Wireless TENS

SUNSET
HEALTHCARE SOLUTIONS

Electronic pulse stimulator

for sore muscle relief

TEN200

Operating Manual

Table of Contents

Introduction..... 1
Indications for Use..... 1
Safety Warnings..... 2
Contraindications..... 2
Warnings..... 2
Precautions..... 2
Adverse Reactions..... 3
Environmental Condition for Transport and Storage..... 3
Operating Instructions..... 4
Cleaning and Maintenance..... 6
Troubleshooting..... 7
Recommended Use Positions..... 8
Product Specifications..... 9
Symbols interpretation..... 11
Safety Test Standards..... 11
Electromagnetic Compatibility and FCC statement..... 12
Contact Information..... 17

Introduction

The Wireless TENS is an Electronic Pulse Stimulator that delivers electric impulses to tired and sore muscles. The different frequencies of impulses covering Transcutaneous Electrical Nerve Stimulation mimic the nerve impulses coming from the central nervous system to trigger muscle contractions. It may be helpful in relieving aches and pains in various parts of the body such as the back, arms, legs, 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, arms, and legs, due to strain from exercise or normal household and work activities.

Safety Warnings

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 symptoms 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 or humid conditions, high temperatures, and direct sunlight.
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, genitals 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 simulation with the device may:
    i. cause lethal rhythm disturbances to the heart in susceptible individuals;

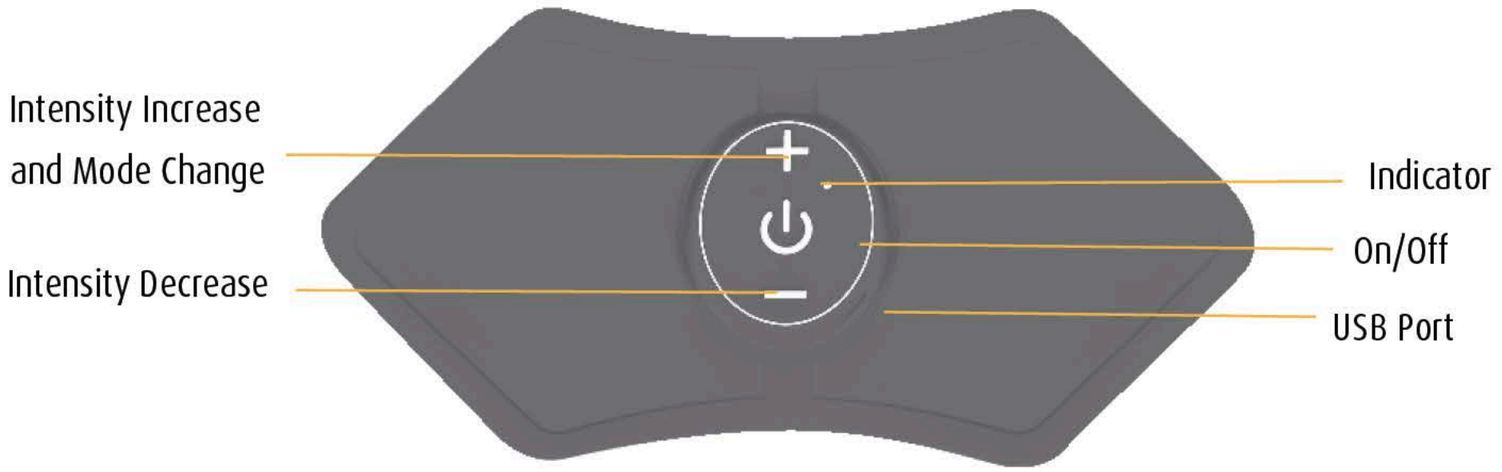
ii. disrupt the healing process after a recent surgical procedure;
(2) that the device is not effective for under-muscle pain, including headache;
(3) that the device is not a substitute for pain medications and other pain management therapies;
(4) that the device has no curative value;
(5) that the 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) Do not share the use of the electrode pads with others.
(14) Do not use the device while it's charging.
(15) The device contains a lithium battery. If overheating of the device occurred during charging, stop charging or operation immediately and report to the seller.
(16) 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 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.

Environmental condition for transport and storage
- Normal working ambient temperature: 5~40°C
- Normal working ambient humidity: 15%~90% RH
- Store and transport ambient temperature: -25 ~70°C
- Store and transport ambient humidity: 0~90% RH
- Atmospheric pressure: 70~106kPa

Operating Instructions



Before Use

It is recommended to charge the Pad with the enclosed USB cable, which could connect to a USB computer port, or a USB AC adapter.

Preparing electrode pads

Peel off the blue plastic film from one of the enclosed gel electrode pads. Adhere the exposed sticky side onto one of the metal parts on the back side of the unit. The shape of the sticky gel pad should match and cover the shape of the metal part of the unit. Repeat with one more pad to cover other half of the backside of the unit. Then, peel off clear plastic, leaving the sticky pads on the unit. Do not discard clear plastic. Place the Therapy Pad onto the treatment areas (such as shoulder or leg). Press down firmly and ensure a full and firm contact with skin.

Operation

Press the On/Off button to turn on the unit, indicated by the LED light and buzz sound on for 1 second.

Changing Mode

MODE 1 (Combination), MODE 2 (Scrapping), MODE 3 (Massager), MODE 4 (Beat), MODE 5 (Acupuncture).

- Device defaults to MODE 1 (Combination) which is a combination of all 4 modes.
- To change mode, HOLD the " +" button for 3 seconds to select desired pulse mode

When the mode is changed, it will BUZZ and FLASH the number of times of which mode you are on. Example, for MODE 2, the device will buzz and flash twice.

Changing Intensity

There are 15 levels of intensity

- Press the "+" button for increased intensity.
- Press the "-" button for decreased intensity.

Each time the intensity is changed, the device will flash and buzz once.

Run Time

The countdown timer is 20 minutes. When the timer is up, the unit will turn off automatically. You can also turn off any time by pressing the on/off button indiciated by the light flashing 3 times and buzzing 3 times.

Note: To conserve battery and prevent unexpected shock, the device will automatically power off when not in use on any treatment area, indicated by the light and sound on for 3 seconds and then flashing and buzzing 3 times.

Recommended practice:

- Duration of 20 minutes for each body area.
- Frequency of 1-2 times per day per area.
- Start from the lowest intensity and gradually adjust to a comfortable level on a scale level from 1 to 15.
- Be sure the area to be treated is free of perspiration, dirt and abrasions.
- Good skin care is important for a comfortable use of device. Be sure the treatment site is clean of dirt and body lotion, and wipe with an alcohol pad if needed.
- After use, place the clear plastic covers over the electrode pads. Keeping pads clean will extend their lifespan, which will vary and depend on the frequency of use. Avoid touching the adhesive area of pads with fingertips
- The electrode pads are disposable and should be replaced when they lose their adhesiveness. To purchase additional pads, please contact the seller.
- If the LED light becomes blurry and/or the stimulation intensity becomes weaker, it means the battery power is running low. It is time to recharge the device. After fully charged, the device will have the LED light resume the brightness.

Cleaning and maintenance

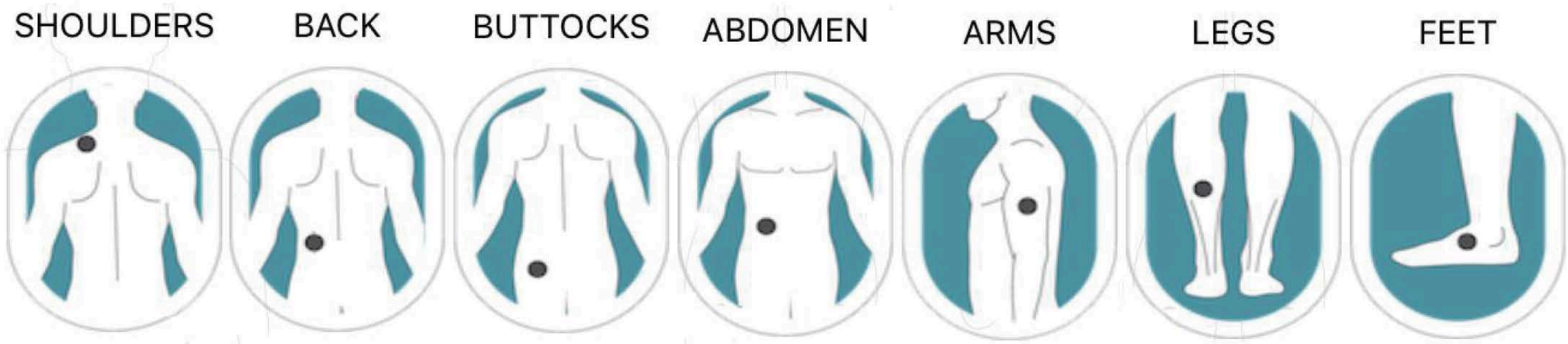
Please use a damp cloth or neutral detergent to clean the device first, and then use a dry cloth to wipe it again. The electrode gel pads included with the device are disposable, and should be replaced when they lose their effective adhesiveness. Contact the seller for replacements. Do not let the sticky side of the pad touch anything, including greasy finger tips. When the device is not in use, use the clear pad covers to keep gel pads clean.

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 the seller.

Problem	Possible Cause	Solution
The intensity is not felt with a very weak intensity level	Pads are not attached to the body firmly	Attach both pads firmly to the skin or replace pad if surface is worn and no longer sticky
	The transparent films are still stuck to the pads	Peel off film on the adhesive surface of pads. Do not discard film
	The pads stack together or overlap	Do not stack pads together or overlap pads
	The intensity setting is getting weak	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 intensity, or manually power down the device by pressing the center button.
	The electrode pad surface if worm out	Replace electrode pad
No power source	The battery capacity is depleted	Charge the battery
It is difficult to attach the pad to the skin	Have you remove 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 get deteriorative	Contact the vendor for replacements.
	Were the pads stored under high temperature, high humidity, or direct sunshine?	Replace the pad.

Recommended Use Positions



Product Specifications

Accessories included in the package.
(1) Tens unit controller * 1pc
(2) Gel pads * **1** pair
(3) USB line *1pc
(4) Manual *1pc

Technical Information

Model/type	TEN200
Power supply	Powered by internal 3.7V li-ion battery
Waveform and wave shape	Biphasic rectangular wave pulse
Pulse duration	50us (Microseconds)
Pulse frequency	1-100Hz (Hz=vibration per second)
Output Voltage	Max. 60Vpp ±20%(at 500ohm load)
Treatment time	20 minutes
Output intensity	0 to 15 levels, adjustable
Modes	5 auto modes
Typical operation time of Battery	To use at highest level 15, the battery can be used approximately for 150 minutes after fully charged.

Weight	19g
Automatic shutoff	20 minutes
Degree of protection against electric shock	Type BF applied part
Type of protection against electric shock	Internally powered equipment
Grade of waterproof	IP22
Product life	1 year
Lifetime for electrode	Storage for 1 year （no use）, Times of reusable: 30 times
Mode of operation	Continuous operation
Software version	A0
The time required for the equipment to warm from the minimum storage temperature between uses until it is ready for intended use	30 minutes

Behaviour of the equipment while the rechargeable internal electrical power source is charging:	The light indictor will flash during charging and will be lit with full capacity after fully charged.
Typical service life of Battery	300 charges

The time required for the equipment to cool from the maximum storage temperature between uses until it is ready for intended use	15 minutes
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

Product Programs

Program name	Time min.	Frequency (Hz)	Pulse Width (μs)
Mode 1	20	6.6-83.3HZ	50
Mode 2	20	35.7	50
Mode 3	20	62.5	50
Mode 4	20	6.6	50
Mode 5	20	83.3	50

Symbols interpretation

	Fragile, handle with care		Type BF applied part
	Keep the product in the dry place Away from water and rain.		CAUTION, Avoid injury. Read and understand owner's manual before operating this product.
	This way up		Manufacturer
	Product package should be recycled.	LOT	Batch code
	Unrecyclable	FDA 510(k)	FDA 510(k) cleared
	Maxium carton layer	IP22	IP code of the device
	Date of manufacture		

Safety Test Standards:

MedicalDevicesDirective 93/42/EEC

IEC60601-1:2005+A1:2012/EN 60601-1:2006Medical electrical equipment - Part 1: General requirements for basic safetyand essential performance

60601-1-2:2007/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements forsafety - Collateral standard: IEC Electromagnetic compatibility - Requirements and tests

IEC 60601-2-10:2012/EN 60601-2-10:2000+A1:2001Medical electrical equipment - Part 2-10: Particularrequirements for the safety of nerve and muscle stimulators

IEC 60601-1-11:2010 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 980 Symbols for use in the labeling of medical devices

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 60601-1-11Medical 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

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The deviceis intended for use in the electromagnetic environment specified below. The customer or the user of the deviceshould 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.
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 devicebe 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user ofthe 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 V_{rms} 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** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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 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 benecessary, such as re-orienting or relocating the device.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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 themaximum 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.

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

Manufactured for

Sunset Healthcare Solutions
180 N Michigan Ave Ste 2000
Chicago, IL 60601
www.sunsethcs.com

This device complies with Part 15 of the FCC Rules