face and burn the anabrosis face uniformly by a scanning manner from down to up; stop for a moment in case of bleeding.
- h. Curing may be possible generally by one time of treatment for Level I and II anabrosis; 2~3 times of treatment is necessary for Level III anabrosis.
- i. It is forbidden to have sexual intercourse within 2 months after the operation.

- † Select proper electrode for cervical erosion with complicate cervical polyp, Nabothian cyst and nympha lipoma; polyp and nympha lipoma may be directly vaporized and for the Nabothian cyst, the cyst wall should be incised to eliminate the content in the cyst and then vaporize the cyst wall. Other procedures are same as those for " Cervical erosion "

VI. Maintenance and repair

Maintenance Repair

Maintenance

- (1) Dustproof and moisture proof measures must be taken for this apparatus during the period it is unused;
- (2) Prevent water from entering the main unit, otherwise the insulation performance may degrade which may result in power leakage and even cause body injury;
- (3) Refer to relevant sections of this Manual for handle and electrode disinfection;
- (4) The main unit should be quarterly cleaned with cleaning paste. User should periodically check the accessories, especially the insulation layer of the operating electrodes to ensure no damage.

Repair

Only approved professional personnel and experienced maintenance personnel is allowed to disassemble this apparatus (there is potential danger from HV inside the unit).

VII. Common failures and troubleshooting

Common failures of this apparatus, cause analysis and troubleshooting

Common failures of this apparatus, cause analysis and troubleshooting:

1. Power indicator is not on when power switch is turned on;
Cause: indicator failure, fuse breaking or power plug not connecting well, or power switch failure.
2. Operating indicator is not on, no beeping is heard and there is no output when stepping down foot switch;
Cause: foot switch failure or loose contact of plug.
3. Electrode does not generate spark;
Cause: loose contact of electrode or cutter head of the electrode; dirty electrode or electrode staying too near the body tissue.
4. For other faults, contact the Technical Service section of our company;

 **For strange, complicated or questionable faults, contact to Technical Service section of the Company, but not repair the apparatus by experienced personnel which may result in accidental failure or personal injury.**

VIII. Safeguard devices and accident disposal

Safeguard devices for the product and precautions

Common accident disposing

Safeguard devices for the product and precautions

- (1) When this apparatus is outputting, there will be acoustic alarming and lighting indicating. At this time, the electrodes must be prevented from contracting position not to be treated.
- (2) For replacing power protector tube(in the back panel), unplug the power plug, unscrew the tube cap and then replace the protector tube(Model No.: F2AL250A)

Common accident disposing

If any scalding occurs during treating, burning ointment should be applied on the scalded position.

IX. Transportation and storage

Climate and environment conditions

Transportation

Storage

Climate and environment conditions

- (1) Temperature: $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$.
- (2) Relative humidity : $\leq 95\%$.
- (3) Atmospheric pressure: $50\text{kPa} \sim 106\text{kPa}$;

Transportation

- (1) The product is suitable for common transport such as highway, railway, water and air etc.
- (2) For the transportation, the products shall be protected against excessive vibration, bumping and falling; it must be kept upright , handled with care and protected against raining and heavy pressure.

Storage

- (1) The product shall be stored indoor with proper ventilation, free of corrosive gas.
- (2) The product should be storied in package after cleaning if not used for a long time and it is better to be electrified once every year to prevent damping and molding.

X. Unpacking and inspection

Cautions for unpacking

Inspection items

Cautions for unpacking

- (1) Check the completeness of package before unpacking.
- (2) Before unpacking, keep it right side up.

Inspection items

(1) Main unit: 1 set

(2) Power cable: 1 pc

(3) Foot switch: 1 set

(4) Electrode handle: 1 set

(5) Electrode:

◆ Type 1 wiry electrode (electrode wire of 0.3mm): 5 pcs

◆ Type 2 wiry electrode (electrode wire of 0.4mm): 5 pcs

◆ Spherical electrode: 1 pc

◆ Needle electrode: 1 pc

◆ Knife-shape electrode: 1 pc

(6) Protector tube: F2AL250V: 2 pc(spare parts)

(7) Instruction Manual: 1 copy

(8) Product warranty card, certificate : 1 copy respectively

(9) Packing list: 1 copy (customer inspects and accepts the product against Such list. The list may vary without advance notice).

XI. Responsibilities of manufacturer

Responsibilities of manufacturer

Responsibilities of manufacturer

1. The Company is responsible for the repair, replacement or return of product in case of any nonconformance with product standard.
2. In case of any personal injury or other property damage due to any defect of this product, our company is responsible for the associated part. Our company holds no reasonability in case of one of the following conditions:
 - ◆ in case of nonexistence of defect causing damage(to personal, property) when product is put into operation;
 - ◆ in case of defect and appearance deficiency not existing at delivery;
 - ◆ in case of operation without perusal of the product manual, out line with the caution, warning;

- ◆ in case of damage to this product, any person and/or any property due to non-conformance with the specification on transportation, installation, usage, maintenance, storage and etc.
- 3. WBL Medial provides high quality service associated to the product, and free charge repair within the warranty period in case of any defect on main machine.(Accessories are not included in the warranty scope! See Warranty Card for detailed warranty terms and conditions!)
- 4. The duration of service for this product is 5 years!
- 5. Exterior of the product: refer to the real object.



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