



TENS UNIT SAFETY WARNING SHEET and INFORMATION

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using the device.

Federal law (USA) restricts this device to sale by or on the order of a physician. Observe your physician's precise instructions and let him show you where to apply the electrodes. For a successful therapy, the correct application of the electrodes is an important factor.

Carefully write down the settings your physician recommended.

Indications for use

This device is a prescription device and only for symptomatic relief of chronic intractable pain.

Contraindications

- Any electrode placement that applies current to the carotid sinus (neck) region.
- Patients with implanted electronic devices (for example, a pacemaker) or metallic implants should not undertake.
- Any electrode placement that causes current to flow transcerebrally (through the head). The use of unit whenever pain symptoms are undiagnosed, unit etiology is determined.
- The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

WARNINGS AND PRECAUTIONS

Warnings

- The device must be kept out of reach of children.
- The safety of device for use during pregnancy or delivery has not been established.
- Do not place electrodes on front of the throat. This may result in spasms of the laryngeal and pharyngeal muscles.
- Do not place the electrodes over the carotid nerve.
- The device is not effective for pain of central origin (headaches).
- The device may interfere with electronic monitoring equipment (such as ECG monitors and ECG alarms).
- Electrodes should not be placed over the eyes, in the mouth, or internally.
- These devices have no curative value.
- TENS devices should be used only under the continued supervision of a physician.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.

Precautions/Adverse Reactions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Stimulation should be stopped and electrodes removed until the cause of the irritation can be determined.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until reevaluation by a physician/clinician.
- Always turn the device off before applying or removing electrodes.
- Skin irritation and electrode burns are potential adverse reactions.

PURPOSE:

A Transcutaneous Electrical Nerve Stimulator, or TENS, unit is designed to relieve post-operative, acute and chronic pain. It is used for pain caused by peripheral nerves and not central. TENS units are prescription-only devices.

OPERATION:

TENS units work in a couple of ways. The first way they are thought to work is by a method called the *Gate Theory*. The Gate Theory states that our brains can only handle one stimulus at a time. When you have chronic pain, this pain signal is constantly being sent to your brain and recognized as pain. When an electrical stimulus is added to the area of pain the body feels this electrical stimulus, and since the brain can only handle one thing at a time, the pain is not transmitted to the brain.

The second method thought to be part of TENS unit's success is by way of stimulating our own bodies to release their own natural painkillers. TENS units do not work for everyone and results may vary. Always follow the instructions and warnings in your user's manual.

USE:

One of the most important tasks that must be performed is battery maintenance. If you are using a nickel-cadmium rechargeable battery, always fully charge it and fully deplete it before charging it again. These batteries can develop memories and by not performing this charging task correctly, your battery's life can be greatly diminished. If your battery does develop a memory you can help expand the memory by charging for 12 - 13 hours and then completely depleting the battery.

Always prepare the skin before applying electrodes. Your skin should be clean and free of any lotions or creams. If you are using electrodes that use conductive gel, apply a small, even layer over the electrode. For carbon, self-adhesive electrodes, apply a drop of water to the electrodes before applying to the skin. The electrodes attach to the lead wires and then the TENS unit. Always grasp the connector and not the cord when inserting or removing.

When making adjustments, always make sure the unit's channels (1 and 2) are in the OFF position. The actual settings should be recommended and prescribed by your physician. Medical equipment suppliers *don't* set or instruct users as to user settings.

When you are using the BURST mode, the unit delivers a series of quick pulses followed by a rest. This cycle repeats itself frequently. Always have channels OFF before changing modes. For MODULATION mode, the stimulation automatically varies the width of the pulse. For CONVENTIONAL mode, the stimulation is constant. After the settings have been fine-tuned, set the timer to 30 or 60 minutes. Your physician should also prescribe the use time. When the lights become dim, it means your batteries should be replaced or recharged.

ACCESSORIES:

The electrodes and lead wires can be obtained from your medical equipment supplier. Your medical equipment supplier can set up a recurring delivery to accommodate your needs. Electrodes should be replaced once a month and lead wires once every 6 months.