PRESCRIBING INFORMATION

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 Electronic Nerve Stimulation (TENS) devices are 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. In patients with known myocardial disease or arrhythmias, 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 is established. Any electrode placement that causes current to flow transcerebrally (through the head) is not allowed.

Warnings: This device should be used only under the continued supervision of a physician. TENS is ineffective for pain of central origin. TENS is of no curative value; it is a symptomatic treatment which suppresses pain sensation which 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.

Precautions: Avoid adjusting controls 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. If TENS therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is reevaluated by the physician or therapist. Use only for the specific pain problem prescribed by physician. Effectiveness is dependent upon patient selection. Turn device to OFF position when changing battery.

Adverse Reactions: Possible allergic reaction to tape or gel. Possible skin irritation or electrode burn under electrode. If skin irritation persists, discontinue use and consult a physician.
INTRODUCTION:
What is Pain: Pain warns our body of injury. This warning system is intended to prevent additional damage. The sensation of pain is important, because without it, vital parts of our bodies might be 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 certain types of chronic and acute pain.

How Does TENS Work? TENS or Transcutaneous Electric Nerve Stimulation, refers to the transmission of small electrical pulses through the skin to the underlying peripheral nerves. The theory of TENS suggests two different modes or operation. Conventional (high frequency) TENS, is based on the theory that continuous mild electrical activity may block the pain signal traveling to the brain. 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 electrical activity may cause the body to release its own pain relieving substances, called endorphins. Ask your physician or therapist for more details. No matter what pain theory is used. TENS has been proven useful in pain management for many pain patients.
**INDICATORS AND CONTROLS**

- Channel 1 Output Indicator Light
- Channel 1 Output Receptacle
- Channel 1 On/Off and Amplitude Control
- Channel 2 On/Off and Amplitude Control
- Channel 2 Output Indicator Light
- Channel 2 Output Receptacle
- Pulse Width Control
- Mode Select Switch: Burst, Normal, Modulation
- Pulse Width (μs) Frequency (Hz)
  - 10: 60
  - 23: 250
  - 250: 6
- Pulse Frequency Control

**PREPARATION FOR USE**

1. **Check Battery.** Insure that you are using a fresh battery.
2. **Prepare Skin.** Before applying electrodes, be sure to confirm correct electrode placement as recommended by your physician or therapist. Each location should be washed, rinsed and thoroughly dried.

3. **Prepare Electrodes.** Apply gel in a thin even layer (about the thickness of a match book cover) to the bottom of the electrode. Avoid using too much gel.

   **Note:** If you are using reusable electrode, please disregard the procedure.
4. Attach Electrodes. The electrode should be attached with adhesive tape. Be sure that all sides are well taped and that the electrode is held firmly against the skin.


6. Insert Pin into Electrode Socket. Insert pin connector into electrode as shown. (When inserting or removing pin connector, hold connector—not cord—to protect cord.) For some electrode locations, it may be preferable to insert the pin connector prior to taping the electrode to the skin.

7. Adjusting the Controls. Ensure that amplitude controls for both Channels 1 and 2 are turned to the “OFF” position.
8. Connect Leads to TENS unit. Insert receptacle end of lead wire set into the channel output receptacle to be used (1 and/or 2), Pushing plug all the way in.

9. High or Low Frequency Tens. Set the mode selector switch to the "N" position.

10. Adjust Pulse Frequency. Turn the Pulse Frequency control to the setting recommended by your medical professional.

11. Adjust Pulse Width. Turn the Pulse Width control to the setting recommended by your medical professional.
12. Adjust Output. Turn Amplitude control knob for Channel 1 or 2 clockwise. The indicator will light up while 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.

13. Using Burst Mode. When operating in Burst mode your TENS produces a series of seven quick pulses followed by a rest. The cycle repeats itself twice every second. Before switching to Burst, turn amplitude controls for channels 1 and 2 “0” (off). Choose “B” (burst mode) with the mode selector switch. Slowly adjust the amplitude and pulse width controls to the setting recommended by your medical professional. Note: In burst mode, the pulse frequency is fixed; adjusting the pulse frequency control has no affect.

14. Using Modulation Mode. When operating in Modulation Mode, your TENS Neurostimulator automatically varies the amplitude of the pulse every four seconds. To use Modulation, first adjust the amplitude controls for channels 1 and 2 to “0” (off). Set the mode selector switch to “M” (modulation) position. Slowly adjust channel 1 and/or channel 2 amplitude, pulse frequency and pulse width controls to the settings recommended by your medical professional.
CONCLUDING TREATMENT

15. Turning Unit Off. Turn both channel controls to 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 and the electrodes thoroughly with mild soap and water. If there is skin irritation from tape or gel, consult your prescriber.

16. Portability. Your TENS is portable and may be clipped to a belt, shirt pocket, bra or other clothing.

CARE AND MAINTENANCE

17. Front Cover. A removable panel covers the controls for pulse frequency, pulse width, mode switch and battery compartment. Your medical professional may wish to set these controls for you and request that you leave the cover in place.

18. Battery. Dimming of the Indicator lights signifies that the battery should be replaced with a new one as soon as possible. However, the stimulator will continue to operate for several more hours. To replace battery, remove front cover (see above), and extract battery. Replace with 9 Volt alkaline or similar rechargeable battery, taking care that the battery is inserted correctly. (See diagram inside battery compartment). This TENS unit is designed to be used with batteries only, and can not be operated from a line-powered battery charger.
19. Care of Electrodes. To avoid skin irritation and ensure good contact with your skin, clean silicone rubber electrodes with soap and water frequently. Allow to dry completely before using.

20. Care of Electrode Cords. Clean the electrode cords by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

**TROUBLESHOOTING**

If your TENS unit does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the unit will need servicing.

The power indicator lights up but unit does not function properly.

- Please turn both amplitude control switches off, then turn on again.
- Check all control settings. Are they set to values prescribed by your medical professional?
- Are electrodes in proper position?
- Check lead wires. Be sure all connectors are firmly sealed.
- Be sure you are using the proper amount of gel. Too much or too little can cause problems.
- Replace cord set with another to check for broken wires.

"On" and "Battery Light" are dim.

- Replace battery with a new one.

None of the indicators light up.

- Replace battery with a new one.
- To obtain service, contact your supplier.
TECHNICAL SPECIFICATIONS

Channels: Dual, isolated between channels
Wave Form: Modified square wave with zero net direct current (DC) component
Pulse Amplitude: 0 to 80 mA each channel, adjustable (500 ohm load)
Pulse Frequency: 2 to 150 Hz, adjustable
Pulse Width: 60 to 250 microseconds, adjustable
Modulation Mode: Pulse width is automatically varied in a cyclic pattern over an interval of nominally 4.0 seconds.
Burst Mode: 7 pulses per burst
2 bursts per second
100 Hz internal frequency of burst
Maximum Charge: 20 micro coulombs per pulse
Power Source: 9 volt alkaline battery or similar rechargeable cell
Battery Life: 70 hours average usage (alkaline)
Size: 24 x 64 x 95mm
Weight: 130 grams (including battery)

All values have 10% ± tolerance