



# Intellect<sup>®</sup> TENS

## *INSTRUCTION MANUAL*

**Please read the instruction manual before use**

*Caution: Federal law (USA) restricts this device to sell by or on the order of a physician.*

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# **I. INTRODUCTION**

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## **I.1 General information:**

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

## **I.2. Cautions**

Federal law (USA) restricts this device to sale by or on the order of practitioners licensed by the State in which they practice to use or order the use of the device.

## **I.3. Indications for use:**

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

## **I.4 Warnings:**

- I.4.1 The long-term effects of chronic electrical stimulation are unknown.
- I.4.2 Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- I.4.3 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.
- I.4.4 Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

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- I.4.5 Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
  - I.4.6 Stimulation should not be applied over, or in proximity to, cancerous lesions.
  - I.4.7 For external use only.
  - I.4.8 Do not use TENS on the eye area.
  - I.4.9 This device should be used only under the continued supervision of a licensed medical practitioner.
  - I.4.10 Safety of TENS devices for use during pregnancy or delivery has not been established.
  - I.4.11 Electronic equipment such as ECG monitors and ECG alarms may not operate properly when TENS is in use.
  - I.4.12 Apply the electrodes to clean, dry, and unbroken skin only.
  - I.4.13 This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
  - I.4.14 This device should be kept out of the reach of children.
  - I.4.15 Keep electrodes separate during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.

### **I.5 Precautions:**

- I.5.1 Caution should be used for patients with suspected or diagnosed heart problems.
- I.5.2 Caution should be used for patients with suspected or diagnosed epilepsy.
- I.5.3 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.

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(c)Over the menstruating or pregnant uterus

(d)Over areas of the skin which lack normal sensation.

I.5.4 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.

I.5.5 Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

I.5.6 This device should be used only with the leads and electrodes recommended for use by the manufacturer.

I.5.7 Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.

I.5.8 Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain-afflicted patients.

I.5.9 If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if problems persist.

## **I.6 Adverse Reactions:**

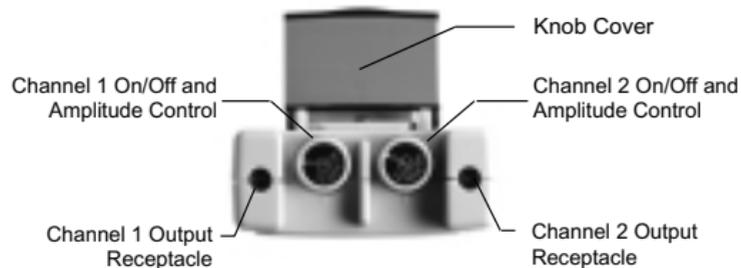
I.6.1 Possible skin irritation or electrode burn under the electrodes may occur.

I.6.2 Possible allergic skin reaction to tape or gel may occur.

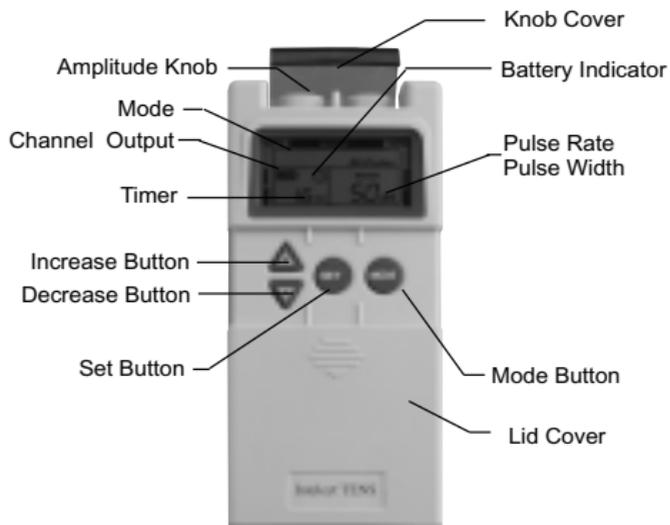
## 2. PRODUCT DESCRIPTIONS

### 2.1 Front and Rear panel:

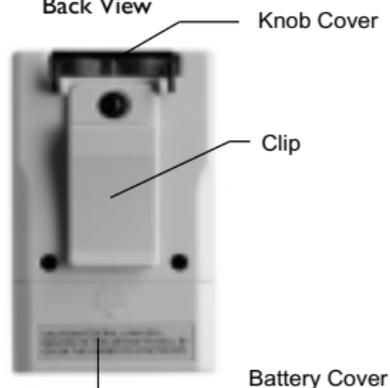
Top View



Front View



Back View





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**Knob Cover:**

An acrylic knob cover protects Amplitude Controls from accidental user touch when the unit is being used. After adjusting the output, remember to have the cover closed.

**Lid Cover:**

A panel covers the controls for Mode, Set, INCREASE and DECREASE adjustments. Your medical professional may ask to set these controls for you and request you leave the cover in place.

**Amplitude Controls:**

It 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 signal 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" control button** (triangle-button)

This button increases the pulse width from 50~300 $\mu$ s, increases the pulse rate from 2 to 150Hz, and increases the timer from 5 to 90 mins in continuous mode.

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**"DECREASE" control button** (inverted triangle-button)

This button decreases the pulse width from 300~50 $\mu$ s, decreases the pulse rate from 150 to 2Hz, and decreases the timer in continuous mode to from 90 to 5 min.

**"MODE" button** (round-button on the right side of the control panel)

This button selects a Stimulation-Mode. It offers the mode status from five types of stimulation modes which are Burst, Normal, MRW (Modulated Rate and Width), SD (Strength Duration) and Bi-Pulse.

**"SET" button** (round-button on the middle of the control panel)

This button sets the rate, width and timer. 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 the timer. The channel output is indicated on the left side (Channel 1) and right side (Channel 2) of the LCD screen. The modes show on the top of the LCD panel. The pulse rate and width show on the middle-right of the screen. The timer and clock symbol show on the middle-left of the screen; the clock symbol will flash in final 5 min.

**Battery compartment**

9 Voltage battery- 1 pc

### 3. STIMULATION MODES

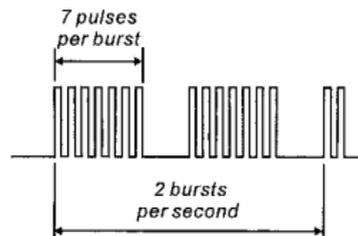
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The Stimulation Mode button is located under the front lid cover and is adjusted by pressing the "MODE" control button.

Be sure that when adjusting these stimulation modes, 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 two bursts that are delivered per second. Positive pulse and negative pulse are delivered continuously at fixed 100 Hz. Pulse width are adjustable from 50~300 $\mu$ s.



#### 3.2 NORMAL Mode:

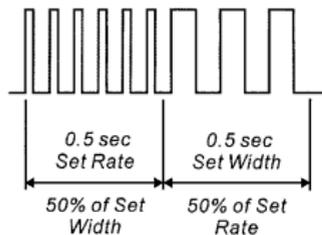
The Normal mode produces a continuous train of impulses. The stimulation parameters are not automatically interrupted nor varied in any way. In this mode, the pulse rate ( from 2 to 150Hz) and pulse width ( from 50 to 300 $\mu$ s) are fully adjustable. The normal mode is quite versatile because it may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



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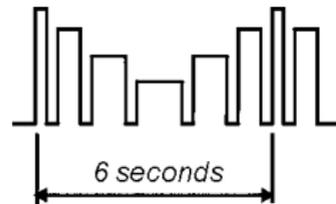
### 3.3 MRW (Modulated Rate and Width) Mode:

The pulse rate and width are automatically varied in a cycle to produce a pleasant, massage-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 offers different electrical stimulation, thus preventing nerve accommodation so less intensity is required for long and effective treatment. In this mode, during the beginning of 0.5 sec. period, the WIDTH is decreased to 50% of its original setting, and during the next 0.5 sec. period, the RATE is decreased to 50% of its original setting. Therefore, the total cycle time is 1 second.



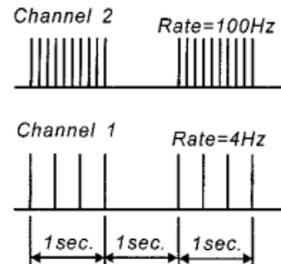
### 3.4 SD (Strength Duration) Mode:

Strength-Duration modulation consists of alternating modulated intensity and pulse width, so the intensity is always increasing while the pulse width is decreasing and vice-versa. The stimulation intensity is modulated to 62.5% maximum of setting (width equal to setting). The pulse width is modulated to 67% of setting (intensity equal to setting). Total cycle time is 6 seconds. Pulse rate (from 2~150Hz) and pulse width (from 50~300 $\mu$ s) 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 to Channel 2 (i.e. the pulse rate of Channel 2 is fixed at 100 Hz). Stimulation is burst on for 1.0 second, then off for 1.0 second (the illustration shows each pulse as a vertical line). Pulse width (from 50~300 $\mu$ s) is fully adjustable.



## 4. INSTRUCTIONS FOR USE

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

### PREPARATION FOR USE

#### 4.1 Check Battery:

Insert a fresh 9V alkaline or rechargeable battery into the battery compartment. Make sure that you are installing the battery 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 battery cover, press and pull down following the direction of the arrow indicated on the battery cover.



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## CONNECTING THE STIMULATOR

### 4.2 Connect electrodes to lead wires:

Insert the lead wire connector into electrodes connector (standard 0.08 inch female connection).  
MAKE SURE NO BARE METAL OF THE PINS IS EXPOSED.

#### **Caution:**

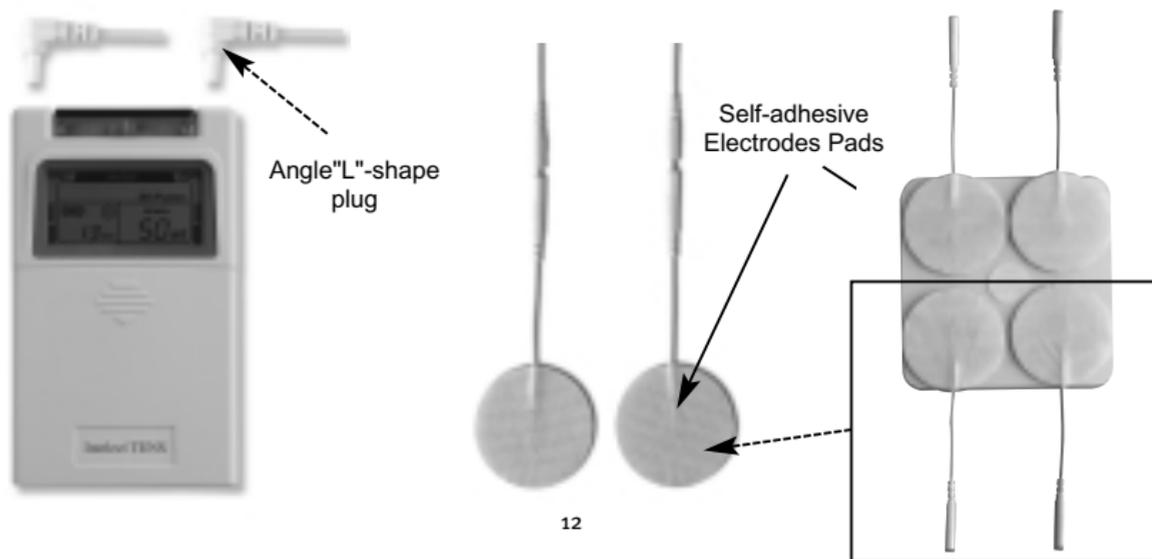
*\* Always use the electrodes with the requirements of the EN60601-1 and EN60601-2, such as with CE mark, or which are legally marketed in the US under 510(K) procedure.*



### 4.3 Connect lead wires to unit:

Before proceeding to this step, be sure the unit is 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. Ensure the lead wires are inserted correctly.

The unit has two 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 gives the user the advantage of stimulating two different areas at the same time.



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#### 4.4 Place electrodes on skin:

Apply electrodes to the exact site indicated by your physician following the instruction included with the electrodes labeling. Before applying electrodes, be sure the skin surface over which electrodes are placed is thoroughly cleaned and dried. Make sure the electrodes are placed firmly to skin and make good contact between the skin and the electrodes. 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 2 clockwise, then you will hear a "beep" sound. Before you increase the Amplitude, you must select the mode, rate and width.

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



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#### 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".

*Caution: Consult physicians for your suitable stimulation mode.*

#### 4.7 Adjust the Pulse Rate:

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

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



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#### 4.8 Adjust the Pulse Width:

The pulse width is adjustable 50~300 $\mu$ s in 10 $\mu$ s increments.

Press the SET button to enter the Pulse Width set function, then press INCREASE or DECREASE buttons 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 minute increments. 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 the 5 minute final count down, the clock symbol will flash once every second.

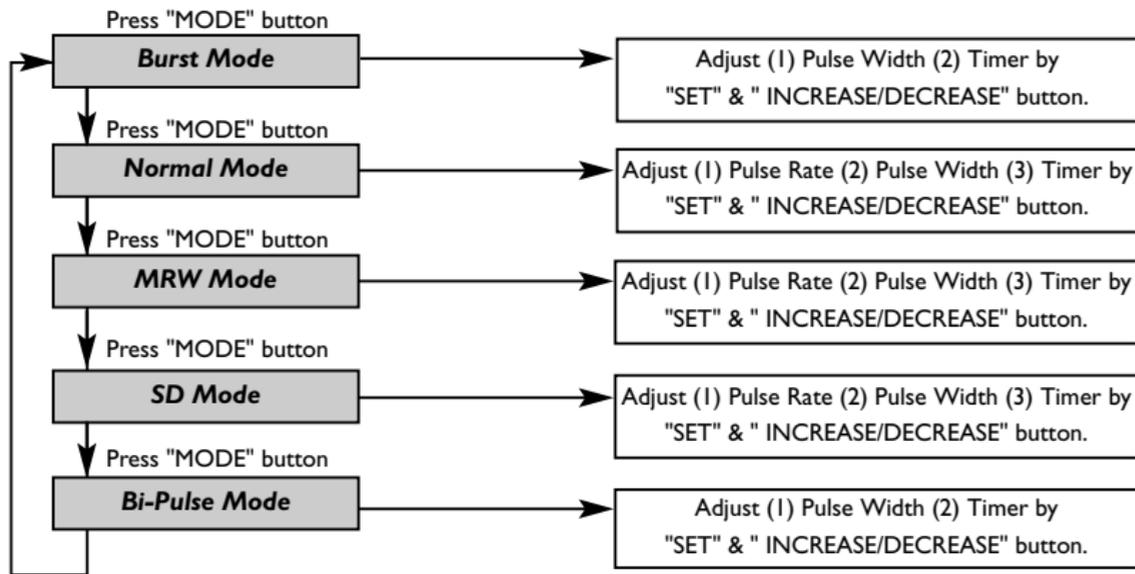


#### 4.10 Adjust Channel Amplitude:

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 medical practitioner if problems persist.*

## Operation Procedure Chart:



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#### **4.11 Turn Unit Off:**

Turn both Channel Amplitude 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 thoroughly with mild soap and water. If there is skin irritation, consult your prescribing medical practitioner.

*Caution: When the therapy time is completed, if the user doesn't turn off the amplitude knob, the unit will continue "beeping" every 10 seconds until the amplitude knob is turned off completely.*

#### **4.12 Patient Compliance Timer:**

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 amplitude knob simultaneously to initiate patient compliance timer.

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**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 displayed record. After the record is deleted, the unit will make a "beeping" sound.

**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.*



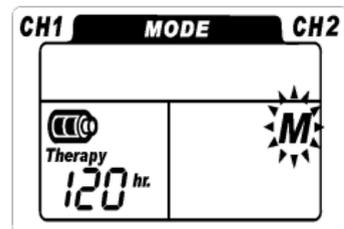
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**Cumulative treatment time:**

When initiating the 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.*  
*To delete all the records, press and hold Set or Mode & Set.*



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## 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 low power indicator flashes, the battery should be replaced with a new one as soon as possible. However, the stimulator will continue to operate for several more hours.



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#### 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. Make sure 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, disregard this procedure.*
- ✿ *Always use the electrodes with the requirements of the EN60601-1 and EN60601-2, such as with CE mark, or which are legally marketed in the US under 510(K) procedure.*

#### 4.17 Care of Electrode cords:

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



## 5. HANDLING AND STORAGE

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Keep this device in the carrying case and store at room temperature.

## 6. SPECIFICATION

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Channel	Dual channels, isolated between channels
Pulse Amplitude	0 ~ 80mA = 0 ~ 40 Volts, adjustable (at 500 ohm load)
Pulse Frequency (Hz)	2 ~ 150
Pulse Width ( $\mu$ s)	50 ~ 300
Waveform	Asymmetric biphasic square pulse.
Timer Control (mins)	5 ~ 90 mins or continuous
Stimulation Modes	Burst, Normal, MRW, SD, and Bi-Pulse
Power Supply	9V DC square shape battery
Size (D x W x H)	0.9" x 2.3" x 4.0" (24 mm x 59 mm x 101 mm)
Weight (including battery)	4.4 oz (124 g)
Safety standard	EN EN60601-1, EN EN60601-1-2, IEC 60601-2-10
Operation Ambient Temperature Range	50 ~ 95° F (10 ~ 35°C)
Operation Ambient Humidity Range	20 ~ 90% RH
Storage & Transportation Temperature Range	32 ~ 158°F (0 ~ 70°C)
Storage & Transportation Humidity Range	20 ~ 90% RH

**\*All values have  $\pm 10\%$  tolerance.**

### Stimulation Modes descriptions

Mode	BURST	NORMAL	MRW	SD	BI-PULSE
Pulse Frequency	Fixed 100Hz	2~150Hz,	2~150Hz	2~150Hz	Channel 1 fixed at 4Hz, Channel 2 fixed at 100Hz
Pulse Width	50~300 $\mu$ s				
Cycle Time	0.5 Sec.	Constant.	1 Sec.	6 Sec.	2 Sec.
Loading: 500 $\Omega$					

*\*All values have  $\pm 10\%$  tolerance.*

## 7 ACCESSORIES

Self-Adhesive Electrodes	4 PCS.
9 V Battery	1 PC.
Lead Wires	2 PCS.
Instruction Manual	1 PC.

## 8. TROUBLESHOOTING

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

<ul style="list-style-type: none"><li>• The LCD indicator lights up but unit does not function properly.</li></ul>	<ul style="list-style-type: none"><li>• Low Battery indicator flash. </li></ul>	<ul style="list-style-type: none"><li>• None of LCD indicators light up.</li></ul>
<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>	<ol style="list-style-type: none"><li>1. Replace battery with a new one.</li></ol>	<ol style="list-style-type: none"><li>1. Replace battery with a new one.</li></ol>

## **9. WARRANTY**

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\* Unit: One year (12 months) from the date of the original consumer purchase.

\* Accessories (consisting of lead wire, AC adapter, electrodes, carrying case, and belt clip): 90 days from the date of original consumer purchase.

To obtain service from Chattanooga Group or the selling dealer under this warranty, a written claim must be made within the warranty period to Chattanooga Group or the selling dealer.

Chattanooga Group shall not be held liable in any event for incidental or consequential damages. Some states do not allow exclusion or limitation of incidental or consequential damages so the above limitation or exclusion may not apply to you.





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