Name: Shenzhen Dongdixin Technology Co., Ltd.
Add: Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate
Xilixiaobaimang 518108 Nanshan District, Shenzhen P. R. China
Tel: 0086-755-27652316
E-mail: service@e-caretalk.com
www. e-caretalk.com

EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg Germany
Tel: 0049-40-2513175 Fax: 0049-40-255726

CE 0197

Wireless transmission

30 min

TENS Stimulator

LT1102 User Manual

CONTENTS

INTRODUCTION

Thank you for purchasing Dongdixin's TENS Stimulator LT1102 for pain relief solution.

Please read the complete manual carefully before using the device for the first time and keep this instruction manual in a convenient place or store with the device for future reference.

LT1102 is a TENS stimulator. What is TENS?
Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

How TENS works? Scientific theory suggests that electrical stimulation therapy may work in several ways:

- The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.

INTRODUCTION

- The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
- Furthermore, it is thought that the electrical stimulation improves blood circulation as well. Muscles contract and relax with the flow of the electrical stimulation. With repeated contracting and relaxing, the blood flows in and out and the blood circulation is improved.

The TENS Stimulator should be applied to normal, healthy, dry and clean skin of adult patients.

The LT1102 contains the following components:

- 6 x AAA batteries
- 2 x TENS Stimulator LT1102
- 1 x Remote Control
- 1 x User manual

IMPORTANT INFORMATION

Intended use

The device is designed to be used for temporary relief of pain, including the acute and chronic pain.

Contraindications

Do not use this device with the following medical devices:

- Implanted electronic medical devices, such as pacemakers. This may cause electric shock, burns, or death.
- Electronic life support equipment, such as respirators.
- Electronic medical devices worn on the body, such as electrocardiographs.
- If you use this device together with other electronic medical devices, these devices may not work correctly.

Warnings

- If you are in the care of a physician, consult your physician before you use this device.
- If you have had medical or physical treatment for your pain, consult your physician before you use this device.
- If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult your physician.
- Consult your physician before you use this device. The device may cause lethal disturbances to the heart rhythm in susceptible individuals.

SAFETY INFORMATION

- Do not use the device if you have a cognitive impairment (e.g. dementia, Alzheimer's disease). People who have a cognitive impairment may be unable to use the device according to the instructions and may become agitated by the treatment.
- Do not use the device on children, as it has not been evaluated for pediatric use.
- Do not use the device on the side of your neck (on the carotid sinus) or any area of the throat (front of the neck). This could cause severe muscle spasms that may result in closure of your airway, breathing difficulties, or adverse effects on heart rhythm or blood pressure.
- Do not use the device across your chest. The device introduces electrical current. Using the device in your chest may cause rhythm disturbances to your heart, which could be lethal.
- Use the device only on normal, intact, clean, and healthy skin.
- Do not use the device over open wounds or rashes, and over swollen, red, infected, or inflamed areas or skin eruptions (e. g., phlebitis, thrombophlebitis, varicose veins).
- Do not use the device over, or close to, cancerous lesions.
- Do not place the electrodes inside body cavities, e.g. the mouth. This may cause skin irritation, skin burns or electrical shocks. This device is not designed for internal application.
- Do not use the device in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms). This equipment may not operate properly when the electrical stimulation device is in use.

SAFETY INFORMATION

- Do not use this device over your eyes, mouth, face, front of neck (especially in the carotid sinus) or across your heart because this could cause severe muscle spasms resulting in closure of your airway, difficulty breathing or adverse effects on heart rhythm or blood pressure.
- Do not use the device when in the bath or shower.
- Do not use the device while sleeping.
- Do not use the device while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Do not modify the device or the electrodes without authorization of the manufacturer. This could cause improper functioning.
- As the electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation, take the following into account:

1. If the electrodes are too small or not correctly applied, this may result in discomfort or skin burn.
2. Contact the manufacturer of the device, if you do not know if the electrode can be used with the device.

Precautions

- TENS is not effective for pain of central origin, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.

IMPORTANT INFORMATION

- TENS devices have no curative value.
- TENS is a symptomatic treatment. It suppresses the sensation of pain that normally serves as a protective mechanism.
- As TENS treatment may not be effective for everyone, consult your physician or healthcare professional to find out if TENS will work in your case.
- The long-term effects of electrical stimulation are unknown.
- Because the effects of stimulation on the brain are unknown, do not use the device on opposite sides of your head.
- Electrical stimulation or the electrical conductive gel may cause skin irritation or hypersensitivity, the irritation can usually be reduced by alternate electrode placement.
- If you have suspected or diagnosed heart disease, follow the precautions from your physician.
- If you have suspected or diagnosed epilepsy, follow the precautions from your physician.
- Use caution if you are likely to have internal bleeding, for instance, after injuries or fractures.
- If you had surgery recently, consult your physician before you use the device. Using the device may disrupt the healing process.
- Use caution when you use the device over areas of skin that lack normal sensation.
- The impact of using this device during pregnancy is unknown. It may be not safe.
- Use caution when you use the device over the uterus during pregnancy or menstruation.

IMPORTANT INFORMATION

- Keep this device out of the reach of children.
- Do not use the device or an electrode if it is damaged. Always check the device and the electrodes for damage before use.
- Do not use plaster or tape to attach the electrodes to the skin.
- Make sure that the electrodes do not touch metal objects, such as belt buckles or necklaces.
- Use this device only with the electrodes, and accessories recommended by the manufacturer.
- Always end the device before you remove the device or the electrodes. If you do not end the treatment, you may get an unpleasant sensation in your fingers when you touch the buckle. This sensation is not harmful, but it can be unpleasant.
- Do not place on your spine or backbone.

General recommendations

- Read this user manual carefully and always follow the treatment instructions.
- Do not use this device for any other purpose than what it is intended for.
- This device is designed for use by and on a single adult person. For hygienic reasons electrodes should not be shared.
- Do not use the device if you are connected to high-frequency surgical equipment. This may result in burns on the skin under the electrodes and may damage the device.

IMPORTANT INFORMATION

- Do not use the device within less than 39 inches (1 meter) from shortwave or microwave medical equipment. Close proximity to this equipment may cause unstable device output.
- Although you can use the device indoors and outdoors, it does not withstand all weather conditions.
- The electrodes have a limited shelf life. Please check the packaging for the use-by date before use.
- Do not use electrodes whose use-by date has expired.
- Always use and store the electrodes according to the instructions.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

RISKS

General risk

TENS only treats symptoms. It reduces the feeling of pain, but it does not cure the cause of the pain. Pain may be a signal from your body that some part of your body is damaged and needs attention.

IMPORTANT INFORMATION

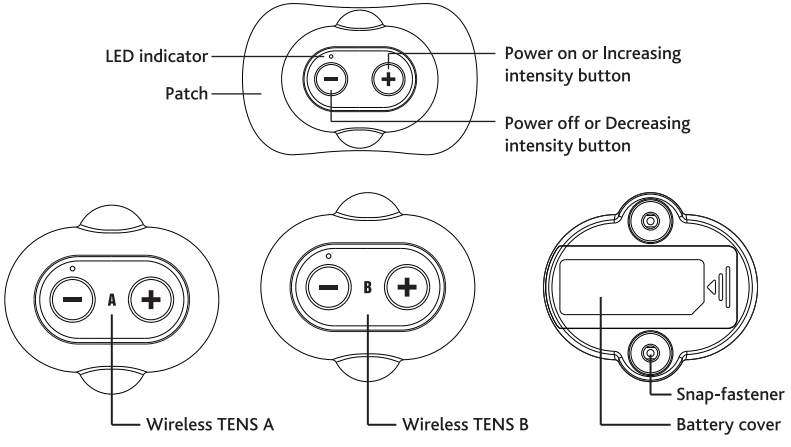
Specific risks

- You may get skin irritation and burns under the electrodes applied to your skin.
- You may get a headache or other pain if you use the device near your eye, or on your head or face.
- You may experience muscle exhaustion or muscle soreness after extended use on the same muscles (more than 30 minutes a session, up to 3 times a day).
- Stop using the device and consult your physician if you experience adverse reactions from the device.
- To ensure safe usage of the device, follow the instructions in this user manual. Read the contraindications, warnings and precautions sections before you use this device. If you are not sure if the device is suitable for you, consult your physician before using this device.

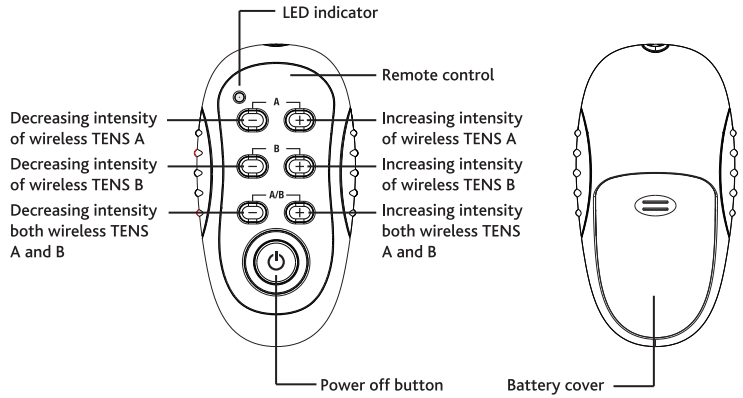
FEATURES

- Mini appearance
- Wireless transmission
- Fast and convenient adjustment
- Single patient use, clean and health
- One therapy mode consist of three different therapy phase

PRODUCT STRUCTURE



PRODUCT STRUCTURE



REMOTE CONTROL

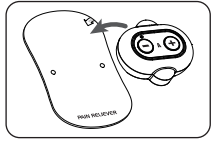
It is a feature that the remote control allows you to adjust output intensity of both wireless TENS A and B through wireless transmission. Before using the remote control, please make sure that wireless TENS which you are going to use has been opened. It is supplied with two 1.5V AAA batteries.

⚠ CAUTION

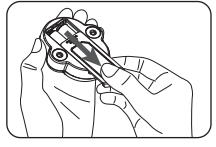
1. Between using, keep the remote control far away from children.
2. Detail of battery replacement, please refer to the battery information on next page.

BATTERY INFORMATION

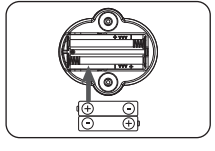
1. Before replacing, please ensure the device has been turned off.
2. Take off the device from the patch.



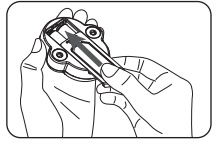
3. Push out the battery cover.



4. Insert the batteries (2 x 1.5V AAA).



5. Close the battery cover.



BATTERY INFORMATION

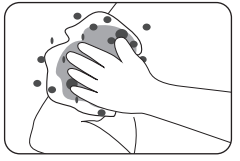
⚠ WARNING

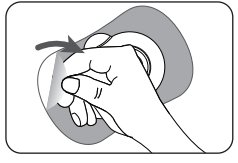
- Remove the batteries if the device is not used for a long time.
- Keep batteries out of the reach of children.
- Dispose the used batteries safely according to the local regulations.
- Do not mix old and new batteries or different types of batteries.
- If battery leak and come into contact with the skin or eyes, wash immediately with copious amounts of water.

Standard for battery replacement
If you feel the stimulation intensity is weak or the device cannot power on, the batteries may be exhausted, please replace the batteries.

TREATMENT INFORMATION

Step 1 Cleaning of skin
Clip excess hair from painful area. Wash area with soap and water and dry completely.



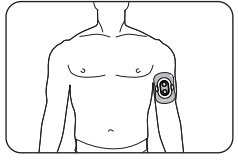


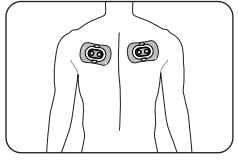
Step 2 Preparation of the Wireless TENS
Connect the device with the patch.
Remove the Wireless TENS from the clear plastic backing.
Save the plastic backing for storing the patches after use or during using.

TREATMENT INFORMATION

Step 3 Placing the Wireless TENS
Place the Wireless TENS on a clean, dry and healthy skin above and below or on either side of the painful area.

NOTE:
1. Make sure that it is contacted well with your skin.
2. During in use, it is allowed to place the device in different area.
3. You can choose to use one or two of the Wireless TENS.

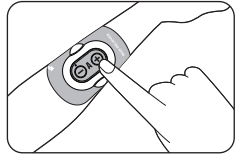




TREATMENT INFORMATION

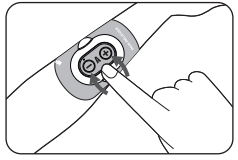
Step 4 Turn on the device
Press the "+"button to turn on the device.

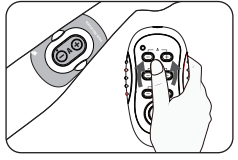
NOTE:
The LED indicator on the device has four conditions:
1. Light, the device is ready for use
2. Blinking, the device is working.
3. Rapid blinking, receiving information from the remote control.
4. Light off, the device is turned off.



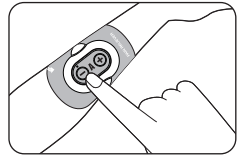
Step 5 Set output intensity
Using either the remote control or buttons on the device, set the intensity level by using the "+/-"buttons.

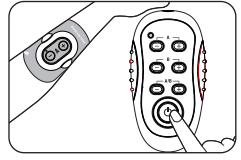
NOTE:
During treatment, if the LED indicator stops blinking, please check whether the device is contacted well with your skin.





Step 6 Turn off the device
The following ways to turn off is allowed:
1. The device will automatically turn off after 30 minutes treatment.
2. Keep pressing the "-"button on the device until the LED indicator is off.
3. The device can be turn off at any time by pressing the " ⏻ " button on the remote control.





CLEANING AND STORAGE INFORMATION

Cleaning the device

1) Take off the device from the patches.
2) Clean device and patch with a lightly moistened cloth (or a cloth soaked in a neutral cleaning solution) and wipe gently.
   - Do not use chemicals (like thinner, benzene).
   - Do not let water get into the internal area.

Storing the device

1. Turn off the device and place the patch onto the plastic film.
2. Store the box in a cool, dry place, -10℃~55℃; 10% ~90% relative humidity.
3. Keep the device out of the reach of children.
4. Remove the battery if the device is not in use for long periods of time.
5. Do not expose the device to any chemical solvent, water lint, direct sunshine or high temperature.

⚠ CAUTION

- If the patches no longer stick to your skin or the patches are broken, you should replace new patches.
- The TENS Stimulator is single patient use. Don't share it with others.

TECHNICAL SPCIFICATION

Type:	TENS Stimulator LT1102
Power supply:	DC3.0V (2×AAA)
Wave form:	Bi-phase square pulse wave
Frequency:	5~125Hz
Pulse Width:	130/250us
Output Voltage:	0~35V(at 500 ohm load)
Output Intensity Level:	0~20 levels
Treatment Time:	30 minutes
Operating Conditions:	5℃ to 40℃; 30%RH to 75%RH; 700hpa to 1060hpa
Storage and transportation Conditions:	-10℃ to 55℃; 10%RH to 90%RH; 700hpa to 1060hpa
Size:	103 (L) x 55.8 (W) x25.2 (H) mm(Remote control) 60 (L) x 53 (W) x17.7 (H) mm(TENS Stimulator A and B)

TECHNICAL SPCIFICATION

Weight:	42.5g without battery(Remote control) 44.4g without battery(TENS Stimulator A and B)
Service life of the device:	3 years
Service life of the electrode pads:	10~15 times
Service life of battery:	New batteries will last for approx.15 times
Applied part:	Electrode

PROGRAM

During in use, the Wireless TENS has three phases. The specific of them as following:

Program	Frequency	Pulse Width	Time	Description
1	80~125Hz	130us	5min	The frequency is changed in a cycle, which is from 80Hz to 125Hz, then back 80Hz. The cycle time is 32s.
2	5-10Hz	250us	20min	The frequency is changed in a cycle, which is from 5Hz to 10Hz, then back 5Hz. The cycle time is 10s.
3	80~125Hz	130us	5min	The frequency is changed in a cycle, which is from 80Hz to 125Hz, then back 80Hz. The cycle time is 32s.

DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of battery correctly.

Please dispose of the device in accordance with the legal obligation.

NORMALIZED SYMBOLS

Disposal in accordance with Directive 2012/19/EU(WEEE)

Type BF applied part

Please refer to instruction manual

SN

Serial number.

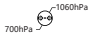
EC REP

The name and the address of the Authorized EC-representative in Europe

Transportation and storage temperature from -10℃ to 55℃

NORMALIZED SYMBOLS

Transportation and storage humidity limits from 10% to 90%



Transportation and storage atmospheric pressure limits from 700 hPa to1060 hPa

CE 0197

Complies with the European Medical Device Directive (93/42/EEC) and amended by directive 2007/47/EC requirements

The name and the address of the manufacturer

Date of manufacture

TROUBLESHOOTING

Problem	Possible causes	Possible solution
The device cannot power on	Is the battery exhausted?	Replace the battery.
	Is the battery installed correctly?	Insert the battery observing polarity.
Stimulation weak or cannot feel any stimulation	Patches dried out or dirty	Replace new patches
	Patches cannot stick skin well	Reconnect the patches
Stimulation is uncomfortable	Intensity is too high	Decrease intensity.
	Mayn't operate the device according to the manual.	Please check the manual before use
The LED indicator on the remote control not light	Is the battery on the remote control exhausted?	Replace the battery.

TROUBLESHOOTING

Problem	Possible causes	Possible solution
The skin becomes red and/or you feel a stabbing pain	Use the Patches on the same site every time	Re-position the Patches.
	The patches aren't stuck onto the skin properly	Ensure the patches are stuck securely on the skin.
	The patches are dirty	Clean the patches according to description in this manual or replace new patches.
	The surface of the patches was scratched.	Replace new patches.

If the unit does not operate after taking the above-mentioned measures, contact the nearest dealer.

WARRANTY

Please contact your dealer or the device centre in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

1) The warranty period for device is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2) Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
3) The following is excluded under the warranty:
   - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
   - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
   - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
   - The battery and patches are subject to normal wear and tear.
4) Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

Important information regarding electromagnetic compatibility (emc)

- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- When the operating environment is relatively dry, strong electromagnetic interference usually occurs. At this time, the

device may be affected as follows:
- the device stops output;
- the device turns off;
- the device restarts;

The above phenomenon does not affect the basic safety and essential performance of the device, and the user can use it according to the instruction. If you want to avoid the above phenomenon, please use it according to the environment specified in the manual.

Important information regarding electromagnetic compatibility (emc)

Table 1

Declaration-electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device 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	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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Important information regarding electromagnetic compatibility (emc)

Table 2

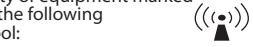
Declaration-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity test	IEC 60601test level	Compliance level	Electromagnetic environment guidance
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 should be wood, concrete or ceramic tie. If floors 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 ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV,±1 kV line (s) to lines ± 0.5kV, ±1 kV, ±2kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Important information regarding electromagnetic compatibility (emc)

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°,45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable	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 batter.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Declaration-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity test	IEC 60601test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3V 0.15 MHz to 80MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of device, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	

			the recommended separation distance in meters (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. 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.

a Field strengths from fixed RF 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 device is used exceeds the applicable RF compliance level above, device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating device.

b Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and 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		
	0.15 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7GHz $d = 2.3\sqrt{P}$
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 meters (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 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.

FCC Compliance information

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

Changes or modifications 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.

FCC Compliance information

FCC Radiation Exposure Statement
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.