Anorectal Physical Therapy Device

Users’ Manual

Zhengzhou Safute Electronic Equipment Co.,ltd
I. Main function and model

1. Main Function

The device is integrated with thermotherapy, magentotherapy, massotherapy, and iontophoresis, can diminish inflammation, lessen swelling, arrest bleeding, and ease pain. It is easy to operate, no trauma, wide application, and so on.

a) Insert the probe with the function of infrared, magnetic gyromagnetic into the rectum to treat.

b) For the iontophoresis, the pharmaceutical ions can be imported into the lesion site directly. Making use of the special pulse stimulation for the medication iontophoresis, it will make the human generate a series of effects, then accelerate the medical effective ion components into the body.

c) For the YDB, it owns the following features, such as wide application, little suffering, no trauma, easy operation, secure and reliable.

2. Product Mode

Product model is divided into 5 types according to the product with different accessories, in which LG2000 owns all of the accessories, please check table 1 for other types.

<table>
<thead>
<tr>
<th>Model</th>
<th>Mainframe</th>
<th>Electrode sheet</th>
<th>Probe</th>
<th>YDB</th>
</tr>
</thead>
<tbody>
<tr>
<td>LG2000</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>LG2000A</td>
<td>√</td>
<td>√</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>LG2000B</td>
<td>√</td>
<td>—</td>
<td>√</td>
<td>—</td>
</tr>
<tr>
<td>LG2000C</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>√</td>
</tr>
<tr>
<td>LG2000D</td>
<td>√</td>
<td>—</td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>

Chart 1
II. Indication

Apply to the adjuvant treatment of pain, pruritus, eczema, edema, bleeding, fall-swell caused by internal/external hemorrhoid and mixed hemorrhoid, proctitis, anal sinusitis disease.

III. Contraindication

Patients with Malignant tumor, blood diseases, serious heart disease, hypertension, liver disease, severe diabetes, epilepsy and psychiatric disorders, crissum abscess, rectal prolapse, and pregnant women.

IV. Working Principle

1. Gyromagnetic infrared probe

1.1 Thermotherapy: Adopt the far infrared heat, it can promote blood circulation, activate blood and dissolve stasis.

1.2 Massotherapy: Push the crissum radial, the massage speed can be adjusted, has good effect for dilating anus, adjust nerve and activate blood, dissolve stasis.

1.3 Magnetotherapy
   a) Magnetic field can adjust crissum nerve and Meridian very well.
   b) Co-use the magnetic field and medication, which is more beneficial for the permeation effect of the pharmaceutical ions, enhance its medication effectiveness.

2. Iontophoresis

   Biological current changes in the process of human life has certain corresponding relationship with the state of physiological functions. Using the special pulse electrical stimulation can control and adjust the state of imbalance of human body's morbid bioelectricity: At an appropriate pace, moderate strength under the action of electric pulse, promote the improvement or recovery of the disease, an obvious synergistic effect. Under the electrical pulse effect with appropriate pace and
strength, Promote the improvement or recovery of the disease, play an obvious synergistic effect.

3. YDB

Infrared treatment head can produce specific infrared electromagnetic wave (0.76 ~ 5μm), this electromagnetic wave has strong penetrating power, can penetrate the skin and subcutaneous tissue, be absorbed by human body. The infrared which penetrate into the human body will cause the vibration of nucleus of molecular, then through the resonance absorption, form heat reaction, promote the temperature of deep skin risen, expand the micro blood-vessel, promote the blood circulation, wide out the obstacle which interfere the metabolism such as extravasated blood, promote the growth of enzyme, and make the organization revive.

The working principle of YDB also includes warm effect, under the infrared radiation, the tissue temperature will rise, blood capillary expand, improve blood circulation, strengthen the metabolism of substances, improve the Tissue cell vitality and regeneration ability, speed up the absorption effect of inflammatory exudate, achieve the goal of diminish inflammation, lessen swelling, ease pain and promote the wound heal up.
V. Main technical Data

1. Rated Voltage: AC220V 50Hz

2. Input power: ≤260W

3. Working environment:
   a) Environment temperature: +10℃~+40℃
   b) Relative humidity: 30%~75%
   c) Barometric pressure: 860hPa~1060hPa

4. Security type: I Class BF Type

5. Spectral range of YDB: 0.76~5μm

6. The output waveform of pulse treatment is square, the width of pulse is 17ms.

7. The output level of pulse treatment: Total 34 grade, can be adjusted continuously, grade range: 1Vp-p~35Vp-p, the deviation is ±20%.

8. Gyromagnetic infrared probe: 7 grade, can be adjusted continuously, range: 5000r/min~12000r/min, the deviation is ±20%; The vibration frequency range: 5000r/min~12000r/min, the deviation is ±20%.

9. The temperature Gyromagnetic infrared probe: 35℃~50℃, can be adjusted continuously, the deviation is ±1℃.

10. The function of output back to zero: When the power recover after it is broken off, there is no output.
VI. Operation Instructions

1. The name and function of operation panel

Chart 1 Operation Panel

Time setting window: Display the working time of iontophoresis, infrared gyromagnetic, infrared treatment (YDB). Increase/decrease the working hours according to the corresponding "+" "-" button, the displaying time will be back to integral multiple of 5 when it is set. (The time unit of time is minute, the max set value is 90 minutes, it start to count down after output, the countdown will decrease "1" per minute.

Intensity setting window: Display the working intensity of iontophoresis, infrared gyromagnetic, Increase/decrease the working intensity according to the corresponding "+" "-" button.

Temperature Setting window: Display the temperature of probe, Increase/decrease the probe temperature according to the corresponding "+" "-" button.
Operation buttons: Operate the “Start”, “Pause”, “Stop” button of iontophoresis, infrared gyromagnetic, infrared treatment.

2. The sketch chart of the device front/back panel, See chart 2, chart 3

![Chart 2: The sketch chart of back panel](image1)
![Chart 3: The sketch chart of front panel](image2)

A: Power socket  
B: Fuse  
C: Fuse  
D: Iontophoresis socket  
E: Gyromagnetic infrared probe socket

3. Operation Instruction

3.1 Insert the power line into the socket of the mainframe, then insert the power line into the three core external power with ground protection.

3.2 Turn the power on, the six working window of the mainframe operation panel will display its initial value, and at the same it will sound warning.

3.3 Iontophoresis

   a) Set the working time according to the corresponding “+” “-” button, the time range is 0-90 minutes, the time will increase or decrease 5 minutes after pressing the “+” or “-” button.

   b) Set the iontophoresis intensity according to the corresponding “+” “-” button, the intensity range is 0-34 grade, the intensity will increase or decrease 1 grade after pressing the “+” or “-” button.
c) Press the “Start” button to work (The device can’t start if don’t set the time and intensity), take 1 minute as countdown. The user can handle the corresponding “+” or “-” button to set time or intensity, if the user want to change them after starting, Press the “Pause” button, it will suspend the treatment and countdown, Please press “Start” button if want to go on the treatment. When the countdown stops, the treatment will stop too and it will sound warning, at the same time the intensity will go back to the initial state.

d) Press the “Stop” button if the user want to stop treatment, the time and intensity setting will go back to the initial state.

3.4 Infrared gyromagnetic

a) Set the working time according to the corresponding “+” “-” button, the time range is 0-90 minutes, the time will increase or decrease 5 minutes after pressing the “+” or “-” button.

b) Set the intensity according to the corresponding “+” “-” button, the intensity range is 0-7 grade, the intensity will increase or decrease 1 grade after pressing the “+” or “-” button.

c) Press the corresponding “+” “-” button to set the probe temperature, the temperature range is 35-50℃, the temperature can be set before or after starting, but it will warm up only after pressing the “Start” button, it need certain time for the probe to heated to the setting temperature.

d) Press the “Start” button to work (The device can’t start if don’t set the time and gyromagnetic intensity), take 1 minute as countdown. The user can handle the corresponding “+” or “-” button to set time, intensity or probe temperature, if the user want to change them after starting. Press the “Pause” button, it will suspend the treatment and countdown, Please press “Start” button if want to go on the treatment. When the countdown stops, the treatment will stop too and it
will sound warning, at the same time the intensity and temperature will go back to the initial state.

e) Press the “Stop” button if the user want to stop treatment, the time, intensity and temperature setting will go back to the initial state.

3.5 Infrared treatment

a) Set the working time according to the corresponding “+” “-” button, the time range is 0-90 minutes, the time will increase or decrease 5 minutes after pressing the “+” or “-” button.

b) Press the “Start” button to work (The device can't start if don’t set the time), take 1 minute as countdown. The user can handle the corresponding “+” or “-” button to set time, if the user want to change it after starting. Press the “Pause” button, it will suspend the treatment and countdown, Please press “Start” button if want to go on the treatment. When the countdown stops, the treatment will stop too and it will sound warning.

c) Press the “Stop” button if the user want to stop treatment, the time setting will go back to the initial state.
VII. Note

1. The operation user of this device must be the diplomate or the medical staff under the supervision and guidance of the diplomate.

2. If the patient don’t get the doctor’s advise, the patients who use the implantable electronic devices (such as cardiac pacing, pulse modulators, artificial heart, etc) shouldn’t be advised to use.

3. When using the high frequency surgical device and the Anorectal Physical Therapy Device for the patient at the same time, it may cause burn at the electrode position of the device, or damage the device; Its output maybe unstable when using the device nearby the shortwave or microwave treating device.

4. The max output range of the pulse treatment is 35Vp-p, the user should pay special attention.

5. Make sure that the grounding guard wire of instrument power socket and the corresponding socket hole pole piece keep in good ground condition, connect with reliable, to ensure the safety of the operator and user.

6. If user want to change the fuse, please disconnect the power switch of device firstly, and unplug the power line, under the safe condition, open the fuse base to change the fuse with tool, then choose the fuse with same model, in case of damaging the device or expanding the breakdown.

7. All of the device plugs should be inserted into corresponding socket. Pull the plug with power is forbidden. Medical staff should always examine the condition of plug, socket, and the line, reduce the times of insertion and extraction. If there is looseness, breakage, should maintain or change in time.

8. Avoid the rubber electrode plate short sub for a long time, touch, move the electrode plate under the condition of pulse output is forbidden, in case of the Accident.
9. When sterile and clean the rubber electrode, should prevent the liquid entering into the wire end of rubber electrode plate to corrode internal wire.

10. Rubber electrode belongs to the consumable with certain life, to use it effectively and long-term, in addition to adopt correct cleaning and disinfection methods, also should pay attention to avoid the rubber plate bending excessively. Its connection wire shouldn’t undertake tensile and pressure, reduce the winding number, reduce small angle bending of the line end.

11. The doctor or nurse should scrub the treating area with alcohol wipes before treatment.

12. The doctor should reduce therapy dose or stop treatment if the patient don’t feel comfortable during the using process.
VIII. Transport, Storage, Safeguard, Maintenance

1. The device should be avoided by the rain and snow, severe vibration and mechanical collision during the transport process.

2. The power of device should be cut off, and the device should be stored in a dry, no dust, no corrosive gas and ventilated indoor properly.

3. The device belongs to sophisticated electronic equipment, should be handled with care, and be avoided to use and store under the extreme environment condition, such as spraying water, sweat, overheating, overcooling and so on.

4. After each treatment, the rubber electrode should be cleaned, sterilized by the medical alcohol or other neutral disinfection cleaner, and be scrubbed by the cleaning cloth.

5. The working life of device is 6 years, please check the production date in product label, please hand over the device to the enterprise which has the authorization of discarded electronic products to deal with.
IX. After service

1. We make commitment that the device has a year warranty, life-long maintenance because of quality problem.

2. The following conditions don’t belong to the scope of quality warranty, should be paid service.
   
   a) The damage of the device due to the operating personnel don’t use according to the instructions.
   
   b) The damage of the device due to the operating personnel disassemble the device without our authorization.
   
   c) The damage of the device due to improper storage.
   
   d) The damage of the device due to irresistible disaster (earthquake, fire, etc)

3. We will not handle the reimbursement if the user tear, modify, or change the component, the resulting loss is beyond the scope of warranty.

4. The adjuncts are belong to consumable and beyond the scope of warranty.

5. Please don’t open main case and contact us or our agent in case of the breakdown of the device, we will send people maintenance or consign to repair, we won’t undertake any maintenance issues if the user open the main case privately.
## X. Accessory list

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mainframe</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
</tr>
<tr>
<td>2</td>
<td>Rubber electrode</td>
<td>1 Set</td>
<td>1 Set</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Gyromagnetic infrared probe</td>
<td>2 Pcs</td>
<td>-</td>
<td>2 Pcs</td>
<td>-</td>
<td>2 Pcs</td>
</tr>
<tr>
<td>4</td>
<td>YDB</td>
<td>1 Piece</td>
<td>-</td>
<td>-</td>
<td>1 Piece</td>
<td>1 Piece</td>
</tr>
<tr>
<td>5</td>
<td>Power line</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
</tr>
<tr>
<td>6</td>
<td>Fuse</td>
<td>2 Pcs</td>
<td>2 Pcs</td>
<td>2 Pcs</td>
<td>2 Pcs</td>
<td>2 Pcs</td>
</tr>
<tr>
<td>7</td>
<td>Abdominal Binder</td>
<td>2 Pcs</td>
<td>2 Pcs</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>Instruction Manual</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
<td>1 Piece</td>
</tr>
</tbody>
</table>
XI. Register information and contact method

Product Name: Anorectal Physical Therapy Device

Manufacture/Register/After service unit: Zhengzhou Safute Electronic Equipment Co., Ltd.

Register address: No. 8 Guohuai Str, High & New Technology Industries Development Zone, Zhengzhou, Henan, China

Manufacture address: B-9th Floor, Torch Building, No. 8 Guohuai Str, High & New Technology Industries Development Zone, Zhengzhou, Henan, China

Tel: (0371) 67897038/67897039  15638216292
Fax: (0371) 67897036  After service: (0371) 67985399
Email: safute@163.com  Website: www.safute.com

Hot-line for free: 400-659-7595

Our enterprise has passed the ISO13485 Medical Device Quality Management System