

Transcutaneous Electrical Nerve Stimulation Device

LUMI-TENS



CE
0120

Operation Manual

Read this manual before operating your LUMI-TENS.

Save this manual for future use.

The most current version of this manual can be found online at
www.grahamfield.com.

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GF Health Products, Inc. is not responsible for typographical errors. For the most updated and current information on packaging, warranties, products and specifications, including the most current version of these instructions, please visit our website at www.grahamfield.com.

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INTRODUCTION TO TENS

What is Pain?

Pain is the body's warning system. Pain is important because it signals an unusual condition in the body and alerts us before additional damage or injury can occur. TENS was developed to help relieve some types of chronic and acute pain.

How does TENS work?

TENS is a method of treating pain that is non-invasive and does not use pharmaceuticals.

The TENS device sends impulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases this stimulation will greatly reduce or eliminate the pain sensation felt by masking the original pain message sent to the brain.

It is also believed that TENS stimulation helps release endorphins into the blood stream thereby further reducing pain.

TENS devices are clinically proven to be useful in pain management for many patients. By reading this manual and carefully following the treatment instructions given to you by your clinician, you can attain the maximum benefit from your TENS device.

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using TENS.

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

Indications

Transcutaneous Electrical Nerve Stimulation (TENS) is indicated to be used under a physician's prescription for the symptomatic relief and management of chronic (long term) pain and for the treatment of postoperative or posttraumatic pain.

Contraindications

- Patients with implanted electronic devices (for example, a pacemaker) or metallic implants should not undergo TENS treatment without first consulting a physician.
- Any electrode placement that applies current to the carotid (neck) region.
- Any electrode placement that causes current to flow transcerebrally (through the head).
- The use of TENS whenever pain symptoms are undiagnosed, and the etiology is unknown.

SAFETY

Always follow basic safety precautions, including the following:

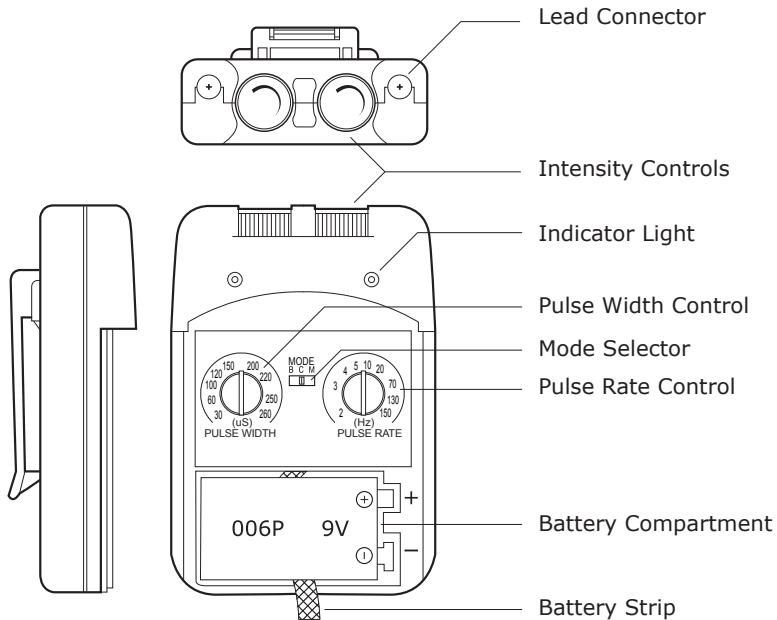
- ⚠ **WARNING:** Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious personal injury.
- ▲ **CAUTION:** Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

WARNINGS

- ⚠ **WARNING:** TENS devices must be kept out of reach of children.
- ⚠ **WARNING:** The safety of TENS devices for use during pregnancy or delivery has not been established.
- ⚠ **WARNING:** TENS is not effective for pain of central origin (headaches).
- ⚠ **WARNING:** If TENS treatment becomes ineffective or unpleasant, stimulation should be discontinued until evaluated by a physician.
- ⚠ **WARNING:** Avoid adjusting controls while operating machinery or vehicles.
- ⚠ **WARNING:** Always turn the TENS device OFF before applying or removing electrodes.
- ⚠ **WARNING:** TENS may interfere with electronic monitoring equipment (ECG monitors/alarms).
- ⚠ **WARNING:** Electrodes should not be placed over the eyes, in the mouth, or internally.
- ⚠ **WARNING:** TENS devices have no curative value.
- ⚠ **WARNING:** TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- ⚠ **WARNING:** Notice for California Customers- California Proposition 65
WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive or developmental harm.

PRECAUTIONS/ADVERSE REACTIONS

- ▲ **CAUTION:** Isolated cases of skin irritation may occur at the site of electrode placement during long term application.
- ▲ **CAUTION:** Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- ▲ **CAUTION:** Skin irritation and electrode burns are potential adverse reactions.



ABOUT THIS DEVICE

Your TENS device is a battery operated device that includes two controllable output channels. This TENS device creates electrical impulses whose amplitude, duration, and modulation can be altered with the controls or switches. The TENS Intensity Controls are very easy to use, and the slide cover protects accidental changes in settings.

UNIT CONTROLS

Panel Cover

A cover which conceals the controls for the Pulse Width, Pulse Rate, and Mode Selector. Press the top portion of the cover and pull down in order to open the cover.

Intensity

The Intensity Knobs located on the top of the unit affect the strength of the stimulation and also function as ON/OFF controls.

Mode

The Mode Switch is used to select the type of treatment utilized. The three modes are Burst (B), Continuous (C), and Modulation (M).

Pulse Width

The Pulse Width Knob regulates the Pulse Width for both channels.

Pulse Rate

The Pulse Rate Knob regulates the number of pulses per second for both channels.

Mode Functions

Burst (B) releases individual bursts twice per second, Pulse Width is adjustable and the Pulse Rate is set at 100Hz per second.

Continuous (C) stimulation is delivered continuously at the settings determined by Intensity, Rate, and Width Knobs.

Modulation (M) Pulse Width decreases the Pulse Width down to 60% of the original width setting. This decreased Pulse Width is maintained for 1.5 seconds before returning to the original width setting, which is maintained for 3.5 seconds. The cycle is then repeated. The Intensity and Pulse Rate are adjustable.

ATTACHING THE LEAD WIRES

The lead wires provided with the TENS device insert into the ports located on top of the unit. Holding the insulated portion of the connector, push the plug end of the wire into one of the ports; one or two sets of the wires may be used. After connecting the wires to the stimulator, attach each wire to an electrode. Lead wires provided with the TENS device are compliant with mandatory compliance standards set forth by FDA.

▲ **CAUTION:** Use care when plugging and unplugging the wires. Pulling on the lead wire may cause wire breakage.

⚠ **WARNING:** Never insert the plug of the lead wire into an AC power supply socket. Personal injury and/or damage to the TENS unit could occur.

ELECTRODE SELECTION AND CARE

Use the electrodes as prescribed.

Follow application procedures outlined in electrode packaging to maintain stimulation and prevent skin irritation. The electrode packaging provides instructions for care, maintenance and proper storage of electrodes.

TIPS FOR SKIN CARE

Good skin care is important for effective and comfortable use of your TENS device.

- Always clean the electrode site with mild soap and water solution, rinse well and dry thoroughly prior to any electrode application.
- Any excess hair should be clipped, not shaved, to ensure good electrode contact with the skin.
- If a skin treatment is recommended by your physician, apply the skin treatment as recommended, let dry, and apply electrodes as directed. Following these recommendations will both reduce the chance of skin irritation and extend the life of your electrodes.
- Avoid excessive stretching of the skin when applying electrodes. Proper application is best accomplished by applying the electrode, then smoothly pressing it in place from the center outward.
- When removing electrodes, always remove by pulling in the direction of hair growth.
- It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.

CONNECTING THE TENS DEVICE

1. Prepare the Skin:

Prepare the skin as previously discussed and according to instructions provided with your electrodes. Before attaching the electrodes, identify the area which your clinician has recommended for electrode placement.

2. Connect lead wires to the electrodes:

Connect the lead wires to the electrodes before applying the electrodes to the skin.

 **WARNING:** Ensure both Intensity Controls for Channel 1 and 2 are turned to the OFF position.

3. Place electrodes on the skin:

Place the electrodes on the skin as recommended by your clinician.

4. Insert the lead wire connector to the TENS device:

Plug the end of the lead wire into the lead connector port to be used, pushing plug in as far as it will go.

5. Select treatment settings:

Ensure the unit is set to the proper settings (Pulse Width, Pulse Rate, and Mode Selector), recommended by your physician.

6. Adjusting Channel Intensity Control:

Locate the Intensity Control Knob at the top of the unit. Turn Channel 1 or 2 clockwise. The indicator light will illuminate when unit is in operation. Slowly turn the Channel Control in a clockwise direction until you reach the intensity recommended by your medical professional. Repeat for the other channel if both channels are to be used.

If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level or cease stimulation and contact your physician.

BATTERY INFORMATION

When the yellow indicator light located on the front of the unit will no longer illuminate, the battery has become too weak to power the unit and it is time to replace the battery. At this point the unit will shut off until the battery is replaced. Dispose of the old battery according to local guidelines and regulations.

▲ **CAUTION:** GF Health Products, Inc. recommends the use of only a 9V alkaline battery with this device.

Changing the battery

When the yellow indicator light on the front of the unit does not illuminate when the unit is turned on, the battery should be replaced.

1. Remove the panel cover by pressing on the top and sliding down until it is completely removed from the unit. This will reveal the battery compartment.
2. Remove the discharged battery from the device.
3. Place a new battery in the battery compartment. Note the proper polarity alignment indicated on the battery and the compartment.

CARING FOR YOUR TENS DEVICE

Your TENS device may be cleaned by wiping gently with a damp cloth moistened with mild soap and water. Never immerse the device in water or other liquids.

Wipe lead wires with a damp cloth moistened with soap and water.

To properly store the TENS device for extended period of time, remove the battery from the unit. Place the unit and accessories in the carrying case and store in a cool, dry location.

TROUBLESHOOTING

If the TENS device does not function properly:

1. Make sure the battery is properly installed or replace the battery. Be sure to observe proper polarity markings when replacing the battery. If the yellow light on the front of the unit does not stay lit when the unit is turned on, replace the battery and check again.
2. If the ON/OFF Indicator Light is flashing and no stimulation is felt, check to ensure lead wires are properly connected and the electrodes are in place. If the unit appears to be functioning and no stimulation is felt, the lead wires or electrodes may need to be replaced.
3. If the battery appears to be charged and the unit is not functioning, turn both Intensity Control Knobs to the OFF position (counterclockwise). Then gradually turn the Intensity Control Knob to the ON position.

If any other problems occur, contact an authorized GF Health Products, Inc. distributor. Do not try to repair a defective device.

SYSTEM COMPONENTS

Your TENS device may include the following components or accessories:

- TENS unit
- Electrodes
- Hard case
- Lead wires
- Operation manual

Also required (not included): One 9-Volt alkaline battery.

TECHNICAL SPECIFICATIONS

- Channel: Dual, isolated between channels
- Modes of Operations: Burst, Continuous, Modulation
- Pulse Intensity: Adjustable 0-80mA peak into 500 ohm load each channel, constant current
- Pulse Rate: 2Hz-150Hz (adjustable)
- Pulse Width: 30uS-260uS (adjustable)
- Burst Mode: Burst consists 2 burst per sec at 100 Hz
- Wave Form: Asymmetrical Bi-Phasic square pulse
- Voltage: 0-100 Volt (open current)
- Power Source: 9 volt battery
- Dimensions: 95(H) x 65(W) x 23.5 (T) mm
- Weight: 115 grams (battery included)

OUTPUT SPECIFICATIONS

Mode	Intensity (mA)	Width (uSec)	Pulse Rate Freq(Hz)	Cycle Time (Sec)
Continuous	Adj. 0-80	Adj. 30-260	Adj. 2-150 Hz	N/A
Burst	Adj. 0-80	Adj.30-260	100Hz fixed 2 burst per sec.	N/A
Modulation	Adj.0-80	Modulates down from preset width setting by 60% then back to original setting	Adj.2-150Hz	5 sec total time

ONE-YEAR LIMITED WARRANTY

SCOPE OF WARRANTY

GF Health Products, Inc. ("GF") warrants to the original purchaser ("Customer") only, that it will replace or repair components, at GF's sole discretion, that are defective in material or workmanship under normal use for a period of one year after the purchase date unless there is an expiration date on the component in which case the warranty shall expire on the earlier of the warranty period or the expiration date. The warranty does not extend to non-durable parts and does not include labor or costs of shipping. This limited warranty is not transferable. All warranties are conditioned upon the proper use of the product strictly in accordance with good commercial practice and applicable GF instructions and manuals, including proper use and maintenance. The warranty is void if the defect is caused by any other reason not related to defects in materials or workmanship.

OBTAINING WARRANTY SERVICE

GF's customer service team must be notified of any warranty claim within the applicable warranty period. Call 770-368-4700, or fax 770-368-2386 or e-mail cs@grahamfield.com. Failure to follow the specific directions provided by the GF customer service team will result in denial of the warranty claim.

ENTIRE WARRANTY, EXCLUSIVE REMEDY AND CONSEQUENTIAL DAMAGES DISCLAIMER

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GF'S TOTAL LIABILITY FOR ANY PRODUCT OR SERVICE PROVIDED IS LIMITED TO THE COST OF THE PRODUCT GIVING RISE TO THE CLAIM. IN NO EVENT WHETHER IN CONTRACT, INDEMNITY, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE WILL GF BE LIABLE FOR ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO: DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVER, OR EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

This warranty gives you specific legal rights. You may have additional rights which vary from state to state.

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