

# **Fisher-Wallace**

## **BODY STIMULATOR**

*Professional*  
**INSTRUMENT MANUAL**

**SBL 501-M**

Federal Law (USAJ restricts this device to sale by, or on the order of an M.D., D.O.,  
or a D.C. licensed in the State in which he practices.

Fisher-Wallace Laboratories, LLC

MODEL # SBL501-M

FISHER-WALLACE Body STIMULATOR

PROFESSIONAL INSTRUCTION MANUAL

TABLE OF CONTENTS	Page
1.0 Introduction	2
2.0 Contraindications	2
3.0 Warnings	2
4.0 Precautions	3
5.0 Adverse Reactions	3
6.0 Federal Labeling	3
7.0 Theory of Operation	3
8.0 Indications for Use of the SBL501-M	4
9.0 Device Controls	4
10.0 Skin Preparation	5
11.0 Application of the Device	5
a. Electrode Preparation	5
b. Setting Device Controls	5
12.0 Electrode Placement	6
13.0 Battery Replacement	6
14.0 Troubleshooting	6
15.0 Device Specification	7
16.0 Limited Warranty	8

## 1.0 INTRODUCTION

The FISHER-WALLACE Body Stimulator Model # SBL501-M is a portable battery powered pulse generator used for symptomatic relief of chronic intractable pain, post-traumatic acute pain and postsurgical pain.

The FISHER-WALLACE Body Stimulator delivers an electrical stimulus which is conducted by the electrical cables to either water/wet sponges (supplied with the device) or self adhesive electrically conducting contacts to the tissue to which they are applied. Frequently, the FISHER-WALLACE Body Stimulator contacts can be applied from the skin over the spinal column to the skin over the peripheral nerves associated with the pain site.

## 2.0 Contraindications

Patients having cardiac pacemakers of the demand or sensing type should be aware that actions of the pacemakers may be inhibited or otherwise interfered with by this Transcutaneous Electrical Nerve Stimulator.

**a.** This device should not be used around the Carotid sinus or around the orbits of the eyes.

**b.** Patients with known or suspected heart disease should not be stimulated.

**c.** Patients who react poorly to the idea of electrical stimulation of any kind should not use this device.

**d.** Do not use this device transcerebrally.

**e.** This device must not be used until the Physician has established the etiology of the Pain through a differential diagnosis. This device must be used only for the purpose for which a physician has prescribed. This device must only be used by the person for whom the prescription has been written.

## 3. Warnings

**a.** The safety of TENS devices for use during pregnancy or delivery has not been established.

**b.** TENS is not effective for pain of central origin.

**c.** TENS devices should be used only under the continued supervision of a physician.

**d.** TENS devices have no curative value.

**e.** TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.

**f.** The User must keep the device out of reach of children.

**g.** Electronic monitoring equipment (such as ECG monitors ECG alarms) may not operate properly when TENS stimulation is in use.

#### 4. Precautions -

**a.** Isolated cases of skin irritation may occur at the site of electrode placement following long term application.

**b.** Effectiveness is dependent upon patient selection and patient compliance.

#### 5. Adverse Reactions -

**a.** There may be skin irritation with people who have sensitive skin. Proceed cautiously with short time exposures to prove skin viability.

**b.** Electrode burns can occur if the sponge deteriorates and contact is made between the skin and the metal contact behind the sponge.

#### 6. Federal Labeling -

Federal law (USA) restricts this device to sale by, or on the order of an M.D., D.O., or a D.C., licensed in the State in which they practice.

### 7.0 THEORY OF OPERATION

**a.** The FISHER-WALLACE Body Stimulator is an electronic signal generator which has been shown to provide symptomatic relief of chronic intractable pain, post-traumatic acute pain and postoperative pain.

The FISHER-WALLACE Body Stimulator provides electrical connection from the signal generator through wire cables to the skin contacting method (either water/wet sponges (supplied with the device) or appropriate self adhesive electrically conductive contacts).

**b.** The electronic waveform of the FISHER-WALLACE Body Stimulator contains a 15,000Hz square wave carrier which is rectified, varying from zero to a maximum of 4 milliamperes. The first modulating signal of 15Hz provides an "on" time of 50 milliseconds and an "off" time of 16.7

milliseconds. The second modulating signal of 500hz changes the "on" time series of 15,000hz carrier pulses (750pulses in 50 milliseconds) into 25 smaller bursts of 15 pulses each of the 15,000hz carrier signal(375 pulses in the same 50 milliseconds). (Waveform sketches are appended hereto.)

**c.** The pulse period for the basic carrier waveform of 15,000Hz is 66.7 microseconds (50% duty cycle).

**d.** The pulse period for the 1st Modulator of 15Hz is 66.7 milliseconds (75 % duty cycle).

**e.** The pulse period for the 2nd Modulator of 500Hz is 2 milliseconds (50 % duty cycle).

**f.** The output voltage is variable from zero to 40 volts and then voltage limited. Therefore, load impedances of up to 10,000 ohms will be able to have constant current up to 4 milliamperes. However, beyond 10,000 ohms, the constant current is limited inversely with the load, (ie: A patient with a 20,000 ohm impedance will be able to receive a maximum of 2 milliamperes.)

**g.** A 9 volt alkaline battery is supplied, (non-rechargeable)

## 8. INDICATIONS FOR OSE OF THE SBL501-M

The Model SBL501-M device is an electronic signal generator which can provide symptomatic relief of chronic intractable pain, post-traumatic acute pain and post-surgical pain.

## 9. DEVICE CONTROLS

The FISHER-WALLACE Body Stimulator Model #SBL501-M has only one knob which encompasses both the on/off switch for turning the device on or off as well as the intensity control for adjusting the level of current which is delivered to the tissue.

**a.** There are two electrode lead receptacles:

1.Red - to receive the Red (+) plug

2.Black- to receive the Black (-) plug

**b.** There is one red LED indicator which flashes for the total time (ten [10] Minutes, set at the factory) when the device is turned on, no matter what the intensity.

**c.** There are four (4) amber LED indicators which flash

according to the intensity:

<u>INTENSITY (Peak ma) No. OF Flashing INDICATORS</u>	
1	1
2	2
3	3
4	4

**d.** Low Battery is indicated by the non indication of the "on" light when the on/off switch is turned into the "on" position.

#### 10. SKIN PREPARATION

Good skin care is important in minimizing any skin irritations that may be encountered with the active use of the electrodes. Prepare the skin before using the FISHER-WALLACE Body Stimulator by:

**a.** Thoroughly washing the skin sites where the electrodes will be placed with a mild soap and water solution to remove non-conducting skin oils.

**b.** Rinsing the area with warm water and drying thoroughly.

#### 11. APPLICATION OF THE DEVICE

##### a. Electrode Preparation

Place the Cellulose Sponge into the electrode receptacle in such a way that the edge of the receptacle fits into the slit depression in the side of the Sponge. This procedure should be done with the Sponge very wet and pliable. Connect the Electrode Receptacle to the Cable using the snap fastener connection. Insert the other end of the Cable via the plug into the Receptacle on the FISHER-WALLACE Body stimulator: Red Plug into Red Receptacle; Black Plug into Black Receptacle. The lead wire cables are color coded for convenience and identification.

##### b. Setting Device Controls

While holding the device in your hand with the Red and Black Receptacles in the upper right side, rotate the intensity knob toward your body (Counterclockwise) using the right thumb. Be sure the device starts from the off position

(Listen for and feel the click when the device is turned to the "off" position.). To start the stimulation, rotate the intensity knob clockwise (Away from the body), listen for and feel the click when the device goes from the "off" position to the "on" position. Continue clockwise rotation, increasing the intensity until the patient feels a sensation (Itching, pins & needles, warmth or mosquito bite. Then turn the intensity knob (Reducing) counterclockwise until the sensation disappears. If the patient feels the perception again, turn it down again. The patient does not have to feel the sensation in order for benefit to be derived. In fact, many people do not feel the sensation and yet, they get benefit, nonetheless.

## 12. Electrode Placement

### Peripheral Placement

For reducing the pain of a particular body part, place the red contact on the spinous process at or above the level of the neural input to the particular body part. Place the black contact directly on the exquisite pain site of the particular body part. Treatment time is up to twenty (20) minutes. Sponge contacts must be wet but not dripping.

## 13. Battery Replacement

In order to replace the battery, remove battery compartment cover by sliding the cover into the open position and detach the nine (9) volt battery from the battery clip and replace with another alkaline nine (9) volt battery. A rechargeable battery can be used if it fits the mechanical configuration of a standard nine (9) volt battery.

## 14. Trouble Shooting

**a.** If the "on" LED lamp does not illuminate when the on switch is turned on, replace the nine (9) volt battery and turn the device on again. If it still does not illuminate, return the device for repair.

**b.** If the "on" LED lamp does go on but the intensity lamps do not illuminate, be sure the sponges are clean and wet; touch sponges together and raise the intensity; replace the wires in the output receptacles with a paper clip rebent to short circuit the Red and the Black receptacles. If the intensity lamps still do not illuminate, return the device for repair.

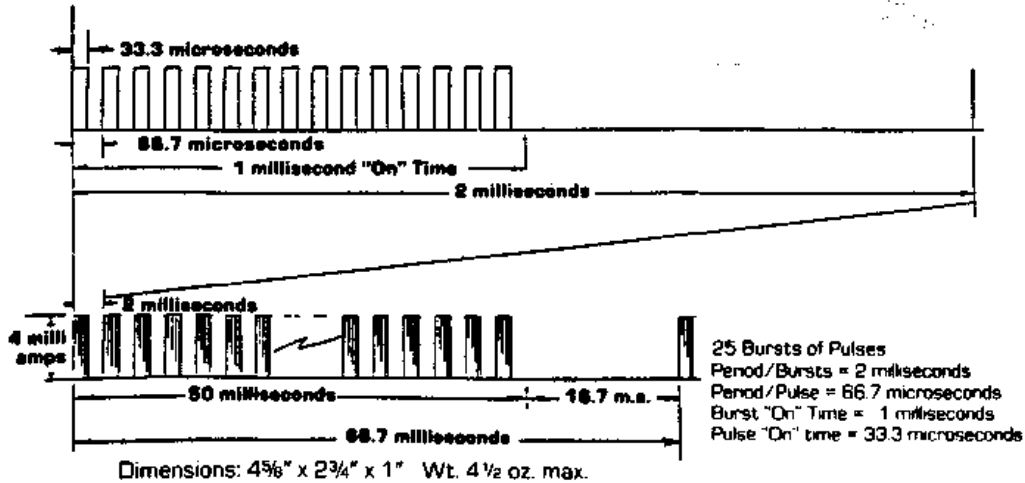
## 15. Device Specification\*

PARAMETER _____	NOMINAL VALUE +/-10%
Output Amplitude into 1,000 Ohms	40 volts Pk.
Rate	15/500/15,000Hz
Pulse Width	33 microseconds
Maximum Charge per Pulse	.13 microcoulombs
On Time per Burst	50 milliseconds
Off Time per Burst	16.7 milliseconds
Power Source	9 volt Alkaline Battery
Contact Dimension	Approx. 1.75" Diam
Power Density:	Power Density
	Load Impedance
	Ohms
	Watts/sq.in.
	<hr/>
	200
	.0013
	1,000
	.0067
	10,000
	.0667

Waveform = Asymmetrical monopolar positive square wave with double modulation. This waveform contains 25 bursts of 15 pulses each. Each pulse is 33.3 microsecond duration in a pulse period of 66.7 microseconds. See appended sketch of the waveform.

•Note; This device can not be connected to the power line.

## Waveform Analysis



### 16.0 LIMITED WARRANTY

Fisher-Wallace Laboratories, LLC warrants each new FISHER-WALLACE Body Stimulator (exclusive of batteries) to be free from defects in materials and workmanship for a period of 18 months and accessories (not including disposables) for a period of 90 days following the delivery of the FISHER-WALLACE Body Stimulator to the original purchaser. The obligation of Fisher-Wallace Laboratories, LLC under this warranty is expressly limited solely and exclusively to the repair or replacement of the unit or any parts thereof, which to MEDI Consultants satisfaction, shall have become defective during the warranty period, and which shall have been returned to Fisher-Wallace Laboratories, LLC within 30 days after the discovery of the defect by the original purchaser. This warranty does not extend to any liability for medical or dental expenses, or for any other direct, indirect or consequential damages caused by failure, defect or malfunction of the FISHER-WALLACE Body Stimulator, except as herein provided, whether such damage claim shall be based on contract, tort, breach of warranty, or otherwise.

This warranty shall not apply to any FISHER-WALLACE Body Stimulator which has been repaired, tampered with or altered by someone other than a duly authorized MEDI Consultant, Inc. representative, or which has been subjected to negligence, accident, mishandling or which has not been used in accordance with the enclosed instructions or for the stated purposes.

This warranty is expressly limited solely to the

original purchaser (user) and does not extend to any transferee, assignee or subsequent purchaser or user of the FISHER-WALLACE Body Stimulator.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY MADE OR WHICH MAY BE DEEMED TO HAVE BEEN MADE BY FISHER-WALLACE LABORATORIES, LLC AND IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO PERSON OR ENTITY HAS ANY AUTHORITY TO BIND FISHER-WALLACE LABORATORIES, LLC TO ANY WARRANTY, GUARANTEE OR REPRESENTATION EXCEPT AS SPECIFICALLY SET FORTH HEREIN.