### ACCESSORIES:
- 2 Leadwires with electrodes
- 1 Instruction Booklet
- 1 Battery
- 1 Carry Pouch

Optional Accessories: 1 recharger kit comprising recharger with matching battery type. Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc.

### Technical Data:
- **Size**: 3.8" x 2.60" x 1" (97 mm x 62 mm x 25 mm)
- **Weight**: 3.1 oz (87.0 g)
- **Power Source**: 9V Battery, E-block, type 6F22
- **Channels**: Dual
- **Waveform**: Asymmetrical, biphasic square-wave
- **Frequency**: 2 - 150 Hz (500 µs)
- **Impulse Width**: 50 - 250 microseconds (µs) adjustable
- **Output**: Constant current
- **Intesity**: Continuously adjustable from 0 - 98 mA peak
- **Continuous**
  - **Stimulation**: Continuous stimulation (see Figure B)
  - **Burst**: 8 pulses per burst/2 bursts per second (see Figure C)

### General Description
This device is a Transcutaneous Electrical Nerve Stimulator. One pair of electrodes can be connected to each output channel using the leadwires supplied. Stimulation pulses are transferred from the device through the leadwires to the electrodes. The intensity, duration, and number of pulses per second can be adjusted.

### Device Description / Operation / Display
(See Figure A)

For safety reasons, the setting controls 7, 8, 9 and 12 are located under the battery compartment cover.

On/Off Switch and Amplitude Control (1, 2)
For safety reasons, the setting controls (1, 2) are located under a plastic cover. Slide the cover to the right to access the CH 1 control (1). Slide the cover to the left to access the CH 2 control (2). Slide the plastic cover to the center of the two controls when the amplitude is set to the desired setting.

If both amplitude controls are in the “O” position (both “O”s are adjacent to the white line on the housing), the device is switched off. By turning the Amplitude controls clockwise, the adjacent control is switched on and the Impulse Display Light (LED, 5 and 6) will illuminate and begin to pulse according to the set frequency (7). The intensity of the stimulation, transmitted through the electrodes, increases as the Amplitude control is turned clockwise. To reduce the intensity, turn the amplitude knob counter-clockwise.

### Connector sockets for the Leadwires (3, 4)
Connection of the electrodes is made using the leadwires with each connector firmly placed into the device sockets.

### Impulse Display Lights (LED, 5 and 6)
Each of these lights illuminates whenever the device is turned on. At settings in excess of 30 pps (Hz) (7) the lights will appear to be constant.

### Frequency Control Dial (7)
By turning this dial, the number of impulses per second (Hz) for both channels can be continually adjusted between 1 - 150 Hz.

### Impulse Width Dial (8)
This dial allows the continuous adjustment of the impulse width between 50 µs and 250 µs. No instructions regarding the impulse width are otherwise given, set the control dial midway between these limits.

### Operating Mode Switch (9)
The switch has 3 positions: A for Continuous stimulation, B for Burst stimulation, and M for Modulated stimulation. (Figure B, C, D)
- **CONTINUOUS stimulation**: In this position, the set therapy current remains constant for the duration of the therapy session. (Figure B)
- **Burst stimulation**: In this position, short electrical pulses are generated. (Figure C)
- **MODULATED stimulation**: The set duration of the pulse width is slowly decreased and increased from the set value. (Figure D)

### Modulation
- Decrease/increase of set width of 50% over a five-second period (see Figure D)

### Tolerance
- ±/− 10%

### Data recorded across a 500 OHM load resistance

### Guidance and Manufacturer’s declaration-electromagnetic emissions
This device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group I</td>
<td>This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR11</td>
<td>Class B</td>
<td>This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.</td>
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</table>

### Patient Safety Information

**Caution**
Federal law (USA) restricts this device to sale by or on the order of a physician so licensed by the State.

**Indications**
Transcutaneous Electrical Nerve Stimulation (TENS) devices are used for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

**Contraindications**
TENS devices can adversely affect the operation of demand-type cardiac pacemakers. TENS is not recommended for patients with known heart disease without a physician’s evaluation of risk. Do not stimulate over the eyes or carotid sinus nerves. Do not apply TENS for undiagnosed pain syndromes until etiology is established. Do not place electrodes in a manner that causes current to flow crossequaterally (through the head).

**Warnings**
This device should be used only under the continued supervision of a physician, or outside the USA, by a qualified pain management specialist. TENS is ineffective for pain of central origin, i.e., (appendicitis, hepatitis). TENS is of no curative value; it is a symptomatic treatment which suppresses pain sensation which would otherwise serve as a protective mechanism on the outcome of the clinical process. Safety of TENS devices for use during pregnancy or delivery has not been established.

Electronic equipment such as ECG monitors and ECG alarms may not operate properly when TENS is in use. The user must keep the device out of the reach of children. TENS is for external use only.

**Precautions**
Avoid adjusting controls while operating machinery or vehicles. Turn the stimulator off before applying or removing electrodes. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Use only for the specific pain problem as prescribed by the physician, or outside the USA, by a qualified pain management specialist. Effectiveness is dependent upon patient selection by a qualified pain specialist.

**Adverse Reactions**
Possible allergic reaction to tape or gel. Possible skin irritation by a qualified pain specialist. Effectiveness is dependent upon patient selection (long-term) intractable pain and as an adjuvant treatment in the management of post-surgical and post-traumatic acute pain problems.

### Operating Instructions

**General description**

**Device Description / Operation / Display**

(See Figure A)

For safety reasons, the setting controls 7, 8, 9 and 12 are located under the battery compartment cover.

On/Off Switch and Amplitude Control (1, 2)
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**Connector sockets for the Leadwires (3, 4)**
Connection of the electrodes is made using the leadwires with each connector firmly placed into the device sockets.

**Impulse Display Lights (LED, 5 and 6)**
Each of these lights illuminates whenever the device is turned on. At settings in excess of 30 pps (Hz) (7) the lights will appear to be constant.

**Frequency Control Dial (7)**
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- **CONTINUOUS stimulation**: In this position, the set therapy current remains constant for the duration of the therapy session. (Figure B)
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- **MODULATED stimulation**: The set duration of the pulse width is slowly decreased and increased from the set value. (Figure D)
Timer (12)
This switch has four positions: “C” for Continuous stimulation (no timer). “15” for 15 minute timer. (The device will automatically shut off after 15 minutes.) “30” for 30 minute timer. (The device will automatically shut off after 30 minutes). NOTE: Both channels (Fig. A 1 & 2) must be turned off and then back on after the timer has run out to re-start stimulation.

Battery

In order to maintain the functional operation of the Impulse® 3000 T, the batteries will have to be changed periodically. The device is supplied with a 9 volt non-rechargeable battery or special rechargeable battery, e.g., Nickel Metal Hydride (NiMH). All rechargeable batteries are initially sent out without any charge. Allow 16 hours for charging. Warning: Do not recharge disposable batteries.

To change batteries:
- Before opening the battery compartment, check to make sure that the device is switched off—both Amplitude controls (1, 2) must be at the “O” position.
- Slide the battery compartment cover (10) in a downward direction. (The cover does not come off.)
- Remove the battery (11) from the compartment by gently pulling the battery toward the left side of the compartment and lifting it out. Gently insert the new battery by matching the +/– symbol found inside the battery compartment and push the opposite end firmly in, securing the battery in place.
- Slide the battery compartment cover in an upward direction to close.
- Remove the battery if you do not plan to use the device for long periods of time. Otherwise leakage and damage to the device can occur.
- Dispose of batteries in a proper manner.

Tips for Skin Care
Skin should be cleaned prior to placement of the electrodes. If the electrodes do not contain gel, then gel should be applied directly to the skin prior to placement of the electrodes. Electrode Placement Alternatives:
- Place directly over the area from which the pain is emanating.
- Encircle the area of pain.
- Place proximally above the main nerve stem of the peripheral nerve responsible for the pain area.
- On specific points such as trigger points or acupuncture points.
- Place in the area of the pain site.

TENS Treatments

The treatment, when applied independently or in conjunction with medication therapy, should first be attempted with Low Frequency TENS treatment settings. A consistent application of approximately 2 Hz has been shown to produce effective stimulation.

The Amplitude and Width settings should be set as high as possible without causing discomfort. The treatment period should be at least 20 - 30 minutes as the pain-inhibiting effect only commences after approximately 15 - 20 minutes. In the most favorable case, treatment lasting thirty minutes could contribute to a reduction in the need for analgesics. This, however, is dependent upon the seriousness of the patient's condition.

Should Low Frequency TENS treatment not yield the desired result, High Frequency TENS treatment should be applied as follows:

(1) Contact condition: Frequent, repetitive, or deep pain. The pulse width settings are generally set between 50 - 100 μs. However, the wide range of settings on this device allows the treatment to be customized to achieve optimal results for the patient.

The pain-inhibiting effect should commence within a few minutes. The treatment period should be between 20 - 30 minutes. In some cases, desensitizing must be carried out for several applications.

The correct level of stimulation should feel comfortable to the patient and should never be set at levels that cause discomfort. Warning: Only electrodes and leadwires authorized by the device manufacturer should be used.

Safety and Technical Checks

Once a year, a maintenance check should be performed on the device as follows:

- Remove the clear plastic case from the device for damage.
- Visually check the input and output sockets for damage.
- Visually check the device for clarity of reading instructions and indicator decals.
- Visually check that the illumination LED (lights) are operating correctly.
- Visually check the leadwires and electrodes for wear.

Maintenance and Care

- The case housing is made of insulated ABS plastic and can be cleaned with isopropyl alcohol.
- Stubborn stains and spots can be removed with a cleaning agent. Do not submerge this device in any liquid or use excessive cleaning liquid when cleaning the surface area. NOTE: Do not smoke or work with an open flame (e.g., cigarette, candles, etc.) when working with flammable liquids!

Warranty

LIMITED WARRANTY (USA only, unless otherwise noted)*
BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any neurostimulator which malfunctions or proves defective in materials or workmanship under normal use during the period of the Warranty. During this time, BioMedical Life Systems, Inc., will provide all labor and parts necessary to correct such defects or malfunctions free of charge. If the product is no longer available, BioMedical Life Systems, Inc., reserves the right to substitute a comparable product. The consumer-purchaser is responsible for all shipping charges when returning the device to the manufacturer or designated service facility.

EXCLUSIONS
This warranty shall not apply to damage resulting from failure to follow these Instructions, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, leadwires, and conductive gel. These items can be provided by your dealer, but costs for repair or replacement will be the responsibility of the consumer-purchaser.
BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the device. In the USA, some states do not allow the exclusion or limitation of incidental or consequential damages, or do not allow limits on how long an implied warranty lasts, so the above limitation may not apply to you.

NO OTHER WARRANTIES
This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth below. This warranty gives you specific legal rights, and you may also have rights which vary from state to state. If the device case is opened or tampered with in any way, all warranty coverage is void.

*In the USA, unless otherwise indicated, the limited Warranty is three years. Outside the USA, please check with your distributor to ascertain the "Limited Warranty Period."