Programming

All pre-programmed stimulation patterns can be programmed for individual needs:
Increase or decrease the P.R. value by increasing the (+) or decreasing the (-) P.R. button (8). The P.R. is adjustable from 1-120 Hz in 5 Hz increments. Increase or decrease the P.W. value by increasing the (+) or decreasing (-) P.W. button (7). The P.W is adjustable from 25-250 µS.

- Select the desired treatment time by pressing the Timer Button (10) until the desired treatment time is displayed; Continuous, Adjustable 10, 15, 20, 30, 45, 60 minutes When a treatment time has been selected, the device will count down the elapsed time and automatically turn off.
- Increase or decrease the intensity of the device by pressing down the +/– for CH1 (4) or CH2 (5). There are 20 levels of intensity available.
- If a new mode selection (6) is made during treatment, the intensity of the device automatically drops to Level 0.
- To immediately turn off the device at any time press the On/Off (9) button.
- After the treatment period, disconnect leadwires from device (1 & 2). Store electrodes as per instructions on electrode package. If the device is not going to be used for long periods of time the batteries should be removed (11).

Batteries

In order to maintain the functional operation of the Impulse®TENS^{D5} the batteries will have to be changed periodically. The device is supplied with 2 AA Alkaline batteries.

To change batteries:

- Before opening the battery compartment, check to make sure that the device is switched off (9).
- Slide the battery compartment cover (11) down.
- Remove the batteries (11) from the compartment. Gently insert the new batteries by matching the +/– end of each battery with the +/– symbol found inside the battery compartment.
- Replace the battery compartment cover and slide up to close.
- Remove the batteries if you do not plan to use the device for long periods of time. Otherwise leakage and damage to the device can occur.

Recommendations for the Therapist

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.

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 will, however, be 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 10 - 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 of the LCD is operating correctly.
- Visually check the leadwires and electrodes for wear.

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 screen (LCD) is illuminated. If not, insert new batteries.
- 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.

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!

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."

BioMedical Life Systems, Inc.
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Vista, California 92081-7830,
USA
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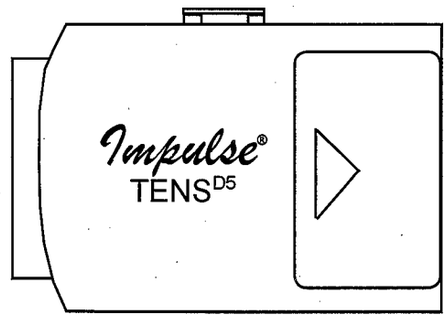
1800 AA Alkmaar,
Netherlands

BioMedical Life Systems,Inc.

Transcutaneous Electrical Nerve Stimulator

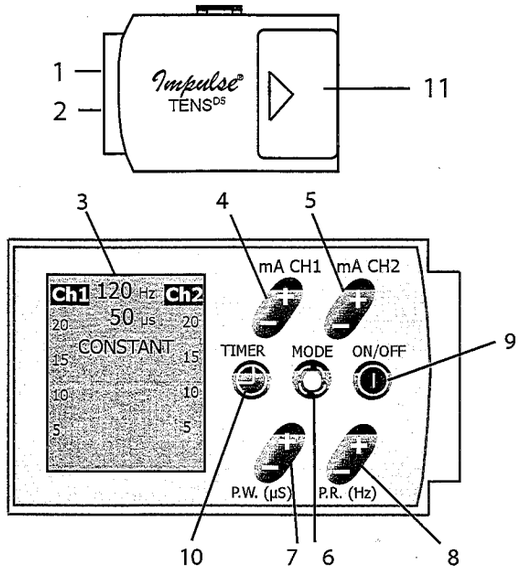
Impulse® TENS^{D5}



Instructions

IMPULSE TENS D5 ENGLISH 04/22/2006 REV.NEW

1



Accessories

2 Leadwires with electrodes
1 Instruction Booklet
2 Batteries
1 Carry Pouch

Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc. We do not recommend the use of rechargeable batteries, as they may weaken the performance and/or read-out of the device.

Technical Data

Dimensions	4.2" x 2.9" x 1.4"(10.7cm x 7.4cm x 4cm)
Weight	3.35 oz (94.97 grams)
Channels	Dual
Power Supply	2 AA Batteries, Type LR6
Waveform	Symmetrical, biphasic square wave
Pulse Rate (Hz)	1 - 120 Hz (Hertz or pps) adjustable
Pulse Width (µS)	25 - 250 microseconds (µs) adjustable
Constant	Continuous stimulation. Pulse Rate/Pulse Width are adjustable.
Pulse Rate Modulation	Pulse Rate modulates from 100Hz down to 20Hz over a 15 second cycle (7.5 seconds down 7.5 seconds up. Pulse width is adjustable.
Pulse Width Modulation	Pulse width modulates from 125-250µS and back down over a 5 second cycle (2.5 seconds down, 2.5 seconds up). Pulse Rate is adjustable.

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Burst I	One second ON. One second OFF. Pulse Rate and Pulse Width are adjustable.
Burst II	Seven Pulses per burst, 2 bursts per second. Pulse Width is adjustable.
Output	Constant current
Intensity	Continuously adjustable from 0- 100 mA peak to peak
Output Voltage	Continuously adjustable from 0-50 V peak to peak
Tolerances	+/- 1%

(Data was recorded across a 500 OHM resistance load.)

Graphic Symbol Definitions

Refer to operating instructions

An IEC 601-1 safety standard (type BF)

CE 0086

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

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. 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. Using this device in proximity to any object that produces an electromagnetic current such as a microwave oven or cellular telephone could affect the performance of the device. The user must keep the device out of the reach of children. TENS is for external use only.

Use of electrodes and accessories
Electrodes used with the device should be no smaller than $^3/_4$" in diameter. Please note that the smaller the size of the electrode used, the greater the intensity of stimulation at the electrode site which increases the likelihood of skin irritation at the site. Only BioMedical Life Systems authorized electrodes and accessories are to be used with this device. If you have any questions, please contact either your dealer/distributor or BioMedical Life Systems directly.

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

Adverse Reactions
Possible allergic reaction to tape or gel. Possible skin irritation or electrode burn.

Operating Instructions

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.

Instructions for use

- Attach leadwires to Channel 1 (CH1) and, if instructed by clinician, to Channel 2 (CH2). (1 and 2)
- Attach electrodes to leadwires following instructions on electrode packaging.
- Place electrodes on body as directed by clinician.
- Turn on device (9).
- Readout similar to (3) will appear on Display Screen.
- **If no electrodes are applied to the body, a safety feature is enabled and the amplitude drops to zero and an "open electrode" symbol flashes on the screen.**

Programming a Stimulation Pattern

- Select the desired stimulation pattern by pushing the Mode Button (6) until the desired stimulation pattern is displayed on the Screen (3). The patterns will appear in the following sequence:

CONSTANT	= Constant/Continuous
BURST I	= BURST I
BURST II	= BURST II
PW. MOD.	= Pulse Width Modulation
PR. MOD.	= Pulse Rate Modulation

Select the desired pre-programmed stimulation pattern by pushing the Mode Button (6) until the desired patten is displayed on the screen (3).

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Figure A
CONST

Figure B
PW MOD

Figure C
PR MOD

Figure D
BURST I & II