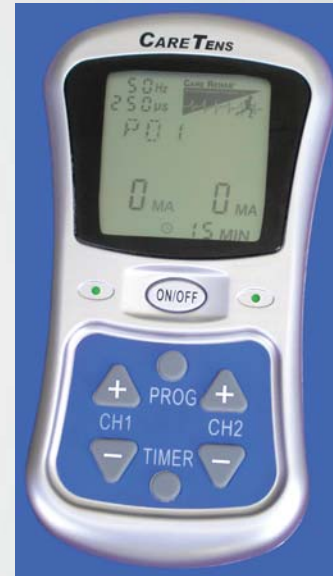


DUAL CHANNEL TENS UNIT

INSTRUCTION MANUAL



CARE TENS™



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Letter to the Patient

Your physician or therapist has prescribed the CARE TENS™ System to help control your pain. Please read this operations manual carefully before using your CARE TENS™. The instructions on the following pages will show you how to use and care for your CARE TENS™ in a general manner.

IMPORTANT NOTE: Please read the prescription information and precautions in this manual before using the CARE TENS™.

You should always consult your physician or therapist if you have specific questions or problems regarding the use of your stimulator.

Your physician or therapist possesses technical knowledge about the CARE TENS™ and is familiar with your specific condition and requirements. In addition, always follow the instructions of your physician or therapist to gain the most benefit from your CARE TENS™.

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a licensed physician. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

How the CARE TENS™ Works

Your CARE TENS™ is a battery powered device that generates small pulses of electrical current. These small pulses of electrical current are delivered through lead cables to electrodes placed on your skin. These electrical pulses pass through your skin, and activate underlying nerves. The relief from chronic and/or acute pain that the CARE TENS™ can provide results from this electrical stimulation. Your physician or therapist will instruct you on the correct degree of stimulation for your particular condition.

The CARE TENS™ has two channels, allowing it to operate two pairs of electrodes. The CARE TENS™ can deliver 12 separate stimulation patterns (“modes”). Your physician or therapist will provide you with directions on the proper mode for your condition.

It is important to realize that pain is a symptom of an underlying condition, and the CARE TENS™ has no curative effect on the cause of your pain. Therefore, TENS is not a substitute for proper medical evaluation and treatment.



The CARE TENS™ System Components



The CARE TENS™ System is provided with:

- 1 CARE TENS™ Stimulator
- 1 package of electrodes (non-sterile, 1.8" X 1.8")
- 2 Lead Cables
- 1 9V battery
- 1 Operations Manual

The CARE TENS™ Operations Controls / Features



Amplitude Controls: Pressing the “+ Plus” button increases the amplitude for each channel. The button can be held in for a continuous increase of amplitude. Pressing the “- Minus” button decreases the amplitude for each channel. The button can be held in for a continuous reduction of amplitude. The amplitude range is between a setting of 0 – 90 mA which corresponds to the strength of the electrical stimulation delivered. Pressing the “ON/OFF” button turns the stimulator on and off. The stimulation changes in discrete steps. Select the amount of stimulation recommended by your physician or therapist. The CARE TENS™ unit will automatically shut off after the set treatment duration has elapsed, but it is recommended that you turn it off whenever you do not use a full treatment cycle in order to conserve the battery.

Program Selection: Pressing the “PROG” button cycles through the 12 stimulation programs. Changing of programs can only be done when no program is running, turn the unit off and on again to reset.

Lead Cable Sockets: The electrode lead cables should be plugged into their sockets

Battery Information: This device requires one 9V alkaline battery to operate. Remove the plastic cover on the back of the unit and insert the battery as indicated by the icons inside the battery compartment and replace the cover to fit tightly. Do not use a rechargeable (e.g. nickel-cadmium) battery, as this will not delivery full amplitude stimulation.



Electrodes

Reusable / Self-adhering electrodes:

To use your electrodes, first attach them to your lead cable. (Note that the “pin” on the electrode wire is protected by a plastic sheath.) Then, grasp the electrode by the corner, and gently peel away the electrode from the plastic sheet it is provided with. Finally, apply the electrodes to the skin area (your physician or therapist will show you the approximate area for treatment) by firmly pressing the electrode against the skin.

When your therapy session is completed, grasp the corner of the electrode (**NEVER REMOVE THE ELECTRODE BY PULLING ON THE LEAD CABLE, AS THIS MAY DAMAGE YOUR ELECTRODES**)

and gently remove it from your skin, and place it on the plastic sheet it originally was adhered to. Another important note in the care of your electrodes is to replace the electrodes in the resealable pouch provided with your electrodes.

If your electrodes dry out, you can place a few drops of water on them to re-moisten them for continued use.

After repeated usage, reusable electrodes begin to lose their adhesion, deliver less stimulation and shorten battery life. **Replace reusable electrodes as needed.**

We recommend using 1.8” x 1.8” electrodes from Care Rehab.



Proper Skin Care

By properly caring for skin covered by electrodes, you will:

- Allow more stimulation to reach the targeted nerves.
- Prolong the life of your electrodes.
- Reduce the chance that any skin irritation will develop.

The following directions for proper skin care will reduce the risk of skin irritation. However, if skin irritation develops, remove the electrodes, discontinue using your CARE TENS™, and consult your physician or therapist.

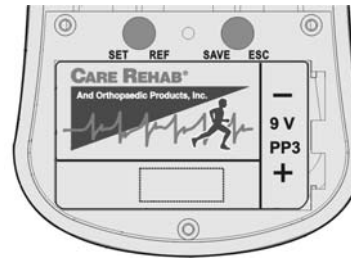
1. Wash all electrode sites with mild soap and water before applying the electrodes.
2. Dry your skin thoroughly before electrode application.
3. Trim excess body hair from electrode sites with scissors.
4. Do not place electrodes on cut, broken or irritated skin
5. Change electrode sites whenever possible, but first consult with your physician or therapist about doing this.



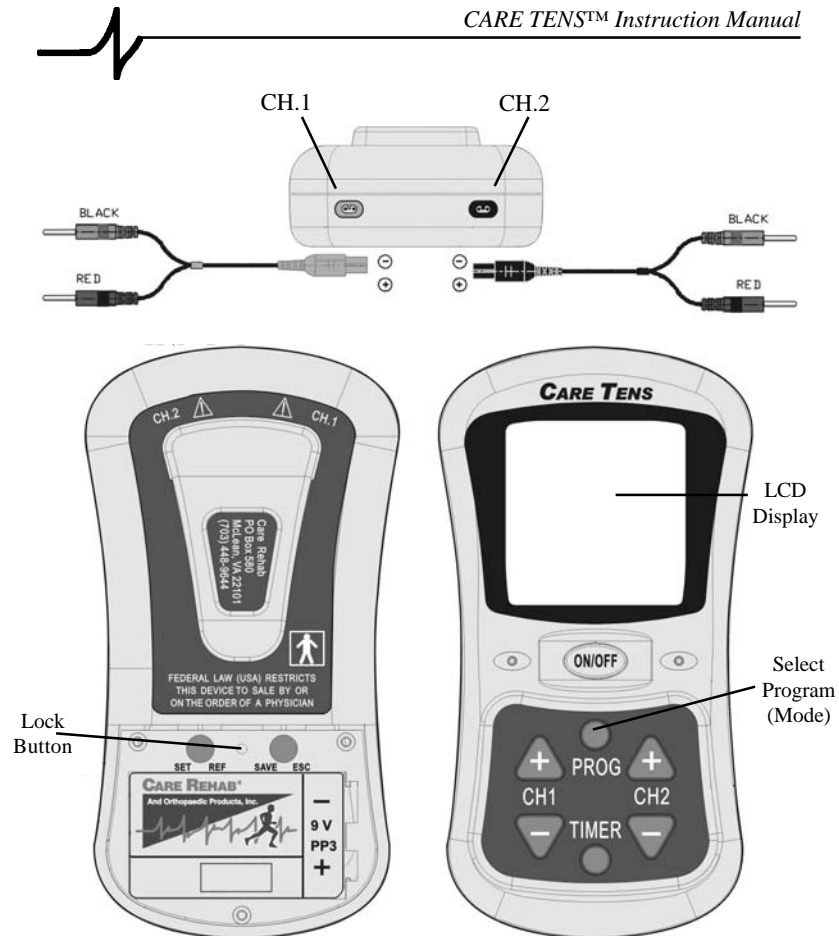
Using the CARE TENS™

FIRST Look at the LCD display and make sure the unit is turned off. If the display is on, press the “ON/OFF” button to turn off the unit.

1. Insert one 9V alkaline battery into the battery compartment as shown on the diagram. Then replace the battery cover.



2. Wash the electrode application sites with mild soap and water and dry your skin thoroughly. Also remove any excess body hair with a pair of scissors, being careful not to cut your skin.
3. Connect the lead cable to the electrodes. Do not use unnecessary force when connecting the electrodes to the lead cables.
4. Place the electrodes on the sites prescribed by your physician or therapist, and press them firmly onto the skin.
5. Insert the plug at the end of the electrode lead cable securely into the CARE TENS™ channel 1 output socket or channel 2 output socket if using a second set of electrodes.
6. Set the “Mode”. Press the “Program” (PROG) button until the number indicating the correct mode is shown. Select the Mode prescribed by your physician or therapist.
7. Set the “Time”. Press the “Timer” button until the correct time is shown prescribed by your physician or therapist - 15, 30, 60 minutes or continuous.
8. Then press the “+ Plus” button until you achieve the amount of stimulation prescribed by your physician or therapist. To reduce the stimulation, press the “- Minus” button.
9. Always operate the CARE TENS™ at the prescribed settings for the amount of time directed by your physician or therapist.



When your treatment session is completed, remember to do the following:

1. Press the “OFF” button and the unit will turn off.
2. Unplug the lead cable(s) from the CARE TENS™.
3. Disconnect the lead cable(s) from the electrodes, and properly store your electrodes for your next treatment session, as prescribed by your physician or therapist.



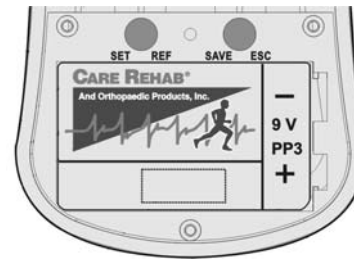
CARE TENS™ Battery Information

Whenever removing or replacing the battery from your CARE TENS™, always remember to press the “ON/OFF” button to turn the unit off.

Always use one 9V alkaline battery when operating your CARE TENS™.

Do not use a rechargeable (e.g. nickel-cadmium) battery.

Battery Care: Remove the battery during storage to prevent damage caused by battery leakage or corrosion.



Care of your CARE TENS™

Maintenance, care and cleaning of your CARE TENS™ are quick and easy procedures when these instructions are followed. When it is not in use, store your CARE TENS™ where it will be safe from accidental damage.

Cleaning: Clean the outside of the CARE TENS™ case as needed with a damp cloth and mild soap.

Never immerse your stimulator or battery in water, alcohol or other fluids, since this could seriously damage the internal electronics. Avoid using cleaning fluids or solvents to remove stains or dirt, because such liquids may damage the carrying case and unit. Lead cables need to be cleaned only if they become dirty. They should never be immersed in water or other fluids.



Important Prescription Information

Please read the following prescription information carefully before using your CARE TENS™. If you have any questions regarding this information, consult with your physician or therapist before proceeding.

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of, a licensed physician. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications: TENS is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of postsurgical and posttraumatic acute pain.

Contraindications: Do not use your CARE TENS™ with demand-type cardiac pacemakers, over the carotid sinus, transcerebrally, over the eyes, or in undiagnosed pain syndromes until etiology has been established.

Warnings: Safety during pregnancy, labor and delivery has not been established for either mother or fetus.

CARE TENS™ is not effective in treating pain of central origin, including headache. CARE TENS™ should be used only under the continued supervision of a physician. CARE TENS™ provides symptomatic pain relief only and has no curative value. CARE TENS™ is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism. The user must keep the CARE TENS™ away from children. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when CARE TENS™ stimulation is in use.

Precautions: Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Consult your physician if skin irritation develops. The effectiveness of CARE TENS™ is highly dependent upon patient selection by a person qualified in the management of pain patients.

Adverse Reactions: Skin irritation and electrode burns are potential adverse reactions.



Instructions for your Physician or Therapist

Setting Customized Programs:

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Set the “Mode” to MEM 1, 2 or 3. Press the “Program” (PROG) button until MEM 1, 2 or 3 is shown. 2. Remove the battery lid. Press the SET / REF button and the Hz symbol will flash on/off, then press the + or - button on the front panel to adjust the Pulse Rate from 2 - 150 Hz. 3. Press the SET / REF button again and the μS symbol will | <p>flash on/off, then press the + or - button to adjust the Pulse Duration from 30 to 240 μS.</p> <ol style="list-style-type: none"> 4. Press the SET / REF button again and the Clock symbol will flash on / off, then press the + or - button to adjust the time. Channel 1 + or - button to change hours and Channel 2 + or - button to change minutes. 5. Press the ESC / SAVE button to store the program. |
|--|--|

Lock Mode Function:

A “Concealed” Lock button is included in the CARE TENS™, which allows the physician or therapist to monitor the use of the unit in two ways:-

One (L:T) to measure the time in use over one hour and the average current used leaving the parameters to be freely altered. Alternatively (L:PT) locks the unit and parameters so they cannot be easily be changed by the patient.

Locking the Unit

1. Remove the battery cover and, using the end of the lead cable, gently press on the concealed lock button as shown on the diagram on page 9 until you hear a double beep.

2. Press the + or - button to select (L:T) or (L:PT). Press the ESC / SAVE button to lock the parameters in place.

Unlocking the Unit

1. Remove the battery cover and, using the end of the lead cable, gently press on the concealed lock button as shown on the diagram on page 9 until you hear a single beep.
2. The information for time in use and the average mA current used can be read on the front LCD display. Press the ESC / SAVE button to unlock the unit and bring the display back to the home position.



Stimulation Modes:

The CARE TENS™ has 12 separate output modes, described in the table below.

Program	Description
CONST 1	Constant 100 Hz, 50 μ S
CONST 2	Constant 80 Hz, 50 μ S
CONST 3	Constant 10 Hz, 80 μ S
BURST 1	Burst of 9 pulses at 150 Hz, 200 μ S repeating twice per second
BURST 2	Burst of 9 pulses at 150 Hz, 180 μ S repeating twice per second
BURST 3	Burst of 9 pulses at 80 Hz, 200 μ S repeating twice per second
MOD 1	Modulates from 50 μ S to 100 μ S to 50 μ S over 10 seconds, 120 Hz
MOD 2	Modulates from 25 μ S to 50 μ S to 25 μ S over 10 seconds, 100 Hz
MOD 3	Modulates from 70 μ S to 180 μ S to 70 μ S over 3 seconds, 80 Hz
MEM 1	Custom
MEM 2	Custom
MEM 3	Custom

Automatic Shut-Off Treatment Timer:

The CARE TENS™ has an automatic treatment timer which will shut off at the end of the selected program (mode). It will shut-off the CARE TENS™ automatically one minute after the end of the set treatment or four minutes after the last button is pressed if no program has been run.



Technical Specifications

1. Dual channel: individually isolated circuits.
2. Amplitude: 0 - 90 mA; indication only; actual mA will tend to be less than indicated due to electrode impedance.
3. Type: Constant Current.
4. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.
5. Selectable pulse width: 30 μ S - 240 μ S [\pm 2% accuracy].
6. Pulse Rate selection: in the continuous mode 2 – 150 Hz [\pm 2% accuracy].
7. Mode: Continuous, Burst or Modulated.
8. Maximum Charge per Pulse: 22 microcoulombs.
9. Maximum Average Current 3.3 mA.
10. Duty Cycle: Ranges from 0.006% at 30 μ S, 2 Hz to 3.6% at 240 μ S, 150 Hz .
11. Time duration of the treatment selectable: 15, 30, 60 minutes or continuous.
12. Low Battery Indicator: If the battery goes below 6.9 volts \pm 0.2 volts the battery symbol will flash on/off once every second.
13. If the battery voltage is below 6.6 (\pm 0.2) volts the unit will not turn on.
14. Open Electrode Detect: If an open circuit is detected at the output of channel 1 or 2 the output current will be reset at zero.
15. Physical dimensions: 5.0" x 2.7" x 1.1".
16. Weight: 8 oz (including battery).
17. Environmental conditions for storage & transport:
+14 to +95 Degrees
0-90% Humidity.
18. Tolerances: All electrical specifications are \pm 10% into 500 ohm resistive load.

Warranty

This unit has a one year limited warranty from the date of purchase.





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