Flex-IT®

Instruction Manual

Please read the Instruction Manual prior to use.

EMSI®

CAUTION: Federal law requires a prescription from your physician before use of this product.

3504 Cragmont Dr. Suite #100 | Tampa, FL 33619
P: 800.588.8383 | 813.931.2369 | **F:** 800.588.9282 | **E:** customerservice@wecontrolpain.com

Flex-IT®

CAUTION: Federal law requires a prescription from your physician before use of this product.

table of contents

1.0 | Intended Use

The EMSI Flex-IT® is designed for symptomatic relief of chronic intractable pain and adjunctive treatment for the management of post-traumatic or post-surgical pain.

2.0 | To The Patient

Please read this operating manual carefully before using the device. The instructions on the following page will show you how to use and care for your device in the general manner. You should be particularly familiar with the prescription information and precautions before proceeding.

You should consult with your clinician if you have specific questions or problems regarding the use of your device.

CAUTION: ***Federal law restricts this device to sell by or on the order of a physician.***

3.0 | Contraindications

1. Any electrode placement that applies current to the carotid sinus (front of neck) region.
2. Any electrode placement that causes current to flow transcerebrally (through the head).
3. Any use of this device on patients who have any kind of implantable devices.
4. The use of this device whenever pain syndromes are undiagnosed, until etiology is established.

4.0 | Warnings

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid (front of neck) sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the front of neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically (through front and back of chest) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
6. Stimulation should not be applied over, or in proximity to, cancerous lesions.
7. For external use only.
8. Do not use device on the eye area.
9. This device should be used only under the continued supervision of a physician.
10. Safety for use during pregnancy or delivery has not been established.
11. Electronic equipment such as ECG monitors and ECG alarms may not operate properly when electrostimulation is in use.

12. Apply the electrodes to clean, dry and unbroken skin only.
13. This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14. This device should be kept out of the reach of children.
15. This device is not effective for pain of central origin, including headaches.
16. This device has no curative value.
17. TENS is a symptomatic treatment, and as it suppresses the sensation of pain which would otherwise serve as a protective mechanism.

5.0 | Precautions

1. Caution should be used for patients with suspected or diagnosed heart problems.
2. Caution should be used for patients with suspected or diagnosed epilepsy.
3. Caution should be used in the presence of the following:
   (a) When there is a tendency to hemorrhage following acute trauma or fracture.
   (b) Following recent surgical procedures when muscle contraction may disrupt the healing process.
   (c) Over the menstruating or pregnant uterus.
   (d) Over areas of the skin which lack normal sensation.

5.0 | Precautions continued

4. Some patients may experience skin irritation of hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
5. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
6. This device should be used only with the leads and electrodes recommended for use by the manufacturer.
7. Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
8. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
9. If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if problems persist.

6.0 | Adverse Reactions

1. Possible skin irritation or electrode burn under the electrodes may occur.
2. Possible allergic skin reaction to tape or gel may occur.
3. Electromagnetic Disturbances: There is a possibility that radio signals from high-frequency transmitters, e.g. mobile phones or similar mobile radio equipment, airport security systems, or metal detection devices (which themselves conform to the EMC regulations), may influence the proper functioning of the device if such equipment is operated in close proximity and with relatively high transmitting power.

The Flex-IT® meets EMC requirements and is designed in such a way, that under normal conditions, there is no risk of malfunction caused by electromagnetic interference. However, in the case of signals from high frequency transmitters, the risk of electromagnetic incompatibility when operated in close proximity to electronic apparatus cannot be totally ruled out. In unusual circumstances, unintended functions of the Flex-IT® could be initiated, possibly giving rise to undesirable risks for the patient or user such as a surge in energy level or ineffective treatment parameters.

7.0 | Unit Description

ON/OFF Button: Turns the unit ON and OFF.

Amplitude Controls: Controls the "INTENSITY" level of stimulating pulses.

TENS/IF Button: Selects the mode of treatment. (TENS or INTERFERENTIAL)

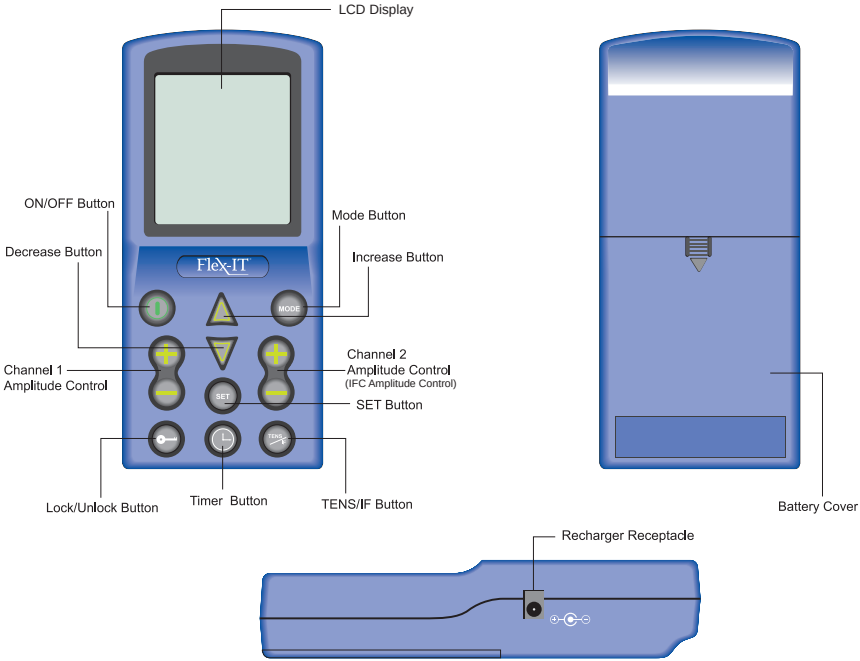
MODE Button: (ONLY in TENS mode) Choose the TENS stimulation modes: Burst, Normal, Modulated rate and width (MRW), Alternating modulated intensity and pulse width (SD) and Bi-Pulse

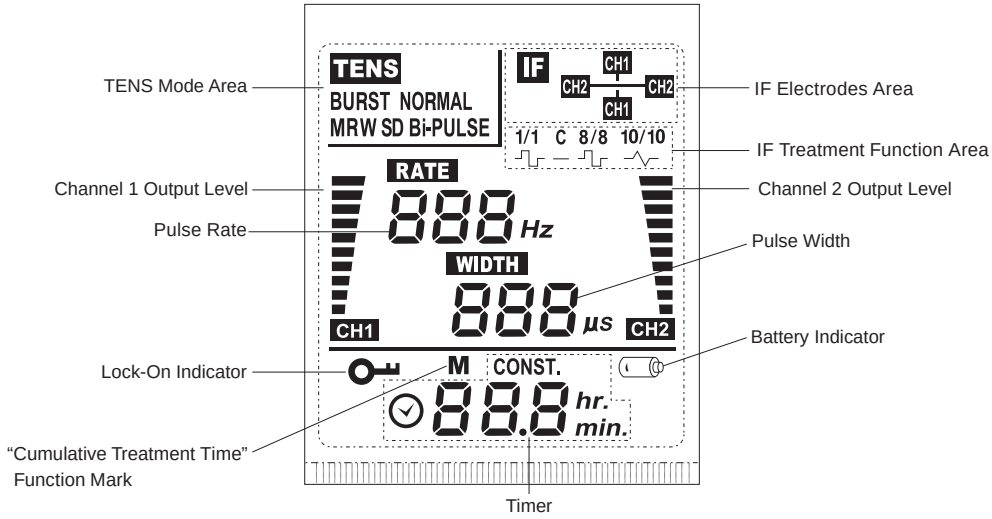
SET Button: Sets the pulse width, pulse rate. (in TENS Mode) Treatment function, pulse rate. (in INTERFERENTIAL mode)

TIMER Button: Sets the timer.

INCREASE & DECREASE Button: Increase and decrease pulse width, pulse rate, and choose the timer in TENS mode. They also are used for choosing the treatment function and pulse rate in the INTERFERENTIAL mode.

LOCK/UNLOCK Button: Locks or unlocks the unit.


LCD Display
ON/OFF Button
Decrease Button
Mode Button
Increase Button
Flex-IT
MODE
Channel 1
Amplitude Control
Channel 2
Amplitude Control
(IFC Amplitude Control)
SET
SET Button
Lock/Unlock Button
Timer Button
TENS/IF Button
Battery Cover
Recharger Receptacle


TENS Mode Area
TENS
BURST NORMAL
MRW SD Bi-PULSE
IF
CH1
CH2
CH2
CH1
IF Electrodes Area
1/1 C 8/8 10/10
IF Treatment Function Area
Channel 1 Output Level
RATE
888 Hz
Pulse Rate
Channel 2 Output Level
Pulse Width
WIDTH
888 µs
CH1
CH2
Battery Indicator
Lock-On Indicator
M
CONST.
88.8 hr. min.
"Cumulative Treatment Time" Function Mark
Timer

8.0 | Specifications

Channel:		**Dual, isolated between channels**
Power Source:		**700 mAh 4.8V Ni-MH rechargeable battery pack**
Output waveform:		**Symmetric waveform**
TENS	**Output**	**0~±27V (Loading: 500Ω)**
	Peak Pulse Output	**54mA (Loading: 500Ω)**
	Level	**1~20 levels: each level increment ±1.35V**
	Pulse Width	**Variable, 50~300 μs**
	Pulse Rate	**Variable, 2~150 Hz**
	Mode	**Burst | Normal | MRW | SD | Bi-Pulse**
IF	**Output**	**0~±15V(Loading: 500Ω)**
	Peak Pulse Output	**30mA (Loading: 500Ω)**
	Level	**First level: ±1.5V. 2~20 level: each level increment ±0.71V**
	Pulse Width	**125 μs for each phase, Fixed**
	Carrier Rate	**4000Hz**
	Difference Rate	**Variable, 1~150 Hz**
	Treatment	**1/1 abrupt | Continuous | 8/8 abrupt | 10/10 ramped**

* All values + or - 10%

8.0 | Specifications continued

Patient Compliance Timer	**Operation count: record of 60 sets (min.), max with 999 mins.** **Operation total time: max with 999 hrs.**
Operation ambient:	**Temperature range: 10°C ~ 35°C** **Humidity range: 20 ~ 90%RH**
Storage & transportation:	**Temperature Range: 0°C ~ 70°C** **Humidity Range: 20 ~ 90%RH**
Timer:	**5~90 minutes auto-shutoff or Constant**

9.0 | TENS Treatment Functions Descriptions

* All Values + or - 10%

Mode	BURST	NORMAL	MRW	SD	BI-PULSE
Pulse Rate	Fixed 100Hz	2~150Hz	2~150Hz	2~150Hz	Channel 1 fixed at 4Hz; Channel 2 fixed at 100 Hz
Pulse Width	50 ~ 300 µs	50 ~ 300 µs	50 ~ 300 µs	50 ~ 300 µs	50 ~ 300 µs
Cycle Time	0.5 Sec	Constant	1 Sec.	6 Sec.	2 Sec.

TENS

MODE	Interpretations
Burst (B)	The burst mode provides a "burst" of seven pulses. There are two bursts that are delivered per second. Positive pulse and negative pulse iterate continuously at fixed 100Hz. Pulse width are adjustable from 50~300μs
Normal (N)	The normal mode produces a continuous train of impulses. The stimulation parameters are not automatically interrupted nor varied in any way. In this mode, the pulse rate (from 2 to 150Hz) and pulse width (from 50 to 300μs) are fully adjustable. The normal mode is quite versatile because it may be applied with a variety of rate and width settings.
Modulated Rate & Width (MRW)	The pulse rate and width are automatically varied in a cycle to produce a pleasant, massage-like sensation. It's believed that nerves can become accustomed to, or "accommodated" to the same electrical stimulus after a period of time and thus would require increasing the intensity to further "block" the pain. The MRW mode was produced to offer a variety of different electrical stimulation, thus preventing nerve accommodation so that less intensity is required for long and effective treatment. In this mode, during the beginning of 0.5 second period, the WIDTH decreased to 50% of its original setting and then during the next 0 5 second period, the RATE is decreased to 50% of its original setting. Therefore, the total cycle time is 1 second.

9.0 | TENS Treatment Functions Descriptions continued

MODE	Interpretations
Modulated Intensity and Pulse Width (SD)	The SD modulation consists of alternating modulated intensity and pulse width, so that the intensity is always increasing while the pulse width is decreasing and vice-versa. The stimulation intensity is modulated to 62.5% maximum of setting (width equal to setting). The pulse width is modulated to 67% of setting (intensity equal to setting). Total cycle time is 6 seconds. Pulse rate (from 2 to 150Hz) and pulse width (from 50 to 300μs) are fully adjustable.
Bi-Pulse (Bi-Pulse)	The Bi-Pulse modulation delivers 4 pulses per second to Channel 1 (i.e. the pulse rate of Channel 1 is fixed at 4Hz) while delivering 100 pulses per second to Channel 2 (i.e. the pulse rate of Channel 2 is fixed at 100Hz). Stimulation is burst on for 1 second, then off for 1 second. There illustrates each pulse as a vertical line. Pulse width (from 50 to 300 μs) is fully adjustable.

10.0 | Interferential Treatment Functions Descriptions

NOTE: In order to receive a true interferential treatment, channel 1 and 2 should be used in a cris-cross pattern.With this setting, only channel 2 is used to increase the intensity.

Functions	Descriptions
1/1 abrupt	When set at "1/1" with the frequency control set at 100Hz, the interference frequency would be at 75Hz for 1 second, then shift abruptly to 155Hz for 1 second, then back to 75Hz. The pattern will be repeated as long as the mode selector switch is set in the "1/1" mode.
C (Continuous)	In the "C" (Continue) mode, there is no change in the pulse rate, When set at the other modes, the interference frequency changes over time.
8/8 abrupt	The option "8/8" is identical to "1/1", except that each interference frequency value (75Hz to 155Hz in the above example) is held for 8 seconds.
10/10 ramped	The option "10/10" work from the –25% value to the +55% value gradually instead of rapidly. For example, when the frequency control was set at 100, the device will sweep gradually from 75Hz to 155Hz over a 10 second period, then from 155Hz to 75Hz during the next 10 seconds.

10.0 | Interferential Treatment Functions Descriptions continued

NOTE: Always read this instruction manual before use.

PREPARATION FOR USE

1. **Check Battery:**

   Proceed to insert battery pack into the battery compartment. BE SURE TO MATCH THE POSITIVE AND NEGATIVE ENDS OF THE BATTERY PACK TO THE MARKINGS IN THE BATTERY COMPARTMENT OF THE UNIT.

   NOTE: Before first and consequent uses, charge battery using the supplied battery charger. To charge: Plug male end of charger to the socket located on the right side of the LCD screen. Make sure the plug fits snugly into the socket. PERMANENT DAMAGE MAY OCCUR IF FORCE IS USED TO PLUG THE MALE END OF THE CHARGER INTO THE SOCKET. A green indicator light will illuminate and alternately flash as it is being charged. If red or flashing red, check battery for proper placement. If not solved, call customer servie. When charging is done (usually 3-4 hours on a fully discharged battery), a green steady light will illuminate. Typical charge may last 2 hours of use depending on frequency and intensity of treatment.

   NOTE: The device will NOT work if the charger is plugged into the device. Nor will the device work if the charger plug is plugged into an outlet. Once charged or not in a charging mode, disconnect the plug from the device. Use of unapproved charger (not issued by EMSI) may cause damage to device and will void any warranty.

CONNECTING THE STIMULATOR

2. **Connect electrodes to lead wires:**

   Insert the lead wire connector into electrodes connector (standard 0.08 inch female connection). MAKE SURE THAT NO BARE METAL OF THE PINS IS EXPOSED

Caution:

1. Always use electrodes whose measure of area are 1.5” x 1 5” (16 cm^2) or larger.

2. The Flex-IT® is compatible and recommended for use with EMSI electrodes (or comparable). Always use electrodes and leadwires that came with the unit. Using other electrodes and leadwires may render the unit non-operable, ineffective, and void the warranty.

3. Connect lead wires to unit:

Before proceeding to this step, be sure the unit is turned OFF.

Holding the insulated portion of the lead wire connector, insert the angled-“L” plug into the receptacle on the top of the main unit. Please ensure the lead wires are inserted securely.

The unit has two output receptacles which are controlled by Channel 1 and Channel 2 Amplitude Control buttons on the front of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires.

Caution: Always use leadwires that came with the unit. Using other leadwires may render the unit non-operable and void the warranty**.**

4. Place electrodes on skin:

Before applying electrodes, be sure that the skin surface over which electrodes are placed is thoroughly cleaned and dried. Apply electrodes to the exact site indicated by your physician following

10.0 | Interferential Treatment Functions Descriptions continued

the instruction included with the electrodes labeling. Make sure that the electrodes are placed firmly to skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly and evenly.

5. **Treat as directed by prescribing clinician.**

NOTE: This device is capable of "locking" out either TENS or IFC features. To isolate device into a specific treatment (IFC or TENS) mode, ensure device is not providing any stimulation and is on the desired treatment mode. Press and hold Channel 1 and Channel 2 negative (-) amplitude button for 5–7 sec until audible beep is heard. This will allow only TENS or only IFC modes to function. To reverse, follow above steps.

6. **Turn Unit Off:**

Press the "ON/OFF" button to turn unit off. Then unplug the electrode lead wires, grasping them by the plug, not the cord. If treatment will be resumed shortly the electrodes may be left on the skin. When the electrodes are removed, clean the skin thoroughly with mild soap and water. If there is skin irritation, consult your medical professional.

Caution: When the timer runs out, the unit will turn off automatically and you are not required to press the "ON/OFF" button. Unit will also turn off automatically after 5 minutes if no activity is made when the unit is initially turned on.

NOTE: This device is safeguarded with a Locking mechanism to avoid possible mishandling when treatment is in session. The user can manually "Lock" the settings for the duration of the treatment by pressing and holding the "key" button for 3 seconds (a beep (if enabled) will confirm device is locked). The device also automatically "locks"if no treatment button is pressed for 1 minute. Once locked, other than the power button, no buttons are active. To disable the "Lock" during treatment session for adjustment or stoppage, press and hold the "key" button for 3 seconds (a beep will confirm device is unlocked). The user can then adjust amplitude, settings, etc.

SPECIAL CARES IN OPERATING

- Clean and dry the skin surface of the body area to be treated.
- Inspect the electrode cords and electrode pads for wear. If they are not in good condition, they should be replaced. If they are acceptable, then insert the cord pins into each electrode pad.
- Make sure the electrode pads are firmly fixed in place to obtain effective conduction.
- Use the electrode sites recommended by your prescribing physician.
- Increase the output level SLOWLY to that recommended by your clinician. Usually, that will mean increasing intensity until you can feel the tingling sensation (high pulse rates) or pulsing sensation (low pulse rates) of the stimulation. Your prescribing clinician will tell you how far they wish you to turn up the intensity.

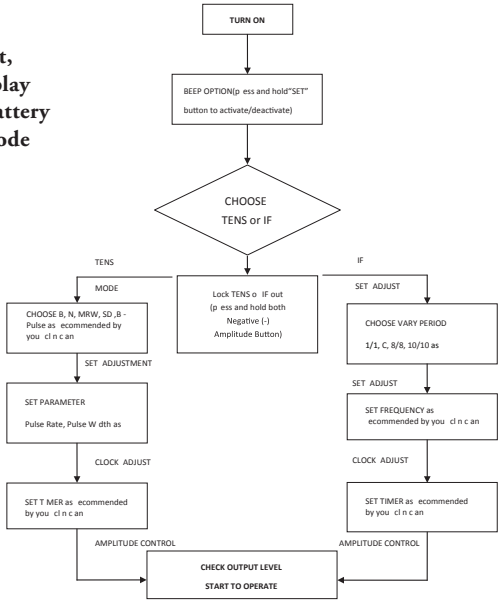
- If at any time the electrical stimulation begins to feel uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if the problem persist.

- The possibility of electromagnetic disturbance from other equipment in or outside your home exist. Use caution in using electrical stimulation in situations which may have a potential high frequency transmitter such as in close proximity to mobile phones in use, airport security systems, or hand held detectors.

10.0 | Interferential Treatment Functions Descriptions continued

Operation Procedure Chart:

When you are finished using the unit, turn the device off and the LCD display will disappear. This will conserve battery life. You may now remove the electrode pads from your body.



11.0 | Patient Compliance Timer

The patient compliance timer can memorize 60 sets of operation records; the total record time is 999 hours. The patient compliance timer is accessible only when the unit is turned off.

Press and hold **"Mode"** button, then press the "ON/OFF" button simultaneously to initiate the patient compliance timer.

1. **Individual treatment time:**

   Press **"INCREASE"** button (triangle button) or **"DECREASE"** button (inverted triangle button) to scroll through the records of treatment times.

   Press and hold **"Set"** button for 3 seconds to delete the displayed record. After the displayed record is deleted, the unit will acknowledge with an audible response "Bi".

   NOTE:

   (a) If the treatment time is under one minute, it will not be recorded. For example, if your treatment time

is 10 minutes and 30 seconds, the patient compliance timer will record 10 minutes, not 11 minutes.

(b) The patient compliance timer will record up to 999 minutes for each treatment. Therefore, if you use the stimulator for over 999 minutes, it will record 999 minutes and the recorded time will flash to indicate the treatment time is over 999 minutes.

2. **Cumulative treatment time:**

When initiating patient compliance timer, press "Mode" to shift the record of individual treatment time with the number of sessions to the record of cumulative treatment time. When showing the record of cumulative treatment time, there will be an "M" mark flashing on the screen.

Press and hold "Mode" & "Set" button simultaneously for 3 seconds to delete all the records including individual treatment time record and cumulative treatment time record.

The patient compliance timer will keep the records even when the battery has no charge. Only when users press and hold "Set" or "Mode" & "Set", the records will be deleted.

12.0 | Principles of TENS Treatment

TENS, Transcutaneous Electrical Nerve Stimulation, is a method of applying controlled, low-voltage electrical stimulation to large, myelinated peripheral nerve fibers via cutaneous electrodes for the purpose of modulating stimulus transmission and relieving pain.

The tissues and cells of our bodies are always emitting electricity, which regulates the organs, nerves and muscle.

TENS, utilizes both positive and negative poles of electricity conducted by electrodes and affixed to the surface skin to have electric currents stimulate the peripheral nerve fibers.

TENS is believed to work by two different mechanisms. First, electrical stimulation of the fast-conducting nerve fibers can block/override a slow-conducting pain signal from being carried to the brain/spinal cord. If the signal is blocked, pain is not perceived. Secondly, the body has its own mechanism for suppressing pain. It does this by releasing non-addictive natural chemicals called endorphins in the brain which act as analgesics. TENS may activate this mechanism. The effectiveness of TENS treatment is not 100% for all pain syndromes. Experimentation with setting and electrode placement may be required for best results.

13.0 | Care and Maintenance

1. **Low Battery Indicator:**
   When the low battery indicator flashes, the batteries should be recharged as soon as possible.
2. **Cleaning**

   Clean the housing by wiping with clean damp cloth only.
   To avoid corrosion, do not immerse in water.
   Do not store in direct sunlight or humid environments, i.e. Bathrooms.

14.0 | Troubleshooting

If your unit does not seem to operate correctly, refer to the chart below to determine possible causes.

The LCD indicator illuminates but unit does not function properly.	**Low Battery indicator flash.**	**None of LCD indicators illuminate.**
1. Check all control settings. Are they set to values prescribed by your medical professional? 2. Are electrodes in proper position and adhering to the skin? 3. Check lead wires. Be sure all connectors are firmly sealed. 4. Replace cord set with another to check for broken wires.	 Recharge battery pack	Recharge battery pack

The charger has steady red or blinking red light

1. Ensure battery pack is inserted in battery compartment
2. Ensure battery pack is matched with correct polarity as shown on battery and compartment
3. Ensure battery pack is not damaged

If none of these measures correct the problem, please contact a Customer Service Representative.

Descriptions

	Manufacturer		Keep Dry		Caution: Read Instruction Manual
	Single patient use		Do not put in regular trash		For Prescription use only

WARRANTY

This product is warranted to the original consumer for a period of one (1) year from the original acceptance of this device. This product warranty extends only to the original consumer of the product. This product is warranted against defect or workmanship for this period. This warranty is voided if this product has been damaged by misuse, abuse, neglect, or otherwise used in a manner not suited or prescribed for this product. This warranty is voided with use of unapproved electrodes, lead wires, chargers, or batteries. This warranty does not cover what is considered to be normal wear and tear, replacement of batteries, lead wires, electrodes, and other accessories. EMSI reserves the right to honor/dishonor product warranty as it sees fit.

CAUTION: Federal law requires a prescription from your physician before use of this product.

3504 Cragmont Dr. Suite #100 | Tampa, FL 33619
P: 800.588.8383 | 813.931.2369 | **F:** 800.588.9282 | **E:** customerservice@wecontrolpain.com

CAUTION: Federal law requires a prescription from your physician before use of this product.