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TAFC Warm-electrode

Intermediate Frequency Electrotherapy Apparatus

Operation Manual

Beijing Yaoyangkangda Medical Equipment Co., Ltd.

Strongly recommend to use the apparatus under instructions of doctors

Please Read this Manual Carefully before Using

⚠ Caution

* Please read the following chapters in this manual carefully:

2 Applicable scope

3 Contraindication

8 Note

* This apparatus is Class I device, protective grounding wire outlet should be supplied to ensure electrical safety.

* This apparatus is the application unit of BF type, its output end should be isolated from the ground. Patients should be strictly forbidden to touch any metal item in operation.

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1 Overview

1.1 TAFC warm-electrode intermediate-frequency electrotherapy apparatus is a physical treatment equipment which combines the sinusoidal wave intermediate-frequency electrotherapy method with the heat therapy method and its has two circuits of output. , the apparatus is able to perform therapy on two patients or two positions of one patient. Heat and current may be simultaneously generated from the output warm-electrode, thus therapy may be performed with both heat and electricity. Since there is both intermediate-frequency content and low-frequency content in the output current waves, the apparatus combines the therapy effects of both intermediate frequency and low frequency.

1.2 The apparatus has the following features:

a) The therapy electrode temperature adopts intelligent fuzzy temperature control technology, the apparatus can be first preheated before starting, the temperature may be manually regulated, to reduce heat accumulation, the electrode temperature will decrease automatically in the process of therapy.

b) The output current is intermediate-frequency sinusoidal wave modified from low frequency which can change automatically according to certain procedures.

c) The therapy method may be divided into two grades, including continuous adjustment and intermittent adjustment.

d) Accurate timing: 6 grades from 5 to 30 minutes for selection, time may be adjusted in the process of therapy.

e) The output indicator window comprehensively displays wave selection, temperature rising indication, output state, current intensity, temperature grade and loss-of-load indication and other information.

1.3 Working conditions

a) Environmental

b) Relative humi

c) Atmospheric

d) Power supply

e) Power frequen

f) Input power:

1.4 Product composition

a) Mobile equ
output cable

rent, BF application unit of class I, the product is composed of host,
lectrode.

b) The electrotherapy has two groups of input;

c) The warm electrode is skin electrode which may be classified into three types: small, medium and large.

d) Apparatus dimension：470mm×350mm×180mm；

e) Weight：approx. 9Kg。

2 Applicable scope

This therapy apparatus applies intermediate-frequency current and thermotherapy on the patient to achieve the purpose of killing pain and swelling, softening scars and loose adhesions, etc.

3 Contraindications

In any of the following cases, treatment can not be accepted:

a) Patients with pacemakers;
b) Lower abdomen of pregnant women;
c) Heart positions;
d) Cancer;
e) Tuberculosis;
f) Acute suppurative inflammation;
g) Bleeding positions;
h) Thrombophlebitis;
i) Positions with relative large metal items

4 Therapy principles

4.1 TAFC warm-electrode intermediate-frequency electrotherapy apparatus adopts sinusoidal modulated intermediate-frequency electrotherapy method

In sinusoidal modulation intermediate-frequency electrotherapy, intermediate-frequency current is modulated with varying low-frequency sinusoidal current, so that the amplitude of the intermediate-frequency current will change with the frequency changes of the current. Such amplitude is also known as modulation wave. There are several variations in the waveform in this therapy, the output of this therapy apparatus selects two forms, including continuous modulation and intermittent modulation.

Continuous modulation output current refers to continuous waveforms of intermediate-frequency current whose amplitude change with the frequency changes of low-frequency. Modulation low-frequency changes continuously or in different stages within the range of 0Hz～200Hz. See Fig. 1.

Intermittent modulation output current refers to the waveforms where intermediate-frequency current waveforms appear alternatively with IF-amplitude sine waves with lower amplitudes. See Fig. 2.

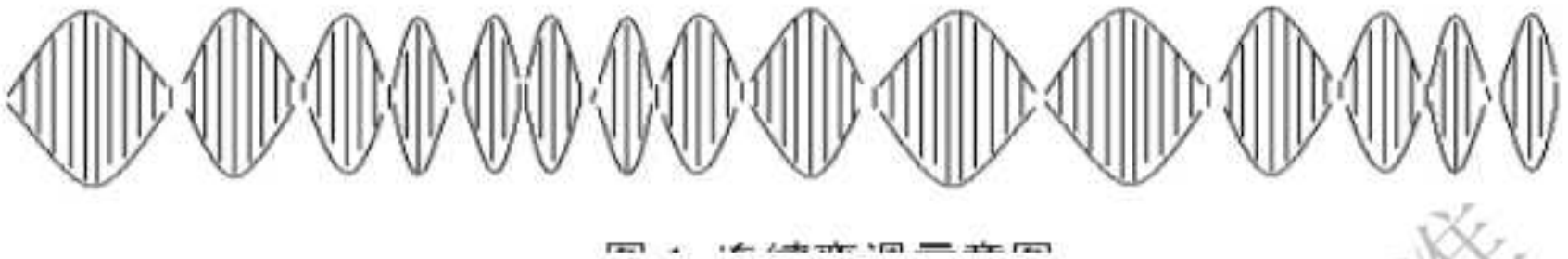


Fig. 1: Diagram of continuous adjustment

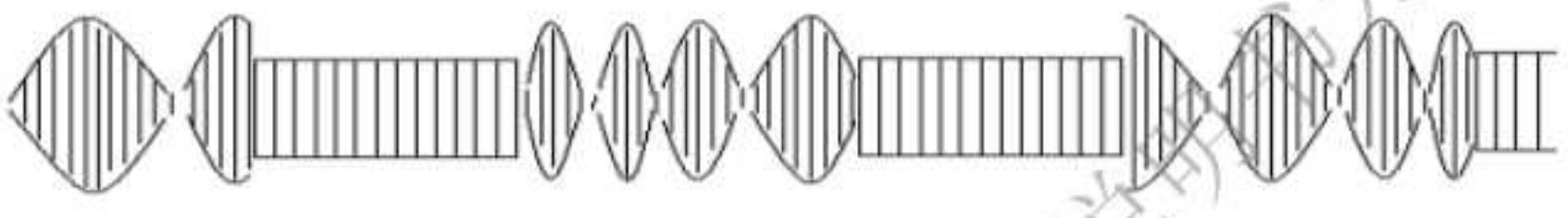


Fig. 2: Diagram of intermittent adjustment

4.2 Therapy methodology of TAFC warm-electrode intermediate frequency electrotherapy apparatus

Both thermal and modified intermediate-frequency current are adopted to perform synchronized therapy, it has the following features and physiological meanings.

a) Intermediate-frequency sinusoidal wave of 4000Hz is applied to play the unique therapy effects of intermediate-frequency.

b) Modulation with low-frequency sinusoidal wave of 0HZ~200HZ to gift the intermediate frequency current with the characteristics of low-frequency current to fully use the unique treatment effects of low frequency. Meanwhile, characteristics of intermediate frequency current are still remained in such current, the body resistance is low and the current effects are significant, free from electrolysis, the stimulation on skin is quite small.

c) Different waves and frequencies appear alternatively, so that to overcome adaptability of human body to current.

d) To reduce heat accumulation on the electrode plate, eliminate excessive heat, prevent scalding and keep thermal balance, fuzzy temperature control technology is adopted in the apparatus, in therapy, when the temperature is adjusted to a proper grade, with the increase of partial heat accumulation, the apparatus will automatically decrease the temperature to enable the patient to maintain the warm sense of comfort.

5 Main technical indicators and basic electrode requirements

5.1 Range of frequency

a) Intermediate frequency: 4000Hz，tolerance : ±20%；

b) Modulated frequency： varying within0Hz～200Hz, tolerance: ±20%。

The effective load impedance range of the parameters listed in 5.2～5.4 is 200Ω～600Ω

Output current: Intermediate-frequency current should vary within 0mA～80mA, tolerance: ±20%。

5.3

Timing： 6 grades of time may be set, including 5min, 10min, 15min, 20min, 25min and

30min, tolerance: ±15%。

5.4 Continuous working hours: not less than 4 hours.

5.5 Electrode temperature: temperature on the electrode plate may be divided into 10 grades, d0-d9 are adjustable continuously, the corresponding minimum temperature should not lower than the environmental atmosphere temperature while the maximum temperature should not exceed 49℃.

5.6 Basic electrode requirements:

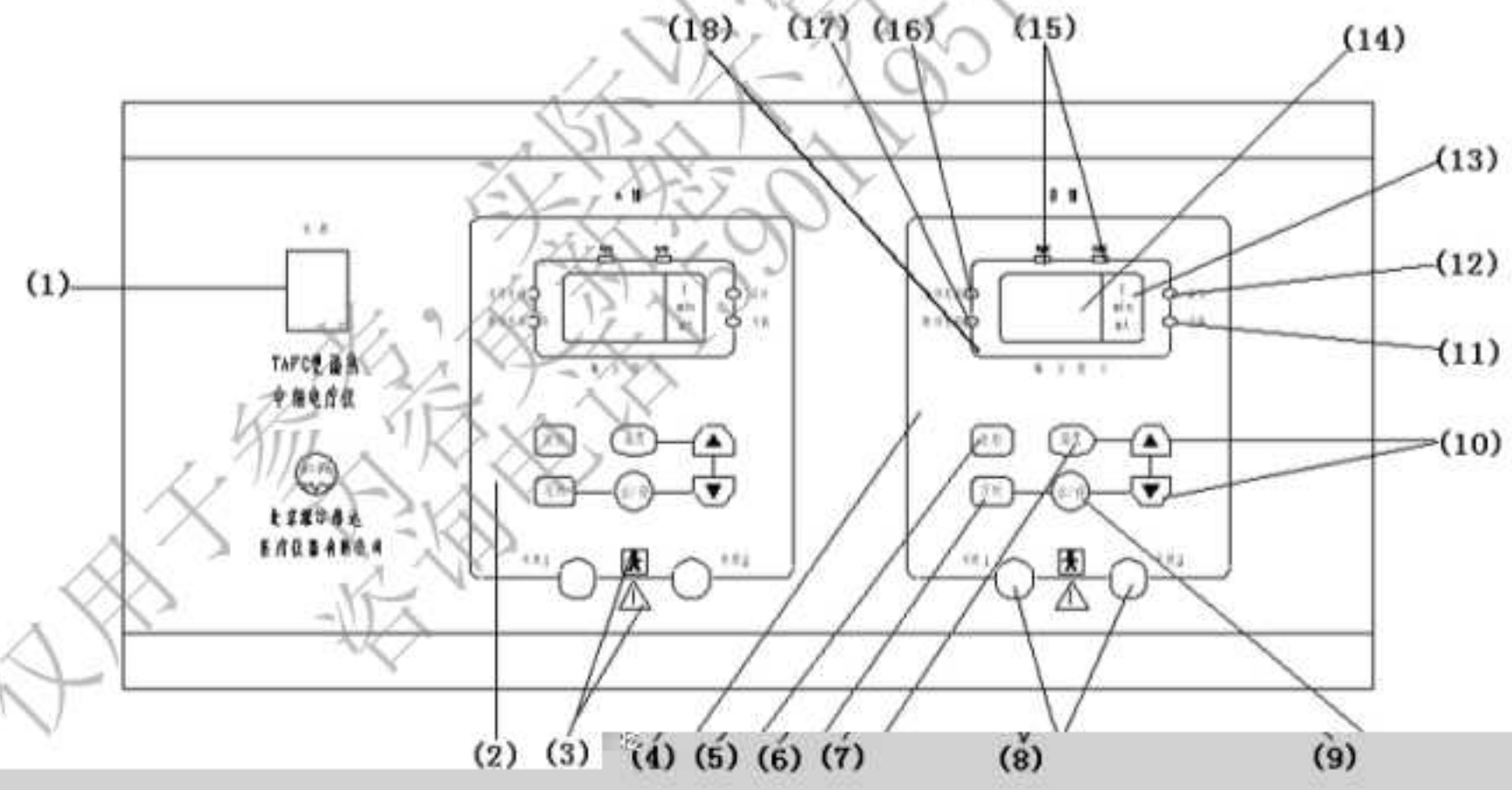
a) Material: conductive rubber.

b) Dimension：big electrode: 95mm×120mm、medium electrode: 75mm×105mm、Small electrode: 53mm×75mm，tolerance: 10%;

c) All products should be those with medical device registration certificates.

6. Panel schematic diagram and description on graphics, symbols and warning notes on the apparatus

6.1 Schematic Diagram and description of the front panel



（1）Power switch: “O” means “Off’ and “ | ”means on.

（2）Operating display-Group A(similar with group B)

（3）Symbol “  ” means the “application unit of BF Type”, the safety grade of the apparatus is Class I, application unit of BF type.

Symbol “  ” is the sign for caution, pay attention to the following warnings ① “The effective output current of the apparatus is over 10mA” ②patient burns may be caused by improperly fixed electrodes (see8.5 and 8.6); ③Never switch the power supply after the

electrode is placed on the patient, otherwise, an instant sense of shock will be generated on the patient (see 8.3); ④The patient may have an instant sense of shock in the course of treatment due to electrode line failures (see 10.4a)"

（4）Operating display-Group B

（5）Wave selection button: two kinds of treatment waves may be selected, i.e. continuously adjustable wave and intermittently adjustable wave.

（6）Timing button: there are 6 grades of time from 5min to 30min for option, after the operation is started, the time will be displayed as countdown， when this button is pressed, the output display screen will indicate the time set, select the time needed through buttons of ▲ and ▼ .

（7）Temperature button: electrode temperature may be set within 10 grades, i.e. D0-D9 from low to high. When this button is pressed, the output indicator screen will indicate the temperature grade, select the temperature grade needed through buttons of ▲ and ▼ .

（8）Electrode socket: plug the electrode line in.

（9）Start/stop button: start or stop current output.

（10）Parameter adjustment button: including buttons of ▲ and ▼ , through pressing such buttons, timing set, working hours and temperature grades may be selected and output current intensity may be adjusted after the operation is started.

（11）Loss-of-load indicator lamp: after the operation is started and the current is adjusted to above 10mA, if the loss-of-load indicator lamp gives light, it means that the circuit of the electrode is not connected properly and circuit broken exists in the circuit.

（12）Starting indicator lamp: when the light is on, it means that the apparatus is entering the working state, the output current intensity are adjustable. When the lamp goes off, it means that the apparatus is in a setting state.

（13）Output indicator lamp: when lamps "T", "min" and "mA" are on, it means that what are indicated on the display screen are temperature grade, time and output current.

（14）Output display: the temperature grade, timing or working hours and output current values may be respectively displayed.

（15） Temperature rising indicator lamp: when the light is on, it means that the temperature is rising. The time used by the lamp to give lights reflects the temperature rising speed.

（16）Continuously adjustment indicator lamp: when the light is on, it means that the continuously adjustment treatment method may be selected.

（17） Intermittently adjustment indicator lamp: when the light is on, it means that the intermittently adjustment treatment method may be selected.

（18） Output display window: display comprehensive output information.

6.2 Schematic Diagram and description of rear panel

（1）Power socket

（2）Fuse drawer　　RF1-20　0.5A φ5×20

7 Operating instructions

7.1 Starting up

7.1.1 Connection of power supply: confirm that the grid voltage complies with the provisions for working conditions of the apparatus, select power socket with grounding protec

rapidly.

7.2 Setting

7.2.1 Setting of temperature

From atmosphere temperature to around 49℃, the temperature of the electrode plate of the apparatus may be divided into 10 grades which can be adjusted continuously. After the apparatus is started, the output display window will display "d9" which means the temperature is beginning to preheat from the highest level, then the temperature rising indicator lamp (15) will blink rapidly, at this time, the temperature of the electrode plate will increase gradually, if no more interference is needed, when the temperature rises to a certain degree, to reduce heat accumulation, the temperature will decrease slowly, i.e. change from d9 to d0. In this circumstance, the button of "▲" should not be pressed immediately to increase the temperature, consider to slightly adjust the temperature according to atmosphere temperature and the sizes (large, medium, small) of the electrode and the actual thermal conditions of the electrode. If large-sized electrode is selected, the temperature grades of d9, d8 and d7 may be selected; if medium-sized electrode is selected, the temperature grades of d8, d7 and d6 may be selected, if small-sized electrode is selected, the temperature grades of d7,d6 and d5 may be selected.

7.2.2 Selection of wave

Pressing the wave selection button (5), two kinds of waves, including continuously adjustable wave and intermittently adjustable waves, may be selected, when the continuously adjustable indicator lamp (16) is on, it means that the continuously adjustment treatment method may be selected, when the intermittently adjustable indicator lamp (17) is on, it means that the intermittently adjustable treatment method may be selected. In general, "continuously adjustable "treatment method may be selected for patients with acute diseases and "intermittently adjustable" treatment method should be selected for patients with chronic diseases.

7.2.3 Selection of timing

Pressing the timing button　(6), the output display window will display information about time, then the time need to be set may be selected through the parameter adjustment button (10), the time may be set can be divided into 6 grades from 5min～30min, after the apparatus is started, time will be displayed as countdown, generally, the therapy period for each patient should be 20-30 minutes.

7.3 Connection of output electrode

7.3.1 Plugging in electrode line: electrodes (Fig. 3) may be divided into three sizes, large, medium and small, a pair of electrodes with proper size should be selected according to the area of the position requiring treatment. Plug the electrode plug into the electrode socket (8), before plugging,

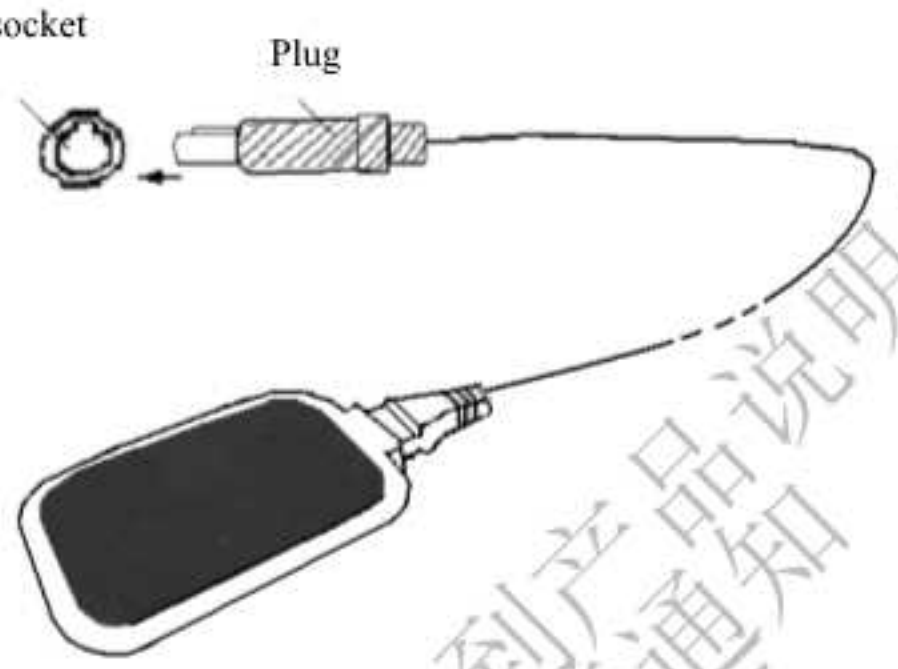


Fig. 3 Warm-electrode and lines

the plug convex should be aligned with the jack slot and then push it until a cracking is heard, the electrode at this time should be unable to be pulled out. When the plug is pulled out, grasp the front part of the plug (the mobile part) and pull backward, never turn left or right or pull the electrode line, otherwise, both the apparatus and the electrode will be damaged.

7.3.2 Placement of electrodes: soak the electrode flannel sleeve into warm water, do not twist it too dry after taking out and cover it on the warm electrode (the velvet surface should be contacted with the black film surface of the electrode), put the electrode on the position requiring treatment and fix it with one or more bandage of sand bags, so that the electrode surface covered with flannel sleeve can be properly contacted with body. **(Attention: Never directly contact the patient's skin with the conductive surface (black film surface) of the electrode, the electrode must be covered with wet flannel sleeve).**

7.4 Adjustment of output current

7.4.1 Pressing "启/停" button（9），the output display window will display information about current, the output current may be adjusted through pressing parameter adjustment button (10), continuously press the buttons of ▲ and ▼, the current will be changed continuously.

7.4.2 election of dose: since the current intensity changes with the change of electrode area, the dose used for treatment is usually determined according to human perception threshold, motion threshold and the maximum tolerance degree, see the following examples, before the output current is adjusted, the current dose needed should be selected according to actual demands.

a) Under perception threshold: ammeter shows indication, the patient has no sense of electric. In adjustment, first increase the current to the point where the electricity may be sensed and then decrease the current till the sense disappears.

b) Perception threshold: adjust the current just to the point where the electricity may be sensed as hemp or fibrillation.

c) Over perception threshold：adjust the current till there is obvious sense of electricity.

d) Under motion threshold: sense of electricity exists, the current intensity can not cause muscle systole reaction.

e) Motion threshold: the current intensity is just enough to cause muscle systole reaction.

f) Over motion threshold: the current intensity can cause obvious muscle systole reaction.

g) Maximum tolerant limit: increase the current to the maximum limit which is tolerable to the patient, such a dose is known as "tolerance limit".

7.4.3 In the process of adjusting the output current, the operator should constantly ask the patient about his/her feeling, when the treatment dose for the patient is achieved, stop output adjustment. Since human body is more sensitive to current in initial stage, the output should be lightly adjusted after a few minutes.

7.4.4 If select the large, medium and small size electrodes provided with the apparatus to carry out treatment, provided that the electrodes are properly fixed, the current intensity will not exceed 2mA(r.m.s)/cm^2 . If electrodes smaller than the above mentioned area are selected for treatment, particular attention should be paid that when the current intensity is over 2mA(r.m.s)/cm^2, the patient is possible to be burnt, thus the current should be adjusted carefully to avoid excessive stimulation.

7.5 Completion of treatment

During treatment, the timing period may be adjusted through pressing timing button (6) and the parameter adjustment button (10). Once the time set in advance is over, the apparatus will automatically stop output and buzz for 30s as warning, meanwhile, the display window will blink continuously and display "00". At this time, press any key to stop warning and reset to the initial state. Finally, remove the electrodes from the patient.

If continuous treatment will be implemented, it is not need to turn off the apparatus, directly perform treatment on the next patient.

In the process of treatment, if the operator wants to complete the treatment, directly press button (9) "启/停", after the output is ceased, remove the electrodes from the patient.

8 Notes

8.1 It is strongly recommended to use the apparatus under the instructions of doctors.

8.2 When the apparatus is operated, it should be kept at least 30m away from ultra short wave, microwave, CT, nuclear electromagnetism and other electromagnetism radiat

should be properly plugged into the socket, do not twist the flannel sleeve too dry, when the electrode is put into the sleeve, inverse placement is not permitted. The electrode covered with flannel sleeve should tightly contact with body. Otherwise, the patient will feel instant shock, in case of "point" contact, the current intensity will increase and there will be risk of burning for patient.

8.6 In output therapy, the patient should not move his/her body or pull the electrode line and bandage, so that to avoid poor connection and the risk of instant current shock or burn.

8.7 When this apparatus is used for treatment, pay attention to patients who are retardant to warm response, such as patients with longer-term paralysis, hemiplegia and dementia, etc.

8.8 Warm electrodes are consumable components and should be carefully protected in use. Do not bend the warm electrodes, the roots of the electrodes should be particularly protected, so that to avoid unnecessary damage and affect the service life of the electrodes.

8.9 Pressing the buttons on the panel film of the therapy panel, heavy press is forbidden.

8.10 In case of any discomfort, the therapy should be immediately terminated.

8.11 In the disposal of the apparatus and its accessories after their service life expires, the lead content contained in the welding tin should be considered, the disposal process should comply with the environmental policies issued by local governments.

9 Apparatus examination

When the apparatus is used for the first time or there is any failure with the apparatus, please check according to the following steps.

a) Power: see 7.1;

b) Wave switching: repeatedly press button (5) for wave switching, the indicator lamp displaying the output wave will change between continuous adjustment and interrupted adjustment.

c) Electrode temperature control: after button (7) for temperature is pressed, the output indicator lamp "T" will give lights, the temperature may be adjusted within the range of d0-d9 through pressing buttons of ▲ and ▼.

d) Timing: after button (6) for timing is pressed, the output indicator lamp "min" will give lights, timing may be adjusted within the range of 5min～30min through pressing buttons of ▲ and ▼.

e) Current adjustment: press button (9) "启/停", the starting indicator lamp (12) will give lights, then the apparatus enters working state, the output indicator lamp "mA" will give lights, the current may be adjusted within the range of 0mA～80mA through pressing buttons of ▲ and ▼.

f) Indication of loss of load: after the electrode is plugged, place the electrode plate on the table, overlap the black film surfaces of two electrodes together and press with hand, start the output and press button ▲ ,increase the output current to around 15mA and then separate the two electrodes, at this time, the indicator lamp (11) for loss of load should give red lights.

10 Failure processing

10.1 The apparatus does not work and there is no indication for starting. Check whether there is any single failure with the apparatus, whether the power fuse is burnt, whether the power line is properly connected and whether the power switch is on, in case of replacement of the fuse, it

should be implemented according to the current identification, the standby fuses are packed in the accessories of the apparatus.

10.2 The apparatus operation is normal yet the patient has no feeling when the current is adjusted. Adjust the current to 20mA and observe:

a) If the indicator lamp (11) for loss of load does not light, adjust the current continuously, if the patient still has no feeling, it means there are internal failures with the apparatus, contact with us for repair.

b) If the indicator lamp (11) gives red lights, it means there is output in the apparatus, the failure is between the electrode and the patient. The possibility is that the electrode circuit is broken or the electrode is not properly contacted with the patient. In such a case, the treatment should be immediately suspended, first exam the connection of the output circuit and then judge whether the electrode line is damaged. The method is as follows: put the electrode on the table, overlap the black film surfaces of the two electrodes together and press it with hand, start the output current to over 10mA, if the indicator lamp (11) for loss of load gives red lights, it indicates that the electrode has been damaged, replace it!

10.4 In case the patient feels that the output is not stable in the treatment, it may be caused by the following reasons and should be solved according to the methods below.

a) The unstable current occurs during treatment may be caused by poor contact between the electrode and the patient or the poor connection on the electrodes themselves. Replace the electrodes according to clause 7.3.2, if the failure can not be solved, exam the electrode lines according to the method set forth in clause 10.2 b).

b) The unstable current is possibly caused by high-frequency radiation interference around the apparatus or excessive voltage fluctuations in the grid. (High-frequency radiation generally refers to the existence of ultra short wave, microwave, high-frequency power, CT, nuclear electromagnetism and other radiation sources). The apparatus should be kept away from high-frequency equipments, do not share a power socket with other equipments.

c) Pushing the power switch of the therapy apparatus in the process of treatment, when the electrode is placed on the patient, never push the power switch.

11 **Sterilization**

11.1 The used conductive rubber pad should be sterilized with clean alcohol tampon, the specific method is to sterilize the entire electrode surface with alcohol tampon.

11.2 The used electrode flannel sleeves should be boiled in boiling water for at least three (3) minutes to achieve the purpose of sterilization and avoid cross infections,

12 **Transport requirements**

Complying with contractual provisions. Strong impact, shock and damp should be prevented in the process of transport.

13 **Transport and storage environmental conditions**

Transport and storage require the following environmental conditions: temperature range: - 40°C ~55°C, relative humidity should not exceed 93%, the atmospheric pressure should be 500hPa. The apparatus should be stored in rooms without corrosive gases and excellently ventilated.

14 **Replacement of fuse**

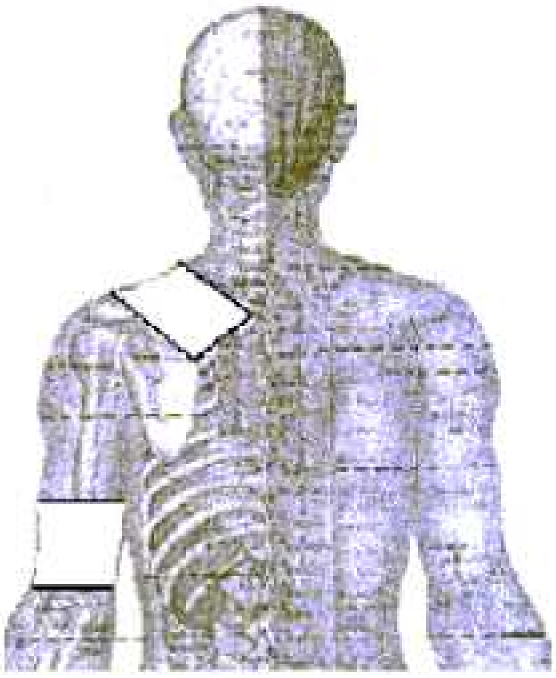
See clause 6.2 and Fig. 2: Power and fuse

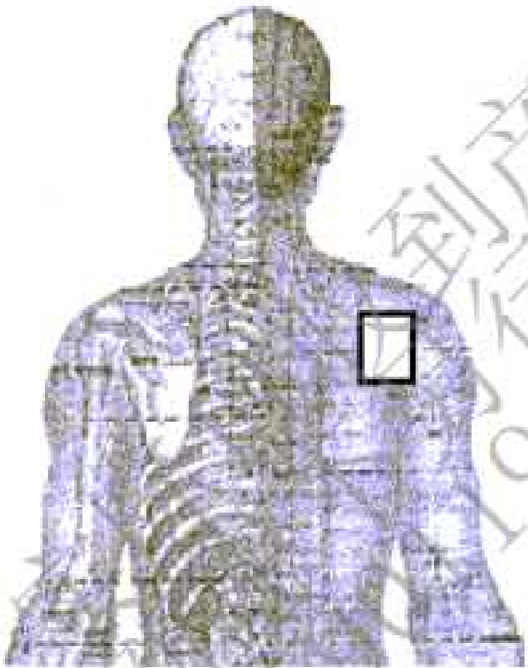
15 Daily maintenance

Keeping the apparatus clean, pay attention to anti-damp and anti-dust. If the apparatus will not be operated for a long term, turn off the power switch and disconnect the power plug, cover the apparatus with protective cloth. No item is permitted to be placed on the apparatus.

16 Commitment to users

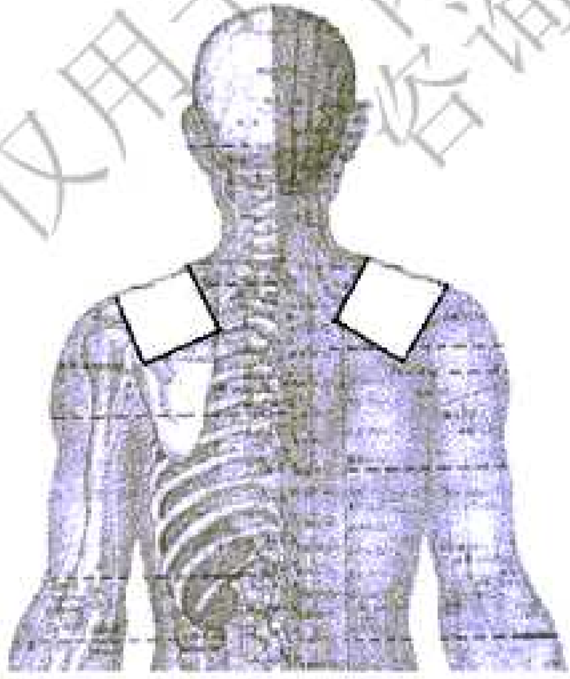
We provide long-life services for our products, the entire apparatus is under warranty within 1 year during which period the maintenance fees, component fees and freights are free (warm-electrode is not covered in the warranty). When the above period expires, we still provide repair services with reasonable charge.



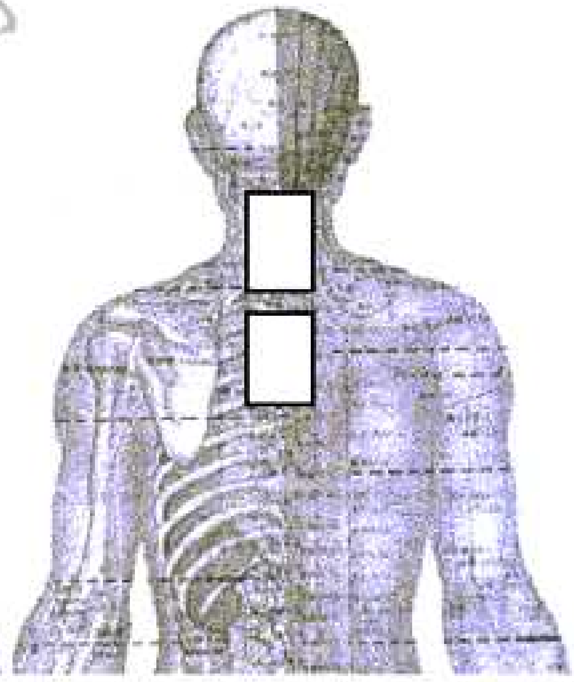


Shoulder Front

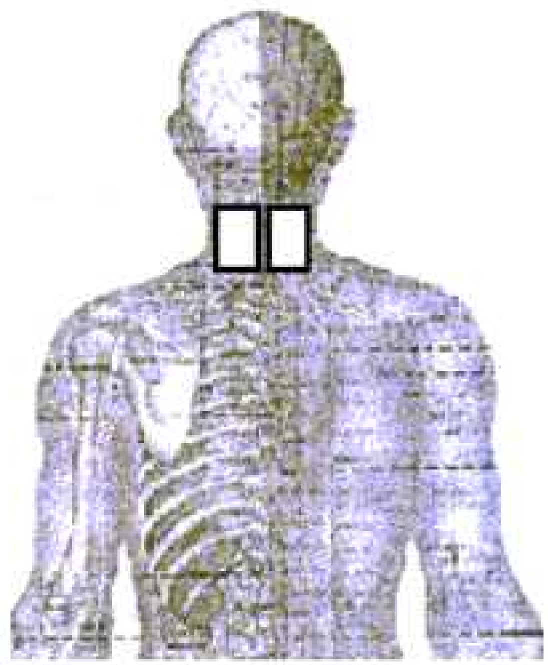
Shoulder Back



Cervical vertebra

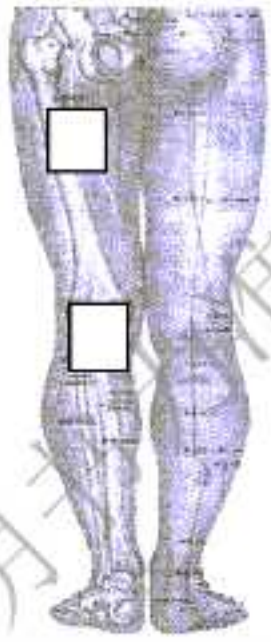


Cervical vertebra

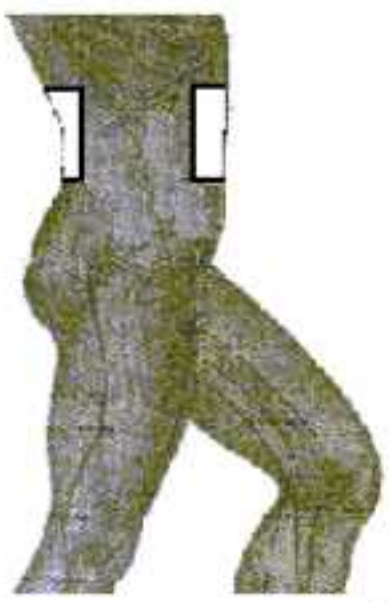


Cervical vertebra

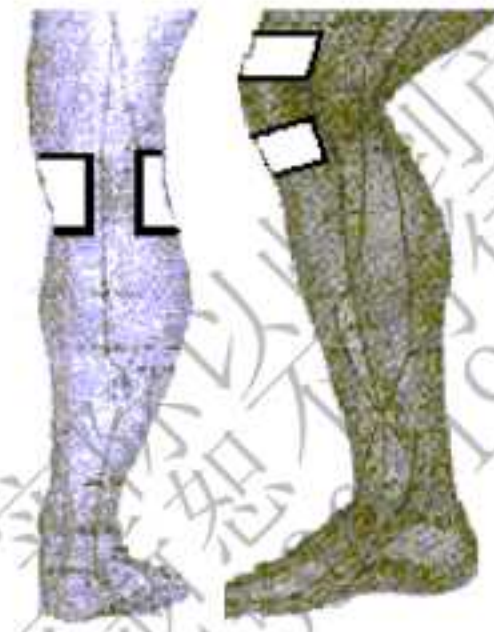
Lumbar muscle strain, lumbar sprain



Sciatic Nerve

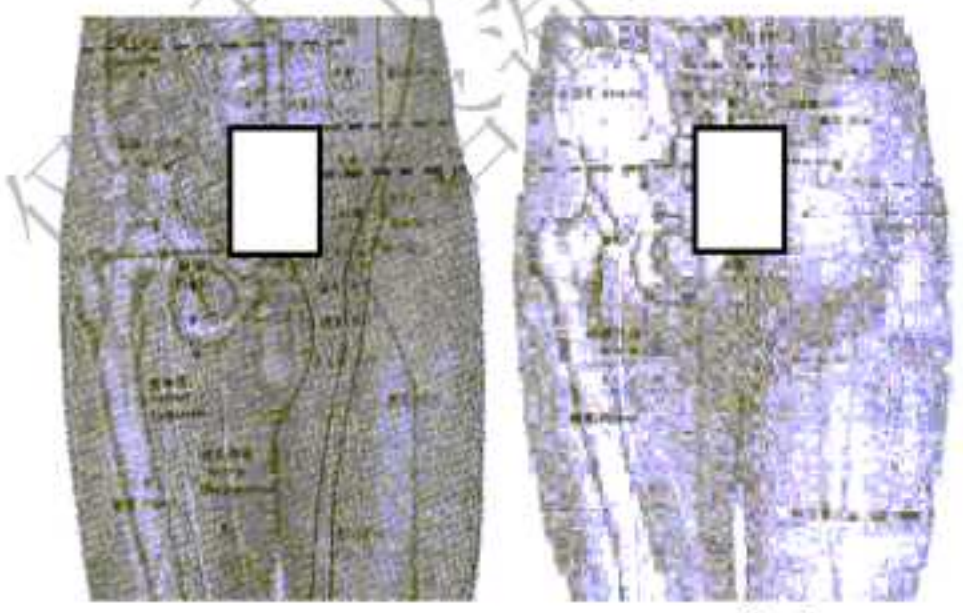


Lumbar nerves root



Keens

Ankles

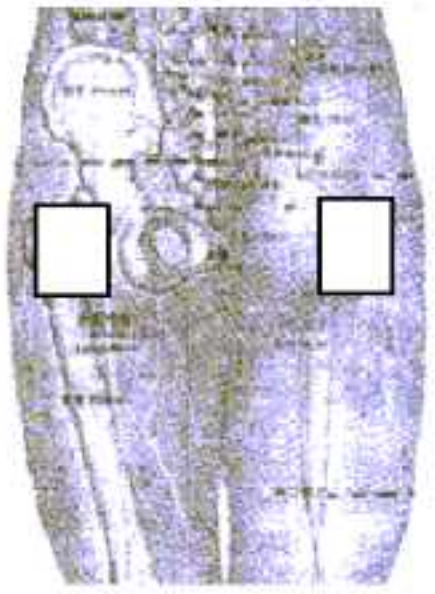


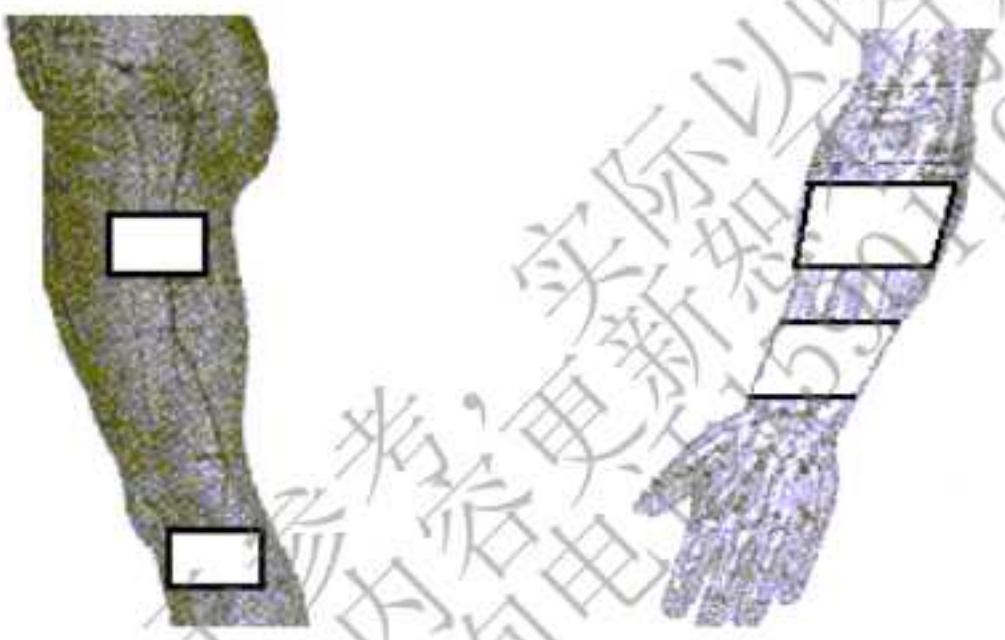
Front

Back

postoperative adhesions, scars

Hip injection induration





Atrophy of quadriceps

Wrist

Elbow

Fig. 2: Power and Fuse

The apparatus uses 3-core power plug, all power sockets should be examined to ensure reliable grounding.

When the power plug is pulled out, be sure to hold the front part of the plug rather than the power line.

There are two 0.5A fuses inside it, pull the small drawer out with a screwdriver to take the fuses out。