

GT-M08

Medical digital
electroacupuncture instrument

(Gastrointestinal motility improving)

INSTRUCTION BOOK

【Preface】

This instruction book is applicable to medical digital electroacupuncture therapeutic instrument which has gastrointestinal motility-stimulating function (abbreviated as therapeutic instrument below), which can be read and consulted by medical staff or family users. Before using, please read this instruction book carefully, so as to operate the instrument correctly and get good effect. After that, please keep this instruction book properly for future usage.

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Preface

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1. Brief introduction of manufacturer of the instrument and the product

(1) Scope of application of this product

This therapeutic instrument is a conventional therapeutic instrument used in alimentary system department or physiotherapy and rehabilitation department, which is suitable for the clinical treatment of gastrointestinal motility disorder and related diseases. It can also be used by families or individuals for prevention and cure of diseases and for healthcare under the guidance of medical staff.

Clinical applications by national drug experimentation base such as Zhujiang Hospital affiliated to Southern Medical University and the 1st affiliated hospital to Guangzhou University of TCM shows: this motility-promoting therapeutic apparatus can be used in patients with gastrointestinal diseases, liver and gall diseases, and patients with chronic diseases such as pneumocardial disease, diabetes mellitus, apoplexy with sequelae accompanied by clinical symptoms of gastrointestinal motility disorders. Using this motility-promoting therapeutic apparatus according to operating instructions can obviously improve symptoms of gastrointestinal motility disorder such as sour regurgitation, epigastric distention, belching, nausea, vomiting and constipation.

(2) Function, configuration and composition of the product

This therapeutic instrument contains mainframe (figure 1) and accessories (figure 2), along with an operating instruction book, please check if



Figure 1 Appearance of the mainframe of the therapeutic instrument

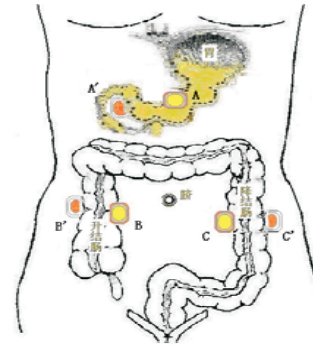


Figure 3 the projection of stomach and colon in body surface and the pasting area of the electrodes (electrodes A, B, C are put on belly, electrodes A', B', C' are put on waist and back)

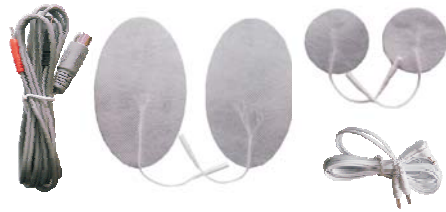


Figure 2 Accessories of the therapeutic instrument

The number of output channels, position of sockets and the intensity-modulating turnbuttons are listed in table 1.

Table 1 Output channels of medical digital electroacupuncture therapeutic instrument (gastrointestinal motility-stimulating)

	Position of big electrode channels and output line sockets	Sign of the turnbutton for modulating output intensity	position of small electrode channels and output line	Sign of the turnbutton for modulating output intensity
Professional Type	Back side of the cabinet 1 group	H1	front side of the cabinet 4 group	H1-E1-E2-E3
Enhanced Type	Back side of the cabinet 3 group	HE1-HE2-HE3	front side of the cabinet 6 group	E1-E2-E3 E4-E5-E6

2. The effecting mode and principles of the instrument

The effect and principle of this instrument

a. Promote gastrointestinal motility

When Complete-motility mode is selected on the therapeutic instrument, para-gastrointestinal bioelectricity pulse complexes will be exported, through electrodes sticked to the abdominal wall of the projecting area of stomach and intestine, to stomach and colon whose functions are not good (figure 3) and these benign effect can be acquired as follows:

- **Promote the motility of gastrointestinal smooth muscle directly**
- Stimulate the gastrointestinal pacemaker cells, or leading to following effect, to urge the gastrointestinal organs to recover to normal rhythm.
- **Modulate the function of enteral nervous system**

Therefore, the therapeutic instrument can effectively prevent and cure diseases of gastrointestinal motility disorder, obviously improve patient's symptoms of abnormal motility such as acid regurgitation, epigastric distention, belching, nausea, vomiting, and constipation etc., so as to enhance the health level and quality of life.

b. Effect of meridian modulation

When Mode of motility plus meridian is selected, the para-gastrointestinal bioelectricity pulse complex will be exported, except for importing into stomach or colon organs, there are other electrodes importing them into points as Zusanli and Sanyijiao etc., through Foot Meridian of Stomach-Yangming and Foot Meridian of Spleen-Taiyin, it can regulate the balance of neuro-endocrine and meridians, so it can benefit the prevention and cure of gastrointestinal motility disorder diseases and healthcare.

c. Partial electric massage and point stimulation

When the complete-meridian mode is selected, classical electric pulse will be exported, it is introduced through electrodes sticking to the painful part or relevant points. Through its meridian effect, it can prevent neuralgia and injury of muscles, tendons and joints.

(2) Kinds of the exporting electrodes and their function

a. Adhesive electrode

Stick the gel adhesive electrode onto the projecting area of stomach-colon on the abdominal wall(P2 Figure3), and points of zusanli, sanyinjiao etc(Figure 4). The para-gastrointestinal bioelectricity can promote gastrointestinal motility, regulate neuro-endocrine and meridian equilibrium through these electrodes, so as to prevent and cure gastrointestinal motility disorder diseases.

Besides, the adhesive electrode can be stucked to the local place of the illness or relevant points. When complete-meridian mode of this apparatus is set, classic electric pulse can be imported into relevant points through these electrodes, and neuralgia or injury of muscle tendons, bones and joints can be treated.

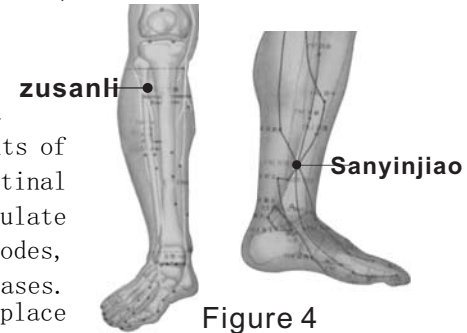


Figure 4

3. Anticipated user and basic requirements

(1) Medical care personnel

After training or reading booklet of directions, this therapeutic instrument can be used to make clinical treatment for patients with gastrointestinal motility disorders or related diseases.

(2) Literate patients with medical knowledge

After training, or under the guidance of medical care personnel, or after reading this booklet of directions, this therapeutic instrument can be applied to cure the disease related to gastrointestinal motility disorder. Also can it be applied to regulate sub-health.

(3) Other literate personnel with medical knowledge

After training, or under the guidance of medical care personnel, or after reading the booklet of directions, this therapeutic instrument can be applied to treat indications of themselves, family members and others, or make prevention and cure for the related disease of gastrointestinal motility disorder, along with sub-health health care.

4. Pre-use preparation of this instrument

Therapeutic instrument Put the instrument horizontally onto the desktop; insert the power line plug into the 220 V alternating current contact socket.

Accessories Insert the output line pins into electrode holes, then put the plug on the other end into the output faucet of the mainframe.

If there is smear on the surface of the electrode, moisten the cotton yarn with clear water, washing the surface of the electrode, then open-air dry it for next use.

5. Operating procedure of the instrument

(1) Skin preparation and sticking of the electrodes

The patient lies in a prostrate position, exposing abdomen and lower back part, then clean it with a damp-dry towel. After it is dry, paste the big adhesive electrode onto the projecting area of stomach and colon. The concrete position or numbers of the pasted electrodes depend on the specific condition of the patient's gastrointestinal motility disorder. Refer to table 2, following text and picture 3.

Table 2 Area for pasting----gastrointestinal motility-promoting electrode

Organ	Pasting area of the electrodes on abdomen	Pasting area of the electrodes on the back
Stomach	A--At the midpoint of the line from the xiphoid process to the umbilicus	A'--Opposite to the point at the abdomen, 3cm deviation to the right
Ascending Colon	B--At the horizontal level of umbilicus, 5cm to the right axillary line	B'--Just opposite to the point at the abdomen
Descending Colon	C--At the horizontal level of umbilicus, 5cm to the left axillary line	C'--Just opposite to the point at the abdomen

* If the patient has only gastric motility disorder, then it is enough to paste only one pair of stomach electrodes.

* If the patient has disease of colon motility disorder, then the electrodes of ascending colon and descending colon should be pasted together.

* If the patient has motility disorder in stomach and colon, then the electrodes of stomach, ascending colon and descending colon should be pasted.

If there are imbalance of neuroendocrine system and meridians, treatment of pi-wei and meridians can be conducted at the same time. The patient exposes lower limbs, after cleaning relevant area, paste the electrodes onto points such as zusanli and sanyinjiao, etc(P5Figure 4).

If the patients have neuralgia or have injury or pain in the locomotor system, then stick the electrodes to the local area of injury or related points.

【Special Attention:】

This therapeutic instrument has specially designed the output safeguards function. After starting the machine, or at any time when the operation is stopped, the therapeutic machine will automatically enter safeguard-detecting program. If there is any output (intensity) modulation turnbutton not turned to the very left (resetting), then the reset character will sparkle on LCD screen, the buzzer generates continuous BB alerting sound; the instrument won't export any pulses, and there are no response when pressing any buttons.

Therefore, before or after turning on the power switch, or after the instrument stops running at any time, all the output modulation turnbuttons should be checked that if they are turned left to the end, if not, then reposition them. After that, the buzzing will stop, the reset character in the status bar of the LCD screen will light on; which means that the machine has prepared well, and treatment can be started. After starting, the output modulation turnbutton should be rotated rightward slowly, thus make the pulses of corresponding channels increase to proper intensity gradually, and preventing the uneasiness made by sudden too big stimulation of pulse to the body.

(2) Opening the machine

Turn on the power switch in the right rear of the therapeutic instrument's mainframe, then the power indicating lamp on the panel and the LCD will shine. The therapeutic instrument then goes into safeguard detecting alert program. When all output (intention) modulation turnbuttons have turned left to the end (i. e., resetting), the character reset in the status bar on the upper-left part of the LCD screen will light on. See P10 picture 6.

If there are any output modulation turnbuttons not repositioned, then the reset character on the LCD screen will flicker, the buzzer utters continuous BB alerting sound, and there is no electric pulse output. At this time, all output modulation turnbuttons should be turned left to the end. Then the reset character on the LCD screen will light on, and the buzzing will stop.

(3) Output line linking

Check if the output wire plug is inserted into the electrode hole, and the other end is inserted into the mainframe output sockets. If it isn't linked well, please do it well according to directions.

(4) Setting of the therapeutic mode

There are 3 working modes in the therapeutic instrument.

Complete motility-promoting mode: there is code for the mode PP displaying on the LCD. All channels export para-gastrointestinal bioelectricity motility-promoting waves; it is introduced through electrodes placed on the abdomen which is the projecting area of stomach and colon, and can enhance or regulate gastrointestinal motility directly. It is used for the prevention and cure of gastrointestinal motility disorder diseases and the healthcare for gastrointestinal function.

motility-promoting plus meridian mode: there is code for the mode PE displaying on the LCD. All the channels export para-gastrointestinal bioelectricity motility-promoting waves; it is introduced through

electrodes on the projecting area of stomach and colon of the abdomen, which can enhance or regulate gastrointestinal motility. Other electrodes are pasted in bilateral zusanli and sanyinjiao, which can regulate neuro-endocrine and meridian balance through Foot Meridian of Stomach-Yangming and Foot Meridian of Spleen-Taiyin; and which benefits the prevention and cure of diseases of gastrointestinal motility disorder and the healthcare for gastrointestinal function.

Complete meridian Mode: there is code for the mode EE displaying on the LCD. All the channels export classic electric pulse combinations; they are imported through electrodes in local painful area or relevant points, and can prevent and cure neuralgia and injury of tendons, bones and joints through meridian effect.

After turning on the power switch, the user can make a cyclical selection of the therapeutic mode (Figure 5) by pressing Mode button on the left panel. At that time, the mode status bar at the right upper corner of the LCD will display corresponding code of mode (picture 6).

If there is any output modulation turnbutton not repositioned, then the reset character on the LCD screen will flicker, the buzzer utters continuous BB alerting sound. At that time, all output modulation turnbuttons should be turned left to the end. Then the reset character in the status bar on the LCD screen will light on, and the buzzing will stop. Then the mode selection can begin.

In the process of running, if the working mode is need to be changed, then all the output modulation turn button should be repositioned first, and press On/Off button to stop running, then the Mode button can be pressed to choose working mode.



Figure 5 Left-side panel and the function key of the therapeutic



Figure 6 LCD displaying screen of the

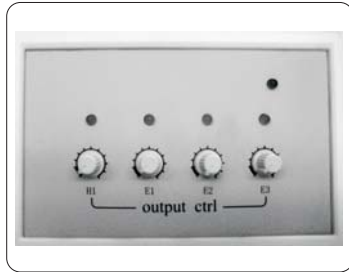


Figure 7
Panel of
professional type
therapeutic
instrument and the
turnbuttons for
modulating output
intensity and their
signs



Figure87
Panel of
enhanced type
therapeutic
instrument and
the turnbutton
for modulating
intensity and
their signs

(5) Start the treatment

After the therapeutic modes are defined, press **【on/off】** button on the left panel once, the therapeutic instrument is on. At this time, Run character in the upper-left status bar on the LCD screen will light on. Refer to P10 picture5 and picture 6.

(6) Setting the therapeutic time

The therapeutic time can be set from 5-60 minutes. Therapeutic time is displayed at the lower-right corner on the LCD (P10 Figure 6).

When the instrument is started, the default therapy time is 35 minutes. The operator can press **【time】** button to step up the therapy time. once the **【time】** button is pressed, another 5 minutes is added up, if the therapy time is added to 60 minutes, it returns to 5 minutes; The setting can be cyclical.

After the motility-improving therapeutic instrument is started, the time that the LCD screen shows is countdown. When the set therapeutic time is reached, the machine stops output automatically, at the same time the buzzer makes 10 times of B sound, which means the preset treatment time is reached.

(7) Output intensity modulation

In order not to make too strong stimulation to the body by the electric pulse, the operator should turn each Output Modulation button slowly rightward, to regulate the outputting electric pulse of corresponding channel to proper intensity, then there will be good feeling of skin electric stimulation, point needling feeling and feeling of gastrointestinal peristalsis, and the best therapeutic effect can be acquired. The output intensity of each channel will be shown directly by the brightness of the corresponding indication lamp. (P11 Picture 7, picture 8)

If there is no slight stimulating feeling at the area of the pasted electrode after gradual output amplification, then the electrodes should be checked that if they are properly pasted, and that the wire is linked well or not. After relative disposal, modulate the output intensity again.

After that, formal therapeutic process begins. During therapeutic time the outputting intensity of related channels can be modulated repeatedly upon demand.

(8) Ending of the treatment and packing up the instrument

When the set therapeutic time is reached, the time shown on LCD screen is zero; the therapeutic machine stops pulse output automatically, at the same time the buzzer makes 10 times of B sound, which means the set therapy time is reached. After that, the reset character will sparkle in the status bar on LCD screen, the buzzer generates continuous BB alerting sound. At this time, users should take steps as follows:

* All the output modulation turn buttons should be turned left to the end. After that, the reset character in the status bar of the LCD screen will light on, and the buzzing will stop simultaneously. At this time, the instrument has prepared well, and can be started once more.

* If the treatment is over, collect the electrodes from the sticking area as routine, and stick them to the film for next use.

* If the machine needn't run for a period of time, then the power can be switched off.

* Pluck up the power plug.

* If the machine won't be used for a long time, then the output wire of the electrode can be pulled out from the socket on the machine.

* Preserve the instrument properly for next use.

In the course when the therapeutic instrument is running, if needed, the 【on/off】 button may be pressed down once more, then the electric pulse output will be stopped. The condition occurred after that and the operating measures are the same as that when the instrument reaches set time.

6. Contraindications

* For the patients with emotional disturbance and unconsciousness, this motility-promoting therapeutic machine can't be used by themselves.

* This motility-promoting therapeutic machine can't be used by children alone.

* For child whose fontanel hasn't closed, electrode is prohibited to paste on parietal region.

* This motility-promoting therapeutic machine can't be used in pregnant woman.

* This motility-promoting therapeutic machine is contraindicated for patients with autogenous hemorrhage or post-injury incessant bleeding.

* This motility-promoting therapeutic machine is contraindicated for severe heart disease with arrhythmia.

* Areas of broken skin, infection, ulcer, scar or tumor are inappropriate for pasting electrodes.

* For the patient who is easy to have acupuncture syncope, or woman who is in menstruation, this motility-promoting therapeutic machine should be carefully used.

* When the patient is hungry, tired, or is overstressed, this motility-promoting therapeutic machine should not be used immediately.

* For the patient who is skinny or whose qi and blood is in deficiency, the output should not be too strong when using this motility-promoting therapeutic machine.

* Pasting of skin electrode should choose proper area, to avoid the imported current passing across the heart.

* For the patient who has installed electronic instrument (such as heart pacemaker), if there is no doctor's advice, this therapeutic instrument cannot be used.

7. Announcements

This motility-promoting therapeutic instrument should be operated by medical staff. If it is used by family members, that should be under medical staff's guidance.

(1) Cautions

* When high-frequency surgical apparatus and this motility-promoting therapeutic instrument are linked to patient's body at the same time, the electrodes of this therapeutic instrument may injure skin, and the therapeutic instrument could be damaged. When using this therapeutic instrument near shortwave or microwave therapeutic apparatus, the output may become unstable, and should be avoided.

* This motility-promoting therapeutic instrument cannot be used simultaneously with heart lung machine.

* The metal pins and electrodes of the output wire should avoid direct contact, in order not to damage the instrument.

* Please do not dismantle, beat or strike this therapeutic machine by yourself.

(2) Possible side effect and easy disposal

* If this therapeutic instrument is applied when the patient is hungry, tired or whose mind is overstrain, discomfort may occur. The electric stimulation should be paused. Resting for a while or drinking a little warm sweet water will release it.

* During or after using the therapeutic machine, there maybe sensations such as sourness, numbness, distension or pain in patient's local body. These are normal responses, after that, it will relieve and recover.

* Other side-effects of electric pulse stimulation and the disposal are the same as the routine in the department of physiotherapeutics and rehabilitation.

8. Performance parameter and specifications of the product

Importing power: alternating current, 220V 10%, 50 Hz

Power input: $\leq 15VA$ 。

Normal operational environmental condition: Ambient temperature: $5^{\circ}C \sim 40^{\circ}C$; Relative humidity: $\leq 80\%$; Atmosphere pressure: $86kPa \sim 106kPa$ 。

Discharged waveform: para-gastrointestinal bioelectricity motility-promoting wave, classic combination of electric pulses.

Output pulse width: 1ms.

Output pulse electric quantity: the maximum output electric quantity of single pulse is greater than $7 \mu C$.

Output energy per pulse: the maximum output energy per pulse is lower than 300mJ.

Maximum output amplitude: In rated load impedance, the effective output voltage of the electric pulse imported into the skin electrode is lower than 25V, and can be modulated continuously and evenly between 0~25V.

Timing of therapy: 5 minutes to 60 minutes, 5 minutes' stepping-up can be modulated. When started, the default time of therapy is 35 minutes.

Environmental condition for transportation and storage: Ambient temperature between $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$; relative humidity range: $\leq 93\%$; Range of atmospheric pressure: $50\text{kPa} \sim 106\text{kPa}$.

Net weight: 1.6 kg.

Size of the mainframe: 210 206 100 mm.



II-level safety common equipment(BF type) avoid dampness handle with care place upwards

9. Maintenance and conservation of the instrument

* **Maintenance of the instrument** The instrument should be kept clean, avoid dropping of liquid onto the instrument, or it will be prone to dysfunction.

* **Preservation of the instrument** After using the instrument, the power should be switched off, the power plug be pulled up, and the output wire plug be pulled out. Store the instrument properly for next use.

* **Storage of the apparatus** This motility-promoting therapeutic instrument should be kept in a room whose temperature is between $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$, the relative humidity no more than 93%, no erosive gas and well-ventilated, sunlight and damp should be avoided.

10. Common-seen trouble and management

Manifestation of the failure	Possible cause	Treatment
No output (No display on the LCD screen)	The power hasn't been well plugged	Plug the power line well
	Malfunction of the power switch	Check the power switch
	Breakout of the fuse	Replace the fuse tube (0.3A ϕ 5 20)
No output or the output is unstable (the LCD screen has display)	The plug of the output wire doesn't insert tightly into the socket of the mainframe	Insert the output wire plug tightly into the socket of the mainframe
	The pin of the output wire doesn't insert tightly with the electrode socket	Insert the pin of the output wire tightly with the electrode socket
	Breakage of the output wire	Change the output wire
	There are dirt on or aging of the skin electrodes	Clean the skin electrodes or change new electrodes
	There is no cotton yarn in the disc electrodes, or no physic liquor dripped in, or doesn't cling to the skin tightly	Put the cotton yarn into the disc electrodes, dripping q.s. physic liquor, and cling the electrodes tightly to the skin

11. Guarantee to keep this product in good repair (Guarantee card)

We will do our best to offer satisfactory after-service, and we promise that after the purchasing date, it can be kept in good repair for free in 2 years; After 2 years, we provide long-term maintenance service, and we only charge cost for spare parts. The freight charge or postal charge coming with the maintenance will be afforded by consumers.

A warm and fragrant remind to you, that these conditions below exceed the range for free repair:

- * Use this instrument beyond the guide of the instruction book, and make artificial damage to this product.

- * The instrument has been disassembled and assembled by maintainer not authorized by our company.

- * Product damage caused by irresistible force such as natural disaster etc.

- * Accessories such as the output wire, skin electrodes, magic band, power line etc.

- * Booklet of instructions, packing case.