

Transcutaneous Electrical Nerve Stimulation Device

LUMI-TENS



Operation Manual
Read Before Using

CE
0434

TABLE OF CONTENTS

| | |
|-----------------------------------|----|
| INTRODUCTION TO TENS | 01 |
| INDICATIONS AND CONTRAINDICATIONS | 01 |
| WARNINGS | 02 |
| PRECAUTIONS/ADVERSE REACTIONS | 03 |
| ABOUT THIS DEVICE | 04 |
| UNIT CONTROLS | 04 |
| ATTACHING THE LEAD WIRES | 05 |
| ELECTRODE SELECTION AND CARE | 05 |
| TIPS FOR SKIN CARE | 06 |
| CONNECTING THE TENS DEVICE | 06 |
| BATTERY INFORMATION | 07 |
| CARING FOR YOUR TENS DEVICE | 08 |
| TROUBLESHOOTING | 09 |
| WARRANTY | 09 |
| SYSTEM COMPONENTS | 09 |
| TECHNICAL SPECIFICATIONS | 10 |
| OUTPUT SPECIFICATIONS | 10 |

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:

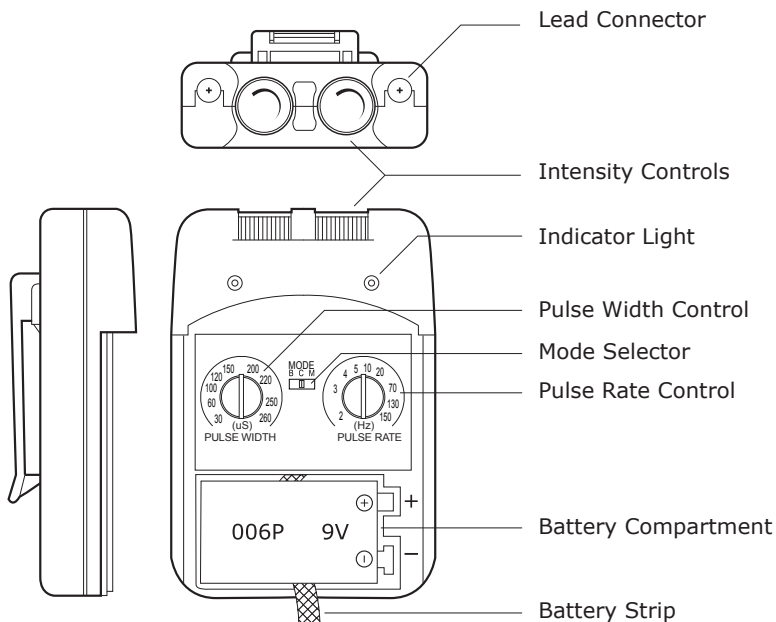
- ⚠ **WARNING:** Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious personal injury.
- ▲ **Caution:** Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

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 (ECGmonitors/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.

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 light up 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 light, 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.

Changing the battery

When the yellow indicator light on the front of the unit does not light up 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(counter clockwise). 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.

WARRANTY

This TENS device carries a the one year warranty from the date of purchase. The warranty applies to the TENS device and necessary parts and labor relating thereto. GF Health Products, Inc. reserves the right to replace or repair the unit at their discretion.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorized individuals.

SYSTEM COMPONENTS

Your TENS device may include the following components or accessories:

- TENS unit
- Electrodes
- Hard case
- Lead wires
- Battery
- Operation Manual

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 N/A 2 burst per sec. | |
| Modulation | Adj.0-80 | Modulates down from preset width setting by 60% then back to original setting | Adj.2-150Hz | 5 sec total time |

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