DUAL CHANNEL TENS UNIT

Polaris Digital TENS

Operators Manual

Warnings

* This unit must be used with the guidance of a Physician or Physical Therapist
* Type BF equipment
* Do not insert lead wires into a mains power supply
* Do not immerse unit into water or any other substance
* Do not use the Polaris TENS unit in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide
* If using rechargeable 9 volt PP3 Nickel Metal Hydride or Ni-Cad batteries be sure to use a CE approved battery charger
* Never connect the Polaris TENS device directly to a battery charger or any other mains powered equipment
* Patient Electrodes are for single patient use only
* Keep out of reach of children

Prescription Information

Please read the following prescription information carefully before using your Polaris TENS. If you have any questions regarding this information, consult your Physician or Physical Therapist before proceeding.

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

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

Contraindications: Do not use your Polaris TENS with demand-type cardiac pacemakers, over the carotid sinus (neck) region, transcerebrally (over the head), over the eyes, or whenever pain syndromes are undiagnosed, until the etiology has been established.

Warning: Safety during pregnancy, labor and delivery has not been established for either mother or fetus. Polaris TENS is not effective in treating pain of central origin, including headache. Polaris TENS should be used only under the continued supervision of a Physician. Polaris TENS provides symptomatic relief only and has no curative value. Polaris 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 Polaris TENS away from children. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when Polaris TENS stimulation is in use.

Precautions: Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application. Consult your physician if skin irritation develops. The effectiveness of Polaris 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.

Contents

What is Pain?

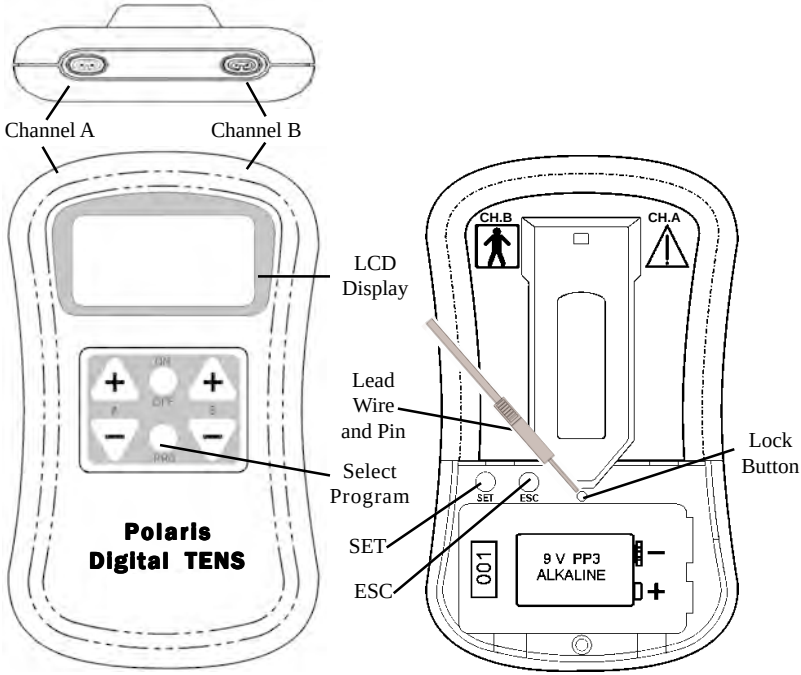
When we feel pain it is the body's process of informing us that something is wrong. To feel pain is important, without this feeling abnormal conditions may go undetected, creating damage or injury to critical parts of the body.

Although pain is essential in warning our body of trauma or malfunction, nature may have gone too far in its design. Continued long-term chronic pain has no useful value apart from its importance in diagnosis. Pain only begins when a coded signal travels to the brain where it is decoded, and analysed. The pain message travels from the injured area of the body along small diameter nerves leading to the spinal cord. At this point the message is switched to a different kind of nerve that travels up the spinal cord to the brain area. The brain then analyses the pain message, refers it back and the pain is felt.

What is TENS?

Transcutaneous Electrical Nerve Stimulation (TENS) uses a small battery operated unit to provide a non-invasive method of controlling acute and principally long term intractable pain. It can also be used as an adjunctive treatment in the management of post surgical traumatic pain problems. In TENS mild electrical impulses are transmuted through the skin via surface electrodes to modify the body's pain perception. TENS does not cure problematic physiological conditions; it only helps to control the pain perception. TENS will not work for every user. However Physical Therapists and Physicians throughout the world prescribe TENS extensively and it is generally seen to work for the majority of users. There are millions of small nerve fibres throughout the body and it only requires a few impulses to produce chronic pain. In addition to small fibres, which allow the sensation of pain to be felt, the body is also made up of larger diameter nerve fibres. These larger nerve fibres transmit less unpleasant sensations such as touch or warmth, assisting us to form an impression of our environment. Stimulating the larger nerve fibres using TENS may have the effect of inhibiting the transmission of pain along the smaller nerve fibres to the spinal cord [known as the 'Pain Gate Theory'].

Description of TENS Unit & Functions.



Front Rear

*	**PRG button**	Selects the desired set program from P01 - P12 or customized program PC1 - PC3.
*	**SET button**	Displays the menu and changes the parameters for Pulse Rate, Pulse Width and Time for custom programs.
*	**ESC button**	Stores customized program and returns to the home position.

Quick Start Instructions

1. Insert a 9 volt PP3 Alkaline battery. Alternatively insert a recharge able Nickel Hydride battery [Which has a much longer life than the Ni-Cad rechargeable batteries] into the battery compartment.
2. Insert lead wire/s into channel A and B if both channels are to be used.
3. Switch on the unit by pressing the ON/OFF key
4. Press the PRG [Program] button to select one of the programs as detailed in table 1 and table 2 on page 8.
5. To start press channel A + and B + button if you are using both channels.
6. To stop the program, press the ON/OFF button which will turn the unit off.

Setting up your own Constant mode parameters.

1. Select PC1 or PC2 by pressing the PRG button on the front panel Remove the battery lid where you will see two buttons SET and ESC.
   Press the SET 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 - 200 Hz. Press the SET button again and the µS symbol will flash ON / OFF, then press the + or – button to adjust the Pulse Duration from 50 - 300 µS
3. Press the SET button again and the Clock symbol will flash ON/OFF, then press the + or – button to adjust the time. Channel A + or – button to hours and Channel B + or – button to change minutes.

After setting up the customized program parameters, press the ESC button to store the information. Simply repeating the above procedure can reprogram customized programs.

Note: You must press the ESC button before locking the unit.

Intensity Lock Out Feature

Once the stimulation current is raised above zero, with no button activity for greater than 10 seconds, the unit will lockout of the increase intensity buttons (A+ and B+).

To unlock channel A or channel B the A- or B- button needs to be pressed.

Programs

Table 1

Prog	P1	P2	P3	P4	P5	P6	P7	P8
Mode	Con	Con	Burst	MF	Con	Con	Con	Con
Freq Hz	80	80	2	100/65	10	100	50	60
Pulse Width	200	175	200	200/100	175	175	100	75
Time	4 hr	4 hr	4 hr	4 hr	4 hr	4 hr	4 hr	4 hr

Table 2

Prog	P9	P10	P11	P12	PC1	PC2
Mode	Con	Con	MF	Burst	Custom	Custom
Freq Hz	2	80	65/100	2		
Pulze Width	175	175	200/100	200		
Time	4 hr	1.5 hr	45 mins	35 mins		

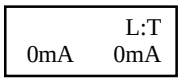
Lock Mode Function

Lock Mode Function

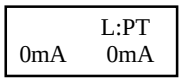
A "concealed" Lock button is included in the Polaris TENS, which allows the Physician to accurately monitor the "Home Compliance" of the patient between appointments. The lock function allows the device to be locked in two ways:- One {L:T} to measure the time in use over one hour, and the average mA current used, leaving the parameters i.e. Constant, Burst, Modulation and the Rate and Pulse Width to be freely altered by the user or alternatively {L:PT} Locking the device to measure, time, mA current used and locking the parameters in place, which then cannot be changed or altered by the patient during use.

Locking the Unit

Remove the battery cover and, using the end of the lead wire, gently press on the concealed lock button as shown in the diagram on page 6 until you hear a double bleep. {L:T} Lock time and Current will appear on the LCD screen. If you want to lock the parameters as well press the +/- button until {L:PT} appears. Press the ESC button to lock parameters in place.



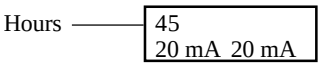
Ch.A Ch.B



Ch.A Ch.B

To Unlock the Unit

To unlock the unit and display the lock information, remove the battery cover, using the end of the 2mm dia pin press the concealed switch once and you will here a single bleep, this indicates the unit is now unlocked. The information for time in use and the average m A current used can be read on the front of the LCD display as seen on the diagram below. When you have noted the information press the ESC button to bring the unit back to the Home position.



Ch.A Ch.B

Treatment Modes

There are three treatment modes available on the Polaris TENS:

1. C**onventional TENS or normal.** This mode enables the user to select any rate between 2 Hz – 200 Hz, and a pulse width between 50 μS – 300 μS. This is the most frequently used of the three modes. The most common selection is 80 Hz with a 200 μS pulse width.

2. **Burst Mode**. This mode is comparable to the low rate TENS technique except that each low rate pulse is substituted for by a short BURST of 9 pulses [200 μS] at 150 Hz. It is a combination of conventional and low rate TENS.

3. **Modulation TENS** This mode was designed to help prevent nerve accommodation that some patient's experience. It is achieved by continuously cycling the pulse width and rate.

Intensity [mA]
Patients respond differently to the level of intensity, this is due to differences in individual patient's skin resistance, enervation and the type and condition of electrode being used.

A good formula for setting the intensity is to increase the current so that the patient feels slight muscle contraction, but not strong enough to move a joint, and then slightly reduce the intensity so that it feels comfortable. When using low rate TENS settings, individual twitches will occur. The higher rate TENS settings will increase muscle tension. It is not advised to increase the intensity to experience strong muscle contraction.

How Long Do I Use TENS For?
This depends on the individual patient's condition, accuracy of electrode placement, stimulation and the characteristics selected, but typically the onset of pain relief starts after 20 - 30 minutes. Generally TENS is used for longer periods of normally 1 hour 30 minutes per session. With some patients it can be much longer.

Electrode Placement

The placement of electrodes is one of the most important parameters in achieving effective pain relief using TENS. This is best left to your Physiotherapist or Physician to advise as to which location is most appropriate.

Electrode Types & Tips

A Few Good Tips [Self- Adhesive Electrodes]

* If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.

* Clip away hairy skin using a scissors; don't use a razor to remove the hairs!

The electrodes conductive material is water- based. If it becomes saturated (e.g. from perspiration), it will lose its adhesive qualities. After use leave the electrodes face up overnight to dry out. At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will give you a few more days of electrode life.

Care & Maintenance

Control Unit:

* Wipe the surface once a week with a damp cloth or antiseptic wipe
* Do not use cleaning sprays or alcohol based cleaning solutions

Battery:

* Check periodically for any discharge from the battery
* Remove battery completely from unit if not in use for any extended period of time (typically one week)
* Low battery indicator of 6.9 volts shown on LCD display, when flashing change battery for a new one
* Preferably use a PP3 alkaline battery

Lead Wires

* The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all
* Examine lead wires before each treatment for loose connections or damage
* Avoid stretching and twisting the lead wires
* Store the lead wires carefully after each use

Self-Adhesive Electrodes

* Check the short connectors have not become separated from the electrodes
* Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to conductive gel rendering the electrodes ineffective

Caution: Static electricity may damage this product

Note: Only appointed distributors/importers are approved to undertake servicing.

Specifications

TENS

1. Dual channel: individually isolated circuits.
2. Amplitude: 0 - 80 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: 50 µS - 300 µS [2% accuracy].
6. Pulse Rate selection: in the continuous mode 2 - 200 Hz [2% accuracy].
7. Mode: Continuous, Burst or Modulated.
8. Burst mode: Bursts of 9 pulses [200 µS] at 150 Hz, repeating twice every second.
9. Modulation mode: 6-second cycle of concurrent width modulation and pulse repetition rate modulation. Width starting at 200 µS and decreasing exponentially to 100 µS in three seconds and then returning back to 200 µS in the next three seconds. Rate starting at 100 Hz, decreasing exponentially to 65 Hz and then returning to 100 Hz.
10. Time duration of the treatment selectable: 1 minute to 12 hours.
11. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
12. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on.
13. Open Electrode Detect: If an open circuit is detected at the output of channel A or B the output current will be reset at zero.
14. Physical dimensions: 108 x 62 x 23 mm.
15. Weight: 0.07KG without battery, 0.1KG with battery.
16. Environmental conditions for storage & transport:
    -10 to +50 degrees Centigrade
    0-90% Humidity.

Warranty

Spectramed, Inc. provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 1 year from the date of purchase [invoice date]. If Spectramed, Inc. are satisfied that the product/s is defective the purchaser may return this unit/s to Spectramed, Inc. or the appointed distributor for repair or replacement with a new unit. All returns must first be authorized by Spectramed, Inc. in advance. The liability of Spectramed, Inc. under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

Customer Service

Any queries should be addressed to Spectramed, Inc. at:
564 Harcourt Road
Mount Vernon, Ohio 43050

Phone: 1-800-643-1917
Fax: 1-877-843-1917

www.spectramedonline.com

Design Registration Numbers: 2095095, 2095096, 2098278

Clinical References

Conventional TENS:

Bates JAV, Nathan PW [1980] Transcutaneous electrical nerve stimulation for chronic pain. Anaesthesia 35: 817-22

Ellis B [1995] Transcutaneous electrical nerve stimulators: outpatient response to a temporary home loan program Br J The Rehabil 2 [8]: 419-23

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Walker J [1992] When self-help begins at home Prof Nurse 7 [10]: 662-4

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