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Made in China

EHE015BLE
V03: 20230421



Electronic Pulse Stimulator



Operating Manual
EHE015BLE

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Introduction

Electronic Pulse Stimulator

The EHE015BLE Electronic Pulse Stimulator is a professional model of the Easy@Home TENS Unit product line. This portable and compact device delivers electric pulses generated to the user's skin through the electrodes and it has multiple modes of different pulse frequencies, covering Electric Muscle Stimulation (EMS) for muscle toning, firming, and strengthening. Also, the modes of Transcutaneous Electrical Nerve Stimulation (TENS) could relieve pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. It includes operating elements of ON/OFF button, intensity increase/mode selection button, and intensity decrease/timer selection button, and could be attached and detached to the electrode through the two snap-on connectors.

Indications for Use

TENS (Modes 1, 2, 4, 5, 6, 8,)

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.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

EMS (Modes 1, 3, 7)

To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Safety Warning

Contraindications

Do not use this device on Users 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 Users 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 with the device may:
 - i. cause lethal rhythm disturbances to the heart in susceptible individuals, and,
 - 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; and,
- (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 the lithium battery. If overheating of the device occurred during the charging, stop the charging or operation immediately and report to the distributor/seller.
- (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 Users may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

Users with suspected or diagnosed heart disease should follow precautions recommended by their physicians.

Users 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

Users may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;

Users may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.

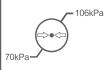
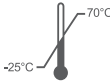
Users should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

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:(70~106)kpa

Symbol Interpretation

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and labeling.

Symbol	Title	Symbol	Title	Symbol	Title
	Batch code		IP code of the device		Fragile, handle with care
	Type BF applied part		Date of manufacture		Product packaging is able to be recycled
	Atmospheric pressure limitation of 70kPa ~ 106kPa		Temperature limit of -25°C ~ 70°C		Humidity limitation of 0% ~ 90%
	Refer to instruction manual		Keep the product in the dry place Away from water and rain.		

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
- IEC 60601-1-2:2007/EN 60601-1-2:2007 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
- 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 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 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

Operating Instruction

Setup

Unpack the box of the product, take the product and accessories out, and connect the electrode pad onto the device.



Electrode pad



Control unit



USB Cable

⊕ Intensity increase and mode change

⊖ Intensity decrease and timer change

⏻ On/Off

● Indicator Light



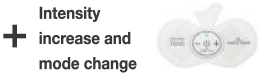
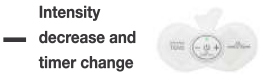
Control unit (side view)

Charging Port-Takes 2 hours for full charge

Instructions for use without APP

The following steps are used to guide the device operation, and the details about each step are listed in the following table.

- 1st Step Check the battery power for the Electronic Pulse Stimulator
- 2nd Step Install the electrode pad onto the Electronic Pulse Stimulator
- 3rd Step Put the electrode pad-installed Stimulator on the stimulation-needed body area
- 4th Step Press the "ON/OFF" to turn on the power
- 5th Step Select one of the stimulation modes
- 6th Step Choose the stimulation time
- 7th Step Adjust the stimulation intensity
- 8th Step Stay with the stimulation
- 9th Step Press the "ON/OFF" to turn off the power after done

1st Step - Check the battery power for the Electronic Pulse Stimulator	 Control unit USB Cable Battery charging
The Electronic Pulse Stimulator comes with a built-in rechargeable battery, and could be used as received. If the control unit has a flashing LED light when turned on, it means the battery is running out of power. Turn off and charge the control unit with the enclosed USB cable. The LED light is flashing during charging, and becomes solid when the control unit is charged fully.	
2nd Step - Install the electrode pad onto the Electronic Pulse Stimulator	 Electrode pad installment
The electrode pad has two snap-on male connectors, and the Electronic Pulse Stimulator has two snap-on female connectors on its back side. Snap the enclosed electrode pad onto the Electronic Pulse Stimulator through the snap-on connectors. This should be done prior to applying the device onto the skin of treatment areas.	
3rd Step - Put the electrode pad-installed Stimulator on the stimulation-needed body area	 Place the device on the body area
Place the pad-installed device onto the treatment areas (such as shoulder and leg). Press down firmly and ensure a full and firm contact with skin. Note: Keep the skin clean before placing the pads	
4th Step - Press the "ON/OFF" to turn on the power	 On/Off
Press the On/Off button to turn on the unit.	
5th Step - Select one of the stimulation modes	 Intensity increase and mode change
Change the output stimulation modes by pressing the + button for 3 seconds.	
6th Step - Choose the stimulation time	 Intensity decrease and timer change
Press the - button for 3 seconds to change the stimulation time.	

7th Step - Adjust the stimulation intensity	 Intensity selection
Press and release the "+" button to increase the stimulation intensity, and press and release the "-" button to decrease the intensity. Note: With the increase of intensity, you may experience sensations like tingling, vibration, etc. Therefore, gradually increase the intensity, and stop increasing when a comfortable level is reached.	
8th Step - Stay with the stimulation	 Stay with the stimulation
Enjoy the stimulation provided by the device, after the above mode, time, and intensity are set up.	
9th Step - Press the "ON/OFF" to turn off the power after done	 On/Off
When the timer runs out, the intensity becomes zero and the device turns off automatically after 10 minutes. The device could be also turned off by pressing the On/Off button. Note: When not in use, store the device and accessory in a cool place, out of direct sunlight.	

The electrode pads could be used until they lose the stickiness and/or conductivity. Their lifetime greatly depends on the body skin condition and protection. Please see the following for the Use Directions, Removal, and Storage for the electrode pad and conductive accessories.

Directions for Use

- Clean skin thoroughly prior to each application of electrodes, which will not stick well if any lotion, make-up, or dirt is left on the body skin.
- Turn the Electronic Pulse Stimulator off before applying the electrode to the body skin.
- Install the pad included onto the back side of the Electronic Pulse Stimulator.
- Apply the pad-installed device firmly to the skin.

Removal and Storage

- Turn the device off before removing the electrode from the body skin.
- Lift at the edge of the electrode and peel.
- When not in use, store the electrode in the re-sealable bag in a cool place, out of direct sunlight and dust.

Recommended Practice

- Duration suggested for each skin area is 20 min and 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 at a scale from 1 to 20.
- Good skin care is important for a comfortable use of device. Be sure the treatment site is clean of dirt and body lotion.
- Keeping the electrode in the storage bag after use will extend its lifespan. The electrode is disposable and should be replaced when it loses the adhesiveness. To purchase additional electrodes, please contact the seller.

Product Specifications

Accessories Included in the Package

- Tens unit controller * 1pc
- Electrode gel pad * 1pc
- USB line * 1pc
- Manual * 1pc

Technical Information

Model/type	EHE015BLE		
Power supply	Powered by internal 3.7V Li-ion battery	Automatic shutoff	10 minutes
Waveform and wave shape	Biphasic rectangular wave puls	Degree of protection against electric shock	Type BF applied part
Pulse width	50~500μsec	Type of protection against electric shock	Internally powered equipment
Pulse frequency	1~500Hz (Hz=vibration per second)	Grade of waterproof	IP22
Output Voltage	Max. 60Vpp ±20%(at 500ohm load)	Product life	3years
Treatment time	10,20,30,40,50,60 minutes	Lifetime for electrode	Storage for 2 years (no use) , Times of reusable: 30 times
Output intensity	0 to 20 levels, adjustable	Mode of operation	Continuous operation
Modes	8 auto modes	Software version	A0
Typical operation time of Battery	If to use at highest level , the battery can be used for about 150 minutes 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

Behavior of equipment while the rechargeable internal electrical power source is charging:	The indication light will flash during charging and will be still with full capacity.	The time required for 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
Size	51.5*43*12.3mm	Weight	20g
Electrode Size		Effective conductive	
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: TENS and EMS (combination mode)	10, 20, 30, 40, 50, 60	1.2-100	100
Mode 2:TENS	10, 20, 30, 40, 50, 60	62.5	100
Mode 3:EMS	10, 20, 30, 40, 50, 60	12.5-55.5	100
Mode 4:TENS	10, 20, 30, 40, 50, 60	1.2	100
Mode 5:TENS	10, 20, 30, 40, 50, 60	100	100
Mode 6:TENS	10, 20, 30, 40, 50, 60	100	100
Mode 7:EMS	10, 20, 30, 40, 50, 60	20	100
Mode 8:TENS	10, 20, 30, 40, 50, 60	160	100

Cleaning and Maintenance

Please use the moisturized cloth of water or neutral detergent to clean the device first, and then use the dry cloth to wipe it again. The electrode pads coming with the device are disposable, and should be replaced when their adhesiveness becomes worse. Contact the seller for replacements. Do not let the sticky side of the pad touch anything, including the greasy finger tips.

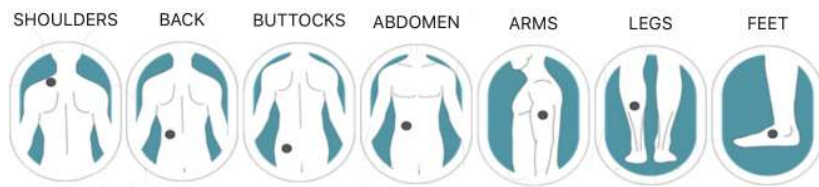
Trouble Shooting

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
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 is not felt or with a very weak intensity level	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 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 application time or reduce the intensity
	The electrode pad surface if worm out	Replace electrode pad
No power output; no display on LCD.	The battery capacity is depleted	Charge the battery
Power cuts off during use	The battery is weak	Charge the battery

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 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



Warranty

This device carries a limited warranty of one year from the date of delivery. The warranty applies to the device only, and the accessories are not covered by this warranty.

During the warranty period, defective items will be repaired or replaced at no charge. Any evidence of misuse, abuse, alterations, or externally caused damage may have this warranty invalid.

For more information, please contact the manufacturer.

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.

FCC ID 2AMJI-TENS1

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 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 emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable (internal battery powered)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable (internal battery powered)	
		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.

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	Not applicable (internal battery powered)	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	Not applicable (internal battery powered)	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% UT (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	Not applicable (internal battery powered)	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: UT is the a.c. mains voltage prior to application of the test level.			

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 $d = 1,2 \sqrt{P}$
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.			
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.			

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 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.			

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.

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

Healthcare-Manager.com

Questions or comments?

Please contact us via email:

service@healthcare-manager.com

Manufactured for Easy Healthcare Corporation

360 Shore Dr., Burr Ridge, IL USA 60527

Made in China