

# Transcutaneous Electrical Nerve Stimulation (TENS)

Model SW-1000



# **Operation Manual**

Read this manual before operating your SW-1000.

Save this manual for future use.

The most current version of this manual can be found online at <a href="https://www.grahamfield.com">www.grahamfield.com</a>.



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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**, **Transcutaneous Electrical Nerve Stimulation**, 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 this TENS device.

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

#### **Indications**

TENS is indicated to be used under a physician's prescription for the symptomatic relief 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 which applies current to the carotid (neck) region.
- Any electrode placement which 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:

- MARNING: 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: The safety of TENS devices for use during pregnancy or delivery has not been established.
- $\triangle$  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.
- MARNING: TENS devices have no curative value.
- MARNING: TENS is a symptomatic treatment and as such suppresses the sensation if pain which would otherwise serve as a protective mechanism.
- MARNING: 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

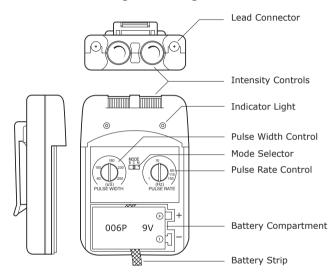
- ▲ CAUTION: Isolated cases of skin irritation may occur at the site of electrode placement during long-term application.
- ▲ CAUTION: Effectiveness is highly dependent upon patient selection of a doctor qualified in the management of pain patients.
- ▲ CAUTION: Skin irritation and electrode burns are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

SW-1000-INS-LAB-RevC14

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## **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.



## SYSTEM COMPONENTS

Your device may include the following components or accessories:

- TENS unit
- · Carrying case
- Lead wires
- Operation manual
- Electrodes

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

## 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

- riangle WARNING: Ensure the device is OFF before connecting the lead wires.
- WARNING: Never insert the lead wire plug into an AC power supply socket. Personal injury and/or damage to the TENS unit could occur.
- ▲ CAUTION: Use care when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

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.

## **ELECTRODE SELECTION AND CARE**

## **Using Electrodes**

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 preparation 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 or preparation is recommended by your physician / clinician, 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

## **Insert battery**

Turn the device to the OFF position before inserting or removing the battery. When inserting the battery, ensure the battery polarity (+ and –) markings match the markings on the device.

## Prepare the Skin

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

- **1. Connect the lead wires to the electrodes:** connect the lead wires to the electrodes before applying the electrodes to the skin.
- MARNING: Ensure both Intensity Control Knobs for Channel 1 and 2 are turned to the OFF Position (counterclockwise) before applying the electrodes.
- 2. Place electrodes on the skin: place the electrodes on the skin as recommended by your physician / clinician.
- 3. Insert lead wire connector into the device: plug end of lead wire into the channel output port (jack) to be used; push the plug in as far as it will go.
- **4. Select treatment settings:** ensure your unit is still set to the proper settings recommended by your physician / clinician.
- 5. Adjusting Channel Intensity Control: locate the Intensity Control Knob (Channel 1 or 2) at the top of the unit. Slowly turn the Intensity Control Knob clockwise until the stimulation is at the level recommended by your physician / clinician (if you don't feel anything, turn the Knob OFF then ON again and carefully turn the Control Knob until you feel a tingling or slight twitch under or around the electrodes). The indicator light will illuminate when unit is in operation. Always start with the lowest setting and increase the intensity slowly.

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

#### BATTERY INFORMATION

When the yellow indicator light on the front of the unit no longer illuminates, the battery has become too weak to power the unit, and the existing battery should be replaced with a new battery. At this point, the unit will turn OFF until a new battery is inserted.

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

## Replacing the Battery

When the yellow indicator light on the front of the unit no longer illuminates, the battery should be replaced.

- 1. Turn unit OFF.
- Remove the front panel cover by pressing on the top of the panel and pressing down in order to slide the panel down. Continue sliding the panel downwards until the panel is completely removed from the unit. This will reveal the battery compartment.
- 3. Remove the discharged battery from the device.
- 4. Place new battery in the compartment.

Note: Ensure the proper polarity (+ and –) markings match the markings in the device.

- 5. Replace the front panel cover.
- 6. Dispose of the old battery according to local guidelines and regulations.

## CARING FOR YOUR TENS DEVICE

Your TENS device may be cleaned by wiping gently with a damp cloth moistened with mild soap and water. Do not immerse the device in water or other liquids.

Wipe lead wires with damp cloth moistened with soap and water. Do not immerse the lead wires.

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

## TROUBLESHOOTING

If the device does not function properly:

- 1. Ensure the battery is properly installed or replace the battery. Be sure to observe proper polarity markings when replacing the battery. If the yellow indicator light on the front of the unit no longer illuminates when it is turned on, replace the battery and check again.
- If the indicator light is flashing, the intensity has been adjusted, and no stimulation is felt, check to ensure the lead wires are properly connected and the electrodes are properly applied to the skin. 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 (clockwise) until stimulation is felt. If device still is not working, turn the unit off and contact your authorized GF Health Products. Inc. distributor.

If there is any other problem, please contact an authorized GF Health Products, Inc. distributor. Do not try to repair a defective device.

## **TECHNICAL SPECIFICATIONS**

Channel	Dual, isolated between channels		
Modes of Operation	Burst, Continuous, and Modulation		
Pulse Intensity	Adjustable 0 mA – 80 mA peak into 500 ohm load each channel, constant current		
Pulse Rate	1 Hz·150 Hz (adjustable)		
Pulse Width	60uS-250uS (adjustable)		
Burst Mode	Burst consists of 2 bursts per second at 100 Hz		
Wave Form	Asymmetrical bi-phasic square pulse		
Voltage	0 – 100 Volt (open current)		
Power Source	9-Volt battery		
Dimensions	95 mm x 65 mm x 23.5 (height x width x thickness)		
Weight	115 g (including battery)		

## **OUTPUT SPECIFICATIONS**

Mode	Intensity (mA)	Pulse Width (uSec)	Pulse Rate Frequency (Hz)	Cycle Time (Sec)
Burst	Adj. 0-80	Adj. 60-250	100 Hz fixed 2 bursts per Sec	N/A
Continuous	Adj. 0-80	Adj. 60-250	Adj. 1-150 Hz	N/A
Modulation	Adj. 0-80	Modulates down from preset width setting by 60% then back to original setting	Adj. 1·150 Hz	5 Sec total time

Note: All values have ±20% tolerance.

#### 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 three years 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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Manufactured for: GF Health Products, Inc. 2935 Northeast Parkway Atlanta, Georgia 30360 USA

tel: 770-368-4700 fax: 770-368-2386



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