

Tera TENS Model GF-TT5



Operation Manual

Read this manual before operating your Tera TENS.

Save this manual for future use.

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

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1 INTRODUCTION

Thank you for purchasing the GF-TT5 Tera TENS.

Important safety, operating, and maintenance instructions that warrant your attention are included in this operation manual. Read the entire manual carefully before using your Tera TENS, and refer to it whenever necessary during use.

TENS DESCRIPTION

TENS, Transcutaneous Electrical Nerve Stimulation,

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 tiny battery-operated electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating pain.

TENS Intended Use (Indications)

TENS is clinically tested and approved with the following applications:

- · Symptomatic relief of chronic intractable pain
- · Post traumatic pain
- · Post surgical pain

TENS CONTRAINDICATIONS

- ▲ WARNING: Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- ▲ WARNING: Do not use this device in the presence of or in proximity to cancerous or other lesions.
- WARNING: Do not apply stimulation over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
- WARNING: Avoid electrode placements that apply current to the carotid sinus region (anterior neck) or transcerebrally (through the head).
- MARNING: Do not use this device over poorly enervated areas.
- A WARNING: Do not use this device over an inguinal hernia.
- WARNING: Do not use this device on scarred areas following surgery for at least ten months after the operation.
- ▲ WARNING: Do not use this device with serious arterial circulatory problems in the lower limbs.

2 SAFETY

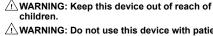
Always follow basic safety precautions.

Please note the following special statements, used throughout this manual, and their significance:

- 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 or moderate personal injury.
- NOTICE: Indicates a potential hazard or unsafe practice that, if not avoided, could result in product or property damage.

Info: Provides application recommendations or other useful information to ensure that you get the most from your product.

WARNING STATEMENTS



NARNING: Do not use this device with patients who are noncompliant or noncommunicative.

WARNING: If you have had medical or physical treatment for your pain, consult your healthcare professional before using this device.

WARNING: If your pain does not improve. becomes more than mild, or continues for more than five days, stop using this device and consult vour healthcare professional.

WARNING: Do not apply stimulation over your neck: this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

WARNING: Do not apply stimulation to the chest area or near the heart. Do not apply the electrode on the front of the thorax (marked by ribs and breastbone), nor on the two large pectoral muscles. The introduction of electrical current into the chest could cause rhythm disturbances to the heart, which could cause death.

WARNING: Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when electrical stimulation device is in use.



WARNING: Do not apply stimulation when in the bath or shower.

WARNING: Do not apply stimulation while sleeping.

WARNING: Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of iniurv.

WARNING: Apply stimulation only to normal, intact, clean, healthy skin,

WARNING: Stimulation should not take place while the user is connected to high-frequency surgical equipment, which may cause burn injuries on the skin under the electrode, as well as problems with the TENS.

- ▲ WARNING: Do not use this device at the same time as other equipment which sends electrical pulses to your body.
- ☆ WARNING: Do not use this device in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the TENS.
- MARNING: Do not use this device in the eye area.
- ⚠ WARNING: Do not use this device in the genital area.
- $\underline{\land}$ WARNING: Do not use this device on areas of the skin which lack normal sensation.
- WARNING: Consult your healthcare professional if you have any questions about the use of this device.
- WARNING: Discontinue use of this device and do not increase the intensity level if you feel discomfort during use.
- MARNING: The long-term effects of electrical stimulation are unknown.
- ▲ WARNING: Electrical stimulation devices have no curative value.
- ▲ WARNING: Notice for California Customers California Proposition 65 WARNING: This product can expose you to chemicals including DEHP which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product.
- WARNING: GF Health Products, Inc. specifically disclaims responsibility for any personal injury or property damage which may occur during any use which does not comply with federal, state, or local laws or ordinances.

CAUTION STATEMENTS / POSSIBLE ADVERSE REACTIONS

- A CAUTION: TENS is not effective for pain of central origin including headache.
- CAUTION: TENS is not a substitute for pain medications and other pain management therapies.
- CAUTION: TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- ▲ CAUTION: Effectiveness is highly dependent upon the patient's selection of a healthcare professional qualified in the management of pain.
- ▲ CAUTION: The safety of electrical stimulation during pregnancy has not been established.
- ▲ CAUTION: Use caution if stimulation is applied over the menstruating or pregnant uterus.
- ▲ CAUTION: You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).
- ▲ CAUTION: Use caution for patients with suspected or diagnosed heart problems; if you have suspected or diagnosed heart disease, you should follow precautions recommended by your healthcare professional.
- ▲ CAUTION: If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your healthcare professional.
- ▲ CAUTION: Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- ▲ CAUTION: Consult with your healthcare professional before using the device after surgery; stimulation may disrupt the healing process.
- ▲ CAUTION: Use caution if stimulation is applied over areas of skin that lack normal sensation.
- ▲ CAUTION: The electrode is intended for single patient use only.
- ▲ CAUTION: Keep yourself informed of the contraindications.
- ▲ CAUTION: The indications for use were listed; any other use may be dangerous.

- ▲ CAUTION: Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- ▲ CAUTION: Skin irritation from the electrode gel and electrode burns are potential adverse reactions. If skin irritation occurs, discontinue use and consult your healthcare professional.
- ▲ CAUTION: If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your healthcare professional if problems persist.

NOTICE STATEMENTS

- ▲ NOTICE: Do not sterilize this device.
- NOTICE: Do not use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
- NOTICE: Check the electrode connections before each use to ensure they are in good working order.
- NOTICE: The Tera TENS should be used only with the electrode recommended by GF Health Products, Inc.

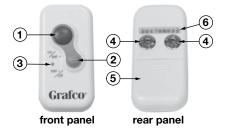
3 FEATURES

COMPONENTS (INCLUDED WITH DEVICE)



ITEM	DESCRIPTION	QUANTITY
1	GF-TT5 Tera TENS Unit	1
2	Electrode pad, self-adhesive 2.83 in. x 2.24 in. (72 mm x 57 mm)	1
3	Battery, 3V CR2032	1
4	Operation Manual	1

TENS UNIT FRONT AND REAR PANELS



1	ON + (increase intensity) button
2	OFF - (decrease intensity) button
3	Function display LED (red LED)
4	Contact plug / snap
5	Battery compartment
6	Serial number

ELECTRODE SNAP AND ADHESIVE SURFACES





snap surface

adhesive surface

1	Electrode pad
2	Contact plug / snap
3	Electrically conductive adhesive surface
4	Insulated surface
5	Protective backing

4 SETUP

SKIN PREPARATION AND CARE

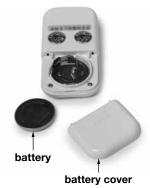
To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

- ☆ WARNING: Never apply the electrode to irritated or broken skin.
- Wash the skin where you will be placing the electrode with mild soap and water, rinse soap off thoroughly, and dry skin well.
- 2. Clip excess hair with scissors; do not shave stimulation area.
- Wipe the area with the skin preparation your healthcare professional has recommended and let it dry before applying the electrode.
- It may be helpful to apply skin lotion to electrode placement area after therapy when electrode has been removed.

CHECK / REPLACE THE BATTERY

If using the device for the first time, install a new 3V CR2032 battery as described below (a battery is included with the device).

To ensure the function of the device, you must occasionally replace the battery as described below.



- 1. Slide open the battery cover as shown above.
- 2. Insert a new 3V CR2032 Battery into the battery compartment.
- 3. After installing the battery, close the battery cover. Ensure the battery cover is tightly closed.

BATTERY SAFETY

Dispose of the battery in accordance with local guidelines and regulations.

- ▲ WARNING: If a battery is swallowed, seek medical attention immediately.
- MARNING: Do not disassemble or short-circuit the battery.
- ▲ WARNING: Do not place the battery in or near fire; explosion may occur.
- MARNING: Protect the battery from excess heat.
- ▲ NOTICE: Remove the battery from the device if you no longer use it.

ELECTRODE PLACEMENT

- ▲ WARNING: Never apply the electrode to irritated or broken skin.
- MARNING: Do not power on the device until after the electrode has been applied.

Electrode placement can be very important to achieving success with therapy. Consult your healthcare professional for electrode placement suggestions. Apply the electrode to the exact site indicated by your healthcare professional. Before application, thoroughly clean and dry the target skin surface. To ensure good contact between the skin and the electrode, attach the electrode firmly and evenly to the skin.

Every patient responds differently to electrical stimulation, and your needs may vary from the conventional settings suggested here. If the initial results are not positive, speak to your healthcare professional about alternative stimulation settings and / or electrode placements. Once an acceptable placement has been achieved, record it for later use.

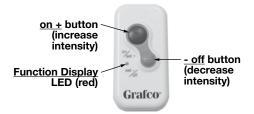
- Remove the protective backing from the electrode adhesive surface. Do not throw away the protective backing because it is reused for storage after the treatment session has been completed.
- Skin problems may arise from the stress of adhesive patches that are excessively stretched across the skin during application. To prevent this, apply the electrode from the center outward; avoid stretching over the skin.
- Place the sticky surface on the prescribed skin area and press the electrode firmly and evenly against the skin.

ELECTRODE REMOVAL

- ☆ WARNING: Before removing or moving the electrode, power off the device in order to avoid irritation.
- ☆ WARNING: Remove the electrode from the skin with a moderate pulling motion in order to avoid injury to sensitive skin.
- ▲ WARNING: If irritation occurs, discontinue use and consult your healthcare professional.
- ▲ CAUTION: The electrode is intended for single patient use only.
- ▲ NOTICE: Replace the electrode when it is no longer sticky.
- When removing the electrode, remove by pulling in the direction of hair growth. Lift the corner of the electrode and gently remove it from the skin.
- 2. Apply the protective backing to the sticky side of the electrode for storage.
- It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turning the surface up to air dry. Oversaturation with water will reduce the adhesive properties.
- 4. Between uses, store the electrode in a cool dry place.

5 OPERATION

Refer to picture below.



TURN THE DEVICE ON

Before using the device for the first time, take careful note of the contraindications in Section 1, INTRODUCTION, and the safety measures detailed in Section 2, SAFETY.

Press the <u>ON +</u> button to turn on the device; the <u>Function Display</u> LED will illuminate.

ADJUST THE TREATMENT INTENSITY

Press the <u>ON +</u> button (increase intensity) or <u>- OFF</u> button (decrease intensity) to control the intensity output.

When increasing (+) or decreasing (-) the intensity, each click of the $\underline{ON +}$ or <u>-OFF</u> button increases or decreases the output intensity by one level, which will show on the Function Display LED.

Info: The device has ten levels of intensity.

Adjusting the intensity may cause a tingling sensation; adjust the intensity to a level that is comfortable to you.

▲ WARNING: If the stimulation levels are uncomfortable or become uncomfortable, reduce the intensity to a comfortable level. If problems persist, contact your healthcare professional.

TURN THE DEVICE OFF

Treatment may be discontinued at any time by pressing the <u>- OFF</u> button repeatedly until the <u>Function Display</u> LED de-illuminates.

Info: The device has an automatic shut-off function which switches it off automatically after twenty minutes of treatment.

6 MAINTENANCE AND STORAGE

CARE AND CLEANING

TENS Unit Care

- MARNING: Remove the battery from the device before cleaning.
- NOTICE: There are no serviceable components inside the TENS case. Contact your authorized GF distributor for repair.
- ▲ NOTICE: Ensure that no water or other liquid penetrates the device.
- NOTICE: Do not use chemical cleaners, abrasive agents, or stiff brushes on any part of this device.

▲ NOTICE: Do not sterilize this device.

Check the unit before each use for signs of wear or damage. Replace worn items as required.

Clean the device after use with a soft, clean, slightly moistened cloth.

In case of more extreme soiling, clean the device with a soft, clean, cloth slightly moistened with mild soapy water.

Electrode Care

- ▲ WARNING: Use this device only with the electrode provided by GF Health Products, Inc., or suggested by your healthcare professional.
- WARNING: Use only the electrode placements and stimulation settings prescribed by your healthcare professional.
- ▲ CAUTION: Overuse of the electrode may cause skin irritation, loss of adhesion and decreased stimulation.

Inspect the electrode before each use, and replace as needed. Replace electrode when it is no longer sticky or shows cracks or blemishes.

STORAGE

- ▲ NOTICE: Remove the battery from the unit if it will not be used for an extended period of time.
- ▲ NOTICE: Do not place heavy objects on the device.

Store the device in a cool, dry, well-ventilated room and do not expose it to heat, sunlight or moisture.

☆ WARNING: Do not dispose of the spent battery in household waste. Dispose of the battery in accordance with local guidelines and regulations.

Battery-operated devices are recyclable material and should not be disposed of in household waste. Dispose of this device in accordance with local guidelines and regulations.

7 TROUBLESHOOTING

If the device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Cause	Remedial Action
LED fails to illuminate	No battery in the device or battery dead	Replace battery
	Battery not inserted correctly	Insert battery again (+ up)
	Device not switched on	Switch device on
LED lights up weakly	Battery low	Replace battery
Low output from device	Electrode pad dirty	Clean or replace electrode pad
	Device not applied properly	Re-apply device
LED function	Battery dead	Replace battery
power output	Electrode pad dirty or short-circuited	Check electrode pad and replace if necessary
Device switches off	Battery dead	Replace battery
prematurely	Electrode pad worn out or dirty	Check electrode pad and replace if necessary
	Device pad not applied properly	Re-apply device

8 SPECIFICATIONS AND SYMBOLS

GF-TT5 PRODUCT SPECIFICATIONS

Device name		Tera TENS	
Model		GF-TT5	
Channel		Single Channel	
Output voltage		0~30V ±20% (at 500 Ohm load)	
Pulse	Intensity	Adjustable from 0 ~ 60mA ±20%	
	Width	150 ~ 250uS	
	Rate	30 ~ 60Hz	
Power Source		1 Lithium Coin Cell battery (CR2032)	
Automatic shutoff		20 minutes	
Environmental Conditions	Operating	50°F to 104°F (10°C to 40°C), 40% - 90% Relative Humidity	
	Storage	14°F to 140°F (-10°C to 60°C), 30% - 95% Relative Humidity	
Dimensions	TENS Unit L x W x H	2.3 in x 1.2 in x 0.5 in (59 mm x 30 mm x 12.15 mm)	
	Electrode L x W	2.8 in x 2.2 in x 0.5 in (72 mm x 57 mm)	
Weight (including battery)		0.5 oz (12.3 g)	

KEY TO SYMBOLS

The following symbols are used on this product's labels.

Ø	Consult instructions for use.
X	Do not dispose of this device in household waste. Dispose of this device in accordance with local guidelines and regulations.
Ŕ	Type BF applied part.

9 LIMITED WARRANTY

SCOPE OF WARRANTY

GF Health Products, Inc. ("GF") warrants to the original purchaser only that it will replace or repair components. at GF's sole discretion, that are defective in material or workmanship under normal use and service. All warranties are conditioned upon the proper use of the products strictly in accordance with good commercial practice and applicable GF instructions and manuals, including proper use and maintenance. To the extent that a component is warranted by a third party. GF conveys all of its rights under that warranty to the original purchaser, to the extent permitted. This limited warranty shall only apply to defects that are reported to GF's customer service team within the applicable warranty period and which, upon examination by GF or its authorized representative, prove to be a warranty item. This limited warranty is not transferable. Within the guidelines set forth in this document, this product is warranted for one (1) year. The applicable warranty period shall commence from date of shipment to the original customer, unless there is an expiration date on the component in which case the warranty shall expire on the earlier of warranty period or the expiration date.

OBTAINING WARRANTY SERVICE

This limited warranty shall only apply to defects that are reported to the Distributor from whom the Customer purchased the product within the applicable warranty period. If there is not a Distributor, you must contact GF directly by calling 1-770-368-4700, sending a fax request to 1-770-368-2386, or by e-mailing a request to cs@grahamfield.com. Specific directions will be provided by the Customer Service Representative. Failure to abide by the specific directions will result in denial of the warranty claim.

EXCLUSIONS

- The warranty does not cover and GF shall not be liable for the following:
- Defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering or failure to seek and obtain repair or replacement in a timely manner;
- Products which are not installed, used, or properly cleaned and maintained as required in the official manual for the applicable product;
- Products considered to be of a non-durable nature including, but not limited to: adhesive electrode pads, casters, filters, fuses, gaskets, lubricants, and charts;
- 4) Accessories or parts not provided by GF;
- 5) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing, in advance, by GF;

- Any labor or shipping charges incurred in the replacement part installation or repair;
- Costs and expenses of regular maintenance and cleaning; and
- Representations and warranties made by any person or entity other than GF.

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THIS WARRANTY IS GF'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES. EXPRESS OR IMPLIED, GF MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IF ANY MODEL OR SAMPLE WAS SHOWN TO THE CUSTOMER, SUCH MODEL OR SAMPLE WAS USED MERELY TO ILLUSTRATE THE GENERAL TYPE AND QUALITY OF THE PRODUCT AND NOT TO REPRESENT THAT THE PRODUCT WOULD NECESSARILY CONFORM TO THE MODEL OR SAMPLE IN ALL RESPECTS. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF THE DEFECTIVE PARTS. GF SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS 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

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For additional information on this product or this warranty, please contact a GF Customer Service Representative.

NOTES:

- 1) Additional terms and conditions may apply.
- 2) Freight claims must be notated on the appropriate shipping documents and must be made with immediacy. International, federal and state regulations govern specific requirements for freight claims. Failure to abide by those regulations may result in a denial of the freight claim. GF will assist you in filing the freight claim.
- Claims for any short shipment must be made within three (3) days of the invoice date.



1.770.368.4700

Information contained herein is subject to change. The most current and complete product information can be found on our website. www.grahamfield.com

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