

# TENS TS-1211

## Instruction Manual



## INTRODUCTION

### 1.1 General Information:

This TENS is a lightweight and portable medical device, which can help to reduce the pain and discomfort. It utilizes the low electric-current to stimulate muscle nerve to achieve the symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain.

### 1.2 Indications for use:

This device is used in symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain.

### 1.3 Warnings:

- 1.3.1 The long-term effects of chronic electrical stimulation are unknown.
- 1.3.2 Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- 1.3.3 Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- 1.3.4 Stimulation should not be applied transthoracically introduction of electrical current into the heart may cause cardiac arrhythmias.
- 1.3.5 Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, et
- 1.3.6 Stimulation should not be applied over, or in proximity to, cancerous lesions.
- 1.3.7 For external use only.
- 1.3.8 Do not use TENS on the eye area.
- 1.3.9 This device should be used only under the continued supervision of a physician.
- 1.3.10 Safety of TENS devices for use during pregnancy or delivery has not been established.
- 1.3.11 Electronic equipment such as ECG monitors and ECG alarms may not operate properly when TENS is in use.
- 1.3.12 Apply the electrodes to clean, dry and unbroken skin only.
- 1.3.13 This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at under risk of injury.
- 1.3.14 This device should be kept out of the reach of children.

### 1.4 Precautions:

- 1.4.1 Caution should be used for patients with suspected or diagnosed heart problem.
- 1.4.2 Caution should be used for patients with suspected or diagnosed epilepsy.
- 1.4.3 Caution should be used in the presence of the following:
  - a. When there is a tendency to hemorrhage following acute trauma or fracture;
  - b. Following recent surgical procedures when muscle contraction may disrupt the healing process.
  - c. Over the menstruating or pregnant uterus; and
  - d. Over areas of the skin which lack normal sensation.
- 1.4.4 Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- 1.4.5 Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- 1.4.6 This device should be used only with the leads and electrodes recommended for use by the manufacturer.
- 1.4.7 Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- 1.4.8 Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

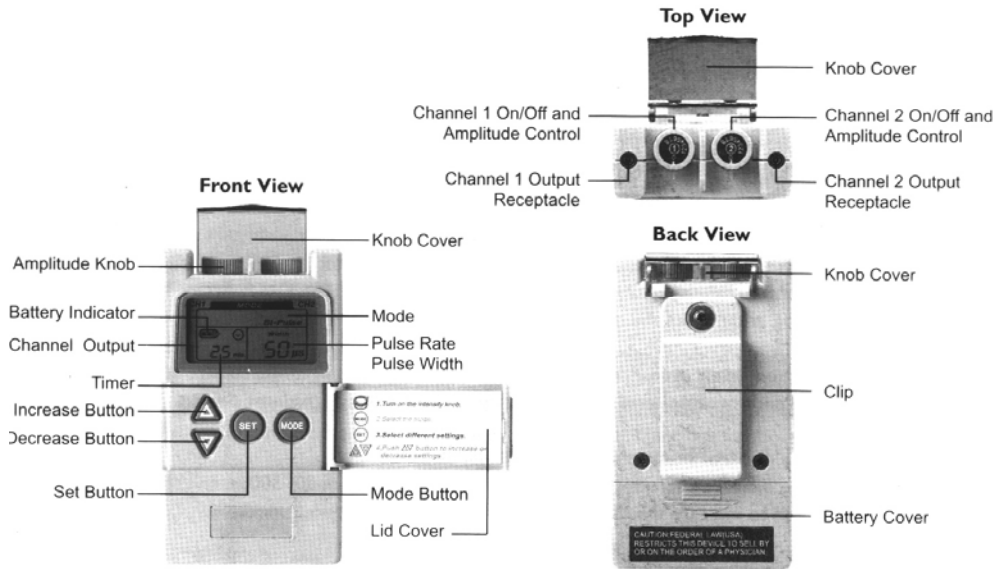
1.4.9 If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if problems persist.

1.5 Adverse Reactions:

- 1.5.1 Possible skin irritation or electrode burn under the electrodes may occur.
- 1.5.2 Possible allergic skin reaction to tape or gel may occur.

2. PRODUCT DESCRIPTIONS

2.1 Front and Rear Panel:



**Knob Cover:**  
An acrylic knob cover can protect from touching Amplitude Controls when the unit is used. After adjusting the output, remember to have the cover closed.

**Lid Cover:**  
A panel covers the controls for Mode, Set, INCREASE and DECREASE Adjusting. Your medical professional may ask to set these controls for you and request that you leave the cover in place.

**Amplitude Controls:**  
In controls the “INTENSITY” level of stimulating pulses. These controls located at the top of the unit regulate the amplitude, or intensity, of the stimulation and are the ON/OFF CONTROL the ON indicator light will stay lit as long as the unit is working and mimics the output of the electrical pulse.

**Caution:** *If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.*

“INCREASE” increase control button (using a triangle-button)  
This button will carry the increase character to increase the pulse with from 50~300μs, and to increase the pulse rate from 2 to 150Hz, and to increase the timer from 5 to 90 mins to continuous mode.

“DECREASE” decrease control button (using an inverted triangle-button)  
This button will carry the decrease character to decrease the pulse width from 300~50μs, and to decrease the pulse rate from 150 to 2Hz, and to decrease the timer from continuous mode to 90 to 5 min.

“MODE” button (using a round-button on the right side of the control panel)  
This button will carry the character to select for a Stimulation-Mode. It Offers the mode status from five type of stimulation modes, which are Burst, Normal, MRW (Modulate Rate and Width). SD (Strength Duration)and Bi-Pulse).

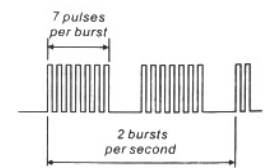
“SET” button (using a round-button on the middle of the control panel)  
This button will carry the character to set the rate, width and timer. Users press the “Set” button to enter a parameter setting mode including rate, width and timer)

“LCD Screen”  
This LCD will be utilized to display stimulating mode/pulse width/pulse rate and to display timer. The channel output will be indicated on the left side (Channel 1) and right side (Channel 2) of the LCD screen. The modes will be showed on the top of the LCD panel. The pulse rate and width will be showed on the middle-right of the screen. The timer and clock symbol are showed on the middle-right of the screen, the clock symbol will flash in final 5 min.

“Battery Compartment”

3. STIMULATION MODES:

9 Voltage battery – 1 pc  
The stimulation mode offers a variety of stimulation modes. The button is located under the front lid cover and is adjusted by pressing on the “MODE” control button.



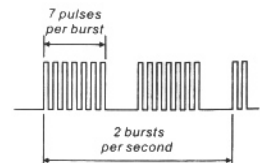
Be sure that when adjusting these stimulation modes, control function that the intensity ( Amplitude), output controls are set to the minimum output positions.

3.1 BURST Mode  
The burst mode provides a “burst” of seven pulses. There are tow bursts that are delivered per second. Positive pulse and negative pulse iterative continuously at fixed 100Hz. Pulse width from 50~300μs.

3.2 NORMAL Mode  
The Normal mode produces a continuous train of impulses. The stimulation parameters are not automatically interrupted nor varied in any way. In this mode, the pulse are (from 2 to 150 Hz), pulse width (from 50 to 300μs) are fully adjustable. The normal mode is quite versatile because it m ay be applied with a variety of rate and width settings.



3.3 MRW (Modulated Rate and Width) Mode:  
The pulse rate and width are automatically varied in a cycle to produce a pleasant, message-like sensation. It’s believed that nerves can become accustomed to, or “accommodated” to the same electrical stimulus after a period of time and thus would require

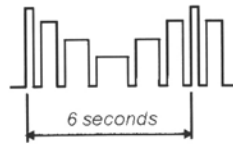


increasing the intensity to further “block” the pain. The Modulation mode was produced to offer a variety of different electrical stimulation, thus preventing nerve accommodation so that less intensity is required for long and effective treatment.

In this mode, during the beginning of 0.5 sec. period, the WIDTH decreased to 50% of its original setting and then during the next 0.5 sec. period, the RATE is decrease to 50% of its original setting. Therefore, the total cycle time is 1 second.

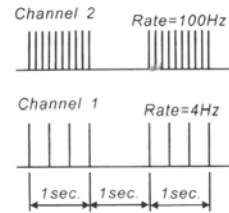
### 3.4 SD (Strength Duration) Mode:

Strength-Duration modulation consists of alternating modulated intensity and pulse width, so that the intensity is always increasing while the pulse width is decreasing and vice-versa. The stimulation intensity modulate to 62.5% maximum of setting (width equal to setting). The pulse width modulate to 67% of setting (intensity equal to setting). Total cycle time is 6 seconds. Rate (from 2~150Hz), width (from 50~300µs) are fully adjustable.



### 3.5 Bi-Pulse Mode:

Delivers 4 pulses per second to Channel 1 (i.e. the pulse rate of Channel 1 is fixed at 4 Hz) while delivering 100 pulses per second the Channel 2 (i.e. the pulse rate of Channel 2 is fixed at 100Hz). Stimulation is burst on for 1.0 second, then off for 1.0 second. There illustration each pulse as a vertical line. Pulse width (from 50~300µs) is fully adjustable.



*Note: Always read this instruction manual before use.*

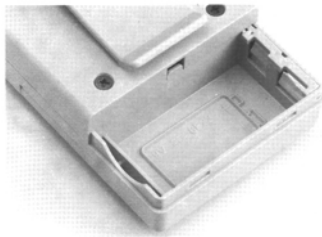
## 4. INSTRUCTIONS FOR USE

### PREPARATION FOR USE

#### 4.1 Check Battery:

Proceed to insert a fresh 9V alkaline or rechargeable battery into the battery compartment. Make sure that you are installing the batteries properly. The battery is inserted in the casing on the back of the stimulator unit. **BE SURE TO MATCH THE POSITIVE AND NEGATIVE ENDS OF THE BATTERY TO THE MARKINGS IN THE BATTERY COMPARTMENT OF UNIT.** To remove the batter cover, press and tug it following the direction of the arrow indicated on the battery cover:

*Note: Please install batteries according to their positive (+) and negative (-) ends correctly*



### CONNECTING THE STIMULATOR

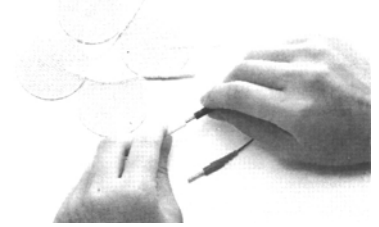
#### 4.2 Connect electrodes to lead wires:

Insert the lead wire connector into electrodes connector (standard 0.04 inch female connection).

**MAKE SURE THAT NO BARE METAL OF THE PINS IS EXPOSED.**

#### Caution:

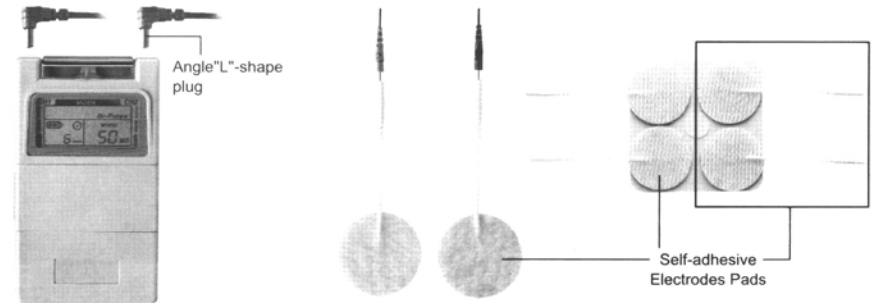
1. Always use electrodes whose measure of area is more than 16 cm<sup>2</sup>
2. Always use electrodes which are legally marketed in the US under 510(k) procedure.



#### 4.3 Connect lead wires to unit:

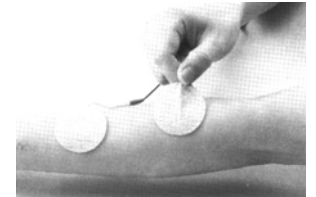
Before proceeding to this step, be sure the unit is completely turned OFF. Holding the insulated portion of the lead wire connector, insert the angled – “L” plug into the receptacle on the top of the main unit. Please ensure the leads are inserted correctly.

The unit has tow output receptacles which are controlled by Channel 1 and Channel 2 Amplitude Control knobs at the top of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires. Using both channels give the user the advantage of stimulating two different areas at the same time.



#### 4.4 Place electrodes on skin:

Apply electrodes to the exact site indicated by your physician following the instruction included with the electrodes labeling. Make sure that the electrodes are placed firmly to skin and make good contact between the skin and the electrodes. Before applying electrodes, be sure that the applied skin surface is thoroughly cleaned and dried. Place the electrodes over the skin, attach them properly, firmly and evenly.



### ADJUSTING THE CONTROLS

#### 4.5 Adjust Output:

Turn Amplitude Control knob for Channel 1 or Channel 2 clockwise. Then you will hear a “BI!” sound. Before you increase the Amplitude, you must select the mode, rate and width.

#### 4.6 Select the Mode:

Press “MODE” button to set the stimulation mode recommended by your physician or therapist. For details about stimulating waveform and sequences, please refer to Sec.3 “Stimulation Modes Descriptions”

**Caution: Please consult physicians for your suitable stimulation mode.**



#### 4.7 Adjust the Pulse Rate:

The pulses rate are adjustable 2~150 Hz, 2 Hz ~20 Hz in 1 Hz increment and 20~150Hz in 5 Hz increment.

Press SET button to enter Pulse Rate set function, then press INCREASE OR DECREASE button to adjust Pulse Rate to the setting recommended by your medical professional.



#### 4.8 Adjust the Pulse Width:

The pulse width is adjustable 50~300µs in 10µs increment.

Press SET button to enter the Pulse Width set function, then press INCREASE OR DECREASE button to adjust pulse width to the setting recommended by your medical professional.

#### 4.9 Adjust Timer:

The timer is adjustable 5~90 minutes or continuous in 5 minutes increment. Continuous option is just the next step to 90 minutes, i.e. from 5-90 minutes to continuous and then to 5 minutes is a cycle. During 5 minutes' final count down, the clock symbol will flash once every on second.

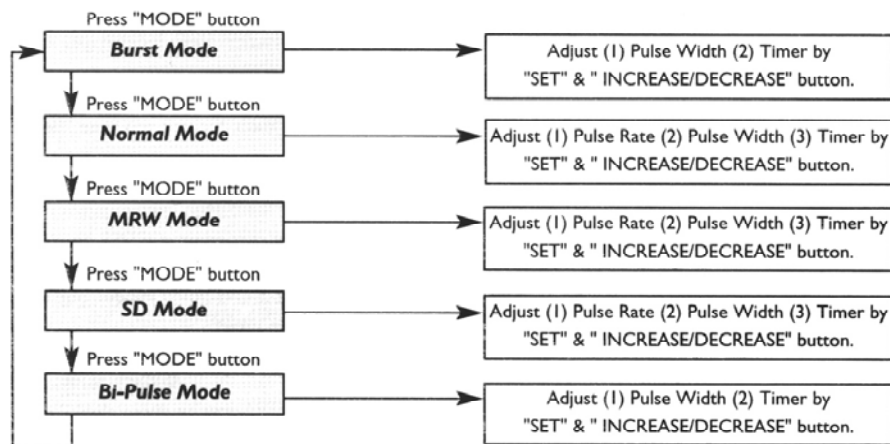


#### 4.10 Adjust Channel Amplitude:

Turn Channel 1 or 2 clockwise. The output indication will be showed on the left side (Channel 1) and right side (Channel 2) of the LCD screen as long as the unit is in operation. Slowly turn the Channel Amplitude control until you reach the setting recommended by your medical professional. Repeat for the other channel, if both channels are to be used.

**Caution: if the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.**

### OPERATION PROCEDURE CHART



#### 4.11 Turn Unit Off:

Turn both channel controls to "OFF". Then unplug the electrode lead wires, grasping them by the plug, not the cord. If treatment will be resumed shortly the electrodes may be left on the skin. When the electrodes are removed, clean the skin and the electrodes thoroughly with mild soap and water. If there is skin irritation from tape or gel, consult your prescriber:

**Caution: When the therapy time is complete, if the user doesn't turn off the amplitude knob, the unit will have "Bi-Bi" sound every 10 seconds until the amplitude knob is turn off completely.**

#### 4.12 Patient Compliance Time:

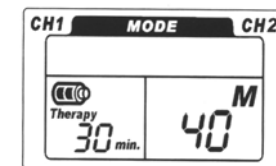
The patient compliance timer can memorize 60 sets of operation records; the total record time is 999 hours.

After the unit is turned off, you can start to use patient compliance timer. First, press and hold "mode" button and turn on the either one amplitude knob simultaneously to initiate patient compliance timer.



#### Individual Treatment Time:

Press "INCREASE" button (triangle button) or "DECREASE" button (inverted triangle button) to see next record of treatment time with the number of times or previous record of treatment time with the number of times.



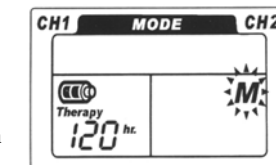
Press and hold "SET" button for 3 seconds to delete the on showing record. After the on showing record is deleted, the unit will sound "Bi!"

#### Note:

1. If the treatment time is under one minute, it will not be recorded. For example, if your treatment time is 10 minutes and 30 seconds, the patient compliance timer will record 10 minutes, not 11 minutes.
2. The patient compliance timer can only record up to 999 minutes for each treatment. Therefore, if you keep using the stimulator for over 999 minutes, it will only record 999 minutes and the record time will flash to mean the treatment time is over 999 minutes.

#### Cumulative Treatment Time

When initiating patient compliance timer, press "MODE" to shift the record of individual treatment time with the number of times to the record of cumulative treatment time. When showing the record of cumulative treatment time, there will be an "M" mark flashing on the upper right corner of middle-right screen.



Press and hold "MODE" & "SET" button simultaneously for 3 seconds to delete all the records including individual treatment time record and cumulative treatment time record.

- ❖ The patient compliance timer will keep the records even when the battery has no charge. Only when users press and hold "SET" or "MODE", and "SET", the records will be deleted.

## CARE AND MAINTENANCE

### 4.13 Portability:

Your unit is portable and may be clipped to a belt, shirt pocket, bra or other clothing.

### 4.14 “Low Battery” Indicator:

When the lower power indicator flashes, it means that the battery should be replaced with a new one as soon as possible. However, the stimulator will continue to operate for several more hours.

### 4.15 Battery:

To replace the battery, remove the battery cover and extract the battery. Replace it with a 9 V alkaline or similar rechargeable battery. Notice that the battery is inserted correctly.

### 4.16 Care of Electrodes:

To avoid skin irritation and ensure good contact with skin, clean silicone rubber electrodes with soap and water frequently. The electrodes must be dried completely before using.

- ❖ If you are using self-adhesive electrodes, please disregard this procedure.
- ❖ The user shall always use the electrodes which fulfill the local regulatory requirements.

### 4.17 Care of Electrode Cords:

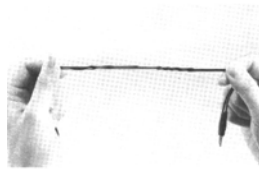
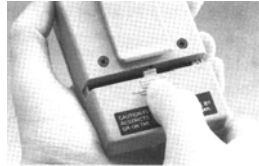
Clean the electrodes cords by wiping them with damp cloth. Coating them lightly with talcum powder will reduce tangles and prolong the life.

## 5. HANDLING AND STORAGE

Keep this device into the handy carrying case and storage at room temperature.

## 6. SPECIFICATION

Channel:	Dual, isolated between channels
Power Source:	9V
Output Waveform:	Asymmetric biphasic square pulse.
Pulse Width:	Variable, 50~300µs
Pulse Frequency:	Variable, 2~150Hz
Adjustable Intensity Levels:	0 to 40 Volts (at load=500 ohm)
Five Massage Modes:	Burst, Normal, MRW, SD, Bi-pulse
Patient Compliance Timer:	Memorize 60 sets of operation records. Total record time is 999 hours
Operation Ambient:	Temperature Range: 10-35°C, Humidity Range: 20-90% RH
Storage & Transportation:	Temperature Range: 10-70°C, Humidity Range: 20-90% RH
Timer:	5~90 Minutes auto-shutoff or Continuous
Lead Wires:	Male connect 2.0Ø+ - 0.1
Safety Standard:	IE 60601-1, IEC60601-1-2(EMC test), IEC 60601-2-10 (Partly applied)



## Stimulation Mode Descriptions:

Mode	Burst	Normal	MRW	SD	BI-PULSE
Pulse Frequency	Fixed 100 Hz	2~150Hz	2~150hz	2~150Hz	Channel 1 fix at 4Hz, Channel 2 fix at 100Hz
Pulse Width	50~300µs	50~300µs	50~300µs	50~300µs	50~300µs
Cycle Time	0.5 Sec.	Constant	1 Sec.	6 Sec.	2 Sec
Unit: Voltage At Load 500Ω					

- ❖ All Values have + - 10% tolerance.

## 7. ACCESSORIES

Self-Adhesive Electrodes 4 PCS


9V Battery 1PCS

Lead Wires 2 PCS

Instructional Manual 1PCS

If your unit 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 unit should be serviced.

## 8. TROUBLESHOOTING

The LCD indicator lights up but unit does not function properly.	Low Battery indicator flash. 	None of LCD indicators lights up
<ol style="list-style-type: none"> <li>1. Check all control settings. Are they set to values prescribed by your medical professional?</li> <li>2. Are electrodes in proper position?</li> <li>3. Check lead wires. Be sure all connectors are firmly sealed.</li> <li>4. Replace cord set with another to check for broken wires.</li> </ol>	1. Replace battery with a new one.	1. Replace battery with a new one.