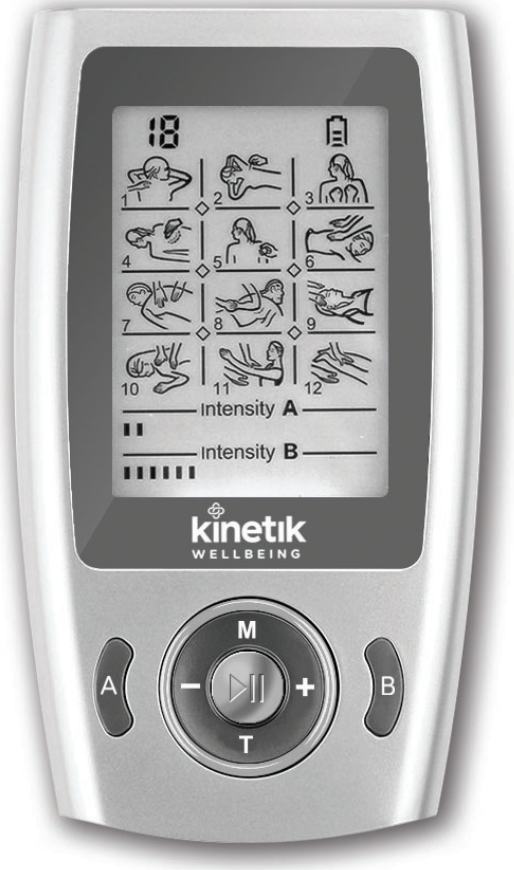
kinetik
WELLBEING



TENS Pain Reliever

User Manual

TD3 Series

Content

Support

Our manual should provide you with all the information you need to set up and use this product.

If you have a question, have a look at our Troubleshooting page!

For further assistance, why not contact our Customer Care team directly? We're here to help!

Our Customer Care team are available from 9am-5pm, Monday to Friday (excluding bank holidays).
We promise to respond to all queries and will ensure to resolve any issue you may be having.
You can reach us by…

Phone:
+44 1483 937969

Live Chat:
Simply visit www.kinetikwellbeing.com and send us a message.

Email:
customercare@kinetikwellbeing.com

Post:
Kinetik Medical Devices Limited
Unit 3, Perrywood Business Park, Honeycrock Lane,
Salfords, Redhill. RH1 5DZ

Introduction

Kinetik TENS Pain Reliever delivers electric impulses to tired and sore muscles. These different frequencies of impulses covering Transcutaneous Electrical Nerve Stimulation mimic the action potential coming from the central nervous system to trigger contraction of the muscle. It may be helpful in relieving aches and pains in various parts of the body such as the waist, shoulders, joints, hands and feet.

Indications for Use

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

Safety Warning

Contraindications

Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.

Do not use this device on patients whose pain syndromes are undiagnosed.

Warnings

Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Do not apply stimulation across the patient's chest, because the introduction of electrical current

into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
Do not apply stimulation over, or in proximity to, cancerous lesions.
Do not apply stimulation when the patient is in the bath or shower.
If you have one of the following conditions, please consult with your physician before purchasing or using this device.

- Acute disease
- Malignant tumor
- Infective disease
- Pregnant
- Heart disease
- High fever
- Abnormal blood pressure
- Lack of skin sensation or an abnormal skin condition,
- Any condition requiring the active supervision of a physician.

Precautions

Do not use this device while driving.
Do not use this device while sleeping.
Do not use this device in high humidity areas such as a bathroom.
Keep the device away from wet, high temperature and direct-sunlight place.
Keep this device out of reach of children.
Stop using this device at once if you feel pain, discomfort, dizziness or nausea and consult your physician.
Do not attempt to move the electrode pads while the device is operating.
Do not use the device around the heart, on the head, mouth, pudendum or blemished skin areas.

Do not apply stimulation of this device in the following conditions:
(1) across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
(2) over painful areas. Please consult with your physician before using this device if you have painful areas;
(3) over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins). Apply stimulation only to normal, intact, clean, healthy skin;
(4) in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms). The electronic stimulator may not operate properly when the electrical stimulation device is in use;
(5) while operating machinery, or during any activity in which electrical stimulation can put you at risk of injury;
(6) on children.
Be aware of the following.
(1) To consult with your physician before using this device. The stimulation from the device may:
    i. cause lethal rhythm disturbances to the heart in susceptible individuals.
    ii. disrupt the healing process after a recent surgical procedure.
(2) That the device is not effective for pain of central origin, including headache.
(3) That the device is not a substitute for pain medications and other pain management therapies.
(4) That the device has no curative value.
(5) That the device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
(6) That the long-term effects of electrical stimulation are unknown.
(7) That the user may experience skin irritation, burns or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
(8) If the user has suspected or diagnosed epilepsy, the user should follow precautions recommended by his or her physician.

(9) To use caution if the user has a tendency to bleed internally, such as following an injury or fracture.
(10) Use caution if stimulation is applied over the menstruating uterus.
(11) Use caution if stimulation is applied over areas of skin that lack normal sensation;
(12) Stop using the device if the device does not provide pain relief.
(13) Use this device only with the leads, electrodes, and accessories that the manufacturer recommends.
(14) Do not share the use of the electrode pads with others.
(15) Do not use the device while it's charging.
(16) The device contains a lithium battery. If overheating of the device occurs while charging, stop the charging or operation immediately and report to Kinetik Wellbeing.
(17) Dispose of the battery-containing device according to the local, state, or federal laws.

The long-term effects of electrical stimulation are unknown.
Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.

The safety of electrical stimulation during pregnancy has not been established.
Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
Use caution if stimulation is applied over the menstruating or pregnant uterus.

Adverse Reactions

Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

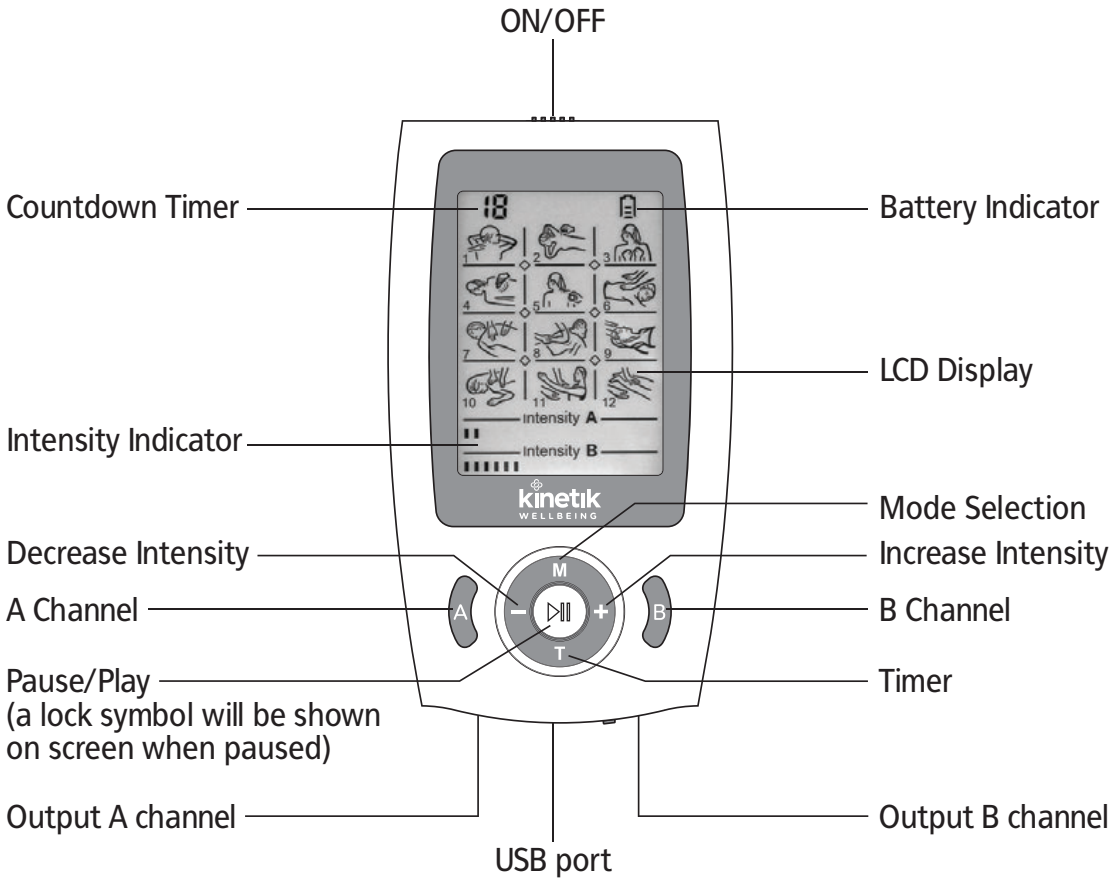
Product Specifications

Accessories included in the package.

- Kinetik TD3 Tens Machine
- 4 x Gel Pads
- 2 x Output Cables
- Micro USB Charger
- Instruction Manual
- Quick Start Guide

Parts & Setup

Unpack the product, take the product and accessories out, charge device and then connect the electrode pad into the device. Then simply turn-on and select mode/intensity as desired.



How to Use

- The Kinetik Wellbeing TD3 TENS Machine needs to be charged for up to 8 hours before the first use.
- Connect a pair of electrode pads to one output cable – this is done by snapping them on. If required, connect the other pair of electrode pads to the remaining output cable.
- Insert the output cables in use into the TD3
- Attach electrode pads to the treatment area, such as shoulders or legs.
- Turn the device on – the device will automatically start at Mode 1
- To change the mode, press the M button until desired.
- Gradually increase the intensity as needed by pressing the + button; to decrease the intensity press the – button.
- When pressing the ►II button, the device will pause treatment – this will be indicated by a lock symbol on the screen.
- When pressing T, one of the six-time options can be selected.
- When pressing the B button once, the device will switch from the control of channel A (left) to channel B – you can independently increase/decrease intensity of the channels.

Recommended practice:

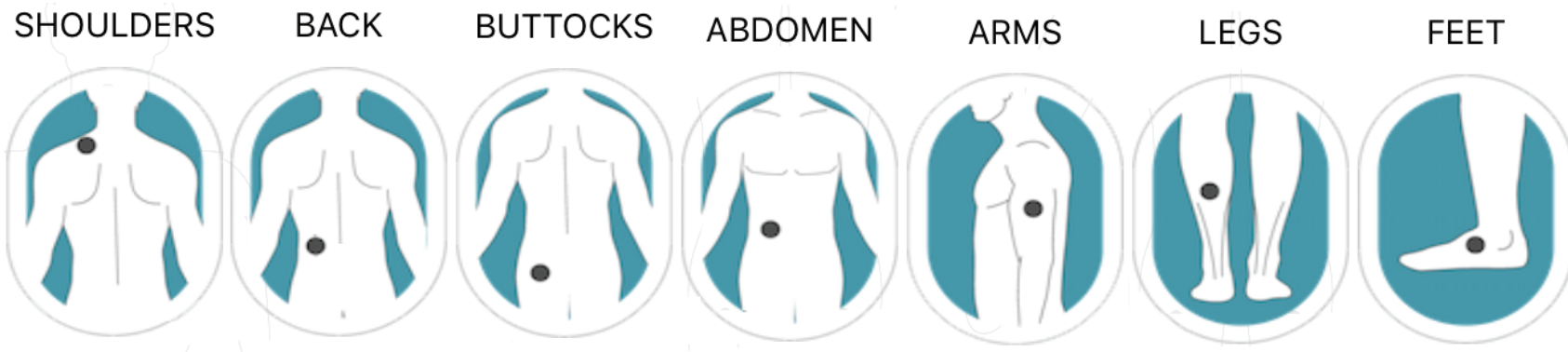
- Suggested duration for each skin area is 20 mins/2 times per day. Consult with your physician for longer and more frequent uses.
- Start from the lowest intensity and gradually adjust the intensity to a comfortable level – from a scale of 1 to 20.

- Good skin care is important for the comfortable use of this device. Be sure that the treatment area is clean of dirt and body lotion.
- Keeping the electrode pads in their plastic storage bags after use will extend lifespan. The electrode is disposable and should be replaced when it loses the adhesiveness. To purchase additional electrodes, please contact Kinetik Wellbeing.

Product Programs

Program name	Time min.	Frequency (Hz)	Pulse Width (µs)	Remarks
Mode 1	10,20,30,40,50,60	68.9	100	Feels like a Massage
Mode 2	10,20,30,40,50,60	12.5-55.5	100	Feels like Acupuncture
Mode 3	10,20,30,40,50,60	1.2	100	Feels like Beating
Mode 4	10,20,30,40,50,60	68.9	100	Feels like Scraping
Mode 5	10,20,30,40,50,60	100	100	Feels like Cupping
Mode 6	10,20,30,40,50,60	12.5-55.5, 1.2,55.5, 1.2,55.5, 1.2	100	Feels like a Thai massage
Mode 7	10,20,30,40,50,60	20	100	Feels like a Shiatsu massage
Mode 8	10,20,30,40,50,60	55.5	100	Feels like an Elbow massage
Mode 9	10,20,30,40,50,60	55.5	100	Feels Relaxing
Mode 10	10,20,30,40,50,60	100	100	Feels like a Foot massage
Mode 11	10,20,30,40,50,60	68.9	100	Feels like Tapping
Mode 12	10,20,30,40,50,60	68.9	100	Feels like a Swedish massage

Recommended Use Positions



Cleaning and maintenance

Please use a slightly wettened cloth or natural detergent to clean the device first, and then use a dry cloth to wipe again.

The electrode pads that come with the device are disposable and should be replaced after they lose their adhesiveness – please contact Kinetik Wellbeing for replacements. We recommend that users avoid the sticky side of the pads from touch.

Technical Information

Model/type	TD3	Weight	40g
Power supply	Powered by internal 3.7V li-ion battery	Automatic shutoff	After 20 minutes without use
Waveform and wave shape	Biphasic rectangular wave pulse	Degree of protection against electric shock	Type BF applied part
Pulse duration	100us (Microseconds)	Type of protection against electric shock	Internally powered equipment
Pulse frequency	1-100Hz (Hz=vibration per second)	Grade of waterproof	IP22
Output Voltage	Max. 70Vpp ±20%(at 500ohm load)	Product life	1 year
Treatment time	10 min, 20 min, 30 min, 40 min, 50 min, 60 min	Lifetime for electrode pad	No use (in storage): 1 year In use: 30 uses
Output intensity	0 to 20 levels, adjustable	Mode of operation	Continuous operation
Modes	12 auto modes	Software version	A0
Typical operation time of Battery	To use both channels together at level 10, the battery can be used 570 mins after fully charged. If to use at level 20, the battery can be used for 180 mins after fully charged.	The time required for equipment to warm from the minimum storage temperature between uses until it is ready for intended use	30 minutes
Behaviour of equipment while the rechargeable internal electrical power source is charging:	The battery icon on the right corner will flash during charging and will be still with full capacity after fully charged.	The time required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use	15 minutes
Typical service life of Battery	300 times of recharging	Adapter for charging	Please use output DC5V and output current 0.3-2.0A adapter for charging
Note: Not intended to be sterilized.			
Not for use in an OXYGEN RICH ENVIRONMENT			

Troubleshooting

If your device is not operating properly, please check below for common problems and suggested solutions. If the recommended action does not solve the problem, please contact Kinetik Wellbeing.

Problem	Possible Cause	Solution
One pad feels stronger than the other	This is normal. Different area of your body will react differently	Nothing needs to be done. Make sure the pads are moist and making good contact.
The intensity feels very weak	Pads are not attached to the body firmly	Attach both pads firmly to the skin
	The transparent films are still stuck to the pads	Peel off film on the adhesive surface of pads
	The pads stack together or overlap	Do not stack pads together or overlap pads
	The cord is not properly connected to the unit	Connect cord correctly into the jack
	The intensity setting is low	Increase the intensity level
	The battery capacity is low	Charge the battery
The skin turns red or the skin feels irritated	The adhesive surface of the pads is dirty or dry	Wash adhesive surface of pads gently with your fingertips for about 3 seconds under slow running water
	The therapy time is too long, or the intensity is set too high	Reduce the application time or reduce the intensity
	The electrode pad surface is worm out	Replace electrode pad

Troubleshooting

Problem	Possible Cause	Solution
No power source; no display on LCD	The battery capacity is depleted	Charge the battery
Power cuts off during use	The battery is weak	Charge the battery
	The cord is broken	Replace the cord
It is difficult to attach the pad to the skin	Have you removed the transparent film from the pad?	Peel off film on the adhesive surface of pads
	Was the pad applied immediately after washing?	Dry the pad
	Is the adhesive surface of the pad damaged?	Replace the pad
Adhesive surface of pad is not sticky	Pads have deteriorated	Contact the vendor for replacements.
	Were the pads stored under high temperature, high humidity, or direct sunshine?	Replace the pad.

Environmental condition for normal working, transport and storage

- Normal working ambient temperature: 5~40°C
- Normal working ambient humidity: 15~90%
- Store and transport ambient temperature: -25 ~70°C
- Store and transport ambient humidity: 0~90%
- Atmospheric pressure: (70~106)kPa

Symbols interpretation

	Fragile, handle with care		Type BF applied part
	Keep the product in the dry place Away from water and rain		Read the instructions (actual symbol colours are white on a blue background).
	This way up		Manufacturer
	Product package should be recycled	EC REP	Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
	Unrecyclable	CE 0197	CE marking, Certificate issued by TUV Rheinland
	Date of manufacture	IP22	IP code of the device
SN	Serial number	RoHS	Restriction of Hazardous Substances

Safety Test Standards

- Medical Devices Directive 93/42/EEC
- IEC 60601-1:2005+A1:2012/EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2：2014/EN60601-1-2：2014 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-10:2012/EN 60601-2-10:2000+A1:2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- IEC60601-1-11:2015. 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.
- EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN 1041 Information supplied by the manufacturer with medical devices
- IEC/60601-1-6/ EN 60601-1-6 Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-11/ EN 60601-1-11 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 home healthcare environment
- IEC 62304/ EN 62304 Medical device software - Software life-cycle processes
- IEC 62366/ EN 62366 Medical devices – Application of usability engineering to medical devices
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EMC and FCC statement

Electromagnetic Compatibility and FCC Compliance Statement

1) This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF) communications equipment.
2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4) Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

Guidance and manufacture's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device use 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.

EMC and FCC statement

Guidance and manufacture's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emission CISPR 11	Class B	The device 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

EMC and FCC statement

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are 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 ±1 kV for input /output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

EMC and FCC statement

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 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 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz /60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

EMC and FCC statement

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$

EMC and FCC statement

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

EMC and FCC statement

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC and FCC statement

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EMC and FCC statement

The subject device 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.

The product generates, uses, and can radiate radio frequency energy and, if not installed and used accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that the interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on or off, the user is encouraged to try to correct the interference by one or more of the following measures:

a) Reorient or relocate the receiving antenna;
b) Increase the separation between the product and the receiver;
c) Consult the dealer or an experienced radio / TV technician for help.
d) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Changes or modifications to this product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Contact Information

Manufacturer:

Harvard Medical Devices Ltd. HK
Unit 1002, 10th Floor, Railway Plaza,
39 Chatham Road South, Tsimshatsui,
Kowloon, Hong Kong.

EC Authorized Representative:

Share Info Consultant Service LLC Repräsentanzbüro
Heerdter Lohweg 83, 40549 Düsseldorf

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