



产品名称

说明书

美国TrendMedical

文件编号

KTR-JS-2230-11-01-A

版 本

A/1

产品名称

经皮神经肌肉刺激器

产品型号

KTR-2230

尺 寸

65x 120mm

编制

吴 昊

日期

20260724

材 质

80G书写纸/骑马钉

审核

日期

颜 色

CMYK

批准

日期

料 号



Transcutaneous Electrical Nerve Stimulator



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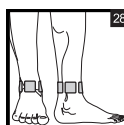
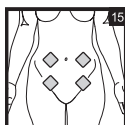
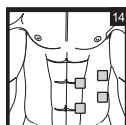
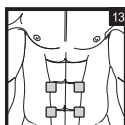
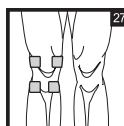
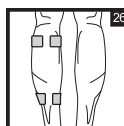
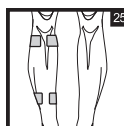
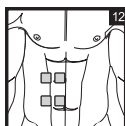
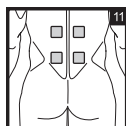
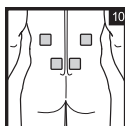
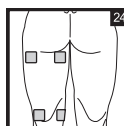
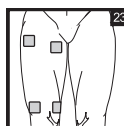
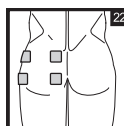
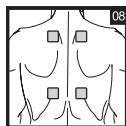
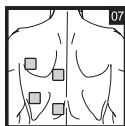
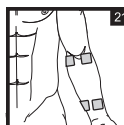
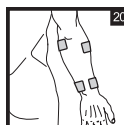
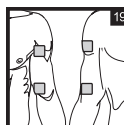
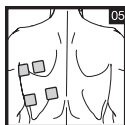
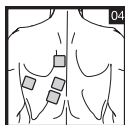
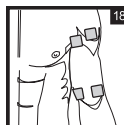
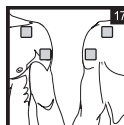
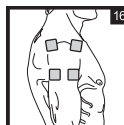
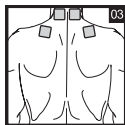
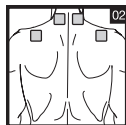
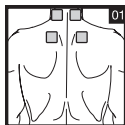


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User Manual KTR-2230

Thanks for choosing this product
please read this User Manual carefully before use

Therapy Position Suggestions



TENS Mode	Reasonable areas of application / Indications	Possible electrode positions	Recommended time (Min)
1	Low back pain 1	4-11	30
2	Low back pain 2	4-11	30
3	Rheumatic pain 1	1-28, especially 27	30
4	Rheumatic pain 2	1-28, especially 27	30
5	Sore thighs 1	22-24	30
6	Sore thighs 2	22-24	30
7	Shoulder pain 1	1-9, 16-19	30
8	Foot pain 1	23-26, 28	30
9	Shoulder pain 2	1-9, 16-19	30
10	Rheumatic pain 3	1-28, especially 27	30
11	Shoulder pain 3	1-9, 16-19	30
12	Sore thighs 3	22-24	30
13	Foot pain 2	23-26, 28	30
14	Shoulder pain 4	1-9, 16-19	30
15	Low back pain 3	4-11	30
16	Foot pain 3	23-26, 28	30
17	Low back pain 4	4-11	30
18	Sore thighs 4	22-24	30
19	Sore thighs 5	22-24	30
20	Shoulder pain 5	1-9, 16-19	30

EMS Mode	Reasonable areas of application / Indications	Possible electrode positions	Recommended time (Min)
21-40	Used to relax muscle spasms, Promotes physical recovery	1-28	30

Fitness Mode	Reasonable areas of application / Indications	Possible electrode positions	Recommended time (Min)
41-50	Strengthening local muscle development	1-28, especially 12-14, 16-24	15

1. Product Introduction

Transcutaneous Electrical Nerve Stimulator (Models: KTR-2230) is a portable and battery powered multifunctional device, offering Transcutaneous Electrical Nerve Stimulator (TENS), Electronic Muscle Stimulator (EMS) and FITNESS qualities.

Transcutaneous Electrical Nerve Stimulator (Models: KTR-2230) has 50 operation modes, which can give certain electrical pulse through 4 pcs of electrode pads placed on the skin to help users to enjoy body massage. The electronic stimulatory module has the operating elements of ON/OFF Key, Display screen, Mode Selection key and Intensity Modification keys. The LCD display screen can show selected mode and program, output intensity, stimulate frequency, and time remaining of an application mode.

The device is equipped with accessories of electrode pads, electrode wires, and batteries. The electrode wire is used to connect the patches to the main unit. All the accessories, including electrode pads, electrode wire, and batteries can only be changed by special person.

The electrode pads are complying with the biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization), are interchangeable.

2. Product Intended use

TENS (Mode 1~20)

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.

EMS (Mode 21~40)

It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

FITNESS (Mode 41~50)

Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen.

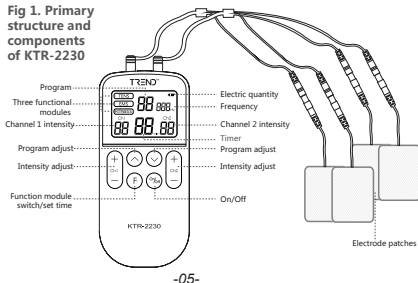
3. Contraindication

- a) The long-term effects of chronic electrical stimulation to the human body are not known.
- b) Patients with cardiac pacemaker are disabled!
- c) Patients with suspected or confirmed have epilepsy, heart disease, pregnancy or menstruating women are prohibited.
- d) Treatment parts have the haemorrhage after acute trauma or fractures, disabling wound healing stage after the operation.
- e) Treatment is not sensitive to heat or electrical stimulation of the skin patients disabled.
- f) Disturbance of consciousness or disabled children.
- g) Treatment of swelling, skin infection or with skin disease, phlebitis patients disabled.
- h) With wet skin after shower, sweating and disabled when you go to sleep.
- i) Driving traffic tools or disable during movement.
- j) Metal allergies are disabled.

4. Primary Structure of Product

Transcutaneous Electrical Nerve Stimulator (Model:KTR-2230) mainly consists of main unit, electrode patches and electrode wires. The primary structure and components as shown below:

Fig 1. Primary structure and components of KTR-2230



5. Product Main Features

- The design is on the basis of ergonomics and is beautiful science, compact easy to carry;
- The LF electric pulse come into being an efficient composite energy field;
- Multi-function and multi-site remission,
- There are alternative functional modules, adjustable treatment time, and adjustable intensity;
- There is LCD display;

6 Product Requirements and Major Parametric Description

6.1 Product Power Requirement

- a) Power source: DC 4.5V (3*AAA LR03 battery), 180mA
- b) Device safety classes: class II type BF

6.2 Product Main Technical Parametric description

- a) Impulse frequency:
TENS:(20-100)Hz, EMS:(1-15)Hz, FITNESS:(2-16)Hz.
- b) Pulse width:
TENS: 120 μ s, EMS: 200 μ s, FITNESS: 200 μ s.
- c) Impulse waveform: square wave
- d) Pulse duration: ≤ 3 seconds
- e) The product output has no the DC component.
- f) The individual pulsing electric quantity when in the maximum output amplitude: $> 7\mu C$.
- g) The maximum output energy of individual pulse: $\leq 300mJ$.
- h) The effective value of maximum output amplitude: 40-110V.
- i) In the open measurement, the output voltage peak: $\leq 500V$.
- j) Influence of output end open circuit and short circuit: it is able to support the influence of output end open and short circuit, and its performance will not be allowed to weaken.
- k) Adjustment of output amplitude: 0-16 levels, the minimum output is 0-10 Vpp, and the maximum output is 40-110 Vpp.
- l) The timer of therapeutic equipment: 15 minutes, 30 minutes, 45 minutes, $\pm 10\%$ franchise.

- m) Safety classification: internal electric source class and type BF equipment
n) Boundary dimension:
Main unit (KTR-2230: length 120mm * width 55mm * height 20.4mm);
Electrodes: 50mm*50mm;
o) Product software version No.: A/0
p) Service life: the shelf life of subject device is 2 years; the use life of the small Electrode Pad is 150 times and shelf life is 2 years

6.3 Product Environmental Requirement

(Transportation and storage environment between secondary uses)

a) Normal work environmental requirements:

Environment temperature: +5 C ~+40 C ;

Environment humidity: 15%-93%RH;

Atmospheric environment conditions: 700hPa-1060hPa.

b) Storage environment requirements:

Environment temperature: -25 C ~+55 C ;

Environment humidity: 0-93%RH;

Environment conditions: 700hPa-1060hPa.

c) Transport environment requirements:

Environment temperature: -25 C ~+55 C ;

Environment humidity: 0-93%RH;

Environment conditions: 700hPa-1060hPa.

Note: When the product is stored at around its minimum or maximum storage temperature, it needs to be placed at a normal ambient temperature (about 20 C) for about 2 hours to restore its function.

7 Method of application

7.1 Power supply operation

1) The installation of battery

Install the 3*AAA LR03 batteries according to the positive and negative electrodes of the screen printing battery on the back cover of the main unit.

2) Connect the components

According to Fig 1, connect the main unit and electrode patches with the electrode wires.

3) Turn on/off

Press the " On/Off " key can turn on the main unit, the power light is

lightened, the working routine is started and the LCD backlight of remote control is lightened. Press the "On/Off " button again, the machine shut down and the screen is off.

7.2 Functional operation

- 1) Attach the electrodes to the stimulate parts, if there is a perspiration in your body, it must be clean to use.
- 2) Press the " On/Off " key can turn on the main unit. The device would be default mode of TENS, there are 20 fixed programs.
- 3) The use of the key " ^ " 、 " v " of program selection:
" ^ "key as an option to Up select; " v " key as an option to Down select
- 4) The use of the key "+ " 、 " - " of intensity adjustment for channel 1 and channel 2. Each channel has 0-16 levels.
"+ " can enhance intensity;
"- " can decrease intensity.
- 5) Mode switch
Short press " F " key to switch three major modes of TENS, EMS, and FITNESS;
- 6) The adjustment of timing
Long press " F " key for 3 seconds to set up the stimulation time of 15 minute, 30 minute, and 45 minute;
- 7) There are 20 fixed programs for TENS, 20 fixed programs for EMS and 10 fixed programs for FITNESS.
- 8) The output frequency of the product is displayed on the LCD.

7.3 The use of battery

- 1) The main unit adopts the 3*AAA LR03 batteries, can use about 50days (according to use 30 minutes a day).
- 2) When pressing the key, the brightness of LCD is distinct weakening or the stimulation intensity changes is very slightly when press the key of intensity adjustment, showing the electric quantity of battery is not enough and please replace the new battery.
- 3) If the product is not used for a long time, please take out the battery, otherwise it may cause the battery leakage and cause the machine error.
- 4) Do not use the outside of the specified battery.
- 5) Do not misplace the positive and negative pole of battery, the positive pole up, and the negative pole down.

- 6) Do not use this battery under the environment which more than 45 °C, otherwise it will affect the performance and life of the battery.
- 7) The discarding method of the post-batteries should be dealt with according to the urban environmental protection.

8 Safety Precautions

- The manual said that the purpose of warning sign and legend is safe and proper using the product by yours, and prevents the harm to you and others.
- The warning sign and legend as well as their meaning is as follows:

Warning Sign	Meaning
 using contraindication	It shows that it will appear the dangerous of casualties or serious injury in the error use.
 Warning	It shows that it will appear the possibility of casualties or serious injury in the error use.
 attention	It shows that it will appear the possibility of personal injury or damaged goods in the error use.

 attention	
-- The therapeutic apparatus cannot be used with the HF apparatus to avoid burns or damaged apparatus -- If the patient himself uses the therapeutic apparatus and HF apparatus at the same time, the part of massage plate may be cause burns on apparatus, it may also damage the apparatus; If use the apparatus near (1 meter) the short wave or microwave therapeutic apparatus, the output of apparatus may be instability. -- It will increase a danger of heart fibrillation by using electrode pads close to the chest. -- Do not modify this equipment without authorization of the manufacturer --When need replacing the lithium batteries, please contact aftersales staff designated and authorized by the manufacturer directly, its accessories shall not be replaceable.	

- Product battery replacement should be replaced by professional maintenance staff, otherwise it will produce risk.
- Shall not make personnel can no longer take care of themselves, infant, or not sensitive person use.
- Simultaneous connection of a patient to a high frequency surgical ME equipment may result in burns at the site of the stimulator electrode pads and possible damage to the stimulator.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- Application of electrode pads near the thorax may increase the risk of cardiac fibrillation.
- Advice that stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrode pads placed on the chest and the upper back or crossing over the heart.
- Prevent inhalation or accidental swallowing of small parts (including 3*AAA LR03 battery).
- Prevent sharp parts from damaging the product.
- Do not use accessories not specified by the manufacturer.



 using contraindication	
Pregnant women and women's menstrual period, person with sensitive skin, heart disease, abnormal blood pressure, malignant tumors, cerebrovascular patients, patients with acute disease or other person treated by doctor must consult a doctor rear can use this product.	
(1) It is contraindicated for use by those who has a skin perceptual disturbance or is not sensitive about the heat. (2) It is prohibited to use when bathing, sweating and sleeping. (3) The patient with cerebral hemorrhage: It should be disabled in unsteady phase; the person who has sequela must be used under supervision of doctors. (4) It is contraindicated for use by those who has purulent inflammation, acute blood poisoning and continuous hyperpyrexia. (5) It is contraindicated for use by those who has acute cardiovascular and cerebrovascular diseases. Please stop using it immediately to the doctor to consult when unwell felt or skin complaint in the process of use.	



precautions

Please do not use in the parts which is nearest heart, head, eyes, front neck (especially the carotid artery), lower back, oral cavity or pudendum, skin disease.



(1) It should be shut down then using again when the apparatus is moved or changed the therapeutic parts in the using process, otherwise there will be a strong stimulation.

(2) It is not permitted to give children or people who were no ability to express consciousness to use.

(3) If you feel unwell because of using the product, please stop using it immediately to the doctor consult.

(4) Please pull up the power plugs when you are done or do not use the product.

(5) Do not used in conjunction with other medical electronic devices, such as cardiac pacemaker, artificial heart and lung and other medical electronic devices with fuels life, electrocardiograph and other medical electronic devices, otherwise it will lead to danger.

(6) Do not use the product in the place where is direct sunlight, high heat, inflammable, electromagnetic radiation and humid.

(7) Do not disassemble, repair and transform the therapeutic apparatus, otherwise cause failure or get an electric shock accident.

(8) The therapeutic apparatus should be placed in the position which is easy to move the plugs to use, it is easy to move the plugs in emergency circumstances.

(9) Check the equipment before each use to avoid the exposed wires caused by accidental damages or other reasons.

(10) Dust may affect the performance of the unit, please use a dry soft cloth to clean the device as needed.

Please check whether the electrode is loose before each use, otherwise it may have adverse effects on performance or cause other problems.

This product contains connecting wires. Please prevent children from misusing them to avoid strangulation accidents.

The patient should be the intended operator.



9 Product maintenance

1) Before turn on the main unit, please check whether the battery is installed correctly, each connecting parts whether is connected in good;

2) If the apparatus runs normally, show key invalidly after press. To turn it off after a few seconds and then opening, if still not normal, check whether it is broken for the apparatus;

3) If all operation of the apparatus are normal but without output (the user without feelings) after turn it on. Please check whether the electrode is directly contacted with

skin, the contacting parts whether has hair, clothes and so on;

4) While cleaning, shutdown first, let the electrode wires stay away from the electric supply socket. You can wipe by using soft cloth or towel with a little water and after dry.

5) After each use, please clean electrodes, you can wipe by using soft cloth or towel with a little water and after dry, when conducting electrodes are particularly dirt, you can wipe by using soft cloth with a little medicinal alcohol (alcohol concentration as 75%).

6) The apparatus should be placed in the place which is dry, ventilated and good insulation use.

7) When the apparatus is moved, must be handled with care, avoiding the shake.

8) The apparatus should be checked the batteries condition, to check whether the output is good, if has abnormal conditions, you should pay attention to it and service it in time.

9) The apparatus' shell board should be pay attention to protection, avoiding the abrasion.

10) The non-professional cannot disassemble the host to avoid getting an electric shock or damaging the apparatus, an accident can happen because of it, all at your peril.

11) The product has a free warranty for one year and provided by the dealer, and there is a compensable maintenance for the goods which expired for the warranty period

10 Product Scrap Processing

The therapeutic equipment belongs to medical device, if the complete machine is already aging and is not able to use, the process mode according to the local legislation carry through scrap processing.

11 Accessories and Parts

Main unit	1 pcs	Battery	3*AAA
Electrode	2 pairs	Electrode wire	2 pcs
Manual	1 pcs		

12 The Paraphrase of Graphic Symbol

Graphic symbol	Paraphrase
	Product batch number tag
	Product serial number tag
	Manufacturer
	Production date
	Precautions
	EU representative
	Warning against danger

	Applied part of type BF
	This product only for indoor use
	It means prohibition (the thing was not permitted to do)
	It means enforcement (the thing must be observed)
	Keep out of the sun
	Keep away from rain
	Contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories.
	CE label and noticed body code
	The dustproofing and waterproofing grade, that is, to prevent the solid object is greater than 12mm to invade, the inclination of 15 degrees can prevent dripping invasion still not cause harmful effects.
	Medical device
	This symbol is used to direct the user to refer to documentation for additional information regarding the system use or description.

13 Executive Standards

The product conforms to the following standards and laws:

1. IEC 60601-1:2005+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.
2. IEC 60601-1-11:2020 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment.
3. IEC 60601-2-10: 2012+A1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
4. IEC 60601-1-2:2014+A1:2020 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.

Appendix EMC Declaration

The equipment is intended for use in the electromagnetic environment specified below.

The customer or the user of the EQUIPMENT should assure that it is used in such an environment.

The Transcutaneous Electrical Nerve Stimulator is suitable for use in a home healthcare environment.

- Do not use the system around strong electric field, electromagnetic field (e.g. MRI scan room) and mobile wireless communication devices. Using the device in an improper environment may cause malfunction or damage.
- The compliance with EMC and EMI regulation cannot be guaranteed by the use of modified cables or those which does not comply with the same standards under what the equipment was validated.
- The system must not be used adjacent or supported by other equipment. The recommendations of this manual must be followed.

- Do not use accessories, transducers, internal parts of components and other cables other than those previously specified by the manufacturer. This may result in increased emission or decreased electromagnetic immunity and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- To maintain basic safety in relation to electromagnetic disturbances during the expected service life, always use the system in the specified electromagnetic environment and follow the maintenance recommendation described in this manual.



- Following cable types must be applied to ensure compliance with standard of radiation interference and noise immunity

Cables	Length (m)	whether shielded
Charging cable	0.5/1	No
electrode connecting wire	1.2	No

The following tables provide information on compliance of the equipment according to the standard EN 60601-1- 2.

Table 1 Compliance class

Emissions Test	Compliance	Electromagnetic Environment and Guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	

Harmonic emissions IEC 61000-3-2	Class A	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2- Compliance standards

Phenomenon	Basic Standard of	Immunity Test	Level of
Electrostatic discharge	IEC 61000-4-2	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15KV air	±8 KV contact ± 2 K V, ± 4 K V, ± 8 KV, ±15KV air
Radiated RF EM fields ¹	IEC 61000-4-3	3V/m 80 MHz-2.7 GHz 80% AM at 1 KHz	3V/m 80 MHz-2.7 GHz 80% AM at 1 KHz
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table	See table
Electrical Fast/Transients bursts	IEC 61000-4-4	±1 KV 100 KHz repetition frequency	±1 KV 100 KHz repetition frequency
Conducted disturbances induced by RF fields.	IEC 61000-4-6	3V 0.15 MHz-80 MHz 6 Vm in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1KHz	3V 0.15 MHz-80 MHz 6 Vm in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1KHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

Table 3- Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipments

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 KHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE 13, 17 Band	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE 5 Band	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE 1, 3, 4, 25 Band, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE 7 Band	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						