Grafco®
A Graham-Field Brand

Transcutaneous Electrical Nerve Stimulation (TENS), Digital

Model GF-TX5

Operation Manual

Read this manual before operating your GF-TX5.

Save this manual for future use.

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

CE 0120

GF-TX5-INS-LAB-RevA09

Contents

GENERAL DESCRIPTION

TENS, **Transcutaneous Electrical Nerve Stimulation**, is a method of relieving symptomatic chronic intractable pain.

This unit is a dual-channel digital stimulator for active treatment application, which has a Liquid Crystal Display indicating operation modes and output as well as an 8-bit microcomputer for controlling the system.

The electronics of the unit create electric impulses; the intensity, duration, frequency per second and modulation of these impulses can be adjusted.

WHAT IS TENS?

TENS is a treatment whereby electrical impulses are applied to nerves through electrode pads placed on the skin. TENS is non-invasive and does not use pharmaceuticals.

TENS uses a two-pronged approach to pain relief. First, sensory nerves are targeted, stimulating them to block pain signals and prevent their transmission to the brain. Second, TENS promotes the production of endorphins — neurochemicals occurring naturally in the brain — which have analgesic properties.

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 intractable pain.

Contraindications

- Any electrode placement which applies current to the carotid (neck) region.
- 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 causes current to flow transcerebrally (through the head).
- The use of unit 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: Explosion hazard**
Explosion hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics.

⚠ **WARNING: Heart disease**
Caution should be used when applying the device to patients suspected of having heart disease. Further clinical data is needed to show if there are adverse side effects on individuals with heart disease.

⚠ **WARNING: Keep this device out of the reach of children.**

⚠ **WARNING: The safety of the device during pregnancy or delivery has not been established.**

⚠ **WARNING: Do not place electrodes on front of the throat. This may result in spasms of the laryngeal and pharyngeal muscles.**

⚠ **WARNING: Do not place the electrodes over the carotid nerve.**

⚠ **WARNING: The device is not effective for pain of central origin (headaches).**

⚠ **WARNING: Avoid adjusting controls while operating machinery or vehicles.**

⚠ **WARNING: The device may interfere with electronic monitoring equipment (such as ECG monitors and ECG alarms).**

⚠ **WARNING: Do not change any mode during treatment.**

⚠ **WARNING: Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. Using an alternate conductive medium or alternate electrode placement can usually reduce the irritation. Consult your physician/clinician before using an alternative conductive medium or electrode placement.**

⚠ **WARNING: Electrodes should not be placed over the eyes, in the mouth, or internally.**

⚠ **WARNING: The device has no curative value.**

⚠ **WARNING: TENS devices should be used only under the continued supervision of a physician/clinician.**

⚠ **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 following long-term application.**

▲ **Caution: If skin irritation occurs TENS treatment should be stopped and electrodes removed until the cause of the irritation can be determined.**

▲ **Caution: Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.**

▲ **Caution: If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until reevaluation by a physician/clinician.**

▲ **Caution: Always turn the device OFF before applying or removing electrodes.**

ABOUT THE DEVICE

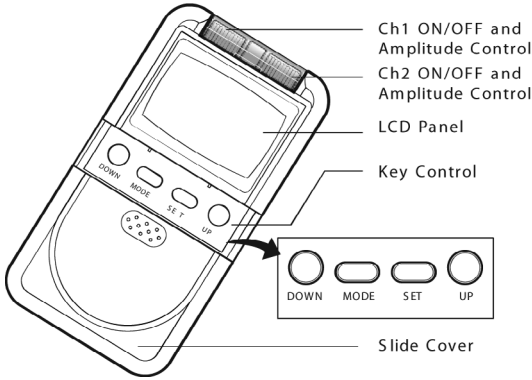
This device is a battery-operated device that includes two controllable output channels. This device creates electrical impulses in which amplitude, duration, and modulation can be altered. The device controls are easy to use and the slide cover protects accidental changes in settings.

System Components

Your device will include the following components or accessories:

- TENS Unit
- Carrying case
- Lead wires
- 9-Volt battery
- Operation Manual
- Electrodes

Device Controls



Slide Cover

This cover located on the front of the unit conceals the controls for DOWN, MODE, SET, and UP. Press the top portion of the cover and pull down in order to open the cover.

EXPLANATION OF KEY / KNOB CONTROL FUNCTIONS

DOWN key	This key decreases the setting when in pulse width or pulse rate. *	This key regulates the number of pulse width or rate of the individual current pulses.
	*Decrease by pressing the DOWN key: The width can be adjusted in 1-20Hz by 1Hz/step, 20Hz-150H by 5Hz/step. The rate can be adjusted in 10us/step.	
MODE key	Timer/Stimulation modes/ Alternate mode/Pulse rate (Hz)/Pulse width (uS) selection	This key changes the different treatment parameters. Each time the mode key is pressed, the next treatment parameter will display. The selected treatment parameter in the current mode will flash.
SET key	This key switches between the different settings in the Timer, stimulation mode, and alternate mode treatment parameters.	Each time the SET key is pressed, the parameter will change to the next setting. The selected mode setting will flash. After the desired parameter is flashing, press MODE to switch to the next treatment parameter. The parameter just set will be displayed and will no longer flash.
UP key	This key increases the setting when in pulse width or pulse rate. *	This key regulates the number of pulse width or rate of the individual current pulses.
	*Increase by pressing the UP key: The width can be adjusted in 1-20Hz by 1Hz/ step, 20Hz-150H by 5Hz/step. The rate can be adjusted in 10us/step.	
Ch1 /Ch2 Knobs	Intensity control knobs	Control the strength of the stimulation and also function as ON/OFF controls.

ATTACHING THE LEAD WIRES

⚠ Ensure the device is OFF before connecting the lead wires.

The lead wires provided with the device insert into the jack sockets located the top of the unit. If only one lead will be used, plug it into the channel 1 jack. After connecting the wires to the unit, attach each wire to an electrode.

Lead wires provided with the device are compliant with mandatory compliance standards set forth by the FDA.

Note: Use care when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

ELECTRODE SELECTION AND CARE

Using Electrodes

Use the electrodes as prescribed. Follow application procedures outlined in electrode packing to maintain stimulation and prevent skin irritation.

TIPS FOR SKIN CARE

Good skin preparation is important for effective 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 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.

Note: Ensure both intensity controls 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.) Always start with the lowest setting and increase the intensity slowly.

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

6. Setting Patient Compliance Counter:
   a) To turn counter on: While the unit is ON, hold down the UP button and press the MODE button at the same time.
   b) To Reset Counter: While the unit is ON, press UP button and press the MODE button at the same time (this will take you into the compliance counter), then push the DOWN button and press MODE button at the same time.
   c) Press the UP and MODE buttons at the same time to return to the treatment status.

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

BATTERY INFORMATION

A 9-volt disposable alkaline and/or nickel-cadmium battery is provided with your unit. When the LCD (Liquid Crystal Display) low battery mark 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.

Changing the Battery

When the LCD low battery mark illuminates, and the unit does not remain illuminated once turned on, the battery should be replaced.

1. Turn unit OFF
2. 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: Be sure the proper polarity (+ and -) markings match the markings in the device.

CARING FOR YOUR DEVICE

Your 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 LCD low battery mark illuminates when the unit is turned on, replace the battery and check again.
2. If 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.

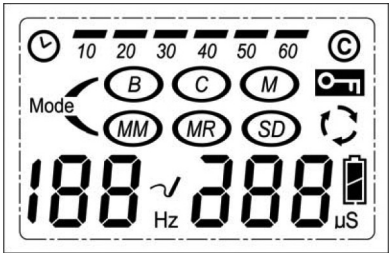
If there is any other problem, please contact an authorized GF Health Product, Inc. distributor. Do not try to repair a defective device.

TECHNICAL SPECIFICATIONS

Channel	Dual, isolated between channels	
Pulse Amplitude	Adjustable 0 – 80 mA peak into 500* load each channel, constant current	
Pulse Rate	1Hz-150Hz (adjustable)	
Pulse Width	30-300uS (adjustable)	
Timer	10, 20, 30, 40, 50, 60 minutes and continuous	
Patient Compliance counter	To show the usage time by user, counted per each 30 minutes treatment time	
Patient Lock System	To prevent changes in any set parameter by physician/clinician. To unlock or lock the unit, press the UP and DOWN button simultaneously for 2-3 seconds	
Wave Form	Mono Positive-Phasic Square pulse, Negative-Phasic Square Pulse, Asymmetrical Bi-Phasic Square Pulse	
LCD	Display Timer, Function Mode, Alternate mode, Pulse Rate, Pulse Width, Battery Low and Patient Compliance Meter, Lock symbols	
Function Mode	M Mode	Modulated width: Pulse width is automatically varied in an interval of 6 seconds. The modulation range of pulse width is from setting value to 60% less than the control setting value, then returns to the setting value. Pulse Rate and Pulse Width are adjustable.
	MM Mode	Modulated Rate and Width: This mode consists of alternating modulated width and modulated rate. One parameter is always decreasing while the other is increasing and vice-versa. The modulation range is 50% decreasing.

Function Mode, Continued	MR Mode	Modulated Rate: The pulse rate is automatically varied in an interval of 0.5 seconds. The modulation range of pulse rate is from setting value to 50% less than the control setting value, then returns to the setting value. Pulse rate is adjustable but pulse width is fixed.
	B (Burst Mode)	Bursts consist of Pulse Width (adjustable), frequency=100Hz. Bursts occur twice every second.
	© (Constant Mode)	Pulse rate and Pulse width are adjustable.
	SD Mode	Strength Duration and Rate/Width modulation adjustable. SD Mode consists of alternating modulated Pulse Rate and Pulse Width. One parameter is increasing while the other parameter is decreasing and vice-versa. The variety value is 50%; full cycle time is 22 seconds.
	Alternate Mode 	Stimulation output will begin from Channel 2, last for 12 seconds, then switch to Channel 1 for 12 seconds. During this mode, the stimulation will continue to alternate between the two channels.
Voltage	0 – 100 volt (open circuit)	
Power Source	9-volt battery (alkaline or nickel-cadmium rechargeable)	
Battery Life	Approximately 70 hours at nominal settings.	

LCD (Liquid Crystal Display)



The LCD displays timer (10, 20, 30, 40, 50, 60 minutes and © continuous), function modes (B, C, M, MM, MR, SD), alternate mode, pulse rate, pulse width, battery low, and patient compliance meter.

1. To check the LCD function, turn device ON and all the parameters will be displayed for 1-2 seconds.
2. After 1-2 seconds, the LCD will go to previous operation parameters.

CHANGING THE LCD PARAMETERS

- To set the treatment parameters on the TENS device, the unit must be in the UNLOCK position. If the device is in the LOCK position it, can be unlocked by pressing the UP and DOWN buttons simultaneously for 2-3 seconds.
- To switch between the different treatment parameters, press the mode button.
- Once in the desired mode, press the up, down, or set button until the desired treatment parameter is obtained.
- Once all of the desired treatment settings are displayed, the unit may be locked by pressing the UP and DOWN buttons simultaneously for 2-3 seconds while in the time function.

LIMITED WARRANTY

GF Health Products, Inc. warrants the Transcutaneous Electrical Nerve Stimulation (TENS), Model GF-TX5, against manufacturer's defects for one year.

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

During the warranty period, defective items will be repaired or replaced at GF Health Products, Inc. option. Warranty does not include any labor charges incurred in replacement part(s) installation or any associated freight or shipping charges to GF Health Products, Inc.

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