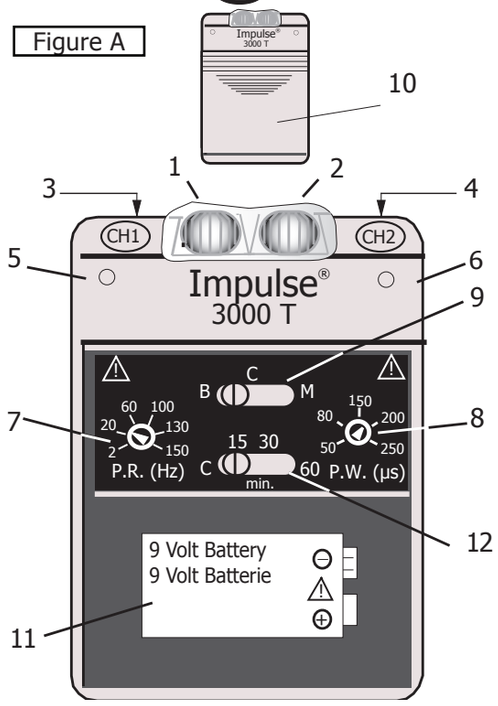
Figure A



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 g)
Power Source	9V Battery, E-block, type 6F22
Channels	Dual
Waveform	Asymmetrical, biphasic square-wave
Frequency	2 - 150 Hz (Hertz or pps)
Impulse Width	50 - 250 microseconds (µs) adjustable
Output	Constant current
Intensity	Continuously adjustable from 0 - 98 ma peak
Continuous	Continuous stimulation (see Figure B)
Burst	8 pulses per burst/2 bursts per second (see Figure C)

Modulation	Decrease/increase of set width of 50% over a five-second period (see Figure D)
Timer	Continuous, 15, 30, 60 minutes
Number of Electrodes/Leadwires	4
Tolerances	+/- 10%

Data recorded across a 500 OHM load resistance

Graphic Symbol Definitions

Refer to operating instructions

An IEC 60601-1 safety standard (type BF)

CE 0086

We herewith declare that the above mentioned product meets the provisions of the Medical Device Directive

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.		
Emissions Test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group 1	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.
RF Emission CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/		
Flicker emissions IEC 61000-3-3	Complies	

This device was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES.

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 transcerebrally (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 or electrode burn.
EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

Operating Instructions

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 underneath 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 channel 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 2 - 150 Hz.

Impulse Width Dial (8)
This dial allows the continuous adjustment of the impulse width between 50 µs and 250 µs. If no instructions regarding the impulse width are otherwise given, set the control dial midway, at 150 µs.

Operating Mode Switch (9)
This switch has 3 positions: C for Continuous stimulation, B for Burst stimulation, and M for Modulated stimulation. (Figures 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)

Figure B
Continuous

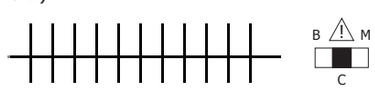


Figure C
Burst

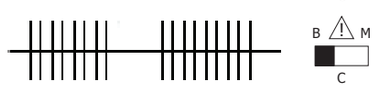


Figure D
Modulated

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). "60" for 60 minute timer. (The device will automatically shut off after 60 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 Hyride (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 pushing the battery toward the left side of the compartment and lifting it out. Gently insert the new battery by matching the +/– end of the battery with the +/– symbol found inside the battery compartment and push the opposite end firmly in, securing the battery in place.
- Slide the battery compartment 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 medicinal therapy, should first be attempted with Low Frequency TENS treatment control 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:

(High Frequency TENS Treatment) Frequencies are found in the range of 100 - 150 Hz. 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:

- Visually check the exterior case of 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 (for example, candles, etc.) when working with flammable liquids!

Malfunctions

Should any malfunctions occur while using this device, check:

- Whether the leadwires and electrodes are correctly connected to the device. The leadwires should be inserted firmly into the device sockets.
- Whether the Impulse Display Light (LED) is illuminated. If not, insert a new battery.
- For possible damage to the leadwires. Change the leadwires if any damage is detected.

Do not attempt to repair a device yourself!

Opening the device case voids the warranty. Please contact the dealer from whom the device was purchased. If they are unable to assist you, please contact:

In the USA and Canada, BioMedical Life Systems, Inc., (760) 727-5600.

In Europe, BMLS BV, Alkmaar, The Netherlands.

This device MUST only be serviced by the manufacturer.

To reorder any accessories or supplies, contact your dealer.

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."

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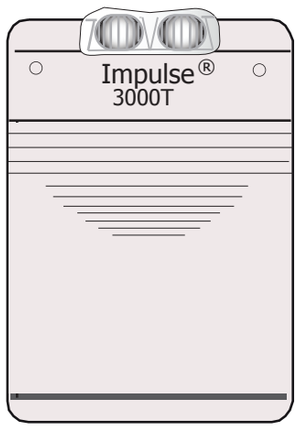
BioMedical Life Systems, Inc.

Transcutaneous Electrical Nerve Stimulator

Impulse® 3000 T



Instructions

Impulse 3000 T ENG 3/15/2016 REV. C