



Foot & Body Circulation Massager (Transcutaneous Electrical Nerve Stimulator)

MODEL NO: PM-615 (KTR-4029)



INSTRUCTION MANUAL

WARNING!

Ensure that all safety precautions are followed when using electrical appliances for the proper operation of the device. This instruction booklet describes the safety precautions to be observed during operation to prevent injuries to yourself, other persons and damage to the device. The content not only is suitable for this product but also suitable for electrical appliances in general.

SYMBOLS EXPLAINED

	For indoor use only.		Please read instruction manual and retain for future use.
	Equipment complies with the applicable EU safety requirements and regulations.		

IMPORTANT!

Do Not Use This Transcutaneous Electrical Nerve Stimulator Until You Have Read This Entire Manual Thoroughly and Keep in a safe place for future reference.

This product is only suitable for well insulated spaces or occasional use.

THANK YOU

FOR BEING OUR CUSTOMER

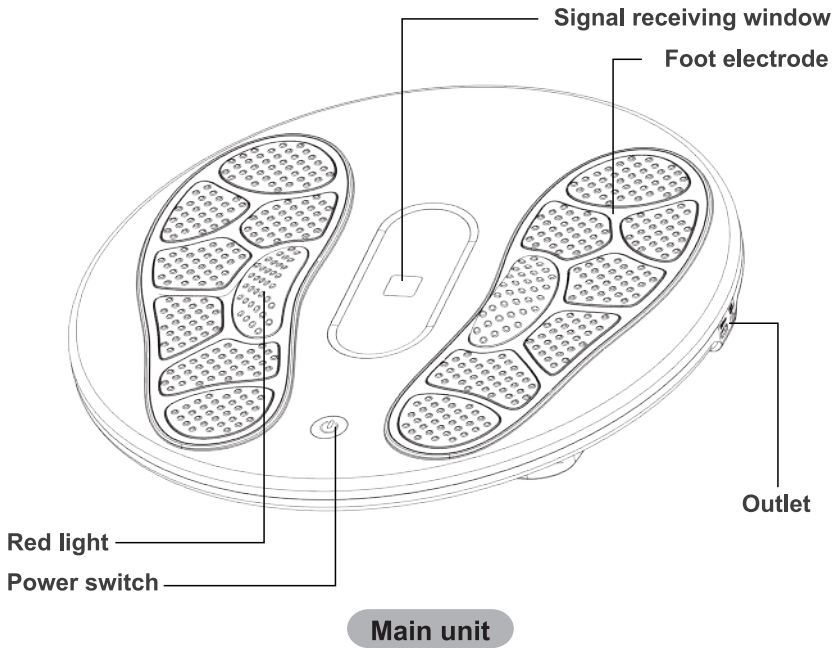
Thank you for purchasing the innovative product the PureMate Foot & Body Circulation Massager

We wish you many years of healthy indoor air with this efficient and effective product.

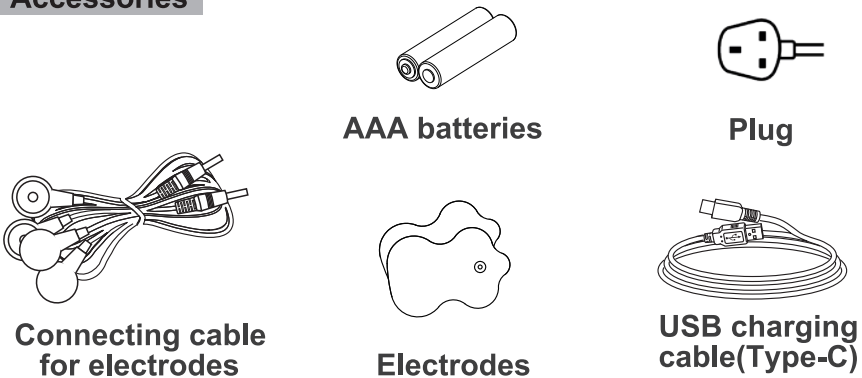
INTENDED USE

- ◎ This product can promote the blood circulation of the feet and legs.
- ◎ Improve the blood pumping function of the veins.
- ◎ Reduce the pain and discomfort of the feet and legs;
- ◎ Reduce swelling;
- ◎ Reduce cramps.
- ◎ Prevention of venous thrombosis;
- ◎ Promote foot ulcer healing of diabetic patients, Promote venous ulcer healing;
- ◎ Knee electrodes can help reduce knee joint pain.
- ◎ Body electrodes can temporarily relieve pain of neck, back, shoulder, arm, leg, hip.

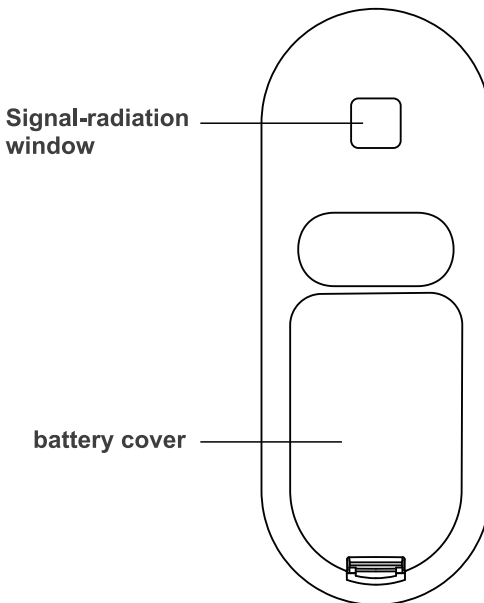
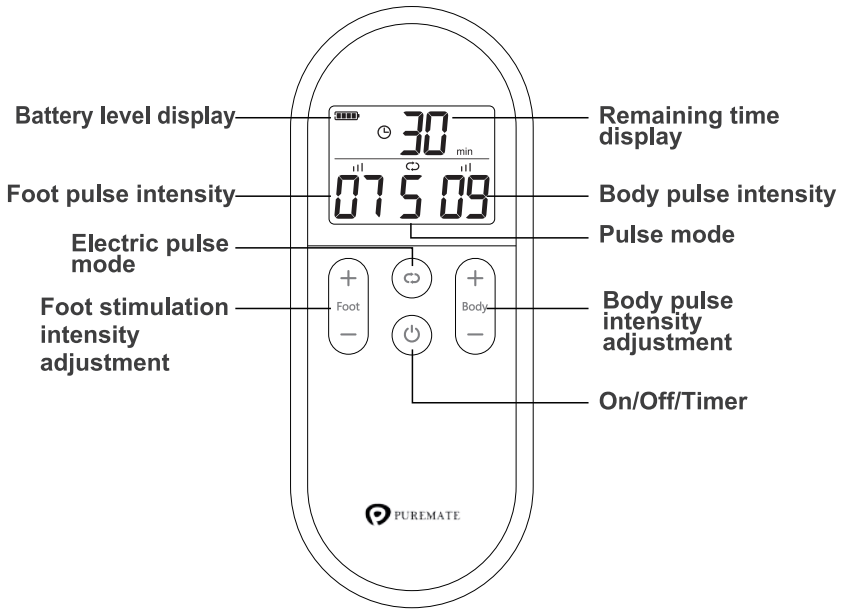
COMPONENTS



Accessories



Remote control



Electrodes:

The electrode is made of medical-grade hydrogel and carbon film, which is of biocompatibility.

Specification	Instructions
Dimensions	70x52 mm
Electrode impedance	150Ω±10%
Service life	2 years
Transport and storage environment	Temperature: 0~45℃ Relative humidity: ≤80%RH Atmospheric pressure: 50~106kPa

(1) Maintenance and cleaning

Electrodes should be always clean on their surfaces, without any dirt, oil, sticky substance, etc., otherwise, their viscosity will decrease. Dirty electrodes could be cleaned with clean water and then dried in air for a period of time of use.

(2) Storage conditions

- Please keep the electrodes out of the reach of children.
- Please store them in a dry and well-ventilated place, and keep them away from direct sunlight, high temperature or humidity.
- Please never try to disassemble, repair or modify the electrodes, otherwise an accident or malfunction may occur.

(3) Instructions on use of electrodes

- Please clean your skin thoroughly before each use of the electrodes, since the lotion, makeup or dirt left on the body skin will cause the poor application of electrodes.
- Please apply the electrodes to your body parts with a pain.
- Please shut down the electric pulse outlet before application of electrodes to your body skin.
- Please insert the circular plug of the electrode connecting cable into the electrode outlet on the product, and connect the other end of the cable to electrodes.

SPECIFICATIONS

Product name	Transcutaneous Electrical Nerve Stimulator
Model No	PM- PM-615 (KTR-4029)
Power supply	Input: 5V DC 1A Battery Capacity: 3.7V DC 2200mAh Remote control: 2 AAA batteries
Input power	5W
Safety category	Type BF of class II
Dimensions of the main unit	365×365×68.5mm
Package Size	395×395×90mm
Net weight	Main unit: 1,180g / Remote control:58g
Weight	About 1950g
Acceptable weight for foot electrode	≥50Kg
Software version No.	A/0
Product service life	3 years

AMBIENT CONDITIONS







	Temperature	Humidity	Barometric pressure
Normal operation	+5℃ -+40℃	15%-93%RH	700hPa-1060hPa
Storage	-20℃ -+70℃	0-93%RH	700hPa-1060hPa
Transport	-20℃ -+55℃	15%-93%RH	700hPa-1060hPa

ELECTRONIC PERFORMANCE

Pulse frequency	1Hz—100Hz
Pulse width	100 μ s~400 μ s
DC component	0V
Peak output voltage	5-80V
Power of a single pulse at the maximum output amplitude	> 7 μ C
Maximum output energy of a single pulse	\leq 300mJ
Maximum output amplitude RMS	< 10V
Peak output voltage during open circuit measurement	\leq 500V
Output amplitude adjustment	Be able to withstand the effects of open and short circuits at output terminal, with no degrading in performance.
Adjustment of output amplitude	Continuous and uniform, keeping the minimum output not greater than 2% of the maximum output
Rated load impedance	500 Ω , with \pm 10% error
Set treatment time	15/30/45/60minutes, with an acceptable error of \pm 10%

SAFETY PRECAUTIONS

- Warning signs and symbols referred in this manual are for safe and proper use of the product by users, thus preventing damages to users or others.
- Warning signs, symbols and their meanings are as follows:

Caution signs	Meaning
 Using	Indicates that when used incorrectly, it may result in death or serious injury to a person.
 Warning	Indicates that when used incorrectly, it may result in death or serious injury to a person.
 Attention	Indicates that when used incorrectly, it may result in death or serious injury to a person.
Symbols	
 	Means prohibition (something that must be prohibited). Specific items prohibited are provided within or near this symbol in text or graphics. The warning sign on the left represents "removal prohibited"
	● means constraint (something that must be followed). Specific items constrained are provided within or near this symbol "●" in text or graphics. The warning sign on the left represents "General Constraints".



Contraindications

1. The product is prohibited from being used to patients with bleeding tendency, local acute suppurative inflammation, local malignant tumor, local pacemaker, local metal implants or skin sensory disorders, Patients with deep venous thrombosis, and to human hearts and the lower abdomen of pregnant women;
2. Please never use the product with any other electronic medical device, such as the life-sustaining medical electronic devices of pacemaker, artificial heart-lung machine, and other medical electronics such as the electrocardiograph;
3. A burn may occur to the patient's body part applied with the electrode when the product, together with a high-frequency surgical equipment, is used to the patient, which also may damage the product; the product may be instable in output when used near a short-wave or microwave therapy equipment (1 meter);
4. Patients with heart disease;
5. Poisoning patients or others with high fever;
6. Infants and children, and those without the ability or consciousness to express;
7. Use of electrodes in close to your chest will increase the risk of fibrillation.



 Warning

1. Please consult the doctor for pregnant women and those in Menstrual period, and patients with sensitive skin, heart disease, abnormal blood pressure, cancer, cerebrovascular disease, acute disease and those undergoing treatment, Patients with deep venous thrombosis, before use of the product.

2. Unless medically suggested by an expert, patients with an electronic device implanted (such as a pacemaker) are not recommended for stimulation with the product.



3. The product isn't allowed for those with skin perception disorders.

4. It is prohibited from using the product in bathing, sweating, or sleeping.

5. Patients with cerebral hemorrhage: prohibited in their unstable conditions; those with sequelae must be supervised by a doctor in use of the product.

6. The product is prohibited for those with purulent inflammation, acute blood poisoning or persistent high fever.

7. The product is also prohibited for those with an acute cardiovascular and cerebrovascular disease.

8. It is prohibited for those with bleeding tendency, acute purulent inflammation or metal implants to use the product.

9. Instruments and accessories used by more than one patient need to be cleaned and disinfected by rinsing with a wet cloth.



 Caution

1. Please don't use the product near your heart and to your head, eyes, front waist (especially carotid artery), lower back, mouth, genitals and body parts with skin diseases.



2. Please don't move the product during use. When changing the body part of treatment, please power off the product first before restarting it, otherwise the stimulation may be strong.

3. Please don't use the product to children or those without the ability or consciousness to express.

4. Please stop using the product immediately and then seek medical advice in case of any discomfort during use of the product.

5. Please unplug the product after use or when not in use.

6. Please never use the product with any other electronic medical device, such as the life-sustaining medical electronic devices of pacemaker, artificial heart-lung machine, and other medical electronics such as the electrocardiograph, otherwise a danger may occur.

7. Please don't use the product in places with high temperature, combustibles, electromagnetic radiation, or humidity.

8. Please don't disassemble, repair or modify the product, otherwise a malfunction or electric shock may occur.

9. Please stop using the product immediately and then seek medical advice in case of any skin discomfort during use of the product.

10. Please don't discard the product at will at the end of its service life. Instead, please follow the local laws and regulations to dispose it. You have to contact the local authority for proper ways to dispose the potentially bio-hazardous components and accessories.





Preparations before use


- (1) First install 2 AAA batteries on the remote control, pay attention to the positive and negative polarities of the batteries, and then close the battery cover.
- (2) Make sure that the lithium battery of the host is fully charged. If the lithium battery of the host is insufficient, it needs to be charged before use.
- (3) Clean your feet and the foot electrodes with a damp towel, and then place your feet on the electrodes; then, position your feet to make them in full contact with the two electrodes, then fully relax your body and begin to operate the remote control.
It is recommended to place a flannel on the electrodes in winter to keep your feet warm during use of the product.

How to operate the remote control

Description on functions of remote control buttons

- ①  : Power on or off, and time adjustment
- ②  : Selection of an electric pulse mode
- ③ + : Increase the intensity of electric pulse
- ④ - : Decrease the intensity of electric pulse

OPERATING INSTRUCTIONS

- (1) First, press "Power" on the main unit with the indicator flashing to wait for the display of signals; then, press "  " on the remote control to start the product; next, the main unit beeps with the indicator always on, and the remote control displays as below and enters the default settings:
 - Timed for 15 minutes;
 - Mode 1
 - Intensity 0

Then, you may operate the remote control to adjust to the treatment mode and intensity you desire; in operating the remote control, please aim its infrared emitter at the infrared receiving port on the main unit. The product will beep once after successfully receiving the infrared signal.

To power off the product, please press "⏻" on the remote control or main unit.

Note: the main unit in standby state will shut down automatically if it fails to receive the power-on signal from the remote control within 3 minutes. To reuse the main unit, you need to press "Power" on it to enter the standby state.

(2) To adjust the intensity, please press "+" to increase a level while "-" to decrease a level. Total is 99 levels of intensity. It defaults to Level "0" after startup.


Note:

◆ When using the product for foot massage, it is necessary to adjust the intensity with the "Intensity" button on the left side of the remote control. The intensity of foot massage will have no change with the intensity adjustment button on the right side of the remote control.

(3) Press "🔄" to switch among 50 treatment modes. Mode 1 provides massage in automatic cycle and combination, that is, automatically switching to the next mode every one minute; Modes 2-50 provide single massage.

(4) After power-on, you may short press "⏻" to select the massage time interval within the range of 15-60 minutes; each press could switch to a different time interval. It defaults to 15 minutes after startup.

Application of electrodes to body parts

- (1) Connect one end of the 2-core connecting cable to the electrode interface (marked with ) on one side of the main unit and the other end to the adhesive electrodes.
- (2) Remove the protective film on electrodes and firmly apply them to your body parts with a pain. Then, follow the instructions on them to operate the remote control.

Note: be sure to adjust the massage intensity with the adjustment button on the right side of the remote control, otherwise the intensity will have no change.

Please refer to the following figures for application of the electrodes:



- (3) After completion of treatment, please store the electrodes in a dry, well-ventilated place for next use.

Note:


- (1) Adhesive electrodes should be always clean on their surfaces, without any dust, oily or sticky substances; otherwise, their viscosity will decrease. If they become dirty, please rinse them with clean water and then dry them in air for repeated use.
- (2) The adhesive electrodes could be used for about 80 times (20 minutes each time). Please consider to purchase new ones from your local dealer or the manufacturer if your electrodes still cannot restore their viscosity after a few washes.
- (3) Please use adhesive electrodes attached with the product. Other types of electrodes are prohibited. Adhesive electrodes attached with the product, with a dimension of 52mm (Width) x 70mm (Height) x 2.5mm (Thickness) approximately, are acceptable only. Please don't use those in other dimensions.
- (4) There are no limitations on special skills, training and knowledge of intended operators or responsible organizations that use the product, and on service location or environment of the main unit. Just follow the instructions for use.
Special education and training are not required for users to operate the product. Just read and follow the instructions for use.

It is recommended to use the product twice a day, 15-30 minutes each time.

BATTERIES

Remote control battery

Note:

- (1) The remote control uses 2 AAA batteries, which can be used for about half a year (according to use 30 minutes a day).
- (2) When "  " is displayed on the remote control screen, it means that the battery of the remote control is low, please replace it with a new one.
- (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) Pay attention to the positive and negative polarity when installing the battery, "+" is positive, "-" is negative.
- (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.

- (1)** When you hear the "beep" 3 times in a row during the use of the host, it means the lithium batteries are low and you can be charged using a power adapter. Use the supplied charging cable, with one end plugged into the DC 5.0V and the other end into the charging port of the host, and the charging LED will light up. When the batteries are fully charged, the charging LED is always ON. It takes approximately 3 hours to fully charge.
- (2)** Fully charged for approximately 60 days of use (30 min of use per day).
- (3)** Under normal use, the service life of the rechargeable batteries is at least 500 times of charges and discharges for approximately 2-3 years (use twice per day for no more than 30 min each time). If the batteries are not used for a long time, their service life will be shortened, and it is recommended to charge at least once every three months.

CLEANING AND MAINTENANCE

- (1)** When the main unit becomes dirty, please wipe it with a dry cloth or towel.
- (2)** Please clean the conductive strip with a damp cloth or towel after each use; if it is too dirty, you may use a cloth damped with medical alcohol (75% concentration) to wipe or disinfect it.
- (3)** No special maintenance is needed for the product during its service life.

Storage

- (1) Please keep the product out of the reach of children.
- (2) Please store the product in a place far away from direct sunlight, high temperature or humidity.
- (3) Please store the product in a dry and well-ventilated place.
- (4) Please never disassemble, repair or modify the product by yourself, otherwise a malfunction or accident may occur.

Note: the product should be disposed in strict accordance with local regulations on environmental protection for prevention of environmental pollution.

TROUBLESHOOTING

The user or operator is not allowed to perform repair or maintenance during use of the product. If it doesn't work, please send it to the dealer for maintenance or repair.

It is very difficult to disassemble the product since the electric isolation isn't provided for the ME device.

Malfunction	Possible Cause	Solution
Fails to work normally	Is the main unit in the standby mode?	Short press the power switch on the main unit to start up the product, with the indicator flashing, and then press " ⏻ " on the remote control to boot.
	Is the remote control sufficient in battery power?	Please replace with new AAA batteries and install them with correct positive and negative poles.
	Is the main unit sufficient in battery power?	If the battery is low, please charge the host.
The product displays normally, but it doesn't work or the user has no feeling.	Are the electrodes in contact with your foot soles or body skin?	The electrodes must be in good contact with your foot soles or body skin.
	Is your skin too dry?	Please wet your foot soles with a damp towel.
	Is the massage intensity too low?	Increase the massage intensity.

There's a tingling sensation	Are the electrodes in contact with your foot soles or body skin?	The electrodes must be in good contact with your foot soles or body skin.
	Is the massage too long?	It is suitable to massage for 15 to 30 minutes each time, twice a day at most.
	Is the massage intensity too high?	Properly decrease the massage intensity.
	Is your skin allergic to the electrodes?	Check for your history of skin allergies. If you are slightly allergic, please shorten the massage time or stop using the product. If seriously allergic, please seek for desensitization treatment first.
	Your skin is dry in the cold weather.	Wet your skin and the surface of foot electrodes with a damp towel.
Low stimulation	Are the electrodes in good contact with your foot soles or body skin?	The electrodes need in good contact with your foot soles or body skin.
	Is there any dirt or oil stain on the electrodes?	Clean the surface of the hydrogel on electrodes.
	Is the main unit in a quite low battery?	Please replace batteries in low power with new ones.
Red spots on the skin after use	Is there a strong tingling sensation during use of the product? Have you applied any other ointment?	Please stop using the product to wait for the disappearing of red spots in 3-5 days.

EMC STATEMENTS

(1) The product requires special attention to EMC and requires to be installed.









Please use it based on the EMC information provided, since it may be affected by portable and mobile RF communication devices.














(2) The product has been thoroughly tested and inspected to ensure its excellent performance and proper operation.




Note: the product should not be used near or on any other device; if it is necessary for this, please observe if it can work normally.

⚠ Warning: using accessories other than those specified may result in increased emissions or decreased immunity of the product. Guidance and Manufacturer's declaration can be seen in the attachment.

SYMBOLS

Notation	Meaning
	Batch/lot number
	Serial No.
	Manufacturer
	European authorised representative
	Date of manufacture
	Warning
	Type BF applied part
	Medical device

	Warning on danger
	Category II medical device
	It means prohibition (something that must be prohibited)
	It means compulsory execution (something that must be followed)
	Indoor use only
	No sun exposure
	No rainwater
	"WEEE (Waste Electrical and Electronic Equipment)". Wastes shall be disposed in accordance with laws.
	CE Mark and Agency Code
	Standby
	Please refer to the user manual
	Temperature limitations. It indicates the range of temperature to which medical devices can be safely exposed. The upper and lower temperature limits shall be indicated near the upper and lower horizontal lines.
	Humidity limits. It indicates the range of humidity to which medical devices can be safely exposed. The humidity limits shall be indicated near the upper and lower horizontal lines.

	<p>Atmospheric pressure limits. It indicates the range of atmospheric pressure to which medical devices can be safely exposed. The atmospheric pressure limits shall be indicated near the upper and lower horizontal lines.</p>
	<p>Direct Current</p>
	<p>Electrodes</p>
<p>IP21</p>	<p>Dustproof and waterproof level, to avoid the falling of solid objects larger than 12.5mm and the vertical penetration of water to cause adverse effects.</p>

EXECUTIVE STANDARDS

The product should be in accordance with the following standards and regulations:

- (1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (EN 60601-1:2006 / AC: 2021)
- (2) Medical electrical equipment - 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 (EN60601-1-11:2015/A1:2020)
- (3) Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (EN60601-2-10:2015/A1:2016)
- (4) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (EN60601-1-2:2015+A1:2021)

APPENDIX

Guidance and manufacture's declaration - electromagnetic emission		
The Transcutaneous Electrical Nerve Stimulator is intended for use in the electromagnetic environment specified below. The buyer or user of the Transcutaneous Electrical Nerve Stimulator should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Transcutaneous Electrical Nerve Stimulator use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emission CISPR 11	Class B	The Transcutaneous Electrical Nerve Stimulator 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.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

**Guidance and manufacture's declaration
- electromagnetic immunity**

The Transcutaneous Electrical Nerve Stimulator is intended for use in the electromagnetic environment specified below. The buyer or user of Transcutaneous Electrical Nerve Stimulator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+8kV contact +2kV, + 4kV. +8kV, + 15kV air	+8kV contact +2kV, + 4kV. +8kV, + 15kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) and neutral	± 1kV line(s) and neutral	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 s</p>	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 s</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Transcutaneous Electrical Nerve Stimulator requires continued operation during power mains interruptions, it is recommended that the Transcutaneous Electrical Nerve Stimulator be powered from an uninterruptible power supply.</p>
<p>Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8</p>	<p>3A/m</p>	<p>3A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>

NOTE

U_T is the a.c. mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communications equipment and the Transcutaneous Electrical Nerve Stimulator.

The Transcutaneous Electrical Nerve Stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The buyer or user of the Transcutaneous Electrical Nerve Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Transcutaneous Electrical Nerve Stimulator as recommended below, according to the maximum output power of the communications equipment.



Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For rated maximum output power of transmitter that's not listed in the above chart, the recommended isolation distance d (unit is meter) can be determined by equation in the corresponding transmitter frequency column. P is the maximum output rated power of transmitter provided by its manufacturer, the unit is watt (W).

NOTE 1 When under 80MHz and 800MHz, use equation of higher frequency.

NOTE 2 These guidelines couldn't possibly fit all situations. Electromagnetic transmission is affected by buildings, objects, the absorption and reflection of human body.

DISPOSAL OF THIS DEVICE

	Waste Electrical and Electronic Equipment (WEEE)	This symbol on the product and/or packaging indicates that Waste Electrical product (WEEE) under Directive 2012/19/ EU which governs used electrical and electronic appliances, should not be disposed of with general household waste.
	The Mobius Loop	This symbol indicates that the product or packaging is capable of being recycled.

FIND US ONLINE



YouTube





Transcutaneous Electrical Nerve Stimulator | MODEL NO: PM-615 (KTR-4029)

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