深圳市健得龙医疗电子有限公司		产品名称	说明书	文件编号	KTR-JS-2492-11-01-A
				日　期	24.01.23
产品名称	经皮神经刺激器	产品型号	KTR-2492	版　本	A/1
编制		日期		尺　寸	L130 x W120mm
审核		日期		材　质	80G书写纸/骑马钉
批准		日期		颜　色	4C

KENTRO

Transcutaneous Electronic Nerve Stimulator

User Manual KTR-2492

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

Content

1. Foreword

Thank you very much for your trust and for you r purchase of Transcutaneous Electronic Nerve Stimulator. Our objective is to help you live a more enjoyable life with less pain. Before use, please read the User's manual carefully, so that you can operate it correctly for best results. The User's manual should be kept for future reference.

2. Warnings

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.

3. Intended use

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 and work activities.

4. Product Introduction

Transcutaneous Electrical Nerve Stimulators (Models: KTR-2492) is a portable and battery powered multifunctional device, offering Transcutaneous Electrical Nerve Stimulators .
KTR-2492 is remotely controllable, there is an accessory remote control, LCD display on remote control, display mode and treatment time And there are 6 modes for auto, and 9 modes for manual. Long press "F" key to choose the auto functions or manual functions. Short press "F" key to choose the Modes.
They can give certain electrical pulse through electrode pads placed on the skin to help users to enjoy body massage.
The electronic stimulatory module has unified the operating elements of ON/OFF button, Intensity Modification button and Mode selection button.
The device is equipped with accessories of electrode pads, batteries and remote control. All the accessories, including electrode pads, batteries and remote control 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.

5. Primary Structure of Product

The Transcutaneous Electrical Nerve Stimulators (Model: KTR-2492)The primary structure and components as shown below:

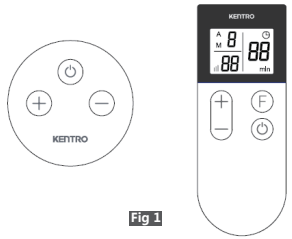


Fig 1

Fig 1. Primary structure and components of KTR-2492

6. Product Main Features

1.The device is convenient to carry, and is suitable for personal health care;
2.Electrode patch intelligent detection and protection, users use more secure;
3.Electric pulse combination, 16 level strength can be adjusted, according to personal preferences to adjust the need;
4.Integrated fuselage design, functional operation, simple and clear;
5.Rechargeable lithium design, built-in power protection circuit, easy to use, safe;
6.Contains a variety of massage procedures, can meet different massage needs, suitable for a wider range of people;

7. Product Requirements and Major Parametric Description

7.1 Product Power Requirement

a) Power source: Rechargeable lithium battery3.7v/100mAh
b) Device safety classes: class II type BF

7.2 Product Main Technical Parametric description

a)Impulse frequency:
TENS:20-100Hz
b)Pulse width:
TENS: 120μs
c)Impulse waveform: square wave
d)The product output has no the DC component.
e)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.
f)Adjustment of output amplitude: 0-16 levels.
g)The timer of therapeutic equipment: 15 minutes.
h)Safety classification: internal electric source class and type BF equipment
i)Boundary dimension:
Main unit :Model KTR-2492: Φ49.8*12.48
j)Product software version No.: A/0

k)Service life: the shelf life of subject device is 2 years; the use life of the Electrode Pad is 80 times and shelf life is 2 years

7.3 Product Environmental Requirement

a)Normal work environmental requirements:
Environment temperature: +5℃~+40℃;
Environment humidity: 0%-80%RH;
Atmospheric environment conditions: 860hPa-1060hPa.
b)Storage environment requirements:
Environment temperature: -25℃~+55℃;
Environment humidity: 0-93%RH;
Atmospheric environment conditions: 500hPa-1060hPa.
c)Transport environment requirements:
Environment temperature: -25℃~+55℃;
Environment humidity: 0-93%RH;
Atmospheric environment conditions: 500hPa-1060hPa.

8. Method of application

(1)Preparation before use
Use the electrode plate for the first time, install the electrode plate to the master machine of the massage machine, and then align the metal buckle of the main machine to remove the film on the electrode sheet;The electrode film is affixed to the main body of the massage instrument;Attach the main body to the use part;
(2)Switch machine
Press ⏻ key, the host boot starts, at the same time will send the “drop” sound prompt, the strength output default is 0, the host starts to work; the default is the first mode of operation. Press the ⏻ key again, then turn off the machine.
(3)Charge
If you can't turn on the machine, or turn it off automatically, or when the buzzer is alerted for 30s, it indicates that the product needs to change the battery.
(4)Regulating intensity
Users can press the “+” key, set the strength, press the “-” key, you can reduce the strength; short press the “+” key or “+” key strength will increase

or lower level, at the same time will send out a “drop”, the user can choose their own strength, in order to the most comfortable; (a total of 0≤16 levels of strength adjustment)

The host computer has the intelligent detection function, when the electrode piece and the skin contact is good, the main opportunity moderates the force, reaches the set strength directly;

(5)Mode selection

There are 6 modes for auto, and 9 modes for manual. Long press “-” key to choose the auto functions or manual functions. Long press “+” key to choose the Modes. When the mode is switched, the strength automatically recovers to the "1" file to prevent the intensity from being very high at the beginning of the mode switching, which makes the user feel uncomfortable. According to their own preferences, the user can choose different working modes.

(6)Automatic / manual mode selection(Remote control)

There are 6 modes for auto, and 9 modes for manual. Long press “F” key to choose the auto functions or manual functions. Short press “F” key to choose the Modes.

(7)shut down

Work from start to end about 15 minutes, 15 minutes after automatic shutdown;

If the host is not used in the boot state, if the host is not used within 30 seconds, the host will automatically shut down the computer.

Press the ⏻ key, you can manually shut down the machine halfway;

8.1 The use of battery

1)The device powered by the lithium battery, which can rechargeable through the adapter.

2)If the indicator is flashing, showing the electric quantity of battery is not enough and please charging in time.

3)If it is not used for one month or long term, please fully charge it first.

4)Do not use the device under the environment which more than 45℃, otherwise it will affect the performance and life of the battery.

5)The discarding method of the post-batteries should be deal with according to the urban environmental protection.

9. 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 Sigh	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,nfant, 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.

10. 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 pads 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 electrode pads, you can wipe by using soft cloth or towel with a little water and after dry, when conducting electrode pads 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.

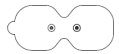
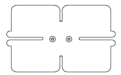
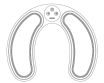
11. Product Scrap Processing

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.

12. Accessories and Parts

12.1 Electrode pads

Electrode Pads of Transcutaneous Electrical Nerve Stimulators
Please see all the electrode pads in the table below. The electrode pads here are for customers to choose

NO.	Model	Picture	Size	Effective Area (cm2)	Material
1	EPAD -H01		125×55mm	26	Hydrogels
2	EPAD -H02		130×60mm	22	Hydrogels
3	EPAD -F01		176×105mm	73	Hydrogels
4	EPAD -F02		166×166mm	80	Hydrogels
5	EPAD -F03		192×160mm	78	Hydrogels
6	EPAD -B01		240×65mm	50	Hydrogels
7	EPAD -T01		393×110mm	92	Hydrogels
8	EPAD -Z01		380×268mm	140	Silver paste

12.2 Remote control

Figure 2 Accessories of Transcutaneous Electrical Nerve Stimulators , This product is equipped with one of the following two remote controllers: KTR-2491A and KTR-2491B.

Fig.2

13. The Paraphrase of Graphic Symbol

Symbol	Explanation
LOT	Production Batch
REF	Product catalogue reference code
	Manufacturer (Regulation (EU) 2017/745 for Medical Devices)
	DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture
	Caution
	Applied part of type BF
EC REP	European Authorized Representative
	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements..
CE 2862	CE marking with the Registration Number of the Notified Body. Regulation (EU) 2017/745 for Medical Devices
IP22	Level of protection against the insertion of solid bodies of size/diameter ≥ 12 mm and liquids in the presence of dripping water when tilted at 15° compared with product.s.
	Refer to instruction manual/ booklet
MD	Medical device

14. 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 60601-1-11：2015 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 60601-2-10：2013 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
4、IEC 60601-1-2:2014 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 Stimulators is suitable for use in a professional health care environment, not including areas where there are sensitive equipment or sources of intense electromagnetic disturbances, such as the RF shielded room of an imaging system magnetic resonance imaging, in operating rooms near active AF surgical equipment, electrophysiology laboratories, armored rooms or areas where short wave therapy equipment is used.

●Do not use the system around strong electric filed, electromagnetic filed (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 by 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.

The following tables provide information on compliance of the equipment according to the standard EN 60601-1- 2:2015.

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 fields1	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 802.1 1 b/g/n, RFID 2450, LTE 7 Band	P u l s e modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	P u l s e modulation 217 Hz	0.2	0.3	9
5500						
5785						

This device complies with part 15 of the FCC Rules. Operation is subject to thefollowing two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that maycause undesired operation.

Warning
Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: —Reorient or relocate the receiving antenna. —Increase the separation between the equipment and receiver. —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. —Consult the dealer or an experienced radio/TV technician for help.

CE 2862

FC
FCC ID: 2AX4D-KTR2491

Shenzhen Kentro Medical Electronics Co.,Ltd
2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdong Province, China
[Tel]: +86(755)33825998, [Fax]: +86(755)33825996

EC REP **WellKang Ltd (www.CE-marking.eu)**
Enterprise Hub, NW Business Complex,1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland