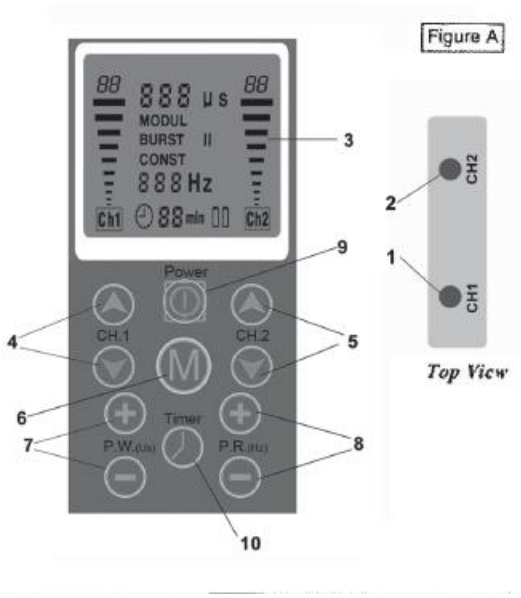
Criterion Med ITENS Operating Instructions

General Description

This device is a Transcutaneous Electrical Nerve Stimulator (TENS). One pair of electrodes can be connected to each output channel using the leadwires supplied. Stimulation pulses are transferred from the device through the leadwires to the electrodes. The intensity, duration, and number of pulses per second can be adjusted.

Figure A



1) Channel 1 Leadwire Port
2) Channel 2 Leadwire Port
3) Display
4) Channel 1 Intensity Control
5) Channel 2 Intensity Control
6) Mode Control
7) Pulse Width Control
8) Pulse Rate Control
9) Power Button
10) Timer

Instructions for Use

1. Attach leadwires to Channel 1 and Channel 2.
2. Attach electrodes to leadwires, following instructions on electrode packaging.
3. Place electrodes on body as directed by your clinician.
4. Turn on Device (Ensure Power Slider on the bottom of the unit is set to the right before hitting the Power Button
5. Select desired mode.
6. Set Pulse Width and Pulse Rate as directed by clinician.
7. Increase or decrease intensity to a strong but comfortable level.
8. (Optional) Set an automatic timer for your treatment by pressing the Timer Button until the desired treatment time is displayed (Continuous, 15, 30, or 60 minutes). When the device has counted down the elapsed time, it will automatically shut off.

Technical Considerations

Pulse Width (µs) and Pulse Rate (Hz)

The Pulse Width indicates the length of time the current is flowing per cycle, which impacts patient comfort. Increase or decrease the P.W. (µs) by using the corresponding + and - buttons. The P.W. (µs) is adjustable from 1 - 250 µs in 10 µs increments.

The Pulse Rate indicates the number of pulses or cycles per second; affects the quality of contraction and can create muscle fatigue at higher rates. Increase or decrease the P.R. (Hz) by using the corresponding + and – buttons. The P.R. (Hz) is adjustable from 1 – 150 Hz in 5 Hz increments.

Programming A Stimulation Pattern

Select the desired stimulation pattern by pushing the Mode Button until the desired stimulation pattern is displayed on the screen. The patterns will appear in the following order:

MODUL - Modulation: 120 HZ and 50 µs. 50% decrease of the Pulse Width (µs) value over 2.5 seconds, then back to its original value over 2.5 seconds. Helps prevent accommodation.

CONST - Constant: Default Setting. Base pulse is 120 Hz and 50 µs; adjustable.

BURST 1 - Burst: 1 Hz and 10 µs. 1 burst per second.

BURST 2 - Double burst: 16 HZ and 10 µs. 2 bursts per second, each burst contains 8 pulses.

NOTE: If a new mode is selected during treatment, the intensity will automatically drop to 0.

NOTE: Ensure the power slider is set to off once you are done using the unit, to prevent any loss of power.

FITTING PATIENTS

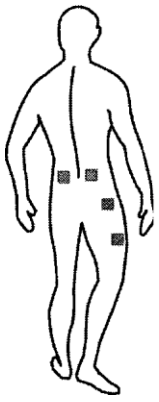
ELECTRODE PLACEMENT

When using electrical stimulation to suppress pain or promote rehabilitation, there are numerous techniques that will assist the doctor in choosing the best electrode placement. Electrotherapy is delivered using similarly sized electrodes that are placed in a sequence and moved around until the patient reports that their pain is diminished. When determining the placement of electrodes, especially when dealing with joint pain, it is essential to place the electrodes in such a way that basic movement of that area (e.g. walking while wearing a TENS hooked up to the knee) will not cause the electrodes to slip, shift, or stretch.

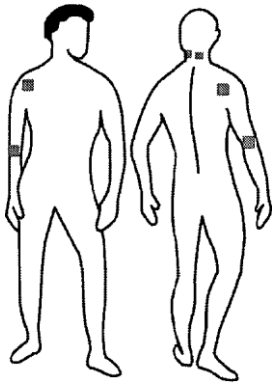
Listed below are some of the suggested placements:

1. Surround the area of pain with electrodes.
2. Place electrodes over the dermatomes, myotomes, or sclerotomes that are relative to the area of pain.
3. Place electrodes close to the spine (near the foramina) where the nerve that is responsible for the area of pain exists (e.g. L-4, L-5; for sciatic pain).
4. Painful areas that are innervated by the peripheral nerves can be stimulated by placing the electrodes over the area where the nerve becomes superficial.
5. Placing electrodes over superficial vascular structures will stimulate the neural tissue and ionic fluids contained within the vascular structure.
6. Certain areas and types of pain are associated with trigger points. Place electrodes on trigger points that correlate with the area of pain. The patient will report an immediate decrease in pain if the trigger point is the source of pain.

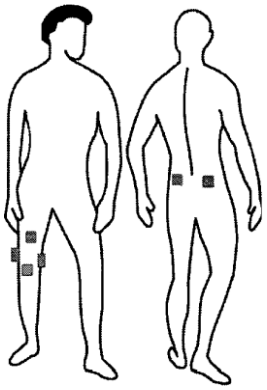
Proper placement of electrodes will achieve maximum results. Systematically change electrode placement if desired results are not achieved. Patients should only use each electrode for 3-4 applications; over-use can result in skin irritation and reduced effectiveness. Below are examples of common conditions and electrode placements:



Low Back and Sciatic Pain

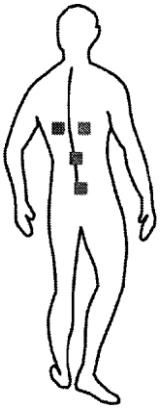


Shoulder and/or Arm Pain



Knee Pain

Head and Neck Pain



Low Back Sacral Pain

Unit Technical Data

Channels = 2

Waveform = Asymmetrical, Biphasic Square

Output = Constant Current

Intensity = Continuous, Adjustable from 0 - 98 mA Peak

Frequency (Hz) = 1 - 200 Hz, Adjustable

Pulse Width (µs) = 10 - 250 Microseconds (µs), Adjustable

Power Supply = 600 mA Rechargeable Battery

Dimensions = 3.9" x 2.5" x 1.1"

Weight = 3.25 oz (92g)

Accessories

Set (2) of Leadwires

"Fitting" Electrodes of various sizes and shapes

Portable Charger for ITENS Unit (1)

Instruction Booklet (1)

Carry Pouch (1)

Patient Safety Information

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician licensed by the State.

Indications

Transcutaneous Electrical 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

Can affect the operation of demand type cardiac pacemakers.

Not recommended for patients with known heart disease without physical evaluation of risk.

Do NOT apply over the anterior aspect of the neck or carotid sinus.

Do not apply TENS for undiagnosed pain syndromes until etiology is established.

Warnings

Electrodes should not be placed over the eyes.

Avoid active epiphyseal regions in children.

Use of abdominal electrodes during labor may interfere with fetal monitoring equipment.

Turn the stimulator off before applying or removing electrodes.

Electrotherapy may cause skin irritation beneath the electrodes.

Use of Electrodes and Accessories

Do not use electrodes smaller than ¾" in diameter. Please note, the smaller the electrode, the greater the intensity of the stimulation

Only Criterion, Inc authorized electrodes and accessories are to be used with this device.

Replace electrodes after 2-4 applications or when conductivity and the adhesion of gel decreases significantly.

Contact

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All Criterion units come with a limited lifetime warranty. The ITENS Criterion Medical Device has a limited lifetime warranty to be free from manufacturing defects or workmanship for the original patient prescribed this unit. Should the stimulator fail due to manufacturing defects or workmanship during the warranty period, Criterion, Inc. may, at its option, replace any defective unit with a new or rebuilt stimulator. Criterion's liability shall be limited only to repair or replacement of the stimulator as described. The limited warranty is made only and expressly to the initial purchaser of the stimulator and is not transferable. No warranty is made with the respect to any accessories including electrodes, lead wires, batteries or any other accessory. Please direct all questions regarding the TENS device, accessories, electrodes, etc. to Criterion, Inc.