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Chapter 1: INTRODUCTION

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies.

Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until a coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation is a non-invasive, drug-free method of controlling pain. TENS uses tiny 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 the pain, allowing for a return to normal activity.

HOW TENS WORKS

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to be used to relieve pain. The TENS unit sends comfortable 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 the patient feels. Pain relief varies by individual patient, mode selected for therapy, and the type of pain. In many patients, the reduction or

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elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may discuss this with your physician or therapist.

Chapter 2: CAUTIONS

1. Read operation manual before use of TENS.
2. We emphasize that patient with an implanted electronic device (for example, a pacemaker) should not undergo TENS treatment without first consulting a doctor. The same applies to patients with any metallic implants.
3. If TENS therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is reevaluated by the physician or therapist.
4. Avoid adjusting controls while operating machinery or vehicles.
5. Turn the T.E.N.S. off before applying or removing electrodes.
6. The T.E.N.S. devices have no AP/APG protection. Do not use it in the presence of explosive atmosphere and flammable mixture.

Chapter 3 : WARNINGS

1. Caution should be used in applying TENS to patients suspected of having heart disease. Further clinical data is needed to show there are no adverse results.
2. Electrical stimulation safety has not been established during pregnancy. Do not use TENS during pregnancy.
3. Do not place electrodes on the front of the throat as spasm of the Laryngeal and Pharyngeal muscle may occur. Do not stimulate over the carotid nerve, particularly with patients with known sinus reflex sensitivity.
4. Care should be taken so that when operating potentially dangerous machinery the stimulator controls are not changed abruptly.

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5. Cases of skin irritation at the electrode site have been reported. Stimulation should be stopped and electrodes removed until the cause of the irritation can be determined.
6. Electrodes should not be placed over the eyes, in the mouth, or internally.
7. Keep this device out of the reach of children.

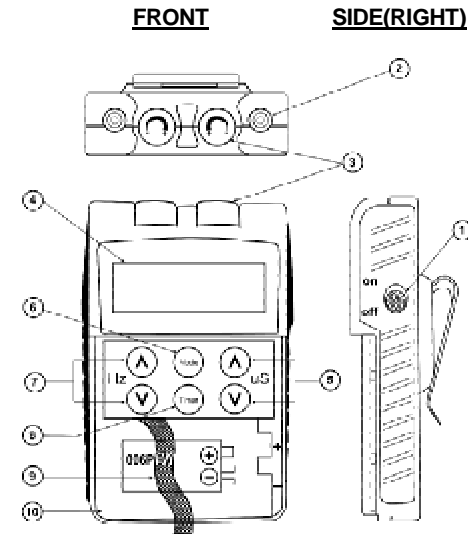
Chapter 4 : GENERAL DESCRIPTION

The EV-803P DIGITAL T.E.N.S. is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves causing pain. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel.

The electronics of the EV-803P DIGITAL TENS create electrical impulses whose Intensity, duration, number per second, timer and modulation may be altered with the controls/buttons. Nine preset programs are available for option as well. Press buttons are very easy to use and the large liquid crystal display showing the exact mode and values of parameters are very convenient for patients.

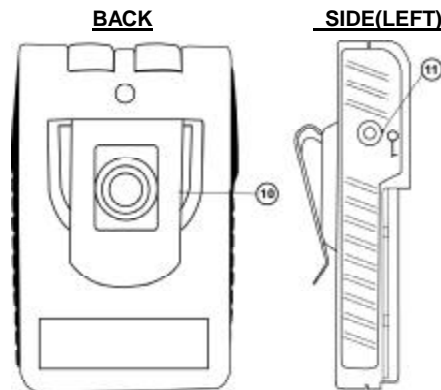
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Chapter 5 : CONSTRUCTION



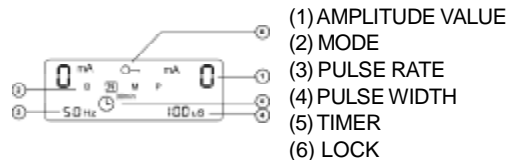
- (1) POWER ON/OFF SWITCH
- (2) LEAD CONNECTOR
- (3) INTENSITY CONTROL
- (4) LCD
- (5) PULSE WIDTH CONTROL
- (6) MODE CONTROL
- (7) PULSE RATE CONTROL
- (8) TIMER CONTROL
- (9) BATTERY STRIP
- (10) BATTERY CASE

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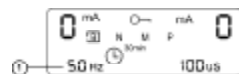
- (10) METAL BELT CLIP
(11) PROGRAM LOCK BUTTON

LIQUID CRYSTAL DISPLAY (MODE N, M)



- (1) AMPLITUDE VALUE
(2) MODE
(3) PULSE RATE
(4) PULSE WIDTH
(5) TIMER
(6) LOCK

LIQUID CRYSTAL DISPLAY (MODE B)



- (1) BURST RATE

LIQUID CRYSTAL DISPLAY (MODE P)



- (1) PROGRAM NUMBER
(2) TIMER

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Chapter 6 : TECHNICAL SPECIFICATIONS

The technical specification details of EV-803P DIGITAL T.E.N.S. are as follows.

MECHANISM	TECHICALDESCRIPTION
01 Channel	Dual, isolated between channels
02 Pulse Amplitude	Adjustable 0-80mA, Max output 80mA peak to peak (15.8mA rms) into 500ohm load each channel, 1mA each step.
03 Output Voltage	Adjustable 0-40V, Max output 40V peak to peak (8.5V rms) into 500ohm load each channel.
04 Wave Form	Asymmetrical rectangular biphasic pulse.
05 Power Supply	One 9 Volt Battery, type 6F22
06 Size	10.1cm(L) x 6.8cm(W) x 2.15cm(H)
07 Weight	155 grams (battery included)
08 Pulse Rate	Adjustable, 1~150Hz, 1Hz / step
09 Pulse Width	Adjustable, 50~300µs, 10µs / step
10 Mode	Four modes available, B(Burst), N (Normal), M(Pulse Rate Modulation) and P(Program). Parameters are adjustable at B, N or M mode. Nine pre-set programs (fixed) are available of options at P mode. (Pulse Width Modulation and Mixed Frequency are included.)
11 Burst	Burst rate adjustable, 0.5~5 Hz Pulse width adjustable, 50~300µs Frequency fixed = 100Hz
12 Normal	Constant output based on the setting value.
13 P.R. Modulation(-40%)	Pulse rate is automatically varied in a cyclic pattern over an interval of nominally 10 seconds. (in max 150Hz) Pulse rate decreases linearly over a

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		period of 5 seconds from the control setting value to a value which is 40% less. Then increase linearly over a 5 seconds period to its original value. The cycle is then repeated.																																																		
14	Timer	Selectable, 30 Minutes, 60 Minutes or Continue.																																																		
15	Program Details	<p>The pre-set parameters of the 9 programs are as given below:</p> <table border="1"> <thead> <tr> <th><u>Program</u></th> <th><u>Mode</u></th> <th><u>Pulse Rate</u></th> <th><u>Pulse Width</u></th> <th><u>Timer</u></th> </tr> </thead> <tbody> <tr> <td>P1</td> <td>Constant</td> <td>80Hz</td> <td>180µs</td> <td>Continue</td> </tr> <tr> <td>P2</td> <td>Burst</td> <td>100Hz (Burst Rate:2Hz)</td> <td>180µs</td> <td>Continue</td> </tr> <tr> <td>P3</td> <td>-70% P.W. Modulation</td> <td>80Hz</td> <td>50µs -180µs</td> <td>Continue</td> </tr> <tr> <td>P4</td> <td>Mixed Frequency</td> <td>15Hz in 3 Sec / 2Hz in 3 Sec</td> <td>180µs</td> <td>Continue</td> </tr> <tr> <td>P5</td> <td>Mixed Frequency</td> <td>80Hz in 3 Sec / 2Hz in 3 Sec</td> <td>180µs</td> <td>Continue</td> </tr> <tr> <td>P6</td> <td>Constant</td> <td>10Hz</td> <td>180µs</td> <td>Continue</td> </tr> <tr> <td>P7</td> <td>Constant</td> <td>80Hz</td> <td>60µs</td> <td>Continue</td> </tr> <tr> <td>P8</td> <td>Constant</td> <td>80 Hz</td> <td>180µs</td> <td>30 Minutes</td> </tr> <tr> <td>P9</td> <td>Burst</td> <td>100Hz (Burst Rate:2Hz)</td> <td>180µs</td> <td>30 Minutes</td> </tr> </tbody> </table>	<u>Program</u>	<u>Mode</u>	<u>Pulse Rate</u>	<u>Pulse Width</u>	<u>Timer</u>	P1	Constant	80Hz	180µs	Continue	P2	Burst	100Hz (Burst Rate:2Hz)	180µs	Continue	P3	-70% P.W. Modulation	80Hz	50µs -180µs	Continue	P4	Mixed Frequency	15Hz in 3 Sec / 2Hz in 3 Sec	180µs	Continue	P5	Mixed Frequency	80Hz in 3 Sec / 2Hz in 3 Sec	180µs	Continue	P6	Constant	10Hz	180µs	Continue	P7	Constant	80Hz	60µs	Continue	P8	Constant	80 Hz	180µs	30 Minutes	P9	Burst	100Hz (Burst Rate:2Hz)	180µs	30 Minutes
<u>Program</u>	<u>Mode</u>	<u>Pulse Rate</u>	<u>Pulse Width</u>	<u>Timer</u>																																																
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16	Program Lock	The intensity and the value of all parameters will be locked when the "Lock" button is pressed.
17	Operating Condition	Temperature:0°~40°C Relative Humidity:30%~75% Atmosphere Pressure : 700Hpa~1060Hpa
18	Remark	There may be up to a +/-5% tolerance of all parameters and +/-20% tolerance of amplitude & voltage.

Chapter 7: REPLACEABLE PARTS

	PARTS
01	LEAD WIRES
02	ELECTRODES
03	9V BATTERY, TYPE 6F22
04	BELTCLIP
05	BATTERY CASE COVER
06	LEADCONNECTOR
08	MAIN PCB
09	INTENSITY KNOB

Chapter 8: ACCESSORIES

Each set EV-803P DIGITAL T.E.N.S. are completed with standard accessories and standard label as given below

I. Accessories

REF. NO.	DESCRIPTION	Q'TY
1. KS4040	40 X 40 MM Adhesive Electrodes	4 pieces
2. KE-26	Electrodes Leads	2 pieces
3. GC-01	9 V Battery, type 6F22	1 piece
4.	Instruction Manual	1 piece
5.	Carrying Case	1 piece










II. LABEL



The label attached to the back of device contains important message about this device- model, serial number, supply voltage, the name of manufacturer, CE number and classification. Please do not remove.

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Chapter 9 : GRAPHIC SYMBOLS

-  Note Operating Instructions
-  Degree of Electrical Protection BF
-  Do not insert the plug into AC power supply socket.
-  Pulse Rate
-  Pulse Width
-  Increase
-  Decrease
-  Program is Locked
-  Timer

Chapter 10 : PARAMETER CONTROLS

PULSE DURATION

Wider pulse duration settings will deliver stronger stimulation for any given intensity setting. As mentioned in the Controls section, by using a combination of intensity and pulse duration, it is felt that various pulse widths are capable of stimulating different groups of nerve fibres.

The wider pulse duration is needed to recruit motor fibres, whereas the narrow pulse duration is used on the more sensory fibres.

The choice of which pulse duration to use is partially dependent upon the Treatment Mode and Protocol selected (refer to the appropriate section).

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PULSE RATE

The Pulse Rate (hertz or pulses per second) chosen depends greatly upon the type of electrode placement given to the patient.

When using contiguous and dermatome electrode placements (i.e. stimulating directly through the area of pain or localized enervation), a quick pulse rate (setting greater than 80Hz on the Pulse Rate Control) is desired. The patient should not perceive individual pulses but rather have the sensation of steady continuous stimulation.

When using point treatments, it has been suggested that slow pulses be utilized (less than 10Hz). With this setting the patient should be able to slightly perceive individual pulses.

When using multiple electrode placement strategies, such as combinations of point and contiguous electrode placements, the quicker pulse rates are suggested.

Despite above recommendations, these individual patients may require slight variations of the above settings, according to the nature of their condition.

TREATMENT MODE

Normal or Conventional TENS offers the practitioners complete control over all the various treatment parameters of the instrument.

Burst Mode is analogous to the Low Rate TENS technique except the low frequency individual pulses are replaced by individual "bursts" of 7-10 individual pulses. It is thus a combination of Conventional TENS and Low Rate TENS. In Burst Mode, the treatment frequency is adjustable at the range between 0.5Hz – 5Hz.

Modulated Mode attempts to prevent nerve accommodation by continuously cycling the treatment intensity. When using Modulated Mode increase the intensity only when the unit is at the maximum intensity of the modulation cycle. If the intensity is increased during a low intensity period of the cycle, the patient may turn up the control very slowly, so that they may feel the intensity any higher.

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INTENSITY

Each patient responds differently to different levels of intensity, due to varying degrees of tissue resistance, enervation, skin thickness, etc. Intensity instructions are therefore limited to the following settings:

Perception – The intensity is increased so that the patient can feel the stimulation, but there is not any muscular contraction.

Slight Contraction – Intensity is increased to a barely visible muscular contraction that is not strong enough to move a joint. When using low pulse rate settings, this will show as individual twitches. At higher pulse rates there will simply be increased muscle tension.

Strong muscular contraction is typically not used in TENS therapy. However, muscular contraction may be useful if the pain involves a cramped or spastic muscle. The TENS can be used as a traditional muscle stimulator in the circumstances to quickly break the spasm. Use a quick pulse rate, wide pulse duration and set the intensity to visible contraction (still within patient tolerance). Twenty or thirty minutes of such a tetanized muscular contraction will generally break the spasm. In all cases, if the patient complains that the stimulation is uncomfortable, reduce intensity and/or cease stimulation.

TIME DURATION

The onset of pain relief should occur shortly after the intensity setting has been determined. However, in some cases, pain relief may take as long as 30 minutes to achieve, especially when using point electrode placements and slow pulse rates.

TENS units are typically operated for long periods of time, with a minimum of 20 – 30 minutes and in some post-operation protocols, as long as 36 hours.

In general, pain relief will diminish within 30 minutes of the cessation of stimulation. Pain relief obtained through point electrode placements may last longer (perhaps because of the presence of endorphins).

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Chapter 11 : ATTACHMENT OF ELECTRODE LEAD

WIRES

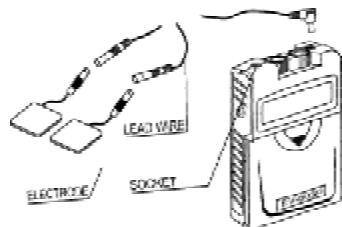
The wires provided with the system insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.

After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires.

Jerking the wire instead of holding the insulated connector body may cause wire breakage.

CAUTION

Do not insert the plug of the patient lead wire into the AC power supply socket.



Chapter 12: LEAD WIRE MAINTENANCE

Clean the wires by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

Chapter 13 : ELECTRODE OPTIONS

Your clinician will decide which type of electrode is best for your condition. Follow application procedures outlined in electrode packing, to maintain stimulation and prevent skin irritation. Use of legally marketed Electrodes is recommended.

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Chapter 14 : ELECTRODE PLACEMENT

The placement of electrodes can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the clinician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, feel free to experiment. Once an acceptable placement has been achieved, mark down the electrodes sites and the settings on the patient's Reference sheet of this manual, so the patient can easily continue treatment at home.

CONTIGUOUS PLACEMENT

This is the most common placement technique. It involves placing the electrodes alongside the area of localized pain site, in such a way as to direct the flow of current through or around the area of pain.

In a single channel application, this would involve placing each pad on either side of the pain site if the pain is localized on a limb and deep within the tissue. Pad placement on the posterior and anterior aspects of the affected limb will allow the current to flow completely through the limb and thus through the endogenous pain site.

With a two channels application, the clinician may either direct the current flow to cross through the pain site or, in what is called the "bracket" method allowing the current flow on either side of the painful area, generally through the nerve branches that feed into the pain site.

DERMATOMES, MYOTOMES AND SCLEROTOMES

These are the regions of the body enervated by one spinal nerve. Electrode placement involves both stimulating across the similarly enervated area and/or placing one electrode (or set of electrodes) at the pain site and another electrode (set) at the point where the nerve root joins the spinal cord.

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MOTOR, TRIGGER AND ACUPUNCTURE POINTS

While these points of high tissue conductivity can differ in location and in theory of use, their use as an electrode site is identical. The easiest technique involves placing one pad directly over the point and completing the circuit by placing the second pad on some area on the affected side. This second electrode site can be within a nerve zone, or a master point located between the thumb and the forefinger on the dorsal web area between the two metacarpal bones.

MULTIPLE PLACEMENT STRATEGIES

Because the TENS has two independently operated channels, the clinician may take advantage of concurrent pad placement strategies.

For example, it is possible to use two different electrode placement strategies at the same time. One channel can be used to directly stimulate the pain site in a contiguous manner; the other channel can be placed along the involved dermatome or utilized for point therapy.

Chapter 15 : TIPS FOR SKIN CARE

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

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
2. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the "pulling stress" from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from centre outward; avoid stretching over the skin.
5. To minimize "pulling stress", tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.

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6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

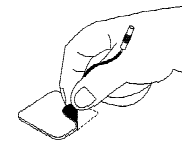
Chapter 16: APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES

Application

1. Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site.

Removal

1. Lift at the edge of electrodes and peel; do not pull on the lead wires because it may damage the electrodes.
2. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



Care and Storage

1. Between uses, store the electrodes in the resealed bag in a cool dry place.
2. It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.

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Important

1. Do not apply to broken skin.
2. The electrodes should be discarded when they are no longer adhering.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your clinician.
5. Read the instruction for use of self-adhesive electrodes before application.

Chapter 17: ADJUSTING THE CONTROLS

1. Slide Cover

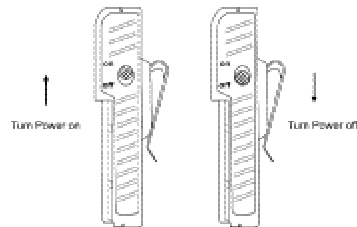
A slide-on panel covers the buttons controlling pulse width, pulse rate and mode.

Your medical professional may wish to set these controls for you and request that you leave the cover in place.



2. Power On/Off Switch

The On/Off position is marked on the right side of unit. Push the switch upward and the power of unit will be turned on. Push it downward, and you will turn it off.



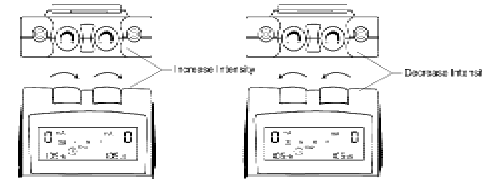
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3. Intensity Adjustment

By turning the controls clockwise, the power will be increased. The exact amplitude value will be revealed on the liquid crystal display. The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise. When the max. value (80mA) is reached, the value won't be changed if you continue to turn it.

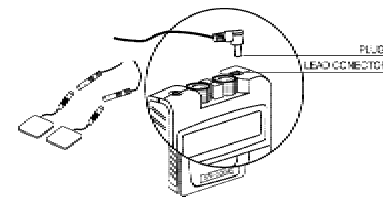
To reduce the current strength, turn the control counter clockwise to the required setting, respectively.

The amplitude value can be adjusted in 1mA each step. After the satisfactory level is reached, you may press the "lock" button on the left side of unit to lock it.



4. Lead Connector

Connection of the electrodes is made with two-lead connector. The device must be switched off before connecting the cables. Electrodes must be pressed firmly on the skin.



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5. Mode Control

Expose the controls by sliding front cover down from top of unit.
 This button controlling 4 modes: B for burst stimulation, N for constant stimulation, and M for pulse rate modulation(-40%) stimulation, P for Program.



About P Mode:

When "P" mode is selected, nine pre-set programs are available. Press the button to select a mode you desire. The pulse rate, pulse width, stimulation mode and timer are not adjustable when the P mode is in use.

Press any "Increase" or "Decrease" button to select a program you need. The treatment time of a program is visible on the liquid crystal display.



Summary of Programs:

Program	Pulse Rate(Hz)	Pulse Width(uS)	Mode	Timer (Min.)
1	80	180	Constant	Continue
2	100	180	Burst	Continue
3	80	50-180	-70% Modulation	Continue
4	15 / 2	180	Mixed Frequency	Continue
5	80 / 2	180	Mixed Frequency	Continue
6	10	180	Constant	Continue

7	80	60	Constant	Continue
8	80	180	Constant	30
9	100	180	Burst	30

6. Pulse Rate Control

Pulse rate is adjustable from 1 Hz to 150 Hz . Its value is visible on the LCD.

This buttons determine how many electrical impulses are applied through the skin each second. By pressing these controls, the number of current impulses per second (Hz) for both channels can be continually adjusted. Unless otherwise instructed, turn the pulse rate control to the 70-120 Hz range.



A. Increase

When pressing this button, the pulse rate will increase gradually.



B. Decrease

When pressing this button, the pulse rate will decrease gradually.



7. Pulse Width Control

Pulse Width is adjustable from 30 μ s to 300 μ s. Its value is visible on the LCD.

These buttons adjust the length of time each electrical signal is applied through the skin, which controls the strength and sensation of the stimulation. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 μ s setting.



- A. Increase
When pressing this button, the pulse width will increase gradually.



- B. Decrease
When pressing this button, the pulse rate will decrease gradually.



8. The device will store the mode that is used before it is switched off automatically.
9. Timer
A timer of 30, 60 minutes or Continue is available of options. Press the "Timer" button to select one proper setting. The output of unit will be terminated when time is up. Turn the power off after treatment program is completed.

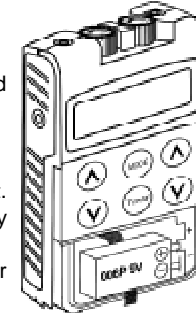


10. Lock Program
Press the red button on the left side of device and the program created will be locked, including intensity level.

11. Check/Replace the Battery:

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary.

1. Make sure that both intensity controls are switched to off position.
2. Slide the battery compartment cover and open.
3. Remove the battery from the compartment.
4. Insert the battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and press to close.



Chapter 18 : BATTERY INFORMATION

The EV-803P DIGITAL T.E.N.S. can be used with 6F22 9V battery.

PRECAUTIONS

1. Remove battery if equipment is not likely to be used for some time.
2. Please recycle the used battery in accordance with domestic regulation.
3. Do not throw the used battery into fire.

If you use rechargeable batteries, please follow the instructions.

RECHARGEABLE BATTERIES:

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this instruction manual.

After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

BATTERY CHARGING

- (1) Plug the charger into any working 110 or 220/240v mains electrical outlet. The use of any attachment not supplied with the charger may result in the risk of fire, electric shock, or injury to persons.
- (2) Follow the battery manufacturer's instructions for charging time
- (3) After the battery manufacturer's recommended charging time has been completed, unplug the charger and remove the battery.
- (4) Batteries should always be stored in a fully charged state. To ensure optimum battery performance, follow these guidelines:
 - (a) Although overcharging the batteries for up to 24 hours will not damage them, repeated overcharging may decrease useful battery life.
 - (b) Always store batteries in their charged condition. After a battery has been discharged, recharge it as soon as possible. If the battery is stored more than 60 days, it may need to be recharged.
 - (c) Do not short the terminals of the battery. This will cause the battery to get hot and can cause permanent damage. Avoid storing the batteries in your pocket or purse where the terminals may accidentally come into contact with coins, keys or any metal objects.
 - (d) WARNINGS:
 1. Do not attempt to charge any other types of batteries in your charger, other than the nickel-cadmium rechargeable batteries. Other types of batteries may leak or burst.
 2. Do not incinerate the rechargeable battery as it may explode!

Chapter 19: MAINTENANCE, TRANSPORTATION AND STORAGE OF TENS DEVICE

1. Non-flammable cleaning solution is suitable for cleaning the device. Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.

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5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accessories in carrying box and keep it in cool dry place.
6. The packed TENS device should be stored and transported under the temperature range of -20°C - + 60°C, relative humidity 20%- 95%, atmosphere pressure 500 hPa - 1060 hPa.

Chapter 20: SAFETY-TECHNICAL CONTROLS

For safety reasons, check your EV-803P DIGITAL T.E.N.S. each week based on the following checklist.

1. Check the device for external damage.
 - deformation of the housing.
 - damaged or defective output sockets.
2. Check the device for defective operating elements.
 - legibility of inscriptions and labels.
 - make sure the inscriptions and labels are not distorted.
3. Check the usability of accessories.
 - patient cable undamaged.
 - electrodes undamaged.

Please consult your distributor if there are any problems with device and accessories.

Chapter 21 : MALFUNCTIONS

Should any malfunctions occur while using the EV-803P DIGITAL T.E.N.S. , check

- whether the parameters are set to the appropriate form of therapy. Adjust the control correctly.
 - whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
 - whether the LCD reveal the menu. If necessary, insert a new battery.
 - for possible damage to the cable. Change the cable if any damage is detected.
- * If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

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Chapter 22 : CONFORMITY TO SAFETY TANDARDS

CONFORMITY TO MDD REQUIREMENTS

The EV-803P Digital T.E.N.S. devices are in compliance with the EN 60601-1-2:1993 and EN 60601-1:1990+A1:1993+A2:1995+A13:1996 safety standards.

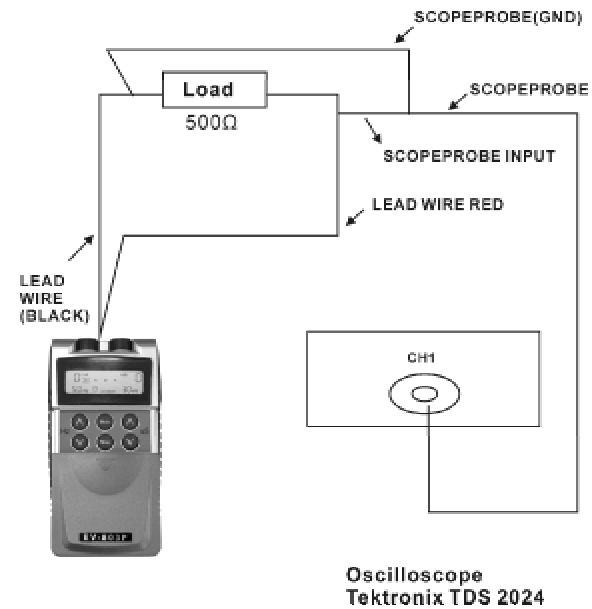
Chapter 23 : WARRANTY

All EV-803P DIGITAL T.E.N.S. devices carry a warranty of one year from the date of delivery. The warranty applies to the stimulator only and covers both parts and labour relating thereto.

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

Appendix I : Test Environment

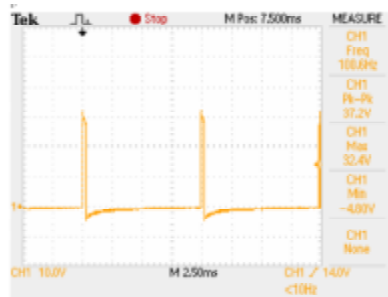
Appendix I : Test Environment



Appendix II : Waveform

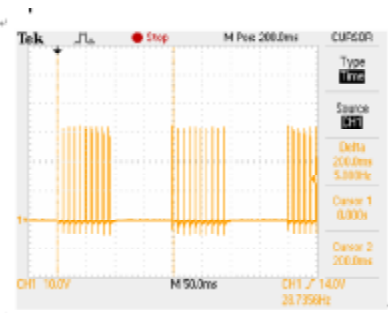
I. Mode : B (Burst)

Test Equipment : Tektronic TDS2024 Oscilloscope
Load: 500 ohm
Pulse Rate: 100Hz
Pulse Width: 300 μ s
Burst Rate: 5Hz



Scope:

VERT.: 10.0V/DIV
HORIZ.: 2.5mS
OUTPUT: 37.2Vpk-pk
Pulse Rate: 100.6Hz



Scope:

VERT.: 10.0V/DIV
HORIZ.: 50mS
Burst Rate: 5Hz

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II. Mode : N (Contant)

Test Equipment : Tektronic TDS2024 Oscilloscope
Load: 500 ohm
Pulse Rate: 150Hz
Pulse Width: 300 μ s



Scope:

VERT.: 10.0V/DIV
HORIZ.: 2.5mS
OUTPUT: 40.4V pk-pk
Pulse Rate: 151.4Hz



Scope:

VERT.: 10.0V/DIV
HORIZ.: 50 μ s
OUTPUT: 40.8V pk-pk
Pulse Width: 294.8 μ s

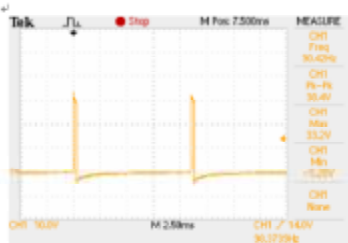
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III. Mode : M (-40% Pulse Rate Modulation)

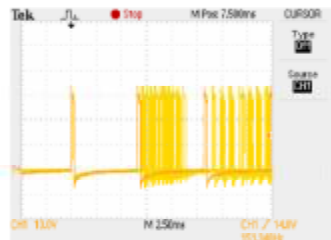
Test Equipment : Tektronic TDS2024 Oscilloscope
Load: 500 ohm
Pulse Rate: 150Hz
Pulse Width: 300µs



Scope:
VERT.: 10.0V/DIV
HORIZ.: 2.5mS
OUTPUT: 40.4V pk-pk
Pulse Rate: 151.4Hz



Scope:
VERT.: 10.0V/DIV
HORIZ.: 2.5mS
OUTPUT: 38.4V pk-pk
Pulse Rate: 190.42Hz

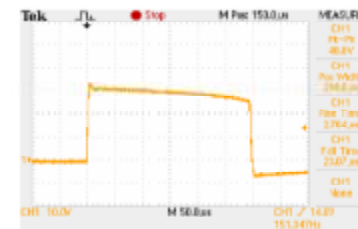


Scope:
VERT.: 10.0V/DIV

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IV. Mode : -70% Pulse Width Modulation(For Program 3)

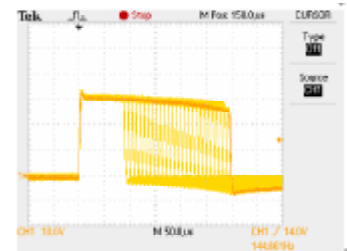
Test Equipment : Tektronic TDS2024 Oscilloscope
Load: 500 ohm
Pulse Rate: 80Hz
Pulse Width: 180µs



Scope:
VERT.: 10.0V/DIV
HORIZ.: 50µs
OUTPUT: 40.8V pk-pk
Pulse Width: 176.8µs



Scope:
VERT.: 10.0V/DIV
HORIZ.: 50µs
OUTPUT: 36V pk-pk
Pulse Width: 49.2µs



Scope:
Modulation: -70%

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