



THE FISHER WALLACE CRANIAL STIMULATOR



INSTRUMENT MANUAL

**Federal Law restricts this device to sale by or on the order of a health care practitioner,
licensed in the state in which he/she practices (US only).**

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1.0 INTRODUCTION

The Fisher Wallace Cranial Stimulator (Model FW-100), formerly the Liss Cranial Stimulator, is a portable battery powered pulse generator used to reduce the symptoms of Depression, Anxiety and Insomnia. It delivers a micro-electrical stimulus which is conducted by electrical cables to wet sponges (supplied with the device) and then to the tissue to which the sponges are applied.

Please see the instructional video on the Fisher Wallace website (www.fisherwallace.com) for a demonstration on how the device is used.

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 the Cranial Electrotherapy Stimulator.

3.0 WARNINGS

- a. The safety of CES devices such as the Fisher Wallace Cranial Stimulator for use during pregnancy or delivery has not been established.
- b. CES devices should be used only under the continued supervision of a physician.
- c. CES is a symptomatic treatment and as such suppresses the symptoms of Depression, Anxiety, and Insomnia that would otherwise serve as a stimulus to see a physician.
- d. Keep the device out of reach of children.
- e. Electronic monitoring equipment (such as ECG monitors, ECG alarms) may not operate properly when CES stimulation is in use

4.0 PRECAUTIONS

- a. Patients whose skin is irritated around either electrode site should discontinue the use of this device.
- b. This device should not be used on the neck.
- c. This device must not be used until a health practitioner has diagnosed the patient

and prescribed the device. This device must be used only for the purpose for which

d. health practitioner has prescribed. This device must only be used by the person for whom the prescription has been written.

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

f. Effectiveness is dependant upon patient selection and compliance.

5.0 ADVERSE REACTIONS

a. There may be skin irritation with people who have sensitive skin. Proceed cautiously with brief 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, or if the sponges are not thoroughly wet before each use.

c. In rare cases, a mild headache can occur upon use.

6.0 FEDERAL LABELING

Federal Law restricts this device to sale by or on the order of a health care practitioner, licensed in the state in which he/she practices (US only).

7.0 THEORY OF OPERATION

a. The Fisher Wallace Cranial Stimulator (Model FW-100), formerly the Liss Cranial Stimulator, is a portable battery powered pulse generator used to reduce the symptoms of Depression, Anxiety and Insomnia. It delivers a micro-electrical stimulus which is conducted by the electrical cables to wet sponges (sponges are supplied with the device) and then to the tissue to which the sponges are applied.

b. The electronic waveform of the Fisher Wallace Cranial Stimulator contains a 15,000 hi 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 (750 pulses in 50 milliseconds) into 25 smaller bursts of 15 pulses each of the 15,000hz carrier signal 375 pulses in the same 50 milliseconds. The subject device is a bipolar version of a CES device, wherein the first major burst of energy (50

milliseconds is positive [above the zero axis], followed by a 16.7 millisecond "OFF " time, is then followed by a second major burst of energy (50 milliseconds is negative [below the axis]) followed by a 16.7 millisecond "OFF " time. Thus, the consecutive positive burst and OFF time is followed by an equal and opposite negative burst and OFF time, balancing the direct current component to zero.

c. The pulse period for the basis 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, first positive and then negative. 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 10,000 ohm impedance will be able to receive a maximum of 2 milliamperes).

g. Two (2) AA batteries are supplied.

8.0 INDICATIONS FOR USE

The Fisher Wallace Cranial Stimulator (Model FW-100) is a portable battery powered pulse generator used to reduce the symptoms of Depression, Anxiety and Insomnia.

Your physician will prescribe the appropriate duration to utilize the Fisher Wallace Cranial Stimulator (Model FW-100).

Typical usage of the Cranial Stimulator (Model FW-100) begins with daily application of the device for twenty (20) minutes over a period of approximately 30-45 days. After this initial period of 30-45 of daily use, patients should use the Fisher Wallace Cranial Stimulator (Model FW-100) twice a week for twenty (20) minutes in order to ensure that they continue receiving beneficial effects of the device.

The device may be used more than once per day, as directed by the patient's health care practitioner. Doctors treating patients who do not respond to daily treatment with the Fisher Wallace Cranial Stimulator are finding success when the device is used twice (2X) per day (typically once in the morning and once in the evening).

The device should only be used on level #1 or #2 when applied to the head.

9.0 DEVICE CONTROLS

Please see the instructional video on the Fisher Wallace website (www.fisherwallace.com) for a demonstration on how the device is used.

The Fisher Wallace Cranial Stimulator 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. Two electrode lead receptacles are supplied.
- b. There is a green LED indicator light that flashes when the device is turned ON, no matter what the intensity.
- c. There are four (4) yellow LED indicator lights that flash according to the intensity of stimulation. To treat the indications described above, users should NOT set the device beyond the second (#2) indicator. The indicator lights will not flash at all if an inadequate connection is made between the electrodes (sponges) and the cranium.

10.0 SKIN PREPARATION

Good skin care is important in minimizing any skin irritations that may be encountered with the active use of the electrodes. Thoroughly wash the skin sites where the electrodes will be placed.

11.0 APPLICATION OF THE DEVICE

Please see the instructional video on the Fisher Wallace website (www.fisherwallace.com) for a demonstration on how the device is used.

11.1 Electrode Preparation

Place the wet cellulose sponges into the electrode receptacles in such a way that the edge of the receptacles overlap the sides of the sponges. Insert the cables extending from the electrodes into the stimulator. Black and red colors should be matched.

11.2 Setting the Device Controls

While holding the device, rotate the intensity knob toward your body (clockwise), using the right thumb, to be sure the device is in 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 counterclockwise (away from the body) and listen for and feel the click when the device goes from the OFF position to the ON position. The green ON light should illuminate. If the green ON light does not illuminate, replace the batteries with fresh ones.

Once the green ON light illuminates, continue counterclockwise rotation until the first (#1) or second (#2) indicator light flashes yellow. When the first or second indicator light flashes yellow, the user has reached the intensity recommended for treatment of Depression, Anxiety or Insomnia. The patient may feel a brief sensation (itching, pins & needles, warmth, or "light" flicker when it is used on the head). The patient does not have to feel the sensation in order for benefit to be derived.

11.3 Electrode Placement

Please see the instructional video on the Fisher Wallace website (www.fisherwallace.com) for a demonstration on how the device is used. See the diagrams below for electrode placement.

11.3.1 Cranial Placement

For reducing the symptoms of Depression, Anxiety or Insomnia, place the headband on the head so that it runs just above the eyebrows (see figure 11.1). Then place each electrode (sponges MUST be very moist) beneath the headband



Figure 11.1



Figure 11.2

on the temple area just above the sideburns (see figure 11.2). The sponges and the scalp beneath the sponges must be sufficiently wet. Some dripping down the

face may occur.

After twenty (20) minutes, an audible beep sound will signal the end of the session, and the device will shut off automatically.

12.0 BATTERY REPLACEMENT

In order to replace the battery, remove the battery compartment cover on the back of the device by sliding the cover into the open position. Only use high quality AA batteries.

13.0 TROUBLE SHOOTING

If the green “ON” LED light does not illuminate when the switch is turned ON, replace the batteries and turn the device ON again. If it still does not illuminate, contact Fisher Wallace for repair or replacement instructions.

If the “ON” LED light does illuminate but the yellow intensity indicator lights do not illuminate, be sure the sponges are clean and thoroughly wet. Touch sponges together and see if the indicator lights go on. If the lights still do not illuminate, contact Fisher Wallace for repair or return instructions.

If the yellow indicator lights do not illuminate when you are attempting to use the device, make sure the sponges are sufficiently wet. Also make sure that the hair and scalp in contact with the sponges are sufficiently wet – if they are not wet enough, conductivity will not occur and the yellow lights will not illuminate.

There are four (#1 thru #4) yellow indicator lights that flash according to the intensity of stimulation. To treat Depression, Anxiety & Insomnia, patients should NOT set the device beyond the second (#2) yellow indicator.

Typically, the effects of using the device are fully achieved after 30-45 days of daily use. Doctors treating patients who do not respond to daily treatment with the Fisher Wallace Cranial Stimulator are finding success when the device is used twice (2X) per day (typically once in the morning and once in the evening). Doctors are also finding success treating patients using level #2 (yellow light #2) who do not respond adequately to level #1.

Please contact Fisher Wallace Laboratories if you experience any difficulty using the device. A company representative will respond to you promptly.

14.0 DEVICE SPECIFICATIONS

<u>PARAMETER</u>	<u>NOMINAL VALUE</u>
Output Amplitude (into 1.000 Ohms)	4.0 volts
Rate	15/500/15.000 Hz
Pulse Width	33 microseconds
Maximum Charge per Pulse	0.13 microcoulombs
On Time per Burst	50 milliseconds
Off Time per Burst	16.7 milliseconds

Waveform: symmetrical bipolar 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.)

Power Source: Two (2) AA Batteries
Contact dimension: Approx. 1.75" diameter

<u>Load Impedance (Ohms)</u>	<u>Power Density (Watts/sq. in.)</u>
200	0.0013
1,000	0.0067
10,000	0.0667

15.0 LIMITED WARRANTY

Fisher-Wallace Laboratories warrants each new Fisher Wallace Cranial Stimulator (exclusive of batteries) to be free from defects in materials and workmanship for a period of one (1) year and accessories (not including disposables) for a period of one (1) year following the delivery of the Fisher Wallace Cranial Stimulator to the original purchaser. The obligation of Fisher Wallace Laboratories under this warranty is expressly limited solely and exclusively to the repair or replacement of the unit or any parts thereof, which to Fisher Wallace's satisfaction, shall have become defective during the warranty period, and which shall have been returned to Fisher-Wallace Laboratories 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 the failure, defect or malfunction of the Fisher Wallace Cranial 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 Cranial Stimulator which has been repaired, tampered with or altered by someone other than a Fisher Wallace Laboratories representative or technician, 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 Cranial Stimulator.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY MADE OR WHICH MAY BE DEEMED TO HAVE BEEN MADE BY FISHER WALLACE LABORATORIES 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 TO ANY WARRANTY, GUARANTEE OR REPRESENTATION EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

16.0 60-DAY GUARANTEE

If the device does not successfully treat the purchaser's symptoms within sixty (60) days after the device is delivered to purchaser, the device may be returned for a full refund. Shipping charges and add-on accessories will not be reimbursed.