THE FISHER WALLACE STIMULATOR FOR THE TREATMENT OF PAIN ON THE BODY
INSTRUCTION MANUAL **Call us with any questions: (800) 692 - 4380**

1.0 INTRODUCTION

The Fisher Wallace Stimulator is a portable, battery-powered device which has been cleared by the FDA for symptomatic relief of chronic pain, post-traumatic acute pain and post-surgical pain when used on the body. The device is also cleared by the FDA for the treatment of depression, anxiety and insomnia. Although the device poses no significant risks to health, patients should be monitored by their physician at least once every three months while using the device; more frequent monitoring is recommended. **Do not attempt to reduce or cease use of other medication without first consulting your doctor.**

The device delivers a micro-electrical stimulus (1-4 mA) that is carried by electrical cables to wet sponges (supplied with the device) that are applied to the skin. When treating site-specific pain on the body, the electrodes are placed on the body. As clearly illustrated in this manual on pages 6-12, the red wire electrode is typically placed at the rear base of the neck and the black wire electrode is placed on the pain site (with the exception of gastro pain treatment). The electrodes are secured to the body with Velcro body straps, which are included in the kit.

Read section 10.0 APPLICATION OF THE DEVICE ON THE BODY for instructions for use, as well as the Treatment Diagrams on pages 6-12 for guidance regarding the treatment of Back Pain, Shoulder Pain, Gastro Pain, Elbow Pain, Phantom Limb Pain, Arthritic Pain and Neck Pain.

Please email us at info@fisherwallace.com or call us at (800) 692 - 4380 with any questions.

2.0 CONTRAINDICATIONS

The device is contraindicated for use in patients who have demand or sensing type cardiac pacemakers.

3.0 WARNINGS

Keep the device out of the reach of children. Electronic monitoring equipment (such as ECG monitors, ECG alarms) may not operate properly when CES stimulation is in use. High Frequency surgical equipment may not be used when CES stimulation is in use. Do not operate the CES stimulator in close proximity to short-wave or microwave therapy equipment.
This device is not suitable for use with oxygen or in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide.

4.0 PRECAUTIONS

This device should not be used on the throat or neck, except the rear base of the neck as indicated in the diagrams for treating pain (see the Chronic Pain Instruction Manual). This device should not be used on the eyes. This device should not be used on or near areas of the body, including the head, that contain implanted devices, such as stimulators, stents, and active or inactive implants such as deep brain stimulators and vagus nerve stimulators. Patients should avoid using the device near areas of the body where there is embedded shrapnel or metal plates. There is no danger in using the device if you have dental fillings.
Do not allow water to enter this device. The Fisher Wallace Stimulator should not be exposed to environmental conditions where the system may get wet.

5.0 ADVERSE REACTIONS (VERY RARE)

Skin irritation may occur at the site of sponge electrode placement, especially if the sponges deteriorate (sponges should be replaced EVERY TWO WEEKS) or if contact is made between the skin and the metal part of the sponge receptacle, or if the sponges are not thoroughly wet before each use. A mild headache or dizziness may occur, and should cease after you stop using the device. Such reactions are very rare.

6.0 FEDERAL LABELING

Federal Law (USA) states that this device must only be purchased by or under the order of a health care practitioner, licensed in the state in which he/she practices.

7.0 INDICATIONS FOR USE

The Fisher Wallace Stimulator is a portable battery powered pulse generator that may be used for symptomatic relief of chronic pain, post-traumatic acute pain and post-surgical pain. Your physician will prescribe the appropriate duration to utilize the Fisher Wallace Stimulator. Please refer to the enclosed diagrams regarding electrode placement and standard treatment durations. **Typically, patients should use the device on the body two to three times a day for twenty to forty minutes per treatment session, at Level #3 or #4.**

8.0 DEVICE CONTROLS

The Fisher Wallace Stimulator has only one knob that encompasses both the ON/OFF switch for turning the device ON or OFF as well as adjusting the level of current.

There is a green LED indicator light that flashes when the device is turned ON.

There are four (4) yellow LED indicator lights that flash according to the intensity of stimulation. Level #2 is typically used when the sponge electrodes are placed on the head, and level #3 and #4 are typically used when the sponge electrodes are placed on the body.

Both the green and yellow lights flicker when lit – this is normal.

9.0 SKIN PREPARATION

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

10.0 APPLICATION OF THE DEVICE ON THE BODY

To treat pain on a particular area of the body, such as the lower back or elbow, apply the red-lead sponge electrodes to the rear base of the neck (except when treating gastro pain) and the black-lead electrode to the pain area. Use the Velcro straps to hold the electrodes in place. Refer to the body diagrams below on pages 6-12 for electrode placement and application. If you have any questions, please call or email us.

10.1 Electrode Preparation

New headsets come with new sponges (dehydrated yellow disks) already installed in the white sponge receptacles. The sponges will expand when submerged in water. You may wet the sponges separately or while they are in the plastic receptacles. The entire plastic sponge receptacle, including the wire, may be dunked into water. The wet sponges should fit into the white receptacles in such a way that the edge of the receptacles overlaps the sides of the sponges.

Snap the red and black wires onto the receptacles and then connect the other ends of the wires into the stimulator. Black and red colors should be matched.

After use, sponges will dry more quickly if removed from the receptacles and allowed to dry by themselves.

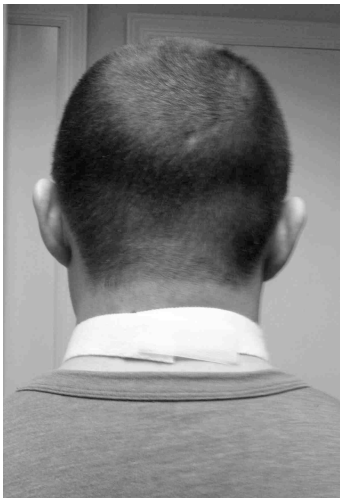
SPONGES SHOULD BE REPLACED EVERY 2-4 WEEKS FOR OPTIMAL PERFORMANCE.
Replacement sponges may be purchased on www.FisherWallace.com.

10.2 Electrode Placement

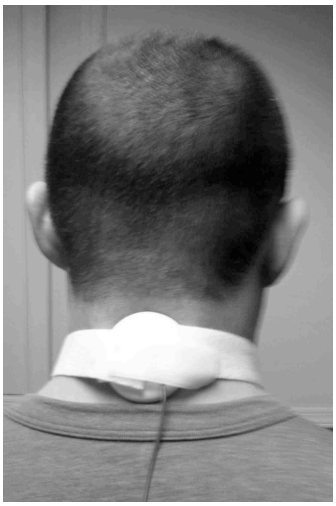
Please refer to the diagrams on pages 6-12 regarding electrode placement and standard treatment durations.

Make sure the sponges are wet. Use the enclosed Velcro body straps to secure the red wire electrode to the rear base of the neck (see below) and the black wire electrode to the area of the body that is experiencing pain as indicated in the diagrams.

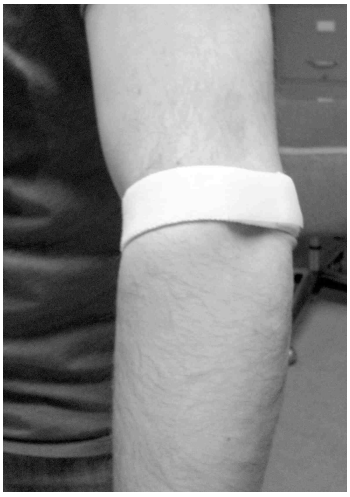
Below is an example of how to use the Velcro body straps to secure the sponge electrodes. You may use other kinds of straps if you prefer, as long as the sponge electrodes are secure:



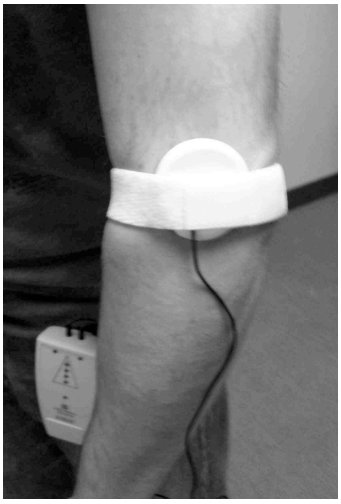
Velcro Strap on base of neck



Red Wire sponge electrode tucked beneath strap, wet sponge against skin



Velcro Strap on elbow



Black Wire sponge electrode tucked beneath strap, wet sponge against skin

10.3 Treatment Duration

When used on the body, the device may be used 2-3 times a day, for 20-40 minutes per treatment session. The device will turn off automatically after 20 minutes. To reactivate the device for another 20 minutes, turn the dial clockwise to the OFF position until you hear an audible click, and then turn the device back on.

10.5 Device cleaning

The device and headset should be thoroughly cleaned every two weeks. To clean the device, remove the black and red wires from the base unit, remove the old sponges from the sponge electrodes, dampen a cloth or paper towel with alcohol and clean the inside and outside of the plastic electrode receptacles in a circular motion. Insert a new pair of sponges and dispose of used sponges. To clean the base unit, dampen a cloth or a paper towel

with alcohol and wipe down the base unit.

Once clean, reinsert the wires into the base unit, matching the wire colors to the circles on the base unit. Now you can continue to use the device.

11.0 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. Use only high quality AA batteries.

12.0 TROUBLE SHOOTING

If your device turns off before the 20 minutes are up, or when the device is set down on a table or lightly jarred or tapped, re-insert the batteries. Sometimes the batteries will misalign with the metal receptors in the battery compartment and as a result, the device will turn off when lightly jarred or tapped.

If the green "ON" light does not illuminate when the device is turned ON, first turn the device completely OFF by rotating the dial clockwise until you hear a click, then try turning the device ON again. Replace the batteries with fresh ones if you still have trouble.

If the yellow indicator lights (1-4) do not illuminate, be sure the sponges are new, clean and thoroughly wet. The hair / skin beneath the sponge electrodes must also be sufficiently wet. People with thick hair may have more difficulty wetting the hair enough to cause the electrodes to conduct. Some people with small heads will require a tighter headband to make the electrodes work properly – adequate pressure is needed against the electrodes by the headband.

To test if the electrodes are working, press the two sponge electrodes together (like an "Oreo cookie"), turn the device ON (green light flashing), and, while continuing to squeeze the sponge electrodes together, continue dialing up (counterclockwise) until you see the yellow lights illuminate.

If the yellow lights illuminate when you test them but not when you have them in use on your head or body, then the wetness of the sponges / hair / skin is insufficient or the tightness of the headband or strap holding the electrodes in place may be insufficient. Make sure the headband or strap provides a snug fit. If the headband or strap is not pressing the electrodes firmly enough, adequate conductivity may not occur. Press the wet electrodes firmly while the device is on and see if this causes the yellow lights to illuminate. If they illuminate, you will need a smaller headband or to tighten the strap.

If your device beeps throughout the treatment session, or fails to beep at the end of the session, replace the batteries.

If, after trying the above suggestions, you are still having trouble with your device, call us at (800) 692-4380 or email us at info@fisherwallace.com. If we cannot fix your problem over the phone, we will repair or replace your device.

If you are required to return your device for repair or replacement, you will be responsible for shipping it to us. We will repair or replace the device for free if it is still under warranty, and ground ship it back to you at no cost. If you would like the repaired or replaced device shipped overnight to you, you will be charged $58.95 for expedited shipping. In-person drop offs by customers are not accepted at our administrative offices in New York City.

13.0 THEORY OF OPERATION

The electronic waveform 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 (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 TENS 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 a constant current of 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).

14.0 DEVICE SPECIFICATIONS

PARAMETER	NOMINAL VALUE
Output Amplitude (milliamperes)	0-4 mA
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 millisecon
Operating temperature range:	41 to 95°F (5 to 35°C)
Storage/transport temperature range:	-4 to 140ºF (-20 to 60ºC)
Operating humidity range:	10% to 80% relative humidity, non-condensing
Storage/transport humidity range:	10% to 90% relative humidity, non-condensing

These output parameters are valid for an impedance load range of 0-700 Ω

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CE 0120

EC REP

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Methodize Europe
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The Netherlands
Telephone +31 6 2129 4150l

Class II Medical Electrical Equipment

Consult instructions for use

TYPE BF

Type BF Applied Part
This stimulator is internally powered only

Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC. – Waste Electrical and Electronic Equipment (WEEE)

15.0 LIMITED 1-YEAR WARRANTY

Fisher Wallace Laboratories warrants each new Fisher Wallace Stimulator (exclusive of batteries) to be free from defects in materials and workmanship for a period of one (1) year following the delivery of the device 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

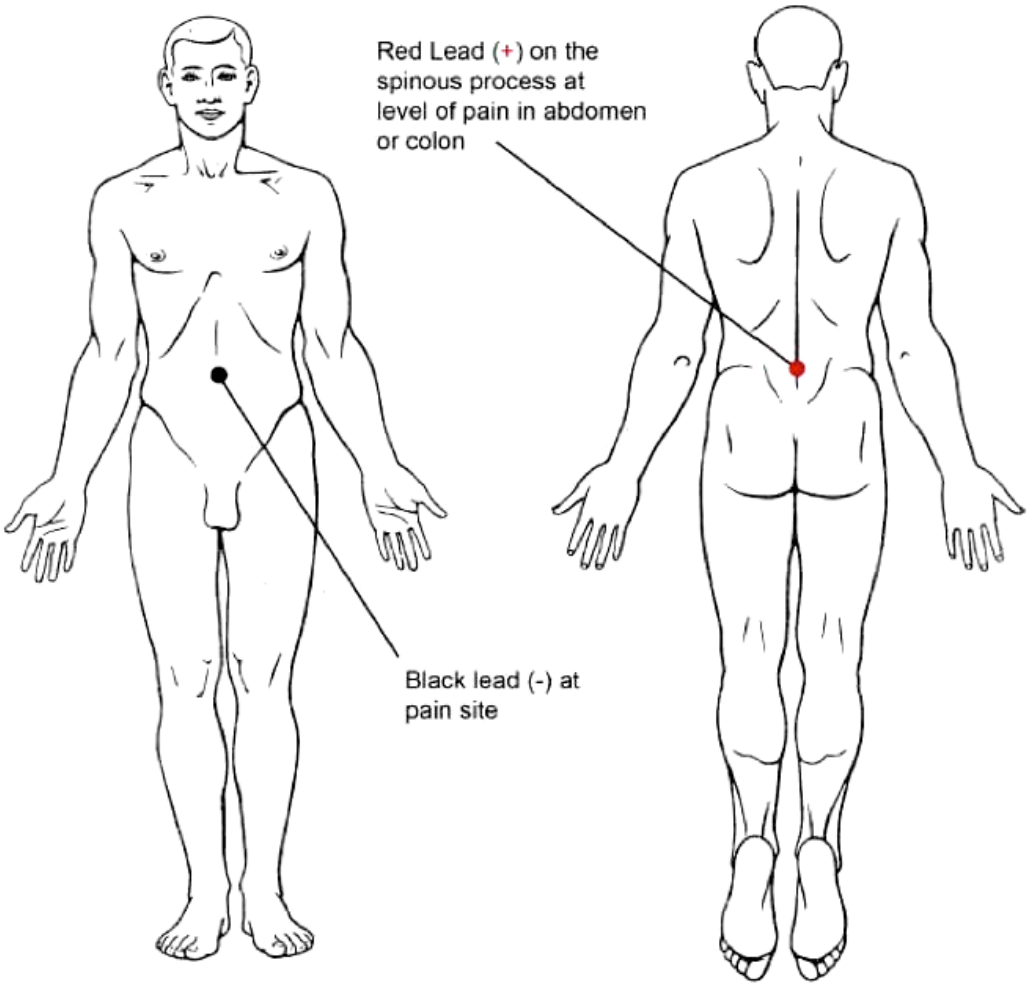
warranty period, and which shall have been returned to Fisher-Wallace Laboratories within 30 days after the discovery of the defect by the original purchaser. This warranty does not extend to any liability for medical or dental expenses, or for any other direct, indirect or consequential damages caused by the failure, defect or malfunction of the Fisher Wallace 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 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 and does not extend to any transferee, assignee or subsequent purchaser or user of the Fisher Wallace Stimulator. This warranty does not cover accessories, like electrodes, which are warrantied for a 60 day period. 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 30-DAY GUARANTEE

If the device is undamaged and does not successfully treat the purchaser's symptoms within thirty (30) days after it is delivered to the purchaser, the device may be returned for a refund. Shipping charges and extra accessories, such as the purchase of extra sponges, extra headbands or extra straps, will not be reimbursed. We issue full refunds for the entire amount of all purchased (not rented) devices in the form of a check, 4-6 weeks from the date we receive a return. Please obtain delivery confirmation.

Please click on the Customer Service menu tab on our website for instructions regarding servicing and returns.

GASTROENTEROLOGICAL PAIN



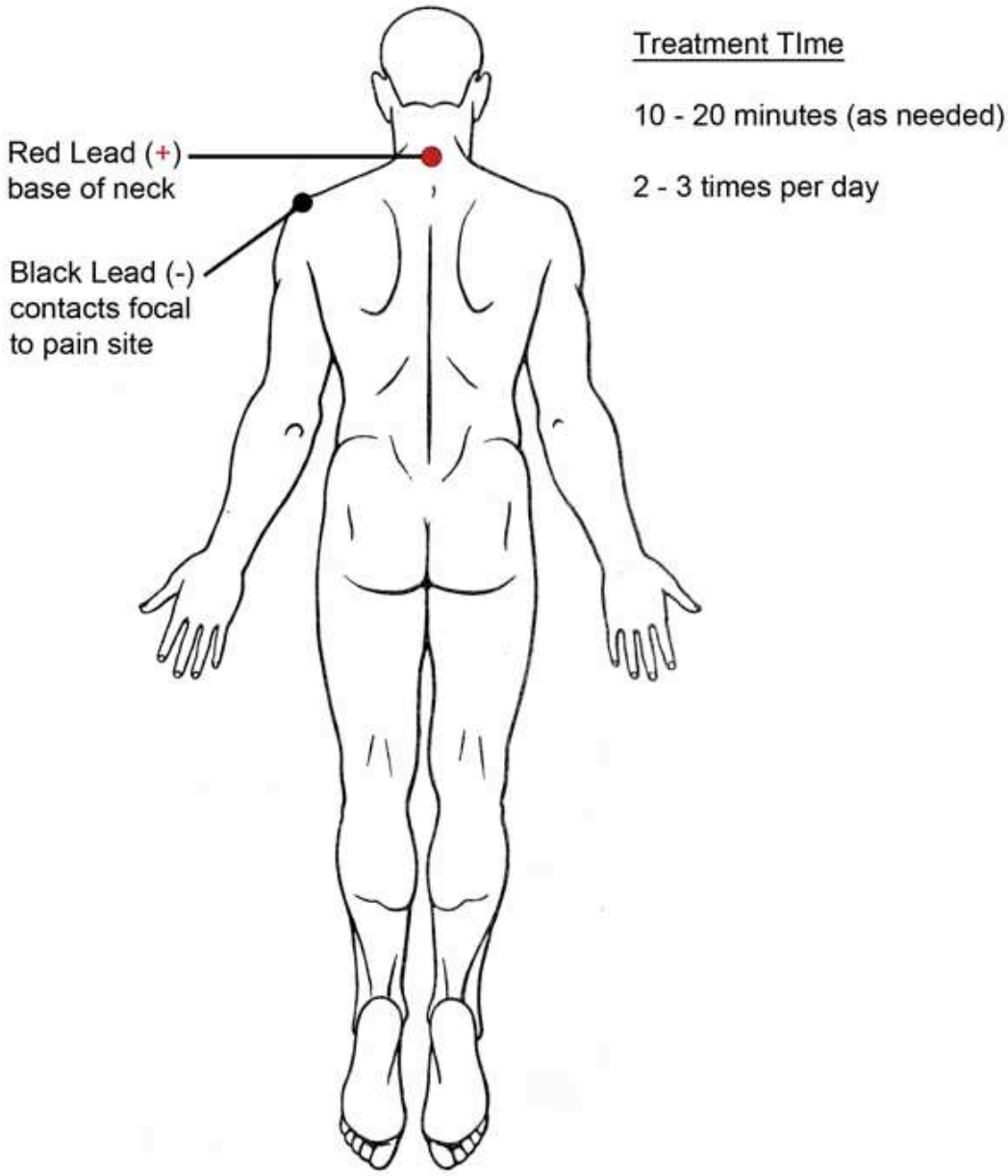
Treatment Time:

10 - 20 minutes (as needed)

1 - 3 times per day or as needed

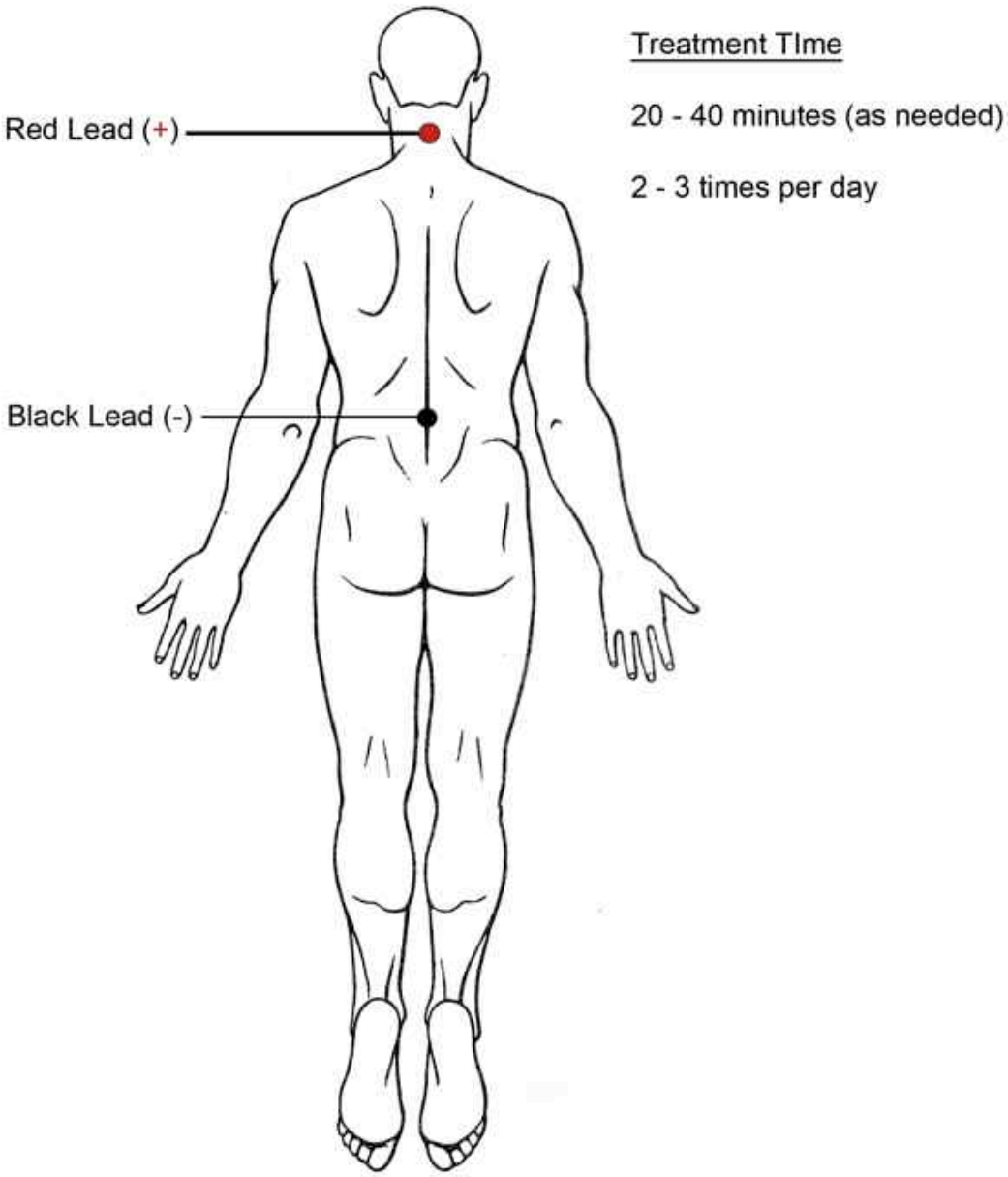
Yellow Light Indicator/ Amperage Level: 3 or 4

SHOULDER PAIN (BURSITIS)



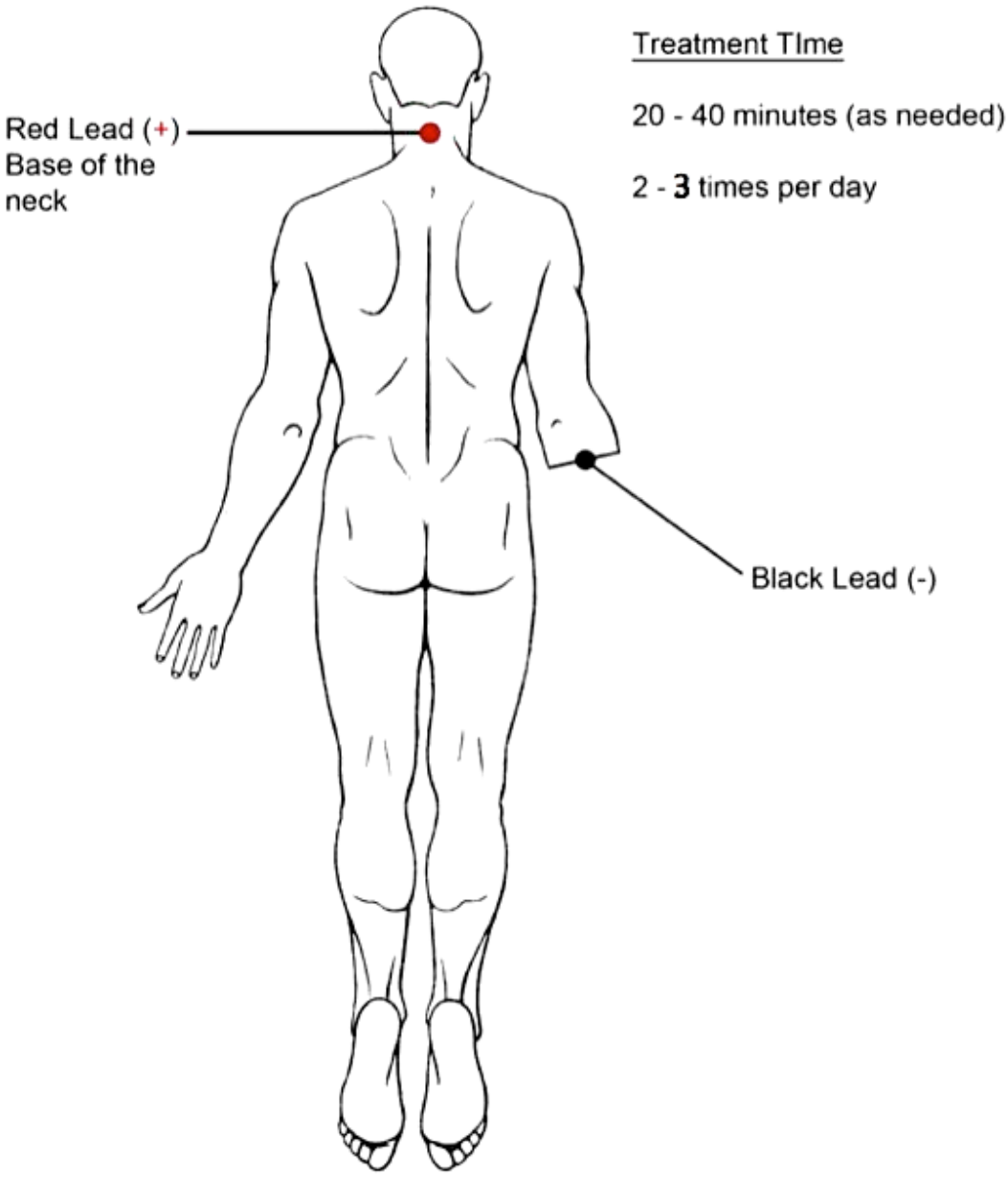
Yellow Light Indicator/ Amperage Level: 3 or 4

BACK PAIN Lumbosacral - Non Radicular
Lumbosacral - Radicular



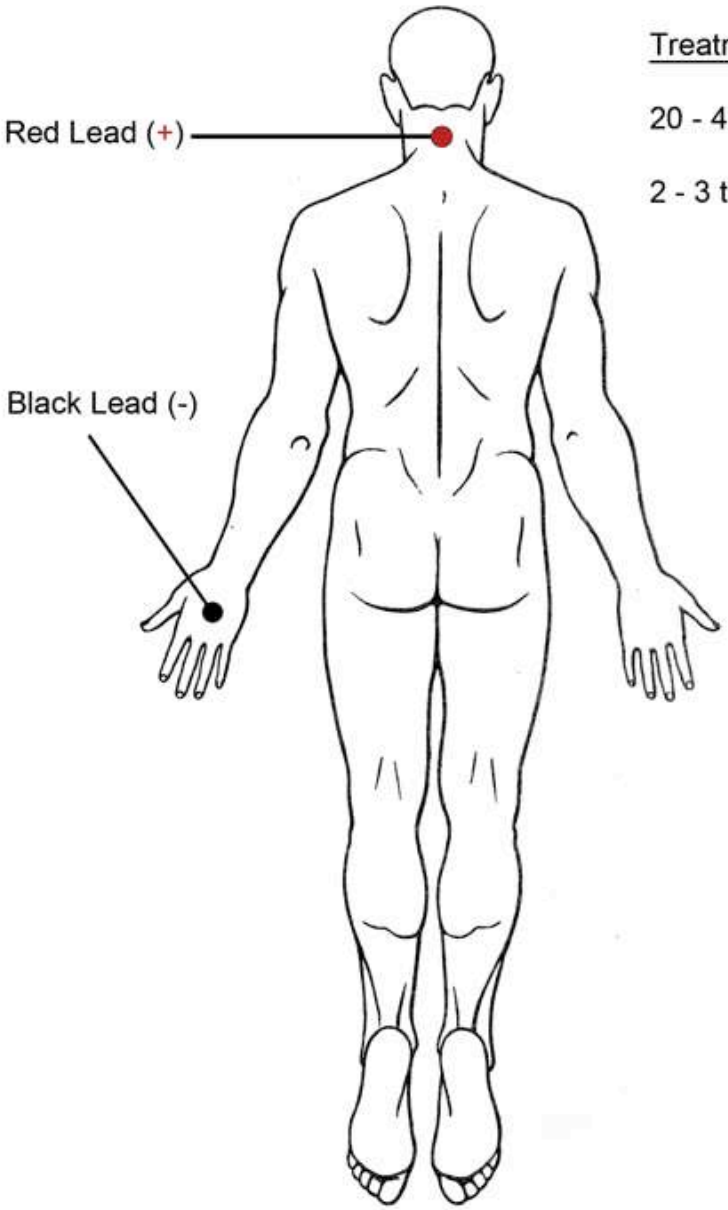
Yellow Light Indicator / Amperage Level: 3 or 4

PHANTOM LIMB PAIN



Yellow Light Indicator/ Amperage Level: 3 or 4

ARTHRITIC PAIN (Fingers)



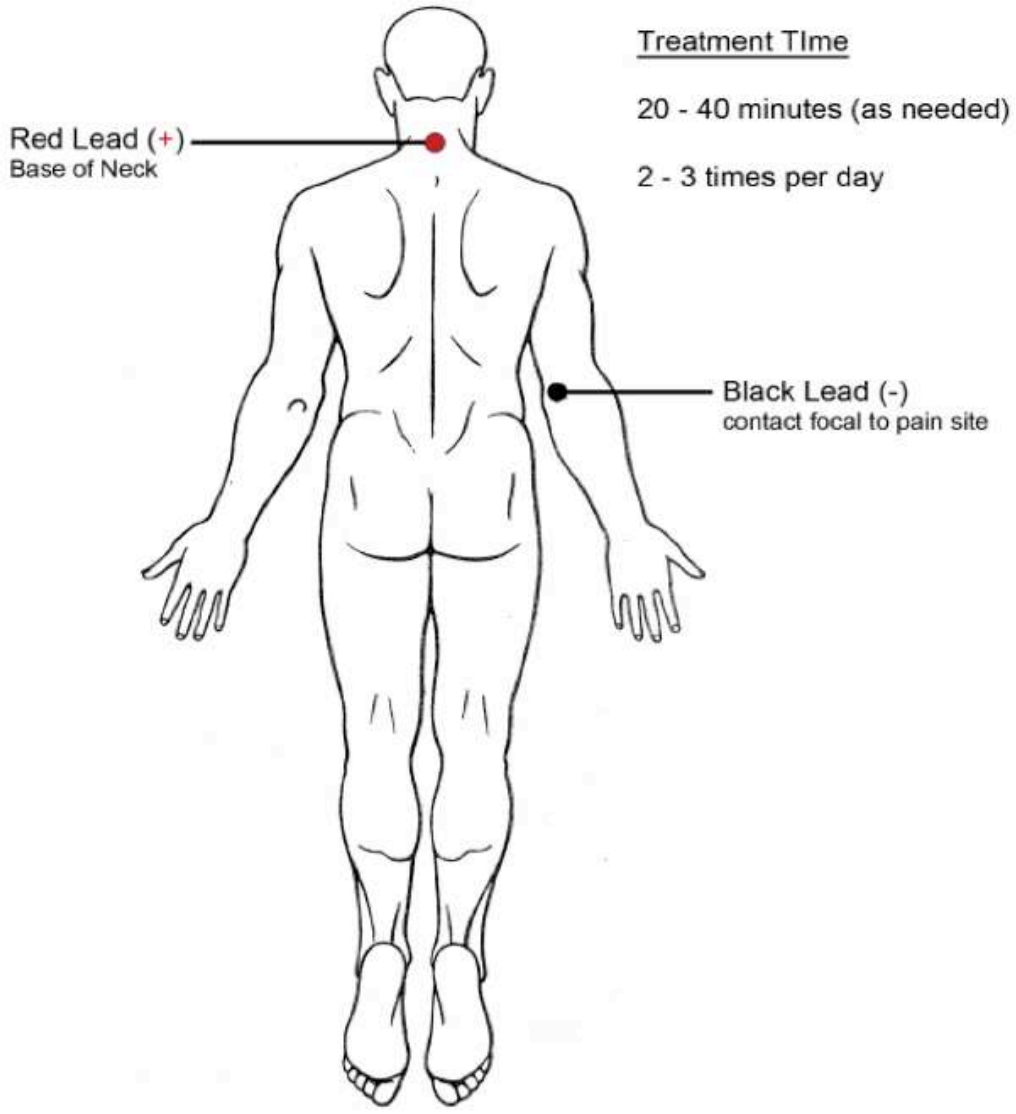
Treatment TIme

20 - 40 minutes (as needed)

2 - 3 times per day

Yellow Light Indicator/ Amperage Level: 3 or 4

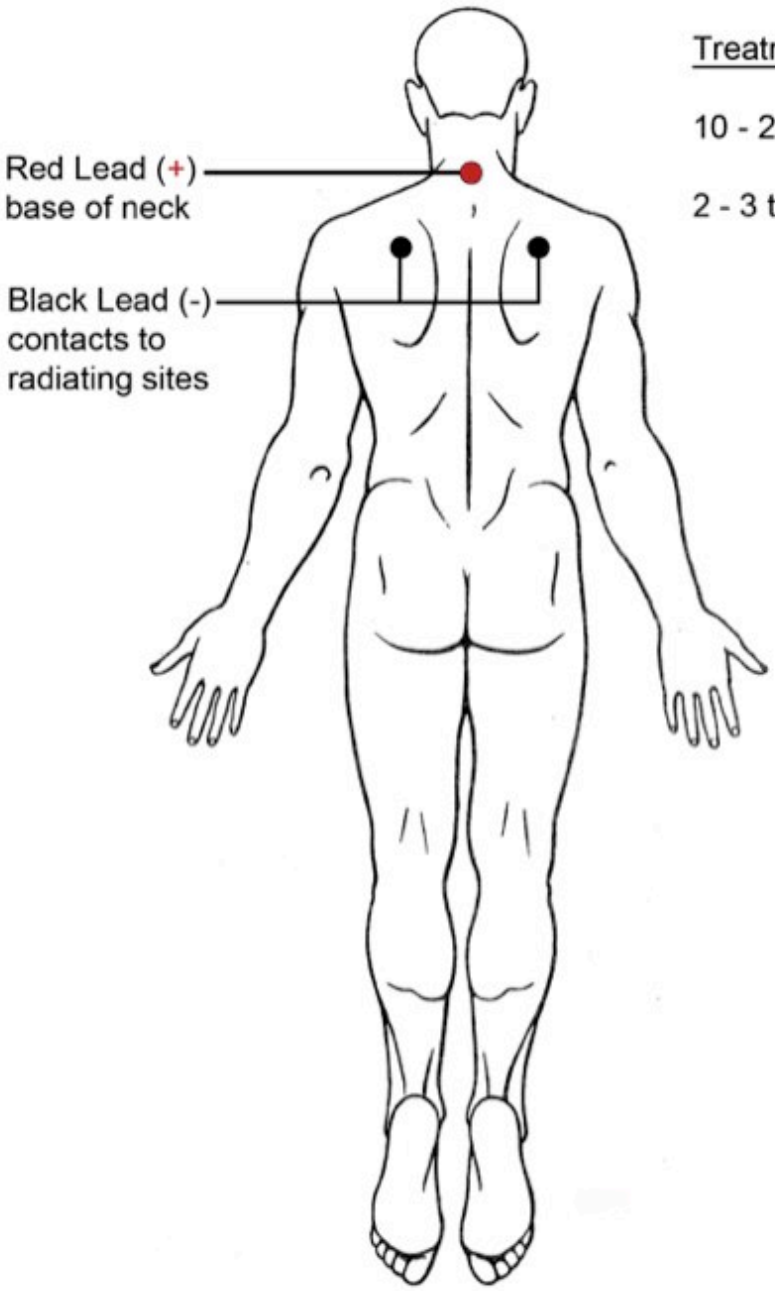
ELBOW PAIN



Yellow Light Indicator/ Amperage Level: 3 or 4

IF NECK PAIN RADIATES TO BOTH SIDES OF THE UPPER BACK, USE THE BLACK LEAD SEPARATELY ON EACH SIDE FOR 10-20 MINUTES.

NECK PAIN



Treatment TIme

10 - 20 minutes (as needed)

2 - 3 times per day

Yellow Light Indicator/ Amperage Level: 3 or 4