Venen Engel

Product Manual

Venen Engel EMS Vein Board

Transcutaneous Electrical Nerve Stimulator

Thank you for purchasing this product. Please read the manual carefully before your first use!

ENGLISH
KTR-4029

CE 4013

Content

I. Product Overview

1.1 Product name

Transcutaneous Electrical Nerve Stimulator

1.2 Product model

KTR-4029

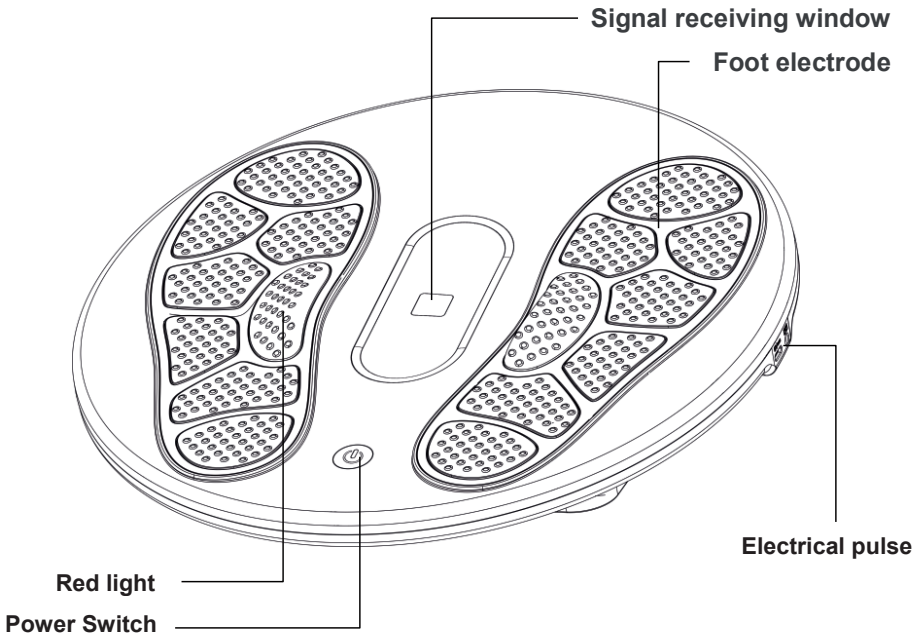
1.3 Intended use

◎ 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
◎ Prevent venous thrombosis
◎ Promote the healing of foot ulcers in diabetic patients and of venous ulcers
◎ The knee electrodes can help reduce knee joint paint
◎ The body electrodes can temporarily relieve pain in the neck, back, shoulders, arms, legs and hips.

1.4 Product description

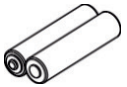
1.4.1 Main structure of the product

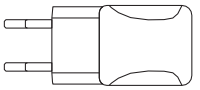
The product is composed of a main unit, remote control, batteries and adhesive electrodes, as shown in the following figure:

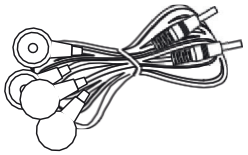


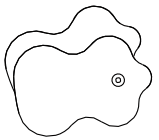
Main Unit

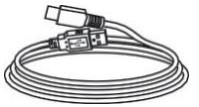
Accessories

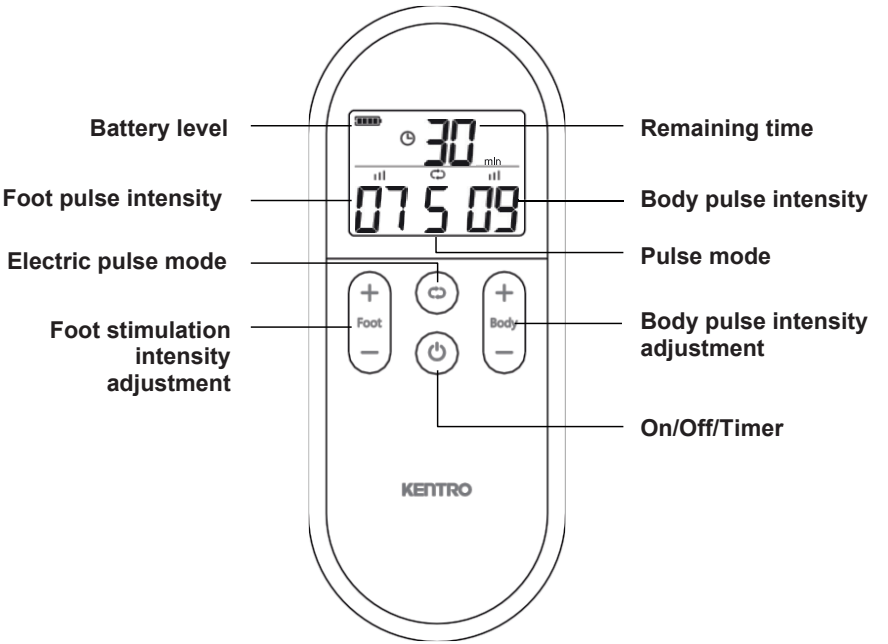

AAA batteries


Adaptor

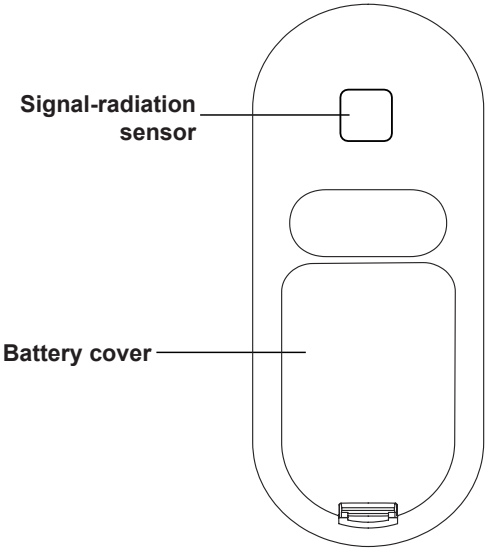

Connecting cable for electrodes


Electrodes


USB charging cable (Type-C)



Remote Control



Application components of the product:
The product's application components include foot and body electrodes.

1.4.2 Electrodes:
The electrode is made of medical-grade hydrogel and biocompatible carbon film.

Specification	Instructions
Dimensions	70 × 52 mm
Electrode impedance	150 Ω ±10 %
Service life	2 years
Transport and storage conditions	Temperature: 0~45 ℃ Relative humidity: ≤80 % RF Atmospheric pressure: 50~106 kPa

(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 must be cleaned with clean water and air-dried before use.
(2) Storage conditions
■ Please keep the electrodes out of reach of children.
■ Store them in a dry, well-ventilated place protected from sunlight, high temperatures and humidity.
■ Never disassemble, repair or change the electrodes as this may lead to an accident or malfunction.
(3) Instructions for using the electrodes
■ Before each use, thoroughly clean your skin – lotion, makeup or dirt left on the body might impede the application of the electrodes.
■ Disconnect the power supply before attaching the electrodes to your body.
■ Attach the electrodes to the aching body part.

■ Insert the circular plug of the electrode connecting cable into the electrode outlet on the device and connect the other end of the cable with the electrode.
■ Remove the protective film on the electrodes and press them tightly to the aching body part. Keep the protective film for later storage of the electrode in the bag.

1.4.3 Accessories
Included accessories: 1 remote control, 2 electrodes, 2 AAA batteries, 1 USB charging cable, 1 adapter, 1 electrode connecting cable. All accessories can be separated from the main unit.
Please use only the electrodes supplied with the product. Using other types of electrodes is prohibited.

II. Technical Specifications

2.1 Product specifications

Product name	Transcutaneous Electrical Nerve Stimulator
Model	KTR-4029
Power supply	Input: 5 V DC 1 A Battery capacity: 3.7 V DC 2200 mAh Remote control: 2 AAA batteries
Input power	5 W
Safety category	Type BF class II
Dimensions main unit	365 × 365 × 68.5 mm
Dimension packaging	395 × 395 × 90 mm
Net weight	Main unit 1,180 g/Remote control 58 g
Weight	Approx. 1,950 g
Acceptable weight for the foot electrode	≤ 50 kg
Software version no.	A/0
Product service life	3 years

2.2 Ambient conditions

	Temperature	Humidity	Barometric pressure
Standard operation	+5 ℃–+40 ℃	15 %–93 %RH	700 hPa–1,060 hPa
Storage	–20 ℃–+70℃	0–93 % RH	700 hPa–1,060 hPa
Transport	–20 ℃–+55℃	15%–93 % RF	700 hPa–1,060 hPa

2.3 Electronic performance

Pulse frequency	1 Hz–100 Hz
Pulse width	100 μs～400 μs
DC component	0 V
Peak output voltage	5–80 V
Charge of a single pulse at maximum output amplitude	＞7 μC
Maximum output energy for a single pulse	≤300 mJ
Maximum output amplitude, RMS value	<10 V
Peak output voltage during open circuit measurement	≤500 V
Output amplitude adjustment	Withstand the effect of open circuit and short circuits at the output terminal without affecting performance.
Adjustment of output amplitude	Continuous and uniform, the minimum output must not exceed 2% of the maximum output.
Rated load impedance	500 Ω with ± 10% error tolerance
Set treatment time	15/30/45/60 minutes, with an error tolerance of ±10 %

Software description:

(1) Software name: KTR-4029-2081A V1.0

(2) Version: V1.0

III. Safety instructions

■ The warning signs and symbols in this manual are intended to ensure safe and proper use of the device and to prevent harm to the user or other persons.

■ The warning signs and symbols have the following meaning:

Warning sign	Meaning
⚠ Use	Improper use can lead to serious injury or death.
⚠ Warning	Improper use can lead to serious injury or death.
⚠ Attention	Improper use can lead to serious injury or death.
Symbols	
 Prohibition (something is prohibited). Prohibited items are indicated within or near this symbol as a graphic or text. The warning sign on the left means "Do not remove".	
 Means obligation (something must be followed). Obligatory actions are indicated within or near the symbol as text or graphics. The warning sign on the left means "General obligations".	

⚠ Contraindications

1. The device must not be used on patients with a tendency to bleed, with local acute purulent inflammation, with local malignant tumors, local cardiac pacemakers, local metal implants or skin sensitivity issues; also not on patients with deep vein thrombosis, not on the human heart and not on the abdomen of pregnant women
2. Never use the device with other electronic medical devices, such as life-sustaining devices like pacemakers or artificial heart-lung machines, or with other electronic medical devices such as electrocardiographs.
3. A burn may occur on the part of the patient's body treated with the electrode if the device is used together with a high-frequency surgical device. This may also damage the device. The performance of the device may become unstable if it is used near (1 meter) a shortwave or microwave therapy device.
4. Patients with heart disease.
5. Patients with blood poisoning or a high fever.
6. Babies, children, unconscious people or those otherwise unable to express themselves.
7. Using the electrodes close to the chest increases the risk of atrial fibrillation.

⚠ Attention

1. Medical advice is required before use on pregnant or menstruating women, patients with sensitive skin, heart disease, abnormal blood pressure, cancer, cerebrovascular disease, acute illness or deep venous thrombosis and patients undergoing medical treatment.
2. Unless a doctor has recommended its use for medical reasons, patients with an implanted electronic device, e.g. a pacemaker, are advised against being stimulated with the device.

3. The device must not be used on persons with skin sensitivity issues.
4. The device must not be used while bathing, sweating or sleeping.
5. Patients with cerebral hemorrhage must not use the device in their unstable condition, patients with secondary damage only under medical supervision.
6. Persons with purulent inflammation, acute blood poisoning or persistently high fever must not use the device.
7. The device must also not be used in the event of acute cardiovascular or cerebrovascular disease.
8. The device must not be used by persons with a tendency to bleed, acute purulent inflammation or metal implants.
9. Instruments and accessories that are used by more than one patient must be cleaned and disinfected with a damp cloth.

⚠ Warning	
1. Do not use the device near the heart, head, eyes, front of the waist (especially the carotid artery), lower back, mouth, genitals or areas of the body with skin conditions.	
2. Do not move the device during use. Before moving to other body parts, switch it off and then on again once placed, otherwise the stimulation may be too strong. 3. Do not use the device on children or people who are unconscious or unable to speak. 4. Stop using the device immediately and consult a doctor if you experience any discomfort during use. 5. Always disconnect the appliance from the power supply after use and when not in use. 6. Never use the device together with other electronic medical devices (e.g. life-sustaining devices such as pacemakers or artificial heart-lung machines) and other electronic medical devices (e.g. electrocardiographs). 7. Do not use the device in places with high temperatures, flammable materials, electromagnetic radiation or high humidity. 8. Do not disassemble, repair or modify the appliance as there is a risk of malfunction or electric shock. 9. Immediately stop using the device and seek medical advice if you experience skin irritation during use. 10. Dispose of the appliance at the end of its service life in accordance with the applicable laws and regulations. The local authorities will inform you about the correct disposal of potentially biohazardous components and accessories.	

IV. Operating instructions

4.1 Before use

1) Insert 2 AAA batteries into the remote control. Observe the positive and negative polarity of the batteries. Close the battery cover.
2) The lithium battery of the main unit must be fully charged, otherwise charge it first before use.
3) Clean your feet and the foot electrodes with a damp towel. Place your feet on the electrodes so that they are in full contact with both electrodes. Relax your body completely and start using the remote control. In winter, it is advisable to place a flannel cloth on the electrodes to keep your feet warm while using the device.

4.2 How to operate the remote control

4.2.1 Functions of the remote-control buttons

① ⏻ : Turn on or off, adjust the timer
② : Select an electric pulse mode
③ + : Increase the intensity of the electric pulse
④ - : Decrease the intensity of the electric pulse

4.2.2 Operate the remote control

1) Press "Power" on the main unit. The display flashes, wait for the signals. Press ⏻ on the remote control to start the appliance. The main unit beeps while the indicator lights up constantly. You will see the following default settings on the remote control:
   • Time: 15 minutes
   • Mode: 1
   • Intensity: 0

You can now use the remote control to set the treatment mode and intensity. To do this, point the infrared transmitter on the remote control at the infrared receiver on the main device. Once the infrared signal has been successfully received, the device beeps once.

The turn the product off, press ⏻ on the remote control or main unit.

Note: The main unit switches off automatically in standby mode if it does not receive the switch-on signal from the remote control within 3 minutes. Press "Power" to use the main unit again and activate standby mode.
2) You can adjust the intensity by pressing "+" for one level higher or "-" for one level lower. There are a total of 20 levels and the default value after switching on is 0.

Note:

- If you are using the device to massage your feet, adjust the intensity using the intensity button on the left-hand side of the remote control. The intensity of the foot massage does not change when you press the intensity button on the right-hand side.
- The rocker starts to move when your feet are sufficiently stimulated. If they do not move, you need to increase the intensity of the stimulation.
- Press to switch between the 9 treatment modes. Mode 1 is an automatic cycle and combination massage, modes 2 to 9 are circular massages; the mode therefore changes automatically every minute.

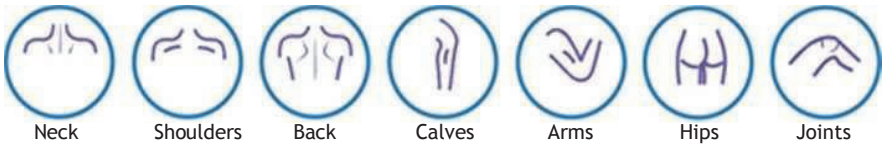
1) After turning the device on, briefly press to select a massage duration between 15 and 60 minutes. Each time you press the button, you switch to a different time interval. The default value after switching on is 15 minutes.
2) Red light irradiation
Red light irradiation is activated automatically when the pulse intensity increases to level 1 or higher after the device is switched on and your feet are in full contact with the electrodes. To deactivate red light irradiation, press and hold "Mode" (does not apply to models without red light irradiation).

4.2.3 Applying the electrodes to body parts

1) Connect one end of the 2-core connecting cable to the electrode interface marked with and the other end to the adhesive electrodes.
2) Remove the protective film from the electrodes and stick them firmly to the sore body parts. Then follow the instructions for the remote control.

Note: Adjust the massage intensity using the setting button on the right-hand side of the remote control, otherwise the intensity will not change.

Please refer to the following illustrations for the correct positioning of the electrodes



3) After treatment, store the electrodes in a dry and well-ventilated place until the next use.

Note:

1) The surfaces of the electrodes must always be clean and free of dirt, oil, sticky substances, etc., otherwise their viscosity will decrease. If they are dirty, rinse them with clean water and allow them to air dry.
2) The adhesive electrodes can be used around 80 times (for 20 minutes each time). If the electrodes still do not retain their viscosity after a few washes, please buy new electrodes from a dealer or the manufacturer.
3) Only use the type of electrodes supplied with the device. Only the electrodes supplied (52 mm wide, 70 mm high and 2.5 mm thick) may be used. Do not use electrodes with other dimensions.
4) There are no restrictions regarding the skills or training of the operators or organizations using the product, or regarding the location/environment of the main unit. Simply follow the instructions. No special education or training is required to operate the device. Simply read and follow the instructions for use.

We recommend using the device twice a day for 15 to 30 minutes at a time

4.3 Battery usage

4.3.1 Remote control batteries

1) The remote control uses 2 AAA batteries, which last about half a year with 30 minutes of daily use.
2) If  appears on the remote-control display, the batteries are low; please replace them with new ones.
3) Remove the batteries if the device is not to be used for a longer period. Otherwise, the batteries may leak and cause the device to malfunction.
4) Do not use any battery other than the one specified.
5) When inserting the batteries, pay attention to the positive and negative polarity. "+" is positive, "-" is negative.
6) Do not use this battery at temperatures above 45 °C, as this will affect the performance and service life of the battery.
7) Empty batteries must be disposed of in accordance with local environmental regulations.

4.3.2 Main unit batteries

1) The lithium batteries are low and can be charged using the mains adapter if you hear a beep three times in succession when using the main unit. Only use the supplied charging cable: connect one end to the 5 V DC port and the other to the charging port of the main unit. The charging LED will then light up. When the batteries are fully charged, the charging LED lights up constantly. Full charging takes around 3 hours.
2) A full charge lasts about 60 days with 30 minutes of daily use.
3) With normal use, the batteries have a service life of around 500 charges and discharges if they are not used for more than 30 minutes a day for 2 to 3 years. If they are not used for longer periods, the service life will be reduced. It is therefore advisable to recharge the batteries at least once every 3 months.

V. Cleaning, Maintenance, Storage

5.1 Cleaning and maintenance

1) If the main unit is dirty, please wipe it with a dry cloth or towel.
2) Clean the conductive strip with a damp cloth or towel after each use. If it is too dirty, you can wipe or disinfect it with a cloth moistened with medical alcohol (75% concentration).
3) No additional maintenance is required for the device during its service life.

5.2 Storage

1) Keep the device out of reach of children.
2) Store the device in a place protected from direct sunlight, high temperatures and moisture.
3) Store the device in a dry and well-ventilated place.
4) Never disassemble, repair or modify the appliance yourself, as this may result in a malfunction or accident.

Note: The appliance may only be disposed of in strict compliance with local environmental protection regulations.

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VI. Troubleshooting

The user or operator must not carry out any repair or maintenance work when using the appliance. If the appliance does not work, please send it to the dealer for maintenance or repair. Dismantling the appliance is very difficult because the ME appliance is not electrically insulated.

Malfunction	Possible cause	Solution
Does not function normally	Is the main unit in stand-by mode?	Briefly press the power button on the main unit to start the appliance while the display is flashing and then press ⏻ on the remote control to start it.
	Are the batteries of the remote control charged?	Replace the batteries with new AAA batteries and insert them with the correct plus and minus polarity.
	Does the main unit have enough battery power?	If the battery is low, please charge the main unit.
The display of the device works normally, but the device itself does not work or the user cannot feel anything.	Are the electrodes in contact with the soles of your feet or the skin on your body?	The electrodes must be in firm contact with the soles of the feet or the skin on the body.
	Is your skin too dry?	Moisten the soles of your feet with a towel.
	If the massage intensity is too low?	Increase the intensity of the massage.
There is a tingling feeling	Are the electrodes in contact with the soles of your feet or the skin on your body?	The electrodes must be in firm contact with the soles of the feet or the skin on the body.
	Was the massage too long?	It is recommended to massage no more than 2 times a day for 15 to 30 minutes.
	Is the intensity of the massage too high?	Decrease the intensity of the massage.
	Is your skin allergic to the electrodes?	Ensure that you do not have or have had any skin allergies. If you have a mild allergy, please shorten the duration of the massage or stop using the product. If you have a severe allergy, please have yourself sensitized first.
	Your skin is dry in cold weather.	Moisten your skin and the surface of the foot electrodes with a towel.
Low stimulation	Are the electrodes in contact with the soles of your feet or the skin on your body?	The electrodes must be in firm contact with the soles of the feet or the skin on the body.
	Are there any dirt or oil stains on the electrodes?	Clean the surface of the hydrogel on the electrodes.
	Is the battery level of the main unit low?	Replace the low batteries with new ones.
Red spots on the skin after use	Does a strong tingling sensation occur when using the device? Did you apply a different ointment?	Stop using the device and wait 3 to 5 days for the red spots to disappear.

VII. EMC Statements

1) Electromagnetic compatibility (EMC) is particularly important for this device.
Observe the EMC information provided, as it can be disturbed by portable and mobile RF devices.
2) 2) The device has been thoroughly tested. This ensures that it delivers outstanding performance and functions safely and in accordance with standards.

Note: Do not use the device near or on another device. If this is necessary, please observe whether it is working properly.

⚠ **Attention:** The use of accessories other than those specified can lead to increased emissions and susceptibility of the device to faults. The manufacturer's instructions and declaration can be found in the appendix.

VIII. Symbols

Notation	Meaning
	Batch / LOT no.
	Serial no.
	Manufacturer
	European Authorized Representative
	Date of manufacture
	Distributor
	Warning
	Type BF applied part

	Warning of danger
	Class II medial device
	Prohibition (something is prohibited)
	Means obligatory action (something must be followed)
	Indoor use only
	Do not expose to sunlight
	No rainwater
	WEEE (*Waste of Electrical and Electronic Equipment)*. Old appliances must be disposed of in accordance with the statutory regulations.
	CE symbol and authority code
	Standby
	Please refer to the user manual
	Temperature limits. Indicates the temperature range to which medical devices can be safely exposed. The upper and lower temperature limits are indicated near the upper and lower horizontal lines.
	Humidity limits. Indicates the humidity range to which medical devices can be safely exposed The upper and lower humidity limits are indicated near the upper and lower horizontal lines.

	Limit value for atmospheric pressure. Indicates the pressure range to which medical devices can be safely exposed. The atmospheric pressure limits are indicated near the upper and lower horizontal lines.
	Direct current
	Electrodes
IP21	Degree of dust and water resistance to prevent objects larger than 12.5 mm from falling, vertical water ingress and unwanted effects.

IX. Applied standards

The device complies with the following standards and regulations:

1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1: 2005/AMD2:2020)

2) Medical electrical equipment - Part 1: 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 (IEC 60601-1-11:2015, AMD1:2020)

3) Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10: 2012, AMD1:2016)

4) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (EN60601-1-2:2014+A1:2020-b)

XI. 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 device must ensure 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 uses RF energy only for its internal function. As a result, its RF emission is very low and is unlikely to interfere with nearby electronic devices.
RF emission CISPR 11	Class B	The transcutaneous electrical nerve stimulator can be used in any facility, including residential buildings and in areas that are directly connected to the public power grid that supplies residential buildings.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	k. 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	+8 kV contact +2 kV, + 4 kV. +8 kV, + 15 kV air	+8 kV contact +2 kV, + 4 kV. +8 kV, + 15 kV air	Floors must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	The electricity grid must be of commercial or hospital quality.
Surge IEC 61000-4-5	± 1 kV line(s) and neutral	± 1 kV line(s) and neutral	The electricity grid must be of commercial or hospital quality.
Voltage dips, short interruptions and voltage fluctuations in input power lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (> 95 % dip in U_T) for 5 s	<5 % U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (> 95 % dip in U_T) for 5 s	The quality of the power supply must be that of a typical commercial or hospital environment. If the user of the Transcutaneous Electrical Nerve Stimulator requires continuous operation during power interruptions, it is recommended to operate the device via an uninterruptible power supply.
Power frequency (50 Hz/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields must have levels that are characteristic of a location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Recommended distances between portable and mobile RF communication devices 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 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the nerve stimulator as recommended below, according to the maximum output power of the communications equipment.

Maximum rated output power of the transmitter (W)	**Distance according to the frequency of the transmitter (in 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**

If the nominal output power of a transmitter is not listed in the table above, the recommended minimum distance (d) results from the equation in the corresponding column for the transmitter frequency. P is the maximum rated output rated power of the transmitter specified by the manufacturer and the unit is watts (W).

NOTE 1 At frequencies below 80 MHz and 800 MHz, use the equation with the higher frequency.

NOTE 2 These guidelines do not apply to all situations. Electromagnetic transmission is affected by buildings, objects, absorption and reflection by the human body.

CE 0413

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