

LogiSTIM[®] TN-11

TENS Pain Relief Unit



User's Guide

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Prescribing Information

BEFORE USE, PLEASE READ THE FOLLOWING CAUTIONS, INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS. IF IN DOUBT ABOUT THE USE OR SUITABILITY OF THE TENS MACHINE, CONSULT YOUR MEDICAL PRACTITIONER BEFORE USE.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Keep out of reach of children.

Indications

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

Contraindications

TENS devices can affect the operation of demand type cardiac pacemakers. In patients with known myocardial disease, arrhythmias or epilepsy, TENS should be used only with consultation and evaluation by a physician.

Do not use TENS on the eyelids.

Do not place electrodes directly over the carotid sinus nerves or arteries and laryngeal or pharyngeal muscles. Do not apply TENS for undiagnosed pain syndromes until etiology (actual cause) is established.

Contraindications *(continued)*

Do not place electrodes in any position that allows current to flow transcerebrally (through the head).

Do not use TENS on broken skin or on areas where normal sensation is absent.

Do not use TENS on children under the age of 12 unless under medical supervision.

Warnings

This device should be used only under the continued supervision of a physician.

TENS is ineffective for pain of central origin, for example, headaches. TENS is of no curative value.

TENS is a symptomatic treatment that suppresses pain sensation that would otherwise serve as a protective mechanism on the outcome of the clinical process.

Safety of TENS devices for use during pregnancy or delivery has not been established.

For external use only.

Electronic equipment such as EKG monitors and EKG alarms may not operate properly when TENS is in use.

Do not attempt to use the TENS or its accessories in any other way than that described in this User's Guide.

Precautions

Turn the unit off before applying or removing electrodes.

Do not pull leadwires to remove pads.

Precautions *(continued)*

Long-term stimulation at the same electrode site may cause skin irritation. If TENS therapy becomes ineffective or unpleasant, discontinue use until re-evaluated by a physician or therapist.

Do not use TENS while driving or operating machinery.

Use only for the specific pain problem prescribed by a physician.

Do not place the TENS unit near excessive heat or in water.

To avoid cross contamination do not use another person's electrodes or allow your electrodes to be used by any other person.

Keep the TENS unit out of the reach of children.

Use only the batteries specified in this user guide.

Remove batteries if the unit is not to be used for a long period of time.

Keep the TENS unit away from sources of high magnetic fields for example TVs, microwave ovens and hi-fi speakers, as these may affect the LCD screen.

Adverse reactions:

Allergic reactions are rare. However, an allergic reaction to the self-adhesive electrodes may occur in the form of skin irritation. An electrode burn on the electrode site may rarely occur. If skin irritation persists, discontinue use and consult a physician.

What is TENS?

TENS stands for Transcutaneous Electrical Nerve Stimulation. TENS has become a recognized and well-proven method of treating pain. Technology, research and quality engineering have made TENS a safe and highly effective method of pain relief recommended by pain specialists and physiotherapists throughout the world.

How does TENS work?

TENS or Transcutaneous Electrical Nerve Stimulation refers to the transmission of small electrical pulses through the skin to the underlying peripheral nerves. TENS theory suggests there are two pain-relieving mechanisms within the body that can be triggered by the use of TENS, resulting in reduction or elimination of the sensation of pain.

Conventional (high frequency) TENS is based on the theory that continuous mild electrical activity may block the pain signal travelling to the brain. If the pain signal does not get through to the brain, the pain is not perceived. This theory is often referred to as the 'gate control' theory.

The second way that TENS is thought to work is by stimulation of the body's own natural pain control mechanism. Low frequency electrical activity may

How does TENS work? *(continued)*

cause the body to release its own pain relieving substances, called 'endorphins'. No matter what pain theory is used, TENS has been proven to be useful in the field of pain management.

Many people feel an immediate benefit from TENS. However, a minority may only achieve benefit after repeated, treatment sessions over an extended period of time.

What conditions can TENS treat?

TENS is commonly used to provide relief from pain associated with the following: backache, cervical arthrosis, torticollis, arthritis, sciatica, sports injuries, ankle sprains, myalgia, rheumatism, neuralgia, after surgery, menstrual pain.

Advantages of TENS

Use of TENS has a number of advantages: it is safe and effective. Many people feel immediate benefit. It is drug-free, non-addictive and non-invasive. It is user friendly, portable and ideal for home use. It is widely used and recommended by physiotherapists and physicians.

Pack contents and assembly for use

Your **LogiSTIM[®] TN-11 TENS** pack should contain the following:

- one TENS unit
- two lead wires
- four self adhesive electrodes with connectors
- two alkaline AA 1.5v batteries
- one user's guide (this booklet)

Please check all the contents are correct before you assemble the unit.

How to assemble the unit

Five simple steps are required to assemble the **LogiSTIM[®] TN-11** unit prior to use.

STEP 1 – Batteries: Remove the battery cover and insert two batteries as shown in the diagram inside the battery compartment.

Note: the unit will not function if the batteries are inserted incorrectly. To check, press the '**ON/OFF**' button once and the LCD display should appear. Having made this check, press the button again to switch the unit off.

If the battery power is low, the battery symbol will flash, indicating that the batteries should be replaced.

Assembly for use *(continued)*

Caution: there is a risk of explosion if the batteries are fitted incorrectly. Only use AA Alkaline 1.5 volt batteries. Do not mix old and new batteries. Used batteries should be removed from the unit and disposed of safely. Do not dispose of batteries in fire. Keep batteries out of the reach of children.

STEP 2 – Leads: the unit can be used with two or four lead wires. See body maps under Electrode Placement on page 15 onwards.

Unravel the leads and insert the plug(s) into either of the sockets in the end of the unit. If only using one lead, insert into the Ch1 (left hand) socket as marked on unit.

STEP 3 – Electrode pads: remove electrode pads from the bag and connect to the leads. Ensure the leadwire plug is firmly pushed into the socket on the pad.

STEP 4 – Placement of electrode pads: make sure the skin is clean and dry before placing electrodes on the skin. See later sections for details of placement for labour and other pain conditions.

STEP 5 – Read section on instructions for use
Adjust settings for required treatment.

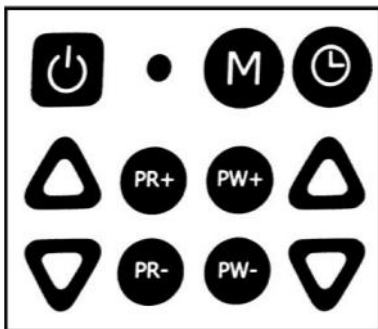
Assembly for use *(continued)*

Note: always make sure the unit is switched OFF before removing the electrode pads. The electrode pads should be carefully peeled back from the corners. Do not remove them by pulling on the leadwire connector as this will cause damage. Return the pads to the clear plastic shields after use and store in a closed bag.

When the pads initially lose their adhesive quality, you can reactivate this by applying a fine spray of water. Shake off excess water and allow to air-dry before applying or storing. Once they have finally lost their adhesion, new pads should be purchased.

Keypad controls

The **LogiSTIM® TN-11** unit is easy to operate using the keypad controls pictured below.



What does each button do?

ON/OFF Press this button to switch the unit ON and OFF. Press once and the display will appear on the LCD screen. Press this button again and the unit will switch OFF. Always switch off before affixing or removing electrodes.

Wave Press this button to select the waveform. One of the following waveforms will be displayed according to your selection.



Keypad controls *(continued)*



Symmetric bi-phasic rectangular



Asymmetric bi-phasic rectangular



Monophasic rectangular

'Symmetric bi-phasic' is the default which is effective and comfortable for the majority of people.

The waveform refers to its shape as a graph of signal strength plotted against time. A bi-phasic waveform means that the current flows in both directions. In the symmetrical bi-phasic rectangular wave the current is equal in magnitude and duration in both directions. This will result in both electrodes being the active electrode at equal alternate phases of the pulse. Equal sensation will come from both electrodes.

By contrast for an asymmetric wave only one electrode will act as the active electrode. Sensation will come predominantly from the active cathode electrode (the black lead connector).

The waveform options allow the user to experience different sensations to find the most comfortable and effective. The waveform can be changed while the unit is in use. Press the key and the LCD will briefly display the new waveform selected. The change will be felt by the user.

Keypad controls *(continued)*

Note: In a very small percentage of people, the Monophasic Rectangular waveform can exacerbate the pain symptoms. If this occurs, stop treatment using this waveform immediately.

Mode Press this button to select required operating mode. There are a total of five modes available: **Constant**, **Burst I**, **Burst II**, **Modulation I** and **Modulation II**



For a description of each mode, refer to the Technical Specification section in this user guide.

Timer Press this key to select the treatment time. The unit can be run continuously or the time can be set to 15, 30, 45, 60 or 90 minutes. The unit will automatically switch itself off on completion of the treatment time.



Treatment time: To display the total treatment time in minutes, press the Channel 2 intensity reduction and the timer button together for 5 seconds. Repeat this to return to the main display screen.

To clear treatment time to zero, press Mode and Timer keys together for 2 seconds.

Keypad controls *(continued)*

Intensity Control



Use these buttons to adjust the intensity of each channel. The left side is for Channel 1 (Ch1) and the right is for Channel 2 (Ch2). The upper and lower arrows increase and decrease the intensity respectively.

You will see the bars changing on the left and right side of the display as you increase or decrease the power on each channel.

Pulse Rate / Width



Press this key to increase the Pulse Rate



Press this key to decrease the Pulse Rate



Press this key to increase the Pulse Width



Press this key to decrease the Pulse Width

When the pulse rate, pulse width or intensity is being adjusted an auto-repeat function is available. If a key is held down for more than 1 second, it will automatically increase or decrease one step per $\frac{1}{4}$ second.

Instructions for Use

There are five easy steps to using the unit:

- Step 1** – Press the On/Off key. The LCD screen will appear.
- Step 2** – Press the Mode key to select the desired program.
- Step 3** – Press the Waveform key to select the desired waveform.
- Step 4** – Press the Timer key to select treatment time.
- Step 5** – Adjust intensity to level required.

Lock function

By pressing the waveform key and the Ch2 intensity reduction arrow key simultaneously for 2 seconds the unit will be 'locked' or 'unlocked'. While the unit is locked, the only parameters that can be adjusted are the timer and the intensity. Removal of the batteries or pressing the ON/OFF key will not affect the locking function.

Memory function

After use, when the unit is switched off, the memory function will remember the last settings used. The unit will start with these settings when it is next switched on (except intensity level which will be zero).

Electrode placement

Note: the following electrode placement illustrations are for general guidance only. Exact location will depend on location of pain and body shape. Consult your physician to establish the electrode positions most suited to your particular condition.

Red and black connectors for lead wires

At the ends of the lead wires supplied, there are red and black adaptors. These are the anode (red) and cathode (black).

Greater sensation may be felt from the red adaptor.

As a general guide, the electrode connected to the red plug should be placed closest to the spinal column. For example, if the arm is to be treated, place the electrode with the red plug higher up the arm than the black one.

Note: when using the Monophasic waveform, the above is reversed and more sensation will be felt from the electrode connected to the black plug. This should also be placed nearer the spine.

In the following diagrams, they are shown as:

1B = Channel 1 black adaptor

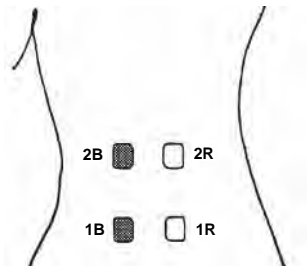
1R = Channel 1 red adaptor

2B = Channel 2 black adaptor

2R = Channel 2 red adaptor

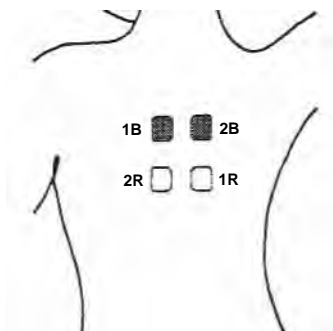
Lower back pain

Using both leads, position electrode pads either side of the spine at the site of the pain.



Back pain

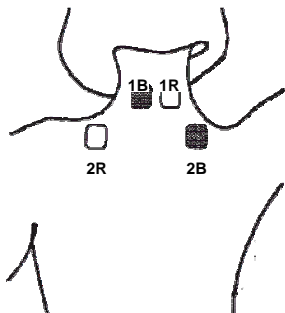
Using both leads, position pads either side of the spine, covering area of pain.



Neck pain

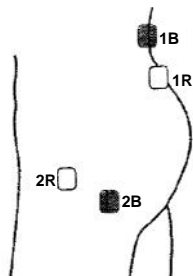
Using both leads, position the electrode pads at the back of the neck and over the top of the shoulders.

Note: never place pads on the side or front of the neck.



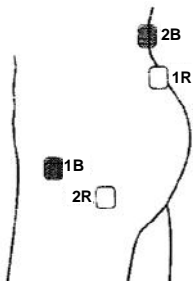
Hip pain

Place the pads from one lead either side of the spine on the lower back. Then place the pads from the second lead onto the area of pain on the hip.



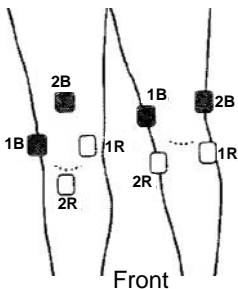
Hip pain (alternative)

Place one pad from each lead either side of the spine on the lower back. Then place the remaining pads on the area of pain on the hip.



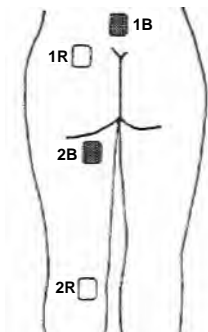
Knee pain

Using both leads, place pads over the top and base of the knees. Avoid placing pads directly on the kneecap.



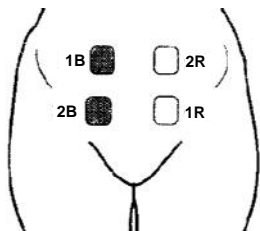
Sciatica

Take the first lead and place the pad with the black adaptor on the lower back on one side of the spine and the second pad with the red adaptor at the top of the back of the leg. Repeat for the second lead, placing the second pad lower down the leg.



Menstrual pain

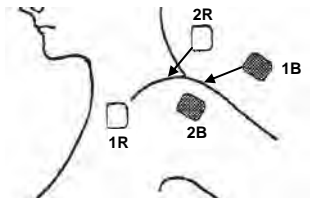
Using both leads, place pads over the abdomen.



Shoulder pain

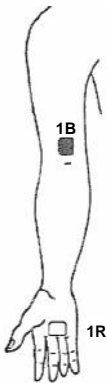
Using both leads, place pads on the front and back of the shoulder.

Note: do not place pads on the side or front of the neck.



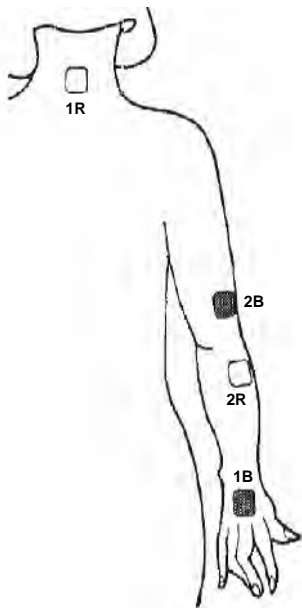
Arthritis of hands and fingers

Using one lead only, place one pad on the top of the hand and the other pad on the top of the arm, close to the bend in the arm.



Elbow pain

Using both leads, place pads on either side of the elbow, on the back of the neck and on the back of the hand.



Electrode information

The electrode pads supplied with your **LogiSTIM® TN-11** unit are self-adhesive and can be used multiple times. The pads should be removed periodically to allow the skin to breath. When not in use the pads should be placed onto the clear plastic shield, and kept in the re-sealable bag.

The condition of the pads does affect the conductivity and consequently the performance of the unit. When the pads initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a drop of water on the adhesive gel. Once the pads finally lose their adhesive quality, new pads should be purchased.

Allergic reactions can occur. In the event of an allergic reaction, discontinue use and seek medical advice.

Do not apply a pad to skin that does not have normal sensation. If the skin is numb, stimulation will not be felt and too great an intensity may be applied.

Care and maintenance

The unit may be cleaned by wiping it with a damp cloth and a solution of mild soap and water. Wipe dry after cleaning. Do not immerse the unit in water.

Replace batteries as soon as flashing symbol appears. No other user maintenance of the main unit is required.

Troubleshooting

If the unit does not appear to be operating correctly, refer below to determine the cause. Should none of these measures correct the problem, the unit will need servicing. In this case, please contact your equipment supplier.

The unit does not function at all

- Check the batteries are inserted correctly
- Replace batteries

Unit switches off unexpectedly

This is likely to be the power-save function. If no buttons are pressed and the intensity levels are both zero, the unit will power-off automatically after a few minutes.

There is no stimulus from one channel

- Check the intensity is set above zero (bars on screen)
- Check the lead wire is inserted into the unit correctly
- Check the lead wire plug is inserted into both electrode pads correctly
- Check both electrodes are attached fully to the skin
- Change over the lead wires and electrodes on the unit to establish whether they are working correctly. If there is now a sensation from the original channel but not the other one, the lead wire is probably damaged and needs replacement.

Technical specification

- **Model:** LogiSTIM[®] TN-11
- **Channels:** Dual, independent intensity
- **Output:** max 130 mA (peak) across 500 Ohm load
- **Pulse width:** From 50 μ s to 250 μ s adjustable
- **Pulse rate:** From 1Hz to 150Hz adjustable
- **Waveform:** Symmetric bi-phasic rectangular
Asymmetric bi-phasic rectangular
Monophasic rectangular
- **Treatment timer:** Continuous, 15 min, 30 min, 45 min
60 min, 90 min selectable.

Mode information

Constant – Both Pulse Rate and Pulse Width are adjustable. Defaults are PR=120Hz and PW=50 μ s.

Burst I – Two bursts per second, 250ms on, 250ms off with 25 pulses per burst. The settings are fixed as PR=100Hz and PW=200 μ s.

Burst II – Two bursts per second, 250ms on, 250ms off. Both Pulse Rate and Pulse Width are adjustable. Defaults are PR=100Hz and PW=50 μ s.

Modulation I – Pulse width automatically steps from 100 to 250 μ s over 6 seconds and is then reversed over the next 6 seconds. Pulse rate is adjustable.

Modulation II – Pulse rate increases from 50Hz to 100Hz while pulse width decreases from 200 μ s to 60 μ s over 5 seconds. The pattern is reversed over the next 5 seconds.

Warranty

In addition to your statutory rights, the distributor agrees that if any defect in materials or workmanship appears in this product within two years of the original date of consumer purchase, it will repair (or at its option, replace) the unit free of charge for parts and labour. This applies only if the product has been used for domestic purposes and not damaged through misuse, accident or neglect nor modified or repaired by anyone other than an authorized distributor or its authorized agents.

If a problem occurs, please check the unit is being used in accordance with instructions. If the fault persists after checking the troubleshooting section, return it with dated proof of purchase to your nearest stockist or original supplier. Please include your name, address and a description of the fault.

Note: only authorized service agents should carry out repairs to the unit. For technical documents, please contact the manufacturer.

As consumable items, batteries, electrodes and lead wires are not included within this warranty.

