Repetitive transcranial magnetic stimulation instrument

Instructions for use

WF-9903

Please read this manual carefully before use.

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Foreword

Notice to users

- Thank you for purchasing the products of Benbu Company. In order to ensure the safety of operation and the long-term stability of equipment performance, it is necessary to read this manual to understand the equipment function, operation and maintenance knowledge before operating the equipment.
- **Pay special attention to the contents of "Warning", "Caution" and "Attention" in the instructions.**
- The Company shall not be liable for any damage or injury caused by the user's improper operation or failure to comply with the manufacturer's instructions for the maintenance of the equipment.
- The following conventions are used throughout this specification to indicate emphasized information.

"Warning" is used to indicate that serious personal injury, death, or actual property damage will result if it is
"Caution" is used to indicate that it will produce minor personal injury or actual property damage if ignored.
"Caution" is used to remind the user of installation, operation, or maintenance information that is important, but not dangerous. A hazard warning is never included in the cautions.

Safety signs

The International Electrotechnical Commission (IEC) has established a set of rules for the special safety classif  n and marking of medical electrical equipment, which are shown below:

Marking of equipm  type BF AC  marking of equipment type II

 Refer to the accompanying documents for some matters not marked and explained externally, such as operation methods and precautions.

"1" and "0" on the power switch respectively indicate "on" and "off" of the power supply.

Handle with care 

ward for fea 

npness Storage  nsportation temperature limit

General safety information

The safety of the operator, the patient and the reliability of the equipment shall be taken into account in the design and manufacture of the products of this company, and the following safety preventive measures must be implemented:

1. The equipment shall be operated by or under the guidance of qualified operators.
2. This product is designated as Class II BF according to IEC60601-1 (Safety Standard for Medical Equipment). Non-AP and APG type common equipment capable of continuous operation. This therapeutic apparatus cannot be used in the presence of flammable anesthetic gas mixed with air or nitrous oxide.
3. Do not change the equipment parameters. If necessary, ask Weifang Benbu Medical Apparatus Co.,Ltd or its authorized agent to provide services.
4. The equipment has been adjusted to the best performance when leaving the factory. Do not adjust any preset control or switch unless the operation is specified in the manual.
5. If the instrument is used less, it shall be powered on at least once a week, and the power-on time shall not be less than 4 hours.
6. The power supply carrying capacity of the power supply line and power supply socket board of the instrument shall not be lower than ~ 220V/3A. For areas with unstable power supply, it is recommended that users be equipped with AC stabilized power supply.
7. The equipment is packed in cartons with soft materials inside. Please handle with care during handling. When the instrument is not used for a long time, it should be put into the packaging box according to the original packaging and stored properly. The storage should meet the requirements of "storage environment". The stacking layers of the equipment are 2 layers.
8. If the equipment breaks down, please handle it according to the instructions in the manual. If the fault still cannot be eliminated, please contact Weifang Benbu Medical Apparatus Co.,Ltd or its authorized agent.
9. If you need to connect electronic or mechanical devices of other companies, please contact Weifang Benbu Medical Apparatus Co.,Ltd or its authorized agent before connection.
10. Operation, storage and transportation environment

● Avoid severe vibration under standard operation conditions, and maintain the following temperature, humidity and atmospheric pressure ranges:
Ambient temperature: 5 ℃ — 40 ℃, relative humidity: ≤ 85%, atmospheric pressure: 86 kPa — 106 kPa — optimal temperature, relative humidity range: 17 ℃ — 23 ℃ 40 — 60%
● Range of temperature, humidity and atmospheric pressure during storage and transportation:
— — Temperature: -20 ℃ — + 55 ℃ — — Relative humidity: ≤ 85% — — Atmospheric pressure: 86 kPa — 106 kPa
● Attention shall be paid to the following items when the product generates magnetic field:
(1) a magnetic field magnetizes a ferromagnetic object;
(2) The magnetic field will magnetize the magnetic information carrier (tape, disk, credit card, etc.), thus losing its function;
(3) The intensity distribution of the magnetic field will be affected when the ferromagnetic object is close to the magnetic field;
(4) Other impacts of the magnetic field on the surrounding environment during use, storage and transportation.
● Equipment operation and storage shall avoid the following environments:
★ The equipment is exposed to direct sunlight, toxic gas, water vapor, dust, mist or splashing water, salt fog, high-density petroleum gas, explosive gas or dust, and high temperature.
★ Because this product uses AC magnetic field and electromagnetic wave to act on the human body together to achieve the purpose of treating diseases, there is a certain amount of electromagnetic radiation in the use process.The therapeutic apparatus should be far away from monitoring products and equipment with high frequency, high voltage and radioactive properties, such as X-ray machine, microwave therapeutic apparatus, high-frequency electrotome and other equipment.
★ Avoid the equipment in the environment of severe impact or vibration.
★ Avoid the inclination of the base plate for placing the equipment exceeding 10 degrees.
★ Avoid serious shortage of AC power voltage.
★ Avoid violent fluctuation of AC voltage during the operation of the equipment, and avoid the equipment in the high-voltage electric field environment.
● Description of environmental protection:
During the use of this product, electrode waste is produced. In order to prevent cross infection, the electrode shall be discarded after use and shall not be discarded at will. The accessory waste of medical devices shall be disposed of in accordance with the corresponding national laws and regulations.
Drugs for adjuvant therapy or disposable consumables, such as gauze, should be disposed of as waste medical waste after one use, and how to dispose of them can refer to relevant national regulations.
● **Safety Precautions for Use Warning:**
★ The user shall carry out maintenance inspection on the instrument once every other month to check whether the magnetic field output is normal and whether the electrical stimulation output is normal, check whether there is any crack in the plastic shell, and check whether the treatment cap, electrotherapy output line and additional connector are damaged or have any place affecting the energy output;
★ Be careful when using this instrument, handle with care, and do not pull or plug the connector rudely or savagely, so as to avoid irreversible consequences caused by improper operation;
★ Patients with implantable electronic devices, such as cardiac pacemakers, should not use this device without a doctor's advice;
★ When the high-frequency surgical equipment and the equipment are connected to a patient at the same time, burns may be caused at the electrode of the equipment or the equipment may be damaged;
★ When the equipment is used near the shortwave or microwave equipment (for example, 1m), the output of the equipment may be unstable;
★ Using electrodes close to the chest increases the risk of heart fibrillation.
● **This product has the following features:**
a) According to the type of electric shock protection, it belongs to Class II;
b) According to the degree of protection against electric shock, it belongs to the application part with BF type;
c) Classified according to the degree of protection against liquid inlet: IPX0 equipment;
d) Classified according to the degree of safety when used in the case of flammable anesthetic gas mixed with air or nitrous oxide: non-AP type, APG type equipment;
e) Classified by operation mode: continuous operation;
f) Not having a signal input portion and a signal output portion; Non-permanently installed equipment;
g) Power supply: AC 220V ± 22V, 50 Hz ± 1Hz; Input power ≤ 60VA.
● The voltage and the current of the output waveform data are alternating current, have no difference between a positive electrode and a negative electrode, and have no direct current component, so that no electrolytic reaction exists under the electrode, no acid-base product is generated, the irritation to the skin is small, and the patient can be treated for a long time.
● Characteristics of the output waveform on the human body (load impedance): human tissue is a conductor, which has the characteristics of resistance and capacitance in electricity: the resistance to low-frequency current is high, and the resistance gradually decreases with the increase of frequency. The higher the frequency is, the lower the capacitive reactance is, and the current is easier to pass through. Therefore, the medium frequency current is easier to pass through the tissue, which can reach 0.1 ~ 0.5 mA/cm ^{2}.The depth of human

tissue is also deeper. Load impedance (load resistance 500 Ω ± 1% as reference) has no effect on the pulse width and pulse repetition frequency in the output waveform data, but has effect on the maximum amplitude: change according to the relationship of I = U/R.

Guarantee conditions

- Weifang Benbu Medical Apparatus Co.,Ltd guarantees to the user that the warranty period is 12 months from the date of purchase and shipment to ensure that the new equipment has no problems in material and technology. Warranty period, the company free of charge for users to repair the failure and the replacement of damaged parts.
- This guarantee applies only to failures that occur when the equipment is operated in accordance with the conditions specified in the instructions, and the equipment guaranteed can only be used within the scope of use recommended in the instructions.
- This warranty does not cover loss or damage due to external causes such as lightning, earthquake, theft, falling, and improper use. Damage caused by reinstallation of equipment is also not covered.
- This warranty is void if the equipment is damaged as a result of accidents, improper conditions of use, or attempts to modify or replace components or assemblies.
- Surface damage that is not repaired or replaced, training materials, or supplies are not included.
- The company is not responsible for damage caused by other equipment or unauthorized connection of other equipment.
- Weifang Benbu Medical Apparatus Co.,Ltd shall not be liable for any loss, damage or injury caused by delay in service request.
- If there is any problem with the product within the Warranty period, please notify the company's after sales service department immediately, stating the model, number, date of purchase, content and nature of the problem.
- After the acceptance of the instrument, the user must fill in the "user registration form" and send it back to the after sales service department of Weifang Benbu Medical Apparatus Co.,Ltd, and keep the "warranty card" properly for recording and checking during maintenance. For the instrument without the "warranty card", the maintenance personnel has the right to refuse to provide services.

Required reading for users

Please read this manual carefully before using this therapeutic instrument. This manual tells the user the operation steps that must be paid attention to, the operations that may cause abnormalities, and the dangers that may cause injury to the therapeutic instrument or personal injury. In the event of all abnormalities and injuries resulting from operations that must be avoided as specified herein,The company does not assume responsibility for safety, reliability and performance! This company also does not give the free service to this kind of breakdown!

- Patients with implantable electronic devices, such as cardiac pacemakers, should not use this device without a doctor's advice;
- When the high-frequency surgical equipment and the equipment are connected to a patient at the same time, burns may be caused at the electrodes of the equipment or the equipment may be damaged;
- When the equipment is used near shortwave or microwave equipment (for example, 1m), the output of the equipment may be unstable;
- The use of electrodes close to the chest increases the risk of cardiac fibrillation;
- The maximum allowable output open-circuit peak value of the equipment electrode is ≤ 200V.

Instrument installation must be carried out by personnel with professional installation skills or trained by the company in instrument installation, or the company can provide installation services for users.

The operator of the instrument must be trained in safety, installation and operation skills, have skilled operation skills and strong safety awareness, and have basic knowledge of human anatomy and medicine.

- Before treating the patient, the patient must be told that during the treatment, there will be a feeling of acupuncture and numbness at the treatment site, and the stronger the feeling, the better the effect.

Patients who receive treatment for the first time, such as mental stress, will lead to a decline in physical tolerance, the choice of electrical stimulation intensity is low, is a normal phenomenon, after the patient adapts to gradually increase the intensity of treatment, the effect will be better.

Because the electrode current density of this therapeutic instrument exceeds 2ma (R. M. S)/cm^2, when using it, the intensity of electrical stimulation should be adjusted slowly from the minimum to the patient's tolerance, and the electrode current density should not be increased too fast or excessively to prevent accidents. Aft that patient has adapted to the current stimulation intensity, with the consent of the patient,The intensity of the electrical stimulation output can be adjusted appropriately.

Fasting, lack of sleep, mental stress and depression after caesarean section can affect treatment.

The treatment electrode must be fully adhered to the treatment site, otherwise the patient will have a strong needling sensation during the treatment.

- The electrodes of the two therapy probes cannot be brought together when power is applied.
- Any part of this machine is the special equipment of this therapeutic instrument, and it is not within the scope of warranty for the user to disassemble, modify and use it for other purposes.
- If the user uses the accessories not provided by our company, our company will not be responsible for any adverse consequences.
- The connecting wire of the therapeutic probe of this therapeutic instrument is a special wire. Please hold the plug and pull it out. The

therapeutic probe must be plugged and pulled out when the work is suspended.

- During treatment, the treatment electrode must be fully adhered to the treatment site. After use, please thoroughly disinfect it with medical alcohol before using it for the next patient.
- It is strictly prohibited to pull out or plug in the power plug when the instrument is not powered off; The instrument should not be turned on or off frequently. If the instrument needs to be turned on immediately after it is turned off, it should wait for at least 1 minute before turning on, so as to avoid damaging the instrument.

Transcranial magnetoelectric therapeutic apparatus (hereinafter referred to as therapeutic apparatus) is developed and produced by Weifang Benbu Medical Apparatus Co.,Ltd, which combines the valuable experience accumulated by medical staff in long-term clinical practice, and is based on modern neurobiology, neuroelectrophysiology, biophysics, magnetic biology and clinical encephalopathy therapy.The physical rehabilitation therapeutic apparatus is developed on the basis of brain physiology, brain electrophysiology, magnetic biology and clinical treatment of cerebrovascular diseases.

一、 Structural composition and performance parameters:

1. Model and structure composition

1.1 Model: WF-9903

1.2 Structure composition

The transcranial magnetoelectric therapeutic instrument consists of a main machine, a power line, a therapeutic cap, an output line and an electrode. The therapeutic cap consists of 5-9 magnetotherapeutic bodies, a connecting belt, a shell and a lead wire, wherein the therapeutic cap is divided into an Oxford belt connecting type structure and a helmet type structure, the magnetotherapeutic bodies consist of cylinders or cuboids with the diameter of 40-70mm and the height of 15-25mm, and the shell is made of ABS plastic.Disposable sanitary cap with medical device registration certificate shall be worn before treatment, and the material of the part in contact with the human body shall be medical non-woven fabric: polypropylene (PP) fiber. Electrodes are divided into main electrode (for EEG) and auxiliary electrode (for body). The electrodes are purchased products with medical device registration certificate. The material of the contact part of the electrode and the human body is sodium polyacrylate colloid).Figure 1 below is the structure diagram of WF-9903 transcranial magnetoelectric therapy instrument.

Fig. 1 Structure of the host of WF-9903 transcranial magnetoelectric therapy instrument

2. Performance parameters

2.1 Timing function

The timing setting range is 0 ~ 99 minutes, and the step increment (decrement) is set to 1 minute. The default setting value is 20 minutes when starting up, and the timing error is ≤ ± 10%.

2.2 Magnetic therapy function

2.2.1 The treatment intensity (maximum value) of magnetic therapy is divided into two levels, the weak level is 3mT ~ 15mT(up to 15mT), and the strong level is 15mT ~ 30mT(up to 30mT). The magnetic field frequency of magnetic therapy is 50 Hz ± 1Hz.

2.2.2 Safe magnetic field intensity limit in the environment The safe distance of 0.5mT (from the upper end of the magnetic therapy body) is 20mm. The output magnetic field of the instrument is distributed in a cylindrical area with a diameter of about 20mm. At a distance of about 20mm away from the magnetic therapy body, the magnetic field intensity is below 0.5mT.

2.3 Vibration function

The vibration intensity can be adjusted to four levels: off, weak, medium and strong. The peak-to-peak values of the driving voltage pulses corresponding to the four levels are 0 V, 10 V, 16 V and 27 V respectively, with an accuracy of ± 30%. The vibration frequency can be adjusted to four levels, including off, weak, medium and strong. The frequencies corresponding to the four levels are 0 Hz, 2 Hz, 5 Hz and 10 Hz respectively, with an accuracy of ± 30%.

2.4 Electrotherapy function

2.4.1 Main pole (EEG) waveform parameters

A) The output frequency of the main pole is disordered wave and cannot be set. The output amplitude (intensity

of output current) of the main pole can be set, and the display range of output intensity setting is 0 ~ 80 levels.

B) Fundamental frequency of output current

The frequency characteristic of the output current is described by the fundamental frequency, which is the frequency of a group of combined pulse currents.

The fundamental frequency of the main pole is 1: 23.81Hz, 2: 15.87Hz, 3: 15.87Hz and 4: 11.90Hz respectively, and the allowable error of the fundamental frequency is ± 30%. Pulse width of main pole 500 μS ± 30%.

2.4.2 Auxiliary electrode (limb) waveform parameters

a) The auxiliary output uses numbers 01-10 to represent different bionic current modes (prescriptions). This parameter can be adjusted in the preparation state (when there is no current output), but cannot be adjusted in the startup state (when there is current output). The display range of output intensity setting is 0 ~ 90 levels.

b) Fundamental frequency of the output current

Basic frequency of auxiliary electrode: 4000Hz ± 15%, pulse width: 80 μS ± 30%.

2.4.3 Output current parameters

Maximum peak output current at maximum intensity Ip-p:

A) When the main electrode of the therapeutic apparatus is in the standard mode, the peak value of the output current Ip-p is 40ma ± 30% when the intensity is maximum.

B) Under 01 ~ 10 mode, the peak value of output current Ip-p is 72ma ± 30% when the intensity is the maximum.

3. Normal working conditions of the therapeutic apparatus:

Working environment: temperature 5 ℃ ~ 40 ℃; Relative humidity: 10% ~ 80%;

Atmospheric pressure: 86 Kpa ~ 106 Kpa

Power supply voltage: AC voltage 220V ± 10%; Power frequency: 50Hz ± 1Hz

二、 Principle and use

2.1 Magnetic Therapy-Repetitive Transcranial Magnetic Stimulation (rTMS)

A magnetic field with certain frequency and intensity is generated during treatment; and according to the Faraday's law and the characteristic that the magnetic permeability of biological tissues is basically consistent, the magnetic field can reach intracranial tissues through a craniocerebral barrier in a non-invasive manner and generate an induced current in the brain tissues to stimulate brain cells and cerebral vascular smooth muscles to form corresponding physiological effects,0 as to achieve the purposes of regulating brain function and preventing and treating diseases. In addition, the vibration massage function of the therapeutic apparatus promotes the blood circulation of the head, thus achieving the purposes of regulating brain function, preventing and treating diseases.

2.2 Fastigial Nucleus Stimulation (FNS):

The therapeutic apparatus outputs electroencephalogram simulation bioelectric current through a main electrode (electroencephalogram), the electrodes are pasted on the epidermis of the mastoid process and other parts of the two ears, the bionic current penetrates the skull barrier outside the skull without trauma to stimulate the cerebellar fastigial nucleus area, and acts on the vasodilation center of the brain through the reticular structure of the brain stem and the striatum to dilate the cerebral vessels so as to increase the cerebral blood flow and improve the ischemic brain damage; In addition,Electrical Stimulation of FN may lower the level of Endothelin (ET), a potent vasoconstrictor, such as vasopressin, epinephrine and catecholamine, thus dilating the blood vessels, smoothing the capillaries, relieving the ischemia and hypoxia of brain tissue, alleviating the inflammatory reaction and edema, and reducing the injury of vascular endothelial cells. The synthesis and release of ET are reduced,Thereby significantly reducing the plasma ET level.

2.3 Somatic Neuromuscular Electrical Stimulation (NMES)

The auxiliary electrode of that therapeutic apparatus output (body) ten different bionic currents to stimulate body neuromuscular tissue, help patients to carry out body functional exercise, prevent neuromuscular atrophy, and facilitate the reconstruction of nerve pathways and functional recovery.

Description: The main electrode (EEG) output, auxiliary electrode (body) output, magnetic therapy output and vibration and other functional units of this series of therapeutic apparatus can be controlled independently. Can be use in combination or singly according to treatment requirement.

三、 Scope of application

The electrotherapy part is used for the auxiliary treatment of the functional recovery of patients with apoplexy and paralysis.

The magnetic therapy part is applicable to the auxiliary treatment of ischemic cerebrovascular diseases, neurasthenia and brain injury diseases.

Treatment site: The main pole (EEG) treatment site of the electrotherapy part is at the mastoid, Fengchi or temple behind the ears on both sides, and the auxiliary pole (body) treatment site of the electrotherapy part is at the motor nerve point or Ashi point of the muscle tissue. The treatment part of the magnetic therapy function and the vibration function of the magnetic therapy part is the head of a human body. The electrotherapy part and the magnetotherapy part can be used simultaneously,Can also be used alone.

IV. △ıtraindications:

☆ **Contraindications:**

(1) It is contraindicated in the acute phase of intracranial hemorrhagic disease.
(2) It is contraindicated in patients with bleeding tendency.
(3) Acute suppurative inflammation and intracranial infection are contraindicated.
(4) It is contraindicated in patients with local malignant tumors and intracranial tumors;
(5) It is forbidden for local metal implants and intracranial metal foreign bodies;
(6) It is forbidden in the heart area and the lower abdomen of pregnant women;
(7) It is forbidden for patients with obvious adverse reactions to magnetic therapy and electrotherapy;
(8) It is forbidden for the extremely weak;
(9) It is contraindicated in patients with severe heart, liver, lung and kidney failure;
(10) It is forbidden for patients with pacemaker and other electronic implantable devices.

☆ **People with caution:**

(1) Pregnant women;
(2) Open wound;
(3) Low white blood cells.

V. Precautions:

5.1 Be familiar with this manual before starting the operation.
5.2 The equipment must be used under the guidance of doctors and operated by full-time personnel.
5.3 The electrotherapy part should be used with caution in elderly and physically weak patients.
5.4 Patients under 10 years old should pay attention to monitoring when using.
5.5 The electrode must be in full and even contact with the skin, otherwise there is a risk of burns.
5.6 The two electrodes shall not be placed in the front, back, left and right of the heart projection area at the same time, and the current shall not flow through the heart by any electrode placement method.
5.7 If there is any discomfort during use, the treatment should be stopped immediately.
5.8 After each use, the part of the electrode in contact with people shall be cleaned and disinfected.
5.9 The electrodes shall be purchased products with medical device registration certificate and within the validity period. Clean the skin with normal saline or alcohol cotton swab before sticking the electrode, and fix the electrode with elastic bandage if necessary to ensure good contact between the electrode and the skin.
5.10 △ ɔre replacing the fuse, first cut off the power supply, unscrew the fuse holder (located behind the electrical stimulator) counterclockwise with a screwdriver, and then put in the fuse of the corresponding model and specification and tighten it. The model of the fuse is F1AL 250V. The model and specification of the fuse in the fuse holder must be consistent with the model and specification marked below the fuse holder, otherwise the instrument cannot work normally.
5.11 △ ıould be avoided that the high-frequency surgical equipment and the transcranial magnetoelectric therapy instrument are connected to a patient at the same time. The simultaneous use of the two devices may cause burns at the electrodes and damage the equipment.
5.12 The therapeutic apparatus shall not be used near (for example, 1m) the equipment emitting electromagnetic interference (such as short wave, microwave, radio frequency and other high-frequency equipment), so as to prevent the i△ ence of interference and unstable output.
5.13 Treatment with electrodes applied to the area of the heart near the chest increases the risk of fibrillation.

5.14 The maximum output current of the electrode of the therapeutic apparatus can reach 82mA (taking the load resistance of 500Ω as the reference).
When using, first configure and install the electrode according to the requirements of 5.5, and then gradually increase the output current of the electrode according to the patient's feelings. Do not increase the output current quickly, so as not to cause discomfort to the patient.
5.15 In order to protect the environment, the instrument shall be valid for 5 years, and the medical devices and accessories shall be disposed of in accordance with national laws and regulations and environmental protection requirements.

VI. Product Instructions

(I) Open the packaging box

Before opening the packaging box, first check whether the box is intact (if it is damaged, please take photos for evidence), open the instrument packaging box, take out the instrument and instructions, open the accessories box to take out the treatment cap and other accessories, please be sure to keep the packaging box and accessories box and its lining for after-sales standby.

(II) Connection of therapeutic apparatus (as shown in Figure 2)

1. **Insert the plug of the treatment cap into the magnetic therapy socket of the therapeutic apparatus (insert the plug upward). When pulling out the plug of the treatment cap, be sure to hold the pull buckle (the gray part of the plug) with your hand and pull it out to avoid damaging the plug.**
2. Insert the electrotherapy output cable plug into the electrotherapy socket of the therapeutic apparatus (insert the plug upward).
3. Insert the 8 prefix of the power cord into the power input socket of the generator.

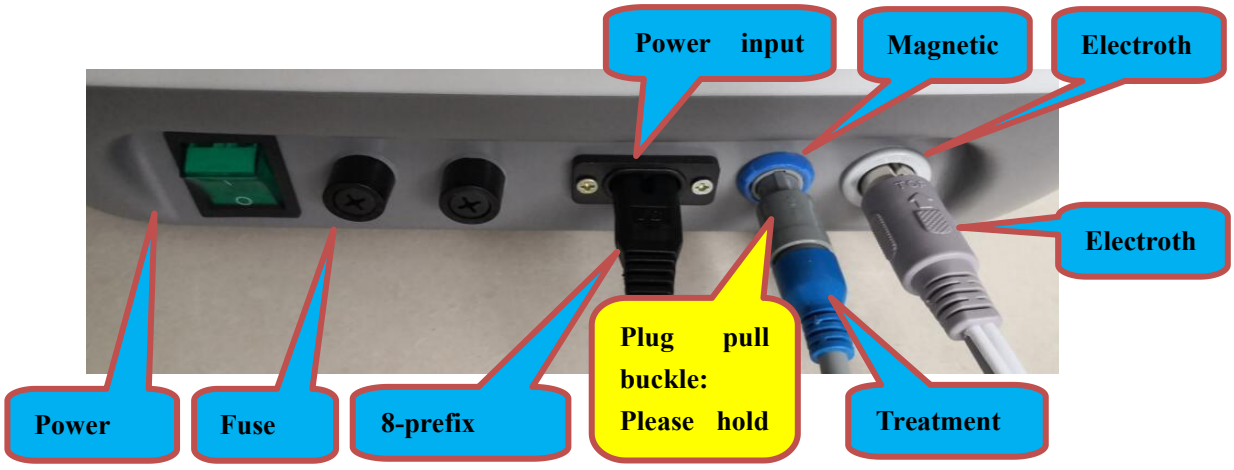


Figure 2: Schematic diagram of input and output connection of therapeutic apparatus

(III) No-load operation process of the instrument

Turn on the power supply, turn on the green power switch at the back of the therapeutic instrument, and the color screen interface will be lit up. The interface is divided into two areas: magnetic therapy and electrotherapy, as shown in Figure 3.

FIG. 3: Schematic of panel display.

Description of function keys

A) "Start/Stop" button-work can be started in standby state, and work can be stopped in working state.

B) "Set" button-various functions can be selected and set circularly.

C) "+" key-add the corresponding parameter.

D) Press the "-" key to reduce the corresponding parameter.

★ Magnetic therapy function no-load operation process:

1. There are four circle touch keys under the corresponding magnetic therapy area, which correspond to the "Start/Stop" key, the "+" key, the "-" key and the "Set" key.

2. Before starting the magnetic therapy, set the magnetic therapy time: press "+,-" to set the treatment time (the time setting range is 0 ~ 99 minutes, and the default treatment time is 20 minutes).

3. Press the "Start/Stop" key to start the magnetic therapy.

4. Press the "Set" key to cyclically select the three functions of "magnetic therapy intensity, vibration intensity and vibration frequency", and then press the "+,-" keys to set the intensity of the corresponding functions.

5. In the working state, if the treatment time is up or the treatment work is stopped by pressing the "Start/Stop" key, the instrument will return to the default state of startup.

★ No-load operation process of electrotherapy function:

1. There are also the same four circle touch keys under the corresponding electrotherapy area, which correspond to the "Start/Stop" key, the "+" key, the "-" key and the "Set" key.

2. Before starting electrotherapy, press the "Set" key to select the "treatment time and treatment prescription", and then press the "+,-" keys to set the corresponding treatment time and treatment prescription (the time setting range is 0 ~ 99 minutes, and the default treatment time is 20 minutes; There are 10 kinds of treatment prescriptions, and the default is prescription 1).

3. Press the "Start/Stop" key to start the electrotherapy.

4. Press the "Set" key to cyclically select the two functions of "EEG intensity and body intensity", and then press the "+,-" keys to set the intensity of the corresponding functions. The EEG intensity can be adjusted from 0 to 80, and the body intensity can

be adjusted from 0 to 90.

5. In the working state, if the treatment time is up or the treatment work is stopped by pressing the "Start/Stop" key, the instrument will return to the default state of startup.

(4) Treatment process

★ Magnetic therapy function treatment process

1. **Wear treatment cap:**

Before wearing the treatment cap, the patient should first wear a disposable sanitary cap (as shown in Figure 4) to prevent cross-infection and ensure the cleanliness and hygiene of the treatment cap. Then, connect the connecting plug of the therapeutic cap with the magnetic therapy output socket on the shell of the therapeutic instrument. The method for wear that helmet-type therapeutic cap comprises the follow steps of: adjusting a knob of the therapeutic cap to loosen and enlarge the therapeutic cap;Can be easily worn on the head of a patient, and then the upper knob, the left knob and the right knob of the treatment cap are adjusted to achieve the best treatment wearing state of being close to the head and having no sense of pressure, and special attention is paid to not exerting too much force when rotating the knob to avoid damaging the knob.

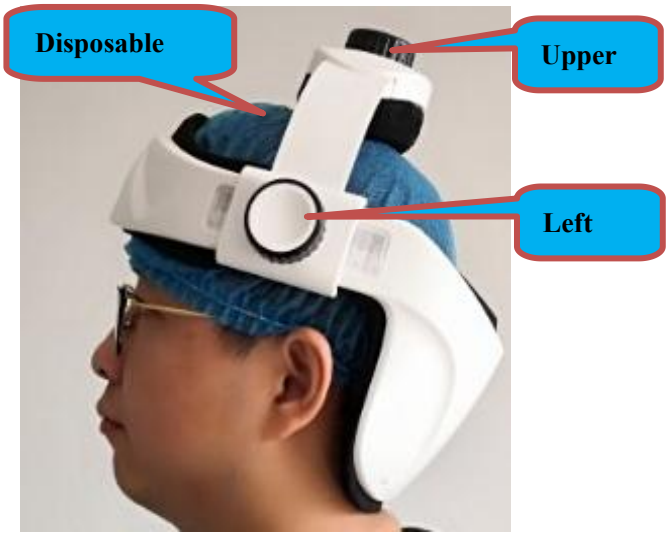


Figure 4: Wear disposable sanitary cap and treatment cap

2. Magnetic therapy process:

Start the operation according to the "magnetic therapy function no-load operation process", → set the treatment time of magnetic therapy → start the work → set the intensity of magnetic therapy → set vibration intensity → set frequency intensity → time to the end of treatment.

The function of magnetic therapy should be used under the guidance of doctors. The recommended treatment parameters are as follows: the weak level of magnetic therapy (3mT-15mT) is used when the condition is mild, and the strong level of magnetic therapy (15mT-30mT) is used when the condition is serious. Treatment time: 20 ~ 30 minutes/time,

1 ~ 2 times a day; Course of treatment: 10 days as a course of treatment, for chronic diseases, it is recommended to stop using for 3 to 5 days after the end of a course of treatment before the next course of treatment.

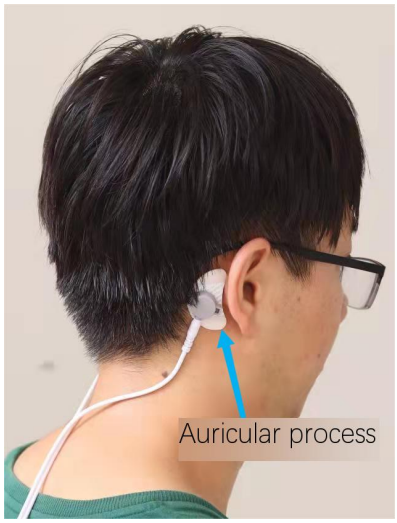
The above treatment time and course of treatment are for reference only. The doctor determines the treatment time and course of treatment according to the patient's condition. Possible side effects: In the course of treatment, if the patient is sensitive to magnetic field, dizziness, vomiting and other magnetic phenomena may occur, the treatment should be stopped immediately.

★ Treatment process of electrotherapy function

1. Preparation before electrotherapy

1) an electrotherapy output wire is connected with an electrode plate;

An electroencephalogram electrotherapy output line is a pair of white line, a connector of that electroencephalogram electrotherapy output line is in a movable snap type and is correspondingly connected with a pair of crescent-shaped snap electrode plate, and the movable snap is pinched by fingers and then clamped into the crescent-shaped snap; The body electrotherapy output wire is a pair of gray wires, the connector thereof is of a pin type and is correspondingly connected with a pair of square electrode plates, and the pin is inserted into the Jack of the square electrode plate; As shown in fig. 5.



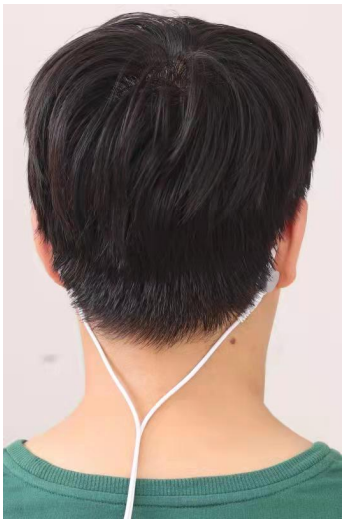


Figure 5: Schematic diagram of the connection between the electrotherapy wire and the electrode sheet Figure 6: Schematic diagram of the paste position of the EEG electrode sheet

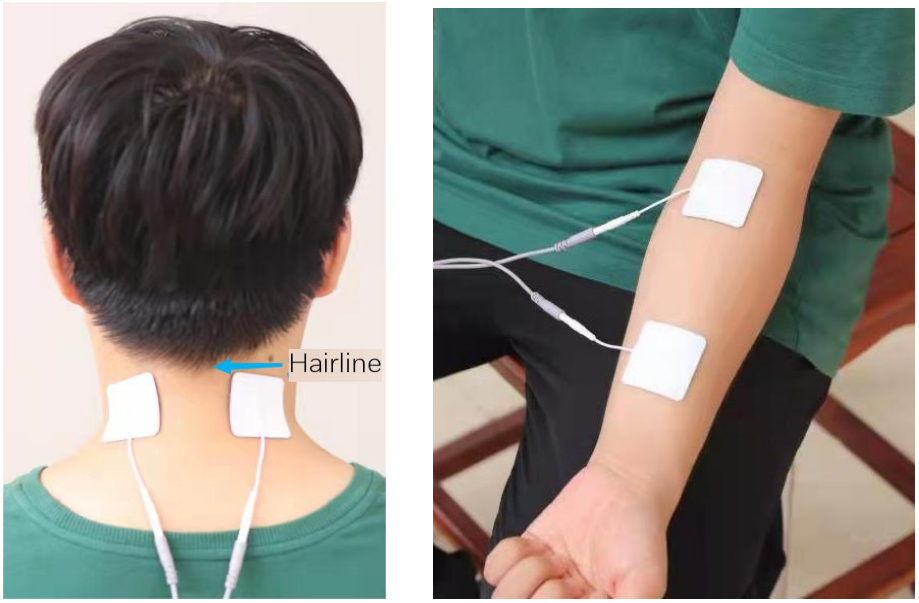


Figure 7: Schematic diagram of body electrode paste position

2) Pasting of electrode plates → [The electrode plates must be connected in pairs to form a loop]

Clean the treatment site with normal saline or alcohol cotton ball before pasting the electrode, and then paste the electrode after the saline or alcohol is dried.

Electrode pasting and placement position: Electrocephalotherapy (main electrode therapy) electrodes are generally pasted on mastoid points, Fengchi points or temples behind the ears on both sides, and body electrotherapy (auxiliary electrode therapy) electrodes are generally pasted on motor nerve points or Ashi points of muscle tissues. For details, see Figure 6-8: Electrode pasting and placement position diagram.

The electrode shall be firmly attached to the skin and fixed with a bandage if necessary. According to different treatment needs, electroencephalogram (EEG) or somatic electrotherapy can be used alone or in combination with primary and secondary electrodes. It is strictly forbidden to use EEG for body therapy and auxiliary electrode for head therapy, otherwise the therapeutic effect will be affected.

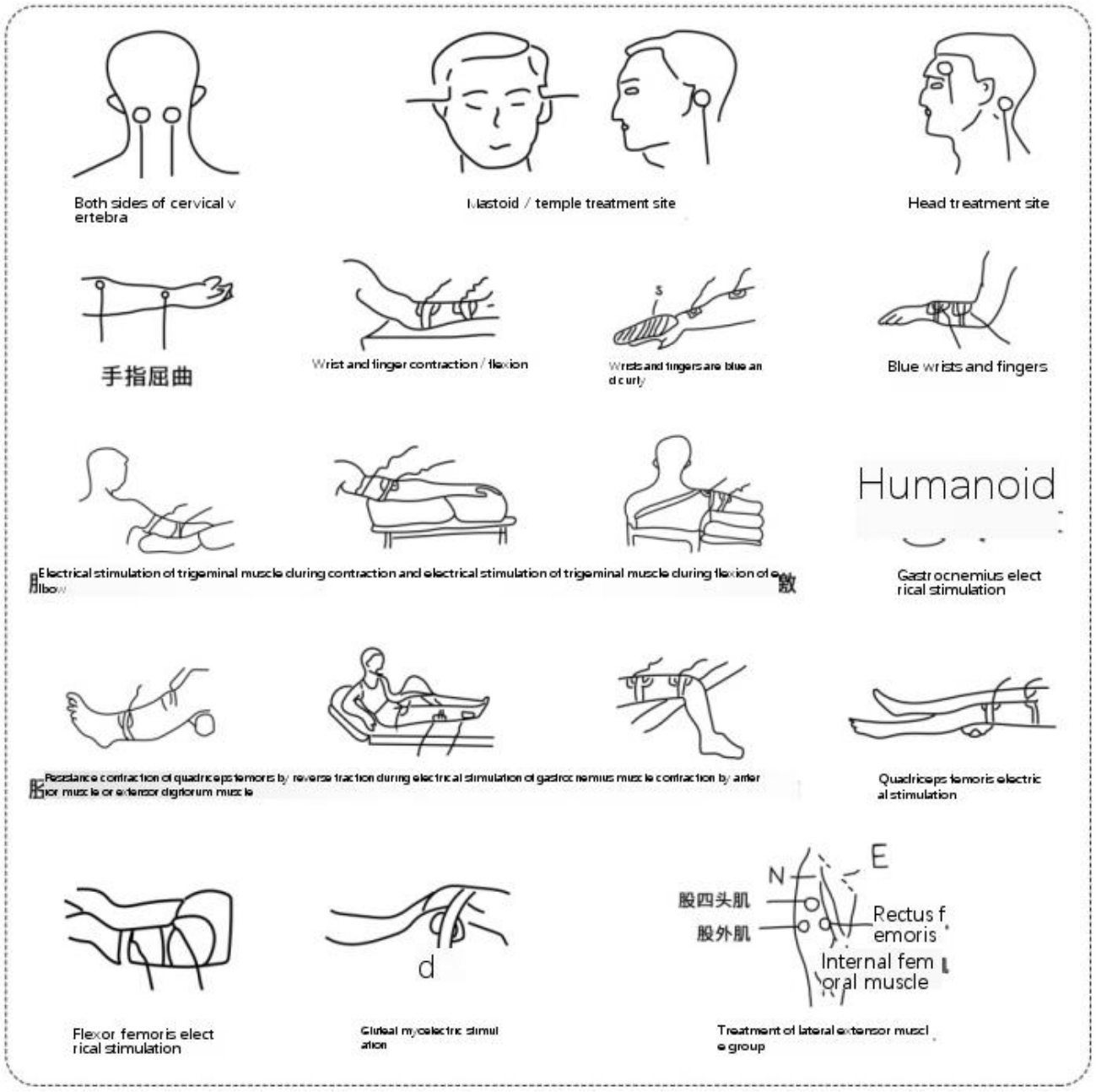


Figure 8: Electrode Pasting and Placement Position Diagram

2. Electrotherapy process:

Start the operation according to the "electrotherapy function no-load operation process", → set the treatment time and treatment prescription of electrotherapy → start the work → set the brain electrotherapy intensity → set the body electrotherapy intensity → time to the end of treatment.

The intensity of EEG (main pole) electrotherapy can be set between 0 and 80. The higher the intensity is, the stronger the patient's sense of electrical stimulation

is. Due to individual differences, each person's perception and endurance of stimulation intensity are not the same. In the treatment, the setting of the main intensity is usually based on the patient's self-perception, and gradually adjusted from weak to high.The setting of the specific intensity can be adjusted according to the actual clinical situation. The general principle of EEG (main pole) intensity setting is: under the premise that the patient can bear, the stronger the stimulation, the better the therapeutic effect.

The intensity of somatic (auxiliary electrode) electrotherapy can be set between 0 and 90, and the higher the intensity is, the stronger the stimulation of patients is. Because of individual difference, each person has different feeling and endurance to that stimulation intensity, dure treatment, the setting of the intensity is usually based on the self-feeling of the patient, and the intensity setting is also gradually adjust from weak to high to the stimulation current that the patient can bear,For patients with sensory dysfunction or inability to express feelings, the adjustment is based on the micromotion of the patient's body as seen by the naked eye (pause for 5 seconds every 2 values to observe whether the patient's body has micromotion). The general principle of setting the intensity of somatic (auxiliary pole) electrotherapy is that the stronger the stimulation, the better the therapeutic effect on the premise that the patient can bear it.

The default prescription of body electrotherapy startup is 1. Indications corresponding to 10 prescriptions:

★ Prescription 01: a pulse current is generated in about 1 second. For mild denervation and muscle weakness. It is more suitable for the treatment of flaccid paralysis.

★ Prescription 02: For the treatment of mild denervation and myasthenia.

★ Prescription 03: For treatment of mild or moderate denervation.

★ Prescription 04: For treatment of moderate denervation.

★ Prescription 05: For the treatment of severe denervation.

★ Prescription 06: It is used for the treatment of severe or extremely severe denervation and high muscle tension (for patients with high muscle tension, low treatment intensity is appropriate at the initial stage of treatment).

★ Prescription 07: There is a strong electrical stimulation in each pulse cycle, which has the same indications as prescription 03, and is used alternately with prescription 03 in the middle and late stages of treatment.

★ Prescription 08: There is a strong electrical stimulation in each pulse cycle, which has the same indications

as prescription 04, and is used alternately with prescription 04 in the middle and late stages of treatment.

★ Prescription 09: There is a strong electrical stimulation in each pulse cycle, which has the same indications as prescription 05, and is used alternately with prescription 05 in the middle and late stages of treatment.

★ Prescription 10: There is a strong electrical stimulation in each pulse cycle, which has the same indications as Prescription 06, and is used alternately with Prescription 06 in the middle and late stages of treatment.

The indications corresponding to the above prescriptions are for reference only, and doctors can choose according to the patient's condition.

Electrotherapy function should be used under the guidance of a doctor, treatment time: 20 ~ 30 minutes/time, 1 ~ 2 times a day; Course of treatment: 10 days as a course of treatment, for chronic diseases, it is recommended to stop using for 3 to 5 days after the end of a course of treatment before the next course of treatment.

The above treatment time and course of treatment are for reference only, and the doctor determines the treatment time and course of treatment according to the patient's condition.

Note: The intensity of the main and auxiliary electrodes can be set only in the startup state. The intensity of the treatment can be adjusted and set according to the comfort of the patient. Small current is used for the first treatment.
The intensity adjustment should be based on the patient's endurance, and the patient should be communicated when the intensity is increased! If the patient can't bear it in the process of increasing the intensity, the intensity can be slightly reduced by several levels, and then strengthened after the patient adapts to it. Try to increase it to the maximum intensity that the patient can bear within 3 minutes. The strength of the instrument design generally does not cause harm to the patient, It should be repeatedly emphasized to patients that the greater the intensity, the better the curative effect. Possible side effects: In the course of treatment, if people who are sensitive to electrotherapy may have dizziness, vomiting, physical discomfort and other phenomena, the treatment should be stopped immediately.

3. End of treatment:

When the countdown of the treatment time returns to zero, the treatment process stops, the host automatically returns to the initial default state, press the power switch to shut down, first remove the paste electrode, then remove the electrotherapy output line and the treatment cap, and the treatment is over.

VII. List of Instruments and Accessories

Serial number	Name	Unit	Quantity	Remark
1	Host	Taiwan	1	
2	Power cord	Root	1	Wearing parts

3	Electrotherapy output line	Group	1	Wearing parts
4	Treatment cap	Set	1	Wearing parts
5	Electrode piece	Piece	10--20	Disposable materials
7	Instructions for use	Ben	1	Including qualification certificate and warranty card
8	Fuse	A	2	
9	Certificate of conformity	Zhang	1	

All replacement parts and accessories and consumables used for maintenance are the original (original) parts of the manufacturer or approved by the manufacturer.

VIII. Instrument cleaning and maintenance

9.1 The instrument shall be placed in a cool, dry place without dust, acid, alkali and steam, and the surface of the instrument shall be kept clean. Use in a well-ventilated room without corrosive gas.

9.2 The instrument shall be protected against high temperature and oxidation. It is not allowed to place the instrument at a temperature ≥ 60 ° C, or under the probe of hyperthermia and microwave instruments, or under high temperature and direct sunlight. The instrument shall be protected against vibration, collision and falling.

9.3 The power cord must be plugged into the power socket of the host to the end, so as to prevent the host from operating inefficiently due to poor contact of the power supply, or even burning out the fusible core.

9.4 It is strictly prohibited to pull the output line by gravity, which may cause damage to the output line and connector.

9.5 If the therapeutic apparatus is not used for a period of time, please clean and maintain it. At the same time, remove the output line and treatment cap, seal them with plastic bags, and put them into cartons for proper storage. When the therapeutic apparatus is not in use, it is required to use a dust cover to cover it. If it is not used for a long time, it should be turned on once every 3-5 days. It should be cleaned and maintained at least once a month. The surface can be cleaned by gently wiping with a damp cloth. The parts to be cleaned and disinfected are the shell of the therapeutic apparatus, the therapeutic cap and all the touchable parts. The cleaning and disinfection process is as follows: use a clean soft cloth to wipe or use a dry wet towel to wipe or use an alcohol cotton with a concentration of 70% to wipe. Do not use volatile oil, diluent, gasoline and other organic solvents and other corrosive

liquids to clean the product.The frequency of cleaning and disinfection is once per working week. It is required that the product must be cleaned under the condition of power off. The product can be used only after it is completely dried in a ventilated place. The dust cover must be covered after shutdown every day.

9.6 Before starting the machine, pay attention to check whether the line is connected correctly and whether it is loose. It is recommended to plug and unplug it again, and then power it on again to prevent the line from being loose or oxidized. If it cannot be started, please contact the company's after sales service department.

9.7 The instrument shall be valid for 5 years, and shall be disposed of according to the corresponding national laws and regulations of medical devices and the requirements of environmental protection when it is scrapped.

9.8 It is recommended to use the electrode of our company. In order to prevent cross infection, the electrode after use shall be scrapped and shall not be discarded at will. It shall be disposed according to the requirements of environmental protection of the accessory waste of medical devices and the corresponding national laws and regulations.

9.9 The company promises that for the user who requires to provide the circuit schematic diagram and the list of components, once the user has the qualified technical personnel trained by the company and assumes the corresponding confidentiality obligations, he can provide the circuit schematic diagram of the designated maintenance parts, the list of components or other necessary information to help the user repair.

IX. Common Simple Faults and Troubleshooting

Fault symptom	Cause of failure	Exclusion method and description
No display after power on	The fuse is blown	To replace the fuse, first cut off the power supply, unscrew the fuse holder counterclockwise with a screwdriver, and then put in the fuse of the corresponding model and specification and tighten it. Fuse type: F1AL 250V
	Power supply failure	Check whether the power supply is connected. For example, the power socket is loose, and the power cord is not plugged in reliably. Re-tighten the plug to ensure that the power connection is reliable.
	Grid supply voltage too high	If the fuse is burned again after replacement, check whether the network power supply voltage is too high. If the mains voltage is greater than 242 V and continues to operate, it is normal for the fuse to burn out. At this time, it can be used when the power supply voltage is stabilized between 220V ± 10%, or an AC voltage stabilizer can be purchased.
	Machine failure	If there is still no indication after the above faults are eliminated, it shall be regarded as the fault of the main engine and shall be reported for repair.
No current output	The output line is broken	The four core pins in the output line connector shall be connected to the four holders respectively. Remove the output line and use the resistance gear of the multimeter to check whether it is connected. If it is not connected or the resistance is greater than 1 Ω, it shall be regarded as abnormal. Solution: Repair or replace the output line.
	Machine failure	If there is no fault in the output line after inspection and there is still

		no output, it shall be regarded as the fault of the main engine and shall be reported for repair.
The button is faulty	Short circuit fault	Troubleshooting method: Sometimes the button is stuck and cannot be reset normally. You can try to press the button repeatedly until it bounces back. If the button does not bounce back after repeated pressing, report for repair.
	Open circuit fault	The phenomenon is that the indicator light or digital display parameter cannot be moved, and the button needs to be replaced.
Current output fault	Current output is too strong or too weak	When the patient complains that the output current is too strong or too weak, the first thing to judge is whether it is a sensory problem or an instrument problem. The instrument adopts the bionic current electrical stimulation technology, one of its characteristics is that it can better avoid the pain threshold point of the patient, and send a proper amount of current into the intracranial, the output current intensity changes in time, which is the fluctuation simulation of bioelectricity, and has its own electrotherapeutic effect. This kind of strong and weak feeling is related to the pattern, frequency and intensity. In addition, the patient's sensory dysfunction will also complain about the change and difference of the stimulus sensation. The above points should be correctly distinguished from whether the machine is faulty or not. The first judgment method is to distinguish through the use of normal people. The second judgment method is to adjust the mode, frequency and intensity to improve the above situation. If the sensory problem is ruled out by the above two judgment methods and similar phenomena continue to occur, it should be suspected that there is an instrument failure that needs to be reported for repair or professional inspection.

Fault symptom	Cause of failure		Exclusion method and description
Current output fault	Asymmetric current output on both sides	The user feels abnormal	When the two sides of the patient's output current are obviously asymmetric, that is, one side is strong and the other side is weak, it should also be judged whether it is a sensory problem or an instrument problem. For example, when the lesion occurs on one side, the side may suffer from dysesthesia, which may cause sensory asymmetry. The first judgment method is to exchange the paired grippers. If the same situation occurs, it should be regarded as a sensory problem. After a period of stimulation, the situation will be improved. The second judgment method is to distinguish by normal people's use. If the sensory problem is ruled out by the above two judgment methods and similar phenomena still occur, it should be regarded as instrument failure and need to be reported for repair.
		Poor contact between the electrode and the skin or poor conductivity of the electrode	1、 Use electrodes with medical registration. Treat the skin before sticking the electrode (wipe the skin with alcohol cotton ball). 2、 Replace with a new electrode and stick it tightly, and fix it with a bandage.
		Instrument failure	If similar phenomena still occur after excluding the causes of the patient's skin sensory disturbance and electrode, it should be regarded as an instrument failure and should be reported for repair.
Treatment cap does not work, no vibration			Check whether the treatment cap is connected to the host and whether the connecting wire is broken.
Other faults			In addition to the above faults, other phenomena that can not work normally should be reported for repair in time.

Users are not allowed to disassemble and repair the machine without authorization. Once the machine breaks down, please eliminate it according to the following table. If it cannot be eliminated, please report for repair in time.

X. Notice to Users

1. The user must read the manual carefully, which will be of great help to the correct use of the machine.

2. After receiving the machine, the user should check the machine carefully, fill in the acceptance form and send it back to our company for filing.

3. Each machine has a warranty with a unique product number. Please keep it properly. When the machine breaks down, please attach the warranty sheet for random repair. If the product number of the machine is inconsistent

with the product number of the warranty sheet, and the request for free maintenance within the warranty period, our company has the right to refuse.

XI. Transportation and Storage

1. The packaged therapeutic apparatus shall be protected from heavy pressure, strong shock, rain and snow during transportation, and shall not be mixed with corrosive substances.

2. The generator shall be transported and stored in the following environment:

Temperature range: -20 ~ +55, relative humidity: not more than 85%, atmospheric pressure range: 86Kpa ~ 106Kpa.

3. The therapeutic apparatus should be stored in a dry and well-ventilated room without corrosive gas.

Appendix

Electromagnetic compatibility hints of transcranial magnetoelectric therapy instrument

CAUTION: Use of accessories, transducers, and cables other than those specified may result in increased emissions or reduced immunity from the TECT instrument, except for transducers and cables sold as internal components by the instrument manufacturer.

Relevant EMC safety reference standards and relevant instructions:

The transcranial magnetotherapeutic instrument shall be implemented in accordance with the national standards YY0505-2012 Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility Requirements and Tests and YY0607-2007 Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators, and the following items shall be observed:

1、 The transcranial magnetoelectric therapy instrument shall be installed and used according to the electromagnetic compatibility information provided in the accompanying documents;

2、 Portable and mobile RF communication devices may affect the use of transcranial magnetoelectric therapy;

3、 Except for the cables sold by the manufacturer of the equipment as spare parts for internal components, the use of accessories and cables other than those specified may result in a reduction in the immunity of the equipment or system;

4、 The equipment shall not be used close to or stacked with other equipment. If it must be used close to or stacked with other equipment, it shall be observed and verified that it can operate normally under the configuration used.

5、 Requirements for cables and other accessories

The transcranial magnetoelectric therapy instrument contains treatment cap accessories and power line cables. When these cables are used with the transcranial magnetoelectric therapy instrument, they meet the requirements of 36.201 and 36.202 in YY0505-2012. The manufacturer and model of the therapeutic output line shall comply with the requirements of the above standard.

6. Functions identified as basic performance

Magnetic therapy function: the treatment intensity is divided into two levels, the weak level is 3mT-15mT, and the strong level is 15mT-30mT; Magnetic field frequency 50Hz ± 1Hz. Vibration function: the vibration intensity can be adjusted to four levels, including off, weak, medium and strong. The peak-to-peak values of the driving voltage pulses corresponding to the four levels are 0 V, 10 V, 16 V and 27 V respectively. The vibration frequency can be adjusted to four levels, namely off, weak, medium and strong, and the frequencies corresponding to the four levels are 0 Hz, 2 Hz, 5 Hz and 10 Hz respectively.

Electrotherapy function: basic frequency of main pole (intensity of main pole: level 80, load 500Ω); Basic frequency 1: 23.81Hz, basic frequency 2: 15.87Hz, basic frequency 3: 15.87Hz and basic frequency 4: 11.90Hz

respectively, and the pulse width of the main pole is 500μS ± 30%. Basic frequency of auxiliary electrode: 4000Hz ± 15%, pulse width: 80 μS ± 30%.

Guideline and Manufacturer's Statement-Electromagnetic Emission-for all equipment and systems

	Guideline and Manufacturer's Declaration-Electromagnetic Emission		
	The transcranial magnetoelectric therapy instrument shall be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment		
	Launch test	Compliance	Electromagnetic environment-a guide
	Radio-frequency emission GB 4824	Group 1	Transcranial magnetoelectric therapy instruments use radiofrequency energy only for their internal functions. As a result, its RF emissions are low, and it has little chance of interfering with nearby electronic equipment
	Radio-frequency emission GB 4824	Category A	The transcranial magnetoelectric therapy apparatus is suitable for use in all facilities that are not in the home and that are not directly connected to the public low-voltage power supply network of the home.
	Harmonic Emission GB 17625.1	Not applicable	
	Voltage fluctuation/flicker emission GB 17625.2	Not applicable	

(Corresponding to Table 201 in YY 0505-2012)

Guideline and Manufacturer's Declaration-Electromagnetic Immunity-for all equipment and systems

Guidance and manufacturer's declaration-Electromagnetic immunity			
The transcranial magnetoelectric therapy apparatus is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment			
Immunity test	**IEC 60601 Test Level**	**Coincidence level**	**Electromagnetic Environment-Guide**
Electrostatic discharge GB/T 17626.2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors shall be wood, concrete, or tile, and if covered with synthetic materials, the relative humidity shall be at least 30 percent
Electrical Fast Transient Burst GB/T 17626.4	± 2 kV to power line ± 1 kV pair input/output links	± 2 kV to power line Not applicable	The mains supply shall be of the quality typically used in a commercial or hospital environment

Surge GB/T 17626.5	± 1 kV wire-to-wire ± 2 kV line to ground	± 1 kV wire-to-wire Not applicable	The mains supply shall be of the quality typically used in a commercial or hospital environment
Voltage dips, short interruptions and voltage variations on the power supply input lines GB/T 17626.11	< 5% UT for 0.5 cycles (> 95% dip on UT) 40% UT for 5 cycles (60% dip on UT) 70% UT for 25 cycles (30% dip on UT) < 5% UT for 5S (> 95% dip on UT)	< 5% UT for 0.5 cycles (> 95% dip on UT) 40% UT for 5 cycles (60% dip on UT) 70% UT for 25 cycles (30% dip on UT) < 5% UT for 5S (> 95% dip on UT)	The mains supply shall be of the quality typically used in a commercial or hospital environment. If the user of the transcranial magnetoelectric therapy device requires continuous operation during power interruptions, it is recommended that the transcranial magnetoelectric therapy device be powered by an uninterruptible power supply or a battery
Power frequency magnetic field (50Hz) GB/T 17626.8	3 A/m	3 A/m	Power frequency magnetic field shall be characterized by power frequency magnetic field levels typical of a typical location in a commercial or hospital environment
Note: UT refers to the AC network voltage before the test voltage is applied.			

(Corresponding to Table 202 in YY 0505-2012)

Guidance and Manufacturer's Declaration-Electromagnetic Immunity-for Non-Life Support Equipment and Systems

Guidance and manufacturer's declaration-Electromagnetic immunity			
The transcranial magnetoelectric therapy apparatus is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment			
Immunity test	IEC 60601 Test Level	Coincidence level	Electromagnetic Environment-Guide
RF conduction	3 Vrms	3 Vrms	Portable and transportable RF communication devices should not be used closer to any part of the transcranial magnetoelectric therapy apparatus than the recommended

GB/T 17626.6 RF conduction GB/T 17626.3	150kHz~80MHz 1V/m、10V/m 26 MHz~1GHz 3V/m 80 MHz~2.5GHz	 1V/m、10V/m 3V/m	isolation distance, including cables. This distance shall be calculated by the formula corresponding to the frequency of the transmitter. Recommended Isolation Distance $d=1.2\sqrt{p}$ $d=1.2\sqrt{p}$ 80 MHz~800MHz $d=2.3\sqrt{p}$ 800 MHz~2.5GHz Where: P refers to the maximum rated output power of the transmitter provided by the design manufacturer, and the unit is Watt (W). D — — Recommended rated distance, in meter (m) The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field, which should be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Note 1: At the frequency points of 80 MHz and 800 MHz, the formula for the higher frequency band is used. Note 2 These guidelines may not be appropriate in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and the human body.			
A. The field strength of fixed transmitters such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radio, am and FM radio broadcasts, and television broadcasts is not theoretically accurately predictable. In order to assess the electromagnetic environment of a fixed RF transmitter, a survey of the electromagnetic field shall be considered. If the field strength measured at the location of the TECT instrument is higher than the RF coincidence level used above, the TECT instrument shall be observed to verify its proper operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting and repositioning the transcranial magnetoelectric apparatus. B The field strength shall be lower than 1V/m and 10V/m in the whole frequency range of 26 MHz ~ 1GHz. The field strength shall be less than 3 V/m over the entire frequency range from 150 kHz to 80 MHz.			

(Corresponding to Table 204 in YY 0505-2012)

Recommended separation distances between portable and mobile radio frequency communication equipment and

equipment or systems

-Non-life support equipment and systems

Recommended separation distance between portable and mobile RF communication devices and transcranial magnetoelectric therapy apparatus			
Transcranial magnetoelectric therapy apparatus is intended for use in an electromagnetic environment with controlled radio frequency radiation disturbance. Base on that maximum rated output pow of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between the portable RF communication device (transmit) and the transcranial magnetoelectric instrument as recommended below.			
Maximum rated output power of the transmitter W	Isolation distance corresponding to different frequencies of the transmitter/m		
	150kHz~80MHz $d=[3.5/3]\sqrt{P}$	80 MHz~800MHz $d=[3.5/3]\sqrt{P}$	800 MHz~2.5GHz $d=[7/3]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.24**
0.1	**0.37**	**0.37**	**0.74**
1	**1.2**	**1.2**	**2.4**
10	**3.7**	**3.7**	**7.4**
100	**12**	**12**	**24**
For the maximum rated output power of the transmitter not listed above, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W). Note 1: At the frequency points of 80 MHz and 800 MHz, the formula for the higher frequency range is used. Note 2 These guidelines may not be appropriate in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and the human body.			

(Corresponding to Table 206 in YY 0505-2012)