
Repetitive transcranial magnetic stimulation instrument

Instructions for use

WF-9902



Please read this manual carefully before use.

Table of contents

| | |
|---|----|
| Preface -- | 2 |
| I. Structural composition and performance parameters -- | 4 |
| II. Principle and use -- | 5 |
| III. Scope of Application -- | 5 |
| IV. Contraindications | 6 |
| V. Precautions -- | 6 |
| VI. Product instructions -- | 6 |
| VII. List of Instrument Accessories -- | 12 |
| VIII. Instrument maintenance -- | 12 |
| IX. Common Simple Faults and Troubleshooting Methods -- | 13 |
| X. Notice to Users -- | 13 |
| XI. Transportation and Storage -- | 13 |
| XII. Appendix -- | 14 |

Foreword

Notice to users

- Thank you for purchasing the products of our company. In order to ensure safe operation and 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.

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| "Warning" is used to indicate that serious personal injury, death, or actual property damage will result if it is |
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| "Caution" is used to indicate that it will produce minor personal injury or actual property damage if ignored. |
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| "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. |
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Safety signs

The International Electrotechnical Commission (IEC) has established a set of regulations for the special safety classification and marking of medical electrical equipment. The specific classification and marking are shown below:

Marking of equipment 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.

"I" and "O" on the power switch respectively indicate "on" and "off" of the power supply.



Place upward, av



isture, handl



care, storage an



portation temperature limit

General safety information

The safety of the operator and the patient and the reliability of the equipment shall be taken into consideration during the design and manufacture of the products of the company, and the following safety precautions must be implemented:

- 1、 equipment is operated by or under the direction of qualified operators.
- 2、 This product is designated as Class II, Type BF in accordance with IEC60601-1 (Standard for Safety of Medical Devices). 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.
Do not change the equipment parameters 3、. If it is really necessary, you can ask Weifang Benbu Medical Equipment Technology Co., Ltd. or its authorized agent to provide services.
- 4、 equipment is factory adjusted for optimum performance. Do not adjust any preset controls or switches except as specified in the instructions.
- 5、, if the instrument is used less, it should be powered up at least once a week, and the power-up time should 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 operates with a voltage between 100-240V. For areas with unstable power supply, it is recommended that users be equipped with AC stabilized power supply.
- 7、 This equipment is packed in cartons with soft materials inside. Please handle the instrument with care. When the instrument is not used for a long time, it should be put into the original packaging box and stored properly. The storage should meet the requirements of "storage environment". The stacking layers of the equipment are 2

layers.

8、 that if the equipment fails, please handle it according to the instructions in the manual. If the failure still cannot be eliminated, please contact Weifang Benbu Medical Equipment Technology Co., Ltd. or its authorized agent.

9、 If you need to connect electronic or mechanical devices of other companies , please contact Weifang Benbu Medical Equipment Technology Co., Ltd. or its authorized agent before connection.

10、 operation, storage and transportation environment

● Avoid severe vibration under standard operating conditions, and maintain the following temperature, humidity and atmospheric pressure ranges:

Ambient temperature: 5 °C — 40 °C, relative humidity: ≤ 85%, atmospheric pressure: 86 kPa — 106 kPa — optimal temperature, relative humidity range: 17 °C — 23 °C 40 — 60%

● Range of temperature, humidity and atmospheric pressure during storage and transportation:

— — Temperature: -20 °C — + 55 °C — — 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 disease treatment, there is a certain amount of electromagnetic radiation in the use process. Therefore, in order to prevent interference with other equipment in use or interference from other equipment to the therapeutic instrument, the therapeutic instrument should be far away from monitoring products and high-frequency, high-voltage, radioactive equipment. 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 treated as waste medical waste after one use, and how to deal with 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 the plastic shell has cracks, and check whether the treatment cap, the electrotherapy output line and the additional connector are damaged or have places affecting the energy output;

★ When using this instrument, you should be careful and handle it with care. It is forbidden to pull and plug the connector rudely and brutally, 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 100-240V/50-60 HZ; 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 acting on the human body (load impedance): the human body tissue is a conductive body, 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 $0.1 \sim 0.5 \text{ mA/cm}^2$, and the depth of the human tissue is deeper. Load impedance (load resistance $500 \Omega \pm 1\%$ 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 Device Technology Co., Ltd. guarantees to the user that the warranty period is 12 months from the date of purchase and shipment, and guarantees that the new equipment has no problems in material and technology. During the warranty period, the company will provide users with free fault repair and 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 parts 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 Device Technology 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 inform the after-sales service department of the company 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 Instrument Technology Co., Ltd., and keep the "Warranty Card" properly for recording and inspection during maintenance. For the instrument without the "Warranty Card", the maintenance personnel have 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 case of all abnormal phenomena and injuries caused by operations that must be avoided as specified in this document, the company will 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 $\leq 200\text{V}$.

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 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 $2\text{mA (R. M. S)}/\text{cm}^2$, when using it, when adjusting the intensity of electrical stimulation, it 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. When the patient has adapted to the current stimulation intensity, the intensity of the electrical stimulation output can be adjusted appropriately with the consent of the patient.

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.
- Do not pull out or plug in the power plug of the instrument when the power is not turned 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 be turned on at least 1 minute later to avoid damaging the instrument.

Transcranial magnetolectric therapeutic instrument (hereinafter referred to as therapeutic instrument) is developed and produced by Weifang Benbu Medical Instrument Technology 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

Model of 1.1: WF-9902

1.2 structure composition

The transcranial magnetolectric therapeutic instrument consists of a main machine, a power line, a therapeutic cap, an output line and an electrode. The therapeutic cap consists of six 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, each magnetotherapeutic body consists of a cylinder or a cuboid with the diameter of 40-70mm and the height of 15-25mm, the shell is made of ABS plastic, The material of the part in contact with the human body is medical non-woven fabric: polypropylene (PP) fiber. The electrode is divided into two types: limb electrode and EEG electrode. The electrode is a purchased product with medical device registration certificate. The material of the electrode in contact with the human body is sodium polyacrylate (colloid). Figure 1 below shows the structure of the desktop WF-9902 transcranial magnetolectric therapy instrument.

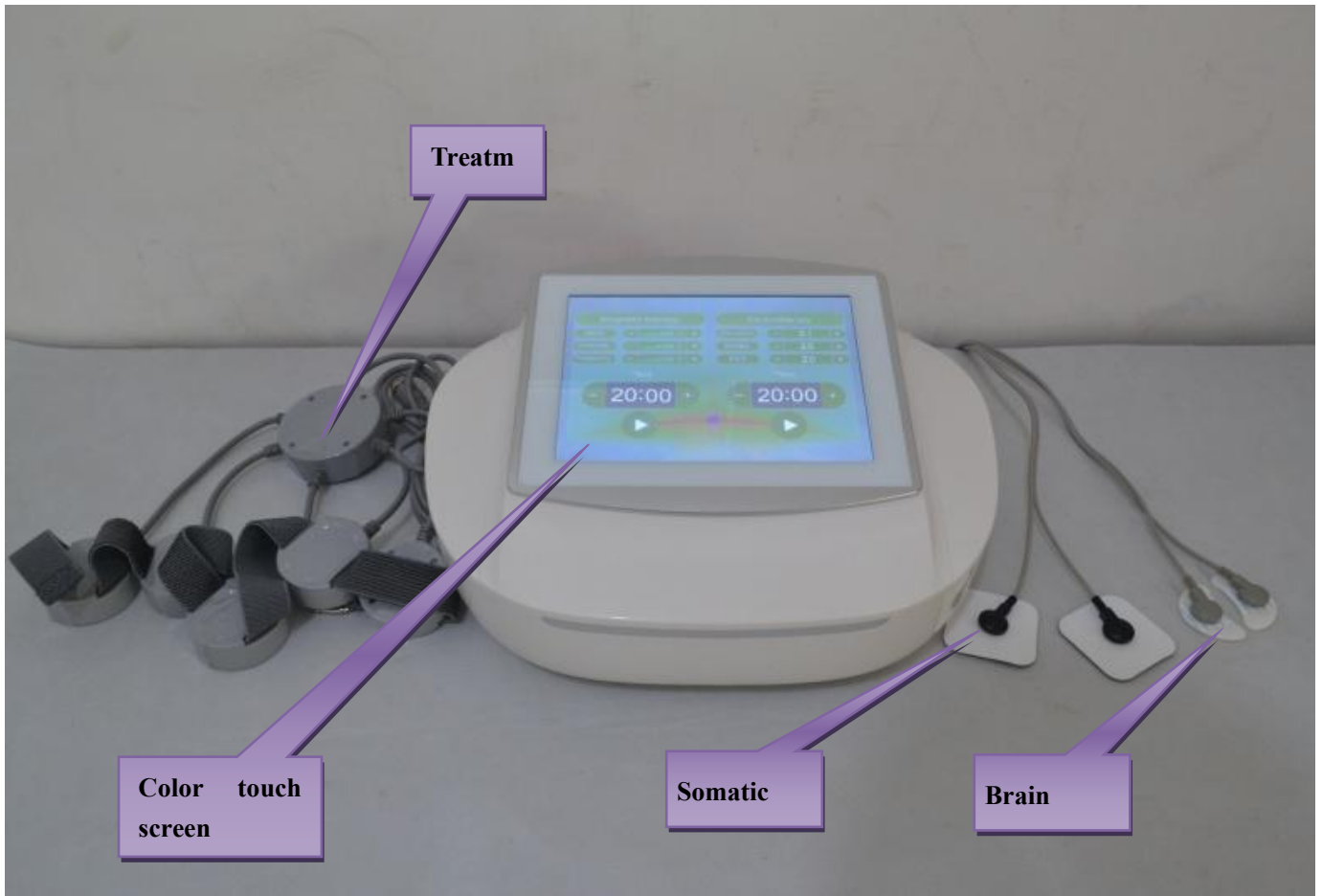


Fig. 1 Structure of WF-9902 Transcranial Magneto-electrotherapy Instrument

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 $\leq \pm 10\%$.

2.2 magnetic therapy function

The treatment intensity (maximum) of 2.2.1 magnetic therapy is divided into two levels, weak level 3mT ~ 15mT (up to 15mT), strong level 15mT ~ 30mT (up to 30mT), magnetic field frequency of magnetic therapy: 50Hz \pm 1Hz. The safe distance (from the upper end of the magnetotherapeutic body) of the 环境中安全磁场强度限值 0.5 mT of the 2.2.2 is 20 mm. The output magnetic field of the instrument is distributed in a cylindrical area with a diameter of about 20 mm. At a distance of about 20 mm from the magnetotherapeutic body, the intensity of the magnetic field is below 0.5 mT.

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 $\pm 30\%$. 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, with an accuracy of $\pm 30\%$.

2.4 electrotherapy function

2.4.1 Limb (NMES) Waveform Parameter

a) The limb output indicates different bionic current modes (prescriptions) with numbers 01-10. 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.

b) Fundamental frequency of the output current

Limb fundamental frequency: 4000Hz \pm 15%, pulse width: 80 μ S \pm 30%.

2.4.2 EEG (FNS) waveform parameter

The EEG output frequency of the a) is disordered wave and cannot be set. EEG output amplitude (intensity of output current) can be set, and the display range of output intensity setting is 0 ~ 80 levels.

B) the fundamental frequency of the 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 basic frequency of EEG was 1: 23.81 Hz, 2: 15.87Hz, 3: 15.87Hz, 4: 11.90Hz, and the allowable error of basic frequency was \pm 30%. Pulse width of main pole 500 μ S \pm 30%.

2.4.3 output current parameter

Maximum peak output current at maximum intensity I_{p-p} :

a) The peak value of output current I_{p-p} is 72ma \pm 30% when the intensity of the limbs of the therapeutic apparatus is the maximum in 01 ~ 10 modes.

In the standard mode of B), the peak value of the output current I_{p-p} is 40 ma \pm 30%.

3. Normal working conditions of the therapeutic apparatus:

Working environment: temperature 5 $^{\circ}$ C ~ 40 $^{\circ}$ C; Relative humidity: 10% ~ 80%;

Atmospheric pressure: 86 Kpa ~ 106 Kpa

Supply voltage: AC voltage 100-240 V; Power frequency: 50-60HZ

二、 Principle and use

Magnetic therapy of 2.1: repetitive transcranial magnetic stimulation (rTMS)

A magnetic field with a certain frequency and intensity is generated during treatment; and according to 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, thereby achieving the purposes of regulating the brain function and preventing and treating diseases.

2.2 Somatic Neuromuscular Electrical Stimulation (NMES)

The therapeutic apparatus body outputs ten different kinds of bionic currents to stimulate somatic neuromuscular tissues, help patients to carry out somatic functional exercises, prevent neuromuscular atrophy, and facilitate the reconstruction of nerve pathways and functional recovery.

2.3 fastigial nucleus stimulation (FNS):

The therapeutic apparatus outputs an electroencephalogram simulation bioelectric current through the electroencephalogram, and the electroencephalogram simulation bioelectric current passes through the electrodes pasted on the epidermis of the parts such as the mastoid processes on the sides of the two ears and the like, 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, so that the cerebral vessels are dilated, the cerebral blood flow is increased, and the On The other hand, electrical stimulation of FN can reduce the plasma Endothelin (ET), which is a polypeptide substance with strong vasoconstrictive effect, such as vasopressin, epinephrine and catecholamine, so as to dilate blood vessels and smooth capillaries, alleviate brain ischemia and hypoxia, reduce inflammatory reaction and edema, and reduce the injury of vascular endothelial cells. The synthesis and release of ET were reduced, and the plasma ET level was significantly decreased.

Description: The functional units such as body output, EEG output, magnetotherapy output and vibration of this series of therapeutic apparatus can be controlled independently. Can be use in combination or singly according to that 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 body treatment site of the electrotherapy part is at the motor nerve point or Ashi point of the muscle tissue, and the EEG treatment site of the electrotherapy part is at the mastoid, Fengchi or temple behind the ears on both sides. The treatment part of the magnetic therapy function and the vibration function of the magnetic therapy part is the head of the human body. The electrotherapy part and the magnetotherapy part can be used simultaneously or independently.

IV. ⚠ Contraindications:

☆ **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:

The 5.1 must be familiar with this manual before starting the operation.

5.2 equipment must be used under the guidance of doctors and operated by full-time personnel.

5.3 that elderly and weak patients should be cautious in using the electrotherapy part.

5.4 should be monitored when used in patients under 10 years of age.

The 5.5 electrode must be in full and even contact with the skin, otherwise there is a risk of burns.

5.6, the two electrodes can not be placed in the front and back, left and right of the heart projection area at the same time, and the current can not flow through the heart by any electrode placement method.

If there is any discomfort during the use of 5.7, the treatment should be stopped immediately.

After each use of the 5.8, the contact part between the electrode and the person should be cleaned and disinfected.

The 5.9 electrode shall be purchased products with medical device registration certificate, and shall be 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.

Before replacing the fuse 5.10, cut off the power supply first, 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 FIAL 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.

The 5.11 should avoid using the high-frequency surgical equipment and the transcranial magnetolectric instrument connected to a patient at the same time, because the simultaneous use of the two equipment may cause burns at the electrodes and may 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 influence of interference and unstable output.

Application of 5.13 treatment electrode to that heart area near the chest increase the risk of cardiac fibrillation.

The maximum output current of the electrode of the 5.14 therapy instrument can reach 82ma (taking a load resistance of 500Ω as a reference).

When in use, the electrode is firstly configured and installed according to the requirements of the 5.5, and then the output current of the electrode is gradually increased according to the feeling of the patient, and the output current cannot be rapidly increased, so as not to cause discomfort to the patient.

5.15 In order to protect the environment, the instrument is valid for 5 years, and the waste of medical equipment and accessories should be disposed according to the national laws and regulations and the requirements of environmental protection.

VI. Product Instructions

(I) Open the packing box

Before opening the packing box, first check whether the box is intact (if it is damaged, please take a photo), open the instrument packing 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 packing box, 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 therapeutic cap into the magnetic therapy socket of the therapeutic instrument (insert the plug downward) and then tighten the nut. When pulling out the plug of the therapeutic cap, be sure to unscrew the nut first and then 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 downward).
3. Insert the pin end of the power cord into the power input socket of the therapeutic apparatus.

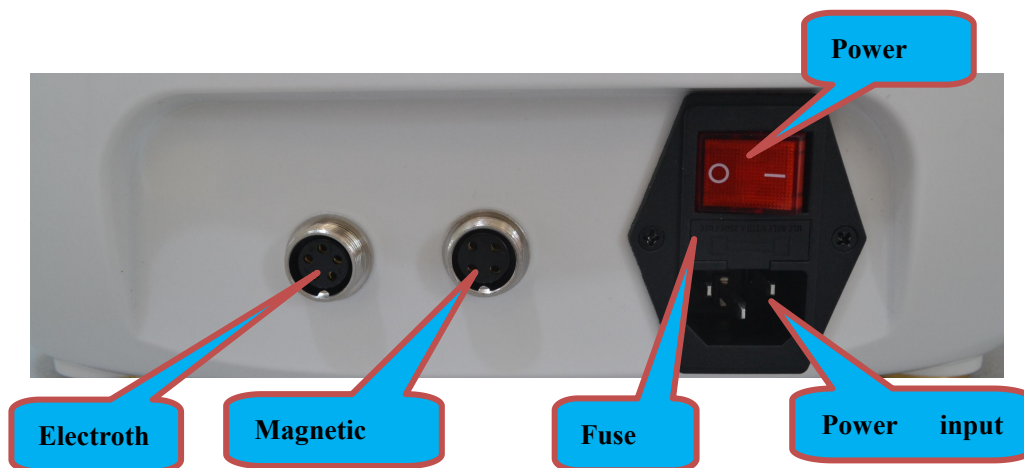


Figure 2: Schematic diagram of input and output connection of therapeutic apparatus

(III) No-load operation process of the instrument

Switch on the power supply, turn on the red power switch at the back of the

therapeutic instrument, and the color screen interface will light up. The interface is divided into two areas: magnetic therapy and electrotherapy, as shown in Figure 3.

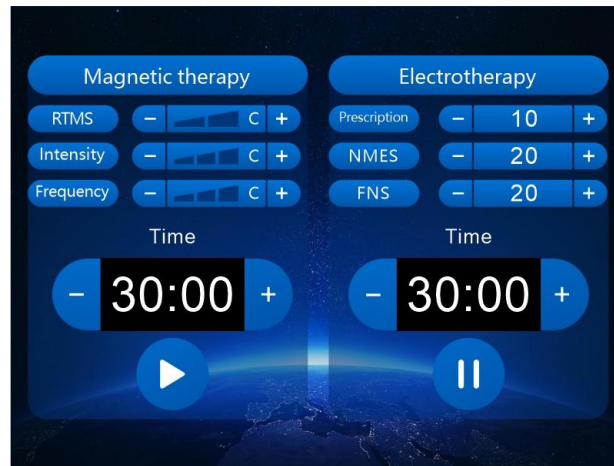


FIG. 3: Schematic of panel display.

Description of function keys

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

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

Press the "-" key in the c) to reduce the corresponding parameters.

★ Magnetic therapy function no-load operation process:

1. The "-" key, the "+" key and the "start/stop" key correspond to the lower part of the corresponding magnetic therapy area respectively.
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 "-", "+" key to set the intensity of the corresponding function.
4. Press the "Start/Stop" key to start the magnetic therapy.

★ No-load operation process of electrotherapy function:

1. The lower part of the corresponding electrotherapy area respectively corresponds to the "-" key, the "+" key and the "start/stop" key.
2. Before starting electrotherapy, press the "+,-" keys for "Treatment Time and Treatment Prescription" to set the corresponding treatment time and treatment prescription (the time setting range is: 0 ~ 99 minutes, the default treatment time is 20 minutes when starting up; there are 10 kinds of treatment prescriptions, the default is prescription 1 when starting up).
3. Press the "+,-" keys to set the intensity of the corresponding functions for the two functions of "body intensity and EEG intensity". The body intensity can be adjusted from 0 to 90, and the EEG intensity can be adjusted from 0 to 80.
4. Press the "Start/Stop" key to start the electrotherapy.

(4) Treatment process

★ Magnetic therapy function treatment process

1. Wear treatment cap:

Wear the treatment cap (shown in Figure 4)

-
1. Wear the treatment cap according to the front and back direction of the treatment cap.
 2. Adjust the position of the treatment body in the treatment cap:
 - A. The frontal lobe treatment head is slightly above the glabella.
 - B. Haoye treatment head is in front of and above both ears:
 - C. The occipital lobe treatment head is slightly behind the two ears;And d, that treatment head of the Baihui acupoint is right above the top of the head;
 3. aft that treatment cap is used, an alcohol cotton ball is use for scrubbing and disinfecting the inner side of the treatment body.



Figure 4: Wearing the 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 → set the magnetic therapy intensity → set the vibration intensity → set the frequency intensity → start the work → time to the end of the treatment.

The function of magnetic therapy should be used under the guidance of a doctor. The recommended treatment parameters are as follows: the weak level of magnetic therapy (3mT-15mT) should be used when the patient's condition is mild, and the strong level of magnetic therapy (15mT-30mT) should be used when the patient's condition is severe. The treatment time is 20-30 minutes per time, 1-2 times per 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 the 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;

The electrotherapy output line is a pair of gray buttons, the connector of which is a snap-button type and is correspondingly connected with a pair of crescent-shaped snap-button electrode plates, and the snap-button type is pinched by fingers and then clamped on the crescent-shaped snap-button; As shown in fig. 5.

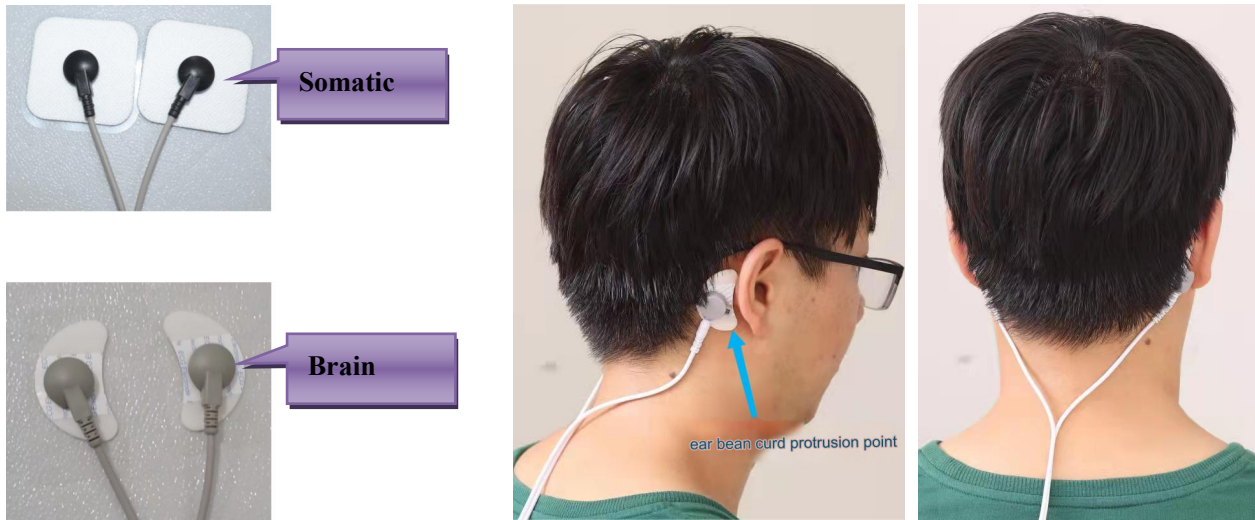


Figure 5: Schematic diagram of the connection between the electrotherapy wire and the electrode sheet Figure 6: Schematic diagram of the paste position of the EEG electrode sheet

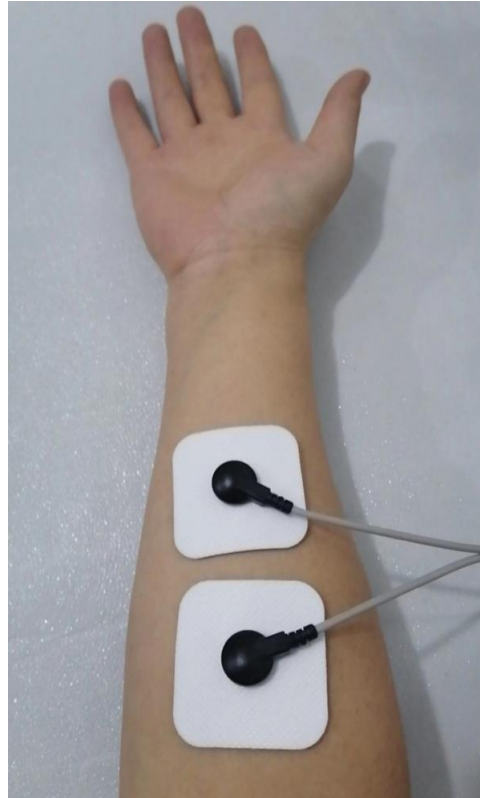


Figure 7: Schematic diagram of body electrode paste position

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: EEG electrotherapy electrodes are generally pasted on mastoid points, Fengchi points or temples behind the ears on both sides, and body electrotherapy electrodes are generally pasted on motor nerve points or Ashi points of muscle tissues. For details, see Fig. 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 needs of treatment, electroencephalogram (EEG) or somatic electrotherapy can be used alone or combined with two electrodes. It is strictly forbidden to use EEG for body therapy and body for head therapy, otherwise the therapeutic effect will be affected.

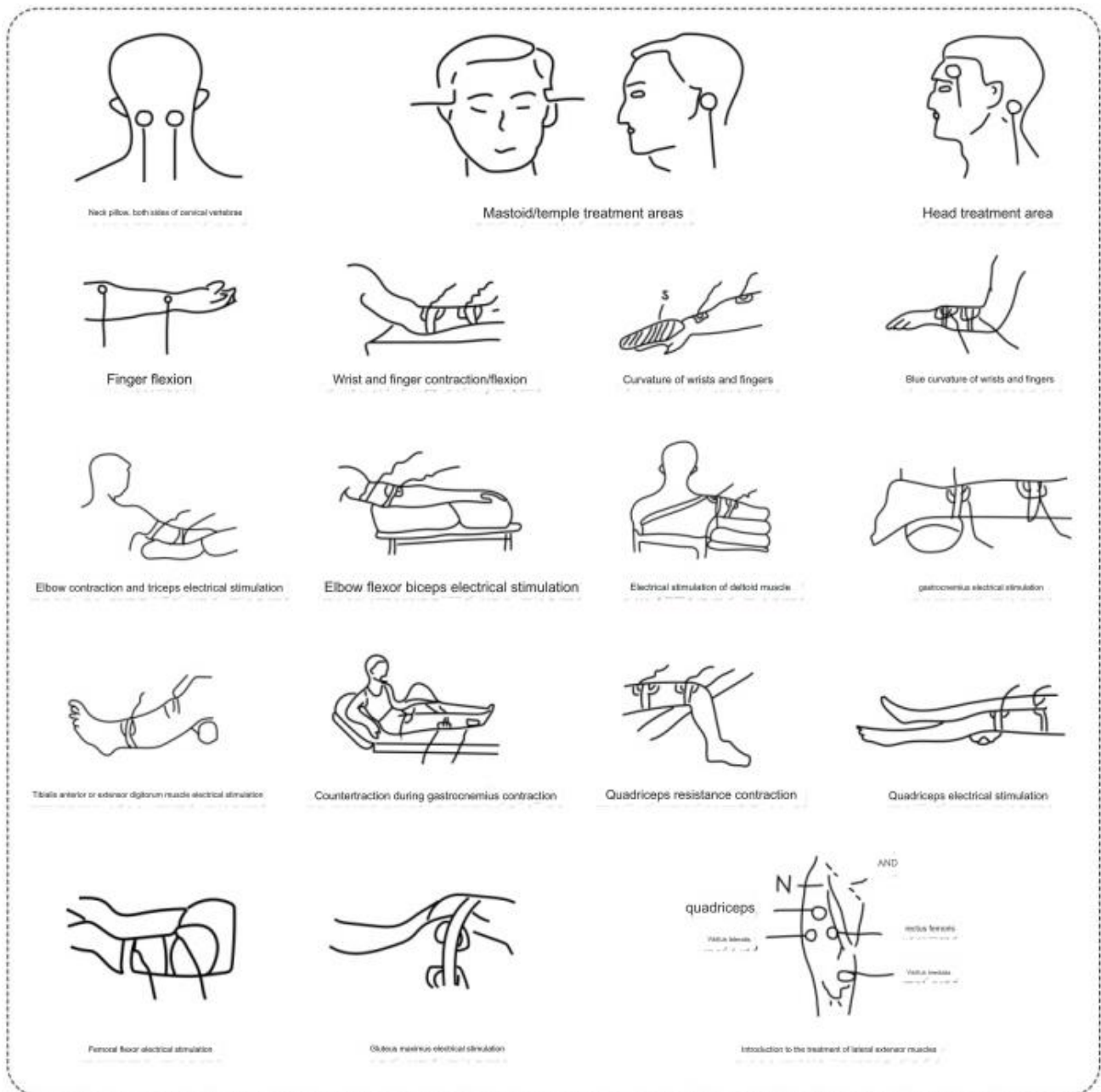


Figure 8: Electrode Pasting and Placement Position Diagram

2. Electrotherapy process:

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

The intensity of somatic electrotherapy can be set between 0 and 90, and the higher the intensity is, the stronger the stimulation of the patient is. Because of individual

difference, each person has different feeling and endurance to that stimulation intensity, during the treatment, the setting of the intensity is usually based on the self-feeling of the patient, and the intensity setting is also gradually adjusted 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 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 the indication corresponding to 1, 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.

The intensity of electroencephalogram therapy can be set between 0 and 80, and 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 intensity setting is that the stronger the stimulation, the better the therapeutic effect on the premise that the patient can bear it.

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 body and EEG intensity can be set only in the startup state, and the intensity of treatment can be adjusted and set according to the comfort of the patient. Small current should be 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, and the intensity can be increased to the maximum intensity that the patient can bear within 3 minutes. The intensity of instrument design generally does not cause harm to patients, and 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:

The countdown of the treatment time returns to zero, the treatment process stops, the host automatically returns to the initial default state, the power switch is pressed to shut down, the pasted electrode is removed first, then the electrotherapy output line and the treatment cap are removed, and the treatment is finished.

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 |
|---|-----------------|-------|--------|----------------------|

⚠ 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 instruments should be placed in a cool, dry place without dust, acid, alkali and steam, and the surface of the instruments should be kept clean. Use in a well-ventilated room without corrosive gas.

The 9.2 instrument shall be protected against high temperature and oxidation. The instrument shall not be placed in a place where the temperature is $\geq 60^{\circ} \text{C}$, or in the probe of hyperthermia and microwave instruments, or under high temperature and direct sunlight. The instrument shall be protected against vibration, collision and falling.

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

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

If the 9.5 therapeutic apparatus is not used for a period of time, please clean and maintain it. At the same time, remove the output line and therapeutic cap, seal them with plastic bags, and put them into cartons for safe storage. When the therapeutic apparatus is not used, 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 wiping it gently with a damp cloth. The parts to be cleaned and disinfected are the shell of the therapeutic apparatus, the therapeutic cap and all accessible parts. The cleaning and disinfection process is to use a clean soft cloth to wipe or a dry wet towel to wipe or 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.

Before starting the 9.6, pay attention to check whether the circuit 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 circuit from being loose or oxidized. If it cannot

be started, please contact the after-sales service department of the company.

The 9.7 instrument shall be valid for 5 years, and shall be disposed of in accordance with the corresponding national laws and regulations and the requirements of environmental protection when it is scrapped.

9.8 suggest using our electrodes. In order to prevent cross infection, the used electrodes should be discarded. They should not be discarded randomly. They should be disposed according to the requirements of environmental protection of the corresponding national laws and regulations.

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, you can wait for the power supply voltage to stabilize between 100-240V/50-60HZ, or purchase an AC voltage regulator. |
| | 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 the button springs 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. The strong and weak sense is related to the mode, frequency and intensity. In addition, patients with sensory dysfunction will also complain about changes and differences in stimulation 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 result in 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 a similar phenomenon still occurs after excluding the patient's skin sensory disturbance and electrode plate, it should be regarded as an instrument failure and need to 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 above table. If it cannot be eliminated, please report for repair in time.

X. Notice to Users

1. Users must read the instructions carefully, which will be helpful for the correct use of the machine.
2. After the user receives the machine, check the machine carefully.

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 therapeutic apparatus shall be transported and stored in the following environment:
Temperature range: $-20 \sim +55$, relative humidity: not more than 85%, atmospheric pressure range: $86\text{Kpa} \sim 106\text{Kpa}$.
3. The therapeutic apparatus should be stored in a dry and well-ventilated room without corrosive gas.

Appendix

Electromagnetic compatibility hints of transcranial magnetolectric 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 magnetolectric therapy 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 shall comply with the following items:

- 1、 The transcranial magnetolectric therapy instrument shall be installed and used according to the electromagnetic compatibility information provided in the accompanying documents;
- 2、 Portable and mobile radio frequency communication devices may affect the use of transcranial magnetolectric 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 lead to 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 magnetolectric therapy instrument contains a treatment cap accessory and a power line cable. When these cables are used with the transcranial magnetolectric therapy instrument, they meet the requirements of the 36.201 和 36.202 in YY0505-2012. The manufacturer and model of the therapeutic output line shall comply with the requirements of the above standard.

Functions identified by the 6、 as essential 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 \pm 1Hz. Vibration function: the vibration intensity can be adjusted to four levels, namely 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: body fundamental frequency: 4000Hz \pm 15%, pulse width: 80 μ S \pm 30%. EEG fundamental frequency (EEG intensity: 80, load 500 Ω): fundamental frequency 1: 23.81 Hz, fundamental frequency 2: 15.87Hz, fundamental frequency 3: 15.87Hz, fundamental frequency 4: 11.90Hz, pulse width of EEG 500 μ S \pm 30%.

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

| Guidance and Manufacturer's Declaration-Electromagnetic Emissions | | | |
|---|----------------|--|--|
| The transcranial magnetolectric 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 magnetolectric 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 magnetolectric 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 | |
| Harmonic Emission GB 17625.1. | Not applicable | | |
| Voltage | Not applicable | | |

| | | |
|---|--|-----------------------------------|
| fluctuation/flicker emission GB 17625.2 | | power supply network of the home. |
|---|--|-----------------------------------|

(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 instrument 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. Uninterruptible power supply or battery power is recommended for TECT if the user requires continuous operation during a power outage |
| 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 instrument 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 GB/T 17626.6 | 3 Vrms 150kHz~80MHz 1V/m、10V/m | 3 Vrms 1V/m、10V/m | <p>Portable and transportable RF communication devices should not be used closer to any part of the transcranial magnetoelectric therapy apparatus than the recommended isolation distance, including cables. This distance shall be calculated by the formula corresponding to the frequency of the transmitter.</p> <p>Recommended Isolation Distance</p> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800\text{MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5\text{GHz}$ <p>Where:</p> <p>P refers to the maximum rated output power of the transmitter provided by the design manufacturer, and the unit is Watt (W).</p> <p>D — Recommended rated distance, in meter (m)</p> <p>The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field, which should be lower than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> <div style="text-align: center;">  </div> |
| RF conduction GB/T 17626.3 | 3V/m 80 MHz~2.5GHz | 3V/m | |

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 applicable 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 magnetolectric 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 magnetolectric therapy apparatus | | | |
|--|--|---------------------------------------|--------------------------------------|
| Transcranial magnetolectric therapy apparatus is intended for use in an electromagnetic environment with controlled radio frequency radiation disturbance. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between the portable RF communication device (transmitter) and the transcranial magnetolectric 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 applicable 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)