

Evocare T.E.N.S.

Transcutaneous Electrical Nerve Stimulator

Model No : LMT2



User Manual for **Evo**care T.E.N.S.

CONTENTS

It is recommended that you read this entire manual thoroughly before using your Neurostimulator.

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GENERAL INFORMATION

What is Pain?

Pain is the body's warning system and is intended to prevent additional injury. Pain is important because, without it, vital parts of our bodies might be damaged or injured without our knowledge. However, long-lasting, persistent pain, often called chronic pain, once diagnosed serves no apparent purpose. TENS is developed to help relieve some types of chronic and acute pain.

How does TENS work?

TENS, or Transcutaneous Electrical Nerve Stimulation, means the transmission of small electrical pulses through the skin to the underlying peripheral nerves. TENS is thought to work in two different ways.

First, "high frequency" continuous, mild, electrical activity may block the pain signal traveling to the brain. Brain cells perceive pain. If the pain signal does not get through to the brain, the pain is not "felt".

The second way TENS is thought to work is by stimulating the body's own natural pain-control mechanism. "Low frequency" or short bursts of mild, electrical activity may cause the body to release its own pain easers, called beta endorphins. Ask your doctor or clinician for more details.

No matter what pain theory is applied, TENS has been proven useful in pain management for many pain patients.

The outcome of treatment will be influenced by the patient's psychological state and use of drugs.

Note to physicians

A TENS unit is an electrical impulse generator that is used to relieve post-operative, acute and chronic pain. It is used for peripheral types of pain and not those of central origin. Assessment of electrode placement involves trial and error, knowledge of neurophysiology to include peripheral nerve roots, dermatomes and trigger points are areas that are most helpful when assessing electrode placement to relieve the patient's pain.

Please be sure to read the safety section including cautions, indications, contraindications, warnings, precautions, adverse reactions as well as the technical specifications and controls adjustment sections before use to this device.

SAFETY

Indications

Transcutaneous Electrical Nerve Stimulation (TENS) is used for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post surgical and post traumatic acute pain problems.

Contraindications

TENS devices can affect the operation of demand type cardiac pacemakers. TENS is not recommended for patients with known heart disease without physical evaluation of risk. Do not stimulate over the eyes or carotid sinus nerves. Do not apply TENS either transcerebrally or transthoracically. Do not apply TENS for undiagnosed pain syndromes until etiology is established.

Warnings

This device should be used only under the continued supervision of a physician. TENS is ineffective for pain of central origin. TENS has no curative value. It is a symptomatic treatment which suppresses pain sensation which would otherwise serve as a protective mechanism. Safety of TENS devices for

use during pregnancy or delivery has not been established. For external use only. Electronic equipment such as ECG monitors and EKG alarms may not operate properly when TENS is in use.

Precautions

Avoid using TENS while operating machinery or vehicles. Turn the stimulator off before applying or removing electrodes. Long-term stimulation at the same electrode site may cause skin irritation. Use only for the specific pain problem prescribed by physician.

Adverse Reactions

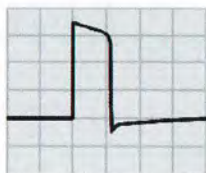
Possible allergic reaction to tape or gel. Possible skin irritation or electro-burn under electrode.

TECHNICAL SPECIFICATIONS

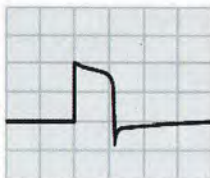
- Channels : Dual
- Pulse Amplitude : Adjustable 0~80mA peak maximum for positive pulse or -20mA peak maximum for negative pulse into 500 ohm load each channel.
- Pulse Rate : (Adjustable) 2Hz~120Hz
- Pulse Width : (Adjustable) 40 μ S~260 μ S
- Timer : 3 operation modes (60 min., 30 min. and continue)
- Modulation Mode : Pulse width is automatically varied in a cyclic pattern over an interval of nominally 5.0 seconds maximum. Pulse width decreases linearly over a period of 1.5 seconds from the control setting value to a value which is decreased 45% maximum. The narrower pulse width will continue for 2 seconds maximum, then increase linearly over a 1.5 second period to its original value. The cycle is then repeated.
- Burst Mode : Bursts consist of 9 ± 2 pulses at maximum pulse rate. Bursts occur twice every second.

Wave Form :

Asymmetrical Bi-Phasic square pulse.



LOAD MODE 500 OHM
VER. MODE CH1
TIME/DIV 0.1 MS
VOLT/DIV 5.0 V



LOAD MODE 1M OHM
(OPEN CIRCUIT)
VER. MODE CH1
TIME/DIV 0.1MS
VOLT/DIV 5.0V

All of the adjustable parameters are setting at the midpoint of the specified range

Voltage (open circuit) : 0-110 Volt maximum (either positive pulse or negative pulse)

Max Charge per pulse : 21 micro coulombs maximum. Positive pulse and negative pulse separate.

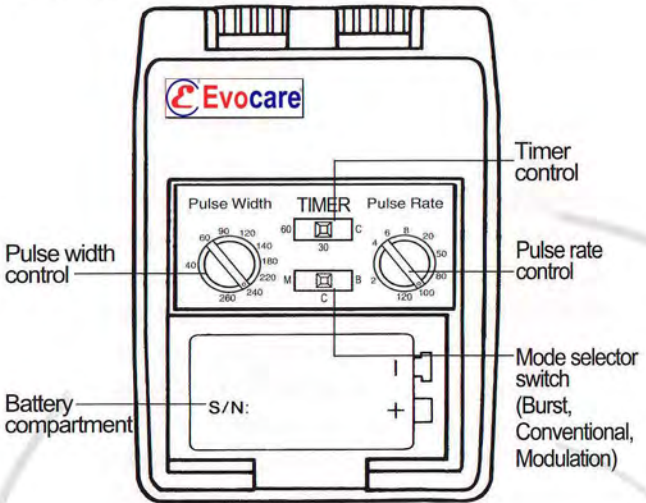
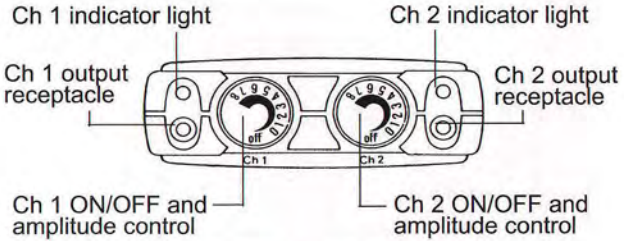
Battery : 9V battery (alkaline, or nickel-cadmium re-chargeable.)

Size : 23X64X91mm

Weight : 130g (Battery included)

There may be up to a +/-20% tolerance of all specifications.

CONTROLS AND INDICATORS



PREPARATION FOR USE

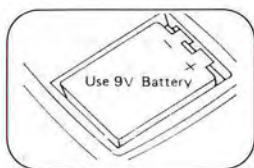
Stimulator can be easily adjustable to you comfort and relief of your pain by two intensity control knobs. The output of the stimulator may decrease slightly as the battery wears down. If you sense no stimulation, check the battery as well as the cables, making sure they are properly inserted.

If you receive no pain relief, consult your clinician for electrode placement or stimulation mode alternatives.

Therapists: Electrode placement diagrams and stimulation diagrams are available from Evocare website link: <http://www.evocare.com.au/lmt2.html>

Check battery

Be sure you are using a fresh battery. Insert battery into compartment correctly.



Prepare skin

Before attaching electrodes, identify those areas where your clinician has recommended electrode placement. Each location should be cleansed, rinsed and thoroughly dried.



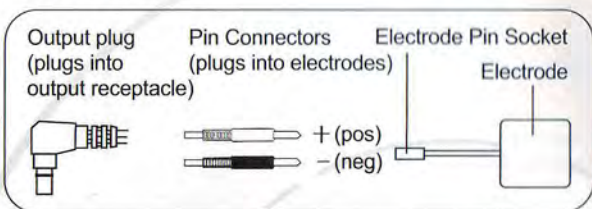
Front cover

At the bottom of the unit press in hinge and lift cover to replace cover, press in tab, press down and release.



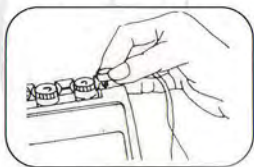
Connecting lead wire to electrode

Insert pin connector to electrode socket. When inserting or removing pin connector, grasp connector, not leadwire to prolong lead wire life. For some electrode locations, it may be preferable to insert the pin connector before attaching the electrode to the skin.



Connect leads to stimulator

Plug end of lead wire set into the channel output receptacle to be used (1 and/or 2), pushing plug in as far as it will go.



ADJUSTING CONTROLS

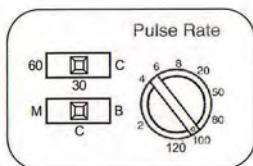
Adjusting the controls

Be sure both amplitude controls for Channels 1 and 2 are turned to "Off" position before applying electrodes on skin.



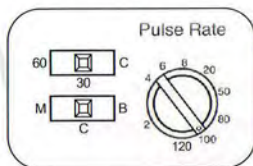
"High rate" or "low rate" TENS

Slide the mode selector switch in the "Conventional" position.



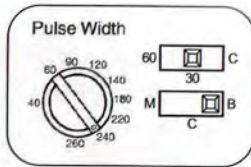
Adjust pulse rate

Turn the Pulse Rate control to the setting recommended by your medical professional.



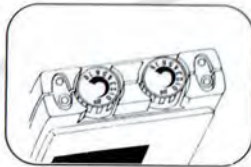
Adjust pulse width

Turn the Pulse Width control to the setting recommended by your medical professional.



Adjust channel amplitude

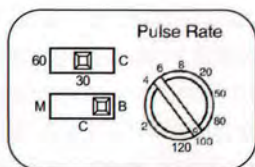
Turn Channel 1 or 2 clockwise. The indicator will light up as long as the unit is in operation. Slowly turn the Channel control in a clockwise direction until you reach the setting recommended by your medical professional. Repeat for the other channel, if both channels are to be used. Indicator light will blink at lower pulse rate setting.



Using burst mode

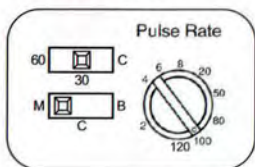
When operating in Burst mode, it produces a series of quick pulses followed by a rest. The cycle repeats it-self twice every second. Before switching to Burst, turn amplitude controls for Channel 1 and 2 to "O" (off). Place the mode selector switch into Burst position. Slowly adjust the amplitude control to the settings recommended by your medical professional.

NOTE : In Burst mode, the Pulse Rate is fixed; adjusting the Pulse Rate control has no effect. Pulse Width control may be set by clinician.



Using modulation mode

When operating in Modulation mode, it automatically varies the width of the pulse every five seconds. To use Modulation, first adjust the amplitude controls for Channel 1 and 2 to "O"(off). Place the mode selector switch into Modulation position. Your medical professional should help set the Pulse Rate and Pulse Width. Slowly adjust Channel 1 and/or Channel 2 amplitude controls to the settings recommended by your medical professional.



Select timer

The timer has three modes, 60 mins, 30mins and continuous. Please ask your physician before setting the timer modes.

The unit is portable

Your Neurostimulator may be clipped to clothing such as a belt, vest, shirtpocket or bra.

REMOVING ELECTRODES LEADWIRES

It is strongly recommended to leave lead wires plugged into the unit to lessen the possibility of breakage. If it is necessary to unplug them, turn both Channel controls to "O" (off). Then unplug by grasping them by the plug and pull straight up. Do not twist. If treatment will be resumed shortly, the electrodes may be left on the skin. When the electrodes are removed, clean the skin thoroughly with soap and water. If there is skin irritation, consult your medical professional.

Low battery indication

When the light becomes dim, it means the battery should be replaced with a new one as soon as possible. However the stimulator will continue to operate for a few more hours.

DO'S AND DON'TS

Do

- 1) Place the electrodes only as your clinician recommends.
- 2) Keep the stimulator clean.
- 3) See your clinician if you have any problems regarding treatment or clinical questions.
- 4) Clean the cables only with water and mild soap. Do not use rubbing alcohol or any other solvents.
- 5) Remove the electrodes and discontinue stimulation if you experience skin irritation, until the source of that irritation is determined by your clinician.
- 6) Turn both intensity knobs to "OFF" before replacing the battery or removing electrodes from skin.

Don't

- 1) Use your TENS when driving or working with dangerous machinery.
- 2) Loan your TENS to another person as it is a prescription device which is specially prescribed for you. Its use may be contraindicated for another person who has not been examined by a doctor.
- 3) Allow children to play with your TENS.
- 4) Immerse your TENS in water or any other liquids.
- 5) Use other electrodes with your TENS unless approved by your clinician or manufacturer. If you have questions, please contact us.

TROUBLE SHOOTING

If your TENS unit seems to be functioning improperly, use the chart below to determine what may be wrong.

Indicator lights on but unit does not function properly

- 1) Check control settings. Are they set as prescribed by your medical professional?
- 2) Are electrodes in proper position?
- 3) Check lead wires. Make sure all connectors are firmly seated.
- 4) Replace lead wires with another to check for broken wires.

On & Battery light dim

Replace battery with a new one.

No indicator lights on

Replace battery with a new one.

If none of these measures correct the problem, the unit should be serviced.

SERVICE/REPAIR

To obtain service, first call your dealer for instructions. You may need to send in your TENS (neurostimulator, lead wires, electrodes only) with a letter describing the problem. **Do not send carry case.**

Evocare warranty their T.E.N.S. for a period of twelve months.

NOTE: This does not cover:

- Accidental damage from misuse or neglect.
- Where the product has been modified.
- Electrodes, leads, batteries or battery chargers.

PROBLEM:

My unit does not work. There is no power coming from it.

SOLUTION:

- [1] If the red channel lights are not on, the unit is probably set on Timer at 30 or 60 minutes. The unit will not start when on the timer. Turn the unit off, start on "C" for constant and then push back to the desired time limit.
- [2] Are the red channel one and two lights on?
- [3] If not the battery may be "dead" or put into the unit the wrong way.
- [4] A lead may be broken and need to be replaced. Check channel by channel by using one lead at a time. If both leads work in channel one and not in channel two, channel two will need to be serviced.

PROBLEM:

There is very little power coming through. It's not as strong as it was.

SOLUTION:

- [1] How old are the electrodes? If they are over three months, they need to be replaced.
- [2] The battery may be old. Each battery that comes with the unit will only last about ten (10) days. The best replacement batteries are Duracell or Energizer which last about three weeks and can be bought from the corner store. Eveready Heavy Duty batteries are not as good, as the TENS draws a lot of power.

PROBLEM:

My TENS starts then stops. It used to just keep going.

SOLUTION:

The unit is set on "M" for Modulation. On this setting the unit will go for a certain time, then stop, and then start again and so on.... This is preferred for some treatments or for people who find the TENS going all the time annoying.

PROBLEM:

The light on the hospital machine (or on this machine yesterday) glowed full red. Now it flickers, so something is wrong.

SOLUTION:

The flickering of the red light is an indication of the number of pulses per second being delivered by the machine. To prove this the patient can turn the machine off, disconnect the leads, and then turn the machine on again. The light will flicker. Have them turn the Pulse Frequency Knob to a higher number slowly. As they do they will notice the flickering become more regular until it becomes a solid red light. It does not mean that the TENS is working better. Quite the contrary, the setting should be left the same as the qualified Practitioner directed.

QUESTION:

What is the standard setting for a TENS?

ANSWER:

- [1] There is no such thing.
- [2] The patient should refer to their qualified Practitioner.

QUESTION:

How long do I use the TENS for?

ANSWER:

- [1] This depends on the patient.
- [2] Patients should consult their qualified Practitioner.

QUESTION:

I feel great – can I now stop taking my medication.

ANSWER:

NO! Talk to your qualified Practitioner regarding anything associated with medication.

QUESTION:

I have a red mark where the pad goes.

ANSWER:

- [1] Is the person usually allergic to other items such as Band-Aids?
- [2] Is there gel on the electrodes? Gel is necessary for conductivity.

QUESTION:

The back of the machine says that this device is restricted to sale by or on order of a Practitioner. Do I have to see my Doctor?

ANSWER:

- [1] This warning applies to the United States. It does not apply in Australia.
- [2] All Evocare T.E.N.S. have the necessary approval from The Therapeutic Goods Administration. The approval numbers are shown on the Evocare website:
www.evocare.com.au.

QUESTION:

Can I get a refund from my Health Fund?

ANSWER:

Funds such as MBF may offer a refund to certain policy holders. The patient must check.

QUESTION:

Can I hire TENS?

ANSWER:

Evocare does not hire equipment but a number of our resellers do hire T.E.N.S. Evocare resellers will also be able to supply replacement self-adhesive pre-gelled pads.

WARRANTY

1. Evocare provides consumers with the following warranty in relation to this Product, in addition to complying with the requirements of any relevant legislation, including the *Competition and Consumer Act 2010* (Cth) in Australia and the *Consumer Guarantees Act 1993* in New Zealand (the Acts), except where a New Zealand consumer acquires the Product for the purposes of a business.
2. In this warranty, we have used the following definitions:
 - (a) **Form** means a warranty claim form issued by Evocare in respect of Products;
 - (b) **Evocare** or **our** means Evocare Australia Pty Limited, ABN 98 078 566 604 of Level 19, 144 Edward Street, Brisbane 4000;
 - (c) **Products** means the goods manufactured for Evocare (including products manufactured by its contract manufacturers);
 - (d) **Material** means a material or component used by Evocare in the manufacture of the Products;
 - (e) **Retailer** means the authorised dealer of Products from whom the Product was purchased;
 - (f) **Warranty Period** means the warranty period commencing from the date of purchase of the relevant Product. If the Product or part (as the case may be) is repaired or replaced, there will be no extension to the original warranty period; and
 - (g) **Workmanship** means the handling, assembly and manufacturing processes performed by or on behalf of Evocare in order to manufacture the Products.
3. Evocare warrants that for the duration of the Warranty Period, all Products will be free of faults arising from defects in Workmanship or Materials, on the terms and conditions set out in this warranty.
4. Evocare undertakes that if during the Warranty Period any Product, or any part of a Product, has failed to operate correctly due to faulty Workmanship or defective Material, it will repair or replace the Product or part (as the case may be) free of charge provided that the following procedures are met :
 - (a) The consumer must contact the Retailer or Evocare upon becoming aware of any defect to a Product upon which the consumer will be required to complete a Form and provide satisfactory proof of purchase.
 - (b) Evocare will review the Form to determine whether there is a defect, and if so Evocare agrees to (at its option) repair, replace or supply equivalent goods, or pay the cost of any of those remedies to the consumer.
 - (c) If Evocare requests the return of the applicable Product or part, the consumer will be responsible for the collection and freight costs of returning that Product or part to Evocare.
 - (d) The consumer acknowledges that it is also responsible for the freight costs to deliver any new Product or replacement part to it.

WARRANTY Continued

5. This warranty is in addition to any non-excludable legal rights or remedies conferred on the consumer under any applicable Act and any similar laws. To the extent permitted by law, Evocare's liability for any non-excludable condition or warranty is limited to rectifying any defect at its option, as set out in paragraph 4(b).

6. Subject to the requirements of any applicable Act or legislation and to the extent permitted by law, no liability (whether expressed or implied) of any nature whatsoever, is accepted by Evocare for any consequential loss, damage or injury arising as a result of any fault in the Products.

7. This warranty does not extend to damage to Products which occurs during transit or transportation, or which is caused by any abuse, accident or improper installation, connection, use, adjustment or repair or use of goods otherwise than in accordance with instructions issued by Evocare.

8. The warranty on Products is waived if any addition or attachment to the Products do not have Evocare's approval or are not sold as Evocare products. The Products are designed to perform specific tasks under established test loads and unauthorised attachments may produce stresses for which the design is not appropriate.

9. The following applies to consumers who purchased a relevant Product in Australia:

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

The image shows the cover of a 'TENS DEVICE'. The design features a light blue background at the top and bottom, with a central horizontal band in shades of purple and blue. The words 'TENS DEVICE' are printed in a stylized, blocky font across the middle of this band. Below the text is a dashed white line. On the right side, there are several overlapping circular lines in shades of blue and purple, suggesting a circular dial or a series of concentric circles. The overall aesthetic is clean and technical.

TENS DEVICE